Green = Instructions

Blue = Fields to complete

**Site Suitability Declaration (VGO)**

**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 and able to perform the intended research. The signed version of Part A becomes part of the submission file.

**Study Information**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, unless indicated otherwise)*

Research/study number submission portal: <ABR number or CTIS Portal number>

Full Study title: <Full Study title>

Name Study Site/Research Institute, city: < Name Study Site/Research Institute> in <city>

Department(s)/ location(s): < Department(s)/location(s)>

Name local Principal Investigator: <Name local Principal Investigator>

**Insurance**

The liability of those conducting the study for damage caused by death or injury to the subject is covered by the liability insurance of the above-mentioned institution:

No (submit certificate of proof of sponsorship liability cover separately)

Yes, Name insurer and policy number: <Name insurer>, <policy number>

*The Board of Directors/Management of the above-mentioned study center declares that the local principal investigator and institution 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 with the researcher 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.

Name mandated person BoD/ Management: <Name>

Position mandated person BoD/ Management: <Position>

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

**Site Suitability Declaration (VGO)**

**Part B - Overview of agreements Local suitability,**

**Local principal investigator and institution**

By signing Part B of the VGO, the (local principal) investigator and the Board of Directors/management declare that the feasibility meeting between the investigator and the supporting departments involved has shown that, given the assessments, the planning and the preliminary budget, they can participate in the research. The results of this consultation 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 of this VGO.

**Study Information**

*(To be completed by the sponsor based on the version of the protocol 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>

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

Phase Study: Choose an item.

Research with medical devices:  Yes  No

Classification (till 26May2021, not applicable, after this date use classification)

Choose an item.

Other type of research:  Observational research without invasive measurements

Observational research with invasive measurements

Interventional research

Healthcare evaluation

Other: <Other>

Research in assignment / initiative of:  Sponsor  Investigator

Number of centers in NL: <number of sites>  Unknown

Target number of patients at site: <Target number of patients>

Intended period of inclusion (in months): <Intended period of inclusion>

Intended/target date first patient in: <month> <Year>

Intended date last visit, last patient: <month> <Year>

|  |  |
| --- | --- |
| **Deadline return of completed and  signed part A of VGO** | Date <DD/MMM/YYYY> |
| **Expected submission date to EC / in EU portal:** | Date <DD/MMM/YYYY> |

**Part B Site Suitability Declaration (VGO) - continued**

**Study Information**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, unless indicated otherwise):*

**Contact details (representative) sponsor**

Organisation: <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: <PI Name>

E-mail: <e-mail>

Phone number: <phone number>

Mobile number: <mobile number>

**Standard clinical trial agreement (CTA CCMO/ DCRF):**  Yes  No

If yes: used version (number and date): <version #>, dated <DD/MMM/YYYY>

*(Current version available on CCMO website)*

Research Network involved:  Yes  No

If yes, please complete the details of the network below:

Network: Choose an item. In case of other, please specify: <Name other network>

Address: <address>

Name contact person : <name contact person>

E-mail: <e-mail>

Phone number: <phone number>

Mobile number: <mobile number>

**Part B Site Suitability Declaration (VGO) - continued**

**Table 1: supporting/ involved departments** *(please add lines if needed).*

*Grey columns to be completed by the sponsor.*

*Other columns to be completed by the local principal investigator after consultation with the departments mentioned below.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Department involved in research | Contact person department | Repsonsibility hospital | 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. |
| 1. Laboratory | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Medical Micro-biology Laboratory | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Pathology | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Cardiology | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Radiology/ Nuclear medicine | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Staff costs | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Other: <Department> | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |

Herewith, the local principal investigator, the above-mentioned supporting departments and the research center declare that they have informed each other about the execution of the above-mentioned study and the study activities required for this purpose and that they are able to carry out the study according to the protocol. The procedures on which this declaration is based are listed in the appendices. Before the start of the study 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 study, adjustments to the agreements made, including financial agreements, will follow in accordance with the changed services.*

**Local information**

*Local principal investigator employed by the hospital and staff at the expense and responsibility of the hospital:   
→ Please attach arrangements for availability of suitable personnel*

*In case of independent medical specialist as local principal investigator who bears costs for research personnel:  
→ Hereby certify that for this study there are sufficient competent and skilled personnel available to carry out the study for the intended number of patients within the envisaged time lines. Herewith Annex Staff costs department local principal investigator is become obsolete.*

**Name local principal investigator:** <name PI>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

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

Position: <position>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Pharmacy**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

Who will provide the service?

External party  Yes  No   
If Yes: costs are with Local Principal Investigator, Annex not applicable

Hospital Pharmacy  Yes  No   
If yes: please complete the information below

**Study procedures**

Is it an Investigational Medicinal Product (IMP) study:

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: <namely>

Studiemedication: *(please add lines if needed).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name, form, strength  For example Paracetamol infusion liquid 1000mg=100 ml / placebo | Route of administration | Storage Conditions | Other |
| 1. | < Name, form, strength> | Oral  IV  SC  other: <other> | fridge 15-25˚C  fridge 15-30˚C  fridge 2-8˚C  other: <other> | Opium Act  High Risk  ATMP\*  GMO\*\* |
| 2. | < Name, form, strength> | Oral  IV  SC  other: <other> | fridge 15-25˚C  fridge 15-30˚C  fridge 2-8˚C  other: <other> | Opium Act  High Risk  ATMP\*  GMO\*\* |

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

**What do the study activities consist of?**

Register in IVRS/ IXRS

Randomization by the pharmacy

Emergency procedure for unblinding

PFA Actions (Preparing for Administration)

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

Administration in the hospital

Other: <namely>

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

Is administration needed outside office hours  Yes  No

Other: <namely>

**Available information**

Documents provided by the sponsor:

Protocol

Pharmacy Manual (draft)\*

Investigator Brochure

SmPC / EPAR

Investigational Medicinal Product Dossier

*\*document optional*

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Clinical Laboratory (CL)**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

Who will provide the service? Tick what is applicable.

Clinical chemistry laboratory of the hospital *(please complete the study procedures below)*

Central laboratory (*costs are not for the hospital)*

**Available information**

Documents provided by the sponsor:

Protocol

Lab Manual (draft)\*

*\*document optional*

**Study procedures** *(please add lines if needed).*

Which study procedures will be used?

*Grey columns to be completed by the sponsor.*

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

*Everything which is mentioned in the schedule of assessments falls in principle under the term study procedure, unless it is specifically stated in the protocol as standard care.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Diagnostic tests by hospital laboratory | Standard care | Study procedure | Staff member hospital | Research Staff member | Evaluation of the clinical chemist |
| <Diagnostic 1> |  |  |  |  |  |
| <Diagnostic 2> |  |  |  |  |  |
| <Diagnostic 3> |  |  |  |  |  |
| <Diagnostic 4> |  |  |  |  |  |
| <Diagnostic 5> |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| External (central) laboratory | Staff member hospital | Research staff member |
| Storing and sending samples |  |  |
| Processing and sending samples |  |  |
| Processing, storing and sending samples |  |  |
| <......> |  |  |
| <......> |  |  |
| <......> |  |  |
| <......> |  |  |
| <......> |  |  |

**Storage location of samples**

In the laboratory

With the Researcher

Other: <other>

Not applicable

**Local data**

A central biobank is involved

A local biobank is involved

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Medical Microbiology Laboratory (MML)**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

Who will provide the service? Tick what is applicable.

Medical Microbiology Laboratory (MML) of the hospital *(please complete below study procedures)*

External (central) laboratory *(costs are not for the hospital)*

**Available information**

Documents provided by the sponsor:

Protocol

Lab Manual (draft)\*

*\*document optional*

ISO15189-accreditated MML?  Yes  No

**Study procedures** *(please add lines if needed).*

Which Study procedures will be used?

*Grey columns to be completed by sponsor.*

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Diagnostic tests by *MML hospital* | Standard Care | Study Procedure | Staff member hospital | Research staff member | Evaluation microbiologist |
| Processing, diagnostic tests (and no storage or shipping) |  |  |  |  |  |
| Processing, diagnostic tests and storage |  |  |  |  |  |
| Processing, diagnostic tests, storage and shipping |  |  |  |  |  |
| Processing and shipping |  |  |  |  |  |
| Processing, storage and shipping |  |  |  |  |  |
| Other: <other> |  |  |  |  |  |
| Other: <other> |  |  |  |  |  |
| Other: <other> |  |  |  |  |  |
| Other: <other> |  |  |  |  |  |
| Other: <other> |  |  |  |  |  |

**Storage location of samples**

In the laboratory

With the Researcher

Other: <other>

Not applicable

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Department Pathology**

(To be completed by the sponsor based on the version of the protocol that will be submitted to the EthicsCommittee, further to be completed by the local principal investigator)

Who will provide the service?

Pathologist, not employed at hospital  Yes  No

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

Clinical Molecular Biologist in Pathology (CMBP)

CMBP, not employed at hospital  Yes  No

If yes: the local principal investigator make arrangements with CMBP

Hospital department/independent pathology organisation  Yes  No

If yes: please complete the below tariff agreements

**Study procedures** *(please add lines if needed).*

*(To be completed by the sponsor, possibly supplemented by the research institute)*

|  |  |  |
| --- | --- | --- |
| Procedure | Part of study protocol? | Standard Care? |
| 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. |
| Costs of 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 | Choose an item. | Choose an item. |
| Selection/Evaluation by Pathologist | Choose an item. | Choose an item. |
| Avaluation by CMBP | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |

**Available information**

Documents provided by the sponsor:

Protocol

Pathology Manual (draft)\*

Material and Data Transfer Agreement (MDTA)

*\*document optional*

**Local information**

To be completed when the materials are collected/delivered. Also describe the methods for the request, preparing and assessing the requested procedures, including time and manner of submitting the results.

**Storage location**

At the pathology department

With the Researcher

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Cardiology**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

**Available information**

Documents provided by sponsor:

Protocol

**Study procedures:** *(please add lines if needed).*

Which study procedures will be used?

*Grey columns to be completed by sponsor.*

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study procedures by cardiology department | Standard care | Study Procedure | Staff member hospital | Research staff member | Evaluation cardiologist |
| Electrocardiogram |  |  |  |  |  |
| Holter examination |  |  |  |  |  |
| Echocardiogram |  |  |  |  |  |
| Trans-oesofageal |  |  |  |  |  |
| Ergometrics |  |  |  |  |  |
| Coronary angiogram |  |  |  |  |  |
| Electrophysiological examination |  |  |  |  |  |
| Invasive circulation measurement |  |  |  |  |  |
| Cardiac CT-scan |  |  |  |  |  |
| Cardiac MRI-scan |  |  |  |  |  |
| Nuclear research |  |  |  |  |  |
| Reading (CIED\*) |  |  |  |  |  |
| Other:<namely> |  |  |  |  |  |
| Other:<namely> |  |  |  |  |  |
| Other:<namely> |  |  |  |  |  |
| Other:<namely> |  |  |  |  |  |
| Other:<namely> |  |  |  |  |  |

*\*CIED = Cardiac Implantable electronic devices*

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Radiology/Nuclear Medicine**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

Who will provide the service?

Radiology

Nuclear medicine

Radiology & Nuclear medicine

**Available information**

Documents provided by the sponsor:

Protocol

Imaging Manual (draft)\*

*\*document optional*

**Study procedures:** *(please add lines if needed).*

Which study procedures will be used?

*Grey columns to be completed by sponsor.*

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Modality  (Type of imaging technique) | Amount | Standard care | Study procedure | Availability guaranteed | Assessment Radiologist | Procedure and storage defined |
| CT - Standard | <#> |  |  |  |  |  |
| - Deviating | <#> |  |  |  |  |  |
| MRI - Standard | <#> |  |  |  |  |  |
| - Deviating | <#> |  |  |  |  |  |
| X-rays - Standard | <#> |  |  |  |  |  |
| - Deviating | <#> |  |  |  |  |  |
| Other: <namely> | <#> |  |  |  |  |  |
| Other: <namely> | <#> |  |  |  |  |  |
| Other: <namely> | <#> |  |  |  |  |  |
| Other: <namely> | <#> |  |  |  |  |  |
| Other: <namely> | <#> |  |  |  |  |  |

**Local price agreements/ offer**

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 negotiable 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

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

Not Applicable

**Annex - Site Suitability Declaration (VGO):**

**Staff costs department local principal investigator**

*(To be completed by the sponsor based on the version of the protocol that will be submitted to the Ethics Committee, further to be completed by the local principal investigator)*

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

*(Excluding supporting departments mentioned above)*

**Study procedures**

*(Consider all procedures performed by local principal investigator and/or his/her department)*

Which study procedures will be used?

*Grey columns to be completed by sponsor.*

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

*Please add per column the total amount of hours for the study procedure per study team member*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study procedures | Study Coordinator | Staff member hospital | Research staff member | Data Manager |
| **Preparation (reviewing protocol, attending meeting(s)/training, provide information and so on)** | <#> | <#> | <#> | <#> |
| **Recruitment** | <#> | <#> | <#> | <#> |
| Shipping of patient letters | <#> | <#> | <#> | <#> |
| Pre-screening + shipping patient information sheet, processing appointment | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| **V1 / Screening** |  |  |  |  |
| Informed consent, (explanation/attendance + processing) | <#> | <#> | <#> | <#> |
| Physical examination / medical history | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **V2 / Run-in** |  |  |  |  |
| Support (explanation/ attendance + processing) | <#> | <#> | <#> | <#> |
| Physical examination / medical history | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| **V3/ Randomization** |  |  |  |  |
| Support (explanation/ attendance + processing) | <#> | <#> | <#> | <#> |
| Study procedures | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| **V4** |  |  |  |  |
| Support (explanation/ attendance + processing) | <#> | <#> | <#> | <#> |
| Study procedures | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| <…> | <#> | <#> | <#> | <#> |
| **V5** |  |  |  |  |
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| **V** <#> **close out visit** |  |  |  |  |
| Support (explanation/ attendance + processing) | <#> | <#> | <#> | <#> |
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| **V** <#> **follow-up** |  |  |  |  |
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| **General activities (in hours)** | <#> | <#> | <#> | <#> |
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| **General fee (per activity)** | <#> | <#> | <#> | <#> |
| Patient travel costs/ per patient | <#> | <#> | <#> | <#> |
| Local submission costs | <#> | <#> | <#> | <#> |
| Purchase of supplies | <#> | <#> | <#> | <#> |
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| Other, <namely> | <#> | <#> | <#> | <#> |

**I certify that our department is qualified to conduct the above study**

Name: <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>