

# Stakeholder Engagement and Diversity and Inclusion in Your Pain Research

## What is Stakeholder Engagement?

Stakeholder engagement is a process of proactively communicating with all those who have an interest in research to consider and incorporate their needs, concerns and perspectives. Stakeholders should be considered as equal partners, in all aspects of research.



## Stakeholders are:

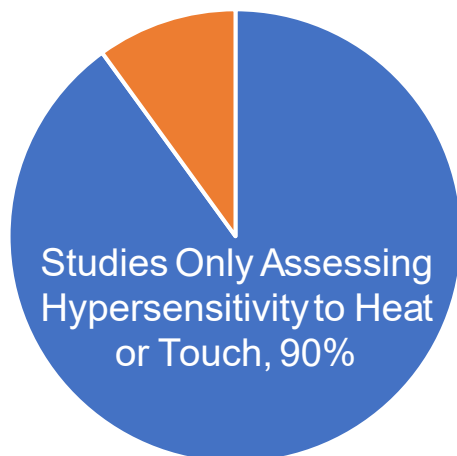
- Scientists
- Patients
- Clinicians
- Policymakers
- Payers
- Industry
- Families
- Caregivers
- Health systems
- Community leaders



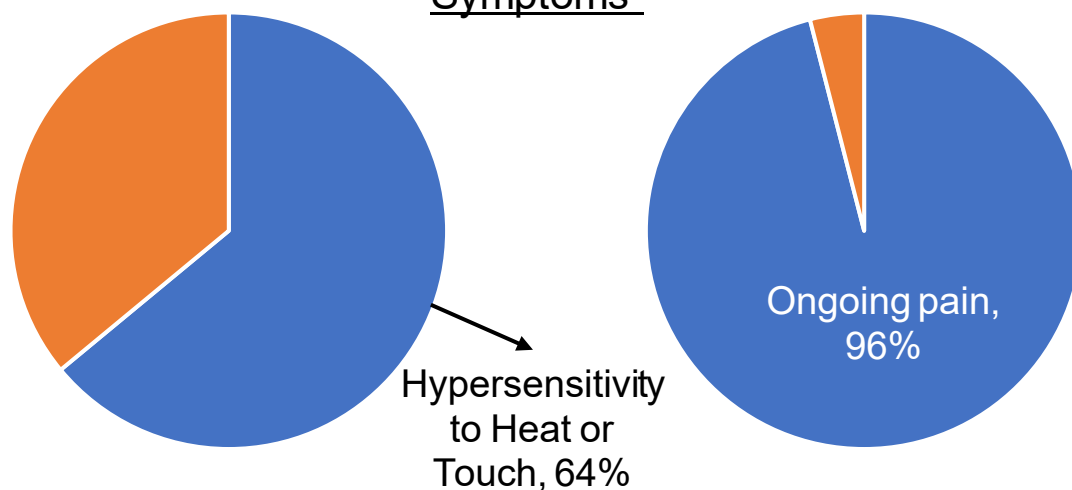
**Engagement leverages the experiences of all stakeholders, which can ultimately increase the use and acceptance of research results.<sup>3</sup>**

Most preclinical neuropathic pain studies only assess hypersensitivity, while more patients with neuropathic pain report ongoing pain as a key symptom. Considering stakeholder perspective can help realize the unmet need for treatments to address chronic pain. Visit [here](#) for more information.

Preclinical Neuropathic Pain Studies<sup>1</sup>



Percentage of Neuropathic Pain Patients Reporting Symptoms<sup>2</sup>



## Plan for Stakeholder Engagement

Start early to plan for active engagement of stakeholders in your research. Consider involving stakeholders at every stage of the research project. Work with your stakeholders to devise an engagement plan that<sup>4</sup>:

- Identifies how a study can benefit from engagement and sets goals to realize these benefits
- Specifies relevant tasks for each stakeholder, particularly in support of recruitment and retention
- Budgets for fair compensation for stakeholder activities
- Describes how engagement will be monitored and how study results will be disseminated

## At the Heart of Engagement is Inclusion

Inclusion of underrepresented populations is mandated by law and critical to ensure that study results apply broadly for chronic pain sufferers<sup>5, 6</sup>. “Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.”<sup>7</sup> Factors such as sex, age, race/ethnicity<sup>8</sup> and life experiences<sup>9</sup> influence the perception and impact of pain. For example, research has shown that past discrimination is associated with increased pain sensitivity in African Americans, mediated by increased activation of frontostriatal brain regions<sup>10</sup>. Therefore, diversity is key to achieve a study population that is representative of chronic pain sufferers in demographics and experience.



### Ensuring Diversity Requires Planning

Barriers to achieving diversity in clinical trials are: 1) Mistrust of research and the research community; 2) Logistical and financial burdens and; 3) Limited awareness of and appreciation for clinical trials and their value<sup>11</sup>.

These barriers can be addressed by adopting inclusive, culturally competent practices for enrollment and retention as well as making trial participation less burdensome.

Specific strategies for improving recruitment and retention of underrepresented populations include:

- Adapting recruitment strategies for cultural and linguistic backgrounds
- Enlisting culturally and linguistically competent investigators and research staff to facilitate acceptance
- Including families and communities in the clinical study process
- Partnering with community organizations to increase awareness and trust

For the newest class of migraine medications (molecules that target Calcitonin Gene Related Peptide) African Americans (13.4% of US population) made up only

**8.4%**

of the participants in the efficacy studies submitted to FDA.

### Consider Diversity in your Animal Studies on Pain

It has been found that mechanisms for chronic pain development may differ by sex<sup>12</sup>. NIH requires that male and female animals and cells be balanced in preclinical studies, however, different rodent species and strains also respond differently to pain. For example, researchers have shown that the common C57BL6 mouse strain is the mouse strain most sensitive to nociceptive measures<sup>13</sup>.

Genetically diverse mouse populations have been developed to better reflect the diversity of human populations<sup>14</sup>. Pain researchers are already leveraging the heterogeneity of diversity mouse strains to identify genes involved in pain responses<sup>15</sup>. These “diversity mouse strains” offer an opportunity to identify analgesic targets that are more likely to successfully translate to clinic.

## **Resources to help implement stakeholder engagement in research:**

- [Principles of Community Engagement 2<sup>nd</sup> edition](#)
- [Patient-Centered Outcomes Research Institute](#)
- NIH Heal Initiative - [Achieving Health Equity](#) and [Patient Engagement](#) Workshops
- [The Commonwealth Fund](#)

## **Resources for maximizing diversity and inclusion in clinical trials:**

- [Food and Drug Administration Guidance](#)
- [NIH Inclusion Outreach Toolkit](#)
- [Clinical Trial Toolkit](#)
- [Increasing Diversity in Clinical Trials: Overcoming Barriers](#)



## **References**

1. Mogil and Crager, *Pain*, 2004.
2. Backonja and Stacey. *Jpain*. 2004.
3. Patient-Centered Outcomes Research Institute, <https://www.pcori.org/engagement/value-engagement>, 2018.
4. PCORI Engagement Rubric. <https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf>, 2015.
5. Clayton and Collins, *Nature*, 2014.
6. Kendall, *BMJ*, 2003
7. Raja et al, *PAIN*, 2020.
8. Grol-Prokopczyk, *PAIN*, 2017.
9. Maly and Vallerand, *Pain Management Nursing*, 2018.
10. Losin et al, *Nat. Hum. Behav*, 2020.
11. Clark et al. *Curr Probl Cardiol*, 2021.
12. Bartley and Fillingim, *Br. J. Anesth*, 2013.
13. Mogil et al, *PAIN*, 1999.
14. French et al, *EHP*, 2015.
15. Recla et al, *PAIN*, 2019.