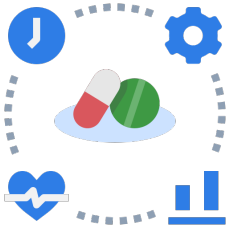
From the theory to the practice, how will we measure success?

Annual ACT EU MSP meeting, 22 October 2024

Building on the ACT EU Vision statement

The **vision of ACT EU** is to make the European Union an **attractive region** for clinical research, enabling **more impactful clinical trials**, with **seamless coordination** among regulators, ethics committees and impacted stakeholders.



ACT EU envisions **smart clinical trials**, that are **meaningful** to the research community and patients, through regulatory, technological and process innovation. The new clinical trial ecosystem will **foster collaboration** by empowering, engaging and supporting **stakeholders**

Focus is on **monitoring** the clinical trial environment in the EU, and how **a multitude of initiatives** in place (ACT EU/CTAG/COMBINE/CTR Collaborate/MedEthicsEU) contribute towards **3 overarching benefits** of rendering the EU a favourable environment for clinical research

Benefits of an improved CT system in the EU

Increased <u>attractiveness</u> of the EU, to be seen as a favourable region for conducting clinical trials, with clear regulatory requirements and smooth process of collaboration between sponsors and Member States

<u>Faster access to treatment</u>, including fast treatment access to patients at the time of the clinical trial but also in the post marketing phase, when applicable

<u>Impactful</u> clinical trials, having the best treatment options, supporting innovations and new methodologies

A few design principles in monitoring

- Only present metrics that can add value to the discourse
- Present time series metrics as such and not as a single number when tracking performance
- Aggregate metrics in reports with a view to the intended user and deliver in a way that is fit for the user group (method and frequency)
- Keep on refining, but also release when ready – have a process

Measuring the benefits – various metrics

Increased attractiveness

⇩

Number of authorised multinational clinical trials in the EU and sub-metrics

Faster access to treatment

⇩

Time from submission to end of trial and other sub-metrics

Impactful clinical trials

⇩

Number and timing of CTs that reach MAA and sub-metrics

ANY QUESTIONS?

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