

What has HARMONY achieved so far?

Several key milestones have been reached since the HARMONY Alliance was established:

- Alignment with the latest European regulations on data privacy
- Implementation of compliance with ethical rules and legislative frameworks across all countries and stakeholders in Europe
- Establishment of a standard operating procedure for the submission of research questions
- Creation and application of data sharing agreements
- Streamlining of processes for data flow within Europe to enable the use of the HARMONY BigData platform without jeopardizing data privacy and compliance with legal and ethical requirements
- Launching the HARMONY Big Data Platform
- Continuous population of the HARMONY Big Data Platform
- Submission and approval of several Big Data-driven studies for the different blood cancers
- Transfer of the first data sets into the HARMONY BigData Platform

With these achievements, researchers are now in the starting blocks for intense analysis of the data in the HARMONY BigData platform.

What are the next steps?

Currently, the first sets of data are being uploaded onto the platform and the HARMONY public and private Partners and Associated Members are working to make their databases available. The immediate next steps are progressing in the pilot studies in the 7 Hematological Malignancies: reach agreement on the set of outcomes for each disease, finishing the data collection and harmonization process, and starting the analysis phase (which has already begun in the case of the AML pilot).

Our partners are also developing software tools to enable powerful analyses and to ensure privacy without reducing the clinical value of the data. In the longer perspective, the power of machine learning and artificial intelligence will be tapped into, to enable the most powerful analyses possible. Such analyses will improve the definition and standardization of endpoints and outcomes for more targeted drug development.

Our final deliverable is a BigData Platform that will integrate and harmonize information on blood diseases from >100,000 patients. This will allow HARMONY's stakeholders to assess new biomarkers, analyze genomes and identify relevant clinical outcomes in some of the largest datasets ever assembled.

How is HARMONY funded?

HARMONY Alliance is funded through the **Innovative Medicines Initiative (IMI)**, Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. HARMONY has received funding from IMI 2 Joint Undertaking and is listed under grant agreement No. 116026.

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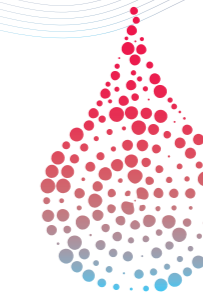


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HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

European Network of Excellence for Big Data in Hematology

Enabling Better and Faster Treatment for Patients with Hematologic Malignancies

Public-private European Network of Excellence for BigData in Hematology. Created to fill specific needs in blood cancer treatments.



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What is HARMONY?

The HARMONY Alliance is a public-private European Network of Excellence, established in January 2017.

Our mission is to unlock and spread valuable knowledge on hematologic malignancies (blood cancers) among a large number of stakeholders, with the goal to harness and mine Big Data to speed up the development of improved treatments for patients and more effective treatment strategies.

We currently have **53 Partners** and **27 Associated Members** from 22 countries, including 8 pharmaceutical companies from the European Federation of Pharmaceutical Industries and Associations (EFPIA).

What is blood cancer?

Blood cancers, or hematologic cancers, account for about 40% of cancer cases in children and about one third of cancer deaths. Important blood cancers are leukemia, lymphoma, and myeloma. The cancers affect the production and function of various blood cells. There is a need for improved treatments for blood cancers. Individual cancers usually need specific therapies. Bone marrow transplant is still a common option, as are chemotherapy and radiation therapy. As many blood cancers are rare and healthcare practice varies across Europe, a lack of data on relevant outcomes represents a challenge for clinicians, researchers, and other decision-makers like regulators and HTA bodies, resulting in limitations for patient access to the best healthcare. The HARMONY Alliance aims to use "Big Data and Big Data analytics" to deliver information that will help to improve the care of patients with these diseases.

What is BigData and why is it important in Hematology?

For blood cancers, BigData means gathering into one single database clinical, genetic and molecular information on patients and diseases which is currently maintained in a number of individual databases from clinical trials and registries in different countries. The HARMONY Alliance is orchestrating the consolidation of all databases into one common platform. This will harness the enormous potential of BigData and BigData analytics to deliver insights into how the care of patients with blood cancers can be improved.

HARMONY's partners from industry are providing access to clinical trials data, showing how drugs work in controlled circumstances. Public registries collect data on how patients are treated and the outcomes of therapies in the real world. Together, these sources are greater than the sum of their parts. For example, by combining the populations from several clinical trials, it is possible to analyze populations with rare diseases with greater statistical power than individual databases can provide.

Other Big Data analyses can reveal molecular data on genomes, what proteins are expressed in different cancers, how treatments affect the expression of important genes, and more.

What are the challenges when working with BigData?

Pan-European BigData transcends borders and details captured in databases vary between healthcare systems, clinical trials, and registries. Maximizing the value of HARMONY's BigData platform presents three challenges:

- **First**, the data need to be harmonized so that data from different databases are in a similar format and can be analyzed.
- **Secondly**, the database must comply with European and local regulations on data exchange, privacy, and ethical rules.
- **And thirdly**, the enormous size of BigData means that new analytical and statistical tools need to be developed. Getting these fundamentals right was the main priority during HARMONY's initial phase.

What makes the HARMONY Alliance unique?

The large number of stakeholders across different European countries makes for a fragmented playing field, from basic hematology research all the way to approval processes for new medicines.

HARMONY was created to fill a specific need in blood cancer treatments. The Alliance functions as the interface between all stakeholders. Never has a European public-private initiative had such ambitious goals for international collaboration in big data and HMs. HARMONY will provide:

- The possibility to utilize the multifaceted comprehensive data on the HARMONY BigData Platform to answer specific research questions
- Access to skilled data scientists/statisticians
- Access to data-mapping tools and data analysts
- Access to ethical and legal guidance for pooling data
- Opportunities to get involved in projects that cover multiple diseases, are drug-specific, and where possible incorporate information on quality of life, common genes, common targets, etc.
- Opportunities to interact with >80 stakeholders from all healthcare-related areas: Patient and societal organizations, hematologists and clinicians, medicines authorities and regulatory institutions, health technology assessment (HTA) organizations, payers, policymakers and funding organizations, the pharmaceutical industry, information, and communications technology companies, and other relevant European and international alliances.