Optimizing the pulmonary hypertension diagnostic network in Belgium.

A Data Management Plan created using DMPonline.be

Creator: Laura Hardy https://orcid.org/0000-0003-4810-5760

Affiliation: KU Leuven (KUL)

Funder: Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

Template: FWO DMP (Flemish Standard DMP)

Grant number / **URL:** 11PAP24N

ID: 204622

Start date: 01-11-2022

End date: 31-10-2026

Project abstract:

This project centers around the diagnostic approach as well as the follow up and identification of prognostic factors for pulmonary hypertension (PH).

Firstly, work package 1 and 2 investigate the use of non-invasive methods to diagnose PH, group 2 (post-capillary PH) in particular. The gold standard to diagnose PH and differentiate between different groups is currently a right heart catheterization. However, this is an invasive procedure, implying financial cost, a limited however realistic risk of complications and patient discomfort. Moreover, the pulmonary arterial wedge pressure (PAWP) on which this investigation relies heavily on, is sensitive to confounding factors, which limits its reliability. Therefore we will investigate the use of the predictive Optiek model (WP1) and lung ultrasound (WP2) to distinguish post-capillary PH.

The third work package will investigate possible predictors and the prognosis of acute pulmonary arterial hypertension decompensation (PAH or group 1 PH). PAH is a progressive disease and can lead to acute deterioration characterized by right ventricular decompensation. PAH decompensation has a very poor short-term outcome and is the first cause mortality in PAH. However, prognostic factors as well as the optimal therapeutic strategy have been insufficiently studied so far.

Last modified: 29-02-2024

Optimizing the pulmonary hypertension diagnostic network in Belgium. Application DMP

Questionnaire

Describe the datatypes (surveys, sequences, manuscripts, objects …) the research will collect and/or generate and /or (re)use. (use up to 700 characters)

WORK PACKAGE 1: OPTIEK

The Optiek study will both reuse existing data as well as generate new data. These are personal data.
Existing data: results of physical examination, laboratory analysis, echocardiography, ECG and spirometry. After inclusion the results of a standard of care indicated right heart catheterization will also be used.
New data: Based on the existing data, the Optiek model will generate a prediction on the probability of post-capillary pulmonary hypertension.

WORK PACKAGE 2: HELP-PRESERVED

The HELP-Preserved study will both reuse existing as well as generate new personal data.
Existing data: results of laboratory analysis, echocardiography and cardiopulmonary exercise testing.
New data: results of right heart catheterization, cardiac MRI and lung ultrasound.

WORK PACKAGE 3: REGISTRY OF ACUTE DECOMPENSATED PAH

The Registry of Acute Decompensated PAH will mainly reuse existing data. Data regarding medical history, physical examination, laboratory analysis, echocardiography, hospitalization information, treatment and outcome (alive/death/transplantation) will be extracted.
New data: assessment by thoracic ultrasound.

Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)

1. Designation of responsible person: Prof. M. Delcroix (WP 1 & 3); Prof. R. Willems (WP 2)
2. Storage capacity/repository
   - during the research:
     All data regarding the studies will be gathered in separate Redcap eCRF's. The Redcap data will be hosted on a dedicated KU Leuven server for WP 1 and 2. Since WP 3 is part of an international multicentric study, the Redcap data will be hosted on a dedicated server by the APHP hospital of Paris (Sponsor of the study).
   - after the research:
     Non-coded data, such as the data stored in the respective patients' files and the signed ICF's on paper, will be kept for 30 years. Coded data will be kept on the Redcap database of KU Leuven for 25 years.

What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)

NA

Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)

All work packages involve sensitive data. Therefore ethical approval has been obtained for work packages 1 and 2 already. Regarding work package 3, ethical approval will be applied for asap; this has not been established yet due to some uncertainties with the sponsor of this international study.
All personal data will be pseudonymized during the studies.

Which other issues related to the data management are relevant to mention? (use up to 700 characters)

NA

Optimizing the pulmonary hypertension diagnostic network in Belgium.
FWO DMP (Flemish Standard DMP)

1. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

See attachment.

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

All three work packages will reuse existing data, such as clinical parameters, results of laboratory, echocardiography, ECG, cardiopulmonary exercise test or spirometry. All existing data will be registered from the patients' respective electronic medical files.

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes, human subject data

All three work packages concern human subject data as a whole.
Personal data will be pseudonymized.
Ethical approval has been obtained for WP1 and 2 (S68038 and S65913 respectively). Ethical approval for WP3 is still in request due to sponsorship issues.

Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.

- Yes

See also the overview of the data of interest. All data will be personal data.
Also all data will be pseudonymized.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- No

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements/ research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

2. Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g., in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).

All datasets, both reused as well as newly generated data, will be gathered in an electronic CRF via Redcap. The definitions and units of measurements are the accepted definitions and units world wide, defined in the eCRF.

Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.

- No

3. Data storage & back-up during the research project

Where will the data be stored?

Digital data will be stored in a Redcap eCRF. REDCap is hosted on dedicated KU Leuven data servers at Campus Heverlee.

How will the data be backed up?

By using UZL REDCap, data is backed up as follows:
§ The web server backup regime is specified below:
- An hourly backup, the last 6 versions of which are saved
- A daily backup, the last 7 versions of which are saved
- A weekly backup, the last 6 versions of which are saved

§ The database backup regime is specified below:
- A nightly cold backup of all databases
- One month’s storage of the nightly cold backups

Data restore, upon request.

Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely.
If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Physical access to the data centers is logged and restricted to authorized KU Leuven Information Technology (IT) personnel, using badge identification. At the clinical database level only study team members, monitors and auditors/inspectors for whom the Coordinating or Principal Investigator (as applicable) has requested project-specific eCRF access, are granted data access. Upon successful training completion each user is centrally assigned a user role, associated with predefined system/data privileges, in accordance with CR DM-WI-001. The gatekeeper for UZL REDCap is UZL CTC (ctc.datamanagement@uzleuven.be)>

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

The expected costs are 80 euro per year per work package, totaling 960 euro. We intend to use the FWO bench fee to cover these costs.

4. Data preservation after the end of the research project

Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

The Sponsor and Investigator are responsible for archiving study specific documentation (such as but not limited to the CIP, any amendments thereto, the final Clinical Study Report (CSR) and the study database). Non-coded data, such as the data stored in the respective patients' files and the signed ICF's on paper, will be kept for 30 years. The pseudonymisation key will be kept on a secured server for at least 25 years according to the Clinical Trial Regulation 536/2014, art. 58. Coded data will be kept on the Redcap database of KU Leuven for 25 years.

Where will these data be archived (stored and curated for the long-term)?

See above.
Most non-coded data remain in the respective patients' medical files. Non-coded data on paper such as the signed ICF's will be stored in the specific storage room for clinical trials of the UZ Leuven pulmonary hypertension research team. Digital data is kept on a secured server of the pulmonary hypertension research team.

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

There are no expected costs.

5. Data sharing and reuse

Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.

- No (closed access)

If access is restricted, please specify who will be able to access the data and under what conditions.

Access to the data is restricted to members of the clinical pulmonary hypertension research team. Access to future members will depend on future continuation of the research projects.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain in the comment section per dataset or data type where appropriate.

- No

Where will the data be made available? If already known, please provide a repository per dataset or data type.

KU Leuven RDR

When will the data be made available?

Upon publication of the research results.

Which data usage licenses are you going to provide? If none, please explain why.

NA

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.

- No

What are the expected costs for data sharing? How will these costs be covered?

No expected costs

6. Responsibilities

Who will manage data documentation and metadata during the research project?

Laura Hardy

Who will manage data storage and backup during the research project?

Laura Hardy

Who will manage data preservation and sharing?

Marion Delcroix

Who will update and implement this DMP?

Laura Hardy

FWO project: Optimizing the pulmonary hypertension diagnostic network in Belgium.

Data management plan

Laura Hardy

11PAP24N

				Only for digital data	Only for digital data	Only for digital data	Only for physical data
Dataset Name	Description	New or reused	Digital or Physical	Digital Data Type	Digital Data format	Digital data volume (MB/GB/TB)	Physical volume
		Please choose from the following options: ○ Generate new data ○ Reuse existing data	*Please choose from the following options:* ○ Digital ○ Physical	*Please choose from the following options:* ○ Observational ○ Experimental ○ Compiled/aggregated data ○ Simulation data ○ Software ○ Other ○ NA	*Please choose from the following options:* ○ .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, …	*Please choose from the following options:* ○ <100MB ○ <1GB ○ <100GB ○ <1TB ○ <5TB ○ <10TB ○ <50TB ○ >50TB	

					○ NA	○ NA	
WP1: OPTIEK							
Inclusion data	-ICF signed -Date of inclusion	Generate new data	Digital	Observational	.csv	<100GB	NA
Demographic & clinical information	-Age, y -Gender, m/f -Weight, kg -Height, m -BMI, kg/m² -Body surface area, m² -NYHA class	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Medical history	-Diabetes mellitus, y/n -Arterial hypertension, y/n -Hypercholesterolemia, y/n -Obesity, y/n -History of left heart disease, y/n -History of valvular surgery (Yes, with/without residual disease/ No) -Smoking (Current smoker/Former smoker/Never smoker) -Number of packyears, y -Date of smoke cessation	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Laboratory values	-Date of laboratory analysis -Hemoglobin, g/dL -Hematocrit, % -Natrium, mmol/L -Uric acid, mg/dL -Triglycerides, mg/dL	Reuse existing data	Digital	Observational	.csv	<100GB	NA

ECG	-Date of ECG -Rhythm (Sinus rhythm/Atrial fibrillation/Atrial flutter/Other: specify) -P axis, ° -QRS axis, ° -T axis, ° -Sum of S V1 + R V6, mm -PR interval, msec -QRS duration, msec	Reuse existing data	Digital	Observational	.csv	<100GB	NA

Echocardiography	-Date of echocardiography -Left ventricular end diastolic diameter, mm -Left ventricular end systolic diameter, mm -Left ventricular diastolic dysfunction, absent/grade I-III -Mitral E Vmax, cm/s -Mitral A V max, cm/s -Mitral E/A ratio -Mitral E/E' ratio -Left atrial dilatation: Absent (LAVI ≤34 mL/m²) Mild (LAVI 35-41 mL/m²) Moderate (LAVI 42-48 mL/m²) Severe (LAVI >48 mL/m²) -LAVI, mL/m² -Left valvular disease, y/n Aortic stenosis (mild/moderate/severe) Aortic regurgitation (mild/moderate/severe) Mitral stenosis (mild/moderate/severe) Mitral regurgitation (mild/moderate/severe) -Right ventricular dilatation (absent/mild/moderate/severe) -Tricuspid regurgitation pressure gradient, mmHg	Reuse existing data	Digital	Observational	.csv	<100GB	NA

Spirometry	-Date of spirometry -FEV1, L and % pred. -FVC, L and % pred. -FEV1/FVC, % -Peak expiratory flow, L/sec and % pred. -DLCO, % pred.	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Right heart catheterization (RHC)	-Catheterization date -Heart rate, bpm -Systolic pulmonary arterial pressure, mmHg -Diastolic pulmonary arterial pressure, mmHg -Mean pulmonary arterial pressure, mmHg -Pulmonary arterial wedge pressure, mmHg -Mean right atrial pressure, mmHg -Cardiac output, L/min -Cardiac index, L/min/m² -Pulmonary vascular resistance, WU -SvO2, % -SaO2, % -Screenshot of the measured pressure waveforms (Pulmonary artery, Pulmonary arterial wedge pressure and Right atrium)	Reuse existing data	Digital	Observational	.csv Image data (screenshots)	<1TB	NA

Diagnosis & conclusion by the participating centre	-Pulmonary hypertension, y/n -Pre-, post-capillary or combined -PH Group -Occurrence of adverse events during RHC -Additional remarks	Generate new data	Digital	Observational	.csv	<100GB	NA
Review of the diagnosis by UZ Leuven team	-Change made to diagnosis, if so specify (based on RHC tracings provided by the participating centre)	Generate new data	Digital	Observational	.csv	<100GB	NA
Optiek model results	-Probability of group 2 PH -Accuracy: correct/false positive/negative	Generate new data	Digital	Simulation data	.csv	<100GB	NA
WP2: HELP-PRESERVED							
Inclusion data	-Date of inclusion -ICF signed		Digital	Observational	.csv	<100GB	NA
Demographic data	-Age, y -Gender, m/f -Weight, kg -Height, m -BMI, kg/m² -Body surface area, m² -NYHA class, I - IV	Reuse existing data	Digital	Observational	.csv	<100GB	NA

Medical history	-Diabetes mellitus, y/n -Arterial hypertension, y/n -Atrial fibrillation, y/n -Obesity, y/n -History of left heart disease, y/n (If yes: specify what) -Smoking (Current/former/never smoker) -Number of packyears, y -Date of smoke cessation	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Medical treatment	-Use of loop diuretics (If yes, specify which and dose) -Use of beta blocker (If yes, specify which and dose) -Use of mineralocorticoid receptor antagonist (If yes, specify which and dose)	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Laboratory results	-Date of laboratory analysis -Hemoglobin, g/dL -NT-proBNP, ng/L -Creatinine, mg/dL -Estimated glomerular filtration rate (eGFR), ml/min/1.73m²	Reuse existing data	Digital	Observational	.csv	<100GB	NA

Echocardiography	-Date of echocardiography -Left ventricular diameter (systolic and diastolic), mm -Left ventricular ejection fraction (LVEF), % -Evaluation of left ventricular dysfunction (absent/mild/moderate/severe) -Left atrial volume index (LAVI), ml/m² -Left atrial dilatation (absent/mild/moderate/severe) -Mitral valve E peak maximum, cm/s -Mitral valve A v max, cm/s -Mitral E/A ratio -Mitral E/E' ratio -Evaluation of right ventricular dilatation (absent/mild/moderate/severe) -RVED/LVED area ratio -Right atrial area, cm² -Vena cava inferior diameter after in- and expiration, mm -Vena cava inferior collapsibility, % -Right atrial pressure (RAP), mmHg (Calculated from VCI expiration diameter and collapsibility) -Tricuspid annular plane systolic excursion (TAPSE), mm -Tricuspid pressure gradient (TRPG), mmHg -Estimated systolic pulmonary arterial pressure (sPAP), mmHg (Calculated from TRPG and RAP)	Reuse existing data	Digital	Observational	.csv	<100GB	NA

	-TAPSE/sPAP ratio, mm/mmHg -Right ventricular Tei index -Pulmonary valve acceleration time (PVAT), ms -Tricuspid regurgitation velocity (TRV), m/s						
Right heart catheterization with exercise protocol	-Catheterization date -Heart rate, bpm -Systemic blood pressure, mmHg -Systolic pulmonary arterial pressure, mmHg -Diastolic pulmonary arterial pressure, mmHg -Mean pulmonary arterial pressure, mmHg -Pulmonary arterial wedge pressure, mmHg -Mean right atrial pressure, mmHg -Cardiac output, L/min -Cardiac index, L/min/m² -Pulmonary vascular resistance, WU -SvO2, % -SaO2, % ***All measurements are taken at rest, in leg raise position, during free riding, at 25% and 50% of previously attained maximal work load***	Generate new data	Digital	Observational	.csv	<100GB	NA

Cardiopulmonary exercise test	-FEV1, L and % pred. -FVC, L and % pred. -FEV1/FVC, % -Maximal attained work load, W and % pred. -Max. heart rate, bpm and % pred. -Respiratory quotient at maximal effort -Lactate at maximal effort, mmol/L -MVV, L/min and % pred. -Peak VE, L/min and % pred. -Peak VO2, mL/min and % pred. -VO2/kg, mL/min/kg -VE/VCO2 slope -SaO2 in rest, % -SaO2 at maximal work load, % -Desaturation during exercise, % -Evaluation of oxygen pulse, normal/abnormal -ECG abnormalities, y/n -Ventilatory limitation, y/n	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Thoracic ultrasound	The number of B-lines will be quantified in a 28-point protocol: -Intraclavicular space 2-5 (right) and 2-4 (left) -Parasternal, mid-clavicular, anterior axillary and mid-axillary axis	Generate new data	Digital	Observational	Image data Images are scored in an .csv file	<1TB	NA

MRI	-Left ventricular end diastolic volume, mL -Left ventricular end systolic volume, mL -Left ventricular stroke volume, mL -Left ventricular ejection fraction, % -Left ventricular muscle mass, g and g/m² -Left ventricular cardiac output, L/min -Left ventricular cardiac index, L/min/m² -Left ventricular end diastolic diameter, mm -Left ventricular end systolic diameter, mm -Fractional shortening, % -Anteroseptal diameter, mm -Interolateral wall thickness, mm -Evaluation of left ventricular motion -Right ventricular end diastolic volume, mL -Right ventricular end systolic volume, mL -Right ventricular stroke volume, mL -Right ventricular ejection fraction, % -Right ventricular cardiac output, L/min -Right ventricular cardiac index, L/min/m² -Evaluation of right ventricular motion	Generate new data	Digital	Observational	Image data Images are scored in a .csv file	<1TB	NA

	-TAPSE, mm and % -Left atrial area, cm^2 -Right atrial surface, cm^2 -Aortic root diameter, mm -Presence of valvular pathology, y/n -Evaluation of pericard -Lung water density, %						
Diagnosis & conclusi	-Pulmonary hypertension, y/n -Pre-, post-capillary or combined pulmonary hypertension -Pulmonary hypertension group	Generate new data	Digital	Observational	.csv	<100GB	NA
WP3: REGISTRY OF ACUTE DECOMPENSATED PULMONARY ARTERIAL HYPERTENSION							
Day 0 (inclusion)							
Inclusion data	-Date of inclusion -Hospital department: regular ward/intermediate or intensive care unit -Date of admission -Date of discharge	Generate new data	Digital	Observational	.csv	<100GB	NA

Pulmonary arterial hypertension related characteristics	-PAH subtype -Date of diagnosis -Last evaluation: Date WHO-FC, I-IV 6-minute walking distance, m NT-proBNP, ng/L -Last hemodynamic assessment Date Right atrial pressure, mmHg Mean pulmonary arterial pressure, mmHg Cardiac output, L/min Cardiac index, L/min/m² Pulmonary vascular resistance, WU Mixed venous oxygen saturation, % -Cardiopulmonary exercise testing Maximal load, W and % pred. Peak VO2, ml/min/kg Ventilatory reserve, L/min VE/VCO2 slope SpO2, % -Prognostic risk stratification during last assessment -Is patient active on transplant list, y/n -First admission with right ventricular failure, y/n If yes: number of right ventricular failure episodes and date of last episode	Reuse existing data	Digital	Observational	.csv	<100GB	NA

Comorbidities	-Arterial hypertension, y/n -Diabetes, y/n -Coronary heart disease, y/n -History of acute myocardial infarction, y/n -Obesity, y/n -Chronic renal insufficiency, y/n -Smoking history, active/never/former Number of packyears Year of smoke cessation -Alcohol abuse , y/n	Reuse existing data	Digital	Observational	.csv	<100GB	NA
Triggering factor	-Triggering factor identified, y/n If yes, specify	Generate new data	Digital	Observational	.csv	<100GB	NA

Treatment at time of admission	**Maintenance treatment** -Anticoagulation; specify which, dose and indication -Diuretics: specify which and dose -Oxygen: specify dose -Beta blockers: specify which and dose -Antihypertensive drugs: specify which and dose **PAH therapy** -Endothelin receptor antagonists: specify which and dose -Phosphodiesterase 5 inhibitors: specify which and dose -Riociguat: specify dose -Calcium channel blockers: specify which and dose -Prostacyclin analogues: specify which, dose and route of admission -Investigational product: Sotatercept or other, please specify which	Generate new data	Digital	Observational	.csv	<100GB	NA

Clinical characteristics	-Presence of arterial line, y/n -Presence of venous central line, y/n -Right heart catheterization performed, y/n If yes: right atrial pressure, mean pulmonary arterial pressure, cardiac output, cardiac index, pulmonary vascular resistance and mixed venous oxygen saturation -Measured weight, kg -BMI, kg/m² -Previous stable weight, kg -Heart rate, bpm -Arterial pressure, mmHg -Oxygen saturation, % If additional O2: FiO2, % -Respiratory rate, /min -Temperature, °C -Central venous pressure, mmHg -SAPS II score	Generate new data	Digital	Observational	.csv	<100GB	NA

Biological variables	-NT-proBNP, ng/L -Blood urea nitrogen, mg/dL -Creatinine, mg/dL -eGFR, ml/min/1.73m² -KDIGO classification -Uric acid, mg/dL -Sodium, mmol/L -Lactate, mg/dL -AST, mg/dL -ALT, mg/dL -Hemoglobin, g/dL -Platelet count, x109/L -Troponin, ng/L -Bilirubin, mg/dL -C-reactive protein, mg/dL -Central venous oxygen saturation, % - Blood gases: pH, PaO2, PaCO2, SaO2, HCO3, FiO2 -Supplemental oxygen, y/n Route of administration FiO2 If HFNC: flow rate, L/min If mechanical ventilation: date of intubation, type and dose of sedation, additional details of intubation, type of mechanical ventilation, PEEP, IPAP, tidal volume, respiratory rate	Generate new data	Digital	Observational	.csv	<100GB	NA

Echocardiograhpy	-TAPSE, mm -S wave (doppler), cm/s -TAPSE/sPAP, mm/mmHg -TR peak velocity, cm/s -TI severity -RV longitudinal strain, % -RA area, cm² -RV/LV area -Eccentricity index -LVEF, % -Mitral E/A ratio -Mitral E/E' ratio -LVOT VTI, cm -Pericardial effusion, y/n If yes : maximal dimension, mm	Generate new data	Digital	Observational	.csv	<100GB	NA
Day 3							
Clinical characteristic	-Measured weight, kg -BMI, kg/m² -Heart rate, bpm -Arterial pressure, mmHg -Oxygen saturation, % If additional O2: FiO2, % -Respiratory rate, /min -Temperature, °C -Central venous pressure, mmHg -24h urine output on day 3, mL	Generate new data	Digital	Observational	.csv	<100GB	NA

Biological variables	-NT-proBNP, ng/L -Blood urea nitrogen, mg/dL -Creatinine, mg/dL -eGFR, ml/min/1.73m² -KDIGO classification -Uric acid, mg/dL -Sodium, mmol/L -Lactate, mg/dL -AST, mg/dL -ALT, mg/dL -Hemoglobin, g/dL -Platelet count, x109/L -Troponin, ng/L -Bilirubin, mg/dL -C-reactive protein, mg/dL -Central venous oxygen saturation, % - Blood gases: pH, PaO2, PaCO2, SaO2, HCO3, FiO2 -Supplemental oxygen, y/n Route of administration FiO2	Generate new data	Digital	Observational	.csv	<100GB	NA

Echocardiography	-TAPSE, mm -S wave (doppler), cm/s -TAPSE/sPAP, mm/mmHg -TR peak velocity, cm/s -TI severity -RV longitudinal strain, % -RA area, cm^2 -RV/LV area -Eccentricity index -LVEF, % -Mitral E/A ratio -Mitral E/E' ratio -LVOT VTI, cm -Pericardial effusion, y/n If yes : maximal dimension, mm	Generate new data	Digital	Observational	.csv	<100GB	NA

Therapeutic management	**Monitoring** -Presence of arterial line, y/n -Presence of venous line, y/n -Right heart catheterization performed, y/n If yes: right atrial pressure, mean pulmonary arterial pressure, cardiac output, cardiac index, pulmonary vascular resistance and mixed venous oxygen saturation -PICCO monitoring, y/n -Other monitoring, y/n If yes: specify **Diuretics** -Intravenous furosemide, y/n If yes: specify start date, duration and maximal dose per 24h -Spironolactone, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Hydrochlorothiazide, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Acetazolamide, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h	Generate new data	Digital	Observational	.csv	<100GB	NA

	Inotropic support -Dobutamine, y/n If yes: specify start date, duration and maximal dose per 24h -Dopamine, y/n If yes: specify start date, duration and maximal dose per 24h -Levosimendan, y/n If yes: specify start date, duration and loading and continuous dose, route of administration and whether administration occurs on ward level or ICU -Milrinone, y/n If yes: specify start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h **Vasopressors** -Norepinephrine, y/n If yes: specify start date, duration and maximal dose per 24h -Vasopressin, y/n If yes: specify start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h						

	PAH therapy initiation -Endothelin receptor antagonists: specify which, dose adjustment vs new therapy, date, dose -Phosphodiesterase 5 inhibitors: specify which, dose adjustment vs new therapy, date, dose -Riociguat: specify dose adjustment vs new therapy, date, dose -Calcium channel blockers: specify which, dose adjustment vs new therapy, date, dose -Prostacyclin analogues: specify which, dose adjustment vs new therapy, date, dose, route of administration -Selexipag: specify dose adjustment vs new therapy, date, dose -Investigational product: Sotatercept or other, please specify which and date **Renal replacement therapy** -Renal replacement therapy required, y/n If yes: specify date, duration, dialysis and/or hemofiltration **Maximum respiratory support** -Room air, y/n -Supplemental oxygen therapy, y/n If yes: route of administration, start date, max FiO2 If HFNC: flow rate						

	If mechanical ventilation: date of intubation, type and dose of sedation, additional details of intubation, type of mechanical ventilation, PEEP, IPAP, tidal volume, respiratory rate **Extracorporeal life support** Requirement for extracorporeal life support, y/n If yes: date of insertion, duration, type of ECLS **Immunosuppression** Initiation of new immunosuppressive medication, y/n If yes: specify which and dose **Ethical level** -Do not resuscitate order, y/n -Do not intubate order, y/n -Palliative care initiated, y/n						
Time of discharge							

Management	**Monitoring** -Presence of arterial line, y/n -Presence of venous line, y/n -Right heart catheterization performed, y/n If yes: right atrial pressure, mean pulmonary arterial pressure, cardiac output, cardiac index, pulmonary vascular resistance and mixed venous oxygen saturation -PICCO monitoring, y/n -Other monitoring, y/n If yes: specify **Diuretics** -Intravenous furosemide, y/n If yes: specify start date, duration and maximal dose per 24h -Spironolactone, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Hydrochlorothiazide, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Acetazolamide, y/n If yes: specify route of administration, start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h	Generate new data	Digital	Observational	.csv	<100GB	NA

	Inotropic support -Dobutamine, y/n If yes: specify start date, duration and maximal dose per 24h -Dopamine, y/n If yes: specify start date, duration and maximal dose per 24h -Levosimendan, y/n If yes: specify start date, duration and loading and continuous dose, route of administration and whether administration occurs on ward level or ICU -Milrinone, y/n If yes: specify start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h **Vasopressors** -Norepinephrine, y/n If yes: specify start date, duration and maximal dose per 24h -Vasopressin, y/n If yes: specify start date, duration and maximal dose per 24h -Other, y/n If yes: specify which, route of administration, start date, duration and maximal dose per 24h						

	PAH therapy initiation -Endothelin receptor antagonists: specify which, dose adjustment vs new therapy, date, dose -Phosphodiesterase 5 inhibitors: specify which, dose adjustment vs new therapy, date, dose -Riociguat: specify dose adjustment vs new therapy, date, dose -Calcium channel blockers: specify which, dose adjustment vs new therapy, date, dose -Prostacyclin analogues: specify which, dose adjustment vs new therapy, date, dose, route of administration -Selexipag: specify dose adjustment vs new therapy, date, dose -Investigational product: Sotatercept or other, please specify which and date **Renal replacement therapy** -Renal replacement therapy required, y/n If yes: specify date, duration, dialysis and/or hemofiltration **Maximum respiratory support** -Room air, y/n -Supplemental oxygen therapy, y/n If yes: route of administration, start date, max FiO2 If HFNC: flow rate						

	If mechanical ventilation: date of intubation, type and dose of sedation, additional details of intubation, type of mechanical ventilation, PEEP, IPAP, tidal volume, respiratory rate **Extracorporeal life support** Requirement for extracorporeal life support, y/n If yes: date of insertion, duration, type of ECLS **Immunosuppression** Initiation of new immunosuppressive medication, y/n If yes: specify which and dose **Ethical level** -Do not resuscitate order, y/n -Do not intubate order, y/n -Palliative care initiated, y/n						
Outcome	-Date of discharge -Survival, y/n If no: date of death -Lung or heart-lung transplantation performed, y/n If yes: specify which kind and date of transplantation	Generate new data	Digital	Observational	.csv	<100GB	NA
Month 3							

Outcome	-Survival, y/n If no: date of death -Lung or heart-lung transplantation performed, y/n If yes: specify which kind and date of transplantation -Recurrent admission because of right ventricular failure, y/n If yes: number of admissions and dates	Generate new data	Digital	Observational	.csv	<100GB	NA

Month 12							
Outcome	-Survival, y/n If no: date of death -Lung or heart-lung transplantation performed, y/n If yes: specify which kind and date of transplantation -Recurrent admission because of right ventricular failure, y/n If yes: number of admissions and dates	Generate new data	Digital	Observational	.csv	<100GB	NA