Welcome

Hello everyone,

We're excited to see you in Paris for EuroVulcan, our inaugural in-person Conference and Connectathon in Europe! There's lots to discover, discuss and plan.

As we prepare for the event, we would like to share some key information with you to make the most of your time at EuroVulcan. The following pages describe the agenda, speakers, networking opportunities and logistics for the event.

We trust everyone will have a safe, enjoyable and engaging time at EuroVulcan.

Amy Cramer, Darren Weston, Vulcan co-Chairs

Let the World Know!

During the Conference & Connectathon we encourage you to Tweet or post on LinkedIn or whatever your favourite social media outlet is.

We want to generate as much noise about Vulcan as we can. Feel free to use the hashtag #HL7Vulcan (but not #Vulcan which is all about building supplies!).

Photography of the event inside the meeting room is encouraged, but not in other areas of the venue.

Programme at a Glance

The EuroVulcan agenda is divided into 2 tracks: **Conference** and **Connectathon** tracks. The Conference Track runs both days, whereas the Connectathon Track is Day 1 only.

	Time	Topic	Where
Day 1	8:30 – 9:30	Light Breakfast	Auditorium Area
	9:30 – 9:45	Welcome & Opening Address	Auditorium, Ground Floor
	Conference Track, Day 1		
	9:45 – 10:20	Conference Presentations	Auditorium, Ground Floor
	10:20 – 10:50	Networking Break	Auditorium Area
	10:50 – 12:20	Conference Presentations	Auditorium, Ground Floor
	12:20 – 13:20	Lunch + **Facilitated Discussions**	Istanbul & Zagreb, Floor 1
	13:20 – 14:40	Conference Presentations	Auditorium, Ground Floor
	14:40 – 15:00	Networking Break	Auditorium Area
	15:00 – 16:30	Conference Presentations	Auditorium, Ground Floor
	Connectathon Track, Day 1		
	9:45 – 16:30	Electronic Product Information (ePI)	Vision Care A1010, Floor 1
		Schedule of Activities (SoA)	A2146, Floor 2
		Real World Data (WRD)	A2146, Floor 2
	13:00 – 14:00	Lunch	Istanbul & Zagreb, Floor 1
	16:30 – 18:30	**Networking Reception**	**IZY, Ground Floor**

Day 2	8:30 – 9:30	Light Breakfast	Auditorium Area
	Conference Track, Day 2		
	9:30 – 10:40	Conference Presentations	Auditorium, Ground Floor
	10:40 – 11:00	Networking Break	Auditorium Area
	11:00 – 12:30	Conference Presentations	Auditorium, Ground Floor
	12:30 – 13:30	Lunch	Istanbul & Zagreb, Floor 1
	13:30 – 14:50	Conference Presentations	Auditorium, Ground Floor
	14:50 – 15:05	Networking Break	Auditorium Area
	15:05 – 16:20	Conference Presentations	Auditorium, Ground Floor

Venue and arrival guidance is provided near the end of this Programme.

Programme Details

Conference Track, Day 1

All Conference Track events will be held in the main Auditorium on the ground floor.

Conference Track, Day 1				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
1	9:30 – 9:45	Welcome & Opening Address		**Amy Cramer** Vulcan co-Chair / J&J **Hugh Glover** Vulcan
2	9:45 – 10:10	Vulcan Overview	• High level overview of Vulcan – origin, what it is & how it functions	**Amy Cramer** Vulcan co-Chair / J&J
3	10:10 – 10:20	Connectathon Overview	• What is a FHIR Connectathon? • A quick look at some past Vulcan Connectathons	**Hugh Glover** Vulcan
	10:20 – 10:50	**Networking Break**		
4	10:50 – 11:20	Vulcan Fundamentals	• A closer look at Vulcan: FHIR as a connector and value via collaboration • Overview of projects • What's next for Vulcan?	**Stacy Tegan** Vulcan / TransCelerate Biopharma
5	11:20 – 11:35	The Vulcan Project Process	• From Idea to Use Case to Project to Standard / Implementation Guide (IG)	**Hugh Glover** Vulcan
6	11:35 – 12:20 (15 min each)	**Perspectives on FHIR (Part 1 - Regulators)**		
		Towards a harmonised EU ePI – the EMA perspective	• Utilising ePI to expand dissemination of up-to-date medicines information to patients, healthcare professionals and regulators • Adoption of an EU ePI Common Standard • Developing and piloting a 'minimum viable product'	**Elizabeth Scanlan** EMA
		National Regulator Perspective of ePI	• National regulator perspective of ePI • Technical overview of ePI portal and API services	**Evinn Drusys** AEMPS

Conference Track, Day 1				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
			• Next steps to incorporate PMS structured data into ePI • High level Introduction of ePI pilot at AEMPS	
		FDA and FHIR, A Regulatory Agency Perspective	• What is being used today for standards and where do we see this moving to in the future? • FHIR as an enabling technology • FHIR examples in a regulatory context	**Jose Galvez** MD FDA (remote)
	12:20 – 13:20	**Lunch**	• Facilitated Discussions (noted later in Programme) • Opportunity to visit Connectathon, in progress, until 13:00	
7	13:20 – 14:40 (20 min each)	**Implementation Insights / Showcase**		
		EHR-to-EDC Transformation of Modern Clinical Trials	• IgniteData examines how advances in technology combined with a collaborative approach are evolving the clinical trial dynamic • The impact of HL7 SMART on FHIR in creating a fast-tracked data conduit between EHR and EDC	**Jessica Jeffries** IgniteData
		Use of Real-World Data in Clinical Research	• An overview to the 21st Century Cures ACT and FDA Real World Evidence Program • Overview to the OneSource Project • Overview to the Common Data Model Harmonization (CDMH)	**Mitra Rocca** FDA (remote)
		EHR2Sponsor - Exchange of Clinical Trial Data; from a Site's Electronic Health Record (EHR) to Sponsor	• ERH2Sponsor is the strategic initiative in Janssen to streamline and automate the transfer of EHR data for clinical studies • Get an understanding of our journey and where and how we rely on FHIR	**Peter Casteleyn** J&J

Conference Track, Day 1				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
		An implementation of care-coordinated ePI access for patients in chronic care	• For chronic disorders it is imperative to empower patients in health literacy and secondary preventive measures • We report on a concept of concentric streams of information where care messages, secondary prevention measures and drug-information share platform in the patient companion app • Our approach necessitates a deep(!) semantic framework	**Martin Ingvar**, Karolinska Institutet
	14:40 – 15:00	**Networking Break**		
8	15:00 – 15:20	Vulcan Implementation Guide Overview	• What goes into an Implementation Guide? • Content and objectives • Quick dive into Vulcan Implementation Guides	**Hugh Glover**, Vulcan
9	15:20 – 16:20 (20 min each)	**Vulcan Electronic Product Information Project (ePI)**		
		ePI Implementation Guide Overview & Relationship with Gravitate Health	• An overview of the Electronic Product Information (ePI) HL7 FHIR implementation guide • How HL7 FHIR ePI is used by the Gravitate Health Project to enable patients to access trustworthy, up-to-date information that better meet their individual needs • Real-world applications of ePI authoring tools	**Giorgio Cangioli** HL7 Europe **Craig Anderson** Pfizer (remote)
		Turning Patient Leaflets into HL7 FHIR	• Patient Leaflets are created / processed / approved as an unstructured word source • Having this leaflet in a structured format is enabling new capabilities	**Sonja Steiner** Acodis **Patrick Bürkle** Acodis

Conference Track, Day 1				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
			• Learn more how patient leaflets can be transformed into FHIR	
		Structured Authoring – Supporting IDMP Submissions using the HL7 FHIR Standard	• Docuvera Structured Authoring Tool Introduction: data model, content reuse, content tagging • Importing unstructured data (word) into a structured authoring tool: overview of process, advantages, metadata tagging • Advanced Export process: overview of process, Export formats (ex: FHIR) • Demo 'OFEV' label example for export of FHIR output: learnings for ePI initiative	**Susie Winn** Author-it Software Corporation **John Jones** Entitech Solutions
10	16:20 – 16:30	Day 1 Review & Day 2 Preview		**Anne Moen** University of Oslo **Catherine Chronaki** HL7 Europe
	16:30 – 18:30	**Networking Reception (see below)**		

[Lunch Time] Facilitated Discussions, Day 1

During the lunch session on Day 1, we will host a number of focused and facilitated discussions, as noted below. Please look for signs at lunch that describe each topic. Discussion highlights will be provided on Day 2, followed by a published paper, post-conference. Thanks for participating and enjoy!

Lunch Time Facilitated Discussions, Day 1		
Topic	**Facilitator(s)**	**Discussion Points**

How can different standards work together?	**Peter van Reusel**
	Catherine Chronaki
		• Collaboration – common values and principles, dangerous pitfalls
		• Differentiate between technical and semantic interoperability
		• Examples:
		  ○ Global Core (and use cases)
		  ○ ICH M11
		  ○ International Patient Summary
		  ○ Interoperability: FHIR & CDISC, OMOP
		  ○ Terminology

How does privacy play into standards, and vice versa?	**Pierre-Yves Lastic**	• Using data for a different purpose (care vs. research) • Privacy by Design • Data management principles (currency, accuracy, etc.) • Privacy impact assessments (PIA) • Perils of ignoring privacy

Enhancing clinical trial efficiency and success using hospital EHRs	**Dipak Kalra**
	Nadir Ammour
		• A brief summary will be given of the European R&D history that has demonstrated the value of hospital EHR for clinical trial design and study conduct.
		• Several success factors have been repeatedly identified, which require multi stakeholder action.
		  ○ Defining and agreeing on core data sets per indication
		  ○ Sponsors needing to express clinical trial eligibility criteria in more precise terms
		  ○ Hospitals willing to allow their EHR data to be queried
		  ○ Hospitals having high quality EHR systems that are eSource ready
		  ○ Hospitals assessing the quality of their data
		  ○ Hospitals and sponsors defining virtual cohort (phenotyping) criteria
		• Lunchtime table participants will be invited to pick the success factors they most want to discuss. We anticipate up to 3 will get covered during the session.

How can Vulcan support clinical research in Europe?	**Michael van Campen**	• How does Vulcan continue European efforts? • Who needs to be part of the conversation? • Are there funding models that can be leveraged? • What will drive value to European organisations?
How do we accelerate the design of a digital clinical trial?	**Andy Richardson**	• Opportunities for a FHIR-based protocol for SOA • How do we get SOA from design to implementation? • How to use FHIR-based tools / IGs effectively • Challenges: terminology, etc.

Connectathon Track, Day 1

Rooms for the Connectathon are as follows:

Electronic Product Information (ePI)	Vision Care A1010, Floor 1
Schedule of Activities (SoA)	A2146, Floor 2
Real World Data (WRD)	A2146, Floor 2

Connectathon Track, Day 1			
#	**Time**	**Topic**	**Notes**
A	9:30 – 9:45	Joint with Conference Track **Location**: Auditorium, Ground Floor	• This is a joint Welcome and Opening Address session for all EuroVulcan participants • Please move to Connectathon rooms following this joint session
B	9:45 – 10:00	Track Introductions	• In separate Connectathon rooms
C	10:00 – 10:30	IG / RI / Scenario Review	
D	10:30 – 13:00	Connectathon Testing	• Participants from the Connectathon Track may join as observers between 12:20 – 13:00 • Breaks can be planned as needed by Track Leads
	13:00 – 14:00	**Lunch**	
E	14:00 – 15:00	Eligibility / Real World Data / Schedule of Activities	• ePi Track will continue Connectathon Tracking at this time
F	15:00 – 16:15	Connectathon Testing	
G	16:15 – 16:30	Wrap up / Review AM read out plans	• Track Leads to prepare a read out of progress, challenges, outcomes, to be presented during the Conference Track, Day 2

Networking Reception, Day 1

Come join your colleagues, network, share ideas

When: 16:30 – 18:30

Where: IZY, Ground Floor

Conference Track, Day 2

All Conference Track events will be held in the main Auditorium on the ground floor.

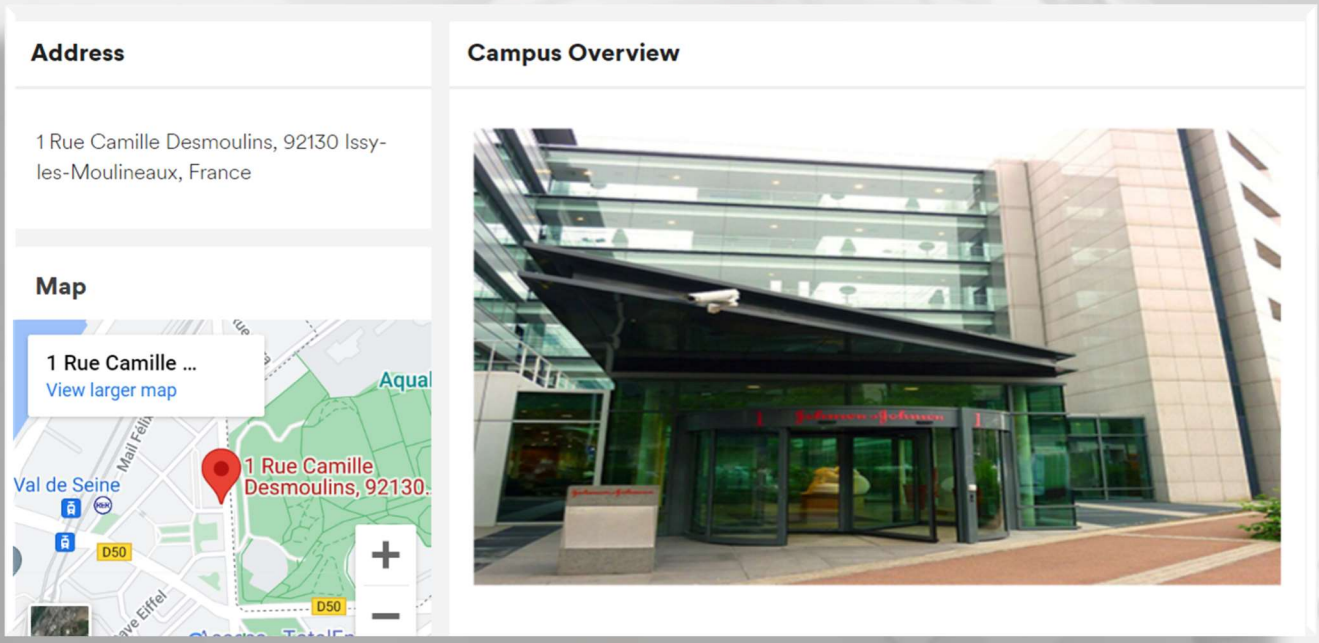
Conference Track, Day 2				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
11	9:30 – 9:40	Welcome, Day 2		**Amy Cramer** Vulcan co-Chair / J&J
12	9:40 – 10:25 (15 min each)	**Connectathon Readout**		
		Real World Data (RWD)		**Shani Sampson** Vulcan / TransCelerate Biopharma **Jean Duteau** Vulcan
		Schedule of Activities (SoA)		**Geoff Low** Medidata Solutions
		Electronic Product Information (ePI)		**Giorgio Cangioli** HL7 Europe **João Almeida** FHIR Consultant, HL7 Europe
13	10:25 – 10:40	Implementing Vulcan	• Vulcan Implementation Strategy Preview • Opportunity for input	**Michael van Campen** Vulcan
	10:40 – 11:00	**Networking Break**		
14	11:00 – 12:30 (15 min each)	**Perspectives on FHIR (Part 2 - European Projects)**		
		Felleskatalogen on FHIR	• Why we are involved in the Electronic Product Information project. • How we will use FHIR in new projects as clinical decision support.	**Bente By Jansen** Felleskatalogen
		Part 1: FHIR4Research in University Hospitals Part 2: Development of French IGs by HL7 France (Interop'Santé) and the French Government Health Agency (ANS)	• Context: Learning Health System, RWE, reinventing clinical trials • Use case #1 – cohort building for AI/ML (RWE) • Use case #2 – optimizing clinical trials • The interoperability challenge & role of FHIR • How to build an implementation guide	**Christel Daniel** Assistance Publique – Hôpitaux de Paris (AP-HP (remote) **Nicolas Riss** French National Agency of Digital Health (ANS), Chair HL7 France
		UK Clinical Research and FHIR Landscape	• Summary of UK landscape with regards to Clinical	**Ben McAlister** Oracle, Chair HL7 UK

Conference Track, Day 2				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
			Research organisations and initiatives and FHIR adoption	
		IDMP-Ontology: a collaborative implementation of IDMP in Pharma	• Introduction to the IDMP Ontology, an initiative of Bayer, Boehringer Ingelheim, GSK, J&J, Merck KGaA, Novartis, Roche, and many more coming together at Pistoia Alliance • Outline of the implementation challenges of ISO IDMP standards at pharma companies • Showcase how an ontology enables deep, semantic interoperability based on FAIR data principles	**Rafail Kasapis**, OSTHUS GmbH – a PharmaLex Company
		The smart hospital - where are we today, where is our near future?	• Digital Transformation of Germany's largest hospital, the Charité in Berlin • Application of the FAIR principles & strategy for interoperability standards (HL7 FHIR) • Democratization of medicine with organizations such as Gematik, the Interop Council and others	**Michael Muzoora**, Berlin Institute of Health **Marco Schaarschmidt**, Berlin Institute of Health
		Creating Interoperability at the Source: UNICOM a Global Game Changer	• Learn about the expected global impact of the project and what has already changed • See the direct connexion with real live implementation of cross border care (eHDSI) and multiple other use cases • Understand how interoperable medicinal products will "flow" towards end-users systems • Apprehend how FHIR® is being considered, adopted and used by different stakeholders	**Luc Nicolas** UNICOM

Conference Track, Day 2				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
			• Provide an outlook of future expected implementation developments and milestones	
	12:20 – 13:30	**Lunch**		
15	13:30 – 13:50	Future Projects for Vulcan	• To be announced at Conference	**Amy Cramer** Vulcan co-Chair / J&J
16	13:50 – 14:10	**Perspectives on FHIR (Part 3 - Government)**		
		Accelerating Discovery through FHIR	• Overview of the National Institutes of Health's (NIH) efforts to encourage the use of the Fast Healthcare Interoperability Resources (FHIR) in research • How the use of standards in general, and FHIR specifically, supports NIH and National Library of Medicine (NLM) data science and open science efforts • Summarize relevant NIH activities to date which include soliciting stakeholder input, funding development projects, and providing relevant training to NIH staff	**Teresa Zayas Cabán,** PhD National Library of Medicine (remote)
17	14:10 – 14:30	**Perspectives on FHIR (Part 4 - Pharma)**		
		What does Vulcan mean to a Pharma company?	• What does Vulcan mean to a Pharma company? • How does Vulcan align with the strategic goals of R&D organizations • How companies are looking to leverage the interoperability of clinical care data with clinical research	**Darren Weston** Vulcan co-Chair / J&J
18	14:30 – 14:50	New Data Challenge of Decentralized Trials	• Discuss the diversity of data as trials are increasingly decentralized • Explore how increased distance between	**Craig Lipset** Clinical Innovation Partners (remote)

Conference Track, Day 2				
#	**Time**	**Topic**	**Key Highlights**	**Presenter(s)**
			investigator and participant will require new strategies for accessing EHR data • Consider the standards and interoperability needed for sites to use their own infrastructure	
	14:50 – 15:05	**Networking Break**		
19	15:05 – 15:20	Day 1 Lunch topic Recap	• Key opportunities, gaps, challenges, barriers	**Michael van Campen** Vulcan
20	15:20 – 16:05	Vulcan Engagement in Europe – Open Discussion	• Grow Vulcan presence in Europe • What's next in Europe?	**Michael van Campen** Vulcan
21	16:05 – 16:20	Where To Next? Wrap Up & Thanks		**Amy Cramer** Vulcan co-Chair / J&J

Venue Details



Address

1 Rue Camille Desmoulins
92130 Issy-les-Moulineaux, Paris

Upon Arrival

Please head to reception where you will be asked for identification and provided a badge. There will a welcome board at the reception area with the meeting room names and floors. You will be guided to the meeting welcome area outside the Auditorium on the Ground Floor.

While on Site

Please note that JNJ employees will be working in the building. We respectfully request that photos/videos are contained to the conference locations. A small room is available for calls and JNJ Docents are available to escort you within the venue outside conference areas.

Conference Auditorium

The Conference Track will be meeting in the Auditorium both days. This room is mic'd and may pick up conversation and / or phone noises. We kindly ask that you keep these noises to a minimum and put phones on vibrate or mute.

Wifi

Wifi will be available during the Conference and Connectathon. Details on connection to the network will be provided at the venue.

COVID Policy

Our hosts have provided the following COVID policy to help Conference and Connectathon attendees stay safe during the event.

Layer of Protection	Meeting Type	Testing & Masking Guidance	Examples & Approvals
Level 1: Green	Long meetings with fewer than 15 people **OR** large meetings less than 3 hours (Indoors)	**HIGHLY RECOMMEND** sponsors and participants consider precautions including masking and testing	• Day-long workshops or conferences with 7 participants • 25 person staff meeting for 90 mins
	Gatherings that include meals (Indoors or Outdoors)		• Luncheons • Receptions
	Meetings with high business continuity risks (Indoors)		• Full leadership team meetings
	Meetings that include large numbers of visitors, especially children (Indoors or Outdoors)		• Year-end celebrations • Community program events

Presenting Organisations

We'd like to thank each of our speakers for presenting over the course of 2 days. Logos for their organizations are noted.

Conference Coordinating Partners

Thanks to our conference coordinating partners who have provided venue, communications and network support to the event.

Organising Committee

Thanks to our Organising Committee for all their efforts in putting the Programme together with great speakers and great participation.

Anne Moen

Catherine Chronaki

Christel Daniel

Amy Cramer

Darren Weston

Hugh Glover

Michael van Campen

Stacy Tegan

Shani Sampson

Sandy Vance

Katleen Renders

Nikki Huysmans

Nicolas Riss

Speaker Bios

Alphabetized by last name.

João Almeida

FHIR Consultant, HL7 Europe

Presenting: Connectathon Readout: electronic Product Information (ePI), topic #12

João is a pharmacist but has been working on health IT for the last 10 years. Specialized in data usage and exchange, works as a consultant for companies across the world regarding HL7 FHIR and health data science.

João is also an assistant professor in the faculty of medicine of Porto University, teaching subjects about interoperability and data science

Craig Anderson

Director, Information Management (Dossier Execution), Pfizer

Presenting: ePI Implementation Guide Overview & Relationship with Gravitate Health, topic #9 (remote)

Director, Information Management (Dossier Execution) at Pfizer. In this role, Craig oversees systems and information driven solutions for Global Regulatory Affairs. Solutions that cover topics such as data standards, terminology management, electronic labelling, and medicinal product information.

In addition to having biopharmaceutical industry experience, Craig also has regulator experience from Health Canada where he led various informatics projects ranging from the implementation of IDMP to Structured Product Labelling.

Craig is also Co-lead of HL7's Vulcan accelerator project for electronic Product Information (ePI) and a member of the Canadian delegation to ISO/TC 215 Health Informatics Working Group 6.

Patrick Bürkle

Chief Customer Officer, Acodis AG

Presenting: Turning Patient Leaflets Into HL7 FHIR, topic #9

Company profile: Acodis is a SaaS company where 25 experts are focusing on data extraction from complex documents. Customers like Roche, Syngenta, and other large Health- and Life Science organisations are using Acodis within the Quality-, Regulatory- or Operations departments to improve data quality for product information or compliance repositories with information that is currently looked inside static documents (Word or PDF). Our enterprise solutions can extract all data (including pictures, tables, and structure) from any document in any language and can be used out of the box. Our human-in-the-loop approach enables business users without any IT or machine learning knowledge to gather and validate data efficiently and with fewer errors than time-consuming manual copy-pasting work.

Giorgio Cangioli

Technical Lead, HL7 Europe

Presenting: ePI Implementation Guide Overview & Relationship with Gravitate Health, topic #9

Presenting: Connectathon Readout: electronic Product Information (ePI), topic #12

Senior Consultant, more than 20 years of experience in health ICT, working with private companies, government agencies and SDOs. Involved in several Regional, National and European projects (e.g. epSOS; UNICOM, X-eHealth and many others).

Technical Steering Committee and Board member of HL7 International. Technical Lead, Board member of HL7 Europe. Chair of the Architecture WG under the eHMSEG Semantic Task Force (EU eHealth Network).

Co-facilitator of the IPS and FHIR for FAIR HL7 projects. Member of the cross-SDO IPS group. Author/contributor of several standards in HL7, DICOM, ISO/TC 215, CEN/TC 251, IHE and standard-based specifications.

Peter Casteleyn

Director Data Collection Solutions – EHR, Janssen R&D

Presenting: EHR2Sponsor - Exchange of Clinical Trial Data; from a Site's Electronic Health Record (EHR) to Sponsor, topic #7

With 20+ years of technology solutions experience in the pharmaceutical industry, Peter is currently focusing on solutions to advance clinical trial execution, and specifically investigating how Electronic Health Records can support this.

Peter is passionate about enabling more efficiency and smarter functioning relying on insights from data and novel technology solutions, and considers collaboration, internally and externally, is a major enabler.

Catherine Chronaki

Secretary General of HL7 Europe

Presenting: Day 1 Review & Day 2 Preview, topic #10

Catherine Chronaki is Secretary General of HL7 Europe. She is a computer engineer by training, active in policy and standards. In 2013-2017, she led the Trillium Bridge and Trillium II projects on International Patient Summary standards under the EU-US Memorandum of Understanding on eHealth and the eStandards roadmap for large scale eHealth deployment.

Catherine is the interoperability co-leader in the Gravitate Health project funded under the European IMI2 program and HL7 Vulcan Accelerator co-lead for the ePI project. She serves as a member of the eHealth Stakeholders group of the European Commission (2023-2026), on the board of HL7 International, and as vice president for IMIA of the European Federation for Medical Informatics (2022-2024).

Amy Cramer

Vulcan co-Chair / J&J

Presenting: Vulcan Overview, topic #2

Presenting: Welcome, Day 2, topic #11

Presenting: Future Projects for Vulcan. Topic #15

Presenting: Where To Next? Wrap Up & Thanks, Topic #21

Amy Cramer draws on her experience as a critical care nurse, clinical research coordinator, healthcare quality professional, informaticist and intrapreneur. She is a Director at Janssen Pharmaceuticals and leads the "Capitalizing on Data Assets" Focus Area for Janssen Clinical Innovation (JCI). JCI is a function within J&J R&D Global Development with a mission to accelerate the discovery, development, and deployment of innovative capabilities in the business. Her team is pursuing innovative opportunities in utilizing clinical care and patient mediated data for research, streamlining processes through intelligent automation, applying novel analytical methods to diverse/emerging data sources, and expanding capabilities in emerging markets.

Amy is a founding member and Co-Chair of Vulcan, the HL7 Fast Healthcare Interoperability Resource (FHIR®) Accelerator dedicated to connecting translational and clinical research with clinical care. Vulcan is comprised of members spanning across the research community collaborating to improve data utilization for research. Amy's expertise for innovation and interoperability is demonstrated in her publications. She is a member of TransCelerate Biopharma, Inc., Vice-Chair of the Society for Clinical Data Management (SCDM) eSource Implementation Consortium and former Co-Chair of HL7 Clinical Interoperability Council.

Christel Daniel, MD, PhD

Associate director at the Data & innovation Department of the IT department of Assistance Publique – Hôpitaux de Paris (AP-HP)

Presenting: FHIR4Research in University Hospitals, topic #14

Dr Christel DANIEL, MD, Pathologist, PhD in Medical Informatics. Associate director at the Data & innovation Department of the IT department of Assistance Publique – Hôpitaux de Paris (AP-HP). Researcher at Inserm & Sorbonne University. 25-year career at AP-HP, 2 years at the French National Agency of Digital Health (ASIP Santé). Pas co-chair of IHE Anatomic Pathology. Expertise in clinical research informatics, health data warehouses, clinical informatics, semantic interoperability and standards (IHE, HL7, FHIR, CDISC ODM, OMOP CDM). Participation to international research projects (DebugIT, EHR4CR, EHR2EDC, HDQ4HP, Periscope, EUCAIM, IDEA4RC, etc.).

Evinn Drusys

NCA Network ePI co-product owner, AEMPS, Spain

Presenting: National regulator perspective of ePI, topic #6

Information Technology specialist with experience in geographical Information systems, database administration, and web development. An employee at AEMPS since 2019 working on ePI pilot project, Gravitate Health, UNICOM WP4, and eAF/DADI.

Jean Duteau

Technical SME, Vulcan / Dogwood Health Consulting

Presenting: Connectathon Readout: Real World Data (RWD), topic #12

Jean is an experienced enterprise architect, systems analyst, and developer with 20+ years of experience in various disciplines and has been working with Healthcare systems since 2000.

Jean has been a key participant in the implementation of pan-Canadian HL7 messaging and terminology specifications in numerous Canadian jurisdictions and has a keen understanding of implementation challenges and resolution strategies. He is currently working as the Technical SME on the Vulcan Real World Data and the Schedule of Activities projects. He is also working on an FDA project around the HL7 Structured Product Labeling specification and is developing HL7 FHIR profiles and Implementation Guides for the US Da Vinci Project.

He is an active volunteer at HL7, serving as a HL7 Biomedical Research & Regulation co-chair, a HL7 Pharmacy co-chair, and a Cross-Group Projects co-chair. He is also the HL7 Technical Steering Committee chair.

Jose Galvez MD

Deputy Director for the Office of Strategic Programs (OSP), FDA

Presenting: FDA and FHIR, topic #6 (remote)

Dr. Galvez currently serves as the Deputy Director for the Office of Strategic Programs (OSP) within the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA). Prior to joining OSP Dr. Galvez spent 10 years with the National Institutes of Health, directing the Biomedical Translational Research Informatics Systems at the NIH Clinical Center as well as Directing the Clinical and Translational Informatics program at the Center for Biomedical Informatics and Information Technology at the NIH National Cancer Institute (NCI).

Dr. Galvez received his Medical Degree at the University of California Davis in 1993, where he also did a residency in Pathology and Informatics fellowship. From 2000-2010 Dr. Galvez was an Assistant professor of pathology and Director of Bioinformatics at the University of California Davis School of Medicine Department of Anatomic and Clinical Pathology. He received his Bachelor of Science in Biochemistry from the University of California Davis in 1997.

Hugh Glover

Technical Director, Vulcan

Presenting: Connectathon Overview, topic #3

Presenting: The Vulcan Project Process, topic #5

Presenting: Vulcan Implementation Guide Overview, topic #8

Hugh Glover is a data modeller, software developer and architect. He has worked on development of clinical decision support systems, national and international drug data bases including IDMP, data modelling including the BRIDG model and implementing that for a leading clinical research organisation. He has been a member of HL7 for over 20 years and was elected fellow in 2016. He is a past co-chair of the Pharmacy WG and of the Biomedical Research and Regulation WG. He has been Technical Director for the Vulcan FHIR Accelerator since it was founded.

Martin Ingvar

Professor MD PhD, Karolinska Institutet

Presenting: An Implementation of Care-coordinated ePI Access for Patients in Chronic Care, topic #7

Background in cognitive neuroscience, semantics, psychiatric health, computational neuroscience, health systems. 300 scientific papers (H-index 90) Contributed to some 12 popular science books.

Co-founded International Consortium for Health Outcome Measurement (ICHOM) in 2011. Member of the board ICHOM, Context vision (AI and imaging).

Present projects focused on process support in health care and semantic interoperability in all dimensions (diagnose, health care unit, care level etc.)

Bente By Jansen

Managing director and Chief editor, Felleskatalogen AS, The Norwegian Pharmaceutical Product Compendium

Presenting: Felleskatalogen on FHIR (ePI), topic #14

Master's degree in pharmacy from 1998. Has been working at Felleskatalogen since 1999, and as Managing director since 2008. Is particularly interested in e-health and how digital solutions can contribute to the safe use of medicines. Currently studying health informatics at the Norwegian University of Science and Technology.

Jessica Jeffries

Strategic Account Director, IgniteData

Presenting: EHR-to-EDC Transformation of Modern Clinical Trials, topic #7

Jessica is responsible for IgniteData's key sponsor relationships, working closely with each partner on the creation of a bespoke Champion Site Network for studies, from initial pilot through to scale-up. She also leads on Archer site relationships, supporting research sites in becoming Archer-enabled, and acting as the conduit between IgniteData sponsor partners and their bespoke Site Network.

Having spent over 10 years within SaaS business development, Jessica has in-depth account management experience within complex environments, including diagnostics, military health and large-scale transformation projects.

John Jones

Life Sciences IT Strategist — EntiTech Solutions

Presenting: Structured Authoring – Supporting IDMP Submissions using the HL7 FHIR Standard, topic #9

John Jones is the Founder and CEO of Entitech Solutions, a system integrator focused on developing innovative technology solutions for unmet business needs in Life Sciences. Prior to starting Entitech, John led Quintiles' IT Consulting Division from 2010 – 2015 focusing on IT Advisory and Implementation services in Life Sciences. John has more than 25 years experience in developing and delivering IT Solutions for various companies, and has extensive experience in the clinical, regulatory, and commercial areas.

His technical specialties include enterprise architecture planning and definition, long-term technology strategy development, knowledge and content management, information architecture and metadata definition, structured component authoring and data integration/business intelligence platform implementation.

Craig Lipset

Managing Partner, Clinical Innovation Partners

Presenting: The New Data Challenge of Decentralized Trials, topic #15

Craig Lipset is an advisor, educator, advocate and innovator focused on novel solutions for clinical trials and medicine development. He is the founder of Clinical Innovation Partners, providing advisory and board leadership with pharma, tech and investors. Craig is Co-Chair for the Decentralized Trials & Research Alliance and Vice President of the Foundation for Sarcoidosis. He is Adjunct Assistant Professor in Health Informatics at Rutgers University and serves on the Advisory Council for HL7 Project Vulcan and External Stakeholder Board for IMI Trials at Home.

Craig was previously the Head of Clinical Innovation and Venture Partner at Pfizer, and on the founding management teams for two successful startup ventures.

Geoff Low

Principal Innovation Scientist with Medidata Solutions

Presenting: Connectathon Readout: Schedule of Activities (SoA), topic #12

Geoff is a Principal Innovation Scientist with Medidata Solutions. He has been working in the Clinical Trials Industry for over 20 years, primarily focused in the topics of data integration and innovation. He is a co-lead of the Vulcan SoA project

Ben McAlister

Lead Product Regulatory Strategist Oracle Health, Chair HL7 UK

Presenting: UK Clinical Research and FHIR Landscape, topic #14

Ben is a Lead Product Regulatory Strategist at Oracle Health where he works on their interoperability development strategy and is Chair of HL7 UK since 2019. Prior to joining Cerner (acquired by Oracle Health) in 2006 he worked at an Acute Hospital Trust as a Service Development Manager for Planning and Commissioning and Information Manager.

Ben studied Health Informatics at University College London and is an Associate Vice Chair of Standards for the British Computer Society (BCS) Health and Care Group and is the BCS nominated representative on the British Standards Institute IST/35 Health Informatics Committee.

Anne Moen

Professor at the Faculty of Medicine, University of Oslo

Presenting: Day 1 Review & Day 2 Preview, topic #10

RN, PhD, FACMI, FIAHSI is full professor at the Faculty of Medicine at the University of Oslo, Oslo, Norway, and adjunct Professor, Norwegian Center for eHealth Research, Tromsø, Norway. She is Director of UiO:eColab, Institute for health and society. Her program of research seeks to better understand digital citizens centered services, based on opportunities to "collect, curate and control" all relevant, personal health information. To do so, she combines in-depth insights in healthcare with design and deployment of accessible digital solutions, emphasizing citizen empowerment, digital health literacy and overall engagement for health and wellness.

Professor Moen is the Coordinator of "*Gravitate – Health*: *Empowering and Equipping Europeans with Health Information from trusted sources for active, safe, secure personal health management and adherence to treatment*" Innovation Medicine Initiative Public-Private Partnership (project 945334, IMI2 JU, 2020-2025). Gravitate-Health's mission is to prepare and test innovative, easy-to-use elegant digital services that actively engage and empower citizens and their support network with access to and understanding of health information from trusted sources. More information is available at www.gravitatehealth.eu

Professor Moen served as EFMI representative in EU eHealth stakeholder group (2015 – 2019), and was rapporteur for special focus on "Citizens – health data". She was EFMI President 2014-2016. Professor Moen is elected fellow of ACMI (American College of Medical Informatics) 2015, is a founding fellow of IAHSI (International Academy for Health Sciences Informatics) 2017, and Honorary Fellow of EFMI 2019.

Michael Muzoora

Research Fellow, Berlin Institute of Health

Presenting: The smart hospital - where are we today, where is our near future?, topic #14

Michael Muzoora is currently working as a Research Fellow, in the Core Unit eHealth and Interoperability (CEI) Team, of Prof. Dr. Sylvia Thun, at the Berlin Institute of Health at Charité, Berlin. His background is in E-Health Management and Telemedicine as well as Business Management.

Luc Nicolas

eHealth Expert

Presenting: Creating Interoperability at the Source: UNICOM a Global Game Changer, topic #14

As an eHealth expert, Luc Nicolas has been directly involved since 2005 in the making of all components necessary to create and maintain an open and generic eHealth infrastructure, be it at national, European and international levels. Luc's academic background is mainly related to politics and economics.

More than 30 years of work in direct contact with the medical sector in both strategic and operational positions have given him a deep understanding of the issues and challenges at stake. Since 2020, Luc is deeply involved in the exploitation strategy of the UNICOM project, a major game changer for interoperability in Europe.

Mitra Rocca

Senior Medical Informatician
Office of Translational Sciences, Center for Drug Evaluation and Research, FDA

Presenting: Use of Real-World Data in Clinical Research, topic #7

Mitra Rocca joined Food and Drug Administration (FDA) in 2009 as the Senior Medical Informatician responsible for developing the health information architecture of the Sentinel System. She serves as the lead for the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) health information technology (health IT) board focusing on the use of health IT to enhance regulatory decision making. She serves as the FDA CDER lead to Health Level Seven (HL7), responsible for the review of HL7 draft standards.

Prior to joining FDA, Mitra served as the Associate Director, Healthcare Informatics at Novartis Pharmaceuticals Corporation focusing on the reuse of the Electronic Health Record (EHR) in clinical research. Mitra has served as the co-chair of the Health Level Seven (HL7) Clinical Interoperability Council (CIC) from 2012-2018. She holds her advanced degree in medical informatics from the University of Heidelberg in Germany.

Nicolas Riss

Interoperability Expert at the French National Agency of Digital Health (ANS), Chair HL7 France at Interop'Santé

Presenting: Development of French IGs by HL7 France (Interop'Santé) and the French Government Health Agency (ANS), topic #14

Nicolas Riss, PharmD, Interoperability Expert at the French National Agency of Digital Health (ANS), Chair HL7 France at Interop'Santé, experience in semantics and standards (HL7, FHIR, OMOP CDM), 2 year experience in Arkhn Startup as medical expert, participation to TNT calls, developer, advising and support for Start-Up in PariSantéCampus (PSC) in Health Data management, support for Meetup FHIR France community.

Elizabeth Scanlan

ePI product owner, European Medicines Agency

Presenting: Towards a harmonised EU ePI – the EMA perspective, topic #6

Elizabeth Scanlan joined the European Medicines Agency in 2016 where she is a Scientific Communication Officer and ePI Product Owner, with a focus on communication of information on safe and effective use of medicines to patients and healthcare professionals. Prior to joining EMA, she worked in communication roles in the biotechnology industry and not-for-profit sector.

Shani Sampson

Associate Technical Director, Vulcan / TransCelerate Biopharma

Presenting: Connectathon Readout: Real World Data (RWD), topic #12

Shani Sampson is a Project Manager (contractor) at TransCelerate Biopharma and Vulcan's Associate Technical Director. She has a BS in Psychology from Wesleyan University. An experienced clinical data professional, Shani has 20+ years in academia and pharma.

During her 19 years in pharma Shani served as a clinical data manager, data science project delivery lead and clinical data domain/ data lake steward, establishing herself as an SME in several areas including clinical trial data sharing, data privacy and governance, endpoint adjudication and clinical trial diversity.

Shani has shared her point of view in peer reviewed publications and speaking engagements including SCDM's annual conference and now brings her combined skillset to help drive the growth of the Vulcan Accelerator.

Marco Schaarschmidt

Research Fellow, Berlin Institute of Health

Presenting: The smart hospital - where are we today, where is our near future?, topic #14

Marco Schaarschmidt is currently working as a Research Fellow in the Core Unit eHealth and Interoperability (CEI) team of Prof. Dr. Sylvia Thun at the Berlin Institute of Health, Charité, Berlin. He has a background in software engineering and is currently studying for a Master's degree in Digital Health.

Sonja Steiner

Chief Executive Officer, Acodis AG

Presenting: Turning Patient Leaflets Into HL7 FHIR, topic #9

Sonja Steiner is CEO of acons IT consulting. Since the completion of her computer science studies, she has worked in IT consulting. Sonja has specialized in serialization and traceability projects within pharmaceutical companies.

In past 2 years she was part of PharmaLedger project to implement Electronic Product Information (ePI) and Detecting Falsified Medicines use case.

Stacy Tegan

Strategy Director, Vulcan / TransCelerate Biopharma

Presenting: Vulcan Fundamentals, topic #4

Stacy Tegan is a Program Director Manager at TransCelerate Biopharma, Inc., a collaborative consortium of the biopharmaceutical R&D community aiming to accelerate how research becomes life-saving healthcare. She oversees initiatives creating solutions to enable information sharing and harmonization across clinical development. She has expertise in Regulatory Operations, Clinical Development processes, and Project Management gain through 25+ years of experience working for sponsor, consulting, technology, and non-profit organizations. Stacy is a volunteer with DIA Global and a founding member of Vulcan, currently serving as the Vulcan Strategy Director.

Michael van Campen

Program Director, Vulcan

Presenting: Implementing Vulcan, topic #13

Presenting: Day 1 Lunch Topic Recap, topic #19

Presenting: Vulcan Engagement in Europe - Open Discussion, topic #20

Michael is a leading expert in the establishment of eHealth / digital strategies, architectures, interoperability standards and IT infrastructures. His experience is drawn from work in Canada, US, Middle East, Singapore, Europe and Australia. Through over 60+ consulting assignments, Michael has developed a keen understanding of eHealth business, strategies, architecture, standards and IT solutions.

Michael has led numerous eHealth standards initiatives in Pharmacy, Claims, Public / Population Health, Registries, Mental Health, etc. Michael was on the HL7 International Board for 5 years as Treasurer and Director responsible for 35+ countries and Chair HL7 Canada for 6 years.

Michael has delivered and facilitated over 300-person days of workshops around the world to executive, clinical and technical staff on numerous topics including: digital strategy, data policy, governance, integration, business transformation, big data, open data, eHealth standards and organizational structures. Michael has also provided interoperability, standards and digital technology related presentations in Canada, US, Mexico, Greece, Turkey, Qatar, UAE, Australia, Saudi Arabia, Tonga, Japan, Netherlands, Mongolia, New Zealand and the UK.

Darren Weston

Vulcan co-Chair / J&J

Presenting: Pharma Perspectives on FHIR, topic #17

Darren Weston is Senior Vice President, Head of Integrated Data Analytics & Reporting (IDAR) and Janssen Clinical Innovation (JCI), Janssen R&D. Darren also serves as the co-chair for Vulcan HL7 Steering Committee.

In this role he is responsible for leading the IDAR organization in delivering our portfolio on time, within budget, and with robust quality while continuously improving to optimize efficiency and drive innovation through JCI in how we execute our programs. IDAR and JCI have a globally distributed workforce of more than 1000 internal and external employees who are responsible for the operational execution of all Phase I – IV studies (including Medical Affairs programs) across all therapeutic areas and all geographic regions. They are accountable for identifying and implementing innovative clinical trial approaches and technologies that meet the current and future needs of our portfolio while also shaping our environment to build for the future. IDAR is comprised of six functions: Data Management, Clinical & Statistical Programming, Risk Management-Central Monitoring, Regulatory Medical Writing, Clinical Data Standards & Transparency, IDAR Business Operations, in addition to IDAR Therapeutic Area leadership.

Prior to joining Janssen in 2017, Darren was the Vice President of Data Sciences & Scientific Operations at Novartis where he had spent 16 years holding positions of increasing leadership scope in Biometrics areas. He has served as an external advisor for SAS and supported several key industry groups such as PhUSE and PSI. He is a UK graduate in Applied Statistics of Brighton University (BSc 1st Class/summa cum laude), and Sheffield Hallam University (MSc Distinction/summa cum laude) and lives in Mendham, NJ.

Susie Winn

Director, Life Sciences Solutions — Author-it Software Corporation

Presenting: Structured Authoring – Supporting IDMP Submissions using the HL7 FHIR Standard, topic #9

Susie is dedicated to creating innovative component authoring solutions for Life Science clients, changing the way these companies think about content authoring and management. Her focus in defining secure, cloud-based systems is to help customers realize the full potential of single- source medical content enabling true “write once, publish to many” capability while gaining unprecedented levels of content reuse. She has over 20 years’ experience in structured component authoring and delivering multi-channel publications across a range of industries globally.

Susie joined Author-it from a multimillion-dollar high-tech company where she spearheaded the implementation of Author-it software, ultimately leading the enterprise to 90% content reuse in 20 languages.

Teresa Zayas Cabán, PhD

Assistant Director for Policy Development,

National Library of Medicine, National Institutes of Health

Presenting: Accelerating Discovery through FHIR, topic #16

Dr. Teresa Zayas Cabán is Assistant Director for Policy Development at the National Library of Medicine (NLM). In this role she leads NLM's policy development and implementation activities.

Dr. Zayas Cabán was previously Chief Scientist at the Office of the National Coordinator for Health Information Technology (ONC) where she led ONC's scientific efforts and activities. In that role she developed, established, or recommended scientific policy to the National Coordinator, directed ONC's Precision Medicine Initiative activities, and provided oversight of ONC's patient-centered outcomes research projects.

Prior to her position at ONC, Dr. Zayas Cabán was the Chief of Health IT Research and Acting Director of the Division of Health IT at the Agency for Healthcare Research and Quality (AHRQ). While at AHRQ, she set new directions for their funding opportunities and coordinated with federal partners, such as the National Science Foundation.

Before joining AHRQ, she served as a post-doctoral trainee in the computation and informatics in biology and medicine program at the University of Wisconsin-Madison. Dr. Zayas Cabán obtained her doctorate in industrial and systems engineering at the University of Wisconsin-Madison where she was a National Science Foundation graduate research fellow in industrial engineering.