The 2024 Avoca
State of the Industry Report

Anticipating ICH E6 (R3): Awareness, Impact & Preparedness

June 2024

Table of Contents

What We Did

Background & Learning Goals

20+ YEARS

For more than 20 years, Avoca, a WCG company, has surveyed the industry to gain an understanding of **key trends affecting clinical development**, in order to provide insights that can **strengthen relationships** and **enhance R&D quality** and **productivity**.

Situation

With the expectation of revised guidance under ICH E6 (R3) to be finalized in the fall of 2024, the topic of this year's industry survey focused on *understanding current awareness of proposed changes and gauging perceived impacts* – both positive and negative – among stakeholders in clinical trial development and execution.

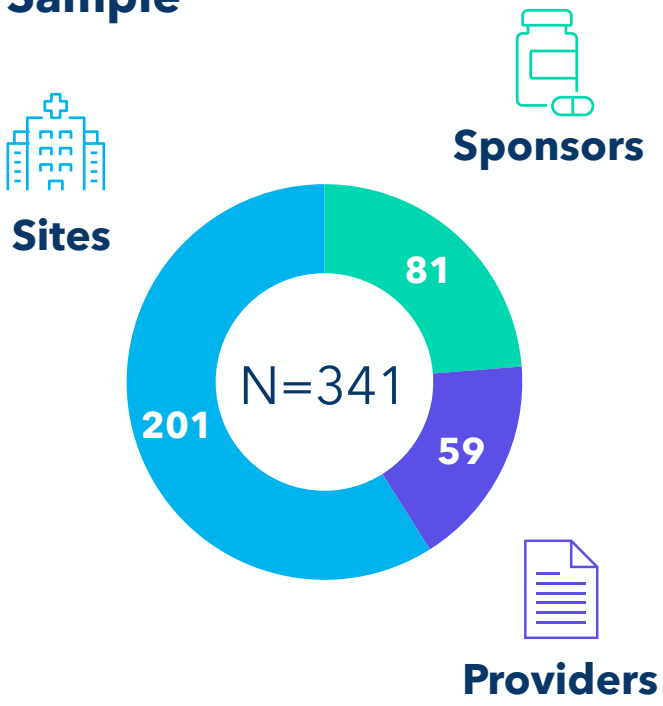
Objectives

Goals of this research were to:

- *Assess current levels of awareness* and engagement with proposed ICH E6 (R3) changes.
- *Understand reaction to select excerpts of the proposed guidance* – key take-aways and perceptions of impact on "how business is done."
- *Identify information and support needs* that will foster collaboration and implementation.

Research Overview

Sample



Note: The total sample has been weighted to achieve equal representation of sponsors, providers, and sites.

Approach

15-minute online survey.

Key topics included:

- Awareness of ICH E6 (R3).
- Exposure to ICH E6 (R3) information.
- Perceived impact of ICH E6 (R3).

Fieldwork was conducted between January and March of 2024.

Recruitment

A variety of channels were used for survey recruitment, including:

- WCG sponsor and site networks.
- The Avoca Quality Consortium (AQC).
- Social networks (e.g., LinkedIn).

Sample Composition

	Sponsors		Providers		Sites	
Type	**Top 20 Biopharma**	**23%**	Large CRO	11%	**Academic Medical Center**	**32%**
	Top 50/Mid-sized Biopharma	15%	Mid-sized CRO	18%	**Physician Practice**	**26%**
	Other Mid-sized Biopharma	6%	**Small/Specialty CRO**	**28%**	Independent Research Site	20%
	Small/Specialty Biopharma	19%	**Consulting Company**	**26%**	Integrated HC Delivery System	9%
	Pre-Revenue Biopharma	**29%**	Non-CRO Clinical Service Provider	5%	Community Hospital	7%
	Medical Device Company	9%	Academic Research Organization	2%	Site Network	6%
			Other	11%	Other	1%
Role/Function	**Clinical Development/Ops**	**45%**	**Clinical Development/Ops**	**51%**	**CRC/CRN**	**38%**
	Quality Assurance/Control	**21%**	**Quality Assurance/Control**	**16%**	**Research Admin Staff**	**20%**
	Clinical Data Management	11%	Executive Management	14%	Regulatory/Compliance	16%
	Executive Management	8%	Regulatory Affairs	5%	Site Leadership/Owner	10%
	Medical Affairs/Scientific	6%	Medical/Scientific	4%	Physician/PI	9%
	Other	9%	Other	11%	Other	8%

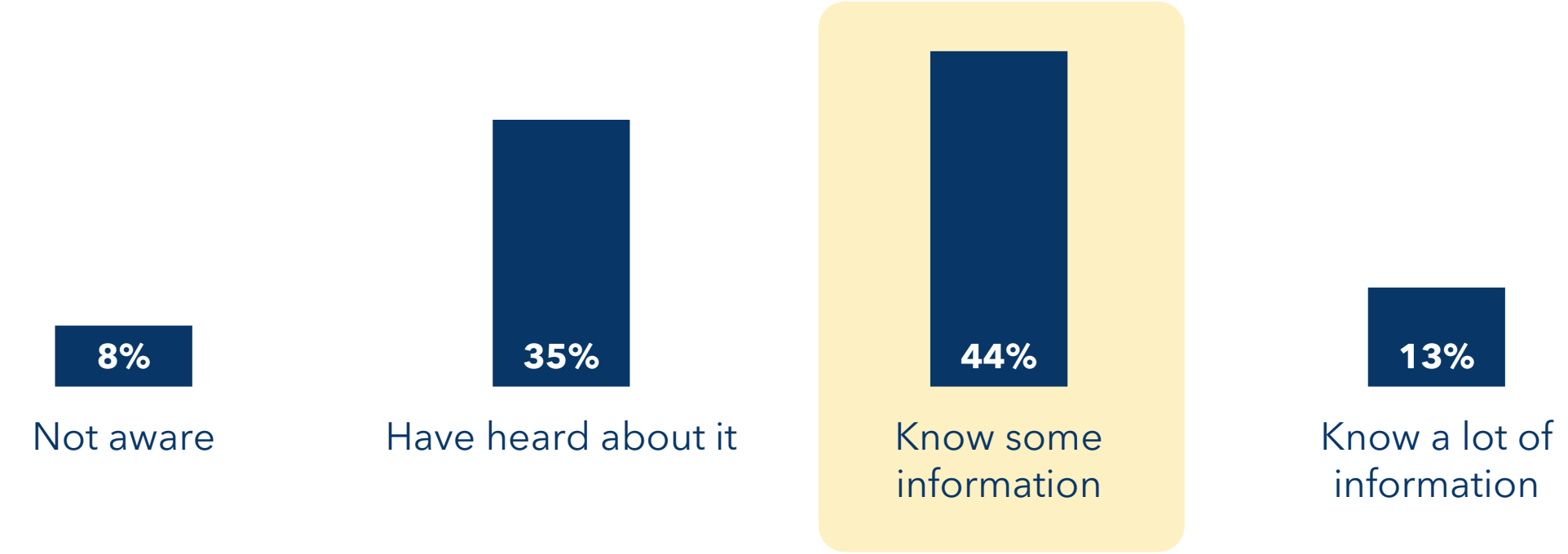
Sample: Sponsors=80, Providers=57, Sites=199

What We Learned

Current Understanding of ICH E6 (R3) Draft Guidance

There is Awareness of ICH E6 (R3), but Not Necessarily *Familiarity*

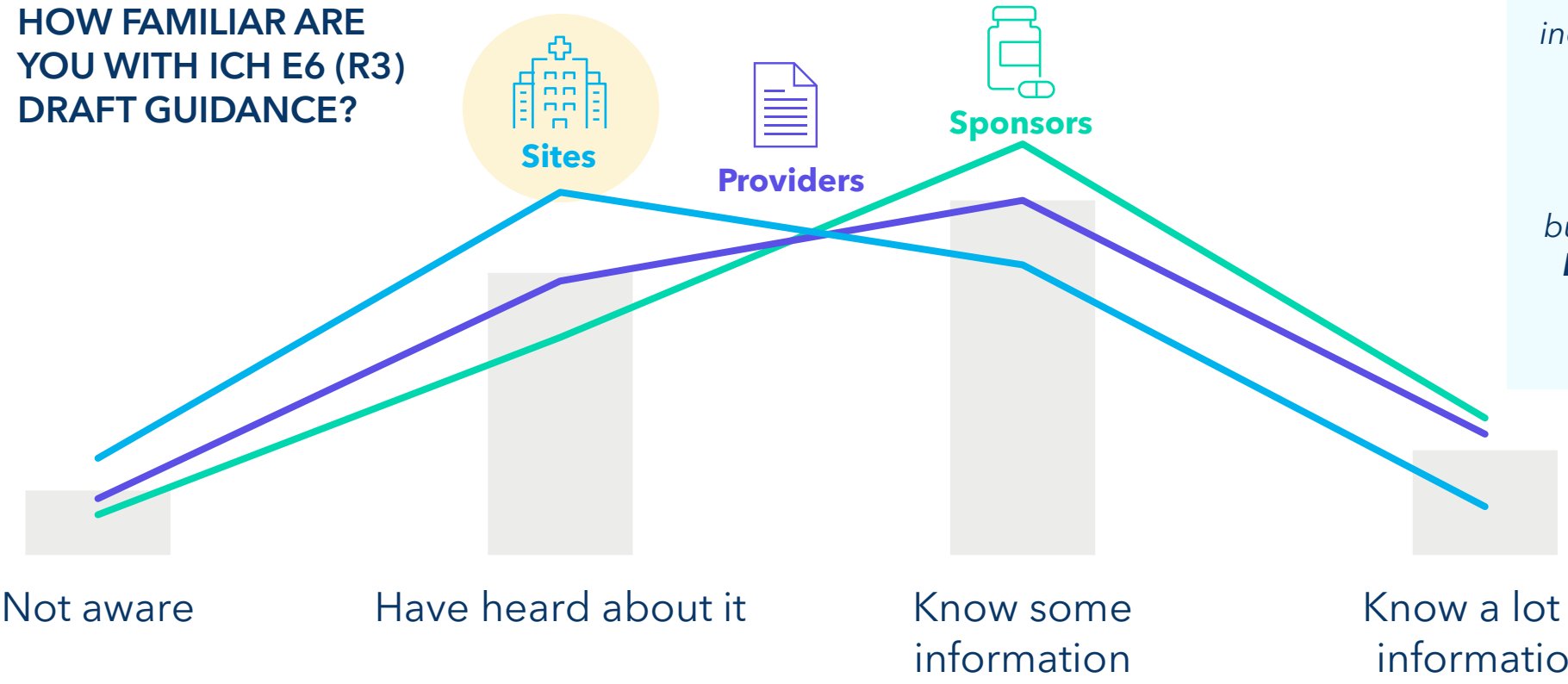
HOW FAMILIAR ARE YOU WITH ICH E6 (R3) DRAFT GUIDANCE?



Sample: Total=341

Sites Appear to Have a Steeper Learning Curve Ahead, Expressing Less Familiarity than do Sponsors and Providers

HOW FAMILIAR ARE YOU WITH ICH E6 (R3) DRAFT GUIDANCE?



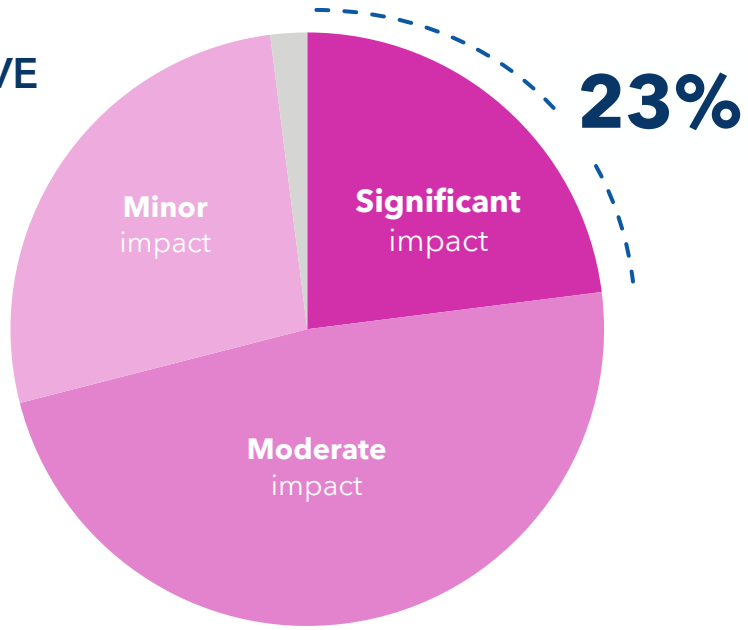
> *[ICH E6 (R3) includes] changes implemented to help reduce unnecessary administrative burdens although* ***I'm not clear on specifics.***
>
> – SITE

Sample: Total=341, Sponsors=81, Providers=59, Sites=201

Potential Impact of ICH E6 (R3) on Trial Conduct is Commensurate to Knowledge – Those Who "Know A Lot" Foresee More Significant Change

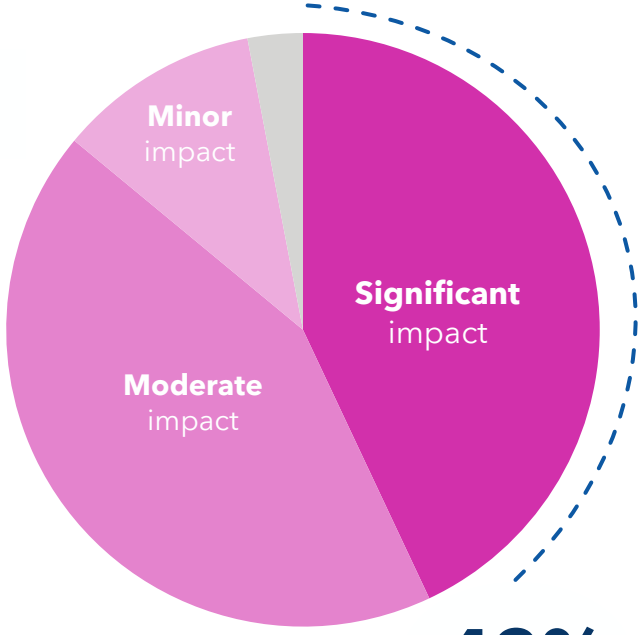
HOW MUCH IMPACT WILL ICH E6 (R3) HAVE ON HOW YOU DESIGN/ CONDUCT CLINICAL TRIALS?

Respondents Who Know **Some Information** About ICH E6 (R3)



23%

Respondents Who Know **A Lot of Information** About ICH E6 (R3)



43%

"Total renovation in structure building upon RBQM themes from ICH E8 (R1). Updating of language to be inclusive of broader technological use and advancement in clinical trials. Inclusion of more oversight driven principles with less prescription and greater description of intent to allow organizations to adopt in a more agile way.

– PROVIDER

Sample: Know some information=127, Know a lot of information=35

Those Most Familiar with ICH E6 (R3) Expect Stronger Emphasis on Risk-based Approaches to Quality Management and Guidance on Emerging Technology

BRIEFLY DESCRIBE KEY UPDATES IN ICH E6 (R3)

(Among respondents indicating they 'know a lot' about ICH E6 (R3))

> *Several key updates in the ICH E6 (R3) draft guidance on Good Clinical Practice (GCP) that are pivotal to modern clinical trial conduct. These updates include a significant emphasis on **Risk-Based Quality Management** (RBQM), advocating for a proactive approach to identifying and managing risks throughout the clinical trial lifecycle.*
>
> *The guidance also underscores the **integration of technology** and **digital tools** in trials, aiming to **enhance efficiency**, data collection, and participant engagement.*
>
> – SPONSOR

> *Changes are around a more **formal look** at **risk identification**, **planning**, and **mitigation**.*
>
> *Other changes are around living and working in a **digital world**.*
>
> – SPONSOR

Some are Taking Steps to Prepare for ICH E6 (R3) by Reviewing Guidance or Conducting Gap Analysis of People or Processes

WHAT EFFORTS DOES YOUR COMPANY HAVE UNDERWAY TO PREPARE FOR ICH E6 (R3)?
(Among respondents with knowledge of ICH E6 (R3))

64%
Reviewing Guidance

54%
Gap Analysis

Fewer are taking steps towards implementation and/or change management…

32%
Implementing Analytics

26%
Implementing Change Management

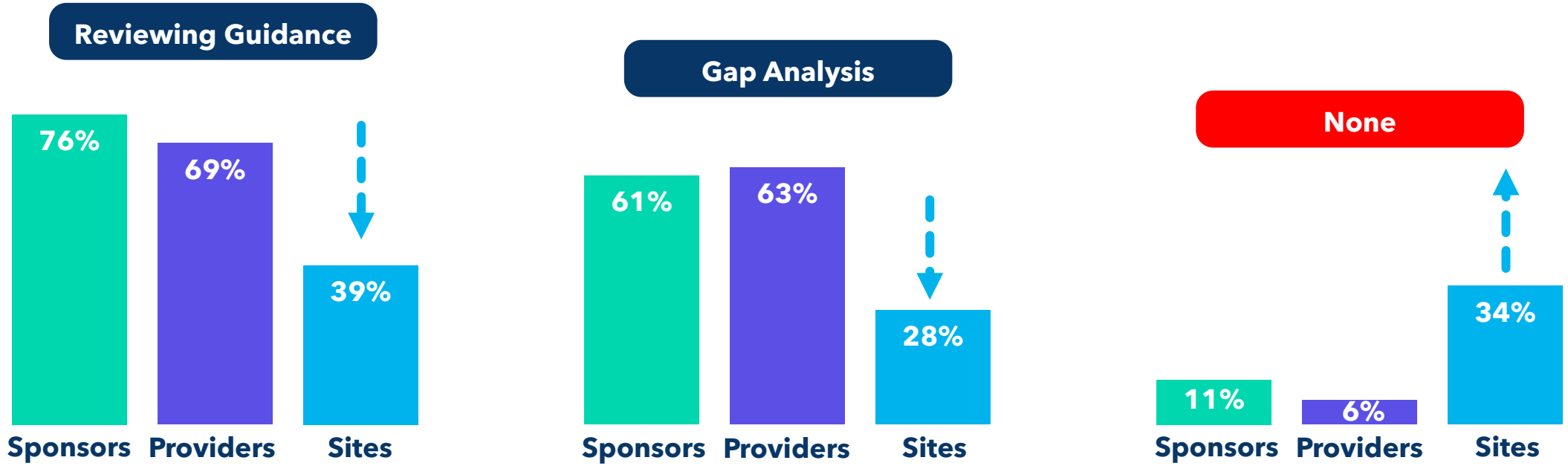
23%
Establishing Benchmarks

Sample: Respondents with knowledge of ICH E6 (R3)=174

Sponsors and Providers Appear More Engaged with ICH E6 (R3) Preparation Than Do Sites

WHAT EFFORTS DOES YOUR COMPANY HAVE UNDERWAY TO PREPARE FOR ICH E6 (R3)?

(Among respondents with knowledge of ICH E6 (R3))



Sample: Respondents with knowledge of ICH E6 (R3): Sponsors=54, Providers=35, Sites=85

Key Take-Aways

Current Understanding of ICH E6 (R3) Draft Guidance

- There is a **moderate level of engagement with ICH E6 (R3) today** – some have more intimate knowledge of what to expect, but most appear to be at the beginning of the learning curve.
- Given this, **the anticipated impact on how business is done is not yet clear and preparations are not yet in full swing** – those who are taking steps are at the early stages of guidance review and gap analysis of processes and procedures; they are generally not yet at a place of initiating change in preparation for new guidance.
- **Sponsors and providers appear to be a step ahead of sites** when it comes to understanding and preparing for ICH E6 (R3) – ensuring that all stakeholders have a shared understanding of impending changes will be important to facilitating smooth implementation.

What We Learned

Reaction to ICH E6 (R3) Excerpts

We Shared Some Excerpts of Proposed ICH E6 (R3) Guidance in *Three Key Areas* – Next, We'll Explore Opinions of Each

Roles & Responsibilities

Guidance on responsibilities of sponsors, providers, and sites for:

- Identification of service providers.
- Access to information for service provider selection and oversight.
- Ensuring an operationally feasible protocol.
- Qualification/supervision of non-site staff.

ICH E6 (R3): Sections 2 & 3

Data Governance

Computerized systems responsibilities outlined for sponsor/investigator.

- Sponsor review of site systems (e.g., EHR) to ensure they are fit for purpose.

ICH E6 (R3): Section 4

Documentation & Records

Determining which clinical trial records are essential using a risk-based approach.

- No longer using a list of essential records as stipulated in ICH E6 (R2).

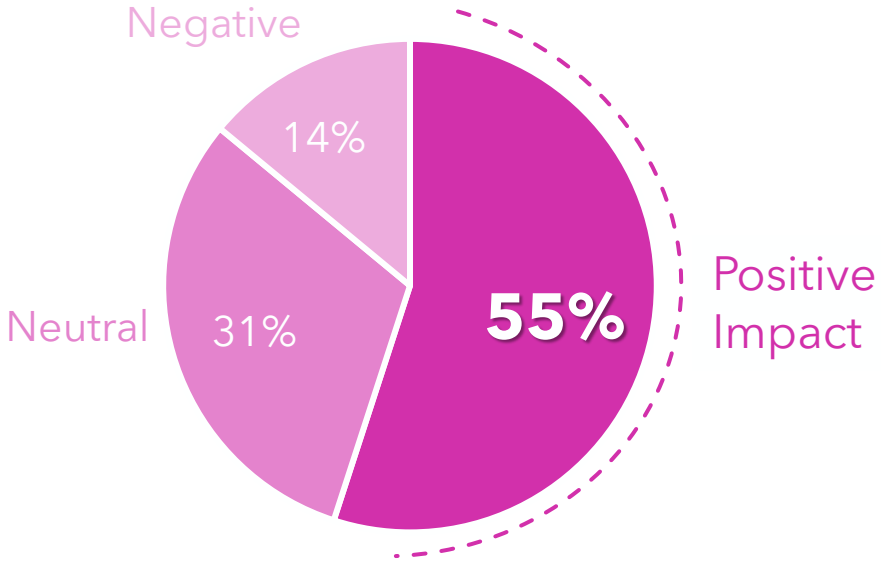
ICH E6 (R3): Appendix C

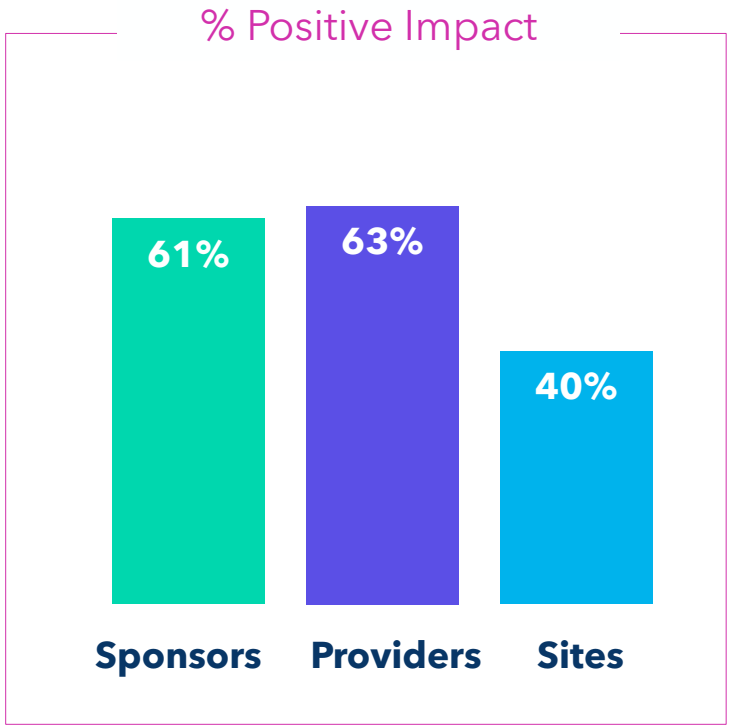
Full text of guidance shown to respondents found in the appendix.

Industry Perceptions of Guidance on Roles & Responsibilities is Positive, Driven by Stronger Sponsor and Provider Favorability

Roles & Responsibilities
ICH E6 (R3): Sections 2 & 3

IMPACT OF ROLES & RESPONSIBILITIES GUIDANCE ON CLINICAL TRIALS





Sample: Total=314, Sponsors=70, Providers=57, Sites=187

Enhanced Collaboration and Transparency Between All Parties, and Simplification of Design and Protocol are Key Positives

Roles & Responsibilities

ICH E6 (R3): Sections 2 & 3

Select commentary on impact of Roles & Responsibilities guidance

> *…we already try to keep [the] protocol **simple** and **fit for purpose** and now I believe after ICH E6 (R3) [is] released, it will further enhance the approach in our daily work.*
>
> – SPONSOR

> *Trial **complexity to decrease** and **more transparency** between the site/vendors/sponsors.*
>
> – PROVIDER

> *More **dedicated communication** with investigator on potential service providers and roles and responsibilities.*
>
> – SPONSOR

That Said, There is a Lack of Clarity as it Relates to the Extent of Site Responsibility for Vendor Selection and Oversight

Roles & Responsibilities
ICH E6 (R3): Sections 2 & 3

Select commentary on impact of Roles & Responsibilities guidance

> *Since the sponsor selects the service providers through the **review of SOPs** and **performance metrics**, but the investigator is responsible to ensure they are qualified, supervised, informed of the protocol, etc., my sense is that investigators will try to do **ALL of the services** themselves. It will be virtually impossible for them to be responsible for the vendor if they **did not select them**.*
>
> – PROVIDER

> *Sponsor-picked vendors and processes are generally proposed before having assigned investigative sites…unclear how the investigator will be able to review and **oversee responsibility**.*
>
> – SITE

> *I think it could be **tricky to have the primary investigator at a given site be responsible for the actions of a vendor** appointed by a pharmaceutical [company].*
>
> – SITE

Sites, Specifically, Have Questions about Accountability; How Will Guidance about Operational Feasibility be Enforced?

Roles & Responsibilities
ICH E6 (R3): Sections 2 & 3

Select commentary on impact of Roles & Responsibilities guidance

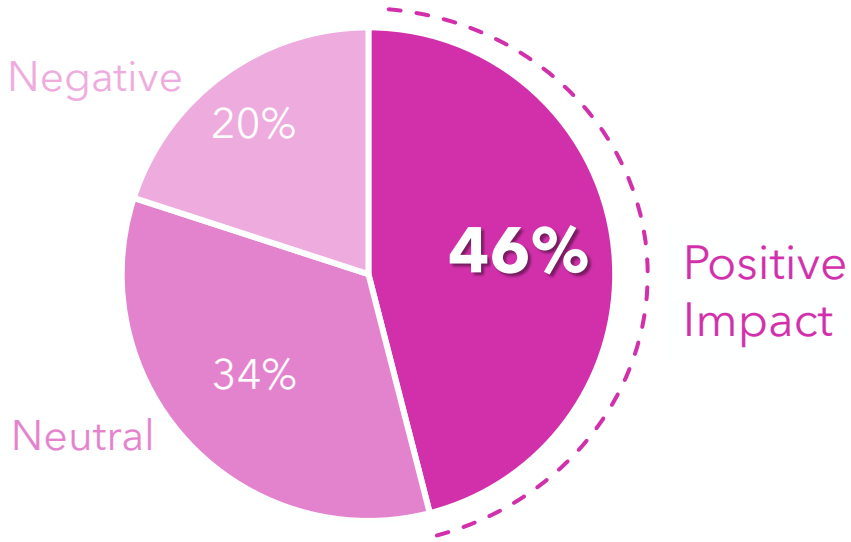
> *Wondering how sponsors will be **held accountable** to ensure their protocols are written in a **feasible** manner, who will that check and balance fall to?*
>
> – SITE

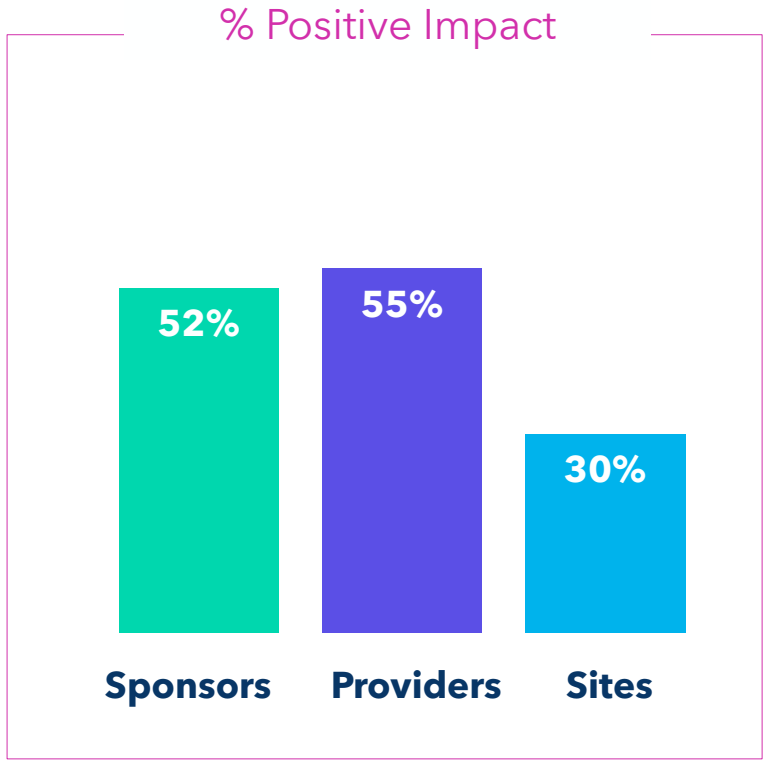
> *It would be nice if protocols were not as complex, but my experience is that sponsors have made **protocols more and more complex**, not less so. I don't see them actually working to make protocols less complex even with this new revision.*
>
> – SITE

Opinions are Somewhat More Diverse as it Relates to ICH E6 (R3) Draft Guidance on Data Governance

Data Governance
ICH E6 (R3): Section 4

IMPACT OF DATA GOVERNANCE GUIDANCE ON CLINICAL TRIALS





Sample: Total=325, Sponsors=75, Providers=109, Sites=190

Sponsors and Providers Express Concerns about the Feasibility of Being Able to Assess Site Technology

Data Governance
ICH E6 (R3): Section 4

Select commentary on impact of Data Governance Guidance

> *We work closely with many academic institutions and have no input into their systems and processes that [are] quite ingrained into the institution. Some institutions also will* ***not provide this information freely****, limiting our evaluations. I also do not feel that CRAs performing evaluation visits have the background to determine these things.*
>
> – SPONSOR

> *This specifically addresses EHR [electronic health records] systems which are something that sponsors have not typically evaluated (nor do they typically have the expertise to do so)…Since these are institution platforms, if not found fit for purpose, this may* ***impact suitability of the site*** *to participate in the clinical trial.*
>
> – PROVIDER

> *I do not see how it would be feasible for a sponsor of* ***hundreds of multi-center trials*** *in multiple therapeutic areas to be able to appropriately assess institution level systems for data capture.*
>
> – SPONSOR

Sites are in Two "Camps" – Some Feel the Guidance Reinforces Processes and Technology Already in Place...

Data Governance
ICH E6 (R3): Section 4

Select commentary on impact of Data Governance Guidance

> ***Our own electronic systems largely meet these requirements to date.*** *The problem is with external systems that are sometimes used/needed in clinical research and over which we have less control even when considering the GCP (R3) requirements for adequate vendor management.*
>
> – SITE

> ***This activity is already in place*** *as part of our privacy protections and risk management.*
>
> – SITE

> *We have* ***already begun to incorporate more up-to-date IT services into our data management.*** *If the PI is now involved it will not sway us much.*
>
> – SITE

...Others Believe There Could be Delays in Start-up, Barriers Related to IT Processes, and Potential Eligibility Issues

Data Governance
ICH E6 (R3): Section 4

Select commentary on impact of Data Governance Guidance

> *As part of a community hospital system the **research site does not have input into the data systems in use.** If they were not of the sponsor's liking, there is nothing we could do about it and might not get a study placed at our site.*
>
> – SITE

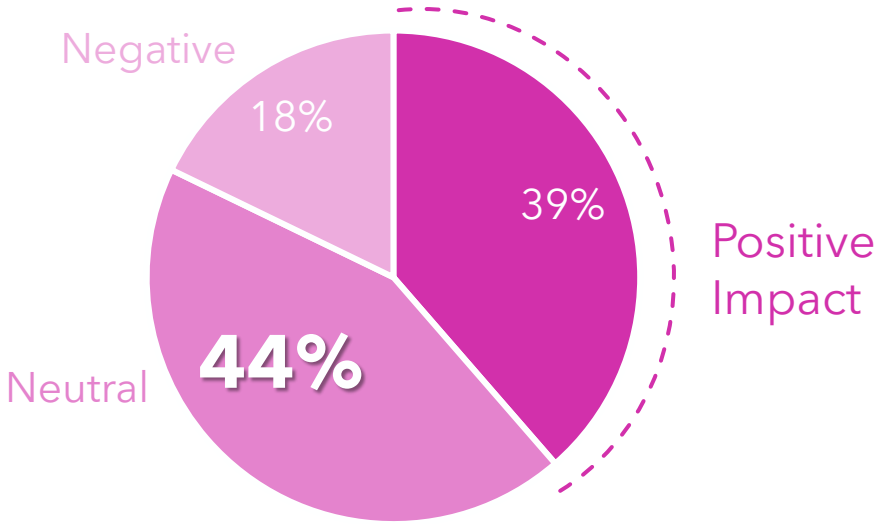
> ***Time-consuming, might increase the time needed for study start up.** Information to be collected about the data system in use and approved by the sponsor.*
>
> – SITE

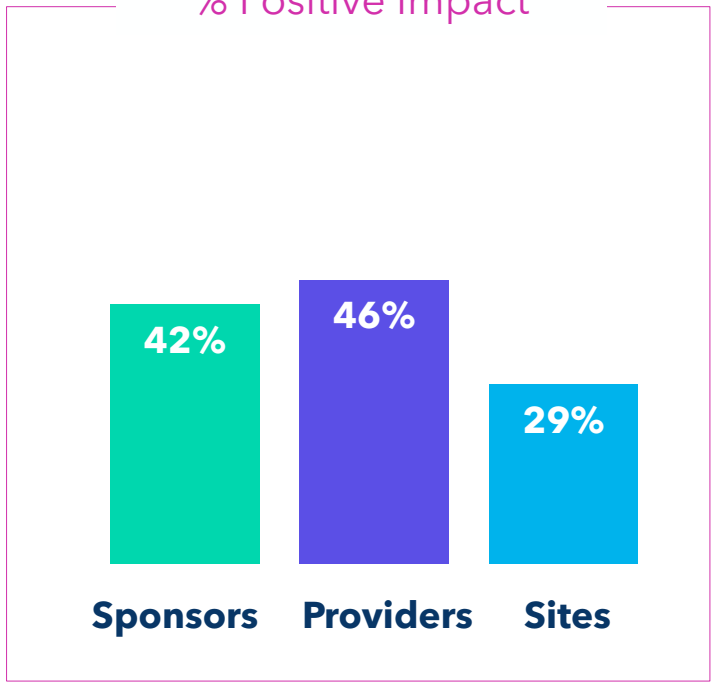
> ***Additional requirements from an IT perspective** that is already difficult to manage with external teams and resources.*
>
> – SITE

Potential Impact of Draft Documentation & Records Guidance Has the Weakest Consensus, Receiving More "Neutral" Response

Documentation & Records
ICH E6 (R3): Appendix C

IMPACT OF DOCUMENTATION & RECORDS GUIDANCE ON CLINICAL TRIALS





Sample: Total=325, Sponsors=75, Providers=109, Sites=190

While the Idea of Streamlining Record-keeping is Appealing...

Documentation & Records
ICH E6 (R3): Appendix C

Select commentary on impact of Documentation Guidance

> *I would think and hope this will result in **less documentation being required**. Our site keeps EVERYTHING – often seems like too much information over what actually is needed. Signal to noise ratio is way off currently. A risk-based approach means we'd only keep information that has actual bearing on the trial.*
>
> – SITE

> *Streamline which documents will **need to be maintained**, reducing unnecessary workload for the site. Less filing, less requests from the sponsor.*
>
> – SITE

> *It will help **streamline the amount of potential data obtained** and retained and in doing so provide **greater protection** against data breeches.*
>
> – SITE

...There is Concern that ICH E6 (R3) Guidance is Ambiguous and Leaves Room for Interpretation in the Absence of a Defined Records List

Documentation & Records
ICH E6 (R3): Appendix C

Select commentary on impact of Documentation Guidance

> *Having a list of essential documents is important to reference. Even if the list states the items and marks them as, "if applicable." I think not having a list, leaves a lot of **room for error**, especially if the research site is not well established. This could **hurt a lot of countries** that do not have well defined research requirements and poor resources.*
>
> – SITE

> *This **removal of details will create confusion**, if not different interpretations.*
>
> – SPONSOR

> *This guidance **provides room for interpretation which lends itself to inconsistent sponsor requirements.** This has potential to increase workload burden and administrative overload for sites.*
>
> – PROVIDER

> *While eliminating the list of essential documents provides perhaps greater freedom, **the reality will be that MORE paper will be collected and stored as sites feel compelled to save anything and everything** in the TMF absence of a clear and direct list.*
>
> – SITE

Key Take-Aways

Reaction to ICH E6 (R3) Excerpts

Roles & Responsibilities

ICH E6 (R3): Sections 2 & 3

- Roles & Responsibilities is seen as having the **most potential to positively impact clinical trials** by bringing much needed simplification to trial design.
- Collaboration that will be required is seen favorably.
- There is a lack of clarity around site "reach" when it comes to selecting and overseeing vendors, as well as accountability for protocol feasibility.

Data Governance

ICH E6 (R3): Section 4

- **Mixed response is observed as it relates to Data Governance guidance**
- Sponsors and providers are unsure about the feasibility of being able to properly assess site technology in the way stipulated by ICH E6 (R3) (requires more staff and/or new skill set).
- Site response varies – some believe their systems are already in compliance, others express concern about the technology evaluation process and whether it could impact eligibility.

Documentation & Records

ICH E6 (R3): Appendix C

- Documentation & Records guidance appears to be the **most "controversial" of the excerpts evaluated**.
- Streamlining documentation *is* an appealing idea; however, the draft language is considered vague, and in combination with the removal of an essential records list (found in ICH E6 (R2)), the industry is skeptical that this will be an improvement on current practice.

What We Learned

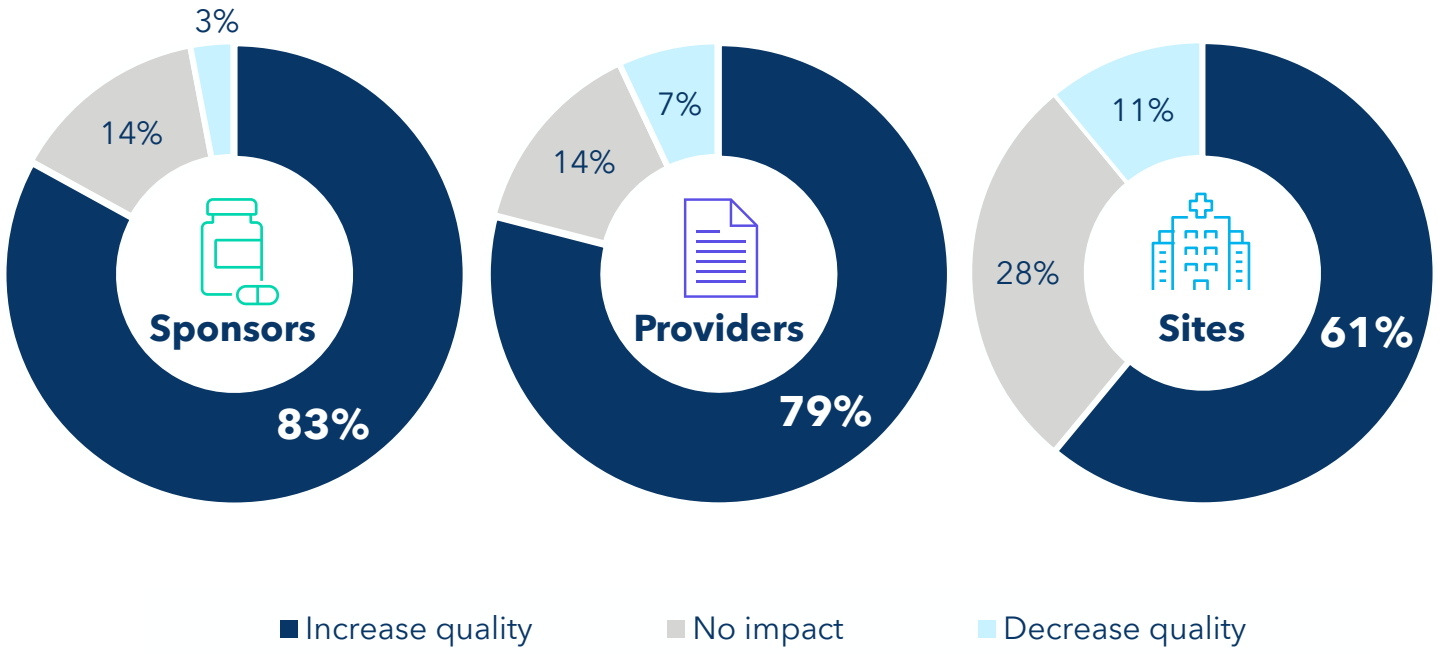
The Industry's Take on ICH E6 (R3) Impact

There is a Shared Belief that Implementation of ICH E6 (R3) will Have a Positive Impact on the Level of *Quality* in Clinical Trials

Sponsors have the **most optimistic** point of view

> *It will **emphasize quality from protocol development** and [will] drive [the] industry to think more about the **purpose of the trial** and how to run a clinical trial efficiently and also reduce the complexity.*
>
> – SPONSOR

IMPACT OF ICH E6 (R3) ON QUALITY IN CLINICAL TRIALS

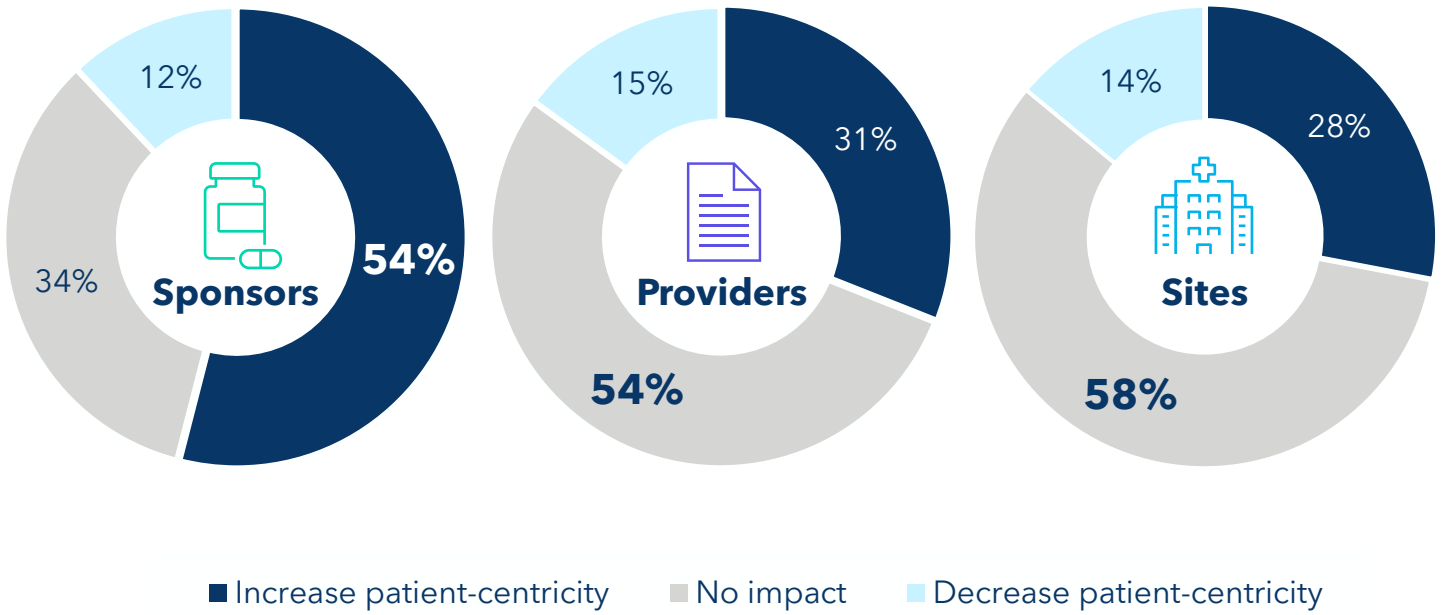


Sample: Sponsors=76, Providers=57, Sites=192

Sponsors, Moreso Than Providers and Sites Also Foresee a Positive Impact on Patient-centricity

> *Another critical update is the **increased focus on patient centricity**, emphasizing the **importance of incorporating patient perspectives** and needs into trial design and execution.*
>
> – SPONSOR

IMPACT OF ICH E6 (R3) ON PATIENT-CENTRICITY IN CLINICAL TRIALS



Sample: Sponsors=65, Providers=54, Sites=168

Of Course, *Challenges* are Also Expected

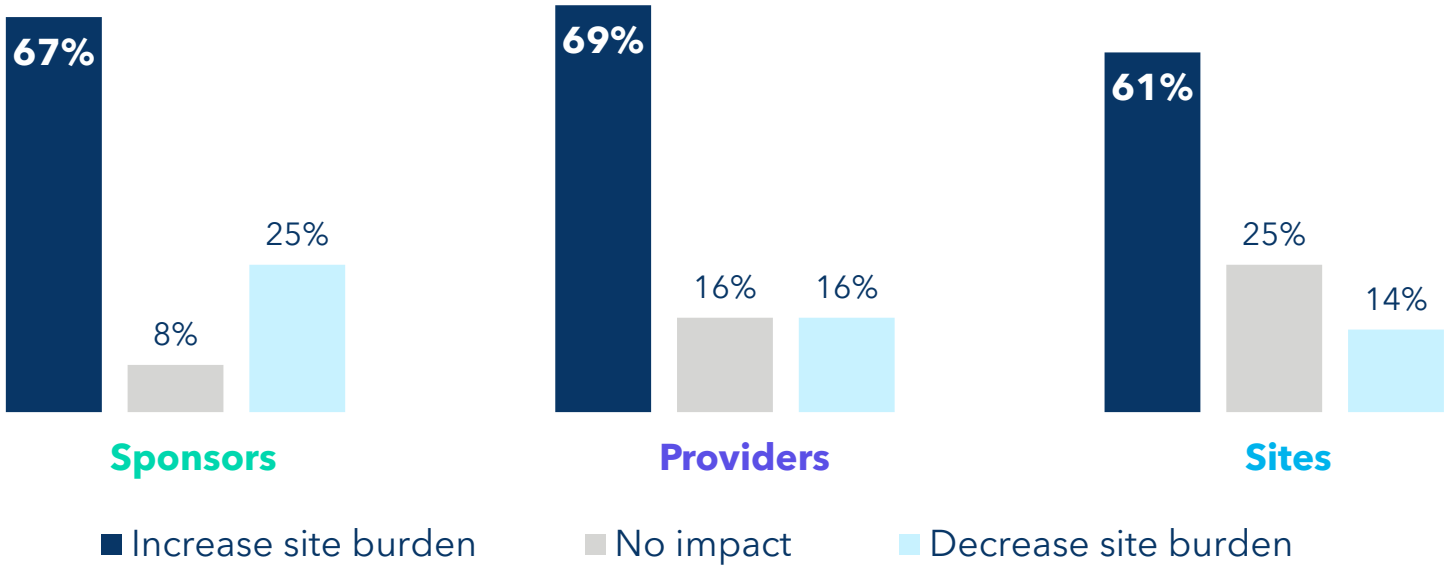
> *As with everything, every time you change,* ***you have a learning curve****. Eventually it may positively impact the trials.*
>
> *But it is going to* ***take a few bumps along the way and a mindset change that is not there now****.*
>
> – SITE

Increased Site Burden is a Notable Concern and One that is Consistent Across Sponsors, Providers, and Sites

> *It seems to **generate more work for the clinical sites** and investigator which will make it harder to conduct trials.*
>
> – SITE

> *I think that some of these changes will put **more responsibility on the investigator**, which they may be reluctant to take on.*
>
> – SPONSOR

IMPACT OF ICH E6 (R3) ON SITE BURDEN IN CLINICAL TRIALS



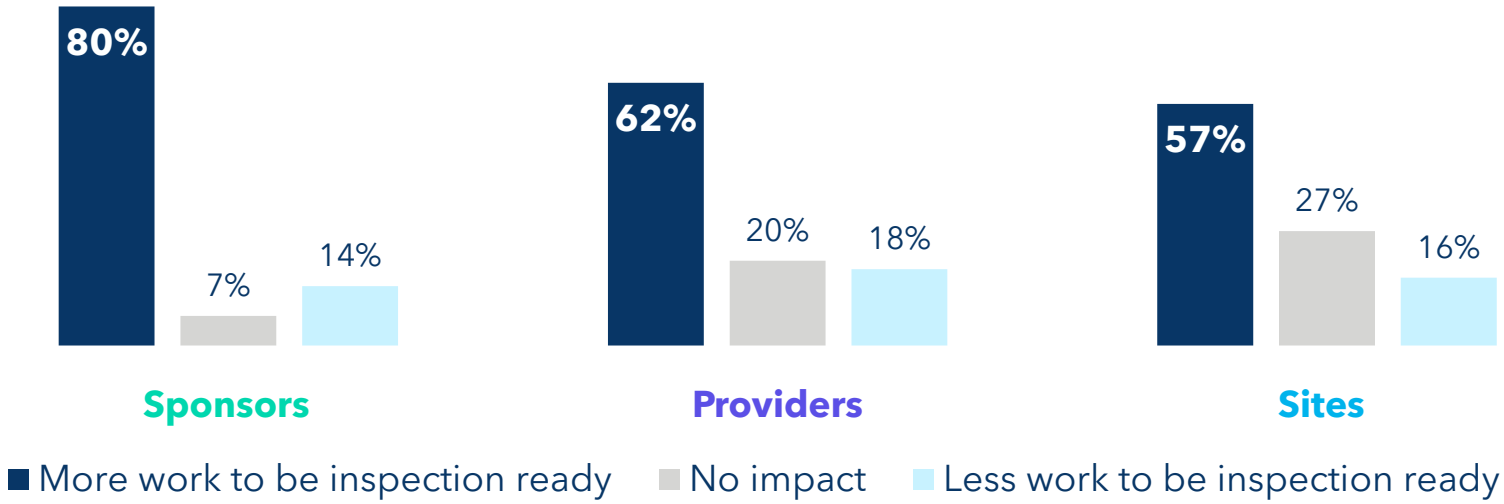
Sample: Sponsor=79, Provider=58, Site=186

There is a Perception that More Work will be Required to be *Inspection-ready*, Especially Among Sponsors

> *ICH E6 (R3) includes many and extensive changes; we'll have to review and likely **revise all our policies, procedures, SOPs, training materials, etc. to ensure compliance**, in addition to investing resources in getting all our research staff (>3,500 people) trained.*
> – SITE

> *The introduction of anything new is **disruptive to a process driven regulatory environment**. Adoption and adaptation is usually slow and interpretation across companies will create difficulties across functions.*
> – SPONSOR

IMPACT OF ICH E6 (R3) ON INSPECTION READINESS IN CLINICAL TRIALS



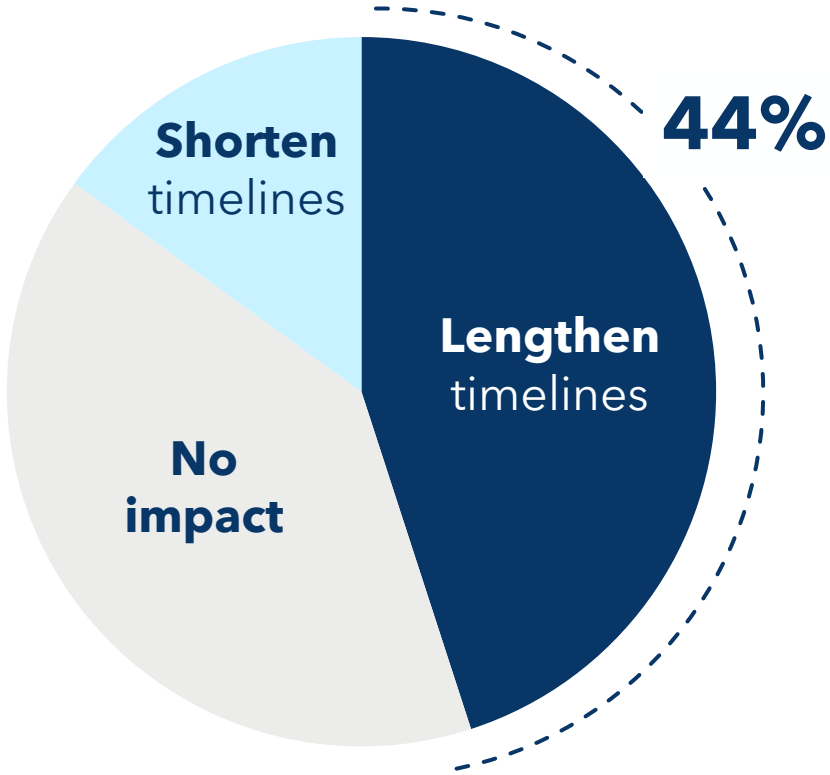
Sample: Sponsor=79, Provider=58, Site=186

Given These Challenges, Timelines Could Lengthen

> *CRO/sponsor carefully vet vendors for clinical trials with limited list of vendors to choose from. There is* ***potential to push out study timelines*** *if a vendor identified for CRO/sponsor does not meet a site's standards.*
>
> – PROVIDER

> *Sponsor review of CRO data systems and vendor data systems may* ***add time to study timelines****.*
>
> – SPONSOR

IMPACT OF ICH E6 (R3) ON STUDY TIMELINES IN CLINICAL TRIALS

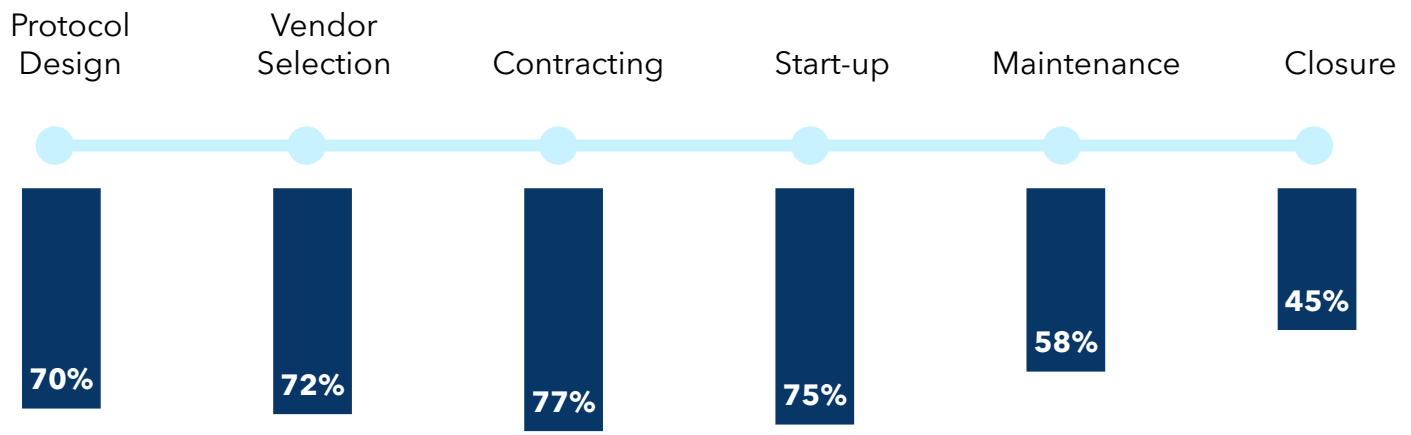


Sample: Sponsor=79, Provider=58, Site=186

The Front-end of Clinical Trials May Feel the Most Substantial Impact

> *It will **take longer for sponsors to start a trial** with finding competent partners, especially for smaller companies with limited scope and resources.*
>
> *It will take longer because the stakes are higher for relying on their providers to do the right thing.*
>
> – PROVIDER

% EXPECTING TIMELINE TO BE LONGER BY CLINICAL TRIAL STAGE



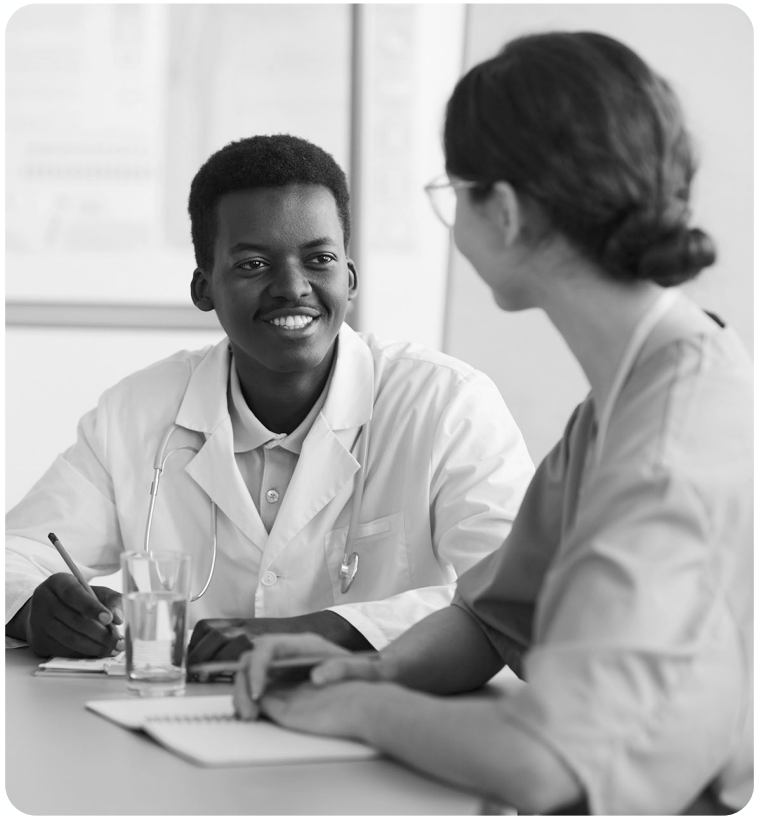
Sample: Total=157

There is a Shared Hope that this Initial "Investment" in ICH E6 (R3) Will Support Greater Efficiency in Clinical Trials in the Future

> *The evolution in QbD [Quality by Design], risk-based approach, fit for purpose use and decisions will ultimately result in a **more efficient, precision deployment of time, resources and budget**.*
>
> – SPONSOR

> *The clarity added to roles and responsibilities, particularly in regards to decentralized trials helps to align stakeholders across the industry. This will help to **set expectations and streamline processes** for all parties.*
>
> – PROVIDER

> *I believe that anytime something as complex as a clinical trial can be **better** and **more efficiently defined**, the better and more efficient we all will be.*
>
> – SITE



Key Take-Aways

The Industry's Take on ICH E6 (R3) Impact

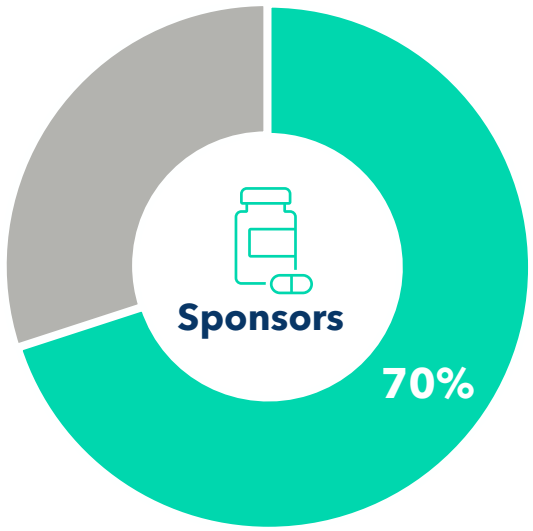
- With a much greater emphasis on utilization of risk-based and "fit for purpose" tools and approaches, **improved quality is seen as a key outcome of ICH E6 (R3)**.
- With change, challenges are also expected – chief among these are **perceptions of increased site burden and greater effort required to be inspection-ready**.
- Further, **some extension of timelines is anticipated, especially at the front-end of clinical trials**, where guidance on Roles & Responsibilities (e.g., vendor selection) and Data Governance (e.g., evaluation of site systems) is expected to have impact on start-up.
- There is a shared sentiment that **increased investment of time at the front-end of clinical trials will ultimately yield efficiencies over time**, as "new norms" are established.

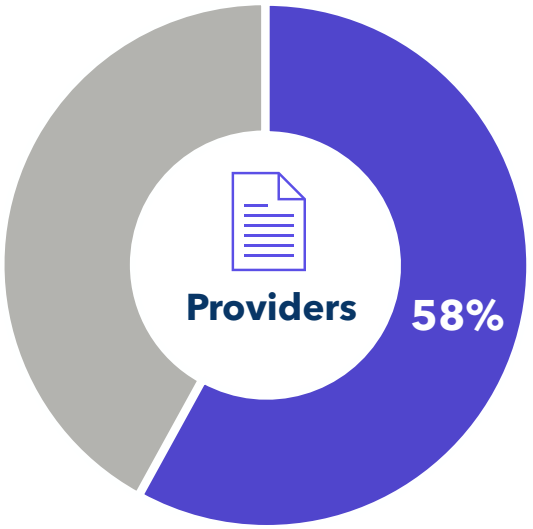
What Happens Next

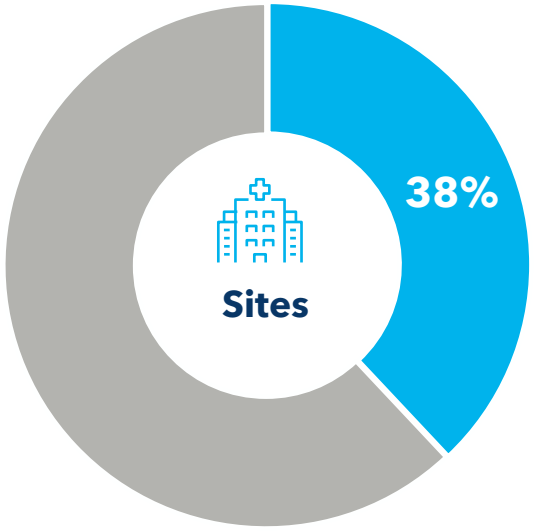
Taking All ICH E6 (R3) Information into Account, Sponsors and Providers Anticipate the Most Change in How Their Work is Done

HOW MUCH WILL ICH E6 (R3) IMPACT HOW YOU DESIGN/CONDUCT CLINICAL TRIALS?

% Significant/Moderate Impact







Sample: Sponsors=80, Providers=59, Sites=185

Sponsors Comment on the Cultural Shift that Will be Required When Adopting ICH E6 (R3)

SPONSORS: IN WHAT WAYS WILL ICH E6 (R3) BE CHALLENGING?

> *This is not as clear as one would like and therefore it is likely to **require outside consultants to get it right**. That adds time and money to the trial set-up.*

> *The finer detail, there is **a lot to read**, **scrutinize**, get every minor requirement into QMS [quality management systems] – **time-consuming**, involving all functions within our company.*

> *Most changes are challenging, and I feel like **we were just getting a handle on ICH E6 (R2)**.*

> ***Culture changes will be hardest**. Expenses for the improved technology and risk management will be difficult to get approved for the first few years, and **educating EVERYONE on a project** on this topic is difficult, particularly for old school siloed teams.*

Providers are Considering the Additional Resources and Skill-sets that will be Needed

PROVIDERS: IN WHAT WAYS WILL ICH E6 (R3) BE CHALLENGING?

> *Having people **understand what quality by design and risk-based approach truly means**. It involves critical thinking, not just a checkbox exercise on a form.*

> *Added requirements puts **extra pressure on people, processes, and systems** after many CROs had lay-offs in 2023 and are working with reduced staff.*

> *Requires new **SOPs**, **re-training for all**, **new contracts with sites**, cross-functional alignments at sponsor sites, initial increased resource needs to cope.*

> ***Extremely challenging and resource-intensive to establish additional infrastructure/resources to meet vague requirements that do not seem to be value-added requirements**. The changes, especially regarding documentation and records, seem to focus on terminology of risk-based processes, versus actually contributing to controlling clinical trials or reducing the risk of conducting clinical trials of low quality.*

Sites, Who Foresee Less Overall Impact of ICH E6 (R3), May Feel They are *Already* Compliant with Proposed Guidance

SITES: IN WHAT WAYS WILL ICH E6 (R3) BE CHALLENGING?

Sites see ICH E6 (R3) as potentially motivating other sites who are **not up-to-date**.

> ***[ICH E6 (R3) will] encourage others to do what we are doing now**. There could be impact on sites not up-to-speed on the guidelines.*

> *I believe that these are **common sense policies** that everyone has been trying to move forward and achieve without the government regulation. **It just helps motivate the unmotivated**.*

> *I don't see much change, since **it is what we do anyway**.*

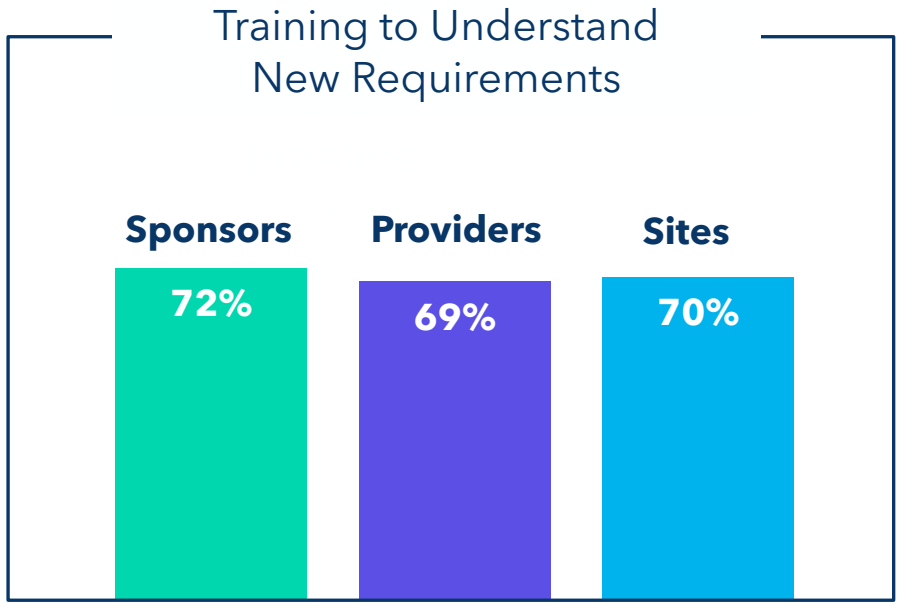
> *It will **help other sites perform better research** if they are not at the new guidelines level yet.*

> *Overall, I don't see much different - for the most part, it seems to be **clarifying things already in place**.*

Looking Ahead, *Training is a Universal Need* as ICH E6 (R3) Guidance Nears Finalization

> *It will be challenging to help the organization adapt to the shifting mindset and we will need a strong* ***training*** *and* ***change management plan***.
>
> – SPONSOR

WHAT DO YOU THINK YOUR ORGANIZATION WOULD BENEFIT FROM TO BE PREPARED FOR ICH E6 (R3)?

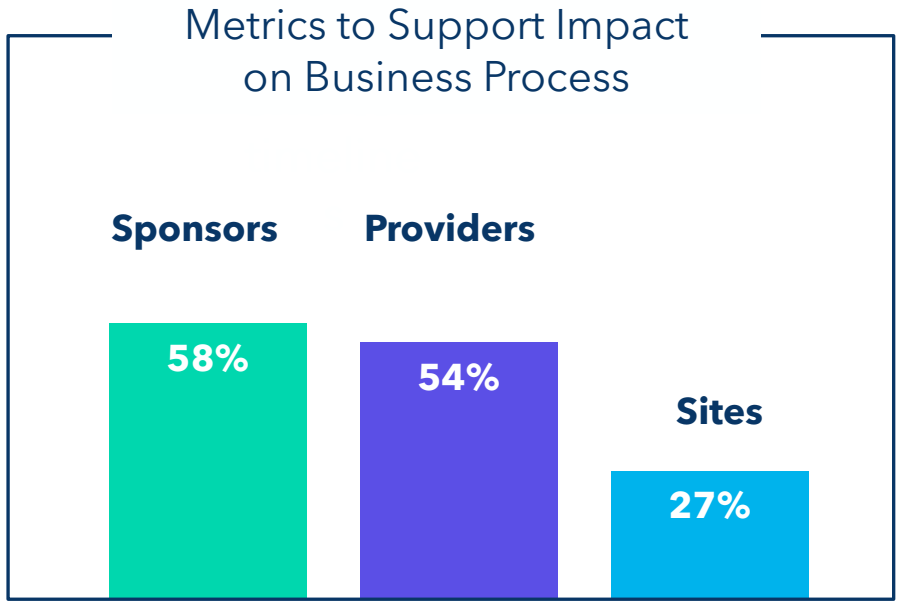


Sample: Sponsors=81, Providers=59, Sites=201

Sponsors and Providers are Also Looking for *Metrics* that Will Inform Them on Expected Impact

> *ICH E6 (R3) is a substantial shift from a standard checklist to a more nuanced risk-based assessment. This means* ***we'll have to undertake a comprehensive evaluation of our documentation processes***.
>
> – SPONSOR

WHAT DO YOU THINK YOUR ORGANIZATION WOULD BENEFIT FROM TO BE PREPARED FOR ICH E6 (R3)?

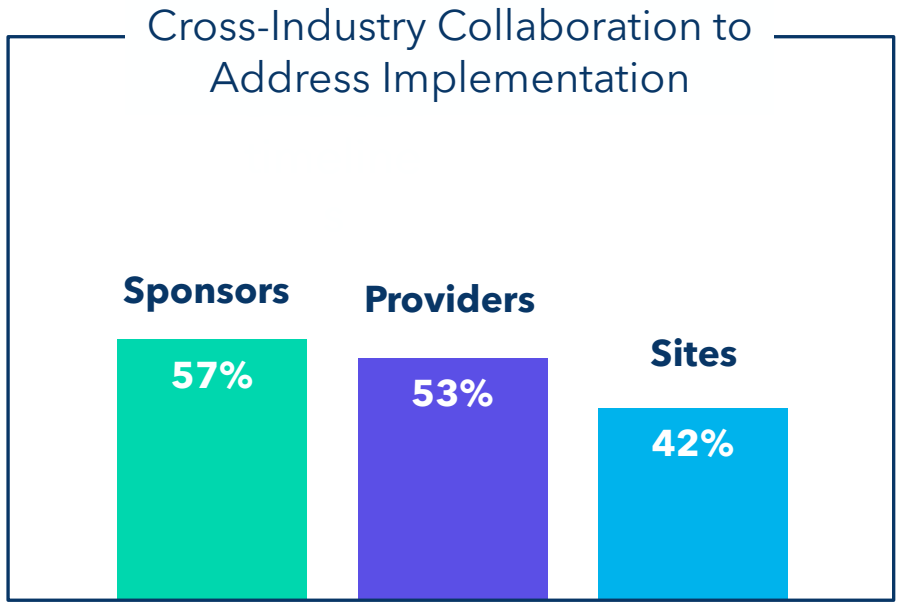


Sample: Sponsors=81, Providers=59, Sites=201

Collaboration Across Industry Stakeholders is Also Seen as an Important Step Forward

> ***Getting all parties involved*** *(investigators, sponsors, CROs) to agree on what is essential for documentation.*
>
> – SITE

WHAT DO YOU THINK YOUR ORGANIZATION WOULD BENEFIT FROM TO BE PREPARED FOR ICH E6 (R3)?



Sample: Sponsors=81, Providers=59, Sites=201

Appendix

ICH E6 (R3): Roles & Responsibilities

Information Presented to Respondents During the Survey

Roles & Responsibilities

ICH E6 (R3) Section 3. **SPONSOR/SERVICE PROVIDER responsibilities** include:

Sponsor identification of service providers/investigator retains final decision
3.6.6 The sponsor should provide information to the investigator on any service provider identified by the sponsor to undertake any activities under the responsibility of the investigator. The responsibility for such activities remains with the investigator.

Sponsor access to information for service provider selection and oversight
3.6.9 The sponsor should have access to relevant information (e.g., SOPs and performance metrics) for selection and oversight of service providers.

Sponsor should ensure operationally feasible protocol
3.1.4 The sponsor should ensure that all aspects of the trial are operationally feasible and should avoid unnecessary complexity, procedures, and data collection. Protocols, data acquisition tools, and other operational documents should be fit for purpose, clear, concise and consistent, when applicable.

ICH E6 (R3) Section 2. **INVESTIGATOR responsibilities** include:

Qualification/supervision of non-site staff
2.3.2 The investigator should ensure that persons or parties to whom the investigator has delegated trial-specific activities are appropriately qualified and supervised and are adequately informed about the protocol, the investigational product(s) and their assigned trial activities (including activities conducted by staff provided by other parties, for example, home nurses arranged by the sponsor). Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfil their delegated trial activities that go beyond their usual training and experience.

Sponsor identification of service providers/investigator retains final decision
2.3.1 The investigator may be supported by the sponsor to identify a suitable service provider(s); however, the investigator retains the final decision on whether the service provider intended to support the investigator is appropriate based on information provided by the sponsor. The investigator retains the ultimate responsibility and maintains appropriate supervision of the persons or parties undertaking the activities delegated to ensure the rights, safety and well-being of the trial participants and data reliability.

ICH E6 (R3): Data Governance

Information Presented to Respondents During the Survey

Data Governance

ICH E6 (R3) Section 4. Data governance is to include:

Computerized systems responsibilities outlined for sponsor/investigator
4.3 In summary, the sponsor is responsible for ensuring that for computerised systems which they put in place, the expectations for computerised systems as described in this section are addressed in a risk proportionate manner.

The sponsor should review whether the systems used by the investigator/institution (e.g., electronic health records and other record keeping systems for source data collection) are fit for purpose in the context of the trial.

In the event that the investigator/institution deploys systems specifically for the purposes of conducting clinical trials, the investigator/institution should ensure that the expectations are proportionately addressed and implemented. Expectations include computer systems security, validation and user management.

ICH E6 (R3): Documentation & Records

Information Presented to Respondents During the Survey

Documentation & Records

ICH E6 (R3) Appendix C. Management of study records is to include:

Determining which clinical trial records* are essential using a risk-based approach
Note: E6 (R2) provided a list of required essential records that is no longer included in E6 (R3).

C.1.1/C.1.2 Many records are generated before and during the conduct of a clinical trial. The nature and extent of those records generated and maintained are dependent upon the trial design, its conduct, application of proportional approaches and the importance and relevance of that record to the trial. Determining which records are essential will be based upon consideration of the guidance in this appendix.

** "Clinical trial records" represents documentation that is maintained in the Trial Master File (TMF) including the Investigator Site File (ISF).*

Learn more about Avoca's Industry Research

For more than 20 years, Avoca, a WCG company, has surveyed industry stakeholders to gain an understanding of key trends affecting clinical development.

Industry leaders rely on our insights to strengthen relationships and enhance R&D quality and productivity.

Access Research Reports →

The Avoca Quality Consortium

Knowledge Center

1,500+ leading practices, tools, templates, and metrics toolkits

Conversations and Connections

ICH E6 (R2)/(R3) Side-by-Side Comparison eBook

Meeting Recordings and Materials

Contact Us to Learn More →

Thank you!

wcgclinical.com