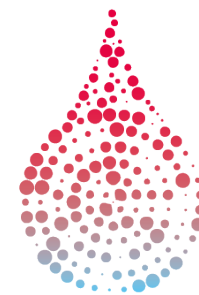


HARMONY: European Network of Excellence for Big Data in Hematology

XI Conferencia Anual de las Plataformas Tecnológicas de Investigación Biomédica: Medicamentos Innovadores, Nanomedicina Tecnología Sanitaria y Mercados Biotecnológicos

Barcelona, 5 de marzo de 2018



HARMONY

Healthcare Alliance for Resourceful Medicines
Offensive against Neoplasms in Hematology

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

Jesús M. Hernández
HARMONY Coordinator
Institute of Biomedical
Research of Salamanca
(IBSAL)

Funded by



innovative
medicines
initiative



efpia

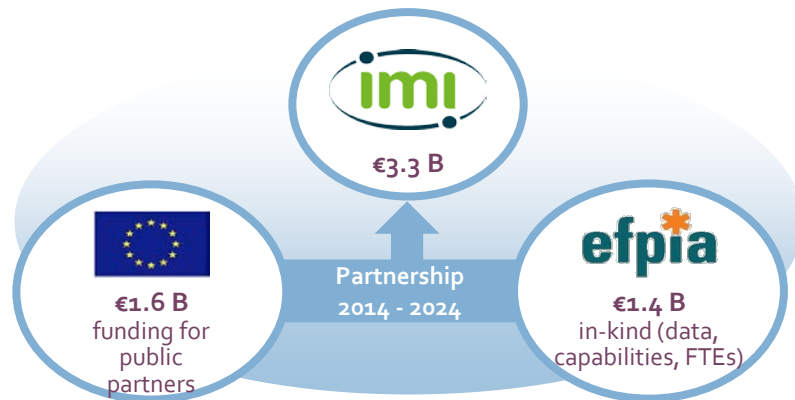


HARMONY

What is HARMONY?

IMI: Innovative Medicines Initiative

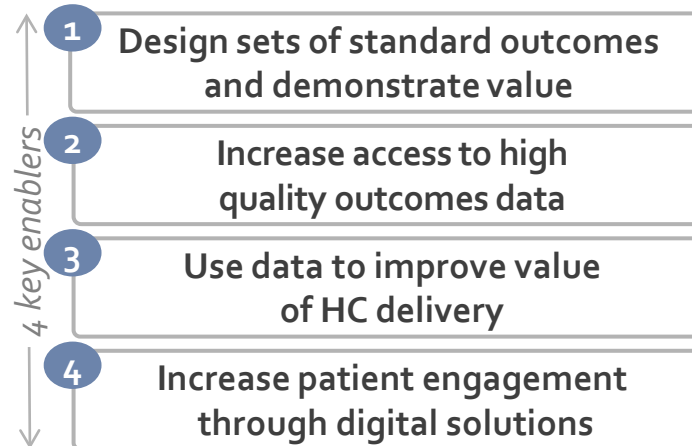
Europe's largest public-private partnership in healthcare to speed up development of and patient access to new medicines



During first phase (2008-2013), IMI budget of €2 billion, half of which came from the EU's FP7, and half of which came from in kind contributions by EFPIA companies

BD4BO: Big Data for Better Outcomes

Initiative within IMI seeking to leverage big data to improve outcomes



Initiatives in different disease areas

IMI projects addressing BD4BO's key enablers in different therapeutic areas

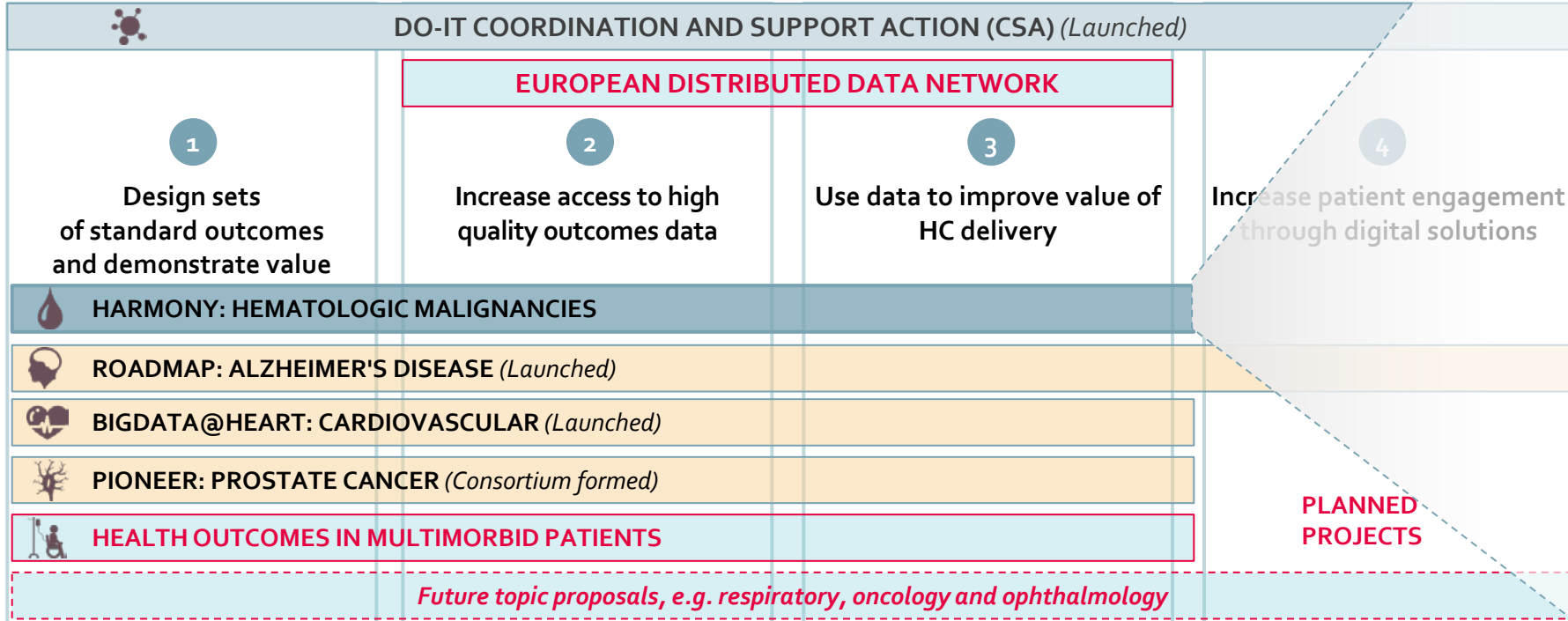


HARMONY is a key initiative within IMI



"Big data for better outcomes"

Goal: Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by large data sets from variable sources



NOVARTIS



AMGEN



abbvie

Under the "BD4BO" umbrella, HMs is currently the largest program



Funded by

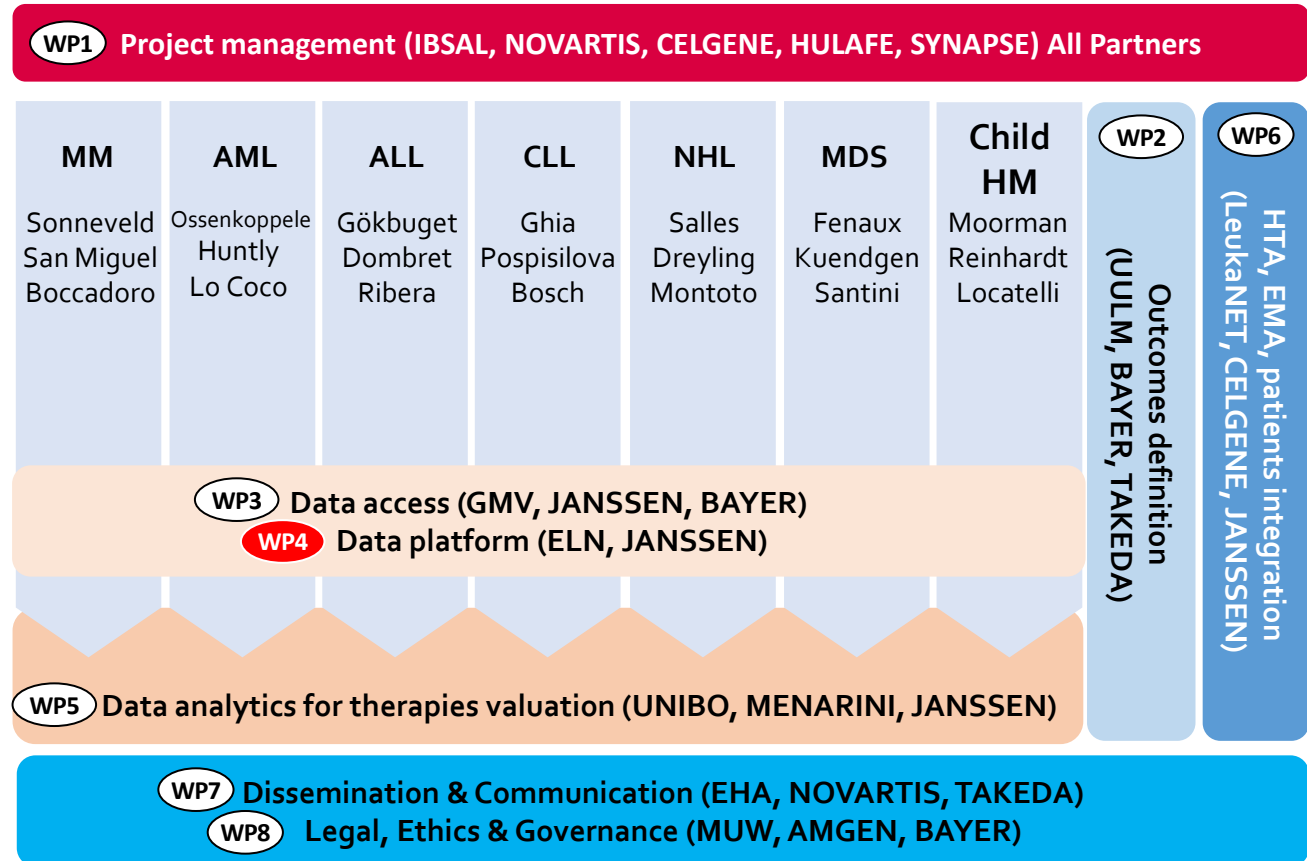


innovative
medicines
initiative

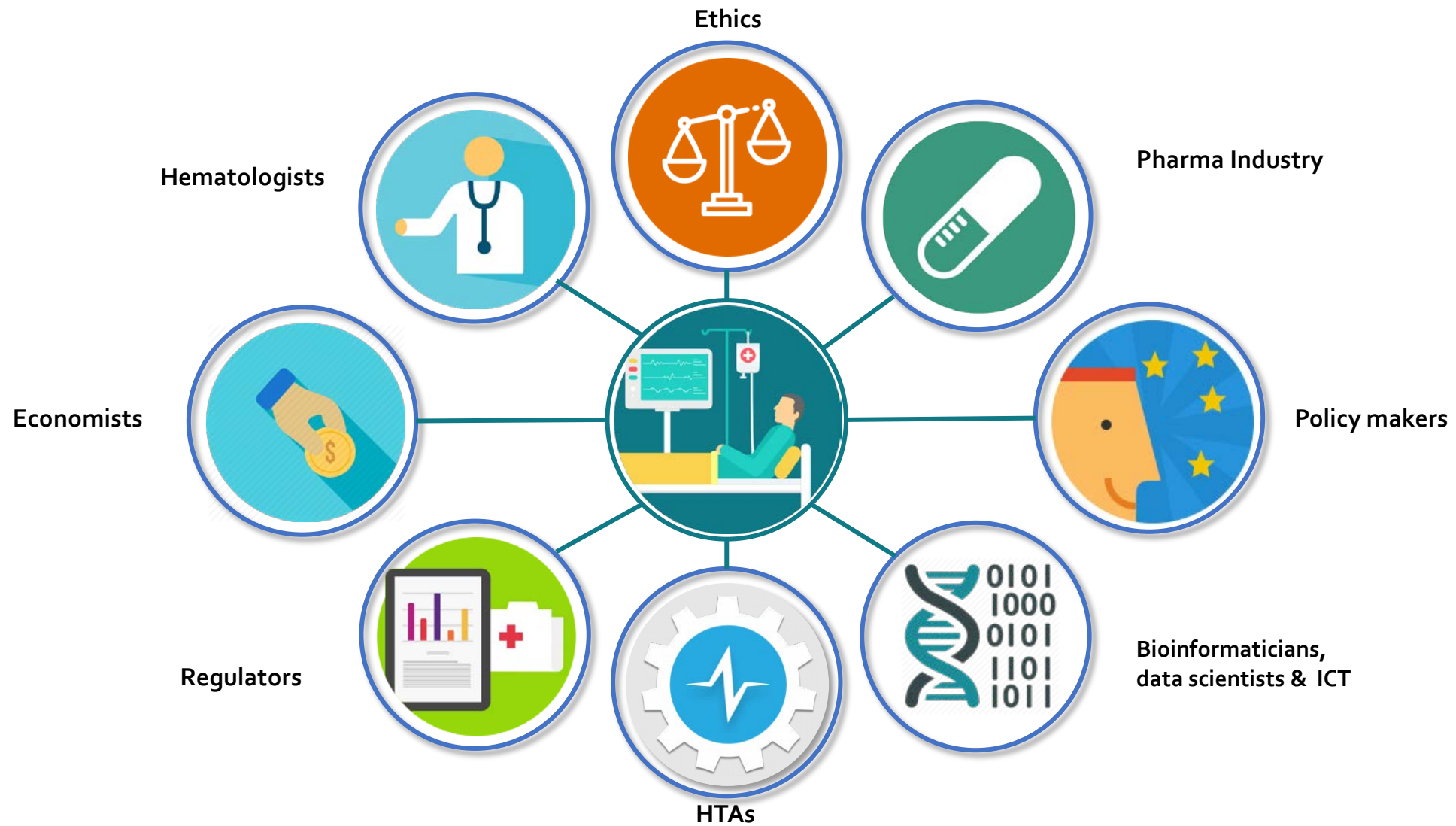


efpia

- Specific questions by disease
- Involvement of KOLs and collaborative Working Groups
- Molecular and Clinical Data



8 Work Packages across 7 diseases



Involving every stakeholder group is necessary to meet patients' needs



HARMONY

Data Sharing



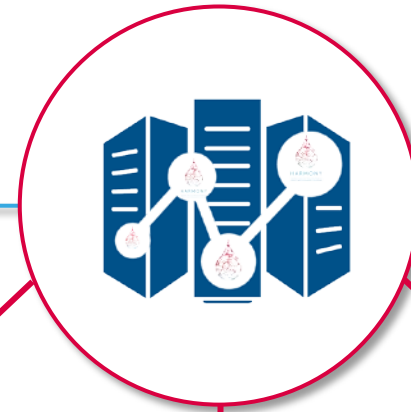
Data Sources

Data preparation



Honest Broker

Data Brokerage



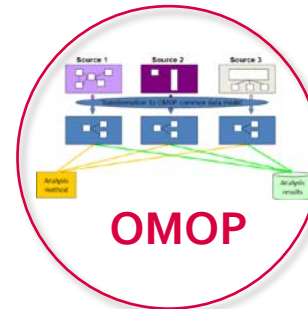
Data intake and
storage

Harmonisation

Analysis



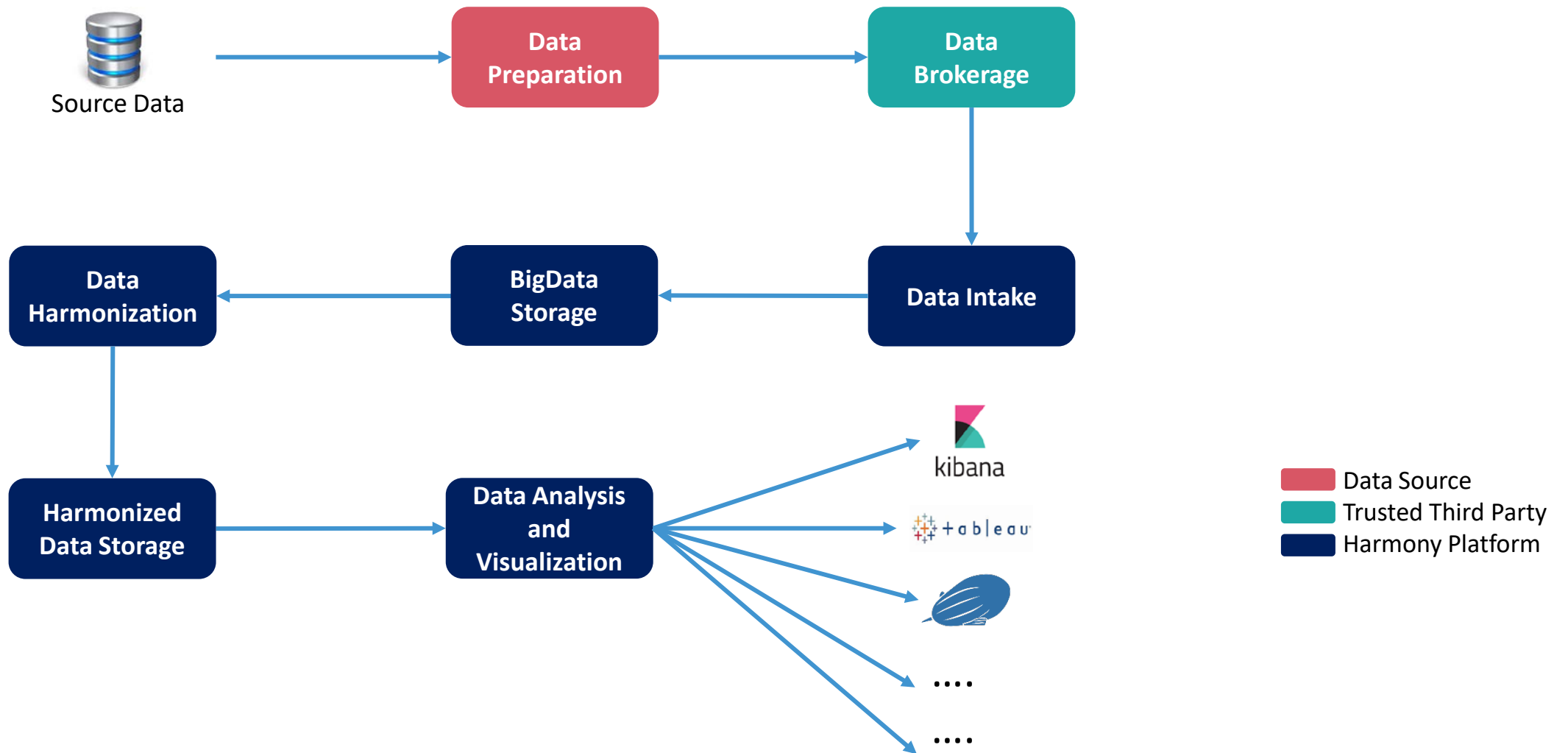
CNAF



OMOP



Our database is **ready to work**



Data Pipeline



HARMONY

Data Privacy And Protection: Legal And Ethical Implications

Objectives of the data management process

Make the data available in a format that optimally addresses the research questions while respecting the applicable legal and regulatory requirements.

“De Facto” Anonymization

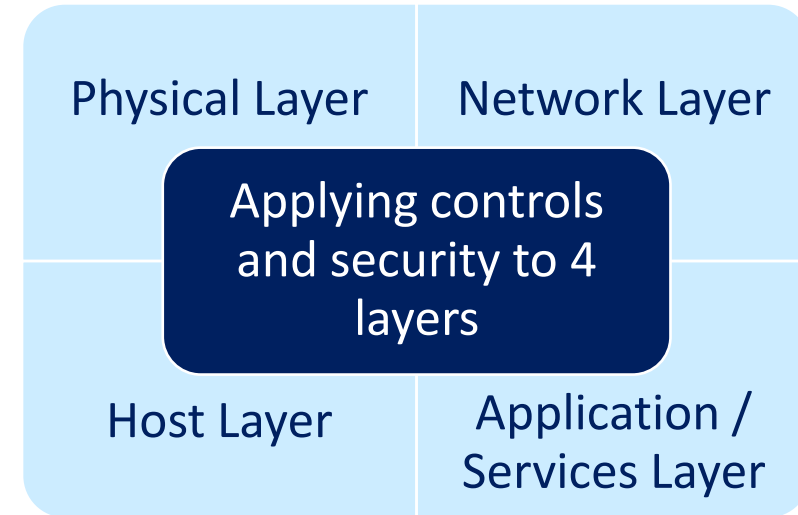
Definition

Data for which attributing the individual data to the relevant individual concerned requires unreasonable effort in terms of time, cost and manpower.

Privacy and Security

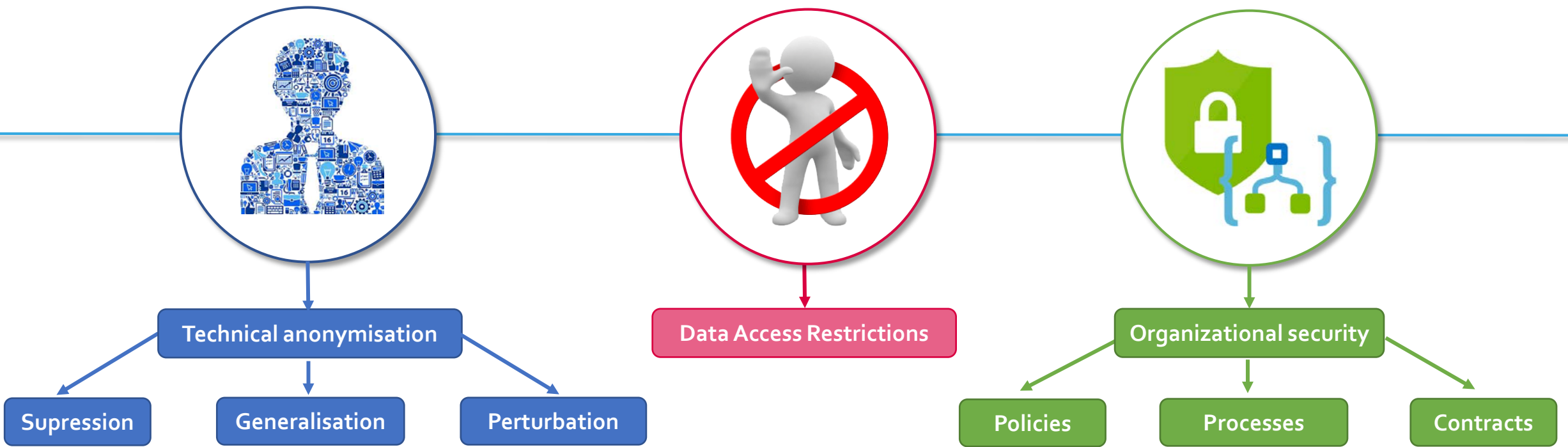
HARMONY Platform protection

- VPN (Virtual Private Network)
- Firewall with two levels
- Audit: WHO, WHEN, WHERE, WHAT, HOW
- Risk analysis
- Named access
- Roles' segregation
- Data governance: **nobody** has access to the data

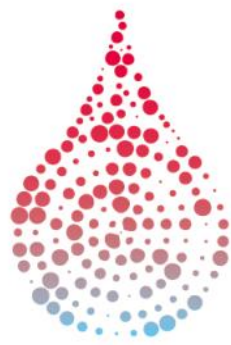


The platform is hosted on
CNAF Hosting with ISO 27001



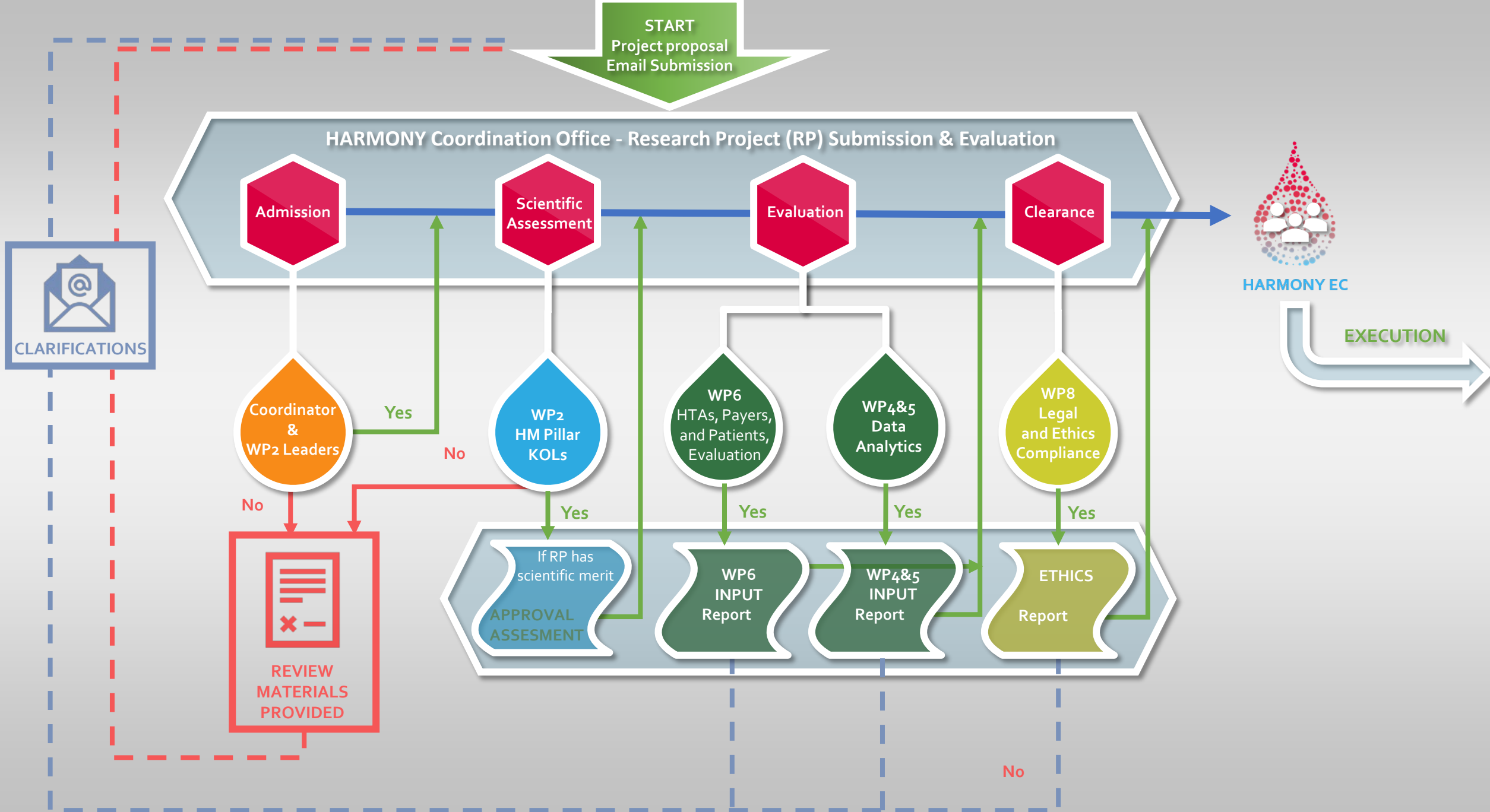


Green light for data intake: *de-facto* anonymization



HARMONY

Research Projects: Standard Operational Procedure



WP2 Outcomes definition (UULM, BAYER, TAKEDA)		WP6 HTA, EMA, patients integration (LeukaNET, CELGENE, JANSSEN)	
		Public KOLs	EFPIA Disease Contacts
Data analytics for therapies valuation (UNIBO, MENARINI, JANSSEN)	WP3 Data access (GMV, JANSSEN, BAYER) WP4 Data platform (ELN, JANSSEN)	ALL	Gökbuget Dombret Ribera Jens Hasskarl, Celgene Marieke Schoonen, AMGEN Zack Pemberton Whiteley
		AML	Ossenkoppele Huntly Lo Coco Christina Lofgren Alberto Vasconcelos, Celgene Rory Goodbody, AbbVie Zack Pemberton Whiteley
		CLL	Ghia Pospisilova Bosch Christina Lofgren, Janssen Sante Cundari, Celgene Nick York
		NHL	Salles Dreyling Montoto Christina Pelizon, Abbvie TBD
		MDS	Fenaux Kuendgen Santini Anne I. Merlat-Guitard, Novartis Sushant Hardikar, Abbvie Sophie Wintrich
		MM	Sonneveld San Miguel Boccardo Christina Lofgren, Janssen Bruno Costa, Celgene Bianca Witting, Abbvie Kate Morgan
WP5		Child HM	Moorman Reinhardt Locatelli TBD Anita Kienesberger

8 Work Packages across 7 diseases



Thank you!

Any Questions?





This material is developed by the HARMONY Alliance

Disclaimer

This presentation is of scientific nature and has been produced by the HARMONY Alliance.

The HARMONY Alliance makes no warranties or representations of any kind as to the content's accuracy, currency or completeness, neither the Alliance nor any party involved in creating, producing or delivering this document shall be liable for any damages, including without limitation, direct, incidental, consequential, indirect or punitive damages, arising out of access to, use of or inability to use this document, or any errors or omissions in the content thereof. This material may not be used for commercial purposes.

Remixing is not permitted except for private use.

Acknowledgement

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under HARMONY Grant Agreement n°116026. This Joint Undertaking receives support from the European Union's Horizon 2020 Research and Innovation Programme and EFPIA.

