Co-designing a Core Outcome Set for and with patients with Idiopathic Pulmonary Fibrosis (COCOS-IPF)

A Data Management Plan created using DMPonline.be

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Project abstract:

Idiopathic pulmonary fibrosis (IPF) and other forms of progressive pulmonary fibrosis (PPF) are rare pulmonary conditions that result in destruction of lung tissue due to the abnormal development of scar tissue. Pulmonary fibrosis mostly affects older people, is often progressive and, especially IPF is associated with a limited life expectancy. Major progress has been made in view of earlier PPF diagnosis and drug treatment. Interdisciplinary holistic care in PPF, however, is still in its infancy. Patient advocacy groups and clinical experts from across Europe stress that gaps in IPF and overall PPF care continue to exist and that patients with PPF have several unmet needs for which urgent action is needed. The key patient-reported and clinical outcomes that patients and professionals deem most relevant to consider within PPF care remain to be determined. This hampers improvement of care and the quality of life of people living with PPF, as well as PPF-related research. The “Co-designing a Core Outcome Set for and with patients with Idiopathic Pulmonary Fibrosis” (COCOS-IPF) project aims to develop a Core Outcome Set (COS) and their corresponding measures for PPF care in Europe. The consortium consists of social scientists, European patient Advocacy Organizations, and IPF experts and has co-design at its core. Five work packages (WPs) combine different well-established social sciences research methodologies:
 WP 1: To identify the range and consistency of outcomes used in IPF-related research, registries or clinical care based on literature reviews, a survey of European PPF healthcare professionals, and focus groups with European patients;
 WP 2: To establish a COS for use in routine IPF care based on a multi-stakeholder Delphi study and a consensus meeting;
 WP 3: To determine the measures of the core clinical and patient-reported outcomes based on literature reviews, consensus meetings and cognitive debriefings ;
 WP 4: Project management, data management and risk management;
 WP 5: Dissemination to the scientific community, patients and society as a whole.
The strengths of the COCOS-IPF project are its interdisciplinary and transnational collaboration, its collaboration with patients as full and equal research partners and its sound methodological underpinning. Moreover, by paying attention to geographical, socio-economic and healthcare system diversity within Europe, we will succeed to create a set of outcomes that patients with PPF (including IPF) value the most within their care.

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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.

				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, .cvs,.pdf, .txt, .rtf, .dwg, .gml, ... • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
project administration data	Research protocol, ethical approval letters, informed consent forms, data analysis plans, meeting reports, agreements (if necessary), information documents for patients, interim reports and publication/manuscripts	generate new data	digital	Other	.doc .PPT .pdf	<100GB	
WP 1 step 1 literature review	manuscripts reviewed for eligibility and integrated in Rayyan, data extraction tables, summaries of findings	generate new data (except for manuscripts reviewed, which fall under 'reuse of existing data')	digital	Other (files linked to systematic review of databases)	.xml .doc .pdf .enl	<100GB	
WP 1 step 2 survey of healthcare professionals	file with survey results, analysis of survey data	generate new data	digital	observational	.xml .doc	<100GB	
WP 1 step 3 focus groups with patients	summary report of findings, informed consent forms, summary of characteristics of participants	generate new data	digital	observational	.doc .pdf .xml	<100 GB	

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:

- References and publications available in PUBMED, Embase, Web of Science to be screened for eligibility for our systematic review
- Use of data publicly available on clinical trials in clinicaltrials.gov (no original data sets will be used, yet this site will be screened to learn which outcomes are currently being used in research projects related to progressive pulmonary fibrosis)

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

- In WP 1 step 3, the European patient advocacy organizations EU-PFF and ELF, who are partners within the COCOS-IPF consortium, will organize focus groups with patients with PPF in the following countries: UK, Norway, Greece and Belgium. We completed the KU Leuven PRET tool, and will submit the protocol for ethical approval to the ethical committee of KU Leuven.

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

We will use pseudonymised data for the focus groups planned in WP 1 step 3. The names of the participants will be mentioned on the informed consent forms, which will be securely stored at OneDrive, which will only be accessible by the PI (prof. Dobbels), the project coordinator (Dr. Delameillieure), and the patient representatives who

will run the focus groups within their country and who will be responsible for patient recruitment, obtaining informed consent, and conducting the focus groups.
We will collect the following data in aggregated form per participating country (Greece, UK, Belgium and Norway), consisting of a summary of focus group participants of following data:
- age (in categories of 5 years each)
- sex
- martial status
- education level (below vs. minimally bachelor level)
- type of progressive pulmonary fibrosis
- stage of the disease (based on severity, divided in 3 stages)

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).

We will make the data for every step of the project findable, by creating a folder in OneDrive that is accessible by project partners containing the following files:
WP 1 step 1: scoping review

- protocol: different versions of the protocol ordered by date of creation
- word document with search strings used in the different databases, containing the date on which the searches were completed and by whom
- rayyan files containing all the titles and abstracts screened within the scoping review, and the full texts of the papers included in the review
- data extraction files ordered by date
- a metafile in word explaining which information can be found in this folder

WP 1 step 2: survey with European PPF healthcare professionals

- protocol: different versions of the protocol ordered by date of creation
- survey:
  - copy of the survey used for the pilot testing
  - copy of the final survey programmed in Qualtrics
- summary report of the findings of the piloting
- excel file containing the raw data of all completed surveys
- summary of main findings (word + excel)
- a metafile in word explaining which information can be found in this folder

WP 1 step 3: focus groups with patients with PPF

- protocol: different versions of the protocol ordered by date of creation
- the approval letter of the ethical committee
- a pdf of the file completed in the PRET tool
- topic guide in English + its translations in Dutch, Norwegian and Greek
- information leaflet and informed consent form in English + its translations in Dutch, Norwegian and Greec
- an overview of the characteristics of all participants (no individual data will be shared)
- a summary report of findings per countries (translated in English) and across countries

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

The data as such presumably cannot be reused by others, but interested researchers can get access to protocols, surveys, reports, etc post-project.

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

Where will the data be stored?

OneDrive KU Leuven

How will the data be backed up?

automated backup by KU Leuven

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?

We will use password to ensure only authorized project partners have access to the files. We will keep a record of whom has access to the different folders or files.

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

shared network drive
Costs (if any) to be covered by the EJP-RD project budget of the primary investigator

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...).

All data described above

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

OneDrive data repository

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

No extra costs involved or to be covered by the PI

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.

- Yes, in a restricted access repository (after approval, institutional access only, ...)

Interested third parties (non-commercial agencies) can reuse the following materials after the project and once the main papers have been published:
- protocols, search strings, data extraction tables of reviews
- topic guides, surveys

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

The above mentioned materials will be shared after written approval by the PI (who may decide to discuss specific requests with the consortium partners first).

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.

to be determined

When will the data be made available?

after completion of the project and once the main papers have been published

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

The consortium holds the intellectual property rights of the COS. However, the research is conducted in the interest of IPF patients, professionals, researchers and society as a whole. In order to ensure its maximal use and exploitation, the COS will be made freely available to clinicians/researchers who want to optimize the care for patients with PPF across Europe.
Pharmaceutical companies who want to incorporate (parts of) the COS in their trials will need to pay a license fee. This revenue will be used to support a research grant (e.g. to be offered by ELF, EU-IPFF or ERS) that focuses on further improving the care for PPF patients, thereby making sure that patients continue to benefit from our work after the project ends.
We will work with the Research and Development Office of KU Leuven to manage IP rights and related contracts towards the end of the project.

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 additional costs

6. Responsibilities

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

Fabienne Dobbels and Anouk Delameillieure

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

Fabienne Dobbels and Anouk Delameillieure

Who will manage data preservation and sharing?

Fabienne Dobbels

Who will update and implement this DMP?

Fabienne Dobbels and Anouk Delameillieure

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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)

During the study: Research data/Administrative data/Publications

We will generate new data using surveys, focus groups, Delphi-studies and interviews. We will use existing literature by conducting scoping literature reviews in WP1 and WP3. All outcomes and their measures will be retrieved from the published literature and further used in our project. In case, we use existing patient-reported outcome measures, we will respect the (questionnaire) copyright/ownership regulations.

Research protocol, ethical approval letters, informed consent forms, data analysis plans, meeting reports, agreements (if necessary), information documents for patients, interim reports and publication/manuscripts: .doc files and PDF files

Scoping literature review WP1 and WP3: tabular data in .doc and .xls files, ris export of hits from databases to Rayyan AI.

Qualitative data WP 1 and WP3:Transcription in .doc files and analysis in .doc files or .nvivo files Audio-recorded interviews: all interviews (mp3 files) will be immediately transcribed and the recordings will be deleted after transcription

Quantitative data (survey, content analysis and Delphi study WP1, WP2, WP3): survey data and tabular data in .xls files and .doc files. Additionally, for the Delphi study, SPSS sav. files will be made with the raw data of the survey rounds

Consensus meetings (meeting reports) and content analysis meetings : .doc files and pdf-files

We will work with personal data for the focus groups, interviews, surveys and Delphi-study. If possible, we will use anonymous data (i.e., Survey WP1). Otherwise we will carefully pseudo-anonymize data. GDPR-related tools (i.e., PRET tool KU Leuven or GPDR questionnaire EC UZ/KU Leuven) will be filled in for review and if necessary we will ask for ethical approval (i.e., focus groups, Delphi study).

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)

It is difficult to estimate the total size of the data, but we expect not to exceed 10GB.

1. Designation of responsible person (Prof. Fabienne Dobbels)
2. Storage capacity/repository
    1. **during the research**: KU Leuven OneDrive Prof. Dobbels
    2. **after the research:** Long-term use of the data Transferring files: .doc to .rtf files; .xls to .cvs files: KU Leuven OneDrive Prof. Dobbels
3. Access to data:
    1. For each research step, we will write protocols where we will specify who will have access to which data and why.
        1. Literature Reviews: all have access as no personal or sensitive data is collected
        2. Primary data collection (e.g., survey, focus groups, Delphi study): data access will be specified in protocols and listed in data exchange agreement plans.

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)

- Data storage: we will use the secured platforms of the KU Leuven (i.e., OneDrive).

- Data anonymization: we will pseudo-anonymize or anonymize sensitive or personal data. Code lists and informed consents will be stored separately and limited access will be provided to the PI (Prof. Dobbels) and project manager.

- Data access: As mentioned previously, we will write protocols for all research steps hereby specifying who will have access to which data and why. This will be reviewed by GDPR experts.

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

NA

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DPIA

DPIA

Have you performed a DPIA for the personal data processing activities for this project?

Question not answered.

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GDPR

GDPR

Have you registered personal data processing activities for this project?

- Yes