Sistema Socio Sanitario
Ospedale Papa Giovanni XXIII
Regione Lombardia
ASST Papa Giovanni XXIII

DELIBERAZIONE NR. 1866 DEL 12/11/2026

OGGETTO: AUTORIZZAZIONE ALL'ATTIVAZIONE DEL REGISTRO EPSA-ERNICA (EUROPEAN REFERENCE NETWORK ON RARE INHERITED AND CONGENITAL ANOMALIES) (REG. 2023/0035) PRESSO LA SC CHIRURGIA PEDIATRICA

IL DIRETTORE GENERALE
nella persona del Dott. Francesco Locati

ASSISTITO DA:

IL DIRETTORE AMMINISTRATIVO	DR. GIANLUCA VECCHI
IL DIRETTORE SANITARIO	DOTT. ALESSANDRO AMOROSI
IL DIRETTORE SOCIOSANITARIO	DR.SSA SIMONETTA CESA

Premesso che Stichting Dutch Institute for Clinical Auditing (DICA), quale promotore e titolare operativo del registro, con il supporto scientifico della rete europea ERNICA (European Reference Network on Rare Inherited and Congenital Anomalies), ha richiesto l'attivazione presso la SC Chirurgia Pediatrica di questa ASST del registro EPSA-ERNICA (Reg. 2023-0035), denominato *"European Pediatric Surgical Audit (EPSA) - ERNICA Registry"*;

Richiamato il "Regolamento aziendale della ricerca" rev. 1.1, approvato con deliberazione n. 813 del 07/05/2026;

Rilevato che il dott. Maurizio Cheli, direttore della SC Chirurgia pediatrica, ha manifestato la disponibilità alla gestione del registro presso la propria struttura, proponendo la dott.ssa Lucia Migliazza quale referente dello stesso;

Atteso che il direttore della SC e il referente incaricato hanno fornito alla SC Ricerca clinica, sviluppo e innovazione la documentazione e i dati necessari per la valutazione delle caratteristiche dello studio e per la definizione della fattibilità locale;

Precisato che:

- trattasi di registro no-profit, con validità di 10 anni, la cui creazione e gestione non comportano oneri aggiuntivi per l'azienda né prevedono la ripartizione di alcun compenso tra quanti collaborano allo stesso;
- l'analisi di fattibilità locale per la valutazione di copertura dei costi a carico dell'azienda ha dato esito positivo;

Preso atto che il Comitato Etico di Bergamo, con parere favorevole condizionato espresso in data 16/02/2023, ha successivamente comunicato lo scioglimento delle riserve in data 25/05/2026 e che il DPO aziendale ha espresso parere favorevole in data 20/10/2026;

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 e del direttore sociosanitario.

DELIBERA

1. di autorizzare l'attivazione del registro EPSA-ERNICA (reg. 2023-0035), con titolo: "European Pediatric Surgical Audit (EPSA) - ERNICA Registry", proposto da Stichting Dutch Institute for Clinical Auditing (DICA) in qualità di promotore, presso la SC Chirurgia Pediatrica;
2. di sottoscrivere, con Stichting Dutch Institute for Clinical Auditing (DICA), la convenzione relativa allo studio citato, nel testo allegato al presente atto, al quale si fa espresso rinvio (all. A);
3. di affidare la responsabilità di referente del registro alla dott.ssa Lucia Migliazza;
4. 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

Documento prodotto in originale informatico e firmato digitalmente dal direttore generale ai sensi del "Codice dell'amministrazione digitale" (d.lgs. n. 82/2005 e s.m.i.)

PARTICIPATION AGREEMENT
European Pediatric Surgical Audit

PARTIES:

1. The foundation **Stichting Dutch Institute for Clinical Auditing** with its registered office in Leiden, The Netherlands and having its offices at Rijnsburgerweg 10, Leiden, registered with the Chamber of Commerce for The Netherlands with registration number 51287404, herein legally represented by B. Jorritsma, chairperson of the board of directors,
hereinafter referred to as "**DICA**",

2. **ASST Papa Giovanni XXIII** (hereinafter referred to as "**Participant**"), headquartered in Piazza OMS, n. 1, 24127 Bergamo, Italy, Tax Code and VAT no. 04114370168, by certified email to the address ufficioprotocollo@pec.asst-pg23.it acting through its legal representative Dr. Francesco Locati, in his capacity as General Director, with appropriate signing powers to this deed, hereinafter referred to as "**Participant**".

Hereinafter jointly also referred to as 'Parties' and individually as 'Party',

CONSIDERING THE FOLLOWING:

A. DICA is a non-profit organization that has developed a system for performing clinical audits to provide insight into the quality of care through reliable comparisons and analyses. Clinical Audits are proven to contribute to improved quality of care.
B. Participant wants to participate in the Clinical Audit 'European Pediatric Surgical Audit' (EPSA), a prospective registry currently covering five diseases: esophageal atresia, congenital diaphragmatic hernia, omphalocele, gastroschisis, and Hirschsprung's disease.
C. Funding is provided under the Grant: Direct grant to the European Reference Network for Rare Inherited Congenital Anomalies (ERNICA) 2023-2027.
D. Parties wish to lay down their respective rights and obligations in this Agreement.

AGREE AS FOLLOWS:

1. Definitions

1.1 In this Agreement the capitalized terms shall have the following meaning, regardless of being used in singular or plural, or in composed form:

Aggregated data	data that is no longer traceable to an identifiable person, representing an average instead of individualized information, thus qualifying as anonymised data within the meaning of the GDPR.
Agreement	this participation agreement including its Annexes.

Annex	any attachment to this Agreement, which forms an integral part of the Agreement.
Article	an article in this Agreement.
Clinical Audit	clinical audit organised and facilitated by DICA for the collection, data storage and further processing of data on a defined client population, defined by the interrelated similarities that the clients show in their condition, disease, type of care or complication, or combinations thereof for the purpose of measuring and improving the quality of care provided to that client population for the purpose of measuring and improving.
Clinical Audit Board	the board of the Clinical Audit composed of physicians representing the participants in EPSA.
Data	all data that Participant enters in the DICA System and that is processed as part of the Clinical Audit.
Dataset	the set of data, based on established evaluation criteria to measure the quality of health care, regarding a specific patient target group, which are required for the performance of the Clinical Audit, as described in the DICA Regulations.
DICA Regulations	the regulations established by DICA regarding (the performance of) Clinical Audits, as provided to the Parties separately and forming an integral part of this Agreement.
DICA System	data entry system in which the Participant is able to register the Data for the Clinical Audi.
General Terms:	the general terms and conditions of DICA as provided to the Parties separately and forming an integral part of this Agreement.
GDPR	General Data Protection Regulation.
Grant	the Grant issued by the Consumers, Health, Agriculture and Food Executive Agency (**CHAFEA**) effective from 1 October 2023 for the duration of 48 months (reference: 1-10-2023- 1-10-2027/NO.101155831), delegated by the European Commission with – among others - the aim to implement the EPSA registry in hospitals which are part of European Reference Network for Inherited and Congenital Anomalies (**ERNICA**), and any further extensions and/or renewals thereof.
IP-rights	any and all intellectual property rights such as copyright, trademark, patents, database rights and neighbouring rights, as well as

	associated and/or similar rights such as trade secrets, domain names and know-how.
DICA Processor	party that processes data on behalf of DICA (included in **Annex C**).
Participant Processor	party that processes data on behalf of Participant (included in **Annex C**).
Pseudonimyzed data	data within the scope of article 4(5) GDPR that by the deletion of identifiable characteristics, such as name, address, residence and individual services numbers, is no longer traceable for DICA to a specific patient, but that in specific cases may be retraceable to a specific patient by Participant Processor.
Results	all information and data as a result of the processing by DICA Processor for the purpose of the Clinical Audit.

2. Clinical Audits

2.1 Participant shall participate in the following Clinical Audit(s): European Pediatric Surgical Audit' (EPSA).

2.2 Participant declares to have sufficiently consulted with – and obtained the consent of – the representatives of its physicians and other professionals involved in the care to which the Clinical Audit(s) relate.

2.3 The manner in which Clinical Audits shall be performed and information from the Clinical Audits is provided are governed by the DICA Regulations.

2.4 The General Terms apply to this Agreement.

2.5 In the event that any provision of the General Terms and Conditions is contrary to provisions of this Agreement, the provisions of this Agreement shall prevail.

3. Data

3.1 Participant registers Data in the DICA System in accordance with the DICA Regulations.

3.2 Registration of Data preferably should be done directly in the DICA system; by the Participant itself. In the event Participant makes use of a Third Party, Participant hereby insofar as necessary gives the instruction and permission to that Third Party to register the Data.

3.3 Participant declares and guarantees that the Data is correct and complete, in accordance with the definitions of the Dataset established for the specific Clinical Audit. Furthermore, Participant declares and guarantees that the Data are not unlawful and do not infringe on the rights of third parties and that all requirements are met for the lawful processing of the Data.

3.4 The Data shall be processed into Pseudonymized data by ASST Papa Giovanni XXIII.

3.5 Participant indemnifies DICA against all damages and costs resulting from or related to a breach of its obligations and/or any warranty under this Article 3.

4. Privacy

4.1 Participant ensures that the patients of which Data shall be registered in the DICA System are properly informed and, based on the information, agreed to be registered for the purposes of this Agreement.

4.2 If Participant works on the basis of informed consent, Participant is responsible for obtaining aforementioned informed consent from patients of which Data shall be registered in the DICA System. In such case, Participant shall provide a yearly overview of the number of patients that refused participation.

4.3 Participant shall no longer process a patient's personal data, if the patient objects to the processing. To ensure that the Dataset remains reliable for the Clinical Audit, Data entered into the DICA System before the objection cannot be deleted.

4.4 DICA takes appropriate technical and organizational measurements to safeguard a safety level that is compatible with the calculated risk, taking into consideration the state of the art, executions costs as well as the nature, scope and context of the purpose for processing and the probability and severity of the risks relating to the protection of individuals' rights and freedoms.

4.5 If DICA becomes aware of a personal data breach as referred to in article 33 of the GDPR, it will inform Participant thereof without unreasonable delay, unless the personal data breach is not likely to pose a risk to the rights and freedoms of patients.

4.6 DICA declares that, with regard to the processing of the Data, it shall act in accordance with the GDPR, the Dutch implementation Act GDPR (in Dutch: de Nederlandse Uitvoeringswet Algemene verordening gegevensbescherming) and other applicable laws – and regulations.

5. Grant

5.1 The Grant, effective from 1 October 2023 for the duration of 48 (forty-eight) months, in principle covers all reasonable costs relating to the facilitating and execution of the Clinical Audit, such as yearly costs for connecting to the Clinical Audit and maintenance of the registry.

5.2 Grant funds are transferred from CHAFEA to the ERNICA coordinator ERASMUS MC and partially to DICA.

6. Scientific Research

6.1 Participant acknowledges that Data may solely be used for the purpose of participation in EPSA and Clinical Audits. The only purpose of collected Data is quality improvement. Data may not be used for the purpose of (clinical) research.

6.2 Data may be used for the purpose of scientific research which is related to the purposes of the Clinical Audit, such as quality improvement. Insofar Parties wish to use the Data for the purpose of scientific research which falls outside the scope of the Clinical Audit, Parties shall make arrangements to that effect in a separate agreement. In this respect, Participant warrants that the Data may be used for such purposes and that all necessary consents have been obtained.

7. Term and termination

7.1 The duration of the Agreement is subject to the duration of the Grant and comes into effect on the day Parties sign the Agreement.

7.2 The Agreement continues as long as Participant takes part in the Clinical Audit and a valid Grant is in place.

7.3 If DICA discovers during the term of the Agreement that funding under the Grant proves insufficient, it will inform Participant of this in good time. In an effort to continue participation in the Clinical Audit, Parties will then enter into consultation to determine if additional funding can be obtained. If additional funding turns out to be unfeasible, DICA has the right to terminate the Agreement.

7.4 When applicable, in addition to the General Terms, either Party may terminate this Agreement by registered mail with immediate effect and without becoming liable for damages of the other Party if the processor agreement between the Participant and Processor, for whatever reason, terminates, unless Participant provides for a substitute that does not impose a disproportionate aggravation of the activities or registration burden of DICA under this Agreement.

7.5 If the Agreement is terminated in accordance with Article 7.4, Parties shall in good consultation make arrangements regarding the succession of the obligations under this Agreement, so that Participant obtains the Results to enable compliance with any obligations regarding health care accountability.

8. Consequences of termination

8.1 Participation in Clinical Audit shall be ceased if the Agreement is terminated, either in full or partially relating to one or more specific Clinical Audits. In the latter case the consequences of termination only apply to the Clinical Audit in question.

8.2 Upon termination of participation in the Clinical Audit:

a. DICA is entitled to solely use Pseudonimyzed data from the Clinical Audit registered by the Participant if this Pseudonimyzed data is converted to Aggregated data and is no longer traceable to a Participant.

b. The Pseudonimyzed data concerning the Participant on which the Results are based, shall be available in the database of the Clinical Audit for a maximum of five (5) years and will solely be used for possible questions or justification of the Results.

8.3 Termination of this Agreement for whatever reason will be without prejudice to the rights and obligations of Parties under this Agreement.

9. Costs and coverage of costs

9.1 The costs for the pseydonimisation and registration of Data in the DICA System shall be for Participant's account. DICA strives to keep the costs for registration as low as possible, by, if possible, deriving the necessary data from other registrations or by sending data directly

from the Participant's electronic patient record system to the database of the Clinical Audit. All this as far as permissible on the basis of applicable legislation and regulations.

9.2 In the event that, contrary or in addition to the funding arrangements described in Article 5, Parties have agreed in writing that Participants will pay a contribution, DICA shall charge the contribution for participation to the Participant by sending an invoice.

10. Miscellaneous

11.1 The applicability of general terms and conditions or other terms of Participant is explicitly rejected.

11.2 Parties shall not transfer their rights and obligations under this Agreement to third parties without the consent of the other Party. The consent of the Parties may be subject to conditions and shall not be withhold on unreasonable grounds.

11.3 If at any time during the Agreement, a provision of this Agreement is or becomes illegal, void or invalid for any reason, such invalidity shall not affect the validity of the remainder of the Agreement. The invalid provision shall be replaced by a provision which, being valid in all respects, shall have effect as close as possible to that of such replaced one.

11.4 Parties undertake to resolve a dispute amicably, within a reasonable period after a Party has informed the other in writing that the former considers there is a dispute.

11.5 The Agreement is drafted and agreed upon in the English language. In the event of any dispute regarding or relating to (the contents and/or interpretation of) the Agreement, the English version shall be binding upon Parties. Any translation of the Agreement provided to Parties for their convenience shall not create any right to either Party.

11.6 This Agreement is governed by Dutch law with the express exclusion of rules of international private law including the Vienna Sales Convention.

Art. 12 — Protection of personal data

The Parties, in performing the activities provided for in this Agreement, undertake to process personal data, of which they become aware for any reason during the clinical investigation, in compliance with the objectives set out in the previous articles and in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, and pursuant to the related national laws and administrative provisions in force, with any subsequent amendments and/or additions thereto (hereinafter, collectively, "Data Protection Laws"), and to any regulations of the Institutions.

The Participant and DICA qualify as independent data controllers pursuant to Art. 4 (paragraph 1 n. 7) of the GDPR. Each Party shall provide at its own expenses, as part of its organisational structure, any appointments of Data Processors and attribution of functions and tasks to designated subjects, who operate under their authority, in accordance with the GDPR and current legislation.

For the purposes of the clinical investigation, personal data will be processed relating to the following categories of data subjects: subjects participating in the clinical investigation; persons working for the Parties. These data subjects are informed about the processing that concerns them by means of appropriate information. For the purposes of the clinical investigation, the following types of personal data will be processed: data pursuant to Art. 4 No. 1 of the GDPR; data falling

under the “special” categories of personal data - and in particular data relating to health and sex life, genetic data - pursuant to Art. 9 of the GDPR. These data will be processed in compliance with the principles of lawfulness, correctness, transparency, adequacy, relevance and necessity referred to in Art.5, paragraph 1 of the GDPR.

DICA may transmit the data to affiliates of the DICA’s group and to third parties operating on its behalf, even abroad, in countries outside the European Union only in compliance with the conditions set out in Articles 44 et seq. of the GDPR. In this case DICA will ensure an adequate level of protection of personal data also through the use of the Standard Contractual Clauses approved by the European Commission.

The Parties shall ensure that persons authorised by them to process personal data for the purposes of the clinical investigation comply with the principles set out to protect the right to protection of personal data and the right to confidentiality, and that persons who have access to personal data are obliged to process them in accordance with the instructions laid down, in accordance with this Article, by the relevant data controller.

The Principal Investigator is identified by the Participant as a person authorised to process data in accordance with Art. 29 of the GDPR

The Principal Investigator must inform each patient in a clear and complete manner, before the start of the Clinical Investigation (including its prodromal and screening phases) about the nature, purpose, results, consequences, risks and modalities of the processing of personal data; in particular, the patient must also be informed that national and foreign authorities, as well as the Ethics Committee, may access, in the context of monitoring, verification and control on research, the documentation relating to the clinical investigation as well as the original health documentation of the patient, and that they may also exceed in vision, within the scope of their respective competences, Monitors and Auditors.

The Principal Investigator must obtain from the duly informed patient the consent document to both the participation in the clinical investigation, and data processing. The Participant is responsible for retention of this document.

If one party finds a breach of personal data, it undertakes to communicate it to the other within 48 hours from the verification of the violation, without prejudice to its autonomy in assessing the existence of the conditions and in the fulfilment of the obligations provided for by Articles 33 and 34 of the GDPR.

The Parties agree that in the event that DICA or third parties request to use the personal data of the patients enrolled by the Participant present in the Registry for future research projects or for any use different from that indicated in the information submitted to the patients, the Participant has exclusive and full right to deny and oppose such.

This Agreement is executed by the Parties by means of digital signatures in accordance with applicable law. All taxes and duties relating to or arising from the execution of this Agreement, including stamp duty on the electronic original document pursuant to Article 2 of the Table in Annex A – Tariff, Part I, to Presidential Decree No. 642 of 26 October 1972, and registration tax, shall be paid in accordance with applicable law. (If the Agreement is exempt from stamp duty, the relevant legal provisions providing for such exemption shall be indicated.)

THUS, AGREED AND DIGITALLY SIGNED:

On behalf of DICA:	On behalf of ASST Papa Giovanni XXIII:
_____	_____
Signature	Signature
_____	Dott. Francesco Locati
Name:	Name
_____	General Director
Function:	Function
_____	
Place and date:	

For acknowledgement

The Principal Investigator

Dr. Lucia Migliazza

Signature _____

SC Clinical Research, Development and Innovation
The Procedure Manager: Dr. Monia M.B. Lorini
Practice treated by Dr. Camilla Quarti
See- proceed Health Director Dott. Alessandro Amorosi

ANNEX A – Overview processors
DICA Processor

The limited liability company Medical Research Data Management B.V., residing at residing at Debussylaan 88, 1082 MD Amsterdam, The Netherlands, registered with the Chamber of Commerce for The Netherlands with number 55207448.

Participant Processor

ASST Papa Giovanni XXIII, headquartered in Piazza OMS, n. 1, 24127 Bergamo, Italy, Tax Code and VAT no. 04114370168

ATTESTAZIONE DI REGOLARITA' AMMINISTRATIVO-CONTABILE (proposta n. 1918/2026)

Oggetto: AUTORIZZAZIONE ALL'ATTIVAZIONE DEL REGISTRO EPSA- ERNICA (EUROPEAN REFERENCE NETWORK ON RARE INHERITED AND CONGENITAL ANOMALIES) (REG. 2023/0035) PRESSO LA SC CHIRURGIA PEDIATRICA

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, 05/11/2026

Il Direttore

Dr. / Dr.ssa Lorini Monia Maria Beatrice

PARERE DIRETTORI

all'adozione della proposta di deliberazione N.1918/2026
ad oggetto:
AUTORIZZAZIONE ALL'ATTIVAZIONE DEL REGISTRO EPSA- ERNICA (EUROPEAN REFERENCE NETWORK ON RARE INHERITED AND CONGENITAL ANOMALIES) (REG. 2023/0035) PRESSO LA SC CHIRURGIA PEDIATRICA

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 : Ha espresso il seguente parere: X FAVOREVOLE NON FAVOREVOLE ASTENUTO	Amorosi Alessandro
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
