Patient perspective on Big Data

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Why big data?

Because we are

way too slow and inefficient

to learn to understand and tackle 200+ different cancers effectively

Silos are for farms, not for pharma!

(neither for patients!)

Courtesy Stefan J. Scherer

Why do we think Big Data is a promising approach to tackle cancer?

Key issues of relevance for patients:

- **Break down the silos:** get clinicians and clinical groups, different industry players, HTA agencies, patients to collaborate
- **Rapid sharing, consolidation and learning from data:** detecting signals from analysing multi-source complex data sets
- **Improve characterization of cancers** in order to improve treatment strategies
- **Re-define treatment goals** based on individualized risk assessments and outcome measures
- Build some basic evidence for the **design of innovative clinical studies**
- **Involve the patient perspective in the definition of relevant outcomes**

Big data is in infancy, but happening: IMI2 HARMONY

HARMONY

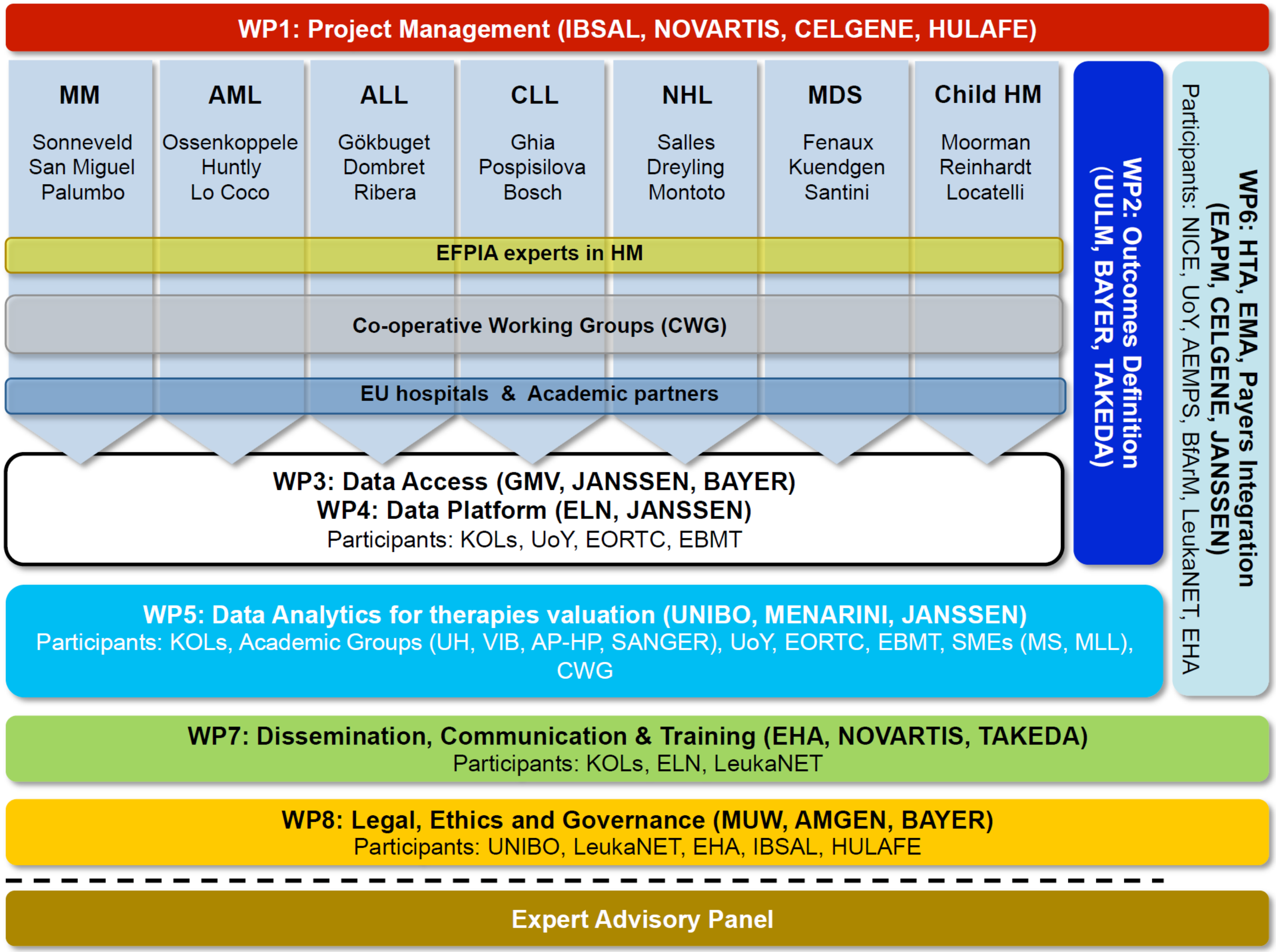
- Pan-European IMI project, 2017-2022
- Goals
  - Speed up drug development, access pathways
  - Improve diagnosis and patient stratification
  - Optimize therapeutic choices and predict efficacy and toxicity of certain treatments
  - Provide robust data on therapeutic value
- Largest Public Private Partnership in hematology 40 M€, 51 public-private partners, 11 European countries
- Patient orgs are involved in consortium and as partners

imi innovative medicines initiative

efpia

Big Data for Better Outcomes

The patient community is part of HARMONY



WP1: Project Management (IBSAL, NOVARTIS, CELGENE, HULAFE)

MM	AML	ALL	CLL	NHL	MDS	Child HM
Sonneveld San Miguel Palumbo	Ossenkoppele Huntly Lo Coco	Gökbuget Dombret Ribera	Ghia Pospisilova Bosch	Salles Dreyling Montoto	Fenaux Kuendgen Santini	Moorman Reinhardt Locatelli

EFPIA experts in HM

Co-operative Working Groups (CWG)

EU hospitals & Academic partners

WP3: Data Access (GMV, JANSSEN, BAYER)
WP4: Data Platform (ELN, JANSSEN)
Participants: KOLs, UoY, EORTC, EBMT

WP2: Outcomes Definition (UULM, BAYER, TAKEDA)

WP6: HTA, EMA, Payers Integration (EAPM, CELGENE, JANSSEN)
Participants: NICE, UoY, AEMPS, BfArM, LeukaNET, EHA

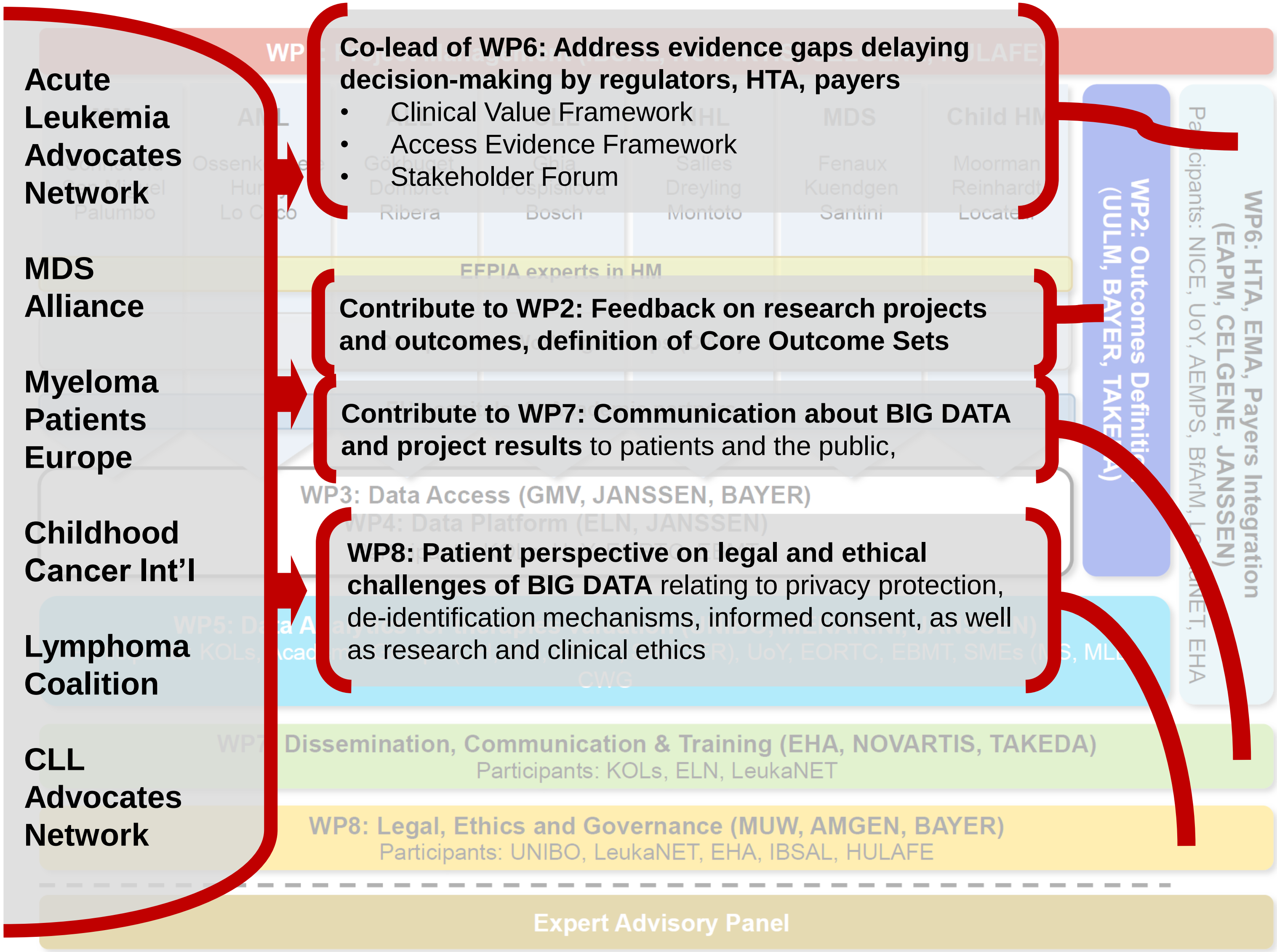
WP5: Data Analytics for therapies valuation (UNIBO, MENARINI, JANSSEN)
Participants: KOLs, Academic Groups (UH, VIB, AP-HP, SANGER), UoY, EORTC, EBMT, SMEs (MS, MLL), CWG

WP7: Dissemination, Communication & Training (EHA, NOVARTIS, TAKEDA)
Participants: KOLs, ELN, LeukaNET

WP8: Legal, Ethics and Governance (MUW, AMGEN, BAYER)
Participants: UNIBO, LeukaNET, EHA, IBSAL, HULAFE

Expert Advisory Panel

The patient community is part of HARMONY



Acute Leukemia Advocates Network

MDS Alliance

Myeloma Patients Europe

Childhood Cancer Int'l

Lymphoma Coalition

CLL Advocates Network

Co-lead of WP6: Address evidence gaps delaying decision-making by regulators, HTA, payers

- Clinical Value Framework
- Access Evidence Framework
- Stakeholder Forum

Contribute to WP2: Feedback on research projects and outcomes, definition of Core Outcome Sets

Contribute to WP7: Communication about BIG DATA and project results to patients and the public,

WP8: Patient perspective on legal and ethical challenges of BIG DATA relating to privacy protection, de-identification mechanisms, informed consent, as well as research and clinical ethics

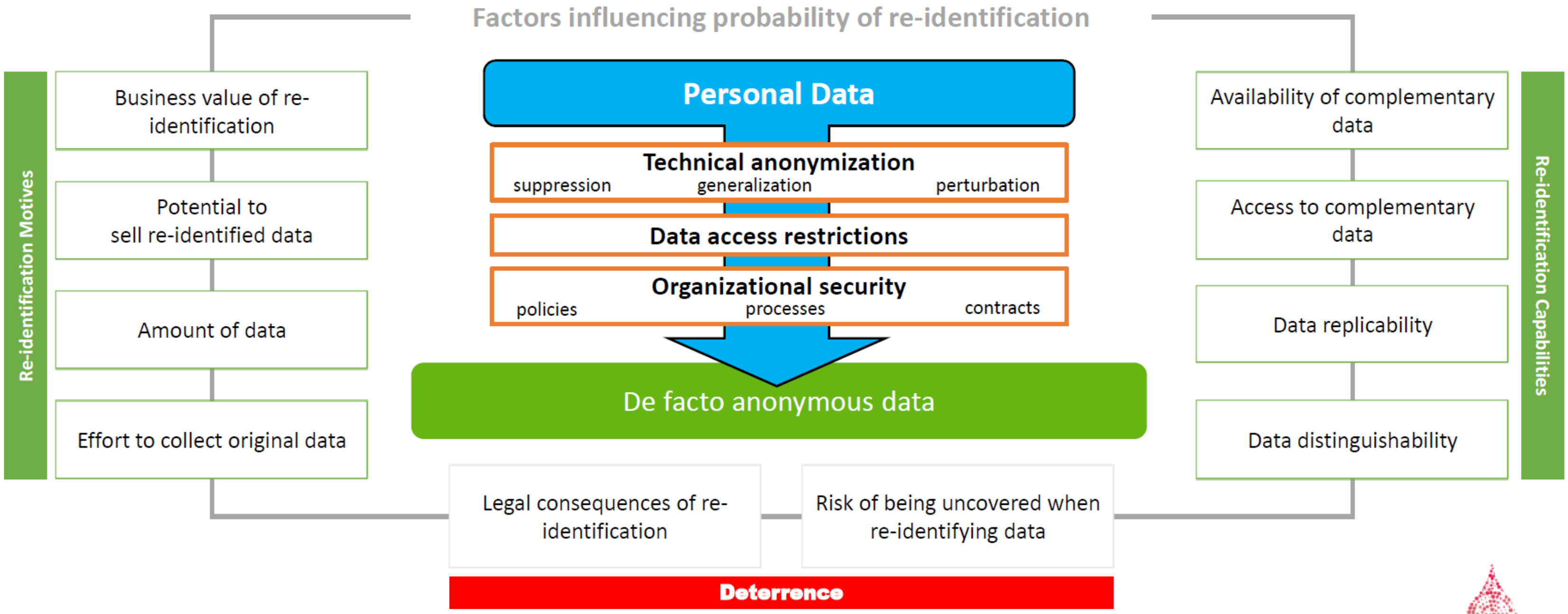
Patient Involvement

Data protection: Paralysis by analysis

- The GDPR has only unified fines – up to 5% of your revenues!
- “Media/NGO can get us”
- “Anonymization (with genomics) is impossible”

- “this is for the advancement of medicine”
- “no one wants to identify patients”
- “there must be valid exceptions”
- “Anonymization renders data useless”

Data protection: Paralysis by analysis … and how we've helped tackle it



Factors influencing probability of re-identification

Re-identification Motives

Business value of re-identification

Potential to sell re-identified data

Amount of data

Effort to collect original data

Personal Data

Technical anonymization

suppression generalization perturbation

Data access restrictions

Organizational security

policies processes contracts

De facto anonymous data

Re-identification Capabilities

Availability of complementary data

Access to complementary data

Data replicability

Data distinguishability

Legal consequences of re-identification

Risk of being uncovered when re-identifying data

Deterrence

- Sufficient anonymity is reached if identification would require an unreasonable effort
- HARMONY Anonymization Concept complies with applicable data protection laws including GDPR

- Big Data can largely influence rapid learning, outcomes, treatments – **which is what matters to patients**
- It requires **leaving the silos** of academia, industry, regulators, patients
- **Patients need to be fully involved** – still a lot of ignorance around there