FWO DMP Template

1. General Information	
Name applicant	Miel Willems
FWO Project Number & Title	1SC9922N "T-EX: Technology-based exercise protocols for knee osteoarthritis: A computational modeling framework combined with wearable technology, to support patient-specific exercise protocols in knee OA patients"
Affiliation	☒ KU Leuven ☐ Universiteit Antwerpen ☐ Universiteit Gent ☐ Universiteit Hasselt ☐ Vrije Universiteit Brussel ☐ Other:
2. Data description	
Will you generate/collect new data and/or make use of existing data?	☒ Generate new data ☒ Reuse existing data
Describe the origin, type and format of the data (per dataset) and its (estimated) volume *If you **reuse** existing data, specify the **source** of these data.* *Distinguish data **types** (the kind of content) from data **formats** (the technical format).*	In the first phase of the project, we will reuse historical data to formulate an answer to the first two objectives of the project. Dataset of Happy Joints & TECH-4-KOA projects will be used for this purpose. These two projects were granted by the FWO. Both projects already received ethical committee approval (Happy Joints: s64286 / TECH-4-KOA: 2021-2269) . In the last phase of the project (proof-of-concept), we aim to recruit patients and consequently generate new data. For this, we aim to write an ethical committee form in a later phase of the project. The historical data and the newly generated data are primary quantitative and qualitative experimental and observational raw, derived and compiled data. Overall, the data will be from in vivo human (biomechanical, medical imaging and functional) experiments and from computational simulations. Data

will be initially collected and used in a variety of file formats, mainly numerical and equipment specific. Raw data will be processed in type-specific software, more specific: Vicon Nexus, Opensim, Matlab and Python for in vivo human biomechanical experiments and computation simulation work; Mimics, 3-matic, 3D-slicer, MAPclient, Matlab and Python software for the medical imaging data. Original data files output from quantitative experiments will be collected in Excel datasheets or matlab structures. For data sharing across platforms, data will be additionally stored in .csv and .txt formats. The volumes of the data are approximations and are indicated per patient:

Type	What	Storage format	Volume/patient
Primary physical data	Informed consent form	Printed paper (.txt)	/
Primary physical data	Patient reported outcomes	Printed paper (.txt, .xlsx)	50Mb
Primary physical data	Clinical examination	Printed paper (.txt, .xlsx)	50Mb
Primary digital data	Gait analysis (including motion analysis, force plates, electromyography)	Numerical software-specific data (.C3D)	750Mb
Primary digital data	Segment accelerations from XSENS	Numerical software-specific data (.mvn)	500Mb
Primary digital data	Movement simulations	Numerical software specific data (.osim, .mot, .trc, . sto, .vtp)	1GB
Primary digital data	MRI	Numerical software-	1GB

				specific data (Dicom format, .DCM)	
		Primary digital data	Musculoskeletal models	Numerical software data (.osim)	1Mb
		Primary digital data	Segmented volumes of musculoskeletal tissue	Numerical software-specific data (.stl)	100Mb

3. Ethical and legal issues	
Will you use personal data? If so, shortly describe the kind of personal data you will use AND add the reference to your file in your host institution's privacy register. *In case your host institution does not (yet) have a privacy register, a reference is not yet required of course; please add the reference once the privacy register is in place in your host institution.*	☒ Yes ☐ No Two types of personal data will be gathered: 1. Personal information for contact purposes (e.g. name, address, phone number, e-mail), which will not be used in any further analysis. Participants will be asked whether this information can be stored in a database for future research, via a separate informed consent procedure in accordance with the General Data Protection Regulation UZ/KU Leuven. 2. Personal information for research purposes, consisting of socio-demographical data (e.g. gender, date of birth, handedness) and data concerning medical status (e.g. disease severity, medication intake, functionality), via the study-related informed consent procedure in agreement with the General Data Protection Regulation.

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, add the reference to the formal approval by the relevant ethical review committee(s).	☒ Yes ☐ No Regarding the reuse data: We will receive anonymized data from research experiments on humans, performed at - Université Laval (TECH-4-KOA study): a separate form was submitted to their local ethical Committee (Institut de réadaption en déficience physique de Québec: 2021-2269) - KU Leuven: patients will be recruited along with the study (S64286) as part of a different and approved research project. Regarding the newly generated data: We will send out a new form to the local Ethical Committee in a later phase of the project.
Does your work possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?	☒ Yes ☐ No Data from this project may be considered to claim intellectual property rights on the advice of Leuven R&D's valorisation team. LRD will be responsible for patent management and eventual licensing. Data may be used for industrial collaborations and will then be defined as KU Leuven background by LRD in good faith.
Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions are in place?	☐ Yes ☒ No No, there are no restrictions on our data at this stage.

4. Documentation and metadata

What documentation will be provided to enable understanding and reuse of the data collected/generated in this project?	The following documentation will be provided: 1. Table of content (excel file and .csv) with all project-related experiments including experiment number, date of implementation and name of the researcher who stored the experiment 2. Brief description of the goal of the experiment and related work package (word and .txt file) 3. Detailed protocol or link to an existing standard protocol (SOP) which will enable other researchers to repeat the experiment. 4. All data or link to another file with the (raw) data 5. If appropriate, illustrations of the data with legends and statistical analysis. In case that documentation is written or available in notebooks or stored on other files a link will be provided. With the help of these documentations every authorized researcher will be able (1) to look up all the information of the performed experiments and (2) to repeat the experiments in exactly the same way. All data will be coded. This will consist of: - Approved Ethical Commission: description of study protocol (.pdf); - Informed Consents Form: original black copies (.pdf) and signed hardcopies (printed paper); - Experimental protocols: description on how the data is 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); - Raw experimental data: storage of original physical data and 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 the included subject, and subject study code (.xls). This patient record file is the only document that provides the link between the study code of the patient and the patient's identity; - Subject recruitment files: only subject study code, personal data (for example, age, weight, height, …,) short overview of assessments. The subject recruitment files described the measurements info for each patient, whereby the patient's identity is coded; - The patient identifier record (PIR) will be stored separately in another location than the subject

	recruitment files. A separate file will be stored for each measurement location (Laval/KU Leuven) for each measurement cohort separately. This file will be password protected and will be supervised by the local PI (Ilse Jonkers for KU Leuven and Katia Turcot for Université Laval).
Will a metadata standard be used? If so, describe in detail which standard will be used. If not, state in detail which metadata will be created to make the data easy/easier to find and reuse.	☐ Yes ☒ No Metadata will be provided as readme, word, excel or xml files, containing all settings and technical descriptions of the experiments and data processing workflows. In addition, readme files and logbooks will be generated to describe the different decisions taken in the processing workflow (filtering, labeling etc.). - Raw experimental data (from the 3D movement analysis and strength tests) will be managed on a software-specific data management platform. - For imaging data (i.e. MRI), a large part of the metadata is included in the header files of the original images. These files contain information regarding the acquisition settings (e.g. acquisition time, flip angle, TE, TR, field of view, slice thickness).

5. Data storage & backup during the FWO project	
Where will the data be stored?	For all WPs, digital data will be stored on a Large Volume Storage (J-drive- of the KU Leuven, specifically developed to store large amounts of data for long periods of time. In addition, data will be stored on the secured servers of Université de Laval (Valeria-platform). Additionally, copies can be made on the individual computer of the researchers involved in the project. The paper copies of the descriptive data and questionnaires will be stored in a secured locker at the Department of Movement Sciences, Building The Nayer of the KU Leuven and at the Department of Kinesiology of the Université Laval. Only authorized personnel will have access to this locked storage room as they will need to be granted access by the PI (Prof. Dr. Ilse Jonkers). Digital copies will be available and stored on the Large Volume Storage of the KU Leuven.

How will the data be backed up?	The paper copies will be digitized and together with the digital data stored on the university's secure network drive with automatic daily backup procedures. Additionally, a mirror of the data is provided in a second ICTS data center for business continuity or disaster recovery purposes. Digital data automatically stored on the acquisition laptop during data collection, will be manually transferred via external hard drive to the secure servers. This external hard drive is provided as an automatic back-up of the acquisition laptop.
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 Sufficient storage and backup capacity are available at KU Leuven and will be purchased from the PhD fellow' bench fee (cfr. Operating Expenditure)
What are the expected costs for data storage and backup during the project? How will these costs be covered? *Although FWO has no earmarked budget at its disposal to support correct research data management, FWO allows for part of* ***the allocated project budget*** *to be used to cover the cost incurred.*	1 Terabyte storage is anticipated as a need and will be covered but the grant (approx. 520/terabyte/year).
Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?	All data will be stored in a protected environment. Research data can only be accessed by a login following KU Leuven's policy for identifier and with password. The digital, pseudonymized, data (i.e. coded and containing no personal information) will be stored in a secure university environment. The PI of this project (Prof. Dr. Ilse Jonkers) will be the only one who can grant access to this network drive. The separate and uniquely double password coded "Subject Identification Code List", which matches identifying codes with the subjects' names, will be managed by the principal investigator (Prof. Dr. Ilse Jonkers and Prof. Dr. Katia Turcot (historical data TECH-4-KOA project)) and stored separately, using the Digital vault for private data service of the ICTS, KU Leuven. This system involves a secure and operating system in ICTS's special, secure environment for private data."

6. Data preservation after the end of the FWO project FWO expects that data generated during the project are retained for a period of minimally 5 years after the end of the project, in as far as legal and contractual agreements allow.	
Which data will be retained for the expected 5 year period after the end of the project? In case only a selection of the data can/will be preserved, clearly state the reasons for this (legal or contractual restrictions, physical preservation issues, ...).	Both raw physical and digital data, as well as the processed data will be stored for a 5-year period after the end of the project.
Where will these data be archived (= stored for the long term)?	Digital data will be archived on the secured university's network drive, described in part 5 of this DMP. Additionally, data will be stored offline on two external hard drives when the project is finished. Hard copies (eg. The Informed Consent forms, measurement forms and paper lab notebooks) are kept in locked cabinets in the PI's lab.
What are the expected costs for data preservation during these 5 years? How will the costs be covered? *Although FWO has no earmarked budget at its disposal to support correct research data management, FWO allows for part of* ***the allocated project budget*** *to be used to cover the cost incurred.*	For this project data storage of 3 TB is anticipated, resulting in a cost of 520 euro per year, that can be partly covered by the different FWO grants (Happy Joints: 3M200048 & TECH-4-KOA: G0E4521N).

7. Data sharing and reuse

Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?	☒ Yes ☐ No IP protection and valorisation initiatives may restrict sharing of the data.
Which data will be made available after the end of the project?	All data will be made available after appropriate IP protection if this is applicable. The full anonymized dataset will be made available after publication of the data (upon simple request to the PI). Importantly, only data of participants who granted their approval for re-use, either within the research group (closed data) or outside the research group (open data), will be made available (also see 'Who will be able to access the data and under what conditions?'). This will be added to the informed consent. During the project as well as after the end of the project, the published data will be available via an open access repository and upon request by email to the PI. These published data contain the results of processed coded data presented in tables. Reference databases for gait analyses (in control and patient populations) will be established by the end or after the end of the project. As part of the valorisation plan, these databases may be put available for external users through open-source pathways. In that case, these data will be made available after appropriate IP protection. Patient-specific data will only be shared ensuring the privacy of the patients (e.g. body weight, body length). Decoded personal data will never be shared.

Where/how will the data be made available for reuse?	☒ In an Open Access repository ☒ In a restricted access repository ☒ Upon request by mail 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 data-sharing platform such as figshare or Znodo using a CC-BY license. 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?	Data will be made available immediately after publication unless specific IP protections remain to be set.
Who will be able to access the data and under what conditions?	All participants will be asked whether the data gathered in the context of this project can be reused for other research purposes, both within the research group (closed data) or with other researchers inside or outside KU Leuven (open data), via an informed consent procedure. Data of participants who granted this permission will only be shared with research groups who submitted a written request to the PI of this project (Prof. Dr. Ilse Jonkers). Data will only be shared if the research is approved by the ethical committee and participants will be informed regarding this secondary use. In principle, any researcher upon reasonable request or through the data repositories. During the post-project trajectory, data remains available for involved researchers and will be made available to external users upon request, with contact via LRD, with a CC-BY license.
What are the expected costs for data sharing? How will these costs be covered? Although FWO has no earmarked budget at its disposal to support correct research data management, FWO allows for part of the allocated project budget to be used to cover the cost incurred.	No costs are expected. If any occur, that will be covered by the requesting parties.

8. Responsibilities	
Who will be responsible for the data documentation & metadata?	The PhD researcher/FWO fellow (Miel Willems, KU Leuven) will be responsible for data documentation & metadata, under supervision of the promotor (Prof. Dr. Ilse Jonkers)
Who will be responsible for data storage & back up during the project?	Data management, storage and back-up will be performed by the PhD researcher/FWO fellow (Miel Willems, KU Leuven) under supervision of the promotor (Prof. Dr. Ilse Jonkers)
Who will be responsible for ensuring data preservation and sharing?	The PhD fellow (Miel Willems) and promotor (Prof. Dr. Ilse Jonkers) will be responsible for ensuring data preservation and reuse.
Who bears the end responsibility for updating & implementing this DMP? Default response: The PI bears the overall responsibility for updating & implementing this DMP	The PhD fellow (Miel Willems) bears the end responsibility of updating & implementing this DMP.