Tools for Advancing Patient-Centered Medical Device Clinical Trials

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• Responsible for supporting patients, their study partners and family to take part in MDD research by removing barriers of participation and simplifying study activities, enabling a better patient experience and increased compliance and retention.

• Passionate about patient inclusion and collaboration and reducing burden of participation including use of remote / Direct to Patient methodologies.
Expert in clinical research, focused on thoughtful and efficient study design and study execution.

Designed and managed device clinical trials ranging from pilot studies to multi-site pivotal trials in a variety of disciplines, including interventional radiology, wound care, surgery, cardiology, urology, and OHNS.
The challenges of medical device and diagnostic clinical trials
Protocol Amends

60%
protocols requiring 1 or more amends (avg 2-3)

34%
amends sponsors deemed partially or completely avoidable

20%
protocol design flaws and difficulties recruiting study volunteers

$453k
average cost of protocol amend

http://www.appliedclinicaltrialsonline.com/protocol-amendments-costly-solution
Tufts CSDD – 2010 research with 17 pharmaceutical & biotechnologies companies
Recruitment Challenges


on average, more than 30% of clinical trial participants drop out before becoming evaluable.

− All visits attended?
− ePRO completed?
− Wearables / sensors worn and transmitting data?
− Follow-up calls completed?

Protocol Compliance
Health Literacy

The ability to **find, understand, and use basic health information** and services needed to **make appropriate health decisions**

- **Only 12 percent** of U.S. adults had proficient health literacy
- **Over a third** of U.S. adults—**77 million people**—would have difficulty with common health tasks, such as following directions on a prescription drug label or adhering to a childhood immunization schedule using a standard chart.

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Increasing Patient Burden

- Study support / follow-up
- Technical support (possibly multiple)
- Compensation
- Courier
- Study app / portal
- Wearable / sensor
- Clinical research site
- ePRO
There has to be a better way
What’s Different for Medical Devices?

- Class I
- Class II
- Class III
- IVD
Surgical implant

• Greater level of invasion
• Smaller study population
• Limited options to “stop treatment”
• Skill of surgeon (investigator) impacts outcomes
• Long term follow-up required
In Vitro Diagnostic

• Healthy study population
• Larger study population
• May require undesirable tests (e.g. colonoscopy)
• Once sample given, “drop-out” options limited
Maximizing patient participation in clinical trials
How can we make it easier for stakeholders to engage patients in the clinical trial design process?
Improved patient participation and compliance

Trials designed with true patient priorities

Sponsors surveying patient preferences
Patient Participation in Clinical Trials: Literature summary

• What research has already been done toward the science of patient input?
• What tools are already available for engaging patients?
Patient Participation in Clinical Trials: Patient Survey

• How are patients made aware of clinical trial opportunities?
• What characteristics encourage patients to participate?
• What characteristics discourage patients from participating?
• What is the level of interest for patients in helping design clinical trials relevant to them?
Patient Participation in Clinical Trials: Patient Survey

- How are patients made aware of clinical trial opportunities?
How did you hear about the clinical trial?

- Doctor, nurse, or other healthcare professional: 10
- Advertisement: 8
- Clinical trial website: 8
- Medical device manufacturer website: 2
- Patient advocacy group: 8
- Patient support group: 4

Number of respondents
Patient Participation in Clinical Trials: Patient Survey

- What characteristics encourage patients to participate?

If you participated in a clinical trial, what made you decide to participate?

- Personal benefits
- Potential benefit to others from the knowledge gained by the study
- Access to new treatments/device
- Perceived higher level of care/follow-up
- The clinical trial did not involve any extra effort
- The clinical trial did not involve any extra costs
- The clinical trial provided some monetary compensation
- My doctor recommended participation
- Other treatments did not work

Number of respondents
Patient Participation in Clinical Trials: Patient Survey

- What characteristics discourage patients from participating?
If invited and you did not agree to participate, why not?

- The study doctor or nurse did not fully explain what would be required of me
- The study doctor or nurse did not fully explain the importance of the study
- Too many required visits
- Each visit would take too long
- Too many exams/procedures
- Too inconvenient (e.g., travel, location, etc.)
- Too much work for me (e.g., patient diary required)
- Chance of receiving placebo/dummy device or a sham procedure was too high
- Clinical trial risks: risk of procedures
- Clinical trial risks: privacy concerns
- Clinical trial risks: concern about the product being tested
- Concern about conflict of interest because the study was sponsored by the company that could profit from it
Patient Participation in Clinical Trials: Patient Survey

• What is the level of interest for patients in helping design clinical trials relevant to them?

What are some ways that you think patients should be involved in the design of a clinical trial?

- Sharing patients' experience of living with a disease or chronic injury via e-mail or web sites
- Providing input on the outcomes measured in a medical device clinical trial
- Completing surveys that measure patient preferences for treatments
- Attending focus groups to talk about patients' disease experience or preference for treatment
- Talking to regulators about patients' preferences for or expectations of the clinical trial experience
- Talking to other patients about participating in clinical trials
- Talking to medical device companies about how they design their clinical trials

Number of respondents
Patient Participation in Clinical Trials: Stakeholder Survey

- How frequently do trial sponsors seek input from patients into clinical trial design?
- What barriers do trial designers face when attempting to solicit patient feedback?
- What mechanisms do sponsors use to find patients interested in providing input, and how do they collect it?
- Do stakeholders understand what truly motivates patients to participate in clinical trials?

Patient Participation in Clinical Trials: Stakeholder Survey

• How frequently do trial sponsors seek input from patients into clinical trial design?

In your estimation how often does your organization gain feedback directly from patients prior to finalizing a study protocol?

- Every study/protocol
- Greater than 75% of the time
- Greater than 50% of the time
- Greater than 25% of the time
- Less than 25% of the time
- Never

Number of respondents
Patient Participation in Clinical Trials: Stakeholder Survey

- What barriers do trial designers face when attempting to solicit patient feedback?

If you have involved (or tried to involve) patients in protocol development or operational strategy planning, did you encounter any internal barriers?

- Perceived compliance/regulatory concerns of involving patients
- Legal/contractual roadblocks
- Understanding how to proceed (unsure methodology)
- Logistical issues (e.g., access to patients to participate)
- Privacy & confidentiality reasons
- Other

Number of respondents
Patient Participation in Clinical Trials: Stakeholder Survey

• What mechanisms do sponsors use to find patients interested in providing input, and how do they collect it?

If you have involved patients in protocol design, what methodologies have you used?

- Patient workshop (patients selected specifically for that workshop only)
- Patient advisory board (patients you work with on a regular basis)
- Patient group representatives
- Patient survey
- Patient interviews
- Other sources of direct or indirect patient input

Number of respondents
Patient Participation in Clinical Trials: Stakeholder Survey

- Do stakeholders understand what truly motivates patients to participate in clinical trials?

What do you believe are the most important factors to patients in deciding to enroll in a device or diagnostic/sample collection trial?

- Personal benefit to their health
- Potential benefit to others from the knowledge gained by the study
- Access to new treatment/device/diagnostic
- Perceived higher level of care/follow-up
- Financial compensation
- Perceived financial cost of participation
- Doctor recommends participation
- Other treatments didn’t work
- Burden of participation (e.g., number of procedures, visits, etc.)
- Distance required to travel to site

Weighted average of responses
What’s next?

MDIC Framework for Patient Input in Medical Device Clinical Trials

The Framework effort comprises three sub-projects:

• Guidelines to integrate patient preferences into the statistical design of clinical trials
• **Methodologies to maximize patient participation in clinical trials**
• A report summarizing the evidence base for the methodologies, guidelines, and framework developed under this project
What’s next?

MDIC Framework for Patient Input in Medical Device Clinical Trials

This summer:

• Draft report: Methodologies to maximize patient participation in clinical trials
What’s next?

MDIC Framework for Patient Input in Medical Device Clinical Trials

Save the Date: November 13, 2019

MDIC Patient Engagement Forum
Submit your questions through the chat box
Resources available

MDIC Science of Patient Input project page
https://mdic.org/program/science-of-patient-input/
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