



DELIBERAZIONE DEL DIRETTORE GENERALE n. 205 del 03 APR. 2025

**OGGETTO:** Autorizzazione del registro osservazionale, non farmacologico, no profit, denominato "Coorte MYONET di pazienti affetti da miopatie infiammatorie idiopatiche" - CODICE PROTOCOLLO: MYONET

DELIBERAZIONE ADOTTATA DAL DIRETTORE GENERALE DOTT.SSA PAOLA LATTUADA

**SU PROPOSTA DEL  
PRESIDENTE DEL COMITATO TECNICO SCIENTIFICO**

accertata la competenza procedurale, sottopone in data 03 APR. 2025 allegata proposta di deliberazione sull'argomento all'oggetto specificato, il cui onere rientra nel budget assegnato.

Il Responsabile del Procedimento  
Il Presidente del Comitato Tecnico Scientifico  
Prof. Pietro Simone Randelli

**ATTESTAZIONE COPERTURA ECONOMICA**

Si attesta la regolarità contabile, la copertura economica e l'imputazione a bilancio degli oneri/introiti derivanti dal presente provvedimento con annotazione:

- il presente provvedimento non comporta oneri diretti a carico del bilancio aziendale.

Il Direttore UOC Bilancio, Programmazione finanziaria e Contabilità  
Dott.ssa Emilia Martignoni



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## IL DIRETTORE GENERALE

### Viste:

- la DGR n. X/4475 del 10/12/2015 di costituzione, a partire dal 1° gennaio 2016, dell'Azienda Socio Sanitaria Territoriale (ASST) Centro Specialistico Ortopedico Traumatologico Gaetano Pini/CTO;
- la DGR XII/2158 del 15/04/2024 di nomina della Dott.ssa Paola Lattuada quale Direttore Generale dell'Azienda Socio Sanitaria Territoriale (ASST) Gaetano Pini-CTO per il periodo 19/04/2024 - 18/04/2027;
- la deliberazione aziendale n. 198 del 18/04/2024 di presa d'atto della predetta DGR XII/2158/2024 e di insediamento dal 19/04/2024 sino al 18/04/2027 della Dott.ssa Paola Lattuada quale Direttore Generale dell'ASST G. Pini-CTO;

**Premesso** che con nota di novembre 2024, agli atti, il Comitato Direttivo di MYONET, in qualità di Promotore, ha chiesto al Comitato Etico Territoriale Lombardia 3 e a questa Azienda, l'autorizzazione a realizzare il registro osservazionale, non farmacologico, no profit, denominato "Coorte MYONET di pazienti affetti da miopatie infiammatorie idiopatiche" - codice protocollo: MYONET, da svolgersi presso l'U.O.C Clinica Reumatologica, diretta dal Prof. Roberto Felice Caporali;

**Richiamata** la vigente normativa nazionale ed europea in materia di sperimentazioni cliniche;

### Preso atto che:

- con nota del 19/03/2025, agli atti, il Dott. Cesare Candela, Direttore Sanitario di questa ASST, ha espresso parere favorevole circa la fattibilità del registro in relazione alle attività clinico-assistenziali proprie di questa Azienda;
- il Comitato Etico Territoriale Lombardia 3 ha espresso parere sospensivo al registro nella seduta del 19/06/2024, con nota del 03/07/2024 agli atti;
- il Comitato Etico Territoriale Lombardia 3 ha rinnovato parere sospensivo al registro nella seduta del 16/10/2024, con nota del 18/10/2024 agli atti;
- il Comitato Etico Territoriale Lombardia 3 ha sciolto ogni riserva ed ha espresso parere favorevole al registro nella seduta del 12/03/2025, con nota del 13/03/2025 agli atti;

**Considerato** che trattandosi di un registro osservazionale non sono previsti costi aggiuntivi in quanto tutte le procedure rientrano nell'ambito della normale pratica clinica;

**Considerato** altresì che l'esito dell'istruttoria condotta, sotto la responsabilità del Presidente del Comitato Tecnico Scientifico, ha evidenziato che:

- si tratta di un registro osservazionale, non farmacologico, no profit il cui obiettivo è approfondire le conoscenze relative alle miopatie infiammatorie idiopatiche, allo scopo di migliorare la gestione dei pazienti e creare percorsi di terapia personalizzati;
- si tratta di un registro multicentrico, cui aderiscono 45 centri partecipanti, di cui 9 italiani;
- il Responsabile Scientifico del registro è la Dott.ssa Nicoletta Del Papa, Dirigente medico in servizio presso l'U.O.C. Clinica Reumatologica, individuata quale Principal Investigator (PI), al quale sono attribuiti i compiti e le funzioni necessarie a procedere con l'attuazione del registro in tutte le sue fasi;





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**Ritenuto** pertanto di autorizzare la realizzazione del registro osservazionale, non farmacologico, no profit, denominato "Coorte MYONET di pazienti affetti da miopatie infiammatorie idiopatiche", codice protocollo: MYONET;

**Viste:**

- l'attestazione di regolarità dell'istruttoria e legittimità del presente provvedimento espressa dal Responsabile dell'UO proponente;
- l'attestazione di regolarità contabile e della relativa copertura economica da parte del Responsabile dell'UOC Bilancio programmazione finanziaria e contabilità;

**Visti** i pareri del Direttore Amministrativo, del Direttore Sanitario e del Direttore Sociosanitario, resi per quanto di competenza, ai sensi dell'art. 3 del D. Lgs. n. 502/1992 e s.m.i;

**DELIBERA**

per i motivi di cui in premessa che qui si intendono integralmente trascritti:

1. di prendere atto del parere favorevole all'esecuzione del registro in oggetto espresso dal Comitato Etico Territoriale Lombardia Area 3, di cui alla nota del 13/03/2025, conservata in atti;
2. di autorizzare la Dott.ssa Nicoletta Del Papa, individuata quale Principal Investigator (PI), ad effettuare presso l'U.O.C Clinica Reumatologica il registro denominato "Coorte MYONET di pazienti affetti da miopatie infiammatorie idiopatiche" - CODICE PROTOCOLLO: MYONET;
3. di procedere alla sottoscrizione del Data Sharing Agreement tra gli enti partecipanti del registro MYONET, che forma parte integrante del presente provvedimento;
4. di dare atto che dal presente provvedimento non derivano oneri diretti a carico del bilancio aziendale;
5. di trasmettere il provvedimento agli Uffici competenti per gli adempimenti conseguenti;
6. di dare atto che il presente provvedimento è immediatamente esecutivo ai sensi dell'art. 17, comma 6, della L.R. n. 33/2009, così come sostituito dall'art. 1, comma 1, lett. w) della L.R. n. 23/2015;



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7. di disporre la pubblicazione del presente provvedimento all'Albo Pretorio on line aziendale, ai sensi dell'articolo 17, comma 6, della L.R. n. 33/2009, così come sostituito dall'art. 1, comma 1, lett. w) della L.R. n. 23/2015.

IL DIRETTORE SANITARIO  
(Dott. Cesare CANDELA)

IL DIRETTORE SOCIO SANITARIO  
(Dott.ssa Rossana GIOVE)

IL DIRETTORE AMMINISTRATIVO  
(Dott. Marco PATERNOSTER)

IL DIRETTORE GENERALE  
(Dott.ssa Paola LATIQUADA)

**Comitato Tecnico Scientifico**

Si attesta la regolarità amministrativa e tecnica del presente provvedimento  
Responsabile del Procedimento ex l. 241/90: Prof. Pietro Simone Randelli  
Pratica trattata da: Dott.ssa Ilaria Riela  
ATTI n. 2022.1.1.6.1





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### RELATA DI PUBBLICAZIONE

Si certifica che la presente deliberazione è pubblicata all'albo pretorio informatico di quest'Azienda sul sito internet istituzionale, così come previsto dall'art. 32, comma 1, L. 69/2009, e dall'art. 8 del D.Lgs. 33/2013, dal 03 APR. 2025 e vi rimarrà per quindici giorni consecutivi.

La deliberazione si compone di n. 5 pagine e n. 1 allegato.

UOC Affari Generali e Legali  
Il Funzionario addetto

Per copia conforme all'originale per uso amministrativo  
Milano, li \_\_\_\_\_

UOC Affari Generali e Legali  
Il Funzionario addetto

## DATA SHARING AGREEMENT

This data sharing agreement (the “**DSA**”) is made and entered into the last date of the last signature affixed hereto (“**Effective Date**”) between:

1. **Karolinska Institutet**, Department of Medicine, Division of Rheumatology, org.nr. 202100-2973, with registered address at 171 77 Stockholm, Sweden (“**KI**”)
2. **The University of Manchester**, a charitable body registered in England under registration number RC000797 incorporated under Royal Charter and having its main administrative offices at Oxford Road, Manchester M13 9PL (“**UoM**”)
3. **Alejandro Posadas National Hospital**, **30-61591554-4**, with registered address in Argentina; Pte. Illia s/n and Marconi; El Palomar, Morón, Buenos Aires (“**BA**”)
4. **Medical University Vienna**, Department of Internal Medicine III, Division of Rheumatology, org.nr **ORG-100006190** [, with registered address in 1090 Vienna, Spitalgasse 23 (“**MUV**”), Austria
5. **Medical University Innsbruck**, Department of Neurology, VAT Nr. ATU57495455, with registered address at Anichstrasse 35, 6020 Innsbruck, Austria (“**MUI**”)
6. **University Hospital Ghent, part of Ghent University**, in accordance with the Special Decree of June 26th, 1991 (Belgian Official Gazette 29/6/1991) with registered office in Belgium, 9000 Ghent, Sint – Pietersnieuwstraat 25, registration number 0248.015.142, and with head office in Belgium, 9000 Ghent Corneel Heymanslaan 10, (VAT number: BE0232.987.862) with regard to this agreement duly represented by Prof. dr. F. Vermassen, executive director [KW/2492/REU/006/004]. Belgium
7. **Universidade Federal de Pelotas**, org nr 771.197.380-20 (Brazilian CPF), with registered address in Rua Santos Dumont 172/ 803 – 96.020-380 – Pelotas (RS) – Brazil
8. **Faculdade de Medicina FMUSP, Universidade de São Paulo**, CPF 127.051.618-30, with registered address in Av. Dr. Arnaldo, 455 – 3 andar, Sala 3184, CEP 01246-903, Cerqueira Cesar, São Paulo, SP, Brazil (BR)
9. **Montreal, Canada**
10. **University of Chile, Clinical Hospital, Rheumatology Section**, [TAX ID 60.910.000-1, with registered address in Dr. Carlos Lorca Tobar 999, Independencia, Santiago, Chile. Zip Code 8380420]



11. **China-Japan Friendship Hospital**, Department of Rheumatology, org.nr. 12100000400014014Y with registered address at No.2, Yinhua East Street, Chaoyang District, Beijing, China
12. Division of Rheumatology, The Chinese University of Hong Kong. Tax ID number: 98-0477422, with registered address in Sha Tin, New Territories, Hon Kong
13. **Institute of Rheumatology**, state budgetary organization, Identification number: 00023728, Tax Identification numb.: CZ00023728, with registered address in Na Slupi 450/4, Prague 2, 128 00, Czech republic ("RU")
14. **Copenhagen University Hospital, Rigshospitalet, Denmark** (CVR-nr 29190623), with registered address in Blegdamsvej 9, 2100 Copenhagen, Denmark
15. **Hôpital Saint-Louis**, Department of Dermatology, Assistance Publique – hôpitaux de Paris, with registered address in 1 avenue Claude Vellefaux, 75010 Paris ("SLS"), France
16. **Hôpitaux Universitaires de Strasbourg**, Centre de Référence des Maladies Autoimmunes Rares, org.nr 670780055 with registered address at 1 avenue Molière 67200 Strasbourg FRANCE
17. **Department of Neurology, Heinrich-Heine-University and University Hospital Düsseldorf**, [Tax ID 106-5773-0045], with registered address in Moorenstraße 5, 40225 Düsseldorf, Germany ("D")
18. **Molecular Physiology & Clinical Applications Unit, Department of Physiology, National and Kapodistrian University of Athens, Greece**, VAT 090010689, with registered address in Mikras Asias 75, 11527, Athens, Greece
19. **University of Debrecen, Faculty of Medicine, Division of Clinical Immunology**, [Tax ID HU17782218], with registered address in [Moricz Zs str. 22. Debrecen, Hungary, 4032] ("UD")
20. **Sanjay Gandhi Postgraduate Institute of Medical Sciences**, Department of Clinical Immunology and Rheumatology, with registered address in Raebareli Road, Lucknow, Uttar Pradesh, India 226014
21. **Rheumatology Department, Rambam Health Care Campus (Haifa)**
22. **SOS Immunologia delle Malattie rare e dei Trapianti, SOD Clinica Medica**, Azienda Ospedaliero Universitaria delle Marche (formerly Azienda Ospedaliero Universitaria Ospedal Riuniti) P.IVA 01464630423 with registered address in via Conca 71, Torrette di Ancona, 60126, Italy
23. **Azienda Ospedaliero-Universitaria Careggi**, Immunology and Cell Therapy Unit, Tax ID number 04612750481 (referring to Azienda Ospedaliero-Universitaria Careggi), with registered address in Largo G.A. Brambilla 3, 50134, Florence, Italy

24. **ASST Gaetano Pini – CTO**, Department of Rheumatology and Medical Sciences, tax code/VAT number: 9320530968, with registered address in Piazza Cardinal Ferrari 1, 20122, Milan, Italy
- 25.
26. **Azienda Ospedaliero-Universitaria Careggi**, Immunoallergology Unit, (pediatrics) Tax ID number 04612750481 (referring to Azienda Ospedaliero-Universitaria Careggi), with registered address in Largo G.A. Brambilla 3, 50134, Florence, Italy
27. **Aienda Ospedaliera Universitaria Meyer IRCCS**, tax code/VAT number 02175680483, with registered address in Viale Gaetano Pieraccini 24, 50139 Firenze, Italy
28. **IRCCS Istituto Clinico Humanitas – Humanitas Mirasole S.p.A.**, with registered office in **Rozzano (Milan)**, at **via Alessandro Manzoni 56, Italy (“ICH”)**
29. **Siena University Hospital**, [00388300527], with registered address in Siena (Italy), viale Mario Bracci, 16, Siena, Italy
30. **Azienda USL IRCCS di Reggio Emilia, with registered offices in Via Giovanni Amendola, 2 - 42122 Reggio nell’Emilia (RE)**, tax code and VAT no.: 01598570354, (AUSL-IRCCS Reggio Emilia), duly represented by the Research & Statistics Unit Director, Dr. Elisa Mazzini, Italy
31. **IRCCS Ospedale San Raffaele**, Unit of Immunology, Rheumatology, Allergy and Rare diseases (UnIRAR) org.nr. 07636600962, with registered address at via Olgettina, 60 - 20132 Milano, Italy
32. **Vilnius University Hospital Santaros Clinics**, Pediatric Centre. VAT ID LT243645610 Santariskiu st. 2, 08661 Vilnius, Lithuania
33. **Royal College of Surgeons in Ireland and University College Dublin University Malaysia Campus**, [Tax ID number/org. nr, with registered address in 4, Jalan Sepoy Lines, 10450 George Town, Penang, Malaysia (“RUMC”)]
34. **O.P.D. Hospital Civil de Guadalajara**, Coronel Calderón 777, Col. El Retiro, CP 44280, Guadalajara, Jalisco, México (OPDHCG)
35. **Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán**, TaxID INC710101RH7 with registered address in Vasco de Quiroga 15, Belisario Domínguez Sección XVI, Tlalpan, 14080, Mexico city, Mexico
36. **Oslo University Hospital (OUS)**, Clinic of surgery, inflammation and transplantation medicine, Division of Rheumatology, Org nr 993 467 049. Address; OUS/Rikshospitalet Pb 4950 Nydalen, 0424 Oslo, Norway



37. **Unidade Local de Saude de Santa Maria**, Rheumatology Department, tax number 501490108, with registered address in Avenida Prof Egas Moniz MB 1649-028, Lisbon, Portugal (“ULSSM”)
38. **Centro Hospitalar Universitário de Santo António** [TaxID: NIPC | 517 392/259] with registered address at Largo Prof. Abel Salazar, 4099-001 Porto, Portugal
39. **Emergency Clinical Hospital for Children, 2<sup>nd</sup> Pediatric Clinic, Department of Rheumatology**, CUI 4426352, with registered address in 68 Motilor str, Cluj Napoca, Romania
40. **FUNDACIÓ PRIVADA PER A LA RECERCA I LA DOCÈNCIA SANT JOAN DE DÉU**, Tax ID G62978689 with registered address in at C/ Santa Rosa, nº 39-57, 4<sup>a</sup> planta, Edificio Docente, 08950 Esplugues de Llobregat (“FSJD”), Spain
41. **Uppsala University hospital**, Department of Special Medicine, Dermatology and Rheumatology, org nr: 232100-0024, with registered address at 751 85 Uppsala, Sweden
42. **University Hospital Zurich, Departement of Rheumatology**, [TaxID: CHE-108.904.325, Hospital ID ZUR], with registered address in [Rämistrasse 100, CH 8091 Zurich, Switzerland
43. Hacettepe University, Faculty of Medicine, Department of Pediatric Rheumatology, with registered address in Hacettepe Üniversitesi, İhsan Doğramacı Çocuk Hastanesi, Çocuk Romatoloji Bilim Dalı, 1. Kat, 06230, Altındağ/Ankara/Turkey
44. **The Center for Rheumatology, Bach Mai Hospital, Hanoi Medical University**, org.nr. 0100923097, with registered address in 78 Giai Phong Road, Dong Da District, Hanoi, Vietnam
45. **ZiteLab ApS**, [VAT number 29178364], with registered address in Peter Bangsvej 7A, 2000 Frederiksberg, Denmark (“ZiteLab” or “Registry Manager”)

referred to below individually as a “Party” and jointly as “Parties”.

## WHEREAS,

- A. The Myonet registry (the “Registry”) was established as a quality register with Karolinska University Hospital as the principal (Sw. ‘huvudman’) according to the Swedish ethical approval with Dnr: 2008/1919-31/3 and since 2013 was KI appointed as the new principal responsible for the Registry, in accordance with the Swedish ethical approval with Dnr: 2013/1390-32. The purpose of

the Registry is providing data (including Personal Data) to the scientific community to conduct research in the field of rare disease myositis.

- B. The Registry has since 2013 been approved by ethics review boards in more than 30 countries and currently contains information from more than 6 000 patients with the rare disease myositis.
- C. The Registry is currently storing Personal Data transferred by Contributors into the Registry for research purposes. The Research Data may be accessed among the Contributors or with third parties for specific research purposes.
- D. The Parties wish to regulate the sharing of Personal Data stored in the Registry between the Contributors and/or with Users in accordance with the applicable laws and regulations, including the General Data Protection Regulation 2016/679.

**IT IS AGREED** as follows:

## **1. DEFINITIONS**

The following terms shall have the following meanings in this DSA.

**“Commercial Purposes”** shall mean the sale, lease, license, or other transfer and/or use of Personal Data or directly or indirectly in connection with any business, or other undertaking intended for profit.

**“Contributor”** shall mean a Party which contributes with Personal Data to the Registry.

**“Data Breach”** shall mean a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to Personal Data.

**“Data Controller”** shall mean an entity that alone or jointly with others determines the purposes and means of the processing of Personal Data.

**“Data Protection Laws”** shall mean the relevant data protection and privacy laws to which the Parties are subject, in particular (but not limited to) 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) (hereinafter **“General Data Protection Regulation”**, **“GDPR”**), and any applicable laws and regulations relating to the processing of Personal Data in the field of research and development.

**“Personal Data”** shall mean any information relating to an identified or identifiable natural person. An identifiable person is one who can be identified directly or indirectly in particular by reference to an identifier such as name, an identification number, location data, or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.



**“Process”** or **“processing”** shall mean any operation which is performed on Personal Data, whether or not by automated means, such as collection, organisation, structuring, storage, use, dissemination or otherwise making available, erasure or destruction.

**“Pseudonymised Data”** shall mean 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.

**“Contributed Data”** shall mean any Personal Data transferred to the Registry and stored as Pseudonymised Data in the Registry. The key code used by each Contributor to pseudonymise the Contributed Data shall be kept separately by each Contributor, subject to technical and organizational measures and shall not be shared with the other Parties.

**“Standard Data Protection Clauses”** shall mean the model clauses for the transfer of Personal Data to Data Processors/Data Controllers established in third countries as approved by the European Commission from time to time, at present the model clauses set out in the European Commission’s Decision (EU) 2021/914 of 4 June 2021.

**“Steering Committee”** shall mean the group of Parties in charge with the management of the Registry

**“Data Access Committee”** shall mean the committee formed by representatives of the Steering Committee, including the Contributor, functioning in accordance with the DSA, that reviews the application of access from Users and grants/declines access as determined by the respective Contributor.

**“Data Use Agreement”** shall mean the data use agreement that a Contributor shall conclude with an User regarding the access and use of its Contributed Data hosted in the Registry.

**“Subject Access Request”** shall mean the same things as “Right of access” by the data subject in GDPR (Article 15).

**“Sub-processor”** shall mean any processor which a Data Processor engages to carry out specific processing activities on behalf of any of the Data Controllers.

**“User”** shall mean an entity receiving access to Contributed Data for research purposes in a specific research project. Such entity may be a third party or a Contributor applying for access of another Contributor’s Data. For clarity, this shall not include situations when a Contributor receives access to its own Contributed Data in the Registry.

Any other terms not defined in this DSA shall have the meaning given to them in GDPR.

## **2. PURPOSE OF THE DSA**

- 2.1 The Parties are entering to this DSA with the purpose of ensuring that the Contributed Data is Processed in accordance with Data Protection Laws.
- 2.2 When a Contributor wishes to Process the Contributed Data of another Contributor for a specific research project, they shall enter into separate written agreements, such as, data user agreements or joint controller agreements, as applicable.
- 2.3 For the performance of a specific research project, approved by an ethical authority, a third party may request access to the Contributed Data for non-commercial research purposes. If the request is approved by the Steering Committee, such third party shall sign a Data User Agreement as contained in Appendix 3, becoming a User.
- 2.4 Any third party that wishes to become a Contributor shall sign the accession form/declaration of acceptance attached as **Appendix 1**.
- 2.5 Any Processing of the Contributed Data performed by the Parties under this DSA shall be subject to applicable Data Protection Laws and needs to be permitted under applicable ethical permits.
- 2.6 The DSA also aims to reflect the Parties' roles and relationships toward the Data Subjects in a transparent manner and to ensure that the Data Subjects can exercise their rights in relation to the Parties' processing of Personal Data.
- 2.7 This DSA further defines the minimum technical and organizational security measures that should be observed by all Parties when implementing and maintaining safeguard measures to protect the Contributed Data.

### **3. ROLES, RELATIONSHIPS AND DUTIES**

- 3.1 Each Contributor shall act as an independent Data Controller when transferring its Contributed Data to the Registry. Each Party is therefore responsible for ensuring compliance with the obligations imposed on Data Controllers by the GDPR and all Data Protection Laws when processing its Contributed Data in the Registry.
- 3.2 When a Contributor is Processing another Contributor's Contributed Data, it shall:
- a) comply with all Data Protection Laws and other laws generally applicable to this DSA,
  - b) ensure that it has a legal basis for the processing of Personal Data, in accordance with GDPR Article 6 and/or Article 9, as applicable,
  - c) not process Contributed Data for Commercial Purposes,
  - d) never use or disclose the Contributed Data for any other purposes unless it is required by applicable law,