# Plan Overview

*A Data Management Plan created using DMPonline.be*

**Title:** 3D printed gastroretentive dosage forms for timed multidrug release

**Creator:** Lotte Willemsen

**Principal Investigator:** Lotte Willemsen

**Affiliation:** KU Leuven (KUL)

**Funder:** Fonds voor Wetenschappelijk Onderzoek - Research Foundation Flanders (FWO)

**Template:** FWO DMP (Flemish Standard DMP)

**Principal Investigator:** Lotte Willemsen https://orcid.org/0009-0003-2239-6069

**Project abstract:**

Patients suffering from cardiovascular disease are often treated with a cocktail of medications, including drugs that reduce cholesterol biosynthesis (e.g., statins), reduce platelet aggregation (e.g., aspirin), and lower blood pressure (e.g., ramipril). However, the high pill burden results in significant problems with patient compliance, which hampers adherence and consequently impacts overall treatment efficacy. Moreover, the administration of these drugs would ideally follow a specific pulsatile release timeline during the evening and night and spanning 10 h after intake. Currently, no solutions exist for such long controlled-release sequences due to the complexity added by gastrointestinal motility. This fellowship will address these challenges by developing a radically new approach to gastroretentive controlled-release dosage forms, namely through 3D printing. The case of cardiovascular disease treatment will be taken as a challenging demonstration to showcase the capabilities of the proposed technology. Nevertheless, the project will result in a platform that can be used for several treatment cases and will open up diverse valorization routes.

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# 3D printed gastroretentive dosage forms for timed multidrug release
# DPIA

**DPIA**

**Have you performed a DPIA for the personal data processing activities for this project?**

- Not applicable

# 3D printed gastroretentive dosage forms for timed multidrug release
# GDPR

**GDPR**

**Have you registered personal data processing activities for this project?**

- Not applicable

# 3D printed gastroretentive dosage forms for timed multidrug release
# Application DMP

**Questionnaire**

**Describe the datatypes (surveys, sequences, manuscripts, objects … ) the research will collect and/or generate and /or (re)use. (use up to 700 characters)**

The project will generate three main types of raw data, all stored in digital format:
(1) Numeric data files. Techniques: NMR spectra, FTIR spectra, DSC data, X-ray diffractograms, …
(2) Images. Techniques: X-ray tomography data sets, optical microscopy, scanning electron microscopy, …
(3) Optimized recipes and protocols for mini-tablet formulation, printing parameters, controlled release testing, …

**Specify in which way the following provisions are in place in order to preserve the data during and at least 5 years after the end of the research? Motivate your answer. (use up to 700 characters)**

1. Designation of responsible person: Lotte Willemsen
    - All generated data will be curated in consultation with the PI (R. Ameloot)
2. Storage capacity/repository
    - All data will be stored via a secure cloud storage solution that offers sufficient space and enables efficient sharing of data with other research group members when required. The same solution will be used for long-term storage. Files will be named according to a pre-agreed convention and will be accompanied by a README file, which will describe the directory hierarchy and file naming convention. Each directory will contain an INFO.txt file describing the experimental protocol used. This way, the data can be understood by other team members and can be reused in the future.

**What's the reason why you wish to deviate from the principle of preservation of data and of the minimum preservation term of 5 years? (max. 700 characters)**

Not applicable

**Are there issues concerning research data indicated in the ethics questionnaire of this application form? Which specific security measures do those data require? (use up to 700 characters)**

Not applicable

**Which other issues related to the data management are relevant to mention? (use up to 700 characters)**

Not applicable

# 3D printed gastroretentive dosage forms for timed multidrug release
# FWO DMP (Flemish Standard DMP)

**1. 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.**

| | | | | 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 |
| | | *Please choose from the following options:*<br>• Generate new data<br>• Reuse existing data | *Please choose from the following options:*<br>• Digital<br>• Physical | *Please choose from the following options:*<br>• Observational<br>• Experimental<br>• Compiled/aggregated data<br>• Simulation data<br>• Software<br>• Other<br>• NA | *Please choose from the following options:*<br>• .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, …<br>• NA | *Please choose from the following options:*<br>• <100MB<br>• <1GB<br>• <100GB<br>• <1TB<br>• <5TB<br>• <10TB<br>• <50TB<br>• >50TB<br>• NA | |
| CAD files pre-processing | CAD files designed in Autodesk Inventor (IPT), exported in STL format and converted into WRL through blender | Generate new data | Digital | Software | .ipt<br>.stl<br>.wrl | <100MB | |
| 3D printing files | 3DPrint software for binder jetting (ZBD)<br>PrusaSlicer for generation of SL1 and GCODE files | Generate new data | Digital | Software | .zbd<br>.sl1(s)<br>.gcode | <1GB | |
| Render images | Rendering through Autodesk Inventor | Generate new data | Digital | Software | .tiff | <100MB | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Sliced images pre-processing | Autodesk Netfabb for image generation<br>Matlab for image processing and output to BMP and TXT | Generate new data | Digital | Software | .bmp<br>.txt | <1GB | |
| Data images | Canon camera<br>Logitech webcam | Generate new data | Digital | Observational | .jpg<br>.mp4<br>.avi | <1TB | |
| Data processing | Performed in Matlab and Excel | Generate new data | Digital | Compiled/aggregated data | .mat<br>.xlsx | <1GB | |
| Text | Proposals, protocols, SOPs | Generate new data | Digital | Observational | .docx<br>.txt | <100GB | |
| Data representation | Electronic lab book<br>Presentations<br>Posters | Generate new data | Digital | Observational | .pptx | <100GB | |

**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:**

Not applicable

**Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? Describe these issues in the comment section. Please refer to specific datasets or data types when appropriate.**

- No

**Will you process personal data? If so, briefly describe the kind of personal data you will use in the comment section. Please refer to specific datasets or data types when appropriate.**

- No

**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

The study holds great potential for tech transfer and valorization. The foundations for valorization of the project's results are already present in the IP portfolio maintained by the host group on the controlled capillary wicking in porous 3D printed objects ('3D printing of porous liquid handling device', Granted WO2018162476 A1, Pending US20200016829 A1, Pending EP3592562 A1). Further opportunities for IP Generation during the project will be identified in close dialogue with the tech transfer office KU Leuven Research & Development (LRD) and the host's group valorization manager Dr. Bart Van Duffel.

**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 in the comment section to what data they relate and what restrictions are in place.**

- No

**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.**

- No

## 2. 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).**

An overview file that contains references to the raw data files will be kept. Regular reports based on the data will be generated using Microsoft Word. PowerPoint files will be used for presentation at regular internal meetings between the WP leaders and researchers involved in the project. In both the Word reports and Powerpoint presentations, the file names of the raw data files will be included.

**Will a metadata standard be used to make it easier to find and reuse the data? If so, please specify (where appropriate per dataset or data type) which metadata standard will be used. If not, please specify (where appropriate per dataset or data type) which metadata will be created to make the data easier to find and reuse.**

- No

No uniform metadata standard is available for all different aspects and disciplines of this project. Therefore, the data management system, implemented by all group members, provides a uniform system to enhance the use of secondary data. The meta data (date, objective, protocol (data types and conducted characterization techniques), processed data, roadmap,…) is covered by a number of predetermined topics which are entailed in the Central Experiment Index and Electronic Lab Book.

## 3. Data storage & back-up during the research project

**Where will the data be stored?**

The data will be stored via a cloud storage solution that allows sharing with the WP leaders and researchers involved in the project.

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

The data on the cloud storage server are automatically backed up. Unlimited versioning is included in the selected plan so that accidental erasing or modifying does not pose a risk.

**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

The total amount of data generated during the project should not exceed a few TB and is therefore compatible with the selected cloud storage solution.

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

A secured environment is provided by the cloud system (Dropbox). Only after receiving an invitational link one can access a predetermined space in the cloud. Hereby unauthorized persons cannot access the information unless personally given.

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

The cost is 12 euro per month per person, which will be covered by the bench fee.

### 4. 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...).**

All the generated data will be stored on the cloud storage server for a period of 5 years after the end of the project.

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

All the generated data will be stored on the cloud storage server for a period of 5 years after the end of the project.
Beyond 5 years after the end of the project, one of the following options will be picked (1) continuation of storing the data on the cloud storage server or (2) transferring the data to the KU Leuven central servers for archiving.

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

The annual cost for long-term storage of the data, either through a cloud storage service or the university's central servers, is estimated at a few hundred euro. Since the budget of the current project will no longer be available, creative solutions will have to be found.

### 5. Data sharing and reuse

**Will the data (or part of the data) be made available for reuse after/during the project? In the comment section please explain per dataset or data type which data will be made available.**

- Yes, in a restricted access repository (after approval, institutional access only, …)

Upon request, access to the samples and data can be granted, upon agreement of the project leaders. Commercial reuse will not be allowed.

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

Upon request, access to the samples and data can be granted, upon agreement of the project leaders. Commercial reuse will not be allowed.

**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 in the comment section per dataset or data type where appropriate.**

- Yes, Intellectual Property Rights

The data will remain accessible among the WP leaders and the researchers involved in the project. Access to the data can be granted to other persons, upon request and agreement among the leaders. A patent application can be a limiting factor in granting access to the data.

**Where will the data be made available? If already known, please provide a repository per dataset or data type.**

Upon request by mail or by depositing research data in the KU Leuven RDR. The data that will not have been uploaded in a repository such as 'Scientific data' (https://www.nature.com/sdata/) to accompany a publication can be requested via email.

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

Description of the full scientific method and results will be made available with journal publications.

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

Question not answered.

**Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, you have the option to provide it in the comment section.**

- Yes

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

Because of the choice for a cloud storage solution for the data, no additional costs will be booked for data sharing.

## 6. Responsibilities

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

The PhD student working on this FWO project will be responsible for the data collection, documentation and metadata. Supervisors will manage the data storage facilities.

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

The PhD student on this FWO project will curate the data in structured folders within a secure cloud storage solution. According to the data management plan in the host group, the files will be named using a predetermined convention, referring to the data,

sample name and brief description. Further description of the samples will be provided in a centralized table.

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

The PIs will be responsible for the data preservation and eventual reuse of obtained data.

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

The applicant bears the end responsibility of updating and implementing this DMP.