The survey was not meant to be specific to Signant Health or to any eConsent solution or provider but rather a broader industry experience survey.

To better understand industry challenges on deployment of eConsent solutions in clinical trials.

To validate business drivers and benefits and to do pulse check on attitudes and intent around eConsent.

To gain insights into the eConsent global market needs and future adoption trends.

Outreach to a database of Sponsor and CRO recipients.

To better understand industry challenges on deployment of eConsent solutions in clinical trials.
PROFILE OF RESPONDENTS
WHICH STAKEHOLDER PERSPECTIVE DO YOU REPRESENT?

- Sponsors: 60%
- CROs: 34%
- Other: 6%

134 RESPONDENTS
ARE YOU CURRENTLY, OR HAVE YOU BEEN INVOLVED, IN THE eCONSENT PROCESS?

The survey received responses from staff at sponsor and CRO organizations who have had hands-on experience with implementing eConsent or were working with teams directly involved in its planning and implementation.

Yes 40%

No 31%

I interact with people who work with eConsent 29%
Thirty-nine percent of respondents worked in clinical operations functions, with a further 13%, 8%, 7%, and 7% in health outcomes, procurement, data management, and regulatory functions, respectively.
WHICH THERAPEUTIC AREA(S) DO YOU CURRENTLY WORK IN? (%)

Therapeutic area responsibilities covered a broad range including oncology, central nervous system, immunology, gastrointestinal, pediatrics, hematology, endocrinology, respiratory, and dermatology, amongst the most common.
WHERE ARE YOU LOCATED?

In terms of geographic spread, 70% of respondents were from NA followed by 27% from Europe and 3% from Asia.
WHICH REGIONS HAVE YOU SUCCESSFULLY IMPLEMENTED eCONSENT? (%)

North America was the most popular region where eConsent has successfully been implemented (73%), followed by Europe and Asia.

- North America: 73%
- Europe: 38%
- Asia: 32%
- Central & South America: 8%
- Middle East: 3%
- Oceania: 0%
- Africa: 0%
GLOBAL EXPERIENCES AND IMPACT OF eCONSENT
HOW MUCH EXPERIENCE DOES YOUR BUSINESS UNIT HAVE WITH eCONSENT?

Majority of the respondents are either extensively using or doing pilots with eConsent.

- Some (1-5 studies): 46%
- Intermediate (6-15 studies): 27%
- Advanced (15+ studies): 27%

Signant Health State of eConsent 2020
FOR WHICH PHASE IS eCONSENT TYPICALLY USED AT YOUR ORGANIZATION? (%)

The trend is clearly that phase III and II are the biggest areas for eConsent deployment currently.

- Phase I: 26%
- Phase II: 43%
- Phase III: 55%
- Phase IV: 30%
From an eConsent design and development perspective, most respondents were largely 'satisfied' with the different components that support the go-live function of eConsent. 63% of respondents reported that they were satisfied with the site setup processes such as procuring digital tablets for site use, training sites, and creating site users.

The industry still has low level of experiences with self-service currently, and it does require setting up new teams and processes so a significant learning curve is involved. So, while most of respondents were largely satisfied, there is room for improvement to get to “very satisfied” for the new self-service function.
Standard features offered by eConsent make a high impact on patient comprehension and engagement. We found 91% of CRO respondents and 73% of sponsor respondents reported that eConsent's user-friendly and interactive interface was a highly impactful feature. Another impactful feature was the ability for patients to flag questions to discuss with site staff. 73% of CROs and 68% of sponsors seemed to agree that this feature resulted in more focused and higher quality interactions between sites and patients leading to improve understanding of the trial by patients.
WHICH ECLINICAL SYSTEMS HAVE YOU INTEGRATED WITH eCONSENT?

28% of respondents had integrated an eConsent solution with an EDC product, with the same number (28%) reporting integration with a clinical trial management system. A further 26%, 19%, and 17% had integrated eConsent with electronic clinical outcome assessment, electronic trial master file, and randomization and trial supply management solutions.

Surprisingly, 28% of respondents had not integrated eConsent with other eClinical systems, and this may be a feature of the early adoption phase of eConsent as the importance and drive to simplify processes and limit reconciliation through eClinical integration continues to be a focus within our industry.
Integration experience has been largely positive with between 56% to 71% of the different user groups responding in the positive. With more study experience, 33% advanced users as compared to 21% of intermediate and 20% of some users seemed to have seen more pain points, most likely related to scalability and growing pains, reinforcing that we are in the early adoption phase of eConsent.
WHAT WERE THE BIGGEST BUSINESS DRIVERS FOR IMPLEMENTING ECONSENT AT YOUR ORGANIZATION?

The most commonly identified top three business drivers were – improved patient comprehension, efficiencies through digitization, improved patient retention, reduced regulatory risk and audit findings and lowered site burden. The top drivers identified were similar between sponsor and CRO respondents as well as the 3 user group categories of advanced/intermediate and some users.

Risk based monitoring, remote and virtual trials support and self-authoring tools ranked lower against the more typical drivers of eConsent, probably because these drivers are typically not part of the early adoption phase and are more advanced and future trends instead.

- Patient Comprehension: 63%
- Efficiencies through digitization: 58%
- Patient retention: 42%
- Regulatory risk and audit findings: 36%
- Site burden: 32%
- Risk-based monitoring analytics: 22%
- Remote and virtual trials: 17%
- Self-authoring tools: 13%
WHAT HAVE BEEN THE BIGGEST CHALLENGES WITH USING eCONSENT? (%)

One of the biggest challenges reported with using eConsent in clinical trials was investment in new technology. As with all new technology, perceived high costs and uncertain return on investment can prove to be a barrier and prevent some organizations from adopting eConsent, with 39% of respondents reporting that investment in new technology can be challenging. Often, the costs of existing processes associated with consent form development, implementation, and monitoring are not being measured, nor the costs of loss of data due to ambiguous or incomplete informed consent documentation or resulting regulatory findings – all leading to investments defined as the biggest challenge.

Another interesting finding - while site support, resistance from IRBs/Ethics Committees and staffing and resource constraints were identified as potential challenges by 38%, 26% and 23% of respondents respectively, those with more experience i.e. the advanced users with experience of >15 studies using eConsent reported these less often—with only between 8% to 15% of advanced users citing these as a challenge. This demonstrates the learning curve involved with eConsent, common to the implementation of all new processes or technologies.
WHAT REPORTING DATA FROM ECONSENT HAS BEEN MOST VALUABLE FOR YOU?

From a data reporting perspective, 59% of respondents placed high value on site performance reporting, closely followed by patient enrollment data 51%, monitoring oversight data 47%, and patient experience data 44%.
THE FUTURE OF eCONSENT
HOW LIKELY ARE YOU TO RECOMMEND eCONSENT TO OTHER STUDY TEAMS?

More than 80% of the respondents will recommend eConsent be used in clinical trials – so there is industry agreement on the value this technology provides and points to overall good experiences to date.

- Not Likely: 4%
- Neutral: 14%
- Very Likely: 81%
WHAT DOES eCONSENT NEED TO ADD OR IMPROVE ON TO BECOME A MAINSTREAM SOLUTION?

We found that 21% of respondents would like increased regulatory standardization and acceptance. A point to note here is that in the near term, the risks for global regulatory acceptance can be mitigated using print-to-sign functionality offered by most eConsent systems.

A common theme within the survey is a need for continued education, and for building more confidence with new processes across the stakeholders involved in eConsent.

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**REGULATORS**
- Increased regulatory standardization and acceptance (21%)

**SITES**
- Seamless site setup and readiness processes (6%)
- Education and building confidence (9%)

**PATIENTS**
- Need improved device connectivity (6%)

**SPONSORS/CROs**
- Need simpler and faster implementation (6%)
- Education and building confidence (6%)
- Acceptance as a necessity; not just an add-on (6%)

**VENDORS**
- Robust Data security and transparency on data storage (4%)
- More integration across systems (4%)
- Support for changing sponsor organizational processes (2%)
HOW DO YOU PREDICT eCONSENT USE AT YOUR ORGANIZATION?

The momentum of adoption looks set to continue with 65% of CRO respondents and 85% of sponsor respondents saying that their organizations will adopt eConsent for some studies over the next 12 months. While in the long term, 76% of CRO respondents and 71% of sponsor respondents state that their organizations will adopt eConsent for many of their studies in the next three years and beyond.
KEY TAKEAWAYS

eConsent is a valuable technology for many organizations in the drive to improve clinical trial processes, efficiency, and quality, and to generate a better patient experience that can positively impact patients' comprehension and their ongoing engagement.

- Key trends include integration of eConsent data with other eClinical systems
- The industry has had positive experiences and is largely satisfied with the technology and its current direction
- It is the intent of many organizations to significantly ramp up their use of eConsent in the next three years

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.