

**CONTRACT FOR THE PERFORMANCE OF OBSERVATIONAL STUDIES WITH MEDICINAL PRODUCTS
FOR HUMAN USE
Protocol Code: [•]**

BY AND BETWEEN

Hospital Universitari Vall d'Hebron (hereinafter, "**HUVH**"), with address at Passeig Vall d'Hebron 119-129, Barcelona (08035), represented by Dr. Albert Salazar i Soler, in his capacity of Chief Executive Officer (CEO) of the HUVH.

Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca (hereinafter, "**VHIR**"), with NIF G-60594009 and address at Passeig Vall d'Hebron 119-129, Edifici Central, Barcelona (08035), represented by Dr. Begoña Benito Villabriga, in her capacity as Director of the VHIR.

Fundación Privada Instituto de Investigación Oncológica de Vall Hebron (hereinafter, "**VHIO**"), with CIF G-64384969 and address in c\ Natzaret 115-117, Centre Cellex, 08035 Barcelona, represented by Dr. Carles Constante, in his capacity as the Managing Director of the VHIO.

[•] (hereinafter, "**Sponsor**"), with NIF [•] and address at [•], represented by [•], in their capacity as [•] of the Sponsor.

[•] (hereinafter, "**CRO**"), with NIF [•] and address at [•], represented by [•], in their capacity as [•] of the CRO.

All the aforementioned participants may be referred to jointly as the "**Parties**" and individually as "**Party**".

All Parties hereby mutually acknowledge their respective legal capacity to bind themselves through this clinical study contract (hereinafter, "**Contract**") and,

WITNESSETH

- I. Whereas the HUVH is part of the Institut Català de la Salut (hereinafter, "**ICS**"). The ICS is a public company of the Generalitat de Catalunya attached to the Health public department of Catalonia (Spain), with its own legal personality, whose objective is to provide public, preventative, primary, diagnostic, therapeutic, rehabilitative, palliative

healthcare services to the general public, as well as developing educational and research activities corresponding to the life sciences, among others. In the performance of its functions, the ICS manages the HUVH.

- II. Whereas the VHIR is a foundation of the public sector, whose purpose is to promote and develop biomedical research, innovation and teaching at the HUVH. Through the excellence of its research, new solutions to the health problems of society are identified and applied, and the results are spread throughout the world.
- III. Whereas VHIO is a fully independent non-profit private foundation, with its own legal personality, whose objective is high-quality research in the area of oncological diseases, specifically research related to new advances in the prevention, early diagnosis and treatment of cancer, with a translational focus that permits the application of basic research discoveries to clinical practice.
- IV. Whereas on 1 May 2015, the ICS, the HUVH, the VHIR and the VHIO signed a framework scientific-collaboration agreement which regulates the collaboration relationships among the four entities and stipulates that the VHIO shall manage the Clinical Trials in which the Principal Investigator, whether a Medical-Oncology Service physician or other HUVH medical practitioner who carries out his research activity in the VHIO (hereinafter, 'HUVH Oncology Trials'), and the VHIR shall manage the financial expenses associated with indirect costs, charges and fees associated with the performance of the HUVH Oncology Trials.
- V. That subsequently on dates January 31, 2017 and August 27, 2018 the transfers of personnel and management of the research activity of the Adult Clinical Hematology and Radiation Oncology services of HUVH to VHIO were formalized, all of them becoming treated as HUVH Oncology Trials. On January 29, 2019, the assignment of the Oncology and Hematology Pharmacy Unit to VHIO was formalized.
- VI. Whereas on July 11, 2025, the ICS, the VHIR and the VHIO signed a framework agreement for scientific collaboration between the *Institut Català de la Salut* (ICS), the *Fundació Hospital Universitari Vall d'Hebron – Institut de Recerca* (VHIR) and the *Fundació Privada "Institut d'Investigació Oncològica de Vall d'Hebron"* (VHIO), in the field of the Hospital Universitari Vall d'Hebron (HUVH). This agreement establishes that, as of January 1, 2026, the VHIO will be the entity responsible for preparing and monitoring all billing derived from its assigned research activities, including clinical trials conducted by the Medical Oncology, Adult Clinical Hematology and Radiation Oncology departments at HUVH.
- VII. Whereas the Sponsor is interested in sponsoring the observational study with medicinal products for human use described in the Protocol (the '**Product**')

VIII. Whereas the Dr [•] (the “Principal Investigator”), member of the [•] Service of the HUVH and researcher of the VHIO, is interested in conducting this post-authorization study under the terms and conditions set out below.

In accordance with the foregoing, all of the Parties hereby agree the following

CLAUSES

1. PURPOSE OF THE AGREEMENT

The Principal Investigator agrees to conduct the post-authorization study proposed by the Sponsor of the study, in accordance with the characteristics described in the Protocol under the Protocol Code: [•] (hereinafter, “Protocol”), whose title is [•] (hereinafter, “Study”).

The Study cannot be initiated until all of the required authorizations have been obtained from the competent authorities and the Ethics Committee for Research with medicinal products (hereinafter, “ECRm”). For this reason, the Contract shall not take full effect until these authorizations have been obtained.

The Parties agree to carry out the Study in compliance with all applicable regulations in force in Spain, including, without limitation

- a) The ethical principles of the Declaration of Helsinki.
- b) The “Good Pharmacovigilance Practice” guidelines, with the modifications in force at any given time.
- c) Royal Decree 957/2020, of November 3, which regulates observational studies with medicinal products for human use (hereinafter, “**Royal Decree 957/2020**”) and any instruction prepared by the Spanish Agency of Medicines and Health Products (hereinafter, the “**AEMPS**”) in collaboration with the ECRm and the competent health administrations of the autonomous communities, as well as any European regulation in force and applicable.
- d) Law 41/2002, of 14 November, regulating patient autonomy and rights and obligations related to information and clinical documentation
- e) The rules related to the protection of personal data, and, in particular, EU Regulation 2016/679 of April 27 and Organic Law 3/2018 of December 5 on Protection of Personal Data and guarantee of digital rights, as well as any other current and applicable regulations.

Likewise, the Parties agree to fulfil their obligations in accordance with all applicable anti-corruption and antitrust law.

The Parties declare and guarantee that they shall not distribute any inappropriate benefit or trade advantage that is unfair, which could influence/induce the taking of public or private decisions, the prescription, or induce someone to breach his professional duties.

Any conflict arising between this Contract and the Protocol shall be settled in the following manner: (i) The Protocol shall prevail in all matters directly related to the science and execution of the Study by the Principal Investigator; (ii) The Contract shall prevail in all other matters, especially those of economic content.

2. INVESTIGATION TEAM

The Principal Investigator should have a team of appropriately qualified collaborating investigators to carry out the Study as successfully as possible. These collaborating investigators will be designated in the delegation of responsibilities document that will be part of the Study master file.

3. MONITORING

The Sponsor designates the company [•], with NIF [•] and address at [•] as the monitor of the Study (hereinafter, the “**Monitor**”). The Monitor will have the responsibility of monitoring the progress of the Study on behalf of the Sponsor.

The Monitor must comply with all of the obligations set out in Article 8 of the Royal Decree 957/2020.

Likewise, the Monitor must maintain the utmost confidentiality regarding the data that they access in the framework of their performance, especially the personal data of patients. The Sponsor will be responsible for ensuring that the Monitor complies with the obligations of confidentiality and those related to the protection of personal data, obliging him to sign with them as many contracts as are mandatory for this purpose.

The Sponsor shall be responsible for ensuring that the Monitor complies with the obligations of confidentiality and protection of personal data, and shall be obliged to sign with the Monitor any contracts that may be required for this purpose.

In any case, the Parties agree to closely collaborate with monitoring activities.

4. RESPONSABILITIES FOR THE STUDY

The Sponsor is responsible for the Study, its management and financing in accordance with the provisions of the Royal Decree 957/2020.

Likewise, the execution of the study at HUVH/VHIO will be carried out under the direct and personal responsibility of the Principal Investigator.

Therefore, the Principal Investigator is responsible of ensuring that the execution of the Study in the HUVH / VHIO is in accordance with the requirements and conditions established set out in the Protocol and in the favourable opinion of the ECRm, and of supervising the work of the Study research team.

5. STUDY LOCATION

The Study shall take place at HUVH and VHIO facilities, using the resources of these institutions. Specifically, the Study shall take place in the [•] Service of the HUVH.

6. OBLIGATIONS OF THE SPONSOR

The Sponsor shall comply with all of the obligations established in Article 9 of Royal Decree 957/2020.

Likewise, the Sponsor agrees to provide the Principal Investigator with:

- a) Basic information on the medicinal Products of the Study: Toxicopharmacological and pharmacokinetic data, studies carried out prior on humans.
- b) Case-report forms and, if applicable, support services and computer hardware, including its repair.
- c) All the documents related to the Study.
- d) Information on the evolution of the Study, if it were multicentre, and the results obtained at the end of the Study or when available, as well as the serious and unexpected adverse reactions detected in relation to the Product.
- e) New information obtained about the Product during the performance of the Study.

The Sponsor agrees to provide the following equipment (hereinafter, the "**Equipment**") during the conduct of the Study:

Type of Equipment: [•]

Model: [•]
Series: [•]
Units to be provided to HUVH / VHIO: [•]
Price: [•] (VAT included)
Temporalidad: During the Study.

[Note to the Sponsor: For the formalization of any transfer of equipment, please contact Carlos López: clopez@vhio.net prior to signing this contract].

The Sponsor agrees to:

- a) Assume the transportation costs related to the delivery and return of the Equipment.
- b) Take responsibility for preventive maintenance and repairs in the event of Equipment failure.
- c) In the event that the Equipment is computer equipment, the Sponsor will ensure that the Equipment includes the software necessary for its operation (operating system and applications) in compliance with current legal regulations regarding licenses.
- d) Collect the Equipment within a maximum period of sixty (60) days after the end of the Study. In the event that this period has elapsed and the Sponsor has not proceeded to collect the Equipment, it will become part of the HUVH / VHIO's fixed assets and the Sponsor will not be entitled to financial compensation in exchange for this assignment.

7. OBLIGATIONS OF THE PRINCIPAL INVESTIGATOR

The Principal Investigator shall comply with all of the obligations established in Article 10 of Royal Decree 957/2020.

The Principal Investigator agrees to carry out all of the tasks necessary for the performance of the Study.

The Principal Investigator agrees to:

- a) Coordinate, supervise and manage the collaborators.
- b) Include, prior to the end of the Study, an estimated number of [•] patients.

- c) Within the framework of current legal requirements applicable to this matter, patients must receive as much information as possible, and their consent form must be obtained in writing.
- d) Perform follow-up on the patients in accordance with the criteria of the Protocol and current regulations applicable to this area.
- e) Collect and store all the Study information and deliver all documents to the Monitor or the Sponsor in accordance with the Protocol.
- f) Immediately report all the adverse reactions, including the unexpected and serious adverse reactions, using the fastest means available, to the Study Monitor appointed by the Sponsor.
- g) Follow the instructions regarding the communication of adverse events established in the Protocol and in the Royal Decree 957/2020.
- h) Communicate to the Sponsor the number of patients who have not attended the monitoring visits, in order to obtain the necessary reserve medication in time.
- i) Provide the Sponsor/Monitor with the information on each visit as soon as the visit occurs, in order to verify the information provided and its consistency with the information provided during previous or subsequent visits.
- j) Respect the confidential nature of the clinical data of each participant and maintain their privacy.
- k) Collaborate with the Monitor and/or his/her collaborator/s in order to guarantee the correct quality control of the Study, particularly with regard to the following elements: available resources, adherence to the Protocol, comparison of observation sheets and the HUVH clinical dossier (Medical Records), samples and recruitment.
- l) In case of the Principal Investigator cease his/her functions as HUVH's physician or, in any manner, stop participating in the Study, the Principal Investigator and/or the VHIO agree to propose a suitable replacement and to manage their acceptance in order to ensure the Study continuity.
- m) In the event of international registration, the relevant forms shall be completed.

8. FINANCIAL CONSIDERATION AND PAYMENT TERMS AND CONDITIONS

The budget for the realization of the Study, as well as the payment method, are detailed in **Annex I** of this Contract, which constitutes the **Financial Budget** of the Study.

9. DURATION

The Study that object of this Contract cannot begin until all the legally pertinent permits and authorizations have been obtained, the initiation visit with the principal investigator and the research team has been carried out and the Sponsor has delivered all the materials, products and equipment detailed in clause 6 of the Contract.

The period of inclusion of patients should end in accordance with the deadlines established in the Protocol.

The estimated duration of the Study is [•] months.

10. INCLUSION OF PATIENTS

The Sponsor reserves the right to interrupt the inclusion of patients in the Study under any of the following circumstances:

- a) If the Principal Investigator does not include, without justification accepted by the Parties, the agreed number of patients during the designated time period.
- b) If the total number of patients that must be included in the Study by the different researchers participating in the Study is reached when a multicentre Study is involved.

Patients may not be recruited after the end of the Study inclusion period, unless the ECRm approves the corresponding modification of the Protocol.

Likewise, patients included in the Study may be eligible to participate in an internal research project of the Oncology / Medical Hematology / Radiation Oncology Department of the HUVH, approved by the ECRm, provided that it does not interfere with the performance and evaluation of the Study that is the subject of this Contract.

11. SUSPENSION AND TERMINATION OF THE STUDY

The Study can be suspended or terminated, prior to its completion, by any of the Parties, by means of written notification, if one of the following circumstances arises:

- a) If the available data gives rise to the inference that continuing to administer the Clinical drug and/or the comparator drug or placebo to patients is neither justified nor safe.
- b) Because of the breach by one of the Parties of any terms of the Contract.
- c) If compliance with the Protocol is deficient or the data is incomplete or imprecise on repeated occasions.
- d) If the Parties agree to suspend the Study.

The aforementioned notification must be sent least thirty (30) days in advance, except in the case that the event is the one provided in section a). In the case that the notification is made by the Sponsor, it must be sent in written form to the VHIO, sending said communication by email to the following address: ybernabe@vhio.net.

The suspension or termination of the Study underway shall require the Parties to adopt the opportune measures to guarantee the safety of the patient, the continuity of the treatment and the compliance with current legislation applicable in this area. The Sponsor must communicate the suspension to the Spanish Agency of Medicines and Medical Devices (AEMPS) and to all other relevant health authorities and to pay for all of the services performed until the date of the early termination within thirty (30) days.

In any case, when a Study is in a state of suspension for more than six (6) months, it will automatically be considered terminated, except in the case there's an agreement between the Parties.

12. CONFIDENTIALITY AGREEMENT

In accordance with the confidential nature of all the documentation on the Product, which is property of the Sponsor, the VHIR, the VHIO, the HUVH, the Principal Investigator and the collaborators of the Study agree to:

- a) Receive and store all of the information in a confidential manner.
- b) Use the information received solely for the purposes and objectives set out in this Contract.
- c) Disclose this information to third parties only with the prior written consent of the Sponsor, and only when the third party is involved in the Study and agrees, in writing, to respect the confidentiality of the information in accordance with the terms established in this contract.

- d) This confidentiality agreement binds both the Principal Investigator and the research team.

The foregoing shall not apply to information that:

- a) Is or becomes part of the public domain outside of the responsibility of the Principal Investigator or the research team.
- b) Is legitimately received by third parties without any violation of this confidentiality agreement by the Principal Investigator or the research team.
- c) Was previously known by the Principal Investigator or the research team at the time it was disclosed.
- d) Had to be disclosed in accordance with legal requirements.

The Principal Investigator and the research team must not use the information provided or any part thereof for their own benefit or for the benefit of third parties and shall not provide third parties with any material containing confidential information, unless this is provided for in this Contract.

13. PERSONAL DATA PROTECTION

The Parties undertake to comply with the applicable data protection regulations in force; in particular, the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data (General Data Protection Regulation, "GDPR"), and Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights (hereinafter "LOPDGDD"), as well as any other applicable data protection regulations.

Data processing of research subjects

The Parties shall each be considered as Independent Data Controllers of the data they process. The Parties must comply with each and every one of the obligations contained in current regulations, within the scope of their respective data processing.

The Site is, in any case, responsible for the medical records of the research subjects and shall also be responsible for the processing of the research subjects' data necessary to carry out the research. The Sponsor shall be responsible for the coded/pseudonymized data of the research subjects.

The Sponsor shall only have access to information relating to the research subjects in this Study, after pseudonymization, unless the informed consent, a norm with the status of law or a judicial authority allows it.

The Site shall be responsible for carrying out the process of coding/pseudonymization of the personal data of the research subjects and, under no circumstances, the Site shall

provide information to the Sponsor that would allow it to access and know, directly or indirectly, the identifying data of the research subjects.

The Sponsor undertakes not to access under any circumstances the documentation relating to the clinical investigation that contains identifying data of the research subjects, unless this is necessary for compliance with the obligations imposed by the applicable regulations or the standards of good clinical practice.

It is forbidden any processing of the data of the research subjects in the Study, without the relevant legal basis.

The Parties undertake and are responsible for ensuring that their employees and third parties who subcontract and participate in any way in the processing of the data of the research subjects comply with these regulations and their duty of confidentiality.

The monitors and/or the auditors appointed by the Sponsor may have access to clinical information and documentation relating to the research subjects in the Study for the purpose of verifying the accuracy and reliability of the data provided by the Principal Investigator. The Site shall also provide access to these data to inspectors of the competent health authorities, when required by the regulations in force.

Processing of personal data of research subjects by monitors, auditors and other third parties appointed by the Sponsor may only be carried out after verification of compliance with the safeguards and corresponding legal basis in accordance with Regulation (EU) 2016/679.

The Sponsor shall be responsible for the contracting of the monitor, the auditor and any third party that decides to contract, and must sign with each of them, where necessary, the corresponding data processing agreement, in accordance with the provisions of Article 28 of the GDPR.

The Site (through the Principal Investigator) shall be responsible for complying with the duty of information in relation to the research subjects, providing them, at the time they are given informed consent, with a specific document containing all the information relating to the processing of their personal data within the framework of the clinical research.

Each Party shall implement appropriate Technical and Organizational Measures in relation to its own processing of personal data to ensure a level of security appropriate to the risk taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of the processing, as well as risks of varying likelihood and severity for the rights and freedoms of natural persons.

Notwithstanding the foregoing, the Parties undertake to collaborate and inform the other Party in the event of any breach or violation of security or request for rights by any data subject, if this could affect the other Party.

(i) Data subject request

The Parties undertake to collaborate and inform the other Party within seventy-two (72) hours of receipt, in the event of a request for rights by any data subject, if this could affect the other Party.

The data subjects may contact each Controller through the following contact persons:

Data Protection Officer of the Sponsor:
Data Protection Officer of HUVH: dpd@ticsalutsocial.cat
Data Protection Officer of VHIR: dpd@ticsalutsocial.cat
Data Protection Officer of VHIO: dpd.cliente@conversia.es

The Parties shall cooperate and provide reasonable assistance to each other to facilitate the processing of such requests.

Furthermore, in accordance with Article 19 of the GDPR, the controller that shares data with the other controller must communicate any rectification or erasure of personal data or restriction of processing to the other controller to whom the personal data have been disclosed, unless this proves impossible or involves a disproportionate effort.

(ii) Personal data breach or security breach

In the case of a personal data breach or a security breach, each Party shall be responsible for notifying the breach to the competent supervisory authority and, where appropriate, for communicating the breach to the data subjects.

The Parties shall cooperate and notify each other within forty-eight (48) hours of any personal data breach or breach of security, if it could affect the other Party.

Each Party shall support the other Party by providing reasonable assistance as necessary to facilitate the handling of any personal data breach and/ or security breach and to assist the other Party with its obligation to notify and report the personal data breach, without the Site being required to provide identifying data of the research subjects to the Sponsor.

Data processing of signatories/participants

In relation to the duty to provide information under Articles 13 and 14 of the GDPR, the Parties inform each other of the processing of personal data of the signatories and/or of the personal data contained in the present Agreement or in previous preparatory documents to this Agreement, for the purpose of allowing the development and fulfilment of the obligations contained herein and for the purposes of the reciprocal relations between the Parties, being the basis of the processing the fulfilment of a contractual relationship and keeping the data for as long as it remains, being able to keep them even later, until they prescribe the possible responsibilities derived from it.

The following are also reported:

- a) The respective Controllers for the processing of personal data, are each of the entities involved.
- b) The Data Protection Officer of each of the Parties is the following:
 - DPO data of Sponsor:
 - DPO data of VHIR: dpd@ticsalutsocial.cat
 - DPO data of HUVH: dpd@ticsalutsocial.cat

- DPO data of VHIO: dpd.cliente@conversia.es
- c) The transfer of the personal data of the participants is not foreseen, by any of the Parties, except if a Public Administration requires it to comply with the legal and fiscal obligations of the entity.
- d) The international transfer of personal data of the signatories is not foreseen unless the other Party is from a country outside the European Economic Area (EEA), or in the event that this Agreement is signed via Docusign or other similar platform. Such transfer shall be carried out in compliance with all the requirements established by data protection regulations, and applying the guarantees and safeguards necessary to preserve their privacy.
- e) The right of access, rectification, deletion, limitation, opposition and portability can be exercised by communicating with the Data Protection Officer of either of the Parties, at the indicated email address. Automated decision-making is not foreseen, including profiling. If they consider that the processing of their personal data violates the regulations, they can also file a complaint with the Supervisory competent authority.

International transfers of personal data

The Parties are aware that Personal Data cannot be transferred to countries that do not provide an adequate level of protection without complying with the provisions of Chapter V of the GDPR, or when these non-EEA countries fall under an Adequacy Decision issued by European Commission allowing the International Transfer of data.

Therefore, the Parties agree to grant a document for the transfer of Personal Data which is included as Annex III to this Agreement and is an integral part to this Agreement.

Comentado [GSE1]: Esta cláusula estará sólo si el Colaborador/Promotor es de fuera de la UE e implicará anexas al contrato las SCC (Cláusulas Contractuales Tipo) en su modelo Controller-Controller, salvo que su país tenga una Decisión de adecuación

14. OWNERSHIP OF THE RESULTS AND INTELLECTUAL PROPERTY RIGHTS

The Sponsor is the owner of all the data of the Study, the results of the Study, the CRFs and all other information and documentation generated as a result or in relation to the conduct of the Study, excluding the medical records of the patients and the personal notes of the Principal investigator. The Sponsor hereby grants HUVH and VHIO the non-exclusive, perpetual, non-transferable and non-sublicensable right to use the results of the Study only for their non-commercial research, teaching and patient care activities.

All inventions, ideas, methods, know-how or discoveries that are made, conceived or reduced to practice by HUVH, VHIO, Principal Investigator or Study staff: (i) as a result of or in connection with the conduct of the Study; (ii) that incorporate or use Confidential Information; or (iii) that are directly related to the Investigational Drug, and all the intellectual property rights related to it (hereinafter collectively, “**Study Inventions**”), will be the sole and exclusive property of the Sponsor. HUVH and VHIO will assign all rights, titles and interests in all Study Inventions to the Sponsor. In the event that the Sponsor requests it, the HUVH and the VHIO will ensure that the Principal Investigator and the Study

Staff carry out the necessary actions to enforce ownership of the Sponsor in the Study Inventions or to obtain patents or otherwise protect the ownership of the Sponsor in the Study Inventions. The Sponsor will assume all the costs derived from the previous steps.

15. PUBLICATIONS

The Sponsor will have the right and obligation to publish the aggregated data of the Study. In the publications made by them, the Sponsor will not cite the name of the Principal Investigator or the research team without their authorization, except in the case of references to already published works.

The Parties recognize that the Principal Investigator and the research team hold the right to publish the results of the research in journals of recognized scientific prestige and its dissemination in seminars and conferences within the professional medical field.

The publication of the results by the Principal Investigator and the research team (hereinafter, "**IP Publication**") can be carried out: (i) after the publication of the results of the aggregated data grouped by the Sponsor; (ii) after a period of twelve (12) months, from the end of the Study, if the Sponsor has not published the results of the aggregated data; (iii) at any time, by agreement of the Parties.

In the case of an IP Publication, the Principal Investigator agrees to provide the Sponsor with a copy of any proposed publication or disclosure of the Study results for review at least thirty (30) days prior to the submission date for publication. (including summaries) or public disclosure (hereinafter, the "**Review Period**"). The Principal Investigator agrees to remove Confidential Information, other than the Study data, from the proposed publication if, during the Review Period, the Sponsor requests it. The HUVH and the Principal Investigator agree to attend to the suggestions proposed by the Sponsor regarding the presentation of the Study data and the timing of the proposed publication or disclosure.

The lack of response from the Sponsor within the Review Period will be understood as a tacit consent to the publication.

In the event that during the Review Period the Sponsor notifies the Principal Investigator of his intention to make a patent application on Study Inventions disclosed or contained in the proposed publication or disclosure, the Principal Investigator will postpone the publication or other disclosure for a period additional maximum of sixty (60) days from the date of communication of the Sponsor.

16. MASTER FILE OF THE STUDY DOCUMENTATION

The Sponsor and the Principal Investigator shall preserve the content of the master in the format and for the time established by the legislation in force.

In order to collaborate with the fulfilment of this storage and preservation duty, the Sponsor may pay an additional amount for this item recorded in the Financial Report (Annex I).

17. SIGNATURES

The Sponsor/CRO, the HUVH, the VHIR, the VHIO and the Principal Investigator agree to sign this Contract and its annexes by electronic signature through the DocuSign application, having these signatures the same legal force and effect as the exchange of handwritten signatures. For these purposes, the Parties determine that the data of each signatory is the following:

HUVH:

Dr. Albert Salazar i Soler

Email: dirgerencia@vallhebron.cat

VHIR:

Dr. Begoña Benito Villabriga

Email: directorsignatures@vhir.org

VHIO:

Dr. Carles Constante i Beitia

Email: cconstante@vhio.net

[Sponsor] / [CRO]:

[•] (Name of the representative)

Email: [•]

Principal Investigator:

Dr. [•]

Email:

The VHIO will be responsible for managing the signature process of the Parties.

18. JURISDICTION AND APPLICABLE LAW

This Contract shall be subject to Spanish Legislation and in order to resolve any discrepancy which could arise with regard to the application or interpretation of the provisions of this Contract, the Parties submit, with an express waiver of any jurisdiction to which they could be entitled, to the jurisdiction of the courts and tribunals of Barcelona.

This Contract shall enter into force on the date it is signed by the last of its signatories (the “Effective Date”).

Dr. Albert Salazar i Soler
Chief Executive Officer
HUVH

Mr. [•]
[•]
[•] (Sponsor)

Dr. Begoña Benito Villabriga
Director
VHIR

Mr. [•]
[•]
[•] (CRO)

Dr. Carles Constante i Beitia
Managing Director
VHIO

ANNEX I

CLINICAL STUDY FINANCIAL BUDGET

I – FINANCIAL CONSIDERATION:

- a) The Sponsor agrees to pay to the VHIO as the entity that manages the research process of the Oncology, Adult Medical Hematology and Radiation Oncology Service of the HUVH the amounts established in the Economic Report in accordance with the provisions of this Annex.

Any modification of the budget contained in the Financial Budget must be mutually agreed to by the Parties.

The amounts indicated in the Financial Budget will accrue VAT corresponding to the Sponsor's account, if applicable, according to current regulations.

- b) The Sponsor will pay the VHIO the amount corresponding to the sections "Internal Costs - Tests", "Internal Costs - Visits" and "Other Costs" specified in the Financial Budget (hereinafter, "**Costs**").

The Sponsor will pay to VHIO the amount corresponding to sections E, F and H of the Economic Report in order to satisfy the foundational purposes of VHIO (promotion of Biomedical Research, Innovation and Teaching of HUVH Campus).

Compensation will be based on the provisions of the patient visit record and case report forms ("CRF").

- c) The Sponsor shall pay the VHIO the following amounts: (i) €1,500 as administrative and contract management costs; (ii) €1,500 as start-up costs of the Study in the Oncology/Hematology Service; and (iii) €1,000 as start-up costs for the Study by the Pharmacy Department.
- d) These initial one-time payments will also be reflected in the Financial Budget in this Annex, will be billed with the signing of the Contract without being conditioned to the effective realization of the Test or to the approval of it by the ECRm or the Regulatory Authority.
- e) The travel, accommodation and subsistence expenses of the patients will be managed through VHIO through a separate agreement.

- f) In case of audit of the Study by the Sponsor, the Sponsor shall pay VHIO the amount of €500 per day for each day of the audit visit to compensate for the costs incurred by VHIO in the preparation, conduct and subsequent follow-up of the audit. This amount will not be applicable to regulatory agency inspections.
- g) The Sponsor shall pay the VHIO the amount of five hundred euros (500.-€), as administrative expenses for the management of any addendum related to this Study. This amount will only be waived when the addendum is generated due to a change in the Principal Investigator of the Study.

II – PAYMENT TERMS AND CONDITIONS:

The Sponsor shall pay the amounts established in the Financial Budget in accordance with following billing calendar:

- a) After the end of each quarter, the Sponsor shall communicate in writing to the VHIO, the total detailed amount to be invoiced for the activities/visits that have been carried out up to that moment. For this purpose, the Sponsor shall send to the VHIO this information following the nomenclature agreed upon in the financial report attached to this Annex.

The VHIO will invoice the total budgeted costs incurred during that quarter, except for the last invoice which will be issued when all the activities related to the Study are concluded.

The first trimester will start from the date of inclusion of the first patient.

- b) The VHIO will invoice the payment for the administrative expenses of the Contract and the Oncology/Hematology Start-Up fee (if applicable) and the Pharmacy Start-Up fee as of the signature of this Contract, without being conditioned its charge to the effective realization of the Study or upon the approval by the ECRm.

III – BILLING:

- a) In these invoices, the bank account owned by the VHIO, the Protocol number, the name of the Study, the Principal Investigator and the Sponsor shall be recorded.
- b) Payment of the invoices must be made to the specific bank account owned by the VHIO.
- c) For any communication related to VHIO billing, the Sponsor should contact: facturacion@vhio.net.

d) The data of the entity to which the Study invoices must be issued are:

Name: [•]

Fiscal address: [•]

NIF: [•]

Invoice delivery address: [•]

Contact person: [•]

Contact email: [•]

[Please indicate the email address of the Sponsor].

- e) The Parties agree that any change related to the information contained in sections c), d) and e) above must be communicated in writing at the indicated e-mail addresses, and no modification to the Contract is required for this purpose.
- f) Premature withdrawal from the Study: In the event that a patient does not complete the Study for any reason, the amount corresponding to all the work performed up to that moment will be paid.
- g) Any modification of the initial Protocol will entail the revision of the Financial Budget, such as in the case of the incorporation of retrospective data or additional data in the CRF, the incorporation of new evidence, or the modification of the visit plan, these being example cases at an illustrative level, but not limitative.

FINANCIAL BUDGET (EXCEL)

(insert the negotiated Excel file of the Financial Budget on this page)

ANNEX II

AGREEMENT OF THE PRINCIPAL INVESTIGATOR

Dr. [•], Principal Investigator of the Study with Protocol Code [•], whose title is [•]

DECLARE

That as Principal Investigator I know and accept each and every one of the clauses contained in this Contract and all its annexes, of which this document is an inseparable part.

And, accordingly, I subscribe to this statement.

Dr. [•]
Principal Investigator

ANNEX III

STANDARD CONTRACTUAL CLAUSES FOR THE TRANSFER OF PERSONAL DATA TO THIRD COUNTRIES

Comentado [GSE2]: Sólo se incluye con Colaborador o Promotor de fuera de la UE, y que no tenga decisión de adecuación.

SECTION I

Clause 1

Purpose and scope

- (a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) ⁽¹⁾ for the transfer of personal data to a third country.
 - (b) The Parties:
 - (i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter 'entity/ies') transferring the personal data, as listed in Annex I.A (hereinafter each 'data exporter'), and
 - (ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each 'data importer')
- have agreed to these standard contractual clauses (hereinafter: 'Clauses').
- (c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.
 - (d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

Clause 2

Effect and invariability of the Clauses

- (a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid

⁽¹⁾ Where the data exporter is a processor subject to Regulation (EU) 2016/679 acting on behalf of a Union institution or body as controller, reliance on these Clauses when engaging another processor (sub-processing) not subject to Regulation (EU) 2016/679 also ensures compliance with Article 29(4) of Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC(OJ L 295, 21.11.2018, p. 39), to the extent these Clauses and the data protection obligations as set out in the contract or other legal act between the controller and the processor pursuant to Article 29(3) of Regulation (EU) 2018/1725 are aligned. This will in particular be the case where the controller and processor rely on the standard contractual clauses included in Decision 2021/915.

down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.

- (b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

Clause 3

Third-party beneficiaries

- (a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:
 - (i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;
 - (ii) Clause 8 – Clause 8.5 (e) and Clause 8.9 (b);
 - (iii) Clause 12 – Clause 12(a) and (d);
 - (iv) Clause 13;
 - (v) Clause 15.1(c), (d) and (e);
 - (vi) Clause 16(e);
 - (vii) Clause 18.
- (b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

Clause 4

Interpretation

- (a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.
- (b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.
- (c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

Clause 5

Hierarchy

In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties, existing at the time these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

Clause 6

Description of the transfer(s)

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

Clause 7
Docking clause

- (a) An entity that is not a Party to these Clauses may, with the agreement of the Parties, accede to these Clauses at any time, either as a data exporter or as a data importer, by completing the Appendix and signing Annex I.A.
- (b) Once it has completed the Appendix and signed Annex I.A, the acceding entity shall become a Party to these Clauses and have the rights and obligations of a data exporter or data importer in accordance with its designation in Annex I.A.
- (c) The acceding entity shall have no rights or obligations arising under these Clauses from the period prior to becoming a Party.

SECTION II – OBLIGATIONS OF THE PARTIES

Clause 8
Data protection safeguards

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

8.1 Purpose limitation

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.

B. It may only process the personal data for another purpose:

- (i) where it has obtained the data subject's prior consent;
- (ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
- (iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

8.2 Transparency

- (a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:
 - (i) of its identity and contact details;
 - (ii) of the categories of personal data processed;
 - (iii) of the right to obtain a copy of these Clauses;
 - (iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.
- (b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the

information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.

- (c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.
- (d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

8.3 Accuracy and data minimization

- (a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.
- (b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.
- (c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

8.4 Storage limitation

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation ⁽²⁾ of the data and all back-ups at the end of the retention period.

8.5 Security of processing

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter 'personal data breach'). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.
- (b) The Parties have agreed on the technical and organisational measures set out in Annex II. The

⁽²⁾ This requires rendering the data anonymous in such a way that the individual is no longer identifiable by anyone, in line with recital 26 of Regulation (EU) 2016/679, and that this process is irreversible.

data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.

- (c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- (d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.
- (e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.
- (f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.
- (g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

8.6 Sensitive data

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

8.7 Onward transfers

The data importer shall not disclose the personal data to a third party located outside the European Union

(³) (in the same country as the data importer or in another third country, hereinafter ‘onward transfer’) unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

- (i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;
- (iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;
- (iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;
- (v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or
- (vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

8.8 Processing under the authority of the data importer

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

8.9 Documentation and compliance

- (a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.
- (b) The data importer shall make such documentation available to the competent supervisory authority on request.

Clause 9

Data subject rights

- (a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest

(³) The Agreement on the European Economic Area (EEA Agreement) provides for the extension of the European Union’s internal market to the three EEA States Iceland, Liechtenstein and Norway. The Union data protection legislation, including Regulation (EU) 2016/679, is covered by the EEA Agreement and has been incorporated into Annex XI thereto. Therefore, any disclosure by the data importer to a third party located in the EEA does not qualify as an onward transfer for the purpose of these Clauses.

within one month of the receipt of the enquiry or request. ⁽⁴⁾ The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.

- (b) In particular, upon request by the data subject the data importer shall, free of charge:
- (i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);
 - (ii) rectify inaccurate or incomplete data concerning the data subject;
 - (iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.
- (c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.
- (d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lay down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:
- (i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and
 - (ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.
- (e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.
- (f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.
- (g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

(4) That period may be extended by a maximum of two more months, to the extent necessary taking into account the complexity and number of requests. The data importer shall duly and promptly inform the data subject of any such extension.

Clause 10

Redress

- (a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.

The data importer agrees that data subjects may also lodge a complaint with an independent dispute resolution body ⁽⁵⁾ at no cost to the data subject. It shall inform the data subjects, in the manner set out in paragraph (a), of such redress mechanism and that they are not required to use it, or follow a particular sequence in seeking redress.

- (b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.
- (c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:
 - (i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;
 - (ii) refer the dispute to the competent courts within the meaning of Clause 18.
- (d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.
- (e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.
- (f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

Clause 11

Liability

- (a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.
- (b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.
- (c) Where more than one Party is responsible for any damage caused to the data subject as a result

⁽⁵⁾ The data importer may offer independent dispute resolution through an arbitration body only if it is established in a country that has ratified the New York Convention on Enforcement of Arbitration Awards.

of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.

- (d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.
- (e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

Clause 12 **Supervision**

- (a) [Where the data exporter is established in an EU Member State:] The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU) 2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.
- (b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES

Clause 13 **Local laws and practices affecting compliance with the Clauses**

- (a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.
- (b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:
 - (i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
 - (ii) the laws and practices of the third country of destination – including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light

- of the specific circumstances of the transfer, and the applicable limitations and safeguards ⁽⁶⁾;
- (iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.
 - (c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.
 - (d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.
 - (e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).
 - (f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

Clause 14

Obligations of the data importer in case of access by public authorities

14.1 Notification

- (a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:
 - (i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to

⁽⁶⁾ As regards the impact of such laws and practices on compliance with these Clauses, different elements may be considered as part of an overall assessment. Such elements may include relevant and documented practical experience with prior instances of requests for disclosure from public authorities, or the absence of such requests, covering a sufficiently representative time-frame. This refers in particular to internal records or other documentation, drawn up on a continuous basis in accordance with due diligence and certified at senior management level, provided that this information can be lawfully shared with third parties. Where this practical experience is relied upon to conclude that the data importer will not be prevented from complying with these Clauses, it needs to be supported by other relevant, objective elements, and it is for the Parties to consider carefully whether these elements together carry sufficient weight, in terms of their reliability and representativeness, to support this conclusion. In particular, the Parties have to take into account whether their practical experience is corroborated and not contradicted by publicly available or otherwise accessible, reliable information on the existence or absence of requests within the same sector and/or the application of the law in practice, such as case law and reports by independent oversight bodies.

these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or

(ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.

- (b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.
- (c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).
- (d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.
- (e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

14.2 Review of legality and data minimisation

- (f) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).
- (g) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.
- (h) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

SECTION IV – FINAL PROVISIONS

Clause 15

Non-compliance with the Clauses and termination

- (a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.
- (b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).
- (c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:
 - (i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
 - (ii) the data importer is in substantial or persistent breach of these Clauses; or
 - (iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.

In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise.

- (d) Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.
- (e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

Clause 16

Governing law

These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the law of Spain.

Clause 17
Choice of forum and jurisdiction

- (a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.
 - (b) The Parties agree that those shall be the courts of Barcelona City, Spain..
 - (c) A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.
 - (d) The Parties agree to submit themselves to the jurisdiction of such courts.
-

APPENDIX

EXPLANATORY NOTE:

It must be possible to clearly distinguish the information applicable to each transfer or category of transfers and, in this regard, to determine the respective role(s) of the Parties as data exporter(s) and/or data importer(s). This does not necessarily require completing and signing separate appendices for each transfer/category of transfers and/or contractual relationship, where this transparency can be achieved through one appendix. However, where necessary to ensure sufficient clarity, separate appendices should be used.

ANNEX I

A. LIST OF PARTIES

Data exporter(s): *[Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

1. Name: **Hospital Universitari Vall d'Hebron.**

Address: Passeig Vall d'Hebron 119-129, Barcelona (08035), Spain.

Contact person's name, position and contact details: Dr Albert Salazar i Soler as Chief Executive Officer.

Data Protection Officer: dpd@ticsalutsocial.cat

Activities relevant to the data transferred under these Clauses: activities necessary to carry out the Study.

Signature and date:

Role (controller/processor): Controller

AND

Name: **Fundació Hospital Universitari Vall d'Hebron - Institut de Recerca.**

Address: Passeig Vall d'Hebron 119-129, Edifici Central, Barcelona (08035), Spain.

Contact person's name, position and contact details: Dr. Begoña Benito Villabriga as Director.

Data Protection Officer: dpd@ticsalutsocial.cat

Activities relevant to the data transferred under these Clauses: activities necessary to carry out the Study.

Signature and date:

Role (controller/processor): Controller

AND

Name: **Fundación Privada Instituto de Investigación Oncológica de Vall Hebron.**

Address: C/Natzaret 115-117, Centre Cellex, 08035, Barcelona, Spain.

Contact person's name, position and contact details: Dr. Carles Constante i Beitia as Managing Director.

Data Protection Officer: dpd.cliente@conversia.es

Activities relevant to the data transferred under these Clauses: activities necessary to carry out the Study.

Signature and date:

Role (controller/processor): Controller

Data importer(s): *[Identity and contact details of the data importer(s), including any contact person with responsibility for dataprotection]*

1. Name:

Address:

Contact person's name, position and contact details:..... as

Data Protection Officer:

Activities relevant to the data transferred under these Clauses:

Signature and date:

Role (controller/processor):

Comentado [GSE3]: To complete

B. DESCRIPTION OF TRANSFER

Categories of data subjects whose personal data is transferred

- Clinical Study participants
- Clinical Study site staff and investigators of the Study Centre involved in the clinical Study
- Employees of business partners and vendors of the Study Centre involved in the clinical Study

Categories of personal data transferred

Clinical Study participants: Date of birth and/or age, initials, personal identification number assigned to Data Subjects participating in the Study, description of characteristics of physical features of the body, medical condition, medical images and scans (such as X-ray and study results), drugs and other treatments administered during the Study.

Clinical Study site staff and investigators of the Study Centre involved in the clinical Study: Contact information, CVs/resumes of clinical Study site staff and investigators.

Employees of business partners and vendors of the Study Centre involved in the clinical Study: Contact information of business partners and vendors of the Study Centre involved in the clinical Study.

Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.

Clinical Study participants: Health information including past medical history, medical condition and its development during the Study, medical test information (such as blood samples results from scans and biopsies) generated during the Study, treatment administered in the course of the Study, data revealing racial or ethnic origin and genetic data.

The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).

Data shall be transferred to the CRF of the Study within the timelines defined in the Protocol.

Nature of the processing

- Performance of Clinical Study services under the Contract as specifically described in the Protocol.
- Safety monitoring
- Completion of data in the CRF system

Purpose(s) of the data transfer and further processing

- Carrying out the activities related to the clinical Study

- Maintaining the integrity of the data collected in the context of the clinical Study
- Complying with legal or regulatory obligations to which the data importer is subject
- Establishing, exercising or defending legal claims

Processing activities include any operations required by the clinical Study protocol including but not limited to collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure, alignment or combination, restriction, anonymization or archiving.

The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period

Data Controller shall retain Personal Data related to the Study for a period of 25 years after the end of the Study or longer, if required by Applicable Law.

For transfers to (sub-) processors, also specify subject matter, nature and duration of the processing

Comentado [GSE4]: To Sponsor: please specify if you will be using third parties processing the information of the patients participating in the Study.

C. COMPETENT SUPERVISORY AUTHORITY

Identify the competent supervisory authority/ies in accordance with Clause 12: SPAIN (AEPD or APDCAT)

ANNEX II

TECHNICAL AND ORGANISATIONAL MEASURES INCLUDING TECHNICAL AND ORGANISATIONAL MEASURES TO ENSURE THE SECURITY OF THE DATA

EXPLANATORY NOTE:

The technical and organisational measures must be described in specific (and not generic) terms. See also the general comment on the first page of the Appendix, in particular on the need to clearly indicate which measures apply to each transfer/set of transfers.

Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.

[Examples of possible measures:

Measures of pseudonymisation and encryption of personal data.
Measures for ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services.
Measures for ensuring the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident.
Processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing.
Measures for user identification and authorization.
Measures for the protection of data during transmission Measures for the protection of data during storage.
Measures for ensuring physical security of locations at which personal data are processed.
Measures for ensuring events logging.
Measures for ensuring system configuration, including default configuration.
Measures for internal IT and IT security governance and management.
Measures for certification/assurance of processes and products.
Measures for ensuring data minimization.
Measures for ensuring data quality.
Measures for ensuring limited data retention.
Measures for ensuring accountability.
Measures for allowing data portability and ensuring erasure]

Comentado [GSE5]: To complete

For transfers to (sub-) processors, also describe the specific technical and organisational measures to be taken by the (sub-) processor to be able to provide assistance to the controller and, for transfers from a processor to a sub-processor, to the data exporter.