More information

Clinical Study Data Submission in Europe: An EMA-CHMP proof-of-concept pilot

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Why this pilot?

The goal is to determine the **regulatory benefit** of submission and analysis of clinical study data in support of the marketing authorisation applications' assessment.

Expected Benefits

EU Patients

- Faster access to medicines
- Enhanced confidence in regulatory decision-making
- Refined product labelling

Network / EU Health Agencies

- Better understanding of clinical study results
- Fewer data interpretation questions
- Facilitation of cross-product analyses
- Inspections' optimisation

Applicants / MAHs

- Workload reduction due to fewer complex questions
- Better informed questions to applicants
- Shorter clock-stops

The pilot

In scope: initial marketing authorisation and post-authorisation applications submitted to EMA

Voluntary participation (applicants/MAHs and CHMP rapporteur teams)

Clinical Efficacy & Safety, PK/PD and GCP site selection analysis

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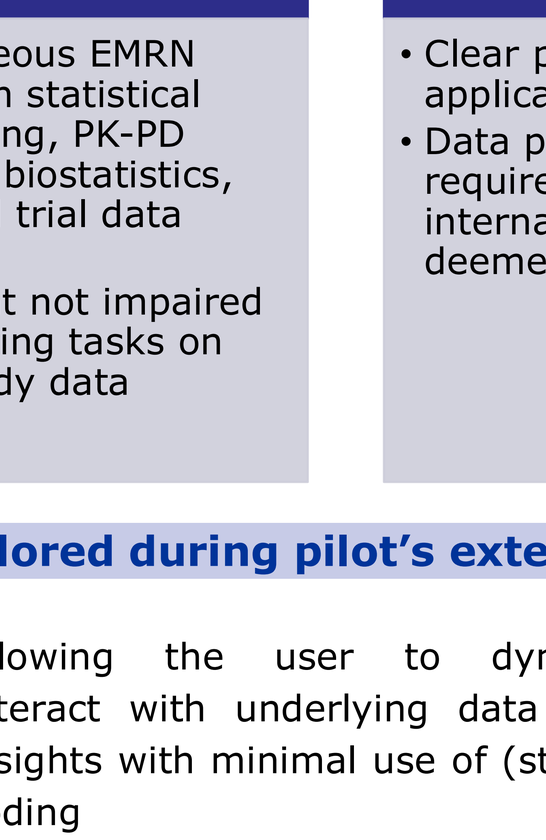
Procedures included



Clinical study data to comply **with CDISC standards** (SDTM, ADaM)

- SAS® XPORT transport file formats accepted as per FDA and PMDA
- Data definition files in CDISC Define-XML format required
- Other file transport formats such as XML or JSON could be considered

Software being explored

- Statistical analysis & visualisation
- Modelling and simulation
- Data validation

Selected pilot interim learnings

Added value for assessment and decision making

- Enhanced understanding of marketing authorisation application dossiers
- Better methodological consensus
- More efficient inspection processes
- Fewer questions to the applicants

Capacity and capability

- Heterogeneous EMRN expertise in statistical programming, PK-PD modelling, biostatistics, and clinical trial data standards
- Assessment not impaired by conducting tasks on clinical study data

Governance and processes

- Clear public guidance for applicants
- Data package requirements by other international regulators deemed suitable

Technical aspects

- Data receipt, storage and analytics infrastructure for EMRN will require optimisation to upscale
- Established off-the-shelf software options to be explored for all analysis objectives

Selected recommendations to be explored during pilot's extension

Benefit of Standardised analysis & visualisations

Allowing the user to dynamically interact with underlying data to gain insights with minimal use of (statistical) coding

- ✓ Preference for open-source tools like **R Shiny**® or similar
- ✓ Potential for future integration with EMA's data storage and analysis infrastructure

The pilot is open for new applications (no end date).
Express your interest via rawdatapilot@ema.europa.eu