LABEL2ENABLE

Project acronym: Label2Enable
Grant Agreement Number: 101057522
Project full title: Adopting ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps
Website: label2enable.eu

Data Management Plan

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Work Package:	WP 1 Coordination
Lead partner for this deliverable:	LUMC
Partner(s) contributing:	

Main author(s):

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Funded by the European Union

Label2Enable2 - Adopting ISO 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

I. General information

I.1 Name of researcher responsible for DMP

Romy Willemsen

I.2 Department of researcher responsible for DMP

Public Health en Eerstelijns Geneeskunde (PHEG)

I.3 ORCID ID of researcher responsible for DMP

0000-0002-2038-8175

I.4 Supervisor(s) of project, if applicable

Petra Hoogendoorn

I.5 If applicable for your study or project, please provide:

If one or more numbers are not applicable for your study or project, please add '/ ' in the appropriate text box.

ABR number	
METC number	
EudraCT number	
GMO number	
CCD application number	

I.6 If applicable: list the partner organisation(s) involved in your study or project.

I-HD, ORCHA, EPF, Empirica, COCIR, HIMSS, EIT Health, UvA, EuroHealthNet, FTSS, OptimIT, ISS, LSMU

II. About this DMP

II.1 Date of first DMP version

2022-10-21

II.2 Consulted LUMC data stewardship expert(s)

Note: This field is a requirement for most funders. DMPs will only be reviewed by funders after you have consulted one of the LUMC data stewardship experts.

To request for review: see section 7.

The LUMC has data stewardship experts both for clinical and preclinical research. This DMP was reviewed by:

Name	Martiene Moester
Telephone number	+31 (0)71-526 9726
E-mail address	adm@lumc.nl
Date of consultation (dd/mm/yyyy)	08/11/2022

II.3 Changes made to an earlier version of this DMP

Part of DMP	**Date of change (in dd/mm/yyyy)**	**Question number(s)**	**Adaptation(s) made**
I. General information			
II. About this DMP			
1. Data collection			
2. Data documentation			
3. Data storage and security			
4. Data access, sharing and reuse			
5. Data preservation and archiving			
6. Additional information			

Remarks:

1. Data collection

1.1 What type of study or project will you conduct?

Use the 'additional information' field to briefly describe the data assets you will produce during the research process.

- Study/project with human participants: observational study

The Label2Enable project (Coordination and Support Action) includes several project tasks. Only some are studies with human participants. Most project tasks have a research element, however they do not include human participants:

2.1 Co-create an EU certification scheme and implementation plan - Desk research, input from subject matter experts via SharePoint and stakeholder consultation

2.2 Align the certification scheme with existing and emerging EU legislation and values - Desk research and stakeholder consultation

2.3 Evaluate applicability other label legislation - Desk research and stakeholder consultation

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers) - Data sharing and assessments via SharePoint

3.2 Co-create communication and support suppliers - Input via SharePoint, interviews

3.3 Evaluate business models for app assessment - Desk research, interviews and discrete choice experiment

4.1 Set up a patient, citizen, carer advisory group (and board) - List of who is in the group and board and their findings in SharePoint

4.2 Patient citizen carer survey - Data gathered via research environment Castor

4.3 Test the label (with people with limited health literacy) - Think aloud testing / interviews in 4 corners of Europe by local organisations

4.4 Co-create supporting communication patients, citizens and carers - Round tables and experimental vignette studies

5.1 Set up a physician nurse public health advisory group (and board) - List of who is in the group and board and their findings in SharePoint

5.2 Health care professional survey - Data gathered via research environment Qualtrics

5.3 Prototype display apps and trusted label in app stores, app libraries and trusted sources - Experimental vignette studies via research environment Qualtrics

6.3 Define, track and guide with stakeholders success of the label - Round table sessions

7.1 Generate TS use stories of health care systems - Interview data

7.2 Explore potential of the label in reimbursement decision-making of health apps
- Round table sessions

The current version of the Data Management Plan focuses on 2.1, 3.1, 3.2, 4.2, 4.3, and 5.2.
Additions will be made over time for the other tasks.

1.2 Describe what you will do to pseudonymize or anonymize your data: How will you pseudonymize, where will identifiable data be stored and who is responsible for managing this data during the study or project?

2.1 Co-create an EU certification scheme and implementation plan

To enable co-creation of the EU certification scheme the project manager of Label2Enable has created a separate SharePoint for task 2.1. SharePoint is the preferred supplier of LUMC given its privacy measures. SharePoint works with 2-factor authentication. Confidential information can be stored on SharePoint. UMCs in the Netherlands have made joint agreements about this.

The project manager of Label2Enable and the task lead moderate the task 2.1 SharePoint. Subject matter experts are granted access to be able to provide input for and feedback on the certification scheme. Each requirement in the certification scheme has one or more invited experts. No personal data other than their names is stored. Anonymous data on inter-rater reliability, efficiency and self-explanatory-ness gathered by task 3.1 is stored to inform finetuning of the certification scheme with the invited experts. Experts will only receive access when needed and access is withdrawn when input is no longer needed to maintain the confidentiality of the certification scheme in progress. A non-disclosure agreement will be set up.

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers)

Task 3.1 tests the certification scheme co-created in task 2.1 with 24 apps and 5 (6) app checkers (app assessment organisations). Each app is assessed by 2 app assessment organisations to evaluate inter-rater reliability. To enable assessments the app manufacturers behind the 24 apps are invited to answer all the 81 questions of the CEN-ISO/TS 82304-2 health app assessment framework and provide the related evidence. Also both app assessment organisation and app manufacturer are asked to provide data if the assessment process is efficient and self-explanatory.

To enable app assessments the project manager of Label2Enable has created a separate SharePoint for task 3.1 with for each app a separate SharePoint folder. The task lead informs the project manager who can be granted access to an individual folder. Access is granted only to the manufacturer of the particular app, the two app assessment organisations who will do the assessment for this particular app and the task lead. A non-disclosure agreement is signed beforehand as commercially sensitive information may be involved. To avoid one app assessment organisation consulting the other app assessment organisation's assessments and thus influence the inter-rater reliability, the task lead ensures that app assessment organisations can not see the other app assessment organisation's assessment results.

The project manager of Label2Enable is responsible for this SharePoint and provides access the folders. No personal information is gathered other than contact person of the app manufacturer and their contact details. Data gathered concerns potentially commercially sensitive information of the 24 apps and outcome measures. As intent is to measure inter-rater reliability of a certification scheme in development as opposed to assessing the app's quality, the data will be anonymised in the publication that is to be delivered. That is, a heat map of results is intended to be provided which does not list which result belongs to which app nor which assessment belongs to which app assessor. App manufacturers are given the (voluntary) option to be mentioned on the Label2Enable website as having contributed to testing the certification scheme.

3.2 Co-create communication and support suppliers

In this task EIT Health will assess with the suppliers who were
engaged in task 3.1 what support is or (preferably) changes are needed to ensure an efficient self-explanatory certification process for suppliers. With these suppliers, EITHealth start-ups and COCIR communication that promotes adoption of
the TS by suppliers is developed. This will include the in Rogers’ theory on diffusion of innovations recommended what is it, how and why to use it information.

To enable suppliers to provide feedback on the certification scheme and process, materials will be provided in the SharePoint folder of that specific supplier, created in task 3.1. The representative from EIT Health will also receive access to these folders. These folders might contain commercially sensitive information. Therefore that information will remain in SharePoint. In reports and communication on this topic information on which supplier provided what feedback will be left out and results will be discussed on

high level.

4.2 Patient citizen carer survey

The obtained data is anonymous. A general link will be generated from the digital research environment Castor and posted on the Label2Enable website. No identifying data will be asked and Castor does not record IP-addresses.

4.3 Test the label (with people with limited health literacy)

Four invited public health organisations in four corners of Europe (Denmark, Hungary, Italy and likely France) will be trained to recruit for and test the health app quality label with people with limited health literacy. Recruitment is done by the local public health organisations. Identifying details of the participants are not shared with the consortium. For adequate analysis audio recordings will be made. Dependent on the chosen method, a data sharing agreement will be created to be able to transfer data from local organisations to the LUMC. This data will be stored in a DataSafe or the I-drive at the LUMC. A consent form is provided as are templates in which the local organisations can make notes on the results of testing. This mainly concerns understandability of the (translation of the) label. The templates do not contain personal data other than demographics with which the participant can not be identified (age, gender, education level, country).

5.2 Health care professional survey

The obtained data is anonymous. A general link will be generated from the digital research environment Qualtrics and posted on the Label2Enable website. No identifying data will be asked and an option will be selected in Qualtrics that IP-addresses are not obtained in Castor .

7.1 Generate TS use stories of health care systems

We will gather qualitative data. This will not be pseudonymised as it will be used for promotional purposes in full agreement with the interviewee.

1.3 Is one of the outcomes of your project software? You can think of scripts, modules, tools, an app, a analysis pipeline etc.

- No

1.4 How will you collect, create and/or capture your data? Briefly describe what you need to collect or access the data. Think about protocols, tools, equipment, hardware etc.

2.1 Co-create an EU certification scheme and implementation plan

Input for and feedback on the certification scheme will be obtained via SharePoint. A separate task 2.1 SharePoint is set up for this purpose. Within the Label2Enable SharePoint task 2.1 folder a folder will be created to keep overview of who has access to the task 2.1 SharePoint. The Label2Enable project manager provides and withdraws access.

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers)

App manufacturers deliver evidence for their app in a separate task 3.1 SharePoint. Two app assessors per app will be given access to assess this evidence using the then version of the EU certification scheme, co-created in task 2.1. The project task lead informs the project manager who should or should no longer get access to which folder.

3.2 Co-create communication and support suppliers

App manufacturers can provide their feedback for task 3.2 in their particular folder in the task 3.1 SharePoint. EIT Health will be given access to be able to create the intended deliverables for this task.

4.2 Patient citizen carer survey

The survey data will be collected and stored in a Castor EDC database (NEN7510 and ISO 27001 certified). After export the data will be stored on the secured server of the LUMC. Only research staff involved in this task and their support have access to the surveys and resulting data.

4.3 Test the label (with people with limited health literacy)

Microsoft teams is considered for Audio recording and a I-drive at LUMC for safe storage of these audio recordings. The anonymous templates created for this task with the test results are stored read-only in the Label2Enable SharePoint. Only researchers involved in this task have access to the audio recordings.

5.2 Health care professional survey

The survey data will be collected in a QUALTRICS database (ISO 27001 certified). The collected data will be stored on the I-drive. Only researchers involved in this task have access to the data.

7.1 Generate TS use stories of health care systems

Audio recordings of interviews will be made. Audio recording will be done via Microsoft Teams and a back-up recording will be made on a phone. The audio file is stored safely immediately after the interview, at which point the recording on the phone will be deleted. Only researchers involved in this task have access to the recordings.

1.5 What is the size and format of your digital data? And what software do you need to collect, process and analyse these data sets?

2.1 Co-create an EU certification scheme and implementation plan

Stage	**Specification of data set**	**Software choice**	**File format**	**Data size estimate***
Data collection	Expert input, expert feedback and results task 3.1	SharePoint	not applicable	<1GB
Raw data	Input and feedback from experts and task 2.2 Inter-rater reliability scores and data on efficiency and level of self-explanatory from task 3.1	Excel	.xlsx .	<1GB
Processed data	Processed feedback from experts Certification scheme	Excel Word	.xlsx .doc	<1GB
Results	Certification scheme template for task 3.1 Certification scheme for publication and further maintenance by task 1.3	Excel Word	.xlsx .doc	<1GB
Other...				

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers)

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	App access, app assessment framework answers, app evidence, app assessments, reported efficiency and level of self-explanatory	SharePoint	not applicable	<1GB
Raw data	App evidence, manufacturer filled out assessment framework template including manufacturer data on efficiency and level self-explanatory and app access instructions	manufacturer decides on evidence software Excel	... .xlsx	<1GB
Processed data	App assessments including app assessor data on efficiency and level self-explanatory Inter-rater reliability scores	Excel	.xlsx	<1GB
Results	Inter-rater reliability and efficiency and self-explanatory tables with recommendations for task 2.1 Article	Excel PDF	.xlsx .pdf	<1GB
Other...				

3.2 Co-create communication and support suppliers

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	Feedback from app manufacturers	Castor EDC	not applicable	
Raw data	Filled out templates Interviews	Excel	.xlsx	<1GB
Processed data	Aggregated analysed results	Word / Excel	.doc / .xlsx	<1GB
Results	Feedback to task 2.1 Communication for suppliers	Excel PDF	.xlsx .pdf	<1GB
Other...				

4.2 Patient citizen carer survey

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	Demographic details, app use, use of and trust in app recommendations, thoughts on role government in reviewing and rating health apps	Castor EDC	not applicable	
Raw data	Filled out surveys	Excel SPSS	.csv .sav	<1GB
Processed data	Aggregated analysed results surveys	SPSS	.sav	<1GB
Results	Article Input for task 4.4	PDF Word	.pdf .doc	<1GB
Other...				

4.3 Test the label (with people with limited health literacy)

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	Notes on understandability translation health app quality label in template and preferences for supporting communication Audio recordings	Sharepoint i-drive	not applicable	<1GB
Raw data	Filled out templates with notes on understandability and preferences for supporting communication Audio recordings	Excel mp3	.xlsx .mp3	<1GB
Processed data	Analysed aggregated results templates with recommendations	t.b.d.	t.b.d.	<1GB
Results	Updated translations label Article Input for task 4.4	JPG/PDF PDF PDF	.jpg/.pdf .pdf .pdf	<1GB
Other...				

5.2 Health care professional survey

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	Which types of health apps are recommended by which types of health professionals to which types of patients with or without the health app quality label	Qualtrics	not applicable	<1GB
Raw data	Filled out surveys	SPSS	.sav	<1GB
Processed data	Aggregated analysed results surveys	SPSS	.sav	<1GB
Results	Publication Input for task 5.1 (article health app report)	PDF	.pdf	<1GB
Other...				

7.1 Generate TS use stories of health care systems

Stage	Specification of data set	Software choice	File format	Data size estimate*
Data collection	Audio recordings Interview notes	Teams SharePoint	not applicable	<1GB
Raw data	1. Interview notes 2. Audiorecordings	Word mp3	.doc .mp3	<1GB
Processed data	1. analysed interview notes 2. coded and thematically analysed transcripts	Word Atlas.ti	.doc .sav	<1GB
Results	Use stories for publication on Label2Enable website Article on analysis aggregated use stories	t.b.d. PDF	t.b.d. .pdf	<1GB
Other...				

** if you don't know the size estimate, you can give a range: < 1 GB, 1-10 GB, 10-100 GB, 100 GB - 1 TB, > 1 TB*

Specification:

1.6 What is the estimated total size of the digital data? You can use the 'additional information' field for more details.

- 0-10 GB

1.7 Are there any non-digital data or outputs that the project will generate?

- No

1.9 Will the project use existing data?

- No

2. Data documentation

2.1 How will files and folders be named and structured?

A folder on the I-drive is created with the following folder structure:
- Application
- Articles
- Data
- Finances
- Materials
- My Endnote Library.Data
- Research protocol
- Meetings
- Planning
- Secretariat
Subfiles will be created for the different studies within the Label2Enable project executed within the LUMC: 4.2; 5.2; 5.3; 7.1
The files will be named as followed: yyyymmdd_[type]_[initials creator]_[name]_[version]
Type can be: raw/clean/analysis/SOP/documentation/etc.

Raw data files will be locked by selecting the 'read-only' option in the file preferences. In SharePoint the file is set on ' Viewing' . The suffix '_locked' will be added to the file name and files will be stored in the '_raw' folder. Obsolete files will be moved to an 'Archive' subfolder of the folder the document was in originally.

Proposed folder structure, example for I:-drive or SharePoint
Label2Enable contains:

- **Label2Enable_WP?.?_raw**
- **Label2Enable_WP?.?_cleaning**
- **Label2Enable_WP?.?_locked**
- **Label2Enable_WP?.?_analysis**
- **Label2Enable_WP?.?_SOP**
- **Label2Enable_WP?.?_documentation**

2.2 How will versions and changes be handled?

Version numbers are incremented for each major change. Minor changes are indicated by adding a/b/c. This applies to internal LUMC documents and documents on SharePoint. And can also be used by project partners in their documentation.

2.3 Business metadata: What metadata (standard) will be used to describe thedata set?
Please use the 'additional information' field to briefly explain this.

- Generic metadata standard (e.g. Dublin Core)

4.2 Patient citizen carer survey

Dublin core generic metadata will be used.

5.2 Health care professional survey

Dublin core generic metadata will be used.

The **Dublin Core**, also known as the **Dublin Core Metadata Element Set (DCMES)**, is a set of fifteen "core" elements (properties) for describing resources. This fifteen-element Dublin Core has been formally standardized as ISO 15836,[1] ANSI/NISO Z39.85,[2] and IETF RFC 5013.[3]

1. Contributor – "An entity responsible for making contributions to the resource".
2. Coverage – "The spatial or temporal topic of the resource, the spatial applicability of the resource, or the jurisdiction under which the resource is relevant".
3. Creator – "An entity primarily responsible for making the resource".
4. Date – "A point or period of time associated with an event in the lifecycle of the resource".
5. Description – "An account of the resource".
6. Format – "The file format, physical medium, or dimensions of the resource".
7. Identifier – "An unambiguous reference to the resource within a given context".
8. Language – "A language of the resource".
9. Publisher – "An entity responsible for making the resource available".
10. Relation – "A related resource".
11. Rights – "Information about rights held in and over the resource".
12. Source – "A related resource from which the described resource is derived".
13. Subject – "The topic of the resource".
14. Title – "A name given to the resource".
15. Type – "The nature or genre of the resource".

Metadata is not applicable for the others tasks.

2.4 Please describe briefly how you will create the business metadata.

4.2 Patient citizen carer survey & 5.2 Health care professional survey

The Dublin Core Standard Generator will be used to create machine-readable metadata for **each specific task (4.2 en 5.2)** (Dublin Core Standard generator). And the XML file will be saved with the study documentation.

Not applicable for other tasks.

2.5 Technical metadata: What metadata (standard) will be used to describe and/or standardize data and variables? Please use the 'additional information' field to briefly explain this.

- No metadata standard is used, but I will provide a detailed description of variables (dictionary)

4.2 Patient citizen carer survey

An elaborate data dictionary will be created describing all variables and the answer categories, for example:

Variable	Answers options	Range
Year of birth	Years	1900-2004

4.3 Test the label (with people with limited health literacy)

For task 4.3 a codebook will be created to explain the codes with examples where these codes will be applied in the text.

5.2 Health care professional survey

An elaborate data dictionary will be created describing all variables and the answer.

7.1 Generate TS use stories of health care systems

For task 7.1 a codebook will be created to explain the codes with examples where these codes will be applied in the text.

2.6 Please describe briefly how you will create the technical metadata.

4.2 Patient citizen carer survey

The data dictionary will be exported from Castor.

4.3 Test the label (with people with limited health literacy)

A codebook explaining all the codes and examples will be created.

5.2 Health care professional survey
The data dictionary will be exported from Qualtrics.

7.1 Generate TS use stories of health care systems
A codebook explaining all the codes and examples will be created.

2.7 What supporting information and/or documentation will you create to enhance understanding of the data? Please describe briefly what is needed for peers to understand, work and/or reproduce the data.

4.2 Patient citizen carer survey
The task lead will store on the LUMC I-drive:
- A PDF of the study protocol after approval by the Medical Ethics Committee, including proof of the approval.
- A PDF of the codebook exported from CASTOR EDC after export of the survey data for analysis.
- A PDF of the survey content (in English) including all the questions as sent out in Castor.
- All syntaxes used in data cleaning and analysis (including annotation describing the goal of processing steps) after the analysis.
- The necessary software and tools needed for reuse including whether embargoes, licences, commercial objectives or other conditions have been imposed on the reuse of data at the end of the project.
- The deliverable (scientific article) once accepted and published.
- A readme.txt with a list of all of the above documents before archiving the data.
- The raw data set at the end of the project.

4.3 Test the label (with people with limited health literacy)
The executing researcher will store on the LUMC I-drive:
- A PDF of the study protocol after approval by the Medical Ethics Committee, including proof of the approval.
- A PDF of the codebook created during the analysis
- A PDF of the interview guide(s)
- Atlas.ti files of the analysis
- The necessary software and tools needed for reuse including whether embargoes, licences, commercial objectives or other conditions have been imposed on the reuse of data at the end of the project.
- The deliverable (scientific article) once accepted and published.
- A readme.txt with a list of all of the above documents before archiving the data.
- The raw data set at the end of the project.

5.2 Health care professional survey
The task lead will store on the LUMC I-drive:
- A PDF of the study protocol after approval by the Medical Ethics Committee, including proof of the approval.
- A PDF of the codebook exported from Qualtrics after export of the survey data for analysis.
- A PDF of the survey content (in English) including all the questions as sent out in Qualtrics.
- All syntaxes used in data cleaning and analysis (including annotation describing the goal of processing steps) after the analysis.
- The necessary software and tools needed for reuse including whether embargoes, licences, commercial objectives or other conditions have been imposed on the reuse of data at the end of the project.
- The deliverable (scientific article) once accepted and published.
- A readme.txt with a list of all of the above documents before archiving the data.
- The raw data set at the end of the project.

7.1 Generate TS use stories of health care systems
The task lead will store on the LUMC I-drive:
- A PDF of the study protocol after approval by the Medical Ethics Committee, including proof of the approval.
- A PDF of the codebook created during the analysis
- A PDF of the interview guide(s)
- Atlas.ti files of the analysis
- The deliverable (scientific article) once accepted and published.
- A readme.txt with a list of all of the above documents before archiving the data.
- The raw data set at the end of the project.
- The necessary software and tools needed for reuse including whether embargoes, licences, commercial objectives or other conditions have been imposed on the reuse of data at the end of the project.

Not applicable for the other tasks.

2.8 Please tick the box to confirm that you are aware of and adhere to the applicable rules and codes of conduct for your study or project:

- **General**
  - **VSNU Code of Conduct for Research Integrity**
  - **LUMC data management guidelines**
  - **LUMC privacy policy**
- **Human research:**
  - **General Data Protection Regulation (GDPR; in Dutch: AVG)**
  - **Medical Treatment Contracts Act (In Dutch: WGBO)**
  - **Medical Research Involving Human Subjects Act (In Dutch: WMO)**
  - **Quality Assurance for Research involving Human Subjects**
  - **Code of Conduct for Medical Research (e.g. GCP)**
  - **Code of Conduct Responsible Use of Human Tissue**
- **Non-human research:**
  - **Experiments on Animals Act**

Please add an explanation when needed in the 'additional information' field.

- I'm aware of and adhere to the rules and codes of conduct that are applicable for my study.

Applicable rules and codes of conduct.

- LUMC data management guidelines
- LUMC privacy policy / Privacy policies of respective (consortium) partners handeling the date
- General Data Protection Regulation (GDPR)

2.9 Indicate which permits apply to your study and add explanation when needed in the 'additional information' field:

- Report the collection of (in)directly identifiable (research) data to the Data Protection Officer
- Letter of non-objection METC

4.2 Patient citizen carer survey
The survey is anonymous and non-invasive and does not fall in the scope of the Medical Research Involving Human Subjects Act (WMO).

4.3 Test the label (with people with limited health literacy)
The survey is anonymous and non-invasive and does not fall in the scope of the Medical Research Involving Human Subjects Act (WMO). This project task is coordinated by consortium partner EuroHealthNet, expert in health inequalities. Participants remain anonymous.

5.2 Health care professional survey
The survey is anonymous and non-invasive and does not fall in the scope of the Medical Research Involving Human Subjects Act (WMO).

7.1 Generate TS use stories of health care systems
Use stories (documenting use of CEN-ISO/TS 82304-2 in health care systems) and its analysis are non-invasive and do not fall in the scope of the Medical Research Involving Human Subjects Act (WMO). Interviews will be held as part of the Label2Enable project. A letter of non-objection METC will be obtained before starting the analysis of the interview data.

3. Data storage and security

3.1 Where will you store the different parts of your digital data? When ticking the option 'other', please use the 'additional information' field to briefly explain this.

- Other (please specify)
- SharePoint Office 365
- Castor
- Department network storage drive (I-drive)

2.1 Co-create an EU certification scheme and implementation plan

SharePoint task 2.1
SharePoint Label2Enable folder task 2.1

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers)
SharePoint task 3.1
SharePoint Label2Enable folder task 3.1

3.2 Co-create communication and support suppliers
SharePoint task 3.1
SharePoint Label2Enable folder task 3.2

4.2 Patient citizen carer survey
CASTOR EDC
LUMC I-drive
SharePoint Label2Enable task 4.2

4.3 Test the label (with people with limited health literacy)
LUMC I-drive
SharePoint Label2Enable folder task 4.3
5.2 Health care professional survey
Qualtrics
LUMC I-drive
SharePoint Label2Enable folder task 5.2

7.1 Generate TS use stories of health care systems
LUMC I-drive
SharePoint Label2Enable folder task 7.1

3.2 Please describe how safe storage is guaranteed for each part of your data during collection, storage and sharing of data: storage location, backup procedures, frequency and who is responsible.

CASTOR EDC
Backups are made four times a day and stored at another geographical location. The backup files are kept for fifteen days. Reserve copies can be restored but this might add additional costs.

LUMC I-drive
Every day a copy is automatically made of any changed files on the I-drive. A full backup of all data is made once per week. Monthly and quarterly backups are made so that earlier data can also be restored if necessary. All LUMC staff can restore files up to four weeks ago from the I-drive themselves. For older versions the IT helpdesk needs to be contacted.

Qualtrics
All respondent data are backed up by Qualtrics using two methods: automatic propagation across servers (immediate upon collection) and daily complete off-site encrypted backups. However, customers are responsible for routine back-up of their data in case of accidental deletion/modification caused by one of their users, and for their own archive/data retention policies. Qualtrics backups data for disaster recovery purposes only. It is the customer’s responsibility to enforce any required retention periods that apply to their data. https://www.qualtrics.com/support/survey-platform/getting-started/qualtrics-gdpr-compliance/#BackupDataRetention

SharePoint
In SharePoint Online, data is backed up every 12 hours and retained for 14 days. Items deleted in SharePoint Online are stored in the Recycle Bin for 93 days before they are deleted permanently.

3.4 How will access to data be managed during the project?

Please specify for each storage device the tools and procedures that you use to ensure that only authorized persons have access to data. Outline roles and responsibilities for all activities during your project, e.g. data capture, metadata production, data quality, storage and backup. For collaborative projects you should explain the coordination of data management responsibilities across partners.

2.1 Co-create an EU certification scheme and implementation plan
The project manager manages the access rights to the SharePoints.

3.1 Test EU certification scheme (with 24 apps and 5 (6) app checkers)
The project manager manages the access rights to the SharePoints.

3.2 Co-create communication and support suppliers
The project manager manages the access rights to the SharePoints.

4.2 Patient citizen carer survey
The task lead will grant access rights to CASTOR EDC and arrange access to the I-drive. Only researchers involved in the task will be granted access.
The project manager manages the access rights to the SharePoint.

4.3 Test the label (with people with limited health literacy)
The researcher working with the data gathered in task 4.3 is responsible for access rights to the LUMC I-drive and/or LUMC Data safe. Only researchers involved in the task will be granted access.
The project manager manages the access rights to the SharePoint.

5.2 Health care professional survey
The researcher working with the data is responsible for access rights to Qualtrics and the LUMC I-drive. Only researchers involved in the task will be granted access.
The project manager manages the access rights to the SharePoint.

7.1 Generate TS use stories of health care systems
The task lead is responsible for access rights to the LUMC I-drive. Only researchers involved in the task will be granted access.
The project manager manages the access rights to the SharePoint.

3.5 Do you have a plan or SOP for quality control of your data? Please explain briefly in the 'comment area'.

- Yes

4.2 Patient citizen carer survey
Data cleaning steps are described in the syntax and will be performed by the researcher.

5.2 Health care professional survey
A statistical analysis plan will be created.

7.1 Generate TS use stories of health care systems
We work with qualitative data. Standard procedures will be followed for transcribing interviews and analysing in Atlas.ti. Which will be described in the protocol. The protocol is a work in progress.

Not applicable for the other tasks.

3.6 Do you expect costs for storage and data management during the study or project?

- No

4. Data access, sharing and reuse

4.1 Are there any restrictions placed on sharing/reuse of some/all of your data due to one or more of the following options? When you tick the box 'other', please specify this in the 'additional information' field. You can also use this field to give more information.

- Consortium agreement

Grant Agreement - Values - Article 14

Results are owned by the beneficiaries that generate them.
However, two or more beneficiaries own results jointly if:
- they have jointly generated them and
- it is not possible to:
- establish the respective contribution of each beneficiary, or
- separate them for the purpose of applying for, obtaining or maintaining their protection.

The joint owners must agree — in writing — on the allocation and terms of exercise of their joint ownership ('joint ownership agreement'), to ensure compliance with their obligations under this Agreement.
Unless otherwise agreed in the joint ownership agreement or consortium agreement, each joint owner may grant non-exclusive licences to third parties to exploit the jointly-owned results (without any right to sub-license), if the other joint owners are given:
- at least 45 days advance notice and
- fair and reasonable compensation.

The joint owners may agree — in writing — to apply another regime than joint ownership.
If third parties (including employees and other personnel) may claim rights to the results, the beneficiary concerned must ensure that those rights can be exercised in a manner compatible with its obligations under the Agreement.
The beneficiaries must indicate the owner(s) of the results (results ownership list) in the final periodic report.

Grant Agreement - Part B – p.10

Open science practices

The data that this proposal will generate includes: patients, citizens and carers and health care professionals' opinions, confidence, experiences, and behaviour in recommending and using health apps. Their inclusion in surveys will also generate personal data such as name, contact details and some demographic data. The data will be collected and stored in accordance with GDPR. The DMP, to be developed in the first months of the project, will address both GDPR compliance and an open science strategy, guided by the FAIR principles.

We will store all data needed to replicate our studies. The DMP will specify what kind of data will be generated, how datasets will be handled during the project and how the data will be preserved and made available after the project has been finished. It will include methodology and standards, documentation, storage characteristics, facilities, software and equipment used. The DMP will also have a section on embargoes, licences, commercial objectives or will contain pro forma versions of privacy information notices and consent agreements. We will store our data sets in preferred file formats, if possible, and add metadata documentation in which we will specify all information needed to replicate our studies, as well as support access to data through open science data repositories.

Publications, if possible, will be submitted online in preprint (such as BioRXiv) and in journals with open access to ensure publications are publicly discoverable, accessible, and re-usable. The costs for "gold" open access publications are eligible and have been included within the budget. Green access is free and will beencouraged. Next to long-term storage at the institutes, we will also deposit the datasets in a (inter)national repository and catalogues, so that others can use and mine (meta)data. This will be done in agreement with the given informed consents and already available (commercial) research agreements, data policies and intellectual property in place.

Knowledge management and intellectual property will be handled under the responsibility of the Project Coordinator. Intellectual property will be managed according to the best international standards and best practices and will be included in the Consortium Agreement to be signed by the partners at the start of the project. For dissemination and communication strategy we aim at an open-data approach, whereby researchers across different disciplines can freely access the relevant data produced by this research within the informed consents and other agreements in place. Relevant research groups are most likely in the fields of mHealth, labelling, health communication, and behaviour change. The dissemination of scientific knowledge will be via peer-reviewed journals, relevant conferences, meetings, workshops, and project events.

4.2 Will you share your data open access or with restricted access?

- Restricted access

4.4 Sharing data with 'restricted access': please explain if this is done to publish or seek for patents, or because your data contains privacy-sensitive information. And how will you share data under 'restricted access'?

Policy may differ per task and is yet to be decided.
As described in 4.3 of the consortium agreement all publications within the timeline of the project and after one year should be in agreement with the whole consortium.

4.6 Is there an embargo period before sharing your data?

- Yes

4.7 Why and for how long do you have an embargo period?

First the Label2Enable consortium should publish about the data before sharing the data.

4.8 Is your informed consent form according to the LUMC-based CCMO model form? If no, please explain in the 'additional information' field why you don't use this standard.

- No

4.2 Patient citizen carer survey
Anonymous survey, therefore no informed consent is needed.

4.3 Test the label (with people with limited health literacy)
Consent for audio recordings will be obtained.

5.2 Health care professional survey
Anonymous survey, therefore no informed consent is needed.

7.1 Generate TS use stories of health care systems
Consent for audio recordings will be obtained.

Not applicable for the other tasks.

4.9 How do you ensure that participants, who have withdrawn their informed consent, are removed from the data and thus are not available for reuse? Do you have a procedure in place for this?

This applies only to consent for audio recordings (task 4.3 and 7.1). Policies are yet to be decided and explained in informed consent.

4.10 Does your agreement or funder requirements include information about intentions for sharing, retention of data, steps taken to protect participants privacy, confidentiality and ownership of data and intellectual property rights?

ARTICLE 16 — INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND
RESULTS —ACCESS RIGHTS AND RIGHTS OF USE

16.1 Background and access rights to background
The beneficiaries must give each other and the other participants access to the background identified as needed for implementing the action, subject to any specific rules in Annex 5.
'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:
(a) held by the beneficiaries before they acceded to the Agreement and
(b) needed to implement the action or exploit the results.
If background is subject to rights of a third party, the beneficiary concerned must ensure that it is able to comply with its obligations under the Agreement.

16.2 Ownership of results
The granting authority does not obtain ownership of the results produced under the action.
'Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

16.3 Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination and publicity purposes
The granting authority has the right to use non-sensitive information relating to the action and materials and documents received from the beneficiaries (notably summaries for publication, deliverables, as well as any other material, such as pictures or audio-visual material, in paper or electronic form) for policy, information, communication, dissemination and publicity purposes — during the action or afterwards. The right to use the beneficiaries' materials, documents and information is granted in the form of a royalty-free, non-exclusive and irrevocable licence, which includes the following rights:
(a) use for its own purposes (in particular, making them available to persons working for the granting authority or any other EU

service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)

(b) distribution to the public (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)

(c) editing or redrafting (including shortening, summarising, inserting other elements (e.g.
meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation)

(d) translation

(e) storage in paper, electronic or other form

(f) archiving, in line with applicable document-management rules

(g) the right to authorise third parties to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority

(h) processing, analysing, aggregating the materials, documents and information received and producing derivative works.

The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned. If materials or documents are subject to moral rights or third party rights (including intellectual property rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned). Where applicable, the granting authority will insert the following information: "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the [name of granting authority] under conditions."

16.4 Specific rules on IPR, results and background
Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5.

16.5 Consequences of non-compliance
If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28). Such a breach may also lead to other measures described in Chapter 5.

ARTICLE 17 — COMMUNICATION, DISSEMINATION AND VISIBILITY
17.1 Communication — Dissemination — Promoting the action
Unless otherwise agreed with the granting authority, the beneficiaries must promote the action and its results by providing targeted information to multiple audiences (including the media and the public), in accordance with Annex 1 and in a strategic, coherent and effective manner. Before engaging in a communication or dissemination activity expected to have a major media impact, the beneficiaries must inform the granting authority.

4.11 Who is responsible for your data and has authority to grant (additional) access to your data after finishing the study or project (e.g. for the long term)?

- Data Access Committee

LUMC: The Label2Enable coordinator or manager of the department in case the coordinator is no longer affiliated with the organisation.

5. Data preservation and archiving

5.1 Which parts of your data will you select for long-term archiving? Please motivate why you would not archive (parts of) your data.

The data will be stored for at least 15 years on the LUMC I-drive. Long-term archiving is meant for large documents (such as X-rays), however our data(sets) are relatively small and will therefore be stored on the I-drive.

5.2 How long must your data be preserved? Please explain briefly in the 'additional information' field.

- Clinical research non-WMO: ≥ 15 years

In line with the Netherlands Code of Conduct for Research Integrity, raw and processed data will be stored for a period of at least 15

years.

5.3 Are there any requirements regarding the disposal of data?

- No

After this period of time the data (all digital) will be deleted (irreversibly destroyed) unless the law, funder or organisation requires otherwise.

5.5 How will you ensure data and/or metadata findability and availability for the long term?

Briefly explain your choices in the 'additional information' field, in which you specify how you ensure long term data availability. If you don't deposit in an established repository, you should explain what resources and systems are in place to enable data to be curated effectively beyond the lifetime of the project.

- I will publish my metadata online
- I will not archive data outside LUMC, but will ensure long term findability and availability

2.1 Co-create an EU certification scheme and implementation plan
Task 1.3 will create a sustainability entity that will maintain the EU certification scheme co-created in task 2.1.

4.2 Patient citizen carer survey /5.2 Health care professional survey
The surveys are relatively short. The data will be downloaded from Castor and Qualtrics once data gathering is finished. The data will be stored on the LUMC I-drive, to which the research team has access. The raw data will be stored in a folder and the folder will be locked for editing. It is made sure that always more than one researcher has access to the folder. When a researcher leaves the LUMC in that case, always another researcher has access to the data. Data dictionaries will be created for 4.2 and 5.2.
It will be considered to store parts of the data in a general or field-specific repository.
Romy Willemsen is responsible for the folder 4.2 and 7.1. Ieva Biliunaite is responsible for the folder of task 5.2.

7.1 Generate TS use stories of health care systems
The qualitative data of 7.1 will be stored on the I-drive. It will not be published in a repository, since the data cannot be made anonymous and does not provide insight when the context is not known.
Romy Willemsen is responsible for the folder of task 7.1.

5.6 Does the chosen publication format (database, archive, repository, catalogue, platform, website etc.) add one or more persistent identifiers to your (meta)data?

Please specify the type of persistent identifier(s) in the 'additional information' field.

- No

5.7 What will you do to prepare your data for archiving? Describe how you intend to meet LUMC, publisher or database/archive/repository requirements.

The data will be stored in a FAIR (Findable, Accessible, Interoperable, Reusable) as possible manner under the Consortium agreement. Since our survey data is very specific and quite a small dataset, we will not invest in making it machine readable.

5.8 Will there be extra costs for this preparation? If you have budget for this in your grant proposal, please specify.

- No

5.10 Do you have costs associated with long-term storage of your data?

- No

6. Additional information

6.1 Here you can put any additional information that you were not able to list above.

-

7. Review request

7.1 Please tick the appropriate box.

- review: feedback and suggestions appreciated