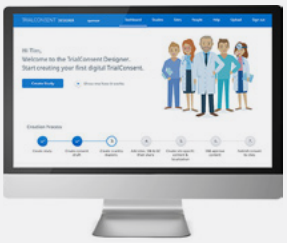
SIGNANT HEALTH

[TRIALCONSENT®]

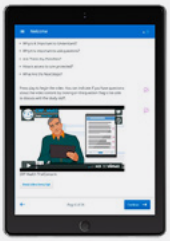
TRIALCONSENT FOR IRB/IECS

THE TRIALCONSENT PLATFORM

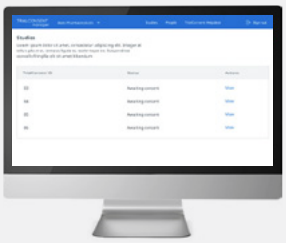
TrialConsent is an eConsent system that has been designed to meet both the user needs and regulatory requirements for the informed consent process.



TRIALCONSENT DESIGNER



TRIALCONSENT PARTICIPANT



TRIALCONSENT MANAGER

PARTICIPANT ENGAGEMENT AND SUPPORT

TRIALCONSENT PARTICIPANT TOOL

- Video with narration
- Pictures/Graphics
- Knowledge checks
- Web based system that allows secure remote review to start before the study visit
- Supportive navigation (e.g., start where they left off, large font, tutorial)
- Organized in sections with subsections to focus on subtopics
- Flagging areas with questions to discuss with the site study team

EFFICIENT CONSENT DEVELOPMENT

TRIALCONSENT DESIGNER TOOL

Signant Health uses the Designer Tool to develop and publish the eConsent to the study site. The TrialConsent Designer supports:

- Working with the Sponsor on the content
- Sponsor content approval with confirmation of IRB/IEC consent approval before releasing the eConsent to the site
- Developing and managing global, country specific, and local site consent content until it is published
- Role-Based privileges in the system to control changes
- Content locking ability for review and approval
- Performing Beta Testing in a preview mode within the Designer to review what the participant will see
- Using a PDF version of the draft eConsent(s) for easier review
- Download of the approved eConsent version published to a site, sponsor and IRB/IEC for TMFs
- Receipt of the change history of an eConsent form
- Easy content development and change without coding through the system editor
- Ready availability of amendments for sites / participants after approval

VERSION CONTROL

TRIALCONSENT DESIGNER TOOL

TrialConsent controls the versioning of consent forms for use at study sites to ensure the eConsent or PDF copy generated has been appropriately approved and content is locked. This ensures:

- Only the IRB/IEC and sponsor approved version is published from the system to sites
- System validated control that the latest approved version of each document is displayed to participants
- Published versions of the documents are locked from editing
- Amendments needed to the published consent require a new draft version to be created in the Designer
- The new approved and published version automatically replaces the old version at sites
- Presentation of multiple documents to participants, e.g. main and procedure-related forms
- Receipt of separate tracking history for each document and change history of each document

SECURITY

TRIALCONSENT DESIGNER, PARTICIPANT TOOL AND MANAGEMENT TOOL

The TrialConsent system ensures electronic security and privacy with built-in design and features including:

User access is role-based and controlled

PHI is stored with highest encryption, military grade AES-256

Password creation and reset standards in place

Changes in Designer to drafts are restricted based on user rights

Minimal PHI collected at the time of signing and not before

Participant code and their unique password used for access

PHI is partitioned to restricted site access rights

Handwritten digital signature linked to the participant

Sites control access to patient PHI to monitors and auditors

All system components are protected behind a firewall

REGULATORY

TRIALCONSENT DESIGNER, PARTICIPANT TOOL AND MANAGEMENT TOOL

The platform has been validated, including the software, hardware and all 3rd party systems. Validation reports are available for audit under an NDA. An audit trail of all changes in the system is automatically maintained.

Deployment of the eConsent can be tailored for regional requirements, e.g. signatures can be collected on paper.

TrialConsent complies with the key global regulations:

- US HIPAA
- EU Data Protection Directive 95/46/EC
- US FDA 21 CFR Part 11
- EU Clinical Trials Directive / Regulation
- FDA 21 CFR Part 50
- Electronic template modeled after the CTTI content flow https://www.ctti-clinicaltrials.org/files/ctti-informedconsent-recs.pdf
- TrialConsent is a validated platform for generation of approved consents

INVESTIGATOR ENGAGEMENT AND SUPPORT

TRIALCONSENT MANAGEMENT TOOL

TrialConsent documents large amounts of the consent process and supports site documentation about participants' consent sessions. It minimizes many risks for investigators present in the paper process. TrialConsent provides the investigator:

- eSource of the signed version of the consent
- eSource of the eConsent session activity journal (audit trail)
- Results of the performance on comprehension assessments
- Documentation of the question and answer session between participant and site
- Assurance that the questions of the participant are addressed and documented before the consent signing
- The participant can provide a reason for not consenting if applicable
- Requirement for the site personnel reviewing questions with the participant is authenticated by the system (present during the question and answer session)
- Source notes to be written in the system regarding the participant's consenting
- Participant consent session metadata
- A system copy of the signed consent form(s) is available for the site; TrialConsent provides the investigator with eConsent study and participant status reports can be made available to sites, sponsors, and ethics committees

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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