SIGNANT HEALTH

[ TRIALCONSENT® ]

# AN INDUSTRY SHIFT: FROM PAPER TO ELECTRONIC INFORMED CONSENT

Securing informed consent from clinical trial participants involves more than a signature – you need to ensure they truly understand what they are signing. A critical first step, consent has a major impact on regulatory compliance, enrollment and retention rates and expenses across the life of your study. A shift from paper to electronic informed consent simplifies processes for sponsors, sites, Institutional Review Boards (IRBs) and Ethics Committees (ECs) and makes consenting traceable and reliable. It is widely accepted that electronic informed consent enables you to enhance participant understanding resulting in more informed decisions, and simplifies consent document management, implementation and monitoring for sponsors and sites.

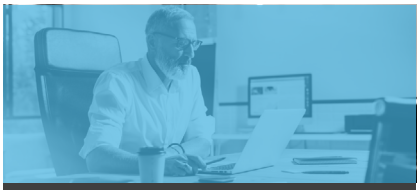
## COMPREHENSIVE eCONSENT FROM SIGNANT HEALTH

Signant Health has over two decades of experience in designing, implementing and supporting complex, multilingual, global patient-facing clinical trial applications through its leading eSource data platform. When you use TrialConsent, you will benefit from our proven and extensive service-excellence including:

- Robust global project management
- Multi-lingual solution development and management
- Experienced international logistics for site hardware provision and maintenance
- Global 24/7 user support
- Comprehensive training

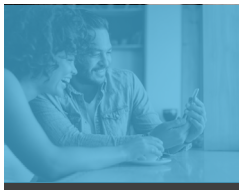
TrialConsent has been developed through in-depth research with sites, patients, sponsors, IRBs and ECs. **It offers a collaborative platform for developing and updating consent documentation and a real-time monitoring tool to track progress.** It can significantly reduce site burden by seamlessly managing documentation across multiple country and site versions, and can support recruitment and retention by ensuring patients are truly informed and providing a robust and engaging digital experience.

TrialConsent offers many key benefits to all stakeholders and users of electronic informed consent:



### SPONSORS/CROs

- Leverage Signant Health's best-in-class platform and services:
  - Therapeutic area expertise
  - Technology innovation
  - Global reach
  - Operational scalability
  - eClinical system integrations
- Improve patient retention rates through more informed decisions on trial participation.
- Improve data integrity and reduce regulatory risks and audit findings through digital audit trials, automated version control and real-time monitoring
- Select from flexible design and deployment models ranging from Full-Service to Self-Service options

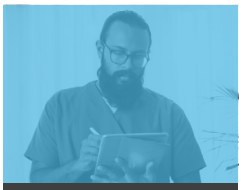


### PATIENTS AND FAMILIES

- Improve study expectations, compliance and comprehension through an engaging digital experience:
  - Interactive multimedia
  - Structured consent flow
  - Question flag prompts
  - Knowledge quizzes
- Provide remote access to review the consent form from home, at own pace and with family

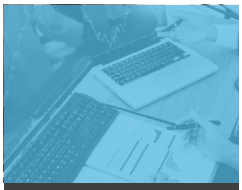
### SITES

- Increase efficiencies for informed consent process:
  - Truly informed patients
  - Streamlined consent and reconsent processes
  - Minimized regulatory risks
  - Simplified and centralized document management
  - Reduce administrative burden
  - Reduce time and costs



### MONITORS

- Centralized monitoring support and real-time visibility on the complete consenting process:
  - Review site performance metrics
  - Get reliable patient enrollment data faster
  - Access and review remote dashboards and consent documentation
  - Identify potential issues for early corrective action



### IRBs/ECs

- Ensures confidence in consent documentation and processes:
  - Robust data security and privacy protection
  - Automated version control and use of only approved consent documents
  - Patient centric approach for ease of understanding
  - Extensive logs of patient experiences and interactions
  - Compliance with global regulations

Our TrialConsent platform is designed to provide comprehensive functionality to design, collect and manage informed consent for today's clinical trials.

**DESIGN**

**TRIALCONSENT DESIGNER**

Create, review, and approve consent forms on this collaborative platform, complete with templates and version control.

**For Sponsors**

**COLLECT**

**TRIALCONSENT PARTICIPANT**

Provide patients with an engaging and intuitive digital experience, including rich multimedia, knowledge checks, and more.

**For Sites and Patients**

**MANAGE**

**TRIALCONSENT MANAGER**

Review progress in real-time and remotely manage re-consent and paper forms using intuitive dashboards to review and understand progress.

**For Sponsors and Sites**

TrialConsent ensures better informed patients, a simple, traceable and transparent consenting process, and eliminates the potential for error inherent in the paper consenting process.

### FLEXIBLE SIGNATURE SOLUTIONS

Obtain the benefits of document management and control, electronic storage, and centralized monitoring even for paper consent forms. Ensure full global acceptance through three approaches to consent form signature:

**Digitized electronic signatures**

Patients review and sign electronically

**Print-to-sign**

Patients review electronically and sign on paper

**Offline consent (Paper consent)**

Review and sign on paper

### REDUCE CONSENT DOCUMENT MANAGEMENT COMPLEXITY

Manage consent document versions for multiple countries and sites, and seamlessly manage consent form updates and re-consenting efficiently within a single system. Collaborate digitally on the development and approval of your informed consent documentation with sites and IRBs/ECs for a more streamlined approval process.

### REMOTE CONSENT SUPPORT FOR PATIENTS

Allow your patients to review, consent and reconsent at home and at their own pace. Records on every patient's consent journey are available for tracking progress. TrialConsent lets you expand your geographical reach of study populations and provides a flexible, device agnostic platform for your patients.

### AVAILABLE AS SELF-SERVICE OR FULL-SERVICE

Use your existing infrastructure to develop your own consent forms and documentation, create libraries for easy re-use across studies and maintain full control over your processes through our self-service platform. Alternatively, let our experienced operational team manage the entire development and implementation process for you.

### INTEGRATE eCONSENT WITH OTHER eCLINICAL SYSTEMS

Minimize site burden and the need to reconcile data in multiple systems by taking advantage of TrialConsent's ability to easily integrate with multiple eClinical systems such as EDC, IRT, ePRO, and CTMS. TrialConsent can also be made available with ePRO and patient engagements apps using the same hardware that sites already use for other applications.

### COMPREHENSIVE FEATURES

- Truly informed participants
- Rich multimedia and interactive assessments
- Print-to-sign and on-screen signature options
- Traceable consenting
- Seamless re-consenting
- Simplified document management
- Minimized regulatory risks
- Remote access
- Platform independent solution
- Global logistics support
- 24/7 site helpdesk in 150 languages
- Full-service and self-service capabilities

## 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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