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

innovative medicines initiative

Planning Patient Engagement

Log of patient engagement activities

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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?

Managing competing interests is essential for meaningful patient engagement. This tool has been developed for patients and their organisations. Using this tool, you will be able to accurately track and declare your interests as required before getting involved in activities along the medicines' lifecycle. You can use this tool as a guidance to set up your own log of activities, or that of your organisation.

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)

Why is a log of activities important?

A declaration of interest (DoI) is commonly required when patients are engaged as experts in activities during medicines development. The potential conflict scenarios vary and may be differently assessed by one stakeholder to another.

Keeping a log of activities of one's participation and engagement would facilitate and ensure the proper completion of a DoI. This would be particularly helpful to patients who may not have

the support and guidance of a PO.

Having an updated log of activities with the date, length and scope of each engagement to refer to when filling DoI forms saves you time and makes the process less tedious. Being accurate and transparent in the log of activities (but respecting confidentiality) should help engaging stakeholders to take an informed decision before the engagement occurs.

Keeping a log of activities can be done at two levels:

- by the individual patient experts engaged in the activities; and
- by the patient organisation, to keep a track record of the activities in which the organisation has been engaged and to help identify which experts would match the requirements of the engaging stakeholder (e.g. an expert free from interests with medicines developers to engage in a scientific advice procedure with a regulatory authority).

  Patient organisations could also use a log of activities to identify the type of relationship with the stakeholders they engage with, to help complete their annual activity report and to disclose the funding associated with a particular activity or project for transparency purposes. If the log of activities is publicly available, the organisation needs to pay attention to not disclose any confidential information therin.

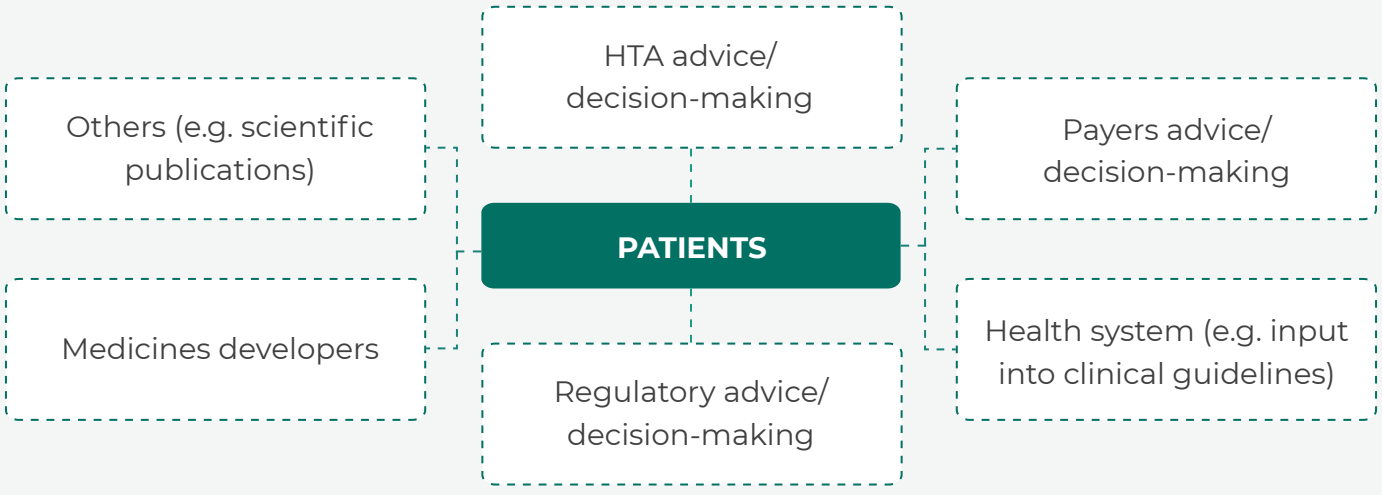

Figure 1. **Multi-stakeholder approach to patient engagement in medicines development**

What should you list in the log of activities?

1. The **date, length** and **scope** of the engagement. These will be required when filling a declaration of interest.
2. The actual time spent for the activity and/or time of engagement (e.g. time specified in the contract/agreement).
3. The country where the activity took place.
4. The type of participation:
   a. Were you participating in your individual capacity?
   b. Were you participating as a representative of your patient organisation?
5. The type of activity you engaged in (see Annex: Patient engagement activities and methods). The detailed description of the activity should not infringe Non-Disclosure Agreements (NDAs) or Confidentiality Agreement(s) (CA) signed with the engaging stakeholder(s).
6. The engaging organisation(s) or other initiatives (e.g. public private partnerships).
7. The type of remuneration received:
   a. Were travel and accommodation covered (including daily allowance for subsistence where applicable)?
   b. Did you receive any additional payment for the expertise and time spent in the activity?
   c. Did your organisation receive any funding (i.e. also unrelated to the activity) from the engaging organisation?

Which activities are relevant?

Annex: Patient engagement activities and methods of engagement summarizes the most relevant activities along the medicine's life-cycle to be tracked in the log of activities, even if the activity in question does not involve discussing any particular medicinal product. This may be particularly important when setting research priorities, as input given by patients may not be targeted to a specific product (e.g. input on unmet medical needs in a particular disease area) or a specific developer (e.g. participation at a strategic meeting of EFPIA). An interaction that takes place in a pre-competitive environment (e.g. Innovative Medicines Initiative (IMI) project on developing a new methodology or research project on Patient-Reported Outcomes) would

also not generally result in a CoI. In all these instances, even if it is assumed that a CoI would not arise, we recommend that details are included in a log of activities. Keeping accurate records of such activities will help to correctly fill-in the DoI form required by regulators, HTA bodies, payers and some medicine developers before an engagement.

NOTE:

Some interactions with medicines developers would be considered as 'consultancy' work by the European Medicines Agency (EMA)[1] and the European network for Health Technology Assessment (EUnetHTA)[2]. EMA defines consultancy as: 'provision of advice (including training on a one to one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration.

A pharmaceutical company means any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. This includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis'.

Declaring such activities does not automatically preclude patients' involvement. Each engaging stakeholder assesses an individual DoI according to its own policies. If a potential conflict of interest is identified, patient involvement may be restricted (fully or partially as per the policy of the engaging stakeholder) or allowed under exceptional circumstances. Involvement may be fully restricted in certain scenarios (for relevant examples, see Annex: Examples of levels of restriction). Annex: Patient engagement activities and methods of engagement lists relevant patient engagement activities along the medicines lifecycle and includes examples from regulators and HTA bodies at European level (i.e. EMA, EUnetHTA). Activities at local/regional/national level may vary according to specific regulations and institutional frameworks.

For further information, see Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders (http://imiparadigm.eu/PEtoolbox/conflict-of-interest)

[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.eunethta.eu/wp-content/uploads/2019/04/EUnetHTA-DOICU-Procedure-Guidelines.pdf, [Last accessed 10 May 2020]

How to set out a log of activities?

Format

There is no established format on how a log of activities should look like. Each individual / organisation can decide how to best set out a log of activities according to the capabilities in terms of tools and systems within the organisation with a preference for an electronic system/ database.

As mentioned earlier, being able to easily identify patient representatives matching certain criteria would be helpful for patient organisations. Likewise, individual patients should put in place their own systems to keep record of their interactions in order to identify when and for how long they engaged in a certain activity. Each individual patient should use the log of activities in a format agreed with the organisation in order to facilitate aggregation of data.

Depending on the amount of data (number of PE activities or individual patient within the organisation) the most common formats for the log of activities would be spreadsheet files (.xls, .xlsx, .ods). Spreadsheets allow the use of standard lists for different items recorded, encryption if needed, rapid aggregation of data and involve rather low expenses. For larger organisations with a more frequent participation in PE, databases might be the best format.

Responsibilities

The responsibility to record the activities in the log ultimately lies on the individual expert who knows the exact details of the engagement. However, coordination by a patient engagement function within the patient organisation would help to fill in any gaps and to keep central records.

Patient organisations may use the log to support writing their annual activity reports. Internal or external audits of the organisational log may be established according to the rules and procedures of each patient organisation.

Individual patients should complete their logs as accurately and comprehensively as possible. However, they should be mindful not to disclose any confidential information when sharing the log with their patient organisations and when disclosing their interests to the engaging stakeholder.

Log of activities template

https://imi-paradigm.eu/PEtoolbox/COI-Log-of-activities-template.pdf

Annex: **Patient engagement activities and methods of engagement**

https://imi-paradigm.eu/PEtoolbox/COI-Annex-PE-activities-and-methods.pdf

Annex: **Examples of levels of restriction**

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

Glossary

https://imi-paradigm.eu/PEtoolbox/COI-Glossary.pdf