



Monitoring the EU clinical trials environment

MSP AG meeting, 12 March 2025

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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





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 \(link\)](#).

A photograph of a laptop keyboard and a calendar with pushpins. The keyboard is silver and black, showing keys like C, V, B, N, M, and command keys. The calendar is white with a grid for days of the week and dates, with several pushpins (blue, yellow, white) placed on it. The background is a solid blue color.

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

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