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ACT EU Clinical Trials Analytics Workshop

Workshop report

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Introduction

Executive summary

A multi-stakeholder workshop focused on the transformative potential of data about clinical trials, has been organised under the ACT EU initiative. The goal was to identify shared research priorities which maximise the value of these data to support evidence-based decision-making and fuel innovation.

The workshop revealed a collective ambition to improve the use of data about clinical trials by taking a multi-stakeholder approach to identifying research priorities. This will speed up the development of an analytics ecosystem that maximises health benefits for EU citizens.

There was consensus on the need for continued dialogue and collaboration between the participants, paving the way for future research projects aligned with the shared objectives identified during the workshop.

Key Takeaways

- Access to data for patients and patient organisations is critical for informed decision-making and effective advocacy.
- Accurate, complete, and timely data underpin not only the integrity of clinical trials but also the reliability of research outcomes.
- Open analytics platforms can optimise research processes, support strategic prioritisation, and guide efficient resource allocation across the research ecosystem.
- Standardised, harmonised, and interoperable data are foundational for advancing research methodologies, facilitating effective collaborations, and streamlining regulatory processes.
- Integrating data about clinical trials with a variety of other data sources, including real-world data, can optimise trial designs and address challenges in accessibility and inclusivity.

Next Steps

- Develop a document outlining shared research priorities to maximise the value of data about clinical trials.
- Initiate specific research projects focusing on optimising the use of data which may be connected to funding opportunities.

Opening remarks by Emer Cooke (EMA), and Lars Bo Nielsen (DKMA/HMA)

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 remain in access and usability. Therefore, a multi-stakeholder approach was taken with a particular focus on patient involvement for identifying priority areas.

The workshop on clinical trial analytics looked at how these data can be better used to improve public health, including but not limited to, regulatory decision-making. The focus of this workshop was on collecting "use cases" with clinical trials data. 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.

Day 1 - Session 1

From data to decisions

Chairs: Peter Arlett (EMA) and Lars Bo Nielsen (DKMA/HMA)

Main themes

Presenters: IJsbrand den Rooijen (EMA), Frederik Grell Nørgaard (DKMA), Nikos Dedes (European AIDS Treatment Group), Elmar Nimmesgern (EU Commission), Denise Umuhire (EMA), Anton Ussi (EATRIS), and Nathalie Seigneuret (IHI).

During this session, there were a few introductory presentations followed by a panel discussion on the high-level benefits of data about clinical trials.

The workshop's opening session emphasised the ambition to optimise the use of data about clinical trials to support better health outcomes and regulatory decision-making. Data about clinical trials, which are captured in clinical trial registers, serve as essential metadata, helping to contextualise trials and facilitate links to other data sources. A vision was outlined for empowering diverse stakeholders to integrate and analyse data from multiple sources within their own systems. The long-term goal is a robust clinical trial analytics ecosystem that supports evidence-based regulatory decisions and fuels innovation in research.

A patient representative highlighted the historical impact of patient advocacy on clinical research and policy. The HIV community's efforts directly led to accelerated drug approvals, demonstrating the importance of patient involvement and emphasising how access to data can play a key role in their decision-making process. Their advocacy brought on further regulatory changes, increasing transparency and accountability through initiatives like public clinical trial registries. Their ongoing mission remains: ensure clinical trials are relevant, build upon existing knowledge, and directly improve patient lives by providing access to essential medicines.

Patient organisations were recognised as valuable partners in designing clinical trials that reflect real-world experiences. The important role of clinical trial registries in helping patients find trials to participate in was emphasised. The potential of data about clinical trials to assess the impact of health guidelines, care delivery measures, and bridge the gap between health technology assessment (HTA) and marketing authorisation processes was highlighted, particularly in understanding discrepancies in drug reimbursement decisions.

From a regulatory perspective, data about clinical trials is essential for horizon scanning by highlighting emerging and evolving trends, needs in regulatory science, and anticipating the need for scientific advice. The potential of the European Health Data Space (EHDS) to accelerate and streamline clinical trial activities within Europe was discussed, and although the EHDS only foresees individual patient data from clinical trials, data from clinical trial registries could provide the relevant context to optimise their use.

The workshop emphasised the important role of data about clinical trials in guiding research funding decisions, particularly towards addressing, for example, neglected disease areas, and for assessing the outcomes of funded projects. Stakeholders underscored the value of (national) research funders having access to comprehensive data about clinical trials, along with analysis tools, to guide their strategic decision-making. Importantly, coordinating research projects on axes other than disease such as on phenotype or molecular aetiology could improve the efficiency of the research ecosystem.

Challenges

- The collection, structuring, and integration of heterogeneous data types to effectively support decision-making by regulators.

- The lack of appropriate infrastructure and tools to ensure broad access to data about clinical trials.

Opportunities

- Integrating patient perspectives and pragmatic design principles has the potential to optimise both clinical trials and related regulatory decisions.
- Developing tools to help research and funders identify under-researched areas/unmet needs can reduce duplication of efforts in clinical trial funding and overall direct resources more efficiently.

Day 1 - Session 2

Clinical trials data: present and future

Chairs: Christophe Lahorte (AFMPS-FAGG), and Michael Berntgen (EMA)

Main themes

Presenters: Julian Isla (European Dravet Syndrome Federation), 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).

During this session, eight speakers presented use cases for data about clinical trials. The session explored how this data has been utilised, identified gaps, and discussed how improved data access could have enhanced research and decision-making.

Main themes

The session highlighted the importance of clinical trial registries for transparency and comprehensive evidence generation. Stakeholders emphasised the need for registries to contain complete, accurate, and up-to-date data to be truly useful for researchers, regulators, and other interested parties, as well as agreed on the value of submitting results after trial conclusion irrespective of their outcome.

Several presentations focused on the inclusion of underrepresented populations in clinical trials. Inspired by the EMA's regulatory science vision, studies examined neglected populations and cited challenges due to a lack of detailed reporting. Other uses of the data included the analysis of treatment evolution, identifying transatlantic trials, and positioning within global research in general.

Speakers discussed the value of linking real-world data with clinical trial data, enabling regulators to gain insights from diverse sources and enhance the design and inclusivity of trials. Presenters demonstrated the use of Natural Language Processing (NLP) methods in extracting critical information from clinical trial data, structuring elements like inclusion and exclusion criteria to enhance their value.

Data quality issues were emphasised, with the need for consistent, timely, accurate, structured, and accessible data reiterated to support research, regulatory decision-making, and foster both human and machine accessibility. Simply having more data is not the solution; rather, better curation of existing data is needed. The session also explored the use of decentralised clinical trial elements and the analysis of protocols to better understand facilitators and barriers in trial design. Discussions highlighted the industry's use of the data on benchmarking and assessing the potential for trial approval based on past data e.g., to assess regulatory acceptance of novel endpoints, intended study population, assessor capacity, and speed.

Challenges

- Retrieving complete, accurate, and consistently structured data within clinical trial registries and relevant databases remains a key challenge.
- Variations in anonymity and data management practices across different countries complicate the use of data for secondary research purposes.

Opportunities

- Harmonisation and enhanced data quality in clinical trial registries can streamline research processes and improve the reliability of findings.
- Increasing the availability of linked research documents through or within registries can further enhance the usability of data about clinical trials.

Day 1 - Session 3

Structuring data to facilitate analysis

Co-chairs: Frank Petavy (EMA), Marianne Lunzer (CTCG/AGES)

Main themes

Presenters: Mumtaz Sultani (EMA), Noemie Manent (EMA), Ina-Christine Rondak (EMA), Benjamin Speich (University Hospital Basel), Vada A. Perkins (EFPIA/Boehringer Ingelheim), Hans Hillege (EMA)

During this session there was a presentation on ICH M11, a demo of a register search tool, and a panel discussion on the value of a standardised protocol.

The session began with a focus on ICH M11's efforts to establish an internationally standardised clinical trial protocol, fundamental for streamlining the development and review process. The dependence of academic researchers on reliable data from clinical trial registries was discussed, highlighting challenges with discrepancies in key information like primary outcomes and trial status across registries. The evolving role of some clinical trial registries as hubs for accessing research documents was mentioned. Discussions emphasised the need for registries to continuously evolve, adapting to new trial designs like platform trials, and ensuring fit-for-purpose data entry formats through regular assessments.

Lack of an internationally standardised protocol creates delays and inefficiencies, underscoring the importance of standardisation for data collection and regulatory decision-making. Standardisation is a prerequisite for interoperability and will enable efficient sponsor-to-regulator information exchange. The session further stressed the significance of standardisation for making informed regulatory decisions, particularly when integrating data from various studies for benefit-risk assessments. The benefits of harmonised protocols, including predictability, consistency, and efficiency, were emphasised along with how structured protocol data enhances regulatory decision-making and research, and offer the potential to improve data sharing and reduce burdens throughout the clinical trial landscape.

Challenges

- The absence of an internationally standardised clinical protocol leads to delays, redundant efforts, and potential inconsistencies.

- Existing registries need to adapt to accommodate new trial designs (like platform trials), providing enhanced data tracking and detail.

Opportunities

- Harmonisation and enhanced data quality in clinical trial registries can streamline research processes and improve the reliability of findings, contributing to a more robust and trustworthy evidence base.
- Enhanced sponsor-regulator communication through a focus interoperability can expedite the clinical trial process.

Day 2 - Session 1

Welcome and setting the expectations for Day 2

Presenters: Lars Bo Nielsen (DKMA/HMA), IJsbrand den Rooijen (EMA)

Main themes

There was a short recap of the main themes of Day 1 and attendees were prepared for the subsequent breakout sessions.

Day 2 - Session 2 - Break-out sessions

Session A: Academia priorities (incl. EU research infrastructures)

Moderator: Frederik Grell Nørgaard (DKMA)

Main themes

Discussions highlighted the importance of detailed, comprehensive clinical trial results reporting, with a growing focus on patient-reported outcomes. The need for granular data on dosage, sequence, effectiveness, side effects, and quality of life metrics was emphasised for being able to save costs and optimise treatment strategies. If these were standardised, they would directly power systematic reviews and other meta-analysis efforts. The Netherlands' cancer registry was presented as an example of standardised data collection, integrating real-world data and patient-reported outcomes to improve symptom management and safety assessments, as well as to inform market access and understand the broader impact of cancer on patients. Regulators stressed the value of analysing rejected trial applications including through requests for information to refine submissions and avoid common mistakes, and how complete trial results inform their decisions regarding marketing authorisation. The potential of clinical trial results, including those from unsuccessful trials, to drive drug repurposing efforts was highlighted, particularly for unmet medical needs, with better collaboration between regulators and academia seen as key for overcoming the present hurdles.

Clinical trial registries could facilitate control group reuse, identify similar trials for collaboration (especially before funding applications), and promote more efficient research (funding). The potential benefits of CTIS, other registries, and the ECRIN Metadata Repository in preventing

redundancy and fostering cooperation were mentioned. The need for a homogeneous approach to entering trial results in CTIS was highlighted. Furthermore, stakeholders stressed the importance of considering medical devices alongside medicines for a comprehensive view of treatment options. The absence of a direct link in CTIS to the MDR portal data however is a missed opportunity, given the challenges of integrating new data models and algorithms from devices in clinical research.

Challenges

- Multiple factors contribute to duplication of clinical trials, including a competitive research environment.
- Integrating new data models and algorithms while ensuring regulatory compliance.

Opportunities

- Moving beyond structured capture and interoperability of data, towards standardising the analytical methods for interpretation.
- Improve learning from clinical trials by making results, including reasons for failure, more accessible and understandable.

Session B: Patient priorities

Moderator: M.G.P. (Mira) Zuidgeest (UMC Utrecht)

Main themes

On the individual level, discussions focused on building tools and platforms to improve patients' access to clinical trials. A clinical trial search tool specifically focused on disease areas was proposed, with potential for a public body to create a template or framework for adaptation by specific disease communities. The importance of patient-friendly language and information, including up-to-date site information, details about trial timelines and procedures, locations, and post-trial treatment access were emphasised to foster a more patient-centric research environment.

On the advocacy level, participants highlighted the need for disease-specific tools to empower patient organisations with data during committee meetings to increase the effectiveness of their advocacy and enable more active participation in drug development and clinical trial design. By using clinical trial metadata organisations could highlight gaps in research, potentially directing attention towards less-researched diseases, underrepresented countries (especially in multi-national trials), and patient populations. Additionally, comparing clinical trial sites to centres of expertise could reveal gaps in clinical trial conduct capabilities among specialised medical centres.

Several discussions centred on patient-centric approaches in clinical trials such as on the inclusion of narrative-driven outcome measures. In addition, integrating with organisations like Orphanet would improve the accuracy of clinical trial searches so they are more based on detailed and nuanced disease classifications. These would equip healthcare professionals to better guide patients towards suitable trials based on individual needs. Taken together these point to a tension between data standardisation and the importance of properly accounting for individual patient characteristics and preferences.

Finally, the breakout prompted reflection on the dynamics underlying the clinical trials landscape, emphasising the importance of a balanced approach that prioritises patient needs alongside the

advancement of medical research. Participants also agreed it would be valuable to continue collecting use cases after the workshop.

Challenges

- Accessing reliable, up-to-date clinical trial information can be difficult, and may require navigating disjointed platforms with complex medical terminology.
- Reconciling the need for standardisation with capturing individual patient characteristics.

Opportunities

- Investing in a template for a centralised clinical trial database and search tool with standardised, patient-friendly information.
- Ongoing collection of use cases to dynamically set research priorities.

Session C: Industry priorities

Moderator: Frank Petavy (EMA)

Main themes

The industry priorities discussions highlighted the critical need for structured, harmonised, and quality data throughout the entire clinical trial lifecycle. This includes meticulous documentation of both results and trial methodology to ensure complete reconstruction of trials is possible, supporting future-proof decision-making. The challenge of balancing high-quality, structured data with administrative burden was acknowledged, underscoring the need for streamlined processes and tools to ensure both comprehensiveness and manageability.

Discussions explored the complexities of data sharing and transparency. The potential benefits of sharing data from discontinued programs, including negative results, were recognised as potential learning opportunities for the broader research community. Careful consideration of the risks and sensitivities of data sharing will remain necessary to balance potential benefits with the protection of sensitive information.

Managing complexity emerged as a central theme in the discussions. Attendees emphasised the fact that it is not necessarily access to new data which is needed, but rather better access to existing data in a more standardised fashion, for instance, to support safety assessments. To manage the complexity attendees expressed a need for analytics platforms with well-documented APIs for data analysis. This would address the limitations of current fragmented and manual methods, though careful consideration of the added value, resource investment, and broader impact would be required to justify such a project. There was a proposal to view Marketing Authorisation status of IMPs in CTIS, and another to create a repository of anonymised data accessible beyond large pharmaceutical companies, to improve control arms in studies. A request went out to regulators to better communicate on the opportunities brought on by the increased granularity and validity of data within CTIS. The breakout concluded on the need for a structured approach to adequately address the richness of the workshop discussions and the topic at large, and the hope that the workshop might lay the foundation for future discussions.

Challenges

- Effective strategies are needed to structure, assess the relevance of, and prioritise the datasets generated in clinical trials. This challenge escalates with the integration of diverse data sources (medical devices, in vitro diagnostics, real-world data).

Opportunities

- Explore the potential to support sharing data of on discontinued programs and negative results to advance scientific knowledge and improve future trials.
- Developing analytics platforms and APIs to facilitate more efficient data analysis and streamline research processes.

Session D: Ethics/HCPs/HTAs priorities

Moderator: Monique Al (CCMO)

Main themes

Discussions initially focused on improving representation in clinical trials, especially for rare and paediatric diseases. Relatedly, an upcoming IHI project will focus on establishing criteria to measure the representativeness of trial populations. Attention centred on better capturing and communicating decentralised elements, such as remote participation and clinic visit requirements, to enhance access and data quality. The value of transparent clinical trial data through public databases was emphasised, along with a goal of agreeing minimal data sets for cross-border research. For HTA bodies, it's essential to establish a baseline of representativeness by triangulating real-world data with trial data for more informed local decision-making on aspects such as diversity and representation.

Health Canada informed attendees of a project inflight to develop a clinical trial portal which consolidates data from multiple registries, using AI to detect discrepancies and ensure data integrity. Protocol-level standards are understood as crucial for consistent data mapping, although requirements for groups such as HTAs might differ from others. There was interest for automating data exchange with systems like EudraCT and CTIS while ensuring wider interoperability. To that end, the C-Path Institute and the European Joint Program for Rare Diseases are looking at interoperability between standards across data types and regions, whilst acknowledging GDPR-related challenges such as the inability to share ethnicity data. There was a suggestion for querying underexplored data sets such as payer data to improve regulatory alignment. For ethics, analysis of Paediatric Investigation Plans (PIPs) reveals a focus on their completion status, including reasons for incompletion like recruitment difficulties and ethical committee decisions. The high prevalence of off-label use in paediatrics complicates reimbursement and is often tracked in small, off-label registries.

Challenges

- Ensuring consistency and reliability of clinical trial data, even when sourced from diverse registries and formats.
- Off-label use in paediatrics and the ethical considerations of relying on paediatricians' discretion for extrapolation of adult data to children.

Opportunities

- Focus efforts on solutions that bridge different standards and data models for collaboration across stakeholders (HTAs, regulators, researchers).
- Leveraging Real-Word Data (RWD) and payer datasets to complement clinical trial information.

Session E: Data standardisation priorities

Moderator: Noemie Manent (EMA)

Main themes

Discussions highlighted the importance of data standardisation including the use of controlled terminologies for enhancing data quality throughout the clinical trial process, including for the reporting of results. Standardised results will enable group analysis of trials to study product, population or other dimension of interest. Interoperability was considered with the need for linking with adverse reaction databases, drug substances, predicting study outcomes, and ultimately establishing an electronic 'source of truth' for clinical trials.

The importance of standardising patient-reported outcomes, including data from e-PROs and importantly the algorithms used to extract them, was discussed for comparability and regulatory use, while acknowledging the challenges in validating these algorithms within an evolving digital ecosystem. Standardisation of protocols was linked to bringing efficiency to the evaluation of medicinal product market authorisation. There was interest in using standardised data to model disease progression and personalise treatments, and to capture predictors of health to inform disease prevention. Combining results from multiple trials through meta-analysis relies heavily on standardised data, for instance to analyse key intercurrent events such as treatment compliance, treatment discontinuation, intake of rescue medication. Using data from time-and-event schedules can improve single-arm trials and real-world evidence studies. Machine learning was highlighted as a tool with great potential, but its accuracy often hinges on standardised data. Early engagement with regulators and model validation are vital for building trust in predictive models.

The need to better integrate patient health records with clinical trial data was discussed, especially for cross-cutting medicines and their systemic effects. The digital health systems were considered promising for improved data linkage and monitoring, with the European Health Data Space playing a unifying role. The importance of differentiating between individual-level and summary data was noted for future standardisation efforts. Standardised eligibility criteria will contribute to a more precise definition of the safety profile of a product. Beyond ICH M11 there is a need for a common technical approach for registering and reporting of clinical trials.

Challenges

- Ensure compatibility of the clinical research ecosystem with evolving digital health systems.
- Defining standards for patient-reported outcomes, including data from wearables.

Opportunities

- Creating unified protocol standards and an electronic source of truth for global regulatory harmonisation.
- Using standardised data about clinical trials to improve the design and comparability of trial results with link to real-world evidence studies.

Day 2 - Session 3

Report back from the break-out sessions

Chair: Rosa Giuliani (Healthcare Professionals Working Party)

Main themes

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

The rapporteurs gave an overview of key themes discussed during the breakout sessions as reflected in the summaries of sessions A-E.

The chair highlighted the importance to think on a global level, as are the patients' needs, and recognise the value of the workshop as an opportunity to have a broad perspective and make the best use of data on clinical trials.

Closing remarks

Chairs: Peter Arlett (EMA), Lars Bo Nielsen (DKMA/HMA)

In closing, the chairs thanked all attendees for their contributions and insights. During the workshop, stakeholders shared their use cases and identified priority areas cutting across the medicines lifecycle. This workshop was the first of its kind, reflecting the growing importance of data about clinical trials as a dedicated topic.

Enhanced use of data can facilitate faster, better, and optimised EU clinical trials, and will directly enable the ACT EU vision of making the EU an attractive region for conducting clinical trials. Given the strong stakeholder interest on the topic, the dialogue on research priorities will continue and will be addressed through the activities of the dedicated ACT EU priority action on clinical trials analytics.

Glossary

ACT EU	Accelerating Clinical Trials in the EU
AGES	Austrian Agency for Health and Food Safety GmbH
API	Application Programming Interface
FAIR	Findable, Accessible, Interoperable, Reusable
CCMO	The Central Committee on Research Involving Human Subjects
CHMP	Committee for Medicinal Products for Human Use
CTCG	Clinical Trials Coordination Group
CTIS	Clinical Trials Information System
CTR	Clinical Trials Regulation
DCT	Decentralised Clinical Trial
DKMA	Danish Medicines Agency
EATRIS	European infrastructure for translational medicine
EHDS	European Health Data Space
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EFPIA	European Federation of Pharmaceutical Industries and Associations
FAMHP	Federal Agency for Medicines and Health Products
HCP	Health Care Professionals
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
IHI	Innovative Health Initiative
IMP	Investigational Medicinal Product
IVDR	In Vitro Diagnostic Regulation
MDR	Medical Device Regulation
MS	Member State
NCA	National Competent Authority
NVMETC	The Dutch Association of Medical Research Ethics Committees

More information

The Accelerating Clinical Trials in the EU (ACT EU) initiative aims to develop the European Union further as a competitive centre for innovative clinical research. ACT EU seeks to deliver on the clinical trial innovation recommendations of the European medicines agencies network strategy and the European Commission's Pharmaceutical strategy for Europe.

ACT EU builds on the Clinical Trials Regulation and Clinical Trials Information System launched on 31 January 2022. The European Commission, EMA and Heads of Medicines Agencies launched ACT EU in January 2022 and run the initiative together, establishing a steering group in March 2022. The programme's strategy paper features ten priority action (PA) areas that are the basis for the ACT EU workplan; an eleventh PA on clinical trials in public health emergencies has been created since the launch of the programme.

The ACT EU workplan was published on 10 November 2023 and sets out deliverables and timelines for the programme for 2023-26. The deliverables for 2024 include:

The **implementation of the Clinical Trials Regulation**, including support for the transition of clinical trials to the CTR and the CTR Collaborate project, which aims to optimise collaboration between national health authorities and national ethics bodies.

The creation of a regulatory **helpdesk for non-commercial sponsors** conducting multi-national clinical trials.

The creation of the **Multi-Stakeholder Platform Advisory Group** of stakeholder representatives.

A **scientific advice pilot** to provide consolidated advice for clinical trial and marketing authorisation applications.

Regulatory support to **clinical trials in public health emergencies**.

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