



HÔPITAL UNIVERSITAIRE
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BRUSSEL



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:

XXX

Commenté [VI1]: Write name of your hospital

(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 [NAME OF PROVIDER’S INVESTIGATOR] 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.

Commenté [VI2]: Complete

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-sublicenseable, 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.

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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. Recipient shall not transfer any other information than specifically provided as per Exhibit 1. Recipient shall not transfer the Limited Dataset to any third party without the prior written consent of Provider. In case of transfer, Provider consents to such transfer only in countries where exists an adequacy decision by the European Commission for the country of the recipient or if Sponsor subjects the transfer to appropriate safeguards (e.g. standard data protection clauses adopted by the European Commission). Any electronic transmission of the Limited Dataset shall be appropriately encrypted in accordance with standards specified by Provider.
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 1 other 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:

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Title: Investigator

Address:

Commenté [VI3]: Complete

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. **DATA PROTECTION:** The Parties agree that they are joint controllers as defined in Article 26 of the Regulation (EU) 2016/679 of the European Parliament and of the Council (General Data Protection Regulation 2016/679, hereafter referred to as the “GDPR”). The Parties acknowledge that they jointly determine the purposes and means of processing of personal data.



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.

The personal data that shall be processed by the Parties for the Project and the categories of data subjects shall be described in the Exhibit I.

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 PROVIDER (**write email address of the Data Protection Officer of the PROVIDER**) and the Data Protection Officer of the RECIPIENT (dpo@erasme.ulb.ac.be),

In addition, the Parties shall:

- implement appropriate technical and organizational measures 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 than 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 Parties acknowledge that subcontractors and third-party collaborators, if any, that perform part of the Project shall act as processors (as defined in GDPR). 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



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(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.

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

Name: Mr Renaud Witmeur

Title:

Title: General Director

Date:

Date:

By:

By:

Name:

Name: Professor Jean-Michel Hougardy

Title:

Title: General Director

Date:

Date:

By:

Name: Mrs Marielle Sautois

Title: Director of Research Administration

Date:

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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:



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Exhibit 1 : Dataset

General information	
Participant code	
Referral 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

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	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	
	Phleboscclerosis 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	

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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	Exposure start date (DD/MM/YYYY) ___ / ___ / _____	
		Exposure end date (DD/MM/YYYY) ___ / ___ / _____	
	If yes, complete	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	Vitamin A supplements YES/NO
			Exposure start date (DD/MM/YYYY) ___ / ___ / _____
	If yes, complete	Exposure end date (DD/MM/YYYY) ___ / ___ / _____	
		Drug exposure YES/NO	Exposure start date (DD/MM/YYYY) ___ / ___ / _____
	If yes, complete		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	
		Bleomycin YES/NO	
		Cytarabine YES/NO	

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		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 glomerulonephritis 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			



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	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 fibrosis 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 ____/____/____
Other causes of chronic liver disease	Active Alcohol consumption YES/NO (If yes ____ unit/day) and number of consumption years ____ years)
	History of alcohol consumption YES/NO
	If yes , complete
	alcohol consumption start date (DD/MM/YYYY) ____/____/____
	alcohol consumption end date (DD/MM/YYYY) ____/____/____
	quantity (unit/day) ____/day
	Hepatitis B virus
HBsAg Positive YES/NO/Not tested	
Antiviral therapy YES/NO	
If yes which agent (describe)	
Hepatitis C virus	
YES/NO/Not tested	
Sustained virological response YES/NO	
If yes, date	

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	(DD/MM/YYYY) ____ / ____ / ____
	Autoimmune YES/NO (If yes describe) _____
	Other etiology YES/NO (If yes describe) _____
History of liver transplantation	YES/NO
	If yes, complete
	Date of liver transplantation (DD/MM/YYYY) : ____ / ____ / ____
	Immunosuppressive regimen at PSVD diagnosis (describe) : _____



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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)	

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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	

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	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

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	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) ____/____/____
		YES/NO/NOT AVAILABLE If yes, complete Date of biopsy (DD/MM/YYYY) ____/____/____
	Nodules biopsy	YES/NO/NOT AVAILABLE If yes, complete
		Date of biopsy (DD/MM/YYYY) ____/____/____

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		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 (%)		
Leucocytes(x10 ⁹ /L)		
Plateletes (x10 ⁹ /L)		
INR. Protrombine t (%)		
Creatinine (mg/dL)		
MELD score		
Child Score (number)		
Last imaging		
Date	DD/MM/YYYY ____/____/____	
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		
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	YES /NO/NOT AVAILABLE	
Spleen size in the largest axis (cm)		
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 _____	

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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

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	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