SIGNANT SMARTSIGNALS® eCOA
eCOA Science Consulting

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY®

Scientific Expertise for Regulatory-Ready COA Strategies

Regulatory success depends on clear endpoints and robust study design. With increasing regulatory focus on clinical outcome assessments (COAs), sponsors need expert guidance to select and implement meaningful endpoints that support approval and health technology assessment (HTA).

Signant Health's 50+ in-house clinical scientists provide comprehensive eCOA consulting from protocol design through regulatory submission.

Why choose Signant Health?

PROTOCOL & STUDY DESIGN EXCELLENCE
Study design, measurement strategy planning, and endpoint selection optimized for regulatory success.

REGULATORY STRATEGY & SUPPORT
PRO dossier development and regulatory meeting support from submission experts.

EXPERT COA SCALE SELECTION
Rigorous evaluation and validation of instruments with proven regulatory precedent to measure study concepts of interest.

THERAPEUTIC AREA EXPERTISE
Specialized teams across CNS, oncology, rare diseases, vaccines, cardio-metabolic, and pediatrics.

CUSTOM MEASURE DEVELOPMENT
Tailored ePRO instruments and digital diaries for unique therapeutic requirements.

END-TO-END PARTNERSHIP
Seamless support from early protocol consultation through post-approval commitments.

Comprehensive Service Portfolio

1. **Study Design & Measurement Strategy**
   Placebo response mitigation, measurement timing optimization, modality selection, implementation best practice, endpoint hierarchy development, and sample size considerations for COA endpoints.
2. **Scale Selection & Validation**
   Systematic instrument evaluation, psychometric assessment, cross-cultural adaptation, and electronic implementation suitability.
3. **Custom Instrument Development**
   Tailored ePRO measures and ediary development, adaptation of existing measures, and evidentiary requirements consulting.
4. **Regulatory Excellence**
   PRO dossier development, regulatory submission and agency meeting support, and post-approval planning.
5. **Implementation & Quality**
   COA migration best practices, rater training and qualification, central review services, and compliance support.

How is Signant's eCOA Science Consulting different?

Deep eCOA Specialization
With 50+ clinical scientists focused exclusively on outcomes assessment

Scientific Advisory Boards
Psychiatry, neurology, and internal medicine advisory boards, providing on-demand opinion-leader expertise

Therapeutic Area Depth
Dedicated medical and scientific specialists across all areas including CNS, oncology, rare diseases, vaccines, cardio-metabolic, and pediatrics

COA-Focused Regulatory Experience
Proven PRO dossier and regulatory meeting planning assistance success

Proven Track Record

50+
Clinical scientists focused on COAs

20+
Therapeutic areas covered

100+
Regulatory submissions

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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