efpia
European Federation of Pharmaceutical Industries and Associations

Vaccines Europe
An industry for healthy lives

EUCROF
European CRO Federation

ACRO
Innovate
Advocate
Collaborate

EuropaBio
The European Association for Bioindustries

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

# ACT EU Clinical Trials Analytics Workshop

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25-26 January 2024

# Session 2: Clinical trials data: present and future

- **Industry Use Cases for clinical trials data held in CTIS/EudraCT:**
  - What it has been helpful for?
  - What has been missing?
  - Which questions could I answer with better data access?
  - Potential future uses of the available data

- **Industry Use Cases for data sources beyond CTIS/EudraCT**

# Current uses of data held in EudraCT/CTIS

- **Used to interrogate (small numbers of) individual entries to inform study design or study feasibility:**
  - Has a novel endpoint been accepted before?
  - Has the intended patient population (age range, comorbidities etc) been accepted before?
  - Has a novel technology been accepted before?

- **Used to benchmark countries via available metrics:**
  - Expertise/capacity per country per phase
  - Expertise/capacity per country per disease area
  - Expertise/capacity per country per product type (e.g. ATMPs)
  - Attractiveness of EU for conducting CTs
  - Speed of assessment

# Current uses of data held beyond EudraCT/CTIS

- **European data sources used to inform the understanding of the disease or the medicine:**
  Some examples:
  - Drug A label expansion using Danish ITP registry,
  - Analysis of UK/German clinical databases to demonstrate no use of Drug B among women of childbearing age to inform pregnancy registry discontinuation
  - Historical comparator data from EU sites to support Drug C approval

- **Observational studies:**
  - many use cases of analysis of non-EU data sources
  - EU PAS register will become an increasingly important database of studies – especially with the increasing use of RWE in regulatory decision-making and Inclusion of study protocols posted by DARWIN EU coordinating centre: the forthcoming relaunch of it in a much more user-friendly format will be a huge improvement.

# Gaps limiting use of available data

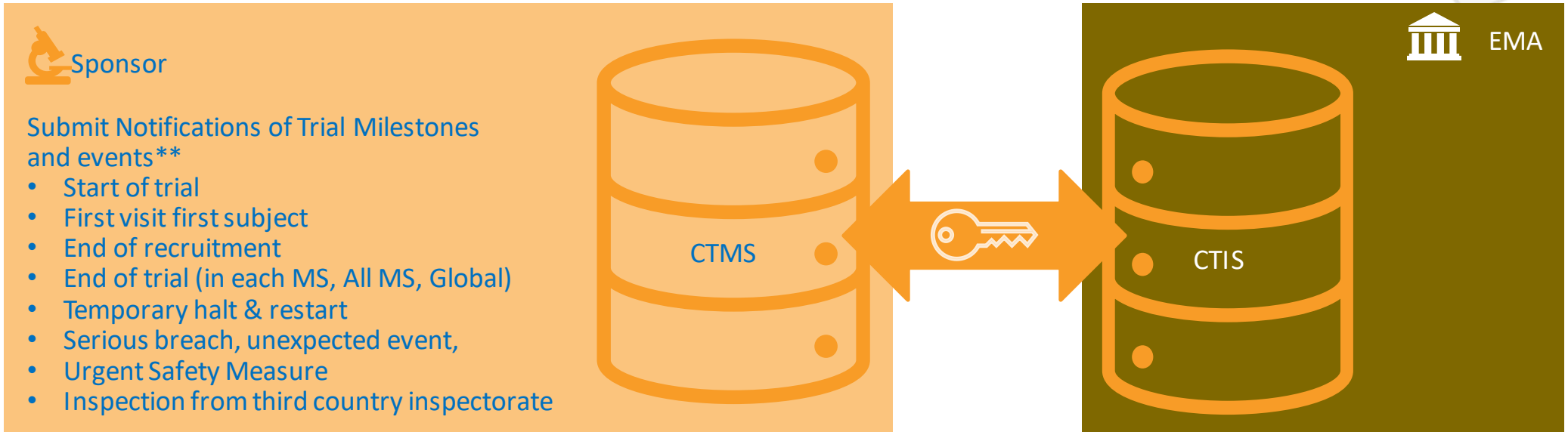
General awareness that the databases exist is low (e.g. patient organisations)

Not necessarily in data **quantity** but in **functionality and usability** of platforms

Summary results data not structured so currently of limited use.

Interoperability of sponsor data→CTIS database to ensure data quality and standardisation

# Future Vision: Direct link between Sponsor CTMS* and the Clinical Trial Information System (CTIS)




- To ensure the timely availability of data in CTIS and avoiding manual entries, a secured transfer of clinical trial milestone data from Sponsor CTMS directly into EMA - CTIS system would be beneficial.
- This will support the CTIS system as a powerful source for data mining and KPI trial metrics.
- Care will be needed when considering end-to-end processes with different database interactions eg CTIS requirement for CSR on MAA can link into CSR EMA requirements to avoid duplication of manual effort in uploading twice and protecting patient data (GDPR) and commercially confidential information(CCI).

*Clinical Trial Master System
**Source: CTIS structured data form - Notifications

# Future Vision: Standardisation of protocol data (ICH M11)

**Establishing digital standards will pave way to move away from "document centric" to "data centric" protocol development, thereby facilitating real-time alignment and automation of downstream processes.**

- One "digital source of truth" and no need to re-enter the data/information manually in downstream documentation/databases, avoiding mistakes, simplifying process, inspections, increasing transparency.

- Digital data and structured content management enable content reuse in other documents/systems: e.g. content is written only once and reused end to end in regulatory documents from protocol to label; protocol content can be reused automatically in training materials for the sites or populating automatically trial master file.

# Conclusions

- **Much of the information in EudraCT/CTIS is supplied directly by trial sponsors**

- **Current use of the available data is limited to:**
  - benchmarking or metrics generation
  - conducting targeted searches of approved trials

- **Future curation, standardisation, intra-operability and user friendliness enhancements will support:**
  - better public and HCP engagement with clinical research --> access to innovation
  - more efficient site selection and patient recruitment
  - more efficient data transfer between (global) systems and interrogation of the data (eg AI)
  - linkages to other data sources, boosting observational research in the EU
  - 'predictive safety' to enhance protocol design for safety monitoring and reporting
  - better understanding of both the IMP and the disease
  - more efficient regulatory oversight and monitoring of innovation
  - the continuum from clinical trial to marketing authorisation and new medicines for patients