



HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

Becoming an Associated Member Information Document

Your data is crucial!



www.harmony-alliance.eu

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1. About the HARMONY Alliance

Funded in January 2017 by the EU with an important contribution of the pharmaceutical industry, the HARMONY Alliance (Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology) is a public-private pan-European Network of Excellence in hematology.

Our final deliverable is a High-Quality Big Data platform that empowers clinicians and other Healthcare System stakeholders to improve decision-making. To do so, HARMONY will integrate and harmonize clinical information on well-annotated very large patient cohorts in whom comprehensive laboratory tests have been performed or can be rapidly performed.

Expected results are:

- Establishing the European HMs landscape;
- Refining prognostic factors as much as possible;
- Coming up with individualized treatments for each patient (“personalized medicine”) whenever possible, and identifying specific markers for new treatment targets.
- The alignment of key stakeholders (pharma companies, policy makers, regulators, payers, healthcare providers, and patients) on the relevance of these outcomes;
- Ultimately leading to early registration of and access to innovative and effective therapies for HMs.

2. Why are Associated Members needed?

HARMONY unites academic institutions, clinical disease networks, patient advocacy groups, clinicians, pharmaceutical companies, regulatory agencies, Health Technology Assessment (HTA) bodies, as well as experts in health economics, ethics, and information and communication technology (ICT) with the purpose of collecting and/or providing multidisciplinary data sources to respond to clinical questions and implement new treatment strategies on blood diseases.

But HARMONY goes beyond the members of the 51 consortium partners. HARMONY is aimed at the entire hematological community.

One of HARMONY’s guiding principles is to be an open and embracing initiative. We welcome your involvement as data custodians in the resolution of key open questions of interest in:

- ALL Acute Lymphoblastic Leukemia
- AML Acute Myeloid Leukemia
- CLL Chronic Lymphocytic Leukemia
- MDS Myelodysplastic Syndrome
- MM Multiple Myeloma
- NHL Non-Hodgkin Lymphoma
- Pediatric leukemias.

Your data will contribute to the extraction of relevant insights, as well as to the identification and definition of uniform and HM specific outcomes that are relevant to patients and healthcare providers across Europe.

3. The HARMONY Big Data Platform

The HARMONY Big Data platform has been designed to accommodate different layers of information: demographic and medical history; diagnosis; cytogenetic, molecular genetics and sequencing data; treatment; health-related Quality of Life (HRQoL); and healthcare resource utilization data. It has been designed in a way that:

- Allows dealing with the heterogeneity of the data sources from which the data will be extracted;
- Provides a common data model that will allow state-of-the-art data analysis of clinical, molecular, treatments and response data, patients' medical history, etc.
- Complies with legal and ethical standards for data protection.

Using Big Data techniques and technologies, HARMONY will model and exploit the data to enrich it, turning it into smart data that provides new value and links concepts. In other words, it complements the original information converting multidisciplinary and multisource raw data into Meaningful and Valuable Information.

4. The relevance of your data for the HARMONY Big Data Platform

We are currently living in the "Golden Age" of data and Big Data technologies: high-volume of information, gathered at high velocity and from a wide variety of sources. The increasing adoption of big data technologies can also bring about dilemmas: quality versus quantity; truth versus trust; correction versus curation; or ontology versus anthology.

'Storing all data because we can' is not an end in itself for HARMONY. We are 'looking at things' whilst 'looking for things'. It is about finding the needle, not getting all the hay in the stack, so the quality of the data that HARMONY will gather is of critical consideration.

For that reason, HARMONY'S work will be based on specific "bench-to-bedside" research projects, the so-called 'deductive approach' of Big Data. HARMONY aims at identifying new outcomes, addressing unmet patients' needs, and overcoming deficits for the development of new products and diagnosis. Each one of these critical issues will include a selection of patients' data sources recommended by our Key Opinion Leaders, experts, consultants, and stakeholders in Hematological Malignancies that will contain the key variables to conduct the research project.

5. What are the steps if you have decided to get involved in HARMONY?

- Step 1: Express your interest
- Step 2: Sign the Associated Member Engagement Framework Agreement
 - Data Fingerprint*
 - Organisation/Registry Profile*
- Step 3: Sign the Associated Member Data Sharing Agreement
 - Data Transfer*



Step 1: Expression of interest

Co-operative Working Groups, Hospitals, Academia, and other data custodians are invited to actively approach the HARMONY Alliance and explore your potential role as Associated Members.

If you want to become one of HARMONY'S Associated Members, the first step forward is sending an email to Harmonyoffice@ibsal.es. At this initial step, you will not need to fill in any forms, although we suggest you include the following information in your email:

- How have you heard about us?
- Why would you like to take part in HARMONY?
- What do you think you can bring to the table?
- In what ways are you planning to support HARMONY?

Step 2: Sign the Associated Member Engagement Framework Agreement (AMEF)

Data Fingerprint Organisation/Registry Profile

After having sent your expression of interest to become one of HARMONY'S Associated Members, the legal representative of your institution will be invited to sign an application document, the 'Associated Member Engagement Framework', to formally articulate the willingness of both parties to collaborate and establish an overarching framework to facilitate interaction and exchange of information between the Parties. No data will be transferred to the HARMONY Platform at this stage.

With the Engagement Framework Agreement, you will be asked to identify and describe the available data with which you may contribute to the Platform. This will include:

- A description of the data source;
- Coverage and method of collection;
- Scope of the data (which type of data has been collected over what interval);
- An identified individual who can address further questions about the data set;
- A data set profile. This is a comprehensive overview of the technical aspects of the respective data set without the need to transfer actual data.

This step is designed to obtain a **"fingerprint"** or profile of your data. Open source tools are available through HARMONY to help you obtain this data set profile. All fingerprint information will be kept confidential and will not be used outside the HARMONY project

unless the Associated Member explicitly allows so.

You will also be invited to complete a profile describing the **registry/repository** where the data is collected, documenting the origin of the data, the purpose for which it was collected, and how this collection is embedded within your standard care practices.

With the “Associated Member Engagement Framework”, data fingerprint and profile, HARMONY Steering Committee will assess whether your organisation is accepted as Associated Member and will return a copy of the AMEF duly signed by both parties.

Step 3. Harmonize your data in the Platform: the ‘Associated Member Data Sharing Agreement’ (AMDS)

When accepted as an Associate Member, HARMONY will provide the legal representative of your institution with an ‘Associated Member Data Sharing Agreement’ and the ‘Technical Requirements for Data Sources’ document.

HARMONY will contact Associated Members every time their data matches the technical, legal, and clinical requirements to help answer one of the “bench-to-bedside” questions under study, according to the fingerprinting information received with their AMEF.

The signature of the “Associated Member Data Sharing Agreement” represents a further formal step in the relationship between you and HARMONY. This agreement will regulate the legal and technical provisions for the effective data contribution by the Associated Member to the HARMONY Platform, as well as their access to the Platform and Intellectual Property Rights. It will also establish the terms for the reimbursement of the effort incurred by the Associated Member to provide the data to the HARMONY Platform (data handling, harmonization, data curation, anonymisation, etc.).

Enclosure

Frequently Asked Questions & Answers

1. Can I, as Associated Member, submit a “bench-to-bedside” research proposal?

Yes. Associated Members are an integral part of the HARMONY Alliance. Therefore, any Associated Member with relevant data contribution to the HARMONY Platform can submit a bench-to-bed research proposal for evaluation.

As Associated Member, you will also participate with the disease groups in the formulation of bench-to-bedside research questions, the definition of new outcomes and end points, and the identification of specific markers for new treatment targets.

2. How are HARMONY “bench-to-bedside” research proposals selected?

All bench-to-bedside research proposals undergo a review and evaluation procedure by peer experts of the HARMONY Alliance. Clinicians, scientists, statisticians and bio-informaticians from academia and industry team up with health economists, regulatory agencies, patient association representatives and ethics experts. All of them aim to assess the significance of the unmet needs covered in the research; also, to guarantee the scientific and socioeconomic merits of the proposal, and its compliance with legal and ethical requirements; and finally, to make sure that the study will contribute to optimize patient care.

If the bed-to-bedside proposal receives a favourable evaluation and is found viable in terms of resources needed, it will be put in the pipeline.

3. Is there any economical compensation for the effort incurred by the Associated Member in providing data?

HARMONY does not pay for data. However, the HARMONY Alliance will reimburse Associated Members for the costs and effort associated to make your data available for the Platform (such as costs related to anonymization activities, data curation and harmonization, data handling, etc.). This is done in a case-by-case basis with each of the Associated Members and after the data is evaluated through a mechanism of data quality assessment.

We want to ensure with you that the data meets all technical, legal, and clinical requirements.

4. Are there specific transfer requirements to provide the data?

The security and privacy of your data are paramount for HARMONY. For that reason, HARMONY has invested in a security program for data transfer and management. The submission of any information by the Associated Member to the HARMONY Platform for the intake process will be made through a secure transmission transfer protocol.

5. How will I get visibility from HARMONY?

Associated Members are an integral part of our pioneer Network of Excellence in Hematology. The many benefits of formalising a relationship with the HARMONY Alliance as Associated Member include obtaining exposure for your organisation in the hematological community, furthering your existent relationships in the community, and reaching out to all forums connected to HARMONY.

Apart from this, you will:

- Receive the HARMONY Welcome Pack (logo, templates, etc.) for communication purposes and a manual, aiming at providing you with guidance on your role as Associated Member and background information about HARMONY communications;
- Appear on the HARMONY website as Associated Member with the name of your organisation and the logo;
- Be co-author of articles, publications, and relevant HARMONY outputs wherein you have contributed with data, documentation, analysis, and writing;
- Feature your events and activities under the condition that HARMONY is included in them;
- Receive all HARMONY internal and external communications;
- Contribute to HARMONY news;
- Participate in the HARMONY General Assembly Meeting with the entire Consortium.

6. Will HARMONY want the data already collected in a specific format?

Yes. Your data sources must be delivered in a digital format that is understandable (talking in computer terms), and well formed to be read and analysed by the intake process. Acceptable formats are:

- csv (comma-separated values);
- xls (Microsoft excel format);
- SAS Data Format

All these documents could be compressed in zip, tar, targz or 7zip format.

7. Who will be the owner of the data I have provided to the HARMONY Platform?

The data owned or the contributions developed by the Associated Member shall remain the property of the Associated Member. However, the AM is expected to grant access rights to the contributed data for research use on royalty-free conditions.

8. Shall I have access to the results generated by my data?

Yes, the AM will be granted access rights for research use to the results on royalty-free conditions.

9. I am not a Data Custodian. Can I still support HARMONY?

Yes. HARMONY is an open initiative and we have established mechanisms to enrol other stakeholders. A Policy Health Stakeholder Feedback Forum (PHSFF, 'Stakeholder Forum'), has been set in the framework of HARMONY as the key platform of interaction and consultation of 6 stakeholder clusters: patient organisations, hematologists, medicines authorities, HTA bodies, payers, and the pharmaceutical industry. A cluster leader chairs each cluster. If you are interested in contributing to HARMONY in some form other than providing data, please contact Harmonyoffice@ibsal.es and we will redirect it to the appropriate contact.

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