|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Clinical trial identifiers** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Trial title: | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| Short name: | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| Protocol no. | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| **Description of the trial** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Question, hypotheses, objective, endpoints, etc.: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study design: | | | |  | | single-centre | | | | | | | | |  | | | multi-centre | | | | | |  |  | |
|  | | | |  | | open-label | | | | | | | | |  | | | single-blind | | | | | |  | double-blind | |
|  | | | |  | | randomised | | | | | | | | |  | | | cross-over | | | | | |  |  | |
|  | | | |  | | verum-controlled | | | | | | | | |  | | | placebo-controlled | | | | | |  |  | |
|  | | | |  | | Investigator initiated | | | | | | | | |  | | | not Investigator initiated | | | | | |  |  | |
|  | | | |  | | other: | | | | | | | | | | | | | | | | | | | | |
| Phase: | |  | I | |  | | II | |  | | | III | |  | | IV | | |  | Other (e.g. Ib, IIa): | | | | | | |
| Total number of subjects/patients: | | | | | | | | | | | |  | | | | | | | of which at USZ: | | | |  | | | |
| Trial start: | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| Planned trial duration: | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| Schedule detailed at USZ: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Parties involved:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sponsor:  (Company/Contact person/Tel/Fax/E-mail) | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| CRO:  (Company/Name Clinical Research Associate (CRA)/Tel/Fax/E-mail) | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| Principal Investigator (PI):  (Clinic/Name/Tel/Fax/E-mail) | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| Pflegepersonal / Study Nurse:  (Clinic/Name/Tel/Fax/E-mail) | | | | | | | | | | | | | | | | |  | | | | | | | | | |
| **Authorities and approvals:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cantonal Ethics Committee (CEC): | | | | | | | | | | |  | | Application pending, expected submission date: | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | Application submitted on: | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | Positive CEC approval received on: | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | CEC number: | | | | | | | | | |  | | |
| Swissmedic notification: | | | | | | | | | | |  | | Application pending, expected submission date: | | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | Application submitted on: | | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | Swissmedic notification received on: | | | | | | | | | | | | | |
|  | | | | | | | | | | |  | | Swissmedic notification number: | | | | | | | | | |  | | | |
| other (e.g. BAG): | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **Tasks for ZüriPharm:** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | product development | | | | | | | | | | | | | | | | | | | | | | | | |
|  | sterile manufacturing | | | | | | |  | | non-sterile manufacturing | | | | | | | | | | |  | no manufacturing | | | |
|  | packaging | | | | | | | | | | | | | | | | | | | | | | | | |
|  | creating the randomisation list/s | | | | | | | | | | | | | | | | | | | | | | | | |
|  | use of computerized systems (IVRS, IWRS, IRT, IXRS) | | | | | | | | | | | | | | | | | | | | | | | | |
|  | blinding of the IMP in accordance with the randomisation list / IVRS | | | | | | | | | | | | | | | | | | | | | | | | |
|  | storage | | | | | | |  | | disposal | | | | | | | | | | |  | accounting | | | |
|  | other: | | | | | | |  | | | | | | | | | | | | | | | | | |
| Order to ZüriPharm:  (Please specify precisely the nature and scope of the order. Please discuss with the responsible person at ZüriPharm.) | | | | | | | | | | | | | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Payment** | | | | **ZüriPharm costumer number (debtor):** | | |
| Pay office | USZ |  |  | | Profitzenter: |  |
| UZH |  |  | | PSE Element: |  |
| Others: | |  |  | | | |
| Invoice recipient: | | | | | | |
| Client / Company | | | |  | | |
| Name: | | | |  | | |
| Department: | | | |  | | |
| Street / No.: | | | |  | | |
| Post code / Town/City / Country | | | |  | | |
| IC no. (Zurich canton intercompany no.) | | | |  | | |
| Remarks: Payment deadline: | | | | days | | |
| Invoice address: (if different to invoice recipient) | | | | | | |
| Client / Company | | | |  | | |
| Street / No.: | | | |  | | |
| Post code / Town/City / Country | | | |  | | |

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| **Application completed by** | | |
| Place: | Date: | Sponsor’s signature |
|  |  | CRA’s signature |
|  |  | PI’s signature |

|  |  |
| --- | --- |
| Contact at ZüriPharm: | Study Coordination  ZüriPharm AG  Südstrasse 3  8952 Schlieren  Tel: +41 (0)43 258 54 12  Email: clinicaltrials@zueripharm.ch |

*Please return this application once completed and signed, along with the draft trial protocol, to the Study Coordination of ZüriPharm.*

*The application will be evaluated by ZüriPharm and an offer created. The work order to ZüriPharm must follow in writing.*