HARMONY

Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology

European Public-Private Data Collection Leads the Way: First Results of the Proof-of-Principle Study in Acute Myeloid Leukemia.

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The HARMONY Alliance is the largest Innovative Medicines Initiative (IMI) European public-private partnership that aims to improve outcomes of patients with Hematological Malignancies by establishing consensus outcomes among all stakeholders through the analysis of data on a large "Big Data" platform.

HARMONY is currently composed of 53 Partners and 37 Associated Members from 22 countries, including the pharmaceutical industry, hospitals, academic, research institutions, regulatory agencies, health technology assessment bodies, and patients' organizations.

Hematological Malignancies (HMs) within scope are Acute Myeloid Leukemia (AML), Acute Lymphoblastic Leukemia (ALL), Chronic Lymphocytic Leukemia (CLL), Multiple Myeloma (MM), Myelodysplastic Syndrome (MDS), Non-Hodgkin Lymphoma (NHL) and pediatric HMs.

Aim

To establish and test the HARMONY platform, we have performed a "Proof-of-Principle" study in AML.

Method

For this study HARMONY has implemented standardized operating procedures and a de facto anonymization process for data intake, quality evaluation, storage, and analysis compliant with the European General Data Protection Regulation (GDPR).

Overview

HARMONY has established a Big Data Platform allowing the analysis and interpretation of data from different Cooperative Working Groups (CWGs), large single academic institutions, and EFPIA (European Federation of Pharmaceutical Industries and Associations) partners by harmonizing all incoming data using the Observational Medical Outcomes Partnership (OMOP) common data model.

To date, HARMONY has started to incorporate AML data sets and based on this first comprehensive public-private data set collection we are aiming to:

- Further define gene-gene interactions;
- Evaluate the clinical impact of these gene-gene interactions on outcome
- Validate and further refine genomic AML classification.

Results

So far, we have incorporated first AML data sets that include both comprehensive clinical information as well as data on targeted myeloid panel sequencing from over 3000 patients. So far, CWG data sets include the AMLSG (~1500), HOVON (~700), AMLCG (~600) and a first EFPIA data set was contributed by Novartis (~600) with plans for additional studies to be incorporated by EFPIA members. Besides, data sharing agreements will be signed for the MRC (~1500), SAL (~1000), ALFA (~1000), GIMEMA (~500), PETHEMA, CETLAM, and CELL (~200 each). Other data that will be entered from large academic centers include Belfast (~300), Madrid (~200) and Berlin (~300). As a first approach, in April a first integrative analysis has been performed on the data that has been included prior to date. Gene-gene interactions will be determined in accordance to our previous study on the genomic landscape of AML (Papaemmanuil et al. NEJM 2016) and results will be interpreted in the light of the current knowledge and publicly available data.

This comprehensive analysis should help to further unravel the heterogeneity underlying AML and provide new insights into novel biomarkers and potential druggable gene-gene interactions.

Summary/Conclusion

The early achievements of the HARMONY Alliance prove that a public–private partnership involving all stakeholders and using the common data format OMOP (able to harmonized big data) is both feasible and can allow us to improve outcomes of patients with HMs. First results of the AML-pilot study will be presented in order to demonstrate both the functionality of HARMONY and its synergistic effects by harmonizing European big data efforts to improve leukemia outcome.

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