ONCOSCREEN

D7.4 ONCOSCREEN EXPLOITATION AND IPR MANAGEMENT PLAN (FIRST VERSION)

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CATALINK LIMITED	CTL
KONNEKT ABLE TECHNOLOGIES LIMITED	KT
BEIA CONSULT INTERNATIONAL SRL	BEIA
UNIVERSIDAD DE LA RIOJA	URIOJA
TIME.LEX	time.lex
CARR COMMUNICATIONS LIMITED	CARR
MINISTRY OF HEALTH	MoHGR
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EUROPEAN SOCIETY OF DIGESTIVE ONCOLOGY	ESDO
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LIST OF ABBREVIATIONS

Abbreviation	Description
AI	Artificial Intelligence
CA	Consortium Agreement
CARRCOMMS	Carr Communications
CRC	Colorectal Cancer
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRN	Colorectal Neoplasia
CTC	Circulating Tumour Cell
D	Deliverable
DNA	Deoxyribonucleic Acid
DoA	Description of Action
DOI	Digital Object Identifier
EC	European Commission
EU	European Union
FIT	Faecal immunochemical test
GA	Grant Agreement
GDPR	General Data Protection Regulation
gFOBT	Faecal occult blood tests
IBD	Inflammatory bowel disease
IP	Intellectual Property
IPR	Intellectual Property Rights
KER	Key Exploitable Results
KPI	Key Performance Indicator
mRNA	Messenger Ribonucleic Acid
NMR	Nuclear Magnetic Resonance
OA	Open Access
ONCO-AICO	ONCOSCREEN Real time AI-Assisted Colonoscopy
ONCO-AITI	ONCOSCREEN AI-Assisted Tissue Image Analysis
ONCO-BIOBA	ONCOSCREEN CRC Biobank
ONCO-CAWA	ONCOSCREEN Awareness Personalised Mobile Application
ONCO-CLIDE	ONCOSCREEN Clinical Decisions Support System for CRC Integrated Diagnosis
ONCO-CRISPR	ONCOSCREEN CRC Screening based on CRISPR-Cas12 biomarkers
ONCO-CTC	ONCOSCREEN CRC Screening based on Circulating Tumour Cells
ONCO-EVIDA	ONCOSCREEN Evidence-based Decision Analytics Dashboard
ONCO-NMR	ONCOSCREEN CRC Screening based on Urinal & Blood NMR Metabolomics
ONCO-RISTE	ONCOSCREEN Risk Stratification Engine
ONCO-VOC	ONCOSCREEN CRC Screening based on Volatile Organic Compounds
QoL	Quality of Life
QR	Quick Response
R&D	Research and development
SWOT	Strengths, Weaknesses, Opportunities, and Threats
URL	Uniform Recourse Locator
VOCs	Volatile Organic Compounds
WP	Work Package

Executive Summary

ONCOSCREEN project aims to develop a ground-breaking set of technologies and methods for colorectal cancer screening. In close cooperation with other Mission Cancer projects, ONCOSCREEN will provide solutions for risk-based stratification cancer screening for citizens, an integrated diagnostic decision support tool for clinicians as well as intelligent monitoring tools for policy makers. Given the focus of the project on providing innovative technologies, the consortium aims at protecting and exploiting the novel project results. This document presents the efforts on task T7.5 led by EXUS, which include an analysis of the exploitation of the key assets identified by the consortium, the intellectual property rights management framework, along with a market, SWOT and PESTLE analysis per identified asset.

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1 Introduction

ONCOSCREEN aims at delivering novel solutions targeting at a critical cancer type of Colorectal cancer that affects a large number of European citizens, many cases of which are undetected or detected late because of the intrusive nature of the existing tests (i.e. colonoscopy).

Given the focus of the project on a significant health condition and the novelty of the proposed technologies, the consortium aims at protecting and exploiting the novel project results with the main aim to secure the intellectual property (IP) of its assets and carry out a rigorous exploitation plan from maximizing the high exploitation potential of the planned results. This document presents the efforts on task T7.5 led by EXUS, which include the implementation of the exploitation plan, the key assets identified by the consortium, the intellectual property rights management framework, along with a market SWOT and PESTLE analysis for each KER and project wide. In addition, initial business models' canvas for each key asset is provided. Updates on the exploitation will be reported in D7.7 ONCOSCREEN Exploitation and IPR Management (Final version) in M48.

This deliverable was prepared by EXUS following an exploitation workshop attended by all partners and a series of questionnaires aiming at guiding partners in completing the applied market and business analysis tools. The deliverable was prepared with the essential contributions by all partners especially those involved in the development of the identified key assets.

1.1 The need of the Exploitation and IPR Management

The deliverable presents a detailed overview of the ONCOSCREEN Exploitation Pathways and IPR Management. ONCOSCREEN develops several novel solutions targeting to improve the diagnosis of a critical type of cancer by making simpler for many more people to engage on early testing.

In order to maximize the exploitation potential of the project results and identify from the early phase of the project market gaps, barriers, and opportunities a market and business analysis of each key exploitable result (KER) was conducted by engaging all contributing partners. The thorough analysis results along with the initial business model for each KER and identified proportional avenues are presented in this deliverable. The used tools and analysis performed in this deliverable form the basis for ensuring the early identification of IP rights and exploitation potential of any tool during the next period of the project. Final updates regarding exploitation and the IPR registry during the project lifetime will be presented within the D7.7.

1.2 Deliverable objectives

Table 1 presents the connection of the contents of the present deliverable with the ONCOSCREEN Grant Agreement (GA) requirements in WP7.

Table 1 Description of Action: WP7.

ONCOSCREEN DoA requirements	Deliverable addressing the requirements	Brief description
Task 7.1 Dissemination, communication activities of ONCOSCREEN Task 7.2 Citizen Awareness Campaign Implementation for Increasing Acceptance in CRC screening programmes Task 7.2 ONCOSCREEN Living Lab for Gender-Based Innovations Task 7.4 Impact Creation Activities with other EU Initiatives and Projects Task 7.5 IPR Management and Exploitation Pathways	D7.2 ONCOSCREEN Dissemination, Communication, and Exploitation Plan	The deliverable includes the Dissemination, Communication, and Exploitation Plans that will guide and structure the implementation of all tasks in WP7.

1.3 Relationship with other deliverables and tasks

This deliverable is closely linked to other projects tasks and the deliverables listed in *Table 2.*

Table 2 Linkages between D7.4 and other ONCOSCREEN deliverables

Deliverable	Description of the deliverable	Link to D7.4
D7.2	Dissemination, Communication and Exploitation Plan	The deliverable reports the key exploitable assets identified by the project and the tools that will be applied for their exploitation which are used in more detail in this deliverable.
D7.7	Exploitation and IPR Management (Final Version)	The final version of the report that summarises the ONCOSCREEN exploitation pathways of each partner and their exploitable assets developed within the project.

2 Exploitation Methodology

Commercialisation and transfer of knowledge are the two mainstream tools to turn science into business. They can though often converge and operate in a complementary fashion. This is the way ONCOSCREEN consortium shall address the use of project's outcomes in the context of future exploitation. ONCOSCREEN's exploitation methodology relies on:

1) Identification of the exploitable assets, whether these are technological, development of standards, components, algorithms, models, or added value services to be delivered to the target users.
2) Conduction of a thorough market analysis aiming at the identification of the market towards which the project's results are targeted, its segmentation, the positioning of current competitors and all emerging trends.
3) Elaboration of an analytical IPR management strategy based on the principles outlined in the project's CA which will guide joint and individual exploitation capabilities.
4) Definition of possible commercial exploitation models.
5) Definition and evaluation of the sustainability and viability of possible business models.

An effective exploitation of the research results relies on a proper management of intellectual property rights, not limited to patents or trademarks, but extended inter alia to copyright and confidential trade information. Our efforts during the initial period of the project are focused on identifying the Key Exploitable Results and setting out an IPR management plan. In particular, in relation to the aforementioned steps, within 6 months since the beginning of the project the consortium performed a preliminary analysis of steps 1, 2, 3, 4 mentioned above, i.e. identifying the main assets that seem to have the highest exploitable potential, and setting out an IPR management strategy. In the following 12 months the consortium focused on performing market analysis for each identified KER, which seem to have the highest potential for joint or individual exploitation of each of them. The consortium identified possible exploitation models, competitors and routes for promoting the proposed novel solutions

The consortium dealt with extra attention with the IPR issues in the Consortium Agreement, on which all partners have agreed. It is identified that a more appropriate channel for future exploitation of ONCOSCREEN results is an informal joint venture between partners that aim to exploit further the development and explore the commercialization of their achievements and the novel KERs that typically involve more than one partner. Working jointly for the exploitation of ONCOSCREEN outcome the consortium has the following advantages:

- Access to resources not present on the market
- Sharing further R&D costs and commercialization opportunities
- Show up as a specialized international and multidisciplinary group
- Ensure knowledge and technology transfer
- Access to new markets
- Investigate the development of new products

- Re-elaborate suitable business models that may boost the commercialisation

The individual exploitation plan for each partner is planned to be discussed over the next period and will be included in the second iteration of this deliverable.

During the first period of the project, the consortium has concluded that the most prominent approach would be the exploitation of group of solutions. In Section 8, further details regarding the identified groups of solutions are presented.

2.1 Overview of possible exploitation strategies for generated IP

The common ways that the consortium partners can use to exploit the intellectual property arising from the project, are described below.

- Patents: A patent is a legal protection granted to an inventor or creator for a specific period. In the context of screening and software products, patents can be used to protect novel and non-obvious software inventions, such as algorithms, software and screening processes, and computer programs. By obtaining a patent, a company can prevent others from making, using, or selling similar products for a set period, obtaining a competitive advantage in the marketplace.
- Copyrights: Copyrights protect original works of authorship. In the context of software products, copyrights can be used to prevent others from copying or using the source code or other parts of the software without permission. Copyrights also allow the company to control the distribution, modification, and adaptation of their products.
- Trade Secrets: Trade secrets refer to confidential information that is critical to a company's success, such as customer lists, financial data, and business strategies. In the context of screening technologies and software products, trade secrets can be used to protect proprietary information related to software design, architecture, and functionality. By keeping this information secret, a company can prevent others from replicating or reverse-engineering their products and technologies.
- Trademarks: Trademarks are used to protect a company's brand identity, such as logos, slogans, and product names. In the context of screening technologies software products, trademarks can be used to distinguish a software product from competitors and to build brand recognition and loyalty.
- Licensing: Licensing is the process of granting permission to use a software product or technology in exchange for a fee or royalty. By licensing their screening technologies or software products, companies can generate revenue from the use of their intellectual property without having to sell the underlying software or screening process itself.
- Open source licensing: Together with licensing the created diagnostics for a royalty can also be licensed under an open source licence. In this case the procedures are made freely available and can be used, modified, and distributed by anyone. This means that anyone can access, use, and even improve the test by modifying the process or source code. The selected open source licence sets out the terms and conditions under which the software can be used, modified, and distributed.

2.2 Exploitation Workshop

In order to facilitate the implementation of the exploitation plan and engage early the consortium on the market analysis and completion of the business tools for each identified KER, EXUS organized an exploitation workshop on 2 February 2024, in Paris. During the workshop partners were informed about the available business tools and were guided on the completion of the identified business tools templates. Partners were also updated about the IPR registry with more details concerning competitive products and existing patents and were informed about the Horizon Results Booster.

Specifically, the workshop covered the following topics, presented by EXUS.

- Innovation management
  - Definitions and Duties
  - Implementation
  - Valley of death
- Exploitation Strategy
  - Definitions
  - Stakeholders, Impact
  - IP Strategy in EU – Rules and Obligations
  - IPR Management
  - SWOT, PESTEL
  - Business Model Canvas
- Horizon Results Booster
- Interactive Session/Open Discussion
  - Identification of KERs
  - SWOT, PESTLE Filling Guidance
  - Business Canvas Filling Guidance

A detailed description of the workshop is provided in Annex A. Following the exploitation workshop, partners were asked via questionnaires to analyse the market, fill in the SWOT, PESTLE and Business Model canvas templates, and identify possible business routes. The collected information was processed and is provided in the following Sections.

2.3 Main tools for Formulating the Exploitation Plan

In order, to formulate the best possible exploitation strategies for ONCOSCREEN KERs, the consortium utilised popular exploitation tools and models such the SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis, and Business Model Canvas as described below. These were completed for the overall project and for each identified KER and are presented in the following Sections. Through this process and the protection of partners' individual interests, we will avoid information bottlenecks related to confidentiality or competitiveness among the Consortium members, securing the chances for market visibility and the exploitation.

2.3.1 SWOT analysis

SWOT (Strengths, Weaknesses, Opportunities and Threats) is a useful tool for organisations to develop strategic plans. By identifying and analysing the strengths, weaknesses, opportunities, and threats for the exploitation of a given KER, SWOT analysis will help the partners to formulate strategies that capitalise on strengths, minimise weaknesses, seize opportunities, and mitigate threats.

Here is a brief overview of each component of a SWOT analysis:

- Strengths: these are the internal factors that give the KER a competitive advantage over what is currently available to relevant stakeholders on the market. For example, a new technology/tool, more performing algorithms, a complete toolbox.
- Weaknesses: These are the internal factors that hinder the exploitability of the KER. For example, low maturity of the technology, lack of resources to scale up.
- Opportunities: These are the external factors that can create new opportunities for the exploitability. For example, emerging markets, new technologies, increased public attention to specific social issues (e.g. accessibility).
- Threats: These are the external factors that can threaten the exploitability. For example, increased competition, already existing solutions, changing markets.

The use of SWOT analysis is helpful in understanding the potential of each KER given the market needs, key players and potential and limitations of the given technology. This will aid the consortium partners in maximising the exploitation output of the project.

2.3.2 PESTLE Analysis

In addition to SWOT analysis, PESTLE analysis is used. PESTLE analysis is a strategic management tool used to analyse the external factors that may impact a business or organisation. By examining each of these factors, the consortium will gain a better understanding of the challenges and opportunities it may face in the marketplace. This analysis will help partners to identify areas where it needs to adapt and make strategic decisions to ensure long-term exploitation of the project's results.

2.3.3 Business Model Canvas

The Business Model Canvas is a strategic tool that will be applied to develop, evaluate, and communicate business models. The Canvas provides a visual framework that will enable partners to identify the essential components of a business, including customer segments, value proposition, channels, customer relationships, revenue streams, key resources, key activities, key partnerships, and cost structure. By focusing on these elements, we will be in a better position to understand stakeholders' needs, how to deliver value to them, and how to generate revenue.

To implement the Business Canvas Model, we follow a series of steps:

1. Initially, we identified the customer segments that will be interested in a specific KER, together with their specific needs.
2. We then determine the value proposition that ONCOSCREEN partners can offer, and how it addresses the needs of the target customers.

3. The channels through which we will communicate and deliver our value proposition to customers are identified.
4. We determine the types of relationships we want to have with our customers and the revenue streams we will use to generate income.
5. Lastly, we identify our key resources, key activities, key partnerships, and cost structure to determine how we will deliver our value proposition effectively and efficiently, ensuring a sustainable exploitation of each KER.

Following this strategy, we have developed a comprehensive, effective and sustainable business model for all the identified KERs, as presented in the following Sections.

2.4 Means of Implementation of the Exploitation Plan

Communications activities will play a major role in the implementation of the Exploitation Strategy for the ONCOSCREEN project. In pursuing the developed exploitation plan, communication channels and key messaging are aligned early in the project to ensure that ONCOSCREEN is being advertised to a receptive audience of stakeholders, with consideration to competitors in the market and the tool's unique selling points. These activities will primarily consist of three areas over the remaining lifetime of the project.

Communication Outputs – Building on the strength of the communications strategy for the ONCOSCREEN project, the project's current communications channels can be leveraged for the purpose of exploitation. This means identifying how the project's outputs can be effectively communicated across existing ONCOSCREEN channels including social media (LinkedIn and Twitter) to identified audiences. It is also envisioned that project partners will provide blogs for the ONCOSCREEN website which will serve as advertising material for the project's tools and technological developments. A comprehensive newsletter including depictions and descriptions of all tools will also be circulated to ONCOSCREEN's mailing list which consists of individuals and organisations already working in the area who could be key to the commercialisation of the project's outputs.

Communication Opportunities – Events such as trade fairs, workshops and international exhibitions will be prioritised over the remaining months of the project with the objective of communicating and advertising the project's tools to receptive audiences, focused on those who are responsible for purchasing within their organisation.

Communication Collateral – In support of exploitation efforts both online and through ONCOSCREEN attendance at industry events, the project will develop a selection of impactful communications collateral to advertise the project to prospective end-users. Material will be developed including project brochures for the ONCOSCREEN tools and Handbook, training videos showcasing how the tools are used for training purposes, a single consolidated infographic to describe the project's outcomes and video interviews with project partners which will be used to effectively explain and advertise the project's tools and technologies to interested groups via the project's social media platforms, website and through direct engagement efforts with identified potential end-users.

2.5 Common Branding

In order to ensure effective exploitation of the ONCOSCREEN project's end results, a common branding approach is implemented. The purpose of this is to present the ONCOSCREEN diagnostic technologies as part of one larger coherent effort which will allow for greater commercialisation opportunities. The developed logos of the identified KERs are shown in *Figure 5.*

Figure 1 ONCOSCREEN diagnostic technologies logos

This branding, in line with the overall Brand Strategy for the ONCOSCREEN Project, is used for exploitation purposes in all future events with ONCOSCREEN involvement, in addition to being used in all marketing material including project brochures and on the project website.

3 Project Wide Market Analysis

According to Fortune Business Insights[1] report titled, "Colorectal Cancer Screening Market, 2022-2029", the Colorectal Cancer Screening Market size is anticipated to reach € 22.88 Billion by 2029. In fact, the market size was € 14.32 billion in 2021 and is anticipated to rise at a CAGR of 4.3%. It is noticed that the market is growing exponentially due to the rising demand for colorectal cancer screening tests worldwide. The rise in awareness among people about colorectal cancer screening and increasing cancer prevention initiatives are some significant factors that have surged the demand for the product to a great extent. Another reason that escalates the need for the product is the growing screening rates for colorectal cancer patients at minimal costs.

In Europe, Colorectal Cancer (CRC) is the second cause of cancer death in men (after lung cancer) and the third one in women (after breast and lung cancers). It is estimated that, in EU-27 countries in 2020, CRC accounted for 12.7% of all new cancer diagnoses and 12.4% of all deaths due to cancer.

The methods that are recommended for CRC screening include stool-based and direct visualization tests. However, in order to achieve the benefits of screening, re-evaluate abnormal results from stool-based and visualisation tests, subjects should be followed up with colonoscopy. In fact, colonoscopy is the Gold standard in CRC screening due to its excellent results in terms of specificity and sensitivity. However, this method encompasses risks for the subjects which include belly pain and discomfort, bleeding, bad reaction to anaesthesia, infection and the colonoscopy preparation risks. Human error in diagnosis of CRC cancer or a diagnosis at a late stage due to unwillingness of human subjects to conduct the screening, leads to multiparametric undesirable consequences ranging from reduced life expectancy of diagnosed patients and changes in their Quality of Life (QoL) and higher costs for the patients and the overall healthcare system. Additionally, the time for the delivery of CRC results is a very important factor. Despite recommendations from EU, it is estimated that only 14% of European citizens participate in CRC screening programmes. Fear and other socio-economic factors of patients are not studied in depth and may contribute negatively to prevention and early diagnosis. Furthermore, several CRC screening solutions have been published in scientific articles, however very few have been validated in large scale clinical trials and certainly not at an EU-wide level with the involvement of an adequate number of countries.

The management of screen-detected pre-cancerous lesions and early disease is intended to reduce CRC mortality. When diagnosed at stage I, the overall 5-year survival rate is around 90%, whereas it is only around 10% in the metastatic stage IV. It is estimated that, only around 13% of patients are diagnosed at stage IV. The overall CRC trends present large disparities among EU countries, especially in the survival rates which are highest in Western Europe and lowest in some countries of Eastern Europe, which is distant from a health-equal Europe in regards to access.

[1] https://www.globenewswire.com/en/search/organization/Fortune%2520Business%2520Insights

Additional factors beyond age, such as sex and gender, race and ethnicity and lifestyle could improve the prevention strategies and update the recommendations from policy makers. From the patient's perspective, other barriers include fear, socio-demographic, psychosocial, economic/geographic factors, as well as awareness, understanding, or lifestyle. For clinicians and healthcare providers, low screening recommendations, poor coordination and communication between patients and providers, or lack of follow-up actions hinders the success of such programs. At a higher scale, health system policy makers, may be hesitant to adopt radical measures due to cost-related constraints and the capacity to move patients from screening to colonoscopy to effective treatment. A more detailed patient-level data risk-based screening program is needed to control for comorbidities, oncological therapies, stage-related variations at time of diagnosis, and other factors in the screened and non-screened populations

Apart from colonoscopy, stool-based screening with a faecal immunochemical test (FIT) is most commonly used worldwide also due to cost effectiveness and non-invasiveness. The adherence to CRC screening is currently poor. It is estimated that nearly 1/3 of eligible adults go unscreened for CRC. Furthermore, less than 50% of patients who have a FIT ordered will subsequently complete the test on the first round and adherence diminishes with each annual interval. It is evident that stool-based methods, is an unpleasant process and a difficult sampling method. In contrary, there is no blood sample test available at this time with prospectively validated sensitivity for advanced adenomas equivalent to either FIT in the CRC screening setting.

3.1 Key Industry Players

According to the 2022 Fortune Business Insights[2] report top firms including the Laboratory Corporation of America Holdings, Clinical Genomics Technologies Pty Ltd, and FUJIFILM Holdings Corporation are investing heavily in R&D activities to expand their market presence. With soaring investments in better design, the market is merged, with few market players for better healthcare treatments which are enlisted below:

Table 3 Key Players Worldwide

Company Name	Country	Geographical Area
NOVIGENIX SA	Switzerland	Europe
Epigenomics AG	Germany	
KARL STORZ SE & Co. KG	Germany	
bioMérieux, Inc.	France	

[2] https://www.fortunebusinessinsights.com/industry-reports/colorectal-cancer-screening-market-101144

Clinical Genomics Technologies Pty Ltd.	U.S.	North America
Exact Sciences Corporation	U.S.	North America
EIKEN CHEMICAL CO., LTD.	Japan	Asia
Olympus Corporation	Japan	Asia
FUJIFILM Holdings America Corporation	Japan	Asia

Note that in Section 5.6 of this deliverable, we provide an enhanced list and a more detailed analysis of the competitors relevant to all KERs.

3.2 Market by Test Type

The global market is segregated into stool-based, colonoscopy and others. The colonoscopy segment, representing 75.7% of the market, generated the highest revenue in 2021 and is expected to grow at a moderate GAGR between 2022-2029. Stool-based tests are expected to grow at the highest rate due to the rising government programs for CRC screening and time efficient results obtained from stool-based tests. The stool based segment is further sub-segmented into faecal occult blood tests (gFOBT), faecal immunochemical tests (FIT) and stool DNA tests. The FIT screening tests are expected to grow at a significant CAGR between 2022-2029 due to their simple use and high positivity rate as compared to other stool-based tests.

Given the issues with colonoscopy mentioned above, the market players are increasing their focus on the development and commercialization of technologically advanced products for efficient screening. For instance, recently, market players developed products for the detection of CRC by identifying cells released by colorectal polyps and tumours into the bloodstream.

3.3 ONCOSCREEN Competitive Position

ONCOSCREEN solutions are timely given the current and forecasted market growth towards more innovative and less intrusive tests compared to colonoscopy. In fact, ONCOSCREEN plans to introduce 3 novel 'liquid biopsy' and 1 'breath biopsy' CRC screening methods into a large-scale clinical study in 4100 citizens/patients in 10 European countries. As it is pivotal to create successful CRC prevention strategies and reduce high increasing health costs of severely diseased CRC patients, wide populations should be able to participate in screening programs. As CRC often slowly aggravates by adenoma-carcinoma sequence for a long time, the early diagnosis is vital to elevate precancerous polyps, identify early cancer stages and eventually improving the survival rates and ease treatment for the earlier diagnosed patients[3].

[3] Kim, E.R., et. Al., Urine-NMR metabolomics for screening of advanced colorectal adenoma and early-stage colorectal cancer. Sci Rep 9, 4786 (2019)

Particularly for high-risk early onset CRC populations, many causes lead to CRC development, often related to unhealthy lifestyle habits, such as overweight or obesity, smoking, intake of processed meat, sedentary lifestyle, and excessively alcohol consumption. In addition, other risk factors that do not depend on the life-style of individuals can be classified into the following categories: (1) having predispositions to cancer diseases, with conditions such as the presence of polyps in the colon or rectum, and inflammatory bowel diseases (IBD) such as Crohn's Disease or Ulcerative Colitis, (2) having previously suffered from CRC which increased risk of subsequent cancers, and (3) having genetic factors, such as Lynch syndrome and familial adenomatous polyposis (FAP), or other family factors, as the incidence is higher in those with relatives who have developed colorectal cancer.

ONCOSCREEN will introduce a multi-tier risk stratification approach that will accumulate for the first-time medical disease history, heredity, genetic mutations, environmental stressors, dietary habits, diagnostic test results (including metabolic pathway), along with other socio-economic factors dictating a personalised risk status considering health inequalities within and across EU countries. The consortium's view is that a more accurate risk-based grouping of citizens that can be screened earlier than 50-55 years age limit will lead to a higher impact for prevention. The CRC survival rates are clearly stage-dependent with 94%, 82%, 67%, and 11% for stages I, II, III, and IV, respectively. Therefore, screening and the early detection of CRC are critical for the individual improvement of long-term survival rates, as well as to ensure significant decrease in the population's CRC incidence and mortality. It is expected that ONCOSCREEN detection solutions will have a bigger adherence due to the ease of use. Furthermore, compared to other similar solutions; ONCOSCREEN has a considerably strong Intellectual property background with 17 Patents for the Volatile Organic Compound test, 1 Patent for the CRISPR-based diagnostic test and 1 Patent for the Circulating Tumour Cells based test. Finally, several studies have also suggested that the utilization of non-invasive tests can contribute positively to the quality of the performed colonoscopies. In regard to AI algorithms in Colonoscopies and Histopathological images, the current results are quite high overpassing clinicians in some categories. The focus of ONCOSCREEN is to utilize AI technologies (retrospectively and not during colonoscopy procedure) for the first time solely for the training of non-experts (e.g. Nurse endoscopists), junior colonoscopists and junior histopathologists respectively. The ambition is to improve the current levels of Adenoma Detection Rate and Polyp Detection Rate with a primary focus on Stages 0, I and II.

Based on the market analysis and cost existing examinations (e.g. colonoscopy >30€), we provide an estimated cost/examination for four of ONCOSCREEN's tools, which indicates the rather competitive pricing compared to existing tests. In the second iteration the final estimated cost will be included given that the broader inflation of the economy may affect overall costs.

Table 4 Targeted Estimated Examination Cost

Component	Initial Estimated Cost/ Examination
ONCO-VOC	< 3€

ONCO-CRISPR	< 9€
ONCO-NMR	<8.5 €
ONCO-CTC	<10€

All technical solutions developed within the project, as well as the knowledge generated through the analysis of retrospective and prospective data, will be deployed and evaluated in a multi-centre proof-of-concept study, scheduled to be conducted in at least 16 clinical sites in 10 EU countries. As such, the ONCOSCREEN technological results will reach TRL 7 at the end of the project. The majority of technical solutions, including data analytics methods, AI-based recommendation systems, and sensing devices, developed within the project have been deployed in other contexts and will be adapted to support ONCOSCREEN.

Overall, we expect that the developed solutions have the potential to identify ~170,000 new CRC cases at an early stage, help to save 153,000 EU citizens due to early detection, benefit 200k family members indirectly, and ultimately positively impact 750,000 EU citizens in 5 years.

The developed technologies have the potential to improve by more than 5% the Expected Life Years and by more than 10% thr Expected Quality-Adjusted Life-Years within 7 years from project closure.

3.4 Key Exploitable Results (KERs)

Based on the initial analysis we have identified a number of Key Exploitable Results (KERs) that we summarize below. KERs are referring to any entity within the range of service/module/integrated solution offerings of ONCOSCREEN as well as any other direct side-product of the consortium partner's effort, which have the property that:

- can be deemed commercially exploitable by one or more project partners in collaboration;
- and/or can become a source of direct/indirect revenue in the near future extending the project's sustainability and spanning beyond its contractual lifetime;
- and/or have potential to contribute for further work, research or innovations;
- and/or can create impact during and (most importantly) after the funding and the project's contractual lifetime.

KERs include the most important and most (commercially) prominent entities (inventions, products, services), elements (knowledge, technology, processes, networks) generated during the project by the consortium partners. They can be either "final end-products or services" or intermediate methodologies, tools and solutions which are both self-contained to constitute exploitable assets themselves, and which might have also led incrementally to the final offering formulation throughout the project's progress.

KERs are the selected subset of the exploitable results which present, according to the consortium view, the biggest potential in Innovation, Exploitability, Market Impact and Readiness to Market

Launch. The ONCOSCREEN consortium has identified the following Key Exploitable Results for joint exploitation that are presented in *Table 7.*

Table 5 Key Exploitable Results of ONCOSCREEN

IP Asset	Technology	Owner
ONCO-VOC	CRC Screening based on Volatile Organic Compounds	TECH
ONCO-CRISPR	CRC Screening based on CRC specific genetic biomarkers detected with CRISPR-Cas	CCASSURED
ONCO-NMR	CRC Screening based on Urinal & Blood NMR Metabolomics	UzL
ONCO-CTC	CRC Screening based on Circulating Tumor Cells	UMINHO
ONCO-AICO	Real Time AI-Assisted Colonoscopy	CERTH, ICCS, KONN, AINIGMA
ONCO-AITI	AI-Assisted Tissue Image Analysis	MUG
ONCO-RISTE	CRC Risk Stratification Engine	EXUS
ONCO-CAWA	CRC Awareness Personalised Mobile Application	iSPRINT
ONCO-CLIDE	Clinical Decisions Support System for CRC Integrated Diagnosis	KONN
ONCO-EVIDA	Evidence-based Decision Analytics dashboard	VITO, ICCS
ONCO-BIOBA	CRC data bank directory (data catalogue)	MUG

3.5 Other Results

Apart from KERs, the consortium has identified other assets that may be 'exploitable results' considered rather supportive than 'Key' enough to stand as separate assets but may complement one or more of the identified KERs.

One of these assets is the Data Fusion tool which is mainly a research-oriented one, aiming to explore available data and identify correlations that are not visible to the human eye. The tool's outcomes will assist tools like ONCO-RISTE, ONCO-CLIDE and ONCO-EVIDA in better assigning risk levels to patients/citizens and provide clinicians/policy makers another dimension in understanding data analysis results in regards to population prevalence to CRC.

Another exploitable item is the Data Lake. ONCOSCREEN in order to demonstrate the information flow among the tools, is developing a database based on FHIR standard where both prospective data (generated by the tools) and retrospective data (obtained from Hospitals) can be stored. Although the FHIR is a well-accepted standard each country or hospital provider may have

different schemas and structures that a commercial product shall comply with. Thus, the data lake cannot be examined as a standalone component but rather being embed as a group of solution.

Furthermore, based on the ONCOSCREEN Architecture a federated approach has been proposed that includes a privacy preservation mechanism. Such an architecture is essential in modern healthcare, to train AI-based models without data of patients exiting hospitals assuming legal and IT compliance to local policies of each hospital. However, this shall be considered supportive to ONCOSCREEN KERs, given some hospitals may already have internal privacy preservation mechanisms in their IT infrastructure or methodologies for making publicly available data.

It is noted, that the above exploitable results will be closely monitored over the next period and if their status change to be considered as 'Key Exploitable Results' the KER table will be updated accordingly.

4 IPR Management

Since the beginning of the project, EXUS who leads the exploitation established a concrete stepwise Intellectual Property Strategy directly linked with the exploitation strategy and commercialization roadmap of the project.

The ONCOSCREEN IPR strategy complies with the procedure depicted in the following figure which is in accordance with the H2020 IPR Guidelines[4]. IPR issues were agreed and handled according to the negotiated Grant Agreement, while key protection measures were documented in the consortium agreement.

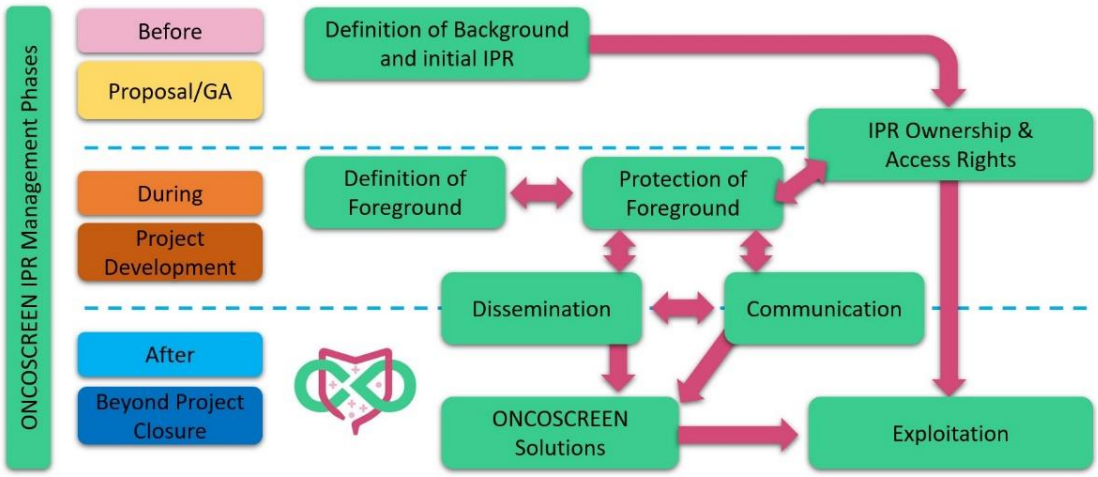

Figure 2. ONCOSCREEN IPR Management Strategy

The ONCOSCREEN IPR strategy encompasses a holistic approach combining exploitation, communication, marketing and IP planning and patent management towards an effective market penetration.

The IPR strategy is implemented by applying the following 5 stages:

1) IP Analysis:

In the IP Analysis stage, the consortium conducted a comprehensive assessment of all IP assets related to the CRC project. This involved identifying existing patents, trademarks, copyrights, and trade secrets within the consortium and mapping these assets against the project objectives. The primary goal was to ensure alignment between the IP assets and the project's commercialization roadmap. Detailed market research was conducted to identify potential gaps and opportunities in the IP landscape. This phase also included evaluating the legal status and scope of relevant IP,

[4] https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/intellectual-property_en.htm

as well as assessing the freedom-to-operate (FTO) to ensure that the project could proceed without infringing on third-party IP rights.

2) IP Strategy Definition:

During the IP Strategy Definition phase, the consortium worked collaboratively to develop a unified IP strategy. This process involved multiple iterations to align the diverse IP strategies of individual partners into a cohesive plan. Key sub-steps included setting strategic IP goals, defining roles and responsibilities, and establishing processes for IP management. The consortium held workshops and strategy sessions to harmonize the differing approaches and expectations. The resulting strategy was designed to support the project's objectives and commercialization roadmap, ensuring that IP assets would be leveraged effectively to gain competitive advantage and market share.

3) IP Operations:

In the IP Operations stage, the consortium focused on operationalizing the IP strategy. This involved setting specific IP goals, such as filing new patents, securing trademarks, or developing licensing agreements. Monitoring tools and metrics were established to track progress and measure the effectiveness of IP activities. The consortium also developed protocols for IP management, including regular IP audits, training sessions for team members, and a system for documenting and protecting new innovations. This stage ensured that the IP strategy was implemented effectively and that all consortium members were actively engaged in IP activities.

4) IP Execution:

The IP Execution phase was dedicated to carrying out the specific IP actions outlined in the strategy. This included filing patent applications, registering trademarks, negotiating licensing deals, and enforcing IP rights. The consortium communicated these actions clearly to all involved partners, ensuring that everyone was aware of their roles and responsibilities. Collaboration tools and platforms were used to facilitate communication and coordination among partners. Regular progress reviews were conducted to ensure that the IP actions were on track and aligned with the overall project goals. This phase was critical for turning the IP strategy into tangible outcomes.

5) IP Positioning:

In the final IP Positioning phase, the consortium analysed the IP strategies of competitors and the broader market. This involved continuous monitoring of industry trends, competitor patents, and emerging technologies. The goal was to identify any potential IP risks that could impact the market uptake of the ONCOSCREEN tools. If necessary, the consortium would re-align its IP strategy to mitigate these risks. This stepwise process was designed to be iterative, allowing for continuous improvement and adaptation. By the end of this phase, the consortium aimed to have

a robust IP strategy that minimized risks and maximized the commercial potential of the project's innovations.

4.1 Proposal Stage

During the proposal phase the ONCOSCREEN partners examined the key IP and innovation aspects through a series of discussions leading to a common understanding. The Consortium Agreement provided an initial agreement on the background, the foreground, the ownership, the knowledge transfer, the access and usage rights during and beyond the project closure for commercial and research purposes. The Consortium Agreement along with the Grant Agreement provide a series of IPR articles to clarify in advance potential issues among partners setting the framework of the protection of partner's results in case of commercialization along with a series of issues like the patent fill, declaration of copyrights etc.

In summary:

- The Grant Agreement sets the key rules and conditions for the project financing and is the main contractual basis for the European Commission (EC) with the ONCOSCREEN consortium. The main article referring to the management of the IP is Article 16, covering also the Agreement on Background, the set of access rights, the ownership and the protection of results. Dissemination of results are covered through Article 17. The GA provides a regulatory framework for partners to avoid disputes and legal claims in advance.
- The Consortium Agreement regulates the rights and obligation among partners with reference to management structures, financial distribution, confidentiality, liability and IPR. The difference with the Grant Agreement is that the European Commission (EC) does not participate as a party to the Consortium Agreement. Related articles are the Articles 8 and 9. The Article 8 clarifies the ownership of results (including the Joint Ownership procedure), the transfer and dissemination of results and the trademark usage. The article 9 refers to access rights on the background, exploitation, the access rights for affiliated entities defaulting and non-defaulting parties.

4.2 Development Stage

During the project development the ONCOSCREEN consortium clearly defined the most prominent technologies that could be commercialized and execute a dedicated IP management procedure for the protection of the results. It is noted that a patent application may last for years, or patent pending status may offer a very small time-frame for the protection of the results. In this case many partners preferred first to advance the product to high TRL and then fill a patent. Which means that while the process for the IP protection was initiated during the project period, it may finish some years after project closure.

In the development stage partners gave access rights to their knowledge so that other partners being able to undertake the foreseen project tasks. Especially when considering the system as a whole, an integrated system could never be developed without the collaboration of the involved

partners. This knowledge sharing mechanism eventually led ONCOSCREEN partners to the identification of KERs, as already presented in the earlier deliverable D7.2 and to their IP assessment.

The key stages of the IP protection during the project development are the following:

- **Production of IP results:** During the initial execution phase of the project, partners advanced their solutions and the most prominent ones are identified as the ONCOSCREEN Key Exploitable Results. The KERs are analysed systematically in this deliverable and represent the main ONCOSCREEN IP portfolio. ONOCOSCREEN KERs are monitored periodically providing updates with regard to changes in licensing, solution focus, result openness and ownership clarification.
- **Results Ownership Identification:** Partners based on the agreement about the foreground and background in the CA and based on the key exploitable results made an initial decision about the ownership or joint ownership of the ONCOSCREEN solutions, which will be updated as the technical solutions mature. In the case of the potential exploitation of the ONCOSCREEN solutions as group, a Joint Ownership Agreement will be signed.
- **Internal Protection of Results:** At this stage, partners discussed their legitimate interests with regard to the produced results following the corresponding articles of the GA and CA.
- **Use of foreground:** There were three different ways in which the foreground could be used, namely:
  - The commercialization of products and services
  - The transfer of the foreground to another partner via a license that will exploit the results
  - The utilization of foreground in research activities to advance the developed outputs
- **Dissemination of results**: In the next phase partners are going to disseminate their results with a series of actions in order to promote them and perform a detailed market analysis. All partners shall respect the conditions that were set in the CA regarding the confidentiality of some results.

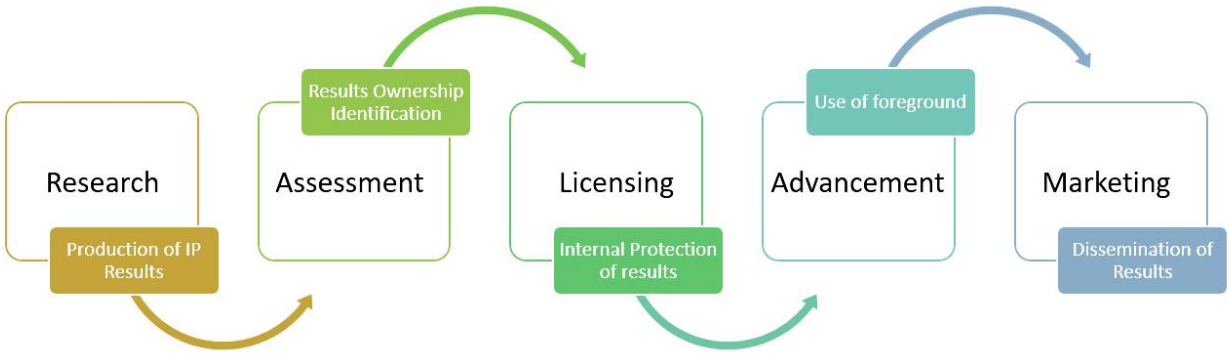

Figure 3. ONCOSCREEN IP Management during development phase

4.3 IP Registry

Towards implementing the IP strategy, an IP registry is setup since the beginning of the project with the aim of allowing easy identification of the Exploitable Results and to monitor for each of them the possible exploitation strategies. During this phase the IPR registry is monitored and updated bi-annualy to ensure the early identification of the maturity and the steps that need to be taken towards the exploitation of the key assets.

The following information is collected for each KER, which is updated every 6 months to avoid any IP related risks and ensure the application of timely protection:

- Relevant WP(s) and/or task(s)
- Ownership of the IP
    - Single ownership
    - Joint ownership
- Identified possible exploitation route (e.g. patenting, licensing, …) and description of the licence if published
- Short description of the IP item
- Location of the IP item (e.g. Github), if available
- Description of any open access results, if applicable
- Short description of the protection mechanisms of each IP item towards commercialization
- Preferred ownership scheme model

A first version of this registry, as documented in D7.2, in which we have identified the KERs, any likely exploitation plans, and target groups, has been used as a foundation for this deliverable. The IP Registry has been nonetheless devised as a live document and is regularly during the course of the project. This allows a clear tracking of the evolution of IP generated by the project, definition of single or joint exploitation paths and immediate identification of the most exploitable technologies and possible risks through the results of the SWOT analysis, mentioned later. The main information extracted from the IP Registry, as compiled during the writing of this deliverable, are reported in the below table.

Table 6 Intellectual Property Registry, main information

No	Exploitable Result	Exploitation Route	Ownership	Target Group
1	**ONCO-VOC**	Commercial Exploitation due to market demand for cost reduction in CRC screening. Market Analysis, Business Plan, IPR protection	TECHNION (lead) ICSS, BEIA, FIRALIS	Medical device manufacturers, Clinicians, Citizens
2	**ONCO-CRISPR**	Commercial Exploitation due to market demand for cost reduction in CRC screening. Market Analysis, Business Plan, IPR protection	CCASSURED (lead)	Medical device manufacturers, Clinicians, Policy Makers

3	**ONCO-NMR**	Scientific Exploitation (further development of existing SOP for Urine/Blood NMR measurement)	UzL (lead)	Clinicians, Policy Makers, Academia, Clinicians
4	**ONCO-CTC**	Commercial & Scientific Exploitation due to demand for early identification of CTCs. Market Analysis, Business Plan, IPR protection	UMINHO (lead) FIRALIS	Medical device manufacturers, Academia, Clinicians
5	**ONCO-AICO**	Scientific Exploitation (Non-clinicians (e.g. Nurses or GPs) experts can use this tool for CRC polyp identification)	CERTH (lead) ICCS, KONN, AINIGMA	Clinicians, Academia
6	**ONCO-AITI**	Scientific Exploitation (Non-experienced histopathologists can use this tool for CRC polyp identification)	MUG (lead)	Clinicians, Academia
7	**ONCO-RISTE**	Commercial Exploitation since the clustering algorithms of the tool can be used as a trade secret in various sectors for customer segmentation enhancing existing or create new products.	EXUS (lead)	ICT-AI industry, Patients, Clinicians, Policy Makers
8	**ONCO-CAWA**	Commercial Exploitation due to increased need for personalised approaches in almost all aspects of life.	ISPRINT (lead) EXUS, TECHNION, BEIA	All
9	**ONCO-CLIDE**	Scientific and Economic exploitation due to the need of DSS to assist Clinicians and application of such tools in multiple industry verticals respectively	KONN	Academia, ICT-AI industry
10	**ONCO-EVIDA**	Policy Exploitation Route to enable evidence decisions in realistic decision scenarios based on real life constraints. Cancer Policy change.	VITO (lead) ICCS, CERTH, CTL KONN	Policy Makers
11	**ONCO-BIOBA**	Scientific exploitation due to the need to further expand existing biobanks with data that can be used worldwide considering privacy rights.	MUG (lead)	Policy Makers, Healthcare Owners

In **Appendix B**, the live registry with more details for each KER is shown. The registry is updated every 6 months from relevant partners as per the GA, to help monitor the progress and maturity

of each KER. The final results will be provided in D7.7, i.e. the final version of the IPR and exploitation management activities.

4.4 Post Project Stage

The ONCOSCREEN consortium intends to exploit the foreground of the solutions. It is noted that in this final version of this deliverable D7.7 a more detailed plan regarding IPR strategy will be presented along with the final version of the IPR Registry and the IPR issues. During the project execution, partners will finalize all IP issues and when solutions get mature towards TRL9, they will proceed to the next steps of the post-project IP Process, which include:

- **IP Assessment**: In this step a diverse set of actions can take place that may include (but not limited to) a) fund raising through different sources of funding for finalizing or scale the product (considering that a defined IP can dictate the range of funding depending on the introduced innovation) b) negotiation rounds for selling or licensing IPRs (evaluation of IP contributes to finalize the price dealing) c) In which country the IPR shall be established is it an EU patent and so on d) tax reduction from the patent submission proof based on the legislative framework.
- **IP Legal Risk Management**: This step aims to reduce the dedicated ONCOSCREEN solution risk. As risks in IP field we mean ownership disputes or third party IP infringement. There are certain types of mitigation such as corporate insurance that can cover legal claims up to certain amount if the risks occurred, relevant contract disclosures etc. During the project period the focus will be to avoid internal ownership disputes from with other project partners, while with an enhanced patent search external risks shall be avoided or minimized.
- **IP Exploitation**: The exploitation of the IPR of the ONCOSCREEN solutions (assuming that the different modules were advanced during the project period) can lead to a) a license agreement with a third party for selling the product for a fee (either on a royalty fee basis from the sales or a lump sum). The licence agreement usually takes place when a partner has not the power to directly exploit the IP or foresees to a better financial income from providing the right to another party (that maybe has a larger network of customers) b) A spin-off company, that is usually more preferable from the university/research institutes c) Joint venture among two or more parties based on ownership agreement. As it can be easily understood prior to such option a thorough market research study along with a legal risk assessment shall take place.
- **IP Enforcement**: When a legal risk occurs (infringement by competitor company) the owner of the IP (e.g. an ONCOSCREEN partner) might need to defend their IP rights in court. A series of actions can take place such as alternative dispute resolution mechanisms. The legal costs in case of a dispute for a global patent can reach up to 2million euros. This risk shall not be ignored from companies when claiming their IP rights. IP enforcement is a quite expensive and time-consuming process that should be taken into consideration into the selection of the territory of the patent (national, European, global) in advance.

Figure 4. ONCOSCREEN IP Management beyond project period

4.5 Current Protection of Assets

ONCOSCREEN partners have already a series of patents relevant to the developed technologies which bring an extra competitive advantage in such a rapidly growing market. Below is a list of patents relevant with each tool and unique expertise gained via recent European projects.

Table 7 Current Protection of Assets

IP Asset	Owner	Protected	Open	Method	Background (Patents, H2020 projects)
ONCO-VOC	TECH	Yes	No	Patent	17 patents including EP2281193A1, EP2376913A1, WO2011083473A1
ONCO-CRISPR	CCASSURED	Yes	No	Patent	WO2018111104A1, STAMINA
ONCO-NMR	UzL	Yes	No	Patent	Internal UzL protocol for NMR from BRUKER
ONCO-CTC	UMINHO	Yes	No	Patent	WO2021038507 and ERA-Chairs FoReCaST
ONCO-AICO	CERTH, ICCS, KONN, AINIGMA	No	Yes	Open Licence	AI@EDGE
ONCO-AITI	MUG	No	Yes	Open Licence	HEAP, BIGPICTURE
ONCO-RISTE	EXUS	Yes	No	Trade Secret	ONCORELIEF (H2020)
ONCO-CAWA	iSPRINT	Yes	No	Trade Secret	Healthentia
ONCO-CLIDE	KONN	Yes	No	Trade Secret	Search & Rescue
ONCO-EVIDA	VITO, ICCS	No	Yes	Open Licence	HBM4EU, EIFFEL
ONCO-BIOBA	MUG	No	Yes	Open Licence	BBMRI, EOSC-Life, FeatureCloud

5 ONCOSCREEN Positioning

5.1 SWOT Analysis

5.1.1 SWOT Analysis as a whole

A SWOT analysis for the ONCOSCREEN project wide methods is shown below.

Table 8 ONCOSCREEN Project Wide SWOT Analysis

Strengths	**Weaknesses**
• Less intrusive screening methods compared to colonoscopy • High detection efficiency • Early detection of cancer • Low cost per examination • Supported by large clinical study • Multi-tier stratification methodology • Intelligent analytics dashboard • Relevant patents and high expertise by key partners • Simple and user-friendly diagnostic methods	• Non-commercialised product yet • Not part of existing commercial solution • New screening solutions are difficult to be adopted • Not CE mark yet (medical devices)
Opportunities	**Threats**
• Rapidly growing market towards new screening technologies • Train large number (>2500) of clinicians on the developed technologies • Inform the public via the mobile app about the new screening technologies • >4000 people will get screened during the project • Adoption of the screening technologies by regional/national programs	• Key players are developing alternative solutions • Clinicians are not familiar and not willing to use the screening technologies • National programs are hesitant to use the developed technologies • Medical approval of new screening methods takes time • Cost for CE Mark and “scale-up”

A detailed SWOT analysis for all the identified IP assets is reported in the following Sections and will be updated in the final deliverable D7.7.

5.1.2 SWOT Analysis of ONCO-VOC

Strengths	**Weaknesses**
• Low cost • User-friendly • Versatile • Sensitivity	• Several other competitor technologies • Not patented (final product) • No CE mark

Opportunities	Threats
• This technology can be extended to other diseases and different kinds of cancers.	• Fail to attract funding • Still more verification studies are needed. • Fast evolving field

5.1.3 SWOT Analysis of ONCO-CRISPR

Strengths	Weaknesses
• Less intrusive screening methods compared to colonoscopy • High detection efficiency • Early detection of cancer • Low cost per examination • Supported by large clinical study • Multi-tier stratification methodology • Relevant patents and high expertise by key partners	• Non-commercialised product yet • Not part of existing commercial solution • New screening solutions are difficult to be adopted
Opportunities	**Threats**
• Rapidly growing market towards new screening technologies from 40 billion now to 80 billion in 2032 • CRISPR market is now 3 billion and expected to grow toward 15 billion in 2032 • Train large number (>2500) of clinicians and local physicians on the developed technologies • Inform the public via the mobile app about the new screening technologies • 4000 people will get screened during the project • Adoption of the screening technologies by regional/national programs	• Key players are developing alternative solutions • Clinicians are not familiar and not willing to use the screening technologies • National programs are hesitant to use the developed technologies • Medical approval of new screening methods takes time • Existing patents and patents submitted by others that are not published yet have an earlier submission date

5.1.4 SWOT Analysis of ONCO-NMR

Strengths	Weaknesses
• Novel glycosylation markers by simple NMR analysis • One measurement yields a range of markers for different diseases	• So far limited testing for diseases • Early stage, no clinical approval so far

• Fast measurement • No chemical processing of samples required	
Opportunities	**Threats**
• Novel clinical test • Highly sensitive for a range of diseases in early tests • Potential as a novel overall concept for laboratory medicine, that provides many parameters at one time	• Somewhat higher cost compared to established lab test • Highly competitive clinical diagnostics market

5.1.5 SWOT Analysis of ONCO-CTC

Strengths	**Weaknesses**
• Low cost • User-friendly • Versatile • Sensitivity • Patented polymers and methods that can be used in the ONCO-CTC tools fabrication • SOP well established	• Several competitors • No filling of patent yet (final product) • No CE mark yet
Opportunities	**Threats**
• Expand technology to different sectors besides diagnostic such as research, cell culture tools and Pharma industry • Expand technology to personalized medicine (organoids-on-a-chip and tumour-on-a-chip)	• Fast evolving field • Fail to attract funding • Long time for validation and requirements for pivotal and post commercialization clinical studies

5.1.6 SWOT Analysis of ONCO-AICO

Strengths	**Weaknesses**
• Explainable AI (XAI) Integration • Focus on training and professional growth • Cost-Effective Solution to training specialists	• Dependence on Quality Data • Early adoption hurdles • User Interface and Usability Challenges
Opportunities	**Threats**
• Market Demand and Expansion • AI Advancements	• Regulatory and Compliance Challenges • Technological Competition

5.1.7 SWOT Analysis of ONCO-AITI

Strengths	Weaknesses
• Web baes learning tool -> easy access • Contains information about pathologists views on WSIs • Offers different explanations for a WSI	• Low amount of annotated data, currently • Low amount of observation data from pathologists, currently
Opportunities	**Threats**
• Could be first learning platform which combines xAI from algorithms and observation pattern from pathologists • Could serve as known tool, to enhance the learning process of junior pathologists	• Inactive partner delays development -> risk to miss the deadlines in the project • Cause of delays, higher risk to have a competitor with similar idea on the market

5.1.8 SWOT Analysis of ONCO-RISTE

Strengths	Weaknesses
• Automatic identification of dependencies and correlations among feature for clustering citizens/patients to risk levels. • Fuzzy logic for handling uncertainty, impreciseness and vagueness in interpretation of empirical rules. • Combine heterogeneous information regarding behavioural, socio-economic and environmental factors, as well as results from diagnostic tools, tests and biopsies. • Dynamic update of risk-score. • Accessibility of the solution, being embed in patient or clinician apps.	• Exploitation as a standalone component may be difficult • Dependency due to the use via another solution (embedded in patient/clinician app), developed by third party.
Opportunities	**Threats**
• Challenges in CRC cancer diagnosis (human error, diagnosis in late stage, unwillingness to conduct screening) and CRC statistics indicate a growing market. • New factors are discovered and there is a need for a tool that can provide them in consideration • Co-design approach enhance end user acceptance.	• Development of the semi-empirical model is dependent to third parties for providing domain-knowledge for building the fuzzy-logic rules and combining heterogenous data. • Large scale clinical testing is dependent to the availability of data from citizens/patients. • Data privacy and security concerns. • Clinicians are hesitant to use of AI

• Big room for bilateral collaborations as independent webservice being sub-part of products	

5.1.9 SWOT Analysis of ONCO-CAWA

Strengths	**Weaknesses**
• Decrease clinical appointments • Use of mobile app anytime, anywhere, increasing the likelihood of consistent usage and engagement • Provide educational content about CRC empowering users with knowledge • Improve adherence by reminders and notifications	• Convincing individuals to download and regularly use the app may be difficult • Not all patients have access to mobile phones and IoT devices for measurements
Opportunities	**Threats**
• Targeted marketing for CRC patients and caregivers increases app's relevance and appeal • Continuous improvement from user feedback and analytics • Expansion of app's services	• Changes in healthcare regulations or privacy laws may require costly updates to ensure compliance • Cybersecurity threats, such as data breaches or malware, can compromise user data and damage the app's reputation • Rapid advancements in technology may render the app outdated or incompatible with newer devices

5.1.10 SWOT Analysis of ONCO-CLIDE

Strengths	**Weaknesses**
• Enhanced Diagnostic Accuracy • Time Efficiency • Improved Patient Outcomes • Standardization of Diagnosis • Continuous Learning and Improvement	• Initial Investment and Implementation Costs • Integration Challenges • Data Privacy and Security Concerns • Risk of Overreliance • Limited Generalizability
Opportunities	**Threats**
• Expanded Clinical Applications • Collaborative Research and Development • Telemedicine Integration • Patient Empowerment	• Regulatory Hurdles • Competitive Landscape • Resistance to Adoption • Technological Obsolescence • Ethical and Legal Challenges

• Global Market Expansion	

5.1.11 SWOT Analysis of ONCO-EVIDA

Strengths	**Weaknesses**
• Focus on medical data visualization and specifically on CRC related data. • User friendly environment. • Customizable dashboards generating useful charts. • Subnational aggregation levels. • Ability to visualize risk factors & screening factors.	• Focus on medical data visualization might limit use cases compared to more general dashboards. • Restricted data sources may potentially limit the flexibility and user adoption. • Residual confounding when comparing geospatial patterning of exposures and outcomes. • Use of (only) aggregated data makes integration with individualised ONCOSCREEN tools challenging. • Ambiguity on hosting & updating responsibility.
Opportunities	**Threats**
• Capitalize on the increasing demand for tools to analyze and interpret complex medical data. • Expand the dashboard's reach by integrating with other data sources beyond ONCOSCREEN. • Offer users the ability to customize dashboards to meet their specific needs and preferences. • Facilitate evidence-based policymaking. • Common interface in implementing regions may encourage standardisation & homogenisation of (medical) data	• Established players in the market might offer similar functionalities; lack of implementation in regions that already have a long-standing CRC screening tradition. • Changing regulations around data privacy could limit data access or increase compliance burdens. • Medical data are sensitive, so security breaches could damage reputation. • Unfair or unwarranted cross-regional comparisons may be misused for political agendas.

5.1.12 SWOT Analysis of ONCO-BIOBA

Strengths	**Weaknesses**
• Project based directory to describe the collection within the project	• Relatively small, compared to organisations like BBMRI-ERIC
Opportunities	**Threats**

• Could deliver a well overview about the provided sample collections within the project, and after the project time above	• Depends on the plan of clinical partners to establish a sample collection at their biobank

5.2 PESTLE Analysis

In addition to SWOT analysis, PESTLE analysis is used. PESTLE analysis is a strategic management tool used to analyse the external factors that may impact a business or organisation. By examining each of these factors, the consortium gains a better understanding of the challenges and opportunities it may face in the marketplace. This analysis helps partners to identify areas where it needs to adapt and make strategic decisions to ensure long-term exploitation of the project's results.

5.2.1 PESTLE Analysis as a whole

In the table below, we present the preliminary PSTLE analysis for the overall ONCOSCREEN assets.

Table 9 PESTLE Analysis for all assets

Political	Economic	Social/Cultural	Technological	Legal
• Lack of national and EU health authorities to adopt innovative digital health solutions due to negatively biased opinions of the public. • Insufficient infrastructure with lack of supplies and personnel. • Other political priorities due to unforeseen events (e.g Covid-19, war). • Knowledge deficits about guidelines and barriers to screening.	• Absence of health insurance or coverage of the costs of screening. • Unavailability of big pharma to invest in CRC screening and detection tools since treatment is more profitable. • Inequalities between countries to use AI/software tools for assistance in detection and diagnosis.	• Lack of awareness for the benefits of CRC screening. • Health care authorities are negatively biased on the use of AI in healthcare. • Patients are unwilling to share their personal bio-data, due to security and/or legal concerns. • Lack of trust between the clinician and the patient/citizen. • Poor knowledge and subsequent dissemination of cancer risk and information.	• Poor performance of clinicians during the screening activities. • Limited or no knowledge of AI utilization in risk-based stratification. • Another initiative or project develops better monitoring solutions for CRC screening with higher accuracy risk prediction.	• Continuous change of legislation. • Legal restriction for the use of the tools. • Developed technologies shall be compliant with GDPR and EU Cookie policy directives.

		• Language and psychosocial reasons. • Negative/Painful experience from previous CRC screening programs.		

The consortium has identified mitigation measures against such external factors by mainly applying an active and effective communication and dissemination actions involving patient and clinicians' associations in co-operation with policy makers in EU level. Moreover, it is planned, and has already started, to engage stakeholders to increase the acceptability of the solutions.

Concerning the economic factors, the ONCOSCREEN solutions will include in the study EY and AXA where novel innovative schemes will be proposed. The cost of the solutions is estimated to be low, and it will get even lower with increasing usage from wider populations. Non-experts will be able to use the ONCOSCREEN AI algorithms to assist in the detection of adenomas in colonoscopies.

Concerning the social factors, the consortium developed detailed communication packages for targeted populations related to CRC early detection based on their needs and understanding as explained in this document. It is also planned to utilize a mobile application which can help towards more personalised approach to citizens/patients' recommendations. Campaigns and material will be prepared for explain to the public the advantages and reliable and under specific rules usage of Trustworthy and explainable AI-assisted systems in healthcare.

Concerning the technological and legal factors, analytical training activities for the ONCOSCREEN tools and feedback loops between developers/clinicians will be carried out. The market landscape will be monitored for new advancements and will liaise with other projects and initiatives aiming to collaboratively improve project results.

5.2.2 PESTLE Analysis of ONCO-VOC

Political	Economic	Social/Cultural	Technological	Legal
• Government and institutional funding seems to be solid in this kind of solution implementation. This particularly encourage	• A common barrier is post-project financing from commercial or public sources to ensure technology	• Involving patients in the mode of action of the ONCO-VOC tool is critical to proper implementation of this breath	• The technology of breath analysis is rapidly developing, yet, one of the most important challenges is its convergence with additional diagnostic	• Rreaching policymakers and recruiting their support may be difficult. • Moreover, ethical and legal challenges associated with the collection of personal data are sensitive and must

future development of PoC technologies to improve and further develop breath analysis solutions.	transfer to the market.	analysis technology. • Moreover, the understanding of the health providers is even more crucial in this implementation.	technologies, for additional accuracy and smooth implementation. • The ONCO-VOC tool is designed to be extremely easy to apply and therefore is naturally additive to most existing as well as future diagnostic methods.	be carefully addressed. However, EU (EMA/198592/2022). • The project methodology complies with the "do no significant harm" principle as per Article 17 of Regulation (EU) No 2020/852 on the establishment of a framework to facilitate sustainable investment

5.2.3 PESTLE Analysis of ONCO-CRISPR

Political	Economic	Social/Cultural	Technological	Legal
• Insufficient infrastructure with lack of supplies and personnel. • Other political priorities due to unforeseen events (e.g Covid-19, war). • Knowledge deficits about guidelines and barriers to screening. • Government incentives for technology	• Absence of health insurance or coverage of the costs of screening. • Unavailability of big pharma to invest in CRC screening and detection tools since treatment is more profitable. • Global economic conditions	• Lack of awareness for the benefits of CRC screening. • Poor knowledge and subsequent dissemination of cancer risk and information. • Negative/Painful experience from previous CRC screening programs. • Lifestyle changes	• Poor performance of clinicians during the screening activities. • Another initiative or project develops better monitoring solutions for CRC screening with higher accuracy risk prediction. • Rapid technological advancements in the field	• Continuous change of legislation. • Legal restriction for the use of the tools. • Developed technologies shall be compliant with GDPR and EU Cookie policy directives. • Consumer protection laws • Intellectual property laws

5.2.4 PESTLE Analysis of ONCO-NMR

Political	Economic	Social/Cultural	Technological	Legal
• While the goal is medical use, IVD approval is needed for the EU and FDA approval for the US. • To generate revenue before this, glycoanalysis will be sold as a computational tool for scientifically driven projects, which has no political implications.	• Buffers and reference compound solutions costs, sell at a much cheaper rate than available now (Bruker is currently the only source) • Data analyses cost and availability (support offering servers, pre-paid packages)	• Initially no social issues are expected, since scientists will buy the solution. • At a later stage IVD approval will be needed for a series of diseases.	• Enhancement of specification of the observed markers. a) Identify a larger number of related proteins. b) Clinical trials to explore the technology. c) Offer our own lipoprotein and small molecule analysis for a comprehensive package.	• US patent office response to ensure the operation in the US. • Need for customer agreements for non-medical scientific use.

5.2.5 PESTLE Analysis of ONCO-CTC

Political	Economic	Social/Cultural	Technological	Legal
• Government policies and their implementation, particularly to encourage future development of PoC technologies to improve healthcare service, require a robust underlying database as well as future monitoring of the impact and success of these policies. The	• A common barrier is post-project financing from commercial or public sources to ensure technology transfer to the market.	• Involving patients in the decision of home care is critical to improving the prognosis of CRC, as is providing proper health literacy and understandable documentation about the ONCO-CTC tool.	• There is currently a lack of technological convergence and standardized methods for early detection of specific biomarkers in non-communicable diseases. • ONCO-CTC brings together a variety of previously independently	• Health legislation varies among countries, and for companion diagnostics has been recently updated in EU (EMA/198592/2022). • The project methodology complies with the "do no significant harm" principle as per Article 17 of Regulation (EU) No 2020/852 on the establishment of a framework to facilitate sustainable investment.

differences in healthcare systems, reimbursement schemes, and organizational workflows among countries are a major barrier to be considered.			used approaches, methods, technologies, and applications to improve CRC diagnosis and, later, healthcare service. • Moreover, difficulties for scale-up, the high-prices of technologies, required expertise's for operation, are major hurdles for successful clinical translations of medical devices in diagnostics.	• Furthermore, reaching policymakers and enlisting their support may be difficult. Moreover, ethical and legal challenges associated to the collection of health and personal data are sensitive areas that must be carefully addressed in the context of innovation.

5.2.6 PESTLE Analysis of ONCO-AICO

Political	Economic	Social/Cultural	Technological	Legal
• Healthcare Policies: Government policies promoting early cancer detection and screening programs can support the adoption of ONCO-AICO.	• Training Costs: ONCO-AICO can reduce the costs associated with training junior colonoscopists and non-physician endoscopists by providing an efficient, scalable solution. • Operational Efficiency: Automated, training, annotation, and diagnosis can lower	• Acceptance of AI in Healthcare: Building trust in AI technologies among patients and healthcare providers is crucial for widespread acceptance and use. • Education and Training: ONCO-AICO's focus on training enhances the skills of junior colonoscopists and non-physician endoscopists,	• AI and Deep Learning: Leveraging cutting-edge AI and deep learning technologies ensures high accuracy and specificity in polyp and adenoma detection. • Explainable AI (XAI): The integration of XAI provides transparent and interpretable results,	• Regulatory Compliance: Adherence to medical device regulations and data privacy laws is critical for legal operation and acceptance.

	operational costs in colorectal cancer screening programs.	addressing workforce shortages in gastroenterology.	increasing trust among users.	

5.2.7 PESTLE Analysis of ONCO-AITI

Political	Economic	Social/Cultural	Technological	Legal
• Lack of rules to handle with observation data from medical staff	• Low potential investment of students or junior pathologists for a learning tool	• Trustworthiness of tracked observation data from pathologists without proven results of there correct pattern and meaning	• Already existing AI algorithms with high accuracy in detection of tissue types or cancer	• Compliance of national and international laws and guidelines.

5.2.8 PESTLE Analysis of ONCO-RISTE

Political	Economic	Social/Cultural	Technological	Legal
• Other political priorities due to unforeseen events (e.g. Covid-19, war) may reduce available budget for innovative solutions in healthcare. • Lack of interest from national and EU health authorities to adopt innovative digital health solutions due to negatively biased opinions of the public in regards to AI.	• Unavailability of investments in CRC diagnosis due to prioritization. • Inequalities among countries to use tools for assistance in diagnosis.	• Lack of awareness of the benefits of new technologies in CRC diagnosis and treatment. • Negative bias and lack of trust for AI in healthcare from health care authorities, citizens and patients. • Citizens/patients are not willing to share personal health data due to ethical or security concerns.	• Accessibility on from the mobile/ clinician app. • Need for integration activities with other components • Difficulty in following all scientific updates and publication for the update of stratification algorithm.	• Compliance with GDPR and EU AI Act. • Liability issues in case of inaccurate / erroneous results. • Changes in legislation. • Regulations for usage and deployment approval as medical software.

5.2.9 PESTLE Analysis of ONCO-CAWA

Political	Economic	Social/Cultural	Technological	Legal
• Government regulations and healthcare policies can impact the adoption and usage of the app • Compliance with data protection laws ensuring legal operation	• Avoid healthcare spending and thus increasing the demand of the app • Rise of digital health solutions create opportunities for the app to attract investment	• Increase health awareness • Aging populations and shifting demographics increase the demand for accessible and personalized health	• Advancements in mobile technology provide a conducive environment • The availability of data analytics tools and techniques allows for the collection and analysis of user data to personalize content and improve user experience	• Compliance with healthcare regulations is crucial for the app's legal operation and credibility • Intellectual property rights of the app must be protected

5.2.10 PESTLE Analysis of ONCO-CLIDE

Political	Economic	Social/Cultural	Technological	Legal
• Government regulations and policies related to healthcare and medical technology can influence the development and adoption of the CDSS. • Funding and support from governmental bodies for research and implementation initiatives. • Political stability and potential changes in healthcare policies that may affect healthcare IT investments.	• Budget constraints within healthcare systems may affect the allocation of funds for the development and deployment of CDSS. • Cost-effectiveness of the CDSS compared to traditional diagnostic methods. • Reimbursement policies for	• Patient attitudes and acceptance of technology-enabled healthcare solutions like CDSS. • Cultural beliefs and practices related to cancer diagnosis and treatment that may influence the adoption of the CDSS. • Demographic trends affecting CRC incidence rates	• Advancements in artificial intelligence, machine learning, and data analytics that enhance the accuracy and efficiency of the CDSS. • Integration capabilities with existing electronic health record systems and medical devices used in CRC diagnosis. • Cybersecurity concerns	• Compliance with data protection regulations such as HIPAA (in the United States) and GDPR (in the European Union) to ensure patient privacy. • Liability issues in case of diagnostic errors or misinterpretation of results by the CDSS. • Intellectual property rights related to the software algorithms and

	healthcare providers using CDSS for CRC diagnosis. • Economic trends that may impact the availability of funding for research and development.	and healthcare needs in different populations. • Public awareness campaigns and educational initiatives about CRC screening and early detection.	related to the protection of patient data within the CDSS. • Accessibility of the CDSS across different devices and platforms.	technologies used in the CDSS. • Regulatory approval processes required for the deployment of medical software and decision support systems.

5.2.11 PESTLE Analysis of ONCO-EVIDA

Political	Economic	Social/Cultural	Technological	Legal
• Increased government funding can lead to more data being collected in ONCO-EVIDA, potentially benefiting the dashboard. • Stricter regulations on data privacy could limit data availability or increase compliance costs for data storage and access. • Government policies supporting data sharing between institutions could benefit the dashboard by	• Growth of the healthcare IT sector creates opportunities for the ONCO-EVIDA dashboard as part of the data analysis ecosystem. • A strong economy might lead to increased hospital budgets for investing in data analysis tools. • Conversely, an economic downturn	• Growing demand for patient access to medical data, could increase demand for user-friendly tools like the ONCO-EVIDA dashboard. • Security breaches or public concerns about data misuse could create resistance to using the dashboard. • The increased focus on	• Advancements in data visualizations tools could improve the dashboard's capabilities and user experience. • Evolving cybersecurity threats necessitate continuous investment in data security for the dashboard. • Integration with other healthcare IT systems or electronic health records (EHR) could enhance the	• Compliance with data security and privacy regulations is crucial for handling medical data. • Protection of Intellectual Property Rights.

expanding data sources.	could limit spending. • The cost of storing large medical datasets could impact the financial viability of the dashboard.	personalized medicine aligns well with the dashboard's goal of data analysis for informed decisions.	dashboard's value.	

5.2.12 PESTLE Analysis of ONCO-BIOBA

Political	Economic	Social/Cultural	Technological	Legal
• n.a.	• Low potential investment to such a small directory and a few amount of collections	• hurdle for interested parties to search for suitable collections in a small directory	• Already directories, aim should be to include the results of BIOBA into a bigger platform, after the time of the project	• Compliance of national and international laws and guidelines.

5.3 Value Proposition (Target Customer Segment)

Component Name	Component Value Proposition	Targeted Customer Segment
ONCO-VOC	Diagnosis tool for early detection of CRC.	Patients and clinicians.
ONCO-CRISPR	Customer need, Technographic, Psychographics, Early detection of CRC, Increased specificity and sensitivity. POCT	Patients and physicians, EU citizens

ONCO-NMR	Diagnosis tool for early detection of CRC. Low-cost methodology.	Citizens, patients, clinicians, diagnostic centres / companies, medical equipment providers.
ONCO-CTC	Diagnosis tool for detection of CRC, primarily. Simple and user-friendly method. Adaptation of the tool for patient stratification and personalised drugs treatments (e.g. metastatic patients).	Patients, health professionals and physicians, and EU citizens.
ONCO-AICO	Integrating the platform to training programs for junior colonoscopists, enhancing the quality of endoscopic procedures and improving patient outcomes	- Hospitals and Medical Centers - Academic Institutions - Endoscopy Training Centers
ONCO-AICO	The platform accelerates skill development and builds confidence in polyp detection, reducing the learning curve associated with traditional training methods.	- Junior Colonoscopists - Non-Physician Endoscopists
ONCO-AITI	Web based learning platform which enables the visualization of regions of interest on a whole slide image during the observation process	- Junior Pathologists - Medical stuff, like nurses - Expert pathologists as trainers
ONCO-RISTE	ONCO-RISTE is a CRC risk-based stratification engine that is based on fuzzy logic and incorporates not only results of diagnostic devices but also information regarding behavioural, socio-economic and environmental factors. More accurate stratification can lead to more accurate behavioural and clinical interventions based on	Clinicians, oncologists, surgeons, physicians, patients.

	individual risk calculation assisting in early diagnosis and human error reduction.	
ONCO-CAWA Healthcare Providers	Seamless access to medical records, personalized recommendations, and direct communication with healthcare professionals	Individuals seeking reliable and personalized guidance on CRC screening, prevention, and management
ONCO-CAWA Health Insurance Providers	facilitates access to information on coverage for CRC screening tests, preventive services, and financial assistance programs and helps users understand healthcare billing and insurance reimbursement	Individuals seeking information on insurance coverage for CRC screening and related services, as well as assistance with navigating insurance claims and expenses
ONCO-CAWA Research Institutions	Access to evidence-based research, clinical guidelines, and educational content on CRC epidemiology, risk factors, and prevention strategies ensuring app's content is informed by the latest scientific advancements	Individuals interested in learning about the latest research findings, emerging trends in CRC prevention and treatment, and evidence-based strategies for reducing their risk of CRC
ONCO-CLIDE	ONCO-CLIDE provides clinicians with real-time guidance and recommendations during the diagnostic process. This includes evidence-based guidelines, clinical pathways, and risk assessment models tailored to CRC diagnosis. By offering decision support at the point of care, these tools help clinicians make more confident and consistent diagnostic decisions, reducing variability in practice and improving patient outcomes.	Clinicians, including primary care physicians, gastroenterologists, oncologists, and surgeons.

ONCO-EVIDA: Dashboard	Offers interactive dashboards with advanced visualizations to explore complex cancer data relationships and gain deeper insights.	Policymakers, screening providers, other data analysts needing to identify patterns and trends in cancer data to inform treatment decisions and research.
ONCO-EVIDA: Dashboard	Enables secure and standardized sharing of dashboards, reports, and data insights with colleagues. Improves communication and collaboration among healthcare professionals.	Policymakers, screening providers, other researchers working in teams who need to share findings and facilitate discussions around cancer data.

5.4 End User Pain Points Vs Value Proposition

In the following table the end user pain point versus the ONCOSCREEN value proposition is presented.

End User Pain Points	How the end user addresses the problem today	ONCOSCREEN Solution	Component Value Proposition
Lack of sensitive and easy to use method that can serve as pre-screening for Colonoscopy.	FIT test, Colonoscopy	ONCO-VOC	The ONCO-VOC tool can provide sensitivity (more than 87%) and be used in combination with additional diagnostic methods to advance medical diagnostic capabilities.
Lack of sensitivity	FIT test, genetic tests	ONCO-CRISPR	CRISPR-Cas diagnostics can provide the required sensitivity of more than 95%
Expensive	Using genetic tests that are also expensive	ONCO-CRISPR	Can put a genetic test into the market that is a factor 20 – 100 cheaper than current existing tests

Fulfilling the ASSURED criteria	Not addressed	ONCO-CRISPR	This is the philosophy of our company which can be achieved by using our CRISPR-Cas technology
At the point of care	Not addressed	ONCO-CRISPR	The CRISPR-Cas technology will allow to bring the diagnostic test without laboratory equipment to the Point of care
Accurate test before invasive procedures and expensive imaging	Not addressed or partly addressed with expensive genetic tests	ONCO-CRISPR	Our CRISPR-Cas technology can be built in as an important gate keeper before patients will be referred to invasive or expensive imaging procedures
Non-invasive screening, via blood and urine sample	Invasive methods, with significantly higher cost	ONCO-NMR	ONCO-NMR tool can be used before patients are referred to invasive procedures, offering better understanding of the metabolic profile of patients with early colorectal neoplasia comparing to other methods.
Lack of sensitivity and no personalization capacity	FIT test, genetic tests	ONCO-CTC	ONCO-CTC tools offer a user-friendly method that can provide sensitivity (more than 90%) and the adaptability to address patient-specificity for precision medicine applications.
Low Adenoma Detection Rates (ADR)	Endoscopists typically undergo traditional training programs, which may include observation of senior practitioners, hands-on experience, and didactic learning sessions.	ONCO-AICO	ONCO-AICO offers a structured and interactive training platform that accelerates the skill development of junior colonoscopists and non-physician endoscopists through XAI, leading to faster improvements in ADR.

Transparency and Trust	AI models currently operate mainly as a black-box with very little insights on why or how they arrive on the results they produce	ONCO-AICO	Integration of Explainable AI (XAI) enhances transparency and trust in the AI-assisted diagnoses, empowering end-users to understand and validate the decision-making process behind lesion detection.
Very long education process of medical absolvent to pathological expert	Learning by doing, mentor system in which expert pathologist supports junior pathologist	ONCO-AITI	Tool will provide information about regions of interest for pathological expert to junior. Possibility to obtain this information without asking the mentor.
Trustworthy, dynamic and unbiased risk calculation based on clinical experts (human in the loop) and individual risk-based classification for CRC for targeted interventions	Currently, CRC diagnosis is based on several bio- / screening-tests and on expert judgement based on minimal or scarce information. Individual's risk calculation and classification is not considered, and only generic rules for broader population are considered. Furthermore, several other factors that may affect CRC (socio-economic, environmental, behavioural, gender, educational background, urbanization, inequalities, etc) are not systematically considered.	ONCO-RISTE	ONCO-RISTE is a CRC risk-based stratification engine that is based on fuzzy logic and incorporates not only results of diagnostic devices but also information regarding behavioural, socio-economic and environmental factors. Individual's classification and risk calculation for CRC can lead in early diagnosis. The output of ONCO-RISTE updates dynamically an internal risk-based score showing to individuals their risk-based classification in 5-levels from very low to very high, triggering clinicians and citizens/patients for more accurate interventions.

Lack of Personalization	Rely on family history and healthcare providers, ignore symptoms	ONCO-CAWA	Differentiates itself by offering personalized recommendations and content based on factors such as age, gender, family history, and lifestyle habits, ensuring relevance and resonance with each user
Limited Access to Information	Seeking information online, Use generic health apps	ONCO-CAWA	Provide comprehensive and easily accessible educational content, empowering users with the information they need to make informed decisions about their health
Time Constraints	Today, healthcare providers rely on a combination of quick patient evaluations, standardized diagnostic protocols and electronic health records (EHR) to manage time effectively. However, these methods can sometimes compromise the depth of individual patient analysis and lead to a one-size-fits-all approach in diagnostic decisions.	ONCO-CLIDE enhances the efficiency of diagnostic processes significantly. By integrating advanced AI-driven diagnostic tools, ONCO-CLIDE provides rapid and accurate analysis of patient data, which reduces the time healthcare providers need to spend on each case. The system's ability to quickly process complex information not only	Incorporates efficient diagnostic methods with some able to be performed by the user saving significant clinical time for the initial assessment. This value proposition is supported by evidence suggesting that AI-enhanced diagnostic tools can reduce the time required for data processing and analysis in clinical settings, allowing healthcare providers to focus more on patient interaction and care management (**Source: Journal of American Medical Informatics Association**). By automating the initial assessment stages, ONCO-CLIDE ensures that healthcare providers can allocate their time more effectively, enhancing both the quality of care and patient satisfaction. The implementation of such AI-driven solutions has been shown to optimize clinical

		alleviates the time pressure on clinicians but also allows for more personalized, data-driven patient care. For example, AI algorithms can analyze historical data trends and individual patient records faster than traditional methods, enabling quicker, yet thorough assessments.	workflows, reduce administrative burdens and support healthcare providers in delivering high-quality care efficiently (**Source: Healthcare Information and Management Systems Society [1], [2]**). This makes ONCO-CLIDE a compelling upgrade over existing solutions, addressing critical time constraints faced by healthcare professionals today.
Interdisciplinary Collaboration	Effective diagnosis and management of CRC often require collaboration among multiple specialists, including gastroenterologists, oncologists, radiologists, pathologists, and surgeons. Coordinating care and communication among these diverse stakeholders can be challenging.	ONCO-CLIDE tackles these challenges by offering a virtual tumor board that enables seamless electronic communication among specialists and oncologists while providing secure access to the patient's pertinent health information,	ONCO-CLIDE facilitates interdisciplinary collaboration by providing a centralized platform for efficient information sharing and communication among healthcare professionals involved in colorectal cancer care. This approach is supported by several studies emphasizing the benefits of centralized platforms in enhancing interdisciplinary collaboration within healthcare settings: "**Interdisciplinary Collaboration for Healthcare Professionals**" highlights that

		thus facilitating efficient collaboration and informed decision-making	interdisciplinary collaboration can significantly affect healthcare outcomes. The study notes that poor collaboration is linked to a large percentage of adverse events, and improving collaboration can enhance patient care outcomes. "**The Impact of Interdisciplinary Collaboration on Patient Care in Pharmacy, Administration, Psychology, Radiology, and Nursing**" demonstrates that integrating diverse medical expertise through collaborative platforms significantly improves the quality of care, leading to better health outcomes and patient satisfaction. "**Interdisciplinary collaboration within Quebec Community Health Care Centres**" provides empirical evidence on how interdisciplinary collaboration within centralized healthcare models enhances the intensity of professional collaboration and improves organizational outcomes.
Inability to visualize complex cancer data relationships	Static reports and basic charts limit the ability to identify patterns and trends in cancer data.	ONCO-EVIDA	ONCO-EVIDA dashboard provides interactive data visualizations that allow users to explore complex relationships within the data and gain deeper insights.

Difficulty in sharing cancer data insights with colleagues	Informal methods are used to share data insights, which can be inefficient.	ONCO-EVIDA	ONCO-EVIDA allows users to create and share dashboards, reports and insights with colleagues in a secure manner, improving the communication and collaboration among healthcare professionals.
Even when freely available, cancer and risk factor data are often disjointed (e.g. managed by different organizations).	Manual joining of data.	ONCO-EVIDA	ONCO-EVIDA is integrated with ONCOSCREEN's Data Lake, which may house both cancer and risk factor data that can be queried simultaneously.
Currently no overview about planned collections in the project	Almost now clear communication if sample collections are planned or will be a benefit	ONCO-BIOBA	ONCO-BIOBA has the possibility to describe planned collections, even before they are published in bigger platforms, like BBMRI-ERIC

5.5 Value Chain

During this period with help of project partners, we have also identified relevant organizations, association and clusters and their potential relation to ONCOSCREEN as presented in the below table. The aim is to showcase the related value chain that can be potentially used for: a) introducing the ONCOSCREEN solution to other countries b) advertising the developed tools c) finding competitors & collaborations d) policy making and e) standardization purposes. These actions can be considered as means that facilitate the exploitation indirectly. Some of the cases can be also considered as potential buyers.

Country	Name (Logo)	Short Description	Website	Potential Relation to ONCOSCREEN
Netherlands	Nederlands Kanker collectief	Cancer hub to fight cancer together	https://nederlandskankercollectief.nl/	Early diagnostics improving molecular diagnostics for cancer
Netherlands	Ministry of health and welfare	Plays roles as a policy maker to put diagnostic tools in the market	https://www.rijksoverheid.nl/ministeries/ministerie-van-volksgezondheid	A policymaker needed to put the diagnostic tools into the market

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Europe	EUDAMED	European database on medical devices	https://ec.europa.eu/tools/eudamed/#/screen/home	Regulation of getting medical devices into the market
Netherlands	CIBG	NOTIS dutch database for IVDD	https://www.farmatec.nl/medische-hulpmiddelen/notificaties	Regulation of getting medical devices into the market
Portugal	Infarmed	Infarmed is a Government agency accountable to the Health Ministry, that evaluates, authorizes, regulates and controls human medicines as well as health products, namely, medical devices and cosmetics for the protection of Public Health.	https://www.infarmed.pt/	Regulator
Ireland	Health Service Executive (HSE)	Responsible for the provision of health and personal social services for everyone living in Ireland.	hse.ie	Key portal for introducing ONCOSCREEN in the Irish healthcare system.

Ireland	Irish Cancer Society	National charity dedicated to eliminating cancer and improving the lives of those affected by it in Ireland.	cancer.ie	Could facilitate introductions and partnerships in cancer care initiatives.
Ireland	Enterprise Ireland	Government organization responsible for the development and growth of Irish enterprises in world markets.	enterprise-ireland.com	Could support ONCOSCREEN's expansion into other countries through funding and network.
Belgium	Belgian Cancer Registry (BCR)	The BCR collects, curates and analyses cancer data for all of Belgium	https://kankerregister.org/nl/node	Data supplier Find competitors / collaborations
Belgium	Centre for Cancer Detection (CvKO)	The CvKO sends out cancer screening invitations in Flanders and possesses data on coverage, response rate and screening result.	https://dikkedarmkanker.bevolkingsonderzoek.be/nl	Data supplier Find competitors / collaborations
Slovenia	Institute of Oncology Ljubljana (OIL)	The Cancer Registry of the Republic of Slovenia (part of OIL) collects, curates and analyses cancer data for all of Slovenia	https://www.onko-i.si/eng/crs	Data supplier Introducing ONCOSCREEN to other countries

international	BBMRI-ERIC	BBMRI-ERIC is a European research infrastructure for biobanking.	https://www.bbmri-eric.eu/	BIOBA can maybe integrated in BBMRI-ERIC directory, after the project to make the collections of ONCOSCREEN internationally known
international	Global Colon Cancer Association (GCCA)	An international organization focused on improving prevention, detection, and treatment of colorectal cancer.	https://www.globalcca.org/	Collaboration for awareness campaigns and integration of CRC risk stratification tools in global initiatives.
UK	UK Biobank	A major biomedical database with genetic and health information from half a million UK participants.	https://www.ukbiobank.ac.uk/	Potential data source for validating and improving the stratification model, and finding collaborators.
US	Cancer Data Access System (CDAS)	Provides access to data from large cancer studies to advance research in cancer prevention and treatment.	https://cdas.cancer.gov/	Data sharing, validation of the ONCO-RISTE model.
US	National Cancer Institute (NCI)	The U.S. government's principal agency for cancer research and training.	https://www.cancer.gov/	Policy-making and standardization of new CRC risk stratification methods.

international	European Society for Medical Oncology (ESMO)	A leading professional organization for medical oncology, aiming to advance the science and practice of oncology.	https://www.esmo.org/	Collaboration for European outreach, policy development, and integration with existing oncology practices.
Belgium	Vlaamse Liga tegen Kanker (VLK)	A cancer league focused on prevention, research, and patient support in Flanders.	https://www.komoptegenkanker.be/	Utilizes various media channels to advertise and promote CRC prevention tools.
Europe	European Cancer Organisation (ECO)	Cancer organization in Europe	https://www.europeancancer.org/	ECO provides a platform for promoting cancer prevention tools across Europe
Germany	Deutsche Krebshilfe (German Cancer Aid)	Focuses on cancer research, prevention, and education in Germany.	https://www.krebshilfe.de/	Engages in public campaigns to advertise CRC prevention tools.

5.6 Competition

Competitor Name, website	Competitor's Relevant Product Description & Weakness	ONCOSCREEN Competitive Advantage
Existing diagnostic tools such as FIT.	N/A	**ONCO-VOC**: Low cost and ease of use.

GC/MS technology	Very cumbersome, takes a long time to process, needs very special personal to carry out. The technology has not been proved to provide unequivocal results	**ONCO-VOC**: Simple method, Low cost and very easy to preform time and time again. Can be coupled with additional methods and therefore can be applied as a pre-screening tool as well.
Scope Biosciences, https://scopebio.com/	Healthcare (HLA typing) & Agriculture (https://scopebio.com/agri)	**ONCO-CRISPR** focuses on human and animal health, have a patent filed first on CRISPR-Cas systems as identified in the eukaryotic genome, primers, guideRNAs and methods allows us to compete
Micronoma, https://micronoma.com/	Using microbiome biomarkers in tissue and liquid biopsies to diagnose cancer. Weakness, there is a discussion ongoing whether the markers are microbiome related or just soley human markers	**ONCO-CRISPR** focuses on human and animal health, have a patent filed first on CRISPR-Cas systems as identified in the eukaryotic genome, primers, guideRNAs and methods allows us to compete. A significant number of markers are CRISPRs which we patented first
SHERLOCK, https://sherlock.bio/platforms/crispr/	Invented the SHERLOCK technology, broad patents	**ONCO-CRISPR** focuses on human and animal health, have a patent filed first on CRISPR-Cas systems as identified in the eukaryotic genome, primers, guideRNAs and methods allows us to compete.
Mammoth Biosciences, https://mammoth.bio/	Invented the DETECTR technology, broad patents	**ONCO-CRISPR** focuses on human and animal health, have a patent filed first on CRISPR-Cas systems as identified in the eukaryotic genome, primers, guideRNAs and methods allows us to compete.
https://www.bruker.com/de/products-and-solutions/mr/nmr-clinical-research-solutions/b-i-methods.html	Bruker sells spectrometers and also offers software and methods, but does not cover glycoproteins.	**For our NMR** we have an issued DE-patent (international has been filed) on our new glycol-technology

Glycan analysis by methods other than NMR is offered by a number of companies. E.g. https://genos-glyco.com/	Most competitors are based on HPLC measurements which requires costly processing of blood samples	**Our NMR**-glyco-analysis is in many ways superior: It is fast and does not require costly pre-processing of blood samples.
SIEVEWELL, https://www.sievewell.com/applications/single-cell-picking?gad_source=5&gclid=EAIaIQobChMIyNPxm87ahQMVCT0GAB1T-wcwEAAYAyAAEgLxtPD_BwE	SIEVEWELL and cell picking system is ideal combination for single cell and spheroid isolation. Cells are hold during cell picking procedure. https://www.sievewell.com/how-it-works	**ONCO-CTC**: Low cost and efficient detection/isolation of several biological entities. Fast isolation of viable cells for further cell culturing and cell/molecular analysis.
Parsortix technology, https://angleplc.com/parsortix-technology/?_gl=1*1bgp73u*_up*MQ..&gclid=EAIaIQobChMInsXu-s_ahQMVclaRBR0nRwRTEAAYASAAEgINQPD_BwE	Bench equipment Parsortix technology is a unique method for capturing and harvesting intact circulating tumour cells (CTCs) and CTC clusters from whole blood for downstream analysis. Parsortix®technology uses a patented microfluidic technology in the form of a single use cassette to capture and then harvest CTCs from whole blood. The cassette captures CTCs based on their less deformable nature and larger size compared to other blood cells https://angleplc.com/wp-content/uploads/2024/03/PTX-MARK115-BR-A-Parsortix-PC1-System-Brochure-Nov-2023.pdf?_gl=1*hdc4j8*_up*MQ..&gclid=EAIaIQobChMInsXu-s_ahQMVclaRBR0nRwRTEAAYASAAEgINQPD_BwE	**ONCO-CTC**: Simple method, Low cost and efficient detection/isolation of several biological entities. Can be coupled to bioprinted in vitro models for precision medicine applications

ENCORD https://encord.com/gastroenterology/	Encord is a platform for annotating GI images and videos, monitoring annotator throughput and quality, and managing the expert review process. Limitation: no XAI feature is provided to either the labelling step or training phase.	**Onco-AICO** focuses on the training aspect of junior colonoscopists, offering individual performance scores vs a baseline, AI-assisted annotation (it Incorporates 3 machine learning algorithms with accuracy >97%), along with explainable AI capabilities (2 modes), and expert colonoscopist reviewing. Thus, it is providing increased efficiency in both annotation creation, by leading the clinicians, and training advanced environment offered.
PathPresenter https://www.pathpresenter.com/	PathPresenter	**ONCO-AITI**: Isn't directly used as training tool, don't contain information about view positions during observation of WSIs
Cologuard, https://www.cologuardtest.com/	A non-invasive stool DNA test that detects altered DNA and blood associated with CRC and precancerous polyps. Limited to stool samples and specific DNA markers, and may miss some cases of CRC.	The competitive advantage of ONCOSCREEN diagnostic solutions against existing solutions is: a) the expected cost/examination to be significant lower b) the multi-tier methodology for validation of results from 2-3 different tests c) the combination of results with a personalised risk stratification that integrate broader socio-economic and behavioural factors d) the projected clinical validation into a diverse set of population across multiple countries in the European region e) the projected high accuracy in terms of sensitivity and specificity f) the ease of use that may lead to bigger adherence compared to stool-based tests.
Epi proColon, https://www.epigenomics.com/products/epi-procolon/	A blood-based test that detects methylated Septin9 DNA, which is associated with CRC. May not detect all cases, particularly in early stages, and focuses on a single biomarker.	
Freenome, https://www.freenome.com/	Utilizes a multiomics blood test to detect early-stage CRC by analysing genomic, proteomic, and other biological data.	

	Technology may have limited availability.	
Guardant360, https://guardanthealth.com/	A liquid biopsy test that detects various cancers, including CRC. Primarily used for advanced cancers and may not be as effective for early detection.	
SOPHiA GENETICS DDM™ Platform, https://www.sophiagenetics.com/	Analyses genomic data to help diagnose and treat cancer, including CRC, using advanced algorithms to interpret genetic variants. Focus on genomic data, and may not integrate real-time diagnostic data and other non-genetic risk factors.	
ColoScape, https://www.singleragenomics.com/	A blood-based assay detecting methylation biomarkers associated with CRC and precancerous conditions. Not fully incorporate socio-economic or behavioural factors.	
Huma	Global health tech company that provides mobile app and platform to provide digital therapeutics	**ONCO-CAWA:** CRC Awareness Personalised Mobile Application: targeted to patients with CRC instead of a general health app
BigHealth	Digital therapeutics for mental health	**ONCO-CAWA**: CRC Awareness Personalised Mobile Application
Habitual	Weight loss programme	**ONCO-CAWA**: CRC Awareness Personalised Mobile Application
CureApp	Evidence-based medical programs, "Digital Therapeutics (DTx)," for patients who suffer from conditions that conventional treatment methods with drugs or devices were not effective	**ONCO-CAWA**: CRC Awareness Personalised Mobile Application

xDECIDE (by xCures) https://xcures.com/xcures-launches-xdecide/	Product Overview: xDECIDE, developed by xCures, integrates AI technologies with clinical decision-making. It utilizes a range of AI models to process patients' electronic medical records, employing natural language processing (NLP) and machine learning to generate structured case summaries and a ranked list of treatment options. These are reviewed in a virtual tumor board setting, ensuring that clinical decisions are informed by both AI-generated insights and human expert opinions. Clinical Integration: The system supports continuous learning from clinical outcomes, which contributes to the refinement of its AI algorithms. This continuous improvement cycle is intended to enhance the precision of treatment recommendations over time. User Interface: xDECIDE offers an interactive portal for treating physicians, allowing them to access all relevant patient data and associated AI-generated reports, which facilitates ongoing monitoring and decision-making.	**ONCO-CLIDE**: 1. Specificity in Adenoma-Carcinoma Sequencing: While xDECIDE provides a broad range of cancer care insights, ONCO-CLIDE specifically introduces an automated process for identifying the right adenoma-carcinoma sequence level, crucial for early and accurate colorectal cancer screening and intervention. ONCO-CLIDE's focus on probabilistic models for data classification and feature selection could potentially offer more tailored and accurate early detection capabilities than the broader approach of xDECIDE. 2. Virtual Tumor Board: Although xDECIDE utilizes a virtual tumor board, ONCO-CLIDE's integration of a Virtual Tumor Board seems to be more focused on continuous feedback loops directly influencing the decision support system. This could result in a more dynamic and continuously improving system, closely integrating expert clinical feedback into the AI's learning process, potentially leading to more refined and accurate recommendations. 3. Algorithm Selection and Testing: ONCO-CLIDE explores and tests multiple classification algorithms (e.g., CNN, RNN, SVM) to select the one that provides the highest quality results. This approach might lead to a more

		optimized and effective model suited for the specific challenges of colorectal cancer screening compared to xDECIDE, which may not be as focused on optimizing across such a diverse range of algorithmic approaches for a specific cancer type. 4. Data Normalization and Processing: ONCO-CLIDE emphasizes z-score normalization and probability distribution in data pre-processing, which could offer more precise data handling and improve the accuracy of the subsequent AI analysis, a detail not specifically highlighted in xDECIDE's description. 5. User Account Types and Communication Hub: ONCO-CLIDE provides different user account types and acts as a communication hub, facilitating more tailored interactions among clinicians, researchers and potentially patients. This aspect of ONCO-CLIDE might enhance user engagement and collaboration more effectively than xDECIDE's platform.
5.6.1 ARCliDS A clinical decision support system for AI-assisted decision-making in response-adaptive radiotherapy (ARCliDS) | Scientific Reports (nature.com)	1. Product Overview: ARCliDS is a clinical decision support system designed for use in response-adaptive radiotherapy. It integrates AI to optimize treatment decisions based on patient-specific data, adapting radiation doses in real-time to maximize treatment	**ONCO-CLIDE**: 1. Cancer Type Specificity: ARCliDS is specifically tailored for use in radiotherapy for cancers such as non-small cell lung cancer and hepatocellular carcinoma, as per the case studies presented. In contrast, ONCO-CLIDE is focused on colorectal cancer screening and progression analysis, which

	efficacy and minimize side effects. 2. AI Integration: ARCliDS utilizes a Graph Neural Network (GNN) and a reinforcement learning framework. Its system, ARTE (Artificial RT Environment), models the treatment process as a Markov decision process, which allows it to predict outcomes for various radiation doses dynamically. The Optimal Decision Maker (ODM) component recommends optimal daily dosage adjustments. 3. Clinical Application: This system is specifically designed for radiotherapy settings, using sophisticated AI to handle complex decision-making processes that require adjusting treatment plans based on ongoing patient response. This can lead to highly personalized treatment strategies.	involves a different set of clinical decision-making challenges and solutions. 2. Screening and Early Detection: Unlike ONCO-CLIDE, which is designed to assist in the early screening and detection of colorectal cancer through adenoma-carcinoma sequencing, ARCliDS's utility is in the optimization of treatment rather than early detection. ONCO-CLIDE's emphasis on early-stage identification and classification provides critical value in preventive care and early intervention, areas not addressed by ARCliDS. 3. Virtual Tumor Board and Collaborative Decision-Making: ONCO-CLIDE integrates a Virtual Tumor Board to facilitate multidisciplinary collaboration and decision-making, enhancing the system's adaptability to new insights and expert feedback. ARCliDS, while advanced in its AI application, does not emphasize such a collaborative platform, potentially limiting its adaptability to diverse clinical insights beyond radiotherapy. 4. Data Processing and Classification Technologies: ONCO-CLIDE employs a variety of data classification and processing technologies, including multiple AI algorithms like CNN, RNN, SVM, etc., tailored to optimize performance for colorectal

		cancer screening. ARCliDS focuses primarily on radiation dosage optimization using GNNs and does not indicate the use of a broad range of AI technologies for various types of cancer data classification and feature selection. 5. User Interaction and Interface: ONCO-CLIDE's design includes various user account types and a communication hub, enhancing interaction among different users (clinicians, researchers, possibly patients). ARCliDS is more focused on backend AI processing and may not offer the same level of user interface customization and interaction.
SATISFAI CADX https://www.satisfai.health/ https://www.google.com/search?client=firefox-b-d&q=satisfai+health+cadx	1. Scope of Application: While Satisfai's CADx system is highly specialized for use during colonoscopy procedures, its application is primarily diagnostic during these procedures. In contrast, ONCO-CLIDE is designed to support broader aspects of colorectal cancer management, including early screening, detailed classification of cancer stages and systematic follow-up through its decision support capabilities. 2. Data Integration and Comprehensive Analysis: ONCO-CLIDE integrates a broader range of data	**ONCO-CLIDE**: Comprehensive Data Integration and Analysis: ONCO-CLIDE integrates a wider array of data types beyond real-time imaging data. It processes clinical data, genetic information and patient history through advanced algorithms, including CNNs, RNNs, SVMs and more. This comprehensive data integration allows ONCO-CLIDE to offer more nuanced and precise screening, diagnosis and treatment planning capabilities, providing a holistic approach to patient management. Predictive Modelling and Risk Assessment: ONCO-CLIDE employs sophisticated predictive models that assess the risk levels of individuals by analysing the

	inputs, including probabilistic models and various clinical data types, which facilitate comprehensive case management from screening through to treatment planning. The CADx system, while effective within its scope, primarily focuses on real-time polyp analysis and may not incorporate as wide a range of clinical data inputs or support longitudinal patient management. 3. Multidisciplinary Collaboration: ONCO-CLIDE supports a Virtual Tumor Board that allows for collaborative decision-making among a diverse set of healthcare professionals. This feature enriches the decision-making process with varied expertise, potentially leading to more nuanced and well-rounded patient care strategies. Satisfai's CADx system, being a more focused tool, does not inherently provide or integrate such multidisciplinary collaboration features. 4. User Interaction and Learning Capabilities: ONCO-CLIDE is designed with a feedback loop from various clinical users to continuously improve its	progression of colorectal cancer from adenomas to carcinomas. This capability allows for early intervention strategies that are tailored to the specific risk profile of each patient, potentially reducing the progression to higher cancer stages. Virtual Tumor Board: A distinctive feature of ONCO-CLIDE is its Virtual Tumor Board, which facilitates multidisciplinary collaboration among healthcare professionals. This feature not only enhances decision-making through diverse expert insights but also integrates these insights into the AI's learning process, continuously improving the system's recommendations and adaptability to new research and clinical findings. User-Centric Design and Feedback Loop: ONCO-CLIDE is designed with various user account types, catering to different roles within the healthcare system—such as physicians, researchers and potentially patients. This design fosters an environment of continuous feedback, where the system learns from real-world applications and user interactions, thereby enhancing its accuracy and utility over time. Regulatory and Ethical Considerations: ONCO-CLIDE is committed to addressing the regulatory and ethical challenges associated with AI in healthcare.

	algorithms and recommendations based on real-world use. The CADx system's learning and adaptation capabilities, while advanced, are primarily confined to the interpretation of imaging data and may not include feedback mechanisms that span across different user interactions or broader clinical inputs. 5. Regulatory and Acceptance Challenges: As noted in its review, integration of AI tools like CADx into clinical practice faces significant barriers, including regulatory challenges and acceptance by healthcare professionals. These systems require substantial validation to gain widespread trust and regulatory approval, which can be a lengthy and resource-intensive process.	By focusing on robust design, validation and testing methodologies, ONCO-CLIDE aims to ensure compliance with healthcare regulations and gain the trust of both the medical community and patients. This commitment also extends to safeguarding patient data, enhancing the system's security and ensuring that the AI's recommendations are transparent and explainable. Targeted at Early Detection and Preventative Care: While Satisfai's CADx excels in real-time polyp characterization during colonoscopy, ONCO-CLIDE's strength lies in its ability to support early detection and comprehensive management of colorectal cancer. This approach not only improves outcomes through early interventions but also aligns with preventative care models, potentially reducing the overall healthcare costs associated with late-stage cancer treatments.
Tableau https://www.tableau.com/	Tableau is a general-purpose data visualization platform. It is widely used offering drag-and-drop interfaces, a vast array of cart types, and connections to various data sources. It caters to a broad range of industries, including healthcare. However, Tableau requires extensive customization to	ONCO-EVIDA's Front-End, offers pre-built features and visualizations optimized for CRC analysis, saving users time and effort. Furthermore, it is more user friendly and has lower cost.

	accommodate the specific needs of CRC data visualization. Furthermore, the template must be built from scratch from the users.	
• European Commission • *European Cancer Inequalities Registry (ECIR) Data Tool* https://cancer-inequalities.jrc.ec.europa.eu/ • European Cancer Organisation • *European Cancer Pulse (ECP)* https://www.europeancancer.org/pulse-map/countries	• The ECIR data tool plots inequality dimensions (sex, income, education, employment, urbanisation, age...) against cancer risk, screening and diagnosis variables but only on a country level. • The ECP tool plots inequality dimensions (gender, income, education, LGBTQ+ community, urbanisation, age...) against cancer risk, screening and diagnosis variables but only on a country level. The ECP offers more visualization options than the ECIR tools, but data can only be consulted on the country level. ECP allows users to submit new data.	ONCO-EVIDA will improve on them in the following respects: 1) Interpretation: In addition to numbers and proportions of the variable(s) of interest in a specified geographical unit, ONCO-EVIDA will provide a correlation coefficient that gives the end-user an idea of the strength of association between the variables, and wrap this coefficient in an easy-to-understand sentence. 2) Breadth of Exposures: In addition to the 'usual suspects', ONCO-EVIDA will enable policymakers to view associations between environmental exposures such as air pollutants and CRC, a field that shows promise but is currently understudied. 3) Customizability: End-users will be able to save the output of their queries in a customizable dashboard to which they can add new graphs and move them around at will for easier visual inspection. 4) Precision: Cancer-related policy is often determined on a subnational level such as the Belgian Regions. ONCO-EVIDA will aggregate and visualize data on NUTS-3 level.

Flemish Regional Government Cancer Surveillance Flanders	Tool still in development; pilot project (started Jan. 2023) focusing on environmental risk factors and cancer outcomes on small aggregation level. Intended to become structural tool to be used by Flemish policymakers.	Unknown
Integral Cancer Centre Netherlands Dutch Cancer Atlas https://kankeratlas.iknl.nl/	The Cancer Atlas plots cancer incidences on the municipal level. It gives accompanying textual interpretations of the result and has an extensive tutorial, but it has no information on risk factors or social inequalities (except stratification by sex).	ONCO-EVIDA will allow the plotting of exposures or inequalities alongside CRC outcomes and will incorporate information on CRC screening. In addition, its output can be saved in a customizable dashboard, unlike the output of the Cancer Atlas.
International Agency for Research on Cancer CanScreen5 https://canscreen5.iarc.fr/?page=analysis	The CanScreen5 analysis tool can show age- and sex-stratified cross-country and cross-region comparisons between cancer screening statistics. The tool allows filtering by screening protocol for greater comparability. The tool is restricted to cancer screening information.	ONCO-EVIDA will improve on them in the following respects: 1) Interpretation: In addition to numbers and proportions of the variable(s) of interest in a specified geographical unit, ONCO-EVIDA will provide a correlation coefficient that gives the end-user an idea of the strength of association between the variables, and wrap this coefficient in an easy-to-understand sentence. 2) Breadth of Exposures: In addition to the 'usual suspects', ONCO-EVIDA will enable policymakers to view associations between environmental exposures such as air pollutants and CRC, a field that shows promise but is currently understudied. 3) Customizability: End-users will be able to save the output of

		their queries in a customizable dashboard to which they can add new graphs and move them around at will for easier visual inspection. 4) Precision: Cancer-related policy is often determined on a subnational level such as the Belgian Regions. ONCO-EVIDA will aggregate and visualize data on NUTS-3 level.
BBMRI-ERIC https://www.bbmri-eric.eu/	Biobank and sample collection directory	BIOBA can directly describe the collections, which will be created in this project.

5.7 Related Policies

In this section the related policies that can either affect the use of the ONCOSCREEN tools or can provide an unfair advantage considering the fact that the introduced tools can contribute to the adoption and implementation of the policy.

Policies, Directives, National & International Law	Short Description	Relevance to Oncoscreen
https://www.infarmed.pt/web/infarmed-en/medical-devices/in-vitro-diagnostic-medical-devices-ivdds-and-applicable-legislation	Under Decree-Law no. 189/2000 of 12th August, transposing the Directive 98/79/CE, an IVDD is: any in vitro diagnostic medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used, in vitro , for the examination of samples derived from the human body with a view to provide information on the physiological or	The presence of the CE marking is a prerequisite for medical devices to be placed on the market and be allowed to circulate freely. It is a guarantee that the products conform to the essential requirements to which they are subject. The marking has a particular graphic design and shall be affixed by the manufacturer in a

	pathological states and congenital anomalies, to determine the safety and compatibility of potential recipients or monitor therapeutic measures; container(s) specifically designed by the manufacturer to contain or preserve samples derived from the human body intended for in vitro diagnosis.	legible, visible and indelible form on all medical devices, except those that are custom-made or intended for clinical research.
GDPR	The General Data Protection Regulation (GDPR) is an EU regulation that enhances data protection and privacy for all individuals within the European Union (EU)	It sets rules on how personal data can be collected, processed, transferred, and stored and is therefore a good orientation during the development process.
https://www.infarmed.pt/web/infarmed-en/medical-devices/in-vitro-diagnostic-medical-devices-ivdds-and-applicable-legislation	Under Decree-Law no. 189/2000 of 12th August, transposing the Directive 98/79/CE, an IVDD is: • any in vitro diagnostic medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system whether used alone or in combination, intended by the manufacturer to be used, in vitro , for the examination of samples derived from the human body with a view to provide information	The presence of the CE marking is a prerequisite for medical devices to be placed on the market and be allowed to circulate freely. It is a guarantee that the products conform to the essential requirements to which they are subject. The marking has a particular graphic design and shall be affixed by the manufacturer in a legible, visible and indelible form on all medical devices, except those that

	on the physiological or pathological states and congenital anomalies, to determine the safety and compatibility of potential recipients or monitor therapeutic measures; container(s) specifically designed by the manufacturer to contain or preserve samples derived from the human body intended for in vitro diagnosis.	are custom-made or intended for clinical research.
HIPAA (Health Insurance Portability and Accountability Act)	US legislation that provides data privacy and security provisions for safeguarding medical information, in the context of the framework provided and in an attempt for ONCO-CLIDE to align with all applicable legislation	Although specific to the US, compliance with HIPAA standards can enhance ONCO-CLIDE's data handling practices, positioning it as a secure tool for international markets.
MDR (Medical Device Regulation)	EU regulations intended to improve the safety and performance of medical devices being produced in or supplied into Europe.	ONCO-CLIDE would need to meet MDR standards, ensuring high safety and performance benchmarks, facilitating easier adoption and marketing in the EU.
FDA Regulations on Digital Health Devices	U.S. FDA regulations govern the development, approval and use of digital health and medical devices.	Compliance ensures ONCO-CLIDE to meet safety and efficacy standards, key for U.S. market entry when and if applicable and user trust.

EU Directive on eHealth	Directives aimed at enhancing healthcare through the use of Information and Communication Technology (ICT).	ONCO-CLIDE can leverage this by aligning with eHealth initiatives, enhancing interoperability and adoption in EU healthcare systems.
Data Governance Act (DGA)	EU legislation designed to foster the availability of data for use within the EU, ensuring that data is used lawfully and fairly.	Helps ONCO-CLIDE in utilizing health data across EU states under a unified framework, increasing operational efficiency and data access.
The 21st Century Cures Act	U.S. law aimed at accelerating medical product development and bringing new innovations and advances to patients who need them faster and more efficiently. ONCOCLIDE would align with this Act in the context of the framework provided and in an attempt to abide by the legislation assisting in medical support acceleration	Encourages ONCO-CLIDE's integration into U.S. healthcare through faster approvals if it meets innovation criteria.
Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC	European Council recommendation that updates current provisions, suggest a wider range of screening protocols and an extension of existing screening programmes	ONCOSCREEN may be used to intuitively evaluate screening effectiveness and identify regions where greater prevention and/or early detection efforts are necessary
Proposal for a regulation of the European Parliament and of the Council of the European Health Data Space	Facilitates sharing of anonymised or pseudonymised health data for research and policymaking while giving	When implemented, it may make it easier to standardize aggregated cancer data for display in ONCO-EVIDA

	patients full control over their own data	
EU AI Act	EU regulation on Artificial Intelligence (AI) for establishing a common regulatory and legal framework for AI in the EU.	All ONCOSCREEN AI tools must ensure their compliance with EU AI Act, ensuring that the end-users are aware that they interact with AI and guaranteeing the robustness and accuracy of the outcomes.
ALTAI (Assessment List for Trustworthy Artificial Intelligence)	ALTAI is presented by the AI HLEG (High-Level Expert Group on Artificial Intelligence), set up by EU Commission, providing an initial approach for the evaluation of Trustworthy AI.	All ONCOSCREEN AI tools must ensure technical robustness and safety, privacy, transparency and fairness.

6 Innovation Assessment

In this chapter we evaluate the innovation behind each solution in order to understand the level of maturity and the foreseen steps that need to be followed in the next period towards bringing the innovation closer to the market.

6.1 ONCO-VOC

Title of the innovation
ONCO-VOC - A novel easy to use breath analyser for CRC diagnosis
Describe the innovation
Overall, CRC has been consistently linked with classes of VOCs such as Alcohols, Alkanes, Aldehydes and Ketones, with the last two commonly found in cancer metabolism. Multiple studies have tried to come up with the CRC breath profile, using GC-MS analysis and later directed sensor array analysis. However, due to several differences in methodologies, limitations, sample sizes etc. and different cancer stages (that is known to affect the VOC profile), a reliable and reproducible pattern of VOCs as biomarkers for general clinical practice is yet to be available. The novelty of the ONCO-VOC approach is by utilizing 6 replicas of 8 different GNP sensors oriented in an array. The sample would therefore be subjected to 48 sensors at once, resembling the mode of activity of mammalian olfactory bulb. Moreover, the ONCO-VOC endeavour is relying on the combination of seven different diagnostic tools to predict the onset and development of CRC. It is therefore likely to discover settle insights emerging from the multimethod approach.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation:
– New product
Level of innovation: What is the level of innovation?:
New disruptive technology
How will the innovation be exploited?:
Start-up or commercialization via an established company

Is there a clear owner of the innovation in the consortium or multiple owners?
– A clear owner
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			X	
Market study			X	
Prototyping in laboratory environment		x		
Prototyping in real world environment			X	
Pilot, Demonstration or Testing activities		x		
Feasibility study	X			
Launch a start-up or spin-off			X	
Standardisation		x		
Application for private or public investment			X	
Securing private investment			X	
Securing public investment			X	

Business plan			X	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

Technion
ICCS/ I-SENSE
BEIA

Indicate their needs to fulfil their market potential

	Technion	**ICCS/ ISENSE**	**BEIA**
Investor readiness training	YES	YES	YES
Investor introductions	YES	YES	YES
Biz plan development	YES	YES	YES
Expanding to more markets	YES	YES	YES
Legal advice (IPR or other)	No	No	No
Mentoring	YES	YES	YES
Partnership with other company (technology or other)	YES	YES	YES
Incubation	YES	YES	YES
Startup accelerator	YES	YES	YES

Market size: What is the approximate market size for this innovation
– > €500M € amounts are for global markets and per year

Market maturity: The market for this innovation is ...
– Emerging: There is a growing demand, and few offerings are available
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Very innovative satisfies a well-known market need
Market competition: How strong is competition in the target market?
– Patchy, no major players
When do you expect that such innovation could be commercialised?
– Between 3 and 5 years
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– IPR – Financing – Trade issues (between MS, globally)

6.2 ONCO-CRISPR

Title of the innovation
ONCO-CRISPR a fast and reliable diagnosis for every CRC patient
Describe the innovation
ONCO-CRISPR is a user-friendly and non-invasive CRISPR-Cas based diagnostic tool for the detection of novel CRC biomarkers, that makes CRC screening easier, faster and more sensitive and specific than existing molecular CRC detection methods. Early detection of CRC ensures that the treating physician can anticipate and react accordingly, and the patient can start an appropriate treatment program at an early stage. As a result, the

patient will live longer and better. In addition, early detection of cancer will ensure that less severe and long treatment is required, which in turn saves costs.
Is the innovation developed within the project:
– Under development – Already developed but not yet being exploited
Characterise the type of innovation
– New product
Level of innovation: What is the level of innovation?:
Breakthrough Innovation
How will the innovation be exploited?:
Patent filing, trade secret, home brew (setting up a reference laboratory), CCassured BV for commercialization of the ONCO-CRISPR tools with a specialised team and investors, licensing to existing diagnostic companies such as Biomerieux, will be crystalized further during the ONCOSCREEN project
Is there a clear owner of the innovation in the consortium or multiple owners?
– For the human CRISPRs single owner for new ONCO-CRISPR developments Multiple owners are expected
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			X	

Market study		X		
Prototyping in laboratory environment	X			
Prototyping in real world environment		X		
Pilot, Demonstration or Testing activities	X	X		
Feasibility study		X		
Launch a start-up or spin-off	X			
Standardisation		X		
Application for private or public investment		X		
Securing private investment		X		
Securing public investment	X			
Business plan	X			
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

CCassured

Indicate their needs to fulfil their market potential

	CCassured	Participant 2	Participant 3
Investor readiness training	Yes		
Investor introductions	Yes		

Biz plan development	Done		
Expanding to more markets	Yes		
Legal advice (IPR or other)	Yes		
Mentoring	Yes		
Partnership with other company (technology or other)	Yes		
Incubation	Ongoing		
Startup accelerator	Yes		

Market size: What is the approximate market size for this innovation
– > €500M € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Emerging: There is a growing demand, and few offerings are available
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Very innovative satisfies a well-known market need
Market competition: How strong is competition in the target market?
– Several major players with strong competencies, infrastructure and offerings
When do you expect that such innovation could be commercialised?
– Between 1 and 3 years
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No

Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– IPR – Regulation – Workforce's skills – Standards – Financing – Trade issues (between MS, globally)

6.3 ONCO-NMR

Title of the innovation
New Glycosylation Markers by NMR
Describe the innovation
A novel patented NMR test to detect glycosylation markers which respond sensitively to inflammatory conditions and cancer and provide
Is the innovation developed within the project:
– Evaluation of the glycosylation test for CRC – The glycosylation test and related software approaches have been developed but not tested for CRC – A DE-patent has been accepted
Characterise the type of innovation:
– Novel NMR test for inflammatory conditions and cancer
Level of innovation: What is the level of innovation?:
An NMR method and software that exploits hitherto unused glycosylation markers. Very fast measurement from blood samples without any need of chemical processing.
How will the innovation be exploited?:
We are working with a business consultant to build a company. The current strategy is confidential.
Is there a clear owner of the innovation in the consortium or multiple owners?
– The University of Lübeck owns the technology
Is the innovation to be introduced to the market or to be deployed within a partner

– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer	X			
Engagement of both research team and partner's business units in project activities			X	
Market study	X			
Prototyping in laboratory environment	X			
Prototyping in real world environment				
Pilot, Demonstration or Testing activities				
Feasibility study				
Launch a start-up or spin-off	X			
Standardisation				
Application for private or public investment				
Securing private investment				
Securing public investment				
Business plan				

Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

UzL

Indicate their needs to fulfil their market potential

	UzL
Investor readiness training	
Investor introductions	X
Biz plan development	X
Expanding to more markets	
Legal advice (IPR or other)	
Mentoring	
Partnership with other company (technology or other)	(x)
Incubation	
Startup accelerator	X

Market size: What is the approximate market size for this innovation
– > €500M € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
–
Market dynamics: is the market ...
– Growing

Level of innovation: What is the level of innovation
– Innovative but could be difficult to convert customers –
Market competition: How strong is competition in the target market?
– Established competition but none with a proposition like the one under investigation –
When do you expect that such innovation could be commercialised?
– Between 1 and 3 years –
How this innovation engaged end-users to ensure their acceptance?
– End user organisations in the consortium –
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– None known –

6.4 ONCO-CTC

Title of the innovation
ONCO-CTC- A new cost-effective microfluidic platform for diagnosis of CRC and isolation of CTC's
Describe the innovation
The ONCO-CTC tool is a simple and cost-effective diagnostic device for the early detection and management of colorectal cancer (CRC), the world's third most prevalent cancer and second leading cause of cancer death. The ONCO-CTC platform introduces a game-changing solution by combining an electropsun filtration technology alongside the efficiency of microfluidics, marking a significant leap forward in cancer diagnostics, in particular in liquid-biopsies. A unique aspect of ONCO-CTC diagnostic chip is its ability to transcend the standard of diagnostic paradigms by utilizing the sensitivity and specificity of circulating tumor biomarkers (CTBs), such as CTCs and possibly EVs. The ONCO-CTC is set to deliver significant impacts across multiple domains, i.e. in the *clinics* as is strategically positioned to enhance CRC diagnosis and

prognosis and treatment outcomes through its emphasis on early and accurate detection; for *society* and economy as it can help reducing the disease's mortality and morbidity rates worldwide, and can be used in early detection and significantly reduce the financial strain on healthcare systems; and in the *research field* as it can be tuned to provide a dynamic platform for future research, opening new avenues for fabricating in vitro tissue/tumour models, thus having a spill-over effect in innovation and progress in the biomedical field.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation:
– New product(s)
Level of innovation: What is the level of innovation?:
Disruptive technology
How will the innovation be exploited?:
Launch of start-up, commercialization of different products or licensing possible patent(s)
Is there a clear owner of the innovation in the consortium or multiple owners?
– A clear owner
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			x	
Market study			x	

Prototyping in laboratory environment		x		
Prototyping in real world environment			X	
Pilot, Demonstration or Testing activities		x		
Feasibility study	X			
Launch a start-up or spin-off			X	
Standardisation		x		
Application for private or public investment			X	
Securing private investment			X	
Securing public investment			X	
Business plan			X	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

UMINHO

Indicate their needs to fulfil their market potential

	UMINHO
Investor readiness training	YES
Investor introductions	YES
Biz plan development	YES

Expanding to more markets	YES
Legal advice (IPR or other)	NO
Mentoring	YES
Partnership with other company (technology or other)	YES
Incubation	YES
Startup accelerator	YES

Market size: What is the approximate market size for this innovation
– > €500M € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Emerging: There is a growing demand and few offerings are available
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Very innovative satisfies a well-known market need
Market competition: How strong is competition in the target market?
– Several major players with strong competencies, infrastructure and offerings
When do you expect that such innovation could be commercialised?
– Between 3 and 5 years
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– IPR – Financing

– Trade issues (between MS, globally)

6.5 ONCO-AICO

Title of the innovation
ONCO-AICO
Describe the innovation
ONCO-AICO innovates by integrating Explainable AI (XAI) to enhance adenoma and polyp detection during colonoscopies. The platform offers a dual-focused training approach, aiding junior colonoscopists and non-physician endoscopists with feedback and customizable learning experiences. By providing transparent AI-driven recommendations and automated annotation tools, ONCO-AICO accelerates skill development and reduces missed lesions. The use of diverse open datasets ensures robustness, while the web-based design enables global accessibility and cost-effective training, addressing workforce shortages and improving colorectal cancer screening outcomes.
Is the innovation developed within the project:
– Yes.
Characterise the type of innovation:
– New service (except consulting ones)
Level of innovation: What is the level of innovation?:
Not yet clear
How will the innovation be exploited?:
Since it will be available as open source, exploitation will be via new synergies and projects. Further, exploitation can be rising if interested stakeholders would ask for additional properties and specifications.
Is there a clear owner of the innovation in the consortium or multiple owners?
– Multiple owners: CERTH, ICCS, KONN, AINIGMA
Is the innovation to be introduced to the market or to be deployed within a partner
– No exploitation planned yet, at least in clear form.

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			x	
Market study				x
Prototyping in laboratory environment		x		
Prototyping in real world environment		x		
Pilot, Demonstration or Testing activities		x		
Feasibility study			x	
Launch a start-up or spin-off			x	
Standardisation				x
Application for private or public investment			x	
Securing private investment			x	
Securing public investment			x	
Business plan			x	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

CERTH
ICCS
AINIGMA

Indicate their needs to fulfil their market potential

	CERTH	ICCS	AINIGMA
Investor readiness training	X		
Investor introductions		X	X
Biz plan development			X
Expanding to more markets	X	X	X
Legal advice (IPR or other)			X
Mentoring	X	X	
Partnership with other company (technology or other)	X	X	X
Incubation	X		X
Startup accelerator	N/A		

Market size: What is the approximate market size for this innovation
– Not known
Market maturity: The market for this innovation is ...
– Not yet existing: customers are not buying such products (or are not yet ready to buy such products/services)
Market dynamics: is the market ...
– Rising and growing

Level of innovation: What is the level of innovation
– Obviously innovative and easily appreciated advantages to customer
Market competition: How strong is competition in the target market?
– Patchy, no major players
When do you expect that such innovation could be commercialised?
– Between 1 and 3 years
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– Others

6.6 ONCO-AITI

Title of the innovation
ONCO-AITI
Describe the innovation
After completing a medical degree, the learning process to become a fully trained pathologist is lengthy and characterized by individual support from experts. AITI would provide a learning tool that highlights regions of interest in a WSI that have previously been tracked by pathologists. The learning process can be discriminated through appropriate scoring and thus assessed more objectively. The trainees can quickly obtain feedback from the expert knowledge of several pathologists.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation
– New product – New service (except consulting ones)

Level of innovation: What is the level of innovation?:
High innovative since it contains a new idea of visualize the observation pattern of pathologists during their diagnose process
How will the innovation be exploited?:
A detailled exploitation plan, is not yet defined.
Is there a clear owner of the innovation in the consortium or multiple owners?
– Yes, the clear owner is MUG.
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation) – Not yet exploitation planned, due to delay of development caused by inactive/leaving partner

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			x	
Market study			x	
Prototyping in laboratory environment		x		
Prototyping in real world environment			x	
Pilot, Demonstration or Testing activities			x	

Feasibility study			x	
Launch a start-up or spin-off			x	
Standardisation				x
Application for private or public investment			x	
Securing private investment			x	
Securing public investment			x	
Business plan			x	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

MUI was key supporting partner/organisation, but is now leaving the project
MUG is only partner as key organisation to deliver the innovation.

Indicate their needs to fulfil their market potential

	MUG
Investor readiness training	x
Investor introductions	x
Biz plan development	x
Expanding to more markets	x
Legal advice (IPR or other)	x
Mentoring	x

Partnership with other company (technology or other)	x
Incubation	x
Startup accelerator	x

Market size: What is the approximate market size for this innovation
– Not known € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Not yet existing: customers are not buying such products (or are not yet ready to buy such products/services)
Market dynamics: is the market ...
– A potential market is rising and growing
Level of innovation: What is the level of innovation
– Obviously innovative and easily appreciated advantages to customer
Market competition: How strong is competition in the target market?
– Patchy, no major players
When do you expect that such innovation could be commercialised?
– Within the next 3-5 years, if delay can be decreased
How this innovation engaged end-users to ensure their acceptance?
– No end user organisation in the consortium or consulted – End users potentially have multiple opportunities to suggest improvements and contribute additional ideas throughout the development process
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– Others

6.7 ONCO-RISTE

Title of the innovation
ONCO-RISTE
Describe the innovation
As CRC often slowly aggravates by adenoma-carcinoma sequence for a long time, the early diagnosis is vital to elevate precancerous polyps, identify early cancer stages and eventually improving the survival rates and ease treatment for the earlier diagnosed patients[5]. Particularly for high risk early onset CRC populations, many causes lead to CRC development, often related to unhealthy lifestyle habits, such as overweight or obesity, smoking, intake of processed meat, sedentary lifestyle, and excessively alcohol consumption. In addition, other risk factors that do not depend on the life-style of individuals can be classified into the following categories: (1) having predispositions to cancer diseases, with conditions such as the presence of polyps in the colon or rectum, and inflammatory bowel diseases (IBD) such as Crohn's Disease or Ulcerative Colitis, (2) having previously suffered from CRC which increased risk of subsequent cancers, and (3) having genetic factors, such as Lynch syndrome and familial adenomatous polyposis (FAP), or other family factors, as the incidence is higher in those with relatives who have developed colorectal cancer. ONCOSCREEN will introduce a multi-tier risk stratification approach that will accumulate for the first-time medical disease history, heredity, genetic mutations, environmental stressors, dietary habits, diagnostic test results (including metabolic pathway), along with other socio-economic factors dictating a personalised risk status considering health inequalities within and across EU countries. Furthermore, it is for the first time that results from volatolomics, along CRISPR-CaS, NMR and CTC will be examined for risk-based calculation. ONCO-RISTE will be based on fuzzy logic. This form of semi-empirical approach associates recommendations with specific cases based on prior knowledge through a pool of "What-If" scenario-rules and membership functions from clinical experts. Furthermore, through ONCOCLIDE, settings panel clinicians will have the ability to indicate which factors they want to participate in the calculation of the score providing a fully dynamic and human-in-the-loop approach which yet is not existent in the market or bibliography to the best of our knowledge.
Is the innovation developed within the project?
– Under development
Characterise the type of innovation:
– New service (except consulting ones)
Level of innovation: What is the level of innovation?

[5] Kim, E.R., et. Al., Urine-NMR metabolomics for screening of advanced colorectal adenoma and early stage colorectal cancer. Sci Rep 9, 4786 (2019)

Product Innovation
How will the innovation be exploited?
EXUS will utilise as a trade secret, sub-parts of the clustering algorithms developed in ONCO-RISTE to fuel its Next Best Action - Customer Segmentation Commercial Product development to be part of its portfolio offering having a client base of successful sales in more than 30 countries around the world.
Is there a clear owner of the innovation in the consortium or multiple owners?
– A clear owner
Is the innovation to be introduced to the market or to be deployed within a partner
– Both. It is foreseeable that will be introduced as new to the market (commercial exploitation) as part of the existing commercial portfolio of EXUS. And also it is foreseen that will be sub-part of group of solutions, where the royalty fee model will apply.

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		
Engagement of both research team and partner's business units in project activities			x	
Market study	x			
Prototyping in laboratory environment		x		
Prototyping in real world environment		x		
Pilot, Demonstration or Testing activities		x		

Feasibility study	x			
Launch a start-up or spin-off				x
Standardisation				x
Application for private or public investment				x
Securing private investment				x
Securing public investment				x
Business plan	x			
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

EXUS

	EXUS
Investor readiness training	NO
Investor introductions	NO
Biz plan development	YES
Expanding to more markets	YES
Legal advice (IPR or other)	YES
Mentoring	NO
Partnership with other company (technology or other)	NO
Incubation	NO

Startup accelerator	NO

Market size: What is the approximate market size for this innovation
– < €25M € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Emerging: There is a growing demand and few offerings are available
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Innovative but could be difficult to convert customers
Market competition: How strong is competition in the target market?
– Established competition but none with a proposition like the one under investigation
When do you expect that such innovation could be commercialised?
– Between 1 and 3 years
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s) – An end user organisation outside of the consortium is consulted and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– Yes
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– Regulation – Financing

6.8 ONCO-CAWA

Title of the innovation
CRC Awareness Personalised Mobile Application

Describe the innovation
Develop a mobile app used for capturing RWD and delivering advice. This facilitates remote patient monitoring and digital therapeutics.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation:
– New service (except consulting ones)
Level of innovation: What is the level of innovation?:
Some distinct, probably minor, improvements over existing products
How will the innovation be exploited?:
Commercial exploitation
Is there a clear owner of the innovation in the consortium or multiple owners?
– A clear owner
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	**Planned in project**	**Not planned in project but needed/desirable**	**Not planned in project and not needed**
Technology transfer		x		
Engagement of both research team and partner's business units in project activities		x		
Market study		x		

Prototyping in laboratory environment	x			
Prototyping in real world environment		x		
Pilot, Demonstration or Testing activities	x			
Feasibility study	x			
Launch a start-up or spin-off				X
Standardisation				X
Application for private or public investment		x		
Securing private investment				x
Securing public investment				x
Business plan	x			
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

iSprint

Indicate their needs to fulfil their market potential

	iSprint
Investor readiness training	
Investor introductions	
Biz plan development	
Expanding to more markets	x
Legal advice (IPR or other)	

Mentoring	
Partnership with other company (technology or other)	
Incubation	
Startup accelerator	

Market size: What is the approximate market size for this innovation
– Not known € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Not yet existing: customers are not buying such products (or are not yet ready to buy such products/services)
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Innovative but could be difficult to convert customers
Market competition: How strong is competition in the target market?
– Patchy, no major players
When do you expect that such innovation could be commercialised?
– Less than 1 year
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is NOT actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– Yes – No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– IPR – Regulation – Financing – Trade issues (between MS, globally)

6.9 ONCO-CLIDE

Title of the innovation
ONCO-CLIDE
Describe the innovation
ONCO-CLIDE is a cDSS tool for CRC Integrated Diagnosis that utilize information from diverse diagnostic solutions such as liquid biopsy, breath biopsy, stool tests, histopathological images, colonoscopies coupled with the personalized background of each individual, that generate recommendations assisting clinicians in a more precise, early, non-invasive diagnosis.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation:
– Significantly improved service (except consulting ones)
Level of innovation: What is the level of innovation?:
Disruptive innovation
How will the innovation be exploited?:
ONCO-CLIDE introduces a novel approach to CRC diagnosis by integrating various diagnostic solutions and personalized patient data, ultimately providing clinicians with more precise and early detection capabilities. This disrupts the traditional methods of CRC diagnosis, which may rely solely on individual diagnostic tests or subjective assessments. By offering a comprehensive and non-invasive diagnostic tool, ONCO-CLIDE has the potential to significantly improve patient outcomes and reshape the landscape of CRC diagnosis and treatment.
Is there a clear owner of the innovation in the consortium or multiple owners?
– Multiple owners
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation)

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer				X
Engagement of both research team and partner's business units in project activities			X	
Market study			X	
Prototyping in laboratory environment			X	
Prototyping in real world environment			X	
Pilot, Demonstration or Testing activities		X		
Feasibility study				X
Launch a start-up or spin-off				X
Standardisation		X		
Application for private or public investment			X	
Securing private investment			X	
Securing public investment			X	
Business plan			X	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

KONN

Indicate their needs to fulfil their market potential

	KONN
Investor readiness training	YES
Investor introductions	YES
Biz plan development	YES
Expanding to more markets	YES
Legal advice (IPR or other)	YES
Mentoring	YES
Partnership with other company (technology or other)	YES
Incubation	YES
Startup accelerator	NO

Market size: What is the approximate market size for this innovation
– > €500M € amounts are for global markets and per year Estimating the market size for AI-assisted Clinical Decision Support Systems (CDSS) like ONCO-CLIDE, specifically in the context of colorectal cancer, involves analyzing the global oncology market along with the growing integration of artificial intelligence in healthcare. As such, the global market for oncology, including **various** types of cancers, was valued at approximately $136.7 billion in 2020 and is expected to reach around $222.4 billion by 2027, growing at a CAGR of about 7.4% during the forecast period. Within this market, the **segment for colorectal cancer** specifically has also been expanding due to increasing incidence rates and the significant cost associated with the disease's diagnosis and treatment.

The AI in healthcare market, which includes AI applications like those in ONCO-CLIDE, was valued at about $6.7 billion in 2020 and is projected to grow to $67.4 billion by 2027 at a CAGR of 46.2%. The integration of AI in oncology represents a significant portion of this growth, as AI tools offer the potential to enhance diagnostics, treatment planning, patient monitoring and outcomes across many cancer types, including colorectal cancer.

Focusing on AI in oncology, the market was specifically valued at around $732 million in 2020 and is anticipated to grow significantly. Given the specific application to colorectal cancer, the market size for CDSS like ONCO-CLIDE could be estimated by considering both the overall growth in the AI oncology market and the proportion attributed to colorectal cancer treatment and diagnostics. If we assume a conservative estimate where colorectal cancer treatments account for around 10-15% of the oncology AI market, this segment alone could represent a market size of approximately $73.2 million to $109.8 million annually by 2027.

These estimates are supported by the increasing adoption of AI systems in clinical settings, driven by the need to improve efficiency, reduce costs and enhance the quality of care, all of which are critical factors in managing chronic and complex conditions like colorectal cancer. The growth in this market is also encouraged by technological advancements, the increasing availability of healthcare data and rising healthcare expenditures globally.

Thus, the market size for innovations like ONCO-CLIDE is positioned for substantial growth within the expanding domains of both healthcare AI applications and oncology.

Market maturity: The market for this innovation is ...

- Emerging: There is a growing demand and few offerings are available
- The market for AI-assisted Clinical Decision Support Systems (CDSS) like ONCO-CLIDE in the field of colorectal cancer is considered emerging. This categorization is due to a growing demand for innovative healthcare solutions that integrate artificial intelligence to improve diagnostic accuracy, treatment efficacy and patient outcomes, coupled with relatively few comprehensive offerings currently available that fully realize this potential.

- The increasing incidence of colorectal cancer globally, combined with advancements in AI technology and data analytics, drives demand for more sophisticated diagnostic and management tools in oncology. However, while there is significant interest and considerable investment in developing AI applications for healthcare, the actual deployment and integration of these systems into everyday clinical practice are still progressing.

- The increasing incidence of colorectal cancer globally, combined with advancements in AI technology and data analytics, drives demand for more sophisticated diagnostic and management tools in oncology. However, while there is significant interest and considerable investment in developing AI applications for healthcare, the actual

deployment and integration of these systems into everyday clinical practice are still progressing. This suggests that while the technology is rapidly advancing, the market is still forming and is not yet saturated with solutions.

Several factors contribute to this market's emerging status:

- **Technological Innovation**: Continuous advancements in AI, machine learning models and computational power are enabling more robust applications in healthcare, which are beginning to be implemented in clinical settings but are not yet widespread.
- **Regulatory Landscape**: The regulatory environment for AI in healthcare is evolving, with significant developments in guidelines and standards still required to facilitate broader adoption. This uncertainty can slow market maturation.
- **Market Adoption**: Healthcare providers and institutions are increasingly open to adopting AI-driven tools; however, challenges related to cost, integration with existing systems and proving clinical efficacy through trials contribute to a cautious approach to full-scale implementation.

Market dynamics: is the market ...

- Growing

The market for AI-assisted Clinical Decision Support Systems (CDSS) like ONCO-CLIDE, particularly in the oncology sector, is growing significantly and this growth is fueled by several converging factors:

1. **Increasing Prevalence of Cancer:** The global rise in cancer cases, including colorectal cancer, is driving demand for more efficient and effective diagnostic and treatment solutions. According to the World Health Organization, cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths. This growing burden is pushing healthcare systems to adopt innovative technologies that can offer better patient outcomes.
2. **Technological Advancements:** There have been significant developments in AI, machine learning and data analytics technologies. These advancements enable the creation of more sophisticated and accurate decision support tools, which can learn from vast amounts of data to provide predictive insights and personalized treatment recommendations.
3. **Healthcare Digitalization:** The healthcare industry is increasingly digitalizing its operations and records, creating large volumes of data that can be utilized by AI systems. The integration of digital health records with AI tools is becoming more feasible and is expected to enhance the accuracy and efficiency of medical services.
4. **Government and Institutional Support:** Many governments and healthcare institutions are promoting the use of AI in healthcare settings through funding,

policy changes and strategic initiatives. This support helps in overcoming barriers to the adoption of advanced technologies like AI-assisted CDSS.

5. **Patient Demand for Personalized Care:** There is a growing patient demand for personalized healthcare services. AI systems are capable of analyzing individual patient data to deliver tailored diagnostic and treatment plans, aligning with the trend towards personalized medicine.

Level of innovation: What is the level of innovation

- *Obviously innovative and easily appreciated advantages to customer*

Konnektable's ONCO-CLIDE represents a high level of innovation within the field of Clinical Decision Support Systems (CDSS) for colorectal cancer. This innovation is evidenced by its integration of multiple advanced artificial intelligence (AI) methodologies, such as convolutional neural networks (CNNs), recurrent neural networks (RNNs) and various other machine learning algorithms, to provide precise diagnostic, prognostic and treatment guidance. This array of technologies allows ONCO-CLIDE to perform sophisticated data analysis, from identifying the adenoma-carcinoma sequence in colorectal cancer progression to offering probabilistic treatment recommendations based on individual patient data.

The advantages of ONCO-CLIDE are easily appreciated in the context of modern healthcare demands, where precision and personalization are at a premium. ONCO-CLIDE's ability to integrate diverse data types (clinical, genetic, patient history) into a cohesive analysis and decision framework supports more accurate screening and early detection of colorectal cancer, potentially reducing the incidence and mortality of the disease. Additionally, the system enhances the efficiency of healthcare providers by automating complex decision processes and presenting actionable insights directly through its interface.

Moreover, ONCO-CLIDE fosters collaborative healthcare approaches via its Virtual Tumor Board feature, which allows various specialists to review and discuss complex cases in a virtual setting, ensuring comprehensive treatment planning. This not only improves the quality of care but also accelerates the decision-making process, which is crucial in oncology.

The level of innovation in ONCO-CLIDE is thus not only technical but also procedural, offering significant advantages to healthcare providers and patients alike by enhancing the accuracy of diagnostics and the efficacy of treatments while streamlining workflows in healthcare institutions. This makes it a distinctly innovative solution in the rapidly evolving landscape of medical technology.

These dynamics indicate not only a growing interest and investment in AI-driven healthcare solutions but also a commitment across the healthcare ecosystem—from policymakers to providers—to implement technologies that can improve clinical outcomes. As such, the market for technologies like ONCO-CLIDE is not only expanding but also evolving to meet the increasingly sophisticated needs of modern healthcare systems.

Market competition: How strong is competition in the target market?

- Established competition but none with a proposition like the one under investigation

The competition in the market for AI-assisted Clinical Decision Support Systems (CDSS) like ONCO-CLIDE is established, yet none of the competitors offers a proposition exactly like ONCO-CLIDE. The market features a range of technologies aimed at enhancing the efficiency and accuracy of cancer diagnostics and treatment planning, but ONCO-CLIDE's specific integration of advanced AI technologies, comprehensive data utilization and a virtual tumor board presents a unique value proposition.

Several systems focus on aspects of AI in oncology, such as image analysis, data-driven diagnostics and predictive analytics. However, ONCO-CLIDE differentiates itself by combining these features into a holistic system that not only aids in early detection and accurate staging of colorectal cancer but also facilitates multidisciplinary collaboration through its Virtual Tumor Board. This allows for real-time, collaborative decision-making that is not commonly offered by other platforms.

While there are other sophisticated systems in the market, the level of integration of machine learning algorithms and the specific focus on colorectal cancer with a fully integrated decision support mechanism make ONCO-CLIDE stand out. Its ability to process and analyse diverse data types (clinical, genetic, histological) and translate these into actionable insights and recommendations provides a clear competitive edge.

When do you expect that such innovation could be commercialised?

- ***Between 3 and 5 years***

Commercializing an innovation like ONCO-CLIDE, which involves AI-assisted Clinical Decision Support Systems specifically for colorectal cancer, **is expected to take between 3 and 5 years**. This timeline is realistic given the various stages required for bringing a medical technology product to market, which includes development, testing, regulatory approvals and market entry strategies.

The initial phase involves further refining the technology, ensuring it integrates seamlessly with existing healthcare IT systems and enhancing the AI algorithms based on initial trials and feedback. Following this, extensive testing and validation are required to demonstrate the clinical efficacy and safety of the system, which is crucial for gaining trust from the medical community and regulatory approval.

Regulatory approval is one of the more time-consuming steps, involving detailed scrutiny by bodies such as the FDA in the U.S. or the EMA in Europe, depending on the target markets. This process ensures that the product meets all necessary safety, efficacy and quality standards.

Finally, the commercialization strategy would need to be executed, which includes marketing the product to healthcare providers and systems, establishing distribution channels and potentially training medical personnel to use the system effectively.

Given these extensive requirements, a timeframe of 3 to 5 years is a realistic estimate for ONCO-CLIDE **to move from its current stage to being commercially available on the market**. This timeline allows for the thorough development and testing needed to ensure the product not only meets regulatory standards but is also ready for widespread clinical use.

How this innovation engaged end-users to ensure their acceptance?

- ***End user organisation in the consortium and is actively engaged in co-creating the innovation(s)***

Konnektable's ONCO-CLIDE has effectively engaged end-users in the development process to ensure their acceptance of the innovation. By involving end-user organizations directly in our Consortium, ONCO-CLIDE benefits from the active participation of these groups in co-creating the system. This collaborative approach allows for the integration of real-world clinical insights and feedback into the development cycle, which helps tailor the system to meet the practical needs and preferences of its users.

The involvement of end-user organizations not only facilitates a design that is more user-friendly and clinically relevant but also promotes a sense of ownership and familiarity among future users, enhancing acceptance. These organizations, which include hospitals and healthcare institutions, contribute their expertise and experience, ensuring that the system addresses actual clinical challenges and integrates seamlessly into existing workflows.

This strategy of co-creation with end-users is crucial for overcoming resistance to new technologies in healthcare, which can often stem from a lack of understanding or misalignment with user needs. By actively engaging the very professionals who will use the system, ONCO-CLIDE is better positioned to achieve widespread acceptance and effectiveness in clinical settings.

FOR FUTURE REFERENCE (thought/food for thought):

· **Health Service Executive (HSE)** - As the public service provider for health and social care in Ireland, HSE operates numerous healthcare facilities and has a significant influence on healthcare practices and innovation adoption across the country. Their involvement could facilitate extensive field testing and integration of ONCO-CLIDE into clinical workflows. (https://www.hse.ie)

· **Irish Cancer Society** - This national charity focuses on cancer research, information provision and support services. Collaboration with the Irish Cancer Society could help in gaining insights into patient care, enhancing patient engagement and promoting ONCO-CLIDE as a tool that can support both patients and healthcare providers. (https://www.cancer.ie)

· **Royal College of Surgeons in Ireland (RCSI)** - As a leading global surgical college, RCSI engages in advanced medical education and clinical training. Partnering with RCSI could

provide opportunities for academic validation and clinical trials of ONCO-CLIDE, as well as integration into educational programs for healthcare professionals. (https://www.rcsi.com/)

Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?

Yes.

In specific, in a consortium focused on developing innovations for colorectal cancer (CRC) detection and management, certain internal intellectual property rights (IPR) issues could arise that may compromise the ability of the ONCOSCREEN partners to exploit the innovation in the marketplace. Some of these issues could include:

-Ownership of Intellectual Property

-Conflicting Interests

-Lack of Clear IP Management Policies

-Unequal Distribution of Benefits

Addressing these internal IPR issues requires proactive communication, collaboration, and the establishment of clear agreements and policies within the consortium. Developing a comprehensive IP management strategy, including mechanisms for resolving disputes and allocating rights and responsibilities, can help mitigate conflicts and facilitate the successful commercialization of the innovation in the marketplace. Additionally, engaging legal experts with expertise in intellectual property law can provide guidance and support in navigating complex IPR issues within the consortium.

Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?

- IPR
- Regulation
- Workforce's skills
- Others
- Standards
- Financing
- Trade issues (between MS, globally)

6.10 ONCO-EVIDA

Title of the innovation

ONCO-EVIDA: Evidence-Based Decision Analytics Dashboard
Describe the innovation
ONCO-EVIDA is an intelligent analytics dashboard that integrates data from diverse sources to enable evidence-based recommendations. It is focusing on increasing CRC screening participation by elucidating 'participation factors', as well as, on finding associations between risk factors (environmental, behavioural, socio-economic) and CRC outcomes (incidence, mortality, etc.). The core innovation lies in its user-friendly data visualization dashboard. This dashboard empowers policymakers, data analysts, and researchers with interactive tools to explore complex cancer data relationships. By visualizing trends and patterns, ONCO-EVIDA can lead to deeper insights to inform treatment decisions, improve research efforts, and ultimately contribute to better patient outcomes in cancer care.
Is the innovation developed within the project:
– **Under development**
Characterise the type of innovation:
– **New product**
Level of innovation: What is the level of innovation?:
Exploring.
How will the innovation be exploited?:
Commercial exploitation.
Is there a clear owner of the innovation in the consortium or multiple owners?
– **Multiple owners**
Is the innovation to be introduced to the market or to be deployed within a partner
– **Introduced new to the market (commercial exploitation)**

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer		x		

Engagement of both research team and partner's business units in project activities		x		
Market study		x		
Prototyping in laboratory environment	X			
Prototyping in real world environment		x		
Pilot, Demonstration or Testing activities	x			
Feasibility study	x			
Launch a start-up or spin-off				x
Standardisation				x
Application for private or public investment				x
Securing private investment				x
Securing public investment				x
Business plan	x			
Other				

Indicate which participant(s) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

VITO *(Vlaamse Instelling voor Technologisch Onderzoek N.V.)*
CERTH *(Ethniko Kentro Erevnas Kai Technologikis Anaptyxis)*
CTL *(Catalink Limited)*

ICCS/ ISENSE *(Institute for Communication and Computer Systems)*

Indicate their needs to fulfil their market potential

	CTL	CERTH	ICCS/ ISENSE	VITO
Investor readiness training				
Investor introductions				
Biz plan development				
Expanding to more markets	x			
Legal advice (IPR or other)				
Mentoring				
Partnership with other company (technology or other)	x	x	x	x
Incubation				
Startup accelerator				

The tool targets being promoted with an open-license for research continuation.

Market size: What is the approximate market size for this innovation
– **Not known** € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– **Mature: The market is already supplied with many products of the type proposed**
Market dynamics: is the market ...
– **Growing**
Level of innovation: What is the level of innovation
– **Innovative but could be difficult to convert customers**
Market competition: How strong is competition in the target market?

– **Established competition but none with a proposition like the one under investigation**
When do you expect that such innovation could be commercialised?
– **Between 1 and 3 years**
How this innovation engaged end-users to ensure their acceptance?
– **End user organisation in the consortium and is actively engaged in co-creating the innovation(s)**
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
– **No**
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– IPR – Regulation – Workforce's skills – Others – Standards – Financing – Trade issues (between MS, globally)

6.11 ONCO-BIOBA

Title of the innovation
ONCO-BIOBA
Describe the innovation
BIOBA represents the directory of the Oncosreen project, which describes the collections of samples planned and created in the project in a uniform and harmonized manner. This description should be compact and efficient, with the aim of summarizing enough information to describe collections and cohorts.
Is the innovation developed within the project:
– Under development
Characterise the type of innovation:

– New product – New service (except consulting ones)
Level of innovation: What is the level of innovation?:
Mediocre innovation, as there are already similar directories, but not for this specific Oncoscreen project. Considerations to make the description of collections as compact and uniform as possible are still relevant and no final answer was found until today.
How will the innovation be exploited?:
Commercial exploitation could be possible via licensing fees. However, an alternative way could be the integration of BIOBA into the platform of BBMRI-ERIC after the project ended.
Is there a clear owner of the innovation in the consortium or multiple owners?
– A clear owner: MUG
Is the innovation to be introduced to the market or to be deployed within a partner
– Introduced new to the market (commercial exploitation) – Not yet exploitation planned, due to delay of development caused by inactive/leaving partner

Indicate the step(s) already done (or are foreseen) in the project in order to bring the innovation to (or closer to) the market

	Done or ongoing	Planned in project	Not planned in project but needed/desirable	Not planned in project and not needed
Technology transfer				X
Engagement of both research team and partner's business units in project activities			x	
Market study			x	
Prototyping in laboratory environment		x		
Prototyping in real world environment		x		

Pilot, Demonstration or Testing activities		x		
Feasibility study			x	
Launch a start-up or spin-off			x	
Standardisation				x
Application for private or public investment			x	
Securing private investment			x	
Securing public investment			x	
Business plan			x	
Other				

Indicate which participant(s) (up to a maximum of 3) is/are the key organisation(s) in the project delivering this innovation. For each of these identify under the next question their needs to fulfil their market potential.

MUI was key supporting partner/organisation, but is now leaving the project
All other clinical partners can be seen as potential partner for ONCO-BIOBA
MUG is owner and key organisation int the project

Indicate their needs to fulfil their market potential

	MUG
Investor readiness training	x
Investor introductions	x
Biz plan development	n.a.
Expanding to more markets	x

Legal advice (IPR or other)	x
Mentoring	x.
Partnership with other company (technology or other)	x
Incubation	x
Startup accelerator	x

Market size: What is the approximate market size for this innovation
– Not known € amounts are for global markets and per year
Market maturity: The market for this innovation is ...
– Emerging: There is a growing demand and few offerings are available
Market dynamics: is the market ...
– Growing
Level of innovation: What is the level of innovation
– Obviously innovative and easily appreciated advantages to customer
Market competition: How strong is competition in the target market?
– Several major players with strong competencies, infrastructure and offerings
When do you expect that such innovation could be commercialised?
– Between 1 and 3 years, if delay can be decreased
How this innovation engaged end-users to ensure their acceptance?
– End user organisation in the consortium and is actively engaged in co-creating the innovation(s)
Are there in the consortium internal IPR issues that could compromise the ability of this innovation to be exploited by the project partner in the market place?
No
Which are the external bottlenecks that compromise the ability of project partners to exploit new products, solutions or services, internally or in the market place?
– Others

7 Business Models

In the below sub sections the Business Model Canvas for the KERs and all relevant technical partners is presented. In addition, the appropriate model i.e. B2B or B2C or B2G is being mentioned for each KER, in case that is already identified.

7.1 ONCO-VOC

<table>
<tr><th>Key Partners</th><th>Key Activities</th><th>Value Propositions</th><th>Customer Relationships</th><th>Customer Segments</th></tr>
<tr><td rowspan="3">• Networking
• Marketing Experts
• Distributors
• Academia/hospitals
• Biotech companies
• CRO’s
• Pharma Industry
• Industrialization partner</td><td>• Research and Development
• Education and Training</td><td rowspan="3">• Fast test
• User friendly
• Sensitivity (87%)
• Versatility
• Accurate
• Low cost</td><td>• Websites
• Conferences
• Trade-fairs
• Networks</td><td rowspan="3">• Cancer patients
• Clinicians
• Researchers
• Industry
• National Health Systems
• Regulators (e.g., Infarmed)</td></tr>
<tr><td>Key Resources</td><td>Channels</td></tr>
<tr><td>• Funding
• Patenting
• Brand registration
• CE mark
• GMP</td><td>• Societies
• Web
• Networks</td></tr>
<tr><td colspan="3">Cost Structure</td><td colspan="2">Revenue Streams</td></tr>
<tr><td colspan="3">• The cost is mainly due to sensor development and device building. Apart of that, the sensor manufacturing is very chip. A few cents per sensor at mass production.</td><td colspan="2">• The stream of revenues is predicted to be generated of device building and serves provision.</td></tr>
</table>

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
Feature #1. ONCO-VOC a breath analyser to detect CRC.	This is still an exploitation possibility	We are not ruling out this option at this stage although, it is very unlikely.

7.2 ONCO-CRISPR

Key Partners	Key Activities	Value Propositions	Customer	Customer Segments

<table>
<tr><td></td><td></td><td></td><td>Relationships</td><td></td></tr>
<tr><td rowspan="2">• Network/Contacts
• Marketing Experts
• Life science related businesses
• Production businesses for the CCassured kits
• Insurance
• Government</td><td>• Funding
• Research and Validation of the CRISPR-Cas POCT tools
• Website/ Social media
• Administration
• Production/Sales</td><td rowspan="2">• Easiness of use
• Reliable results
• Specific treatment
• Accurate
• Sensitive
• Specific
• Delivering what is required
• Cost effective
• End-user friendly
• Reducing healthcare costs</td><td>• Face to face meetings
• Websites
• Social media
• Alumni day
• Customer day</td><td rowspan="2">• Colorectal cancer patients
• Physicians
• Governments
• Insurance companies
• EU citizens (preventive screening)</td></tr>
<tr><td>Key Resources
• Funding
• Patents
• Knowledge
• Laboratory facilities</td><td>Channels
• Patient organisations
• Newsletters
• Website
• Blogs
• Social Media</td></tr>
<tr><td colspan="2">Cost Structure
lab materials, Salary, Marketing Sales, Taxes, overhead, licenses, Patent</td><td colspan="3">Revenue Streams
• EU and national Subsidies.
• When put into the market 10 - 25 euro per test, Royalties, Reference laboratory revenues, patent license</td></tr>
</table>

Exploitation Type (B2B, B2C, or B2G):

This had not been crystalized out yet and has to do with technological developments, IP filing and awarding or setting up a reference laboratory in which our technology is used. This will become clear the coming months, although CCassured anticipates towards the B2C model.

7.3 ONCO-NMR

<table>
<tr><th>Key Partners</th><th>Key Activities</th><th>Value Propositions</th><th>Customer Relationships</th><th>Customer Segments</th></tr>
<tr><td rowspan="2">• Network
• Marketing Experts
• Distributors</td><td>• Funding
• Research and Validation
• IVD / FDA approval
• Administration
• Production
• Sales</td><td rowspan="2">• Easiness of use
• End-user friendly
• Reliable results
• Delivering what is required
• Cost effective</td><td>• Face to face meetings
• Websites
• Social media
• Conferences
• Networks</td><td rowspan="2">• Cancer patients
• Clinicians
• Researchers / Scientists
• Citizens (preventive screening)
• Diagnostic centres</td></tr>
<tr><td>Key Resources</td><td>Channels</td></tr>
</table>

	• Funding • Patents • Knowledge • Laboratory facilities		• Patient organisations • Newsletters • Website • Blogs • Social Media	• Diagnostic companies • Medical Equipment Providers
Cost Structure		**Revenue Streams**		
Lab materials, Salaries, Marketing, Licenses costs, Patent costs		• Licencing fees • Commercialization of product(s) • Strategic collaborations with industry/clinics/health systems		

The business model canvas is expected to be further elaborated during the next project period.

Exploitation Type (B2B, B2C, or B2G):

ONCO-NMR is targeting towards a B2C and B2B model. In case of B2C, the prospective customers are diagnostic centres, for lab examination. In case of B2B, the prospective customers are other diagnostic companies or medical equipment providers. However, the above will be further examined during the second period of the project.

7.4 ONCO-CTC

Key Partners	**Key Activities**	**Value Propositions**	**Customer Relationships**	**Customer Segments**
• Networking • Marketing Experts • Distributors • Academia/hospitals • Biotech companies • CRO's • Pharma Industry • Industrialization partner	• Attract funding • CE mark • Pilot Study • Pivotal studies • Post approval study **Key Resources** • Funding • Patenting • Brand registration • CE mark • GMP	• Fast test • User friendly • Sensitivity (90%) • Versatility • Accurate • Low cost	• Face to face meetings • Websites • Conferences • Trade Fairs • Networks **Channels** • Societies • Website • Networks	• Cancer patients • Clinicians • Researchers • Industry • National Health Systems • Regulators (e.g., Infarmed)
Cost Structure			**Revenue Streams**	

Consumables, Reagents, Cell culture studies, GMP production costs, Human resources costs, Marketing Sales, Taxes, overheads, licenses, Patent filling costs, CE mark costs	• Licensing fees • Commercialization of product(s) • Strategic alliances with industry/clinics • EU national health systems

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
Feature #1. Portable and low-cost diagnostic device with integrated in vitro tissue/tumour model for CRC		

7.5 ONCO-AICO

<table>
<tr><th>Key Partners</th><th>Key Activities</th><th>Value Propositions</th><th>Customer Relationships</th><th>Customer Segments</th></tr>
<tr><td rowspan="2">• CERTH
• ICCS
• KONN
• AIN</td><td>• Platform Development: Design, development, and maintenance of the ONCO-AICO web platform, including user interface
• AI algorithm integration
• Explainable AI (XAI) functionality</td><td rowspan="2">• Accelerated Skill Development
• Reduced Missed Lesions and Interval Cancers
• Cost-Effective Training Solution</td><td>• Face to face meetings
• Websites
• Conferences
• Trade Fairs
• Networks</td><td rowspan="2">• Hospitals
• Medical Centers
• Academic Institutions
• Endoscopy Training Centers
• Junior Colonoscopists
• Non-Physician Endoscopists
•</td></tr>
<tr><td>Key Resources
• Human Resources: Expertise in AI
• medical imaging, software development, and healthcare training to support platform development and deployment.</td><td>Channels
• Societies
• Networks</td></tr>
<tr><td colspan="3">Cost Structure</td><td colspan="2">Revenue Streams</td></tr>
</table>

• Research and Development • Infrastructure Costs • Personnel Expenses • Marketing and Sales	• Licensing fees • Subscription Model • Commercialization of product(s) • Strategic alliances with industry/clinics

7.6 ONCO-AITI

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
No key partner available, since previous partner is leaving the project. In the project closest partner probably the team for ONCO-AICO since both tools are in the same task and may have the same user management	• Needed key activities would be annotation of WSIs, which is currently not available due to inactive partner **Key Resources** Key resources would be the expertise of pathologists as well as supporting technical partners	• Possibility to have assess to observation pattern of WSIs from expert pathologists • New learning tool, additionally to the existing tools and methods	• Our team works at the MUG and has access to medical students and medical staff to pronounce the tool and obtain feedback afterwards **Channels** • University lessons • social media platforms	• Medical students • junior pathologists • medical staff without university degree

Cost Structure	Revenue Streams
Innovation and Development Facility Costs and Overhead Expenses Personnel costs Costs for Marketing and sales	• If not free to use, but treated as product the revenue streams would be: • Sales of the product • Licencing fees

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
ONCO-AITI can be included in existing WSI viewers or be treated as a new viewer with new options to visualize regions of interest	Tool can be included in education strategies for medical staff	Customers can increase their learning process, maybe becoming an expert faster

7.7 ONCO-RISTE

Key Partners	Key Activities	Value Propositions	Customer	Customer Segments

<table>
<tr><td></td><td></td><td></td><td>Relationships</td><td></td></tr>
<tr><td rowspan="2">• AI/ML Experts
• Patient App Providers
• Clinician App Providers
• Clinical Experts
• IPR Experts</td><td>• Co-design activities with end users
• Research and Development
• Data Integration
• Laboratory Testing
• Education and Training</td><td rowspan="2">• Human in the loop approach increases transparency and acceptance
• More accurate risk stratification leads to more accurate behavioural and clinical intervention
• Reducing human error
• Contribution to evidence based decision making
• Measuring the impact of population wide policies
• Dynamic Scoring
• Continuous Monitoring
• Transferability and replicability of the method to other cancer types</td><td>• Collaborative Partnerships: collection institutions for tool experimentation and further refinement
• Customer Support/Training
• Saved Lives for patients/Improved QoL due to risk reduction
• Adherence to Screening</td><td rowspan="2">• Patients having a personalised mobile app wanted to have behavioural interventions to reduce their score
• Clinicians that want to reduce the risk of their patients using an intelligent clinician app
• Other customers from EXUS commercial portfolio interested in customer segmentation strategies</td></tr>
<tr><td>Key Resources
• Human Capital, Specialised Personnel
• Technological Infrastructure
• Intellectual Property Experts
• Data Providers</td><td>Channels
• Direct Sales B2B/B2C
• Existing Local Partners Network
• Existing EU Project Partners</td></tr>
<tr><td colspan="2">Cost Structure
• Research and Development
• Infrastructure Costs
• Personnel Expenses
• Marketing and Sales
• Clinical Testing
• Regulatory and security compliance and certifications</td><td colspan="3">Revenue Streams
• Product Sales to EXUS Client List(B2C)
• Royalty Fee Model (B2B)
• Licensing Fees (B2B)</td></tr>
</table>

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Customers
ONCO-RISTE can integrate with Healthcare Systems at Patient or Clinician level,	Sub-part of Clustering algorithms and their infrastructure will be used as a trade secret for

contributing to CRC risk-estimation and stratification facilitating early diagnosis. In this case the most prominent model is that the 3rd party provider will be sole responsible for the commercialisation offering royalty fees for the new joint product under Joint Ownership Agreement contract.	enhancing the EXUS's portfolio of products in reagrds to next best action customer segmenation AI-based solution that will be promoted in the EXUS client list that spans to more than 30 countries around the world.

7.8 ONCO-CAWA

<table>
<tr><th>Key Partners</th><th>Key Activities</th><th>Value Propositions</th><th>Customer Relationships</th><th>Customer Segments</th></tr>
<tr><td rowspan="3">• Healthcare Providers: Collaboration for medical accuracy, referral pathways, and integration with electronic health records.
• Also, access to treatment information, clinical trials, and medication management resources.
• Content providers</td><td>• App development (create new features/ update old)
• Technical maintenance</td><td rowspan="3">• Personalized CRC Awareness
• Accessible information and resources anytime, anywhere
• Tools for self-assessment, symptom tracking, and decision-making support</td><td>• Self-Service: Users independently access and navigate the app
• Customer Support: Helpdesk for technical assistance and inquiries</td><td rowspan="3">• Healthcare providers (and via them access to Individuals at risk of CRC)</td></tr>
<tr><td>Key Resources</td><td>Channels</td></tr>
<tr><td>• Content creators
• Healthcare professionals
• Developers
• Designers
• IT support staff</td><td>• Mobile app stores
•
• Online platforms: website and social media</td></tr>
<tr><td colspan="3">Cost Structure</td><td colspan="2">Revenue Streams</td></tr>
<tr><td colspan="3">• Personnel costs
• Hosting, maintenance, and software licenses for app development
• Marketing and advertising</td><td colspan="2">• ONCO-CAWA is free to use.
• Healthcare organizations pay per subject and healthcare provider.</td></tr>
</table>

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
Healthcare organizations distribute ONCO-CAWA to subjects.	N/A	N/A

7.9 ONCO-CLIDE

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
• Diagnostic Solution Providers • Academic Institutions • Healthcare Providers	• Research and Development • Data Integration • Clinical Trials • Education and Training	• Precise Diagnosis: Offer clinicians advanced diagnostic tools that combine information from diverse sources to provide more accurate and personalized diagnoses for CRC. • Improved Patient Outcomes: Enable early detection and personalized treatment recommendations, leading to better patient outcomes and survival rates. • Efficiency: Streamline the	• Collaborative Partnerships: Foster long-term partnerships with healthcare providers, academic institutions, and diagnostic solution providers to co-create and refine diagnostic solutions. • Customer Support: Provide ongoing support and training to healthcare professionals using the diagnostic tools, ensuring optimal utilization and customer satisfaction.	• Healthcare Providers • Academic Institutions • Diagnostic Solution Providers • Patients • Healthcare Payers and Insurers
	Key Resources		**Channels**	

	• Technology Infrastructure • Human Capital • Intellectual Property	diagnostic process by automating data integration and analysis, saving time and resources for healthcare providers.	• Product Sales • Subscription Model • Licensing Fees	

Cost Structure	**Revenue Streams**
• Research and Development • Infrastructure Costs • Personnel Expenses • Marketing and Sales	• Product Sales • Subscription Model • Licensing Fees

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
ONCO-CLIDE integrates smoothly with existing healthcare IT systems, enhancing workflow efficiency without disrupting current operations.	ONCO-CLIDE can process and analyze health data at a population level, aiding governments in public health decision-making and policy development.	ONCO-CLIDE provides users with a personal dashboard to track their health data and receive tailored health recommendations based on AI analysis.
Feature #2. Multi-Disciplinary Collaboration Tools	*Feature #5. Compliance Tracking*	*Feature #8. Direct Patient Engagement*
Features tools that facilitate collaboration among healthcare providers, enhancing team-based care and treatment planning.	ONCO-CLIDE helps government agencies monitor and ensure compliance with health regulations and standards.	Enables direct communication channels between patients and their care providers, enhancing engagement and satisfaction.
Feature #3. Customizable AI Models	*Feature #6. Health Program Management*	*Feature #9. Educational Content*
Allows healthcare organizations to customize AI-driven models to suit specific clinical needs and patient demographics.	Supports the management and evaluation of public health programs, integrating data across	Provides patients with accessible educational materials about colorectal cancer

	platforms for comprehensive oversight.	prevention, care, and management strategies.

7.10 ONCO-EVIDA

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments
• **Healthcare data providers**: Hospitals and healthcare institutions with relevant cancer data stored in EHR systems and other sources. • **Oncology data analysis tool developers**: Partnerships to enable data exchange and integration with complementary oncology tools. • **Government agencies or healthcare regulatory bodies**: Collaboration on data standardization and compliance initiatives for cancer data.	• **Software development and maintenance**: Continuously improve the ONCO-EVIDA tool with new features and functionalities. • **Data integration development**: Maintain and enhance the connection between ONCO-EVIDA and various hospital data sources. • **Sales and marketing**: Promote the ONCO-EVIDA tool to target customers and drive adoption. • **Customer support**: Provide training, technical support, and address user questions and issues. • **Key Resources** • **The ONCO-EVIDA data visualization dashboard**: Provides	**For Policymakers**: • Improved decision-making through data-driven insights for cancer treatment and care. • Increased efficiency by streamlining data access and analysis workflows. • Improved communication and collaboration with colleagues through data sharing. **For Data Analysts and Researchers**: • Powerful data visualization tools for exploring complex cancer data relationships. • Ability to gain deeper insights from cancer data to inform research efforts. • Time savings through a centralized	• **Sales support**: Providing training and technical support to help users get the most out of the ONCO-EVIDA tool. • **Online knowledge base**: Offering user manuals, tutorials, and FAQs to facilitate self-service learning. • **Customer support**: A dedicated team to address user questions and issues. **Channels** **Direct sales**: Sales team targeting hospitals and	• Environmental and public health policy makers. • Epidemiologists, data analysts, researchers in hospitals and healthcare institutions focusing on cancer care and research. • Health Insurance.

	interactive tools for exploring and analysing cancer data. • **Technical infrastructure**: Servers, databases, and other technologies to support the ONCO-EVIDA platform. • **Sales and support team**: Personnel to acquire new customers and provide ongoing support.	platform for data access and analysis.	healthcare institutions. **Website**: Providing information, demos, and free trials of the ONCO-EVIDA tool. **Partnerships**: Collaborating with electronic health record (EHR) vendors or other oncology data system developers for integration and distribution. • **Conferences and events**: Showcasing the ONCO-EVIDA tool at industry conferences and healthcare IT events.	

Cost Structure	Revenue Streams
• **Software development and maintenance**: Costs associated with developers, infrastructure, and tool maintenance. • **Sales and marketing**: Costs of sales personnel, marketing materials, and participation in industry events. • **Customer support**: Costs of providing training, technical support, and maintaining a support	• **Subscription fees**: A monthly or annual subscription fee for access to the ONCO-EVIDA dashboard and its functionalities. • **Freemium model**: A basic free version with limited features to drive adoption, upselling to paid subscriptions with advanced functionalities. • **Per-user fees**: Charging a fee per user accessing the platform, potentially relevant for large institutions.

Exploitation Type (B2B, B2C, or B2G):

ONCO-EVIDA is targeting towards a B2G, under open licence, for the continuation of research and adoption by national / regional authorities, to facilitate the evidence-based decision making and the interconnection with data registries. However, the above will be further examined during the second period of the project.

7.11 ONCO-BIOBA

Key Partners	Key Activities	Value Propositions	Customer Relationships	Customer Segments

<table>
<tr>
<td rowspan="3">• All clinical partners can serve as partner</td>
<td>• Active communication of the partners, if samples are planned to be stored at there hospital/biobank for further research purposes</td>
<td rowspan="3">• Overview of all planned or existing collections within the oncoscreen project</td>
<td>• Clinical partner would be the provider of collections and can be at the same time potentional partner with interest in collections of other partners</td>
<td rowspan="3">• Clinical partners, as provider of collections.
• Clinical parties, research institutes, companies, as interested costumer to use have access to the collection, which are described in BIOBA</td>
</tr>
<tr>
<td>Key Resources</td>
<td>Channels</td>
</tr>
<tr>
<td>• Description of planned or already available collections on meta level</td>
<td>• Website for BIOBA, social media platforms</td>
</tr>
<tr>
<td colspan="3">Cost Structure</td>
<td colspan="2">Revenue Streams</td>
</tr>
<tr>
<td colspan="3">- Innovation and Development
- Facility Costs and Overhead Expenses
- Personnel costs
- Costs for Marketing and sales</td>
<td colspan="2">• If not free available use, but treated as product the revenue streams would mainly be from licencing fees</td>
</tr>
</table>

Exploitation Type (B2B, B2C, or B2G):

Business 2 Business (including organizations)	Business 2 Government	Business 2 Customers
BIOBA can be included in existing collection directories	n.a.	Customer can contact BIOBA and the provider of the collections for future projects and partnerships, as well as agreements to get access to the provided collections

8 ONCOSCREEN Portfolio Offering

The consortium after various discussions that they had the first period of the project concluded that the exploitation of the system as whole will be a high risk approach and the most prominent approach would be the exploitation of group of solutions. Small group of solutions are more prominent to be exploited, can share IP and commercial risks, have a smaller cost for potential buyers and provide a realistic pathway to commercialisation. Public procurement shouldn't be underestimated for healthcare solutions and large and complex offerings may not be convenient, also due to disparities in terms of public healthcare spending across EU countries.

In this Section, we classify the ONCOCREEN Solutions in groups providing a portfolio of solutions that will follow a closer collaboration across the project, aligning their technical implementation strategies with their commercial and exploitation strategies.

No.	Key solutions	Possible Add on Solutions	What is it for?	What is the target group?
1	ONCOVOC, ONCOCRISPR, ONCOCAWA, ONCORISTE	Data Fusion, Data Lake, ONCOSCREEN Back-end Infrastructure (Zero Trust Framework, Kafka/REST services set up)	At home CRC early stage (1st level) diagnosis and risk monitoring	Citizens/Patients
2	ONCONMR, ONCOCTC, ONCOCLIDE, ONCORISTE	Data Fusion, Data Lake, ONCOSCREEN Back-end Infrastructure (Zero Trust Framework, Kafka/REST services set up)	At Lab/Hospital Setting CRC 2nd level diagnosis, genetic profiling, metastasis detection	Clinicians/Hospitals/Lab-based Examination - Diagnostic Centres
3	ONCOEVIDA, DATA FUSION, DATA LAKE	Privacy Preservation, ONCOSCREEN Back-end Infrastructure (Federated Data Mesh, Zero Trust Framework, Kafka/REST services set up) for obtaining information from hospitals and cancer registries	For policy makers to make evidence based decisions based on multiple layers of information	Regional and National Level Policy Makers

4	ONCOBIOBA, DATA FUSION, DATA LAKE	Privacy Preservation, ONCOSCREEN Back-end Infrastructure (Federated Data Mesh) for obtaining information from hospital	For scientific community and companies to access open information for new knowledge generation	Scientific Community for further continuation of research
5	ONCOAICO, ONCOAITI	Privacy Preservation, ONCOSCREEN Back-end Infrastructure (Federated Data Mesh, Zero Trust Framework, Kafka/REST services set up) for obtaining information from hospitals and cancer registries	Getting trained to reduce junior-to-senior time period, reduce human error at junior levels, reduce public healthcare cost from the usage of senior clinicians	Junior Colonoscopists, Nurse Endoscopists, Junior Pathologist, healthcare system (indirectly)

It is noted that the above grouping of solutions is in alignment with the ONCOSCREEN Architecture that is referred within D4.1 – ONCOSCREEN Co-Designed System Architecture (First Version) and is shown in the following figure.

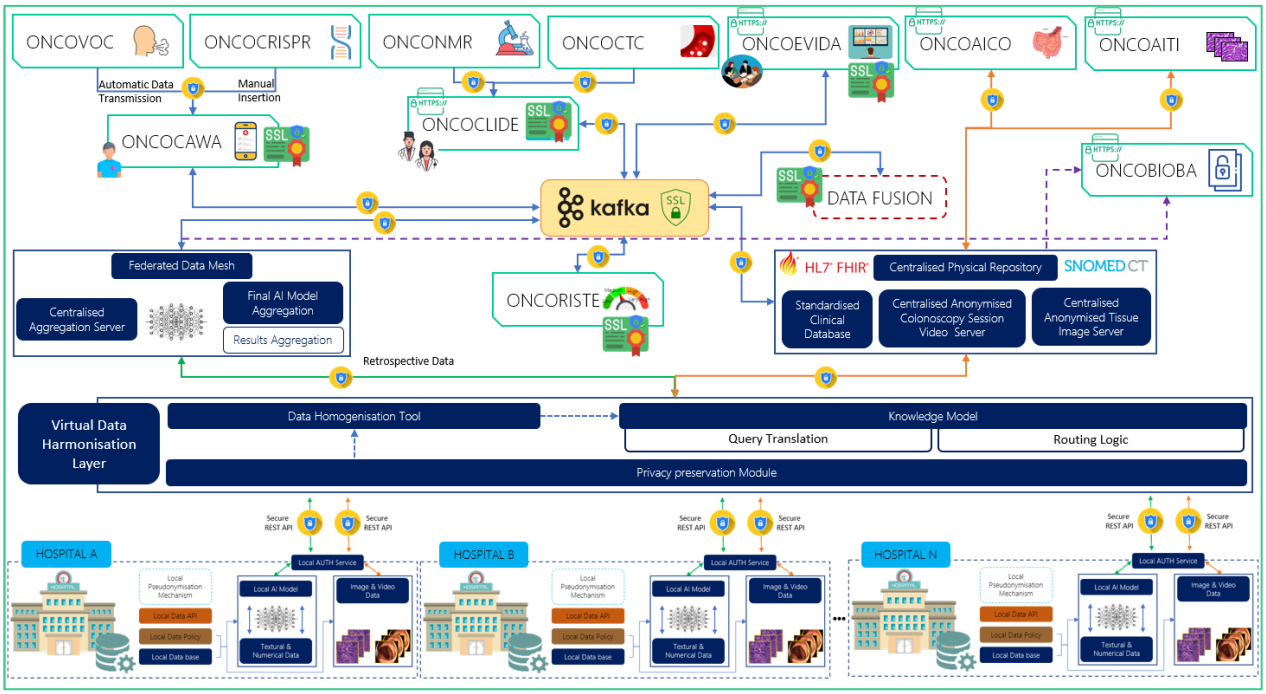


Figure 5. D4.1, ONCOSCREEN Architecture

9 Roadmap to Commercialization

For each KER we try to identify the current and future TRL level. In general, the TRL levels relate to the following development phases[6]:

- **TRL 1 –** Basic principles observed.
- **TRL 2 –** Technology concept formulated.
- **TRL 3 –** Experimental proof of concept.
- **TRL 4 –** Technology validated in lab.
- **TRL 5 –** Technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies).
- **TRL 6 –** Technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies).
- **TRL 7 –** System prototype demonstration in operational environment.
- **TRL 8 –** System complete and qualified.
- **TRL 9 –** Actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space).

Phase	TRL	Expected Date	Milestones Achieved	Approx. Funded Needed
Current State	5	Today	**ONCO-VOC** prototypes	Covered through the project
Project period	6-7	Q2|2025	Clinically validated in phase A and patents filed	Covered through the project
Final phase	8-9	Beyond Project end	Accuracy of over 90%.	1.000.000 to reach TRL 9

[6] https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf

Current State	5	Today	**ONCO-CRISPR** prototypes (4)	Covered through the project
Project Period	6-7	Q3|2024	Clinically validated in phase A/B and patents filed. Contacted EUDAMED and NOTIS	Covered through the project and partly via investors 500.000-euro additional investments required as a minimum
Final phase	8-9	Q4|2025 Q2|2026	Round robin test further optimized toward a single diagnostic test w/o lab	An additional 500.000euro required as a minimum to reach TRL 9 Investors on board, reading toward market implementation
Current State	5	Today	**ONCO-NMR** prototypes, SOP established	Covered through the project
Project Period	6-7	Q3|2025	Clinically validated in phase A and patents filed	Covered through the project
Final Phase	8-9	Beyond project end	Productization, CE Marking, Marketing/Business Plan fulfilled	500.000-700.000 to reach TRL 9
Current state	2	Today	**ONCO-CTC** tool developed, and SOP established	Covered through the project
Project Period	3-4	Q4|2024	ONCO-CTC tool developed. Pre-clinical optimization and validation according to end user requirements	Covered through the project

Midterm Period	6	Project end	Pilot test concluded (at least 50 patient test)	Covered through the project
Final phase	7-9	1-3 Years beyond project closure	Large scale examination, CE Marking, Patent Finalisation	Additional 400-700.000 covered from new EU funds or investors
Current State	5	Today	**ONCO-AICO** prototypes (4)	Covered through the project
Project Period	6	Q2|2025	Prototype development and fulfilment of requirements	Covered through the project
Final Phase	7-8	1-2 Years beyond project closure	Further continuation of research through Open Licence	Covered through further national and EU funding
Current State	3-4	Today	**ONCO-AITI** prototype	Covered through the project
Project Period	5-6	Q2|2025	Prototype development and fulfilment of requirements	Covered through the project, higher TLR could be reached, if supporting partner would not leave the project or with approx. 200.000 additional funding.
Final Phase	7-8	1-2 Years beyond project closure	Further continuation of research through Open Licence	Covered through further national and EU funding
Current State	5	Today	**ONCO-RISTE** stratification algorithm	H2020 ONCORELIEF

Project Period	6-7	Q4|2025	Lab validated, approved from clinical experts	Covered through the project
Final Phase	8-9	2-4 years beyond project closure	Further validation, standardisation, commercial agreement signed.	400.000-600.000
Current State	5	Today	**ONCO-CAWA** prototypes and requirements	Covered through the project
Project Period	6-7	Q3|2024	ONCO-CAWA adjustments based on feedback and user requirements	Covered through the project
Final Phase	8-9	Q4|2025 Q2|2026	ONCO-CAWA final prototype	Covered through the project
Concept and Feasibility	1-3	Q4 2023	**ONCO-CLIDE**: Initial concept validation, feasibility studies	Covered with own funds before project start
Technology Development	4-5	Q2 2024 - Q4 2024	Prototype development, lab testing, initial algorithm training	Covered through the project
System Integration	6-8	Q1 2025 - Q3 2025	Integration into clinical workflows, initial pilot testing	Covered through the project
Final Testing and Launch	9	Q3 2026 - Q4 2026	Final adjustments, compliance and regulatory approval	€1,000,000
Commercial Roll-out	9	Q1 2027	Marketing launch, distribution setup, sales start	€500,000

Current State	4	Today	**ONCO-EVIDA** prototypes and requirements	Covered through the project
Project Period	5-6	Q3|2024	ONCO-EVIDA updates and modifications based on collected feedback.	Covered through the project
Final Phase	7-8	1-3 Years beyond project closure	Further continuation of research through Open Licence	Covered through further national and EU funding
Current State	4	Today	**ONCO-BIOBA**: prototype presented during LIT1 & LIT2	Covered through the project
Project Period	5-6	Q4|2025	Prototype available for all partners in the project	Covered through the project
Final Phase	7-8	1-3 Years beyond project closure	Further continuation of research through Open Licence	Covered through further national and EU funding

It is noted that the above table represents an early indication of the commercial roadmap of the KER. A further analysis, discussion will be conduct during the second half of the project when the results of the project are more mature and the final updates will be included in the second iteration of this deliverable.

10 Replicability and Transferability of Solutions

ONCOSCREEN Component	In which sectors can be transferred?	How?	What are the Limitations?
ONCO-VOC	Other cancers and diseases	The same way it is directed towards CRC.	Only research data.
ONCO-CRISPR	Other cancers and diseases, our next focus is on prostate and bladder cancer	Same process as followed in ONCOSCREEN	Competition Funding Technological (offering a single test) EMA/FDA approval
ONCO-NMR	Other cancers	Research required via similar process as in this project	No major limitations are foreseen
ONCO-CTC	Research	Product for cell culture	No major limitations are foreseen.
ONCO-AICO	Other types of cancer where imaging is used as input and method for assessment	Mainly either via transfer learning for the employed prediction models and similar input, or by from-scratch model development. Front end and XAI features can be left as it is.	No major limitations apart from adequate number of training data, are foreseen.
ONCO-AITI	All medical section with medical imaging challenges	Adapt regions of interest to other medical fields, which include medical imaging	Collecting eye tracking data or other observation data is challenges, technologically and legally

ONCO-RISTE	Customer segmentation, risk stratification for other type of cancer	Following similar data infrastructure, DevOps, AIOps, and similar algorithmic setup	Different data, validation and testing needs to start from the beginning (TRL3-4)
ONCO-CAWA	Wellness programs	Use ONCO-CAWA to track participation and health outcomes	Digital literacy
ONCO-CAWA	Health insurance	integrate ONCO-CAWA into their member benefits packages	Health disparities and privacy concerns
ONCO-CLIDE	Security	DSS for emergency crisis management	No major limitations
ONCO-EVIDA	Other disease areas with complex data (e.g., genomics, immunology)	Adapt the data visualization components to be compatible with the specific data types used in those areas. Develop new visualizations tailored to the research questions relevant to other diseases.	The effectiveness of visualizations depends on the inherent characteristics of the data being analysed. Customization might be needed for different disease areas.
ONCO-BIOBA	Platform of BBMRI-ERIC	Include information from BIOBA to cohort and collection description of BBMRI-ERIC	Maybe further agreements are needed, like DTA

ONCOSCREEN Component	**From 1(Difficult) to 10 (Easy) how easy**	**What are the Needs in Modifications?**

	is for end users to adopt the solution?	
ONCO-VOC	9	Can be offered as a health service / facility to the patient / citizen.
ONCO-CRISPR	9	Our goal is to offer our diagnostic device as a single test to fulfil the need of the end-users, but requires tailor-made modifications
ONCO-NMR	9	The goal is to offer a diagnostic test, which is based on non-invasive methodology
ONCO-CTC	7	Needs tailor-made modifications
ONCO-AICO	7	Model retraining at the backend of the tools to be aligned with the new "clinical" assessment
ONCO-AITI	7	Needs tailor-made modifications
ONCO-RISTE	8	Needs tailor-made modifications
ONCO-CAWA	7	Minor modifications are needed
ONCO-CLIDE	9	Minor modifications are needed
ONCO-EVIDA	6	Minor modifications are needed Can be offered as a service
ONCO-BIOBA	9	Needs communication to developers what kind of information are needed or wished, from the end users

The above represents a self-assessment of the technical partners. In the second iteration a willingness to buy questionnaire will be created that will assess the end user opinion.

11 Potential Risks, Barriers or limitations

11.1 ONCO-VOC

Component	ONCO-VOC	**Responsible Partner**	TECHNION
Risk Description		**Barriers**	**Limitations**
Technology fails to reach sensitivity of 90%. Drift in sensor read that is to high. Legal issues		No capability of reaching this level of accuracy	Internal limitations of the technology itself
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

11.2 ONCO-CRISPR

Component	ONCO-CRISPR	**Responsible Partner**	CCASSURED
Risk Description		**Barriers**	**Limitations**
Technology fails Unable to patent Legal issues Pandemic Financing		Getting approval of the EMA/FDA and IP recognition / awarding by the EU patent office, fulfilling regulatory roles and measures	Time, funding, awareness, legal penalties, reputational damage, adequate training and support are crucial for ensuring that end users are comfortable and proficient with new technology.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

11.3 ONCO-NMR

Component	ONCO-NMR	**Responsible Partner**	UzL
Risk Description		**Barriers**	**Limitations**
Unable to patent IVD / FDA approval		Patent related activities and approval require long lasting processes	Currently no foreseen limitations

Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	Medium	3	Low

ONCO-NMR related risks, barriers and limitations, are expected to be further specified and crystalized during the next project period.

11.4 ONCO-CTC

Component	ONCO-CTC	**Responsible Partner**	UMINHO
Risk Description		**Barriers**	**Limitations**
Technology fails to reach sensitivity of 90% Unable to patent CE mark costs Legal issues		Patent related activities require long lasting processes. Legislation changes.	Time limitations. Adherence to regulation difficulties.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	Medium	3	Low

Note that related barriers and limitations will be examined and elaborated in more detail during the next project period.

11.5 ONCO-AICO

Component	ONCO-AICO	**Responsible Partner**	CERTH
Risk Description		**Barriers**	**Limitations**
User acceptability User usability Limited availability timewise of users to be trained. This mainly applies for the expert clinicians that would lead the training of junior clinicians.		Access to clinicians for training	Late access Lack of awareness
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

Limitations will be further crystalized during the next project period.

11.6 ONCO-AITI

Component	ONCO-AITI	**Responsible Partner**	MUI
Risk Description		**Barriers**	**Limitations**
Inactive and leaving partner, no partner for annotations available, stop of development of the tool		Difficult to find medical and technological partner	Time of project, already strong delay in development
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
High	High	6	High

11.7 ONCO-RISTE

Component	ONCO-RISTE	**Responsible Partner**	EXUS
Risk Description		**Barriers**	**Limitations**
Data availability. The effectiveness and robustness of the risk-based stratification engine is highly dependent on available data and rules from clinical experts from diverse sources, for design and testing purposes.		Required time to gather data.	Volume: Data from diverse sources are needed, where in some cases insufficient data may appear. Late access: Access to some data sources may be late, and thus the time for their utilization limited. Regulatory Restrictions: Privacy related laws, like GDPR, may cause limitations in data accessibility and sharing from hospitals.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

11.8 ONCO-CAWA

Component	ONCO-CAWA	**Responsible Partner**	iSprint
Risk Description		**Barriers**	**Limitations**

Technical issues due to incompatible mobile phone types		Lack of testing to all types of phones	Dependency on mobile device
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	Low	2	Low

Risk Description		**Barriers**	**Limitations**
Data breach		Weak encryption protocols	Legal repercussions
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

Risk Description		**Barriers**	**Limitations**
Low user adoption		Limited marketing budget and resources	Lack of awareness, competition
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

Risk Description		**Barriers**	**Limitations**
Platform dependency		Inability to adapt quickly to new requirements	Risk of app becoming obsolete
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**

Low	High	4	Medium

Risk Description		**Barriers**	**Limitations**
Regulatory compliance		Lack of understanding/misunderstanding	Fines, legal penalties, reputational damage
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

11.9 ONCO-CLIDE

Component	ONCO-CLIDE	**Responsible Partner**	KONN
Risk Description		**Barriers**	**Limitations**
Availability of early diagnostic data. The effectiveness of ONCO-CLIDE heavily relies on the availability and quality of early diagnostic data, such as initial screening results, genetic testing information and early symptom reports. The risk here is that incomplete or inaccurate data could lead to suboptimal predictions and recommendations from the system.		Clinical trials	**Volume of Data**: In some regions or settings, the volume of available data may not be sufficient to train the AI algorithms effectively. **Late access**: We may receive access to the relevant data towards the end of the project with insufficient time to utilise them.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	High	5	High

Component	ONCO-CLIDE	**Responsible Partner**	KONN
Risk Description		**Barriers**	**Limitations**
Quality of early diagnostic data		Clinical trials	**Reliability of new tools**: Since the system is dependent upon the input of the novel tools developed during the

			scope of the project, it will be affected in cases where they prove unreliable.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	Low	2	Low

Component	ONCO-CLIDE	Responsible Partner	KONN
Risk Description		**Barriers**	**Limitations**
<u>Availability of traditional diagnostic data</u>		Data sharing	**Regulatory Restrictions**: Privacy laws and regulations, such as GDPR in Europe or HIPAA in the United States, strictly control how patient data can be accessed and shared. These regulations, while crucial for protecting patient privacy, can limit the availability of necessary data for comprehensive analysis.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
High	High	6	High

Component	ONCO-CLIDE	**Responsible Partner**	KONN
Risk Description		**Barriers**	**Limitations**
<u>Participation of clinical partners</u>		Effective communication	**Doctor input**: The intelligent suggestions that we are going to implement, are mainly based on empirical observations of the clinical staff, so their participation is crucial to achieve this.

			Outdated Information: Healthcare data can quickly become outdated if not regularly updated, particularly in fast-evolving fields like oncology where treatment protocols and diagnostic criteria can change rapidly.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

Component	ONCO-CLIDE	**Responsible Partner**	KONN
Risk Description		**Barriers**	**Limitations**
<u>User Adoption and Acceptance</u> The successful deployment and effectiveness of Konnektable's ONCO-CLIDE are contingent upon its acceptance and adoption by healthcare professionals. Resistance to adopting new technology can be a significant risk, especially if users are accustomed to traditional methods of diagnosis and treatment.		**Technological Familiarity**: A common barrier is the varying levels of technological proficiency among healthcare providers. Those less familiar with digital tools may be hesitant to rely on an AI-based system for critical tasks like diagnosis.	**Training and Support**: Adequate training and ongoing support are crucial for ensuring that users are comfortable and proficient with new technology. Insufficient training can limit user adoption and reduce the effectiveness of the system.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

11.10 ONCO-EVIDA

Component	ONCO-EVIDA: Dashboard	**Responsible Partner**	CERTH

Risk Description		**Barriers**	**Limitations**
Data Integration Issues		Incompatibility with some data providers (e.g. hospital data systems)	Limited data sources integrated initially
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
High	High	6	High

Component	ONCO-EVIDA: Dashboard	**Responsible Partner**	CERTH
Risk Description		**Barriers**	**Limitations**
Data Quality Issues		Inaccurate or incomplete data in source systems.	Limited ability to clean or standardize data within ONCO-EVIDA.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	High	5	High

Component	ONCO-EVIDA: Dashboard	**Responsible Partner**	CTL, VITO, ICCS
Risk Description		**Barriers**	**Limitations**
User Adoption		Resistance to change in workflow among clinicians.	Limited training or support for users.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

Component	ONCO-EVIDA: Dashboard	**Responsible Partner**	CTL, CERTH
Risk Description		**Barriers**	**Limitations**
Data Security Breach		Security vulnerabilities in the platform or data storage.	Potential for unauthorized access to sensitive patient data.

Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Low	High	4	Medium

Component	ONCO-EVIDA: Dashboard	**Responsible Partner**	CTL, CERTH
Risk Description		**Barriers**	**Limitations**
Compliance Issues		Evolving data privacy regulations.	Difficulties in ensuring ONCO-EVIDA adheres to all relevant regulations.
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

11.11 ONCO-BIOBA

Component	AITI	**Responsible Partner**	All clinical partner
Risk Description		**Barriers**	**Limitations**
Clinical partners are not planning to collect samples and store them in biobanks		Clear plan of planning collections in this project	Time of project, financial amount, planned for clinical studies
Risk Probability (High Medium Low)	**Risk Impact** (High Medium Low)	**Severity Score (2-Low to 6-High)**	**Severity Status**
Medium	Medium	4	Medium

12 Promotion, Advertising Channels

To effectively promote ONCOSCREEN's results, a multifaceted approach utilizing various channels can maximize reach and engagement with different target audiences.

1. *Social Media:*

- **LinkedIn**: Target healthcare professionals and institutions with posts about the specific ONCOSCREEN's KER benefits and case studies demonstrating its effectiveness.
- **Twitter**: Share updates on specific ONCOSCREEN's KER, industry news and participate in relevant healthcare discussions to increase visibility.
- **Facebook**: Engage broader audiences by sharing user testimonials, informational videos and interactive posts about the specific ONCOSCREEN's KER.
- **Instagram**: Utilize visual content to highlight specific ONCOSCREEN's KER features, behind-the-scenes development and real-life impact on patient care.
- **YouTube**: Create and share videos that explain how the specific ONCOSCREEN's KER works, customer stories and expert interviews to educate and engage potential users.

2. *Mail Marketing:* Develop and execute targeted email campaigns that reach out to healthcare providers and decision-makers, showcasing the benefits and unique selling propositions of the specific ONCOSCREEN's KER, along with invitations to webinars or live demos.

3. *Newsletter:* Regular newsletters will provide updates on product developments, case studies, new integrations, or partnerships that might interest current and potential customers.

4. *Blogging:* Maintain a blog that offers valuable content related to colorectal cancer care, the role of AI in healthcare and detailed posts about the specific ONCOSCREEN's KER functionalities and updates to build thought leadership.

5. *Brochures:* Design informative brochures that succinctly describe specific the ONCOSCREEN's KER, its benefits and use cases. These can be distributed at healthcare conferences, in hospitals and clinics, or sent directly to potential business clients.

6. *Local Partner Network:* Collaborate with local healthcare providers, clinics and regional distributors to promote the specific ONCOSCREEN's KER through their networks. Partners can help demonstrate the product's value proposition directly to end-users in a more personalized manner.

7. *Public Relations:* Potentially/tentatively outsource/engage a PR agency to help position the specific ONCOSCREEN's KER in healthcare industry publications and mainstream media. Press releases and stories can highlight the specific ONCOSCREEN's KER innovation in technology, customer success stories and its potential impact on healthcare outcomes.

Component Name	In which channels you will promote your product?
ONCO-VOC	- Large EXPOs - Newsletter - Web Ads - Brochures - Local Partner Network - Outsource to consultancy companies
ONCO-CRISPR	- Newsletter - Substack & related email lists - BLOGs - Web Ads - Network - Symposia, Conferences - Consultancy, Lobbying, Social Media
ONCO-NMR	- Network - Social Media - Newsletters (via ONCOSCREEN channel) - Conferences
ONCO-CTC	- Newsletter - Dedicated webpages - Brochures - Networks - Mailing lists - Conferences and trade fairs (e.g. MEDICA) - Outsource to consultancy companies - Consulting
ONCO-AICO	- Local Partner Network - Social Media (X, LinkedIn) - Mailing Lists - Newsletters (via ONCOSCREEN channel)
ONCO-AITI	- Social Media - Newsletter - Local Partner Network - Outsource to consultancy companies - Public Relations
ONCO-RISTE	- Local Partner Network

	- Existing Client Networ
ONCO-CAWA	- Social Media (LinkedIn, Facebook, X) - Large EXPOs - Mail marketing - Newsletter - Blogging - Local Partner Network - Public Relations
ONCO-CLIDE	- Social Media (LinkedIn, Twitter, Facebook, Instagram, YouTube) - Mail marketing - Newsletter - Blogging - Brochures - Local Partner Network - Public Relations
ONCO-EVIDA	- Social Media (X, LinkedIn) - Large EXPOs - Web Ads - Blogging - Brochures - Local Partner Network - Public Relations
ONCO-BIOBA	- Social Media - Newsletter - Local Partner Network - Outsource to consultancy companies - Public Relations

12.1 Related Events & International EXPOs

Event Name	Short Description	Website	Average Number of Visitors

TERMIS	ADVANCING TISSUE ENGINEERING & REGENERATIVE MEDICINE WORLDWIDE TO GENERATE KNOWLEDGE WITH A VIEW TO IMPROVING PATIENT OUTCOMES GLOBALLY *Our international community strives to achieve our mission through* • Best practice in governance • Providing forums for dissemination of knowledge • Interacting with diversified expertise, topics & culture • Advancing basic, translational & clinical research • Supporting our "Student and Young Investigator Sections" (SYIS) • Advocating for public policies	https://termis.org/	More than 1000
ESB	The European Society for Biomaterials is a non-profit organization at the forefront of the scientific community determined to tackle unmet clinical needs	https://esbiomaterials.eu/	More than 1000
MEDICA	MEDICA in Düsseldorf is one of the largest medical B2B trade fairs in the world. A wide range of innovative products and services from the fields of medical imaging, laboratory technology, diagnostics, health IT, mobile health as well as physiotherapy/orthopaedic technology and medical consumables are presented here. The extensive programme of first-class forums, conferences and special shows provides opportunities for interesting presentations and discussions with experts and politicians and also includes pitches of new products and award ceremonies.	https://www.medica-tradefair.com/	>5,300 exhibitors from almost 70 countries and 83,000 visitors annually
HIMSS Conference	HIMSS hosts several conferences and events globally, focusing on healthcare information technology, digital health, and innovation. These events offer opportunities to showcase CDSS solutions, network with industry leaders, and stay updated on trends and developments in healthcare IT.	https://www.himss.org/	Varies depending on the event

European Society of Radiology (ESR) Congress	ESR Congress is one of the largest radiology conferences in Europe, attracting radiologists, imaging specialists, and healthcare professionals. It provides a platform for presenting research, innovations, and technologies in medical imaging and diagnostics, including those related to cancer detection and diagnosis.	https://www.myesr.org/congress/	>20,000 visitors
Healthcare Innovation Expo (UK)	Organized by the National Health Service (NHS) in the United Kingdom, the Healthcare Innovation Expo showcases innovative healthcare solutions, technologies, and best practices. It brings together healthcare professionals, policymakers, and industry leaders to explore opportunities for collaboration and improvement in healthcare delivery.	https://www.england.nhs.uk/expo/	Thousands
American Society of Clinical Oncology (ASCO) Annual Meeting	Prominent event in oncology, featuring presentations on cancer treatment and research.	https://conferences.asco.org	>40,000 visitors
Arab Health	A major healthcare exhibition and congress is held annually in Dubai, United Arab Emirates. It attracts healthcare professionals, manufacturers, distributors, and innovators worldwide, offering opportunities for collaboration, market expansion, and knowledge exchange.	https://www.arabhealthonline.com/	>100,000 visitors
ASCO Annual Meeting	A key event for oncology professionals to discuss cancer care advancements. ASCO Meetings	https://conferences.asco.org/am/attend	Thousands
American Medical Informatics Associatio	Focuses on technology innovations in healthcare. AMIA 2024	https://amia.org/education-events/amia-2024-annual-symposium	Thousands

n (AMIA) Clinical Informatics Conference			
Healthcare Innovation Congress (thINc360)	Covers topics like health equity and care delivery innovations. thINc360	https://thinc360.com/2024event/	Thousands
Digital Healthcare Innovation Summit (DHIS) East Coast	Focuses on revolutionizing healthcare through digital innovations. DHIS	https://dhis.net/east	Thousands
ViVE 2024	- Combines health IT innovations with business transformation in healthcare. ViVE	https://www.lacclink.com/events/detail/vive-2024/	Thousands
American Association for Cancer Research (AACR) Annual Meeting	Highlights the latest discoveries in cancer research. AACR Meetings	https://www.aacr.org/meeting/aacr-annual-meeting-2024/	Thousands
Health 2.0 Conference	Features cutting-edge innovations in healthcare technology. Health 2.0	https://www.health2conf.com/	Thousands
MGMA Annual Conference	Focuses on medical practice management and executive leadership. MGMA	https://www.mgma.com/conferences	Thousands

Oncology Nursing Society (ONS) Congress	Provides updates on oncology nursing. ONS Congress	https://www.ons.org/develop-your-career/professional-development/conferences	Thousands
Best of ASCO® Memphis	Shares highlights from the ASCO Annual Meeting with a regional audience. Best of ASCO	https://www.totalhealthoncology.com/asco-memphis	Thousands
ASCO Direct™ Washington, DC	A direct broadcast of the latest science from the ASCO Annual Meeting. ASCO Direct DC	https://www.totalhealthoncology.com/ascodirectwashingtondc	Thousands
Rise National 2024	Focuses on Medicare, Medicaid and policy innovation in healthcare. Rise National	https://national.risehealth.org/	Thousands
Becker's Hospital Review Annual Meeting	Discusses critical issues affecting hospital management and patient care. Becker's Hospital Review	https://conferences.beckershospitalreview.com/beckers-annual-meeting-2024	Thousands
Fierce Trial Master File Summit	Focuses on the latest best practices for clinical trial management. TMF Summit	https://www.eutmfsummit.com/	Thousands
Community Oncology Conference	Focuses on the practice and economics of oncology care. Community Oncology Conference	https://coaconference.com/	Thousands
European Society of Medical Oncology (ESMO) Congress	Europe's leading medical oncology conference. ESMO Congress	https://www.esmo.org/meeting-calendar/esmo-congress-2024	Thousands

DiCE CRC Screening Summit	Annual virtual event in November on CRC screening hosted by Digestive Cancers Europe (DiCE)	https://digestivecancers.eu/events/4th-dice-crc-screening-summit/	Unknown; ~20 speakers & panellists
European Public Health Conference	Annual physical event in November on public health issues in Europe	https://ephconference.eu/	~2300
DMEA	Digital health in Europe, for industry professionals.	https://www.dmea.de/en/	>15K
Intelligent Health AI	AI medicine summit	https://intelligenthealth.ai/	200K community members
Health.tech conference	Annual conference, powered by Bits & Pretzels, in Munich, Germany	https://www.health.tech/	>3K

13 Timeline of the exploitation plan

13.1 Actions During the Project

The consortium has already established a legal framework in the Consortium Agreement of the project in order to provide clear regulations for issues within the consortium related to the work, IP-Ownership, Access Rights to Background. During the project beyond the value proposition determination and the market and business innovation study, a dedicated IPR management procedure is developed via a live IP registry where the Foreground and ongoing activities is reported and updated every 6 months considering the Open Science and FAIR principles. Towards the end of the project a dedicated plan for the after-project period will include IP Assessment, IP Legal Risk Management, IP Exploitation and finally IP enforcement.

Following the plan described in D7.2, EXUS who leads T7.5 hold a workshop during the 1st plenary meeting on February 2024, in Paris as mentioned also in Section 3.1 During this workshop partners were informed about the business tools and guided them on the completion of the SWOT, PESTLE and, Canvas templates based on the project wide example described in Section 2. Partners were also updated about the status of the IPR registry with more details concerning competitive products and existing patents and were informed about the Horizon Results Booster platform.

Based on this workshop and the information collected by relevant partners, this deliverable D7.4 (first version) was prepared including analysis and completed tools for each KER. Updated information is planned to be collected in the D7.7, the final version planning to include a detailed market analysis, and updated SWOT and PESTLE analysis for each KER along with an update on implemented business strategies.

Based on D7.4/D7.7, the consortium will deliver a two-version business model which will be presented in as a first step towards marketisation of project results. This plan will describe a roadmap of necessary activities for commercializing the ONCOSCREEN solution and to become “market ready” in a midterm horizon. Finally, a business plan addressing the 2 to 5-year period beyond project closure will be implemented, covering the long-term vision of the project.

The business plan will describe concrete measures of how follow up funding will bring the developed solutions to higher TRLs, before proceeding with the definition of plans for the economic exploitation of results, either via a joint-venture vehicle or for each partner individually.

13.2 Actions Post Project

1-6 months after the project, we intend to implement: a) continuous networking with Cancer patient organisations & Cancer Experts’ Societies b) a potential sign of MoUs with non-participating Regional/National Authorities for adopting the developed diagnostic tools and risk-

based screening methodology is foreseen. c) Continuous Legal search from technical partners for Active Patents and patent applications in EU within the domain of their interest.

6-18 months after, policy makers promote the adoption of out screening and early detection strategies in other countries and in associated regions, while health owners promote the adoption of replicable measures in regard to risk factor reduction for environmental related parameters. Technical partners work on minimising threats and weaknesses (derived from SWOT), risks/barriers/limitations (derived from individual exploitation plans) or other negative factors (derived from PESTL).

Finally, 24-48 months beyond project end, the market analysis performed during project will be considered for the developed tools. Then, additional necessary funding opportunities (National & EU funding frameworks, VCs, bank loans, etc) towards TRL increase and thus commercialization will be considered. Utilization of all available EU tools to find potential investors for the uptake of modules and tools. Patent mapping and potential application of patents of the modules that exhibit the most promising results.

14 Exploitation Highlights

The early application of the exploitation and IPR management plan, the strong emphasis in exploitation activities from the exploitation manager (EXUS) and the strong commitment of involved parties resulted in some success stories and promising outcomes at a rather early stage of the project, that are summarised below:

1. UzL has filed a patent application for Germany entitled 'NMR-MESSUNG VON GLYKOPROTEINEN' with particular application to cancer to the German patent office on April 19th and it has been already approved by the German patent office (See Annex C).
2. UzL has initiated the process for an International PCT[7] patent
3. UMINHO has initiated the process is preparing a provisional patent application on ONCO-CTC tool. The expected finalisation of this step and thus the expected submission is currently planned for September 2024. The provisional patent, introduces ONCO-CTC, an innovative, non-invasive diagnostic platform that combines microfluidic technology with circulating tumor cell (CTC)-based diagnostics to address the limitations of traditional colorectal cancer (CRC) detection methods. By integrating electrospinning technology into microfluidic devices, it selectively isolates CTCs within nanofiber matrices, significantly enhancing non-invasiveness, accuracy, and sensitivity in CRC diagnostics.
4. CCAssured and UFC have signed an Invention Disclosure Form (See Annex D) as a first step for invention agreement on ONCO-CRISPR and methylation detection
5. CCAssured and UFC are in preparatory actions and analysis for filling jointly a patent in the coming months
6. CCAssured and UMINHO are in discussions for the preparation and sign up of an MoU agreement for boosting the synergies between different technologies, i.e. CRISPR and Microfluidics
7. IPO and CCAssured are in discussions for the preparation and sign up of an MoU agreement for hCRISPR mRNA biomarker discovery
8. As a side activity, the preliminary development of a low-cost fluorescent microscope is currently being tested by CCAssured enabling the detection of hCRISPR biomarkers in CRC related tissue coupes for educational purposes, which could lead to another patent filing and will be examined over the next period of the project.
9. ONOCO-CAWA utilises as a basis the commercial product of Healthentia mobile application, extending it for the case of CRC with new capabilities as provided in the requirements. In this manner ONCOCAWA was benefitting from the fact of Healthentia being a CE-marked medical device. Currently it is a self-certified Class I medical device based on the Medical Devices Directive (MDD). Class I medical devices are low risk ones, non-invasive, mainly for measurement. iSPRINT has made significant efforts for the certification process of the of Healthentia (that however share same infrastructure with

[7] https://www.wipo.int/pct/en/

the ONCOCAWA) for a Class IIa medical device based on the Medical Device Regulation (MDR). Class IIa medical devices are medium risk ones, more invasive than Class I, used for diagnostic or therapeutic purposes. Due to this parallelisation of activities between the commercial product and the ONCOCAWA prototype, ONCOCAWA is expected that will speed up its commercial roadmap.

10. VITO along with University of Antwerp are in collaboration in terms of scientific exploitation, in particular for the ONCO-EVIDA tool that will result in a PhD-degree for a student from University of Antwerp in the frame of the ONCOSCREEN Project.

All the above consist a very strong exploitation basis for the project even at an early stage and efforts for bilateral agreements will be further intensified towards a strong impact in terms of exploitable results of ONCOSCREEN.

15 Next Steps

In the next period, the consortium will focus on monitoring and updating the current information for the KER presented in this deliverable. As the project evolves in case that any new KER is derived, the list of KER will be updated along with the subsequent chapters. As soon as the tools increase their maturity and the end user have a clear view, a 'Willingness to buy' questionnaire will be designed and disseminated to end users and responses will be recorded, analysed and presented in the second iteration of this deliverable in 'D7.7 ONCOSCREEN Exploitation and IPR Management (Final version)'. Furthermore, a more thorough market analysis will be conducted per different KER to analyse the specific market segment and niche market opportunity. In addition, since the consortium possess a strong family of patents in order to protect its IP, a thorough Patent Market Surveillance will be conducted to ensure an IP differentiation, avoiding related IP risk and contribute to securing the patent application acceptance. In the second iteration (D7.7) it is also planned to have individual exploitation plans for all consortium partners and a post-project exploitation plan for each KER with concrete steps and potential sources of funding towards reaching TRL9.

It is noted that during the 2nd Annual Meeting of the 'Prevention & Early Detection (Screening)' cluster that took place on 14.06.2024 in Greece, with ONCOSCREEN being the host, it was discussed on whether we should seek for support from 'Horizon Results Booster'. EXUS as the Exploitation Manager (and ONCOSCREEN project coordinator) had already in its plans to seek support from Horizon Results Booster at the Project Level, contacted them and received the response that the service 'Go 2 Market – Innovation Management' can be delivered to a Project Group/Cluster of projects in the form of workshops. However, the service 'Business Plan Development' or a follow-up support service can be delivered to individual projects, as it is not feasible to deliver it to a Project Group/Cluster. Another decision that needs to be made among the cluster of projects is the fact the current Horizon Results Booster initiative is about to end on November 7th 2024, while the new one will be launched in September and thus it should be decided when we will seek support. By sure, ONCOSCREEN, will seek for support from the Horizon Result Booster to support individual solutions especially for the diagnostics, where business planning is more challenging than software solutions to complement existing exploitation activities. Any updates will be reported in the D7.7.

16 Conclusions

ONCOSCREEN has followed a front-heavy approach in regards to exploitation methodology, providing a thorough analysis of the different aspects needed for a successful commercial roadmap. Various market and business analysis tools were used such as SWOT and PESTLE along with business model canvas, allowing to evaluate systematically various aspects for each KER early in the project and help plan for the next steps in the following period of the project. The analysis clearly demonstrates that there is a high potential on the proposed solutions due to their competitive advantages with emphasis on the cost-reduction, addressing the immediate need for non-invasive testing procedures towards new CRC strategies. The systematic analysis performed at this early stage of the project indicates the interest on the identified KERs as individual components or as group of solutions to which more than one partner is contributing. A series of exploitation highlights have been already reported, providing a strong indication for an even more successful exploitation activities over the next period. As soon as the ONCOSCREEN solutions become more mature and upgrade their TRL levels, any potential updates will be included in the second iteration along with a more thorough analysis in regards to market, patents, end users willingness to buy. Based on the progression of WP6 as well individual exploitation plans will be documented for all partners in regards to the adoption of policy, handbook and guideline suggestion. The consortium will seek for further support from Horizon Result Booster to complement the training on exploitation (see Annex) as another measure to contribute to the credibility of the exploitation pathways of ONCOSCREEN project. All the above updates will inform and guide the final report on exploitation, D7.7 (M48).

Annex A: Exploitation Workshop

Contents

- Innovation Management
- Exploitation Strategy
- IP Strategy in EU Projects
- Exploitations Tools
  - SWOT-PESTEL
  - Business Model & Value Proposition Canvas
- Exploitation Timeline

2

Innovation Management - Definitions

- Innovation is about introducing something new or performing something in a new way.
  - The goal of innovation is to take an idea from concept to realization and solve an existing problem or satisfy a specific need
  - Innovation begins with an idea that is transformed into a concept that includes some new combination of what is already known and can be implemented to serve a purpose
- Innovation Management is a process which requires an understanding of both market and the technical problems of the project, with a goal of successfully implementing appropriate creative ideas.
  - It is important because it is the only way to make steps towards more markets and thus socioeconomic impact

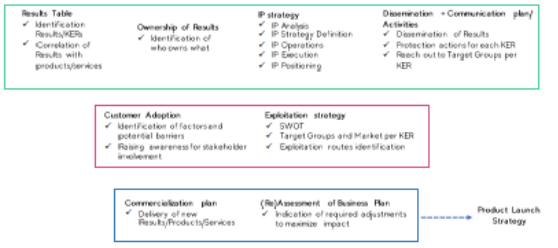
3

Innovation Management - Duties

- Monitor and collect market needs and customer requirements
- Observe additional added-value which may be created during the project implementation
- Identify any mismatch between the project values and market/customer needs.
- Bring necessary attentions to the consortium for decisions so as to respond to an external or internal opportunity.
- Implement the decisions into exploitation activities to seize the opportunity.
- Patent search

4

Innovation Management – Implementation



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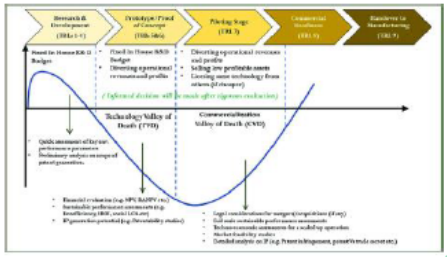
Innovation Management – Valley of Death



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Innovation Management – Questions to Answer...

1. Do you have a clear problem that your technology solves for?
2. Does your technology add extra value or reduce cost for your customers?
3. Do you know application areas of your technology/solution? (market segments)
4. Have you done any market research on the application areas?
5. Have you established a network in your application areas?
6. How many products or services you can make from your technology?
7. What is the size of your target market?
8. Do you know the key players in the market
9. Do you know any legal implications of your technology/solution?
10. Do you think that there is an upcoming policy that will affect your technology negatively?
11. Do you know any incoming rules that will affect your new technology positively?
12. Does your technology need infrastructural changes before being market ready?
13. What is readiness level of your technology?
14. Have you patented or submitted patent application for your technology?
15. Do you need an IP to before you can sell your technology?
16. Do you currently have prototype or solution sample now?
17. Do you know your suppliers?

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Exploitation Strategy - Definitions

Exploitation:

The use of results in further research and innovation activities, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardization and policy making activities

- Recognize exploitable results and their stakeholders; identify the value added from their use
- Partners can exploit their results or let them being exploited by interested third parties

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Exploitation - Definitions

Results:

Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights...

Key results are the outputs generated during the project which can be used and create impact, either by the project partners or by other stakeholders

Project results can be reusable and exploitable (eg inventions, prototypes, services) as such, or elements (knowledge, technology, processes, networks) that have potential to contribute for further work on research or innovation

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Stakeholders – Results - Impact

Stakeholders	Results	Impact
Industry	Patenting, prototypes, Transfer agreements, Joint venture/Start-ups, New products and services	Generate economic growth, Improvements of production processes and competitiveness, Improve product quality and consumer protection
Research community	Publications (Papers, Books), Data, Software	Further research activities and publications containing new insightful results, Knowledge transfer
Citizens	New products, services or technology Trainings, Educational materials Skills and knowledge	Increase quality of life, Improve living environment, Improve urban and rural services, Improve employability
Policy makers	Reports, Policy papers and recommendations, Roadmaps, Operational guidance	Revision or creation of a new directive or regulation (EU Law)

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Exploitation - Definitions

Dissemination VS Exploitation

Describe and make results visible to audiences that may use the results That may enable their use and uptake

Actual use of the results for scientific, societal, economic purposes or for policymaking

All results generated during the project lifetime but also after its end

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Exploitation Strategy

- Identification of Key Exploitable Results (KERs)
- Patents/Publications/Whitepapers
- IP Rights (IPR)
- Market Analysis
  - Demographics & Segmentation
  - Target Market - Market need
  - Competition
  - Barriers to entry
  - Regulation
- Business schemes
  - Spin-off
  - Joint ventures
- Funding opportunities
  - EC funding instruments
  - Private funding

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Exploitation - Tools

- IP Strategy, IPR registry
- SWOT/PESTEL
- Business canvas
- Value proposition

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IP Strategy in Horizon Europe (6 pillars)

IP used	IP created	IP assessed	IP protected	IP disseminated and exploited	IP post project managed
IP needed to implement the project. Involves the background knowledge of every partner as stated in the CA	The generation of results and new knowledge. The challenge is to capture, agree on ownership, who will manage and how	Are the results generated to be commercialized ? If yes, analysis of market landscape, patent freedom, strategies for protection should be defined	Methods and routes to protect potential commercial results (patents, CR, databases rights, design rights, etc)	After the definition of IP rights and protection methods target groups can be reached and exploitation can start	Maintain protection of results, manage agreements and costs, share revenue for joint collaborations

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IP strategy in EU projects - Rules

- Results from collaborative projects are often built on the combined knowledge of several partners
- so are jointly created and jointly owned; therefore, it is important for the partners to agree on appropriate and shared strategies for their management, protection, and exploitation.
- Management of all of these intellectual assets is crucial.
- Consider the strategic value of protecting these results in order to support its commercial exploitation
- Knowing and matching expectations among consortium partners is a pre-requisite for developing the trust and credibility necessary for the exploitation of collaborative project results

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IP strategy in EU projects - Obligations

- Obligation to protect: Each beneficiary must examine the possibility of protecting its results and must adequately protect them, for an appropriate period and with appropriate territorial coverage
- Obligation to disseminate: Horizon follows the "Open Science" approach that focuses on spreading knowledge as soon as it is available using digital and collaborative technology. The as open as possible and as closed as necessary principle may be applied
- Obligation to exploit : Partners should be fully aware that they must, up to four years after project completion, take measures aiming to ensure exploitation of its results (either directly or indirectly, in particular, through transfer or licensing)
- Joint Ownership Agreement for partners that co-develop a result
- Within the CA (the agreement between the partners) project partners need to create a list of background IP

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IP strategy in EU projects - Phases

Start of the Project	During Project Implementation	After Project End
• Define existing IP that is brought into the R&I cooperation • Take a look at the patent landscape and/or other relevant IP rights • Look at opportunities and risks of sharing knowledge with consortium partners • Check whether default Horizon IP rules or other relevant default rules are suitable	• Consider existing and potential knowledge creation and management tools • Discuss possible IP protection methods (e.g. patents, copyright, trade secrets, defensive publications, semiconductor topographies, etc.) and their pros and cons • Identify potential complementary IP protection methods	• Discuss and agree on (joint) exploitation strategies on d pathways • Look at possible IP ownership arrangements and related responsibilities including the definition of relative contributions of joint-owners • Weigh potential (licensing) agreement and resulting obligations linked to the use of IP resulting from the project and options for renumeration

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IP Rights

- Patents (technical inventions)
- Copyright (software, written words, engineering drawings)
- Design rights (appearance)
- Database rights (creation and arrangement of data)
- Trade marks
- Plant breeders rights
- Utility models

Decision on how to commercialize a specific result with high innovation potential

Examples:

- Commercializing IP: Assignment or Licensing Agreements
- European/International Trademarks
- Copyrights
- European/International Patent

The choice of the most suitable form of IP depends on the results at stake, but also the business plans for their exploitation and legitimate interests of consortium partners

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IP Rights - Registry

RESULTS TABLE					
RESULTS	Short Description	Relevant Task(s)	Relevant Deliverable (where applicable)	Dissemination level of this Deliverable (where applicable)	Relevant background IP (where applicable)

IPR strategy				
OWNERSHIP DRAFT	EXPLOITATION ROUTE	PRODUCTS	Current TRL	Expected TRL

Shares of IP rights (%)/ Nature of parties involvement in the development					
Partner 1 (%)	NATURE of involvement	Partner 2 (%)	NATURE of involvement	Partner 3 (%)	NATURE of involvement

SWOT analysis for KERs			
Strengths	Weaknesses	Opportunities	Threats

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KERs in ONCOSCREEN

IP Asset	Technology	Owner
ONCO-VOC	CRC Screening based on Volatile Organic Compounds	TECH
ONCO-CRISPR	CRC Screening based on CRISPR Cas9 biomarkers	CCAGSSURED
ONCO-NMR	CRC Screening based on Urinal & Blood NMR Metabolomics	UoL
ONCO-CTC	CRC Screening based on Circulating Tumor Cells	LUMINHO
ONCO-AICO	Real Time AI-Assisted Colonoscopy	ICCS, CERTH
ONCO-AITI	AI-Assisted Tissue Image Analysis	MUG, MUI
ONCO-IRETE	CRC Risk Stratification Engine	EXUS
ONCO-CAWA	CRC Awareness Personalised Mobile Application	ISPRINT
ONCO-CLIDE	Clinical Decisions Support System for CRC Integrated Diagnosis	INONN
ONCO-EVIDA	Evidence-based Decision Analytics dashboard	VITO, ICCS
ONCO-BIOBA	CRC Bio Bank	MUG, MUI
Data Fusion	Data fusion components for identification of tumors	CERTH, EXUS

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IP Rights - Registry

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Exploitation Tools

- SWOT (strengths, weaknesses, opportunities, and threats) analysis is a tool used to evaluate the competitive position and to develop strategic planning.
  - SWOT analysis assesses internal and external factors, as well as current and future potential.
- PESTLE stands for Political, Economic, Social, Technological, Legal and Environmental factors. A PESTLE analysis is a tool used to gain a macro picture of an industry environment.
  - It allows a company to form an impression of the factors that might impact a new business or industry.
  - Some factors will be more important to different types of businesses, and a PESTLE analysis will help identify risk factors for the SWOT analysis.

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Preliminary SWOT

Strengths	Weaknesses
• Less intrusive screening methods compared to colonoscopy • High detection efficiency • Early detection of cancer • Low cost per examination • Supported by large clinical study • Multitier stratification methodology • Intelligent analytics dashboard • Relevant patents and high expertise by keypartners	• Non-commercialised product yet • Not part of existing commercial solution • New screening solutions are difficult to be adopted
Opportunities	**Threats**
• Rapidly growing market towards new screening technologies • Train large number (>2500) of clinicians on the developed technologies • Inform the public via the mobile app about the new screening technologies • >5000 people will get screened during the project • Adoption of the screening technologies by regional/national programs	• Keyplayers are developing alternative solutions • Clinicians are not familiar and not willing to use the screening technologies • National programs are hesitant to use the developed technologies • Medical approval of new screening methods takes time

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Preliminary PESTLE Analysis

Political	Economic	Social/Cultural	Technological	Legal
• Lack of national and EU health authorities to adopt innovative digital health solutions due to negatively biased opinions of the public. • Insufficient infrastructure with lack of supplies and personnel. • Other political priorities due to unforeseen events (e.g Covid19, war). • Knowledge deficits about guidelines and barriers to screening.	• Absence of health insurance or coverage of the costs of screening. • Unavailability of big pharma to invest in CRC screening and detection tools since treatment is more profitable. • Inequalities between countries to use AI/software tools for assistance in detection and diagnosis.	• Lack of awareness for the benefits of CRC screening. • Health care authorities are negatively biased on the use of AI in healthcare. • Patients are unwilling to share their personal bio-data, due to security and/or legal concerns. • Lack of trust between the clinician and the patient/citizen. • Poor knowledge and subsequent dissemination of cancer risk and information. • Language and psychosocial reasons. • Negative/Painful experience from previous CRC screening programs.	• Poor performance of clinicians during the screening activities. • Limited or no knowledge of AI utilization in risk-based stratification. • Another initiative or project developed/set to monitoring solutions for CRC screening with higher accuracy risk prediction.	• Continuous change of legislation. • Legal restriction for the use of the tools. • Developed technologies shall be compliant with GDPR and EU Cookie policy directives.

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Tools & Exploitation

- The Business Model Canvas is a business tool used to visualize all the building blocks when you want to start a business, including customers, route to market, value proposition and finance.
- The Value Proposition Canvas focuses on understanding customers' problems and producing products or services that solve them.

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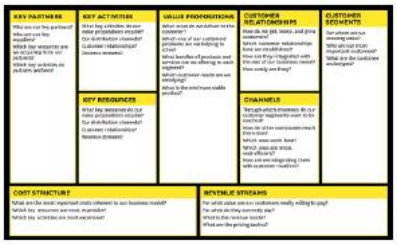
Business Model Canvas



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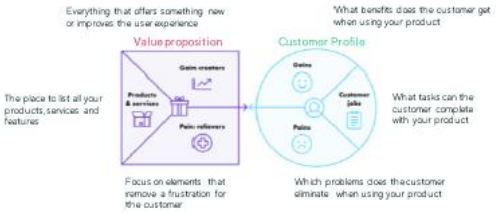
Value Proposition Canvas



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Exploitation Timeline in ONCOSCREEN

- IPR registry
  - Update IPR for D7.4 (due 06/24)
  - Identify and pursue opportunities for JoA, MoU between partners
- SWOT/PESTEL, Market/Patent Search
  - Prepare individual (per KER/tool) for D7.4 (due 06/24)
- Business canvas
- Value proposition
- Utilize the Horizon results Booster

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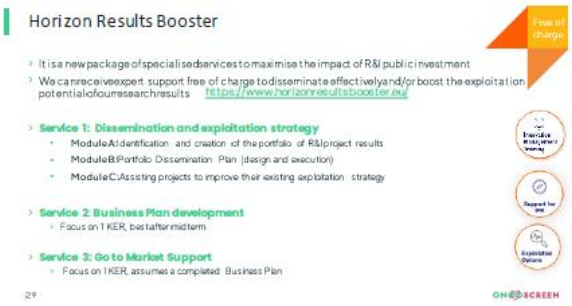
Horizon Results Booster
Free of charge
It is a new package of specialised services to maximise the impact of R&I public investment
We can receive expert support free of charge to disseminate effectively and/or boost the exploitation potential of our research results https://www.horizonresultsbooster.eu/
Service 1: Dissemination and exploitation strategy
Module A: Identification and creation of the portfolio of R&I project results
Module B: Portfolio Dissemination Plan (design and execution)
Module C: Assisting projects to improve their existing exploitation strategy
Service 2: Business Plan development
Focus on 1 KER, best after mid-term
Service 3: Go to Market Support
Focus on 1 KER, assumes a completed Business Plan
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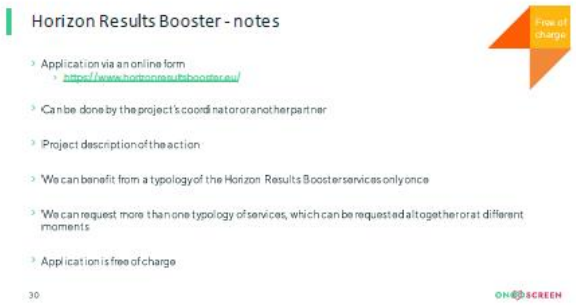
Horizon Results Booster - notes
Free of charge
Application via an online form
https://www.horizonresultsbooster.eu/
Can be done by the project's coordinator or another partner
Project description of the action
We can benefit from a typology of the Horizon Results Booster services only once
We can request more than one typology of services, which can be requested altogether or at different moments
Application is free of charge
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ONCOSCREEN


ONCOSCREEN 1st Plenary Meeting, 01-02.02.2024, Paris – France
Funded by the European Union


ONCOSCREEN

Annex B: IP Registry

As discussed in Section 4, the consortium is monitoring any updates relevant with the IP in a live registry shared with all partners, which is depicted below.

ONCOSCREEN Foreground Results

No.	Key Exploitable Result (KER) Title	Created in (WP)	Copyright/Ownership	Expected License (if applicable)	Published License	License check	Description of the IP item	Location of the item (URL?)	Open Access	Open Access Results	Protection of Results	Joint Ownership Scheme
KER No.	*(name of the component etc.)*	*Which task or WP was the work done*	*Who holds the © or ownership*	*What License do you expect to use?*	*If the work is published (legally "distributed") what license was used?*	*Have you checked that your indented license is compatible with the licenses of pre-existing work?*	*What does it do?*	*URL to repository internal or external (e.g. Github, bitbucket, etc.)*	*Are you going to offer any part of your work as open? E.g. Open Dataset, Open Source codes*	*If answered yes in the previous column please name here the expected open access of results*	*Please refer here to how you are going to protect your results towards commercialization*	*For the cases of joint ownership describe the preferred ownership scheme model*
Numeric Value	e.g. ONCO-RISTE	e.g. WP4	EXUS (40%), ICCS (60%)	CC, BSD3, GPL v3, LGPL v3, Apache v2, Consortium-only, you can google for more licences and select the one that fits your needs	No additional licenses are required. / Same as previous column	Yes/No	Give a one sentence description		Yes/No	e.g. The x service will be offered as open source.	e.g. Submit a Patent in the next 3 years, no protection, keep innovation confidential to allow further development, sui generis right for databases (96/9/EC)	e.g. X partner will receive LL% royalty fees from Y partner, joint venture, public-private partnership etc.
1	ONCO-RISTE	WP4	EXUS (100%)	Consortium-only	No additional licenses are required.	Yes	ONCORISTE solution provides a semi-empirical risk stratification process to automatically identify dependencies and reveal correlations among a variety of features concerning the clustering of citizens/patients	N/A	No	N/A	Trade Secret	N/A

							into their respective risk-Level CRC classification					
2	ONCO-CRISPR	WP3	CCASSURED (lead)	Patent and depending on the partner it can be an exclusive license or shared one, which will become clear during the negotiations if the patent is successfully filed	None yet	Partly	The IP will focus on patent filing to protect our CRISPR-Cas based tools, related modules and its usage in CRC	https://patents.google.com/	No, when patented, only the related scientific paper accompanying the patent will be Open Access	CRISPR-Cas tool performance and related results	Patent	This depends on who or whom is/are doing the discovery and intellectual property contributions added, the guidelines for that are quite strict in the Netherlands, but if one or more partners have come up with the ID for the invention, X partner will receive LL% royalty fees from Y partner, joint venture, public-private partnership depending on its percentage of contribution related to the invention.
3	ONCO-NMR	WP3	UzL (lead)	Consortium only, exclusive or shared license	None yet	N/A	CRC Screening based on Urinal & Blood NMR Metabolomics. Primarily targeting scientific exploitation with a potential for an exclusive license depending on commercial interest	N/A		Results planned to be included in publications	Keep some information confidential for future exploitation	Based on mutual agreements between partners
4	ONCO-CTC	WP3	UMINHO (lead) FIRALIS (supporting for biobanking part)	UMINHO is analysing the process for filling a patent on the basis of ONCO-CTC technologies (generation 1st and 2nd). ONCO-CTC will be used in the consortium.	No additional licenses are required	Ongoing license check.	The patent to be filled will focus on the method and application of a size separation of biological entities (e.g. CTC's and EV's) and possibly non-biological entities	N/A	No	N/A	Patent	N/A
5	ONCO-AICO	WP3	CERTH (lead) ICCS (supporting) KONN (supporting) AINIGMA (supporting)	Apache v2	No additional licenses are required.	N/A	The platform serves as a training tool for junior colonoscopists, offering automated annotations and analysis of colonoscopy videos to enhance their learning and skill development.	TBD	Yes	The expected open access results include providing access to the source code and related	As the onco-aico tool is open-source, commercialization can be pursued through separate	The preferred ownership scheme model will be based on mutual agreements and legal arrangements between the parties involved, taking into

										resources through the repository to be defined.	commercial agreements or licenses, allowing for dual-track availability for both open-source and commercial usage Commercialization may occur if interested stakeholders require additional features to be provided.	account factors such as contributions, responsibilities, and rights to ensure fair and equitable distribution of ownership.
6	ONCO-AITI	WP3	MUG (lead)	Lesser General Public License v3.0 (GPLv3)	No licence yet	N/A	A training tool based on an AI algorithm for young pathologists during the observation of WSIs and in some kind a decision support system.	N/A	Yes	the usage of the tool should be offered as open access	not yet determined	N/A
7	ONCO-EVIDA	WP3	VITO (lead) ICCS (supporting) CERTH (supporting) CTL (supporting) KONN (supporting)	Consortium only or exclusive licence depending if commercial interest is identified	No licence yet	N/A	Evidence-based Decision Analytics dashboard	N/A	No	Results planned to be included in publications	Keep some information confidential for future exploitation	Based on mutual agreements between partners
8	ONCO-CLIDE	WP4	KT(Lead)	BSD3, GPL v3, Apache v2 depending on the tools that will be used further licenses maybe will be provided	No additional licenses are required. / Same as previous column	Yes	TBD	TBD, when the tool is ready (M29)	Yes.	Instances of the tool will be provided	Copyright-upon creation	TBD
9	ONCO-BIOBA	WP3	MUG (lead)	Lesser General Public License v3.0 (GPLv3)	not yet	Yes	catalogue of bio data banks	N/A	Yes	it should be possible to search in the catalogue for datasets	not yet determined	N/A

10	ONCO-VOC	WP3	TECHNION (lead) ICSS (supporting) BEIA (supporting) FIRALIS (supporting)	Consortium-only for now. Later, Patent and depending on the partner it can be an exclusive license or shared one, which will become clear during the negotiations if the patent is successfully filed	None yet	Yes	Cancer detection from exhaled breath samples.	TBD by ICCS	No, only the related scientific paper accompanying the patent will be Open Access	N/A	Patent	N/A
11	ONCO-CAWA	WP4	ISPRINT (lead) EXUS (supporting) TECHNION (supporting) BEIA (supporting)	N/A	N/A	N/A	Collect data from subjects and display data to them.	Installed on phones of subjects	No	N/A	Keep innovation confidential to allow further development	N/A
12	Data Fusion	WP4	CERTH (analytics) EXUS (connection / architecture) TLBG (privacy part) ICCS (supporting) SERVTECH (supporting) CTL (supporting)	Apache v2	No additional licenses are required.	N/A	The data fusion tool integrates diverse data sources to uncover insights and relationships related to non-communicable diseases.	TBD	Yes	The expected open access results include providing access to the source code and related resources through the repository to be defined.	As the data fusion tool is open-source, commercialization can be pursued through separate commercial agreements or licenses, allowing for dual-track availability for both open-source and commercial usage.	The preferred ownership scheme model will be based on mutual agreements and legal arrangements between the parties involved, taking into account factors such as contributions, responsibilities, and rights to ensure fair and equitable distribution of ownership.
13	FIT thresholds optimisation	WP5	IPO (lead)	N/A	N/A	N/A	Only statistical analysis will be performed using data from FIT test from the patients enrolled in clinical studies in order to evaluated if better cut-offs could be used to discriminate the high-risk groups.	N/A	TBD	TBD	N/A	N/A

ONCOSCREEN Background

No	Technical Partner Name	Related ONCOSCREEN Solution	Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
1	EXUS	ONCORISTE	Part of the solution ONCOSCREEN CRC Risk Stratification Engine (ONCO-RISTE is based on the developments of the ONCORELIEF project that will be further enhanced and extended to the needs of the ONCOSCREEN project.	The access to background will be provided from EXUS to the consortium on a royalty-free basis for the necessary developments of the ONCOSCREEN project only.	Access to the background of EXUS for the exploitation of results is limited for the other partners. In case of a request, a consent form shall be signed beforehand for the provision of the background under fair and reasonable condition according to Art. 16.4/GA. Specific details will be examined on a case-by-case approach.
		Data Fusion	Part of the algorithms and system infrastructure of "Multisource Data Fusion" task is based on the EXAITE (EXUS AI Suite) referred to Part A, that will be further enhanced for the needs of the ONCOSCREEN project.		
2	UMC-Mainz	N/A	No data, know-how or information of UMC-Mainz is Needed by another Party for implementation of the Project	N/A	N/A
3	CERTH	ONCO-AICO	No data, know-how or information of ICCS is Needed by another Party for implementation of the Project	None	None
4	FIRALIS	Biomarker Development	Expertise and know-how in biomarker development, as well as in clinical study management and monitoring from Firalis.	Expertise and know-how in biomarker development, as well as in clinical study management and monitoring from Firalis, which are directly involved in carrying out the Project and necessary for the development of the Project, will be made available for the duration of the Project itself.	In case a Party/ies wishes to use the listed Background for another project, or beyond the duration of the Project, its use will be subject to specific agreements between Firalis and the Party/ies.
5	UKSH	ONCO-NMR	No data, know-how or information of UKSH is Needed by another Party for implementation of the Project	N/A	N/A
6	LSMU	N/A	No data, know-how or information of LSMU is Needed by another Party for implementation of the Project	N/A	N/A

7	MUG	ONCO-AITI	SAAT-Semi-automated annotation tool: The SAAT toolset is a system to extract structured information out of unstructured pathologic diagnosis data. It uses a ruleset-based algorithm and regular expressions to structure the data.	Software code is still closed source; license model has to be negotiated.	Software code is still closed source; license model has to be negotiated.
			Visualization glyphs for patient timelines: It is a visual language designed to give a quick overview of timelines. Users can get an impression of a patient's history without reading the diagnosis text of each event in the timeline.	Graphical elements (icons) available under the GNU General Public License (GNU GPL) Commercial use to be negotiated	Graphical elements (icons) available under the GNU General Public License (GNU GPL) Commercial use to be negotiated
			Multilevel data glyphs: It is a visualization system to dive into structured data from a scale of millions of data points down to individual events, including clustering, searching, and filtering the data.	https://doi.org/10.1186/1471-2105-15-S6-S5 the software code is still closed source; the principle is available under the GNU General Public License (GNU GPL)	https://doi.org/10.1186/1471-2105-15-S6-S5 the software code is still closed source; the principle is available under the GNU General Public License (GNU GPL)
			BIBBOX framework and APP store: BIBBOX is a modular, component-based toolkit for biobanks and bioinformatics. BIBBOX provides an app store for software solutions, mainly in the fields biobanking and bioinformatics.	Published as open source Details see https://github.com/bibbox	Published as open source Details see https://github.com/bibbox
8	IPO	FIT threshold optimization	No data, know-how or information of IPO is Needed by another Party for implementation of the Project	N/A	N/A
9	IOB	N/A	No data, know-how or information of IOB is Needed by another Party for implementation of the Project	N/A	N/A
10	TECHNION	ONCO-VOC	No data, know-how or information of TECHNION is Needed by another Party for implementation of the Project	N/A	N/A
11	UMINHO	ONCO-CTC	No data, know-how or information of UMINHO is needed by another Party for implementation of the Project	N/A	N/A

12	TLBG	N/A	No data, know-how or information of TLBG is Needed by another Party for implementation of the Project	N/A	N/A
13	VITO	ONCO-EVIDA	No data, know-how or information of VITO is Needed by another Party for implementation of the Project	N/A	N/A
14	CERTH	ONCO-EVIDA	Visual Analytics (VA)-based, decision support technologies for policy makers, as it has been developed in the WELCOME project.	Access Rights to CERTH's Background is only granted to the extent that is needed for the implementation of the action, being agreed that no Access Rights to source code will be granted by CERTH. CERTH may freely use them in the Project or in any other collaborative R&D project. All Background IP rights included is subject to the terms described in this Consortium Agreement and cannot be used for commercial purposes or any other economic purposes without the prior authorization of CERTH.	No provision of source code. Access by other beneficiaries to background needed to exploit their own tasks under the action will be given under fair and reasonable conditions in the framework of a bilateral license agreement. Excludes all background and confidential information which is the subject of other contractual agreements with third parties which restrict access to said information
		ONCO-BIOBA	Scoring algorithms for user evaluation.		
		Data Fusion	Algorithms for information fusion and data aggregation using, among others, ontology patterns and rules.		
		Data Fusion	Other background generated by the Centre for Research and Technology Hellas (CERTH).	Centre for Research and Technology Hellas (CERTH) hereby informs that the following information is excluded: (i) All Background developed by Centre for Research and Technology Hellas (CERTH) personnel not participating in the ONCOSCREEN Project; (ii) All Background developed by Centre for Research and Technology Hellas (CERTH) researchers participating in the ONCOSCREEN Project which is outside the scope of the tasks allocated to Centre for Research and Technology Hellas (CERTH) under the ONCOSCREEN Project. (iii) All Background, which Centre for Research and Technology Hellas (CERTH), due to existing or pending third party rights, is unable to grant Access Rights to	Centre for Research and Technology Hellas (CERTH) hereby informs that the following information is excluded: (i) All Background developed by Centre for Research and Technology Hellas (CERTH) personnel not participating in the ONCOSCREEN Project; (ii) All Background developed by Centre for Research and Technology Hellas (CERTH) researchers participating in the ONCOSCREEN Project which is outside the scope of the tasks allocated to Centre for Research and Technology Hellas (CERTH) under the ONCOSCREEN Project. (iii) All Background, which Centre for Research and Technology Hellas (CERTH), due to existing or pending third party rights, is unable to grant Access Rights to
15	iSPRINT	ONCO-CAWA	Healthentia is an eClinical platform that is used for capturing and processing of RWD.	The described background will be made accessible to project partners for the purpose of the project as defined in the workplan	Prior to exploitation involving any of the stated background, explicit consent must be obtained from INNOVATION SPRINT SPRL in the form of a written agreement.

16	SERVTECH	ONCOSCREEN DATA LAKE	Medical Digital Twin environment for cancer and CVD patients. This environment represents patient, disease symptoms and cure procedures and can be used for querying and simple analytics purposes	Prior to any exploitation /commercial use of this environment explicit consent must be affirmed in a clear formal written statement.	Prior to any exploitation/commercial use of this environment explicit consent must be affirmed in a clear formal written statement.
17	AINIGMA	ONCO-CLIDE	No data, know-how or information of AINIGMA is Needed by another Party for implementation of the Project	N/A	N/A
18	CATALINK	Data Fusion	No data, know-how or information of CATALINK is Needed by another Party for implementation of the Project	N/A	N/A
19	KONN	ONCO-CLIDE	No data, know-how or information of KONN is Needed by another Party for implementation of the Project	cDSS strongly depends on the incoming data in order to provide the required outcome. The code will be stored into a KT's repository (gitlab). Instances maybe provided after request.	TBD
20	BEIA	ONCO-CAWA	No data, know-how or information of BEIA is Needed by another Party for implementation of the Project	N/A	N/A
21	URIOHA	N/A	No data, know-how or information of URIOHA is Needed by another Party for implementation of the Project	N/A	N/A
22	TIMELEX	N/A	No data, know-how or information of TIMELEX is Needed by another Party for implementation of the Project	N/A	N/A
23	CARR	N/A		N/A	N/A

			No data, know-how or information of CARR is Needed by another Party for implementation of the Project		
24	MoH-GR	N/A	No data, know-how or information of MoH-GR ICCS is Needed by another Party for implementation of the Project	N/A	N/A
25	POLA	N/A	No data, know-how or information of POLA is Needed by another Party for implementation of the Project	N/A	N/A
26	ECPT	N/A	No data, know-how or information of ECPT is Needed by another Party for implementation of the Project	N/A	N/A
27	HSGO	N/A	No data, know-how or information of HSGO is Needed by another Party for implementation of the Project	N/A	N/A
28	ESDO	N/A	No data, know-how or information of ESDO is Needed by another Party for implementation of the Project	N/A	N/A
29	YCE	N/A	No data, know-how or information of YCE is Needed by another Party for implementation of the Project	N/A	N/A
30	MUI	N/A	Colorectal cancers are a very heterogeneous group of cancers and not all of them respond to the same drugs in the same way. By collecting	Sensitive data have to be requested from access committee of ONCOTRACK	Sensitive data have to be requested from access committee of ONCOTRACK

			tumour samples from patients and then analysing them in the laboratory, the OncoTrack project found molecular fingerprints of those tumours and then correlated them to how these tumours respond to various drugs. The project's outputs are already helping doctors in choosing the right treatment for the right patient, and could also help in the future search for more effective drugs. As a result of the project, two spin out companies have been created and several patents filed, demonstrating tangible socio-economic benefits.		
31	MoH-LT	N/A	No data, know-how or information of MoH-LT is Needed by another Party for implementation of the Project	N/A	N/A
32	EY	N/A	No data, know-how or information of EY is Needed by another Party for implementation of the Project	N/A	N/A
33	CSIC	N/A	No data, know-how or information of CSIC is Needed by another Party for implementation of the Project	N/A	N/A
34	UFC	N/A	No data, know-how or information of UFC is Needed by another Party for implementation of the Project	N/A	N/A
35	ROSENBAUM	N/A	No data, know-how or information of ROSENBAUM is Needed by another Party for implementation of the Project	N/A	N/A
36	AXA	N/A	No data, know-how or information of AXA is Needed by another Party for implementation of the Project	N/A	N/A

37	GERCOR	N/A	No data, know-how or information of GERCOR is Needed by another Party for implementation of the Project	N/A	N/A
38	CCRL	ONCO-CRISPR	No data, know-how or information of CCRL is Needed by another Party for implementation of the Project	N/A	N/A
38	CCSV	ONCO-CRISPR	No data, know-how or information of CCSV is Needed by another Party for implementation of the Project	N/A	N/A

Annex C: UzL Patent in Germany

Deutsches
Patent- und Markenamt

Empfangsbescheinigung

Hiermit wird bestätigt, dass ihr im folgenden bezeichneter Antrag auf Erteilung einer PCT-Anmeldung beim DPMA eingegangen ist. Anmeldenummer und Tag des Eingangs wurden automatisiert vergeben.

Eingangsnummer	2024041913455400DE
Anmeldenummer	PCT/DE2024/100346
Tag des Eingangs	19.04.2024
Anmeldeamt:	RO/DE
Ihr Zeichen	UzL22053WO
Anmelder	Universität zu Lübeck
Anzahl der Anmelder	1
Titel	NMR-MESSUNG VON GLYKOPROTEINEN
Eingereichte Dokumente	request.XML SPECPDF.pdf DRAW.pdf application-body.xml pct101.pdf fee-sheet.XML fees.pdf package-data.XML pkgheader.xml application-body.pdf
Eingereicht von	C=DE, CN=Sven Heeschen, GIVENNAME=Sven, SURNAME=Heeschen, SERIALNUMBER=DTR220079591P0001
Tag und Zeit der Erstellung dieser Bescheinigung	19.04.2024 13:45:54
Komprimat	8A0F8EDECC0B700D7BB6AC7E90281864017E3876

Annex D: UFC – CCAssured Invention Declaration form

DECLARATION AND SIGNATURE(S) OF THE INVENTOR(S):

The undersigned hereby declare(s) that the above-mentioned information is correct and has been completed in good faith and to the best of my/our knowledge. The invention was made as a part of my/our work for CCassured and UFC both partners and involved in the ONCOSCREEN project. Any revenue derived from the invention will be shared with the inventor(s). In case CCassured and UFC would decide to apply for patent protection or build a reference laboratory for the above-mentioned invention, the undersigned will fully cooperate with all formalities and sign all required documents.

Please make sure to complete accurately all the information requested below [3]. Nationality and a private address are required by the patent authorities when a patent application is filed.

Signatures are required!

Inventor 1		Inventor 2	
Full name	Sanne Voogd	**Full name**	Rogier Louwen
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Private address		**Private address**	
Nationality	Netherlands	**Nationality**	Netherlands
..... **Date and Signature**  **27-06-2024**		..... **Date and Signature** **11-06-2024**	
Inventor 3		**Inventor 4**	
Full name	Christophe Borg	**Full name**	**Adeline Bouard**
Position	Professor	**Position**	**Study Engineer**
Employer	University of Franche Comté	**Employer**	University of Franche Comté
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[3] *Since the patent granting procedure is long, please keep the Technology Transfer Office updated on any change concerning your contact details (new e-mail address, new employer, etc.).*

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