

TRIALCONSENT® SELF-SERVICE AND ITS ENABLEMENT

WHAT IS TRIALCONSENT®

TrialConsent® offers a collaborative eConsent platform for developing and updating consent documentation and a real-time monitoring tool to track the consenting process. 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 by providing them a robust and engaging digital experience.

AVAILABLE AS FULL-SERVICE OR SELF-SERVICE

Our Full-Service model allows our experienced operational delivery team to manage the entire consent development and implementation process for you. Under this model, you will benefit from our proven and extensive service-excellence including: robust project management, multilingual solution development and management, maintenance, intuitive multimedia and design, experienced international logistics for site hardware provision, and comprehensive training and global 24/7 user support.

Alternatively, under our Self-Service license model, you can 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 the TrialConsent® platform.

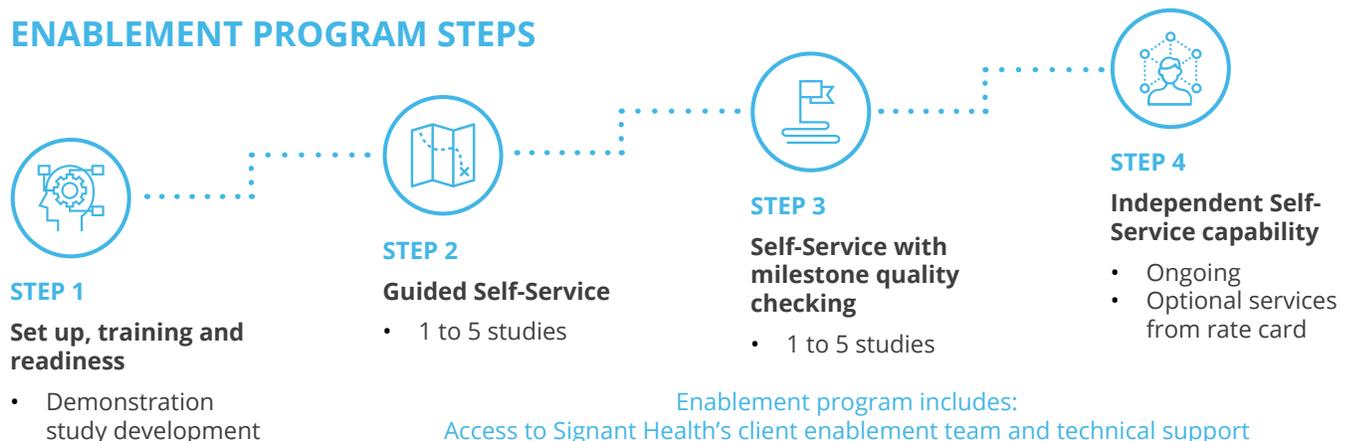
SELF-SERVICE: SPONSOR ENABLEMENT

The Sponsor Enablement program is designed to ensure that you are:

- Fully equipped to design and deploy your own electronic informed consent studies using the TrialConsent® platform
- Fully equipped to monitor and manage your own ongoing studies deployed on the TrialConsent® platform
- Continuously updated on new software versions in a timely manner
- Aware of optional services available on a study-by-study basis
- Have a direct access to Signant Health experts to troubleshoot queries and questions
- Fully supported by Signant Health’s robust hosting and support services

We offer and recommend a phased Sponsor Enablement Program as below.

ENABLEMENT PROGRAM STEPS



Enablement program includes:
Access to Signant Health’s client enablement team and technical support
Regular release updates, and updates to manuals and training materials

STEP 1. TRAINING AND READINESS

Led by Signant Health, the first enablement step is an in-depth implementation and readiness training on the TrialConsent® platform for your teams. This phase includes classroom training, provisioning of manuals and training guides, course certifications, and developing sponsor requirements specification and testing documentation. Sandbox, user accounts and operational environments are set up by Signant Health. A client enablement team comprised of technical specialists and led by Signant Health's Project Lead is assigned to you and works closely with you on customizing your training and ensuring your teams are fully ready to transition to the next enablement phase.

STEP 2. GUIDED SELF-SERVICE

In the second enablement phase, Signant Health's client enablement team shadows your team on configuration and consent form development while your team continues to learn the technology. We support this phase through on-site guidance on the design and build of eConsent, followed by remote monitoring during study go-live and for a time-period that meets your needs. Remote monitoring by Signant Health is also available during your study for any updates and re-consenting workflows.

STEP 3. MILESTONE QUALITY CHECKS

In this phase, your teams would manage the form development, implementation and related processes, while Signant Health oversees and conducts quality checks on system configuration and at defined study milestones. The Signant Health Project Lead assists in creating project plans and continues to meet with you on a regular basis. Remote quality checks are also available during your study for any updates and re-consenting workflows.

STEP 4. INDEPENDENT SELF-SERVICE

We recommend transitioning to independent Self-Service on completion of the three enablement phases. You can manage the entire eConsent workflow through your teams and your defined processes. The 'pay per use' license for TrialConsent® enables unlimited access to the design environment. By licensing the TrialConsent® platform, you can create your own electronic libraries of consent forms for easy re-use across studies as well as maintain full control over your processes. Signant Health continues support related to any new product releases and ensures knowledge transfers to new staff that need onboarding. Optional services such as language translations, device procurement and logistics, and user help desk support are also available from Signant Health.

STEP 1 DELIVERABLES:

- On-site, customized classroom training
- Instructions for Use
- Training materials
- Project documentation templates
- Sandbox and operational environments
- User accounts
- A client enablement team

STEP 2 DELIVERABLES:

- On-site shadowing for design and configuration
- Remote monitoring of go-live and initial maintenance phase
- Remote monitoring of re-consenting and mid-study updates

STEP 3 DELIVERABLES:

- Quality checks by client enablement team at multiple, predetermined study milestones.

STEP 4 DELIVERABLES:

- Pay per use license
- Continued knowledge transfers
- Support for feature releases
- Multiple optional and add-on services

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.

