

European Affairs at EHA2023

- overview

Update: May 26, 2023

Towards a cure for all blood disorders

European Affairs at EHA2023

Sessions (Frankfurt)

- EHA-Patient Joint Symposium Sessions I + II

 Combined with Guidelines session: PRO in clinical trials
- EHA-HARMONY: Big Data in Hematology

Sessions (virtual)

- EHA-EMA Joint Symposium
- IVDR Session
- European Projects in Hematology Session

Spotlight Talks (Frankfurt/on-demand)

- Health data (Ananda Plate)
- Reducing Bureaucracy in Clinical Trials (Martin Dreyling)

Collaboration Plaza (Frankfurt)

- Patient Advocacy Hub
- European projects & networks

Meetings (Frankfurt)

- EuroBloodNet network meeting*
- Community Leadership Dinner** HTA & Value session
- AGM panel on hematologists in regulatory affairs
 - * ERN members only
 - ** Invitees only



EHA-Patient Joint Symposium

Session I: Novel clinical trials in hematology – the comparator challenge and the need for new formats

Friday June 9, 08:00-09:30

Room: Illusion (Messe Frankfurt)

"How do we design clinical trials that meet patient, clinical and regulatory needs given that innovation in clinical development is making RCTs in hematology increasingly difficult?"

- Jan Geissler patient / co-chair
- Martin Kaiser hematologist / co-chair
- Francesco Pignatti, EMA regulator
- Michelle Boyer, Roche/EFPIA industry
- Camille Thomassin, HAS HTA



EHA-Patient Joint Symposium

Session II: From approval to access – integrating patient preferences into clinical, HTA and payer decisions

Friday June 9, 10:00-11:15

Room: Illusion (Messe Frankfurt)

"How do we integrate patient-reported outcomes and patient preferences into treatment optimization and access decision making?"

- Zack Pemberton-Whiteley patient perspective: malignancies / co-chair
- Marie-José Kersten hematologist / co-chair
- Camille Thomassin, HAS HTA
- Conny Berlin, Novartis + IMI-PREFER industry
- Eda Omür patient perspective: Sickle Cell Disease



Integral programming: EHA-Patient & Guidelines sessions

Guidelines Session: PROs in clinical trials in multiple myeloma

Friday June 9, 09:30-10:00

Room: Illusion (Messe Frankfurt)

- Sam Salek, co-chair
- Kate Morgan, co-chair
- Edward Laane
- Esther Oliva





EHA-HARMONY Alliance Session

Big Data in Hematology: The impact of Real-World Data and Real-World Evidence on research and clinical care now and in the future

Sunday June 11, 09:45-10:45

Room: Hall 3.2 (Messe Frankfurt)

- Introductions Ignacio Quiles, EHA; Jesús Maria Hernández Rivas, IBSAL; Guillermo Sanz, La Fe Health Institute
- The power of big data to improve treatment of HMs Amin Turki, UK Essen (ALL); Marta Sobas,
 Medical University of Wroclaw (AML); Andreas Hochhaus, FSU Jena (CML)
- Data analysis in regulatory assessments Kelly Plueschke, EMA
- RWD/RWE driven research in hematology Kimmo Porkka, University of Helsinki; Natacha Bolaños,
 Lymphoma Coalition; Farzad Ali, Pfizer



European Projects in Hematology Session

European Projects with participation/support EHA

Wednesday June 14, 15:45-16:45 Virtual Room 2

Presenters:

- **ASCERTAIN** Carin Uyl-de Groot
- **SUPPLY** Petar Kos
- GoCART Jürgen Kuball
- **T2EVOLVE** Michael Hudecek
- TOLERATE Karen Vanhoorelbeke



EHA-EMA Joint Symposium

Regulators, clinicians and data

Thursday June 15, 11:00-12:30 Virtual Room 1

- Meet the regulator Pierre Demolis (presentation on how EMA works)
- Multi-stakeholder panel on data generation for regulatory purposes
 - Regulators: Pierre Demolis, Edward Laane (co-chairs)
 - Hematologists with regulatory experience: Ole Weis Bjerrum, Julio Delgado
 - Patient advocate with regulatory experience: Loris Brunetta
 - HTA: Anja Schiel
 - Industry: Ian Thomson



IVDR Session

What can we do to protect innovative diagnostics in the face of IVDR?

Thursday June 15, 13:15-14:15 Virtual Room 2

- Brief introduction by Bart Lubbers (NL)
- Regulatory Scientist: Alan Fraser (UK)
- The approach taken for Orphan diagnostics and rare diseases: Els Dequeker (BE)
- Hematology Researcher: Francesco Buccisano (IT)
- National authority: Ortwin Schulte (DE)



Spotlight Talks

Stand-alone lectures offering a preview of the 'hematology of tomorrow'

15-18 minutes each

Recorded in front of a small live audience in Frankfurt Available as on-demand content on the congress platform

Two European Affairs talks:

- Health Data
 - Ananda Plate (EHA PAC)
- Reducing Bureaucracy in Clinical Trials
 - Martin Dreyling (EHA / Coalition for RBinCTs)



EHA Collaboration Plaza

The 'home' for EHA's not-for-profit partners at the heart of the Exhibition (patients, projects, scientific networks)



- Patient Advocacy Hub (14 PAC organizations)
- MSCA Carreras Leaders
 & InnoCAR-T
- HNHCP
- SUPPLY
- HARMONY
- ERN-EuroBloodNet
- T2EVOLVE & GoCART
- EuNet-INNOCHRON
- EGALITE
- ESLHO



EuroBloodNet network meeting

Network meeting for ERN-EuroBloodNet members (105 centers) hosted by EHA

Thursday June 8, 14:00-17:00

Hall: Fantasie Invitation-only

'The Role of ERN-EuroBloodNet and ENROL Registry in Advancing Translational and Clinical Research in Hematology'

Session 1: Improving access to diagnosis and treatments (chair: Pierre Fenaux)

Session 2: ENROL Registry and endorsed initiatives (chair: **Béatrice Gulbis**)

Session 3: Artificial Intelligence (AI) based models in hematology: Genomed4all and Synthema (chair: Mar

Mañu Pereira)

Panelists include **Matteo Della Porta**, EuroBloodNet lead research & registries (oncological), and **Federico Alvarez**, coordinator Genomed/Synthema



EHA Community Leadership Dinner

Panel session 'HTA and value assessment of new drugs'

Thursday June 8, 19:00-22:00 Frankfurt Marriott Hotel EHA Board + invitees

Panel (19:40-20:40):

- Bernhard Wörmann, German Society of Hemato-Oncology (DGHO)
- Robin Doeswijk, EHA
- Antje Behring, G-BA
- Anne-Pierre Pickaert, ALAN / MPE
- Daniel Coriu, Romanian Society of Hematology
- John Gribben, EHA European Affairs Committee



Annual General Meeting (AGM)

Incl. panel/Q&A: 'Why a dose of regulatory affairs is good for you (and all of us)'

Friday June 9, 13:30-14:30

Hall: Panorama 1

What is EHA's role in regulatory affairs and why should hematologists get involved?

Panel (13:05-13:30):

- Ulrich Jäger, EHA Past President and chair European Affairs Committee (2010-2019)
- Elizabeth Macintyre, EHA President / co-chair European Affairs Committee
- Robin Doeswijk, Head of European Affairs

