# Problem statement

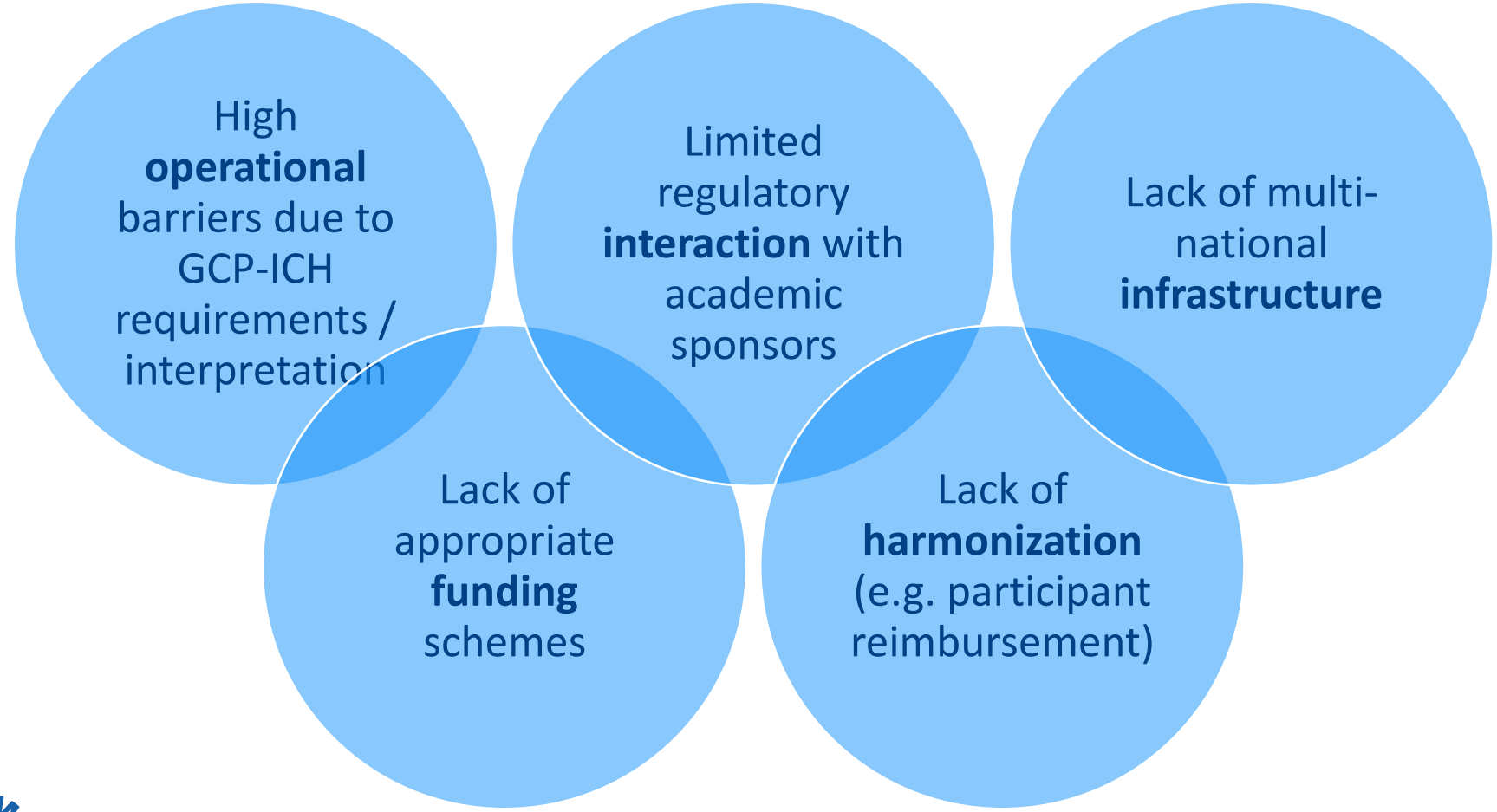
**It is becoming increasingly challenging to perform multi-country Investigator Initiated Trials in the EU.**

Nevertheless, these trials are crucial for :

- improving patient care in the European context,
- retention of scientific excellence in the EU,
- driving innovation in clinical trials,
- continuing as a relevant area for industry sponsored clinical trials.

UMC Utrecht
Mira Zuidgeest, Associate Professor Clinical Trial Innovation

# IIT challenges- mixture of regulatory and operational issues

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# Ask: ACT-EU to facilitate the conduct of multi-country IITs & remove barriers by a combination of the following:

**Regulatory**

Drive paradigm shift from registration trials to clinical implementation trials needed for IITs

- Provide sandbox environment for simplification and cost reduction of IITs, regarding e.g. outcome adjudication, decentralisation, pragmatic approaches, EMR based trial
- Provide (joint) scientific advice opportunities for academic sponsors
- Align revision & interpretation of GCP ICH with academic trialist

**Operational**

Support academic trialists in the set-up of IITs

- Facilitating funding of IITs (e.g. funding of pilots)
- Develop CTIS training package for academia
- Providing uniform EU template for smooth cross boarder multi-country Investigator Initiated Trial collaboration