

## GUIDELINES FOR THE SPONSOR

### Clinical Trial Center

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#### Register your clinical trial via the Clinical Trial Management System (CTMS).

Go to <https://azsintjan.myresearchmanager.com/> and request your login via “**Log on or request an account.**”

Make sure you have the **complete study file** ready when submitting your application.

Under “workflow (in English)”, you will find **CTMS instructional videos** that guide you step-by-step through the submission process.

## Feasibility

### Below you can find guidelines regarding the content of a CDA/NDA:

- The CDA should take either of two forms
  - a **two-party** agreement, where the sponsor and the principal investigator, as an independent physician affiliated with the institute, are included as parties;
  - a **three-party/tripartite** agreement, which includes the sponsor, the institute, and the principal investigator as an independent physician affiliated with the institute.

The same design applies to service providers where an independent physician is the head of the department. Pharmacy is an integral part of the institute, but co-signs for notice.

- It is always important to include the following clauses in the CDA/NDA (see below)
  - Regarding the self-employment of the physician/investigator

*"This Confidentiality Agreement ("Agreement") is made effective as of the "Effective Date", by and between [sponsor/CRO], itself and on behalf of its Affiliates, a [type] corporation with a place of business at [address]. (hereinafter referred to as "Company"), and **AZ Sint-Jan Brugge AV with an address at Ruddershove 10, Brugge, 8000 Belgium, legally represented by [name General Director], General Director (hereinafter referred to as "Institution") and Dr. [name physician], a self-employed [type of specialisation] with a place of business at the Institution (hereinafter referred to as "Investigator")**. Institution and Investigator are hereinafter jointly referred to as "Receiving party"."*

- Regarding data protection

*"As some [name sponsor/CRO] studies are being conducted worldwide, the personal information collected may be transferred outside the European Union to the United States and other countries that may not provide the same level of data protection as the European Union. In order to provide for the protection of personal data, [name sponsor/CRO] has established policies and procedures governing the security of and limited access to this data that are uniform throughout [name sponsor/CRO] and its affiliates and comply with all applicable national and European data protection rules and legislation including the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, "GDPR"), Belgian law of 30 July 2018 on Privacy Protection in relation to the Processing of Personal Data and the Belgian law of 22 August 2002 relating to patient's rights. In accordance with the laws pertaining to the protection of personal data, the individuals whose data are collected have a right to access, to modify, to rectify, and to suppress their personal data. This agreement does not have a specific expiration date, but the information collected will not be kept for longer than is permitted by applicable law. Individuals whose data are collected have a right to lodge a complaint with the Data Protection Authority in their member state if they believe their data protection rights are infringed, by first contacting [name sponsor/CRO]."*

- Regarding law and venue

*"All issues, questions and disputes concerning the validity, interpretation, enforcement, performance or termination of this Agreement, and any non-contractual obligations arising out of or in connection with it, shall be governed by and construed in accordance with Belgian law, excluding its conflicts of law provisions.*

*The Parties shall attempt to settle all disputes arising out of or in connection with the present Agreement in an amicable way. Any dispute concerning the validity, interpretation, enforcement, performance or termination of this Agreement, and any non-contractual obligations arising out of or in connection with it, shall be submitted to the exclusive jurisdiction of the Courts of Brugge or the Brugge division of such Courts."*

- All parties included in the agreement must also sign it.
  - In case of a two-party agreement, the PI signs for his own responsibilities or thus "on behalf of". Revision of the CDA/NDA by the Clinical Trial Center is then not an obligation.
  - In case of a three-party agreement, revision by the Clinical Trial Center is mandatory. To do so, please submit your CDA/NDA at [ctc@azsintjan.be](mailto:ctc@azsintjan.be).

## Administrative start-up of a clinical trial

### Registration through the Clinical Trial Center

Every clinical trial - whether it is retrospective or prospective in nature - must be registered with the CTC prior to submission to the ethics committee.

With the Clinical Trial Management Software in place, we ask that you register your study electronically via <https://azsintjan.myresearchmanager.com/> and request your login via "Log on or request an account".

Please have the complete study file by hand to enable registration and upload of the required documentation. We refer to the CTMS instructional videos available on the webpage "Workflow (in English)" to properly submit your study.

After registration a unique AZSJ number will automatically be generated, which is needed for all further internal communication concerning your clinical study.

The project manager/PI needs to upload the following documentation on the CTMS portal, to proceed with the submission:

- CV of the local principal investigator;
- GCP of the local principal investigator;
- the protocol of the clinical study;
- patient information and consent form, if applicable;
- a budget proposal;
- a clear schematic overview of all required medico-technical procedures in the context of the study;
- draft clinical trial agreement (CTA), if there is a refusal to work with the SJ CTA template (based on the pharma.be template);
- the necessary manuals for the PI and support services (e.g. lab, pharmacy, medical imaging, etc.);
- a proof of study insurance;
- approval of the ethics committee and/or FAMHP (upon availability).

Upon completion of the electronic “application form” and upload of the required documents via the “documents” tab, the applicant changes the study status from “Draft application” to “Approval of principal investigator”. In that way, the applicant receives a confirmation of good receipt of his/her registration and the PI is notified a new study awaits his approval. Next step prior to CTC submission is approval by the head of department. Once both have approved the study, the study has the status “Application completed” and the dossier will be reviewed by the dedicated CTC file manager. The submitter can follow the process via the tab “Approvals” and “Communication”, and via the study status. When the submitter is required to take action, a notification email will be send out containing the required instructions.

*Regarding the legal review:*

- The duration of a first legal review is on average 14 calendar days, if the AZ Sint-Jan commercial CTA template is used. This is based on the pharma.be CTA template that is supported nationally and is an all-in-one template where the service providers involved are included in annex. This can be requested via [ctc@azsintjan.be](mailto:ctc@azsintjan.be) or downloaded directly via the CTMS library .
- The CTC refrains from separate contracts for each department involved.
- Sponsors who frequently work together with AZ Sint-Jan Brugge AV are free to make a proposal concerning the negotiation of a master agreement.

*Regarding budgets:*

- The CTC also includes central budget negotiation as a service.
- The CTC will request all necessary information from the sponsor and propose a clarifying call if necessary. With knowledge of internal policies, the CTC will perform a first breakdown of budgets and propose them to the departments involved, along with the manual received from the firm. The concerned departments strive to communicate their comments on the given budget to the CTC within 10 working days. These budgets and any comments will be bundled and returned to the sponsor via the “Documents” and “Communication” tab. In the “Approvals” tab, the submitter will be able to follow the internal process. Once bundled feedback can be provided, the status is set to “in processing externally” triggering an automatic mail with instructions to the submitter.

*Regarding specifics:*

If it was indicated in the electronic “Application form”, or if it became clear in communicating with the parties involved, that as part of this study

- medical equipment is to be purchased, the CTC initiates the procedure with the purchasing department;

- software needs to be implemented, then the CTC initiates the procedure with ICT;
- if the services of an external party are called upon, because the necessary equipment/expertise is not available within our institution, then the CTC contacts the external party concerned in order to agree on a subcontract.

*Regarding the "payment terms" included in the contract:*

- The CTC aims to standardize the payment terms across all services and all contracts for the sake of clarity for the sponsor.
- There will be one central hospital account that will only be used for the collection of funds related to clinical trials.
- The contact details of the CTC will be given as the first point of contact for questions about invoicing from the sponsor.
- The details regarding the central hospital account, required contact info and uniform payment terms can be found in Appendix A.

*In general:*

- In order to reduce e-mail load for the parties involved, the CTC is in direct contact with the sponsor's legal team and/or project manager.
- When the revision and internal budget negotiation is taken up, this is reported to the legal team and/or the project manager of the sponsor, as well as to all internal involved parties (i.e. PI, study coordinator and service provider contact). In addition, a time estimate is given as to when a first revision can be expected again, with the explicit request not to contact the internal parties involved directly in order to avoid confusion.
- When the contract and budget negotiations have reached a final stage, this is communicated by the CTC to all internal parties involved. The study status in the CTMS portal will be set to "pre-green light" and final documentation will be requested from the submitter (i.e. ethic and FAMHP approval, no fault insurance, SIV date, CRA contact info, EPD login request form).
- The CTC asks the sponsor's legal team to submit the clean pdf copies with the sponsor's electronic signature in order to initiate the electronic signature round from AZ Sint-Jan parties via the CTMS portal.

### Contract signing in the context of ICT login monitoring

To obtain a personal login that gives limited access rights to the electronic medical record (Clinical Workstation, KWS), the necessary contracts need to be signed.

The contract templates between on the one hand CRO/sponsor and AZ Sint-Jan Brugge AV (i.e. annexed to the clinical trial agreement), and on the other hand PI and CRA will be forwarded to the sponsor/CRA when the contract negotiations are in a final stage (i.e. study status "pre-green light").

The signing and registration of these contracts follows the same path as the clinical trial agreement (CTA).

### Registration with the ethics committee AZ Sint-Jan Brugge AV

In case submission to the Ethics Committee of the AZ Sint-Jan is required, this submission is fulfilled by submission to the CTC through the CTMS. You will receive a confirmation e-mail.

Review of the study dossier by the CTC and ethics committee run in parallel.

For instructions on submitting a dossier to the ethics committee, see [Werkwijze Commissie voor Ethiek | AZ Sint-Jan Brugge](#).

### Green light from the CTC

Once the following documents and information are uploaded in the CTMS, the study status will be changed to “green light” and a status mail will be send out that allows you to start the study:

- approval from the (central) ethics committee;
- clinical trial agreement (CTA), signed by all parties;
- document for the registration of (medical or ICT) devices in the context of clinical trials (if applicable; the PI and/or study coordinator have this document);
- date on which the SIV is planned;
- CRA EPD login request form;
- No fault insurance certificate;

### Site Initiation Visit (SIV)

SIV can only take place if there is a final study contract signed by all parties. First patient recruitment can only take place after a final green light from the CTC.

### Guidelines for monitoring visits (or as agreed upon with your study coordinator of contact)

To obtain a personal login that gives limited access rights to the electronic medical record (Klinisch Werkstation, KWS), you are required to request the necessary documents via the CTC department when the contract negotiations are at a final stage.

These include 2 standard contracts that will be concluded between the sponsor and AZ Sint-Jan Brugge AV on the one hand (normally already present as an annex to the CTA), and between the principal investigator and the external person to whom the login will belong on the other hand (i.e. “CRA request form”).

Signing and registration of these contracts follow the same path as the clinical trial agreement (CTA).

The following guidelines regarding monitoring visits should be respected:

- Monitoring visits start at 9 am at the earliest (or as agreed with the study coordinator).

- CRAs are kindly requested to complete their monitoring visit at 4.30 pm at the latest (or as agreed with the study coordinator).
- A time slot will be agreed upon prior to the monitoring visit during which the study coordinator and CRA can discuss the results of this visit. The time of this consultation will be confirmed upon arrival.
- The CRA may never leave the study files unattended.
- Please arrange the next visit at the end of your monitoring visit with the respective study coordinator.
- Please schedule telephone calls in advance for remote monitoring, discussion of study protocols, or other matters that take some time.

### Amendment

- If during the course of the study, changes occur in the protocol or budget that lead to a contract amendment, these should be submitted in the CTMS portal via the “Amendment” section instead of the “Documents” section. The submitter or monitor is authorized to change the study status to “notification of amendment” notifying all parties of the submission. Comparable to submission of the initial dossier to the ethics committees, amendments are also automatically submitted to our local ethics committee upon submission to the CTMS (when required).
- Amendment dossiers should always be accompanied with a clear overview of the substantial amendments, as well as a clear highlight or modification via track changes.

### End of trial report

- The CRA or study coordinator (upon mutual agreement) reports the study close-out through adaptation of the study status to “closed” and upload of the “end of trial” notification under the “Documents” tab.

## APPENDIX A

|                     |                                                        |
|---------------------|--------------------------------------------------------|
| Payment beneficiary | AZ Sint-Jan Brugge AV                                  |
| Address             | Ruddershove 10, 8000 Brugge, Belgium                   |
| General director    | Dr. Hans Rigauts                                       |
| Contact             | <a href="mailto:ctc@azsintjan.be">ctc@azsintjan.be</a> |
| Account number      | 091-0098552-29                                         |
| Bank name           | Belfius                                                |
| Bank address        | Pachecolaan 44, 1000 Brussels, Belgium                 |
| BIC/swift code      | GKCCBEBB                                               |
| IBAN                | BE26 0910 0985 5229                                    |
| VAT No              | BE 0266.559.859                                        |
| Company number      | 0266559859                                             |
| Reference number    | Reference number on invoice:<br>+++000/0000/00000+++   |

- Within the first month after the site initiation visit, an initial invoice will be sent by the institute/beneficiary of payment containing the start-up costs of all respective parties involved in the study. If the invoices are to be addressed to a CRO/sponsor within Belgium then their VAT number must be provided to us. If the invoices are to be addressed to a CRO/sponsor outside Belgium, their country code should be mentioned with us.
- The sponsor will send at least quarterly invoice proposals to the Clinical Trial Center (via [ctc@azsintjan.be](mailto:ctc@azsintjan.be)) based on data entered in the sponsor's electronic data collection system. The Institute will provide feedback on the correctness of the invoice proposal within 30 calendar days of receipt. All payments shall be electronically transferred quarterly to the bank account listed above, within thirty (30) calendar days from the date of receipt of the valid invoice in accordance with this agreement.

- In case of drop-out of subjects, payment may be made to the Institute on a pro rata basis. Payment shall include only subjects enrolled prior to the interim termination of the study or data received prior to such interim termination, whichever is later.
- Payments for subjects deemed to have violated the protocol may be paid up to the point that the violation occurred at the discretion of the sponsor and/or CRO.
- If the CRO or sponsor terminates the study before it is completed, pro rata expenses and fees will be paid for each subject visit conducted prior to the premature termination of the study or prior to the day notice of such termination was received, whichever is later.
- Final payments will be made based on invoices received within one hundred twenty (120) days of the study visit.