

DigiCore

CONNECT TO WIN

November 9, 2022

DATA SCIENCE INFRASTRUCTURE

AND STRATEGIES FOR PRAGMATIC DIGITAL MEDICINE
SOLUTION IMPLEMENTATION

Gemelli 
Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Università Cattolica del Sacro Cuore

 GSteP
Genomic Science and Technology Platform

 GemelliGenerator
Clinical research beyond tomorrow

 GDMH
Gemelli Digital Medicine & Health



Dr. Alfredo Cesario

- CEO at Gemelli Digital Medicine & Health
- Open Innovation Manager at Fondazione Policlinico Universitario A. Gemelli IRCCS
- Board Member European Forum for Good Clinical Practice (EFGCP)
- Chair Scientific Advisory Board EraCoSysMed (2015-2020)
- Co-founder European Association for Systems Medicine (EASYM)

From «closed innovation»

The rigid and structured **in-house innovation** process is based on the belief that successful innovation requires **control and exclusivity**.

This approach is no longer sustainable in an increasingly competitive, interdisciplinary, globalized, dynamic and mature environment.

To «open innovation»

In 2003, professor and economist Henry Chesbrough demonstrates how some well-known successful companies (IBM, Xerox) have been able to face major crises by opening up to the outside world.

The concept of “**Open Innovation**” indicates a process of interconnecting ideas, knowledge and assets inside and outside the organization to accelerate the organization's innovative potential.





Shared protection & Management of knowledge

“Open” does not mean “Free”

To manage the continuous interactions, companies develop an environment that fosters innovative processes and, at the same time, train personnel to accompany these processes, sometimes creating dedicated units or departments.

Therefore, it becomes relevant to determine how to innovate, what to innovate and how to manage the innovation process, especially if one intends to create a knowledge-based trust network in which to reduce the risk of opportunistic behavior.

For this reason, the innovation process needs to be protected by **non-disclosure agreements** and is often coordinated by professional figures dedicated to ensuring brokerage of Intellectual Property.

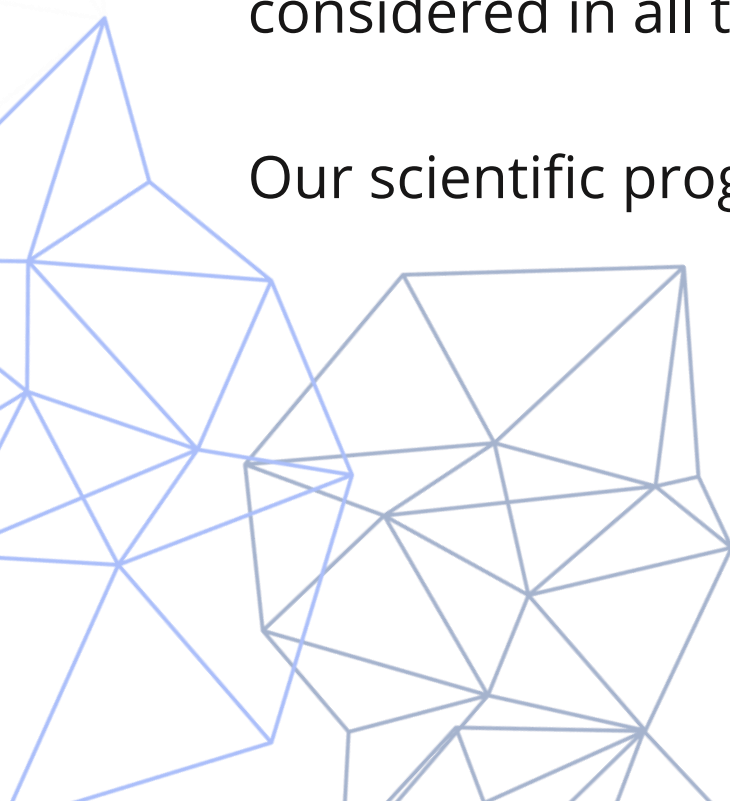
Evolving toward the concept of “federated innovation” (e.g., MIND Milan)

The case of «Fondazione Policlinico Universitario A. Gemelli IRCCS»

“In 2018, FPG was recognized as “research hospital” by the Ministry of Health for the disciplines of Personalized Medicine and Innovative Biotechnology.

Being a research hospital means that research and clinical care must have mutual implications, providing patients with the best and innovative solutions, considered in all their aspects.

Our scientific progress is based on 5 pillars.



CLINICS



G-STEP



CLINICAL RESEARCH



DATA SCIENCE



OPEN INNOVATION



Gemelli Science & Technology Park

BASIC SERVICES FOR RESEARCH

- 3D BIOPRINTING
- BIOBANK FOR RESEARCH AND PERSONALIZED MEDICINE
- ELECTROPHYSIOLOGY
- FLOW CYTOMETRY
- IMMUNOHISTOCHEMISTRY
- IMMUNOLOGY
- MICROSCOPY
- NEW** RADIOPHARMACY



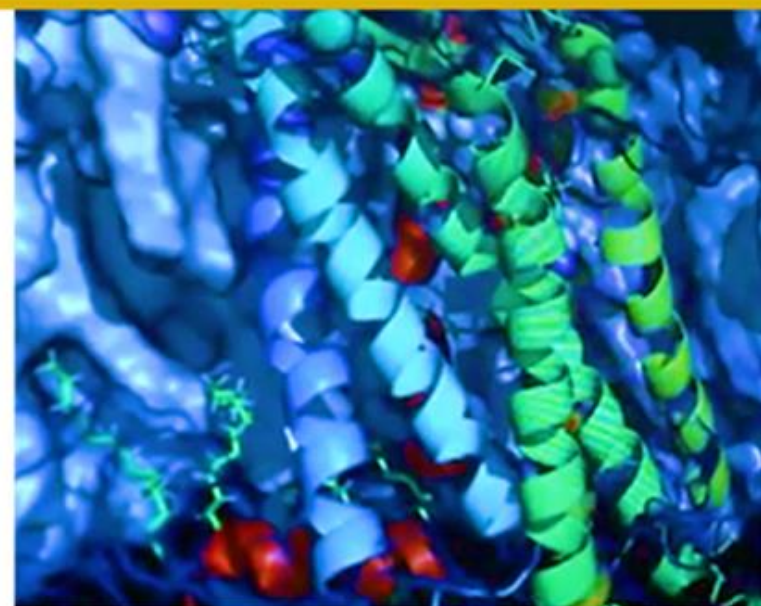
BIOLOGICAL MODELS

- EXPERIMENTAL MODELS
- ORGANOIDS
- PREANALYTICAL AND CELL BIOLOGY



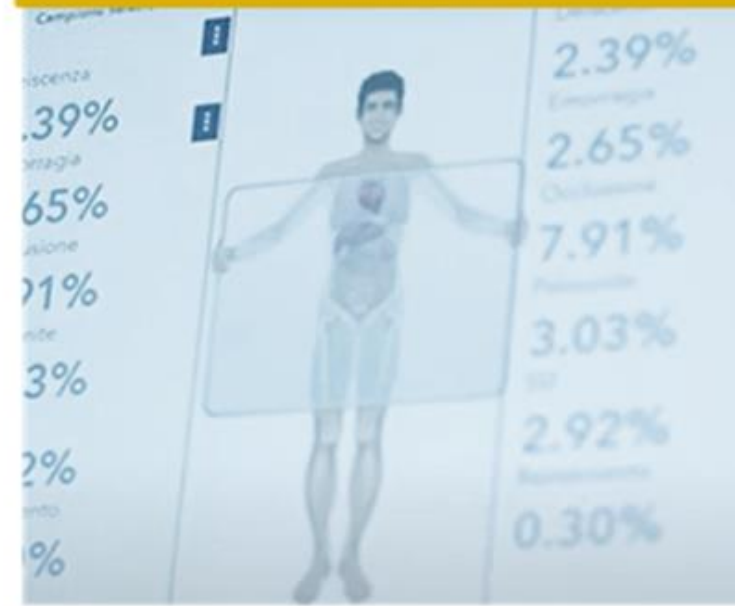
-OMIC SCIENCES

- GENOMICS
- METABOLOMICS
- LIQUID BIOPSY
- MICROBIOTA ANALYSIS AND MICROBIAL WGS
- PROTEOMICS
- RADIOMICS
- SINGLE CELL ANALYSIS



GEMELLI GENERATOR

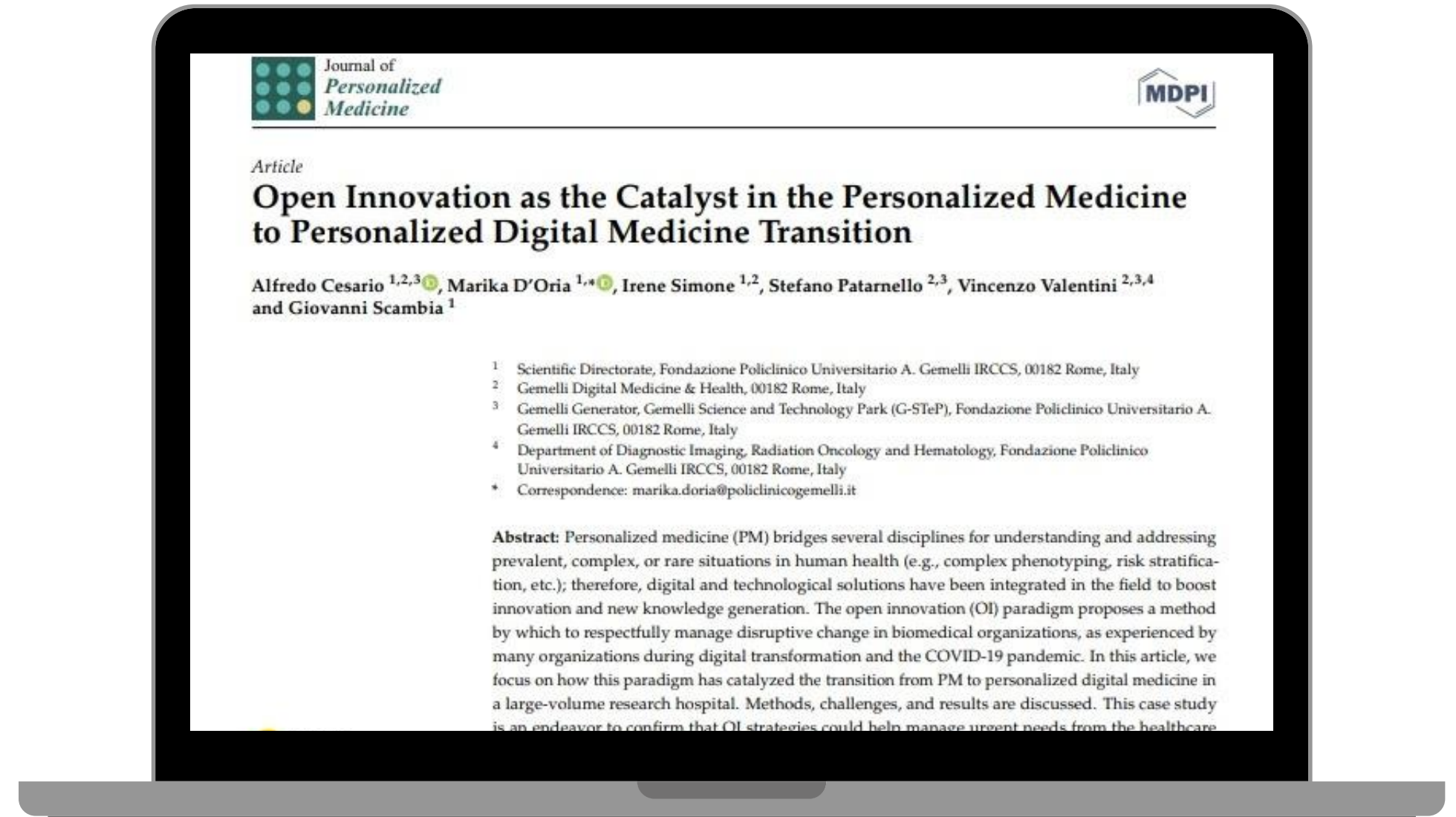
- DATA COLLECTION
- BIOINFORMATICS
- EPIDEMIOLOGY/BIOSTATISTICS
- REAL WORLD DATA

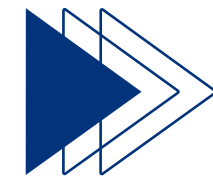


Open Innovation as the Catalyst in the Personalized Medicine to Personalized Digital Medicine Transition

Cesario, A.; D'Oria, M.; Simone, I.; Patarnello, S.; Valentini, V.; Scambia, G. *Open Innovation as the Catalyst in the Personalized Medicine to Personalized Digital Medicine Transition*. J. Pers. Med. 2022, 12, 1500.
<https://doi.org/10.3390/jpm12091500>

[To access to the full PFD Article](#)





How do we innovate?



1

SCOUTING OF AN INTERNAL OR EXTERNAL IDEA TO VALORIZE



2

IDENTIFICATION OF THE POTENTIAL PARTNER
(**MATCH MAKING**)



3

CREATION OF A PROTECTED ENVIRONMENT FOR THE **BROKERAGE OF INTELLECTUAL PROPERTY** (NON-DISCLOSURE AGREEMENT)



4

DEFINITION OF THE CO-CREATION AND CO-DEVELOPMENT PROJECT
(**CROSS-FERTILIZATION**)



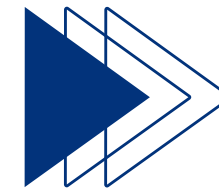
5

IMPLEMENTATION OF THE CO-CREATION AND CO-DEVELOPMENT PROJECT



6

CREATION OF A **GO-TO-MARKET STRATEGY** SHARED WITH THE PARTNER



First interactions of the open innovation platform & birth of our value network

Mission

To implement a pathway to accelerate internal innovation by fertilising it with external knowledge and expand the use of internally generated innovation towards our referral Value Network.

What

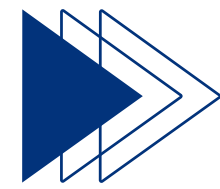
A formal working group built under the context of Open Innovation, consisting of different stakeholders willing to closely collaborate during the early stage of research, in a pre-competitive phase, in order to co-create and generate new ideas.

Why

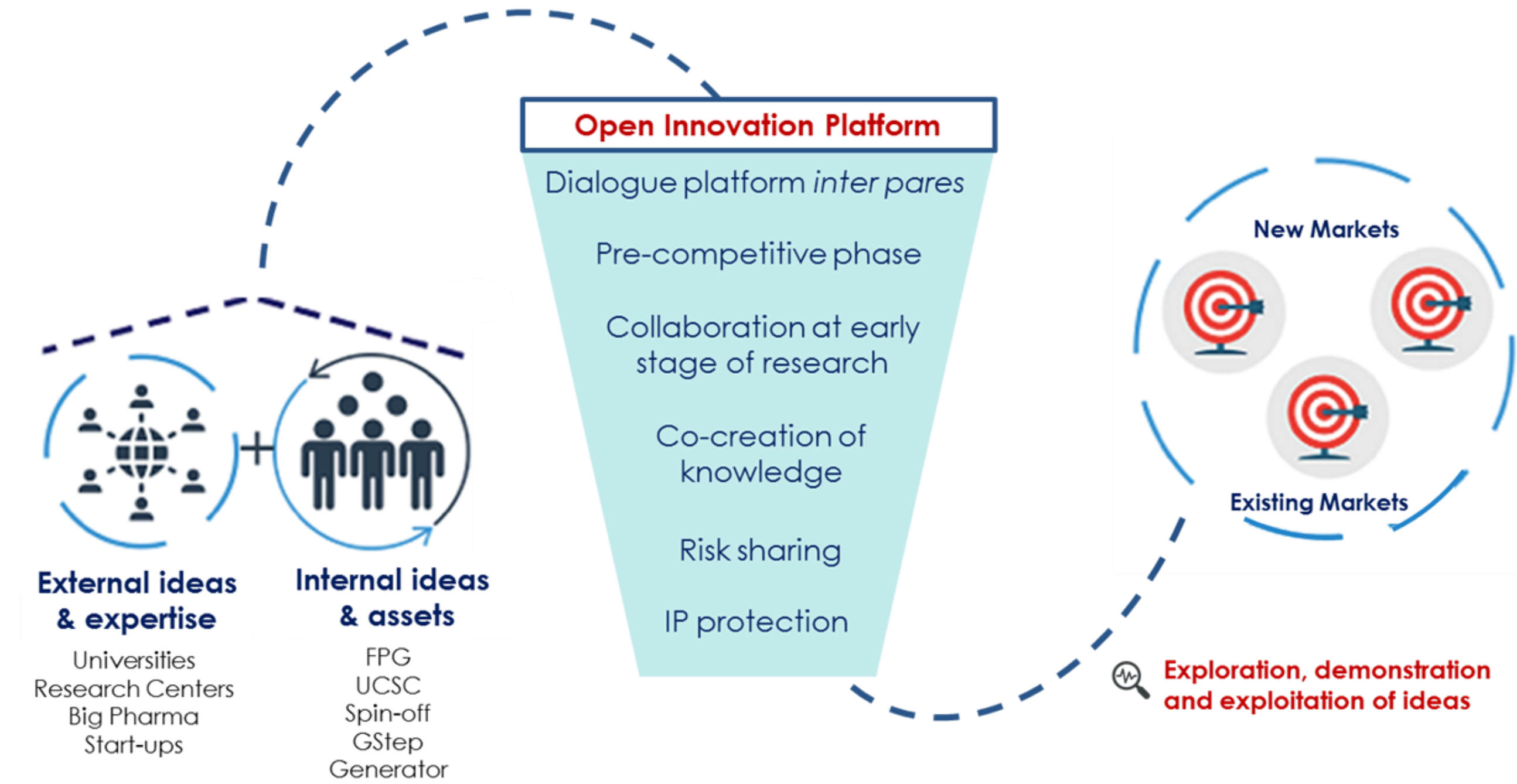
To leverage internal and external sources of ideas to create value, new business models and new paths to market.

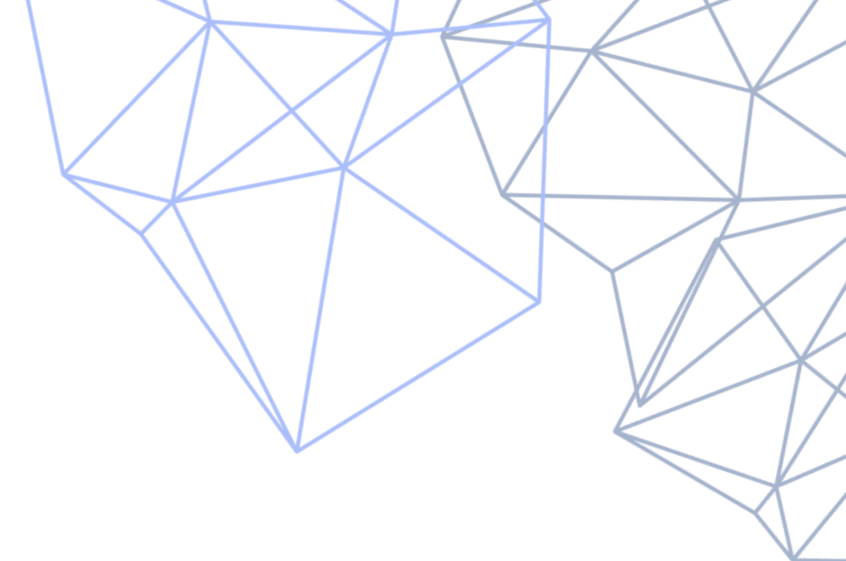
Governance | Strategic Planning | Sustainability





Cross-fertilization in practice





Our Evolution



- Publication on **Business Journal**
- Workshops** on Digital Medicine & Health



Set-up **Gemelli Generator @GStEP**
 Incorporation of an **Open Innovation logic**
 Co-design and co-development in digital medicine with industrial partners



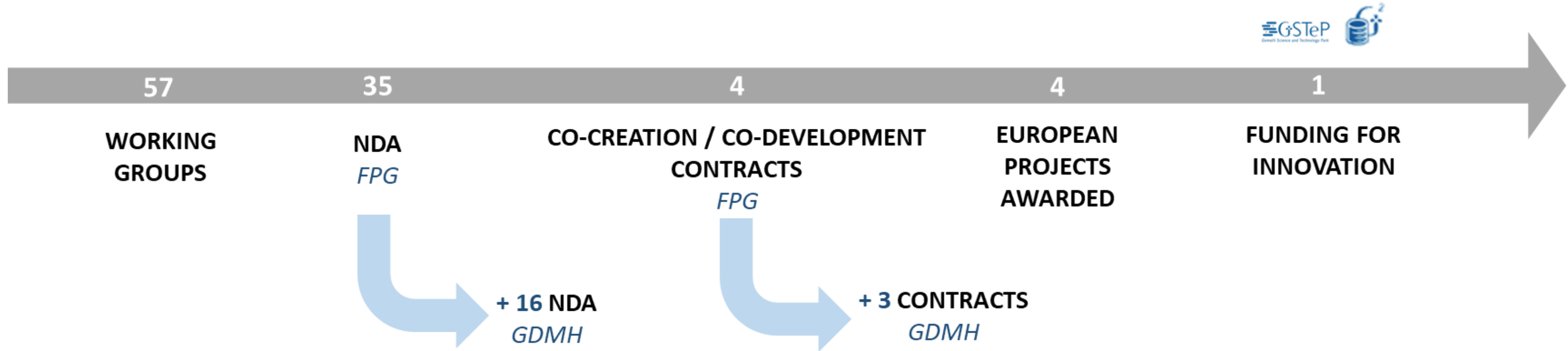
First co-creation and co-development **contracts**
Traction & Pipeline
October. Incorporation of **Gemelli Digital Medicine & Health Srl**



- GDMH scale up:**
Organizational ramp up
Business Plan
Industrial exploitation
- Liaison with **Milano Innovation District (MIND)**
 - Opening of our Offices at Mind
 - Active Participation in Federated Innovation



Results from the cross-fertilization activity



Results from the cross-fertilization activity

TOTAL
14.220.250 €

FUNDING FOR INNOVATION
12 MLN €

OPEN INNOVATION UNIT + GEMELLI
GENERATOR
+ FUND RAISING AND EVENTS UNIT @FPG

EQUITER is an investor and advisor in the infrastructure sector in Italy, that selects, structures, implements and manages Mission Related Investments, venture capital investments aimed at the socio-economic development of territories, with a long-term impact.

Awarded
DECEMBER 2021

Due diligence
Q2-Q4 2021

Digital platform and AI solutions
BY THE END OF 2023

EUROPEAN PROJECTS
1.723.250 €

WITH CLINICAL STAFF
(DIFFERENT DEPTS) AND
GEMELLI GENERATOR



Total submitted projects
32

Total requested funding
16.550.356 €

INDUSTRIAL PROJECTS
497 K €

WITH GEMELLI GENERATOR +
CLINICAL STAFF

TRACTION



CONTRACT SIGNED | VALUE **77 K**



CONTRACT SIGNED | VALUE **91 K**



CONTRACT SIGNED | VALUE **189 K**

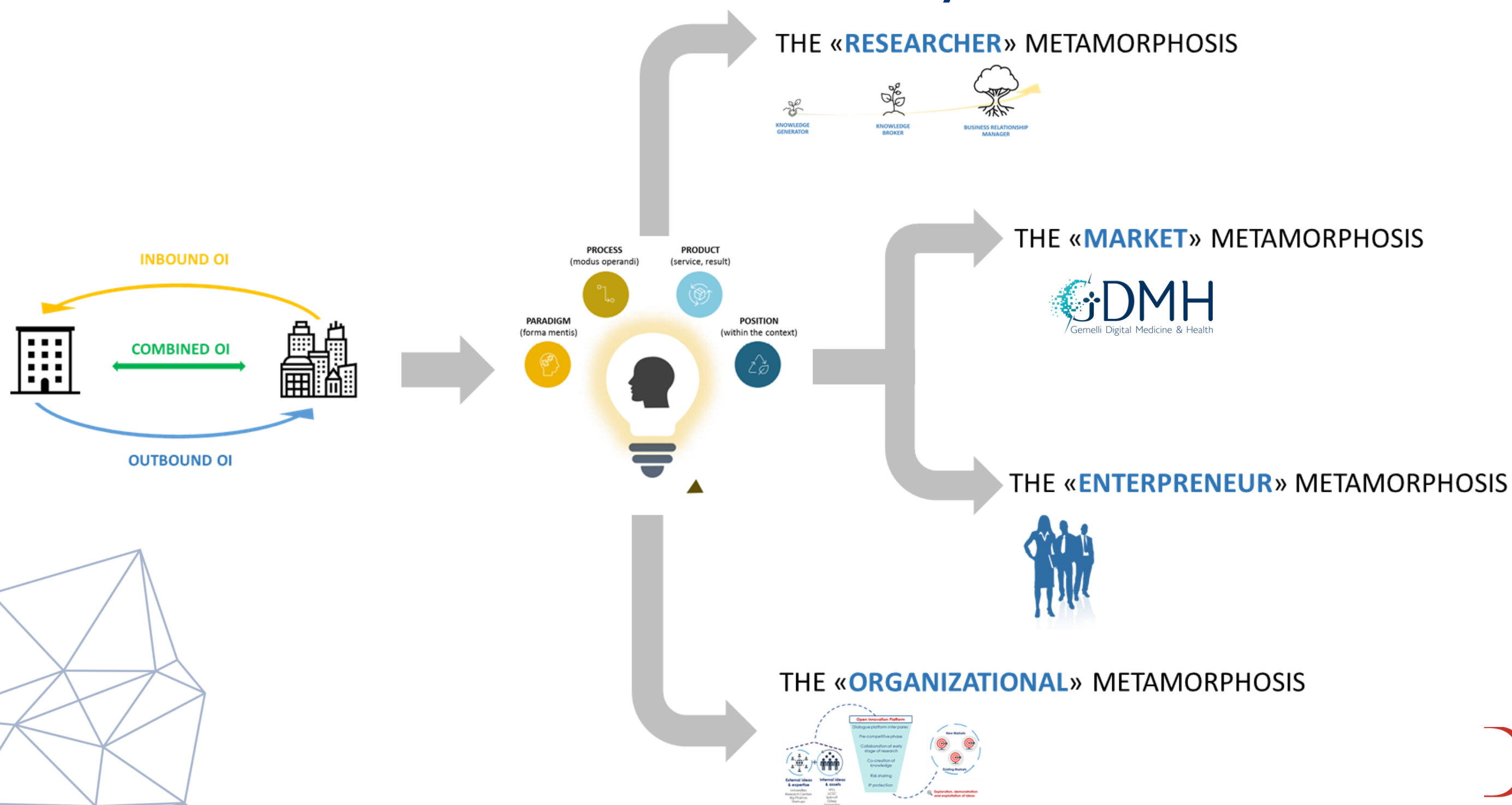


CONTRACT SIGNED | VALUE **140 K**

PIPELINE | 2022 ONWARDS



The impact of cross-fertilization on the «innovation ecosystem»





Promoting scientific and social innovation towards interdisciplinarity

The adoption of the OI attitude has created a new «editorial business» focused on the topic. This editorial line is characterized by the scientific valorization and dissemination of «Personalized Medicine» with an interdisciplinary effort, by creating literacy and engagement towards multiple stakeholders.

We are reviewers for the following Journals

- Elsevier – Technovation (IF: 6.6)
- Nature – Phenomics (Hybrid –Transformative Journal)
- Nature – Scientific Reports (IF: 4.3)
- Nature – Digital Medicine (2 Year IF: 11.6)
- MDPI - Journal of Cardiovascular Development and Disease (IF: 4.4)

Promoting scientific and social innovation towards interdisciplinarity

Position Papers for social impact

Position Papers for Social Impact

- ..., D'Oria M., et al. (2022). *XIII. Le possibilità dell'intelligenza artificiale e dei big data per i pazienti oncologici*. In "14°Rapporto sulla condizione assistenziale dei malati oncologico – Terapie oncologiche e Intelligenza Artificiale", Federazione delle Associazioni di Volontariato in Oncologia (FAVO). Documento presentato il 12 maggio 2022 presso il Senato della Repubblica (Sala Capitolare, Roma, IT)
- ..., D'Oria M., Cesario A (2020). *Gli IRCCS nella competizione internazionale di Horizon Europe. La prospettiva della Fondazione Policlinico Universitario "Agostino Gemelli" IRCCS*. IRIS Magazine (Ministero della Salute), 1:43-4.

Educational activities

Academic

- 2022.07.01. Master di II livello "Big data and value generation in biomedical research and clinical practice" (Università Cattolica del Sacro Cuore)
- 2021.11.25. Master di II livello "Bio-Executive account managers" (ALTEMS, Roma)
- 2020. Master di II livello "Big data and value generation in biomedical research and clinical practice" (Università Cattolica del Sacro Cuore)

Specializations

- 2021.06.22. Ambrosetti "Computer modelling and simulation: il game changer nei clinical trials?" (online)
- 2021.06.18. LabOnLung "La telemedicina nella gestione del paziente con patologie respiratorie croniche" (online)
- 2020.06.03. Konzept "The Needs of Clinicians" (online)

Industrial

- 2020.12.16. Roche "Learning Healthcare System"
- 2020.11.24. Daiichi-Sankyo/Astrazeneca "iJourney"
- 2020.11.18. ECM Novartis sull'uso dell'intelligenza artificiale per la personalizzazione dell'arruolamento dei pazienti negli studi clinici

Clinical

- 2019.09.18. ECM "L'importanza della relazione e della comunicazione nei clinical trials" (Fondazione Policlinico Gemelli).

Our "Open Innovation" a case study for master thesis at

- 2018-2019. (Dr.ssa B. Cibin) | Università Ca' Foscari
- 2019-2020. (Dr. D. D'Amario) | Università LUISS

Tutoring & Monitoring

- 2021.11 – 2022.02. (Dr.ssa P. Alunni Gaetani) | Master di I livello in "Comunicazione Sanitaria" (ALTEMS – ALMED)

From local to global



PURPOSE

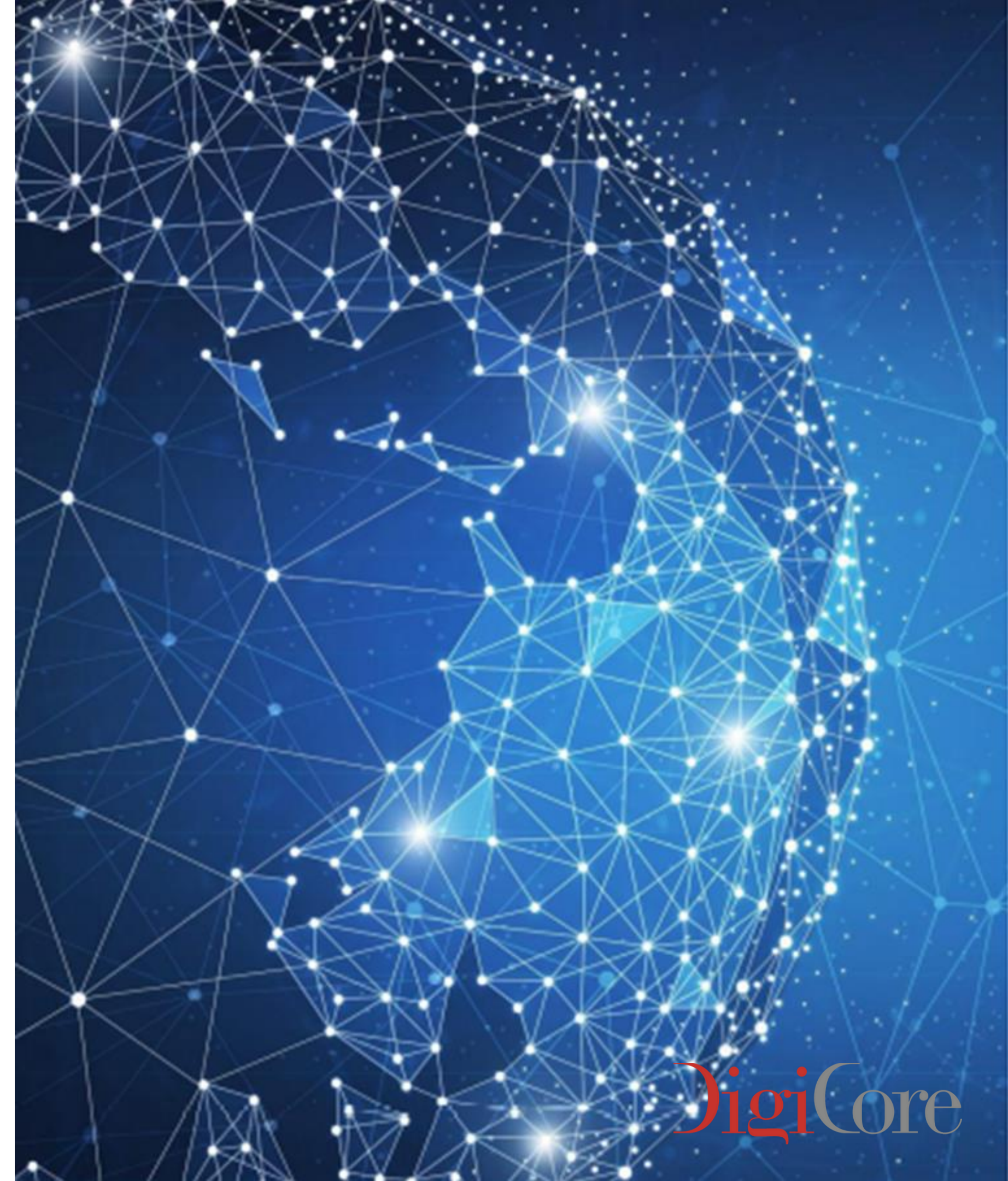
Exploit the full potential of knowledge base and clinical expertise of Gemelli and promote the Hospital as a global player in Digital Health.

MISSION

Generate, implement and deploy global digital medicine & health solutions with full ethical, technical and regulatory credentials.

VISION

Becoming a global player in Digital Health.



GDMH – Gemelli Digital Medicine & Health

WHY NOW

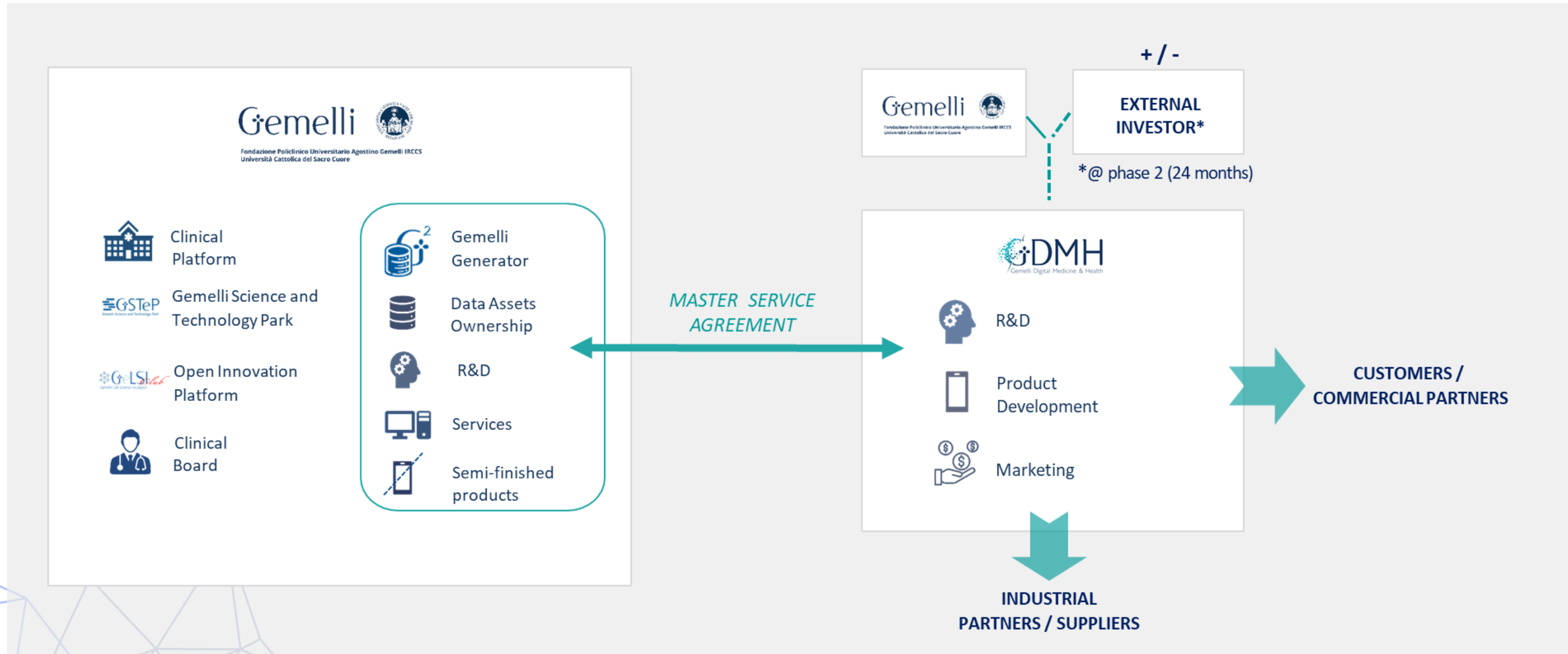
- Readiness of in-house technology
- Strong strategic alliances already in place
- Successful POCs –traction
- Potential to go faster and scale globally
- Explore and exploit new business opportunities
- Attraction of private funds and private investments
- Firstmovers

UNIQUE SELLING POINT

- Data & Technology (AI, Cybersecurity, Blockchain, NFT, Quantum Computing and others)
- Certificates –Credentials (ISO, GDPR, MDR) Global Network
- Exclusive & long term Master Service Agreement with Gemelli Hospital*
- High Market Entry Barriers –Low rate of potential new competitors
- One of the largest in Europe (>1,600 beds)



▶ Gemelli & GDMH relationship



▶ Gemelli Generator – Real World Data

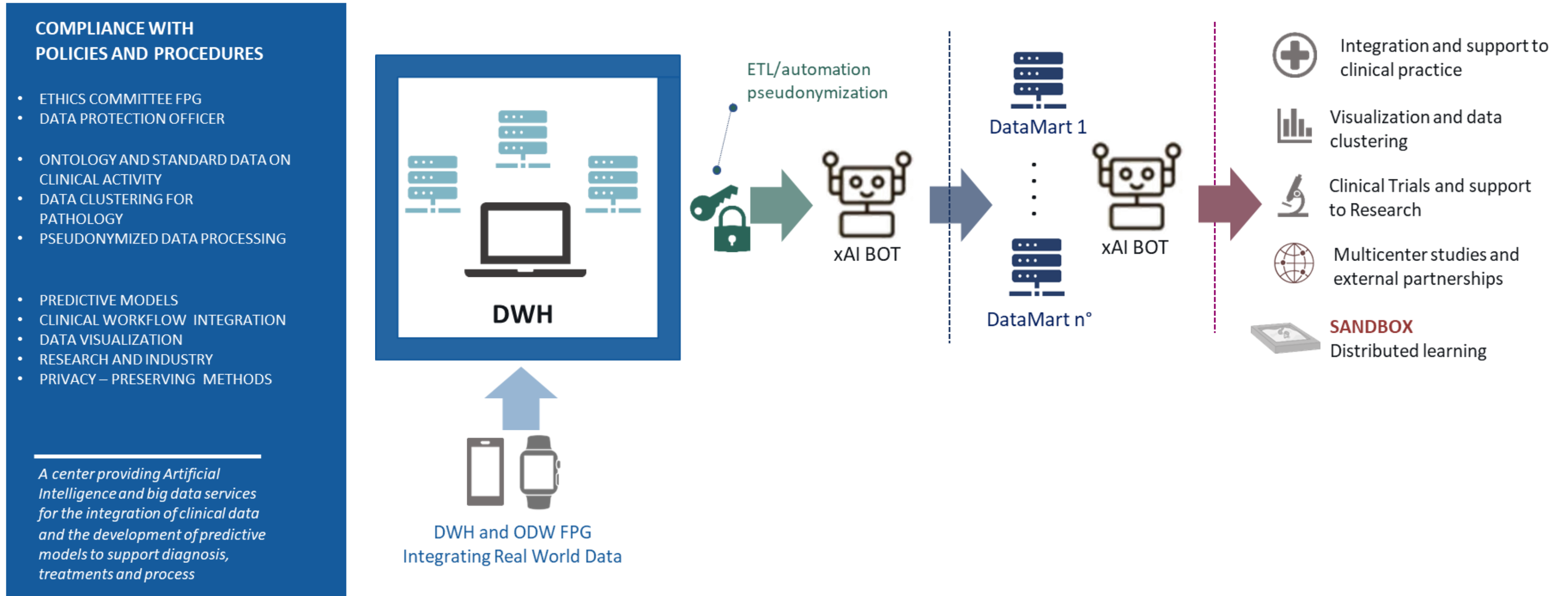


Gemelli Generator - Real World Data is a multidisciplinary center of the Gemelli Science and Technology Park (G-STeP) specifically dedicated to data collection and analysis to support biomedical research in a GDPR-fully compliant and safe by-design infrastructure.

- Provides **artificial intelligence** and **big data** services for the integration of clinical knowledge and the development of predictive models,
- Its primary objective is the **clinical and scientific valorization of competences, processes and data from the Data Warehouse (DWH)** of Fondazione Policlinico Universitario Agostino Gemelli IRCCS.
- Supports clinical research, diagnosis, treatment and healthcare process improvement through the creation of highly innovative projects in compliance with the Foundation's ethical policies.

The conceptualization and the execution of data strategies coupled with clinical know-how makes Gemelli Generator the factory creating prototypes with intermediate technology readiness level (TRL) that GDMH transforms in **fully-fledged certified and validated digital medicine solutions** via co-creation and co-development activities.

Gemelli Generator RWD Architecture



The valorization of existing data

Gemelli Big Data Warehouse
#over 1 BLN datapoints



#12 MLN
PHARMACOTHERAPIES



#1,3 MLN
HISTOPATHOLOGIES
SINCE 1999



#1,5 MLN
ACCESS TO E.R.
SINCE 1991



#82 MLN
OUTPATIENTS



#1,7 MLN
DRUGS
SINCE 2006



#680 K – 28,6 MLN
SIAS
SINCE 2012



#82 MLN
CONSULTANCIES



#9,2 MLN
SURGERY CONSUMPTIONS
SINCE 2000



#3,4 MLN
HOSPITALIZATIONS



#51 MLN
NURSING DIARIES



#845 K
SURGICAL PERFORMANCES
SINCE 2001



#36 K
CEDAP
SINCE 2012

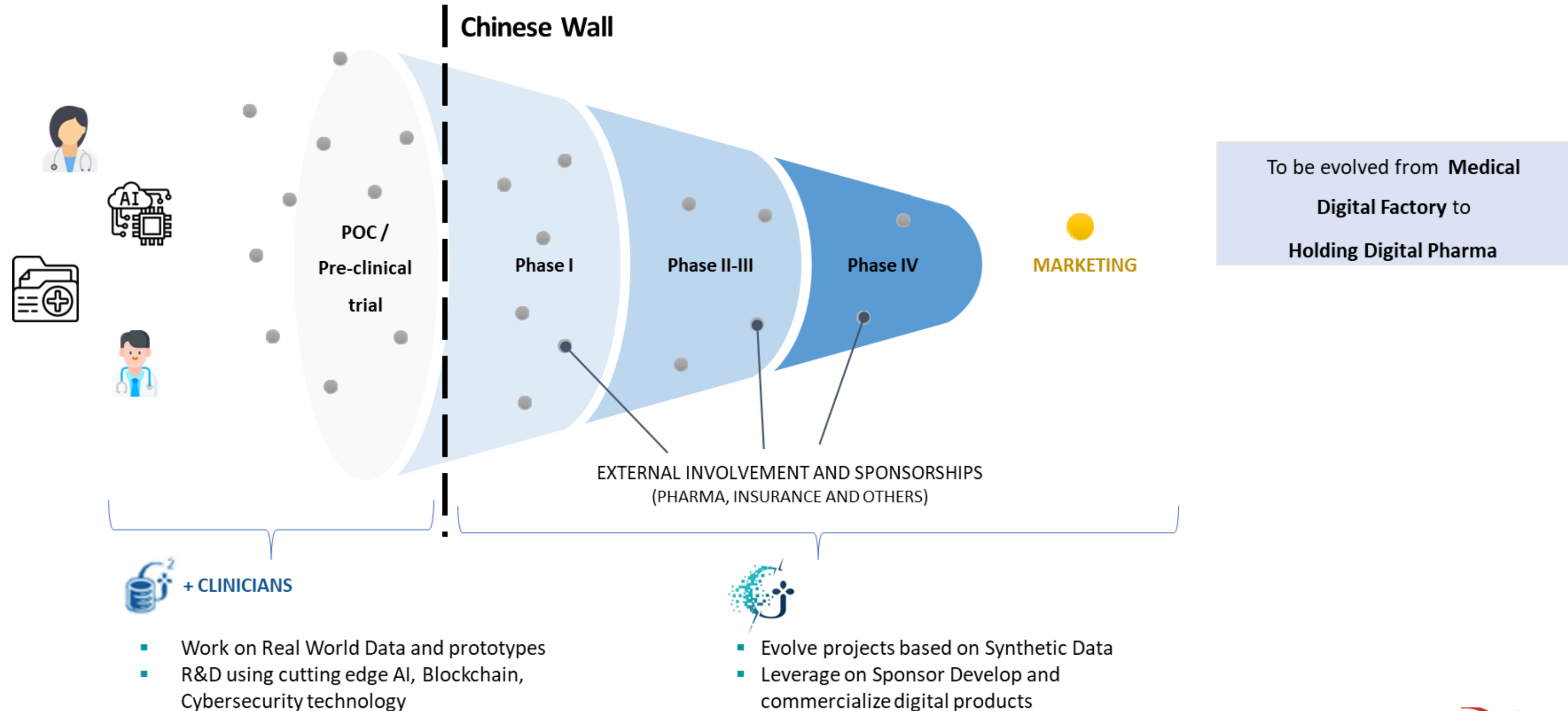


#4,3 MLN
PATIENTS

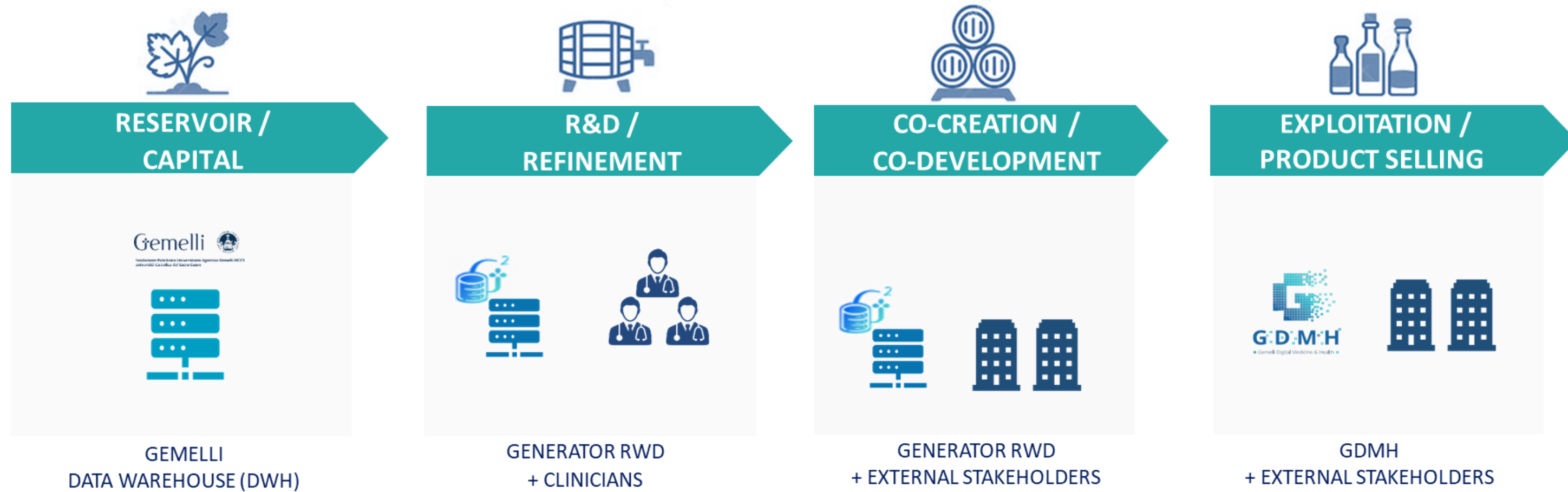


#780
REGIONAL FLOWS

Funnel dynamics: from generator research prototypes to GDMH products



GDMH & Gemelli Generator RWD Relationship



TECHNOLOGY READINESS LEVELS	3	EXPERIMENTAL PROOF OF CONCEPT	6	TECHNOLOGY DEMONSTRATED IN RELEVANT ENVIRONMENT	9	ACTUAL SYSTEM PROVEN IN OPERATIONAL ENVIR.
	2	TECHNOLOGY CONCEPT FORMULATED	5	TECHNOLOGY VALIDATED IN RELEVANT ENVIRONMENT	8	SYS. COMPLETE AND QUALIFIED
	1	BASIC PRINCIPLES OBSERVED	4	TECHNOLOGY VALIDATED IN LAB	7	SYS.PROTOTYPE DEMONST. IN OPERATIONAL ENVIR.
	RESEARCH		DEVELOPMENT		DEPLOYMENT	

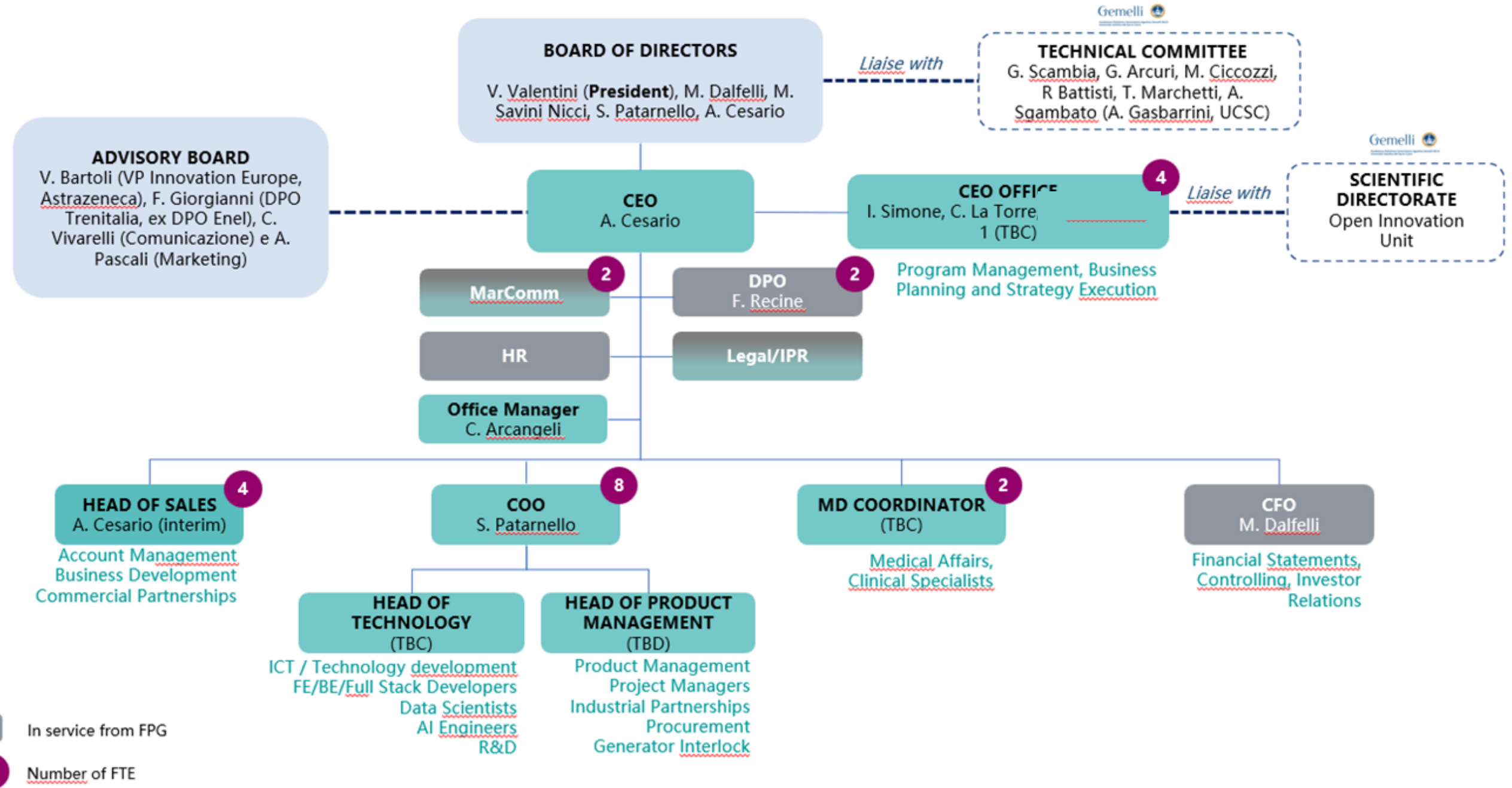
GDMH's collaborations in the Digital Health Scenario so far



Pipeline:

- **9** Advanced negotiations
- **11** Initial negotiations

GDMH's Human Resources



GDMH's Roadmap



RAMP UP

- Sales Pipeline development
- **9 co-sponsored projects** with major industry players
- **€1M+** funding from FPG
- Operations in **Rome** and **Milan** (MIND)

2022



CONSOLIDATION

- 20+ co-sponsored projects, generation **€2M revenue**
- **40 employees**
- **€2M+** additional funding from FPG

2023



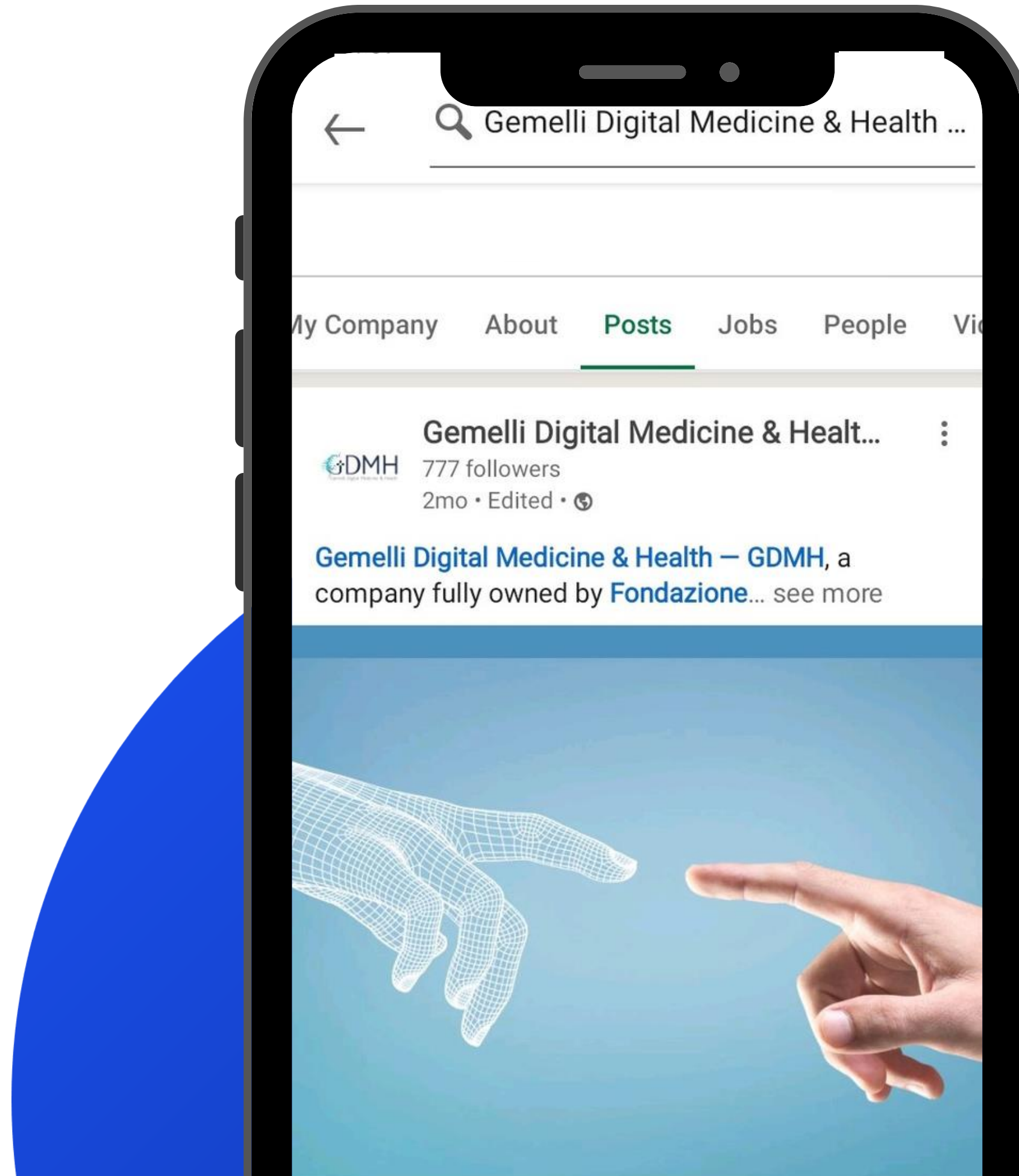
SCALE-UP

- First digital product launched in **2024** (*marketing phase*)
- **€35M** total revenue during the period 2024-2026 from **10+ digital products**

2024-2026

Our Social Impact

- Almost 800 followers within two months: the goal is to significantly keep growing our social media presence by also building a Video Channel
- Keep delivering scientific, editorial content on our online platforms
- 1.1K of search appearances based on 7-days count. To keep sharing our company updates about future collaborations in the Digital Health scenario





"One such societal question is how we can make available to qualified scientists increasing number of individual virtual clouds of billions of data points so that we can mine for the predictive medicine of the future".

CESARIO A. AUFRAY C, RUSSO P, HOOD L. P4
MEDICINE NEEDS P4 EDUCATION. CURR. PHARM
DES. 2014;20(38):6071-2. DOI:
10.2174/1381612820666140314145445. PMID:
24641231

A. Cesario, M. D'oria, C., Auffray G. Scambia:
**"Personalized Medicine Meets Artificial Intelligence:
Beyond Hype, Towards the Metaverse"**, Springer, New York.

Thank You

To discover more, reach us at:
Policlinico Universitario A.Gemelli IRCCS
<https://www.policlinicogemelli.it/>
Gemelli Generator - Real World Data <https://gemelligenerator.it/it/>
Gemelli Science & Technology Park
<https://gstep.policlinicogemelli.it/#/>
GDMH - Gemelli Digital Medicine & Health <https://gdmh.it/>