Break-out session 4

Enhancing CTIS Functionality and Operational Efficiency

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Key Topics

- Blocking issues in CTIS, especially substantial modifications and RFIs for large clinical trials.
- Important improvements for technical limitations of CTIS (e.g. technical solutions for innovative trials, document submission, metadata, display and download, article 11 partial submission workaround).
- Functionalities to ensure efficient and transparent communication between sponsors, RMS and Member States.

Blocking issues

- Loss of information (data and documents) in applications or responses or information not visible.
- Duplication of applications by CTIS –> incorrect ones need to be found and erased → problem if already actioned on.
- Inability to submit notifications on halted trials (e.g. serious breaches).
- Inability to submit subsequent applications for trials with large number of documents.

Delaying and burdensome issues

(that can become blockers)

- Scalability issues (managing user management, sponsor supervision and archiving obligations when the number of trials increases)
- Bugs with timelines and timetable.
- Sponsor supervision limitations (lack of audit trail, limitation in notice & alert accuracy…)
- Lack of interplay of CTIS with TMF filing obligations (resource heavy work arounds in order to extract trial activites from CTIS to adequately document them in TMF)
- List of known issues not helpful if there is no solution yet or soon to be expected
  → could be enhanced with e.g. „Ignore" recommendation for repetitive reminders
- CT admins should have the same rights in case of a resubmission after a rejection (when increasing the last digits e.g. from 00 to 01)

Important improvements for technical limitations of CTIS

- Overview on conditions Part I and Part II
- Only visualize the new/uploaded docs applicable to the planned SM/NSM
- More conclusive information in error messages.
- Messaging system outside of CTIS to be notified of important timepoints.
- Improve download functionality e.g. download of documents with metadata.
- Soften up hard timers (especially Part I conclusion [not tacit], Submit RFI response)
- To allow for most of documents to be updated via NSM while the same part is under evaluation.

Future and innovative improvements

- Communication tool from sponsor to MSCs (NCA or EC) within CTIS (for clarifications).
- Reference to other databases repositories (e.g. for PIP or SciAdv).
- Keeping information separate between groups within CTIS (quality, blinding).
- Multi-SMs for Part II.
- Parallel submissions for SMs of the same part.
- Access to API code for sponsors to integrate CTIS and sponsor IT systems.
- Rethink Part I vs. Part II (core vs. country/translation).
- Restructure CTIS to allow product centric (IND-like) trial management with possibility to link to individual sponsor trials (alternative to IMPD-Q-only)