European Network of Excellence for Big Data in Hematology, consisting of 51+ partners from 11 countries.

Enabling Better and Faster Treatment for Patients with Hematologic Malignancies by using big data technology.

Will you join our challenge?
Introducing the HARMONY Alliance
Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in Hematology

• A pan-European IMI project uniting and aligning healthcare system stakeholders and key opinion leaders in the field of Hematologic Malignancies. (blood cancers)
• The first and largest Public Private Partnership in Hematology 40 M€ | 2017-2022
• The largest project within IMI Big Data for Better Outcomes program.

WHO WE ARE

WHAT WE OFFER

• A high-quality multidisciplinary sources Big Data Platform that integrates outcome measures and endpoint definitions for HMs.
• Tools to empower clinicians and other Healthcare system stakeholders to improve decision-making.
HARMONY is the Key Initiative within IMI

Europe’s largest public-private partnership in healthcare to speed up development of and patient access to new medicines

BD4BO: An IMI program seeking to leverage big data to improve outcomes:
- Design sets of standard outcomes and demonstrate value;
- Increase access to high quality outcomes data;
- Use data to improve value of HC delivery;
- Increase patient engagement through digital solutions

During first phase (2008-2013), IMI budget of €2 billion:
50% EU FP7
50% in-kind contributions EFPIA companies
PATIENTS affected by Hematologic Malignancies still have unmet needs. We will address their urgent unmet needs, such as faster diagnosis and personalized therapies.

By using BIG DATA SHARING among all relevant stakeholders involved, HARMONY aims to improve patient outcomes.
Unmet needs in Hematologic Malignancies in adult and pediatric patients

- Harmonize outcome measures and endpoint definitions for HMs at European level
- Increase the available omics data to better predict efficacy and toxicity of certain treatments
- Speed up drug development, access pathways and "bench-to-bedside" process
- Improve the optimal use of resources

Focus on 7 HM diseases: MM Multiple Myeloma, AML Acute Myeloid Leukemia, ALL Acute Lymphoblastic Leukemia, CLL Chronic Lymphocytic Leukemia, NHL Non-Hodgkin Lymphoma, MDS Myelodysplastic Syndrome, Pediatric HMs.
Involving every stakeholder group is necessary to **meet patients' needs**

- Hematologists
- Bioinformaticians, Data Scientists & ICT
- Pharma Industry
- Ethics
- Economists
- Policy Makers
- Regulators
- HTAs
- Bioinformaticians, Data Scientists & ICT
The HARMONY Alliance: **What makes us unique?**

- **First IMI project on BD4BO for Hematologic Malignancies (HMs)**
- **Main aim: building a high-quality Big Data platform on HMs**
- **Stakeholders involvement: Academia, Industry, Payers, HTA, Regulators and Patients**
- **Public-Private partnership (PPP)**
- **Open project: EU Cooperative Groups and Hospitals welcome**
51+ Publi-Private Partners from 11 european countries, including 8 pharmaceutical companies

Internal and external communications with: Patient Organizations and Societal Organizations focusing on ethical aspects.
Communication with **Patient Groups** is **key**
Patient Groups are involved as Alliance Partners.
Many more **European Patient Organizations** are
invited to become actively involved.
The HARMONY Alliance: **Our approach**

- Collect, share and harmonize Big Data from high-quality **multidisciplinary** sources.
- Assess and integrate a large amount of **molecular data**.
- **Enable** identification of novel pathways for **drug development**.
- Generate evidence to encourage **healthcare systems** to pay particular attention to the value of healthcare and to improve outcomes.
- Facilitate drug development pipelines and accelerate the “**bench-to-bedside**” process in drug development.
- Empower **clinicians, policy makers and payers** to improve decision-making and **optimize care for patients with HMs**.
- Generate **multi stakeholder** activities.
HARMONY 1st Year Achievements

- Communications, Dissemination activities
- Associated Members’ Engagement Framework and Data Sharing Agreements
- SOP for the approval of bench-to-bedside research proposals
- Establishment of the Ethics Advisory Board and External Advisory Panel
- Platform for Data-Intake Ready
- New Partners and new Associated Members
- Policy Health Stakeholder Feedback Forum (PHSFF)
- “Bench-to-Bedside” Projects
HARMONY Expected Results

- A **clinical data-sharing platform** including Big Data series from patients with hematological malignancies
- A **community** of European hematological malignancies stakeholders
- Meaningful and harmonized **clinical endpoints** and **outcome measures** in hematological malignancies
- **Tools** for analyzing complex data sets including genomic data
- **Biomarkers** that will contribute to timely patient access to more effective and better tolerated innovative therapies
- A **framework** for legal, ethical and governance issues

With the aim to provide answers to the **unmet needs** of patients suffering from Hematologic Malignancies.
How can you contribute?

Contribute data through an Associated Member Agreement

Propose a Bench-to-Bedside Project

Communicate and use the HARMONY communication tools and channels
What can you expect from HARMONY?

Content of this slide to be customized to audience – this slide can be used to start a discussion – or can be left out.
Thank you and let’s connect

HARMONY Coordination Office
Institute of Biomedical Research of Salamanca
• harmonyoffice@ibsal.es

HARMONY Communications Office
European Hematology Associations
• communications@harmony-alliance.eu

@HarmonynetEU

www.harmony-alliance.eu
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Read more at: www.imi.europa.eu