DistillerSR

Pulse of the Medical Devices Market Report

Literature Review Automation Adoption Insights and Trends

2023

CITELINE

“In a time when literature reviews have become a critical component of the regulatory process from pre-market approval through post-market surveillance, it is especially important to establish a rigorous and systematic approach towards evidence collection and continuous literature monitoring.”

Peter O'Blenis, CEO at DistillerSR

A talent shortage and a dynamic regulatory landscape continue to challenge the medical devices industry. It is an exciting time of accelerated transformation and organizational change as companies look to improve productivity while efficiently managing cost. DistillerSR, in partnership with Citeline, surveyed global professionals in the medical device and in-vitro diagnostics industry to gain a comprehensive understanding of the level of organizational preparedness and management maturity in literature review practices in the industry. In a time when literature reviews have become a critical component of the regulatory process from pre-market approval through post-market surveillance, it is especially important to establish a rigorous, systematic and scalable approach for evidence collection and continuous literature surveillance.

Findings indicate that organizations who have invested in literature review software platforms are significantly more confident in their ability to meet regulatory requirements compared to those relying on manual spreadsheet-based processes. We also observed a shift in evidence management practices to leverage data reuse within an organization to reduce redundant work.

I hope this report provides you with valuable insights into the importance of investing in new technology and automation to streamline evidence management practices.

Peter O’Blenis
CEO, DistillerSR

Table of Contents

Executive Summary

Executive Summary

01

Literature Review Software Users Are Two Times More Confident in Their Regulatory Submissions

Sixty-six percent of the respondents who invested in a literature review software platform are more confident that their regulatory submissions will be approved versus 38% of the respondents who are currently using spreadsheets and conducting literature reviews manually. Ensuring timely and compliant regulatory submissions remains a challenge for global medical device companies. Rejected submissions result in unforeseen costs and negatively impact planned product launches and device availability.

02

Seventy-three percent of Literature Review Software Adopters Trust the Quality of Their Data

Almost three quarters of the respondents using literature review software platforms are confident in the quality of their literature reviews while only thirty-seven percent of the ones still using spreadsheets trust the quality of their data. Manual literature reviews are time consuming, error-prone and resource intensive. These errors lead to omitted references, mistakes, and regulatory submissions likely to raise red flags with notified bodies.

Executive Summary

03

Literature Review Software Adoption Is Enabling Real-time Data Traceability for Sixty Percent of the Respondents

Over 60% of the survey respondents who adopted a software platform trust their ability to track literature reviews in real-time and the traceability of included and excluded references versus only 4% of respondents who use spreadsheets. Data traceability throughout literature reviews results in audit-ready, compliant regulatory submissions and effective project management practices.

04

Manufacturers Are Integrating Literature Reviews Throughout the Medical Device Development Lifecycle

Literature reviews bring together research and literature related to a particular topic or subject. Different types of literature reviews can be used throughout the medical device lifecycle, from ideation through post-market surveillance. They are time consuming, labor intensive and complex but the outcome is a source of truth that is reliable, trustworthy and serves as the cornerstone of policies and regulations that ensure the safety of medical devices. All respondents are utilizing literature reviews through different stages of the device lifecycle: to inform product development deliverables and market access policies, and to comply post-market surveillance regulatory requirements.

Executive Summary

05 Continuous Data Collection is Driving Efficient Evidence Management for Sixty-four Percent of Literature Review Software Users

Sixty-four percent of the respondents who have implemented a literature review software solution are continuously collecting and analyzing evidence compared to thirty-five percent of spreadsheet users. Systematic and proactive evidence monitoring is critical to complying with rigorous post-market surveillance regulatory requirements.

06 Data Reuse Is Reducing Redundant Work for Half of Literature Review Software Adopters

Over half of the respondents who have adopted a literature review software are employing data reuse to reduce redundant work and accelerate completion rates versus only thirty-eight percent of spreadsheet users. For research professionals, the burden of searching and analyzing growing volumes of scientific literature is compounded by the time-consuming effort of repeatedly collecting data from the same references across multiple projects. Leveraging an integrated data warehouse for evidence management will benefit an entire organization and result in cost savings, improved productivity and efficient processes.

Executive Summary

07

Regulatory Compliance is the Main Driver for Literature Review Software Adoption

Implementing a single source of truth such as a cloud-based software solution enables data auditability and timely regulatory submissions, streamlining compliance. Over half all respondents chose regulatory compliance followed by improved literature review quality as the top motivators for adopting a literature review software platform.

08

Cost Remains the Top Barrier for Software Adoption

People, processes and technology are the three most important components of a successful organizational transformation. Adopting a new technology is not easy, especially for manufacturers already chasing the clock to comply with regulatory timelines. Cost was mentioned by over half of all respondents as the main barrier to adopt a literature review software platform.

Introduction

Introduction

What You'll Find in This Report

This inaugural edition of the **Pulse of the Medical Device Market Report** is based on the findings from an industry survey conducted by DistillerSR in partnership with Citeline and on observations from various customer touch points and interviews conducted throughout 2022 to explore how literature review automation and software adoption impact:

- Confidence in regulatory submissions and faster path to compliance
- Literature review data quality
- Continuous and efficient evidence management practices
- Standardized and repeatable organizational processes

Market Survey Overview

Market Survey Overview

Methodology

The market study referenced in this report was conducted by Citeline, on behalf of DistillerSR, surveying the medical device and in-vitro diagnostic industry throughout September 2022 and generated 146 responses from global professionals. The purpose of the study was to understand overall organizational preparedness, literature review management maturity, as well as barriers and motivators to adopt automation and implement literature review software solutions.

Key Findings

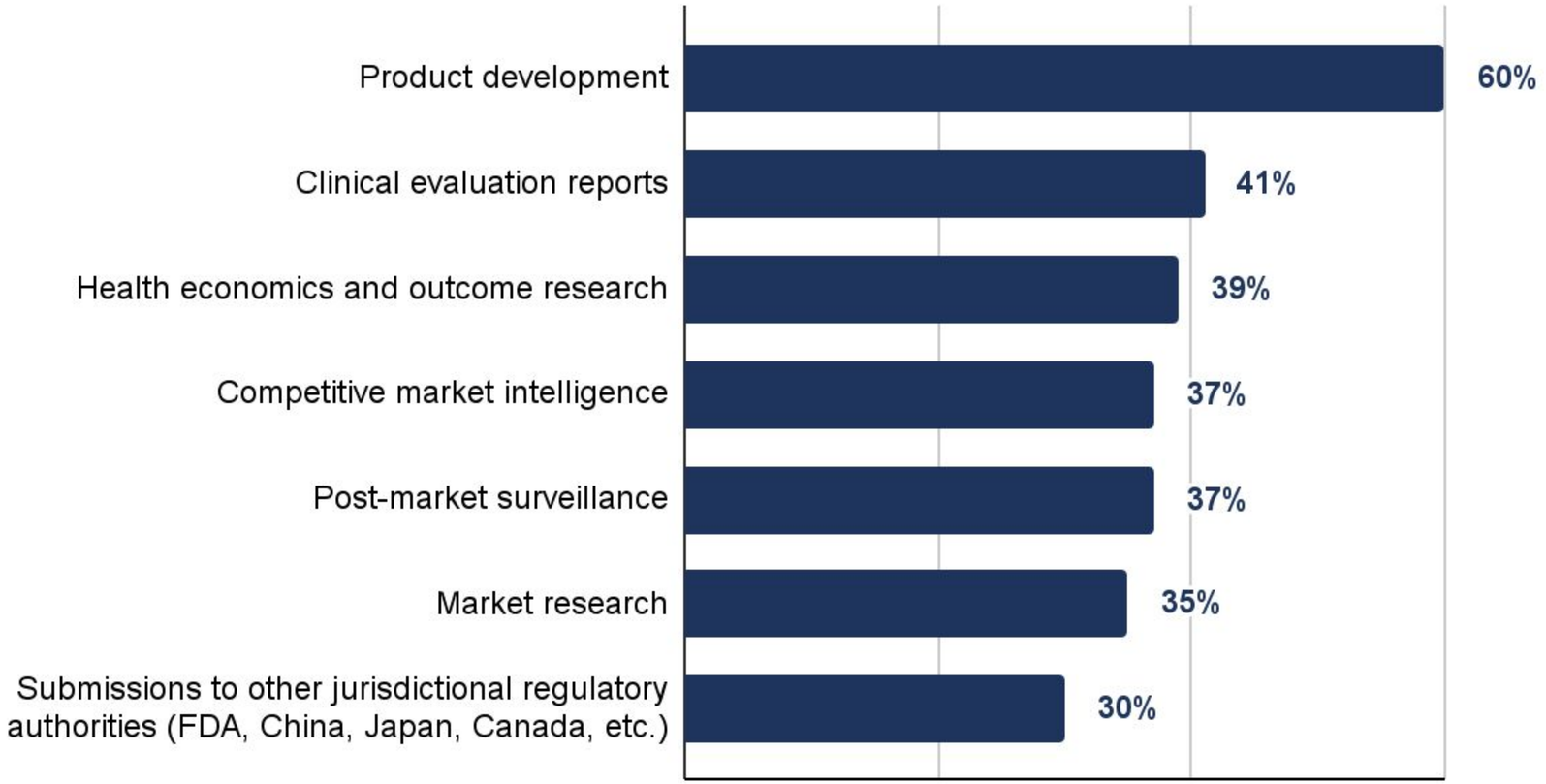
Part 1: Literature Review Software Adoption is Driving Confident Regulatory Submissions, Trust in the Quality of Data and Standard Evidence Management Practices

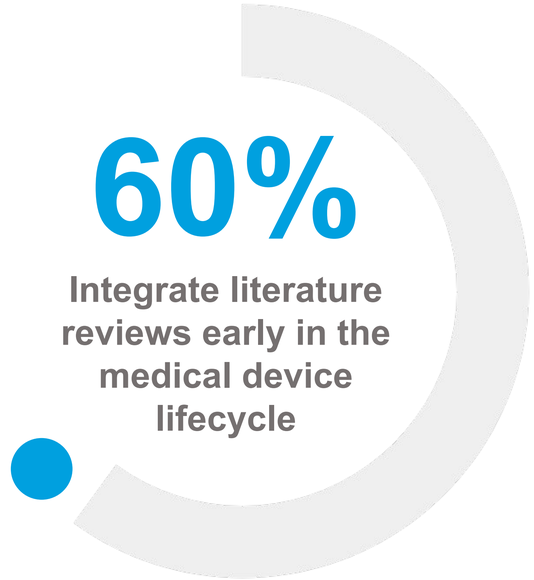
66% of literature review software platform adopters are confident in their regulatory submissions.

73% of literature review software platform adopters trust the quality of their literature review data.

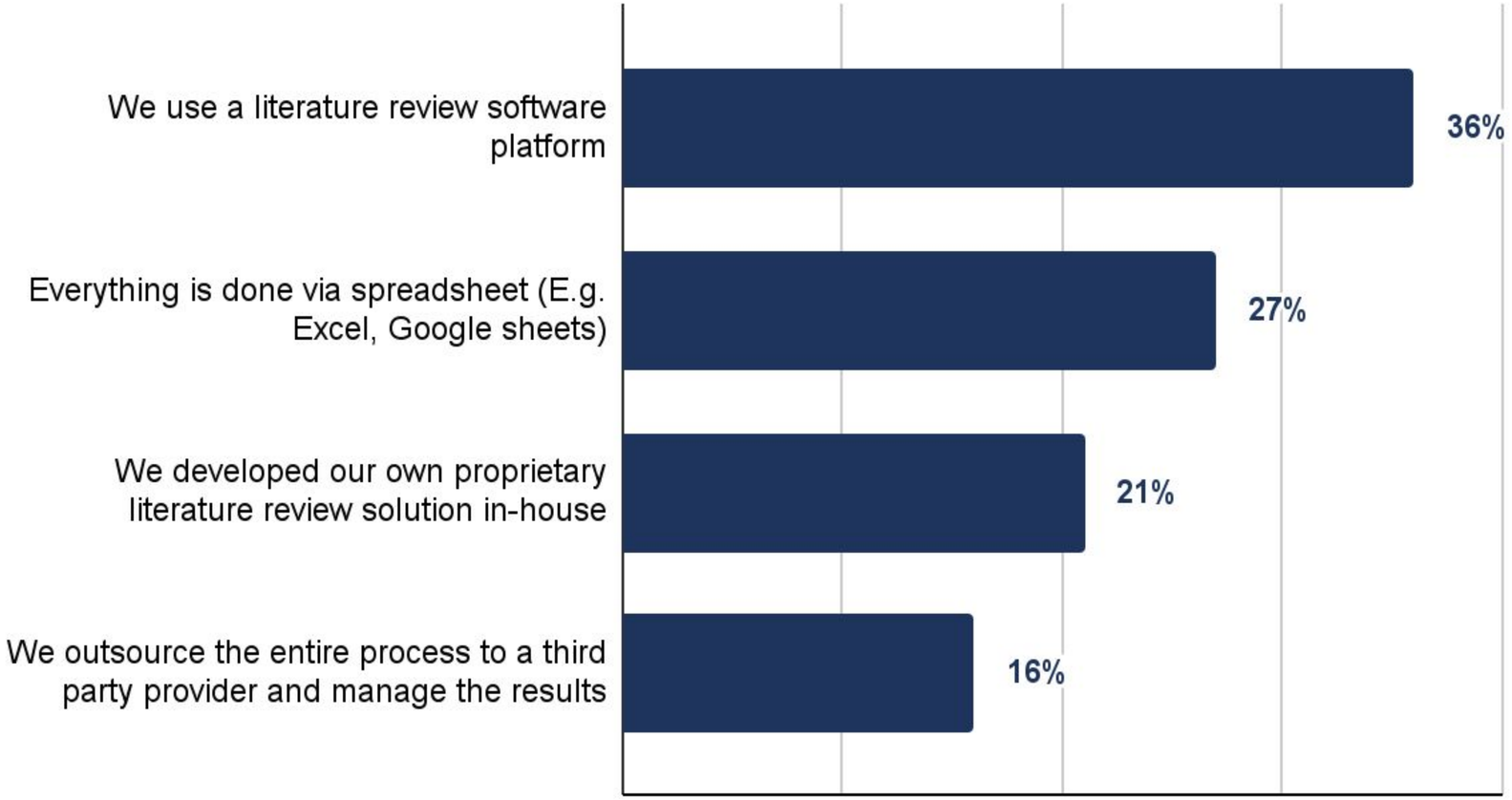
Over half of all respondents are implementing standard evidence management practices.

Literature Reviews Are Used From Product Ideation Through Post-Market Surveillance

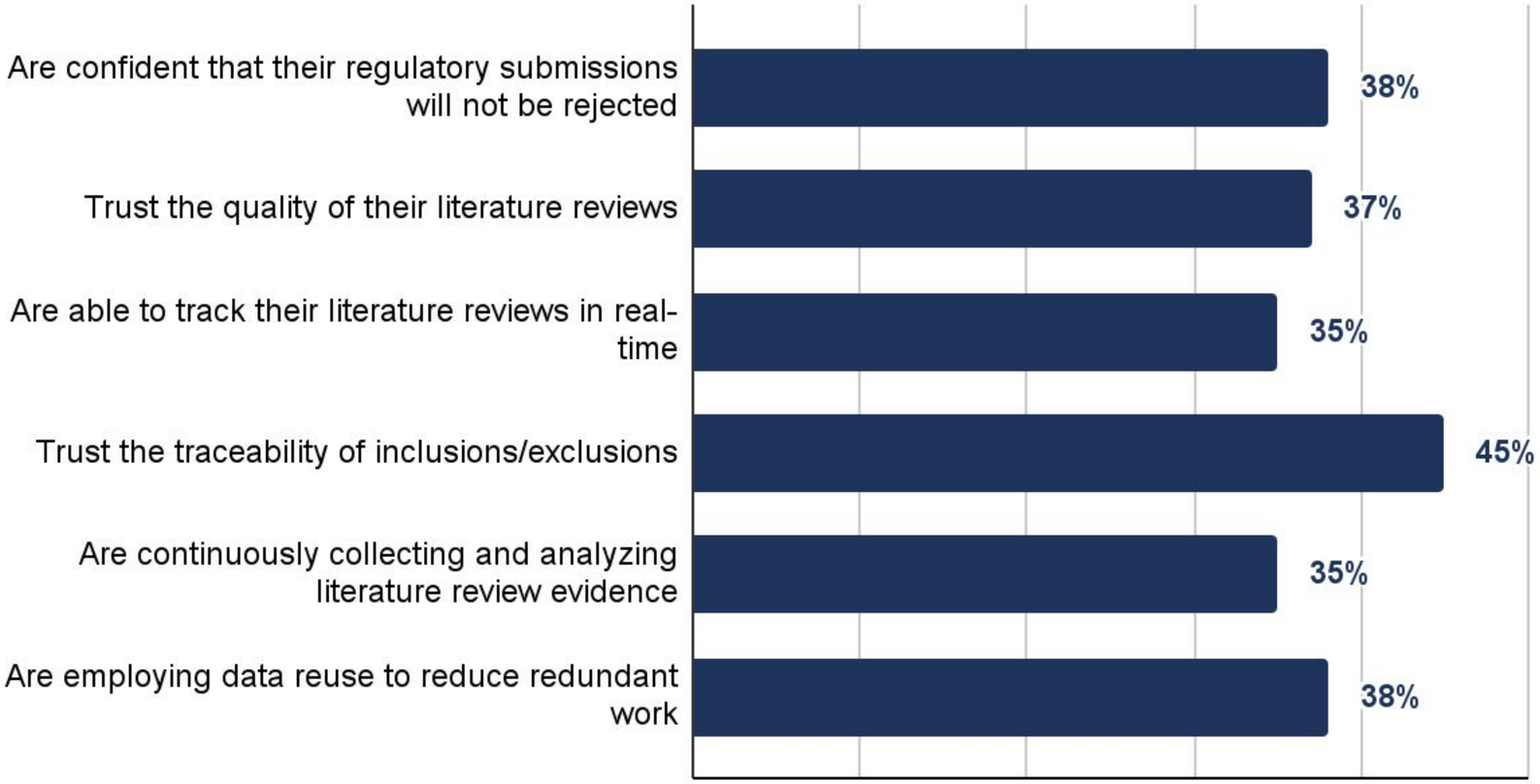




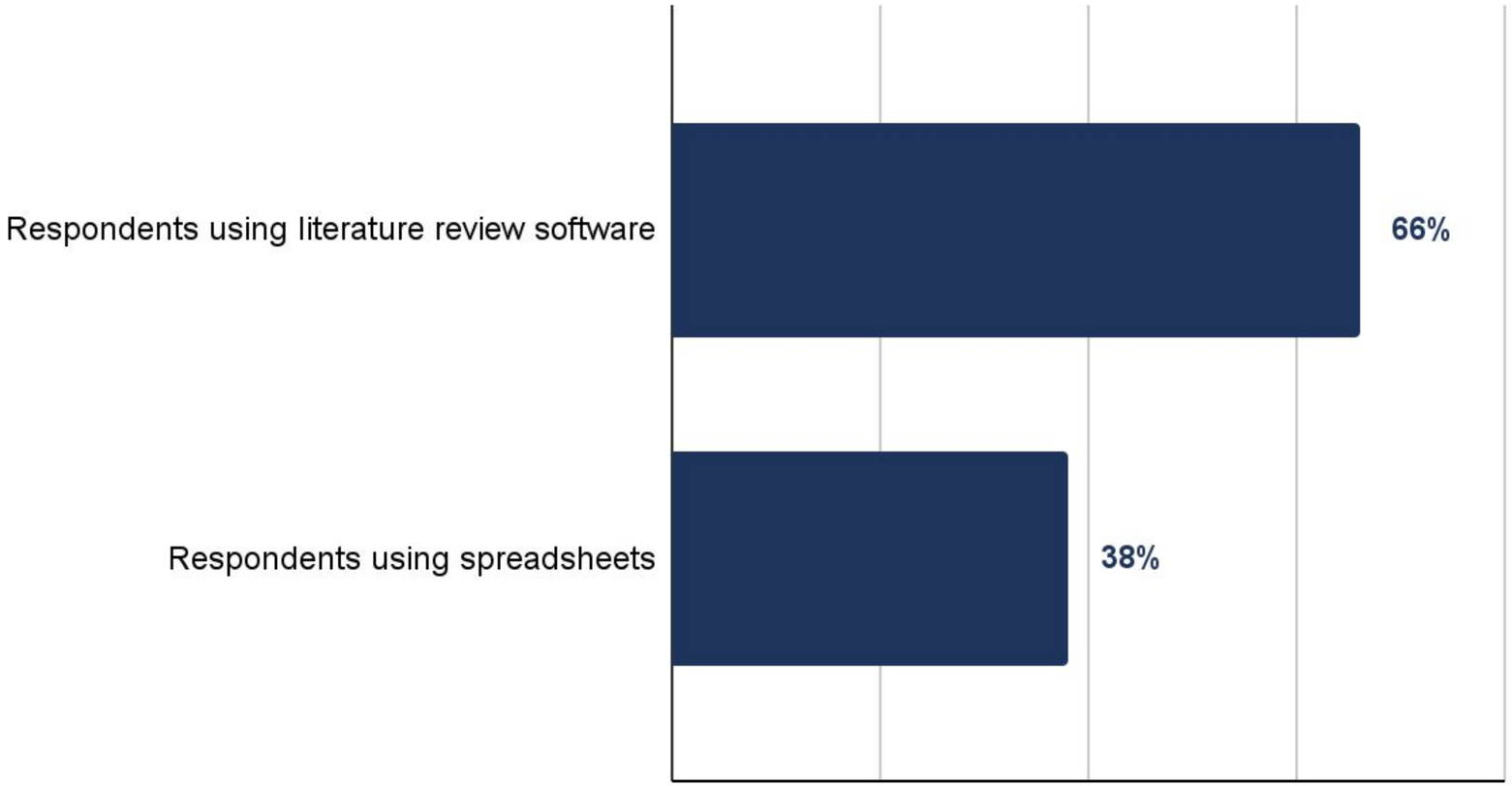
Just Over One Third of Respondents Have Adopted a Literature Review Software Platform



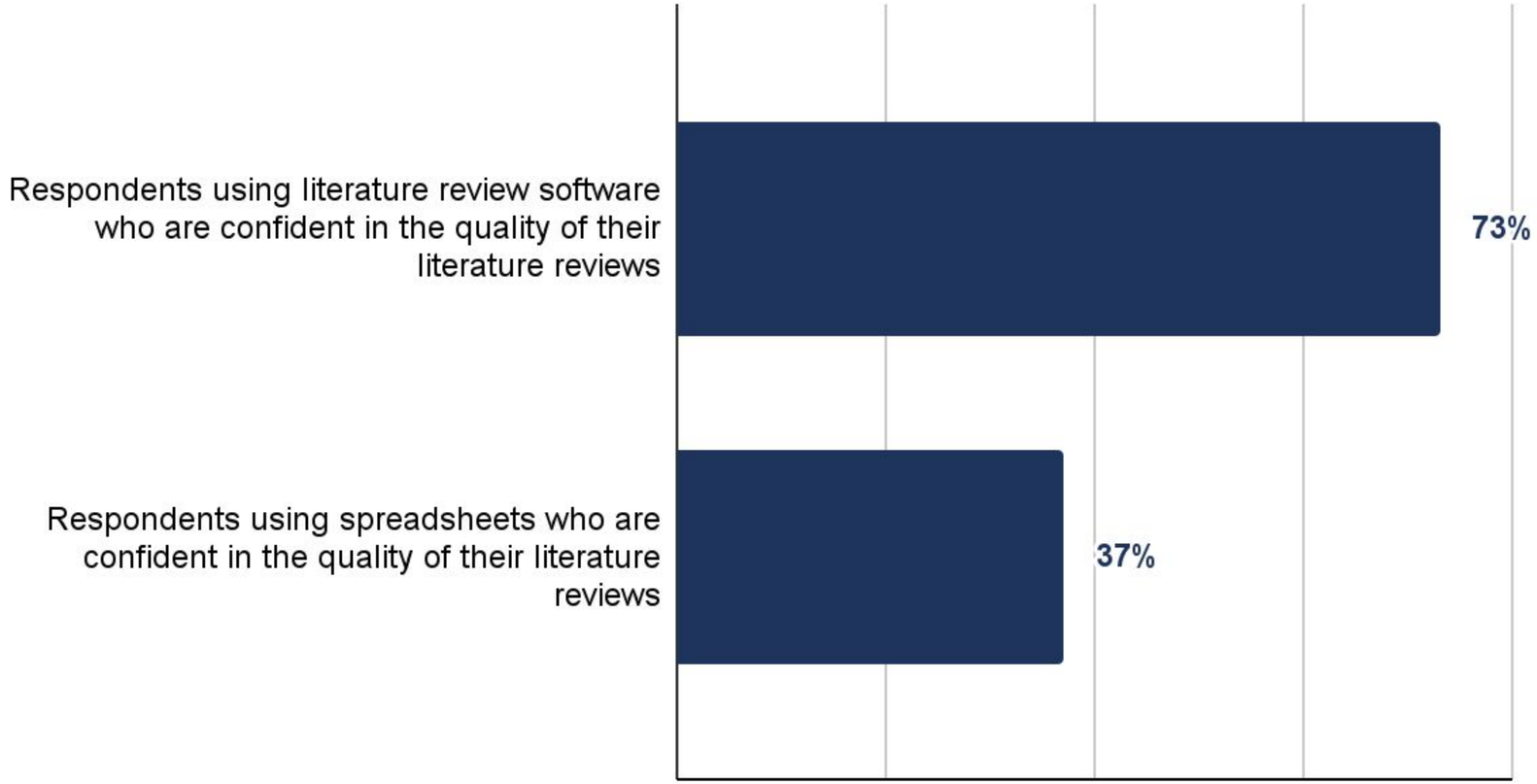
Spreadsheet Users Struggle to Manage Literature Reviews Lifecycle and Are Less Confident in Their Regulatory Submissions



Literature Review Software Adopters Are More Confident in Their Regulatory Submissions



Literature Review Software Automates and Manages the Entire Literature Review Lifecycle = Greater Confidence in Data Quality

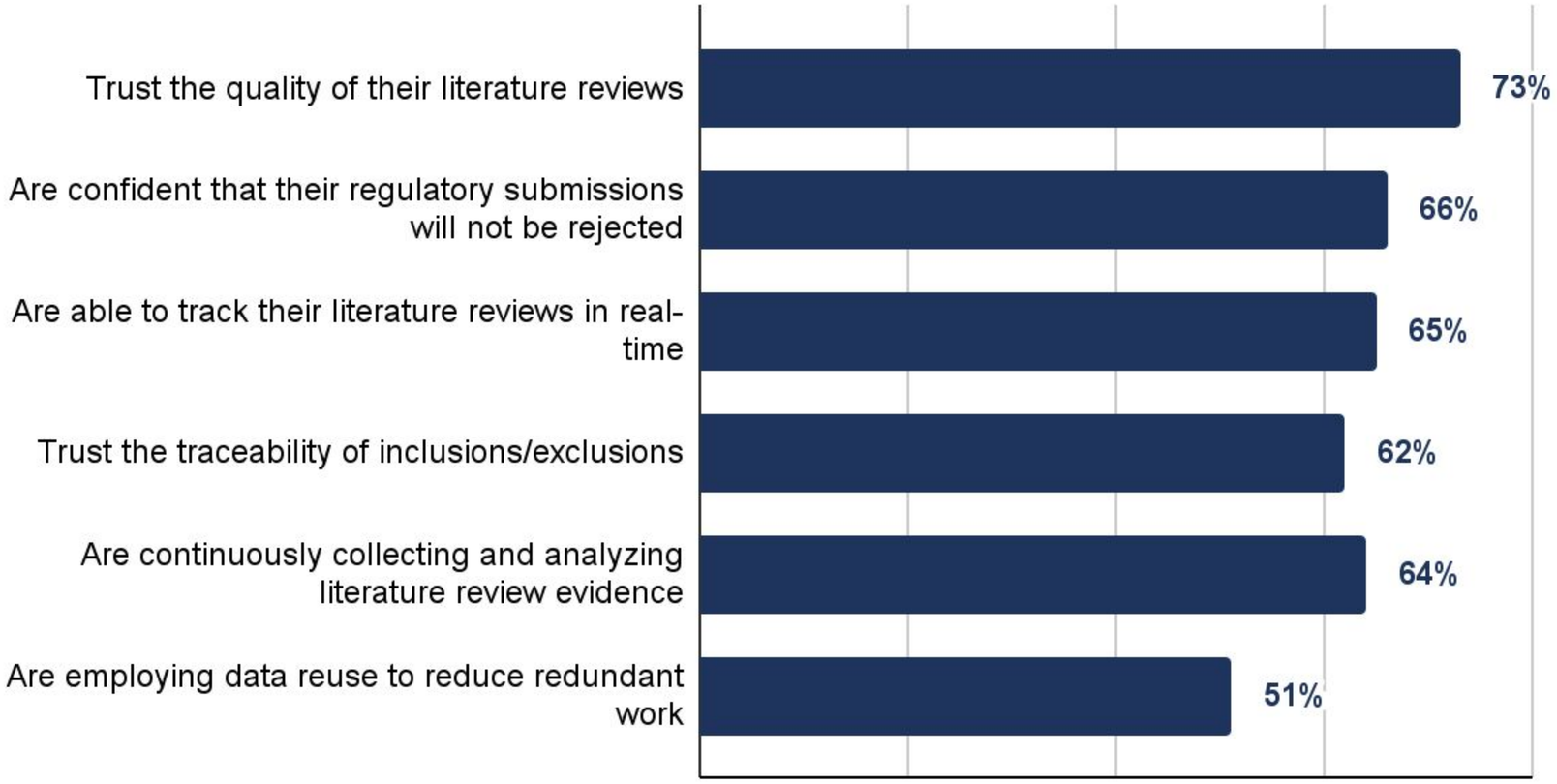


Literature review software platform adopters are

2x

more confident in the quality of their literature review data

Literature Review Software Adopters Are Implementing Standard Evidence Management Practices



Over 50%

Are employing cross-functional evidence management practices

Automated Evidence Management Lowers Product Development Costs and Manages Enterprise-wide Research Consortia

Challenges with Research Data	Business Problem	Business Impact			Automated Evidence Management
Multiple Systems	Centralizing all data to support a medical device from pre-market approval through post-market surveillance is difficult to achieve.	Repeat Questions from Notified Bodies	Regulatory Delays	Costly Management of Evidence	Quickly identify previously reviewed, screened, and appraised data
Massive Volume		Misalignment of Evidence and Outcomes	Duplicated work between departments	Inconsistent results between departments	Continuously updated to keep up with latest evidence
Inconsistent Structure	Misalignment of efforts and failure to leverage research data that may be ongoing in other departments.		Lengthy Reimbursement Profitability	Compromised Data Integrity	Save time and effort in regulatory compliance process
Fragmented Management		Lack of Data Traceability	Inadequate Payer Support Pricing		Evidence database that can be reused for medical devices with similar intended purpose

How? By Creating a Dynamic Knowledge Center to Continuously Manage Evidence-Based Data

Continuous Literature Surveillance

Continuously monitor and manage literature review data for consistent and timely regulatory submissions.

Shared Research Consortia

Securely manage and share literature review data for medical devices with similar intended purpose across teams and functions.

Dynamic Knowledge Center

Centrally manage and reuse all evidence-based research data across an organization.

Data Reuse for Faster Screening

Reuse previously collected data to reduce research time and improve productivity.

Rapid Data Extraction

Dynamically populate forms and tables from previously collected data from company stakeholders.

Reduced Subscription Costs

Access shared references from different review projects to lower annual publication subscription costs.

Centrally and dynamically manage evidence-based research to continuously curate, share, update, and reuse data enterprise wide.

DistillerSR

CuratorCR

Part 2: Literature Review Software Adoption is Tied to Enterprise-Grade Security, Cost, and Integration with Internal Tools

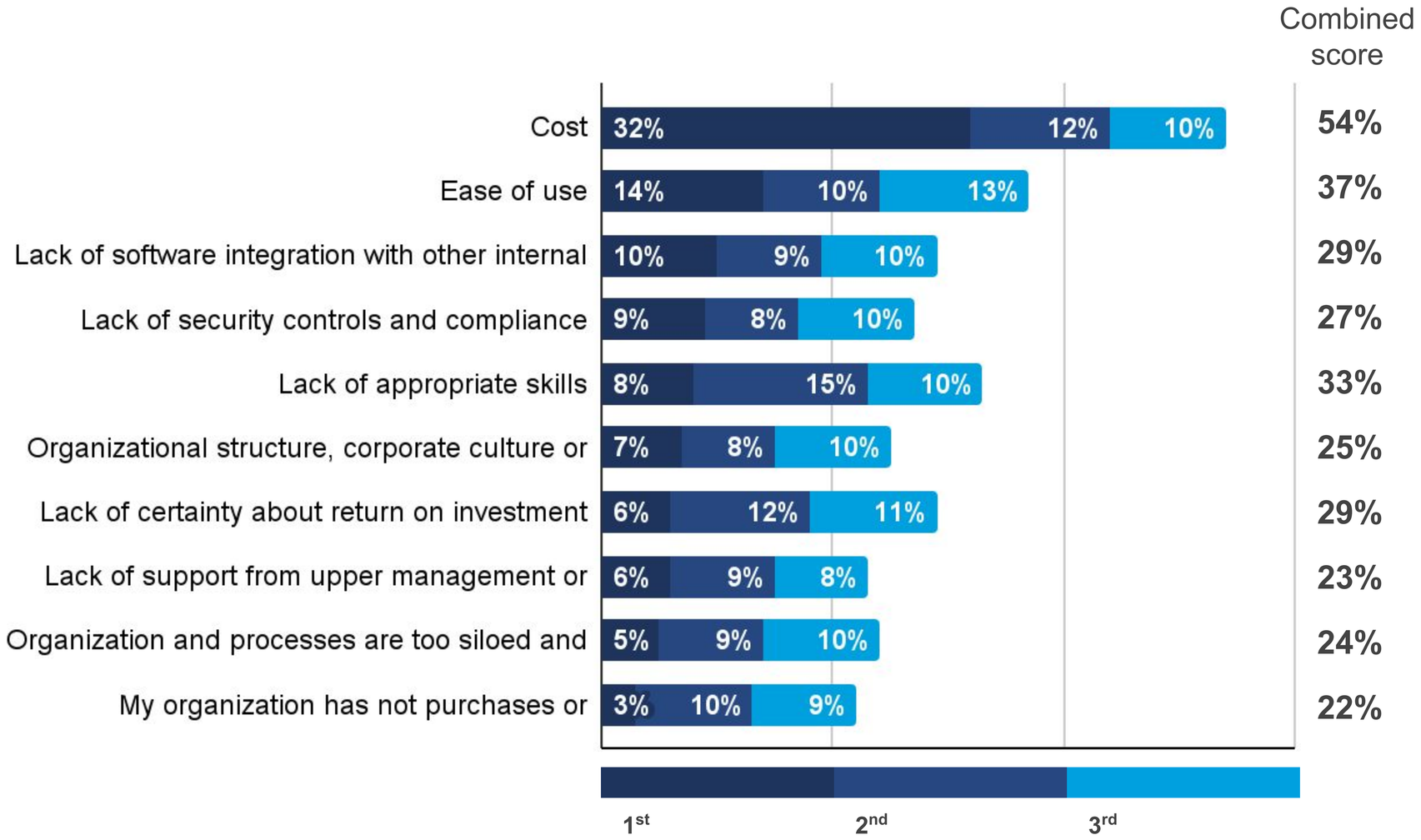
Top Barriers: Literature Review Software Adopters

1. Cost
2. Ease of use
3. Lack of security controls and compliance with IT requirements
4. Lack of integration with internal tools
5. Lack of support from upper management

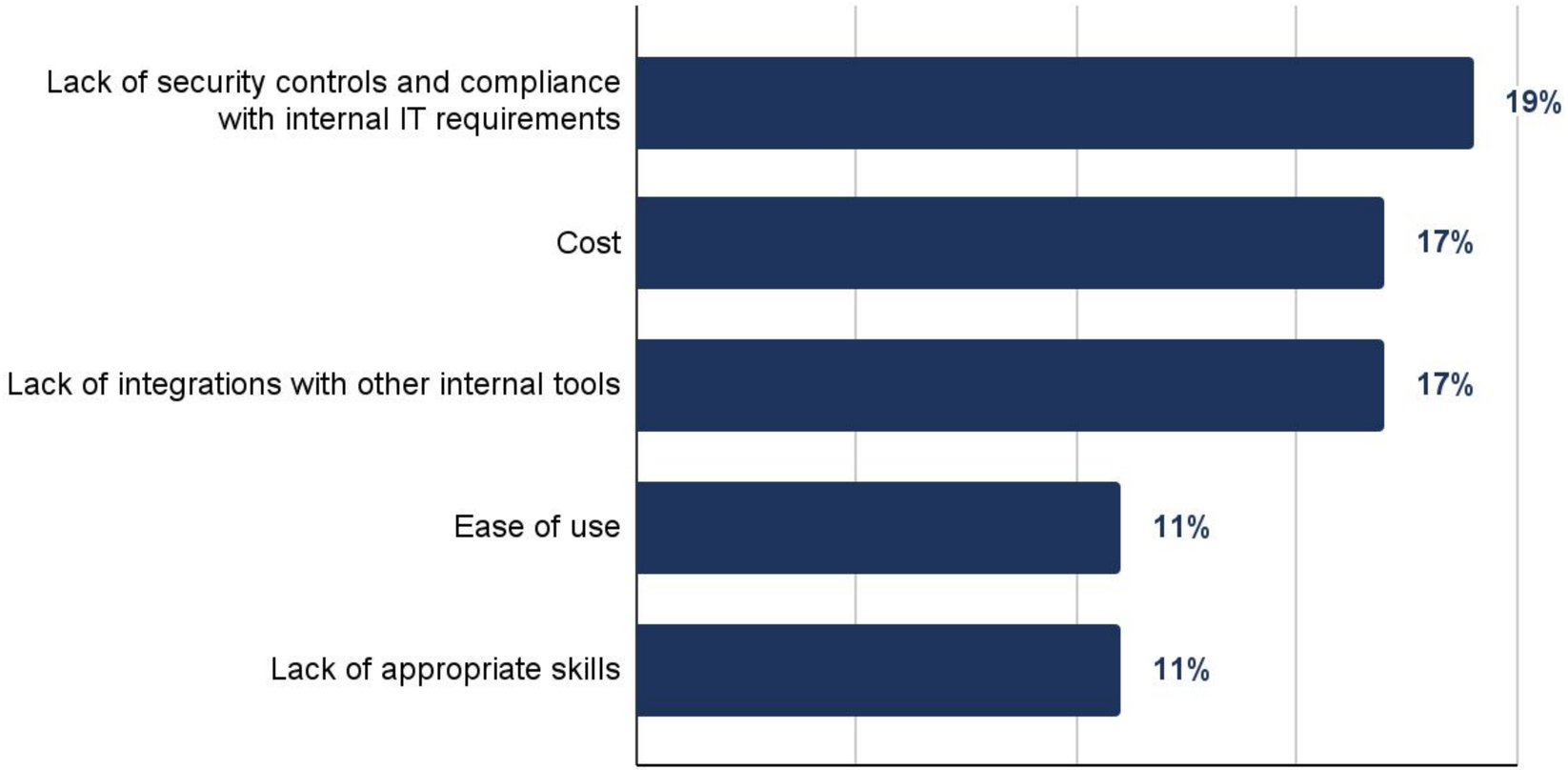
Top Barriers: Spreadsheet Users

1. Lack of security controls and compliance with IT requirements
2. Cost
3. Lack of integration with internal tools
4. Ease of use
5. Lack of appropriate skills

Cost, Ease of Use, and Integration with Internal Tools Are the Top Literature Review Software Adoption Barriers



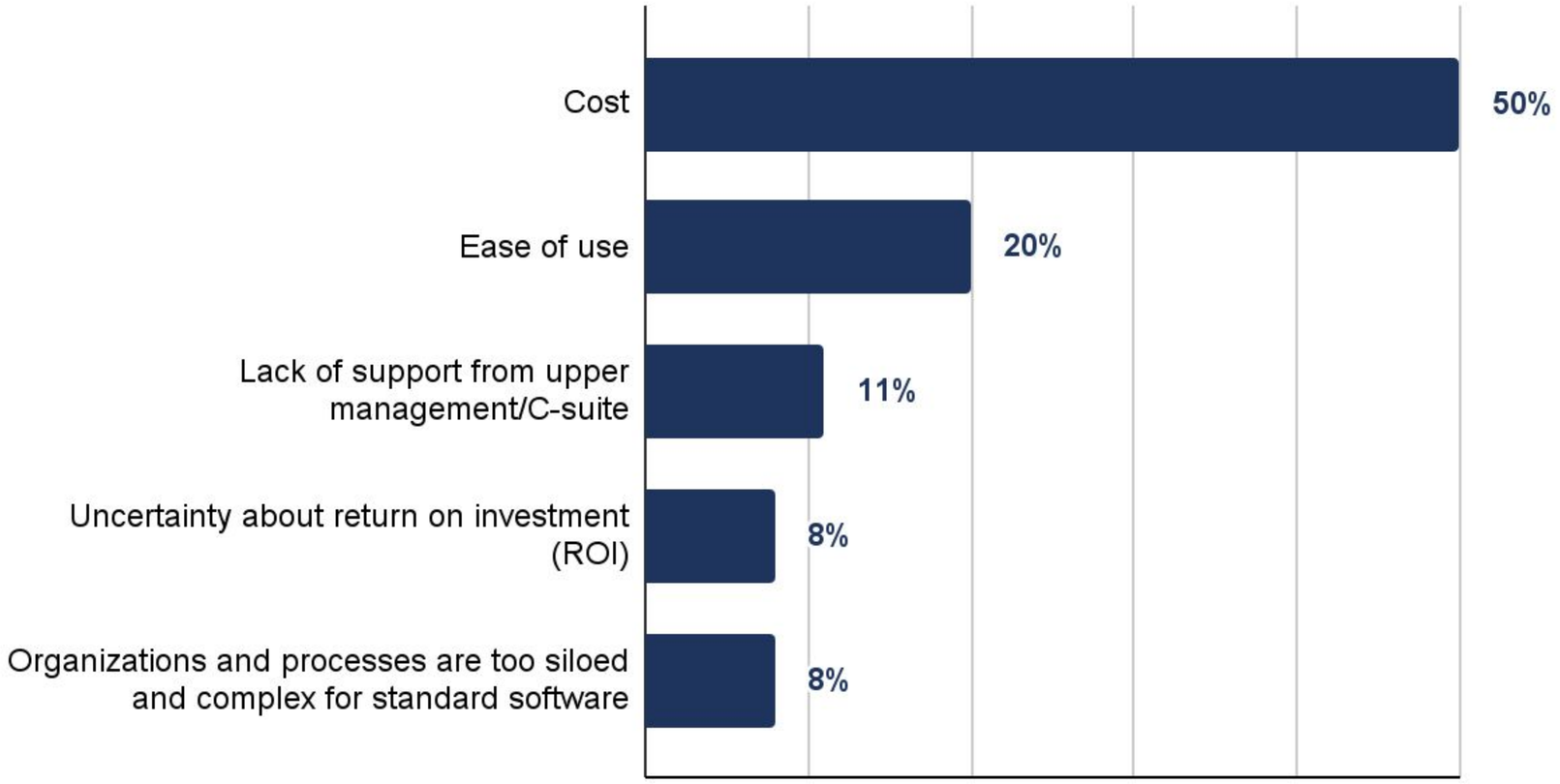
Barriers for Enterprise-Wide Literature Review Software Adoption Suggest a Desire for Greater Platform Integration

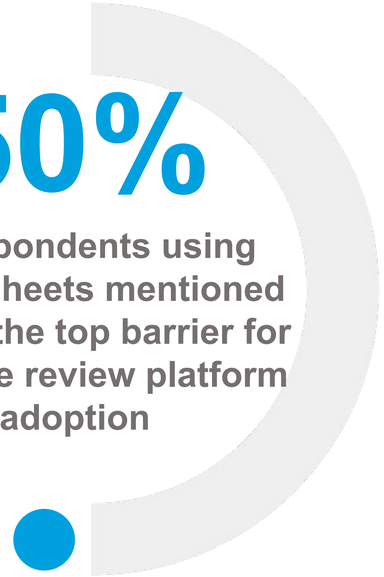


19%

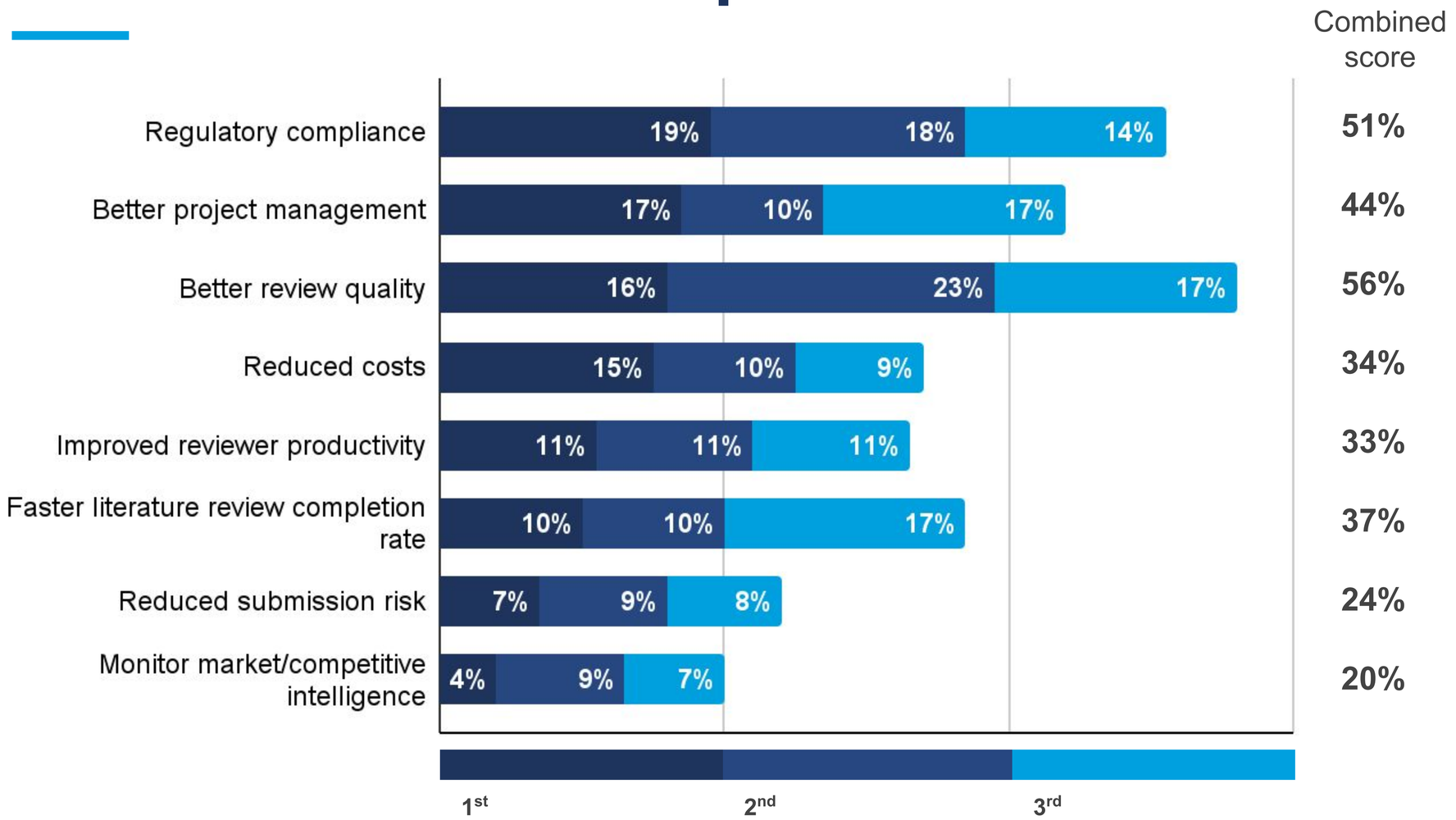
of respondents using literature review platform mentioned lack of security controls and compliance with internal IT requirements as the top barriers for adoption

Spreadsheet Users Considering Literature Review Software Should Ensure Enterprise-wide Integration and Proven ROI

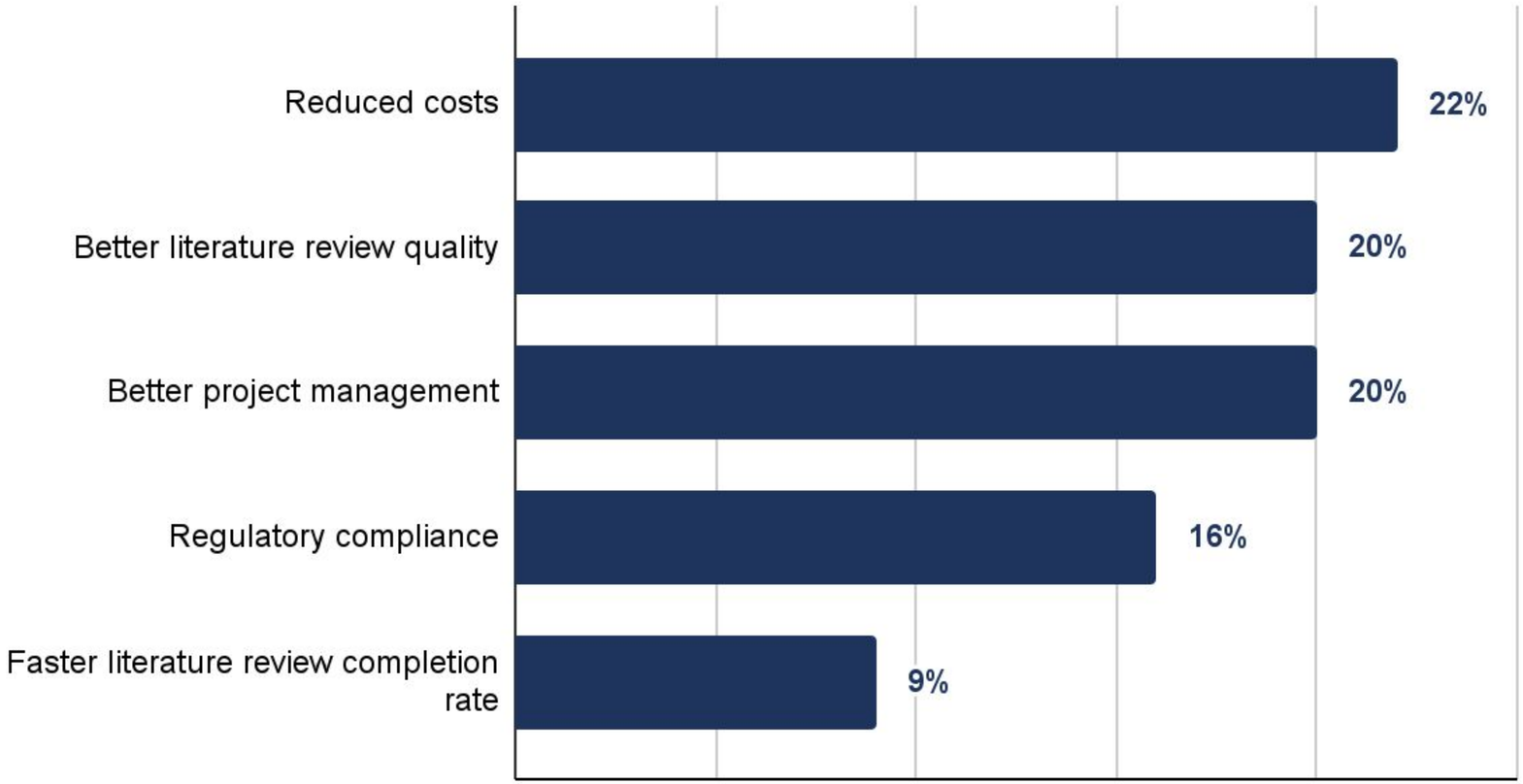




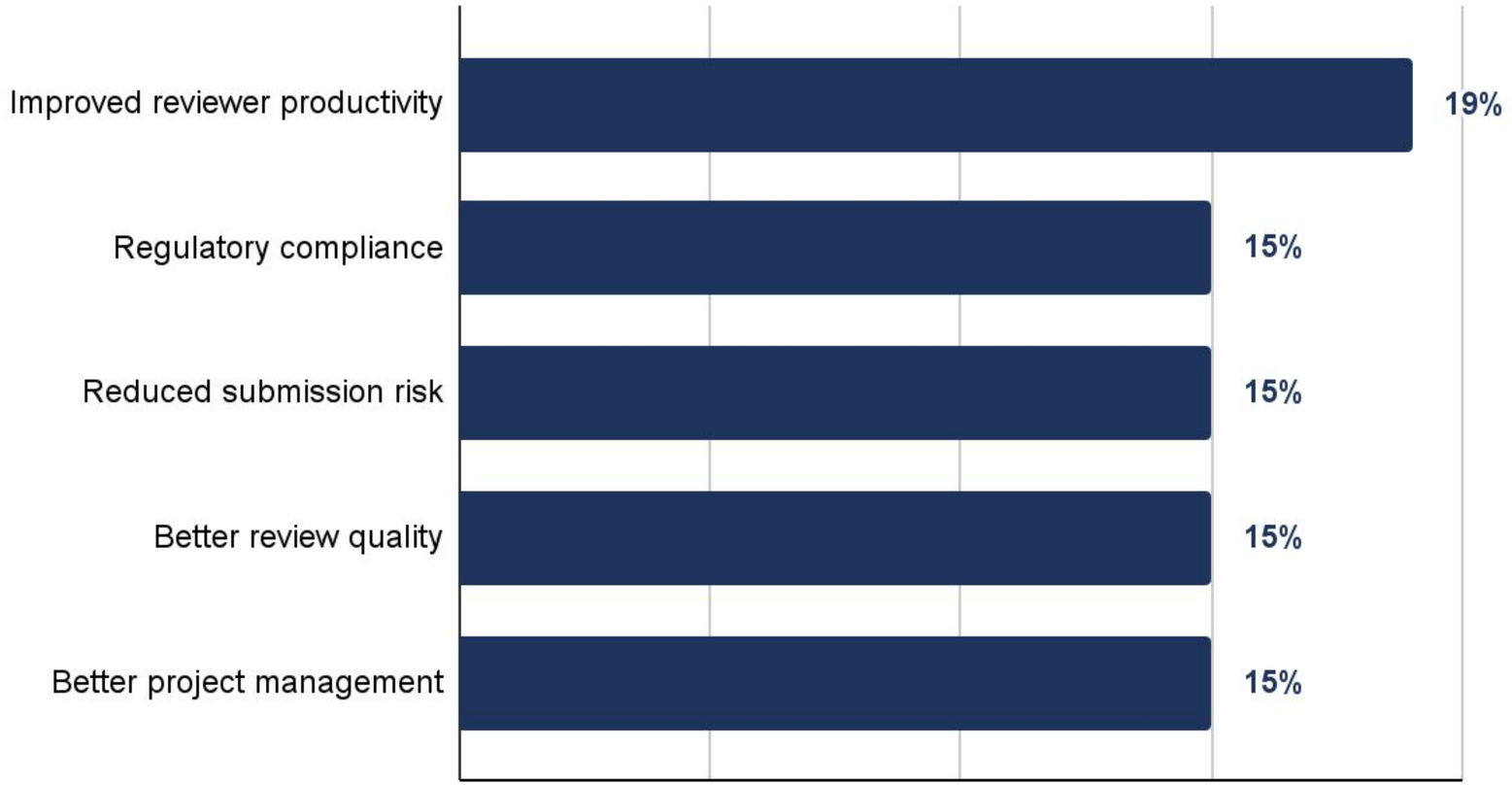
Regulatory Compliance, Better Project Management, and Improved Quality of Data Are the Main Literature Review Software Adoption Drivers



No Surprise: Productivity and Cost Reduction Are the Main Business Motivators for Enterprise Users



Spreadsheet Users Are Early in the Adoption Curve: Regulatory Risks Largely Shape Adoption Motivation



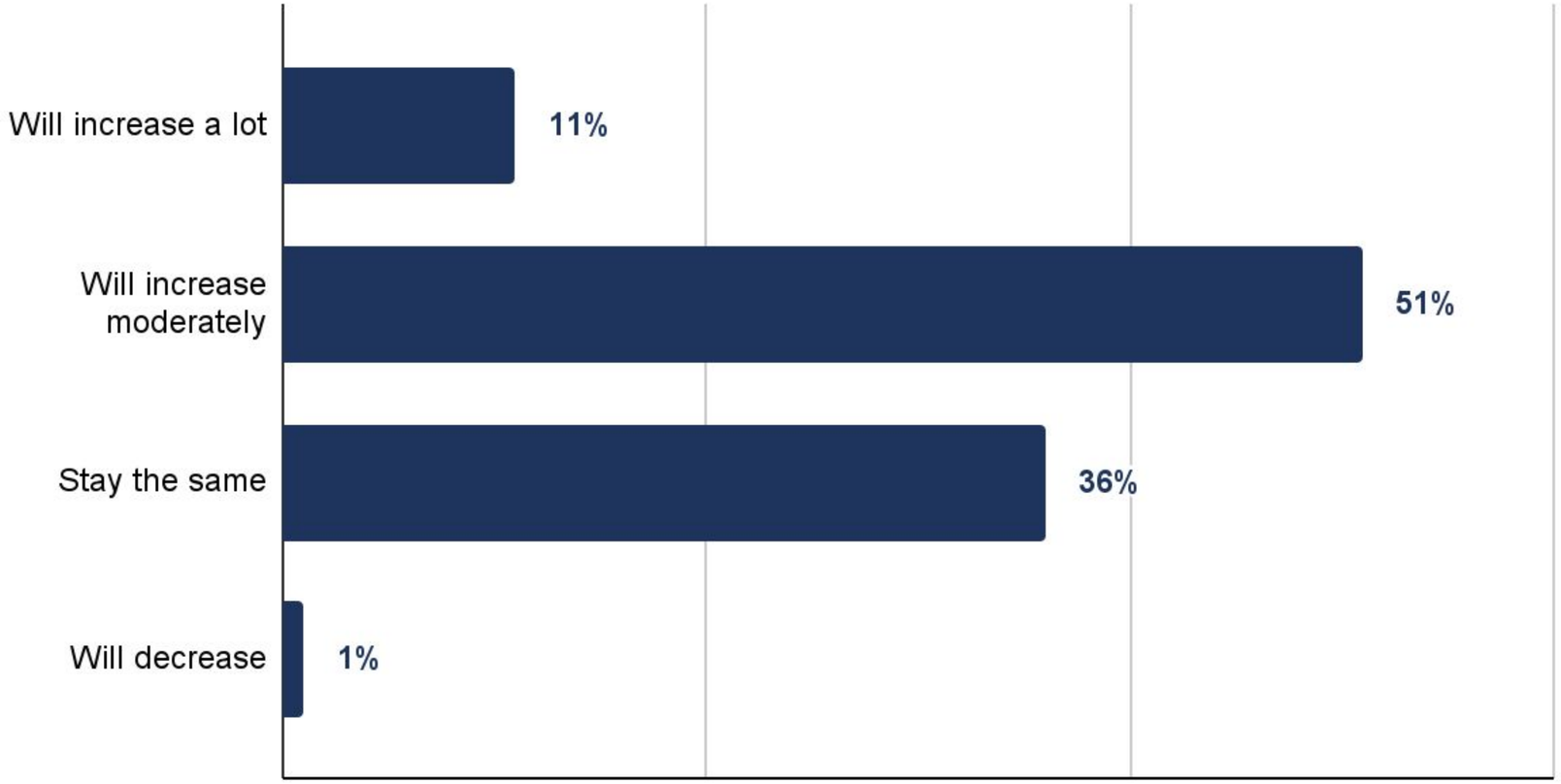
Part 3: Budgets and Training Funding for Literature Review Software Adoption Will Remain Steady for the Next 12 Months

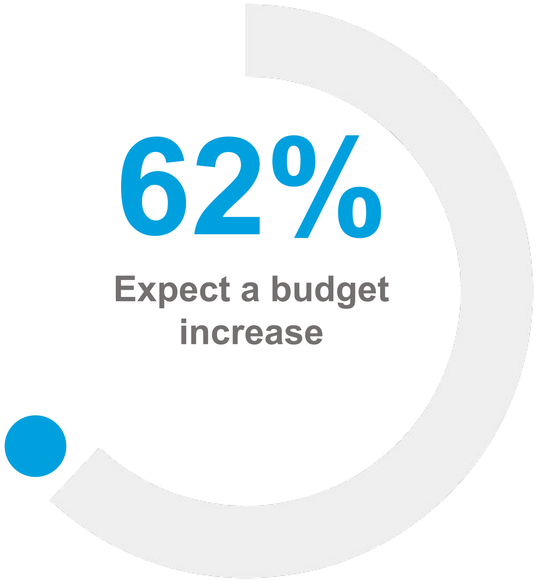
62% of all respondents expect literature review software management budget to increase.

41% of all respondents have standard evidence management practices in place.

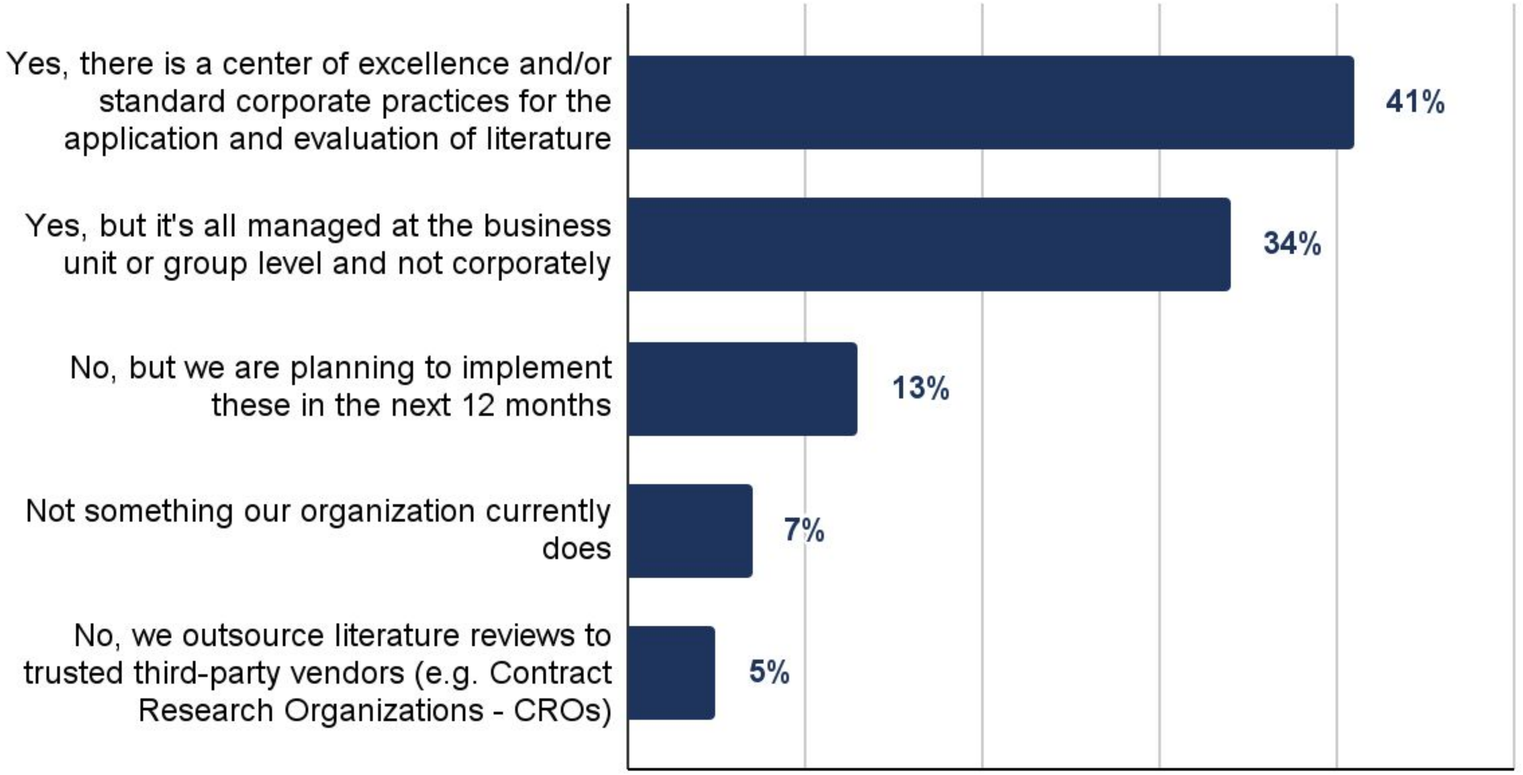
56% of all respondents are investing in training.

Literature Review Management Budgets Are Generally Expected to Increase in the Next 12 Months

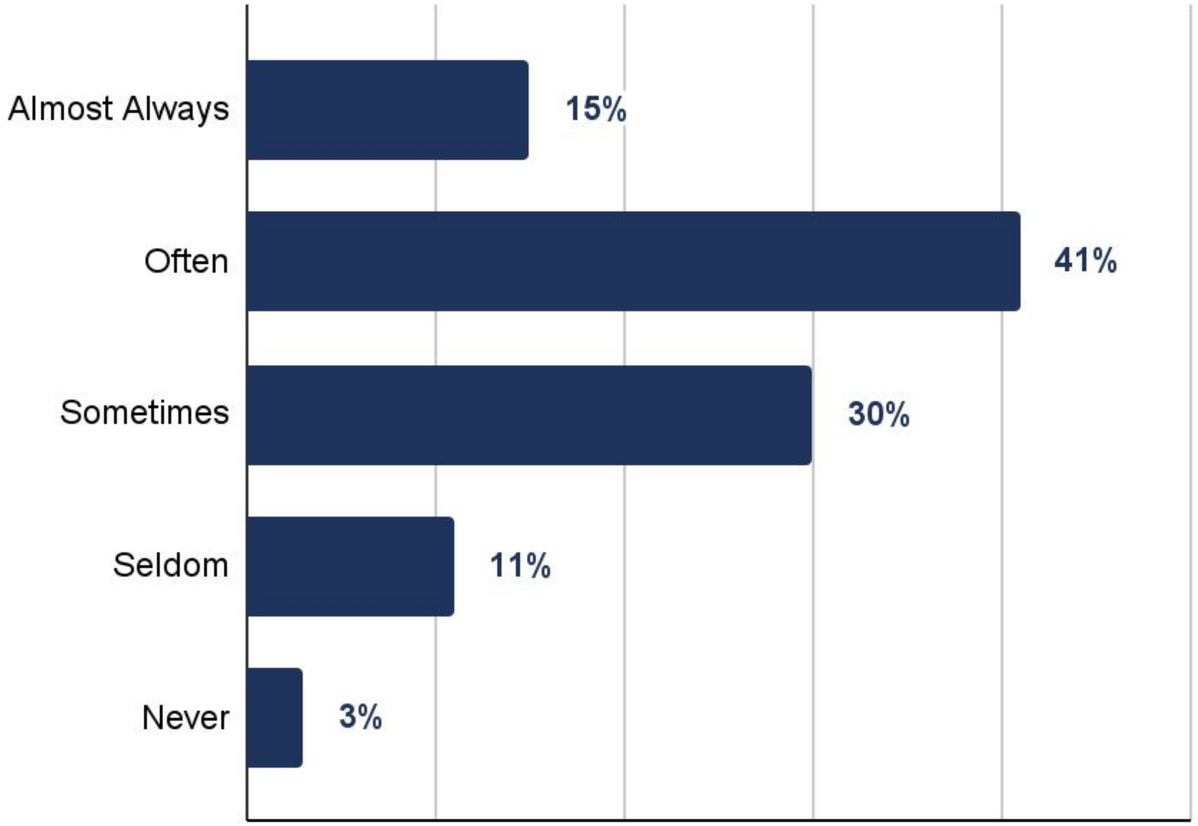




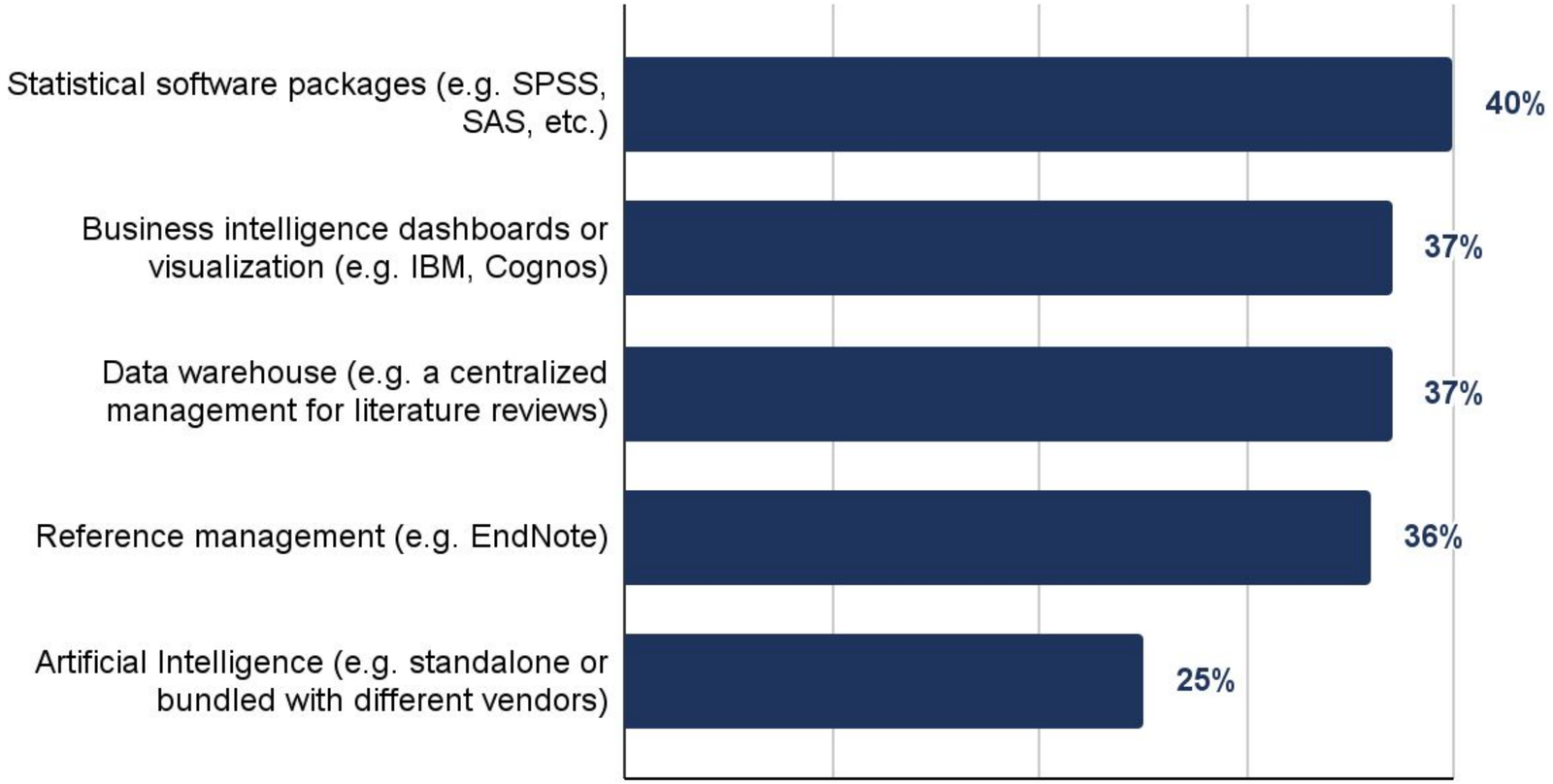
Budget Consideration: Expand Centers of Excellence and Standard Evidence Management Practices Enterprise Wide



Budget Consideration: Expand Training Investment with Standard Evidence Management Practices



Prioritize Budget for Analytics Readiness: Respondents Expect Literature Review Software to Integrate with at Least One Existing Application



Customer Spotlights

Spotlight on Philips

Faster, More Accurate Screening

Philips' clinical evaluation team cut down title and abstract screening by 74%, full-text screening by 70%, and flowcharts/diagrams creation by 50%.

Consistent, Audit-Ready CER Submissions

DistillerSR enabled transparent, consistent literature reviews and reduced the chance for errors and red flags in the auditing process for CER submissions.

More Time to Focus on Research

Since implementing DistillerSR, Philips reported gaining 3 extra days per literature review to focus on research, rather than the mentally-burdensome task of shifting through references.

Spotlight on Geistlich Pharma

Audit-Ready, Traceable CER Submissions

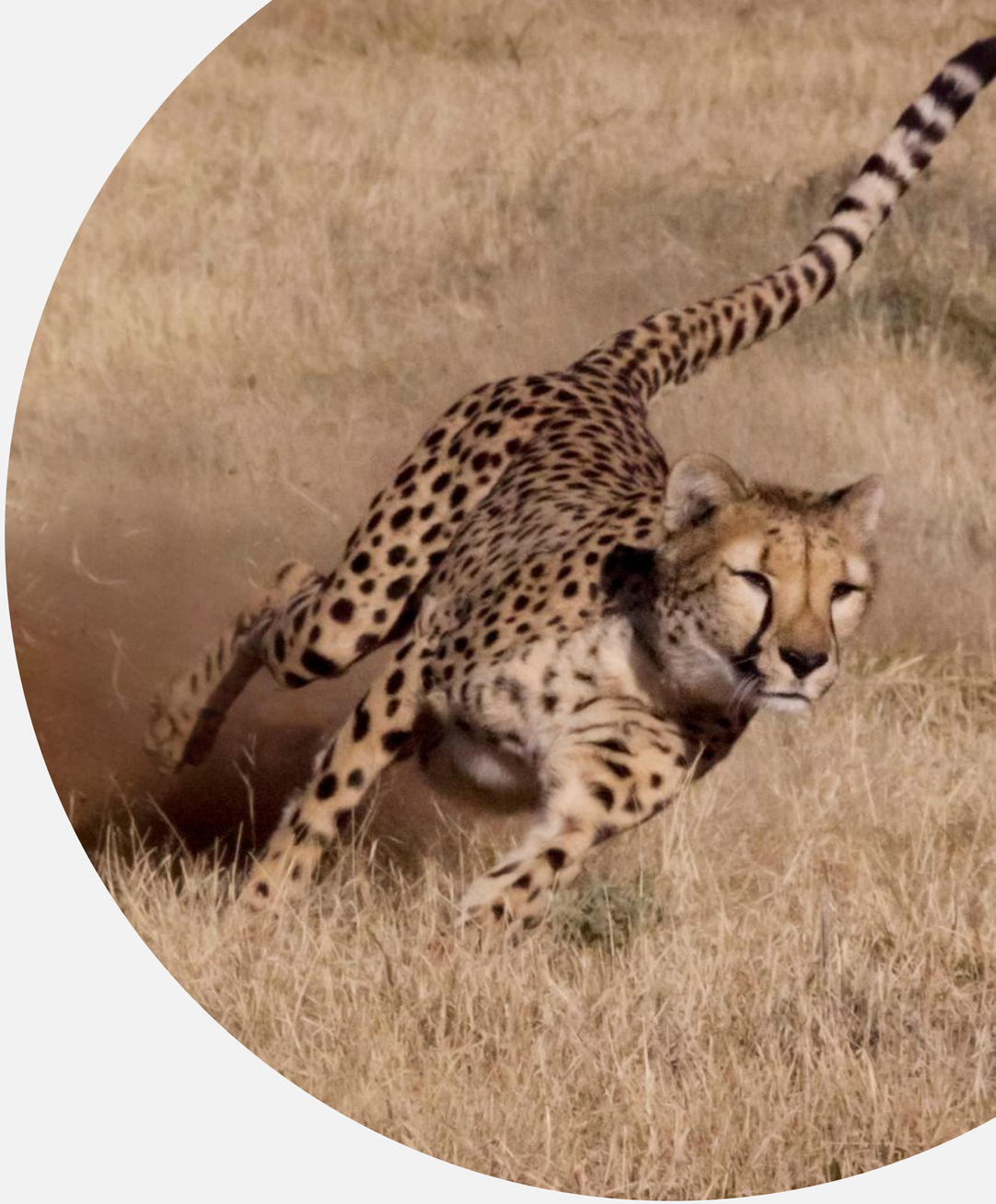
DistillerSR enabled a complete and integrated audit trail ensuring data traceability for all literature reviews, streamlining regulatory submissions.

Faster Literature Review Screening

AI-powered screening prioritized relevant references and dramatically decreased title and abstract screening time by 85% from nearly 4 minutes to 35 seconds per reference.

Repeatable, Configurable Processes

DistillerSR's configurable platform generated custom templates and reusable forms, creating a reproducible literature review management process that can be replicated across a large medical device portfolio.



Spotlight on NuVasive

Consistent, Repeatable Processes

DistillerSR enabled a consistent, repeatable literature review management process that can be replicated across multiple projects.

Audit-Ready CER Submissions

Every literature review conducted in DistillerSR is audit ready, which means every decision is recorded in an audit log throughout the entire review process.

Always Available Data Company Wide

DistillerSR has become a centralized, living archive for every medical device in NuVasive's portfolio. Everyone has access to the data they need, when they need it.

Spotlight on Global Eye Care Device Manufacturer

Faster, More Efficient Screening

Before DistillerSR, the clinical evaluations team completed 15 literature reviews every year. Since implementing the platform, the number raised to 100 reviews annually.

Consistent, Audit-Ready CER Submissions

Project managers can centrally track progress in real-time through a complete and transparent audit trail, simplifying the CER submission process to notified bodies.

Cost Savings and Reduced Errors

By eliminating manual processes from literature review screening, the company dramatically reduced human errors while achieving significant cost savings.

Appendix:
Survey Demographics

Country

Africa	29%
Asia Pacific	35%
Central America & Caribbean	31%
Europe	71%
Middle East	34%
North America	66%
South America	29%

Organization Size

Under 1,000	32%
1,000 - 4,999	21%
5,000 - 9,999	16%
10,000 - 49,999	12%
50,000 or more	20%

Organizational Function

Clinical and/or Evidence-Based Research	32%
Product and Engineering	29%
Quality Assurance	16%
Health Economics	10%
Regulatory Affairs	8%
Market Access	3%

Seniority

Senior executive responsible for clinical evidence and/or regulatory affairs	20%
Literature review and clinical evidence program manager	21%
Individual practitioner responsible for conducting literature reviews	28%
Functional unit area supervisor reporting to the most senior executive	32%

Purchasing Role

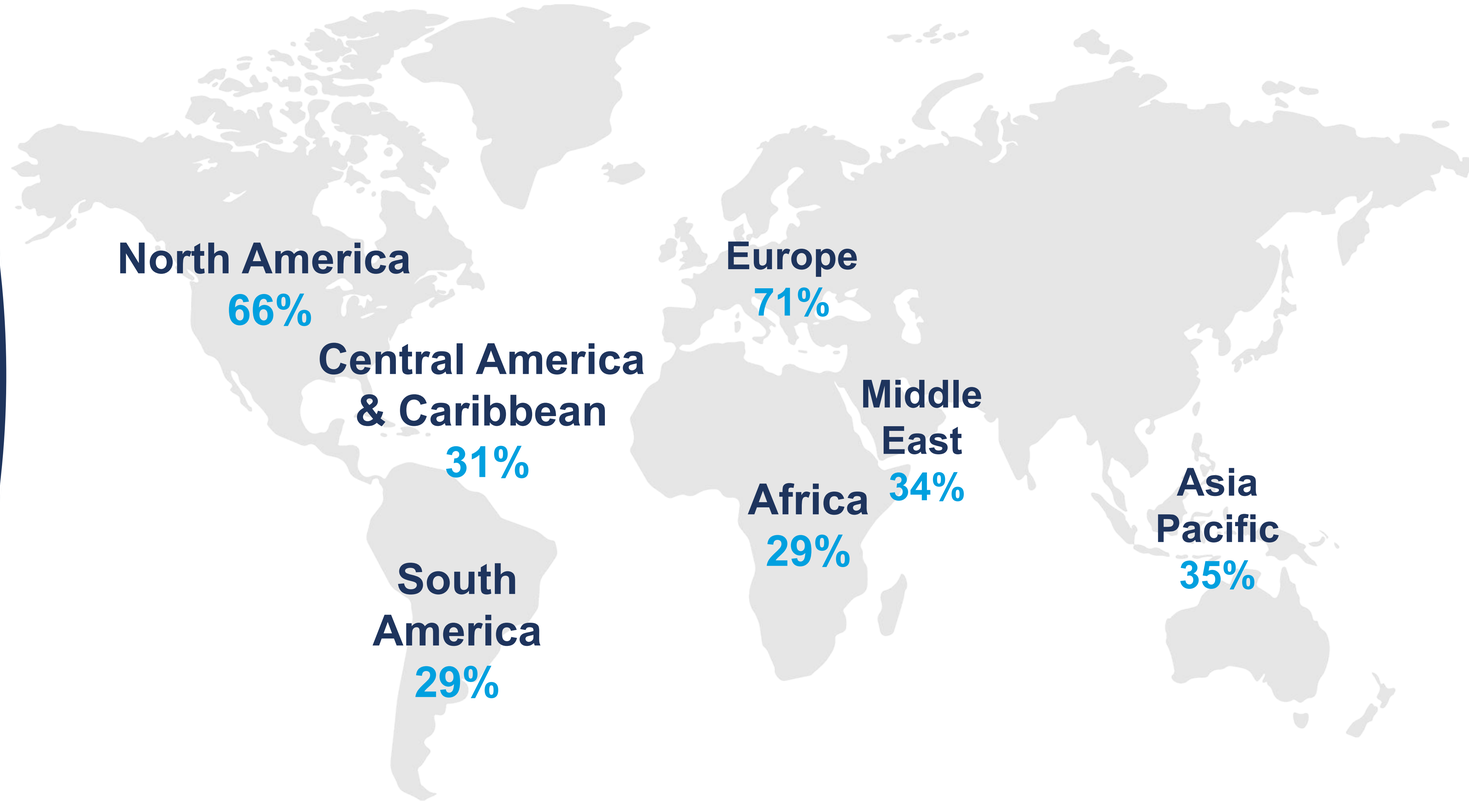
Authorize expenditures	17%
Recommend or select products to purchase	38%
Qualify vendors' products bids/proposals	14%
Influence purchasing decisions	23%
None of the above	8%

Medical Device Segment

Immunology	33%
Cardiovascular	29%
Diabetes Care	23%
Neurological	23%
Gastroenterology	20%
Gynecological	19%
Orthopedic	19%
Hematology	18%
Diagnostic Imaging	18%

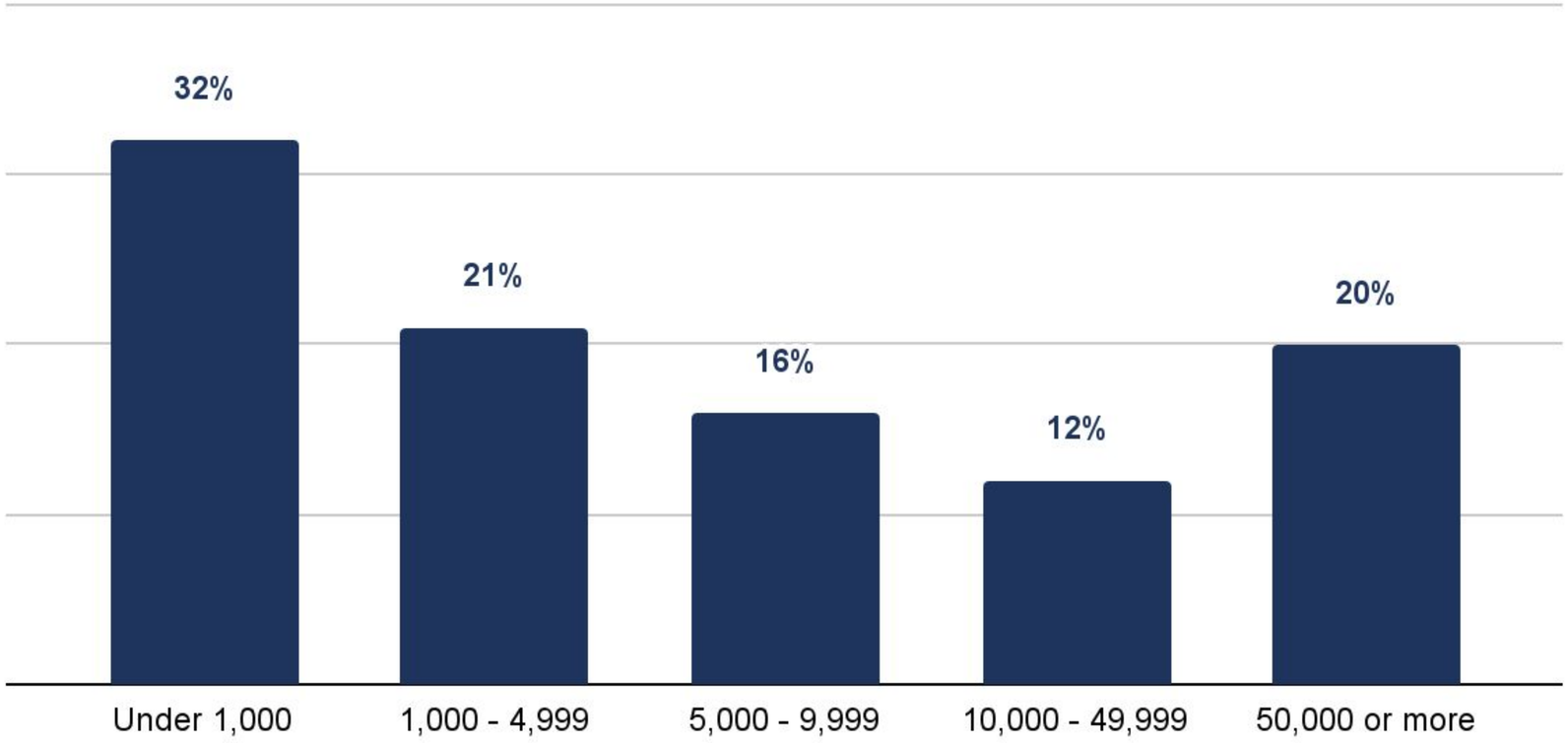
Demographics

The sample included manufacturers operating across all regions of the globe but predominantly in Europe and North America.



Organization Size

Small organizations (under 1,000 employees) account for a third (32%) of the sample, while organizations (50,000+ employees) account for a fifth (20%).

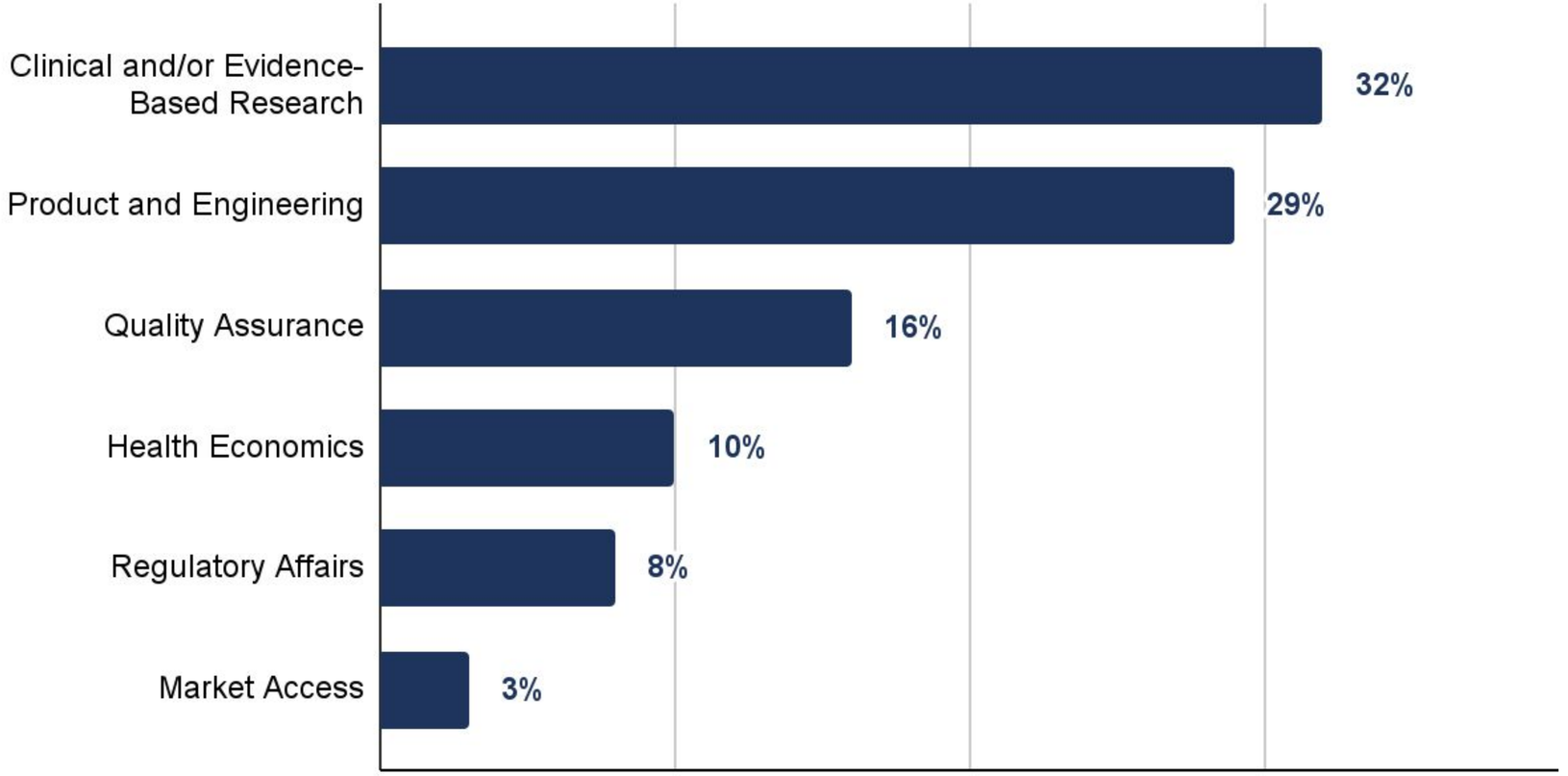


32%

Under 1,000 has the highest employee representation

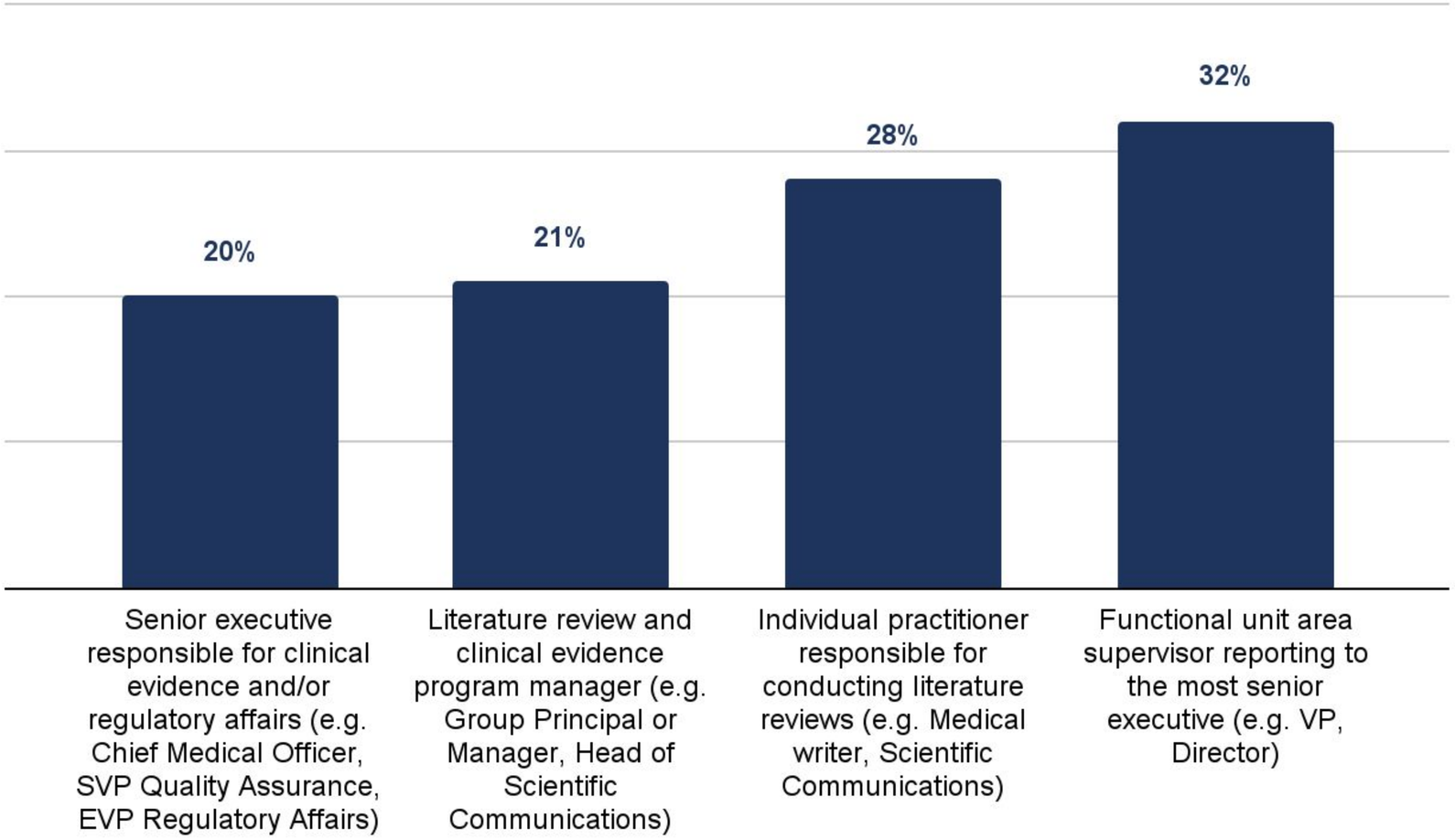
Organization Function

A variety of organization functions are represented in the sample, most commonly Clinical and/or Evidence-Based Research (32%) and Product and Engineering (29%).



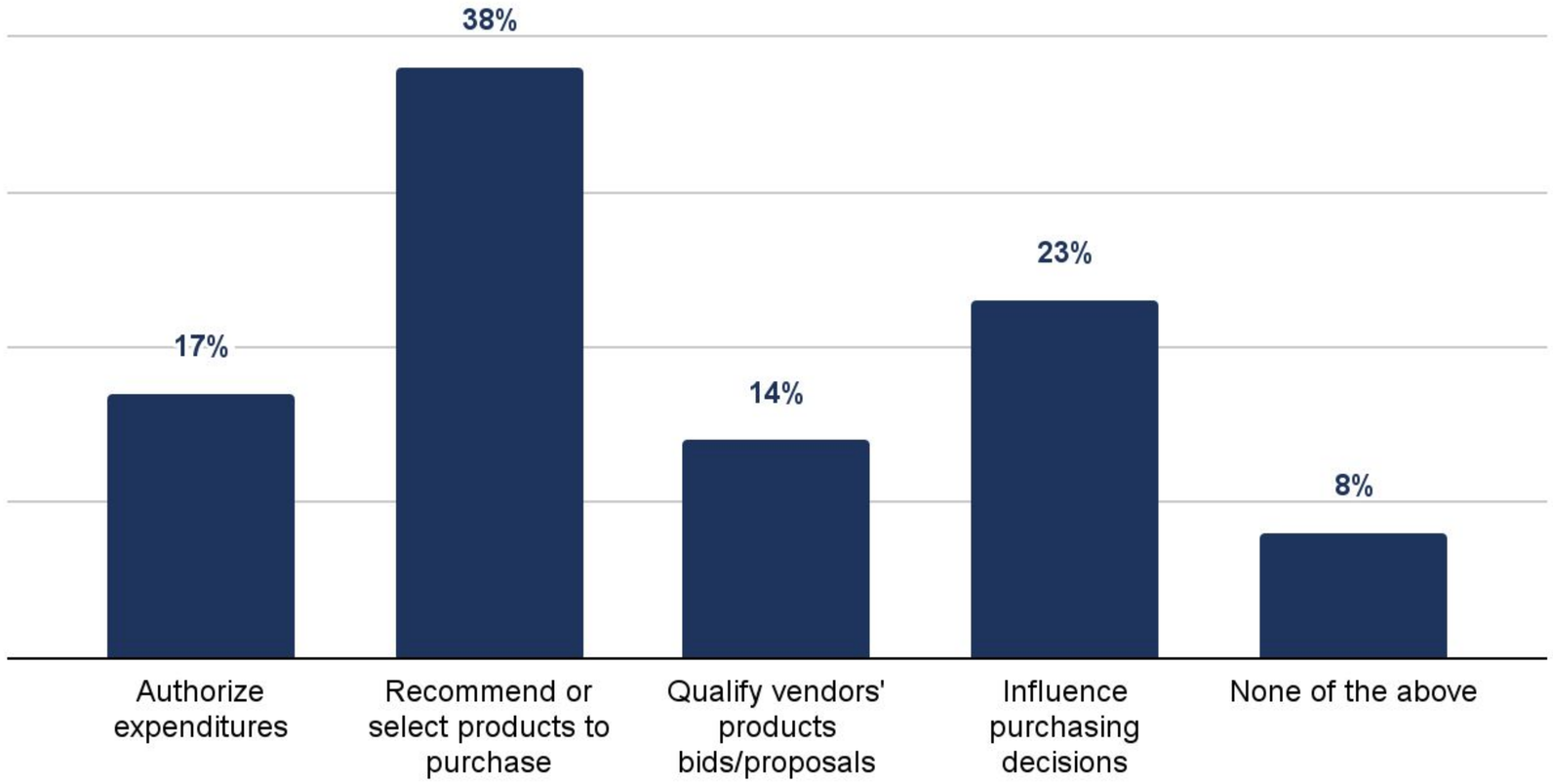
Level of Seniority

Functional unit area supervisors account for just under a third (32%) of the sample, followed by individual practitioners (28%).



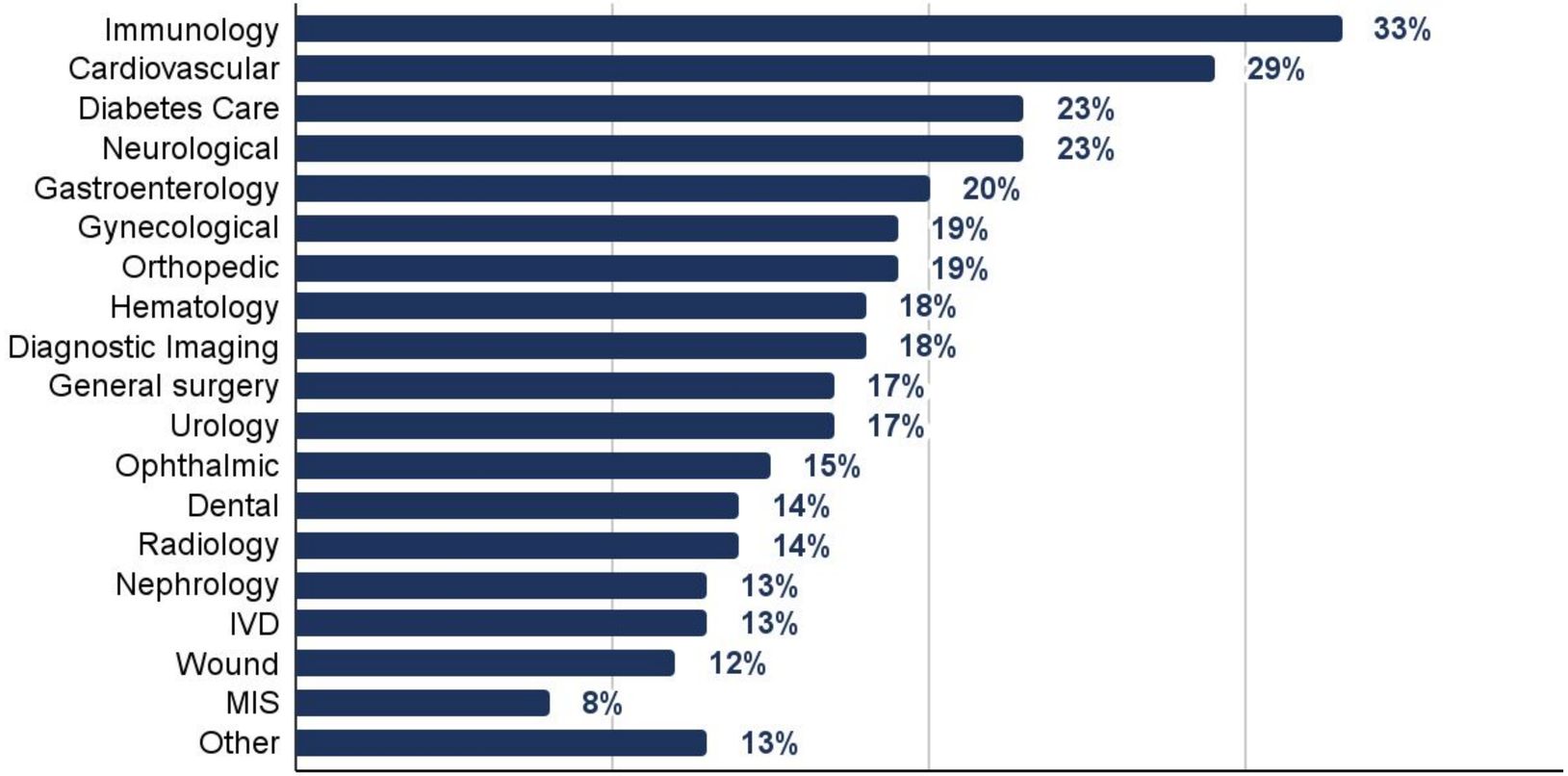
Purchasing Role

Purchase recommenders/selectors account for over a third (38%) of the sample, while authorizers account for just under a fifth (17%).



Medical Device Segment

A variety of medical device segment areas are represented in the sample, most commonly Immunology (33%) and Cardiovascular (29%).



33%

Immunology has the highest representation

Toll free: (844) 622-8727
505 March Road, Suite 450
Ottawa, Ontario, Canada, K2K 3A4
distillersr.com