

Sponsor's perspective on transition of on-going trials to CTR/CTIS

The view of a non-commercial sponsor

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Sponsor

A **sponsor** takes responsibility for the initiation, for the management and for setting up the financing of a clinical trial.

The **sponsor remains ultimately responsible** for ensuring the **safety** of the subjects and the **reliability and integrity** of the data generated in the clinical trial.

Delegation agreement

The sponsor may **delegate trial-related tasks/functions** to an individual, company, institution or organization

Investigator Initiated Trial: MUI acts as sponsor and **transfers sponsor responsibilities** to PI or other qualified person (= sponsor representative) after they have passed a mandatory internal training.

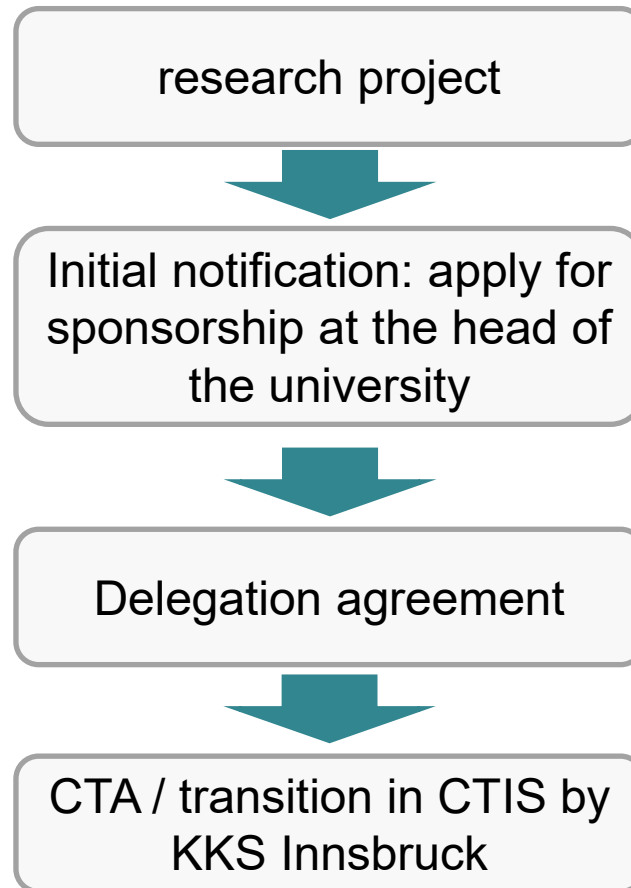
Nevertheless, there are tasks which will be centrally managed by KKS (monitoring reports, project status, recruitment status, protocol deviations etc.)

Delegation agreement

Central management by KKS Innsbruck:

- Submission / Transition of a CTA including life cycle management and reporting of serious breaches
- Management pharmacovigilance and safety reporting

Authorization process



KKS Innsbruck

Head of KKS

- Super User, High-Level Sponsor Admin

8 CRAs

- trained in CTIS
- CT Admin roles
- responsible for application (part I and part II)

2 vigilance management representative

- responsible for safety reporting
- ASR

KKS Innsbruck

1 Quality management associate

- Internal audits: each trial will be audited at least once

MUI oversight:

- Status reports
- Central CTIS regulatory life cycle management
- Transparency obligations

Preparing for CTIS

A variety of helpful information to get started is available:

- Online training modules (CTIS Sponsor training, CTIS Walk-in Clinics, CTIS informational webinar, self training with CTIS training environment)
- European Commission's Questions and Answer documents on CTR
- European Commission's Guidance for the Transition
- CTIS Handbook for clinical trial sponsors / Sponsor quick guides
- External trainings on CTIS (commercial providers)

Preparing for CTIS

1. Organisation registration in OMS (ORG-ID for MUI)
2. Create EMA account
3. User management
 - High-Level Sponsor Admin
 - CT Admin
4. Preparation of SOPs to define a quality standard for the proper submission of clinical trials through CTIS
5. Preparation of templates according to EudraLex Vol. 10

Clinical study registry

The sponsor is obliged to report the conduct of the clinical trial to the Medical Director **before** it begins and after it **ends**.

(according to national law (TirKAG and AMG))

Every clinical trial conducted at the MUI or Tirol Kliniken (hospital) needs to be registered in the **clinical study registry**.

MUI as sponsor

The Medical University of Innsbruck as sponsor for **non-commercial clinical trials**:

- Since 2009: 76 clinical trials on medicinal products
- Since 2009: 76 clinical trials on medical devices
- Transitional trial in CTIS:
 - 5 planned, 2 in submission (mononational trials)

Essentials for transition

- Duration of the trial – transition needed?
- Substantial amendment planned before transition?
- Deputy PI?
- Strategic choice of submission date to react to RFIs

The clock is ticking

All trials which are expected to **continue after 30 January 2025** need to be transitioned.

Recommendation: submit application at the latest **16 October 2024**

Intern: End of August as final date for transition

Which steps to take for transition

1. Preparation of a „transitioning application“

- Preparation of documents
 - Redaction of public documents
- Check if metadata has been removed from documents
- Name documents according to the naming convention
- Blank documents (“placeholders”) for mandatory documents besides the minimum dossier

Which steps to take for transition

2. Prepare transition trial and upload documents

- Four-eyes principle
- Submission after final check – MUI oversight

Technical requirements

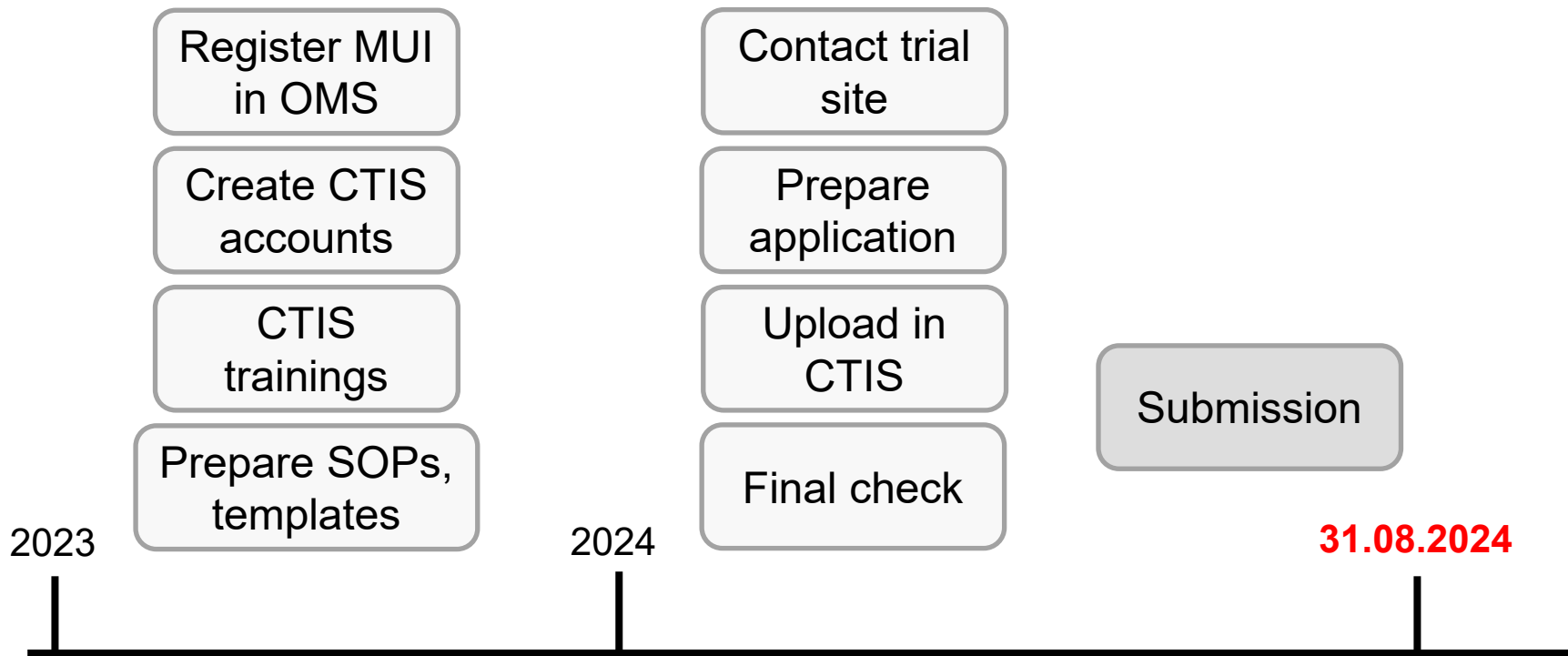
- Chrome as internet browser
- PDF viewer and Word need to be installed on PC/laptop
- Windows recommended
- Two factor authentication to log into CTIS

Minimum dossier documents

Mononational clinical trials:

- Cover letter
- GDPR statement
- Protocol
- IB
- GMP relevant documents
- IMPD
- Documents related to non-investigational MPs
- ICF
- Subject's Information Sheet

Timeline for transition



Benefits of CTIS?

- Good oversight for academic sponsors
- Harmonization of the application for multinational trials
- Harmonised application procedures
- Single point of entry
- Easy access to clinical trial information for patients, scientists and general public

Resolved issues

- Duration of trial: prolongation of the trial does not need to be approved by EC/NCA before transition (is a fictive date)
- Substantial amendments to the trials should be approved before transition

Personal advice

- Learning by doing!
- Plan enough time to update/prepare documents
- Plan enough time to prepare and submit a CTA
- Remove metadata in redacted documents
- Ask questions – everyone has the same problems when starting with CTIS

Thank you for your attention!

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