

2021 Oracle Artificial Intelligence/Machine Learning Survey Report

February 2021

Introduction

The Oracle Artificial Intelligence/Machine Learning Survey conducted by WCG CenterWatch was initiated in the fourth quarter of 2020 to evaluate the clinical trials industry's attitudes toward and plans for using AI/ML. Respondents were asked to indicate their level of experience with the technologies – business understanding, technical understanding, a combination of the two or no understanding.

Executive Summary

Experience

When asked to indicate their level of experience with AI/ML, 41% said “no understanding,” a response that shows a need for more education and awareness around the topic.

The next largest group to the “no understanding” group included those who said they had a “business understanding” of AI/ML at 26%. Respondents who said they had “technical understanding” of the topics and a combination of both business and technical understanding were nearly even at 16% and 17%, respectively.

Only respondents who indicated they had some level of understanding of the topics were asked to answer subsequent survey questions about the benefits, prerequisites, uses, challenges and implementation of AI/ML. However, survey questions about the impact of AI/ML on eight different characteristics of trial operations included the entire pool of respondents – both those who said they had no understanding and those who said they had some level of experience with the technologies.

Executive Summary (continued)

Benefits

A substantial number of respondents (62%) indicated that increased trial speed was the top benefit of AI/ML; 65% of those with business understanding put speed at the top of the list. Improved quality came in second at 50%.

Reduced cost was the top choice among 54% of respondents with both business and technical understanding. Increased innovation and increased safety were most popular among the technical understanding group at 50% and 44%, respectively.

“Other” responses to the benefits question included better representation of rural regions (telemedicine), greater efficiency in meeting trial participation efforts for patients and sites, identifying trends, easing inclusion, better and quicker aggregation of trial outcomes and results, and advancements in data collection.

Ways of Using AI/ML

While 17% said they were not currently using AI/ML (the top answer), 16% said they were using it for data management. Regulatory/IRB approval came in at the bottom of the list at 7%, tying with central and local testing.

Prerequisites

Asked what the most important characteristics needed to use AI/ML successfully were, quality data topped the list for all respondents at 23%. Availability of staff with technical knowledge came in a close second at 22%. Availability of real-time data came in third at 16%.

Executive Summary (continued)

Challenges

Lack of knowledge was the most important challenge to adopting AI/ML at 21%, followed by funding at 17% and changes in procedures and systems at 17%. Not surprisingly, 20% of respondents who said they had a business understanding of AI/ML ranked funding as the top challenge. Changes in procedures and systems came in third overall at 17%, although 20% of respondents with technical understanding of AI/ML ranked it as the top challenge. Unclear regulatory acceptance ranked fourth overall with 16% of all respondents but was ranked as the No. 2 challenge among respondents with technical understanding at 18%.

Implementation

The largest number of respondents, 39%, said they planned to implement AI/ML through in-house initiatives, followed by strategic partnerships with 26% of all respondents. Vendors and industry collaborations came in at the bottom of the ranking at 14% and 13%, respectively.

Impact of AI/ML

Faster site activation was cited as AI/ML's most positive impact by 40% of all respondents, although respondents with both business and technical understanding of the topics (76%) rated that the highest. Reduced risk came in second overall at 32%. As for negative impact, 57% of respondents expected AI/ML to lead to an increase in system complexity. Few respondents overall (7%) expected AI/ML to have a negative impact on trial staff levels.

Executive Summary (continued)

Conclusion

Although the three different level of understanding groups provided similar responses in most cases, there were some clear standouts in each of the groups. Respondents in the technical understanding group said they primarily use AI/ML for trial and document management. They also found increased innovation to be its biggest benefit and expressed the most concern about system changes.

Respondents with business understanding focused mostly on the benefit of increased speed and were most concerned about the cost of the technology.

Respondents with a combination of business and technical understanding valued the promise of increased speed and improved quality most highly, expected more changes in patient engagement and loyalty, and were most concerned about lack of institutional knowledge and technical capabilities.

All three groups, however, agreed that increased trial speed and improved quality would be the most valuable outcomes of using AI/ML.

Survey Methodology

Survey period: Oct. 27 to Dec. 16, 2020

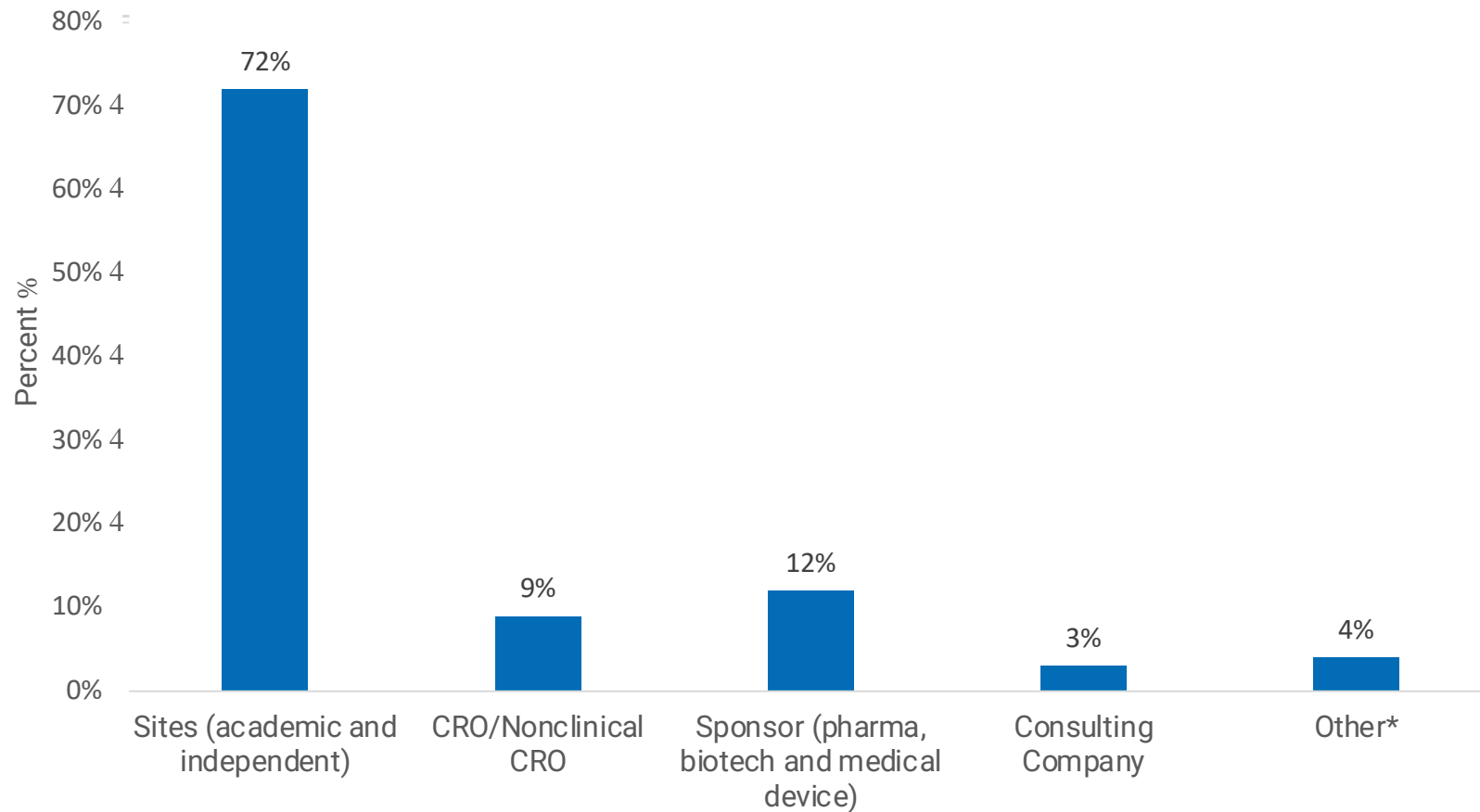
Number of responses: 311

Respondents by type: Sites (academic and independent), 72%; sponsors, 12%; CROs and nonclinical CROs, 9%; consulting companies, 3%; other, 4% (including software provider, nonprofit organization, market research organization, data analytics provider and government entity).

Respondents by functional area of responsibility: Clinical operations, 43%; senior management, 12%; regulatory, 8%; quality, 7%; data management, 6%; medical affairs, 6%; information technology/management, 3%; pharmacovigilance, 1%; statistical sciences, 1%; other, 12% (including study/site coordination or management, regulatory or compliance, contracting, financial management, facilities, business development and outsourcing).

Section 1 – Respondent Profile

Respondents by Type of Organization .



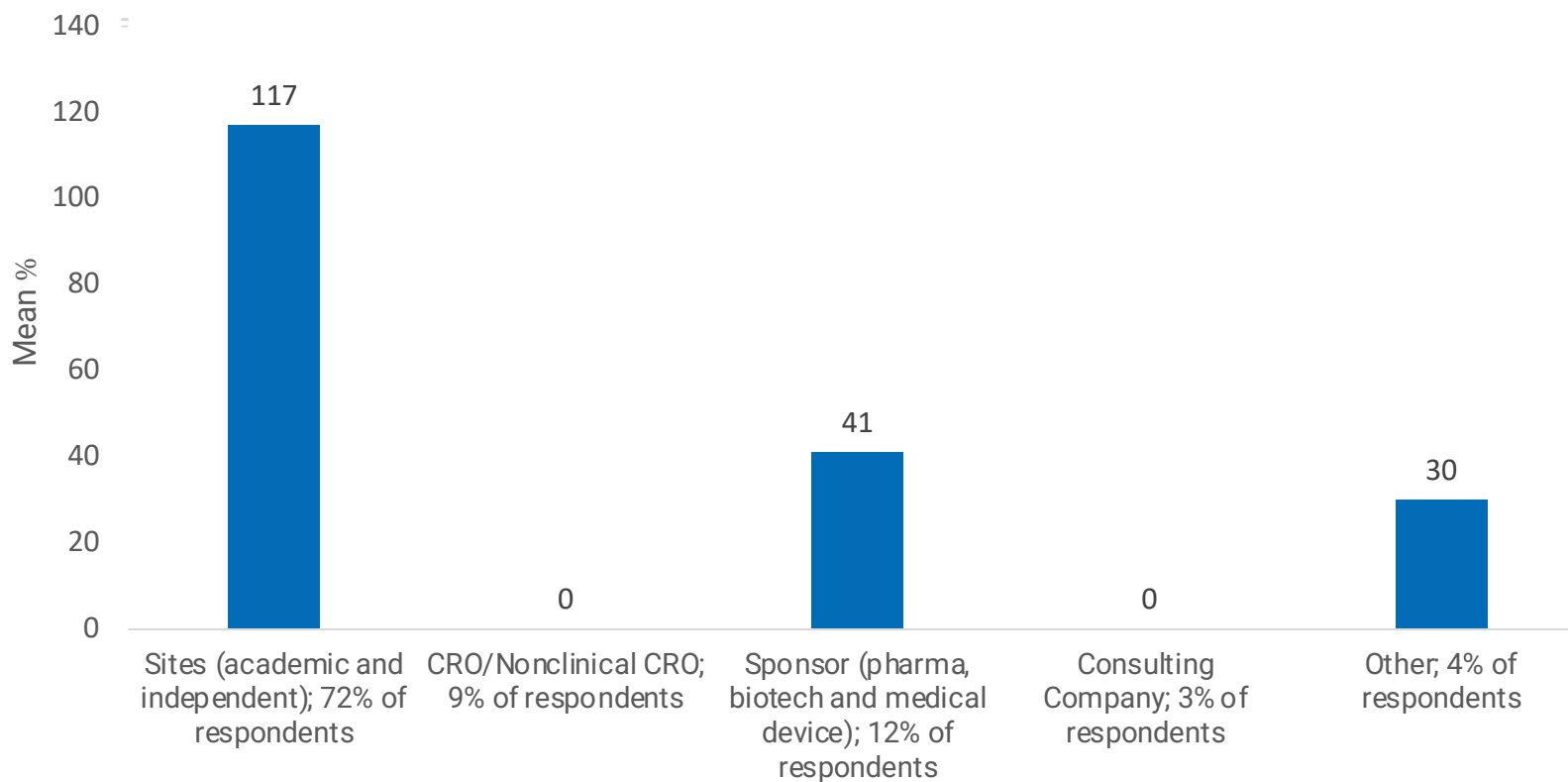
*Other types of organizations responding included software provider, nonprofit organization, market research organization, * data analytics provider and government entity. *

Sample size: Total (n= 311)

Sites (academic and independent) (n= 224), CRO/Nonclinical CRO (n= 28), Sponsor (pharma, biotech and medical device) (n= 36), Consulting Company (n= 11), Other (n= 12) *

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Mean Number of Trials Sponsored in 2020, by Type of Organization



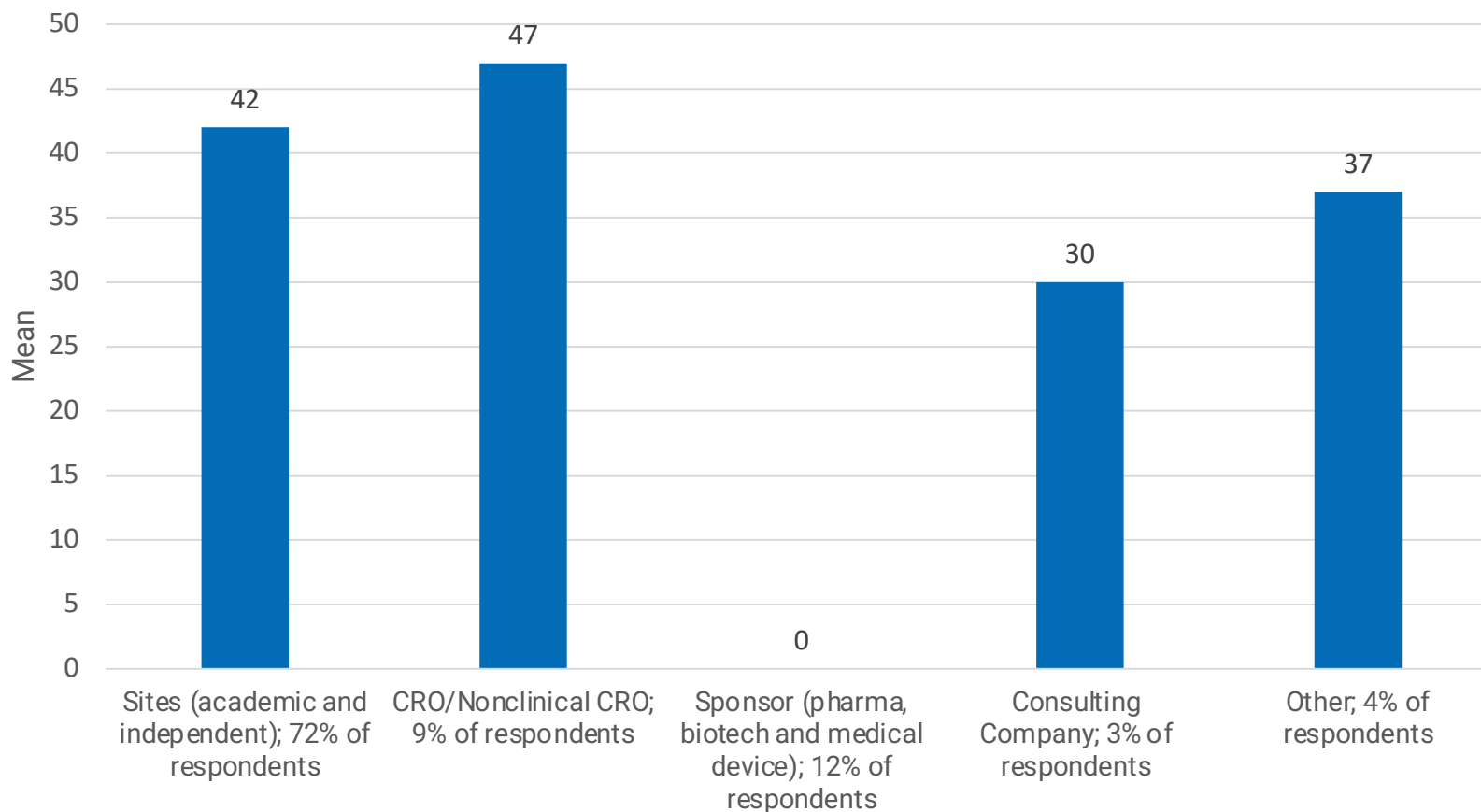
Note: 53 site respondents indicated that they sponsored trials in 2020, which likely is a misinterpretation of the original * question. *

Sample size: Total (n= 84) *

Sites (academic and independent) (n= 53), CRO/Nonclinical CRO (n= 0), Sponsor (pharma, biotech and medical device) (n= 30), Consulting Company (n= 0), Other (n= 1) *

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Mean Number of Trials Conducted in 2020, by Type of Organization

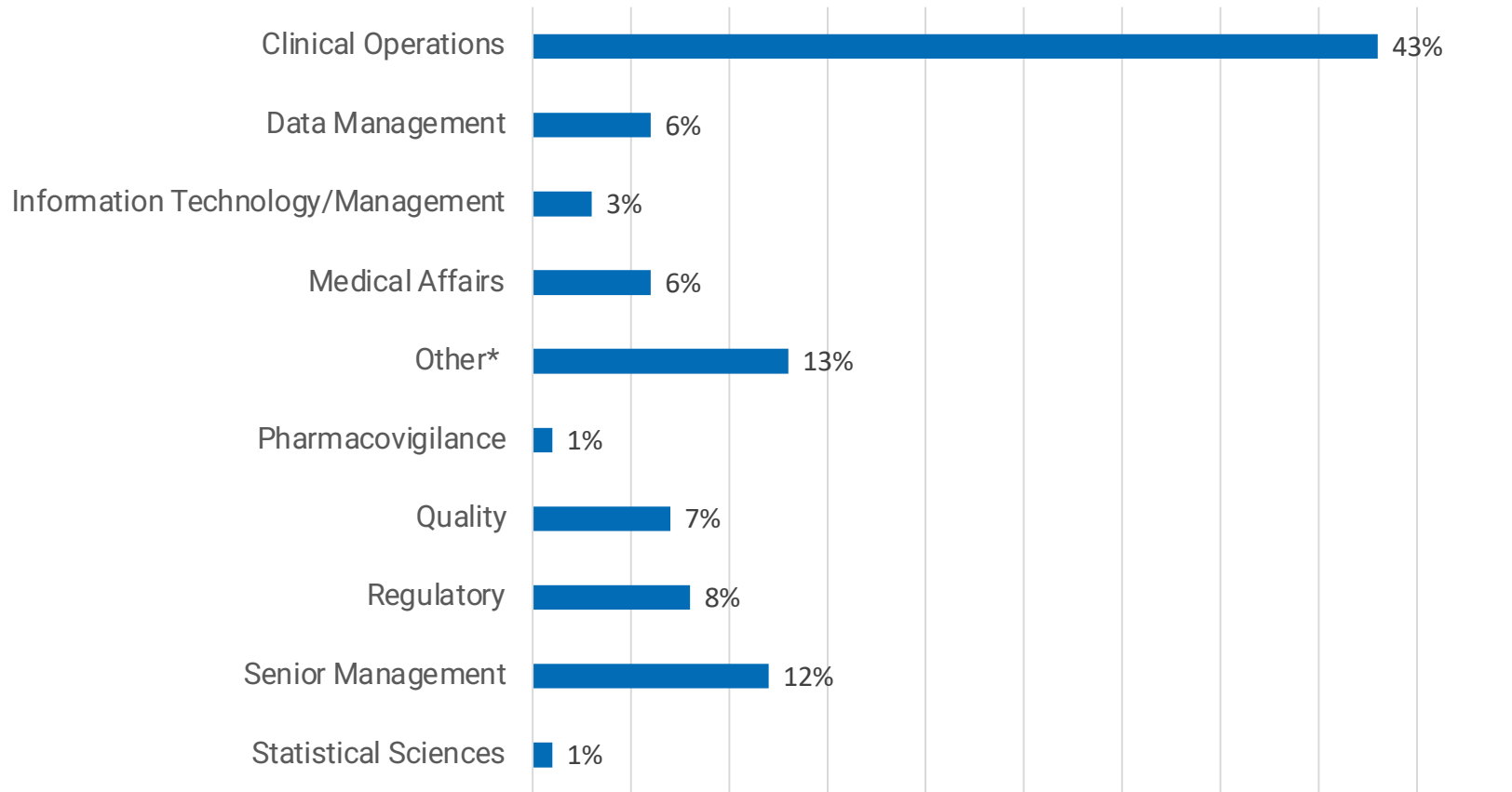


Sample size: Total (n= 163)

Sites (academic and independent) (n= 128), CRO/Nonclinical CRO (n= 18), Sponsor (pharma, biotech and medical device) (n= 0), Consulting Company (n= 8), Other (n= 9)

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Respondents by Functional Area of Responsibility

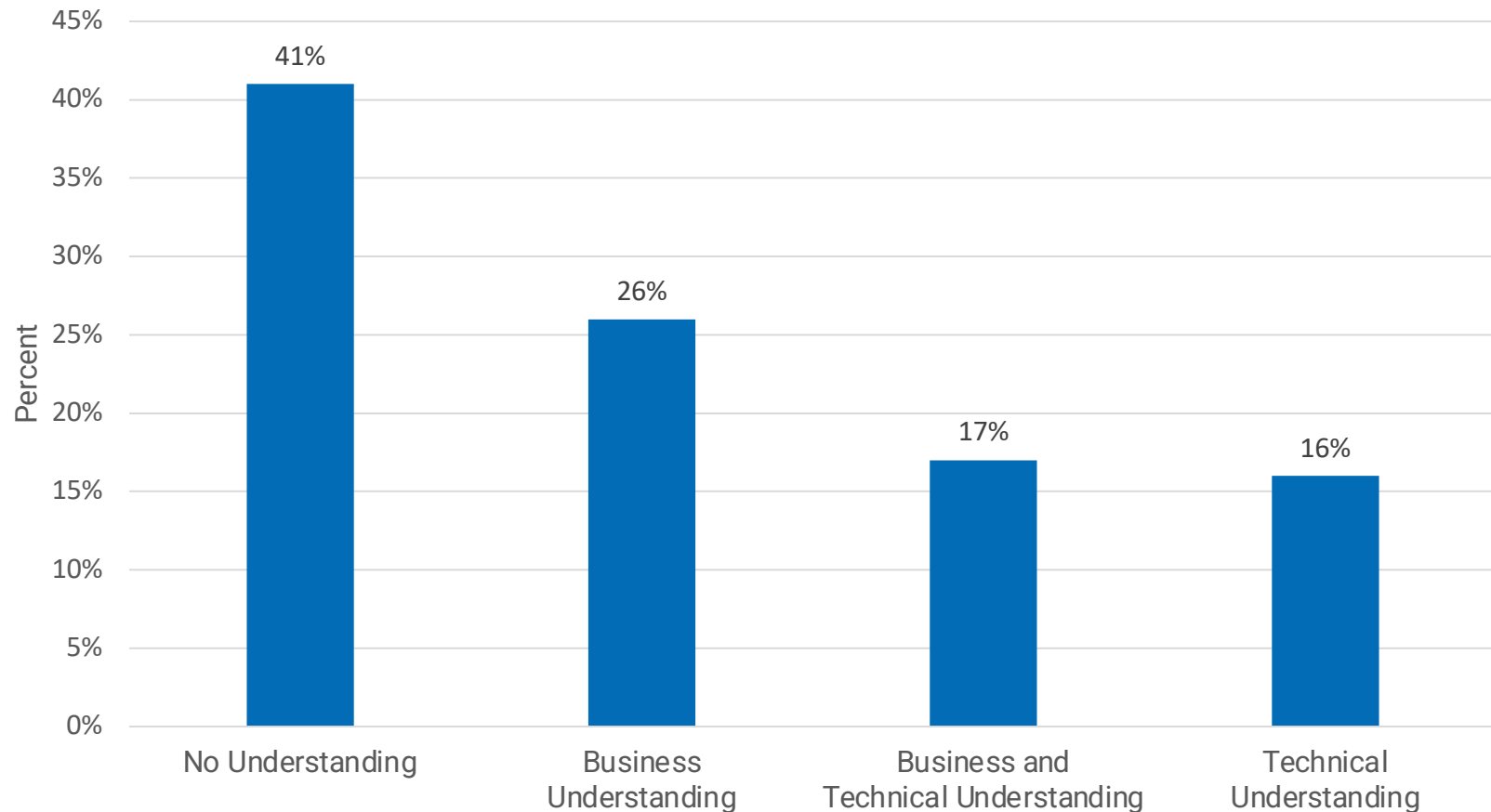


*Other areas of responsibility respondents cited included study/site coordination or management, regulatory or compliance, contracting, financial management, facilities, business development and outsourcing.

Sample size: Total (n= 242)

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Respondents' Level of Experience with Machine Learning



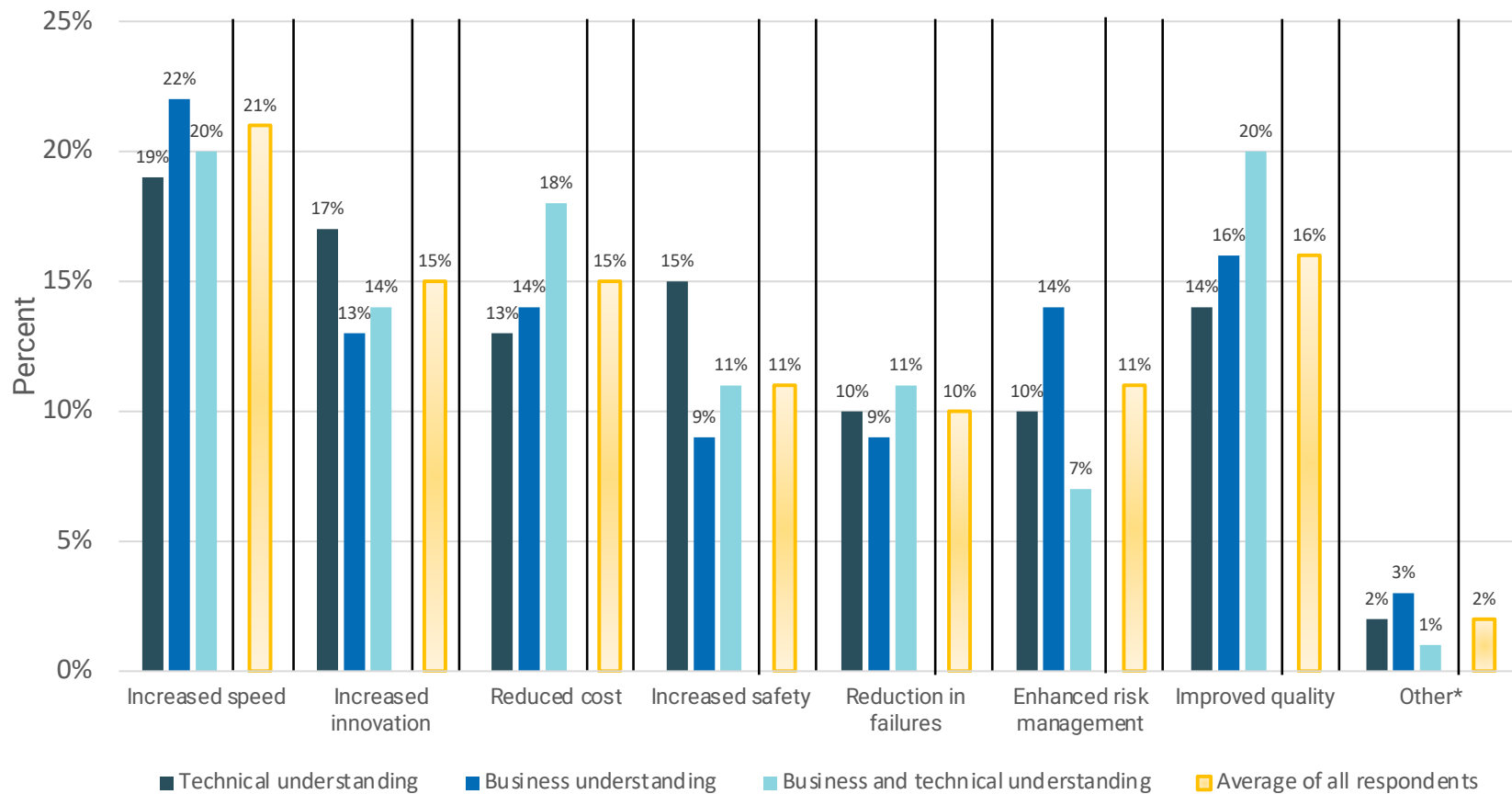
Sample size: Total (n= 242)

Business Understanding (n= 63), Technical Understanding (n= 38), Business and Technical Understanding (n= 42), No Understanding (n= 99)

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Section 2 – Survey Results

Question 1: What are the top three benefits you think machine learning will have on clinical trials in the next 10 years?



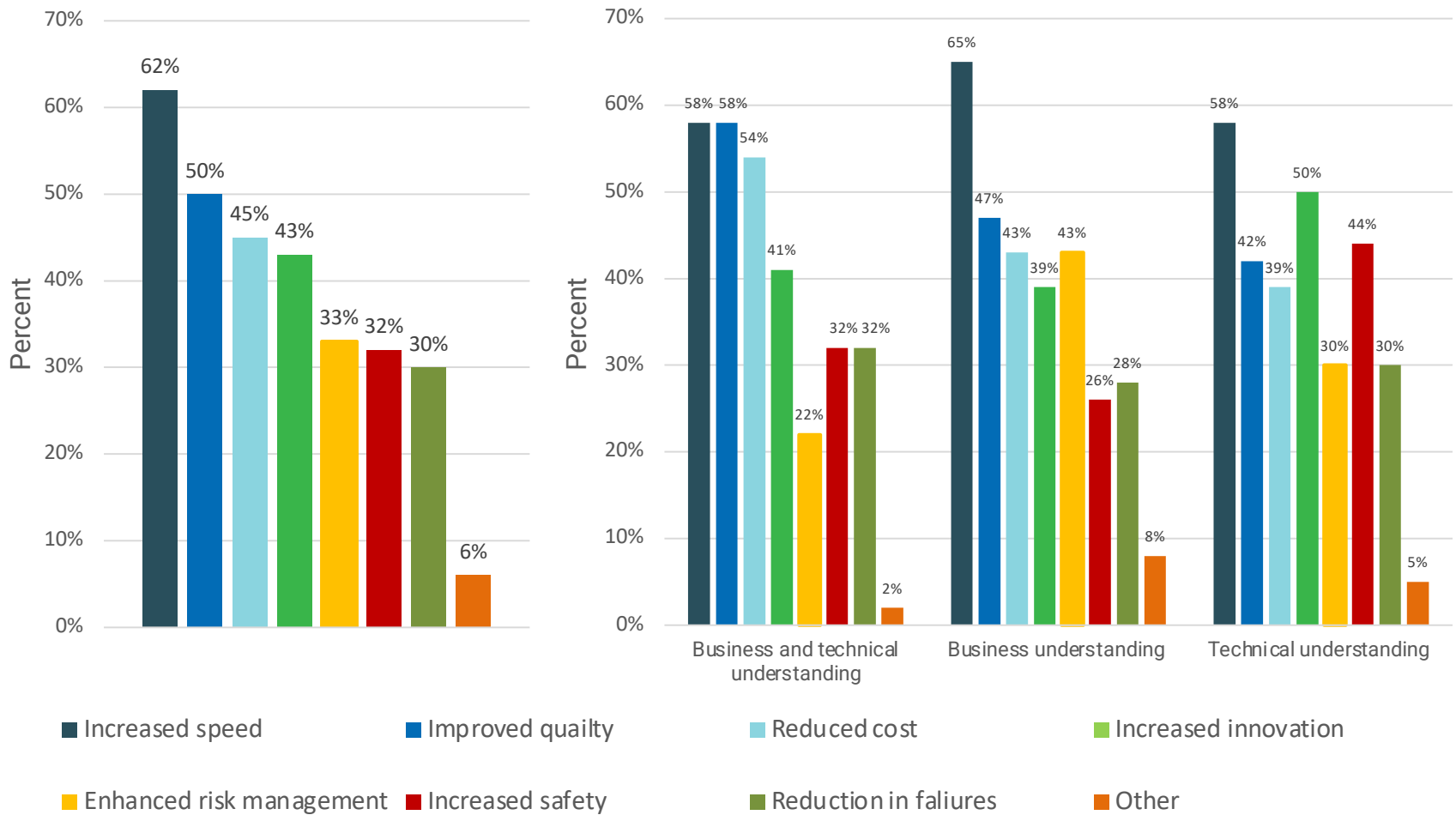
*Other responses included better representation of rural regions (telemedicine), greater efficiency in meeting trial participation efforts for patients and sites, identifying trends, easing inclusion, better aggregation of patient-reported outcomes and all outcomes and results more quickly, and advancements in data collection.

Note: The 41 percent of respondents who indicated they have “No Understanding” of machine learning did not answer questions 1 through 5.

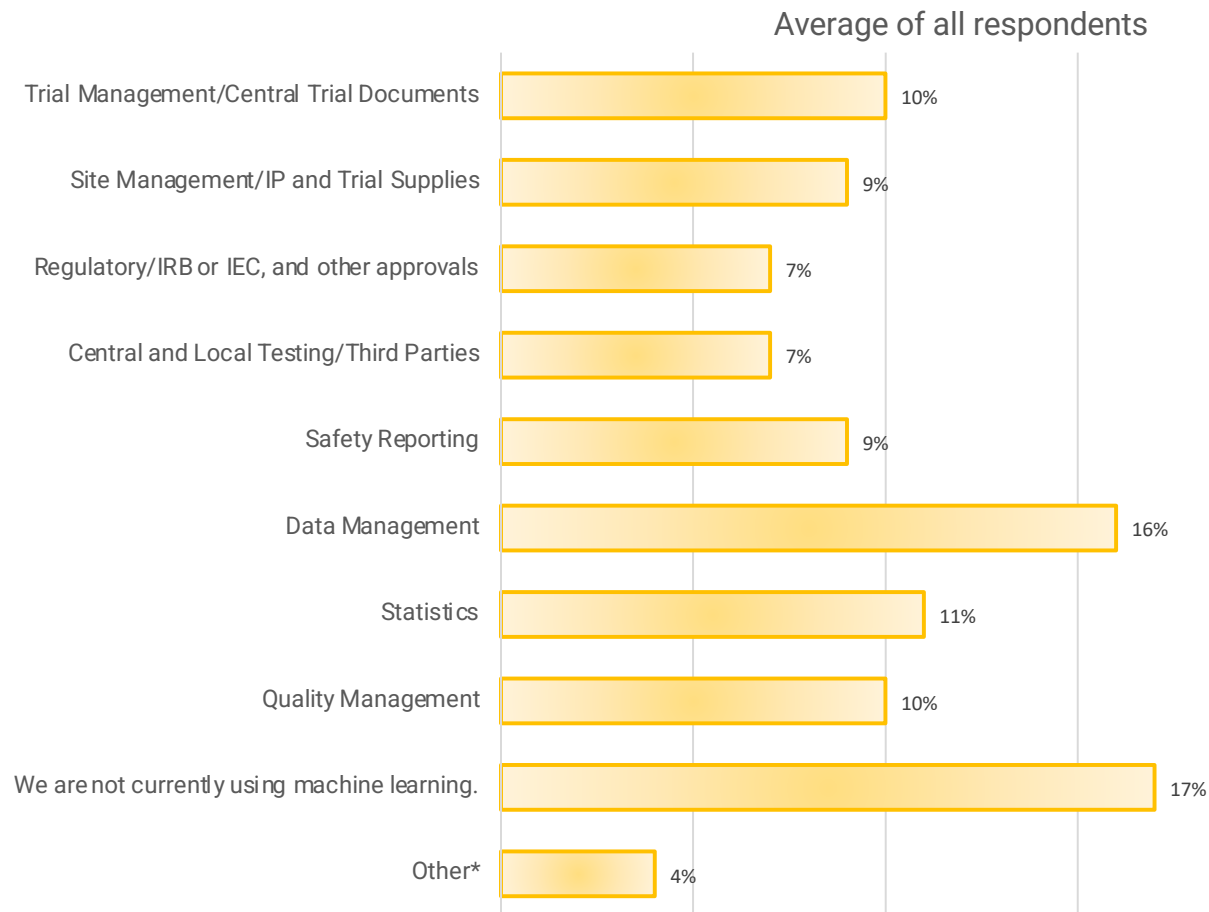
Sample size: Total (n= 143)

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What are the top benefits you think machine learning will have on clinical trials in the next 10 years (select top three)?



Question 2: In what areas are you using machine learning?



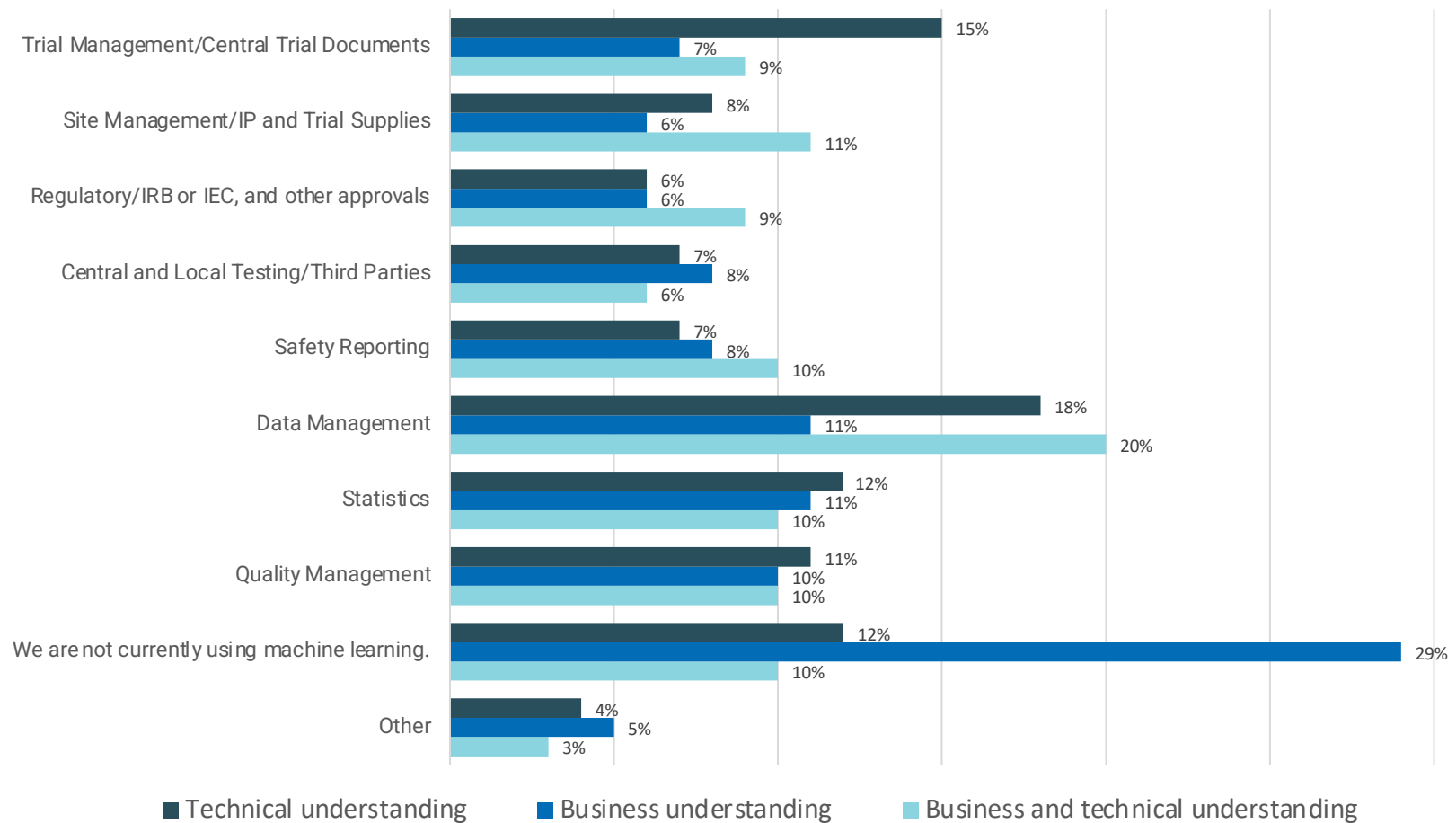
*Other responses included patient identification, research on predictive analytics, labs and conducting industrywide discussions.

Note: The 41 percent of respondents who indicated they have "No Understanding" of machine learning did not answer questions 1 through 5.

Sample size: Total (n= 143)

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Question 2 (cont.): Uses of Machine Learning by Respondents' Level of Understanding

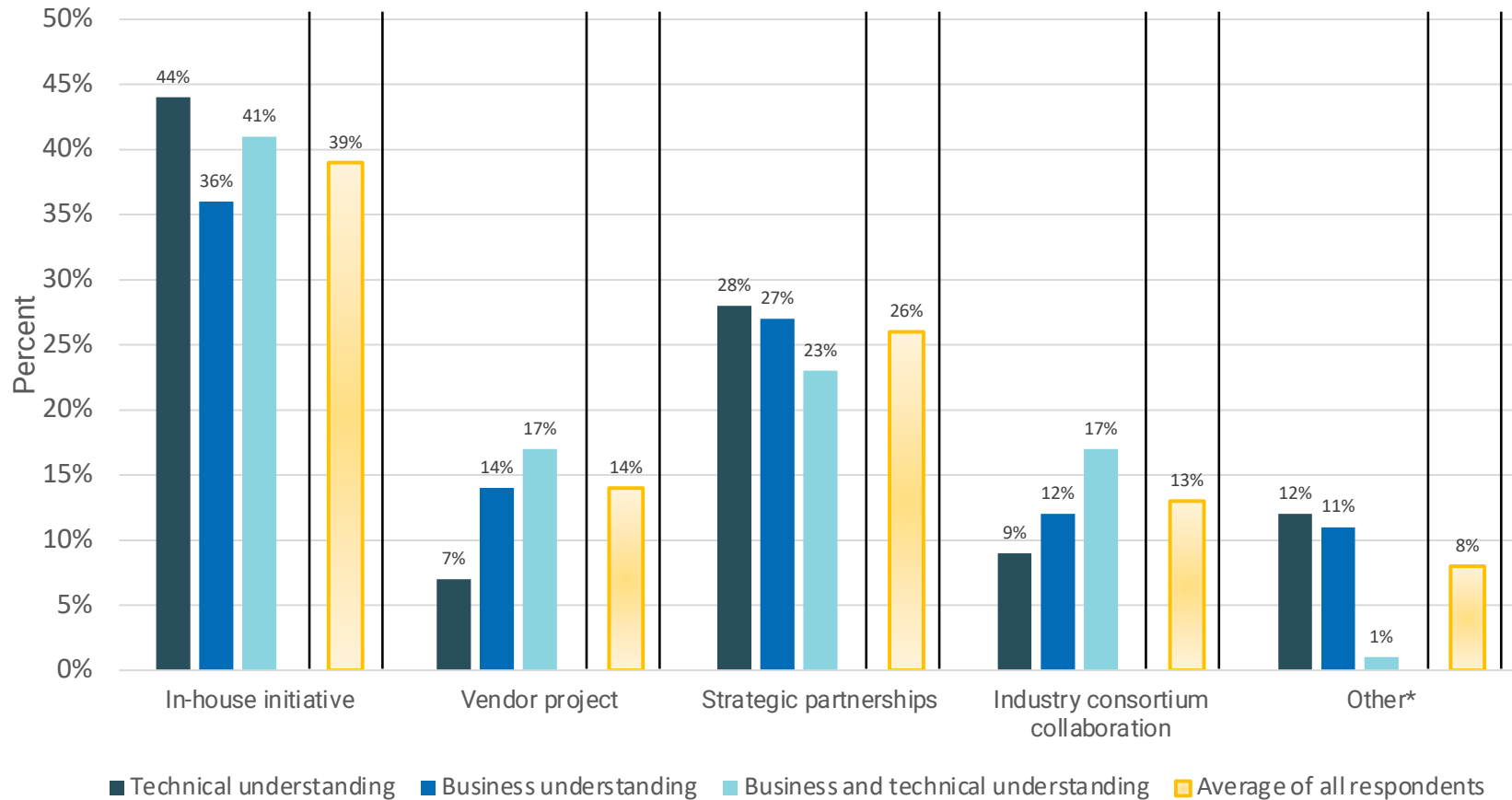


Note: The 41 percent of respondents who indicated they have “No Understanding” of machine learning did not answer questions 1 through 5.

Sample size: Total (n= 143)

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Question 3: How have you implemented or are planning to implement your machine learning capabilities?



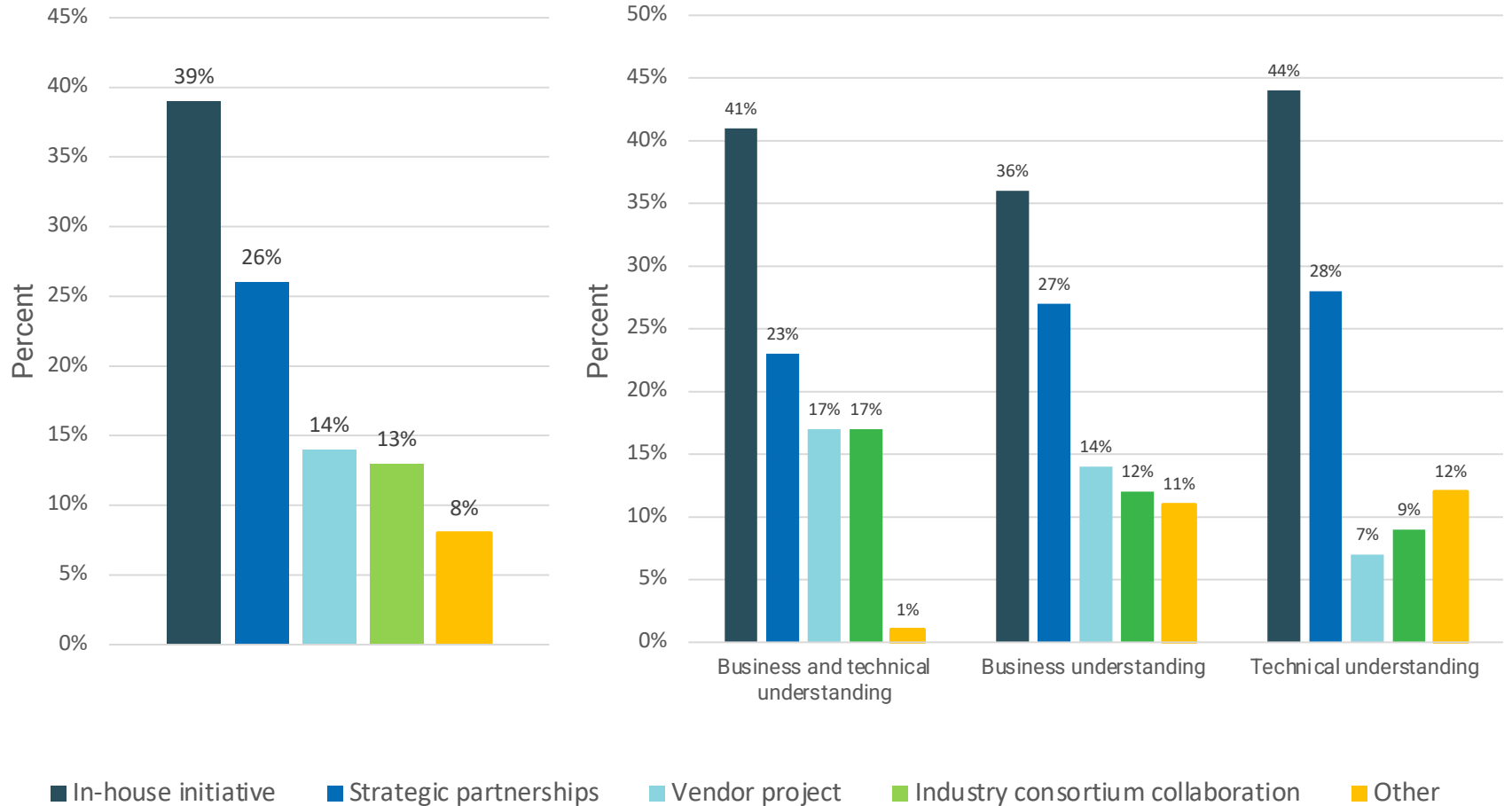
*Other responses included none, not implementing and “I don’t know.”

Note: The 41 percent of respondents who indicated they have “No Understanding” of machine learning did not answer questions 1 through 5.

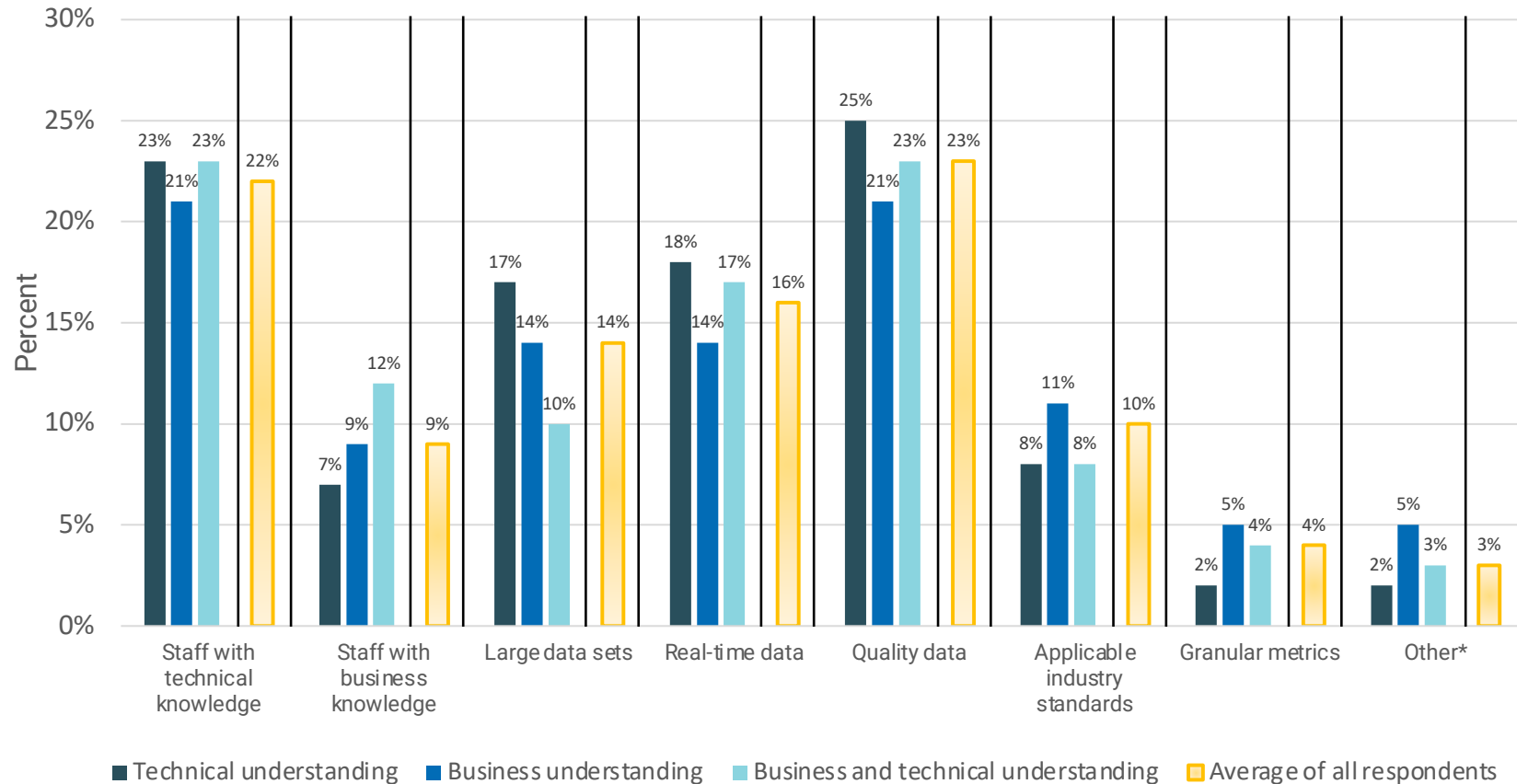
Sample size: Total (n= 143)

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How have you implemented or are planning to implement your machine learning capabilities? (select all that apply)



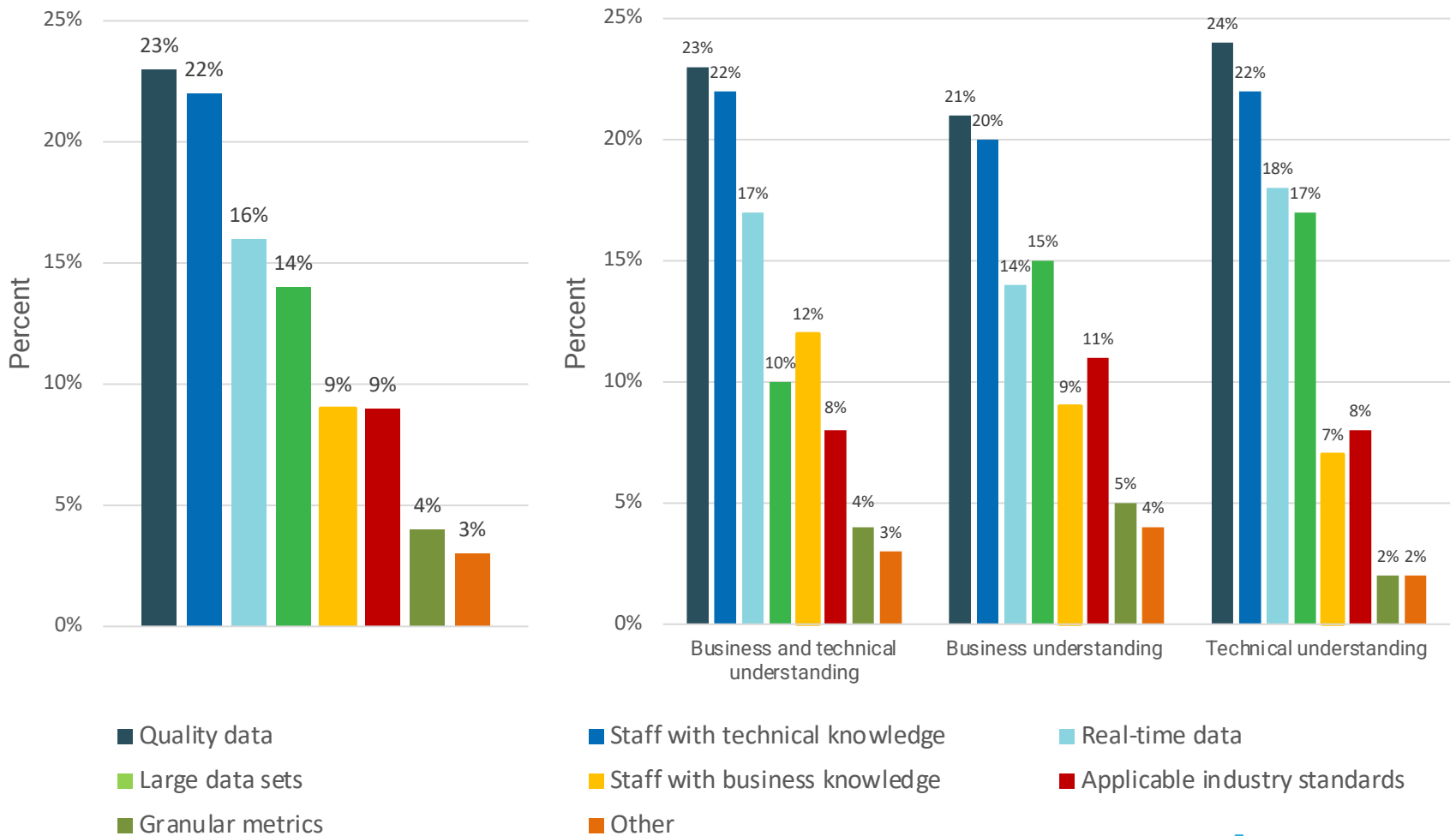
Question 4: In your opinion, what are the three most important prerequisites for making machine learning a reality?



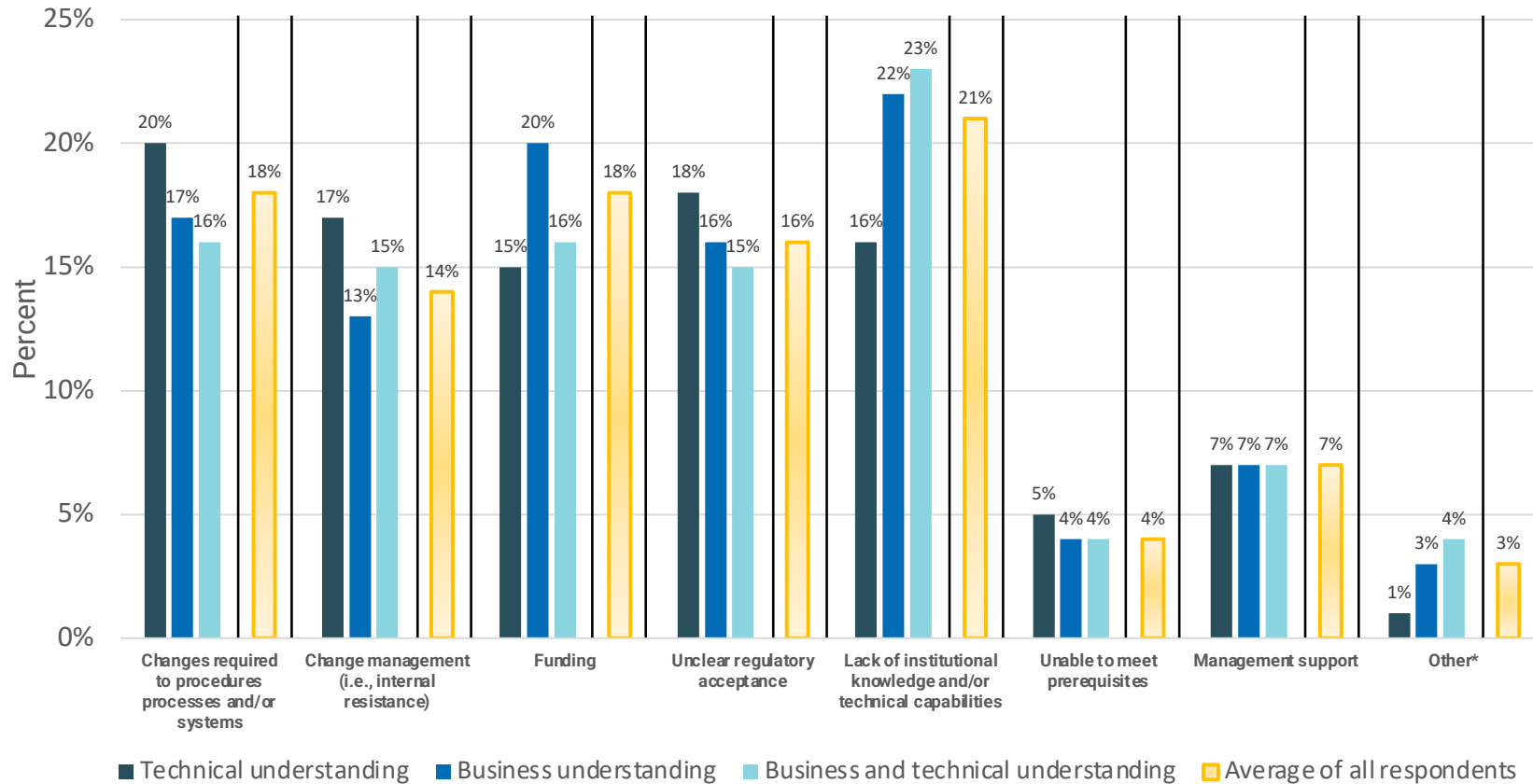
*Respondents with technical understanding cited cost and collaboration. Respondents with business understanding cited granular business use cases to test the technology, regulators' blessing, compatibility with current software systems, investing in the database infrastructure and programs, safety, focus on user interface design, subject matter expertise in therapeutic areas partnered with technical knowledge of how to normalize volumes of qualitative data, and ethical principles. Respondents with both business and technical understanding cited willingness of early adopters to understand and apply the potential benefits of AI and ML in clinical research, broad multicenter collaborations, and data and privacy security.

Note: The 41 percent of respondents who indicated they have "No Understanding" of machine learning did not answer questions 1 through 5.
 Sample size: Total (n= 143)

In your opinion, what are the most important prerequisites for making machine learning a reality? (select top three)



Question 5: In your opinion, what are the three biggest challenges facing the adoption of machine learning?

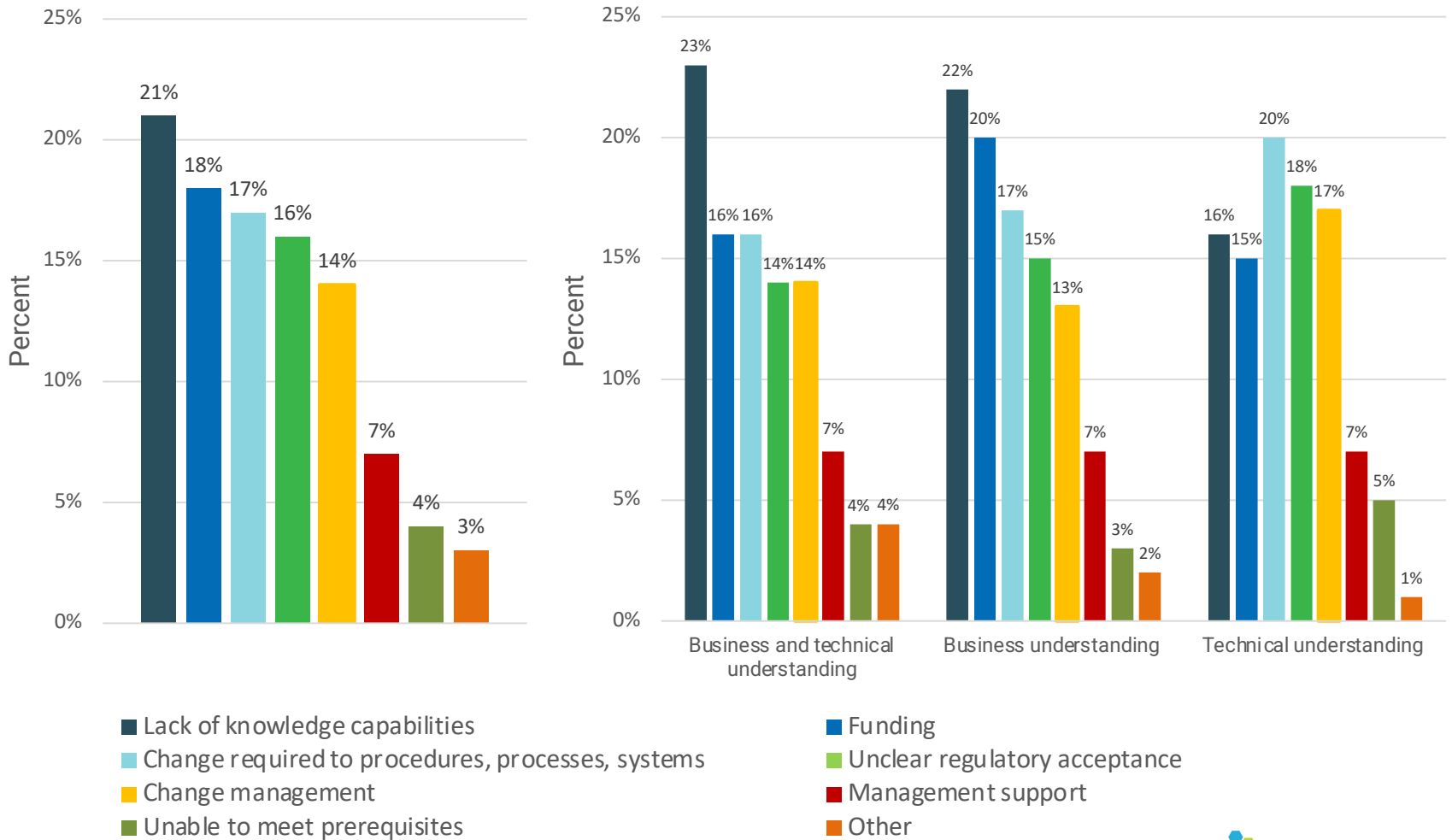


*Respondents with business understanding cited taking into account human factors, commercialization of sites causing reduced quality of data management, unclear methods for detecting and correcting AI errors and biases and effective comparators for its conclusions, generalizability and validation standards. Respondents with business and technical understanding cited the need for planning, resistance from individuals – both direct users and management, unproven value proposition, IT security and institutional HIPAA compliance, and lack of IT skills.

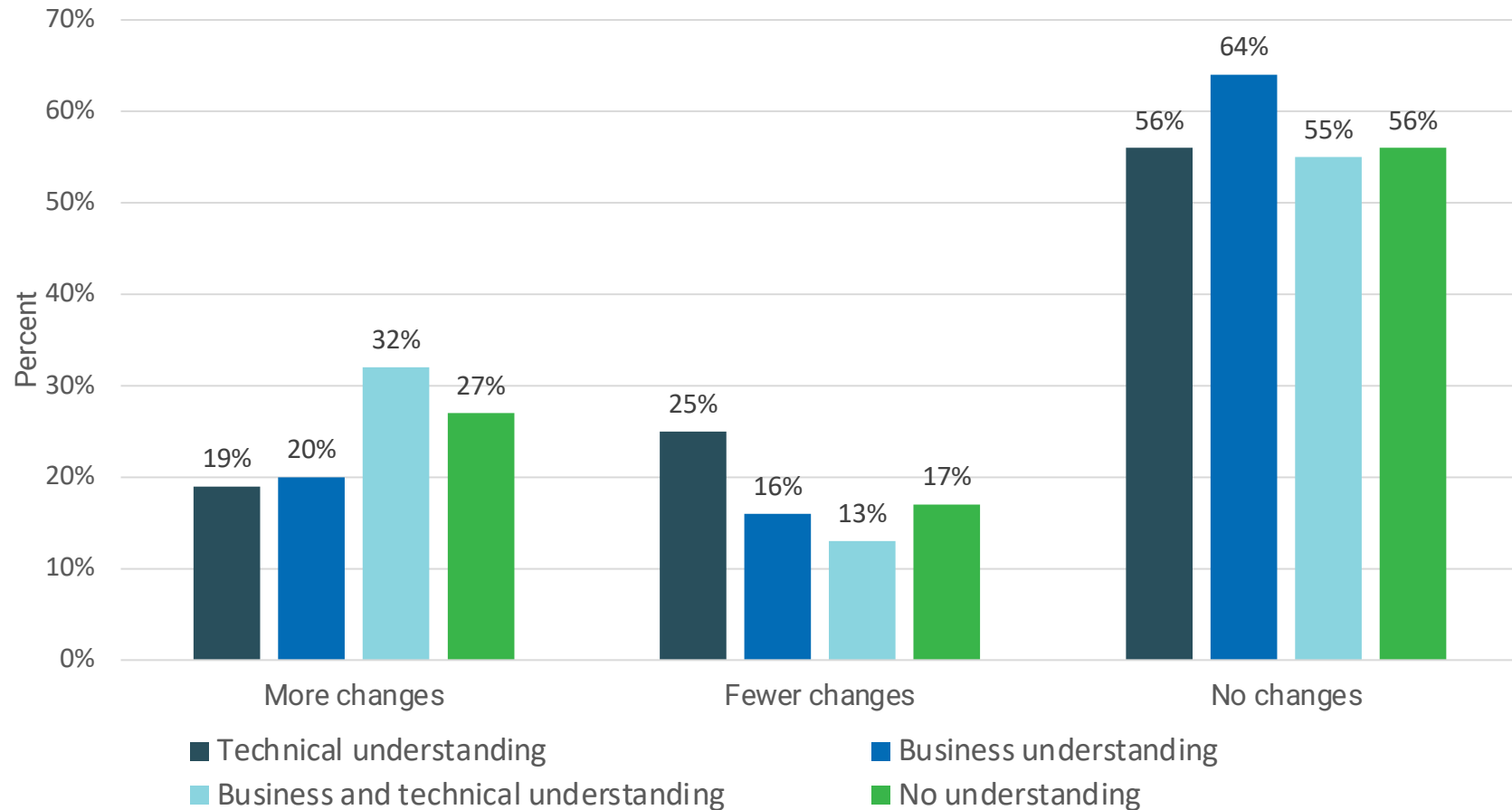
Note: The 41 percent of respondents who indicated they have “No Understanding” of machine learning did not answer questions 1 through 5.
 Sample size: Total (n= 143)

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In your opinion, what are the biggest challenges facing the adoption of machine learning (select top three)?

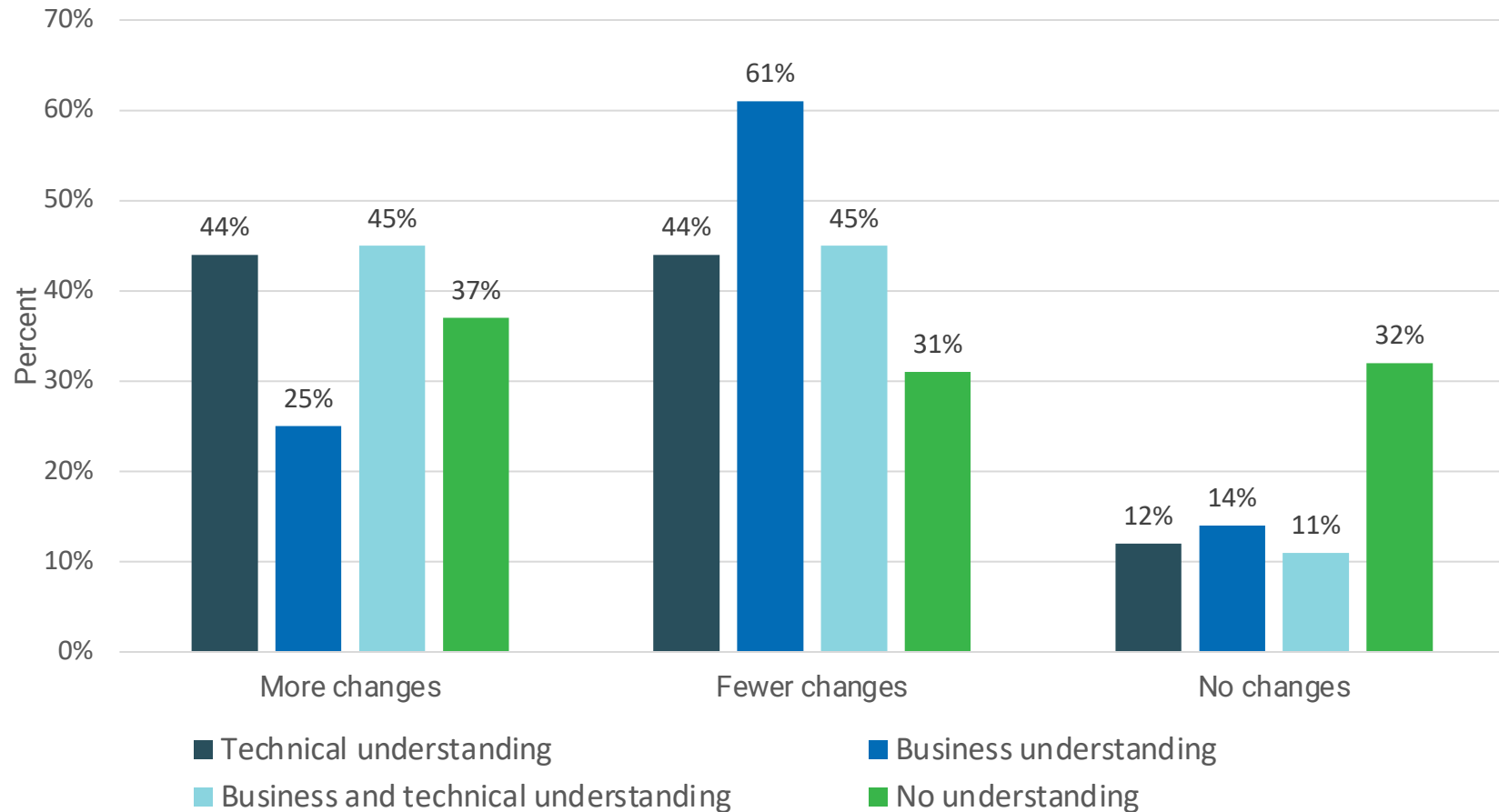


Question 6: In your opinion, how would machine learning affect clinical staff?



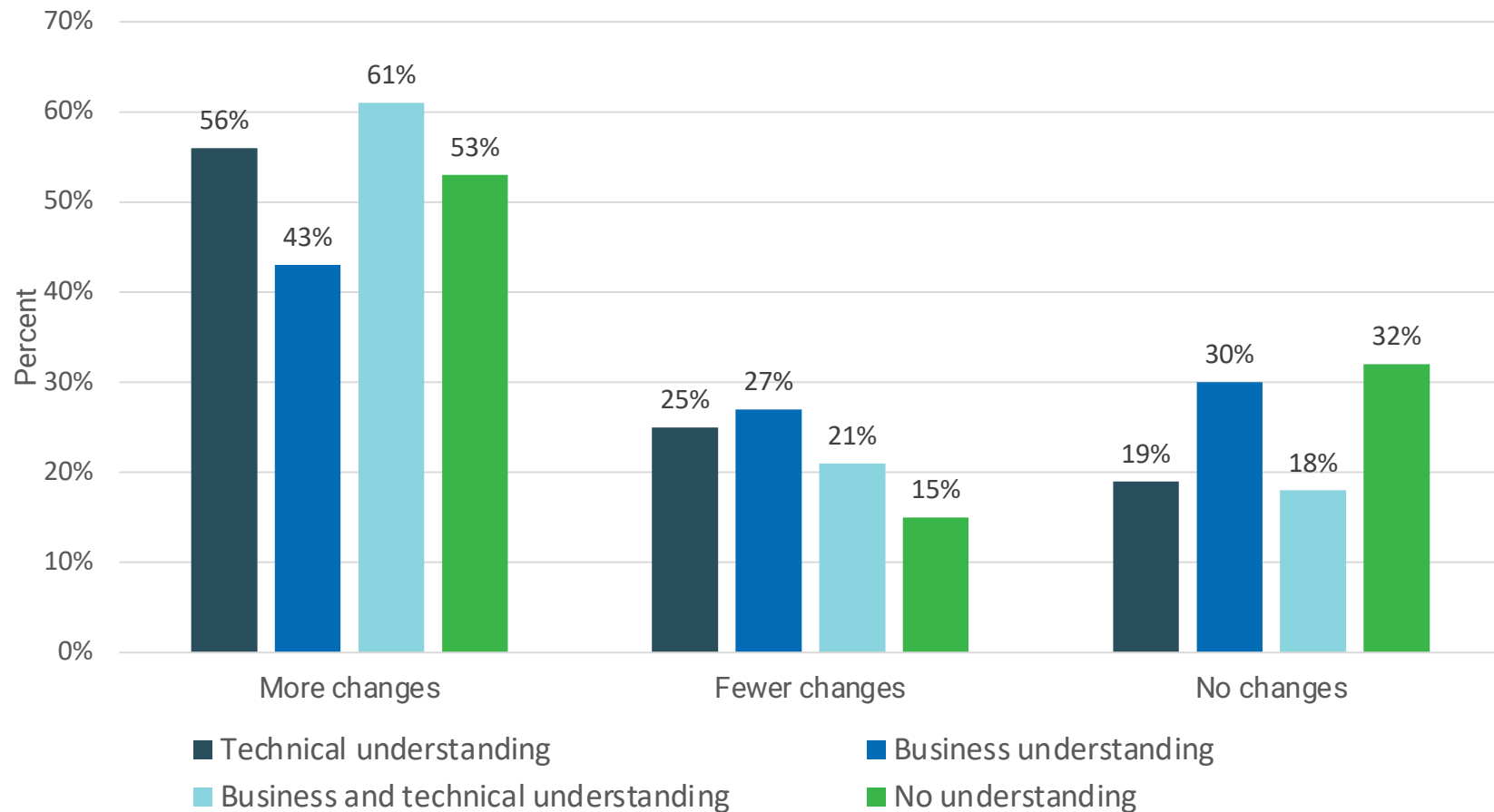
Sample size: Total (n= 214)

Question 7: In your opinion, how would machine learning affect quality issues?



Sample size: Total (n= 214)

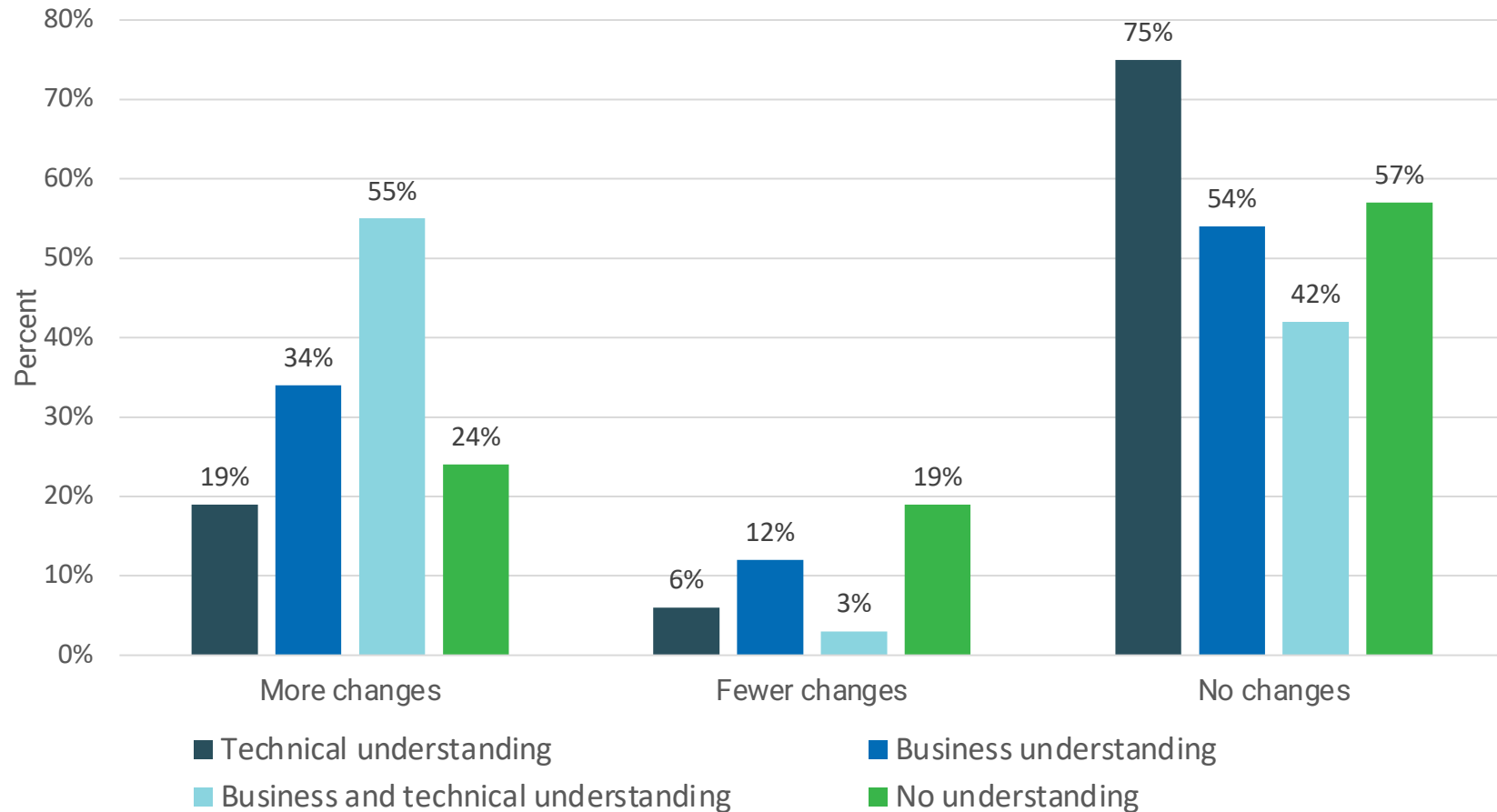
Question 8: In your opinion, how would machine learning affect identified risks?



Sample size: Total (n= 214)

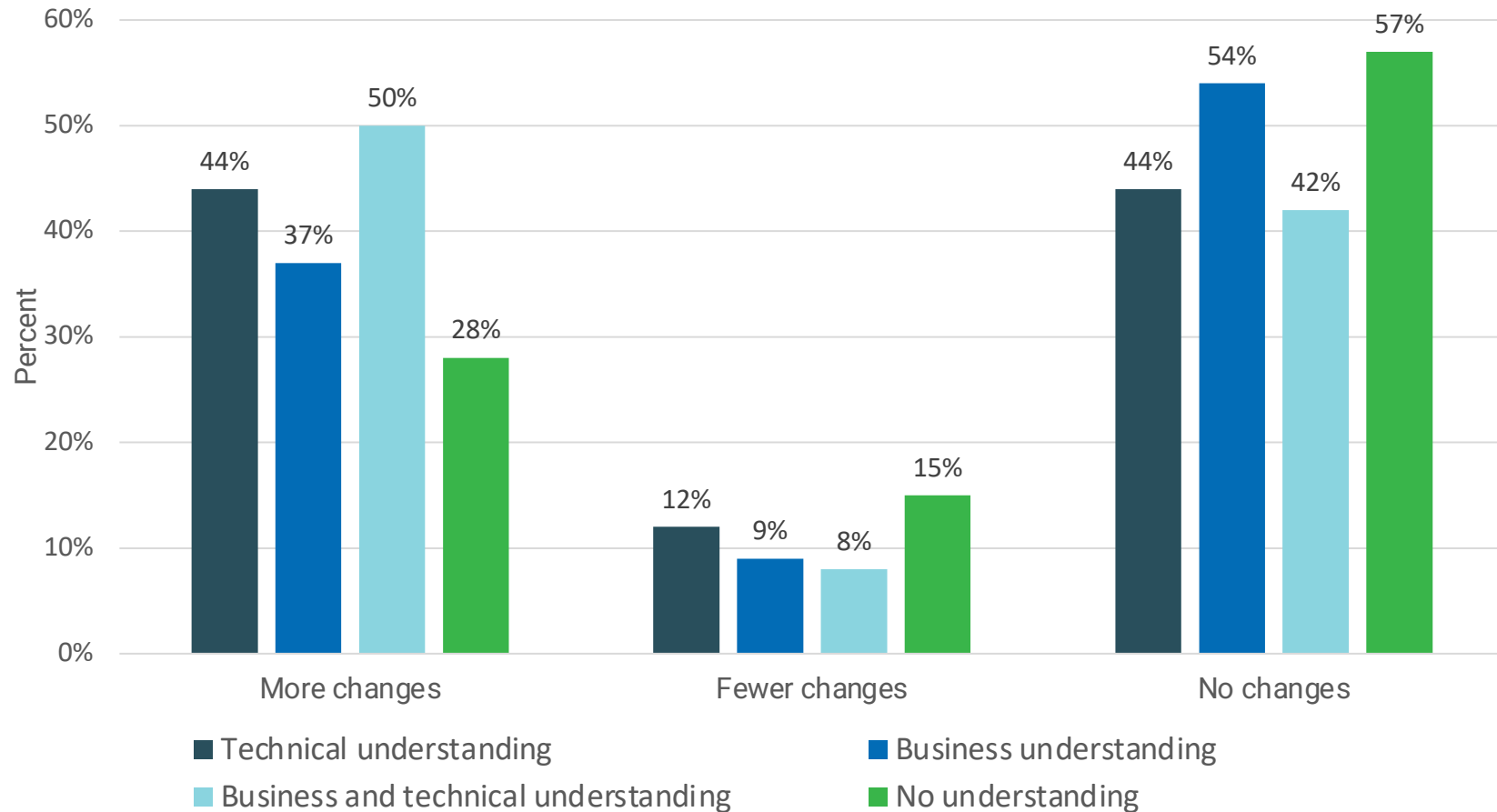
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Question 9: In your opinion, how would machine learning affect customer loyalty (patient engagement)?



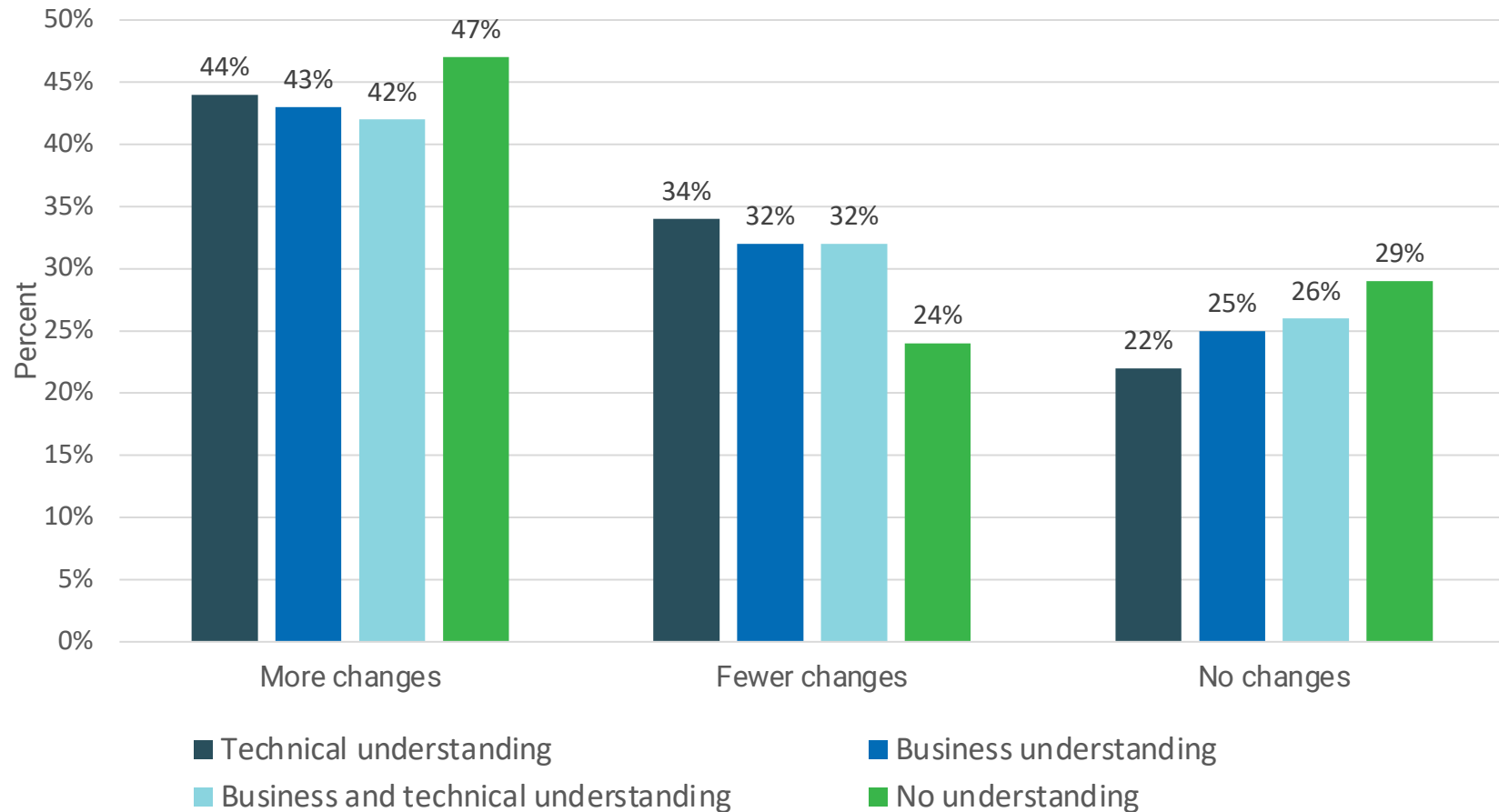
Sample size: Total (n= 214)

Question 10: In your opinion, how would machine learning affect patients?



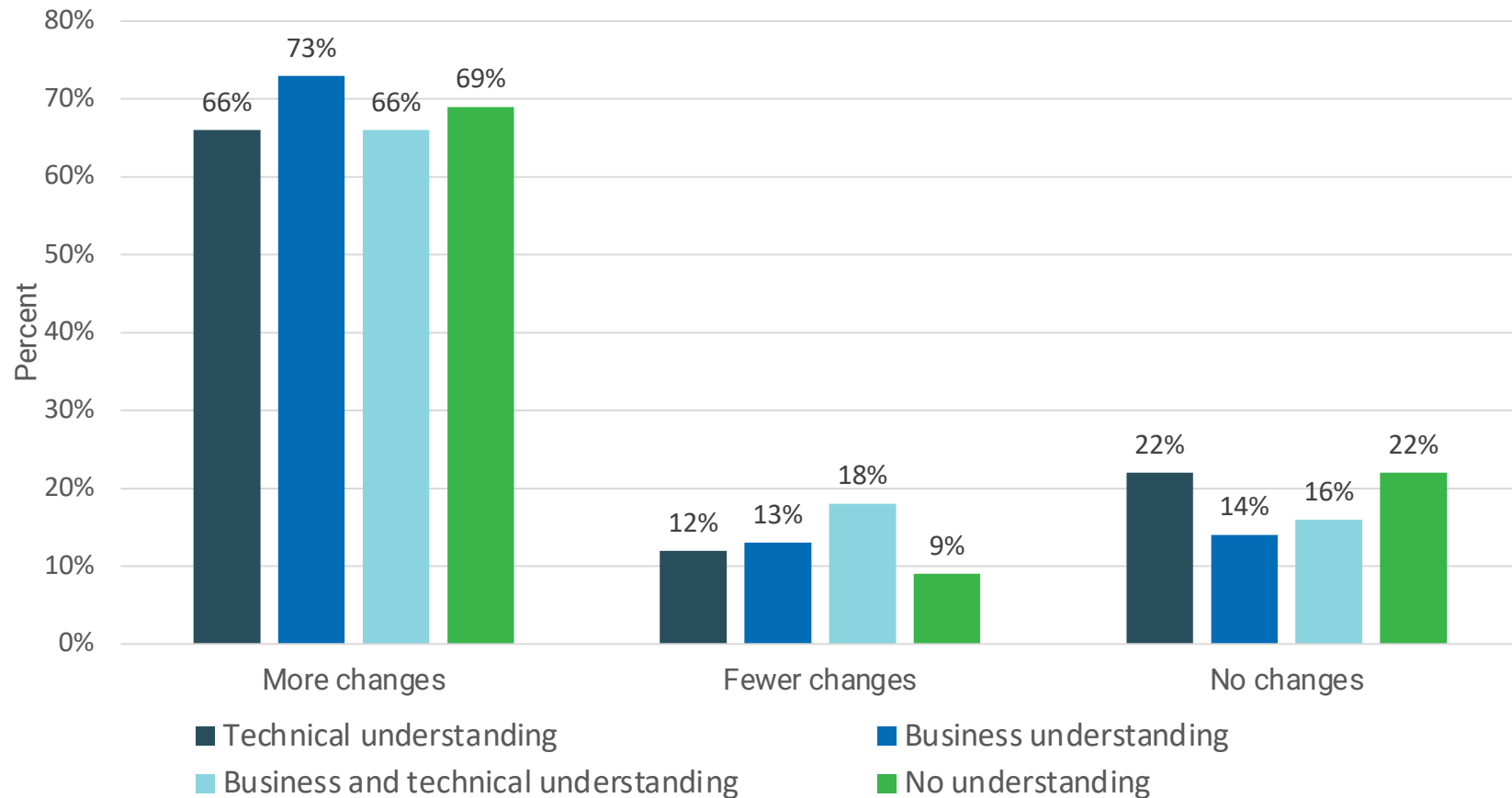
Sample size: Total (n= 214)

Question 11: In your opinion, how would machine learning affect costs?



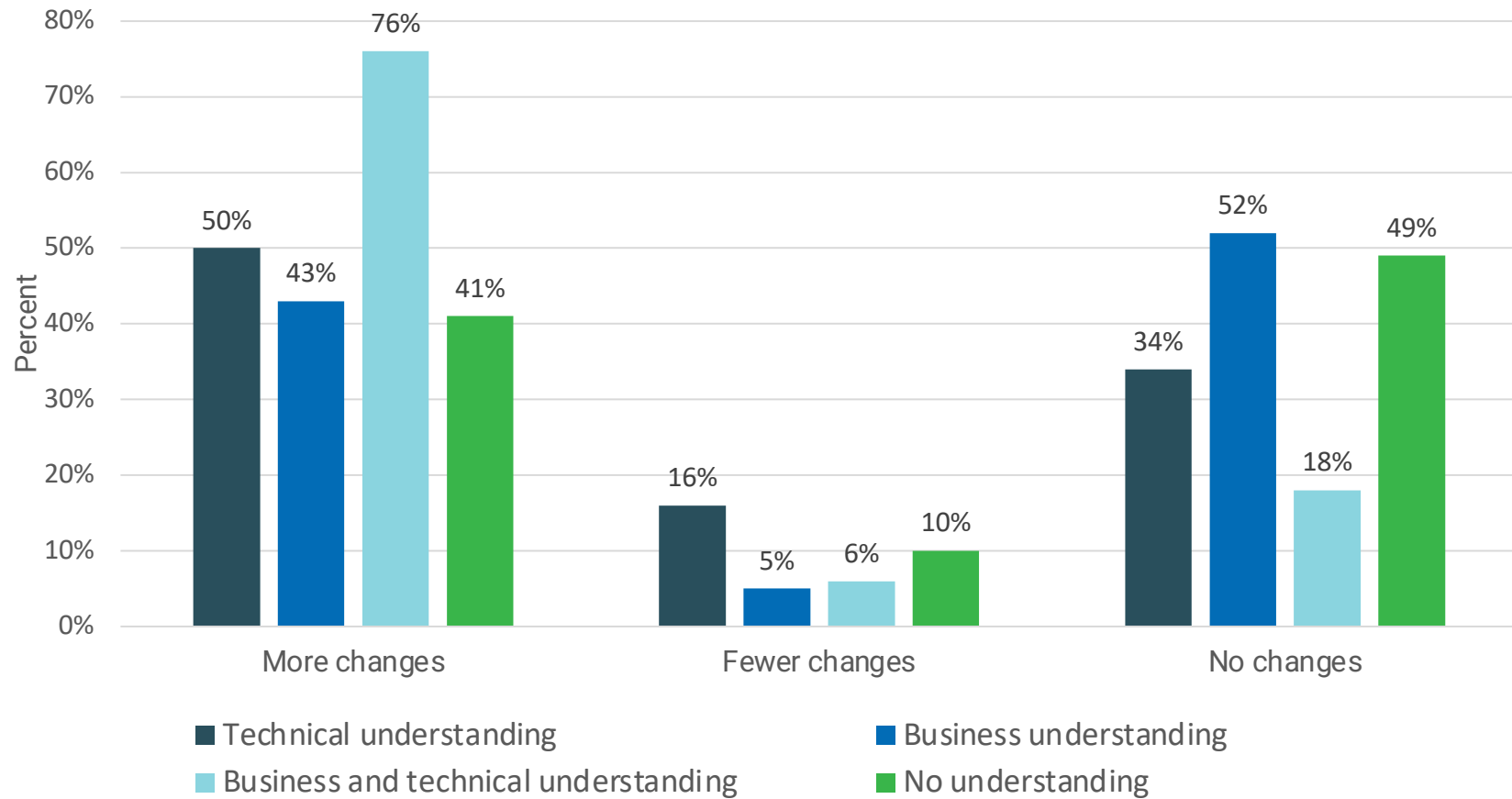
Sample size: Total (n= 214)

Question 12: In your opinion, how would machine learning affect system complexities?



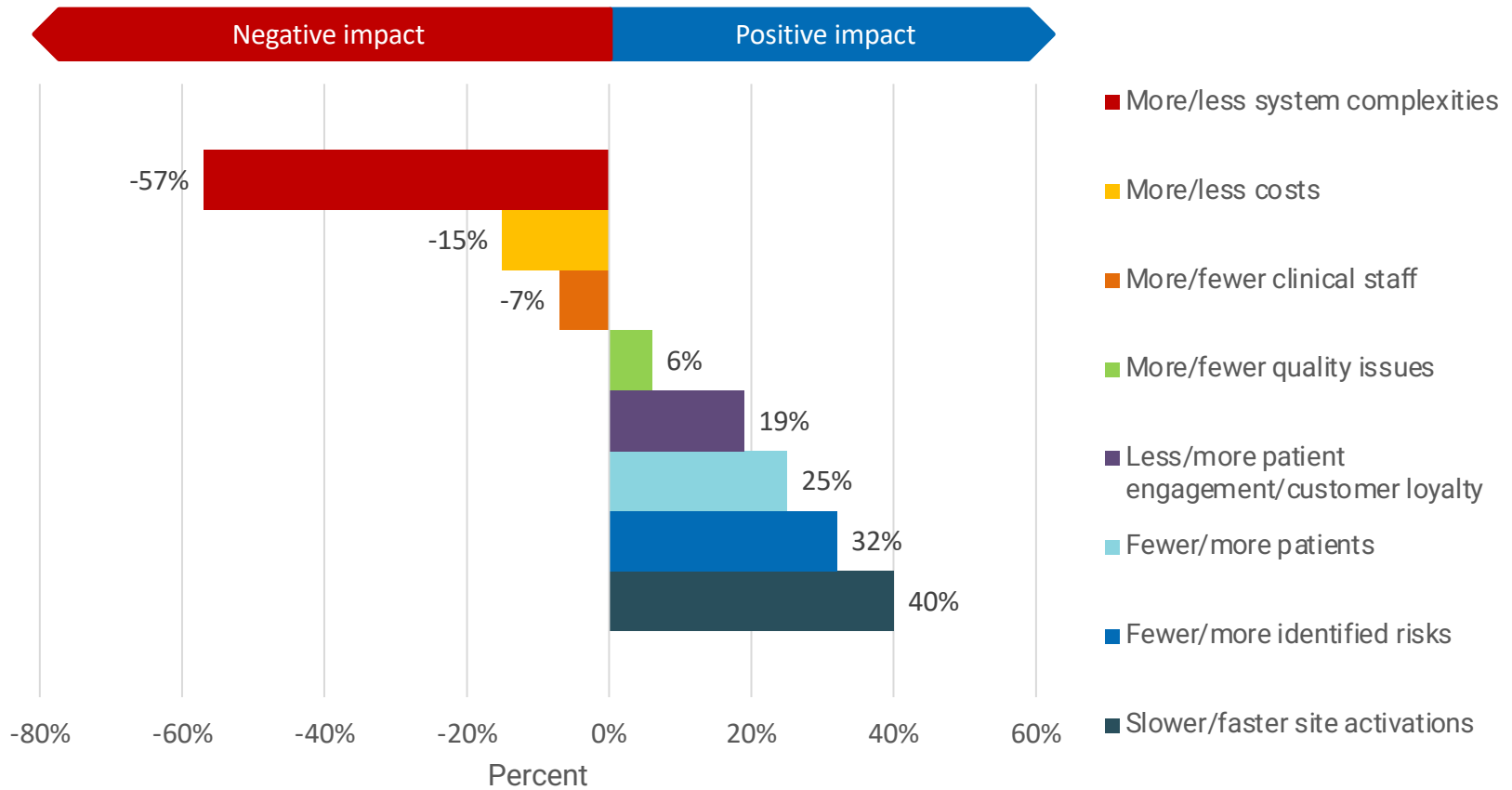
Sample size: Total (n= 214)

Question 13: In your opinion, how would machine learning affect faster site activations?



Sample size: Total (n= 214)

In your opinion, would machine learning result in more/no change/or fewer...?





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