PATIENT FOCUSED
MEDICINES DEVELOPMENT

BoGP
2nd edition

The PFMD
Book of Good Practices

2nd edition I 2019

@The_Synergist
@PFMDwithPatient

#PEQualityGuidance
#PEQualityCriteria

www.PatientFocusedMedicine.org
October 2019

Message from PFMD

Dear reader,

Patient Focused Medicines Development (PFMD) was established in 2015 out of a need that was expressed by many stakeholders in various roundtable discussions. This need was eventually translated into a dedicated organisation that aims to drive systematic patient engagement and involvement forward in the research, development and delivery of medicines.

Today we are very proud that you are reading the Book of Good Practices, as this too was born from a need expressed by many stakeholders. As patient engagement is becoming a norm instead of an exception or a one-off practice, there was a need to share knowledge about

- how other organisations have involved patients in their activities,
- what can be considered as high quality patient engagement, and
- how can different organisations reach the level of patient engagement that is both meaningful to patients but also to the research and development processes so that the output or outcomes will serve the end users better.

The PFMD Patient Engagement Quality Guidance, that was launched in 2018, introduces 7 Quality Criteria for good patient engagement that can be used to plan patient engagement activities, or to assess the level of patient engagement in ongoing or completed activities. Where the Patient Engagement Quality Guidance serves as a tool to help you to do patient engagement, the Book of Good Practices serves as a set of real life cases from a variety of organisations, that illustrate in detail how they have done it. These cases have been chosen from a big pool, assessed by an external group of reviewers and chosen to be included because they exemplify exceptionally well the 7 Quality Criteria. For detailed descriptions of the criteria and explanations for icons used, check the annexes at the end of the book.

The Book of Good Practices will be growing year by year with new cases. To contribute to this work, you can also submit your patient engagement experiences to the PFMD team.

We hope this book will inspire and help you in your patient engagement journey. We encourage you to explore all the tools at your disposal within PFMD and Synapse - the mapping and networking tool, and connect with us for more guidance if needed.

We'd like to extend our thanks to all the reviewers, all case owners and all readers for making the Book of Good Practices possible.

PFMD Team

PATIENT FOCUSED MEDICINES DEVELOPMENT

NIHR | Sheffield Biomedical Research Centre

HeadUp Collar: Co-creation of a new cervical orthosis for patients with Motor Neuron Disease/ neck weakness

Organisation: Sheffield Biomedical Research Centre

The PFMD
Book of Good Practices

2nd edition I 2019

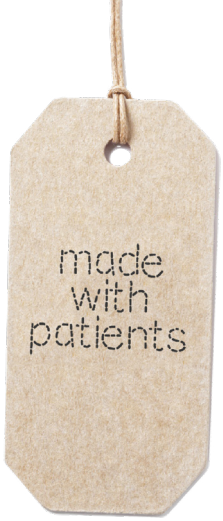
Table of content

THE BOOK OF GOOD PRACTICE INITIATIVES ARE ALSO AVAILABLE IN SYNAPSE.

TO DOWNLOAD THE FULL BOGP, PLEASE VISIT:
https://involvement-mapping.patientfocusedmedicine.org/book-of-good-practices

PATIENT FOCUSED MEDICINES DEVELOPMENT

NIHR | Sheffield Biomedical Research Centre



HeadUp Collar: Co-creation of a new cervical orthosis for patients with Motor Neuron Disease/ neck weakness

Organisation: Sheffield Biomedical Research Centre

Basic Information

Many people with Motor Neurone Disease (MND) develop weak neck muscles, leading to pain, restricted movement, and problems with swallowing, breathing and communication. Available neck collars were reported to be of limited use for people with MND and frequently rejected by patients. This issue was identified directly by patient representatives in the NIHR DeNDRoN clinical research network and confirmed by clinicians in the same network. The project leader, as a member of the DeNRoN network, consultant neurologist and academic clinical researcher began to look more closely into the lack of suitable neck support for MND patients. Initial work centered on finding out exactly what the patient identified problems with existing neck supports were and their requirements for an ideal neck support through patient engagement.

A cross-organisation collaboration of NIHR Devices for Dignity Med Tech Co-operative (D4D), Sheffield Hallam University (SHU) and The University of Sheffield (incorporating the Sheffield Institute for Translational Neuroscience) secured funding from NIHR Invention for Innovation (i4i) to enable focus groups with patients, their families and with a multidisciplinary group of health professionals and design engineers in order to develop and explore new prototypes.

Patients helped to input into multidisciplinary design workshops to reach new prototype design concepts. A local research advisory group, the Sheffield Motor Neurone Disorders Research Advisory Group

(SMNDRAG) remained engaged with the project over a long-term period from 2010 -2015 and a member of SMNDRAG was a co-applicant on the NIHR i4i grant to develop and test prototype design.

Patient views from expert user group workshops fed in to an iterative co-design process with technical experts to arrive at a final collar design that was patented. An extension of NIHR i4i grant funding in conjunction with the Motor Neurone Disease Association charity was secured and used to manufacture 100 collars of the new design (the 100 collars project) to test for support, durability, freedom of movement and wearability with patients with neck weakness from MND and other neurological causes at 10 sites across the UK. This HeadUp study received Trial and Project Management from D4D, who also established an Expert Patient Group in order to monitor trial participation experience and also to test out iterative collar design aspects from data obtained during the trial.

The panel of patients in the SMNDRAG helped to review, evaluate and improve a data collection tool to evaluate existing cervical orthoses for comfort and aesthetics during the development of the HeadUp collar. The tool specified the location and perceived scale of discomfort as well as overall perception of wearing cervical orthoses. For the latter assessment 10 statements were used based on the experiences of people living with MND when wearing orthoses. All statements were positively phrased e.g. 'this device caused no restriction to my breathing'. SMNDRAG provided feedback on consent forms and patient information sheets to help run the study.

This multidisciplinary collaborative project involved patients, researchers, clinicians, academics and designers across the different organizations. Patients were involved at all stages of the research cycle – from identification of the need for a new fit for purpose orthotic device, involvement as co-applicants for grant funding requests, providing input into the design process and developing protocols for user testing of prototype designs, through to disseminating the research results by featuring in press coverage upon market release of the product.

Patients and carers living with MND who are members of the SMNDRAG at the core of involvement activities have been able to benefit directly from the development of the HeadUp neck collar (http://www.youtube.com/watch?v=Db7yrIDNszs).

The quarterly meeting group continues to support a broad range of MND research through regular interaction with researchers. This and the HeadUp Study Expert Patient Group are, providing an exemplar model for patient engagement in different areas of neurology across NIHR Sheffield Biomedical Research Centre (BRC) and beyond. The SMNDRAG established documentation provides templates for new research advisory groups that have been set up within the NIHR Sheffield BRC. The HeadUp collar (previously known as the Sheffield Support Snood) is now available for patients with neck weakness through 25 NHS Trusts across the UK as of May 2018 and to purchase commercially through TalarMade worldwide.

Which phases of research, medicines development, lifecycle or disease area does your PE project cover?

Research and discovery phase | Pre-clinical phase | Clinical study phase 1-3 | Health technology assessment | Regulatory review and approval or registration phase | **Post-registration/ -launch activities** | **Other**

Post-registration/ -launch activities: marketing insights

Other: Research advisory input into observational clinical studies

Which stakeholders does this initiative involve?

- **Patients and carers**
- **Patient advocates, patient organisations and associations**
- **Healthcare professionals**
- Policymakers
- Regulators
- Payers
- Health technology assessment organisations
- Pharmaceutical companies or industry
- **Researchers**
- **Research funders**
- Other

The quality of patient engagement

1. Shared purpose

What did you do to achieve this criterion?

- Held focus groups to define patient needs for a neck collar
- Developing project discussed at 18 meetings over 5 years with the Sheffield MND Research Advisory Group (SMNDRAG) panel and the HeadUp Expert Patient Study Group of patients
- Co-developed questionnaire to systematically record limitations of existing cervical orthoses
- Patient expert attendance at further design workshops and ongoing SMNDRAG panel involvement in iterative design process and protocol development for user testing of prototype designs

What is your stated "shared purpose"?

The key shared objective was to develop a cervical orthosis to meet previously defined unmet needs of patients with neck weakness due to neurological disease.

How have you confirmed with all stakeholders that your purpose is understood, that contributions have influenced the original plans and that disagreements have been addressed?

Patients defined the limitations of existing neck collars and their requirements for an ideal collar. This included aspects of aesthetic appearance for a discrete orthosis for daily use not previously considered by the clinical and engineering collaborating researchers.

Have you reviewed the shared purpose and its understanding among stakeholders?

The patient and carer members of SMNDRAG were tenacious to see the project through and expressed that it should not be given up on even when it had been rejected for funding twice and volunteered to attend workshops to establish prototype designs anyway.

As the project progressed the group requested that the prototype be brought in to the next meeting to facilitate their continued involvement.

At what time points?

The HeadUp project was reviewed by SMNDRAG research advisory panel as a standing agenda item at every meeting, 4 times a year between 2010 and 2015.

Dissemination of the project outcomes has been shared by and with members of the all patient groups.

2. Respect and accessibility

How have you addressed respect and accessibility in this project?

- The meeting time and place, frequency of meetings and defined dates for email contact between

meetings are all agreed by the SMNDRAG panel and the HeadUp Study Expert Patient Group.

- SMNDRAG provided patient consultation on developing wording for a tool to user test neck collars and study information for patient audiences.
- This formed part of SMNDRAG's input into recruitment strategy for the 100 collars project
- The project adhered to INVOLVE guidance on payment for travel expenses to design workshops and co-applicant involvement on project
- Respect for participants during the collar design and trial phases is evidenced by the strength of impact that patient feedback had on specifying the design requirements for the collar, and the selection by the PPIE groups of a preferred design for the clinical trial.
- Careful discussions were held with patients taking part in the dissemination and publicity campaigns in order to respect what information was made public and which aspects of dissemination they wished to participate in – and to what degree.

How have you assessed with stakeholders that they acknowledge mutual respect, and that access to engagement has been optimised?

The SMNDRAG panel of patients and carers are invited to report annually via a questionnaire on their experience of involvement (engagement) in research. Regarding the specific HeadUp project, a member of this group recorded a testimony about her experience of the workshops during the project and noted https://youtu.be/ZrtM2quaelA

D4D received very complimentary feedback from panel members (in the form of social media acknowledgement and personal written correspondence) regarding the element of mutual respect and participation in the project.

3. Representativeness of stakeholders

How have you ensured broad, competent, diverse representation of stakeholders?

The SMNDRAG group set out agreed terms of reference, person specifications and application for membership includes checking for time commitment, email and computer skills, the ability to read and comment on potentially complex documents. This group was at the core of patient engagement for the HeadUp project.

To widen the representation of stakeholders, the MNDA charity helped to advertise the HeadUp project through their channels and featured a focus group meeting at their AGM in 2011 to giving people outside the limited membership of SMNDRAG a voice in the development of the project. The opportunity to share their thoughts on the current neck collars available and whether another design was needed was given at this meeting including the chance to make suggestions on how to make a new collar more suitable.

In 2012 the MNDA helped again to identify people to take part in a working group to be involved in the design process. Subsequently patient attendance at design workshops was kept accessible through providing travel costs, offering reimbursements and expenses.

During the clinical evaluation stage of the project, the project team engaged with clinicians and patient groups across 10 sites in the UK and Ireland in order to reach a diverse population of stakeholders. D4D also linked in with Sheffield Teaching Hospitals NHS FT (STH) Consultant Nursing Staff in order to offer trial

participation to patients with neck weakness resulting from Late Stage Effects on cancer treatment. This was welcomed by these patients as they have had difficulty accessing ongoing multidisciplinary support in the community for head drop problems.

How did you check that the representation of stakeholders in your project supported achieving project outcomes?

A strong case was put together for funding after the MNDA AGM.

The HeadUp Study Expert Patient Group provided ideas for further iterative neck collar improvements. These were shared with the whole project team and novel prototypes (for example incorporating flesh coloured collars and supports and a trial of a side fastening collar) were developed and evaluated by the HeadUp Expert Patient Group members.

Their feedback helped ensure the project not only delivered on the shared outcomes identified at project outset, but also provided very valuable ongoing information for further developments for the collar and offers from the group of help with dissemination and publicity.

4. Roles and responsibilities

What did you do to achieve clarity and communication as well as regular check-points on roles and responsibilities?

SMNDRAG meetings are open discussion forums with a friendly mix of at least 50% patient and carer or past carer, members together with clinical and scientific staff members. The group has been chaired well by past carers on voluntary basis who ensure that all voices are heard at meetings. The meetings are minuted by an administrative member of staff and all members have the chance to modify or approve the minutes at the next meeting.

The HeadUp study expert patient group was held in a slightly more informal capacity, without the need for a designated chair. Communications and practical arrangements for meetings (via a range of contact methods, as convenient to individual group members (e.g. telephone, email, or text messages). Discussions were regularly held regarding different roles and/or responsibilities so that individuals could select these at all stages according to their health, other time commitments and individual preferences.

How did you check that all participants understood what their roles and responsibilities are, and what is expected of them?

SMNDRAG agreed terms of reference sets out the role and expectations of the group. A membership application form was co-developed to check new members would be capable of fulfilling the role.

At what frequency have you checked this in?

Issues can be raised freely on a quarterly basis at the face to face meeting or intervening dates for email contact.

5. Capacity and capability for engagement

What did you do to support building the required capacity and capability for engagement?

In conjunction with the Clinical Research and Innovation Office at Sheffield Teaching Hospitals NHS Foundation Trust, members of SMNDRAG are invited to training days and educational activities such as International Clinical Trials Day and a wide range of public outreach event around Sheffield Neurosciences.

A free online training course (European Patient Ambassador Programme) was also advertised through the SMNDRAG group.

SMNDRAG members can access some University of Sheffield library services with day passes organised through the group.

Reimbursement for travel expenses was offered to SMNDRAG and HeadUp Study Expert Patient Group members. Members were aware that they could opt out of the project at any stage if they wished to do so.

How did you check that all stakeholders have what they need to contribute effectively and meaningfully?

Through open discussion at SMNDRAG meetings and feedback forms of training and public outreach events offered. A member of SMNDRAG completed the EPAP course in 2013 and recommended it to other members of the group. A further member subsequently applied for a place on the training course.

The PPIE focus groups were given information about the project and care was taken to ensure that they felt that they could speak freely on both positive and negative aspects of different neck collar prototype designs. They fed back that they felt their input had a very meaningful and powerful impact since they could see how their feedback had been incorporated into iterative prototype models, and they had selected their overall preferred design to be used in the clinical evaluation.

6. Transparency in communication and documentation

What did you do to achieve and implement processes for timely communication and updated documentation throughout the project?

The Sheffield MND Research Advisory Group decided democratically the pattern for email communication between face to face quarterly spaced meetings. The meetings are minuted and feedback and updates are recorded, circulated and approved by the membership at the next group meeting. HeadUp remained a standing item on the meeting agenda over the course of a 5-year period in which the HeadUp project was discussed at 18 out of 20 meetings. The group were kept updated on the study they helped to develop and secure funding for once it was underway with recruitment and other information. Study information was kept updated online and the link was circulated to the group.

Ongoing communication with the HeadUp Study Expert Patient Group was maintained using whichever medium preferred by each participant (telephone, email, text and/or social media). This communication was two-way (i.e. not always initiated by the project team) and is ongoing after completion of the project, at the request of the group members.

How did you validate that your communication and documentation plans were useful and appropriately implemented?

At the face to face meetings the minutes of the last meeting were checked for approval as a standing agenda

item. The group Chair checked that all members had received the link for and were able to access online information. The minutes of the meetings are stored on a secured drive for the Faculty of Medicine, Dentistry and Health at the University of Sheffield.

It is a testament to good documentation of the meetings that they were sufficient that an appropriate third party (the Patient and Public Involvement and Engagement Lead for Sheffield BRC) was able to recount the long-term involvement in the project retrospectively for assessment against PFMD quality guidance criteria.

In preparation for the HeadUp Study, the Protocol and Patient Information documents were shared for feedback. During the clinical trial communication with the Expert Patient Group was maintained via newsletters, telephone, social media and email.

7. Continuity and sustainability

What did you do to achieve this criterion?

Continued PE was enabled by the collectively funded SMNDRAG of patient and carer members. A stable membership (that is open to new members) meet regularly every quarter to discuss a variety of projects with researchers, clinicians and academics. The HeadUp project remained a standing item on the agenda of these meetings for 5 years from June 2010 until December 2015 and the group was kept updated with all aspects of the developing design process and the deliverables of clinical assessment of the collar, including recruitment rates for participation in user testing. Members of the group were involved again in disseminating the research and featured in a short film (available on youtube) and press releases.

- https://youtu.be/ZrtM2quaelA
- https://vimeo.com/272414469
- https://www.youtube.com/watch?v=Z6tmADMDSgM

Forward looking budgeting for the group to be sustained beyond the duration of the HeadUp project was applied for and this is providing a model for funding newly set up groups in other neurological disease areas.

All organisations collaborating in this project feel strongly that the collaboration between academics, clinicians and patients has been the key factor contributing to the success of the project and that it has been a powerful experience for all involved to experience the power of Patient and Public Involvement and Engagement when it is fully optimised. Learning from this experience has been an additional impact of the project and is being shared via conference presentations, publications and social media in order to share this learning beyond this particular project.

How did you gather feedback on what you have done?

The SMNDRAG group continues to minute their meetings and operate as normally.

The HeadUp Study Expert Patient Group have volunteered their feedback (via personal written communication, and via social media). One group member also made his own YouTube video to document his experience: https://www.youtube.com/watch?v=66Lgyv1r6E0

How did you check that your planning to secure continuity and sustainability was appropriate also for the stakeholders you've involved in the project?

Through direct consultation with the members of SMNDRAG and HeadUp Study Expert Patient Groups.

Results and outcomes

Expert user panels fed into the development of a new design for a neck collar and reviewed funding applications and protocols for user testing to the eventual success of the objective to create a new product. The panel of patients in the Sheffield MND Research Advisory Group helped to review, evaluate and improve a data collection tool to evaluate existing cervical orthoses for comfort and aesthetics during the development of the HeadUp collar. The tool specified the location and perceived scale of discomfort as well as overall perception of wearing cervical orthoses. For the latter assessment, 10 statements were used based on the experiences of people living with MND when wearing orthoses. All statements were positively phrased e.g. 'this device caused no restriction to my breathing'. Details published in 'A comfort assessment of existing cervical orthoses Ergonomics 61(2):329-338 01 Feb 2018.

Positive impact for specific medicines development phases

For example,

- identifying unmet medical needs,
- accurately prioritised research agenda,
- improved study design (for example, fewer protocol amendments to procedure),
- financial impact due to faster set-up and fewer amendments,
- possible decreased timing to registration,
- patient-driven solutions,
- increased patient adherence to medication and treatment,
- extension of a medicine or treatment to new patient groups or new country/ regions.

All of the above! The results of the HeadUp Study 100 collars project showed that 80% of patients preferred the HeadUp collar - a patient prioritized and co-designed solution to patient identified unmet need – over existing designs.

Continued patient involvement in press-related activities following the launch of the product has helped to raise awareness, drive and drive demand for the collar with a spike in healthcare providers and private customers making enquiries for the product after these activities, extending the reach of the new device.

Direct or indirect positive impact for patients

The impact is the international availability of a novel cervical orthosis that is adaptable to a patient's needs using adjustable removable supports that can be changed according to requirement during different daily activities and that is comfortable and wearable over time in the case of chronic and progressive diseases. This has led to the direct impact of improved quality of life for patients using the HeadUp collar referred to by a patient and carer couple featured in communications about the new collar (https://www.youtube.com/watch?v=Db7yrIDNszs).

Indirectly, the promotion and widespread recognition of the impact true partnership with patients has had through the HeadUp project is helping to endorse and inform further patient engagement activities around

the NIHR Sheffield BRC and of the other project partners, thus maximizing the chances for positive patient influence on many areas of research.

Direct or indirect positive impact for stakeholders involved in the project (other than patients)

- New IP generation through patient driven research prioritisation and better investments in research and development.
- A better understanding of patients' requirements for cervical orthoses made for compelling cases to fund development of a new product that could be competitive on the over-the-counter market.

Lessons learned

The format of the regularly meeting Research Advisory Group of patients and carers facilitated long-term co-development of research and succeeded in taking a patient priority from an idea to a clinically adopted and commercially available product. The value of patient engagement from early stages of research can sometimes be overlooked when overstretched investigators need to arrange activities ad hoc or find budget for any service charges incurred. A relatively small amount of public or collective funding to run such a group that a variety of researchers can access with ease can have a large impact. In this exemplar case the total cost to run such a group was no more than £1500 per year including the salary costs for administrative time. The total global market potential for cervical orthoses is $27M. Applied over many different research areas the value of patient engagement as an investment should not be underestimated.

This project illustrated how PPIE can and should be a central theme throughout each stage of health research and innovation. This helps protect against risks of tokenistic collaboration, instead achieving partnership working at a genuinely impactful level – thus optimising opportunities for the final output to be successful and fit for purpose.

NIHR | Sheffield Biomedical Research Centre

@SheffieldBRC

NIHR | Devices for Dignity MedTech Co-operative

@Devices4Dignity

About the Sheffield Biomedical Research Centre

NIHR Sheffield Biomedical Research Centre (BRC) is a Translational Neuroscience research partnership between the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust. Our mission is to improve the treatment and care of patients living with chronic neurologic disorders by pulling through advances in neuroscience into clinical evaluation.

http://sheffieldbrc.nihr.ac.uk/

About the Devices for Dignity MedTech Co-operative

NIHR Devices for Dignity MedTech Co-operative (D4D) is a national body, hosted at Sheffield Teaching Hospitals NHS Foundation Trust. We work with patients, families, researchers, academic organisations and strategic partners to develop new medical devices, healthcare technologies and technology-dependent interventions to help people with long term health conditions to live well for longer.

https://devicesfordignity.org.uk/

About the team

The HeadUp project was led by Professor Chris McDermott of the Sheffield Institute for Translational Neuroscience (SITraN), University of Sheffield, Deputy Director of the NIHR Sheffield BRC and leader of the Long-Term Neurological Conditions Theme of the NIHR D4DMIC.

The project involved 12 cross-disciplinary researchers from across The University of Sheffield, Sheffield Teaching Hospitals and Sheffield Hallam University and was made possible by the insight of patients experiencing an unmet need and contributing to the design process, in particular Mr Philip Brindle who partnered with the project throughout.

This project was facilitated by the continued involvement of the Sheffield Motor Neurone Disorders Research Advisory Group whose mission is to empower and enable patient and public involvement in motor neurone disorders research.

Annex 1: How to read the Book of Good Practices

The Book of Good Practices cases are all structured in the same way as the Patient Engagement Quality Guidance. You will find that each case has a basic description, followed by icons to show in which phases of medicines continuum they fit in and which stakeholders they have involved in their work (see description of icons below). In section 2 these cases will describe how they reached each of the 7 Quality Criteria. You will see from the wheel in the beginning, which of the Quality Criteria they exemplified in (judged by an external group of reviewers). Finally, you will find the results and outcomes of each case and the lessons learned.

Which phases of research, medicines development, lifecycle or disease area does this PE project cover?

Research and discovery phase | **Pre-clinical phase** | **Clinical study phase 1-3** | **Health technology assessment** | **Regulatory review and approval or registration phase** | **Post-registration/ -launch activities** | **Other**

- ✔ **Research and discovery phase**
  1. unmet medical needs identification
  2. disease understanding [patient experience of the disease]
  3. drug discovery, non-clinical and candidate-identification phase
- ✔ **Pre-clinical phase** (including non-clinical, pre-clinical research, safety and efficacy tests)
- ✔ **Clinical study (phase 1-3)**
- ✔ **Health technology assessment**
- ✔ **Regulatory review and approval or registration phase** (including submitting for market authorisation request and approval)
- ✔ **Post-registration / -launch activities**
  - clinical study phase 4,
  - drug safety monitoring and pharmacovigilance,
  - Pricing and reimbursement
  - real-world evidence generation,
  - adherence,
  - patient education,
  - patient and carer support programmes,
  - disease management,
  - public health,
  - marketing insights
- ✔ **Other**

Which stakeholders does this PE project involve?

Patients and carers | **Policymakers** | **Health technology assessment organisations** | **Research funders**

Patient advocates, patient organisations and associations | **Regulators** | **Pharmaceutical companies or industry** | **Other**

Healthcare professionals | **Payers** | **Researchers**

- ✔ **Patients and carers** (including caregivers, and family members)
- ✔ **Patient advocates, patient organisations and associations**
- ✔ **Healthcare professionals** (including clinical investigators, general practitioners , specialists, pharmacists and nurses)
- ✔ **Policymakers**
- ✔ **Regulators**
- ✔ **Payers**
- ✔ **Health technology assessment organisations**
- ✔ **Pharmaceutical companies or industry** (including medical devices and biotech companies)
- ✔ **Researchers** (academic researchers and investigators)
- ✔ **Research funders**
- ✔ **Other** (for example, contract research organisations (CRO) and hospitals)

Annex 2: Descriptions of the Patient Engagement Quality Criteria

1. Shared purpose

This refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project. Consider putting in place processes to help facilitate discussions between all stakeholders to identify each other's values, expectations and objectives, and review and discuss priorities in the planning of the project. It can be valuable to enable stakeholders to exchange views openly to understand the scope and objectives of the project, acknowledging that some of their objectives may differ. All parties concerned should also have a shared written description of the common goals of the project.

2. Respect and accessibility

This refers to (1) respecting each other, and respectful interactions within the project to be established among partners, and (2) openness to and inclusion of individuals and communities (to the project) without discrimination. Considerations to ensure good conditions to implement the project should be made from the beginning. For example:

- simplification of wording
- budget and payment considerations
- cultural adaptations to procedures
- practicalities such as meeting timing, location and format
- accessibility of project materials
- written co-developed rules of conduct

Accessibility to participate may be facilitated by enabling multiple ways to involve stakeholders who could benefit from and/ or contribute to the project. For example, patients with cognitive impairment might need more time to go through project material, or need printed versions rather than electronic documents or PDFs for easier reading.

3. Representativeness of stakeholders

This refers to the mix of people you involve, which should reflect the needs of the project, and the interests of those who may benefit from project outputs (for example, target population). Consider diversity in expertise, experience, demographics, and other relevant criteria for inclusion. When selecting PE stakeholders, patients, attention will be given to awareness of the diversity required to achieve visible representative voice.

4. Roles and responsibilities

This refers to the need for clearly agreed, and ideally co-created roles and responsibilities, in writing, addressing that all aspects of project needs will be established upfront and revisited regularly.

Annex 2: Descriptions of the Patient Engagement Quality Criteria

5. Capacity and capability for engagement

This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (for example, providing a dedicated point of contact by the sponsor and having allocated sufficient time by all stakeholders to allow genuine engagement); and (2) capabilities for all stakeholders to enable meaningful engagement. (For example, the level of knowledge, expertise and training stakeholders might need to deliver PE activities throughout the project).

Consider supporting stakeholders to build the required capacity and capabilities for this project in different forms of training both with sponsor organisations and with each stakeholder (for example, helping to understand the context, processes, involved terminology etc.).

Both capacity and capability building are intended to facilitate participation and lower barriers to collaborate. Stakeholders can be given access to learning resources and given dedicated support (if needed). Capability needs may vary depending on the project needs, but also e.g. personal circumstances of PE representatives.

6. Transparency in communication and documentation

This refers to the establishment of communications plan and ongoing project documentation that can be shared with stakeholders. Communication among stakeholders must be open, honest and complete.

In addition, adequate up-to-date documentation must facilitate communication with all stakeholders throughout the project. Consider proactively and openly sharing progress updates throughout the project externally. In addition, communicating outcomes of the project to all stakeholders and how their contribution was of value to the success of the project is critical.

7. Continuity and sustainability

This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationship with stakeholders. Consideration should be given for the role of stakeholders beyond a single project. When starting the project, consider including in your project plan the actions needed for maintaining expected flow of the project from beginning to end.

Create a plan to nurture relationships with your partners and stakeholders involved during the project, and when needed and requested, beyond the project as well. For all stakeholders successful planning and personal and organisational resilience should be anticipated.