PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

innovative medicines initiative

Planning
Patient Engagement

Patient Engagement Agreements Explained

For collaborations between the patient community and stakeholders in the health care system

efpia

PARADIGM is receiving funding from the Innovative Medicines Initiative Joint Undertaking 2. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Table of contents

Introduction

PARADIGM (Patients active in research and dialogues for an improved generation of medicines) was an IMI funded multi-stakeholder consortium to provide a framework for structured, effective, meaningful and ethical patient engagement along the lifecycle of medicines. The project focused on three decision-making points: research priority setting; clinical trial design; and early dialogues with regulators and health technology assessment (HTA) bodies. The result of the consortium / the output of the consortium is a comprehensive set of tools and practices to support the integration of the patient perspectives into medicines development beyond the focal areas of the project. Patient engagement should be a standard practice to improve medicines development and deliver results that are focused on patients' needs

The way patients interact with regulators, payers, policy makers, researchers, and industry are evolving and the patient community is playing an active role in the healthcare ecosystem. By drawing upon the unique expertise and experiences of the patient community we can make healthcare more patient-centered.

Collaboration between pharmaceutical companies and patient advocates should be based on contracts signed by both parties covering various types of activities such as consultancy, collaborations, speaking engagements and advisory boards. These contracts define the terms and conditions of the engagements, covering such matters as confidentiality, intellectual property, copyright, data protection, compensation and other responsibilities of both parties. They typically also contain provisions, mandated by the pharmaceutical industry or regulatory authority codes, designed to ensure an appropriate relationship between a patient and the engaging partner. In the past, the complexity of these agreements has often been challenging for the patient community and in particular patient advocates to work with due to the contracts being long, difficult to understand and sometimes containing ambiguous clauses.

The patient-led multi-stakeholder project led by WECAN/MPE/PFMD, "Reasonable agreements between patient advocates and pharmaceutical companies (RAPP)", aimed to streamline the legal framework between the patient community and the pharmaceutical industry, providing guidance for the content of legal contracts while maintaining reasonable safeguards for both contractual parties. The RAPP project applied a collaborative and consensus-driven approach to developing the "Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies". The Principles aim to serve as a baseline for the development of contracts and contract templates for patient advocate engagements with industry to ensure reasonable protection for signing parties and to provide guidance to patient advocates

whenever they need to review a legal agreement. The goal of the Guiding Principles is not only to simplify the language and terms of typical agreements, but also to prevent the addition of unnecessary clauses for either party. These Principles were then applied in the development of Reference Agreements, which are meant to be used as a resource for legal parties and patient advocacy leaders in industry responsible for drafting agreements with the patient community.

How to use this tool

The Reference Agreements require tailoring depending on the situation: each country has rules and regulations, different types of engagements may have unique parameters, and the people signing the agreement may have unique needs that need to be considered. Legal agreements typically need to address similar aspects of cooperation, however the four Reference Agreements have some key differences due to the nature of the different types of activities. This depends on whether the engagement has shared objectives (e.g. collaboration), or if the patient or patient advocate is offering a service (e.g. speaking, consultancy, participation in an advisory board).

The Reference Agreements aim to be as simple as possible. However, they are still legal documents that need to be precise in order to ensure that both parties signing the contract have their interests, their rights, and the nature of their work protected.

Within this document you will find:

1. The annotated versions of the reference documents: These versions will provide you with additional descriptions to the sections and terminology used in the reference agreements.

- **The Guiding Principles** aim to provide the basic understanding for the development of contracts and contract templates for patient engagements with industry to ensure reasonable protection for signing parties and to provide guidance to patient advocates whenever they need to review a legal agreement.
- **The four reference agreements** are meant to be used as a resource for legal parties responsible for drafting agreements with the patient community.Use them as is if they fit your purpose or use them as a basis to create your own contracts.

2. The original versions that you can download and use when you are drafting your contracts.

Tools

1. Annotated versions of the reference agreements

a. The Guiding Principles

- Annotated version (pdf)

b. The reference agreements:

1. Advisory Board Agreement
   - Annotated version (pdf)
   - Original version (word template)
2. Collaboration Agreement
   - Annotated version (pdf)
   - Original version (word template)
3. Consultancy Agreement
   - Annotated version (pdf)
   - Original version (word template)
4. Community Speaker Agreement
   - Annotated version (pdf)
   - Original version (word template)

2. Glossary (Annex)

Annex 1 - Glossary

The specific terminology used in the PE Agreements is listed first. For a more general glossary of terms used within PARADIGM, see after this section.

Term	Explanation
Adverse event	An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product (see GVP Annex IV, ICH-E2D Guideline).
Agency	A governmental body that gives marketing authorisation to a new medicine or decides on the conditions for access to it.
Agent	Agent in this context (in section 10.3 Data privacy) means that any 3rd party consultants or temporary staff within each contracting organisation (should also observe the data protection obligations within this agreement).
Alteration	Making a change to
“Anything of value”	Anything of value refers to any good (or service provided) that has a certain benefit to the recipient that is real and that is ordinarily purchased rather than given away for free.
As per	In accordance with
Assigns	Gives
Construed	To interpret or understand words or actions in a particular way.
Contemporaneous	Existing or done at the same time
Data subject	Data subject is a generic legal terminology used to mean the individual(s) to whom data that is being collected during the agreement/ project relates and who can be identified. Data subject also refers to the patient advocate (consultant) who is giving his or her consent for the purposes described specifically in the Appendices.

Term	Explanation
Declare	In context of the contracts, "declare" means that, when presenting or referring to the project in public, the patient will need to formally disclose his/her collaboration with the Company
Encumbrance	This and the next two terms refer to interests of third parties in an asset that may restrict what the owner of the asset can do with the asset. A classic example of this is a mortgage on a home or a builder's lien on new construction. Usually it is a form of security for a lender: if the borrower doesn't repay the money owed, the third party has a claim against the asset. This means the lender can be certain what is owed is repaid before the owner can get the full benefit of the asset (e.g. forced sale of the house so that the bank can recoup the outstanding debt under a mortgage). In other words, the broader term refers to any sort of claim against a property.
Improper	Acts with "wrongful intent" which could include threats, violence, trespass, defamation, and misrepresentation of fact.
In-kind contribution	In-kind contribution is a non-monetary contribution as opposed to "in cash" (=money), for example when the service is offered by the patient free of charge (e.g. the person prefers not to be paid for his/her involvement in the Project). On the company's side, this could be providing a meeting room to a patient organisation.
Inter alia	Among other things
Joint venture	A commercial activity undertaken jointly by two or more parties which otherwise retain their distinct identities
Lien	A right which entitles a party to hold on to assets in their possession pending payment of a debt owed.
Pledge	A form of security to assure that a person will repay a debt or perform an act under contract.
Performed hereunder	Provided under this Agreement
Reasonable (expenses)	Moderate travel, lodging, and subsistence expenses incurred during the allocated period

Term	Explanation
Rendered under	For the services or charges “stated” or “delivered” in an agreement
Staff	Employees, contractors, interns etc. of a company/organisation
Seek to exert	Aim to apply
Set forth herein	Set forth herein means that a more detailed statement or explanation is addressed somewhere else in the document.
Subsidiary	An entity that is majority- or wholly-owned by another entity or a company or organisation owned and controlled by another company.
Supersedes	Supersedes means to take the place of or replace something that is older.
Wilful omission	Deliberately or knowingly failing to do or say something

PARADIGM Glossary

Disclaimer: The terms used here have been defined or agreed upon within the context of this project. They should not be considered as exhaustive, finite or purposely exclusive of other considerations, but are representative of the specific focus of this project and its actions.

Code of conduct: collection of rules and regulations that include what is and is not acceptable or expected behaviour (PARADIGM)

Community Advisory Board: Community Advisory Board (CAB) refers to a group of patients who offer their expertise to sponsors of clinical research and who advise several sponsors in their field. CABs are autonomous bodies, not related to the sponsor or chosen by them. (Source: EURORDIS)

Confidentiality Agreement (CA)/Non-disclosure agreement (NDA):
Legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes but wish to restrict access to. (Wikipedia https://en.wikipedia.org/wiki/Non-disclosure_agreement)

Consultancy:
Advice provided on company- or academia sponsored clinical trial protocols including related documents, regulatory documents or information about the products under discussion (e.g. medicinal products, biomarkers), strategic initiatives and other projects of commercial or academic relevance (PARADIGM)

Design of clinical trials: Designing protocols, discussing patient burden, discussing patient related outcomes (PARADIGM)

Early dialogues with regulators and Health Technology Assessment bodies: Early (multi-stakeholder) discussions between industry, HTA agencies and/or regulators (and in some contexts with payers) to discuss developmental plans for a medicinal product and to ensure they meet the requirements.

** Early dialogue is not a decision-making time for any party. In practice it more closely resembles consultation with the chance for feedback and input (two-way communication). (PARADIGM)*

Health Technology Assessment (HTA): systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods (HTA glossary http://htaglossary.net/health+technology+assessment)

Health technology assessment (HTA) body: A body that undertakes or commissions health technology assessment to form recommendations or advice for healthcare funders and decision-makers on the use of health technologies (PARADIGM)

Healthcare professional (HCP): This category of stakeholders is broad and heterogeneous as it encompasses general practitioners, nurses, clinical investigators/academics, pharmacologists, etc. (PARADIGM)

Medicine developer: Includes any organisation involved in the research, development, manufacture, marketing and/or distribution of medicinal products and/or any other health products such as medical devices or digital solutions. Clinical/contract research organisations (CROs) or consultancy companies providing advice or services relating to the above activities, fall under the definition of medicines developers. Research organisations including universities and learned societies (i.e. an organisation that exists to promote an academic discipline, profession) are also included in the definition of medicines developers (PARADIGM)

Medicines development/medicines research and development (R&D)/ medicines lifecycle (in PARADIGM these terms are used interchangeably): A medicines lifecycle comprises research and discovery, development (preclinical and clinical), marketing authorisation, post-approval, HTA, pricing and reimbursement, commercialization, lifecycle management and Pharmacovigilance until deregistration. (PARADIGM, adapted from: EUPATI; https://toolbox.eupati.eu/resources/making-a-medicine-step-7-phase-ii-proof-of-concept /European Commission: https://ec.europa.eu/competition/sectors/pharmaceuticals/cycle.html EFPIA: https://www.efpia.eu/about-medicines/ Frontiers 'The Life Cycle of Health Technologies. Challenges and Ways Forward, Iñaki Gutiérrez-Ibarluzea et. al. 2017' https://www.frontiersin.org/articles/10.3389/fphar.2017.00014/full)

Memorandum of Understanding (MoU): Type of agreement between two (bilateral) or more (multilateral) parties. It is not legally binding, but it expresses willingness between the parties to take forward a common line of action. (Investopedia https://www.investopedia.com/terms/m/mou.asp)

Participating organisation/engaging partner: An organisation which is organising and/or participating in a PE activity (PARADIGM)

Patient: covers the following definitions:

- **"Individual Patients"** are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.
- **"Carers"** are persons supporting individual patients such as family members as well as paid or volunteer helpers.
- **"Patient Advocates"** are persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organization.
- **"Patient Organization Representatives"** are persons who are mandated to represent and express the collective views of a patient organization on a specific issue or disease area.
- **"Patient Experts"**, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D.

  (The European Patients' Academy on Therapeutic Innovation (EUPATI) https://www.frontiersin.org/articles/10.3389/fmed.2018.00270/full)

Patient community: Patients, patient representatives including their family and carers, patient advocates and patient organisations (PARADIGM)

Patient engagement: the effective and active collaboration of patients, patient advocates, patient representatives and/or carers in the processes and decisions within the medicines lifecycle, along with all other relevant stakeholders when appropriate (PARADIGM)

Patient organisations: Patient organisations are defined as not-for profit organisations which are [patient-]focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies (EMA 2018a)

Payer: Institution, organisation or individual paying for healthcare or health services (PARADIGM)

Pharmaceutical industry: The pharmaceutical industry is comprised of many public and private organizations that discover, develop, manufacture and market medicines for human and animal health. In short, the term "industry" is used to refer to the pharmaceutical industry (PARADIGM)

Policy-maker(s) (or policymaker(s)): A member of a government department, legislature, or other organization who is responsible for making new rules, laws, etc. (https://dictionary.cambridge.org/dictionary/english/policymaker)

Regulatory authority (or regulatory agency or in short 'regulators'): A body that carries out regulatory activities relating to medicines, including the processing of marketing authorisations, the monitoring of side effects, inspections, quality testing and monitoring the use of medicines. (EMA)

Representative for pharmaceutical industry: An employee of the pharmaceutical industry designated to represent the company position in project/consortium/body (PARADIGM)

Research priority setting: Providing opinion, providing evidence and/or being part of a group that decides what is important to research. Design of clinical trials (PARADIGM)

Three main decision-making points: The term, 'decision-making points' is defined as the key points in the development lifecycle of medicinal products. The three decision-making points relevant to PARADIGM are: research priority setting, design of clinical trials and early dialogues with regulators and Health Technology Assessment bodies (PARADIGM)

Vulnerable / underrepresented groups: Children and young patients, people living with dementia and their carers. This definition can also include underrepresented groups (e.g. migrant and non-settled populations, substance users, incarcerated people and people with mental health disorders other than dementia). (PARADIGM)

Annex 2 - Methodology

The need for a legal framework within which collaboration between pharmaceutical industry and patients can happen in a mutually respectful way was identified by PARADIGM as part of its gap analysis on patient engagement tools and practices. To address this need, the co-created Guiding principles and reference agreements from the WECAN/MPE/PFMD project were tested and discussed at the Patient Engagement Open Forum in 2019 with a conclusion, that something additional was needed to make them more user-friendly and practical to the patient community. WECAN/MPE and PARADIGM consortium (including PFMD) agreed to collaborate to co-create this digital tool, which aims to provide more in-depth descriptions for the terminology, clauses, sections and a rationale to each agreement.

A task force of volunteers gathered at the end of 2019, consisting of industry, an industry association, patient representatives, patient organisations and others. The group agreed on the scope of work, main objectives and the delivery timeline with milestones in January 2020. The next step was to have a group of patient collaborators review the documents (February 2020). After the review, two work streams were created to tackle the challenges (of difficult legal language) highlighted by the patient collaborators in an efficient way. Once the content is reviewed by the PARADIGM consortium, the toolkit will be finalised and released in August 2020.

Annex 3 - Authoring group

Main Authors
The Synergist (task force lead) Chi Pakarinen & Nicholas Brooke • with team: Carina Prelucan & Bonaventure Ikediashi
Ana Diaz (Alzheimer Europe) • Coordinating with reviewers living with dementia and their carers
Karen Druckman (EURORDIS)
Laiba Husain (University of Oxford, CASMI)
Lisa Power (EATG)
Nicole Wicki & Julia Tolley (WECAN/MPE Europe)
Contributors
Julie Bonhomme (EFPIA)
Anna Claire Julienne (Servier)
Nenad Petkovi (EATG)
Sheuli Porkess (ABPI)
Susanna Van Tonder (coordination by Camilla Habre) (EPF)
Sixtine Crouzet (* Field Fisher (lawyers involved in WECAN project))

Coordination	Editorial Committee
Karina Huberman (EATG) Wolf See (Bayer) Ingrid Klingman (EFGCP)	Stuart Faulkner (Oxford University) Michaela Dinboeck (Novartis)