



Remuneration and Fair Market Value Project Expertise Framework

This Expertise Framework is part of a global project, led by Patient Focused Medicines Development (PFMD), aimed at harmonizing previous collaborative work and establishing a trusted process for fair remuneration of the patient community for interactions with the pharmaceutical industry. Please see the end of this document for more information about this Framework and the overall project.

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.

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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.

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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	<p>Understanding of unmet needs and disease burden.</p> <p>Understanding of clinical / health research and ability to reflect the experiences of the study population.</p>	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			

About this 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. This Framework supports the operationalization of the Global Principles, which state that hourly remuneration should represent the Fair Market Value (FMV) of legitimate and necessary services provided, considering the complexity of the task and the expertise required.

The Framework facilitates consistently defining the expertise types and levels required for a patient engagement activity, and also supports good practice in defining patient engagements and participant matching based on expertise needs for activities. Not all expertise types listed may apply in a given activity. The Framework was adapted based on previous work from the IMI PARADIGM project¹.

About the PFMD Remuneration and FMV 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 conducted to ensure the representativeness of all communities, drive adoption, and the 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

¹ 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/>