FWO DMP Template

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.

1. General Information	
Name applicant	Heleen Bollen- PI Sandra Nuyts
FWO Project Number & Title	1SE9822N
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).*	**Existing data:** Clinical and imaging data will be available in electronic patient files (KWS) of the UZ Leuven (n=200-300 patients). Pathological data (tumor resection pieces and sections;) and associated images and data to calculate the shrinking factor (n=13 patients). Data available PROCHAN project see (Van der Veen J, Radiother Oncol 2019) **Raw data to be generated:** WP1: Clinical; pathological data (tumor resection pieces and sections;) and associated images and data to calculate the shrinking factor (n=30 patients). Dice similarity coefficient (DSC) calculation based on PROCHAN project data to assess IOV. WP2: delineation of CT images (and registration of additional functional imaging modalities) of 200 HNSCC patients as part of the training set for the CNN tool for automated delineation of GTV. Manual and automated delineation and registration of the images of 100 HNSCC patients as part of the validation set for the CNN tool for automated delineation of GTV. WP3: delineation of CT images 300 HNSCC patients as part of the training set for the CNN tool for automated delineation of CTV taken into account the existing and new generated data from WP1. WP4:generation of dose volume histograms to calculate the dosimetrical relevance WP5:Generation of prospective delineation data using the generated tool in UH Leuven, other national RT centres and MD Anderson cancer centre (Houston Texas). WP6: Generation of adjustments to the CNN tool to include CB-CT data. **Processed data:** Statistical analysis of the existing data from and new generated data, lab meeting presentations, intermediate PhD reports, manuscripts and posters will be stored on the shared drives and hard disks. File format: doc, .ppt, .xls files, statistica, R files,.

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 If yes: - Privacy Registry Reference: WP 1.1: S54730 WP 1.2: S64638 WP 2: S61855 WP3: S61855 WP4: S61855 WP5: Awaiting EC approval WP6: S61855 - Short description of the kind of personal data that will be used: Data will be re-used or collected in UH Leuven HNSCC in context of study with EC. The study will be conducted according to the guidelines of good clinical practice (ICH/GCP) and according to the most recent version of the Declaration of Helsinki prepared to protect people participating in clinical studies. Data collected as part of the study will be treated with the utmost confidentiality. In doing so, the medical secrecy, the international guidelines (ICH-GCP) and the Belgian legislation are observed (including the legal requirements as stipulated in the Belgian Law of 8 December 1992 on the protection of privacy and the Belgian Law of 22 August 2002 on patient rights). Data that will be used will be all anonymized before any transfer to third parties. The link between the participant and his/her data is kept by the researcher/research team.

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 If yes: - Reference to ethical committee approval: WP 1.1: S54730 WP 1.2: S64638 WP 2: S61855 WP3: S61855 WP4: S61855 WP5: Awaiting EC approval WP6: S61855
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 If yes, please comment: We will generate an automated delineation tool that we aim to introduce in daily clinical practice. We will seek advice from the University Research and Development Office. This consultation will take place prior to any publication or disclosure of results.
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 If yes, please comment: If yes, please comment: IPR will apply for delineation tool, for part 2 if we think an output is worthy of registering as IPR, here also IPR will apply.

4. Documentation and metadata	
What documentation will be provided to enable understanding and reuse of the data collected/generated in this project?	Each researcher, involved in the project will provide detailed descriptions of data acquisition in electronic or paper notebooks, according to good laboratory practices. Detailed protocols are documented on shared drives (.doc/txt/xls files). Clinical and imaging data will be available in electronic patient files (KWS) of the UZ Leuven. Information of Pathological data (tumor resection pieces and sections) will be documented as txt/xls/doc files and stored on the shared drives. The final CNN based auto-delineation tool will be generated with MeVisLab and avalailable commercial software at our department.

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 If yes, please specify: No real metadata standard will be used. Each researcher provides a clear overview (summary) of the generated or processed data in their (e-)lab-books. Clinical data will be Clinical and imaging data will be available in electronic patient files (KWS) of the UZ Leuven. Processed data will be provided as digital info on the shared and on the portable hard disks of the lab. Later on, the data will be stored on the K-drives, the data are ordered per researcher/per project.

5. Data storage & backup during the FWO project	
Where will the data be stored?	Digital data files are stored on local KU Leuven/UZ Leuven PC or shared KU Leuven/UZ Leuven drives and also will be stored on external SSDs. The first author is responsible for storing raw and processed data of the paper concerned. Clinical and imaging data will be available in electronic patient files (KWS) of the UZ Leuven. Information of Pathological data (tumor resection pieces and sections) will be documented as txt/xls/doc files and stored on the shared drives. Generation of the auto-delineation platform will made available to the participating organizations.
How will the data be backed up?	Besides regularly provided automated backups by ICTS (of J-drive, K-drive), the data stored on personal PCs, personal KUL SharePoint and J-drive will be back-up on external hard disks. External SSD hard-disks (up to 12 TB storage capacity) keep the storage costs feasible.
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: Yes. The lab of experimental radiotherapy shares a shared drive with the lab of experimental oncology. The J-drive has a capacity 400GB, the K-drive has a capacity 500GB. Extensions of this volume can be asked for at ICTS for an additional cost. We have currently several external hard disks (12TB, 5TB, 1TB capacities). Same for liquid nitrogen tanks or freezers, but sufficient capacity is currently available.

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.*	Currently the expenses for the shared drives are covered by the shared budgets of the labs. The external hard disks on lab budget are available. Extra data storage can be covered by the FWO budget.
Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?	Clinical and imaging data will be available in electronic patient files (KWS) of the UZ Leuven and will only be available to the involved researchers by passwords. The archives and SharePoint both KUL/UZ Leuven will be available to the involved researcher by passwords.

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, ...).	Generated data will be preserved, raw and processed, for at least 5 years. Unpublished data from unfinished work will be kept for longer than 5 years since there is a possibility to use in publications. The final delineation tool will be made public after consultation and advice from the University Research and Development Office.
Where will these data be archived (= stored for the long term)?	K-drive and external SSD hard disks.

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.*	K-Archive drive costs: around € 12 /year/100 GB J-drive costs: around €50/year/100GB External hard disks: max. 1000€ (2x 12TB) Drivers, available within UH Leuven, will be used as storage for the clinical data and imaging. Should there be any additional expenses, it will be funded by the FWO Bench Fee.

1. 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 If yes, please specify: Data sharing will occur through publications (open access policy). The planned depositions of data in the relevant responsible repositories will occur after publication. We do not plan to share any unpublished data. Delays to the above data sharing policy may only arise through IPR. We will seek advice from the University Research and Development Office. This consultation will take place prior to any publication or disclosure of results.
Which data will be made available after the end of the project?	Publications and tool will be available with IPR.
Where/how will the data be made available for reuse?	☒ In an Open Access repository ☐ In a restricted access repository ☐ Upon request by mail ☐ Other (specify):
When will the data be made available?	After finalization of the tool and upon publication during the project, or as soon as possible upon publication after the project.
Who will be able to access the data and under what conditions?	Publications will be all open access. For unpublished data: only the PIs of the lab and scientific collaborators involved.

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.*	Publication costs (open access) will be covered by the project budget.

2. Responsibilities	
Who will be responsible for the data documentation & metadata?	All researchers involved in data collection and evaluation of the project. The final responsibility lies with the PI of the project.
Who will be responsible for data storage & back up during the project?	The PI of the project
Who will be responsible for ensuring data preservation and sharing?	The PI of the project
Who bears the end responsibility for updating & implementing this DMP? *Default response: The PI bears the overall responsibility for updating & implementing this DMP*	The PI of the project (prof. Sandra Nuyts) and researcher (Heleen Bollen).