



EuroVulcan 2 | 18th January 2024
Royal Olympic Hotel, Athens

HL7 Working Group Meeting
EUROPE

HL7 FHIR
MARATHON



EuroVulcan 2

European Meeting of the Vulcan Accelerator

Connecting clinical care and clinical research through HL7 FHIR

Athens, Thursday January 18, 2024, Royal Olympic Hotel

Theme: Regulatory policy development and Agile HL7 FHIR Implementation in Europe and worldwide

Following the successful inaugural EuroVulcan Conference & Connectathon in Paris March 15-16, 2023, the next EuroVulcan event will take place in Athens on January 18, 2024. This event will coincide with the 1st HL7 Europe Working Group meeting, which will be hosted by HL7 Hellas from January 15 to 19, 2024 as part of the Athens Digital Health Week.

EuroVulcan 2 will be a full-day event attended by invitation. It will feature outstanding speakers from Europe and beyond from leading organizations in clinical and translational research. The outcomes of the meeting will influence strategic priorities and plans for Vulcan and the research community at large.

Preliminary Program

9:00-10:30 Opening Session - Welcome to Athens and EuroVulcan 2 Conference

- Catherine Chronaki, HL7 Europe
- Amy Cramer, co-Chair Vulcan
- Representative*, National Organization for Medicines, Greece
- Panagiotis Telonis, Chief Information Office, European Medicines Agency

Session Chair: Amy Cramer, co-Chair Vulcan

1. Opening Welcome & Vulcan Background: *Amy Cramer, Vulcan co-Chair*
2. Implications of EU Data Protection regulation for Vulcan: *Sabine Brosch (online), Data Protection Officer, European Medicines Agency*
3. Collaboration among EU-funded projects on data-driven approaches in cancer – towards data interoperability, *Bianca Baluta (online), European Commission*
4. Data Standardization Strategy of the EMA: *Panagiotis Telonis, European Medicines Agency*

10:30-11:00 Morning Break

11:00-12:30 Panel #1: Vulcan ePI/eLabeling Project and EMA/SPOR: The way forward

Session Chair Anne Moen, University of Oslo and Gravitare-Health

Panelists and topics to be addressed:

1. SPOR the way forward: *Isabel Chicharo, SPOR lead, European Medicines Agency*
2. ePI Pilot Project: *Elisabeth Scanlan, ePI pilot, European Medicines Agency*
3. GIDWG, PhPID operating model: *Magnus Wallberg, WHO-UMC, Sweden*
4. Gravitare-Health “4+1 Compendia ePI Pilot”: *Bente By Jansen, Felleskatalogen, Norway*
5. <title to be confirmed>: *Christer Backman, Swedish Medicines Agency, Farah Fahim, Empirica*
6. EU policy perspective: *George Georgianakis, European Commission*
7. < title to be confirmed > *Kate Porch, IATF*

12:30-13:45 Working Lunch Sessions

Tables will be set up with an assigned moderator and scribe. Current topics include:

- What European projects should Vulcan be involved with / help?
- How can Vulcan support patient opt-in to clinical trials?
- How Vulcan can engage the academic research community?
- How Vulcan can engage the industry and CRO community?

13:45-15:15 Panel #2: Vulcan Utilizing the Digital Protocol / UDP Project (was ICH M11):

Focus: Mission, Plans, Key Challenges, European Involvement

Session Chair: Panagiotis Telonis, European Medicines Agency

Panelists and topics to be addressed:

1. M11 History: *Rebecca Kush, Vulcan Advisory Council co-Chair*
2. M11 in US / Decentralized Clinical Trials in US: *Ron Fitzmartin (online), Sr. Informatics Advisor, ICH M11 Rapporteur, CBER (FDA)*
3. The perspective of CROs in Europe: *Yoanni Matsakis, EUCROF*
4. The perspective of Academic Centers: *Meletis Dimopoulos, National and Kapodistrian University of Athens*
5. Capacity building for decentralized medical trials: *Christos Lionis, University of Crete*
6. Pharma perspective: *Rob DiCicco, TranCelerate BioPharma*
7. European Shortages Monitoring Platform: *Officer from European Medicines Agency on-site and Sofia Zastavnik (online), Medicines and Medical Devices Shortages Specialist, European Medicines Agency*

15:15-15:45 Afternoon Break

15:45-17:15 Panel #3: Regulators Moving to FHIR with support from the Vulcan Accelerator

Session Chair: Hugh Glover, Technical Director Vulcan

Panelists and topics to be addressed:

1. What's next in CDISC for Vulcan: *Peter Van Reusel, Chief Standards Officer CDISC*
2. What's next in HL7 FHIR for Vulcan: *Julia Skapik, Chair HL7 International*
3. What's next in US Policy for Vulcan: *Stephen Konya, ONC, United States*
4. What's next in personalized eLabeling for Vulcan: *Craig Anderson (online), coLead Vulcan ePI/eLabeling*
5. What's next in the HL7 FHIR Connectathon for the GIDWG/UNICOM/ePI track after the Athens Marathon: *Joao Almeida product owner Gravitate Health*

17:15-17:30 Closing Remarks

Amy Cramer, co-chair Vulcan