EurOPDX CONSORTIUM AGREEMENT

BY AND BETWEEN

INSTITUT CURIE,
A private, not for profit state approved foundation,
Having a registered office at 26 rue d'Ulm, 75005 Paris, France,
Officially represented by M. Thierry Philip, Chairman of the Executive Board and by delegation [redacted], Director of the Research Centre,

Hereinafter referred to as "**INSTITUT CURIE**",

ON THE ONE HAND,

AND,

KATHOLIEKE UNIVERSITEIT LEUVEN,
A university,
For the purposes of this agreement represented by [redacted] in his capacity as Rector,
Having its office in 3000 Leuven, Oude Markt 13, Belgium,

Hereinafter referred to as "**KU LEUVEN**",

ON THE OTHER HAND,

AND,

VALL D'HEBRON INSTITUTE ONCOLOGY,
A private, not for profit research Foundation,
Having its principal offices at Calle Natzaret 115, 08035 Barcelona, Spain,
Represented by [redacted] in his capacity as Managing Director,

Hereinafter referred to as "**VHIO**",

ON THE OTHER HAND,

AND,

INSTITUT CATALÀ D'ONCOLOGIA,
A public body,
Having its principal offices at Avda Gran Via de l'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat, Barcelona, Spain,
Represented by [redacted] in his capacity as General Director,

Hereinafter referred to as "**ICO**",

ON THE OTHER HAND,

AND,

UNIVERSITY OF TORINO, DEPARTMENT OF ONCOLOGY,
A public research and higher education institution,
Having registered offices in 10124 Torino, Via Verdi n. 8 and administrative office in Regione Gonzole 10, 10043 Orbassano (Torino), Italy,
Represented by Professor [redacted] in his capacity as Director of the Department of Oncology,

Hereinafter referred to as "**UNITO**",

ON THE OTHER HAND,

AND,

UNIVERSITAIR MEDISCH CENTRUM GRONINGEN (UNIVERSITY MEDICAL CENTER GRONINGEN),
A not-for-profit research and education institution,
Having its principal office at Hanzeplein 1, 9713 GZ Groningen, The Netherlands,
Represented by the Board of Directors,

Hereinafter referred to as "**UMCG**",

ON THE OTHER HAND,

AND,

STICHTING HET NEDERLANDS KANKER INSTITUUT – ANTONI VAN LEEUWENHOEK ZIEKENHUIS,
A not-for-profit research foundation and dedicated cancer clinic,
Having its principal offices at Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands,
Represented by [redacted] in his capacity as Director of Operations,

Hereinafter referred to as "**NKI-AVL**",

ON THE OTHER HAND,

AND,

THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF CAMBRIDGE,
A UK higher education institution,
Having its principal offices at The Old Schools, Trinity Lane, Cambridge, CB2 1TN, United Kingdom,
Represented by [redacted] in his capacity as Assistant Director School, of Clinical Medicine, on behalf of Professor [redacted] of the CRUK Cambridge Institute and Cambridge Cancer Centre,

Hereinafter referred to as "**CAMBRIDGE**",

ON THE OTHER HAND,

AND,

THE UNIVERSITY OF MANCHESTER,
A Royal Charter Corporation (no RC000797),
Having its principal offices at Oxford Road, Manchester M13 9PL, United Kingdom,
Represented by [redacted] in his capacity as Director of Research and Business Engagement Support Services,

Hereinafter referred to as "**MANCHESTER**",

ON THE OTHER HAND,

AND,

THE UNIVERSITY COURT OF THE UNIVERSITY OF GLASGOW,
Incorporated under the Universities (Scotland) Act 1889 and having its principal office at University Avenue, Glasgow G12 8QG, a registered Scottish charity in terms of Section 13 (2) of the Charities and Trustee Investment (Scotland) Act 2005 (Charity Number SC004401, Charity Name 'University of Glasgow Court'),
Represented by Mr [redacted] in his capacity as Research Support Manager,

Hereinafter referred to as "**GLASGOW**",

ON THE OTHER HAND,

AND,

OSLO UNIVERSITETSSYKEHUS HF,
A University Hospital,
Established in Kirkeveien 166 Tarnbygget, Oslo 0450, Norway,
Represented for the purpose of signing this agreement by [redacted], Head of Department – Administrative Research Support,

Hereinafter referred to as "**OUS**",

ON THE OTHER HAND,

AND,

ROYAL COLLEGE OF SURGEONS IN IRELAND,
A body corporate constituted by Royal Charter in 1784 (as has been amended, supplemented and/or replaced from time to time),
Having its address at 123 St Stephens Green, Dublin 2, Ireland,
Represented by [redacted] in her capacity as Associate Director of Research,

Hereinafter referred to as "**RCSI**",

ON THE OTHER HAND,

AND,

MASARYK UNIVERSITY,
A public university,
Having its principal offices at Žerotínovo nám. 617/9, 601 77 Brno, Czech Republic,
Represented by Prof. [redacted],

Hereinafter referred to as "**MASARYK UNIVERSITY**",

ON THE OTHER HAND,

AND,

ISTITUTO EUROPEO DI ONCOLOGIA srl,
A private institution,
Having its offices at via Ripamonti 435, 20141 Milano, Italy,
Represented by [redacted] in his capacity as Chief Executive Officer,

Hereinafter referred to as "**IEO**",

ON THE OTHER HAND,

AND,

JOAN AND SANFORD I. WEILL MEDICAL COLLEGE OF CORNELL UNIVERSITY,
A New York not-for-profit educational corporation,
Having an office at 1300 York Avenue, New York, NY 10065, USA,
Represented by [redacted], in her capacity as Executive Director, Office of Sponsored Research Administration,

Hereinafter referred to as "**CORNELL**",

ON THE OTHER HAND,

AND

UNIVERSITY OF BASEL,
A public university,
Having its principal offices at Petersplatz 1, 4051 Basel, Switzerland,
Represented by Prof. [redacted] in his capacity as Vice President for Research, acting on behalf of Prof. Dr. [redacted], Department of Biomedicine,

Hereinafter referred to as "**UNIBAS**",

ON THE OTHER HAND,

AND,

LUXEMBOURG INSTITUTE OF HEALTH (LIH),
A public research institution formed under the laws of the Grand Duchy of Luxembourg,
Having its principal offices at 1A rue Thomas Edison, L-1445 Strassen, Luxembourg,
Represented by [redacted] in his capacity as CEO and Mr Marc Grabowski in his capacity as CFAO,

Hereinafter referred to as "**LIH**",

ON THE OTHER HAND,

AND,

INSTITUTE OF MOLECULAR GENETICS OF THE CZECH ACADEMY OF SCIENCES, V.V.I.,
A public research institution,
Having its principal offices at Videnska 1083, 142 20 Prague 4, Czech Republic
Represented by [redacted]. in his capacity as Director,

Hereinafter referred to as "**IMG**",

ON THE OTHER HAND.

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RECITALS

WHEREAS, the Parties, through one or several of their affiliated researchers, have independently developed clinically relevant preclinical models of cancer called patient derived tumour xenografts ("PDX" or "xenopatient", please refer to Appendix A for a list of abbreviations), and/or have an expertise in basic, preclinical, translational and/or clinical oncology, and/or are operators and developers of supporting e-infrastructures. Primary scientific contacts for each Party ("Institution's Scientists") are listed in Appendix B.

WHEREAS, through the founding of the EurOPDX Consortium ("Consortium"), the Parties would like to create a network of academic institutions acting for non-profit purposes and researchers focusing on PDX models ("Models"), in order to share their expertise and, as the case may be, Models with corresponding characterisation and annotation data, and perform collaborative research programs and multicentre xenopatient trials among the Consortium, as well as with other academic institutions and/or commercial entities ("Third Party(ies)"). The Consortium will be driving the performance of a certain number of objectives, which are listed in the present Consortium Agreement (hereinafter the "Agreement") and will seek appropriate funding to achieve these objectives.

WHEREAS, the Parties have signed a multilateral non-disclosure agreement (hereinafter the "NDA"), effective on 2 May 2013 and valid until 1 May 2015 in order to be able to discuss unrestrictedly until the signature of the present Agreement. Therefore, since the effective date of the NDA, the Parties may have disclosed to each other confidential information in written or oral form, as well as documents pertaining to their expertise relevant to the goals of the Consortium.

WHEREAS, the Parties want to enter into the present Agreement to define their respective rights and responsibilities as members of the Consortium ("Members"), and to organise the sharing of the Models and performance of studies within the Consortium and with Third Parties.

NOW, THEREFORE, it is agreed between the Parties as follows:

Article 1 - DEFINITIONS

As used herein, capitalised terms in this Agreement (including its Appendices) and any amendments hereto, shall always have the meanings expressly given to them in the following definitions, without any exceptions. Definitions in the singular form shall include the plural and vice versa.

1.1 Models and materials

"Member Models" shall mean any and all patient-derived tumour xenograft (PDX) animal models developed by the Parties prior to accession to the Agreement or during the Term but outside the framework of a Consortium or Third Party Study, as defined below, that they are free to use.

"Member Materials" shall mean any and all material other than Member Models developed by the Parties prior to accession to the Agreement or during the Term but outside the framework of a Consortium or Third Party Study, including cell lines, other types of animal models than PDXs, and 2D or 3D PDX-derived primary cells, that they are free to use.

"**Consortium Models**" shall refer to new PDX animal models engrafted and developed by the Parties in the course of a Consortium Study or Third Party Study.

"**Models**" shall refer to Member Models and Consortium Models.

"**Consortium Materials**" shall refer to any new material other than PDX models generated by the Parties in the course of a Consortium or Third Party Study, including cell lines, other types of animal models than PDXs, and 2D or 3D PDX-derived primary cells.

"**Materials**" shall refer to Member Materials and Consortium Materials.

1.2 Data and results

"**Background Data and Results**" shall mean any and all data and results obtained by the Parties prior to accession to the Agreement or during the Term but outside the framework of a Consortium or Third Party Study, including annotation and characterisation data (e.g. omics and efficacy data) on Member Models and Member Materials.

"**Foreground Data and Results**" shall mean any and all data and results obtained by the Parties during the Term and the performance of a Consortium Study, including annotation and characterisation data (e.g. omics and efficacy data), on Member Models, Member Materials, Consortium Models and Consortium Materials.

"**Data and Results**" shall mean Background Data and Results and Foreground Data and Results.

"**Third Party Study Data and Results**" shall mean any and all data and results obtained by the Parties during the performance of a Third Party Study.

1.3 Additional definitions

"**Access Rights**" shall mean licences and user rights to Background Data and Results and Foreground Data and Results, which shall be requested in writing by a Member if such rights are Needed. The burden of proof in relation to a claimed need for Access Rights shall be on the Receiving Party. It is understood that Access Rights to Background Data and Results for the purpose of this Agreement refer only to Background Data and Results generated by the researchers and their research groups directly involved in this Agreement, thereby excluding Access Rights to any other Background Data and Results owned by the Parties.

"**Affiliate**" shall mean any firm, corporation or legal entity that directly or indirectly controls, is controlled by, or is under common control with, a Party. A legal entity is deemed to control another if:

(i) it holds, directly or indirectly, a portion of that other legal entity's capital giving it a majority of voting rights at general meetings thereof; or

(ii) it is the sole owner of a majority of voting rights pursuant to an agreement entered into with other partners or shareholders; or

(iii) in view of the circumstances, it is in fact enabled by the voting rights owned by it to have its opinion prevail at general meetings ("de facto control" situation).

"Confidential Information" shall mean all information and data of whatever nature Shared by the Parties in any form whatsoever, written, graphic, oral or by any other means, irrespective of form, whether or not protected by intellectual property rights, including, but not limited to, a copy of a patent application, industrial plans, documents marked "confidential", know-how, technical or business information, prototypes. In particular, Models, Materials, Background, Foreground and Third Party Data and Results and all information included in the Database are Confidential Information unless otherwise specified by the disclosing Party.

"Consortium Coordination Activities" shall mean activities directly linked to the existence and the project of the Consortium, which include: project management, coordination of networking activities and studies performed by the Consortium other than EU Studies, preparation and negotiation of Consortium Study and Third Party Study Agreements, organisation of meetings for reviewing the achievement of the Consortium's objectives, and dissemination, communication and business development activities.

"Consortium Study" shall mean a collaborative multicentre research program or xenopatient trial performed between one, few or all Members only, without involvement of any Third Party in the performance of the study, and managed as part of the Consortium Coordination Activities. If required by a particular Consortium Study, the Parties will eventually sign a

separate material transfer agreement or collaborative research agreement (hereinafter **"Consortium Study Agreement"**).

"Database" shall mean the common laboratory information management system set-up for the Consortium collection of Models and including the Shared Data and Results.

"Effective Date" shall mean retrospectively the date of May 1, 2015, at which the Members started to participate to the costs of the Consortium Coordination Activities through the payment of Membership Fees.

"Force Majeure" shall mean any unforeseeable and exceptional event materially affecting the fulfilment of any duty under this Agreement and/or any Consortium Study and/or any Third Party Study by a Party/Parties, which is beyond its/their control and cannot be cured or overcome despite its/their reasonable efforts. Any default of a product or service or delays in making them available for the purpose of performing this Agreement or any Consortium Study and/or any Third Party Study and materially affecting such performance, including for instance, anomalies in the functioning or performance of such product or service, changed circumstances making performance more difficult or expensive or other financial difficulties shall not constitute Force Majeure or relieve a Party/Parties of its/their duty to perform.

"Institution's Scientist" shall mean the affiliated researcher designated as the primary contact for the project of Consortium in each Party, as listed in the present Appendix B.

"Needed" for the implementation of a Consortium Study or a Third Party Study, Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the Receiving Party would be impossible, significantly delayed, or require significant additional financial or human resources. For use of own Foreground Data and Results, Access Rights are Needed if, without the grant of such Access Rights, the use of own Foreground Data and Results would be technically or legally impossible.

"Shared" for Models, Materials and for Data and Results shall mean information or material made accessible by a Member to the other Members of the Consortium, in particular through information included in the Database and for the purpose of Consortium and/or Third Party Studies and, in the case of Foreground Data and Results, internal non commercial research and development and academic teaching, and subject to the provisions of Articles 6.1.3, 6.3, 7 and Article 11 "Non Disclosure of Information".

"Third Party" shall mean a research institution not member of the Consortium and participating in a collaborative multicentre research program or xenopatient trial with some Members, and may include pharmaceutical and biotechnological companies, contract research organisations, non-for-profit organisations and private and public academic research institutions.

"Third Party NDA" shall mean a non-disclosure agreement using the template in Appendix D executed with a Third Party to allow for its participation in some Consortium activities or discussions for the performance of a Third Party Study.

"Third Party Study" shall mean a collaborative multicentre research program or xenopatient trial performed between some Members and one or several Third Parties, and at least partly funded through a collaborative research agreement of the Members with (a) Third Party(ies) (hereinafter **"Third Party Study Agreement"**). Projects funded by the European Union (**"EU Studies"**) or collaborations with pharmaceutical or biotechnological companies within the framework of the Consortium are Third Party Studies.

"Working Group" shall mean a group of scientists affiliated to or employed by the Members and actively participating in a particular aspect of the Consortium activities and/or objectives, such as the Logistics, Ethics and Bio-info-statistics Working Groups.

Article 2 – PURPOSE AND SCOPE

2.1 The Consortium will be governed by the present Agreement, to be signed by each Party wanting to become a Member. Once a Member, each Party may decide to participate in a particular Consortium Study or Third Party Study, on a per project basis. The present Agreement sets forth the legally binding definitions, the general rules and principles and the general rights and obligations applicable to the Parties, including those dealing with membership, benefits, governance, participation, initiation and performance of a Consortium Study or Third Party Study, access to Data and Results, Models and Materials, Database, intellectual property rights, confidentiality, publications, termination, etc.

2.2 It is understood that for each Consortium Study or Third Party Study, a Consortium Study Agreement or Third Party Study Agreement shall be negotiated in good faith and executed between the Members involved and eventually the Third Party(ies), unless otherwise agreed by the Members involved. In the event of an inconsistency between the terms and conditions of the present Agreement and the terms and conditions of any Consortium Study Agreement or Third Party Study Agreement, the terms and conditions of the present Agreement shall prevail except where expressly stipulated and agreed otherwise.

2.3 It is understood that EU Studies as defined above will be governed by separate grant agreements with the European Commission and separate consortium agreements between EU Studies participants, and will necessitate dedicated project management capabilities not included in the Consortium Coordination Activities.

2.4 Non-Exclusivity Provision

This Agreement does not create an exclusive relationship between the Parties, and any activities in furtherance requiring exclusivity will be specifically defined and agreed upon by the Parties as a separate agreement.

2.5 Relationship of the Parties

The Parties acknowledge that this Agreement does not create a fiduciary relationship between them, that each Party is an independent contractor of the other Party, and that nothing in this Agreement is intended to make either Party an agent, legal representative, subsidiary, joint venture, partner, employee or servant of the other for any purpose whatsoever. A Party will not have the power to exercise dominion or control over the other Party's operations, except as expressly provided herein.

Article 3 – OBJECTIVES OF THE CONSORTIUM

The objectives of the Consortium are listed below:

- Create a multidisciplinary network of academic researchers in preclinical and translational oncology, clinical oncologists, pathologists, biostatisticians and bioinformaticians, as well as operators and developers of the supporting e-infrastructures, carrying research in this area, with a common goal of harnessing clinically relevant models of cancer, and in particular Models, and avoiding duplication of efforts. This network will drive collaboration and exchange of information, expertise and experience in the field of preclinical and translational oncology;
- Share Models and harmonise characterisation and annotation of the Models in a common database ("**Database**", as defined in Article 1.3) implemented for the Consortium collection of Models;
- Elucidate standard operating procedures and harmonise working practices for implementation of Models, biobanking, biostatistics, protocol design and logistics for multicentre xenopatient trials, data analyses and reporting, with the goal to improve the reproducibility and predictability of preclinical and co-clinical studies. The approach of co-

clinical trials, which are performed in parallel in humans and in mice, facilitates on a real-time basis the determination of patient selection strategies, the discovery of response biomarkers and of resistance mechanisms to the treatment;

- Perform research programs aiming in particular at i) a better characterisation of the Models, ii) the development of new methodologies to overcome current limits of PDXs (e.g. humanisation strategies), iii) the implementation of new models in specific cancer subtypes to increase the representativity of the collection, metastatic models or models resistant to standard therapies, iv) the development of complementary models for integration in innovative preclinical screening strategies (e.g. ex vivo 2D and 3D assays with PDX-derived primary cell cultures), v) the identification of new targets and novel therapeutic strategies for overcoming drug resistance, and vi) the discovery of predictive biomarkers for targeted therapies;
- Perform proof-of-concept collaborative multicentre and multipathology xenopatient preclinical trials for novel anticancer drugs or combinatorial strategies, within molecularly-defined tumour subsets and on a population scale, using the standards agreed, between the Members or with Third Parties, as a prelude for prospective clinical trials in humans. The Consortium will also perform co-clinical trials;
- Gather experience with use of the underlying e-infrastructures and provide feedback to the relevant communities;
- Seek funding through calls for proposals, public-private and public-public partnerships for the Consortium Coordination Activities, the implementation and maintenance of the Database and other logistical aspects, and the performance of research programs and multicentre trials under Consortium or Third Party Studies;
- Organise the work to be performed in several Working Groups in order to meet the objectives;
- Develop a website and a general dissemination strategy for description of the project and the Members involved, and ultimately and whenever possible make publicly available the results and data obtained from the work performed (e.g. as regards to standards) to further reduce duplication of efforts within the scientific community;
- Teach young researchers state-of-the-art techniques related to PDX models and preclinical drug development;
- Participate in the improvement of the drug development process in oncology through more predictive preclinical and co-clinical studies;
- Become the reference in Europe and worldwide as regard to translational research in oncology using PDX models.

Article 4 – MEMBERSHIP AND BENEFITS

4.1 Membership

4.1.1 Two (2) levels of scientific participation to the activities of the Consortium are defined:

- **Research Members** agree, subject to any third party rights, to contribute their Member Models and/or Member Materials and/or expertise to the Consortium, and transfer their Member Models and/or Member Materials ad hoc when included in a particular study, subject to the provisions of specific material transfer agreements, but are willing to be performing experiments only when the topic of the study will fit to their particular research interests;
- **Trial Members** agree, subject to any third party rights, to contribute their Member Models and/or Member Materials and/or expertise to the Consortium, and transfer their Member Models and/or Member Materials ad hoc when included in a particular study, subject to the provisions of specific material transfer agreements, and agree to be centres for centralisation of experiments for xenopatient trials and for centralisation of side activities

such as bioinformatics and biostatistics, even if the topic of a particular study does not fit to their primary research interests.

4.1.2 In addition, two (2) levels of involvement in the management and strategic deployment of the Consortium are defined:

- **Full Members** take an active part in the management and strategic deployment (e.g. funding, business development) of the Consortium, and will be represented in the Board of Coordinators (hereinafter the **"BC"**);
- **Associate Members** are willing to participate in the scientific activities of the Consortium but not to be actively involved in its management.

4.1.3 As a consequence, four (4) levels of membership are defined: Full/Research or FullR Member, Full/Trial or FullT Member, Associate/Research or AssociateR Member and Associate/Trial or AssociateT Member. **"Member"** refers to any member of the Consortium. Roles and responsibilities, as well as benefits, will differ between the different levels of membership as detailed below. The list of Members with their respective levels of membership is provided in Appendix B.

4.1.4 Members will have the possibility to change their membership level each year by informing the BC in writing, during the first quarter of each calendar year in order to allow the BC to work on the following year's budget pursuant to the terms of Article 8.4. Any request by a Member to change its membership level received by the BC after March 31st will not be taken into account until the year after.

4.2 Accession to the Agreement for new members

4.2.1 Any other academic research institution may apply, at its own initiative or at the invitation of a Member, to be part of the Consortium after the Effective Date and during the Term. Its application shall be brought to the BC, which shall evaluate the expertise and/or models brought to the Consortium by the applicant. After consultation of the Scientific Steering Committee (as defined in article 5.2.3) when relevant, the BC shall make the final decision regarding the acceptance of the application.

4.2.2 Upon acceptance of its application as a new Member, any new institution wanting to join the Consortium shall agree with the BC on its level of membership. Any new Member shall fully agree with the terms and conditions of the present Agreement and shall sign an Accession Agreement, which template is provided in Appendix C. The Accession Agreement shall be signed by the Authorised Representative, as defined below, on behalf of the other Parties and the Consortium. The new Member shall designate an Institution's Scientist within its institution, and the updated Member list shall be communicated to the Members by the BC, together with an electronic copy of the Accession Agreement.

4.3 Benefits to Members

The Consortium is not intended at interfering with any project that the Parties may be carrying, but at offering the Parties with additional opportunities to have an impact on precision medicine in oncology, and in particular:

- Contribute and have access to the Models and scientific expertise of the Members for the performance of more reliable and reproducible multicentre xenopatient studies, more predictive of efficacy in the clinic, subject to the provisions of the specific material transfer agreement for the specific Models;
- Increase the level of characterisation of the Models and develop new strategies to overcome current shortcomings of PDXs;
- Participate in the discovery and preclinical or co-clinical validation of new therapeutic strategies and predictive biomarkers, to the benefits of cancer patients;

- Participate in grant applications for funding of the Consortium activities, and in particular of Consortium Studies and EU Studies;
- Co-publication of Foreground Data and Results, subject to the provisions of Article 10;
- Visibility of their participation as Members through dissemination activities (e.g. website, press releases, events), subject to the provisions of Article 10;
- Project management capabilities provided under the Consortium Coordination Activities. Considering their higher involvement in Consortium or Third Party Studies and higher investment in Consortium management as detailed in Article 4.1, Full Members and Trial Members will benefit more from project management capabilities than Associate and Research Members;
- Financial retribution according to membership status and/or research budget linked to the participation in a particular study, as detailed in Articles 6, 7 and 8.

Article 5 - GOVERNANCE AND MEETINGS

5.1 Authorised Representative

The Parties agree to designate INSTITUT CURIE as the "**Authorised Representative**" for the Consortium. As a consequence, the Parties hereby give to INSTITUT CURIE power of attorney to act in their name and behalf for the following, and only for the following:

- managing the budget for the Consortium Coordination Activities as detailed in Article 8, and in particular Membership Fees and Consortium Margins. Whenever necessary and agreed by the BC, the Authorised Representative shall be in charge of sub-contracting some activities linked to the Consortium Coordination Activities to third parties, such as project management;
- signing an unmodified Accession Agreement (as per Appendix C) with any new member for which application has been accepted by the BC, as detailed in Article 4.2, as well as signing an unmodified Third Party NDA (as per Appendix D).

5.2 Governance

5.2.1 *Board of Coordinators*

A Board of Coordinators ("**BC**") is established as the main governance body of the Consortium and the ultimate decision-making body. The BC shall exist until the end of the Term.

The BC is composed of the Institution's Scientists of Full Members and includes the Institution's Scientist for the Authorised Representative. The BC composition as of the Effective Date is provided in Appendix B.

The BC is in charge, after consultation of the Steering Committee or the Scientific Steering Committee (as defined in Articles 5.2.2 and 5.2.3, respectively) whenever relevant and necessary, of:

- The coordination and overall follow-up of the activities of the Consortium, in order to ensure the achievement of the objectives listed in Article 3;
- Making critical strategic decisions for the Consortium as a whole, in particular as regard to funding of the activities of the Consortium;
- Deciding on the use of any remaining budget from yearly Membership Fees and Consortium Margins after funding of the Consortium Coordination Activities costs, pursuant to Article 8.4.5;
- Coordinating communication and dissemination activities pertaining to the Consortium as a whole, and validating communication and dissemination documents;
- Resolving any issue, such as an authorship issue in a co-publication;

- Deciding on new academic members to join the Consortium;
- Evaluating the consequences of a breach by a Party and of the termination of the Agreement by a Party pursuant to Article 12, and implementing the necessary actions;
- Deciding on modifications of Appendices B, E and F of the Agreement without the necessity to sign an amendment to the Agreement.

5.2.2 *Steering Committee*

A Steering Committee ("**SC**") is established and shall exist until the end of the Term. The SC is composed of all Institution's Scientists. The SC composition as of the Effective Date is provided in Appendix B.

Whenever considered reasonably necessary by the BC on the matters under its responsibilities, decisions shall be brought to a vote by the SC. In addition, the SC shall be in charge of:

- Agreeing on the detailed content of the Consortium website, whereas relevant to the description of each Member or to information and Data and Results on Models and Materials;
- Agreeing on any matter related to access to Data and Results and the Database.

5.2.3 *Scientific Steering Committee*

A Scientific Steering Committee ("**SSC**") is established and shall exist until the end of the Term. The SSC is composed of one (1) representative from each research team within each Party. It is the responsibility of each Institution's Scientist to agree with its collaborators on the researchers to be represented in the SSC. The SSC composition as of the Effective Date is provided in Appendix B.

The SSC is in charge of:

- Expressing interest in a particular Consortium Study proposed by a Member, pursuant to Article 6.3;
- Advising on the performance or not of a Third Party Study, pursuant to Article 7. The SSC shall in particular evaluate the potential conflicts of interest or problematic competition between Members that the performance of a particular Third Party Study would cause and their consequences, and have the possibility to exercise a veto;
- Proposing for each Third Party Study a Principal Investigator ("PI") and a steering committee dedicated to the study, composed of one (1) representative from each research team of each Party participating in the Third Party Study and if the Third Party is an industrial, a member of the Technology Transfer Office of each Party participating in the Third Party Study ("**Project Steering Committee**" or "**PSC**");
- Agree on the establishment of standards among the Members, such as those mentioned at Article 6.1.5.

5.2.4 *Project Manager*

A Project Manager ("**PM**") will be in charge of, until the end of the Term:

- Coordinating the operational aspects of the Consortium (e.g. organisation of meetings, payment of Membership Fees), under the lead of the BC. The PM shall interact at least on a bi-monthly basis with the BC for decision-making by teleconference and by sending a concise report on his/her activities, and otherwise by email whenever necessary;
- Assisting the BC, SC, SSC, Working Groups and different PSCs in the coordination of research and dissemination activities (e.g. preparation and negotiation of Consortium Study and Third Party Study Agreements, set-up and maintenance of the Consortium website,

other communication activities, co-publication). Consortium Studies and Third Party Studies, to the exception of EU Studies, shall be coordinated with the help of the PM as part of the Consortium Coordination Activities. However, unless otherwise decided by the BC, EU Studies shall have their dedicated project management capability;

- Seeking funding opportunities through calls for proposals or development of public-private partnerships and assisting in the application of the Consortium to calls for proposals.

5.3 Meetings and decision-making process

5.3.1 The BC, SC and SSC shall meet face-to-face at least twice a year, together with the other scientists involved in activities of the Consortium, to review the progress of the Consortium objectives and current pipeline of collaborative projects.

In addition, the BC shall meet at least every three (3) months by teleconference or in a face-to-face meeting, or whenever necessary operate via email. Each meeting of the BC will be summarised in minutes by the PM, with description of the decisions made, which shall be sent within ten (10) calendar days after the BC meeting. The members of the BC shall have two (2) weeks after receipt of the draft minutes to ask for modifications. In case of no modification received within this delay, the provisions of the minutes shall be considered as agreed by all members of the BC. Final minutes shall be sent to the SC for information.

The SC and SSC shall meet via tele/video conference (provided reasonable notice is given) or operate via email whenever needed. Each meeting of the SC or SSC will be summarised in minutes by the PM, with description of the decisions made, which shall be sent within ten (10) calendar days after each meeting. The members of the SC or SSC shall have two (2) weeks after receipt of the draft minutes to ask for modifications. In case of no modification received within this delay, the provisions of the minutes shall be considered as agreed by all members of the SC or SSC.

5.3.2 Members of the BC, SC and SSC shall make their best efforts to participate in all meetings or be represented. The BC, SC, or SSC shall not deliberate and decide validly unless at least two-thirds (2/3) of its members are present or represented (quorum). In exceptional circumstances, if the quorum has not been reached for a specific meeting, the PM can solicit Members of the BC, SC or SSC that were not able to be present or represented, for them to give their approval or vote via e-mail, as regards decisions that were on the agenda of the said meeting, in order to reach the quorum and to decide validly a posteriori.

5.3.3 Members of the BC, SC and SSC shall make their best efforts to reach a consensus on all matters that are under their responsibility.

Upon a vote, a decision shall be reached with a majority with respect to the total number of members of each Consortium body (> 50%).

In no case shall a Party be imposed obligations not mentioned in this Agreement or be retired rights mentioned in this Agreement, without its prior written agreement.

Article 6 - PERFORMANCE OF CONSORTIUM ACTIVITIES

6.1 Commitments by all Members

6.1.1 All Members shall make their best efforts to actively participate in the activities of the Consortium and take part in at least one Working Group, in order for the Consortium to meet its overall objectives, and to act in a spirit of cooperation and mutual trust with respect to the activities of the Consortium. Each Party will comply in full with all laws, regulations, rules, ordinances, and policies applicable to its activities under the present Agreement.

6.1.2 Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties. Each Party shall as soon as reasonably practicable

provide all information reasonably required by a Consortium body or by the PM to carry out their tasks as listed in Article 5.

6.1.3 *Sharing Data and Results, Models and Materials between Members*

- Subject to third parties rights, all Members agree to Share as much Member Models and Member Materials, both subject to the provisions of the specific material transfer agreement for the specific Member Model or Member Material, and Background Data and Results with the Consortium as possible, whereas published or not;
- Subject to third parties rights, all Members having developed Member models agree to share at least a minimal set of characterisation and annotation data on their Member Models to be included in the Database, as listed in Appendix E;
- Subject to third parties rights, Foreground Data and Results, Consortium Models and Consortium Materials shall automatically be Shared;
- Subject to third parties rights and compliance with ethical regulations, all Members agree to transfer their Member Models and/or Member Materials to any other Member, both subject to the provisions of the specific material transfer agreement for the specific Member Model or Member Material and upon decision of the SSC and on an ad hoc basis for the performance of a Consortium Study or Third Party Study;
- Notwithstanding the above, the Parties acknowledge and agree that Members' contribution may consist of expertise and participation in studies only, and that such Members will not be required to contribute Member Models and Member Materials to the extent that the use or transfer of such Member Models and Member Materials is subject to third party rights. For the avoidance of doubt, Members' contributions and/or limitations thereof, including those referred to Member Models and Member Materials, as well as to Background Data and Results are identified in the present Appendix F as of the date of execution of the present Agreement. Any later amendment of Appendix F should be sent to the BC by the Party concerned, for acknowledgement of receipt and circulation to all Parties to the Agreement;
- All Members having developed Member Models agree to make their best efforts to have, at all times, except under extraordinary circumstances, a minimal amount of material for their Member Models biobanked and subject to the provisions of the specific material transfer agreement for the specific Member Material for the Member Model, made available for use in a Consortium Study or Third Party Study;
- All Members should whenever reasonably possible retrieve historical biobanking information related to their Member Models to be uploaded in the Database, and implement a data tracking system to evolve the quality of multicentre xenopatient trials.

6.1.4 *Ethics*

- As the Parties will use human cells/tissues and/or laboratory animals in Consortium Studies and Third Party Studies, the Parties shall conduct all work in accordance with the applicable national and European laws and regulations regarding the use of human cells/tissues and the experimentation in laboratory animals. Moreover, subject to limitations in Appendix F, the Parties herewith confirm that the patients have given their informed consent or have not opposed to the use of the human cells/tissues in research projects such as the ones foreseen in the frame of the Consortium, and if applicable allowing the transfer of the human cells/tissues and laboratory animals to the other Parties as academic institutions, for the use in collaborative research projects;
- Each Party agrees to provide any ethical document promptly upon request, and in particular to the Ethics Working Group of the Consortium;

- Each Party, upon withdrawal of its consent or non-opposition by a patient, shall immediately inform the BC, in order for all related data and results to be withdrawn from the information Shared by the Consortium, and in particular the Database;
- Each Party shall be solely responsible for obtaining the necessary regulatory authorisations for the performance of a Consortium Study or Third Party Study in its premises;
- The Parties will Share pseudonymised clinical data, which shall remain the property of the disclosing Party limited to third parties rights;
- As applicable, the Parties undertake to comply with the General Data Protection Regulation regarding the processing of personal data. Notwithstanding this clause, the Parties shall execute a specific material and/or data transfer agreement to cover for the transfer of personal data linked to specific Models or Materials, unless otherwise agreed by the Members involved. A separate material and/or data transfer agreement shall be provided by a providing Party or alternatively, the present Appendix G may be used.
- In any case, and whatever stated otherwise in this Agreement, the Parties will conduct all work and meet any commitment under this Agreement solely as long as their applicable national and European laws permit it.

6.1.5 *Standards*

- All Members agree to be in compliance with standards and recommended protocols agreed within the Consortium under the provisions of Article 5 (e.g. standards for the establishment and characterisation of models, for the performance of multicentric studies). Standards will have to be in line with all national and European ethical rules;
- All Members agree to involve the Bio-info-statistics Working Group from the beginning of each multicentre project of the Consortium for protocol design and data analyses. The local bioinformaticians shall be primarily involved in data analyses for each centre, however following the Consortium-wide agreed guidelines.

6.1.6 *Database & Access to Data and Results*

- Access to the Database or to any form of repository of information on Models, Materials and Data and Results shall be strictly limited to the Parties and their affiliated researchers and students, whether on temporary or permanent positions provided they are bound to the Party by a contract with confidentiality obligations, unless otherwise decided by the SC for authorised third parties and planned in a separate Data Access Agreement;
- The Database shall be set-up with the highest standards in terms of security, due to the Sharing of anonymised data from cancer patients, including genetic data. Upon set-up of the Database, a Data Management Plan shall be prepared by the PM together with the Members involved in the set-up of the Database and regularly updated during the Term.
- No study shall be initiated by a Member based on or using information Shared in the Database without the prior written approval of the Party(ies) that own the data and/or the approval by the SSC under the provisions of Article 6.3;
- Data and Results are being Shared WITHOUT ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY OTHER WARRANTY EXPRESSED OR IMPLIED. The disclosing Party and its directors, officers, employees or agents assume no liability and make no representations in connection with the Data and Results or their use by the receiving Party.

6.1.7 *Funding of the Consortium Coordination Activities*

- All Members agree to participate to the Consortium Coordination Activities costs by paying a Membership Fee, as detailed in Article 8.

6.1.8 *Involvement of third parties*

- A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliates) in the Consortium activities remains responsible for carrying out its relevant part of the Consortium activities and for such third party's compliance with the provisions of this Agreement. This Party shall ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Agreement.

6.1.9 *Dissemination*

- All Members agree that as many Data and Results as possible should be made publicly available and shared with the scientific community for non-commercial purposes, in particular through open access publication, to avoid duplication of efforts. Data to be made public (e.g. minimal characterisation and annotation data on the Models, available via the Consortium website) should be defined between the Members and endorsed by the SC. All Members shall make reasonable efforts to make publicly available not publishable Data and Results after three (3) years.

6.2 Additional commitments for Trial Members

- Subject to Article 6.4, Trial Members agree to allocate the necessary resources, among receipt of appropriate funding, for the performance of a Consortium Study or Third Party Study using their own Models and the Models transferred from other Members;

- Subject to Article 6.4, as used for centralisation of the Consortium activities, Trial Members shall make their best efforts to, on a mid-term basis, retrieve historical biobanking information to be uploaded in the Database, and implement a data tracking system to evolve the quality of multicentre trials.

6.3 Initiation and performance of a Consortium Study

6.3.1 Each Member will be welcome to submit at any time a proposal of Consortium Study to the SSC, in order to ask for interest of Members and availability of relevant Models. The Member proposing the potential Consortium Study shall designate a PI within its institution.

6.3.2 The SSC will have two (2) weeks to express first interest and the PM to look into the Database when available, before further discussions and set-up of a multicentre study, under the responsibility of the PI and with the help of the PM and relevant Working Groups. Appropriate funding will be leveraged whenever necessary.

6.3.3 A separate and dedicated Consortium Study Agreement, either in the form of a collaborative research agreement or a material transfer agreement, shall be signed for each Consortium Study unless otherwise agreed by the involved Members. The Consortium will work on a common template of material transfer agreement, to be adapted to each Consortium Study, in order to accelerate the initiation of each Consortium Study and Sharing of Models. It is understood that the provisions of those separate agreements shall be in accordance with and not in opposition to the provisions of the present Agreement unless agreed otherwise.

6.3.4 All Members, through an email to the SSC, shall be made aware of the application of some Members to any call for proposals with a project linked to the objectives of the Consortium, for participation or at least information.

6.3.5 Each Party undertakes to promptly notify the PI of a particular Consortium Study and the BC with any significant information, fact, problem or delay likely to affect the performance of the Consortium Study.

6.4 Entering into the present Agreement does not represent any obligation to any Party to Share any Background Data and Results, all Member Models and Materials or perform any particular Consortium Study.

Article 7 - INITIATION AND PERFORMANCE OF A THIRD PARTY STUDY

7.1 Initiation and performance of a Third Party Study

7.1.1 Each proposal of Third Party Study by a Member or the PM shall be sent to the SSC, in order to ask for interest of Members and availability of relevant Models. The SSC will have two (2) weeks to express first interest and the PM to look into the Database when available. Within two (2) months ("**Evaluation Period**") after receipt of a Third Party Study proposal, the SSC shall organise the necessary discussions between the interested Members and with the Third Party(ies) involved if necessary, by email and/or tele/video conference and shall bring the decision to a vote. A confidentiality disclosure agreement shall be signed. In the case of no final consensus or decision within the Evaluation Period following the decision process laid down in Article 5.3.3, the particular Third Party Study will not be performed not to compromise the sustainability of the Consortium.

7.1.2 A separate Third Party Study Agreement shall be negotiated and executed for each Third Party Study approved by the SSC, following the guidelines laid down in Article 9.5. The provisions of this Third Party Study Agreement shall respect and comply with the provisions of the present Agreement, unless agreed otherwise.

7.1.3 Upon approval of a Third Party Study, the SSC will propose a PI and a PSC. The PI and PSC, with the help of the PM, will be responsible for agreeing with the Third Party(ies) on the overall goals and strategy of the Third Party Study, defining the protocol and detailed work plan, drafting and negotiating the budget pursuant to Article 8.3.1, coordinating the negotiation of the agreement with the Third Party(ies), organising the logistics for the performance of the Third Party Study with the help of the Logistics Working Group, reviewing its progress, discussing any modifications and amendments to the protocol with the Third Party(ies), and coordinating publication.

7.1.4 The PI may appoint ad hoc the Authorised Representative or another Party participating in the Third Party Study, who may appoint a delegate from the institution (i.e. technology transfer officer), to be leading the negotiation of the confidentiality disclosure agreement with the Third Party(ies) and/or of the Third Party Study Agreement on behalf of the Parties involved, for the best benefits of the Consortium and the Parties and as detailed in Article 9.5. It is understood that the appointed Party may refuse this role.

7.1.5 Each Party shall promptly provide all information reasonably required for the initiation and performance of a Third Party Study that they are involved in. In the case where, for the performance of the Third Party Study, the Parties involved need to communicate to the Third Party any Confidential Information of another Party, it shall obtain the prior written consent of this other Party.

7.1.6 In case of a EU Study in line with the objectives of the Consortium, the PM shall support the Members in the preparation of applications to call for proposals in collaboration with Third Party(ies). The performance of a EU Study shall be organised in a separate agreement and with dedicated coordination and project management capabilities.

7.1.7 A Member inviting other Members to join a collaboration with a Third Party after the effective date of the collaboration (e.g. inclusion of Member Models in an ongoing study with an industrial third party), or including Models from other Members in a starting Third Party Study, shall be responsible for ensuring that the participation of the other Members will be at least reflected in the publications arising from the study and using the Member Models, according to their input to the study. Besides, in application of the provisions of Article 8 below, the Consortium Margin shall be applied to all starting Third Party Studies benefitting from the existence of the Consortium.

7.2 Transfer of Data and Results, Models and Materials to any Third Party for the performance of a Third Party Study, and in particular to private companies, will be negotiated on an ad hoc basis and in a separate Third Party Study Agreement, and in any case shall be

in compliance with the patients' informed consents and shall not compromise the anonymity of the patients from which Models or Materials have been developed. For avoidance of doubt, each Member shall be free to transfer Member Models exclusively owned by such Member to a Third Party, such transfer shall not require any consultation with the other Members.

7.3 Subject to third parties rights, the relevant Members will ensure that any Third Party Study Agreement allows for Third Party Study Data and Results to be automatically Shared for research purposes.

7.4 The relevant Members shall negotiate with Third Parties the possibility to co-publish the Third Party Study Data and Results with the Third Parties, subject to the terms of the present Article 10.

7.5 Subject to third parties rights, the relevant Members will ensure that any Third Party Study Agreement includes that, as often as possible, at least part of the Third Party Study Data and Results corresponding to pharmacological and molecular characterisation of the Models and Materials are ultimately made available to the wide scientific community by being included in the Database.

7.6 Entering into the present Agreement does not represent any obligation to any Party to participate in all Third Party Studies.

Article 8 - FUNDING

8.1 Several opportunities will be pursued for the funding of the Consortium Coordination Activities and the performance of Consortium Studies. Consortium Coordination Activities costs include fees for project management and coordination of the Consortium (salary or honoraria and travel costs), communication and dissemination costs (e.g. website), set-up and maintenance of the Database, and costs linked to the networking activities and organisation of meetings (e.g. reservation of meeting rooms, travels to and accommodation at the meeting place for all Members, catering). Costs of Consortium Studies include in particular the consumables and personnel costs linked to the performance of multicentre research programs and xenopatient trials.

8.2 Research funds obtained by the Members for the performance of Consortium Studies and Third Party Studies including EU Studies shall be managed through separate agreements.

8.3 Third Party Studies excluding EU Studies - Consortium Margin

8.3.1 In case of a Third Party Study, either negotiated by the Authorised Representative or another Member, the Authorised Representative or the other Member shall establish a draft budget based on its usual fees, submit it to the Members involved and have it validated prior to any communication to the Third Party. The budget allocated to Members involved by only transferring their Models to other Members for inclusion in a particular Third Party Study shall be decided on a case-by-case basis. The draft budget shall detail the direct costs linked to the Third Party Study, together with all indirect, infrastructure and general and administrative costs usually charged, which shall include the administrative costs linked to the negotiation of the Third Party Study Agreement by the concerned Member. In addition, the draft budget shall include an additional operative margin ("**Consortium Margin**") corresponding to five per cent (5%) of the total direct costs VAT excluded. The Authorised Representative or other Member shall negotiate the final budget with the Third Party according to the type of study, the contribution of the Consortium in the collaboration, and intellectual property share in the Third Party Study Data and Results for the Consortium, according to the guidelines provided in Article 9.5, provided however that in the case of CORNELL, CORNELL shall be solely responsible for negotiation of the final budget for Third Parties Studies it is involved in. CORNELL may in its sole discretion incorporate comments and feedback from the Authorised

Representative and/or other Members also involved in the Third Party Studies concerned. CORNELL shall keep Members involved in a given Third Parties Study regularly aware of the negotiation status and shall seek approval of the final terms by involved Members.

8.3.2 The Consortium Margins shall be primarily used for covering the Consortium Coordination Activities costs. The Authorised Representative shall be responsible for managing the Consortium Margins, and any Member receiving the funds of a Third Party Study shall transfer the amount corresponding to the Consortium Margin to the Authorised Representative, via bank transfer, on the bank account held and designated by the Authorised Representative and within thirty (30) days of receipt of an appropriate invoice issued by the Authorised Representative.

8.3.3 The budget of any study with a Third Party initiated thanks to the Consortium, even if only involving a single Member, shall include a Consortium Margin, with an amount to be determined on a case-by-case basis between the involved Member(s) and the BC.

8.4 Funding of the Consortium Coordination Activities

8.4.1 All Members agree to participate to the Consortium Coordination Activities costs by paying a Membership Fee. As the Membership Fees for the years spanning from May 2014 until December 2022have been managed through separate agreements, the funding of the Consortium Coordination Activities and payment of Membership Fees will be governed by the present Agreement starting the year spanning January – December 2023.

8.4.2 A budget validated by the BC and proposal of yearly Membership Fee will be provided to the SC on February 1st of each year for the period spanning May of the same year to April of the following year, taking into account all external funding sources that would reduce these costs for Members such as Consortium Margins.

8.4.3 The total yearly Consortium Coordination Activities budget will be divided between Members according to their membership level, as a percentage of the following Membership Fee amounts:

8.4.4 Membership Fees payment will be managed by the Authorised Representative, which will directly invoice all Parties for the yearly amounts according to their membership level. All invoices shall be paid within thirty (30) days from each invoice date, via bank transfer, on the bank account held and designated by the Authorised Representative. The exchange rate from Euros (EUR) to USD or any other currency will apply at the time of payment.

8.4.5 It is understood that the yearly Membership Fees will not be refundable, either partially or fully, unless decided otherwise during the relevant year by the BC. However, in any case, all costs already engaged at the time of such a decision by the BC shall not be refundable.

8.4.6 *Use of remaining budget*

After consultation of the SC and the SSC, the BC shall be responsible for deciding on the use of any budget remaining from the yearly Membership Fees and Consortium Margins after funding of the Consortium Coordination Activities costs, either for activities of the Consortium (e.g. set-up and maintenance of the Database, characterisation of Models, performance of a particular Consortium Study) or to be refunded to the Members by lowering the Membership Fees for the following year.

In case of use for activities of the Consortium, the remaining budget shall be distributed between Members to reflect the percentage of investment in Consortium activities defined in the different levels of membership, and as follows: 70% to activities performed by Full

Members and 30% to Associate Members, further distributed between 60% for Trial Members and 40% for Research Members.

Upon decision of the BC, the remaining budget distributed to each Member shall be transferred by the Authorised Representative to each Member, via bank transfer, on the bank account held and designated by each Member and within thirty (30) days of receipt of an appropriate invoice issued by each Member.

Article 9 - INTELLECTUAL PROPERTY, ACCESS RIGHTS AND EXPLOITATION

[redacted]

Article 10 - COMMUNICATION, DISSEMINATION AND GRANT APPLICATIONS

10.1 Any Party shall be free to mention another Party as a Member of the Consortium, whether in writing or orally.

10.2 Any extensive communication on the Consortium as a whole, its goals and status, including press releases, review articles, scientific articles, oral presentations or posters at meetings or conferences shall be first validated by the co-authors and the BC as per the process set out in Article 5.3.3.

10.3 All Parties when presenting the Consortium or results obtained under the frame of the Consortium shall use the presentation slides and the Consortium logo.

10.4 Website

A website dedicated to the Consortium will be set-up, which detailed content should be validated by the SC before release. Guidelines for public release of information and Data and Results on Models and Materials on the Consortium website shall be agreed by the SC.

10.5 Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

10.6 It is the intention of the Members to publish and make publicly available as many data and results as possible, including Data and Results and Third Party Data and Results, subject to third parties rights.

10.7 All communications and scientific articles arising from Consortium Studies or any activity done under the framework of the Consortium will recognise the role of the Consortium in some way, either in the manuscript title or byline. Options include:

- listing the Consortium as an author;
- including the statement “on behalf of/for the EurOPDX Consortium” in the byline;
- including "EurOPDX Consortium" in the manuscript title.

10.8 Authorship

It is anticipated that articles arising from the work performed under the framework of the Consortium will vary by type, will be Consortium-wide or arising under the framework of a Working Group or of a particular Consortium Study or Third Party Study. Authorship will therefore vary somewhat by type of study. The following general model will be applied:

- Articles will list only active contributors as named authors;
- The number and position of authors per contributing Party will be determined by input to the study in question. It shall be the responsibility of the PI to agree on authorship with the Parties. Members having only provided Models to the study and not contributed otherwise shall be acknowledged only or, if listed as author, shall have a less favourable place than Members having actually performed the experiments and/or having provided intellectual input to the study;
- However, all relevant contributors may be listed in an appendix or in acknowledgments, at the discretion of the PI;
- All authors or relevant contributors who are members of the Consortium shall be listed as such in the acknowledgements section of ALL publications as "Initials is a member of the EurOPDX Consortium";

- In the case of authorship conflict, the recommendations of the International Committee of Medical Journal Editors (ICMJE) will be used to govern resolution of authorship issues and resolution will be managed by the BC.

10.9 Communication and publication reviewing process

For all communications and scientific articles arising from Consortium Studies or any activity done under the framework of the Consortium, a copy of the proposed disclosure shall be provided to the co-authors of each Party, with a copy to the BC, at least thirty (30) days prior to the submission of any written publication or any oral public disclosure ("**Review Period**") to allow the other Parties to perform a substantive review of the disclosure, and to determine whether any of their inventions or Confidential Information or their other sensitive information would be disclosed. Publication can be delayed, for a maximum of four (4) months from the end of the Review Period, for the identification and filing of any potentially patentable inventions and the removal of Confidential Information. Failure to respond within the appropriate Review Period will be taken as agreement to the manuscript.

The final version of any publication or communication, and in particular the final draft of a manuscript, shall be emailed to all named authors with a copy to the BC before release or first manuscript submission, for final approval within one (1) week. Failure to respond within one (1) week will be taken as agreement to the manuscript.

Reviewer comments should be e-mailed to all named authors. Author agreement to the initial manuscript submission will be considered as an implicit agreement to the communicating author for resubmission to alternative journals, assuming there are no major changes to the manuscript. However, the communicating author shall be responsible for re-circulating the accepted final manuscript to all co-authors.

10.10 Grant applications

Preparation of grant applications for Consortium Studies involving several Members shall be subject to the same provisions as in Section 10.9.

However, Members shall be free to disclose their participation in the Consortium in grant applications not involving other Members, without prior notice.

Article 11 - NON-DISCLOSURE OF INFORMATION

[redacted]

[redacted]

Article 12 - ENTRY INTO FORCE, DURATION AND TERMINATION

12.1 Entry into force

Notwithstanding the date(s) of signature hereof, this Agreement shall have effect from the date of May 1st, 2015 (hereinafter the "**Effective Date**"), which corresponds to the end of the NDA term, except for CORNELL for which the effective date is set to 1st May 2016, for UNIBAS and LIH for which the effective date is set to 1st May 2017 and for IMG for which the effective date is set to 1st December 2022.

An entity becomes a Party to this Agreement following the rules and process laid down in Article 4.2, and upon signature of the Accession Agreement provided in Appendix C by the new Party and the Authorised Representative. Such accession shall have effect from the date identified in the executed Accession Agreement.

12.2 Term

This Agreement shall continue in full force and effect during ten (10) years from the Effective Date (hereinafter the "Term"). It may be renewed by some or all Parties by mutual consent and signature of an amendment.

12.3 Breach

In the event that a Member identifies a breach by another Member of its obligations under this Agreement, the Member shall report so to the BC, which shall decide on the appropriate measures (without the vote of such Defaulting Party) and eventually give formal notice to such Party requiring that such breach will be remedied within sixty (60) calendar days.

A default by a Party shall be considered a breach if such default is not due to Force Majeure and is irremediable, or if such default is not due to Force Majeure and is not remedied within sixty (60) calendar days of the written notice from the BC requiring that such Default be remedied if remediable.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the BC may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof, which may include termination of its participation as detailed in Article 12.4.1 below.

12.4 Termination

12.4.1 *Termination for breach*

In the event of a breach of obligations under this Agreement by a Defaulting Party, the BC (without the vote of such Defaulting Party) may terminate this Agreement in relation to such Defaulting Party by a written notice of not less than thirty (30) calendar days. Upon termination for the Defaulting Party, the following shall apply:

i) any and all Access Rights granted to the Defaulting Party by the other Parties under this Agreement and/or other Consortium Study Agreement and/or other Third Party Study Agreement shall cease immediately while any and all Access Rights granted by the Defaulting Party to the other Parties shall remain in full force and effect for the term of any Consortium Study Agreement and/or Third Party Study Agreement;

ii) the work and tasks remaining to be performed by the Defaulting Party may be assigned, by decision of the BC after consultation of the SC (without the vote of such Defaulting Party), to one or more of the other Parties or to Third Parties, which agree to be bound by the terms of this Agreement and/or the applicable Consortium Study Agreement and/or Third Party Study Agreement;

iii) the Defaulting Party shall pay all the sums it is engaged to pay before the effective date of the termination.

If a Party enters into bankruptcy or liquidation or any other arrangement for the benefit of its creditors, the other Parties hereto shall undertake all reasonable efforts to take over the fulfilment of such Party's obligations under this Consortium Agreement and/or any other applicable Consortium Study Agreement and/or other Third Party Study Agreement in respect thereof. In such event, all rights of such Party under this Agreement and any other Consortium Study Agreement and/or other Third Party Study Agreement shall, to the fullest extent legally possible, be assigned and transferred to the benefit of the other Parties.

12.4.2 *Termination without Cause*

Upon ninety (90) days prior written notice to the other Parties, and in particular to the BC, any Party may terminate this Agreement without cause. The BC will be responsible for determining the consequence of the termination of the Agreement by the given Party.

The Party leaving the Consortium shall pay the sums it is engaged to pay before the effective date of the termination and shall not be reimbursed of the Membership Fees paid for the ongoing year.

The leaving Party can stop access by the other Members and Third Parties to its Member Models, Member Materials, Background Data and Results and Confidential Information.

12.4.3 *Termination of a Consortium Study Agreement and/or Third Party Study Agreement*

The termination of any agreement undertaken to effect the terms of this Agreement and entered into by the Parties, including, but not limited to, a Consortium Study Agreement and/or Third Party Study Agreement, will not result in the termination of this Agreement, so long as the Parties otherwise continue to meet their obligations pursuant to this Agreement.

12.5 Survival of rights and obligations

12.5.1 Termination of this Agreement for any reason shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the BC and the leaving Party.

12.5.2 For all Consortium Study and/or Third Party Study affected by termination of this Agreement, the Parties agree to work together and to follow the reasonable directions of the BC.

12.5.3 Termination of this Agreement for any reason will not release either Party from any liability which has already accrued to the Party or which is attributable to any event occurring during the Term of this Agreement prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring during the Term of this Agreement prior to such termination.

12.5.4 The provisions relating to Access Rights and Confidentiality, for the time period mentioned therein, as well as for Liability, Applicable law and Settlement of disputes shall survive the expiration or termination of this Agreement.

Article 13 - LIABILITY

13.1 No warranties

Subject to the provisions of Article 6.1.2, in respect of any information or materials, including Models, Materials, Data and Results, supplied by one Party to another under this Agreement, no warranty or representation of any kind is made, given or implied as to merchantability, sufficiency or fitness for a particular purpose, accuracy, completeness or violation of third party intellectual property rights, and it shall be the other Parties' responsibility to make all usual checks and validations, as required for the achievement of the objectives described in Article 3.

Therefore, (i) any Receiving Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and (ii) no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliates) exercising its Access Rights.

13.2 Limitations of contractual liability

13.2.1 No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality.

13.2.2 Each Party shall be held liable for direct damages arising out of or in connection with any disclosure of all or any part of the Confidential Information received, whether by itself, its employees, or any other person with whom it is committed in a legal relationship. Each Party will bind such employees to keep such Confidential Information confidential both during and after their current employment and will take appropriate steps to enforce the obligations of such employees in relation thereto.

13.2.3 A Party’s aggregate liability towards the other Parties collectively shall be limited to twice the Party’s total Membership Fees paid since the Effective Date, provided such damage was not caused by a wilful act or gross negligence.

13.2.4 The terms of this Agreement shall not be construed to amend or limit any Party’s statutory liability.

13.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Agreement or from its use of Background and Foreground Data and Results.

13.4 Force Majeure

13.4.1 No Party shall be considered in breach of its obligations under this Agreement or any Consortium Study Agreement or Third Party Study Agreement if it has been prevented from complying by Force Majeure. However, all necessary measures shall be taken to limit damage to the minimum.

13.4.2 A Party shall notify the BC without undue delay and in writing of any Force Majeure that may affect the fulfilment of its obligations under this Agreement and/or any Consortium Study Agreement and/or any Third Party Study Agreement. If the consequences of Force Majeure for the Consortium are not overcome within six (6) weeks after such notification, the necessary consequences such as amendments to this Agreement and/or any Consortium Study Agreement and/or any Third Party Study Agreement to redress the situation shall be decided by the BC.

Article 14 - MISCELLANEOUS

14.1 Attachments, inconsistencies and severability

This Agreement consists of this core text and its Appendices. In case the terms of this Agreement are in conflict with any other agreement such as any Consortium Study Agreement and/or any Third Party Study Agreement, the terms of the present Agreement shall prevail, unless agreed otherwise. In case of conflicts between the attachments and the core text of this Agreement, the latter shall prevail.

Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.

14.2 No representation, partnership or agency

Except as otherwise provided in Article 5.1 regarding the Authorised Representative, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the Consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

14.3 Entire agreement

This Agreement and the NDA embody the entire agreement between the Parties with regard to the subject matter hereof, and supersedes all prior representations, negotiations, covenants, oral or written communications, consents, agreements and understandings between the Parties relating to the provisions to which this Agreement applies or which are stipulated herein.

This Agreement may be executed in one or more counterparts, each of which will deemed an original but which will together constitute one instrument. The facsimile/electronic transmission of a signed counterpart is deemed proof of signature of the original. The signed transmitted facsimile/electronic versions are deemed an original.

14.4 Notices and other communication

14.4.1 Any notice to be given under this Agreement shall be in writing to the Institution's Scientists and addresses as listed in the most current address list kept by the Project Manager.

14.4.2 *Formal notices*

If it is required in this Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

14.4.3 *Other communication*

Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Project Manager. The address list shall be accessible to all concerned.

14.5 Assignment and amendments

No rights or obligations of the Parties arising from this Agreement may be assigned or transferred, in whole or in part, to any third party including Affiliates without the other Parties' written consent.

Amendments and modifications to the text of this Agreement require a separate written agreement to be signed between all Parties.

14.6 Mandatory national law

Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

14.7 Language

This Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

14.8 Applicable law

In order to be in accordance with any future agreement with the European Commission for funding of the Consortium, this Agreement shall be governed by the law of Belgium.

14.9 Settlement of disputes

In the event that a disagreement cannot be settled amicably beyond three (3) months of notification in writing of one Party to another Party or other Parties, the courts of Brussels shall have exclusive jurisdiction.

Nothing in this Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

- Signature Pages Follow –

IN WITNESS WHEREOF, the Parties hereto intending to be bound hereby have caused this Agreement to be duly signed by the undersigned authorised representatives in separate signature pages.

INSTITUT CURIE

[redacted]

Title: Director of the Research Centre
Date: 15/12/2022

Initials:

[redacted]

Title: Head, Translational Research Department
Date: 14/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

[redacted]

Title: Rector
Date: 13/12/2022

Initials:
For approval:

[redacted]

Title: Head of the Trace Platform
Date: 11/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

VHIO

Title: Managing Director
Date: 07/12/2022

Title: Scientific Research Manager
Date: 07/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

ICO

Title: General Director
Date: 22/12/2022

Initials:

Title: Principal Investigator, Program Against Cancer Therapeutic Resistance (ProCURE)
Date: 21/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

UNITO

[redacted]

Title: Director, Department of Oncology
Date: 13/12/2022

Initials:

[redacted]

Title: Full Professor, Department of Oncology
Research Unit: Laboratory of Translational Cancer Medicine
Date: 09/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

UNIVERSITAIR MEDISCH CENTRUM GRONINGEN (UMCG)

[redacted]

Title: Member Board of Directors
Date: 22-12-2022

The undersigned INSTITUTION'S SCIENTIST hereby acknowledges that he has read the above Agreement and understands his obligations as the discloser/receiver of the information and as employee/staff member of UMCG to abide by the terms of this Agreement.

Initials:

[redacted]

Title: Professor of Preclinical and Translational Oncology
Research Unit: Department of Medical Oncology
Date:
11-01-2023

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

NKI-AVL

[redacted]

Title: Director of Operations
Date: 10 December 2022

[redacted]

Title: Group leader
Research Unit: Division of Molecular Pathology
Date: 15 December 2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

CAMBRIDGE

[redacted]

Title: Head of Clinical Contracts
Date: 24/01/2023

Initials:

[redacted]

Research Unit: CRUK Cambridge Institute - Cambridge Cancer Centre
Date: 25/01/2023

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

MANCHESTER

[redacted]

Title: Director of Research and Business Engagement Support Services
Date: 10/12/2022

Initials:

[redacted]

Research Unit: Breast biology group
Date: 09/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

GLASGOW

[redacted]

Title: Senior Contracts Manager
Date: 25/01/2023

[redacted]

Title: Regius Chair of Surgery and Director of Translational Research Centre
Research Unit: Institute of Cancer Sciences
Date:

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

OUS

[redacted]

Title: Head of Department - Administrative Research Support
Date: 07/12/2022

Initials:

[redacted]

Research Unit: Department of Tumor Biology
Date: 06/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

RCSI

Title: Associate Director of Research
Date: Nov 28, 2022

Initials:

Title: Professor and Head
Research Unit: RCSI Precision Cancer Medicine Group
Date:
Dec 9, 2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

MASARYK UNIVERSITY

[redacted]

Date: 26/01/2023

Initials:

[redacted]

Title: Vice-Head of the IT Infrastructure Division, Institute of Computer Science MU
Date: 30/01/2023

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

IEO

[redacted]

Title: Chief Executive Officer
Date: 25/01/2023

Initials:

[redacted]

Title: Unit Director, Department of Experimental Oncology
Date: 20/01/2023

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

CORNELL

[redacted]

Title: Executive Director, Office of Sponsored Research Administration
Date: 23/01/2023

Read and understood:

[redacted]

Title: Professor of Pathology and Laboratory Medicine
Date: 25/01/2023

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

UNIBAS

[redacted]

Title: Vice President for Research
Date:

Initials: [redacted]

Title: Professor
Date: 06.12.2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

LIH

[redacted]

Title: CEO
Date: 31/01/2023

[redacted]

Title: CFAO
Date: 12/01/2023

Initials:

[redacted]

Title: Director of the Department of Oncology, Head of the NORLUX Neuro-Oncology Laboratory
Date: 15/12/2022

EurOPDX Consortium Agreement
Authorised signature(s) of the Party:

IMG

Title: Director
Date:

APPENDIX A - Abbreviations

AssociateR = "Associate Research" Member, as defined in Article 4.1

AssociateT = "Associate Trial" Member, as defined in Article 4.1

BC = Board of Coordinators

FullR = "Full Research" Member, as defined in Article 4.1

FullT = "Full Trial" Member, as defined in Article 4.1

NDA = Multilateral non-disclosure agreement signed between the Parties, effective on May 2nd, 2013 and valid until May 1st, 2015

PDX = Patient derived tumour xenograft model

PI = Principal Investigator

PM = Project Manager

PSC = Project Steering Committee

SC = Steering Committee

SSC = Scientific Steering Committee

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

APPENDIX C - Accession to the EurOPDX Consortium Agreement

BY AND BETWEEN

INSTITUT CURIE,
A private, not for profit state approved foundation,
Having a registered office at 26 rue d'Ulm, 75005 Paris, France,
Officially represented by [redacted], Director of the Research Centre,

Hereinafter referred to as "**INSTITUT CURIE**",

ON THE ONE HAND,

AND

[OFFICIAL NAME OF THE NEW PARTY]
A [type of institution],
Having its principal offices at [full address],
Represented by [name of duly authorised representative] in his capacity as [position of representative],

Hereinafter referred to as "**[ACRONYM of the new party]**",

ON THE OTHER HAND.

PREAMBLE

WHEREAS, INSTITUT CURIE is acting for the present Accession Agreement on behalf of the Parties of the EurOPDX Consortium Agreement (hereinafter the "Consortium Agreement"), and in particular on behalf of the Board of Coordinators, the governing body of the EurOPDX Consortium (hereinafter the "Consortium").

WHEREAS, [ACRONYM of the new party] desires hereby to accede to the Consortium Agreement and has, upon application, been duly informed that its application has been accepted by the Board of Coordinators of the Consortium.

WHEREAS, INSTITUT CURIE desires hereby to confirm the accession of [ACRONYM of the new party] to the Consortium Agreement, in order that [ACRONYM of the new party] may participate in the activities of the Consortium undertaken pursuant to the Consortium Agreement.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. [ACRONYM of the new party], starting [date], hereby consents to become a Party to the Consortium Agreement as a [insert level of membership], and agrees to all the rights and obligations of a Party pursuant to the terms and conditions of the Consortium Agreement, which are incorporated by reference as if set forth in full herein. It also agrees to respect them.

2. INSTITUT CURIE hereby certifies that the Board of Coordinators of the Consortium has accepted in the meeting held on [date] the accession of [ACRONYM of the new party] to the Consortium, starting [date].

3. Notices required to be sent to [ACRONYM of the new party] shall be addressed to the following contact persons:

For legal aspects:	Institution's Scientist:
[Insert contact name, department and full address]	[Insert principal scientific contact name, department and full address]

IN WITNESS WHEREOF, the Parties hereto have caused this Accession Agreement to be hereafter executed in two (2) original copies by their duly authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]
Signature(s)
Name(s)
Title(s)

[Date and Place]

INSTITUT CURIE
Signature(s)
Name(s)
Title(s)

APPENDIX D - Template Third Party NDA

NON-DISCLOSURE AGREEMENT
-
EUROPDX CONSORTIUM

BY AND BETWEEN

INSTITUT CURIE,
A private, not for profit state approved foundation,
Having a registered office at 26 rue d'Ulm, 75005 Paris, France,
Officially represented by [redacted], Chairman of the Executive Board and by delegation [redacted], Director of the Research Center,

Hereinafter referred to as "**INSTITUT CURIE**",

ON THE ONE HAND,

AND

[OFFICIAL NAME OF THE THIRD PARTY]
A [type of institution],
Having its principal offices at [full address],
Represented by [name of duly authorised representative] in his capacity as [position of representative],

Hereinafter referred to as "**[ACRONYM of the third party]**",

ON THE OTHER HAND.

PREAMBLE

WHEREAS, the EurOPDX Consortium (hereinafter the "Consortium") is a network of academic not-for-profit institutions and researchers focusing on clinically relevant models of human cancer, and in particular patient-derived tumour xenograft (PDX) models.

WHEREAS, the objectives of the Consortium are to share PDX models in order to constitute a unique collection of models and perform collaborative multicentre and multipathology xenopatient trials, perform various research programs for the evolution of PDX models and elucidate standard operating procedures in the field.

WHEREAS, INSTITUT CURIE is acting for the present non-disclosure agreement (hereinafter the "Agreement") on behalf of the members of the Consortium (hereinafter the "MEMBERS") as further defined in Article 1.2. The parties listed above and the MEMBERS are hereinafter individually referred to as the "PARTY" and collectively as the "PARTIES".

WHEREAS, [ACRONYM of the third party], and in particular its employee [Name of main contact/PI], is willing to [description of the objectives of the discussions] (hereinafter the "PURPOSE").

WHEREAS, in order to be able to discuss unrestrictedly for the PURPOSE, the PARTIES agree to previously execute the present Agreement.

NOW, THEREFORE, IN CONSIDERATION of the premises and the covenants herein contained, it is agreed between the PARTIES as follows:

Article 1 – DEFINITIONS

As used herein, capitalized terms in this Agreement (including its Appendices) and any amendments hereto, shall always have the meanings expressly given to them in the following definitions, without any exceptions.

Definitions in the singular form shall include the plural and vice versa.

1.1. CONFIDENTIAL INFORMATION

CONFIDENTIAL INFORMATION shall mean all information and data of whatever nature exchanged between the PARTIES in connection with the PURPOSE in any form whatsoever, written, graphic, oral or by any other means, irrespective of form, whether or not protected by intellectual property rights, including, but not limited to, a copy of a patent application, industrial plans, documents marked "confidential", know-how, technical or business information, prototypes. In particular, description of particular PDX models developed by a PARTY, their annotation and characterisation data, description of a particular project performed by a PARTY and of a potential biomarker of response or resistance to a given therapy in a given cancer pathology are considered CONFIDENTIAL INFORMATION unless otherwise specified by the disclosing PARTY.

1.2. MEMBERS

MEMBERS shall mean the institutions listed in the present Appendix 1, which are members of the Consortium on the EFFECTIVE DATE as defined below.

1.3. KNOW-HOW

KNOW-HOW shall mean a set of practical information (procedural knowledge, processes, manufacturing formulas, trade secrets, innovations that can not be protected by patent law, such as discoveries, scientific theories and methods, schemes, rules and methods, etc., and generally all the innovations that do not have an inventive enough to be patentable), non-patented, resulting from experience and testing of the disclosing PARTY, and which is secret and substantial.

1.4. EFFECTIVE DATE

EFFECTIVE DATE shall mean [date].

1.5. AFFILIATE

AFFILIATE shall mean any firm, corporation or legal entity that directly or indirectly controls, is controlled by, or is under common control with, a PARTY. A legal entity is deemed to control another if:

(iv) it holds, directly or indirectly, a portion of that other legal entity's capital giving it a majority of voting rights at general meetings thereof; or

(v) it is the sole owner of a majority of voting rights pursuant to an agreement entered into with other partners or shareholders; or

(vi) in view of the circumstances, it is in fact enabled by the voting rights owned by it to have its opinion prevail at general meetings ("de facto control" situation).

Article 2 – CONFIDENTIALITY OBLIGATION

2.1 Each PARTY undertakes to treat confidentially and maintain in strict confidence any and every CONFIDENTIAL INFORMATION received from another PARTY from the EFFECTIVE DATE and for five (5) years after the TERM, as defined in Article 7.

Each PARTY further undertakes not to divulge CONFIDENTIAL INFORMATION of another PARTY to third parties and undertakes that all necessary steps are taken to limit the risks of disclosure of said CONFIDENTIAL INFORMATION.

CONFIDENTIAL INFORMATION of the other PARTY shall not be disclosed to another company, institution, or any other third party, whatever their capitalistic or legal relations are, without the prior written consent of the disclosing PARTY.

2.2 Notwithstanding the foregoing, each PARTY is entitled to make CONFIDENTIAL INFORMATION available to its AFFILIATES.

2.3 Each PARTY shall use its best efforts to have CONFIDENTIAL INFORMATION treated as such by its employees and any individuals howsoever in its service.

Each PARTY undertakes in particular:

- to disclose CONFIDENTIAL INFORMATION received from the other PARTIES only to persons working under its authority on a temporary or permanent basis, its advisors, AFFILIATES, subcontractors – if any, for instance the project manager of the Consortium –, and any individuals howsoever in its service having an absolute need-to-know to carry out the PURPOSE;

- to ensure that persons working under its authority on a temporary or permanent basis, its advisors, AFFILIATES, subcontractors – if any, for instance the project manager of the Consortium –, and any individuals howsoever in its service to whose knowledge CONFIDENTIAL INFORMATION will come, are obligated (whether in a written agreement or otherwise) to treat confidentially and maintain in strict confidence any and every CONFIDENTIAL INFORMATION received from the other PARTIES ;

- to adopt all such reasonable preventive measures as might prove necessary to prevent said employees and other persons to divulge CONFIDENTIAL INFORMATION, in whole or in part, to any third parties; and

- to immediately so inform the other PARTY(IES) should it become aware of any established or suspected unauthorized use or disclosure of CONFIDENTIAL INFORMATION.

2.4 Each PARTY shall promptly advise the other PARTY in writing of any unauthorised disclosure, misappropriation or misuse of CONFIDENTIAL INFORMATION after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

2.5 If any PARTY becomes aware that it will be required, or is likely to be required, to disclose CONFIDENTIAL INFORMATION in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure, notify the disclosing PARTY, and comply with the disclosing PARTY's reasonable instructions to protect the confidentiality of the information.

Article 3 – INFORMATION TO WHICH THE CONFIDENTIALITY OBLIGATION DOES NOT APPLY

It is specified that CONFIDENTIAL INFORMATION for purposes of this Agreement shall not include information which:

- the PARTIES have mutually agreed in writing is not to be treated as CONFIDENTIAL INFORMATION;

- the receiving PARTY can prove was already known to it at the time of the disclosure thereof and was not acquired directly or indirectly from the disclosing PARTY, as evidenced through the written records of the receiving PARTY;

- was already publicly available at the time of the disclosure thereof, or thereafter became publicly available through no fault of either PARTY or its employees;

- either PARTY previously received or will subsequently receive lawfully from a third party not under a similar legal obligation of secrecy to the other PARTY hereto, for which evidence can be provided;

- is independently generated by the receiving PARTY other than in violation of this Agreement, as evidenced through the written records of the receiving PARTY; or

- is required to be disclosed by law or a court order.

Article 4 – OWNERSHIP

4.1 All CONFIDENTIAL INFORMATION disclosed by either PARTY, as well as any copies thereof, shall remain the property of the disclosing PARTY.

4.2 There shall be no transfer of ownership as a result of this Agreement, nor any licence under any intellectual property right is granted or implied by this Agreement or the disclosure of CONFIDENTIAL INFORMATION.

4.3 In particular, each PARTY agrees not to file any application for a patent or other industrial property title involving CONFIDENTIAL INFORMATION that belongs to any other PARTY without the prior written consent of said other PARTY.

Article 5 – PURPOSE AND USE

5.1 The PARTIES shall only use the CONFIDENTIAL INFORMATION for the PURPOSE.

5.2 The PARTIES agree, except with the prior written consent of the disclosing PARTY, not to use CONFIDENTIAL INFORMATION disclosed to them by another PARTY for any direct or indirect scientific, clinical, commercial and industrial purposes.

Article 6 – CONSTRUCTION

6.1 Nothing contained herein shall be construed as an obligation to a PARTY to disclose information to another PARTY.

6.2 It is expressly agreed that mutual disclosure of CONFIDENTIAL INFORMATION between the PARTIES pursuant hereto may under no circumstances be construed as a waiver by a proprietor to protect its own CONFIDENTIAL INFORMATION.

6.3 It is, however, explicitly understood and accepted by each PARTY that this Agreement contains no covenants with respect to the terms and conditions of a subsequent agreement pertaining to the exploitation of CONFIDENTIAL INFORMATION, or even to the conclusion of any such agreement.

Article 7 – TERM

This Non Disclosure Agreement comes into force as of the EFFECTIVE DATE. The PARTIES may exchange CONFIDENTIAL INFORMATION during a one (1)-year period (the "TERM"). As mentioned at Article 2.1, the PARTIES undertake to treat confidentially and maintain in strict confidence any and every CONFIDENTIAL INFORMATION received from another PARTY during the TERM and five (5) years after the TERM. It is understood that in the case where CONFIDENTIAL INFORMATION is KNOW-HOW, this KNOW-HOW shall be kept confidential until the disclosing PARTY decides to divulge it or only upon written agreement of the disclosing PARTY. The PARTIES shall sign an amendment to the Agreement if they wish to extend the period of disclosure of CONFIDENTIAL INFORMATION.

Article 8 – LIABILITY

Each PARTY shall be held liable for direct damages arising out of or in connection with any disclosure of all or any part of the CONFIDENTIAL INFORMATION received, whether by itself, its employees, or any other person with whom it is committed in a legal relationship. Each PARTY will bind such employees to keep such CONFIDENTIAL INFORMATION confidential both during and after their current employment and will take appropriate steps to enforce the obligations of such employees in relation thereto.

Article 9 – GUARANTEE

Neither PARTY guarantees the quality or accuracy of information disclosed by it, and provides all information "as is", without any express or implied warranty of any kind, including any warranty as to merchantability, fitness for a particular purpose, accuracy, completeness or violation of third party intellectual property rights, and it shall be the other PARTY' responsibility to make all usual checks and validations, as required for the achievement of the goal described in the preamble.

Article 10 – TERMINATION

10.1 Either PARTY may terminate this Agreement upon thirty (30) days prior written notice to the other PARTY.

10.2 Any termination or expiration of this Agreement shall not affect any rights which have vested in either PARTY to the effective date of such termination and/or expiration. In particular, Article 4 and Article 5 shall survive any termination and/or expiration of the Agreement.

10.3 Upon the expiration or termination of this Agreement, the PARTIES undertake within one (1) month thereafter to return or destroy any and all documents and materials containing CONFIDENTIAL INFORMATION received from the other PARTY hereunder, without prejudice to the PARTY' right to retain a copy solely for their records.

10.4 Notwithstanding this clause 10, the receiving PARTY may retain one copy of any CONFIDENTIAL INFORMATION if, and only to the extent, necessary to comply with its present obligation, any regulatory or other legal obligations.

Article 11 – ENTIRE AGREEMENT

This Agreement embodies the entire agreement between the PARTIES with regard to the subject matter hereof, and supersedes all prior representations, negotiations, covenants, oral or written communications, consents, agreements and understandings between the PARTIES relating to the provisions to which this Agreement applies or which are stipulated herein.

This Agreement may be executed in one or more counterparts, each of which will be deemed an original but which will together constitute one instrument. The facsimile/electronic transmission of a signed counterpart is deemed proof of signature of the original. The signed transmitted facsimile/electronic versions are deemed an original.

Article 12 – ASSIGNMENT

This Agreement is personal in its character, and as such shall not be assigned or transferred without the prior written consent of the other PARTY.

Article 13 – APPLICABLE LAW

In order to be in accordance with the consortium agreement of the Consortium, the present Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

Article 14 – NOTICES

Notices required to be sent to one of the PARTIES of this Agreement shall be addressed to the main contact(s) of MEMBERS listed in Appendix 1 or to the project manager of the Consortium, as relevant.

In the case of [ACRONYM of the third party], notices shall be addressed to _____.

Article 15 – RESOLUTION OF DISPUTES

In the event that a disagreement cannot be settled amicably beyond three (3) months of notification in writing of one PARTY to the other PARTY, the courts of Brussels shall have exclusive jurisdiction.

IN WITNESS WHEREOF, the PARTIES hereto intending to be bound hereby have caused this Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

INSTITUT CURIE	**[ACRONYM of the third party]**
_____	_____
By: [redacted]	By:
Title: Director of the Research Centre	Title:
Date:	Date:

Initials:

_____	_____
Title:	Title:
Date:	Date:

APPENDIX 1

-

List of MEMBERS [to be updated as relevant upon NDA signature]

Member	Main contact
INSTITUT CURIE	[redacted]
KU LEUVEN	
VHIO	
UNITO	
NKI-AVL	
ICO	
CAMBRIDGE	
UMCG	
RCSI	
IEO	
CORNELL	
MASARYK UNIVERSITY	
MANCHESTER	
GLASGOW	
OUS	
UNIBAS	
LIH	
IMG	

APPENDIX E - Minimal information to be Shared on the Models

Minimal annotation and characterisation Background Data to be Shared on the Models were discussed and agreed between the Members in Working Groups and in a global meeting of the SSC on November 17-18, 2014.

General principles:

> Definition of passages used within EurOPDX: P0 = material fresh from patient, P1 = first passage into mice, ...

> General rule = EurOPDX working on the earliest passage possible, as soon as model considered stable.

> Minimal characterisation to be available on a model for inclusion in the EurOPDX collection:

- same analyses as on a patient at diagnosis (H&E and/or IHC on particular markers and/or hotspot mutations depending on the cancer type), to be agreed for each pathology represented in the collection (work already done for BC, CRC, and PDAC). Ideally performed by same pathologist + images should be available;
- no comparison with the original patient tumour required;
- analyses above done on passage shared, otherwise need to be redone.

> Quality control: generalisation of fingerprinting (24 SNPs, Sequenom technology, ~10€/sample). Information of last date of fingerprinting needed when sharing a model.

The idea is therefore to consider each model as a xenopatient, characterised like a patient at diagnosis at each passage Shared. No pairing with original tumour of the patient or control of drifting across passages is required, only that these minimal analyses are available for the passage Shared with EurOPDX centres, together with proof of fingerprinting for quality control.

Below is the **list of minimal information that should be available on each Model included in the EurOPDX collection**. Level 1 are to be included in the Database and updated every 6 months, Level 2 are to be available upon request. The Parties will only Share pseudonymised clinical data.

Level 1:

- **Clinical information**
  - Sex, age
  - Localisation of the patient sample (primary, metastasis (localisation), LN)
  - Histology of the patient tumour (description only, rely on pathology report although sampling bias)
  - Size and grade of tumour (TNM)
  - Pre-treatment of the patient tumour prior to resection and grafting
  - Pathology-specific markers (e.g. ER/PR/HER2 in BC, description only)
  - (consent code & coded patient ID)
- **Model characteristics**
  - Histology and IHC for pathology-specific markers (image(s) should be available)
  - Mouse strain used for propagation
  - Biopsy or single cell suspension
  - Subcutaneous/orthotopic
  - Development of metastases (Y/N, site)

- Lag time from implantation, stability, doubling time (if available, useful for planning of exp. and regulatory purposes)

- **Molecular characteristics**
  - Molecular subtype
  - Last date of fingerprinting
  - Mutational status (pathology-specific minimal gene list)
  - Additional profiling data available, and on which platform (see below): WES, …

Level 2:

- Validation as compared to patient's tumour (Y/N, which passage)
- Drug monitoring data available
- Biobanking information (availability of original tumour FFPE/frozen, normal DNA, PDX model at which passage…)

APPENDIX F - Limitation on Member Models and Member Materials

[redacted]

APPENDIX G - Processing of personal data

For the interpretation of this schedule, the following definitions are added to the Consortium Agreement:

The providing Party and the receiving Party are designated as "**the Co-controller Parties**" in the meaning of the GDPR as defined below; the Co-controller Parties are the persons or bodies who collectively "*determine the purposes and means of the processing*".

I. Purpose

The purpose of this article is to define the conditions in which the Co-controller Parties undertake to carry out the personal data processing operations defined below.

As part of their contractual relations, the Co-controller Parties shall undertake to comply with the applicable regulations on personal data processing and, in particular, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 which is applicable from 25 May 2018 (hereinafter "the General Data Protection Regulation" or "GDPR"), and any national legislation related thereto.

Definitions of the terms of the article 4 of the GDPR shall apply to the present article.

II. Description of the processing being subcontracted out

The receiving Party is authorised to process the necessary personal data for performing a particular Consortium Study or Third Party Study, subject to the provisions of the specific material transfer agreement for the specific Models and/or Materials, and Data and Results, unless otherwise agreed by the Members involved.

The nature of operations carried out on the data by the providing Party is: collection of the data and transfer.

The nature of operations carried out on the data by the receiving Party is: reception, register, use, analysis and destruction.

The purpose(s) of the processing is to perform the said Consortium Study or Third Party Study.

The data are the personal data associated to the Models and/or Materials.

The categories of data subjects are the patients of the providing Party.

III. Receiving Party's obligations with respect to the providing Party

The receiving Party shall undertake to:

1. process the data **solely for the purpose(s)** defined in the said Consortium Study or Third Party Study;

2. process the data **in accordance with the documented instructions** from the providing Party. Where the receiving Party considers that an instruction infringes the General Data Protection Regulation or any other legal provision of the Union or of Member States bearing on data protection, it shall **immediately inform** the providing Party thereof. Moreover, where the receiving Party is obliged to transfer personal data to a third country or an international organisation, under Union law or Member State law to which the receiving Party is subject, the receiving Party shall inform the providing Party of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest;

3. guarantee the **confidentiality** of personal data processed hereunder;

4. ensure that the persons authorised to process the personal data hereunder:

- have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality
- receive the appropriate personal data protection training

5. take into consideration, in terms of its tools, products, applications or services, the principles of **data protection by design and by default**

6. **Data subjects' right to information**

It is the providing Party's responsibility to inform the data subjects concerned by the processing operations at the time data are being collected.

7. **Exercise of data subjects' rights**

The receiving Party shall assist the providing Party, insofar as this is possible, for the fulfilment of its obligation to respond to requests for exercising the data subject's rights: right of access, to rectification, erasure and to object, right to restriction of processing, right to data portability, right not to be subject to an automated individual decision (including profiling).

Where the data subjects submit requests to the receiving Party to exercise their rights, the receiving Party must forward these requests as soon as they are received by email to the Data Protection Officer of the providing Party.

8. **Notification of personal data breaches**

The receiving Party shall notify the providing Party of any personal data breach not later than twenty-four (24) hours after having become aware of it and via written means to the Data Protection Officer of the providing Party. Said notification shall be sent along with any necessary documentation to enable the providing party, where necessary, to notify this breach to the competent supervisory authority.

9. **Assistance lent by the receiving Party to the providing Party regarding compliance with its obligations**

The receiving Party assists the providing Party in carrying out data protection impact assessments. The receiving Party assists the providing Party with regard to prior consultation of the supervisory authority.

10. **Security measures**

The receiving Party undertakes to implement the following security measures:

- the pseudonymisation and encryption of personal data;
- the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
- the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
- a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing;

The receiving Party undertakes to implement technical and organizational measures and notably

- Physical access control

- Systems access control
- Data access control
- Disclosures control
- Entries data control
- Orders control
- Availability control
- Dissociation control

11. **Fate of data**

At the end of the said Consortium Study or Third Party Study bearing on the processing of such data, the receiving Party undertakes to:

At the parties' choosing:

- destroy all personal data, or
- return all personal data to the providing Party, or
- return the personal data to the processor designated by the providing Party.

Together with said return, all existing copies in the receiving Party's information systems must be destroyed. Once destroyed, the receiving Party must demonstrate, in writing, that this destruction has taken place.

12. **The Data Protection Officer**

The receiving Party communicates to the providing Party the name and contact details of its Data Protection Officer, if it has designated one in accordance with Article 37 of the GDPR.

13. **Record of categories of processing activities**

The receiving Party states that it maintains a written record of all categories of processing activities carried out on behalf of the providing Party, containing:

- the name and contact details of the providing Party on behalf of which the processor is acting, any other processors and, where applicable, the data protection officer;
- the categories of processing carried out;
- where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1) of the GDPR, the documentation of suitable safeguards;
- where possible, a general description of the technical and organisational security measures, including inter alia:
    - o the pseudonymisation and encryption of personal data;
    - o the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
    - o the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
    - o a process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

14. **Documentation**

The receiving Party provides the providing Party with the necessary documentation for demonstrating compliance with all of its obligations and for allowing the providing Party or any other auditor it has authorised to conduct audits, including inspections, and for contributing to such audits.

IV. Providing Party's obligations with respect to the receiving Party

The providing Party undertakes to:

- provide the receiving Party with the data mentioned in II hereof that is necessary for the performance of the said Consortium Study or Third Party Study;
- document, in writing, any instruction bearing on the processing of data by the receiving Party;
- ensure, before and throughout the processing, compliance with the obligations set out in the General Data Protection Regulation on the processor's part;
- supervise the processing, including by conducting audits and inspections with the receiving Party.

V. Audit right

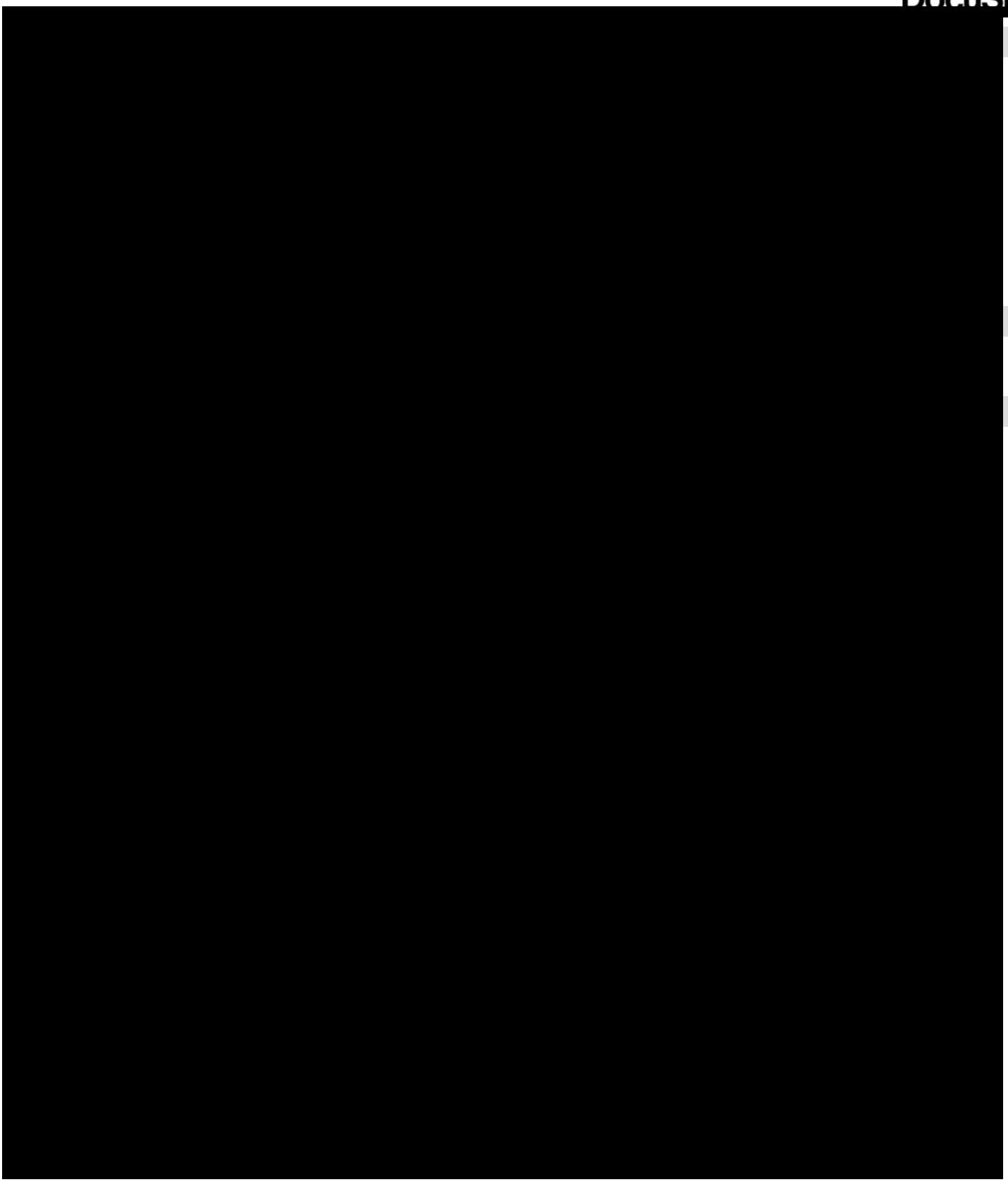
The providing Party may, before the beginning of the processing and regularly, proceed to an audit of the compliance, by the receiving Party, of the processing of the data.

In the framework of this audit, the providing Party can choose the following options:

- The providing Party can request for information relating to the purpose of the audit as well as a written documentation to the receiving Party, unless the commercial interest of the receiving Party regarding confidentially prevails.
- The providing Party can request the receiving Party for the communication of a certificate issued by an independent expert.

If the providing Party identifies the need of an extra audit, a written request will be communicated to the receiving Party. The receiving Party has the possibility to answer to this request. Insofar as the providing Party, after this dialogue, deems necessary the realization of an audit; it may, prior to an approval formulated in a reasonable delay and during the hours worked and without causing an unjustified interruption of the activities of the receiving Party, perform an audit or assign the performance of this audit to a qualified third party who is not a competitor of the receiving Party.

All costs incurred by the receiving Party or the providing Party relating to an audit by the providing Party will be taken in charge by the providing Party. The providing Party will reimburse, in a proper way, the receiving Party and its sub-processor, for the hours dedicated to the performance of the audit by the providing Party.



Divulgation relative aux Signatures et aux Dossiers électroniques:
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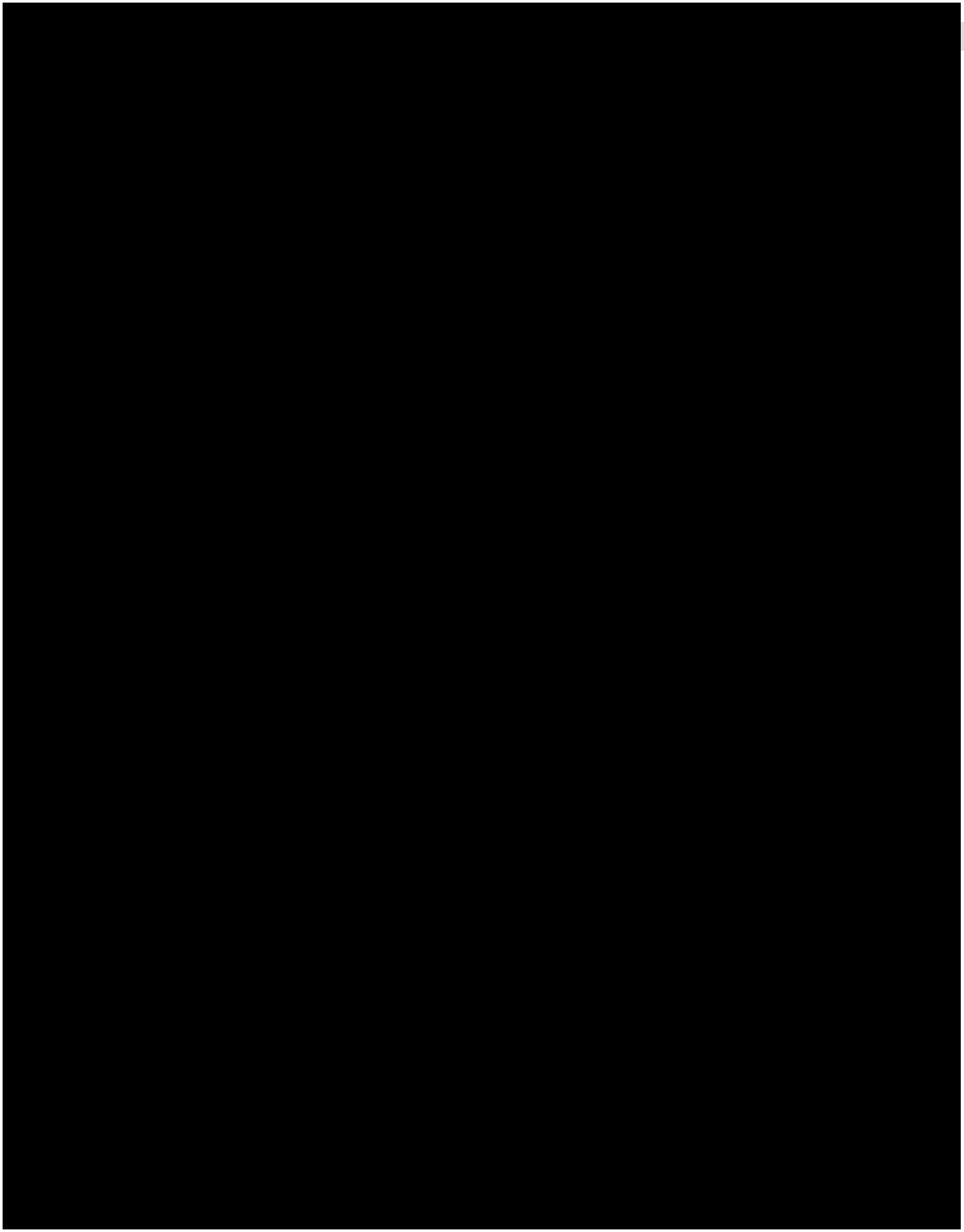

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Événements de livraison à l'agent	**État**	**Horodatage**
Événements de livraison intermédiaire	**État**	**Horodatage**
Événements de livraison certifiée	**État**	**Horodatage**
Événements de copie carbone	**État**	**Horodatage**
Événements de témoins	**Signature**	**Horodatage**
Événements notariaux	**Signature**	**Horodatage**
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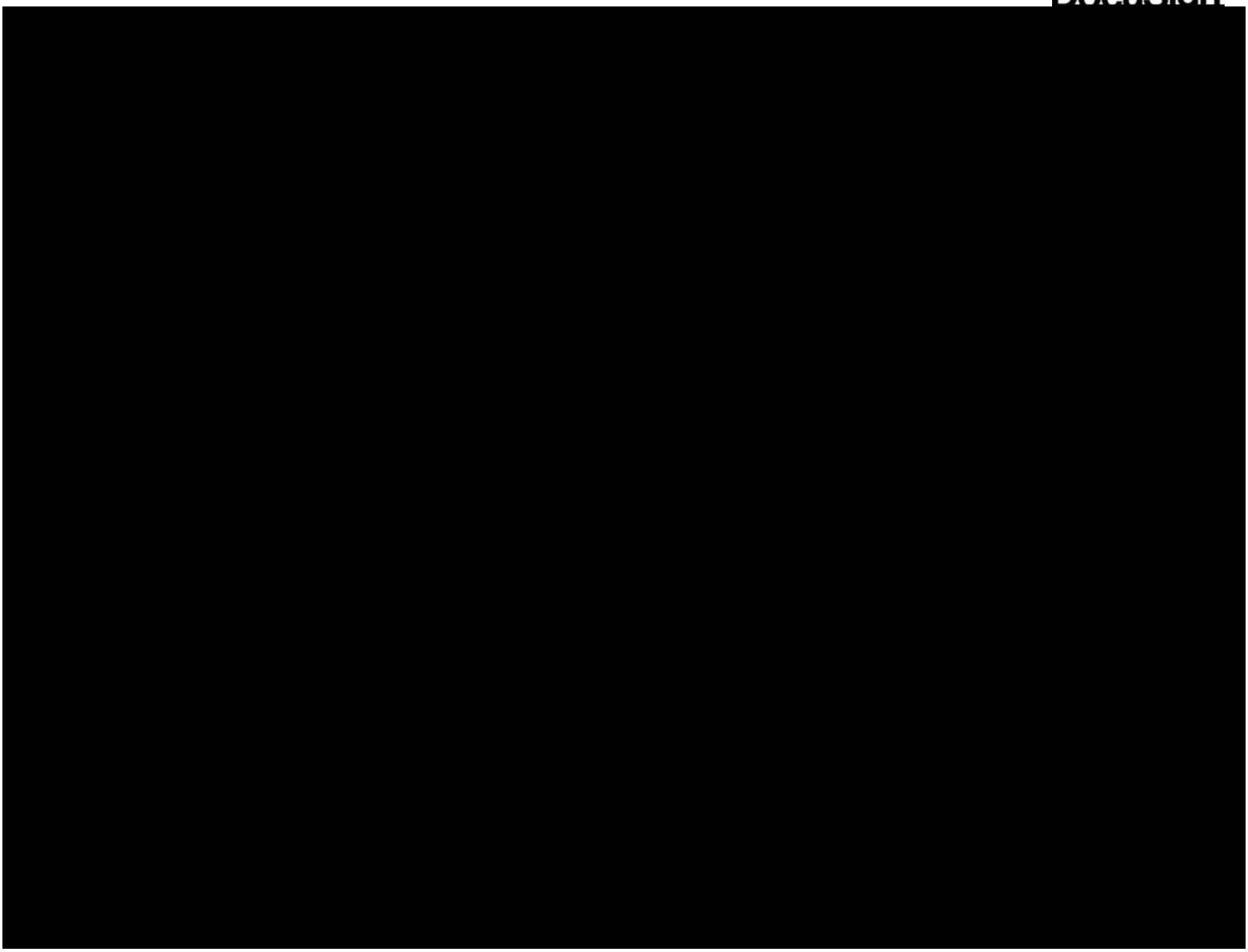

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Verzendingsgebeurtenissen voor vertegenwoordiger	**Status**	**Tijdstempel**
Verzendingsgebeurtenissen voor tussenpersoon	**Status**	**Tijdstempel**
Gecertificeerde verzendingsgebeurtenissen	**Status**	**Tijdstempel**
Carbon copy-gebeurtenissen	**Status**	**Tijdstempel**
Getuige evenementen	**Handtekening**	**Tijdstempel**

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Événements de signataire en personne	**Signature**	**Horodatage**
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Événements de livraison à l'agent	**État**	**Horodatage**
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Événements de témoins	Signature	Horodatage

Événements notariaux	Signature	Horodatage

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Événements de paiement	État	Horodatages

EurOPDX CONSORTIUM AGREEMENT_FINAL_EXECUTABLE

Final Audit Report 2022-12-09

Created:	2022-11-28
By:	[redacted]
Status:	Signed
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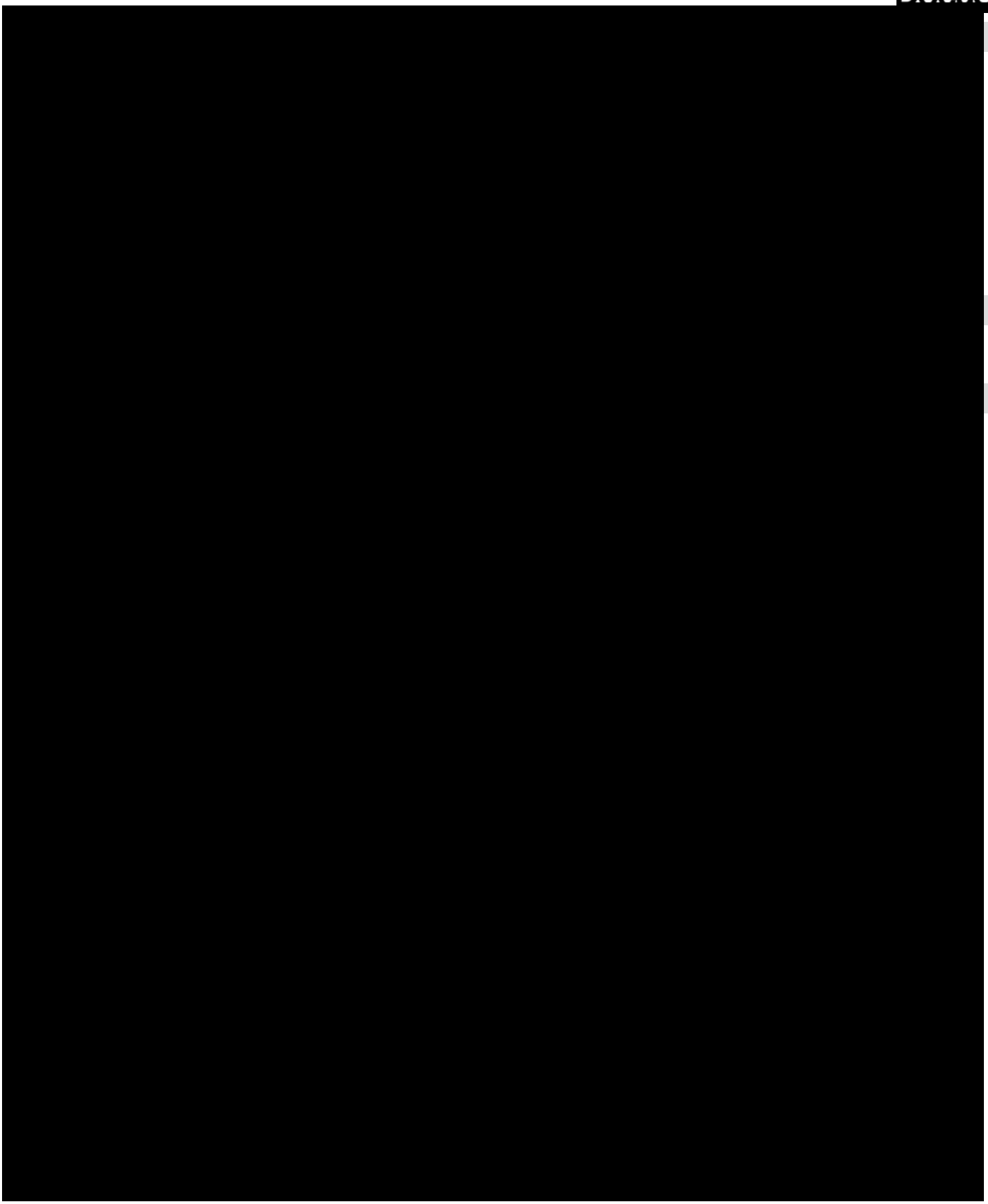

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Événements notariaux	Signature	Horodatage

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Événements de paiement	État	Horodatages

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Événements de paiement	**État**	**Horodatages**

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Divulgation relative aux Signatures et aux Dossiers électroniques:
Non offert par DocuSign

Événements de signataire en personne	**Signature**	**Horodatage**
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Événements de copie carbone	**État**	**Horodatage**

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Consultée: 25/01/2023 00:04:11

Divulgation relative aux Signatures et aux Dossiers électroniques:

Événements de copie carbone	État	Horodatage
Non offert par DocuSign		

Événements de témoins	Signature	Horodatage

Événements notariaux	Signature	Horodatage

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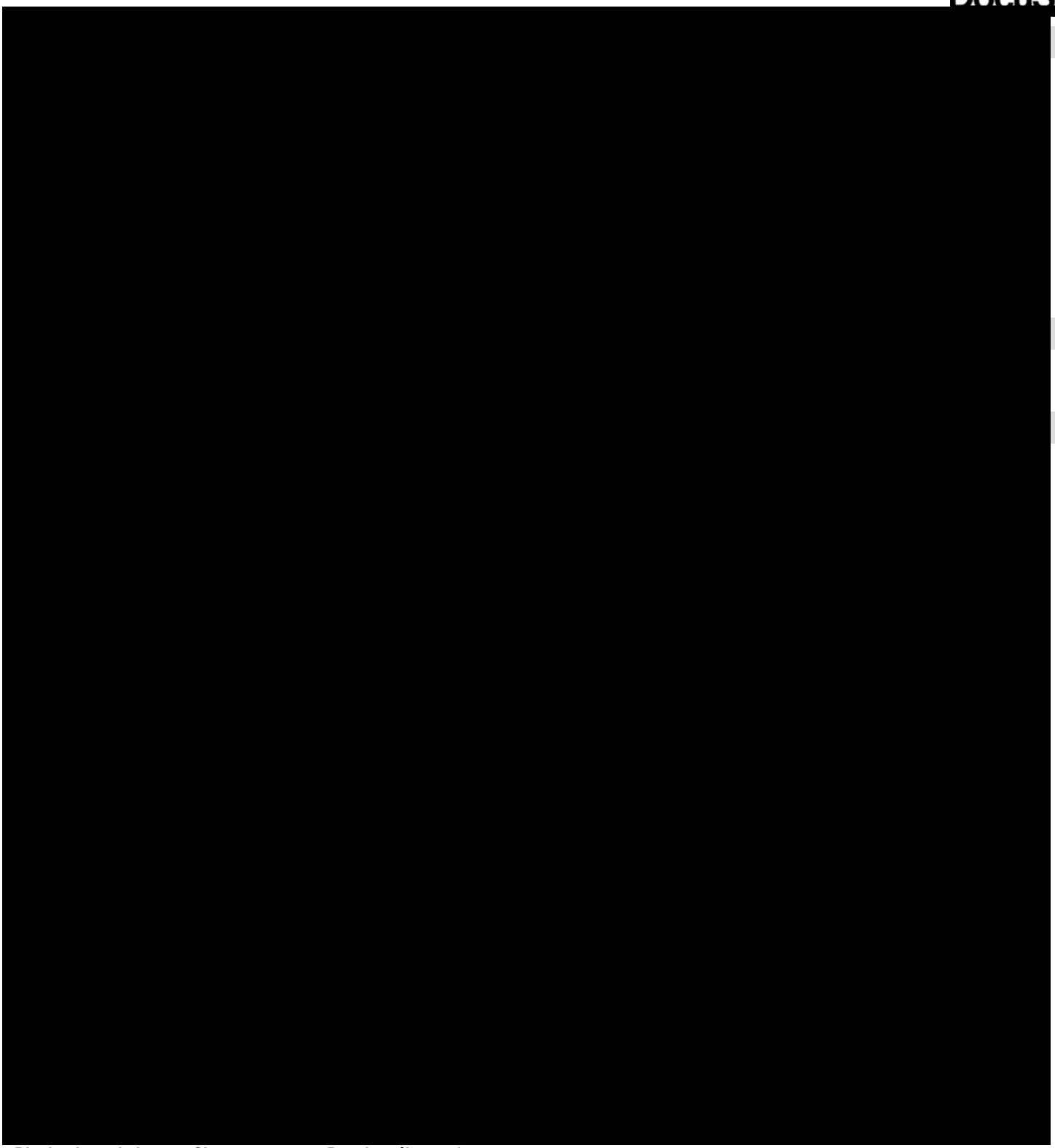
Événements de paiement	État	Horodatages



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Événements de livraison à l'agent	**État**	**Horodatage**

Événements de livraison intermédiaire	État	Horodatage

Événements de livraison certifiée	État	Horodatage

Événements de copie carbone	État	Horodatage
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Événements de témoins	Signature	Horodatage

Événements notariaux	Signature	Horodatage

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Complétée	Sécurité vérifiée	31/01/2023 01:30:47

Événements de paiement	État	Horodatages