This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 8[illegible]".

REVERT FINAL EVENT

10 December 2024

"Spazio Europa", via IV Novembre, 149, Rome, Italy

L'evento avrà luogo presso Spazio Europa, gestito dall'Ufficio del Parlamento europeo in Italia e dalla Rappresentanza in Italia della Commissione europea

REVERT
Final Meeting

2024

Pioneering Advances in Personalized Cancer Therapy

Fiorella Guadagni

IRCCS San Raffaele
REVERT Coordinator

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

TaRgeted ThErapy for AdVanced ColorEctal CanceR PaTients (REVERT) H2020 Project G.A. 848098

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

The taRgeted thErapy for adVanced colorEctal canceR paTients (REVERT) project addressed the Topic “Systems approaches for the discovery of combinatorial therapies for complex disorders” (SC1-BHC-02-2019), which belongs to the Work Programme Part: Health, demographic change and wellbeing of the H2020 Work Programme 2018-2020.

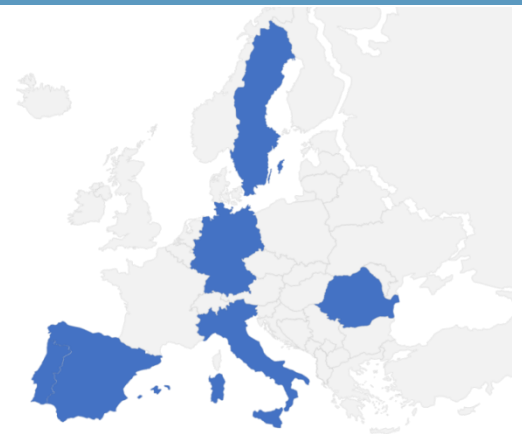
The REVERT consortium involved many excellent EU research institutes and SMEs, as well as several certified biobanks in different countries (Italy, Spain, Germany, Romania, Luxembourg, Sweden) to ensure access to a large amount of data and the involvement of numerous clinical centres.

The project has seen the participation of the following organizations:

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 848098”.

REVERT - taRgeted thErapy for adVanced colorEctal canceR paTients

Acronym	Beneficiary
San Raffaele	San Raffaele Roma Srl
ProMIS	Azienda Ulss 4 Veneto Orientale
MU	Malmo Universitet
GXP	Genxpro Gmbh
BAM	Bundesanstalt Fuer Materialforsch
UMU	Umea Universitet
BioV	Biovariance Gmbh
UCAM	Fundacion Universitaria San Antonio
IRO-IASI	Regional Institute Oncology
LIH-IBBL	Luxemburg Institut of Health
IMAGO_MOL	Clusterul Regional Inovativ De Imagistica Moleculara Si Structurala Nord-est
UTGAD	Univveritatea Tehnica Gheorghe Asachi Din IASI
ROMSOFT	Romsoft Srl
SPIRIDON IASI	Spitatul Clinic Judetean De Urgenta "SF. Spiridon" IASI
EUROCLINIC	Centrul De Oncologie-Euroclinic Srl



REVERT Consortium

IMIB-HGUSL	Servicio Murciano De Salud
FFIS	Foundation Para la Formacion e Investigacion Sanitarias de la Region De Murcia
OLO	Olomedia Srl
UNITOV	Università Degli Studi Di Roma Tor Vergata
UNITOV-PTV	Medical Oncology Operational Unit
JRU-AOUP	Azienda Ospedaliera Universitaria Paolo Giaccone Palermo
JRU-ISPRO	Istituto per lo studio e la prevenzione e la Rete Oncologica
JRU-UNIFI	Università degli Studi di Firenze
JRU-AULSS3	Local Health Unit 3 “Serenissima”
UNITOV-AI	CLaK (Center for Language and Knowledge)

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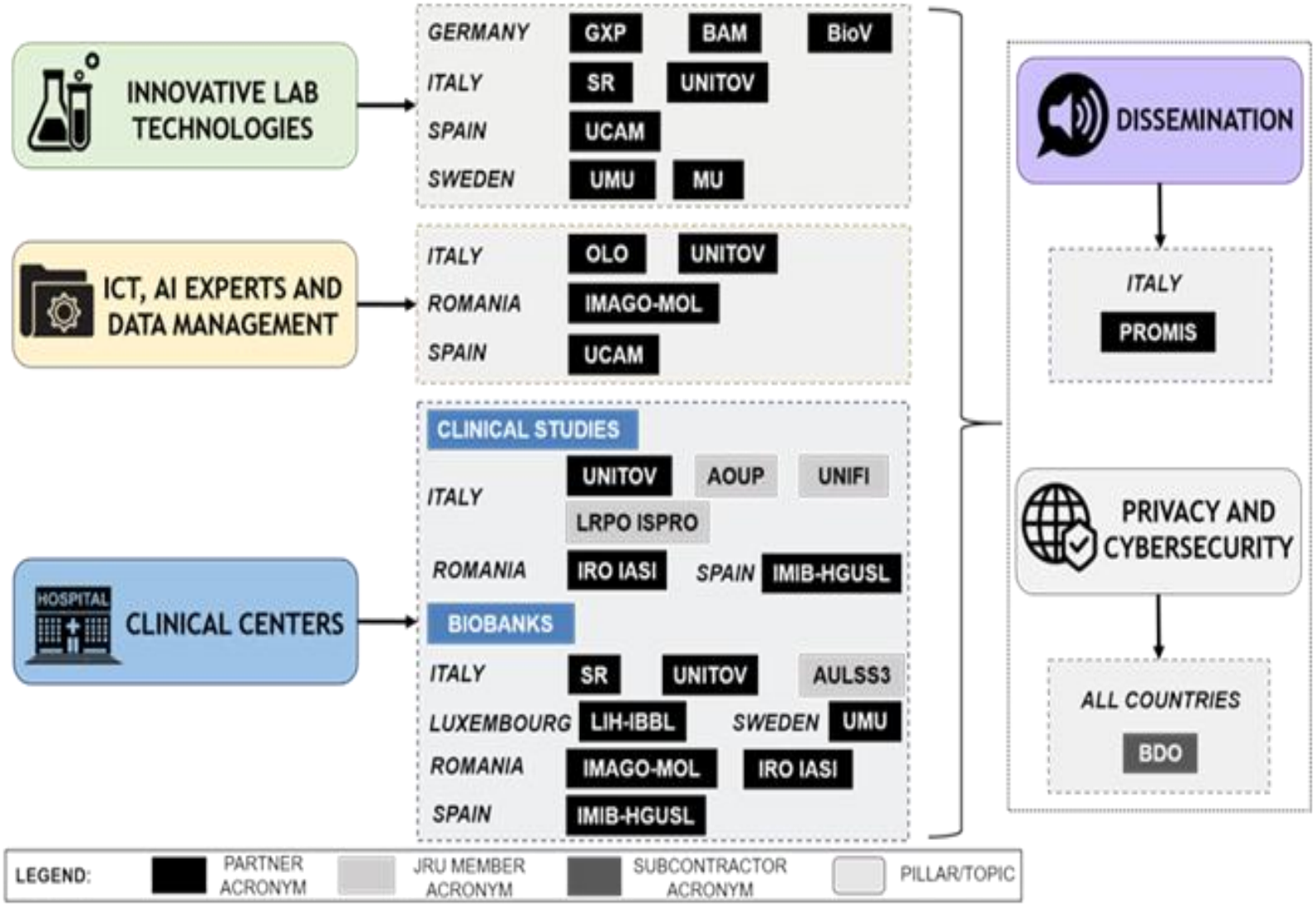

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The REVERT project

1 focused to improve cancer treatment and quality of life with the final goal of a personalized treatment

2 based on the integration of AI into the healthcare systems

3 multidisciplinary structure that foresees an interdisciplinary collaboration among

- ✓ healthcare practitioners
- ✓ AI developers
- ✓ national bodies
- ✓ patients and citizens
- ✓ and across domains

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The REVERT challenge

understanding at system level the pathophysiology of mCRC cancer in patients responding well or poorly to therapies, in order to design optimal strategy for mCRC on a case by case basis, with therapeutic interventions modulated depending on patient's features.

Main target

To develop an improved and innovative model of combinatorial therapy - based on a personalised medicine approach - that identifies the most efficient and cost-effective therapeutic intervention for patients with unresectable mCRC.

REVERT will build up ***an innovative artificial intelligence (AI)-based decision support system*** using a network of biobanks and the experience and the real-world data of several general Hospitals operating in the EU healthcare system

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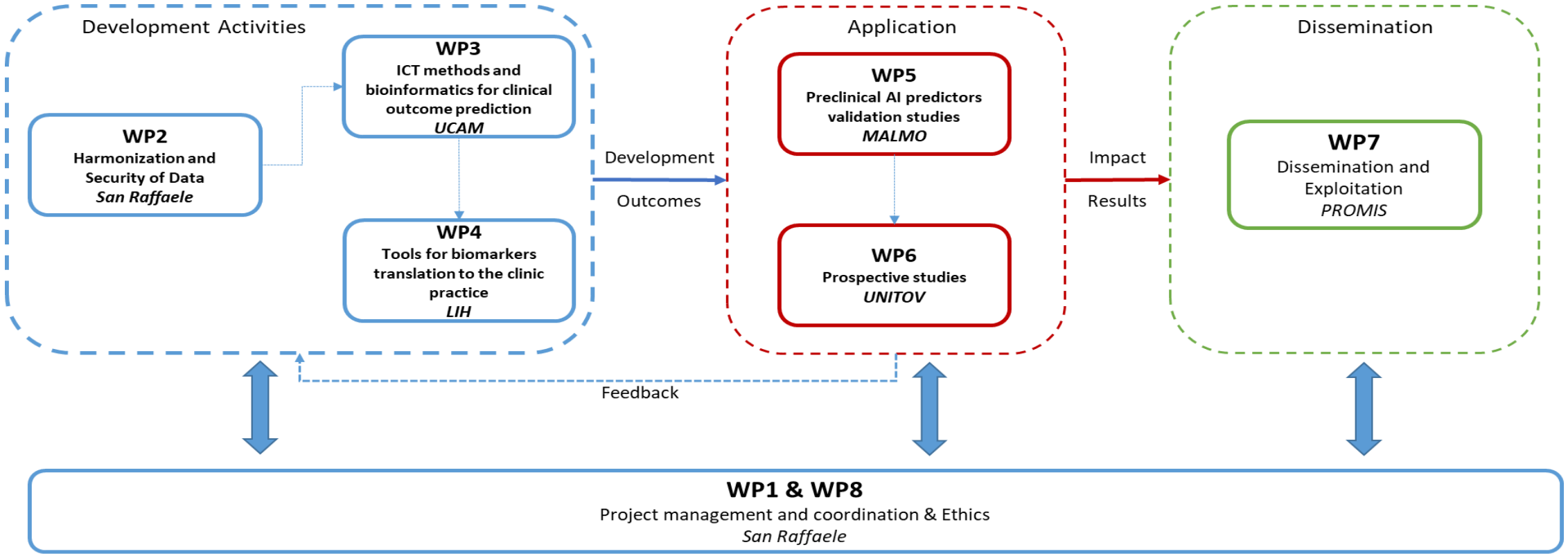

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The project used an information system, the REVERT PLATFORM, that collected and harmonized the data and consists of two main components: the REVERT-DataBase (REVERT-DB) and the REVERT-AI (REVERT software systems).

The REVERT software systems guarantees data integrity and privacy management, in compliance with the EU GDPR (EU Reg. 2016/679), with the beneficiaries' national regulations and with the EU Charter of Fundamental Rights.

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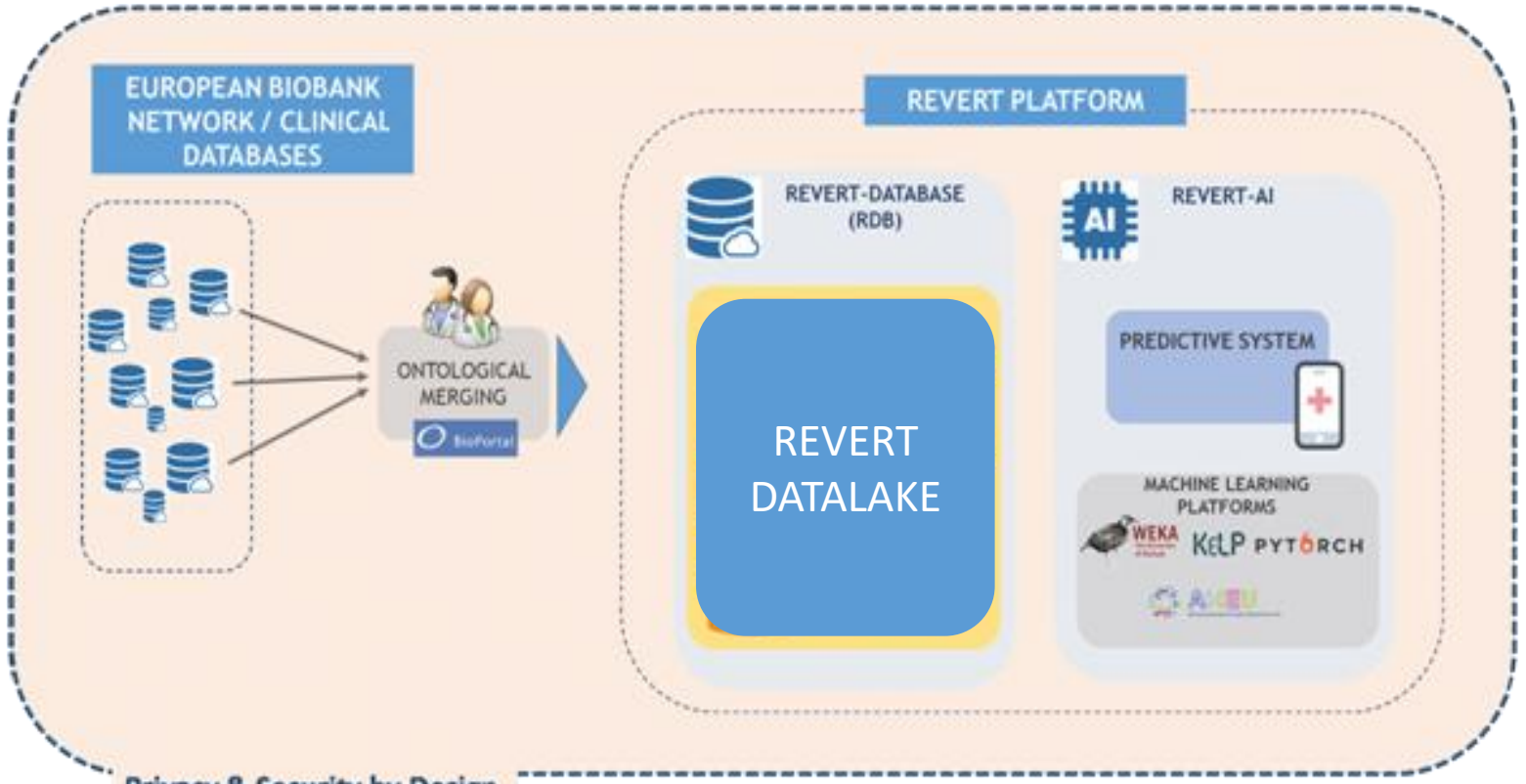

Privacy & Security by Design

Privacy by Design will model all the technical and functional elements of the data processing system. One of the aspects of this Privacy by Design will be the Security by design that will ensure the security of the whole system.

This goal was pursued through the building of the REVERT-DataBase (RDB) thanks to a large number of standardized biobank samples with related structured data, and clinical databases (including known clinical and biological features as well as new, potential prognostic/predictive biomarkers) from several major clinical European centres.

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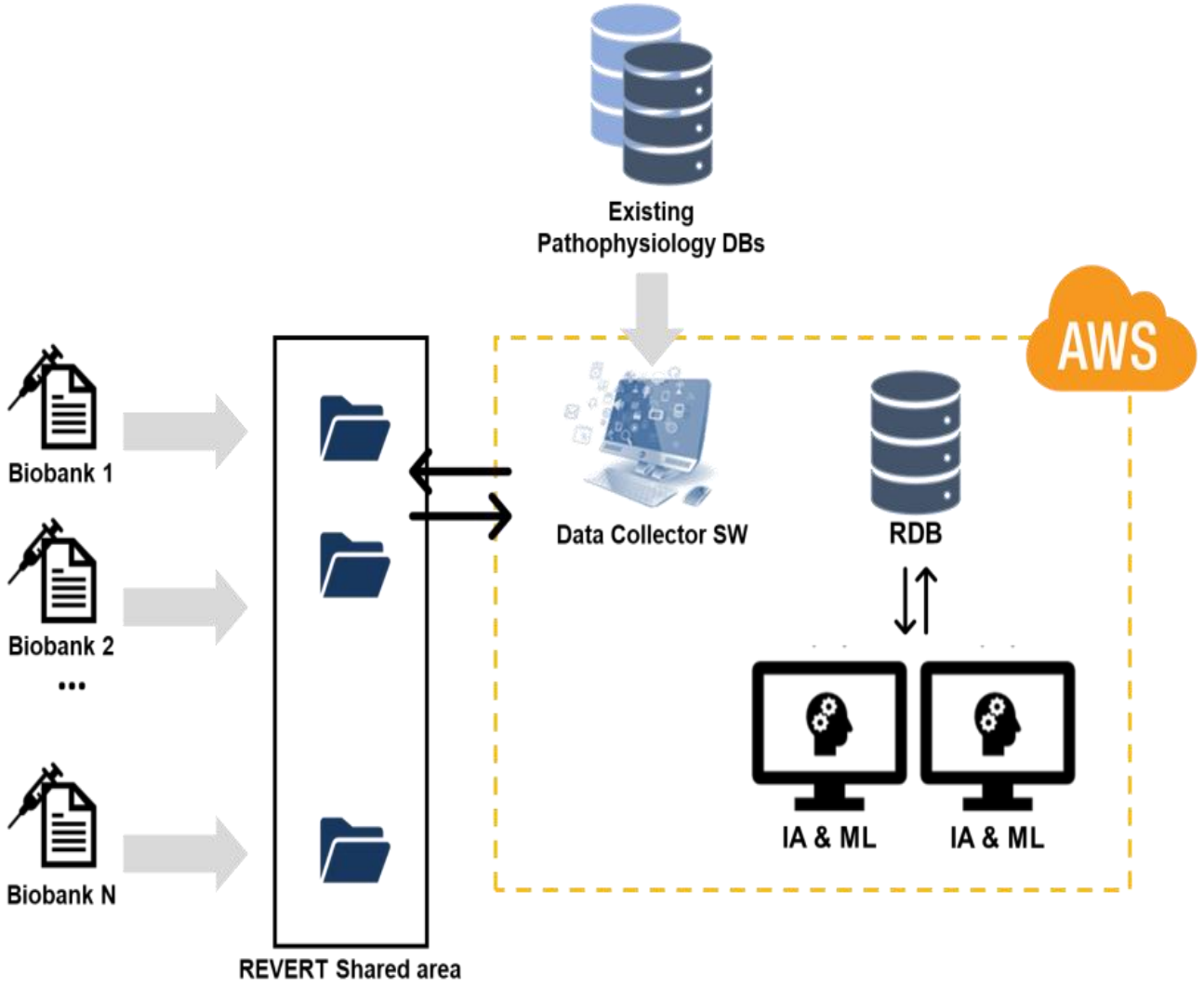
The REVERT architecture



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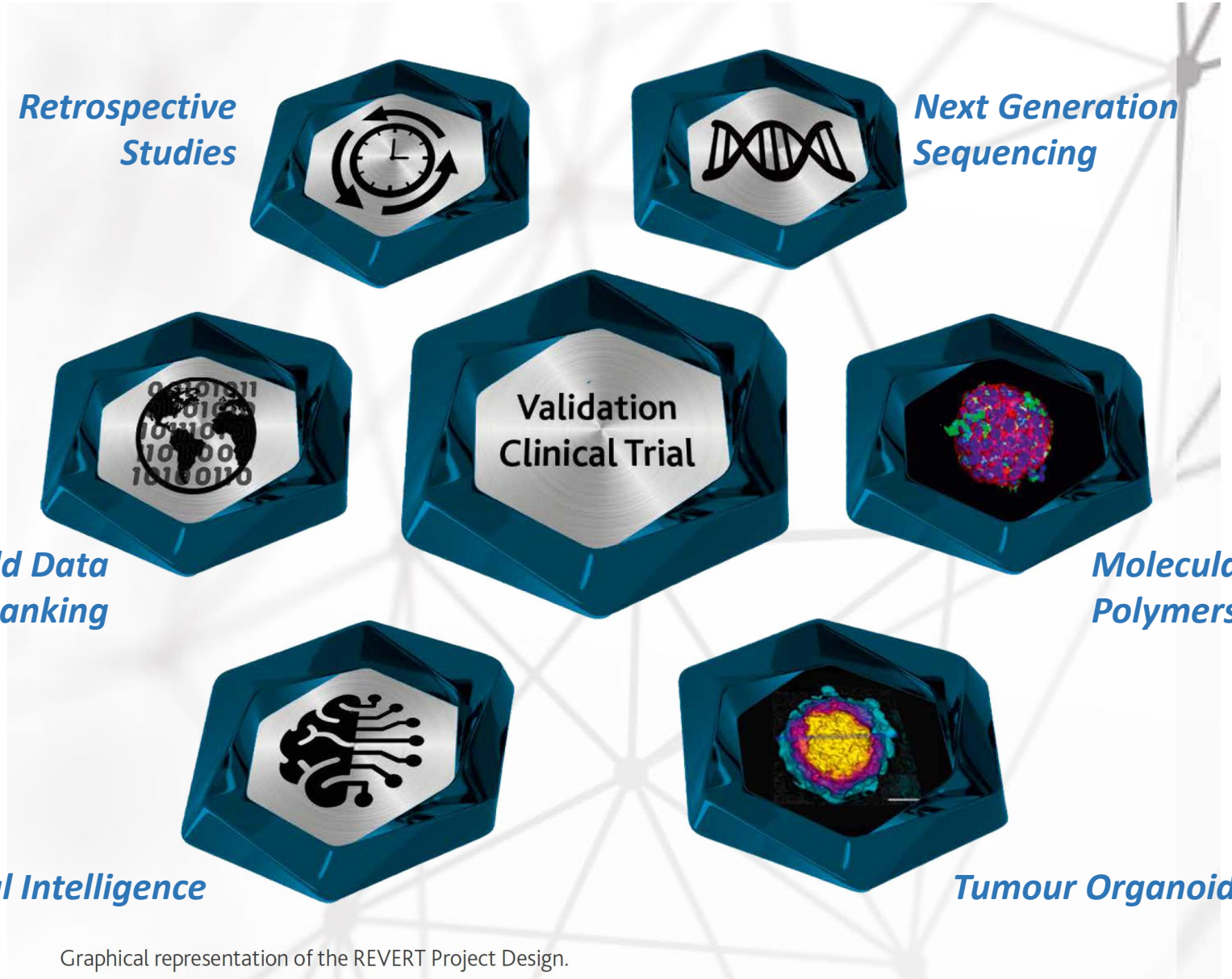

Graphical representation of the REVERT Project Design.

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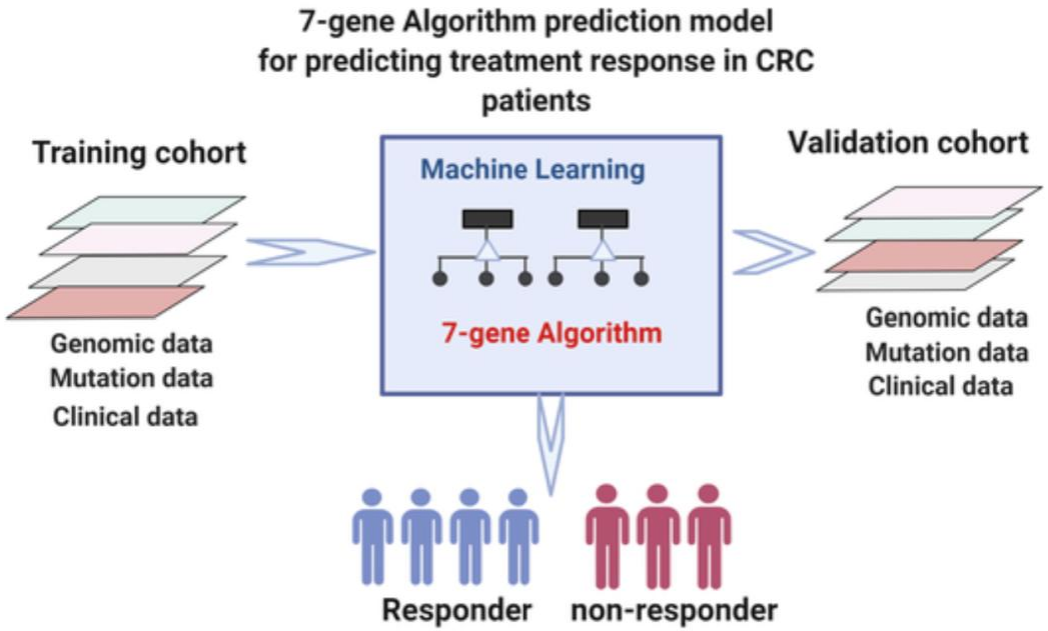
Article

Gene-Mutation-Based Algorithm for Prediction of Treatment Response in Colorectal Cancer Patients

Heather Johnson [1], Zahra El-Schich [2], Amjad Ali [3], Xuhui Zhang [4], Athanasios Simoulis [5], Anette Gjörloff Wingren [2] and Jenny L. Persson [2,3,*]



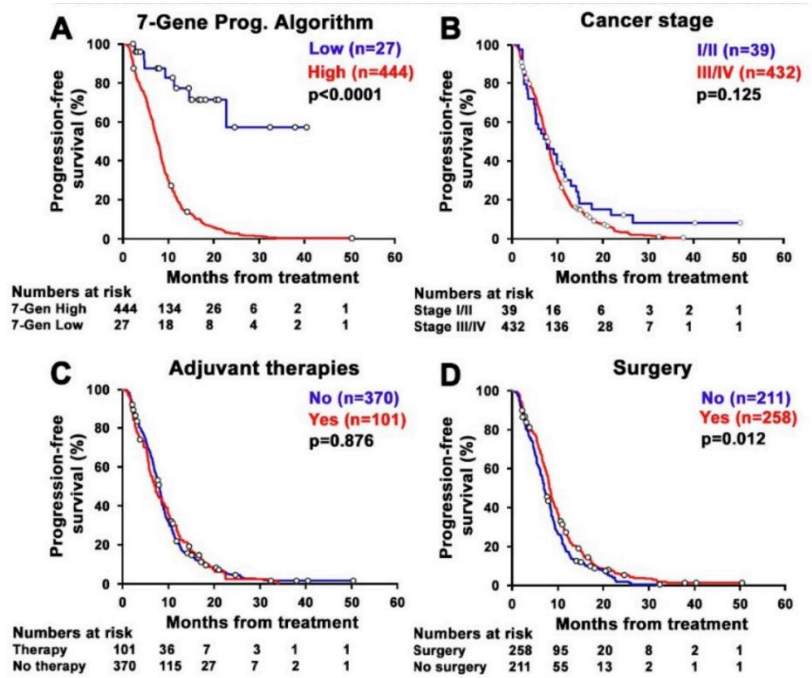


Figure 3. Kaplan–Meier survival analyses of the 7-Gene Algorithm and the clinical and pathological indicators for prediction of PFS in the MSK cohort. (**A**) The difference in PFS between two groups of CRC patients stratified based on the scores of the 7-Gene Algorithm. The statistical significance between the high and low group is indicated. (**B**) The difference in PFS between two groups of CRC patients stratified based on cancer stage. (**C**) Adjuvant therapies. (**D**) Surgery on primary tumor.

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Cancers 2022, 14, 2045. https://doi.org/10.3390/cancers14082045

The ML-based 7-Gene Algorithm, which consists of mutation profiles of seven genes (KRAS, BRAF, ERBB2, MAP2K1, TSC2, TP53, and APC) showed a statistically significant accuracy as a classifier to distinguish between patients who responded to first-line chemotherapy and those who did not.

This novel 7-Gene Algorithm can be further developed as a biomarker model for prediction of treatment response in mCRC patients to improve personalized therapies.

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Challenges faced by the REVERT Project Compliance to:

GDPR
2017/745 MDR

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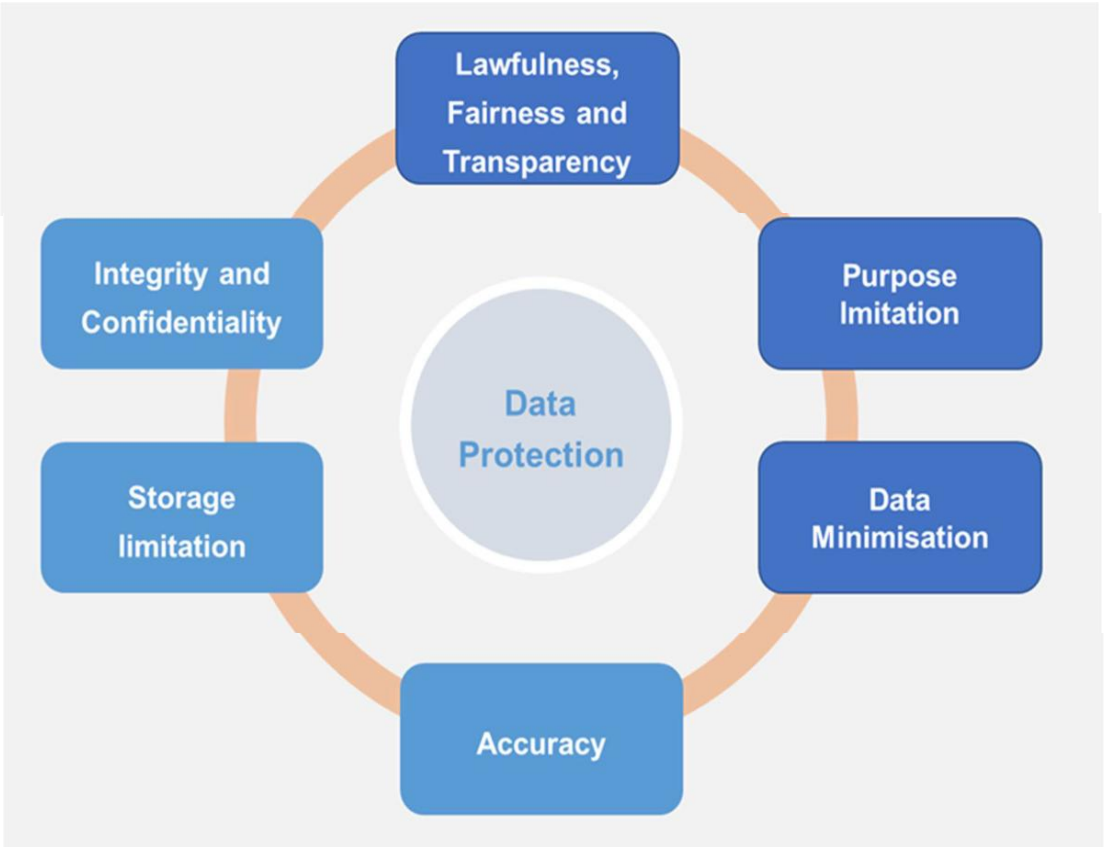

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Published on April 2019, Corporate author(s): Directorate-General for Communications Networks, Content and Technology (European Commission)

5.5.2017 | EN | Official Journal of the European Union | L 117/1

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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Six principles to ensure AI works for the public interest in all countries

1. **Protecting human autonomy**: In the context of health care, this means that **humans should remain in control of health-care systems and medical decisions;** ….

2. **Promoting human well-being and safety and the public interest.**

3. **Ensuring transparency, explainability and intelligibility.**

4. **Fostering responsibility and accountability.**

5. **Ensuring inclusiveness and equity.**

6. **Promoting AI that is responsive and sustainable.**

*These principles will guide future WHO work to support efforts to ensure that the full potential of AI for healthcare and public health will be used for the benefits of all***.**

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How these challenges have been approached in the REVERT Project

The REVERT paves the way **for building AI prediction systems** in the field of medicine, in general, and cancer treatment, in particular. Indeed, one of the significant obstacles to the wide adoption of these systems **is their opacity, which undermines clinicians' trust in AI.** **Explainable AI** is the current approach to gaining the trust of clinicians, and it is extremely promising.

Explainable AI to gaining the trust of clinicians in the use of AI algorithms for a personalised therapeutic intervention

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

Towards the Interpretability of Machine Learning Predictions for Medical Applications Targeting Personalised Therapies: A Cancer Case Survey

by Antonio Jesús Banegas-Luna [1,*], Jorge Peña-García [1], Adrian Iftene [2], Fiorella Guadagni [3,4], Patrizia Ferroni [3,4], Noemi Scarpato [4], Fabio Massimo Zanzotto [5], Andrés Bueno-Crespo [1] and Horacio Pérez-Sánchez [1,*]

1 Structural Bioinformatics and High-Performance Computing Research Group (BIO-HPC), Universidad Católica de Murcia (UCAM), 30107 Murcia, Spain

2 Faculty of Computer Science, Universitatea Alexandru Ioan Cuza (UAIC), 700505 Jashi, Romania

3 Interinstitutional Multidisciplinary Biobank (BioBIM), IRCCS San Raffaele Roma, 00166 Rome, Italy

4 Department of Human Sciences and Promotion of the Quality of Life, San Raffaele Roma Open University, 00166 Rome, Italy

5 Dipartimento di Ingegneria dell'Impresa "Mario Lucertini", University of Rome Tor Vergata, 00133 Rome, Italy

* Authors to whom correspondence should be addressed.

Academic Editor: Jung Hun Oh

Int. J. Mol. Sci. **2021**, *22*(9), 4394; https://doi.org/10.3390/ijms22094394

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

Cognitive Computation (2024) 16:1436–1446
https://doi.org/10.1007/s12559-024-10297-x

Evaluating Explainable Machine Learning Models for Clinicians

Noemi Scarpato[1,2] · Aria Nourbakhsh[3] · Patrizia Ferroni[1,2] · Silvia Riondino[4] · Mario Roselli[4] · Francesca Fallucchi[5] · Piero Barbanti[1,6] · Fiorella Guadagni[1,2] · Fabio Massimo Zanzotto[3]

Our study aims to introduce a standard practice for evaluating XAI methods in medicine. By establishing a rigorous evaluation framework, we seek to provide healthcare professionals with reliable tools for assessing the performance of XAI methods to enhance the adoption of AI systems in clinical practice.

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Multi-party, responsibility-sharing AI algorithms for a personalised therapeutic intervention

Explainable AI is the current approach to gaining the trust of clinicians, and it is extremely promising.

Yet, it has an inherent limitation: it relies on a single model built using a set of data and a single algorithmic approach.

In REVERT, we defined a novel approach to gain the trust of clinicians:

the multi-party, responsibility-sharing AI algorithms

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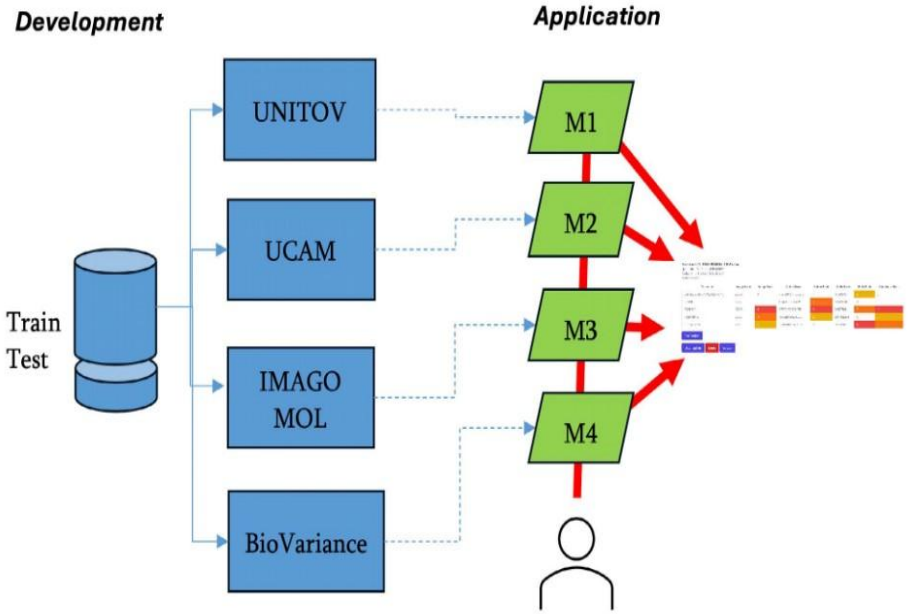
A Multi-party Decision Support System Model Based on Artificial Intelligence



Enrollment_STRING_UNITOV_CT023.xlsx

Upload time: Thu Feb 1 16:05:36 2024

Analysis time: Thu Feb 1 16:05:36 2024

Analysis results:

Treatment	Imago Score	Imago Rank	Unitov Score	Unitov Rank	Sibila Score	Sibila Rank	Cumulative Rank
5-FU/DE GRAMONT/CAPECITABINE	275.08	0	-1.9439815777576943	1	0.15903187	2	3
FOLFIRI-E	275.77	1	0.544175037874785	3	0.032322466	1	5
FOLFOX-E	276.09	4	5.779746718291755	4	0.6677584	3	11
FOLFOXIRI-E	276.05	3	-0.3626572432103574	2	0.014925361	0	5
XELOX/CAPOX-E	276.0	2	-3.045940072421052	0	0.8792847	4	6

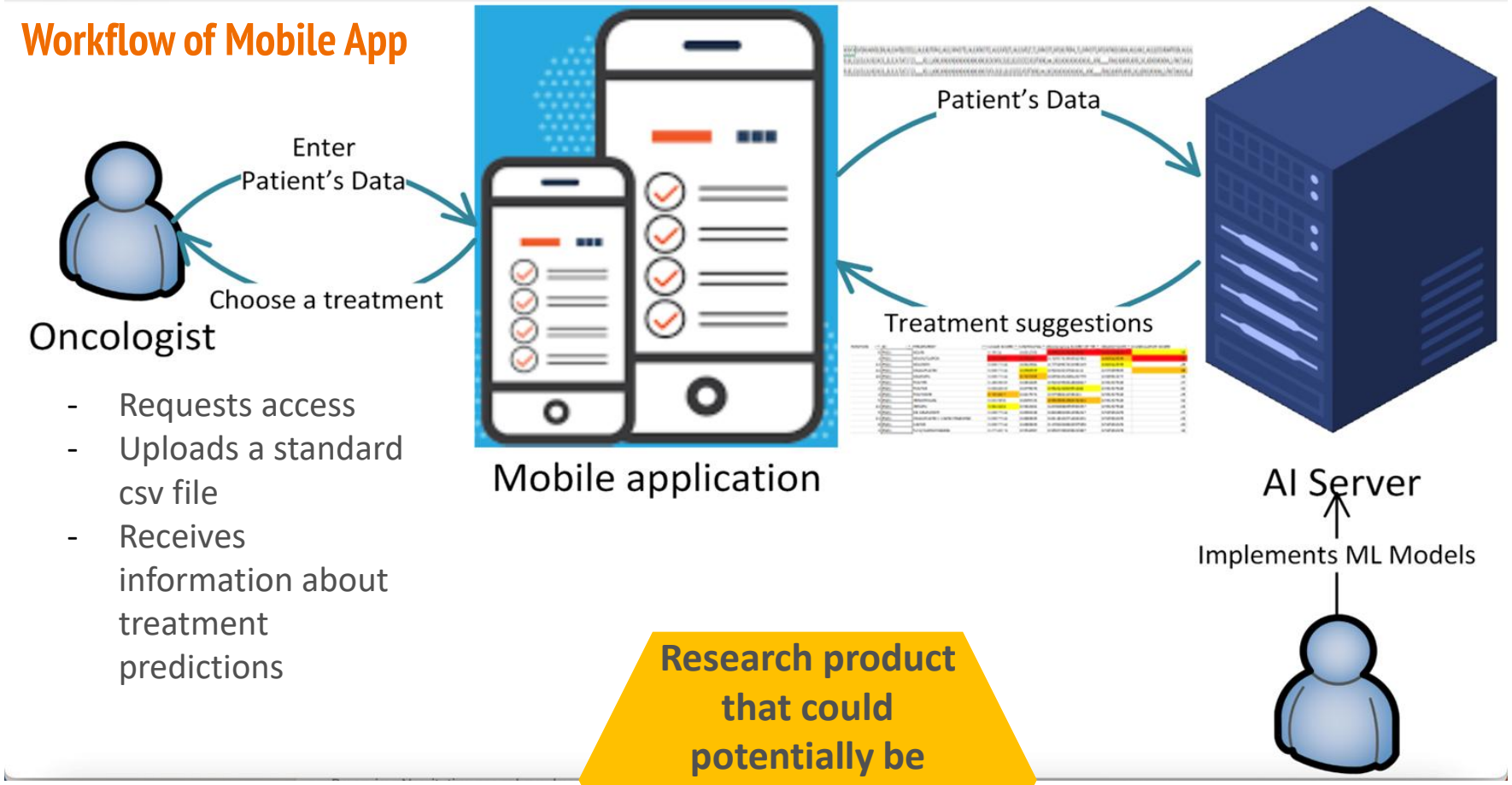
Run Analysis

Download File | Delete | Go Back

Figure 2: DSS Interface for Clinical Centres

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

Mobile App that allows the access to the predictive models containing a user interface for patient monitoring



- Requests access
- Uploads a standard csv file
- Receives information about treatment predictions

Research product that could potentially be beneficial for exploitation and future project!

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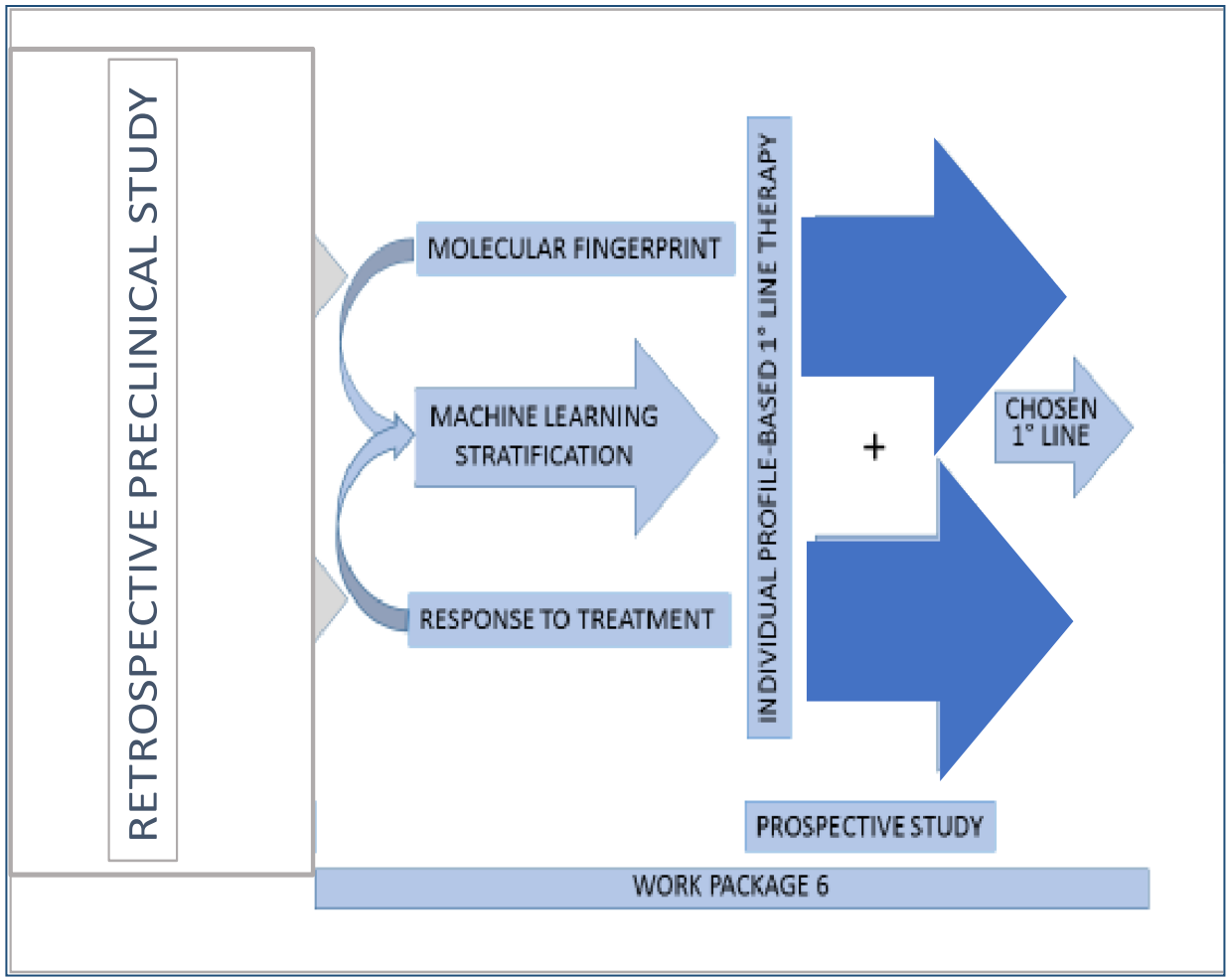
Pre-marketing validation multicentric Clinical trial



The defined computational framework AI-based was used to evaluate its impact on survival and quality of life in a prospective clinical trial through testing of new treatment sequences of the available and authorised molecular targeted drugs in patients with mCRC.

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AI Class IIa - Premarket Medical Device “early phase”

ClinicalTrials.gov PRS ID: NCT05396807

The results achieved are highly encouraging as they demonstrate that the use of the AI-based multi-party Decision Support System Model led to a significant improvement in progression-free survival 1 (PFS1), thus demonstrating that the use of AI can aid in treatment decisions in mCRC.

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Q: What makes some people with unresectable metastatic colorectal cancer (mCRC) respond well to treatment and others do not?

The REVERT project proved that mCRC patients can benefit from targeted therapy that incorporates predictive medicine and AI.

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REVERT - taRgeted thErapy for adVanced colorEctal canceR paTients

Helping doctors treat advanced colorectal cancer

What makes some people with unresectable metastatic colorectal cancer (mCRC) respond well to treatment and others not? The REVERT project seeks to improve targeted therapy for mCRC patients by combining predictive medicine and AI.

DIGITAL ECONOMY HEALTH

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The EU-funded REVERT project has developed an AI-based decision support system (DSS) to help clinician find the best treatment combination for individual patients with mCRC. The DSS is currently being tested in a clinical study carried out at six medical oncology units in three European countries.

https://cordis.europa.eu/project/id/848098

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REVERT project
www.revert-project.eu

The REVERT Team

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REVERT

Final Meeting

2024

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Round Table 1: Regulatory Aspects and Clinical Validation

Fiorella Guadagni
IRCCS San Raffaele
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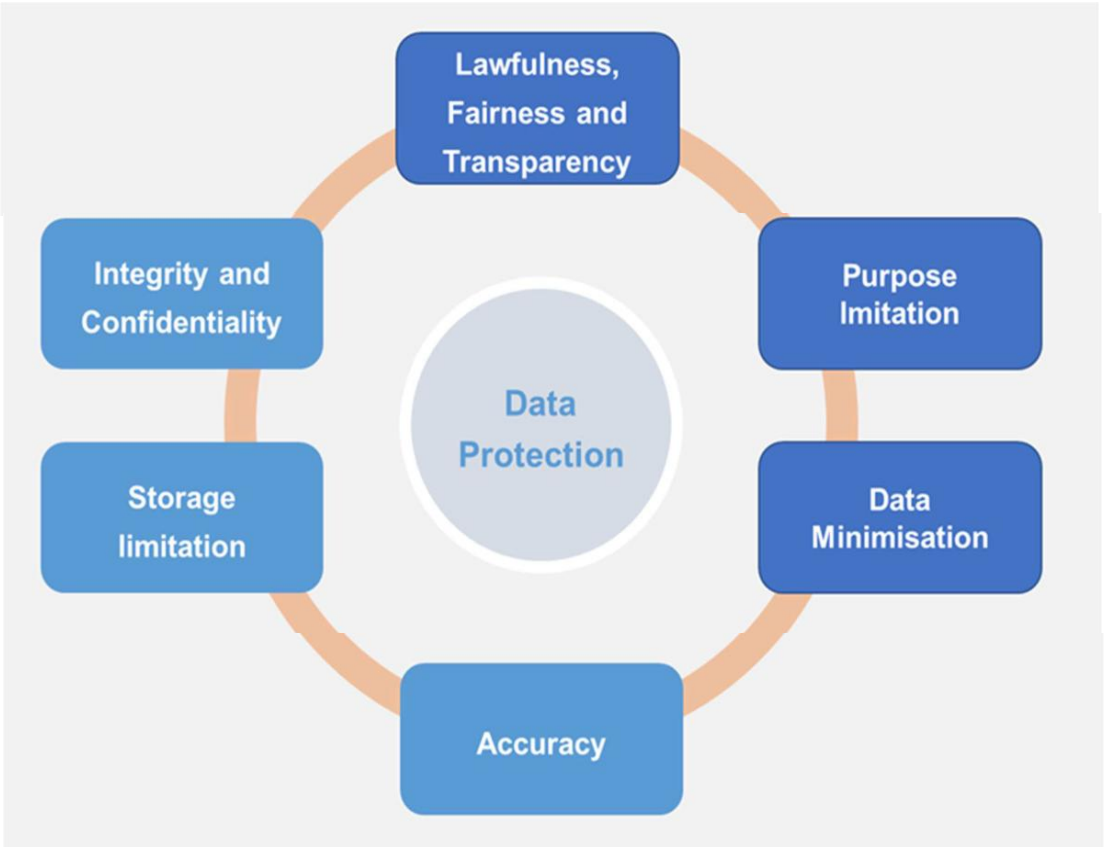

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REVERT APPROACH

FIRST: RISK ASSESSMENT AND MITIGATION PLAN

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In the initial phase, a **risk assessment and mitigation plan** has been drafted, pinpointing various potential risks associated with software implementation and data management, which will be integrated into the **DMP**.

Any risks pertaining to the main IT and legal aspects will be managed as outlined in the Figure below represented i.e., will be identified, analysed, evaluated and mitigated in the best possible way as detailed in the Risk Management Plan:

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DATA MANAGEMENT PLAN

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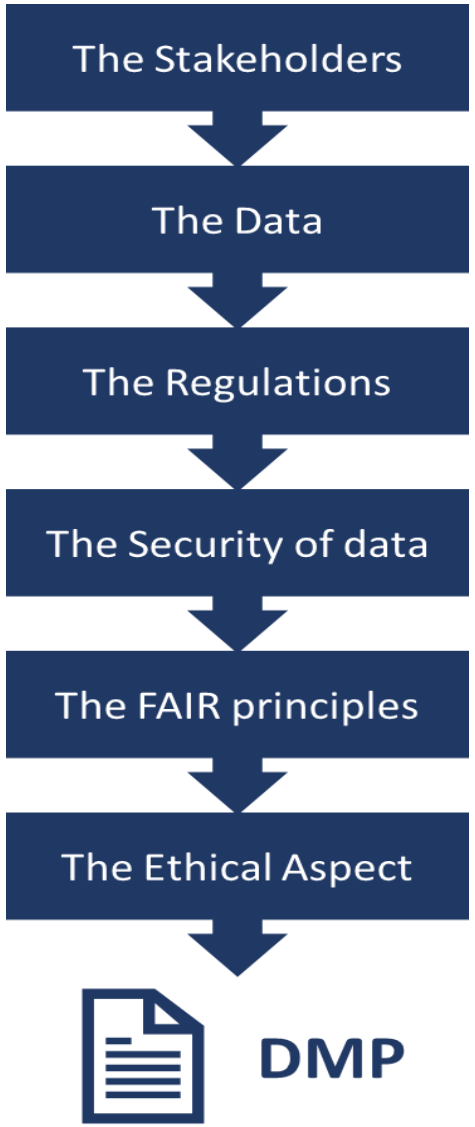

The main aspects that a DMP should consider

The Stakeholders who participate in the project and are involved in providing, manipulating or using the data

The Data that will have to be managed during the project, also considering the restrictions imposed for some types of data

The Regulations in the countries where the stakeholders operate and in those where the data will be shared

Data security, obtained through both technical and organizational measures

The FAIR Principles and their application to the project

The Ethical Aspects to consider in the execution of project activities and in the use of data

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CHOICE OF THE SERVER

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One of the first issues addressed by the REVERT project was the **choice of the server/DB** management model and the data contained in them.
The need to have machines compliant with:

1. the security requirements indicated by the GDPR and necessary for the nature of the data processed,
2. to guarantee adequate levels of security,
3. to keep management costs low
4. and to be able to make use of some features and tools,
5. have in fact shifted focus from in-house management to a cloud solution.
6. In this scenario, Amazon (AWS) was chosen among the different cloud services for multiple reasons.

AWS is Amazon's cloud platform and is perhaps the most complete and most widely used in the world, offering more than 175 comprehensive data center services globally.
AWS offers significantly more services and features within the services themselves than any other cloud provider, including computing power, storage and database infrastructures, machine learning and artificial intelligence options, data lakes, analytics and interfacing with the Internet of Things.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

PROCEDURAL APPROACH FOR DATA SHARING AND FOR BUILDING A SECURE REVERT DB

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 848098".

The REVERT project aims to build a database (RDB) that collects the clinical data of patients from different biobanks located in several European countries.

Since the data of different biobanks can vary with respect to the measurement units that parameters are stored with or to the formulae with which secondary data are calculated, the **data have to be harmonized upon import** to ensure that the corresponding entries of all the records have the same meaning across all institutions that provide the samples the RDB will be built upon.

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All the processing will be executed exclusively on an AWS platform.

The only data that can be downloaded to external IT infrastructures will be the final results of the processed data.

This workflow ensures to control and trace when and by whom data have been accessed and exported. All the risks concerning IT security will be mitigated by using an Amazon cloud platform, **certified** according to GDPR and characterized by **high-level security standards**.

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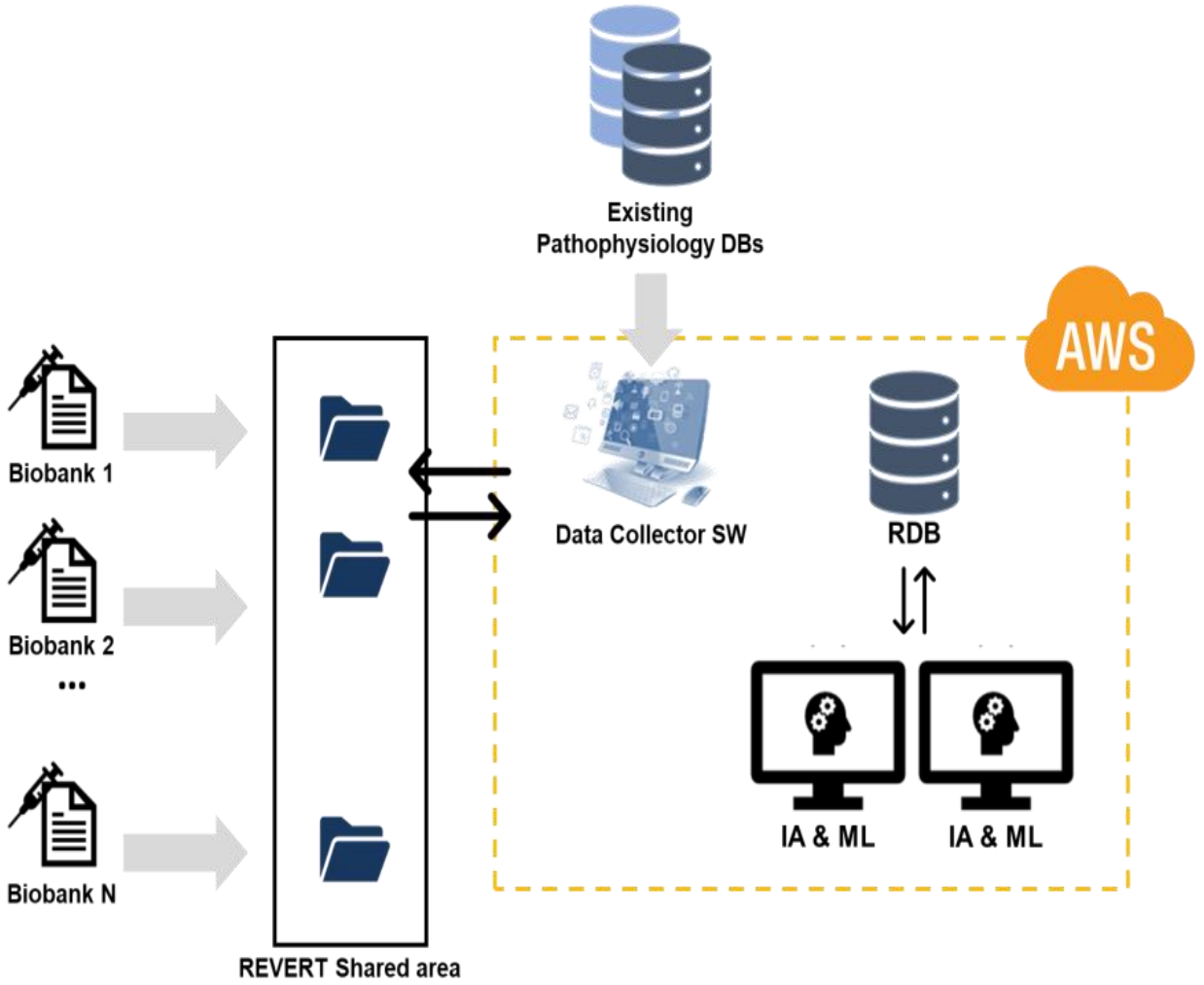
The REVERT architecture



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SECURITY MEASURES

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Security measures implemented in the REVERT project

One of the most important activities has been the risk assessment within REVERT and the definition of strategies to avoid, mitigate or remove risks.

The approach used in the REVERT project has been that of **risk assessment**, evaluated according to quality management models. As required by current regulations, all the most modern technologies has been used, based on **GDPR compliance and ISO 27001: 2013 certification**.

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ACTIONS PLANNED IN THE REVERT PROJECT

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To do this, the following activities have been planned during all the project execution:

1. **Constant vulnerability assessment**,
2. **Ensuring privacy by design at every stage** of the project
3. **Application of international security standards**
4. **Use of encryption formats** of the exchanged input and output flows
5. **Calculation of the hash of records** (exchanged, stored) to ensure that there is no corruption
6. **Mapping and risk analysis of the entire data use** cycle

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FAIR PRINCIPLES

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The FAIR principles

The nature of the data and the consent signed by the patients did not strictly allow the data to be made public.

The REVERT project, in relation to the question of keeping data open, applies the principle "as open as possible, as closed as necessary".

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DATA PROTECTION IMPACT ASSESSMENT

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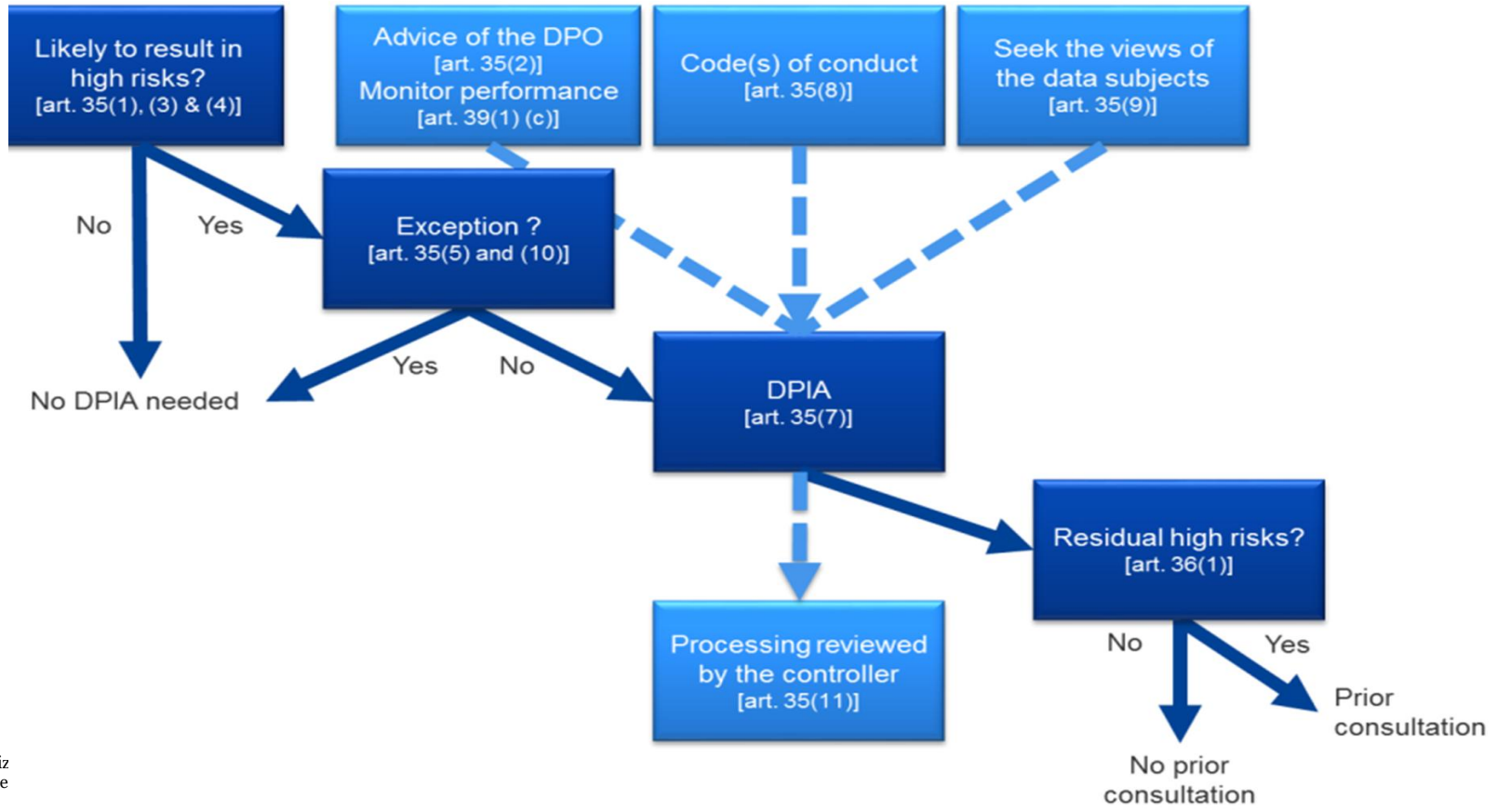
For the conduct of the DPIA, the Data Protection Officer of the Coordinator San Raffaele was consulted who –after several meetings with Partners– expressed a favourable opinion on the correctness of the conduct of the DPIA. The methodology used for the DPIA is graphically represented in the figure below.



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JOINT CONTROLLER AGREEMENT

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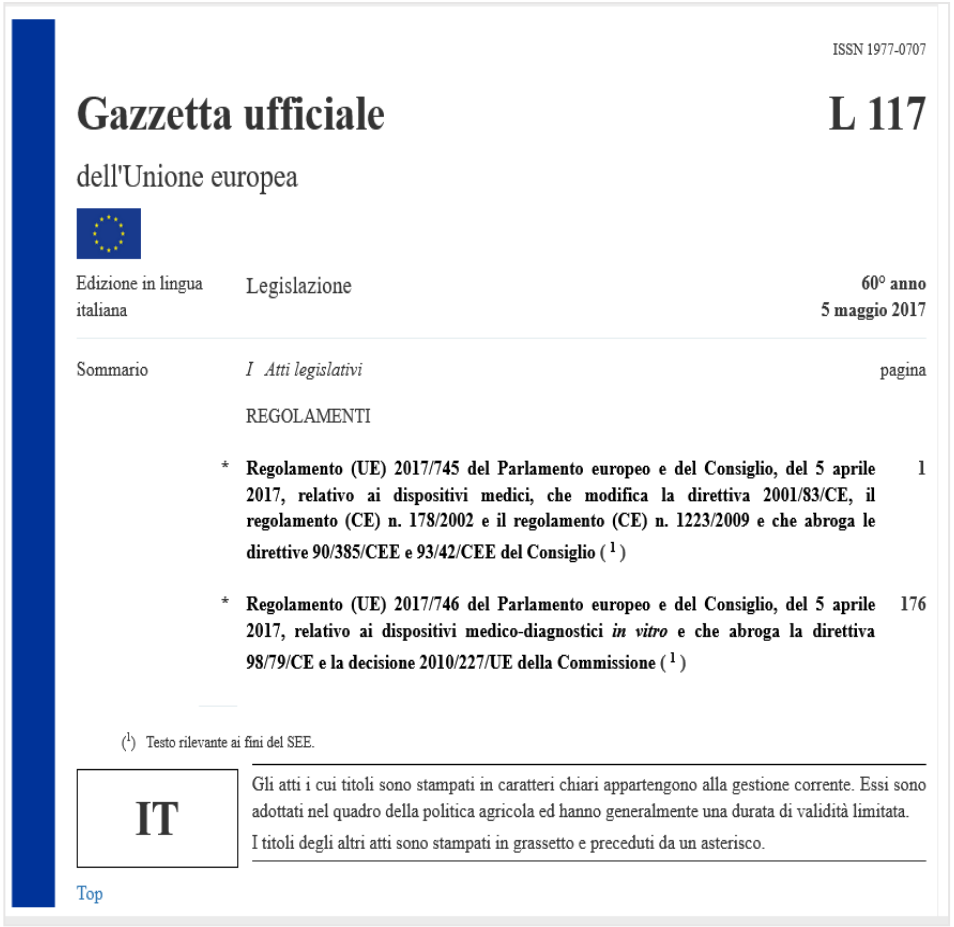

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Sommario | *I Atti legislativi* | pagina

REGOLAMENTI

([1]) Testo rilevante ai fini del SEE.

IT

Gli atti i cui titoli sono stampati in caratteri chiari appartengono alla gestione corrente. Essi sono adottati nel quadro della politica agricola ed hanno generalmente una durata di validità limitata.

I titoli degli altri atti sono stampati in grassetto e preceduti da un asterisco.

Top

This Regulation aims to ensure the **smooth functioning of the internal market as regards medical devices**, taking as a base **a high level of protection of health for patients and users,** and taking into account the **small- and medium-sized enterprises that are active in this sector**. At the same time, this Regulation sets **high standards of quality and safety** for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued **simultaneously and are inseparably linked** whilst one not being secondary to the other.

….. placing on the market and putting into service of medical devices … thus allowing them to benefit **from the principle of free movement of goods.** As regards Article 168(4)(c) TFEU**, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected**

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DECRETO LEGISLATIVO 5 agosto 2022, n. 137

Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio, nonche' per l'adeguamento alle disposizioni del regolamento (UE) 2020/561 del Parlamento europeo e del Consiglio, del 23 aprile 2020, che modifica il regolamento (UE) 2017/745 relativo ai dispositivi medici, per quanto riguarda le date di applicazione di alcune delle sue disposizioni ai sensi dell'articolo 15 della legge 22 aprile 2021, n. 53. (22G00145) (GU Serie Generale n.214 del 13-09-2022)

note: Entrata in vigore del provvedimento: 28/09/2022

L'Autorità Competente sulle indagini cliniche dei dispositivi medici è il Ministero della salute

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Art. 16 Indagini cliniche

1. Nessuna indagine clinica può essere avviata senza l'invio di idonea comunicazione al Ministero della salute e senza che siano state realizzate le condizioni previste per l'avvio dell'indagine.
2. Con decreto del Ministro della salute sono stabilite le **modalità** amministrative di pertinenza nazionale per la presentazione **della domanda di indagine clinica per i dispositivi non recanti la marcatura CE e per quelli recanti la marcatura CE** di cui all'articolo 74, paragrafo 2, del regolamento, prevedendo che nella documentazione ad essa allegata **sia ricompreso il parere favorevole espresso dal comitato etico competente**. ……

Per i dispositivi appartenenti alla classe III e per quelli invasivi appartenenti alle classi IIa oppure IIb, i richiedenti potranno iniziare le pertinenti indagini **cliniche solo dopo avere ottenuto** la relativa autorizzazione ministeriale **da rilasciarsi entro quarantacinque giorni dalla data di convalida della domanda di autorizzazione**, fatta salva la possibilità di estendere tale periodo di ulteriori venti giorni ai fini della eventuale consultazione di esperti.

Per i dispositivi oggetto di indagine della classe I o **per i dispositivi non invasivi delle classi IIa** e IIb, i richiedenti **possono iniziare l'indagine clinica trenta giorni dopo la data di convalida della domanda**, a meno che il Ministero della salute non notifichi entro tale termine che la domanda e' stata respinta per ragioni di tutela della salute pubblica, della sicurezza o della salute dei soggetti e degli utilizzatori, **purché il comitato etico competente abbia reso un parere favorevole in relazione all'indagine clinica**.

L'Autorità Competente sulle indagini cliniche dei dispositivi medici è il Ministero della salute

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Il Regolamento (UE) 2017/745 sui dispositivi medici (Medical Device Regulation, MDR) è direttamente applicabile in tutti gli Stati membri dell'Unione Europea.

Tuttavia, l'attuazione pratica e la sorveglianza del mercato sono gestite dalle autorità nazionali competenti di ciascuno Stato membro.

Queste autorità sono responsabili dell'applicazione del regolamento, della vigilanza sui dispositivi medici e della supervisione degli organismi notificati

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Autorità competenti in alcuni Stati membri dell'UE

✓**Italia**: Il Ministero della Salute
✓**Germania**: L'Istituto Federale per i Farmaci e i Dispositivi Medici (Bundes institut für Arzneimittel und Medizin produkte, BfArM)
✓**Francia**: L'Agenzia Nazionale per la Sicurezza dei Medicinali e dei Prodotti Sanitari (Agence Nationale de Sécurité du Médicament et des Produits de Santé, ANSM)
✓**Spagna**: L'Agenzia Spagnola dei Medicinali e dei Prodotti Sanitari (Agencia Española de Medicamentos y Productos Sanitarios, AEMPS)
✓**Paesi Bassi**: L'Ispettorato per la Sanità e la Gioventù (Inspectie Gezondheidszorg en Jeugd, IGJ)

https://health.ec.europa.eu/publications/factsheet-healthcare-professionals-and-healthcare-institutions_it

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