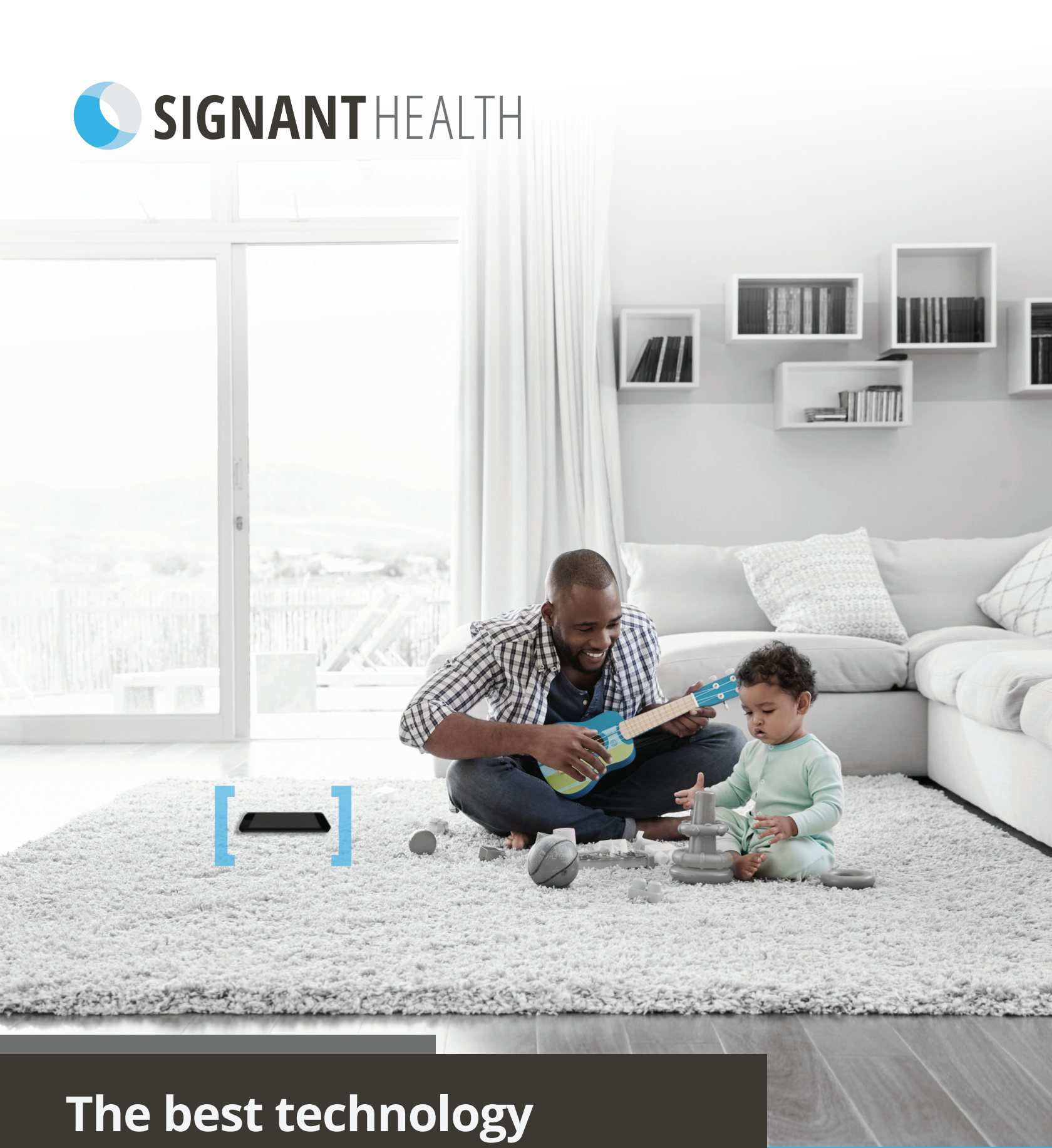
SIGNANT HEALTH



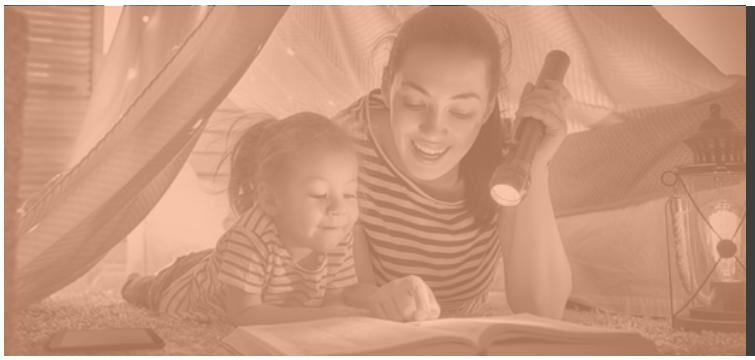
The best technology succeeds in the background

Helping patients, sites and study teams uncover the life-changing insights your global trials deserve

signanthealth.com

OUR PATIENT-CENTRIC TECHNOLOGY WITH 20 YEARS OF LEGACY

Signant believes technology providers have a responsibility to create a seamless experience for patients, sites and study teams. That is why we have created one unified suite – supported by expert developers, project managers, data analysts, scientists and clinicians – that improves key aspects of clinical research from planning and startup through closeout and beyond.



PATIENT DATA

- eCOA/ePRO
- eCOA/eClinRO
- Sensors & Wearables

PATIENT EXPERIENCE

- eConsent
- Patient Engagement

CLINICAL SUPPLIES

- IRT
- Forecasting & Planning
- Inventory Management

ENDPOINT QUALITY

- Rater Training & Data Quality Monitoring
- Scientific & Clinical Consulting
- Data Quality Analytics

PATIENT DATA ECOA/EPRO

WHAT DO YOU REALLY WANT TO KNOW?

ECOA/EPRO

Signant's eCOA/ePRO is the gold standard for capturing accurate, timely and reliable data from patients around the world. Ensuring your success, however, requires more than a mobile app. Signant pioneered the use of ePRO over 20 years ago and the essential experience gained from thousands of trials enables us to provide exclusive design best practices, global logistics expertise, therapeutic area depth, regulatory requirement understanding, and project management capabilities proven to mitigate risk and ensure success. The TrialMax® platform let's you design, capture, and analyze eCOAs.

DESIGN

TrialStudio™ is a collaborative design tool and usable preview simulator that features a built-in library of design elements, effortless localization IRB/Ethics submissions and inherent responsive design – with a drag-and-drop interface and no manual coding required – that helps you develop and deploy eCOA solutions faster and more reliably than ever.

CAPTURE

TrialMax® is offered on multiple modalities. Whether deployed on provisioned devices, site-based tablets, web browsers or as a BYOD mobile app, TrialMax's hallmark usability provides a friendly experience for patients and sites featuring robust SMS reminders and alarms, global offline capabilities, on-device push notifications, and integrations with sensors and wearables. TrialMax makes it easy for patients to comply with your protocol and provide critical insights based on legible, logical and timely data from anywhere in the world.

ANALYZE

TrialManager™ monitors eCOA clinical trial data and patient medical alerts in real time via a robust online reporting portal – with on-demand data extracts, dynamic graphical charting and color-coded data visualizations that make it easy to identify (and act on) meaningful data trends.

PATIENT DATA | ECOA/ECLINRO | SENSORS & WEARABLES

COLLECT CLINICIAN-RATED ENDPOINT DATA WITH ACCURACY AND RELIABILITY

ECOA/ECLINRO

In certain therapeutic areas, such as neuroscience and dermatology, asking patients to self-report on their symptoms and well-being may not be realistic or feasible. Our eCOA platform features an eClinRO solution for site-based data capture that guides and supports raters – especially when combined with our Endpoint Quality solution – to ensure you receive the most accurate and reliable endpoint data.

It improves accuracy and consistency of subjective scoring and assessments by helping raters administer scales correctly with scripting and logic that provides on-screen guidance during interviews, rule alerts, audio/video capture for remote clinician review, and real-time edit checks. It also supports sites by integrating with Signant's IRT system.

Customized to meet the clinical, scientific and usability needs of each protocol and patient population, our eClinRO provides the tools you need to improve the trial experience for patients and sites – and ensures raters provide trustworthy and consistent assessments to optimize endpoint reliability for key outcomes.

SENSORS & WEARABLES

Signant's Sensors & Wearables solution can enhance your ePROs with objective real-world patient data. We offer out-of-the-box, regulatory compliant integrations to a range of devices including blood glucose and respiratory function monitors, and other external sensor devices. Connected device adherence can be improved by triggering data-driven notifications, reminders and alerts to patients through the TrialMax ePRO solution. Ask us how we can help you collect objective real-world data.

PATIENT EXPERIENCE | ECONSENT

PATIENT RETENTION BEGINS WITH UNDERSTANDING AND TRUST

ECONSENT

Informed consent is much more than a signature. Patients who truly understand what they are signing up for are able to make an educated decision on whether participation is right for them, and as a result those who enroll are more likely to be engaged, compliant and active throughout the duration of the study – improving satisfaction, eliminating consent-related protocol deviations, and potentially increasing retention.

An essential part of our patient-centric technology suite, TrialConsent®, provides a familiar and intuitive guide through the consent process featuring digestible content chapters, explainer videos, remote consent capabilities, question prompts, interactive assessments and more.

For study teams, it offers robust document management for version control, real-time progress monitoring, and flexible signature options (e.g. eSignature, print-to-sign, and offline paper) to meet global requirements. Whether you are implementing eConsent on a pilot study or enterprise-wide, TrialConsent easily scales as you go with minimal up-front investment and it features design options for self-service and full-service development. TrialConsent is also the only system that allows you to collaborate on design, document management and reporting in a singular workflow shared by sponsors, sites and IRBs.

TrialConsent is an eConsent solution your patients, sites and study teams will appreciate – and it will start your trial on the right foot to improve satisfaction, compliance and retention worldwide.

PATIENT EXPERIENCE | PATIENT ENGAGEMENT

MAKING IT EASY FOR PATIENTS TO PROVIDE RELIABLE DATA

PATIENT ENGAGEMENT

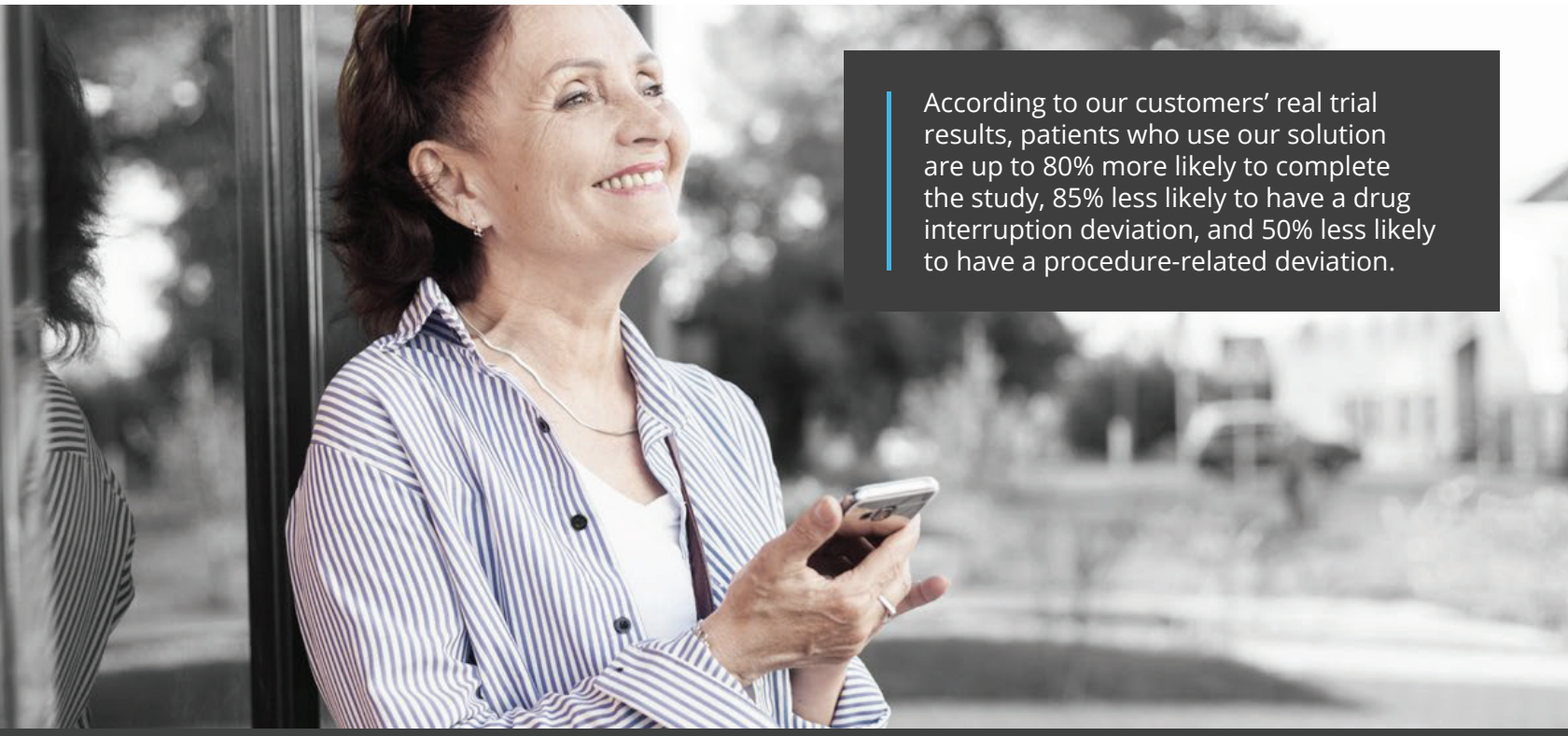
Show the people in your trials how much you appreciate and respect them (and their time) by removing burden, sharing the information they need and making it easier for them to participate. Signant blends your trial into the normal flow of their lives with a single mobile app for visit reminders, study updates, notes of appreciation, transportation, payment visibility and more – ensuring your trial remains top of mind without disrupting their day.

Deployed as a BYOD solution or on provisioned devices, our solution is a consumer-grade, regulatory-compliant mobile app and reminder system that is configured for your unique protocol and patient population requirements.

Features include:

- Automated visit reminders, notes and instructions
- In-app integration with trusted financial and transportation providers such as Greenphire and Uber
- Gamification for pediatric and adolescent trials
- Culturally relevant visuals and content
- Helpful site contacts and documentation
- 24x7 helpdesk support in local languages

We help you reduce the participation burden and improve compliance and interaction with patients worldwide. It is one more way to ensure your patients have a positive study experience, keeping them invested in your research for the duration of the study.



According to our customers' real trial results, patients who use our solution are up to 80% more likely to complete the study, 85% less likely to have a drug interruption deviation, and 50% less likely to have a procedure-related deviation.

CLINICAL SUPPLIES | IRT | FORECASTING & PLANNING | INVENTORY MANAGEMENT

PEACE OF MIND FOR A SEAMLESS TRIAL

Even things that patients never see can make all the difference in how seamless their experience is. Signant helps study teams save time and cost while managing behind-the-scenes logistics that patients, sites and study teams rely on.

IRT

Signant provides a rapid-deploy IRT solution for randomization and clinical supply management. Featuring a proprietary deployment framework, CUBE™, which stands for Configuration by User Based Experience, it offers the industry's fastest system setup process while ensuring even your most complex requirements are implemented correctly. With IRT powered by CUBE, you will realize:

- 50% less study team effort required at startup
- 2X faster system delivery (in 1-4 weeks)
- 50% faster implementation of mid-trial changes

FORECASTING & PLANNING

SmartSupplies® Forecasting & Planning solution is the industry's only fully integrated enterprise-wide solution that dynamically predicts how much investigational product you need and puts you in full control of your clinical supply chain. It forecasts and recommends optimal manufacturing plans using lot-based scenarios with factors such as expiry dating, expected yields, lead times and asset capacities – then visually depicts real-time projections of changing demand using live enrollment metrics. By facilitating risk-based scenario planning for supply and demand at the study and program level, SmartSupplies provides the confidence of avoiding stock-outs globally while eliminating waste and reducing drug supply budgets by up to 20% annually. It enables you to forecast accurately and make better manufacturing decisions.

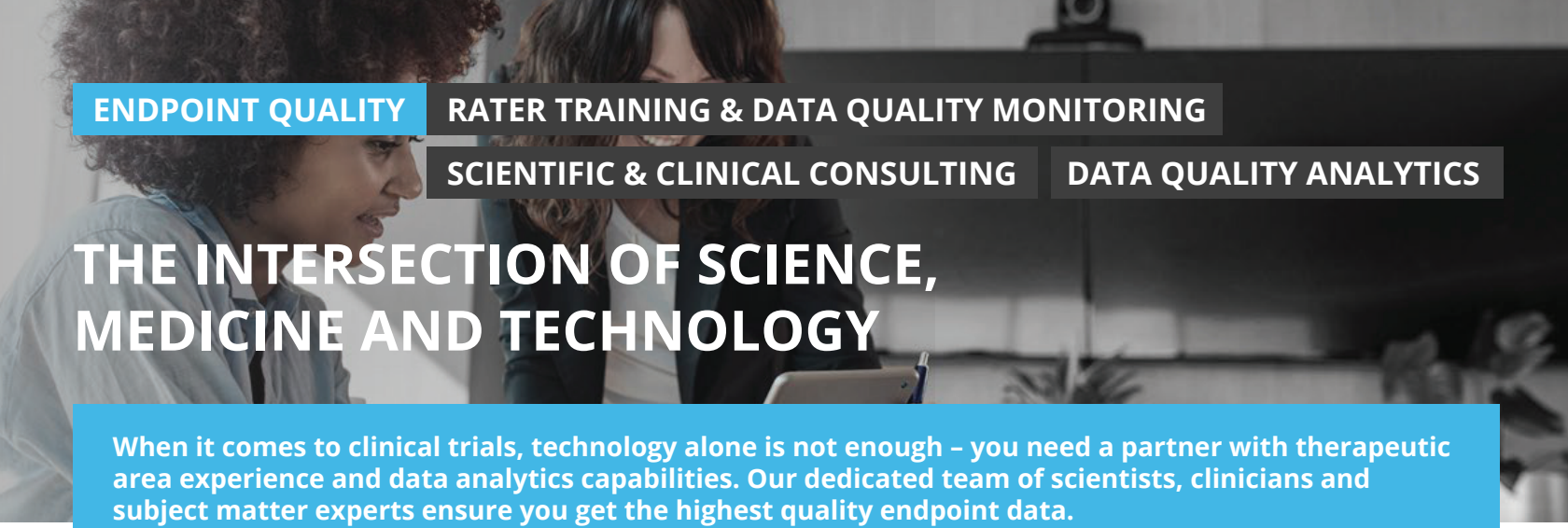
INVENTORY MANAGEMENT

SmartSupplies Inventory Management is the most extensive end-to-end solution to digitally control, track and trace the entire clinical supply chain. The software specializes in labeling, distributing, managing and reconciling clinical supplies and supports any internal or external supply chain strategy. As a robust enterprise-wide solution, it eliminates error-prone and archaic paper processes and centralizes inventory visibility across systems with tightly coupled integrations to ERP, IVR/IRT, CTMS and third-party packagers/distributors/CMOs. This provides unparalleled insight and a single source of truth of your clinical supply chain. SmartSupples is a fully validated and GxP, Annex 13 and 21 CRF Part 11 compliant system, enabling lot recall functionality and full traceability to ensure your success.

AstraZeneca

"I can't ever imagine going back to Excel... By experiencing >10% savings on drug supply costs from accurate forecasting, AstraZeneca has been able to put those funds back into our business."

John Murray, Director of Supply Chain Capability, AstraZeneca



ENDPOINT QUALITY | RATER TRAINING & DATA QUALITY MONITORING | SCIENTIFIC & CLINICAL CONSULTING | DATA QUALITY ANALYTICS

THE INTERSECTION OF SCIENCE, MEDICINE AND TECHNOLOGY

When it comes to clinical trials, technology alone is not enough – you need a partner with therapeutic area experience and data analytics capabilities. Our dedicated team of scientists, clinicians and subject matter experts ensure you get the highest quality endpoint data.

RATER TRAINING & DATA QUALITY MONITORING

You place tremendous trust in your raters – however, it can be challenging to ensure consistency across raters of varying experience at disparate sites around the world. Our platform combines online or in-person training, data quality monitoring, and proven methodologies to increase rater reliability. We ensure accurate scale administration using a case-oriented approach to target areas commonly scored erroneously with a focus on adherence to scale rules, placebo response, interview technique, and the use of annotated anchor points. We also standardize scoring across raters, assessing their proficiency level and interview technique to optimize inter-rater reliability and reduce variance. Coupled with in-study data quality monitoring and maintenance, such as central review and analytics, we ensure rater accuracy and calibration throughout the study.

SCIENTIFIC & CLINICAL CONSULTING

Our dedicated scientists and clinicians will take an evidence-based approach to tailor a program that helps you select optimal sites, ensure enrollment of only appropriate patients, and ultimately maximize the precision and reliability of your outcomes data. Services include...

- Scale evaluation, selection and management
- Subject eligibility and diagnostic review
- Central rating, central review and central scoring
- Endpoint reliability

DATA QUALITY ANALYTICS

You cannot afford to leave the quality of your outcomes data to chance. Data Quality Analytics from Signant is a proprietary risk-based monitoring solution that extracts insights from your data to identify inconsistencies and at-risk sites and raters in near real time – before they adversely affect your trial. Evaluating data from eCOAs, audio and video files, worksheet reviews, diagnostics, IRT systems and more, it proactively flags potential bias, errors and fraud at the study, site, rater and patient level. It also uses predictive analytics to identify which data quality concerns you should expect, so you can prevent errors before they occur. Working collaboratively with you and your sites, we help you interpret the results and customize a corrective intervention plan to ensure your data is reliable. Partnering with Signant will help you better detect a signal, make faster go/no decisions and prepare a trustworthy submission.

SIGNANT HEALTH

WHO IS SIGNANT HEALTH?

In 2018, CRF Health and Bracket became one company. Today, we are Signant Health, building on 20 years of legacy and investing in the future of clinical research technology. Signant 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 solutions for eCOA, eConsent, Patient Engagement, IRT, Clinical Supplies and Endpoint Quality into the industry's most comprehensive solutions suite. Our intense focus on the patient experience, deep therapeutic area expertise and global operational scale enable 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.

signanthealth.com