CLINICAL TRIAL COORDINATION AGREEMENT

This Clinical Trial Coordination Agreement ("**Agreement**")

Effective as of _____***day of*** _____ ***March 2021***

is made between:

1. **Cardiff University,** a registered charitable institution with registered Charity No. 1136855 and whose offices for administrative purposes are at McKenzie House 30.36 Newport Road Cardiff CF5 2LB(hereinafter known as th***e*** "**SPONSOR**"),

   and

2. **University Hospital Brno**, with its registered office at Jihlavska 20, 625 00 Brno, Czech Republic, represented by prof. MUDr. Jaroslav Štěrba, Ph.D., Director

   ("hereinafter referred to as "Authorized Organization"),

(SPONSOR and Authorized Organization hereinafter individually or collectively referred to as "**Party**" or "**Parties")**

Preambles

WHEREAS funding partners have agreed that Cardiff University will act as the SPONSOR for those international participating trial sites involved in the Trial and have provided funds to Cardiff University to act in the role of SPONSOR with SPONSOR oversight of the international participating trial sites ("International Sites").

WHEREAS SPONSOR has assumed legal sponsor responsibilities defined in article 2.e of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (hereinafter "**Directive 2001/20/EC**") for the conduct and co-ordination of a clinical Trial entitled ***"***[redacted] (the "**Trial**") as described in the protocol and its amended versions with number ***and title*** [redacted]

[redacted] ("**Protocol**"), attached to this Agreement as **Exhibit A.**

WHEREAS Authorised Organization has in place, the necessary and appropriate insurance to act in its role as Authorised Organization and to conduct the Trial in accordance with the terms and conditions of this Agreement, and its Exhibits.

WHEREAS the Authorized Organization has in place the necessary knowledge and expertise and trial set know how to recruit and appoint trial sites within the Country of the Authorized Organization ('Country's Trial Sites').

WHEREAS, Authorised Organization appoints [redacted] ***("National Coordinating Investigator"),*** to lead on the functions, roles and responsibilities of the Authorized Organization under this Agreement. The Trial at the Country's Trial Sites shall be coordinated under the supervision of Authorized Organization's National Coordinating Investigator.

WHEREAS SPONSOR wishes to delegate certain legal sponsor responsibilities and tasks to Authorized Organization as set out in the task list attached hereto as **Exhibit B** ("**Task List Table**"), and Authorized Organization is willing to assume and perform same;

WHEREAS Authorized Organization wishes to conduct the Trial and is willing to assume national delegated sponsor tasks as specified in the Task List and Table for the conduct and co-ordination of the Trial within the Country of the Authorized Organization.

WHEREAS Authorised Organization undertakes to contract with each of the Country's Trial Sites to perform the Trial in accordance with the Protocol and, prior to signing any agreement with the Country's Trial Sites, the Authorised Organization shall ensure all necessary regulatory approvals and appropriate insurance is in place at each of the Country's Trial Sites.

WHEREAS Any supply of investigational medical product ('IMP') as required by the Protocol will be arranged by each Participating Site via the clinical supply route determined by each Participating Site and any use of the IMP shall be in compliance at all times with the Protocol and GMP-Guidelines and applicable law.

WHEREAS Sponsor appoints Centre for Trials Research (CTR) as hosted at the Sponsor institute to be the appointed clinical trials unit for the purposes of the Trial and as the host of the Trial database and recipient of the Trial Data from the Country's Trial Sites.

Therefore, Parties agree the following:

1 SPONSOR RESPONSIBILITIES

1.1 SPONSOR shall respect and follow all applicable laws, rules, regulations and guidelines of any type, including but not limited to the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and other good clinical practice requirements as are specified in Directives 2001/20/EC and 2005/28/EC, of the European Parliament and the Council relating to medicinal products for human use and published by the European Commission pursuant to such Directives, and all legislation and guidelines regarding the privacy of persons and the protection of personal data, and all rules and regulations of the governmental agencies governing the testing and approval of pharmaceuticals for use in humans ("**Regulatory Authority**") (collectively: "**Laws and Regulations**").

1.2 SPONSOR shall coordinate and be the international legal sponsor of the Trial.

1.3 SPONSOR will provide Authorized Organization with documents, to the extent necessary to perform the Trial, except those which are specific for the country or which need to be translated in native language, all as set out in the SPONSOR responsibilities Task List attached hereto in **Exhibit B**.

1.4 In particular, SPONSOR shall provide the relevant documentation regarding the Study Drug to Authorized Organization, including the SmPC, Letters to Investigators ('DILs'), as well as each of their subsequent updates in a work format and in track changes and in a timely manner, for the duration of the Study. The contact addresses for these communications are the following:

Contact: University Hospital Brno (Fakultní nemocnice Brno), Jihlavska 20, 625 00 Brno, Czech Republic
tel :+420 532 232 000
e-mail: fnbrno@fnbrno.cz

SPONSOR shall make its best efforts to help Authorized Organization by providing justification for modifications, e.g. for the information of investigators or the competent authorities.

1.5 SPONSOR shall invite at least one representative of Authorized Organization to the Trial Management Group ('TMG') as active members of the TMG and attendance at TMG meetings.

1.6 The SPONSOR shall appoint:
- a legal representative established in the European Union (in accordance with Article 19 of the DIRECTIVE 2001/20/EC);

- a representative in the European Union for the purposes of personal data processing (in accordance with the article 27 of the REGULATION (EU) 2016/679 of 27 April 2016 (General Data Protection Regulations).

1.7 It is agreed between the Parties that the generation and collection of Trial Data will be processed on the basis of the legitimate interests pursuant to GDPR art. 6.1.f, namely, for the conduct of scientific research, in accordance with GPDR art. 9.2.j.

2. Authorized Organization RESPONSIBILITIES

2.1 Authorized Organization shall respect and follow all applicable laws, rules, regulations and guidelines of any type, including but not limited to the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and other good clinical practice requirements as are specified in Directives 2001/20/EC and 2005/28/EC of the European Parliament and the Council relating to medicinal products for human use and published by the European Commission pursuant to such Directives, and all legislation and guidelines regarding the privacy of persons and the protection of personal data, and all rules and regulations of the governmental agencies governing the testing and approval of pharmaceuticals for use in humans.

2.2 The Trial Sites in the Authorised Organisation's Country's Trial Sites' will be identified to the SPONSOR by the Authorised Organisation and the Trial, at those agreed Trial Sites will be coordinated by the Authorized Organization, in accordance with those tasks, duties, roles and responsibilities identified in **Exhibit B**. Together with delegation of those tasks and duties to the Country's Trial Sites as set out in **Exhibit B**, with day to day oversight of those task and duties at the Country's Trial Sites by the Authorized Organization.

2.3 Authorized Organization shall perform the obligations as listed in the Task List Table attached in Exhibit B). Any third party delegated to perform responsibilities by the Authorized Organization should be appropriately identified to the Sponsor and a relevant written agreement shall be entered in to between the Authorized Organization and the identified third party and made available to the Sponsor upon request for the purposes of Sponsor oversight and monitoring purposes.

3. SUPPLY OF TRIAL DRUGS

Sponsor shall ensure that sufficient quantities of the study drugs are available throughout the study.

3.1 The Authorized Organization shall ensure that at each of the Country's Trial Site has and makes available all quantities of the necessary Trial Drugs for use in

the Trial and shall ensure that each of the Country's Trial Sites use the Trial Drug in accordance with the requirements of and as set out in the Protocol.

3.2 The Authorized Organization shall ensure and is responsible for ensuring that each of the Country's Site Trial, appoint a pharmacist to be responsible for overseeing the receipt and dispensing of the Trial Drugs ('Trial Site Pharmacist(s)')**.**

3.3 Randomization of Trial Participants shall happen in accordance with the Trial Protocol. Upon randomization the Trial Drugs shall be sent direct from the respective Pharmaceutical Companies responsible for supplying the Trial Drugs for the Trial, to the Trial Site Pharmacy.

3.4 The Trial Site Pharmacists shall be responsible for dispensing the Trial Drugs in accordance with the Trial Protocol and the administration of the Trial Drugs shall be in accordance with the Trial Protocol and be overseen by each of the Country's Trial Sites and in particular the lead principle investigator ('Lead Principle Investigator') of the Trial at each of the Country's Trial Sites.

3.5 Authorized Organization shall oblige the Country's Trial Sites via the Trial Site Pharmacists to ensure that such measures are in place to detail and retain records in respect of complete accountability of the Trial Drugs as used in the Protocol and as is required in accordance with ICH-GCP.

3.6 Authorized Organization agrees it will, and shall, oblige the Country's Trial Sites to agree they will store the Trial Drugs adequately and that no expired Trial Drugs will be given to any participant in this Trial ("Trial Participant").

3.7 At the conclusion or termination of this Trial, a record of all Trial Drugs used in accordance with the Protocol shall be provided to the Authorized Organization in the first instance and then to CTR on behalf of the Sponsor.

3.8 The Country's Trial Sites shall ensure the IMP as identified is made available for the Trial, is in accordance with the European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use ("**GMP-guidelines**") and the Trial Drugs is appropriately labeled and dispensed in respect of each Trial Participant in accordance with current laws and regulations in place of the Authorized Organization and in accordance with local guidelines, regulations protocols and requirements at the Country's Trial Site and each of them individually as required.

3.9 Authorized Organization shall support the Sponsor to ensure that each Participating Site has an adequate supply of the IMP and all other commercial drugs (when applicable) for the purpose of performing the Trial as required in the Protocol.

4. PHARMACOVIGILANCE

4.1 All specific tasks will be defined in the table in Exhibit B.

5. OWNERSHIP AND USE OF TRIAL DATA

5.1 Ownership

All case report forms and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer database or computer readable form) created or developed during the course of the Trial at Authorized Organization's Country's Trial Sites (the "**Trial Data**") shall be the property of SPONSOR. All rights in the Trial Data and the Trial database designed and set up by the Sponsor for the purposes of the Trial ('the Trial Database') shall be owned by and at all times vest in the SPONSOR. The SPONSOR may utilize the Trial Data in any way it deems appropriate, subject to and in accordance with applicable Laws and Regulations and the terms of this Agreement.

SPONSOR shall have unrestricted access to all Trial Data relevant to the Trial under the terms and conditions of this Agreement. Trial Data shall be provided to SPONSOR in accordance with the Protocol and case report forms.

Authorized Organization including National Coordinating Investigator warrant that all the Country's Trial Sites and Principal Investigators at the Country's Trial Sites have executed a written agreement with Authorized Organization in which each such person assigns to Authorized Organization all right, title and interest in and to Trial Data, in order that Authorized Organization may fully assign the rights to SPONSOR as provided above. All sub-investigators (if any) and all Study staff members are covered by these written agreements.

Subject to provisions in relation to confidentiality and publication rights as set out herein and any other rights of the SPONSOR in the Trial Data, the Authorized Organization may use the Trial Data collected in respect of the Country's Trial Sites for its internal academic, non-commercial research purposes only, upon the prior written submission to the SPONSOR. Upon such prior application by the Authorized Organization to the SPONSOR for use of the Trial Data collected from the Country's Trial Sites for its non-internal academic, non-commercial research purposes, then such application shall be considered in good faith and shall not be unreasonably withheld. Any data transfer request as approved pursuant to this provision shall, once agreed, be reduced into written format in the form of an appropriate data transfer agreement, including agreement on the format of the dataset to be transferred. Where it is intended that the Trial Data as collected from the Country's Trial Sites is to be used with commercial partners for commercial

activities then the Authorised Organisation is aware that the Sponsor maybe required to obtain the approval of the Funder. Accordingly, where commercial collaborations are anticipated the Sponsor must be expressly notified and the approval of the Sponsor sought, such approval shall not be unreasonably withheld but subject to the approval of the Funder if also required. The Authorised Organisation also recognises that in any collaborative agreement with a commercial entity, then such agreement may be required to take in account the interests of the Funder and the Sponsor in contributing to the Trial Data in respect of the Country's Trial Sites.

In the event that the Trial Data is, exploited commercially, by the Sponsor, the Sponsor shall make a fair and reasonable financial benefit to the Authorized Organization based on the contribution of the Authorised Organisation to the Trial Data and the Trial as a whole. The size and nature of any such financial benefit shall reflect the respective contributions of the Parties and shall be mutually agreed in a further written revenue sharing agreement which shall be completed by the Parties within one year following each arrangement of commercial use of the Data by Sponsor.

5.2 Record-Keeping and Access to Records

Authorized Organization shall and shall ensure the Country's Trial Sites maintain complete, accurately written records, accounts, notes, reports, data and radiographic examinations ("Records") relating to the Trial and the Protocol which will be used to prepare and submit Patient case report forms to SPONSOR, as detailed in the Protocol and/ or SOP's.

5.3 Record Retention

Authorized Organization shall and shall ensure the Country's Trial Sites retain, maintain and archive the essential documents related to the Trial for the period defined (at least 15 years following completion of the trial) in a way that ensures that they are readily available, upon request, to the competent authorities.

5.4 Intellectual Property

a) The existing inventions and technologies of the SPONSOR or the Authorised Organization are their separate property and are not affected by this Agreement. Any developments to existing inventions and technologies which are not detailed as part of the Protocol, but which may be developed during the Trial, will be owned by, the owner of the pre-developed background.

b) It is expressly acknowledged and understood that neither Party transfers, by operation of this Agreement to the other Party, any patent right, copyright, or other proprietary right either party owns as of the Effective Date of this Agreement. Each Party shall be and remain the sole owner of all its knowledge, know-how and its improvements or results, whether patentable or not, whether patented or not, that it owns before this Agreement comes into force or it possesses outside the scope of this Agreement. The Parties does not get any right on the aforesaid knowledge,

know-how and its improvements or, results, patent right, copyright, or other proprietary right, owing to the fact of the signing of this Agreement.

c) The entire right, title and interest in and to the Trial Data and any inventions or other intellectual property rights that are conceived or developed from the Trial ("Inventions"), including all improvements or modifications which are anticipated by the Protocol or rely on, use, or incorporate any Confidential Information of the SPONSOR, shall be the exclusive property of SPONSOR.

d) The Authorised Organization shall promptly report in writing to the SPONSOR each Invention or discovery and shall ensure that all Trial staff and the Country's Trial Sites and their staff assign to the Sponsor all of the rights, title and interest, if any, in and to the Trial Data and any such Inventions.

e) The Parties shall execute such documents as are necessary to give effect to these provisions.

f) The SPONSOR hereby grants to the Authorised Organization a fully paid up, non-exclusive, non-sub-licensable right to use the Inventions for internal non-commercial research and teaching purposes, subject to the terms of confidentiality of this Agreement and the provisions of this Clause 5 and Clause 8. The Authorised Organisation recognises that where a commercialisation pathway for the Inventions have been identified then the provisions of Clause 5.4g) apply and a restriction on such use of the Inventions may be appropriate pending any application to protect such Inventions and any commercialisation of the same.

g) The SPONSOR is free to commercially use the Inventions, and in the event that the Inventions are to be exploited commercially by the Sponsor, the Sponsor may in their sole discretion and after seeking the approval of Cancer Research UK, whose decision shall be final, make a fair and reasonable financial benefit to the Authorized Organization. The size and nature of any such financial benefit shall reflect the respective contributions of the Parties and shall be mutually agreed in a written revenue sharing agreement which shall be completed by the Parties within one year following each arrangement of commercial use of the Inventions thereof by SPONSOR.

6. PAYMENT

6.1 The Parties hereby agree that monies are to be provided by the Sponsor to the Authorized Organization under this Agreement, in accordance with Exhibit D Payment Schedule.

6.2 Saved as provided for in Exhibit D, the Authorized Organization shall be responsible for ensuring that the Authorized Organization itself and each of the Country's Trial Sites and any other third parties identified to meet the requirements of the Protocol (e.g. payments to laboratories undertaking testing and analysis of Trial Samples, hereinafter known as 'Trial Third Parties') have sufficient finances and be responsible for securing sufficient finances in order to meet the requirements of the Trial Protocol, for the purposes of delivering the Trial.

6.3 The SPONSOR shall not be liable to make any payments to the Authorized Organization and/or the Country's Trial Sites other than as provided for in Exhibit D and the Authorized Organization shall ensure the Country's Trial Sites are made aware of the provisions of this Clause 6 in any legal Site Agreement entered in to between the Authorized Organization and the Country's Trial Sites.

6.4 The Sponsor shall not be responsible or liable for any payments not made or remain owing and outstanding to any Trial Third Parties and/or any other third parties and/or persons involved in the Trial and/or in Trial related activities, whether at the Authorized Organization and/or at any of Country's Trial Sites or otherwise, whether such payments are deemed to be properly owing and due or otherwise.

6.5 The Authorized Organization shall ensure of itself and ensure in respect of each the Country's Trial Sites any monies and payments required to be secured in relation to any matters relating to the conduct of the Trial at the Country's Trial Sites and any other Trial Third Parties involved in Trial related research activities are in secured for the duration of the Trial in order to avoid the possibility of the Country's Trial Sites having to terminate the Trial early on the grounds of lack of finance.

6.6 Any payments authorized by the Sponsor to any Country's Trial Site shall be made in accordance with **Exhibit D**, shall only be made at the rate as agreed between the Sponsor and the Pharmaceutical Company and no other monies or payments can be expected to be made, nor shall be made.

6.7 Accordingly, in line with the above funding is in place as outlined in **Exhibit D** Payment Schedule to cover inter alia costs in association with **Exhibit B** Task List, and is deemed to include all necessary costs associated with insurance cover and otherwise as required to be in place to conduct the Clinical Trial, whether by the Authorized Organization and/or the Country's Trial Sites and/or any Trial Third Parties and/or otherwise.

6.8 It is understood that any agreement between the Authorized Organization and each Country's Trial Sites shall ensure that any employment taxes that may be due and payable by the Country's Trial Sites shall be entirely the responsibility of the Country's Trial Sites.

6.9 It is understood the Authorized Organization in its agreement with the Country's Trial Sites shall ensure that each of the Country's Trial Site also undertakes to pay all employment taxes on such payments for which it may be liable for as and when they fall due to be paid.

6.10 It is understood that any employment taxes that may be due and payable by the Authorized Organization shall be entirely the Authorized Organization's responsibility.

6.11 It is understood that, the Authorized Organization also undertakes to pay all employment taxes on such payments for which it may be liable for as and when they fall due to be paid.

7. CONFIDENTIAL INFORMATION

7.1 "**Confidential Information**" means, information, data and material of any nature or that which is a trade secret, including know how, whether disclosed before or after execution of this Agreement, except the information specified in **Section 7.4 below**.

7.2 Confidential Information may be written or spoken. It includes pictures, diagrams and electronically stored information belonging to a Party and disclosed by one Party (the "**Disclosing Party**") to the other Party (the "**Receiving Party**") in connection with this Agreement.

7.3 Personal Data, as defined in the General Data Protection Regulations 2016 and the Data Protection Act 2018 ("together the GDP Legislation"), which relates to any staff of Authorized Organization and/or the Country's Trial Sites and/or Trial Participant.

7.4 Where such Personal Data relates to a Trial Participant at the Country's Trial Sites or his or her treatment or medical history, or other information, in relation to the Trial, which is reasonably viewed to be Personal Data of a Trial Participant, should be known as Clinical Data and shall be handled and processed in accordance with the General Data Protection Regulations 2016/679 and ("Act No. 110/2019 Coll., on the Processing of Personal Data"), both together hereinafter known as the General Data Protection Legislation. This provision shall also apply in respect if any Clinical Data in relation to clinical biological samples ("Samples") collected for the purposes of the Trial and whether such Samples are tested at the Country's Trial Sites, or within the Country of the Authorised Organization and/or in circumstances where such Samples are and/or such associated Clinical Data is transferred to the Sponsor's nominated laboratory and tested as provided for in the Protocol and all in accordance with the Protocol.

7.5 The obligations of confidentiality concerning Confidential Information, which is not Personal Data, shall survive for a period of seven (7) years following termination or expiry of this Agreement. The obligations of confidentiality of this clause 6 regarding Clinical Data which is Personal Data as defined in General Data Protection Legislation, shall remain in full force and effect after termination or expiry of this Agreement.

7.6 The Parties obligations concerning Personal Data processed in the scope of the Agreement are set out in summary in **Exhibit C**.

7.7 Disclosure of Confidential Information

a) Each Party shall use the other Party's Confidential Information only in the conduct of the Trial and shall return to the Disclosing Party all written Confidential Information at the request of the Disclosing Party.

b) Neither Party shall disclose Confidential Information to any third party not involved with the Trial, without prior written consent of the other Party, and shall take all reasonable precautions to prevent the disclosure of Confidential Information to third parties. In the event that Confidential Information is required to be disclosed to a third party to allow the performance of the Trial then the Party disclosing the information to the third party will ensure that said third party are bound by terms of confidentiality no less stringent than those contained herein and will at all times remain liable for the use made by the third party of the Confidential Information.

7.8 The provisions of Section 7.1 do not apply to any Confidential Information which:

a) the Receiving Party can demonstrate by written records was known to the Receiving Party prior to receiving that Confidential Information either directly or indirectly from the Disclosing Party;

b) is generally known to the public or which becomes generally known to the public through no act or omission on the part of the Receiving Party; or

c) is lawfully obtained by the Receiving Party from sources independent of the Disclosing Party and who, to the best of their knowledge after due inquiry, have a lawful right to disclose such Confidential Information.

7.9 Specifically authorized is the disclosure of Confidential Information:

a) under obligation of law, regulation or court order, provided the information disclosed is necessary to comply with legal requirements, and confidentiality is maintained to other third parties;

b) to the EC/IRB, Trial Authority and representatives of the health-care inspectorate or a medicines evaluation board;

c) as part of publication of the results of the Trial based on Trial Data, subject to the provisions of section "confidential agreement" of this Agreement, regarding publications and disseminations of results.

8. PUBLICATION

8.1 The Sponsor will be responsible for preparing the analysed outcomes of the Trial for first formal publication (the 'Results'). In doing so and where necessary the Authorised Organization will, where required, procure the investigators and staff at the Trial Sites to ensure that contributing to Trial Data, analyses and comments, are made available in a timely manner and in doing so it shall be coordinated by SPONSOR. First formal publication of the Results being as described in the Protocol.

8.2 Authorized Organization will, and will oblige Principal Investigator and other Trial Staff and each Participating Site (if applicable) to, comply with the provisions of this paragraph. Authorized Organization agrees that the first publication of the Results of this Trial shall be made in conjunction with the presentation of a joint, multi-center publication of the Trial Results. with the investigators and the Organizations from all the Country's Trial Sites across the contributing to Data, analyses and comments, and coordinated by SPONSOR, as described in the Protocol, unless otherwise agreed by Parties. The results of the final analysis as well as all analyses that deal with the primary and secondary endpoints listed in the Protocol will be initiated and/or authorized by SPONSOR.

8.3 After Trial has completed at all the County's Trial Sites and all Trial Data has been received by the Sponsor and following on from the multi-site publication then if the Authorised Organization and/or any Country's Trial site wishes to make further publication in relation to results from Trial, then any such further publication shall be subject to the following notice requirements.

a) The Authorised Organization and/or any of the Country's Trial Site shall send the Sponsor a draft of all intended publications in advance of publication for the Sponsor to review for the possible inclusion of any of its Confidential Information. The Sponsor shall have sixty (60) days, after the receipt of the draft to request in writing the delay or amendment of such proposed publication on the grounds that there is subject matter which needs patent protection or similar protection or to prevent publication of any Confidential Information of the Sponsor failing which, without comment after the expiry of this period, the Authorised Organization will be free to publish.

b) The Sponsor may request the Authorised Organization to refrain from publishing for a maximum of six months in order to allow for application for patent protection in the name and at the cost of the relevant owner of any Inventions, counting from the day the review-period started.

c) The Authorised Organization shall require the Country's Trial Sites to provide a copy of all publications and publicity communications related to the Trial to be sent to the Sponsor.

8.4 The contributions of either Party shall be credited in all publications and communications related to the Trial and authorship determined in accordance with the Protocol.

8.5 At least one author from the Authorized Organization shall be cited in all Trial-related publications, as well as an acknowledgement for the Authorized Organization.

9. PUBLICITY

9.1 Neither Party shall use the logo or name of the other Party, nor of any member of the its Staff, for promotional purposes or in any publicity without the prior written approval of an authorised representative of that Party, such approval not to be unreasonably withheld.

9.2 Notwithstanding the abovementioned, Parties may use the other Party's name however, if required for transparency purposes and to comply with laws or regulations.

9.3 Notwithstanding the foregoing, Authorised Organization logos shall be placed on all Trial-related documents (such as, ICF, reports, etc.) for use in the Country of the Authorised Organization.

10. INDEMNIFICATION AND LIMITATION OF LIABILITY

10.1 The Authorized Organization is responsible for obtaining clinical trials insurance and for ensuring that Trial Sites in Country of the Authorised Organisation will obtain insurance cover or arranging appropriate indemnification, as required by applicable regulatory requirements, including Article 3 (2f) of the European directive 2001/20/EC for claims arising due to their responsibilities as detailed in **Exhibit B**, and shall provide evidence of the same to the Sponsor upon request.

10.2 The Authorized Organization hereby indemnifies the SPONSOR in respect of the negligent failure on the part of the Authorised Organisation in relation to the Authorised Organisation's responsibilities as set out in Exhibit B and this Agreement and in accordance with Clause 10.6, including where the same has been caused by the negligent failure and/or negligent act and/or negligent omission, on the part of a Participating Site, including the clinical negligence at a Participating Site.

10.3 The SPONSOR has in place insurance to cover its responsibilities as Sponsor as set out in **Exhibit B** and as provided for at Clause 10.6 and shall provide evidence of the same to the Authorized Organization upon request.

10.4 Authorized Organization shall assure that each of the Country's Trial Sites provides an indemnity or compensation in the event of injury or death to a Trial Participant attributable to the part of the Trial conducted by each of the Country's Participating Site.

10.5 Authorized Organization hereby confirms that it will arrange the mandatory insurance as is required by applicable law for all the Country's Trial Sites to conduct the Trial and to enable them to conduct their respective roles and responsibilities as is required by this Agreement without undue delay after executing this Agreement before the Trial starts. In the event that there are any changes to the mandatory insurance arrangements, then the Authorised Organisation shall ensure that the Authorised Organisation and all and any of the Country's Trial Sites are covered under any amended relevant government scheme, or such other competent insurance scheme which covers all of their respective liabilities in the performance of the Trial and the obligations as set out in this Agreement.

10.6 SPONSOR shall indemnify, defend and hold harmless Authorized Organization, its agents, officers, and employees from any and all liability, loss, including attorney's fees, or damage it may suffer as the result of claims, demands, costs or judgments against it which arise from or are connected with:

a) the negligence or willful misconduct on the part of the Sponsor, its agents, officers, employees; or

b) a breach of this Agreement, or any applicable law, by Sponsor or its employees, its agent's officers.

10.7 Authorized Organization shall indemnify, defend and hold harmless SPONSOR and Investigator Coordinators from any and all liability, loss, including attorney's fees, or damage they may suffer as the result of claims, demands, costs or judgments against them which arise from or are connected with:

a) injury or death to a Trial Patient treated without respecting the Protocol by a Participating Site, Authorized Organization or injury or death to a Trial Participant treated without respecting the Protocol pursuant to any agreement entered in to by the Authorized Organization with its Country's Trial Sites.

a) negligence or willful misconduct on the part of the Authorized Organization, its agents, officers, employees, or Authorized Organization Investigator, or on the part of the `Country's Trial Sites, its agents, officers, staff and/or employees; or

b) a breach of this Agreement, the Protocol, the SOPs, any reasonable written instructions from SPONSOR or any applicable law, by Authorized Organization or Authorized Organization Trial Staff and/or the Country's Trial Sites, its agents, officers, staff and/or employees.

10.8 Nothing in this Clause 10 shall operate so as to restrict or exclude the liability of a Party in relation to death or personal injury caused by the negligence of that Party or its servants, agents or employees or appointed third parties or to restrict or

exclude any other liability of either Party which cannot be so restricted or excluded in law.

10.9 Conditions for Indemnification

Each Party's agreement to indemnify, defend and hold the other harmless is conditioned on the indemnified Party:

a) providing written notice to the indemnifying party of any claim, demand or action arising out of the indemnified activities within fifteen (15) days after the indemnified party has knowledge of such claim, demand or action;

b) permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend against any such claim, demand or action

c) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation of, preparation for and defense of any such claim, demand or action; and

d) not compromising or settling such claim, demand or action without the indemnifying party's written consent.

10.10 Limited Warranty and Disclaimer:

It is understood that the Trial Drug as provided for in the Protocol is part of a programme of research, which is in itself experimental in nature. SPONSOR makes no representation of any kind, express or implied, regarding the safety or efficacy with respect to the Trial Drug and/or the Protocol.

11. TERM AND TERMINATION

11.1 The term of this Agreement shall commence on the date upon which this Agreement is executed by both Parties and shall remain in effect, for the duration of the Trial, unless terminated in accordance with 11.2. The term may be extended by a written amendment to the Agreement signed by both Parties.

11.2 Termination

a) By SPONSOR: SPONSOR may terminate this Agreement upon thirty (30) days written notice in cases listed in point c), unless termination is required to be immediate due to serious adverse reactions as provided for in the Protocol and such reactions represent an unreasonable and significant risk to Trial Patients, and which requires the immediate termination. (except if patient not yet enrolled); or where the Sponsor identifies a serious breach of GCP at the Authorized Organization and/or at one of the Trial Sites.

b) By Authorized Organization: Authorized Organization may terminate this Agreement upon thirty (30) days written notice in cases listed in point c), unless termination is required to be immediate due to serious adverse reactions as provided for in the Protocol and such reactions represent an unreasonable and significant risk to the Trial Patients, which requires an immediate termination. (except if the patient is not yet enrolled)

c) Each Party may terminate this Agreement upon thirty, (30) days' written notice to the other party in the following events, only:

i) if one of the Parties is dissolved;

ii) if one of the Parties becomes or is declared insolvent or a petition in bankruptcy has been filed against it;

iii) if the purpose of the Trial, as confirmed by the IRB/EC, becomes obsolete;

iv) if, through no fault of a Party, the Trial does not receive official approval from the EC/IRB or Trial Authorities, or this approval is permanently revoked;

v) if the Trial ceases to be in the interests of the health of the Trial Patients as determined by the EC/IRB or Trial Authority;

vi) any material breach of or failure to comply with any of the terms or conditions of this Agreement or Protocol or breach of GCP by the other Party, which breach or failure, if capable of remedy, is not remedied within thirty (30) days after notice from the aggrieved Party demanding such remedy, and provided the termination is in reasonable proportion to a termination for such cause;

vii) if, for reasons beyond a Party's reasonable control, the performance of the obligations under this Agreement, reasonably can no longer be demanded from that Party.

11.3 Payment upon Termination

Subject to section 6 of this Agreement, if SPONSOR terminates this Agreement prior to its originally planned completion point, SPONSOR will not be liable to compensate Authorized Organization or any of the Country's Trial Sites for any monies not received or paid pursuant to any agreements entered into by the Authorized Organization with the Country's Trial Sites.

11.4 Survival

Clauses 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 and its Exhibits shall remain in full force and effect upon termination or completion of this Agreement without regard to whether the Parties have fully performed their obligations under this Agreement, and, as the case may be, during a time period mentioned in each respective section. Nothing in this Agreement shall prevent a Party from being able to rely on any wording, sentence, provision and/or Clause in order to assist a Party in giving interpretation, meaning and context or where there is a need to rely on the same in order to resolve any dispute between the Parties and/ or matter which is required to be resolved between the Parties.

12. MISCELLANEOUS

12.1 General Terms

a) This Agreement, including those documents attached hereto as Exhibits or referenced herein, constitutes the entire understanding of SPONSOR and Authorized Organization.

b) In the event of any inconsistency between the terms of this Agreement and the terms of any Exhibit attached hereto such as the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Trial and the treatment of Patients in connection therewith; in all other respects, the terms of this Agreement shall prevail.

c) No changes, amendments, or alterations shall be effective, unless in writing and signed by both Parties.

d) If for any reason a court of competent jurisdiction finds any provision of this Agreement, or portion thereof, to be unenforceable, that provision of this Agreement shall be enforced to the maximum extent permissible so as to affect the intent of the parties, and the remainder of this Agreement shall continue in full force and effect.

e) Failure by either Party to enforce any provision of this Agreement shall not be deemed a waiver of future enforcement of that or any other provision.

f) In case Authorized Organization uses a translated native language version of documents for the Trial and/or of this Agreement, this English language version Agreement shall remain the working document and the terms of this English language Agreement shall prevail over the translated documents.

12.2 Governing Law

a) This Agreement recognizes that the Trial at the Authorized Organization and at the Country's Trial Sites and the regulatory set up and approval of the Trial in in the Country of the Authorized Organization shall be regulated in accordance with the regulations and approvals as granted in respect of the Trial as are required to conduct the Trial in the Country of Authorized Organization.

b) This Agreement also recognizes that the obligations upon the Sponsor and/or the CTR as set out in this Agreement and its Exhibits, which are governed by the laws and regulations of England and Wales.

c) Subject to 12.2 a) and 12.2 b) the above, the Parties recognize that in the event of any dispute relating to the construction of this Agreement it shall be exclusively governed by the laws and Courts of the Sponsor, excluding its conflicts of laws rules.

d) The Parties shall at all times act in good faith towards each other and in the event of a dispute arising under this Agreement, the Parties shall use all means and efforts to resolve the dispute amicably as between themselves and in doing so, shall endeavor to take such actions to mitigate the effects of the dispute and in doing so, shall also seek referral of the dispute to management level within their respective organisations, in order to seek resolution of the same.

e) If it transpires the dispute cannot be resolved nor a remedy found as between the Parties, then the Parties agree that nothing in this Agreement shall prevent either Party from applying to have the matter in dispute heard before Court of competent jurisdiction. Subject to the applicability of laws and regulations governing this Agreement as referred to above at 12.2.a) and 12.2b) and 12.2c), the potential defendant can apply to the Court upon application for the matter in dispute to be heard under the Jurisdictional Court of the Defendant. Alternatively, in the event it is prudent and effective both as to time and cost and given the nature of the dispute, the Parties can agree for the matter in dispute to be heard by a Mediator or an Arbitrator.

12.3 Notice

Any notice required to be given under this Agreement shall be sent to the other Party by certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties as set forth below, and shall be deemed given as of its date of receipt, which shall be no later than five (5) days after the date of postmark. Notice shall be given to each Party at the address set forth below, or such address a Party may indicate:

To SPONSOR:
[redacted]
Attn. SPONSOR Acting Head of Research Integrity, Governance and Ethics
Cardiff University, 30-36 Newport Road, Cardiff, CF24 0DE

Email [redacted]

Notices to CTR
Email address: [redacted]

To Authorized Organization:
University Hospital Brno
Attn. Director
Jihlavska 20, 625 00 Brno, Czech Republic

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12.4 Relationship of the Parties

a) Neither Authorized Organization nor the National Coordinating Investigator nor any Participating Site, or its agents, staff, or employees shall be deemed an agent or employee of SPONSOR, and in no instance do they have the authority to bind SPONSOR.

b) As an independent contractor, neither Authorized Organization National Coordinating Investigator, nor any associated staff at the Country's Trial Sites performing the Protocol shall participate in any SPONSOR employee benefit plans nor receive any other compensation.

12.5 Assignment

This Agreement shall not be assignable in whole or in part by either Party. Delegation of roles and responsibilities by the Sponsor to the Authorized Organization are agreed to be as set out in Schedule Exhibit B to this Agreement.

IN WITNESS WHEREOF, Parties have executed this Agreement by their respective officers hereto duly authorized on the day and year hereinafter written.

SPO

By:__[redacted]

Print

Title: Director, Research & Innovation Services

Date: 18th March 2021

Authorized Organization:

By:_____

Print Name: prof. MUDr. Jaroslav Štěrba, Ph.D.

Title: Director

Date: _____

APPENDICES:

EXHIBITA: PROTOCOL

EXHIBIT B: TASK LIST TABLE Delegation of Roles and Responsibilities between SPONSOR/Authorized Organization

EXHIBIT C: Data Protection Requirements

EXHIBIT D: Payment Schedule

EXHIBIT A
PROTOCOL

EXHIBIT B:
TABLE OF DELEGATED ROLES AND RESPONSIBILITIES

Exhibit B

[redacted]

R: main responsible party for the task
r: review of the document prepared by the main responsible party
S: supporting the main responsible party for the task
T: task subcontracted to a third party

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
I	[redacted]				
1					
2					
3					
4					
5					
II					
1					
2					
3					
4					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
5	[redacted]				
6					
7					
8					
III					
1					
2					
3					
4					
5					
6					
IV					
1					
2					
3					
4					
V					
1					
2					
3					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
4	[redacted]				
5					
6					
7					
8					
9					
VI					
1					
2					
3					
VII					
1					
2					
3					
4					
VIII					
1					
2					
3					
4					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
5	[redacted]				
6					
7					
8					
9					
10					
IX					
1					
2					
3					
4					
5					
X					
1					
2					
3					
4					
5					
6					
7					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
XI	[redacted]				
1					
2					
3					
4					
5					
6					
7					
8					
XII					
1					
2					
3					
4					
5					
6					
7					
8					
XIII					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
1	[redacted]				
2					
3					
4					
5					
6					
XIV					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
15	[redacted]				
16					
17					
18					
19					
20					
21					
XV					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
XVI	[redacted]				
1					
2					
3					
4					
5					
6					
XVII					
1					
XX					
1					
2					
3					
4					
5					
6					
7					
8					
9					
XXI					
1					
2					

	Activity	Cardiff University (Sponsor)	CTR	COUNTRY'S National Lead Organisation FN Brno [redacted]	Sites
3	[redacted]				
4					
5					
6					
XXII					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
XXIII					
1					
2					

	Activity	Cardiff University (Sponsor)	CTR	**COUNTRY'S National Lead Organisation** FN Brno [redacted]	Sites
3	[redacted]				

EXHIBIT C: DATA PROTECTION

1. Participant Confidentiality

1.1. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to Trial Patients.

2. Data Processing Terms

2.1. For the purposes of the Data Protection Legislation, Cardiff University ("the Sponsor") is the Controller. The Authorized Organization and the Country's Trial Sites are the Sponsor's Processors in relation to all Processing of Personal Data carried out for the purpose of the Trial.

2.2. In the event where UK should be considered as a "Third Country" within the meaning of GDPR, the Sponsor has to designate a Representative of the Controller inside the EU, which cannot be the Authorized Organization. The Sponsor informs the Authorized Organization of the Representative.

2.3. The Parties acknowledge that whereas the Sponsor is the Controller in accordance with Clause 2.1, Country's Trial Sites are the Controller of the Personal Data collected for the purpose of providing clinical care to the Trial Participants. This Personal Data may be the same Personal Data, collected transparently and processed for research and for care purposes under the separate Controllerships of the Sponsor and the Country's Trial Sites.

2.4. The Sponsor ensures to comply with all local regulation applicable to it as Data Controller.

2.5. Where the Authorized Organization and/or the Country's Trial Sites are the Sponsor's Processor and thus where the processing is undertaken by the Authorized Organization or by the Country's Trial Sites on behalf of the Sponsor for the purposes of the Trial, Clauses 2.4 to 2.8 below will apply. For the avoidance of doubt, such clauses do not apply where Authorized Organization's Country's Trial Sites are processing the Trial Participant's clinical Personal Data as a Controller.

2.6. The Authorized Organization agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the Trial and to ensure the Sponsor's compliance with the Data Protection Legislation for its conduct in the Country of the Authorized Organization;

2.7. The Authorized Organization shall procure that the Country's Trial Sites comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:

2.7.1. to implement and maintain appropriate technical and organizational security measures sufficient to comply at least with the obligations imposed on the Controller by Article 28(1);

2.7.2. to not engage another Processor without the prior written authorization of the Sponsor (Article 28(2));

2.7.3. to Process the Personal Data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Authorized Organization (where applicable) shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a));

2.7.4. to ensure that personnel authorized to process Personal Data are under confidentiality obligations (Article 28(3b));

2.7.5. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

2.7.6. to respect the conditions described in Article 28(2) and (4) for engaging another Processor (Article 28(3d));

2.7.7. to, taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organizational measures, insofar as this is possible, to respond to requests for exercising Trial Patients' rights (Article 28(3e));

2.7.8. to assist the Controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the Processing and the information available to (Article 28(3f));

2.7.9. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Authorized Organization and/or the Country's Trial Sites as Controller for the purpose of clinical care or other legal purposes;

2.7.10. to maintain a record of processing activities as required by Article 30(2) GDPR.

2.8. The Authorized Organization shall ensure and procure that the Country's Trial Sites shall ensure that:

2.8.1. its agents do not process Personal Data except in accordance with this Agreement (and in particular the Protocol);

2.8.2. it takes all reasonable steps to ensure the reliability and integrity of any of its Agents who have access to the Personal Data and ensure they:

2.8.2.1. are aware and comply with the Participating Site's duties under this clause;

2.8.2.2. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

2.8.2.3. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

2.9. The Authorized Organization agrees to and shall procure that the Countries Trial Sites agree to:

2.9.1. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Authorized Organization's or as appropriate the Participating Site's compliance with the obligations described by this Agreement, Data Protection Legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the Authorized Organization and/or the Country's Trial Sites and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

2.9.2. obtain prior agreement of the Sponsor to store or Process Personal Data outside the European Economic Area.

2.10. Where the Authorized Organization stores or otherwise Processes Personal Data outside of the European Economic Area as the Sponsor's Processor, it warrants that it does so in compliance with the Data Protection Legislation.

Data Protection Particulars

The subject matter and duration of the Processing	Collection and processing of data for research purposes to inform, analyse Trial Data and assess results of Trial outcomes, prepare publications and inform further research and potentially direct clinical outcomes and inform potential secondary research options before data is archived
The nature and purpose of the Processing	Delivering the Trial including analysis of Trial Data for Trial end points, preparation of analysed data in the form of published results and conducting/supporting secondary research using Trial Data. Data will be processed on the basis of the legitimate interest (GDPR art. 6.1.f) for the conduct of scientific research (GPDR art. 9.2.j).

The type of Personal Data being Processed	Clinical trial participant data, including medical and personal data Professionals involved in Research Data.
The categories of Data Subjects	Clinical Trial Participants recruited through the identified and appointed by the Authorized Organization's Country's Trial Sites

EXHIBIT D: Payment Schedule

The parties agree that the EURO equivalent of [redacted] per randomized patient will be provided by the Sponsor to the Authorised Organisation, whose payee details are shown below. In order to support the Authorised Organisation in opening the trial in the Czech Republic, the following payment schedule has been agreed:

Deliverable	Payment (in GBP £)	Cumulative (GBP £)
[redacted]		

Further payments may be made at the rate of the Euro equivalent of [redacted] for every 3 patients randomized in Czech Rep.

Payments to the Authorized Organization will be made based on invoice, and the invoice will include full details of Sponsor's required payment details. Invoice will be issued by the Authorized Organization within 15 days of receipt of calculation prepared by the Sponsor, responsible person [redacted]. Date of receipt of the calculation is also date of taxable supply. The Sponsor is obliged to consistently indicate the variable symbol (invoice number) for each payment, when it is paid from abroad; it will be included in the report for the beneficiary.

Bank charges: SHA (shared) – the payer pays the fees of the payer´s bank, the payee pays the fees of the beneficiary´s bank, Intermediary banks.

In case the Sponsor does not observe the invoice maturity (45 days) the Institution is authorized to charge statutory interest on late payments.

Payee Details

Payee	Payee Details
Protocol Number	[redacted]
Site Number	
Payee Name	Fakultní nemocnice Brno
Payee Address	Jihlavská 20
City- Město	Brno
Postal Code	625 00
Country	Czech Republic
Payee Contact	[redacted]
Payee Contact Phone Number	
Remittance E-mail Address	
Tax ID (VAT/GST Registration/TIN/SSN) - DIČ	CZ65269705
Bank Account Holder Name	Fakultni nemocnice Brno
Bank Account Number	71234621
IBAN (International Bank Account Number) - IBAN	CZ3407100000000071234621
Bank Name	Česká národní banka
Bank Number	0710
Bank Identification Code –SWIFT Code	CNBACZPP
Bank Type	
Variable symbol	Invoice number

Invoices

Itemized invoices to be sent to the following address:
Cardiff University
Accounts Payable
8th Floor, McKenzie House
30-36 Newport Road
CF24 0DE
CARDIFF
United Kingdom
Registered VAT Number: GB615860927