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

innovative medicines initiative

Planning Patient Engagement

Enhancement EUPATI industry guidance:

Events and hospitality

PARADIGM is receiving funding from the Innovative Medicines Initiative Joint Undertaking 2. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA

Contents

1. 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.

2. Purpose of the document

The EUPATI Guidance for Patient Involvement in Medicines Research and Development (R&D); Guidance for Pharmaceutical Industry-Led Medicines R&D was published in Frontiers in October 2018[1]. It is recommended that the original EUPATI guidance be read alongside this document, which supports the integration of meaningful patient involvement across the entire process of medicines research and development and recognises the value of relevance, fairness, equity and capacity building when developing working practices.

During the PARADIGM project further expansion of specific sections of this EUPATI guidance were required. The decision was to provide this in the form of appendices, thereby avoiding revision to the existing published guidance but giving more detailed contents for better usability of the guidance.

The considerations for events and hospitality required further emphasis to provide more detail on the level of attention needed when arranging patient engagement activities to ensure patients have the best experience.

The output of this work is a checklist in Section 5: a practical tool which may be used during the planning process.

[1] https://www.frontiersin.org/articles/10.3389/fmed.2018.00270/full

3. What is this tool?

The checklist is designed to help individuals responsible for coordinating and planning patient engagement activities consider specific patient needs for travel, meeting venues, accommodation and associated elements. It is written for general application across all different scenarios and aims to be simple to follow by all stakeholders involved.

Individuals responsible for coordinating and planning patient engagement activities should use this checklist to enable the activity to reflect the recommendations. For example, individuals in a patient engagement role, groups directly organising the activity; legal and other support functions should be aware of these recommendations.

It is important to note that patient engagement does not only occur within the area of a specific disease; there will be interest in obtaining patient input/collaboration in areas not specifically linked to a disease. Therefore, the checklist should be considered for all interactions.

4. Recommendations

It should be recognised that the COVID-19 pandemic has had a severe effect on the lives of many patients and their families. There is a high level of anxiety around the lifting of restrictions, willingness to travel, safety provisions when travel is possible and measures required to protect individual health.

This is likely to be the situation for the foreseeable future, therefore in the early stages of planning meetings with patients, it is important that organisers speak to patients / carers to get the arrangements right: everyone is individual and will have different needs, preferences, concerns and considerations.

The main person coordinating the activity and other people in direct contact with patients should be appropriately trained to work with patients. It is crucial that they have the right mind- set and empathy.

There are different ways to interact with patients (e.g. face to face meetings, online meetings, written feedback etc.). Always consider running a patient engagement activity using virtual methods, such as videoconferencing and teleconferencing, direct to patient surveys, to minimise the need for participants to travel.

For virtual interaction, consider that technical equipment (hardware, software and infrastructure requirements, e.g., high-speed internet) you intend to use should be accessible to patients. In advance of the activity, familiarise your participants with the use and particulars of interacting in this environment, which may include support through a facilitator for testing, setup and troubleshooting.

Of course, sometimes in person meetings will be preferable, or necessary due to the complexity of the subject, and patients do value the opportunity to meet the other participants and learn from each other.

Depending on the planned duration of a patient engagement activity it is advisable to organise at least one face-to-face (F2F) meeting per year (keeping the limitations of the specific disease in mind). F2F meetings, especially during the starting phase of a patient engagement activity, help create an increased understanding and trust between participants and should be designed to identify and discuss concerns and any roadblocks/risks in advance of the activity.

Optimise activities at a time of day to suit patients and keep meetings short and focused. Build in regular and/or longer breaks to allow attendees to relax/take medicine or for guide dogs to take a break outside (a minimum of 30 minutes is recommended).

If the activity appears to exceed the scheduled time, let the patient(s) know – they can decide if they wish to stay or leave at the scheduled time.

Organisers and attendees should share the responsibility to ensure patients participating in conferences are treated equally and involved in the right manner, included in the agenda so the patient view is included: everyone should be pushing for change

Ensure compliance with the PARADIGM code of conduct , as well as legal/local requirements. Refer to Appendix 1 within EUPATI guidance document.

5. Events and hospitality checklist

This checklist has been designed as a practical tool which may be used during pre- engagement planning of patient engagement activities. It defines high level considerations for events and hospitality and is not intended to be an exhaustive list. Best practice is to have basic knowledge of the disease, typical symptoms and then apply as appropriate for the patients being engaged and their associated needs.

Considerations	Comments
Travel	
Identify in advance the patient's travel preferences, plus understand (and if possible) support the provisions patients may need to make at home to allow them to participate (i.e., childcare, eldercare).. For example, they may prefer train travel to flights. Try to achieve these where possible. Consider patient journey from start to finish. Identify all points of the activity requiring transport:	
Think about travel from the patient's home to the airport/ station and return journey home	
Avoid long transfer times and instances where heavy traffic is likely. Arrange assistance and adapted vehicles for meet-and-greet service at meeting destination and airport or train station if required. Arrange for similar transport to restaurants if required.	
Can early starts be avoided by travelling the day before an activity? Many patients have a morning routine to manage their disease. Check what the patient's needs are to enable optimal participation in the meeting.	
Make sure you agree on arrival and departure times with the patients, allow ample time between arrival time and activity start time in case there are delays.	
Arrange for patients to be dropped by taxi (or suitable transportation) as close to the venue entrance as possible.	

Considerations	Comments
Patients may wish to drive themselves, in these cases remember to reserve appropriate car parking close enough to the entrance of the venue.	
Support the patient when arranging their travel so that the extra luggage allowance in the cabin and the hold and special allowance for taking medication/oxygen, wheelchair etc. on the plane is organised with the airline beforehand.	
Remind patients to bring necessary medication, replacement oxygen cylinders, etc., with them. Inform the patient on what they need to bring as extra documentation (medication overview such as list of treatments, allergies, medicine passport, health records, letter from dietician and doctor on what is necessary like extra fluids/special foods/ oxygen/needles or other devices (like implants, insulin pumps) etc). Identification may also be required by meeting venues, and at hotels. Remind patients to pack essential medicines and equipment (to the extent possible) in their hand luggage to avoid difficulties due to loss of luggage.	

Companions/supporters	
Considerations	**Comments**
To facilitate and encourage patient involvement, allowing a patient to be accompanied by an adult supporter (carer, family member, friend, member of a patient organisation) even if not for health reasons is really important. Some people may be intimidated by the travel itself (particularly international travel), being in another country, with unknown people, in a completely different environment or need support at the meeting. If this is the case, the cost of travelling and accommodation, etc., of the supporter should be covered. It is easier for the patient/carer if bookings are made under one reservation: this may guarantee adjacent seating or enable changes to the booking.	

Considerations	Comments
In some cases, the supporter may be required before and/or during the meeting. If the latter, the supporter should be able to receive pre-readings and have a seat at the meeting next to the patient. If a supporter is needed, this person is expected to be able to provide the support needed and it should be made clear what is expected from them.	
Accompanying minors	
Considerations	**Comments**
For rules on accompanying minors, before arranging travel please check EU Reference document or legal regulations within the country the child is travelling both to and from. Each country has their own rules and individual insurance and permission from the other parent may be required.	
Travel time	
Considerations	**Comments**
Remember that travelling is tiring so providing support and adequate facilities is important. Depending on meeting duration be flexible, give patients the option to travel the day before the meeting and leave the day after the meeting. For example, if meeting start means the patient is expected to travel earlier than 07:00 and meeting end means the patient is likely to arrive home later than 22:00. Treat on a case by case basis, but ensure compliance with guiding principles. Think about the proximity of the venue closer to, or central to, where patients are generally located bearing in mind to keep their journey times manageable.	
Any meeting organiser should arrange and pay for travel and hospitality for patients and carers in advance to avoid patient(s) needing to pay in advance and then request reimbursement. (In order for payments to reflect fair market value, as an example for the U.S reference can be made to https://nationalhealthcouncil.org/tools-to-support-sponsor-patient-engagement-fair-market-value-calculator-and-engagement-templates/ and for UK to	

Considerations	Comments
https://www.invo.org.uk/resource-centre/payment-and-recognition-for-public-involvement/)	
Accessibility	
Considerations	**Comments**
Understand what special accessibility requirements are required. Don't forget toilet facilities sufficient for the number of patients expected to use them. Ensure transport provider (airline/airport/railway station) is advised of special assistance requirements and this is organised at the time of booking. For example, some airlines have seating for patients with Inflammatory Bowel Disease (IBD) or a meet and greet service for people with reduced mobility or disability, which may include provision of wheelchair (where needed).	
Technical	
Considerations	**Comments**
For virtual interaction, in advance of the activity check that technical equipment (hardware, software and infrastructure) you intend to use is accessible to patients and any potential barriers to participation. Where possible, provide support through a facilitator for testing, setup and troubleshooting. Consider the following:	
Is internet in their area strong enough to support a virtual conference?	
Do they have a plan that allows for anticipated data usage?	
Will they be the only participant without a camera on?	
Do they have access to a suitable computer to enable them to view slides or other documents shared by presenter on screen?	
If running meetings where some people are attending in-person and others are attending virtually, ensure equity in ability to contribute.	

Hotel accommodation	
Considerations	**Comments**
Where applicable and possible, try to ensure availability of accessible accommodation for individuals with mobility restrictions or cognitive impairment considering the following requirements:	
Additional hostess assistance (shown to their room, wheelchair navigation, etc.).	
Bedrooms that are within close proximity to meeting space and/or near elevators to promote independence by aiding spatial orientation (check for preferences before booking).	
Wider door access with low spy holes, low-level wardrobe rails, and furniture. Avoid steps in room.	
Low-mounted (or remote control), comfort-control panel, and light switches (ideally with dimmable lighting) at bedside.	
Minimalist furniture, wall art, and coverings; wooden or laminated flooring; easy-pull blinds (rather than curtains); contrasting colours such as light switch next to doors (where possible).	
No transparent glass walls, such as those leading to bathroom.	
Telephone easily accessible (by bedside).	
Soft furnishings that can be changeable (such as pillows). Be aware of items that may trigger atmospheric allergies (dust, pillows, carpets, etc).	
Option to have adjoining room for carers.	
Option to have a fridge/freezer in the room to keep medication cool and/or option for ice to be available for medical treatments.	
Where possible, rooms should have temperature control panels, if this cannot be provided then heaters/fans should be available.	

Considerations	Comments
Facilities for service animals to accompany patient.	
Bed and mirror height suitable for wheelchair users.	
Seating (chair) available in the hotel room.	
Wider bathroom door access and wheelchair-friendly shower with fold down seat.	
Easy-to-use shower mechanics.	
Grab rails on both sides of a higher-level toilet, shower and bath.An emergency pull cord in bathroom linked directly to the Guest Services desk, which must be manned 24/7.	
Low-mounted towel storage and shelving as well as soap and other amenities. Ensure soap and amenities can be easily opened and ideally contrasted with sink (not white on white).	
Meeting venues	
Considerations	**Comments**
Walk the route patients will take, are there elevators available where needed? Complete this with people living with the condition where possible. Plan an alternative route if patients have limited mobility to avoid too much walking or stairs.	
Are the toilets clearly signposted, in easy reach and wheelchair accessible?	
Are you familiar with the fire evacuation and emergency procedures (and are these made available for participants)?	
Consider onsite medical assistance to be available (or where to go in case medical assistance is needed).	
Provide easy access and plenty of space around tables and chairs in the meeting room and catering areas. All meeting space / breakouts on one floor in a quiet/secluded area (for privacy reasons), if possible.	

Considerations	Comments
Designated reserved seating for people with limited mobility or cognitive impairment should be available during large events. Table height should enable wheelchair users to be seated alongside other participants.	
Consider event registration of carer.	
You may need additional facilities such as fridges (for medication), provision for guide dogs, etc.	
Check if your venue requires a risk assessment.	
Choose a meeting venue with natural daylight if possible.	
If you are video recording your activity, consent from the participants should be obtained well in advance. Cameras require extra space and should not be intrusive, use of this equipment may make patients uneasy and nervous; always put patients at ease.	
Ensure all attendees are included in all activities (so as not to discriminate); for example, if a group photograph is required on the stage, ensure ramps are available. Remember consent for photographs.	
Other senses can be heightened, so keep noise to a minimum and avoid bright lights.	
Provide an additional meeting room / quiet room so patients can take medicine / time out.	
Provide tissues in the room if emotional topics are to be discussed.	
Rooms should have temperature control panels. If this cannot be provided then heaters/fans should be available. Check patients are comfortable.	

Meet and greet	
Considerations	**Comments**
Make sure someone is assigned to meet and greet the patient and companions on arrival at the meeting venue and ensure departure process is smooth. Exchange mobile numbers for ease of contact on the day between the patient and the host. Build in time for patients to settle, receive refreshments, meet hosts and others plus for receiving any final briefing or clarification, if they are willing so – otherwise allow them to take their time until the meeting starts. Make sure the patient is comfortable before the activity starts.	

Catering / Dietary Requirements	
Considerations	**Comments**
Hospitality is essential. Never underestimate the importance of hospitality, whether in the meeting venue or hotel bedroom. Tea and cakes/cookies/vegetable sticks/fruit are a small cost but provide great benefit.	
Understand the patient's dietary requirements and make these available for the patient also in the small snack selection.	
Make sure water and other refreshments are available throughout the meeting. If, for example, people with dementia are at the meeting, remind them/encourage them to drink, hydration is very important.	
Consider (disease-specific) dietary requirements i.e. Paleo/ vegan, remember certain food types can severely affect medicines.	
Consider certain patients have a heightened sense of smell, so try and keep very strong-smelling foods to a minimum.	
Ensure accurate and large font food labelling to allow for allergies and avoidance of food cross-contamination.	
Allow adequate time for comfort breaks and meals.	

Considerations	Comments
Avoid working lunches/coffee breaks if possible (lunch is a break).	
Ensure social inclusion by providing sufficient seating in the meal areas for people who cannot, or do not wish to, stand and eat.	
If the venue/ hotel is not in a central location provide information about restaurants near the venue / hotel where the person stays and their accessibility.	
For meals outside the scheduled meeting, consider providing meal vouchers with a set monetary value or authorise meals to be charged to the room and paid by the meeting organizer, rather than expecting patient to request reimbursement.	
If off-site meals have been arranged (for example, an evening dinner) and a patient doesn't want to attend, respect their wishes and ensure their meals will still be reimbursed.	
Communication	
Considerations	**Comments**
Communication is essential, make sure to ask patients about their preferences for methods of communication and do not make assumptions about them. If possible, provide the phone number of a person who could provide support or clarify any issue to the person before, during or after the event if necessary.	
Send detailed pre-meeting information, including any pre-reads, slides, agenda, and information about the venue and how to get there (maps, useful info).	
Some people may prefer to receive the documents electronically and others as printed materials (ask the person about his/her preference).	
Consider alternative registration process (telephone, email, etc). Possibly communicate with carer rather than patient.	

Considerations	Comments
Be discreet – i.e. use closed discussion between event planner and some high-need patients.	
Use blind copy option when communicating to groups via email so you do not share email addresses without the patients' consent (either within group of patients or within your organisation).	
If a patient is asked to give a presentation, find out in advance what they require on stage. Consider: Do they need a lectern to hold their notes? Would an autocue be helpful? Comfort screen to see slides to front? Would they like someone else to move the slides on for them? Would they prefer a handheld, lapel microphone or headset?	
Materials developed for use during patient engagement activities should use lay language and participants from industry or academia may need to adapt the language they use to communicate and describe scientific and medical topics clearly. Use short and clear sentences and avoid use of jargon and acronyms (if these are necessary, include a glossary of terms). Consider larger font size on printed materials and clear layout (e.g. colour contrast, line space/ white space, bullet points).	
Make sure everyone feels comfortable and has opportunities to speak. Remember that some people may not be speaking in their mother tongue (provide "extra time" for them and ensure facilitators/ chair/ presenters do not speak too fast).	
If required, provide an interpreter and allow extra time for instantaneous translation during interactions.	
Are there other tools required to enable communication and provide appropriate time/opportunities for meaningful participation?	

6. Limitations

Advice given in this document is not intended to be exhaustive or applicable at all times. Use your own professional judgement to decide whether or not a recommendation can, should or must be followed.

7. References

European Patients Academy (EUPATI) focuses on education and training to increase the capacity and capability of patients to understand and contribute to medicines research and development and also improve the availability of objective, reliable, patient-friendly information for the public. https://www.eupati.eu/

Patient Focused Medicines Development (PFMD)) aims to transform the way in which we understand, engage, and partner with patients globally in the design and development of research and medicines by focusing on unmet patient needs.

https://patientfocusedmedicine.org/about-pfmd/

8. 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 https://en.wikipedia.org/wiki/Non-disclosure_agreement)

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 http://htaglossary.net/health+technology+assessment)

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: https://toolbox.eupati.eu/resources/making-a-medicine-step-7-phase-ii-proof-of-concept/ European Commission: https://ec.europa.eu/competition/sectors/pharmaceuticals/cycle.html EFPIA: https://www.efpia.eu/about-medicines/ Frontiers 'The Life Cycle of Health Technologies. Challenges and Ways Forward, Iñaki Gutiérrez-Ibarluzea et. al. 2017' https://www.frontiersin.org/articles/10.3389/fphar.2017.00014/full)

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 https://www.investopedia.com/terms/m/mou.asp)

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) https://www.frontiersin.org/articles/10.3389/fmed.2018.00270/full)

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)