

General process for Clinical Investigation division

Customer

CTU Bern

Contact

- Contact CI via phone +41 (0)31 632 34 57 or email clin-invest@ctu.unibe.ch

Request Services

- Discuss/Outline requested services by CI
- Send available information on study (protocol, CRF etc.)

Costing

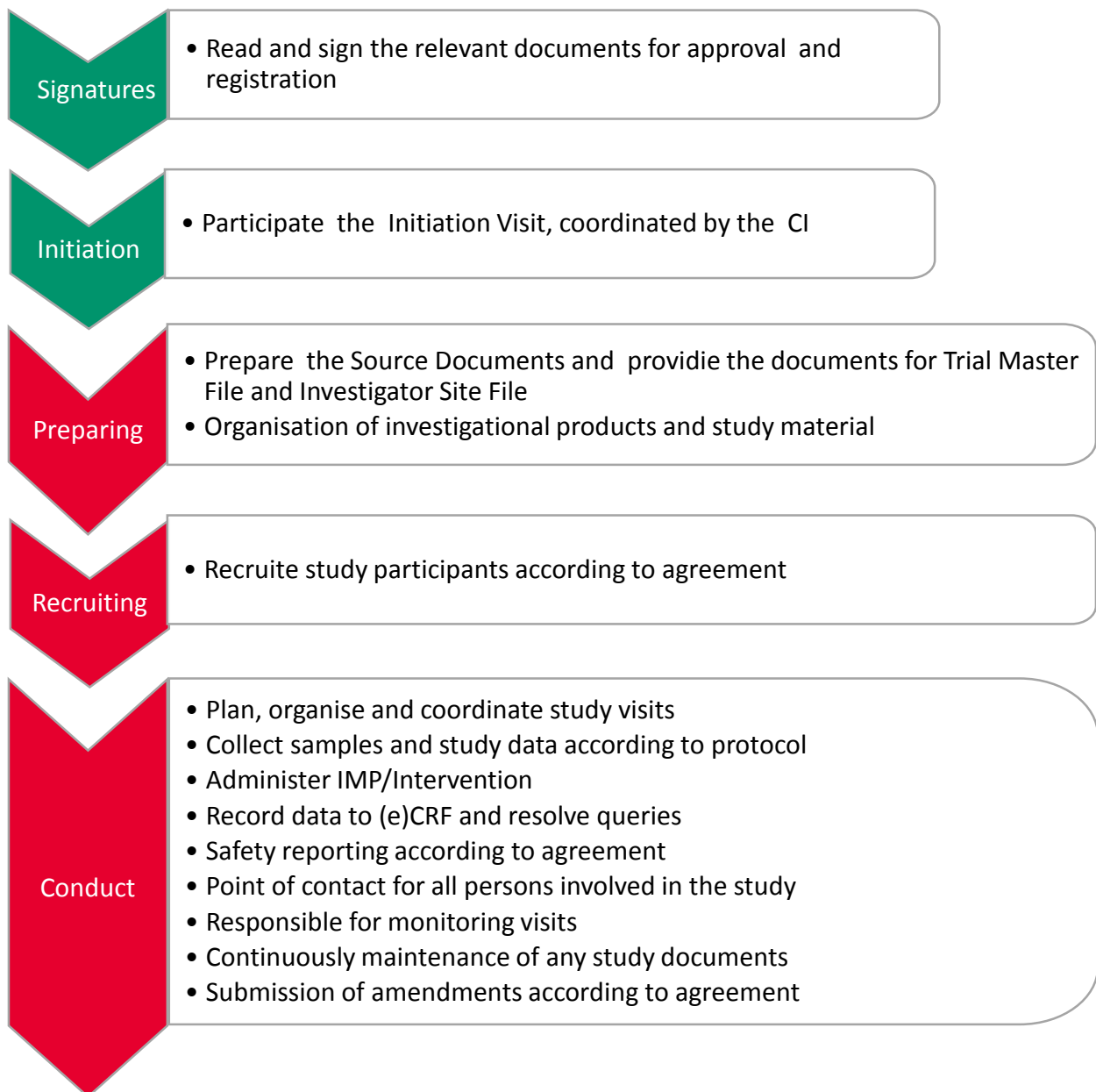
- CI prepares a costing
- Head of division CI contacts you

Agreement

- If you agree, CTU prepares an agreement and sends it to you for review and signature

Preparing Submission

- According to the requested services the CI prepares the submission to EC, swissmedic and the registration to Inselspital



Conduct

- Responsibility for the study according to HFG and GCP
- Recruit study participants according to agreement
- Check eligibility criteria
- Clinical Visit, prescription of medication
- Safety reporting

Study Closure

- Sign the verified (e)CRF
- Sign the relevant logs
- Communicate to the authorities

Study Closure

- Coordinate and organise the Close out Visit and participate
- Sign off the study at Inselspital

Archiving

- Archive the study documents according to the specifications by law