



D6.3 Business model & marketing strategy for products/services derived from FAIR data reuse in health domains

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Executive Summary

This document provides information about the strategy and the outcomes that the FAIR4Health project embodied during its exploitation plan and business plan development. This document also provides some part of the detailed results of those plans since the results are released in several sub steps. The FAIR4Health project received the support of the Horizon Results Booster for the following two services:

- Portfolio Dissemination & Exploitation Strategy (PDES)
- Business Plan Development (BPD)

In an 8-months period, 5 meetings, 2 workshops and 1 seminar conducted by the Horizon Results Booster (HRB) experts and the project partners. In the scope of PDES service, market analysis and risk assessment were performed according to the guidelines of the HRB experts and exploitation roadmap was built. After the successful completion of PDES, BPD service was started. In the scope of this service, market analysis was further improved by customer validation, and value proposition canvas and lean canvas were filled in. Finally, financial analysis containing market sizing, pricing and costs was performed and a final business plan was developed.

In FAIR4Health Final General Assembly, which was held on 24 November 2021, a session for virtual demonstration of the tools was organized for exploiting the results of the project. 52 people external to the FAIR4Health were registered to the event and 11 of them expressed their interest to FAIRify their own datasets through the FAIR4Health solution.

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List of Acronyms

BPD	Business Plan Development
ESS	Exploitation Strategy Seminar
HRB	Horizon Results Booster
IPR	Intellectual Property Rights
JTBD	Jobs to be Done
PDES	Portfolio Dissemination & Exploitation Strategy
UVP	Unique Value Proposition
VPC	Value Proposition Canvas

1. Introduction

In the frame of the FAIR4Health project, the main objective of WP6 "Sustainability, Economic Impact and Digital Single Market" is to identify and generate the models of commercialization agreements and the IPR, the roadmap for certification for the use of the datasets, the business models & marketing strategy, and the analysis of the impact on health research outcomes. The objective of this deliverable (D6.3) is to present the business model & marketing strategy for the FAIR4Health solution together with the exploitation strategy and analysis of potential customers.

In order to create an effective exploitation roadmap, business model and marketing strategy, the FAIR4Health consortium has received expert support from the Horizon Results Booster (HRB) initiative which is backed by the European Commission. The aim of this initiative is to provide support and guidance on how best to increase project results' exploitation potential and to improve access to markets in order to maximize the impact of research projects funded by FP7, Horizon 2020 and Horizon Europe. In the HRB, three services are provided:

- Portfolio Dissemination & Exploitation Strategy (PDES)
- Business Plan Development (BPD)
- Go To Market

The aim of **Exploitation Strategy service** is to support projects in exploiting their research results and enhance beneficiaries' capacity to improve their exploitation strategy. It provides guidance and training to improve the existing project strategies towards effective exploitation of Key Exploitable Results (KERs) which correspond to project activities and results having commercial and/or societal significance.

The aim of **Business Plan Development service** is to assist beneficiaries to bring their results closer to the market by developing an effective business plan which include market analysis, business strategy, operations plan and competitor identification and analysis.

In the scope of Task 6.3, we first utilized the Exploitation Strategy service. Two experts (Alessio Gerardo Maugeri and Monica Ferraioli) were appointed on 8 March 2021 and a first introductory meeting was held on 23 March 2021. Following this meeting, the exploitation roadmap, characterization table, use options, and risk matrix documents were filled out by the FAIR4Health consortium and shared with the experts by 31 May 2021. The experts reviewed and consolidated these documents into a Preliminary Report (provided as Annex I to this deliverable) with comments requesting clarification and prompting additional consideration. Then, an exploitation strategy seminar (ESS) was held on 7-8 June 2021 with the participation of six partners: SRDC as WP6 and Task 6.3 leader, SAS as project coordinator and contributor, ATOS as the other contributor of Task 6.3; IACS, IMISE, and PLRI as voluntarily. The seminar took place online due to the COVID-

19 restrictions in Europe. During the seminar, the experts provided detailed feedback on the exploitation roadmap and characterization tables created by the FAIR4Health consortium. In particular, it was recommended to consider more carefully what entities might be beta users for commercially exploitable KERs, to provide more precise target market information, and to (generally speaking) take into account the needs of various stakeholders in completing the KER characterization table and exploitation roadmap. Based on these, the FAIR4Health consortium revised and improved all the exploitation roadmap, characterization table, use options, and risk matrix documents; and finally defined the exploitation strategy of FAIR4Health results. As a result, the final report was generated on 24 June 2021.

After the successful completion of Exploitation Strategy service, we applied for the second service which is Business Plan Development on 18 July 2021. Two experts (Arno Schoevaars and Monica Ferraioli) were appointed on 23 July 2021 and an introductory meeting where the experts introduced the set of guidelines to prepare an effective business plan was held on 8 September 2021. Then, in the next two weeks, we worked on preparing the first version of the Lean Canvas for the FAIR4Health solution. The feedbacks of experts were retrieved in a webinar that took place on 22 September 2021. Based on the comments in this meeting, the FAIR4Health consortium organized an internal workshop to generate a Value Proposition Canvas on 1 October 2021 and presented the results to the experts in the 1st BPD workshop on 6 October 2021. In this workshop, we also focused on revenue streams and cost structure. Based on these, we worked on the TAM SAM SOM analysis during the next two weeks and shared the results with the experts in the 2nd BPD workshop on 21 October 2021. As a result, the final version of the Lean Canvas was generated on 27 October 2021. All these together constituted the final Business Plan. Finally, after the initial version of D6.3 was produced by the FAIR4Health partners on 8 November 2021, the experts reviewed it and provided feedback in the final coaching session on 9 November 2021, which was also the date that the service ended.

In FAIR4Health Final General Assembly, which was held on 24 November 2021, a session for virtual demonstration of the tools was organized for exploiting the results of the project. 52 people external to the FAIR4Health were registered to the event and 11 of them expressed their interest to FAIRify their own datasets through the FAIR4Health solution.

In the next two sections, we present and the final Exploitation Strategy and Business Plan, together with the outputs that we generated during the work we performed in Task 6.3.

2. FAIR4Health Exploitation Strategy

Exploitation strategy of FAIR4Health solutions has been defined in 4 steps: First, 7 Key exploitable results of the FAIR4Health project have been identified (Section 2.1). Then, according to the feedbacks and suggestions of the HRB experts, this number has been

reduced to 3 based on their commercialization potential, and market analysis (Section 2.2) and risk assessment (Section 2.3) related to the exploitation of results have been performed for each of them. Finally, exploitation roadmaps of different KERs have been developed (Section 2.4).

2.1. Key Exploitable Results (KERs)

In the context of this deliverable, we consider a **result** as any tangible or intangible output of the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, which are generated in the action as well as any attached rights, including intellectual property rights.

A **Key Exploitable Result (KER)** is an identified main interesting result (as defined above) which has been selected and prioritized due to its high potential to be “exploited” – meaning to make use and derive benefits downstream the value chain of a product, process or solution, or act as an important input to policy, further research or education. The following criteria were used to determine the KERs: For the identification of the KER’s the following criteria should be applied: a) degree of innovation, b) exploitability and c) impact; and following should be considered:

- Different types of exploitable results (knowledge, methods, agreements, networks, technologies) should clearly be identified and their direct and indirect value and impact for different stakeholders should be considered
- The barriers and risks for exploitation (actual use of the results after project funding) should be recognized and countered with appropriate measures
- Concrete measures should be described to ensure that the results meet real needs, and will be taken up by potential users (e.g., engaging them in project)
- The roles and responsibilities of partners should be described in exploiting results or supporting results exploitation by other (intermediate or end) users

Based on the considerations and criteria mentioned above, In FAIR4Health, we identified 7 KERs residing at different layers of the FAIR4Health architecture as shown in the Figure 1 below.

1. **FAIRification Workflow**¹ – FAIRification on health data: Knowledge, experience, consultancy, specialization of the workflow for local/specific needs.
2. **FHIR4FAIR**² – HL7 FAIRness for FHIR Project: FHIR4FAIR
3. **Data Curation Tool**³ – Tool for making health-related data FAIR
4. **Data Privacy Tool**⁴ – Tool for anonymization and de-identification

¹ <https://pubmed.ncbi.nlm.nih.gov/32620019/>

² <https://confluence.hl7.org/pages/viewpage.action?pageId=91991234>

³ <https://github.com/fair4health/data-curation-tool>

5. **Health Digital Terminology** – Software as a Service for semantic interoperability
6. **FAIR4Health Platform**^{5,6} – Consists of Graphical User Interface, PPDDM (Privacy Preserving Distributed Data Mining) Agent, PPDDM Manager, OAuth Server, Service Registry, Training Datasets, Partial Models and Aggregated Models
7. **FAIR4Health Machine Learning Hub** – FAIR4Health Machine Learning Hub constitutes the complete FAIR4Health solution including all the FAIRification Tools, FAIRification Workflow, and FAIR4Health Platform.

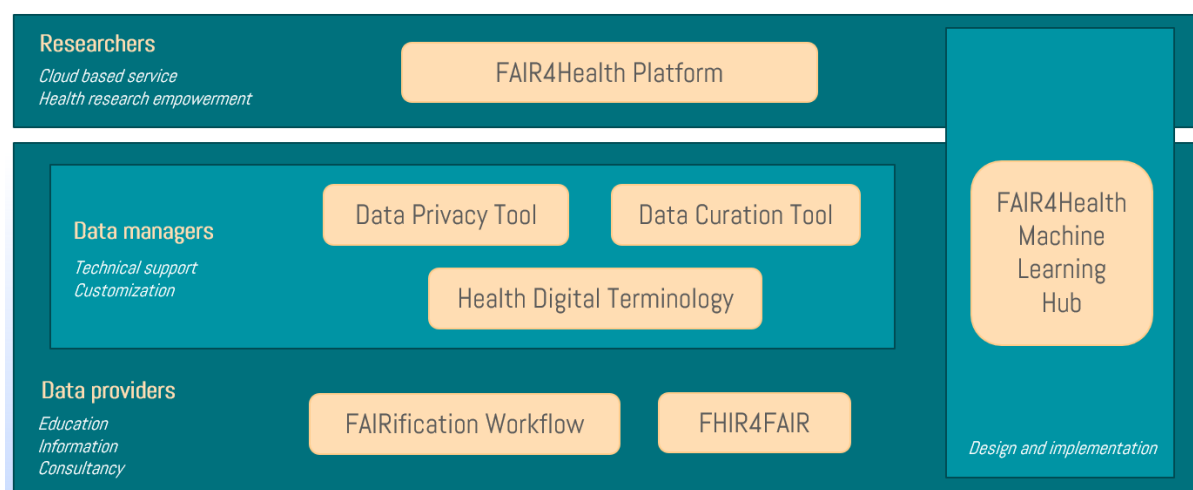


Figure 1. FAIR4Health Key Exploitable Results

After we shared the identified KERs with the HRB experts, they recommended us to select the three most important KERs to focus on while creating the Exploitation strategy. We selected FAIRification Workflow, Data Curation Tool and FAIR4Health Machine Learning Hub, because they have more commercialization potential than the others.

Then, for each KER, we identified a responsible partner, exploitation intention, intended market/customers, contribution of responsible partner to the generation of this KER, and role of each organization with regards to the KER and according to the Grant and Consortium Agreements of FAIR4Health Project (Table 1).

Table 1. FAIR4Health exploitation intentions summary table.

Partn er name	KER	Exploitation intention, intended market / customers	Contribution to the generation of this KER	Role of each organization
SAS	FAIRification Workflow	FAIRification workflow is a methodology that aims to generate FAIR datasets from raw health datasets. The FAIRification	The partners will share their knowledge and experience with data providers, provide	This KER has been developed jointly by the whole FAIR4Health consortium (SAS, IACS, UC3M, ATOS, HL7,

⁴ <https://github.com/fair4health/data-privacy-tool>

⁵ <https://osf.io/6wevp/>

⁶ <https://osf.io/q63uv/>

		Workflow would be exploited to the data providers through education, information, and consultancy.	consultancy services, training materials and specialize the workflow based on the local/specific needs.	IMISE, AMC, UNIGE, PLRI, UCSC, EFMI, UEDIN, GAR, SRDC, UP, IPBV).
SRDC	Data Curation Tool	Data Curation Tool is a powerful tool for health-related organizations who would like to make their health data FAIR. The intended market would be facilities holding healthcare data such as Health Institutions, Health Research Centers, Regional Governments, Ministries of Health, Research Data Repositories, Research Networks.	SRDC is the core developer of Data Curation Tool. The requirement analysis, architectural design, software implementation, and documentation have been performed by SRDC. After the project ends, SRDC will carry out the maintenance work and perform further implementations.	SRDC designed and implemented the tool in accordance with the principles developed within the FAIRification Workflow. SAS, IACS, UNIGE, UCSC, UP and IMISE tested and validated the tool.
SRDC	FAIR4Health Machine Learning Hub	FAIR4Health Machine Learning Hub constitutes the complete FAIR4Health solution including the following FAIR4Health assets: FAIR4Health Platform, Graphical User Interfaces, PPDDM Agent, PPDDM Manager, OAuth Server, Service Registry and Partial Models. The intended customers would be the health research community performing studies on FAIRification of health data and aiming to perform machine learning tasks jointly with other organizations without sharing any data.	The clinical partners (SAS, IACS, UNIGE, UCSC, UP, IPBV) provided requirements for the whole system and validated it against them. The technical partners (SRDC and ATOS) managed the implementation of the system. They will also be responsible for the maintenance of the system.	SRDC implemented the backend software and built the PPDDM architecture consisting of PPDDM Manager and PPDDM Agents. ATOS implemented the Terminology Server and GUI of FAIR4Health Platform. The clinical partners (SAS, IACS, UNIGE, UCSC, UP, IPBV) provided requirements for the whole system and validated it against them. Furthermore, they provided real patient data for demonstrating the tools in real environment.

2.2. Market Analysis

In the market analysis, first, we described the **problem** that the potential users of each KER has and that we address. Potential users are the “customers” such as funding agencies, pharma industry companies, data managers, hospitals etc. that are expected to use the result (and generate a value). Then, we analyzed the **alternative solutions** that the “customers” had been using so far to solve the problem. After that, we identified the **competitive advantages** and **innovative aspects** of our solutions compared to the alternative ones. At this step, we tried to address following questions:

- What does our solution do better?

- What are the benefits considering what the user/customer wants?
- How does our solution solve the problem in hand better than alternative solutions?
- What distinguishes the FAIR4Health KER from the competition/current solutions?

In the next step, we continued with the in-depth market analysis. In this regard, we first described the **target market** in which our solution can be used and compete with others. Then, we identified the **early adopters** that we are willing to address first. Early adopters are usually the ones that feel the problem harder than all the others. In the third step of market analysis, we studied who our **competitors** are offering alternative solutions and what their strengths and weaknesses are compared to us. Finally, we decided on our **use model** explaining how the KER will be made available to customers such as provision of a service or license agreement, defined the **time** to go to market.

The following Table 2, Table 3 and Table 4 present the market analysis performed for the three identified KERS, namely the FAIRification Workflow, Data Curation Tool, and FAIR4Health Machine Learning Hub, respectively.

Table 2. FAIRification Workflow market analysis.

FAIRification Workflow market analysis	
Problem	<p>Funding agencies (such as the European Commission and National Institutes of Health) and pharma industry spend a lot of money for health and biomedical research. In this regard, vast amounts of data are needed to be collected and processed. However, since health data reside in isolated silos of healthcare and/or health research institutions in various formats, the cost of achieving this is extremely high.</p> <p>Likewise, the European Union has issued a report about the costs of NOT having FAIR data⁷. This report states, that the cost of NOT having FAIR data is approximately €10.2bn per year for the EU. In addition to these costs, the open data economy suggests that the impact on innovation of FAIR could add another €16bn to the minimum cost estimated. That would make a total of at least €26.2bn per year.</p> <p>However, FAIR principles lay the foundations to pave the way for health data sharing, but those institutions need clear guidance on how to achieve FAIRness. FAIRification needs to focus on the specific requirements of the data source (because health data is sensitive), the domain and the target objectives of the data provider. They need concrete, step-by-step and interactive guide to increase the level of FAIRness of their health data. To apply the FAIR principles in the health domain, it is necessary to address technical, ethical, security, legal, cultural, behavioral and economic barriers and requirements that health data include due to its nature.</p>
Alternative solution	<ul style="list-style-type: none"> • Specialized FAIRification process for healthcare and health research data is a comparatively new concept. The FAIR4Health FAIRification Workflow is the first concrete and comprehensive workflow definition for

⁷ Report issued by the European Union about the costs of NOT having FAIR data: <https://op.europa.eu/en/publication-detail/-/publication/d375368c-1a0a-11e9-8d04-01aa75ed71a1>

	<p>processing existing health data and making them FAIR to open up the data for new opportunities.</p> <ul style="list-style-type: none"> The customers have ad-hoc solutions for some specific steps of the FAIRification workflow without a holistic view.
Competitive advantages and innovative aspects	<p>FAIR4Health FAIRification Workflow is a methodology providing a holistic approach utilizing the already available and widely-used data and communication standards. It reflects the deep expertise of the stakeholders who take part in different parts and levels of health data management in this arena. We showed that we can implement this workflow to open up new use-cases and financial opportunities with the FAIRified data.</p> <p>In the “Cost of not having FAIR research data” report⁸ published by European Commission in 2018, it has been shown that the implementation of the FAIR principles can have a positive impact on the quality and the Return of Investment (ROI) of research. Considering the high cost of finding and integrating health research data, implementation of such FAIRification Workflow specialized on the healthcare domain can bring a great value for the stakeholders, especially for funding agencies and pharma industry companies, since it would reduce the cost of finding, accessing, interoperating, and reusing different health research data.</p>
Description	<p>The FAIRification Workflow is a methodology providing clear guidance for health providers and Health Research Performing Organizations, covering the ethical, legal and technical aspects of the health research data, so that they can increase the level of FAIRness of their existing data and make it shareable to exploit for secondary/further purposes.</p>
Target market	<p>Although the FAIR4Health FAIRification Workflow is designed as a generic methodology that could work seamlessly worldwide, our initial target market will be the following bodies in the European Union:</p> <ul style="list-style-type: none"> Funding agencies aiming to improve the capacity for sharing and reuse of health research data, Pharma industry companies aiming to access academic EHR data, Data managers in health research institutions aiming to collaborate with other institutions in order to improve the impact of their research, Public and private hospitals aiming to improve the value of their research.
Early Adopters	<p>Data scientists and data managers in health research organizations, private hospitals and pharma industry companies are the customers that we would like to address first, because FAIR health research data in all of Europe would mean accessing to vast amount of dispersed data, hence improving the quality of their research.</p>
Competitors	<p>There are more general FAIRification workflows such as GO FAIR’s FAIRification Process, which is not specialized for health data, hence not specialized for sensitive data either. To the best of our knowledge, FAIR4Health FAIRification Workflow is the first comprehensive workflow definition addressing the challenges of healthcare and health research data.</p>
Use model	<p>The FAIR4Health FAIRification Workflow has already been published as an open-access guideline to the scientific community. In the scope of the FAIR4Health project, a FAIR data certification roadmap for EU health research institutions aiming to FAIRify their datasets is being implemented as well.</p>

⁸ <https://op.europa.eu/en/publication-detail/-/publication/d375368c-1a0a-11e9-8d04-01aa75ed71a1>

	In the next step, it can evolve to a standard with the joint work of technical and clinical partners with HL7 Foundation (which is a not-for-profit standard developing organization, also a partner of the FAIR4Health project).
Timing	In the scope of FAIR4Health project, technical and functional validation of the FAIRification Workflow has been performed. After the successful completion of the project, validation of applicability of the workflow with another research authority outside the project will be performed to find the answer to the question "Will customers adapt it?". We expect this process to take only few months, then it will be time to go to market.

Table 3. Data Curation Tool market analysis.

Data Curation Tool market analysis	
Problem	<p>Funding agencies (such as European Commission and National Institutes of Health) and pharma industry spend a lot of money for health and biomedical research. In this regard, vast amount of data is needed to be collected and processed. However, since health data reside in isolated silos of healthcare and/or health research institutions in various formats, the cost of achieving this is extremely high.</p> <p>Likewise, the European Union has issued a Report about the costs of NOT having FAIR data⁹. This report states, that the cost of NOT having FAIR data is approximately €10.2bn per year for the EU. In addition to these costs, the open data economy suggests that the impact on innovation of FAIR could add another €16bn to the minimum cost estimated. That would make a total of at least €26.2bn per year.</p> <p>FAIR principles and health data standards are important concepts to achieve health data sharing and increase the potential of available healthcare data for secondary use and health research data/results for wider, more accurate and ground-breaking results.</p> <p>HL7 FHIR is a well-established and widely-used health data exchange standard. It is a troublesome and laborious work to transform already available data to HL7 FHIR and to follow the FAIR principles while utilizing HL7 FHIR and performing the transformation. Software/Tooling support can significantly decrease the burden of data transformation.</p>
Alternative solution	<p>Most of the potential customers solve this problem by developing and maintaining custom adapters from their own proprietary information models to the standard models. Often, these potential customers invest in several custom software to maintain their integration with different networks (OMOP, i2b2, PCORnet etc.) or standards (openEHR).</p> <p>There are a number of tools to ease the task of FHIR transformation such as Microsoft FHIR Converter, but such existing solutions do not yet provide intuitive graphical user interfaces and they require a deep technical understanding of both the software itself and the FHIR standard.</p> <p>There are three major software tools which help transform existing data into HL7 FHIR:</p>

⁹ Report issued by the European Union about the costs of NOT having FAIR data: <https://op.europa.eu/en/publication-detail/-/publication/d375368c-1a0a-11e9-8d04-01aa75ed71a1>

	<ul style="list-style-type: none"> • Microsoft FHIR Converter • Firely • CAMP FHIR <p>None of them provides a GUI. None of them programmatically supports FHIR profiles.</p>
Competitive advantages and innovative aspects	<ul style="list-style-type: none"> • The most important advantage of the Data Curation Tool is that it provides an intuitive graphical user interface (GUI) which enable the users to define the mapping rules between the source data and HL7 FHIR, implicitly following the FAIR principles. Thanks to the GUI, users do not need to deal with configuration files and command line screens as in the existing solutions to perform the task. As a result, curation process can be handled in an easier way with less amount of work in less amount of time. • The Data Curation Tool supports versions of existing mappings, so changes to existing use cases or future use cases can be served more quickly. In existing custom solutions, the software is needed to be updated and new version needs to be released. However, in Data Curation Tool, this is just an update on the existing configuration. Therefore, the Data Curation Tool enables speeding up the process. • The Data Curation Tool supports HL7 FHIR profiles which enforces the users in a non-technical way to meet the criteria set by the target information model to become FAIR and standards compliant. • In this way, the Data Curation Tool facilitates the re-use and sharing of research data, aiming to accelerate the discovery of scientific knowledge and facilitate research advances.
Description	<p>The Data Curation Tool is a standalone, desktop application to transform existing healthcare and/or health research data (from relational databases or Excel/CSV files) to HL7 FHIR standard in line with the FAIR principles. In FAIR4Health, we have analyzed how HL7 FHIR can support the application of the FAIR Principles in the following document: https://osf.io/ghxz9/</p>
Target market	<p>In our exploitation plan, our initial target market are the following bodies in the European Union:</p> <ul style="list-style-type: none"> • Funding agencies or research networks aiming to improve the capacity for sharing and reuse of health research data, • Pharma industry companies aiming to access academic EHR data, • Data managers in health research institutions aiming to collaborate with other institutions in order to improve the impact of their research, • Public and private hospitals aiming to improve the value of their research. <p>In addition, in the future, there will be a lot of data preparation tasks that currently conform to some arbitrary XML schema but are likely to “move” to HL7 FHIR standard in some time. Some examples are:</p> <ul style="list-style-type: none"> • Data for reimbursement (health insurances) • Data for controlling • Quality reports for external agencies • Data exports for clinical or epidemiological registries (e.g. cancer) • Data for infection control (COVID-19 and others) • Data portability for patients (Article 20 of GDPR) • e-Source for clinical trials <p>The Data Curation Tool can be used for achieving this, hence our next target</p>

	market will be the hospitals that are required to do it, by laws or by getting money.
Early Adopters	<p>Data scientists and data managers in health research organizations, private hospitals and pharma industry companies are the customers that we would like to address first, because FAIR health research data in all around the Europe would mean accessing to vast amount of dispersed data, hence improving the quality of their research.</p> <p>In addition, healthcare institutions that</p> <ul style="list-style-type: none"> • want to share and re-use their existing data for secondary purposes (through associated license and financial agreements). • want to publish their results to be re-used and utilized with results derived from other research initiatives. • have to comply to external-mandated data exports to HL7 FHIR.
Competitors	There are no competitors.
Use model	<p>The Data Curation Tool is implemented as an open-source software within the scope of FAIR4Health project, hence it is free for everyone. Although the tool as it is can be used by the users themselves without any technical support, we aim to provide four services for meeting the customers' further needs:</p> <ul style="list-style-type: none"> • Service for assisting health research performing organizations to convert their raw data to HL7 FHIR by analyzing their source data format and creating mapping definitions for them through Data Curation Tool. • Consultancy and support service for any question they have in mind or any problem they face while using the tool. • Service for adjusting the tool based on specific needs of the customers. • Service for providing verified mappings for quality reporting standards.
Timing	<p>In the scope of FAIR4Health project, the tool has been tested and validated in real environment in five healthcare institutions (SAS, IACS, UNIGE, UPORTO, UCSC). After the successful completion of the project, a second phase of development will be needed in order to provide better logging and error handling mechanisms for a commercialized product. This task is expected to be performed within 6 months after the project ends. After that we will be ready to provide the services listed above.</p>

Table 4. FAIR4Health Machine Learning Hub market analysis.

FAIR4Health Machine Learning Hub market analysis	
Problem	<p>In today's healthcare systems, health data reside in isolated silos of healthcare and/or health research institutions on different technologies, formats, and access methods. In order to perform effective machine learning operations on these scattered data, data need to be integrated and collected in a single location. Although it may sound feasible to represent the data in different technologies and formats, and to support different access methods; this makes it difficult to re-use and share. Once this existing data is FAIR (i.e., machine-accessible and machine-processable), it can be used for machine learning and prediction algorithms by combining with FAIR data of other institutions/organizations, making results more robust and reliable. However, sharing of sensitive health data is strictly controlled by laws and regulations in all around the world such as the Health Insurance Portability and Accountability Act (HIPAA) enacted by the</p>

	<p>United States Congress in 1996, and the General Data Protection Regulation (GDPR) enforced by the European Union in 2018 to preserve the privacy of patient information. As a result, traditional machine learning operations are hard to be applied to healthcare data scattered among different institutions.</p> <p>The FAIR4Health Machine Learning hub overcomes this problem by providing a federated learning platform which enables different organizations to perform joint machine learning operations on their FAIR health related research data without sharing them among themselves or with another third party.</p>
Alternative solution	<ul style="list-style-type: none"> Health data providers usually join health research networks such as OMOP, i2b2 and PCORnet and transform their data into specific data formats of those networks. And then, they implement the necessary adapters to handle the queries within the network. However, these are mostly eligibility-related queries (also called feasibilities) to find eligible patients for clinical and translational research. To the best of our knowledge, there is no “federated learning” environment in production, where the health data providers participate without letting their data out.
Competitive advantages and innovative aspects	<p>The FAIR4Health Machine Learning Hub (MLH) is beneficial for both scientific and healthcare communities. For scientific community, it helps solving the need of discoverability, robustness and representativeness. Researchers need to have “enough” amount of high-quality data to perform statistical and predictive analysis for their research. With MLH, they do not need to search for suitable datasets, try to understand their format and develop custom adapters. They will just use the MLH to perform their analysis in federated way.</p> <p>For healthcare community, MLH will enable developing learning healthcare systems using machine learning technologies by utilizing the information coming from others, but without sharing any sensitive patient data. Once a data provider wants to become a part of the FAIR4Health Machine Learning Hub, our solution provides a unique mechanism to utilize existing health data for a federated machine learning architecture in which the source data never leaves the data source premises.</p>
Description	<p>The FAIR4Health Machine Learning Hub is a digital platform providing the necessary software which helps health data providers to transform their data according to the FAIR principles and to participate in a federated machine learning hub with the FAIRified datasets. The federated machine learning hub provides privacy-preserving distributed model training and prediction capability on top of the connected FAIRified datasets of different health data sources (healthcare/health research institutions, governmental organizations etc.).</p> <p>In this way, the FAIR4Health Machine Learning Hub allows accelerating the discovery of scientific knowledge in the health domain and improving the strength and quality of the scientific evidence provided by the members of the FAIR4Health community and increasing its reproducibility by opening the community to society. The FAIR4Health Machine Learning Hub provides innovative eHealth services that enable the seamless application of new evidence in clinical practice</p>
Target market	<p>In our exploitation plan, our initial target market will be the following bodies in the European Union:</p> <ul style="list-style-type: none"> Data managers and data scientists in health research institutions aiming to perform machine learning operations in a federated way by utilizing

	<p>the data provided by data provider organizations which are member of FAIR4Health Machine Learning Hub,</p> <ul style="list-style-type: none"> • Health data providers (healthcare or health-research organizations, regional/national governments) organizations who would like to enable their existing health data for machine learning algorithms and benefit from others' datasets without sharing any data. • Public and private hospitals aiming to improve their healthcare through learning about the data (AI/ML for healthcare).
Early Adopters	Data managers and data scientists in health research institutions, health data providers (healthcare or health-research organizations, regional/national governments), and public and private hospitals are the first ones that we would like to address first.
Competitors	Users currently perform machine learning practices on data residing at a single location or by using the publicly available research data. To the best of our knowledge, there is no "federated learning" environment in production where the health data providers participate without letting their data out, hence we cannot identify a competitor.
Use model	The FAIR4Health Machine Learning Hub will be commercialized with a subscription mechanism after the FAIR4Health project ends. There will not be need of any further improvements before going to the market, since the Hub will have already been tested and validated in FAIR4Health pilot applications.
Timing	Just after the successful completion of the FAIR4Health project, the FAIR4Health Machine Learning Hub will be fully usable by new users.

2.3. Risk Assessment

During risk assessment, we used the Priority map and a risk matrix template suggested and provided by the HRB experts to identify for each KER the type of risks, their level of importance related to the use of the concerned KER, the probability for such a risk to happen, remedy actions and their probability to succeed.

The Risk Matrix analyses the following six different categories of risks:

1. **Partnership Risks:** internal risk factors related to the composition of the partnership or specific behaviors of the partners, conflict of interests, etc.
2. **Technological Risks:** external factors related to the feasibility of the technology, its level of development, presence of other emerging technologies, etc.
3. **Market Risks:** external risk factors related to fulfilment of marked needs, presence of competitors or alternative products, etc.
4. **IPR Risks:** factors related to the presence of similar previous patents, the possibility to protect the developed technology/product, patent counterfeit, etc.
5. **Environmental risks:** external factors related to the presence or changing in legislations, standards, etc.
6. **Financial risks:** factors related to the availability of funds for bringing the research stage to prototyping industrialization/commercialization.

The severity grade is scored for each risk (1 = low; 10 = high). The grade shows the importance of the risk with respect to successful exploitation. After scoring the severity grade, the second step is to evaluate the probability for the risk to happen (1 = low; 10 =

high). The product of the severity and the probability grade will give the risk grade of the concerned risk factor.

The risk grade coupled with the probability of success positions the risk in the Priority Map:

- A high-risk grade and a low probability of success of the intervention identifies a situation where we may consider discussing to stop the project (**Warning**).
- A high-risk grade with a high probability of success for the remedy action defines a situation where there is the need for an immediate action to ensure exploitation (**Action**).
- A low-risk grade coupled with a high probability of success of the planned remedy defines a situation where it would be preferable to keep an eye on what is happening (**Control**) to be ready to act.
- A low-risk grade and a low probability of success for the remedy, it is a situation does not call for immediate action (**No action**).

Based on these, the risk assessment and priority map of selected KERs are presented in Figure 2, Figure 3 and Figure 4.

	Description of Risks	Degree of criticality	Probability of risk happening	Risk Grade	Potential intervention	Success of Intervention	Conclusion
Partnership Risk Factors							
1	A partner withdraws	8	4	32	Analyze the impact and transfer the role of partner who withdraws to the others	5	Between Control & No Action
2	Disagreement between the partners	10	5	50	Regular meetings to follow the previous experience in FAIR4Health meetings	7	Between Control & Action
Technological Risk Factors							
3	Better technology/methodology exists	9	4	36	Try to find the weaknesses of corresponding technologies and solve them in your solution	4	No Action
Market Risk Factors							
4	Workflow is not validated by external authorities	10	3	30	Find the reasons that cause external authorities to not validate the workflow, revise the solution and update if necessary.	4	No Action
IPR/Legal Risk Factors							
5	It is owned by several partners with different commercialization interests	8	6	48	Negotiate a joint exploitation agreement during the last period of the project (before commercialization)	8	Control
Financial/Management Risk Factors							
6	Marketing and distribution fail due to a weak strategy	7	8	56	Revise the strategy: Who are the early adopters? How to contact them? How to make them use the solution?	6	Action
7	Marketing and distribution fail due to a lack of resources	7	8	56	a.) Adapt strategy to low cost activities b.) Dedicate staff more specifically	5	Between Action & Warning
8	Inadequate communication among partners	5	4	20	Enforce face-to-face meetings to improve the communication among partners	4	No Action
Environmental/Regulation/Safety risks:							
9	Product/service does not comply with FAIR principles	7	2	14	Improve the implementation of tool/service according to the specifications	4	No Action

Figure 2. FAIRification Workflow risk assessment.

	Description of Risks	Degree of criticality	Probability of risk happening	Risk Grade	Potential intervention	Success of Intervention	Conclusion
Partnership Risk Factors							
1	Partners carry out low quality trainings/consultancy	5	7	35	Regular meetings to improve performance and update partners on new developments, exchange on experiences etc	5	Between Control & No Action
2	Disagreement between the partners	10	5	50	Regular meetings to follow the previous experience in FAIR4Health meetings	7	Between Control & Action
Technological Risk Factors							
3	Clients do not like the platform/tool and thus also the trainings are not of interest	8	6	48	Adapt the trainings so that they are more methodological and focus less on one specific software	4	No Action
4	Better technology/methodology exists	9	4	36	Try to find the weaknesses of corresponding technologies and solve them in your solution	4	No Action
5	Earlier patent exists	7	3	21	Analyze the existing patents, revise the solution and update the scope if necessary	4	No Action
6	Performance issues arise during the usage of platform/tool	5	8	40	Find the cause and fix it. Improve the specifications of servers	4	No Action
Market Risk Factors							
7	Nobody buys the product. Nobody needs it	9	3	27	Change the marketing strategy (needs a business model validation before go-to-market strategy)	4	No Action
8	Similar product developed by other people	7	5	35	Change the marketing strategy. Include the list of the potential competitors in the final deliverable regarding exploitation and assessing the benefits of our solution against potential competitors.	4	No Action
9	No partner or third party is willing to carry out the commercialization	9	3	27	Explore different possibilities before project ends.	4	No Action
IPR/Legal Risk Factors							
10	It is owned by several partners with different commercialization interests	8	6	48	Negotiate a joint exploitation agreement during the last period of the project (before commercialization)	8	Control
Financial/Management Risk Factors							
11	Marketing and distribution fail due to a weak strategy	7	8	56	Revise the strategy: Who are the early adopters? How to contact them? How to make them use the solution?	6	Action
12	Marketing and distribution fail due to a lack of resources	7	8	56	a.) Adapt strategy to low cost activities b.) Dedicate staff more specifically	5	Between Action & Warning
13	Inadequate communication among partners	5	4	20	Enforce face-to-face meetings to improve the communication among partners	4	No Action
Environmental/Regulation/Safety risks:							
14	Product/service does not comply with GDPR	10	4	40	Improve the implementation of tool/service according to the regulations	4	No Action
15	Product/service does not comply with FAIR principles	7	2	14	Improve the implementation of tool/service according to the specifications	4	No Action

Figure 3. Data Curation Tool risk assessment.

	Description of Risks	Degree of criticality	Probability of risk happening	Risk Grade	Potential intervention	Success of Intervention	Conclusion
Partnership Risk Factors							
1	Partners carry out low quality trainings/consultancy	5	7	35	Regular meetings to improve performance and update partners on new developments, exchange on experiences etc	5	Between Control & No Action
2	A partner withdraws	8	4	32	Analyze the impact and transfer the role of partner who withdraws to the others	5	Between Control & No Action
3	Disagreement between the partners	10	5	50	Regular meetings to follow the previous experience in FAIR4Health meetings	7	Between Control & Action
Technological Risk Factors							
4	Clients do not like the platform/tool and thus also the trainings are not of interest	8	6	48	Adapt the trainings so that they are more methodological and focus less on one specific software	4	No Action
5	Better technology/methodology exists	9	4	36	Try to find the weaknesses of corresponding technologies and solve them in your solution	4	No Action
6	Earlier patent exists	7	3	21	Analyze the existing patents, revise the solution and update the scope if necessary	4	No Action
7	Performance issues arise during the usage of platform/tool	5	8	40	Find the cause and fix it. Improve the specifications of servers	4	No Action
8	Lack of suitable PPDDM methods	8	5	40	Implement new PPDDM methods	4	No Action
Market Risk Factors							
9	Nobody buys the product. Nobody needs it	9	3	27	Change the marketing strategy (needs a business model validation before go-to-market)	4	No Action
10	Similar product developed by other people	7	5	35	Change the marketing strategy: include the list of the potential competitors in the final deliverable regarding exploitation and assessing the benefits of our solution against potential competitors	4	No Action
11	No partner or third party is willing to carry out the commercialization	9	3	27	Explore different possibilities before project ends.	4	No Action
IPR/Legal Risk Factors							
12	It is owned by several partners with different commercialization interests	8	6	48	Negotiate a joint exploitation agreement during the last period of the project (before commercialization)	8	Control
Financial/Management Risk Factors							
13	Marketing and distribution fails due to a weak strategy	7	8	56	Revise the strategy: Who are the early adopters? How to contact them? How to make them use the solution?	6	Action
14	Marketing and distribution fails due to a lack of resources	7	8	56	a.) Adapt strategy to low cost activities b.) Dedicate staff more specifically	5	Between Action & Warning
15	Inadequate communication among partners	5	4	20	Enforce face-to-face meetings to improve the communication among partners	4	No Action
Environmental/Regulation/Safety risks:							
16	Product/service does not comply with GDPR	10	4	40	Improve the implementation of tool/service according to the regulations	4	No Action
17	Product/service does not comply with FAIR principles	7	2	14	Improve the implementation of tool/service according to the specifications	4	No Action

Figure 4. FAIR4Health Machine Learning Hub risk assessment.

2.4. Exploitation Roadmap

The Exploitation Roadmap is a method designed to help the consortium to identify and plan activities to be performed after the end of the project. It is designed to mitigate the risks and pave the way toward use and a stronger impact.

In the exploitation plan, we described the actions planned to be executed 3-6 months after the end of project and the role of the partners involved in these actions. When applicable, we listed the milestones to be used for monitoring the implementation. Then, we performed the cost estimation to implement planned activities, and estimated the initial revenues and eventual profits once the KERs will be commercialized (1 and 3 years after use). We further improved the calculation of revenues during the Business Plan creation which is explained in Section 3. Finally, we described the impact in terms of growth and benefits for the society.

Table 5, Table 6 and Table 7 present the exploitation roadmap of the FAIRification Workflow, Data Curation Tool and the FAIR4Health Machine Learning Hub, respectively.

Table 5. FAIRification Workflow exploitation roadmap.

FAIRification Workflow exploitation roadmap	
Actions	<p>The exploitation roadmap for the FAIRification Workflow will be shaped around two items which will run in parallel after the end of the project: standardization and proposition of a new research project.</p> <p>The FAIRification Workflow is a methodology which has already been published as open access¹⁰. The partners seek to exploit it through a new research project in the upcoming Horizon Europe work programme of European Commission.</p> <p>Technical and functional validation and certification mechanism of the FAIRification Workflow have already been performed in the project. After the project ends, first, a second-phase validation will be performed to assess the adoption of external research authorities. Then the standardization activities for the workflow will be initiated.</p>
Roles	<p>The FAIRification Workflow has been developed jointly by the whole FAIR4Health consortium (SAS, IACS, UC3M, ATOS, HL7, IMISE, AMC, UNIGE, PLRI, UCSC, EFMI, UEDIN, GAR, SRDC, UP, IPBV). The partners who would like to be part of new research project will be involved in the preparation of the proposal. The proposal will be led by the existing project coordinator SAS. SAS will be responsible from organizing the work and inviting partners.</p> <p>The second-phase validation and standardization activities will be led jointly by SAS, SRDC and HL7</p>
Milestones	<p>New research project (by the first half of 2022):</p> <ul style="list-style-type: none"> • corresponding Horizon Europe call Identified – December 2021 • new project idea developed, and consortium built– January 2022 • Proposal submitted – April 2022 <p>Since the work programme of Horizon Europe has not been announced yet, the dates are currently estimated.</p> <p>We aim to perform the second-phase validation within the 3 months after the project ends, which is by March 2022. After successful validation, we will start the work on standardization immediately</p>
Financial costs	N/A
Revenues	Participation in further R&D activities will bring new funds to FAIR4Health partners to continue working on the research of the FAIRification of health data. It may not be revenue, but it can be considered as a profit in some way.
Other sources of coverage	The cost of participating in the proposal writing and submission work of a new Horizon Europe research project, as well as staff and technical resources, will be covered by the participating partners' own budget.
Impact in 3-year time	Health data reside in different data silos in various formats in all around the Europe, which creates a crucial interoperability challenge for data reuse and

¹⁰ Sinaci, A. A., Núñez-Benjumea, F. J., Gencturk, M., Jauer, M. L., Deserno, T., Chronaki, C., ... & Parra-Calderón, C. L. (2020). From raw data to FAIR data: the FAIRification workflow for health research. *Methods of Information in Medicine*, 59(S 01), e21-e32.

	<p>exploitation. In addition, due to the nature of the health data, that is sensitive data, it is necessary to address ethical, security and legal, requirements. The FAIRification Workflow focuses on specific requirements of health data and proposes step-by-step guidelines to apply FAIR principles in healthcare domain. Application of FAIRification Workflow on health data by research institutions and healthcare facilities will provide FAIRness on those data. As a result, the time and money usually spent on finding, accessing, integrating and using different data for research purposes will not need to be spent. In addition, since there will be more rich data, facilitating the secondary use of them as well as the application of better statistical and artificial intelligence operations will be enabled.</p>
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Table 6. Data Curation Tool exploitation roadmap.

Data Curation Tool exploitation roadmap	
Actions	<p>At the end of FAIR4Health project, the Data Curation Tool will be at TRL6 (technology demonstrated in relevant environment) after its successful demonstration in two pilot studies by five healthcare institutions. These institutions will continue using the tool with all the functionalities after the project ends.</p> <p>Although the software itself has been completely developed against its functional requirements (v1), a second phase of development will be needed in order to provide better logging and error handling mechanisms for a commercialized product. Then, it can be solved as v2.</p> <p>SRDC will take advantage of the dissemination and communication activities during the last phase of the project to create awareness of this tool among stakeholders and pave the way for the commercialization after the project.</p> <p>The actions planned to be executed after the end of the project are:</p> <ul style="list-style-type: none"> • Final improvements and making v2 ready (January 2022) – It will start immediately after the project ends. • Development of a website for the tool (January 2022) – It will start immediately after the project ends and will run in parallel with the first item. • Provision of freemium and premium membership opportunities (February 2022)– They will be decided and announced after the website is ready. • Establishing Customer Support & Marketing teams (March 2022) – Marketing activities will start just from the beginning. Customer support services will be made available at M4. • Release publications & media appearances (May 2022) – This will be performed just after the above items are finished. • Further R&D activities (June 2022) – Together with the “Adjustment service for adding new functionalities based on customer’s needs” explained below, R&D activities on the tool will be continued and the tool will be kept improved.
Roles	All the work will be led and carried out by SRDC.
Milestones	N/A
Financial costs	For customer support and marketing, 1 Marketing Manager, 1 Product Manager and 2 Developers will be hired in the first year. In the second year, one more developer will be hired. In the third year, since no further major development is

	<p>expected, the developers will start working part-time.</p> <p>Considering average PM rate of €4500, the financial costs will be:</p> <p>1st year - €216,000</p> <p>2nd year - €270,000</p> <p>3rd year - €216,000</p> <p>In addition, a patent application will be made to protect the rights on the tool - €7,350 calculated with the information provided by European Patent Office (https://www.epo.org/service-support/faq/own-file.html)</p>
Revenues	<p>Free version – Direct use of open-source version of the tool which is available in the GitHub repository (https://github.com/fair4health/data-curation-tool).</p> <p>Premium version – Consists of following four services:</p> <ul style="list-style-type: none"> • Training service - €250 per person for two-days long online training service • Consultancy and support service for answering the questions of customer – €250 SME / €1,000 large organization monthly fee (only e-mail communication) • Assistance service by using the tool on behalf of customer <ul style="list-style-type: none"> ◦ Mapping configuration for a single data source – €15,000 ◦ Implementation of code system mappings – €2,500 ◦ Maintenance – 20% of the initial cost • Adjustment service for adding new functionalities based on customer's needs – cost depends on the needs, hence €500 per hour <p>1st year – The target numbers are: (i) 5 SME and 5 large organization per month for the consultancy and support service, (ii) 5 organization to use assistance service, each require 2 data sources with 3 code system mappings, (iii) 3 organization to use adjustment service, each require one month of time (144 hours), (iv) 60 persons for the training service. The revenue would be: (i) €75,000 + (ii) €225,000 + (iii) €216,000 + (iv) €15,000 = €531,000</p> <p>2nd year - The target numbers are: (i) 10 SME and 10 large organization per month for the consultancy and support service, (ii) 10 organization to use the assistance service, each require 2 data sources with 3 code system mappings, (iii) 6 organization to use the adjustment service, each require one month of time (144 hours), (iv) 120 persons for the training service. The revenue would be: (i) €150,000 + (ii) €450,000 + (iii) €432,000 + (iv) €30,000 = €1,062,000</p> <p>3rd year - The target numbers are: (i) 20 SME and 20 large organization per month for the consultancy and support service, (ii) 20 organization to use the assistance service, each require 2 data sources with 3 code system mappings, (iii) 2 organizations to use the adjustment service, each require one month of time (144 hours), (iv) 240 persons for the training service. The revenue would be: (i) €300,000 + (ii) €900,000 + (iii) €144,000 + (iv) €60,000 = €1,404,000</p>
Other sources of coverage	<p>After the FAIR4Health project ends, the financial resource to cover costs incurred before collecting the first revenues will be the SRDC's own budget.</p>
Impact in 3-year time	<p>Benefits for the society: The analysis of data and extracting knowledge from it has become an important concept for many different domains including healthcare. However, as the data resides in heterogenous and isolated data silos, extraction of actionable insights / intelligence is troublesome. Therefore, application of FAIR principles in health domain is an important concept for enabling secondary use of health data. The Data Curation Tool enables the FAIRification of raw health data through a GUI in an easier way, hence it can</p>

	<p>provide interoperability between different health data sources. Likewise, the Data Curation Tool provides a potential impact on health research outcomes due to facilitate the data sharing and reuse to accelerate the knowledge discovery and improve the strength and quality of scientific evidence.</p> <p>Benefits for the economy: By enabling health data to be FAIR, the Data Curation Tool will provide direct economic savings for the customers (health research institutions, healthcare delivery organizations, insurance companies, pharma industry among others) derived from the optimization of resources devoted to their respective activities.</p>
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Table 7. FAIR4Health Machine Learning Hub exploitation roadmap.

FAIR4Health Machine Learning Hub exploitation roadmap	
Actions	<p>The actions planned to be executed after the end of the project are:</p> <ul style="list-style-type: none"> • Development of a product website for the Machine Learning Hub, including user guide and video tutorial (December 2021) – It will start immediately. • Provision of subscription opportunities (January 2022)– They will be decided and announced after the website is ready. • Establishing Customer Support & Marketing teams (March 2022) – Marketing activities will start just from the beginning. Customer support services will be made available at April 2022. • Release publications & media appearances (May 2022) – This will be performed just after the above items are finished.
Roles	<p>Since Machine Learning Hub is a tool jointly co-owned by SRDC and ATOS, all the work will be carried out by these two partners as following:</p> <ul style="list-style-type: none"> • Development of a product website – ATOS • User guide and video tutorial – ATOS • Provision of subscription opportunities – SRDC • Establishing Customer Support & Marketing teams – SRDC • Release publications & media appearances – SRDC & ATOS together.
Milestones	N/A
Financial costs	<p>A powerful machine at Amazon Web Servers will be bought to serve the FAIR4Health Machine Learning Hub. It will cost around \$100 per month.</p> <p>For customer support and marketing, 1 Marketing Manager and 1 Product Manager will be hired in the first year.</p> <p>Considering average PM rate of €4500, the financial costs will be:</p> <p>1st year - €108,000</p> <p>2nd year - €108,000</p> <p>3rd year - €108,000</p>
Revenues	<p>The FAIR4Health Machine Learning Hub will be commercialized with subscription mechanism. Before this, there will be a preliminary step where the data owners connect their data to the environment. Data owners will pay a fee to FAIRify their data and serve their FAIR data within the FAIR4Health Machine Learning Hub. This fee is equivalent to the pricing of the Data Curation Tool. On the other hand, there is an incentive for the data owners to FAIRify and connect their data to the hub; they will receive their share from the subscription fees paid by the</p>

	<p>customers who want to use the hub to train machine learning models.</p> <p>Another group of users, i.e., researchers who does not have their own data or want to exploit the power of several other datasets, will subscribe to the machine learning hub and will be able to train models and use them for predictions using the already connected datasets. Data owners who connect their datasets to the hub are inherent subscribers of the system, meaning that they will be able to use the hub to train models and use the already trained models for predictions.</p> <p>The monthly subscription prices will be</p> <ul style="list-style-type: none"> • 100 prediction requests – €990 • Unlimited prediction requests – €4990 • 5 training + 100 prediction requests – €5990 • 5 training + unlimited prediction requests – €9990 • Unlimited training and prediction requests – €19990 <p>50% of the revenue retrieved from the subscribers will be distributed to the connected data owners. 50% will remain in the house to be distributed for the maintainers of the software, namely ATOS and SRDC.</p> <p>1st year – €200,000 subscription fee, hence €100,000 revenue 2nd year – €500,000 subscription fee, hence €250,000 revenue 3rd year – €800,000 subscription fee, hence €400,000 revenue</p>
Other sources of coverage	<p>After the FAIR4Health project ends, the financial resource to cover the costs incurred before collecting the first revenues will be the partners' own budget. The cost of development of a product's website, user guide and video tutorials will be covered by ATOS, while the other costs will be covered by SRDC.</p>
Impact in 3-year time	<p>The FAIR4Health Machine Learning Hub will enable the reproducibility of research by providing health research community a trusted platform in which high-quality FAIR data derived from health research will be accessible under specific requirements required by the data owner, such as specific licence terms, citing conditions, approval from the owner's local research ethical board, etc. Additionally, re-use of research data can cross-fertilize interdisciplinary research, which is essential for addressing the grand challenges of our time.</p>

3. FAIR4Health Business Model

The FAIR4Health Business Model is shaped around the Data Curation Tool as it is the main component enabling FAIRification of health datasets. The business model was developed in several iterations: First, an initial Lean Canvas was filled in (Section 3.1). Then, a more detailed market analysis including customer validation was performed (Section 3.2). After that, a Value Proposition Canvas (VPC) was built according to the results acquired in the first step (Section 3.3). The VPC enabled us to find out the Unique Value Proposition (UVP) of the Data Curation Tool. Then, based on the market analysis, VPC and UVP, we generated the final version of Lean Canvas (Section 3.4). Finally, as the last step constituting the FAIR4Health Business Model, we performed the financial analysis including market sizing, pricing, and costs (Section 3.5).

3.1. Initial (Draft) Lean Canvas

For preparing the Exploitation/Business Plan of a R&D result and define the use mode, it is useful to work with the Lean Canvas. The Lean Canvas is an adaptation of Business Model Canvas by Alexander Osterwalder which Ash Maurya¹¹ created in the Lean Startup spirit (Fast, Concise and Effective startup). Lean focuses on problems, solutions, key metrics and competitive advantages.

The canvas is a good method to focus on the exploitation/business model and start collecting information for it. Among the different type of canvas, the lean business model canvas, by Ash Maurya, is the most suited for R&D projects. It is a powerful tool to be used by the partners to further develop the characterization of their KERs, prepare the materials to be discussed at consortium meetings and draft the exploitation/business plan for a KER.

The end goal of the lean canvas is that an unknowing third-party will be able to review the information provided and understand what the KER and its use is about. They will understand the problem in focus, the customer groups targeted, the solution provided, how it differentiates from competitors, etc. The lean canvas is very important for an effective implementation of dissemination actions. Due to this, it is very important to avoid the use of highly technical language, abbreviations etc., because this may result in third parties not understanding the nature of corresponding KER.

A description of the main steps to draft the lean canvas is:

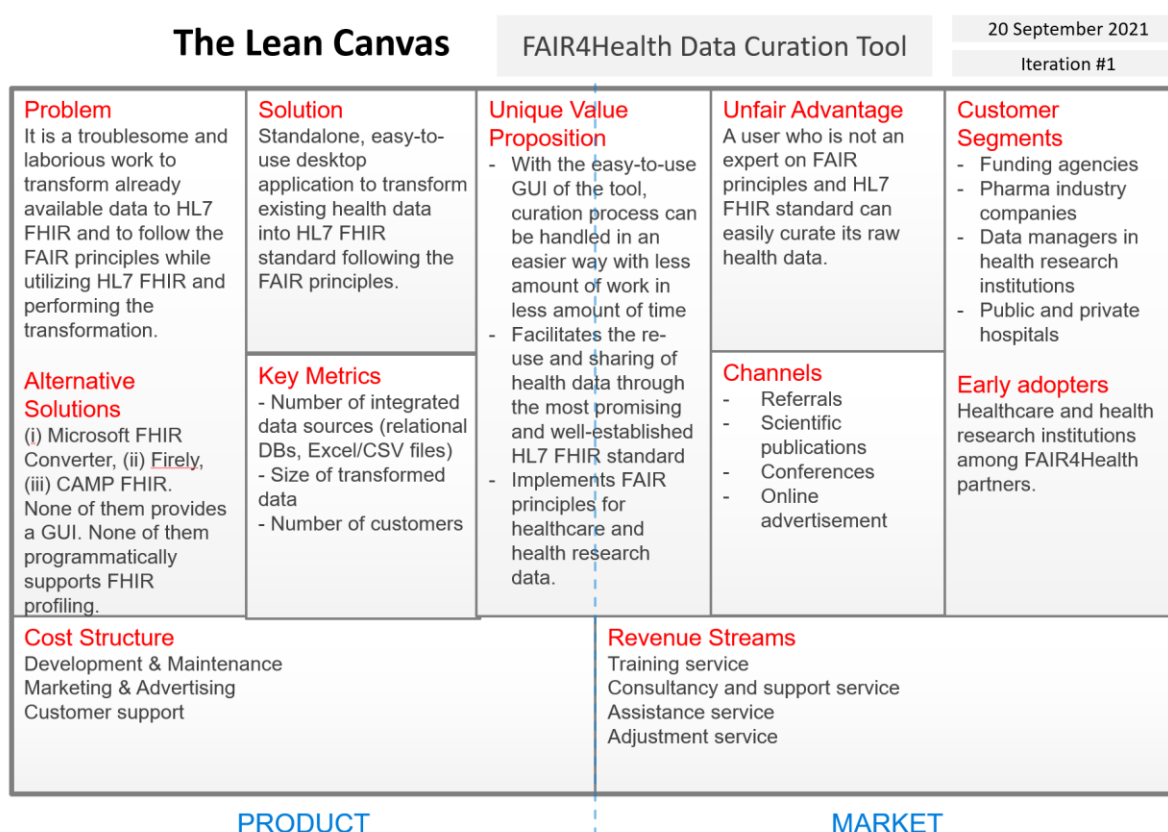
- 1) Problem:** 3 main problems that are addressed.
- 2) Customer Segment:** Who has the problem.
- 3) Early Adopters:** A small niche that is having the biggest problem, the ones that suffer the most.
- 4) Unique Value Proposition:** A single and compelling sentence that makes everybody understand why the solution is unique and far better.
- 5) Solution:** Main features of the solution, what it does, how it does.
- 6) Unfair Advantage:** The thing that gives the solution an advantage in front of the competition with other competitors.
- 7) Channels:** How to reach the customers.
- 8) Revenue Streams:** Main revenue streams when the solution is ready for the market.

¹¹ <http://www.ashmaurya.com/2012/02/why-lean-canvas/>

9) Key Metrics: Key activities to be measured to track the success such as units sold, users registered, number of complaints etc.

10) Cost Structure: Main costs when the solution is ready for the market.

The initial Lean Canvas that we filled in for Data Curation Tool based on this information is presented in Figure 5 below.



Lean Canvas is adapted from The Business Model Canvas (<http://www.businessmodelgeneration.com>) and is licensed under the Creative Commons Attribution-Share Alike 3.0 Unported License.

Figure 5. The initial Lean Canvas.

3.2. Market Analysis (Customer Validation)

During the market analysis while defining the Exploitation Strategy, we focused on the problems of the customers, alternative solutions to this problem, and competitive advantages of our solutions compared to them. However, without validation of specific pain points of customers, it is not possible to know how to focus market segmentation for proper market sizing. In addition, it is also hard to estimate the cost in customer pain points. Therefore, with the guidance of the experts from HRB, we implemented a customer discovery and validation process by using **Jobs to be Done¹² (JTBD)** style

¹² <https://jtbd.info/the-jtbd-research-process-we-used-to-build-our-mvp-for-userlist-io-e300025ab487>

interviewing to understand customers' responsibilities and motivations, current way of working, pain points in their current way of working, and finally view on whether the Data Curation Tool can solve their pain points. JTBD is an interview style that is designed to understand why customers have purchased a certain product/service or what pain point they were trying to solve by buying that product/service. Even if the customer does not already use a solution, it is still possible to use the JTBD style interview to understand customer's motivations, current way of working, and pain points in that way of working.

In our case, since we already have the FAIR4Health solution, we did the interview in two different groups: The first one was consisting of the members of FAIR4Health consortium who had used the tool already or had an idea about what it is. We organized an internal workshop on 1 October 2021 to understand whether the tool solved their pain points, and they have any remaining pain points that the tool did not solve. In the second one, we did an interview with two data managers from a private hospital in Turkey. During these interviews, we did not try to sell the product. Instead, we just gave them the floor in order not to canalize them to a specific point that we have in our mind. As a result of these interviews, we were able to see patterns emerge in pain points and motivations. We utilized this information while filling in the Value Proposition Canvas as explained in the next section.

3.3. Value Proposition Canvas

The objective of Value Proposition Canvas is to find a better approach for creating value for customers and lowering risk of failure. Value proposition describes the benefits customers can expect from a novel solution. It consists of two elements:

Customer profile is for visualizing what matters to the customers. For this, we tried to find answers to the following questions:

- What customers are trying to get done? (Customer jobs)
- What annoys the customers before, during and after getting the job done? (Customer pains)
- What outcomes and benefits customers want? (Customer gains)
- What is the customer priority? (Ranking)

Value map is for describing explicitly how the product and/or service create value. For this, we specified:

- What we offer customers
- How exactly our solution alleviates specific customer pains (Pain relievers)
- How our solution creates customer gains (Gain creators)

As a result of the internal workshop that we held within the consortium and interviews that we had with external data managers, we identified customer jobs, customer pains, and customer gains; and ranked them by importance/relevance. Then, we specified the pain relievers and gain creators for the Data Curation Tool. After that, we matched the gain creators with customer gains and pain relievers with pains. The output Value

Proposition Canvas¹³ is shown in Figure 6 below. As it can be seen in the figure, the tool has a number of features to reduce the customer pains, and benefits to increase customer gains.

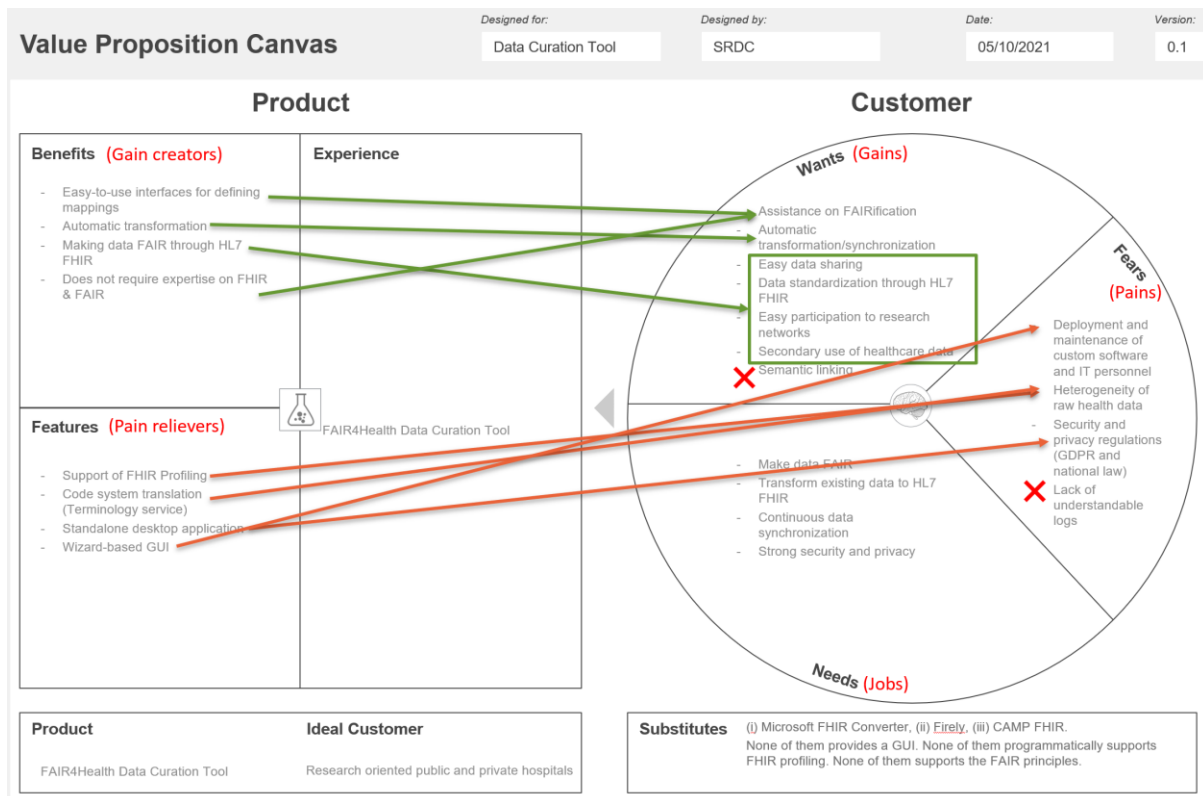


Figure 6. Value Proposition Canvas for Data Curation Tool.

The VPC also helps us to understand the Unique Value Proposition of our solution better. Based on the sentence template "Our(product) helps(ideal customer) who want to(jobs to be done) by(verb such as reducing, avoiding)(a customer pain) and(verb such as increasing, enabling)(a customer gain) unlike(substitutes)", the Unique Value Proposition of Data Curation Tool became:

Our Data Curation Tool helps research-oriented hospitals who want to make their existing health data FAIR by eliminating data heterogeneity and enabling standardization through HL7 FHIR unlike existing solutions having no GUI and not supporting FHIR profiling.

¹³ The template was designed by: Peter J. Thomson, based on the work of Steve Blank, Clayton Christensen, Seth Godin, Yves Pigneur and Alex Osterwalder. (<https://www.strategyzer.com/canvas/value-proposition-canvas>).

3.4. Final Lean Canvas

According to the work presented in previous sections, the updated Lean Canvas (which is also the final version) is presented in Figure 7.

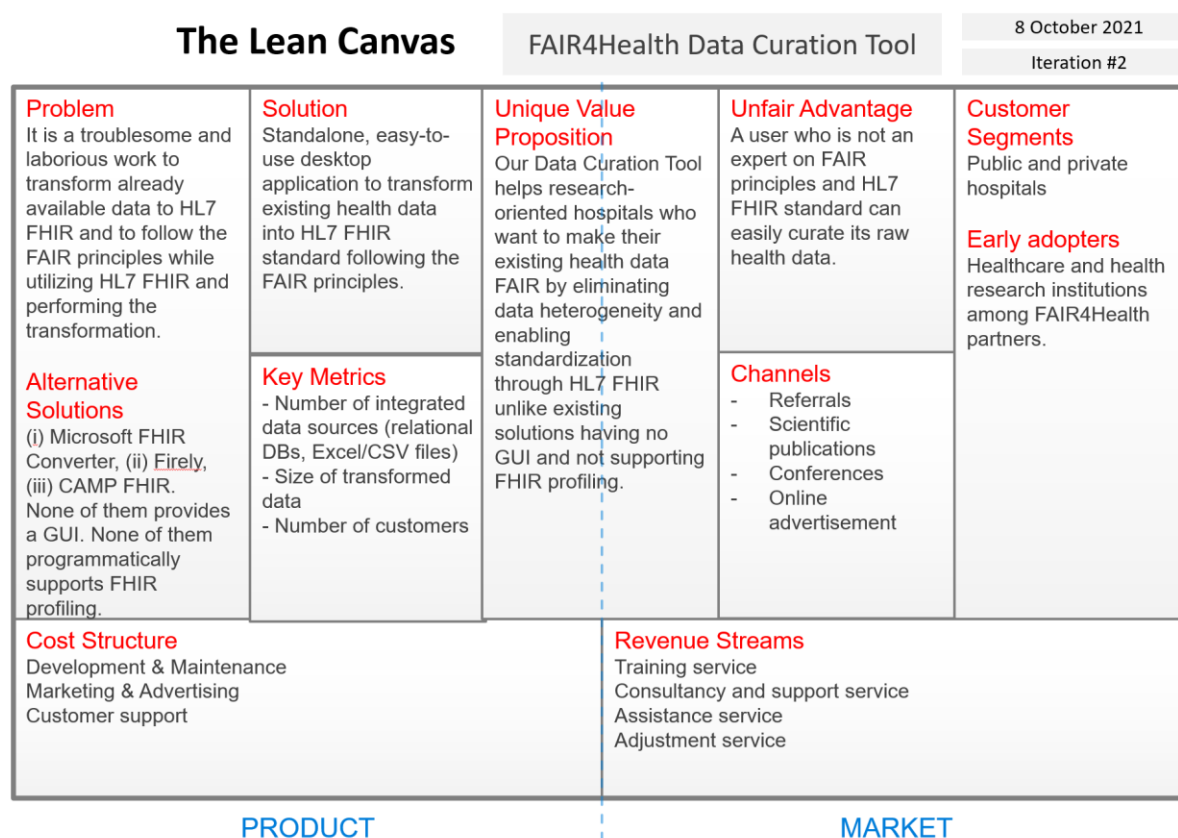


Figure 7. The final Lean Canvas.

3.5. Financial Analysis

3.5.1. Market Sizing

In order to build a solid business plan, we first needed to find out accurate target market sizing. To do this, we used **TAM SAM SOM metrics**¹⁴. These metrics are one of the key components of a business plan, since it enables setting realistic revenue goals, and choosing whether it is worth to enter the target markets in terms of time and resources.

Total addressable market or TAM refers to the total market demand for a product or service. It's the maximum amount of revenue a business can possibly generate by selling

¹⁴ <https://blog.hubspot.com/marketing/tam-sam-som>

their product or service in a specific market. It answers the question of “How big is the largest market”.

Serviceable addressable market or SAM refers to the estimate portion of the market that you could reach now, because due to the limitations of business models, it is not likely to be able to service the total addressable market.

In short-term, it is not possible to capture 100% of the serviceable addressable market with limited resources. Even if there is only one competitor, it would still be extremely difficult to convince an entire market to only buy our product or service. That’s why it’s crucial to measure the **serviceable obtainable market (SOM)** to determine how many customers would realistically benefit from buying our product or service.

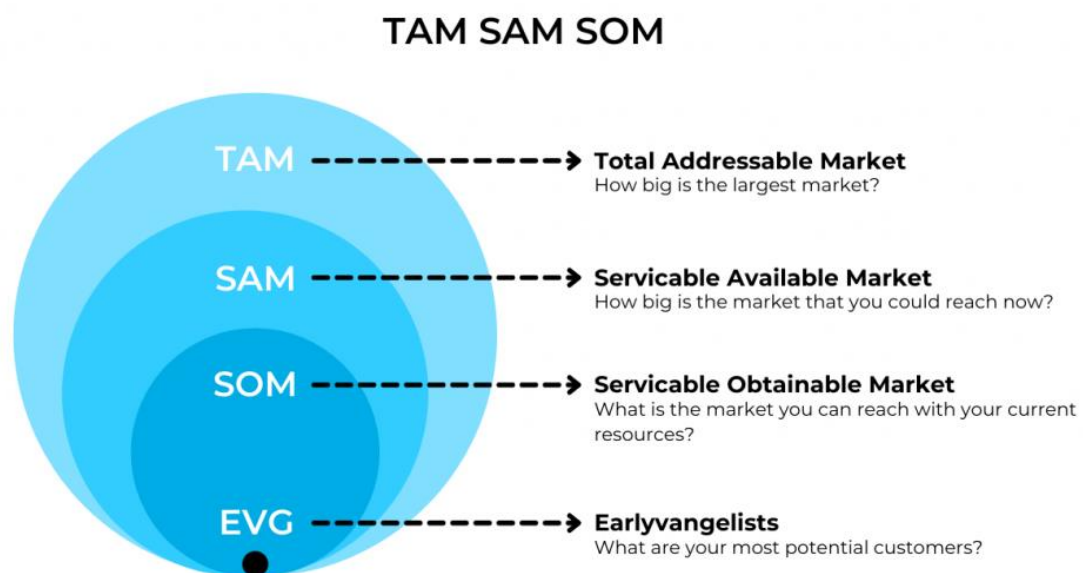


Figure 8. TAM SAM SOM metrics.

According to the “Health at a Glance Europe 2020¹⁵ (2020)” report, in the year 2014, Europe had on average 2.9 hospitals for 100,000 inhabitants, ranging from 1.4 in Slovenia to 9.8 in Cyprus. There were on average 521 hospital beds for 100,000 inhabitants, ranging from about 254 in Sweden and 826 in Germany. We cross-checked different reports reflecting numbers from specific countries and from Europe in total. Based on the “Hospitals In Europe Healthcare Data¹⁶ (2018)”, “Hospitals in Europe - statistics & facts¹⁷ (2021)” reports and information available at “WHO European Health

¹⁵ https://ec.europa.eu/health/sites/default/files/state/docs/2020_healthatglance_rep_en.pdf

¹⁶ https://www.hope.be/wp-content/uploads/2018/07/2018_Hospitals-in-EU-28-Synthesis-final-for-publication-002.pdf

¹⁷ <https://www.statista.com/topics/8361/hospitals-in-europe/>

Information Gateway: Hospitals, total¹⁸, the total number of hospitals in Europe is estimated as 11,500. In theory, our target market can be broadened to all public and private hospitals in Europe, hence we can accept **our TAM as 11,500**.

When it comes down to SAM, our analysis included the potential customers by analysing their willingness through their existing efforts for FAIRification and standardization. We aimed to identify number of hospitals which are actively participating clinical research networks for secondary use of health data. We chose the Observational Health Data Sciences and Informatics (OHDSI), which was previously known as Observational Health Outcomes Partnership (OMOP), as one basis of our SAM analysis. OHDSI-Europe publishes their data notes in Europe¹⁹ and 64 European healthcare organizations are providing data to this clinical research network by transforming their raw data into the format dictated by OHDSI which is called OMOP Common Data Model (CDM). It is also reported that many other European consortia are working with the OMOP-CDM and are enlarging the European data network¹⁹ such as H2O, PIONEER, SOPHIA, MIRACUM, and EHDE. Another basis for our SAM analysis has been these research projects where we identified the potential customers by analysing the partners of these consortiums as shown in Table 8. Among those consortium partners, we eliminated the ones which were already a data partner for OHDSI-Europe and we also eliminated the ones which are not healthcare or health research organizations. And, we counted 56 of such partners from those project consortiums and accepted **our SAM as 120**.

After our extensive analyses on TAM and SAM, we can say that we made a guess for SOM. Once we start addressing the SAM in total as our potential customers, we claim that we can obtain the 1/3 of that market. As a result, **we calculated the SOM as 40**.

It is not unrealistic to expect these numbers to increase in time and that this scenario is not only an interest to a single clinical research network. Organizations want to standardize and FAIRify their health data for other reasons also, but mostly for the secondary use. Sharing data with pharma companies through some (sponsorships) paid approaches is common.

Table 8. European consortia working with the OMOP-CDM (duplicates removed)

Project	The Health Outcomes Observatory project (H2O)	
Coordinator	Medical University of Vienna	https://www.meduniwien.ac.at/web/en/
Partners (Universities, research organization s, public bodies, non- profit groups)	Charité University Hospital	https://www.charite.de/en/
	Karolinska University Hospital	https://www.karolinska.se/en/karolinska-university-hospital/
	King's College London	https://www.kcl.ac.uk/
	KU Lueven	https://www.kuleuven.be/english/
	The Vita-Salute San Raffaele University	https://www.unisr.it/en/
	Vall d'Hebron University Hospital	http://en.vhir.org/portal1/homepage.asp
	The European Institute for Innovation	https://www.i-hd.eu/

¹⁸ https://gateway.euro.who.int/en/indicators/hlthres_78-hospitals-total/

¹⁹ <https://www.ohdsi-europe.org/index.php/national-nodes>

	through Health Data	
Project	PIONEER - The European Network of Excellence for Big Data in Prostate Cancer	
Coordinator	European Association of Urology	https://uroweb.org/
Partners (Universities, research organization s, public bodies, non- profit groups)	European Institute for Systems Biology & Medicine	http://www.eisbm.org/
	Lund University	https://www.lunduniversity.lu.se/
	eCancer	https://ecancer.org/en/
	European Alliance for Personalized Medicine	https://euapm.eu/
	Göteborg University	https://www.gu.se/en
	Imperial College London	http://www.imperial.ac.uk/
	Radboud University Medical Center	https://www.radboudumc.nl/patientenzorg
	Dresden Technical University	https://tu-dresden.de/?set_language=en
	University of Aberdeen	https://www.abdn.ac.uk/
	The UKE Clinic	https://www.ukc.de/english/index.html
	Tampere University	https://www.tuni.fi/en
	Weizmann Institute of Science	https://www.weizmann.ac.il/pages/
Project	SOPHIA - Stratification of Obesity Phenotypes to Optimize Future Therapy	
Coordinator	University College Dublin	https://www.ucd.ie/
Partners (Universities, research organization s, public bodies, non- profit groups)	University of Dundee	https://www.dundee.ac.uk/
	University of Exeter	https://www.exeter.ac.uk/
	Maastricht University	https://www.maastrichtuniversity.nl/
	University of Ulm	https://www.uni-ulm.de/en/
	APC Microbiome Ireland	https://www.ucc.ie/en/
	Swiss Institute of Bioinformatics	https://www.sib.swiss/
	The Institute of Clinical Physiology	http://www.area.pi.cnr.it/
	Dr. Josep Trueta Hospital in Girona & the University of Girona	https://idibgi.org/en/content/presentation
	University Hospital Tübingen	https://www.medizin.uni-tuebingen.de/en-de/das-klinikum
	University Hospital of Lille	https://www.chu-lille.fr/
	European Association for the Study of Obesity	https://easo.org/
Project	MIRACUM - Medical Informatics in Research and Care in University Medicine	
Coordinator	University Hospital Erlangen	https://www.uk-erlangen.de/en/
Partners (Universities, research organization s, public bodies, non- profit groups)	Faculty of Medicine of the Friedrich-Alexander	https://www.med.fau.eu/
	University Hospital Carl Gustav Carus	https://www.uniklinikum-dresden.de/en
	Johann Wolfgang Goethe University Frankfurt	https://www.goethe-university-frankfurt.de/61839351
	University Hospital Frankfurt	https://www.kgu.de/#top
	Medical Faculty of the University of Freiburg	https://www.med.uni-freiburg.de/en
	Medical Center – University of Freiburg	https://www.uniklinik-freiburg.de/en/uniklinikum.html
	Faculty of Medicine of the Justus-Liebig-University Giessen	https://www.uni-giessen.de/fbz/fb11

	University Hospital Giessen	https://www.ukgm.de/home.html
	Faculty of Health Sciences, University of Applied Sciences Giessen	https://www.thm.de/ges/en/
	University Medicine Greifswald	https://www.medizin.uni-greifswald.de/de/home/
	Medical Faculty of the Otto-von-Guericke University Magdeburg	http://www.med.uni-magdeburg.de/en/
	University Medical Center Johannes Gutenberg University Mainz	https://www.unimedizin-mainz.de/index.php?id=240&L=1
	Medical Faculty of the Philipps-University Marburg	https://www.uni-marburg.de/en/fb20
	University Hospital Giessen-Marburg	https://www.ukgm.de/ugm_2/deu/home.html
	University Medical Center Mannheim	https://www.umm.uni-heidelberg.de/fakultaet/
Project	EHDEN - European Health Data & Evidence Network	
Coordinator	Erasmus University Medical Center	https://www.erasmusmc.nl/en
Partners (Universities, research organizations, public bodies, non-profit groups)	National Institute for Health and Care Excellence	https://www.nice.org.uk/
	University of Tartu	https://www.ut.ee/en
	Uppsala Monitoring Center	https://www.who-umc.org/
	University of Oxford	https://www.ox.ac.uk/
	University of Aveiro	https://www.ua.pt/en/university
	Odysseus Data Services	https://odysseusinc.com/

3.5.2. Pricing

The pricing for the Data Curation Tool without VAT and travel expenses of the experts (it will be added if requested) is determined as shown in Table 9. There will be different prices for different services based on the work it requires. For the maintenance, 20% of the total initial cost will be incurred.

Table 9. Pricing for the Data Curation Tool.

Pricing for the Data Curation Tool without VAT and travel expenses	
Software (The DCT)	Free, open-source
Online training service (per person for two-days long online training service)	€ 250
Onsite training service (per person for two-days long onsite training service (+ travel expenses of the expert))	€ 350
Mapping configuration for a single data source (up to 10 entities) (11. entity/table/sheet is considered as a separate data source)	€ 15,000
Implementation of code system mappings (if the mappings are already defined) (per field: from one code system to another code system)	€ 2,500
Maintenance (infrastructure to be provided by the customer)	20% of the total initial cost

(yearly)	
For 1 customer: Mapping of 2 data sources with 3 code system mappings Initial cost = $2 \times 15,000 + 3 \times 2,500$	€ 37,500
Maintenance for the same customer (yearly cost)	€ 7,500

When we combine the numbers we retrieved in TAM SAM SOM with the pricing model of Data Curation Tool, we obtain the numbers presented in Table 10 below. The table shows the maximum amount of revenue that can be retrieved when the maximum number of customers are reached in Serviceable Obtainable Market in one, two, and three years. Please note that the numbers presented in this table is different than the ones presented in Table 6, because we calculate the numbers in here according to the maximum number of customers that can be reached, while it was the minimum in Table 6.

Table 10. Revenue streams on TAM, SAM, SOM.

Revenue streams on TAM, SAM, SOM		
TAM	initial	€ 431,250,000
	yearly	€ 86,250,000
SAM	initial	€ 4,500,000
	yearly	€ 900,000
SOM	initial	€ 1,500,000
	yearly	€ 300,000
	After 1 st year	€ 1,800,000
	After 2 nd year	€ 2,100,000
	After 3 rd year	€ 2,400,000

3.5.3. Financial Costs

The financial costs of the Data Curation Tool are presented in Table 11 below.

Table 11. Financial costs the Data Curation Tool.

Financial costs of the Data Curation Tool	
Personnel	For customer support and marketing, 1 Marketing Manager, 1 Product Manager and 2 Developers will be hired in the first year. In the second year, one more marketing professional will be hired. In the third year, since no further major development is expected, the developers will start working part-time.
PM rate	€ 4,500
1 st year	€ 216,000 ($€ 4,500 \times 4$ full time employee $\times 12$ months)
2 nd year	€ 270,000 ($€ 4,500 \times 5$ full time employee $\times 12$ months)
3 rd year	€ 216,000 ($€ 4,500 \times 3$ full time, 2 part time employee $\times 12$ months)

4. Conclusions and Future Work

In this document, we presented the FAIR4Health exploitation roadmap, business model and marketing strategy. In order to create an effective exploitation roadmap, business model and marketing strategy, the FAIR4Health consortium has received expert support from the Horizon Results Booster (HRB) initiative which is backed by the European Commission. The work and results presented in this document have been achieved as a result of 4 meetings, 2 workshops and 1 seminar conducted with the HRB experts and the project partners.

In the next steps, after the successful completion of the FAIR4Health project, the partners aim to accomplish the exploitation and business plan.

In terms of research & development, Horizon Europe is opening up (and has plans to open up) related calls where the Data Curation Tool can be used and improved for further research and development. A proposal has already been submitted with several partners from the FAIR4Health consortium to "HORIZON-HLTH-2021-TOOL-O6 Innovative tools for use and re-use of health data". Considering the future work on the Data Curation Tool which include: (i) FHIR-to-FHIR conversion for version migration, i.e., from FHIR R4 to R5; (ii) Connect to standardized models and APIs, i.e., HL7 v2; (iii) Auto-configure with already available mappings with FHIR mapping language²⁰, upcoming calls will also be considered with new proposals with these research directions.

On the other hand, in terms of marketing & business, we aim to accomplish following steps:

1. Continue to reach data managers to perform additional interviews with them in several rounds in order to improve the Unique Value Proposition even further.
2. At the end of this, UVP will be proven to be strong, and then we will move to the validation step. We aim to perform validation with OHDSI Europe (OMOP), IMI projects, H2020 projects and pharmaceutical companies (During validation, we can come up with a new UVP for pharma-companies, In such a case, we will use the same methodology described in this document for reaching them).
3. Finally, for marketing & business, we aim to:
 - a. Contact with OHDSI Europe (OMOP): the coordinator is Erasmus MC - Department of Medical Informatics
 - b. Contact with IMI project coordinators to promote the Data Curation Tool and its possible utilization in their projects.

²⁰ <https://www.hl7.org/fhir/mapping-language.html>

- c. Contact FAIR related H2020 projects to promote the Data Curation Tool and its possible utilization in their projects.
- d. Contact with GoFAIR and RDA, identify the related work groups to promote the Data Curation Tool.
- e. Contact with national initiatives for FAIRifying research data such as the NFDI in Germany
- f. Contact with national initiatives for making health care data accessible for research such as the Medical Informatics Initiative in Germany

Last but not least, the partners also aim to apply for the “Go To Market” service of Horizon Results Booster in near future.

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