1. Technical instructions for registering a new clinical study in ClinicalTrials.gov

- A copy of the ethical approval/application or other agreement confirming KI is the responsible registrant for the clinical study should be sent to CDO prior to registration. Copies should be sent to compliance@ki.se.
- Once CDO confirms KI is the responsible registrant, researchers will receive a confirmation email and can then begin registering their study.
- Log into ClinicalTrials.gov using "KarolinskaI" as the organization.
- Select on 'New Record' in the Quick Links on the left side of the page.
- A protocol registration form will generate.
- Complete the necessary fields and select 'Entry Complete' (the green button at the top left under the 'Record Summary' page).
- The lead researcher (PI) must then log in and review the study.
- Once reviewed, the lead researcher (PI) must select 'Approve' (same green button as in the step above).
- The lead researcher (PI) must then select 'Release' (green button).
- The protocol registration will be sent to NIH for review.
- NIH takes 2-5 business days to approve a study registration.
- The clinical study will then receive an NCT ID number from ClinicalTrials.gov.
- If NIH has comments on the protocol registration, the lead researcher (PI) must log in and correct it, and then complete the steps 'Entry Complete', 'Approve' and 'Release' again.

2. Technical instructions for registering a new clinical trial in EudraCT

- A copy of the ethical approval/application or other agreement confirming KI is the Sponsor for the clinical trial should be sent to CDO prior to registration. Copies should be sent to compliance@ki.se.
- From the log in page, select EudraCT number.
- Complete all required fields and select 'Get EudraCT number'.
- The EudraCT number will be generated on the page and sent via email.
- A 'Clinical Trial Application' must be completed.
- Select 'Create' and then 'Clinical Trial Protocol'.
- Select 'EEA CTA'.
- A protocol registration will generate.
- Complete all required fields.
- Select 'Create'.
- Review information and select 'Validate'.
- Save the CTA as xml-file and then pdf-file.
- Complete a Submission Package.
- Select 'Package'.
- Create Submission Package for MPA.
- Select 'Save'.
- Create Submission Package for Swedish Ethical Review Authority.
- Select 'Save'.
- Submit CTA package to MPA via Eudralink or email.