Agreement on secondary use of patient data for research purposes

Template Draft of 6 October 2025 developed by pharma.be and Van Bael & Bellis in concertation with the Belgian university hospitals (represented by the RUZB), and Belgian general hospitals

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DRAFTING NOTES – TO BE REMOVED BEFORE SHARING

This document serves as a template agreement between hospitals (***Institution***) and pharmaceutical industry governing the secondary use of personal data.

This agreement is intended as a starting point for discussions between the parties and is subject to further negotiations. It is not to be deemed a final binding agreement until such negotiations are complete and a definitive agreement is executed by the parties. The provisions outlined in this template agreement will require careful review and confirmation to ensure that the terms appropriately address the specific circumstances at hand.

The present agreement template is intended to cover the following use case:

Data request from pharma companies for research (which may include reimbursement) purpose, hospitals need to process this data to an aggregated report with the results.

- This agreement is intended to function as a standalone document – and should not be complemented by a general "services agreement" or terms and conditions.
- The arrangement follows a classic data processing model from the Institution to the Company (through the delivery of an aggregated report). Remote access by the Company (as might be the case in a federated system) is not considered.
- The sole deliverable of the project is a written report containing aggregated information.
- The secondary processing by the Company is strictly for scientific research purposes (recorded in a written protocol).

How to adapt the template to the situation at hand?

The legal relationship between the parties under GDPR. The template assumes that the pharmaceutical company will always act as a controller, determining the purpose and the means of the Secondary Use (as defined in Article 1, below). The Institution may either act as joint controller or as processor (on behalf of the controller). This role is determined by operation of law based on factual situation at hand. Parties should use the "Decision Tree - Roles of the Parties" in the Pharma.be "*Secondary use of patient data for scientific purpose – Guideline on the applicability of the General Data Protection Regulation (GDPR) and the Belgian Personal Data Protection Law*" (the ***Pharma.be Guideline***). The questions in this decision tree relate specifically to the role of the Institution for the purpose of the "Secondary Use" of the data (i.e., the research purpose as defined in Article 1 of this Agreement). Based on the outcome of the Decision Tree, the following options can arise:

- *OPTION A – Company is controller for the Secondary Use and Institution acts as processor*: the Institution (which acts as the controller for the Primary Use) assumes the role of processor for the Secondary Use that is the object of the Agreement because it processes personal data under the instruction and on behalf of the Company (note: this relates to the specific processing operations that are performed by the Institution specifically for the Secondary Use – in other words, these are processing operations that the Institution would not perform on its own initiative).
- *Option B – Parties are joint controllers for the Secondary Use*: Parties both have an essential influence on the purpose and means of the Secondary Use processing and are joint controllers for this Secondary Use.

Optional language is highlighted in yellow in the template. Any optional language that relates to options that are not relevant for the scenario at hand should be deleted.

For your information, the following articles contain optional clauses:

- **Recitals: (D)(G).**
- **Article 1. Definitions.**
- **Article 2. Subject matter: 2.2(b).**
- **Article 3. Order of preference: 3.1(a).**
- **Article 4. Role of the parties: from 4.24.4 until 4.2.**
- **Article 5. Data Protection Obligations of the Parties: 5.3 and 5.18.**
- **Article 12. Intellectual Property.**
- **Article 15. Insurance and Indemnification.**
- **Article 16. Miscellaneous: 16.8 and 16.9.**
- **Schedule B: This schedule should be incorporated only in case of Option A.**
- **Schedule D: This schedule should be incorporated only if applicable.**

The text highlighted in blue consists of further instruction for the writing and has to be removed before finalizing.

Any variations on the above use case conditions may require further modifications to the agreement. Changes on a per project basis may occur due to specificities of the project or specific requirements of the parties.

For the avoidance of doubt, no separate or additional services agreement between the Parties shall be required for the creation, preparation, or provision of the Report.

THIS AGREEMENT ON SECONDARY USE OF PATIENT DATA FOR RESEARCH PURPOSES (this ***Agreement***) has been made on [insert date].

BETWEEN:

1. **[Name Party]**, a [legal form] [organised/incorporated] under the laws of [Jurisdiction], with registered office at [Street, City, Country], filed with [Name relevant register] under number [number], registered in the [Location of Register of Legal Entities (*Rechtspersonenregister* / *Registre des Personnes Morales*)] (***the Institution***);

   [OPTIONAL:]

   And in presence of [its employee]: dr. XXX

   And in presence of [its employee]: prof. XXX, Head of Department XXX

AND:

2. **[Name Party]**, a [legal form] [organised/incorporated] under the laws of [Jurisdiction], with registered office at [Street, City, Country], filed with [Name relevant register] under number [number], registered in the [Location of Register of Legal Entities (*Rechtspersonenregister* / *Registre des Personnes Morales*)] (***the Company***).

The Institution and the Company are individually also referred to as a ***Party***, and collectively as the ***Parties***.

WHEREAS:

(A) The Institution is a healthcare organisation that collects, processes, and manages personal data (including sensitive health-related information) in accordance with applicable laws and regulations, as part of its operations to provide healthcare services;

(B) The Company is a pharmaceutical company engaged in the research, development, and commercialization of pharmaceutical products in accordance with applicable laws and regulations and for the purpose of conducting research activities, in particular **[insert a short description of the research purpose]** (the ***Research Purpose***), wishes to process Data (including personal data) held by the Institution;

(C) In that regard, the Parties acknowledge and agree that the Research Purpose must be aligned with, *inter alia*, the following frameworks:

- The interpretation of scientific research under Recital 159 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April on the protection of natural persons

with regard to the processing of personal data and on the free movement of such data (the ***GDPR***);

- The interpretation of scientific research under Recital 61 of Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space (the ***EHDS***);
- The purposes for which electronic health data can be processed for secondary use under Article 53 (e)(i) of the EHDS; and
- Article 29 Working Pary Guidelines on consent under the GDPR which specifies that "*the notion of scientific research may not be stretched beyond its common meaning and understand that 'scientific research' in this context means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice."*

(D) [**OPTIONAL**] The Parties acknowledge that each Party may engage one or several Third-Party Organisation(s) to assist in the processing of personal data for the purposes of this Agreement under the conditions as set out in this Agreement;

(E) Both Parties acknowledge the importance of safeguarding personal data and ensuring compliance with all applicable data protection and privacy laws, including but not limited to the GDPR and the Belgian Law of 30 July 2018 (*Loi relative à la protection des personnes physiques à l'égard des traitements de données à caractère personnel* / *Wet betreffende de bescherming van natuurlijke personen met betrekking tot de verwerking van persoonsgegevens* - the ***Belgian Data Protection Act***);

(F) The Parties recognise that the secondary use of personal data, after the initial purpose for which it was collected, must be justified by an appropriate legal basis, including legitimate interests such as scientific research, and that such use must occur within the confines of Applicable Data Protection Laws, ethical standards, and the informed consent of data subjects (where required);

(G) [**OPTIONAL**] The National Institute for Sickness and Disability Insurance (RIZIV/INAMI) requested the Company to provide real world evidence in relation to its product **[insert name of the product]** (the ***Product***);

(H) The Company has requested that the Institution provides a Report in accordance with the Instructions as set out in Schedule A - Instructions;

(I) The Parties agree that this request serves the common good, that it can bring great societal benefits, and that the benefits pursued outweigh the interference with patient privacy during the processing of the dataset and the risk of unintended use outside the scope of the current research question;

(J) Accordingly, the Institution, through [name researcher] (the Researcher), has agreed to make its patient data available, subject to Anonymisation or pseudonymisation where applicable, for the Research Purpose (within the meaning of recital 159 GDPR) upon the terms and subject to the conditions set forth in this Agreement;

(K) The Parties agree that data Anonymisation may be appropriately achieved through aggregation, and that small cell analysis may be employed to assess the risk of re-identification. The Parties may adopt additional or alternative methods to meet Anonymisation in the Instructions. In cases of ambiguity as to whether particular data constitute personal data, the Parties shall presume that such data are pseudonymized (i.e., not fully anonymous within the meaning of the GDPR);

(L) For the avoidance of doubt, the Company shall have no access to or visibility of any directly identifiable personal data, including any personal data of the patients of the Institution.

THEREFORE, IT IS AGREED AS FOLLOWS:

1. DEFINITIONS

Definitions

1.1 In this Agreement, and unless already defined elsewhere in this Agreement, the following terms shall have the following meanings:

Anonymisation	means the irreversible process of transforming personal data in such a way that the data subject is no longer identifiable, directly or indirectly, by any means reasonably likely to be used by the Parties, or any other third party. "Anonymised" shall mean the result of Anonymisation.
Affiliate	means, if applicable, any business entity which controls, is controlled by, or is under the common control according to article 1:14 of the Belgian Companies and Associations Code of 23 March 2019.
Agreement	This Agreement on secondary use of patient data for Research Purpose.
Applicable Data Protection Laws	The relevant laws of Belgium and the European Union (EU) to which both the Institution and the Company are subject, including but not limited to the GDPR and the Belgian Data Protection Act.
Background IP	As defined in Article 12.3.
Confidential Information	As defined in Article 10.1.
Data	Refers to both personal and non-personal data processed by either Party in the context of this Agreement.
Effective Date	Refers to the date on which this Agreement is signed by both Parties. In the event of signatures being affixed on different dates, the Date of the Agreement corresponds to the date of the last signature.

ICMJE	As defined in Article 12.9.
Intellectual Property	means all rights, titles, and interests in and to any inventions, discoveries, works of authorship, designs, data, know-how, trade secrets, software, trademarks, trade names, logos, domain names, database rights, copyrights, mask works, and all other intellectual or proprietary rights, whether registered or unregistered.
Instructions	Refers to the document that describes the Research Purpose and format of the Report, the security and data minimisation measures and the design, methodology and/or statistical considerations for which the report will be used and attached hereto as Schedule A – Instructions.
[**OPTIONAL**]***Know-How***	Means all technical and other information that is not in the public domain (other than through a breach of confidentiality) including, but not limited to, information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, creations, pharmaceutical products or treatments, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by Intellectual Property or any applications for such rights.
Protocol	Refers to the documents that describes, inter alia, the scientific objectives, design, methodology of the research and attached hereto as Schedule E – Protocol.
Primary Use	Refers to the initial collection, processing, and management of personal Data by the Institution as part of its operations to provide healthcare services.
Report	Means any written, digital, or otherwise recorded document, summary, analysis or other deliverable containing aggregated (and where possible Anonymised) Data only and created, compiled or prepared by the Institution as set out in this Agreement and the Instructions for the Research Purpose.
Report Data	means all Data contained in the Report.
Researcher	The person, as appointed by the Institution, who processes Data, subject to Anonymisation or pseudonymisation, for the Research Purpose.

Research Purpose	As defined in consideration (B), above.
Secondary Use	Refers to the use of Data initially collected for the Primary Use for the Research Purpose in accordance with the Instructions, including any further legitimate use of the Report and the Report Data by the Company **[OPTION B –** and the Institution**]**.
Staff	As defined in Article 9.2.
[OPTIONAL]*Third-Party Organisation*	Refers to a third-party that is engaged by either Party to process Data for the Secondary Use.

1.2 Furthermore, the terms personal data, data subjects, processing, personal data breach, supervisory authority and pseudonymisation shall have the meaning ascribed to them in the GDPR.

2. SUBJECT MATTER

2.1 This Agreement defines the terms and conditions governing the processing of Data held by the Institution and made available by the Institution to the Company for the Secondary Use and any related services provided by the Institution, as set out in the Instructions, in line with Applicable Data Protection Laws.

2.2 The Institution warrants that all personal Data processed under this Agreement:

(a) Have been collected and processed in compliance with Applicable Data Protection Laws;

(b) **[OPTIONAL]** upon Instruction of Company the data subjects can be properly informed about the scope and purpose of the processing as set out in the Instructions in accordance with Applicable Data Protection Laws.

2.3 Both Parties warrant that, in the performance of the present Agreement, they shall process the personal data solely in accordance with the terms of this Agreement, the Instructions, and Applicable Data Protection Laws, and that they shall implement appropriate technical and

organizational measures to ensure the security and confidentiality of the personal data during processing.

2.4 Each Party shall perform their obligations timely and in accordance with good industry practice.

2.5 The Company is solely responsible for obtaining and maintaining any and all permits, licenses and other documents, approvals or registrations required under applicable laws and regulations for the performance of the services hereunder, including but not limited to ethics committee approval.

3. ORDER OF PRECEDENCE

3.1 This Agreement, together with the Instructions **[OPTION A** - and the Data Processing Addendum (DPA)**]** shall govern the entire legal relationship between the Parties. In case of any inconsistencies between the terms of this Agreement and the Instructions [**OPTION A** - or the DPA], the following order of precedence shall apply, meaning that the interpretation of the higher ranked document shall prevail over the lower ranked document:

(a) **[**Only if **OPTION A - If OPTION B, remove (a) since there will be no Data Processing Addendum between the Parties.]** The Data Processing Addendum in [ONLY IF OPTION A] Schedule B – Data Processing Addendum for the processing operations that fall within its scope;

[Drafting note: In a controller-processor situation, Schedule B will be required to set out the mandatory contractual terms of Article 28 GDPR. By contrast, in a joint controller situation, the present Agreement would suffice to set out the "arrangement" under Article 26 GDPR. However, when handling situations that are more complex in terms of obligations and responsibilities of both parties (for instance in a federated learning context), it could be appropriate to use and adapt the schedule B in case of joint controllership situation]

(b) This Agreement;

(c) The Instructions.

4. ROLES OF THE PARTIES

4.1 The Parties agree that the Institution is the sole controller for any personal data it processes for the Primary Use, and it solely determines the purposes and means of any processing activities related to the Primary Use.

[OPTION A -

4.2 The Parties agree that the Company determines the purposes and means of the Secondary Use and shall therefore be regarded as the sole controller for any processing of personal data for the Research Purpose.

4.3 When processing personal data for the Research Purpose as set out in the Instructions, the Institution shall act as processor processing personal data on behalf of the Company. When acting as a processor, and only to the extent that it processes personal data for the Research Purpose, the Institution shall comply with the obligations set out in [ONLY IF OPTION A] Schedule B – Data Processing Addendum.**]**

[OPTION B -

4.4 The Parties agree that the Parties jointly determine the purposes and means of the Secondary Use and shall therefore be regarded as joint controllers (within the meaning of Article 26(1) of the GDPR) for any processing of personal data for the Research Purpose.**]**

5. DATA PROTECTION OBLIGATIONS OF THE PARTIES

General collaboration

5.1 The Parties will identify in Article 13 of this Agreement a point of contact within its organisation authorised to respond to enquiries concerning the processing of personal data in the context of this Agreement, and will cooperate in good faith with each other, data subjects and the competent authorities to address such enquiries within a reasonable time.

5.2 The Parties shall ensure that for the purposes of this Agreement, only personal data which are strictly necessary for the Secondary Use shall be processed, in accordance with Article 5 GDPR.

[Drafting note: the next clause depends on whether data subjects can be duly informed (whether the Institution can send individual information to the data subjects).]

5.3 **[if data subjects can be duly informed and if instructions are provided by Company -** The Institution warrants that the data subjects will be duly informed about the scope and purpose of the processing described in the Instructions [including the fact that their personal data would pseudonymised, but not anonymised] [**OR**] [and regarding any restrictions on their rights (if any) as described below]. [**If applicable -** If the personal data relate to minors, this information shall be adapted for their understanding]. The content of the relevant information notice is [attached to the Agreement in Schedule D]] [**OR**] [kept on file by the Institution].**]**

[if data subjects cannot be duly informed/information to data subjects is not required - Direct and individual information to patients in accordance with Article 14 of the GDPR is impossible or would require disproportionate efforts considering the fact that [insert explanation]. In accordance with Article 14(5)(b) GDPR, a publicly available general information to concerned data subjects will be provided as follows: [PLEASE COMPLETE].**]**

5.4 Each Party is responsible for ensuring that the processing of personal data under this Agreement is recorded in its internal records of processing operations as required under Article 30 GDPR and Article 196 of the Belgian Data Protection Act and as set out in this Agreement.

Purpose of the Secondary Use

5.5 The Company shall process any personal data it may receive in the context of this Agreement solely for the Research Purpose, i.e. for the purposes of conducting scientific research or statistical purposes in accordance with Article 6, Article 9(2)(j) juncto Article 89 GDPR.

Data Breach

5.6 In case of an actual or suspected personal data breach affecting personal data that are processed for the purpose of this Agreement, each Party shall promptly take adequate measures to remedy the breach and mitigate negative consequences for data subjects and implement appropriate technical and organisational measures for the fulfilment of the other Party's obligation to respond to such incidents. The Parties shall inform each other of any personal data breach without undue delay and where feasible within seventy-two (72) hours after becoming aware of the personal data breach. Parties shall consult each other prior to notification to the supervisory authority to describe and assess the severity of the breach and, to the extent applicable, forward to each other the information required for the notification of the personal data breach to the competent supervisory authorities, or, if applicable, communicate the breach to the affected data subjects. Whether notification or communication is required shall be determined [IF OPTION A] by the Company, or [IF OPTION B] in case of a joint controller relation, jointly by the Parties.

5.7 [IF OPTION A] If it determines that such communication is required for a processing operation for which it acts as controller, the Company may request the Institution to inform the affected data subjects regarding personal data breaches in the manner determined by the Company. The Institution shall comply with such requests unless it can provide objective reasons why it cannot comply with the request or propose an alternative approach that is compatible with the Company's obligations under Applicable Data Protection Laws.

5.8 The information that is provided to the other Party in case of a personal data breach includes at least the following:

(a) The nature of the personal data breach, stating the categories and approximate number of data subjects concerned, and stating the categories and approximate number of the personal data registers affected (datasets);

(b) The likely consequences of the personal data breach;

(c) A proposal for measures to be taken to address the personal data breach, including (where appropriate) measures to mitigate any possible adverse effects of such breach.

5.9 Each Party shall document (and shall keep such documentation available for the other Party) any personal data breaches, including the facts related to the personal data breach, its effects and the corrective measures taken.

Data subjects' requests

5.10 Considering that the Company may not have access to identifiable information about data subjects, any requests that the Company may receive from data subjects to exercise any of their rights under the GDPR, shall be transferred to the Institution as set out in Article 5.13 below. The Institution shall confirm receipt of the request and inform the Company of the action taken pursuant to this request.

5.11 If data subjects' rights of access, rectification, restriction or objection must be restricted for the Research Purpose, [IF OPTION A] the Company / [IF OPTION B] the Parties shall record a justification for the restriction and ensure that the essence of the data subjects' rights and freedoms is still protected as required under Article 89 of the GDPR and Title 4 (art. 186 *et seq*.) of the Belgian Data Protection Act.

5.12 If Article 5.11 is applicable, justifications for the restriction of data subjects' rights include:

(a) [Insert]. *[Drafting note: it is highly unlikely that there would be any restriction necessary in the scope of Secondary Use (exceptional situation); however, should it be the case this justification has to be added to be compliant with applicable legislation.]*

5.13 The Institution must, without undue delay, in writing, notify the Company about:

(a) Any request for disclosure of personal data processed under the Instructions by authorities in relation to any potential violation of Applicable Laws, unless expressly prohibited under Union or Member state law;

(b) any request for access to the Data (with the exception of medical records for which the Institution is considered a controller) received directly from data subjects or from third parties, or any other complaints or inquiries from a data subject with respect to personal data processed for the Research Purpose, including, when feasible, , correction, objection, erasure or data portability or allegations that the processing infringes a data subject's rights under Applicable Data Protection Laws.

5.14 The Institution is responsible for answering requests or objections it receives directly from data subjects, subject to the prior information to the Company as set out in Article 5.13 above. The Institution shall give the Company reasonable time to provide input before the Institution sends its response to data subject. The Company shall provide the Institution, upon its reasonable request, with information about the processing of the personal data provided that such information is necessary in order to inform the data subject according to Applicable Data Protection Laws.

Transfers of personal data to third countries

5.15 The Parties undertake that no personal data shall be transferred to, processed in, or accessed from any third country, unless such transfer, processing, or access is in full compliance with Applicable Data Protection Laws (for instance, because the recipient is located in a jurisdiction that is subject of an adequacy decision of the European Commission or has signed standard contractual

clauses).

[OPTIONAL] Appointing Third-Party Organisation

[OPTION A

5.16 If the Institution appoints a Third-Party Organisation as a sub-processor, such appointment shall be subject to and governed by the Data Processing Addendum as set out in Clause 8 of Schedule B. The Institution shall be responsible for the Third-Party Organisation it involves.

5.17 The Institution shall inform the Company of the Third-Party Organisations it appointed before or independently from this Agreement and that may process Data within the scope of this Agreement.**]**

. **[OPTION B – processing agreement between either Party and the Third-Party Organisation**

5.18 If either Party appoints a Third-Party Organisation to process personal data on their behalf in the context of this Agreement, this Party shall enter into a written agreement with that Third-Party Organisation, which shall at least include the following requirements:

- The Third-Party Organisation shall implement appropriate technical and organisational security measures that provide at least the same level of protection for personal data as required under this Agreement.
- The Third-Party Organisation shall be bound by confidentiality obligations that are at least equivalent to those set forth in this Agreement.
- The Third-Party Organisation shall not engage any subcontractor for data processing activities without the prior written authorization of the Controller
- The agreement between the relevant Party and the Third-Party Organisation shall comply with all mandatory requirements under Article 28 GDPR.**]**

6. SECURITY OF DATA PROCESSING

6.1 The Institution (and the Company to the extent that it has access to personal data under this Agreement) shall provide appropriate safeguards in respect of the administrative, technical and organisational measures for processing Data in the context of this Agreement and take all necessary measures to protect the confidentiality, privacy and prevention from accidental or unauthorized destruction, accidental loss, as well as from alteration, access and any other unauthorized processing of the Data.

6.2 In accordance with Article 89(1) of the GDPR and Articles 194 *et seq.* of the Belgian Data Protection Act, the Parties shall provide appropriate protection of the patients and their data during the processing. These protection measures will be set out in the Instructions (see Schedule A – Instructions for Secondary Use of personal data).

6.3 Each Party undertakes to put in place appropriate measures to ensure a level of security appropriate to the risk and to minimize the risk of personal data breaches or unintended access to

the personal data of the data subjects concerned.

7. COOPERATION

7.1 The Report will be provided to the Company by the Institution in a format as stipulated in the Instructions.

7.2 To ensure the scientific integrity of the Report, the Parties agree to involve the Researcher of Institution in all relevant stages of the research process, including data collection, analysis, and reporting.

7.3 Each Party must reasonably assist the other Party with meeting the other Party's obligations under Union or Member State law where the assistance of the other Party is reasonably required to comply with their obligations. This includes, but is not limited to, providing all necessary information about an incident under Article 5.6 of this Agreement, and all necessary information for an impact assessment in accordance with Article 35 and Article 36 of the GDPR, at the other Party's request.

7.4 Each Party shall upon request provide the other Party with sufficient information to enable the other Party to ensure that the Party's obligations under this Agreement are complied with, including ensuring that the appropriate technical and organisational security measures have been implemented.

7.5 Each Party is entitled to appoint at its own cost an independent expert, reasonably acceptable to the other Party, who shall have access to the other Party's data processing facilities and receive the necessary information for the sole purpose of auditing whether the other Party has implemented and maintained adequate technical and organisational security measures. The expert shall sign a non-disclosure agreement and treat all information obtained or received in the frame of this audit confidentially. In addition, Company shall be entitled to audit or have audited at regular intervals and on reasonable notice, the records and procedures of Institution or Institution's sub-contractors (as the case may be) to the extent that they are relevant to the performance of the services to verify Institution's compliance with the provisions of this Agreement.

7.6 Each Party understands that the other Party may be required under EU or Member State law to give public authorities or their representatives access to their facilities and data processing systems of the other Party. If, in the context of their mandate, such public authorities demand access to facilities or systems of the other Party, the other Party shall only have to provide access if required by law and after verifying identity and mandate, during normal business hours and upon reasonable prior written notice.
[Drafting note: this clause aims to address the (unlikely) event of inspections by a data protection authority or other regulatory bodies targeting either the controller or processor. The Company must ensure that the Institution permits such inspections to avoid liability for obstruction.]

8. REMUNERATION

8.1 The Company shall provide remuneration to the Institution as set out in Schedule C -

Remuneration, in consideration for the services to be provided by the Institution under the terms of this Agreement and upon receipt of a valid invoice, (a) fee(s) as set out below.

8.2 The amounts in this Agreement are in EURO, excluding VAT and [INCLUDING / EXCLUDING overhead]. Payments shall be made by the Company within thirty (30) days of receipt of a valid invoice.

Bank Details of the Institution:

Account number	
Bank account holder	
Account holder's address	
VAT number of the account holder	
Name and address of the Bank	
BIC/SWIFT code:	
IBAN number:	
Reference:	
Point of contact financial services	

Invoice will be billed to:

[Name of the Company]

[Address of the Company]

[VAT Number of the Company]

And will be sent to:

[E-mail address of the Company]

8.3 Disclosure of transfers of value shall only be done on a non-individual and aggregated basis in accordance with art. 42§1 and 43§1 of the Belgian Sunshine Act of December 18, 2016.

9. RELATIONSHIP BETWEEN THE PARTIES

9.1 The Parties shall at all times be and act as independent contractors. The Parties shall act in their own name and not make any representations for or on behalf of the other Party. This Agreement shall not be deemed to create any agency, distribution, employment, partnership or joint venture relationship between the Institution and the Company. Neither Party hereto shall have the power or authority to bind, commit or oblige the other Party in any manner whatsoever without the other Party's prior written consent or to use the other Party's name in any way not specifically authorized by this Agreement. No representations of either Party shall be binding upon the other Party, without the other Party's consent.

9.2 Each Party shall appoint individual(s), irrespective of whether they are employees, consultants, agents, contractors or sub-contractors (the Staff), that have the necessary qualifications, experience and skill required to duly perform under the Agreement.

9.3 Each Party shall at all times be and remain the sole employer of any employed Staff and shall assume any and all obligations (including but not limited, tax and social security), responsibilities and risks related to such employment and the possible termination thereof.

10. CONFIDENTIALITY

10.1 Each Party shall use all reasonable endeavours to keep strictly confidential (and shall divulge the Confidential Information only to its officers, employees, agents and professional and other advisers and Affiliates on a strict need-to-know basis and shall ensure that such officers, employees, agents and professional and other advisers and Affiliates are bound by equivalent confidentiality undertakings) any personal data processed for the other Party in the context of this Agreement, as well as any other information which relates to the contents of this Agreement or of any agreement or arrangement entered into pursuant to this Agreement. The receiving Party shall use the Confidential Information solely for the purpose of performing this Agreement. Neither Party shall use for its own business purposes or disclose to any third party any such information (collectively, Confidential Information) without the consent of the other Party.

10.2 Upon a Party's request or termination or expiration of this Agreement, the other Party shall promptly delete and/or return all Confidential Information. Notwithstanding the return and/or destruction of the Confidential Information, each Party will continue to be bound by its obligation of confidentiality and non-use under this Agreement until 5 years after the termination or expiration of this Agreement. Notwithstanding the termination or expiration of this Agreement by Company, Institution shall be allowed to retain 1 copy of the Confidential Information for the purpose of verification of compliance with this Agreement.

11. PUBLICITY

11.1 The Institution and the Company may not use any information other than publicly available information regarding the collaboration covered in the present Agreement in any publicity and advertising without the other Party's prior written consent.

12. INTELLECTUAL PROPERTY

[Drafting note: this clause has been simplified to reflect a standard scenario in which the intellectual property arising from the Agreement is expected to be limited in scope and commercial value. It provides for straightforward ownership, assignment, and licensing terms. However, if the Parties anticipate the development of significant or commercially valuable IP, this clause should be tweaked accordingly. This section remains subject to further negotiations and may require additional revisions to align with company internal policies and hospital/university organisations].

12.1 The Institution shall retain all right, title, and interest, including all Intellectual Property rights in and to the Data used for the analysis and preparation of the Report.

12.2 The Company shall be the sole and exclusive owner of all right, title, and interest, including all Intellectual Property rights, in and to the Report. The Institution hereby assigns to the Company, with full title guarantee, all such rights in the Report, effective upon its creation.

12.3 Nothing in this Agreement transfers ownership of Intellectual Property that the Parties owned prior to the effective date of this Agreement and/or developed outside of the performance of this Agreement (***Background IP***), even if contained in the Report Data.

For the avoidance of doubt, Institution's Background IP shall include but not be limited to any clinical procedure, improvements thereto that are clinical procedures owned by the Institution and database rights (including but not limited to patient files).

12.4 Subject to the confidentiality provisions of this Agreement, the Company hereby grants to the Institution a perpetual, worldwide, non-exclusive, non-transferable, non-assignable, and non-sublicensable right to use the Report Data for academic and ([**OPTIONAL**] commercial or non-commercial) Research Purposes, patient care purposes and, subject to Article 12.7, for publication purposes.

[Drafting note: due to different organizational structures at Institutions, there can be two options:
1° The Institution: to be used when the hospital and the university are one legal entity;
2° XXX: to be used when the hospital and the university are separate legal entities (wording for xxx is to be confirmed)].

12.5 The Institution warrants, to the best of its knowledge, that the Report Data and any Background IP, do not infringe any third-party rights, and that it has full authority to assign or license the Intellectual Property to the Company as set forth in this Agreement.

12.6 The Company will maintain the right to the first publication related to the Report for a period of six (6) months after the Report is shared by the Institution with Company.

12.7 The Institution may publish Report Data or results derived from the Report, subject to the following:

- a draft publication in the form of a manuscript shall be submitted to the Company at least forty-five (45) days prior to submission for publication and a draft of the publication in the form of an abstract, an oral communication or any other type of disclosure shall be

submitted to the Company at least twenty (20) days before the forecasted date of submission to the editor or to the organiser of a scientific meeting or of said other type of disclosure;

- The Company shall have the right to make comments on the content of the draft of the publication within thirty (30) days for a manuscript and fourteen (14) days for an abstract, an oral communication or any other type of disclosure, after the receipt of the draft of the publication, it being understood that Institution remains in full control over the content and editorial changes;
- The Institution shall, at the request of the Company, remove any Company's Confidential Information or Intellectual Property rights provided that it shall allow for information necessary to the appropriate scientific presentation or understanding of the results of the research.
- Should the Institution fail to erase Company's Confidential Information or Intellectual Property rights, the Company shall be entitled to refuse and impede the disclosure of the publication.
- If the Company did not respond within the delays granted to it in above provisions, the Institution may proceed with the Publication.

12.8 Any publication shall explicitly make reference to the publication made by the Company if any and, where applicable, acknowledge the Company's sponsorship and financial support of the research.

12.9 Both Parties shall comply with recognized ethical standards concerning publications and authorship, including the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, http://www.icmje.org/index.html#authorship, established by the International Committee of Medical Journal Editors (***ICMJE***) and agree that the authorship of any publications should be determined by the said requirements of ICMJE.

13. NOTIFICATION

13.1 All notifications under this Agreement, shall be carried out by e-mail, effective from the working day following the date of mailing, and addressed to the below-mentioned e-mail addresses of the Parties.

Institution

Address: [please complete]

Data Protection Officer: [please complete]

E-mail: [please complete]

Tel n°: [please complete]

For the attention of: [please complete]

Company

Address: [please complete]

E-mail: [please complete]

Tel n°: [please complete]

For the attention of: [please complete]

14. TERM

14.1 This Agreement will be effective on the Effective Date and will expire on [date], unless sooner terminated as provided herein or extended in mutual written agreement by the Parties.

14.2 Either Party shall promptly inform the other Party if it is unable to comply with the obligations under this Agreement, for whatever reason.

14.3 If the Company is in breach of its obligations under this Agreement or unable to comply with its obligations under this Agreement, the Institution shall suspend the processing of personal data to the Company until compliance is again ensured or terminate the Agreement in accordance with this Article 14.

14.4 Either Party can terminate this Agreement upon one (1) month prior written notice. [**OR**]

Each Party shall be entitled to terminate the Agreement with immediate effect without payment of any amount in the lieu if:

(a) the other Party is in material or persistent breach of this Agreement and fails to remedy such breach within thirty (30) days after notification of the breach by the other party, or

(b) the other Party fails to comply with a binding decision of a competent court or the competent supervisory authority regarding its obligations under this Agreement.

14.5 Clauses that are expected or intended by their nature to survive termination or expiration of this Agreement, shall survive the termination or the expiration of this Agreement.

15. INSURANCE AND INDEMNIFICATION

15.1 [OPTIONAL] The liability of both Parties under this Agreement shall be capped at [insert cap amount or formula], except in cases of gross negligence, wilful misconduct, or breach of Applicable Data Protection Law or of confidentiality obligations. Neither Party shall be liable for any indirect, consequential, or punitive damages, including but not limited to loss of profits, revenue, or business opportunities.

15.2 In case of any breach or alleged breach of this Agreement or any applicable laws, the liability of the Parties acting as joint controllers shall be non-severable and non-joint. Each Party shall be responsible only for its own actions, omissions, or breaches that contributed to the damage or loss.

15.3 Notwithstanding the foregoing, the Parties acknowledge that they may be held jointly and severally liable by third parties or regulatory authorities for breaches of data protection laws or other applicable regulations. In such cases, the Parties shall cooperate in good faith to determine the extent of each Party's responsibility and to allocate the liability accordingly.

15.4 This clause shall not limit or exclude any liability that cannot be limited or excluded under applicable law.

16. MISCELLANEOUS

Disclosure of transfer of values

16.1 The Institution acknowledges that the Company needs to adhere to the financial disclosure obligation on an aggregated basis in accordance with applicable laws.

Force majeure

16.2 Neither Party shall be held liable for non-fulfilment or delayed performance of this Agreement or of part thereof due directly or indirectly to any cause outside the reasonable control of either Party, and which the affected Party was reasonably unable to foresee at the time of the coming into force of this Agreement, provided that notice of its inability to perform and the causes thereof shall be given immediately by the affected Party to the other. If such inability to perform shall continue for a period of three (3) months, the other Party shall have the right to terminate this Agreement by written notice to the affected Party at any time thereafter.

Modification and waiver

16.3 No modification of this Agreement shall be deemed effective unless in writing and signed by each of the Parties hereto, and no waiver of any rights set forth herein shall be deemed effective unless in writing and signed by the Party against whom enforcement of the waiver is sought.

Non-assignment

16.4 Unless specifically agreed in writing, neither Party shall, nor shall purport to, assign, transfer, charge or otherwise deal with all or any of its rights and/or obligations under this Agreement, nor grant, declare, create or dispose of any right or interest in it, or sub-contract the performance of any of its obligations under this Agreement in whole or in part. Notwithstanding the foregoing, the Company may assign or transfer its rights and/or obligations under this Agreement to an Affiliate.

Invalidity

16.5 If any provision of this Agreement is, or is held to be, invalid or unenforceable, then, so far as it is invalid or unenforceable, it has no effect and is deemed not to be included in this Agreement. This

shall not invalidate any of the remaining provisions of this Agreement. The Parties shall then use all reasonable endeavours to replace the invalid or unenforceable provision by a valid and enforceable provision the effect of which is as close as possible to the intended effect of the invalid or unenforceable provision.

Warranties

16.6 Each Party shall be responsible towards the other Party for its obligations, representations or warranties under this Agreement and the Instructions.

16.7 Both Parties acknowledge that the signatories to this Agreement are authorized representatives of each of the Parties and legally authorized to sign this Agreement.

Anti-corruption

16.8 [OPTIONAL (subject to Company specific wording)] Each Party represents, warrants, and undertakes that, in connection with this Agreement and any activities related to it, neither it nor any of its directors, officers, employees, agents, subcontractors, or Affiliates has engaged, or will engage, in any activity that constitutes bribery, corruption, fraud, or any other unlawful conduct, including but not limited to conduct prohibited under:

(a) The U.S.Foreign Corrupt Practices Act:

(b) The UK Bribery Act 2010;

(c) The OECD Anti-Bribery Convention; and

(d) Any other relevant anti-bribery and anti-corruption laws applicable to either Party.

Records retention

16.9 [OPTIONAL (subject to Company specific wording)] Each party shall create, maintain and retain accurate records, documents and data (whether in physical or electronic form) related to this Agreement, including but not limited to:

(a) Personal data and processing records;

(b) Financial records, invoices, and payment documentation;

(c) adverse event reports, and pharmacovigilance records (if applicable);

(d) Research and development documentation;

(e) Compliance and audit records; and

(f) Any other records required to be maintained under applicable laws or regulations.

16.10 Unless a longer period is required by law or regulatory authorities, each Party agrees to retain all relevant records for a minimum period of [insert] years following:

(a) The termination or expiration of this Agreement, or

(b) The last use of the records for the purposes of this Agreement, whichever occurs later.

17. GOVERNING LAW AND DISPUTE RESOLUTION

17.1 This Agreement will be construed, governed, interpreted and enforced according to the laws of Belgium. All disputes arising out of or in relation to this Agreement will be brought before the competent courts of [insert relevant jurisdiction] Belgium.

*

This Agreement has been signed by the Parties on the date first mentioned above in [Place], in [number] original copies. Each Party hereby confirms having received one original copy. [[Name Party] and [Name Party] hereby unconditionally and irrevocably waive the application of section 8:20 of the Belgian Civil Code.]

The Parties agree that this contract may be signed electronically, in accordance with the eIDAS regulation (no. 910/2014) and the Belgian law of 21 July 2016. This electronic signature has the same legal value as a handwritten signature. Each Party will receive an original electronic copy of the signed contract. In the event of a dispute, the electronic records will be deemed authentic.

This agreement was signed electronically by the Parties via electronic signature on [**date**]. Each Party confirms having received an original electronic copy.

do not sign	*do not sign*
[Name] [Title] Represented by [Name] For the **Institution** [Title]	[Name] [Title] Represented by [Name] **For the Company** [Title]
do not sign	*do not sign*

[Name] [Title] Represented by [Name] [Title]	[Name] [Title] Represented by [Name] [Title]

SCHEDULE A – Instructions for Secondary Use of personal data

[Drafting note: This schedule is provided by way of example. Parties can choose to use their own templates, or adapt this example as the case requires.]

1. OBJECTIVE

[Drafting note: This section outlines the reason for the Report and the purpose for which the Data will be analysed and reported (or any related services provided by the Institution. This section could also present how the Report would contribute to the common good. This schedule is provided for illustrative purposes only and does not bind the Parties to the manner in which the instructions are formulated. The current wording may be more appropriate for a controller-processor relationship. In the case of joint controllership, we recommend that the Parties collaboratively draft these instructions.]

- ***Objective***: [Describe the goal of using the data (considering that it shall always be for scientific research)].
- ***Scope****:* [Define the boundaries of the Report (e.g., types of data (anonymous?, pseudonymous?) specific variables, time periods, or populations being studied).]

[Drafting note: See latest guidelines from the EDPB on pseudonymisation (public consultation)]

2. METHODOLOGY

[Drafting note: This section could contain several sub-sections. See for example below].

- ***Security measures***: [This sub-section could describe how the data should be securely managed to protect confidentiality and integrity to adhere to legal requirements (encryption, access control, storage, etc) It should also ensure establishing sufficient measures to protect.]
- ***Data minimisation measures***:[This sub-section could describe how to reduce the data to its minimal necessary to achieve the objective (anonymisation, pseudonymisation, retention policies, etc).]
- ***Statistical considerations***
- ***Reporting format and publication policy.***

[ONLY IF OPTION A] SCHEDULE B – DATA PROCESSING ADDENDUM

This Data Processing Addendum (the ***DPA***) is an integrated part of the Agreement on the secondary use of patient data for Research Purposes between [the Institution] and [the Company].

All defined terms within the Agreement shall have the same meaning when used in this DPA, unless explicitly defined otherwise in this Data Processing Addendum.

[Drafting note: In a controller-processor situation, Schedule B will be required to set out the mandatory contractual terms of Article 28 GDPR. By contrast, in a joint controller situation, the present Agreement would suffice to set out the "arrangement" under Article 26 GDPR. However, when handling situations that are more complex in terms of obligations and responsibilities of both parties (for instance in a federated learning context), it could be appropriate to use and adapt the schedule B in case of joint controllership situation.]

It has been agreed as follows:

1 The Institution acts as a ***Processor*** as defined under Article 4(8) GDPR for the Company who acts as ***Controller*** as defined under Article 4(7) GDPR, when the Institution processes personal data for the Company as set out in the Instructions (Schedule A). For these processing operations, the following provisions shall apply in compliance with Article 28 GDPR and in addition to the Parties' other obligations under the Agreement, which continue to apply to these processing operations.

This processing concerns the following types of personal data: [fill in the types of personal data concerned] **[OR]** [Refer to the relevant section of the Instructions];

This processing concerns the following data subject categories: [fill in the categories of data subjects concerned] **[OR]** [Refer to the relevant section of the Instructions].

2 The Processor is instructed to process the personal data for the term of this DPA and only for the purposes of providing the data processing tasks set out in the Instructions. Controller understands that Processor will perform these tasks using personal data that it already processes for medical records or other processing operations for which it acts a data controller. For the avoidance of doubt, Processor can continue to process these personal data for those purposes (in its capacity of data controller).

3 The Processor shall, in accordance with Article 5.6 of the Agreement, without undue delay inform the Controller upon discovering a personal data breach involving the personal data that it processes under this DPA. This notification will include sufficient details to enable the Controller to fulfil any reporting or notification requirements to data subjects under Applicable Data Protection Laws.

4 The Processor shall collaborate with the Controller and take all reasonable actions as directed by the Controller to assist in investigating, mitigating, and remedying any personal data breach.

5 The Processor shall at all times maintain a record of processing operations in accordance with Applicable Data Protection Laws and if the Processor considers an instruction from the Controller to be in violation of the Applicable Data Protection Laws, the Processor shall promptly inform the Controller in writing about this. The Processor will process the personal data only on documented instructions from the Controller, unless required to do so by Union or Member State law to which the Processor is subject. In such case, the Processor will inform the Controller of that legal

requirement before processing, unless that law prohibits such information on important grounds of public interest.

6 The Processor ensures that it provides sufficient guarantees to implement appropriate technical and organisational measures in such a manner that processing will meet the requirements of the GDPR and to protect the personal data of data subjects.

7 [The Controller authorizes the Processor in general to engage other processors (hereinafter "**Sub-processors**").] **OR** [The Processor shall not engage other processors (hereinafter "**Sub-processor"**) without prior specific written authorization of the Controller.]

8 If applicable, the Processor will inform the Controller in writing about the identity and contact details of its sub-Processors, about any modifications thereof, and about any intended changes concerning the addition or replacement of other sub-Processors. The Controller will be entitled to object to such changes.

9 If the Processor engages a sub-Processor, it will enter into a written agreement with this sub-Processor including the same or substantially equivalent obligations as those of the Processor's set forth in this Addendum and meeting the requirements of Article 28 GDPR, and the Processor shall remain fully liable vis-à-vis the Controller for the performance of the sub-Processor's obligations.

10 The Processor will respect the conditions referred to in Articles 28.2 and 28.4 GDPR for engaging a sub-Processor.

11 The Processor ensures that persons authorized to process the personal data are bound by a duty of confidentiality and non-use or are under an appropriate statutory obligation of confidentiality.

12 Taking into account the nature of the processing, the Processor will assist the Controller by appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of the Controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III GDPR.

13 The Processor will assist the Controller in ensuring compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of processing and the information available to the Processor.

14 The Processor will make available to the Controller all information necessary to demonstrate compliance with the obligations laid down in the GDPR, including Article 28 GDPR, and will allow for (and contribute to) audits, including inspections, conducted by the Controller and/or by an auditor mandated by the Controller. The Processor will immediately inform the Controller if, in its opinion, an instruction infringes the GDPR or other Union or Member State data protection provisions.

15 The Controller is entitled to appoint at its own cost an independent expert, reasonably acceptable to the Processor, who shall have access to the Processor's data processing facilities and receive the necessary information for the sole purpose of auditing whether the Processor has implemented and maintained said technical and organisational security measures. The expert shall upon the Processor's request sign a non-disclosure agreement provided by the Processor, and treat all information obtained or received from the Processor confidentially, and may only pass on, the findings of (a) breach of security that results in accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed by the Processor under the Agreement, or (b) other failure to comply with the Processor's obligations to the Controller.

In witness whereof, the Parties hereto have caused this Addendum to be executed by their duly authorized representative. This Addendum shall be binding on the Parties even if it is only executed and exchanged by electronic means.

[The Company], acting on its own behalf and on behalf of its Affiliates	**[The Institution]**, acting on its own behalf and on behalf of its Affiliates
Name:	Name:
Title:	Title:
Date:	Date:

SCHEDULE C – REMUNERATION

[IF APPLICABLE] SCHEDULE D – RELEVANT INFORMATION NOTICE

SCHEDULE E – PROTOCOL

[Drafting note: while a protocol for re-use of data can be substantially different from a protocol for a clinical trial, it would be good to have a common understanding of the minimum elements that should always be described.

The design and conduct of all studies involving the re-use of medical data should be clearly described in a research protocol. This protocol should contain a statement of the ethical issues involved and indicate how the principles of protection have been taken into account. In addition to information on funding, sponsors, institutional affiliations and potential conflicts of interest, the protocol should include an assessment of the scope of the research in terms of the public interest.]