FWO DMP Template - Flemish Standard Data Management Plan

Version KU Leuven

Project supervisors (from application round 2018 onwards) and fellows (from application round 2020 onwards) will, upon being awarded their project or fellowship, be invited to develop their answers to the data management related questions into a DMP. The FWO expects a **completed DMP no later than 6 months after the official start date** of the project or fellowship. The DMP should not be submitted to FWO but to the research co-ordination office of the host institute; FWO may request the DMP in a random check.

At the end of the project, the **final version of the DMP** has to be added to the final report of the project; this should be submitted to FWO by the supervisor-spokesperson through FWO's e-portal. This DMP may of course have been updated since its first version. The DMP is an element in the final evaluation of the project by the relevant expert panel. Both the DMP submitted within the first 6 months after the start date and the final DMP may use this template.

The DMP template used by the Research Foundation Flanders (FWO) corresponds with the Flemish Standard Data Management Plan. This Flemish Standard DMP was developed by the Flemish Research Data Network (FRDN) Task Force DMP which comprises representatives of all Flemish funders and research institutions. This is a standardized DMP template based on the previous FWO template that contains the core requirements for data management planning. To increase understanding and facilitate completion of the DMP, a standardized **glossary** of definitions and abbreviations is available via the following link.

1. General Project Information	
Name Grant Holder & ORCID	**Robin Lemmens.** 0000-0002-4948-5956
Contributor name(s) (+ ORCID) & roles	**Anke Wouters** investigator. 0000-0001-5229-2699 **Annemie Devroye** research nurse
Project number [1] & title	S70315
Funder(s) GrantID [2]	TBM- T000325N
Affiliation(s)	X KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other: ROR identifier KU Leuven: 05f950310

[1] "Project number" refers to the institutional project number. This question is optional. Applicants can only provide one project number.

[2] Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

Please provide a short project description	**Background** Non-traumatic intracerebral haemorrhage (ICH) is a devastating cardiovascular disease that causes 48% of years of disability-adjusted life years due to stroke. ICH survivors are at 7-19% annual risk of further major adverse cardiovascular events (MACE, i.e. stroke [ischaemic or ICH], myocardial infarction, or cardiovascular death [by ischaemia, bleeding or other vascular causes]). **Aim:** We seek definitive evidence for the superiority of antiplatelet monotherapy to prevent MACE for any ICH survivor in five countries in a pragmatic, randomised, open-label, phase 3, international clinical trial. **Patients:** ASPIRING will recruit participants aged ≥18 years who have not started antiplatelet/anticoagulant therapy after ICH in the UK (n=2,828), Canada (n=440), Australia (n=300), The Netherlands (n=356), and Belgium(n=240). **Intervention:** Antiplatelet monotherapy available in standard clinical practice (e.g. aspirin) without concomitant therapeutic dose anticoagulation. **Comparator:** Avoidance of antiplatelet therapy. Patients will be randomized by a secure, concealed, web-based computerised randomisation (with minimisation involving baseline prognostic factors) to allocate participants 1:1 to intervention or comparator. **Primary Outcome:** MACE: o Hospitalisation due to any stroke o Hospitalisation due to myocardial infarction o Cardiovascular death (including deaths of unknown cause) **Impact and dissemination:** ASPIRING will provide level A evidence for guidelines.

2. 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 [3].

				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
ASPIRING eCRF	Clinical data of patients included in the ASPIRING study.	☒ Generate new data ☐ Reuse existing data	☒ Digital ☐ Physical	☐ Audiovisual ☐ Images ☐ Sound ☒ Numerical ☒ Textual ☐ Model ☐ Software ☐ Other:		☐ < 1 GB ☒ < 100 GB ☐ < 1 TB ☐ < 5 TB ☐ > 5 TB ☐ NA	

Guidance:
The data description forms the basis of your entire DMP, so make sure it is detailed and complete. It includes digital and physical data and encompasses the whole spectrum ranging from raw data to processed and analysed data including analysis scripts and code. Physical data are all materials that need proper management because they are valuable, difficult to replace and/or ethical issues are associated. Materials that are not considered data in an RDM context include your own manuscripts, theses and presentations; documentation is an integral part of your datasets and should described under documentation/metadata.
RDM Guidance on data

[3] Add rows for each dataset you want to describe.

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.	
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: EC approval is happening via CTIS and currently pending. ☐ Yes, animal data; provide ECD reference number: ☐ Yes, dual use; provide approval number: ☐ No Additional information:
Will you process personal data[4]? 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) ☐ No Additional information: S70315
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.	☐ Yes ☒ No If yes, please comment:
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 to what data they relate and what restrictions are in place.	☒ Yes ☐ No If yes, please explain: All data will be collected in Edinburgh as described in the project. A data transfer agreement will be signed.

[4] See Glossary Flemish Standard Data Management Plan

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 to what data they relate and which restrictions will be asserted.	☐ Yes ☒ No If yes, please explain:

3. 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). *RDM guidance on documentation and metadata*.	Study data will be collected via direct entry to an eCRF. A bespoke eCRF has been developed by the Chief Investigator and ECTU for this purpose, as per ECTU Data Management and IT SOPs. The eCRF was designed, reviewed, and approved by the CI, Trial Managers, Senior Software Developer, Trial Statistician, Trial Monitor, and Data Manager. The database specification documentation (including Training and Description document, Validation Plan and Validation Document) was prepared by the Senior Software Developer and signed by the Trial Manager or designee. Final approval of the CRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007). Amendments to the live eCRF will follow the ECTU Data Management and IT additional requirements process, and the process defined in ACCORD SOP CR013. Changes to the dataset must be reviewed and approved by the Trial Manager or designee, Trial Statistician or designee and Trial Monitor. Minor administrative changes (e.g. spelling, formatting) that do not impact on how the data is collected do not require formal approval by the Trial Statistician or designee. Final approval of the eCRF prior to initial release is granted by the Trial Manager or designee and Sponsor representative (as per ACCORD Policy POL007).

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. *REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.*	☐ Yes ☒ No If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used: If no, please specify (where appropriate per dataset or data type) which metadata will be created: No specific standard will be used.

4. Data Storage & Back-up during the Research Project	
Where will the data be stored? *Consult the interactive KU Leuven storage guide to find the most suitable storage solution for your data.*	☐ Shared network drive (J-drive) ☐ Personal network drive (I-drive) ☐ Teams ☐ Sharepoint online ☐ Sharepoint on-premis ☐ Large Volume Storage ☐ ManGO ☐ Digital vault ☒ Other: eCRF
How will the data be backed up? *WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS?*	☐ Standard back-up provided by KU Leuven ICTS for my storage solution ☐ Personal back-ups I make (specify) ☒ Other (specify) Servers in Edinburgh with standard back-up procedures**.**

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 ☐ No If no, please specify:
How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons? *CLEARLY DESCRIBE THE MEASURES (IN TERMS OF PHYSICAL SECURITY, NETWORK SECURITY, AND SECURITY OF COMPUTER SYSTEMS AND FILES) THAT WILL BE TAKEN TO ENSURE THAT STORED AND TRANSFERRED DATA ARE SAFE.* *Guidance on security for research data*	Initial database training will be provided via web-based investigator training and any remaining questions addressed at each site's SIV. Ongoing database training (post-SIV) for new study staff at site will be provided via web-based investigator training with further support delegated to the local PI. All users must review the training material and access the training system before access to the live database is provided. The Trial Manager or designee will be responsible for granting access to the study databases (training and live) thereafter. Prospective users must complete a User Access Form and return signed and dated to the Trial Manager or designee. Once approved, access will be granted to the live system. All users will be assigned a unique username, and the site(s) at which they currently work specified, and access to the system is role based and password controlled. Sites will be instructed to contact the Trial Office if user details change or to remove access when no longer working on the study. The Trial Manager or designee will review the user list periodically (approximately every 6 months) and liaise with sites to remove user access where appropriate. An overview of the user roles and their associated access rights are described in Appendix B. Read-only access to the live system will be granted to the ACCORD study monitor and ACCORD QA Coordinator. Additional read-only access for Inspectors/Auditors can be granted on request by contacting the Data Management Team
What are the expected costs for data storage and backup during the research project? How will these costs be covered?	NA

5. 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...). *Guidance on data preservation*	☐ All data will be preserved for 10 years according to KU Leuven RDM policy ☒ 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 ☐ Certain data cannot be kept for 10 years (explain)
Where will these data be archived (stored and curated for the long-term)? *Dedicated data repositories are often the best place to preserve your data. Data not suitable for preservation in a repository can be stored using a KU Leuven storage solution, consult the interactive KU Leuven storage guide.*	☐ KU Leuven RDR ☐ Large Volume Storage (longterm for large volumes) ☐ Shared network drive (J-drive) ☒ Other (specifiy): The trial data will be stored and archived on secure servers at the University of Edinburgh, which use strict user authentication procedures, encryption, and adherence to institutional Information Governance standards.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	**NA**

6. 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. *NOTE THAT 'AVAILABLE' DOES NOT NECESSARILY MEAN THAT THE DATA SET BECOMES OPENLY AVAILABLE, CONDITIONS FOR ACCESS AND USE MAY APPLY. AVAILABILITY IN THIS QUESTION THUS ENTAILS BOTH OPEN & RESTRICTED ACCESS. FOR MORE INFORMATION: HTTPS://WIKI.SURFNET.NL/DISPLAY/STANDARDS/INFO-EU-REPO/#INFOEUREPO-ACCESSRIGHTS*	☐ Yes, as open data ☐ Yes, as embargoed data (temporary restriction) ☒ Yes, as restricted data (upon approval, or institutional access only) ☐ No (closed access) ☐ Other, please specify: A de-identified version of the entire trial datasetused for analysis with individual participant data and a data dictionary will be available for other researchers to apply to use 1 year after publication. Researchers will be able to apply for the trial data via Edinburgh DataShare.
If access is restricted, please specify who will be able to access the data and under what conditions.	
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, intellectual property rights ☐ Yes, ethical aspects ☐ Yes, aspects of dual use ☐ Yes, other ☒ No If yes, please specify:
Where will the data be made available? If already known, please provide a repository per dataset or data type.	☐ KU Leuven RDR ☐ Other data repository (specify) ☒ Other (specify) Edinburgh DataShare

When will the data be made available?	☒ Upon publication of research results ☐ Specific date (specify) ☐ Other (specify)
Which data usage licenses are you going to provide? If none, please explain why. *A DATA USAGE LICENSE INDICATES WHETHER THE DATA CAN BE REUSED OR NOT AND UNDER WHAT CONDITIONS. IF NO LICENCE IS GRANTED, THE DATA ARE IN A GREY ZONE AND CANNOT BE LEGALLY REUSED. DO NOTE THAT YOU MAY ONLY RELEASE DATA UNDER A LICENCE CHOSEN BY YOURSELF IF IT DOES NOT ALREADY FALL UNDER ANOTHER LICENCE THAT MIGHT PROHIBIT THAT.* *Check the RDR guidance on licences for data and software sources code or consult the License selector tool to help you choose.*	☐ CC-BY 4.0 (data) ☒ Data Transfer Agreement (restricted data) ☐ MIT licence (code) ☐ GNU GPL-3.0 (code) ☐ Other (specify)
Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here. *INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.*	☐ Yes, a PID will be added upon deposit in a data repository ☐ My dataset already has a PID ☒ No
What are the expected costs for data sharing? How will these costs be covered?	**NA**

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	**Trial manager from Edinburgh: Lauren Craig.**

Who will manage data storage and backup during the research project?	**Data manager from Edinburgh: Han Xiao**
Who will manage data preservation and sharing?	**Data manager from Edinburgh: Han Xiao**
Who will update and implement this DMP?	**Anke Wouters**