**CLINICAL TRIAL AGREEMENT**

This agreement (hereinafter referred to as the "Agreement") is concluded on the date of its signing by the last party, as specified on the signature page, between:

*Click or press here to enter the text.*, hereinafter referred to as the “Site,” represented by *Click or press here to enter the text.*,

and

*Click or press here to enter the text.*, hereinafter referred to as the "CRO", represented by *Click or press here to enter the text.*,

and

*Click or press here to enter the text.*, referred to as the “Principal Investigator”,

each individually referred to as a “Party” and jointly as the “Parties,”

who agreed as follows:

Whereas:

1. the Parties adopt the following definitions for the purposes of this Agreement:

|  |  |
| --- | --- |
| Clinical Trial: | *enter the name of the clinical trial* |
| Sponsor: | *enter the name of the Sponsor* |
| Sponsor’s Legal Representative: | *enter the name of the representative, if applicable* |
| Investigational Medicinal Product: | *enter the name of the IMP* |
| Protocol: | *enter the name and title of the Protocol* |
| EudraCT Number/EUCT number\*: | *enter the EudraCT number* |
| Place of the Clinical Trial conduct: | *enter the place of Clinical Trial conduct at the Site* |

\* For studies registered in CTIS we use the EUCT number, the EUdraCT number is still in place for studies registered in the previous system, prior to the launch of the CTIS portal.

1. the Sponsor has requested the CRO to act for the Sponsor but on the CRO’s own behalf while negotiating and concluding agreements with the Site and Principal Investigator;
2. the CRO contracts the Site and the Principal Investigator to conduct the Clinical Trial using the Investigational Medicinal Product in accordance with the Protocol;
3. the Principal Investigator is prepared to conduct the Clinical Trial in accordance with the Protocol and the Site agrees to have it conducted on its premises as specified in this Agreement.

**Section 1.**

**Subject matter of the Agreement**

1. The subject matter of this Agreement is the Parties’ cooperation as part of the Clinical Trial being performed by the Principal Investigator in cooperation with the Site, in accordance with the Protocol and applicable laws.
2. Unless otherwise specified in the Agreement, capitalised terms shall have the meanings ascribed to them in Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC and in the recitals hereof.
3. The CRO hereby entrusts the Principal Investigator with the conduct of the Clinical Trial in accordance with the Agreement, the Protocol and the applicable laws. During the Clinical Trial, the Site undertakes to cooperate with the CRO, the Principal Investigator, and the Trial Team in accordance with the Agreement, the Protocol and the applicable laws.
4. The Principal Investigator undertakes to conduct the Clinical Trial in accordance with the Protocol, which is incorporated into this Agreement as its integral part, the applicable laws, and the instructions of the CRO or the Sponsor.
5. The planned duration of the Clinical Trial: from *dd-mm-yyyy* to *dd-mm-yyyy*.
6. The Parties expect that under this Agreement, the Clinical Trial will recruit *enter the number* Trial Participants, to be enrolled at the Site, meeting all criteria set out for the evaluation of effects of the Investigational Medicinal Product and the eligibility criteria specified in the Protocol. Enrolling a larger number of Trial Participants requires written approval of the CRO or the Sponsor.
7. The Parties acknowledge that national, foreign or international authorities involved in supervising or controlling clinical trials, as well as independent auditors appointed by such authorities or by the Sponsor, may perform audits or inspections of the Trial-related procedures, devices and documents, including medical records of all the Trial Participants. The Principal Investigator and the Site shall immediately notify the CRO in writing of any inspection carried out by authorised bodies in relation to the Clinical Trial and provide copies of relevant correspondence. The above also applies in the event that any authorised body in any other way requests information from the Principal Investigator in relation to the Clinical Trial. In such an event, the Principal Investigator and the Site undertake, within the limits of applicable law, to cooperate with authorised bodies.
8. The Parties also acknowledge that Trial monitors or other assignees of the Sponsor may perform reviews and inspections of the Site’s infrastructure used to perform the Clinical Trial, as well as of the data and results of the Trial-related activities, in order to ensure that the Clinical Trial is being conducted in accordance with the Protocol and the applicable laws.
9. By signing this Agreement, the Site and the Principal Investigator represent that they have received the Trial Protocol, and the Principal Investigator also declares that he has read and accepted it. The Sponsor reserves the right to introduce written changes to the Protocol (listed in protocol amendments) that will subsequently apply during the performance of the Clinical Trial. Any amendment to the Protocol shall be immediately communicated in writing by the CRO to the Principal Investigator and the Site, no later than within 14 days of introducing such an amendment.

**Section 2.**

**Investigational Medicinal Product**

1. The CRO shall ensure that the Principal Investigator be provided with the relevant quantities of the Investigational Medicinal Product necessary to perform the Clinical Trial, to be delivered to the Site pharmacy, where the Investigational Medicinal Product shall be documented, prepared and stored in accordance with the applicable laws and the Protocol. Neither the Site nor the Principal Investigator shall use the Investigational Medicinal Product for any other purpose except conducting the Clinical Trial.
2. The Principal Investigator undertakes to only use the Investigational Medicinal Product in the manner specified in the Protocol.
3. Once the Agreement expires or is terminated, the Site and the Principal Investigator shall immediately return any unused Investigational Medicinal Products to the CRO at the CRO’s cost and upon the Sponsor’s written instructions. Should the Investigational Medicinal Products supplied for the purposes of the Clinical Trial need to be disposed of, the CRO shall cover the relevant costs in accordance with the price list applicable at the Site and shall issue the necessary instructions.

**Section 3.**

**Responsibilities of the CRO**

1. The CRO undertakes to:
	1. provide the Site and Principal Investigator with the complete Protocol. If the Protocol is provided in English, the CRO shall have the Protocol Synopsis translated into Polish;
	2. provide the Site and the Principal Investigator, no later than 14 days before the planned date of first patient recruitment, with official approval for the conduct of the Clinical Trial;
	3. notify the Site and Principal Investigator of the name and contact details of the Trial monitor at the beginning of the Clinical Trial and each time the monitor is replaced;
	4. provide the Principal Investigator with complete documentation necessary to conduct the Clinical Trial, including the Protocol and the Investigator’s Brochure, within a time that makes it possible for them to get acquainted with the way the Clinical Trial is to be conducted;
	5. organise an initiating visit and train the Principal Investigator and members of the Trial Team to ensure proper performance of the Clinical Trial at the Site;
	6. collect any unused or expired Investigational Medicinal Product supplied for the purposes of the Clinical Trial or cover the costs of its return or disposal;
	7. notify the Site, within the agreed reporting periods, of the number of Participants and their completed visits, as well as of the optional procedures performed, as referred to in Appendix No. 1 hereto, along with the dates of such visits and optional procedures, and of the Clinical Trial completion date (end of the active phase and closing the Clinical Trial at the Site);
	8. if Trial data are to be processed using methods based on IT systems, the CRO shall provide the members of the Trial Team with free access to these systems along with written instructions for their use.

**Section 4.**

**Responsibilities of the Principal Investigator**

1. The Principal Investigator undertakes to:
	1. conduct the Clinical Trial in accordance with the Protocol and the applicable laws;
	2. adhere to any instructions regarding the conduct of the Clinical Trial, as received from the Sponsor or set forth in the Good Clinical Practice;
	3. perform the Clinical Trial, which includes Trial Participants recruitment, performing services specified in the Protocol and the Investigator’s Brochure, providing – in cooperation with the Site – proper medical care to the Participants during the Trial, completing CRFs, and reporting on Trial progress to the Sponsor;
	4. comply with the principles of collecting, reporting and storing data as set forth in this Agreement, the Protocol, and generally applicable laws, within the timeframes and according to the requirements specified by the Sponsor;
	5. ensure the protection of data, including personal data of the Trial Participants collected as part of the Trial, and to keep such data confidential;
	6. hand over, upon each request of the Sponsor, any materials and studies collected and developed as part of performance hereunder.
2. Upon the consent of the CRO, the Principal Investigator shall appoint a trial team among the employees and contractors of the Site, as necessary to perform the Clinical Trial, exhibiting the necessary skills and qualifications (the “Trial Team”). The Principal Investigator represents that every member of the Trial Team abide by the provisions of this Agreement and the Protocol. The Principal Investigator shall be liable for the actions or omissions of the Trial Team during the conduct of the Clinical Trial as if they were the Principal Investigator’s own actions or omissions.
3. The Principal Investigator shall exercise direct supervision over the correct performance of the activities entrusted by him/her to selected persons and shall evaluate and accept the work once delivered.
4. The Principal Investigator represents that he/she has the necessary qualifications and licences to act as an investigator, which shall be evidenced, upon the Sponsor’s request, by presenting the relevant documents (as required by the applicable laws).
5. If a Serious Adverse Event (SAE) occurs, the Principal Investigator is obliged to adhere to the Sponsor’s instructions, as set out in the Protocol or in other instructions handed over by the Sponsor, and to report such an event immediately to the Site and the Sponsor within 24 hours of becoming aware thereof. In the event of receiving queries from the CRO or the Sponsor regarding adverse events, the Principal Investigator shall respond to any such questions to the best of his/her knowledge.
6. If a serious breach of the Protocol or the provisions of EU Regulation 536/2014 occurs, the Principal Investigator is obliged to immediately report such a breach to the Site and the Sponsor within 24 hours of becoming aware thereof. In the event of receiving queries from the CRO or the Sponsor regarding said serious breaches, the Principal Investigator shall respond to any such questions to the best of his/her knowledge.
7. The Principal Investigator is responsible for maintaining the Trial documentation in accordance with applicable laws and the Protocol, including ensuring appropriate conditions for archiving the Trial documentation, during the Trial and after its conclusion.
8. The Principal Investigator shall perform this Agreement in person and shall not assign any rights or obligations arising herefrom without the prior written consent of the Sponsor and the Site.
9. When conducting the Clinical Trial, the Principal Investigator shall always exercise his/her best professional judgment, in compliance with the Trial requirements, in relation to all individuals participating in the Clinical Trial.
10. The Principal Investigator represents that no proceedings are currently pending that could lead to the Principal Investigator’s debarment or suspension of his/her medical licence. The Principal Investigator represents that as part of performance hereunder he/she shall not procure services from any person known by the Principal Investigator to have been debarred or suspended.
11. The Principal Investigator undertakes to establish the amount of remuneration due to the members of the Trial Team on the basis of the actual workload of individual members of the Trial Team, and shall provide the CRO with a relevant list within the agreed billing periods. The CRO shall conclude appropriate cooperation agreements with the members of the Trial Team.
12. Pursuant to art. 60 of the Polish Act on clinical trials of medicinal products for human use, the Principal Investigator/Site shall inform, in paper or electronic form, the competent provincial branch of the Polish National Health Fund about the following:
	1. name and surname of the Investigator and information on the entity providing healthcare services,
	2. the Polish Personal Identification Number (PESEL) of a Trial Participant, and in the event that this number has not been assigned – the type and number of the document confirming identity and date of birth,
	3. the date on which a Trial Participant was enrolled into the Clinical Trial, understood as the date of signing the informed consent to participate in the Trial, if applicable, as well as the date of termination of such Participant's participation in the Clinical Trial,
	4. classification of the Clinical Trial – commercial clinical trial or non-commercial clinical trial,
	5. unique EU trial number, as referred to in art. 81(1) of Regulation 536/2014.

**Section 5.**

**Responsibilities of the Site**

1. The Site undertakes to cooperate with the Sponsor and Principal Investigator in performing Trial-related activities, in particular to:
	1. allow the Clinical Trial to be conducted, which includes making available qualified medical staff and access to appropriate premises, equipment and devices. The equipment and devices made available for the purposes of the Clinical Trial shall meet the relevant technical requirements, have valid certificates and undergo maintenance in accordance with current requirements. At the request of the Sponsor, the Site shall present the relevant certificates for the equipment or devices;
	2. provide medical services as set forth in the Protocol and ordered by the Principal Investigator or members of the Trial Team;
	3. provide pharmaceutical surveillance over the Clinical Trial in accordance with the law;
	4. supervise the development of medical records constituting source documentation for the Clinical Trial;
	5. be prepared to enable the Principal Investigator to provide immediate medical assistance to the Subjects at the Site.
2. The Site will enable the Principal Investigator to maintain the Trial documentation in an appropriate manner for the period required by law. The Trial documentation cannot be destroyed without the prior written consent of the Sponsor. At the Sponsor's request and expense, after the said period has elapsed or at any other time, the Trial documentation must be delivered to the Sponsor or destroyed.

**Section 6.**

**Confidentiality and Intellectual Property**

1. The Parties undertake to abide by all applicable laws associated with personal data protection and use and with data privacy while performing hereunder. The rules of processing personal data, in particular personal data of the Participants, are set out in Appendix No. 2 hereto.
2. During the term of this Agreement and for the period of ten (10) years from the end of the Clinical Trial, the Principal Investigator and the Site shall keep confidential any information received from the Sponsor or generated as part of the Clinical Trial (“Confidential Information”). The above restriction shall not apply to Confidential Information which:
	1. has been made public without the involvement of the Principal Investigator or the Site;
	2. has already been in the possession of the Principal Investigator or the Site;
	3. is required to be disclosed by law;
	4. has been provided to the Principal Investigator or the Site in accordance with the law;
	5. has been disclosed in accordance with this Agreement.
3. The results and data of the Clinical Trial conducted hereunder shall be the sole property of the Sponsor. The Principal Investigator agrees to provide to the Sponsor any Trial results and data in the form agreed with the Sponsor.
4. The Sponsor will publish information about the Clinical Trial, consisting only of the data that may be made available to the public, at the following website: www.clinicaltrials.gov. The published information will be publicly available on the said website before the first Participant is enrolled into the Clinical Trial. The Sponsor shall ensure that the published data about the Clinical Trial are up to date in order to provide complete and valid information.
5. The Site may publish basic information about the Clinical Trial on its website, to the extent equivalent to the clinical trial information published at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).
6. Any publication or public presentation of the Trial results by the Principal Investigator requires prior consent from the Sponsor.

*or*

1. The Principal Investigator undertakes to publish or present the results of the Clinical Trial to the public on the terms set out in this Agreement.
2. The Principal Investigator undertakes to provide the Sponsor, forty-five (45) days in advance, with written notice before submitting any materials for publication or presentation, in order to enable the Sponsor to review draft abstracts and manuscripts for publication (which includes, in particular, slides and texts of oral or other public presentations), hereinafter referred to as the "Presentation", reporting any results of the Clinical Trial. The Sponsor has the right to review and provide comments to any Presentation. The Principal Investigator agrees to include the Sponsor's comments in the Presentation only if it is necessary for the protection of Confidential Information, personal data or intellectual property, provided that such changes must not be against the reliability of the data, the law, as well as the safety and welfare of the Participants.
3. The Sponsor acknowledges that it has no right to request the deletion or correction of the information contained in the Presentation, except where such deletion or correction is necessary for reasons related to data confidentiality, data protection, or intellectual property protection. The Parties agree to cooperate in good faith in order to discuss and resolve any contentious issues. At the Sponsor's request, the Sponsor will be named as the sponsor of the Clinical Trial.
4. If the Sponsor reports that the Presentation submitted for review contains content suitable for patent protection, the Sponsor shall immediately indicate such content to the Principal Investigator, and then the Principal Investigator shall refrain from publishing the Presentation for further ninety (90) days. If requested by the Sponsor and at its expense, the Principal Investigator shall use its best efforts to assist the Sponsor in filing a patent application with respect to such content with the relevant patent office prior to any publication.
5. To the extent that the participation of the Principal Investigator in the Clinical Trial is part of a multicentre trial, the Principal Investigator agrees that the initial Presentation of the results will take place only simultaneously with other centres, unless prior written consent is obtained from the Sponsor for the Presentation of separate results. The Sponsor will inform the Principal Investigator as to the suggested dates of any Presentation in the event that clinical trials are still ongoing in trial centres other than the Site. The Principal Investigator may publish the results of the Clinical Trial in accordance with this Agreement if the joint publication is not completed within twelve (12) months after the conclusion of the Clinical Trial in all centres conducting thereof and the closure of the database.

**Section 7.**

**Financing health care services and Clinical Trial insurance**

1. The Sponsor finances the health care services related to the Clinical Trial that are covered by the Protocol, in accordance with the provisions of law.
2. The CRO represents that the Sponsor has concluded an insurance contract to insure the Sponsor and the Principal Investigator against any damage arising in connection with the Clinical Trial, in accordance with the applicable laws. A copy of the insurance certificate is attached hereto as Appendix No. 3.
3. The Site holds third-party insurance required by applicable Polish law.

**Section 8.**

**Remuneration and payment terms**

1. For the performance hereof, the CRO shall pay the Site, the Principal Investigator, and the members of the Trial Team the remuneration set out in Appendix No. 1 hereto (“Trial Budget”).
2. A detailed Trial Budget and payment schedule for the Site, the Principal Investigator, and the Trial Team are set out in Appendix No. 1 hereto.

**Section 9.**

**Term and termination**

1. This Agreement is concluded for a fixed term, until the date of Clinical Trial conclusion.
2. The Parties mutually agree that this Agreement shall enter into force on the day it is signed by all Parties, except that the respective rights and obligations of the Parties arising herefrom will be suspended until the day the Sponsor provides the Site and the Principal Investigator with a copy of the approval for the conduct of the Clinical Trial.
3. The Sponsor has the right to terminate the Clinical Trial at any time. If this is the case, this Agreement shall be terminated on the date the Site or the Principal Investigator receives a written notification (whichever is later) of Trial termination from the CRO or the Sponsor. In such an event, the settlements among the Parties will be based on a trial progress protocol drawn up by the Parties as of the Clinical Trial termination date, specifying e.g. the number of visits completed until that time by each Participant and the health care services performed for the purposes of the Clinical Trial.
4. The Site and the Principal Investigator have the right to terminate this Agreement by 30 days’ written notice in the event of non-performance or undue performance hereof by the CRO. This right is available to the Site and the Principal Investigator upon the ineffective lapse of 30 days from issuing to the CRO a notice calling for due performance of its obligations.
5. The Site has the right to terminate this Agreement for an important cause by 90 days’ written notice.

**Section 10.**

**Final provisions**

1. Any amendments and supplements to this Agreement must be made in a written form, otherwise null and void, or in a documentary form if the Agreement has been concluded in a documentary form.
2. Any Protocol amendments that would affect the scope of responsibilities of the Principal Investigator or the Site, in particular any changes that necessitate revisiting the costs of the Clinical Trial, require the amendment hereof to adjust the remuneration due to the Principal Investigator and the Site accordingly.
3. This Agreement shall be governed by Polish law and construed according to the generally applicable provisions of Polish law.
4. Any notices and other information resulting from this Agreement must be provided in a written form to the addresses specified below and will be deemed served also if delivered in person, by fax, or by email, or if sent by registered mail or against acknowledgement of receipt (acknowledgement return required). The said notices must be duly addressed to the following addresses of the Parties:

For the Sponsor:

*Click or press here to enter the text.*

If to the Principal Investigator:

*Click or press here to enter the text.*

If to the Site:
*Click or press here to enter the text.*

1. The Parties agree that the court competent for any possible disputes arising from or in connection with this Agreement shall be the common court having jurisdiction over the registered office of the Site.
2. This Agreement has been drawn up in Polish and English in three counterparts, one copy for each Party. In the event of any discrepancies between the Polish and English versions of the Agreement, the Polish version shall prevail.

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| --- | --- | --- |
|  |  |  |
| On behalf of the CRO | For the Site | Principal Investigator |

*(signatures of the Parties and signature date)*

Appendices:

1. Clinical Trial budget,
2. Principles of personal data processing,
3. Copy of the insurance certificate for the Trial.

Appendix 2

**Rules of personal data processing
(“Rules”)**

*Principles of personal data presuming that each Contracting Party acts as an independent controller of personal data.*

1. The Parties to this Agreement agree to process the personal data of the Trial Participants and members of the Trial Team in accordance with the provisions of applicable law, including in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, “GDPR”), regulations on the conduct of clinical trials, including the Good Clinical Practice, as well as this Agreement and the Protocol.
2. Sponsor, Site and Principal Investigator remain independent personal data controllers in relation to the personal data of the Trial Participants and members of the Trial Team within the following scope and purposes:
3. the Sponsor is the controller of personal data processed for research purposes, including for the analysis of data collected pursuant to the Protocol and in the scope of fulfilling its own legal obligations in relation to the Clinical Trial, including its documenting and monitoring;
4. the Site is the controller of data processed for the purposes related to the provision of health services, including for the supervision over the medical records of the Trial Participants and for the fulfilment of its own legal obligations in relation to the Clinical Trial;
5. the Principal Investigator is the controller of data processed for the conduct of the Trial, including for the fulfilment of his/her own legal obligations in relation to the Clinical Trial.
6. It is considered that any data collected in connection with the conduct of the Clinical Trial may be used by the Site and the Principal Investigator to provide appropriate health care services to the Trial Participants.
7. Sponsor, Site and Principal Investigator are separately responsible for fulfilling their respective legal obligations related to the processing of personal data, in particular for:
8. ensuring that the legal basis for the processing of personal data is given and for the implementation of information obligations towards the Trial Participants and members of the Trial Team;
9. ensuring the security of personal data by implementing appropriate administrative, technical and physical security measures, with the application of current industry practices;
10. maintaining procedures for detecting and responding to personal data breaches,
including breaches of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure, or unlawful access to the personal data transmitted, stored or otherwise processed. The Parties agree to inform each other about any personal data breach related to the processing of personal data under the Clinical Trial and to cooperate in limiting the effects of such a breach and in possible reporting thereof to the data protection authority;
11. ensuring that the Trial Participants and members of the Trial Team can effectively exercise their rights in relation to the processing of their personal data. The Parties to this Agreement shall cooperate in responding to personal data requests made by the Trial Participants or members of the Trial Team, if necessary;
12. determination of personal data retention periods appropriate to the purposes of data processing and legal obligations, as well as for the retention of personal data for the period necessary to achieve such purposes or as required by applicable law.
13. The Principal Investigator will provide the Trial Participants, in accordance with applicable law, with a declaration of informed consent to participate in the Clinical Trial, on the form provided by the Sponsor. The declaration of informed consent for the participation in the Clinical Trial, containing, among others, the rules for the processing of personal data related to the participation in the Clinical Trial, must be signed by the Trial Participant before he/she is enrolled into the Clinical Trial. The Investigator will immediately inform the Sponsor about the withdrawal of consent to participate in the Clinical Trial by the Trial Participant or the objection to the use of his/her personal data. The Parties agree to cooperate in the implementation of the requests submitted by the Trial Participants in relation to the processing of their personal data.  Due to the fact that the Sponsor processes only encrypted (pseudonymised) personal data of the Trial Participants, the Principal Investigator will provide the Sponsor with all necessary support in processing and implementing the Trial Participant’s requests.
14. The Principal Investigator is responsible for collecting and documenting the data of Trial Participants needed for the conduct of the Clinical Trial and providing such data to the Sponsor in an encrypted (pseudonymised) form, in accordance with the Protocol. The Sponsor shall process the personal data of the Trial Participants only in an encrypted form, with the exception of the monitor who supervises the proper conduct of the Clinical Trial and may have access to unencrypted data.
15. In connection with the conduct of the Clinical Trial, the Sponsor may collect and process personal data related to the Principal Investigator and members of the Trial Team, for the purposes and on the terms set out in a separate document.

*The data processing principles set out above reflect the approach taken by most clinical trial Sponsors and should therefore be the default solution for structuring the relationship between the contracting parties with regard to the processing of personal data.*

*An alternative to the above proposed principles for the processing of personal data is the different definition of the roles of the parties with regard to the processing of personal data (e.g. as joint controlling or the use of entrustment agreements for the processing of personal data).*