

5 Top Clinical Research Themes and Trends of 2023 (and 2024)

Happy New Year! While we're constantly publishing content on the latest science and trends in clinical research, we took a moment to reflect on what resonated with you the most in 2023.

We analyzed web traffic, content downloads, social media engagement, video views, webinar attendance, and other metrics to determine the themes that caught your attention which happen to align with broader industry trends.

Focus on emerging biotech and biopharma

Biotech and emerging biopharmaceutical organizations drive innovations in healthcare through novel therapeutic discovery and development, but they need agile solutions, ondemand expertise, and efficient resources to succeed. They also often rely on CROs to recommend eClinical solutions that can help meet critical milestones on time.

That's why we launched <u>Signant Biotech</u> – an integrated clinical research approach leveraging software and services tailored to small- to mid-sized biopharmaceutical organizations' unique needs as well as the CROs who support them.

Emerging biopharma can utilize our Unified Platform for any trial and any phase. Our case studies demonstrate this:

- Rapid Setup of EDC and RTSM for Phase I Oncology Trial
- eSource for Phase II COVID Treatment Trial
- Unified Platform Solutions Help Rescue Phase III CNS Trial

The case studies have been downloaded hundreds of times, our campaign to introduce Signant Biotech garnered thousands of reactions across social media channels, and dozens of sponsors and CROs have received demos of the Unified Platform. We can't wait to see how it helps more study teams simplify clinical trial design and management.

Applications of AI and ML in clinical development

We can't talk about trends in clinical development without covering practical and aspirational applications for artificial intelligence and machine learning. Our experts discussed opportunities and real uses cases for this technology in two recent webinars. Several hundred of you attended the live sessions to hear industry experts share examples of how AI/ML are currently used in clinical trials as well as how they can be used in the future as these technologies mature.

Don't worry if you missed it; get summary recaps of the webinars and watch the full events here:

- Applied AI for Enhanced Clinical Data Operations
- How EDC Can Support Modern Trials

Innovation and Success in CNS

In 2023, we saw regulatory approvals for the first new treatments for Alzheimer's disease in decades. Signant supported the trials that led to the approval of lecanemab with many of our endpoint quality solutions leveraged throughout the course of the years-long program. Solutions that enhanced clinical data quality and reliability included:

- Scale Management, which ensured study-appropriate scales were selected, acquired, translated, and implemented correctly
- Electronic clinician ratings, which helped the sponsor adapt the trials in response to disruptions caused by the COVID-19 pandemic
- Rater Training and Qualification, which helped the sponsor select highly qualified clinical raters and ensure they administered and scored clinical outcome assessments accurately and consistently
- Central Ratings/Reviews provided assurances by independent experts that clinical ratings were accurate

We have two case studies about the aforementioned Alzheimer's trials which you can find here and here. We also launched our scientific video series, Clinical Viewpoints, which features eight CNS-specific videos laden with insights from experts.

Another important innovation we announced in 2023, Signant partnered with The Epilepsy Study Consortium to co-develop the first standardized electronic seizure diary. The <u>press</u> release announcing this made such a splash, the traffic to it nearly took down our whole website!

As the global leaders in CNS research optimization for over 20 years with proven endpoint quality solutions supported by renowned leaders in dementia, schizophrenia, Parkinson's research and more, Signant is well-positioned to continue helping sponsors tackle the toughest challenges in neuroscience.

Oncology COA Measurement Strategy & Focus on PROMs

Here are recent examples of the results of our continuous investment in innovation, each of which continue to be our most popular content:

- Signant is the first major eClinical provider to offer PROMIS CAT, a novel PROM that generates precise outcomes data using fewer questions. Our <u>white paper</u> and <u>brochure</u> provide plenty of details.
- We updated our popular <u>white paper</u> and published <u>an article</u> in applied Clinical Trials in which our experts interpret recent FDA guidance on the use of patient-reported outcomes in oncology trials, including a deep dive on measurement specificity and frequency.
- We have an <u>on-demand webinar</u> on that same topic which has been viewed thousands of times
- AND we're <u>hosting another webinar</u> soon with even more current information and best practice recommendations.

Patients' and Sites' Perspectives

In October 2023, we proudly published our <u>Site & Patient Research Compendium</u>, which nearly 500 of your industry colleagues have downloaded (it's free of course!). On that page, a video introduction by Katie Garner, Senior Manager Site- and Patient-Centered Research, explains why we invest in such research efforts.

Essentially, we routinely engage with sponsors, sites, and potential or current trial participants in <u>qualitative research</u> to ensure our solutions meet the needs and expectations of patients and sites.

The eBook offers conclusions as well as study and eCOA design recommendations across several themes including: ePRO and older participants, ePRO considerations for oncology patients, and sites' perspectives and preferences on offering ePRO on provisioned vs. BYOD devices.

Learn more on similar topics, such as:

- How site and patient research optimizes clinical trials
- Exploring the Potential of Non-Consumer Smartphones in Clinical Trials: A User-Focused Evaluation
- 5 Considerations for BYOD Studies
- More content on how to support older participants in eCOA-enabled clinical trials
- PROMIS CAT: A Patient-focused, novel PROM (see oncology section above)

There you have it – five trends and themes that made an impact in 2023 and which we suspect will continue to be areas of focus in 2024.

Let us know your thoughts or questions by sharing this article on social media with your comments or you can contact us directly.