eClinical Forum

Virtual Workshop October 19-28, 2021

AGENDA

Day 1: Tuesday, Oct 19 2021

Session 1: Europe and Asia Pacific

UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:20	9:20	10:20	11:20	13:50	16:20	17:20	18:20
8:20	9:20	10:20	11:20	13:50	16:20	17:20	18:20
9:00	10:00	11:00	12:00	14:30	17:00	18:00	19:00
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas

UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:20	9:20	10:20	11:20	12:20	13:20	17:20	18:20
16:20	9:20	10:20	11:20	12:20	13:20	17:20	18:20
17:00	10:00	11:00	12:00	13:00	14:00	18:00	19:00
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 1**		
20	**Welcome to our Virtual Workshop**	Richard Perkins, eClinical Forum Ken Nakano, eClinical Forum	Suzanne Bishop, eClinical Forum Richard Perkins, eClinical Forum
	Computerised Systems And Electronic Data In Clinical Trials		
40	**Regulatory Expert Group (REG)** - Status of activities - EMA DRAFT Guideline on computerised systems and electronic data in clinical trials - Overview of issues - Instructions for Breakout Groups	Alan Yeomans, Viedoc Neil Konopka, Oracle Cinzia Piccini, Eli Lilly Mika Lindroos, Signant Health	Linda King, Astellas Devry Spreitzer, Astellas Babette Von Hagen, CSL Behring Valeria Orlova, Medidata
60	**Breakout Groups** Small group discussion of the top issues in the EMA draft Guideline on computerised systems and electronic data in clinical trials 1. Source Data, and when does audit trail begin 2. Validation vs, Qualification vs. Certification 3. Timing and frequency of investigator oversight / signatures 4. eConsent	Alan Yeomans, Viedoc Neil Konopka, Oracle Cinzia Piccini, Eli Lilly Mika Lindroos, Signant Health	Linda King, Astellas Devry Spreitzer, Astellas Babette Von Hagen, CSL Behring Valeria Orlova, Medidata
0	**CLOSE OF DAY 1**		

Day 2: Wednesday, Oct 20, 2021

Session 1: Europe and Asia Pacific

UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:05	9:05	10:05	11:05	13:35	16:05	17:05	18:05
9:05	10:05	11:05	12:05	14:35	17:05	18:05	19:05
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9:50	10:50	11:50	12:50	15:20	17:50	18:50	19:50
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas

UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:05	9:05	10:05	11:05	12:05	13:05	17:05	18:05
17:05	10:05	11:05	12:05	13:05	14:05	18:05	19:05
17:20	10:20	11:20	12:20	13:20	14:20	18:20	19:20
17:50	10:50	11:50	12:50	13:50	14:50	18:50	19:50
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 2**		
5	**Welcome**	Ken Nakano, eClinical Forum	Suzanne Bishop, eClinical Forum
60	**Feedback from Breakout sessions** EMA draft Guideline on computerised systems and electronic data in clinical trials	Alan Yeomans, Viedoc Neil Konopka, Oracle Cinzia Piccini, Eli Lilly Mika Lindroos, Signant Health	Linda King, Astellas Devry Spreitzer, Astellas Babette Von Hagen, CSL Behring Valeria Orlova, Medidata
15	**Progress in eClinical** - Overview of eCF Teams	Ken Nakano, eClinical Forum	Suzanne Bishop, eClinical Forum
30	**CTIS – What to expect?** CTIS will be the single EU entry point for clinical trials information in the EU/ EEA. This will include a single clinical trial application dossier, maintenance process and timeline, covering clinical trial applications and registration of the clinical trial in a public register; all in one integrated submission.	Mireille Muller, Novartis	Mireille Muller, Novartis
10	**Discussion**		
0	**CLOSE OF DAY 2**		

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Day 3: Thursday, Oct 21, 2021

Session 1: Europe and Asia Pacific

UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:05	9:05	10:05	11:05	13:35	16:05	17:05	18:05
8:30	9:30	10:30	11:30	14:00	16:30	17:30	18:30
9:00	10:00	11:00	12:00	14:30	17:00	18:00	19:00
9:30	10:30	11:30	12:30	15:00	17:30	18:30	19:30
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas

UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
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16:30	9:30	10:30	11:30	12:30	13:30	17:30	18:30
17:00	10:00	11:00	12:00	13:00	14:00	18:00	19:00
17:30	10:30	11:30	12:30	13:30	14:30	18:30	19:30
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 3**		
5	**Welcome**	Richard Perkins, eClinical Forum	Suzanne Bishop, eClinical Forum
25	**Electronic Trial Master File (eTMF) and Investigational Site File (eISF) Survey** Developing an understanding of the state-of-the-art and future trends for Electronic Trial Master Files (eTMFs)	Pinar Benet, Veeva Manuela Hornberger, Boehringer Ingelheim	Pinar Benet, Veeva Steven Carr, CSL Behring
30	**eTMF Case Study: Trial Specific eTMF for Sponsor, CRO and Site**	Lina Gaggi, Viedoc Technologies	Lina Gaggi, Viedoc Technologies
30	**Eucrof GDPR Code of Conduct**	Yoani Matsakis, Eucrof Victoria Watts, Premier Research	Yoani Matsakis, Eucrof Victoria Watts, Premier Research
30	**Latest News**	Richard Perkins, eClinical Forum Ken Nakano, eClinical Forum	Suzanne Bishop, eClinical Forum
0	**CLOSE OF DAY 3**		

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Day 4: Tuesday, Oct 26, 2021

Session 1: Europe and Asia Pacific							
UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:05	9:05	10:05	11:05	13:35	16:05	17:05	18:05
8:30	9:30	10:30	11:30	14:00	16:30	17:30	18:30
9:30	10:30	11:30	12:30	15:00	17:30	18:30	19:30
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas							
UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:05	9:05	10:05	11:05	12:05	13:05	17:05	18:05
16:30	9:30	10:30	11:30	12:30	13:30	17:30	18:30
17:30	10:30	11:30	12:30	13:30	14:30	18:30	19:30
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 4**		
5	**Welcome**	Ken Nakano, eClinical Forum	Suzanne Bishop, eClinical Forum
25	**Trends and Changes Affecting Clinical Trials in 2021** A summary of what we have learned from changes and trends during 2021. Such as... vaccine trials, disruption to clinical trials, growth of remote trials, personalised medicines, expanded access and post-trial monitoring, digital transformation, remote working, growing Digital Endpoints, Data analytics and Visualisation, evolution of data management, emerging technologies	Noa Berkovich, Servier	Steve Walker, CSL Behring
60	**Round Table Discussion Groups** 1. **CT Trends in 2021**. Is Clinical Research in a better place post covid? What do we want to keep/build on? 2. **eTMF**. What does it mean to be 'perpetually inspection ready'? Is it a reality? Is it achievable? 3. **Study Feasibility**. Current best practices, use of RWD, predictive analytics and innovative approaches to maximise success. 4. **CT Timelines**. What is being achieved today? What transformations are needed to achieve clinical research "at the speed of science"?	Group Leaders: Noa Berkovich, Servier Lina Gaggi, Viedoc Technologies / Pinar Benet, Veeva To be announced Manuela Hornberger, Boehringer Ingelheim	Group Leaders: Steve Walker, CSL Behring Lina Gaggi, Viedoc Technologies / Pinar Benet, Veeva / Steven Carr, CSL Behring To be announced Karen Reilly
30	**Feedback from Round Table sessions**	Group Leaders	Group Leaders
0	**CLOSE OF DAY 4**		

Day 5: Wednesday, Oct 27, 2021

Session 1: Europe and Asia Pacific							
UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:05	9:05	10:05	11:05	13:35	16:05	17:05	18:05
8:15	9:15	10:15	11:15	13:45	16:15	17:15	18:15
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9:30	10:30	11:30	12:30	15:00	17:30	18:30	19:30
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas							
UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:05	9:05	10:05	11:05	12:05	13:05	17:05	18:05
16:15	9:15	10:15	11:15	12:15	13:15	17:15	18:15
16:30	9:30	10:30	11:30	12:30	13:30	17:30	18:30
17:00	10:00	11:00	12:00	13:00	14:00	18:00	19:00
17:30	10:30	11:30	12:30	13:30	14:30	18:30	19:30
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 5**		
5	**Welcome**	Richard Perkins, eClinical Forum	Suzanne Bishop, eClinical Forum
10	**Update from Trial of the Future**	Yvonne Rollinger, ToF Team	David Stein, ToF Team
15	**Digital Endpoints Ecosystem and Protocol (DEEP)** An update on DEEP and the potential role of the eCF.	Erwin De beuckelaer, Janssen	Erwin De beuckelaer, Janssen
30	**NLP Case Study: Use of NLP to Build a Patient-centric Digital Platform** This session will provide an overview of modern NLP technology and its application in healthcare. Ciitizen's patient-facing platform allows patients to collect and store their medical records, and turns documents into structured, longitudinal data that can be shared for clinical treatment, observational research and clinical trials with consent.	Amir Tahmasebi, CiiTIZEN	Amir Tahmasebi, CiiTIZEN
30	**Information Security - What to Look for in Your Own Organisation and in Your Vendors** The implementation of an information security management system (ISMS) and associated controls is the Information Security equivalent to our industry's QMS - and is just as necessary. How much work is it to implement an ISMS in a company that already has a detailed QMS and what does it entail?	Jens Pettersson, Viedoc Technologies	Jens Pettersson, Viedoc Technologies
30	**Utilising Advanced Visualisations for Automated Data Review** A Case study on how advanced visualisation is reducing the time taken in data review and discovering insights from clinical trial data in real-time.	Ravi Prakash Gupta, Eli Lilly	Ravi Prakash Gupta, Eli Lilly
0	**CLOSE OF DAY 5**		

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Day 6: Thursday, Oct 28, 2021

Session 1: Europe and Asia Pacific							
UTC	London	Brussels	Helsinki	Mumbai	Beijing	Tokyo	Sydney
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
8:00	9:00	10:00	11:00	13:30	16:00	17:00	18:00
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8:20	9:20	10:20	11:20	13:50	16:20	17:20	18:20
8:35	9:35	10:35	11:35	14:05	16:35	17:35	18:35
8:50	9:50	10:50	11:50	14:20	16:50	17:50	18:50
9:05	10:05	11:05	12:05	14:35	17:05	18:05	19:05
9:20	10:20	11:20	12:20	14:50	17:20	18:20	19:20
9:50	10:50	11:50	12:50	15:20	17:50	18:50	19:50
10:00	11:00	12:00	13:00	15:30	18:00	19:00	20:00

Session 2: Americas							
UTC	San Diego	Denver	Chicago/ San Jose	NYC	Sao Paulo	London	Brussels
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:00	9:00	10:00	11:00	12:00	13:00	17:00	18:00
16:05	9:05	10:05	11:05	12:05	13:05	17:05	18:05
16:15	9:15	10:15	11:15	12:15	13:15	17:15	18:15
16:20	9:20	10:20	11:20	12:20	13:20	17:20	18:20
16:35	9:35	10:35	11:35	12:35	13:35	17:35	18:35
16:50	9:50	10:50	11:50	12:50	13:50	17:50	18:50
17:05	10:05	11:05	12:05	13:05	14:05	18:05	19:05
17:20	10:20	11:20	12:20	13:20	14:20	18:20	19:20
17:50	10:50	11:50	12:50	13:50	14:50	18:50	19:50
18:00	11:00	12:00	13:00	14:00	15:00	19:00	20:00

Mins	Topic	Session 1 Presenter/Facilitator	Session 2 Presenter/Facilitator
0	**START OF DAY 6**		
5	**Welcome**	Richard Perkins, eClinical Forum	Suzanne Bishop, eClinical Forum
10	**Artificial Intelligence and Machine Learning Team** - eCF/Eucrof AI/ML Team update	Nathalie Townsend, Veeva Sofoklis Kyriazakos, Innovation Sprint	Nathalie Townsend, Veeva Sofoklis Kyriazakos, Innovation Sprint
5	**Artificial Intelligence Panel: Introduction**	Yvonne Rollinger, ToF Team	David Stein, ToF Team
15	**The First Artificial Intelligence Regulation: Overview of the proposal for regulations on the use of Artificial Intelligence in the European Union** A summary of the European Commission's recent proposal for regulations laying down harmonized rules on the use of artificial intelligence, the world's first legal framework on AI. It aims to provide a concise overview of the document, outline its significance and exploring the potential implications for the healthcare and life sciences industries.	Fiona Maini, Medidata	Fiona Maini, Medidata
15	**Enhancing Trust in AI Using Machine Learning Operations** AI is clearly advancing new clinical opportunities and disrupting the status quo in a way that can benefit all. This growth however is outstripping the advances made for ensuring accountability, security, ethics and trust. As AI becomes commoditized it is increasingly used by non-experts, which while democratizing, is risky and may erode trust. An emerging solution to such problems is provided by Machine Learning Operations (MLOps). MLOps brings the discipline of rigorous software engineering operations practise to ML. As such it reduces risks around critical issues of accountability, regulations compliance, ethics, security explainability and transparency. Through automation and standardization, the requirements around such elements can be embedded in the production pipeline allowing for continuous monitoring, auditing, alerting and updating of prediction capability at run time. All decisions and in particular those which impact a clinical decision can be traced back to changes in data, algorithm or code through an auditable process. Such an approach can enhance trust in AI-driven clinical trials management and benefit innovators in the industry.	Willie Muehlhausen, Dublin University	Willie Muehlhausen, Dublin University
15	**Key Validation Deliverables Required to Demonstrate Suitable Validation of an AI Solution.** An overview of how to validate AI Solutions, covering: - Data Acquisition and Selection - Model Evaluation and Selection - Model Deployment - Ongoing monitoring and Performance Evaluation - Key deliverables produced, and what evidence is expected to be appropriate - How AI Solution Validation complements and links to the relevant Computer Systems Validation process	Joanne Donald, Roche Products	Joanne Donald, Roche Products
15	**A platform approach to AI as 'Compliant Components'** This session will explore: •Shifting paradigms of algorithms in healthcare that challenge existing frameworks •Alternative frameworks to enable AI to be trusted for clinical use at scale •Opportunities to leverage emerging standards to create industry standards for AI in Health •Need for standardisation to enable AI 'assets' to be interoperable and reusable •A platform approach to enable AI 'assets' for clinical use in a 'Compliant Component' format •AI Asset marketplace	Sheena Macpherson, Miotify	Sheena Macpherson, Miotify
30	**Panel Discussion**	Facilitators: Yvonne Rollinger, ToF Team Valdo Arnera, eResearch Technology	Facilitators: David Stein, ToF Team
10	**Summary of eCF Autumn Workshop and Plans for 2022**	Richard Perkins, eClinical Forum	Richard Perkins, eClinical Forum
0	**CLOSE OF DAY 6 AND WORKSHOP**		