Plan Overview

A Data Management Plan created using DMPonline.be

Title: 1S06425N_Nanoparticle synthesis in an ultrasonic flow microreactor for drug delivery applications

Creator: Huiyu Chen

Principal Investigator: Huiyu Chen

Project Administrator: Simon Kuhn

Affiliation: KU Leuven (KUL)

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

Template: FWO DMP (Flemish Standard DMP)

Principal Investigator: Huiyu Chen

Project abstract:

Nanomedicines based on poly(lactide-co-glycolic acid) nanoparticles (PLGA NPs) hold great promise for biomedical applications. However, the transfer from lab to clinic is obstructed by the lack of a reproducible synthesis technique for nano-sized particles and the limited versatility of present techniques. This project aims to use the synergistic effects of ultrasound and flow microreactor to develop an efficient and versatile nanomedicine production technology for pharmaceutical industry applications.

An ultrasonic microreactor is used to synthesize PLGA NPs via emulsion-solvent evaporation method, utilizing ultrasound cavitation to reduce particle size by promoting emulsification. Design of Experiments (DoE) is applied to determine the process parameters' impact and interaction, and to optimize synthesis conditions to fulfill the optimal size range for different biomedical applications. An Artificial Neural Network (ANN) model is constructed to predict the particle size and size distribution based on experimental data.

Following this, the reactor's application expands to the synthesis of two advanced derivatives: PLGA-lipid hybrid nanoparticles & double-emulsion PLGA nanoparticles. The aim is to improve the bioavailability of hydrophobic drugs and hydrophilic biomolecules, respectively. Subsequently, the particles undergo characterizations and biological evaluations to assess size, morphology, surface charge, encapsulation, drug release, cytotoxicity, and cellular uptake.

ID: 211699

Start date: 01-11-2024

End date: 31-10-2028

Last modified: 15-12-2024

1S06425N_Nanoparticle synthesis in an ultrasonic flow microreactor for drug delivery applications 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)

1) The research will generate photos (.tif) from microscope and SEM.
2) Data from DLS/ELS/FTIR/DSC/XRD/HPLC/Microplate reader are stored in .dat, .asc, .raw, .xlsx, .pdf, and .txt (other) when storage in respective software is not available.
3) Data analysis performed and stored in .xlsx (Excel), .m (Matlab).
4) Designs and re-elaborations performed and stored in .psd/.eps (Photoshop), .stl (Solid Edge).
5) Data summaries and manuscripts in .ppt (PowerPoint), .docx (Word), .tex (LaTeX) files.
6) Daily lab notes are stored in paper notebooks and OneNote.
7) Main research outcomes will be publicly available via open-access
Estimated volume: 500 GB

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)

To ensure data preservation, the research data will be stored across multiple platforms including the researcher's drive, an external hard disk drive (1 TB capacity), KU Leuven OneDrive, and OneNote.

Upon completion of experiments, detailed lab notes will be compiled on OneNote, integrating text, tables, photos, videos, and records. Additionally, data will be stored on KU Leuven's I:// and J:// drives, which are automatically backed up and safeguarded against security breaches.

During the research period, I am responsible for the data. Once the project is completed, Prof. Kuhn will become responsible for the preservation of the data for 5 more years.

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)

I am committed to adhering to the principle of data preservation and the minimum retention period of 5 years. The data will be securely stored on the university's central servers, in compliance with the KU Leuven RDM policy, which includes automatic backup procedures.

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.

1S06425N_Nanoparticle synthesis in an ultrasonic flow microreactor for drug delivery applications 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: • Generate new data • Reuse existing data	*Please choose from the following options:* • Digital • Physical	*Please choose from the following options:* • Observational • Experimental • Compiled/aggregated data • Simulation data • Software • Other • NA	*Please choose from the following options:* • .por, .xml, .tab, .csv,.pdf, .txt, .rtf, .dwg, .gml, … • NA	*Please choose from the following options:* • <100MB • <1GB • <100GB • <1TB • <5TB • <10TB • <50TB • >50TB • NA	
Liquid samples	Aqueous suspension of polymeric nanoparticles (empty or drug-loaded)	Generate new data	Physical				Every sample < 10 mL
SEM (Scanning electron microscopy)	SEM images of polymeric nanoparticles	Generate new data	Digital	Observational Experimental	.tiff	< 1 GB	
Photos	Photos of setups and experiments	Generate new data	Digital	Experimental	.png, .jpeg, .tiff	< 1 GB	
Plots and graphs	Data elaboration and visualization	Generate new data	Digital	Compiled/aggregated data	.tif, .png, .emf	< 100 GB	
Lab notes	Lab notebook (electronic and physical)	Generate new data	Digital	Compiled/aggregated data	.docx, .xlsx	< 1 GB	
Manuscripts	Written texts/scientific publications	Generate new data	Digital	Compiled/aggregated data	.docx, .pdf, .tex	< 1 GB	
Presentations	Slides and presentations of progress meetings, group meetings, and conferences	Generate new data	Digital	Compiled/aggregated data	.pdf, .ppt	< 1GB	

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.

- Yes, human subject data

WP 2.4 & WP 3.3 Both WPs involve the use of human cells (HEK293T, HUVEC), the aim is to evaluate the cytotoxicity and drug delivery efficacy of our synthesized nanoparticles. The raw data will be stored in .xls and visualised using GraphPad Prism. WP 2.4 will be performed through collaboration with Prof. Anna Sablina, the head of the Laboratory for Mechanisms of Cell Transformation (VIB-KU Leuven). WP 3.3 will be performed through collaboration with Prof. Rosario María Sánchez Martín, the group leader of NanoChemBio Lab at the University of Granada in Spain. In both cases, ethics approvals are already available and the cell lines mentioned in my proposal are already routinely utilized in their laboratories. Approval of using human cells - Use of commercial human cell lines: Ethics committee UZ/KU Leuven (S66004)

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.

- No

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).

- Liquid samples: Vials containing liquid solution are stored in the lab according to safety standards. Every sample will be labeled
  unambiguously (“name_time_conditions”) and will be recorded in a lab notebook. Subsequently, the sample name (combined with the
  corresponding conditions and observations) is added and saved into an electronic list (.docx, .xlsx), which also contains a more detailed
  description of the followed experimental procedure.
- Scanning electron microscopy: Pictures are captured according to SOPs and saved as .tiff files with the name “name_time_conditions”. The
  device settings are also automatically displayed in the saved pictures. Afterwards, samples cannot be stored.
- Photos: Relevant photos of the setup, samples, observations, etc. taken in the lab are saved in .jpeg, .png, or .tiff format.
- Plots and graphs: Data from experiments are provided as .txt files that can be plotted using GraphPad Prism software. Both the
  data for plotting and the output will be saved digitally. The output can be .tif or .png, depending on the final application of the plot/graph.
- Images: Images will be created using Paint.net and stored as .pdn files. The exported images will have the .eps, .png, .pdf, .tikz format
  depending on the final application.
- Notes: The physical lab notebook is used for setup design (sketches) and writing down observations. When not used in the lab, the
  notebook will be stored in a locked drawer in the office. Important notes (sample names, conditions, etc.: see above) are compiled into an
  electronic list (.docx or .xlsx).
- Manuscripts: Communication of scientific results is done via manuscripts and saved in .docx, .pdf, or .tex.
- Presentations: Presentations containing scientific results are produced using PowerPoint and stored accordingly (.ppt or .pdf).

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

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

Where will the data be stored?

All data will be stored on the work laptop of the researcher and in a shared cloud (OneDrive). After completion of WPs, the data will be additionally stored on the KUL service servers.

How will the data be backed up?

Data are backed up on the cloud (OneDrive) immediately. The software indicates the update status (green, blue, or red) and, in case of a non-sync,
action can be taken using the online version of the tool. After completion of
WPs, data will be additionally backed up on the KUL service 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.

- Yes

Data storage can be up to 1.5 TB.

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

Only authorized researchers have access to the OneDrive account: all users need to use two-factor authentication to log in (MFA app from
KUL). On lab computers, a log-out is always performed to prevent modification by unauthorized people.

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

The expected costs for data storage and backup during the research project are around €5000. These costs will be covered by Prof. Simon
Kuhn.

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 data will be retained for the expected 5 years period after the end of the project.

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

All the data will be stored for the long-term on the KUL service servers (with automatic backup procedures), conforming with the KUL RDM
policy.

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

The expected costs of data storage and preservation are around €5000. These costs will be covered by Prof. Simon Kuhn.

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

Data relevant for publication will be made available in an Open Access repository. Full datasets will only be made available upon request.

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

Not applicable.

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.

- No

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

Data relevant for publication will be made available in an Open Access repository. Further data can be made available upon valid request via
email to the researcher and/or the responsible of the data after project ending.

When will the data be made available?

Data will be made available upon publication of scientific findings.

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

There is no data that needs a usage license.

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.

- No

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

The expected cost for data sharing is €0. Free tools like Belnet FileSender (KUL account) will be used for data sharing. In the unlikely event
that there would be costs, these costs will be covered by Prof. Simon Kuhn.

6. Responsibilities

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

Huiyu Chen

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

Huiyu Chen

Who will manage data preservation and sharing?

Prof. Simon Kuhn

Who will update and implement this DMP?

Huiyu Chen and Prof. Simon Kuhn