STRADACEF

A Data Management Plan created using DMPonline.be

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Template: FWO DMP (Flemish Standard DMP)

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Project abstract:

The general objective of the STRADA-CEF trial is to perform a randomised controlled trial (RCT) investigating the clinical benefit of stratified every 24-hour (q24h) vs. q12h 2g ceftriaxone therapy in patients with severe community-acquired pneumonia (sCAP) based on the predicted probability of augmented renal clearance on the next day (P*ARC*).

Patients: patients admitted to the intensive care unit (ICU) and treated with ceftriaxone for sCAP.

Intervention: dose stratification for ceftriaxone from 2g q24h to 2g q12h based on daily assessment of P *ARC*.

Comparison: patients receiving the standard-of-care 2g q24h ceftriaxone dose regimen, regardless of P*ARC*.

Outcome: reduction of the ICU length of stay.

In a population PK and exposure-response (i.e., efficacy and safety) analysis and pharmaco-economic analysis , the dose-exposure-(biomarker-)response-cost relationship of ceftriaxone will be investigated, providing more insight into the study results. Finally, all results will be disseminated to the relevant stakeholders to facilitate and promote implementation of this simple dose stratification strategy in daily clinical practice.

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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	
STRADACEF_REDCAP	Experimental and quantative data of the participants	New	Digital	Observational and experimental	.xml	<100GB	
STRADACEF_Bio	Biological material from the patients	New	Physical				1500 samples
STRADACEF_stat	Statistical data	New	Digital	Other	.csv	<1GB	
STRADACEF_mod	Statistical models created from data	New	Digital	Simulation	.mod	<1GB	

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:

Not applicable

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

The STRADACEF_REDCAP dataset contains personal data from the patients such as age, sex, medical history, biochemical data. This data is considered sensitive and must therefore be handled accordingly as to not raise ethical concerns. All data will be pseudonymised at the level of participating centres.
Informed consent will be asked from the patients, guardian, or relatives upon inclusion in the trial.

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

The STRADACEF_REDCAP dataset will contain personal data, such as age, sex, medical history, and biochemical data, which will be used for descriptive statistics as well as for the creation of a predictive model.

Data will not contain person-identifiable information and will be pseudonymised.

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).

Data will be collected in a common electronic CRF, each participating centre will have access to the eCRF files of their patients. Only the coordinating investigators will have access to all patient eCRF files.
Samples will be collected by local staff at participating centres, and shipped every 6 months to the coordinating centre. Samples will be linked to patient data (from STRADACEF_REDCAP) using QR-coded sample vials.
Statistical and model data will be created within specific software, e.g. R, NONNEM. The statistical code will contain in-file documentation to clarify the statistical analysis.

For all datasets, README.txt files will be made to make the information in each dataset explicit and understandable to third parties.

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

We will export a metadata survey from REDCAP providing an overview of all contained data within REDCAP.
All sampling moments will also be collected in REDCAP and therefore also be available from the metadata survey.

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

Where will the data be stored?

During the project all patient information will be stored in REDCAP, which is stored on a UZ Leuven server. The REDCAP database will be locked after completion of the study.
After the study all processed data will be stored in a password protected folder on a server at UZ Leuven and KU Leuven.
Biological data will be stored in the UZ Leuven Biobank.

How will the data be backed up?

The UZ/KU Leuven servers provide automatic back-ups.
We will regularly, i.e. monthly, back-up the data from REDCAP by using the integrated back-up function.
Samples will be divided in three aliquots.

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

The UZ/KU Leuven server provides amply enough storage space and back-up capacity for all our data. We anticipate a data volume of no more than 10 GB which amply fits the storage space.

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

The data folders will be password protected. The biobank is only accessible for members of the research team with an authorisation.
Only members of the research team will have access to these folders and to the biobank.

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

The cost for REDCAP (€ 80/year) has been included in the FWO/TBM funding application.
REDCAP is provided by UZ/KU Leuven, and the costs (approximately € 29.000) for support by the clinical trial centre of UZ Leuven for eCRF design and validation, and access and data management are covered by the FWO/TBM funding.

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...).

In accordance with the KU Leuven research data management data policy, all data will be retained for a period of minimum 10 years after the end of the project in a safe, secure, and sustainable way for the purposes of reproducibility, verification, and potential reuse. All this will be done in accordance with the General Data Protection Regulation.

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

After the study all processed data will be stored in a password protected folder on a server at UZ Leuven and KU Leuven.
Biological data will be stored in the UZ Leuven Biobank.

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

Storage on the UZ/KU Leuven folder is provided by the organisation.
Storage in the UZ Leuven Biobank will approximately cost € 1000/year.

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, …)

Data will be stored on our internal servers and will be made available to (internal or external) third parties upon reasonable request and after ethical approval.
Biological samples for which after the completion of the study aliquots are left, can be made available to (internal or external) third parties upon reasonable request and after ethical approval.

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

Research team members will have access to the data and will provide a copy to authorized third parties after ethical approval and data transfer agreement.

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.

- Yes, Ethical aspects

For ethical concerns, as mentioned in part 1, patient data contains no person-identifiable information and will be pseudonymised.
Data or biological samples will only be shared after ethical approval.

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

Data will not be made publicly available.

When will the data be made available?

N/A

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

Upon sharing data with third parties, a data transfer agreement will be drafted and signed by all involved parties.

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?

N/A

6. Responsibilities

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

Isabel Spriet, Matthias Gijsen, and Dorian Vanneste

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

Isabel Spriet, Matthias Gijsen, and Dorian Vanneste

Who will manage data preservation and sharing?

Isabel Spriet

Who will update and implement this DMP?

Isabel Spriet, Matthias Gijsen and Dorian Vanneste