

Information Leaflet Naam Site

1. Contact details

Tel
Fax
website
VAT nr
KvK

Contact / PI

Email
Tel
Mobile

Communication preferably by email/phone/....

Communication regarding feasibility, start-up, contract, invoices through

General communication to all staff: info@xxxx.nl (also used for lab results or confirmations IVRS)

Direct email addresses staff: voornaam@xxxx.nl

2. Feasibilities

Can be sent directly by email toI. Answer can be given within days with budget if a flowchart is included.

Should there first be a signed CDA, this can be drawn up for the at the address Please clearly state the deadline and return address / fax no.

3. Site Selection

Appointments can be made by phone or email with We reserve hours for a site selection (depending if we have already worked with sponsor / CRO). If we are selected as a site, we assume that this leaflet has been taken into account and that our method as set out in our SOPs are approved.

4. Site Initiation

Appointments can be made by phone or email Present at the site will be We reserve hours (depending if we have already worked together with sponsor / CRO)

5. Submission

IRB contact details
Deadlines for submission
Specific document required (i.e. contract / advertisement).

6. ATP

Dbase /Ads (text must be approved by the METC) / In local / regional newspapers / Our website /

patients support groups / Social Media / referrals

7. ICF procedure

8. ICF

In the ICF should be included in next sentence

9. Quality

We have a quality manual with SOPs. This can be reviewed upon request. No copies may be made. SOPs are no to be distributed digitally.

10. Terms of delivery (in dutch)

These are available on request and filed at the Chamber of Commerce.

11. Pharmacy

Contact person: Mr C Thoor

Tel:

Fax:

Email:

Transport between pharmacy and department.

12. Contract / Finance

Correspondence regarding the contract / finance is done with Contract is drawn up with the following parties. The financial section should consist of a number of standard components.

- Setup Fees
- Recruitment Budget
- Travel expenses for patient
- Participants fees
- Re-consenting costs
- Audit fees
- We do not accept retention fee per visit, which is paid only at the end of the study
- If contract with a CRO is not accepted that we are paid only when the CRO is paid by the sponsor

The budget is based on final flowchart of the protocol and specific protocol version and the information provided to the site in the pre-trial questionnaire. When amendments to the protocol / flowchart are made this may lead to revisions of the budget. For the preparation of the budget, we ask you to fill in a questionnaire that provides insight into all activities that apply in conducting the study. Invoicing takes place each quarter based on conducted visits and activities or as otherwise agreed in the contract (this should then be clearly described eg based on payment batch, monitored visits etc). Payment term is 14 days as per Dutch Law. In case of violation of terms (supply billing / payment) interest will be charged as per Dutch Law.

13. Bank details

IBAN

14. Sources

Digital / paper. Access to digital sources can be arranged through:

15. Procedures

PT & R has a quality manual with SOPs. This is periodically reviewed and updated where necessary. If in the protocol a certain procedure is not described our SOP will be followed.

16. Monitoring

Monitoring visits should be planned xx weeks in advance. Please indicate the priority of the SMV and any outstanding actions that we need to follow up upon. There is a spacious monitoring room with Internet access through wireless WiFi (access key is provided). Only one SMV per day will be planned. Small / admin questions can be raised, depending on the workload, continues during the day at one of the assistants. Final assessment will be done in the afternoon with the PI. The site is open from xxxx am until xxxxxx pm. The ISF are kept in locked cabinets in the monitoring room. When changing CRA, we expect a good transfer between the CRAs about our methods, current state of affairs, and any details in the course of the study. If changes of a CRA result in extra work or time of the site this will be invoiced to the sponsor

17. Telecommunications

There is an analog phone line for fax and other equipment. CRAs can log on to the wifi network that allows access to the Internet. It doesn't give access to our intranet / server.

18. Equipment

The following equipment is present

Refrigerator

Freezer (-20)

Several centrifuges (including refrigerated centrifuges)

ECG

.....

Where applicable the equipment is being calibrated every ... year(s) and calibration reports can be viewed upon request. The temperatures of the medication storage, refrigerator and freezer are noted in in.....

19. External Collaborations / Networking Site

We have continued collaboration with

20. Other activities

21. Staff

All employees of PT & R are GCP trained and have experience and certificates in various IVRS, eDiary, ECG, spirometry, etools (including ediaries) and EDC systems. The PI has a IATA certificate and is CPI certified

22. Archiving

Looking forward to a productive collaboration.