CBIG-SCREEN

Working collaboratively with vulnerable women to identify the best implementation gains by screening cervical cancer more effectively in European countries

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Data Management Plan

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Lead Beneficiary: Inserm, *Marc Bardou*

Dissemination level		
PU	Public	**x**
PP	Restricted to other programme participants (including Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

History of changes

Version number	Submission date	Description of changes	Authors / Reviewers
01	02/09/2021	Initial version	Marc Bardou

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1. Introduction

1.1. CBIG-SCREEN project overview

CBIG-SCREEN aims to tackle inequality in cervical cancer screening (CCS) continuum. Cervical cancer is the third most common gynaecological cancer and the second most common in women under 45 years. In Europe, over 61,000 women are diagnosed with cervical cancer each year and almost 26,000 of them will die of it – each death a tragedy considering that cervical cancer is today a preventable and treatable disease. The relatively high death rate has been largely attributed to low vaccination coverage and low cervical cancer screening rates among vulnerable women. Though screening programmes have been shown to drastically reduce cervical cancer mortality, they remain largely inaccessible and underused by subpopulations of vulnerable women, creating inequality in the European healthcare system and adding to the challenges underserved populations already face in their efforts to maintain their socioeconomic wellbeing and physical health.

Healthcare inequality is at the heart of CBIG-SCREEN's effort to provide vulnerable subpopulations with functioning access to cervical cancers screening and thus improve health outcomes and reduce associated healthcare and societal costs. The vulnerable subpopulations CBIG-SCREEN will focus on are women of low socioeconomic status, women living with HIV or other sexually transmitted diseases (STDs), incarcerated women, sex workers and migrants who may not have had access to cancer screening in their country of origin but find it difficult to navigate health care systems in their new homes. The Consortium will work in collaboration with these women to identify and develop strategies to meet their varied and specific needs, in order to attract them to the screening programmes, and to retain them from initial test to treatment. Through continuous dialogue we aim to convince policymakers to adopt these strategies ensuring that national screening programmes reach out to promote these interventions to communities of the underserved women. CBIG-SCREEN will create a Europe-wide knowledge framework around barriers to cervical cancer screening and generate policies, programmes, communications and other required services to meet the needs of these underserved sub-populations of women with inherent high-risk of cervical cancer and low (perceived) access to proper healthcare routes. Our interventions aim to reduce health inequality by increasing screening ratios among vulnerable women from 26% to 45% which could ensure 6,000 to 7,000 more women will survive each year.

The CBIG-SCREEN Consortium - List Partners

No	Participant organisation legal name	Short name	PI	Country
1 (CO)	Institut national de la santé et de la recherche médicale	Inserm	M. Bardou	France
2	Regionshospitalet randers	RHR	B. S. Andersen P. Kirkegaard	Denmark
3	London school of hygiene and tropical medicine	LSHTM	R. Legood M. McKee	UK
4	Azienda Unita Sanitaria Locale di Reggio Emilia	AUSL-IRCCS	P.G. Rossi	Italy

5	Instituto de saude publica da universidade do porto	ISPUP	N. Lunet	Portugal
6	Tartu Ulikool	UTARTU	A. Uusküla	Estonia
7	Universitatea Babes Bolyai	UBB	A. Baban	Romania
8	Institute of Oncology Cluj-Napoca	IOCN	F. Nicula	Romania
9	European institute of women's health limited	EIWH	R. Moore	Ireland
10	Centre international de recherche sur le cancer	IARC	P. Basu	France
11	Ecole d'économie de Paris	PSE	L. Rochaix	France
12	Health psychology research center	HPRC	I. Todorova	Bulgaria
13	European cancer leagues	ECL	D. Ritchie	Belgium
14	Inserm Transfert SA	IT	C. Dascher-Nadel	France

Description and purpose of this document

This document is the **CBIG-SCREEN data management plan** (DMP). The DMP describes the data management life cycle for all datasets to be collected, processed and/or generated by the research project. The H2020 DMP describes, among others:

- the handling of research data during and after the project
- the type of data that will be collected, produced, or processed
- what methodology and standards will be applied
- whether and how the data will be made (openly) accessible
- how the data is stored

The present DMP follows the template document available in the «Guidelines on FAIR Data Mangement in Horizon 2020» provided by the European Commission (version 3.0 ; 26 July 2016). This document is the first version of the DMP, which will be constantly updated over the course of the project according to the needs and progress of the consortium and whenever significant changes arise, including new data and changes in consortium policies.

2. Data summary

2.1. What is the purpose of the data collection/generation and its relation to the objectives of the project?

The purpose is to collect data to assess the existing screening policies, define contextualized policies adapted to the need of vulnerable women based on dedicated models, qualitative interviews, focus groups, discrete choice experiments, and results of co-creation with stakeholders to develop interventions for pilot testing of these proposed models. The data collection will comply with all national and EU ethics and legal requirements. Access to use these data is needed to address the different CBIG-SCREEN objectives as specified in the grant agreement and summarized below.

- **Objective 1**: Assess current CCS status among vulnerable women, including existing policies, stakeholder landscape, barriers, and preferences for CCS among subgroups of vulnerable women (**WP2, 3, 4**);
- **Objective 2**: Develop tailored intervention models that increase CCS in subgroups of vulnerable women (**WP2, 3**).
- **Objective 3**: Assess implementability and demonstrate scalability of intervention packages (**WP6**);
- **Objective 4**: Assess health benefits and cost-effectiveness of intervention packages (**WP5**);
- **Objective 5**: Disseminate findings and deliver recommendations to EU representatives and policy makers, so they will translate into profound and long-lasting benefits for vulnerable women (**WP7**)

#	Dataset	Purpose and relation to objectives of CBIG-SCREEN	Origin	Types and forms	WP #
1	Policies	Mapping of existing policies	Survey	Quantitative/Qualitative, Excell	2
2	Uptake and performance data	Collect data on implementation, efficacy, and quality indicators etc.	Administrative databases	Quantitative, Excell, SAS	2
3	Previous projects	To provide a knowledge base for the CBIG-SCREEN	Previous projects e.g. EU-TOPIA, HARP, ELEVATE, VALID-SCREEN, CEDICROM, IPAC	Qualitative	2,3,5
4	Systematic review	To provide point of departure for developing state of the art intervention for discussions in the Collaborative User Boards and testing in exemplar countries	Developed in CBIG-SCREEN	Quantitative	
5	Model parameters for cost-effectiveness model	To provide cos-effectiveness and budget impact analyses of tailored interventions across European countries	Developed in CBIG-SCREEN	Quantitative, Excell	3
6	Collaborative User Board outputs	To propose intervention models for testing in exemplar countries	Collaborative User Board meetings	Qualitative, audiorecordings/transscripts, RedCap, NVivo	2
7	Pilot testing of the intervention	To ensure implementability and assess	Developed in CBIG-SCREEN	Quantitative, SAS	3

		contextual impact of the proposed interventions			
8					

Table 1 (below) describes the datasets and the purpose of the data collection and generation in relation to the objectives of the project.

#	Datasets	Description, purpose and relation to the objectives of the CBIG-SCREEN project	WP#
1	Uptake and performace data from administrative databases	Collect data on implementation, efficacy and quality indicators for CCS across Europe to Assess current CCS status among vulnerable women. Existing screening policies will be mapped from across Europe. A map of stakeholders in each partner country will be also be created – including representatives from organiztions, health professionals, and representatives from vulnerable women. Aggregated data, with subgroups analyses whenever feasible	**WP2,3,4**
2	Stakeholder engagement, perspectives, preferences and recommedenations	Data will be collected to identify stakeholders at the macro, meso and mirco level. At the meso and micro level, participatory methods will be employed to understand the perspectives, barriers faced, preferences and recommendations of stakeholders. The datasets will include interview and focus groups(trancripts), digitat stories	**WP2,3,4**
3	Results from intervention to reach vulnerable women	We will perform systematic review of the published literature to : Develop tailored intervention models that increase CCS in subgroups of vulnerable women, based on existing data and assess health benefits and cost-effectiveness of intervention packages	**WP2,3,5**
4	Data from previous research projects such as the the EU funded Eu-topia, ELEVATE, HARP, VALID-SCREEN, CEDICROM, IPAC. Individual data will be asked where ever needed	Built our proposed intervention to reach vulnerable women based on data gained during these research projetc.	**WP2,3,5**
5	Prospectively colleted efficacy,cost and qualtitative data	These data will be collected during the pilot testing of the proposed strategies in the 3 exemplar countries, to refine the strategies and feed the cost-effectiveness model.	**WP5,6**

Table 1. Description of CBIG-SCREEN datasets

2.2. What types and formats of data will the project generate/collect?

The project will essentially produce and collect quantitative data to ssess current CCS status among vulnerable women, including existing policies, stakeholder landscape, barriers, and preferences for CCS among subgroups of vulnerable women, and to assess efficacy and implementation results during the pilot testing of the proposed interventions.

Qualitative data will also be collected during collaborative user boards meetings with stakeholders (representatives for vulnerable women, healthcare professionals, and policy makers), through interviews with vulnerable women, and through discrete choice experiments and co-creative workshops.

Table 2 (below) describes the types and formats of the datasets that CBIG-SCREEN will generate and collect.

#	Datasets	Types	Forms and Formats
1	Datasets on implementation, efficacy and quality indicators for CCS across Europe	Screening policies: Quantitative data collected with data collection tools (survey) developed or adapted for the purpose of mapping screening policies in Europe. The survey will be completed by the cancer screening experts in all EU countries.(WP2)	Survey data collected/stored in Excel, Sas datasets
2	Stakeholder engagement, perspectives and recommdenations	Stakeholder mapping: Data on stakeholders from 6 partner countries at the macro and meso level will also be collected though the above tool (WP2). Participatory methods: Focus groups(workshops) will be conducted with stakeholders and qualitative data will be collected, audiorecorded and translated (WP2). Digital stories will be developed based ion qualitative data (WP3). They will be discussed at stakeholder focus groups. Interviews about barriers faced for screening, as well as preferecnes for interventions will also be conducted (WP4)	Qualitative data from participatory methods will be collectd in audio files and stored/transcribed in de-identified Word documents.

3	Model parameters for cost-effectiveness model	Quantiative data	Excel dataset
4	Results from intervention to reach vulnerable women	Quantitative data	SAS datasets

Table 2. Types, forms and formats of the datasets

2.3. What is the origin of the data?

All datasets will be created by CBIG-SCREEN partners

Table 3 (below) describes the origin of the datasets that will be produced within CBIG-SCREEN.

#	Datasets	Origin
1	Uptake and performace data from administrative databases	▪ Administrative databases (health insurance claim databases, screening programmes administrators, public health agencies, cancer agencies) according to what is avalaible and appropriate
2	Systematic review	▪ Dataset created by the partners. Excell files will be used to collect studies information and extract data for metaanalysis purpose
3	Data from co-production workshops	▪ Data will be collected from stakeholders i.e. vulnerable women/people from underserved groups, healthcare professionals and policy makers

Table 3. Origin of the datasets

2.4. Will you re-use any existing data and how and to whom it be useful ('data utility)

CBIG-SCREEN will use results from published studies assessing interventions aimed a improving CCS in vulnerable women and messuring efficiency of such interventions. Whenever needed individual data may be requested from original investigation teams. These data will be used to build our model of CCS approaches tailored to the need of vulnerable women. CBIG-SCREEN will also generate its own data as previously explained.

Table 4 (below) describes to whom the CBIG-SCREEN data might be useful (data utility).

#	Datasets	Utility
1	Model parameters for cost-effectiveness models	▪ Data will be collated from the literature and also the other work packages WP4 and WP6.

2	Model parameters for efficacy models	▪ Data will be collated from the literature and also the other work packages WP4 and WP6 to suggest interventions to be proposed, and tested in the 3 exemplar countries, to increase CCS adherence among groups of vulnerable women

Table 4. Utility of the datasets

2.5. What is the expected size of the datasets

The expected size of the data is to be determined. This section will be updated throughout the duration of the project.

3. FAIR data

The CBIG-SCREEN consortium follows the **FAIR principles of scientific data management**, aiming at making data « **findable, accessible, interoperable and reusable** ».

Open data generated within CBIG-SCREEN will follow the instructions from the European Commission from the « *Guidelines to the Rules on Open Acces to Scientific Publications and Open Access to Research Data in Horizon 2020* » (version 3.2, 21 March 2017) as well as the « *Guidelines on FAIR Data Management in Horizon 2020* » (version 3.0, 26 July 2016).

Open access refers to provide online access to scientific information that is free of charge to the reader. Open access typically focuses on access to « **scientific information** » or « **research results** », which refers to two main categories:

- **Peer-reviewed scientific research articles**
- **Research data**

The **open access mandate** leads to disseminate / share scientific results and comprises :

- Publishing scientific articles in journals and depositing them in repositories
- Depositing research data in repositories (see below for the definition of “research data”)

However, if confidentiality, security or personal data protection obligations or Intellectual Propreties rights (IPR) forbid open access to given data generated within the project, access will be restrained to the consortium members only (exploit / protect path).

3.1. Making data findable

Within CBIG-SCREEN, scientific research publications and other research data will be available as :

- articles in scientific journals accessible through gold or green access. Gold route will be preferred whenever possible. Articles will also be deposited in repositories.
- and/or data in self-archiving repositories.

3.2. Making data openly accessible

3.2.1 Data accessibility

All published and/or desposited data will be accessible without restriction. For other data, users interested will be required to contact the data owner in order to potentially get access to the anonymised data. IPR relative procedures might be used if needed.

3.2.2 Making research data openly available

As outlined in the Table 5, the CBIG-SCREEN consortium will share data by publishing scientific articles and depositing these articles as well as research data in repositories.

Before publication, the consortium members will enquire about publisher's publishing /copyright /licensing policy. If the publishers' policy does not allow compliance with EU requirements for Open Access, the authors will try to negotiate an amendment or request an authorisation to self-archive. If negotiations are unsuccessful, the authors of the publication will store the publisher's proof of refusal. An updated list of publishers and their Open Access policy will be provided to consortium members in the initial stage of the project. All publications (final articles or manuscripts accepted for publication) will be deposited into the institutional repository (Table 6) of the research institution with which they are affiliated or in an appropriate subject based/thematic repository. Depositing will be done at the latest upon publication. Publishing and depositing may or may not occur simultaneously, depending on whether open access publishing (gold open access) or self-archiving (green open access) is used, and, in the case of self-archiving, depending on the embargo period (if any). The repositories used by the CBIG-SCREEN team will make sure that the embargo period is respected and will make connection with the EU repository xxxxxxx. The consortium members will ensure an open access to the publication within a maximum of six months.

Open access publishing (gold open access)

- An article is immediately provided in open access mode on the publisher/journal website.
- Publishers sometimes charge so called Article Processing Charges (or APCs) to make articles open. Such costs are eligible for reimbursement during the duration of the project as part of the overall project budget.
- Open access must be granted at the latest on the date of publication.
- The article will also be deposited in a research repository.

Self-archiving (green open access)

- A published article or the final peer-reviewed manuscript is archived (deposited) in an online repository before, at the same time as, or after publication.
- Some publishers request that open access be granted only after an embargo period has elapsed. Repository software usually allows authors to delay access to the article ('embargo period').
- The publication must be openly accessible within a maximum of six months.

Repositories

The table below lists the repositories that will be used by the CBIG-SCREEN consortium.

Name	Website	Country
Hal	http://www.hal.inserm.fr/	France
LSHTM research online	https://researchonline.lshtm.ac.uk/	UK

Table 6. Institutional repositories of CBIG-SCREEN Consortium

Data are in majority produced in common electronic forms and formats which do not require specific tools or softwares to access them.

3.3. Making data interoperable

Interoperability, as well as findability and resusability of data, will be facilitated by using the sets of metadata. This section will be enriched throughout the course of the project.
Interoperable software will be used, both to collect data, for example Excell and SAS, or proceed data.

3.4. Making data reusable

Data will be made available and reusable by publishing scientific articles and depositing them as well as research data in repositories, as specified in section 3.2. Scientific publications following the gold access route will be available immedialtely upon publication while the ones following the green access route will be available upon the end of the embargo period set by the publisher. CBIG-SCREEN publications will adhere to the Recommendations from the International Committee of Medical Journal Editors on Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Ethical Considerations in the Conduct and Reporting of Research, Authorship and Contributorship (http://www.icmje.org). CBIG-SCREEN will follow the guidelines for submission in open access electronic databases maintained by the European Bioinformatics Institute (EBI - http://www.ebi.ac.uk) and the European Scientific Research Infrastructure for life-science information (ELIXIR - http://www.elixir-europe.org), making it possible for others to access, mine, exploit, reproduce and disseminate the results free of charge, thus ensuring data sustainability beyond the project duration.

Metadata will help make easier to understand the data that will be produced within CBIG-SCREEN and hence, facilitate their reusability.

This section will be enriched over the timecourse of the project if relevant.

4. Allocation of resources

4.1 Estimation of costs for making data FAIR

Dissemination of data	Costs for making the data FAIR
Publication of scientific articles	Fees associated with the article processing charges (APC) that will be claimed as part of the Horizon 2020 grant. In case of multiple authors, the cost sharing shall be decided by the authors on a case-by-case basis.
Data archiving (institutional repositories)	Free of charge
Participation in medical meeting	Fees associated with presenting CBIG-SCREEN findings at medical meeting that will be claimed as part of the Horizon 2020 grant. Only the presenting author will be covered

Table 7. Estimation of costs for making data FAIR

4.2 Responsabilities for data management

Every partner owns and is responsible for the data they produce (Grant agreement, Article 26.1)

Our Data Management Plan (DMP) is managed by Partner 1, Inserm.

5. Data security

Data security and personal data protection

Every partner is responsible for the storage of the data they produce and/or collect.

To keep the data safe and secure, local computers and/or servers at partner's institutions will be used. Access to the computers and servers are restricted to the participants of the CBIG-SCREEN project. While collecting, processing and analysing data (dynamic phase), regular back-ups will be implemented regularly to avoid accidental or malicious data loss.

CBIG-SCREEN takes into account the guidelines for data security and personal data protection according to the General Data Protection Regulation (GDPR ; EU Regulation 2016/679). Any and all confidential information will be governed by the Consortium Agreement and direction provided by the Innovation Management Board (IMB) to the partner RMIT EU in order to facilitate compliance within the consortium and adherence to all EU rules, regulations and laws. During the project, the consortium partners will gather data for specific purposes, based on engagement with key stakeholders including the public, parents of premature babies, industry representatives and civil

society. Participant ID numbers will be assigned to questionnaires and surveys to ensure that they are anonymised before storage. Any audio-recordings of interviews or focus groups will be stored securely. If transcribed, any identifying information will be removed during the transcription process. As part of stakeholder qualification to participate in the project activities, all potential participants will complete an informed consent form and confirm that they are participating on a voluntary basis in advance. Anonymised aggregated data will be analysed, and findings disseminated through the project's communication channels and public reports.

Data long term preservation and curation

Data long term storage and curation will be ensured by individual partner institution's data repositories.

6. Ethical aspects

The CBIG-SCREEN consortium addresses scrupulously all the ethical, legal, social, and safety issues raised by its research activities, with the help of an Ethics Advisory Board included in the project management structure. All research activities and stakeholders (patient/consumers representatives) engagement will have prior approval from our local institutional boards, all of which adhere to the EU regulations on the reduction, refinement and replacement of animals as and when possible to still facilitate meaningful data collection.

Research involving humans and personal data

The partners are aware that, in principle, data processing is prohibited, unless the explicit consent of the person whose data are processed has been obtained (according Art. 6 para. 1 a) GDPR). Also, with all future persons, this consent will be obtained first following the principles of personal data processing (Art. 5 GDPR). All partners fully respect the rights of the data subjects according to Art. 13; 15 GDPR and Art. 16 - 21 GDPR.

7. Other

There is no other issue to report at this time.