HARMONY
Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology

# HARMONY Platform
# Using Big Data to fight Blood Cancers

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**HARMONY, the Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in hematologY, aims to develop a Big Data platform to facilitate research on blood cancers. Main focus is unlocking valuable knowledge on hematological malignancies (HMs) such as multiple myeloma (MM), acute myeloid leukaemia (AML), acute lymphoblastic leukaemia (ALL), chronic lymphocytic leukaemia (CLL), non-Hodgkin lymphomas (NHL), myelodysplastic syndromes (MDS), and paediatric HMs.**

**Funded through the Innovative Medicines Initiative (IMI), HARMONY is a public-private partnership of 53 Partners and 27 Associated Members, that brings together academic partners, clinical practice experts, product manufacturers, data providers, patient advocacy organisations, regulatory agencies, and HTA bodies.**

There is a need to standardize outcome measures and endpoint definitions important **for all stakeholders alike** in Hematological Malignancies (HMs). Patients, physicians, or decision-makers' assessment may differ on the best variables to measure outcomes, and therefore in how data is collected for clinical trials or patient repositories within different EU member states.

HARMONY has built a **high-quality Big Data-sharing Warehouse** for the collection and harmonization of high-quality 'real-life' datasets in HMs to address uncertainties in decision-making regarding access to new drugs and development of treatment guidelines (**HARMONY research projects**), providing a solid base to inform increasingly personalized therapeutic approaches, increase knowledge, and generate evidence (Figure 1).

HARMONY covers a wide range of HMs and the first project will be based on acute myeloid leukemia (AML). AML is a genetically complex and heterogeneous disease, which translates into highly-divergent clinical behavior. Large datasets are necessary to fully reflect this heterogeneity, determine the impact of genomics on outcome and disease classification, and evaluate the clinical benefit of intensive therapy. Thus, an **AML Proof-of-Concept Study** from heterogeneous data sources has been designed to benchmark HARMONY workflows: data anonymization, intake and harmonization, analysis pipelines, and results validation.

**Identified Data Providers** of existing intensively-treated AML patients with detailed molecular genetic information include the AMLSG, HOVON and MRC study groups, other Cooperative Working Groups, and EFPIA sponsored trials (Novartis RATIFY study). Data collection has been based on patient-related information: demographic, diagnostic variables, follow-up data, treatment received, quality-of-life, and molecular data from targeted Next Generation Sequencing (NGS) approaches.

**Appropriate anonymization techniques and organizational strategies** have been implemented to comply with EU Data Protection legislation regarding confidentiality and data privacy but ensuring that collected data is of sufficient quality and that the analytics are still useful and meaningful (Figure 2).

**Data curation and harmonization** into a standard codification system (OMOP Common Data Model) allow the systematic analysis of all datasets by using **statistical methods and innovative data modeling:** pairwise gene-by-gene and within gene hotspot interaction analyses; genotype-phenotype correlations; predictors of clinical outcome analyses; survival models; and cross-validations. Outcome measures and results based on the available datasets, and with regard to potential novel variables that should be incorporated into future projects, will be further discussed by all stakeholders.


Figure 1. HARMONY main objectives.

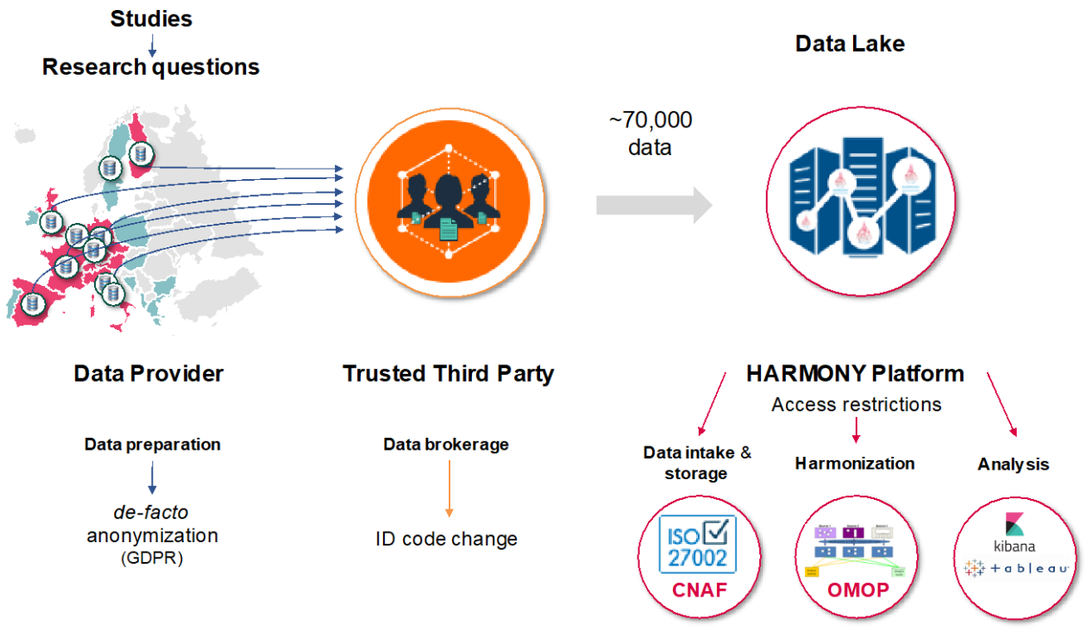


Figure 2. Outline of the HARMONY Data flow

**Conclusion** – In addition to the validation of the platform performance, the results of this Pilot will contribute to novel biological insights, based on which personally-tailored management decisions might become feasible, better guide hematopoietic cell transplants in AML, and improve overall survival rates.

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