Plan Overview

A Data Management Plan created using DMPonline.be

Title: The Changing Landscape in the Assessment of Steroid Hormone concentrations: is it time to set them free? (CLASH-free)

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Template: KU Leuven BOF-IOF

Project abstract:

In circulation, steroid hormones (such as testosterone or vitamin D) bind to specific binding proteins and albumin, with only a small fraction circulating freely. The ‘free hormone hypothesis’ suggests that this free fraction is mainly responsible for biological activity. Though experimental and clinical data support this, routinely available methods measure total hormone levels, which could lead to incorrect diagnosis and treatment, especially in conditions with altered binding protein production (e.g. obesity, pregnancy). Direct free hormone measurements are not available in clinical routine. With CLASH-free, we aim to improve the clinical applicability of free steroid hormones by using state-of-the-art methods. We will develop methods for direct free steroid hormone measurements. We will investigate how changes in binding proteins affect total and free hormone levels. Finally, we will study the interplay between free steroid hormone concentrations and health parameters.

ID: 212047

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The Changing Landscape in the Assessment of Steroid Hormone concentrations: is it time to set them free? (CLASH-free)

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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware **O**ther (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
FREEDOM	s67385	N	D	N/T	Redcap	<1GB	
EMAS	s19410/ML1903	E	D	N/T	Stata	<1GB	
UK Biobank	UK Biobank	E	D	N/T	web-based	NA	

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:

A copy of the EMAS dataset was made available by prof. Wu from the University of Manchester.
UK Biobank: https://www.ukbiobank.ac.uk/

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

FREEDOM: approval S67385
EMAS: EC approval S19410/ML1903 and approved via PRET KULeuven (G-2021-3841)

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

FREEDOM: approval S67385
EMAS: EC approval S19410/ML1903 and approved via PRET KULeuven (G-2021-3841)

Types of personal data:
- Human serum samples

- Information on health status obtained by surveys and questionnaires
- Information on use of drugs and supplements obtained by interviewer-assisted questionnaires
- Anthropometric data (height, weight, BMI, ...)
- Body composition and bone density data (measured by dual X-ray absorptiometry)
All personal data will be pseudonymised. UZ Leuven EC research GDPR questionnaire has been completed.

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 or 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.

- Yes

EMAS: Collaboration with University of Manchester, for which there is a signed data transfer agreement.
UK Biobank: I am a registered user, application for data access for this project still has to be completed.

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

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).

The FREEDOM datasets will be accompanied by a file (text or spreadsheet) explaining variable names and coding of categorical variables.
For EMAS, this is already available.
Statistical analysis will be done by using scripts (file type depending on the statistical package used).

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Descriptive metadata will be created for the FREEDOM dataset.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- Personal network drive (I-drive)
- OneDrive (KU Leuven)

Data will be stored on KULeuven secure internal servers, with automatic back-ups.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Automatic back-ups provided by KULeuven.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

KULeuven secure internal servers.

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

Data access will be limited to staff directly working on this project and will be password protected (multifactor authentication, provided by KULeuven).

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

€ 450/TB/year, covered by project funding.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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 will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans

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

- Shared network drive (J-drive)
- Large Volume Storage (longterm for large volumes)

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

€95/TB/year, covered by project funding.

Data Sharing and Reuse

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

- Yes, as restricted data (upon approval, or institutional access only)

As it is human personal data/patient data, only available after approval.

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

As it is human personal data/patient data, only available after approval and with data sharing agreements approved by LRD KULeuven.

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 per dataset or data type where appropriate.

- Yes, privacy aspects
- Yes, ethical aspects

Human personal data/patient data

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

KU Leuven RDR

When will the data be made available?

- Upon publication of research results

Upon publication of research results.

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

Depending on the data sharing agreement as approved by LRD KULeuven.

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

TBD

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

To be determined

Responsibilities

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

Leen Antonio

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

Leen Antonio

Who will manage data preservation and sharing?

Leen Antonio

Who will update and implement this DMP?

Leen Antonio