D7.3 Data Management Plan

777450 - PARADIGM

Patients Active in Research and Dialogues

for an Improved Generation of Medicines

WP7 – Project Coordination and Management

Lead contributors	Matthias Gottwald (19 - BAYER) - *on the behalf of the Steering Committee* Eva Molero (13 - SYNAPSE) - *on the behalf of the Steering Committee* Mathieu Boudes (1 – EPF) - *on the behalf of the Steering Committee*
	matthias.gottwald@bayer.com; emolero@synapse-managers.com; mathieu.boudes@eu-patient.eu
Other contributors	Steering Committee members

Due date	31/08/2018
Delivery date	27/11/2018
Deliverable type	R
Dissemination level	PU

Description of Action	**Version**	**Date**
	V1.1	7/05/2018

Table of Contents

Document History

Version	Date	Description
V1.1	28/08/2018	First Draft
V2	15/10/2018	Comments
V3	27/11/2018	Final Version

Definitions

Partners of the PARADIGM Consortium are referred to herein according to the following codes:

- **EPF**. EUROPEAN PATIENTS FORUM (Luxembourg) – **Project Coordinator**
- **EURORDIS**. EUROPEAN ORGANISATION FOR RARE DISEASES ASSOCIATION (France)
- **EATG**. EUROPEAN AIDS TREATMENT GROUP (Germany)
- **AE**. ALZHEIMER EUROPE (Luxembourg)
- **AIFA**. AGENZIA ITALIANA DEL FARMACO (Italy)
- **HTAi**. HEALTH TECHNOLOGY ASSESSMENT INTERNATIONAL (Canada)
- **IACS**. INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD (Spain)
- **FSJD**. FUNDACIO SANT JOAN DE DEU (Spain)
- **VU-ATHENA**. STICHTING VU (The Netherlands)
- **UOXF-CASMI**. THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD (United Kingdom)
- **EFGCP**. EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE (Belgium)
- **SYNERGIST**. THE SYNERGIST (Belgium)
- **SYNAPSE**. SYNAPSE RESEARCH MANAGEMENT PARTNERS SL (Spain)
- **EFPIA**. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (Belgium) - **Project Leader**
- **MSD Corp.** MERCK SHARP & DOHME CORP (United States)
- **UCB**. UCB BIOPHARMA SPRL (Belgium)
- **ABPI**. THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (United Kingdom)
- **AMGEN**. AMGEN LIMITED (United Kingdom)
- **BAYER**. BAYER AKTIENGESELLSCHAFT (Germany)
- **GSK**. GLAXOSMITHKLINE RESEARCH AND DEVELOPMENT (United Kingdom)
- **GRT**. GRUENENTHAL GMBH (Germany)
- **JANSSEN**. JANSSEN PHARMACEUTICA NV (Belgium)
- **LILLY**. Eli Lilly and Company Limited (United Kingdom)
- **LUNDBECK**. H. LUNDBECK AS (Denmark)
- **MERCK**. MERCK KOMMANDITGESELLSCHAFT AUF AKTIEN (Germany)
- **NOVO NORDISK**. NOVO NORDISK A/S (Denmark)
- **PFIZER**. PFIZER LIMITED (United Kingdom)
- **ROCHE**. F. HOFFMANN-LA ROCHE AG (Switzerland)
- **SERVIER**. INSTITUT DE RECHERCHES INTERNATIONALES SERVIER (France)
- **VFA**. VERBAND FORSCHENDER ARZNEIMITTELHERSTELLER EV (Germany)
- **SARD**. SANOFI-AVENTIS RECHERCHE & DEVELOPPEMENT (France)
- **NOVARTIS**. NOVARTIS PHARMA AG (Switzerland)
- **COVANCE**. COVANCE LABORATORIES LTD (United Kingdom)
- **ALEXION**. ALEXION SERVICES EUROPE (Belgium)

- **Consortium.** The PARADIGM Consortium, comprising the above-mentioned legal entities
- **Consortium Agreement**. Agreement concluded amongst PARADIGM participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties' obligations to the Community and/or to one another arising from the Grant Agreement

Introduction

PARADIGM will provide a framework that will enable structured, effective, sustainable and meaningful patient engagement (PE) and will demonstrate the 'return on the engagement' for all players. Much needed PE processes and tools for three key decision-making points (research priority setting, design of clinical trials and early dialogue) will be developed by consensus integrating perspectives and expectations of all stakeholders. There will be a "stakeholder tailored" set of criteria to measure the impact of PE. PARADIGM will deliver recommendations to support the implementation of PE, leveraging pre-existing information and developing new tools needed by the community of PE.

The purpose of the data collection/generation is to generate evidence about the need for and impact of PE activities in the overall process of medicines research and development, key objectives of this project.

The PARADIGM project will collect information from various stakeholders all over Europe in surveys, interviews and workshops; will create consensus on optimal solutions for facilitation of patient engagement in the medicines development process in a structured approach involving stakeholder representatives and will discuss the conclusions with stakeholders at large. This approach is considered as Patient and Public Involvement (PPI) and thus not subject to any European or national regulatory requirement for ethics committee approval. However, the consortium partners commit to the same safeguards than applied when conducting research, e.g. informed consent, personal data protection and confidentiality in accordance with the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 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 management of data falls into the legal responsibility of each partner organisation. The Steering Committee, supported by the WP7 leaders, will coordinate the data management plan within PARADIGM.

1. Data set reference and name

n.a.

2. Data set description

The data will be qualitative and quantitative information on individuals in as much as they reflect the effort put into integrating PE in the overall process of medicines development. The data format will be in tables (Excel). Part of the data will be generated, while the rest will be collected from diverse institutional sources (pre-existing): however, none of the data constitutes "personal data" in the sense of the General Data Protection Regulation as it will not allow for any individuals to be identified. The data required is exclusively institutional (FTE, cost, timelines of PE projects, impact metrics) or anecdotal on experience. Institutional in this context means "from legal entities of the stakeholders" and not "personal data". Thus, the data collection and processing is not restricted as to the original purpose of the data collection had been or is by no means connected to any previous consent.

The data size will be manageable with standard versions of Excel. At this point, we assess the size of these tables to be of maximum 1,000 entry points.

The data will be useful to the consortium partners as it should illustrate best practices in PE coupled with a qualitative and quantitative analysis of the impact of such PE activities.

The data that will be collected will be related to the experience on patient engagement, as described below:

- WP1 will collect data from various stakeholders, using an online survey about the needs, expectations and aspirations in relation to patient engagement, i.e., what is currently needed to perform more systematic, ethical and meaningful patient engagement during the development of medicines. This will be supplemented with data from focus groups and interviews with certain stakeholders. This will then be prioritized during three expert panels. The questionnaire that will be answered during the Delphi exercise T1.2 and T1.3 will built on the analysis of the answers coming out of the survey. This data set, once anonymized -to avoid identification of respondents where there are few answers coming from one country for example- will be made public on the PARADIGM website after the completion of the project, and, to enrich the possibility of further analysis, it will also be available on the PFMD and EUPATI platforms. WP2, WP3 and WP4 will collect case examples on actual practices of patient engagement. The case studies examples belong to their respective institutional owner. The institutions that organised the engagement remain owner of the raw data, the institutions that collect and analyse the cases remain owner of the individual analyses. The collecting institutions guarantee that in reporting on the cases all data is anonymised and no product name, individual identifying information, no company name or financial details, etc. will be made public. The products based on the case studies (like engagement tools, handbooks, evaluation methods) will be made publicly available as described in the DoA. A high-level database of cases, not containing identifying information, will be integrated into SYNaPsE, the online tool of PFMD. This will allow further analysis by the community.

- WP5 will collect email addresses to be able to communicate about the project outcomes and to seek engagement. This dataset collection is on a voluntary basis, the data can be deleted upon request to comms@imi-paradigm.eu and will be deleted after the completion of the project. It will not be used for communications unrelated to PARADIGM.

- WP6 will interview representatives of organisations and initiatives that have been sustainable for some time. The interviews will be analysed to inform the development of the sustainability roadmap of patient engagement. The interviews will not be made public, but the consolidated learnings will. This was requested by most of the interviewees.

- WP7 will collect institutional data to carry out efficient project management. The dataset will be deleted after the completion of the project, ensuring compliance with the Grant Agreement obligations (keeping information for audits, etc.).

3. Standards and metadata

No metadata will be necessary during the course of this work. PARADIGM Consortium aims at using standard vocabularies for all data collected.

4. Data sharing

PARADIGM will follow the FAIR data principles.

4. 1. Making data findable, including provisions for metadata

This Data Management Plan will always follow the principles that research data must be findable, accessible, interoperable and reusable (FAIR) as well as being attributable, legible, contemporaneous, original and accurate (ALCOA). All documents will have clear version numbers.

4.2. Making data openly accessible

All non-personal data produced and/or used in the project will be made openly available. If certain datasets could not be shared (or only under restrictions such as IP protected dataset coming from case studies), this document would contain a proper justification and description.

The results-based data will be made accessible mainly by publication in relevant journals, blog articles, oral and poster presentations and press media. Standard methods and software tools are needed to access the data - most likely Excel - but specific technical decisions will have to be taken further in time. Accordingly, no documentation about the used software is included. This will be duly updated if any other software programmes are incorporated in the DMP. No central data repository will be established during the course of the project. The Steering Committee will provide adequate oversight considering that the data collection and processing **is not sensitive.** Indeed, no sensitive data such as health-related records (e.g. patient records, biographic data, medical photographs, diet information, hospital information records, biological traits and genetic material) will be collected. The only personal data collected will be email addresses with specific consent from the participants on a purely voluntary basis. Those email addresses will be used to forward the results of the survey and progress of PARADIGM to the participants. These data will be destroyed after the completion of the project in September 2020.

The PARADIGM project will collect perspectives on patient engagement needs and approaches from various stakeholders all over Europe in surveys, interviews and workshops; it will create consensus on optimal solutions for facilitation of patient engagement in the medicines development process in a structured approach involving stakeholder representatives and will discuss the conclusions with stakeholders at large. This approach is considered as Patient and Public Involvement (PPI) and thus not subject to any European or national regulatory requirement for ethics committee approval.

- **Publications of data and allocation of resources**

The principles ruling the dissemination of results are depicted in the section 9 “Dissemination activities” of the Project Handbook (Deliverable 7.2, M5).

In case the collected data will contribute to the elaboration of a scientific publication, each publishing participant must ensure open access to such scientific publications related to its results, in accordance with Article 29.2 of the Grant Agreement. The process concerning the scientific publications is explained in point 7.4.3 of the Consortium Agreement.

The rules for the dissemination of results stated in the section 9.2.3 “What is the internal procedure for dissemination of results?” apply to publications elaborated by means of the use of non-personal data: a Participant may disseminate any Results only after submission of the proposed dissemination for approval:

- to the Steering Committee and
- to all Participants

by written notice at least thirty (30) days prior to such dissemination.

The Participants seeking dissemination shall take the comments from the Steering Committee and the Participants reasonably into account. If no objection is received in writing within a fifteen (15) days' period from the date of notification of the proposed dissemination, the Participant seeking dissemination shall send an e-mail reminder to those Participants who have not yet responded. **If no objection is received in writing within the thirty (30) days' period mentioned above, the Participant seeking dissemination will be free to proceed with the dissemination as submitted to the other Participants.**

A specific budget of €20,000 to cover open access publication costs is included in the PARADIGM Grant Agreement.

4.3. Making data interoperable

No data standards are used in general in PARADIGM to enable interoperability of data, but the PARADIGM Consortium is striving to use file formats that are interoperable, such as .txt, .csv, or .rtf files.

PARADIGM Consortium is striving to use standard vocabularies for all data types present in our data set to allow inter-disciplinary interoperability.

4.4. Increase data re-use (through clarifying licenses)

The data re-use is not a key objective in this project. Data will be used to develop insights, illustrate best practices and reach conclusions and recommendations about effective and meaningful patient engagement. No need for temporal data embargoes is foreseen beyond the needed embargo for scientific publication as defined in the Consortium agreement and the D7.2 Project Handbook.

The data produced and/or used in the project may be usable by third parties, in particular through cross referencing. No re-use restrictions are foreseen at this point in time.

All data will be deleted at the end of the project and after ensuring compliance with all auditing processes.

No data quality assurance processes appear necessary, as this is not a scientific project. The Consortium will collect illustrative cases of and opinions about PE; a type of field that would not require a data quality assessment.

5. Archiving and preservation

Partners will follow their internal policies and regulations for archiving data, including the requirements imposed by IMI audits.

Each partner storing project data will have to establish sufficient measures to ensure an acceptable level of data security, in compliance with their own internal rules. Such measures will be reported in subsequent deliverables (i.e. monitoring of personal data protection matters will be reported in deliverable D7.5 *Ethics Expert Panel brief activity report* -in month 12- for the interim review and in deliverable D7.7 *Ethics Expert Panel final activity report* - in month 30).

The resources needed for long term preservation (costs and potential value, who decides and how what data will be kept and for how long) will be discussed within the sustainability planning under the responsibility of WP6.

All the results generated through the utilization of the non-confidential data gathered will be exploited during the Project and structured in order to guarantee their further use in research activities both outside and during the action as per Article 28 — *Exploitation of the Results* of the Grant Agreement.

6. Ethical aspects

6.1 General ethical aspects

The participants of PARADIGM are requested to adhere to all relevant international, and national legislations and IMI guidelines relating to the conduct of prospective case studies as detailed below.

As explained above, PARADIGM will collect information from various stakeholders in surveys, interviews and workshops; it will create consensus on optimal solutions for facilitation of PE in the medicines development process in a structured approach involving stakeholder representatives and will discuss the conclusions with stakeholders at large. This approach is considered as Patient and Public Involvement (PPI) and thus not subject to European or national regulatory requirement for ethics committee approval. However, the Consortium partners commit to the same safeguards that when conducting research will be applied, e.g. informed consent, personal data protection and confidentiality in accordance with the Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 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 Consortium members will apply in PARADIGM general procedures to safeguard the privacy of participants, including obtaining prior written informed consent from all the participants in surveys, interviews and roundtables to use their personal data.

The proposed activity will comply with the highest ethical standards, including those outlined in the Grant Agreement (Article 34 of the Model Grant Agreement) and the European Code of Conduct for Research integrity. The balance between the objectives and the means used to achieve them will be given special attention. To ensure this, PARADIGM is supported by its Ethics Expert Panel. The Ethics Expert Panel will consist of a maximum of 10 experts on ethics, law, and drug development representing the key areas of the project. The Ethics Expert Panel will monitor the progress of the project and ensure a high standard of research by taking part in the annual General Assembly meetings. In addition, it will develop:

- An Ethics framework for the Consortium's project work;
- An ethical expertise built into the project as activities, in order to actively promote ethics in the work carried out;
- An Ethics Expert Panel to steer this process, provide ethical expertise and promote collaborative reflection to find solutions acceptable within the Consortium and to relevant external stakeholders, in relation to specific ethical issues which have been identified or raised by project partners or external stakeholders involved in patient engagement.

The complete description of the function of the Ethics Expert Panel can be found in the section 2.3.6 *Ethics Expert Panel* of the Project Handbook. It is also worthy to mention that the Panel has the core function of including monitoring of any personal data protection issues that may arise during the project.

6.2 Interviews and focus groups

The methodologies for eliciting patient engagement best practice and expectations will be surveys, complemented by interviews and focus groups. This may include the possibility of approaching vulnerable patient populations, children, parents, care givers, and healthy volunteers.

Our foremost principles for the conduct of any data collection involving human participants within PARADIGM are:

- respect for the rights, integrity, and privacy of people;
- protection of vulnerable populations;
- generation of meaningful, high-quality data;
- timely publication of results

We do not expect any potentially critical ethical implications of the research results such as the protection of dignity, autonomy, integrity and privacy of persons, biodiversity, protection of the environment, sustainability or animal welfare. PARADIGM does not include research activity aimed at human cloning, intended to modify the genetic heritage of human beings, to create human embryos, or involving the use of human embryos or embryonic stem cells. This research proposal does not include any security sensitive issues.
The partners in the PARADIGM consortium are aware of, and will comply with, relevant guidelines, codes but also recommendations and opinions, in particular:

- The **Nuremberg Code** (1947) addressing volunteer consent and proper acting
- The European Legal Framework and will apply its ethical standards and guidelines. Furthermore, the Consortium will comply to relevant EU legislation for human studies, including **The Declaration of Helsinki** in its latest version;
- The Council of Europe's Convention on Human Rights and Biomedicine (**Oviedo Convention**);
- The UNESCO's Universal Declaration on Bioethics and Human Rights;
- The CIOMS' Guidelines for Health-related Research Involving Humans;
- The United Nations' Convention on the Rights of Persons with Disabilities;
- The **Charter of Fundamental Rights of the EU** (2000/C 364/01);
- The **New Brunswick Declaration**: a declaration on research ethics, integrity and governance resulting from the 1st Ethics Rupture Summit, Fredericton, New Brunswick, Canada (2013);
- The **Respect Code** focused on socio-economic research;
- The **Regulation (EU) 2016/679)** of the European Parliament and of the Council (27 April 2016) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);
- The European Group on Ethics in Science and Technology's (EGE): *The ethical implications of new health technologies and citizen participation* and *Ethics of information and communication technology*.

The activities conducted in PARADIGM do not have the potential for malevolent/criminal/terrorist abuse. There are no other ethics issues currently identified beyond those discussed above. Any potential issues that arise during the project duration will be presented to the Ethics Expert Panel who will ensure they are addressed by taking the appropriate steps.