1) Delivering a research agenda
2) Identifying relevant data sources

25-26 January 2024

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Outline

- What is clinical trials analytics?
- Research agenda on clinical trials analytics
- Identifying relevant data sources

What is clinical trials analytics?

Launched in 2022: Accelerating Clinical Trials in the EU

ACT EU was partly a response to COVID
to get **bigger** trials off the ground **faster**

As the programme formed there were natural categories:

- GCP
- Methodologies
- Clinical trials regulation

We all agreed that data from clinical trials is important

Defining clinical trials analytics as a topic

The data is important, but what should the analytics be about?

We knew there was interest in the data for:

- Informing clinical guidelines
- Tracking uptake of innovation
- Designs associated with marketing approval
- Benchmarking development pipelines
- Finding and joining ongoing trials
- …

But where should we be focusing our efforts specifically?

Objective of CT analytics

"Analyse data about clinical trials leveraging academic, non-profit, European, and international initiatives, improving the impact of policymaking and funding on research outputs to support evidence-based decision making."

The benefits of the Clinical Trials Regulation (CTR)

- CTIS is the register of the **Clinical Trials Regulation**
- CTIS generates substantially **higher quality data** than EudraCT
- Opportunity to capitalise on **technological developments** in *advanced analytics* (i.e., machine learning, AI, NLP)

Image 1.
Since 31 January 2023, sponsors submit all new clinical trial applications in the EU/EEA via CTIS.

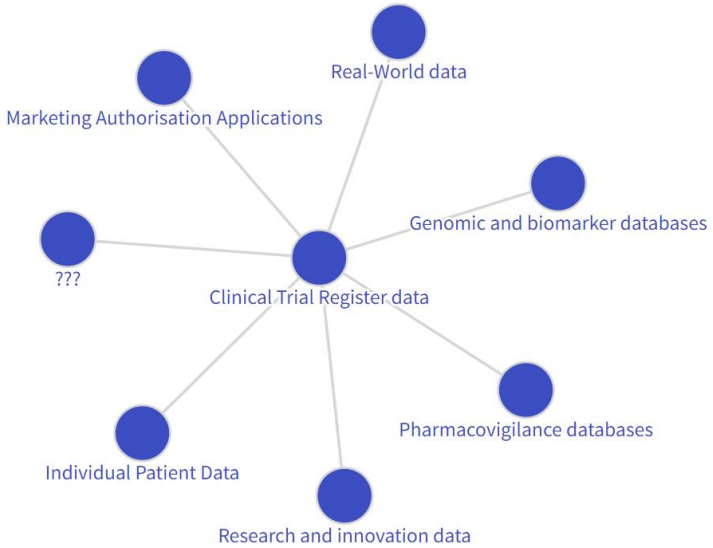
Where should we focus to make better use of the data we collect about clinical trials?

What is data about clinical trials?

Data about clinical trials are held in CT registers and contain summary-level information on clinical trials

Data from clinical trials are Individual Patient Data and are not kept in the registers

CT register data is centrally positioned and play a bridging role, facilitating the link between data sources



Collecting use cases for data about clinical trials

We will collect detailed, actionable use cases to have concrete examples of how the data is being used

Use cases highlight where there is a need to focus

Day 2 is geared to towards collecting use cases

Definition of use case

"A use case for the data refers to a description of how an individual or organisation intends to use the data to accomplish a specific objective, these could include steps they will take, expected outcomes, and the benefits of using the data in that way."

Research agenda on clinical trials analytics

Research agenda on clinical trials analytics

Use cases will be analysed for **common themes** across stakeholders

Use cases will be distilled into **research questions**

Questions gathered into a **research agenda** on clinical trials analytics

Delivering the research agenda

Planning to **publish agenda** in Q2

Empower stakeholders to deliver different parts of the agenda:

- Foster funding opportunities for research projects under the agenda
- Enhancing data access and utility

Supporting a clinical trials analytics ecosystem equipped to deal with the challenges and opportunities of the digital world

Identifying relevant data sources

High level perspectives

National Competent Authorities (my affiliation)

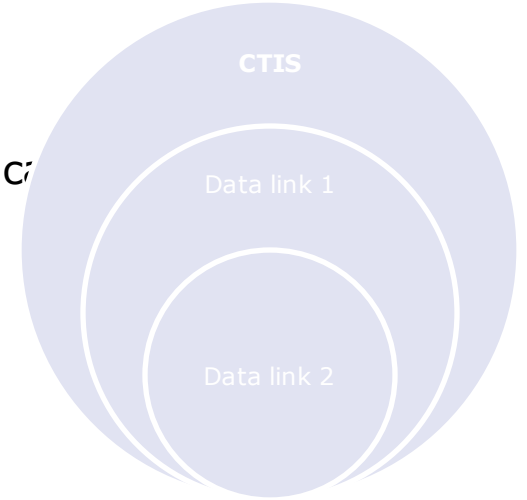
- Are the curators of CTIS data
- Ensures that data in CTIS has high validity
- Data quality improved significantly compared to EudraCT

As previously stated; the ‘how’ is not the focus of this workshop.

Primary goals

- Use data to optimise regulatory decision making
- Enabling the research agenda. This may eventually include to enable stakeholders to conduct within their own systems analyses with data from different sources

The central clinical trial hub of intelligence



Central for the use-cases and the research agenda is the Clinical Trial Information System (CTIS)

- Provide important characteristics of clinical trials, e.g.
  - Which
  - Where
  - Why

Hence, CTIS provide the overarching descriptors

- Descriptors which can be easily linked to other available data
- The development of a research agenda will help us to identify relevant data sources and motivate such data linkage
- May also raise awareness of essential data which cannot be linked for future improvements of existing databases

Challenge

How to support collaboration and awareness of the existing scientific knowledge for more impactful clinical trials - benefitting patients and healthcare in EU

Question: Is my research question/hypothesis currently being investigated or has it been in previous trials?

- Facilitating multi-site and multi-national clinical trials
- Ensuring that we build on existing knowledge

In addition, assessment of relevance in compliance with the Clinical Trial Regulation (Article 6)

The anticipated therapeutic and public health benefits taking account of all of…
- the relevance of the clinical trial, including whether the groups of subjects participating in the clinical trial represent the population to be treated…

Use-case: Is my research question/hypothesis currently being investigated or has it been in previous trials?

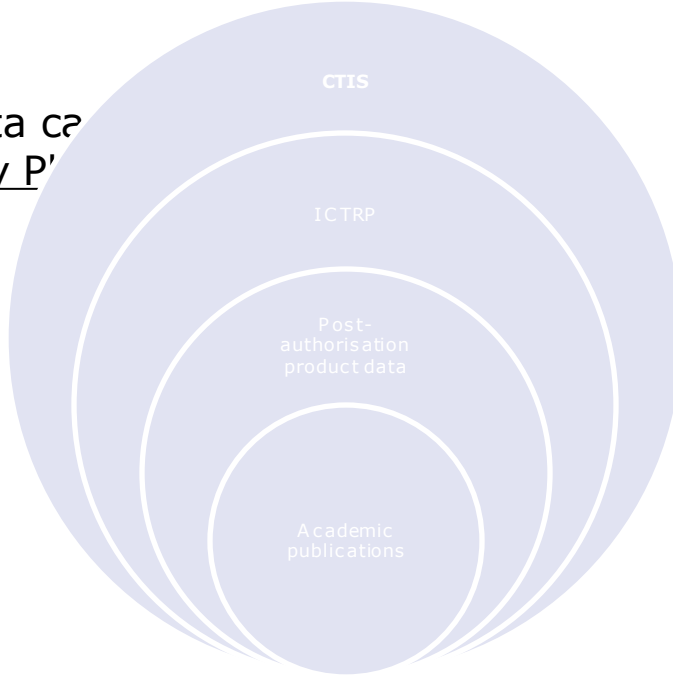
Types of data

CTIS data captures similar clinical trials in EU. Linked data ca
overview from WHO's International Clinical Trials Registry P

→*Facilitate collaboration*

CTIS results data together with additional data links with product data and academic publications

→*Enhanced capabilities for high quality assessments*



Data sources, non-exhaustive

CTIS: Investigational medicinal product being used, study designs, methodologies, endpoints, results and much more.

Marketing Authorisation Applications: Data from regulatory processes including their assessments and outcomes.

Pharmacovigilance databases: Adverse events and adverse drug reactions and repositories of established medicines safety information.

Real-World Data (RWD) sources: Encompasses EHRs, patient registries, health surveys, data from wearables, mobile health apps, insurance claims, etc.

Genomic and biomarker Databases: Genetic, proteomic, metabolomic and other biomarker data relevant to drug responses and diseases.

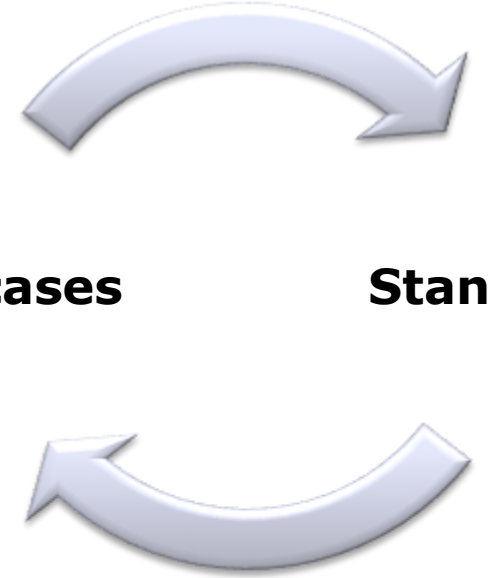
Individual Patient Data (IPD): Detailed data from clinical trial participants for in-depth analysis of treatment effects.

Research and innovation data: Academic research, proprietary datasets, funder databases and joint research projects.

And many more to be specified from the use-cases identified at this workshop

The use cases require data standardisation

- Establish requirements for structuring information



- Enable use cases by making data more accessible

Data standardisation

The process of creating a common language by establishing consistent rules for organising and formatting data. These rules facilitates interoperability and data integration.

- Making data easily shareable and understandable across various platforms

Use cases may rely on the work in ICH M11 (Clinical Electronic Structured Harmonised Protocol Template)

- Provides a comprehensive clinical protocol organisation with standardised content

This workshop is about the use cases important for you – the clinical trials ecosystem

Describing specific use cases from your area of work where data on clinical trials play, or could play, a crucial role?

- What is the significance?
- What is the needed data sources?

Most importantly, the benefits of using data from a patient perspective

Any questions?

Further information

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