Instruction sheet Verklaring Geschiktheid Onderzoeksinstelling (VGO)

VGO-form: is the site suitable?

- Investigator would like to participate in a study and the protocol is (pre)final.
- Sponsor provides VGO with completed attachments, if available (concept) manuals.
- Departments therefore know what the protocol requires of them and when.
- Departments declare if they *can* do this (preliminary scope of work arrangements).
- (Mandated) BoD signs VGO (preliminary agreement).

parallel process

Submission METC

- Sponsor submits clinical trial application.
- Including VGO of every selected site and CV of Principal Investigator.
- VGO attachments are *not* submitted.
- Sponsor shares submitted study documentation with investigator in accordance with DCRF Local Feasibility Checklist (Lokale Uitvoerbaarheid).

Request for information EC

- Sponsor responds to findings.
- Sponsor keeps investigator/ institution informed of changes relevant to local feasibility during review period.
- Sponsor shares modified final document versions with all investigators.
- Finalizing scope of work arrangements and budget based on final study documents.

Local feasibility (Lokale uitvoerbaarheid)

(follow DCRF Local Feasibility Checklist)

- Participating study sites will further develop preliminary arrangements.
- Scope of work arrangements: manuals available, training, scheduling.
- Documents: contact details ICF, standard contract (CTA), etc.
- Financial: arrangements: edit internally and with sponsor.
- Local document management in systems.

Contract/ CTA and finalize local feasibility

- In this step, the institution decides on final participation.
- CTA negotiation will be completed after round of EC questions.
- If applicable: think about other contracts (e.g., grants).
- Local feasibility is finalized.
- (Mandated) BoD signs the CTA[1].

EC approval and study start

- The following signed documents are linked and required for study start: VGO + CTA* + EC approval.

  * Excluding investigator initiated mono-center study: if no CTA is used, BoD approval letter is sufficient.

[1] In parallel with signing of the CTA, additional verification by BoD, local committee, or other body may take place at local level. This should not delay the process.

DCRF Dutch Clinical Research Foundation