Sistema Socio Sanitario

Ospedale Papa Giovanni XXIII

Regione Lombardia

ASST Papa Giovanni XXIII

DELIBERAZIONE NR. 922 DEL 06/06/2025

OGGETTO: AUTORIZZAZIONE ALL'AVVIO DELLO STUDIO "THE NATURAL HISTORY OF EARLY PORTO-SINUSOIDAL VASCULAR DISORDER" (REG. 2025-0019) PRESSO LA SC GASTROENTEROLOGIA 1 - EPATOLOGIA E TRAPIANTOLOGIA DI CUI SONO PROMOTORI LE CLINIQUES UNIVERSITAIRES DE BRUXELLES - HÔPITAL ERASME E STIPULA DELLA RELATIVA CONVENZIONE.

IL DIRETTORE GENERALE
nella persona del Dott. Francesco Locati

ASSISTITO DA:

IL DIRETTORE AMMINISTRATIVO	DR. GIANLUCA VECCHI
IL DIRETTORE SANITARIO	DOTT. MAURO MORENO
IL DIRETTORE SOCIOSANITARIO	DR.SSA SIMONETTA CESA

Premesso che il promotore, Cliniques Universitaires de Bruxelles - Hôpital Erasme, ha proposto la conduzione presso la SC Gastroenterologia 1 - Epatologia e trapiantologia di questa azienda, in qualità di centro unico in Italia, dello studio con titolo: "The natural history of early porto-sinusoidal vascular disorder" (reg. 2025-0019);

Richiamato il "Regolamento aziendale per la gestione delle sperimentazioni e collaborazioni scientifiche. rev. 1.0" approvato con deliberazione n. 2110 del 29/12/2015;

Rilevato che con scritto ricevuto in data 11/02/2025 il prof. Stefano Fagiuoli, direttore della SC Gastroenterologia 1 - Epatologia e trapiantologia, ha espresso parere favorevole e manifestato la disponibilità alla gestione dello studio per gli aspetti scientifici e clinici presso la propria struttura, con la previsione di arruolamento di n. 15 pazienti, proponendo la dott.ssa Elisa Farina quale sperimentatore principale;

Atteso che il direttore della SC e lo sperimentatore principale 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 studio no-profit con validità di 3 mesi, senza oneri aggiuntivi per l'azienda e senza la ripartizione di alcun compenso tra quanti collaborano allo stesso;

- l’analisi di fattibilità locale ha dato esito positivo, come risulta dalla documentazione agli atti;

Precisato, inoltre, che la sperimentazione verrà condotta in collaborazione con la Fondazione per la ricerca Ospedale di Bergamo – Ente del Terzo Settore (FROM ETS), la quale si farà carico delle attività di data management e delle attività di supporto alle procedure non strettamente cliniche o sanitarie, restando queste ultime a carico della SC sede della sperimentazione;

Vista la proposta di convenzione relativa allo studio in esame, ritenuta idonea a disciplinare gli impegni delle parti,

Preso atto che il Comitato etico territoriale Lombardia 6 ha espresso parere favorevole condizionato in data 11/03/2025 e ha sciolto le riserve in data 16/05/2025;

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’avvio dello studio con titolo: “The natural history of early porto-sinusoidal vascular disorder” (reg. 2025-0019), proposto dalle Cliniques Universitaires de Bruxelles - Hôpital Erasme in qualità di promotore, presso la SC Gastroenterologia 1 - Epatologia e trapiantologia;
2. di affidare la responsabilità di sperimentatore principale alla dott.ssa Elisa Farina;
3. di sottoscrivere con il promotore Cliniques Universitaires de Bruxelles - Hôpital Erasme, la convenzione relativa allo studio citato, nel testo allegato al presente atto, al quale si fa espresso rinvio (all. A);
4. di precisare che l’adozione del presente provvedimento non comporta alcun onere aggiuntivo per l’azienda;
5. 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

DATA USE AGREEMENT FOR LIMITED DATASETS

THIS AGREEMENT is made and entered into as of the date of the last signature by the Parties, by and between:

ASST Papa Giovanni XXIII (hereinafter the "Institution"), headquartered in Piazza OMS, n. 1, 24127 Bergamo, Italy C.F. e P. IVA n. 04114370168, through its Legal Representative Dott. Francesco Locati, in his capacity as General Director, endowed with appropriate signing authority for this act (hereinafter referred to as "Provider"),

and

Cliniques Universitaires de Bruxelles - Hôpital Erasme ("CUB Hôpital Erasme") - entity part of l'Université Libre de Bruxelles registered under number 0407.626.464, located at Avenue Franklin Roosevelt 50 1050, Brussels - registered under number 0941.792.893, located at 808 Route de Lennik at 1070 Brussels, duly represented by Prof. Michel Verstraeten, as President of the Board of Directors, and for the purpose of signing this Agreement by the General Director, by the General Medical Director and the Administrative Director of Research (hereinafter referred to as "Recipient"),

Provider and Recipient are hereinafter also referred to individually as a "Party" and collectively as the "Parties".

WHEREAS, Recipient has requested that Provider provides Recipient the dataset described in exhibit 1, through [Dr Elisa Farina] and Provider desires to provide Recipient such dataset described in exhibit 1, through Pierre DELTENRE. For the purposes of this Agreement, the dataset described in exhibit 1 shall mean data generated through electronic Case Report Form.

WHEREAS, Recipient intends to use the dataset described in exhibit 1 for the purposes of conducting a retrospective study entitled: **"The natural history of early porto-sinusoidal vascular disorder".**

NOW, THEREFORE, the parties hereby agree as follows:

1. Provider hereby grants Recipient, which accepts, a non-exclusive, non-transferable, non-sublicenseble, irrevocable, perpetual, worldwide license to use, reproduce, and transmit the dataset described in exhibit 1 in accordance with this Agreement. The parties to this Agreement specifically intend to comply with all applicable laws, rules and regulation, including, 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 (General Data Protection Regulation - GDPR), the Belgian law of 30 July 2018 on the protection of individuals with regard to the processing of personal data and the Law of August 22, 2002 relating to Patient's Rights.

2. Provider shall retain ownership of the dataset described in exhibit 1. Recipient shall have no right, title or interest in the dataset described in exhibit 1 except for the license described herein.

3. The parties agree that any and all new inventions, ideas or discoveries, including but not limited to analysis, technical data or reports, which are reduced to practice, conceived, or written as a result of the dataset described in exhibit 1 shall be the exclusive property of Recipient.

4. The dataset described in exhibit 1 provided pursuant to this Agreement was collected or will be collected in accordance with all applicable data protection rules and legislation including the Belgian law of 30 July 2018 on Privacy Protection in relation to the Processing of Personal Data and the Belgian law of 22 August 2002 relating to patient's rights and informed consent procedures of Provider in effect at the time of collection and, if applicable, subject to approval or appropriate waiver by Provider's Ethics Committee. By signing below, Provider certifies that the dataset described in exhibit 1 transferred under this Agreement has been stripped of the identifiers specified above to create a Limited Dataset in accordance with applicable European and Belgian legislation. Any electronic transmission of the dataset described in exhibit 1 shall be appropriately encrypted in accordance with standards specified by Provider.

5. The Sponsor may transmit the data to affiliates of the Sponsor 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 the Sponsor will ensure an adequate level of protection of personal data also through the use of the Standard Contractual Clauses approved by the European Commission. If the Sponsor is established in a State which does not fall within the scope of European Union law and if the European Commission has decided that such country does not guarantee an adequate level of protection pursuant to Articles 44 and 45 of the EU GDPR 2016/679, the Sponsor and the Institution shall complete and sign the Standard Contractual Clauses document.

6. Recipient agrees that the dataset described in exhibit 1:

   (a) is to be used for the research, public health and/or health care operations purposes and may also be shared with regulatory authorities.

   (b) will not be used in clinical trials or for diagnostic purposes involving human subjects.

   (c) will not be used or further disclosed other than as permitted in this Data Use Agreement or as required by law.

7. Recipient will use appropriate safeguards to prevent the use or disclosure of the dataset described in exhibit 1other than as permitted in this Agreement.

8. Recipient will report to Provider any use or disclosure of the dataset described in exhibit 1, that is not permitted by this Agreement of which it becomes aware. Such reports can be made to:

Name of the Investigator providing the Data: Dr. Elisa Farina
Title: Investigator
Address: ASST Papa Giovanni XXIII, headquartered in Piazza OMS, n. 1, 24127 Bergamo, Italy

9. Recipient will not utilize the dataset described in exhibit 1 to contact the individuals who are the subject of the dataset described in exhibit 1.

10. **Term.** This Agreement shall become effective on the Effective Date of the Agreement and shall continue in effect for a period of one year. The following provisions shall survive expiration of this Agreement: 1, 2, 5 -11.

    On termination of the Project, all Confidential Information, whether in documentary, permanent or machine-readable form, including any copies of all or any part thereof shall be returned to the disclosing Party, save that the receiving Party may retain one copy of such Confidential Information solely for record-keeping purposes.

11. **Limitation of liability.** notwithstanding anything to the contrary in this agreement, neither party shall be liable to the other party for any consequential, incidental indirect, special or punitive damages concerning the subject matter hereof, including for loss of profits, or loss of opportunity or use of any kind, suffered by the other party or its affiliates, whether in contract, tort or otherwise.

12. Publications will be coordinated by the Coordinating Investigator. Authorship to publications will be determined in accordance with the requirements published by the International Committee of Medical Journal Editors and in accordance with the requirements of the respective medical journal. The International Committee of Medical Journal Editors (ICMJE) requires study registration before recruitment of the first patient as a condition of the publication of study results. To fulfill this obligation the Study can be registered on ClinicalTrials.gov or another international registry.

13. This Agreement shall not prevent or delay publication of research findings resulting from the use of the dataset described in exhibit 1, provided that such publication does not breach the terms and conditions of this Agreement. Recipient agrees to provide appropriate acknowledgement of the source of the dataset described in exhibit 1 in all such publications. The Local Investigator who provided complete dataset described in exhibit 1 will be co-author of any publication of the Study.

14. Recipient certifies that the dataset described in exhibit 1 will be used in compliance with all applicable statutes, laws and regulations.

15. The Parties 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.

16. The Parties shall process the personal data in accordance with the GDPR. The Parties agree to not process the personal data for any purpose other than to perform the Project and its obligations under the Agreement.

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."

The Parties acknowledge that the data subjects are entitled to exercise their rights under the GDPR against both Parties.

The Parties agree that the point of contact who can be contacted in respect of queries or complaints regarding the processing of the data subjects' personal data and GDPR compliance is the Data Protection Officer of the RECIPIENT (dpo@erasme.ulb.ac.be).

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.

In addition, the Parties shall:

- implement appropriate technical and organizational measurer to protect the personal data against unauthorized or unlawful processing, loss, damage, or destruction, and to evaluate at regular intervals the adequacy of such security measures, amending these measures where necessary;

- not disclose the personal data to any person other that its Personnel as necessary to perform its obligations under this Agreement and ensure that such Personnel is subject to statutory or contractual confidentiality obligations;

- ensure that access, inspection, processing and provision of the personal data shall take place only in accordance with the need-to-know principle, i.e. information shall be provided only to those persons who require the personal data for their work in relation to the performance of this Agreement;

The RECIPIENT shall be responsible for concluding a written agreement with the processors, in which at least the same data protection obligations as set out in this Agreement shall be imposed on the processors, including obligations to implement appropriate technical and organizational measures. The PROVIDER has the right to receive a copy of the relevant provisions of the data processing agreement

with the processors related to data protection obligations. The Recipient shall remain fully liable to the PROVIDER for the performance of the processors' obligations and compliance with the GDPR.

The RECIPIENT agrees not to analyze or make any use of the data in such a way that has the potential to:

(a) lead to the identification of any patient; or

(b) compromise the confidentiality of any patient in any way.

Each Party will be held responsible for any damages resulting from failure to comply with its obligations under this Agreement and the GDPR.

17. This Agreement shall be construed according to the laws of Belgium without regard to its choice of law principles. The Courts of Bergamo shall have exclusive jurisdiction in case of dispute.

18. The signatories to this Agreement represent and warrant that they are duly authorized to execute this Agreement on behalf of the party that they purport to represent.

(Signature page to follow)

AGREED BY:

PROVIDER	**RECIPIENT**
By:	By:
Name: Dott. Francesco Locati	Name: Mr Renaud Witmeur
Title: General Director	Title: General Director
Date:	Date:
By:	By:
Name: Dott.ssa Elisa Farina	Name: Professor Jean-Michel Hougardy
Title: Principal Investigator	Title: General Director
Date:	Date:

By:

Name: Mrs Marielle Sautois

Title: Director of Research Administration

Date:

Read and acknowledged:

By:

Name: Professor Pierre Deltenre

Title: Investigator

Date:

Read and acknowledged:

By:

Name: Professor Christophe Moreno

Title: The Head of Department of Gastroenterology and Hepatology

Date:

SC Clinical Research, Development and Innovation
The Procedure Manager Dr. Monia M.B. Lorini
Practice handled by Dr. Silvia Sala tel. 035 2674211

Seen – proceed Health Director Dr. Mauro Moreno

Exhibit 1 : Dataset

General information	
Participant code	
Referal hospital	
Age at diagnosis (years)	
Sex	Male YES/NO
	Female YES/NO
Height (cm)	
Weight (kg)	
Ethnicity	Caucasian YES/NO
	African YES/NO
	Asian YES/NO
	Latin America YES/NO
Date of PSVD diagnosis	
Date of liver biopsy (DD/MM/YYYY)	____ /____ /_____
Histologic inclusion criteria	
Obliterative portal venopathy	YES/NO
Nodular regenerative hyperplasia	YES/NO
Incomplete septal fibrosis	YES/NO
Coexistence of 2 PSVD lesions	YES/NO If yes, describe the 2 coexisting lesions _____
Histologic exclusion criteria	
Biopsy size (only for core biopsy) < 20 mm	YES/NO
Histological portal tract changes	Portal vein obliteration YES/NO
	Portal fibrosis YES/NO
	Phlebosclerosis YES/NO
Other exclusion criteria	
Cirrhosis	YES/NO
Portal vein thrombosis	YES/NO
Budd-Chiari syndrome / hepatic venous outflow obstruction	YES/NO
Vascular invasion by a tumor	YES/NO
Severe comorbidity with limited estimated life expectancy	YES/NO (If yes, describe the severe comorbidity) _____
Presence at diagnosis of signs of PH Or History of signs of PH	Gastric varices YES/NO
	Esophageal varices YES/NO
	Ectopic varices YES/NO
	Obvious porto-systemic collaterals at imaging YES/NO
	Portal hypertensive bleeding YES/NO
	Clinical ascites YES/NO
	Platelet count < 150'000/mm3 YES/NO
	Spleen size ≥13 cm in the largest axis YES/NO

Other histological data		
Indication for liver tissue	Abnormal liver tests YES/NO	
	Incidental diagnosis of PSVD YES/NO If yes, complete	Liver resection for metastasis YES/NO If yes describe the primary tumor _____
		Protocol biopsy after liver transplantation YES/NO
		Other (describe) _____
	Other (describe)	_____
Length of the sample (only for core biopsy) (mm)	YES /NOT AVAILABLE	
Fragmentation	YES/NO	
Number of portal tracts (only for core biopsy)	_____/NOT AVAILABLE	
Valoration of biopsy quality	Adequate / Not adequate	
Architectural changes	YES/NO	
Sinusoidal dilatation	YES/NO	
Sinusoidal dilatation grade	0 YES/NO	
	I Slight YES/NO	
	II moderate YES/NO	
	III several YES/NO	
Slight perisinusoidal fibrosis	YES/NO	
Dilated vessels like a cavernoma	YES/NO	
METAVIR score	F0 YES/NO	
	F1 YES/NO	
	F2 YES/NO	
Lobular inflammation score	0 YES/NO	
	1 YES/NO	
	2 YES/NO	
Portal inflammation score	0 YES/NO	
	1 YES/NO	
	2 YES/NO	
	3 YES/NO	
Conditions associated with PSVD at diagnosis		
History of drug/Toxine exposure	YES/NO If yes, complete	
	Chemical exposure YES/NO If yes, complete	Exposure start date (DD/MM/YYYY) ____ / ____ /_____
		Exposure end date (DD/MM/YYYY) ____ / ____ /_____
		Copper sulphate YES/NO
		Vinyl chloride monomer YES/NO
		Thorium sulphate YES/NO
		Spanish toxic oil YES/NO
		Arsenic as Fowler's solution YES/NO
	Vitamine exposure YES/NO If yes, complete	Vitamin A supplements YES/NO
		Exposure start date (DD/MM/YYYY) ____ / ____ /_____

		Exposure end date (DD/MM/YYYY) ____ / ____ /_____
	Drug exposure YES/NO If yes, complete	Exposure start date (DD/MM/YYYY) ____ / ____ /_____
		Exposure end date (DD/MM/YYYY) ____ / ____ /_____
		Drug indication (describe) _____
		Stavudine YES/NO
		Didanosine YES/NO
		Azathioprine YES/NO
		6-Mercaptopurine YES/NO
		6-Thioguanine YES/NO
		Oxaliplatin YES/NO
		Methotrexate YES/NO
		Busulfan YES/NO
		Doxorubicin YES/NO
		Cyclophosphamide YES/NO
		Chlorambucil YES/NO
		Bleomycyin YES/NO
		Cytarabine YES/NO
		Carmustine YES/NO
		Cytosine arabinoside YES/NO
	Other YES/NO If yes, complete	Exposure start date (DD/MM/YYYY) ____ /____ /_____
		Exposure end date (DD/MM/YYYY) ____ /____ /_____
		Indication (describe) _____
History of immunological disorders	YES/NO If yes, complete	
	Date of diagnosis (DD/MM/YYYY) ____ /____ /_____	
	Chronic glomerulenephritis YES/NO if yes specify the subtype _____	
	Common variable immune deficiency YES/NO	
	Autoimmune hepatitis YES/NO	
	Systemic lupus erythematosus YES/NO	
	Systemic sclerosis (scleroderma) YES/NO	
	Rheumatoid arthritis YES/NO	
	HIV YES/NO	
	Celiac disease YES/NO	
	POEMS syndrome YES/NO	
	Autoimmune thyroiditis YES/NO	
	Multiple sclerosis YES/NO	
	Felty's syndrome YES/NO	
	Polyarteritis nodosa YES/NO	

	Antiphospholipid syndrom YES/NO	
	Crohn's disease YES/NO	
	Ulcerative colitis YES/NO	
History of hemocoagulative disorders	YES/NO If yes, complete	
	Date of diagnosis (DD/MM/YYYY) ____ /____ /_____	
	Aplastic anaemia YES/NO	
	Idiopathic thrombocytopenic purpura YES/NO	
	Sickle cell anemia YES/NO	
	Myeloproliferative disorders YES/NO If yes complete	Polycythemia vera YES/NO
		Essential thrombocythemia YES/NO
		Primary myelofibrosis YES/NO
		Chronic myeloid leukemia YES/NO
	Hodgkin's lymphoma YES/NO	
	Non-Hodgkin's lymphoma YES/NO	
	Chronic lymphocytic leukemia YES/NO	
	Multiple myeloma YES/NO	
	Macroglobulinemia YES/NO	
	Protein C deficiency YES/NO/NOT SCREENED	
	Protein S deficiency YES/NO/NOT SCREENED	
	Prothrombin (Factor II) gene mutation YES/NO/NOT SCREENED	
	Factor V Leiden YES/NO/NOT SCREENED	
	Antiphospholipid syndrome YES/NO/NOT SCREENED	
	ADAMTS13 deficiency YES/NO/NOT SCREENED	
	MTHFR deficiency YES/NO/NOT SCREENED	
History of congenital and Hereditary Disorders	YES/NO If yes, complete	
	Date of diagnosis (DD/MM/YYYY) ____ /____ /_____	
	Portal vein agenesis YES/NO	
	Congenital heart defect YES/NO, if yes describe _____	
	Turner's syndrome YES/NO	
	Adams-Oliver syndrome YES/NO	
	TERT mutations YES/NO/NOT SCREENED	
	Cystic fbrosis YES/NO	
	Familial cases YES/NO	
	KCNN3 mutation YES/NO	
History of infection	More than one abdominal infection at birth (including omphalitis) YES/NO	
	Tuberculosis YES/NO	
History of congestive heart failure	YES/NO	
Other comorbidities at diagnosis		
Other comorbidities at diagnosis	YES/NO If yes, describe and add date of comorbidity diagnosis DD/MM/YYYY ____ /____ /_____	

<table>
<tr><td rowspan="9">Other causes of chronic liver disease</td><td colspan="2">Active Alcohol consumption YES/NO
(If yes _____unit/day) and number of consumption years___ years)</td></tr>
<tr><td rowspan="3">History of alcohol consumption YES/NO
If yes , complete</td><td>alcohol consumption start date
(DD/MM/YYYY) ____ /____ /_____</td></tr>
<tr><td>alcohol consumption end date
(DD/MM/YYYY) ____ /____ /_____</td></tr>
<tr><td>quantity (unit/day) ____ /day</td></tr>
<tr><td rowspan="2">Hepatitis B virus</td><td>HBsAg Positive YES/NO/Not tested</td></tr>
<tr><td>Antiviral therapy YES/NO
If yes which agent (describe)
_____</td></tr>
<tr><td rowspan="3">Hepatitis C virus</td><td>YES/NO/Not tested</td></tr>
<tr><td>Sustained virological response YES/NO</td></tr>
<tr><td>If yes, date
(DD/MM/YYYY) ____ /____ /_____</td></tr>
<tr><td colspan="2">Autoimmune YES/NO (If yes describe) _____</td></tr>
<tr><td colspan="2">Other etiology YES/NO (If yes describe) _____</td></tr>
<tr><td rowspan="3">History of liver transplantation</td><td colspan="2">YES/NO
If yes, complete</td></tr>
<tr><td colspan="2">Date of liver transplantation (DD/MM/YYYY) :
____ /____ /_____</td></tr>
<tr><td colspan="2">Immunossupressive regimen at PSVD diagnosis (describe) :
_____</td></tr>
</table>

Thrombophilia screen performed at diagnosis YES/NO If yes, complete		
Date of thrombophilia screen	DD/MM/YYYY ____ /____ /_____	
Antithrombin deficiency	YES/NO/NOT SCREENED Value (%):_____ *Normal range: (80-140%)*	
Protein C deficiency	YES/NO/NOT SCREENED Value (%):_____*Normal range: (80-140%)*	
Protein S deficiency	YES/NO/NOT SCREENED Value (%):_____*Normal range: (80-140%)*	
Activated protein C resistance	YES/NO/NOT SCREENED	
Factor V mutation	YES/NO/NOT SCREENED	
Factor II mutation	YES/NO/NOT SCREENED	
Antiphospholipid syndrome	YES/NO/NOT SCREENED	
Lupus anticoagulant antibodies IgM	YES/NO/NOT SCREENED	
Lupus anticoagulant antibodies IgG	YES/NO/NOT SCREENED	
Anticardiolipin antibodies IgM	YES/NO/NOT SCREENED	
Anticardiolipin antibodies IgG	YES/NO/NOT SCREENED	
Anti-beta2-GP I antibodies IgM	YES/NO/NOT SCREENED	
Anti-beta2-GP I antibodies IgG	YES/NO/NOT SCREENED	
Myeloproliferative disorder	YES/NO/NOT SCREENED if yes, describe	Polycythemia vera YES/NO
		Essential thrombocythemia YES/NO
		Primary myelofibrosis YES/NO
		Chronic myeloid leukemia YES/NO
Marrow bone biopsy	YES/NO If yes, complete	date (DD/MM/YYYY) ____ /____ /_____
		Results (describe) _____
JAK 2 mutation	YES/NO/NOT SCREENED	
CALR mutation	YES/NO/NOT SCREENED	
Paroxysmal nocturnal hemoglobinuria	YES/NO/NOT SCREENED	
Ongoing oral contraception at diagnosis	YES/NO if yes, which agent (describe) _____	
Laboratory data at diagnosis		
Date	DD/MM/YYYY ____ /____ /_____	
Bilirubine total/direct/indirect (mg/dl)		
Aspartate aminotransferase (AST) (U/L)		
Alanine aminotransferase (ALT) (U/L)		
Alkaline phosphatase (U/L)		
Gamma-glutamyl transpeptidase (GGT) (U/L)		

Albumine (g/L)	
Hemoglobine (g/L).	
Hematocrite (%)	
Leucocytes(x10^9/L)	
Plateletes (x10^9/L)	
INR. Protrombine t (%)	
Creatinine (mg/dL)	
MELD score	
Child Score (number)	
Imaging at diagnosis	
Date of 1st liver imaging (the closer imaging test to diagnosis)	DD/MM/YYYY ____ /____ /_____
Select the type of imaging study, select more than one if more than one.	US / CT-Scan / MRI
Hepatic artery diameter (mm)	YES /NO/NOT AVAILABLE
Hypertrophy of segment IV	YES /NO/NOT AVAILABLE
Hypertrophy of segment I	YES /NO/NOT AVAILABLE
Nodular liver surface	YES /NO/NOT AVAILABLE
FibroScan® (Echosens, Paris, France) at diagnosis YES / NOT DONE If yes, complete	
Date	DD/MM/YYYY ____ /____ /_____
Performer	Experienced hepatology nurse/Hepatologist/Other (describe) _____
Liver stiffness (kPa)	YES /NOT AVAILABLE
IQR (kPa)	YES /NOT AVAILABLE
Spleen stiffness (kPa)	YES /NOT AVAILABLE
IQR (kPa)	YES /NOT AVAILABLE
**If several FibroScan® please add all of them with the date	

Last clinical information		
Extra-hepatic comorbidities occurring follow-up and different from those at diagnosis	YES/NO If yes , complete	Date of diagnosis (DD/MM/YYYY) ____ /____ /____
		Describe_____
Endoscopic data	YES/NO If yes, complete	
	Date : DD/MM/YYYY ____ /____ /_____	
	Esophageal varices (specify :small/medium/large) YES /NO/NOT AVAILABLE	
	Gastric varices (specify : IGV I – IGV II) YES /NO/NOT AVAILABLE	

	Esophagogastric varices (specify : GOV I – GOV II) YES /NO/NOT AVAILABLE
	Portal hypertensive gastropathy Specify : Slight/moderate/severe YES /NO/NOT AVAILABLE
	Ectopic varices (describe the location) YES /NO/NOT AVAILABLE
Ascites	YES/NO/NOT AVAILABLE If yes, complete
	Date of occurrence (DD/MM/YYYY) ____ /____ /_____
	Specify : grade I –II – III
	Diuretic controlled YES/NO/NOT AVAILABLE
	Refractory ascites YES/NO/NOT AVAILABLE
	Paracentesis YES/NO/NOT AVAILABLE. How many per month _____*/month*
Spontaneous bacterial peritonitis	YES/NO/NOT AVAILABLE If yes : date (DD/MM/YYYY) ____ /____ /_____
Acute kidney injury	YES/NO/NOT AVAILABLE If yes, date (DD/MM/YYYY) ____ /____ /____ specify: grade IA, IB, II, III
Hepatorenal syndrome	YES/NO If yes, date (DD/MM/YYYY) ____ /____ /____ specify : Type I/II
Hepatic encephalopathy	YES/NO/NOT AVAILABLE If yes , complete
	Date of occurrence (DD/MM/YYYY) ____ /____ /_____
	Specify grade I – II – III – IV
	Pharmacological control lactulose YES/NO/NOT AVAILABLE
	Rifaximine needed to control YES/NO/NOT AVAILABLE
	Chronic HE: YES/NO/NOT AVAILABLE. Number of episodes Maximum severity I-II-III-IV
	Precipitant YES/NO/NOT AVAILABLE. If yes which one (constipation, infection. ..describe) _____
Portal hypertension hemorrhage	YES/NO/NOT AVAILABLE If yes , complete
	Date of occurrence (DD/MM/YYYY) ____ /____ /_____

	Gastric varices YES/NO/NOT AVAILABLE (Specify : IGV I – IGV II)	
	Esophagogastric varices YES/NO/NOT AVAILABLE (Specify : GOV I – GOV II)	
	Ectopic varices YES/NO/NOT AVAILABLE Describe the location _____	
	Portal hypertensive gastropathy YES/NO/NOT AVAILABLE Slight/moderate/severe	
Hepatopulmonar Syndrome	YES/NO/NOT AVAILABLE If yes, date (DD/MM/YYYY) ____ /____ /____	
Portal cholangiopathy	YES/NO/NOT AVAILABLE If yes, date (DD/MM/YYYY) ____ /____ /____	
	Severity I, II, III	
	Ursodeoxycholic acid treatment YES/NO If yes, date (DD/MM/YYYY) ____ /____ /_____	
Hepatocellular carcinoma	YES/NO/NOT AVAILABLE If yes, complete	
	date of diagnosis (DD/MM/YYYY) ____ /____ /_____	
	Within Milan Criteria YES/NO/NOT AVAILABLE	
Nodules	YES/NO If yes,complete	Date of nodule diagnosis (DD/MM/YYYY) ____ /____ /_____
		Number of nodules 1 / 2-4 / >5
	Nodules growth	YES/NO/NOT AVAILABLE If yes,complete
		date of growth (DD/MM/YYYY) ____ /____ /_____
	Nodules biopsy	YES/NO/NOT AVAILABLE If yes, complete
		Date of biopsy (DD/MM/YYYY) ____ /____ /_____
		describe histology _____
Last laboratory data		
Date	DD/MM/YYYY ____ /____ /_____	
Bilirubine total/direct/indirect (mg/dl)		
Aspartate aminotransferase (AST) (U/L)		
Alanine aminotransferase (ALT) (U/L)		
Alkaline phosphatase (U/L)		
Gamma-glutamyl transpeptidase (GGT) (U/L)		

Albumine (g/L)	
Hemoglobine (g/L).	
Hematocrite (%)	
Leucocites(x10^9/L)	
Plateletes (x10^9/L)	
INR. Protrombine t (%)	
Creatinine (mg/dL)	
MELD score	
Child Score (number)	
Last imaging	
Date If absence of thrombosis during follow-up = date and findings of the last liver imaging If presence of thrombosis during follow-up = date and findings of liver imaging showing thrombosis	DD/MM/YYYY ____ /____ /_____
Select the type of imaging study, select more than one if more than one.	US / CT-Scan / MRI
Hepatic artery diameter (mm)	YES /NO/NOT AVAILABLE
Hypertrophy of segment IV	YES /NO/NOT AVAILABLE
Hypertrophy of segment I	YES /NO/NOT AVAILABLE
Nodular liver surface	YES /NO/NOT AVAILABLE
Splenomegaly Spleen size in the largest axis (cm)	YES /NO/NOT AVAILABLE
Portal velocity at diagnosis (cm/s)	YES /NO/NOT AVAILABLE
Thrombosis of right or left portal branch	YES /NO/NOT AVAILABLE
Thrombosis of portal trunk	YES /NO/NOT AVAILABLE
Thrombosis of splenic vein	YES /NO/NOT AVAILABLE
Thrombosis of mesenteric vein	YES /NO/NOT AVAILABLE
Obvious porto-systemic collaterals	YES /NO/NOT AVAILABLE
Ascites	YES /NO/NOT AVAILABLE
Other findings and the techniques at which was found	Describe _____
FibroScan® (Echosens, Paris, France) during follow up YES / NOT DONE If yes, complete	
Date	DD/MM/YYYY ____ /____ /_____
Performer	Experienced hepatology nurse/Hepatologist/Other (describe) _____
Liver stiffness (kPa)	YES /NOT AVAILABLE
IQR (kPa)	YES /NOT AVAILABLE
Spleen stiffness (kPa)	YES /NOT AVAILABLE
IQR (kPa)	YES /NOT AVAILABLE
**If several FibroScan® please add all of them with the date	

Hepatic and cardiovascular hemodynamic at follow-up YES / NOT DONE If yes, complete	
Date of hepatic vein catheterization	DD/MM/YYYY ____ /____ /_____
Hepatic Venous Pressure Gradient (mmHg)	
Wedged hepatic vein pressure (mmHg):	
Free hepatic vein pressure (mmHg):	
Medical intervention during follow-up	
Transjugular intrahepatic portosystemic shunt (TIPS)	YES/NO If yes, complete
	date (DD/MM/YYYY) ____ /____ /_____
	Indication for TIPS (describe) _____
Liver transplantation	YES/NO If yes, complete
	Date (DD/MM/YYYY) ____ /____ /_____
	Indication for liver transplantation (describe) _____
Tumors occurring during follow-up	
Extrahepatic tumors	YES/NO If yes, complete
	Diagnosis date (DD/MM/YYYY) ____ /____ /_____
	Type of tumor (describe) _____
Mortality	
Liver-related mortality	YES/NO If yes, complete
	Date (DD/MM/YYYY) ____ /____ /_____
	cause of death (describe) _____
Non-liver-related mortality	YES/NO If yes, complete
	Date (DD/MM/YYYY) ____ /____ /_____
	cause of death (describe) _____
Last follow-up	
Date of last follow up	DD/MM/YYYY ____ /____ /_____
Patient lost to follow-up	YES/NO

ATTESTAZIONE DI REGOLARITA' AMMINISTRATIVO-CONTABILE (proposta n. 934/2025)

Oggetto: AUTORIZZAZIONE ALL'AVVIO DELLO STUDIO "THE NATURAL HISTORY OF EARLY PORTO-SINUSOIDAL VASCULAR DISORDER" (REG. 2025-0019) PRESSO LA SC GASTROENTEROLOGIA 1 - EPATOLOGIA E TRAPIANTOLOGIA DI CUI SONO PROMOTORI LE CLINIQUES UNIVERSITAIRES DE BRUXELLES - HÔPITAL ERASME E STIPULA DELLA RELATIVA CONVENZIONE.

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, 28/05/2025

Il Direttore

Dr. / Dr.ssa Lorini Monia Maria Beatrice

PARERE DIRETTORI

all'adozione della proposta di deliberazione N.934/2025
ad oggetto:
AUTORIZZAZIONE ALL'AVVIO DELLO STUDIO "THE NATURAL HISTORY OF EARLY PORTO-SINUSOIDAL VASCULAR DISORDER" (REG. 2025-0019) PRESSO LA SC GASTROENTEROLOGIA 1 - EPATOLOGIA E TRAPIANTOLOGIA DI CUI SONO PROMOTORI LE CLINIQUES UNIVERSITAIRES DE BRUXELLES - HÔPITAL ERASME E STIPULA DELLA RELATIVA CONVENZIONE.

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	Moreno Mauro
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
