Eudract number

Protocol number

1. Parties

The Supplier (1.1) Apoteket AB (Apoteket), Dalvägen 12, SE-169 56 Solna, Sweden		
Visiting address for local pharmacy (1.2)		Company reg. number (1.3) 556138-6532
Contact (1.4)	Telephone number – switchboard (1.5)	Telephone number – direct (1.6)
E-mail (1.7)	Mobile number (1.8)	Fax number (1.9)
Customer (1.10)		Company reg. number (1.11)
Address (1.12)		(1.13) ☐ Sponsor ☐ CRO
Invoice address or e-mail address (1.14)	Other information for invoice (1.15) Payment reference, Apoteket AB´s invoice number from the invoice needs to be used.	
Contact (1.16)	Telephone number – switchboard (1.17)	Telephone number – direct (1.18)
E-mail (1.19)	Mobile number (1.20)	Fax number (1.21)

2. General terms and conditions and payment

In addition to the terms stated herein, the *General Terms and Conditions for Apoteket's Services in the Field of Clinical Trials*, dated 11-03-2022, Appendix 1, shall apply.

The prices set out in the *Prices for Apoteket's Services in the Field of Clinical trials*, Appendix 2, shall apply to the performance of services under this agreement.

Prices are annually adjusted as described in Appendix 2.

3. Power of Attorney

In the event that another legal entity or person enters into agreement on the Customer's behalf or declares that he represents the Customer by Power of Attorney, such legal entity or person warrants and represents that he has the authority and competence to enter into agreement on the Customer's behalf and that he otherwise has the right to act on the Customer's behalf.

4. Value-added tax clause

Swedish value-added tax will be charged on Services, purchased material and purchased pharmaceutical under this Agreement. Swedish value-added tax will, however, not be charged on Services if the Customer signs point 4 A or 4 B and provides information in accordance with these points.

4 A. ☐ The Customer hereby certifies that it has the following foreign value-added tax registration number: and is a foreign, taxable person in an EU country other than Sweden and carries out the Services in this capacity and that the Customer does not have a permanent establishment in Sweden to which the Services shall be provided.

4 B. ☐ The customer hereby certifies that it is a foreign, taxable person in a country outside the EU and carries out the Services in this capacity and that the customer does not have a permanent establishment in Sweden to which the Services shall be provided.

In the event that the Swedish Tax Agency charges Apoteket output value-added tax, interest or tax increments as a result of the provided services, Apoteket is entitled to invoice the Customer the added output value-added tax, added interest or added tax increments. The Customer is obliged to reimburse Apoteket such added output value-added tax, added interest or added tax increments.

5. Basic services

Definition of basic services

- Drafting of handling instructions and other required study specific documentation are included at up to two (2) hours.
- Handling and keeping of study related pharmacy documentation, storage of investigational product and any other study related materials, expiry date monitoring and temperature monitoring are included at up to three (3) years.
  Thereafter a yearly fee is charged for aforementioned services, until archiving of pharmacy documentation has been performed.
- Customer contacts regarding ongoing study/agreement in question.

Eudract number

Protocol number

6. Description of the trial

The agreement concerns (6.1)

- Distribution to single trial site ☐
- Distribution to multiple trial sites ☐
- Trial including preparation of IMP performed by pharmacy ☐

Number of trial sites in this agreement (6.2)

A site list must always be attached with information on the trial site number, principal investigator, contact details, delivery address and details on who has the right to order investigational products at the relevant unit. (6.3)

Protocol number (6.4)	Eudract number (6.5)

Any working name for the trial (6.6)

Title (6.7)

Indication (6.8)

For trials where the investigational product is prepared at the pharmacy, handling instructions must be attached. (6.9)

The number of patients per trial site (6.10)	Period of treatment per patient (only filled in for studies where the investigational product is prepared at the pharmacy) (6.11)

Estimated start and end date (6.12)

-

Trial design (6.13)

☐ Double blind ☐ Single blind ☐ Open

Eudract number

Protocol number

7. Investigational product, supplied by Customer/Sponsor

1 Name and designation of investigational product, preparation form, strength (7.1)	Generic name (7.2)
Each package contains (no of tablets, vials etc).(7.3)	Dosage (7.4)
Storage (7.5) ☐ Freezer (< -15 degrees) ☐ 2-8 degrees ☐ 15-30 degrees ☐ - degrees	
2 Name and designation of investigational product,, preparation form, strength (7.6)	Generic name (7.7)
Each package contains (no of tablets, vials etc) (7.8)	Dosage (7.9)
Storage (7.10) ☐ Freezer (< -15 degrees) ☐ 2-8 degrees ☐ 15-30 degrees ☐ - degrees	
3 Name and designation of investigational product,, preparation form, strength (7.11)	Generic name (7.12)
Each package contains (no of tablets, vials etc) (7.13)	Dosage (7.14)
Storage (7.15) ☐ Freezer (< -15 degrees) ☐ 2-8 degrees ☐ 15-30 degrees ☐ - degrees	
Additional investigational product is listed under point 14 (7.16) ☐ Yes ☐ No	

8. Other investigational products / other material

Apoteket procures other investigational products/other material (8.1) ☐ Yes ☐ No
Specify medication / other material, strength, package size and number of packages (8.2)

Eudract number

Protocol number

9. Delivery to Apoteket

Customer distributes without order (9.1)

☐ All investigational products at the same time ☐ Regularly during the study

Delivery address to the Pharmacy (9.2)

By order (9.3)

Must Apoteket order the investigational product? ☐ Yes ☐ No

Apoteket orders as follows from (9.4)

The investigational product(s) (IP) will be distributed as: (9.5)

☐ Site-specific deliveries for pass through distribution to trial site

☐ Deliveries of IP for storage at pharmacy, for subsequent ordering by trial site as/when needed

The delivery is confirmed by Apoteket (9.6)

☐ Not relevant ☐ By IWRS/IVRS ☐ By fax to:

☐ By e-mail to:

Temperature control (distribution to pharmacy) (9.7)

Will the delivery contain a temperature monitor? ☐ Yes ☐ No

- If “Yes”, is the temperature monitor to be stopped and read out at the pharmacy? ☐ Yes ☐ No

Will the delivery be transported in temperature-validated transport boxes? ☐ Yes ☐ No

- If “Yes”, can the transport box be further used for shipping from pharmacy to trial site? ☐ Yes ☐ No

10. Labelling (in addition to existing labelling on receipt)

The following labelling is requested on the investigational product specified under point 7 (10.1)

☐ Labelling not required

☐ Principal investigator's name

☐ Folding of booklet

☐ Extended expiration date if applicable

☐ Centre number

☐ Other, specify labelling:

The following labelling is requested on the other investigational product specified under point 8 (10.2)

☐ Labelling not required

☐ Other, specify labelling:

Labels (10.3)

☐ Produced by Apoteket ☐ Produced by Customer

Documentation (10.4)

☐ Apoteket's forms ☐ Customer's forms

The following labelling is requested for investigational product prepared at Apoteket (10.5)

The following details must be included on the label:

Eudract number

Protocol number

11. Dispensing and transport

The investigational product is ordered from Apoteket by requisition, and is dispensed and dispatched (11.1)

☐ To the patient

☐ To the trial site

Any other information regarding dispensing (11.2)

When dispatching to the trial site, specify the following (11.3)

Sent with temperature-validated packaging requested: ☐ Yes ☐ No ☐ Hired box

Sent with temperature monitoring requested: ☐ Yes ☐ No ☐ Hired temperature monitor

Way of transportation to trial sites (11.4)

Before drugs can be dispensed, the Pharmacy needs to have copies of the approvals of the study from the Medical Products Agency (MPA) and Ethics Committee for all trial sites included in the agreement. (11.5)

12. Returns/Destruction

Investigational products from the trial sites will be returned to Apoteket (12.1)

☐ Yes ☐ No

Study medication at Apoteket (12.2)

☐ Sent for destruction ☐ Returned to Customer

Returns/Destruction documented with (12.3)

☐ Customer's forms ☐ Apoteket's forms

Destruction takes place after written certification from Customer (12.4)

☐ On a regular basis ☐ At end of trial

Other information (12.5).

13. Archiving

Requested archiving period for pharmacy documentation (13.1)

☐ 10 years archiving required

☐ 15 years archiving required

☐ 25 years archiving required

☐ 30 years archiving required

The archiving period starts when the Customer provides approval for archiving.
Apoteket destroys the pharmacy documentation at the end of the agreed archiving period.

Should the Customer wish to extend the archiving period beyond what was originally agreed, the Customer is responsible for contacting Apoteket well in advance of the due date of the agreed archiving period. The parties may then enter into a new agreement to extend storage of the documentation.

14. Other details/Additional details about the trial

Other (14.1)

15. Entire Agreement

Regulation of the agreement (15.1)
This Agreement constitutes the parties' entire agreement of all matters to which the Agreement relates and supersedes all written or verbal undertakings, commitments and arrangements which precede the signing of this Agreement.

Eudract number

Protocol number

16. Signatures

Method of signature (16.1)

☐ Electronic signature

Parties explicitly agree to execute this Agreement by way of an electronic signature and agree this shall constitute a valid and enforceable agreement between the Parties.

The present Agreement is made in pdf-version which is signed electronically by each Party.

☐ Wet-ink signature

This Agreement has been drawn up in two (2) originals, of which the Parties have one original each.

Apoteket AB

Place and date	Place and date
Signature	Signature
Print name	Print name
Title	Title
Place and date	Place and date
Signature	Signature
Print name	Print name
Title	Title

Appendicies

Appendix 1 General Terms and Conditions for Apoteket's Services in the Field of Clinical Trials, dated 11-03-2022

Appendix 2 Prices for Apoteket’s Services in the Field of Clinical trials