HARMONY

Final presentations | PPTs

HARMONY Session
'Big Data in Hematology'
15 June 2019 | 14:45 - 16:15 hrs

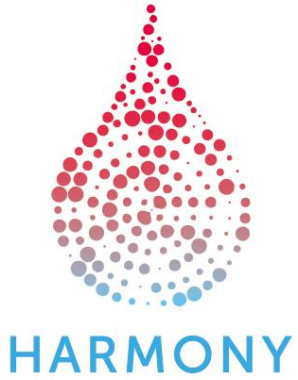
24th Annual Congress of the European Hematology Association

#Bigdataforbloodcancer:
HARMONY can accelerate your research to benefit patients with Hematologic Malignancies

imi innovative medicines initiative

efpia

Session Speakers



- **Bob Löwenberg,** Chair HARMONY Advisory Board / Erasmus MC
- **Pam Bacon**, Celgene & Guillermo Sanz, HULAFE
- **Zack Pemberton-Whiteley**, Representing the HARMONY Patient Cluster / Acute Leukemia Advocates Network;
- **Anthony Moorman**, Newcastle University
- **Lars Bullinger**, Charité University Medicine
- **Lesley-Ann Sutton**, ERIC
- **Pierre Fenaux**, AP-HP
- **Allessandra Larocca**, Università di Torino
- **Natacha Bolaños**, Lymphoma Coallition
- **Bruno Costa**, Celgene
- **Jesus Maria Hernandez Rivas**, IBSAL

HARMONY

Posing a few questions? Opportunities

Bob Löwenberg

Deptartment of Hematology
Erasmus University Medical Center,
Rotterdam

Chair HARMONY Advisory Board

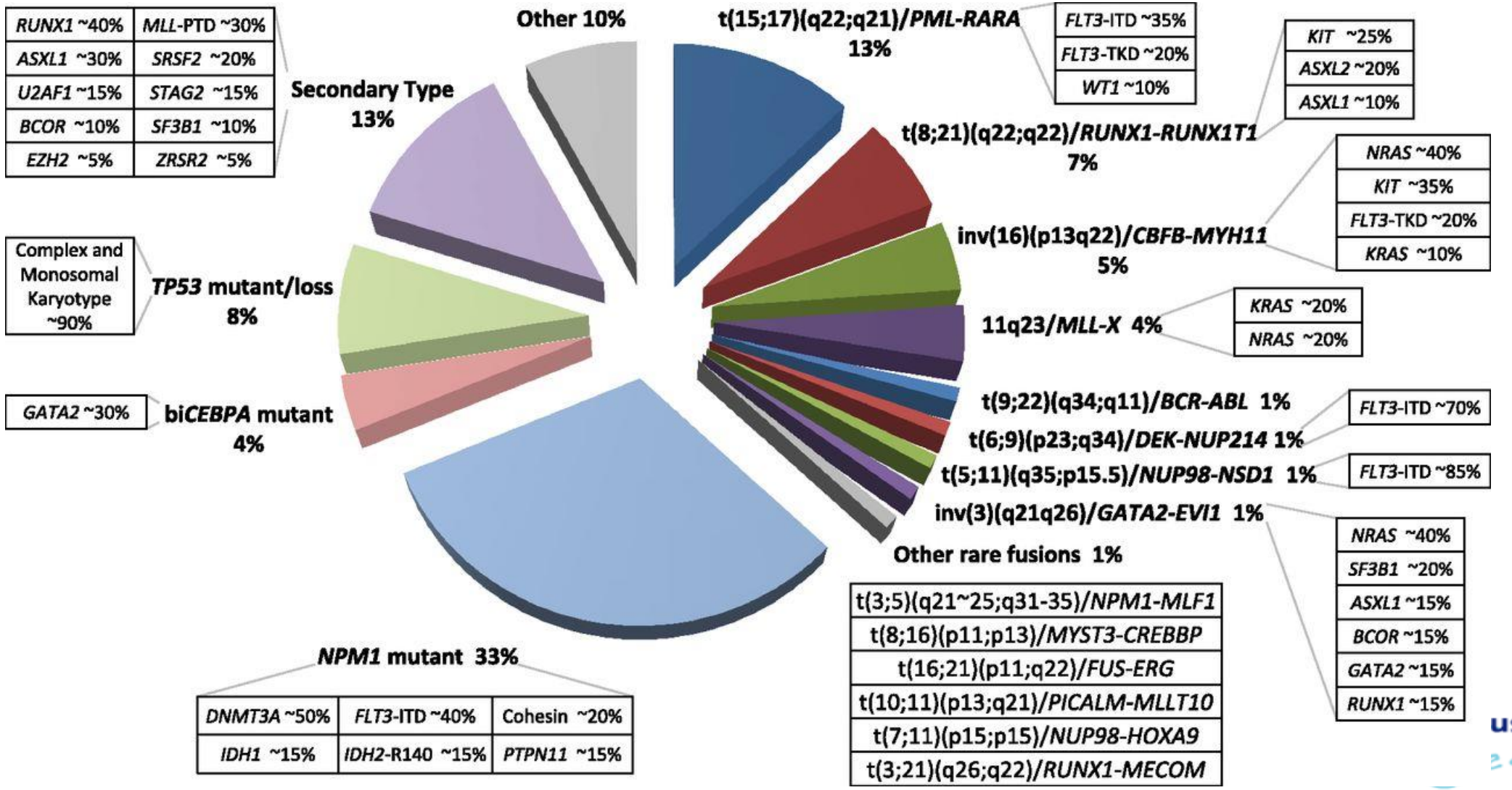
EHA24 | 15 June 2019 | Amsterdam | NL

HARMONY Motto

HARMONY

- **Unique**
- **Feasible**
- **Impactful**

Distribution of cytogenetically and molecularly defined subsets of AML presenting in younger adults.



David Grimwade et al. Blood 2016;127:29-41

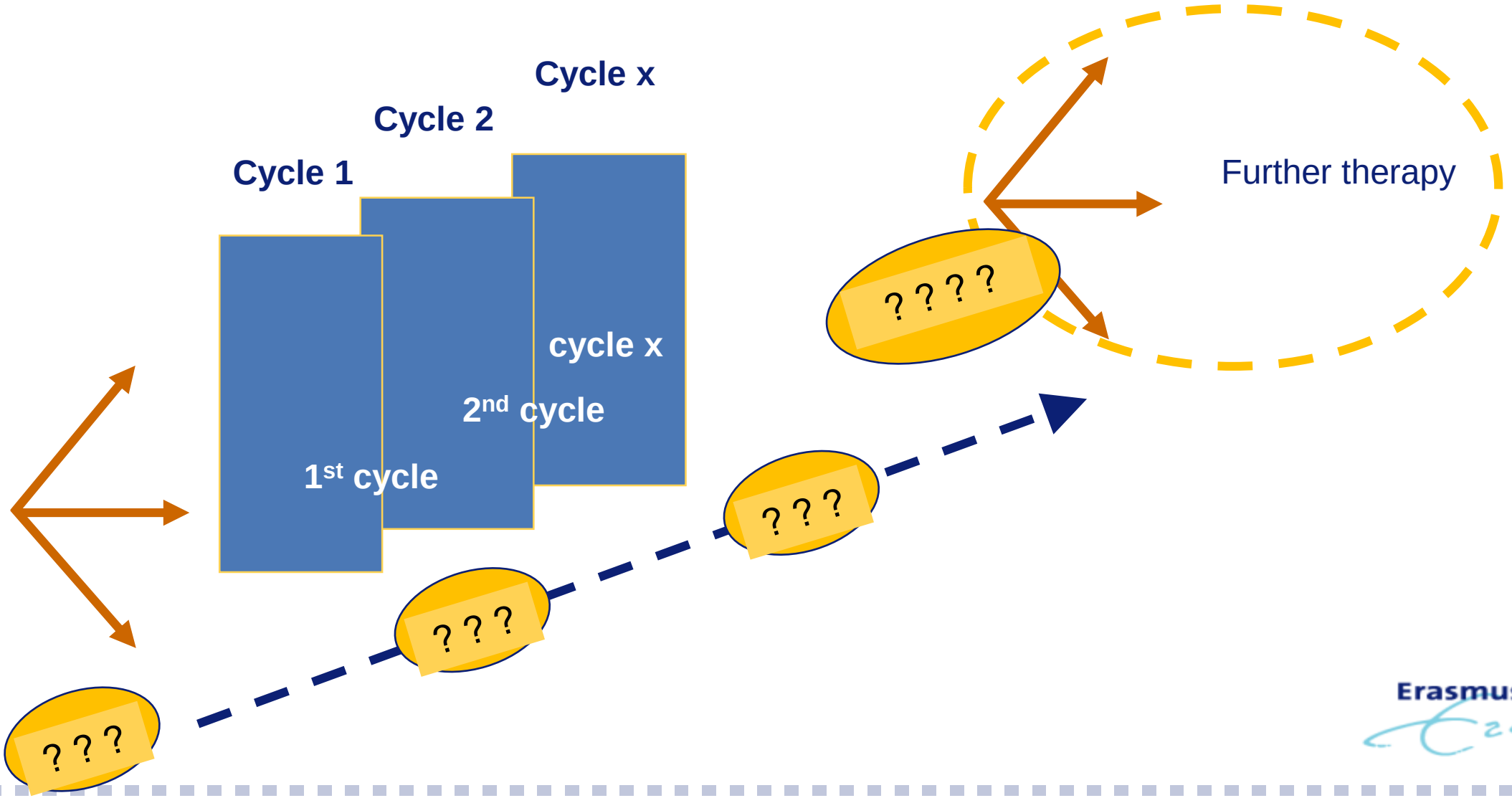
Acute Myeloid Leukemia (AML) towards a better understanding and better care for our patients

Disease variation: who is who?
(relation to therapy options, relation to outcome, relation to costs, …)

Huge challenge
Huge numbers needed

Erasmus MC

Treatment: from start to finish



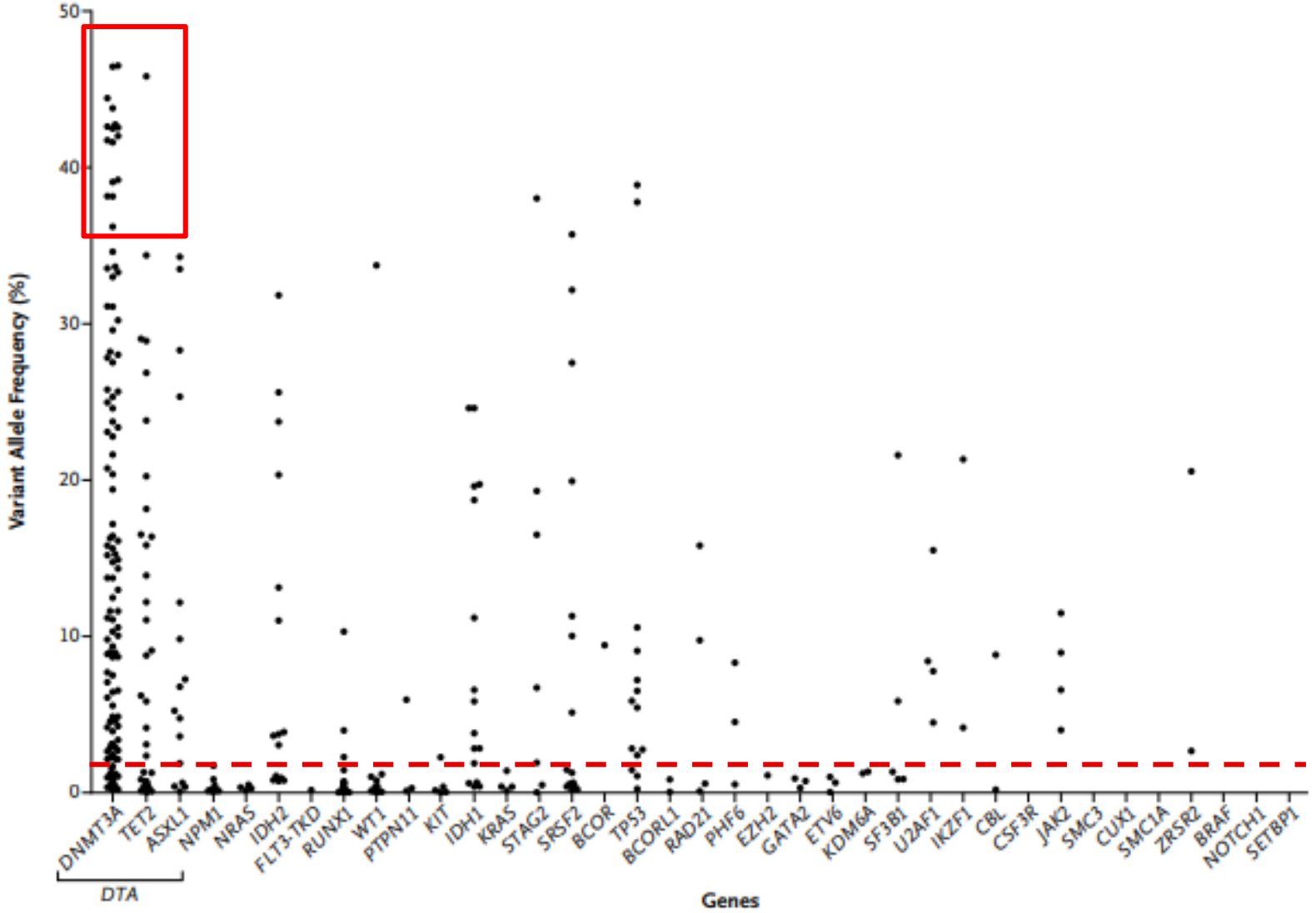
Follow up of patients with AML

Residual gene mutations: their meaning? What do they represent?

- Preleukemic alterations
- Antecedent disease
- Residual leukemia/ source of emerging relapse

Erasmus MC

Variant Allele Frequencies (VAF) of Gene Mutations in CR



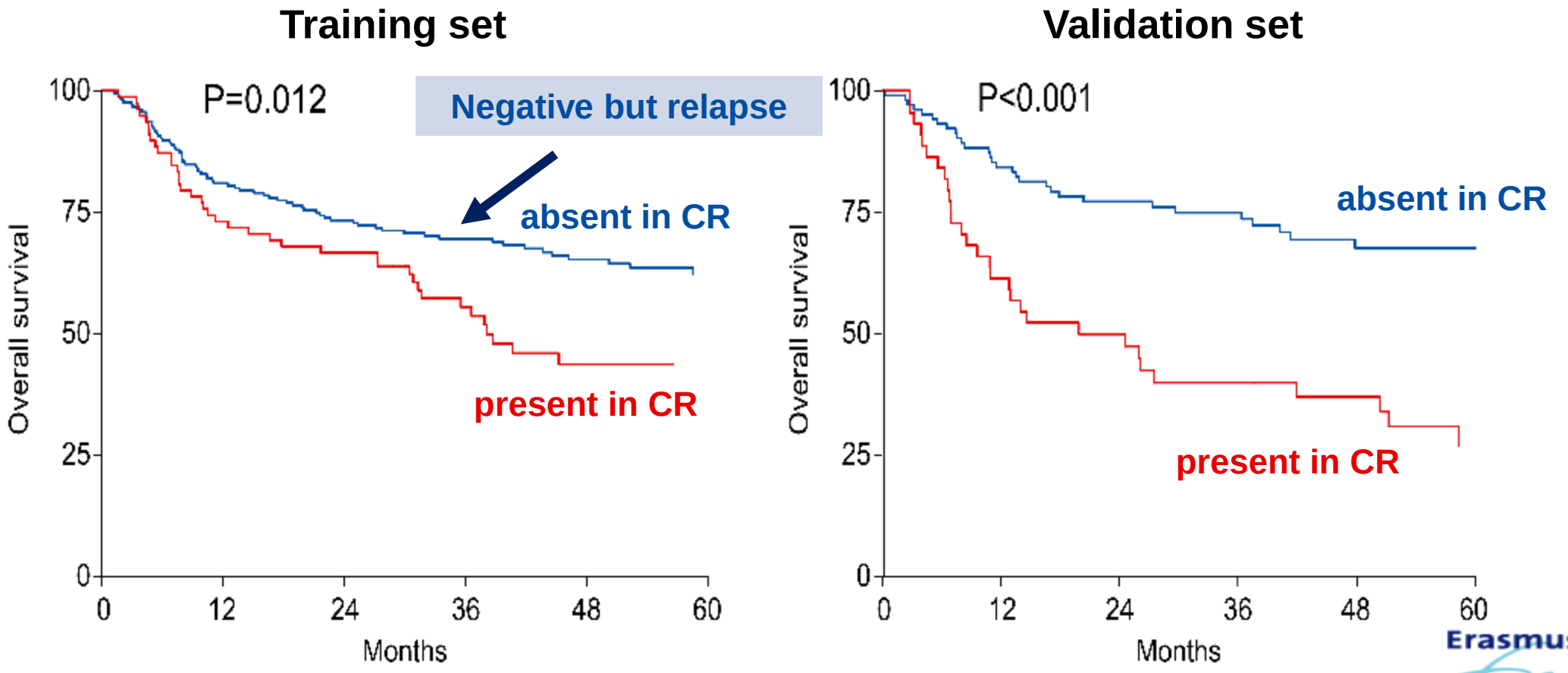
CR threshold

Jongen-Lavrencic M, et al. *N Engl J Med.* 2018;378(13):1189-1199.

VAFs of BCOR, BCORL1 and STAG2 (X-chromosome) were divided by two in case of male patients.

Overall Survival of Residual Leukemia

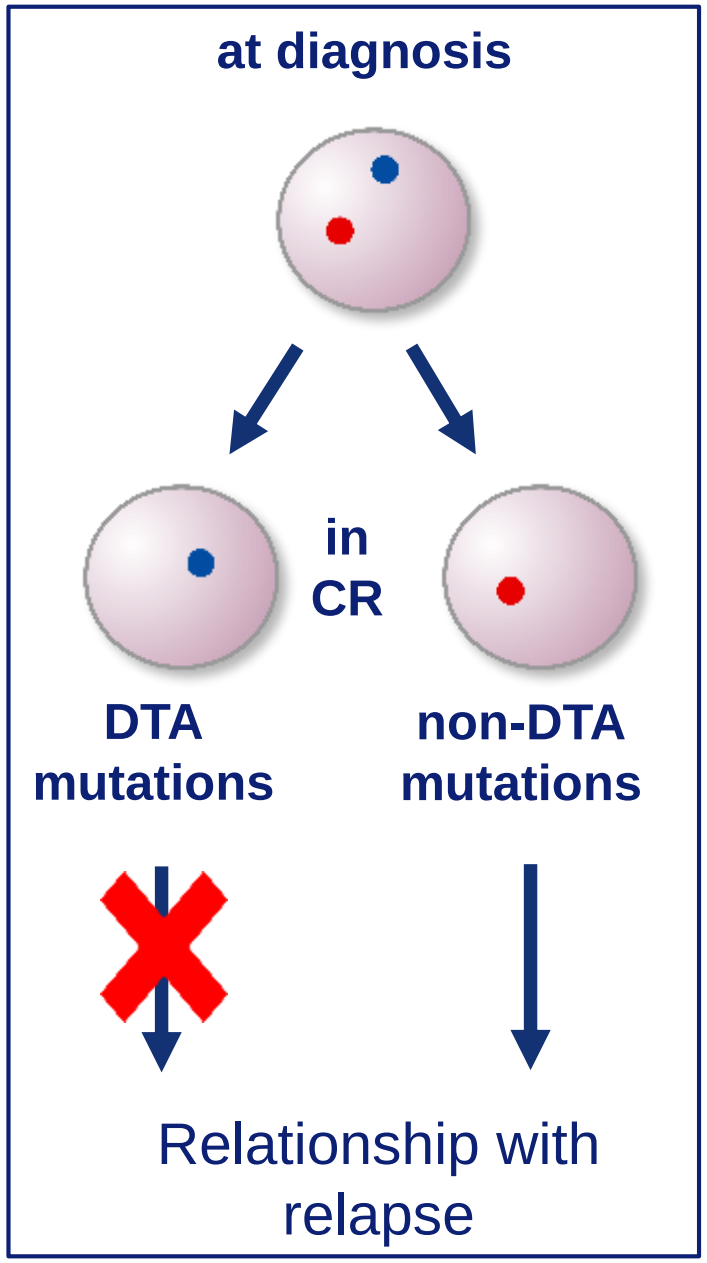
Non-DTA Mutations Highly Predictive for Overall Survival in AML



Erasmus MC

Jongen-Lavrencic M, et al. *N Engl J Med.* 2018;378(13):1189-1199.

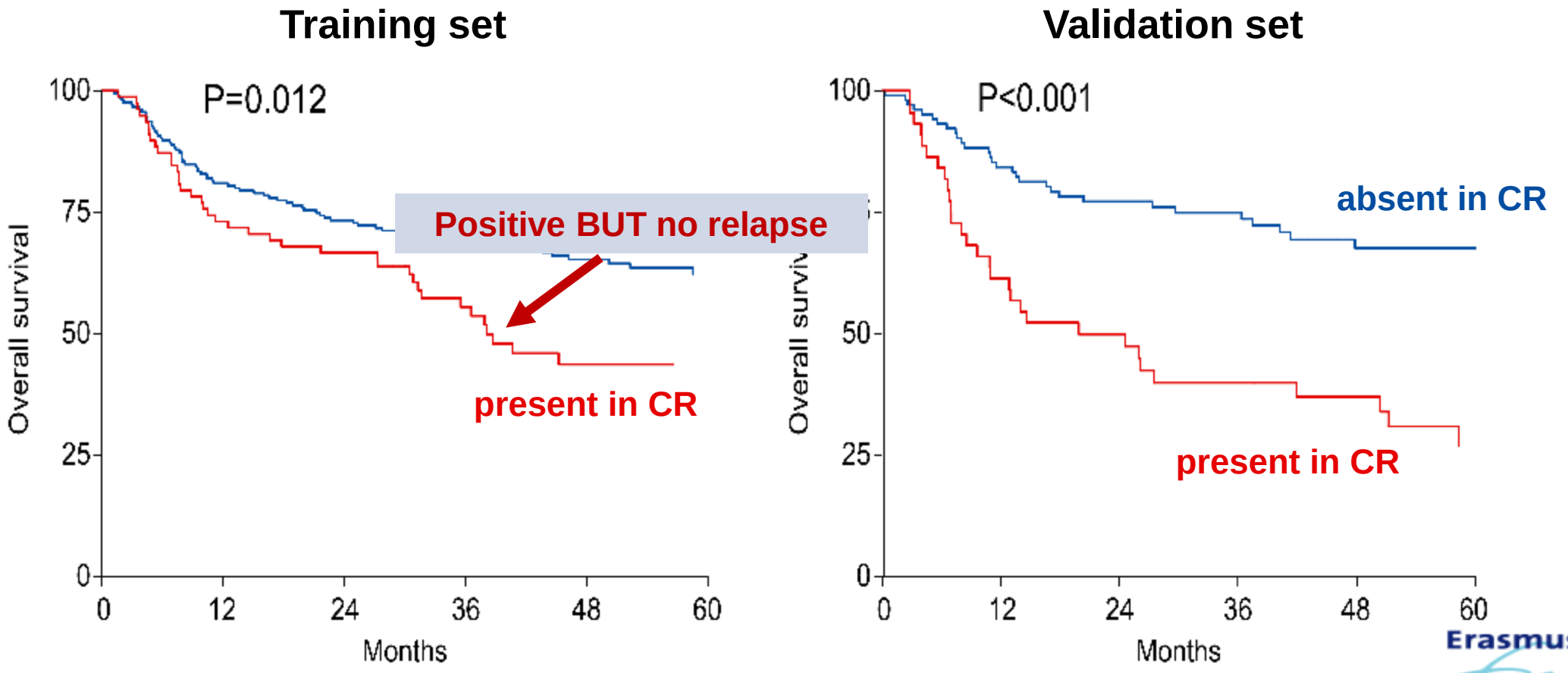
Next questions: why is detection imperfect ??



1. **Why recurrence in the absence of persisting clonal markers?**
   - **missing markers**
   - **missing minor clones (assay sensitivity)**
   - **relapse with evolving genotype**

Overall Survival of Residual Leukemia

Non-DTA Mutations Highly Predictive for Overall Survival in AML



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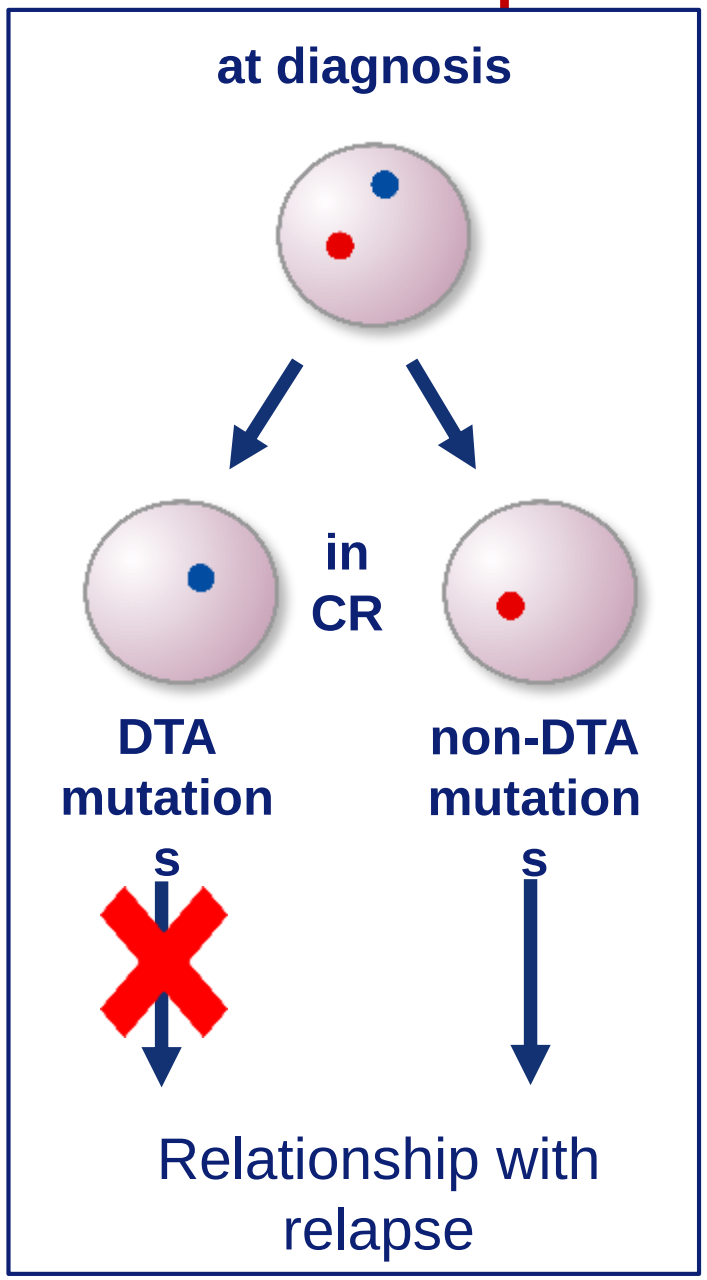


2. **Why don't persisting clonal markers herald relapse??**

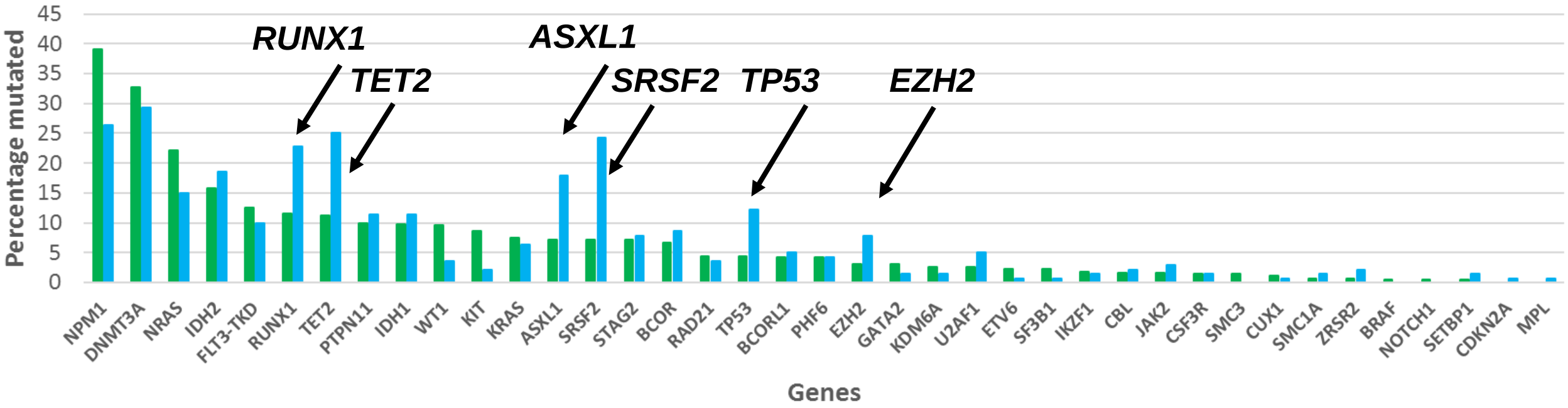
- More detailed insight in functional diversity of treatment resistant subclones needed

- Specifically distinguish clonal hematopoiesis for infrequent mutations?

Comparative mutation frequencies in AML CR cohorts

(< 65 versus >65 years)

AML <65 years (n=430)
AML >65 years (n=157)



<u>AML >65 years versus <65 years</u>

Less frequent mutations in: *NPM1, WT1, KIT* and *NRAS*

More frequent mutations in: *RUNX1, TET2, ASXL1, SRSF2* and *TP53*

ZRSR2, U2AF1, BCOR, EZH2 (not: *STAG2/SF3B1*)

Erasmus MC

Unpublished

HARMONY: a compelling rationale for international cooperation

- Understanding the impact of the inter-individual diversity of hematologic malignancies
- Its relevance for treatment outcome and treatment choice
- Informing strategies for developing new treatments
- Societal impact

There is no alternative

Erasmus MC

HARMONY

1. How can Big Data in hematology accelerate research
2. Big Data is going to make a difference
3. Your data is needed and you can benefit

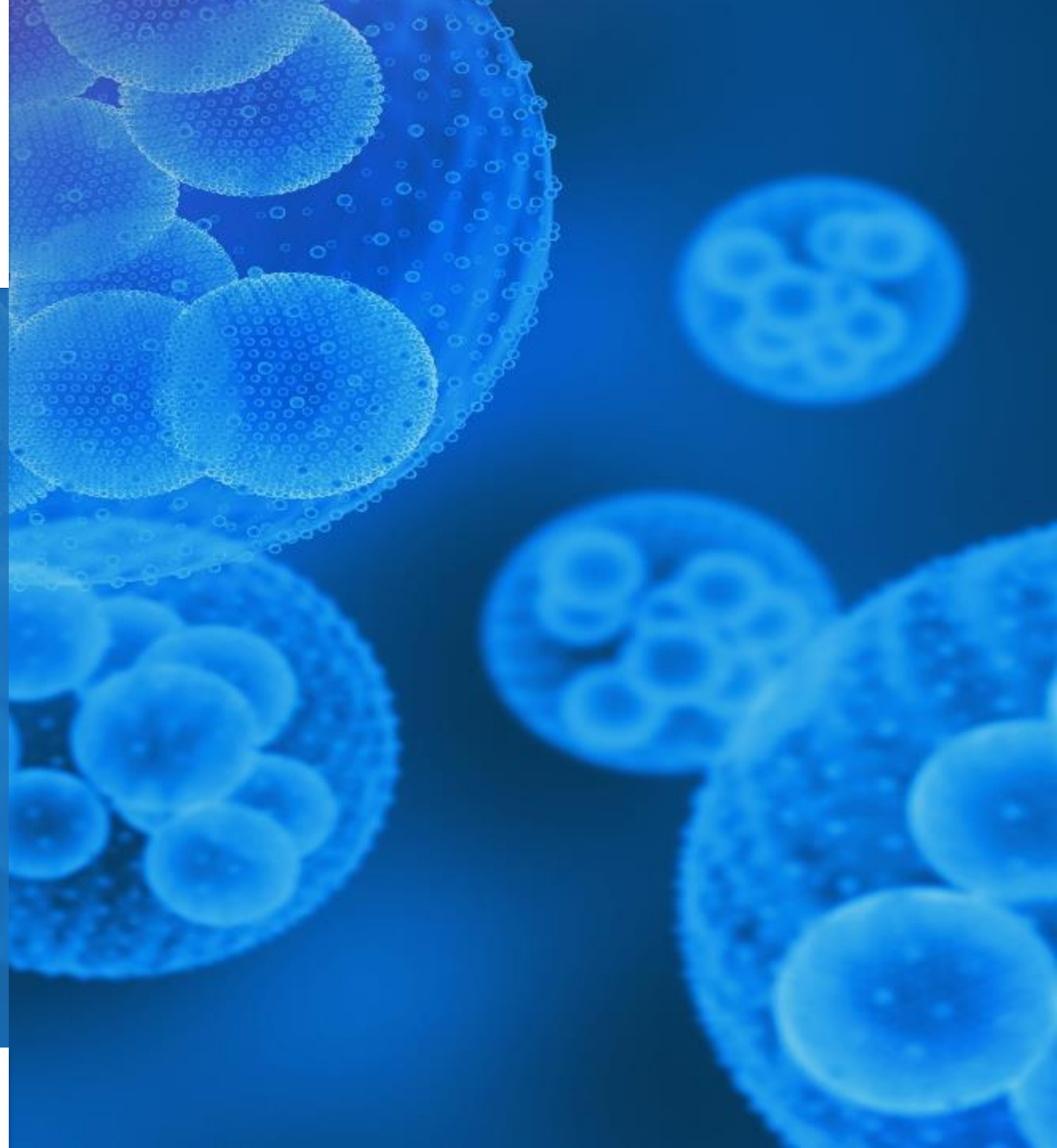
HARMONY

Milestones & Outlook

Guillermo Sanz
HARMONY Co-Chair, HULAFE

Pam Bacon
HARMONY Project Co-Leader, CELGENE

EHA24 | 15 June 2019 | Amsterdam | NL

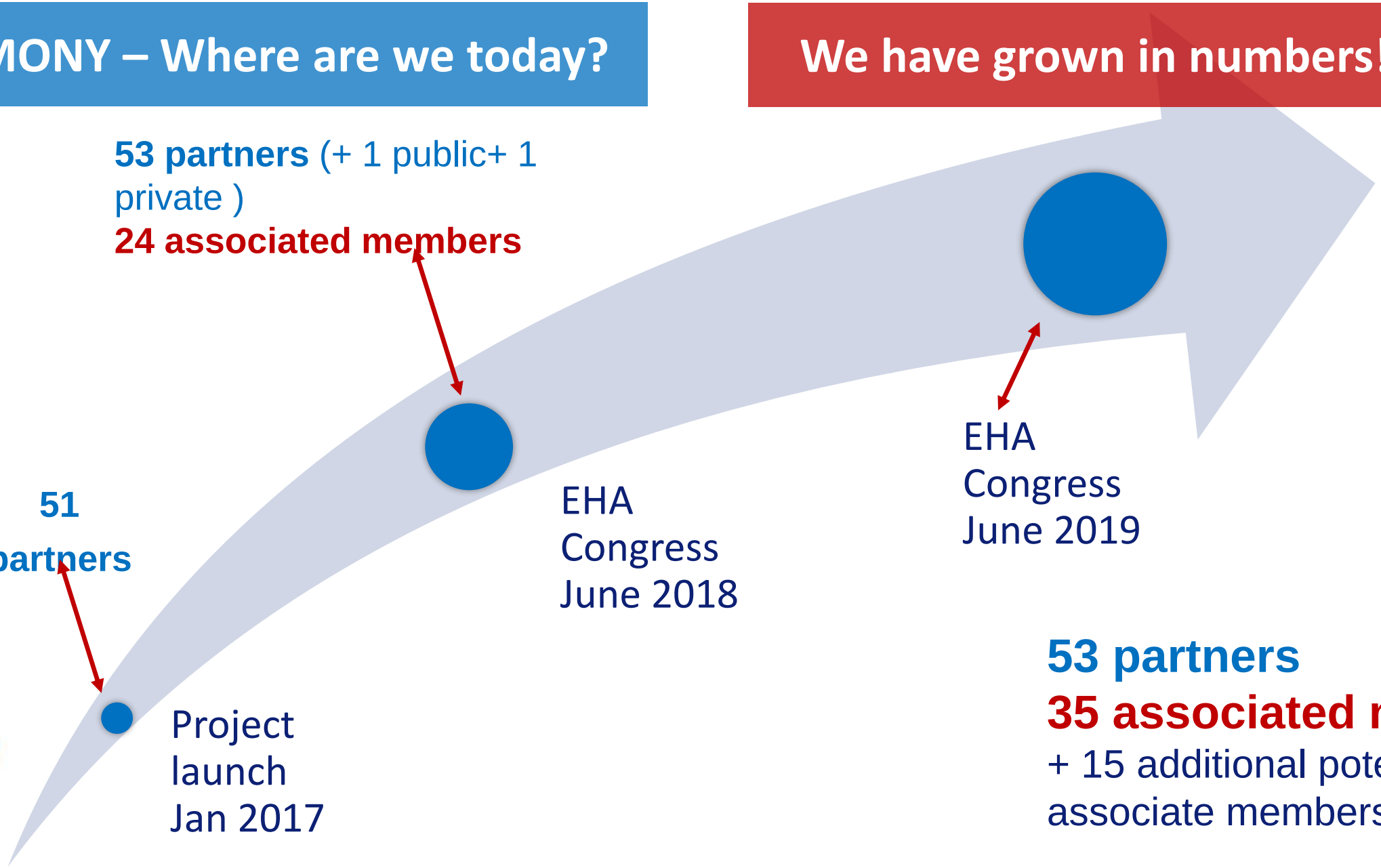


Involving all stakeholder groups to meet patients' needs

HARMONY

HARMONY – Where are we today?

We have grown in numbers!

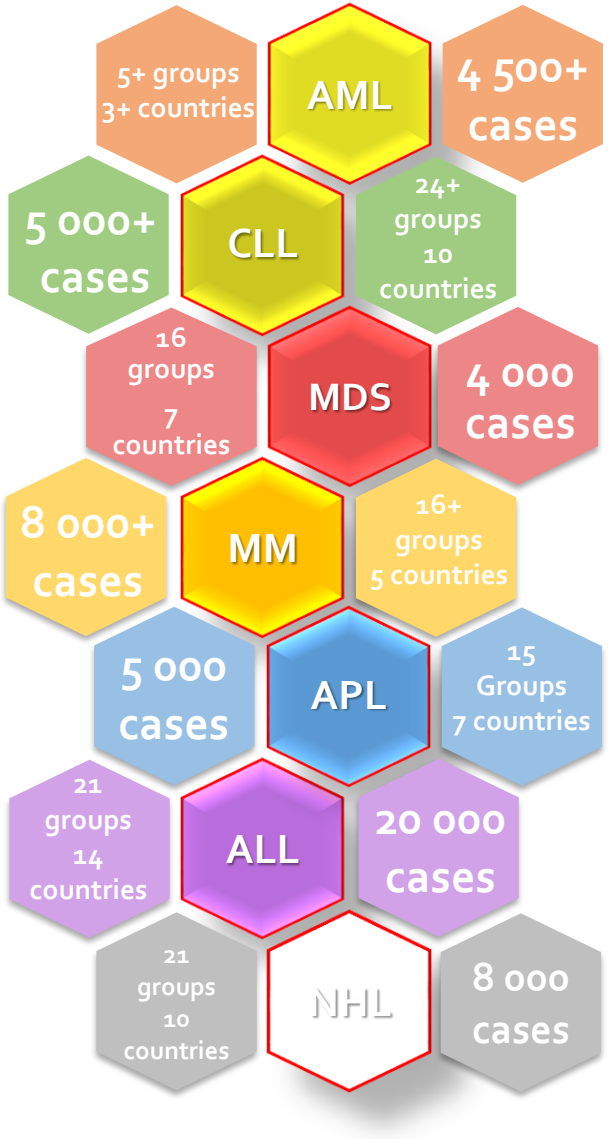


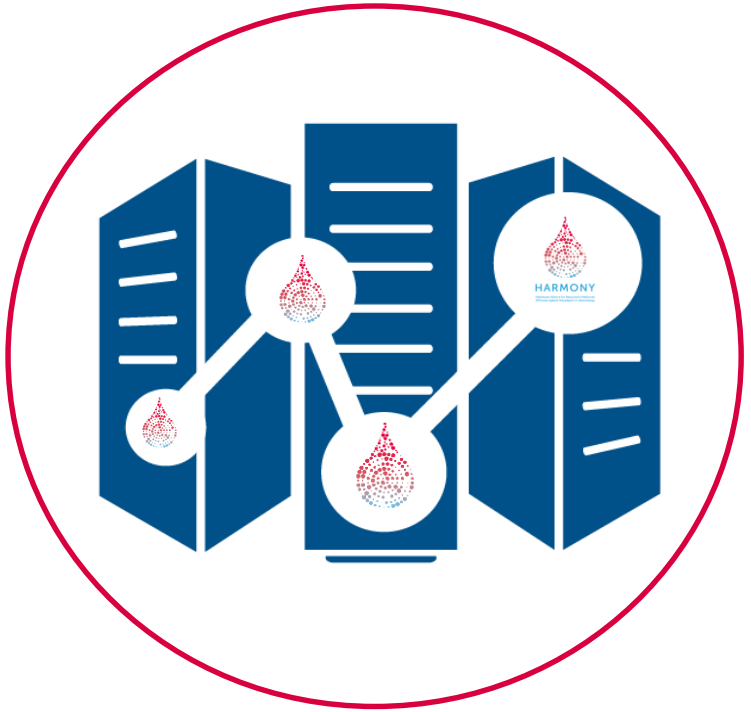
53 partners

35 associated members

+ 15 additional potential associate members

We now have active research projects across all HMs





HARMONY

The HARMONY Big Data Platform

>45,000 data records

expected by December 2019

Many key milestones achieved across all work packages

Policy Health Stakeholder Feedback Forum (PHSFF)

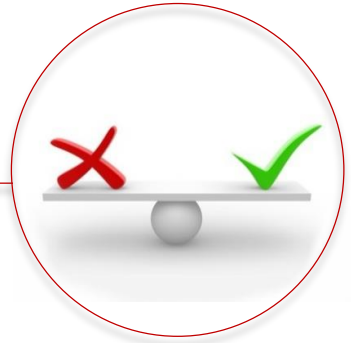
Modus Operandi on the **secondary use of medical data ethically and legally approved**

First Results of the **Proof of Principle study in AML** (Poster PS1003)

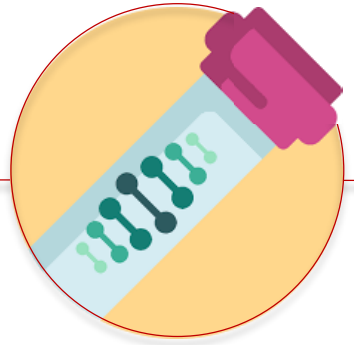
Core Outcome Set definition for HMs started & ongoing *Delphi Survey*

Communication & Dissemination activities

Associated Members' Engagement Framework and **Data Sharing Agreements**



Standard Operational Procedure (SOP) for submission of **Research proposals**

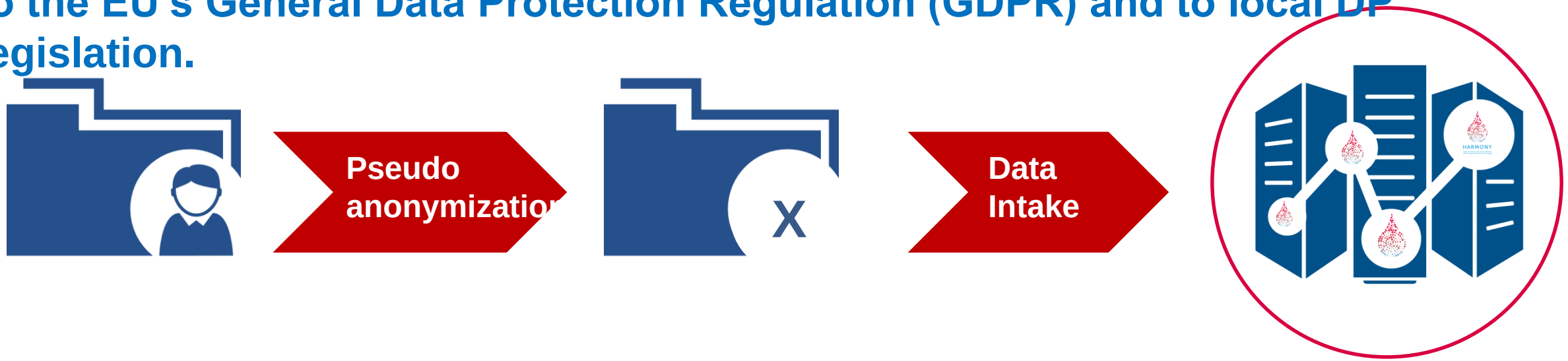


7 HM Big Data Research Projects kicked off

HARMONY

The HARMONY Anonymization Concept

**Ensuring careful, judicious, and uncompromising adherence to ethical guidelines,
to the EU's General Data Protection Regulation (GDPR) and to local DP legislation.**



State-of-the-art data processing solutions with maximum protection

DP = data protection

HARMONY - present at key meetings in 2019

ORLANDO, FLORIDA
61st ASH Congress
7th – 10th December

FLORENCE
4th HARMONY
General Assembly
26th-27th September

AMSTERDAM
24rd EHA Congress
13th-16th June

THE HAGUE
HARMONY KOLs Meeting
5th February

MANNHEIM
ELN Symposium
12th February

Different F2F HARMONY intra and inter WP Meetings and International Workshops per disease

HARMONY Patient Cluster

1st Patient Masterclass
February 4th
The Hague, The Netherlands

2nd patient Masterclass
End of 2019

MDS

May 8-11th
Copenhagen, Denmark

NHL

June 15-17th
Lugano, Switzerland

MM

September 12-15th
Boston, MA, USA

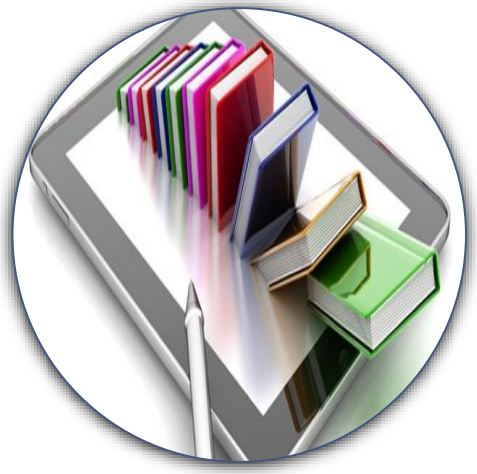
CLL

September 20-23rd
Edinburgh, Scotland, UK

Main focus in 2019

Algorithms To Transform Knowledge Into Better Medicine Outcomes

HARMONY



More Research Projects

Patients' active engagement

Sustainability plan

Finalize the first COS Delphi AML Survey and initiate across all HMs

COS = Core Outcomes Set

7 HARMONY Research Projects ongoing... more to follow

Next-generation science: Sharing data and knowledge

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Your HARMONY Research Project?

HARMONY

www.harmony-alliance.eu

#bigdataforbloodcancer

@HarmonyNetEU

Join us!

Patient involvement in HARMONY alliance

Zack Pemberton-Whiteley

Acute Leukemia Advocates Network

Representing the HARMONY Patient Cluster

EHA24, 15 June 2019, Amsterdam, NL

DISCLOSURE OF AFFILIATIONS

Z. Pemberton-Whiteley

Leukaemia Care (Patient advocacy director)
Acute Leukemia Advocates Network (Chair)
CML Advocates Network (Treasurer and Steering Committee Member)
HARMONY (AML and ALL patient organisation representative)
AbbVie (Advisory board, speaker)
Amgen (Advisory board, speaker)
Bristol-Myers Squibb (Advisory board, speaker)
Gilead (Advisory board, speaker)
Incyte (Advisory board, speaker)
Janssen (Advisory board, speaker)
Jazz (Advisory board, speaker)
Novartis (Advisory board, speaker)
Pfizer (Advisory board, speaker)
Sunesis (Advisory board, speaker)

Focus:

- Who are the Patient Organisations involved in the HARMONY Patient Cluster?
- Why do we need patient involvement in HARMONY?
- How to involve the patient organisations?
- What is the role of the patient organisations in HARMONY?

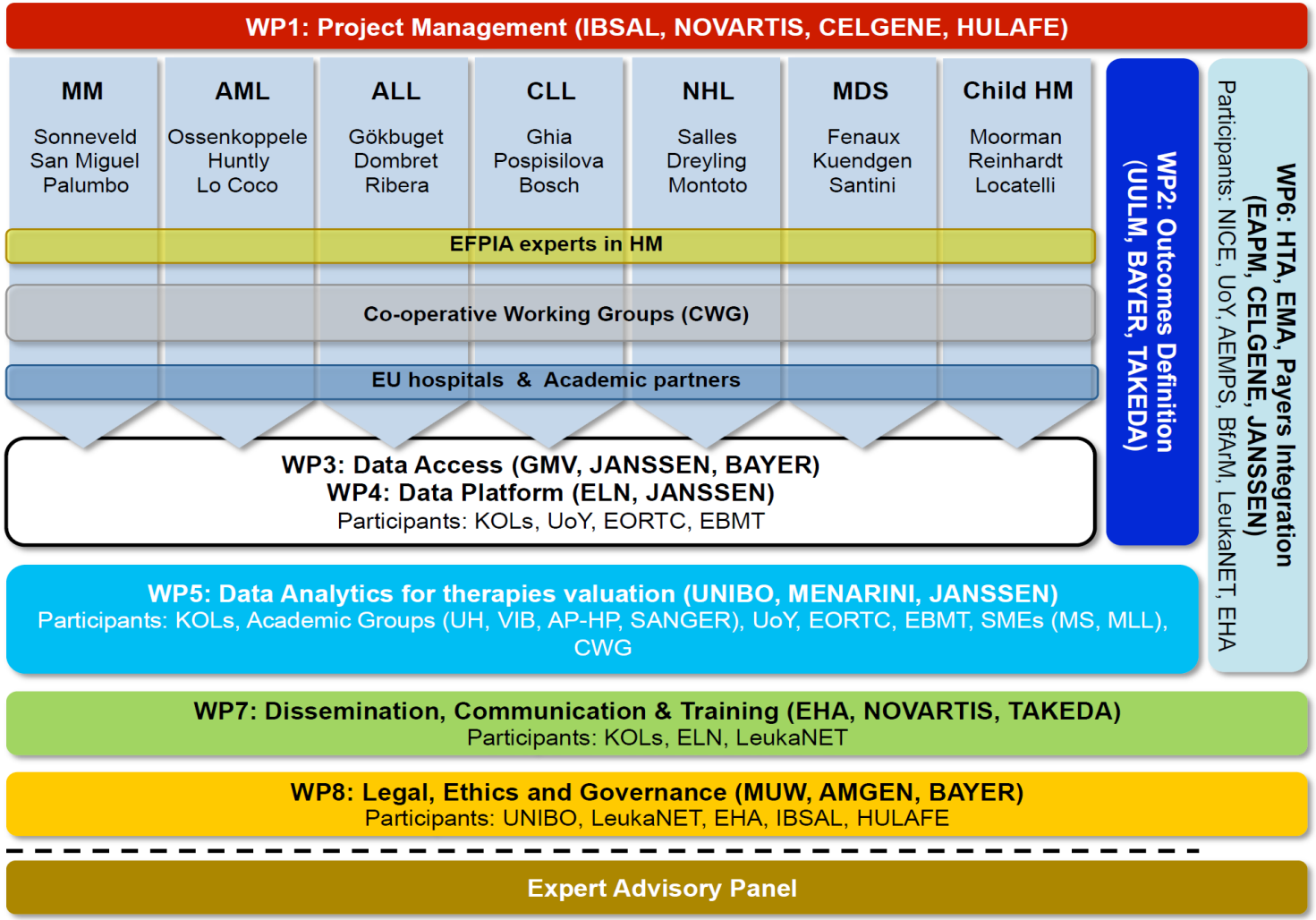
Who are the patient organisations in WP6?

- **Coordinators / Cluster lead:** LeukaNET (leuka.net)
  Tamás Bereczky, Jan Geissler
- **Multiple Myeloma: Myeloma Patients Europe** (mpeurope.org)
  Kate Morgan, Ananda Plate
- **AML and ALL: Acute Leukemia Advocates Network** (ALAN, acuteleuk.org)
  Zack Pemberton-Whiteley
- **CLL: CLL Advocates Network** (clladvocates.net) and **Lymphoma Coalition**
  Nick York and Pierre Aumont (CLLAN), Natacha Bolanos (Lymphoma Coalition)
- **MDS: International MDS Alliance** (mds-alliance.org)
  Sophie Wintrich
- **Pediatric Hematological Malignancies: Childhood Cancer International**

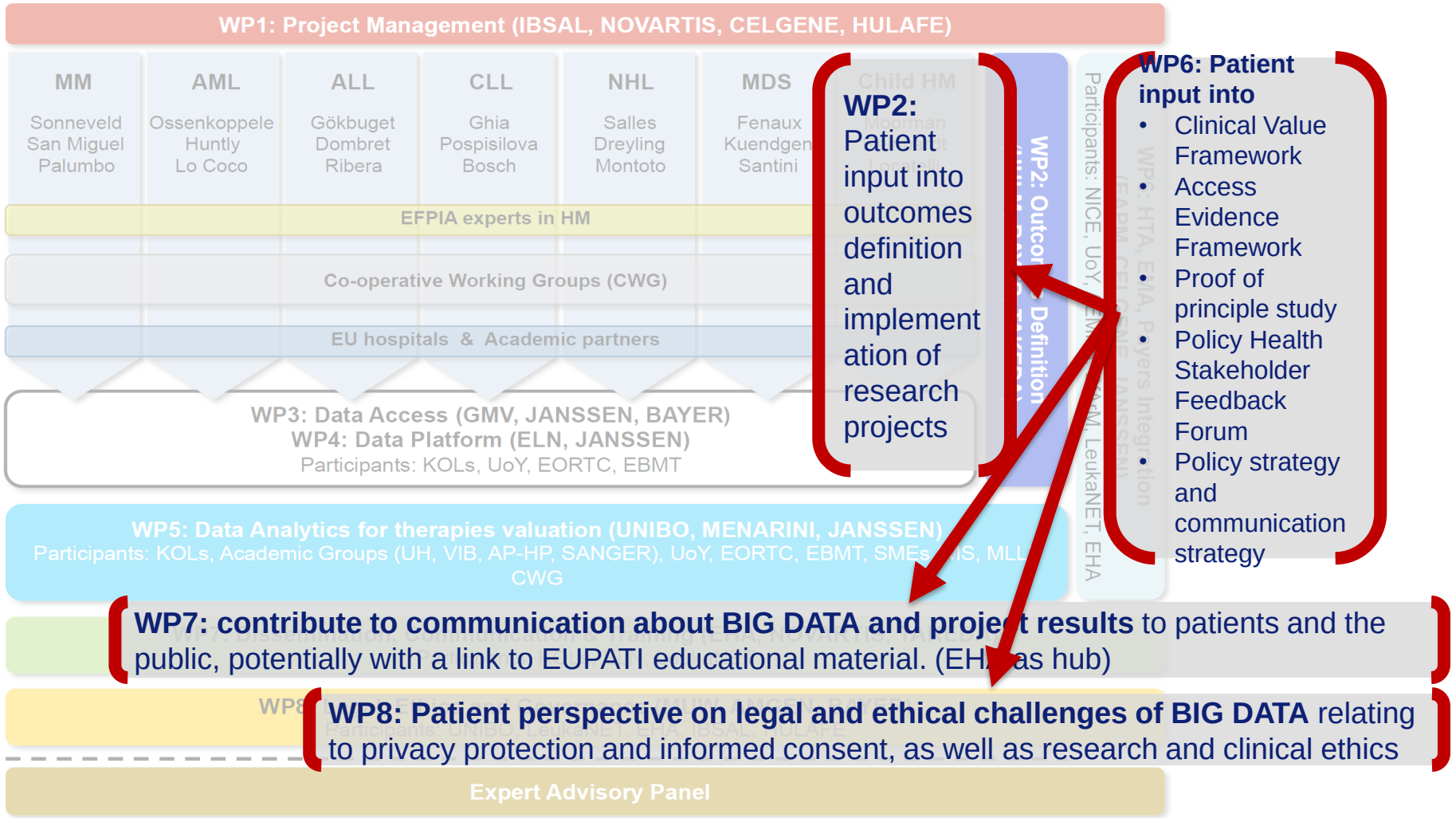
Why do we need patient involvement in HARMONY?

Image: https://twitter.com/headinthebooth/status/1092096892094296064 (Accessed, 24/03/2019 at 22:52)

How to involve the patient organisations?



How to involve the patient organisations?



What is the role of the patient organizations in HARMONY?

- Partner in HARMONY Research Projects
- Contributes to defining the right research questions
- Access to patient input - e.g. Delphi Surveys
- Communication and dissemination activities to help spread the word about patient relevance of Big Data

What are the challenges of patient involvement?

- Willingness of KOLs to involve patients in research projects varies
- We need to push for involvement, we are rarely invited
- Information gap about HARMONY activities
- What knowledge do we need to contribute?
- Not just patients, caregivers and also other stakeholders (e.g.

Summary

- Patient organisations are willing and have the capability/capacity to engage in the HARMONY project
- Current engagement of the patient community is not effective in all areas of the HARMONY initiative. There are lots of challenges.
- We need project leads to reach out to the stakeholder forum to involve patient advocates in HARMONY initiatives
- Without effective involvement of the patient community, the project (e.g. core outcomes) will not be relevant to all stakeholders

Algorithms to transform knowledge into better medicine outcomes

Highlighting HARMONY Projects where Big Data in Hematology accelerates research to improve outcomes for patients with HM.

- ALL: Anthony Moorman, Newcastle University, United Kingdom
- AML: Lars Bullinger, Charité University Medicine, Germany
- CLL: Lesley-Ann Sutton, ERIC
- MDS: Pierre Fenaux, AP-HP, France
- MM: Allessandra Larocca, Università di Torino, Italy
- NHL: Natacha Bolaños, Lymphoma Coallition
- EFPIA: Bruno Costa, Celgene, Switzerland

HARMONY

Research Project ALL

Use of Big Data to improve outcomes for patients with Acute Lymphoblastic Leukemia

Anthony Moorman

Newcastle University,

HARMONY Partner

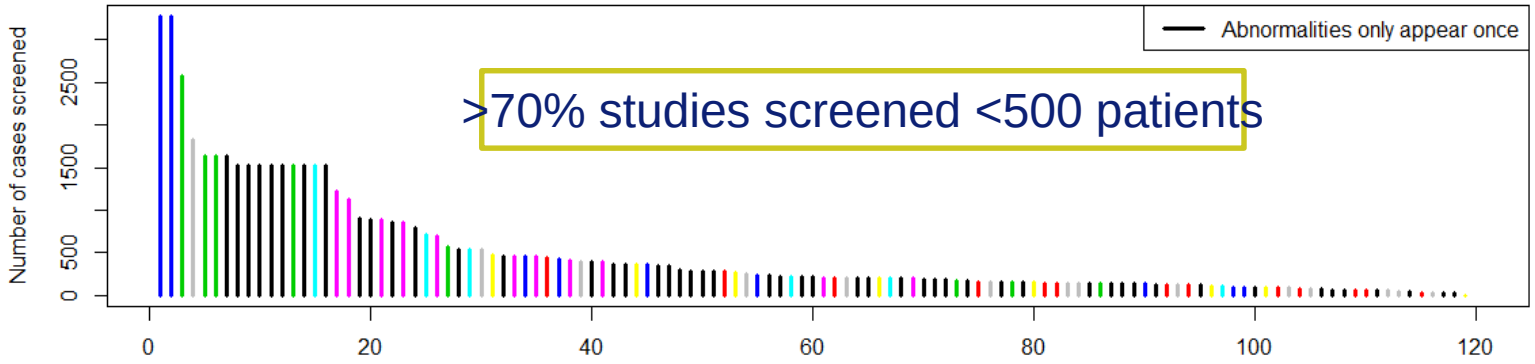
EHA24, 15 June 2019, Amsterdam, NL

imi innovative medicines initiative

efpia

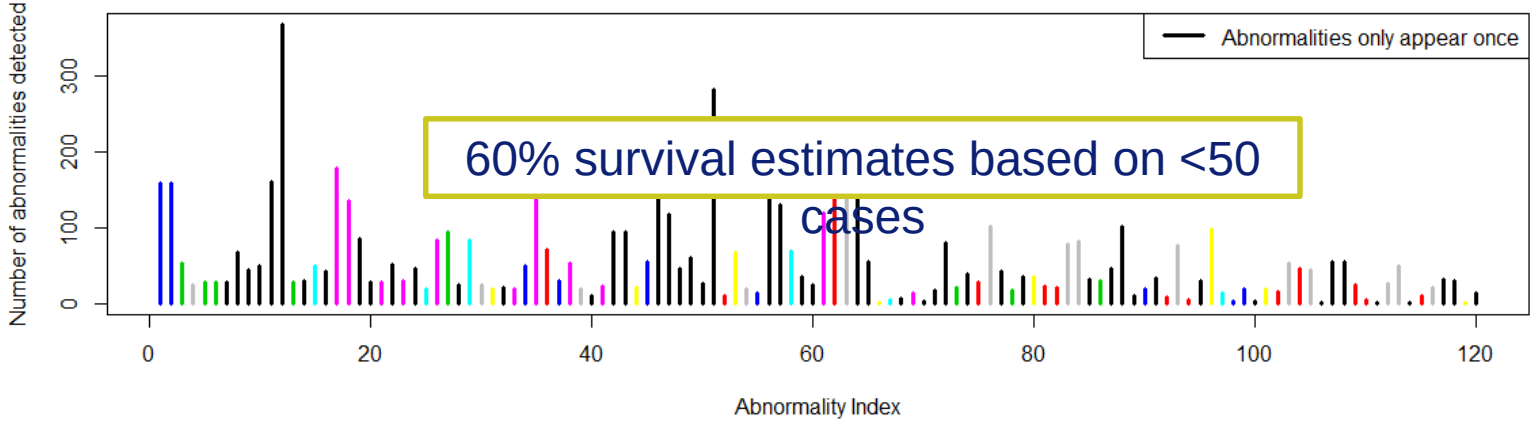
The Challenge (1) – Robust biomarker analysis

Review of >100 published studies (2000-2016) on ALL genetic biomarkers from European-based groups



>70% studies screened <500 patients

Most genetic abnormalities are present in <15% patients



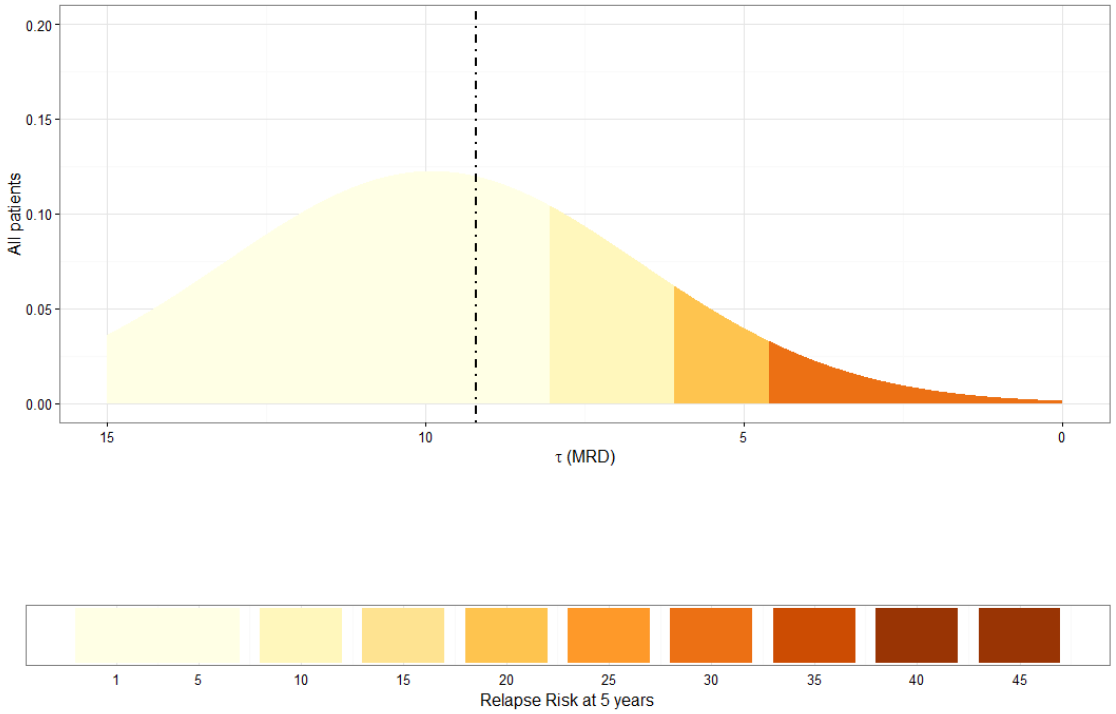
60% survival estimates based on <50 cases

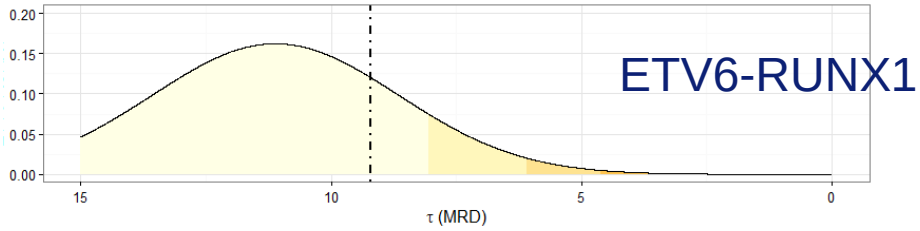
The Challenge (2) – Integrate risk factors

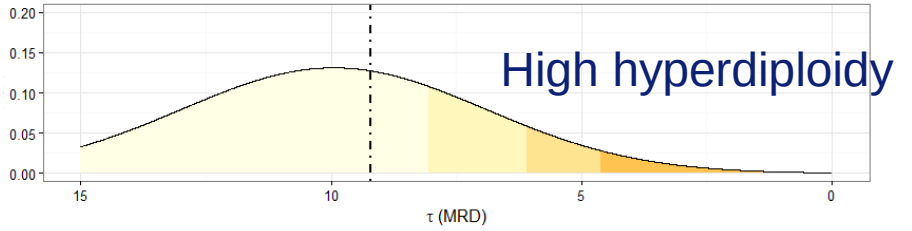
Relapse risk associated with a specific MRD value varies by genetics

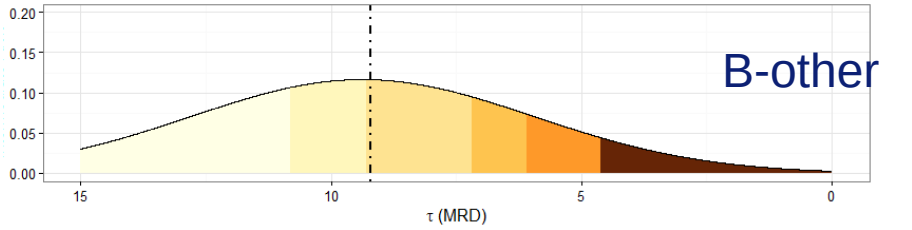
All cases

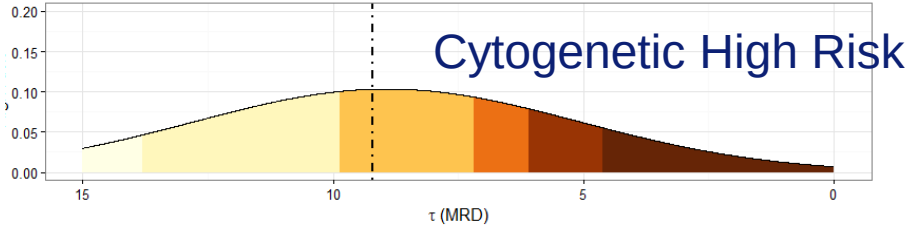
0.01%

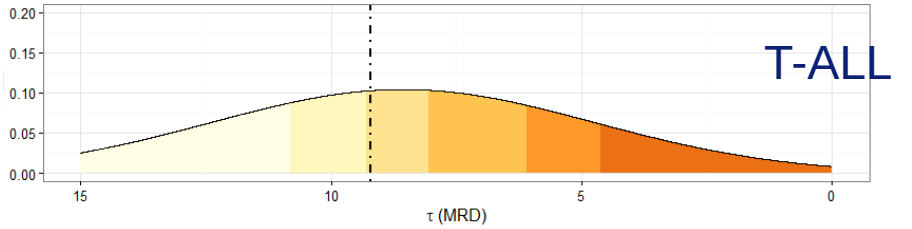








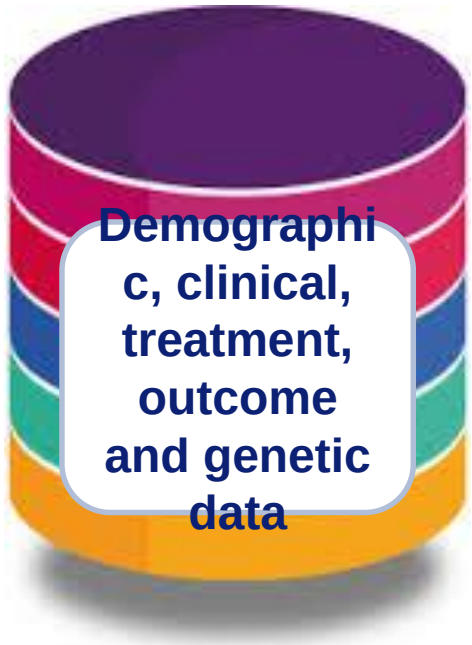




J Clin Oncol. 2018 Jan 1;36(1):34-43

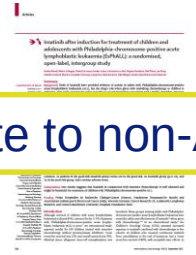
The Approach - European knowledge bank

Pool published datasets for secondary analyses



Feed in new datasets when published

Extend core dataset with multi-omic data, toxicity data, QoL, second cancers, etc.



Contribute to non-ALL studies

High quality and in-depth analysis of risk factors

Impact HARMONY Research Project ALL

- Identify robust biomarkers to improve management of patients with ALL
- Design efficient risk stratification algorithms which will assign patients to optimal treatment groups
- Facilitate the use of targeted therapy
- Contribute to novel biological insights

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Research Project AML

Use of Big Data to revise treatment strategies in Acute Myeloid Leukemia

Lars Bullinger
Charité

EHA24, 15 June 2019, Amsterdam, NL

imi innovative medicines initiative
efpia

HARMONY

Evaluate gene–gene interactions in patients with AML, which may influence treatment outcomes. Develop a proof-of-concept study to establish the legal and ethical framework.

Project Partnership

- **VU University Medical Center Amsterdam**
- **University of Ulm**
- **Novartis**
- **Klinikum der Universität München**

Challenge

- Need for a large number of patients to be recruited in order to fully understand the heterogeneous nature of AML and the potential of gene–gene interactions and their clinical impact.

Approach

- CWG data sets:
  - AMLSG (~1500)
  - HOVON (~700)
  - AMLCG (~600)
  - …
- EFPIA data sets:
  - Novartis (~600)
  - …

⇒ >8000 cases in 2019

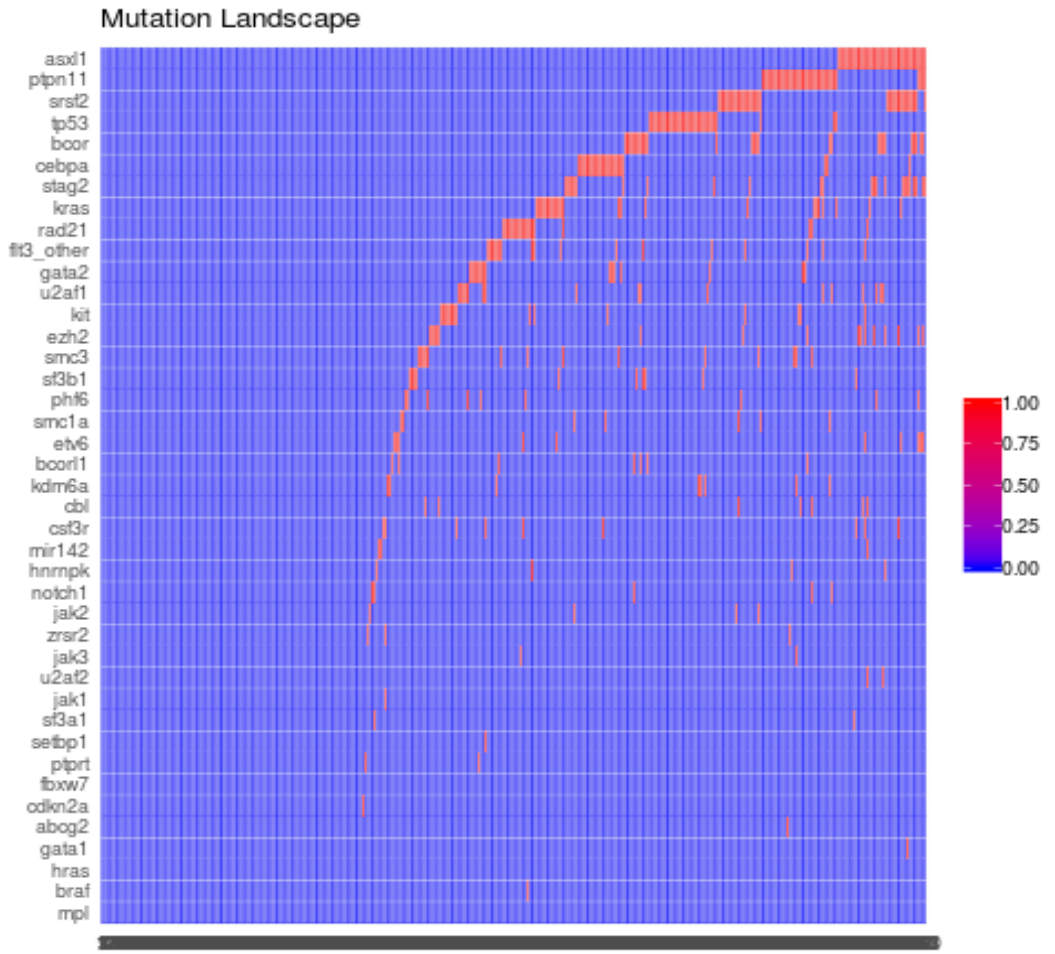
Results

Classical Tools

Number of patients	3000
Variables	patient_id, date_diagnosis, age_at_diagnosis, os_days, os_months, os_status, efs_days, efs_months, efs_status, relapse_occurrence, rfs, rfs_status
48 genes: mutation status	asxl1, idh1, idh2, wt1, tp53, runx1, sf3b1, jak2, dnmt3a, tet2, ptkn11, srsf2, ptpn11, stag2, bcor, cebpa, kras, flt3_other, rad21, ezh2, gata2, smc1a, smc3, bcorl1, kit, u2af1, phf6, cbl, etv6, csf3r, kdm6a, mir142, hnrnpk, zrsr2, notch1, setbp1, jak3, sf3a1, jak1, braf, abcg2, cdkn2a, u2af2, fbxw7, hras, ptprt, gata1, mpl

	Female	Male
Sex	1526	1474

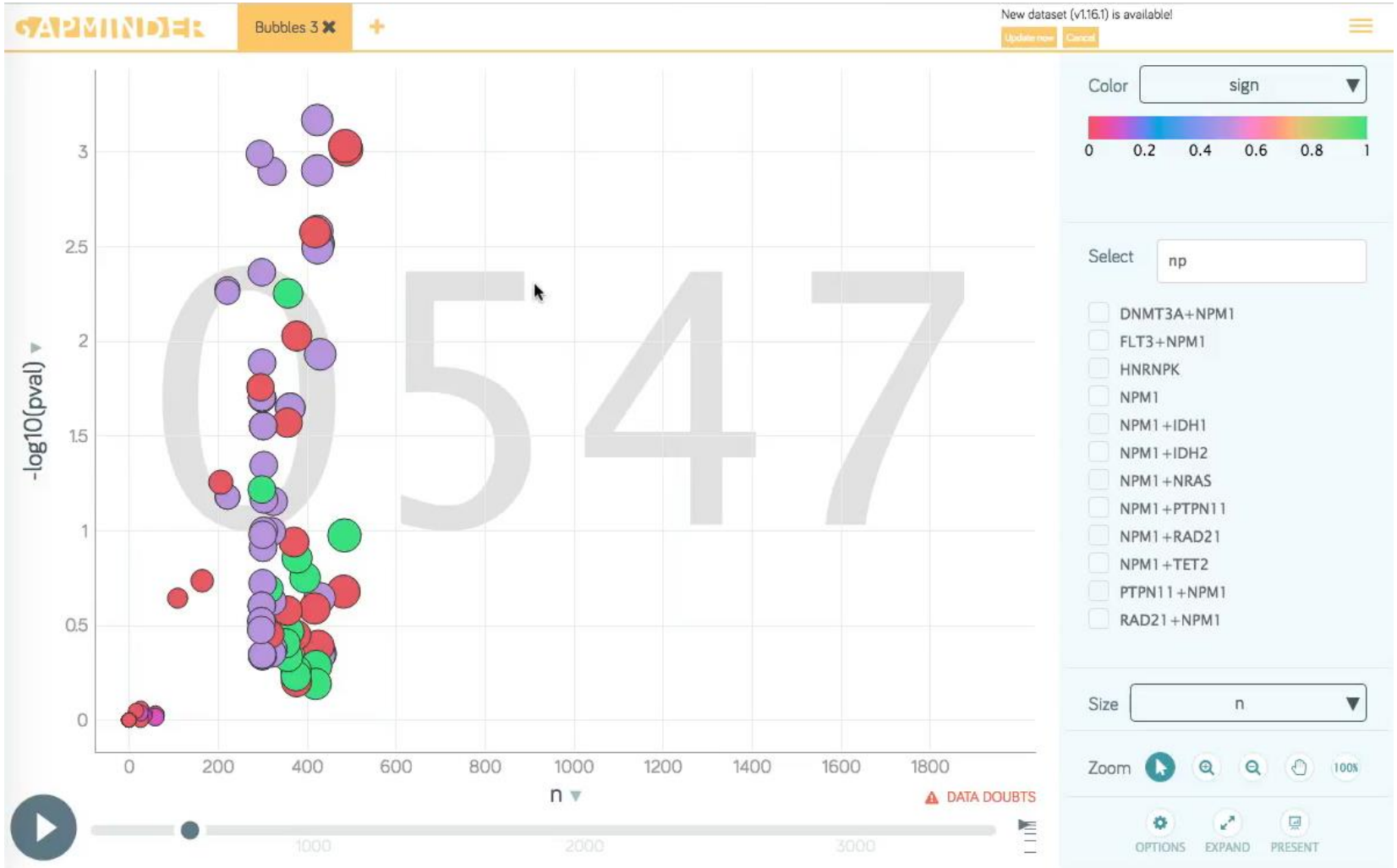
	min	median	max
Age at diagnosis	18.0	52.0	91.4
Overall survival	1.0	773.5	55005.5
Event free survival	1.0	292.0	55005.5



Bullinger et al. PS1003 (Saturday, June 15th 17:30-19:00)

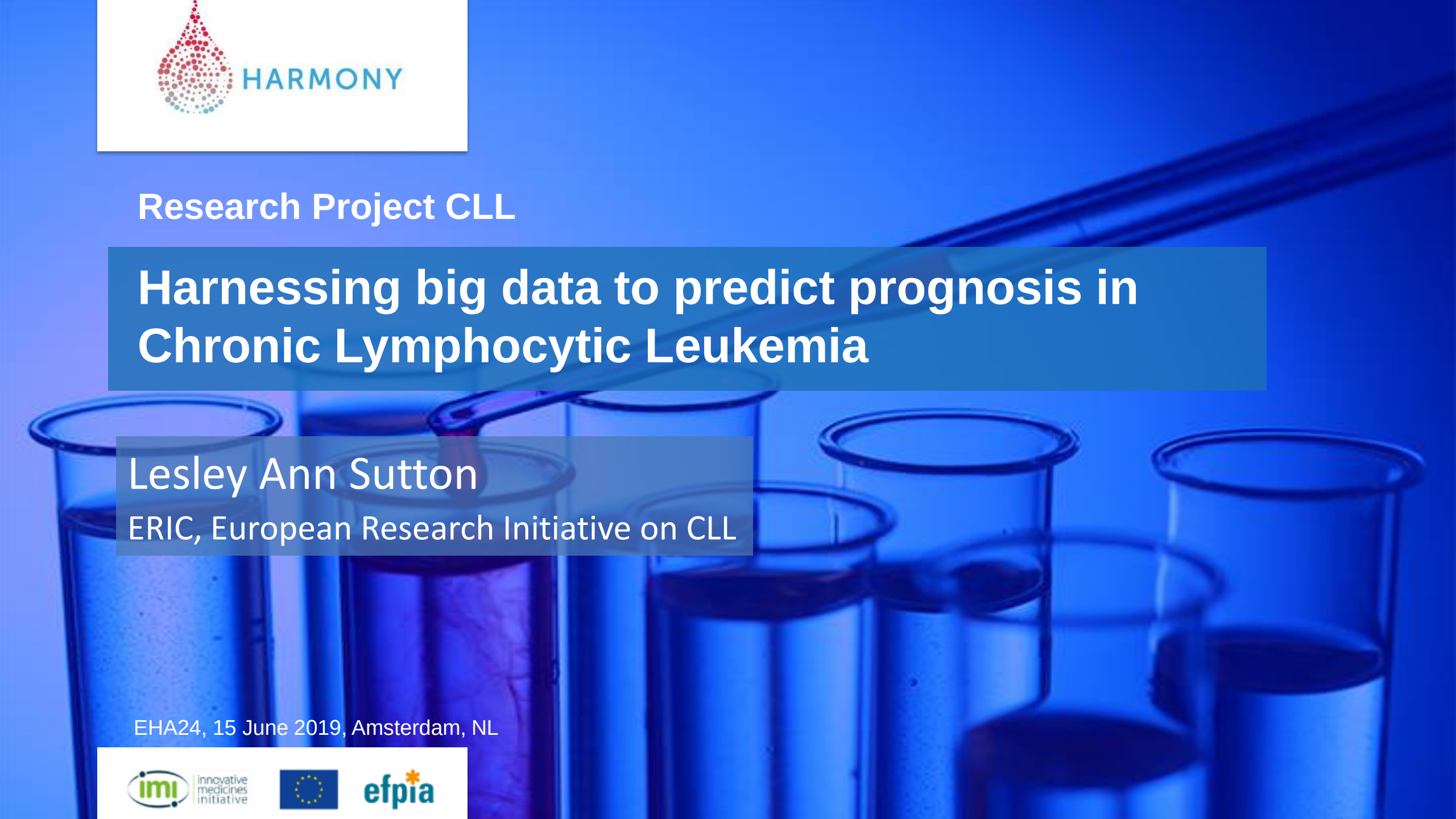
Results

Interactive Tools



Impact HARMONY Research Project AML

- Contribute to novel biological insights
- Facilitate personally tailored management
- Better guide hematopoietic cell transplants in AML and improve overall survival rates
- Form the basis for a HARMONY knowledge bank that facilitates personally tailored therapeutic decisions



HARMONY

Research Project CLL

Harnessing big data to predict prognosis in Chronic Lymphocytic Leukemia

Lesley Ann Sutton

ERIC, European Research Initiative on CLL

EHA24, 15 June 2019, Amsterdam, NL

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HARMONY

Evaluate 11 of the most frequently mutated genes in CLL and assess their prognostic and clinical relevance.

Project Partnership

- **CZ_CEITEC Masaryk University; DE_MLL GmbHDK_Rigshospitalet; ES_Vall d'Hebron Institut de Recerca (VHIR); ES_Hospital del Mar, Barcelona; ES_Centro de Investigación del Cáncer de Salamanca; IT_Azienda Ospedaliero Universitaria di Ferrara; IT_University of Eastern Piedmont and Oncology Institute of Southern Switzerland; Hospital 12 de Octubre; NI_Belfast Trust- QUB; GR_Institute of Applied Biosciences-CERTH; University of Southampton; SE_Karolinska Institute; UK_Royal Bournemouth Hospital.**

27 Institutes – 12 countries

Challenge

- Recurrent mutations have been reported in CLL but their frequency in an unselected cohort are low (< 10%)
- Large patient cohorts are needed to pinpoint the role of genetic mutations in CLL pathobiology, in particular the impact on disease progression and prognosis.

Approach

- Through ERIC, initiation of a multicenter study with the aim to generate data from > 4000 CLL patients
- Strict criteria set for patient inclusion: molecular and clinical parameters
- Samples tested must be diagnostic or pre-treatment

Impact HARMONY Research Project CLL

- Determine the ***mutational status*** of several ***prognostic genes*** in a large and well-annotated CLL cohort, in fact the largest series of CLL cases studied to date
- Assess the ***prognostic impact*** and ***clinical relevance*** **of** ***recurrent gene mutations***.
- Identify ***distinct patterns of associations*** between ***recurrent mutations*** with other ***clinicobiological features*** in CLL
- Improve existing ***prognostication models*** with the ***inclusion of key gene mutations*** able to guide clinical decision-making

HARMONY

Research Project MDS

Prognostic factors to hypomethylating agents and intensive chemotherapy in higher risk Myelodysplastic Syndromes

Pierre Fenaux AP-HP
Valeria Santini – Univ of Firenze
Andrea Kuendgen – Univ of Dusseldorf

EHA24, 15 June 2019, Amsterdam, NL

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Identify prognostic factors to assist in identifying patients with myelodysplastic syndromes who will respond to treatment with hypomethylating agents and intensive chemotherapy

HARMONY

Project Partnership

— **Centro de Investigación del Cáncer de Salamanca (FICUS); Hôpital St Louis, Paris and French GFM; Firenze University Hospital and Italian FISM; Salamanca University hospitals and Spanish GESMD; Karolinska Institute and Nordic MDS group; Leipzig and Dusseldorf Heinrich Heine University hospitals and German MDS group; University Clinic Salzburg and Austrian MDS group; Kings College, Oxford; University Hospital and the UK MDS forum; Celgene and Janssen.**

Challenge

- Not all patients with Myelodysplastic Syndromes (MDS) respond to treatment with hypomethylating agents and intensive chemotherapy

- Lack of validated prognostic markers to facilitate the accurate prediction of patient outcomes

Approach

Study population

- Higher risk MDS (IPSS) and CMML treated with an HMA:
  - AZA or DAC
  - Alone or with other drugs
  - Followed or not by allo SCT

- Patients receiving intensive chemotherapy)

Impact HARMONY Research Project MDS

Scientific questions

1) Prognostic value of:

- Reaching various types of response (hematological, cytogenetic, molecular)
- Specific cytogenetic abnormalities (isolated -7, +8)
- Specific mutations (TP53)
- Treatment duration
- prophylactic antibiotics / antifungals/ G-CSF

2) Subgroup description:

- Elderly patients
- CMML
- patients with prolonged response

3) Candidates for transplant (how many cycles of HMA before transplant ? comparison with chemotherapy pre transplant)

Impact HARMONY Research Project MDS

— Patient population identified

Participating groups

- **S**: Karolinska (170)
- **E**: Salamanca (250), GESMD (500)
- **UK**: Oxford (30) King's college (300) Leeds (90)
- **D**: Dusseldorf (130) Dresden(200)
- **I:** FISM (480)
- **A**: Austria (450)
- **F**: GFM (1100) Nice(350)
- Company sponsored trials

→ **About 1500 cases with molecular data**

Coordinating team

P Fenaux, V Santini, A Kuendgen, G Sanz, M Diez Campelo, R Itzykson, L Adès
A Vasconcelos, M Doyle

HARMONY

Research Project MM

Optimizing prognostication and personalizing treatment in Multiple Myeloma

Alessandra Larocca
Mario Boccadoro
Università di Torino , Italy

EHA24, 15 June 2019, Amsterdam, NL

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HARMONY MM pilot project

Revised International Staging System for Multiple Myeloma: extended follow-up in the European clinical trial population and evaluation of the efficacy of different novel agents and treatment approaches in subsets of patients with standard- and high-risk features

Project Partnership

— **European Myeloma Network (EMN), uniting: Programa Español de Tratamientos en Hematología (PETHEMA); Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON); Gruppo Italiano Malattie EMatologiche dell'Adulto (GIMEMA); Università di Torino (UNITO); Università di Bologna (UNIBO); Intergroupe Francophone du Myelome (IFM); German-Speaking Myeloma Multicenter Group (GMMG); Nordic Myeloma Study Group (NMSG); Celgene; Takeda; Janssen.**

Challenge

- The clinical outcome for patients with Multiple Myeloma (MM) is heterogeneous with wide-ranging survival times.

- The **Revised-International Staging System** (LDH, Chromosomal Abnormalities and ISS) identify NDMM patients with different prognosis and survival, however, this has only partly guided therapeutic choices

(Palumbo A. et al J Clin Oncol 2015, 33(26):2863-9)

Approach

- Provide an extended follow-up of the original trials included in the R-ISS project, **adding other relevant datasets with mature data of NDMM patients treated with novel agents**
- Identify suitable datasets: **15 academic clinical trials enrolling NDMM** treated with novel agents (**European Cooperative groups**)
- Data from large completed **Phase III studies from EFPIA partners** will be extremely relevant (VISTA, FIRST trials….)
- **Define variables to be collected and harmonize data**

R-ISS: Revised International staging system, NDMM: newly diagnosed multiple myeloma

Data workflow: MM Pilot Study

Other Cooperative Groups

EMN

EFPIA

HARMONY

Data received and harmonized

- EMN01: MPR vs CPR vs Rd induction followed by R vs Rp maint in NTE MM patients
- GIMEMA-MM-03-05: VMPT followed by VT maint vs VMP in NTE MM patients
- IST-CAR-506: KCd continuous in NTE MM patients
- MMY2069: VCp vs VP vs VMP induction followed by V maint in NTE MM patients
- PAD-Mel100: Pad induction + Mel100/ASCT + Rp consolidation + R maint in TE MM patients
- RV-MM-PI-209: Rd induction + MPR vs HDM/ASCT consolidation + R vs no maint in TE MM patients
- RV-MM-EMN-441: Rd induction + CRd vs HDM/ASCT consolidation + R vs Rp maint in TE MM patients
- HOVON 65MM/GMMGHD4: VAD vs PAD induction + HDM/ASCT + T maint if VAD arm or V maint in PAD arm in TE MM patients
- HOVON 87/NSMG18: MPT induction followed by T maint vs MPR induction followed by T maint in NTE MM patients
- GEM05MENO65 : VBMCP/VBAD/B vs Td vs VTd induction + HDM/ASCT + IFNα2b vs T vs VT maint in TE MM patients
- GEM05MAS65: VMp vs VTp induction + Vp vs VT maint in NTE MM patients
- GEM2010MAS65: VMP-Rd sequential vs VMP-Rd alternating in NTE MM patients
- MM-BO2005: VTd vs Td induction + HDM/ASCT + consolidation with same induction arm + Dex maint in TE MM patients

5089 patients from Academic Partners received by EMN | Transplant eligible patients 2578 | Transplant ineligible patients 2511 | Median Follow-up 77 months | (Revised-ISS JCO 2015 median follow-up 46 mo)

Next steps

- HARMONY fully approved the **pilot project**
- **EMN is officially an Associated Member** in Harmony project.
- **EMN as an intermediate depository** between Cooperative Working Groups and Harmony for data collection and reimbursement distribution.
- **Timeline**: data on Harmony platform in June/July 2019, first abstract by summer 2019 for ASH
- After the pilot project → **big data**, not only big database (toxicity data, real-life registry data, minimal residual disease data, molecular data, omics….)
- **Proposal of new projects within Harmony umbrella involving Cooperative Groups and including new datasets and adding new data**

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UNIBO
GIMEMA

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HOVON
NMSG

EMN

European
Cooperative Groups

HARMONY

Research Project NHL

Using big data to optimize outcomes in T-cell Non-Hodgkin Lymphomas

Natacha Bolaños
Lymphoma Coallition

EHA24, 15 June 2019, Amsterdam, NL

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Better understand the molecular basis of T-cell lymphomas, leading to improved diagnosis and prognosis prediction, better disease sub classification and improved knowledge to guide treatment decisions

Project Partnership

- **Data registries Austria, Denmark, France, Germany, Italy, the Netherlands, the Nordic countries, Poland, Portugal, Serbia, Spain, Sweden, Turkey and the UK**
- **Active engagement with the pharmaceutical industry**

Challenge

- Complex molecular pathogenesis of T-cell non-Hodgkin lymphomas
- Rare disease
- Paucity of data
- Large patient cohorts needed

Approach

- Capture large datasets derived from registries (RW) and clinical trials
- Explore the underlying molecular and genetic drivers of T-cell lymphomas
- To establish and validate precision diagnostic and prognostic markers
- Potentially revealing novel drug targets

Impact HARMONY Research Project NHL

- Providing novel biological insights into T-cell lymphomas
- Help to steer and direct clinical treatment decisions
- Personally tailored disease management and novel therapeutic targets.
- The ultimate aim of the project is to build an EU registry holding data on all T-cell lymphomas in order to advance and accelerate understanding and disease management moving forward.

Stronger Together: Research based Pharmaceutical companies in HARMONY

Bruno Costa

Celgene, Representing the HARMONY EFPIA Partners

EHA24, 15 June 2019, Amsterdam, NL

Partnership (From Wikipedia, the free encyclopedia)

A **partnership** is an arrangement where parties, known as partners, agree to cooperate to advance their mutual interests

HARMONY WP6: The Stakeholders' Forum

Academic institutions

Patient Organisations

Regulatory & HTA Agencies

HARMONY from an Industry representative perspective

— **Why EFPIA Industries are part of the HARMONY**

- Possibility to work on a common project with top experts and relevant stakeholders in the field (payers, patients' organizations and Regulatory bodies)
- Chance to submit research questions
- Mutual trust and mutual interest
- Image and reputation

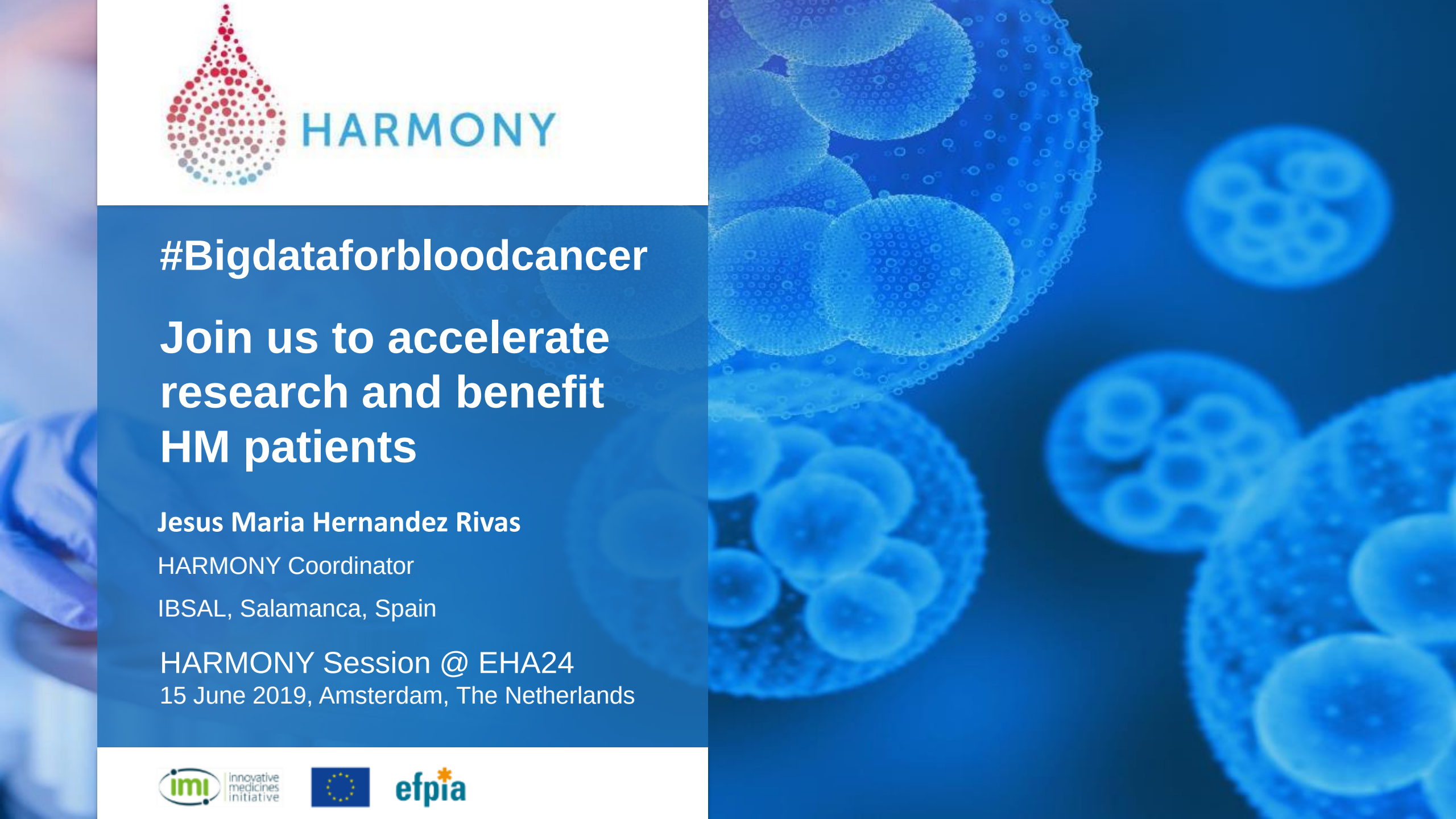
— **What EFPIA Industries bring to HARMONY**

- Data from large company-sponsored trials, registration quality, data on up to date standards of care
- Technical expertise (clinical data and Core Outcome Sets, methodological skills)

HARMONY from an Industry representative perspective

— **What are the challenges**

- **Global organizations are in continuous evolution**
- **Data privacy and internal processes internal regulations**
- **IP potential concerns, mitigation of litigation risks**
- **Lengthy Internal review processes for data transfer**



HARMONY

#Bigdataforbloodcancer

Join us to accelerate research and benefit HM patients

Jesus Maria Hernandez Rivas

HARMONY Coordinator

IBSAL, Salamanca, Spain

HARMONY Session @ EHA24

15 June 2019, Amsterdam, The Netherlands

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The HARMONY Network continues expanding

23 European institutions have already signed the agreement for sharing data with HARMONY

HARMONY DATA READY FOR ANALYSIS

HARMONY

AML	5 organisations	5 countries	~3 500 cases
CLL	27 organisations	12 countries	~ 5 000 cases
MM	11 organisations	10 countries	~ 5 000 cases

HARMONY

Contribute with your data and become part of our analytics teams

26th – 27th September, 2019
Florence, Italy

Join us at our 4th General Assembly

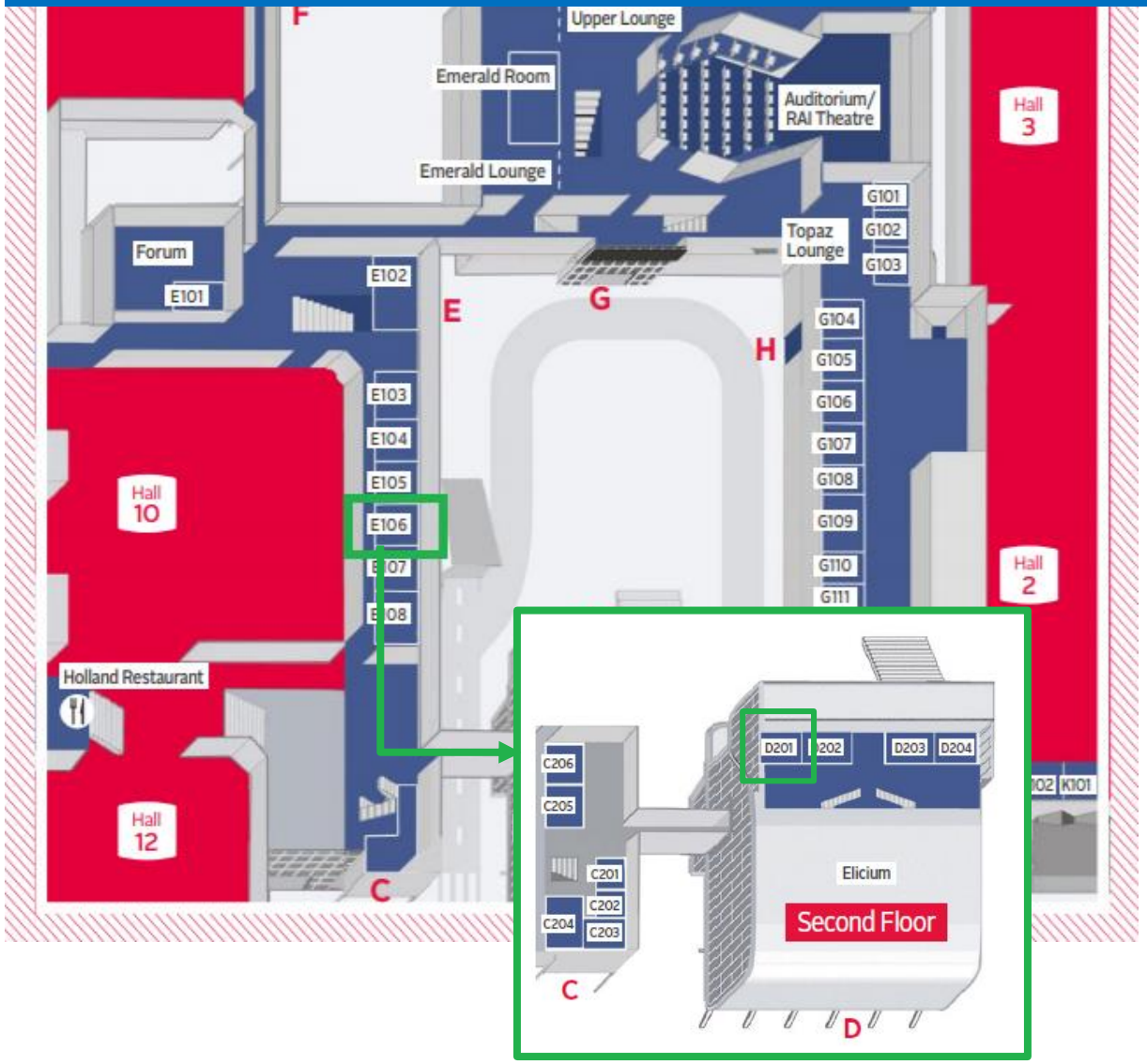
- Get involved in our ongoing research proposals, become a data provider!
- Be part of the **research-a-thon** sessions, where we will define the next wave of HARMONY Research projects!
- Registration is already open!

December 7-10, 2019
Orange County Convention Center Orlando, FL

HARMONY @ 61st ASH Congress

AML, CLL, and MM projects analysis are expected to be finished in the second half of 2019

Join us!



HARMONY Partnering meeting
15 June 2019, 16:15 - 17:15 hrs.
Hall D201

UPSTAIRS!
2nd Floor

Funded by

HARMONY

Thank You
Join us!

www.harmony-alliance.eu

@harmonyNet | #bigdataforbloodcancer

HARMONY Alliance | European Network of Excellence for Big Data in Hematology

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Acknowledgement

- HARMONY Alliance is funded through the Innovative Medicines Initiative (IMI), Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. HARMONY has received funding from IMI 2 Joint Undertaking and is listed under grant agreement No. 116026.
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- Read more at: www.imi.europa.eu