Overview: what do I need to do as a sponsor / CRO?

1. You apply for an EDGE number through the link https://www.uza.be/apply-new-projectstudy (discuss in advance with the department you work with whether they already did this).
    a. **Notice**: as a staff member of the sponsor / CRO, you will not receive access to EDGE. The EDGE-number can only be created if a UZA representative has access to the study / project.
2. As soon as you have an EDGE-number, you could start 5 different flows which will run analogously (legal department, DPO, budget…).
3. Three flows (legal department, Biobank and GDPR / DPO) will be started by sending 4 documents to ctms@uza.be:
    - Draft contract
    - ICF (informed consent – in all languages)
    - Protocol
    - eCRF (a blank print-out is accepted)

    Notice: please mention the EDGE-number of the study when sending these documents.
    Only after receiving these 4 documents (all combined in one e-mail), we can start the flows and the CTC (= Clinical Trial Center) will send the documents to the involved departments (Biobank, legal department, DPO).
4. The 'Budget' flow starts with sending the budget proposal to the departments. The involved departments negotiate the price for the activity performed by the department in the study. The UZA departments send their approval by e-mail to the sponsor / CRO in regard to the agreed budget. When you received all the approvals of all the individual parts of the budget, you send these approvals (the e-mails wherein the departments give their approval) with the budget to ctms@uza.be.
5. The flow 'Ethics Committee' can be started as soon as you have all the required documents.
    a. Read here the SOPs for the Ethics Committee (in Dutch): https://www.uza.be/sites/default/files/uploads/sop_ethisch_comite_versie_6.9_-_goedgekeurd_dd._06.05.2019.pdf
    b. Contact information Ethics Committee: https://www.uza.be/ethics-committee-uza
6. The departments further consult with the sponsor / CRO (e.g. legal department, involved UZA departments, DPO…).
7. Once you received the approval of the following parties, you send a final, approved and cleaned WORD-version (with version number) of the contract to the CTC (ctms@uza.be):
    a. Legal department for the contract
    b. DPO for the GDPR form (the DPO will give his approval to the legal department, not to the sponsor / CRO)
    c. Biobank for the use of samples
    d. CTC in regard to the budget
8. After the check-up, the CTC sends this WORD-version to the legal department, who draws up the final contract and sends it to you. The final contract will be delivered in pdf.
9. All involved departments sign the final contract.
10. When signed by all the involved parties, you send the contract to ctms@uza.be.

More information: https://www.uza.be/clinical-studies

Consult the workflow in more detail: https://www.uza.be/sites/default/files/uploads/extern_v0.2_-_eng_-_proces_aanvraag_klinisch_onderzoek_bij_het_ctc.pdf