

HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

European Network of Excellence for Big Data in Hematology,
consisting of 51 partners from 11 countries.

Aliki Taylor,
HARMONY Alliance Partner
Director Global Health Outcomes,
Takeda

EU Big Data Initiatives

R & D Data Intelligence
Leaders Forum

Day 2: Clinical and
Patient Data-Level Excellence

24 January 2018
Basel, Switzerland

Funded by



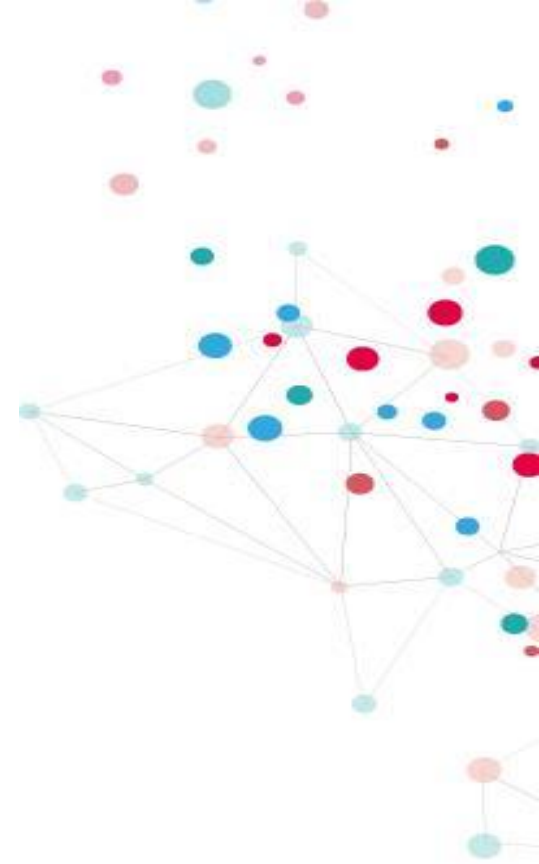
innovative
medicines
initiative



efpia

Overview

- Innovative Medicines Initiative (IMI)
- IMI-2 Big Data for Better Outcomes (BD4BO) and current Big Data Initiatives
- HARMONY Alliance
- New and future IMI-2 Big Data Initiatives
- Conclusions

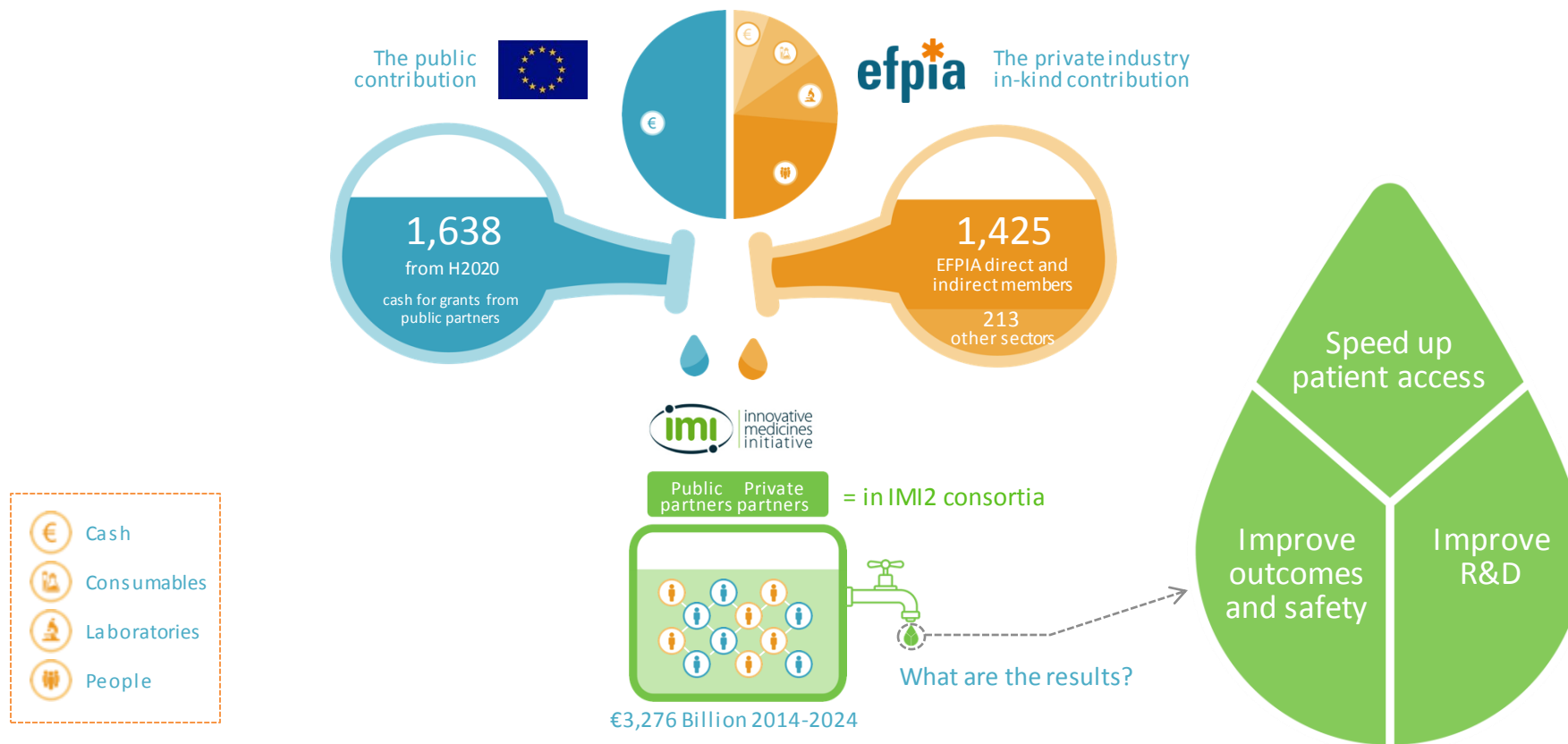




About IMI

the Innovative Medicines Initiative

The world's largest public-private partnership
in the life sciences



Key concepts

- Non-competitive collaborative research
- Competitive Calls for Proposals
- Industry contribution is in kind
- Open Collaboration in public-private consortia
 - Data sharing, dissemination of results
- Industry contribution is in kind

Strategic Research Agenda IMI-2

- Antimicrobial resistance
- Osteoarthritis
- Cardiovascular diseases
- Neurodegenerative diseases
- Psychiatric diseases
- Respiratory diseases
- Immune-mediated diseases
- Ageing-associated diseases
- Cancer
- Rare/Orphan diseases
- Vaccines



A typical IMI Consortium

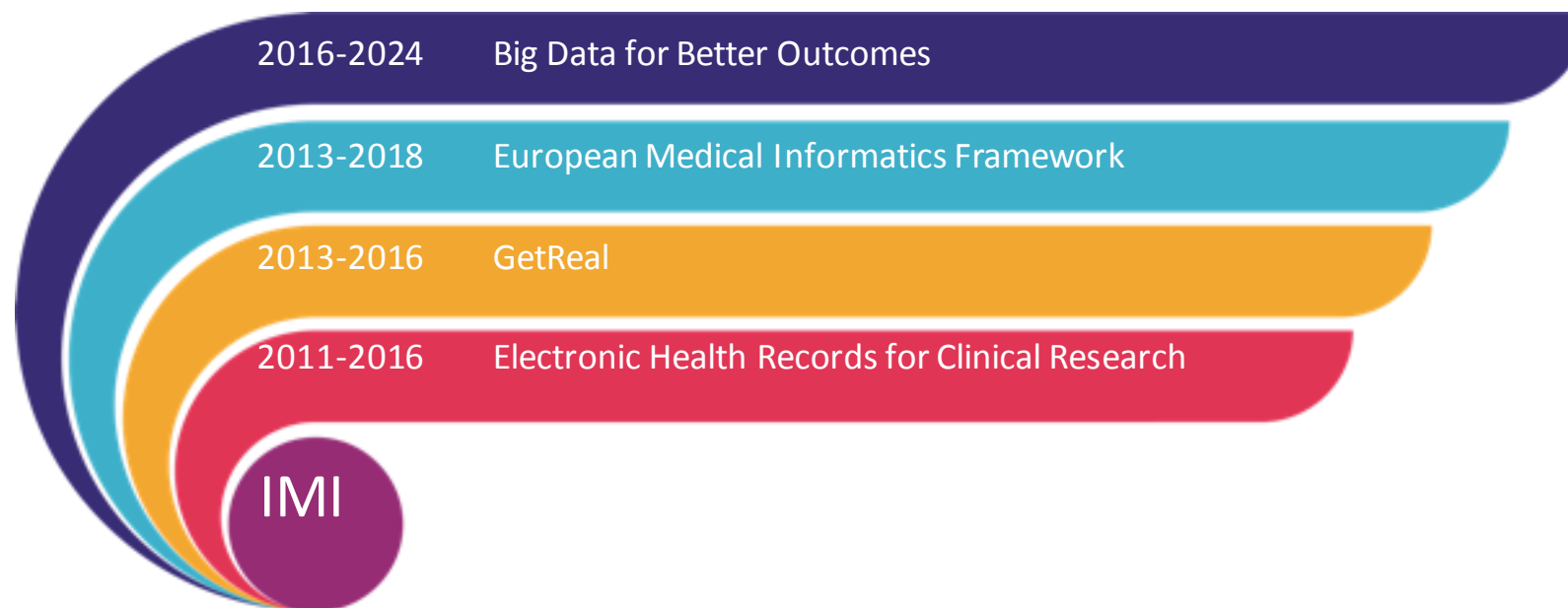




IMI-2 Big Data for Better Outcomes (BD4BO) and current Big Data Initiatives

How can Big Data Improve Health Outcomes?

- Big data can help us to better understand human biology which can in turn will facilitate research and development towards more effective and personalized therapies for patients.
- With big data, we can make healthcare delivery more efficient and improve health outcomes.
- Ultimately, this can lead to a better quality of life and more affordable healthcare.



Improve health outcomes and healthcare systems in Europe by maximising the potential of Big Data

THEMES/ENABLERS:

Design sets of standard outcomes and demonstrate value

Increase access to high quality outcomes data

Use data to improve value of HC delivery

Increase patient engagement through digital solutions

DISEASE-SPECIFIC PROJECTS:

ROADMAP: Alzheimer's disease

HARMONY: Haematologic malignancies

BigData@Heart: Cardiovascular diseases

PIONEER: Prostate cancer

More to come....

CO-ORDINATING PROJECTS:

European Health Data Network (EHDN)

DO->IT: Coordination & support actions

Objective	Expected outputs	Timeline
Provide the foundation for a Europe-wide, integrated data environment and framework for RWE across the spectrum of Alzheimer's disease	<ul style="list-style-type: none"> • Minimum set of measurable real-world patient outcomes • Recommendations on RWE appropriate AD-related endpoints • Identification of data sources and outline a data integration strategy for RWE outcomes • Development of new methods for collecting RWE data to improve health care value for AD • Recommendations for disease progression and health economic modelling • Guiding principles and recommendations from HTA groups/payers/regulators for the development and incorporation of RWE into clinical and market access development plans for AD 	2016 - 2018

www.roadmap-alzheimer.org

Objective	Expected outputs	Timeline
Deliver clinically-relevant disease phenotypes, scalable insights from RWE and insights driving drug development and personalised medicine through advanced analytics	<ul style="list-style-type: none">• Definitions of diseases and outcomes that are universal, computable and relevant for patients, clinicians, industry and regulators• Informatics platforms that link, visualise and harmonise data sources of varying types, completeness and structure• Data science techniques to identify new phenotypes and construct personalised predictive models• Guidelines that allow for cross-border usage of Big Data sources acknowledging ethical and legal constraints as well as data security	2017 – 2022

www.bigdata-heart.eu





European Health Data Network (EHDN)

A federated network of relevant and high quality data sources

Objective	Expected outputs	Timeline
As an enabling component of the BD4BO programme – to deliver the vision of large-scale medical outcomes research that develops a data network to enable other researchers to ‘find’ and safely ‘reuse’ data.	<ul style="list-style-type: none">• An open, transparent call process for third party data providers, with financial support for mapping to OMOP common data model• Delivery of an operational, federated network equivalent to a representative 20% of the EU population, or approximately 100 million people (~200 data sets)• Data quality management framework, supportive of both validation and benchmarking• European SMEs with relevant experience in innovative services for data providers and/or consumers• Certification of these SMEs across the RWE technical continuum• EHDN project governance for engagement of third party datasets, oversight of data harmonisation and interaction with BD4BO• Evolution of health outcomes research and incorporation of novel data sources	2018 – 2023

EHDN

Co-ordinating Projects

DO->IT

The overarching coordination structure for all BD4BO projects

Objective	Expected outputs	Timeline
Serve as the pivotal point of programme coordination providing expertise for communication, collaboration, dissemination and stakeholder engagement for some areas common for all BD4BO projects	<ul style="list-style-type: none">• Develop and coordinate the overall BD4BO programme strategy• Develop recommendations for new IMI2 scientific priorities• Identify best practice for data management & collection - the standardisation, selection and measurement of outcomes• Build an online repository to share knowledge and learning across the BD4BO programme• Lead communication activities of the BD4BO programme and provide coordination of communications with BD4BO projects• Facilitate stakeholder engagement with key healthcare system stakeholders to foster policy discussions and build consensus• Develop minimum data privacy standards for ICFs• Develop explanatory information and training material to improve awareness of data privacy issues and engage with stakeholders to ensure buy-in for ICF templates	2017 – 2019



www.bd4bo.eu

Co-ordinating Projects

A microscopic image showing a cluster of cells. Some cells are stained with a bright red dye, while others are stained with a green dye. The background is a dark blue, out-of-focus field of similar cells.

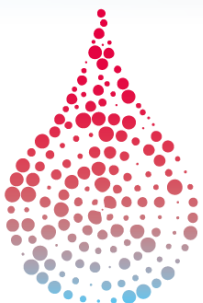
HARMONY Alliance

**Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology**



PATIENTS affected by Hematologic Malignancies still have unmet needs.

We will address their urgent unmet needs, such as faster diagnosis and personalized therapies.



HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

By using **BIG DATA SHARING** among all relevant stakeholders involved, **HARMONY** aims to improve patient outcomes.

Enabling Better and Faster Treatment for Patients with Hematologic Malignancies by using big data technology

WHO WE ARE

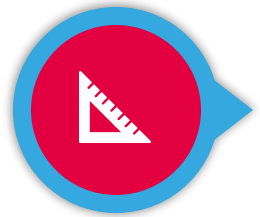
- A pan-European IMI project uniting and aligning healthcare system stakeholders and key opinion leaders in the field of blood cancers
- The first and largest Public Private Partnership in Hematology
- The largest project within the IMI BD4BO

WE OFFER

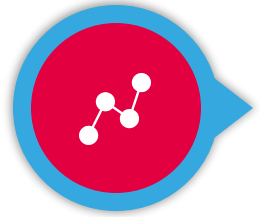
- A high-quality multidisciplinary sources Big Data Platform that integrates outcome measures and endpoint definitions for blood cancers (HMs)
- Tools to empower clinicians and other Healthcare system stakeholders to improve decision-making.



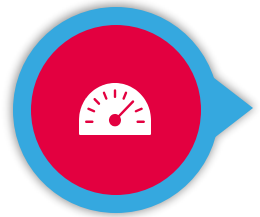
Unmet needs in Hematologic Malignancies in adult and pediatric patients



The need to harmonize outcome measures and endpoint definitions for HMs at European level



The need to increase the available omics data to better predict efficacy and toxicity of certain treatments



The need to speed up drug development, access pathways and "bench-to-bedside" process



The need to improve the optimal use of resources



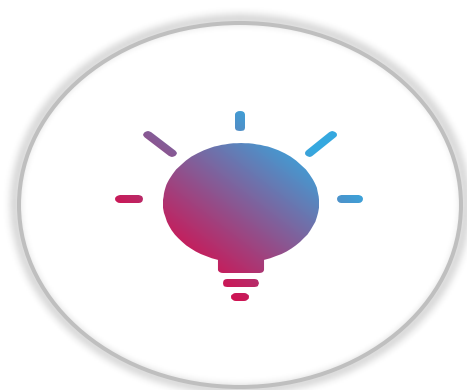
51 Public/Private Alliance Partners: Working Together to Maximize HARMONY's Results



40 M € | 2017-2022

44 organizations from 11 European Countries, 7 pharmaceutical companies.

The HARMONY approach



- Collect, share and harmonize Big Data from high-quality **multidisciplinary** sources.
- Assess and integrate a large amount of **molecular data**.
- **Enable** identification of novel pathways for **drug development**.
- Generate evidence to encourage **healthcare systems** to pay particular attention to the value of healthcare and to improve outcomes.
- Facilitate drug development pipelines and accelerate the “**bench-to-bedside**” **process in drug development**.
- Empower **clinicians, policy makers and payers** to improve decision-making and **optimize care for patients with HMs**.
- Generate **multi stakeholder** activities.



Patients / Patient Organisations are core members

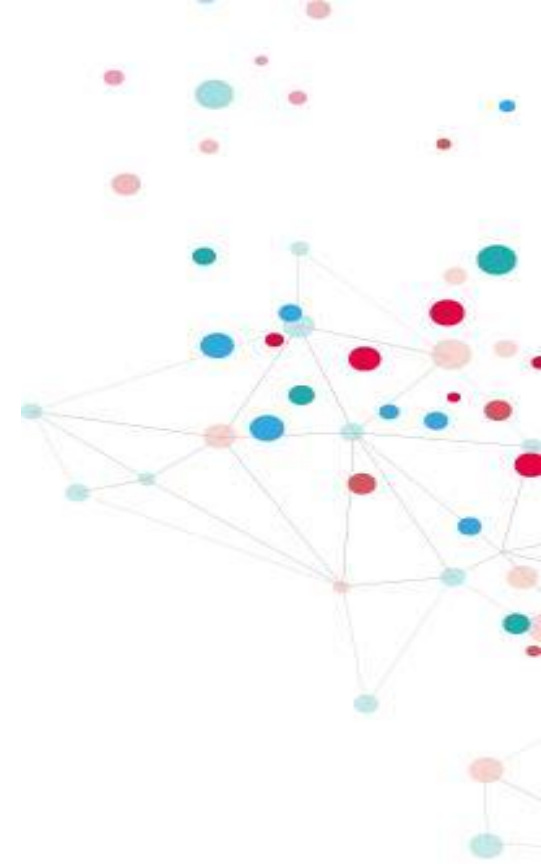


- Patient Groups are involved as Alliance Partners (LeukaNet, European LeukemiaNet)
- Many more European patient organizations are invited to become actively involved:
 - As representatives in the HARMONY Policy Health Stakeholder Forum (PHSFF)
 - A member of our Community
- Communication within HARMONY and our patient groups is key:
 - Create awareness and understanding for big data and what it means for patients now and in the future
 - Engage through consultations, polls, debates and meetings for input on the 7 therapeutic areas: and on patient-related outcomes



Our achievements in 2017

- **HARMONY's Big Data platform** has been established;
- HARMONY has started **analyzing description of datasets**;
- **Policy Health Stakeholder Feedback Forum** has been established for Patient organizations, Hematologists/clinicians, Medicines Authorities, HTA bodies and Pharmaceutical Industry;
- An **Independent External Ethics Advisory Board (EAB)** was installed to monitor the Public Interest, the Informed Consent and the Tracking Data Records;
- **Legal and ethical compliant approaches** were developed to the processing of clinical data for research.

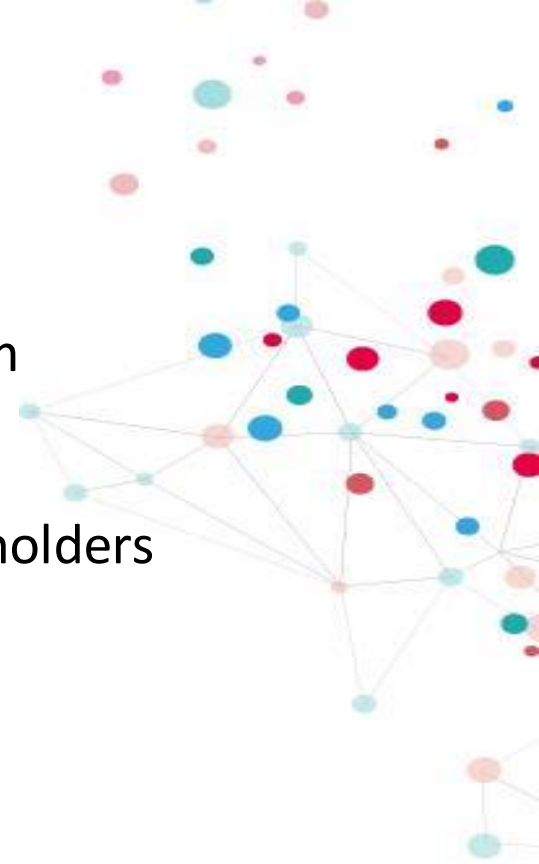


More expected Results

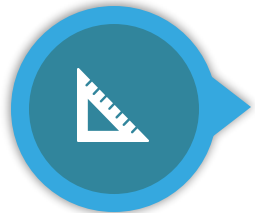


- A **clinical data-sharing platform** including Big Data series from patients with hematological malignancies
- A **community** of European hematological malignancies stakeholders
- Meaningful and harmonized **clinical endpoints and outcome measures** in hematological malignancies
- **Tools** for analyzing complex data sets including genomic data
- **Biomarkers** that will contribute to timely patient access to more effective and better tolerated innovative therapies
- A **framework** for legal, ethical and governance issues

With the aim to provide



..... answers to the **unmet needs** of patients suffering from Hematologic Malignancies



Harmonized outcome measures and endpoint definitions for HMs at European level



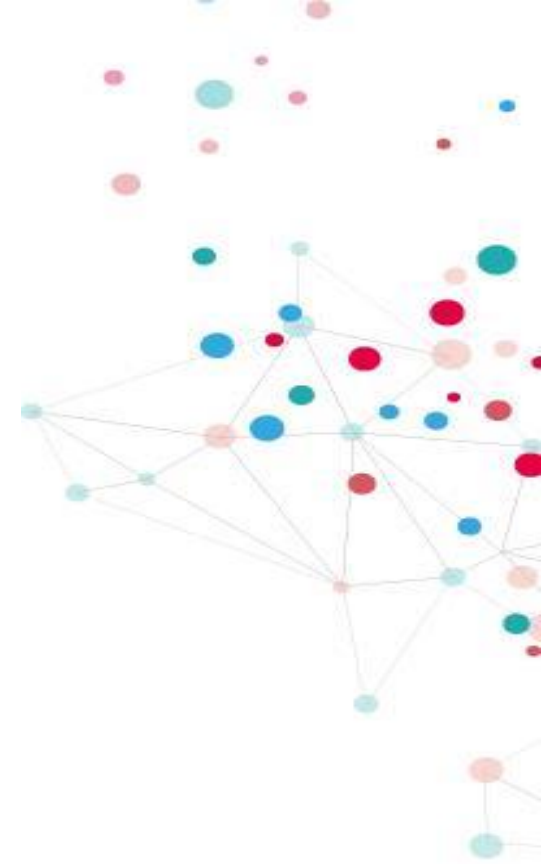
Availability of omics data to better predict toxicity of certain treatments



Faster drug development, access pathways and "bench-to-bedside" process



Optimal use of resources



The background is a deep blue field filled with a complex network of thin, glowing white and light blue lines that crisscross the frame. Interspersed among these lines are numerous small, semi-transparent squares in various shades of blue, some appearing as bright highlights. The overall effect is one of dynamic energy and digital connectivity.

New and future IMI-2
Big Data Initiatives

New IMI -2 Big Data Initiatives

- **RADAR-AD (Call 12 - Topic 1)** Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's disease
- **FAIRification of IMI and EFPIA data (Call 12 - Topic 2)** Focus on IMI projects that have data that is scientifically valuable and amenable to being made FAIR. It is expected that the databases of more than 20 IMI projects will be made FAIR in this project.

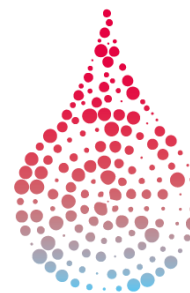
Future Big Data Initiatives

- **Call 13 - Topic 7:** Linking digital assessment of mobility to clinical endpoints to support regulatory acceptance and clinical practice

Conclusions

- IMI-2 is focusing on many new data sharing initiatives
- BD4BO is the biggest European data sharing set of projects in healthcare and HARMONY is the largest such initiative for haematological malignancies
- By combining data in health we can improve health of patients
- The patients ultimately must be at the centre of these projects so they can input and benefit the most.

**Thank you
And let's connect.**



HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

European Network of Excellence for Big Data in Hematology

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www.harmony-alliance.eu

[@HarmonynetEU](https://twitter.com/HarmonynetEU)



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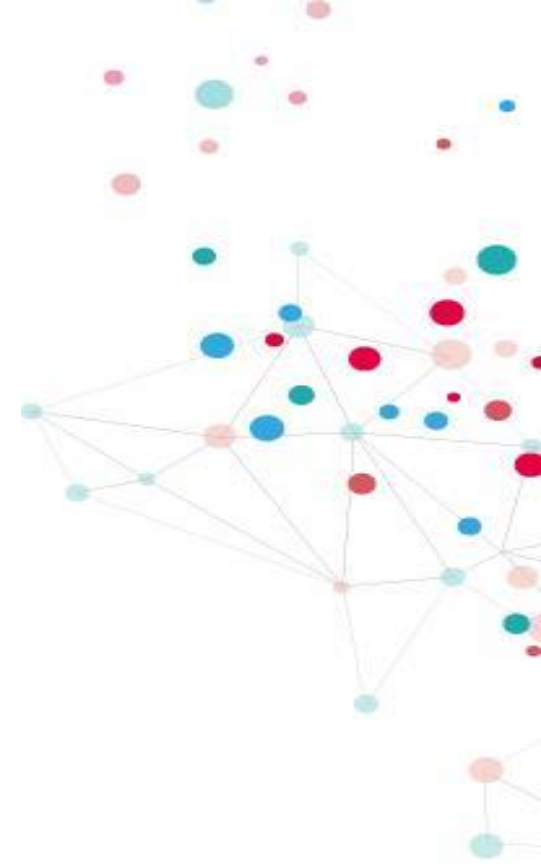
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- www.harmony-alliance.eu

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- This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.
- Read more at: www.imi.europa.eu



Useful Links

- HARMONY <https://www.harmony-alliance.eu/>
- BD4BO <http://bd4bo.eu/>
- GetReal RWE Navigator: <http://www.imi-getreal.eu/Tools/RWE-Navigator>
- Link to EMIF <http://www.emif.eu/about/emif-platform/emif-catalogue>
- EHR4CR (<http://www.i-hd.eu/>)

