# Data Processing Agreement (Commercial Clinical Trials and/or Clinical Investigations)

**Between**

[**INSERT** NAME OF PARTICIPATING ORGANISATION and ADDRESS OF PARTICIPATING ORGANISATION]

“**Participating Organisation**”

AND

[**INSERT** NAME OF SPONSOR AND REGISTERED ADDRESS OF SPONSOR]

“**Sponsor**”

Each of which shall be a “**Party**” and collectively the “**Parties**”

# Data Processing Agreement (Commercial Clinical Trials and/or Clinical Investigations)

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**Whereas**

1. The Sponsor is a pharmaceutical/medical device/technology company involved in the research, development, manufacture and sale of medicines/medical technologies/devices for use in humans;
2. The Participating Organisation is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare;
3. The Sponsor has previously contracted with the Participating Organisation to undertake the Clinical Trial(s) and/or Clinical Investigation(s) listed in Appendix 1;
4. As the Participating Organisation is a Processor of the Sponsor of Personal Data for the purpose of the Clinical Trial(s) and/or Clinical Investigation(s), the Sponsor intends to govern this Processing through this Agreement, in addition to existing contracting and in compliance with its obligations as a Controller under GDPR Article 28 (3);
5. References throughout this Agreement to Sponsor shall be construed to include reference to XXXX, as Affiliate empowered by the Sponsor to legally bind the Sponsor to this Agreement and to act on its behalf, in accordance with Appendix 2;
6. Where the Participating Organisation is an HSC organisation in Northern Ireland, references throughout this document to the NHS should be construed to include NHS/HSC as applicable.

It is therefore, agreed that the following terms and conditions shall apply to the Processing of Personal Data by the Participating Organisation for the purpose of the Clinical Trial(s) and/or Clinical Investigation(s) (as further defined below):

## Definitions

* 1. In this Agreement, the following words shall have the following meanings:
* **Agreement**
means this Agreement comprising its clauses, schedules and any appendices attached to it and any amendments made thereto in accordance with Clause 5.2;
* **Clinical Investigation(s)**means the investigation(s) listed at Appendix 1, to be or being conducted at the Site/s in accordance with the Clinical Investigation Plan(s), including Clinical Investigations that have closed to recruitment and follow-up but for which the Participating Organisation is still Processing (including storing) Personal Data in accordance with the instructions of the Sponsor;
* **Clinical Investigation Plan**means the document that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the Clinical Investigation together with any amendments thereof made in accordance with the agreement between the Sponsor and Participating Organisation governing that (those) Clinical Investigation(s), and incorporated into this Agreement by reference;
* **Clinical Trial(s)**
means the investigation(s) listed at Appendix 1, to be or being conducted at the Site(s) in accordance with the Protocol/s, including Clinical Trials that have closed to recruitment and follow-up but for which the Participating Organisation is still Processing (including storing) Personal Data in accordance with the instructions of the Sponsor;
* **Clinical Trial/Investigation Subject**
means a person enrolled to participate in the Clinical Trial(s)/Clinical Investigation(s) according to criteria detailed in the Protocol/Clinical Investigation Plan;
* **Controller**
shall have the meaning set out in the Data Protection Laws and Guidance;
* **Data Protection Laws and Guidance**means the GDPR, the Data Protection Act 2018, the Privacy and Electronic Communications (EC Directive) Regulations 2003, as well as any legally enforceable NHS requirements, Codes of Practice or Guidance issued by the Information Commissioner’s Office, in each case in force from time to time in England, Northern Ireland, Scotland and/or Wales; and, pending a favourable decision from the competent authorities of the EU on the adequacy of the UK data protection regime will include the requirements set out or referenced in Part Three, Title VII, Article 71(1) of the Withdrawal Agreement signed by the UK and the EU in December 2019;
* **Data Subject**
shall have the meaning set out in the Data Protection Laws and Guidance;
* **EEA**
means the European Economic Area comprising the countries of the European Union as well as Iceland, Liechtenstein and Norway;
* **Effective Date**means the date on which the final signature is placed on this Agreement;
* **Personal Data**
means any and all information, data and material of any nature received or obtained by any Party in connection with this Agreement which is personal data as defined in the Data Protection Laws and Guidance and which relates to a Clinical Trial/Investigation Subject (or potential Clinical Trial Subject) and/or their treatment or medical history;
* **Personal Data Breach**means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored or otherwise Processed;
* **Personnel**
means the persons who will undertake the conduct of the Clinical Trial(s)/ Clinical Investigation(s) at the Site(s) on behalf of the Participating Organisation under the supervision of the Principal Investigator;
* **Process**shall have the meaning set out in the Data Protection Laws and Guidance (and “Processing” and “Processed” shall be construed accordingly);
* **Processor**shall have the meaning set out in the Data Protection Laws and Guidance;
* **Principal Investigator**means the person(s) who will take primary responsibility for the conduct of the Clinical Trial(s) or Clinical Investigation(s) at the Site(s) on behalf of the Participating Organisation;
* **Protocol**
means the full description of the Clinical Trial(s) together with any amendments thereof made in accordance with the agreement between the Sponsor and Participating Organisation governing that (those) Clinical Trial(s), and incorporated into this Agreement by reference;
* **Pseudonymised Data**means individual-level data relating to a natural person (as opposed to aggregated data) who is made no longer identified or identifiable from that data by virtue of the replacement of personal identifiers with a code, or equivalent, and which is safeguarded as non-identifiable in accordance with this Agreement;
* **Site**means the physical location(s) where the Clinical Trial(s) and/or Clinical Investigation(s) will be conducted, under the primary responsibility of the Principal Investigator(s), within the Participating Organisation;
* **Site Trial Completion**
means the conclusion of all Protocol / Clinical Investigation Plan required activities for all enrolled Clinical Trial/Investigation Subjects at the Site;
* **Sub-Investigator**
means any individual member of Personnel designated and supervised by the Principal Investigator at the Site to perform Clinical Trial / Investigation related procedures and/or to make important Clinical Trial / Investigation related decisions;
	1. As the mutual exchange of obligations and promises is regarded as consideration, this Agreement forms a legally binding contract.
	2. Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.
	3. The headings to clauses are inserted for convenience only and shall not affect the interpretation or construction of this Agreement.
	4. Where appropriate, words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders.
	5. A reference to this Agreement or to any other agreement or document referred to in this Agreement is a reference to this Agreement or such other agreement or document as amended, varied or novated (in each case other than in breach of the provisions of this Agreement) from time to time.

## Data Protection

* 1. The Parties agree:
		1. To comply with all Data Protection Laws and Guidance in Processing the Personal Data of Clinical Trial/Investigation Subjects. This Agreement is in addition to and does not replace, relieve or remove a Party’s obligations or rights under the Data Protection Laws and Guidance.
		2. When one Party is Processing Personal Data, as Controller, for which the other Party is at that time a separate and independent Controller, to promptly and without undue delay, notify and inform that other Party in the event of any Personal Data Breach that relates to that Personal Data.
	2. **Processing of Clinical Trial/Investigation Subject Personal Data**
		1. For the purpose of the Data Protection Laws and Guidance, the Sponsor is the Controller and the Participating Organisation is the Processor of Personal Data Processed for the purpose of the Clinical Trial(s)/ Investigation(s).
		2. The Participating Organisation’s Processing of Personal Data, as a Processor of the Sponsor, shall be governed by this Agreement, including the Protocol(s)/Clinical Investigation Plan(s), which sets out the subject matter, duration, nature and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of the Sponsor as Controller.
		3. The Participating Organisation is the Controller of Personal Data Processed for purposes other than the Clinical Trial/Investigation, e.g. the provision of medical care.
		4. The Participating Organisation, in its role as Processor of the Personal Data under Clause 2.2.1, agrees to only Process Personal Data for and on behalf of the Sponsor in accordance with the documented instructions of the Sponsor, including with regard to transfers of personal data to a third country or an international organisation. If the Participating Organisation is required by law to otherwise Process the Personal Data, the Participating Organisation shall notify the Sponsor before undertaking the Processing, unless such notification is prohibited on important grounds of public interest in accordance with GDPR Article 28(3)(a). In the case of such prohibition, the Participating Organisation shall notify the Sponsor as soon as possible once the prohibition is lifted, if it is lifted.
		5. The Participating Organisation agrees to comply with the obligations applicable to Processors described by Article 28 of the GDPR, as well as those additional obligations required by the Sponsor pursuant to this Agreement, including but not limited to the following:
			1. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems, in keeping with its obligations as an NHS organisation, thereby providing guarantee to the Sponsor pursuant to GDPR Article 28(1);
			2. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality (Article 28(3)(b));
			3. taking all measures required by GDPR Article 32 in relation to the security of Processing (GDPR Article 28(3)(c));
			4. subject to Clause 2.2.6 complying with the conditions described in GDPR Article 28(2) and (4) for engaging another Processor (GDPR Article 28(3)(d));
			5. taking into account the nature of the Processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects’ rights (GDPR Article 28(3)(e));
			6. assisting the Controller, to ensure compliance with the obligations pursuant to GDPR Articles 32 to 36, taking into account the nature of the Processing and the information available to the Participating Organisation (GDPR Article 28(3)(f));
			7. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR Article 30(2);
			8. in the event of any Personal Data Breach by the Participating Organisation as a Processor of the Sponsor, the Participating Organisation shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [**insert**]; (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without Sponsor’s prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor.
		6. In furtherance of its obligations under Article 28 GDPR, the Participating Organisation agrees that it will not engage another Processor for the purpose of the Clinical Trial without the prior written authorisation of the Sponsor (GDPR Article 28(2)), excepting where that other Processor is a Participant Identification Centre (PIC), in which case Clause 2.2.6 (a) shall apply:
			1. In accordance with GDPR Article 28(2), the Participating Organisation may appoint PICs, on the basis of an unmodified template data processing agreement agreed in advance with the Sponsor, by notifying the Sponsor that they intend to contract the PIC. The Sponsor will be considered to have authorised this sub-processing if it does not notify the Participating Organisation to the contrary within [**INSERT NUMBER, FOR EXAMPLE, FIVE (5)**] business days.
		7. At the expiry or lapse of this Agreement, the Participating Organisation shall, at the choice of the Sponsor, destroy or return all Personal Data to the Sponsor unless there is a legal requirement for retention and storage (GDPR Article 28(3)(g)), and/or where that Personal Data is held by the Participating Organisation as Controller for its own purpose(s).
		8. The Participating Organisation will:
			1. ensure that its Personnel and the Principal Investigator, do not Process Personal Data except in accordance with the Protocol(s)/Clinical Investigation Plan(s) and this Agreement;
			2. take all reasonable steps to ensure the reliability and integrity of the Principal Investigator(s) and any of its Personnel who have access to the Personal Data and will ensure that the Principal Investigator(s) and the Personnel:
				1. are aware and comply with the Participating Organisation’s duties under this Clause 2 (Data Protection);
				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 Personal Data; and
				3. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.
		9. The Participating Organisation agrees to:
			1. Provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement, and/or, at the Sponsor’s discretion and on reasonable notice, to allow the Sponsor, or a third party appointed by the Sponsor, to audit the Participating Organisation’s compliance with the obligations described in this Agreement, Data Protection Laws and Guidance (including but not limited to Article 28 GDPR), subject to the Sponsor, or its appointed third party, complying with all relevant health and safety and security policies of the Participating Organisation;
			2. Obtain prior written agreement of the Sponsor to Process Personal Data outside of the UK and the EEA.
		10. In addition to the Participating Organisation’s obligations under Clause 2.2.9(b), where the Participating Organisation, acting as the Sponsor’s Processor, Processes Personal Data outside of the UK and the EEA, the Participating Organisation warrants that it does so in compliance with the Data Protection Laws and Guidance.

## Term

* 1. This Agreement will commence on the Effective Date and shall remain in effect until the Participating Organisation ceases Processing Personal Data (including storage thereof) for the purpose of the Clinical Trial(s)/Investigation(s) listed at Appendix 1, or earlier termination in accordance with this Agreement.

## Termination

* 1. Either the Sponsor or the Participating Organisation (the “**Terminating Party**”) may terminate this Agreement with immediate effect at any time if the other Party or the Principal Investigator (the “**Defaulting Party**”) is:
		1. in breach of any of the Defaulting Party’s obligations hereunder and fails to remedy such breach where it is capable of remedy within twenty-eight (28) calendar days of a written notice from the Terminating Party specifying the breach and requiring its remedy.
	2. Termination of this Agreement will be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

## Agreement and Modification

* 1. **Order of Precedence**: Should there be any inconsistency between the Protocol(s)/Clinical Investigation Plan(s), and/or other agreements in place between the Sponsor and the Participating Organisation, and the terms of this Agreement or any other document incorporated herein, the terms of the Protocol(s)/Clinical Investigation Plan(s) and/or the other agreement shall prevail to the extent of any inconsistency except insofar as the inconsistency relates to Clause 2 of this Agreement and provisions relating to Personal Data.
	2. Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.

## Miscellaneous

* 1. **Counterparts and Signatures**: This Agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement. This Agreement may be executed through the use of an electronic signature. Transmission of the executed signature page of a counterpart of this Agreement by e-mail (in PDF, JPEG or other agreed format) to the other Party shall take effect as delivery of an executed counterpart of this agreement. If transmission by e-mail is adopted, without prejudice to the validity of the Agreement thus made, each Party shall provide the others with the original of such counterpart as soon as reasonably possible thereafter. No counterpart shall be effective until each Party has executed and delivered at least one counterpart.

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| Signed for and on behalf of:[**INSERT** NAME OF SPONSOR]Signature:Title: Date: | Signed for and on behalf of:[**INSERT** NAME OF PARTICIPATING ORGANISATION]Signature:Title:Date: |

# Appendix 1: List of Clinical Trials and/or Clinical Investigations Subject to this Agreement

The Clinical Trials/Clinical Investigations listed below have previously been contracted between the Sponsor (including, where applicable, with a Contract Research Organisation) and Participating Organisation. The list may include:

* + - 1. Clinical Trial(s)/Clinical Investigation(s) that is/are actively recruiting Clinical Trial/Clinical Investigation Subjects;
			2. Clinical Trial(s)/Clinical Investigation(s) that are following-up Clinical Trial/ Clinical Investigation Subjects, as well as;
			3. Clinical Trial(s)/ Clinical Investigation(s) where the Participating Organisation is now only Processing Personal Data (including storing it) for the purpose of the Clinical Trial/Clinical Investigation.

The list may, or may not be, a comprehensive list of all such studies but only those studies listed here are governed by this Agreement. Studies not yet contracted between Sponsor and Participating Organisation should not be added to this list (the mCTA, CRO-mCTA or mCIA should be used for this contracting as appropriate, including the Data Processing terms in those agreements). Studies contracted using a GDPR Article 28(3) compliant data processing agreement (such as is formed by the 2020 and 2021 unmodified mCTA and CRO-mCTA) need not be added to this list. Sponsors may choose to propose the addition, at a later date, Clinical Trials/Clinical Investigations to this list if it has not initially listed all Clinical Trials/Clinical Investigations contracted between itself and the Participating Organisation (e.g. if the initial list includes only actively recruiting Clinical Trials/Clinical Investigations, a Sponsor might choose to propose the addition, at a later date, of older Clinical Trials/Clinical Investigations) by modifying the Agreement in accordance with Clause 5.2. This Agreement should not be modified to reflect the Participating Organisation ceasing to Process Personal Data for any one Clinical Trial/Clinical Investigation listed below, although the Agreement terminates once the Participating Organisation is no longer Processing Personal Data for any of the Clinical Trials/Clinical Investigations listed.

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| **IRAS ID** | **Sponsor Study ID (if applicable)** | **Full Title of Clinical Trial or Clinical Investigation** |
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(Please add rows as necessary).

# Appendix 2: Formal Delegation of Authority to a Corporate Affiliate of the Sponsor to Contractually Bind Sponsor – DELETE IF NOT USED

**FINAL PAGE**