DATA TRANSFER AGREEMENT

This Data Transfer Agreement (hereinafter called the "Agreement"), effective as of the date of the last signature (hereinafter called "**Effective Date**"), is entered into by and between:

F**ondazione IRCCS Istituto Nazionale dei Tumori**, located at Via Giacomo Venezian, 1, 20133 Milano MI, (hereinafter referred to for brevity as the "**Provider**")

represented by the General Manager, Dr. Carlo Nicora Authorized Official, under the scientific responsibility of prof. de Braud, Director of s.c. Oncologia Medica 1 (referred the "Provider Scientist");

and

Ospedale San Raffaele s.r.l.
Via Olgettina, 60 Milan, Italy, tax code and VAT no. 07636600962, through its Research Director Dr. Anna Flavia d'Amelio Einaudi
(hereinafter referred to for brevity as th "**Recipient**") under the scientific responsibility of Prof. Stefano Partelli, Director of the operating unit of pancreas surgery (referred the **"Recipient Scientist")**;

Provider and Recipient shall hereinafter also be referred to, jointly, as the "**Parties**" and, individually, as the "**Party**"

Provider agrees to provide to Recipient with Personal Data as described below as requested by prof. de Braud **("Provider Scientist")** for use in a research project, subject to the terms and conditions set forth in this Data Transfer Agreement (hereinafter, the "**Agreement**").

1. This Agreement applies to data (referred the "**Personal Data**") collected in specific CRFs within the clinical research promoted by the Recipient as further specified under Annex A and any related information and know-how which are received by Recipient under this Agreement for use only in the Recipient's research clinical project regarding the evaluation of the financial toxicity reported by patients affected by GEP-NEN (Gastroenteropancreatic neuroendocrine neoplasms) during the first year of treatment after diagnosis and its correlations with patient-reported outcomes and quality of life (QoL), Recipient protocol n. FiReNEN, (referred the "**Research**").

For the purpose of this Agreement, the following definitions and the definitions anywhere else included in this Agreement shall apply:

"**Personal Data**" means any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

"**Confidential Information**" shall mean all information disclosed by the Parties including, but not limited to non-public, confidential or other proprietary information, whether written, oral or otherwise, including confidential or proprietary know-how or other information, whether or not patentable, including the Research results, in each case that is clearly designated or marked as

confidential, or which under the circumstances surrounding disclosure or given the nature of the information shall reasonably be believed to be confidential.

"**Pseudonymisation**" means the processing of Personal Data in such a manner that the Personal Data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person.

"**GDPR**" means the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

"**Controller**", "**Processing**", "**Processor**" shall have the meaning as set forth in the GDPR.

1. Provider provides the Recipient with Personal Data collected at the Provider's facilities that can be used by the Recipient to carry out the Research.

2. The Parties warrant and undertake to transfer and process the Personal Data in accordance with any applicable laws, rules and regulations and other requirements of the applicable governmental authorities, including without limitation those applicable to patient's informed consent, the GDPR and any applicable data protection laws with the same level of protection.

The Parties acknowledge and agree that both the Provider and the Recipient shall act as independent Data Controllers for the processing activities carried out under this Agreement. For the avoidance of doubt, this data transfer agreement is not an agreement as meant in article 26.1 GDPR (Joint controllers) nor article 28.3 GDPR (Data Processors).

The Recipient warrants and undertakes to:

a) use the Personal Data only for Research purposes under this Agreement;

b) not carry out any procedures or activities with the Personal Data (such as linking and comparing) aimed at patients' identification;

c) have in place appropriate technical and organisational measures to protect the Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the Personal Data to be protected.

The Provider warrants and undertakes:

a) that the Personal Data has been collected, processed, stored by Provider in compliance with any applicable laws, rules, regulations and other requirements of the applicable governmental authorities, including without limitation those applicable to patient informed consent, the GDPR and any applicable data protection laws.

b) that it has obtained any regulatory or ethics approvals necessary to collect the Personal Data and transfer the Personal Data to the Recipient.

c) to provide the individuals whose Personal Data is transferred under this Agreement with the

privacy policy attached under ANNEX B on data collection activities carried out by the Recipient within the Research.

3. Prior to the transfer of Personal Data to Recipient and Recipient Scientist, Provider will ensure that Personal Data are pseudonymised so they can no longer be attributed to a specific data subject (natural person) without the use of additional information, provided that such additional information shall be kept separately and shall be subject to technical and organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person.

4. Recipient agrees not to transfer the Personal Data to any other party except the Recipient Scientist without Provider's prior written consent, which shall not be unreasonably withheld. Scientist agrees not to transfer the Personal Data to anyone who does not work under his or her direct supervision at Recipient's institution without Provider's prior written consent, which shall not be unreasonably withheld.

5. (a) Except as otherwise provided in this Agreement, the Party receiving the Confidential Information (hereinafter, the "Receiving Party") from the disclosing party (hereinafter, the "Disclosing Party") will maintain a strict confidentiality on any Confidential Information for a period of five (5) years from the date of execution of this Agreement.
The Receiving Party shall not disclose or make known Confidential Information to third parties, except to those who work under his or her direct supervision (bound by confidentiality obligations substantially equivalent to those in this Agreement as they apply to the Receiving Party) and only on a "need to know basis" in order to perform the Research. It is understood and agreed that the Receiving Party shall be primarily responsible to the Disclosing Party for any breach also by any such third parties of the confidentiality obligations hereunder.

The obligations of confidentiality set forth in Section 7(a) hereof shall not apply, however, to Confidential Information which

1. Is at the time of disclosure to the Receiving Party, in the public domain;

2. Is published or otherwise becomes part of the public domain after receipt through no fault of the Receiving Party;

3. Was already within the Receiving Party's possession (as is evidenced by the Receiving Party's written records) at the time of receipt and was not acquired, directly or indirectly, from the Disclosing Party;

4. Was received by the Receiving Party (as is evidenced by the Receiving Party's written records) from a third party who did not require the Receiving Party to hold it in confidence and who did not acquire it, directly or indirectly, from the Disclosing Party under a continuing obligation of confidence; or

5. In the event that Confidential Information is required to be disclosed pursuant to a valid court order, the Receiving Party may disclose such Confidential Information, provided that the Receiving Party shall give reasonable prior written notice to the Disclosing Party and shall make a reasonable effort to obtain a protective order requiring that the Confidential Information be disclosed only to the extent required by such order or laws, and that it will be used only for the purposes for which the order or laws require such disclosure to be made.

The Receiving Party agrees to promptly notify the Disclosing Party if the Receiving Party receives any third-party request for the Confidential Information.

(b) The Recipient retains ownership of all the Research results such as data, results, information, materials, discoveries and inventions (patentable or not) resulting from the execution of the Research.

(c) The Recipient undertakes to disclose all the results of the Research, even if negative, in accordance with the protocol of the Research.

Provider Scientist has the right to disseminate and publish the results obtained from its institution, in accordance with the current laws on the confidentiality of sensitive data, data protection and intellectual property, and in accordance with the terms and conditions of this Agreement.

Provider Scientist shall send copy of the document to be presented or published, at least 60 days before it is presented or published. The Recipient shall have 60 days (tacit consent) from receipt of the manuscript to suggest changes. Provider Scientist shall agree to include in the publication any comments or suggestions of the Recipient necessary to protect the confidentiality of the personal data and information and to protect intellectual property of the Recipient.

If the study is multicenter, it is understood that any publication by the Scientist Provider may take place only after the multicenter publication by the Recipient or a third party designated by the latter. If, after twelve (12) months from the end of the multicenter study no publication is initiated by the Recipient, or by the third party designated by the latter, the Provider Scientist may publish the results obtained at its institution, in compliance with the provisions set out in this Article.

Recipient Scientist and Recipient will acknowledge Provider as the source of the Personal Data in any publication of Research results.

7. It is understood that the Provider shall indemnify and hold the Recipient harmless from any claim for compensation for any damage caused to third parties as a result of the breach of the GDPR and any applicable data protection laws.

8. The Parties declare that they are aware that Italian Legislative Decree no.231 of 8 June 2001 (the "**Decree**") provides for the direct liability of companies in relation to the commission of a series of offences committed by its employees, suppliers or business partners, which is in addition to the personal liability of the person who committed the offence.

The Parties also acknowledge that: (i) the Recipient has adopted an organization, management and control model in compliance with the principles set forth in the Decree (referred the "**Organisational Model**") and a Code of Ethics (referred the "**Code of Ethics**"), which can be freely consulted on Recipient's website at https://www.hsr.it/strutture/ospedale-san-raffaele/trasparenza, in order to prevent the liability envisaged for committing the offences provided for in the Decree and the application of the relevant sanctions; (ii) the Provider, in compliance with the provisions of Italian Law no.190/2012 and subsequent amendment and additions, and the laws on transparency referred to in Italian Legislative Decree no.33/2013 and subsequent amendments and additions., has adopted its own code of ethics and a three-year plan for the prevention of bribery and transparency, published on its company website at [https://www.istitutotumori.mi.it/documents/848032/981529/Codice_Etico_Comportamentale_2018.pdf/12b0ebfc-5fab-e0d5-525b-ac0b228bc083], undertaking to comply with the rules and principles expressed therein.

The Parties undertake to comply with the rules stated above, to the extent applicable to each of them, in the performance of this Agreement.

The violation of the aforesaid obligation will constitute a serious breach of the obligations under the Agreement and will entitle the other Party to terminate the latter with immediate effect, pursuant to and in accordance with article 1456 of the Civil Code, without prejudice to compensation for any damages caused.

9. This Agreement is not assignable, in any way, without the prior written consent of the Parties.

10. (a) This Agreement will terminate on the earliest of the following dates: on completion of Scientist's current Research with the Personal Data or (2) on thirty (30) days written notice by Recipient to the Provider. Sections 5, 7 and any other clause which will be expected or intended by its nature to survive the termination or the expiration of this Agreement shall survive.

(b) Recipient reserves the right to withdraw unilaterally and with immediate effect from the agreement, if the Provider does not comply with the provisions set forth at article 8, does not provide the documentation requested by the Recipient or provides false and/or incomplete data, or opposes the audits requested by Recipient.

11. This Agreement shall be governed according to the Italian Law. The Court of Milan shall have exclusive jurisdiction for any controversy arising from or related to the present Agreement.

This Agreement is signed digitally in accordance with the applicable regulations. All the taxes and duties relating to or resulting from the stipulation of this Agreement, including the revenue stamp on the digital original as referred to in Article 2 of the table in Annex A – tariff part I of Presidential Decree 642/1972, and the registration tax, must be paid in accordance with the applicable regulations.

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PROVIDER
Fondazione IRCCS Istituto Nazionale dei Tumori
The General Manager
Dr. Carlo Nicora
Digital Signature

RECIPIENT
Ospedale San Raffaele S.r.l.
Il Direttore Ricerca
Dr.ssa Anna Flavia d'Amelio Einaudi
Digital Signature

Firmato digitalmente da: D'AMELIO EINAUDI ANNA FLAVIA
Data: 01/08/2023 14:39:58

Read and understood

Provider Scientist
Prof. Filippo de Braud
Digital Signature:

Firmato da:
FILIPPO GUGLIELMO MARIA DE BRAUD
Codice fiscale: DBRFPP56P19D612D
Valido da: 19-07-2022 10:14:06 a: 19-07-2025 02:00:00
Certificato emesso da: InfoCert Qualified Electronic Signature CA 3, InfoCert S.p.A., IT
Riferimento temporale 'SigningTime': 10-08-2023 12:27:51
Motivo: Approvo il documento

Recipient's Scientist
Stefano Partelli
Digital Signature:

19/7/23

ANNEX A

The study is designed as a prospective multicentre observational clinical study, which will be coordinated by the Pancreatic Surgery Unit of San Raffaele Scientific Institute (Lead Study Centre). Anamnestic, clinical and pathological data will be collected in specific electronic CRFs. Furthermore, patients will be asked to keep a diary of their out-of-pocket costs, defined as tumor related costs paid by the patient during the last 30 days. "Out-of-pocket costs" is an umbrella term for direct payments that individuals make with their own money (these expenses may be or may not be later reimbursed by a third party). In the present study out-of-pocket costs will be evaluated at 1-2-3-6-12 months from diagnosis and they will be classified into the following categories:

- direct medical costs:
    - ✓ hospital;
    - ✓ physician services;
    - ✓ other health care professionals;
    - ✓ prescription drugs;
    - ✓ medical devices;
    - ✓ complementary/alternative care.
- direct non-medical costs:
    - ✓ travel;
    - ✓ accommodation;
    - ✓ personal care and homemaking.

Patients will be also asked to fill the following two questionnaires at time of enrolment (initial diagnosis) and after 3, 6 and 12 months:

- COmprehensive Score for financial Toxicity (COST) regarding the burden of financial toxicity;
- EORTC QLQ-C30 version 3.0 evaluating quality of life in patients affected by cancer.

CRF, questionnaires and out-of-pocket costs diary data will be collected by a specific web-platform (REDCap)

ANNEX B

Ospedale San Raffaele Privacy Policy for Research Participants under art. 14 of Regulation (EU) 2016/679 (GDPR)

Dear Sir/Madam,

Ospedale San Raffaele is a clinical and research institute that carries out scientific studies, many of them in partnership with other organisations.

Ospedale San Raffaele S.r.l., with registered office in Milan, via Olgettina no. 60, 20132, Tax Code 07636600962, VAT no. 07636600962, e-mail hsrsanraffaele@hsr.postecert.it, represented by Chief Executive Officer and legal representative, in his capacity as data controller (the "**Data Controller**"), hereby provides you, as the data subject ("the **Data Subject**"), with specific information on the processing of your personal data pursuant to art.14 of Regulation (EU) 2016/679 of the European Parliament and Council of 27 April 2016 ("**GDPR**") and the European and national legislation on data privacy and protection.

1. Data Protection Officer

The Data Controller has appointed a data protection officer ("**Data Protection Officer**" or "**DPO**"), as provided for in the GDPR, responsible for surveillance, supervision and specialist consultancy in privacy matters, who can be contacted at the following email address: dpo@hsr.it

2. Source of the personal data

Your personal data have not been obtained by the Data Controller directly from You.

Your personal data have been collected for clinical and research purposes by the following third-party sources (other clinical and/or research institutions within or outside the European Economic Area, partners of the Data Controller) and shared with the Data Controller for research purposes within the scope of the Research:

- (Fondazione IRCCS Istituto Nazionale dei Tumori, located at Via Giacomo Venezian, 1, 20133 Milano MI).

3. Categories of personal data subject to processing

The Data Controller will process your common data (including, for example, your sex and age) and the special categories of your data (anamnestic, clinical, pathological data, out-of-pocked and quality of life data, (hereinafter, jointly referred to as the "**Personal Data**").

4. Purposes and legal basis of the processing

Your Personal Data shall be processed by the Data Controller for the purposes of the Scientific Research "**Financial Toxicity and Patient-Reported Outcomes in Italian Patients affected by Gastroenteropancreatic Neuroendocrine Neoplasms (GEP-NEN)"** aimed to evaluate the financial toxicity reported by patients affected by GEP-NEN during the first year of treatment after diagnosis and its correlations with patient-reported outcomes and quality of life (QoL). (the "**Research**").

This Research is designed as a prospective multicenter national study and is carried out in collaboration with other Italian partners.

You can have more information about the Research contacting directly the Principal Investigator at the following email address (partelli.stefano@hsr.it).

The legal basis for processing Your Personal Data is (i) Your specific consent provided to the Research Institution where your Personal Data have been collected in compliance with the local privacy and data protection regulation, and/or (ii) the performance of a task carried out in the public interest and/or (iii) scientific research purposes, in particular for observational studies, under art, 9, para. 2, letter j), of the GDPR and 110-bis, para 4, of Italian Legislative Decree 196/2003.

Personal Data collected for research will not be used for any other purpose.

5. Storage of personal data

Personal Data will be stored only for the time necessary for the purposes for which it has been collected, respecting the principle of minimisation referred to in article 5, paragraph 1, letter c) of the GDPR, as well as in compliance with the legal obligations and regulatory requirements specific to research. More information in this regard is available from the Data Controller or the DPO at the contact addresses stated above.

6. Scope of disclosure of the personal data

Your Personal Data will not be disclosed, except in the case where its disclosure is requested, in compliance with the law, by public parties for the purposes of defence or security or prevention, investigation or prosecution of offences. In the performance of its activities and for the pursuit of the Research purposes, the Data Controller may share your Personal Data (pseudonymized or anonymized as needed), including your healthcare information, with the following subjects:

- associated researchers and the academic community, as part of a research publication or conference presentation or public talk. Where researchers wish to use any information that would identify you, specific consent will be sought.

- the Ethics Committee and the Italian and foreign health authorities, as independent data controllers, will be able to access Your Personal Data, for control and auditing purposes, in such a way as to guarantee the confidentiality of your identity.

- companies or professionals providers of services that are functional to the Data Controller's Research activities, appointed as data processors pursuant to art.28 of the GDPR, including for example IT service providers that manage the technological infrastructure, the computer systems and telecommunication networks.

Your Personal Data will not be transferred to third countries outside the EU or to international organisations. If this transfer is necessary for the pursuit of the Research purposes, this processing will be carried out exclusively in Countries considered adequate by the European Commission or, in any case, according to the methods permitted in articles 46 *et seq.* of the GDPR, such as for example the consent of the data subject, the adoption of Standard Clauses approved by the European Commission and the selection of parties subject to international programmes for the free circulation of data.

7. Rights of the Data Subject

Pursuant to articles 15 to 22 of the GDPR, Data Subjects are entitled to:

- obtain, from the Data Controller, the confirmation that the personal data are processed and, in this case, obtain access to the data, as well as, if the data has not been collected from the Data Subject, to receive all the information available on its origin;
- be aware of the purposes of the processing, the categories of data processed, the recipients or categories of recipient to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organisations, the envisaged data storage period or the criteria used to determine this period;
- ask the Data Controller for the rectification, erasure of the data or the restriction of the data processing;
- object to the processing of the data, without prejudice to the right of the Data Controller to assess the request, which may not be accepted in the event of the existence of compelling legitimate grounds to proceed with the processing that override data subjects' interests, rights and freedoms;
- withdraw consent to the processing at any time, without this affecting the lawfulness of the processing based on consent before its withdrawal;
- be made aware of the existence of an automated decision-making process, including profiling;
- obtain the portability of the data, in the cases provided for by law;
- lodge a complaint with a supervisory authority (Data Protection Authority).

Please note that many of these rights might not apply when the data is being used for research purposes and Your rights to access, change or move your information are limited, as the Data Controller needs to manage Your Personal Data in specific ways in order for the Research to be reliable and accurate.
The Data Controller is committed to making every effort to respect Your wishes and will always try to respond to concerns or queries that You may have. Requests can be made in writing to the Data Controller or to the DPO at the addresses stated above.