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DECRETO DEL DIRETTORE GENERALE - N. 114-DG del 27/02/2024 - Allegato Utente 1 (A01)

Data Transfer Agreement (DTA)

This Data Transfer Agreement (the “Agreement”), with an effective date of the date of last signature (the “Effective Date”) is entered by and between :

Institut Jules Bordet having its office at rue Meylemeersch, 90, 1070 Anderlecht, Belgium, under registration number 0257.981.101, represented for the purposes hereof by R. Tollet, as President of the Board of Directors, and for the purpose of this Agreement by the General Director, by the General Medical Director and the Director of Research Administration;

Hereinafter referred to as “**the Provider**”

AND

Fondazione IRCCS Istituto Nazionale dei Tumori di Milano (“INT”), an European Comprehensive Cancer Center, that is engaged in the conduct of Cancer Biomedical Research Study, duly established and validly existing under Italian law, having its registered office at Via Venezian 1, 20133, Milan, Italy, represented by Dr. Carlo Nicora, General Manager

Hereinafter referred to as “**the Recipient**”

The Provider and the Recipient are hereinafter individually referred to as a “**Party**” or collectively referred to as the “**Parties**”.

INTRODUCTION

Whereas the Recipient and the Provider have decided to collaborate on a project entitled *ctDNA in operable HER2-low breast cancer* (hereinafter the “**Project**”) according to the agreed protocol, attached hereto and incorporated herein by reference as Appendix I, with Dr Michail Ignatiadis as **Principal Investigator** at Provider.

Whereas the Data belongs to the Provider;



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Whereas the Recipient wants to have access to the Data collected within the framework of the routine clinical practice to the Provider under the terms and conditions as set forth hereinafter;

NOW, THEREFORE, the Parties hereby agree as follows:

DEFINITIONS

The following are defined terms:

Background IP: the intellectual property rights either held prior to the Effective date or developed outside the Project.

Confidential Information: (a) all not public information and data in connection with the Project and/or the Biological Material and other not public information or not public data, including information derived from the Project and (b) any other not public information actually disclosed between the Provider and the Recipient, and which is (i) disclosed in tangible form and marked "Confidential" or "Proprietary" or similarly marked by the disclosing Party before disclosure to the receiving Party; or (ii) Confidential Information disclosed in intangible form such as electronically, orally or by visual inspection, and identified as confidential at the time of disclosure and summarized in writing by the disclosing Party within thirty (30) days of disclosure. Notwithstanding the forgoing, Confidential Information shall also include information which is obviously confidential in nature from context and subject matter or would appear to a reasonable person to be confidential.

Data: The Data listed in Appendix I. Data relating to patients shall remain confidential and no Data which would enable the Recipient to identify Data donors shall be provided by the Provider to the Recipient. The Data are owned by the Provider.

Effective Date: the last date on which this Agreement is executed by a duly authorized representative of the Parties;

Inventions: any and all inventions, know-how, materials, substances and other results conceived or generated by the Parties within the Project (whether patentable or not) and related to the Data or their use, or developed using the Data.



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Personnel: each person employed by a Party and who intervenes in the Project, including but not limited to sub-investigators, scientists/physicians, assistants, nurses and administrative personnel and who is not a subcontractor.

Results: all data, information, reports, or analysis generated or obtained as a result of conducting the Project using the Data.

TERMS & CONDITIONS

I. Transfer of Data

The Provider shall transfer the Data as defined here above to the Recipient within the timelines defined by the Parties.

II. Use of Data

1. The Data are provided for the internal, non-clinical purposes of the Project only, and shall not be used for any other purpose or commercially sponsored research, or shall not be transferred to any third party, commercial or not, except for the support of the validation of the Results or as otherwise agreed upon in written by the Parties.
2. The Provider warrants that the Project has obtained a positive opinion of the Ethics Committee (**CE2557**).
3. The Recipient warrants that the Personnel employed is qualified by training and experience to perform the Project and shall be responsible for the proper and safe storage of the Data in accordance with all and any instructions or advice which may be given by the Recipient or the Provider and in accordance with all applicable laws and regulations.
4. The Data must only be used by the Recipient or by its Personnel. The Recipient undertakes that the Personnel shall be aware of and bound by the terms of this Agreement. The Recipient undertakes that nobody else, except as expressly provided in this Agreement, shall have access to the Data.
5. For the avoidance of doubt, the Recipient and its Personnel agree that they shall not acquire any rights, title, or interest whatsoever in respect of the Data at all times, except as agreed upon in this Agreement.

III. Intellectual Property Rights



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It is understood and agreed that a Party may have Background Intellectual Property and that such Background Intellectual Property remains the sole property of such Party. For the avoidance of doubt, each Party shall retain the entire right, title, and interest in and to its respective Background Intellectual Property.

Each Party shall treat the other Party's Background Intellectual Property as Confidential Information belonging to that other Party.

Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any intellectual property rights of Provider.

The Provider hereby grants to the Recipient a non-exclusive, royalty-free, personal, non-assignable license to use such Data solely for the purposes of carrying out the Project and subject to the terms of this Agreement.

The Results shall be owned by both Parties. In the case that the Provider and the Recipient work together and that Results are developed jointly by the Parties, this section III (Intellectual Property Rights) does not apply and the intellectual property rights will be handled in a specific Jointly ownership agreement.

The Provider shall have the right to use the Project's data or Results for its internal non-commercial research or teaching purposes.

If the Project which involves the Data results in Inventions, all such Inventions shall be jointly owned by the Provider and Recipient. Inventorship and share in the joint ownership of such invention shall be determined in accordance with applicable patent laws. For the sake of clarity, the Recipient, in all circumstances, shall grant to the Provider a non-exclusive, royalty free, personal, non-assignable license to use such Inventions for its own internal non-commercial research or teaching purposes.

IV. Confidentiality

Confidential Information shall be treated, at all times, in strictest confidence by both Parties and shall not be disclosed to anyone other than its Personnel.

Neither the Provider nor the Recipient shall have any obligation of confidentiality with respect to information that:

- a) has become public knowledge other than through an unauthorised disclosure by the receiving Party;
- b) was already in the possession of the receiving Party in recorded or other verifiable form prior to being disclosed;



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- c) was disclosed to the receiving Party by a third party not under a confidentiality obligation to the disclosing Party;
- d) was expressly authorised by the disclosing Party in writing to be released from confidential status;
- e) was independently developed, according to his/her records, by the receiving Party or its Personnel, without the support of the Confidential Information of the disclosing Party; or
- f) is required to be disclosed by law or by a requirement of a regulatory body or the information is required to be disclosed by a court or administrative order. The receiving Party will furnish prompt and prior written notice of such requirement to the disclosing Party and will cooperate with the disclosing Party in contesting a disclosure.

The receiving Party undertakes to only provide its Personnel with the Confidential Information strictly necessary for the accomplishment of their tasks. The Personnel shall be subject to these same obligations of confidentiality and restricted use.

This provision will survive the termination of this Agreement for ten (10) years.

V. Data protection

The Parties agree that they are **joint controllers** as defined in **Article 26 of the Regulation (EU) 2016/679 of the European Parliament and of the Council** (General Data Protection Regulation 2016/679, hereafter referred to as the “GDPR”). The Parties acknowledge that they jointly determine the purposes and means of processing of personal data.

The Parties shall process the personal data in accordance with the GDPR. The Parties agree to not process the personal data for any purpose other than to perform the Project and its obligations under the Agreement.

The personal data that shall be processed by the Parties for the Project and the categories of data subjects shall be described in the Protocol, attached as Appendix I.

The Parties acknowledge that the data subjects are entitled to exercise their rights under the GDPR against both Parties.

The Parties agree that the point of contact who can be contacted in respect of queries or complaints regarding the processing of the data subjects’ personal data and GDPR compliance is the Data Protection Officer at the Provider (dpo@bordet.be).



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In addition, the Parties shall:

- implement appropriate technical and organizational means to protect the personal data against unauthorized or unlawful processing, loss, damage, or destruction, and to evaluate at regular intervals the adequacy of such security measures, amending these measures where necessary;
- not disclose the personal data to any person other than its Personnel as necessary to perform its obligations under this Agreement and ensure that such Personnel is subject to statutory or contractual confidentiality obligations;
- ensure that access, inspection, processing and provision of the personal data shall take place only in accordance with the need-to-know principle, i.e. information shall be provided only to those persons who require the personal data for their work in relation to the performance of this Agreement;

The Parties acknowledge that subcontractors and third-party collaborators, if any, that perform part of the Project shall act as processors (as defined in GDPR). The Recipient shall be responsible for concluding a written agreement with the processors, in which at least the same data protection obligations as set out in this Agreement shall be imposed on the processors, including obligations to implement appropriate technical and organizational measures. The Provider has the right to receive a copy of the relevant provisions of the data processing agreement with the processors related to data protection obligations. The Recipient shall remain fully liable to the Provider for the performance of the processors' obligations and compliance with the GDPR.

The Recipient agrees not to analyze or make any use of the Biological Materials in such a way that has the potential to:

- (a) lead to the identification of any patient; or
- (b) compromise the confidentiality of any patient in any way.

Personal data processed in the context of this Agreement may not be transferred to a country outside the European Economic Area unless expressly agreed between the Parties. If personal data processed under this Agreement is transferred from a country within the European Economic Area to a country outside European Economic Area, the parties shall ensure that the personal data are adequately protected. To achieve this, the parties shall, unless agreed otherwise, rely on EU approved standard contractual clauses for the transfer of personal data.

Each Party will be held responsible for any damages resulting from failure to comply with its obligations under this Agreement and the GDPR.

VI. Publications



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Results from Recipient's assessment shall be publicly disseminated by publications and presentations.

Authorship of publications and acknowledgement of contributions shall be in accordance with standard academic and scientific practices.

The Parties agree that the Provider and the Recipient shall be co-authors of any and all publications.

A Party seeking to publish or present the Results shall provide a draft to the other Party for comment and approval at least thirty (30) days in advance of an anticipated submission. If the other Party does not object within the thirty (30) days, the submitting Party is free to submit and then subsequently publish the submitted material.

However, if the other Party objects for any reason, including, but not limited to, the fact that the submission contains Confidential Information or patentable subject matter, the submitting Party shall refrain from submitting the document for an additional ninety (90) days. In any case, the objecting Party may require that any Confidential Information not previously published be removed entirely from the publication submission, at least for the period of confidentiality as set forth in Section IV.

VII. Term

This Agreement (the "Term") shall remain in force until the termination of the Project, unless earlier terminated. The Term may be extended, in writing, for one (1) year to accommodate additional transfers. It is anticipated that transfer of additional Data may involve additional or modified terms and the Parties shall negotiate said terms in good faith.

In case an event prevents pursuing this Agreement, the Parties will agree on termination terms.

On termination of this Agreement, all Confidential Information, whether in documentary, permanent or machine-readable form, including any copies of all or any part thereof shall be returned to the providing Party within thirty (30) days or destroyed within forty-five (45) days upon a written confirmation sent by the disclosing Party to the receiving Party, save that the receiving Party may retain one copy of such Confidential Information solely for record-keeping purposes.

VIII. Liability



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Except to the extent prohibited by law, the Recipient assumes all liability for any and all claims, suits and liabilities arising from any use, storage or disposal of the Data by the Recipient or its Personnel. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Data by the Recipient, except to the extent permitted by law for damages caused by gross negligence or the willful misconduct of the Provider.

The liability of either Party for any breach of such Party's obligations under this Agreement will in no event extend to any indirect damages or losses, or to any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity (whether direct or indirect), even if the other Party has advised such Party of the possibility of those losses, or even if they were within such Party's contemplation.

IX. Miscellaneous

1. This Agreement shall be construed in accordance with and governed by the laws of Belgium;
2. The Provider and the Recipient shall endeavour, in good faith, to settle amicably any dispute. If the Provider and the Recipient have not reached a settlement of such dispute within ninety (90) days of written notice by one to the other of such dispute, the territorially competent court shall be that of the place where the defendant resides. The applicable law will be the national law of the defendant court.
3. This Agreement shall be executed in counterparts, each of which shall be deemed an original and which shall constitute one and the same agreement. Each party declares having received an original thereof. Any modification or renewal of this Agreement shall be in a writing signed by all parties.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

<p>On behalf of the PROVIDER</p> <p>DocuSigned by: <i>Renaud Witmeur</i> 357E44C3FEBA4F2...</p> <p>Name: Renaud Witmeur Title: General Director</p> <p>DocuSigned by: <i>Jean-Michel Hougardy</i> C6DA43734B034E8...</p> <p>Name: Jean-Michel Hougardy Title: Medical General Director 5/2/2024</p> <p>DocuSigned by: <i>Marielle Sautois</i> E68E0031ACBD456...</p> <p>Name: Marielle Sautois Title: Director of Research Administration 5/2/2024</p>	<p>Read and acknowledged by: The INVESTIGATOR</p> <p>DocuSigned by: <i>Michail Ignatiadis</i> 7D15F40D993A43A...</p> <p>Name: Dr Michail Ignatiadis Title : Clinical Investigator</p> <p>Read and acknowledged by : The HEAD OF DEPARTMENT</p> <p>DocuSigned by: <i>Awada Ahmad</i> BA213EEC9C514B0...</p> <p>Name : Dr Ahmad H. Awada Title Head of department 31/1/2024</p>
<p>On behalf of the RECIPIENT</p> <p>Name: Carlo Nicora Title: General Manager Date:</p> <p>Date:</p>	<p>Read and Acknowledged by:</p> <p>Name: Serena Di Cosimo Title: Investigator Date: 12/2/2024</p> <p>DocuSigned by: <i>Serena Di Cosimo</i> 015950C530924E5...</p>



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	<p>Name: Paolo Verderio</p> <p>Title: Investigator</p> <p>Date: 14/2/2024</p> <p>DocuSigned by: <i>Paolo Verderio</i> 4BC5EFE11EE547E...</p>
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Appendix I – Project

Protocol is incorporated herein by reference.



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Appendix II – Joint Processing Agreement

This Joint Processing Agreement, including any Annex 1 hereto, (together the “Joint Processing Agreement”) is an integrated part of the Agreement.

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

Preamble and Scope of the Joint processing agreement

The parties agree on the importance of protecting the right to privacy and declare that they are aware of the legislation on the protection of personal data.

In order to comply with this legislation and in particular Article 26 of the European General Data Protection Regulation (hereinafter referred to as "GDPR"), the Parties have agreed to draw up this Joint Processing Agreement in order to specify the rights and obligations of each of them in terms of the protection of personal data which arise from the main contract(s) in force or to come.

With this in mind, the following has been agreed.

1. Purpose

The purpose of this Joint Processing Agreement is to define the rights and obligations of the Parties acting as Joint Controllers of personal data processing under one or more main contracts, and in particular in the course of activities in which persons under their responsibility process or have access to personal data on their behalf, but also with regard to their respective obligations concerning the communication of information to data subjects, the management of their consents, the exercise of their rights, notifications of personal data breaches and other exchanges with the competent supervisory authority.

2. Definitions

For the purposes of this Joint Processing Agreement and its Annex 1, the terms used shall have the meaning assigned to them by the GDPR and the Law of July 30, 2018 on the protection of individuals with regard to the processing of personal data.



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3. Determination of the processing operation(s)

The Parties agree to jointly carry out the processing operation(s) of personal data defined in Annex 1.

Any addition, deletion of processing or modification of one of the characteristics of a processing operation listed in the appendix will give rise to an amendment to this Joint Processing Agreement.

4. Commitments of the Parties

4.1. General commitments

4.1.1. The Parties undertake to process Personal Data in accordance with the Data Protection Legislation (as in force) and to :

- Not to do or allow anything that may imply that the other Party is in any way violating the Data Protection Legislation in any way, and
- Inform the other Party immediately if either Party considers that any action taken by the other Party constitutes a breach of the GDPR or any other provision of Union or Member State law relating to data protection;

4.1.2. For Personal Data processed by the Parties under this Agreement, each Party undertakes and shall ensure that its representatives, collaborators or employees as well as its own subcontractors and their representatives, collaborators or employees comply with the commitments detailed in this Agreement.

4.1.3. The Parties warrant to each other that they, their representatives, collaborators or employees and their own subcontractors and their representatives, collaborators or employees have the necessary legal competence to carry out the processing in the countries where the processing of personal data is carried out in accordance with this Joint Processing Agreement and the Agreement, and ensure that they are in compliance with the data protection legislation applicable in that country.

4.2. Record of Processing Activities

The Parties undertake to establish and maintain a register of processing activities that includes at least the elements listed in Article 30.2 of the GDPR.

4.3. Technical and organizational measures



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4.3.1. The Parties undertake to implement appropriate technical and organizational measures and shall ensure that their representatives, collaborators or employees as well as their own subcontractors and their representatives, collaborators or employees implement such measures in order to guarantee a level of protection appropriate to the risk associated with the processing operation(s). Such measures shall in particular protect personal data against accidental or unlawful destruction, loss, alteration, unauthorized disclosure or access. They shall take into account the state of the art and the nature, scope, context and purpose of the processing as well as the risk and damage that may result from it.

4.3.2. The Parties undertake in particular to ensure that access to personal data is limited exclusively to those persons for whom it is necessary for the purposes of the main contract, while ensuring that such persons :

- are informed of the confidential nature of the personal data ;
- have received appropriate training in data protection legislation;
- are subject to confidentiality provisions or a legal or professional obligation of confidentiality.

4.3.3. The Parties shall keep all personal data and resulting analyses, profiles or documents separate from other data belonging to the Parties or to third parties.

4.4. Information and consent of data subjects

4.4.1. The Party in charge of data collection shall disseminate all necessary information to data subjects when data are collected directly from them. It also ensures that it obtains the consent of these persons (if applicable). The documents relating to the information of the data subjects and the consent form (if any) are drafted by the Party defined in the Annex 1.

4.4.2. Where data is not collected directly from data subjects, the dissemination of information will be carried out in accordance with Article 14 of the GDPR and will be the responsibility of the Party or Parties defined in the Annex 1.

4.5. Personal Data Breach Management and Notification

4.5.1. The Parties undertake to inform each other of any Personal Data Breach (or of circumstances that could possibly lead to a Personal Data Breach) as soon as possible after becoming aware of it.



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If necessary, the Parties will exchange the information and documentation necessary to draft the notification and will validate the final version before sending it to the competent authority. If the notification is incomplete at the end of the 72-hour period or has not been validated by the Parties, it will be notified with provisional status and will be followed by a supplementary notification once all the information has been collected and the notification has been validated by all the Parties. This validation must be carried out within the time limit set by the competent authority for responding, failing which it will be notified, incorporating any reservations of the Parties, as attached.

4.5.2. Any notification to the competent control authority shall be the responsibility of the Party or Parties defined in the Annex. The notification shall include at least the information required by the competent control authority.

4.5.3. The Parties also undertake to cooperate and take the necessary measures to facilitate the investigation, mitigation and correction of any personal data breach.

4.6. Management of data subject rights requests

Each Party shall assume the obligation to respond to requests for the exercise of data subjects' rights that it receives.

For the purpose of enabling each Party to respond to data subject requests, the Parties agree to cooperate so that each Party may respond to requests, in accordance with data protection law, including:

- transmit by e-mail to the contact persons mentioned in the Annex I all the information requested within 5 working days from the receipt of the request;
- provide, if necessary, the information on the requested medium to enable the Party processing the request to respond within the time limit provided for by the data protection regulations; and
- implement technical and organizational measures to ensure that each Party is able to respond effectively to relevant requests.

4.7. Use of Subcontractors

4.7.1. The Parties may jointly use a processor where the processor has been appointed by mutual agreement and in accordance with the Parties' instructions.



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4.7.2. The Parties agree not to individually use a processor to process Personal Data without the prior written consent of the other Party, and subject to:

- providing the other Party with full details of the processing that is intended to be carried out by the processor;
- providing evidence that the contract to be entered into with the subcontractor contains obligations identical to those set out in this Master Agreement;
- to assume, for the Party that decides to subcontract, full responsibility towards the data subjects, the competent supervisory authority and the other Party for any failure of the subcontractor to comply with its obligations under this Joint Processing Agreement.

4.8. Transmission of data to third parties

4.8.1. The Parties may jointly transfer (or facilitate the transfer of) Personal Data to the following third parties, where they are not subcontractors :

- Those jointly designated by the Parties and in accordance with their instructions ; or
- Those required by a European Union law applicable to one of the Parties or a legal provision of a Member State.

4.8.2. The Parties undertake not to transfer personal data to third parties, other than subcontractors, independently of the other Party, without the prior written consent of the other Parties, and subject to:

- providing the other Party with all details specific to the intended transfer (including the personal data transferred, the data subjects, the identity of the third party recipient(s) and the basis for lawfulness) and providing evidence that the contract to be entered into with the third party contains obligations identical to those set forth in this Master Agreement.

If the transfer is required by an applicable Union law or a legal provision of a Member State, the Party affected by the legal obligation shall only notify the other Party of the existence of such legal obligation prior to the processing of the personal data;

- to assume, for the transferring Party, full responsibility towards the data subjects, the competent supervisory authority and the other Party for any breach of its obligations under this Joint Processing Agreement.



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4.9. Transfer of personal data to third countries

4.9.1 The Parties shall comply with the provisions of Articles 46 to 49 of the GDPR, for any joint processing requiring a transfer of data to a country outside the European Economic Area and not included in the European Commission's list of suitable countries. In particular, the transfer will have to be based on the Commission's standard contractual clauses or other mechanisms provided for in order to ensure appropriate protection of the personal data transferred.

4.9. 2 The Parties undertake not to transfer personal data individually to a country outside the European Economic Area and not included in the Commission's list of suitable countries without the prior written consent of the other Parties, unless the transfer is required by an applicable Union law or a legal provision of a Member State, in which case the Party subject to the legal obligation shall notify the other Party prior to the processing of the personal data of the existence of such legal obligation, unless such legislation prohibits such notification on important public interest grounds.

If the transfer is required by an applicable European Union law or a legal provision of a Member State, the transferring Party will assume the full obligations of the controller to the data subjects, the competent supervisory authority and the other Party or Parties in accordance with Article 7 of this Joint Processing Agreement.

4.10. Relationship with the competent supervisory authority

4.10.1 The Parties shall cooperate and support each other with respect to :

- Any prior agreement to be obtained from the relevant supervisory authority ;
- Any complaint, accusation or request from the competent supervisory authority regarding the joint processing of personal data.

4.10.2 The Parties shall provide each other with all the necessary cooperation and assistance that may reasonably be expected in this context, including the provision of all necessary information and the joint preparation of documentation to be submitted to the competent supervisory authority, within 10 working days prior to the deadline set by the latter, or within a shorter period of time in the event of a complaint, accusation or request.

4.10.3. The Party in charge of the exchanges with the competent control authority is defined in the Annex.

4.11. Monitoring



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Without prejudice to the other provisions of this Joint Processing Agreement and the Agreement, each Party may, subject to notification by e-mail to the relevant contact person listed in the Annex, request a written and detailed description of the technical and organizational measures used by the other Party and its subcontractors / the other Parties and their subcontractors in connection with the processing of personal data. Within 20 working days of receipt of the written request, the Party in question shall provide the other Party / Parties with a written report in sufficient detail to reasonably verify whether the personal data concerned are or have been processed in accordance with the data protection legislation.

The findings of the report may give rise to an examination at a date to be determined by mutual agreement, but within a period of less than six weeks after the report is submitted to the requesting Party.

5. Termination Provisions

Subject to the contractual termination provisions of the Agreement, the Party ceasing to jointly process Personal Data shall be entitled to recover all Personal Data for which it is a data controller, with the other Party(ies) retaining it only if it is/they are also a data controller.

Failing this, the other Party/Parties undertake to completely and securely erase the personal data and any copies of such data or information contained therein (such that the personal data can no longer be reconstructed or repaired) within a maximum period of 1 month from the end of the main contract(s). It shall be confirmed in writing that this obligation has been duly complied with.

6. Liability

Each of the Parties shall comply with Article 82 of the GDPR as to the right to redress and liability.

Where one of the Parties has borne the full cost of the misapplication of the data protection regulation or has fully compensated the damage suffered by the data subject, it shall be entitled to claim from the other Party/Parties the share of the compensation corresponding to its share of responsibility for the damage. This apportionment of liability is defined in the annex.

The compensation is subject to the following conditions



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- The Party sued communicates the complaint as soon as possible to the other Party / Parties; and
- The latter/latters is/are given the opportunity to cooperate with the former in the defence or settlement of the complaint.



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Annex 1 – INFORMATION ON THE PERSONAL DATA PROCESSING OPERATION(S) CARRIED OUT BY THE JOINT CONTROLLERS

1) Contact details

1.1) Contact person for **Provider**

Surname & First name: Marielle Sautois
Function: Director of Research Administration
E-mail address: marielle.sautois@hubruxelles.be
Telephone : (+32) 02 541 32 14

1.2) Data Protection Officer for **Provider** (if applicable)

Surname & First name: Yasmina Coomans
E-mail address: dpo@hubruxelles.be
Telephone: (+32) 02 555 68 64

1.3) Contact person for **Recipient**

Surname & First Name: Serena Di Cosimo
Function : Clinical Investigator
E-mail address : Serena.DiCosimo@istitutotumori.mi.it
Telephone :

Surname & First Name: Paolo Verderio
Function : Clinical Investigator
E-mail address : Serena.DiCosimo@istitutotumori.mi.it
Telephone :

1.4) Data Protection Officer for **Recipient** (if applicable)

Surname & First Name:
E-mail address:
Telephone:

If, during the term of the main contract(s), another contact person is appointed, the Party making the change shall inform the other Party(ies) within a maximum of 5 working days of the appointment.

2) Joint Processing No. 1

2.1) Contractual reference document (or main contract)

Data Transfer Agreement



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2.2) Nature of the processing on personal data

The nature of the Processing is mandatory, since it is necessary in order to reach the internal, non-clinical purposes of the Project.

2.2.1) Nature of operations and allocation of responsibility:

Data Operations	Allocation of Responsibility	
	Provider	Recipient
Collection	50 %	50 %
Encoding	50 %	50 %
Storage	0 %	100 %
Consultation	50 %	50 %
Modification	N/A	N/A
Extraction	N/A	N/A
Transfer	50 %	50 %
Communication	50 %	50 %
Archiving	N/A	N/A
Destruction	N/A	N/A
Other(s) :		

N/A: Not applicable

2.2.2) Duration of the study :

☒ Duration of the main contract

☐ Other:

.....

2.2.3) Destination of the data at the end of the processing:

☐ Destruction of data

☐ Return of data to the controller

☒ Other:

.....

2.2.4) Location of data:

☐ European Economic Area or country included by the Commission in the list of suitable countries.

☒ Other:

.....

2.3) Purpose of processing (only one purpose per processing operation)



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Specify the purpose: As planned by the original studies approved by the ethical committee.....
....

2.4) Lawful basis of processing

Specify the lawful basis: Consent of Data Subject

2.5) Category(ies) of personal data processed and of data subjects

☐ Identification data

(Data subjects:)

☐ Unique Social Security Identification Number (NISS)

(Data subjects:)

☐ Social data

(Data subjects:)

☐ Financial data

(Data subjects:)

☐ Insurability data

(Data subjects:)

☒ Health data

(Data subjects: As reported in the Appendix 1)

☐ Educational or occupational data

(Data subjects:)

☐ Other types of data:

.....
(Data subjects:)

2.6) Division of obligations between the Parties

Operations on data	Party(ies) in charge	
Drafting of information documents to affected individuals	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient
Drafting the consent form	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient
Informing data subjects when data are not collected directly from them	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient
Notification of personal data breaches	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient
Handling of requests to exercise rights of data subjects	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient



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Handling of exchanges with the competent supervisory authority	<input checked="" type="checkbox"/> Provider	<input checked="" type="checkbox"/> Recipient
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Certificato di completamento

ID busta: 93172ED2D1C04F2D9847971F71213C77

Stato: Inviato

Oggetto: Complétez l'enveloppe avec DocuSign : DTA_JB_INT_01_2024_final31012024_N°4725

Busta d'origine:

Pagine documento: 23

Firme: 7

Creatore busta:

Pagine certificato: 9

Iniziali: 0

Administrative Assistants - CTC

Firma guidata: Abilitato

administrative.assistants.ctsu@hubruxelles.be

Timbro ID busta: Abilitato

Indirizzo IP: 193.191.184.200

Fuso orario: (UTC+01:00) Bruxelles, Copenaghen, Madrid, Parigi

Verifica record

Stato: Originale

Proprietario: Administrative Assistants - CTC

Posizione: DocuSign

31/01/2024 12:09:02

administrative.assistants.ctsu@hubruxelles.be

Firmatario - Eventi**Firma****Timestamp**

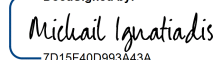
Michail Ignatiadis

michail.ignatiadis@hubruxelles.be

Prof

Livello di protezione: E-mail, Autenticazione account
(nessuna)

DocuSigned by:


7D15F40D993A43A...

Inviato: 31/01/2024 13:15:28

Visualizzato: 31/01/2024 13:18:16

Firmato: 31/01/2024 13:19:07

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Mediante l'indirizzo IP: 193.191.184.202

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Accettato: 15/01/2024 17:20:21

ID: cbb60db3-e1d9-4200-8917-f348ffaa9e5b

Awada Ahmad


ahmad.hussein.awada@hubruxelles.be

Head of Oncology Department

Institut Jules Bordet

Livello di protezione: E-mail, Autenticazione account
(nessuna)

DocuSigned by:


BA213EEC9C514B0...

Inviato: 31/01/2024 13:19:11

Visualizzato: 31/01/2024 13:32:27

Firmato: 31/01/2024 13:32:41

Scelta della firma: Stile preselezionato

Mediante l'indirizzo IP: 193.191.184.202

Record elettronico e divulgazione della firma:

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Marielle Sautois

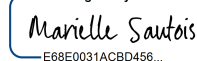
marielle.sautois@hubruxelles.be

Directrice Administrative de la Recherche

H.U.B.

Livello di protezione: E-mail, Autenticazione account
(nessuna)

DocuSigned by:


E68E0031ACBD456...

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Visualizzato: 05/02/2024 08:04:39

Firmato: 05/02/2024 08:04:47

Scelta della firma: Stile preselezionato

Mediante l'indirizzo IP: 193.191.184.202

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Accettato: 05/07/2022 16:54:35

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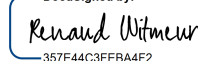
Renaud Witmeur

renaud.witmeur@hubruxelles.be

RW

Livello di protezione: E-mail, Autenticazione account
(nessuna)

DocuSigned by:


357E44C3FEB44F2...

Inviato: 05/02/2024 08:04:52

Visualizzato: 05/02/2024 08:05:04

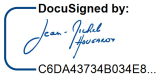
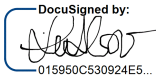
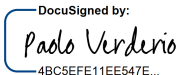
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Mediante l'indirizzo IP: 109.88.66.54

Firmato tramite mobile

Record elettronico e divulgazione della firma:

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Accettato: 08/07/2022 13:37:31 ID: 39ad787b-ea9d-492a-9b28-7f1976f7ea56 Jean-Michel Hougardy Jean-Michel.Hougardy@hubruxelles.be General Medical Director Livello di protezione: E-mail, Autenticazione account (nessuna)	 Scelta della firma: Immagine della firma caricata Mediante l'indirizzo IP: 104.28.40.7 Firmato tramite mobile	Inviato: 05/02/2024 08:05:18 Visualizzato: 05/02/2024 08:41:15 Firmato: 05/02/2024 08:41:23
Record elettronico e divulgazione della firma:		
Accettato: 16/06/2023 14:55:53 ID: 7caaa262-647b-4275-a892-4fbbc806ec84 Serena Di Cosimo Serena.DiCosimo@istitutotumori.mi.it Livello di protezione: E-mail, Autenticazione account (nessuna)	 Scelta della firma: Tracciata sul dispositivo Mediante l'indirizzo IP: 193.206.16.201	Inviato: 12/02/2024 14:47:51 Rinvio: 12/02/2024 14:48:27 Visualizzato: 12/02/2024 16:02:16 Firmato: 12/02/2024 16:02:32
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Accettato: 12/02/2024 16:02:16 ID: a35cc600-104d-4487-9a7e-8b137249018f Paolo Verderio Paolo.Verderio@istitutotumori.mi.it Livello di protezione: E-mail, Autenticazione account (nessuna)	 Scelta della firma: Stile preselezionato Mediante l'indirizzo IP: 193.206.16.200	Inviato: 12/02/2024 16:02:41 Visualizzato: 14/02/2024 10:43:21 Firmato: 14/02/2024 10:45:10
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Record elettronico e divulgazione della firma:		
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Agente - Eventi recapito	Stato	Timestamp
Recapito intermedio - Eventi	Stato	Timestamp
Recapito consegna certificata - Eventi	Stato	Timestamp
Copia nascosta - Eventi	Stato	Timestamp

Copia nascosta - Eventi	Stato	Timestamp
Hortense Devroede hortense.devroede@hubruelles.be Juriste CTSU - Institut Jules bordet Livello di protezione: E-mail, Autenticazione account (nessuna) Record elettronico e divulgazione della firma: Non disponibile tramite DocuSign Administrative Assistants - CTC administrative.assistants.ctsu@hubruelles.be Livello di protezione: E-mail, Autenticazione account (nessuna) Record elettronico e divulgazione della firma: Non disponibile tramite DocuSign Alessandro Sambiase Segreteria.TTO@istitutotumori.mi.it Livello di protezione: E-mail, Autenticazione account (nessuna) Record elettronico e divulgazione della firma: Non disponibile tramite DocuSign	In copia	Inviato: 31/01/2024 13:15:26 Visualizzato: 31/01/2024 13:34:46

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Pubblico ufficiale - Eventi	Firma	Timestamp
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Riepilogo busta - Eventi	Stato	Data e ora
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Busta aggiornata	Controllo protezione eseguito	06/02/2024 15:55:06
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Consegna certificata	Controllo protezione eseguito	08/02/2024 14:10:16

Eventi di pagamento	Stato	Data e ora
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