ACT EU MSP: July 2024

PA2: CTA review process and CTR implementation

4 July 2024

Introduction

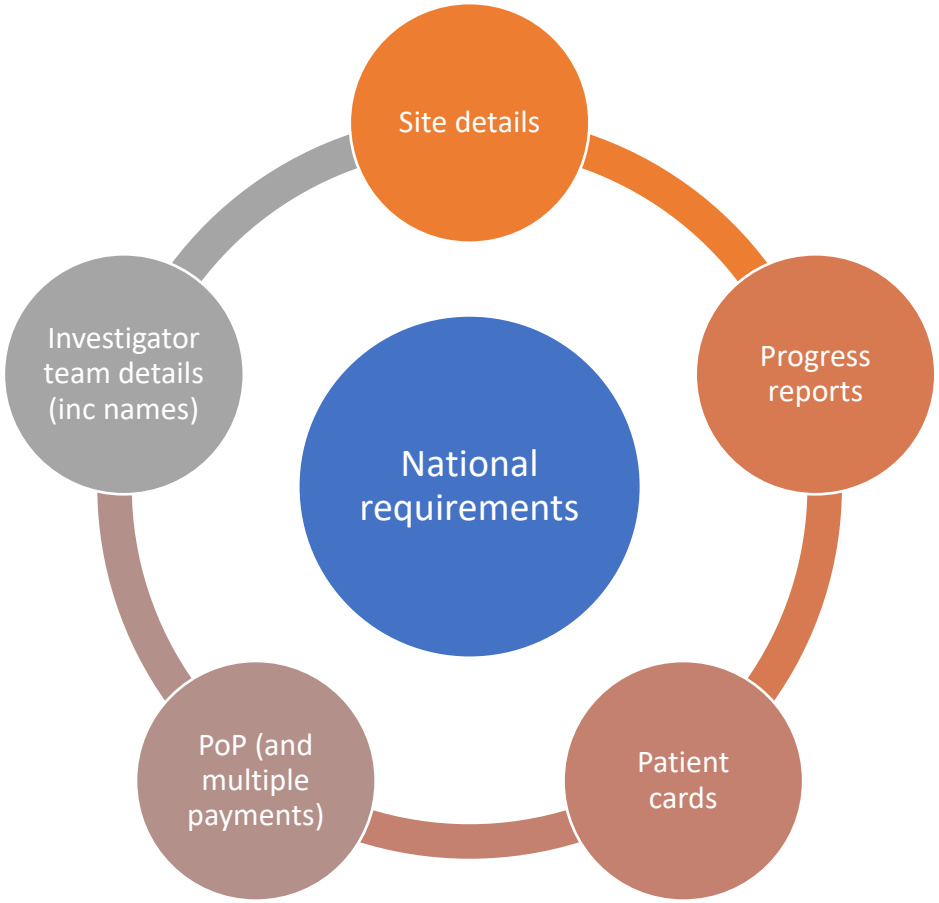
Overarching goals of the EU CTR:

- To ensure that the EU offers an **attractive and favourable environment** for carrying out clinical research on a large scale, with high standards of public transparency and safety for clinical trial participants.
- To **harmonise the processes for assessment and supervision** of clinical trials throughout the EU, facilitating the conduct of larger clinical trials in multiple EU Member States/EEA countries.
- To **foster innovation and research** in the EU.

These link with the ACT-EU vision for :

***Better**, **faster**, **optimised** clinical trials: Improving the clinical trials environment in the European Union through harmonisation, innovation and collaboration with stakeholders*

Issue



Example Impact

Bespoke application for each MS!

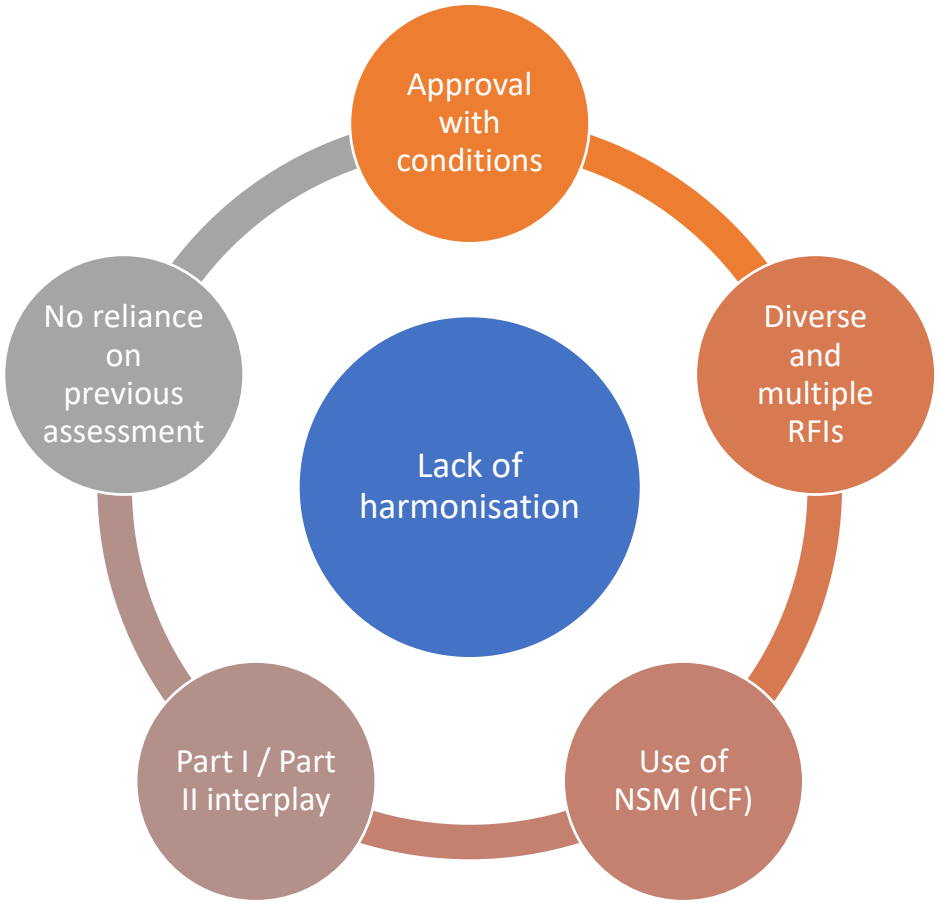
Relation to ACT EU

Does not meet ACT EU objective of increasing multi-country trials in EU

Does not support ACT EU vision of enabling collaboration and innovation at all stages of the clinical research lifecycle

Need to agree on common requirements limiting / eliminating the current national flexibility for requirements beyond CTR.

Issue



Example Impact

Unpredictable outcome of validation and assessment!

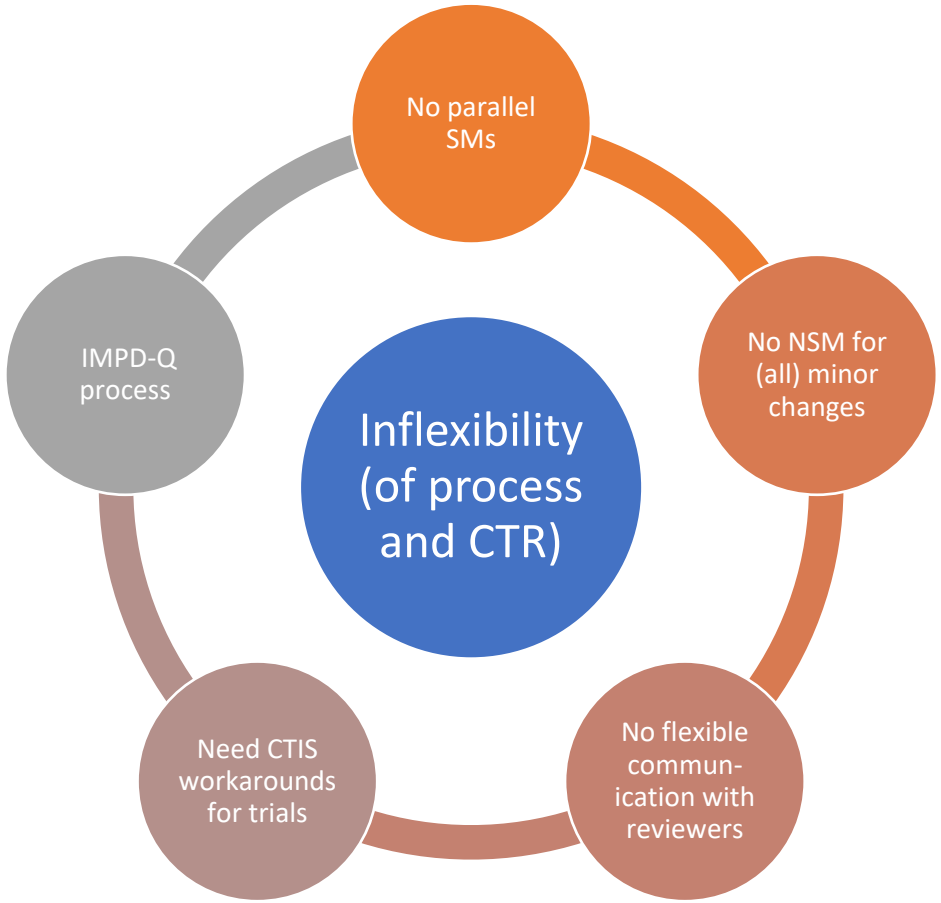
Relation to ACT EU

Does not meet ACT EU objective to reduce administrative burden

Does not promote seamless coordination among stakeholders, regulators and ethics committees

Need to streamline the process(es) and reduce the current lack of predictability, by strengthening the role of the RMS, allowing consistent use of currently existing as well as new efficiencies / flexibilities, and applying a risk-proportionate approach for review.

Issue



Example Impact

Difficult to run innovative trials in EU!

Relation to ACT EU

Does not meet ACT EU objective to support smarter clinical trials through regulatory, technological and process innovation.

Does not meet ACT EU objective to support Multinational clinical trials by non-commercial sponsors

A truly holistic and future-ready approach to improving the EU regulatory framework for clinical research is needed. Further flexibilities should be applied, while CTIS also requires improvement, including allocation of new capabilities.