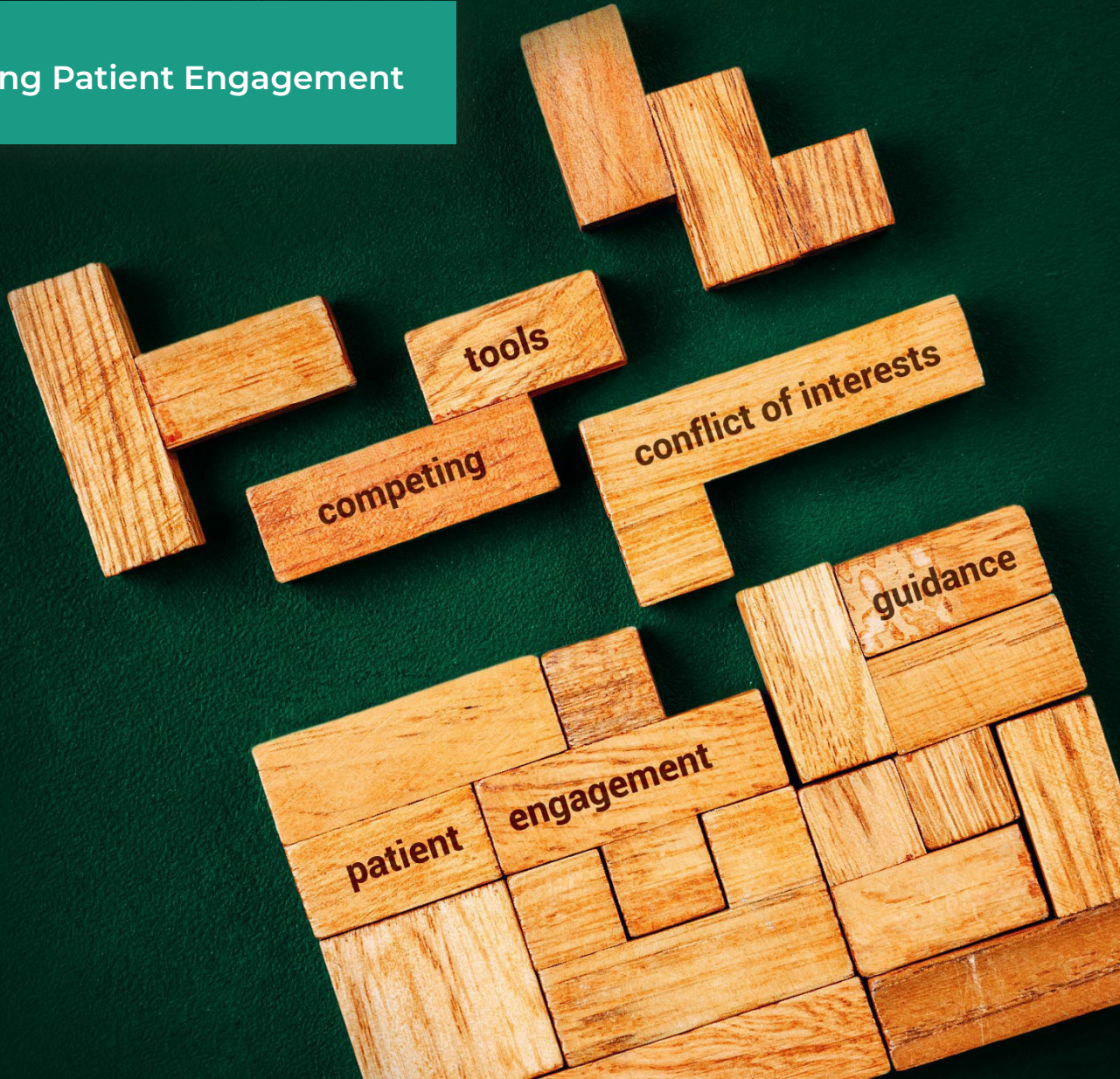




Planning Patient Engagement



Short guidance on managing competing interests and conflicts of interest

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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.

What is this tool?

This tool is a short guidance to raise awareness among all stakeholders about the process of managing competing interests and conflicts of interest when planning, considering and conducting patient engagement activities.

The first part covers general considerations applicable to all relevant stakeholders and the second part gives specific guidance to patient and patient organisations, medicines developers and regulatory and HTA bodies (and payers).

Using this tool, you will:

- understand the difference between competing interests and conflicts of interests;
- learn how to assess the impact they may have on the process of engagement; and
- how to manage competing interests using risk mitigation strategies.

This tool is based on the document **Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders** (<http://imi-paradigm.eu/PEtoolbox/conflict-of-interest>).

General considerations when managing competing interests and conflicts of interest

1. Why is it important to understand competing and conflicts of interests and how to manage these?

Interactions between the patient community and the engaging stakeholder should be based on mutual transparency, respect, autonomy and independence. Raising awareness of the consequences the patient engagement activity might have is important for both patients and the engaging stakeholder organisation.

Early identification of potential competing interests is key for their effective management. Measures could be put in place to avoid or limit the extent of the conflict and the subsequent impact on the patient's ability to engage in present and future interactions. Mitigation measures may vary according to the stakeholder type. Patient organisations may diversify their workforce capabilities by separating engagement from advocacy activities to ensure that there will be always someone *free from conflict* to engage with other stakeholders.

Regulators might allow patients with a known conflict to participate under exceptional circumstances (e.g. some rare disease and underrepresented groups) and in a limited role.

2. Who is under scrutiny?

Patients are at the centre of the medicine lifecycle. They engage with various stakeholders and their participation is often under scrutiny by any possible stakeholder looking to engage patients in an activity.

3. What is the difference between competing interests and a conflict of interest?

Although both terms are often used interchangeably, and each engaging stakeholder has its own definitions of those, for the purpose of this document we define [1]:

- **Competing interests** as those that may affect an individual's impartiality but that do not constitute a conflict per se. They should be declared for transparency purposes.
- **Conflict of interest** as a situation in which the individual's judgement may be perceived as being affected by a secondary interest, as defined by the engaging stakeholder(s).

Stakeholders will assess declared patient engagement activities in accordance with their

own policies and decide what constitutes a conflict of interest (or not). See [Annex: Example of competing interests vs conflicts of interest](#).

4. Are all interests the same?

In general, interests can be classified as follows:

- **Direct interests** arise when the individual involved is likely to benefit from the activity. Examples include: employment, consultancy, strategic advisory and financial interests.
- **Indirect interests** may occur when the activity may cause a third party or someone closely related to the individual in question to benefit. Examples include: close family member interests (e.g. spouse is an employee of a pharmaceutical company) and being an investigator involved in a clinical trial, among others.

5. Do interests have the same impact on the ability to get involved in a patient engagement activity?

Direct and indirect interests may have low, moderate or high impact which can restrict the involvement (fully or partially) of the individual. They must be declared and will be carefully assessed in accordance with the policies of the engaging stakeholder. Such interest may lead to some restrictions in the scope and activities that the individual can be involved in both, in the short term and long term (see [Annex: Examples of levels of restriction](#)). Restrictions to engage are usually time-bound. Declaring an interest does not necessarily imply the existence of a conflict, nor should it automatically disqualify a person from participating in the activities of the engaging stakeholder.

6. How can interests be prospectively managed?

- **Follow established codes of conduct:**

All relevant stakeholder groups should have clear rules on how to interact with each other. Codes of conduct contain provisions governing patient engagement in the medicine lifecycle and on competing interest management within overarching ethical principles applicable to those interactions.

Stakeholders should abide by their respective codes of conduct to ensure ethical and meaningful interactions. It is essential that codes of conduct are introduced and implemented, made publicly available and reviewed periodically.

In addition, PARADIGM has developed a code of conduct (<http://imi-paradigm.eu/PEtoolbox/>

[code-of-conduct](#)) specific to patient engagement and applicable to all stakeholders during the lifecycle of a medicine. The PARADIGM code of conduct encourages comprehensive and consistent patient engagement in all aspects of medicines' research, development and access to treatment activities by protecting all involved stakeholders' interests and rights and ensuring reliable transparency in such collaboration.

- **Establish a policy to manage competing interests and conflicts of interest:**

Patients and medicines developers should be able to effectively understand the implications and consequences of patient engagement. Policies should clarify how a previous engagement with a developer (or any other stakeholder) could affect the individual's impartiality and consequently impact the present engagement. Therefore, it is essential that policies on conflict of interest are developed by the relevant stakeholder and are transparent, publicly available and easily accessible to all patient populations. Such policies may also consider engagement with other stakeholder groups (e.g. healthcare professionals) and be kept high level. Additional specifications including the level of restriction in activities expected to involve individual patients, as well as patient organisations and community advisory boards (CABs) may also be considered.

7. Are there any other strategies to help mitigate potential conflicts of interest?

- **Diversification of human resources in stakeholder organisations:**

Building firewalls between engagement and advocacy activities in patient organisations, or between patient engagement and promotional activities in medicines developers organisations, is one of the strategies to mitigate potential conflicts of interest. Patient organisations, through their patient engagement functions, should inform individual patients about the need to be transparent as some interactions might limit the possible engagement with other stakeholders.

- **Granting experts special status:**

The European Medicines Agency (EMA)¹ and the European network for Health Technology Assessment (EUnetHTA)² may allow under exceptional circumstances, an expert with an existing conflict of interest to be involved in some activities. The EMA may use the 'expert witness' option to enable patients (and other experts) with a certain level of conflict to

¹ European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts. Available at: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agencypolicy-handling-declarations-interests-scientific-committees_en.pdf. [Last accessed 10 May 2020]

² EUnetHTA Procedure Guidance for handling Declaration of Interest and Confidentiality Undertaking (DOICU) Form. Available at: <https://www.eunetha.eu/wp-content/uploads/2019/04/EUnetHTA-DOICU-Procedure-Guidelines.pdf>. [Last accessed 10 May 2020]

participate in some procedures with a limited role¹. This is a valuable tool that permits the participation of patients with declared conflicts under particular circumstances, e.g. where there is only a very limited number of patient representatives available.

In general, transparency and disclosure of patient engagement activities (e.g. keeping track of those in a log of activities) should help each engaging stakeholder to take a decision before the engagement occurs.

¹ European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts. Available at: https://www.ema.europa.eu/en/documents/other/policy-44-european-medicines-agency-policy-handling-declarations-interests-scientific-committees_en.pdf. [Last accessed 10 May 2020]

Stakeholder-specific considerations when managing competing interests and conflicts of interest

Please review the definitions of relevant stakeholders in the [Glossary](#) section.

Medicines developers	Patient engagement should take place systematically across the product lifecycle, and should be conducted by applying foundational principles of respect for and independence of the patient community.
	Set up conflict of interest policy/declaration of interest (DoI) procedure as part of due diligence procedure before engaging patients in your activities.
	Mitigation measures should be developed/considered whenever necessary before any patient engagement activity.
	Inform patients of potential consequences of the act of engagement (e.g. potential conflict of interest with other stakeholders such as regulatory and HTA bodies, and payers).
Regulators, HTA bodies, payers	Adapt the processes and documents to patients (e.g. clear and accessible DOI forms and policies) and provide support for patients during the DoI procedure.
	Mitigation measures should be developed/considered whenever necessary before any patient engagement activity. Patients and their organisations should be made aware of the existence of such measures.
	Acknowledge that there might be potential limitations in expertise in the patient community (e.g. rare diseases, underrepresented groups) and ensure that special status is granted where necessary and appropriate.
Patients and their organisations	Keep accurate records of your interactions with different stakeholders, by using the log of activities, for example, and disclose the interactions before any engagement.
	If you engage with a given stakeholder, prepare your own DoI form and update it periodically.
	Make sure that engagement and advocacy activities at your organisation are done by different individuals to ensure that there will be always someone <i>free from conflict</i> to engage with other stakeholders.
	Ask about the potential consequences of the particular engagement activity to the engaging stakeholder.
	Be aware and make use of any accepted mitigation measures in situations that might lead to Col

Annex: **Example of competing interests vs conflicts of interest**

<https://imi-paradigm.eu/PEtoolbox/COI-Annex-Competing-interests-vs-conflicts-of-interest.pdf>

Annex: **Examples of levels of restriction**

<https://imi-paradigm.eu/PEtoolbox/COI-Annex-Levels-of-restriction.pdf>

Glossary

<http://imi-paradigm.eu/PEtoolbox/COI-Glossary.pdf>