**Gynecologic Cancer InterGroup (GCIG) Agreement Template**

1 of 2 originals

(short name of trial here) CLINICAL TRIAL

RESEARCH AGREEMENT FOR THE PERFORMANCE

OF AN INTERGROUP CLINICAL TRIAL

BETWEEN

( Enter Name of Legal Entity represented by or acting through- Lead group/Sponsor name here, )

AND

**( Enter Name of Legal Entity represented by or acting through - Participating GCIG group here)**

**CLINICAL TRIAL RESEARCH AGREEMENT**

**BETWEEN**

**(name of legal entity here)**, describe type of entity here and full address, hereby represented by or acting through the (**Lead GCIG Group name here** ) (name of scientific structure here if applicable),

**(hereafter referred to as “Lead Group/Sponsor”)**[*Note: Legal Entity acting on behalf of group may or not be the sponsor of the study if this is the case details should be recorded here explaining this and detailing who the sponsor of the study is]*

**AND**

**(name of legal entity here )**, describe type of entity here, and full address, hereby represented by or acting through the (**Participating GCIG Group name here**) name and address of scientific structure if applicable) (**hereafter referred to as ”Participating Group”)** [*Note: Legal Entity acting on behalf group may or not be the sponsor of the study if this is the case details should be recorded here explaining this and detailing who the sponsor of the study is ]*

each a **“Party”**, and together the **“Parties.**

**WHEREAS**

**A** Members of **(scientific structure of Participating Group )**, an association of practicing clinicians, has identified the need for medical research into (Insert type of gynecologic cancer ) and has recommended to **Participating Group** that it pursue such research.

**B** **(scientific structure of Participating Group )** has independently assessed the proposal and agrees with the recommendation. In accepting this proposal **Participating Group** has not relied on any statements or interpretations on the part of **(scientific structure of Participating Group )** but relies on its own independent assessment.

**C** Both **Participating Group** and **Lead Group/Sponsor** wish to collaborate in the conduct of an intergroup clinical trial entitled:

**”full title of the trial here”**

EUDRACT# XXXXXXXXXXX

(“the Study”)

which is to be conducted according to the  **Lead Group/Sponsor** protocol named the “short title of protocol here” protocol, hereinafter referred to as the “Protocol”.

**D Lead group/Sponsor** has access to clinical centres in XX countries and possibly other countries from which to recruit study participants and **Participating Group** has access to clinical centres in XX countries from which to recruit study participants.

**E** it is acknowledged that **(Name of Third Party/Company here)** has agreed to support the Study by providing (insert type support for e.g. Investigational Medicinal Product, analysis of translational samples etc) and that the **Lead Group/Sponsor** holds an agreement(s) with **(Name of Third Party/Company here)**  in relation to the support. *[Note: Optional Clause to be used when company/3rd party involved delete clause if not applicable]*

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## **NOW IT IS HEREBY AGREED AND DECLARED** as follows:

# Definitions and glossary

**“Adverse Event (AE)**” means any untoward medical occurrence or effect in a patient treated on a trial protocol, which does not necessarily have a casual relationship with trial treatment. An AE can therefore be any unfavourable and unintended sign (including any abnormal laboratory finding), symptom or disease temporally associated with the use of a trial treatment, whether or not related to that trial treatment;

“**Adverse Reaction (AR**)” means all untoward and unintended responses to a trial treatment related to any dose administered. A causal relationship between a trial treatment and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out;

**“Agreement”**means this agreement and all Schedules, Appendices and other documents as may be incorporated by reference;

**“Background Intellectual Property”** means Intellectual Property owned by **Participating Group** at the commencement of the Agreement, which is reasonably required by **Lead Group/Sponsor** to utilise Project Intellectual Property provided that:

1. such Background Intellectual Property is not a registered or unregistered trademark;
2. such Background Intellectual Property is not the subject of an exclusive licence to a third party or parties;

**“Biological Samples”** means any physical samples of tissue or other biological materials obtained from Trial Participants in accordance with the Protocol and the informed consent document signed by the Trial Participants, and includes any derivatives, portions, progeny or improvements, and any documentation supplied with the samples as detailed in the Protocol;

**Brexit** means the date the UK formally ceases to be a member state of the European Union;

**Brexit Trigger Events** means any of the following events caused by Brexit including but not limited to change in law, trade tariff, currency fluctuation, licence or consent or other change (including without limitation an unforeseeable change to the business or economic environment in which a Party operates)(*delete definition if not applicable – note specific to UK or contracting with UK*);

**“Chief Investigator**” means the Chief Investigator responsible for co-ordination of the Trial as defined in the Protocol;

“**Clinical Site Agreement(s**)” means the clinical site agreements between the Participating Group and their Clinical Centres which set out the rights and obligations of those parties in relation to the conduct of the Trial at the Participating Group’s Clinical Sites;

**“Clinical Trials Directive”** means European Union Clinical Trials Directive 2001/20/EC 2001 of 4th 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 together with any laws implementing the Clinical Trials Directive in the Country and any amendments thereto and including the European Union Clinical Trials Regulation (Regulation EU no 536/2014) once in effect; (*delete definition if not applicable- note specific to studies being conducted involving EU countries for -CTIMPs*)

**“Confidential Information”** means all information, data, results and Intellectual Property and Know How relating to the Trial including Trial Treatment, its/their use(s), any new indication or novel use of Trial Treatment and all information concerning arrangements contemplated by this Agreement or the business affairs of one Party that it discloses to the other Party pursuant to or in connection with this Agreement;

**“CRF”** means Case Report Form: A printed optical or electronic document designed to record all of the protocol-required information to be reported to **Lead Group/Sponsor** on each study participant;

“**Data Protection Laws”** means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the Processing of Personal Data to which a Party is subject, including the [add in country legislation if applicable] *e.g. in UK Data Protection Act 2018 ("DPA")* and the GDPR and all legislation enacted in the UK and EU in respect of the protection of personal data as well as the Privacy and Electronic Communications (EC Directive) Regulations 2003; and (b) any code of practice or guidance published by the competent data protection authority of the parties from time to time;

“**DPA”** means Data Protection Authority. DPAs are independent public authorities that supervise, through investigative and corrective powers, the application of the data protection law. They provide expert advice on data protection issues and handle complaints lodged against violations of the General Data Protection Regulation and the relevant national laws. There is one in each EU Member State.

“**DPIA**” means Data Privacy Impact Assessment. A DPIA is a process designed to help systematically analyse, identify and minimise the data protection risks of a project or plan. It is a key part of accountability obligations under General Data Protection Regulation.

“**DSUR**” means Development Safety Update Report: A comprehensive, thoughtful annual review and evaluation of pertinent safety information collected during the reporting period related to a drug under investigation, whether marketed or not by:

1. Examining whether the information obtained by the sponsor during the reporting period is in accord with the previous knowledge on the investigational drug safety.
2. Describing new safety issues that could have an impact on the protection of clinical trial subjects
3. Summarising the current understanding and management of identified and potential risk
4. Providing an update on the status of the clinical investigation/development programme and study results;*(**delete definition if non-CTIMP study or if otherwise not applicable - note DSUR EU & ICH requirement*)

**“GCIG”** means the Gynecologic Cancer InterGroup, An Organisation of International Cooperative Groups for Clinical Trials in Gynecologic Cancers, consisting of appointed representatives from international and national research groups, including (scientific structure of Lead Group/Sponsor here) and (scientific structure of participating group here), which perform clinical trials in gynaecological cancer;

**“GCP”** means Good Clinical Practice: A standard for the design, conduct, performance, monitoring, recording, analyses and reporting of clinical trials that provides assurance that the data and recorded results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected;

“**GDPR”** means General Data Protection Regulation. The General Data Protection Regulation (EU) [2016/679](https://eur-lex.europa.eu/eli/reg/2016/679/oj) (GDPR) is a [regulation](https://en.wikipedia.org/wiki/Regulation_(European_Union)) in [EU law](https://en.wikipedia.org/wiki/EU_law) on [data protection](https://en.wikipedia.org/wiki/Data_protection) and privacy in the [European Union](https://en.wikipedia.org/wiki/European_Union) (EU) and the [European Economic Area](https://en.wikipedia.org/wiki/European_Economic_Area) (EEA). It also addresses the transfer of [personal data](https://en.wikipedia.org/wiki/Personal_data) outside the EU and EEA areas;

**GMP** means Good Manufacturing Practice and refers to 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 and/or any locally equivalent laws, regulations, principles and/or guidelines in the country relating to the manufacture of clinical trial products, and any amendments thereto;

“**GSA**” means Group Specific Appendix. An appendix to the protocol which details the participation of the Participating GROUP clinical centres in the Study. The content of this appendix is applicable only to the Participating GROUP investigators, for whom the sections supersede entirely or partially the corresponding chapters in the Protocol.

**“GST”** has the same meaning as GST Law; *(delete definition if not applicable to countries participating in study*);

**“GST Law”** means “*A New Tax System (Goods and Services Tax) (delete definition if not applicable to countries participating in the study*);”

**“GST Rate”** has the meaning giving in GST Law; *(delete definition if not applicable to countries participating in the study*);

**“IDMC”** means the Independent Data Monitoring Committee**,** an independent data monitoring committee that may be established by the Lead Group/Sponsor to assess at intervals the progress of the Study, the safety data and the critical efficacy endpoints, and to recommend to the Lead Group/Sponsor whether to continue, modify or stop the Study;

**In-Scope Personal Data** means any Personal Data provided in connection with this Agreement or that is acquired, collected, generated or otherwise Processed by one party in connection with this Agreement. In-Scope Personal Data includes the following categories of data subjects and Personal Data:

Categories of data subjects

• Patients, Employees, Health Care professionals

Categories of Personal Data

• Patients – Patient Key Code identifier number, date of birth, age, ethnicity, medical records and history, samples

• Employees – name and contact details

• Health Care Professionals – name, contact details, CV, financial interest

**“Institutional Review Board/Ethics Committee”** means an independent body constituted of medical, scientific and non-scientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in the Study, among other things, reviewing, approving and providing continuing review of the (short study title here) protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the study participants;

**“Intellectual Property”** means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights;

**Investigator** means a clinician entering patients in the Trial at a Clinical Site and includes the Principal Investigators, Lead Investigators and the Chief Investigator where appropriate;

**Lead Investigator** means the authorised health care professional who takes primary responsibility for the conduct of the Trial in participating countries;

**“Participating Group Clinical Centres”** means those hospital sites in (countries XX) at which

**Participating Group** Study Participants receive treatment as part of the Study;

“**Personal Data**” as per General Data Protection Regulation **(GDPR**), “**personal data**” is any information from which a person (a data subject) can be identified or potentially identified from;

**Principal Investigator** means the Investigator responsible for the Trial at a particular Clinical Centre;

**Protocol** means the protocol for the Trial attached at Appendix 2 to this Agreement, and any Participating Group created GSA for their Participating Clinical Centres only and approved by **Lead** **Group/Sponsor** and as amended from time to time during the Trial;

**“Project Intellectual Property”** means any Intellectual Property arising from the Study;

**“RCTI”** means a Recipient Created Tax Invoice and has the meaning given in GST Law; *(delete definition if not applicable*);

**“Registrable Intellectual Property”** means Intellectual Property capable of being registered according to relevant local legislation granting monopoly rights to the registrant and includes but is not limited to patents, patentable inventions, trademarks, copyrights, circuit layouts, designs and plant breeders rights. *(delete definition if not applicable*);

**“Role and Responsibilities”** means the roles and responsibilities for the Parties hereunder and are outlined in appendix 1 of this agreement;

**“Serious Adverse Event (SAE), Serious Adverse Reaction (SAR)”** means an Adverse Event or Adverse Reaction that at any dose

* Results in death
* Is life threatening (The term “life-threatening” refers to an event in which the patient was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.)
* Requires in-patient hospitalisation or prolongs existing hospitalisation
* Results in persistent or significant disability/incapacity
* Is a congenital anomaly or birth defect
* Is otherwise medically significant (e.g. important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed above);

**“Serious Breach”** means a breach of GCP or of the Protocol which is likely to affect to a significant degree, the safety or physical or mental integrity of the Trial Subjects; or the scientific value of the Trial;

**“SPONSOR”** means an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

**“Study Drugs”** means the investigational medicinal products and includes the medicinal products under investigation, xx for this study

**Suspected Unexpected Serious Adverse Reaction “SUSAR”** means a Serious Adverse Reaction the nature or severity of which is not consistent with the reference safety information;

**“TMF**” means the Trial Master File. The TMF is a file that contains all the essential documents relating to a clinical trial, before the trial commences, during trial conduct and after the completion of trial. Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements;

**“TMG”** means the Trial Management Group**,** a group that may be established by the Lead Group/Sponsorfor reviewing the progress of the Study within all clinical centres;

**“TSC”** means Trial Steering Committee. The TSC is an oversight committee which provided supervision of the overall conduct of the trial on behalf of the funder(s) and sponsor. The TSC reviews recommendations of the IDMC and, on consideration of this information, recommends appropriate amendments/actions for the trial as necessary; *(delete definition if not applicable or modify as required. Generally the members of TSC are independent of the investigators, employing organisations, funders and sponsors of the study. it should be noted however the Chief Investigator/Lead Investigator and, if appropriate, other Trial Management Group members are an important contributor to the TSC and no major decisions would be made without their involvement*);

**By signature of the Agreement by both Parties, it is hereby agreed that:**

# Conduct of the Study

## The Study is an intergroup study in which **Lead Group/SPONSOR** is the leading group as well as the Sponsor of the Protocol where **Lead Group/SPONSOR** has delegated via **PARTICIPATING GROUP** certain ‘Sponsor responsibilities’ to **Participating Group.** Each Party shall undertake the Study as the respective entities on behalf of their clinical centres within the Study as set down in the Protocol. [*Note: this clause may need to be amended appropriately where lead group is not sponsor to clarify the sponsor has delegated certain sponsor responsibilities to the lead group and to participating group].*

## **Lead Group/SPONSOR** shall be responsible for compliance with clinical and/or regulatory procedures in (countries XX) and for their affiliated clinical centres where **Lead Group/SPONSOR** conducts the Study, and **Participating Group** shall be responsible for compliance with clinical and/or regulatory procedures in (countries YY) and for the **Participating Group** Clinical Centres. Each party will assure that each of the clinical centres for which that party has responsibility obtains all necessary local and national regulatory approvals from the relevant competent authority (ies)..

## The Study shall be conducted by **Lead Group/SPONSOR** and **Participating Group** severally under the obligations imposed on each of them respectively under the Agreement:

### In accordance with the Protocol and any amendments to the Protocol as approved by the competent (name different governing bodies here) authorities;

### In clinical centres to be selected respectively by **Lead Group/SPONSOR** and **Participating Group** in each of their jurisdictions. Clinical centres in (countries YY) shall be known as **Participating Group** Clinical Centres, the suitability of such centres ultimately subject to **Lead Group/SPONSOR** agreement;

### With study participants selected in accordance with the eligibility criteria specified in the Protocol and only after all necessary legal, regulatory or other approvals have been granted including those of the Institutional Review Board or of any ethics committee, at the clinical centres and strictly in accordance with the terms of any such approval;

### In accordance with the Declaration of Helsinki, and with the principles of Good Clinical Practice (GCP) as laid down by the ICH topic E6 (Note for Guidance on GCP), and the European Directive.

### In accordance with the requirements laid down by laws applicable in the countries where the Study is conducted.

# Duties

## **Obligations of** **LEAD GROUP/SPONSOR**

**LEAD GROUP/SPONSOR** agree that:

### **Lead Group/SPONSOR** shall be responsible for the operational management of the Study at its participating clinical centres in (countries XX);

### **Lead Group/SPONSOR** shall be responsible for the central data management of the Study, including the collection and analysis of the data and its inclusion in the study database. **Lead Group/SPONSOR** shall ensure the collected data are kept as required by GCP and GDPR (see appendices 4 and 5)and shall create a database for the Study;

### **Lead Group/SPONSOR** will be responsible for drawing up CRF completion guidelines and all other guidelines required for the proper conduct of the Study;

### **Lead Group/SPONSOR** shall process the data in accordance to the law applicable with regard to data protection and shall ensure that the Patient Information Sheet and Informed Consent models found in the Protocol contain all the required information in this regard;

### **Lead Group/SPONSOR** shall be responsible for documenting operating procedures for randomisations, either centrally (all done through **Lead Group/SPONSOR** or by participating groups.) [*Note: update clause according to set up of study for randomization or delete if NA}*

### **Lead Group/SPONSOR** shall be responsible for setting up a system of pharmacovigilance within the Study (in consultation with **Participating Group** and other participating groups) including data recording, assessment, expedited and periodic reporting to regulatory authorities, relevant ethics committees and investigators;

### **Lead Group/SPONSOR** shall provide **Participating Group** with information on the progress of the Study in clinical centres managed by both **Lead Group/SPONSOR** and **Participating Group**. Such information will be provided as 6-monthly reports including study participant accrual, eligibility status, and treatment status;

### **Lead Group/SPONSOR** is responsible to conduct all statistical analyses and shall provide **Participating Group** with a copy of the final study report within a year’s time after completion of the Study;

### Upon completion of the Study and after the final analysis, **Lead Group/SPONSOR** agrees to transfer the section of the database to **Participating group** containing **Participating Group** Clinical Centres, investigators and study participants in the agreed format;

### **Lead Group/SPONSOR** agrees to form an independent DMC to regularly and confidentially review the accumulating data. P**articipating Group** may have the opportunity to nominate at least one member to the DMC;

### **Lead Group/SPONSOR** may form a TMG which will include trial statisticians, data management staff and chief investigators from several participating GCIG Groups. The TMG will meet regularly in person or by phone to review the progress of the Study within all clinical centres including recruitment, problems with protocol compliance, unexpected toxicities and need for protocol amendments;

### **Lead Group/SPONSOR** shall ensure that clinical trial insurance to the coverage limits normally applicable to a study of this type is in place for their participation and their clinical centres participating in the Study,.**LEAD Group/SPONSOR** will also wish to ensure each **Participating Group** holds appropriate insurance cover for their participation and their Clinical Centres. Insurance shall remain in effect for the duration of the Agreement and Study, covering any liability of **Lead Group/SPONSOR, Participating Groups** and the study participants in accordance with the requirements laid down by laws applicable in the countries where the Study is conducted.

### **Lead Group/SPONSOR** may form an independent Trial Steering Committee and will consult **Participating Group** and other GCIG groups on this matter as appropriate.

### **Lead Group/SPONSOR** is responsible for setting-up and maintaining a Trial Master File (TMF). The TMF must be kept in a secure location for the duration of the study and archived after completion or premature termination of the study in a secure fire-proof facility for a minimum of xx years (*Note: length time TMF to be retained/archived will depend on national requirements of countries involved with study and sponsors requirements)*. In case of audits or inspection, **Lead Group/SPONSOR** may have to request copies of additional documentation from **Participating Group** TMF.

## **Obligations of Participating Group**

**Participating Group** agrees that:

### **Participating Group** shall be responsible for the operational management of the Study at its **Participating Group** Clinical Sites in (countries YY), as set down in the Roles and Responsibilities table of **Appendix 1**;

### **Participating Group** shall be responsible for the , collection of CRFs (if not using e-CRFs) and may be responsible for the randomization of its study participants from **Participating Group** Clinical Centres, and forwarding them to **Lead Group/SPONSOR**;

### **Participating Group** will ensure that **Participating Group** Clinical Centres understand the CRF completion guidelines, both in terms of data completeness and the timescale for completing and returning completed CRFs. **Participating Group** will perform on-site monitoring of **Participating Group** Clinical Centres as described in the monitoring plan; (this paragraph to be adjusted as appropriate),

### **Participating Group** will screen completed CRFs before forwarding them to **Lead Group/SPONSOR**, to ensure that forwarded CRFs are complete and accurate if using paper CRF;

### **Participating Group** shall ensure that its Clinical Centres inform **Lead Group/SPONSOR** of all protocol-defined Serious Adverse Events (SAEs and SUSARs) occurring at **Participating Group** Clinical Centres during the conduct of the Study, and shall report unexpected and related SAEs, per regulatory requirements, to the (enter name of authorities here) as appropriate;

### The P**articipating Group** will undertake an insurance coverage normally applicable to a study of this type for patients from Participating groups Clinical Centres. Insurance shall remain in effect for the duration of the Agreement and or Study, in accordance with laws applicable in the country where the study is conducted.[*Note – this clause should be amended accordingly in instance where lead group/sponsor takes out insurance to cover the study as whole.]*

### **Participating Group**’s Data Centre shall require clinical investigators and **Participating** **Group** Clinical Centres to handle any information provided by **Lead Group/SPONSOR** in accordance with terms equivalent to the confidentiality provisions of clause 12 of the Agreement.

### **Participating Group** is responsible for setting-up and maintaining a local version of the Trial Master File (TMF) containing documents and written communications for the management of the Study in their territory. All documents to be filed in the TMF according to GCP requirements must be clearly identifiable. The TMF must be kept in a secure location for the duration of the Study and archived after completion or premature termination of the study in a secure fire proof facility for a minimum of xx years. [N*ote: length time TMF to be retained/archived will depend on national requirements of countries involved with study and sponsors requirements*]In case of audits or inspection, **Lead Group/SPONSOR** may have to request copies of additional documentation from **Participating** **GROUP** TMF.

# Protocols and Forms

## **Lead Group/SPONSOR** will create and provide **Participating Group** withthe study CRFs, whether paper-based or electronic. **Participating Group** will be responsible for distribution of the CRFs to **Participating Group** Clinical Centres as appropriate.

## **Lead Group/SPONSOR** has ownership of the master protocol and CRFs.

## Changes to the Protocol and CRFs/eCRFs can only be made by **Lead Group/Sponsor** and after discussion with the Participating GCIG groups, the Trial Management Group (if applicable, including representatives from **Lead Group/SPONSOR** and **Participating Group**)

# Financial Support

## **Lead Group/SPONSOR** agrees to compensate **Participating Group** for their work performed on the Study per the Table 1 below:

**Table 1**

|  |  |
| --- | --- |
| **Task achieved** | **Per study participant payment in Euros** |
| For each study participant randomised but not treated (with the exception of non-eligibility) | € XXXXXX |
| For each study participant randomised, treated, monitored and CRF completed | € XXXXXX |

## **Lead Group/SPONSOR** agrees to compensate **Participating Group** according to the schedule of payments described in the Table 2 below:

**Table 2**

|  |  |
| --- | --- |
| **Milestones** | **Payment**  **in Euros** |
| Upon Intergroup Agreement finalisation and sign-off | €XXXXXX \* |
| Upon 1st dose administered to each study participant | € XXXXXX |
| Upon completion and submittal to **Lead Group/SPONSOR** of each complete study participant CRF | € XXXXX |

\* € XXXXXXX to be deducted from the total per study participant payments

## After achieving each of the milestones set out in Table 2, **Participating Group** shall notify **Lead Group/SPONSOR** and send a payment request on a quarterly basis. All payments shall be made within ninety (90) days of receipt of the payment request of **Participating Group**. No additional costs will be reimbursed.

Reference for payments to**Participating Group**:

Account number : XXXXXXX

Bank Name :

Account name holder :

IBAN :

Swift code :

Name of contact person at bank :

Payment requests shall be addressed to:

**(Lead Group/ SPONSOR NAME HERE)**

(contact person)

(address)

Tel:

Fax:

Email :

# GST (Goods and Services Tax)

6.1 If GST is payable on any supply by one party to the other party under the Agreement (including the supply of any goods, services, rights, benefits or other items) it will be specified on tax invoices issued or provided to **Lead Group/SPONSOR** by **Participating Group**. Under current GST Law…….(specify here if GST tax to be paid or not, and by whom whenever applicable)[*Delete clause if not applicable*]

# Drug Supply

[This section and clauses may be deleted if not applicable]

## **Lead Group/SPONSOR** agrees to arrange for **Participating Group** Clinical Centres to be provided with Study Drug for all study participants, to be randomised and distributed by (name of 3rd party whenever applicable). The Study Drug is defined here as (name of Study drug(s). (name of 3rd party) will provide (name of Study drug(s) directly to **Participating Group** Clinical Centres and will organise re-supply throughout the Study;

## (name of supplied Study Drug[s]) will be used solely for the purposes of the Study;

## **Participating Group** Clinical Centres will be required to provide all other medications to study participants;

## (name of 3rd party) will provide to **Participating Group** evidence of quality assurance for (name of Study drug(s);

# Indemnity

## **Participating group** shall indemnify, release and discharge **Lead Group/SPONSOR**, its agents and employees from any loss, costs, claims, demands or actions which may be made by reason of personal injury (including death) to any person, or damage to property, arising out of or in connection with liability resulting from the negligent acts or omissions of **Participating** **Group**, its agents or employees in the performance of its obligations pursuant to the Agreement;

## **Lead Group/SPONSOR** shall indemnify, release and discharge **Participating Group,** its agents and employees from any loss, costs, claims, demands or actions which may be made by reason of personal injury (including death) to any person, or damage to property, arising out of or in connection with liability resulting from the negligent acts or omissions of **Lead Group/SPONSOR**, its agents or employees in the performance of its obligations pursuant to the Agreement.

# Project Intellectual Property as Study Data

## **Lead Group** as legal sponsor will be the owner of the data generated in the course of the conduct of the study; **[**Note: *amend wording of clause accordingly if lead group is not legal sponsor]*

## After completion of the study and after the final study report, **Participating Group** will receive the dataconcerning their patients in an agreed format.

## In the event that **Lead Group/SPONSOR** wish to make available to a third party data generated from the study. Agreement will be required by all parties, e.g. **Participating Groups** and **Lead Group/SPONSOR** prior to transfer ofdata. Further to be agreed would be provision that any such transfer of data would not breach laws relating to personal or private information;

## Any invention or discovery arising from the study data which is related to the contribution of **Participating Group**, shall be the property of **Lead Group/SPONSOR**, provided such invention or discovery is directly related to the Study. Serendipitous discovery with applications not contemplated in the Study shall be subject to negotiation in good faith between **Participating Group** and **Lead Group**/**SPONSOR** regarding Registrable Intellectual Property;

# Publication

## The publication of the final report of the results of the Study shall be in accordance with the Protocol, and the Trial Steering Committee (if applicable)

*[Note: Suggested GCIG Publication Guidelines are available for reference via GCIG website ]*

## 

## **Lead Group/SPONSOR** may wish to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. **Lead Group/SPONSOR** agrees that 30 days prior to submission of publication or any other dissemination of results, **Lead Group/SPONSOR** shall invite **Participating Group** to comment on the content of the material to be published or presented. **Participating Group**shall have the opportunity to review and comment upon such submissions for an agreed period of time prior to submission for abstract, and for an agreed period of time prior to submission for manuscripts.

## **Participating group** may wish to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. **Participating group** agrees that 30 days prior to submission of publication or any other dissemination of results including oral dissemination, **participating group** shall invite **Lead Group/SPONSOR** to comment on the content of the material to be published or presented. **Lead Group/SPONSOR** shall have the opportunity to review and comment upon such submissions for an agreed period of time prior to submission for abstract, and for an agreed period of time prior to submission for manuscripts.

## **Participating grou**p shall not publish any material from their component of the Study before the primary publication of the study without prior written agreement from **Lead Group/SPONSOR** and any other parties according to contractual responsibilities.

## Following final analysis of the mature results of the Study and submission of any abstract(s), **Lead Group/SPONSOR** and **Participating Group** agree that the final paper must be submitted for publication within an agreed period of time.

# Biological Material

[*This section and clauses may be deleted when not applicable]*

## All logistics and management of tissues and human material (“Biological Material”) collected and/or used during the Study and according to the Protocol and the Informed Consent document signed by the subject is organized by **Lead Group/SPONSOR** and **Lead Group/SPONSOR** subcontractors in agreement with **participating group**.

## The **Lead Group/SPONSOR and/or TSC and /or TMG** shall have sole authority to govern all rights to access by any party to all data received from biological material. **[**Note: *amend clause to delete TSC/TMG if this is not applicable}*

## **Lead Group/SPONSOR** is responsible for ensuring the analyses of the Biological Material is performed as described in the protocol and to subcontract and cover the costs of the laboratory(ies).[Note: *This clause may need amended where participating groups will be doing analyses locally ]*

## The Biological Material will be kept at [NAME, ADDRESS] (the RECIPENT) for a minimum of 20 years in accordance with the requirements laid down by the all applicable laws, regulations and guidelines, in particular in accordance with the Declaration of Helsinki and with the principles of good clinical practice as laid down by the ICH topic E6, Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 and the European Directive on the protection of personal data. The **Lead Group/Sponsor** shall ensure that the RECIPENT shall not sell destroy or use or further distribute the Biological Material without the written consent of the **Lead Group/ SPONSOR and/or** **TSC**.

## Biological Material collected and/or used for the Study cannot be used for any purposes different from those described in the protocol and the Informed Consent document signed by the subject providing Biological Material. *[Note: In case of future additional research/analysis on biological material collected for the study other than those described in protocol it would be required for consent to have been given by study subjects to cover samples being used for additional research purposes and for approval to be given by relevant authorities – this clause may need to be amended to cover this*]..

## **Lead Group/SPONSOR** and **Participating Group** will secure that if a study subject withdraws his or her consent to allow their samples to be used any patient material of such study subject which is in **Lead Group/SPONSOR** possession is immediately destroyed and no longer used.

## It is agreed that for contributing Biological Materials to the study biobank the **Participating** **Group** shall be granted a privileged access to Biological Materials provided by study subjects from its own territories for its own research projects. Access of **Participating Group** to samples provided by other institutions will be considered by **Lead Group/SPONSOR** in good faith and according to **Lead Group/SPONSOR’s** policies on such matter. **Participating Group** shall be the exclusive owner of any data, discoveries, derivative materials and commercial products (Project IP) resulting from research projects conducted by **Participating Group** with its own samples and material.[*Note: This clause will need amended to accurately reflect the arrangement for the study in particular where there is not a study biobank. Also in instances where protocol has translational research planned using all samples there may not be option to access samples. In case of transfer of samples between groups, additional contractual arrangements would be required. It is recommended the GCIG template material transfer agreement is used.]*

# Term and Termination of the Agreement

## The Agreement shall take effect at the date of signature of the last Party thereto, and shall remain in force for the duration of the Study;

## The Agreement can, only after discussing between the Parties, be terminated by written notice in case of:

* an early termination of the Study for reasons which could include study participant safety, unsatisfactory study participant enrolment or the decision of a regulatory body;
* a material and irremediable breach by one Party of the Agreement;
* any technical or methodological impossibility to pursue the Study;

## In the event the Agreement or Study is terminated by **Lead Group/SPONSOR** during the recruitment period for any reason other than an irremediable material breach of the Agreement by **Participating Group**, **Participating Group** is entitled to recover from **Lead Group/SPONSOR** or retain from **Lead Group/SPONSOR** funding an amount reflecting the number of study participants under recruitment at the date of termination. The Parties agree to negotiate a fair commercial settlement which takes into consideration the amounts actually or irrevocably committed by **Participating Group** in relation to the Agreement or Study at the date of termination.

## Clauses XX and YYof this Agreement shall remain in force after termination of this Agreement.

# Confidentiality

## All information related to the Study shall be confidential within the participating GCIG group and none of the Parties shall disclose any information to a third party, without the prior written permission of the **Lead Group/SPONSOR** other than as required to perform the Study except if required by law. This does not apply to any information which:

* is in the public domain
* is made public by a third party acting without impropriety in doing so
* is made by investigators at clinical centres in the report of his/her activities that is requested by competent authorities
* is independently developed by the receiving Party
* is in possession of the receiving Party prior to the date of this Agreement before agreement
* is made by investigators at clinical centres or the parties in the report of his/her activities that is requested by competent authorities

# Entire Agreement

## The Agreement constitutes the entire agreement between the Parties and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing.

# Sub-contracting

## If either Party subcontracts its obligations, it shall remain responsible for the acts and omissions of its sub-contractors as if they were its own employees.

# Governing Law

## The Agreement is governed by the law applicable in the (generally name of country where Sponsor is located in) and the Parties unconditionally submit to the Courts exercising jurisdiction in (name of country where Sponsor is located in).

# No Partnership

## No servants or agents of either Party shall by virtue of the Agreement be deemed to be employees of the other Party, and nothing in the Agreement shall create a partnership between the Parties or give to a Party any rights of a Partner or subject such Party to any liabilities of a partner in relation to the other Party’s business.

# Counterparts

## The Agreement may consist of a number of counterparts, and those counterparts taken together constitute one and the same instrument.

# Form of written notice

Any written notice to be given under the terms of the Agreement shall be sent to:

**For Lead Group/SPONSOR :**

Name & address

Tel:

Email

**For Participating Group:**

Name & address

Tel:

Email

# SIGNATURE PAGE

**EXECUTED** by the Parties as an Agreement effective at the date of the last signature hereto.

Signed for and on behalf of **(**name of legal entity overseeing **Participating Group),**

by its duly authorised representative:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

name of person, title

place of business

in the presence of:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness, name and title

Name of city, date

Signed for and on behalf of (name of legal entity behind **Lead Group/SPONSOR**)**,**

by its duly authorised representative:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

name of person, title

place of business

in the presence of:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Witness, name & title

Name of city , date

# Appendix 1 – Roles and Responsibilities Checklist

**(LEAD GROUP/SPONSOR**)/**(Participating Group**) ROLES AND RESPONSIBILITIES

| GCIG HARMONISATION ROLES AND RESPONSIBILITIES CHECKLIST | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | \*Note details of roles and responsibilities for 3rd party are recorded for information purposes only. 3rd party is not party to agreement. [ This can be deleted where not applicable e.g. no 3rd parties involved.] | LEAD GROUP/ SPONSOR | (PARTICIPATING GROUP NAME HERE)  Centre | (participating group name here) Clinical  Centres | \*(3rd party) |
| 1 | PROTOCOL, Country/ Group Specific Appendices |  |  |  |  |
|  | Protocol preparation |  |  |  |  |
|  | Protocol review |  |  |  |  |
|  | Protocol printing |  |  |  |  |
|  | Protocol distribution to the groups |  |  |  |  |
|  | Preparation of country/group specific appendices |  |  |  |  |
|  | Protocol & country/group specific appendix distribution to clinical centres |  |  |  |  |
| 2 | PROTOCOL AMENDMENTS |  |  |  |  |
|  | Amendment preparation |  |  |  |  |
|  | Amendment review |  |  |  |  |
|  | Amendment printing |  |  |  |  |
|  | Amendment distribution to the groups |  |  |  |  |
|  | Amendment distribution to the clinical centres |  |  |  |  |
|  | Tracking approvals |  |  |  |  |
| 3 | CASE REPORT FORMS (CRFs) |  |  |  |  |
|  | CRF design |  |  |  |  |
|  | CRF printing |  |  |  |  |
|  | CRF distribution to groups |  |  |  |  |
|  | CRF distribution to the centres |  |  |  |  |
| 4 | PATIENT INFORMATION SHEET (PIS) AND CONSENT (IC) FORM |  |  |  |  |
|  | PIS and IC master template preparation, review and approval |  |  |  |  |
|  | Update/Amendments to PIS and IC preparation, review and approval |  |  |  |  |
|  | PIS and IC national template preparation, review and approval |  |  |  |  |
|  | PIS and IC local preparation, review and approval |  |  |  |  |
|  | Local PIS and IC translation to local language |  |  |  |  |
|  | Approval of local PIS and IC (if required by lead group) |  |  |  |  |
| 5 | HEALTH/REGULATORY AUTHORITY AND ETHICS/IRB SUBMISSION- APPROVALS/ACTIVITIES |  |  |  |  |
|  | Preparation of regulatory and ethics/IRB submissions |  |  |  |  |
|  | Submission of regulatory and ethics/IRB submissions |  |  |  |  |
|  | Preparation of amendment(s) |  |  |  |  |
|  | Submission of amendment(s) |  |  |  |  |
|  | Notification of protocol/amendment approval/refusal to SPONSOR , Participating Group and Company |  |  |  |  |
|  | Tracking of approvals |  |  |  |  |
|  | Investigator Brochure (IB) submission to RAs |  |  |  |  |
|  | Provide Electronic IB to participating groups |  |  |  |  |
|  | Forwarding updated IB’s to centres |  |  |  |  |
|  | Providing updated IBs to groups |  |  |  |  |
|  | Tracking proof of submission of Safety Letters (SL’s)/Investigator Safety Letters (ISL’s) to ECs |  |  |  |  |
|  | Regulatory and Ethics/IRB fees where applicable |  |  |  |  |
|  | End of Study Notification |  |  |  |  |
| 6 | PHARMOCOVIGILANCE/SAFETY |  |  |  |  |
|  | Reporting of SAEs to SPONSOR |  |  |  |  |
|  | Reporting of SAEs to company |  |  |  |  |
|  | Review and assessment of SAE reports |  |  |  |  |
|  | Identification and preparation of SUSAR reports |  |  |  |  |
|  | Reporting of SAEs/SARs/SUSARs to regulatory authorities and ethics/IRB |  |  |  |  |
|  | Reporting of SAEs/SARS/SUSARs to participating groups |  |  |  |  |
|  | Reporting of SAEs/SARS/SUSARs to investigators/participating sites |  |  |  |  |
|  | Reporting of SAEs/SARS/SUSARs to company |  |  |  |  |
|  | Preparation of annual safety report/development safety update reports (DSUR) annually |  |  |  |  |
|  | Submission of annual safety reports/development safety update reports (DSUR) to regulatory authorities |  |  |  |  |
|  | Submission of annual safety reports/development safety update reports (DSUR) to ethics/IRB |  |  |  |  |
|  | Submission of annual safety reports/development safety update reports (DSUR) to investigators/participating sites |  |  |  |  |
|  | Reporting of SAE’s/SARS/SUSARS from other trials (ISL’s) to HA (pending discussion w/ EMA) and to Investigators/participating sites |  |  |  |  |
|  | Reporting of SAE’s/SARS/SUSARS from other trials (ISL’s) to Groups (same as above) |  |  |  |  |
|  | Provision of unblinding information for individual patients for regulatory reporting. |  |  |  |  |
| 7 | INVESTIGATIONAL MEDICINAL PRODUCT (IMP) (delete if non-CTIMP) |  |  |  |  |
|  | Manufacturing, packing and release |  |  |  |  |
|  | Import License |  |  |  |  |
|  | Packaging/Labelling and release |  |  |  |  |
|  | Label compliance with regulations |  |  |  |  |
|  | Shipping/Distribution to CRO (if applicable) |  |  |  |  |
|  | Shipping / Distribution to centres |  |  |  |  |
|  | Provision of shipping receipts to participating group (if applicable) |  |  |  |  |
|  | Re-ordering |  |  |  |  |
|  | Blinding/unblinding |  |  |  |  |
|  | Randomisation |  |  |  |  |
|  | Notification of IMP recall |  |  |  |  |
|  | Complying with IMP recall notifications |  |  |  |  |
|  | Authorisation of IMP destruction |  |  |  |  |
|  | IMP destruction |  |  |  |  |
|  | Drug Accountability |  |  |  |  |
|  | IMP reconciliation |  |  |  |  |
| 8 | INSURANCE |  |  |  |  |
|  | Ensure adequate insurance covering legal responsibility with respect to patients prior to conducting study |  |  |  |  |
|  | Provision of copy of insurance policies to prior to commencement of study |  |  |  |  |
|  | Ensuring provision of clinical negligence insurance cover at local centres |  |  |  |  |
| 9 | SELECTION OF INVESTIGATORS/CLINICAL CENTRES |  |  |  |  |
|  | Selection of Investigators/Clinical centres |  |  |  |  |
|  | Release of authorized centres list |  |  |  |  |
|  | Closure of centres |  |  |  |  |
|  | Assurance that sites work according to GCP |  |  |  |  |
| 10 | AUDITING AND MONITORING |  |  |  |  |
|  | Central Monitoring |  |  |  |  |
|  | Monitoring Plan |  |  |  |  |
|  | Auditing Plan |  |  |  |  |
|  | On site monitoring |  |  |  |  |
|  | Centre Audits |  |  |  |  |
|  | Pre NDA/regulatory submission audits |  |  |  |  |
| 11 | TRIAL/CENTRE INITIATION |  |  |  |  |
|  | Participating Centre Agreement |  |  |  |  |
|  | Additional Contract as required |  |  |  |  |
|  | Financial disclosure information / 1572 if applicable |  |  |  |  |
|  | Conduct of initiation/opening visit |  |  |  |  |
|  | Checking of documentation |  |  |  |  |
|  | Formally activating a centre |  |  |  |  |
| 12 | INVESTIGATOR MEETINGS |  |  |  |  |
|  | International Investigator Meeting if required |  |  |  |  |
|  | National investigator meeting |  |  |  |  |
|  | Costs of investigator meetings |  |  |  |  |
| 13 | DATA MANAGEMENT |  |  |  |  |
|  | Initial patient registration |  |  |  |  |
|  | Randomisation process |  |  |  |  |
|  | Timely CRF flow from centres |  |  |  |  |
|  | Data Entry of paper CRF received from centres |  |  |  |  |
|  | Updating database, data checking |  |  |  |  |
|  | Cross checks of database |  |  |  |  |
|  | Final clinical validation of cases |  |  |  |  |
|  | Data Queries generation |  |  |  |  |
|  | Data query delivery to centres |  |  |  |  |
|  | Data query retrieval from centres |  |  |  |  |
|  | Timely Data Query resolution |  |  |  |  |
|  | All data queries from Company (including SAE queries) will be routed via Group (delete if not applicable) |  |  |  |  |
|  | Coding and cleaning of concomitant medication database |  |  |  |  |
|  | Provision of database relating to contribution of participating group will be provided to participating group in agreed format within a reasonable timeframe after the final analysis |  |  |  |  |
|  | Coding of adverse events |  |  |  |  |
| 14 | TRIAL CLOSE OUT |  |  |  |  |
|  | Decision on appropriate time for closure according to number of patients required. |  |  |  |  |
|  | Informing company that trial is closed |  |  |  |  |
| 15 | OTHER STUDY RELATED ACTIVITIES |  |  |  |  |
|  | Retention of CRFs |  |  |  |  |
|  | Scanning of CRF if required |  |  |  |  |
|  | Retention of regulatory files |  |  |  |  |
|  | Archive of TMF and study data |  |  |  |  |
|  | Writing of Investigator Brochure/addendums |  |  |  |  |
| 16 | COMMUNICATION |  |  |  |  |
| 1. . | Sponsor should receive a copy of all relevant mail sent to the investigators by participating group |  |  |  |  |
|  | Forward relevant clinical and preclinical information to lead groups |  |  |  |  |
|  | Outline of communication flow for study |  |  |  |  |
|  | Sponsor to provide SAE listings 3-monthly. |  |  |  |  |
|  | Primary contact with clinical centres |  |  |  |  |
| 17 | STATISTICAL ANALYSIS AND TRIAL REPORT |  |  |  |  |
|  | Analyses for DSMC and final analyses |  |  |  |  |
|  | Preparation of final report and all primary publications |  |  |  |  |
|  | Review of final report and publication |  |  |  |  |
|  | Preparation of the Company final study report |  |  |  |  |
| 18 | TRANSLATIONAL RESEARCH |  |  |  |  |
|  | Retrieval archival tissue for Tumour Bank |  |  |  |  |
|  | Coordination of sample collection and shipping |  |  |  |  |
|  | Supply of sample collection kits |  |  |  |  |
| 19 | TRIAL MASTER FILE |  |  |  |  |
| 1. . | Set-up and maintain a Trial Master File (TMF) containing documents essential to the management of the study |  |  |  |  |
| 20 | CONTRACTS (if applicable) |  |  |  |  |
|  | Selection of Project Management CRO |  |  |  |  |
|  | Enter into contract with Project Management CRO |  |  |  |  |
|  | Approval and Provisions of Costs of PM CRO contract |  |  |  |  |
|  | Inspection and QA of PM CRO |  |  |  |  |
|  | Selection of Country CRO |  |  |  |  |
|  | Enter into contract with Country CRO’s |  |  |  |  |
|  | Approval and Provision of Costs for Country CRO contract |  |  |  |  |
|  | Inspection and QA of Country CRO |  |  |  |  |
|  | Selection of Drug Warehousing CRO |  |  |  |  |
|  | Enter into contract with Drug Warehousing CRO |  |  |  |  |
|  | Approval and Provision of Costs for Drug Warehousing CRO contract |  |  |  |  |
|  | Inspection and QA for Drug Warehousing CRO |  |  |  |  |
| 21 | MISCELLANEOUS (Note: below is list of other roles and responsibilites which may need considered for studies. As a whole the checklist should be modified to suit individual needs/requirements of each study. Additional consideration may be required depending on countries involved for e.g EU Countries) |  |  |  |  |
|  | Obtaining appropriate permission to use QoL instruments as well as validated translations |  |  |  |  |
|  | Pharmacokinetic analyses of Study Drug |  |  |  |  |
|  | PK report for study drug prior to final analysis |  |  |  |  |
|  | Pharmacokinetic analyses of concomitant chemotherapy |  |  |  |  |
|  | PK report prior to final analysis |  |  |  |  |
|  | Central Pathology Review |  |  |  |  |
|  | Central Radiology/Imaging Review |  |  |  |  |
|  | Central Laboratory |  |  |  |  |
|  | Responsibilities/classification regarding Data Controller/processor/ sub-processor – depending on circumstance of the study |  |  |  |  |

# Appendix 2 – Protocol and Country/Group Specific Appendix

***Supplied as separate document, and as amended during the conduct of the trial***

# Appendix 3 – SAE Flow

Insert SAE flow for study

# Appendix 4 – Data Protection

*Note: for appendices 4 and 5 these are suggested appendices for use to outline responsibilities for each party to the agreement in relation to their responsibilities in relation to data protection. The* ***Lead******Group/Sponsor*** *may already have agreed text which is used by their organization in agreements for Date protection/GDPR obligations, which could be substituted here rather than options included in the template.*

1. **Definitions**

In this Appendix 4 the following additional definitions shall apply:

|  |  |  |  |
| --- | --- | --- | --- |
| "**Applicable EU Law**" | | means any law of the European Union (or the law of one or more of the Member States of the European Union); | |
| **"Controller", "Processor" and "Data Subject"** | | shall have the meaning given to those terms in the applicable Data Protection Laws;  *(Note: In some circumstances the Lead Group and Participating Group may be considered Joint Controllers; however, in this appendix the participating Group is considered to be a Data Processor and the clinical centres as sub-processors. This may vary between trials/countries and should be adapted as necessary).* | |
| "**Data Protection Impact Assessment**" | | means an assessment of the impact of the envisaged Processing operations on the protection of Personal Data, as required by Article 35 of the GDPR; | |
| "**Data Processing Particulars**" | | means, in relation to any Processing under this Agreement:  (a) the subject matter and duration of the Processing;  (b) the nature and purpose of the Processing;  (c) the type of Personal Data being Processed; and  (d) the categories of Data Subjects;  as summarised at Appendix 5 | |
|  | |
|  | |
|  | |
| "**Data Subject Request**" | | means an actual or purported request or notice or complaint from or on behalf of a Data Subject exercising his rights under the Data Protection Laws in relation to Personal Data including without limitation: the right of access by the Data Subject, the right to rectification, the right to erasure, the right to restriction of processing, the right to data portability and the right to object; | |
| " **Competent data protection authority Correspondence**" | | means any correspondence or communication (whether written or verbal) from the competent data protection authority of the parties country in relation to the Processing of Personal Data; | |
| **"Losses"** | | means all losses, fines, penalties, liabilities, damages, costs, charges, claims, amounts paid in settlement and expenses (including legal fees (on a solicitor/client basis), disbursements, costs of investigation (including forensic investigation), litigation, settlement (including ex gratia payments), judgment, interest and penalties), other professional charges and expenses, disbursements, cost of breach notification including notifications to the data subject, cost of complaints handling (including providing data subjects with credit reference checks, setting up contact centres (e.g. call centres) and making ex gratia payments), all whether arising in contract, tort (including negligence), breach of statutory duty or otherwise; | |
| "**Permitted** **Purpose**" | | means the purpose of the Processing as specified in the Data Processing Particulars at Appendix 5; | |
| "**Personal Data**" | | means any personal data (as defined in the Data Protection Laws) Processed by either Party in connection with this Agreement, and for the purposes of this Agreement includes Sensitive Personal Data (as such Personal Data is more particularly described in Appendix 5 (Data Processing Particulars)); | |
| "**Personal Data Breach**" | | has the meaning set out in the Data Protection Laws and, for the avoidance of doubt, includes a breach of Paragraph xx | |
| **"Personal Data Breach Particulars"** | | 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 as set out in Article 33(3) of the GDPR; | |
| "**Personnel**" | | means all persons engaged or employed from time to time in connection with this Agreement, including employees, consultants, contractors and permitted agents; | |
| "**Processing**" | | has the meaning set out in the Data Protection Laws (and "**Process**" and "**Processed**" shall be construed accordingly); | |
| "**Restricted Country**" | | means a country, territory or jurisdiction outside of the European Economic Area which the EU Commission has not deemed to provide adequate protection in accordance with Article 25(6) of the DP Directive and/ or Article 45(1) of the GDPR (as applicable); | |
| "**Security Requirements**" | | means the requirements regarding the security of Personal Data, as set out in the Data Protection Laws (including, in particular, the seventh data protection principle of the DPA and/ or the measures set out in Article 32(1) of the GDPR (taking due account of the matters described in Article 32(2) of the GDPR)) as applicable; | |
| **"Sensitive Personal Data"** | | means Personal Data that reveals such special categories of data as are listed in Article 9(1) of the GDPR; | |
| "**Third Party Request**" | | means a written request from any third party for disclosure of Personal Data where compliance with such a request is required or purported to be required by law or regulation. | |

1. **DATA PROTECTION**
   1. **Arrangement Between The Parties**
      1. The Parties shall each Process the Personal Data. The Parties acknowledge that the factual arrangements between them dictate the classification of each Party in respect of the Data Protection Laws. Notwithstanding the foregoing, the Parties anticipate that, in respect of the Personal Data, as between **Lead Group/Sponso**r and the **Participating** **Group** for the purposes of this Agreement, **Lead** **Group/Sponsor** shall act as the Controller and the **Participating Group** shall act as the Processor, where the **Participating Grou**p shall act as the Processors and shall procure that the [Country] Clinical Centres shall act as their sub-processors, as follows:
         1. **Lead Group/SPONSOR** shall be the Controller where it is Processing Personal Data in relation to the Trial; and
         2. The **Participating Group** shall be the Data Processors, and shall procure that the [Country] Clinical Centres shall be their subprocessors where they are Processing Personal Data on behalf of the Sponsor in relation to the Trial.
      2. Each of the Parties acknowledges and agrees that Appendix 5 (*Data Processing Particulars*) to this Agreement is an accurate description of the Data Processing Particulars.
      3. Nothing within this Agreement relieves the **Participating Group** and the [Country] Clinical Centres of its own direct responsibilities and liabilities under the Data Protection Laws.
      4. Each Party shall make due notification to any relevant Regulator.
      5. The **Participating Group** undertakes, and shall procure that the [Country] Clinical Sites undertake, to **Lead Group/SPONSOR** that they will take all necessary steps to ensure that they operate at all times in accordance with the requirements of the Data Protection Laws and the **Participating Group** will, and shall procure that the [Country] Clinical Centres will, at their own expense, assist **Lead Group/SPONSOR** in discharging its obligations under the Data Protection Laws as more particularly detailed in this Paragraph 2 *(Data Protection)*. The **Participating Group** shall not, and shall procure that the [Country] Clinical Centres shall not, whether by act or omission, cause **Lead Group/SPONSOR** to breach any of its obligations under the Data Protection Laws.
   2. **Data Processor Obligations**
      1. To the extent that the **Participating Group** and the [Country] Clinical Centres Process any Personal Data as a Processor for and on behalf of **Lead** **Group/SPONSOR** (as the Controller) the Collaborating Group shall, and shall procure that the [Country] Clinical Centres shall:
         1. only Process the Personal Data for and on behalf of **Lead Group/SPONSOR** for the purposes of performing its obligations under this Agreement, and only in accordance with the terms of this Agreement and any documented instructions from **Lead Group/SPONSOR**;
         2. unless prohibited by law, notify **Lead Group/SPONSOR** immediately (and in any event within twenty-four (24) hours of becoming aware of the same) if it considers, in its opinion (acting reasonably) that it is required by Applicable EU Law to act other than in accordance with the instructions of **Lead Group/SPONSOR,** including where it believes that any of **Lead Group/SPONSOR's** instructions under Paragraph 2.2.1(a) infringe any of the Data Protection Laws;
         3. take, implement and maintain appropriate technical and organisational security measures which are sufficient to comply with:
            1. at least the obligations imposed on **Lead** **Group/SPONSOR** by the Security Requirements;

and where requested provide to **Lead Group/SPONSOR** evidence of its compliance with such requirements promptly, and in any event within forty-eight (48) hours of the request;

* + - 1. hold the Personal Data in such a manner that it is capable of being distinguished from other data or information processed by the **Participating Group**;
      2. within thirty (30) calendar days of a request from **Lead Group/SPONSOR**, allow its data processing facilities, procedures and documentation to be submitted for scrutiny, inspection or audit by **Lead Group/SPONSOR** (and/ or its representatives, including its appointed auditors) in order to ascertain compliance with the terms of this Paragraph 2 (*Data Protection*), and provide reasonable information, assistance and co-operation to **Lead Group/SPONSOR** including access to relevant Personnel and/ or, on the request of **Lead Group/SPONSOR**, provide **Lead Group/SPONSOR** with written evidence of its compliance with the requirements of this Paragraph 2 (*Data Protection*);
      3. not disclose Personal Data to a third party (including a sub-contractor) in any circumstances without **Lead Group/SPONSOR’s** prior written consent, save in relation to Third Party Requests where the **Participating Group** is prohibited by law or regulation from notifying **Lead Group/SPONSOR** , in which case it shall use reasonable endeavours to advise **Lead Group/SPONSOR** in advance of such disclosure and in any event as soon as practicable thereafter;
      4. promptly comply with any request from **Lead Group/SPONSOR** to amend, transfer or delete any Personal Data;
      5. notify **Lead Group/SPONSOR** promptly (and in any event within forty-eight (48) hours) following its receipt of any Data Subject Request or competent data protection authority Correspondence and shall:
         1. not disclose any Personal Data in response to any Data Subject Request or competent data protection authority Correspondence without first consulting with and obtaining **Lead Group/SPONSOR**’s prior written consent; and
         2. provide **Lead Group/SPONSOR** with all reasonable co-operation and assistance required by **Lead Group/SPONSOR** LEG/SPONSOR in relation to any such Data Subject Request or competent data protection authority Correspondence;
      6. notify **Lead Group/SPONSOR** promptly (and in any event within twenty-four (24) hours) upon becoming aware of any actual or suspected, threatened or ‘near miss’ Personal Data Breach in relation to the Personal Data (and follow-up in writing) and shall:
         1. conduct or support **Lead Group/SPONSOR** in conducting such investigations and analysis that **Lead Group/SPONSOR** reasonably requires in respect of such Personal Data Breach;
         2. implement any actions or remedial measures necessary to restore the security of compromised Personal Data; and
         3. assist **Lead Group/SPONSOR** to make any notifications to the competent data protection authority and affected Data Subjects;
      7. comply with the obligations imposed upon a Processor under the Data Protection Laws;
      8. use all reasonable endeavours, to assist **Lead Group/SPONSOR** to comply with the obligations imposed on **Lead Group/SPONSOR** by the Data Protection Laws, including:
         1. compliance with the Security Requirements;
         2. obligations relating to notifications required by the Data Protection Laws to the competent data protection authority and/ or any relevant Data Subjects;
         3. undertaking any Data Protection Impact Assessments (and, where required by the Data Protection Laws, consulting with the competent data protection authority and/or any other relevant Regulator in respect of any such Data Protection Impact Assessments); and
         4. without undue delay and where feasible not later than 72 hours after having become aware of it notify Personal Data Breaches to the competent data protection authority and/or any other relevant Regulator unless the Personal Data Breach is unlikely to result in a risk to the rights and freedoms of natural persons;
      9. not make (nor instruct or permit a third party to make) a transfer of any Personal Data to a Restricted Country except with the prior written consent of **Lead Group/SPONSOR** and in accordance with any terms **Lead Group/SPONSOR** may impose on such transfer as **Lead Group/SPONSOR** deems necessary to satisfy the requirements to ensure that transfers of Personal Data outside of the EEA have adequate protections in place as set out in the Data Protection Laws;
    1. Except as otherwise provided, this Agreement does not transfer ownership of, or create any licences (implied or otherwise), in any intellectual property rights in any Personal Data.
  1. **Personnel**
     1. The **Participating Group** shall take all reasonable steps to ensure the reliability and integrity of any of the Personnel who shall have access to Personal Data (including, without limitation, ensuring such Personnel shall have undergone reasonable levels of training in Data Protection Laws and in the care and handling of Personal Data), and ensure that each member of Personnel shall have entered into appropriate contractually-binding confidentiality undertakings.
  2. **Appointing Sub-contractors**
     1. The **Participating Group** shall not sub-contract the performance of any of its obligations under this Agreement without the prior written consent of **Lead Group/SPONSOR** , for the avoidance of doubt the Parties agree that the **Participating Group** will appoint [Country] Clinical Centres as subprocessors;
  3. Notwithstanding anything in this Agreement to the contrary, this Appendix 4 (*Data Protection*) shall continue in full force and effect for so long as the **Participating Group** and [Country] Clinical Centres Process any Personal Data.
  4. **Contact**
     1. To exercise rights of individuals under data protection laws, for the reporting of data breaches or for any other communication in relation to the data protection, Parties can contact:
* Insert details of **Lead Group/SPONSOR** Data Protection Officer: xxxx@xxx
* Insert details of **Participating Group** Data Protection Officer: xxxx@xxx

1. **Recoverable Loss** 
   1. No provisions of this Agreement shall prevent **Lead Group/SPONSOR** from recovering any Losses it incurs.
2. **INDEMNITY** 
   1. The **Participating Group** shall indemnify on demand and keep indemnified **Lead Group/SPONSOR** from and against:
      1. any monetary penalties or fines levied by the competent data protection authority and/or any other Regulator on **Lead Group/SPONSOR** ;
      2. the costs of an investigative, corrective or compensatory action required by the competent data protection authority and/or any other Regulator, or of defending proposed or actual enforcement taken by the competent data protection authority and/or any other Regulator;
      3. any Losses suffered or incurred by, awarded against, or agreed to be paid by, **Lead Group/SPONSOR** pursuant to a claim, action or challenge made by a third party against **Lead Group/SPONSOR** (including by a Data Subject); and
      4. except to the extent that Paragraphs 4.1.1 and/ or 4.1.2 and/ or 4.1.3 apply, any Losses suffered or incurred, awarded against, or agreed to be paid by, **Lead Group/SPONSOR**,

in each case to the extent arising as a result of a breach by the **Participating Group** (or its sub-contractors) of this Agreement and/ or their respective obligations under the Data Protection Laws.

* 1. Nothing in this Agreement will exclude, limit or restrict the **Participating Group's** liability under the indemnity set out in Paragraph 4.1.

1. **INSURANCE**
   1. The **Participating Group** agrees:
      1. to obtain and keep in full force and effect at all times a policy or policies of insurance which meets the following conditions:
         1. it must cover liability for damage arising to any person;
         2. it must apply in relation to the Processing of Personal Data; and
         3. it must have policy limits and provisions conforming to such requirements as **Lead Group/SPONSOR** may from time to time reasonably prescribe;
      2. to deliver to **Lead Group/SPONSOR** :
         1. copies of all applicable insurance policies taken out pursuant to the provisions of this Agreement; and
         2. evidence of premiums paid in relation to such insurance; and
      3. to ensure that **Lead Group/SPONSOR** shall be entitled to the benefit under such insurance and that **Lead Group/SPONSOR’**s interest will be noted on the policy.

# Appendix 5 DATA PROCESSING PARTICULARS

*Completed as an example – please remove/amend text in italics as necessary.*

|  |  |
| --- | --- |
| **The subject matter and duration of the Processing** | *Processing in relation to (the “Trial”) for the duration of the Agreement* |
| **The nature and purpose of the Processing** | *The collection, processing and submission/transfer of data and Biological Samples at [Country] Clinical Sites for the conduct of the Trial as outlined in this Agreement.* |
| **Data Controller’s lawful basis for Processing** | *Task carried out in the public interest (under GDPR article 6 – 1.(e))* |
| **The type of Personal Data being Processed** | *Submission by [Country] Clinical Sites to* ***Lead******Group/SPONSOR*** *via electronic Case Report Forms of Trial Participant data and accessed by Participating Group:*   * *numeric Trial identifier* * *date of birth* * *initials* * *clinical, medical and safety data, including special category data (health data)* * *Biological Samples*   *Processed by [Country] Clinical Sites:*   * *full patient identifiable clinical data of patients in the care of the [Country] Clinical Sites* |
| **Categories of Data Subjects** | *Trial Participants* |
| **Agreed subprocessors** | *[Country] Clinical Centres* |

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[Guidance Note: The above information is required by the GDPR (Article 28(3)) which requires data processing agreements to include details of the subject-matter, duration, nature and purpose of the processing and the type of personal data and categories of data subjects involved in the data processing.]