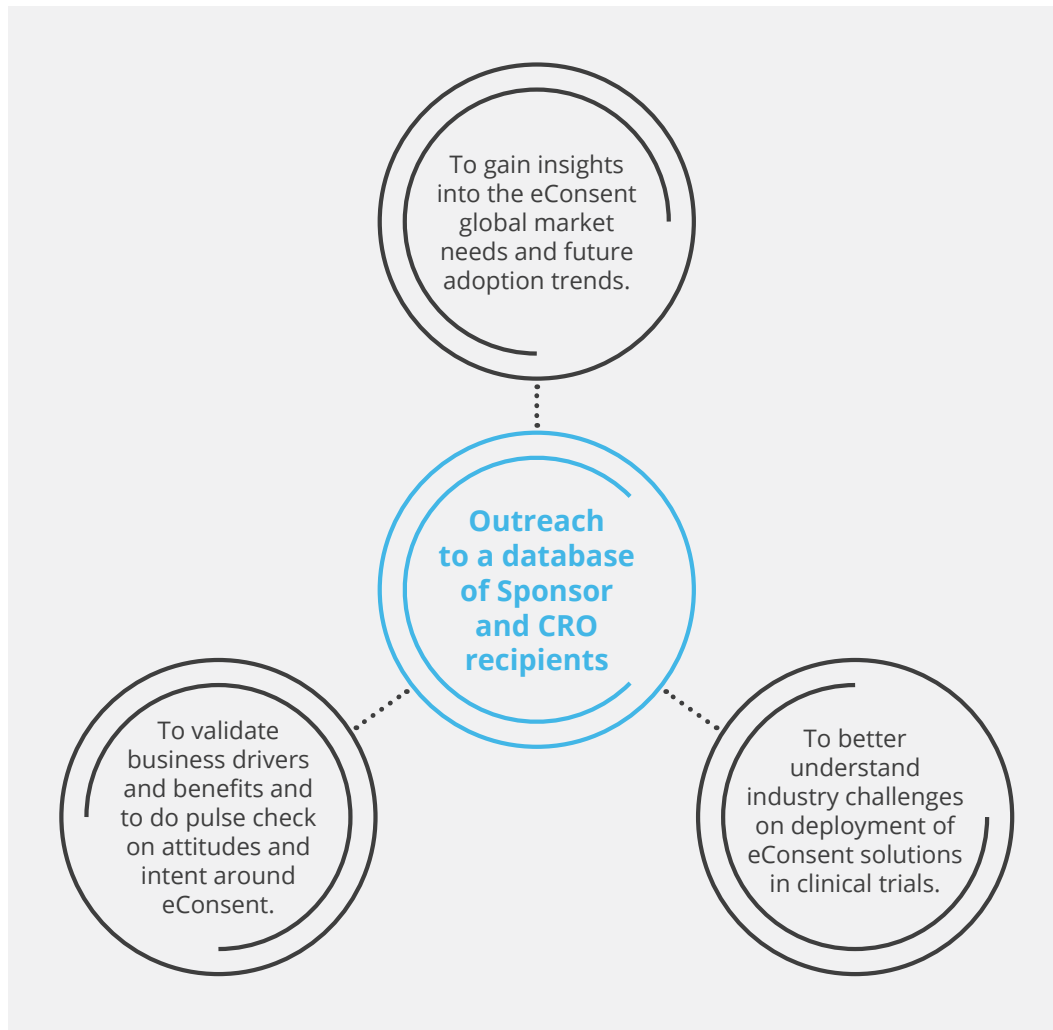# SIGNANT HEALTH

State of eConsent 2020

INSIGHTS FROM OUR INDUSTRY GLOBAL EXPERIENCE SURVEY
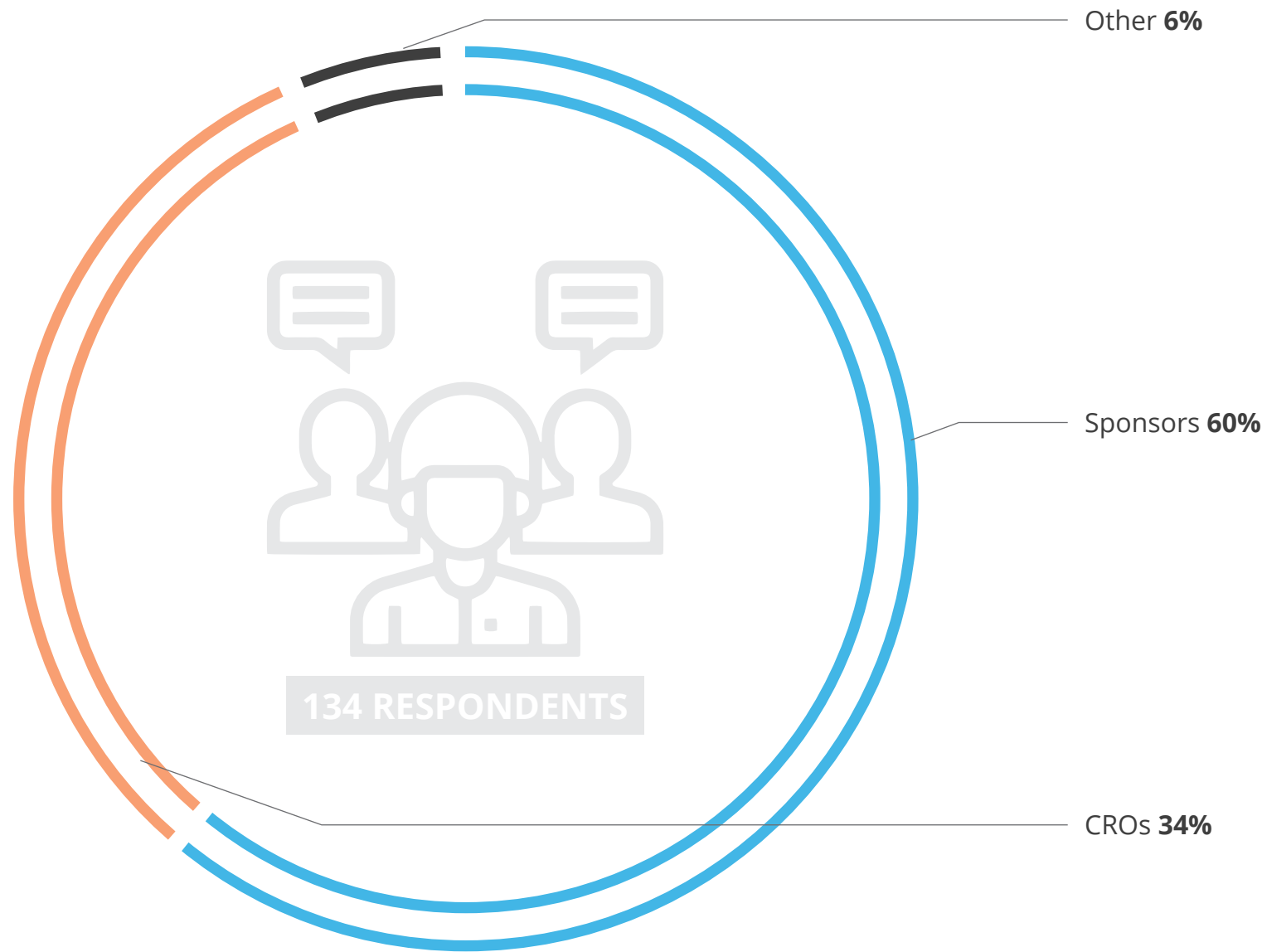
SURVEY OBJECTIVES & METHODOLOGY

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

Outreach to a database of Sponsor and CRO recipients

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

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

PROFILE OF RESPONDENTS

WHICH STAKEHOLDER PERSPECTIVE
DO YOU REPRESENT?

Other **6%**

Sponsors **60%**

134 RESPONDENTS

CROs **34%**
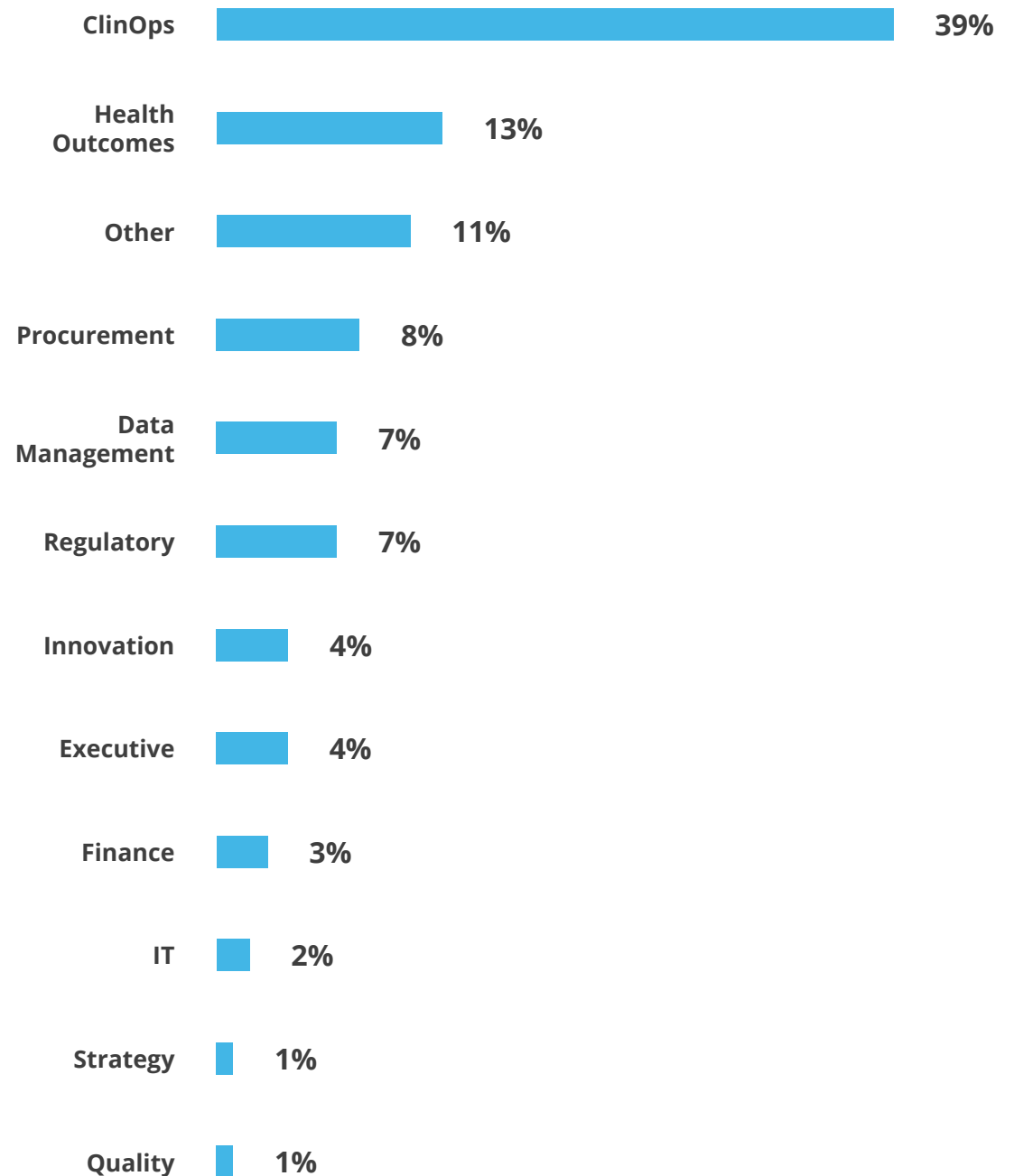
ARE YOU CURRENTLY, OR HAVE YOU BEEN INVOLVED, IN THE eCONSENT PROCESS?

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%**

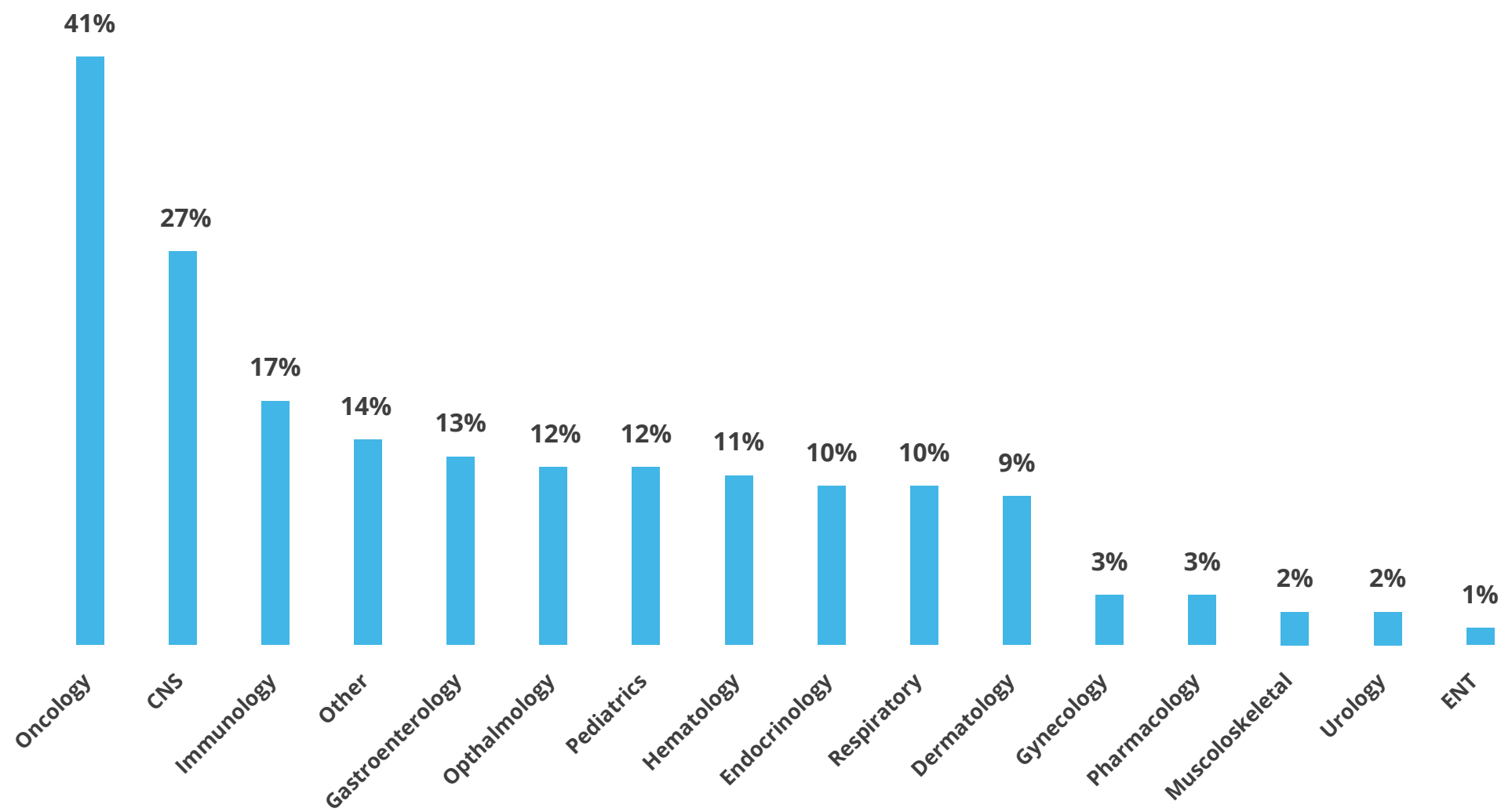I interact with people who work with eConsent **29%**

YOUR CURRENT ROLE WITHIN YOUR ORGANIZATION (%)

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.

ClinOps — 39%

Health Outcomes — 13%

Other — 11%

Procurement — 8%

Data Management — 7%

Regulatory — 7%

Innovation — 4%

Executive — 4%

Finance — 3%
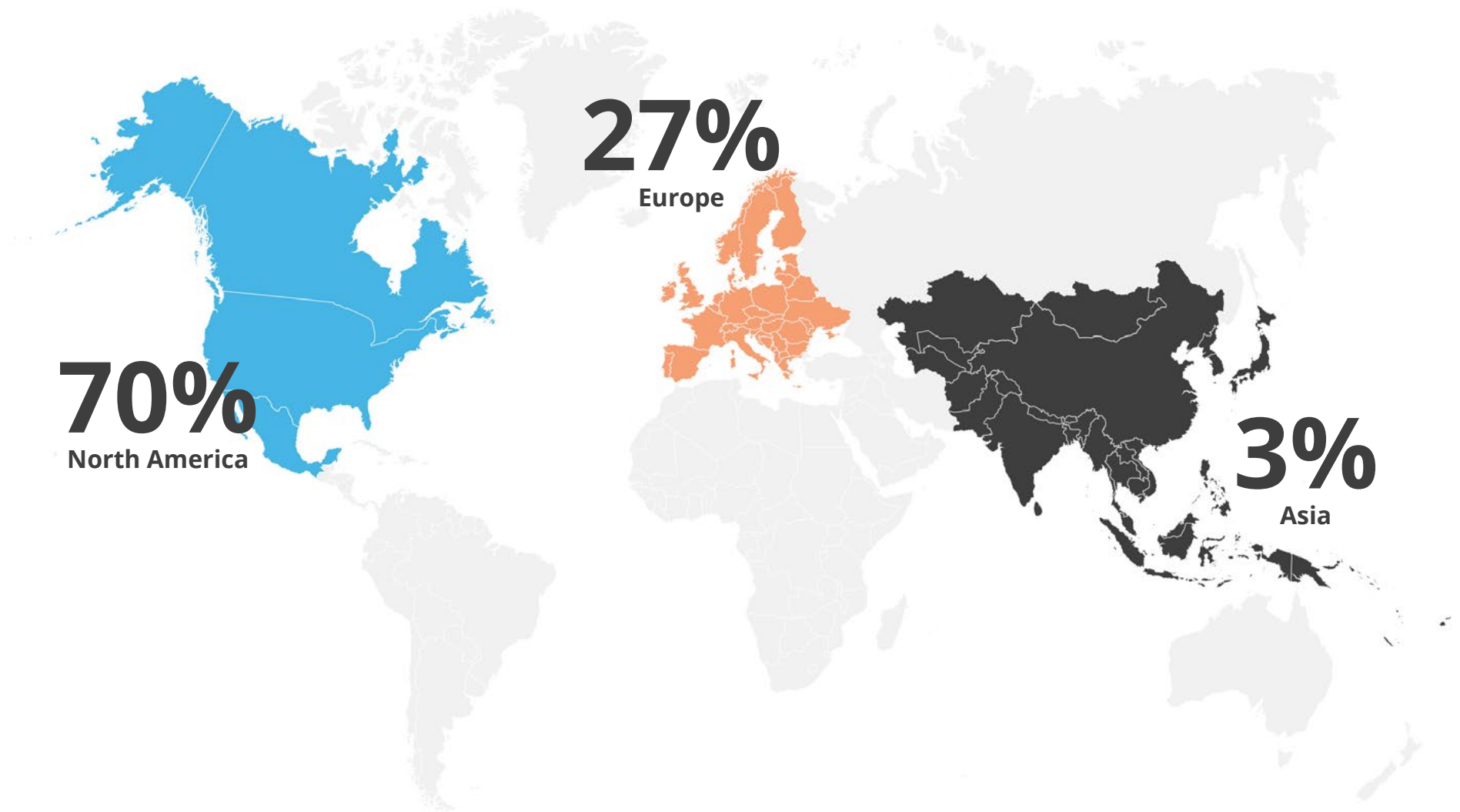
IT — 2%

Strategy — 1%

Quality — 1%

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.

Therapeutic Area	%
Oncology	41%
CNS	27%
Immunology	17%
Other	14%
Gastroenterology	13%
Opthalmology	12%
Pediatrics	12%
Hematology	11%
Endocrinology	10%
Respiratory	10%
Dermatology	9%
Gynecology	3%
Pharmacology	3%
Muscoloskeletal	2%
Urology	2%
ENT	1%

WHERE ARE YOU LOCATED?

In terms of geographic spread, 70% of respondents were from NA followed by 27% from Europe and 3% from Asia.

27%
Europe

70%
North America

3%
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.
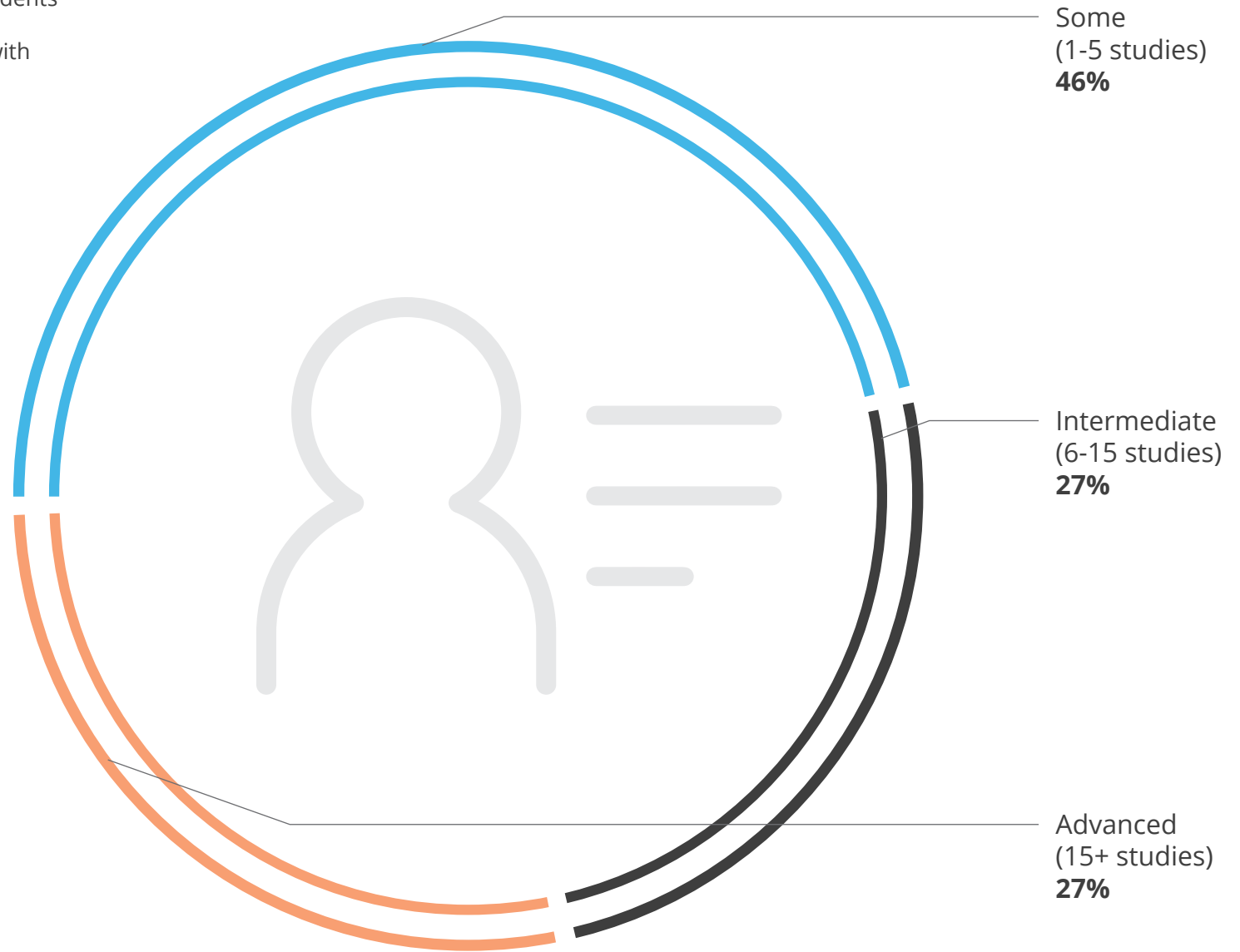
Region	%
North America	73%
Europe	38%
Asia	32%
Central & South America	8%
Middle East	3%
Oceania	0%
Africa	0%

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%

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%

RATE YOUR ORGANIZATION'S LEVEL OF SATISFACTION ON ITEMS RELATED TO DESIGN AND DEVELOPMENT OF eCONSENT FORMS (%)

From an eConsent design and development perspective, most respondents were largely 'satisfied' with the different components that support the go-live fu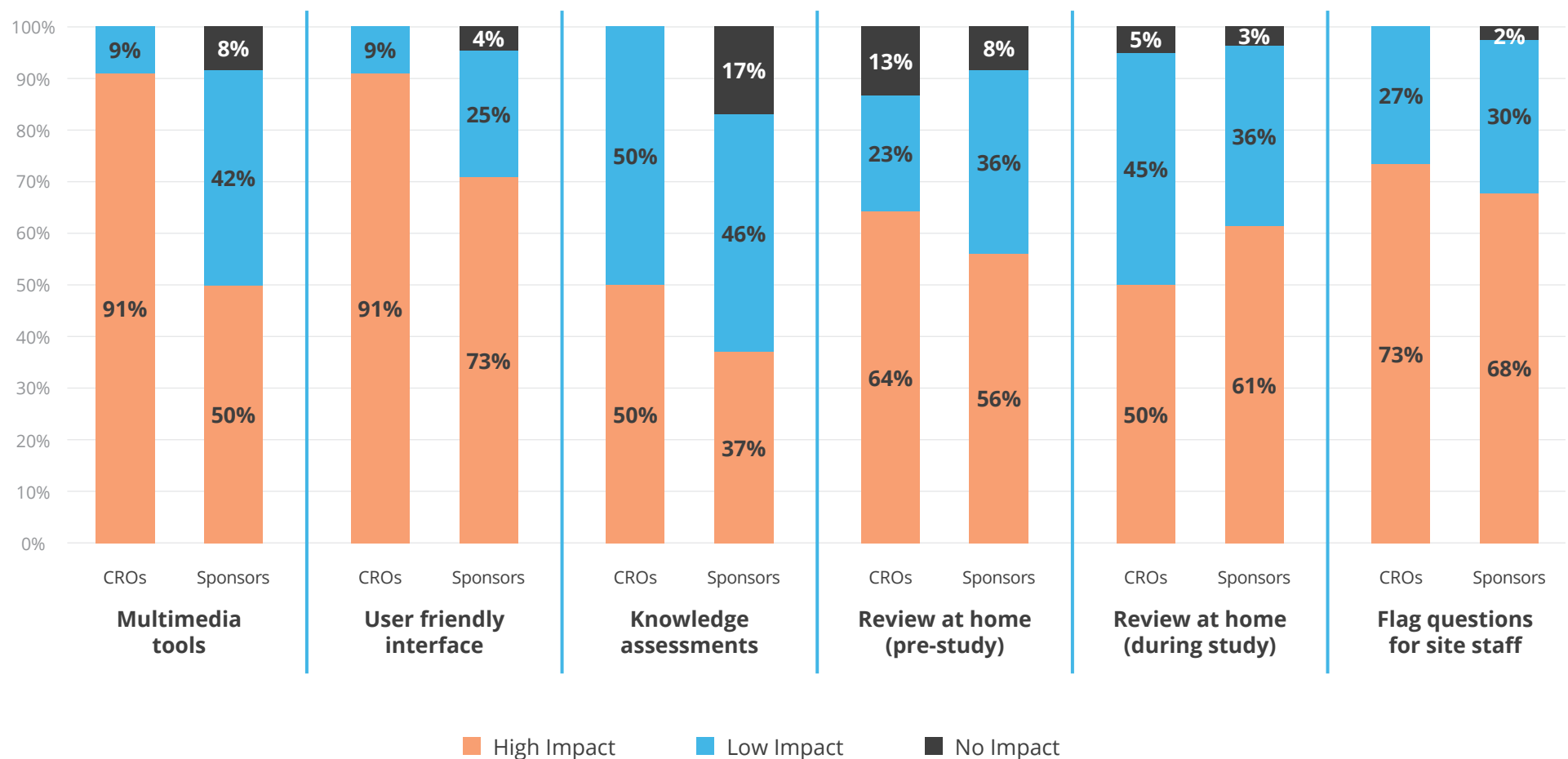nction of eConsent. 63% of respondents reported that they were satisfied with the site setup processes such as procuring digital tablets for site use, training sites, and creating site users.

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.

Category	Not Satisfied	Satisfied	Very Satisfied
Ability for Study teams to Self-author	16%	46%	8%
Workflow and Regulatory Consultation	12%	54%	10%
Translations	8%	51%	9%
Multimedia Production	8%	49%	14%
Site Setup Processes	9%	63%	6%

■ Not Satisfied ■ Satisfied ■ Very Satisfied

RATE HOW MUCH IMPACT YOU THINK EACH FEATURE HAS ON PATIENT COMPREHENSION AND ENGAGEMENT (%)

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.

Chart: Stacked bar chart showing High Impact, Low Impact, and No Impact percentages for CROs and Sponsors across six features.

Multimedia tools
- CROs: High Impact 91%, Low Impact 9%
- Sponsors: High Impact 50%, Low Impact 42%, No Impact 8%

User friendly interface
- CROs: High Impact 91%, Low Impact 9%
- Sponsors: High Impact 73%, Low Impact 25%, No Impact 4%

Knowledge assessments
- CROs: High Impact 50%, Low Impact 50%
- Sponsors: High Impact 37%, Low Impact 46%, No Impact 17%

Review at home (pre-study)
- CROs: High Impact 64%, Low Impact 23%, No Impact 13%
- Sponsors: High Impact 56%, Low Impact 36%, No Impact 8%

Review at home (during study)
- CROs: High Impact 50%, Low Impact 45%, No Impact 5%
- Sponsors: High Impact 61%, Low Impact 36%, No Impact 3%

Flag questions for site staff
- CROs: High Impact 73%, Low Impact 27%
- Sponsors: High Impact 68%, Low Impact 30%, No Impact 2%
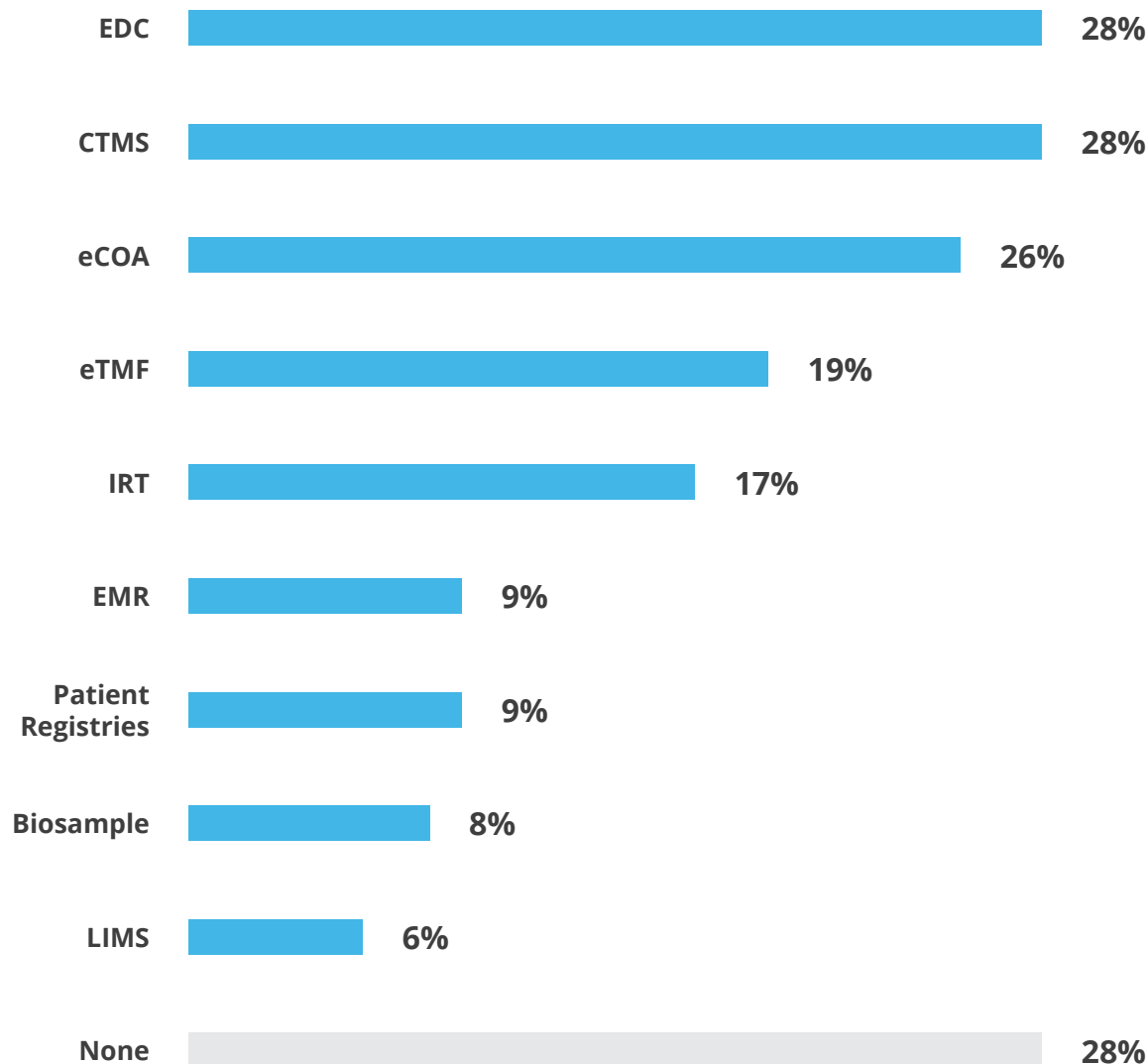
Legend: ■ High Impact ■ Low Impact ■ No Impact

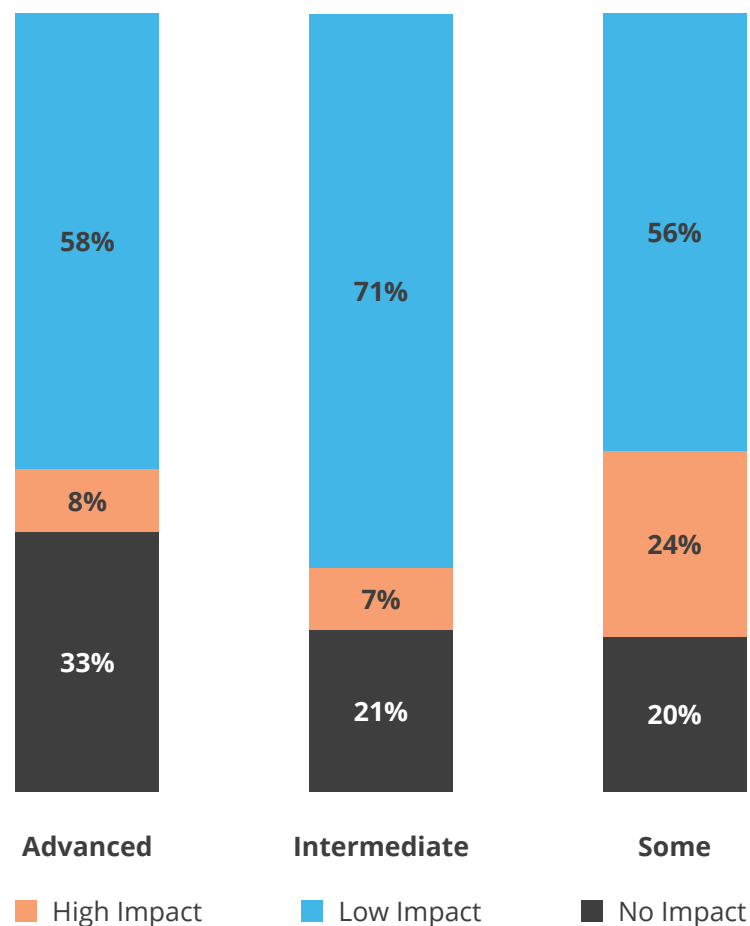# WHICH ECLINICAL SYSTEMS HAVE YOU INTEGRATED WITH eCONSENT?

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.

System	Percentage
EDC	28%
CTMS	28%
eCOA	26%
eTMF	19%
IRT	17%
EMR	9%
Patient Registries	9%
Biosample	8%
LIMS	6%
None	28%

WHAT WAS YOUR OVERALL EXPERIENCE WITH THESE INTEGRATIONS?

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.
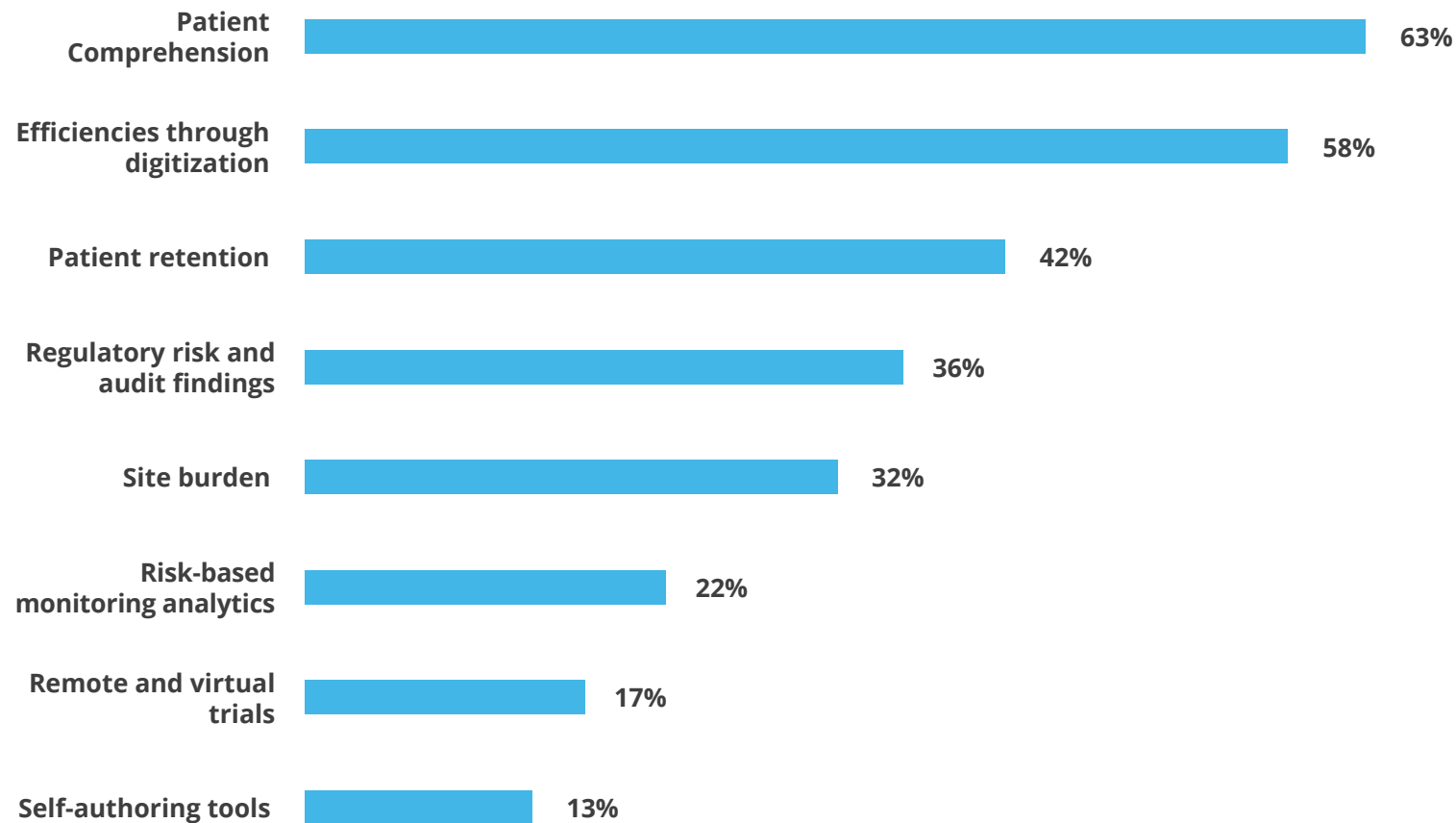

Advanced: 58%, 8%, 33%
Intermediate: 71%, 7%, 21%
Some: 56%, 24%, 20%

High Impact • Low Impact • No Impact

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.

Driver	Percentage
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%

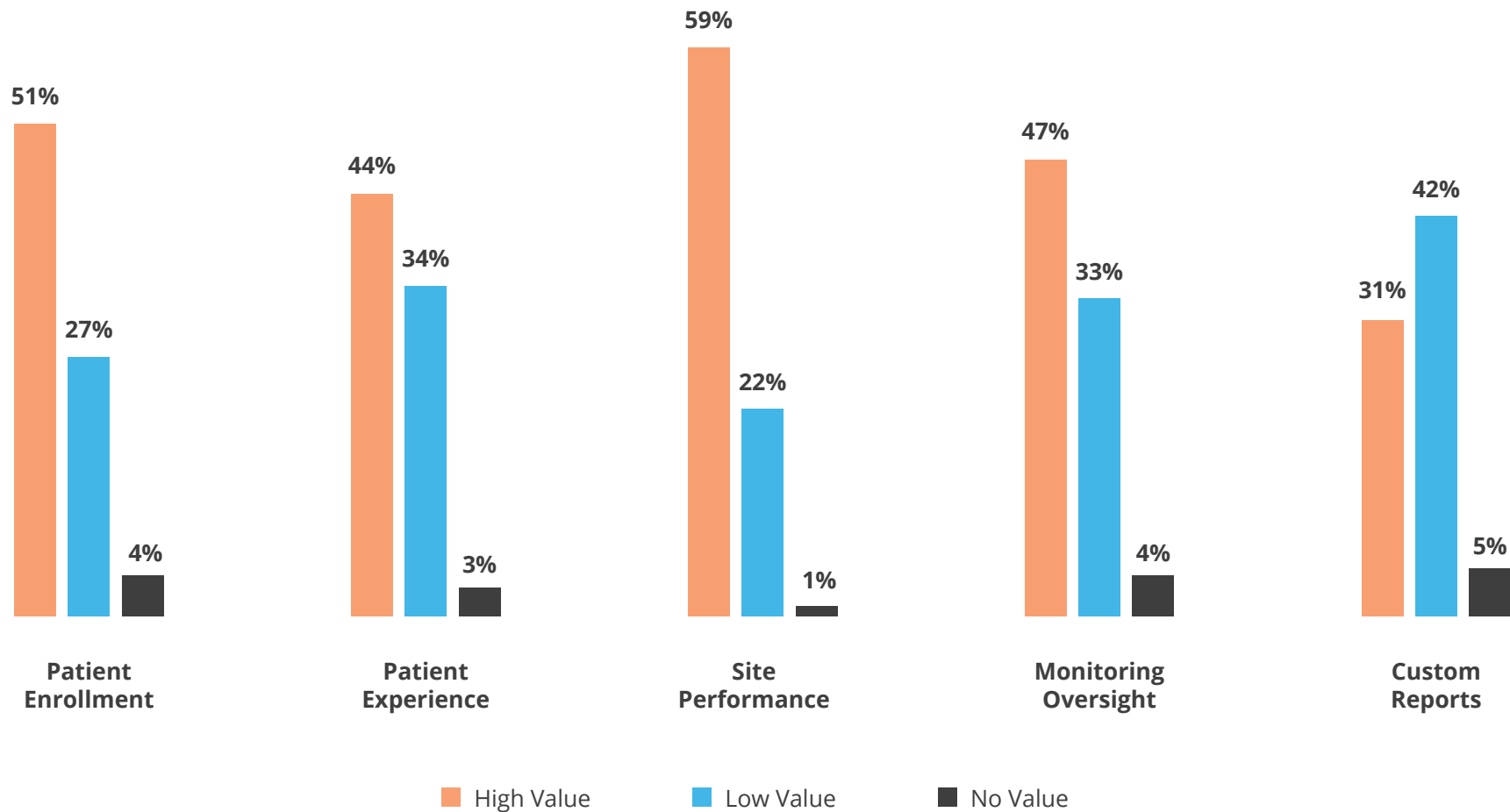# WHAT HAVE BEEN THE BIGGEST CHALLENGES WITH USING eCONSENT? (%)

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.

Investment in New Tech — **39%**
Site Support — **38%**
Regulatory — **37%**
Data Security / Privacy — **36%**
Internal Resistance — **30%**
Devices and Connectivity — **29%**
Site Burden — **29%**
IBR/EC Resistance — **26%**
Staffing and Resource Constraints — **23%**
Lack of Patient Understanding — **23%**
Lack of Executive Support — **7%**

Legend: Total | Advanced | Intermediate | Some

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%.

Bar chart data:

Patient Enrollment: High Value 51%, Low Value 27%, No Value 4%
Patient Experience: High Value 44%, Low Value 34%, No Value 3%
Site Performance: High Value 59%, Low Value 22%, No Value 1%
Monitoring Oversight: High Value 47%, Low Value 33%, No Value 4%
Custom Reports: High Value 31%, Low Value 42%, No Value 5%
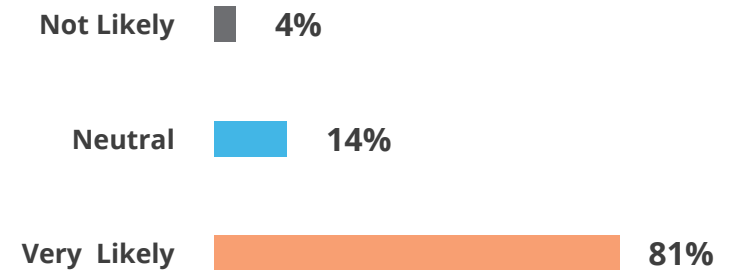
Legend: ■ High Value ■ Low Value ■ No Value

THE FUTURE OF eCONSENT

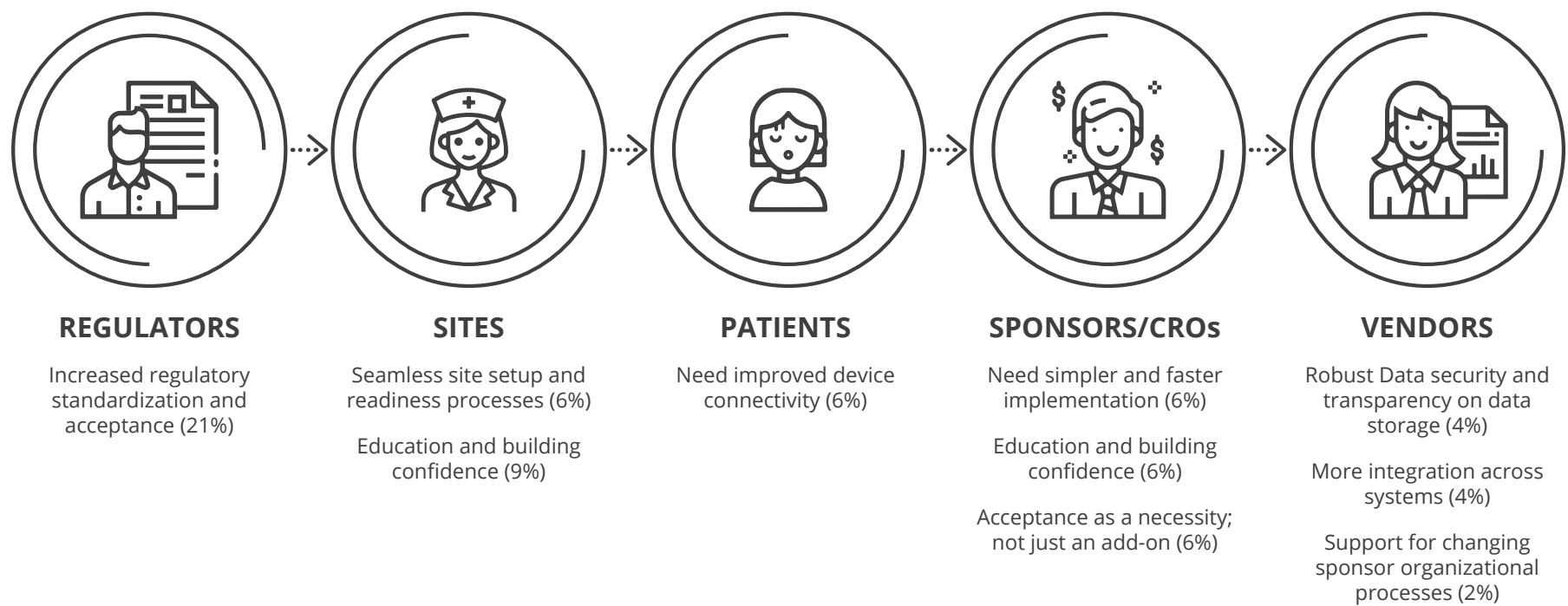# HOW LIKELY ARE YOU TO **RECOMMEND eCONSENT** TO OTHER STUDY TEAMS?

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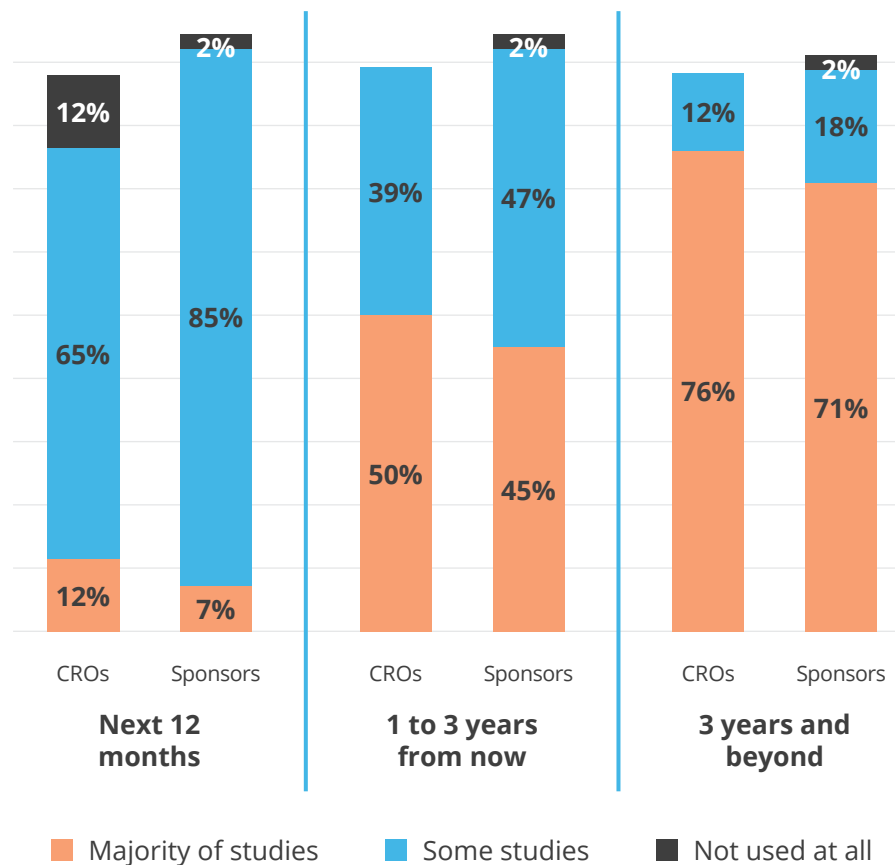
We found that 21% of respondents would like increased regulatory standardization and acceptance. A point to note here is that in the near term, the risks for global regulatory acceptance can be mitigated using print-to-sign functionality offered by most eConsent systems.

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.

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.

Next 12 months
- CROs: 12% (Not used at all), 65% (Some studies), 12% (Majority of studies)
- Sponsors: 2% (Not used at all), 85% (Some studies), 7% (Majority of studies)

1 to 3 years from now
- CROs: 39% (Some studies), 50% (Majority of studies)
- Sponsors: 2% (Not used at all), 47% (Some studies), 45% (Majority of studies)

3 years and beyond
- CROs: 12% (Some studies), 76% (Majority of studies)
- Sponsors: 2% (Not used at all), 18% (Some studies), 71% (Majority of studies)

Legend:
- Majority of studies (orange)
- Some studies (blue)
- Not used at all (black)

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.

eConsent is a valuable technology for many organizations

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.

SIGNANT HEALTH