

# **Reflections from ISOQOL Conference** 2024



Greta Marie van Schoor, PhD

Greta van Schoor attended the 31st Annual ISOQOL Conference in Cologne, Germany, where global leaders in health-related quality of life (HRQOL) research gathered to share innovations and insights.

Her takeaways from the conference are outlined below. Key themes included optimizing collection and implementation of electronic clinical outcome assessments (eCOAs), integrating patient-reported outcomes (PROs) into practice, and the role of digital health in transforming clinical research.

## **Optimizing Electronic Clinical Outcome Assessments (eCOAs)**

eCOAs are essential tools in modern clinical trials, enabling streamlined and patientcentered data collection. The conference highlighted several areas for growth and improvement:

## Enhancing eCOA Implementation

- *Flexibility and Accessibility:* Tailor and optimize electronic solutions to meet diverse patient needs, informed by feedback from patients and sites.
- *Guideline-Driven:* Follow and utilize existing evidence to ensure high-quality results.
- *Stakeholder Timelines:* Align perspectives between sponsors, eCOA providers, and copyright holders to streamline implementation.

## The Collaboration Imperative

- *Translation Challenges:* Simultaneously translating and implementing eCOAs introduces complexities requiring coordination across multiple stakeholders.
- *Copyright and Technology:* Involved stakeholders should engage early to align expectations and ensure mutual understanding of eCOA systems.



**Key takeaway:** Early and continuous communication between all parties is critical for successful eCOA deployment.

## ePROs in Clinical Practice

Utilizing PROs in clinical practice, especially in oncology, is transforming care by improving patient engagement and real-world data collection.

## Patient Benefits

- Enables remote symptom monitoring and enhanced side-effect management.
- Provides insights into treatment outcomes and adverse events.
- Incorporates PRO data into electronic health records (EHRs) for real-world application.

## Challenges and Strategies

- Digital literacy among patients must be considered, especially in telehealth applications.
- Clear standard operating procedures (SOPs) can improve system usability and support efficient data collection.

**Key takeaway:** To maximize benefits, providers must focus on implementation strategies and actionable follow-ups.

## **HRQOL** in Oncology

## Modular Approach and Flexible Measurement

The conference spotlighted the FDA's guidance on modular PRO measurement. Additionally, flexible tools, such as item libraries, are reshaping how HRQOL is measured in cancer trials.

## Signant's Research

## Poster Presentation: Modular PRO Measurement Supported by EORTC QLQ-C30 Correlation Analyses in Breast Cancer Patients

- *Goal:* Explore the relationship between individual domain scores of the EORTC QLQ-C30 (specifically, physical and role function domains) and the summary score.
- *Findings:* High correlation between domain and summary scores supports modular measurement in cancer trials.

• *Impact:* Our findings added further support to the suitability of the independent use of PRO subscales in line with the FDA's recommended modular approach in cancer trials.

**Key takeaway:** Flexible PRO measurement and the FDA-recommended modular PRO measurement approach are key areas of focus in oncology research.

## **Digital Health Measures in Clinical Research**

THE SIGNAL BLOG BY SIGNANT HEALTH

Digital health measures are reshaping clinical research by enabling continuous, sensitive, and comprehensive data collection.

## Advantages

- Easier, objective, and more complete data collection.
- Composite measures combining sensor and eCOA data offer more complete insights and enhance understanding of patient outcomes.

## Challenges

- Lack of standardization makes it difficult to pool results across studies.
- Terminology inconsistencies (e.g., sensor-based functional outcomes vs. digital health measures) create confusion.

## The Way Forward

- Engage patients and regulators early to ensure measures are meaningful and interpretable.
- Focus on demonstrating both the validity and relevance of the measure.

**Key takeaway:** Digital health measures in clinical research present many benefits, while challenges in its adoption exist. Early engagement with all stakeholders is key.

## **Utilizing Artificial Intelligence (AI)**

Advanced AI tools are unlocking new possibilities for HRQOL research.

## The Role of AI

- Al is emerging as a powerful tool for analyzing unstructured PRO data from EHRs.
- Generative AI has the potential to clarify ambiguous scores, facilitate early disease detection and improve diagnostic precision, and uncover new insights in HRQOL.



**Key takeaway:** Al-powered tools can complement traditional measures by enhancing both the collection and interpretation of HRQOL data.

If you're interested to learn more about these takeaways, please contact us.

## About the Author

**Greta Marie van Schoor, PhD** provides scientific expertise and guidance relating to the implementation of electronic clinical outcome assessments (eCOAs) and has a special focus on eDiary design and accessibility of eCOA best practices. She completed her PhD in Physiological Sciences at Stellenbosch University, which focused on the bacterial and inflammatory involvement in colorectal carcinogenesis and has 3+ years' experience in the clinical research industry. She has given scientific consultation for projects across a wide range of therapeutic areas, including oncology, infectious disease, dermatology, and gastroenterology.



## WHO IS SIGNANT HEALTH?



Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at **www.signanthealth.com**.