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A Novel Collaborative Approach to Building Better Clinical Trials: New Insights From a Patient Engagement Workshop to Propel Patient-Centricity Forward

Alyson Gregg, MBA[1], Nova Getz, BA[2], Jasmine Benger, BS[2], and Annick Anderson, MBA[2]

Abstract

Background: (1) A growing number of pharmaceutical and biotechnology organizations are engaging patients, their support networks, and clinical trial site staff at various touchpoints along the clinical research development spectrum to solicit feedback on how to reduce the burden of clinical trial participation and administration. (2) However, many organizations are still evaluating how to best implement such engagement initiatives in a manner that will evoke meaningful, sustainable results and change. *Methods:* In an effort to support meaningful engagement in a novel way, Janssen organized a 2-day innovative workshop designed to promote collaboration and foster mutual understanding among a cross-functional group of clinical research stakeholders. Over the course of the workshop, patients, sponsor team members, and clinical trial site staff each leveraged their unique experiences to address the challenges of today's clinical trials, and collectively envision the ideal clinical trial of the future. *Results:* The workshop design created a level playing field for the stakeholders to interact with one another as partners with the shared goal of building better clinical trials. A significant number of transformative ideas were generated as a result of the innovative workshop exercises. Participants agreed that future clinical trials must be convenient and customizable and truly put the patient at the center of research. *Conclusion:* Creating a comfortable atmosphere and engaging environment for patients, site staff, and pharmaceutical companies to discuss current challenges of clinical trial participation and potential solutions together as partners in real time is critical and has proven to be a valuable novel engagement option for other organizations to consider adopting.

Keywords

workshop, patient engagement, patient centricity, protocol design, clinical trial design, stakeholder, partnership, innovation

Background

Historically, many organizations have been reluctant to solicit feedback directly from patients and their support networks as a means to improve the clinical research process, largely because of a lack of clarity around how and when it is most effective and beneficial to engage with these stakeholders, and amid concerns of avoiding conflicts of interest or promotion of investigational products.[1] Yet, patient engagement is becoming the new standard for designing patient-centric clinical trials and developing treatments that successfully address study volunteer needs. This is increasingly becoming evident with government, public agencies, and organizations engaging patients at various checkpoints throughout the clinical research process now more than ever through patient advisory boards, surveys, and in-depth interviews,[2] and patient advocates vocalizing their need to be involved with slogans such as "nothing about me, without me."[3]

The literature suggests that while patient engagement practices are still in their infancy and in need of improvement,[4] the inclusion of patients in the clinical trial design process is critical to the advancement of clinical trial design[5] because it can help create a mutual understanding of issues and potential solutions that affect diverse stakeholders.[6] Major industry

[1] Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), Titusville, NJ, USA
[2] Center for Information and Study on Clinical Research Participation, Boston, MA, USA

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Corresponding Author:
Annick Anderson, MBA, The Center for Information and Study on Clinical Research Participation (CISCRP), One Liberty Square, Suite 1100, Boston, MA 02109, USA.
Email: annickanderson@ciscrp.org

organizations are spearheading initiatives with the goal of encouraging patient engagement across clinical research endeavors. The Patient-Centered Outcomes Research Institute's (PCORI's) stipulation to only offer grants to research that exhibits meaningful patient engagement, and the FDA's Patient Engagement Collaborative (a group composed of patient advocates who regularly discuss how to engage patients in the medical development process),[5,7] are both testaments to the significance of giving patients a seat at the table early in the development stages and treating them as valued partners.

Another facet of creating patient-centered clinical trials entails engaging principal investigators and clinical trial site staff to better understand what challenges and opportunities exist from a site and operational perspective.[8] Despite the value that site staff could offer to discussions around clinical trial design, a recent literature review found that of the 70 articles reviewed, only about 15% reported engagement with principal investigators.[9] The same literature review cautioned that excluding these groups could potentially lead to more challenges in clinical trials if decisions were made without their interests in mind.[9]

Currently, initiatives to improve clinical trials are often conducted with stakeholders isolated from one another, without much opportunity for real-time multistakeholder collaboration. A literature scan revealed only a handful of articles referencing the use of this type of approach, including one daylong conference where investigators and patients discussed how to best learn about and engage in clinical trials for neurologic disorders.[5] Results from the meeting suggested that the participants valued the "team" approach and felt that it was necessary to include patients early in the development process.

A siloed approach may perpetuate the reservations that prevent organizations from engaging with patients directly, and in turn continue patients' perception of not being a valued partner in the process. Sponsors may perceive that some patient groups lack education or might make suggestions that are challenging to implement from a protocol or operational standpoint when providing feedback on clinical trials.[10] Our experience has been that when patients are exposed to perspectives of principal investigators, sponsors, and regulatory stakeholders, and are provided the opportunity to envision changes that are realistically possible for the industry as a whole, they are an informed and vital source of input.

Several patient groups are taking the time to educate themselves, so they can effectively collaborate with industry and academia on clinical trials.[10] Furthermore, the National Center for Advancing Translational Sciences (NCATS) has also developed toolkits that help patient groups learn how to communicate with researchers to fuel therapeutic innovations.[11] In some cases, organizations who conduct patient engagement initiatives proactively bridge the knowledge gap by educating the patients they engage on clinical trials.

In an effort to move away from the siloed approach and take patient engagement to the next level, The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) adopted a novel multistakeholder initiative where all the parties were encouraged to collaboratively build their ideal clinical trial together through a creative workshop format. To that end, a workshop was designed where a group of patients, investigators, site staff, and sponsor representatives partnered in a creative forum to better understand each other's perspectives and experiences.

This article discusses the methods that Janssen utilized to facilitate and execute this workshop to collaboratively brainstorm solutions and ultimately build better clinical trials. Best practices and key findings are also shared in the hopes that other industry members may adopt this novel approach to supplement current engagement initiatives, expand use of this holistic approach and workshop design, and continue to progress toward the ideal clinical trial for future study volunteers.

Methods

Janssen collaborated with an independent nonprofit organization, The Center for Information and Study on Clinical Research Participation (CISCRP), to execute the project. Janssen and CISCRP staff members comprised the project team. The project team designed a unique workshop platform that would leverage each stakeholder's unique perceptions and experiences with regard to clinical trials. The workshop was conducted in June of 2018 where patients, clinical trial site staff, and Janssen team members worked in partnership to brainstorm ideas to create better clinical trials.

Workshop Planning and Logistics

The workshop required 4 months to organize, with the project team collaborating on the development of a pre-read document as well as the workshop's objectives, flow, structure, activities, and outputs over a series of regular web conferences. Several weeks were allocated to identifying, recruiting, and obtaining consent from the external workshop participants, as well as to draft and disseminate correspondence about the meeting to those invited. The workshop was designed as 2 half-day events that allowed participants to build rapport with each other and helped to ensure all participants remained engaged. To inspire creative thinking and provide the participants with ample opportunities to move around (if able) and utilize the space during the breakout sessions, the workshop took place in a remote setting with natural scenery, rather than a more traditional office/conference room setting.

Workshop Participants

Workshop participant eligibility was collaboratively determined in advance by the project team to ensure diversity in perspectives. The workshop consisted of approximately 30 participants, including 5 patients representing multiple therapeutic areas (Lupus, respiratory failure, pediatric and dermatological oncology, and type 1 diabetes) ranging in age from early 20s to early 60s; 2 clinical research coordinators; a principal investigator; a site director; cross-functional representation from Janssen R&D

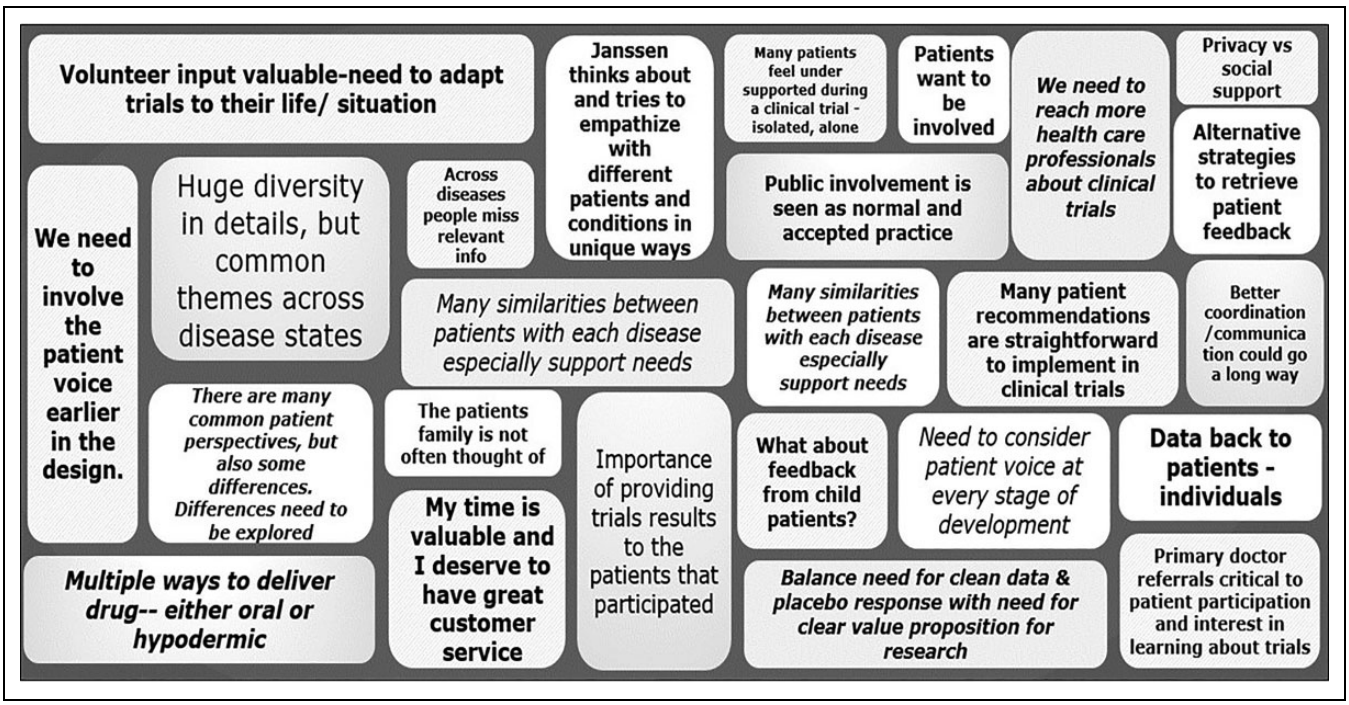

Figure 1. Key insights from pre-read.

and clinical operations teams; and CISCRP facilitators. It was important that patients had clinical trial experience to ensure they were familiar with the clinical research process, and that site staff represented study clinics specialized in various therapeutic areas, as the diversity of the group ensured that various perspectives were represented in each breakout session.

Size and Structure

Given the large group of participants, a panel discussion for introductions and 3 breakout sessions into predetermined mini-teams were used over the course of both days so that each workshop participant had an opportunity to personally share her or his experience with clinical trials to the group and build upon each other's ideas. Each breakout session consisted of at least 1 patient, a site staff member, Janssen staff, and an experienced facilitator to ensure that each stakeholder's perspective was represented and captured.

Pre-workshop

Prior to the workshop, a series of individual patient and caregiver interviews were conducted across therapeutic areas to identify the unique perceptions and needs that patients and their caregivers have regarding clinical trials specific to their condition, as well as what opinions were consistent regardless of condition. In general, the patients and their caregivers shared many of the same motivations for participation, as well as hesitations about participation across therapeutic areas, with some exceptions depending on the condition.

These findings were consolidated and presented in a visually engaging format. This report was provided in advance to all workshop participants as a pre-read to establish baseline knowledge on patient and caregiver perspectives in clinical research before attending the workshop.

Innovative Workshop Activities

Workshop activities were designed to promote open communication and creativity to reach the goal of transforming clinical trials and brainstorming innovative ideas together.

To help instill the participants with a sense of purpose for the workshop on a more personal level, each person shared her or his unique objectives for the outcome and her or his top insights from the pre-read at the beginning of the workshop (Figure 1). The ability to hear the similarity of the goals and insights among the patients, site staff, and the Janssen team helped foster a sense of partnership among all participants.

The workshop participants were then provided with a brief presentation that reviewed key findings from the pre-read and was supplemented with global survey data to provide additional quantitative learnings.

The initial breakout sessions were designed to have mini-teams generate a "quantity" of innovative ideas as opposed to focusing on "quality" or more complex ideas. Ground rules were set prior to the breakout sessions to encourage participants to be respectful of one another's ideas and not to stifle creative thought process.

To stimulate innovative thinking, "spark cards" (ie, cards that are used to brainstorm solutions in a less conventional way) were available for each of the mini-teams to use in

	COST-OF-ENTRY (Non-negotiable) Yellow	INCREMENTAL (+ 1) Blue	REVOLUTIONARY (First-of-its-kind) Green
Time to Implement	Immediate	Near-term	Multi-year
Ability to Address	Simple Process, Not Complex	2-3 Step Process, Somewhat Complex	Multi-phase Process, Potentially Complex
Resources Required	Minimal	Minimal → Moderate	High
Benefit to Patient	Meets Basic Need	Meets Intermediate Need	Exceeds Needs
Benefit to Site	Meets Basic Need	Meets Intermediate Need	Exceeds Needs

Figure 2. Prioritization criteria.

addition to other materials (eg, sticky notes, pipe cleaners, etc) during the daily breakout sessions. After each session, a full-group discussion commenced so that all workshop participants were collectively updated on the ideas that each mini-team had discussed.

After the first day of the workshop, the ideas generated were categorized under different themes by the project team to help organize the content in a more manageable and structured way. On the second day of the workshop, these themes were shared with the workshop participants to help orient them as they continued to build upon and ideate additional ways to improve clinical trials.

To continue to inspire more creative and outside-the-box thinking, the project team developed "homework assignments" for each of the workshop participants to complete individually after the first day of the workshop. The patients were prompted to create collages representing their ideal clinical trial experience. Conversely, the site staff and Janssen participants were provided with worksheets that prompted them to think of past "extraordinary" customer experiences outside of the clinical trials industry, to help them think of innovative approaches to patient engagement. As a result, qualities that might be helpful to incorporate into clinical trial experiences were identified. At the beginning of day 2, all were asked to share their "homework," to provide inspiration to the group.

Given the volume of ideas generated over the course of the workshop, a final prioritization exercise was crucial at the end of day 2 to help the project team determine which solutions might be the most efficacious, revolutionary, and important to begin working on to improve clinical trials.

Prioritization criteria were created before the workshop commenced (Figure 2). By setting clear criteria and definitions for the participants to rate the ideas, the project team was able to control for possible varying interpretations of "high, medium, and low" priority ideas. Each workshop participant was given a batch of small dot stickers whose colors corresponded with the chart. Over lunch, the participants were prompted to "walk the gallery" of ideas written on the flip charts during a previous ideation session and to place stickers by the ideas that stood out to them based on the criteria identified. This activity helped the group quickly and visually assess the innovativeness and priority for each idea and help the project team select 3 "big ideas" to further develop and pursue after the workshop.

As a final activity, clinical trial site staff and patients were then able to begin the process of bringing these ideas to life by participating in a high-level business build-out exercise with the project team.

Outcome

The workshop and its design succeeded in generating a significant number of transformative ideas by fostering open communication and partnership between key clinical research stakeholders. The activities ultimately yielded 3 ideas accompanied with high-level implementation plans. All parties agreed these ideas were innovative and transformative as they addressed the critical need for convenient, customizable, and truly patient-centered clinical trials.

Follow-up

After the workshop, a follow-up thank-you letter was sent to the clinical trial site staff and patients to express gratitude for their participation, as well as to inform them of how their feedback during the workshop would be used to help shape better clinical trials. Thanking participants, especially patients, was important because many frequently expressed disappointment that they did not receive any follow-up correspondence after

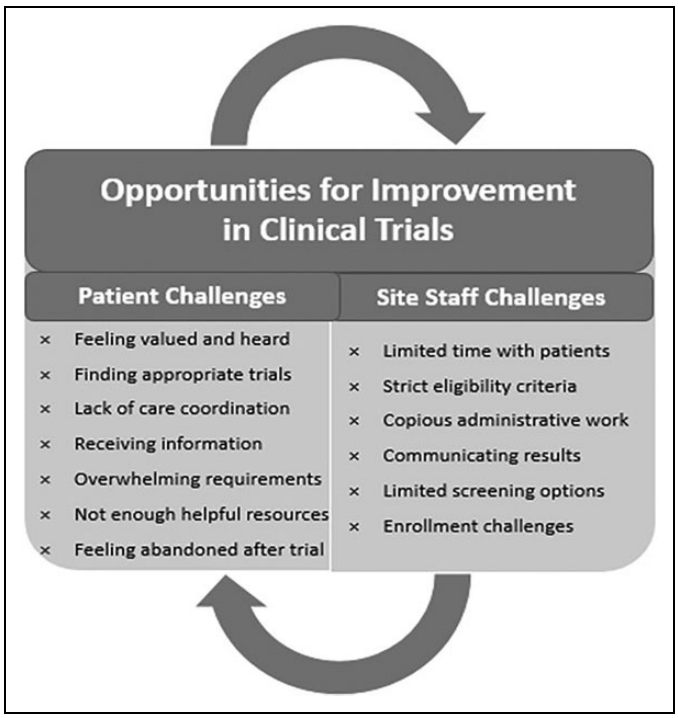

Figure 3. Opportunities for improvement.

their clinical trial participation was over despite finding this to be very important.[12]

Results

This novel approach to patient engagement provided patients and clinical trial site staff several opportunities to voice the challenges they faced when participating or administering a clinical trial, and in general helped provide insight into where the pain points of the clinical research process lie. Some of the challenges were highlighted by the site staff and patients during the workshop which point to major opportunities for improvement (Figure 3).

As a result of understanding these challenges, several recommendations and ideas were brainstormed regarding how clinical trials could be improved (Figure 4). Nine key themes around better clinical trials solutions were identified after the first day of the workshop. Each of the themes are discussed at a high level below.

Awareness and Education

The need to raise clinical trial awareness in community settings was highlighted as imperative to attracting diverse communities to participate, and increasing the public's understanding of clinical research through plain language communication in a setting they feel comfortable in. Opportunities to have meet and greets at the study site and to learn from peers or community leaders were thought to be critical by both patients and site staff alike, as this could potentially help connect patients to clinical trials that were right for them, and improve enrollment in clinical trials.

Moving Toward Data Centralization

Better streamlining and centralizing patient medical data (ie, pre-enrollment baseline characteristics) was thought to accelerate the identification and recruitment of eligible patients into clinical trials, as well as optimize the sharing of study results between physicians and investigators. Additionally, creating a global cross-sponsor platform that clearly and concisely communicates clinical trial options to patients was thought to help patients more easily find appropriate clinical trials.

Communication of Milestones and Study Results

Disseminating more information about either the clinical trial or individual study results at various checkpoints throughout participation was thought to not only help make patients feel more engaged and valued but also to help them understand how their participation made an impact on their individual health as well as other patients' health.

Digital and Technological Innovation in Clinical Research

The use of technological innovations to make clinical trials more accessible to patients was critical to all stakeholders because this could better support enrollment and aid retention. Mobile nurses, health tracking devices, and better integration of study tests with patients' electronic health records (EHRs) were discussed as ways to alleviate current burdens of participation and make clinical trials more patient-centered.

More Patient-Centric Study Design

Avoiding an overwhelming number of visits to a study site, or other burdensome study requirements, was advocated for by both the patients and the site staff, as this could help make clinical trials appear less daunting and may better support enrollment and retention. Furthermore, integrating study visits into regular doctor office visits might help streamline the study site visit schedule. The efficient sharing of study assessment results with regular doctors or specialists could additionally help reduce the number of repeat assessments that patients would have to endure.

Continuous Engagement With Local Communities

The patients and site staff encouraged sponsors to engage with local communities on a regular basis to help foster trusting relationships that extended beyond enrollment for clinical trials. Alumni networks made up of past trial participants were thought to be a great resource for members of the community to connect with if interested in participating in a clinical trial.

Customization, Personalization, and Flexibility for Study Volunteers

Site staff and patients alike communicated the desire to have more customizable options with clinical trial participation and study requirements. With patients leading busy lives and juggling various work and life responsibilities, all agreed that

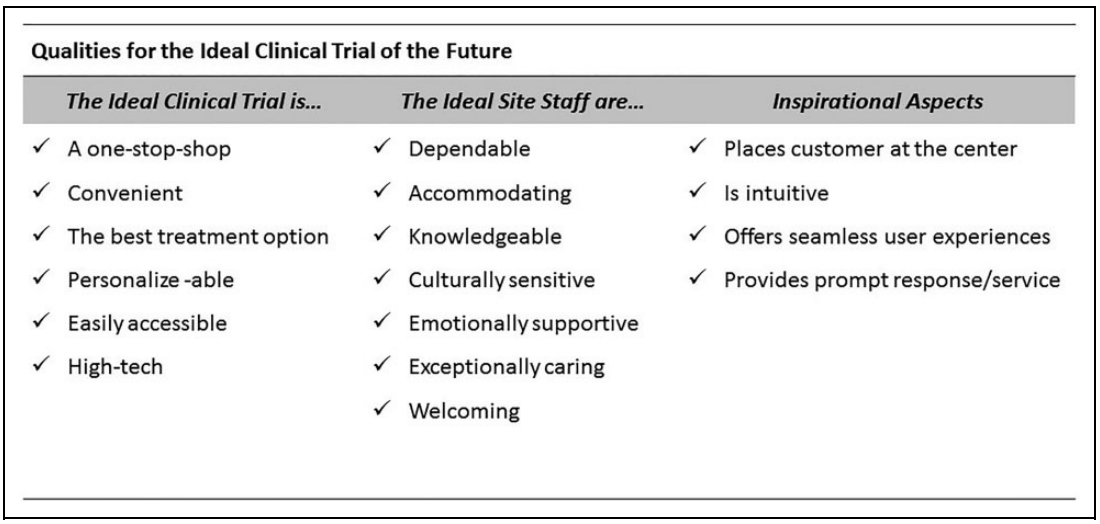

Figure 4. The ideal clinical trial of the future.

offering varying levels of commitment in a clinical trial might help make these trials more accessible to patients who otherwise might not be able to participate.

Issues With Compensation

The workshop participants agreed that in some cases, compensation for study volunteers was not sufficient particularly if they needed to miss work for clinic visits.

Better Follow-Through and Accountability

Patients expressed the desire to know which study arm they were in at the end of their clinical trial participation so that they could determine whether the study drug was of any benefit to them, and if it would be of any value to continue to participate in an open label extension. A plain-language summary of clinical trial results was also regarded as very important.

A collage exercise allowed the patients to visually communicate additional themes such as the need to be reassured that the clinical trial was the best possible treatment option for them; and be provided with exceptional care, emotional support, and culturally sensitive site staff. Patients also highlighted the importance of continued care and support from the site staff at the end of participation and having the site staff clearly express that their participation was valued by expressing gratitude and providing adequate compensation.

In addition to the transformative ideas generated, key qualities essential to the clinical trial of tomorrow were also highlighted as a result of the workshop's homework assignment and were used to help guide further ideation and eventual build out of the prioritized ideas.

Workshop Impact

Engaging patients, site staff, and members from a pharmaceutical company in a space dedicated to listening to experiences and finding solutions for better clinical trials generated valuable insights and resulted in a number of innovative ideas that were made with all stakeholders' best interests in mind. One of the most impactful aspects of the multistakeholder workshop was the ability for all parties to interact on a more personal level and to have open discussions in real time. This helped the participants have a better understanding about the unique challenges that each stakeholder faced, as well as helped them build upon one another's recommendations in a collaborative and mutually beneficial way—ultimately resulting in the creation of ideas to help all parties have improved clinical trial experiences.

Conclusion

This novel collaborative patient engagement approach underscored that the challenges with enrollment and retention are likely to remain if attempts to improve clinical trial design are made without the input of the most important stakeholders—patients and clinical site staff. The following are highlights of best practices for this type of approach that will ensure successful collaboration among patients, site staff, and sponsors:

- *Level the playing field*. Providing workshop participants with the same background information despite their varying levels of knowledge and expertise can help ensure that all participants are on the same page.
- Being in a *comfortable location* outside of an office environment can help promote innovative thinking. Providing artistic materials can also help participants think more creatively and freely.
- Having an *independent party facilitate* the workshop can help ensure feedback is shared without bias.
- *Valuing each individual perspective* as valid and important. Constraining ideas or critiquing feedback may stifle innovation.
- *Showing appreciation* for workshop participant feedback is critical. At the end of the workshop, repeat back the ideas heard and thank the participants.

- Establish *a collaborative approach* between the sponsor organization and workshop participants. This energizes those involved and communicates that the takeaways from the workshop were taken seriously.
- Hold a *debrief session* shortly after the meeting among the project team to download relevant top-of-mind thoughts and determine next steps.
- Determine appropriate metrics to *measures success*—agreeing on metrics prior to the project start and ensuring these measures are tracked over time.

This type of workshop, specifically its unique multistakeholder collaborative approach, can be beneficial to all clinical research stakeholders in many ways. This approach can be utilized in multiple capacities and applied when discussing specific aspects of research regulation, clinical trial protocols, or the clinical research enterprise in general. Sponsors may additionally benefit from implementing this approach on a regular basis in concert with the extended clinical research community—such as with regulatory authorities, clinical research organizations (CROs), or with other sponsors—so that learnings can be applied broadly with the common goal of improving study volunteer experiences. With more widespread implementation of this method, meaningful patient engagement can be achieved while also building the better clinical trial of the future.

Declaration of Conflicting Interests

No potential conflicts were declared.

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ORCID iD

Annick Anderson, MBA https://orcid.org/0000-0003-3279-8689

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