

# **A. Contact information and timelines**

Clinical Study Agreement

**Detta dokument är framtaget och kvalitetssäkrat av Kliniska Studier Sverige.**

Vi utvecklar och erbjuder stöd för kliniska studier i hälso- och sjukvården.

Stödet vi erbjuder ger goda förutsättningar för kliniska studier av hög kvalitet.

## About the document

A. Contact information and timelines was first published 2021-06-10. This is version 2.0.

The information in this document needs to be specified for each agreement process. The document can be used as a template to specify contacts and timelines with the purpose to simplify and speed up the process.

## A. Contact information and timelines

### Clinical Study Agreement

The information in this document needs to be specified for each agreement process. The document can be used as a template to specify contacts and timelines with the purpose to simplify and speed up the process.

|  |
| --- |
| **Study title and/or study name** |
| **Protocol number** | **EudraCT number or SIN/CIV ID number** |
| **Sponsor** | **Contact Research Organisation (CRO)** |
| **Principal Investigator (PI)** | **Site** |

## Contact information agreement- and budget negotiations

|  |  |  |  |
| --- | --- | --- | --- |
| **Contact negotiation** | **Name** | **Phone** | **e-mail** |
| **PI** |  |  |  |
| **Site** |  |  |  |
| **CRO** |  |  |  |
| **Sponsor** |  |  |  |
|  |  |  |  |

## Contact information signing

|  |  |  |  |
| --- | --- | --- | --- |
| **Person signing agreement** | **Name** | **Title** | **Contact information (e-mail/phone)** |
| **Sponsor** |  |  |  |
| **CRO** |  |  |  |
| **PI (signs in acknowledgement)** |  |  |  |
| **Principal (site****representative) 1\*** |  |  |  |
| **Principal 2** |  |  |  |

\*The PI and the Principal cannot be the same person

## Timelines agreement process

Please fill in agreed estimated dates in the fields below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Site receivesbudget and agreement and all other relevant documents | Site proposaland comments to sponsor/ CRO followed by negotiation as applicable | Final documentsready for signatures | Signature bysite represen­tatives | Signature bysponsor/CRO representatives | Final agreementand budget signed  |
| Date: |  | Date: |  |  | Date: |

**Cost calculation and agreement review**

**Negotiation process**

**Signing process**

## Other agreements

Specify collaborating partners that needs separate agreements to perform the study

|  |  |  |
| --- | --- | --- |
| **Agreement partner** | **Contact person** | **Contact information (e-mail/phone)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |