ACT EU Clinical Trials Analytics Workshop

25-26 Jan 2024

[Hybrid meeting / EMA, Amsterdam, Meeting Room]

Over the years the EMRN (European Medicines Regulatory Network) has collected a wealth of data about clinical trials through their clinical trials registers CTIS and EudraCT. These data are used to support regulatory decision-making, but their potential uses extend far beyond that scope. Stakeholders may have diverse interests, from locating trials for certain health conditions to monitoring innovation in healthcare and even applying Artificial Intelligence for novel insights. While these data hold immense potential, challenges still remain in access and usability.

The workshop on clinical trial analytics will look at how these data can be better used to improve public health. The focus of this workshop will therefore be on collecting "use cases" with clinical trials data. A use case for the data might be, for example, a description of how an individual or organisation intends to use the data to accomplish a specific objective, the expected outcomes and benefits of using the data in that way.

Use cases might require identifying additional data sources that, taken together, have the potential to reveal fresh insights, maximizing their value for EU citizens' health and well-being.

Objectives include:

- gather use cases for data about clinical trials from a wide range of different stakeholders' groups;

- identify evidence gaps in the EU environment that might be addressed by access to data, data analysis and funding;
- identify relevant data sources beyond CTIS and EudraCT;
- inform stakeholders about current data standardisation efforts led by ICH M11;
- establish continued communication through the multi-stakeholder platform on the topic.

The use cases will be gathered into an *EU research agenda* on clinical trials analytics under which specific research projects may be funded.

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ACT EU CT Analytics Workshop

Day 1 – 25 Jan 2024, 13:00 – 18:00 CET

13:00 Joining and technical checks

13:15 Welcome and opening speech

Opening remarks from EMA ***5'***
Emer Cooke (EMA)

Opening remarks from the DKMA ***5'***
Lars Bo Nielsen (DKMA/HMA)

13:30 Session 1: From data to decisions

Co-chairs: Peter Arlett (EMA) – Lars Bo Nielsen (DKMA/HMA)

Unlocking the value of data on clinical trials is a priority for the EMRN. The research agenda will collect practical examples of use of data (use cases) to focus efforts where stakeholders have identified their needs. Are there evidence gaps which could be addressed by better use of the data?

During this session, attendees are invited to share their views on data sources and their importance.

Delivering a research agenda ***15'***
Jsbrand den Rooijen (EMA)

Identifying relevant data sources ***15'***
Frederik Grell Nørgaard (DKMA)

Patient perspective on the value of clinical trials data ***15'***
Nikos Dedes (European AIDS Treatment Group)

Panel discussion ***45'***

Nikos Dedes (European AIDS Treatment Group)
Elmar Nimmesgern (EU Commission)
Denise Umuhire (EMA)
Anton Ussi (EATRIS)
Nathalie Seigneuret (IHI)

14:45 Coffee break

15:15 Session 2: Clinical trials data: present and future

Co-chairs: Christophe Lahorte (AFMPS - FAGG) – Michael Berntgen (EMA)

A panel discussion where representatives from different stakeholder groups will first give short presentations after which there will be discussions.

Panellists will share their use cases for the data: what it has been helpful for, but also what has been missing. Which questions could I answer with better data access?

Julian Isla (European Dravet Syndrome Federation) ***80'***
Till Bruckner (TranspariMED)
Jakob Wested (DKMA)
Helga Gardarsdottir (Utrecht University)
George Paliouras (Duchenne Data Foundation/NCSR Demokritos)
Martin O'Kane (EFPIA / Novartis)
Michel Zwaan (NVMETC)
Shu Chin Ma (C-Path)

Question and Answer session **30'**

17:05 Coffee break

17:15 Session 3: Structuring data to facilitate analysis

Chair: Frank Petavy (EMA) – Marianne Lunzer (AGES)

This session aims to provide an introduction to the standardisation efforts of clinical trial protocols that are currently underway as part of ICH M11 and a demo of how scientific information could be accessed using structured clinical trial protocols.

A panel discussion will illustrate how structured clinical trial protocols could support assessment and evidence generation, clinical trials approval, academic research, clinical development in special populations, as well as pharmacovigilance activities.

Stakeholders are encouraged to share their use cases on how they already are or would like to use scientific information from clinical trial protocols in the various break-out sessions planned for the 2nd day.

Speaker

Mumtaz Sultani & Noemie Manent (EMA) ***10′***

Ina-Christine Rondak (EMA) ***10′***

Panel discussion ***30′***

Benjamin Speich (University Hospital Basel)

Vada A. Perkins (EFPIA / Boehringer Ingelheim)

Hans Hillege (EMA)

18:05 Closing remarks

Wrap up ***10′***

Peter Arlett (EMA) – Lars Bo Nielsen (DKMA)

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Day 2 – 26 Jan 2024, 09:00 – 12:30 CET

09:00 Session 1: Welcome and Setting the expectations for Day 2

Recap of Day 1 and setting the scene for the breakouts.

Recap of Day 1 ***15′***

Lars Bo Nielsen (DKMA)

Setting up the expectations for day 2 ***15′***

IJsbrand den Rooijen (EMA)

09:30 Logistic break

09:45 Session 2: Breakout sessions: What are your use cases for the clinical trials data?

These breakout sessions will provide all attendees with the opportunity to discuss how clinical trials data can support, or already is supporting, their specific use cases. It is understood that clinical trials data may be just one element among several data sources required to fully realise a use case.

Attendees are encouraged to describe their use case, articulate its importance, and specify what they would (further) need from the data to successfully implement it.

Room 1B	Room 2C	Room 2B	Room 0B	Room 1G
Academia Priorities	**Patients' Priorities**	**Industry Priorities**	**Ethics/HCPs/HTAs Priorities**	**Data standardisation priorities**

Room 1B ***Breakout session A: Academia Priorities (incl. EU research infrastructures)***

Facilitator & Rapporteur: Frederik Grell Nørgaard (DKMA)

Wrap up and key messages to report to plenary ***75'***

Room 2C ***Breakout session B: Patient Priorities***

Facilitator & Rapporteur: M.G.P. (Mira) Zuidgeest (UMC Utrecht)

Wrap up and key messages to report to plenary ***75'***

Room 2B ***Breakout session C: Industry Priorities***

Facilitators & Rapporteur: Frank Petavy (EMA)

Wrap up and key messages to report to plenary ***75'***

Room 0B ***Breakout session D: Ethics/HCPs/HTAs Priorities***

Facilitator & Rapporteur: Monique Al (CCMO)

Wrap up and key messages to report to plenary ***75'***

Room 1G ***Breakout session E: Data standardisation Priorities***

Facilitator & Rapporteur: Noemie Manent (EMA)

Wrap up and key messages to report to plenary ***75'***

11:00 Coffee break

11:30 Session 3: Report back from Break-out sessions

Chair: Rosa Giuliani (co-chair of the Healthcare Professionals Working Party)

Reporting on the breakouts per stakeholders group. The outcome of the breakout sessions will form the basis of the research agenda.

Presentation of key messages per session ***60'***

Frederik Grell Nørgaard (DKMA)
M.G.P. (Mira) Zuidgeest (UMC Utrecht)
Frank Petavy (EMA)
Monique Al (CCMO)
Noemie Manent (EMA)

12:30 Closing remarks

Wrap up and Next steps ***20'***

Peter Arlett (EMA) – Lars Bo Nielsen (DKMA)