# PRACTICAL GUIDE
# Patient and Public Involvement

## Antimicrobial Medicines Development Research

COMBACTE MAGNET

innovative medicines initiative

efpia

# CONTENTS

# FOREWORD

As infection researchers we all feel that our work is in the best interests of patients and their families, so with the wealth of knowledge and experience in any research team it can come as a surprise that there may be a gap in our knowledge. In our view that is the patient perspective. Patient and public involvement (PPI) is partly about filling that gap and making patient views central to research.

Changes in society are moving us towards more transparent and inclusive ways of working and there are many positive ethical and moral arguments for PPI in research. However, many of us only consider PPI as a mandatory part of securing funding or to comply with a requirement from a research authority. Our first experience of PPI was for such reasons. We needed a PPI group to work with us on a bloodstream infection study. It took some effort to find a group of people with relevant experience, which included former Intensive Care Unit (ICU) patients and their relatives, and someone who had previously been involved with research ethics review.

Our experience was that this group made very positive contributions to the project. They were committed to working with us for the benefit of the research. We were so convinced of the value of working with the PPI panel, that now we are committed to involving them at all stages of the research process from applying for funding to disseminating research findings. We have found that their perspective has changed our plans to make them more appropriate for patients, they have suggested new outcome measures that are more relevant to patients, adding to the more 'scientific' outcomes. Both of the Toolkit documents offer a wealth of information about how to work with patient and public contributors at each stage of research, with the potential for their experience and knowledge to benefit each aspect of the research process.

Overall, our feeling is that PPI has both saved us time, improved the relevance of our research, and optimised our recruitment of patients into studies. At the same time, we feel that it has ensured that our research is ethically sound, and appropriate to the patients that we recruit as participants. It ensures our processes are transparent, which makes us more accountable. The key factor seems to be the relationship between the research team and the PPI group. The research team need to be committed to PPI, and open to the perspective that it brings. It can take time to develop a collaborative working relationship at first, but the benefits to research are well worth the effort. We hope that these documents are helpful to those of you who embark on patient and public involvement in your research, and help you establish fruitful working with your PPI group.

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# 1. INTRODUCTION

Patient and public involvement (PPI) in antimicrobial medicines development research is new and unfamiliar. There are few established patient support groups or voluntary organisations in the field of infection sciences given the short-term nature of many microbial infections.

Due to the lack of literature and clear practical guidance focusing on PPI in this area (Evans *et al.*, 2017), we developed this toolkit to provide systematic and evidence-based guidance on how and when to involve the public in medicines development research, in particular antimicrobials. There are two versions of the toolkit available for your use:

(i) **Practical Guide**: This version sets out the **practical steps** of doing PPI, including how to find public contributors, how to plan and prepare for PPI, what the role of PPI is at different stages of the medicines development lifecycle, and how to evaluate PPI. References are not included in this document to keep it concise, but complete lists of references as well as a glossary of terms can be found in the main toolkit.

(ii) **Main Toolkit**: This version describes the content of the Practical Guide in more detail, providing **case examples** and **evidence** to support the practical steps recommended. Toolkit content is presented as individual chapters, allowing you to select and read topics that are relevant to you.

This toolkit project is part of **COMBACTE-MAGNET**'s clinical coordinating work package, **WP6i.** COMBACTE-MAGNET (www.combacte.com) is a consortium funded by the Innovative Medicines Initiative Joint Undertaking and EFPIA companies seeking new ways of treating multi-resistant bacterial infections.

Training workshops to support the use of this toolkit may be available. Please contact Andy Gibson at andy.gibson@uwe.ac.uk for more information or to arrange for a toolkit training workshop.

## 1.1 ACKNOWLEDGEMENTS

The production of this toolkit was a collaborative effort between the following:

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**Sally Grier,** PPI Coordinator and Acting Programme Manager, Infection Sciences Partnership, North Bristol NHS Trust (NBT)
**Michele Kok,** Research Associate in Public Health, UWE, Bristol
**Alasdair MacGowan,** Professor of Antimicrobial Therapeutics and Consultant in Infection, NBT

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# 2. THE BASICS OF PPI

## 2.1 WHAT IS PPI IN RESEARCH

- PPI in research refers to research that is carried out **'with'** the public rather than **'to'**, **'about'** or **'for'** them.
- PPI is an **active** involvement of the public in the research process, and is different from:
  - public *participation* in a research study or clinical trial; or
  - public *engagement* through provision and dissemination of information about research
- The most helpful way to think of PPI is as a **conversation** between researchers and the public to exchange ideas, values, assumptions and experiences, e.g. in developing research questions and identifying relevant research outcomes.
- Researchers may not have the same perspectives as potential research study or clinical trial participants. Therefore, PPI seeks to include the perspectives of people who may have insight or a shared understanding of the issues that future research or trial participants may have. These people may include former patients, close relatives and carers, as described in the next section.
- To repeat, it is important to understand that PPI is **not** the same as involving potential research study or clinical trial participants in research.

## 2.2 WHO ARE THE PATIENTS AND THE PUBLIC

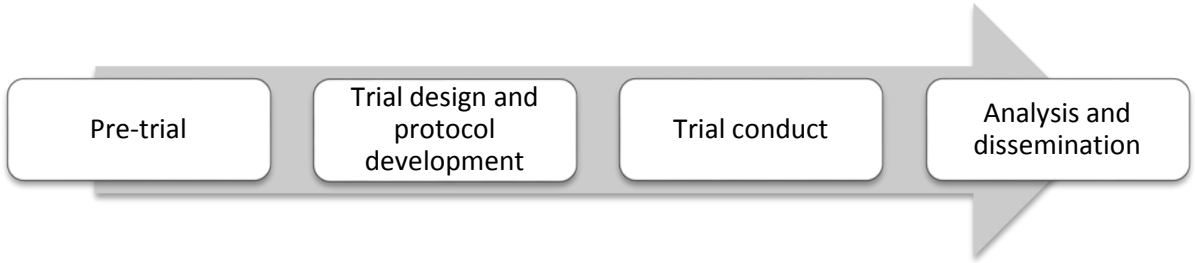
The term **'public'** (e.g. public contributors, public member) used in this toolkit includes:

- patients (past, current, and potential patients)
- carers/close relatives
- parents/guardians
- people who use health and social care services (or the organisations that represent them)

The term **'patients'** may be used instead of 'public' where it specifically relates to users of medicines.

## 2.3 WHEN TO INVOLVE THE PUBLIC IN MEDICINES DEVELOPMENT RESEARCH

PPI has the potential to benefit all aspects of medicines development research. Clinical trials will form a considerable part of the medicines development lifecycle, and PPI can have a role at every stage of the clinical trial continuum, as shown in the figure below:




The potential contributions of PPI depend on its aims at each stage; sections 5-8 discuss this in further detail.

## 2.4 HOW TO HAVE EFFECTIVE PPI

- Be open to what PPI might offer to your research – be prepared to change the research plan if PPI contributions enhance the quality of the proposed research, or if practical suggestions improve the research for potential participants.
- Spend time planning PPI.
- Establish clarity about the role of public contributors *(see section 4.1)*.
- Have several public contributors with diverse and relevant experiences, who will develop confidence as a cohesive group over the course of the research project.
- Work in an inclusive manner, focusing on processes and building trust relationships.
- Provide sufficient training/education so that public contributors can offer opinions with confidence and from an informed perspective.
- Provide practical and emotional support to public contributors.
- Break down the areas of research the public contributors are involved in into manageable tasks.
- Communicate and feedback regularly to public contributors about their impact on the research between meetings – remember that they are a part of the research team.
- Be willing to learn and committed to overcoming challenges.
- A commitment to PPI on the part of research funders, as well as within the whole research team; Principle Investigators need to be fully committed and attend PPI meetings.

# 3. CREATING LINKS WITH PATIENTS AND THE PUBLIC

- Consider the following when deciding on the people to involve:
  i. **Who do you want to involve?** For example, do you want people with direct or indirect (carer) experience of a specific infection; does the infection experienced need to be serious to the point of hospitalisation; would you involve people who have or do not have previous experience of research involvement?

     Some infections are more common in particular communities, e.g. tuberculosis (TB), and you may need to consider how to access them. Almost everyone has taken antibiotics at some time for an infection, but the perspective of someone who has been seriously ill with an infection, or suffers ongoing problems due to a resistant or chronic infection, may be different to opinions in the rest of the population.

  ii. **What do you want them for?** For example, what role or activities are you expecting to involve them in?

  iii. **What time commitment do you expect from them?** For example, how often do you plan to meet; how long are meetings likely to run for; when is the expected end date for their involvement?
- Depending on the role of the public contributors, you may want to ask whether they would like to continue being involved after a maximum of two years.
  - Some may welcome the opportunity to withdraw if their personal circumstances have changed and no longer support involvement in research.
  - Involving new members of the public can potentially bring fresh skills and perspectives. However, it takes time to build a good working relationship with public contributors, and it may be counterproductive to completely refresh a group after two years due to training implications.

- Aim to involve **at least two and up to twelve** members of the public, depending on the role or activity they will be involved in. For example, two public contributors may be sufficient for a research steering group, while six to ten people may be required to participate in research topic prioritisation workshops.
  - A reasonable number of public contributors, as suggested above, would be able to effectively generate discussion, and confidently hold their position among the professionals within the research team, to challenge and influence their opinions when required.
  - If the planned PPI is over a series of meetings, it is likely that not everyone will be able to attend all the meetings.

## 3.1 HOW TO FIND PUBLIC CONTRIBUTORS FOR ANTIMICROBIAL RESEARCH

- Start with a clear idea of the characteristics of public contributors you are looking for *(see 'Who do you want to involve?' above)*.
- Devise a strategy and make one person responsible, but supported by the whole research team. Be aware that the process of finding public contributors can take time and requires perseverance if initial attempts are unsuccessful.
- Design leaflets/advertisements of the PPI opportunity, which include a clear description of the criteria, what tasks might be involved, and how long for. Include your contact details so that people who may have questions or want further information can approach you.
- Consult community members or patients, and other healthcare professionals, how best to find people who might be interested in getting involved.
- Advertise the PPI opportunity in places like clinics, local newspapers, and/or online social media platforms.
- Search online for relevant organisations that promote PPI in research who could include details of the involvement opportunity on their website or newsletter.
- Coincide the campaign to find public contributors with events that will be attended by people that would potentially fit the inclusion criteria for the panel: include flyers (colourful, illustrative, attractive) advertising the opportunity inside delegates' information packs.
- Directly approach patients who attend a relevant clinic, or who are known personally to fulfil the inclusion criteria and may be interested and willing to be involved. Be aware that permission may be required to approach current patients directly. Current patients, e.g. in a clinic or hospital ward, may need to be approached by their direct care team.
- It is possible to invite former intensive care patients or their relatives, but depending on local rules they may need to be invited by the intensive care physician or other direct care team. These people are often not well enough to be involved as public contributors for some time after discharge from hospital.
- If applicable and necessary, extend an invitation to members of a previous project-specific panel to re-collaborate on the new panel.
- Invite all those who respond to an initial meeting to receive more information, ask questions, and complete a short expression of interest form or application form *(see main toolkit for a template)*.
- Make it clear how and when you will inform those interested whether they have been successful. Do not make decisions at the initial meeting; discuss with the team away from the meeting.

### 3.2 ETHICS AND CONSENT

- PPI in research does not require ethical approval unless the members of the public involved will be in direct contact with trial participants, that is if they will be collecting and analysing data.
- **Confidentiality clauses** can be included in consulting agreements between pharmaceutical companies and public contributors to alleviate any concerns about legal or regulatory restrictions.

## 4. PLANNING AND PREPARING FOR PPI

### 4.1 STRATEGIC PLANNING OF ORGANISATIONAL RESPONSIBILITIES

- If PPI is a completely new idea in your organisation, it may be necessary to inform the appropriate heads of department. This is unlikely to be a problem once they understand that the intention is to work with patients in their capacity as members of the public, and not as current patients.
- Make early contact with the relevant departments within your organisation, such as finance and research departments, to inform them about the proposed arrangements for PPI. This is important to ensure the smooth implementation of PPI activities within research.
  - Finance department advice may be needed in how to set up expenses for public contributors.
  - The research department may need to be informed that you intend to commit to PPI in your research. They may be supportive to you in getting started. However, if they are largely unaware of PPI, some explanation may be required.
- Appoint an experienced and adequately resourced member of the research team to be the PPI lead, so there is a point of contact for all involved.
- Develop terms of reference and/or a role description for the PPI panel.
- Make sure that public contributors understand that they can withdraw involvement at any time.
- Identify appropriate facilities or put professionals in place that can provide emotional support to those who may find the process of involvement distressing in terms of the information discussed – if applicable, this should be addressed when applying to the research ethics committee *(see section 3.2)*.
- Where appropriate, discuss in advance what will happen should people become ill for periods of the research, or decide to withdraw from the panel. A larger panel may be able to accommodate this, but a small panel may not.
- Devise a maintenance plan for PPI to enable public contributors to continue using the skills they have developed after completion of the current research project, for example signposting to opportunities for involvement in further research.
- Plan timelines and include these in a Gantt chart to guide the organisation and implementation of PPI activities within the research.

## 4.2 COSTS AND PAYMENTS

- Plan and prepare a budget for PPI at the earliest stage possible, considering the following costs:
  - Training and support
  - Childcare and carer costs
  - Venue hire
  - Translation and interpretation costs
  - Telephone, photocopying and postage
  - Attendance at conferences and events
  - Travel and subsistence expenses
  - Payment for time and work undertaken
  - Refreshments cost
  - Administrative support
  - Additional support, e.g. independent facilitator
  - Writing publications and journal articles
- It is good practice to offer payment to public contributors whenever possible. This does not have to be money, but can be other forms such as a shopping voucher.
- Be aware of local tax rules – some public contributors may be liable to pay tax on any payment received for their involvement in research.
- More practical advice on budgeting for PPI in research is provided by INVOLVE, including a useful Involvement Cost Calculator. Whilst this is a UK example, it may provide useful guidance to researchers elsewhere.

## 4.3 TRAINING AND SUPPORT

- Both researchers and public contributors may require training and support:
  - If researchers are new to PPI, they will benefit from attending any available training on how to build research partnerships with the public, and group facilitation skills.
  - Appropriate training that is available for a joint audience of researchers and public contributors, can be even more useful.
- Offer specialised training to provide public contributors with specific information about antimicrobial resistance, the issues around antimicrobial medicines development, clinical trials, and other related topics. EUPATI and Involving People in Research are examples of organisations that offer such specialised training.
- Training may be done 'on the job', that is while the researcher or public contributor is doing the actual PPI. Be aware that researchers' perceived training needs of public contributors may be different to their actual needs. Therefore, the training programme should be flexible enough to incorporate relevant requests from the public contributors, while giving them sufficient knowledge to enable them to fully participate in discussions.
- Training can occur through sharing knowledge and experiences with colleagues and peers.
- Support researchers or managers responsible for PPI through regular team meetings or one-to-one meetings with line managers, or by having a mentor with experience in PPI where this is available.
- Support public contributors by offering:
  - advice and guidance
  - access to training
  - mentoring
  - networking opportunities
  - resources and information

## 4.4 ACCESSIBILITY

### 4.4.1 COMMUNICATION

- Ensure style of written and verbal communication is friendly, simple and clear, avoiding jargon.
- Check preferences for postal or email communications – do not assume that everyone would have easy access to a computer or be able to print out long documents.
- Find out how specific accessibility needs can be met, for example people with visual or hearing impairments, learning difficulties, chronic long-term conditions, or non-native language speakers (pan-European meetings may need to be interpreted into multiple languages).
- Provide information about meetings (timings and directions to the venue) and any preparatory reading well in advance and in a relevant format.

### 4.4.2 MEETINGS

Face-to-face meetings are the best way to build good working relationships. However, if some of the meeting members are unable to attend in person, it is also possible to hold virtual (online) meetings via Skype or WebEx, or telephone conference meetings.

- Consider the following when selecting a meeting **venue**:
  - Easy for people to get to, with nearby parking and public transport – the distance from the carpark to the meeting room can make it difficult for some public contributors to attend.
  - Reasonable cost of travel to the venue, in terms of mileage and public transport fares.
  - On neutral ground – would not be associated with difficult experiences, e.g. use a community venue instead of a hospital meeting room.
  - Accessible to people who use a wheelchair, have mobility problems, or other disability.
  - Essential equipment available, such as a projector or microphones.
  - Capabilities to facilitate virtual or telephone conference meetings.
  - Ask public contributors if the venue is convenient and comfortable for them. Consider alternatives that they might suggest.
- Consider the following when deciding on a **time** to meet:
  - Lunchtime meetings might suit those who are not working.
  - Breakfast meetings, or late afternoon/early evening meetings (outside of office hours) might suit groups where some people are working, have young children or who are carers – venue hire during these times may also cost less.

## 4.5 MEETINGS

### 4.5.1 PLANNING FOR MEETINGS

- In addition to considerations of accessibility (section 4.4), plan and prepare a budget for your meeting.
- Plan topics over a series of meetings to benefit both researchers and public contributors.
- Plan meetings to last for a reasonable length of time, e.g. no longer than two hours, including a break midway through.
- Presentations that are too long will inhibit discussion. Plan intervals throughout a presentation to allow discussion to develop, and to ensure that public contributors are not ‘left behind’.

- Enquire about dietary requirements when planning refreshments. Timing of the meeting will influence the type of refreshments required.
- Where necessary, arrange to have microphones and hearing loops for people with hearing impairments, large print for people with visual impairments, interpreters for non-native language speakers, or for sign language.
- Key people like the PPI lead and principal investigator should have a pre-meeting or telephone discussion to agree on meeting objectives and to plan an agenda, including timings for discussions and presentations. These key people should attend every meeting if possible, to demonstrate commitment and value placed on the involvement of public contributors.
- Whilst a clinical trial is in progress, you may plan meetings with public contributors to occur less frequently or as necessary, but it is important to maintain communication and keep them informed.

### 4.5.2 CONDUCTING THE MEETINGS

- Create a safe and supportive environment where public contributors feel welcomed, included, and able to make comments and share ideas, e.g. introduce everyone (professionals and public contributors) using first names.
- Consider providing public contributors with an information sheet that includes a small photo and brief description of who the professionals in the meeting are.
- Conduct administration as people arrive, such as asking public contributors to sign for receipt of travel and attendance expenses – this gets more difficult as the meeting progresses.
- Provide name badges in a large clear text font, and ask people to introduce themselves at the beginning of the meeting. Desk labels also work well, but put names on both sides of the label so that people sitting alongside can read them too.
- Ensure even distribution in sitting arrangement, i.e. professionals and public contributors should sit among each other, and not in separate groups.
- Assign a member of the research team to take notes, ideally someone who is not involved in facilitating group discussion. If the meeting needs to be audio-recorded, ask the group for permission to do this.
- Agree ground rules for how meetings will be conducted to foster mutual respect and ensure everyone has an equal opportunity to contribute.
- Encourage the use of clear and simple language, avoid jargon and explain acronyms; the lead facilitator should regularly check that the content of the meeting is understood.
- Have sufficient breaks and refreshments not only because people might need to take medication or find sitting for long periods difficult, but also to keep them engaged with discussions.
- Depending on the size of the group and purpose of the meeting, it might be necessary to break off into smaller groups to give everyone the opportunity to contribute to the discussion. If necessary, consider using two rooms, or a large enough room to make this comfortable.
- Whenever possible, start meetings on time or try not to delay for too long before starting. End the meetings at the time advertised.

### 4.5.3 AFTER THE MEETINGS

- Write up and distribute notes taken during the meeting, along with any action points. Send these to all public contributors, not just those who attended the meeting, so that all of them are informed.
- Provide feedback to public contributors on any recommendations or outcomes that arose out of the meeting.
- Request for feedback and any suggestions for improvement for future meetings.
- Offer the opportunity for any additional and relevant comments to be sent in after the meetings.

## 4.6 DOCUMENTATION

- Store personal data about public contributors securely in accordance with relevant data protection policies; these should be accessible only to authorised members of the research team.
- Use an impact log to record the various PPI activities carried out during the course of the research, as well as their outcomes *(see section 10.1)*.
- Store or file meeting notes and any feedback securely.
- Keep all expense-related documentation, as required by your organisation and project funders.

# 5. PPI IN SETTING THE RESEARCH AGENDA

The two common approaches used to structure the process of collaboration between patients and professionals in setting the research agenda are:

I. The Dialogue Model – a validated approach to facilitating interaction between patients and professionals to establish shared understanding and agendas.

II. The James Lind Alliance Priority Setting Partnerships – focus on specific conditions or healthcare settings to raise awareness of research questions that are of direct relevance and potential benefit to patients, carers and clinicians.

The phases/stages involved in these formal approaches are described in the main toolkit.

## 5.1 A SIMPLE APPROACH

Following discussions with the Patient and Public Involvement Panel for Antimicrobial Drugs, a simple approach to PPI in research agenda setting was proposed.

- Ideas can be generated by a relatively small group of public contributors, provided there is a good and open relationship of mutual respect between the researchers and public contributors.
- The stakeholders involved and their proposed roles are as follows:
  - Patients/public – mainly responsible for generating ideas for research questions.
  - Professionals (clinicians and academics) – advisors, and partners in developing ideas that are realistic, feasible and most important to patients.
  - Pharmaceutical industry – advisors *(optional involvement)*; could increase likelihood of a research agenda being taken up.
- This is a potentially time-saving approach since researchers and public contributors are in the room at the same time, e.g. researchers may know if a proposed research idea has already been pursued and is not feasible.

# 6. PPI IN DRUG DISCOVERY AND PRECLINICAL DEVELOPMENT

- The role of PPI in **developing a target product profile (TPP)**: participate in the identification and prioritisation of key attributes of the drug, as well as the ideal and acceptable values for these attributes, such as the route of administration, dosing, efficacy, acceptable levels of adverse events, and possibly even willingness to pay.
- The role of PPI at the **lead optimisation stage**: re-assess the benefit-risk profile and the relevance of proposed clinical endpoints to patients, to update the TPP.
- The role of PPI in the **preparation for clinical trials**: input into clinical trial design; provide feedback to regulators about the TPP and preclinical results; attend regulatory meetings alongside the sponsor.

# 7. PPI IN CLINICAL TRIALS

PPI should be included at all stages of clinical trials, even though its ability to influence Phase 1 studies may be relatively minor due to regulatory constraints. Planning for later phase studies begins very early. Therefore, PPI needs to be part of the process as early as possible to maximise its benefit.

## 7.1 THE ROLE OF PPI IN TRIAL DESIGN AND PROTOCOL DEVELOPMENT

The following **applies to all trial phases**; any concerns about confidentiality can be resolved by requiring public contributors to sign a confidentiality agreement.

- Ensure the suitability of the proposed **trial design** for future trial participants. This includes ensuring that the proposed trial schedule is not too burdensome for trial participants, and is appropriate to the patient journey through the healthcare system.
- Advise on the trial participant **recruitment strategy**. This is particularly important if the trial includes vulnerable patients, or when urgent consent is required. For example, if critically ill patients form part of the study population, public contributors can advise on who to approach to discuss consent – close family or a professional legal representative – and when and how to approach the patients for consent retrospectively, if they recover enough to consent for themselves. The support of public contributors in phrasing documents for family members and how to approach them can be invaluable in optimising recruitment.
- Advise on the relevance of **patient-reported outcomes (PROs)** and **outcome measures**. For example, public contributors may suggest additional outcomes that might enhance the quality and value of the research.
- Comment on the proposed **data collection plan**. For example, public contributors may reveal weaknesses in the plan by identifying data items that might be particularly difficult to collect, or gaps in the proposed data to be collected. They can also advise on the most appropriate time to approach patients with questionnaires.
- Assist in the development of **patient-related materials** (informed consent documents, data collection tools e.g. questionnaires), to ensure that they are easy to understand, informative, and appropriate.
- Advise on **aspects of training** required for research staff, including how to explain trial procedures to participants and how to obtain consent.

### 7.2 THE ROLE OF PPI IN CLINICAL TRIAL CONDUCT

- Support trial operations and clinical infrastructure, for example through involvement in the trial steering committee, or data and safety monitoring committee.
- Advise on any trial adaptations or modifications. Ongoing PPI ensures that advice about poor recruitment to the study is available. Amendments to the study protocol should be endorsed by public contributors and subsequent ethics committee submissions can be supported.
- Ensure that researchers remain accountable throughout the trial.
- Help to clarify misperceptions or to resolve any misunderstandings between trial participants and pharmaceutical sponsors.

### 7.3 THE ROLE OF PPI IN TRIAL DATA ANALYSIS AND DISSEMINATION OF RESULTS

- Ensure coherence in the understanding and interpretation of trial data.
- Contribute to the analysis of participant feedback on trial experiences.
- Assist in the development of patient-level communication, including ensuring relevance, and suggesting avenues for disseminating results.

The successful implementation of PPI in clinical trials requires clear goals and well-developed plans for responsive and managerial PPI roles, equal partnership, and the provision of ongoing information and education to empower and facilitate the active involvement of patients.

## 8. PPI IN REGULATORY REVIEW AND APPROVAL

- The European Medicines Agency (EMA) and United States Food and Drug Administration (US FDA) have established a range of independent schemes to facilitate PPI in the regulatory process. Both agencies have also set up a collaborative workgroup to share best practices in regulatory PPI**.**
- Patients can be involved in various pre- and post-approval processes along the medicines lifecycle. Their involvement can be as representatives of patients in general, representatives of patient organisations, or as individual experts.
- Patient testimonies at EMA and FDA hearings can provide meaningful evidence to support regulatory decision-making.

## 9. APPROACHES TO PPI

There are two broad approaches to PPI in antimicrobial medicines development research: **consultation** and **collaboration**. The boundaries between these two approaches are not clear cut, and they usually co-exist within a research project.

There are times when consultation is entirely appropriate, for example, when developing patient-related materials. However, it is important to avoid ‘tokenistic’ PPI, where researchers consult public contributors with no intention of being influenced by their opinions.

Developing collaboration may take time, as mutual trust and respect grows between the researchers and public contributors. Better relationship can lead to improved dialogue, which would increase the chances of achieving the full potential benefits of collaborative PPI, for example, in trial design.

## 9.1 CONSULTATION VS COLLABORATION

- Consultation:
  - Public contributors are asked for their **views** and **advice** on any aspect of the research process.
  - May be a one-off meeting or a series of meetings, involving individuals or groups of public contributors.
- Collaboration:
  - **Shared decision-making** between professionals and public contributors.
  - Collaborations tend to involve multiple and more frequent meetings over an extended period of time.

## 9.2 HOW TO CONSULT OR COLLABORATE WITH PUBLIC CONTRIBUTORS

- Involve groups of public contributors that were convened especially for the consultation/collaboration, or that are established patient organisations. This may include individual or groups of 'patient experts', such as EUPATI Fellows (graduates of the EUPATI Expert Training Course).
- Distribute any relevant literature or reading material ahead of meetings – public contributors need to be sufficiently informed to be able to engage in discussions. Avoid using PPI simply to endorse professional decisions.
- Give public contributors enough time to respond.
- Feedback on the actions taken as a result of the consultation.
- Ask if they would like to be informed about the findings of the research.
- The following are methods of involving public contributors in research through consultation and collaboration; examples of these from real-world research are described in the main toolkit:
  - Grant applications (details in the next section)
  - Workshops
  - Patient and public forums, e.g. online via Skype or social media platforms (may require caution if confidentiality is an issue, but a useful option especially with international collaborations)
  - Reference groups
  - Public advisory panellists or groups
  - Steering groups

## 9.3 HOW TO SEEK PUBLIC INPUT INTO RESEARCH GRANT APPLICATIONS

### 9.3.1 WHEN THERE IS A LOCAL ORGANISATION PROVIDING SUPPORT AND ADVICE TO RESEARCHERS WHO WANT PPI:

- Contact the local organisation that provides support and advice for researchers who want to have PPI in their research projects.
- Meet with the PPI representative or advocate to discuss the project and how you would want to involve people with lived experience to provide input into the research.
- Co-produce an advertisement in plain language and distribute.
- Wait for a response from a potential public member.
- The organisation's PPI officer can help facilitate an initial meeting with the interested public member.

- Send a draft application to the public member with specific information on what aspects require feedback.
- Meet with the public member, take notes, and arrange payment.
- Receive feedback from the PPI officer on the process and interactions with the public member.
- Amend the grant application based on public member feedback.
- If appropriate, invite the public member to be a co-investigator on the project.

### 9.3.2 WHEN NO SUCH LOCAL ORGANISATION EXISTS:

- Ask colleagues with experience of PPI, if any.
- Directly approach other relevant organisations, such as community groups, carer support groups, GP surgeries/family physicians and pharmacies.
- Use suggestions in section 3.1 to seek out potential public contributors.

## 10. EVALUATING THE PROCESS AND IMPACT OF PPI

The simplest ways of evaluating PPI are to keep records of meetings and correspondence with public contributors, and to maintain an impact log. There is an effective tool described in the main toolkit that can be used for a formal evaluation of PPI.

### 10.1 IMPACT LOG TO RECORD THE OUTCOMES OF PPI

The following is an example of a research project impact log as a basic way of recording the outcomes of PPI in research to enable PPI to be monitored and evaluated:

| Date | Attendees | Discussion | Impact (Outcomes) | Other comments |
|---|---|---|---|---|
| dd/mm/yy | Prof. AB<br>Prof. CD<br>Mrs. EF<br>Mr. GH<br>Mr. IJ<br>KL<br>MN<br><br>Apologies:<br>Mrs. ZY<br>Mr. XW<br>Mr. VU | The existing *[project name]* questionnaire was made available and patient panel members were asked to rate each question based on how important/relevant the issue was to them. Patient panel members were invited to provide their responses anonymously if preferred. The panel was also asked to comment on the domains or themes each question related to. Comments were gathered from the panel. | [From notes of dd/mm/yy]<br>There was some discussion on why certain questions deemed "definitely important" in this patient panel exercise were not included in the final questionnaire, whilst others voted only "quite important" were instead used. CD explained that psychometric and statistical analysis helped to distinguish what questions performed most effectively. This information was used alongside the panel input to decide on which questions to take forward. These results were then used to refine the questionnaire for the next cycle, and help make a decision on which questions to put forward for the final version of the questionnaire. | Copies of the draft questionnaires before and after the panel meetings as evidence of the impact of the panel's contribution. |

In cases where PPI consultations are conducted via email instead of a face-to-face meeting, you may prefer to record the start and end dates as it may take several days for the outcome to become apparent.

## 10.2 REPORTING IN RESEARCH PAPERS

The GRIPP2-SF (short form) reporting checklist is suitable for studies where PPI is not the primary focus, e.g. PPI in clinical trials:

| Section and topic | Item | Reported on page no. |
|---|---|---|
| 1: Aim | Report the aim of PPI in the study | |
| 2: Methods | Provide a clear description of the methods used for PPI in the study | |
| 3: Study results | Outcomes—Report the results of PPI in the study, including both positive and negative outcomes | |
| 4: Discussion and conclusions | Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects | |
| 5: Reflections/critical perspective | Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience | |

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