FWO DMP Template - Flemish Standard Data Management Plan

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	Ineke Verreydt - 0000-0001-6575-440X
Contributor name(s) (+ ORCID) & roles	Kaat Desloovere – 0000-0002-8507-5276 - Supervisor
	Daisy Rymen – 0000-0002-6409-5868 – Co-supervisor
	Anja Van Campenhout – 0000-0002-8158-5535 – Co-supervisor
	Els Ortibus – 0000-0002-1020-4408 – Co-supervisor
Project number ¹ & title	1131223N - Influencing factors on impaired muscle growth in children with cerebral palsy: a pathway to
	improved treatment paradigms
Funder(s) GrantID ²	D-2023-1884
Affiliation(s)	⊠ KU Leuven
	☐ Universiteit Antwerpen
	☐ Universiteit Gent
	☐ Universiteit Hasselt
	☐ Vrije Universiteit Brussel
	☐ Other:
	Provide ROR3 identifier when possible: https://ror.org/05f950310

¹ "Project number" refers to the institutional project number. This question is optional since not every institution has an internal project number different from the GrantID. 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.

³ Research Organization Registry Community. https://ror.org/

Please provide a short project description

Impaired muscle growth has a major impact on quality of life in children with cerebral palsy (CP). However, optimal treatment of intrinsic muscle impairment is hindered by insufficient understanding of its pathogenesis. To enhance muscle growth in CP, individualized treatment plans that include all influencing factors on muscle growth are needed. Yet, longitudinal studies investigating both muscle growth and influencing factors in one cohort are lacking. We aim to unravel potential influencing factors on altered muscle growth, by studying intrinsic muscle impairments in relation to neuromuscular symptoms, physical activity, nutrition and treatment, and by launching pathways for optimized treatment. A first part involves longitudinal assessments of intrinsic muscle impairment using muscle imaging, combined with measures of neuro-muscular symptoms (spasticity, strength, gait), physical activity trackers, food diaries and treatment history in growing CP children. This multidimensional dataset creates the opportunity to perform unique data integration to delineate potential mechanisms to impaired muscle growth. In a second part, we will investigate the effect of a novel multicomponent intervention to accelerate recovery of reduced muscle growth induced by spasticity treatment, by combining strength training with nutritional supplements in a randomized controlled trial. This project will pave way for optimized treatments, ultimately leading to improved motor functioning.

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 data⁴.

				ONLY FOR DIGITAL DATA	ONLY FOR DIGITAL DATA	ONLY FOR DIGITAL DATA	ONLY FOR PHYSICAL DATA
Dataset	Description	New or	Digital or	Digital Data Type	Digital Data	Digital Data	Physical Volume
Name		Reused	Physical		Format	Volume (MB, GB,	
						TB)	
ICF	Informed consent forms	⊠ Generate	□ Digital	\square Observational	☐ .por	⊠ < 100 MB	Printed papers (1
		new data	oxtimes Physical	\square Experimental	☐ .xml	□ < 1 GB	large ring binder)
		☐ Reuse		\square Compiled/	☐ .tab	□ < 100 GB	
		existing data		aggregated data	□ .csv	□ < 1 TB	
				☐ Simulation	□ .pdf	□ < 5 TB	
				data	☐ .txt	□ < 10 TB	
				☐ Software	\square .rtf	□ < 50 TB	
				⊠ Other	\square .dwg	□ > 50 TB	
				□NA	☐ .tab	□NA	
					☐ .gml		
					\square other:		
					□NA		
3DfUS	Three-dimensional	⊠ Generate	□ Digital	□ Observational	⊠ .csv	⊠ < 1 TB	/
	ultrasound data of the	new data		(data images)	\boxtimes other:		
	medial gastrocnemius	⊠ Reuse		Other:	Software specific		
	(muscle morphology and	existing data		numerical	files. Stradwin		
	composition parameters)			software specific	(.sw, .sxi files)		
				data			

⁴ Add rows for each dataset you want to describe.

ISA	Instrumented spasticity assessment of the medial gastrocnemius (muscle activation, joint kinematics and joint torque)	☑ Generate new data	⊠ Digital	☑ Other: numerical software specific data	⋈ .csv⋈ .pdf⋈ .txt	⊠ < 1 GB	/
Clinical_exa mination	Data acquired during the clinical examination (Modified Ashworth and Tardieu scale data of the medial gastrocnemius, Manual muscle testing scale data of the medial gastrocnemius, Anthropometric measurement data (height, weight, leg length, BMI))	⊠ Generate new data	⊠ Digital	□ Observational	☑ .pdf☑ .txt☑ other: .xls	⊠ < 100 MB	/
IWA	Instrumented assessment of muscle strength data of the medial gastrocnemius (maximum voluntary isometric contraction)	⊠ Generate new data	⊠ Digital □ Physical	⊠ Other: Numeric software specific data	☑ .csv☑ other: .xls(Biofet software data)	⊠ < 100 MB	/
3DGA	Three-dimensional gait analysis data (kinematics, kinetics, surface EMG and gait variable score for the ankle)	⊠ Generate new data	⊠ Digital	☑ Other: Numerical software specific data; Movies	⊠ other: .c3d files (vicon software); .avi (video clip)	⊠ < 100 GB	/

PA	ActiGraph wGT3X+BT accelerometer data (counts/min during all assessed min, time (min/day) spent in physical activity class)	⊠ Generate new data	☑ Digital☑ Physical(diaryrecord)	☑ Other: Numerical software specific data	⊠ other: .xls	⊠ < 100 MB	Printed papers (1 small ring binder)
PAQ	Physical activity questionnaire data	⊠ Generate new data	⊠ Digital		⊠ other: .xls	⊠ < 100 MB	/
EFR	3-day estimated food record data (energy intake and percentages)	⊠ Generate new data	⊠ Digital	○ Observational	⊠ other: .xls	⊠ < 100 MB	/
FFQ	Food frequency questionnaire data	□ Generate new data	⊠ Digital		⊠ other: .xls	⊠ < 100 MB	/
Historical_D ata	Treatment history and retrospective data from patient medical record	⊠ Generate new data	⊠ Digital	☑ Other: reports	☑ .pdf☑ other: .xls	⊠ < 100 MB	/
GMFM	Gross motor function measure item set data	⊠ Generate new data	□ Digital		☑ .pdf☑ other: .xls	⊠ < 100 MB	/
Functional_ strength	Lower limb functional strength measure data	☐ Generate new data	⊠ Digital		□ other: .xls	⊠ < 100 MB	/
PEDI-CAT	Pediatric Evaluation of Disability Inventory (PEDI), computer adaptive test (CAT) data	☐ Generate new data	⊠ Digital	□ Observational	⊠ other: .xls	⊠ < 100 MB	/

GUIDANCE:	
DATA CAN BE DIGITAL OR PHYSICAL (FOR EXAMPLE BIOBANK, BIOLOGICAL METHOD.	SAMPLES,). DATA TYPE: DATA ARE OFTEN GROUPED BY TYPE (OBSERVATIONAL, EXPERIMENTAL ETC.), FORMAT AND/OR COLLECTION/GENERATION
	SOR READINGS, SENSORY OBSERVATIONS); EXPERIMENTAL (E.G. MICROSCOPY, SPECTROSCOPY, CHROMATOGRAMS, GENE SEQUENCES); ARIABLES, 3D MODELLING); SIMULATION DATA (E.G. CLIMATE MODELS); SOFTWARE, ETC.
EXAMPLES OF DATA FORMATS: TABULAR DATA (.POR,. SPSS, STRUCTURED DATA, DOCUMENTATION & COMPUTATIONAL SCRIPT.	D TEXT OR MARK-UP FILE XML, .TAB, .CSV), TEXTUAL DATA (.RTF, .XML, .TXT), GEOSPATIAL DATA (.DWG,. GML,), IMAGE DATA, AUDIO DATA, VIDEO
DIGITAL DATA VOLUME: PLEASE ESTIMATE THE UPPER LIMIT OF THE VOLU	IME OF THE DATA PER DATASET OR DATA TYPE.
PHYSICAL VOLUME: PLEASE ESTIMATE THE PHYSICAL VOLUME OF THE RES AFTER).	EARCH MATERIALS (FOR EXAMPLE THE NUMBER OF RELEVANT BIOLOGICAL SAMPLES THAT NEED TO BE STORED AND PRESERVED DURING THE PROJECT AND/OR
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.	Through previous research, we already established a mixed cross-sectional-longitudinal muscle database for the medial gastrocnemius of children with CP, which will be exploited and further developed through the WP1-studies. The current database consists of muscle morphology (volume, Cross-sectional area, length) and composition (echo intensity) properties defined by <u>3DfUS</u> , at multiple time points (2 to 3), over a time period of 12 to 24 months, for a group of 72 children with CP.
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, please describe these issues further and refer to specific datasets or data types when appropriate.	 ✓ Yes, human subject data ☐ Yes, animal data ☐ Yes, dual use ☐ No If yes, please describe: We will conduct research experiments on humans. The study activities of WP1 were approved by the Ethical Committee UZ / KU Leuven (S-number: S62187). For the study activities of WP2, a file will be submitted by the Ethical Committee UZ / KU Leuven in a second phase (in the second PhD year).

⁵ These data are generated by combining multiple existing datasets.

Will you process personal data ⁶ ? If so, briefly describe the kind of personal data you will use. Please refer to specific datasets or data types when appropriate. If available, add the reference to your file in your host institution's privacy register.	□ No
Does your work have potential for commercial valorization (e.g. tech transfer, for example spinoffs, commercial exploitation,)? If so, please comment per dataset or data type where appropriate. 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 comment: ☐ Yes ☑ No If yes, please explain:

⁶ See Glossary Flemish Standard Data Management Plan

Are there any other legal issues, such as	□ Yes
intellectual property rights and ownership, to be	⊠ No
managed related to the data you (re)use?	If yes, please explain:
If so, please explain to what data they relate and	
which restrictions will be asserted.	

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).

All data will be coded.

- Approved Ethical Commission: description of study protocol (.pdf)
- Informed Consents Form: original black copies (.pdf) and signed hardcopies (printed paper)
- Experimental protocols: description how the data are collected and generated (software, materials, set-up, settings (.docx) and how data are processed (software, protocol, guidelines, ...) (.docx, read.me text files)
- Measurement forms: notes during data collection (printed paper) are stored in a locked closet.
- Raw experimental data: storage of folders with original digital data in software-specific files
- Processed data: folder with digital data in the software-specific files, spreadsheets with results (.csv, .xls)
- Patient identifier record: name of included subject, and subject study code (.xls). This patient record file is the only document that provide the link between the study code of the patient and patient's identity. The patient identifier record (PIR) will be stored separately on another location than the subject recruitment files, using the service from UZ Leuven (password protected network location) to keep private data safe and this is supervised by the PI.
- Patient data collection form (printed paper): Data is collected for example, age, weight, height, short overview of assessments, ..) and a subject specific code is added. Printed paper, only with subject specific code, is stored in a locked closet. Because all experimental data are also used for clinical purpose, the metadata are primarily stored in the established clinical databases of the Clinical Motion Analysis Laboratory. Once metadata are extracted for research (for example for data analysis), data files, which only contain the subject specific code, are extracted.

Will a metadata standard be used to make it	☐ Yes
easier to find and reuse the data ?	⊠ No
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.	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:
REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.	At the Clinical Motion Analysis Laboratory, raw experimental data are managed on a lab-specific data management platform for storing metadata, linking with safe storage of software-specific files, keeping track of data use and associated extra processing related to each experimental step, and enabling data query filtering of the collected data. The data management platform generates metadata and this will be done in a uniform and consistent way for all datasets. Metadata will follow Data Cite's recommendations.

	4. Data Storage & Back-up during the Research Project
Where will the data be stored?	Raw and processed digital data will be collected per assessment. Digital data files will be stored on secure KU/UZ Leuven servers and networks (UZ Leuven Drive: UZ/admin/ganglaboresearch). Hard copies of the Informed Consent forms, measurement forms and paper lab notebooks are kept in locked cabinets in the lab of the PIs concerned.

How will the data be backed up? What storage and backup procedures will be in place to prevent data loss? Describe the locations, storage media and procedures that will be used for storing and backing up digital and non-digital data during research. ⁷ Refer to institution-specific policies regarding backup procedures when appropriate.	We will use the back-up facilities of the KU Leuven and UZ Leuven IT services. The KU/UZ Leuven servers and networks are backed up automatically. Digital data that are automatically stored on the acquisition laptop during data collection will be manually transferred via external hard drive to the secure servers.
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.	∀es □ No If yes, please specify concisely: Sufficient storage and backup capacity are provided on the UZ/KU Leuven servers and networks. 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. 7	All printed forms and notebooks are present in the labs, which are secured. The access to the KU Leuven server is u-number and password controlled. Data on the UZ Leuven networks is only accessible for researchers with personalized UZ Leuven login and password, and thus secured by a strict access right management controlled by the PI. Patient record files will be stored with password security only accessible for researchers involved in the projects and controlled by the PI. Patient data can only be accessed by clinicians who are both involved in this project and who are taking care of these patients.

⁷ Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

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

The storage space is provided by KU/UZ Leuven networks. Approximately two terabyte storage is anticipated as a need (approx 200€/terabyte/year). Costs are covered by research budgets (3D-MMAP: "Evaluation of macroscopic muscle properties in infants and young children with cerebral palsy", available left budget of the Clinical Motion Analysis Laboratory (to initiate new storage facilities, as well for external hard drives), and budget from new projects (to sustain novel storage facilities)).

	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).	Raw data will be stored for a 10 year period after the end of the project, in accordance with the KU Leuven guidelines. All processed data will be stored for a 20 year period after the end of the project, in accordance with ethics committee guidelines.
Where will these data be archived (stored and curated for the long-term)?	The digital data will be archived at special space provided by KU/UZ Leuven networks with restricted access, controlled by the PI. Hard copies (eg. the Informed Consent forms, measurement forms and paper lab notebooks) are kept in locked cabinets in the lab of the PIs concerned.
What are the expected costs for data preservation during the expected retention period? How will these costs be covered?	For this project data storage of 1Tb is anticipated, resulting in a cost of approx 200€/terabyte/year. Costs will be covered by research budgets (3D-MMAP: "Evaluation of macroscopic muscle properties in infants and young children with cerebral palsy", available left budget at the KU Leuven (to initiate new storage facilities), and budget from new projects (to sustain novel storage facilities)).

	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.	 ✓ Yes, in an Open Access repository ✓ Yes, in a restricted access repository (after approval, institutional access only,) ☐ No (closed access) ✓ Other, please specify: Upon request by mail
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	During the project as well as after the end of the project, the published data will be available via an open access repository (e.g figshare or KU Leuven specific repositories) and upon request by email. These published data contain the results of processed anonymized data presented in tables. Data to reveal patient-specific reports will be available for clinicians who are treating the study patients and for the patient-specific caregivers in the hospital. Patient-specific data will only be shared ensuring the privacy of the healthy children and patients (e.g. body weight, body length). Decoded personal data will never be shared.
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: IP protection and valorisation initiatives may restrict sharing of the data.

Where will the data be made available? If already known, please provide a repository per dataset or data type.	The main output of the project will be original scientific research papers. These will adhere to KU Leuven's and FWO's Open Access policy. In the context of Open and accessible science, original datasets will be made available with publication, either as supplementary files or using a datasharing platform such as figshare or Znodo using a CC-BY license or KU Leuven specific repositories. Upon reasonable and specific request, any data subset and analysis can be made available. For data transfer filesharing via KU Leuven Box or Belnet transfer (secure) will be used.
When will the data be made available? This could be a specific date (DD/MM/YYYY) or an indication such as 'UPON PUBLICATION OF RESEARCH RESULTS'.	 After an embargo period. Publication of the research results Published data will be made available at the time of publication in case of open access or upon request for other publications. Additional, not-published data will be made available for external users upon request during the post-project trajectory (based on LRD contract).
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. EXAMPLE ANSWER: E.G. "DATA FROM THE PROJECT THAT CAN BE SHARED WILL BE MADE AVAILABLE UNDER A CREATIVE COMMONS ATTRIBUTION LICENSE (CC-BY 4.0), SO THAT USERS HAVE TO GIVE CREDIT TO THE ORIGINAL DATA CREATORS." 8	The main output of the project will be original scientific research papers. These will adhere to KU Leuven's and FWO's Open Access policy. In the context of Open and accessible science, original datasets will be made available with publication, either as supplementary files or using a datasharing platform such as figshare or Znodo using a CC-BY license or KU Leuven specific repositories. Upon reasonable and specific request, any data subset and analysis can be made available. For data transfer filesharing via KU Leuven Box or Belnet transfer (secure) will be used.

⁸ Source: Ghent University Generic DMP Evaluation Rubric: https://osf.io/2z5g3/

Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.	 ☑ Yes☐ NoIf yes: The data will be made available via publications.
INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.	
What are the expected costs for data sharing? How will these costs be covered?	No costs are expected. If any occur, they will be covered by research budgets (3D-MMAP: "Evaluation of macroscopic muscle properties in infants and young children with cerebral palsy", available left budget at the KU Leuven (to initiate new storage facilities), and budget from new projects (to sustain novel storage facilities)).

7. Responsibilities		
Who will manage data documentation and metadata during the research project?	The PhD researcher (Ineke Verreydt) associated with this project will be responsible for data documentation & metadata, under supervision of the PI (Prof. Kaat Desloovere).	
Who will manage data storage and backup during the research project?	Data management, storage and back up will be performed by the PhD researcher (Ineke Verreydt) associated with this project, under supervision of the PI (Prof. Kaat Desloovere).	
Who will manage data preservation and sharing?	The PI (Prof. Kaat Desloovere) will be responsible for ensuring data preservation and sharing.	
Who will update and implement this DMP?	The PhD researcher (Ineke Verreydt) associated with this project and the PI (Prof. Kaat Desloovere) bears the end responsibility of updating & implementing this DMP.	