

RESOURCE GUIDE

MARCH 2023

Good Patient Engagement Practices®

**HOW TO START OR  
ENRICH YOUR PATIENT  
ENGAGEMENT STRATEGY  
& ORGANIZATION**

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*Maarten Beekman, MD*

# Introduction

The main reason for being for Medical Affairs is to catalyze a change in clinical practice and/or policy based on robust science and real world experience with the ultimate goal to provide better lives to people living with a disease (and to their caregivers).

***“Therefore, it is of utmost importance that Pharma and Biotech companies engage with patients (and their caregivers) to ensure these better outcomes.”***

The reality is that there are still many Pharma and Biotech companies without a strong Patient Engagement strategy fully implemented, often as a result of perceived compliance risks.

But not engaging with patients (and their caregivers) may become a bigger risk than engaging with them. In this resource guide, you will find useful information, standards, documents and tools to compliantly start or enrich your Patient Engagement strategy and organization.

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# Organizations

The following three organizations, who have developed standards and guidances for Patient Engagement were consulted:



## Patient Focused Medicine Development (PFMD)

PFMD's goal is to improve global health by co-designing the future of healthcare for patients WITH patients. Its mission is to bring together initiatives and best practices that integrate the voice of the patient thereby speeding up the creation and implementation of an effective, globally standardized framework – that involves patients as partners – as well as the necessary tools, services and support to allow the adoption of the framework by various stakeholders.

[Visit patientfocusedmedicine.org](http://patientfocusedmedicine.org)



## PARADIGM: Patients Active in Research And Dialogues for an Improved Generation of Medicines

There is increasing consensus among stakeholders that Patient Engagement at different points of the medicines life cycle is critical to fostering patient access to innovative therapeutic solutions, and delivering better health outcomes for patients.

Despite such development, patients continue to be a largely underutilized resource in medicines development. While there are many initiatives emerging to involve and engage with patients, inconsistency and fragmentation remain the norm. For key stakeholders, such as researchers/drug developers, regulatory authorities, HTA bodies (reimbursement agencies), pertinent and basic issues across all groups are: who should be involved, how and when.

[Visit imi-paradigm.eu](http://imi-paradigm.eu)



## EUPATI: European Patients' Academy in Therapeutic Innovation

EUPATI's vision is to improve health outcomes through the contribution of patients and patient representatives as valued stakeholders. EUPATI's mission is to provide accessible, innovative and inclusive education that empowers patients and patient representatives with the right knowledge, skills and competencies to effectively engage and partner with all other stakeholders in medicines R&D. EUPATI is committed to enhancing Patient Engagement through patient education.

[Visit eupati.eu](http://eupati.eu)

# How do I start?

Building trust with the patient and caregiver's community is a critical success factor in Patient Engagement. Pharma and Biotech companies should develop a transparent framework with a clear description of roles and responsibilities, quality measures and ways of working.

*The following resources are recommended to use as a foundation on which to build your Patient Engagement strategy and operations:*

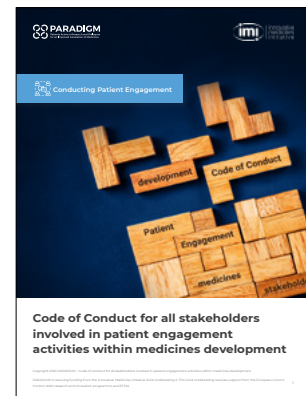
## Code of Conduct for all stakeholders involved in patient engagement activities within medicines development

This Code of Conduct is intended to be a stand-alone document that highlights, summarizes and refers to the key Patient Engagement principles, rules and recommendations for collaboration presented in the different PARADIGM documents in the Toolbox in a comprehensive, understandable format. Fact Sheets summarizing the content of the different documents can be found in the Annex of this Code of Conduct. It should be read in conjunction with these.

This Code of Conduct describes the essentials for meaningful collaboration of all stakeholders involved in Patient Engagement activities within medicines development.

Adherence to this Code of Conduct is essential to ensure an open and fruitful interaction of engaging partners with patients and their representatives.

All stakeholders of the Patient Engagement community should voluntarily integrate the rules of this Code of Conduct into their collaborations and insist on observance, especially in cases of non-compliance.



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### THIS CODE OF CONDUCT CONTAINS SECTIONS ON THE FOLLOWING TOPICS:

- Ethical Principles for Patient Engagement in the Life Cycle of a Medicine
- Contractual Framework
- Competing Interests, Conflict of Interest, and Conflict Management
- Intellectual Property, Confidentiality and Data Protection
- Access to Information and Transparency
- Accessibility of Patient Engagement Opportunities
- Representativeness
- Competencies and Capacity Building
- Adherence to the Code of Conduct
- References
- Annex 1: Fact Sheets of PARADIGM Documents



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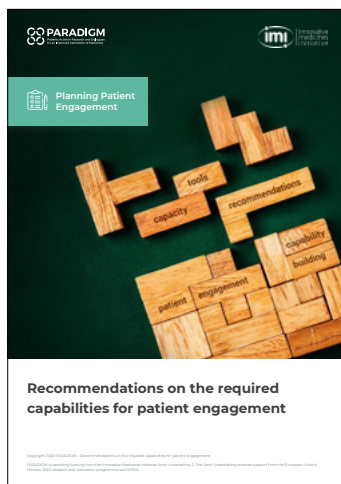
## Patient Engagement Quality Guidance

The Patient Engagement Quality Guidance is a practical guide to planning, developing and assessing the quality of Patient Engagement activities and projects throughout the development and life cycle of medicines.

# How do I know we have the right capabilities to engage with patients?

Understanding the capabilities needed to ensure quality and effective engagement with patients and caregivers is also a critical success factor in Patient Engagement. Pharma and Biotech companies should perform a thorough assessment of the available capabilities within the companies as well as a proper gap analysis. Training and/or acquisition of talent may be needed to ensure the right capabilities for Patient Engagement.

*The following resource is recommended:*



## Planning Patient Engagement

This tool provides recommendations on the competencies (understood as knowledge, skills and behaviors) and resources that each stakeholder organization should aspire to have in place in order to plan, implement and evaluate meaningful and sustainable Patient Engagement activities across the medicines life cycle.

The objective of the recommendations is to increase preparedness of stakeholder organizations by identifying the capabilities required by those individuals involved in implementing Patient Engagement activities and the resources (processes, tools and systems, organizational structure) needed within the organization. This tool does not address the specific competencies of the patient participants involved in Patient Engagement activities.

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### THIS CODE OF CONDUCT CONTAINS SECTIONS ON THE FOLLOWING TOPICS:

- Shared purpose and roles and responsibilities of all stakeholders
- Respect and accessibility
- Transparency in communication and documentation:
  - Legal agreements and confidentiality
  - Management of competing interests
  - Codes of conduct and rules of engagement
  - Reach-out to and interact with patients and patient organizations
- Representativeness of all stakeholders
- Continuity and sustainability
  - Financial compensation and
  - Measuring Patient Engagement impact
- What to consider when engaging with potentially vulnerable populations

# Are their practical guidances available that will help me to accelerate my Patient Engagement activities?

The following guidance documents are worthwhile to consult:



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The EUPATI Guidance Document in this article aims at providing recommendations for ground rules and proposals for the integration of patient involvement across the entire process of medicines R&D in the pharmaceutical industry and outlines specific activities where patients can be involved and influence future medicines research and development.

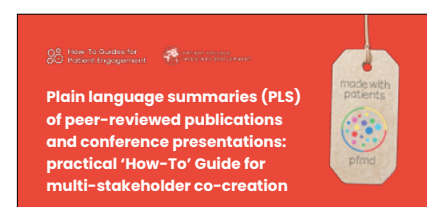
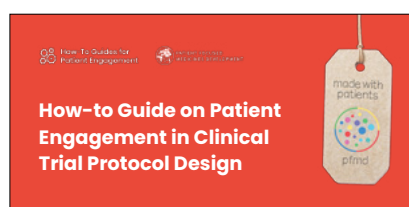
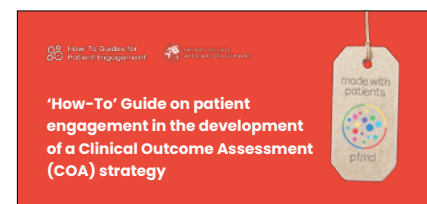


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PFMD developed a number of practical “How To Guides” for Patient Engagement that aim to provide specific support in Patient Engagement efforts, on key activities across the medicine development life cycle. [Read the peer-reviewed article describing the process of the development of these “How To Guides”](#)

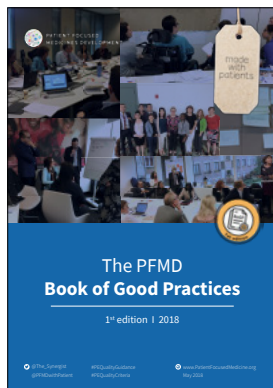
“How To Guides” for Patient Engagement

[Click Guide to Download](#)

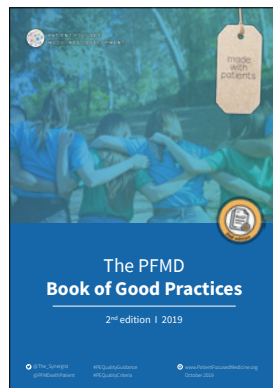


# Are there examples of Best Practices in Patient Engagement?

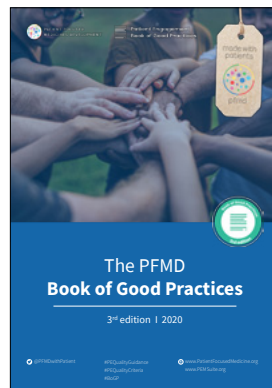
PFMD have published three “Books of Good Practices”. If you are a starter in Patient Engagement, this book can offer you guidance and ideas on how to get it right. This tool can also be used to reach a common agreement about what is “good practice” in Patient Engagement. The examples in the books demonstrate the quality and impact of the Patient Engagement activities.



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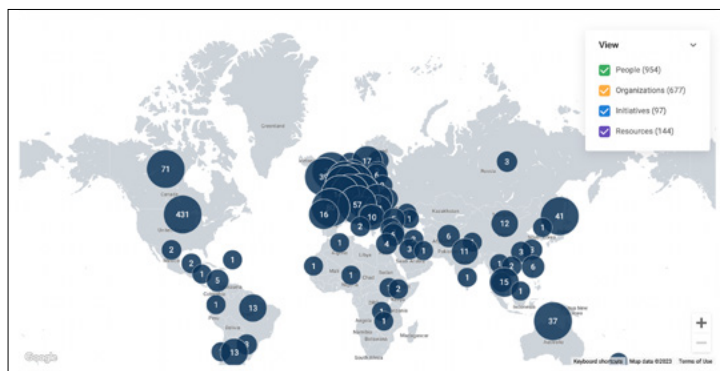
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PFMD Book of Good Practices  
[Download All Editions](#)

In the next link you can find Patient Engagement additional resources, country relevant resources such as guidelines and importantly for Patient Engagement quality and impact measure, the Metrics selector: [patientengagement.synapseconnect.org](https://patientengagement.synapseconnect.org)



The Patient Engagement Synapse is an online tool to capture and map key information from Patient Engagement initiatives across the globe. The maps will inform the development of a measurable and reliable meta-framework for Patient Engagement that involves patients as partners, incorporating good practice from the many initiatives that already exist. The

screenshot of the countries allows you on the website to discover some of the most active organizations, people, initiatives and resources in Patient Engagement.

# Additional Relevant Resources for your Patient Engagement Strategy and Organization

- EUPATI Toolbox: [toolbox.eupati.eu](https://toolbox.eupati.eu)
- Both EUPATI and PFMD offer Patient Engagement training sessions for patients and Pharma:
  - [eupati.eu/training](https://eupati.eu/training)
  - [patientengagement.synapseconnect.org/trainings](https://patientengagement.synapseconnect.org/trainings)
- Discover tools from PFMD to support fair remuneration of the patient community for interactions with Pharma; enabling fair remuneration and good practice in Patient Engagement through harmonized global standards: [pemsuite.org/fmv](https://pemsuite.org/fmv)
- EUPATIconnect is a place where both EUPATI patient experts and researchers can connect, to create mutually beneficial opportunities and to enhance the future of Patient Engagement: [connect.eupati.eu](https://connect.eupati.eu)

## DISCLOSURE STATEMENTS

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The author of this hand-out has selected relevant material from the EUPATI website, did not change any of the content and would like to thank and give credit to the authors and contributors of the relevant documents from EUPATI in the hand-out.

The author of this hand-out has selected relevant material from the PARADIGM website, did not change any of the content and would like to thank and give credit to the authors and contributors of the relevant documents from PARADIGM in the hand-out.





**Meet**  
**Maarten Beekman, MD**

Maarten Beekman is a Dutch physician by background and an experienced International Pharmaceutical Executive with a strong track record in global clinical development and local, regional, and global medical affairs. After over 33 years in Corporate Pharma, of which the past 11 years were at AstraZeneca, he has now moved to the next chapter in his life to help medical leaders and companies to increase the impact of the medical affairs function for the benefit of the patients they serve. He is an author on recent publications on the role and the future of medical affairs and on several publications as a result of his work in medical affairs.

***“The risk of not engaging with patients and caregivers may become a bigger risk than engaging with them to ensure better health outcomes. I trust this guidance document will allow you to truly include patients in all what you do”.***

**– MAARTEN BEEKMAN, MD**

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