



BigData@Heart

Big Data for Better Hearts

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Rationale



Progress Drug development in CVD is frustrated by:

- Poor definition of disease ignoring underlying (molecular) mechanisms and co-/multi-morbidities
- Lack of approved relevant patient-centered outcomes
- Data access limited to selected small patient populations

This results in:

- Mismatch trial and real-world patients
- Large inter-individual variation in prognosis
- Heterogeneous treatment response

Big-Data: The next revolution in science?



Join forces to improve patient outcome



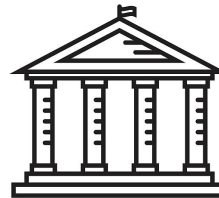
- Launched in March 2017, BigData@Heart brings together a consortium of 19 stakeholders under an Innovative Medicines Initiative-2 (IMI-2) funded project.
- The aim of the project is to apply big data approaches to improve patients outcomes in the most common cardiovascular diseases in Europe today: acute coronary syndrome, atrial fibrillation and heart failure.



Unprecedented consortium



- The European Society of Cardiology (ESC), numerous European academic research groups, and European Federation of Pharmaceutical Industries and Associations (EFPIA)-based pharmaceutical industry have joined forces to develop a big data-driven translational research platform.
- This platform will deliver clinically relevant disease phenotypes, scalable insights from real-world evidence driving drug development and personalized medicine through advanced analytics.



ESC



Unprecedented scale: Data on over 25 million subjects across Europe



The BigData@Heart consortium encompasses all relevant stakeholders and an unparalleled array of data

Opportunities unleashed in a European research infrastructure and collaboration



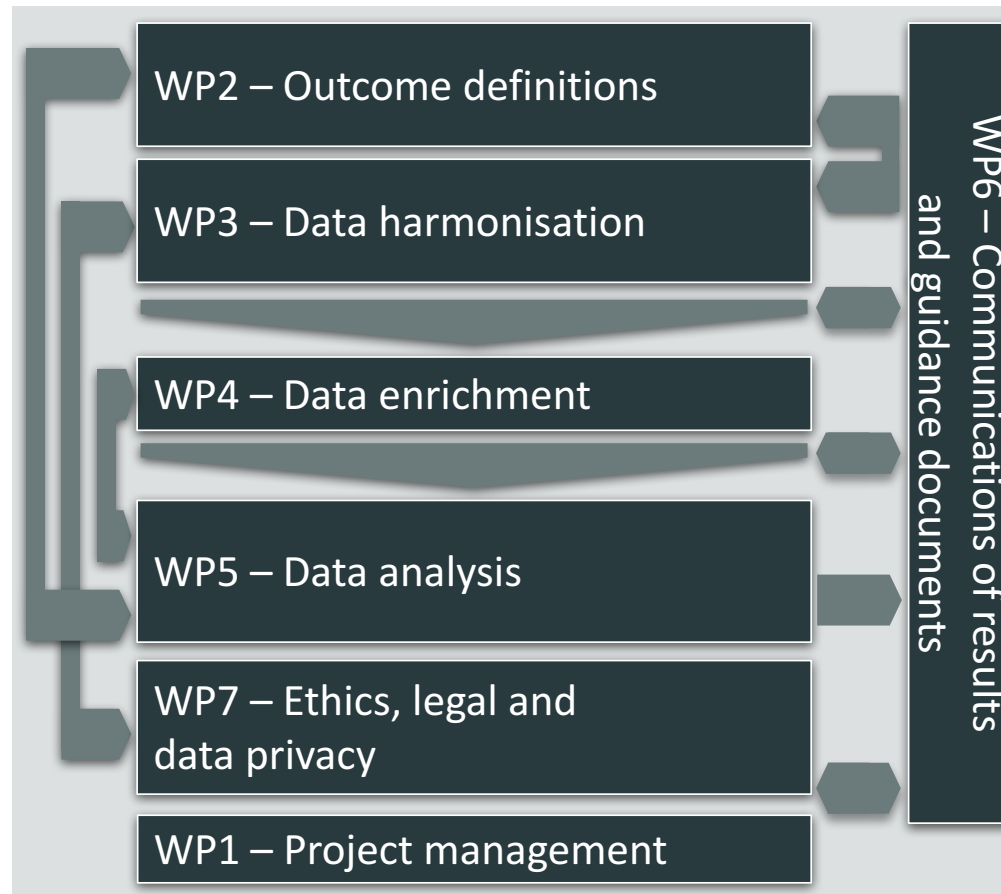
European Heart Journal (2017) 00, 1–19
doi:10.1093/eurheartj/ehx487

CLINICAL REVIEW
Prevention and epidemiology

Big data from electronic health records for early and late translational cardiovascular research: challenges and potential

Harry Hemingway^{1,2*}, Folkert W. Asselbergs^{1,2,3}, John Danesh⁴,
Richard Dobson^{1,2,5}, Nikolaos Maniadakis⁶, Aldo Maggioni⁶,
Ghislaine J.M. van Thiel³, Maureen Cronin⁷, Gunnar Brobert⁸, Panos Vardas⁶,
Stefan D. Anker^{9,10}, Diederick E. Grobbee¹¹, and Spiros Denaxas^{1,2}; On behalf of the
Innovative Medicines Initiative 2nd programme, Big Data for Better Outcomes,
BigData@Heart Consortium of 20 academic and industry partners including ESC[†]

Work packages in BigData@Heart



Ambition



- New definitions of diseases and outcomes in ways that are universal and computable, and relevant for patients, clinicians, industry and regulators.
- Informatics platform that allow to link, visualize and harmonise data sources of varying types, completeness and structure.
- Data science techniques to develop new definitions of disease, identify new phenotypes, and construct personalised predictive models.
- Guidelines that allow for cross-border usage of big data sources acknowledging ethical and legal constraints and data security.

More info



- www.bigdata-heart.eu
- D.E.Grobbee@umcutrecht.nl



efpia



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This work has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking BigData@Heart grant n° 116074

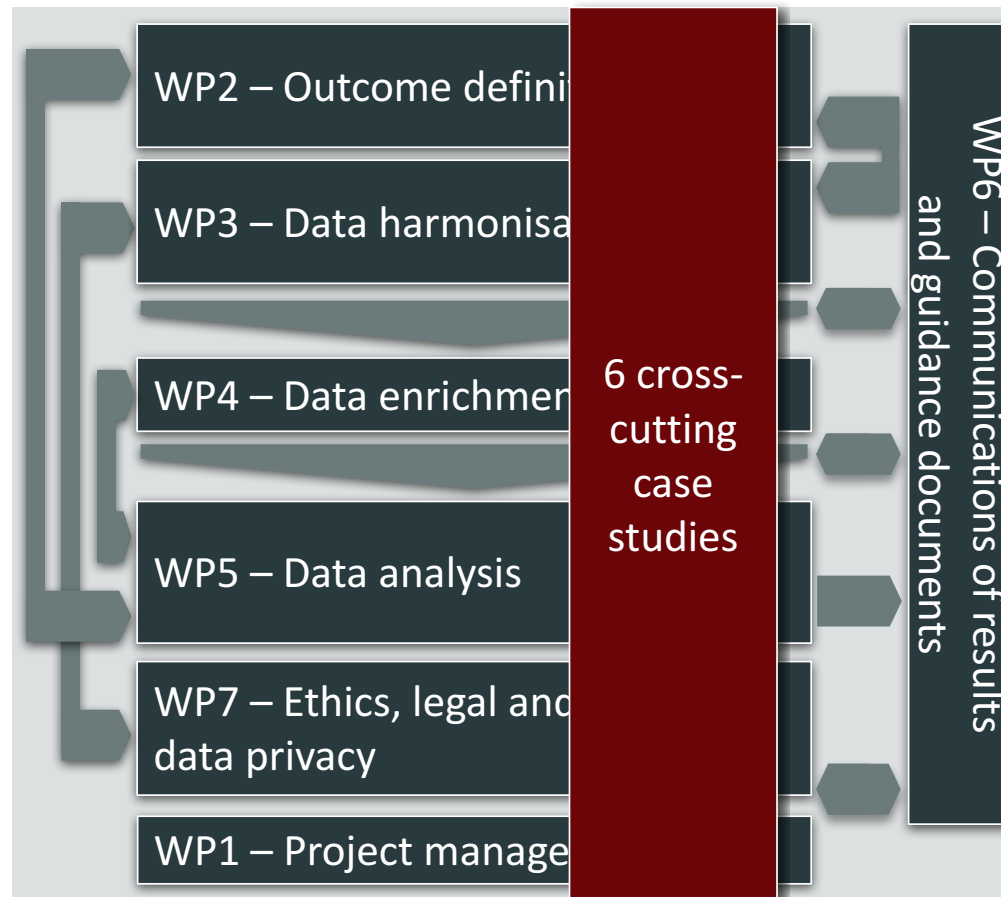


BigData@Heart

Big Data for Better Hearts

Folkert Asselbergs - UMC Utrecht
Consultant Cardiologist,
Professor of Cardiovascular Genetics,
Scientific Coordinator BD@H

Casestudies BigData@Heart



#1 Comparison of real world heart failure patients to trial patients to guide future trials



Kennedy-Martin *et al. Trials* (2015) 16:495
DOI 10.1186/s13063-015-1023-4



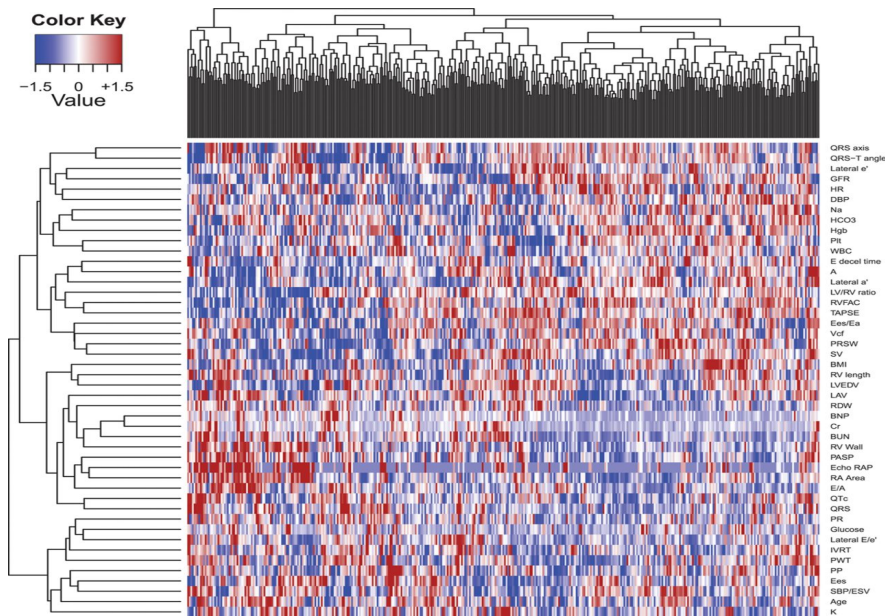
REVIEW

Open Access

A literature review on the representativeness of randomized controlled trial samples and implications for the external validity of trial results



#2 Deliver clinical relevant definition of HF subphenotypes and outcomes using -OMICS and EHR data resources



**HEART FAILURE
MOLECULAR
EPIDEMIOLOGY** *for*
THERAPEUTIC TARGETS



GENIUS
CHD

www.genius-chd.com
www.hermesconsortium.org

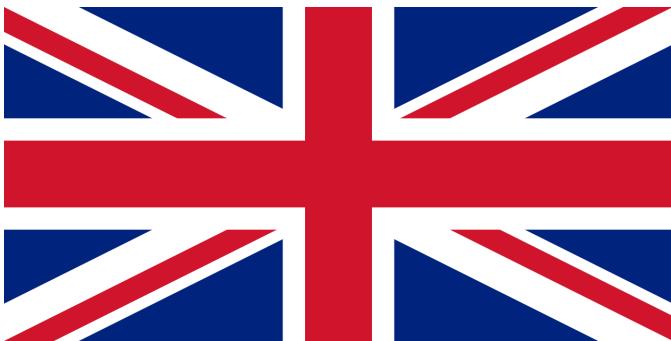
#3 To compare clinical outcomes derived from public registries with formally adjudicated endpoints



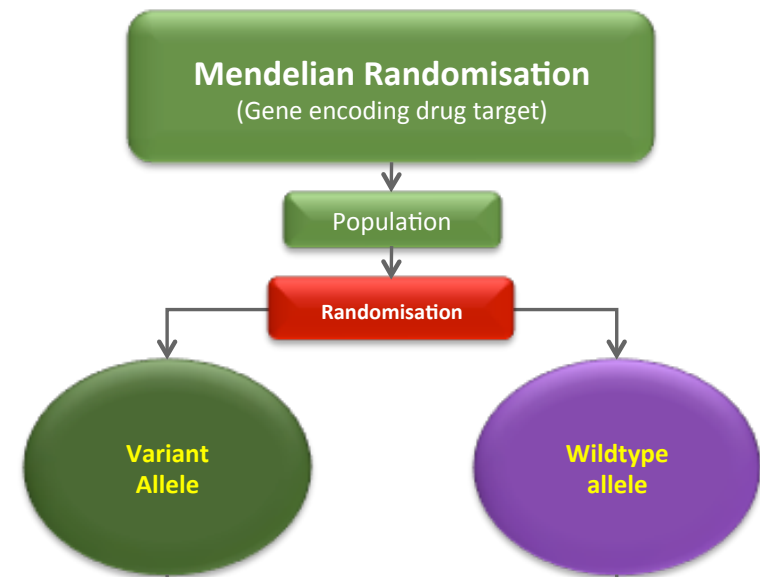
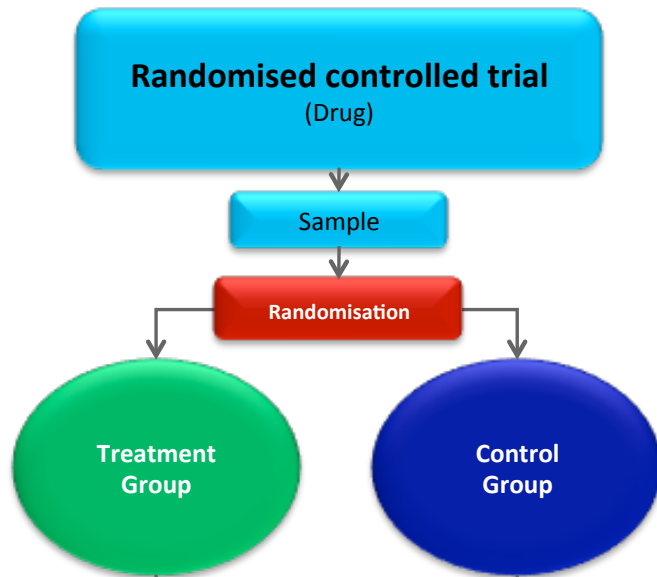
The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?

Michael S. Lauer, M.D., and Ralph B. D'Agostino, Sr., Ph.D.

#4 Compare HF epidemiology across EU countries

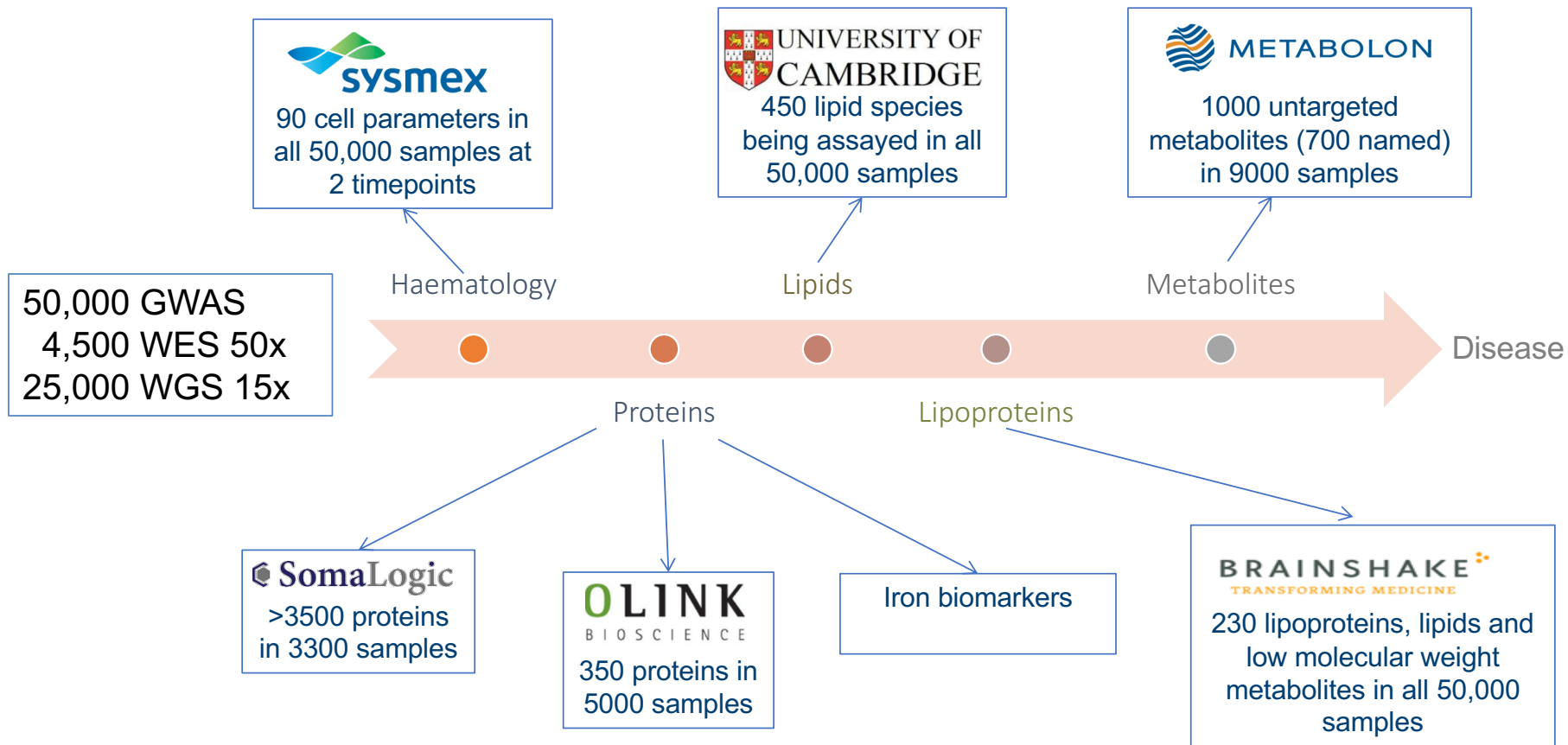


#5 Identify novel druggable targets using proteomics and genomics in iron depletion





Dense multi-omic phenotyping



+RNAseq pilot, mass spec protein pilot, autoantibody assays, virome sequencing, nasal microbiome coming soon

#6 Investigate how data from wearables/Apps can be used as premarket and postmarket evidence



www.radar-cns.org/



More info regarding case studies



- www.bigdata-heart.eu
- F.W.Asselbergs@umcutrecht.nl



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BigData@Heart

Big Data for Better Hearts



Webinar – IMI Public Private Partnership

Overview

September 13, 2017

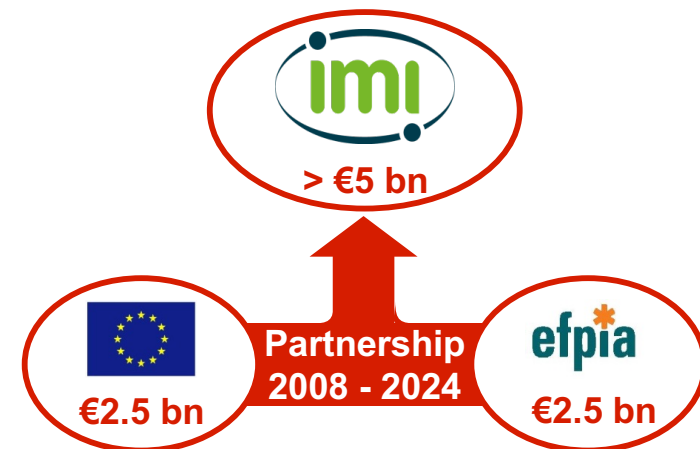
Panos Vardas, Chief Strategy Officer, European Heart Agency

Gunnar Brobert, Director of Epidemiology, Bayer AG

Innovative Medicines Initiative IMI

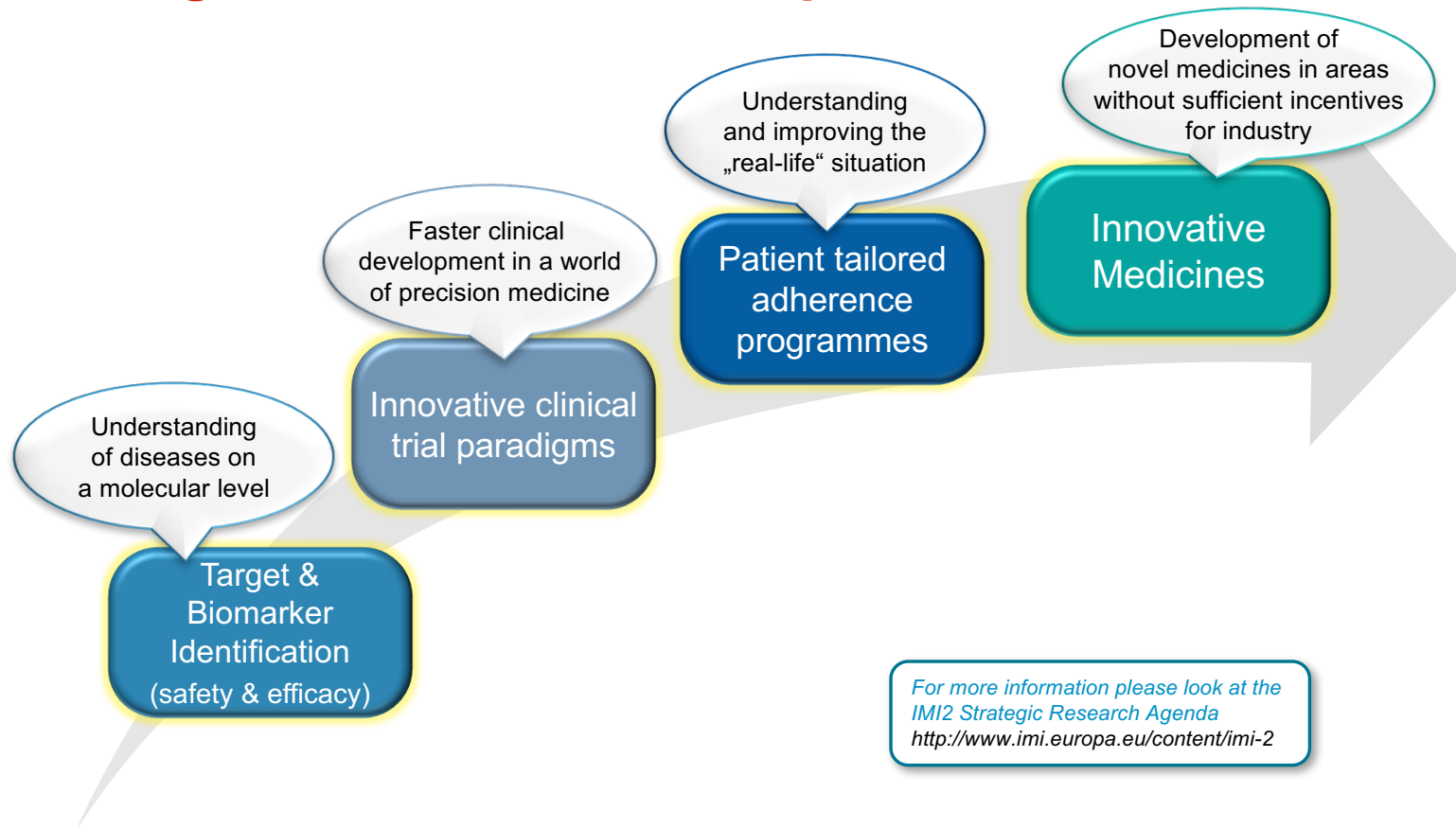


- Establishing critical mass consortia to make drug R&D processes in Europe more innovative and efficient
 - Industry defines strategic research agenda & projects
 - Agenda addresses WHO healthcare priorities
 - Projects in discovery, through development to healthcare delivery and access models

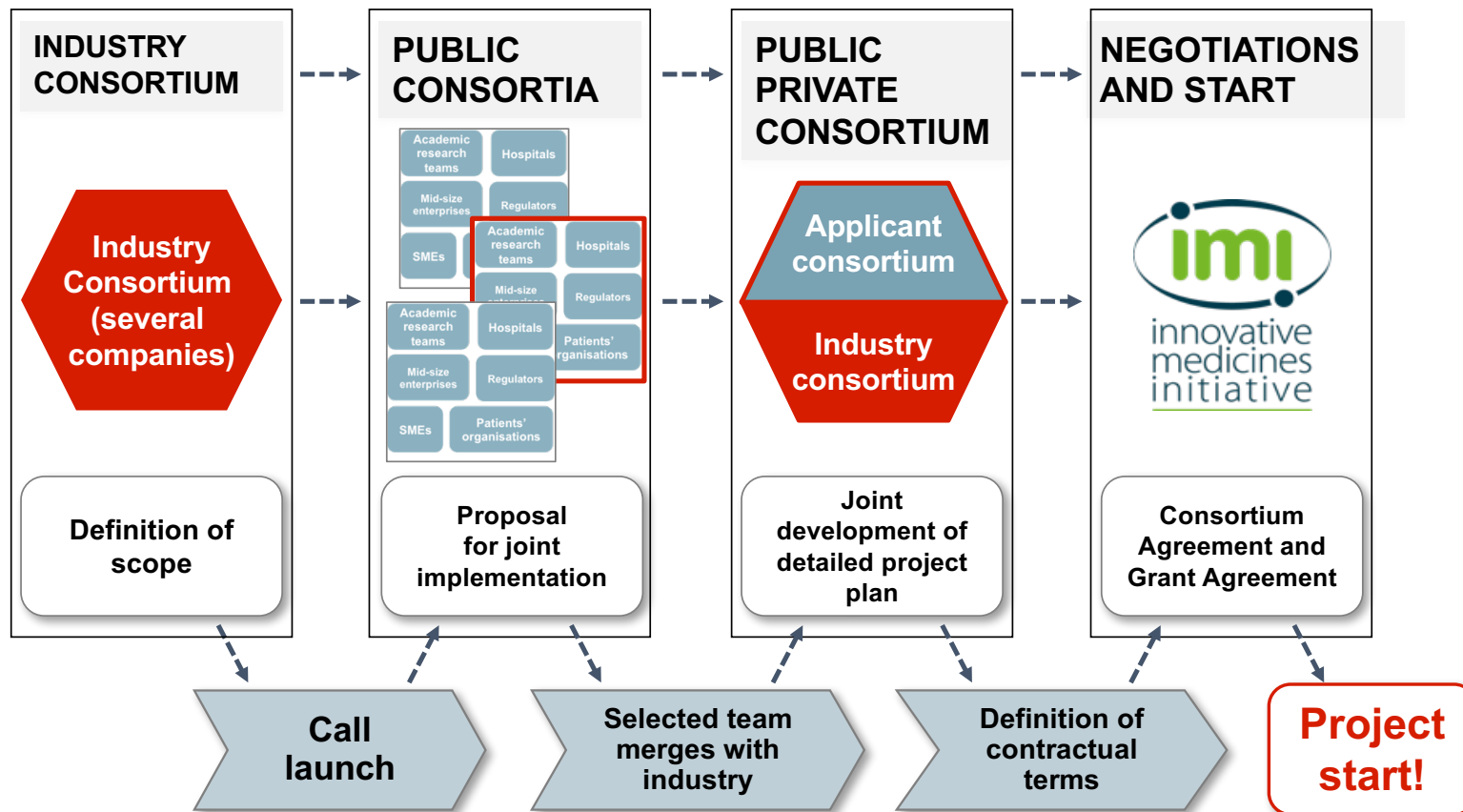


IMI2 – From Science to Patients

Drive change in real life medical practice



IMI – From idea to project start



Big Data for Better Outcomes Programme

Investing in key enablers

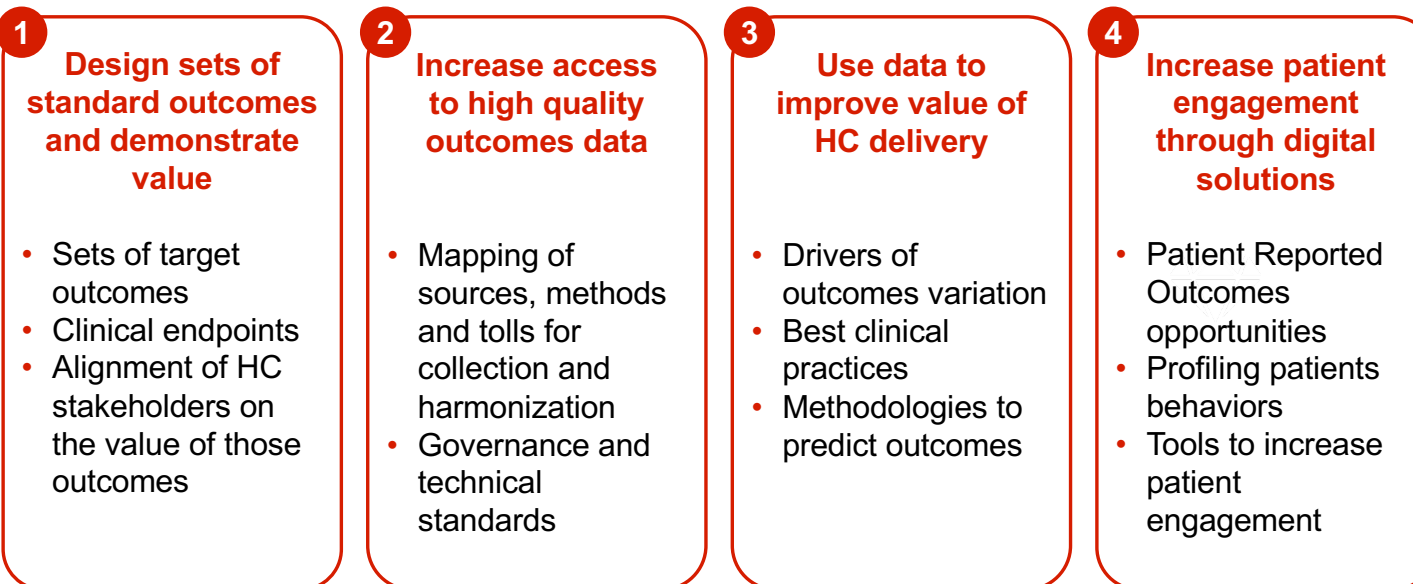


Goal

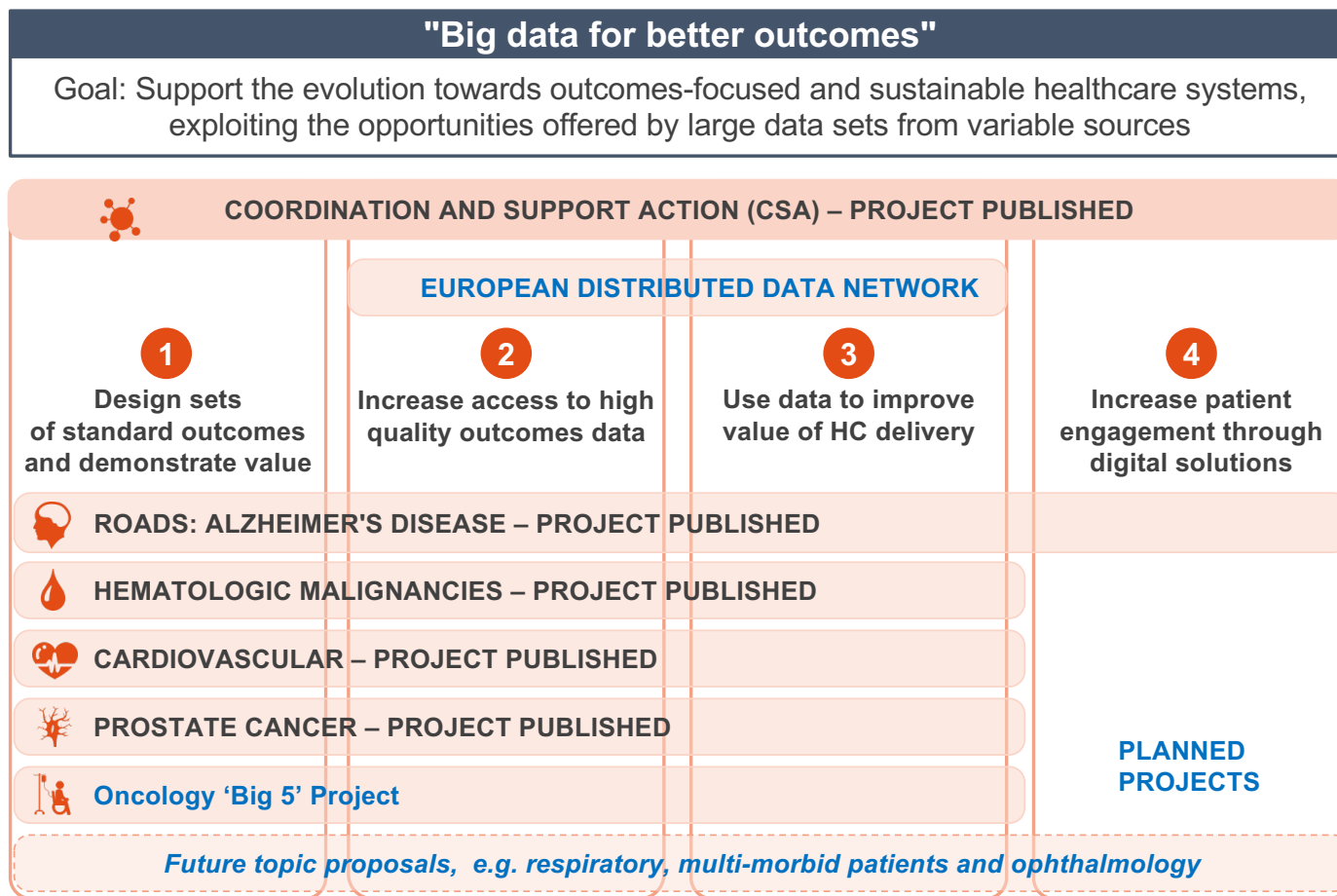


- Support the **evolution towards outcomes-focused and sustainable healthcare systems**
- **Exploit** medical innovation and opportunities offered by **large data sets** from variable sources

Themes/Enablers



Big Data for Better Outcomes (BD4BO) Programme at a glance



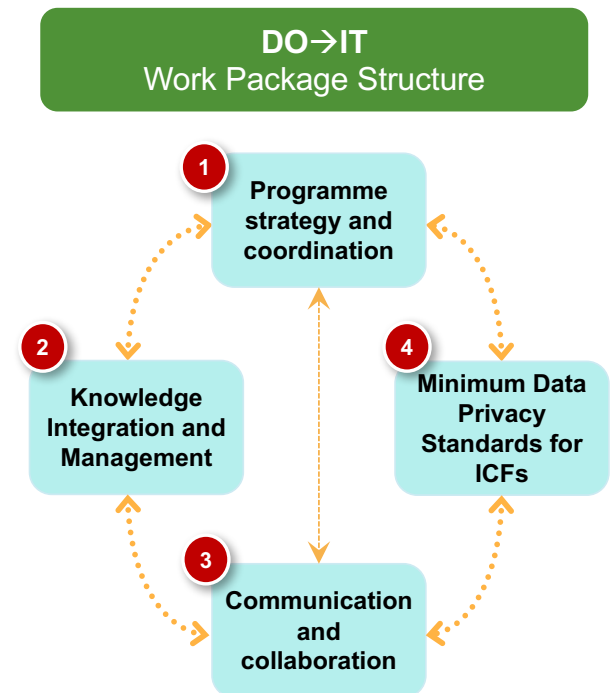
Coordination and operational topics

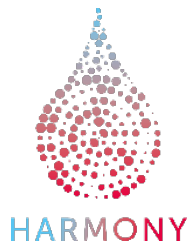
Themes / Enablers

Disease-specific topics

DO→IT Structure at a glance

- BD4BO Programme strategy and coordination
- Integration of knowledge incl. knowledge repository (incl. sustainability)
- Communication and Collaboration with Healthcare Systems Stakeholders
- Minimum Data Privacy Standards for ICFs and Supporting Materials





HARMONY



Big Data Analysis to Improve Outcomes in 7 fields of Hemato-Oncology:

- Non-Hodgkin lymphoma (NHL)
- Chronic lymphocytic leukemia (CLL)
- Myelodysplastic syndromes (MDS)
- Acute lymphocytic leukemia (ALL)
- Acute myeloid leukemia (AML)
- Multiple myeloma (MM)
- Pediatric

no exhaustive
list of partners;
51 partners total

- Others**
- GMV, Barcelona (IT-Infrastructure)
 - Patient Organizations
 - EMA / BfARM / NICE
 - EORTC, EHA

- Pharma Industry**
- Novartis (Coord.)
 - Celgene (Coord.)
 - Bayer
 - Janssen
 - Amgen
 - Menarini
 - Takeda

- University Hospitals**
- Clinic Barcelona
 - Ulm
 - Bologna
 - Wien
 - Erasmus, Rotterdam
 - Navarra
 - Torino
 - Amsterdam
 - Cambridge
 - Rome 'Tor Vergata'
 - Frankfurt
 - Masaryk Univ. / Brunn
 - LMU München
 - Duesseldorf
 - Newcastle upon Tyne
 - Helsinki
 - York
 - Ospedale Pediatrico Bambino Gesù, Roma
 - Assistance Publique – Hôpitaux de Paris
 - La Fe, Valencia
 - IBSAL, Salamanca

More info

- <https://www.bigdata-heart.eu/>
- <http://www.imi.europa.eu/>



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