



PATIENT FOCUSED
MEDICINES DEVELOPMENT



The PFMD Book of Good Practices

2nd edition | 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

rareLife
solutions

made
with
patients

A sickle cell community built by the community for the community

Organisation: Rare Life Solutions

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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>

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A sickle cell community built by the community for the community

Organisation:
Rare Life Solutions



Basic Information

oneSCDvoice.com is an online platform specifically designed to empower its members in the sickle cell community to "self-advocate" through learning by example and by having a support group and resources at their fingertips guided by expert advocate mentors. oneSCDvoice.com is created by rareLife solutions on the backbone of its "onevoice community building software" designed to be customized from the start with the input and guidance of individuals on our "Working Groups" who represent perspectives of the multi-stakeholder community. rareLife solutions is powered by knowledgeable and experienced technologists, medical information researchers, and community engagement specialists.

BACKGROUND: Initial investigatory research and interviews with leading healthcare professionals, advocates, caregivers, patients and researchers in the area of sickle cell revealed (1) an advocacy landscape that was fractured, (2) individuals in need of trustworthy disease and lifestyle information and (3) objective resources about participating in clinical trials.

While the sickle cell community has long standing advocacy representation provided by the Sickle Cell Disease Association of American (SCDAA), founded in 1971, the landscape of organizations in the United States has proliferated yielding anywhere from 100-150 different groups, ranging in sophistication, longevity, scope and purpose. Consequently, there is a disparity within the advocacy arena making it difficult for individuals seeking guidance.

Likewise, the scientific literature in the National Library of Medicine demonstrates the large volume of papers on sickle cell with almost 28,000 papers, of which approximately 3,800 note "sickle cell" as its MeSH Major Topic. The numerous papers when combined with the explosion of information aggregated by search engines, only serves to compound the frustration and difficulty for individuals attempting to

learn more about sickle cell disease.

In the United States, approximately 97% of those diagnosed with sickle cell disease are African American. As studied and reported in the scientific literature, African Americans have historically had a reluctance to participate in clinical trials. Such trepidation is well-known and attributed in some part to programs such as the “Tuskegee Syphilis Experiment” and the experience of Henrietta Lacks at Johns Hopkins University; each have been memorialized in books and movies popularizing a disregard for humanity in the clinical trial process that occurred before improvements and safety measures created to protect patients.

THE PROJECT: The fractured advocacy landscape, proliferation of information, and the historical trepidation of African American participation in clinical trials, all conspired for the oneSCDvoice.com team to investigate initiatives to provide solutions to these issues to the sickle cell community. Seeking to “build the advocacy power of the individual” to self-advocate, we embarked on a fact-finding and perspective gathering mission to understand multi-stakeholder views of the patients, advocates, caregivers, healthcare professionals, researchers and pharmaceutical manufacturers.

The results of the discovery process, which involved numerous individual and group virtual and in-person meetings, surveys, demonstrations, conversations, and reports, yielded the following solutions:

1. an online platform, free to users was the most efficient form of media to provide the desired solution packages;
2. the platform should offer:
 - a private, registration only community social wall for people to connect and share;
 - a multi-disciplinary library of resources addressing topics related to not only sickle cell disease but also the lifestyle considerations of having a lifelong rare condition;
 - the vetted library should contain resources from various formats and sources to provide accessibility to varying degrees of educational ability and preferred learning channels (video, reading, audio);
 - the vetted library should be a “curated” experience of trustworthy resources already produced and that are available on the internet, to avoid duplication, dilution of resources, and competition with the efforts of advocacy organizations and other educators; and
 - a section dedicated to debunking the historical myths surrounding African-American participation in clinical trials and seek to create diversity in participant populations.
3. The platform should be co-created by a coalition of patients, advocates, caregivers, healthcare professionals, researchers and pharmaceutical manufacturers to provide initial and ongoing guidance to the development and research teams, which in turn, provide regular feedback to the coalition for consideration of implementation of new features or resources.

THE PLAN: The oneSCDvoice.com team set out to build a coalition of “working groups” by assessing the landscape of individuals involved in sickle cell disease from the vantage point of patients, advocates, caregivers, healthcare professionals, researchers and pharmaceutical manufacturers. Once the Working Groups had been built, they were regularly convened by the oneSCDvoice.com team to investigate such topics as content resources, look and feel of the platform, features and functions, nomenclature, taxonomy structures, search effectiveness and engagement materials including social media digital assets, conference giveaways, logos, and socialization slide decks. The Working Groups participate in the ongoing management of oneSCDvoice.com with ad hoc and regular quarterly meetings where use metrics, new resources and other issues are discussed and action plans decided to keep the platform up-to-date and address community feedback.



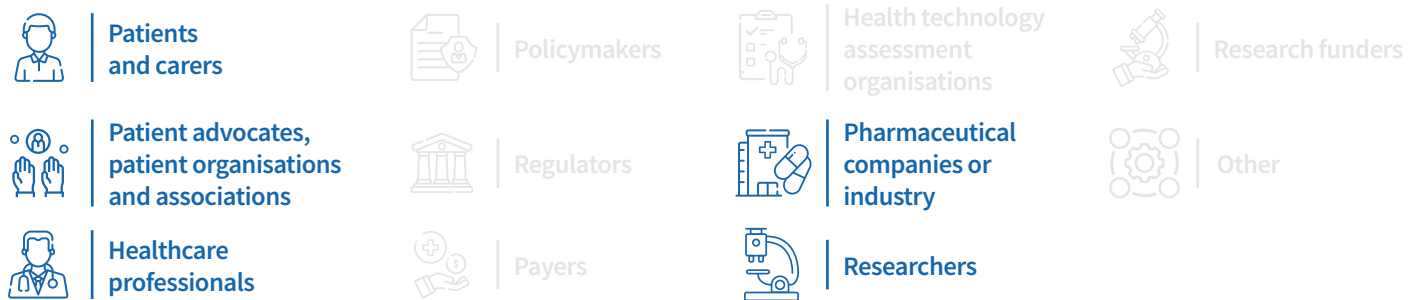
Which phases of research, medicines development, lifecycle or disease management does your PE project cover?



Post-registration/ -launch activities: real-world evidence generation, patient and carer support programmes

Other: oneSCDvoice.com is not tied directly to a lifecycle phase; in fact, its launch and longevity are development phase agnostic; we have only chosen those phases for which this particular community has been created in a point in time.

Which stakeholders does this PE project involve?



The quality of patient engagement

1. Shared purpose



What did you do to achieve this criterion?

The oneSCDvoice.com team consisting of professional developers, patients, advocates, community builders, researchers and engagement professionals, built a complex “Working Group Framework” that provided structure internally for the team to organize, solicit and track Working Group feedback and exposure to the progress of the development of all of the platform components – from user interfaces, the vetted resource library, and social wall management. This framework allowed the oneSCDvoice.com team to produce a simple yet effective communication network to obtain input and feedback on slide decks, surveys, research guidances and engagement plans from the Working Group.

Each member had their own individual assignment based on their experience, talent and interest, in addition to assignments given to all members (for example, features, functions and “look and feel” of the platform). Advocates were focused on engagement tactics while healthcare professionals and researchers were focused on guiding the oneSCDvoice.com resource research team).

Feedback was garnered through multiple avenues – surveys, individual & group meetings. During these meetings the oneSCDvoice.com team would address questions and request guidance from the Working Group member(s). Members of the Working Groups received copies of the analyzed and raw data for their own review, consumption and comment.

Having a pre-built framework for the Working Groups and submitting elements of it to the Working Group for review and comment, proved a powerful step forward in efficiency to move from planning to iteration and then actual deployment.

What is your stated “shared purpose”?

oneSCDvoice.com is specifically designed to empower its members to “self-advocate” through learning by example and by having a peer support group and trustworthy resources at their fingertips guided by expert advocate mentors from the Working Groups.

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?

Confirmation of the value and influence of the Working Groups, both individually and as a whole, is sought and procured through individual conversations, group meetings, survey results and iterative acknowledgement on the development of the platform which is shown to and accessible by the Working Groups during development and after deployment. Every quarter, the oneSCDvoice.com team meets with the Working Groups and prepares reports demonstrating how the feedback provided at earlier meetings has or has not been addressed in the platform.

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

Yes. The oneSCDvoice.com model is built on the foundational dependency of integrating multi-disciplinary leaders (patients, advocates, caregivers, healthcare professionals and researchers) on to the Working Groups to ensure balance and coverage of the topics and expertise of topics relevant to the actual community

members who are learning to self-advocate. The purpose of developing “self-advocacy” capabilities for the community members is paramount, shared and acknowledged by the Working Group members. Such agreement is parsed out during an interview process and memorialized in a written contract with each individual member.

At what time points?

Potential candidates are introduced to the concept platform and invited to apply for the Working Groups. We meet regularly with the Working Groups. At each meeting, the Working Groups are given updates followed by discussions or demonstrations to advance to the next milestone. In addition, at each meeting, the focus for each discussion is: “Is this what the community needs and/or wants?”

2. Respect and accessibility



How have you addressed respect and accessibility in this project?

The oneSCDvoice team readily acknowledges its position and role as a steward of the sickle cell community information and a facilitator of building solutions that reflect the stated needs and wants of the community.

There are two aspects to consider for the oneSCDvoice.com initiative to address respect and accessibility. The first is the Working Group membership. As part of the outreach process, candidates with expertise in a particular aspect of SCD and / or extensive advocacy work, are extended an invitation to apply to the Working Groups. Such individuals are also interviewed for their capacity and desire to be involved in a collaborative coalition.

The other aspect is the community membership who are using oneSCDvoice.com social wall and the trusted resources library. A measure of success for oneSCDvoice.com is to build a “safe and positively-charged” social wall experience where members can participate to seek answers, knowing their most private information is being shared.

The oneSCDvoice.com team, in conjunction with the Working Groups, built a multi-tiered process to protect our members and provide them with a positive experience:

1. appropriate disclosures and participation guidelines:
 - the Code of Conduct provides a simple, easy to read understanding for the membership regarding the guardrails around communicating on the social wall and with other members;
 - the Privacy Policy provides a straightforward explanation of how data collected on the social wall is used and reminds members to guard their privacy to the extent they wish;
 - the “First-Post PopUp” reminds the community member about salient points of the Code of Conduct before they post their first message;
 - FAQs are available for additional easy-to-read guidance surrounding conduct using the platform; and
 - the Terms of Service provides guidance to the membership regarding the use of oneSCDvoice.com;
2. the oneSCDvoice.com team, selects, interviews and hires individuals from the community (typically a patient, caregiver or advocate) and after completing training by the oneSCDvoice team on diplomacy and dispute-resolution methods, who moderates and responds to all posts using text and links from the knowledge library to create a positively-charged and educational environment; and

3. a software system that scans all posts for various “trigger words” (for example, foul or inappropriate language) which violate the Code of Conduct and may require some additional action that ranges from deletion of the post, or revision. In that case the Community Manager contacts the community member directly and explains why the post is not adherent to the Code of Conduct and suggests how it could be modified to be compliant.

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

With respect to our Working Groups, there is a high level of professional decorum and respect. The oneSCDvoice.com team provides access to engagement by tailoring communication channels and media review to the individual’s particular needs and preferences. For example, to ensure the 25 Working Group members could review and be heard on a particular aspect of development, the oneSCDvoice.com team held 6 “webex” virtual meetings over 2 days to provide scheduling convenience to each member (considering existing responsibilities, geographic time zones, and other commitments).

With respect to our community members, the oneSCDvoice.com platform has proven to provide civil online conversation due to (1) the particular disposition of individuals attracted to a “serious” educational platform and (2) the multi-tiered safety program (code of conduct, software monitoring, and human moderation with dispute resolution capabilities). The oneSCDvoice.com platform provides accessibility to anyone with an internet connected device anywhere in the world taking into account: (a) responsive design for a user-friendly mobile experience across desktops, smartphones and tablets, and (b) the trusted resources library is open to anyone without registration to oneSCDvoice.com (only the social wall and some additional features require minimal email registration).

3. Representativeness of stakeholders



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

The Working Groups have experiences and perspectives of varied roles valuable to the sickle cell ecosystem including: patients, advocates, caregivers, healthcare professionals, researchers and pharmaceutical manufacturers.

The oneSCDvoice.com team has a process for assessing the literature and information needs of the community to gain a basic knowledge regarding the issues surrounding the disease and lifestyle. Consequently, a matrix of specific expertise categories is created to ensure that the various aspects of the disease and lifestyle will be addressed by inviting leaders who have expertise in that particular category. Within each role are members with expertise to address particular topics (for example, the Working Group would not have multiple hematologists per se due to their “key opinion leader” reputation, but rather a hematologist for adults, and a pediatric hematologist to help parents understand their children’s needs would both be invited). Additional expertise may include: psychosocial issues, community healthcare, medical specialties and subspecialties, genetic counseling, advocacy, caregiving, social networking, etc.

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

The Working Groups and community members are queried through regular contact, polls or formal surveys to determine their level of satisfaction with the outcomes of their guidance and feedback in the co-creation,

development, deployment and ongoing iteration of oneSCDvoice.com. The results of those polls and surveys are digested and analyzed by the oneSCDvoice.com team to share back with the Working Groups for additional feedback.

The community members are also surveyed using “Customer Satisfaction” surveys to understand various specific issues (including content topics and formats). The oneSCDvoice.com also surveys the community membership to calculate the Net Promoter Score (NPS) of oneSCDvoice.com. NPS is a management tool that can be used to gauge the loyalty of a brand’s customer relationships. Given the NPS range of -100 to +100, a “positive” score or NPS above 0 is considered “good”, +50 is “Excellent,” and above 70 is considered “world class”. Based on global NPS standards, any score above 0 would be considered “good.”

oneSCDvoice.com achieved NPS of +50 (excellent). By comparison, Amazon has a +61 NPS and facebook has a NPS -21.

4. Roles and responsibilities



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

Written contracts provide the formal relationship memorializing the roles and responsibilities of each Working Group member, including a schedule of meetings, time commitments, and a description of the work to be performed.

Each member of the Working Group is given specific written assignments to provide feedback and review materials including:

1. surveys (both taking individually and reviewing the collective Working Group results);
2. links to content for potential inclusion in the resource library to match with pre-established quality criteria;
3. guidance strategies and tactics for research and engagement of the community-at-large; and
4. static mockups and staging versions of oneSCDvoice.com

Virtual ad hoc or structured meetings are held weekly and monthly, respectively, before the launch of the platform and post-launch virtual meetings are held quarterly.

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

As part of the contractual arrangement, in the event a Working Group member is unable to complete an assignment, a oneSCDvoice.com team member is assigned to connect with that Working Group member to provide any assistance or clarity that might enable completion of the assignment.

At what frequency have you checked this in?

The oneSCDvoice pre-launch process requires frequent contact, including daily, weekly or monthly depending upon the situations being presented.

5. Capacity and capability for engagement



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

Members of the Working Groups were objectively evaluated using criteria that allowed the oneSCDvoice.com team to select individual candidates that were “fit for purpose” based on the needs and wants expressed by the community. Additional evaluation was performed regarding the candidate’s capabilities and interests, and the candidate’s feedback of the oneSCDvoice.com team’s expectations.

The role of community management is an emerging profession. Upon completion of the training provided by the oneSCDvoice team, the Working Group members understand how to manage a social wall to resolve disputes, enforce adherence to the community Code of Conduct, and create a safe, positive experience which engenders membership satisfaction and trust.

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

During our ad hoc conversations and as part of our regular meetings, we provide the opportunity for each Working Group member to comment on the delivery of their assignments and engage in live discourse with other Working Group members.

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 oneSCDvoice.com team used its Working Group Framework to provide a schedule of milestones to the Working Group members. The schedule provided details of the communications the Working Groups would be receiving as part of any pre-meeting preparation and any post-meeting follow up.

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

The Working Groups are contracted using simple and easy to understand language setting out their roles, responsibilities, deliverables and a schedule for completion. The oneSCDvoice.com team tracked each Working Group member against the contract obligations to understand compliance and implementation.

7. Continuity and sustainability



What did you do to achieve this criterion?

At the outset, the oneSCDvoice.com team provided long term contracts to each Working Group member using simple language ensuring that each individual understood the commitment was not just to build an online community and launch it, but to nourish and grow it over time. The commitments were clearly delineated during both the pre-launch phase and the post launch maintenance phase.

While the Working Group Framework selected virtual “webex” meetings and teleconferences over face to face meetings (mostly to respect time commitments of Working Group members), the oneSCDvoice.com team traveled to numerous patient conferences to meet face to face with Working Group members also in attendance. These face to face meetings provided positive relationship building opportunities that are reflected in expanded activities.

As relationships were building between the oneSCDvoice.com team and the Working Group Members, additional projects with members outside the scope of the original oneSCDvoice project began to blossom. Understanding more about the missions of the individual patients and advocates deepened the learning for the oneSCDvoice.com team to become aware of many new ways to engage with the community (for instance, awareness tours, educational programming, conferences, social media campaigns).

How did you gather feedback on what you have done?

The Working Group-oneSCDvoice.com-Community Member feedback loops consist of formal surveys, polls, group teleconferences / webex meetings and informal ad hoc discussions.

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

The initial discussions between the oneSCDvoice.com team and the potential candidate for a position on the Working Groups were very clear about the roles and responsibilities of becoming a member. The details were set forth in writing for consideration by each invitee prior to such individual applying for membership on the Working Group.

Results and outcomes

The oneSCDvoice.com team set numerous key performance indicators (KPIs) to measure the success of the oneSCDvoice.com platform. The development of the KPIs took into consideration the innovative nature of the project and the lack of appropriate surrogate benchmarks which may normally provide relative assessment measures.

Objective KPIs evaluated that were collected by the interaction of people with the oneSCDvoice.com platform:

1. registered members – number of members, frequency of over specific periods
2. engagement with social wall – number of posts, frequency of posting, length of posts
3. polls & surveys – number of polls completed
4. engagement with trusted resources – click data regarding links, including time on page
5. visitor traffic for unregistered members – engagement with trusted resources
6. SEO page ranking changes over time
7. Net Promoter Score – currently +50 (excellent)

Additional feedback was collected using “Membership Surveys” and polls administered to registered members.

Positive impact for specific medicines development phases

The use metrics of the knowledge library has identified unmet educational needs of the community including deeper education about clinical trials and overcoming the barriers to diversity in clinical trial participation. The polls and survey results demonstrate numerous insights about patient preferences and perspectives, however, a valued insight is the high percentage of registered members answering multiple polls. Attraction opportunities using social media has identified topics of interest to the community that are compelling, and conversely, topics that are of little interest.

Direct or indirect positive impact for patients

Patients have overwhelmingly communicated that oneSCDvoice.com provides a sickle cell “home on the internet” for them which they will recommend to others (as evidenced by an excellent Net Promoter Score of +50). The patient segment of the membership scores the quality of and access to vetted resources as 9.3 (out of 10) and that having such a library has improved their knowledge of sickle cell issues “significantly” (76%).

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

The non-patient members of the Working Groups and the registered community members have expressed a “significant” (53%) or “slight” (19%) increase in their understanding of the patient experience, preferences and needs from prior to their interaction with the oneSCDvoice.com platform. Only 5% responded the platform had a “negative impact” on their knowledge of sickle cell disease and its associated lifestyle issues, while the remaining 23% responded “no change” with respect to the same.

Lessons learned

The oneSCDvoice.com team has culled the following lessons:

1. active listening to all stakeholders provides a platform for open sharing;
2. creating a coalition of multi-disciplinary stakeholders on par with each other exponentially increases ideation and creativity;
3. feedback loops to the at-large community provides not only insights but invaluable loyalty by the community members;
4. general email solicitations and awareness campaigns generally do not resonate with the sickle cell community;
5. consultation with community leadership from the outset in creating oneSCDvoice.com allowed avoidance of costly missteps and provided a patient-focused service that truly resonates with the end user as an authentic home on the internet.



 @rarelifetalks

About the organisation

rareLife solutions specializes in 3 elements critical to the successful development of treatments for rare diseases: collaboration, science and technology. We offer integrated scientific communications, medical publication services, and authentic online community building solutions for advocacy groups, pharmaceutical and device companies, medical and research centers, and professional healthcare associations.

About the team

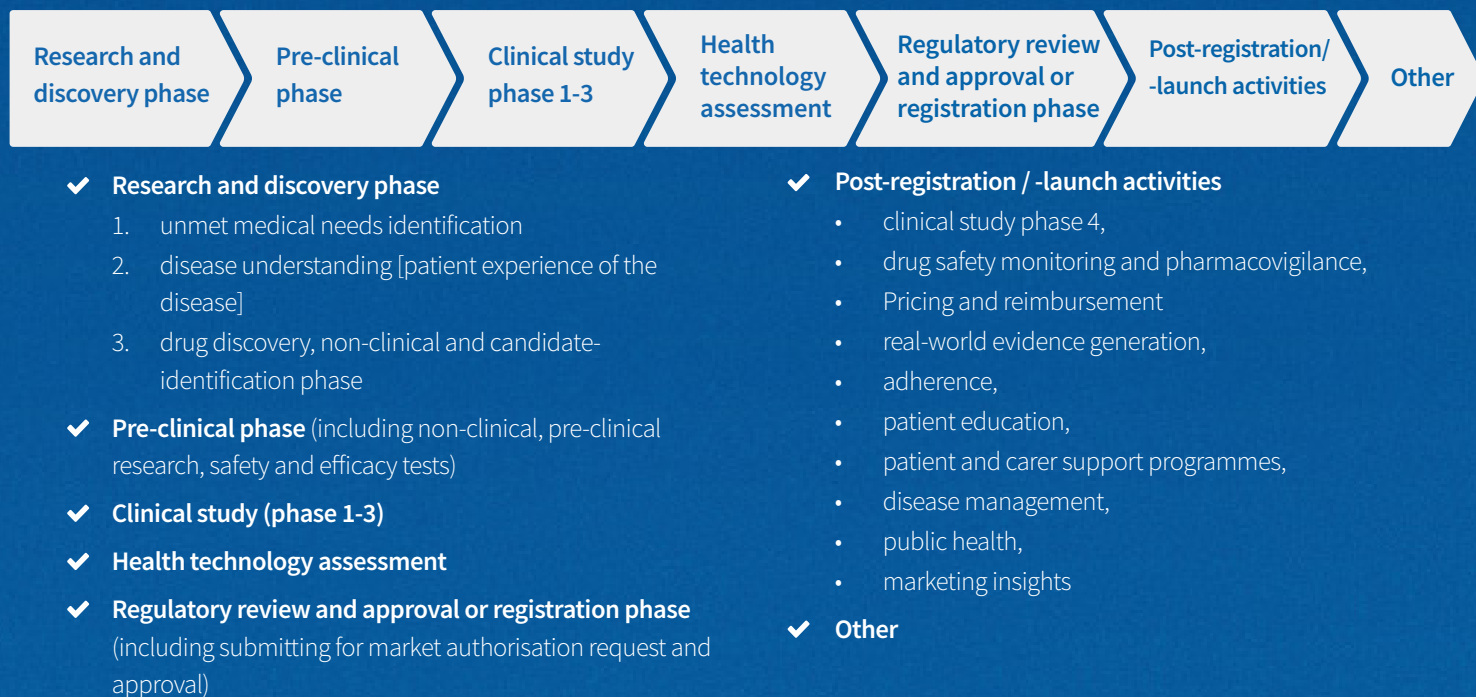
Individually we are scientists, planners, techies, creatives, writers, thinkers, and doers—but together we are rareLife solutions. We are veterans of pharma, med comm, publishing, and advocacy who realize that saying “rare is different” or “we are patient-centric” isn’t enough. At rareLife, we recognize that in rare diseases, patients, advocates, and caregivers (PACs) are the primary shapers of their rare disease ecosystem—we call this insight rareForward. We use disruptive rareForward thinking and doing to transform how people living with a rare disease talk with, listen to, and learn from each other—ultimately redefining success for rare PACs and rare industry. One of the ways we do this is by harnessing the power of collaboration, science, and technology in our flagship onevoice platforms. Each disease-specific onevoice platform builds a high-performance community of diverse stakeholders who are educated, motivated, and engaged. Our rareForward way of thinking and doing ensures that all of our work— integrated scientific communications, medical publication services, and authentic online community building solutions— is optimized for the special challenges and opportunities in the rare space.



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?



Which stakeholders does this PE project involve?



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.