Standard contract template for clinical trials with medicines under the responsibility of a pharmaceutical company (industrial sponsor) based on the German Standard Contractual Clauses Ordinance - Standardvertragsklausel-Verordnung (StandVKlV)

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- *Preamble/Foreword*

For many years, Germany was well positioned and internationally competitive as a location for conducting clinical trials. This was reflected, among other things, in its position as number one in Europe and number two worldwide, behind the United States, in terms of the number of clinical trials conducted. Unfortunately, this has not been the case for several years now, and several countries, including some in Europe, have overtaken Germany. Regaining a strong position at the top is in the common interest of all those involved in clinical research, patients, trial centres and sponsors of clinical trials.

The conduct of clinical trials is often subject to time pressure, and the factor of "time" plays an important role in international comparison, especially until the start of a clinical trial. To be able to start a clinical trial as early as possible, the underlying contracts between the parties involved should also be able to be concluded quickly, easily and comprehensively in terms of content.

Against this background, it is helpful if the potential contracting parties have guidance in the form of model contract clauses in their respective negotiations, in which certain, constantly recurring contractual provisions in contracts for the conduct of clinical trials are compiled as examples, thus simplifying contract negotiations in these areas. For this reason, model contract clauses have been jointly drafted by representatives of the German Association of Medical Faculties (MFT), the German Association of Academic Medical Centres (VUD), the Coordinating Centers for Clinical Studies (KKS Network) and the Association of Research-Based Pharmaceutical Companies (vfa), considering the different interests of all parties involved. The Federal Association of the Pharmaceutical Industry (BPI) and the Federal Association of Medical Contract Research Organisations (BVMA) have also contributed to version 2.0 of the model contract clauses for clinical trials with medicinal products.

As part of the discussions on the Medical Research Act, the Federal Ministry of Health (BMG) has now gone one step further and introduced "Standard Contract Clauses for the Conduct of Clinical Trials" into the German Medicines Act as Section 42d. Section 42d AMG created the legal basis for a regulation in this area.

On 18 September 2025, the "Regulation on the Simplification of the Conduct and Approval of Clinical Trials" was published, which contains Article 1, the "Regulation on Standard

Contractual Clauses for the Conduct of Clinical Trials (Standard Contractual Clauses Regulation – StandVKlV)" and the associated provisions in Annex 1.

The Regulation on Standard Contractual Clauses for the Conduct of Clinical Trials (StandVKlV) will apply after 17 December 2025 to all contracts in Germany for the conduct of clinical trials with medicinal products. The regulation primarily covers commercial sponsors (e.g. pharmaceutical companies) who initiate clinical trials with economic objectives. Sponsors that are not commercial (e.g. academic, non-profit initiatives) and act without economic objectives are not subject to the obligation to apply the specified standard contractual clauses. The Standard Contractual Clauses Regulation – StandVKlV (Germany) is important because it addresses several key objectives in the field of clinical trials:

- Acceleration of the contract process
- Strengthening Germany as a research location
- Clarity and legal certainty
- Reduction of bureaucratic hurdles before the start of a study

Against this background, the institutions affiliated with the association platform (MFT/VUD, KKS Network and the associations BPI, BVMA and vfa) have decided to draw up a comprehensive standard contract template for clinical trials with medicinal products, which reproduces the wording of the StandVKlV 1:1 in the grey-shaded areas of the text. Text not shaded are added text passages and yellow-shaded areas of the text indicate the need for additions or variations.

This standard contract template represents a fully formulated, completed contract template using the provisions of the regulation. Where the previous model contract clauses already contained agreed clarifications (e.g. for deadlines) and additions that went beyond the regulation, these were adopted where possible. The aim of this standard contract template is to support the application of the BMG's standard contract clauses and to bring them into widespread use quickly.

Disclaimer: The following standard contract template was drafted by representatives of the participating organisations to the best of their knowledge and based on joint technical discussions and practical experience gained in each case. The sections highlighted in grey reflect the wording of the StandVKlV. The legality and compatibility of clauses that go beyond the StandVKlV with German or European law may be assessed differently by any courts that may be called upon. Furthermore, users of this standard contract template are not exempt from recording the specific facts and the respective intentions of the parties in each individual case to decide on the use of the standard contract template on this basis. The authors accept no liability whatsoever.

We would like to point out that, in accordance with the provisions of Section 42d of the German Medicines Act (AMG), the sponsor and the trial centre may agree to deviate from the standard contract clauses by mutual consent.

Clinical Trial Agreement

for

the Clinical Drug Clinical Trial with the (short) title:

between

[Name of Trial Site]

represented by the Administrative Director of the Faculty

[Address of Trial Site]

conducted in the [Institute name]

Address _____

by Principal Investigator _____ (hereinafter referred to as

"Investigator")

Optional: Other involved institutions _____

– hereinafter "Trial Site" –

and

[Name of Sponsor]

[Address of Sponsor]

– hereinafter "Sponsor" –

together **"Contracting Parties"**

Preamble

The Sponsor intends to conduct the following clinical trial of a medicinal product according to the Trial Protocol:

Title: _____ (hereinafter the "**Clinical Trial**")

Phase: _____

ECTR_____

Multicentre/Single-centre (*delete as appropriate*)

OPT: Legal representative of the Sponsor in the EU: _____ (*Only required if the Sponsor is located outside the EU*)

The Sponsor is the regulatory sponsor of the aforementioned Clinical Trial. The Trial Site has received the Trial Protocol, confirmed the feasibility of the Clinical Trial and the presence of all necessary qualifications and requirements in the clinic. The Trial Site wishes to participate in the Clinical Trial and is able and willing to ensure the agreed services for conducting the Clinical Trial.

The Contracting Parties hereby enter into the following agreement:

1. Subject Matter of the Contract

(1) The Sponsor commissions the Trial Site and the Investigator of the Trial Site to conduct a clinical trial in accordance with the provisions set out in the protocol (as attached in Annex 1) (the "Trial Protocol").

(2) The Trial Protocol and other written instructions of the Sponsor in their respective valid versions, including the described services and obligations of the Contracting Parties, are part of this agreement. In case the Trial Protocol contains provisions that contradict this agreement, the provisions of the Trial Protocol shall prevail concerning scientific and clinical matters, while the provisions of this agreement shall prevail for all other matters.

(3) The Contracting Parties shall regularly exchange information on the status of the Clinical Trial.

2. Legal Framework / Recruitment

(1) The conduct of the Clinical Trial, including the services, shall be carried out in accordance with the provisions of Regulation (EU) 536/2014 ("EU-CTR"), the German Medicinal Products Act, the applicable ICH GCP Guidelines, the latest version of the Declaration of Helsinki, GxP, and in compliance with the General Data Protection Regulation (GDPR), the Federal Data Protection Act, and any applicable state data protection laws. The Contracting Parties undertake to observe these regulations and guidelines.

(2) All members of the study team are not a contracting party to this agreement; the Trial Site shall assign the respective obligations to the Investigator. The Investigator acknowledges this contract by signature and also acts based on their obligations as Investigator in accordance with statutory provisions.

(3) It is planned that the Clinical Trial shall commence (insert date/ immediately), with a trial participant enrolment period of (insert numbers) months, and is expected to be completed by approximately (insert date). At the Trial Site, it is anticipated that by (insert date) (insert numbers) subjects will be enrolled in the Clinical Trial. Enrolment is subject to the Trial Site's capacities; achievement of the intended number of subjects cannot be guaranteed.

3. Obligations of the Trial Site

(1) Tasks under this agreement shall only be assigned to qualified persons, and, if necessary, such persons shall be appropriately instructed in their duties. The Trial Site undertakes to establish and maintain the necessary equipment, personnel, and internal administrative requirements for the conduct of the Clinical Trial throughout its duration. The Trial Site is registered as an organization in the Organization Management Service of the European Medicines Agency (EMA) and shall maintain the necessary entries during the Clinical Trial, as well as provide the Sponsor with an up-to-date scientific curriculum vitae and a description of the qualifications, education, and experience of the Investigator in clinical trials and patient care for documentation in the Clinical Trial Information System.

(2) The Trial Site undertakes to notify the Sponsor immediately if the Investigator is no longer able to fully perform their duties due to their role or if it becomes clear that the Investigator will leave their employment. The Trial Site and the Sponsor shall promptly agree on a qualified replacement.

(3) The Trial Site and the Investigator shall provide the Sponsor or a designee of the Sponsor (e.g., a Clinical Research Organisation (CRO)) upon request all documentation required by legal and company-specific requirements to enable the participation of the Trial Site in the Clinical Trial.

(4) The Trial Site and the Investigator shall document all cases in accordance with the Trial Protocol. For every enrolled subject, the Sponsor shall be provided with a completed case report form (CRF) within 5 working days after examination, or the data shall be entered into the electronic study database.

(5) The Trial Site shall ensure that:

a) The Investigator obtains informed consent from subjects before the start of any study procedure, informing them of the essential content, significance, risks, and scope of the Clinical Trial, existing insurance coverage, rights regarding personal data, and the right to withdraw from the Clinical Trial at any time. The consent and information process shall be fully documented, and subjects shall be granted a reasonable period to consider participation or ask further questions.

b) The investigational medicinal product is handled properly, and adverse events occurring in study subjects are documented by the Investigator in accordance with the Trial Protocol and reported to the Sponsor.

c) The Investigator is fully informed according to GCP about the nature, significance, risks, and scope of the Clinical Trial based on documents provided by the Sponsor (Trial Protocol, investigator's brochure, etc.).

(6) The Investigator observes the requirements of the Trial Protocol, including any changes or amendments during the Clinical Trial, and other written determinations from the Sponsor. The Investigator shall ensure and monitor compliance with these requirements at the Trial Site and promptly document any transfer of activities or changes as stipulated by the Sponsor.

(7) If the Investigator determines that conduct of the Clinical Trial with the agreed subject population or investigational medicinal product is not possible or is medically inadvisable due to unexpected results, the Investigator shall promptly inform the Sponsor. If continuation of the Clinical Trial is medically inadvisable, the Sponsor may order immediate termination or the Investigator may inform the Sponsor that the study treatment was not conducted. In both cases, the Sponsor must also inform the ethics committee. The Sponsor is not entitled to compensation claims resulting from this but remains obligated to pay compensation corresponding with the total effort to date.

(8) Agreements with other participating departments of the Trial Site (e.g., pharmacy, radiology, etc.) may be regulated in separate annexes to this agreement (see Annex 3).

4. Obligations of the Sponsor

(1) The Sponsor is primarily responsible for compliance with patient safety and data security requirements during the conduct of the Clinical Trial. This includes maintaining the study data in the CTIS database, unless the Trial Site has assumed responsibility for the data pertaining to itself or the Investigator.

(2) The Sponsor shall provide the necessary approvals as well as the approved documents and forms, especially for obtaining consent.

(3) The Sponsor shall obtain and maintain subject insurance.

5. Disclosure of Financial Information

(1) The Investigator must agree to provide the Sponsor with the financial information required by FDA regulations for submission to the FDA and ensure that all persons involved in the Clinical Trial are also willing to provide the required information.[1]

(2) With its signature, the Investigator confirms not to be listed on the FDA Debarment list and ensures that all study team member will confirm this as well. The Institution will promptly inform the Sponsor in the event it receives information of any study member being FDA debarred.

6. Compensation and Payment Terms

(1) For the services rendered by the Trial Site and the Investigator, the Sponsor shall pay the amounts agreed in Annex 2 to an account managed by the Trial Site, plus VAT at the applicable statutory rate. Any compensation for study participants or the Investigator (e.g. travel expenses, costs for presentation of study results etc.) shall be paid separately. Unless otherwise agreed in Annex 2, services for subjects who withdraw prematurely from the Clinical Trial shall be remunerated on a pro-rata basis according to provided services.

(2) Should the scope of work (e.g. protocol amendment) or essential circumstances for remuneration change occur e.g. unexpected costly side effects, the Clinical Trial starts with significant delay, or due to extraordinary inflation, the compensation payable by the Sponsor should be adjusted by written supplementary agreement between Sponsor and Trial Site.

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[1] Editor's Note: For this financial information, the "Form 1572" should not be used, as it contains references to U.S. legal regulations that are not applicable for this Study and may potentially be contradictory to applicable German law.

(3) The Sponsor undertakes to pay any invoice within a maximum of two months after receipt. Each payment must be clearly assigned to the service performed by the Trial Site or Investigator and documented by the Sponsor.

(4) OPT: Departments of the Trial Site providing study-related ancillary services, such as radiology or pharmacy, may invoice their services separately. Details are attached to this agreement as Annex 3.

7. Archiving

(1) The Trial Site shall retain all documentation relating to the Clinical Trial either in print or digital format (trial documentation), if its retention is required due to statutory retention requirements related to the conduct of clinical trials, in accordance with the statutory provisions underlying the respective retention requirements. The following minimum retention periods must be observed:

a) 25 years after the last visit of the last trial participant or such later point of time defined in the trial protocol (End of the clinical trial);

b) A minimum of 30 years after the end of the clinical trial for clinical trials covered by radiation protection laws; or

c) <STATE PERIODS>.

(2) The Trial Site shall store the trial documentation securely in an appropriate location and manner such that it is available and without undue delay accessible on request and – particularly in the case of digital trial documentation – readable. The Trial Site shall keep a record on the physical or digital location where the trial documentation is retained. The Trial Site shall take measures that prevent any accidental or premature destruction of the trial documentation to be retained. It shall inform the Sponsor without undue delay if it will no longer be able to retain the trial documentation for reasons unforeseeable at the time of conclusion of the contract.

(3) The Trial Site may destroy the trial documentation once the applicable statutory retention period has expired provided that the Sponsor has checked compliance with the statutory retention period no later than three months prior to expiry and confirmed it to the trial site. If the Sponsor objects to the destruction of the trial documentation, the Trial Site and the Sponsor shall consider concluding a separate written agreement on the further retention of the trial documentation at the sponsor's expense.

(4) If the Sponsor does not confirm compliance with the statutory retention period within the time period specified above, the Trial Site has the right to destroy the Trial Documentation.

8. Audits/Inspections

(1) The Sponsor or its representative shall monitor the conduct of the Clinical Trial. For the purpose of conducting announced audits, the Sponsor or its representative shall coordinate a date with the Trial Site at an early stage that is scheduled within the usual business hours of the Trial Site. The Trial Site shall provide reasonable support to the Sponsor or its representative in conducting the audits, in particular it shall grant the Sponsor or its representative access to the property, office premises, operating rooms and facilities as well as to all documentation and original documents of the Clinical Trial as necessary for the conduct of the respective audit. Patient data may only be accessed to the extent permitted by law, particularly if the person concerned or – if they are unable to give informed consent, their legal representative – has consented to access or if and insofar as

access is permitted by law even without the consent of the person concerned. The Sponsor or its representative shall inform the Trial Site without undue delay of any and all findings of the respective audit that suggest that the safety of the trial participants might be compromised or the conduct of the Clinical Trial affected.

(2) The Trial Site acknowledges that the Clinical Trial is subject to regulatory inspection prior to, during and after conclusion. The Trial Site shall inform the Sponsor without undue delay if an authority announces an inspection of the Trial Site in connection with the Clinical Trial or carries out an unannounced inspection. The Trial Site hereby agrees to the Sponsor or its representative being present during inspections related to the Clinical Trial. To the extent possible and legally permissible, the Trial Site shall give the Sponsor the opportunity to comment or have a representative comment in advance on statements from the Trial Site on regulatory inspections related to the Clinical Trial and shall provide the Sponsor with copies of the statements. To the extent legally permissible, a contracting party shall inform the other contracting party as soon as it receives the inspection report on the inspected Clinical Trial at the Trial Site or a draft version of the inspection report and shall share with it on request a copy of the passages of the inspection report that are related to the Clinical Trial.

(3) The Trial Site shall cooperate with the representatives of the authorities, the Sponsor or its representative during the performance of the measures referred to in numbers 8.1 and 8.2. It shall ensure that any and all documentation of the Clinical Trial is managed in such a way that it is accessible without restriction during these measures.

(4) The Trial Site shall take all necessary steps to eliminate the deficiencies identified by a measure referred to in numbers 8.1 and 8.2 without undue delay. If in the course of an inspection at the Trial Site that relates to a clinical trial other than the one covered by this contract a critical or major finding is identified that constitutes with respect to the contractual Clinical Trial a hazard for patient safety or data integrity at the Trial Site, the Trial Site shall inform the Sponsor without undue delay.

(5) This clause continues to apply after the end of the clinical trial for the duration of the statutory retention period referred to in number 7.1.

9. Results, Rights, and Inventions

(1) If the Clinical Trial conducted at the Trial Site in accordance with the contract and Trial Protocol generates results that constitute patentable inventions as defined in the Employee Inventions Act (Gesetz über Arbeitnehmererfindungen), the Trial Site shall inform the Sponsor in writing without undue delay after notification by the Inventor in accordance with section 5 of the Employee Inventions Act, to the extent that this is legally possible. In concluding this contract, the Trial Site grants the Sponsor an exclusive option to acquire the right to these patentable inventions by assignment (option right). The Sponsor can exercise this option right within a period of two months after it has received the notification referred to in sentence 1 by submitting a declaration to the Trial Site in writing. The date of receipt at the Trial Site shall be decisive for the timely declaration. Upon timely declaration, the Trial Site shall claim the invention in accordance with the provisions of the Employee Inventions Act and shall transfer the rights thereto to the Sponsor.

Alternative option - later agreement:

(2) If an invention as referred to in number 9.1 sentence 1 is made which, while resulting from the conduct of the Clinical Trial in accordance with the contract and the Trial Protocol, only arises from an additional inventive contribution made by employees of the Trial Site, the Sponsor shall owe the Trial Site equitable remuneration in line with the prevailing market standard for the transfer of the rights to this invention, which shall be agreed upon by the Contracting Parties in writing. The Contracting Parties hereby agree that the remuneration referred to in sentence 1 will be made in the form of a one-time payment upon exercising the option or as recurring payment related to income, based on mutual agreement. When determining this remuneration, they shall apply the principles for calculating employee invention remuneration accordingly, provided the recognised factors for calculating employee invention remuneration are adapted to the prevailing interests of the Contracting Parties in the contractual relationship in question, in terms of the value. When calculating the remuneration, they also consider the contractually agreed remuneration, the costs calculated for the Clinical Trial, the various inventive contributions, the value of the invention, any amounts the Trial Site might have to pay to the employee inventor for claiming the invention or its exploitation, any ongoing rights of use and exploitation options as well as, in the case of a one-time payment, the expected useful life of a patent to the invention.

Alternative option - lump-sum payment:

(3) If an invention as referred to in number 9.1 sentence 1 is made which, while resulting from the conduct of the Clinical Trial in accordance with the contract and the Trial Protocol, only arises from an additional inventive contribution made by employees of the Trial Site, the Sponsor shall pay remuneration in the amount of <STATE AMOUNT> plus any applicable VAT per invention to the Trial Site for the transfer of the rights to this invention within 30 days of transfer. Where a property right is granted to the Sponsor or to a third party authorised by the Sponsor, the Sponsor shall pay an additional sum in the amount of <STATE AMOUNT> plus any applicable VAT to the Trial Site. If it is an extraordinary invention where the amounts referred to in sentences 1 and 2 would be grossly inequitable, the parties shall mutually agree on an additional equitable remuneration at market conditions. To this end, the Sponsor and the Trial Site shall conclude an additional agreement in which they establish equitable remuneration and its details in good faith.

(4) Where this is deemed necessary to secure the invention or where required under the Employee Inventions Act, the Trial Site can, in close consultation with the Sponsor, file or prepare a priority-establishing patent application on its own behalf and at its own expense before the expiry of the period for exercising the option right. If the Sponsor exercises its option right in a timely manner, the Trial Site shall also transfer all rights to any patent application to the Sponsor in return for the reimbursement of all expenses incurred in filing or preparation of the application. The Trial Site undertakes to provide the Sponsor at the latter's expense any reasonable support in patenting the invention.

(5) In the event that the Sponsor does not exercise its option right in a timely manner, the Trial Site is entitled, subject to the provisions of the Employee Inventions Act, to exploit the invention.

(6) With the conclusion of this contract the Trial Site hereby already assigns any rights to results which are developed or produced as part of the conduct of the Clinical Trial in accordance with the contract and the Trial Protocol other than patentable inventions, to the Sponsor, with the exception of the copyright. Where these results are subject to copyright or covered by a related industrial property right and transfer is not possible under the relevant property rights law, the Trial Site shall grant the Sponsor an irrevocable right of use for all types of use that is, subject to number 9.6, exclusive, sublicensable, transferrable and unlimited in time, place and content. The

Sponsor accepts the assignment pursuant to sentence 1 or the granting of the right of use pursuant to sentence 2. The assignment pursuant to sentence 1 or the granting of the right of use pursuant to sentence 2 is fully compensated with the remuneration agreed under this contract.

(7) This contract does not affect the Trial Site's research and teaching activities. Consequently, the Trial Site has a non-exclusive, royalty-free and non-transferrable right that is unlimited in time and place, to use the results generated at the Trial Site for the purposes of its internal, non-commercial research, teaching and patient care.

(8) Patient records remain to be owned by the Trial Site. The Sponsor is allowed to use them in compliance with the statutory provisions and in line with the terms of this contract.

10. Confidential Information

(1) Subject to §10.2, Confidential Information within the meaning of this contract is any and all Information, irrespective of its form, that is disclosed by a contracting party or a company affiliated to this contracting party within the meaning of section 15 of the Stock Corporation Act (Aktiengesetz) to the other contracting party in respect of the Clinical Trial, its conduct or this contract, as well as any and all results of the Clinical Trial.

(2) Information is deemed non-confidential if it

a) was already in the possession of the receiving contracting party or known to it at the time of disclosure

b) was already or becomes accessible to the public in the absence of a contract violation or failure by the receiving contracting party,

c) was lawfully purchased by the receiving contracting party from a third party that, to the best knowledge of the receiving party, was or is not bound to confidentiality towards the disclosing contracting party or a company affiliated to this contracting party within the meaning of section 15 of the Stock Corporation Act at the time of purchase, or

d) was newly generated by a contracting party in the context of the Clinical Trial independently of and without using the disclosed confidential information.

(3) The Trial Site and, subject to number 10.4, the Sponsor, shall keep any and all confidential information strictly secret, set up suitable and appropriate measures to prevent any unauthorised access to it and store it in such a way that it can be identified as confidential information. The Trial Site and, subject to number 10.4, the Sponsor shall only use confidential information for the purposes of this contract and only disclose it to third parties if the initially disclosing contracting party has given its prior consent in writing. When deciding whether or not to agree to disclosure, particular considerations shall be given to the general interest in the transparency and reproducibility of clinical trials. The disclosure of confidential information to a company affiliated with either contracting party within the meaning of section 15 of the Stock Corporation Act does not require prior consent. Nor is prior consent required for the disclosure to persons for whom the confidential information is essential to provide services under this contract and who are bound to confidentiality towards the receiving contracting party on the basis of a written agreement that is comparable to the provisions on confidentiality provided for in this contract. Such persons include, in particular, employees of the receiving contracting party as well as freelance workers or other third parties recruited to conduct the Clinical Trial as specified in the contract and the Trial Protocol.

(4) The Sponsor is not bound by the obligations under number 10.3 insofar as these results of the Clinical Trial are generated by conducting the Clinical Trial in accordance with the contract and the Trial Protocol. In particular, this can be information that is necessary for the further clinical development of the medicinal product that is the subject of the Clinical Trial or needs to be disclosed for the marketing authorisation of the medicinal product that is the subject of the Clinical Trial.

(5) The Contracting Parties may disclose confidential information without the consent referred to in number 10.3 to the extent necessary to comply with applicable law or an enforceable administrative or court order. The other contracting party must be informed without undue delay of the imminent disclosure on the basis of the enforceable administrative or court order where doing so is within the law and does not contravene the order. The contracting party requested by the order to make the disclosure shall undertake reasonable and appropriate efforts to support the other contracting party in securing preliminary or other appropriate legal protection and to ensure that the confidential information to be disclosed is treated as confidential.

(6) At the request of the disclosing contracting party, the other contracting party shall return, erase or destroy confidential information unless prohibited by statutory provisions, particularly statutory retention requirements.

(7) Numbers 10.1 to 10.6 do not affect any statutory provisions regarding protection of confidentiality of information as well as statutory disclosure requirements. The confidentiality obligation pursuant to number 10.3 does not apply if the contracting party is entitled to publish the confidential information within the scope of a publication pursuant to number 1 or if publication serves to exercise the rights under numbers 9.3, 9.4 or 9.6.

(8) This clause continues to apply for a period of ten years after the end of the Clinical Trial.

11.Rights to a name and trademark rights

The Contracting Parties mutually acknowledge each other's name and trademark rights. Neither contracting party shall use the name or trademark of the other contracting party without the latter's prior written consent. Exemptions are use of the names or trademarks of the other contracting party

a) to conduct the clinical trial as specified in the contract and the trial protocol,

b) for regulatory purposes,

c) with respect to authorities,

d) in registers for clinical trials, or

e) within the scope of the usual naming of authors in scientific journals.

This does not affect the provisions regulating publication referred to in number 13 and the provisions regulating confidentiality referred to in number 9.

12.Data Protection

(1) The contracting parties undertake to comply with the data protection provisions, particularly Regulation (EU) 2016/679 (General Data Protection Regulation) and Regulation (EU) 536/2014 in the version of 6°September 2022 and the Medicinal Products Act (Arzneimittelgesetz). OPT: The contracting parties will agree the details in the Joint Controller Agreement attached as Appendix 4.

(2) Each contracting party shall decide autonomously and in compliance with the data protection provisions whether and for which concrete purpose and by which means it processes the personal data of the other contracting party's employees or the employees of cooperation partners and subcontractors. To the extent permitted by law, each contracting party shall grant the other contracting party access to these data or shall provide it with these data, especially names and business contact details (e.g. telephone numbers and email addresses). The contracting party responsible for the respective data processing shall ensure compliance with the relevant statutory provisions, particularly including information obligations towards persons whose personal data is being processed. For the purpose of processing these data, the contracting parties provide each other with a data protection policy that meets the requirements of Articles 13 and 14 of the General Data Protection Regulation and ensure that this data protection policy is shared with the persons affected.

(3) Where a contracting party intends to transfer personal data to a country outside the European Union or the European Economic Area (third country), and the European Commission has not adopted an adequacy decision pursuant to Article 45 (3) of the General Data Protection Regulation, the contracting party shall ensure and give the assurance that, in an effort to uphold an appropriate data protection level, data will only be transferred in the presence of appropriate safeguards pursuant to Article 46 (2) or (3) of the General Data Protection Regulation or a derogation pursuant to Article 49 of the General Data Protection Regulation.

(4) This clause applies beyond the end of the clinical trial until completion of personal data processing.

13.Publications

(1) The Sponsor has the right to first publication of the results of the Clinical Trial. Statutory publication obligations remain unaffected by this right. If the Clinical Trial is part of a multi-centre clinical trial, the first publication shall be coordinated by the Sponsor and cover the overall result of all of the trial sites participating in the Clinical Trial. If the Sponsor does not proceed to first publication within 12 months after the Clinical Trial has ended, the Trial Site is entitled to publish the results generated at the Trial Site in accordance with numbers 12.2 and 12.3. If first publication by the Sponsor within the period of time stipulated in sentence 4 is not possible for scientific reasons set out in the Trial Protocol, the period will be extended at the Sponsor's request by a maximum of six months.

(2) The Trial Site is entitled to publish the results generated at the Trial Site for non-commercial scientific purposes in oral or written form and in compliance with the following procedure, irrespective of whether the results are favourable or unfavourable:

a) The Trial Site shall provide the Sponsor with the manuscript intended for publication at least 45 days before the scheduled submission for publication. The Sponsor shall confirm without undue delay the receipt of the manuscript to the Trial Site in writing, stating the date of receipt.

b) Within 35 days of receiving the manuscript, the Sponsor shall inform the Trial Site whether the manuscript includes any Confidential Information and, if so, specify the Confidential Information the Sponsor wants to have removed, or if any industrial property rights prevent publication of the manuscript. When deciding to request the removal of Confidential Information, the Sponsor shall give particular consideration to the general interest in the transparency and reproducibility of Clinical Trials. Within the period referred to in sentence 1, the Sponsor can also comment on the contents of the manuscript and suggest changes. At the

Sponsor's request, the period referred to in sentence 1 will be extended by a maximum of 90 days to allow the Sponsor to secure and apply for industrial property rights or patent rights.

c) Before submitting the manuscript for publication, the Trial Site shall remove the information from the manuscript that the Sponsor wanted to have removed for confidentiality reasons. The Trial Site shall consider the Sponsor's comments or suggestions for changes provided that they do not compromise scientific accuracy and neutrality.

d) If the Sponsor does not inform the Trial Site within the period referred to in letter b sentence 1 or the period extended as set out in letter b sentence 4, the Trial Site is free to publish the manuscript presented.

(3) The Trial Site shall adhere to the current academic standards in all publications related to the Clinical Trial. If the Clinical Trial is part of a multi-centre clinical trial, the Trial Site shall disclose this fact when publishing the results generated at the Trial Site and shall also indicate that the publication does not include the results of all of the trial sites participating in the Clinical Trial. The Trial Site shall indicate the Sponsor in all publications related to the Clinical Trial.

(4) To the extent possible and reasonable, publications should be made in accessible format.

14.Provisions on Equipment and Materials Provided

(1) Where the Sponsor provides devices or materials for use by the Trial Site and its employees for the conduct of the Clinical Trial or arranges for provision by a third party, the Contracting Parties shall document such provision in writing. Devices are objects, and materials may include computer software, methods or assessment scales owned by the Sponsor or a third party or licensed by the Sponsor or the third party for usage. Medical devices and investigational medicinal products are not devices or materials for the purposes of this contract.

(2) The Contracting Parties agree that provision of the devices and materials does not constitute remuneration nor a component of remuneration. Ownership of the devices and materials is not transferred when such are provided to the trial site. The Sponsor shall bear the costs of delivery, setup, installation, servicing and maintenance of the devices and materials as well as the costs of the accessories necessary for the devices and materials provided and the consumables necessary for the devices and materials provided.

(3) The Trial Site shall ensure that the devices and materials provided are used exclusively for the conduct of the Clinical Trial in accordance with the contract and the Trial Pprotocol, are handled with due care and are kept in an appropriate and reasonable manner in an environment that protects the devices and materials from unauthorised use, theft and damage.

(4) Provision of the devices and materials is limited to the duration of the Clinical Trial. The Trial Site shall return the devices and materials to the Sponsor at the latter's expense without undue delay as soon as it has concluded the Clinical Trial. The Sponsor shall take the devices and materials back at its own expense or shall ensure that the devices or materials it arranged to be provided by a third party are taken back by the third party.

(5) The following equipment will be made available for the conduct of the Clinical Trial:

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15.Liability

(1) The Trial Site does not guarantee that a specific deliverable will be achieved or that the deliverable is not covered by industrial property rights of third parties. If the Trial Site becomes aware of conflicting industrial property rights, it shall inform the Sponsor to that effect without undue delay.

(2) In the case of slight negligence, the liability for damages not arising from injury to life, limb or health shall be limited to

a) damages typical for this contract that were foreseeable at the time of conclusion of the contract, if the damage results from the violation of a material contractual obligation, and

b) the contract value, if the damage results from the violation of any other obligation.

Material contractual obligations are those obligations whose fulfilment enables the proper execution of the contract and compliance with which the other contracting party regularly relies on or may expect to rely on.

16.Termination/Cancellation

(1) This contract ends, if and when

a) the Clinical Trial cannot be initiated due to a negative decision by the competent ethics committee or due to a refusal by the competent higher federal authority,

b) the contract is terminated pursuant to number 16.2 or 16.3 or

c) all contractual duties are fulfilled.

(2) This contract may be terminated by the Sponsor in writing by giving 14 days' notice to the Trial Site.

(3) Each contracting party may terminate this contract with immediate effect for good cause by informing the other contracting party in writing. Good cause is deemed to exist, in particular, if

a) the Trial Site is required by the competent authority to end the Clinical Trial,

b) the clinical trial has to be ended on ethical grounds or because there is a reason to fear that the trial participants' health or well-being is at risk,

c) a contracting party repeatedly or grossly breaches the duties arising from this contract, statutory provisions or requirements issued by the ethics committee in spite of having been warned by the other contracting party, or

d) facts exist in the light of which, considering all circumstances of the case at hand and weighing the mutual interests of the contracting parties, the terminating contracting party cannot reasonably be expected to continue this contract.

(4) Without undue delay after the Clinical Trial at the Trial Site has ended, the Trial Site shall return to the Sponsor any unused or opened investigational medicinal products provided for the conduct of the Clinical Trial.

(5) Once the Trial Site has received or issued a notice of termination, the trial site shall not recruit or enrol any further trial participants in the Clinical Trial.

(6) In the event that the Clinical Trial ends early, especially if the contract is terminated, the Trial Site shall without undue delay inform the trial participants enrolled that the Clinical Trial has ended and shall continue to treat them in line with acknowledged medical standards where possible and reasonable

17. Separation Principle
The Contracting Parties confirm that entering into this agreement does not influence commercial transactions, especially procurement or pricing, of the Trial Site, and that no related expectations exist. The Contracting Parties undertake not to provide any gift, payment, or other advantage, directly or indirectly, to any party involved in the execution of this agreement without legal basis, which could be viewed as an incentive or reward for the conclusion or execution of any part of the agreement.

18. Applicable Law / Jurisdiction
This agreement is governed exclusively by German law. German conflict-of-law rules shall not apply. Jurisdiction shall be at the location of the Trial Site.

19. Written Form
Any amendments or supplements to the mutual obligations require written or electronic form. No side agreements have been made; should any be made, they must also be in writing.

20. Severability Clause
Should any provision of this agreement be invalid or become invalid, the effectiveness of the remaining contractual provisions remains unaffected. Instead of the invalid provision, a legally permissible provision shall apply that best reflects the intent of the invalid provision. The same applies to any contractual gaps.

For the Sponsor:

Place _____, Date _____

.....

Management/Authorized representative of the company

For the Trial Site:

Place _____, Date _____

.....

Authorized representative of the Trial Site (name and title)

Acknowledged and agreed:

Place _____, Date _____

.....

Investigator

Annexes:

Annex 1: Trial Protocol

Annex 2: Trial Site Budget

OPT: Annex 3: Budget for Clinical Trial-related Ancillary Services

OPT: Annex 4: Data Protection Provisions for Joint Responsibility

Annex 1: Trial Protocol

Annex 2: Trial Site Budget

OPT: Annex 3: Budget for Clinical Trial-related Ancillary Services

OPT: Annex 4: Data Protection Provisions for Joint Responsibility

JOINT CONTROLLERSHIP AGREEMENT IN ACCORDANCE WITH ARTICLE 26 PARAGRAPH (1) SENTENCES 2, 3, PARAGRAPH (2) SENTENCE 1 GDPR

between

[Please insert the name and address of the sponsor]

- hereinafter referred to as "**Sponsor**" –

and

[Please insert the name and address of the site]

- hereinafter referred to as "**Trial Site**" –

Hereinafter, the Sponsor and the Site will also be individually referred to as a "**Party**" and jointly as "**Parties**".

For any enquiries relating to this agreement, the Parties designate the following contacts who are knowledgeable in data protection law:

Sponsor: [please provide the contact and the contact data of the person in charge] and

Site: [please provide the contact and the contact data of the person in charge].

Preamble

The Sponsor desires to conduct the clinical trial [please insert the study title] (hereinafter referred to as "**Study**") which is the subject matter of this agreement. Details can be found in the protocol (Appendix). The Site shall support the Sponsor in the planning and conduct of the Study and has the requisite knowledge, experience and capabilities for the conduct of the Study.

The Parties will process personal data in the Study. In this context, the Parties are joint controllers, as defined in Art. 4 no. 7, 26 GDPR.

This joint controller agreement in accordance with Article 26 paragraph (1) sentences 2,3, paragraph sentence 1 GDPR (hereinafter referred to as **"Agreement"**) sets out the rights and obligations of the Parties in the joint processing of personal data. This Agreement applies to all activities in which employees of the Parties or data processors commissioned by them process personal data for the controllers in the context of the Study. The Parties have jointly determined the means and purposes

of the processing activities described in more detail below. Unless otherwise defined, the terms used in this Agreement shall have the meanings assigned to them in the GDPR.

1. Joint controllership

1.1 Unless otherwise agreed in the following, each contracting party shall ensure its respective compliance with the legal provisions, particularly concerning the lawfulness of the data processing carried out.

1.2 In the context of the joint controllership, the sponsor shall be responsible for processing the subjects' pseudonymised data gathered for the purposes of the clinical trial in accordance with the trial protocol and forwarded to the sponsor, the provision and security of the electronic case report form (eCRF), and for monitoring and reviewing the proper conduct of the clinical trial <where relevant, include any other data flows actually taking place concerning personal data subject to the joint controllership>. The sponsor shall be particularly responsible for ensuring that the transmission path between the trial site and the eCRF complies with the requirements set out in Article 32 of the General Data Protection Regulation.

1.3 In the context of the joint controllership, the trial site shall be responsible for processing the subjects' personal data relating to the conduct of the clinical trial. This includes collecting the trial data, monitoring and documenting the subjects' responses to the investigational medicinal product, preparing the findings and transmitting them via eCRF to the sponsor in pseudonymised form as well as reporting adverse events to the sponsor <where relevant, include any other data flows actually taking place concerning personal data that are subject to the joint controllership>. The trial site shall be particularly responsible for processing the personal data in compliance with the requirements set out in Article 32 of the General Data Protection Regulation up until it is forwarded to the transmission path between the trial site and the eCRF for which the sponsor is responsible.

1.4 Activities carried out prior to signing the contract on the conduct of the clinical trial shall not be covered by the Regulations on Data Protection under Joint Controllership.

1.5 Activities carried out after the completion of the investigations listed in the trial protocol, after the transmission of all duly completed eCRFs by the trial site to the sponsor and after close-out of the trial site, including final data cleaning and locking the trial database for the trial site, shall not be part of the joint controllership. These activities include, for instance, scientific evaluation as well as marketing authorisation of the medicinal product that is the subject of the trial, or archiving.

1.6 The sponsor will provide the trial site with the patient information sheet with details regarding the processing of personal data in accordance with the trial protocol as well as the informed consent form, reviewed by the ethics committee and issued in accordance with the provisions in the General Data Protection Regulation. The trial site shall not be responsible for reviewing the informed consent form. The trial site will provide to the sponsor in pseudonymised form the data gathered from the subjects as required by the trial protocol and the data subjects' declarations of consent.

2. Informing the data subjects

The contracting parties are legally obliged to provide the data subjects with the information required pursuant to Articles 13 and 14 of the General Data Protection Regulation as well as information concerning the main elements of this agreement in precise, transparent language understandable to laypersons and in easily accessible form free of charge. This information shall be part of the patient information sheet the sponsor has to produce. The contracting parties agree that the trial site shall provide the information provided by the sponsor regarding the processing of personal data pursuant to Articles 13 and 14 to the data subjects in advance of collecting the personal data. This trial site

shall not be obligated to check whether the information provided by the sponsor is compliant with the legal provisions.

3. Rights of the data subjects

3.1 Data subjects may exercise the rights they are entitled to pursuant to Articles 15 to 22 of the General Data Protection Regulation ("Rights of the data subjects") in respect of all contracting parties, with the trial site being offered as the primary contact point for data subjects. When a data subject approaches the sponsor to exercise their data subject rights, the sponsor will generally refer to the patient information sheet handed out and to the trial site, which serves as a primary contact point for data subjects to uphold data subject rights.

3.2 The contracting parties shall support one another in complying with the rights of the data subjects while maintaining pseudonymisation. Where needed, the contracting parties shall provide one another with the required information from their respective area of responsibility. This is carried out in pseudonymised form using the trial-specific identification number.

3.3 In all other respects, the contracting partners shall themselves be responsible for implementing and complying with the rights of the data subjects with respect to the data processed at their organisation or that of their contractors.

3.4 Requests from data subjects concerning the erasure of their personal data that are the subject to joint processing shall be disclosed to the other contracting party upon receipt without undue delay. If a contracting party is not required or not permitted to erase all or part of the personal data according to Article 17 (3) of the General Data Protection Regulation, that contracting party shall ensure it erases the personal data as soon as the legal obligation to erase the data arises pursuant to Article 17 (1) of the General Data Protection Regulation. If a request regarding the erasure of personal data is justified or the legal basis for data processing no longer applies, the contracting parties shall erase the corresponding personal data. Each contracting party shall put in place a protocol on erasing personal data, which shall be provided to the other contract partner upon request. To ensure timely erasure in compliance with the law, the contracting parties shall develop an erasure concept that specifies what personal data are to be erased and by whom.

4. Irregularities, data protection breaches and doubts concerning the lawfulness

4.1 The contracting parties shall fully inform each other without undue delay if, when reviewing the processing activities performed under this agreement, they notice any errors or irregularities with respect to data protection provisions.

4.2 The contracting parties are responsible pursuant to Articles 33 and 34 of the General Data Protection Regulation for notifying and reporting any personal data breaches within their respective area of responsibility to the supervisory authority and the data subjects concerned. The contracting parties shall inform one another without undue delay of any reports submitted to the supervisory authority concerning breaches of the protection of personal data in the context of the clinical trial at issue and shall support one another to the extent legally permitted with regard to submitting the report.

4.3 The contracting parties are entitled to not make available or transmit to the other contracting party any further personal data if and to the extent that there are doubts regarding the legal basis for the processing, provision or transmission of personal data. Doubts may arise in particular from changed legal or factual circumstances leading to a new legal assessment of the statutory basis, such as a new or changed requirement of a statutory basis pursuant to Articles 44 to 50 of the General Data Protection Regulation. Such circumstances may arise from administrative or court orders as well

as through publications by supervisory authorities. The contracting parties shall work towards clarifying the statutory basis.

5. Data protection impact assessments

The contracting parties shall ensure within their area of responsibility that data protection impact assessments pursuant to Article 35 of the General Data Protection Regulation are carried out where required. The contracting parties shall support one another to the extent necessary.

6. Retention of documentation

Documentation that serves compliance with proper data processing in accordance with Article 5 (2) of the General Data Protection Regulation shall be retained by each contracting party in accordance with the legal rights and obligations beyond the end of contract.

7. Confidentiality and data security

7.1 The contracting parties shall ensure, within their respective area of responsibility, that all employees engaged in data processing maintain data confidentiality in line with Articles 29 and 32 of the General Data Protection Regulation, without breaching Section 203 of the German Criminal Code (Strafgesetzbuch) and, in the case of foreign partners, in accordance with a comparable standard of protection of confidentiality for the duration of their activities related to the processing of personal data as well as following conclusion of their activities and that the employees are placed under an obligation to maintain data confidentiality and are instructed on the data protection provisions of relevance to them prior to commencing their activities.

7.2 The contracting parties each shall ensure that they adhere to all the legal retention requirements in place with respect to data. They shall take adequate data security precautions in accordance with Article 32 of the General Data Protection Regulation. This applies in particular in the case of the collaboration coming to an end.

7.3 The implementation, default settings and operation of the data processing systems used are to be carried out under adherence to the requirements of the General Data Protection Regulation and other regulations, in particular the principles of data protection by design and data protection by default and using state-of-the-art technical and organisational measures.

8. Processors

When utilising the services of data processors within the scope of this agreement, the contracting parties undertake to conclude a contract pursuant to Article 28 (3) of the General Data Protection Regulation. Activities and processing performed by the data processors of a contracting party are attributable to that contracting party.

The contracting party commissioning the data processor shall ensure compliance with any additional provisions from Chapter 5 of the General Data Protection Regulation.

9. Record of processing activities

The contracting parties shall record the processing activities in their respective records of processing activities pursuant to Article 30 (1) of the General Data Protection Regulation, in particular with a note on the nature of the processing activity performed under joint or individual controllership.

10. Duration and termination

10.1 The contractual provisions regarding data protection in case of joint controllership shall be in effect for the duration of the processing of personal data. Separate ordinary termination of these provisions is excluded.

10.2 The contracting parties may terminate this agreement with immediate effect if the other contracting party commits a serious or ongoing breach of data protection law or the provisions of this agreement. A serious breach applies in particular if a contracting party does not fulfil the obligations stipulated in this agreement, in particular the necessary technical and organisational measures, to a significant extent.

11. Liability

11.1 This is without prejudice to Article 82 of the General Data Protection Regulation. Moreover, the contractual provisions regarding data protection in the case of joint controllership do not establish any claims by data subjects or any other third parties nor do they establish a joint or several liability by the contracting partners.

11.2 In their internal relationship, each contracting party is liable for damages to the other contracting party that arise from processing within its area of responsibility.

12. Miscellaneous

12.1 In the event of any conflicts between this Agreement and the main agreement, the provisions of this Agreement concerning data protection shall prevail. If individual parts of this Agreement are invalid, this shall not affect the validity of the remaining provisions of the Agreement. The Parties agree that they will replace such parts with a valid provision that most closely reflects the intended purpose of the Parties. The same applies if there is a contractual gap in the Agreement.

OPT: 12.2-12.5 and signatures required if parties are not identical to Study Agreement

12.2 Amendments and additions to this Agreement and all its components – including any representations made by the contractor – require a written agreement and the specific reference that it is an amendment or addition to this Agreement. This also applies to a waiver of this formal requirement.

12.3 The defence of right of retention, as defined in Section 273 of the German Civil Code (BGB), is excluded with respect to all data and the related data storage media provided to a Party by the other Party under this Agreement.

12.4 This Agreement shall be governed by German law under exclusion of the conflict of law principles.

12.5 The place of jurisdiction for any dispute arising under this Agreement is–where permitted – the city where the registered office of the Site is located.

For the Trial Site

_____ _____

(Place, date) (Signature)

For the Sponsor

_____ _____

(Place, date) (Signature)