

FLEXIBLE SOLUTIONS

TO FACILITATE COMPREHENSION AND COMPLIANCE

An effective clinical trial consent process entails more than just obtaining a signature. Signant Health designed SmartSignals eConsent to enhance participant understanding, simplify consent document management, and increase efficiency in workflows. Leveraging decades of experience and research in their design, our eConsent solutions improve comprehension compared to paper-based methods and eliminate common errors that cause inspection issues.



**DIGITIZE AND SIMPLIFY
THE PROCESS**



**ENHANCE PARTICIPANT
UNDERSTANDING**



ELIMINATE ERRORS

Why choose Signant SmartSignals® eConsent?

With a range of feature options that can be tailored to your study, flexible implementation models, and integration capabilities, your study's consent process will be faster as well as more transparent and traceable. Enhance the consent experience with a variety of features available depending on your study's needs, including:

01 Multi-lingual solution development and management

03 Remote access, traceable consent and re-consent

05 Simplified document management

02 Robust global project management, comprehensive training, and 24/7 user support

04 Paper and electronic signature options

06 Self-Service implementation

FLEXIBLE OPTIONS TO MEET ALL STUDY NEEDS

Choose between pdf-based or fully interactive eConsent options to meet your study requirements.

PDF-BASED

This PDF-based eConsent process imports and presents existing PDF versions of the informed consent form (ICF) and enables electronic or digitized signature sign off. Available remotely and during a site visit, it contains important additional elements associated with eConsent, such as ICF version control, and re-consent process management. PDF-based eConsent is ideal for simple studies, phase I, and rapid implementation.

INTERACTIVE

Our most advanced option, our interactive eConsent offers a leading, engaging experience for the participant. Interactive content includes embedded video and audio playback, comprehension tests, and the ability to flag content to ask focussed questions about aspects of the study during discussions with the investigator.

Self-service customers will have access to template libraries to speed ICF assembly and study build. Reporting dashboards will provide further insights to aid ICF revision and future development – indicating, for example, questioning hotspots where more detail may be helpful.

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| FUNCTIONALITY | PDF-based | Interactive |
|---|-----------|-------------|
| Basic PDF eConsent Design | ✓ | |
| Remote Consent and Reconsent | ✓ | ✓ |
| PII Security, Encryption and Consent Tracking | ✓ | ✓ |
| Virtual Visits | Add-on | Add-on |
| Multi-lingual Capability | ✓ | ✓ |
| Automated Version Control | ✓ | ✓ |
| Self-Service Implementation | ✓ | ✓ |
| Batch Archiving | ✓ | ✓ |
| Single-Click UAT | ✓ | ✓ |
| Remote Monitoring by CRAs | ✓ | ✓ |
| Dashboards for Study Teams and Sites | ✓ | ✓ |
| Ongoing Patient Access | ✓ | ✓ |
| Electronic, Handwritten or Digitized Signatures | ✓ | ✓ |
| Assent Workflow | ✓ | ✓ |
| Flagging Content for Pre-consent Managed Discussion | | ✓ |
| Test Comprehension with built-in Q&A | | ✓ |
| Consent for Biosample Collection | | ✓ |
| Editor - Document Templates Library | | ✓ |
| Editor - Word Import | | ✓ |
| In-Solution Translations Management | | ✓ |
| Dynamic Drill-In Reporting Dashboards | | ✓ |
| Rich Multimedia | | ✓ |
| Enable Single Sign-On with Site and Sponsor Systems | | Add-on |
| eClinical Integration | | Add-on |

WHO IS SIGNANT HEALTH?

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.