Monitoring the EU clinical trials environment

MSP AG meeting, 12 March 2025

Presented by Jacobus van Wyk, EMA

Background

- **Focus** on monitoring the clinical trial environment in the EU, how a multitude of initiatives (ACT EU/COMBINE/Collaborate/MedEthicsEU, etc..) **contribute** towards the identified overarching benefits: **rendering the EU a favourable environment for clinical research**
- **Discussed** with working groups (CTCG, DG RTD, DG SANTE, EMA) at ACT EU extended trilateral and Steering Group
- Overarching benefits are **based on the ACT EU vision: faster, better and optimised clinical trials in the EU**
- KPIs and targets presented at the ACT EU MSP in October 2024
- KPI and targets identified for the first 2 benefits
- MSP AG views on the KPI for the third benefit are welcome

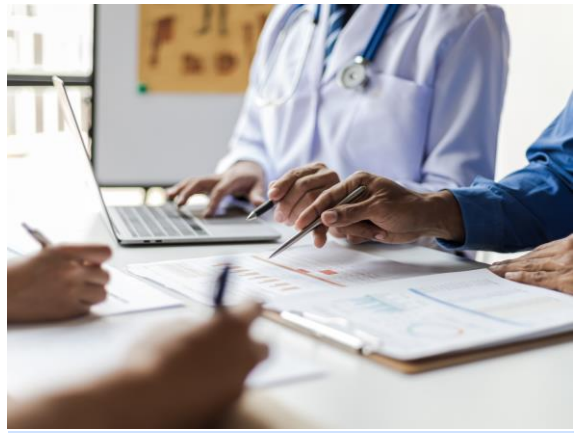
Benefits on an improved CT environment in the EU

Increased attractiveness of the EU

A favourable region for conducting clinical trials, with clear regulatory requirements & smooth collaboration between sponsors and Member States

Faster access to treatment

Fast treatment access to patients at the time of the clinical trial & also in the post marketing phase, when applicable



Impactful clinical trials

Having the best treatment options, supporting innovations and new methodologies

Increased attractiveness

Key performance indicator:

Number of authorised multinational clinical trials in the EU

Additional sub-metrics:

- Global trend on clinical trials in other regions
- Analysis of commercial/non-commercial sponsors per Member State
- Number of patients in the EU* vs number of patients worldwide
- Number of Scientific Advice in correlation with Request for Information (RFI)
- Number of first-in-human and/or first-in-class and Phase I studies

*Estimated number of patients

European Commission | EMA | HMA Heads of Medicines Agencies

Faster access to treatment

Key performance indicator:

Time from submission of CTA to start of patient recruitment at the site of the first MSC (stratified by mono/multi-national trials)

Additional sub-metrics:

- Time from submission of CTA to authorisation
- Time from start of recruitment to end of recruitment and end of trial
- Time from submission of the CTA to end of trial
- Measuring estimated duration of trial vs real duration
- Time needed to stipulate site contracts
- Time between end of trial and a Marketing Authorisation Application (MAA)
- Time from submission to the start of recruitment per Member State

Impactful clinical trials: your feedback requested

Key performance indicator:
Proportion of EU clinical trials whose results are included in MAAs

Additional sub-metrics:

- Number of clinical trials in the EU that reach a MAA
- Number of participants per clinical trials phase
- Number of clinical trials that do/not reach recruitment goals
- Trial population representing target population
- Number of clinical trials that don’t run until completion/early terminated
- Number of clinical trials with decentralised elements/complex clinical trials
- Clinical trials and medical devices
- Number of repurposing trials (previously under attractiveness)

- KPI measurement needs to be reliable and reproducible over time
- Different options are being considered for measurement, including a composite approach where different parameters are measured and not an individual KPI
- Input from MSP AG is welcome
- Feedback on this benefit/metric through slido*

*Responses are anonymous. If you wish to share personal data this is at your discretion. Personal data will be handled according to EMA's data protection notice (link).

Accessibility of the information and reporting

European Medicines Regulatory Network

- Dashboard in secure domain accessible to the regulatory authorities

ACT EU Steering Group, ACT EU Matrix, CTCG, other EMRN bodies

- Quarterly reports

Public

- Quarterly – KPIs and new metrics to complement the already existing KPI reports published on ACT EU website

Thank you

ACTEU@ema.europa.eu