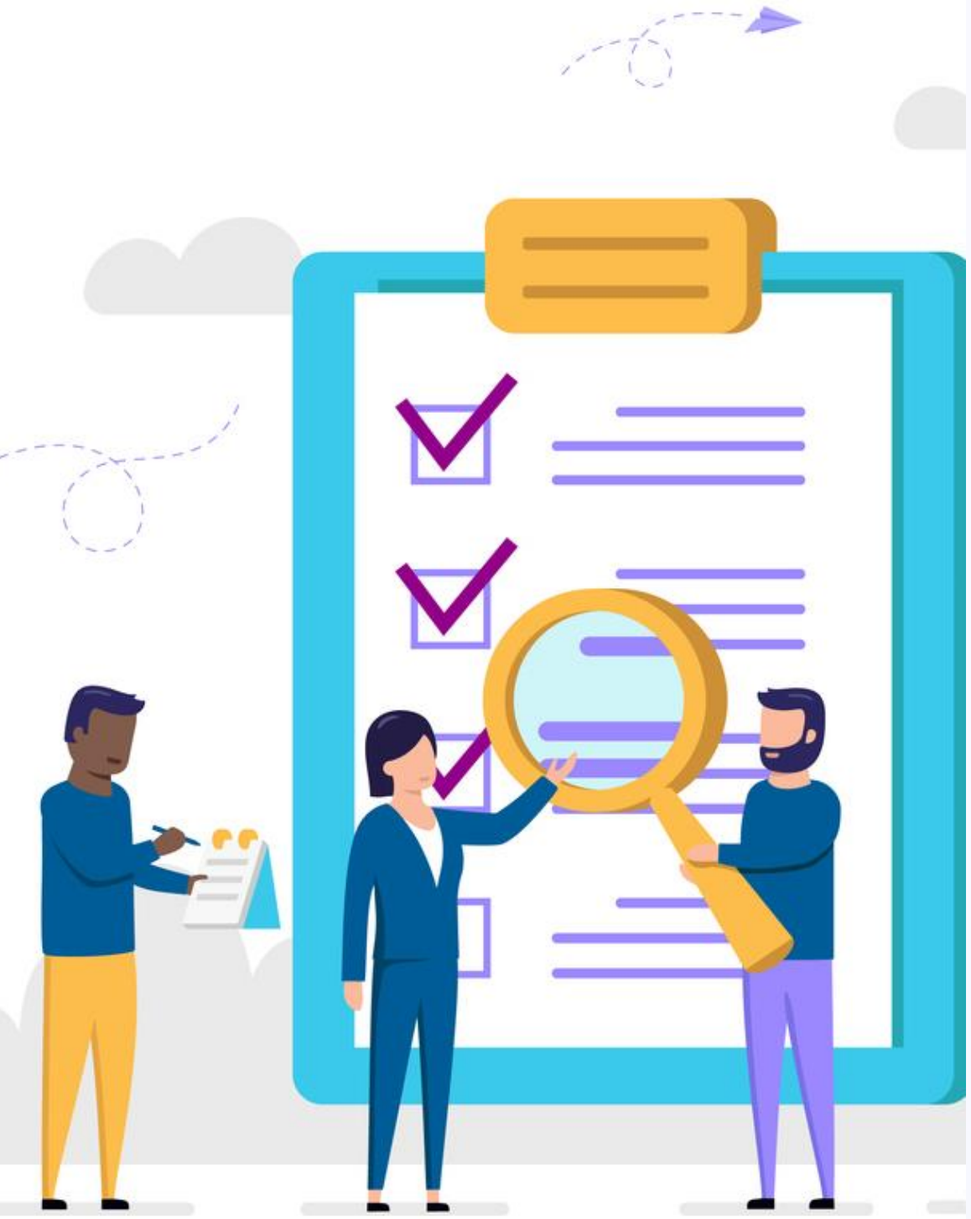


Participant Experience in Research Surveys: An exploration of Local and International Approaches

The White Coats Foundation Participant Experience in Research Surveys webinar aimed to explore various approaches and strategies for utilising surveys to capture participant experiences in clinical research and a key focus area of the discussion centered on exploring preferences around localised and standardised approaches to survey administration and data collection. The discussion also looked at the value of surveys as a means to collect data, understand participant experiences, and ensure that feedback is integrated into the clinical trial process to improve participant-centric care.

The content of this report focuses on the valuable insights and viewpoints shared by presenters, panelists and attendees at the webinar conducted on 16 October, 2024.

Presented by white coats foundation

The Webinar Agenda

4.00pm-4.15pm - Welcome Address, Introductions, and Webinar Poll

Speakers/Facilitators: Christine Zahren(Co-Founder and Director White Coats Foundation) & Elizabeth Wilson (Director Prime and Partner Sites, IQVIA and Advisory Board Member, White Coats Foundation)

4.30pm Participant in Research Experience Survey (PRES): A National Perspective (UK)

The Participant in Research Experience Survey (PRES) has been conducted annually by the NIHR Clinical Research Network (CRN) since 2015/16.

Through PRES, the NIHR aims to put research participant experience at the centre of research delivery by providing an opportunity for as many research participants as possible to share their experience of taking part in research.

Speaker: Mana Golsorkhi, Public Engagement Manager, NIHR Research Delivery Network Coordinating Centre (RDNCC) UK

4.30pm-4.45pm - Participant Experience in Research Survey: A Local Perspective (Australia)

Despite the increased emphasis on involving patients and the public in trial design, there is no systematic or standardised means of capturing participants' experiences in clinical research in Australia. Sarah Piplica will provide a local perspective on participant experience in research survey's drawing on her experience developing a validated survey tool at the University of Sunshine Coast Clinical Trial Centre, to test hypothesis about the patient experience in research.

Speaker: Sarah Piplica, Regulatory, Start-Up and Patient Partnerships Manager University Sunshine Coast Clinical Trials Centre

5:00pm - Consumer/Patient perspectives on Participant Experience in Research Surveys

Dr Shyamsundar Muthuramalingam and Sarah Lukeman provide feedback from a consumer lens on the potential value of surveys for evaluating the participant experience in research with a focus on national vs local approaches. We also consider what needs to be taken into consideration from a consumer perspective so that it's not just a tick box exercise and how to engage consumers without adding to survey fatigue.

Speakers: Sarah Lukeman (Patient Perspectives Partner) and Dr. Shyamsundar Muthuramalingam (Consumer Advocate)

5.00pm-5.30pm Panel Discussion, Q&A and Poll

Facilitators: Christine Zahren and Elizabeth Wilson

Panellists:

- Shyamsundar Muthuramalingam
- Sarah Lukeman
- Sarah Piplica
- Mana Golsorkhi

5.30pm - Close

PRE - POLL QUESTION 1

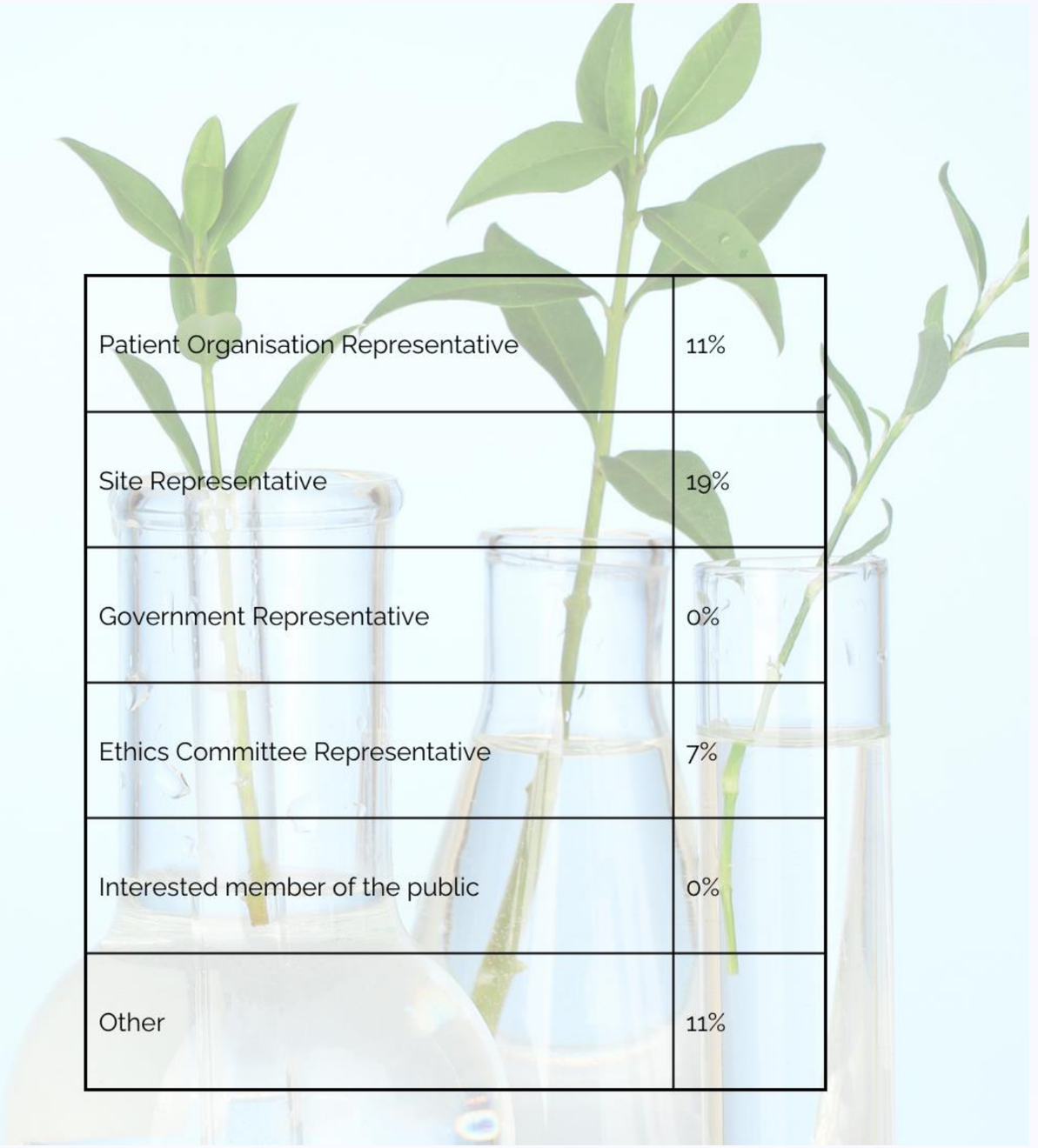
Please select one of the following that represents you current view on this topic:	**% of Votes**
Clinical trial sites should take responsibility for developing their own site specific surveys to collect and learn from information on the participant experience in research at their location.	22%
A standardised survey should be developed that can be used by all trial sites to collect and learn from aggregated and de-identified information on the participant experience in research nationally.	52%
Neither of the above	0%
Not sure	22%
Other	4%

PRE - POLL QUESTION 2

I am .... (multiple answers are allowed)

Patient	19%
Carer	11%
Consumer Advocate	26%
Health Care Professional	11%
Researcher	15%
Biopharmaceutical Industry Representative	4%

Patient Organisation Representative	11%
Site Representative	19%
Government Representative	0%
Ethics Committee Representative	7%
Interested member of the public	0%
Other	11%



Survey Landscape: Overview

Participant in Research Experience Survey (PRES)

PRES is a survey that has been conducted annually by the NIHR Clinical Research Network (CRN) in England since 2015/16.

It aims to give a voice to as many research participants as possible.

Transcelerate Study Participant Feedback (SPF) Questionnaire

SPF is a survey template that can be accessed online for free by sites to be provided to study participants at the beginning, middle and end of a clinical study. It is used to measure participant satisfaction, barriers to trial participation and areas for improvement.

Australian Hospital Experience Question Set (AHPEQS)

AHPEQS is a survey used by hospitals and healthcare services to ask recent patients about their experiences of treatment and care.

University of Sunshine Coast (USC) Patient Voice Survey (PVS)

First validated Australian survey co-created with participants which measures clinical trial site performance as perceived by the participant. It is delivered during and after clinical trial conduct.

UCB Pharmaceuticals has also produced evidence-based best practice for the development and deployment of patient experience surveys.

Impact of Institution- Specific Surveys in a National Setting

Benefits

Allows for exploration into specific community challenges and requirements to uncover valuable insights.

Can tailor surveys to specific audiences like children, adults, or disease areas.

Delivers real-time data on site/trial effectiveness at a site-specific level.

Supports continuous improvement at the site level.

Challenges

Managing various question sets has profound implications for national data collection, aggregation, and analysis.

Challenges year-on-year data comparison as questions differ across sites.

Variations in survey questions could limit the data available to drive actionable change and inform strategic recommendations.

Diverse question sets could compromise the strength of the evidence base to enact change.

Varying areas of focus can hinder continuous improvement.

Survey development can be time-consuming. Sites have varying resources available to develop surveys.

Impact of Standardised Surveys in a National Setting

Benefits

Standardization streamlines data aggregation and comparison, facilitating detailed year-on-year analysis at site and national levels.

When trial and site identifiers are collected, it provides real-time feedback to sites for improving trial processes and services.

This approach generates a robust evidence base for strategic recommendations, promoting continuous improvement at a site and national level.

Provides sites, especially those with limited resources, with a standardized feedback instrument, eliminating the need for them to develop their own.

This approach is also time-saving. The Participant in Research Experience Survey (PRES) in the UK has proven to be effective in identifying areas for improvement in real-time and providing insights into the participant experience at both site and national levels.

Challenges

A standardized approach may sacrifice the specificity of a localized approach that captures individual and community nuances.

Effective national coordination hinges on assigning responsibilities for administration and funding in stewardship practices.

Key Survey Focus Areas and Timepoints Unlocked

Service Delivery/Site Performance

Surveys can explore various aspects of clinical trials, encompassing service delivery and trial protocol design. USC prioritizes service delivery/site performance in their survey, including questions about staff, facilities, and physical/digital spaces. They strategically focus on areas within their control, recognizing that protocol changes may be outside their scope.

Protocol Design and Feedback

USC believes consumer involvement in shaping protocols should occur before finalisation. However, real-time feedback on protocol issues can lead to valuable amendments during a study. These amendments can positively impact participant satisfaction, recruitment, and retention rates and presents an opportunity for a more comprehensive overview of the participant experience in research.

Participant Journey Timepoints

Other critical areas of focus in surveys relate to various timepoints in the participant journey. These include the period before the trial starts, known as the screening phase, as well as the during-trial and post-trial experiences.

Understanding perspectives during the screening process is crucial, as this is often a delicate and uncertain time for potential participants. Surveys can shed light on the challenges and concerns they face as they navigate the eligibility requirements and prepare to embark on the clinical trial.

During Trial Insights

Equally important are the insights gained from surveys conducted during the trial itself. These can reveal how participants are coping with the study protocols, any side effects they are experiencing, and their overall level of satisfaction with the process. This feedback can help researchers make improvements and adjustments to enhance the participant experience.

Post-Trial Impact

Finally, post-trial surveys offer a valuable opportunity to capture the lasting impact of the clinical research on participants lives. These surveys can uncover long-term benefits, as well as any lingering concerns or unmet needs that require further attention.

Uncovering Depths: The Length of Surveys

Short Form Surveys (SFS)

Short form surveys with single item measures provide straightforward feedback. They are easy to administer and interpret. For example, "How satisfied were you with the information you received about the trial?" Simplicity and speed can lead to higher response rates. However, single-item questions can also lead to misinterpretation. For example, "How satisfied were you with the doctor?" This question might be misinterpreted as satisfaction with the doctor's communication, clinical expertise, or personal demeanor.

SFS have lower reliability because they don't account for potential random error or variability in how patients interpret the questions.

SFS cannot capture the full complexity of the participant experience and may not be sensitive enough to detect small but significant changes in participant experience, making it hard to track progress over time.

Long Form Surveys (LFS)

Long form surveys, or multi-scale, multi-version surveys, ensure misinterpretation of a question won't lead to inconsistencies in how the experience is reported. They offer a more nuanced understanding of the participant experience and provide more reliability and validity.

The respondent burden can be an issue as LFS are more time-consuming and mentally taxing. This could lead to lower response rates.

Interpreting multi-scale items requires proper statistical validation and probably can't be analysed at a site level.

Some items may be perceived to overlap (item redundancy), causing frustration or disengagement.

Addressing Survey Fatigue and Inclusivity

Concise and Relevant Questions

Incorporating both quantitative and qualitative data points can help ensure the richness of feedback while avoiding overwhelming participants with lengthy surveys.

Quick Takes: Bite-sized Reviews

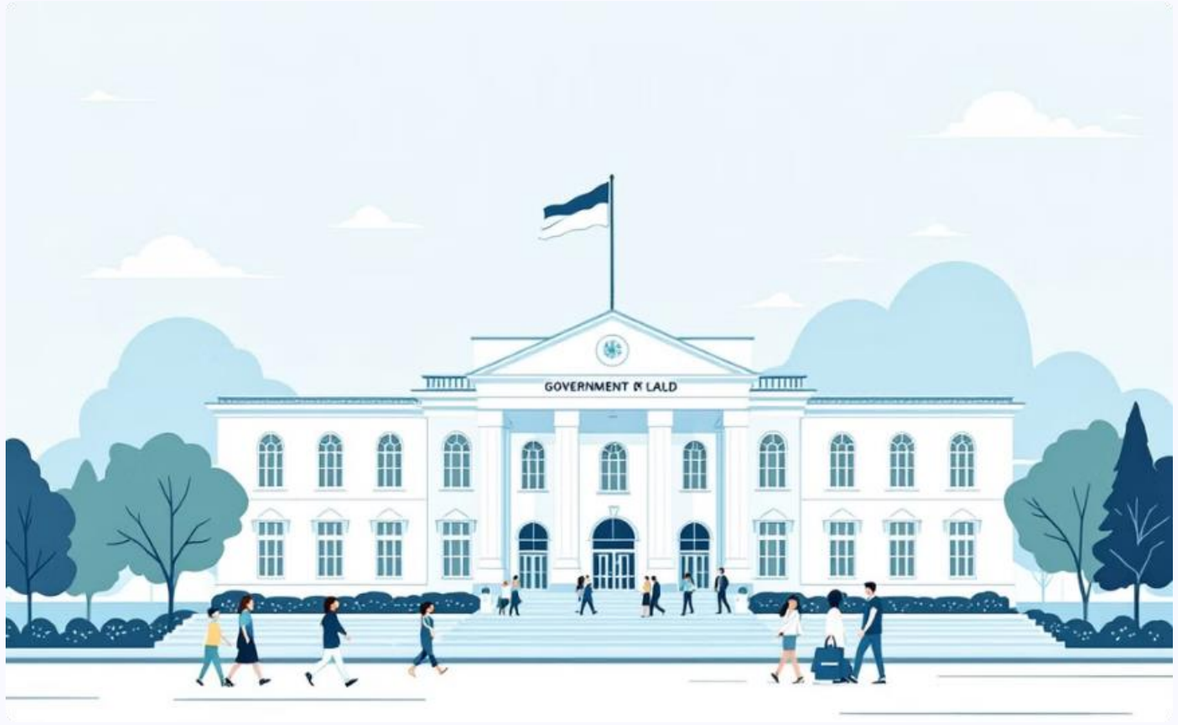
A centralized platform for participants to share their experiences and insights about clinical research was suggested. A "google review" type system for research facilities could become a way of fostering greater transparency and accountability within the industry.

It would avoid the need for complex local and national data sets and provide an immediate feedback option for participants.

Tailoring for Underrepresented Groups

Special attention should be paid to underrepresented groups in research, such as people from rural areas, LGBTQIA+ communities, or those experiencing homelessness. Surveys should be tailored to ensure accessibility and inclusivity for diverse populations. It leads to richer, more representative data that can drive meaningful change.

Clinical Trials Survey Empowerment: Governance Framework or One Stop Shop Alliance



National Clinical Trials Governance Framework

The National Clinical Trials Governance Framework was noted as a contributing factor to the increased initiative seen from sites in developing their own surveys. It was noted in the webinar that the framework emphasizes the importance of consumer involvement at both healthcare provider and clinical trial site levels. Partnering with consumers is a core principle, and one of the key actions outlined is to gather feedback from clinical trial participants, their caregivers, and families through well-designed, validated surveys.

Potential for National Standardized Systems

The webinar raised the possibility of integrating a national, standardized survey system into a broader clinical trial governance framework, which could help ensure consistency across trials while still allowing for local adaptations. There were apprehensions about the risk of this turning into a superficial or box-ticking exercise. With a thoughtful governance structure, clear data use agreements, and a commitment to ethical data stewardship, this may offer a transformative potential for data collection.

'Australian sites require a low-resource, high-impact solution to incorporate patient voices and meet national governance standards.'

Consumer Insights Unlocked

- **Sites should proactively collect feedback on the participant experience in research.**

  Failing to measure the participant experience represents a 'missed opportunity' to elevate the participant voice. By incorporating robust participant experience surveys into the research workflow, organizations can gain invaluable insights that extend far beyond the clinical endpoints.

- **Striking the right balance between standardization and localisation is a key consideration when designing surveys and gathering consumer data.**

  A standardised approach can provide valuable benchmarks and allow for broader comparisons, while a localized approach can uncover nuanced, context-specific insights that are tailored to the unique needs of a particular market or community.

- **Dive into the entire research journey, not just isolated moments of care.**

  Encompassing the journey from when a clinical trial begins, not just its conclusion, and uncover the reasons behind participant exclusion. It's crucial to explore socioeconomic factors, drop-out rates in specific communities (e.g., CALD), and other pertinent considerations.

- **We need to move beyond solely quantitative questions for benchmarking.**

  Qualitative questions offer valuable insights into participant stories and experiences. These open-ended questions provide a window into the unique perspectives and personal narratives of those impacted by clinical research. By inviting participants to share their thoughts, emotions, and challenges in their own words, researchers can gain insights beyond clinical data points. Qualitative insights can uncover unmet needs, reveal pain points, and highlight opportunities for improving the overall quality of care.

- **A hybrid model could effectively capture both community-specific and national nuances.**

  This could involve a standardized, validated survey tool that incorporates localized sections with validated question sets representing the specific community being researched. This could include underserved, marginalized, and minority groups. Additionally, the survey could adapt to different disease indications and age groups (e.g., adult vs. children's surveys).

- **Despite substantial sponsor investments in clinical research recruitment, challenges like trust, misinformation, and inadequate care often lead to low retention rates. Surveys offer a transformative opportunity for improvement, rather than a mere assessment.**

  By taking a thoughtful approach to survey design and implementation, sites can transform the participant experience and build stronger connections with the communities they serve. Rather than seeing surveys as a box to check, sites should leverage them as a powerful tool to truly understand the needs, concerns, and preferences of diverse patient populations.

Consumer Insights Unlocked

Surveys can be powerful tools for driving positive change. 'What we measure, we can manage'.

Building consumer trust is crucial for any successful product or service. By actively incorporating consumer feedback and insights, organizations can demonstrate a genuine commitment to addressing the needs and preferences of their target audience. Surveys must lead to tangible outcomes. This will foster trust and engagement among participants.

Surveys play a crucial role in capturing the voices and experiences of research participants, but used to simply improve recruitment of participants is not enough.

The survey design and implementation process must go beyond basic data collection to provide a comprehensive, actionable understanding of the whole research journey.

Designing Inclusive and Accessible Surveys

It's essential to embrace diversity and ensure accessibility for all demographic groups. Survey questions and language should be accessible to individuals with varying levels of literacy, language proficiency, and cognitive abilities. By proactively addressing these considerations, you can create a survey experience that is truly inclusive and empowering for all.

Sharing Data Across Organizations

When stakeholders can pool their insights and learnings, it unlocks a wealth of opportunities to improve the participant experience. By fostering a culture of data sharing, we can break down silos, eliminate redundancies, and leverage complementary strengths.

While survey tools can provide valuable insights, they should not be used in isolation. Instead, they should be part of a comprehensive strategy that incorporates various methods for engaging with research participants.

Surveys are a powerful tool, but they are just one piece of the puzzle. Surveys should not replace other engagement approaches, such as focus groups, interviews, and patient advisory panels. These allows sites to gain a more holistic understanding of the participant experience and perspectives.

When surveys are designed with empathy and a commitment to inclusivity, they can become a catalyst for positive change.

This means incorporating community-specific elements, adapting to diverse disease indications and age ranges, and ensuring the voices of underserved groups are amplified. By striking the right balance between standardization and localization, sites can create a rich tapestry of data that informs more impactful, participant-centric clinical research.

The Role of Consumer Advisory Panels in Survey Design

Capturing Relevant Feedback

Collaborating with consumer advisors can help uncover valuable perspectives on essential aspects of their trial experiences, including impactful staff interactions, ensuring appropriate informed consent etc.

Improving Trial and Service Delivery

Co-creation helps shape surveys that prioritize patients' needs in addition to site performance and trial satisfaction.

Empowering Participant-Centered Research Experiences

Co-creation can support solutions to challenges seen in trials that are faced by patients to ensure more accessible and participant friendly research. It can help uncover blind spots and ensure the final survey resonates with the full breadth of the audience.

POST - POLL QUESTION 1 REASKED

Please select one of the following that represents you current view on this topic:	% of Votes when reasked	% of Votes in poll at commencement of webinar
Clinical trial sites should take responsibility for developing their own site specific surveys to collect and learn from information on the participant experience in research at their location.	0	22 %
A standardised survey should be developed that can be used by all trial sites to collect and learn from aggregated and de-identified information on the participant experience in research nationally.	64%	52%
Neither of the above	7%	0%
Not sure	14%	22%
Other	14%	4%

When comparing the pre and post-webinar poll results, there was a clear shift in how respondents viewed site-specific versus standardised survey approaches. Initially, 22% of respondents favoured a site-specific approach. However, after the webinar, no respondents felt that a site-specific approach was suitable.

Key Takeaways

Importance of Trust and Accountability

The webinar highlighted the critical need to build trust with participants by demonstrating that their voices are valued and their feedback will drive meaningful improvements.

Standardized vs. Localized Survey Approaches

The discussion centered around the balance between adopting a standardized approach to surveys and allowing trial sites to manage surveys independently. A hybrid model combining both approaches emerged as a potential solution to achieve both standardization and flexibility.

Survey Mastery: Essential Focus Areas and Timepoints for Administration

The webinar emphasized the importance of identifying key focus areas and strategic timepoints for administering participant surveys. By carefully planning and executing survey administration, researchers can gather actionable insights that enhance the overall participant experience as well as the site operations supporting and delivering clinical trials.

In Summary

Participant experience

Surveys used to capture the participant experience in research are valued as an option to deliver improvements in clinical trial service delivery and design.

National survey tool

There is a preference for a standardised national survey collection tool.

Driving change

Using survey outcomes to drive change is crucial. Building consumer trust is essential.

Stewardship

Responsibility of stewardship needs to be determined. A partnership with the One Stop Shop or National Clinical Trials Governance Framework should be explored.

Missed opportunity

Not capturing the patient voice in research is a missed opportunity.

Hybrid approach

A hybrid survey model capturing local and national nuances should be considered.

Engagement plan

Sites should integrate survey tools strategically within a comprehensive engagement plan to enhance participant interactions. Surveys should not be used in isolation.

Collaboration

By embracing a spirit of collaboration and collective impact, we can amplify the collective participant voice, and ultimately deliver better care and outcomes for patients.