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Ordinance on Standard Contractual Clauses for the Conduct of Clinical Trials (Standard Contractual Clauses Ordinance)

(Standardvertragsklauselverordnung – StandVKlV)

Ordinance on Standard Contractual Clauses for the Conduct of Clinical Trials of 16 September 2025 (Federal Law Gazette 2025 I no. 215)
The Ordinance on Standard Contractual Clauses for the Conduct of Clinical Trials comes into effect on 18th December 2025.

Section 1
Stipulation of standard contractual clauses

(1) For the contractual provisions on specific rights and obligations of the sponsor and the trial site when conducting a clinical trial as defined in Article 2 (2) (2) of Regulation (EU) No 536/2014 in the version of 6 September 2022, the standard contractual clauses laid down in Annexes 1 and 2 are established. The standard contractual clauses laid down in Annex 2 are established only for contractual provisions in which the sponsor and the trial site agree their obligations as joint controllers of personal data as set out in Article 26 (1) sentences 2 and 3 as well as subsection (2) sentence 1 of Regulation (EU) 2016/679, provided that the actual stipulations of the purposes and means of the processing of personal data by the sponsor and the trial site do not require other contractual provisions.
(2) The standard contractual clauses included in Annexes 1 and 2 are not established for contractual provisions that are agreed to conduct a clinical trial which is commissioned by a non-commercial sponsor and does not pursue any commercial intent.
(3) This is without prejudice to the provisions contained in the Employee Inventions Act (Gesetz über Arbeitnehmererfindungen).

Section 2
Use of the standard contractual clauses

(1) Insofar as placeholders marked with “<“ and “>“ in the standard contractual clauses laid down in Annexes 1 and 2 indicate that the contracting parties are to agree on additions to the wording of the contract, the sponsor and the trial site shall insert the relevant additions to the contract. With respect to the placeholders in Annex 2, additions shall only be made where further personal data are processed in the contractual relationship between the sponsor and the trial site that are subject to their joint controllership and the standard

contractual clauses do not conclusively regulate the responsibility for processing of these data in this respect.
(2) Where Annex 1 provides alternatives to a standard contractual clause as derogation options, the sponsor and the trial site have to agree which alternative to incorporate into the contract.

Section 3
Application provision

This Ordinance applies to contracts concluded after 17th December 2025.

Annex 1 (to section 1 (1))
Standard contractual clauses

1. Standard contractual clause for contractual provisions regarding the right of the sponsor to first publication as well as the requirements for publications by the trial site

1.1 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 1.2 and 1.3. 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.

1.2 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.

1.3 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.

1.4 To the extent possible and reasonable, publications should be made in accessible format.

2. Standard contractual clause for contractual provisions regarding rights to results

2.1 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:

2.2 If an invention as referred to in number 2.1 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:

2.2 If an invention as referred to in number 2.1 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.

2.3 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.

2.4 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.

2.5 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 2.6, 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.

2.6 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.

2.7 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.

3. Standard contractual clause for contractual provisions regarding confidential information

3.1 Subject to number 3.2, 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.

3.2 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 and was not deemed confidential information at that time,

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.

3.3 The trial site and, subject to number 3.4, 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 3.4, 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.

3.4 The sponsor is not bound by the obligations under number 3.3 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.

3.5 The contracting parties may disclose confidential information without the consent referred to in number 3.3 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.

3.6 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.

3.7 Numbers 3.1 to 3.6 do not affect any statutory provisions regarding protection of confidentiality of information as well as statutory disclosure requirements. The confidentiality obligation pursuant to number 3.3 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 2.3, 2.4 or 2.6.

3.8 This clause continues to apply for a period of ten years after the end of the clinical trial.

4. Standard contractual clause for contractual provisions regarding 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 1 and the provisions regulating confidentiality referred to in number 3.

5. Standard contractual clause for contractual provisions regarding devices and materials provided

5.1 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.

5.2 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.

5.3 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.

5.4 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.

6. Standard contractual clause for contractual provisions regarding inspections and audits

6.1 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 subjects might be compromised or the conduct of the clinical trial affected.

6.2 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.

6.3 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 6.1 and 6.2. 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.

6.4 The trial site shall take all necessary steps to eliminate the deficiencies identified by a measure referred to in numbers 6.1 and 6.2 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.

6.5 This clause continues to apply after the end of the clinical trial for the duration of the statutory retention period referred to in number 8.1.

7. Standard contractual clause for contractual provisions regarding liability

7.1 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.

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

1. 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

2. 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.

8. Standard contractual clause for contractual provisions regarding the documentation of the clinical trial and archiving of the documentation

8.1 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: <STATE PERIODS>.

8.2 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.

8.3 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.

9. Standard contractual clause for contractual provisions regarding data protection

9.1 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).

9.2 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.

9.3 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.

9.4 This clause applies beyond the end of the clinical trial until completion of personal data processing.

10. Standard contractual clause for contractual provisions regarding the ending and termination of the contract

10.1 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 10.2 or 10.3 or

c) all contractual duties are fulfilled.

10.2 This contract may be terminated by the sponsor in writing by giving 14 days' notice to the trial site.

10.3 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 subjects' 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.

10.4 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.

10.5 Once the trial site has received or issued a notice of termination, the trial site shall not recruit or enrol any further subjects in the clinical trial.

10.6 In the event that the clinical trial ends early, especially if the contract is terminated, the trial site shall without undue delay inform the subjects enrolled that the clinical trial has ended and shall continue to treat them in line with acknowledged medical standards where possible and reasonable.

Annex 2 (to section 1 (1))
Regulations on Data Protection under Joint Controllership

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.