Sistema Socio Sanitario

Ospedale Papa Giovanni XXIII

Regione Lombardia

ASST Papa Giovanni XXIII

DELIBERAZIONE NR. 1449 DEL 04/09/2025

OGGETTO: STIPULA DEL COLLABORATION AGREEMENT E DATA SHARING AGREEMENT CON UNIVERSITÄTSKLINIKUM HEIDELBERG PER LE ATTIVITÀ DEL REGISTRO ERKNET (REG. 2018-0158) IN CORSO PRESSO LA SC NEFROLOGIA

IL DIRETTORE GENERALE
nella persona del Dott. Francesco Locati

ASSISTITO DA:

IL DIRETTORE AMMINISTRATIVO	DR. GIANLUCA VECCHI
IL DIRETTORE SANITARIO AD INTERIM	DOTT. FRANCESCO LOCATI
IL DIRETTORE SOCIO SANITARIO	DR.SSA SIMONETTA CESA

Premesso che con deliberazione nr. 1843 dell'11/10/2018 è stata autorizzata l'attivazione del registro ERKNet (reg. 2018-0158), con titolo: "European Reference Network (ERN) on Rare Kidney Diseases", proposto dal promotore Universitätsklinikum Heidelberg, in corso presso la SC Nefrologia;

Rilevato che:

- il promotore ha comunicato che la Commissione europea ha stanziato fondi per remunerare l'attività di inserimento dati nel registro stesso;
- Universitätsklinikum Heidelberg ha comunicato che il compenso per le attività di inserimento dati sarà determinato in funzione della disponibilità di fondi allocati dalla Commissione europea e che l'entità del finanziamento è definita annualmente dall'Executive Board della European Reference Network (ERN);

Atteso che il direttore della menzionata SC ha comunicato che:

- è previsto l'inserimento di circa 100 pazienti ogni anno;
- il compenso medio corrispondente a ciascun paziente arruolato sarà definito sulla base della tipologia dei dati inseriti e sarà aggiornato annualmente dalla ERN;
- per l'anno 2025 la quota per paziente è stata determinato in € 12,50;

Quantificato, quindi, in € 1.250,00 il ricavo che verrà introitato al conto economico 401810190 "Contributi c/esercizio da privati vincolati" del bilancio aziendale;

Preso atto che il testo del Collaboration Agreement e del Data Sharing Agreement (DSA) è stato concordato con il promotore e allegato al presente provvedimento;

Dato atto che la dr.ssa Monia Maria Beatrice Lorini, direttore della SC Ricerca clinica, sviluppo e innovazione, è responsabile del procedimento;

Acquisito il parere del direttore amministrativo, del direttore sanitario ad interim e del direttore sociosanitario;

DELIBERA

1. di sottoscrivere con il promotore Universitätsklinikum Heidelberg, il Collaboration Agreement e Data Sharing Agreement per le attività del registro ERKNet (reg. 2018-0158) attivato presso la SC Nefrologia, nel testo allegato al presente atto (all. A);
2. di introitare l'importo di € 1.250,00 al conto economico 401810190 "Contributi c/esercizio da privati vincolati" del bilancio aziendale;
3. di dare atto che la dr.ssa Monia Maria Beatrice Lorini, direttore della SC Ricerca clinica, sviluppo e innovazione, è responsabile del procedimento.

IL DIRETTORE GENERALE
Dott. Francesco Locati

COLLABORATION AGREEMENT:
Participation in the European Rare Kidney Disease Registry (ERKReg)

This Agreement defines the terms and conditions applicable to the collaborative research effort agreed upon

between

Universitätsklinikum Heidelberg, represented by **Commercial Managing Director:** Katrin Erk
Im Neuenheimer Feld 672, 69120 Heidelberg, Germany
Institution in Charge: University Hospital for Pediatric and Adolescent Medicine
Im Neuenheimer Feld 430, 69120 Heidelberg (Director: Prof. Dr. G.F. Hoffmann)
Investigator in Charge: Prof. Dr. Dr.h.c. Franz Schaefer

(in the following called “ERKNet” or “Klinikum Heidelberg”)

and

ASST Papa Giovanni XXIII (hereinafter the “**Contractor**" or “**PG23**”), headquartered in Piazza OMS, n. 1, 24127 Bergamo, Italy, tax code and VAT no. 04114370168, with certified email address ufficioprotocollo@pec.asst-pg23.it, through its Legal Representative Dr. Francesco Locati in the capacity of General Director, with the powers to enter into this Agreement

Whereas:

a. The **European Reference Network for Rare Kidney Diseases** (ERKNet) is a consortium of expert paediatric and adult nephrologists working in rare diseases throughout Europe. ERKNet allows healthcare professionals to work together to support patients with rare or complex kidney conditions which need highly specialized management. ERKNet aims to improve knowledge about rare kidney diseases and supports clinical research for improved diagnosis and risk prediction and the development of innovative therapies.

b. **ERKNet** runs the **European Registry for Rare Kidney Diseases** (ERKReg ERK-Reg) as a core registry for all rare kidney diseases. Participation is open to all European nephrology centers interested in rare renal disorders. ERK-Reg collects basic diagnostic information as well as disease-specific key performance and outcome indicators to allow monitoring and benchmarking of management quality.

c. **ERKNet and the Contractor wish to collaborate** for the purpose of studying the epidemiology and demography of kidney rare diseases and for promoting studies on this disease and treatment outcomes. To this end, ERKNet has entered into an agreement with the Contractor related to the use of the ERK-Reg database, online data collection, control and analysis.

d. By resolution no. 2110 of 29.12.2015, the Contractor has adopted the "Hospital regulation for the management of clinical trials and scientific collaborations Rev.1.0" which defines the criteria and procedures for the conduct of clinical trials and scientific collaborations to be carried out at the hospital;

The Parties agree on the following:

1. **Responsibilities of Contractor**

The Contractor will:

(a) use the ERKReg online database as a platform to collect patient data;

(b) inform the families of children and adolescents in his/her center about the contents and objectives of ERKReg, and will obtain consent from the patients and/or their legal guardians for online submission of pseudonymized patient-related information to the ERKReg website;

(c) provide data of all patients affected by a rare kidney disease who agreed to take part in ERKReg by signing the patient informed consent form;

(d) provide annual status updates of the patients enrolled in the database;

(e) submit all data in a timely manner, and maintain locally adequate written records of subject identification and clinical observations;

2. **Compliance With Laws**

Participation in the network will be conducted in accordance with the Note for Guidance on Good Clinical Practices (CPMP/ICH/135/95), the EU General Data Protection Regulation (GDPR) and any national rules and regulations regarding data protection. The Contractor and Klinikum Heidelberg will also comply with all applicable laws and regulations (including data protection laws and regulations) relevant to the registry and any guidelines governing the performance of research in the hospital or other place at which data is collected.

3. **Confidentiality**

(a) Access of authorized users to the registry is controlled by assignment of a secure, individualized password. A hierarchical access authorization system is implemented with super-administrator, administrator (Affiliated Registry lead) and center user levels.

(b) The data entered will only be visible to the investigators of the Contractor and will not be shared with other users of the registry, except in aggregated format for benchmarking purposes.

(c) All patient data are entered and stored in a pseudonymised fashion. Only the authorized user is able to identify the patient through an identification code, automatically generated at the time of patient registration.

(d) The data will be stored on a commercial server in Germany, inaccessible to non-authorised personnel or entities. Regular back-ups are made. These back-ups are kept in a secured location. They guarantee the protection of (identifiable) data and the security of all information.

(e) The data will be kept in the database for at least 15 years. At request of one Party, after expiry of the mandatory conservation period, the Parties may agree the terms of a further conservation period. Data will not be destroyed without permission of

the Contractor. The investigators of the Contractor will be provided continuous exclusive access to their current center statistics and benchmarking in comparison to all patients in the ERK-Reg database.

4. **Term of ERK-Reg Registry**

ERK-Reg is initiated within the first quarter of 2019 and is open-ended.

5. **Case-Related Compensation**

The ERKNet coordinating office will pay to the Contractor a case-based compensation for the data entry effort depending on the availability of central funds for this purpose.
The compensation fees will be adapted on annual basis according to available funds. Case-based compensation fees for the subsequent year will be determined by the ERKReg Board in the month of October of the preceding year and will be published on the ERKReg website.
Payments will be made every 6 months, for patients documented by June 30th and December 31st.
The ERKNet will pay the amount due to PG23 on the basis of a valid statement of account/supporting document agreed between the Parties and only upon receipt of an invoice from the Contractor. The payment must be made within 45 days from receipt of the invoice.

All payments shall be made payable plus VAT (if applicable) to

Name of bank account holder (if not your name): Azienda Socio-Sanitaria Territoriale Papa Giovanni XXIII

Name of bank: Banca Popolare di Sondrio

Bank Code (SWIFT): POSOIT22

International Bank Account No. (IBAN): IT75Z0569611100000008001X73

Reference: Clinical Trial Coordination Office (CTC) email address *ctc@asst-pg23.it*

All payments will be in euro.

In relation to the Registry, the Principal Investigator and the Co-investigators of PG23 may not receive any direct or indirect compensation from ERKNet / Klinikum Heidelberg , nor have any contact or dealings with ERKNet / Klinikum Heidelberg or relations of any kind that are not of a technical or scientific nature.

6. **Processing of personal data**

6.1 In executing the contractual activities the Parties shall treat all the personal data they receive for any reason in relation to the Registry in accordance with the objectives of the foregoing articles and in conformity with the provisions of Regulation (EU) 2016/679 of the European Parliament and Council of 27 April 2016 (GDPR), and with the related provisions of law and orders of national administrations,

including any subsequent amendments (collectively the "Data Protection Laws") as well as any regulations of the Parties.

6.2 The terms used in this article, in this Agreement, in the informed consent documents and in any other documents used for the purposes of the Trial shall be construed and utilized in accordance with the meanings given in Annex A.

6.3 The Parties are independent data controllers for the purposes of article 4 paragraph 7 of the GDPR. Each of the Parties will arrange at its own expense, as part of its organizational structure, for the appointment of Data Processors and assignment of functions and tasks to designated subjects, who operate under their authority, in accordance with the GDPR and current legislation.

6.4 For the purposes of the Registry, personal data relating to the following categories of data subjects will be processed: persons taking part in the study; persons operating on the Parties' behalf. Such data subjects will be appropriately informed of the processing of their data. For the purposes of the Registry, the following types of personal data will be processed: the data referred to in article 4 paragraph 1 of the GDPR; data classified as "sensitive" – and in particular, data relating to health, sexual life and genetic data – referred to in Article 9 GDPR. Such data shall be processed in accordance with the principles of legality, fairness, transparency, adequacy, relevance and necessity as contained in Article 5 paragraph 1 of the GDPR.

6.6 The Parties warrant that the persons authorized by them to process personal data for the purposes of the Registry will comply with the principles in force to safeguard data protection and the right to confidentiality and that any persons having access to the personal data will be obligated to process the data in accordance with the instructions given, in accordance with this article, by the data controller.

6.7 The Principal Investigator of PG23 has been identified by PG23 as a person authorized for the data processing for the purposes of Article 29 GDPR and as a designated party for the purposes of Article 2 quaterdecies of the Italian Law Decree 196/2003.

6.8 The Principal Investigator of PG23 shall provide clear, complete information to all patients before Registry's enrollment (also before the preliminary phases or screening) to all patients, regarding the nature, purpose, results, consequences, risks and methods of the processing of personal data; in particular, all patients must be informed that the national and international authorities and the Ethics Committee may, in connection with the monitoring, checking and control of the Registry, have access to the related documentation and also to the original healthcare records of the patient, and that the data may also be accessed by the Monitors and Auditors in connection with their respective duties.

6.9. After the patient has been duly informed, the Principal Investigator of PG23 shall obtain the consent form for participation in the Registry and also the consent to the processing of personal data. PG23 is responsible for storing the consent forms.

6.10 If either Party discovers a data protection breach, the other Party shall be informed within 48 hours from the breach having been verified, without prejudice to such Party's independent assessment of the existence of the conditions and fulfilment of the obligations contained in Articles 33 and 34 GDPR.

6.11 All data regarding individuals (excluding that belonging to the Subjects in the Registry, to whom the provisions indicated in the paragraphs before) pertaining to the PG23 or ERKNet, will be reciprocally processed by the two data controllers in accordance with Regulation 679/2016/UE. This processing will be for the following purposes:

a) fulfilment of specific accounting and taxation obligations;

b) management and execution of the relations and the contractual obligations;

c) research and trial activities;

d) purposes associated with the obligations set out in law, regulations or EU legislation as well as provisions issued by the Authority legitimated to do so by law;

e) dispute management;

f) statistical purposes;

g) internal control services.

The provisions referred to in this Article fulfil the information requirements pursuant to Article 13 of Regulation 679/2016/UE.

The Parties therefore expressly state that they are aware of the rights acknowledge to them in Articles 15, 16, 17, 18, 20, 21, 22 of Regulation 679/2016/UE, specifically the right to request the update, correction or deletion of their personal data.

The obligations and provisions of this Article will remain in force and in effect including at the end of the Agreement and/or its effects, regardless of the reason for this.

7. **Anti-corruption**

The Parties will comply with all applicable anticorruption laws.

8. **Duration and Termination**

This agreement becomes effective at the date of the last party signing the agreement. Termination of the agreement will follow after withdrawal of one of the parties, at any time and without the need of giving a reason. Termination of the agreement is without any further obligation or compensation, except for the activities completed to the day of termination.

This Agreement is fiduciary in nature and therefore the Parties may not assign or transfer or subcontract this Agreement to any third party without the prior consent of the other Party. Each Party will allow the other Party to assign and/or transfer all or part of the rights and obligations received directly or indirectly from the signing of this Agreement to a successor or to an affiliated company, on condition that the transferee accepts all the terms and conditions herein. Any transfer of rights taking place in the absence of such conditions shall be considered null and void and shall be disregarded.

The persons signing this Agreement confirm that they have the necessary authority to agree to the commitments and obligations inherent in participating in this Registry.

Klinikum Heidelberg

Katrin Erk
Commercial Managing Director
University Hospital Heidelberg
Im Neuenheimer Feld 672
69120 Heidelberg, Germany
for Ruprecht-Karl University Heidelberg

Read and acknowledged

Prof. Dr. Georg F. Hoffmann
Director
University Children's Hospital Heidelberg (executing department)
Ruprecht-Karl University Heidelberg, Germany
Im Neuenheimer Feld 150
69120 Heidelberg, Germany

Prof. Dr. Dr.h.c. Franz Schaefer
ERKNet Coordinator
Division of Pediatric Nephrology
University Children's Hospital
Im Neuenheimer Feld 150
69120 Heidelberg, Germany

Contractor

Francesco Locati
General Director
ASST Papa Giovanni XXIII
Piazza OMS n.1
24127 Bergamo, Italy

ANNEX A

• **Personal Data** - any information relating to an identified, or identifiable, natural person (the "Data Subject"). An identifiable natural person is a person who can be identified directly or indirectly using an identifier such as: a name, an identification number, location data, an online identifier or one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual;
• **Processing** - any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;
• **Pseudonymisation** - 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 individual;
• **Data Controller** - the natural or legal person, public authority, agency or any other entity which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;
• **Data Processor** - a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Data Controller;
• **Consent of the Data Subject** - any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;
• **Personal Data Breach** - any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure, or access to, personal data transmitted, stored or otherwise processed;
• **Medical Data** - personal data pertaining to the physical or mental health of an individual including the provision of medical services, which may reveal information about his or her state of health;
• **Genetic data** - personal data relating to the hereditary genetic or acquired characteristics of an individual which provides unequivocal information about the physiology or health of that individual and which results, in particular, from the testing of a biological sample from the individual in question;
• **Biological sample** - any sample of biological material from which the characteristic genetic data of an individual can be extracted;
• **Sponsor/Promoter** - the person, company, institution or body that is responsible for starting, managing and/or funding a clinical trial;
• **CRO** – the contractual research organisation to which the sponsor may entrust all or part of its competencies relating to clinical trials;
• **Monitor** – the party responsible for monitoring the Trial, appointed by the sponsor/CRO;
• **Auditor** – the party responsible for auditing the conduct of the Trial as an integral part of quality assurance, appointed by the sponsor/CRO.

Data Sharing Agreement

This Data Sharing Agreement ("**Agreement**") is aiming at regulating the sharing of data and is effective as of the date of last signature below (the "**Effective date**") is entered into

by and between:

Heidelberg University Hospital, represented in law by its Commercial Managing Director Katrin Erk, Im Neuenheimer Feld 672, 69120 Heidelberg, Germany
- on behalf of the University Heidelberg, Faculty of Medicine Heidelberg -

Executing Department: University Hospital for Pediatric and Adolescent Medicine
Medical Director: Prof. Dr. Georg Friedrich Hoffmann
Im Neuenheimer Feld 430, 69120 Heidelberg, Germany

with ERKReg (The European Rare Kidney Disease Registry), represented by:
Head of Registry: Prof. Dr. Dr. h.c. Franz Schaefer
ERKNet Coordinator

(in the following called „the **Requestor**"),

and

ASST Papa Giovanni XXIII, represented in law by its General Manager dr. Francesco Locati, with legal address at Piazza OMS n.1, 24127 Bergamo, Italy (in the following called „the **Supplier**"),

The Requestor and the Supplier may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS:

a) The **European Reference Network for Rare Kidney Diseases** (ERKNet, www.erknet.org) is a consortium of expert paediatric and adult nephrologists working in rare diseases throughout Europe. ERKNet allows healthcare professionals to work together to support patients with rare or complex kidney conditions which need highly specialized management. ERKNet aims to improve knowledge about rare kidney diseases and supports clinical research for improved diagnosis and risk prediction and the development of innovative therapies.

b) ERKNet runs the **European Registry for Rare Kidney Diseases** (ERKReg, www.registry.erknet.org), a European core registry collecting data from adult and paediatric patients with rare or complex kidney diseases. Participation is open globally to all nephrology centers interested in rare renal disorders. ERKReg allows healthcare professional to work together to support patients with rare and complex kidney diseases which require highly specialised care. ERKReg collects basic diagnostic information as well as disease-specific key performance and outcome indicators to allow monitoring and benchmarking of management quality and to support clinical research for improved diagnosis, risks prediction and the development of innovative therapies (the "**Purpose**);

c) ERKReg also serves as a platform for **disease-specific subregistries**. The participation in certain subregistries is optional. Upon approval an extended case report form is collected for the

respective patients.

d) In the support of the Purpose, the Requestor and the Supplier will be engaged in various activities including, but not limited to, the conduct of future research studies (each a "**Study**" and collectively "**Studies**");

e) The Parties intend to contribute and form the ERKReg registry according to the terms and conditions of this Agreement;

Definition

"**Data Protection Legislation**"	means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of Supplier Data to which a Party is subject and the GDPR or all legislation enacted in each Country in respect of the protection of Personal Data; and (b) any code of practice or guidance published by a Regulatory Body from time to time;
"GDPR"	means 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 repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119/1, 4.5.2016;
"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 organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person
"Regulatory Body"	means any competent governmental, statutory, regulatory or enforcement authority or regulator concerned with the activities carried on by any Party or any part, division or element thereof, in respect of the activities carried out pursuant to this Agreement.
"Study Data"	means study data entered in ERKReg Registry;

For the purposes of this Agreement, "**Controller**", "**Processor**", "**Data Subject**" and "**Process**" shall have the meanings set out in the GDPR (Article 4) and "**process**" "**processing**" and "**processed**" when used in relation to the processing of Supplier Data, will be construed accordingly, and will include both manual and automatic processing.

NOW, THEREFORE, in consideration for the mutual promises and for valid consideration, the Parties agree to the following terms of the Agreement:

Section 1 Data storage

1.1 The European Rare Kidney Disease registry (ERKReg) is a centralised registry. The Study Data collected by the Supplier will be transferred to the ERKReg central database using a customized system (based on PHP and Java Script) („the **Software**"). The Software, developed by will-be GmbH is the electronic data capture and transfer software chosen to develop the ERKReg Registry. The Study Data will be stored on a secured commercial server (1&1, Montabaur) with an appropriate level of encryption based in Germany.

1.2 The Study Data will be stored for 15 years. After the expiry of this period, the Parties may agree on the conditions for a further storage period.

1.3 In the event it is required to destroy the Study Data, patient data will be eliminated from the server. If the data have already been included in scientific evaluations or have been anonymized, deletion is no longer possible.

Section 2 Data Ownership and Access

2.1 The Supplier is and shall remain the owner of the data collected for the ERKReg registry;

2.2 The data entered by the Supplier will not be shared with other users of the ERRKeg registry, except in aggregated anonymised format for benchmarking or research purposes;

2.3 The Requestor is the owner of the electronic data capture system and provides secured access to the system to authorized users (listed in Data Access Policy). The Requestor ensures that all the data is stored on a secured server with appropriate level of encryption;

2.4 The Data Access Committee of the ERKReg registry may grant access to third parties not belonging to the ERKReg registry consortium, who can request access to the data upon the presentation of a research protocol that has to be approved by the ERKReg registry Data Access Committee accordingly to the procedure described on the website and the data access policy https://www.erknet.org/patients-registry/data-access-requests;

2.5 When processed, the Study Data becomes research data and is then the intellectual property of the investigator. To guarantee the validity of any research performed, data already processed cannot be withdrawn.

Section 3 Obligations of the Parties

3.1 <u>The Requestor</u>

i. The Requestor is the coordinator of the ERKReg registry. He shall provide the electronic data capture system and, as the central data Controller, be responsible for the storage and the processing of the transferred data as well as the administration of user rights. Compliant with all applicable national, federal, state, and local statutes, legislations, directives, regulations, and rules pertaining to the activities contemplated herein, including without limitation the following: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation that will be repealed by the Clinical Trials Regulation, Regulation EU No 536/2014; 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 (GDPR); the principles of ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) E6 and E11, as well as generally accepted professional standards for clinical and research standard of care will be guaranteed;

ii. The Requestor will set up the ERKReg registry help desk to support the Supplier;

iii. The Requestor shall ensure that appropriate technical and operational measures are in place to safeguard against any unauthorized or unlawful processing of the Study Data and against accidental loss or destruction of the Study Data, or damage to the Supplier. The Requestor shall promptly, without undue delay, and in any event within 48 hours, notify the Supplier about any actual or suspected data breach in relation to Study Data processed as a result of this Agreement;

3.2 The Supplier

i. The Supplier is responsible to obtain and keep on file any license, approval or similar, necessary for the participation in the ERKReg registry;

ii. As the local data Controller, the Supplier shall fully comply with all applicable national, federal, state, and local statutes, legislations, directives, regulations, and rules pertaining to the activities contemplated herein, including without limitation the following: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation that have been repealed by the Clinical Trials Regulation, Regulation EU No 536/2014; 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 (GDPR); the principles of ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) E6 and E11, generally accepted professional standards for clinical and research standard of care as well as any guidelines governing the performance of research in the hospital or other place where the data is collected;

iii. According to the national and local laws, the Supplier is responsible for obtaining an informed consent from each participant before enrolling them into the ERKReg registry. To that regard the Supplier shall use the patient information and informed consent form as approved by its competent Ethics Committee. The consent shall cover inter alia the processing of pseudonymized data (i.e., removing all sensitive personal data, including but not limited to patient names, initials, dates of birth, and other personally-identifiable information, and leaving visible a coded subject number) and the use within scientific research projects approved by the ERKReg Data Access Committee;

iv. The Supplier shall provide the personnel and hardware equipment necessary for the participation to the ERKReg registry;

v. The Supplier shall ensure completion of the data as foreseen by the registry protocol and make available the responsible Investigator for query resolution; the Supplier submits all data in a timely manner, and maintains locally adequate written records of subject identification and clinical observations. The Supplier will provide annual status updates of the patients enrolled in the database.

vi. The Supplier agrees that, upon prior notice, the Requestor or his designees on behalf of the ERKReg registry will, in accordance with applicable data protection laws, including but not limited to the GDPR, and the patient informed consent, be granted access to all documents necessary for auditing and monitoring purposes and that the responsible Investigator will be made available for questions.

3.3 Both Parties

i. Each Party shall not, by its acts or omissions, cause the other Party to breach its respective obligations under the applicable Data Protection Legislations and its national implementations.

ii. If a Regulatory Body notifies one of the Party of an audit or other investigation of the Regulatory Body regarding the ERKReg registry, the Party first notified shall promptly inform the other Party of such notification, including the provision of a copy of any

correspondence received from such Regulatory Body with respect to the audit or investigation and provide the other Party with the audit response or any other comment received immediately upon receipt;

Section 4 Term

4.1 This Agreement shall begin on the Effective Date and shall continue as long as the ERKReg registry exists.

4.2 Upon expiration or termination of this Agreement, the right to use the Study Data will automatically end. However, the Requestor may retain one copy of the Study Data solely to comply with the Study Data transfer requests that third parties may make for replication of research projects conducted before the termination of this agreement. In any case, the data will not be kept longer than 15 years.

Section 5 Confidentiality

5.1 Each Party undertakes that it shall not disclose at any time during the Term or thereafter to any person any confidential information concerning the business, affairs, customers, clients or suppliers of the other Party, including but not limited to the Study Data (the "Confidential Information") of the other Party, except as permitted by the subsequent Clause.

5.2 Each Party may disclose the other Party's Confidential Information: to its employees, officers, representatives or advisers who need to know such information for the purposes of carrying out its obligations under this Agreement or fulfilling the Purpose. Each Party shall ensure that its employees, officers, representatives, or advisers to whom it discloses the other Party's Confidential Information comply with this Clause 4; and as may be required by law, court order or any governmental or Regulatory Body or authority.

5.3 No Party shall use the other Party's Confidential Information for any purpose other than to perform its obligations under this Agreement or for fulfilling the Purpose.

Section 6 Amendment

No change, amendment or modification of this Agreement shall be valid unless set forth in a written document signed by a duly authorized representative of each Party.

Section 7 Severability

In the event of any provision of this Agreement is held to be invalid or unenforceable, the remainder of this Agreement shall remain in full force and effect as if the invalid or unenforceable provision had never been a part of the Agreement.

Section 8 Violation/Termination of Agreement

8.1 This Agreement will terminate immediately upon any breach of a provision of this Agreement.

8.2 Either Party shall have the right to terminate this Agreement with immediate effect upon giving written notice of termination to the other party.

Section 9 Regulatory requirements

The Parties agree to comply with all applicable laws and regulations relating to the privacy of subject health information, including, but not limited to 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) ("GDPR") as each apply to the Parties and their activities.

Section 10 Entire Agreement

This Agreement and the documents attached hereto and/or specifically referenced herein constitute the final, complete and exclusive Agreement between the Parties with respect to the subject matter of the Agreement, and it supersedes any and all prior or contemporaneous agreements, understandings, promises, or representations, whether oral or written, made between the Requestor and the Supplier concerning the subject matter of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement, in one original for each Party, as of the EFFECTIVE DATE.

The persons signing this Agreement confirm that they have the necessary authority to agree to the commitments and obligations inherent in participating in this Registry.

Heidelberg University Hospital	**ASST Papa Giovanni XXIII**
Name of Institution	Name of Institution
Katrin Erk **Commercial Managing Director**	**Dr. Francesco Locati** **General Manager**
Authorized representative of institution	Authorized representative of institution
Date and Signature	Date and Signature

Read and acknowledged:

Prof. Dr. Georg Friedrich Hoffmann
Medical Director Centre for pediatrics and Adolescent Medicine

Prof. Dr. Franz Schaefer
Division of Pediatric Nephrology, Centre for Pediatrics and Adolescent Medicine, Im Neuenheimer Feld 430, 69120 Heidelberg

ATTESTAZIONE DI REGOLARITA' AMMINISTRATIVO-CONTABILE (proposta n. 1479/2025)

Oggetto: STIPULA DEL COLLABORATION AGREEMENT E DATA SHARING AGREEMENT CON UNIVERSITÄTSKLINIKUM HEIDELBERG PER LE ATTIVITÀ DEL REGISTRO ERKNET (REG. 2018-0158) IN CORSO PRESSO LA SC NEFROLOGIA

SC PROPONENTE

Si attesta la regolarità tecnica del provvedimento, essendo state osservate le norme e le procedure previste per la specifica materia.

Si precisa, altresì, che:

A. il provvedimento:

☐ prevede
☒ non prevede

COSTI diretti a carico dell'ASST

B. il provvedimento:

☒ prevede
☐ non prevede

RICAVI da parte dell'ASST.

Bergamo, 28/08/2025

Il direttore

Dr.ssa Monia Maria Beatrice Lorini

GESTORE DI BUDGET

Si attesta che i RICAVI previsti:

✓ sono contabilizzati su: ☐ finanziamenti SSR e/o ricavi diretti

☒ fondi di struttura e/o contributi vincolati

polo ospedaliero	rete territoriale	importo imponibile	importo IVA	importo totale
X		€ 1.250,00	€ 0,00	€ 1.250,00

Si attesta, altresì, che i RICAVI relativi al presente provvedimento sono derivanti da:

(indicare centro di costo e autorizzazione se esistente)

☐ cessione beni cdc aut /anno
☐ cessione servizi cdc aut /anno
☐ libera professione cdc aut /anno
☐ solvenza aziendale cdc aut /anno
☐ contributi pubblici cdc aut /anno
☐ contributi privati cdc aut /anno
☐ erogazioni liberali cdc aut /anno
☒ altro cdc. aut /anno
☐ vedi allegato

Bergamo,28/08/2025

Il direttore

Dr.ssa Monia Maria Beatrice Lorini

SC BILANCIO PROGRAMMAZIONE FINANZIARIA E CONTABILITÀ

Viste le attestazioni del gestore di spesa, si certifica che:

B i RICAVI derivanti dal presente provvedimento saranno contabilizzati al/ai seguente/i conto/i del bilancio:

n. conto	descrizione del conto	n. autorizzazione/anno	n. sub-autorizzazione	importo imponibile	importo IVA	importo totale
401810190	Contributi c/esercizio da privati vincolati			€ 1.250,00	€ 0,00	€ 1.250,00

Bergamo, 28/08/2025

Il direttore

Dr.ssa Coccoli Antonella

PARERE DIRETTORI

all'adozione della proposta di deliberazione N.1479/2025
ad oggetto:
STIPULA DEL COLLABORATION AGREEMENT E DATA SHARING AGREEMENT CON UNIVERSITÄTSKLINIKUM HEIDELBERG PER LE ATTIVITÀ DEL REGISTRO ERKNET (REG. 2018-0158) IN CORSO PRESSO LA SC NEFROLOGIA

Ciascuno per gli aspetti di propria competenza, vista anche l'attestazione di regolarità amministrativo-contabile.

DIRETTORE AMMINISTRATIVO : Ha espresso il seguente parere: X FAVOREVOLE NON FAVOREVOLE ASTENUTO	Vecchi Gianluca
Note:	

DIRETTORE SANITARIO Facente funzione: Ha espresso il seguente parere: X FAVOREVOLE NON FAVOREVOLE ASTENUTO	Locati Francesco Angelo
Note:	

DIRETTORE SOCIOSANITARIO : Ha espresso il seguente parere: X FAVOREVOLE NON FAVOREVOLE ASTENUTO	Cesa Simonetta
Note:	

CERTIFICATO DI PUBBLICAZIONE

Pubblicata all'Albo Pretorio on-line
dell'Azienda socio sanitaria territoriale
"Papa Giovanni XXIII" Bergamo

per 15 giorni
