

**The Drug Information Association
Diversity and Inclusion in Life Sciences Community
Response to the 2021 PCORI RFI**

[The Drug Information Association \(DIA\)](#) appreciates the opportunity to provide comments and perspectives from various members of our Diversity and Inclusion in Life Sciences Community, referred to herein as the DIA D&I Community. Please find them below for your consideration.

DIA D&I Community Response:

1. People Groups: The DIA D&I Community is introducing the term “people groups” to simplify discussion of the various ways that people can be differentiated. People can be grouped by many combinations of race, ethnicity, educational background, geography, gender identity, sexuality, or many other defining characteristics. This term is meant to allow as much flexibility as possible in designing research questions which seek to measure the degree of difference in access, outcomes, and engagement. It allows examination of how various combinations of the social determinants of health (SDOH) may impact which approaches work well without specifying or limiting those combinations. It is also more human than the term demographics.

PCORI RFI: “In reference to the table above, Potential Topics of Inquiry to Understand the Science of Engagement, do you feel these are the right topics? Are other topics or areas of inquiry missing? How would you prioritize or stage addressing these topics?”

1. PCORI RFI: What defines successful engagement, and for whom? What outcomes demonstrate whether engagement has achieved the stated aims or goals? What impact does engagement have on longer-term aims (e.g., improving decisions and health outcomes) and how can impact be increased and sustained?
 - a. DIA D&I Community Response: Please refer to the following that includes great examples of various levels of engagement:
New research to define, facilitate and assess successful engagement should build upon existing scholarship and practice. For example, the global coalition for Patient Focused Medicines Development (PFMD) has developed quality guidance for patient engagement in “the active and meaningful involvement of patients and carers as active participants and collaborators in developing medicines”.³ They involved many stakeholders, including patient advocates, the public, research organizations, and independent experts in their work to research, develop and implement a “practical and actionable framework”¹ for starting and sustaining patient engagement (PE). The resulting framework¹ defines specific levels of engagement, which from highest to lowest are:
 - i. **Co-design** (*where higher level is empowerment*): Patients are involved in innovating, designing, developing, and formulating solutions and alternatives, and in each aspect of the decision-making process. Recommendations are incorporated into decisions to the maximum extent possible.
 - ii. **Higher level**: Patients have decision-making power

- iii. **Involve** (*including collaboration*): Working or partnering with the patient community directly and throughout the process; preferences, concerns, and expectations are taken into consideration; and patients know how their input influenced the decision.
 - iv. **Consult**: Obtaining input, preferences, and feedback on project, analyses, decisions, etc.
 - v. **Inform**: No involvement or engagement. Main goal is to keep the patient or public informed about the project.
 - vi. To facilitate meaningful engagement, the consortium releases an annual Book of Good Practices with case examples of research reviewed against the criteria for strong PE. Each of the seven PE quality criteria they use, “contain a definition, a rationale and questions for consideration by the initiative owners used for planning and/or evaluation purposes for each criterion”.³
 - vii. Additional tools and knowledge may be available from other fields doing community engaged research and scholarship.⁴
- b. DIA D&I Community Response: Please consider the following perspective: Greater engagement of populations underrepresented in COR research is essential to close the efficacy-effectiveness gap and should result in improved outcomes in these populations.
A desirable outcome of funding from this RFI is improved health, particularly for patient groups that currently have relatively poor outcomes (as can be seen when looking at outcome differences by factors such as race, ethnicity, sex, gender, socioeconomic status, geography, age, education level, and environmental exposures). These differences are contextual factors that contribute to efficacy-effectiveness gaps as health innovation moves from clinical research into wider clinical practice.⁸ Closing these gaps requires learning from the experience and needs of patients, their families, their caregivers, and the wider networks that influence their options and choices. This requires inclusion of diverse patient groups and the diversity of settings where people live and receive health care.
- c. DIA D&I Community Response: Please clarify how the definition of success differs across diverse people groups.
- d. DIA D&I Community Response: Please consider the following recommendation to include a sub question regarding how to ensure you have a representative sample of the people PCORI would like to measure.
- e. DIA D&I Community Response: Please clarify which of the following is PCORI's goal versus endpoint?
 - i. Health Equity
 - ii. Health Disparities
- f. DIA D&I Community Response: Please clarify what PCORI means by successful engagement?
- g. DIA D&I Community Response: Please carefully consider the power of data. If acquisition of additional data is a consequence of successful patient

engagement, then those collecting or in possession of the data must demonstrate responsibility with its use and earn the trust of contributors. Please consider these points for reflection:

- i. What power will patients and individuals have over their data?
 - ii. How do we demonstrate that the purpose for the collection of data is not simply to build new commercial marketplaces (beyond and including precision medicine and personalized medicine/treatments)?
 - iii. How do public health policy minders and those in clinical research avoid breaking trust and not create modern day abuses of trust or misuses of data, therefore, leaving no control to the contributor?
 - iv. What protections need to be put in place for patients and individuals to protect their data/information?
 - v. What role(s) do public health policy makers and other clinical research stakeholders play?
 - vi. How does PCORI fit into this equation?
 - h. DIA D&I Community Response: Please consider the practice of PE and patient education and consider the following point for reflection:
 - i. What other industries can we learn from that have achieved successes and addressed challenges while learning to spread knowledge and unite communities? (e.g., virtual education platforms in public school and medical school/clinical research training) (Related references can be found in the references section under reference 6 and 7 of our response document)
2. PCORI RFI: How can engagement be measured? What indicates that a study is patient-centered? More robust evidence also requires the development and use of validated measures of engagement, patient centeredness, and their influence on research conduct, and impact and uptake of results.
- a. DIA D&I Community Response: Please consider the following comment: What steps need to be taken to ensure measures are effective across different people groups?
 - b. DIA D&I Community Response: Please consider the following comment: How do engagement measures differ across different people groups?
3. PCORI RFI: What are the approaches that support and achieve successful engagement? For example, what specific tools and interventions support engagement, particularly what approaches support diversity, equity, and inclusion in both engagement and in research findings.
- a. DIA D&I Community Response: Previous work has described critical factors that researchers must consider when seeking to engage communities and other stakeholders. It is already established that engagement is not a “just-in-time” checkbox needed to start a study⁴. These points cited and made in 2008 by Goering et al. remain unaddressed by most initiatives that seek to improve trust and engagement with patients and their communities:
 “It is not rational to trust those who have a track record of disrespectfully treating members of a community you identify with...or who take no interest in

what members of your community have to say to them or in the effects that their views about your community have on the people in it. Given the depth and pervasiveness of social, political, and economic inequality in the United States today, it needn't take malevolence or malfeasance for researchers to act in ways that give rise to such perceptions. Ordinary, orthodox scientific method is frequently sufficient.'

In other words, individual researchers need not intend any neglect of marginalized populations, but their active participation in a practice whose structure maintains that marginalization, even while treating it as an object of study, means that they must respond to the neglect. The responsible thing to do...is to share the power with those who are less privileged and work with them for their benefit."⁴

- b. DIA D&I Community Response: Please consider the following comment: What impact do the social determinants of health have on which approaches work well for different people groups?
- c. DIA D&I Community Response: Please clarify or consider for reflection how this question/point differs between differing people groups.
- d. DIA D&I Community Response: Please consider integrating learnings from other industries which depend on critical connections and engagement (e.g., education/academia)
- e. DIA D&I Community Response: DIA and the DIA D&I Community could partner with Dr. Jennifer Kim to investigate one of the following:
 - i. The types of deterrents (e.g., racial microaggressions) that people groups experience in their everyday healthcare that could deter them from participating in clinical trials
 - ii. Discrimination experienced by patient person groups, such as Asian Canadian and Asian Americans, during the COVID-19 pandemic as an extension of work already published on this topic among healthcare workers (ref: <https://www.cmajopen.ca/content/9/4/E998>)
- f. DIA D&I Community Response: Please consider the following two organizations that have been very successful at both engaging patients and ensuring diversity of all types. Both organizations work directly with communities and, therefore build the relationships and levels of trust necessary for successful engagement.
 - i. ClinArk - <https://www.clinark.org> - contact Adam Brown
 - ii. Lazarex Cancer Foundation - <https://lazarex.org> - contact Marya Shegog
- g. DIA D&I Community Response: Please consider the researcher Dr. Glenna Crooks as she has done extensive work to illuminate the power of the community and highlight that we are ultimately influenced by our community. She states that when working with people, we have got to consider community.
 - i. Link to presentation of Dr. Crooks' work - <https://inspiredhealthstrategies.com/wp-content/uploads/2021/11/Slide1-1.jpeg>
 - ii. Link to Dr. Crooks' website - <https://glennacrooks.com/>

4. PCORI RFI: Under which conditions do approaches work best and how should they be modified and resourced for different contexts, settings, and communities? This question focuses on the context in which a study or engagement is being carried out (e.g., the type of study, patient and stakeholder partners, history of (mis)trust, experience with research partnership).
 - a. DIA D&I Community Response: Please consider reversing the question as such: Which approaches work best under different conditions for different contexts, settings, and communities? You can change the approach, but it is difficult to change the "conditions".
 - b. DIA D&I Community Response: Please consider which and how methods and measurements are applied that can lead to successful and equitable engagement, without having a negative impact on patients.

PCORI RFI: "What methods and study designs would be appropriate for producing evidence to address the areas identified in the Potential Topics of Inquiry to Understand the Science of Engagement table? Can you provide any illustrative examples?"

1. PCORI RFI: What defines successful engagement, and for whom? What outcomes demonstrate whether engagement has achieved the stated aims or goals? What impact does engagement have on longer-term aims (e.g., improving decisions and health outcomes) and how can impact be increased and sustained?
 - a. DIA D&I Community Response: Please consider the following example, Analysis of patient engagement landscape done by the Patient Focused Medicines Development initiative: <https://innovations.bmj.com/content/5/1/43>

PCORI RFI: "What innovations in research approaches are needed to most effectively produce the evidence needed?"

1. DIA D&I Community Response: Please consider the sensitivity to culture, race, ethnicity, gender identity, and sexuality.
2. DIA D&I Community Response: Please consider involving patients and communities in designing this research on their engagement so that the results are relevant for them.
3. DIA D&I Community Response: Please consider building upon the numerous examples of guidance/practices for engagement of patients and communities in research.
4. DIA D&I Community Response: Please consider the implementation of a standard format for collecting data or delivering information upfront. Consider including the study team, community members, and advocacy group and ensure they are comfortable with what is being collected or distributed to their communities.
5. DIA D&I Community Response: Please consider the implementation of a standard format for collecting data or delivering information upfront. Please consider ensuring that the study team, community members, and advocacy group are comfortable with what is being collected or distributed to their communities.
6. DIA D&I Community Response: Please consider the implementation of practices and study designs that address technology and social media platform disparities and consider the 360-degree surrounding environment of the patient, their family, their caregiver, their community needs, and the lack of social and political structures that can support an improved quality of life.

PCORI RFI: “What outcomes are important and appropriate for studies of engagement? What measures are most important to develop, validate, and use to quantify and to understand the quality and impacts of patient and stakeholder engagement in health research?”

1. DIA D&I Community Response: Please consider the following outcomes that are important and appropriate for studies of engagement:
 - a. Please ensure that the patients feel a sense of belonging. Belonging is one of the essential elements of engagement, in addition to elements such as trust and psychological safety. Dimensions of belonging have been described by Erik Carter² and range from the most basic experiences - being present and invited to higher levels that reflect active engagement - being accepted, supported, and cared for. This work has been applied to engagement in workplaces and in education⁷ but remains relatively unexplored in the context of engagement for COR. Please consider belonging as one of the recommended areas for study under this RFI.
 - b. Diagnosis
 - c. Access
 - d. Response to prescribed treatment or other intervention
2. DIA D&I Community Response: The role of trust for engagement in biomedical research has been the subject of past research but has not yet been sufficiently applied to engagement of patient groups in research and health implementation. Consuelo Wilkins and colleagues at Meharry-Vanderbilt developed an early framework for dimensions of trust that consider historic and ongoing influencers of key patient groups¹⁵ which was presented at the November 19, 2015, National Academy of Medicine workshop, “Taking an Implementation Science Approach to Genomic Medicine.” A more extensive analysis of trust for engagement in research has been published by Dr. Wilkins in the context of community participation in the NIH All of Us initiative.¹⁴ Please consider that further work under this RFI, prioritize effective implementation of these and similar approaches.
3. DIA D&I Community Response: Please consider:
 - a. How to support agency, power, ownership, legitimacy, and presence within patients and others.
 - b. How to support individuals’ understanding of how data is being used, encourage their input into study designs, and design in the ability to ask questions and receive answers.
 - c. How to counter feelings of powerlessness and vulnerability.
 - d. The use or collaborative work with Participatory Action Research (PAR) projects within communities.¹⁰
 - e. The PhotoVoice tool to visualize the voices of those PCORI seeks to engage and as a narrative of their experiences. This anthropology-based tool has been used to amplify actual experiences and provide awareness to public health policy makers and other stakeholders.⁹
4. DIA D&I Community Response: Please consider the usage of social network analysis tools (e.g., sociocentric network analysis and egocentric network analysis). For example, Sociocentric network analysis could be used to deeply examine, better understand, and seek deficits between the network of connections between patients (as a stakeholder

group) and all other clinical research stakeholders. Measurements such as number, intensity, and frequency of links between patients and stakeholders, can be used for evaluating the density and strength of existing connections, as well as opportunities for improved cross-stakeholder network connections.⁶

PCORI RFI: “What challenges do you foresee for stand-alone research studies on engagement? What award characteristics (e.g., structures, requirements, areas of flexibility), resources, or other supports would facilitate stand-alone research studies?”

1. DIA D&I Community Response: Please consider defining comparator groups. Please note that there is a need to look at results by people group and results by intervention type.
2. DIA D&I Community Response: Please note that some groups that work in this space may not be as formally trained as one would hope. Therefore, please consider structuring the funding to ensure that people in these various communities are not excluded because they do not have a staff member with a higher degree such as a PhD.

PCORI RFI: “What challenges do you foresee for SWAS on engagement? What award characteristics (e.g., timing relative to parent study, requirements), resources, or other supports would facilitate stand-alone research studies?”

1. DIA D&I Community Response: Please note that engagement is a variable that can change over time. Therefore, please consider framing the funding to support studies on improving and sustaining engagement.
2. DIA D&I Community Response: Please note the challenge of developing transferable methods. Effective methodologies are not necessarily one-size-fits-all and may be dependent on unique characteristics of communities, populations, groups, etc., and thereby may require unique solutions.

PCORI RFI: “What questions do you have about the potential development of a future funding initiative that PCORI should address as we develop materials for potential funding opportunities?”

1. DIA D&I Community Response: Please consider the following question for reflection: What are the lessons learned from PCORI-sponsored studies using patient or community engagement? (Note: There are up to 95 on clinicaltrials.gov as of 2-Nov-2021)
2. DIA D&I Community Response: Please consider the following question for reflection: What was added or changed in engagement after the 9-Dec-2019 Board of Governors mtg - slides 32-69 in <https://www.pcori.org/sites/default/files/PCORI-Board-Meeting-Presentation-Slides-120919.pdf>
3. DIA D&I Community Response: Please consider the following question for reflection: How will the new initiatives be informed by existing initiatives from the National Academy of Medicine, FDA, patient organizations, and other stakeholders?

PCORI RFI: “Would you or your organization be interested in pursuing this funding initiative, including as a partner, based on the above description? Why or why not? If not, please elaborate on the reasons.”

1. DIA D&I Community Response:
 - a. DIA would be very interested in pursuing this funding initiative and partnership with PCORI. DIA’s mission includes providing neutral forums to exchange vital information and discuss current issues related to healthcare products, technologies, and services while also building, maintaining, and facilitating

trusted relationships with and among individuals and organizations that drive and share our values.

- b. DIA understands that a patient's engagement throughout the medicine's lifecycle contributes to a better understanding of their needs and preferences, which ultimately leads to improved health outcomes. One other important aspect is looking at the organization's readiness to put the patient at the heart of all they do across the entire drug development lifecycle. DIA held our first [Diversity, Equity, and Inclusion in the Drug Development Lifecycle](#) meeting in April 2021 to convene various stakeholders where they moved beyond describing the problems that exist in this space by emphasizing approaches and solutions in which our field has been investing. DIA is actively looking for partners as we are currently working on developing a follow-up workshop in 2022 to continue the conversations and provide hands-on approaches and learnings that attendees can take back to their own organizations and companies for implementation.
- c. DIA has engaged in research to support leadership adoption of best practices in patient engagement since 2014. In 2020, DIA created a new research functional area within the organization to further support future and current efforts through our strategic partnerships in patient engagement and medical product development. We would welcome the opportunity to discuss a research partnership to meet the needs of the community flowing from this RFI, particularly where DIA and the DIA D&I Community could contribute our collective expertise and access to stakeholder groups (in this case primarily patients, industry leadership and regulators) to inform a project. In the DIA model we would partner with a research institute or researcher to execute the project collaboratively.

PCORI RFI: "What should PCORI keep in mind to ensure that these potential research opportunities (stand-alone research awards on the science of engagement, and SWAS) are inclusive of and accessible to all types of organizations and communities? How can we best support the community to ensure high-quality applications?"

1. DIA D&I Community Response: Please consider including leaders of the people groups in question when designing the offer and judging the awards.
2. DIA D&I Community Response: Please consider asking the people and communities directly what it means to be inclusive and accessible.
3. DIA D&I Community Response: Please consider providing culturally, ethnically, racially, etc. sensitive education on the process to the various people groups and communities. Please clearly define what "high -quality" means in this context.
4. DIA D&I Community Response: Please consider requiring proponents to include details about the involvement of diverse communities in creating their research plan.

PCORI RFI: "How can PCORI promote connections between organizations, communities, and qualified researchers for this potential future funding initiative if not currently available to them?"

1. DIA D&I Community Response: Please consider the perspective that going into communities and organizations that don't value their own work on this scale, could potentially scare them away.

PCORI RFI: "Science of engagement research projects (stand-alone research awards or SWAS) may vary in intensity. What level(s) of funding for a science of engagement research project would you or your organization consider pursuing? Check all that apply"

1. DIA D&I Community Response: DIA has typically executed on research projects with funding in the \$250,000-750,000 range that have a duration of 12-18 months. These funds support DIA research and staff time, the inclusion of patients and community members, and work of a university partner. Research projects focus on furthering patient engagement, diversity, equity, and inclusion in the life sciences research and development space.

PCORI RFI: Science of engagement research projects (stand-alone research awards or SWAS) may vary in length. What timeframe for a science of engagement research project would you or your organization consider preferable? Check all that apply.

1. DIA D&I Community Response: One year and Two years

PCORI RFI: Please select the stakeholder group you primarily identify with to help PCORI contextualize subsequent responses:

1. DIA D&I Community Response: Other: Global life sciences research and development nonprofit

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- DIA’s Diversity and Inclusion in Life Sciences Community collaborated on these efforts utilizing the website MURAL. The below is a screenshot of our collaborative efforts to produce our response to the RFI. Thank you for your consideration.**

