



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

HL7 Working Group Meeting

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 feature outstanding speakers from leading organizations in Europe and beyond to discuss interoperability standards in clinical and translational research. The outcomes of the meeting will influence strategic priorities and plans for Vulcan and the research community at large in Europe.

Useful Links

Registration: [EuroVulcan 2 Event Registration](#)

Digital Health Week / HL7 Europe WGM: <https://www.hl7.eu/wgm2024/index.html>

Hotel booking: <https://royalolympic.reserve-online.net/?bkcode=athens%20digital%20health%20week&checkin=2024-01-15&adults=1>

Final Program

9:00-10:30 Panel Session #1: Clinical & Translational Research Landscape in Europe

Welcome to Athens and EuroVulcan 2 Conference

- Michael van Campen, EuroVulcan 2 Planning Committee
- Amy Cramer, co-Chair Vulcan
- Panagiotis Telonis, Chief Information Office, European Medicines Agency

Session Chair: Amy Cramer, co-Chair Vulcan

1. Vulcan Background: *Amy Cramer, Vulcan co-Chair*
2. Data Standardization Strategy: *Nick Halsey (online), European Medicines Agency*
3. EU Data Protection Regulations and Implications for Vulcan: *Sabine Brosch (online), Data Protection Officer, European Medicines Agency*
4. The European Shortages Monitoring Platform (ESMP): *Sofia Zastavnik (online), ESMP Product Owner, Supply and Availability of Medicines and Devices, EMA*
5. XpanDH - Expanding Digital Health through a pan-European EHRxF-based Ecosystem: *Henrique Martins, Associate Professor, ISCTE*
6. Digital4Cancer – Landscaping data driven projects and initiatives in cancer – Towards Data Interoperability: *Bianca Baluta (online), European Commission*
7. What's next in HL7 FHIR for Vulcan: *Julia Skapik, Chair HL7 International*

10:30-11:00 Morning Break

11:00-12:30 Panel #2: Vulcan ePI/eLabeling Project, IDMP and EMA/SPOR: The Way Forward

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

Panelists and topics to be addressed:

1. ePI Pilot Project: *Elizabeth Scanlan, ePI pilot, European Medicines Agency*
2. Compendia ePI Pilot: *Bente By Jansen, Felleskatalogen AS, Norway*
3. Improving Package Leaflets: Summary of IATF Recommendations: *Kate Porch (online), Global Labeling, Johnson & Johnson*
4. PhPID operating model, GIDWG: *Magnus Wallberg, Uppsala Monitoring Centre*
5. UNICOM achievements and next steps from an NCA perspective: *Farah Diehl-Fahim, empirica, Christer Backman & Pelle Persson, Swedish Medical Products Agency*
6. Health Data and the Link to ePI: *George Georgiannakis (online), DG SANTE - European Commission*
7. SPOR the way forward: *Isabel Chicharo (online), SPOR lead, European Medicines Agency*
8. Scaling IDMP for Global use cases: *Panagiotis Telonis, European Medicines Agency*

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 #3: Vulcan Utilizing the Digital Protocol / ICH M11 CeSHarP: Focus on Mission, Plans, Key Challenges, European Involvement

Session Chair: Panagiotis Telonis, European Medicines Agency

Panelists and topics to be addressed:

1. History of Clinical Research Protocol Standardization: *Rebecca Kush, Vulcan Advisory Council co-Chair*
2. ICH M11 Clinical Protocol Template and Exchange Standard: *Ron Fitzmartin (online), PhD, MBA, ICH M11 Rapporteur, U.S. FDA*
3. The perspective of CROs in Europe: *Yoani Matsakis, EUCROF*
4. The perspective of Academic Centers: *Meletis Dimopoulos, National and Kapodistrian University of Athens*
5. Decentralized clinical trials (or elements in clinical trials): *Christos Lionis, University of Crete*
6. ICH M11, Digital Protocols: A Pharma Perspective: *Rob DiCicco (online), TransCelerate BioPharma*
7. The Vulcan UDP Project: *Hugh Glover, Vulcan Technical Director*

15:15-15:45 Afternoon Break

15:45-17:15 Panel #4: Regulators Moving to FHIR with support from the Vulcan Accelerator

Session Chair: Hugh Glover, Vulcan Technical Director

Panelists and topics to be addressed:

1. What's next in CDISC for Vulcan? Focus on Utilizing Digital Protocol: *Peter Van Reusel, Chief Standards Officer, CDISC*
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3. What's next in personalized eLabeling for Vulcan: *Joao Almeida presenting for Craig Anderson (online), coLead Vulcan ePI/eLabeling*
4. What's next in the HL7 FHIR Connectathon for GIDWG/UNICOM/ePI: *Joao Almeida, product owner Gravitare Health*
5. Can Clinical Care Data Replace Clinical Research Data?: *W. Ed Hammond, Ph.D., Director, Duke Center for Health Informatics, Clinical and Translational Science Institute*
6. Implications for Joint Action Xt-EHR for Primary & Secondary use of health data in the EHDS: *Christos N. Schizas, Coordinator of Xt-EHR and President of the National eHealth Authority – Cyprus*

17:15-17:30 Closing Remarks

Michael van Campen, Vulcan Program Director & Amy Cramer, co-chair Vulcan