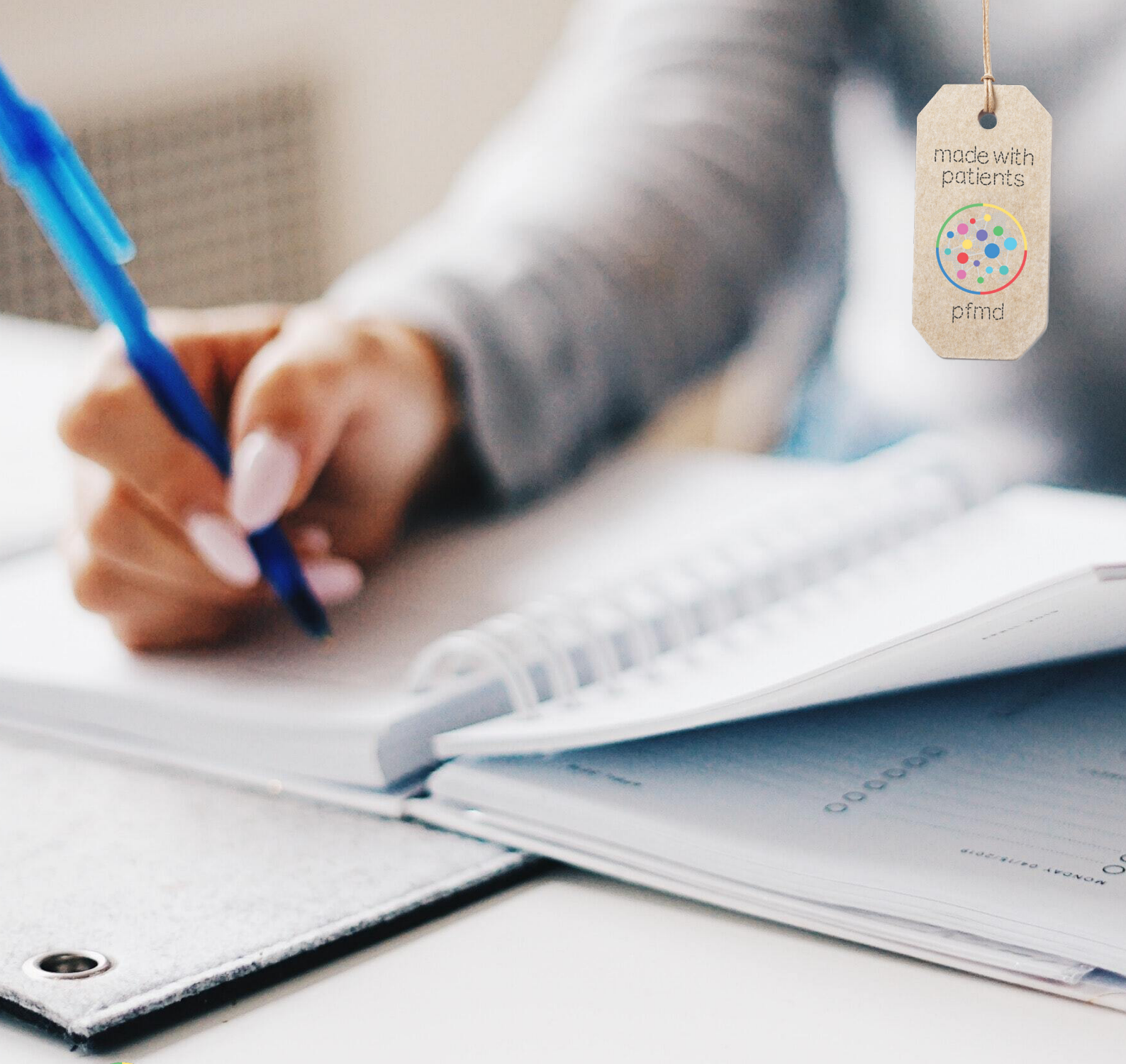

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Global Principles for remunerating the patient community for interactions with the pharmaceutical industry

Introduction to this document and supporting work

The *Global Principles for remunerating the patient community for interactions with the pharmaceutical industry* are part of a broader global project examining the overall process and methodology for remunerating the patient community and determining Fair Market Value (FMV), led by PFMD.

Background

In recent years there has been substantial collaborative work to enable ethical and compliant interactions between the patient community and the pharmaceutical industry. Key initiatives and deliverables have laid the foundation, such as the Reasonable Agreements between Patient Advocates and Pharmaceutical Companies project[1] led by the Workgroup of European Cancer Patient Advocacy Networks (WECAN), Myeloma Patients Europe (MPE) and PFMD, The European Federation of Pharmaceutical Industries and Associations (EFPIA) Working Together With Patients Principles[2], the National Health Council (NHC) Patient Compensation Tools[3], International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Note for Guidance on Patient and Patient Organization Interactions[4], the EU funded IMI-PARADIGM[5] project and others. However, remuneration of the patient community continues to be a tension point, reducing the ability of both parties to have trustworthy and efficient interactions, leading to a call to action for global consistency and transparency.

About the Project

Building on the significant work already published on the subject of remuneration, this project has harmonized standard Global Principles and co-created a transparent methodology to support the determination of fair remuneration for the patient community for interactions with pharmaceutical companies.

The project was led by a Steering Committee with representatives from the patient community and the pharmaceutical industry. Broad public consultation on all deliverables was utilized to ensure representativeness of all communities, drive adoption, and the cultivate systemic change required whilst ensuring compliance with relevant Codes of Conduct and local regulations.

For more information on this Project, the resources available, and good practices harmonized within this work, please visit pemsuite.org/fmv

About the Principles

The Principles included here harmonize and build on previous collaborative work to encompass globally recognized and co-created Principles for remunerating the patient community for interactions with the pharmaceutical industry.

For more information on this project please contact Nicole Wicki nicole@thesynergist.org

[1] WECAN, PFMD, MPE (2018), https://wecanadvocate.eu/rapp/
[2] EFPIA (2019), https://www.efpia.eu/media/413114/workingtogetherwithpatients_patient-remuneration-principles.pdf
[3] NHC (2020), https://nationalhealthcouncil.org/additional-resources/patient-compensation-tools/, including the US FMV Calculator https:// nationalhealthcouncil.org/fair-market-value-calculator/
[4] IFPMA, (2020), https://www.ifpma.org/wp-content/uploads/2020/07/NfG-Interactions-with-Patients_final_202001313-1.pdf
[5] PARADIGM (2017), https://imi-paradigm.eu/

Structure

I. Purpose of this document

The purpose of this document is to set out the Principles and objective criteria on which remuneration is paid to the Patient Community, including those living with a condition (Individual Patients), Carers/Caregivers[6], Patient Advocates, Patient Experts, Patient Organization Representatives (jointly referred to as "Participants") for the work undertaken with pharmaceutical companies and pharmaceutical associations (jointly referred to as "Companies").

The Principles were co-created by PFMD, in collaboration with individual patients, representatives from patient organizations, pharmaceutical companies, and pharmaceutical associations.

The Principles were developed in the context of existing provisions for contracting with and remunerating Participants and aim to cover the specific activities and key elements related to remuneration of such interactions.

Like other types of experts or consultants, Participants should be reasonably compensated for their time, expertise, and contributions based on these global Principles.

This document also includes Principles related to reimbursement for related expenses such as travel (see Section 9 "Reimbursement of related expenses").

The Principles listed here are general and not intended to be prescriptive. They should be adapted as required by individual circumstances.

These Principles are intended to be embedded in Codes of Conduct.

II. Scope of the Principles

The Principles relate to remuneration for services provided by Participants (see "Types of Participants" section) to Companies. These may include various activities, e.g. developing and reviewing materials, contributing as an invited expert to a set topic or questions, participation in Company internal events or non-promotional external events and conferences (see "Activity Framework" section). Participants require specific expertise to be engaged in an activity (see "Expertise Framework" section).

If local laws or regulations do not allow transfers of value to the Participants, an interaction with such Participants falls out of scope for this document.

The Principles relate to the Participant providing services and therefore differ from the support given to a patient organization for a specific project (i.e. providing in-kind support for organizing a congress, etc., covered by grants, sponsorships, and/or donations). These activities are out of scope for this document.

These Principles should apply to interactions between Participants and Companies. However, these Principles do not apply to remuneration for clinical trial participation. For further guidance on remunerating patients for participation in clinical trials please refer to Guideline 13 of Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans[7].

For Principles governing confidentiality, intellectual property, recordings of meetings, data protection, indemnification and remedies, adverse event reporting please refer to "Guiding principles on legal agreements between patient advocates and pharmaceutical companies"[8].

[6] Carer and caregiver terms can be used interchangeably and in some countries a specific term might be more prevalent than the others.
[7] Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2016) International Ethical Guidelines for Health-related Research Involving Humans
[8] WECAN, PFMD, MPE (2018) Guiding Principles on legal agreements between Patient Advocates and Pharmaceutical Companies.

III. Core Principles

1. Right to remuneration

1. It is appropriate that Participants are remunerated for their experience, contribution time, and expertise. This remuneration should be based on the Principles detailed in this document, local regulations and Industry Codes that govern the pharmaceutical industry ("Codes of Conduct").
2. Participants have the right to refuse remuneration and should know that working as a non-remunerated volunteer does not impact their ability to participate.
3. In the event that the Participant declines monetary compensation, if allowed by local regulations, non-monetary forms of remuneration may be offered (e.g., provision of IT and technical equipment), however, the non-monetary forms of remuneration should be fair and consistent and not exceed the value of the monetary compensation that is offered. If non-monetary payment is made to a patient organization it should be disclosed by both parties.
4. Participants should be aware that their social benefits, payable taxes or tax status may be affected when receiving remuneration for an activity. While it is not the responsibility of the Company to provide tax or legal advice, the Company may suggest that the Participant seek tax or legal advice before entering into agreements to avoid unintended/unanticipated tax liability or tax status issues.
5. Participants should be educated via a clear disclosure or other communication that accepting payment from a Company could affect disability payments or other forms of government benefits. Participants should be made aware that accepting non-monetary remuneration can still have tax or social security implications.

2. Fair remuneration

1. When determining fair market value, these principles refer to the remuneration for work performed by the Participants that should inform decision making within a Company.
2. It is expected that Participants receive fair remuneration for interactions with Companies, similar in philosophy and process to the widely established practice for health care professionals[9].
3. A fair market value can only be determined by examining the market (i.e. country) where the Participant resides. Typically, this is carried out by the third parties conducting market research with the aim to ensure that compensation paid for work performed is comparable to similar activities in that market.
4. Remuneration for services should be reasonable, appropriate, and represent the fair market value of the legitimate and necessary services provided, considering complexity of tasks, expertise required and training, total amount of time invested, urgency, country of residence, local regulations, and other contributing factors.
5. Companies should take into account a number of factors to determine the appropriate remuneration, including:
    - Wages lost. Since the Participant is being compensated for their time commitment for the activity, it is not recommended to compensate them for wages lost. This should be considered if it impacts recruitment of a representative target population and assessed on a case-by-case basis.
    - Care Support. To ensure representativeness of a target population, it may be necessary to provide care reimbursement for a dependent. This should be considered on a case-by-case basis.

[9] IFPMA Code of Practice, Section 7.4 Fee for Service (2021), https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019-1.pdf

3. Non-discrimination

1. All Participants should be treated equally and fairly.
2. This includes Participants with mental health conditions, older adults, young patients, and patients who are being represented by a Carer/Caregiver due to their legal or physical incapacity.
3. There should be no discrimination on any other factor related to gender, marital status, family status, age, disability, race, sexual orientation, religious belief, or ethnic background[10].
4. There should be no discrepancies, especially for any one activity when remunerating Participants from the same country, doing the same work requiring the same expertise for the same Company.

4. Respect

1. Companies respect the mission, autonomy, and independence of the Participants, and do not seek to exercise any improper influence on their objectives, activities, or decisions. Specifically, any views or decisions of the Participants should be respected and not influenced by the Companies.
2. In order to respect the independence of Participants, Companies should not request nor expect exclusivity from Participants, meaning that the Participants are free to engage with any other Company of their choosing.

5. Non-promotional scope

1. Interactions with Participants should be conducted professionally and ethically.
2. Companies shall not request, nor shall Participants undertake, the direct or indirect promotion of a particular medicinal product, device or service, unless it is allowed by local laws and regulations.
3. The engagement of Participants should not be an inducement to recommend a particular medicinal product, device or service.
4. Participants should not be offered reduced-price goods or services that may influence switching from competitor medicinal products, devices or services.

6. Consistency

1. Companies should be consistent in the way they remunerate Participants.
2. Companies should ensure that any legal entities and affiliates of a Company remunerate the Participants they engage by using these Principles and applying the same methodology while taking into account that such legal entities and affiliates are required to adhere to applicable local laws and regulations.

[10] See United Nations Human Rights office of the High Commissioner grounds for discrimination: https://ohchr.org/EN/Issues/Discrimination/Pages/discrimination.aspx

7. Payment terms

1. Payment terms should be sensitive to the needs of Participants. The parties should strive to agree on settlement of a payment within 30 days. The same should apply to reimbursement of expenses incurred.
2. Participants and the Company should agree in advance of the activity how and when the remuneration and/or reimbursements will be paid, in what currency, whether the Company will cover banking and transfer fees, and if any conditions are attached or documentation required.

8. Time invested

1. Remuneration for an activity is paid on an hourly basis and the calculation should consider the total time invested by the Participant.
2. Time commitment should include the onboarding for the specific activity, preparation, meetings (including planning and review meetings), the activity itself, follow-up for project deliverables, and other post-activity engagement.
3. Expected total number of hours for all events and all activities, including the process of amending the hours, if they exceed the pre-agreed number of hours, should be mutually agreed in writing prior to an engagement, unless it is not possible given the specifics of an activity.
4. Subject to local regulations, the Participant may be compensated for travel time, including local or long-distance travel. Participant travel time may be compensated at the full hourly rate, some portion thereof, or based on distance traveled. Expenses incurred as a result of travel are discussed under Section 9 "Reimbursement of related expenses".

9. Reimbursement of related expenses

1. Reimbursement for travel, associated costs or other expenses required to participate in an activity should be viewed as separate and distinct from remuneration, as the associated costs and reimbursement represent expenses incurred by the Participant that he/she would not otherwise incur.
2. The Company should make every effort to arrange and pay for major expense items such as patient travel in advance (e.g. air, train, taxi fares, accommodation) and only incidental expenses, such as meals, own car mileage, parking (small ticket items) should fall under the definition of reasonable reimbursable expenses. For further considerations please refer to "Enhancement EUPATI industry guidance: Events and hospitality"[11]. If this is not possible, the payment terms stated under Section 8 "Payment terms" should be followed.
3. The Company should clearly lay out in advance for the Participants what is reimbursable. Descriptions for expenses should be included, e.g.:
    - transportation (mileage, car-sharing service, taxi, or shuttle)
    - accommodations
    - meals
    - conference registration
    - banking and transfer fees
    - incidental expenses such as hotel internet or parking, or if the Company has limits to expenses (e.g., daily rates)
4. All travel-related expenses shall be reasonable and directly related to the meetings. Limits may be placed on the amounts covered for travel and meal expenses in accordance with local laws and regulations.
5. Sometimes Participants' work requires having two subsequent meetings at different locations. A Participant should not be required to travel from/to their home city to each meeting separately. Such travels should be permitted and also reimbursed by Companies, subject to a valid reason based on proof of reason for travel. The additional costs related to such travel should be reasonable in relation to the cost of travel to the Company meeting from the home city. Generally, these trips should be paid by the Company or third party to which the Participant is traveling. Alternatively, the costs can be shared whenever this is possible with the Company or third party where the second meeting is held.
6. If the Participant or, when applicable, the accompanying person, provides a justified professional or medical reason for staying at the same location for more than 24 hours after the meeting ends, the Company should cover the return flight and associated costs even though it is more than 24 hours before and/or after the meeting.
7. Where air travel is required and there are underlying health reasons, considerations should be given for traveling in business class.
8. Companies should take into account a Participant's specific needs, physical or mental, e.g. mobility limitations, when arranging transportation (e.g. deciding on whether or not to hire a car service).
9. Before signing the agreement the Participant should notify the Company about additional expenses that may be medically necessary (e.g., adequate number of hotel nights before and after a meeting, rental mobility scooter, rental oxygen, or certain seat assignments for air travel).
10. In case a Participant has a justified medical need to be accompanied by other persons, travel costs of the accompanying person should be paid by the Company at the same level as the Participant.

[11] PARADIGM (2020), Enhancement EUPATI industry guidance: Events and hospitality.

10. Transparency

1. The objectives and scope of any direct and indirect interaction between Participants and Companies should be open and transparent to both parties.
2. Financial and non-financial support provided by the Company should always be clearly and publicly acknowledged by both parties as required under local regulations and Codes of Conduct.

11. Disclosure of Conflict of Interest

1. Any potential financial and non-financial conflicts of interests should be disclosed to a third party as required under local regulations, including respective Codes of Conduct, including, but not limited to relevant public authorities when it relates to the activities between the Participant and the Company.
2. Participants should be aware that accepting a payment from a Company can result in a conflict of interest when the Participant takes part in other patient engagement activities with government and other public organizations, such as serving as a patient representative on a formulary, technical, Health Technology Assessment (HTA), or guideline writing committee. In such cases Company and Participant should assess whether a conflict exists and if conflict mitigation is possible.

12. Contractual party

1. If allowed by local regulation, the Participants should have the choice of whether the contracting party receiving the remuneration is the legal entity or the individual.
2. Patient Organizations should consider implementing conflict-of-interest policies that specify if and when their employees can receive payment individually for work done for the Companies.

13. Written agreement

1. A written agreement between the Participant and Company should be developed outlining terms, responsibilities of the Company, the Participant and any other third party, which will support the activity, time frame, expectations, type of the activity, scope, amount of the payment or the type of support prior to the start of the activity and considering all provisions of this document.
2. An agreement should be written in a clear and easy-to-understand language. Companies are encouraged to use co-created templates of such agreements[12].
3. The Company should identify a contact person from a non-commercial function whom Participants should contact if any questions or concerns arise regarding remuneration or reimbursement.

[12] See the PFMD Patient Engagement Management Suite Legal and Contracting Tools: Consultancy, Community Speaker, Collaboration, Advisory Board reference agreements:
https://pemsuite.org/legal-and-contractual-tools/

14. Raise concerns

1. Participants should be aware they have the right to express concern if they believe the remuneration offered for their participation is insufficient or excessive, or if the Participants feel the activity they are asked to be engaged in is in conflict with these principles.
2. Discussion of remuneration and options should be in private with individual Participants before they agree to participate in the activity. This encourages the Participants to make specific needs or accommodation requests without fear of judgement.

IV. Activity Framework

This Activity Framework provides a list and definitions of the most common patient engagement activities between pharmaceutical companies and the patient community. It aims to drive consistency in remuneration dialogue and approaches. The Framework was adapted based on previous work, primarily from the National Health Council.[13]

Activity Framework	
Type of Activity	**Definitions/Descriptors**
Pre-activity engagement	Pre-engagement discussions, planning to agree on the patient engagement activity. May include preparatory meetings, initial brainstorming or research, and/or pre-screening participants for an activity.
Group engagement	Group activity, when more than one patient representative is in attendance, advising on a specific topic, sharing experience, or overseeing the conduct of a project (e.g. advisory boards, councils, focus groups, roundtables, etc.)
Content co-creation	Collaboration with shared objectives to develop deliverables and documents (e.g., interview guides, inclusion/exclusion criteria, surveys, reports, manuscripts, patient support materials, consent forms, disease education, awareness materials, multi-stakeholder projects, etc.).
Personal testimonial	Sharing one's personal experience; typically, a presentation, recording, or written account.
Reviewer	Reviewing documents/materials to provide input, critique, suggestions, edits, etc. (e.g. review of study-related documents, educational materials, etc.)
Facilitating Community Review	Dissemination of a document or materials to individual patients or broader patient community to provide feedback or approval. May include compiling a summary of inputs (e.g. review of study-related documents, educational materials, packaging, etc.).
Dissemination	Supporting communication, dissemination, and awareness-raising activities.

[13] National Health Council (2020). Patient Engagement Activities Framework: https://nationalhealthcouncil.org/wp-content/uploads/2020/06/NHC_FMV_Activities_List.pdf

Activity Framework	
Type of Activity	**Definitions/Descriptors**
Panel or roundtable speaker	Speak as part of a small group of presenters; typically, each speaker addresses the same topic from various perspectives.
Event, Conference, Symposium speaker	Speaking as an expert to experts at medium- to large-size gatherings, typically with a scientific or policy theme.
Keynote speaker	Provide an extended speech, as the sole speaker, on a thematic topic.
Facilitator / moderator / chair	Lead and facilitate discussions and provide thought leadership at an event or meeting.
Interview participant	A one-on-one interview. Typically includes a trained interviewer who follows a discussion guide.
Interview facilitator	Facilitating an interview utilizing a prepared discussion guide.
Governance Board participant	Invited to participate as an expert to oversee the conduct of a project, organization, etc.
Chair or Co-Chair of a Governance Board	Lead and facilitate discussions and provide thought leadership on the conduct of a project, organization, etc.
Survey responder	Answer a set of standard questions in a questionnaire.
Pilot testing	Testing a data collection tool (e.g. interview guide, survey).
Data collection	Collecting or compiling data from patients and/or patient community, including anonymization (e.g. surveys, registries).
Data Analysis	Analyzing or synthesizing data, including patient registries.
Data Interpretation	Interpreting or placing findings in context.
Support for patients in a study or clinical trial	Supporting and/or navigating participants through a study or clinical trial.
Mock Trial Participant	Walk through the experience of being part of a clinical trial according to the protocol.
Other	Any other engagement activity not listed.

V. Expertise Framework

This Expertise Framework provides a list and definitions of different types of expertise that may be required to perform a given patient engagement activity with a pharmaceutical company. It also captures and defines different levels (i.e. Basic, Intermediate, Advanced) for each type of expertise. Not all expertise types listed may apply in a given activity. The Framework was adapted based on previous work from the IMI PARADIGM project [14].

Expertise Framework				
Expertise	**Definition**	**Basic**	**Intermediate**	**Advanced**
Interaction and involvement with the patient community	Active and structured involvement in the patient / carer community in a specific area and ability to share the views of people living with a disease	Direct experience of, or interaction and shared experience with other people living with a disease through informal networks.	Broad insights into the different needs of a specific patient community and frequent interaction with different community members regionally or internationally.	Experience in structured approaches, decision making and collaboration when representing or interacting with people across an entire disease community (including subpopulations or sub-groups); or recognized and acknowledged as a formal representative by patient organizations, institutional, or industry bodies on a global or international level.
Regulatory understanding, knowledge and expertise	Knowledge and understanding of regulatory processes related to evaluation, market authorization & safety/ pharmacovigilance	Basic knowledge of applicable regulatory assessments, approval processes or safety monitoring.	Understanding and demonstrated experience with regulatory processes in medicines development; or completion of a recognized relevant training program.	Advanced regulatory knowledge and recognized expertise on specific regulatory topics. For instance, experience representing patients/carers as an official member of regulatory committees at national or international level or experience as an advisor to industry or regulatory bodies.

[14] IMI PARADIGM. (2020). PARADIGM Patient Engagement Toolbox - Patient engagement in medicines development: Recommendations on how to find the right match for the right patient engagement activity: https://imi-paradigm.eu/petoolbox/

Expertise Framework				
Expertise	**Definition**	**Basic**	**Intermediate**	**Advanced**
Market access, reimbursement and Health Technology Assessment (HTA) expertise	Knowledge of market access, reimbursement and Health Technology Assessment (HTA), e.g. evaluation process, access barriers and conditions	Basic knowledge of reimbursement and HTA processes, most likely at local or national level.	Understanding of reimbursement and HTA decision making, methodology, or data collection and submission. For instance, experience in committees on market access or reimbursement committees, or participation in processes at national or international level.	Advanced understanding of and involvement in reimbursement systems and HTA, or expertise to help shape global access and HTA decision-making (e.g. contribution to committees or publications).
Health systems expertise	Knowledge and participation in healthcare delivery, decision making systems, policy and processes	Basic understanding of the organization of healthcare delivery at a national level from public and private healthcare providers in the relevant field of activity.	Understanding of services and policy in the healthcare system across countries in the relevant field of activity, or understanding of measurement and metrics related to healthcare systems use or performance (e.g. related to patient impact or patient care).	Advanced understanding of healthcare systems funding, organization, performance, policy, or metrics in different countries; or experience with initiatives involving various healthcare system stakeholders at the national or international level; or expertise in shaping healthcare decisions on a global scale (e.g. contribution to committees or publications).
Communication expertise	Navigation and delivery of purpose-driven communications and engagement practices.	Ability to communicate key perspectives, messages and topics to a defined audience or in a collaborative/group setting; or knowledge and ability to use basic communication tools (e.g. e-mail, digital and social media, presentations)	Ability to tailor and adapt communication to different stakeholders and audiences considering different viewpoints; or confidence in public speaking and contributing to collaborative activities; or ability to convey ideas and information through different dissemination channels (e.g. articles, presentations, social media, interviews, etc.)	Advanced skills in public speaking and presenting to large and varied audiences; or experience contributing to international and multi-stakeholder collaborative activities, including facilitation or moderation; or experience defining multi-channel communication strategies and navigating social, political and cultural factors in a given expertise area; or experience authoring peer-reviewed publications.

Expertise Framework				
Expertise	**Definition**	**Basic**	**Intermediate**	**Advanced**
Disease-specific scientific and medical expertise	Knowledge about the disease, treatments, care requirements and quality of life of those affected by a disease	General understanding of the disease, available treatments, care requirements and patient reported outcomes.	Intermediate understanding of the disease, including treatment options, side-effects, complications, co-morbidities, or clinical developments.	Advanced understanding of the disease. Including standards of care for different patient sub-populations, treatment pathways in different countries, clinical guidelines, or medical/scientific advancements; or co-authorship of relevant peer-reviewed publications.
Research and development expertise	Knowledge about the research process for the discovery of medicines and their development	Understanding of unmet needs and disease burden. Understanding of clinical / health research and ability to reflect the experiences of the study population.	Experience with and understanding of research protocols, clinical trials and methodology, and consent forms, data collection, identification of patient-important endpoints or themes in data, ethical considerations, or completion of a recognized relevant training program.	Advanced understanding of the medicines discovery and development process; or advanced understanding of clinical endpoints and research; or experience in evidence generation and co-authoring peer-reviewed publications; or experience co-designing clinical research.
Other	Please provide a description			

VI. Types of Participants

1. In this document, the term "Participants" includes:
   - "Individual Patients" who are persons with personal experience of living with a disease. Their main role is to contribute with their subjective disease and treatment experience.
   - "Patient Advocates" who 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 Experts", who, in addition to disease-specific expertise, have the technical knowledge (e.g. in research and development and/or regulatory affairs) through training or experience.
   - "Patient Organization Representatives" who are persons who are mandated to represent and express the collective views of a patient organization on a specific issue or disease area.
   - "Carers/Caregivers", who are persons supporting Individual Patients such as family members as well as paid or volunteer helpers.
2. Companies sometimes contract with celebrities (i.e. a person of public interest) who have been diagnosed with a certain condition. These individuals often have an established contractual rate for speaking and other efforts. Interactions with these patients are outside the scope of these Principles. Companies should have separate policies in place for remunerating celebrity patients.
3. Individuals, who regularly generate digital content online, including via blogs, vlogs, or various social media platforms may also be identifiable as "Social media influencers". Such individuals can be Individual Patients, Patient Advocates, Patient Experts, Patient Organization Representatives, or Carers/Caregivers. However, for a meaningful patient engagement activity, it is not their social media status that is compensated for, but their personal experience, attributable to one of the Participants types and should be remunerated similarly to other Participants within the same category. If individuals do not fall under any of the Participant types, then such interactions are outside the scope of these Principles. Companies should have separate policies in place for remunerating such individuals.

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