KU LEUVEN BOF-IOF

It is advised to use DMPonline.be to complete this template, as it provides KU Leuven guidance.

A. RESEARCH DATA SUMMARY

1. **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 Other (specify)		*Indicate:* < 1 GB < 100 GB < 1 TB < 5 TB > 5 TB NA	
WP1: demographics	180 healthy older adults (65-80 years) & 60 young adults (20-30 years, 50% ♀)	New	Digital	Numerical	xlsx	< 1 GB	
WP1: F-v profiling	Data of 180 + 60 participants (all baseline, 72 also mid- and post-intervention test)	New	Digital	Numerical	xlsx TDMS txt	< 100 GB	
WP1: training data	Data of 72 participants, 24 training sessions	New	Physical	Numerical			3 pages per person, 216 pages
WP1: training data	Data of 72 participants, 24 training sessions	New	Digital	Numerical	xlsx	< 1GB	
WP1: adherence	Data of 72 participants, 24 training sessions	New	Digital	Numerical	xlsx	< 1GB	
WP1: adverse events	Adverse events recording throughout intervention period	New	Digital	Numerical Textual	xlsx	< 1GB	
WP1: functional ability	10mFW, CMJ, TUG, 5xSTS & SA	New	Digital	Numerical	xlsx JSON	< 100 GB	

	for 72 participants (baseline, mid- and post-intervention test)				OMX		
WP1: scripts	Data processing & analyses scripts in Matlab	New	Digital	Compiled		< 1GB	
WP2: demographics	160 healthy older adults (65-80 years)	New	Digital	Numerical	xlsx	< 1 GB	
WP2: F-v profiling	160 healthy older adults (65-80 years), baseline, mid- and post-intervention	New	Digital	Numerical	xlsx TDMS txt	< 100 GB	
WP2a&b: functional ability	160 healthy older adults (65-80 years), 10mFW, CMJ, TUG, 5xSTS & SA (baseline, mid- and post-intervention test)	New	Digital	Numerical	xlsx JSON OMX	< 100 GB	
WP2: training data	Data of 120 participants, 24 training sessions	New	Physical	Numerical			3 pages per person, 360 pages
WP2: training data	Data of 120 participants, 24 training sessions	New	Digital	Numerical	xlsx	< 1GB	
WP2a&b: adverse events	Adverse events recording throughout intervention period	New	Digital	Numerical Textual	xlsx	< 1GB	
WP2a&b: scripts	Data processing & analyses scripts in Matlab	New	Digital	Compiled		< 1GB	
WP2c: questionnaires	Filled in questionnaires (after two weeks of training, post-intervention and at 12- and 24-week follow-up)	New	Digital	Numerical Textual		< 1GB	
WP2c: logbook	Patient exercise logbook	New	Physical	Numerical Textual			6 pages per person, 960 pages

2. **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:**

Specify: NA

3. **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)
☐ Yes, animal data (Provide ECD reference number below)
☐ Yes, dual use (Provide approval number below)
☐ No

Additional information: Ethical approval will be requested within 6 months from the start of the study. The approval number will be added to this DMP at a later stage.

4. **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)
☐ No

Additional information:

- Personal data for organizing the research: name, address, e-mail, phone number. This data will not be included in the analyses and will be stored separately from the research data.

- Personal data for research purposes (both WP1 & 2): age, sex, education, nationality, profession, height, body mass, medical history. These data will be pseudonymized during data collection.

- PRET for WP1 is approved (G-2023-7288), the approval number for WP2 will be added at a later stage.

5. **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

Additional information:

6. **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
☒ No

Additional information:

7. **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.**

☐ Yes
☒ No

Additional information:

B. DOCUMENTATION AND METADATA

8. **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).**

   Description:

   - At project level

     o A README file will be provided for each of the WPs separately. We will use KU Leuven's template.

     o For each WP, a detailed protocol is provided, including the research methods, practices, instructions given to participants and questionnaires. This will be provided in a .pdf format.

   - At data level

     o For each work package, a standardized case report form (CRF) will be completed during data collection, containing researchers notes, remarks concerning data quality, contextual information, deviations from the protocol, etc. These CRFs will be kept online, using REDCap.

     o For each work package, a user guide on data processing & handling will be provided as a .pdf file.

     o For each work package, a data dictionary will be provided (either in the same file, or provided in the same folder) as a .csv file.

9. **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.**

   ☒ Yes
   ☐ No

   Additional information:

   - At project level: the RDR metadata standard, i.e. DataCite, will be followed.

C. DATA STORAGE & BACK-UP DURING THE RESEARCH PROJECT

10. **Where will the data be stored?**

☐ ManGO
☐ Shared network drive (J-drive)
☐ Personal network drive (I-drive)
☒ OneDrive (KU Leuven)
☐ Sharepoint online
☐ Sharepoint on-premis
☒ Large Volume Storage
☐ Digital Vault
☒ Other (specify below)

Additional information: REDCap; on paper

11. **How will the data be backed up?**

☒ Standard back-up provided by KU Leuven ICTS for my storage solution
☒ Personal back-ups I make (specify below)
☐ Other (specify below)

Additional information: FreeFileSync for synchronization between OneDrive & KU Leuven network drive

12. **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
☐ No (explain solution below)

Additional information:

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

Response:

- **KU Leuven network drive, specifically J/L-drive**. The KU Leuven network drives are incorporated within secured KU Leuven environments, are password-protected (including smartphone-based multi-factor identification) and are only accessible by registered collaborating researchers. Only the PI can request access to the network drive for study personnel.

- **REDCap**. When using KU Leuven REDCap, physical access to the data centers is logged and restricted to authorized KU Leuven Information Technology (IT) personnel, using badge identification. At the clinical database level only study team members, monitors and auditors/inspectors for whom the Coordinating or Principal Investigator (as applicable) has requested project-specific access, are granted data access. Upon successful training completion each user is centrally assigned a user role, associated with predefined system/data privileges, in accordance with CR DM-WI-001. The gatekeeper for UZL REDCap is UZL CTC (ctc.datamanagement@uzleuven.be).

- **OneDrive**. Multifactor authentication with the KU Leuven authenticator app can be activated to ensure the safe storage of strictly confidential data. Only the PI can provide access to the OneDrive for study personnel.

- **On paper**: Data collected on paper (e.g. informed consents) will be stored in a locked cabinet in a locked room at the Department of Movement Sciences. During data collection the cabinet will

only be accessible to study personnel. Informed consent forms will be stored separately from research data.

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

    Response:

    - **KU Leuven network drive, specifically L-drive**: The Department of Movement Sciences provides an L-drive of 5 TB for our research group and costs (€ 522.1/5TB/year) will be carried by the department. At the moment, 4.9 TB is available, thereby covering the project of ± 25GB.

    - **REDCap**. €80/project/year

    - **OneDrive**. The use of OneDrive for Business is free for KU Leuven personnel and students.

D. DATA PRESERVATION AFTER THE END OF THE RESEARCH PROJECT

15. **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
    ☒ 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 below).

    Additional information:

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

    ☒ Large Volume Storage (long term for large volumes)
    ☐ Shared network drive (J-drive)
    ☐ KU Leuven RDR
    ☐ Other (specify below)

    Additional information:

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

    Response: € 11.38/100GB/year, from which 50% of the costs are covered by the Group Biomedical Sciences. Given the expected size of the project of 25 GB and the minimum purchase of 100GB storage, costs for long-term storage are estimated at € 11.38/year. The costs will be carried for 50% by the project and 50% by the Group of Biomedical Sciences.

E. DATA SHARING AND REUSE

18. **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 open data
    ☐ Yes, as embargoed data (temporary restriction)
    ☒ Yes, as restricted data (upon approval, or institutional access only)
    ☐ No (closed access)
    ☐ Other (specify below)

    Additional information:

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

    Response: The minimal requirement is approval of an ethical committee for the project that wants to re-use the data.

20. **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

    Additional information:

21. **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)
    ☐ Other data repository (specify below)
    ☐ Other (specify below)

    Additional information:

22. **When will the data be made available?**

    ☒ Upon publication of research results
    ☐ Specific date (specify below)
    ☐ Other (specify below)

    Additional information:

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

    ☐ CC-BY 4.0 (data)
    ☒ Data Transfer Agreement (restricted data)
    ☐ MIT license (code)
    ☐ GNU GPL-3.0 (code)
    ☐ Other (specify below)

    Additional information:

24. **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
    ☐ Yes, my dataset already has a PID
    ☐ No

    Additional information:

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

    Response: RDR is free for KU Leuven personnel, hence, no costs are expected for data sharing.

F. RESPONSIBILITIES

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

    Response: The PhD researcher (Jolien Deboutte) and postdoctoral researcher (Evelien Van Roie) will be responsible for data documentation & metadata, under supervision of the PI (Christophe Delecluse).

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

    Response: Data management, storage and back up will be performed by the PhD researcher (Jolien Deboutte) and postdoctoral researcher (Evelien Van Roie), under supervision of the PI (Christophe Delecluse).

28. **Who will manage data preservation and sharing?**

    Response: The PI (Christophe Delecluse) will be responsible for ensuring data preservation and sharing.

29. **Who will update and implement this DMP?**

    Response: The PhD researcher (Jolien Deboutte) and postdoctoral researcher (Evelien Van Roie) will be responsible for updating this DMP. The PI (Christophe Delecluse) bears the end responsibility for updating and implementing this DMP.