
Plan Overview

A Data Management Plan created using DMPonline

Title: Client satisfaction survey breast cancer screening Bonaire, Saba, Sint Eustatius

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Template: UMC Utrecht DMP with DPIA V.3.0

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Project abstract:

In 2020, the Centre for Population Screening of the National Institute of Public Health and the Environment (RIVM-CvB) was commissioned by the Dutch Ministry of Health, Welfare, and Sport to set up and conduct cancer screening in the Caribbean Netherlands. The screening program for breast cancer was introduced on 26 May 2021. While conducting this program, RIVM-CvB applied knowledge and expertise of the existing program in the European Netherlands (EU-NL), carefully adapting routines when local circumstances and cultural differences demanded alternative procedures. The screening performance of the program is evaluated regularly and annual so-called monitors are publicly available (<https://www.rivm.nl/en/documenten/monitor-breast-cancer-population-screening-bonaire-2022-2023>).

Until now, a survey to determine to what degree the screening program is appreciated by the participants of the screening program was not conducted. Therefore, we set up the current study to investigate the level of satisfaction among participants of this breast cancer screening programme on the Caribbean Islands Bonaire, Saba and Sint Eustatius, sampling various domains of participant satisfaction. With the results of the survey, we are able to better adapt the practice of the program to the needs of the participants.

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Client satisfaction survey breast cancer screening Bonaire, Saba, Sint Eustatius

1. General features

1.1. Acronym/short study title

Client satisfaction survey breast cancer screening Bonaire, Saba, Sint Eustatius

1.2 Division of Principal Investigator

- Julius Centrum (Julius Center)

1.3 Department

Global Public Health and Bio-Ethics

1.4 Path of the Research Folder

\\ds\data\JC\Datamanagement\Research\

1.5 WMO/DEC

- non-WMO

1.6 Research type(s)

- Use of questionnaires

The research plan has been uploaded on the Vidatum website.

1.7 Research design(s)

- Observational

1.8 Mono or multicenter study (one choice)

- Monocenter

1.10 Which organization is the sponsor of the study?

The National Institute of Public Health and the Environment (R.I.V.M.) and Julius Centre

1.11 Name of datamanager consulted

Question not answered.

1.12 Last check date by datamanager

Question not answered.

1.13 Indicate which laws and regulations are applicable for the project (please check all that apply)

- Richtlijn Kwaliteitsborging Mensgebonden Onderzoek (Quality Assurance for Research Involving Human Subjects)
- Algemene Verordening Gegevensbescherming (AVG) or General Data Protection Regulation (GDPR)

2. Data Collection

2.1 Give a short description of the research data.

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Personal data involved?
Human	60-200	questionnaire	MSForms	quantitative	MSExcel	Yes

2.2 Describe the flow of the data (name systems used and/or third parties, recipients) <add link to location where diagram is stored in RFS>

Subject will use a MSForms digital questionnaire. Data will be stored in an online Excel file. After the collection phase of the study, the Excel file will be transferred to \\ds\data\JC\Datamanagement\Research\ and the data in the online Excel file discarded. Data in the Excel file on \\ds\data\JC\Datamanagement\Research\ will be analysed and summarized data published in a report to be shared with RIVM. Summarized results will possibly be reported in a scientific paper to be submitted to a peer-reviewed scientific journal. Raw data will remain on \\ds\data\JC\Datamanagement\Research\ for ten years after which the data will be discarded. Please note that only pseudonymized data is recorded and stored.

2.3 Estimated storage space for your project

- < 250 GB (e.g. questionnaires, textfiles, datasets)

2.4 Can you reuse existing data? If so, list the data source(s)

- No, please specify below

The data is collected for the intended client satisfaction survey. Additional use of collected data for secondary use is not planned, nor is it foreseeable that collected data could be fit for any secondary use.

2.5 Describe how you will take care of good data quality.

#	Question	Yes	No	N/A
1.	Do you use a GCP-compliant Data Capture Tool or Electronic Lab Notebook?			X
2.	Have you built in skips and validation checks?	X		
3.	Do you perform repeated measurements?			X
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?			X
6.	Are your data fully up to date?			X
7.	Do you lock your raw data (frozen dataset)	X		
8.	Do you keep a logging (audit trail) of all changes?			X
9.	Do you have a policy for handling missing data?		X	
10.	Do you have a policy for handling outliers?		X	

2.6 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Department	Funder	Other (specify)
1.	Time of data manager	X			
2.	Design of questionnaire				Personnel RIVM
3.	Questionnaire license fee				license RIVM
4.	Collection				Personnel RIVM
5.	Storage	X			
6	Archiving	X			

2.7 Please give some more details on other centers and organizations involved. What are the roles of the other centers and organizations involved? (What research activity does this organization carry out in relation to the study and the data?)

Organization	Role/research activity
R.I.V.M	Questionnaire design in collaboration with MSc student of R.I.V.M. and R.I.V.M colleagues at Bonaire-Netherlands. Colleagues at Bonaire also assist with sending the digital questionnaire to putative participants

2.8 Which contracts are in place?

Organization	Contract Type with UMCU	JOIN number
RIVM	Secondment agreement for PI Peter (P.C.J.I.) Schielen	

2.9 State how ownership of the data and intellectual property rights (IPR) to the data will be managed

UMC Utrecht Julius Centre and R.I.V.M have joined ownership of the collected data. After the study, data remains at UMCU, RIVM will not archive raw data. IPR are shared. The data will be used to write a summary report. If used in a scientific report, authorship is shared between RIVM and UMCU-JC.

2.10 Use of new technology. Does your study involve the implementation of a technology that has not been used before at UMC Utrecht?

- No

2.12 Will the study need/use personal data (directly or indirectly identifying)? For example, from the Electronic Patient Files (EPD; HiX), DNA, body material, images or any other form of personal data?"

- No.

The dataset is pseudonymized and only age and genderidentity of participants are recorded with the answers to the questionnaires.

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

- We use the secured Research Folder Structure

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

- All (research) data is stored in the RFS on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

The metadata are archived in a research protocol to obtain a non-WMO declaration (template research protocol nWMO, version 3.2, February 2025), which is uploaded in Vidatum. Aim of study, design of questionnaire, collection period, location of the study, intended number of participants and key parameters to report are recorded in that research protocol.

5.2 Describe your version control and file naming standards.

Only one file will be used. We will use version control of Windows/Microsoft as provided by UMCU.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

- Other
- I have written an analysis plan in which I state why I will use which data and which statistical analysis we plan to do in which software. The analysis plan is stored in the project folder, so it is findable for my peers.
- It is anticipated that we are going to write a paper and publish it, which will make the research accessible to peers.
- I will make an overview of datasets and analysis scripts, such that it is fully clear how the statistical analysis is performed. Peers will be able to repeat the analysis based on my overview.

We will use simple statistics in MSEXcel to get one-dimensional answers to our research questions. Statistics will be mostly descriptive, higher order statistics is not anticipated.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The research protocol as archived in Vidatum and the MSforms questionnaire, archived as an annex of the Vidatum-archived protocol, and the datafile with raw data stored at \\ds\data\JC\Datamanagement\Research\

7.2 Describe which archive or repository (include the link!) you will use for long-term

archiving of your data and whether the repository is certified.

- After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group. The (meta)data will be published in DataverseNL, the preferred UMCU repository.
- We will use Archivematica to archive our research data, we will follow the UMC Utrecht guidelines for archiving data.

7.3 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

- I cannot publish the dataset in an external repository. Therefore, I do not have a PID.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

I intend no reuse of this dataset, nor do I foresee such reuse.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- No, all data generated in this project will be made publicly available without any restrictions
1. As the data is privacy-sensitive, we publish the descriptive metadata in the data repository with a description of how a data request can be made (by sending an email to the corresponding author). In the event that peers like to reuse our data this can only be granted if the research question is in line with the original informed consent signed by the study participants. Every application therefore will be screened upon this requirement. If granted, a data usage agreement is signed by the receiving party.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

1. All data and documents in the data package mentioned in 7.1 will be available upon request to the PI. The final report can be made available upon request. The study protocol and this Data Management Plan will also be available.

8.4 Describe when and for how long the (meta)data will be available for reuse

- (Meta)data will be available upon completion of the project

8.5 Describe where you will make your data findable and available to others.

The final report will contain a statement indicating that data, metadata and study protocol are available upon request.