Probiotic dry toothpastes as a superior delivery method for oral probiotics

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.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
Clinical parameters	Clinical parameters with pseudonomisation of data. Clinical parameters investigated: pocket probing depth (PPD), recession (REC), clinical attachement level (CAL), full-mouth bleeding score (FMBS), full-mouth plaque score (FMPS)	N	D	N	.csv & .xlsx	<1GB	/
Microbial outcomes: qPCR	qPCR of specific bacteria	N	D	N	.csv	<10 GB	/
Microbial outcomes:	Sequencing of bacterial 16S rRNA	N	D	N	.fastq	<1TB	/
Data analysis	Statistics run in R	N	D	N	.R	<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:

No existing data will be used

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, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)

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Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- 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

No data will be used for commercial ends. The tested product is aimed to be commercialized once clinically validated.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or 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.

- Yes

The tested product may be patented on content or formulation.

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).

Performed experiments will be documented (specifications, protocols, test reports) to allow for repetition by a different operator versed in the techniques used in the lab.
Data will be converted to commonly used file extensions that are readable and supported by most applicable programs (.csv, .xlsx, .fastq, .R).

Will a metadata standard be used to make it easier to find and reuse the data?
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.

- Yes

Following DataCite properties, metadata will include: Identifier (project name), creator, title (subproject and experiment names), publisher (KU Leuven), publication year (and exact dates), resource type, description of A) techniques used, B) the experimental setup and C) method of data analysis, contributors and funding reference.

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Shared network drive (J-drive)
- Large Volume Storage

How will the data be backed up?

- Personal back-ups I make (specify below)

Weekly back ups on personal hard drives.
Monthly upload on shared server and shared lab hard drives.

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

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

The shared server is only accessible to lab members and the hard drives only to people with badge access and knowledge of the location. Sensitive data will be stored on an encrypted hard drive.

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

Low, already covered by lab funding.

Data Preservation after the end of the Research Project

Which data will be retained for 10 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 data will be preserved for 10 years according to KU Leuven RDM policy

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

- Large Volume Storage (longterm for large volumes)
- Shared network drive (J-drive)
- KU Leuven RDR

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

Low, covered by lab funding.

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, as restricted data (upon approval, or institutional access only)
- Yes, as embargoed data (temporary restriction)

Patient data will be restricted to comply with privacy regulations.

Patentable data will be made available after patent approval.

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

Only supervisors and collaborators actively performing the experiments and data analysis.

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

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Specific date (specify below)

After patent filing or decision not to patent.

Which data usage licenses are you going to provide?

If none, please explain why.

- CC-BY 4.0 (data)
- Data Transfer Agreement (restricted data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

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

Low, covered by lab funding.

Responsibilities

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

The individual generating the data with supervision of the data manager and the principal investigator as primary responsibility. Current lab members serve as supporting staff.

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

The individual generating the data with supervision of the the data manager and principal investigator as primary responsibility.

Who will manage data preservation and sharing?

The data manager and principal investigator.

Who will update and implement this DMP?

All current members of the lab, but primarily the data manager and principal investigator.