Local preparation for start-up clinical trial - sites/sponsor – *belonging to CTR-VGO process regarding clinical drug research according to the Medical Research Involving Human Subjects Act (WMO)*

General remark: when sending draft documents, we advise the sponsor to clearly state that the documents are draft documents to prevent that incorrect documents are used by the research centers.

Documents to deliver locally before submission as part of the VGO process by sponsor:

Section	Documents	When to provide
C1	Study protocol *version to be submitted to the MREC*	Upon delivery VGO
I2	Site Suitability Declaration (Verklaring Geschiktheid Onderzoeksinstelling, VGO), incl. global budget)	As soon as possible after Site selection

To be supplied to sponsor prior to submission - by investigator/research center:

Section	Documents	When to provide
I3, 4	Resume Principal Investigator own research center	Before submission CTIS portal
	Declaration of Interest (Available on CCMO.nl)	Before submission CTIS portal

Documents to be delivered locally after VGO process for completion of local process for research centers - by provider:

Section	Documents	When to provide
B1	ABR-form or comparable alternative from CTIS *if available*	After submission and again immediately after question round[1]
C1	Study protocol	After submission and if modified final version after question round [1 2]
D1	Investigators Brochure	After submission and if modified final version after question round[1]
E1/E2	Subject Information Sheet (SIS) and Informed Consent Form (ICF) *incl. local details and logo*	After submission and final version after question round (potentially draft documents can be shared at an earlier stage)[1 2]
I3, 4	Resume Principal Investigator own research center[3]	When available, at the latest immediately after question round [1]
	GCP certificate principal investigator own research center[3]	When available, at the latest immediately after question round [1]
K	Clinical Trial Agreement, incl. final budget *In the absence of a research contract, written permission for the execution of the research must be granted by the Executive/Managing Board*	When available, discuss draft , final version immediately after question round[1]
	Manuals for supporting departments	When available, at the final version immediately after question round(potentially draft documents can be shared at an earlier stage) [1]

To be delivered locally a.s.a.p. after MREC decision:

Copy of the primary reviewing MREC/CCMO decision, including appendix with approved documents.[2]

What happens locally?

In parallel to the MREC assessment the verification of local feasibility occurs by means of the local feasibility checklist. The latest version of the local feasibility checklist can be downloaded from the DCRF website. The sponsor shares the submitted documents and subsequently after the question round, the final documents with the participating sites, so there is sufficient insight into the final form of the study so the institutions can prepare for the actual local implementation. This involves checking within the site whether:

- the ICF contains the local information
- the principal investigator is suitable according to local requirements,
- operational and financial agreements have been finalized
- working documents have been developed

Caution:

This checklist pertains to the initiation of clinical trial and not to the maintenance of the Investigator Site File (ISF) during the study. The Investigator, conform GCP, has the responsibility to maintain the ISF and the method will vary from study to study. The above mentioned documents are needed to finalize the local feasibility procedure at the research center and to proceed with the signing of the CTA (After the initial question round, the signing process can start based on the final protocol).

[1] This means: the latest versions of documents that are submitted to the METC for final assessment in drug studies via the CTIS portal. This concerns the commencement of the last assessment period of maximum 19 days at the MREC; so this is (immediately) after the MREC question round.

[2] If the protocol and/or the information letter are approved on condition that a (minor) adjustment is made, these documents must be submitted again to the participating centers after the adjustment.

[3] These documents can be supplied by the investigator.