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Infographic

The Changing Landscape of Clinical Monitoring

Large scale decentralized clinical trials (DCT) which acquire high-volume data from multiple sources have permanently changed the paradigm for clinical monitoring towards remote and risk-based approaches. Medidata recently commissioned an independent industry survey to understand the current landscape for clinical monitoring modalities and expectations for the future.

About the Survey
Industry Standard Research (ISR) conducted a web-based quantitative survey with 70 participants involved with clinical development clinical monitoring within pharmaceutical, biopharma, biotech, and/or a contract research organizations. This survey was conducted in April/May 2022.

Clinical Monitoring Elements Defined
Throughout the survey, respondents were asked to refer to the following definitions:

On-Site Monitoring
On-site monitoring is defined as site-specific assessment elements that are reported in a visit template format, including SDV/ SDR.

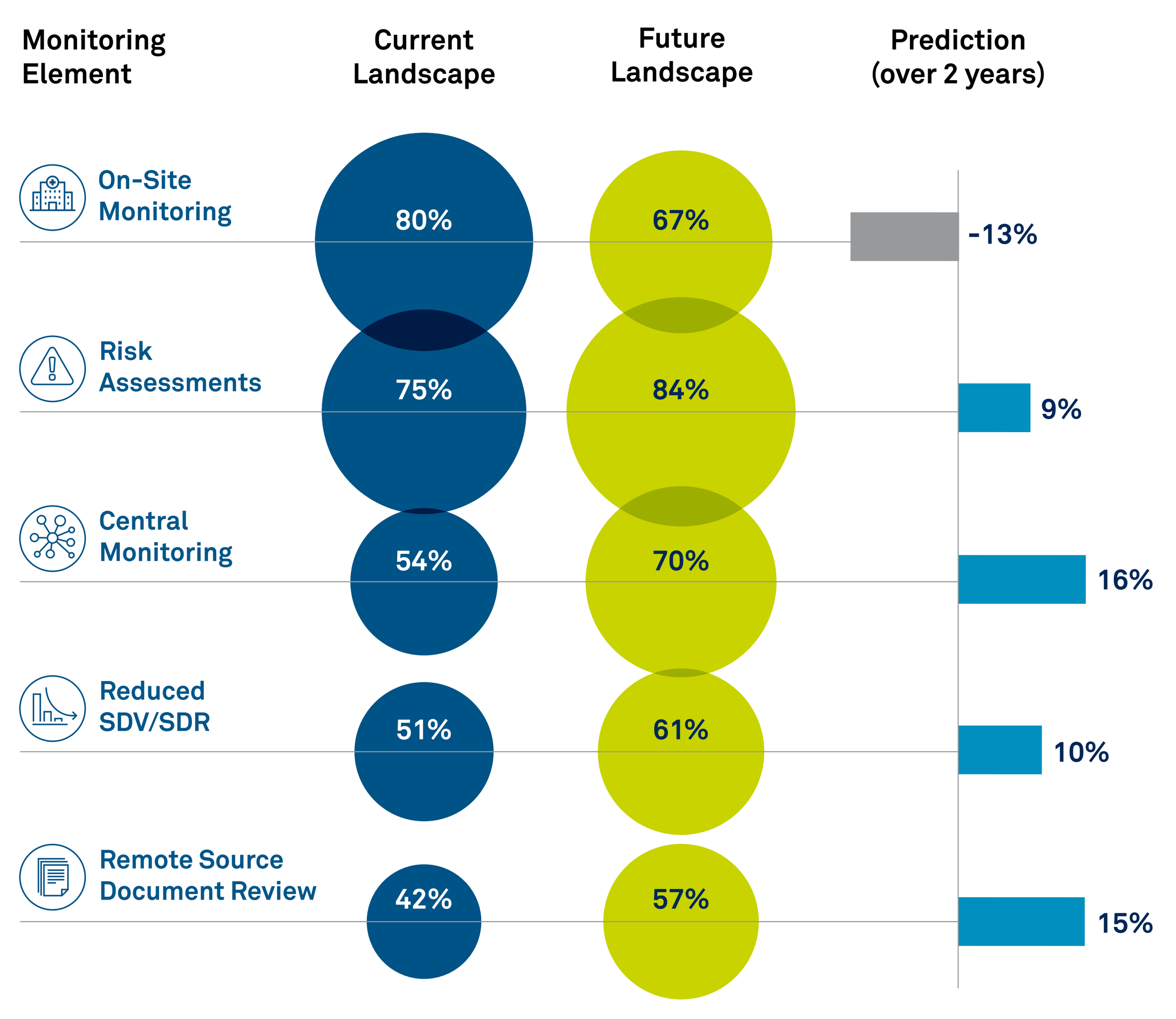
Risk Assessments
Risk Assessments involve the determination of critical quality factors, risks, and associated mitigation strategies and are done in the planning stage and throughout the course of the trial.

Central Monitoring
Central Monitoring is defined as monitoring processes, happening outside of a traditional investigative site, that provide additional monitoring capabilities that can complement and reduce the extent and/or frequency of on-site monitoring.

Reduced or Targeted Source Data Verification (SDV)/Source Document Review (SDR)
Reduced or Targeted SDV/SDR is defined as performing less than 100% review of all data and documents.

Remote Source Document Review
Remote source document review is defined as the completion of SDR activities outside of a traditional investigation site.

1 Monitoring Component Utilization



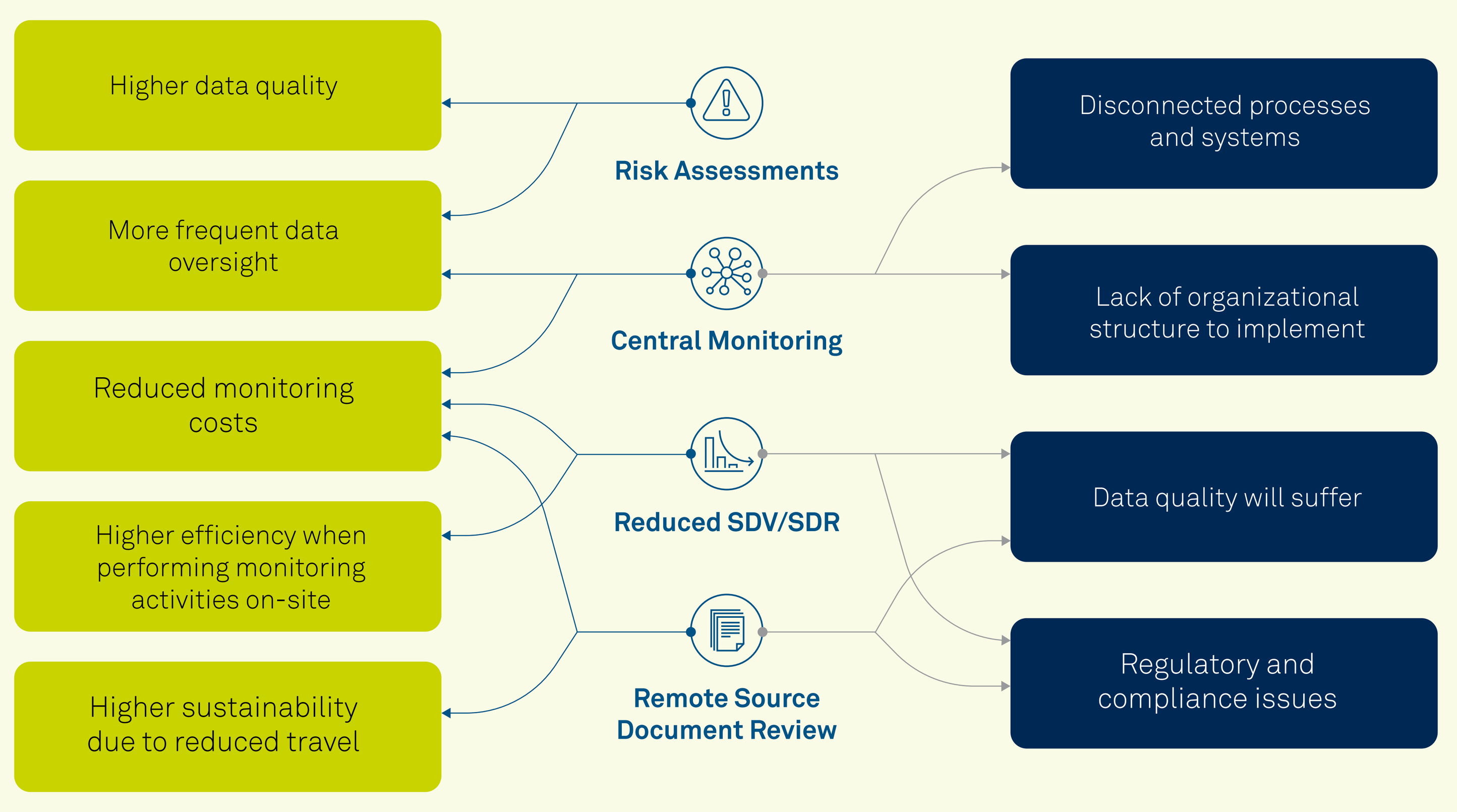
Highlights

Respondents reported their companies still use **on-site monitoring** in a majority of trials, 8 out of 10 on average, but expect this proportion to decrease over the next two years being replaced with central and remote monitoring elements.

Usage of **central monitoring** and **remote source document review** are predicted to increase the most, by 16 and 15 percentage points, respectively, over the next two years.

Respondents noted reasons for not using some of these clinical monitoring elements including they felt more confident with 100% **SDV / SDR** or that their organizations were slower to adopt remote and centralized monitoring practices.

2 Perceptions Around Adopting Clinical Monitoring Elements



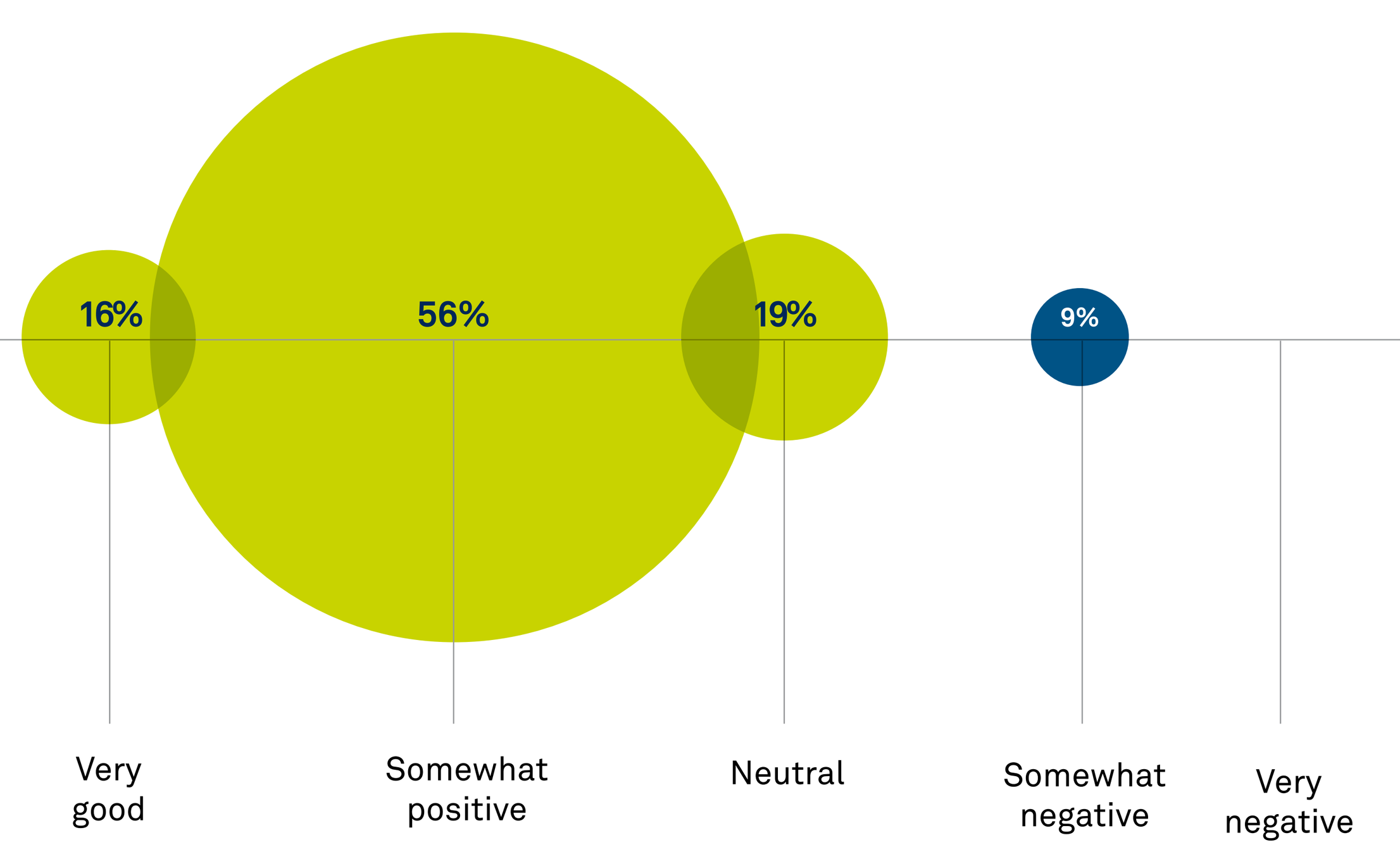
Highlights

"Reduce monitoring costs" was frequently selected as a top benefit and "too expensive" was not commonly selected as a top barrier.

Very few respondents (1% on average) indicated that they see no benefits in using [each] clinical monitoring practice.

3 Adoption of Attitudes and Impact

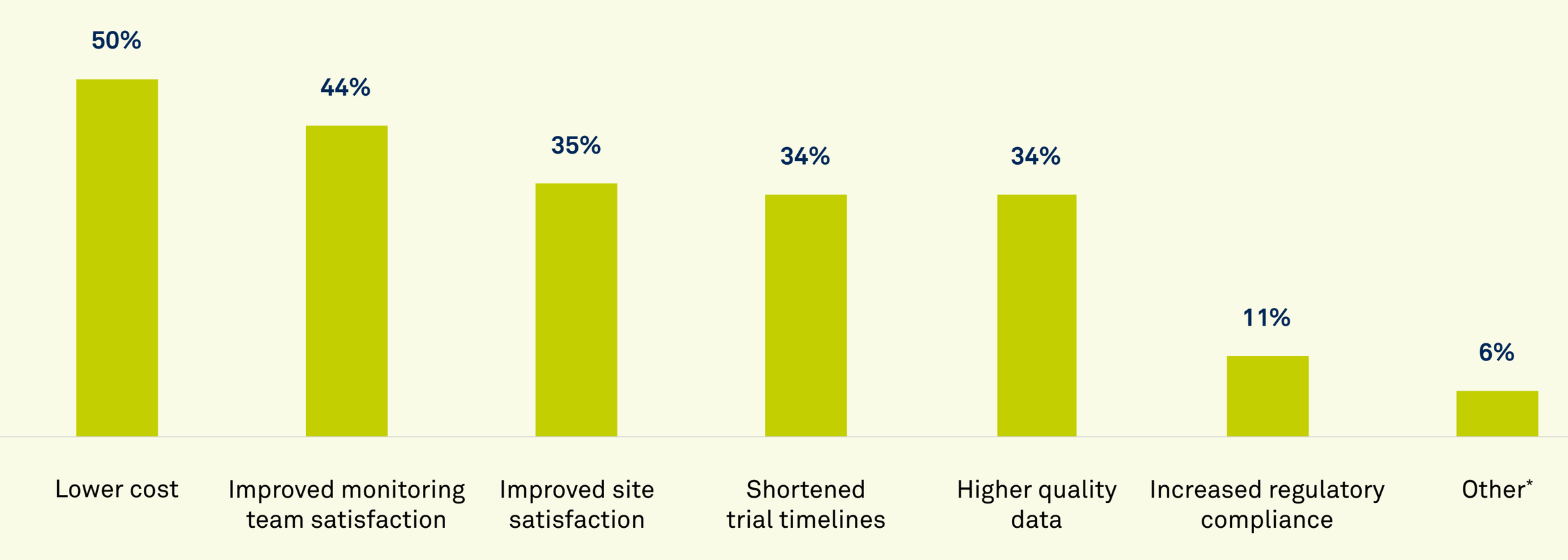
Attitudes Toward Adoption



Highlights

~75%
of respondents expressed a positive impression towards adopting newer clinical monitoring elements

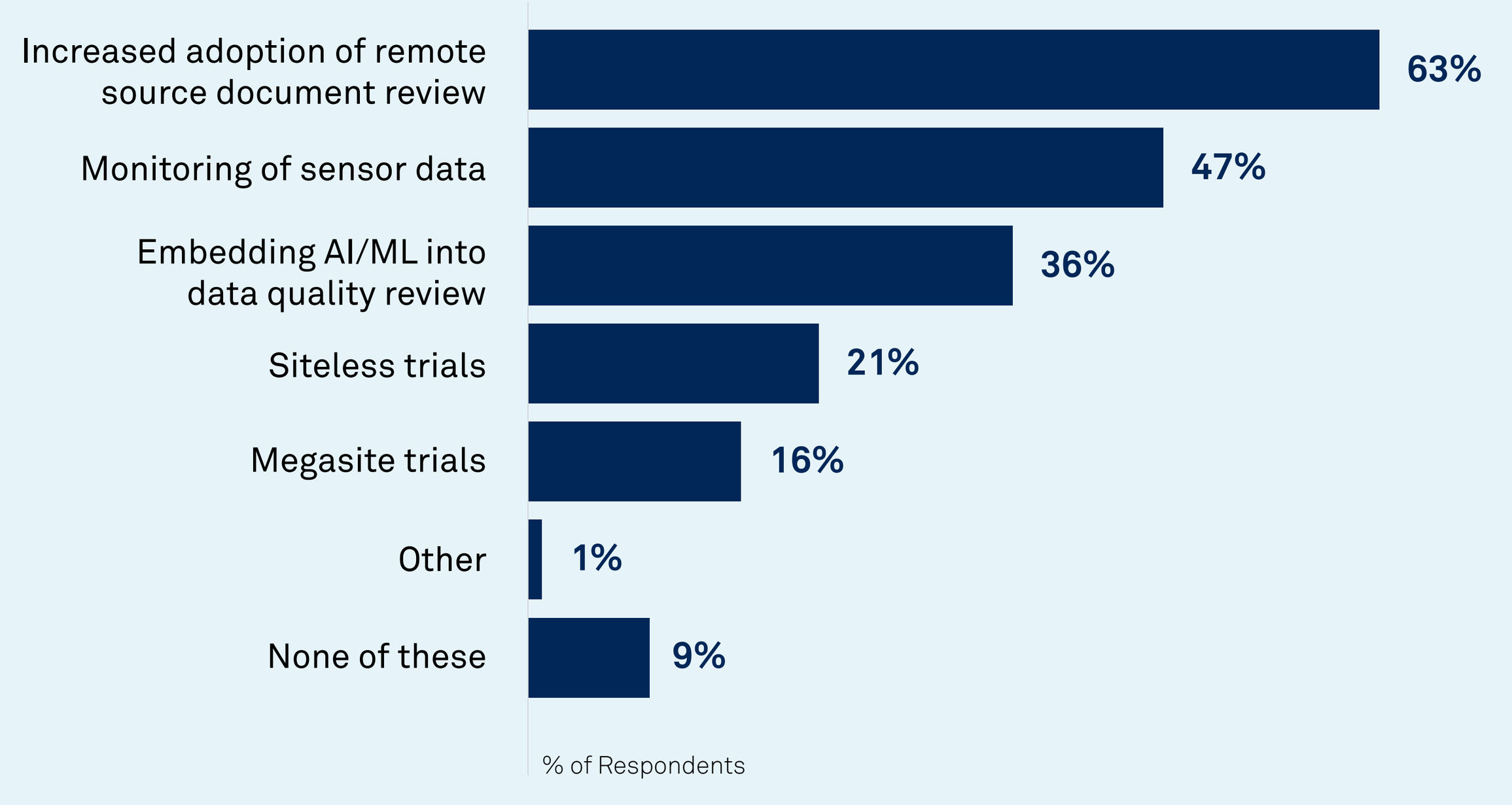
Positive Impacts



*'Other' includes:
- Focus on what matters the most
- Step in the right direction
- Adapting to the corona pandemic
- Continued oversight during COVID-19 when onsite visits were not practical

% respondents with a neutral or positive impression

4 Emerging Approaches

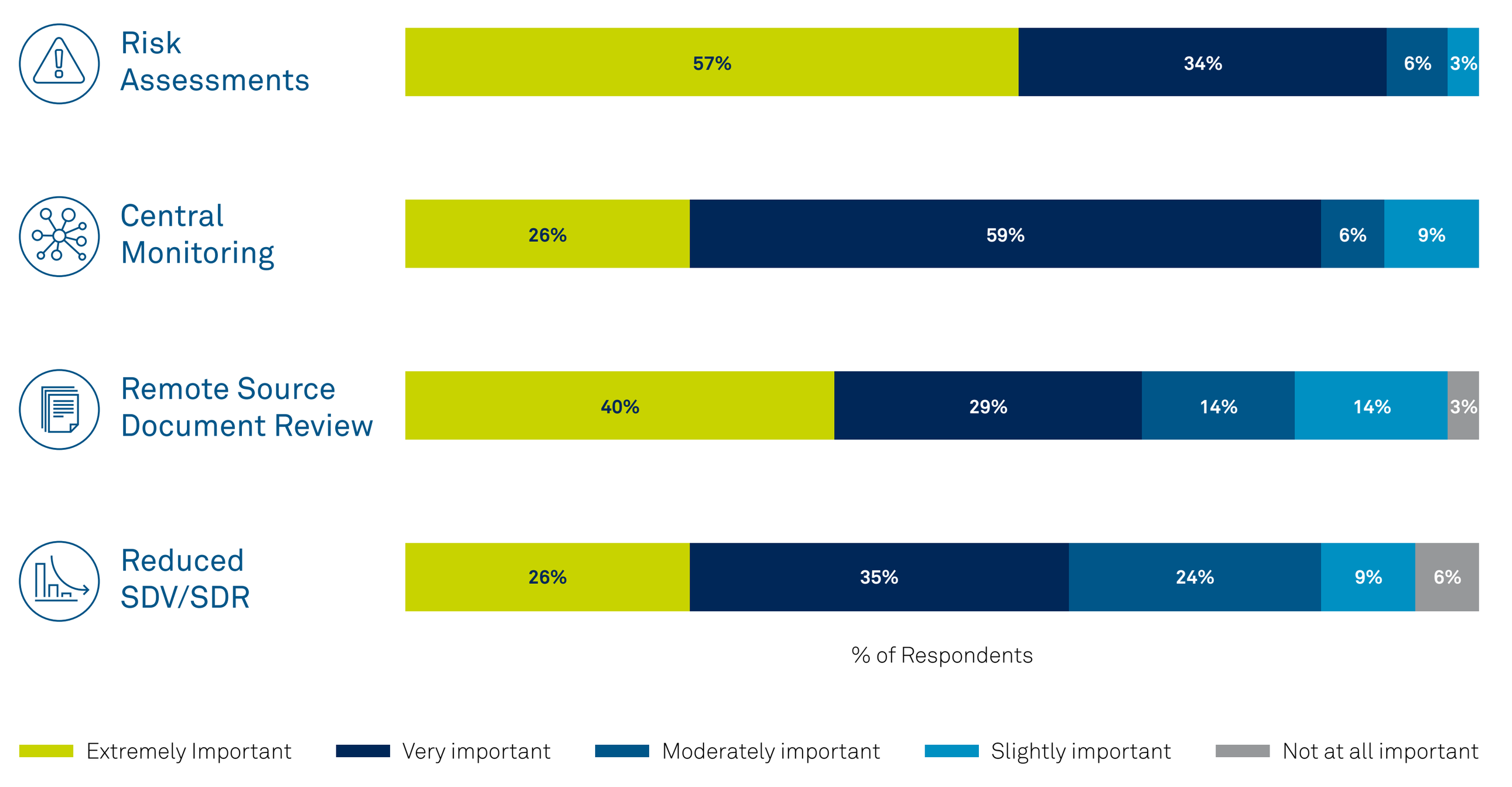


Highlights

~2/3
of survey participants selected "Increased adoption of remote source document review" as a practice they expect their company to adopt in the next 36 months.

This is consistent with the increase across ~15% of trials that respondents predict in the next two years from the usage question.

5 Impact of Clinical Monitoring Elements on Operationalizing DCTs



Highlights

Among the survey participants that are currently running decentralized / hybrid trials (50%), **risk assessments** and **central monitoring** were valued by most as very or extremely important in running this type of trial.

6 Impact on Sites

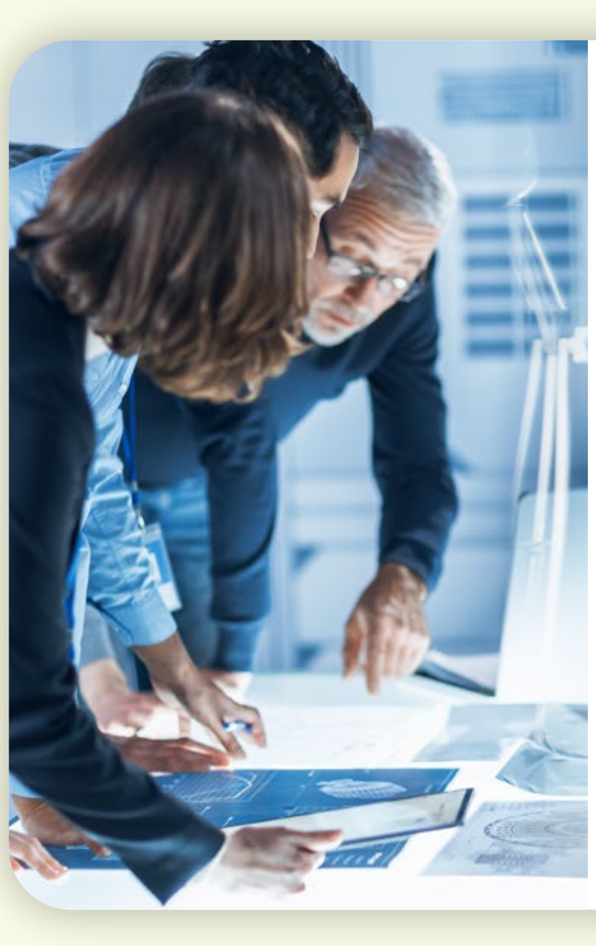
Sites found that using technology to enable remote document review provides some real benefits:

3.4
On-site monitoring visits saved per month

80%
Remote Source Review Site users believe monitors are able to address safety concerns quickly

3.4
Hours are saved in prep for SDV/SDR review per month

Source: Survey conducted with Remote Source Review Site users in March 2021 n=126



Highlights

Sponsors who have not yet adopted these technologies perceive that adoption of these new clinical monitoring technologies will garner resistance from their sites and lower site satisfaction

While time is saved for sites who have supported remote monitoring by removing the on-site visit, it is replaced by additional work to manage/upload the documents for monitoring.

A new model for compensating sites for the additional work associated with remote monitoring should also be considered.

Clinical Operations is evolving at the pace of the research it supports. Optimized clinical trial operations are a key differentiator for delivering high-quality treatments, on-time and efficiently. By layering in systems that address the fundamental maturity of their processes, companies can realize optimized trial design, continual data quality review, early risk, and issue detection, and an improved relationship with the sites, on a scale not seen historically in clinical trials.

Medidata RBQM supports excellence in trial execution, enabling companies to achieve digital oversight, which Medidata sees as the future of Clinical Trial Operations.

TO LEARN MORE, VISIT:
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