HARMONY ALLIANCE

Interoperability between registries and other data sources: the HARMONY Big Data Platform

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Joint HMA/EMA multi-stakeholder workshop on Patient Registries | 12th-13th February 2024
Session 2: Experience gained, and lessons learnt from initiatives aiming to leverage the use of registries

BIG DATA FOR BLOOD CANCER

imi innovative medicines initiative

efpia

The need for Real-World Data research in Hematological Malignancies (HMs)

- Good quality data used to stay isolated
- HMs are rare diseases, with a very precise diagnosis
- RCT data is not always representative of the whole population

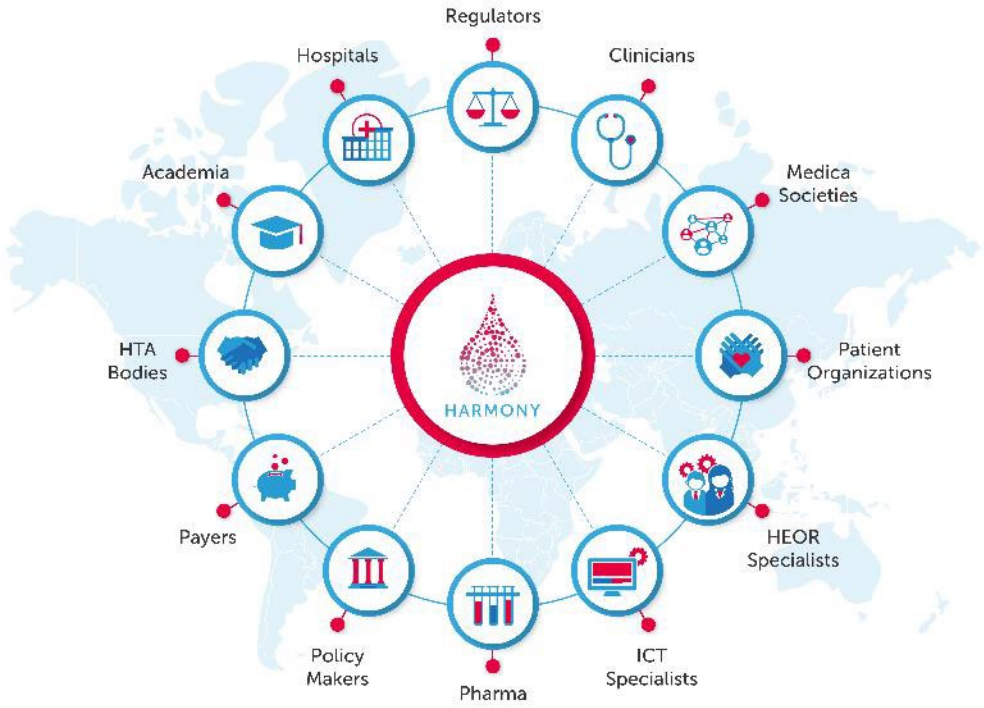
HARMONY

About the HARMONY Alliance

European Public-Private Partnership for big data in hematology

- The HARMONY Alliance is composed of **HARMONY and HARMONY PLUS**
- HARMONY (2017-2023) and HARMONY PLUS (2020-2024) are **IHI funded projects**

  The Innovative Health Initiative is a European Public-Private Partnership for health research and innovation between the EU and Europe's life science industries.
- We have built a **community with a wide representation of all stakeholder groups**
- Both projects have clear objectives, with an interest in medicines intended for the **treatment of hematological malignancies.**
- Ultimately, the goal is to increase the application of omics data in clinical practices, **speed up drug development**, access pathways and bench-to-bedside processes



About the HARMONY Alliance

A 7-year-long history of European Public-Private collaboration

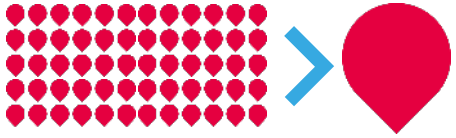
Community of approx.
500 professionals

> 140 Data Providers from 34 countries, 19 being European

9 European Patient Organizations, also involved in carrying out research

9 Pharma companies, providing in-cash and in-kind support, and data

Big Data Platform with **165,000** records identified in all HMs Integrated Data Services



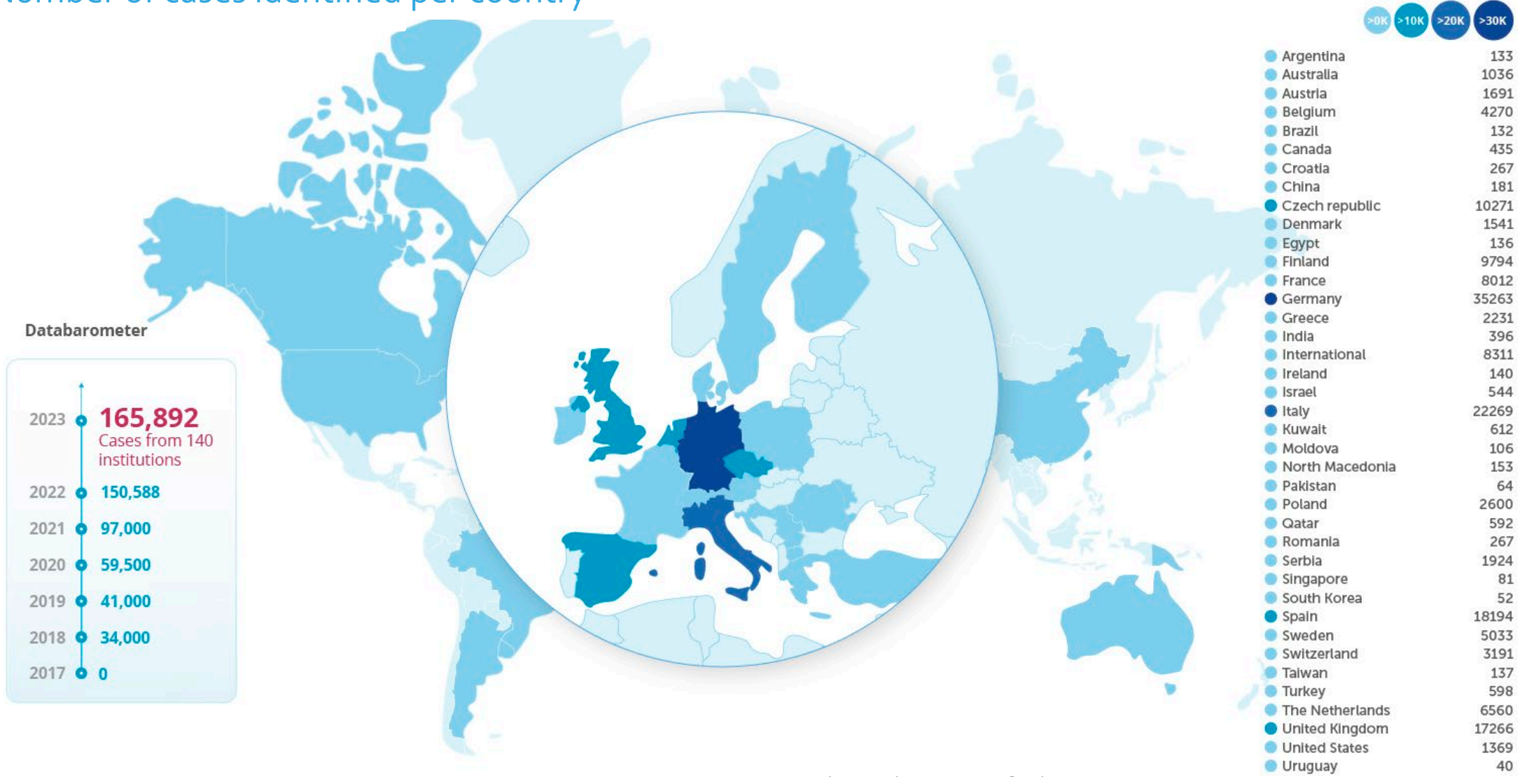
+100 Databases harmonized to OMOP common data model

+30 Collaborative projects, comprising research ideas, definition of COS, and other multi-stakeholder activities

Robust Big Data Platform, GDPR-compliant data life cycle, and visualization tools

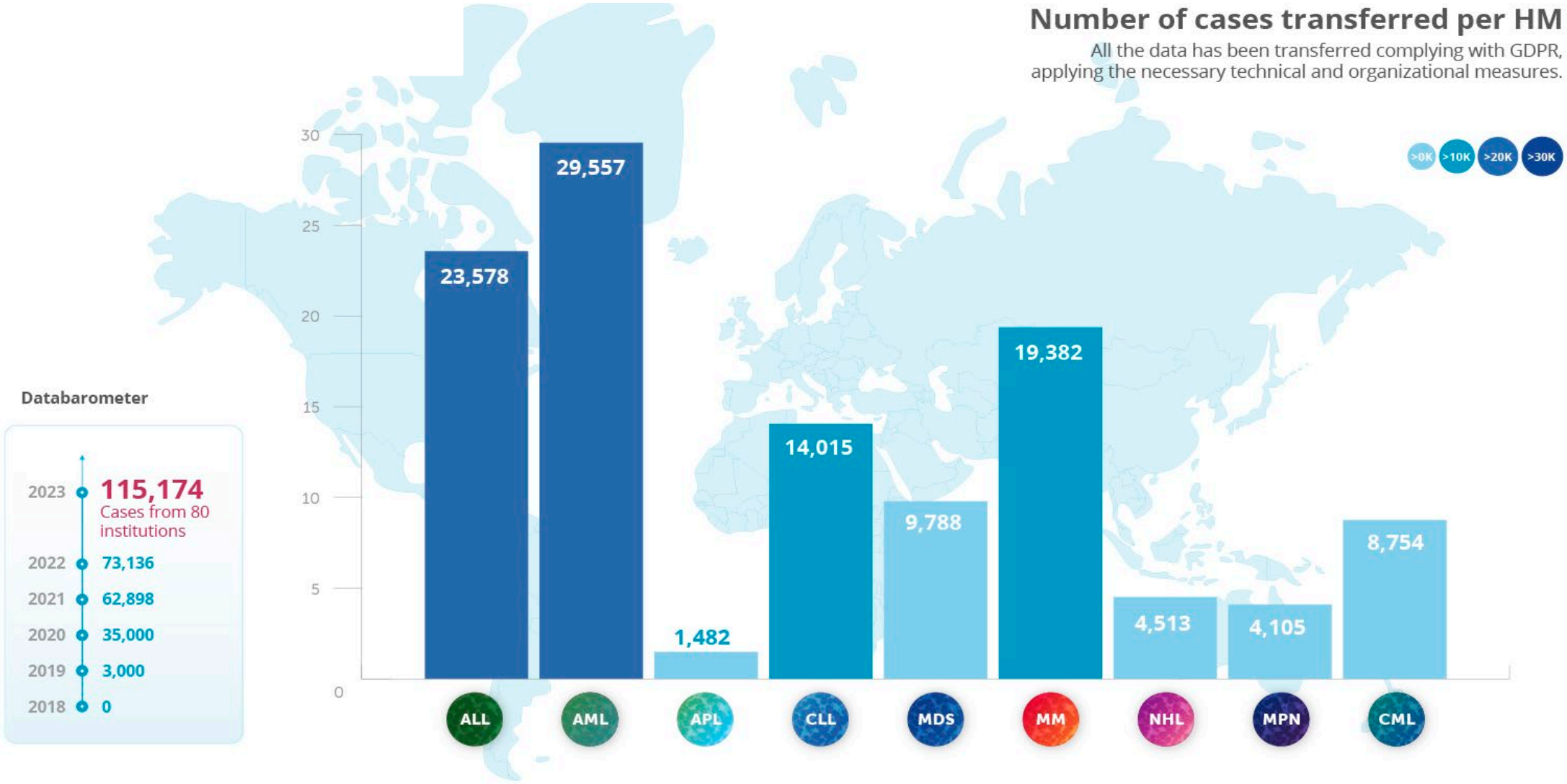
The HARMONY Big Data Platform is open to receive data from organizations worldwide

Number of cases identified per country



The HARMONY Big Data Platform is open to receive data from organizations worldwide

Number of cases transferred – per disease



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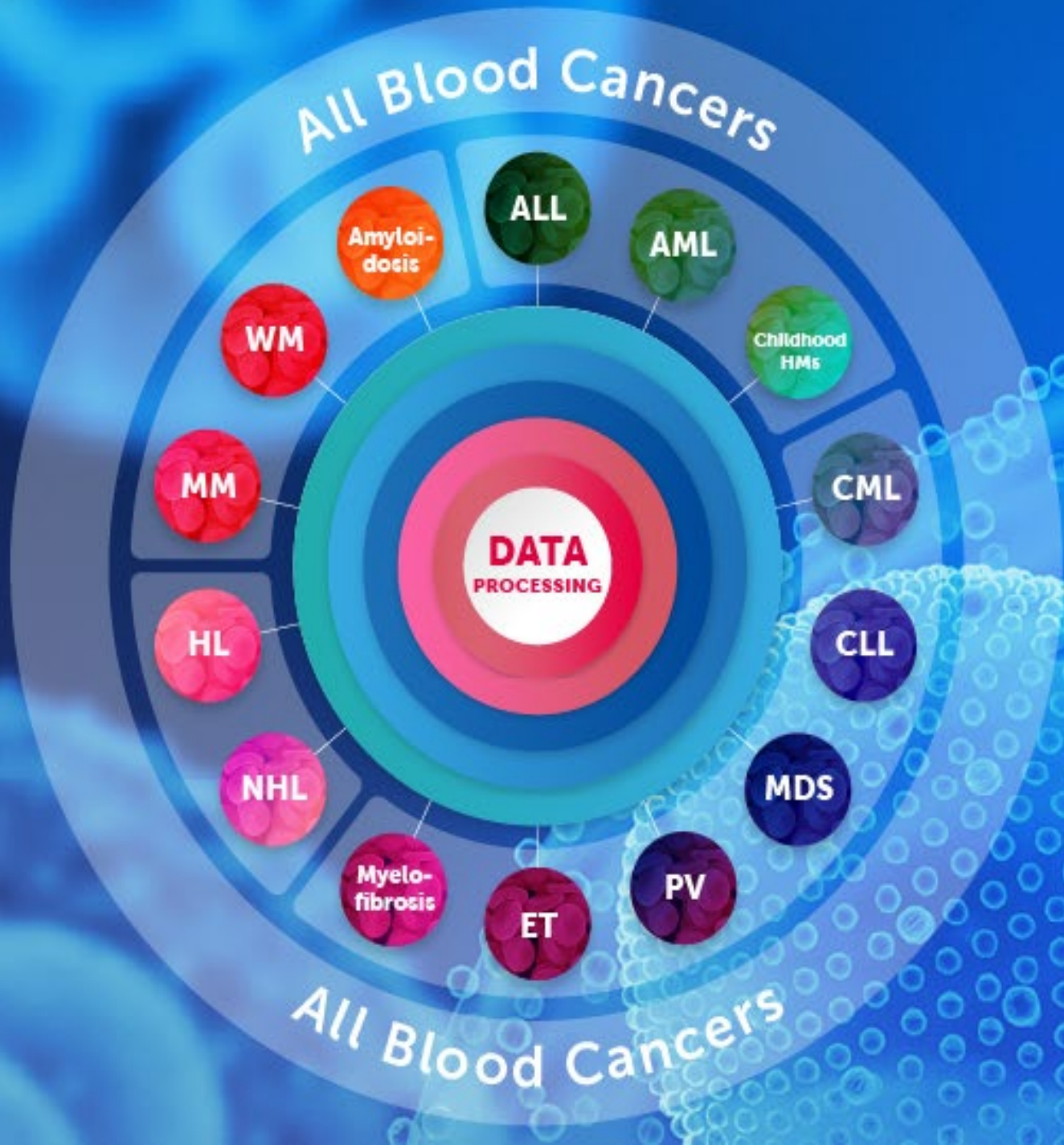
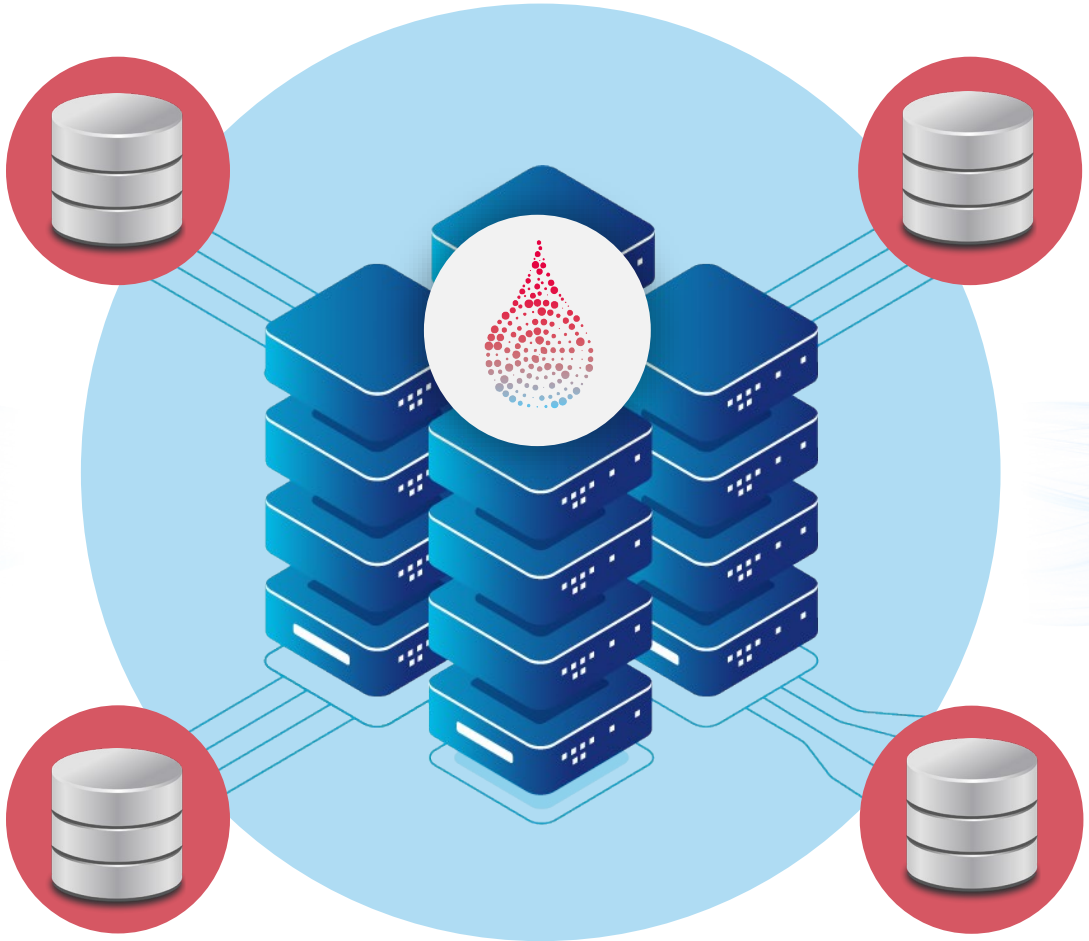
Big Data Platform



The HARMONY Platform: towards a mixed model

Established as a Data Lake -> transitioning to a mixed model to seize the advantages of data federation



The quest for data interoperability

Mapping to OMOP

The HARMONY Platform uses OMOP data model, terminologies, vocabularies, and coding schemes to standardize the format of the data bases received

Anonymization

Data undergoes a double-step anonymisation process and is checked by a TTP before entering the HARMONY Platform

Curation

Each dataset is checked for completeness and accuracy

Identification of data sources

The HARMONY Platform contains data from national registries, hospitals, study groups, universities, pharmaceutical companies…

Dissemination

We make sure sure that the results produced by our community not only reach the scientific community, but also the wider public.

Analytics

The HARMONY Platform counts with a team of analysts that support researchers implement state-of-the art analysis techniques.

Visualization

We have developed visualization tools to support the generation of new research project ideas and assess their feasibility with the data that is currently available on the HARMONY Platform.

The quest for data interoperability

Data Standardisation - OMOP Common Data Model

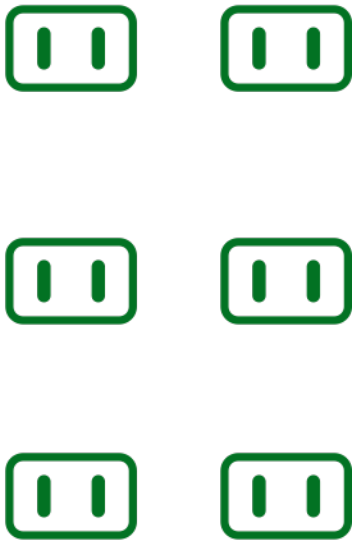
Raw data

North America

Southeast Asia

Europe

OMOPed data



Data with common

data model

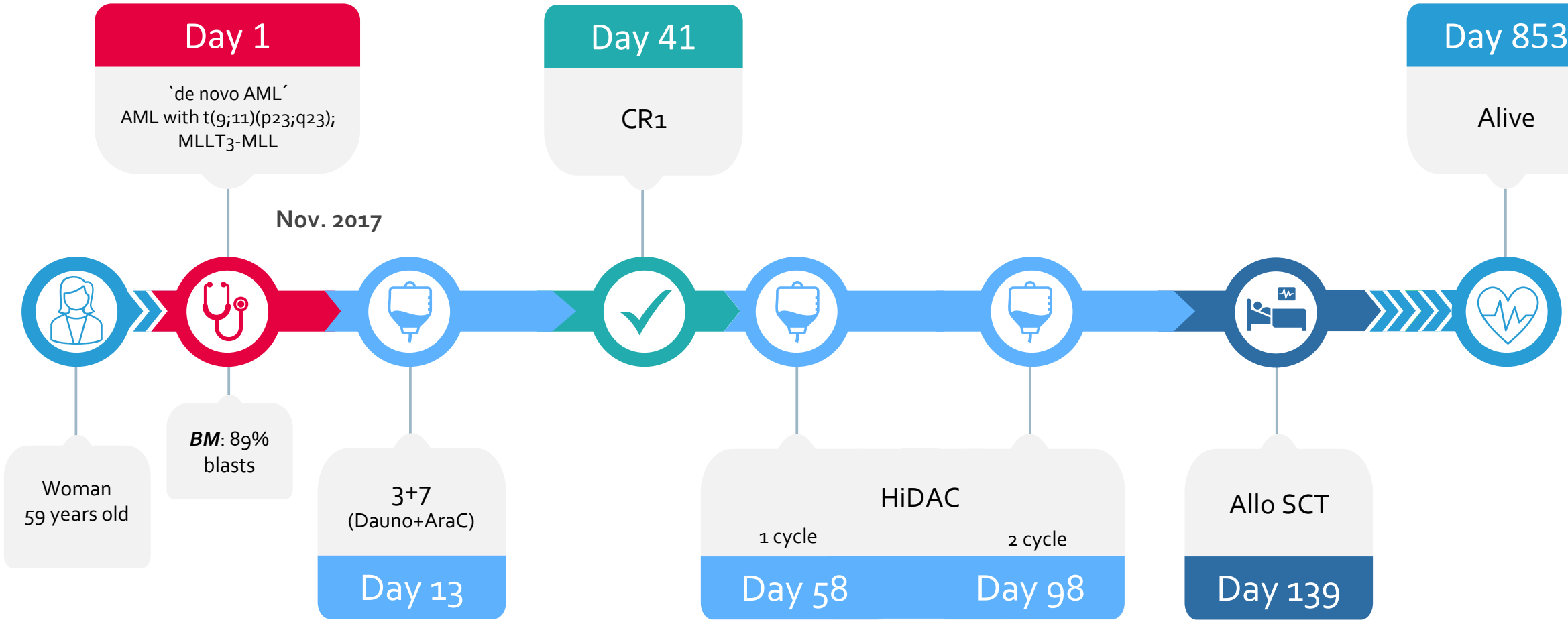
terminologies

vocabularies

coding schemes

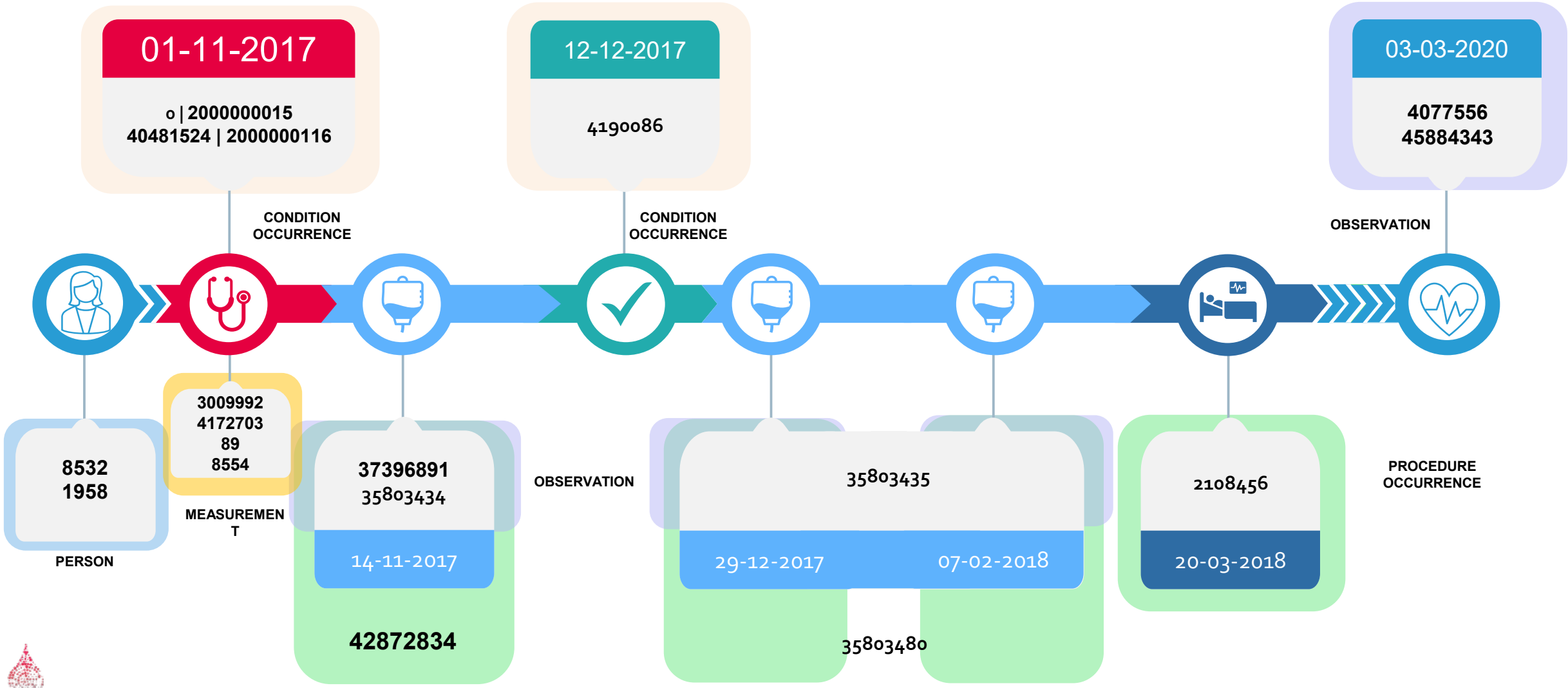
The quest for data interoperability

Data Standardisation - OMOP Common Data Model



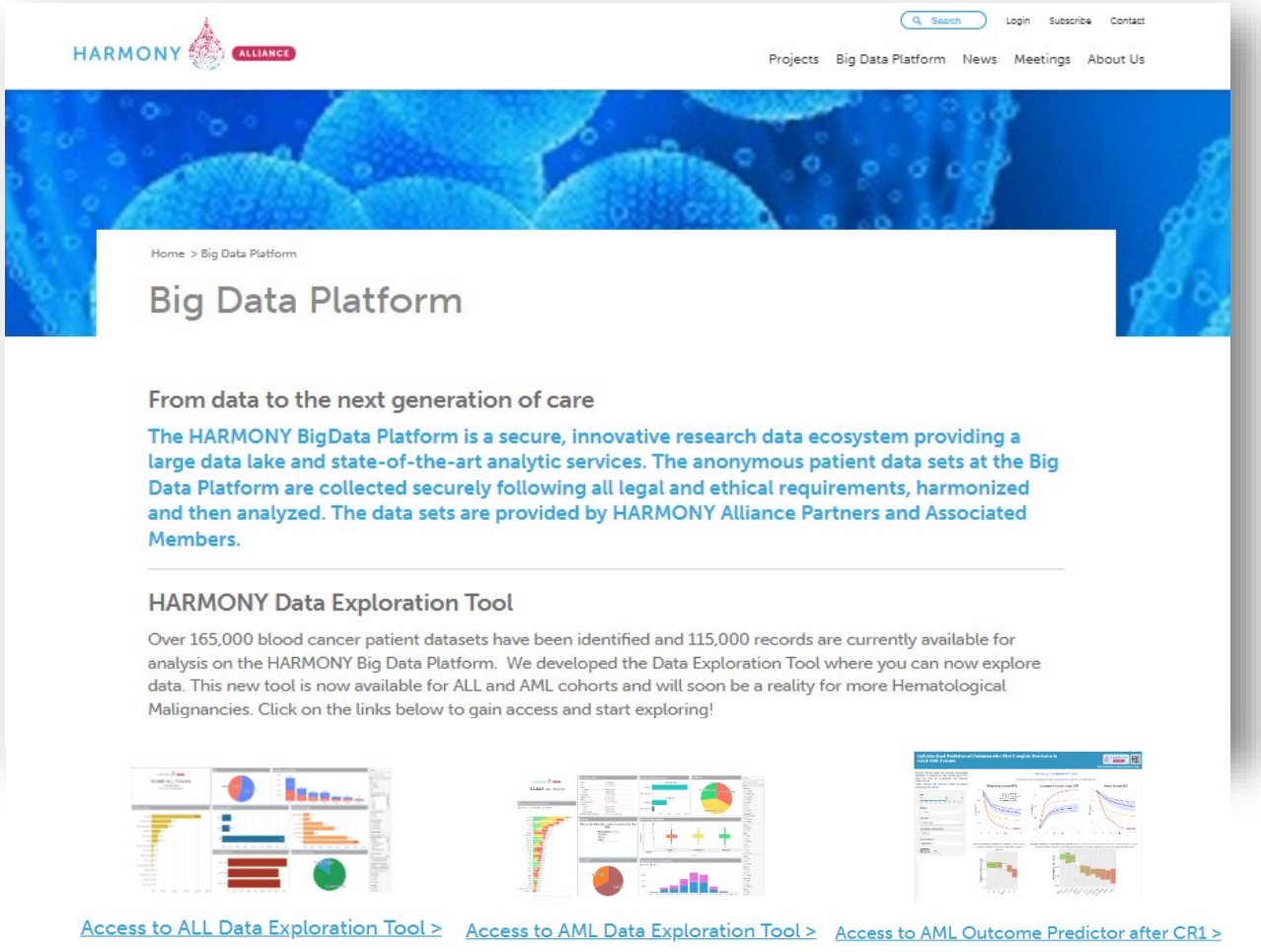
The quest for data interoperability

Data Standardisation - OMOP Common Data Model



Data visualization tools

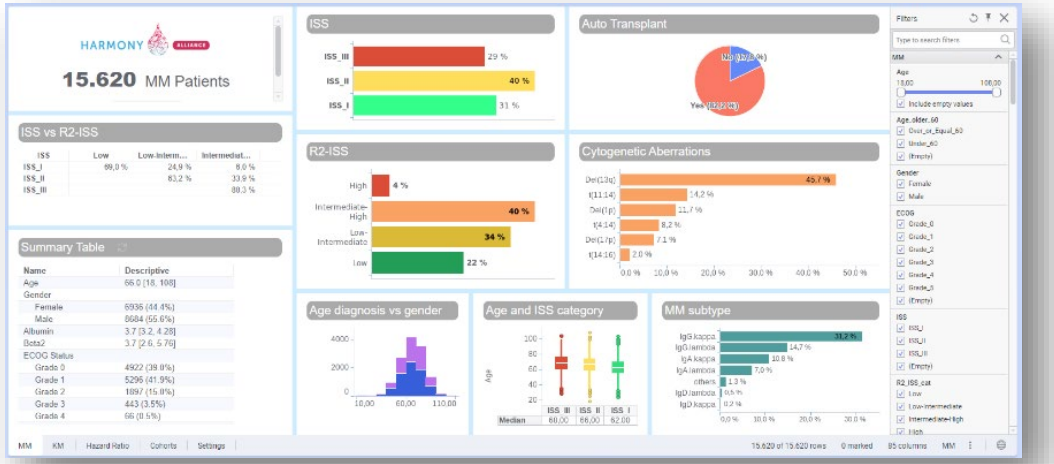
Check our website to assess the feasibility of conducting a research question in AML and ALL to the HARMONY Platform

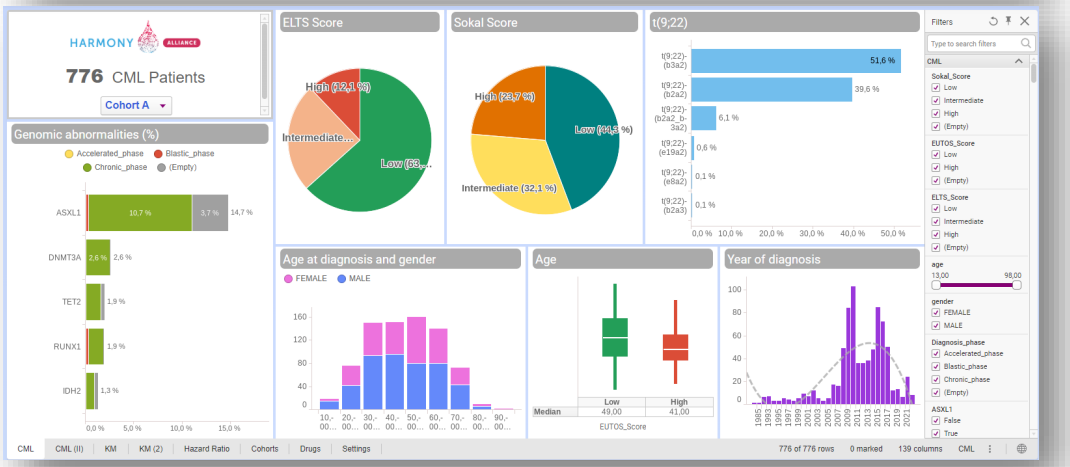


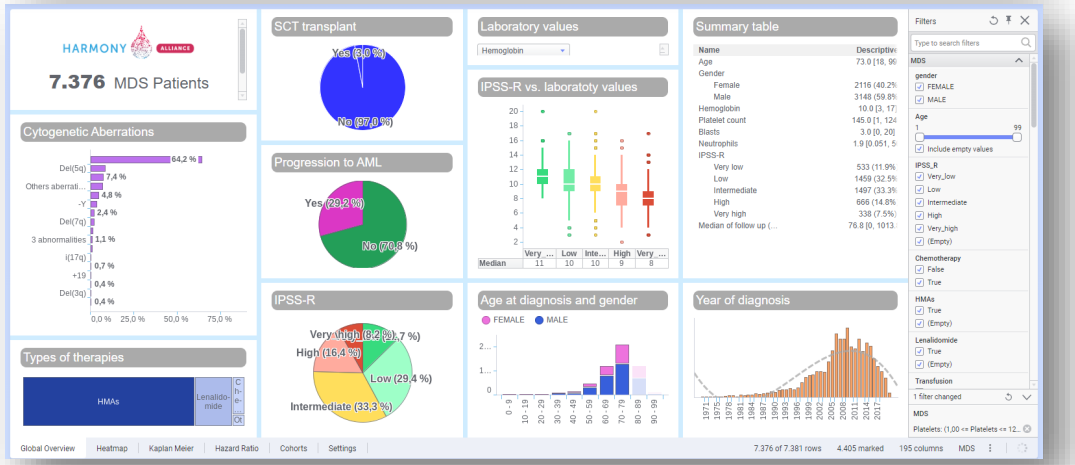
Check them here!

Tools for analysis and production of results

Dashboards to support data analysis have been developed
in AML, MM, ALL, MDS, and CML



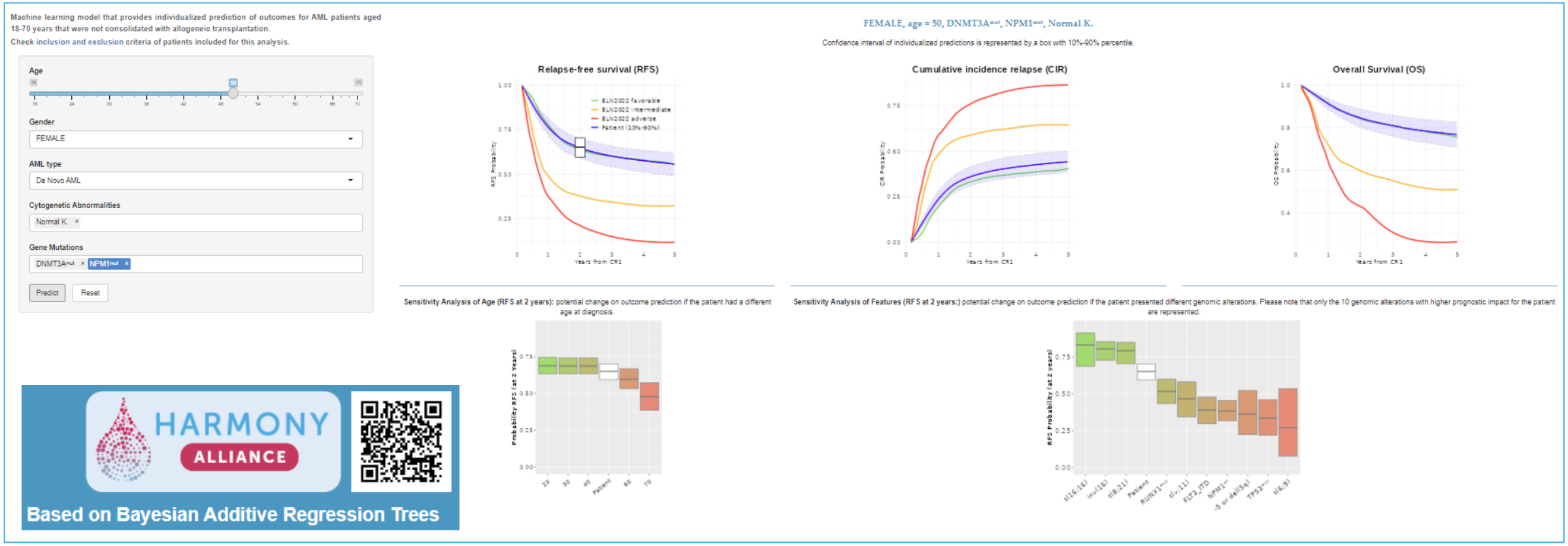




Tools to support decision-making

Individualized prediction of outcomes in AML

The aim of this **online tool** is to create a more accurate risk prediction to easily visualize the likelihood of relapse and help **to determine in which patient alloHSCT should be performed in CR1**



Unique Value Proposition

Offering **comprehensive services,** being the perfect **interface** and **interlocutor** to connect with over 500 **peers** and diversified **stakeholders** of the **pan-European** and **international hematology community**.

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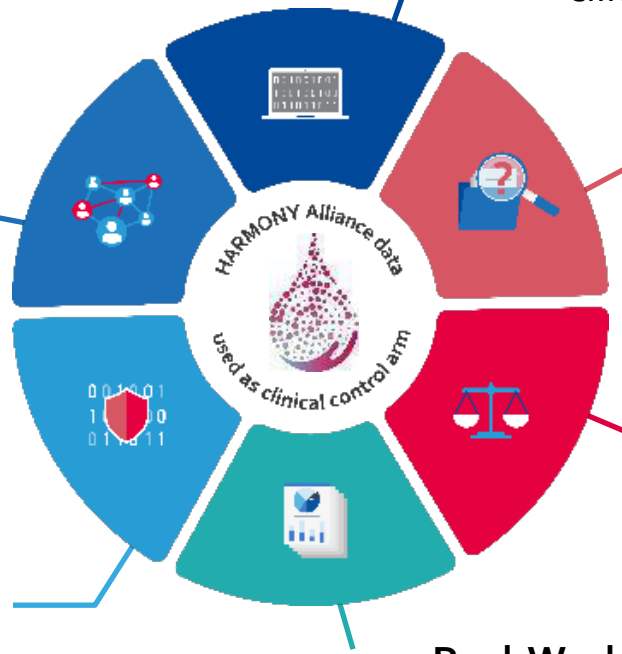
Virtual / in-silico data generation for clinical trials

Access to **a robust, safe, consolidated, GDPR-compliant, Big Data Platform** with **visualization and analytical tools, algorithms and Artificial Intelligence**



Dedicated **Research Questions**

Insights and decision-making tools for Regulatory Bodies

Data Science **Consultancy**

Real-World Evidence

The HARMONY Platform

Added Value for each Stakeholder Group

Clinicians and researchers

- Research questions, study design
- High-tier publications
- Improving clinical outcomes

Pharma

- Evidence generation when submitting dossiers to HTA agencies
- Generation of historic or synthetic arms for single arm trials/external comparison
- Contextualization of RCT-based evidence package with real-world evidence

All stakeholders

- Submit research proposals
- Become a member of a dedicated research group that includes skilled data scientists
- Contribute to scientific publications under the umbrella of the HARMON Alliance
- Contribute to improving outcomes for individuals with blood cancer

Patients

- Patient engagement process
- Consents & anonymisation
- Access to QoL data and possibility to send their own research questions
- Identification of prognostic factors

Regulators and HTAs

- Critical appraisal of company submissions
- Proper definition of the PICO parameters and the place in therapy
- To explore real-life treatment sequencing over time
- Research and validation of surrogate endpoints
- Support development of external controls to inform decision making

HARMONY

Lessons learnt

Barriers to harnessing the full value of health data

Technical

- Data heterogeneity
- Lack of interoperability
- Unfriendly software & manual processing
- Outdated technology
- Lack of data science skills

Data Quality

- Relevant data limited
- Endpoint recognition lacking
- Unstructured data not allowed
- Inefficient quality control

Funding & Sustainability

- Insufficient funding
- Fragmentation of funding
- Complex Access to funding

Competition

- Misalignment limits data sharing
- Scarce experience with research collaborations
- Very competitive environment

Legal & Political

- Multiple regulatory frameworks
- Different stakeholders' vision
- Concerns on data privacy

Governance & Trust

- Lack of clarity for data collection & access
- Complex access: TTP required
- Different interests & incentives among stakeholders
- Complex patient consent
- Need for strong data protection requirements

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HARMONY ALLIANCE

Uniting the hematology community

Working to produce results that improve the lives of patients with hematologic malignancies

HARMONY ALLIANCE FOUNDATION

HARMONY ALLIANCE

Thank you

Join us in creating the next generation of care for blood cancer patients

www.harmony-alliance.eu
www.bigdataforbloodcancer.eu

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Public-Private Partnership
for Big Data in Hematology

Big Data for Blood Cancer