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CAPABLE

Cancer Patients Better Life Experience

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Intellectual property report V1

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Deliverable Type		
R	Document, report	**[X]**
DEM	Demonstrator, pilot, prototype	
DEC	Websites, patent fillings, videos etc.	
OTHER		
Dissemination Level		
PU	Public	**[X]**
CO	Confidential (Consortium members including the Commission Services)	
CI	Classified Information (Commission Decision 2015/444/EC)	

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Table of Contents

List of Figures

List of Tables

Versions History

Version	Date	Author	Comments
0.1	11th October 2021	UPM	First Table of content
0.2	25th October 2021	UPM	Description of overall methodology
0.3	5th November 2021	CAPABLE Consortium	Contribution to the asset table
0.4	19th November 2021	UPM	Route to exploitation contribution
0.5	6th December 2021	UPM	Document completed
0.6	15th December 2021	UPM	Final version
0.7	20th December 2021	UNIPV	Final revised version

1.Executive Summary

Deliverable 8.3 presents the activities related to the Intellectual Property (IP) Management for the CAPABLE project. The report presents the overall process of management of the IP, describes the general rules for background and foreground taken from the Consortium Agreement (CA) and Grant Agreement (GA) and then presents the foreground assets classified in software, data, and knowledge results. Possible strategies for result valorisation are presented together with different routes of commercialization of the results. Finally, the document presents the IP procedures that will be taken to monitor, assess and protect the project's results.

2. Introduction

This deliverable discloses the guidelines for Intellectual Property Rights (IPR) management as derived from the CAPABLE GA and CA. A procedure is presented covering identification of potential innovations, documentation, tracking and protection of Intellectual Property derived from the CAPABLE project.

Before presenting the work, the following definitions of terms relevant to the domain of knowledge and IPR management will be provided.

Intellectual property: means inventions, discoveries, developments, methods, processes, compositions, works, concepts, recipes and ideas (whether or not patentable or copyrightable or constituting trade secrets or trademarks or service marks) conceived, made, created, developed or reduced to practice by the partner (whether alone or with others, whether or not during normal business hours or on or off Company premises) during the partner's employment that relate to either the business activities or any prospective activity of the Company or any of its Affiliates.

Background: Any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is held by the beneficiaries before they acceded to the CA, and is needed to implement the action or exploit the results; background, together with any data, knowhow or information that is developed or acquired by a Party independently from the work in the Project even if in parallel with the performance of the Project, to the extent that such data, knowhow, or information is introduced into the Project by the owning Party (GA, Article 24).

Foreground/Results: Any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights (GA, Article 26).

Access rights: Any rights to use results or background under the terms and conditions laid down in the GA, Access rights must be exercised in writing as well as waivers of access rights. the upon written agreement. Unless agreed otherwise, access rights do not include the right to sub-license (GA, Article 25).

Owner: A party, public or private, holding legal title to Intellectual Property, consistent with national or international laws and regulations. The Owner owns an idea or concept that can be sold and exploited. Ownership of the Results are owned by the Party that generates them (CA, Article 8.1.). The Joint Ownership is possible if the beneficiaries have generated the results and it is not possible to (i) establish the respective contribution or (ii) separate the, for the purpose of applying for, obtaining or maintaining their protection (GA, Article 26.2 and CA, Article 8.2.).

Beneficiary: Legal person, other than the European Commission, who is a Party in the Grant Agreement.

Use/Exploitation: Utilization of results in further research activities other than those covered by the action concerned, or in developing, creating, and marketing a product or process, or in creating and providing a service, or in standardization activities that may generate an economic return for the organization, based on Intellectual Property Rights.

3.Management of IP

The intellectual property management activities have been framed around four key aspects:

- Result's management: according to the GA document ownerships, access right to results and background has been identified.
- Result's protection: that means the process of seeking the best strategy of IP protections.
- Result's valorisation: that aims to define a portfolio of the strategy for exploitation and a proper communication strategy and portfolio of results for the CAPABLE project.
- IP procedures: to describe roles and responsibilities and procedures to monitor the IP activities during and after the project.

The overall IPR management framework considers the above activities for the different project's phases (Figure 1).

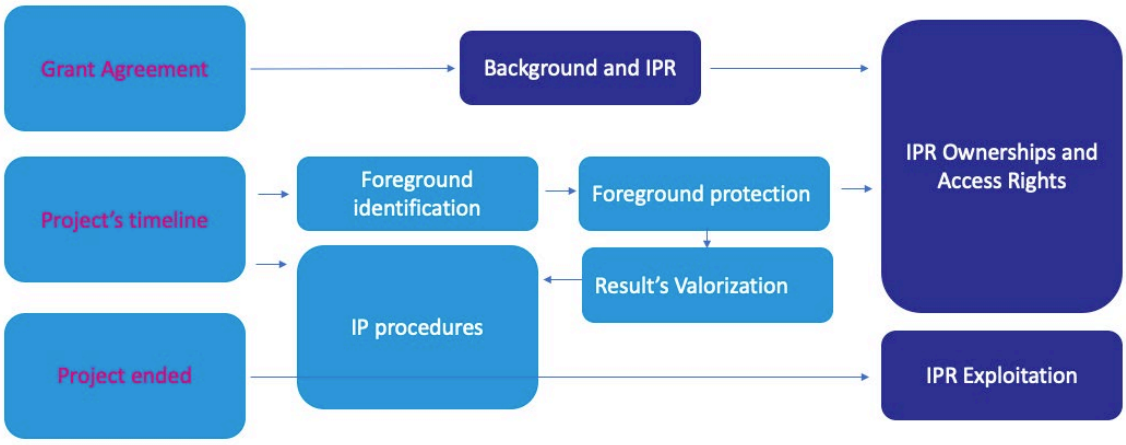

Figure 1: Phases of the IPR management

The Grant Agreement represents the starting point to define background and IPR at the beginning of the project. The CAPABLE GA is based on the DESCA[1]. The latter stipulates procedures and rules related to knowledge and IPR management in section 8 (results), 9 (access rights), 10 (non-disclosure of information) and Attachment 1 (background information).

3.1 Background and Foreground general rules

Background declaration

The use of Background is strictly limited for use to the achievement of the project goals and for the duration of the project. The receiving partner or partners will sign appropriate non-disclosure agreements with the providing partner upon request. An exhaustive overview of the Background over which the partners agreed and are entitled to grant access rights will be included as an annex to the consortium agreement.
At this stage of the project, Background is not shared by the Partners but used to complete the specific tasks.

Ownership of the results

[1] https://www.desca-agreement.eu/what-is-desca/

Results are owned by the Party that generates them or on whose behalf they are generated (see above, section 2 – Owner definition). Each Partner that owns a specific Result must take measures aiming to ensure exploitation (GA, Article 28).

Access Rights
Access Rights to Background and/or Results that are owned by one or more of the partners shall be granted on fair and reasonable conditions (GA, Article 25.2. and 25.3.). The beneficiaries must give each other access to background needed for exploiting their own results (GA, Article 25.3.). For this purpose, the involved partners are entitled to conclude appropriate agreements.

Access Rights for implementation
Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis.

Access Rights for Exploitation
Access Rights to Background, if needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on Fair and Reasonable conditions and are subject to a separate written agreement between the Parties in question.
Access Rights to Results, if needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions and are subject to a separate written agreement between the Parties in question.

Access Rights for Affiliated Entities
Each Party grants access Rights to Results and Background to Affiliated Entities (GA, Article 25.4. and CA Article 9.5). Access Rights granted to any Affiliated Entity are subject to the continuation of the Access Rights of the Party to which it is affiliated and shall automatically terminate upon termination of the Access Rights granted to such Party (CA Article 9.5).
Upon cessation of the status as an Affiliated Entity, any Access Rights granted to such former Affiliated Entity shall lapse.
Further arrangements with Affiliated Entities may be negotiated in separate agreements.

3.2 Project assets

WP8 launched a set of meetings and document templates to collect information on potential foregrounds generated by the project that can be mapped to three categories: software assets, data assets and know how.

3.2.1 Software assets

Software assets are the CAPABLE components of the system architecture.
Each discernible software asset has been defined in the IPR Identification Sheet according to several dimensions:

- Name of the exploitable software.
- Description of the result.
- Ownership, intended as Partner(s) that generate the software asset.
- Background underlying assets (if any), namely background item(s) on which the software asset is built upon.
- Other underlying assets (if any), non-background item(s) on which the software asset is built upon.
- IP condition, e.g., proprietary, FOSS (Free Open Source Software).
- License, e.g., copyright, Apache License Version 2.0, BSD, MIT X11.
- Public availability of the result, e.g., no, only demo, GitHub, SourceForge.

The next table provides the reader the overall summary of the CAPABLE software assets.

Table 1: overview of the SW assets

SW Asset	Short description	Ownership
Multimorbidity Controller (GoCom) - UoH	The Multimorbidity Controller (GoCom) will receive information from the guidelines after they have completed a run and check for interactions between the guideline recommendations and the patient's existing medications.	UoH
Physician Decision Support Component (Physician DSS).	Physician DSS is an adaptor component that interfaces the Deontics Computer-Interpretable Guideline engine to the CAPABLE system.	DEON
Predictive models (risk prediction and disease progression)	Accurate data-driven prediction models that provide an aggregated prediction for patient's outcome given their current state, past history and potential interventions	IBM
Natural Language Processing algorithm	This algorithm is used to analyse a rich set of patient related unstructured data in the form of text, such as from patients' and caregivers' forums, potentially mails and communication inside the system	UniPV 90%; AIMAC 10%
Virtual Coaching system	The Coaching System implements interventions to facilitate and monitor provision of prescribed therapies and mental wellbeing interventions, to increase the motivation and competence of patients and thus to improve their engagement in and compliance with these therapies.	PUT, UoH, UNIPV
Care provider (Clinicians) dashboard	Web app developed to dynamically configure the patient application with the information provided to the patient (e.g., drug prescriptions) and manage patient data by clinicians.	BIT
Patients & caregivers mobile app	Mobile app to allow their disease management, including functionalities such as recording their symptoms, managing personal data and care plans, receiving coaching advice, alerts and recommendations; and communicating with the care provider.	BIT
Ontology-based knowledge-data mapper	The Knowledge-Data Ontology Mapper (KDOM) is a tool that allows mapping different schemas of knowledge and data to each other.	UoH
Data Platform	CAPABLE data platform aims at storing all the data that are relevant for the project (coming both from the EHR and generated within the project context). The persistence layer is constituted by an extended version of the OMOP Common Data Model, while data communication occurs through HL7 FHIR standard.	BIOM
Case Manager	The Case Manager is the component responsible for driving the reasoning process within the system. The approach adopted by CAPABLE is based on the advertisement of Events: each component hosting a Knowledge Source specifies a set of Events in terms of a combination of facts about the patient.	UNIPV
Knowledge model related to CAPSULE	The knowledge model of the capsules related to evidence-based recommendations behind the capsule activity, to its properties according to Fogg's behavioral model, and to representation as FHIR resources	1/3 each for UNIPV, PUT, UH

These initial assets have been defined and the proper dependencies with Background have been identified. For every software asset the IP condition, the level of access and the model of fee has been specified. This information will be periodically revised every 6 months. The following tables present the details of the assets.

Table 2: software assets - Multimorbidity Controller

Component Name/Result	Multimorbidity Controller (GoCom)
Short description	The Multimorbidity Controller (GoCom) will receive information from the guidelines after they have completed a run and check for interactions between the guideline recommendations and the patient's existing medication
Ownership	UoH
Background underlying assets	Previous publications in scientific journal on Go Comm component
IP Condition	Proprietary
Differences between context of commercial and no commercial purpose (Differences)	No difference
Specify level of access	API
Model of fee	Perpetual
Public availability	No. Available for demonstration

Table 3: software assets - Physician Decision Support Component

Component Name / Result	Physician Decision Support Component (Physician DSS / PDSS)
Short description	Physician DSS is an adaptor component that interfaces the Deontics Computer. Interpretable Guidelines engine to the CAPABLE system
Ownership	DEON
Background underlying assets	PDSS uses the Deontics Runtime Engine API (DRE API) to interface to the Deontics DSS Engine service, as do some other components (GoCom, VC)
IP Condition	Proprietary
Differences	No difference is expected
Specify level of access	API
Model of fee	Annual license
Public availability	Yes

Table 4: software assets - Predictive models

Component Name/Result	Predictive models (risk prediction and disease progression)
Short description	Accurate data-driven prediction models that provide an aggregated prediction for patient's outcome given their current state, past history and potential interventions
Ownership	IBM
Background underlying assets	No
IP Condition	Proprietary
Differences	No
Specify level of access	API

Model of fee	N/A
Public availability	No

Table 5: software assets - Natural Language Processing algorithm

Component Name/Result	Natural Language Processing algorithm
Short description	This algorithm is used to analyse a rich set of patient related unstructured data in the form of text, such as from patients' and caregivers' forums, potentially mails and communication inside the system.
Ownership	UniPV 90%; AIMAC 10%
Background underlying assets	Expertise in NLP applied to clinical text reports Natalia Viani, Timothy A. Miller, Carlo Napolitano, Silvia G. Priori, Guergana K. Savova, Riccardo Bellazzi, Lucia Sacchi, Supervised methods to extract clinical events from cardiology reports in Italian, Journal of Biomedical Informatics, Volume 95, 2019 Viani N, Larizza C, Tibollo V, Napolitano C, Priori SG, Bellazzi R, Sacchi L. Information extraction from Italian medical reports: An ontology-driven approach. Int J Med Inform. 2018 Mar;111:140-148. doi: 10.1016/j.ijmedinf.2017.12.013. Epub 2017 Dec 23. PMID: 29425625. E. Parimbelli, S. Quaglini, C. Napolitano, S. Priori, R. Bellazzi, and J. H. Holmes, "Use of Patient Generated Data from Social Media and Collaborative Filtering for Preferences Elicitation in Shared Decision Making," in AAAI Fall Symposium Series, 2014
IP Condition	OpenSource
Differences	N/A
Specify level of access	API and source code
Model of fee	None
Public availability	Yes

Table 6: software assets - Virtual Coaching system

Component Name/Result	Virtual Coaching system
Short description	The Coaching System implements interventions to facilitate and monitor provision of prescribed therapies and mentall wellbeing interventions, to increase the motivation and competence of patients and thus to improve their engagement in and compliance with these therapies.
Ownership	PUT
Background underlying assets	1) A method extending the system development lifecycle with a stage that realizes psychobehavioral techniques as concrete 2) Backend architectural components and graphical user-interface designs that implement behavioral interventions 3) Know how 4) Publications: * Peleg M, Michalowski W, Wilk S, Parimbelli E, Bonaccio S, O'Sullivan D, Michalowski M, Quaglini S, Carrier M. Ideating Mobile Health Behavioral Support for Compliance to Therapy for Patients with Chronic Disease: A Case Study of Atrial Fibrillation

	Management. J Med Syst. 2018 Oct 13;42(11):234 * Sz. Wilk, D. O'Sullivan, M. Michalowski, S. Bonaccio, W. Michalowski, M. Peleg, M. Carrier: A Data- and Expert-driven Decision Support Framework for Helping Patients Adhere to Therapy: Psychobehavioral Targets and Associated Interventions. in D. Riano, M. Peleg, R. Lenz, M. Reichert, K. Denecke, Y. Deng, T. Declerck, F. van Harmelen (eds): Proceedings of the International Joint Workshop on Knowledge Representation for Health Care, Process-Oriented Information Systems in Health Care, Extraction and Processing of Rich Semantics from Medical Texts (KR4HC-ProHealth-RichMedSem 2017). 2017, 53-66
IP Condition	Open source
Differences	Additional services available commercially (e.g., customization for specific conditions, like other CIG execution engine)
Specify level of access	Source code
Model of fee	None
Public availability	Yes

Table 7: software assets - Care provider dashboard

Component Name/Result	Care provider (Clinicians) dashboard.
Short description	Web app developed to dynamically configure the patient application with the information provided to the patient (e.g., drug prescriptions) and manage patient data by clinicians.
Ownership	BIT
Background underlying assets	N/A
IP Condition	Proprietary
Differences	In non-commercial setting the system can be used for demonstration purposes and/or research without alteration of its source code (except for bug corrections that should be reported to BIT). It should not be used in real life set-up nor to be sold or access-given to third parties.
Specify level of access	Web access
Model of fee	N/A
Public availability	Only demo

Table 8: software assets - Patients & caregivers mobile app

Component Name/Result	Patients & caregivers mobile app
Short description	Mobile app to allow their disease management, including functionalities such as, record their symptoms, management personal data and care plans, receive coaching advice, alerts and recommendations; and communicate with the care provider.
Ownership	BIT
Background underlying assets	NA
IP Condition	Proprietary

Differences	In non-commercial setting the system can be used for demonstration purposes and/or research without alteration of its source code (except for bug corrections that should be reported to BIT). It should not be used in real life set-up nor to be sold or access-given to third parties.
Specify level of access	App
Model of fee	Perpetual license per installation on a mobile device, with an option to renewal fees every year.
Public availability	Demo video.

Table 9: software assets - Ontology-based knowledge-data mapper

Component Name/Result	Ontology-based knowledge-data mapper
Short description	The Knowledge-Data Ontology Mapper (KDOM), is a tool that allows mapping different schemas of knowledge and data to each other.
Ownership	UoH
Background underlying assets	Pre-existing result, expanded in the CAPABLE research: Peleg M, Keren S, Denekamp Y. Mapping computerized clinical guidelines to electronic medical records: Knowledge-data ontological mapper (KDOM). Journal of biomedical informatics. 2008 Feb 1;41(1):180-201.
IP Condition	Proprietary
Differences	No difference
Specify level of access	API
Model of fee	Perpetual
Public availability	No. Available for demonsration.

Table 10: software assets - Data Platform

Component Name/Result	Data Platform (DP)
Short description	CAPABLE data platform aims at storing all the data that are relevant for the project (coming both from the EHR and generated within the project context). The persistence layer is constituted by an extended version of the OMOP Common Data Model, while data communication occurs through HL7 FHIR standard.
Ownership	BIOM
Background underlying assets	Background for DP is the omop on fhir open-source project, which DP constitutes a fork of.
IP Condition	OpenSource
Differences	N/A
Specify level of access	Source code
Model of fee	None
Public availability	Yes

Table 11: software assets - Case Manager

Component Name Result	Case Manager

Short description	The Case Manager is the component responsible for driving the reasoning process within the system. The approach adopted by CAPABLE is based on the advertisement of Events: each component hosting a Knowledge Source specifies a set of Events in terms of a combination of facts about the patient.
Ownership	UNIPV 100%
Background underlying assets	Know how
IP Condition	Proprietary
Differences	Commercial services provided to hospitals by third party
Specify level of access	API
Model of fee	Perpetual license
Public availability	No. Available for demonstration

Table 12: software assets - knowledge model related to CAPSULE

Component Name/Result	Knowledge model related to CAPSULE
Short description	The knowledge model of the capsules related to evidence-based recommendations behind the capsule activity, to its properties according to Fogg's behavioral model, and to representation as FHIR resources
Ownership	1/3 each for UNIPV, PUT, UH
Background underlying assets	None
IP Condition	Open source
Differences	Commercial consulting services (e.g., customizing capsules to specific conditions, adding new capsules on request)
Specify level of access	knowledge repo (no "typical" source code)
Model of fee	None
Public availability	Yes

3.2.2 Data assets

The Data assets are data generated/processed in the project. This type of asset has been defined with the following metrics:

- Name of the Dataset
- Description of the data
- Ownership: the partner/s who generate/s the result
- Underlying background and other assets
- Data type: it can be a dataset or a data model
- Format: supported format of the data sets
- License: the type of license.
- Privacy level: if the data set has sensible information that may be protected
- Confidentiality level: if the data asset can be accessible or not and what are the measures to protect the confidentiality.

Table 13: dataset asset table

Name of the data-set	Description	Ownership	Background underlying data assets	Data type	Format	License	Privacy level	Confidentiality level
Patient raw dataset	Data already available and extracted from the EHR at the hospitals.	ICSM, NKI	For ICSM and NKI: The data is intended for the only use in the project.	dataset	CSV	N/A for ICSM	Data are anonymized	Accessible under request through Zenodo
Patients CAPABLE dataset	New data generated by the CAPABLE system. Data collected through questionnaires, wearable or environmental sensors located at the patient home, during the execution of the CAPABLE project.	AMC, ICSM, NKI, BIOMERIS	For NKI: The data is intended for the only use in the project.	dataset	CSV	No exclusive license	Data are anonymized	Accessible under request through Zenodo
UX studies data sets	New data generated during the User Experience studies. Data are formed by qualitative and quantitative studies. According to the study protocol and informed consent data are anonymized	UPM, AMC, ICSM, NKI, UNIPV, AIMAC	For NKI: The data is intended for the only use in the project.	dataset	Excel format	No	Data are anonymized (transcripts not considered fully anonymous)	Data will be stored by ICSM, NKI, UPM, UNIPV
AIMAC forum data	Data from the AIMAC forum	AIMAC	Data are part of the background. The data can be only used in the project	dataset	CSV	No	Partly, they are the data of the AIMAC forum	Available in the AIMAC forum (not the raw data)
AIMAC questionnaires data	Data from the AIMAC questionnaires	AIMAC	Data are part of the background. The data can be only used in the project	dataset	CSV	No	Data are anonymous	Data have been provided to UNIPV for the project requirement analysis

CAPABLE extended OMOP Datamodel	OMOP CDM is a structure for representing data plus a set of vocabularies to describe them. For CAPABLE scope it has been extended by BIOM	BIOMERIS	OMOP CDM	Datamodel	SQL Database + Data	Open-source	N/A, no data inside the datamodel	Public

3.2.1 Knowledge assets

The following table details the assets grouped by domain of knowledge.

Table 14:knowledge asset table

Partners	Domain	Knowledge description
UNIPV, UoH, DEON, PUT	Computer models	Modelling clinical practice guidelines (CPGs), modelling additional domain knowledge in form of ontological models expressed in the OWL language
AMC,UNIPV, BIOMERIS	Information modelling/system interoperability	Identification and configuration of FHIR resources
UoH	System requirements	Definition of user needs
PUT, UNIPV	Software design and development	Designing complex software systems (e.g., employing multi-agent or actor-model paradigm) and their implementation using modern technologies
BIOMERIS	Data integration	Harmonize separate data sources towards a data model and make them available for secondary use
ICSM, NKI, UNIPV, AMC,	Study design	Definition of study protocols for control cohorts
ICSM, NKI, UNIPV,AMC, UPM	Study design	Definition of study protocols for study cohorts
UPM, ICSM, NKI, UNIPV, AMC	Study design	Definition of study protocols for the user experience evaluation
ICSM, BIOMERIS, NKI, UNIPV	System deployment	Existing environments in the two hospitals
UNIPV, ICSM, NKI, UoH, PUT, DEON, AMC, UPM	System evaluation	Knowledge validation
IBM, PUT	Machine Learning	Developing predictive models for patients' outcomes, application of simulation and machine learning (including reinforced learning) to construct models for adjusting wellbeing activity prompts sent to patients
PUT	Wearable sensors	Developing software solutions for communicating with sensors (wearable devices) and dedicated data platforms, processing of data extracted from sensors

3.3 Result valorisation and exploitation

These activities represent the analysis of the different routes of exploitation of the results considering a wide spectrum targeting results to industry, research communities, policymakers, and the civil society, as the following diagram of the EC depicts:

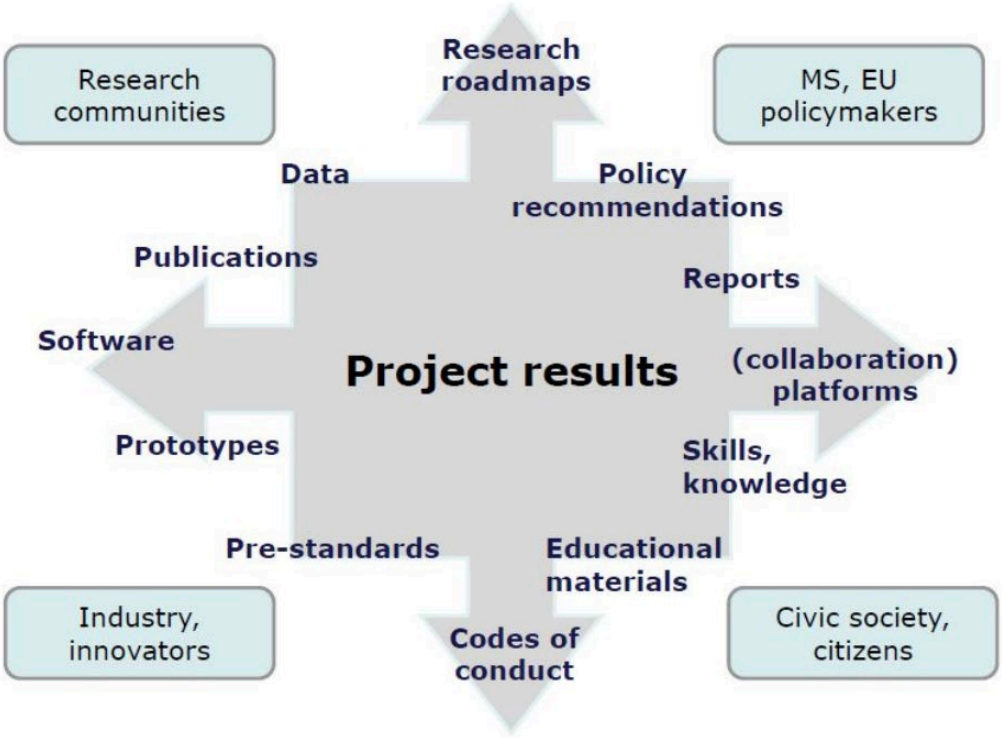

Figure 2: spectrum of possible project results (source: European Commission)

At this stage of the research, **WP8 proposed to focus on the commercial exploitation** and to early start defining possible routes of commercialization of the overall results. To do so, WP8 launched a poll giving to the Partners the option to choose up to 3 results to further analyse the exploitation potential. WP8 selected as option all the results identified in the previous chapters and two main joint results identified during the WP8 teleconferences: the overall CAPABLE system and the patient app working in standalone mode.

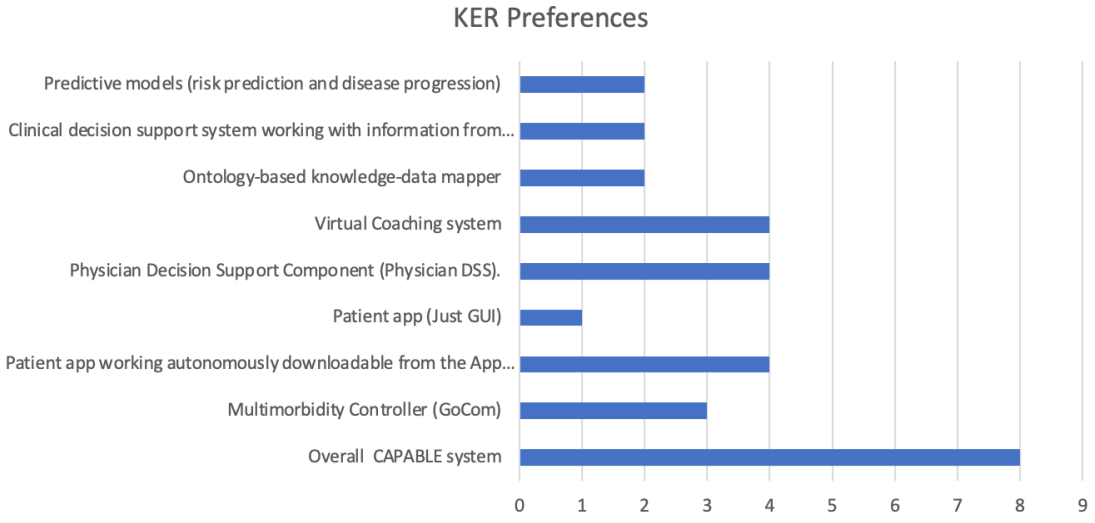

Figure 3: result of the survey to select the Key Exploitable Results (KERs).

The results of the survey highlight the interest of the Consortium to start working on the exploitation strategy of the Overall Capable system, and of the patient APP (in the presented chart the APP preference was given with two options: as a standalone system or as an independent component). This result has been combined with inputs and ideas during the WP8 teleconference and 3 Key Exploitable Results have been proposed:

- KER1: Overall Capable system
- KER2: Technological stack for Digital Health products
- KER3: Digital therapeutics for cancer self-management

The 3 selected KERs are joint results that have in common the CAPABLE technology to be re-used, personalized, or modified in 3 different contexts. The first implication of the selection of these KERs was the need to define a schema for joint exploitation. This exploitation will focus on the software and knowledge assets of the Project. The KERs are described in the Deliverable 8.4.
At this stage two interesting scenarios of exploitation have been identified:
Scenario 1: service replication. In this scenario a third legal entity (formed by some partners of the consortium or not) will take profit of the CAPABLE software assets to provide the same service developed in CAPABLE. In this case it has been agreed that the license schema is the most appropriate solution. Since the license will have different ownerships, the level of participation of every partner is still under definition.
Scenario 2: service personalization. In this business case, the third party requests a modification (e.g., it personalizes the Overall Capable system for another type of cancer, add specific contents in the patient app, etc.). The knowledge asset represents an opportunity for exploitation and specific commercial collaboration could take place between the third party and specific partners having the results involved in the request of modifications.

3.3.1 Route to commercialization

There are different options that the Partners can consider to create a legal entity for the commercialization of the CAPABLE system:

- Internal Product Development: the consortium can decide to support most of the activities to start a commercial activity. This approach requires the team having all the skills to face the business challenges and scale-up activities
- Spin-off Company, in the meaning of a separate legal entity created to exploit IP assets, which are transferred or licensed to the spin-off company to commercialize them.
- Joint Venture, in the general meaning of model of business association between two or more partners to undertake a common project or to achieve a certain goal. IP assets are usually brought by the partners for further R&D advancements, production, marketing, and commercialization.

According to the Owner's policy, the legal entity can commercialize CAPABLE IP assets through:

- License agreement: allows a third party to access and use its software asset for a certain time period in return for economical compensation (e.g. royalties, subscription, single payment), under specific conditions and terms (exclusivity or non-exclusivity of the licensed technology, restriction to a particular purpose). This route is usually preferred when the Owner / legal entity does not have the necessary financial or technical capability to directly exploit the IP asset.
- Assignment (like a sale, different from licensing): the ownership of the IP asset is permanently transferred to an assignee in return for a payment of a lump sum, royalties, or a combination of both. The assignee gets the full rights to dispose of it.

3.3 IP procedures

This last step aims to define rules and processes to ensure the proper management of the IP that can also cover the post project phase. The following activities are proposed:

Creation of the official exploitation repository for CAPABLE.
The asset tables will be periodically revised and discussed with the consortium every six months. The assets will be refined and revised according to the specific business interests and must represent a systematic revision. The first version of this repository has been presented in the previous section and it will be updated in the next WP8 IPR deliverable at month 36 and 48.

Risk management
To minimize the risks of IP-related problems for the exploitation of the results, CAPABLE aims to early identify risks, discuss with the Consortium and define measures to avoid these situations. The following table represents the risks that have been identified so far:

Table 15: risk analysis table

	Risk description	Criticality (1 low-10 high)	Probability of risk happening (1 low - 10 high)	Risk Grade	Potential intervention
1	Difficulties to agreed participation on a joint exploitation (e.g., define % of royalties of a license)	*8*	6	**48**	Propose a clear joint participation schema based on agreed criteria. At this stage the initial share will depend on the distribution of budget and on the level of participation on the exploitation activities.
2	Conflict of IPR	*2*	*3*	**6**	Existing IPR repository. Definition of IP enforcement procedures.
3	A competitor copies the overall CAPABLE service	*5*	*7*	**35**	Register trademark, copy-right the software. Patent is not possible.

Dissemination and portfolio
The exploitation repository will be used to create a proper portfolio of services to be promoted in the official project's Web site.

Market surveillance
WP8 started the activities of market surveillance since the beginning of the project. An initial market analysis of digital therapeutics tools has been carried out. New analysis has been performed for KER2 and KER3. Aside from the business perspective (some competitive analyses is presented in deliverable 8.4) this activity also benefits the IPR management to better refine the strategy of IP protection.

IP enforcement
In case an IP allocated to a new service/product is violated by competitors, the owner has the right to defend the IP by taking proper measures existing in the juridical system (e.g., letter of demand, custom notice, alternative dispute resolution mechanisms, court actions, etc.). The IP enforcement could be time-consuming and expensive.

4.Conclusions and next steps

This document dealt with activities related to the IPR management. Several achievements have been presented:

- Proposed approach to pursue and ensure the IP management.
- Identification of project's assets (software, datasets, and knowledge).
- Identification of 3 KERs as combination of software assets.
- Initial risk analysis of the IP measures.

The activities that will be carried out in the next period will focus on:

- Periodic revision of the exploitation table, every 6 months.
- Revision and formulation of IP rules for joint exploitation considering the KERs and any other business case proposed by the partners, for individual or joint exploitation.
- Extend the assets to other dimensions, analysing opportunities to maximize the impact of more intangible assets like the knowledge that can be exploited as whitepapers, roadmaps, educational courses.