SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

# The Signal

## Webinar Recap: How EDC Can Support Modern Clinical Trials

If you missed Signant's Fall 2023 webinar about utilizing EDC for modern clinical trials, we've summarized the key takeaways and provided a link for you below.

### WEBINAR TAKEAWAYS

With increasing decentralization in several aspects of trial conduct and management, are EDC systems still relevant? And if so, how can EDC systems address the evolving requirements of modern clinical trials?

The webinar discussion explores how EDC can support modern working practices and trial designs over four themes.

#### Theme 1: Direct data capture, or eSource, and whether this plays an increasing role in today's clinical trials.

An audience poll revealed that 67% of attendees use DDC or eSource in less than 10% of their trials. Sven Vogelgesang felt this number showed progress but still needs improvement. In most cases, it may not be convenient for sites to enter the data twice (once directly in a template and then again in the EHR system).

When electronic monitoring visit reports were introduced approximately 25 years ago, no one wanted to bring their heavy laptops, and they had to replicate the data after a visit. With the combination of technological evolution (accessible tablets and lighter laptops) and working with sites to communicate the benefits of DDC, Vogelgesang predicts more trials will utilize it.

#### Theme 2: The practice of remote source data verification (SDV) and the practicalities of that from a site perspective.

This trend picked up during the pandemic, and Jan Breemans predicts the use of remote SDV will continue to increase. COVID-19 obviously forced us to do things remotely, and legislators and regulators have been accepting that for the sake of the pandemic, but regulatory clarification is lagging to a certain extent but more with be forthcoming as the practice becomes more common.

Jan Breemans pointed out that some countries still won't accept remote access to data source documents, while others take them by default. Important considerations for expanding the use of rSDV include sites' acceptance of the practice, and sites need reassurances that the data remain safe, compliant, and private, and that investigators maintain full control.

### Theme 3: How or if EDC can support the increasing implementation of decentralized elements in clinical trials, such as remote assessments and at-home data capture.

The audience was polled on which systems they prefer to use when integrating non-CRF data. Most said into a clinical data repository (CDR), followed by EDC and separate files.

David Stein pointed out that the big challenge is that sites typically have software they prefer to use. It's often all separate, for example, one for televisits and one for calendaring. The other challenge is following the draft FDA guidance on DCT, which means the PI is responsible for anything that's taking place remotely. This could cause friction when setting up video conferences or scheduling when sites are trying to provide the same level of service.

### Theme 4: The future of data cleaning with the increasing promise of artificial intelligence and machine learning and how EDC systems might support these new approaches.

The final poll of the discussion asked the audience if they were already using AI/ML to support data cleaning. Most of the audience said no, but a small portion said they were using it to create queries or detect potential issues in data.

Vogelgesang pointed out that no conversation is off-limits when it comes to efficiencies in data. But it's also important to consider how many queries are needed, and AI's role could be in detecting the importance of the query, along with setting up the database.

## MEET THE EXPERTS

### David Stein

David Stein is an Independent eClinical Consultant with over 30 years of experience developing and implementing technology solutions for biopharma companies and vendors. He specializes in product strategy, new product development and launches, due diligence for M&A activities, Strategic Advisory Board needs, and market analysis.

Recently, David has been working with industry groups, such as the eClinical Forum, and sponsors and vendors on advancing clinical technologies such as Artificial Intelligence, Real-World Evidence, Direct Data Capture, and various elements for decentralized trials and trial optimization.

### Sven Vogelgesang

Sven Vogelgesang is an Executive Leader in Clinical Data Sciences/Clinical Data Management, working for more than 28 years in the pharmaceutical industry and leading various global sponsor functions from Knowledge Management, Clinical Information Management to Clinical Data Sciences, Clinical Data Management. In parallel, he is currently working on a new start-up in the area of innovation – from pharma technology to computer games and media.

### Jan Breemans

Jan Breemans is advising Signant Health and its customers on the value and use of data analytics in the oversight of their clinical development programs. Prior to joining Signant Health, Jan worked on the sponsor side for over 20 years and gained substantial experience in the field of data management & analytics, project management &and clinical systems management. Jan has a Master's in Biochemistry and a post-graduate in Relation & Communication Management.

### Bill Byrom

Dr. Byrom has worked in the pharmaceutical industry for more than 30 years. He has authored 80+ publications and two industry textbooks on electronic patient-reported outcomes (ePRO). His recent scientific work includes the use of wearable technology and bring-your-own-device (BYOD) eCOA in clinical trials.

## WATCH THE RECORDING

You can watch the recorded webinar here.