Literature Review: Patient Engagement Clinical Trials

A Report of the Science of Patient Input Program of the Medical Device Innovation Consortium (MDIC)

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AUTHORS

Carrie M Kuehn, M.A., M.P.H., L.P.D, RAC
Lead, Patient Science & Engagement
Edwards Lifesciences

Wendy KD Selig, MS
Founder & CEO
WSCollaborative, LLC
OVERVIEW

This document provides an updated Literature Review for the Medical Device Innovation Consortium (MDIC) Science of Patient Input (SPI) Working Group for submission as a deliverable under the MDIC BAA contract. This high-level review reflects a broad scan of publicly available information about relevant organizations, initiatives, materials and publications. While it is up to date as of March 2019, this summary is not exhaustive and should be viewed as a representative snapshot of activities and resources within the highly active and evolving field of patient engagement in clinical research. As new organizations, resources, and publications are being developed and launched continually, this work should be updated regularly to ensure its completeness and relevance over time.

MDIC received funding for this project from FDA BAA HHSF223201810116C “Framework for Patient Input in Medical Device Clinical Trials.”
Organizational Patient Engagement Initiatives (alphabetical order)

Center for Information & Study on Clinical Research Participation
Center for Information and Study on Clinical Research Participation is an independent nonprofit organization dedicated to educating patients about clinical research.

Web Site: https://www.ciscrp.org/
Engagement Focus: Clinical Trial Design
Therapeutic Areas: Drugs, Biologics, Devices

Activities: CISCrP is an organization devoted to educating and informing stakeholders in clinical research, including patients, about clinical studies and what it means to be a clinical research participant. CISCrP organizes and facilitates patient panels and advisory boards to address clinical study issues, including patient perceptions on clinical trial design. The organization also conducted a global study on public and patient perceptions of clinical research.

Education Center provides resources for patients about participating in clinical research, including an interactive online community. https://www.ciscrp.org/education-center/

Clinical Trials Transformation Initiative (CTTI)
CTTI is a public-private partnership to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.

Web Site: https://www.ctti-clinicaltrials.org/
Engagement Focus: Clinical Trial Design
Therapeutic Areas: Drugs, Biologics, Devices

Activities: CTTI is engaged in multiple activities related to increasing patient engagement in the design and conduct of clinical trials. Recent activities include:

- CTTI is the co-host with FDA of a March 2019 workshop on Enhancing the Incorporation of Patient Perspectives in Clinical Trials. https://www.ctti-clinicaltrials.org/news/ctti-and-fda-workshop-will-explore-how-best-include-patient-perspectives-clinical-trials/
- Clinical Trials Recruitment Planning initiative led to publication of a proposed framework to enhance trial recruitment strategies, including the central recommendation of engaging the patient as an equal partner in trial planning. https://www.sciencedirect.com/science/article/pii/S155171441730753X?via%3Dihub/
- Mobile Technology in Clinical Trials is an effort to encourage the wide-spread use of mobile technology in clinical trials. One of the main objectives of this work is the focus on novel endpoints that reflect measures that are meaningful to patients. https://www.ctti-clinicaltrials.org/programs/mobile-clinical-trials/
- Patient Groups & Clinical Trials is an effort to engage patient groups early and often in the clinical trial process. CTTI has published recommendations for successful collaborations between sponsors and patient groups working on clinical trials. https://journals.sagepub.com/doi/full/10.1177/2168479017720247/
• **Financial Value of Patient Engagement** is an effort to provide evidence of value from patient engagement to sponsors conducting clinical trials. This work also resulted in a recent publication. [https://journals.sagepub.com/doi/full/10.1177/2168479017716715/](https://journals.sagepub.com/doi/full/10.1177/2168479017716715/)

• **Effective Engagement with Patient Groups Around Clinical Trials** provides recommendations for trial sponsors (academic and industry) and patient groups to advance collaboration in this area. [https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf](https://www.ctti-clinicaltrials.org/files/pgctrecs.pdf)

CTTI's website has a large volume of information and tools for use by sponsors and patient groups interested in engaging patients in all aspects of the clinical trial process, regardless of therapeutic area.

**Core Outcome Measures in Effectiveness Trials (COMET) Initiative**
The COMET Initiative is focused on the development of standardized sets of outcomes, called Core Outcome Sets (COS). COMET hosts a database of COS across therapeutic areas.

**Web Site:** [http://www.comet-initiative.org/](http://www.comet-initiative.org/)

**Engagement Focus:** Clinical Outcome Development

**Therapeutic Areas:** Drugs, Biologics, Devices

**Activities:** The COMET People and Patient Participation, Involvement and Engagement (PoPPIE) working group hosted a meeting in 2014 to discuss how to engage patient organizations in developing outcomes. The PoPPIE working group developed a strategy for public involvement and offer resources to researchers who wish to include patient input in developing Core Outcome Sets (COS). [http://www.comet-initiative.org/ppi/researchers](http://www.comet-initiative.org/ppi/researchers)

**DIA**
DIA is a membership organization focused on innovation in life sciences and product development. It was formerly known as the Drug Information Agency, but more recently has expanded its scope of interest to all medical products.

**Web Site:** [https://www.diaglobal.org/en/resources/areas-of-interest/patient-engagement/](https://www.diaglobal.org/en/resources/areas-of-interest/patient-engagement/)

**Engagement Focus:** General Patient Engagement

**Therapeutic Areas:** Drugs, Biologics, Devices

**Activities:** DIA has been focused on patient engagement initiatives since 2006, developing resources for the public and its members and focusing on related topics during its meetings.

**DIA Patient Engagement Community** is an online forum for DIA members, consisting of blog posts, discussion boards, event notifications and other resources. [https://communities.diaglobal.org/communities/community-home?CommunityKey=70bca11e-66ab-45cd-b92c-fb7815d3d491&_ga=2.167907426.297563242.1550515532-714288693.1548869872/](https://communities.diaglobal.org/communities/community-home?CommunityKey=70bca11e-66ab-45cd-b92c-fb7815d3d491&_ga=2.167907426.297563242.1550515532-714288693.1548869872/)

**Study of Patient-Centric Initiatives:**
• **Considerations Guide** is a practical resource for companies launching or advancing patient-centered initiatives that support health care product research and development.
Capturing the Value of Patient Engagement presents key insights in the following areas: adoption of patient-centric initiatives, barriers to adoption, comparative analytics and results of patient-centric initiatives.

DIA-Tufts Center for the Study of Drug Development (CSDD) Patient Engagement Research Project funded by 17 pharmaceutical companies and contract research organizations.

FasterCures -- A Center of the Milken Institute

FasterCures is a non-profit think tank focused on cutting through roadblocks that slow medical progress by expanding the science of patient input, fostering policies to support biomedical innovation, and spurring cross-sector collaboration in research to get better outputs.

Web Site: http://www.fastercures.org/

Engagement Focus: General Patient Engagement

Therapeutic Areas: Drugs, Biologics, Devices

Activities: Patients Count is the patient engagement initiative at FasterCures. Within Patients Count, there are focused initiatives that promote the use of patient perspectives throughout the product lifecycle, including clinical research. These include:

- Landscape of Legal Issues: an effort to help patient groups and industry better navigate the legal landscape. https://www.fastercures.org/programs/patients-count/landscape/
- Recent webinars: https://www.fastercures.org/events/webinars/show/fdas-patient-focused-drug-development-initiative-what-have-we-learned; https://www.fastercures.org/events/webinars/show/patient-centered-measurement-how-close-are-we/
HTAi is a membership organization focused on the understanding and use of health technology assessment to inform health care decision-making and efficient use of healthcare resources.

**Web Site:** [https://htai.org/](https://htai.org/)

**Engagement Focus:** General Patient Engagement

**Therapeutic Areas:** Drugs, Biologics, Devices

**Activities:** The Patient and Citizen Involvement special interest group (PCIG) is focused on obtaining patient perspectives to improve health technology assessment. This group has generated multiple resources for its members relating to patient engagement in HTAi. [https://htai.org/interest-groups/pcig/](https://htai.org/interest-groups/pcig/)


- **For HTA Agencies and Policy Makers**, including multiple resources to support HTA submissions. [https://htai.org/interest-groups/pcig/resources/for-hta-agencies-and-policy-makers/](https://htai.org/interest-groups/pcig/resources/for-hta-agencies-and-policy-makers/)

- **For Patient Groups and Individual Patients**, [https://htai.org/interest-groups/pcig/resources/for-patients-and-patient-groups/](https://htai.org/interest-groups/pcig/resources/for-patients-and-patient-groups/)

- **For Industry and Researchers**, including links to ethical guides and national codes of practice for patient engagement collaborations. [https://htai.org/interest-groups/pcig/resources/for-industry-and-researchers/](https://htai.org/interest-groups/pcig/resources/for-industry-and-researchers/)


**MDIC**

The Medical Device Innovation Consortium (MDIC) Science of Patient Input (SPI) initiative comprises several projects aimed at enhancing patient engagement in medical device clinical trials and product development efforts. This initiative, previously known as Patient Centered Benefit-Risk, relies on multi-stakeholder working groups and committees to evaluate the landscape, identify gaps and generate resources on these topics for the medical device community.

**Web Site:** [https://mdic.org/program/science-of-patient-input/](https://mdic.org/program/science-of-patient-input/)

**Engagement Focus:** Patient Preference Assessment, Clinical Trial Design

**Therapeutic Area:** Devices

**Activities:** MDIC and its partners are collaborating to improve the field’s ability to include patient perspectives in the development, pre-market approval, and post-market evaluation of medical devices. The vision of the MDIC Science of Patient Input Steering Committee is to provide a venue for continued collaboration to advance the art and science of patient engagement in regulatory science, including advances in methodologies and tactical considerations for integrating the patient’s perspective and preferences in the design, clinical development and regulatory review of innovative medical technologies. The MDIC SPI website includes multiple relevant resources: [https://mdic.org/program/science-of-patient-input/](https://mdic.org/program/science-of-patient-input/)
• **MDIC’s Patient Input in Clinical Trial Design project**, is focused on three workstreams to develop: methodologies to systematically identify outcomes that matter most to patients and establish these outcomes as primary or secondary endpoints for clinical studies; guidelines to integrate patient preferences into the statistical design of clinical trials; and methodologies to maximize patient participation in clinical trials. [https://mdic.org/project/patient-input-in-clinical-trial-design/](https://mdic.org/project/patient-input-in-clinical-trial-design/)

• **MDIC’s Patient Centered Benefit-Risk (PCBR) project**, launched in 2013 with the vision “to establish a credible framework for assessing patient preferences regarding the probable benefits and risks of a proposed medical device and for incorporating patient preference information into pre-market and post-market regulatory submissions and decisions.” This project resulted in publication of “A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology” (May 2015). [https://mdic.org/resource/patient-centered-benefit-risk-pcbro-framework/](https://mdic.org/resource/patient-centered-benefit-risk-pcbro-framework/)

National Cancer Institute
The National Cancer Institute Office of Advocacy Relations links advocate stakeholders with NCI to ensure collective patient perspectives are included in NCI cancer research activities.

**Web Site:** [https://www.cancer.gov/about-nci/organization/oar](https://www.cancer.gov/about-nci/organization/oar)

**Engagement Focus:** Clinical Trial Design

**Therapeutic Area:** Drugs, Biologics, Devices

**Activities:** NCI’s Office of Advocacy Relations (OAR) is the primary resource at the organization for engaging with the cancer advocacy community. [https://www.cancer.gov/about-nci/organization/oar/research-advocacy/](https://www.cancer.gov/about-nci/organization/oar/research-advocacy/)

A summary of OAR’s engagement activities was presented at the FDA Patient Engagement Advisory Committee (PEAC) meeting in October 2017. Included in these activities are:

• **Clinical Trials and Translational Research Advisory Committee (CTAC)** an external multi-stakeholder oversight committee that advises NCI on ways to strengthen its intramural and external research enterprises, leveraging several ad hoc working groups that engage with patient advocates within various high priority tumor types. [https://www.cancer.gov/about-nci/organization/ccct/ctac/](https://www.cancer.gov/about-nci/organization/ccct/ctac/)

• **NCI’s Council of Research Advocates (NCRA),** the only federal advisory committee comprised solely of advocate leaders at NCI. NCRA convenes around broad cancer research issues and provides the Director with advice and strategic insights from the community’s perspective. [https://www.cancer.gov/about-nci/organization/oar/ncra](https://www.cancer.gov/about-nci/organization/oar/ncra)

• **The Scientific Steering Committees and Task Forces,** which include patient advocates, guide NCI’s clinical trial enterprise.

**National Health Council (NHC)**
National Health Council (NHC) is an advocacy organization whose mission is to provide a voice for patients with chronic diseases and disabilities as well as their caretakers. NHC is a
membership organization with participation from advocacy groups, industry, payer, and other medical product and healthcare stakeholders.

Web Site: https://www.nationalhealthcouncil.org/
Engagement Focus: General Patient Engagement
Therapeutic Areas: Drugs, Biologics

Activities: One of NHC’s public policy areas is patient engagement. Though NHC has participation from all therapeutic areas, including devices, NHC’s work in patient engagement in clinical research is limited to drugs and biologics. NHC desires to identify and implement best practices for engaging patients in the research, development, and regulatory review of new drugs. http://www.nationalhealthcouncil.org/public-policy/patient-engagement/

In collaboration with the Genetic Alliance, NHC has generated white papers on the topic of patient engagement in clinical research and is working to generate recommended language for use in FDA patient engagement guidance documents.

- **Clinical Outcomes Assessment** is an area of current focus for NHC, which has convened several webinars on the topic https://www.nationalhealthcouncil.org/public-policy/clinical-outcome-assessment/

Patient Centered Outcomes Research Institute (PCORI)
PCORI was established to fund clinical-effectiveness research that can help patients and caregivers make better-informed healthcare decisions. PCORI also funds projects focused on research methods and capacity, and works to influence research funded by others to be more useful to patients and other healthcare decision makers.

Web Site: https://www.pcori.org/
Engagement Focus: Clinical Outcomes Development
Therapeutic Areas: Drugs, Biologics, Devices

Activities: PCORI has supported engagement of multiple stakeholders in clinical research through their Engagement in Research PCORI program. Some of these activities include:

PCORI Engagement Resources & Guidance Documents
- **Engagement Rubric**, which provides guidance for methods of engaging stakeholder partners throughout each phase of a research study. Developed in 2014, this Rubric is currently being

- **Compensation Framework**, which provides guidance for developing fair compensation levels for patients, caregivers and organizations that participate in research.  https://www.pcori.org/sites/default/files/PCORI-Compensation-Framework-for-Engaged-Research-Partners.pdf/

- **PCORI Methodology Standards** provide specific benchmarks for researchers across an array of aspects. There are four standards associated with Patient Centeredness, and standard PC-1 focuses specifically on engagement.  https://www.pcori.org/research-results/about-our-research/research-methodology/pcori-methodology-standards#Associated%20with%20Patient-Centeredness/

**PCORI Fact sheets:**


**PCORI Webinars Archive:** https://www.pcori.org/events/past?type=110/

- **Engagement Strategies, Challenges and Resources**  https://www.pcori.org/events/2017/patient-and-stakeholder-engagement-research-engagement-strategies-and


**PCORnet Engagement Assessment Report** (PCORnet) deals with engagement of patients and stakeholders in research networks rather than individual research studies but there may be common lessons and challenges about engagement.  https://pcornetcommons.org/resource_item/pcornet-engagement-assessment-project-findings-and-recommendations/

**TransCelerate**

TransCelerate BioPharma’s mission is to collaborate across the global biopharmaceutical research and development community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines. TransCelerate membership is available to biopharmaceutical research and development organizations who engage in innovative discovery,
development and manufacturing of new drugs. TransCelerate’s growing portfolio of Initiatives focuses on the shared vision of accelerating and enhancing the research and development of innovative new therapies. Our Initiatives develop practical solutions to overcome inefficiencies in clinical research and are drawn from the combined expertise of our members and industry collaborators.

Website: https://www.transceleratebiopharmainc.com/

Engagement Focus: Clinical Trial Design, Patient Experience
Therapeutic Areas: Drugs

Activities: TransCelerate leverages collaboration among multiple companies to improve clinical trial efficiency and advance drug development. The organization has many activities across multiple areas of focus, including its Patient Experience (PE) Initiative, which seeks to facilitate and accelerate the industry’s progression towards a future where the patient experience is enhanced in clinical trials and patient burden is reduced, and its Patient Technology (PT) Initiative, which seeks to facilitate and accelerate the industry’s progression towards a future where patients have access to innovative technologies that enhance the patient experience and reduce patient burden in clinical trials.


**FDA Activities, Guidances & Resources**

**Patient Engagement Collaborative (PEC),** a work group created with CTTI, comprised of patient advocacy organizations convened to discuss patient engagement at the FDA. https://www.fda.gov/forpatients/patientengagement/default.htm#collaborative

**Patient Participation in Medical Product Discussions (FDASIA Section 1137),** which recognizes the value of patient input by facilitating increased involvement of patients earlier in the regulatory process for medical product review. https://www.fda.gov/forpatients/patientengagement/default.htm#fdasia1137

**Patient Reported Outcomes – Clinical Outcomes Assessment Qualification**
https://www.fda.gov/drugs/developmentapprovalprocess/drugdevelopmenttoolsqualificationprogram/ucm284077.htm

**Patient Focused Drug Development (PFDD)**
CDER Guidance Series FDA is developing a series of four methodological patient-focused drug development (PFDD) guidance documents to address, in a stepwise manner, how stakeholders can collect and submit patient experience data and other relevant information from patients and caregivers for medical product development and regulatory decision making. This series of guidance documents is intended to facilitate the advancement and use of systematic approaches to collect and use robust and meaningful patient and caregiver input that can better inform medical product development and regulatory decision making. These guidance documents are part of FDA’s PFDD efforts in accordance with the 21st Century Cures Act and The Food and Drug Administration Reauthorization Act of 2017 Title I. [https://www.fda.gov/drugs/developmentapprovalprocess/ucm610279.htm](https://www.fda.gov/drugs/developmentapprovalprocess/ucm610279.htm)

- Guidance 1: Collecting Comprehensive and Representative Input
- Guidance 2: Methods to Identify What is Important to Patients
- Guidance 3: Selecting, Developing or Modifying Fit-for-Purpose Clinical Outcomes Assessments
- Guidance 4: Title forthcoming, will address topics related to COA-related endpoint development and interpretation, including topics related to instrument administration and meaningful within-patient score changes.

Plan for Guidance Development

- Voice of the Patient Meetings [https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm](https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm)
- 2018 Meeting materials: [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm)
- 2017 Meeting Materials: [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm578522.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm578522.htm)

CDRH Patient Preference Initiative


CDRH Patient Engagement Advisory Committee (PEAC), which provides advice to the Commissioner or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The Committee may consider topics such as: Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues, and other patient-related topics. [https://www.fda.gov/advisorycommittees/committeesmeetingmaterials/patientengagementadvisorycommittee/default.htm](https://www.fda.gov/advisorycommittees/committeesmeetingmaterials/patientengagementadvisorycommittee/default.htm)

- 2018 Meeting materials: [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm)
- 2017 Meeting Materials: [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm578522.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm578522.htm)
MyStudies App, launched by CDER to facilitate the input of real-world data directly by patients which can be linked to electronic health data supporting traditional clinical trials, pragmatic trials, observational studies and registries. [https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm](https://www.fda.gov/Drugs/ScienceResearch/ucm624785.htm)

**US-Based Conferences & Meetings (reverse chronological order)**

A selection of meetings that occurred or are planned with a specific focused on patient engagement in clinical trials. Materials produced by these meetings are available at the conference websites.

- CTTI-FDA Patient Engagement Workshop March 2019  
- CDRH Patient Engagement Advisory Committee (PEAC) Meeting. November 2018  
  [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PatientEngagementAdvisoryCommittee/ucm621264.htm)
- DIA Measuring Impact in Patient Centered Drug Development Conference October 2018  
- MDIC Patient Centered Clinical Trials Workshop May 2018  
- Patients as Partners, U.S. (Annual). Conference focused on involvement of patients throughout medical products lifecycle.  
  [https://theconferenceforum.org/conferences/patients-as-partners/overview/](https://theconferenceforum.org/conferences/patients-as-partners/overview/)
  Inaugural PEAC meeting focused on engagement of patients in clinical trials.  
  [https://www.fda.gov/advisorycommittees/calendar/ucm568511.htm](https://www.fda.gov/advisorycommittees/calendar/ucm568511.htm)
  [https://www.pharmacy.umd.edu/centers/cersievents/patient-focused-drug-development/](https://www.pharmacy.umd.edu/centers/cersievents/patient-focused-drug-development/)

**Engagement Resource Compendia (alphabetical order)**

There are multiple organizations that provide assemblies of information on patient engagement. Each of these “engagement resource compendia” includes large volumes of information:

- **Alliance for Clinical Research Excellence and Safety (ACRES)**  
  [http://www.acresglobal.net/](http://www.acresglobal.net/)
- **Patient Empowerment Initiative (PEI)**

**Resource:** Collect, synthesize, and test best practice methods for engagement in clinical research. Integrate patient centricity efforts across the research and health care environment.
Therapeutic Areas: Drugs, Biologics, Devices
Focus: General Patient Engagement

BIO

Key Considerations for Developing and Integrating Patient Perspectives in Drug Development: Examination of the Duchenne Case Study

Resource: Shares best practices for the development of disease-specific patient preference studies based on the PPMD experience. The paper outlines key considerations to help guide stakeholders on the development of patient preference studies and the multitude of ways they can be used, including to help inform the drug development and regulatory processes.

Therapeutic Areas: Drugs, Biologics
Focus: Benefit Risk, Patient Preferences

MDIC

Patient Centered Benefit Risk Framework (PCBR)

Resource: Provides background on the concepts of benefit-risk and patient preference, discusses the potential value of including patient benefit-risk in a regulatory submission and when in the product lifecycle such information might be collected, outlines factors to consider when selecting a patient preference method, and discusses considerations regarding the use of patient preference information in the regulatory process.

Therapeutic Areas: Devices
Focus: Benefit-Risk, Patient Preferences

Patient Focused Medicines Development
www.patientfocusedmedicine.org

SYNAPSE: Synergizing Patient Engagement

Resource: A registry of patient engagement initiatives across the globe. Includes a search engine to identify specific patient engagement efforts.

Therapeutic Areas: Drugs, Biologics, Devices
Focus: General Patient Engagement

PCORI
https://www.pcori.org/literature/engagement-literature/

Engagement in Health Research Literature Explorer

Resource: Searchable database of publications about engagement in health research, not limited to PCORI studies.

Therapeutic Areas: Drugs, Biologics, Devices
Focus: General Patient Engagement, Technology

TransCelerate
https://www.transcelebratebiopharmainc.com/

Patient Experience Initiative: Enable greater patient engagement and partnership between patients and sponsors to design and execute clinical protocols that create better patient experiences in clinical trials:

Patient Technology Initiative: Address the barriers to the use of patient-facing technologies (PT) in clinical trials to benefit individual patients and the broader patient community, as well as sponsors, sites, and vendors.

Therapeutic Areas: Drugs, Biologics
Focus: General Patient Engagement

The Research Acceleration and Innovation Network (TRAIN)
http://train.fastercures.org/

Resource: A collection of tools, publications, webinars, and events related to patient engagement, including patient input to clinical research.

Therapeutic Areas: Drugs, Biologics, Devices

Focus: General Patient Engagement

Selected References

This curated list contains selected references identified through a high-level review of published literature, literature database searches, and citations in other documents. The list is divided into categories of literature pertaining to development of clinical outcomes, clinical trial design, and general patient engagement literature. These categories are not mutually exclusive; they are intended to provide some guidance as to which articles cover the two specific topic areas of interest. New publications on the topic of patient engagement in research are being disseminated frequently and this list should be updated regularly.

Patient Engagement in Clinical Trial Design


Patient Engagement in Developing Clinical Outcome Measures


General Patient Engagement in Clinical Research


**Patient Preference in Clinical Trial Design**


Contact information

For more information, please contact
Stephanie Christopher at schristopher@mdic.org