SIGNANT HEALTH

[TRIALMAX®]

A PROVEN eCOA PLATFORM BACKED BY 20 YEARS OF INDUSTRY EXPERTISE

STAY AHEAD OF POTENTIAL RISKS

Whether you are using electronic clinical outcome assessment (eCOA) to collect primary or secondary endpoint data or to evaluate an exploratory endpoint, sacrificing quality or risking delivery failure is never an option. Clinical researchers choose TrialMax® eCOA for its proven track record of consistently delivering the best solution for each study—a result of Signant Health's renowned scientific and clinical leaders, fine-tuned operational infrastructure, and regulatory insights across therapeutic areas and countries.

TrialMax can be used for home or site-based ePROs, eClinROs, eObsROs, and collection of integrated wearable and sensor data. It is globally accessible via app, provisioned device, or web. It supports any combination of provisioned device and/or bring your own device (BYOD) strategy; the mobile app solution is available to use on Android or iOS devices; and it can integrate with clinical data systems, such as EDC and IRT. TrialMax offers you complete control over your eCOA data via TrialManager™, its companion data management solution which provides reports and analytics to help you monitor study data and performance in real-time and ensure complete audit readiness.

DRIVE MODERN TRIALS

TrialMax eCOA works alongside TrialConsent®, Signant's eConsent solution, and TrialGuide, Signant's patient engagement solution, to give patients a seamless technology experience. It also connects to Signant's Sensors & Wearables solution, which collects objective real-world data from a range of devices, including activity and sleep, blood glucose and respiratory function monitors. Patient adherence to remote sensor requirements can be improved by triggering data-driven notifications, reminders and alerts through the TrialMax platform.

THE TRIALMAX ePRO SOLUTION IS DESIGNED WITH UNIQUE PATIENT POPULATIONS IN MIND

Accessible on any device type
You can choose from TrialMax Touch, a provisioned smartphone; TrialMax App, a BYOD solution; and TrialMax Web, an online portal. We also offer TrialMax Slate, a tablet solution for collecting site-based eCOA data. These offerings support any language, global connectivity, and offline mobile use.

Tested for usability
The TrialMax solution has been extensively tested and can be adapted for various patient populations, including those struggling with vision, fine motor control, or memory problems.

Robust reminders included
You can schedule email, SMS, or internal alarm reminders to boost timely adherence to diaries, medications, and site visits.

TrialMax delivers the gold standard in data quality and reliability on a platform that uses the latest technology, supported by the industry's most robust operational infrastructure.

ENSURES SCIENTIFIC AND CLINICAL EXCELLENCE

Our Scientific & Clinical Consulting team works directly with study teams to ensure endpoint quality and we work with instrument owners to ensure electronic equivalence and localization.

STREAMLINES GLOBAL LOGISTICS

We ship devices worldwide from our warehouses across North America and Europe. Our in-house teams are experienced at handling customs and device requirements for 75+ countries.

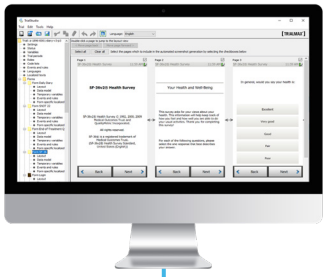
MAXIMIZES YOUR GLOBAL REGULATORY COMPLIANCE

For 20 years, TrialMax has collected primary efficacy endpoint data for study drugs that have been approved by both the FDA and EMA.

ENSURE ENDPOINT QUALITY FROM START TO FINISH

Every study presents uncertainties—whether it is the risk of inconsistent results or the lack of robust effect sizes. Why not maximize your chances of success by ensuring the accuracy and reliability of your endpoint data? To complement TrialMax, we also offer unparalleled scientific and clinical services to support you in designing, capturing, and analyzing eCOAs.

DESIGN



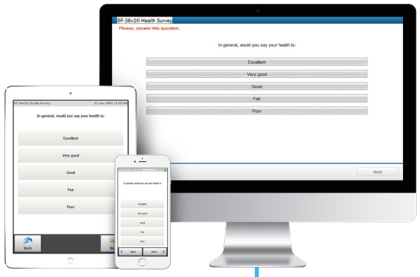
Design & equivalence

Our proprietary tool, TrialStudio™ comes with every TrialMax project, allowing us to collaboratively design instruments and diaries with your input. It expedites design decisions and generates screen reports for early IRB/EC submission. Where needed, we also offer cognitive interview and quantitative equivalence studies to provide evidence of electronic migration acceptability.

Scale management

We support questionnaire licensing, development, validation, testing, and all translation processes to make certain your instruments are culturally and conceptually equivalent.

CAPTURE



Logistics & helpdesk

We manage device inventory and shipment globally. We also provide 24/7 helpdesk support for your patients, sites, and other study stakeholders in over 150 languages.

Data management

TrialManager provides data integrity and audit trail reporting, data change management capabilities, archiving, and access control management for TrialMax studies. Additionally, our data management team oversees data delivery, ensuring clean, quality data and reporting.

ANALYZE

Operational analytics

The TrialManager reporting interface also provides exportable data and color-coded dashboards displaying real-time operational metrics (i.e. recruitment, questionnaire completion rates, etc.) and scoring algorithms, in addition to its full audit trail capabilities.

Clinical analytics

You can gain further insights about your TrialMax clinical data using our proprietary, evidence-based Data Quality Analytics solution. It identifies and interprets real-time risks (e.g. bias, errors, and fraud) so you can remediate quality issues early.

WHO IS SIGNANT HEALTH?

The best technology succeeds in the background. Signant Health provides solutions that simplify every step of the patient journey to make it easier for people to participate in, and for sites and study teams to run, clinical trials. Signant unites eCOA, eConsent, Patient Engagement, IRT, Clinical Supplies and Endpoint Quality into the industry's most comprehensive patient-centric suite – an evolution built on more than 20 years of proven clinical research technology. Our intense focus on the patient experience, deep therapeutic area expertise and global operational scale enable hundreds of sponsors and CROs (including all Top 20 pharma) to extend the reach of drug development, expand patient opportunities and improve data quality – helping them bring life-changing therapies to our families and communities around the world. Take a significant step toward patient-centricity at signanthealth.com.

CRF Health and Bracket are now Signant Health.

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