Development and validation of affordable analytical methods for the quality control of antimicrobial and antihypertensive medicines

A Data Management Plan created using DMPonline.be

Creator: Erwin Adams https://orcid.org/0000-0002-4545-2989

Affiliation: KU Leuven (KUL)

Funder: KU Leuven (KUL)

Template: KU Leuven BOF-IOF

Principal Investigator: Erwin Adams https://orcid.org/0000-0002-4545-2989, Haile Kassahun Desta

Grant number / URL: ZB/22/036

ID: 206064

Start date: 01-01-2024

End date: 31-12-2027

Project abstract:

The quality of drugs is an important aspect in the framework of public health. However, developing countries like Ethiopia face regularly fraudulent practices and together with a lack of resources and well trained analysts, good quality drugs can not be guaranteed. Consequently, more control is necessary. This requires the availability of (relatively) affordable analytical methods. Since these are not always available, this project will mainly focus on their development and validation for antimicrobial and antihypertensive medicines because these are most prone to counterfeiting. For the most important ones, screening methods for identification and assay will be presented using liquid and gas chromatography.

Last modified: 06-05-2024

Development and validation of affordable analytical methods for the quality control of antimicrobial and antihypertensive medicines

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
HPLC measurements	chromatograms raw data	new	digital	images numerical textual	.dat .txt .csv .xlsx .pdf	<100 GB	
lab notes	experimental data (e.g. weights), observations, calculations, results,... written in notebooks	new	physical				5-10 notebooks
samples and reference substances	samples and references used in experiments	new	physical				20 dm^3
literature and experimental data	literature overview, protocols, processed data (e.g. validation)	new	digital	figures images tables calculations text	.docx .xlsx .pdf .tif .jpg .dat .csv	<100 GB	
dissemination	drafts, revision, final version of research articles, presentations	new	digital	figures tables text slides	.docx .pdf .ppt	<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:

No existing data will be used (except literature that will be consulted).

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.

- No

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).

- No

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.

- 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

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 research will be divided into work packages. An overview will be provided in the documentation. Collected data will be attributed to the different work packages and properly labelled for each experiment. It will contain a description of the experimental parameters, sample name, concentration, etc.
Processed data, calculation sheets, reports, presentations,... will be stored in KU Leuven OneDrive with regular back-ups. Information can be shared with interested parties upon request.
Experimental raw data will be stored on the respective equipment computer.

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

Data sets will be stored in a structured way, related to the work packages.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- OneDrive (KU Leuven)
- Other (specify below)

Accepted versions of articles will be deposited in Lirias.

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution
- Other (specify below)

Physical samples are stored in boxes in the lab.

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

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

According to the policy, each PC requires a username and password. So, unauthorized users can't access or change the data.

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

Using KU Leuven's OneDrive to store data does not involve additional costs.

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 10 years according to KU Leuven RDM policy

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

- Other (specify below)

KU Leuven's OneDrive.
At the end of the project, all relevant data will be transferred to a portable drive that will be stored by the supervisor.

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

There will be no additional costs.

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)

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

The most important findings will be summarized in papers which will be published in peer-reviewed journals that can be consulted by other researchers having access to those. More data can be made available upon reasonable request.
Publications are also stored on the Lirias platform of KU Leuven.

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.

- No

Where will the data be made available?

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

- Other (specify below)

It is common to publish the most relevant additional data as supplementary material.

When will the data be made available?

- Upon publication of research results

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)

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.

- No

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

No additional costs are expected.

Responsibilities

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

Haile Kassahun

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

Haile Kassahun

Who will manage data preservation and sharing?

Erwin Adams

Who will update and implement this DMP?

Haile Kassahun