DECRETO DEL DIRETTORE GENERALE

N. 1254 del 12 NOV. 2026

Protocollo di Studio codice "SPARKLE", proposto da University Hospitals di Leuven, Belgium. Titolo: "Metastatis-directed therapy for oligorecurrent prostate cancer: a randomized phase III trial", autorizzazione all'avvio dello Studio e stipula del Contratto.

IL DIRETTORE GENERALE

Richiamata la deliberazione n. 63 del 31.07.2025 con la quale il Consiglio di Amministrazione della Fondazione IRCCS San Gerardo dei Tintori, prendendo atto del Decreto del Presidente della Regione Lombardia n. 370 del 28.07.2025:

- ha nominato il dott. Michele Brait quale Direttore Generale della Fondazione IRCCS San Gerardo dei Tintori con decorrenza dal 05.08.2025 sino al 04.08.2028;
- ha confermato al Direttore Generale, al fine di assicurare la semplificazione dei procedimenti amministrativi e garantire la dovuta tempestività e celerità nell'adozione di atti e provvedimenti, le deleghe di funzioni e di firma di cui alle deliberazioni n. 15 del 27.02.2023 e n. 17 del 27.03.2023;

Ricordato che – secondo quanto previsto dall'art. 16 dello Statuto di questo Ente – "*al Direttore Generale compete la gestione della Fondazione*";

Richiamato il decreto del Direttore Generale n. 1 del 05.08.2025 avente ad oggetto "*Semplificazione dell'azione amministrativa: conferma delle attività delegate*", nonché i conseguenti decreti del Direttore Generale, in ultimo il decreto n. 419 del 16.04.2026, con il quale il Direttore Generale, al fine di continuare con il percorso di semplificazione dei procedimenti amministrativi e garantire la dovuta tempestività e celerità nell'adozione di atti e provvedimenti, ha attribuito al Direttore Scientifico alcune deleghe di funzioni e di firma, come da prospetto allegato al predetto provvedimento;

Premesso che con Decreto del Direttore Generale n. 1273 del 19.12.2024 la Fondazione IRCCS San Gerardo dei Tintori ha approvato il nuovo "Regolamento per la ricerca e la sperimentazione clinica" (di seguito "Regolamento");

Vista l'adesione, come da documentazione acquisita agli atti, espressa dal Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia, redatta conformemente alle disposizioni contenute nel sopracitato "Regolamento", alla partecipazione al protocollo di Studio codice "SPARKLE", dal titolo: "Metastatis-directed therapy for oligorecurrent prostate cancer: a randomized phase III trial", proposto da University Hospitals Leuven, Belgium, con mail del 09/09/2025 (protocollo n. 0013067 del 22/05/2026), da condursi sotto la propria responsabilità scientifica presso la propria S.C.;

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Preso atto che il Comitato Etico Territoriale Campania 3, nella seduta del 22.07.2026, approva l'esecuzione dello studio e che AIFA, l'Agenzia Italiana del Farmaco, competente per la sperimentazione in oggetto, ha autorizzato l'avvio dello studio in data 28/07/2026, come si evince da apposita relazione di valutazione della documentazione, in atti;

Considerato che:

- lo scopo primario dello Studio è quello di valutare la sopravvivenza libera da metastasi nel tumore della prostata;
- trattasi di Studio interventistico farmacologico, prospettico, multicentrico no profit, come da protocollo, in atti;

Riscontrato che nella fase istruttoria e di valutazione della fattibilità della sperimentazione sono state seguite le procedure previste dalla normativa e dal "Regolamento" vigenti;

Considerato che, ai sensi di quanto disposto dal predetto "Regolamento", in relazione alle sperimentazioni cliniche di natura non commerciale, detta attività non determina un orario aggiuntivo a carico dei sanitari interessati;

Dato atto che per l'esecuzione dello Studio è prevista la stipula di un Contratto per la conduzione di sperimentazione clinica indipendente su medicinale con University Hospitals Leuven, Belgium, come da testo allegato al presente provvedimento quale parte integrante e sostanziale;

Rilevato che lo Sperimentatore Principale (PI), Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia si impegna, tramite sottoscrizione del predetto contratto, a condurre lo Studio nel rispetto della normativa nazionale ed europea applicabile alla ricerca clinica e della normativa in materia di privacy come previsto dal regolamento europeo n. 679/2016/UE (cd. "GDPR" – General Data Protection Regulation);

Precisato che dal presente provvedimento non derivano costi aggiuntivi a carico del Bilancio della Fondazione, come riportato nel Modulo di fattibilità locale sottoscritto dal Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia;

Dato atto che le rendicontazioni dell'attività scientifica e la gestione delle risorse connesse allo Studio è affidata al PI, Prof. Stefano Arcangeli, che all'uopo sottoscrive il Contratto *de quo*;

Preso atto dell'attestazione del Proponente l'adozione del presente provvedimento nonché Responsabile del Procedimento, Dott.ssa Lavinia Vercesi, Dirigente Responsabile della S.S. Gestione Amministrativa della Ricerca e delle Sperimentazioni Cliniche, circa la regolarità tecnica e la legittimità del presente decreto;

Acquisiti i pareri favorevoli del Direttore Amministrativo, del Direttore Sanitario e del Direttore Scientifico, espressi ai sensi delle norme legislative e statutarie;

D E C R E T A

per le motivazioni citate in premessa e che qui si intendono integralmente trascritte e riportate:

1) di dare atto che il Comitato Etico Territoriale Campania 3, nella seduta del 22.07.2026, approva l'esecuzione dello studio e che AIFA, l'Agenzia Italiana del Farmaco, competente

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per la sperimentazione in oggetto, ha autorizzato l'avvio dello studio in data 28/07/2026, come si evince da apposita relazione di valutazione della documentazione, in atti;

2) di autorizzare il Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia, ad effettuare il protocollo di Studio codice "SPARKLE", dal titolo: "Metastatis-directed therapy for oligorecurrent prostate cancer: a randomized phase III trial", proposto da University Hospitals Leuven, Belgium;

3) di stipulare un Contratto per la conduzione di sperimentazione clinica indipendente su medicinale con University Hospitals Leuven, Belgium, come da testo allegato al presente provvedimento quale parte integrante e sostanziale, parimenti sottoscritto dal P.I., Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia, anche per l'impegno al rispetto della normativa nazionale ed europea applicabile alla ricerca clinica e alla normativa in materia di Privacy come previsto dal Regolamento Europeo n. 679/2016/UE (cd. "GDPR" General Data Protection Regulation);

4) di dare atto che dal presente provvedimento non derivano costi aggiuntivi a carico del Bilancio della Fondazione, come riportato nel Modulo di fattibilità locale sottoscritto dal Prof. Stefano Arcangeli, dipendente dell'Università degli Studi di Milano Bicocca e Direttore della S.C. Radioterapia (P.I.) in data 26/03/2026, in atti;

5) di dare atto che le rendicontazioni dell'attività scientifica e la gestione delle risorse connesse allo Studio è affidata al PI, Prof. Stefano Arcangeli, che all'uopo sottoscrive il Contratto *de quo*;

6) di dare atto dell'attestazione del Proponente l'adozione del presente provvedimento nonché Responsabile del Procedimento, Dott.ssa Lavinia Vercesi, Dirigente Responsabile della S.S. Gestione Amministrativa della Ricerca e delle Sperimentazioni Cliniche, circa la regolarità tecnica e la legittimità del presente decreto;

7) di dare altresì atto che il presente provvedimento è immediatamente esecutivo e sarà pubblicato all'Albo Pretorio ai sensi dell'art. 17, della Legge Regionale n. 33/2009 e ss.mm.ii.

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Esprimono parere:

Direttore Amministrativo: Francesco Ozzo _____ Favorevole ☒ Contrario ☐

Direttore Sanitario: Aida Andreassi _____ Favorevole ☐ Contrario ☐

Direttore Scientifico: Pietro Invernizzi _____ Favorevole ☒ Contrario ☐

Il Direttore Generale

(Michele Brait)

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Allegato al Decreto del Direttore Generale n. 1254 del 12 NOV. 2026

Protocollo di Studio codice "SPARKLE", proposto da University Hospitals di Leuven, Belgium. Titolo: "Metastatis-directed therapy for oligorecurrent prostate cancer: a randomized phase III trial", autorizzazione all'avvio dello Studio e stipula del Contratto

ATTESTAZIONE DI REGOLARITA' TECNICA E LEGITTIMITA'

Il Responsabile del Procedimento:

Il Dirigente Responsabile della S.S. Gestione Amministrativa della Ricerca e delle Sperimentazioni Cliniche

Dott.ssa Lavinia Vercesi

ATTESTAZIONE DI REGOLARITA' CONTABILE E CONFORMITA' ECONOMICA

Il Direttore S.C. Bilancio, Programmazione Finanziaria e Contabilità:

Dr. Toni Genco

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ALLEGATO

CONTRACT FOR THE CONDUCT OF INDEPENDENT CLINICAL TRIALS ON MEDICINAL PRODUCTS

"Metastasis-directed therapy for oligorecurrent prostate cancer: a randomized phase III trial"

Protocol Code: ***SPARKLE***

BETWEEN

UZ LEUVEN, located at Herestraat 49, 3000 Leuven, Belgium, legally represented by Prof.dr. Paul Herijgers, CEO, VAT (registration) number 0419.052.173 (hereinafter: "Sponsor")

AND

Fondazione IRCCS San Gerardo dei Tintori (hereinafter referred to as the "Participating Site") with registered office in Monza, via Pergolesi, 33 C.F. and VAT number. 12698710964, in the person of the Scientific Director, Prof. Pietro Invernizzi, duly delegated pursuant to the resolution of the Board of Directors no. 63 of 31.07.2025 and Decree of the General Manager no. 419 of 16.04.2026.

Sponsor and the Participating Site hereinafter also referred to individually as a "Party" and collectively as the "Parties".

WHEREAS:

- Sponsor has initiated the clinical study (the "Study") as set out in the document that describes the objective(s), design, methodology, statistical considerations and organisation of the Study, including – but not limited to - the clinical trial plan that defines the clinical tests to be performed on and/or with the "Study Drug" (as defined in Article 12) ("Protocol") entitled: "Metastasis-directed therapy for oligorecurrent prostate cancer: A randomized phase III trial".
- Sponsor has appointed prof. dr. Gert De Meerleer as Principal Investigator for conducting the Study. Principal Investigator shall coordinate the Study which will be performed at the Participating Site.Sponsor wishes to have part of the Study performed at the Participating Site under the supervision of Prof. Stefano Arcangeli ("Investigator") employee of the University of Milan Bicocca and Director of the S.C. Radiotherapy ("Experimentation Centre") of the Participating Site who is willing to perform under the terms of this Agreement;
- the Participating Site confirms that it has, through its Experimentation Centre, the technical and scientific skills for the conduct of the Study and that it is an adequate structure for conducting the Study in compliance with current legislation;
- the Participating Site confirms that Investigator and his/her direct collaborators, qualified to intervene with discretionary powers in the execution of the Protocol (hereinafter "Co-investigators"), as well as all other subjects who carry out any part of the Study under the supervision of the Investigator, are suitable to conduct the Study in accordance with applicable legislation, are familiar with the Protocol and the rules of good clinical practice and possess the necessary legal and regulatory requirements, including compliance with current legislation regarding conflict of interest;
- except as may be agreed in writing by the Parties at a later date, the Participating Site shall conduct the Study exclusively at its own facilities;

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- the Study has been duly authorised pursuant to Chapter II of the Regulation (EU) 536/2014 ("Clinical Trial Regulation"), subject to AIFA national authorisation in Italy for Participating Site, uploaded on the EU portal referred to in art. 80 of the Clinical Trial Regulation on 9 December 2025, which includes the opinion issued by the Lombardy 3 Territorial Ethics Committee;

the following is agreed and stipulated between the Parties

Responsibilities of the Parties

1.1 Participating Site and Investigator

1.1.1. Participating Site

The Participating Site and Investigator will perform (part of) the Study at Participating Site's facilities fully in accordance with the terms of the Protocol, this Agreement including all its appendices and Applicable Laws and Regulations (as defined as follows: the current version of the World Medical Association's Declaration of Helsinki, the guidelines and guidance documents specifying Good Clinical Practice ("GCP") and guidelines of competent authorities; all applicable laws, rules and legislation in relation to clinical trials, use of human biological material, data protection and the processing of personal data, and patient's rights, including but not limited to the General Data Protection Regulation 2016/679 ("GDPR") and the Belgian law of 30 July 2018 on the protection of natural persons with regard to the processing of personal data). The Participating Site will ensure that the Investigator and all employees, agents, contractors and/or the representatives involved in the performance of the Study (jointly "Staff") are properly trained and sufficiently qualified. The Participating Site shall provide Staff with all necessary documentation to allow the proper performance of the Study, which shall be conducted in compliance with the Protocol. The Participating Site shall be responsible to ensure that all work performed by Staff is done in compliance with the Protocol, this Agreement and all Applicable laws and Regulations. The Participating Site undertakes to impose on all employees, agents, contractors and/ or representatives the terms and conditions not less strict than those set out in this Agreement.

The Study requires the Participating Site through Investigator to recruit participants for the Study, as described in the Protocol ("Study Subjects"). Enrolment will be stopped as soon as the total number of Study Subjects to be enrolled in this Study, if multicenter, has been reached or has been anticipated to be reached based on the actual number of the screened Study Subjects by all involved participating sites/investigators. For the avoidance of doubt, Sponsor may at any time limit the number of Study Subjects to be recruited by the Participating Site through Investigator if the total number of Study Subjects recruited in the Study has been reached.

The Protocol shall not be deviated from, except if required due to a medical emergency.

If in the medical judgment of the Investigator, alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and /or deviations and reasons for their use, will be documented and be forwarded to Sponsor as described in the Protocol.

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The findings of the Study (as defined in the Protocol and Case Report Form (CRF) will be reported by the Participating Site through Investigator to Sponsor in the form of reports, to be submitted to Sponsor at such stages or intervals as set out in the Protocol (including for instance the progresses and the number of included Study Subjects) and/or as further agreed in writing between the Parties.

Investigator

The Study at the Participating Site will be conducted under the supervision of Investigator. Investigator is an approved health care professional with the necessary professional experience for conducting the Study. If for any reason, the Investigator is unable to continue to serve as Investigator, Participating Site will inform Sponsor in writing and an appropriate and qualified successor will be mutually agreed by the Parties. The Investigator will be assisted in the execution of the Study by Co-investigators, as well as by the Staff, including health and non-medical personnel appointed by the Participating Site. The Co-investigators and Staff will operate under the responsibility of the Investigator for aspects relating to the Study.

The Investigator agrees to provide Sponsor all the information related to pharmacovigilance (SAEs, SUSARs, etc.) in English as stated in the European Union guidelines.

In case of Serious Adverse Event (SAE), Investigator shall use best efforts to notify the Sponsor within 24 hours.

Medical care will be ensured to the Study Subject with a Study-related injury, when appropriate.

The Investigator shall ensure that all procedures defined in the Protocol and in the Agreement are complied with, so that all data coming from the Participating Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and shall ensure that the content of the case report form (CRF) shall accurately reflect source documents. The Investigator also undertakes to resolve the queries generated by the Sponsor within the deadlines set out in the Protocol.

1.2 Sponsor

In order to ensure the same quality and safety standards in patient and health care for clinical research as commonly applied in the regular activities, Sponsor shall comply with the following obligations:

Sponsor will not grant incentives to Study Subject or Staff that would compromise the integrity of the research activities in the Study;

- Sponsor will use trained and qualified staff to manage and coordinate the Study;
- Sponsor will be responsible for ensuring that any Suspected Unexpected Serious Adverse Reaction (SUSAR) are appropriately reported to the Member States according to applicable laws and regulations;
- to the extent required by Applicable Laws and Regulations, Sponsor will publicly register a protocol summary (e.g. Clinicaltrials.gov);
- Sponsor will comply with Applicable Laws and Regulations, in particular but not limited to: (a) requiring notification of the Investigators of new safety information about the Study Drug as defined in article 11, and Sponsor further commits to notify Investigator of any other new information of which Sponsor becomes aware that could affect the safety of the Study Subjects or influence the conduct of the Study;

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and (b) protecting the privacy and confidentiality of the Study Subject data in accordance with article 6;

- Sponsor is responsible for monitoring and evaluating the quality, safety, and ethics of the Study as set out in this Agreement, and will respect Participating Site's policies and processes when performing such monitoring and evaluation activities. Sponsor will promptly notify Investigator of any monitoring findings that could affect the safety of Study Subjects or influence the conduct of the Study. Investigator will inform Study Subjects of such findings as appropriate.

After analysis of Study Data (as defined in Article 8) from all participating sites involved is complete, Sponsor will provide Investigator with a summary of the overall results of the Study before publication (as described in Article 7). During and for a period of at least two years after the completion of the Study, the Sponsor shall in a timely manner appropriate to the level of risk involved report to the Investigator any information that could directly affect the health or safety of past or current Study Subject or influence the conduct of the Study, including but not limited to the Study results and information in site monitoring reports and data safety monitoring committee reports, as required by the Protocol. In each case the Investigator and the Sponsor, in consultation with the ethics Committee ("EC"), will cooperate to ensure that those results are appropriately communicated to the Study Subjects.

Sponsor will ensure that multi-center Study reporting is reliable and valid, statistically accurate, ethical, and unbiased. The same requirements are applicable if multi-center Study data and multi-center Study results are provided to Participating Site.

Article 2. Audit, Monitoring and Inspection

The Investigator and the Participating Site agree that the Sponsor, any third party (e.g. a CRO) acting on behalf of the Sponsor, upon prior written notice can monitor or audit the conduct of the Study at Participating Site's facility and verify the compliance with the Protocol and with Applicable Laws and Regulations.

The Investigator and the Participating Site agree that any domestic or foreign regulatory agencies can come at any time to respectively inspect the facility of the Participating Site, to inspect the facility and compliance with Applicable Laws and Regulations. Investigator and Participating Site shall inform Sponsor in writing prior to any such inspection in order to allow Sponsor to be present during the inspection. The Investigator and the Participating Site agree to make available for direct access all requested Study-related records which means that monitors, auditors and regulatory authorities will be granted direct access to the Study Subject's original medical records for verification of Study procedures and/or data, without violating the confidentiality of the Study Subject, to the extent permitted by the Applicable laws and Regulations and in accordance with Participating Site's procedures. The ICF (as defined below) will mention that the Study Subject or the Study Subject's legally acceptable representative is authorizing such access.

All information learned by Sponsor, its representatives or subcontractors, during their presence at the Participating Site, that is not directly related to the Study or this Agreement shall be deemed Participating Site's Confidential Information, which will be subject to the same level of protection by Sponsor as is required of Participating Site to protect Sponsor's Confidential Information, with the same rights, obligations and exceptions as set forth in Article 6 of this Agreement.

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Article 3. Competent authorities - Ethics committee approval / Informed Consent

Before beginning any clinical research activities under the Study, the Study and Protocol will be submitted to the competent authorities/ relevant ethics committee(s) ("EC").

The Participating Site through Investigator shall obtain a signed informed consent form ("ICF") for all Study Subjects (or his/her legal representative) prior to their enrollment and participation in the Study in compliance with all Applicable Laws and Regulations and the approval of the relevant EC, if required. The Participating Site through Investigator shall retain such ICF's in accordance with the requirements of all Applicable Laws and Regulations.

It is understood an agreed that the conduct of the Study may be suspended upon request of EC, competent authorities or either Party, for Study Subject's safety reasons.

Article 4. Term

This Agreement shall enter into effect on the Effective Date as defined hereunder in article 22 and shall continue until completion of the Study, unless terminated by prior written notice.

Termination of the Study may be initiated:

1) By either Party

- immediately for safety and efficacy reasons concerning the Study Subjects enrolled;
- immediately if the Investigator is unable to continue to serve and Parties do not agree on appointing a successor for the Investigator;
- if the other Party commits a breach of any term of this Agreement or its appendices and fails or is unable to remedy the same within 30 days of receipt of notice specifying the breach;
- immediately if competent authorities request that the Study is terminated, or if relevant EC approval withdraws its approval;
- immediately if the other Party becomes bankrupt, or goes into liquidation otherwise than for the purpose of reconstruction or amalgamation, or has a receiver appointed of its assets or enters into a compromise or other arrangement with his creditors.

2) by Sponsor

- upon 30 days prior written notice if Sponsor discontinues the Study for scientific or administrative reasons;

Any notice of termination must be made in writing by registered mail.

If the Agreement is completed or terminated:

- Investigator shall stop enrolling Study Subjects into the Study and shall cease conducting procedures on Study Subjects already enrolled, to the extent medically permissible and appropriate;
- the Parties will secure the safety of the Study Subjects involved and will discuss the on-going treatment needs of Study Subjects and if appropriate given the circumstances of the Study termination will agree

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a plan for discontinuing treatment of Study Drug to ensure enrolled Study subjects have continuity of care as appropriate.

If the Agreement is terminated for any reason other than by Sponsor for cause, Sponsor shall pay such amount for the services duly rendered by and non-cancelable costs incurred by Participating Site and Investigator hereunder prior to termination.

Article 5. Force majeure

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

Article 6. Confidential Information and Data Protection

6.1 Confidential Information

Unless otherwise agreed or required by Applicable Laws and Regulations the Parties shall treat all information and data relating to the Study ("Confidential Information") or provided by the disclosing Party as confidential and shall not disclose such Confidential Information to any third parties or use such Confidential Information for any purpose other than the performance of the Study. This undertaking does not apply to Confidential Information (i) that is or has become publicly known, through no breach, fault or omission of the receiving Party; (ii) which was in the possession of the Investigator or the Participating Site prior to receipt as supported by written records; (iii) which is obtained by the Investigator or the Participating Site from a third party who is entitled to disclose such Confidential Information in a non-confidential manner; (iv) which has been developed independently by the Investigator or the Participating Site without the support of the Confidential Information relating to the Study; (v) which is required to be disclosed by Applicable Laws and Regulations or by a final judicial decision or binding decision of a competent authorities; (vi) which is published in accordance with article 8 as mentioned hereunder.

If the receiving Party is required to disclose by Applicable laws and Regulations, by a final judicial decision or a binding decision of regulatory competent the receiving Party shall (i) promptly notify the disclosing Party of such requirement prior to disclosure - to the extent reasonably possible - in order to allow them the opportunity to oppose the requirement; (ii) disclose only that Confidential Information required to comply with the legal requirement and (iii) continue to maintain the confidentiality of this Confidential Information with respect to all other third parties.

This confidentiality undertaking shall be valid for a period of five (5) years from the termination date of the Study. The Participating Site and the Investigator may disclose Confidential Information to Staff necessary for the conduct of the Study and who are bound by similar obligations of confidentiality.

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6.2 Data Protection

Parties shall comply with the GDPR and the Belgian law of 30 July 2018 regarding the protection of personal data ("Data Protection Laws").

In particular, Sponsor is subject to the rights and obligations as "data controller" set forth under the Data Protection Laws in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol. In that respect Sponsor shall be considered as data controller of all Study Data pseudonymized for Study purposes.

Participating Site is subject to the rights and obligations as "data processor" set forth under the Data Protection Laws in relation to the processing of personal data for the purpose of conducting the Study in accordance with the Protocol.

Participating Site is also subject to the rights and obligations as a separate "data controller" set forth under the GDPR in relation to the processing of personal data of its patients for purposes other than conducting the Study. In particular, Participating Site remains data controller of the data contained in its patients' medical records for the purposes of providing medical care.

Pursuant to art. 28.3 GDPR Sponsor and Participating Site have concluded a data processing agreement attached in Exhibit 3.

Article 7. Study Data

The Participating Site shall keep, complete, and maintain accurate and authentic accounts, notes, technical reports, data, information, and records of the work performed under this Agreement, including case report forms ("Study Data"), source documents for at least 25 years (or such other period as required by Applicable Laws and Regulations) from Study completion and medical records during 30 years. Sponsor or its representative shall have the right to audit such Study Data during regular business hours upon reasonable prior written notice to the Participating Site.

Article 8. Publication of Study Report

The Parties will use reasonable efforts to make a joint publication.

The Sponsor will be given the choice to be the first author on any publication relating to the Study. In most instances, the order of the subsequent authors is to be based on recruitment i.e. the number of Study Subjects randomized/enrolled, on data quality and significant scientific input to the Study or on mutual agreement between the Parties. The Sponsor will retain the right to include in the authorship list, names of significant contributors to the research, other than Investigators. Participating Site will be considered as co-author in any publication regarding to the Study and shall have the right to review the publication by Sponsor following the same Review Procedure as set forth herein for Sponsor review.

The Participating Site and Investigator undertake and agree that they will not:

(A) present abstracts of any information derived from the Study or the Study Data at professional meetings until the Study has been completed and the Study Report has been notified to the

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competent authorities unless a written approval has been obtained from the Sponsor to publish earlier. Any publications of any information derived from the Study or the Study Data, by Participating Site/ Investigator or their Staff will also be the subject of pre-submission review and comment by the Sponsor in accordance with the provisions set out in the Review Procedure below.

(B) publish, communicate or otherwise disclose to the public in whatever manner or through any vehicle any information derived from the Study or the Study Data (i) for the whole duration of the Study, (ii) before the clinical trial summary report based on the Study Data and drafted by the Sponsor which ("Study Report") is notified to the competent authorities (either in part or in total) (e.g. abstracts in journals or newspapers).

If no Study Report of Sponsor has been notified within 12 months after the termination or completion of the Study at all other sites, the Participating Site shall have the right to publish independently any information derived from the Study or the Study Data of the Participating Site, subject to the Review Procedure set forth herein.

Review Procedure: The Participating Site shall notify Sponsor thereof by forwarding a copy of the publication and/or presentation by courier or registered mail to Sponsor at least thirty (30) days prior to the disclosure of the manuscript to a third party or the oral disclosure. If, within thirty (30) days following receipt of the manuscript, Sponsor indicates that the publication would affect its interests in confidential Information as defined in article 6 with the exempt of the information contained in the Study Report and Study Data, then the Participating Site shall take the action necessary to ensure that the publication will not proceed or that the information that Sponsor deems confidential Information as defined in Article 6 of this Agreement with the exempt of Study related information necessary to the appropriate scientific presentation or understanding of the Study Report and Study Data, will be deleted. In any case, Sponsor shall not unreasonably withhold or delay its consent to such publication.

Article 9. Use of Names

Each Party hereto shall not use the other Party's names, service marks or trademarks without the prior written approval of that Party, such approval shall not be unreasonable withheld or delayed.

Article 10. Patent Rights and Property rights

It is recognized and understood that all intellectual property rights existing as of the Effective Date ("Background IP") and know how owned or controlled by a Party are that Party's separate property and are not affected by this Agreement, and no Party hereunder shall have any claims to or rights in such Background IP of the other Party. Under this Agreement each Party shall have the right to use the other Party's Background IP solely and to the extent necessary for the performance of the Study and only for the duration of the Study under this Agreement. This usage right of the other Party's Background IP does not grant to either Party any option, grant, or license to commercialize, or otherwise use the other Party's Background IP.

Any know how, inventions, methods, developments, innovations and discoveries, whether patentable or not, arising from the Study or made in the performance of work under this Agreement ("Inventions") shall vest in the Sponsor. The Participating Site, its employees and Investigator(s) shall promptly disclose to Sponsor any such Inventions.

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Parties have expressly agreed that any and all Study Data as collected and prepared in the performance of the Study shall be the sole property of Sponsor. The Sponsor hereby grants to the Participating Site a license to use the Study Data for its patient care, educational and non-commercial research purposes and, in accordance with the obtained ICF.

Article 11. Study Drug supply

The drug Enzalutamide (the "Drug Study") is provided via the standard of care.

Article 12. Representations and Warranties

Each Party warrants and represents that proceeding and performing hereunder is not inconsistent with contractual or other legal obligations it has and shall not be inconsistent with any contractual or other legal obligations it may hereafter have.

Article 13. Insurance

Participating Site, Investigator and Sponsor shall have and maintain in full force and effect during the term of this Agreement (and following termination or completion of the Study to cover any claims arising from the Study) adequate insurance coverage for: (i) medical professional and/or medical malpractice liability; (ii) general liability and (iii) adequate insurance coverage for other possible damages resulting from the Study at the Participating Site, as required by local law. Each such insurance coverage shall be in amounts appropriate to the conduct of the services of the Participating Site under this Study.

Participating Site and Sponsor shall be solely responsible for any deductible or self-insured retention under any such policies.

Article 14. Independent contractor

All Parties are independent contractors and neither are employees nor agents of the other Party. None of the Parties hereto intend to create any partnership, joint venture, or employment or agency relationship pursuant to this Agreement. Neither Party shall have authority to make any statements, representations, or commitments of any kind, or take any action, which shall be binding on the other Party, unless with the specific written consent to do so of the other Party.

Article 15. Assignment

Neither Party may assign, transfer or convey this Agreement without the other Party's prior written consent.

Article 16. Entirety of Agreement

This Agreement (together with any documents referred to herein) constitutes the entire and only agreement and understanding between the parties with respect to its subject matter and supersedes any previous agreements, understandings, or arrangements between the Parties in respect to the Study (whether oral or written). Any claimed representation, promise of condition in connection with the subject matter of the Agreement that is not incorporated herein shall not be binding upon any Party. No modification, extension, waiver, or other variance of any provision hereof, or any release of any right hereunder, shall be valid or binding unless the same is in writing and signed by all Parties.

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Any amendment(s) to this Agreement must be in writing and signed by both Parties and shall form an integral part of this Agreement.

Article 17. Governing law and dispute resolution

The validity, interpretation and performance of this Agreement shall be governed and construed in accordance with the laws of Belgium. Prior to taking any legal action, the Parties shall endeavour to settle by amicable arrangement any disputes arising between them regarding this Agreement. Should the Parties fail to reach an amicable arrangement, the competent court shall be the courts competent for the registered offices of the defending Party and agree that such courts shall be the sole courts utilized and hereby waive any jurisdictional or venue objections to such court.

Article 18. Severability

Should a provision of this Agreement in any manner whatsoever contravene any Applicable Laws and Regulations, such a provision shall be deemed to be severable and shall not affect any other provision of this Agreement, nor affect the enforceability of those remaining provisions which are not in contravention of any such Applicable Laws and Regulations.

In the event that a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, which will continue in full force and effect.

Article 19. Hierarchy of documents

In case of any conflict between any article of this Agreement and the Protocol, the terms of the Agreement shall prevail to the extent of such inconsistency, discrepancy or contradiction except with this respect to medical, scientific or clinical matters for which the provision of the Protocol shall take precedence. In the event of any conflict between the operative provisions of this Agreement and the Annexes hereto (other than the Protocol), the operative provisions of this Agreement shall govern.

Article 20. Financial arrangements

No financial compensation is foreseen in this Study.

Article 21. Effective Date

This Agreement shall be effective as of the date of last signature [which in any case shall not be before Sponsor shall have obtained all and any necessary approval for the performance of the Study from the EC and the competent authorities, if applicable,] ("Effective Date").

The Parties acknowledge and agree that this Agreement can be executed by means of electronic signature or by signing in wet ink. The Parties recognize the use of simple electronic signatures (e.g., DocuSign) as legally valid and binding for entering into agreements and agree that electronic signatures and wet-ink signatures shall have the same value as a traditional handwritten paper signature. The Participating Site will initiate the signature process and send an electronic document (such as a PDF document) of such signed document to the other Party, to allow the other Party to execute the Agreement respectively with e-signature

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and/or a wet-ink signature. Electronically executed or electronically transmitted signatures shall have the full force and effect of original signatures.

IN WITNESS WHEREOF, the undersigned by their duly authorised representatives have executed this Agreement on the date of last signature.

SIGNED by UZ Leuven as SPONSOR:

On behalf of the INSTITUTION	Read and acknowledged by the INVESTIGATOR
Signature: Name: Prof Dr Paul Herijgers Title: Chief Executive Officer Date:	Signature: Name: prof. dr. Gert De Meerleer Title: Investigator Date: .....

SIGNED by Participating Site:

On behalf of the INSTITUTION	Read and acknowledged by the INVESTIGATOR responsible for scientific reporting and resource management
Fondazione IRCCS San Gerardo dei Tintori (di seguito indicata come "Beneficiario") con sede legale in Monza, via Pergolesi, 33 C.F. e P.IVA. 12698710964, nella persona del Direttore Scientifico, Prof. Pietro Invernizzi, giusta delega di cui alla deliberazione del C.d.A. n. 63 del 31.07 2025 e Decreto del DG n. 419 del 16.04.2026. Direttore Scientifico Prof. Pietro Invernizzi	Prof. Stefano Arcangeli Title: Investigator

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EXHIBIT 1: LIST OF SPONSOR AND PARTICIPATING SITE DUTIES, STUDY SPECIFIC

Duties of the Sponsor	Sponsor	Participating Site	Not applicable
Request of authorization to the Competent Authorities/Ethics Committee			
Application EudraCT number	X		
Provision of all document required by Belgian law	X		
Request of authorization to the Competent Authorities/Ethics Committee of Belgium	X		
Study registration in a public registry (Clinicatrials.gov)	X		
Notification of substantial amendments			
Provision of all documents required by Belgian law	X		
Request of authorization to the Competent Authorities/Ethics Committee of Belgium	X		
Declaration of the end of the Study			
Provision of all document required by Belgian law	X		
Declaration to the Competent Authorities/Ethics Committee of Belgium	X		
Pharmacovigilance			
Immediate report of serious adverse events to the Sponsor		X	
Evaluation of adverse events	X	X	
Provision of the required documents on Suspected Unexpected Serious Adverse Reactions (SUSARs) or other safety issues requiring expedited reporting	X		
Reporting of SUSARs to the Member States	X		
Reporting of other safety issues to the Member States	X		
Reporting of safety profile changes and safety issues to the investigators	X		
Immediate report of unexpected events affecting the benefit-risk balance to the Sponsor		X	
Reporting of unexpected events affecting the benefit-risk balance to the Member States	X		
Submission of the Development Safety Update	X		

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Reports to the Member States			
Transmission of Development Safety Update Reports to the investigators	X		
Monitoring			
On site monitoring according to ICH/GCP in all participating sites in Belgium	X		

Further Duties			
Selection of qualified investigators and participating sites in Belgium	X		
Selection of further participating sites in Belgium during the course of the study in consideration of all legal regulations	X		
Translation of all relevant documents of the study incl. the patients' informed consent form in the national languages	X		
Written Clinical Study Site Agreements with participating sites in Belgium	X		
Provision of a No Fault insurance for the Study Subjects in Belgium	X		
Assuring the financing of the Study	X	X	
Setup of adequate procedures for quality control and quality assurance in Belgium	X	X	
Archiving according to ICH/GCP, EU Directive 2005/28 and relevant laws in Belgium	X	X	
Database management and statistical analysis	X		
Study report and publication	X	X	

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EXHIBIT 2: FINANCIAL ARRANGEMENTS

Not applicable

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EXHIBIT 3: DATA PROCESSING AGREEMENT

This data processing agreement, including any annexes hereto, (together the "Data Processing Agreement") is an integrated part of the Agreement.

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

1. SCOPE OF THE DATA PROCESSING AGREEMENT

1.2 The Participating Site acts as a data processor as defined under article 4, 8) of the Regulation (EU) 2016/679 ("Data Processor") for the Sponsor who acts as data controller as defined under article 4, 7) of the Regulation (EU) 2016/679 ("Data Controller"), as the Participating Site processes Personal Data for the Sponsor as set out in Annex 1.

1.3 "Applicable Law" means any applicable data protection or privacy laws, including

(a) the European Data Protection Directive (95/46/EC) and upon its entry into force the Regulation (EU) 2016/679 also referred as the General Data Protection Regulation ("GDPR"),

(b) other applicable laws that are similar or equivalent to or that are intended to or implement the laws that are identified in (a) of this definition,

1.4 "Personal Data" means any information relating to an identified or identifiable natural person ('Data Subject'), including without limitation pseudonymized information, as defined in Applicable Law and described in Annex 1.

2. PROCESSING OF PERSONAL DATA

2.1 Instructions: The Data Processor is instructed to process the Personal Data for the term of this Data Processing Agreement and only for the purposes of providing the data processing tasks set out in Annex 1. The Data Processor may not process or use Personal Data for any purpose other than a Data Subject's medical records, or other than provided in the instructions, including with regard to transfers of personal data to a third country or an international organization, unless the Data Processor is required to do so according to Union or Member State law. In that case, the Data Processor shall inform the Data Controller in writing of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest.

2.2 Data Processor shall at all times maintain a record of processing of Personal Data in accordance with Applicable Law and if the Data Processor considers an instruction from the Data Controller to be in violation of the Applicable Law, the Data Processor shall promptly inform the Data Controller in writing about this.

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3. THE DATA PROCESSOR'S OBLIGATIONS

3.1 The Data Processor must ensure that persons authorized to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

3.2 The Data Processor shall implement appropriate technical and organizational measures to prevent that the Personal Data processed is:

i. accidentally or unlawfully destroyed, lost or altered,

ii. disclosed or made available without authorization, or

iii. otherwise processed in violation of Applicable Law.

3.3 The Data Processor must also comply with the special data security requirements of Annex 1.

3.4 The appropriate technical and organizational security measures must be determined with due regard for:

i. the current state of the art,

ii. the cost of their implementation, and

iii. the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

3.5 The Data Processor shall upon request provide the Data Controller with sufficient information to enable the Data Controller to ensure that the Data Processor's obligations under this Data Processing Agreement are complied with, including ensuring that the appropriate technical and organizational security measures have been implemented.

3.6 Taking into account the nature of the processing, the Data Processor shall assist the Data Controller, by means of appropriate technical and organizational measures, insofar as this is possible, in fulfilling its obligation to respond to requests from Data Subjects pursuant to laws and regulations in the area of privacy and data protection (such as, the right of access, the right to rectification, the right to erasure, the right to restrict the processing, the right to data portability and the right to object).

3.7 The Data Controller is entitled to appoint at its own cost an independent expert, reasonably acceptable to Data Processor, who shall have access to the Data Processor's data processing facilities and receive the necessary information for the sole purpose of auditing whether the Data Processor has implemented and maintained said technical and organizational security measures. The expert shall upon the Data Processor's request sign a non-disclosure agreement provided by the Data Processor, and treat all information obtained or received from the Data Processor confidentially, and may only pass on, after conferral with Data Processor, the findings as described under article 3.9, (ii) below to the Data Controller.

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3.8 The Data Processor must give authorities who by Union or Member State law have a right to enter the Data Controller's or the Data Controller's processors' facilities, or representatives of the authorities, access to the Data Processor's physical facilities against proper proof of identity and mandate, during normal business hours and upon reasonable prior written notice.

3.9 The Data Processor must without undue delay in writing notify the Data Controller about:

i. any request for disclosure of Personal Data processed under the Agreement by authorities, unless expressly prohibited under Union or Member State law,

ii. any finding of (a) breach of security that results in accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed by the Data Processor under the Agreement, or (b) other failure to comply with the Data Processor's obligations under Clauses 3.2 and 3.3, or

iii. any request for access to the Personal Data (with the exception of medical records for which the Data Processor is considered data controller) received directly from the data subjects or from third parties.

3.10 Such a notification from the Data Processor to the Data Controller with regard to a breach of security as meant in Clause 3.9 (ii)(a) will contain at least the following information:

i. the nature of the Personal Data breach, stating the categories and (by approximation) the number of Data Subjects concerned, and stating the categories and (by approximation) the number of the personal data registers affected (datasets);

ii. the likely consequences of the Personal Data breach;

iii. a proposal for measures to be taken to address the Personal Data breach, including (where appropriate) measures to mitigate any possible adverse effects of such breach.

The Data Processor shall document (and shall keep such documentation available for the Data Controller) any Personal Data breaches, including the facts related to the Personal Data breach, its effects and the corrective measures taken. After consulting with the Data Controller, the Data Processor shall take any measures needed to limit the (possible) adverse effects of Personal Data breaches (unless such consultation cannot be awaited due to the nature of the Personal Data breach).

3.11 The Data Processor must promptly reasonably assist the Data Controller (with the handling of (a) responses to any breach of security as described in 3.9 (ii) above and (b) any requests from Data Subjects under Chapter III of the GDPR, including requests for access, rectification, restriction of processing or erasure. The Data Processor must also reasonably assist the Data Controller by implementing appropriate technical and organizational measures, insofar as this is possible for the fulfilment of the Data Controller's obligation to respond to such requests. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such costs and expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to any breach of this Exhibit 3 or the Agreement by Data Processor.

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3.12 The Data Processor must reasonably assist the Data Controller with meeting the other obligations that may be incumbent on the Data Controller according to Union or Member State law where the assistance of the Data Processor is implied, and where the assistance of the Data Processor is necessary for the Data Controller to comply with its obligations. This includes, but is not limited to, the request to provide the Data Controller with all necessary information about an incident under Clause 3.9 (ii), and all necessary information for an impact assessment in accordance with Article 35 and Article 36 of the GDPR. Any reasonable documented costs and expenses pre-approved in writing by the Data Controller related to the above will be reimbursed by the Data Controller to the extent such expenses are not related to any requirements according to Applicable Law imposed on the Data Processor or due to breach of this Exhibit 3 or the Agreement by Data Processor.

4. SUBPROCESSORS

4.1 The Data Processor may only engage a subprocessor, with prior specific or general written consent from the Data Controller. At the time of this Data Processing Agreement, the Data Processor uses the subprocessor listed in Annex 2. The Data Processor undertakes to inform the Data Controller of any intended addition or replacement of a subprocessor by providing a reasonable prior written notice to the Data Controller. The Data Controller may reasonably and in a duly substantiated manner object to the use of a subprocessor. The Data Processor must promptly inform the Data Controller in writing of the discontinued use of a subprocessor.

4.2 Prior to the engagement of a subprocessor, the Data Processor shall conclude a written agreement with the subprocessor, in which at least the same data protection obligations as set out in this Data Processing Agreement shall be imposed on the subprocessor, including obligations to implement appropriate technical and organizational measures and to ensure that the transfer of Personal Data is done in such a manner that the processing will meet the requirements of the Applicable Law.

4.3 The Data Controller has the right to receive a copy of the relevant provisions of Data Processor's agreement with the subprocessor related to data protection obligations. The Data Processor shall remain fully liable to the Data Controller for the performance of the subprocessor obligations under this Data Processing Agreement. The fact that the Data Controller has given consent to the Data Processor's use of a subprocessor is without prejudice for the Data Processor's duty to comply with this Data Processing Agreement.

5. CONFIDENTIALITY

5.1 The Data Processor shall keep Personal Data confidential.

5.2 The Data Processor shall not disclose the Personal Data to third parties or take copies of Personal Data unless strictly necessary for the performance of the Data Processor's obligations towards the Data Controller according to this Data Processing Agreement, and on condition that whoever Personal Data is disclosed to is under the responsibility of a professional subject to the obligation of professional secrecy under Union or Member State law or rules established by national competent bodies or by another person also subject to an obligation of secrecy under Union or Member State law or rules established by national competent bodies.

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5.3 The Data Processor shall ensure that its employees comply with this Data Processing Agreement.

5.4 The Data Processor shall limit the access to Personal Data to employees for whom access to said data is necessary to fulfil the Data Processor's obligations towards the Data Controller.

5.5 The obligations of the Data Processor under Clause 5 shall continue until such time as provided by Applicable Law and regardless of whether the cooperation of the parties has been terminated.

6. TERM AND TERMINATION OF THE DATA PROCESSING AGREEMENT

6.1 Regardless of the expiry or termination, for whatever reason, of the Agreement, this Data Processing Agreement remains in force and applicable as long as the Data Processor processes the Personal Data for the Data Controller under the Agreement.

6.2 In case of termination of the Agreement, the Data Processor must provide the necessary transition services to the Data Controller. The Data Processor is obliged to reasonably assist Data Controller at Data Controller's expense.

6.3 Data Processor shall have appropriate procedures in place for the archiving of the Personal Data after the end of the Study in accordance with Applicable Law and at the end of the legally mandated archiving period ensure the destruction of the Personal Data and promptly inform Data Controller of such destruction.

6.4 If the Data Processor is required based on Union or Member State law to retain all or part of the Personal Data for a longer period than is possible based on the period mentioned in the Data Processing Agreement, the Data Processor shall immediately communicate this to the Data Controller, stating the basis, term and scope of such obligation. Once compliance with the obligation is no longer impeded by Union or Member State law, the Data Processor shall as yet erase the data in accordance with the provisions in the Data Processing Agreement.

Annexes:

Annex 1: Instructions

Annex 2: Sub-processors

Annex 3: EU Standard Contractual Clauses

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Annex 1 – Instructions

This Annex 1 constitutes the Data Controller's instruction to the Data Processor in connection with the Data Processor's Personal Data processing for the Data Controller, and is an integrated part of the Data Processing Agreement.

Contact details of the Data Controller (including its Data Protection Officer, if applicable):

dpo@uzleuven.be

Contact details of the Data Processor (including its Data Protection Officer, if applicable):

dpo@irccs-sangerardo.it

The processing of Personal Data

a) Purpose and nature of the processing operations

Performance of Clinical Study services under the Agreement and for the purpose of mandatory safety monitoring– as specifically described in the Protocol.

I. Transfer of Personal Data to a third country: YES

II. If YES to I., transfer outside the EU: NO

III. If YES to II., please complete Annex 3.

b) Categories of Data Subjects

I. Former, current or future persons and/or patients who voluntarily enrolled in the Study, and/or their relatives, and/or

c) Categories of Personal Data

Re b) I: Date of birth and/or age, initials, personal identification number assigned to Data Subjects participating in the Study, description of characteristics of physical features of the body

d) Special categories of Personal Data

Re b) I: Health information including past medical history and medical test information (such as blood samples results from scans and biopsies), data revealing racial or ethnic origin, genetic data and/or social security number

e) Processing will be performed at [Insert address, city and country of all locations where the processing will be performed.]

f) Specific security requirements

The following requirements reflect the minimum data processing requirements expected of the Data Processor. It is a condition that other agreed documents, legislation or industry standards laying down requirements of the processing of Personal Data in connection with Study/ /mandatory safety monitoring are complied with as well.

1. The Personal Data may only be used for the Study and/or mandatory safety monitoring.

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2. The collection, registration and other processing of Personal Data must be legally authorized under Applicable Law, or applicable policies issued of the supervisory authorities.
3. Any person who takes part in the processing of Personal Data must be familiar with these requirements.
4. Premises used for the storage and other processing of Personal Data must be arranged in such a way as to prevent unauthorized access.
5. Appropriate security measures must be implemented to protect data against accidental or unlawful destruction, loss or impairment. Furthermore, it must be ensured that no incorrect or misleading Personal Data is processed. Incorrect or misleading data, or data processed in contravention of the above Applicable Law, policy of the competent authorities or these requirements, shall be rectified or erased.
6. Personal Data may not be stored in a way that makes it possible to identify the Data Subjects for longer than is necessary for the achievement of the Study and/or mandatory safety monitoring.
7. The publication of results from clinical studies must take place in such a way that it is impossible to identify individual persons.
8. It is a condition that other legislation laying down requirements of the processing of Personal Data in connection with Study and/or mandatory safety monitoring is complied with.

Electronic data

9. Identification data must be encrypted or replaced by a code number or similar. Alternatively, all data stored can be encrypted. Encryption keys, code keys, etc. must be stored securely and separately from the Personal Data. This also applies to Personal Data that is stored on portable devices such as laptop PCs, tablets, etc.
10. Data may only be accessed by using a unique user name and a confidential password. The password must be renewed at least once a year and when otherwise necessary in order to ensure the secure processing of the data.
11. On the transfer of Personal Data via the internet or other external networks, the necessary security measures must be taken to ensure that the Personal Data does not come to the knowledge of any unauthorized persons. This includes that encryption is required if sensitive Personal Data is transferred via the internet (or other open networks), and security of authenticity (identities of transmitter and recipient) and integrity (the authenticity of the transmitted Personal Data) must be appropriately ensured by the use of suitable security measures. On using internal networks, it must be ensured that no unauthorized persons can gain access to the data.
12. Removable storage media, safety copies of Personal Data, etc. must be stored securely and under lock and key, so that unauthorized access is prevented.

Manual ("paper") data

13. Manual material, including print-outs, error and control lists, etc. with Personal Data, must be stored securely under lock and key, and in such a way as to prevent unauthorized access.

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Information to be given to the clinical Study Subject/Data Subject

17. Where the Personal Data is obtained from the clinical Study Subject/Data Subject (via interviews, questionnaires, clinical or para-clinical examination, treatment, observation, etc.), detailed information concerning the clinical Study/testing/safety monitoring shall be distributed/forwarded to the Data Subject in accordance with Article 13 of the GDPR. The clinical Study Subject must, via the notification or informed consent form (as applicable) as drafted by the Data Controller and as approved by the relevant ethics committee and /or relevant authorities, be informed of the name of the Data Controller, the purpose of the trial/testing/safety monitoring, the fact that it is voluntary to participate in the trial/testing, the identity of any recipients of Personal Data, and the purpose of the disclosure of Personal Data, as well as any further information which is necessary for the clinical Study Subject / Data Subject to be able to safeguard his/her interests. The Data Subject has been informed about the right of access to the Personal data that is processed concerning the person in question.

Disclosure

18. Disclosure/issue of Personal Data to other parties may take place to the extent that this is legally authorized under Applicable Law.

On the conclusion of the project

19. At the latest on the conclusion of the trial/testing/safety monitoring the Personal Data (including biological material) shall be erased, made anonymous, or destroyed as soon as reasonably possible, unless Union or Member State law requires continued storage of the Personal Data. In accordance with Belgian Law as defined in the Agreement the Data Processor shall be allowed to store the medical records for 30 years. It must not subsequently be possible to identify Study Subjects participating in the clinical Study/testing/safety monitoring. The deletion of Personal Data must be properly documented.

20. Alternatively, the Personal Data may be transferred for further storage in archives according to the Data Controller's instructions. Any costs related to such transfer and further storage of Personal Data shall be borne by the Data Controller.

21. Erasure of Personal Data from electronic media shall take place in such a manner that it is impossible to recover the Personal Data and such erasure must be properly documented.

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Annex 2 – Sub-processors

The Data Controller agrees that the Data Processor – subject to compliance with Clause 4 of the Data Processing Agreement – engages the parties listed below as subprocessors.

NONE

Annex 3 - EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries

Not applicable

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