This application form has to be submitted together with the initial CTU submission package. For more information please contact Dr. Joris Penders on +32 89 32 46 67 or via clinicaltrials.laboratory@zol.be. In case a quotation is necessary or in case there are questions regarding the study you will be contacted by the laboratory itself.

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| **Acronym** |       |
| **Study number in ZOL** | Z-       |
| **Principal investigator in ZOL** |       |

1. **Are all lab analyses performed as per standard of care?**

[ ]  Yes (answer question 2 and read the information for the sponsor)

[ ]  No (answer all questions)

1. **Which documents of the clinical laboratory need to be provided to the sponsor?**

[ ]  No lab documents

[ ]  Lab accreditation certificate

[ ]  Normal ranges

[ ]  CV of laboratory director/head of laboratory

[ ]  GCP certificate

[ ]  IATA certificate

[ ]  Other documents or certificates:

*Please note: an administrative start-up fee will be charged for providing these documents*

1. **Will the sponsor use a central or external lab for sample analyses?**

[ ]  No

[ ]  Yes, more specifically:

 [ ]  The sampling, processing, temporary storage and shipment of samples is done by the study team of the principal investigator

 [ ]  The sampling, processing, temporary storage and shipment of samples is done by the local lab\*

 [ ]  Other procedure:

*\*In this case the lab manual and shipment procedures should be added to the CTU submission package in order for the laboratory to evaluate the feasibility of the requested services. If these documents are not available when submitting the study to CTU, the PI needs to inform CTU about this.*

1. **Will the sponsor use the local lab of ZOL for sample analyses?**

[ ]  No

[ ]  Yes, more specifically\*:

* Description of the procedure:
* Lab analyses not standard of care (= study specific):
* Lab analyses standard of care:
* Additional remarks:

*\*Describe the study visits/time points of the protocol at which lab samples should be collected. Describe every sample analysis that has to be performed by the local lab of ZOL. Indicate which analyses are part of the routine care and which are study specific. In case both routine care samples and study specific samples are being collected, this has to be clearly mentioned. Add the flow chart or visit scheme to clarify when each sample has to be collected. For example: Potassium on visit 1 Month, 6 Month and 12 Month; Creatinine/AST/ALT on visit 1 Month; RBC/WBC/Thrombocytes on screening, visit 1 Month and 2 Month. Discuss with the clinical laboratory how this will be explained in the application form.* *Provide all possible tests, including those that are only performed in case of an incident, since non-agreed additional requests are not possible. If the study has started and this was not foreseen but still necessary, the contact person of the clinical laboratory should be consulted.*

1. **Does the processing and storing of these samples require specific equipment?**

[ ]  Cooled centrifuge

[ ]  Ambient centrifuge

[ ]  Freezer -20°C

[ ]  Freezer -70°C

[ ]  Ice bath

[ ]  Temperature logger for temperature monitoring of the freezer

[ ]  Specific collection material:

[ ]  Weighing scale (desired accuracy:      )

[ ]  The following equipment will be provided by the sponsor free of charge:

1. **Which information has to be mentioned on the yellow stickers for the lab request form?**

For the analyses of study samples that are not standard of care, a paper lab sample request form should be used (no electronic request) in order to avoid RIZIV-charging. These paper request forms can be ordered at the ZOL printing services. A yellow label, containing (at least) the acronym and Z-number of the study, should be provided on every lab sample request form.

* Acronym:
* Z-number:
* Additional remark(s):

**Information for the sponsor regarding the start-up conditions in case the laboratory is involved in a clinical trial**

The study can only be executed once the following conditions have been met:

* The multi-party clinical trial agreement
	+ Contains an appendix describing the payment schedule for the lab services
	+ Is fully signed by the hospital management of ZOL, the sponsor and the principal investigator. The laboratory representative signs the contract for acknowledgement. The signature of the laboratory representative is provided on the main signature page. The lab is represented by: Dr. Joris Penders – Clinical biologist– clinical trials representative.
* A start-up fee of €500 is payed. Payment of the start-up fee is required in order to receive the essential documents.
* The approval of the leading Ethics committee is available.
* The study is registered at a biobank. According to the biobank law all human body material that is collected for scientific research purposes has to be registered in a biobank. Only samples that are being collected for a clinical trial with an investigational medicinal product approved by FAMHP and that will be used for this study or for future research regarding the same disease, treatment or drug as the original clinical trial, do not have to be registered in a biobank. For more information you can contact UBiLim (biobank Limburg), via Kimberly.Vanhees@jessazh.be.
* The sample request form has been completed and provided to the laboratory. This is required for sample reception. The request form has to mention the requested analyses that have to be performed free of charge for the patient.

If the previous criteria have not been met, the lab sample request form (even with the yellow label on it) is considered a routine standard form and the analyses are not free of charge for the patient. Consequently, the samples are processed as regular patient samples. In that case, the laboratory has no agreement with the sponsor. Trial participants will have to pay patient contributions and the sponsor will **not** receive any (signed) documents (e.g. normal ranges, methods, accreditation).

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| **Additional information** |
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