

## FÖRSÄTTSBLAD

### Clinical Study Agreement

- Denna avtalsmall kan användas när VGR har initierat och ska leda en klinisk studie (som varken är en läkemedelsprövning eller en prövning av en medicinteknisk produkt) och ska uppdra åt ett deltagande sjukhus (prövningsställe) att utföra en del av studien hos sig.
- Avtalsmallen utgår från ett förhållande där båda parter är svenska och lyder under svensk lagstiftning. Mallen kan också användas som utgångspunkt för utländska prövningsställen, men då finnas det behov av nationella tillägg för den utländska parten och justeringar i avtalet.
- Under parter ska det för VGR stå både Västra Götalandsregionen och vilken förvaltning som ingår avtalet.
- Gula markeringar ska fyllas i med information.
- Ord och meningar som anges inom klamrar utan gul markering är sådana som eventuellt ska tas bort, beroende på omständigheterna i den aktuella studien. Även andra delar av avtalet kan behöva anpassas till omständigheterna i den aktuella studien.
- Röda texter är hjälptexter och raderas innan avtalsutkast delas med motparten. Likaså tas detta försättsblad bort innan delning med motpart.

Ärende/D-nr:

## CLINICAL STUDY AGREEMENT

**THIS CLINICAL STUDY AGREEMENT** (this “**Agreement**”) is entered into between:

- (1) **Västra Götalandsregionen**, through [insert hospital], (reg. no. 232100-0131), a public teaching hospital organised under the laws of Sweden, through [insert department at hospital], having its principal place of business at [insert address] (“**VGR**”) and
- (2) [**Name of Institution**] (reg. no. [insert reg.no.]), a public teaching hospital organised under the laws of [Sweden], through [insert department], with its offices at [insert address] (“**Institution**”).

The above parties are hereinafter also referred to each as a “**Party**” and jointly as the “**Parties**”.

Study Acronym	
Study Title	
Registration number for the initial approved application at the Swedish Ethical Review Authority (diarienumret hos EPM)	
Anticipated completion of the Study	Qx 20xx
Estimated number of subjects to be included at Institution	

### BACKGROUND:

- (A) Whereas VGR has initiated and designed the above-mentioned study (the “**Study**”) and wishes to have part of the Study performed at Institution, under the direction of [insert name of Principal Investigator at Institution] (“**Principal Investigator**”), an employee of Institution, who is willing to perform the Study under the terms of this Agreement.

(B) Whereas Institution has the skills, knowledge, expertise and resources to conduct the Study.

(C) Now therefore the Parties have agreed as follows.

## **1. DEFINITIONS**

### **1.1 In this Agreement, the following definitions are used:**

“**Applicable Laws**” shall mean all applicable laws, regulations, ethical principles and guidelines, especially those governing the performance of the Study, including but not limited to, (A) the current version of the Helsinki Declaration; (B) all data protection and data privacy laws and regulations including the GDPR; and (C) all anti-bribery and anti-corruption laws and regulations.

“**GDPR**” shall mean Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

“**Intellectual Property**” means any inventions whether patentable or not, patents for inventions, certificates of inventions, utility models, chip protection, design patents, registered designs or other design rights, trademarks, service marks, trade secrets, right(s) in unpatented know-how, right of confidence and the like as well as applications therefore, and copyrights and any other intellectual or industrial property of any nature whatsoever in any part of the world.

“**Result**” means any Intellectual Property rights arising as a result of the work performed under this Agreement.

1.2 In this Agreement, save where the context otherwise requires, words in the singular shall include the plural, and vice versa.

## **2. AUTHORISATIONS**

- 2.1 VGR shall be responsible for obtaining required regulatory approvals for the conduct of the Study from the Swedish Ethical Review Authority. Institution shall not initiate the Study until such proof of required approvals for the conduct of the Study is obtained.

## **3. CONDUCT OF THE STUDY**

- 3.1 Principal Investigator will be responsible for the performance of the Study on behalf of Institution. For the sake of clarity, all obligations to the Principal Investigator, as well as to other Institution personnel, will apply to them as representatives of Institution and Institution will be solely liable under this Agreement.
- 3.2 The Parties shall conduct the Study in accordance with the Protocol, as amended from time to time, and shall comply with all Applicable Laws, informed consents, the terms and conditions of the approval from the Swedish Ethical Review Authorities and the terms of this Agreement.
- 3.3 Institution and Principal Investigator shall be fully informed of the Protocol. VGR shall provide all relevant clinical information to Institution, which are required for the proper planning and conduct of the Study. Principal Investigator shall attend, or ensure that a delegate attends, all Investigators' meetings for the Study from time to time as reasonably required by VGR.
- 3.4 Institution agrees to provide, and shall cause Principal Investigator to provide, VGR periodically and in a timely manner with all Study data called for in the Protocol. Institution/Principal Investigator shall submit the Study data using an electronic case report form ("eCRF"). Institution and Principal Investigator agrees to collect all Study data in source documents prior to entering it into the eCRF. The eCRF shall be completed within the time period described in the Protocol.

## **4. DATA AND SAFETY REPORTING**

- 4.1 VGR will promptly report to Institution any findings that could affect the safety of Study subjects, influence the conduct of the Study, or that VGR determines could alter the regulatory approvals for the Study from the competent authorities.

## **5. RECORD KEEPING**

- 5.1 Institution will archive its clinical study documentation for at least 10 years after the end of the clinical trial or longer period if required by Applicable Laws. The documentation shall be archived in a way that ensures that it is readily available and accessible, upon request, to the competent authorities. The media used to archive the content of the Investigator Site File shall be such that the content remains complete and legible throughout the period referred to above. Any alteration to the content of the Investigator Site File shall be traceable.

*[Använd stycket nedan (om Biological Materials) om Institution ska samla in studiespecifika prover. Radera den här röda texten innan avtalsutkast skickas till motparten.]*

## **6. [BIOLOGICAL MATERIALS]**

- 6.1 Institution shall ensure that any collection, handling, transportation, and retention of any biological materials is carried out in accordance with the Protocol, the informed consents of Study subjects, and Applicable Laws. Institution shall further ensure that the security, integrity, quality and identity of the biological materials are maintained at all times.
- 6.2 The biological materials shall only be used for purposes of the Study and as allowed by the Study subjects' informed consent form and ethical review permit from the Swedish Ethical Review Authority.
- 6.3 After the Study is completed, the biological materials will be retained or destroyed in accordance with the Protocol, any biobank agreement, the informed consents of Study subjects and the ethical review permit from the Swedish Ethical Review Authority.]

## **7. STUDY SUBJECT ENROLMENT**

- 7.1 Institution shall make its best efforts to ensure that the recruitment target of eligible Study subjects in accordance with the Protocol is met timely. Institution shall continuously inform VGR about the recruitment status.

7.2 Institution may enrol Study subjects in mutual competition with other participating sites. VGR reserves the right to end the Study subject enrolment under this Agreement when the desired number of Study subjects for all sites has been reached. Further, Institution agrees that continued screening or randomisation of subjects must not take place after Study subject enrolment has been ended by VGR and notice hereof has been given to Institution by VGR.

## **8. INFORMED CONSENT**

8.1 Institution undertakes to use the subject information sheet as approved by the Swedish Ethical Review Authority to obtain written informed consent from each Study subject or, where the subject is not able to give informed consent, his or her legally designated representative prior to inclusion of any Study specific procedures for screening according to the Protocol.

## **9. AUDITS AND INSPECTIONS**

9.1 Institution shall during the Study, on reasonable prior written notice and at an agreed upon time, permit authorised personnel of VGR to access the site during normal business hours to conduct audits and monitoring. Institution and Investigator shall permit VGR and its representatives' access to relevant records relating to the Study for such purposes. VGR is aware that the Swedish Patient Data Act (*in Swedish: patientdatalagen (2008:355)*) prevents direct access with login to patient records for auditing and monitoring clinical studies. Such records will therefore only be provided in paper or in other permitted forms.

9.2 Institution shall promptly inform VGR of any intended or actual inspection, written enquiry and/or visit to Institution by any regulatory authority in connection with the Study and shall forward to VGR copies of any correspondence from any such regulatory authority relating to the Study. Institution and Investigator shall make themselves available and shall reasonably cooperate with any regulatory authority with respect to inspections performed according to Applicable Laws. Unless prohibited by law, Institution will permit VGR, or its representative, to be present during such a regulatory authority inspection.

## **10. PAYMENTS**

- 10.1 [ALTERNATIV 1:] Each Party shall bear its own costs and expenses incurred or to be incurred in performing the Study. No payments shall therefore be made between the Parties in connection with this Agreement.
- 10.2 [ALTERNATIV 2:] The budget and compensation to be paid by VGR for the Study is included in **Appendix 1** (“**Payment Schedule**”). Payment shall be due and payable in accordance with the schedule and details set forth in Appendix 1. Invoices shall contain a specification of the work carried out during the period and any additional costs incurred. Institution shall, upon request, be able to show documentation in support of a certain phase having been attained. Such documentation shall include necessary receipts and supporting documentation as further detailed in the Payment Schedule. Invoices are payable within thirty (30) days of invoice date. In case of overdue payment, interest may be charged in accordance with the Swedish Interest Act SFS 1975:635.

## **11. PUBLICATION**

- 11.1 Institution acknowledges that the Study is a multicenter study and that VGR retains the right to make a first publication of the results of the Study based on the Study data from all participating sites (a “**Multicenter Publication**”). All participating sites shall be appropriately acknowledged in the Multicenter Publication. Following the earliest of (i) VGR’s Multicenter Publication; or (ii) VGR’s confirmation that there will be no Multicenter Publication, Institution shall have the right to prepare and submit Institution’s Study data for a scientific publication in scientific journals or other professional publication or presentation (an “**Institution Publication**”). VGR’s role in support of the Study shall be appropriately disclosed in any Institution Publication.
- 11.2 Institution shall provide VGR with a draft of any proposed Institution Publication at least thirty (30) days prior to submission of such publication for VGR to ascertain whether any patentable subject matter or Confidential Information are disclosed therein. VGR shall return to Institution within thirty (30) days after receipt of the draft Institution Publication (“**Review Period**”), and Institution agrees and shall require Institution personnel to agree that due consideration shall be given to VGR’s comments. Institution shall delay any proposed Institution Publication an additional sixty (60) days beyond the Review Period in the event

VGR so requests to enable VGR to secure patent or other proprietary protection (“**Delay Period**”). Institution agrees to: (i) keep the proposed Institution Publication confidential (to the extent so permitted by Applicable Laws) until expiration of the Review Period and any Delay Period, and (ii) delete Confidential Information (other than Institution’s Study data) from any Institution Publication. In the event that Institution and VGR differ in their conclusions or interpretation of data in the Institution Publication, the Parties shall use good faith efforts to attempt to resolve such differences through appropriate scientific debate, but, subject to removal of Confidential Information (other than Institution’s Study data), Institution shall retain control over the final version of the Institution Publication.

## **12. PUBLICITY**

12.1 None of the Parties shall use the name of the other Party for marketing or promotional purposes without the prior written consent of the Party whose name is proposed to be used. For clarification, Institution and Principal Investigator may without prior written approval, disclose their participation in the Study (including the name of VGR, the name of the Study, funding source, and total funding amount) as required by Applicable Laws, court order, or state regulation, or in (i) curriculum vitae, (ii) internal reports, (iii) grant applications to government funding sources, (iv) required government reports and filings, (v) and (vi) conflict of interest disclosures.

## **13. CONFIDENTIALITY**

13.1 Each Party shall treat all information received from the other Party during the course of the Study as confidential to the extent such information is considered confidential in accordance with applicable law including the Public Access to Information and Secrecy Act (offentlighets- och sekretesslagen SFS 2009:400) (“**Confidential Information**”).

## **14. INTELLECTUAL PROPERTY AND STUDY DATA**

14.1 Nothing in this Agreement shall affect either Party’s rights to its pre-existing Intellectual Property owned or controlled at the Effective Date (“**Background IP**”) nor imply grant of any license to such Background IP unless expressly set forth herein.

*[Använd styckena nedan om VGR ska ersätta Institution för dess kostnader. Radera annars. Radera den här röda texten innan avtalsutkast skickas till motparten.]*

- 14.2 All data and Results generated by Institution or Principal Investigator in the direct course of conducting the Study (excluding Institution's original works of authorship in publications made in accordance with this Agreement) shall belong to VGR ("VGR IP").
- 14.3 Institution may use VGR IP for further non-commercial research, education and patient care purposes.
- 14.4 Institution retains ownership of all clinical data as contained in Institution's patient and medical records or other original source documentation.

*[Använd stycket nedan om var och en av VGR och Institution ska stå för sina egna kostnader. Radera annars. Radera den här röda texten innan avtalsutkast skickas till motparten.]*

- 14.5 Title to a Result shall vest solely in the Party who generated it. If both Parties have jointly generated a Result, such Result shall be jointly owned by the Parties in proportion to the contribution made by each Party or, where the shares in the Result are not possible to determine, in equal shares.
- 14.6 The Parties hereby grant each other a non-exclusive, gracious licence, without the right to transfer or sublicence, to use each other's Result (also includes jointly owned Results) for the purpose of carrying out their respective obligations under the Study in accordance with this Agreement and for purposes of non-commercial education, research and patient care.
- 14.7 If a Party in order to use its own Results (also includes jointly owned Results) for other purposes than above, needs access to or use the other Party's Results (also include jointly owned Results), such license shall be agreed upon on commercially reasonable terms in accordance with a separate agreement between the Parties.

**15. LIMITATION OF LIABILITY**

15.1 Neither Party shall be liable to the other Party for lost profits, or for any special, indirect, incidental, consequential or punitive damages, arising out of this Agreement.

**16. INSURANCE**

16.1 VGR warrants that it at Study start has in place and will maintain a general liability insurance in at least the minimum amounts to cover its obligations under this Agreement.

16.2 Institution warrants that the Study subjects are covered under the Swedish patient insurance (*in Swedish: patientförsäkringen*) with Lof (the Swedish county councils' and regions' mutual insurance company) in accordance with the Swedish Patient Injury Act (*in Swedish: patientskadelagen SFS 1996:799*). Institution further warrants that it has in place and will maintain a general liability insurance sufficient to cover its obligations under the Agreement.

**17. DATA PRIVACY**

17.1 In respect of the processing of personal data related to the performance of the Study and for the purpose of this Agreement, each Party shall be data controller and thereby individually and separately responsible for complying with the obligations that apply to it as controller under GDPR. The Parties further acknowledge that Institution will serve as independent controller for the Study subjects' personal data to the extent such Study subject personal data is processed by Institution or Principal Investigator in the treatment of Study subjects as patients of Institution or Principal Investigator.

17.2 VGR and Institution ensure that they each have proper legal basis for the processing of personal data in compliance with GDPR.

17.3 Personal data of Study subjects, when transferred to VGR, will be pseudonymized to replace any information that directly identifies a Study subject with a subject identification code. Neither Institution nor Principal Investigator will provide VGR with the key or code that enables Study subjects to be re-identified. The personal data shall at all times be transferred to VGR by appropriate technical and organisational measures to ensure a level of security appropriate to the risk of the transfer. Both Institution and VGR shall maintain appropriate

technical and organisational security measures to protect the personal data they process in relation to the Study and this Agreement. VGR shall safeguard the personal data from unauthorised access, use and theft.

- 17.4 Where VGR's processing of the personal data will be carried out by a processor on behalf of VGR, VGR shall ensure that the processor will implement appropriate technical and organisational measures in such a manner that the processing will meet the requirements of data protection laws.
- 17.5 VGR shall only use the personal data of Study subjects for the purposes of the Study and within the limits set by the Protocol, Ethical or other regulatory permits, any biobank agreement, informed consent from Study subjects and Applicable Laws. VGR shall not otherwise use or disclose the data unless required to do so by Applicable laws.
- 17.6 VGR shall ensure that confidentiality, to the full extent permitted by Applicable law, applies to the personal data and that access to the personal data is strictly limited to authorised users. VGR shall ensure that all authorised users (i) are informed of the confidential nature of the personal data, (ii) have received appropriate training of their responsibilities, and (iii) have executed written confidentiality agreements or are under an appropriate statutory obligation of confidentiality. VGR shall ensure that such confidentiality obligations survive the termination of their personnel arrangement.

## **18. TERM AND TERMINATION**

- 18.1 This Agreement shall become effective on the date of the last signature of this Agreement by the Parties ("**Effective Date**") and shall remain in effect until completion of the Study (which means the conclusion of all Protocol required activities for all enrolled Study subjects) and close-out of Institution or earlier termination in accordance with this Agreement.
- 18.2 VGR may terminate this Agreement at any time in exercise of its sole discretion upon giving thirty (30) days advance written notice to Institution.
- 18.3 Institution may terminate this Agreement with immediate effect upon written notice to VGR if VGR commits a material breach under this Agreement and – after receipt of a written notice

specifying the breach – fail to remedy the breach within thirty (30) days from the date of the said notice.

- 18.4 Either Party may terminate this Agreement with immediate effect by notice in writing to the other Party (i) if the other Party becomes insolvent or bankrupt or subject to reorganisation, reconstruction or liquidation, makes any arrangement with its creditors, has an administrator, receiver or manager appointed, or ceases or threatens to cease to carry on its business; (ii) if the regulatory permissions and approvals previously granted to perform the Study are withdrawn; or (iii) if the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement to both Parties is not found; (iv) if either Party, in its sole discretion, determines that any of the Study results support termination of the Study for the safety or welfare of Study subjects.

*[Använd stycket nedan endast om VGR ska betala ut ersättning till Institution för dess arbete och/eller kostnader för studien. Om i stället var och en av parterna ska stå för sina egna kostnader så ska stycket raderas. Radera den här röda texten innan avtalsutkast skickas till motparten.]*

- 18.5 Upon termination or expiration of this Agreement, VGR shall be obligated to pay Institution solely for those items set forth in the Study budget that have been incurred prior to the date of termination, and any non-cancellable expenses incurred by Institution pursuant to this Agreement and the Study budget prior to such termination. Institution shall promptly refund to VGR any advance payments for work not yet performed made by VGR under the Payment Schedule. In no event shall VGR be required to pay for Study activities not performed.

## **19. NOTICES**

- 19.1 All notices and other communications required or permitted under this Agreement shall be deemed to have been received by a Party when:
- (a) delivered by certified or registered mail with postage prepaid, on the third (3<sup>rd</sup>) business day after the date it is so mailed;
  - (b) delivered by hand and receipted for by the Party to whom said notice or other communication shall have been directed, on the day of delivery; or

- (c) sent by e-mail, the receipt of which has been confirmed by the receiving Party, on the day of receipt.

19.2 All notices and communications required or permitted under this Agreement shall be addressed as set out below or to such other addresses as may be given by written notice in accordance with this Section.

- (a) If to VGR, to:

[Insert name of hospital]  
Attn. [insert name of contact person]  
[insert address]  
Sweden

[insert e-mail address]

- (b) If to Institution, to:

[Insert name of Institution]  
Attn. [insert contact person]  
[insert address]

[insert e-mail address]

## 20. MISCELLANEOUS

20.1 **Entire Agreement.** This Agreement represents the entire understanding and constitutes the whole agreement between the Parties in relation to its subject matter and supersedes all prior agreements, covenants, arrangements, communications, representations or warranties, whether oral or written, by any officer, agent, employee or representative of either of the Parties.

20.2 **Amendments.** This Agreement may only be amended, changed or modified by an instrument in writing duly executed by the Parties.

20.3 **Survival.** Any rights or obligations set forth herein which by their nature are intended to extend beyond the term of this Agreement shall survive the expiration or termination or the Agreement.

- 20.4 **No Waiver.** In no event shall any delay, failure or omission of a Party in enforcing, exercising or pursuing any right, claim or remedy under this Agreement be deemed as a waiver thereof, unless such right, claim or remedy has been expressly waived in writing.
- 20.5 **Assignment.** This Agreement shall not be assignable by either of the Parties without the prior written consent of the other Party which shall not be unreasonably withheld.
- 20.6 **Severability and Replacement.** If any provision of this Agreement or the application of it shall be declared or deemed void, invalid or unenforceable in whole or in part for any reason, the remaining provisions of this Agreement shall continue in full force and effect. The Parties shall seek to amend such void, invalid or unenforceable provisions and thereby this Agreement in order to give effect to, so far as is possible, the spirit of this Agreement and to achieve the purposes intended by the Parties.
- 20.7 **Mandatory National Law.** Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

## **21. GOVERNING LAW AND DISPUTE RESOLUTION**

- 21.1 This Agreement shall be governed by and construed in accordance with the laws of Sweden without regard to any conflict of law provisions. Any dispute, controversy or claim arising out of or in connection with this Agreement, which cannot be settled by the Parties themselves, shall be settled by a Swedish court of general jurisdiction.

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This agreement is executed by the authorized representatives of the Parties of the dates indicated below.

Each Party agrees that this Agreement may be electronically signed, and that electronic signatures appearing on this Agreement are the same as handwritten signatures for the purposes of validity, enforceability and admissibility.

**Authorised representative of VGR, [insert  
name of hospital]**

\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name printed and title

**Authorised representative of VGR, [insert  
name of hospital]**

\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name printed and title

**Authorised representative of [insert name  
of Institution]**

\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name printed and title

**Authorised representative of [insert name  
of Institution]**

\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name printed and title

The undersigned Principal Investigator hereby declares that he/she has read and acknowledged the Agreement:

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Place and date

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Signature

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Name printed and title

**Appendix 1**  
**PAYMENT SCHEDULE**