



Knowledge and data management activity V3 ehcoBUTLER Project

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1 INTRODUCTION

1.1 Purpose of this document.

The Knowledge and Data Management Activity (KDMA) provides evidence of the activity done in the management of the foreground knowledge and data generated by the project by providing an update of the previous KDMA about the data and distinctive knowledge that has been produced by the ehcoBUTLER consortium until the end of the project with a specific focus on pilots' execution.

The KDMA V3 is not a fixed document but evolves during the Project. As a matter of fact, KDMA belongs to an updated version of D7.9.

1.2 Intended audience

This document is oriented to:

- The project's participant organizations;
- The local Ethics Committees;
- The beneficiaries' personnel and all stakeholder involved by the project;
- The European Commission.

1.3 Overview of the document

This document contains:

- a description of the data and knowledge that is produced by the project during its lifecycle. This description is based on the current status of project development, and it is subject to a periodic update according to the project knowledge and data production processes;
- a brief description of the access policies according to the type of the data and knowledge, the typologies of stakeholders potentially interested to them and the degree of relevance for the project exploitation and consortium IPR.

1.4 References and applicable documents

Reference documents are:

- D7.3 – Knowledge and Data Management activity;
- D7.4 - Knowledge and data management plan;
- Commission Recommendation of 23 June 2009 on reference metadata for the European Statistical System (2009/478/EC);
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016.
- D7.9 - Knowledge and Data Management activity V2.

1.5 Terminology

1.5.1 Abbreviations and acronyms

- EC: European Commission.
- DOW: Description of Work
- OI: Open Innovation
- WP: Work Package
- ISI: International Scientific Indexing
- KDMA: Knowledge and Data Management Activity



1.5.2 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Rules or in the Grant Agreement related to the project.

1.5.3 Additional Definitions

- **Project:** Project refers to the ehcoBUTLER project funded from the European Union's Horizon 2020 research and innovation programme under Grant Agreement 643566;
- **Knowledge:** All data and knowledge produced during the project.

2 KNOWLEDGE AND DATA ACCESS POLICIES

2.1 General principles

As reported in Deliverables 7.3 & 7.9, ehcoBUTLER project has been managed as an **open innovation** (OI) project. In order to maximize the efficiency and effectiveness of knowledge sharing among the partners and relevant stakeholders, a web-based platform has been developed and adopted for enabling and supporting collaborative working on project documents, databases and information.

2.2 Access policies

According to the OI model fully described in Deliverables 7.3 & 7.9, the access policies to ehcoBUTLER knowledge and data are:

- “golden” open access, for all data and knowledge that will be immediately made available to the public through the project web site,
- “green” open access, for all data and knowledge with no restricted open access and involving specific stakeholders on the basis of their previous registration and identification. In this case, the project Knowledge will be shared only with organizations/individuals aimed at using them for research purposes and willing to make open the further findings produced by the use of ehcoBUTLER Knowledge.

In Chapter 3, all data and knowledge that has been produced during the Project lifecycle is analysed in relation to the OI strategy and related access policies.

Both “golden” and “green” Knowledge has been managed by the Dissemination Manager in a specific section of the project web portal.

2.3 Recommendations for the knowledge and data repository

- Documents have been be produced under the Word, Excel, PowerPoint and PDF formats.
- The Knowledge Repository allows downloading and uploading each format below listed.

3 KNOWLEDGE AND DATA PRODUCED BY THE PROJECT

3.1 Description of data and knowledge

In this paragraph, we provide a description of the knowledge and data that has been generated for each work package.

This exercise is useful for several reasons:

- It helps defining what type of knowledge and data are produced by the project;
- It specifies when they have been produced;
- It clarifies the relevance of project data for the exploitation purposes and IPR;
- It allows deciding to what extent the Knowledge and data generated can be open to stakeholders and to the public.

In the following subparagraph we specify all these issues in details in terms of:

- Key characteristics;
- Relevance for the project exploitation and IPR;
- Type of stakeholders addressed from those identified in D7.1;
- Access policy as specified in Chapter 2;
- The metrics that have been used to evaluate the knowledge produced by each Work Package.

3.1.1 Knowledge and data produced in WP2

Scope of this WP was to collect all relevant information about innovation context system, including elder people experiencing cognitive decline and feedbacks from other relevant stakeholders. They include health professionals, caregivers, public and private organizations dealing with health care and social services for the target users of ehcoBUTLER as well as health authorities. Moreover, the WP2 aims to collect evidences on the usability and acceptability of the current solution and the new functionalities that will be deployed during the project lifetime (Lead beneficiary: Consorcio Centro de Investigacion Biomedica EN RED M.P. – CIBER).

Under these perspectives the relevant data and knowledge that have been collected during this WP are:

- Needs and requirements of elder people that experience a cognitive decline from end users and other relevant stakeholders perspectives;
- Results from usability evaluation of ehcoBUTLER functionalities.

Measurement metrics:

- # of publications in scientific papers that will use the data and knowledge that will be done by the project Consortium;
- # of public events where the project consortium will use the data and knowledge.

WP2_1	Knowledge/Data ID	Needs and requirements of older people that experience a cognitive decline from end users and other relevant stakeholders perspectives.
	Related Task/Deliverable	T2.1; D2.1
	Description	Use cases and reports
	Format	Written format and UML
	Time of publication	M27
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will be shared only among the consortium members (including Commission services).
	Type of stakeholders addressed	Organizations and individuals aimed at using them for research purposes. Mainly universities and research centres.

	Access policy	Green open access
WP2_2	Knowledge/Data ID	Results from usability evaluation of ehcoBUTLER functionalities
	Related Task/Deliverable	T2.3 and T2.4; D2.3 and D2.4
	Description	Statistics and reports
	Format	Written format and datasets with statistical indicators
	Time of publication	M72 and M71
	Relevance for the project exploitation and IPR	Core knowledge –The data and knowledge will be shared only among the consortium members (including Commission services).
	Type of stakeholders addressed	Organizations and individuals aimed at using them for research purposes. Mainly universities and research centres.
	Access policy	Green open access
WP2_3	Knowledge/Data ID	Validation protocol fully tested
	Related Task/Deliverable	T2.6; D2.5 (validated through the pilots implementation activity on the field)
	Description	Check lists, questionnaires, protocols and related manuals of use
	Format	Written format and pptx
	Time of publication	M33
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will be shared only among the consortium members (including Commission services).
	Type of stakeholders addressed	Mainly university and research centres.
	Access policy	Green open access

3.1.2 Knowledge and data produced in WP3

Scope of this WP was to design, develop and integrate the ehcoBUTLER platform. It is based on the results of the WP2 activities and it also provides evidence of a further evaluation of the usability of the solution from the end users' perspective (Lead beneficiary: NTT DATA SPAIN SL).

Relevant data and knowledge that has been collected during this WP are:

- Guideline for the developers.

Measurement metrics:

- # of publications in scientific papers that will use the data and knowledge that will be done by the project Consortium;
- # of public events where the project consortium will use the data and knowledge.

WP3_1	Knowledge/Data ID	Guideline for developers.
	Related Task/Deliverable	T3.3; D3.3
	Description	Statistics and reports
	Format	Written format
	Time of publication	M72
	Relevance for the project exploitation and IPR	Core knowledge – it will be made available for the platform developers.



	Type of stakeholders addressed	Organizations and individuals that could be interested to exploit the ehcoBUTLER platform: Health insurance companies, Health care professionals (GPs, Nurses, Specialists), Health and social care providers, Services and consultancy companies; industry, University and research centres, Others (Alliances, associations clusters, networks, etc.).
	Access policy	Golden open access.

3.1.3 Knowledge and data produced in WP4

Scope of this WP was to develop further MCI modules which functions in the ehcoBUTLER ecosystem, using the API developed in WP3. This WP is mainly related to the development of new modules of ehcoBUTLER solution (Lead beneficiary: SENLAB DRUZBA ZA INFORMACIJSKO TEHNOLOGIJO DOO – SENLAB).

The data and knowledge generated under WP4 will be shared only among the consortium members (including Commission services).

3.1.4 Knowledge and data produced in WP5

The activities of WP5 were focused on conducting the pilots in 5 countries (Spain, Greece, Italy, Serbia and Israel) and 7 organizations; however, the project has finally piloted the ehcoBUTLER suite in 2 countries (Spain and Italy) and 4 organizations (INTRAS, TME, AIMA and ASBAR) due to COVID-19-related issues.

The objective of WP5 was to validate the ehcoBUTLER business cases and perform an analysis on the impact and cost effectiveness of the solution. WP5 has created a large amount of data that is mainly used for analysis in WP6. According to the ethical issue regulations, all this data have been completely anonymized. End users and their relatives and caregivers has been informed on the use of the data through the Informed Consent and Participant Information Sheet (Lead beneficiary: FUNDACION INTRAS – INTRAS).

Under these perspectives the relevant data and knowledge that has been collected during this WP are:

The results from the evaluation protocol pre-and post-measurements (see D2.6), including:

- Participant form;
- Mini Mental State Examination (MMSE);
- Clock Drawing Test (CDT);
- Geriatric Depression Scale (GDS);
- Multicultural Quality of Life Index;
- Lubben Social Network Scale (LSNS-6);
- Usability and Acceptability evaluation metrics;
- Mood evaluation metrics;
- Final questionnaire for the users;
- Training material and installation guide of ehcoBUTLER solutions;
- Results from focus group sessions.

Measurement metrics for the restricted knowledge developed by the project:

- # of publications in scientific papers that will use the data and knowledge that will be done by the project Consortium;
- # of public events where the project consortium will use the data and knowledge.

Measurement and metrics for the whole knowledge developed by the project:

- # of publications in scientific papers that will use the data and knowledge that will be done by third parties;
- # of public events where the third parties will use the data and knowledge;
- # of download of the publication from the ehcoBUTLER web site;
- # of followers of ehcoBUTLER account of online research networks;
- # of access for ehcoBUTLER data use registered from the ehcoBUTLER web site.

WP5_1	Knowledge/Data ID	Evaluation protocol results
	Related Task/Deliverable	T5.4; D5.3
	Description	Anonymised raw data from the pilots
	Format	xlsx format, csv format
	Expected time of publication	M81
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	Research centres and universities, internal used for WP6 analysis on cost effectiveness.
	Access policy	Golden open access
WP5_2	Knowledge/Data ID	Usability and acceptability evaluation metrics
	Related Task/Deliverable	T5.4; D5.3
	Description	Anonymised raw data from the pilots
	Format	xlsx format, csv format
	Expected time of publication	M81
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	Mainly university and research centres, internal used by the Change -Management Board and Innovation Board Committee of the ehcoBUTLER project.
	Access policy	Golden open access
WP5_3	Knowledge/Data ID	Mood evaluation metrics
	Related Task/Deliverable	T5.3 and T5.4, D5.3
	Description	Anonymised raw data from the pilots
	Format	xlsx format, csv format
	Expected time of publication	M81
	Relevance for the project exploitation and IPR	Non-core knowledge –The data and knowledge will be open to public
	Type of stakeholders addressed	Mainly university and research centres, internal use by WP6 analysis.
	Access policy	Golden open access
WP5_4	Knowledge/Data ID	Final questionnaire
	Related Task/Deliverable	T5.4; D5.3
	Description	Anonymised raw data from the pilots
	Format	xlsx format, csv format
	Expected time of publication	M81

	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	Health care authorities and policy makers; Health insurance companies; Health and social care providers; Services and consultancy companies; industry; University and research centres; Others (Alliances, associations clusters, networks, etc.).
	Access policy	Golden open access
WP5_5	Knowledge/Data ID	Training material and installation guide of ehcoBUTLER solution
	Related Task/Deliverable	T5.1, T5.2, D5.1 and D5.2
	Description	Manual and slides
	Format	Written format and pptx
	Time of publication	M63 and M69
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will contain confidential input
	Type of stakeholders addressed	Internal for consortium partners, especially pilot partners.
	Access policy	No open access
WP5_6	Knowledge/Data ID	Results from the focus group sessions
	Related Task/Deliverable	T5.4; D5.3
	Description	Raw transcriptions from the sessions and written format.
	Format	Doc.
	Expected time of publication	M81
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will contain confidential input for the business model design of ehcoBUTLER.
	Type of stakeholders addressed	Only internal for WP6 analysis.
	Access policy	No open access
WP5_7	Knowledge/Data ID	Results from the issue tracker tool
	Related Task/Deliverable	T5.3; D5.3
	Description	Issues managed through the bug tracker tool (JIRA & Helpdesk) of the project during pilot stage.
	Format	xlsx format, csv format
	Expected time of publication	M81
	Relevance for the project exploitation and IPR	Non-Core knowledge – The data and knowledge will contain confidential input
	Type of stakeholders addressed	Internal for consortium partners.
	Access policy	No open access
WP5_8	Knowledge/Data ID	Impact indicators and RoI measurements
	Related Task/Deliverable	T5.3; D5.3
	Description	Anonymised raw data from the pilots

Format	xlsx format, csv format
Expected time of publication	M81
Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will contain confidential input for the business model design of ehcoBUTLER.
Type of stakeholders addressed	Only internal for WP6 analysis.
Access policy	No open access

3.1.5 Knowledge and data produced in WP6

Scope of this WP was to provide evidences of the impacts that the project could produce on target population and how it can contribute to develop sustainable services for eldercare population. It also aims at developing a sustainable business model for exploiting ehcoBUTLER solution (Lead beneficiary: ASESORIA DE BARRERAS ARQUITECTONICAS ASBAR SL – ASBAR).

Under these perspectives, the relevant data and knowledge collected during this WP are:

- Results from the impact evaluation of the data collected from pilot trials;
- Results from the cost benefit analysis of the use of ehcoBUTLER solution in different health care systems existing in Europe;
- Exploitation strategy, business model and related business plan.

Measurement metrics for the restricted knowledge developed by the project:

- # of publications in scientific papers that will use the data and knowledge that will be done by the project Consortium;
- # of public events where the project consortium will use the data and knowledge.

Measurement and metrics for all the knowledge developed by the project:

- # of publications in scientific papers that will use the data and knowledge that will be done by third parties;
- # of public events where the third parties will use the data and knowledge;
- # of download of the publication from the ehcoBUTLER web site;
- # of followers of ehcoBUTLER account of online research networks;
- # of access for ehcoBUTLER data use registered from the ehcoBUTLER web site.

WP6_1	Knowledge/Data ID	Results from the impact evaluation of the data collected from the pilot trials
	Related Task/Deliverable	T6.1; D6.1
	Description	Reports and statistics
	Format	Written format and pptx
	Expected time of publication	M83
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	Health care authorities and policy makers; Health insurance companies; Health care professionals (GPs, Nurses, Specialists), Health and social care providers; Services and consultancy companies; industry; University and research centres; Others (Alliances, associations clusters, networks, etc.).
Access policy	Golden open access	

WP6_2	Knowledge/Data ID	Results from the cost benefit analysis of the use of ehcoBUTLER solution in different health care systems existing in Europe
	Related Task/Deliverable	T6.2; D6.2
	Description	Reports and statistics
	Format	Written format and pptx
	Expected time of publication	M85
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	Health care authorities and policy makers; Health insurance companies; Health and social care providers; Services and consultancy companies; industry; University and research centres; Others (Alliances, associations clusters, networks, etc.).
	Access policy	Golden open access
WP6_3	Knowledge/Data ID	Exploitation strategy, business model and related business plan
	Related Task/Deliverable	T6.3; D6.3
	Description	Reports, economic evaluation, logic model
	Format	Written format, xlsx and pptx
	Expected time of publication	M87
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will be shared only among the consortium members (including Commission services).
	Type of stakeholders addressed	Only those partners that will be engaged in the exploitation activities.
	Access policy	No open access
WP6_4	Knowledge/Data ID	Catalogue of Services
	Related Task/Deliverable	T6.3; D6.4 and D6.5
	Description	Collection of any business and information technology related to the services that can be performed by ehcoBUTLER solution
	Format	Written format
	Expected time of publication	M70; M82
	Relevance for the project exploitation and IPR	Core knowledge – The data and knowledge will be shared only among the consortium members (including Commission services).
	Type of stakeholders addressed	Only those partners that will be engaged in the exploitation activities.
	Access policy	No open access

3.1.6 Knowledge and data produced in WP7

Scope of this WP is to disseminate and communicate the project results to targeted stakeholders and to the public (Lead beneficiary: YOUR DATA SRL).



Under these perspectives the relevant data and knowledge that will be collected during this WP are:

- Results from the dissemination and communication activities;
- Results from the knowledge and data management activity.

Measurement metrics:

- Number of yearly publication in peer reviewed conferences (ISI listed);
- Number of yearly accepted articles for publications in ISI listed journals;
- Average number of participants to the events organized by the consortium;
- Number of citations of *ehcoBUTLER* consortium publications;
- Numbers of events organized by the consortium during the project lifetime;
- Number of download from the Project website;
- Number of followers (and what kind of stakeholders they are) of social accounts;
- Number of access on data use registered form Project website.

WP7_1	Knowledge/Data ID	Results from the dissemination and communication activities
	Related Task/Deliverable	T7.2; D7.2; D7.7; D7.8
	Description	Dissemination material, feedbacks from the participants to the dissemination initiatives; statistics.
	Format	Docx; pptx; csv; web contents
	Time of publication	M28; M72; M87
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	All type of stakeholders identified in D7.1.
	Access policy	Golden open access
WP7_2	Knowledge/Data ID	Results from the knowledge and data management activity
	Related Task/Deliverable	T7.3; D7.3 ; D7.9; D7.10
	Description	Statistics and reports on organizations/individual accessing the knowledge repository.
	Format	Docx, pptx, xlsx; csv
	Expected time of publication	M6; M75; M87
	Relevance for the project exploitation and IPR	Non-core knowledge – The data and knowledge will be open to public
	Type of stakeholders addressed	All type of stakeholders identified in D7.1.
	Access policy	Golden open access

4 SPECIFICATIONS OF THE KNOWLEDGE AND DATA REPOSITORY

4.1 General overview

Knowledge and data produced during the ehcoBUTLER project has been organized according to the OI model and to the access policies fully described in Deliverable 7.3.

In the case of data and knowledge that have been immediately made available to the public (Golden open access rule), the ehcoBUTLER Web Site, ZENODO and research networks have been the tools through which knowledge and data have been shared. In order to assess the open access policy strategy, in the ehcoBUTLER web site has been recorded and reported:

- # of accesses to the ehcoBUTLER web site;
- # of publications downloaded.

For all data and knowledge with restricted open access and involving specific stakeholders on the basis of their previous registration and identification (Green open access rule), Knowledge and data produced during the project have been organized into a repository, containing all the Knowledge produced by the project activities. This Knowledge, as clarified in the Data Management Plan (D7.4), must be stored in a secure environment with control access and other security measures.

The main issues treated in this document are the relevant troubles caused during each phase in the Knowledge management. These issues also depend on the type of knowledge considered; for example, for sensitive data, security is a key issue. In contrast, for non-sensitive Data, verifying respect of IPR and copyright rules may be the primary issue.

Appropriate disciplinary actions, according to the Grant Agreement, will follow towards any breach, unauthorized use, disclosure, alteration, or destruction of project data, in violation of this policy.

4.2 Key functionalities specifications for the knowledge and data repository

In order to provide a secure environment where the Consortium partners could share data, but also a restricted area for knowledge and data regulated by the Green open access rule, *Microsoft Sharepoint* is used. The access to the repository system must be applied sending an email (ehcobutler.management@nttdata.com) to the project Technical Office and must be approved by the Project Director. People or institutions obtaining the access to project Knowledge must comply with security and policy rules established by this document and any other project document. All results and materials, whether stored in the ehcoBUTLER repository or copied into other data systems, remain the property of the ehcoBUTLER project as defined into the Grant Agreement.

Using *Microsoft Sharepoint* allows:

- Centralizing the Knowledge and making it easier to find, reuse and update;
- Organizing the project data and keeping information accessible depending on permission given to stakeholders (e.g. for Knowledge with Green open Policy);
- Monitoring number of accesses for ehcoBUTLER data use.

5 DATA MANAGEMENT AND GDPR

At the time of writing Deliverable 7.4 dealing with Data Management, the EU legislation standards for human studies include the following regulations as for the protection of individuals:

- The Declaration of Helsinki in its latest version (recommendation for conduct of clinical research).
- Directive 95/46/EC on the protection of individuals with regard to processing of personal data and on the free movement of such data Council Directive 83/570/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC dealing with proprietary medicinal products.
- Directive 95/46/EC (amendment 2003) of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the protection of privacy, storing of personal data and on the free movement of such data.
- The charter of fundamental rights of the EU (2000/C 364/01).
- EU Good Clinical Practice Directive (2001/20/EC).

In addition, all researchers and clinical professionals involved in the ehcoBUTLER project have complied with the ethical guidelines of their respective professional associations.

On May 25, 2018 the General Data Protection Regulation (GDPR), the toughest privacy and security law in the world, was put into effect. It is addressed to organizations dealing with collection and management of personal data related to people in the EU and describes procedures, rules and penalties¹.

According to the information provided by the “*Complete guide to GDPR compliance*” cited above, the main GDPR principles are:

- *Lawfulness, fairness and transparency*: Processing must be lawful, fair, and transparent to the data subject;
- *Purpose limitation*: You must process data for the legitimate purposes specified explicitly to the data subject when you collected it;
- *Data minimization*: You should collect and process only as much data as absolutely necessary for the purposes specified;
- *Accuracy*: You must keep personal data accurate and up to date;
- *Storage limitation*: You may only store personally identifying data for as long as necessary for the specified purpose;
- *Integrity and confidentiality*: Processing must be done in such a way as to ensure appropriate security, integrity, and confidentiality (e.g. by using encryption);
- *Accountability*: The data controller is responsible for being able to demonstrate GDPR compliance with all of these principles.

For what concerns *accountability*, data controllers have to be able to demonstrate they are GDPR compliant and, in the case of ehcoBUTLER, it means that for each project team:

- *A responsible for data protection should be designated*;
- *Detailed documentation of the data collected should be maintained* by declaring how data is used, where it's stored, which employee is responsible for it, etc.;
- *Team staff should be trained*;
- *Technical and organizational security measures should be implemented*;
- *Data Processing Agreement contracts with third parties that process data should be signed*;
- *A Data Protection Officer should be appointed by each partner*.

Moreover, organizations are required to handle data securely by implementing “appropriate technical and organizational measures”. Technical measures mean anything from requiring employees to use two-factor authentication on accounts where personal data are stored to contracting with cloud providers that use end-to-end encryption. Organizational measures are things like staff trainings, adding

¹ For more information <https://gdpr.eu/>

a data privacy policy to employee handbook, or limiting access to personal data to only those employees in your organization who need it.

In GDPR, strict new rules are set about what constitutes *consent* from a data subject to process their information:

- ✓ Consent must be “freely given, specific, informed and unambiguous.”
- ✓ Requests for consent must be “clearly distinguishable from the other matters” and presented in “clear and plain language.”
- ✓ Data subjects can withdraw previously given consent whenever they want, and you have to honor their decision. You can’t simply change the legal basis of the processing to one of the other justifications.
- ✓ You need to keep documentary evidence of consent.

Data generated in ehcoBUTLER are mostly related to personal data of ehcoBUTLER solution’s end users and they will be collected during trials at the project’s Pilot sites.

An internal protocol defined by the Consortium has been established to save the integrity of sensitive data collected during pilots.