A “HOW TO” GUIDE FOR RESEARCHERS

PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT IN RESEARCH

Ludwig Boltzmann Gesellschaft

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Preface

Research shows that early and continuous involvement of the public and patients has a positive impact both on conducting more patient-centered research and on how research is conducted, namely towards more involvement of patients in research activities, and that this significantly impacts research findings. Involving the public in research empowers people with lived experience and improves the quality and impact of research (Staley, 2009).

Providing a ‘How to’ guide for Patient & Public Involvement and Engagement (PPIE) is relevant to aligning the mission of the Ludwig Boltzmann Gesellschaft (LBG) to conduct more patient-centered research in the medical field and more inclusive research in social sciences and the humanities that addresses societal needs. The LBG therefore co-created this document for conducting research based on PPIE principles including various perspectives from all involved stakeholders to serve as a central entry point for research based on PPIE principles.

In this document, you will find a detailed description about what PPIE stands for, why it is necessary to get involved, and how we co-created this ‘How to’ guide (Chapter 1). In Chapter 2, you will find the main outcomes from all co-creation workshops regarding PPIE principles. This includes patient and public interaction, relevant governance structures (including budget and project oversight) and the organizational framework that facilitates PPIE activities. In chapter 3, we provide self-assessment checklists and present self-assessment PPIE tools. Chapter 4 covers suggestions on how to monitor PPIE activities, followed by additional resources such as key papers, databases or other important guides (Chapter 5).

The target audience for this ‘How to’ guide is people working in research. Therefore, please read this guide through the “researchers’ lens,” as it is intended to be a manual that will ultimately help and support research projects in applying PPIE principles. Please remember this perspective when browsing through the document.

Be aware that PPIE research projects all started from scratch and took a step-by-step approach. You do not have to change the world - in your case, your research - overnight. Start by introducing minor changes in your scientific workflow depending on your level of PPIE activities. We are convinced that every small step towards more patient/public involvement will lead to better outcomes. We hope this guide supports you in developing meaningful PPIE into your projects, and we are happy to receive feedback and hear about your experiences applying PPIE principles in your own research.

The PPIE Consortium.

1. Public and patient involvement and engagement (PPIE)

Engaging citizens and patients in research co-design is one of the key tools to drive innovation processes within the European research landscape (Mazzucato, 2019). In order to ensure that research is highly relevant to the public, there is a need for meaningful involvement of end-users with the aim to reduce 'research waste' and bring science and society closer together (Glasziou 2016; Chalmers 2009). Involving the public in research empowers people with lived experience and improves the quality and impact of research (Staley, 2009).

1.1. Characteristics of PPIE

PPIE stands for ‘Public and Patient Involvement and Engagement’ in research. PPIE aims to actively involve citizens and patients in research processes and activities. According to the definition of the National Institute of Health Research (NIHR, UK):

> *“User or public and patient involvement in research means doing research ‘with’ patients and the public so they are not just participants in the research. This requires users to have a say in the decisions made about research, so that the methods and outcomes are more appropriate to research participants and patients.”*

LEVELS OF INVOLVEMENT

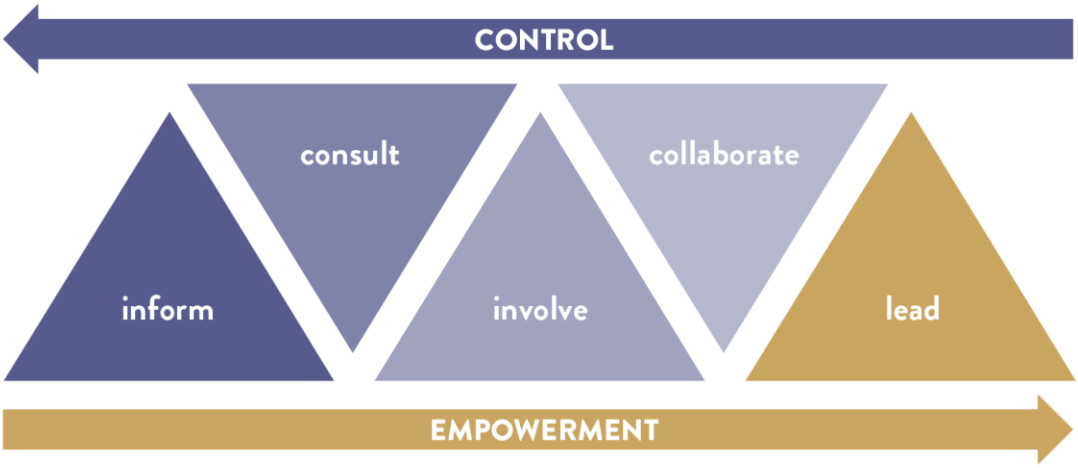
The degree of interaction between researchers, patients, and the public is measured by the ways in which they are involved. This can include patients and the public taking part in research studies, patients actively providing and disseminating research to the general public through different formats, or even patients and the public becoming actively involved in the research process. We distinguish between three levels of activities (INVOLVE NIHR, UK):

- **PARTICIPATION: Citizens and patients take part in research studies.**
    - E.g., being recruited in clinical trials, completing questionnaires, participation in interviews and focus groups.
- **ENGAGEMENT: Information and knowledge about research is provided and disseminated.**
    - E.g., dissemination of research to public (via media, social media), raising awareness of research through media, science festivals and open days at universities and research centers.
- **INVOLVEMENT: Citizens and patients are actively involved in research.**
    - E.g., as grant holders and co-applicants, through identifying research opportunities, agenda setting, members of project advisory and steering groups, co-developing patient information or materials, undertaking interviews with participants, and carrying out research.

Depending on the activity and degree of involving patients and public members in research, several levels of involvement can be differentiated: from purely receiving information about research projects (passive) to getting involved in research decision-making and becoming equal collaboration partners (active). From the perspective of a researcher, introducing PPIE components into research projects may increase the general empowerment of those who are affected by research and introduce a shift of power and ownership towards patients and the public (see Figure 1).

FIGURE 1: LEVELS OF INVOLVEMENT

(Modified from Arnstein, 1969)



1.2. Organizational framework to facilitate PPIE

The following chapter describes the benefits and challenges of involving patients and the public in research on an individual and organizational level. Challenges may promote future opportunities and professional development for researchers, patients and organizations.

1.2.1. Benefits and challenges for researchers

WHAT ARE THE BENEFITS FOR RESEARCHERS IN USING PPIE?

- Identification of the most socially relevant research questions
- Improvement in socially relevant research outcomes
- Increased participant enrolment
- Decreased participant attrition
- Wider impact and applicability of findings
- Stronger rapport with patient/public communities
- Better understanding of and insights into gaps and priorities in the research area
- Overall improvement in research effectiveness
- Increasingly a requirement for funders

WHAT ARE THE BARRIERS AND CHALLENGES FOR RESEARCHERS IN USING PPIE?

- Not knowing how to involve patients or the public
- Limited understanding of potential roles and levels of involvement
- Investment of time, effort and other resources
- Lack of organizational support and processes (coordination, policies)
- Special considerations for involving people with lived experience (individual and organizational readiness, support structures, policies etc.)
- Fear of doing it wrong and consequences of this
- Lack of buy-in as to the benefits of PPIE
- Backlash from colleagues / resistance to change

1.2.2. Benefits and challenges for patients and the public

WHAT ARE THE BENEFITS FOR PATIENTS AND THE PUBLIC?

- Intrinsic motivation: provide a valuable contribution to society and make an impact
- Space to share personal experiences and stories
- Influencing questions explored and researched
- Opportunity to develop their own voices and become empowered

- Gaining research skills and research language
- Enriching personal resumes and building networks
- Having their own experience recognized as expertise
- Building trust and rapport with researchers and other stakeholders (e.g., clinicians, policy makers)
- Receiving improved care through application of research findings
- Recognition of time (incentives, reimbursement, etc.)

WHAT ARE THE BARRIERS AND CHALLENGES FOR PATIENTS AND THE PUBLIC?

- Unfamiliarity with research and jargon
- Lack of confidence in research abilities and literacy
- Perception of being in a disadvantaged position on the research team
- Uncertainty of the potential roles and importance they could have
- Time and costs of involvement
- Negative previous experiences with research/academia or with the (healthcare) system

1.2.3. Benefits and challenges for organizations

WHAT ARE THE BENEFITS FOR ORGANIZATIONS?

- Demonstrate broader engagement, societal impact of research outputs
- Cultural change by including external knowledge, opportunity to reflect structures and team culture
- Innovative research, patient-centered research
- Address gaps in system: priority setting
- Informed decisions by patients/youths in residence (as staff)
- Involvement of patients and the public in hiring staff to help select people who will better meet the needs of the PPIE process/values
- Performance reviews: patients and the public in leadership roles, societal relevant topics addressed
- Fundraising and charity work if patients are involved in a meaningful role

WHAT ARE THE BARRIERS AND CHALLENGES FOR ORGANIZATIONS?

- Organizational policies (e.g., recruitment HR, board structures, categorization of employees, etc.)
- Lacking support structures (e.g., supervision, safety plan etc.)
- Hierarchies in research teams
- Lack of clarity regarding roles
- Cost investments (time and money)
- Lack of management buy-in

1.3. Why PPIE at Ludwig Boltzmann Gesellschaft?

The Ludwig Boltzmann Gesellschaft (LBG) is a non-profit research organization that covers a variety of different fields (medicine, life sciences, humanities, social sciences, and cultural sciences) and specifically targets innovative research topics in Austria. Together with partners from academic and applied research, the LBG is currently running 19 research units and develops and tests new forms of collaboration between science and society (LBG Open Innovation in Science Center).

Previous projects established within the LBG Open Innovation in Science Center set out to experiment with new forms of stakeholder involvement in research in standalone projects, i.e. through crowdsourcing research questions as a priority setting exercise (Tell-us.online), developing innovative formats for conceptualizing research projects (Ideas Lab) and experimenting with new forms of governance (LBG Research Group) , LBG Research Group DOT).

PPIE takes a more systematic approach by providing a ‘How to’ guide that can serve every researcher within the LBG research ecosystem across all disciplines. With this approach, we aim to step beyond previous implementation projects at the Open Innovation in Science Center (as described above) by co-creating the design and content of the project with multiple stakeholders. This PPIE ‘How to’ Guide for Researchers might be also helpful to other researchers applying PPIE in their research activities. We welcome other researchers to use this guide.

MISSION STATEMENT

LBG supports PPIE activities across the LBG research ecosystem. The PPIE mission of LBG aims to:

- **Create awareness about the importance and possible impact of including PPIE elements in research activities**
- **Provide consulting services and resources to support PPIE activities on an individual level and for Ludwig Boltzmann Institutes**
- **Support PPIE capacity building for LBG researchers and beyond**
- **Create a PPIE-friendly infrastructure to implement PPIE activities in research projects**

The co-created PPIE ‘How to’ guide and principles serve as a basis for future PPIE funding schemes at LBG and suggest assessment criteria for monitoring the implementation of PPIE in research projects.

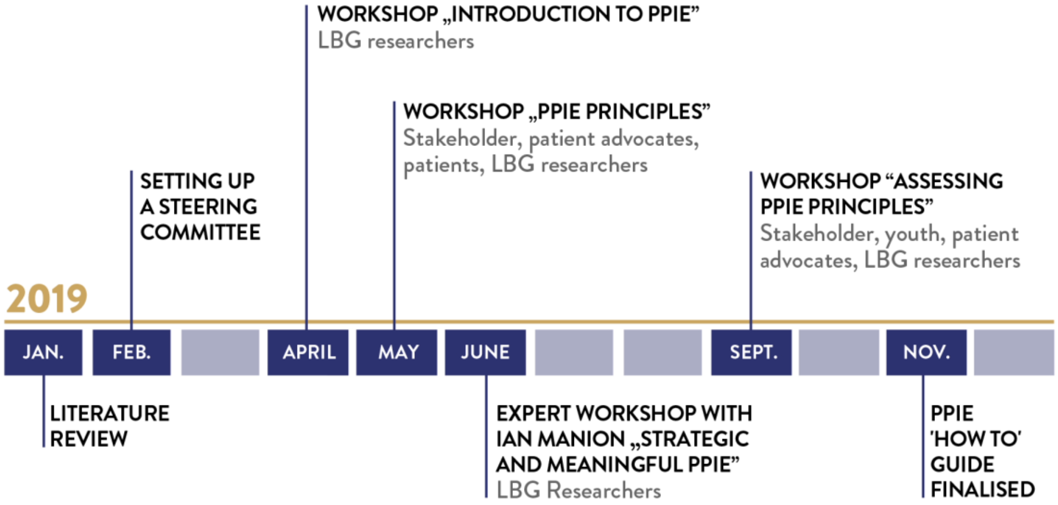
1.4. Co-creation process: A multi-stakeholder approach

According to our mission, LBG's aim is to prioritize public and patient involvement and engagement in research. The systematic implementation of PPIE activities started in the beginning of 2019 with a literature review and thorough co-creation process conducted by researchers from the LBG research ecosystem, patients, and the public. This process aimed to co-create a shared vision of future PPIE activities by considering several different perspectives.

A MULTI-STEP PROCESS (SEE FIG. 2):

- **Literature review:** As a first step, we conducted a literature review on public and patient involvement and engagement. In total, we analyzed 63 articles published in academic journals and databases (e.g., PubMed, Web of Science) between 1969-2019; these informed the design of workshops and the information given.
- **Setting up a Steering Committee:** We invited all LBG Institutes to express interest in being part of the PPIE Steering Committee to co-create a PPIE 'How to' Guide and learn from existing PPIE activities and initiatives. Representatives from 11 LBG Institutes from various disciplines formed the PPIE Steering Committee.
- **Co-creation workshops:**
    - In the first workshop, we introduced PPIE to LBG researchers covering disciplines ranging from the natural and life sciences to humanities and social sciences. In this workshop, expectations and needs were interactively co-developed and discussed from the perspective of researchers.
    - In a second workshop, we organized a stakeholder meeting that brought together researchers, patient advocates and citizens interested in research. The goal of the second workshop was to co-create principles and needs for future PPIE projects in a partnership between representatives of researchers and patients/the public.
    - In a third workshop, we invited the internationally recognized and highly experienced PPIE expert Ian Manion (Canada) to cover the big picture of PPIE importance on an organizational and strategic level. The workshop participants and interested members of the LBG Institutes attended the event.
    - In a fourth step, we conducted a workshop on defining assessment criteria of good PPIE practice together with representatives of youths, researchers, and patients/the public.
- **Co-writing the PPIE 'How to' Guide for Researchers:** The PPIE Steering Committee and PPIE Core team was invited to co-write and give feedback on the structure and content of the PPIE 'How to' Guide.

FIGURE 2: CO-CREATION PROCESS & TIMELINE



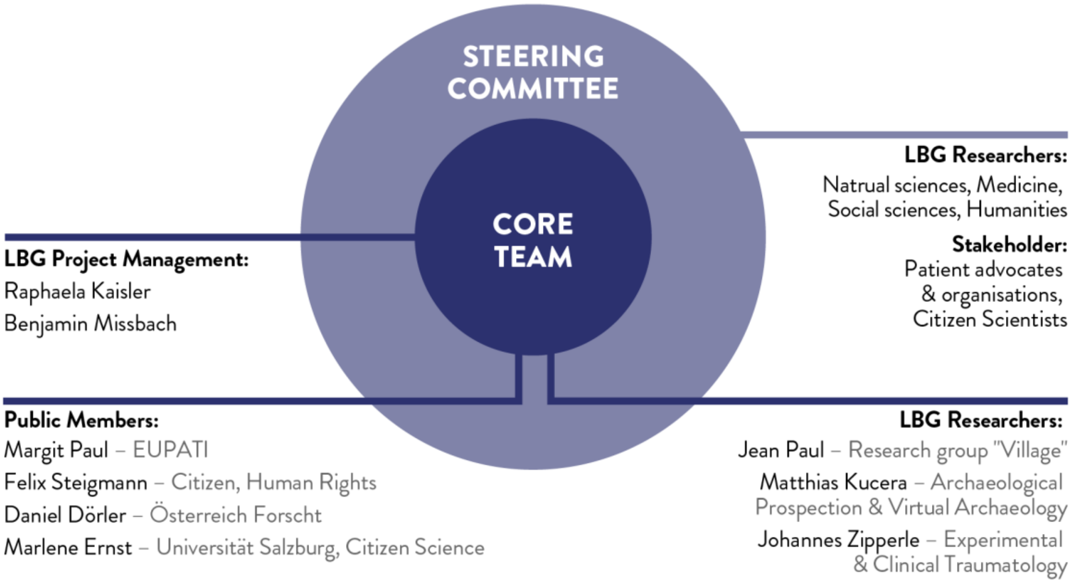
WHO WAS INVOLVED?

The management of the project was co-developed in the first and second workshops by recruiting stakeholders from research groups and the public to join the core team. The core team worked closely with the project management team from LBG. Typically through online collaboration, we strived to co-design workshops topics and activities to address PPIE principles across various disciplines. All other representatives and workshop participants were part of the PPIE Steering Committee (see Figure 3) and co-created the PPIE principles in the workshops.

Throughout the multi-step process, 24 different stakeholders ranging from young students to researchers from different fields were involved:

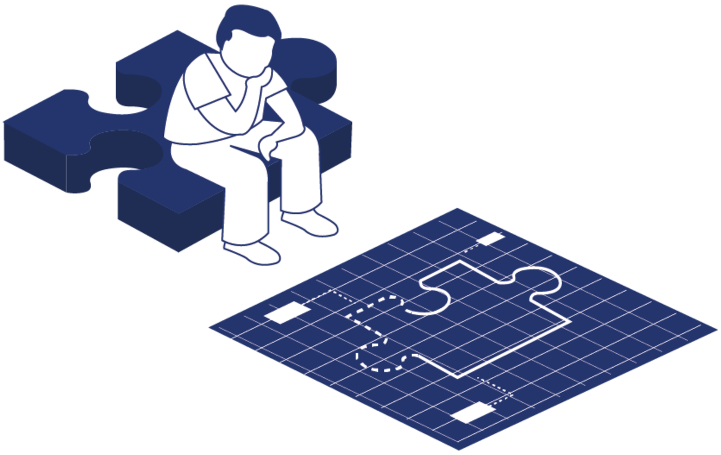
- **11 researchers from various fields and different levels of PPIE experience**
    - Natural & Life Sciences
    - Humanities
    - Artistic Research
    - Medicine
- **13 public members with different backgrounds**
    - Citizen Scientists
    - Patients
    - Patient Advocates
    - Undergraduate students
    - Youths (16-18 years)

FIGURE 3: PPIE PROJECT MANAGEMENT



2. PPIE principles for research projects

The following chapter describes the PPIE principles that have been co-created with multiple stakeholders, addressing two overarching themes to involve patients and the public throughout the research process: interactions between researchers and the public/patients, and governance that facilitates active involvement. It describes the necessary considerations to meaningfully involve patients and the public on individual, project-based, and organizational levels.



2.1. Interaction with patients and the public in research

Interaction between researchers, patients and the public in research is key for this user-centered approach and in actively and meaningfully involving the latter in specific research activities. By “patients,” we mean people with a mental or physical illness or people with lived experience in a certain area, and by “the public,” we mean people with a general interest in research or those people affected by research. The following PPIE principles and considerations have been identified regarding involving the public and patients in research.

2.1.3. General considerations

In general, patients and the public can be involved in every step of the research cycle (e.g., agenda setting, research design and methods, data collection, data analysis and interpretation, dissemination of results). Depending on your discipline or research area, involvement may be more or less reasonable in some of the steps (see chapter 3).

WHAT GENERAL PRINCIPLES SHOULD BE CONSIDERED WHEN INVOLVING PATIENTS AND THE PUBLIC IN THE RESEARCH CYCLE?

- Consider offering involvement to patients and the public at different steps of the research process (one-time or multiple events of patient/public participation are possible)
- Check current research activity with respect to societal relevance
- Assign a mentor (i.e., researcher, person with lived experience) to guide patient/public work in the research team
- Involve patients and the public from the beginning (e.g., in the ideation phase, grant/funding application writing), before the project starts
- Provide mutual learning activities for researchers and patients/public and career development opportunities (e.g., talks, visit events and workshops, conferences, etc.)
- Make patient and public contributions to the project visible (i.e., authorship for patients/ public and/or consortium on publications)
- Make meetings as easy to get to as possible (e.g., in community center, patient organizations, etc.)
- Consider availability of patients/public if appropriate (e.g., late afternoon, weekends, public holidays)
- Focus on societal relevant outcomes for patients/public
- Use CC licensing for contributions (https://creativecommons.org/licenses/)
- Co-write grant/funding applications and (peer-reviewed) publications, folders for patients and the public (ensure official co-authorship)

Organizations may consider negotiating a “research leave” with employers in order to enable patients and the public to take part in research.

2.1.1. Interactions between researchers and the public/patients

Involvement of patients and the public should consider:

- **Open and honest communication (act on a level playing field)**
  - Provide informational documents, informational events
  - Contact details and clarify availability
  - Nominate a representative in case of absence/leave
  - Use informal language instead of addressing each other with academic titles
- **Build trust (e.g., investing time on getting to know each other)**
  - Stay in regular contact with patients/the public
  - Value time commitments and offer ‘work-friendly’ appointments
  - Consider choosing a neutral location for a first meeting or contact
- **Flat hierarchies among researchers and patients/public members (e.g., informal language, no academic titles)**
- **Comprehend and value each other’s expertise by providing clear expectations (also regarding reimbursement of time) and job descriptions**
- **Avoid the use of (academic/research/medical) jargon to describe the research project and results (especially when disseminated to the wider public)**
  - Avoid abbreviations
  - Consider language barriers
- **Continuous and transparent communication throughout and after the project**
  - e.g., regular in person meetings between researchers and patient/public members, regular project updates, annual conferences with stakeholders, newsletters, informal and official events for stakeholders, social media, etc.
  - make project updates and decision visible for the project team and the public (e.g., platform, website)
  - celebrate the project kick-off and the end of the project, big milestones and achievements
  - foster peer to peer exchange among the patients/public members
- **Offer different communication strategies in order to cater to individual expectations and needs**
- **Address potential conflicts of interest (e.g., funding, cooperation partners)**
- **Describe and agree on their roles in different phases of the project (job description) - adapt role during cooperation if necessary, opt-out/in options for different tasks**
- **Always inform patients/the public about the adoption of research activities based on their feedback (demonstrate value of public/patient input and communicate ways in which feedback has been incorporated into research processes)**

2.1.2. Recruiting patients and public members

Identify knowledge gaps and experience that is needed in the project and recruit a suitable number of patients (broader network) in order to add different perspectives to the project if needed. The following strategies may be used to find patients and members of the public to recruit for projects.

RECRUITMENT STRATEGIES

- Local societies, associations (e.g., hobby historians), community/youth centers
- Patient support groups
- Patient organizations
- Patients recruiting other patients
- Other research organizations and existing networks from previous projects
- News, media, special interest publications
- Networks and platforms (snowball effect)
- Roadshows, science festivals and fairs (i.e., Lange Nacht der Forschung, Forschungsfest, European Researcher’s Night)
- Platforms for patients, forums and online hubs (i.e., patent innovation platforms)
- Social media, influencer relations (i.e., Twitter, Instagram, Facebook)
- Existing citizen science platforms (i.e., Österreich *forscht*)

WHAT SHOULD BE CONSIDERED IN RECRUITMENT?

- Define target group (potential people to involve)
- Consider relevant demographics (e.g., age, patients with the same context, geography, previous experiences)
- Never recruit just a single individual for a task or in the project
- Tactics and approaches differ by group
- If recruiting patients: think about their stage of recovery
- Think about diversity and equity
- Think about individual existing skills matrices
- Invest in support and orientation processes

2.2. Governance that facilitates active involvement

Meaningful Patient and Public Involvement and Engagement follows a systematic approach, implementing involvement activities in all phases of the research cycle, not as single instances of involvement. It can help to "build the new relationships and shifts of power and resources required for 21st century governance, and develop individuals' skills, confidence, ambition and vision." (INVOLVE, People and Participation, 2005)

In order to implement successful PPIE activities, organizations need to provide appropriate organizational structures to enable meaningful involvement in research. Organizations need to be structured in a way that maintains long-term direction of involvement activities and provides adequate space for experimentation. The organization's and researchers' readiness for involvement activities is essential for the implementation of PPIE activities in research. To enable patients and the public to get actively involved in research, the following governance structure should be established in each project.

2.2.1. Project oversight

IN THE INVOLVEMENT OF PATIENTS AND THE PUBLIC, CONSIDER:

- **PROJECT STEERING BOARD (PSB):** The PSB should include at least two patients or people with lived experience or members of the public. The board meets regularly (recommended twice a year) and makes decisions or advises the research team about the planned project activities and cooperation (see chapter 4.1 for details)
- **STUDY ADVISORY GROUP (SAG):** The SAG consists of 3-6 patients or members of the public with lived experience on a specific topic needed in the project. The SAG consults and advises the project team on a regular basis (i.e., once a month as appropriate and feasible for the individuals and the research project). The SAG should be established before the project starts. Each project establishes their own SAG. Similar research projects might share the same SAG, depending on their availability. The SAG may recruit new members and exchange members if needed (see chapter 4.1 for details).
    - **SAG Speaker:** One or two persons could be nominated to represent the SAG in meetings with the researchers and others. This person might be part of the research team as a co-researchers/research fellow and act as a role model for other members of the SAG.
- **SAFETY PLAN:** Working with patients or people with lived experience requires an appropriate safety plan (depending on the topic and research area), for example, for physical or mental wellbeing, a clinician should be on call in case of emergency and should be present at big events.
- **SUPERVISION:** External supervision should be provided for patients and the public on demand and on a regular basis (e.g., every 8 weeks). Supervision should be provided by an external coach, supervisor or psychotherapist. The PPIE Officer may coordinate this action (see chapter 2.3.4)

2.2.2. Budget

IN THE INVOLVEMENT OF PATIENTS AND THE PUBLIC, CONSIDER:

- **Allocating budget for PPIE activities in the funding application**
- **Honoring and valuing expertise by asking what would be beneficial for the patients and the public (monetary and non-monetary)**
- **Reimbursing travel costs and cover expenses**
- **Reimbursing childcare if needed**

2.2.3. Training for researchers and patients/the public

A "one-size-fits-all" training approach may not be useful for PPIE projects. Instead, individual training formats, content design and the process need to be co-developed together with the research team and participating patients/members of the public. Generally speaking, training should be tailor-made, modular, needs-oriented and co-creative.

Consider co-leading the training with an experienced patient or a member of the public interested in research. Patient or public "champions" may also provide support in recruitment and could act as an entry point for new members. The training might be outsourced depending on the available facilitation skills, including a person with lived experience/from the public.

IN DESIGNING TRAININGS FOR/WITH PATIENTS AND THE PUBLIC, CONSIDER:

- **Customize the training with an experienced patient or member of the public for the specific patient and public group in the project**
- **Provide a comprehensive training at the start, including an introduction to the research project (or planned project) and research process, and training for specific tasks if necessary**
- **Agree on a communication structure within the project team**
- **Address conflicts of interests, concrete next steps and use of data in the project**

TRAINING EVALUATION TOOLBOX

In order to assess the training success, all training efforts need evaluation. For this, an "Evaluation Toolbox" can serve as the basis for evaluating the success of implemented trainings. An "Evaluation Toolbox" should consist of both quantitative measures (e.g., questionnaires) and qualitative measures (e.g., group feedback). The "Evaluation Toolbox" should be accompanied by a handbook of good practices and a "How to" guide in order to create a thorough, useful evaluation.

IF TRAINING IS PROVIDED BY RESEARCHERS, THEY SHOULD:

- **Be open-minded, modest and respectful**
- **Value different experiences and perspectives**
- **Communicate transparently and without jargon**

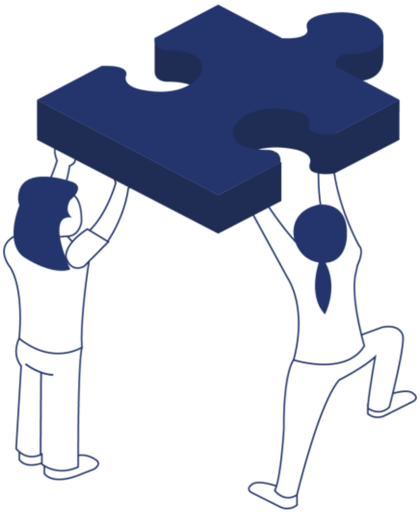
2.3.4. Support structures

In order to enable patients and the public to be involved in research, support structures must be provided both on an individual and organizational level:

- **PATIENT OMBUDSMAN:** The Patient Ombudsman is a neutral contact person that can be addressed in the event of complaints and concerns. He or she is an independent, external person. He or she investigates complaints from individuals and organizations about maladministration by the research organization. Maladministration is present if an institution or researcher fails to act in accordance with the Declaration of Helsinki or the principles of PPIE or violates human rights. Maladministration can include administrative irregularities, unfairness, discrimination or the abuse of power, such as in the management of PPIE funds, procurement, or recruitment policies. It also includes the failure to reply, or refusal to grant access or unnecessary delay in granting access to information in the public interest. Complainants do not have to have been affected by the issue(s) complained about.
    - The Patient Ombudsman should be available in person and via a hotline if complaints occur.
    - The ombudsman may support mediation between the patients/the public and researchers and provides guidelines for complaints and concerns.
- **PPIE OFFICER:** The PPIE Officer coordinates PPIE activities at an organizational level and has an oversight of all PPIE activities in the organization. The PPIE officer acts as a consultant or advisor. The PPIE officer may be approached by researchers and interested patients and members of the public.
- **NETWORK MEETINGS:** The PPIE Officer organizes regular network meetings and learning events to foster mutual exchange among researchers, patients and members of the public participating in PPIE activities throughout the organization.
- **CHILD CARE:** It is important to provide a child-friendly work environment by setting up childcare or reimbursing participants for childcare, so patients and the public can take part in research activities. This action may be coordinated by the PPIE officer.
- **PUBLIC PLATFORM:** This introduces PPIE projects and activities for the wider public. The platform should inform and connect different stakeholders, interested public members and patients regarding available research projects and their opportunities to be involved and matchmaking with researchers and research projects. The platform might be provided by the organization or in synergy with existing platforms.

3. Assessing my PPIE activities

The following chapter provides tools to prepare for and assess your PPIE activities in research projects. It describes general considerations for implementing PPIE principles and activities before, at the beginning of, during and after research projects. We provide a step-by-step checklist and self-assessment tool to monitor your PPIE activities.



3.1. Preparing for PPIE activities

Every PPIE project is different. Not only can the content of the project vary, but researchers' PPIE skill levels and the skill levels of patients and/or the public can vary as well. This should be kept in mind in any training activity and effort. For this reason, a tailor-made approach is necessary. One option is a step-by-step approach:

- **Step #1: Co-developing the PPIE project**
  - Is my research project a PPIE project at all?
  - What changes in the project are necessary for a PPIE project and what kind of training do researchers need in order to fulfill this goal?
- **Step #2: Training for the target group**
  - What is the main target group of my project?
  - Who do we want to involve - what are inclusion and exclusion criteria for training (e.g. basic IT skill level)?
  - What are the main needs of the target group?
- **Step #3: Define the organization & administration criteria**
  - How do we want to work together during training?
  - How should roles and responsibilities be clarified?
  - How can we communicate and develop a timeline that is feasible and practicable?
  - How should the training to be documented and shared?
  - What are the main training goals in general and for each training session?
  - What are the expected outcomes for all involved groups?
- **Step #4: Co-Development of training content & process design**
  - Will training be offered for researchers and the public together or separately?
  - Is there a common training module that is useful for working together (e.g., social skills and/or communication)?

A portfolio of different training modules is necessary in order to cover a wide range of training needs. With this approach, trainings will be based on formats that have already been developed and can be developed further. Each step of the training should reflect a co-creative approach. This includes shared leadership and steering, co-creative decision-making, co-defining common goals and co-selection of the forms and scope of evaluation.

3.2. Checklist for my PPIE activities

The checklist describes the major steps of PPIE activities before, in the beginning of, during and after the research project. This list should support you in preparing to involve patients and the public in your research project.

BEFORE THE RESEARCH PROJECTS STARTS:

- ☐ Clarify the organization's management buy-in and eligibility of costs for funders
- ☐ Clarify researchers' motivation for including patients/the public before approaching organizations/individuals
- ☐ Clarify the role and expectations of patients/the public
- ☐ Job description for patients/public: tasks and responsibilities, terms of reference
- ☐ Training for members of the research team that will be in direct contact with patients/the public
- ☐ Guideline for raising complaints and concerns (provided by the 'Ombudsman')
- ☐ Academic credit: what to contribute and how to receive authorship
- ☐ Safety plan: emotional, psychological and physical safety plan developed and set up
- ☐ Evaluation plan and assessment of activities (may be co-created with patients/the public)
- ☐ Recruitment of patients/the public: define search strategy for patients/public and how many people are needed to support the project
- ☐ Establish Study Advisory Group: e.g., for consultation on agenda setting before the project starts

BEGINNING OF THE RESEARCH PROJECT:

- ☐ Training patients/the public (research project and research process)
- ☐ Clear the legalities with patients/the public (e.g. usage of data)
- ☐ Align your description of the role and expectations with patients/the public and adapt if necessary
- ☐ Set up monetary and non-monetary honorarium (agreement or subcontracting)
- ☐ Check societal relevance of your research plan with patients/the public

☐ Assign an experienced and trained ‘mentor’ to serve as a point of contact with patients/the public

☐ Establish the Project Steering Board: experts in the field and patients/the public

☐ Set up supervision for patients/the public (PPIE Officer)

DURING THE RESEARCH PROJECT:

☐ Regular updates on project progress, results and plans

☐ Meet regularly with the Study Advisory Group for feedback and consultation on current activities

☐ Meet annually with the Project Steering Board to discuss progress

☐ Co-design and co-analyze elements of the research

☐ Co-write (scientific) publications and media coverage

☐ Co-lead (scientific) presentations

☐ Co-convene conferences and events

☐ Create learning opportunities and further career development (e.g., experts on patient boards)

AFTER THE RESEARCH PROJECT:

☐ Updates and dissemination of research outcomes and future opportunities to be involved

☐ Co-lead in conference presentations and events

☐ Co-write funding applications for future projects

3.2. PPIE self-assessment tool

Assess your PPIE activities and level of involvement of patients and the public in research based on the following tables. You may use the self-assessment tool to evaluate your performance before, during and after the research projects. Please be honest, it is an opportunity for improvement!

TABLE 1: CURRENT STATE OF PATIENT/ THE PUBLIC INVOLVEMENT – RESEARCHERS AND STUDY LEVEL

(Modified from Ian Manion)

Research cycle activity	LEVEL OF INVOLVMENT				
	never	rarely	occasionally	frequently	always
Identifying the relevant research question					
Developing the research design and strategy					
Choosing research methods and measures					
Collecting and analyzing research data					
Interpreting research data					
Participating in knowledge translation and dissemination activities					
Receiving academic credit (e.g. publications)					

TABLE 2: CURRENT LEVEL OF INVOLVEMENT – ORGANIZATIONAL LEVEL

(Modified from Ian Manion)

Level of involvement	FREQUENCY OF PRACTICE				
	never	rarely	occasionally	frequently	always
Inform					
Consult					
Involve					
Collaborate					
Lead					

LEGEND:

Inform: Patients/the public are informed about the different aspects of the study (press, study descriptions) in lay terms. Patients/the public participate in the study as subjects only.

Consult: Patients/the public shape the study through consultation (e.g., interviews, focus groups, public forums)

Involve: Patients/the public are actively involved in specific research activities.

Collaborate: Patients/the public are active members of the research team (co-researchers).

Lead: Patients/the public drive the research study, own the process and are self-organized.

TABLE 3: CURRENT STATE OF PATIENT/ PUBLIC INVOLVEMENT – ORGANIZATIONAL LEVEL

(Modified from Ian Manion)

Organizational activity	FREQUENCY OF PRACTICE				
	never	rarely	occasionally	frequently	always
Project steering, governance structure					
Policies and guidelines					
Setting the research agenda					
As staff members					
Hiring staff					
Performance reviews					
Allocation of resources (i.e., budget, personnel)					
Communications/ public relations					
Fundraising					

4. Monitoring PPIE activities

Successful PPIE activities and projects in research need a structured method for monitoring the quality and implementation of PPIE activities. The following chapter describes suggestions on who to involve in the monitoring process and how to monitor these PPIE activities.

4.1. Who monitors PPIE activities?

- **STUDY ADVISORY GROUP (SAG) Speaker:** The SAB Speaker is part of the Study Advisory Group and acts on behalf of the group. He or she is the contact point for the PPIE Officer and research team. The group elects the speaker for a term of 6 months. After this period, the group will elect a new speaker (shared leadership) for the next 6 months. The SAG speaker is responsible for:
  - Coordinating and facilitating the SAG activities
  - Providing aligned feedback to the research team
  - Acting as a contact point to the PPIE Officer and Patient Ombudsman if necessary
  - Providing information for monitoring meetings
- **PPIE OFFICER:** The PPIE Officer is part of the organization to support researchers and helping interested patients and the public to be involved in research activities. He or she offers tailor-made training concepts for research units and individual consultation for researchers. The PPIE Officer is responsible for co-developing funding schemes and quality criteria to monitor PPIE activities. The PPIE Officer is responsible for:
  - Being the contact person for the SAG speaker
  - Offering individual consultation for project applications
  - Advising interested researchers on how to do PPIE activities and allocate budgets
  - Coordinating and collecting information from all PPIE projects and activities
  - Coordinating exchanges and learning events for PPIE project members
  - Providing infrastructure to support PPIE activities (e.g., public forums, platforms, etc.)
  - Updating the PPIE ‘how to’ guide for researchers and other guidelines
  - Promoting current projects in public (e.g., website, social media, etc.)
- **PRINICPAL INVESTIGATOR:** The Principal Investigator leads the research team and the research program/activities. He or she acts as a contact point for the PPIE Officer and the SAG Speaker. The Principal Investigator is responsible for:
  - Providing opportunities for patients/public to be involved in research activities
  - Providing funding to honor patient/public members for their time
  - Providing information for monitoring meetings

4.2. ‘How to’ monitor PPIE activities

The Study Advisory Group (SAG) Speaker, PPIE Officer and the Principal Investigator jointly monitor the implementation of PPIE activities in the research project. In regular meetings (e.g., we suggest 2-4x per year and on demand), the team evaluates past and current PPIE activities and discusses further steps for implementation and improvement. They may consult with the Patient Ombudsman regarding conflicts between the parties and/or individual complaints, should they occur. The team will document their results, give recommendations for promoting the implementation of future PPIE activities and inform their colleagues about the outcomes.

MONITORING TEAM

- **Study Advisory Group (SAG) Speaker (patient/member of the public)**
- **PPIE Officer (from the organization)**
- **Principal Investigator (researcher)**

THE MONITORING SHOULD INCLUDE: 2-4X PER YEAR

- **Self-assessment: to ensure the quality of PPIE activities**
    - Reflect on current activities regarding their ‘level of involvement’ and ‘frequency of practice’ (Table 1-3, see chapter 3.2)
    - Reflect on each project phase (before, in the beginning, during and after the project, ‘Checklist for my PPIE activities,’ see chapter 3.1.)
- **Check PPIE expenditures / budget**
- **Recommendation for future activities: to improve and successfully implement planned activities**
- **Report (documentation) and action plan: to achieve these goals**

5. Resources

In this chapter, we provide additional PPIE resources such as key articles and short summaries, links to literature databases, other PPIE guides and 'good practice' examples, case studies and important journals and blogs in this field.

5.1. Literature

Arnstein, S. R. (1969). A ladder of citizen participation. Journal of the American Institute of Planners, 35(4), 216-224.http://tiny.cc/Arnstein1969

Short Summary:

In this classic paper, Arnstein describes the different levels of participation in science and society. In this work, Arnstein makes an attempt to discuss the typology of citizen’s participation from her experiences with federal social programs, including urban renewal, anti-poverty, and Model Cities. Based on this, Arnstein developed levels of citizen participation arranged as rungs on a ladder, with each rung corresponding to the amount of “citizen control” within the process of determining a program or policy.

Deane, K., Delbecque, L., Gorbenko, O., Hamoir, A. M., Hoos, A., Nafria, B., ... & Brooke, N. (2019). Co-creation of patient engagement quality guidance for medicines development: an international multistakeholder initiative. Bmj Innovations, bmjinnov-2018. http://tiny.cc/hge49y

Short summary:

Meaningful patient engagement (PE) can enhance the development of medicines. However, the current PE landscape is fragmented and lacks comprehensive guidance. The authors systematically searched for PE initiatives. Multistakeholder groups integrated these with their own PE expertise to co-create a draft of PE Quality Guidance which was evaluated by public consultation. Projects exemplifying good PE practice were identified and assessed against the PE Quality Criteria to create a Book of Good Practices. Seventy-six participants from 51 organizations participated in nine multistakeholder meetings (2016–2018). The co-created INVOLVE guidelines provided the main framework for PE Quality Guidance and were enriched with the analysis of the PE initiatives and the PE expertise of stakeholders. Seven key PE Quality Criteria were identified. The PE Quality Guidance was generally agreed to be useful for achieving quality PE in practice, understandable, easy to use, and comprehensive.

Greenhalgh, T., Hinton, L., Finlay, T., Macfarlane, A., Fahy, N., Clyde, B., & Chant, A. (2019). Frameworks for supporting patient and public involvement in research: Systematic review and co-design pilot. Health Expectations. shorturl.at/bqR15

Short summary:

There are numerous frameworks for supporting, evaluating and reporting patient and public involvement in research. The literature is diverse and theoretically heterogeneous. This article aims to identify and synthesize published frameworks, consider whether and how these have been used, and apply design principles to improve usability. The plethora of frameworks combined with evidence of limited transferability suggests that a single, off-the-shelf framework may be less useful than a menu of evidence-based resources which stakeholders can use to co-design their own frameworks.

Slattery, P., Saeri, A. K., & Bragge, P. (2019). Research co-design in health: a rapid review. Open Science Framework. https://doi.org/10.31219/osf.io/q5tyk

Short summary:

In this rapid review, a systematic approach to research papers covering co-design processes along the research cycle is depicted. Results show that research co-design appears to be widely used but seldom described or evaluated in detail. Though it has rarely been tested empirically or experimentally, existing research suggests that it can benefit researchers, practitioners, research processes and research outcomes. Realizing the potential of research co-design may require the development of clearer and more consistent terminology, better reporting of the activities involved, and better evaluation.

Staley, K. (2015). 'Is it worth doing?' Measuring the impact of patient and public involvement in research. Research involvement and engagement, 1(1), 6. http://tiny.cc/staley2015

Short summary:

In recent years, there has been considerable interest in finding out what difference patient and public involvement makes in research projects. Researchers gain an understanding of involvement through their direct experience of working with patients and the public. This is 'knowledge in context' or 'insight' gained in the same way that patients gain expertise through their direct experience of a health condition. This means that detailed accounts of involvement from researchers already provide valuable learning to others, in the same way that patients' insights help shape research. However, the impact of involvement will always be somewhat unpredictable, because at the start of any project, researchers 'don't know what they don't know'—they do not know precisely what problems they might anticipate until the patients/members of the public tell them.

5.2. Guides and databases

LITERATURE DATABASE

- Patient-Centered Outcomes Research Institute (PCORI) Literature Database
  https://www.pcori.org/literature/engagement-literature
- NICE - National Institute for Health and Care Excellence Literature Database
  https://www.evidence.nhs.uk/search?q=patient+and+public+engagement
- NIHR INVOLVE evidence library

  https://www.invo.org.uk/resource-centre/libraries/evidence-library/

OTHER PPIE GUIDES

- NIHR INVOLVE Briefing Notes for Researchers
  http://tiny.cc/BriefingNotes
- NIHR INVOLVE: Guidance on co-producing a research project
  https://www.invo.org.uk/wp-content/uploads/2019/04/Copro_Guidance_Feb19.pdf
- NHS: Public Engagement - a practical guide
  https://senseaboutscience.org/wp-content/uploads/2017/11/Public-engagement-a-practical-guide.pdf
- How to partner with young people, Orygen, Australia
  https://www.orygen.org.au/About/Youth Engagement/Resources/YouthPartnershipToolkit.aspx

PPIE CASE STUDIES

- NIHR INVOLVE: Case Studies
  https://www.invo.org.uk/resource-for-researchers-case-studies/
- NHS Impact of Patient, Carer and Public Involvement in Cancer Research
  http://www.ncri.org.uk/wp-content/uploads/2013/07/2012-NCRI-PPI-report.pdf
- Gordon, J., Franklin, S., & Eltringham, S. A. (2018).
  Service user reflections on the impact of involvement in research.
  Research involvement and engagement, 4(1).

INTERESTING BLOGS & JOURNALS

- https://www.pcori.org/establishing-definition-patient-centered-outcomes-research
- https://blogs.bmj.com/bmj/category/patient-perspectives/
- https://simondenegri.com/
- https://oxfordbrc.nihr.ac.uk/blog/
- https://patientfocusedmedicine.org/blog/
- https://kristinastaley.com/

5.3. Case Study: LBG Mental Health Research Groups

The LBG Open Innovation in Science Center (www.ois.lbg.ac.at) is an integral part of the Ludwig Boltzmann Gesellschaft (LBG), which operates 19 research institutes with about 550 employees. The LBG Open Innovation in Science Center investigates and experiments with open research practices. It generates and disseminates insights into the use of Open Innovation principles and methods along the entire research process. The goal is to establish and provide knowledge about the qualified implementation of Open Innovation in Science (OIS):

- Re-thinking and re-designing scientific research through a shift towards making research more open, collaborative, and interdisciplinary
- Developing and testing new methods for integrating Open Innovation principles into scientific research and innovation processes
- Establishing new forms of stakeholder interactions and collaborations within science

The OIS initiative has led to various outcomes, such as:

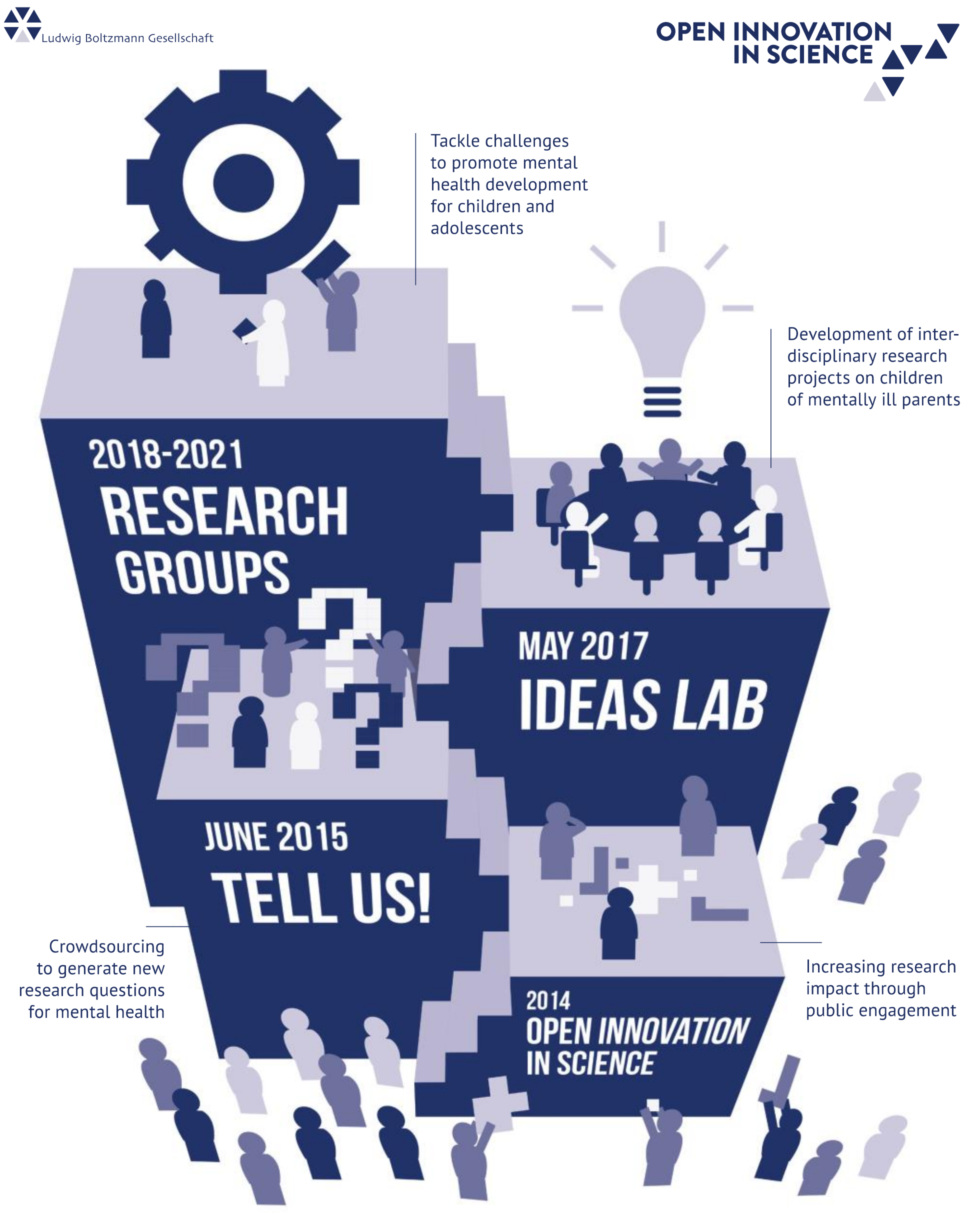
- New ways of learning about and experimenting with Open Innovation in Science (LOIS - Lab for Open Innovation in Science)
- New forms of generating research questions (CRIS - Crowdsourcing Research Questions in Science) for basic and applied sciences
- New ways of conceptualizing research projects and forming interdisciplinary research groups (Ideas Lab)
- Introducing new governance structures (Advisory Board including people with lived experience and competence group – experts by experience consulting and co-creating research projects)

MAKING AN IMPACT THROUGH PUBLIC INVOLVEMENT

In an example of applying OIS principles in the field of mental health, the LBG involved the public and patients in several phases of the research cycle. LBG took a novel approach towards creating interdisciplinary Research Groups on Mental Health. “Tell Us!” was Europe’s first crowdsourcing project to generate research questions in collaboration with patients, family members and health care professionals. Out of 400 high-quality contributions, the topic “Children of mentally ill parents” emerged as highly societal relevant. LBG announced a research call representing an interactive workshop, Ideas Lab, to bring together 30 researchers for a five-day event, during which researchers were specifically encouraged to think out of the box and dissolve disciplinary boundaries. Novel evaluation criteria focusing on interdisciplinary and involvement were applied to find innovative solutions to existing challenges by co-creating research with the public. Two Research Groups were funded with a budget of EUR 6 million (2018-2021). To ensure public engagement and interdisciplinary research throughout the research process, the Research Groups are embedded in a dynamic network and supported by a Research Group and Relationship Manager to foster community engagement and collective impact. The

Research Groups operate with a new governance structure, and people with lived experience are represented in the Advisory Board and on Study Advisory Group, called the Competence Group.

FIGURE 4. TIMELINE OF THE NOVEL APPROACH TO FORM RESEARCH GROUPS ON MENTAL HEALTH WITH AN OPEN INNOVATION METHODOLOGY.



Tackle challenges to promote mental health development for children and adolescents

Development of inter-disciplinary research projects on children of mentally ill parents

Crowdsourcing to generate new research questions for mental health

Increasing research impact through public engagement

6. Bibliography

Arnstein, S.R. (1969).

A ladder of citizen participation. Journal of the American Institute of planners, 35(4), 216-224.

Chalmers, I. & Glasziou, P. (2009).
Avoidable waste in the production and reporting of evidence. The Lancet, 374:786–786.

INVOLVE, National Institute of Health Research (NIHR), UK: https://www.invo.org.uk/

INVOLVE, People & Participation. How to put citizens at the heart of decision-making (2005). https://www.involve.org.uk/sites/default/files/field/attachemnt/People-and-Participation.pdf

Glasziou, P. & Chalmers, I. (2016).
Is 85% of health research really "wasted"? – Biomedical Journal (BMJ).
http://tiny.cc/kve49y

Mazzucato 2019:
https://ec.europa.eu/info/sites/info/files/research_and_innovation/contact/documents/ec_rtd_mazzucato-report-issue2_072019.pdf

Staley, K. 2009.
Exploring impact: public involvement in NHS, public health and social care

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