National Institutes of Health (NIH)
Helping to End Addiction Long-term℠ (HEAL) Initiative
Virtual Workshop: Engaging Patients in the Research Process
August 26, 2020

Workshop Summary

Background and Overview

The virtual workshop was held as a Zoom webinar on August 26, 2020, from 1:00 to 3:30 p.m. ET. The agenda, slides, and recording can be found on the HEAL Initiative website at https://heal.nih.gov/events/2020-08/patient-engagement-workshop.

The purpose of the workshop was to increase the understanding of how to incorporate patients' perspectives and insights at all levels and phases of clinical studies, from conception and design through recruitment and dissemination of findings. Patients and patient engagement experts discussed opportunities, challenges, and benefits, as well as best practices for incorporating patients in the scientific process. The discussions included relevant ethical and policy issues, patient enrollment, community engagement practices, and more. Attendees learned how patient engagement transforms study processes and outcomes for the better.

Welcome and Objectives

Rebecca Baker, Ph.D., Director, HEAL Initiative, Office of the Director, NIH

Dr. Baker opened the webinar by thanking the participants for joining such an important discussion. She presented slides to provide background information on why patient engagement is important for the HEAL initiative and all research endeavors, making the following points:

- Patient engagement is a vital issue across all NIH research.
- Opioid use disorder (OUD) is a public health emergency that is worsening. Every day, more than 100 Americans die from opioid overdose.
- Lasting solutions must account for the millions of Americans living with chronic pain on a daily basis, including those with high-impact chronic pain.
- The mission of the HEAL Initiative is to provide scientific solutions to the opioid crisis. The U.S. government is investing more than $500 million per year in this effort. In 2019, NIH awarded almost $1 billion to 400 investigators in 41 states.
- The funded HEAL Initiative projects are focused on enhancing pain management and improving treatments for opioid misuse and addiction. Research areas include:
  - Preclinical and translational research in pain management
  - Clinical research in pain management
  - Novel medication options
  - Enhanced outcomes for affected newborns
  - New prevention and treatment strategies
  - Translating research into practice
- The HEAL Initiative's patient engagement process began in May 2019. The program conducted an environmental scan and developed recommendations during the second half of 2019. From February through April 2020, it worked on establishing a patient engagement

workgroup. This workshop is the first step toward holding a series of workshops, identifying stakeholders, setting goals, and gathering feedback.

- The key objectives of this workshop are to:
  - Discuss opportunities, challenges, and benefits to incorporating patients in research
  - Share best practices in community and patient engagement
  - Address challenges in engagement, recruitment, and the new virtual environment
  - Learn how patient engagement has transformed study processes and outcomes for the better
  - Discuss engagement in the context of the HEAL Initiative
- After this workshop, HEAL Initiative staff and researchers will:
  - Use the insights gained to inform the initiative's engagement framework and future meeting needs
  - Understand engagement issues unique to populations in HEAL
  - Gather input from community stakeholders and organizations to guide best practices for patient engagement
  - Develop a plan to promote representation in clinical trial participants

Lessons from the United States Food and Drug Administration (FDA) Patient-Focused Drug Development Program

Captain Robyn Bent, RN, M.S., U.S. Public Health Service, Director, Patient-Focused Drug Development (PFDD), FDA Center for Drug Evaluation and Research (CDER)

In her presentation, "Incorporating the Patient Voice into Clinical Trial Design and Conduct," Captain Bent showed slides to describe how to integrate patient perspective at critical decision-making points in the drug development life cycle. She said that there is value for researchers in doing so and made the following points:

- There are key times when patient input can be valuable in translational research studies, clinical trials, premarket review, and postmarket surveillance.
  - In translational studies, patients can help identify and measure the outcomes and burdens that matter most to patients.
  - In clinical trials, patients can help researchers design better studies and recruit and retain study participants.
  - During premarket review, study sponsors can incorporate patient-reported outcomes and patient preference information into benefit versus risk assessments.
  - In the postmarket surveillance period, patient input can help sponsors better communicate information about drugs to patients and providers. This facilitates the informed decision-making process.
- PFDD is a systematic approach to help ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and evaluation.
- From 2013 to 2016, the FDA conducted 24 disease-specific PFDD meetings. The FDA recognized the value of these meetings and has continued to host them since 2017. Most are now organized by patient advocacy organizations and follow the FDA format established in 2013. These meetings strengthen the understanding of the disease and treatment burden. Summaries from these meetings can be found on the FDA's PFDD website.

- Because patients are experts on their condition, it is important to obtain their input early in the drug development process. Chief complaints should be explicitly factored into medical product development plans, and the benefit of the product must be measured against a chief complaint. Patients want to be active in this process, because the most obvious symptoms of a disease or illness are not always the most bothersome to patients.
- In July 2018, the FDA hosted a PFDD meeting on chronic pain. A large and diverse group of participants described and discussed the impact of pain on daily life, current treatment approaches, and challenges or barriers to accessing treatments. The Voice of the Patient summary from this meeting was published in March 2019 and is available on the PFDD website. Key takeaways included the following:
  - The health effects of chronic pain are pervasive and wide-ranging.
  - Chronic pain affects all aspects of individuals' lives.
  - Management of chronic pain requires a multidisciplinary approach tailored to the needs of the individual.
  - There are several challenges and barriers to accessing treatments for managing chronic pain.
  - There is a need for increased awareness and understanding of chronic pain across the medical and policymaking communities.
- In April 2018, the FDA hosted a PFDD meeting on OUD. Although it was smaller than the chronic pain meeting, participants described and discussed the health effects and daily impacts of living with OUD and provided individual and family perspectives on current treatments for OUD. The Voice of the Patient summary from this meeting was published in November 2018 and is available on the PFDD website, along with the audio recording and transcript.
- Overall, the FDA's PFDD meetings have produced the following common themes:
  - More attention should be paid to the social, psychological, and financial impacts of living with a disease.
  - Participants need to have a clear understanding of the risks and benefits of participating in a clinical trial.
  - Participants want to reduce the barriers to clinical trial participation and streamline the informed consent process.
  - Quality-of-life endpoints should be included in the design of clinical trials.
  - Other considerations include the burden of travel to the study site, the invasiveness of the procedure, side effects, drug toxicity, and how participation might affect an individual's lifestyle.
  - There is a need for more awareness of clinical trial participation opportunities and a need to establish more trust and respect between researchers and patients.
- In the development of clinical trials, patients can provide natural history data, relevance, eligibility criteria, meaningful endpoints, communication with a patient community, protocol input and feasibility, awareness, feedback on the trial experience, input on the informed consent process, and more.
- Additional examples of how clinical trials can be improved for patients and how patients can contribute to clinical trials can be found on drug company websites and on the Clinical Trials Transformation Initiative website.

- The PFDD website contains a large variety of resources on this topic and a link to subscribe to email announcements about the program's activities. Information can also be obtained by sending an email to patientfocused@fda.hhs.gov.
- The following websites provide valuable resources on this topic:
  - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
  - Clinical Trials Transformation Initiative
  - National Health Council
  - SWOG Cancer Resource Network (formerly the Southwest Oncology Group)
  - Patient-Centered Outcomes Research Institute (PCORI)
  - TransCelerate

Panel Presentations: Challenges, Opportunities, and Goals of Patient Engagement

Walter J. Koroshetz, M.D., Director, National Institute of Neurological Disorders and Stroke (NINDS)

Dr. Koroshetz introduced the panel discussion by saying that the outcomes from this workshop are important because NIH spends $924 million per year on pain research and is incredibly committed to developing better treatments for people who suffer with pain. He noted that engaging patients to inform preclinical research or develop clinical trials could reduce the risk for failure. The goals for the panel discussion are to determine what contributions patients can make to research and how to effectively engage patients in the research process.

Dawn P. Edwards, Chief Executive Officer, New York State Chronic Kidney Disease (CKD) Champions; Wellness Ambassador, Rogosin Institute

Ms. Edwards said that patient engagement is a crucial part of any clinical trial. Participating in clinical trial development has been a rewarding experience for her, because she takes pride in contributing to science and improving the services that are available to the patients who desperately need them. Ms. Edwards made the following points:

- Having a patient seated at the table when developing a clinical trial is important because the trial is developed for the patient.
- When the disease effects that are important to a patient's quality of life are not understood by researchers or incorporated into clinical trials, patients are able to redirect the project to become more meaningful in this way.
- Allowing patients to participate in the development of a clinical trial helps patient recruitment for that trial and helps make the trial's requirements more tolerable or less burdensome for patients.

Paul L. Kimmel, M.D., M.A.C.P., HOPE Program Director, Division of Kidney, Urologic, and Hematologic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH

Dr. Kimmel said that including patients in the research process has completely changed his approach to solving scientific problems. He made the following points regarding patient

involvement in research:

- Researchers must plan to include patients in all stages of developing and completing a research study. Patients can assist in the development research funding announcements (e.g., contribute to how a study is structured). Along with investigators, patients should be included in NIH workshops, steering committees, subcommittees, expert panels, and research regulation bodies, such as observational study monitoring boards and data and safety monitoring boards (DSMBs). Published study results should include patients as authors.
- When patients are invited to participate in the research process, they must be treated as equals. Every member of a research team has different skill sets, experiences, and perspectives. The patient perspective is essential to the project in clinical research, and it is important for patients to "be in the room where it happens" (to quote a popular musical). Patient participation meaningfully shapes the outcome of a study in ways that are clinically important to patients.
- NIDDK's Hemodialysis Opioid Prescription Effort (HOPE) consortium, a part of the HEAL Initiative, used a community council to develop a research funding announcement (RFA) and includes patients on its steering committee, recruitment committee, and DSMB. Patients also wrote the first draft of the HOPE study's informed consent document. Patient input is especially important in studies with risk and studies where participant recruitment is difficult.

Christin Veasley, Co-founder and Director, Chronic Pain Research Alliance

Ms. Veasley said that she agreed with the ideas mentioned thus far and made the following additional points:

- It is important to avoid tokenism and treat patients who are participating in the research process as equals.
- Clinical trial design and conduct can be optimized when patients are recognized as having as valuable a perspective as every other member of the research team. This process includes shared decision making, bidirectional flow of information, transparency, and mutual respect and trust.
- Besides patients, the end users of any data or products that come out of the research should also be included.
- Patients and clinicians must recognize the importance of incorporating basic training before engagement. For example, researchers need to learn how to operationalize the engagement process, and patients need to learn how clinical trials work and how research decisions are made.
- The impact of patient engagement, including downstream impacts and costs, should be measured. For example, a Phase II study that added a patient-suggested protocol amendment saved $62 million in expected costs after spending $100,000 on the patient engagement process. Measuring costs is likely to lead to greater use of patient engagement.

Panel Discussion

- On the subject of tokenism, Dr. Koroshetz asked Captain Bent to share any lessons learned from the FDA perspective. Captain Bent responded that the PDFF team cautions against allowing the process to become a series of checkbox exercises. The effort needs to be truly holistic, with patients being equally and continually involved in the entire process.

- When asked to define what constitutes true patient engagement, Ms. Veasley said that the answer depends on the type of research that is being conducted, the stage of research, and the patient population(s) affected. There is no magic number of patients, and input from other stakeholders should also be considered. Ms. Veasley said that despite being a patient, she cannot speak to the experience of every patient, especially when there is a wide range of ages, races, genders, backgrounds, socioeconomic circumstances, and life experiences. PCORI and other resource groups provide patient engagement guidelines for each type of research, and these guidelines should be considered before the process of designing a study begins.
- Dr. Koroshetz said that one way that NINDS gains input from more than one patient at a time is by engaging with advocacy groups that represent a large number of patients.
- In response to a question about how NIDDK implements its patient engagement efforts, Dr. Kimmel said that NIDDK asks that each grant application specify the names of at least two patient advisors from each proposed study site. A 10-site study would then have 20 patients and, therefore, as many patient advisors as researchers. The investigator groups must also support the logistics of bringing patients into meetings and pay each patient advisor an honorarium. Dr. Kimmel also suggested ensuring that the diversity of the patient advisors closely mimics the expected patient population of the study.
- In response to a question about how she became interested in contributing to research, Ms. Edwards said that she was approached by a physician at the Rogosin Institute who asked her to serve as a wellness ambassador. When that physician mentioned that he was doing a study on opioid misuse and pain, Ms. Edwards said that she could identify with many of the issues involved in managing pain while living with her own disease. Because she speaks regularly with other patients who are managing painful illnesses, she felt confident that she could immerse herself in the process of helping with research and sharing her experiences along with the experiences of other patients. Ms. Edwards looked forward to participating and then realized during the process that the patients were asked to play quite a large role (e.g., serving on the recruitment committee, writing the informed consent document). While performing these tasks, she felt that the researchers placed a high value on everything that the patients said, and this made her happy to have become involved. Every member of the consortium was welcoming, stopped to listen to what the patients had to say, thought about it, and treated it as valuable information. Feeling valued as a member of the research team and seeing her input being put to use made Ms. Edwards excited about research. This is a message that she takes back to her advocacy organizations—along with the message that their experiences can be used to help others.
- Ms. Edwards emphasized the importance of increasing diversity in the patient engagement process. She now encourages reluctant African-American, Latino/a, and other underrepresented people to get involved and share their experiences, because these experiences matter and this community has an obligation to participate and improve medicine, science, tools, products, and drugs. Ms. Edwards said that she tries to debunk some of the preconceived notions held by the community.
- When asked about the differences that exist between a researcher's priorities and the patients' priorities, Ms. Veasley said that patient involvement can help with study recruitment and retention. She added that this is especially true when patients understand the broad implications of participating in a clinical trial. Researchers are thinking about rigorous scientific results. Patients are thinking about feasibility, whether participating is important

enough for them to commit a large amount of time, and whether the results will be measurable and relate to real life. Ms. Veasley said that communication and trust are essential to resolving differences between researcher and patient priorities. She provided an example from a back pain study.

- Dr. Koroshetz said that the messaging about a trial can make a difference to patients who are considering participating. Ms. Veasley agreed, saying that it was especially important for pain studies, because of the language around OUD and other stigmatized diseases. She encouraged researchers to take a business communications or market research approach to clinical study messages. Patients are also interested in knowing why investigators care about their research topics. Ms. Edwards described the messaging process that she and other committee members were working on while developing a meaningful recruitment brochure for the HOPE consortium.
- When asked about ongoing participant communications after enrollment, including answering questions and sharing results, Ms. Edwards said that patients feel valued when they are included in any aspect of the study. She emphasized that continual engagement over time improves outcomes and prevents negative experiences.
- Ms. Edwards added that her experience with the HOPE consortium has been valuable and positive. It has made her feel better as a person, because her opinions and input have been so highly valued. She noted that Dr. Kimmel and the other investigators sit down and have lunch with the patient representatives as a unified group; the patients are not separated from the researchers. Participating in research has been a meaningful life experience for Ms. Edwards, especially because she knows that she is helping future patients with the same disease. She said that she often shares about her experiences with others. Participating in research has improved her self-worth and self-esteem as a dialysis patient and made her feel like a vital member of society once again.
- When asked how to encourage patients to persist when initial studies are disappointing, especially for chronic pain, Ms. Veasley suggested using frequent and open communication. She added that the data show that research gives patients hope, even when a trial fails before it has been completed. Negative or null results should be communicated back to patients (both those in the clinical trial and the engagement partners), along with the message that failures lead to new ideas and new attempts. Ms. Veasley noted that proper training incorporated in the beginning of the research process can set expectations and include statistics on how many trials fail and how the stages of clinical trials work.
- Captain Bent said that it was important to delineate communication differences between patient engagement partners and patients enrolling in a clinical trial. She noted that asking engagement partners for input can be quite different from obtaining investigational review board (IRB) approval of patient communications for a clinical trial.
- Ms. Stroud emphasized the importance of Ms. Edwards' comments. She said that studies in the Vanderbilt Institute for Clinical and Translational Research (VICTR) Recruitment Innovation Center always begin by asking how the study will affect its participants. Ms. Stroud also applauded the HOPE consortium approach to patient engagement and said that the NIDDK model should be the gold standard. She noted that funding patient engagement is a concern, which is why Ms. Veasley's comments about measuring costs were notable.
- For their HEAL study, VICTR used a community engagement resource team to recruit representative (e.g., by gender, age, life experience) patient engagement participants. The lead researchers then met with the participants to truly listen to the patients' concerns and

input on the invasiveness of the procedures, the logistics of participating, and recruitment materials. The VICTR recruitment and retention plan requires stakeholder engagement.

- With COVID-19, VICTR has successfully transitioned to conducting its community engagement studios on a virtual platform, allowing the institute to expand recruitment across the country to a wider geographic area. Ms. Stroud said that virtual expansion could be particularly beneficial for pain studies, because people who suffer from addiction often have trust issues and possibly a degree of shame.
- When asked to summarize the discussion, Dr. DeBar said that many of the comments resonate with her. She agreed with Captain Bent that for a particular disease or condition, the most obvious symptoms observed by researchers are not always the most troublesome or important symptoms to patients. It is important to think about a patient's whole life and quality of life (e.g., physical abilities, social life, sleep, stress), not solely the symptoms of living with a disease such as chronic pain. Social isolation from COVID-19 has had a negative impact on many patients.
- Dr. DeBar emphasized the importance of engaging a diverse group of patients and treating them as equals when beginning to plan a research study. She noted that patients who have suffered from pain have many experiences with interventions that have not worked. Many of these patients are incredibly frustrated, and the frustrated voices should be included. VICTR has been successful in bringing in groups of patients to meet together. Having as large a group of patients as researchers has been powerful and effective. VICTR emphasizes the importance of patient training and explains the study design and retention processes to its patient groups.
- As an example of an innovative approach, Dr. DeBar said that VICTR has employed an "encouragement design" to identify participants who have undergone a large number of interventions. The group then invites those patients to participate in trials.

Question and Answer Session

Walter J. Koroshetz, M.D., Director, NINDS (moderator)

Dr. Koroshetz asked attendees to use the Q&A feature of the Zoom platform to ask questions. Dr. Haney read the submitted questions aloud, and the speakers provided the answers.

Q. How do we go to the next step in HEAL?

- Ms. Edwards said to remember that building trust is an important part of the process when approaching patients to ask them to become involved. Patients need to feel emotionally safe, valued as members of the team, and heard. The process does not work when patients sit in one area of the room and researchers sit in another area.
- Dr. Kimmel added that the steering committee chair and sponsor must emphasize early and often that patient engagement is essential to all phases of every study. Everyone involved must be committed to the process. Dr. DeBar agreed, saying that developing the original research question and designing the study are important aspects of the patient engagement process. She added that mixed-methods studies (e.g., qualitative data, anthropologist involvement) should also be incorporated to gain a deeper understanding of the issues involved. The pandemic has created opportunities to connect with people in their homes.
- Ms. Veasley encouraged attendees to think more broadly about collecting and distilling evidence (e.g., benefits, cost incomes) to support the impact of incorporating patient

engagement into research studies. This would likely go farther toward increasing its practice than requiring it for funding. Dr. DeBar agreed and suggested partnering with organizations that have resources in this area. There are many entry points.

Q. Is there a way to incorporate patient evaluations and surveys from prior studies into the new research protocol development process? Does all patient engagement need to be qualitative?

- Captain Bent said that studies do not need to start from the ground up every time; a lot of patient information already exists. She did not recommend asking patients the same questions over and over again; instead, the FDA is using a strong methodology to develop a standard core set of endpoints for different disease areas. These resources will become available to researchers.

Q. What approaches can be used to incorporate minority patients and those from groups that are underrepresented in biomedical research?

- Ms. Stroud suggested developing and maintaining relationships with a variety of community leaders for each population well ahead of when they might be needed for patient engagement. Doing so takes time and can include church pastors, community organizers, physicians, and trustworthy leaders.
- Dr. Kimmel said that due to genetic susceptibility, the dialysis patient population is overrepresented with African Americans. Therefore, he requires each research site to include African-American patients as part of their patient engagement group. He suggested working with patient advocacy groups and added that most research commitments are for a minimum of 5 years.

Q. What is your advice when a patient population is limited, such as when studying a rare disease?

- Dr. Koroshetz said that NINDS is studying more than 200 rare diseases. Patients with a rare disease, and their caregivers, tend to coalesce and form advocacy organizations. Working with these advocacy organizations is a good approach for studying rare diseases. He noted that pain studies can often include patients with several of the rare conditions.
- Dr. Kimmel added that the researchers who study certain diseases also form networks to share information.
- Captain Bent said that in-person and online community support groups can also be helpful.

Q. How can patient engagement be addressed during the COVID-19 pandemic when the digital divide is growing, especially for older adults, rural communities, and low-income patients?

- Dr. Koroshetz said that most clinical trials were put on hold to keep participants away from the hospital environment, but now many patients have been using telehealth and patient engagement groups have been using virtual platforms to stay connected. He worries that limited access to Internet resources will introduce bias into patient recruitment.
- Dr. DeBar said that although telehealth opportunities and virtual video visits are becoming more common and accepted, they illuminate challenges and inequities in access to technology. To combat these issues and provide access, the University of Washington purchased mobile phones and data minutes for some patients. Furthermore, Medicaid has

developed creative systems to create access for its recipients. Ms. Stroud said that VICTR also purchased mobile phones to connect with its study patients.

Q. How can we effectively engage patients in basic science and preclinical studies?

- Ms. Veasley said that although it is challenging, many laboratories send postdoctoral researchers to the clinic to spend time with patients, ask questions about the disease, and begin to think more broadly about the research problems. Patients can assist with developing basic research questions about their disease.
- One example from pain research is that after researchers discovered that pain affects multiple body systems (i.e., endocrine, immune, sleep, mood, cognitive), basic researchers began to develop animal models with multisystem illness.

Q. What are some ways to mitigate the power differential between patients and researchers?

- Dr. Koroshetz said that the patient engagement process must always be bidirectional and positive. It involves compromise and respect for every point of view. He suggested creating communication ground rules and a system for conflict resolution before the process begins.
- Dr. Kimmel said that research leaders often arrive at meetings with an entourage of fellows, biostatisticians, and junior investigators. He sets the tone and ground rules for the meeting, designs the agenda to give patients an equal voice with principal investigators, and assigns seats so that investigators and patients are intermingled.
- Ms. Veasley emphasized that training and education is needed for both the investigators and the patient stakeholders. The training creates open communication and trust between the parties.
- Ms. Edwards said that patients, investigators, and IRB representatives do not always agree. Each side must be open to compromise and solving problems for the greater good. She added that the training process created a fantastic experience for the patients.
- Dr. Kimmel said that after one or two meetings, investigators quickly learn the importance of asking patients to contribute to the research process. It can be a revelation when investigators begin to use patient engagement.
- When asked how the FDA communicates with patient groups about changing study endpoints or primary outcome measures, Captain Bent said that the FDA staff members try to be open and transparent while explaining their thinking. She added that patients and advocacy groups often underestimate their own power and gave an example from a drug company that was able to improve recruitment and retention by partnering with an advocacy group. Captain Bent emphasized that study sponsors and researcher are not including patients to do them a favor. They are including patients because it is the right thing to do and the best way to achieve good scientific outcomes.

Q. What are your experiences in recruiting patients from stigmatized and marginalized groups, such as those with substance use problems?

- Dr. DeBar said that stigma is a concern for patients with chronic pain and that many have been told, "It's all in your head." Researchers must use careful outreach methods and work with clinicians who have developed communication methods that are inviting and encouraging when asking patients to participate in a particular intervention. Research design should allow patients time to deliberate about interventions. Finally, researchers should

engage with the patients' families, because family members often have rich insights to share. Ms. Stroud agreed that families are an important part of patient support and communication.
- Ms. Stroud said that one technique that VICTR has used when caring for patients with suicide or depression is to develop alternative, more private recruitment materials, such as bar codes that can be scanned and read later.

Closing Remarks

Rebecca Baker, Ph.D., Director, HEAL Initiative, Office of the Director, NIH

Dr. Baker thanked the panelists, moderators, and participants for being an incredible group of leaders. She said that the HEAL Initiative will sustain, reflect on, and continue efforts in this area and that patient engagement will be formally included in the governance of the initiative. She noted that the different approaches to patient engagement are as diverse at the HEAL community and its partners.

Some themes that resonated with Dr. Baker were communication, trust, and ongoing efforts to improve. She said that HEAL research provides hope to people with chronic pain and OUD, so the workshop directly addressed the HEAL Initiative's goals and mission.

Workshop Presenters, Participants, and Planners

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Attendance

More than 300 individuals joined the Zoom webinar.

Abbreviations and Acronyms

CDER	Center for Drug Evaluation and Research
CKD	chronic kidney disease
DSMB	data and safety monitoring board
FDA	United States Food and Drug Administration
HEAL	Helping to End Addiction Long-term
HOPE	Hemodialysis Opioid Prescription Effort
IRB	investigational review board
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
OD	Office of the Director
OUD	opioid use disorder
PCORI	Patient-Centered Outcomes Research Institute
PFDD	patient-focused drug development
RFA	research funding announcement

VICTR	Vanderbilt Institute for Clinical and Translational Research