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

innovative medicines initiative

Reporting and evaluation

Guidance for Reporting and Dissemination of Patient Engagement Activities

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Contents

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?

Why is reporting a relevant issue?

In the context of patient engagement (PE) activities within medicines development, a gap analysis by PARADIGM has evidenced inconsistent and partial reporting and dissemination of these activities (Gap analysis report). This work indicated that in many cases, there is no available information reported in the public domain about PE activities and the discoverability (i.e. where to find information) of PE activity reports is fragmented. When this information exists, it often lacks the necessary details to make it possible for others to fully understand what was done, with whom, when, using what methods and process, and most importantly, the outcomes - both the positive and negative, the learning experiences, and the resulting value gain from the activity itself. For example, what actually changed or improved as a result of the PE activity, or was identified as a less favourable outcome and deserves further reflection and application in the future.

Currently, internal communication tools and strategies exist within organisations for reporting PE activities. In the case of clinical trials there are clear reporting requirements in the legislation (EMA, 2019). These are complemented with additional principles for the reporting of lay summaries of clinical trials (EC, 2018). In the context of PE there is an academic need to publish the outputs/outcomes of PE activities, for which clear guidance exists (Staniszewska et al., 2011, Staniszewska et al., 2017)

For the dissemination of the reporting of PE activities, while there are some platforms where 'case-study' style reports of some PE activities and projects/strategies exist (for example, European Patients' Academy (EUPATI) and Patient focused medicines development (PFMD), there is currently no central or organised repository for consolidating PE reporting. Additionally, there is not yet enough awareness among researchers, companies, patients/patient organisations (POs) and healthcare professionals about the importance of consistent, timely and jointly developed reporting and dissemination of all PE activities, and the high value this transparency creates for the whole PE ecosystem. Practical guidance and stimulus are lacking to help participating organisations reflect upon and action coordinated reporting and dissemination plans and the possible pathways and mechanisms to move from internal reporting into the accessible and discoverable public domain. Similar issues with the reporting of PE activities in other types of research have also been highlighted in the literature.(Staniszewska et al., 2011, Staniszewska et al., 2017)

Patient engagement is a joint undertaking between all stakeholders involved. Patients/PO should always be invited to jointly plan and implement reporting of PE activities and, where practical to do so, be actively involved in the joint reporting of such activities (or joint authoring of materials about a PE activity for dissemination). This can help to prospectively and proactively manage the expectations of all individuals involved – who is involved, when, co-creating what material, through what methods, and with the early involvement and consultation with existing legal and compliance departments on what material that is discussed and shared between parties can be disseminated into the public domain and when.

All stakeholders involved in PE activities need to be more transparent about when and how patients were involved in PE activities and both the positive and negative experiences from those PE activities need to be identified and addressed. For example, those PE activities that did not come to an end or which did not create an important value gain or change in process or strategy are just as important as the ones that did. All stakeholders can learn successful strategies and how to avoid common pitfalls through a balanced approach to reporting and dissemination.

Open and timely reporting and dissemination can contribute towards a more positive public perception of public and private collaborations, thereby reducing duplication and burden for all involved (including time and resources), reducing reporting bias and misrepresentation or misinterpretation of the activities conducted, and impacting positively on resource allocation in the broader healthcare ecosystem.

Timely reporting of PE activities can depend on available processes, resources, expertise, the level of detail involved, and prior agreements between the stakeholders involved as to what constitutes 'timely'. Whereas specific guidelines for timely reporting of PE do not exist, in the case of results of clinical trials, according to the EU Clinical Trial Regulation (CTR), for clinical trials in adults only, the lay summary must be submitted no later than 12 months from the end of the clinical trial. This is the case irrespective of the trial outcome (EMA, 2019).

Another example is the journal publication of research based on PE activities which can take 6-12 months for the peer review cycle and publication. An important consideration in the planning phase is the balance between speed, impact and value generation for the stakeholders involved, while reducing possible duplication and redundancy of material produced.

Purpose of the tool

The complete and reliable reporting and dissemination of all PE activities is essential to ensure transparency and enable continuous broad learning for all relevant stakeholders undertaking PE activities. Progress is best achieved through an agile learning ecosystem.

The purpose of this tool is to address issues specifically related to the reporting and external dissemination of PE activities in the public domain. It is important to bear in mind that the main aim of this tool is not intended to address financial reporting in any way or override efforts of organisational considerations for any party involved. It builds upon

- relevant principles such as those for improved transparency of reporting clinical trial data set out by the European commission (EC, 2018) and EMA (EMA, 2019), and an ongoing joint effort on the practical implementation of lay summaries by the European Forum for Good Clinical Practices (EFGCP) and the The European Federation of Pharmaceutical Industries and Associations (EFPIA)
- 'case study' formats of PE activities on open access platforms (such as EUPATI (EUPATI, 2014) and PFMD (SYNAPSE, 2015)
- standardised publishing of PE projects in journals (for example, Guidance for Reporting Involvement of Patients and the Public - GRIPP (Staniszewska et al., 2011) and GRIPP2 (Staniszewska et al., 2017)) (See Appendix 1).

In doing so this tool is intended to provide participating organisations with guidance, planning checklist and a practical template to move beyond anecdotal reporting of broad PE strategies, high level plans, or organisational projects. It also aims to act as a bridge between internal-to-external reporting and dissemination channels (i.e. organisation websites, open platforms

and journal publication) (Figure 1) to promote consistent, timely, accessible and discoverable PE activities as part of a learned dissemination and communication continuum.

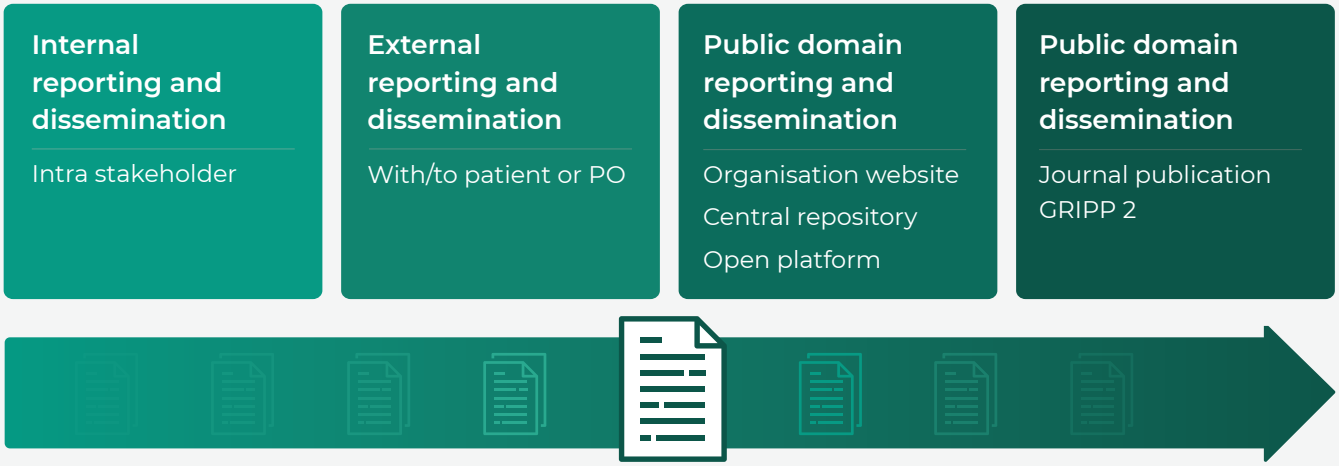

Figure 1. **Diagram showcasing where this guidance fits in the reporting and dissemination continuum**
It acts as a bridge between internal to external reporting and dissemination channels, and external to public domain channels, in order to optimise impact for all stakeholders and minimise duplication of reporting and dissemination.

The principles in this tool are broadly relevant to all stakeholders undertaking PE in medicines development, to help highlight where process and practices may be divergent across agencies, competent authorities and organisations, and where these could be strengthened. Its main focus however is on the activities between the pharmaceutical industry and patients/POs and in the different ways in which they can collaborate, including for example, Community Advisory Boards (http://imi-paradigm.eu/PEtoolbox/community-advisory-board).

Some organisations such as health technology assessment (HTA) bodies and regulatory authorities either have existing internal reporting mechanisms or are in the process of developing their own (PARADIGM, 2019) (http://imi-paradigm.eu/PEtoolbox/pe-in-hta). General HTA and regulatory processes for PE exist and are available in the public domain (for example, HTA assessment and reports that involved patients, etc). However, specific information may differ depending on the HTA body and regulatory authorities regulations such as: the nature of the interactions, themes addressed and discussed during the meetings, level of patient involvement, how patients were selected, and what experiences and input were shared by the patients. In addition, global networks and forums such as the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment International (HTAi) and international organisations devoted to delivering training (e.g. TOPRA-The Organisation for Professionals in Regulatory Affairs, DIA – Drug Information Association) are used to share periodic learnings of PE approaches across HTA process and assessments and regulatory process (see Appendix 1).

The confidentiality policies of these stakeholders for the reporting and disseminating content of some types of PE activities, for example in early dialogues, means that public dissemination or academic publication may be restricted or not possible.

What this tool consists of

This tool consists of three elements:

- Guiding principles and recommendations covering themes such as the dissemination strategy, process and planning, style and format of outputs, translation into other languages, and involvement of patient populations.
- An accompanying checklist to aid users in the planning phases, summarising the key considerations and principles to follow.
- A template to be used to promote consistent PE reporting and dissemination, which includes aspirational core elements or minimum criteria to be included in the dissemination material.

Figure 2 shows how these three elements could - or should- be used together.

In addition to this, Appendix 1 provides signposting out to resources from key stakeholder groups and harmonisation efforts that cover in greater detail information on creating lay summary material, translation into other languages and the use of direct and indirect dissemination mechanisms and open platforms.

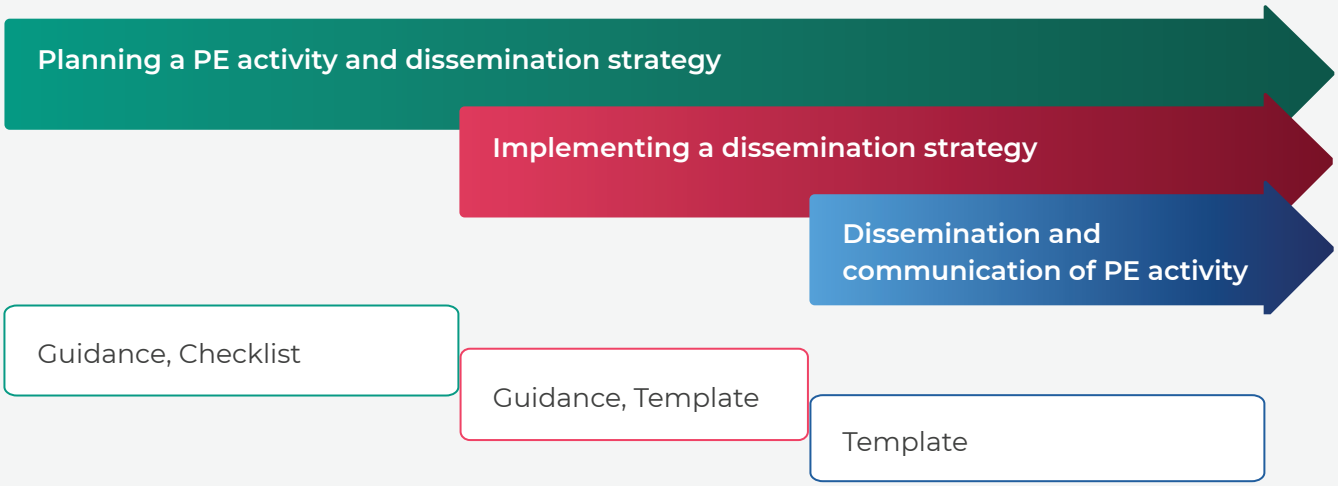

Figure 2. **Schematic of how the tools can be used together and at different time point in a reporting and dissemination strategy**

Guiding Principles

Overall questions to reflect upon and address in an ongoing manner when considering reporting and dissemination of PE activities

- What are the intended audience(s) for the reporting and dissemination of the patient activity?
- What is the overall goal and timeframe for reporting and dissemination of the PE activity?
- What are the possible dissemination mechanisms and channels for the PE activity?
- What is the plan to involve patient(s)/PO in the joint development and/or dissemination of PE activities?
- How can the timing of the reporting and dissemination be managed to balance speed with value generation and how can it be coordinated with other reporting requirements?
- How can continuous learning be encouraged and how can other organisations benefit from this specific PE initiative?
- Is knowledge-sharing facilitated and is information easily accessible and understandable to all stakeholders involved (i.e. design of plain language documents, literacy levels, etc., in addition to any required technical documents)?
- Is there a plan in place to maintain the relationship with the stakeholders involved after the PE activity ends? How would this influence the strategy, reporting audience and dissemination channels used?
- How will it be checked that documentation and communication (internal and external) are appropriately stored, managed and discoverable for all relevant stakeholders?
- What level of flexibility to the reporting and dissemination strategy being followed is needed to permit agility of the stakeholders involved in the PE activity, while maximizing the possibility for broader knowledge sharing?

Key principles when reporting on and disseminating PE activities

1. Mechanisms and channels

Questions for reflection

- What are the intended audience(s) for the reporting and dissemination of the patient activity?
- Is the reporting only to internal teams and the participating patient(s)/PO or is it also going into the public domain? And if it is only to internal teams, how is this justified?
- What dissemination pathway and infrastructure is needed for direct (i.e. to the participating patient/PO) and indirect (i.e. on an organisation's website) dissemination?
- What planning, capacity and capability considerations are needed for each mechanism and channel?
- What resources (time and money) are needed for each mechanism and channel?
- What tools and templates already exist to help facilitate the chosen mechanisms and channels?

Good practice

The following recommendations deserve reflection and careful individual decision-making on what is possible and appropriate for the parties involved and the end user (i.e the intended audience), resources available and infrastructures used. These are not considered mutually exclusive and several may be combined as part of a broader strategy.

- Company website of the engaging stakeholder (including possible social media channels)
- Website of the involved patient organisation (including possible social media channels)
- Joint proactive dissemination by engaging stakeholder (i.e. company) and patient organisation
  - Individual members/national member/sister organisations of that patient organisation (including webinars, newsletters, annual meetings and conferences)
  - Other patient organisations, e.g. in that area of indication or interested/active in these types of PE activities (including webinars, newsletters, annual meetings and conferences)
- Utilise a central storage opportunity
  - In a neutral multi-stakeholder organisation platform such as EUPATI, PFMD, EFGCP, HTAi, DIA, or TOPRA
  - In a type of block-chain solution between organisations.
  - Publication of conference proceedings, periodicals or journal publication of the PE activity that are applicable to the PE process, theory and application in medicines development (e.g. whole PE initiative, or part of it such as a novel methodology, or outcomes and learnings in novel settings).

- It is advisable to become familiar with some of the existing resources used for engaging and documenting PE activities such as: organisation or stakeholder principles for communication and use of social media, company internal reporting templates, PFMD quality guidance, EUPATI case study reports and related guidance such as lay summary reports of clinical trial data (see Appendix 1). Of note, the use of some social media platforms for communication and dissemination purposes may be restricted or prohibited by some organisations – check first as part of the planning process.

2. Process

Questions for reflection

- When will the planning of the reporting begin?
- What capacities and capabilities are needed by the involved stakeholders to facilitate writing, review, approval and implementation of reporting strategy and dissemination channels?
- Has there been mutual agreement between all parties, either formal or informal, as to the parameters set, and mechanisms to be used for sharing of materials between partners, and subsequent material moving into the public domain? What must remain confidential, what could be modified to make it fit for public consumption? (See Appendix 1).
- Are translations into languages other than English expected and what extra considerations are needed?
- What is the understanding and which are the expectations for reporting by each of the different stakeholders involved?
- Do all stakeholders have a clear understanding of the benefits and challenges for timely reporting of this specific PE activity once completed?
- How could existing reporting styles, structures and templates be streamlined across different teams, partners, and stages to reduce duplication and redundancy in content?
- What formal or informal monitoring and evaluation mechanisms have been considered to optimize reflection and learning post PE completion?

Good practice

Where possible and appropriate all steps should be conducted jointly between the participating partners:

- **Planning**
- **Writing**
- **Review – cross functional teams and patient(s)/PO**
- **Quality check- legal and compliance**
- **Approval**
- **Dissemination and translation in different languages**
- **Continuity and learning**

The following basic principles can be applied during planning and implementation process activities (EMA, 2019, EC, 2018).

- Start discussions about reporting and dissemination strategy at the time of the PE activity design (or as early as possible).
- Identify the dissemination channels that have the desired reach. Consider options to make information available and easily discoverable, for example, on a company website or 3rd party open platform.
- Assess and ensure that organisation communication functions have the required capacities and capabilities for the desired strategy (http://imi-paradigm.eu/PEtoolbox/pe-capabilities).
- Assess the capacities and capabilities of the involved patients, and support that can be provided, to be jointly involved with creating or authoring material (see also http://imi-paradigm.eu/PEtoolbox/identification-of-patient-representatives)
- Budget for all expected communication, and if required, translation activities.
- Discuss and agree with all stakeholders involved about the desirable timing of reporting. Reporting should be done as soon as possible after completion of the PE activity.
- Ideally this should be within 12 months and irrespective of the outcome. This is aligned with EC Clinical Trials Regulation 536/2014 guidance for reporting of clinical trial results(EMA, 2019).
- Reporting both successes and challenges is important. If journal publication of PE activities is planned (for example using the GRIPP/GRIPP2 template) this can take between 6-12 months for peer review and acceptance. Timely reporting may increase the impact and value of the knowledge shared. Align all the reporting requirements ahead of time for the strategy chosen to reduce further delays.
- Create an opportunity to explain the possible challenges in timely reporting to the partners involved (for example, host a workshop) and identify solutions and/or manage expectations for content and format of reports and dissemination. Aim for the right balance between timeliness of reporting and potential delays due to approvals and legal and compliance checks.

- Quality Control: Ensure that legal and compliance departments are involved as early as possible. Generally, confidentiality issues arise where, for example, exact product details, or concrete study results are included that could affect a marketing authorisation application (MAA). This information is unlikely to be required for PE reporting in the public domain. General organizational policies and codes of conduct for the involvement of patients, managing confidentiality and and potential conflicts of interest (http://imi-paradigm.eu/PEtoolbox/conflict-of-interest) should be followed (http://imi-paradigm.eu/PEtoolbox/code-of-conduct).

3. Meaningful involvement of patients

Patient engagement contracts should state clearly that patients will be "offered" to be involved as much as is possible and feasible in the joint production of outputs, and if possible also in reporting. A flexible "person-centred approach" to PE should be supported – i.e. where each patient can decide their own type/level of involvement based on available time and experience and where possible be supported in those actions with the appropriate resources and individuals from the respective PO or company representative. Where formal contracts are not used such mutual agreements should be clear.

Questions for reflection

- What is the best way to facilitate patient involvement in the decisions about the reporting and dissemination of the activity?
- Which challenges need to be resolved in order to meaningfully involve patients in reporting?
- What capacities, capabilities and support are needed at each stage of reporting and dissemination?

Good practice

- Involve patients in the development and review of the report (e.g. co-creation through "patient and partner perspectives") see EUPATI template as an example (http://imi-paradigm.eu/PEtoolbox/enhanced-eupati-guide).
- Offer flexible solutions for all types of patient involvement from co-creating, consulting and review of materials that fit the needs and experience of each individual. This should be assessed on a case-by case basis.

- Involve legal/compliance department(s) early and throughout in how to manage the involvement of patients, if necessary.
- Assess and agree on how and if PO can assist with direct and indirect communication channels.
- Agree on roles, responsibilities and tasks between all parties (Synapse, 2018).

4. Content and format of material created

Questions for reflection

- What is important to report on from the perspectives of the different stakeholders involved?
- What amount and type of information would be necessary for someone not involved in the activity to understand the activity and what information would be necessary for others to be able to use, compare or replicate the activity elsewhere?
- How can complete and reliable reporting be achieved through joint advice or production of material with patient(s)/PO?
- What type of instruments or tools exist? Are the existing templates and tools suitable, flexible and adaptable for all of the reporting and dissemination?
- How can it be ensured that the reporting is understandable and accessible to a diverse audience including individuals with different types of impairments (e.g. in which language/s will the reporting be available, literacy level, format, layout, visual impairment, colour blindness etc.)?

Good practice

The following "Minimum" elements should be included in the content:

Of note, none of the following elements are considered to be confidential and should not preclude this information being disseminated. Jointly involving legal and compliance departments and the patient(s)/PO early should help manage any specific considerations. (See also a detailed summary of current recommendations from EU Commission, and see Appendix 1)

- Introduction into the topic/rationale
- Objectives of the PE activity
- Partner identification, patient selection (http://imi-paradigm.eu/PEtoolbox/identification-

of-patient-representatives) and contract process PE tools applied (http://imi-paradigm.eu/PEtoolbox/contract-templates).

- Time frame of PE activity
- The timelines of the collaboration between partners (this may exceed the duration of the PE activity)
- Resource requirements
- Organisational challenges and their solutions
- Outcomes/results
- Lessons learned
- Recommendations and conclusions

To promote accessibility and readability consider the following requirements:

- Do not assume any prior knowledge of the PE activity - explain the context (take the reader on a journey).
- Provide enough details of the PE activity without disclosing any personal or proprietary information (i.e. individual names, product names, or product under development, detailed financial information are not required). If appropriate, discuss with organisations' legal department what type of information may be considered as confidential and how to best report the relevant information described above. For the EU, follow the General Data Protection Regulation (GDPR).
- Use a layout and format which is suitable for the general public:
  - Avoid formal, scientific, or academic style or tone in the text
  - Aim at a literacy proficiency level of 2-3 (see (NIHR, 2020, EC, 2018))
  - Consider using formulae to assist with the readability level of text such as the Fry readability formulae or Flesh reading ease text score (see (Synapse, 2018, EC, 2018))
  - Use simple, everyday language and terms. For example, 'use' not 'utilise'.
  - Avoid long sentences, abstract concepts, multisyllabic words, jargon, acronyms, complex words, ambiguous sentences, and the passive voice.
  - Use headlines, bullet points, inverted pyramid writing style, white space, and limit use of unnecessary imagery (icons and logos).
  - Whenever possible use large fonts (e.g. size 12 sans serif), appropriate white and line space and high contrast which helps readers to clearly differentiate each section.
  - If appropriate, use infographics and clear visual aids.

- Keep the document short. One to three pages is a useful guide.
- Be consistent in the use of terms/words throughout the document and define them explicitly.
- Present the "big picture" before the details (inverted pyramid writing style).
- Use respectful language which reflects patient preferences and is suitable for a diverse set of audiences.

5. Outcomes/outputs

Questions for reflection

- What challenges exist in the field that may have an impact on reporting: is the information or part of the information shared during the PE activity considered confidential?
- What extra considerations might be needed for translation into languages other than English (i.e. in the country where the PE activity took place)?
- How can the outcomes and outputs create shared value and knowledge gain for all stakeholders?
- How can the outcomes and outputs be easily discoverable (see point 1#)?

Good practice

- In organisations with legal or compliance departments, involving them in early discussions may be helpful in finding the right language to use for reporting without breaching confidentiality agreements and obligations.
- Consider, when appropriate, existing legal/policy frameworks in the country(s) or within the organisations involved.
- Identify the mechanisms and tools for shared learning of all positive and negative experiences for the PE activity, methods of knowledge exchange within and between organisations. For example, utilizing a monitoring and evaluation framework in the planning, implementation and reflection phases alongside a dissemination strategy (http://imi-paradigm.eu/PEtoolbox/monitoring-evaluation).
- Consider how other initiatives, platforms and infrastructures could be best utilised to transition learnings into the public domain (see point #1).
- Publish the report in English and consider translating material into the language where the PE activity took place, to improve visibility and reach.

Template for PE Reporting

The template below is a guide to help in the proactive reporting and dissemination of PE activities in a structured and reproducible way. It can be used flexibly in line with existing stakeholder specific reporting tools and templates in order to reduce duplication and redundancy of material. While some questions might not be appropriate for all PE activities, returning brief but detailed information into each and every field is highly recommended.

The template should be used in combination with the planning checklist, and the detailed guiding principles. A completed template with example text as a guide, is included in Appendix 2.

Title of the PE activity/ initiative:	
When was the activity carried out (start date-completion date)	
What stage of medicines research and development (R&D) was it most applicable to:	
Date of reporting:	
Organisation(s) who is/are reporting and contact details of person to contact in case of questions:	

Introduction/rationale:

- What was the activity about and what was aim of the PE?

Who was involved and how?

- Who was involved?
- How were patients selected?
- Were patients trained/ provided with relevant information?

Describe the concrete activity that was carried out

- What type of activity was conducted?
- How long was the activity?
- How was the activity organized?

What did the individuals involved jointly tell you (i.e. the engaging stakeholder and patient or PO)?

- What information or experiences were shared?
- What concrete advice was given (e.g. for a clinical trial protocol)

How was the input/feedback provided by patients used?

- Did anything change as a result of the activity? If so, what changed and how?
- If nothing changed, why not?

Benefits - What were the main benefits to each stakeholder- in the short or long term - of conducting this activity?

- What was the benefit in the short term?
- What was the benefit in the long term?

What worked well and what did not in undertaking the PE activity?

- What elements of the planning and execution worked well?
- What elements of the planning and execution didn't work well?

What are the most important aspects to consider or that need to be addressed in the future for the activity to be successful?

Reporting and Dissemination Planning Checklist

The following checklist is designed to help facilitate the planning and completion and reliable reporting and dissemination of all PE activities by highlighting key principles and considerations to keep in mind during the planning phase.

It is intended to be used alongside the guiding principles and practical template to move beyond anecdotal reporting of broad PE strategies, high level plans, or organisational projects, to act as a bridge between internal-to- external reporting and dissemination channels to promote consistent, timely, accessible and discoverable PE activities as part of a learned dissemination and communication continuum.

Where the answer is 'No', reflect why this is so and if it is appropriate and needed to be included in the strategy used

Key Principles to consider when reporting and disseminating PE activities			
Mechanisms and channels	**Yes**	**No**	**Comments**
Have you identified all intended audience(s) for the reporting and dissemination of the patient activity?	☐	☐	
Will reporting and dissemination materials be available to both internal teams as well as the participating patient(s)/ PO, and be available in the public domain?	☐	☐	
Is there a dissemination pathway and infrastructure identified, and in place for both direct and indirect dissemination channels?	☐	☐	
Will planning and, capacity and capability considerations be put in place for each chosen dissemination mechanism and channel?	☐	☐	
Does the plan aim to include appropriate resources (time and money) for each mechanism and channel to be used?	☐	☐	
Will tools and templates be used to facilitate and implement the chosen mechanisms and channels?	☐	☐	
Process	**Yes**	**No**	**Comments**
Is there a time-frame that has been jointly agreed upon with the participating organisations for the entire reporting and dissemination process?	☐	☐	
Will the required capacities and capabilities to facilitate writing, review, approval and implementation processes be identified and agreed upon by all involved stakeholders?	☐	☐	
Are there extra considerations such as a need for translation of material into other languages that need to be planned for in advance?	☐	☐	
Do all the stakeholders involved have an appropriate level of understanding and expectations for reporting and dissemination?	☐	☐	

Key Principles to consider when reporting and disseminating PE activities			
Process	**Yes**	**No**	**Comments**
Do all stakeholders involved have a clear understanding of the benefits and challenges for timely reporting of this specific PE activity?	☐	☐	
Are existing reporting styles, structures and templates being streamlined across different teams, partners, and stages to reduce duplication and redundancy in content?	☐	☐	
Is there a plan to involve legal and compliance departments early in the planning and implementation phases to help manage potentially confidential material generated between the involved stakeholders?	☐	☐	
Meaningful involvement of patients	**Yes**	**No**	**Comments**
Is it confirmed that patients will be involved jointly in decisions about the reporting and dissemination of the activity?	☐	☐	
Does the plan aim to resolve challenges that may arise in an appropriate manner in order to meaningfully involve patients in reporting?	☐	☐	
Will the capacities, capabilities and support that are needed at each stage of reporting and dissemination be discussed with patients prior to the start of PE activity?	☐	☐	
Is there a plan in place to maintain the relationship between all stakeholders involved after the PE activity has ended?	☐	☐	
Content and format of material created	**Yes**	**No**	**Comments**
Will the perspectives of the different stakeholders involved be included in the reporting and dissemination material?	☐	☐	
Is the amount and type of information in material sufficient for someone not involved in the activity to understand the	☐	☐	

Key Principles to consider when reporting and disseminating PE activities			
Content and format of material created	**Yes**	**No**	**Comments**
activity so that they can use, compare, and/or replicate the activity elsewhere?	☐	☐	
Does the plan aim to achieve complete and reliable reporting through joint advice and/or production of material with patients/PO?	☐	☐	
Are the existing templates and tools that are to be used suitable, flexible and adaptable for all of the reporting and dissemination material?	☐	☐	
Is it confirmed that any material created will be understandable and accessible to a diverse audience including individuals with different types of impairments (e.g. in which language/s will the reporting be available, literacy level, format, layout, visual impairment, colour blindness etc.)?	☐	☐	
Outcomes/outputs	**Yes**	**No**	**Comments**
Is the overall goal for reporting and dissemination of the PE activity clear to all involved stakeholders?	☐	☐	
If needed, will extra considerations be put in place for translation into languages other than English (i.e. into the language in the country where the PE activity took place)?	☐	☐	
Will the outcomes and outputs that are being created contribute to shared value and knowledge gain for all stakeholders?	☐	☐	
Are the outcomes and outputs of the PE activity easily discoverable to other stakeholders?	☐	☐	

Limitations of the tool

Reporting and external dissemination in the public domain defined here includes; context, methods used, practices and process followed, outcomes, learning and improvement for all stakeholders involved, demonstrating impact and value gain.

It is important to bear in mind that the main aim of this tool is not intended to address financial reporting in any way or override efforts of organisational considerations for any party involved - this type of reporting should not typically involve disclosure of personal, financial, or proprietary information. Rather it is to encourage ethical, social and collective knowledge gain and transfer as part of a learning PE ecosystem in which all stakeholders are equal participants and can benefit, improve practices, and learn from all successes and failures.

This guidance, template and checklist have been developed for flexible use alongside existing reporting documents that may be use by each stakeholder and should not replace those.

These tools have been developed from a consolidation of key elements from some of the common materials and literature on reporting and dissemination. They do not represent an exhaustive or definitive list of all that could or should be considered during the reporting and dissemination process for all involved stakeholders.

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Appendix 1

Further relevant material and templates to assist in the planning and implementation phases of reporting and dissemination

Resource	Link
EU Commission Summary of Clinical Trial Results For Laypersons	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf
EUPATI Case Reports of PE	https://www.eupati.eu/wp-content/uploads/2016/10/CASE-REPORT-combined-20141126.pdf
GRIPP2 reporting checklists Tools to improve reporting of patient and public involvement in research	https://www.bmj.com/content/358/bmj.j3453
INVOLVE (UK) Support and Resources for researchers undertaking PPI	https://www.invo.org.uk/makeitclear/support-and-resources
EUPATI Roadmap Initiative to Good Lay Summary Practices	https://www.eupati.eu/blog/roadmap-initiative-to-good-lay-summary-practices-meeting
PFMD Patient Engagement Quality Guidance – tool and checklist	https://patientfocusedmedicine.org/the-patient-engagement-quality-guidance
NICE Example assessment report from HTA involving patients	https://www.nice.org.uk/guidance/ta342 and https://www.nice.org.uk/guidance/ta342/chapter/4-Consideration-of-the-evidence
HTAi	https://htai.org/interest-groups/pcig/
INAHTA (The International Network of Agencies for Health Technology Assessment)	http://www.inahta.org/hta-tools-resources/
EUnetHTA (European network for HTA)	https://eunethta.eu/

Appendix 2

Exemplar completed template from a real PE activity undertaken.

It demonstrates the level of detail, language and length required in order that the key principles, methods and learning coming from the completed PE activity can be understood by all other stakeholders.

Title of the PE activity/ initiative:	RADAR-AD Patient Advisory Board
When was the activity carried out (start date-completion date)	Ongoing - PAB was set up in March 2019. The specific PE activity reported in this template was carried out in June 2019
What stage of medicines research and development (R&D) was it most applicable to:	Design of clinical trials
Date of reporting:	March 2020
Organisation(s) who is/are reporting and contact details of person to contact in case of questions:	Alzheimer Europe. Ana Diaz, Project Officer, ana.diaz@alzheimer-europe.org
Timeframe of involvement:	The project started in January 2019. The PAB was set up in March 2019 and will continue until the end of the project. PAB members meet face-to-face at least 3 times a year and keep ongoing written communication in between meetings. A few selected PAB members attend the project Annual General Meeting.

Introduction/rationale:

- What was the activity about and what was aim of the PE?

It was organized in the context of a Patient Advisory Board (PAB) set up in an Innovative Medicines Initiative (IMI) project. The PAB is involved in all work of the project, including understanding of functioning in Alzheimer's disease, technologies used by individuals and a planned trial.

Introduction/rationale:

- What was the activity about and what did you want to achieve with the PE?

Aim: To provide input regarding potential challenges and strategies for recruitment and retention and compliance of participants in a clinical trial for Alzheimer's disease. The trial involves the use of technology and remote monitoring in Alzheimer's disease. A few members of the PAB (four individuals with dementia and three carers) also tested and provided feedback on the tests and games envisaged for the trial.

Who was involved and how?

- Who was involved?
- How were patients selected?
- Were patients trained/ provided with relevant information?

The PAB is composed of individuals with dementia, individuals with Mild Cognitive Impairment (MCI) and carers. Information about the PAB composition and members can be found here: https://www.radar-ad.org/patient-engagement/patient-advisory-board

Individuals with dementia and carers are members of an existing Working Group (information about the WG can be found here; https://www.alzheimer-europe.org/Alzheimer-Europe/Who-we-are/European-Working-Group-of-People-with-Dementia)

The PAB members with dementia have different types of dementia, are at different stages of the disease (mild to moderate) and live in different European countries.

Individuals with MCI had participated in a focus group organised by the project and expressed interest in participating long term in the project. Inclusion of individuals with MCI in the PAB was important as it reflects the type of patients included in the project.

PAB members did not receive any specific formal training. The majority of members have been previously involved in research and PPI activities and in providing feedback to the protocol of the trial. In addition, the consultation is based on their lived experience of the disease. Lay terms are used for all communications, so no previous technical knowledge is required. Prior to the meeting PAB members received relevant information about recruitment and retention issues.

Describe the concrete activity that was carried out

- What type of activity was conducted?
- How long was the activity?
- How was the activity organized?

PAB members participated in a 1-day workshop in Brussels. Travel was organized and pre-paid by AE for all members. Members were not compensated for their time. The meeting was facilitated by two AE staff with expertise in PPI and dementia and four researchers from the project. All were widely involved in the preparation of the protocol and conduct of the trial. The AE staff and researchers developed a detailed protocol with the aims of the consultation, pre-readings and activities to be carried out during the meeting. Several preparatory meetings were held with the PAB to clarify what needed to be addressed with the PAB and how to ensure that it was suited to its member's needs. For further information about PPI in dementia: https://www.alzheimer-europe.org/Policy/Our-opinion-on/Involving-people-with-dementia-in-research-through-PPI-patient-and-public-involvement/(language)/eng-GB

As many PAB members experience cognitive challenges (i.e. dementia or MCI) additional considerations were implemented:

- Pre-reading materials were sent to all members 2 weeks in advance to the meeting.
- Appropriate breaks were organised throughout the day and members were reminded that they could leave the room at any time for a short break if necessary.
- Presentations were kept short (up to 20 minutes) and slides were reviewed by AE staff before the meeting for accessibility.
- Different types of sessions were organised: e.g. two plenary sessions with all members were used for brainstorming and general discussions and a breakout session in smaller groups for deeper discussions and more active participation of all members.
- In all the sessions, hand-outs with the questions printed in large font (to facilitate members to remember the questions discussed) and flipcharts (to facilitate that members could more easily keep track of conversations) were used. To facilitate the discussion around possible retention issues in this particular trial, a vignette describing a typical day of a person participating in the trial was used in the session.
- Some non-native English speaker members were supported for translations of pre-reading materials by their carer and on the day, with extra time allocated.
- All sessions were approached in a flexible manner and adapted to the pace and needs of the members on the day (e.g. longer breaks if required and reducing the number of topics addressed).

What did the individuals involved jointly tell you (i.e. the engaging stakeholder and patient or PO)?

- What information or experiences were shared?
- What concrete advice was given (e.g. for a clinical trial protocol)

PAB members discussed potential barriers for recruiting and retaining individuals with Alzheimer's disease in a trial using technology for remote monitoring of the disease, possible solutions (facilitators) for the researchers, and about the games and tests planned for the trial.

Details of the provided input can be accessed in RADAR-AD Deliverable 3.1 (IMI link)

https://cordis.europa.eu/project/id/806999/results

How was the input/feedback provided by patients used?

- Did anything change as a result of the activity? If so, what changed and how?
- If nothing changed, why not?

The research team made several changes to the protocol and to the platform used for collecting information of remote monitoring based on the discussions with the PAB.

Also, changes were made to the research process (e.g. the games will be introduced by a trained researcher) and to the games (e.g. participants will receive feedback on performance, the design of some parts of the game was adapted and the instructions of some tasks were changed).

Further details of the changes can be accessed in RADAR-AD Deliverable 3.1 (IMI link) https://cordis.europa.eu/project/id/806999/results

Benefits - What were the main benefits to each stakeholder- in the short or long term - of conducting this activity?

- What was the benefit in the short term?
- What was the benefit in the long term?

In the short term, the PAB provided to the research team:

- A better understanding of the potential concerns and barriers that participants may have when invited to take part in the trial.
- Concrete ideas and suggestions for overcoming some of these barriers and ensuring

Benefits - What were the main benefits to each stakeholder- in the short or long term - of conducting this activity?

- What was the benefit in the short term?
- What was the benefit in the long term?

the wellbeing of the participants.

- Improvement of the process and accessibility of test and games used in the trial.

In the long term, it is hoped this will contribute towards a better experience for the participants of the trial, quicker time for recruitment and fewer participants' dropping out or not complying with the different tasks which are included in the trial.

Another important benefit of having a PAB in the project, is that some researchers changed their attitudes to and opinion of the relevance of the contributions of individuals with MCI and dementia to research.

This may help to address the existing stigmatization of and preconceptions around dementia. Also, this activity is important for the individuals involved in the PAB as it gives them a greater feeling of value and meaning.

What worked well and what did not in undertaking the PE activity?

- What elements of the planning and execution worked well?
- What elements of the planning and execution didn't work well?

Elements that worked well were:

- Careful and detailed preparation of the meeting (e.g. by research team and AE staff)
- Social interactions: PAB members and AE facilitators were already familiar so they felt at ease to participate and there was an atmosphere of trust and openness to share their views.
- Breaks during the day and a relatively long break for lunch. Participants were all in the hotel the night prior to the meeting so no one had to travel on the morning of the meeting.
- The team in the RADAR-AD project was very open to feedback by the PAB and four researchers came to the meeting and helped to facilitate the discussions. It is important that the right individuals from the team is in the room and can answer questions to the PAB as well as to listen to the feedback first-hand.
- A report was sent to the research team shortly after the meeting and the PAB also received information of the progress of the project.

What worked well and what did not in undertaking the PE activity?

- What elements of the planning and execution worked well?
- What elements of the planning and execution didn't work well?

Elements that didn't work as well:

- It was difficult to find a good balance between the number and length of breaks and time for discussion which works well for all members due to the different types and stages of dementia but also their personal backgrounds.
- This PAB is a large group, which is very valuable for providing diverse opinions and experiences, but it was more challenging to facilitate a large group of members with different needs and to ensure all members have equal opportunities for participating.
- Certain issues ideally would have had more time for discussion.
- Some members of the PAB did not like the vignette activity, however the majority found it very useful.

What are the most important aspects to consider or that need to be addressed in the future for the activity to be successful?

- Careful planning of the PE activity is very important, this has to be done in close collaboration between the research team (who understand well the needs of the project and where feedback from PAB members is important) and the patient organization (to address the specific needs of individuals with dementia (wellbeing) but also to ensure other principles such as autonomy).
- Adequate financial and human resources (e.g. ensure that PAB members can arrive the day before, and have booked and prepaid their travel and accommodation).
- Flexibility at all times of the meeting and a person-centered approach is very important for individuals with dementia.
- As some individuals with moderate dementia may find it more challenging to participate, it is important to combine different activities as for example plenary and breakout sessions.
- PAB members need to be well prepared for the meeting (e.g. receive relevant information in advance) and receive feedback about the value of their contributions.

Glossary

Disclaimer: The terms used here have been defined or agreed upon within the context of this project.They should not be considered as exhaustive, finite or purposely exclusive of other considerations, but are representative of the specific focus of this project and its actions.

Code of conduct:

Collection of rules and regulations that include what is and is not acceptable or expected behaviour (PARADIGM)

Community Advisory Board:

Community Advisory Board (CAB) refers to a group of patients who offer their expertise to sponsors of clinical research and who advise several sponsors in their field. CABs are autonomous bodies, not related to the sponsor or chosen by them.

Confidentiality Agreement (CA)/Non-disclosure agreement (NDA):

Legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes but wish to restrict access to.(Wikipedia)

Consultancy:

Advice provided on company- or academia sponsored clinical trial protocols including related documents, regulatory documents or information about the products under discussion (e.g. medicinal products, biomarkers), strategic initiatives and other projects of commercial or academic relevance (PARADIGM)

Design of clinical trials:

Designing protocols, discussing patient burden, discussing patient related outcomes (PARADIGM)

Early dialogues with regulators and Health Technology Assessment bodies:

Early (multi-stakeholder) discussions between industry, HTA agencies and/or regulators (and in some contexts with payers) to discuss developmental plans for a medicinal product and to ensure they meet the requirements.

* *Early dialogue is not a decision-making time for any party. In practice it more closely resembles consultation with the chance for feedback and input (two-way communication).* (PARADIGM)

Health Technology Assessment (HTA):

Systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies. HTA is conducted by interdisciplinary groups that use explicit analytical frameworks drawing on a variety of methods. (HTA glossary)

Health technology assessment (HTA) body:

A body that undertakes or commissions health technology assessment to form recommendations or advice for healthcare funders and decision-makers on the use of health technologies (PARADIGM)

Healthcare professional (HCP):

This category of stakeholders is broad and heterogeneous as it encompasses general practitioners, nurses, clinical investigators/academics, pharmacologists, etc. (PARADIGM)

Medicine developer:

Includes any organisation involved in the research, development, manufacture, marketing and/or distribution of medicinal products and/or any other health products such as medical devices or digital solutions. Clinical/contract research organisations (CROs) or consultancy companies providing advice or services relating to the above activities, fall under the definition of medicines developers. Research organisations including universities and learned societies (i.e. an organisation that exists to promote an academic discipline, profession) are also included in the definition of medicines developers (PARADIGM)

Medicines development/medicines research and development (R&D)/ medicines lifecycle (in PARADIGM these terms are used interchangeably):

A medicines lifecycle comprises research and discovery, development (preclinical and clinical), marketing authorisation, post-approval, HTA, pricing and reimbursement, commercialization, lifecycle management and Pharmacovigilance until deregistration. (PARADIGM, adapted from: EUPATI; European Commission: Frontiers 'The Life Cycle of Health Technologies. Challenges and Ways Forward, Iñaki Gutiérrez-Ibarluzea et. al. 2017')

Memorandum of Understanding (MoU):

Type of agreement between two (bilateral) or more (multilateral) parties. It is not legally binding, but it expresses willingness between the parties to take forward a common line of action. (Investopedia)

Participating organisation/engaging partner:

An organisation which is organising and/or participating in a PE activity (PARADIGM)

Patient covers the following definitions:

- **"Individual Patients"** are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.
- **"Carers"** are persons supporting individual patients such as family members as well as paid or volunteer helpers.
- **"Patient Advocates"** 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 Organization Representatives"** are persons who are mandated to represent and express the collective views of a patient organization on a specific issue or disease area.
- **"Patient Experts"**, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience, for example EUPATI Fellows who have been trained by EUPATI on the full spectrum of medicines R&D.

  (The European Patients' Academy on Therapeutic Innovation (EUPATI)

Patient community:

Patients, patient representatives including their family and carers, patient advocates and patient organisations (PARADIGM)

Patient engagement:

The effective and active collaboration of patients, patient advocates, patient representatives and/or carers in the processes and decisions within the medicines lifecycle, along with all other relevant stakeholders when appropriate (PARADIGM)

Patient organisations:

Patient organisations are defined as not-for profit organisations which are [patient-]focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies (EMA 2018a)

Payer:

Institution, organisation or individual paying for healthcare or health services (PARADIGM)

Pharmaceutical industry:

The pharmaceutical industry is comprised of many public and private organizations that discover, develop, manufacture and market medicines for human and animal health. In short, the term "industry" is used to refer to the pharmaceutical industry (PARADIGM)

Policy-maker(s) (or policymaker(s)):

A member of a government department, legislature, or other organization who is responsible for making new rules, laws, etc. (https://dictionary.cambridge.org/dictionary/english/policymaker)

Regulatory authority (or regulatory agency or in short 'regulators'):

A body that carries out regulatory activities relating to medicines, including the processing of marketing authorisations, the monitoring of side effects, inspections, quality testing and monitoring the use of medicines. (EMA)

Representative for pharmaceutical industry:

An employee of the pharmaceutical industry designated to represent the company position in project/consortium/body (PARADIGM)

Research priority setting:

Providing opinion, providing evidence and/or being part of a group that decides what is important to research. Design of clinical trials (PARADIGM)

Three main decision-making points:

The term, 'decision-making points' is defined as the key points in the development lifecycle of medicinal products. The three decision-making points relevant to PARADIGM are: research priority setting, design of clinical trials and early dialogues with regulators and Health Technology Assessment bodies (PARADIGM)

Vulnerable / underrepresented groups:

Children and young patients, people living with dementia and their carers. This definition can also include underrepresented groups (e.g. migrant and non-settled populations, substance users, incarcerated people and people with mental health disorders other than dementia). (PARADIGM)

Specific terminology of the Guidance for Reporting and Dissemination of Patient Engagement Activities

Report and dissemination:

Structured and timely reporting of objectives and results of a Patient Engagement (PE) activity; not considered confidential, yet sufficiently detailed to permit knowledge gain and transfer between stakeholders and the public with a strong focus on the patient community, as part of a broader and continuous dissemination and communication and change management strategy. In this tool, the term 'reporting' should not be considered as part of the financial or formal reporting of activities of an organisation (PARADIGM)

Communication:

In the context of European projects, the European Commission defines communication as a strategically planned process that starts at the outset of the action and continues throughout its entire lifetime, aimed at promoting the action and its results. It requires strategic and targeted measures for communicating about (i) the action and (ii) its results to a multitude of audiences, including the media and the public and possibly engaging in a two-way exchange.

Public domain:

For the purposes of this tool, it is considered that information is in the public domain if it is realistically accessible to a member of the general public at the time of the request. https://ico.org.uk/media/1204/information-in-the-public-domain-foi-eir-guidance.pdf

Participating organisation:

This term refers to the organisation which is responsible for organising and/or participating in the PE activity. In the context of this tool, this mainly refers to PE activities which involve pharmaceutical companies and patients (including patient organisations and other structures such as Community Advisory Boards).