3-party standard contract template for clinical trials with medicines under the responsibility of a pharmaceutical company (industrial sponsor) and involvement of a CRO (contract research organization) based on the German Standard Contractual Clauses Ordinance - Standardvertragsklausel-Verordnung (StandVKlV)

As of June 23rd, 2026

- *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 – after the United States – in terms of the number of clinical trials conducted. Regrettably, this has not been the case for several years, and a number of countries, including some in Europe, have overtaken Germany in this regard. Restoring its leading position is in the common interest of all stakeholders in the field of clinical research, patients, trial sites and sponsors of clinical trials.

The conduct of clinical trials is often subject to time pressure, and the factor of "time" plays a particularly important role in international comparison, especially in the phase leading up to the initiation of a clinical trial. In order to facilitate the earliest possible commencement of a clinical trial, the underlying contracts between the parties involved should be concluded quickly, easily and on a basis of comprehensive terms.

Against this background, it is helpful for prospective contracting parties to have guidance in the form of model contract clauses in their respective negotiations. These clauses provide examples of specific, frequently recurring contractual provisions in agreements for the conduct of clinical trials, thus expediting contract negotiations in these areas. For this reason, 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 drafted model contract clauses, which take the differing interests of all stakeholders involved into account. 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 in accordance with Section 42d of the German Medicines Act the so-called "Standard Contract Clauses for the Conduct of Clinical Trials". Section 42d AMG created the legal basis for a regulation in this area.

On September 18th, 2025, the "Ordinance on the Simplification of the Conduct and Approval of Clinical Trials" was published, which contains the "Ordinance on Standard Contractual

Clauses for the Conduct of Clinical Trials (Standard Contractual Clauses Ordinance – StandVKlV)" as its Section 1 with associated provisions in Annex 1.

The Ordinance on Standard Contractual Clauses for the Conduct of Clinical Trials (StandVKlV) applies to all contracts in Germany for the conduct of clinical trials with medicinal products after December 17th, 2025. The Ordinance primarily covers commercial sponsors (e.g. pharmaceutical companies) who initiate clinical trials with commercial objectives. Non-commercial sponsors (e.g. academic, non-profit initiatives) that conduct studies without commercial objectives are not subject to the requirement to use the stipulated standard contractual clauses. The Standard Contractual Clauses Ordinance – StandVKlV (Germany) is important because it addresses several key objectives in the field of clinical trials:

- Acceleration through standardization of the contracting process
- Strengthening Germany as a research hub
- Providing clarity and legal certainty
- Reducing bureaucratic hurdles before the initiation of a study

Against this background, the institutions affiliated with the association platform (MFT, VUD, KKS and the associations BPI, BVMA and vfa) have decided to draft a comprehensive standard contract template for clinical trials with medicinal products, which reproduces the wording of the StandVKlV verbatim in the sections of the template highlighted in grey.

This standard contract template constitutes a comprehensive contract template based on the requirements of the Ordinance. To the extent that the previous model contract clauses already contained mutually agreed-upon clarifications (e.g., deadlines) and additions that went beyond the requirements of the Ordinance, these were incorporated wherever possible. The aim of this standard contract template is to support the application of the BMG's standard contract clauses and to facilitate their widespread adoption quickly.

The contract template presented here represents the tripartite version between a pharmaceutical company, a CRO, and a study site. In addition, the association’s platform also published a bipartite version between a pharmaceutical company and a study site on December 8th, 2025.

Disclaimer: The following standard contract template was drafted by representatives of the participating organizations to the best of their knowledge and based on their joint professional discussions as well as accumulated practical experience. The grey-highlighted sections reproduce 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 court to which the matter is referred. Furthermore, users of this standard contract template are not exempt from assessing the specific circumstances and the intentions of the parties in each individual case in order to determine whether and how to apply the template. The authors accept no liability whatsoever.

Translations of any material into languages other than German are intended solely as a convenience to the non-German-reading public and are not legally binding. We have attempted to provide an accurate translation of the original material in German, but due to the nuances in translating to a foreign language, slight differences may exist.

We are providing this information as a public service. It is not intended to provide legal advice to an individual or entity and should not be construed as legal advice on any matter.

We make no guarantees about the accuracy, legality, relevance, timeliness or completeness of the information contained in this document.

The user should also be aware that, while we try to keep information in the template below timely and accurate, there will often be a delay between official publications and their appearance or modification in this document. We will make every effort to correct errors brought to our attention.

We therefore disclaim all liability in respect to actions taken or not taken based on any or all the contents of this document to the fullest extent permitted by law.

Clinical Trial Agreement

for

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

between

[Name of Trial Site]

represented by […]

[Address of Trial Site]

conducted by 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" –

and

[Name of CRO]

[Address of ACRO]

– hereinafter "CRO" –

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_____

Multi-centre/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 at the clinic. Accordingly, it wishes to participate in the Clinical Trial as a Trial Site and is both willing and able to provide the services agreed upon for the conduct of the Clinical Trial.

This study agreement governs the respective relationship of the Sponsor and the CRO with the Trial Site. Under a separate agreement, the Sponsor has engaged the CRO, as a contract research organization, to coordinate and/or perform certain activities on behalf of the Sponsor that are necessary for the conduct of the study.

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 the abovementioned Clinical Trial in accordance with the provisions set forth 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 current versions, describing the services and obligations of the Contracting Parties, shall form an integral part of this agreement. To the extent that the Trial Protocol contains provisions that contradict this agreement, the provisions of the Trial Protocol shall generally prevail concerning scientific and clinical matters, while the provisions of this agreement shall generally prevail for all other matters.

(3) The Contracting Parties shall regularly exchange information regarding the progress of the Clinical Trial.

2. Legal Framework / Recruitment

(1) The conduct of the Clinical Trial, including the services to be performed hereunder, shall in particular comply with the provisions of Regulation (EU) 536/2014 ("EU-CTR"), the German Medicinal Products Act, the applicable ICH GCP Guidelines (International Conference on Harmonisation: Harmonised Tripartite Guidelines for Good Clinical Practice), as amended from time to time, the current version of the Declaration of Helsinki, GxP, and with the General Data Protection Regulation

(GDPR), the Federal Data Protection Act, and any applicable state data protection laws. The Contracting Parties undertake to comply with these regulations, laws and guidelines.

(2) No member of the study team shall become a Contracting Party to this agreement; the Trial Site shall delegate relevant contractual obligations to the Investigator. The Investigator signifies his or her acknowledgement of this contract by signature and shall perform his or her duties as an 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 of trial participants is subject to the resources and capacity available at the Trial Site; achievement of the targeted number of trial participants cannot be guaranteed.

3. Obligations of the Trial Site

(1) Tasks under this agreement shall only be delegated to qualified persons, who shall, if necessary, receive adequate instruction. 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, for the duration of the Clinical Trial, maintain the necessary entries as well as provide the Sponsor / the CRO with a current scientific curriculum vitae of the Investigator, along with a description of his or her qualifications, education, and experience in clinical trials and patient care, for documentation in the Clinical Trial Information System.

(2) The Trial Site undertakes to notify the Sponsor without undue delay if the Investigator is no longer able to fully perform his or her obligations in such capacity or if it becomes clear that the Investigator will leave his or her employment. The Trial Site and the Sponsor shall agree on a qualified replacement without undue delay.

(3) The Trial Site and the Investigator shall, upon request, provide the Sponsor and / or a designee of the Sponsor (e.g., the CRO) with the documents required under applicable legal and company-specific requirements to enable the Trial Site's participation in the Clinical Trial.

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

(5) The Trial Site shall ensure that:

a) The Investigator informs the trial participants and obtains their written informed consent to participate in the Clinical Trial and to the use of their date before the start of any study procedure. The Investigator shall inform the trial participants of the essential content, significance, risks, and implications 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. The trial participants shall be granted a reasonable period to consider their participation or ask further questions.

b) The investigational medicinal product is handled in accordance with professional standards, and any adverse events occurring in trial participants 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 implications of the Clinical Trial on the basis of the 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 and the CRO. The Investigator shall ensure and monitor compliance with these requirements at the Trial Site. In particular, the Investigator shall document any delegation of study-related activities, including any changes thereto, in accordance with the Sponsor's requirements.

(7) If the Investigator determines that it is not possible to conduct the Clinical Trial with the agreed-upon trial participant population or the investigational medicinal product or doing so is medically unjustifiable due to unexpected results, the Investigator shall inform the Sponsor without undue delay. If the continuation of the Clinical Trial is medically unjustifiable, the Sponsor may order immediate termination or the Investigator may inform the Sponsor that the study treatment was not conducted. In either case, the Sponsor must also notify the ethics committee. This does not give rise to any claims for compensation by the sponsor. The Sponsor remains obligated to pay compensation commensurate 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. Obligations of the CRO

(1) The Sponsor has engaged the CRO under a separate agreement to assume various tasks in connection with the Study.

(2) The Sponsor and the CRO shall inform the Trial Site of the specific allocation of tasks and responsibilities insofar as it concerns the Trial Site.

6. Disclosure of Financial Information

(1) The Investigator agrees 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 inform the Sponsor in the event it receives information of any study member being FDA debarred without undue delay.

7. Compensation and Payment Terms

(1) For the services rendered by the Trial Site and the Investigator, the Sponsor as the recipient of the services [if applicable: through the CRO / a designee], shall pay the amounts set forth in Annex 2, plus any applicable VAT at the applicable statutory rate, to a third-party account or bank account managed by the Trial Site. Any compensation for study participants or the Investigator (e.g. travel expenses, costs for presentation of trial results etc.) shall be remunerated separately. Unless otherwise agreed in Annex 2, services for trial participants who withdraw from the Clinical Trial prematurely shall be remunerated on a pro-rata basis i to the total effort.

(2) Should the scope of work (e.g. protocol amendment) set forth in this agreement or circumstances materially effecting remuneration change ,e.g., if unexpected costly side effects occur, the Clinical Trial starts with significant delay, or due to extraordinary inflation, the compensation payable by the Sponsor shall be adjusted by written supplementary agreement between the Contracting Parties.

(3) The Sponsor undertakes to pay any invoice within a maximum of two months of receipt [if applicable: by the CRO / a designee]. Each payment shall be clearly attributable to the services performed by the Trial Site or Investigator and shall be 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.

8. 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 a later date if 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

[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.

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.

9. 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 and / or its representative (e.g., CRO) 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 and its representative 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 respective other contracting parties 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 them 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 9.1 and 9.2. 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 and the CRO 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.

10. 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 10.1 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:

(2) If an invention as referred to in number 10.1 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.

(3) 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.

(4) 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.

(5) 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 10.6, 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.

(6) 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.

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

11. Confidential Information

(1) Subject to §11.2, 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 respective other contracting parties 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 one or both receiving contracting parties 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 11.4, the Sponsor and / or the CRO, 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 11.4, the Sponsor and / or the CRO 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 11.3 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 11.3 to the extent necessary to comply with applicable law or an enforceable administrative or court order. The other contracting party/ parties 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 disclosing 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/ parties shall return, erase or destroy confidential information unless prohibited by statutory provisions, particularly statutory retention requirements.

(7) Numbers 11.1 to 11.6 do not affect any statutory provisions regarding protection of confidentiality of information as well as statutory disclosure requirements. The confidentiality obligation pursuant to number 11.3 does not apply if the contracting party is entitled to publish the confidential information within the scope of a publication pursuant to number 14 or if publication serves to exercise the rights under numbers 10.4, 10.5 or 10.7.

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

12. 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 14 and the provisions regulating confidentiality referred to in number 11.

13. 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: With regard to the data processing carried out under this Agreement and the protection of the corresponding personal data of the trial participants, the Sponsor and the Study Site shall be considered joint controllers within the meaning of Article 4(7) and Article 26 of the GDPR. Sponsor and Trial Site set forth further details in the Joint Controller Agreement attached as Appendix 4.

(2) With respect to study-related personal data, the CRO acts solely as a data processor on behalf of the Sponsor.

(3) Each contracting party which is acting as a controller 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.

(4) Where a contracting party which is acting as a controller 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.

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

14. 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 14.2 and 14.3. 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.

15. 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 the CRO or 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 CRO or a third party or licensed by the Sponsor or CRO 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 Protocol, 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 transmitting party shall take the devices and materials back at Sponsor's 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:

- [...]
- [...]
- [...]

16. Warranty and 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 of all Contracting Parties 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.

(3) The CRO shall be liable for the proper performance of the contractual services delegated and/or assigned to it; in particular, any liability in connection with the investigational medicinal product or the study protocol is excluded.

17. 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 17.2 or 17.3 or

c) all contractual duties are fulfilled.

(2) This contract may be terminated by the Sponsor and / or the CRO 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 and / or CRO 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

(7) Upon the effective termination of the agreement between the CRO and the Sponsor, the Sponsor shall assume the CRO's duties under this Agreement as of the CRO's withdrawal date. If the Sponsor transfers the duties to a new CRO, the new CRO may accede to this Agreement by way of a contract amendment. In the event of a change of CRO, the Sponsor shall immediately inform the Study Site of the planned transfer of rights and obligations as well as the relevant points of contact.

18. 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 such expectations exist. The Contracting Parties undertake not to provide, without legal cause, any gift, payment, or other advantage, directly or indirectly, to any party involved in the execution of this agreement, which could be viewed as an incentive or reward for the conclusion or execution of any part of the agreement.

19. 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.

20. Written Form

Any amendments or supplements to the mutual obligations require written or electronic form. No side letter and/or collateral agreements have been made; should any be made, they shall also be in writing.

21. Severability Clause

Should any provision of this agreement be invalid or become invalid, the validity of the remaining contractual provisions remains unaffected. The invalid provision shall be replaced by provision that is legally permissible and best reflects the intent of the invalid provision. The same shall apply to any gaps in this agreement.

For the Sponsor:

Place _____, Date _____

.....

Management/Authorized signatory of the company (name and title)

For the CRO:

Place _____, Date _____

.....

Authorized signatory of the CRO (name and title)

Place _____, Date _____

.....

Authorized signatory of the CRO (name and title)

For the Trial Site:

Place _____, Date _____

.....

Authorized signatory of the Trial Site (name and title)

Acknowledged and agreed:

Place _____, Date _____

.....

Investigator (name and title)

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)