SIGNANT SMARTSIGNALS® eCOA SOLUTION FOR
EARLY-PHASE ONCOLOGY

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

Early-Phase Oncology

Electronic Patient-Reported Outcomes Solution

Tolerability evidence in early-phase oncology research is incomplete without patient-reported adverse events data. Here's why sponsors should consider including patient-reported outcomes data in early phase research:

Dose Response

Newer, targeted treatments often show good efficacy at a **range of doses** below the maximum tolerated dose

Dose Selection

Characterising the **dose-tolerability relationship** is essential to optimal dose selection

PRO Insights

The **patient perspective** is a vital component of reliable tolerability assessment

At Signant, we understand the speed and accuracy required by early-phase oncology work, which is why our clinical scientists have developed a pre-configured ePRO solution containing all the measures needed to accurately assess tolerability, delivered at the speed expected by early-phase research.

Why choose Signant Health's early-phase ePRO?

1. Rapid out-of-the-box implementation
2. Detailed tolerability assessment using validated library measures
3. Frequent assessment schedule for comprehensive insights
4. Bring-your-own-device efficiencies, with provisioned devices where needed
5. Completion compliance monitoring to drive complete datasets

Patient-reported outcome measures

Our ready-to-use patient-reported outcomes measures are tailored towards accurate early-phase research requirements. We measure adverse events, and the impact of adverse events, to provide a full tolerability assessment.

ADVERSE EVENTS

PRO-CTCAE
- Full list of 78 AEs
- Branched by body system for rapid navigation and completion
- Free text items included

Custom additions:
Treatment-specific items e.g., infusion site reactions

IMPACT OF ADVERSE EVENTS

- **Overall impact of side effects** (single item) FACT GP5
- **Physical function** - EORTC Physical Function Item List
- **Role function** - EORTC Role Function Item List

Benefits of electronic data collection

1 Assured data quality and integrity

- Unsupervised paper diaries are associated with data ambiguities limiting data quality
- Ensure timely completion, to generate evidence that can be relied upon

2 Enable remote patient oversight

- Real-time reports and automated notifications ensure Investigators maintain effective patient oversight between clinic visits

3 Competitively priced vs paper

- Our solution is priced commensurate with early- phase research budgets, and competitive to paper processes

4 Simplify complex implementation

- Paper version of full PRO-CTCAE is cumbersome and impractical
- Our electronic version simplifies navigation to score only the relevant AEs
- Free text data captured electronically – reduces data management burden

WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

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**.

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