



imi innovative medicines initiative

SANOFI 

DIGITAL PORTFOLIO

Few years back...

IMI1 objective was to 'significantly improving the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines'

IMI2 remains focused on the needs of patients and society, and on delivering tools and resources to speed up the development of urgently-needed treatments AND on accelerating patient access to new treatments.

IMI1 (2008 – 2013)
Partnership between the EU and EFPIA
€2 billion (Half from EU/half from EFPIA)

IMI2 (2014 – 2020)
€3,276 billion (Half from EU/half from EFPIA)

153 projects from a total of 30 funding calls (IMI1 + IMI2)

First Call for proposals
on 30 May 2008

EHR4CR
2011-2016

EHR4CR aimed to improve the design of patient-centric trials by developing a platform that provides access to existing patient electronic health record systems (EHRs). The commercial platform InSite was launched in 2016, enabling scientists to find suitable candidates for trials by searching millions of EHRs throughout Europe while maintaining patient privacy.

April 2018
SGG DIGITAL HEALTH
KICK-OFF

Big Data for Better Outcomes

is generating knowledge, data and methodologies needed to support the transition towards more outcomes-focused, sustainable healthcare systems in Europe

The Strategic Governing Groups (SGGs)

- The Strategic Governing Groups ensure the coordination of Innovative Medicines Initiative (IMI) work in certain strategic areas and work to make the development of new topics more transparent and effective.

+ IMMUNOLOGY

+ DIABETES / METABOLIC DISORDERS

+ NEURODEGENERATION

+ TRANSLATIONAL SAFETY

+ DIGITAL HEALTH AND PATIENT-CENTRIC EVIDENCE GENERATION

+ INFECTIONS CONTROL

+ ONCOLOGY



TERTTU HARING
Sanofi



VAIBHAV NARAYAN
Janssen



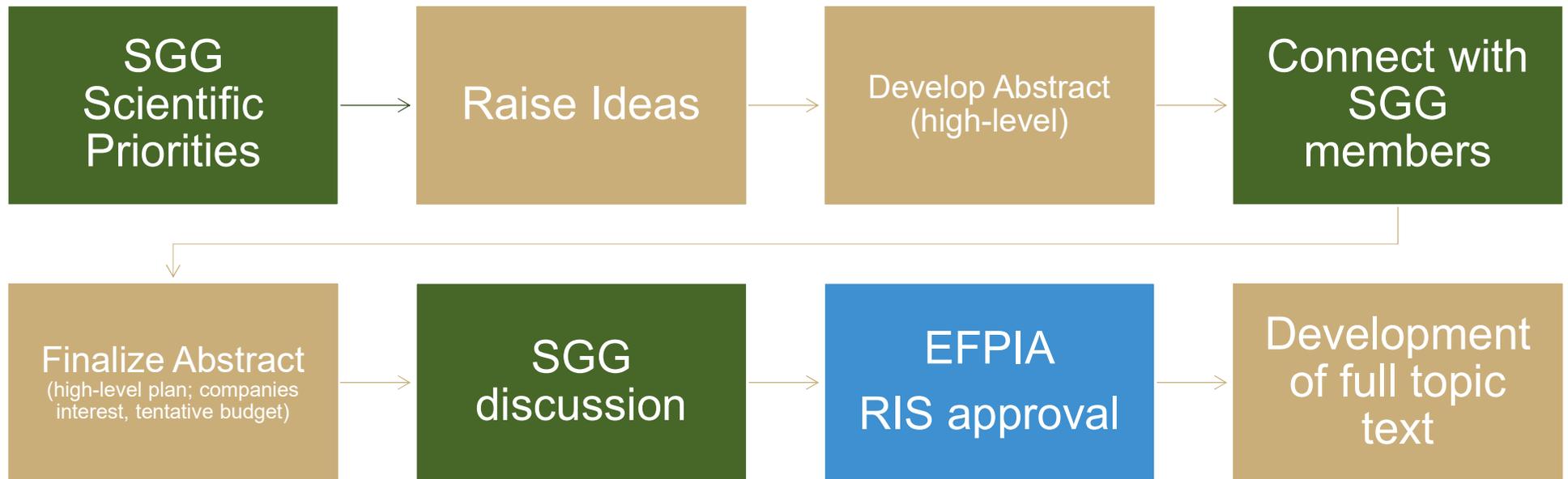
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Janssen



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From Scientific Priority to a topic text





DIGITAL
PROJECTS

SANOFI 

SGG DIGITAL HEALTH mandate

- **3 main areas defined**

- **Transformation of R&D and healthcare delivery through integration of digital health approaches to enable predictive and precision medicine:** digital technologies, e-health, m-health and **exploitation of big and deep data**. This includes, but is not limited to, enabling remote, continuous and objective measurement of clinical parameters;
- **New open collaboration models in clinical research and development,** **integration of real world data** in processes and decision making and new concepts of clinical platform trials and decentralisation of clinical (adaptive) trials to overcome traditional trial design limitations;
- **Enabling full exploitation and sustainability of IMI-generated data:** Support to development and maintenance of standardised, robust and state-of-the-art data management; development of new ways to source, manage and analyse data in compliance with ethical, GDPR and security standards.



key themes that should be tackled first

Clinical Trials

- Alternative CT
- CT at home
- Real world clinical trial design /EHR & EMR

Data

- Security & Privacy
- Standardisation
- data use and re-use
- data sharing (placebo, controls, outcomes, etc.)

Patient

- Voice of patient
- creating trust for patient
- PRO
- Digitizing Patient Engagement

Standardisation

- SmPCs application
- Validation
- Evidence standards for digital health solutions

Regulatory

- Acceptance of digital approaches and/or stakeholder acceptance
- Digital endpoints

Tools

- to enable compliance and adherence
- How to support the EHDN as an infrastructure project

SGG DIGITAL PROJECTS ongoing

9 projects launched – 230 M€

Call	Topic	Objective	status	start	END
13	MOBILISE-D	Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement	execution	01Apr19	31/03/2024
14	Trials@Home	Explore the opportunities of moving clinical trials from the traditional clinic setting to the participant's immediate surroundings. These so-called Remote Decentralised Clinical Trials (RDCTs) make use of new – digital – innovations and enable participants to visit a clinical trial centre less frequently	execution	01-sept-19	31/08/2024
14	MELLODDY	to establish a machine learning platform that would make it possible to learn from multiple sets of proprietary data while respecting their highly confidential nature, as data and asset owners will retain control of their information throughout the project.	execution	01-juin-19	31/05/2022
15	IDEA-FAST	Identifying digital endpoints to assess fatigue, sleep and activities in daily living in neurodegenerative disorders and immune-mediated inflammatory diseases	execution	01-janv-20	30/04/2025
15	EU-PEARL	EU patient-centric clinical trial platform	execution	01-nov-19	30/04/2023
15	Pharmaledger	to provide a widely trusted platform that supports the design and adoption of blockchain-enabled healthcare solutions while accelerating delivery of innovation that benefits the entire ecosystem, from manufacturers to patients.	execution	01-janv-20	31/12/2022
18	Health Outcomes Observatory (H2O)	To create 'health outcomes observatories' that will amplify the patient voice both in their own healthcare and in healthcare systems more broadly.	execution	01-oct-20	30/09/2025
18	Integrated digital health information - GRAVITATE-HEALTH	To demonstrate how the use of an integrated, digital, user-centric health information solution could enable a tangible improvement in the ability of citizens to access and understand reliable, relevant health information from different sources	execution	01-nov-20	31/10/2025
23	Returning Clinical Trial Data to study participants within a GDPR compliant and approved ethical framework - FACILITATE	Two main objectives, which are equally important: To align local and pan-European implementations and best practice for handling personal data protection regulations in order to foster the harmonisation of the legal framework applicable to medical research in EU	Agreements finalization	Q3-2021	2024

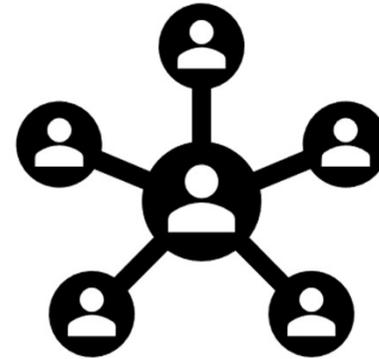
Think and talk



IMI project



Spread the change



Benefit together



How has IMI addressed the challenge -
and what is NEXT



THANKS!