

Site Suitability Declaration (VGO)

Green = instructions/ explanations

Blue = fields to complete

Part A – Site Suitability Declaration (VGO)

By signing Part A, the board of directors/ management of the research institute declares that the center *is suitable* to perform the intended research.
The signed version of Part A becomes part of the submission file.

Study Information

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, unless indicated otherwise.

Research number submission portal: <ABR number or CTIS Portal number>
Full Study title: <Full Study title>

Name research institute, city: < Name research institute> in <city>
Department(s)/ location(s): < Department(s)/location(s)>
Name local principal investigator: <Name local principal investigator>
Role research institute: Choose an item.

Proof coverage liability¹

The submitter of the research file provides the reviewing committee with proof of liability coverage for damage caused by death or injury to the test subject of the:

- ☐ the above-mentioned institution as executor and/or provider of the investigation, name of insurer and policy number: <Name insurer>, <policy number>²
☐ sponsor of the research, name of sponsor: <name of sponsor>³

The board of directors/ management of the above-mentioned research institute declares that the investigator(s) and institute have sufficient expertise and facilities to carry out this research.

This decision is based on the agreements as described in Part B in which an overview is given of the agreements between the principal investigator and the relevant departments of the research institute about the local feasibility of the research.

Conduct of the research

The implementation of the research in this center can only be carried out after the reviewing Ethics Committee has assessed the research file and the suitability of this institution and has issued a positive decision and after the research contract with the sponsor has been signed or, in the absence of a research contract, written permission for the execution of the research has been granted by the Executive Board/management.

Name mandated person BoD/ Management: <Name>

Position mandated person BoD/ Management: <Position>

Signature: _____ Place, date: <place>, <DD/MMM/YYYY>

¹ Proof of cover for liability can be liability insurance or another guarantee of financial security, such as a bank guarantee (article 7 paragraph 9 WMO). The proof does **not** concern the WMO test subjects insurance as referred to in Article 7(1) of the WMO. Proof from the executor or sponsor is sufficient, but it is up to the assessing review committee whether it deems proof from both the executor and the sponsor necessary under specific circumstances.

² If the institution provides liability insurance, the investigation file does not have to contain proof of this. In this case, the name of the insurer and the policy number will suffice. This also applies to an institution that not only carries out the research, but also carries out the research.

³ Does the sponsor, not being the institution, provide proof of liability cover? In that case, this evidence must always be part of the investigation file.

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Part B - Overview of agreements local principal investigator and relevant departments

*VGO Part B (overview local agreements) is to be completed based on the research protocol.
Other study documents are to be provided by sponsor to the participating centers after METC question round.*

By signing Part B, the local principal investigator and the Board of Directors/ management declare that the feasibility meeting between the investigator and the relevant departments has shown that given the assessments, the planning and the preliminary budget, they *could* participate in the research. The results of this meeting are recorded conform Part B, based on the appendices completed by the supporting departments. The completed and signed Part B is the information source for the Board of Directors/ management to sign Part A.

Study Information

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, unless indicated otherwise.

Study title: [<study title>](#)

Study name/short title/acronym: [<Study name/short title/acronym>](#)

EudraCT-number: [<EudraCT-number>](#) *(applicable to research with medicines)*

Protocol number Sponsor: [<Protocol number sponsor>](#)

Protocol version and date (on which the agreements are based): [<version>](#), [<DD/MMM/YYYY>](#)

Research with medicines:

☐ Yes ☐ No

Research phase:

[Choose an item.](#)

Research with medical devices:

☐ Yes ☐ No

Classification per May 26th, 2021:

[Choose an item.](#)

Or other type of research:

☐ Observational research without invasive measurements

☐ Observational research with invasive measurements

☐ Other interventional research

☐ Healthcare evaluation

☐ Other: [<Other>](#)

Research in assignment/ initiative of:

☐ Sponsor ☐ Investigator

Number of centers in NL:

[<number of sites>](#) ☐ Unknown

Intended number of patients at institute:

[<intended number of patients at institute>](#)

Intended period of recruitment (in months):

[<intended period of recruitment>](#)

Intended date first patient in:

[<month>](#) [<year>](#)

Intended date last visit, last patient:

[<month>](#) [<year>](#)

Deadline return of completed and signed VGO Part A	<DD/MMM/YYYY>
Expected submission date to EC or in EU portal CTIS	<DD/MMM/YYYY>

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To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, unless indicated otherwise.

Contact details (representative) sponsor

Organization: <organization>
Name contact person 1: <name contact person 1>
E-mail: <e-mail>
Phone number: <phone number>
Mobile number: <mobile number>
Name contact person 2: <name contact person 2>
E-mail: <e-mail>
Phone number: <phone number>
Mobile number: <mobile number>

Details Local Principal Investigator

Name: <name>
E-mail: <e-mail>
Phone number: <phone number>
Mobile number: <mobile number>

Details research coordinator

Name: <name>
E-mail: <e-mail>
Phone number: <phone number>
Mobile number: <mobile number>

Standard clinical trial agreement (CTA CCMO/ DCRF)

☐ Yes ☐ No

If yes, note used template version: <version>
(current version available on CCMO website)

Global budget (per subject): <amount> Euro

In case of medical equipment delivery:

☐ Not applicable

Medical technology department involved? ☐ Yes ☐ No

Research Network involved?

☐ Yes ☐ No

If yes, complete the details of the network below:

Network: Choose an item.
Address: <address>
Name contact person: <name contact person>
E-mail: <e-mail>
Phone number: <phone number>
Mobile number: <mobile number>

In case of other, please specify: <Name other network>

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Part B continued

Table 1: supporting/ involved departments

Grey columns to be completed by sponsor.

Remaining columns to be completed by local principal investigator after consultation with departments listed below.

Services/ departments	Department involved in research	Contact person department	Responsibility institute?	Responsibility Investigator?	Annex signed by head of the department?
1. Pharmacy	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
2. Laboratory	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
3. Medical Micro- biology Laboratory	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
4. Pathology	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
5. Cardiology	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
6. Radiology/ Nuclear medicine	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
7. Staff workload*	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.
8. Other: <Department>	Choose an item.	<name contact person>	Choose an item.	Choose an item.	Choose an item.

**Please indicate who bears the costs for research personnel. The Annex is not applicable in the case of an independent medical specialist with their own research entity.*

Herewith the local principal investigator declares (on behalf of the above-mentioned relevant departments) and the research institute that they have informed each other about the execution of the above-mentioned research and the activities required for this purpose and that they are able to carry out the research according to the research protocol. The procedures on which this declaration is based are listed in the appendices. Before the start of the research the necessary agreements will be further elaborated and laid down in the (standard) clinical trial agreement (CTA) indicated above.

Disclaimer: If changes occur before the start of, or during the research, adjustments to the agreements made, including financial agreements, will follow in accordance with the changed services.

Local information (tick what applies)

☐ Local principal investigator employed by the institute and staff at the expense and responsibility of the institute:
→ Attach arrangements for availability of suitable personnel.

☐ In case of independent medical specialist as local principal investigator who bears costs for research personnel:
→ Hereby I declare that for this research there are sufficient competent and skilled personnel available to carry out the research for the intended number of patients within the envisioned timelines.
→ Indicate on Annex(es) whether they are applicable or not.

Name local principal investigator: <name>

Signature: _____

Date: <DD/MMM/YYYY>

Name of person mandated by the Board of Directors: <name>

Position: <position>

Signature: _____

Date: <DD/MMM/YYYY>

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☐ Not Applicable

Annex Part B: Pharmacy

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Who will provide the service?

External party

☐ Yes ☐ No

If Yes: costs are with Local Principal Investigator, Annex not applicable (NA)

Hospital Pharmacy

☐ Yes ☐ No

If yes: please complete the information below

Radioactive materials?

☐ Yes* ☐ No

**consult radiation safety department*

Available information *(documents provided by sponsor)*

☐ Research protocol

☐ Pharmacy Manual (draft)*

☐ Investigator Brochure

☐ SmPC / EPAR

**document optional*

Research procedures

Is it an Investigational Medicinal Product (IMP) research:

☐ Which meets the requirements of GMP (no manufacturing or labelling required and IMP has EU QP release certificate)

☐ For which import must be arranged

☐ Requiring manufacture or labelling by the pharmacy, namely: [<name>](#)

Research medication

Grey columns to be completed by sponsor.

	Name, form, strength <i>For example Paracetamol infusion liquid 1000mg=100 ml / placebo</i>	Route of administration	Storage Conditions	Other
1.	<name research medication/ placebo> <form> <strength>	<input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> other: <other>	<input type="checkbox"/> fridge 15-25°C <input type="checkbox"/> fridge 15-30°C <input type="checkbox"/> fridge 2-8°C <input type="checkbox"/> other: <other>	<input type="checkbox"/> Opium Act <input type="checkbox"/> High Risk <input type="checkbox"/> ATMP* <input type="checkbox"/> GMO**
2.	<name research medication/ placebo> <form> <strength>	<input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> SC <input type="checkbox"/> other: <other>	<input type="checkbox"/> fridge 15-25°C <input type="checkbox"/> fridge 15-30°C <input type="checkbox"/> fridge 2-8°C <input type="checkbox"/> other: <other>	<input type="checkbox"/> Opium Act <input type="checkbox"/> High Risk <input type="checkbox"/> ATMP* <input type="checkbox"/> GMO**

**ATMP: Advanced Therapy Medicinal Products; **GMO: Genetic Modified Organism*

What do the research activities consist of?

☐ Register in IVRS/ IXRS

☐ Randomization by the pharmacy

☐ Emergency procedure for unblinding

☐ PFA Actions (Preparing for Administration)

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Where are PFA procedures described:

- ☐ Supplied Pharmacy Manual
- ☐ If no Pharmacy Manual is provided, describe here whether there is dissolution and required time, form (infusion, injection, etc.), volume of final product, product specific issues: [<description>](#)

Shelf Life after PFA: [<Shelf life after PFA>](#)

Storage conditions after PFA: ☐ Fridge 15-25°C ☐ Fridge 15-30°C ☐ Fridge 2-8°C ☐ other: [<other>](#)

Should temperature of IMP after PFA be recorded ☐ Yes ☐ No

Does the pharmacy itself have to supply the placebo product ☐ Yes ☐ No

Delivery

- ☐ To the patient in hospital
- ☐ In the hospital for administration
- ☐ Other: [<namely>](#)

Are there scheduled deliveries/ administrations (*> 24 hours prior*) ☐ Yes ☐ No

Are there scheduled deliveries for administration needed outside office hours ☐ Yes ☐ No

☐ Other: [<namely>](#)

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: [<DD/MMM/YYYY>](#)

Attachment local price list (*for internal use only*)

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

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☐ Not Applicable

Annex Part B: Clinical Laboratory (CL)

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Who will provide the service?

☐ Clinical chemistry laboratory of the institute (*complete research procedures below*)

☐ Central laboratory (*costs are not for the institute*)

Available information (*documents provided by sponsor*)

Documents provided by the sponsor:

☐ Research protocol

☐ Lab Manual (draft)*

**document optional*

☐ ISO15189-accredited CL? ☐ Yes ☐ No

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Other columns to be completed by the local principal investigator, after consultation with the department.

<i>Local CL: diagnostic tests hospital</i>	Standard care	Research procedure	Staff member department	Research Staff investigator	Evaluation of the clinical chemist*
<diagnostic 1>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<diagnostic 2>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<diagnostic 3>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<diagnostic 4>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<diagnostic 5>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Evaluation procedure after execution occurs locally or centrally (item not applicable when done centrally)*

<i>Central laboratory: activities institute</i>	Staff member department	Research staff investigator
Storing and sending samples	<input type="checkbox"/>	<input type="checkbox"/>
Processing and sending samples	<input type="checkbox"/>	<input type="checkbox"/>
Processing, storing and sending samples	<input type="checkbox"/>	<input type="checkbox"/>
<.....>	<input type="checkbox"/>	<input type="checkbox"/>
<.....>	<input type="checkbox"/>	<input type="checkbox"/>
<.....>	<input type="checkbox"/>	<input type="checkbox"/>
<.....>	<input type="checkbox"/>	<input type="checkbox"/>

Storage location of samples

☐ In the laboratory

☐ With the investigator

☐ Other: <other>

☐ Not applicable

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Details biobank

- ☐ Not applicable
- ☐ A central biobank is involved
- ☐ A local biobank is involved

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: <DD/MMM/YYYY>

Attachment local price list (*for internal use only*)

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

Site Suitability Declaration (VGO)

☐ Not Applicable

Annex Part B: Medical Microbiology Laboratory (MML)

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Who will provide the service?

☐ Medical Microbiology Laboratory (MML) of the hospital (*complete below research procedures*)

☐ External (central) laboratory (*costs are not for the institute*)

Available information (*documents provided by sponsor*)

☐ Research protocol

☐ Lab Manual (draft)*

**document optional*

☐ ISO15189-accredited MML? ☐ Yes ☐ No

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Other columns to be completed by the local principal investigator, after consultation with the department.

Local MML: diagnostic tests hospital	Standard Care	Research Procedure	Staff member department	Research staff investigator	Evaluation microbiologist*
Processing, diagnostic tests (and no storage or shipping)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Processing, diagnostic tests and storage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Processing, diagnostic tests, storage and shipping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Processing and shipping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Processing, storage and shipping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <other>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <other>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <other>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Evaluation procedure after execution occurs locally or centrally (item not applicable when done centrally).*

Storage location of samples

☐ In the laboratory

☐ With the investigator

☐ Other: <other>

☐ Not applicable

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: <DD/MMM/YYYY>

Attachment local price list (*for internal use only*)

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

Site Suitability Declaration (VGO)

☐ Not Applicable

Annex Part B: Pathology

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Who will provide the service?

Pathologist, not employed at institute

☐ Yes ☐ No

If yes: the local principal investigator make arrangements with the pathologist

Clinical Molecular Biologist in Pathology (CMBP)

CMBP, not employed at institute

☐ Yes ☐ No

If yes: the local principal investigator make arrangements with CMBP

Institute department/independent pathology organization

☐ Yes ☐ No

If yes: please complete the below tariff agreements

Available information (documents provided by sponsor)

☐ Research protocol

☐ Pathology Manual (draft)*

☐ Material and Data Transfer Agreement (MDTA)*

**document optional*

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Research procedure	Standard Care	Research procedure
Implement and embedding tissue (paraffin)	Choose an item.	Choose an item.
Cut blank sections	Choose an item.	Choose an item.
HE and other histological colorings	Choose an item.	Choose an item.
Immunohistology	Choose an item.	Choose an item.
Molecular determinations	Choose an item.	Choose an item.
Make Tissue Multi Array (TMA)	Choose an item.	Choose an item.
Request external pathology department	Choose an item.	Choose an item.
Collection and storage of freezing and/or biopsy material	Choose an item.	Choose an item.
Laser Microdissection Microscopy	Choose an item.	Choose an item.
Whole Slide Image (WSI) Scanning	Choose an item.	Choose an item.
Storage/ release Central Biobank	Choose an item.	Choose an item.
Shipping of frozen material on dry ice by courier	Choose an item.	Choose an item.
Printing of anonymous reports	Choose an item.	Choose an item.
Shipping (not on dry ice)	Choose an item.	Choose an item.
Selection/ Evaluation by Pathologist	Choose an item.	Choose an item.
Evaluation by CMBP	Choose an item.	Choose an item.
Processing radioactivity*	Choose an item.	Choose an item.
Other: <please specify>	Choose an item.	Choose an item.

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Other: <please specify>	Choose an item.	Choose an item.
Other: <please specify>	Choose an item.	Choose an item.

**When applicable, consult radiation safety department.*

Storage location

- ☐ At the pathology department
- ☐ With the investigator
- ☐ Other: <other>

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: <DD/MMM/YYYY>

Attachment local price list (*for internal use only*)

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

Site Suitability Declaration (VGO)

☐ Not Applicable

Annex Part B: Cardiology

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Available information (documents provided by sponsor)

☐ Research protocol

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Other columns to be completed by the local principal investigator, after consultation with the department.

Research procedures	Standard care	Research Procedure	Staff member department	Research staff investigator	Evaluation cardiologist**
Electrocardiogram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Holter examination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Echocardiogram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trans-oesophageal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ergometrics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coronary angiogram	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Electrophysiological examination	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Invasive circulation measurement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac CT-scan*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cardiac MRI-scan*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nuclear research*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reading CIED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <namely>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <namely>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <namely>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*When applicable, consult radiation safety department.

**Evaluation procedure after execution occurs locally or centrally (item not applicable when done centrally).

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Attachment local price list (for internal use only)

Date: <DD/MMM/YYYY>

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

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☐ Not Applicable

Annex Part B: Radiology/ Nuclear Medicine

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Who will provide the service?

- ☐ Radiology
☐ Nuclear medicine
☐ Radiology & Nuclear medicine

Available information *(documents provided by sponsor)*

Documents provided by the sponsor:

- ☐ Research protocol
☐ Imaging Manual (draft)*

**document optional*

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Other columns to be completed by the local principal investigator, after consultation with the department.

Modality (type of imaging technique)*	Units per patient	Standard care	Research procedure	Availability guaranteed	Contrast and/ or tracer**	Procedure and storage defined
<procedure>	<#>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<procedure>	<#>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<procedure>	<#>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**E.g. CT, MRI, echo, intervention, SPECT, PET, or radionuclide therapy. Consult radiation safety department.*

***In case of SPECT/ PET/ radionuclide therapy also complete preferred tracer.*

Additional explanation research procedures as mentioned in research protocol

Like specification of the parameters.

[Complete here](#)

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: <DD/MMM/YYYY>

Attachment local price list *(for internal use only)*

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.

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☐ Not Applicable

Annex Part B: Staff workload department local principal investigator

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Which procedures will fall under the responsibility of the department of the local principal investigator?

This includes all activities performed by the local principal investigator and/or his/her department.

Excluding all the above mentioned departments.

Activities in the role of sponsor fall outside the scope of the VGO and are not included in this appendix.

Personnel costs are covered by:

Please indicate who bears the costs for research personnel. The Annex is not applicable in the case of an independent medical specialist with their own research entity – unless principal investigator has requested the annex to be completed.

☐ Local principal investigator (tick box at top of the page)

☐ Research institute

Research procedures

Grey columns to be completed by sponsor – indicate which visits are part of the research protocol (remove or duplicate rows as needed).

Remaining columns to be completed by local principal investigator on the basis of the research protocol's visit scheme. Complete per visit the total amount of hours of workload. Amount of hours for preparations are a one-off, screening is monthly and visits are per patient.

General workload	Research staff (total amount of hours)	Other: <other> (total amount of hours)
Preparations (reading research protocol, meeting(s)/ training(s)/ providing information, etc.)	<#>	<#>
Screening <...> months recruitment period	<#> (amount of hours per month)	<#> (amount of hours per month)
Close-out (closing research)	<#>	<#>
<...>	<#>	<#>

Beside the personnel workload there are other important costs, like monitoring visits, administration, maintaining Investigator Site File, etc. These costs need to be included in the final budget.

Workload per patient	Research staff (total amount of hours)	Other: <other> (total amount of hours)
V1 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V2 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V3 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>

Site Suitability Declaration (VGO)

<...>	<#>	<#>
V4 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V5 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V6 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V7 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V8 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V9 <title/ visit description>		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V #> final visit		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>
V <#> follow-up		
Visit, including preparations and follow-up	<#>	<#>
Data processing, if not outsourced to third a party	<#>	<#>
<...>	<#>	<#>

Site Suitability Declaration (VGO)

☐ Not Applicable

Annex Part B: Other <department>

To be completed by sponsor based on the research protocol version that will be submitted to the Ethics Committee, local principal investigator to further complete.

Available information (documents provided by sponsor)

☐ Research protocol

☐ Other: <namely>

Research procedures

In principle, all activities mentioned in the schedule of assessments falls under the term research procedure, unless it is specifically stated in the research protocol as standard care.

Grey columns to be completed by the sponsor.

Other columns to be completed by the local principal investigator, after consultation with the department.

Research procedures	Standard care	Research Procedure	Staff member department	Research staff investigator
<procedure>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<procedure>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<procedure>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Local price agreements/ quote

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than:

Date: <DD/MMM/YYYY>

Attachment local price list (for internal use only)

☐ Yes ☐ No

Local agreement of the investigator and the relevant department to be recorded locally.