wcg™ Avoca®

The 2020 Avoca State of the Industry Report

Innovation by Fire, Diversity, and the Next Normal

June 2021

Introduction

- The focus of the 2020 Avoca Industry Survey was to gather data regarding how the events of 2020 may have accelerated operational and study design innovations within clinical development, as well as how respondents perceived various aspects of clinical trial quality and efficiency to have been impacted, how their organizations adapted management practices accordingly, and whether respondents anticipated a “snap back” to pre-innovation approaches and perceptions, or an acceleration of innovation, post COVID-19. The survey also explored respondents’ perceptions surrounding workforce readiness for clinical trial innovation and diversity in clinical trials.
- The 2020 Avoca Industry Survey was conducted between September and December of 2020.
- Invitations to participate were sent to contacts in Avoca’s database. The survey was also discussed during the 2020 Avoca Quality & Innovation Summit with an open invitation to participate, and the link for the survey was posted on the Avoca website and on LinkedIn.
- This work coincides with and is part of the launch of the Avoca Innovation Alliance (AIA).

Usage Guidelines

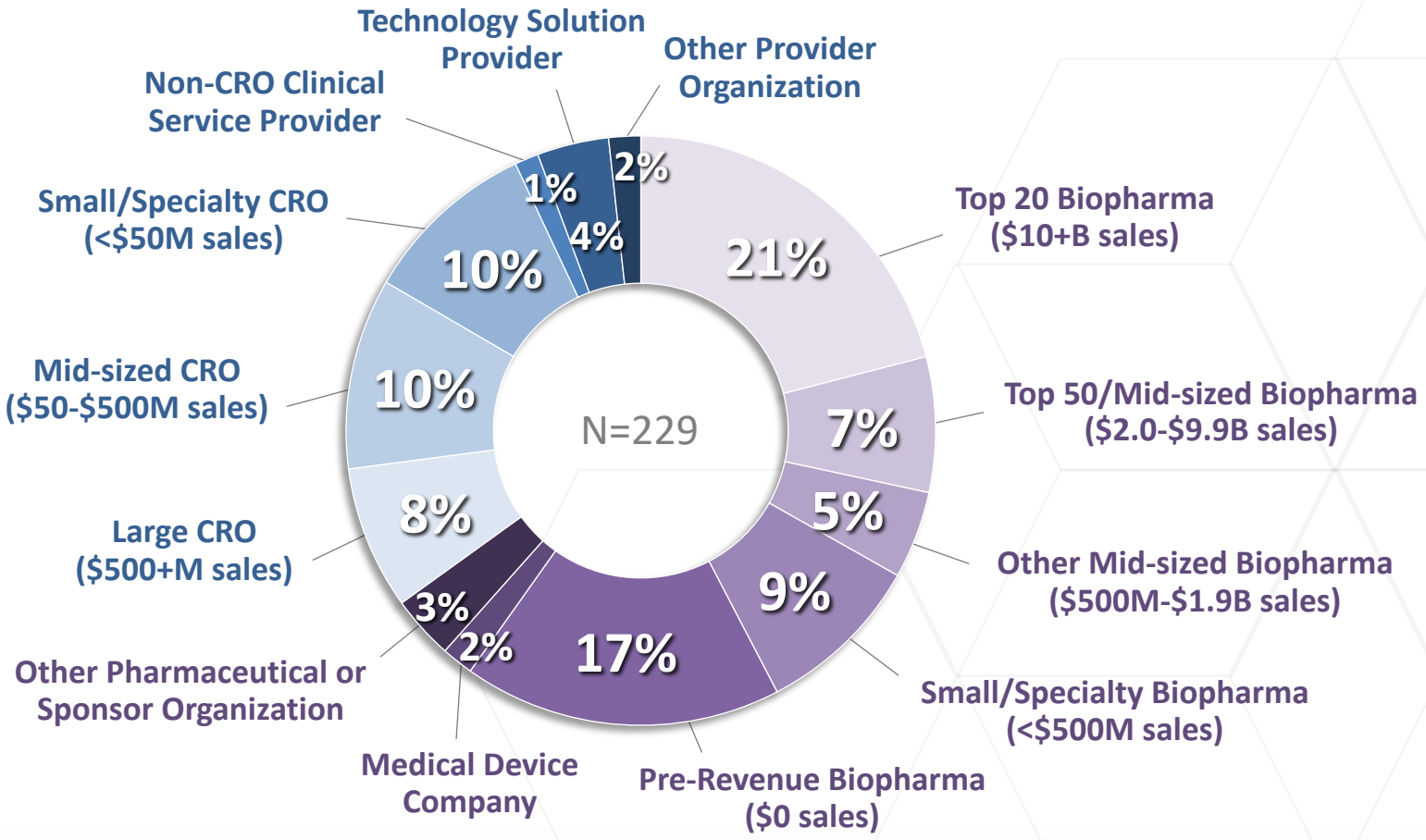
Characteristics of the Sample

Respondent Characteristics

- There were 229 respondents, 145 representing sponsor companies and 84 representing provider companies.
- Most of the survey respondents representing sponsors worked for companies in the Top 20 in terms of revenue. Respondents representing providers worked for a wide range of provider types, most commonly CROs.
- Approximately half of the respondents represented Clinical Development/Operations; slightly more than a quarter represented Quality Assurance; and the remainder represented a wide spectrum of management and functional roles.
- Respondents represented companies that sponsored or conducted a variable number of clinical trials in 2020, from more than 50 (31%) to fewer than 5 (25%). A very small number of respondents represented companies that conducted or sponsored no clinical trials at all that year.
- The vast majority of respondents resided in the US and worked for companies that were headquartered there, most commonly in the Northeast and West. Approximately one-fifth had headquarters in Western Europe or Japan.
- Where numbers allowed, subset analyses were performed by all of the above variables to examine trends by respondent and company type. Only selected highlights of these analyses are provided in this report.

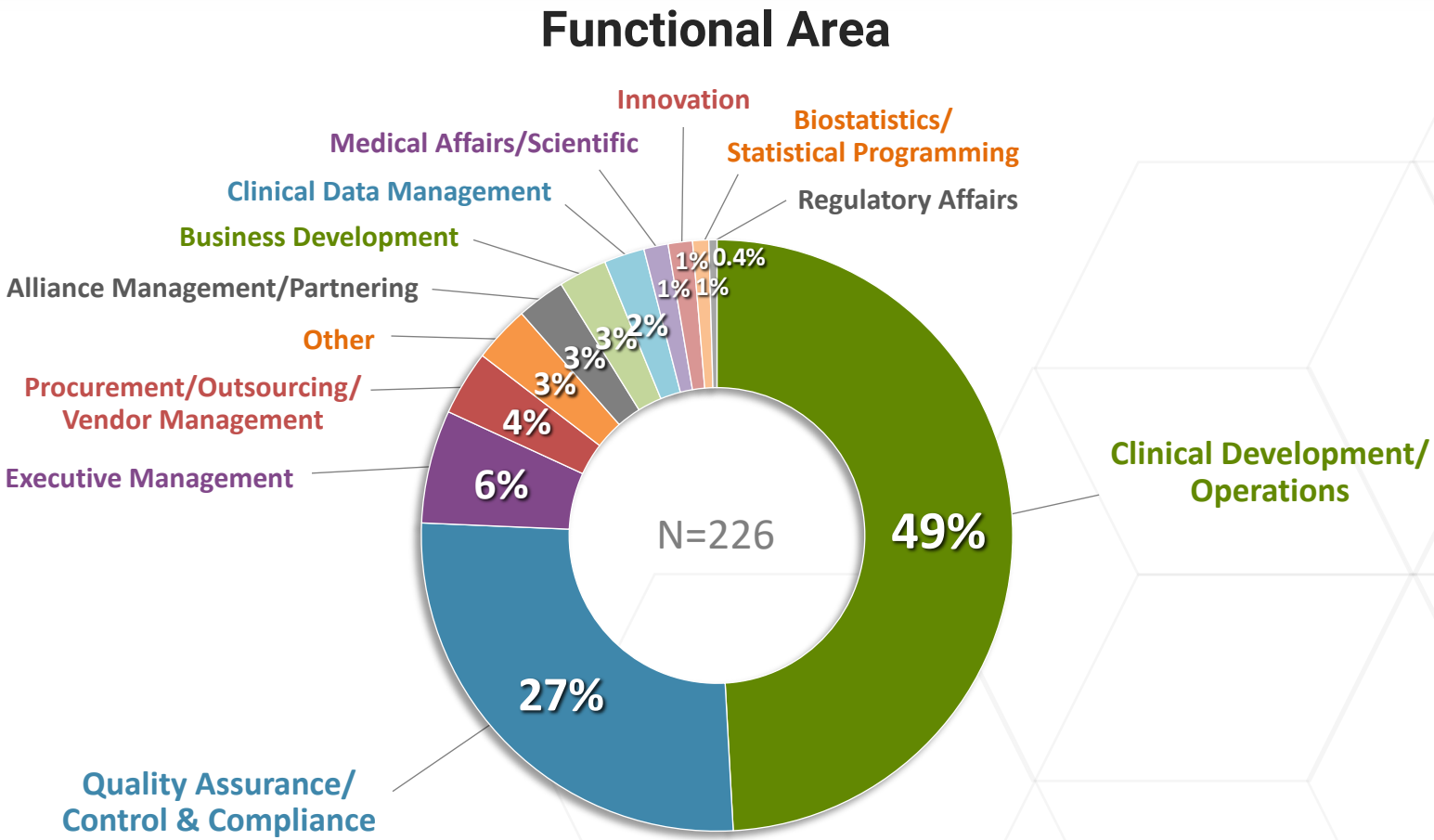
Respondent Characteristics

Company Type



Q: Please indicate your company type.

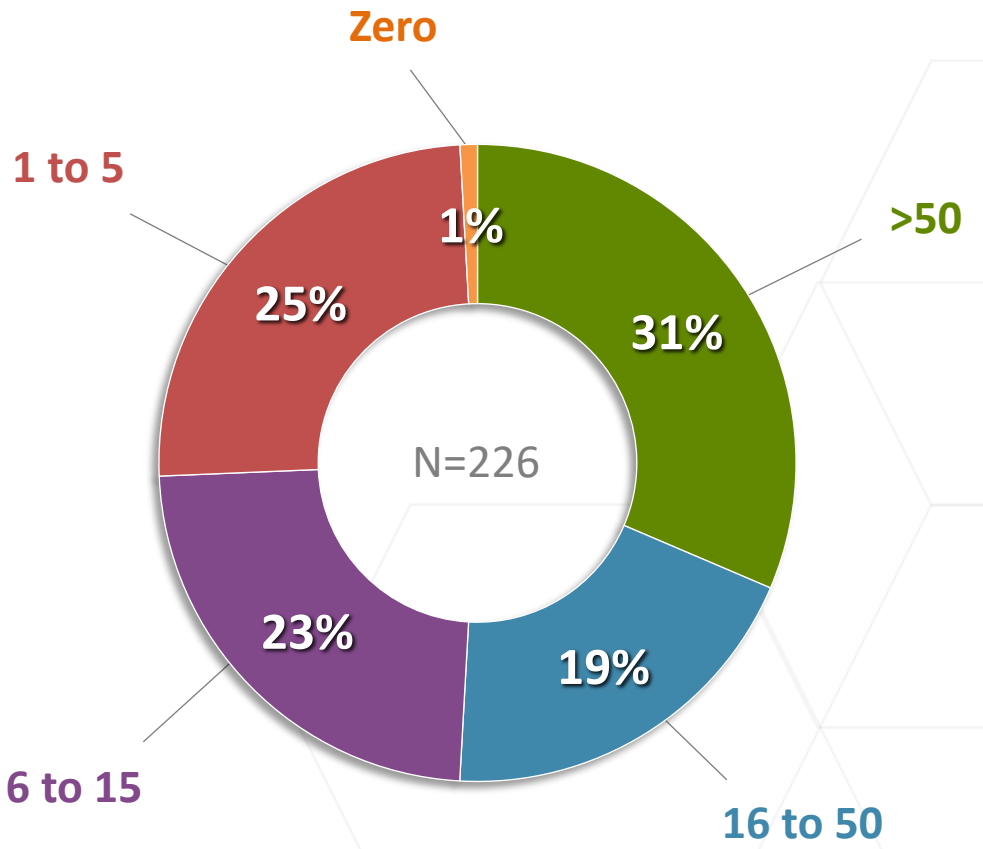
Respondent Characteristics



Q: What is the functional area in which you work?

Respondent Characteristics

Number of Clinical Trials Sponsored or Supported in 2020

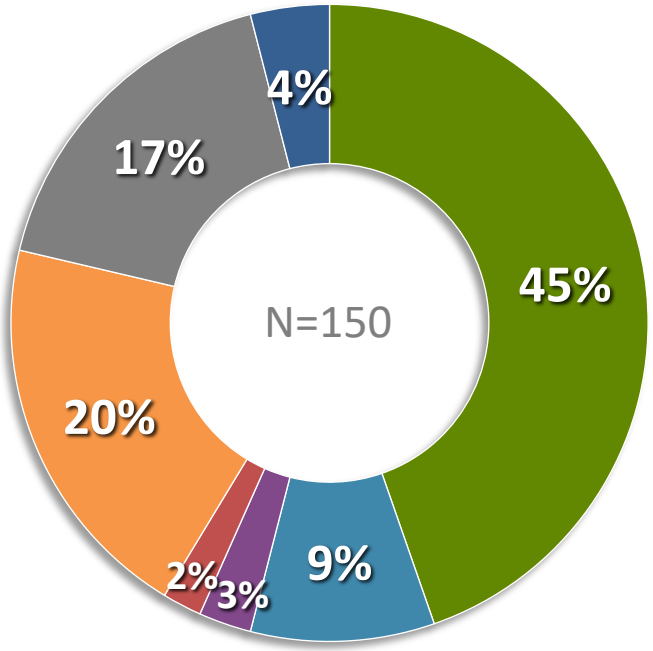


Q: In 2020, approximately how many clinical trials will your company sponsor, or support through services you offer?

Respondent Characteristics

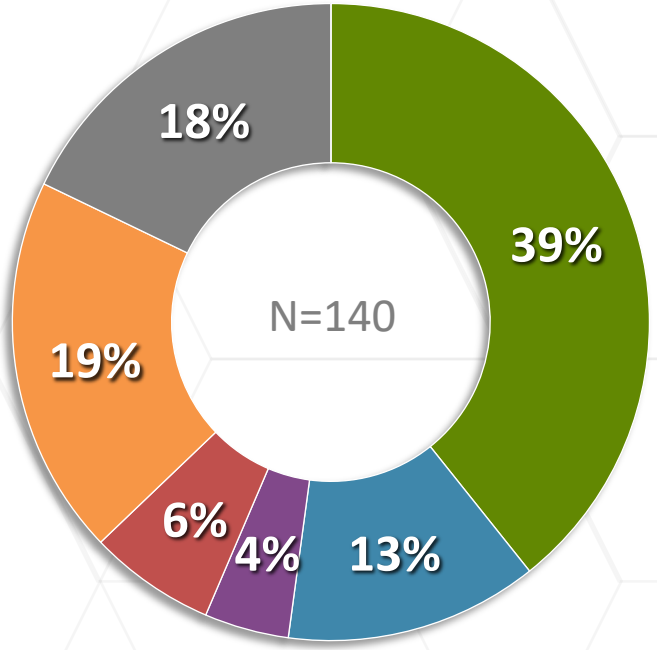
Geographic Area

Company Headquartered



US Northeast
US Southeast
US Southwest
US Midwest
US West
Western Europe
Japan

Specifically Located



Q: In which geographic area: ...is your company headquartered? ...are you specifically located?

Perceptions of Companies' Innovativeness

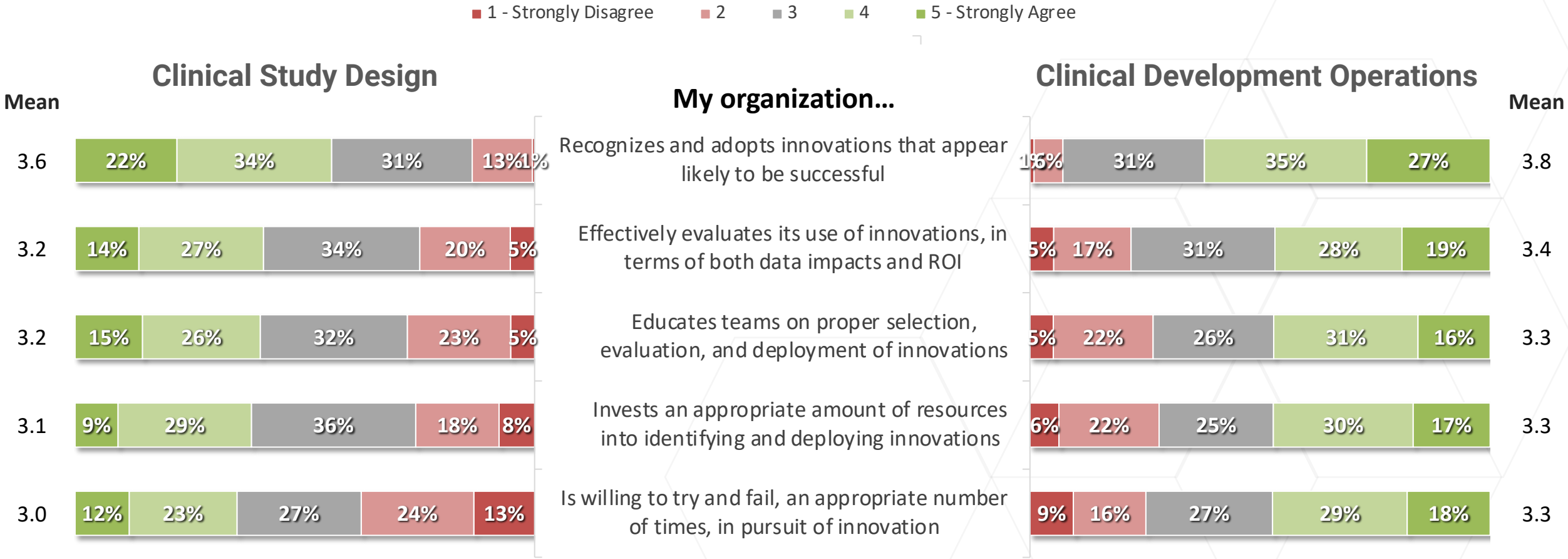
Strengths and Weaknesses

Perceptions of Innovativeness

- When asked to respond to a variety of positively phrased statements about their organizations' innovativeness, respondents' mean ratings on a scale of 1 (strongly disagree) to 5 (strongly agree) ranged from the low to mid 3s, indicating slightly positive assessments. Mean ratings were uniformly higher for statements relating to clinical development operations than for those relating to clinical study design. For innovativeness in clinical study design, the percentages providing positive ratings ranged from 35% to 56%, and those providing negative ratings ranged from 14% to 37%. For innovativeness in clinical development operations, positive ratings ranged from 47% to 62%, and negative ratings ranged from 7% to 28%. For both, the most positive ratings, on average, highlighted organizations' recognition and adoption of innovations likely to become successful. The willingness of organizations to accept occasional failures and to allocate and educate resources effectively received lower mean ratings.
- On average, providers rated every statement, both in the clinical study design and in the clinical development operations categories, higher than sponsors did, but the magnitude of the difference was generally small (≤0.6 unit).

Perceptions of Innovativeness: Strengths and Weaknesses

Overall, to what extent do you view your organization as innovative?



N: 188-224

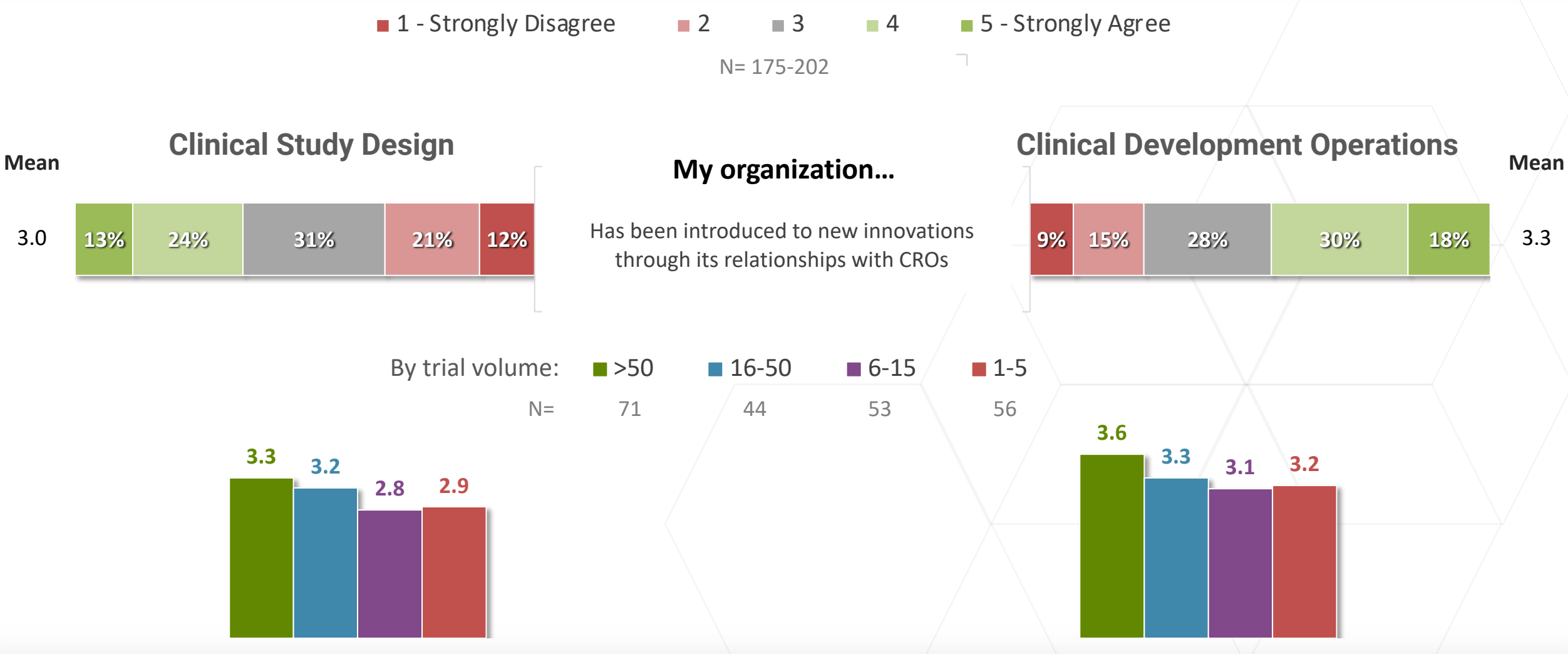
Q: Overall, to what extent do you view your organization as innovative with respect to each of clinical development operations (including but not limited to use of Decentralized Trial Activities), and clinical study design (including but not limited to use of Digital Endpoints)? Please indicate the extent to which you agree or disagree with each of the following statements using a scale of 1 to 5, with 1 being "Strongly Disagree" and 5 being "Strongly Agree":

Perceptions of Innovativeness: Strengths and Weaknesses

Overall, to what extent do you view your organization as innovative?

N: Sponsor=120-145, Provider=61-79
Note: Discrepancies in the calculated difference of +/- 0.1 are due to rounding.
Q: Overall, to what extent do you view your organization as innovative with respect to each of clinical development operations (including but not limited to use of Decentralized Trial Activities), and clinical study design (including but not limited to use of Digital Endpoints)? Please indicate the extent to which you agree or disagree with each of the following statements using a scale of 1 to 5, with 1 being "Strongly Disagree" and 5 being "Strongly Agree":

Role of CRO Relationships in Introducing Innovations



Q: Overall, to what extent do you view your organization as innovative with respect to each of clinical development operations (including but not limited to use of Decentralized Trial Activities), and clinical study design (including but not limited to use of Digital Endpoints)? Please indicate the extent to which you agree or disagree with each of the following statements using a scale of 1 to 5, with 1 being "Strongly Disagree" and 5 being "Strongly Agree":

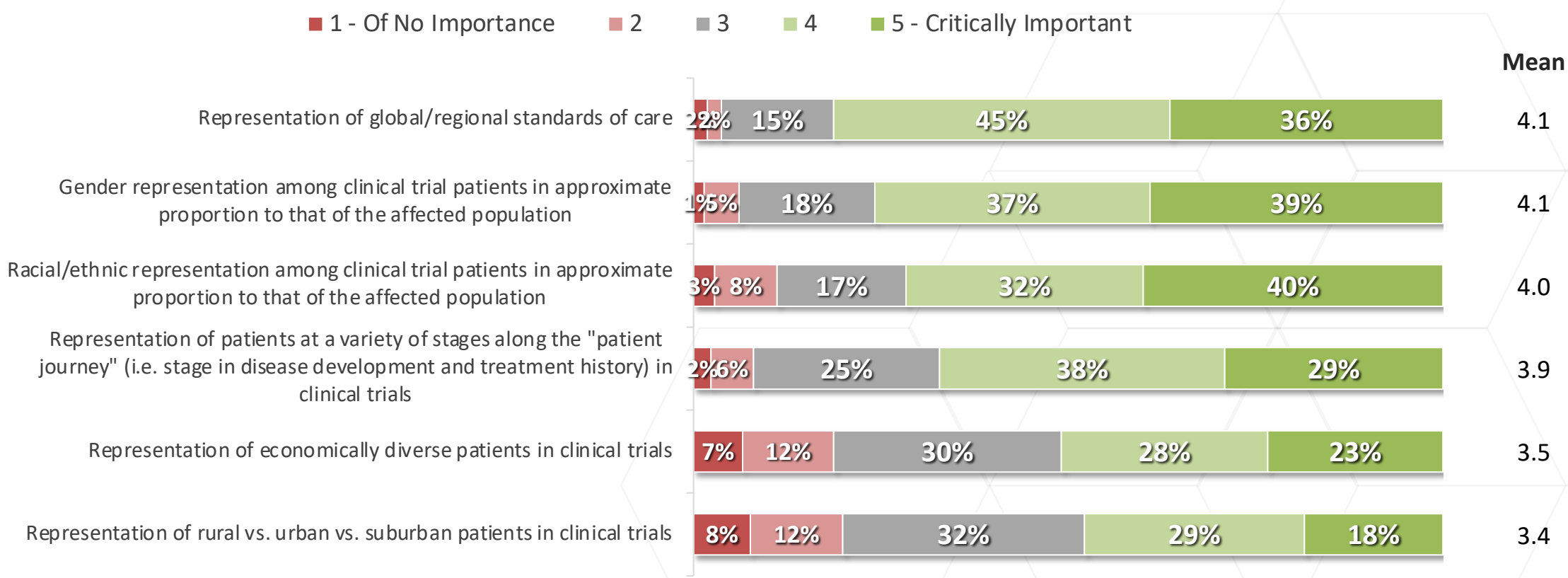
Diversity in Clinical Trial Participation

Diversity in Clinical Trial Participation

- When survey participants were asked to rate how critical various types of diversity among clinical subjects were to the quality of clinical research, their responses varied quite widely. Diversity across global/regional standards of care and gender were most uniformly seen as critical. Opinions about diversity across economic strata and community types (rural vs. urban vs. suburban) were more varied.
- When asked how each of their own companies and the industry as a whole were performing in each category of clinical trial subject diversity, respondents rated their own companies higher than the industry as a whole in every respect. Mean ratings for “my company” were in the neutral to positive range (3.0 to 3.7 on a scale of 1-5), whereas those for the industry as a whole ranged from negative to slightly positive (2.5 to 3.5). This discrepancy may reflect the failure of communication across companies about practices and performance related to clinical trial subject diversity.
- Given the generally mediocre performance of their companies in the area of diversity, as judged by respondents, it is not surprising that fewer respondents were familiar with the FDA Guidance on Enhancing the Diversity of Clinical Trial Populations (41%) than with other FDA or ICH Guidance documents relevant to their work.

Diversity in Clinical Trial Participation: Importance

How critical to the quality of clinical research do you consider each of the following?

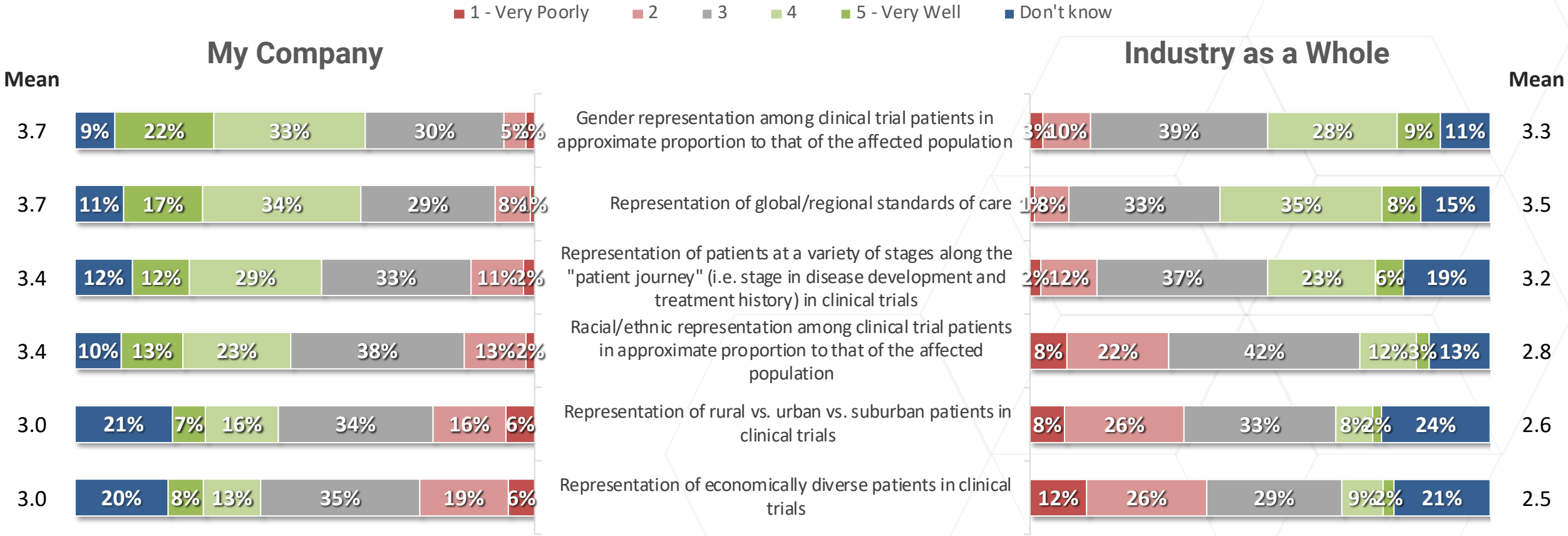


N: 211-215

Q: How critical to the quality of clinical research do you consider each of the following, using a scale from 1 (of no importance) to 5 (critically important)?

Diversity in Clinical Trial Participation: Performance

Overall, what are your perceptions of how your company, and the drug development industry as a whole, are performing in each of the following areas?

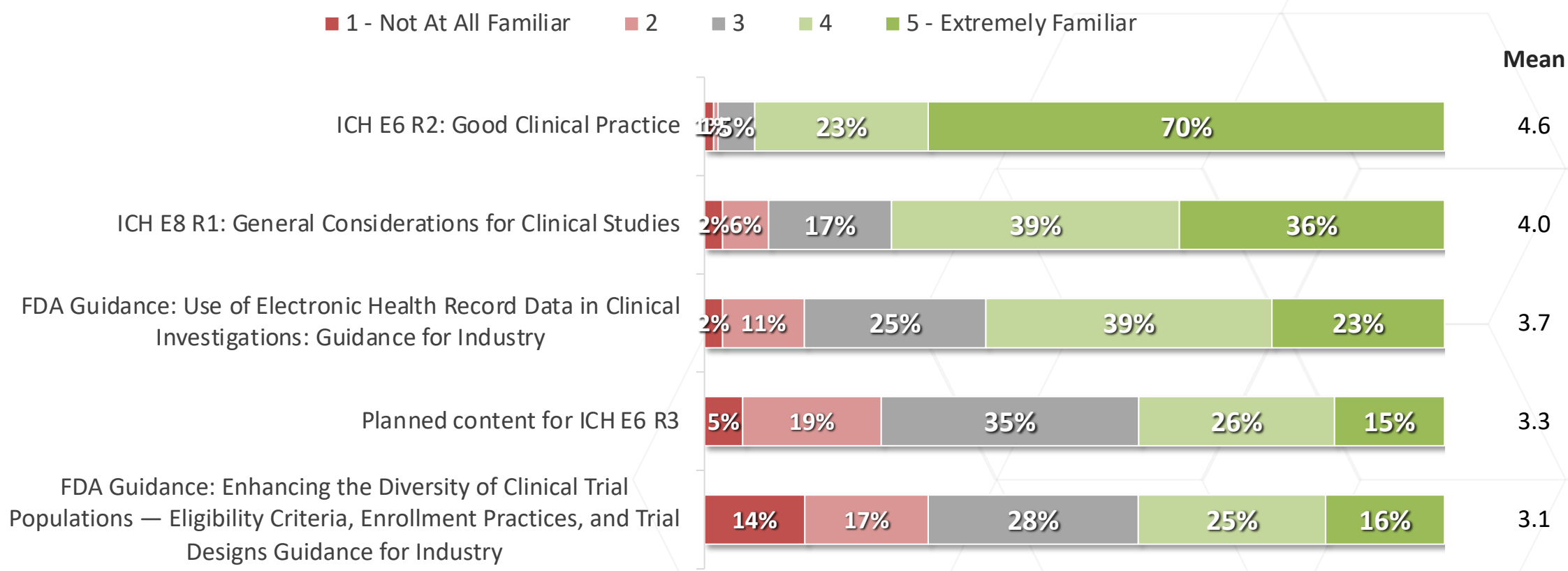


N: 208-213

Q: Overall, what are your perceptions of how each of your company, and the drug development industry as a whole, are performing in each of the following areas, using a scale from 1 (very poorly) to 5 (very well)?

Diversity in Clinical Trial Participation: Relative Knowledge

Familiarity with Guidance Documents



N: 155-163

Q: How would you rate your familiarity with each of the following Guidance documents?

Innovations by Type

Bird's Eye View

Innovations by Type: Bird's Eye View

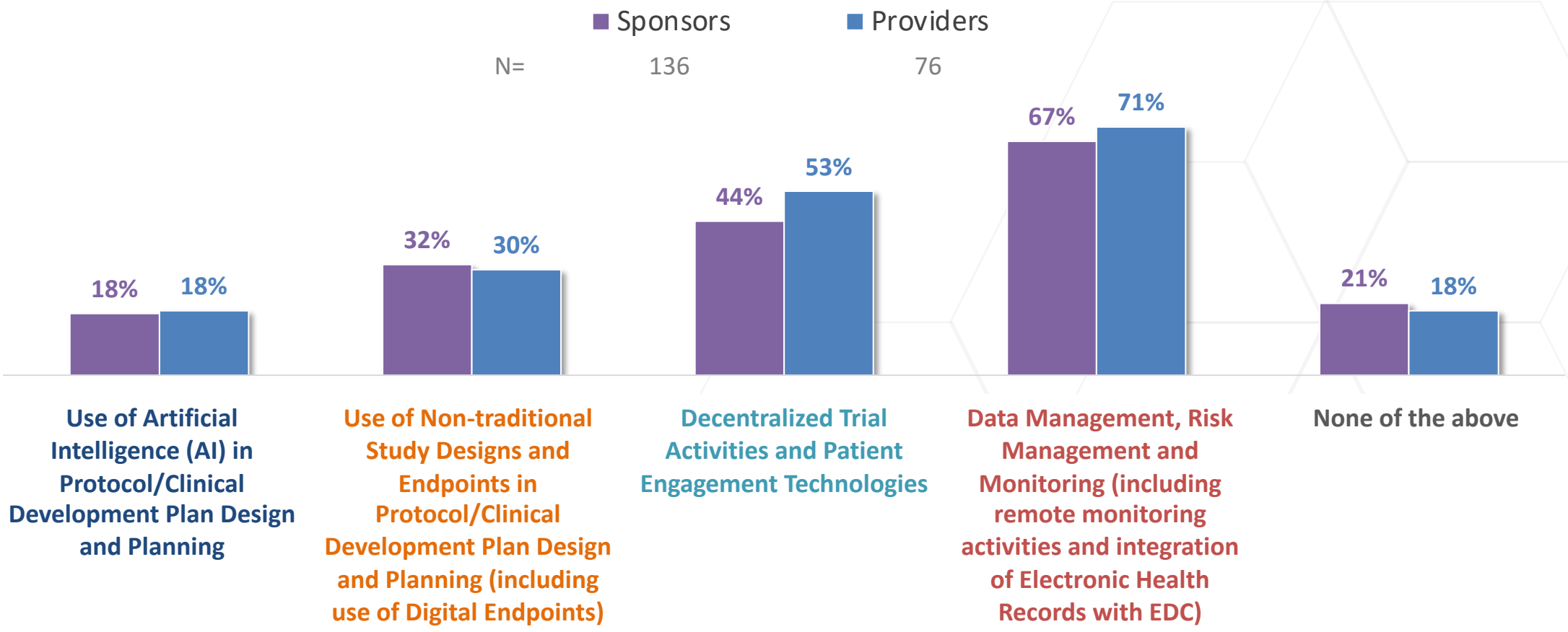
- When respondents were asked about which types of innovations they could report on behalf of their companies, the majority stated that they were able to report on innovations related to data management, risk management, and monitoring. Approximately half were able to report on decentralized trial activities and patient engagement technologies. Fewer were able to report on use of non-traditional study designs and endpoints (30-32%) and on use of artificial intelligence in protocol/clinical development plan design and planning (18%). Fractions able to report did not differ significantly across sponsors vs. providers.
- For each item in a list of 35 specific innovations, respondents were asked whether their companies adopted or were planning to adopt the innovation prior to the COVID-19 pandemic, because of COVID-19, during COVID-19 but not because of COVID-19, or not at all. Very few respondents had no plans to adopt remote monitoring and patient-related activities such as remote source data review (3%), remote source data verification (5%), risk-based monitoring tools (7%), electronic patient diaries (7%), e-consent technologies (8%), study visits by telemedicine (6%), or home health care providers (8%). On the flip side, approximately half or more had no plans to adopt completely siteless trials (49%), synthetic control arms (53%), or use of AI to detect possible unreported AEs (58%).
- Innovations most likely to be adopted independent of COVID-19 included electronic patient diaries (85%), risk-based monitoring/study management tools (83%), application of AI to clinical trial data to more fully understand efficacy and safety (82%), observational trials using real-world data (80%), and adaptive trials (78%). Innovations least likely to be adopted independent of COVID-19 included other risk management and monitoring technologies (27%), use of AI to detect possible AEs that may not have been reported (36%), completely siteless trials (39%), ship-to-home of clinical supplies (45%), and other “alternative” research or data collection settings (46%).

Innovations by Type: Bird's Eye View

- On the other hand, innovations most likely to have been adopted because of COVID-19 included largely those in the *Decentralized Trial Activities and Patient Engagement Technologies* and *Data Management, Risk Management and Monitoring* categories: ship-to-home of clinical supplies (47%), remote source data review (45%), remote source data verification (41%), study visits via telemedicine (40%), and remote review of electronic investigator site files (40%).
- Respondents who stated that their companies adopted innovations because of COVID-19 were asked about their plans to continue using these innovations post-COVID-19. For every innovation listed, most respondents said "yes," at least under some circumstances, and often in each applicable instance. Innovations most likely to be permanently and broadly adopted included synthetic control arms (100%), other "alternative" research or data collection settings (100%), and other patient engagement technologies (100%). Respondents who were uncertain about permanent adoption most often cited questions about continued regulatory acceptance of "alternative" approaches post-COVID-19.
- Overall, the vast majority of respondents felt that the COVID-19 pandemic was highly impactful in accelerating the industry's move toward a more sustainable clinical research model in terms of the ability to withstand not only pandemics, but also demographic, process, and economic shifts, as well as natural disasters and other unforeseen events. Forty percent felt that the industry had been critically impactful in this respect.

Innovations by Type: Respondents

Percentage of respondents able to report on behalf of their companies' use of innovations in each of the following areas:



Q: Please select all of the below areas that are relevant to your current job function, and for which you feel you could report on your company's use of innovations.

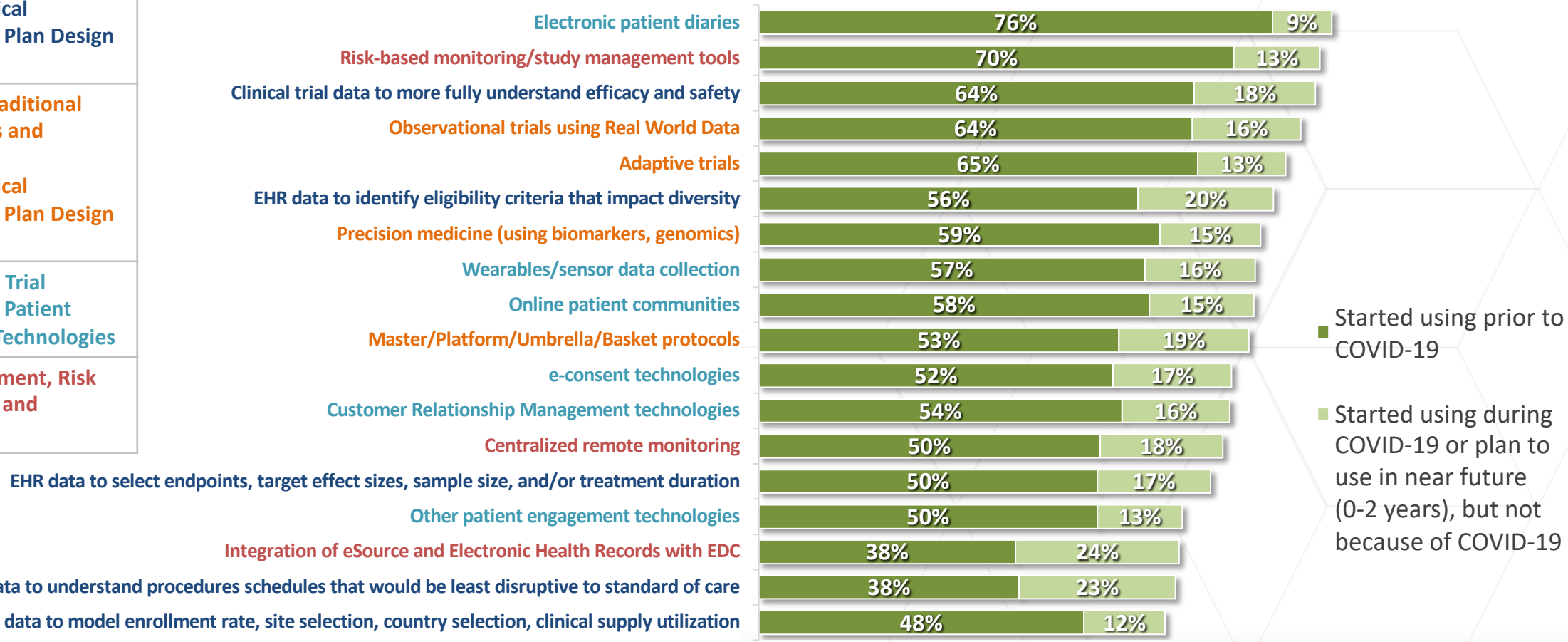
Innovations by Type: Overall Use/Plans to Use

Key:

- Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
- Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
- Decentralized Trial Activities and Patient Engagement Technologies
- Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

Fraction Started Independent of COVID-19 *(Slide 1 of 2)*



N: 24-134

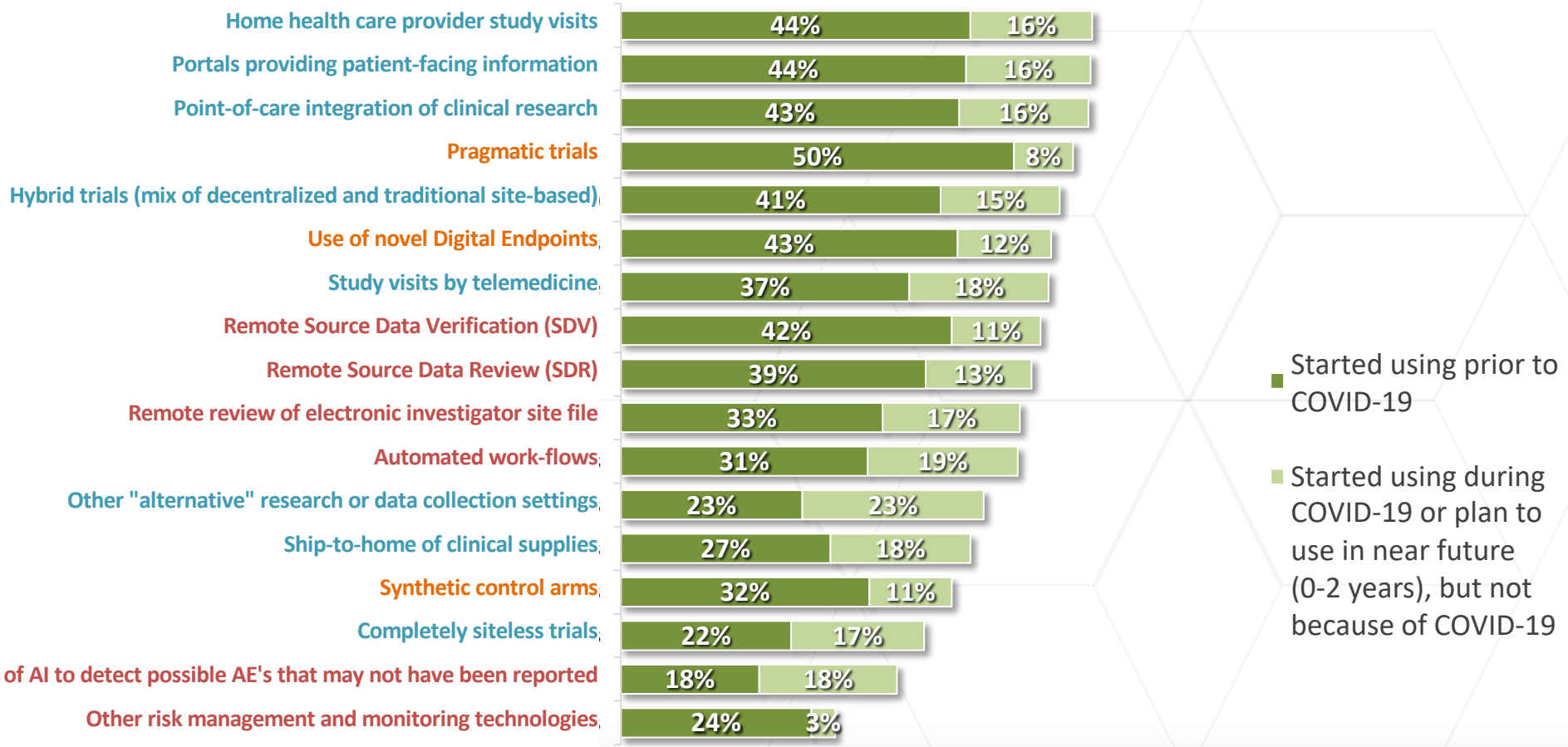
Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Innovations by Type: Overall Use/Plans to Use

Key:
Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

Fraction Started Independent of COVID-19 *(Slide 2 of 2)*



N: 24-134

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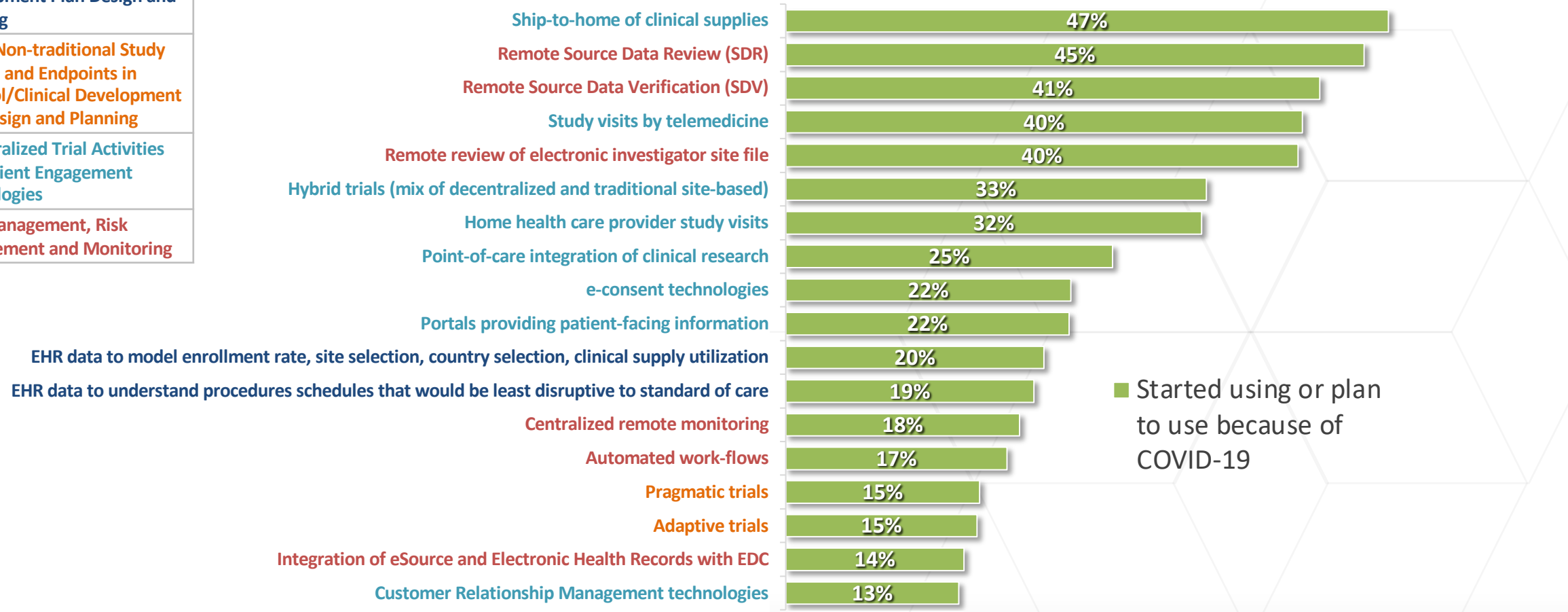
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

Fraction Started Because of COVID-19 *(Slide 1 of 2)*



N: 24-134

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Innovations by Type: Overall Use/Plans to Use

Key:
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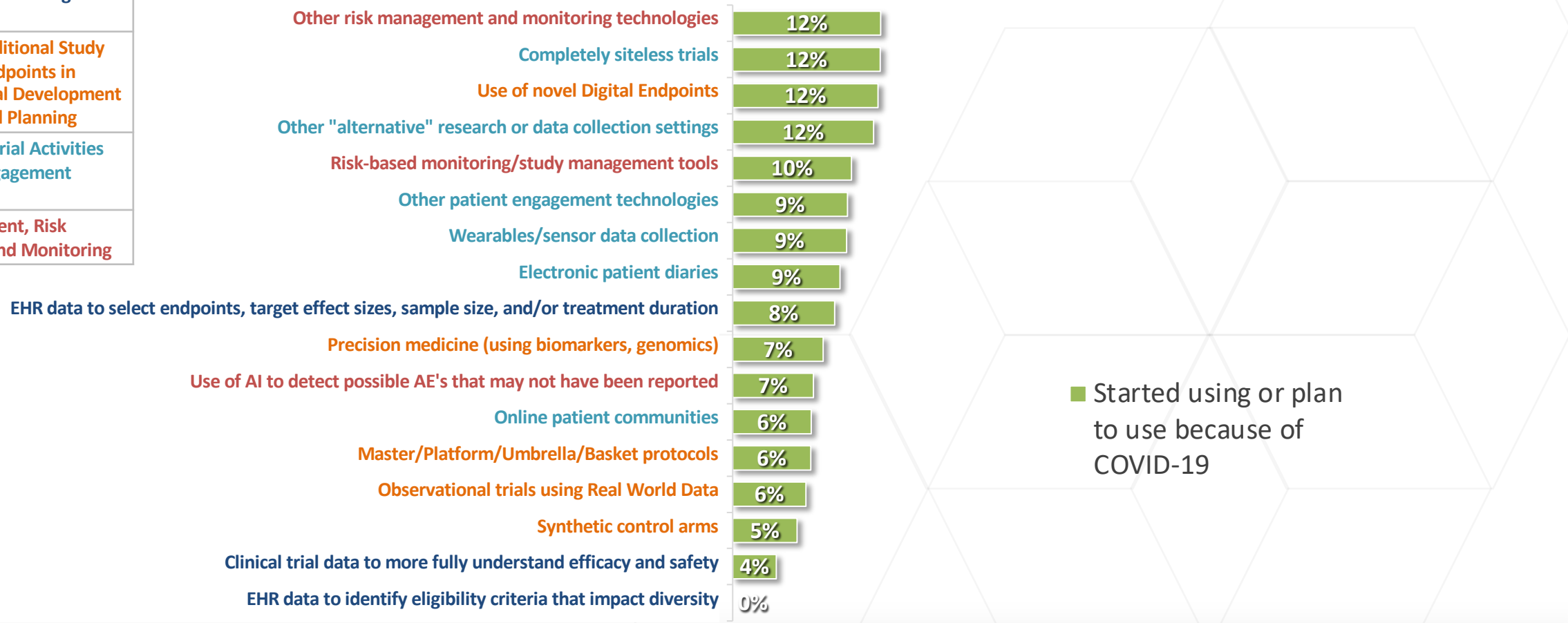
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

Fraction Started Because of COVID-19 *(Slide 2 of 2)*



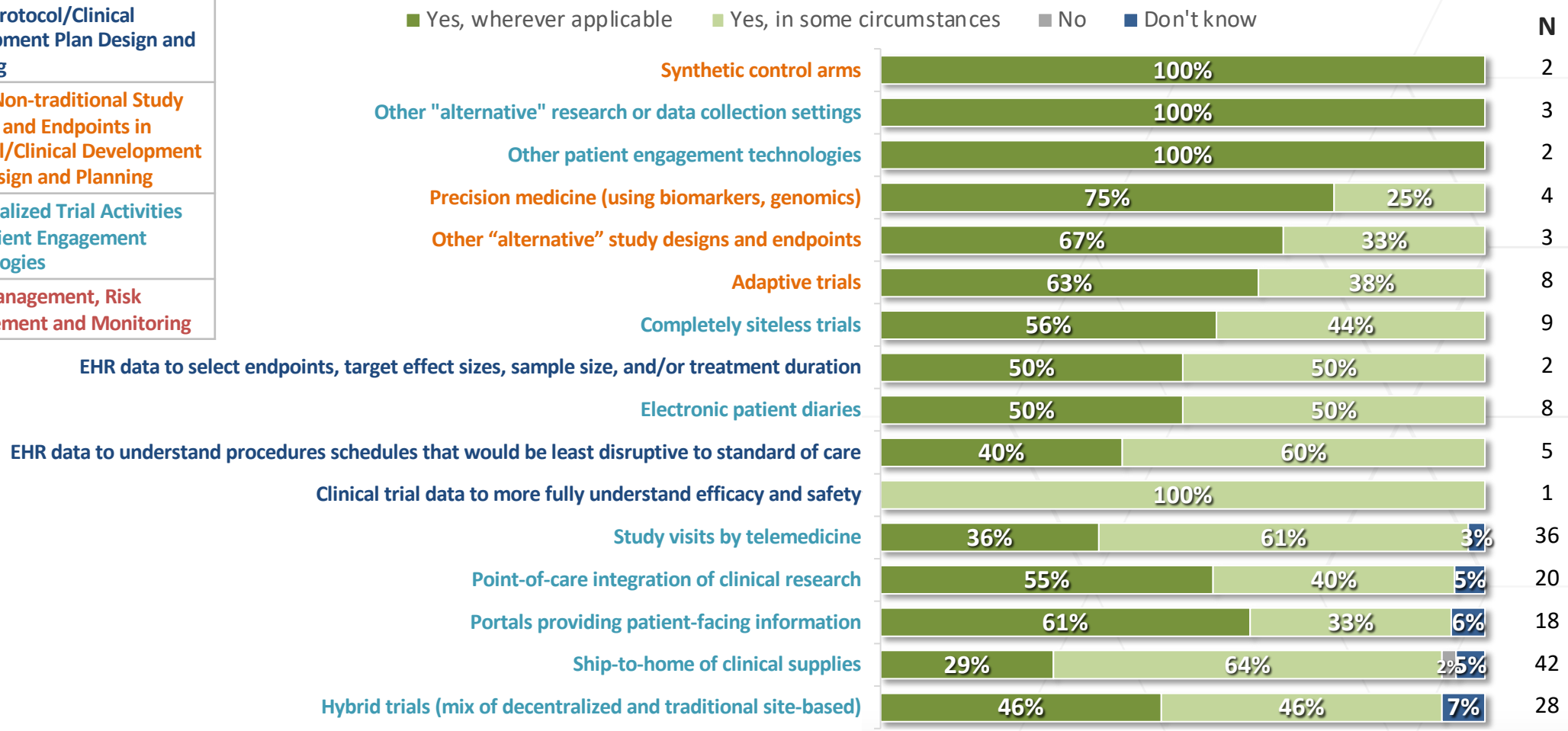
N: 24-134

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Innovations by Type: Overall Use/Plans to Use

Key:
Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Plans to Continue Using Innovations Post-COVID-19 *(Slide 1 of 2)*

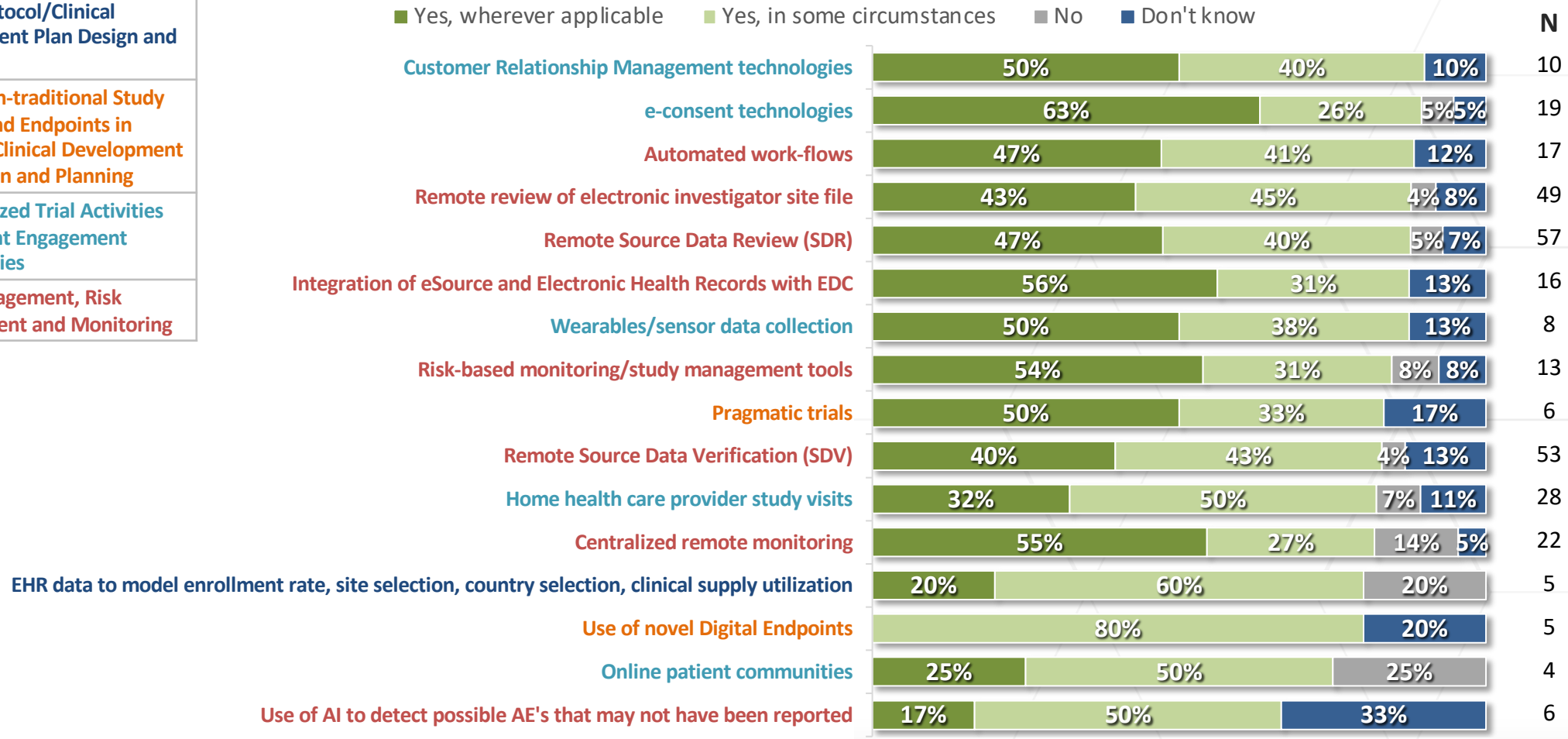


Q: You mentioned that your company started using "…" because of COVID-19. After concerns surrounding COVID-19 abate, do you believe that your company will continue to use this innovation?

Innovations by Type: Overall Use/Plans to Use

Key:
Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Plans to Continue Using Innovations Post-COVID-19 *(Slide 2 of 2)*



Q: You mentioned that your company started using "…" because of COVID-19. After concerns surrounding COVID-19 abate, do you believe that your company will continue to use this innovation?

Innovations by Type: Overall Use/Plans to Use

Key:
Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

Fraction No Plans to Use *(Slide 1 of 2)*

N: 24-134

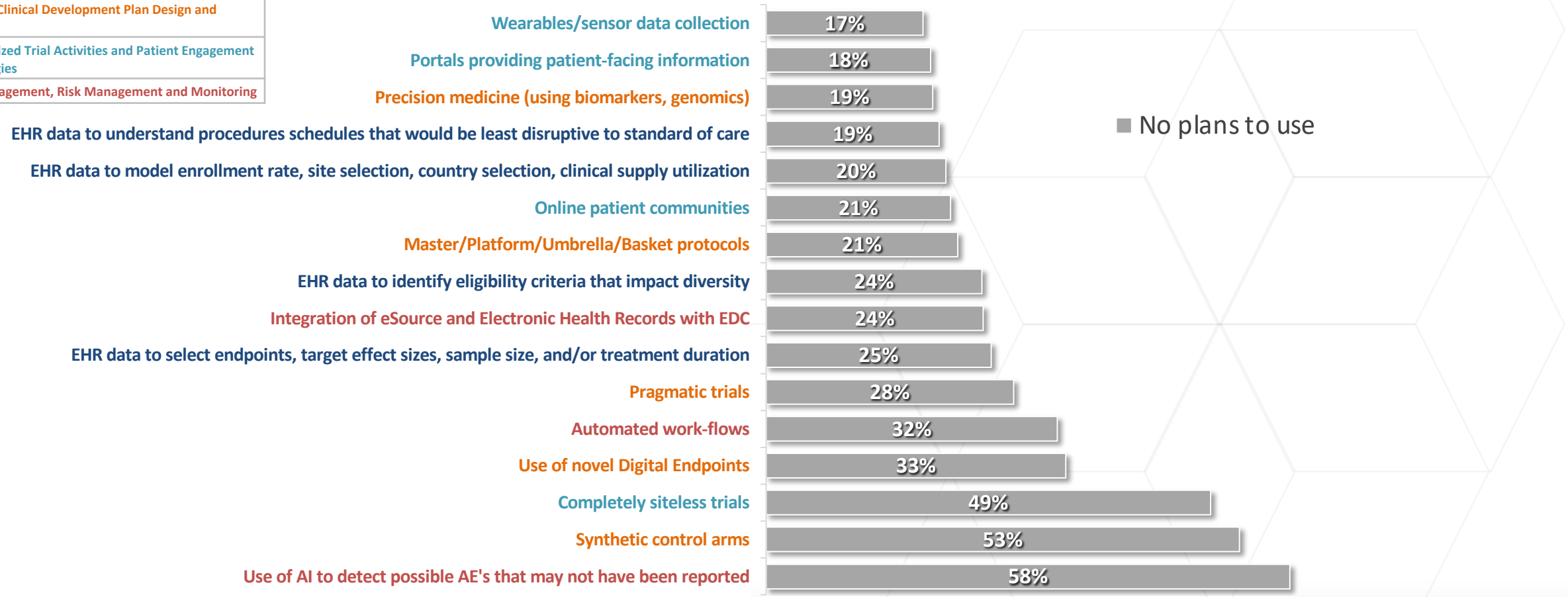
Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Innovations by Type: Overall Use/Plans to Use

Key:
Use of Artificial Intelligence (AI) in Protocol/Clinical Development Plan Design and Planning
Use of Non-traditional Study Designs and Endpoints in Protocol/Clinical Development Plan Design and Planning
Decentralized Trial Activities and Patient Engagement Technologies
Data Management, Risk Management and Monitoring

Companies' Use of the Following Clinical Trial Tools

All, Fraction No Plans to Use *(Slide 2 of 2)*

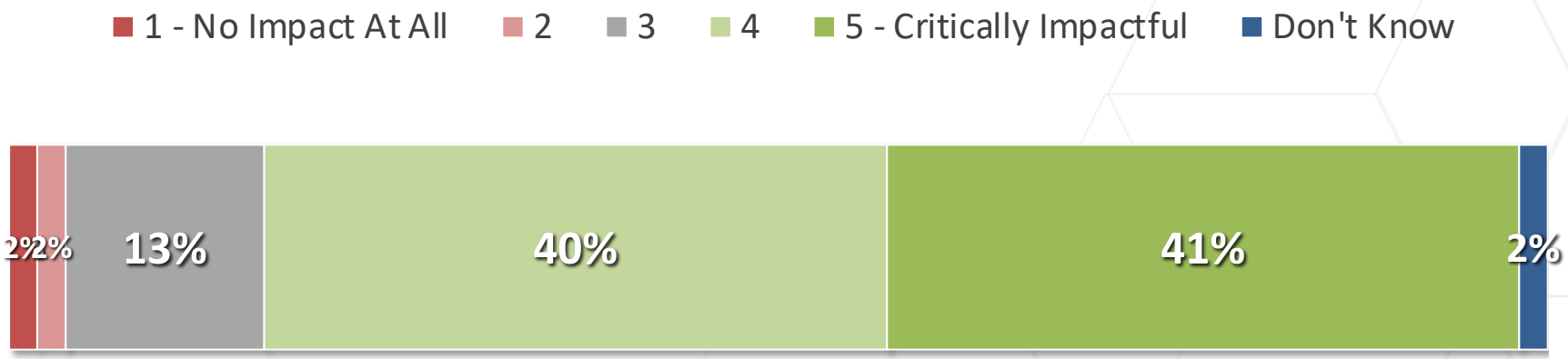


N: 24-134

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Impact of COVID-19 on Clinical Research Model Sustainability

To what extent do you feel that the COVID-19 pandemic has served to accelerate the industry toward a more sustainable clinical research model, in terms of the ability to endure pandemics, demographic shifts, process shifts, economic shifts, natural disasters, etc.?



N: 163

Q: On a scale of 1 (no impact at all) to 5 (critically impactful), to what extent do you feel that the COVID-19 pandemic has served to accelerate the industry toward a more sustainable clinical research model, in terms of the ability to endure pandemics, demographic shifts, process shifts, economic shifts, natural disasters, etc.?

Innovations by Type

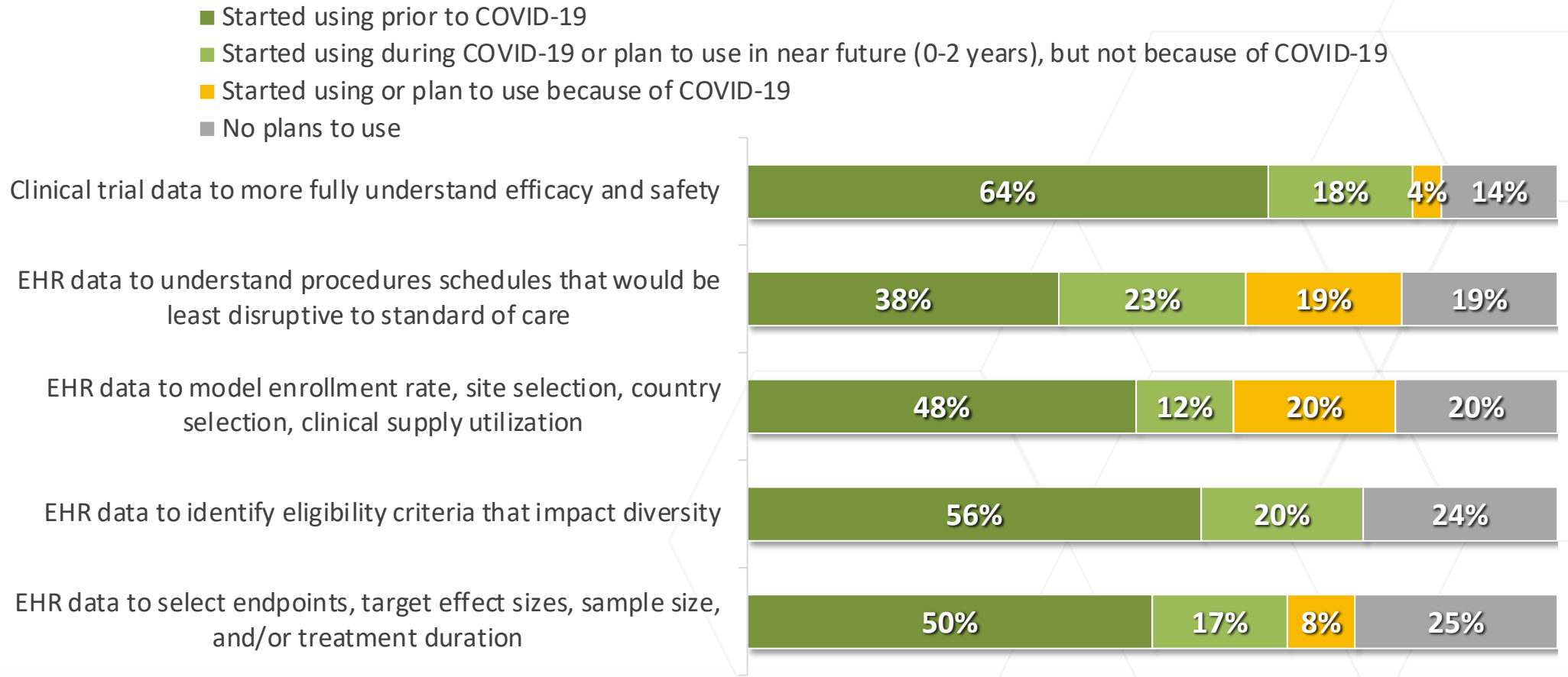
Use of AI in Protocol/Clinical Development Plan Design/Planning

Innovations by Type: Use of Artificial Intelligence

- With respect to the use of AI in protocol and clinical development planning specifically, many respondents reported that their companies had employed or planned to employ these innovations independent of COVID-19; only 0%-20% adopted these innovations because of COVID-19. Significant percentages (14%-25%) had no plans to adopt innovations in this area.
- Despite the relatively low adoption rate of AI compared to other types of innovations studied in this survey, respondents' perceptions of the impact of AI-related innovations on clinical trial quality were largely positive. Most respondents felt that innovations of this type contributed positively to data completeness and accuracy, protocol compliance, streamlining of clinical development programs, retention and diversity of clinical trial participants, and the ability to interpret study data. Few respondents felt that such innovations posed significant quality risks.
- Among respondents whose companies had deployed AI-related innovations, the primary drivers for doing so most commonly included the possibilities of accelerating timelines for both individual clinical trials and clinical development programs as a whole, increasing protocol compliance, and reducing operational risk and protocol amendments. These drivers were essentially the same among both sponsor and CRO respondents.
- Among all respondents, including those whose companies had not yet deployed AI innovations, the primary challenges associated with adoption and effective use of innovations in this category included lack of understanding of the innovation and lack of clarity about the value proposition. These impediments were followed distantly by concerns about start-up costs, operational, process, and systems integration, and many other perceived challenges. Again, this pattern was common to both sponsor and provider respondents.

AI in Protocol/Clinical Development Plan Design/Planning

Please rate your company's plans for use of each of the following clinical trial tools, using the below scales:

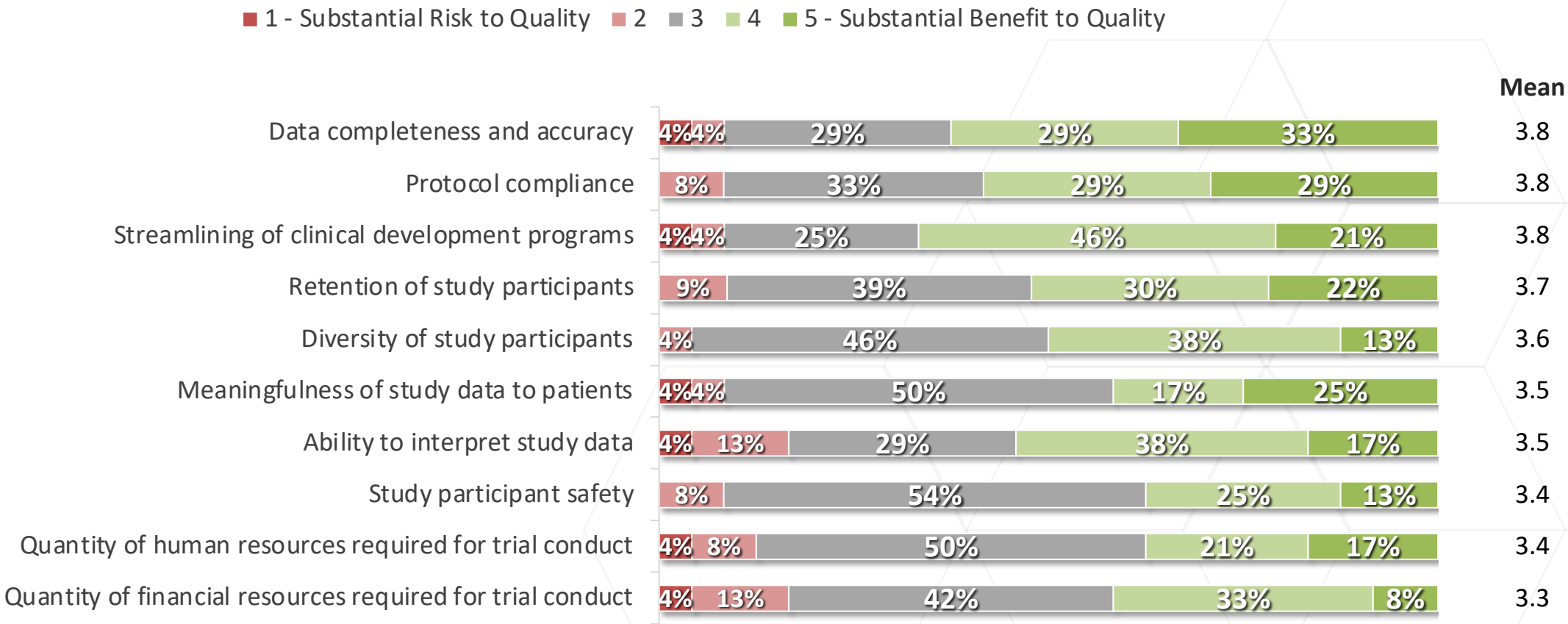


N: 24-28

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

AI in Protocol/Clinical Development Plan Design/Planning

Perception of Innovations' Impacts on Clinical Trial Quality

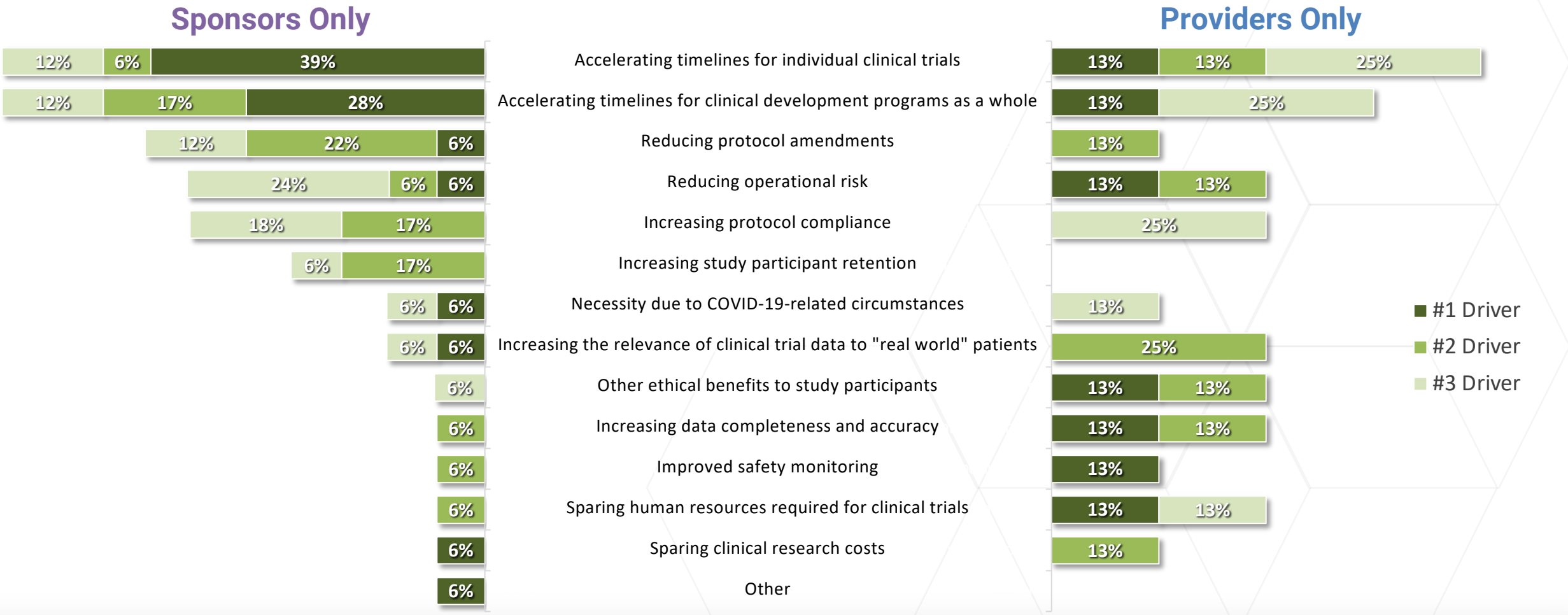


N: 23-24

Q: On a scale from 1 (substantial risk to quality) to 5 (substantial benefit to quality), with a rating of 3 being neutral, how do you perceive each of the below innovations to impact clinical trial quality in each of the following areas?

AI in Protocol/Clinical Development Plan Design/Planning

Top 3 Drivers for Adoption and Effective Use



N: Sponsor=17-18, Provider=8

Q: Out of these potential drivers, what would you say are your company's top 3 when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top driver? Note that by "driver," we mean a factor that actually contributed to decisions about whether or not to adopt an innovative approach, and not simply a perceived (incidental) benefit.

AI in Protocol/Clinical Development Plan Design/Planning

Top 3 Challenges to Adoption and Effective Use

N: Sponsor=95-109, Provider=39-52

Q: Out of these potential issues, what would you say are your company's top 3 challenges when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top challenge?

Innovations by Type

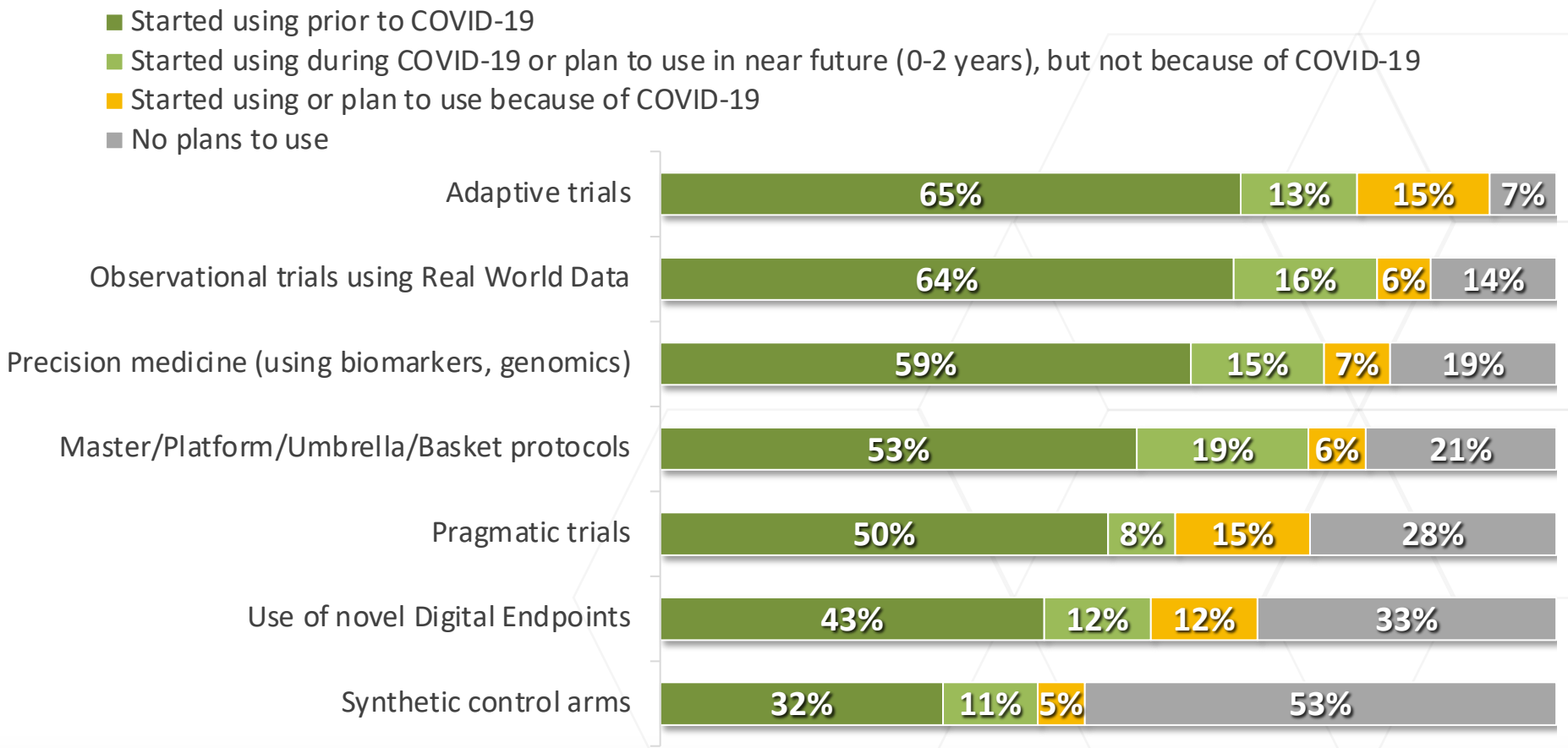
Use of Non-traditional Study Designs and Endpoints

Innovations by Type: Use of Non-traditional Study Designs and Endpoints

- With respect to the use of non-traditional study designs and endpoints, many respondents again reported that their companies had employed or planned to employ these innovations independent of the COVID-19 pandemic; only 5%-15% adopted them because of it. Responses varied quite widely by specific innovation. For example, the majority had already begun to use adaptive trials, observational RWD (real-world data) trials, and precision medicine-focused trials (using biomarkers, genomics), whereas more than half had no plans at all to use synthetic control arms and a third had no plans to adopt novel digital endpoints.
- About half of respondents felt the impact of innovations in this category to be neutral with respect to most aspects of clinical trial quality, and most of the remainder perceived impacts to be positive. The “ability to interpret study data” was an exception; 32% of respondents were concerned that the use of non-traditional study designs and endpoints could pose significant risks in this area.
- Among respondents whose companies had deployed non-traditional study designs and endpoints, the primary drivers for doing so most commonly included accelerating timelines for both individual clinical trials and clinical development programs as a whole, and increasing the relevance of clinical trial data to “real-world” patients. The pattern of priority in drivers was essentially the same among both sponsor and provider respondents.
- Among all respondents, including those whose companies had not yet deployed innovations in this category, the primary challenge associated with adoption and effective use involved regulatory concerns. This impediment was followed distantly by general concerns about risk, lack of understanding of the innovations and their value propositions, and many other perceived challenges. Again, this pattern was largely common to respondents from both sponsors and providers.

Use of Non-traditional Study Designs and Endpoints

Please rate your company's plans for use of each of the following clinical trial tools, using the below scales:

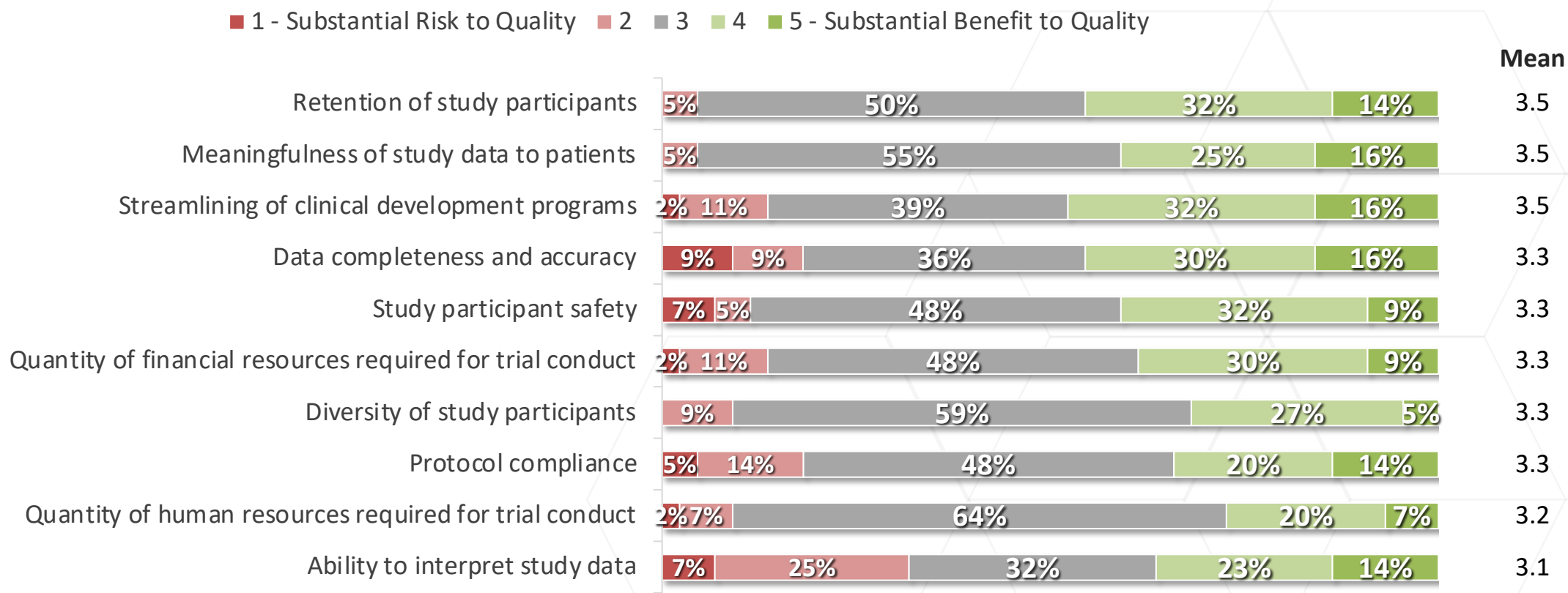


N: 38-54

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Use of Non-traditional Study Designs and Endpoints

Perception of Innovations' Impacts on Clinical Trial Quality

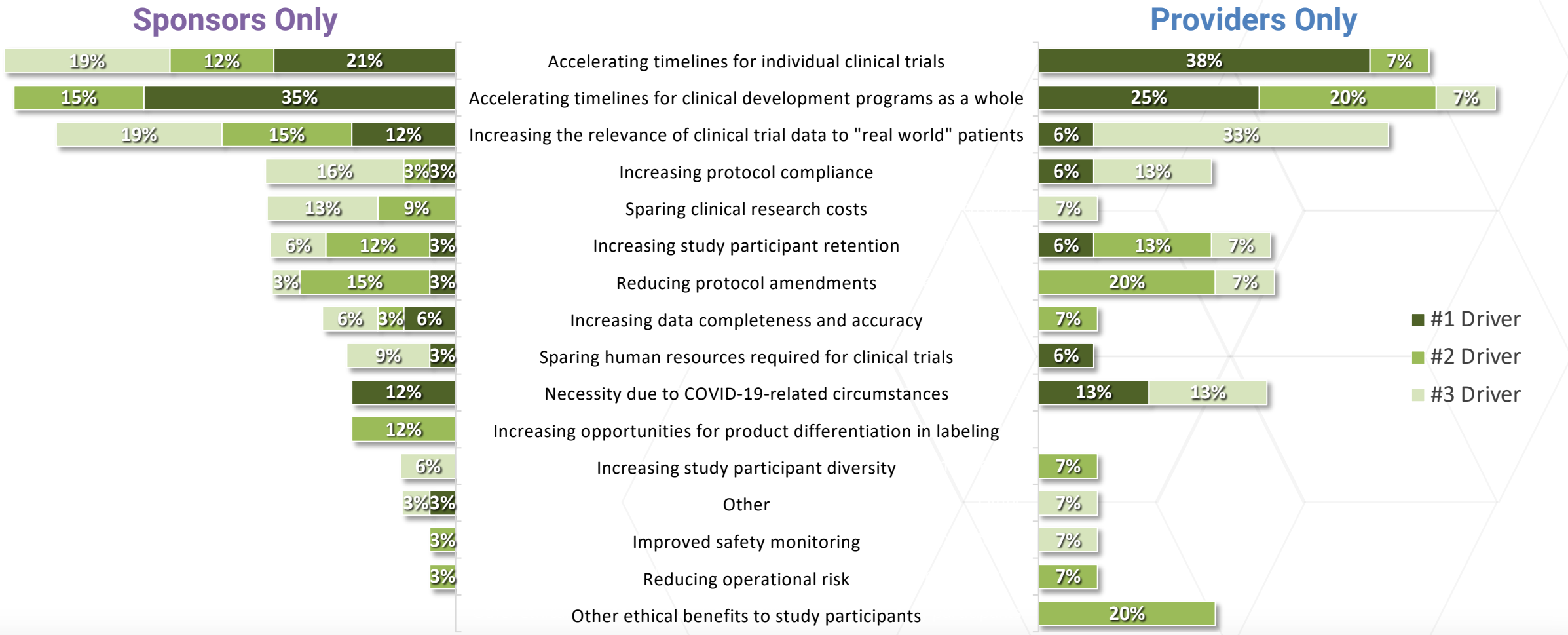


N: 44

Q: On a scale from 1 (substantial risk to quality) to 5 (substantial benefit to quality), with a rating of 3 being neutral, how do you perceive each of the below innovations to impact clinical trial quality in each of the following areas?

Use of Non-traditional Study Designs and Endpoints

Top 3 Drivers for Adoption and Effective Use



N: Sponsor=32-34, Provider=15-16

Q: Out of these potential drivers, what would you say are your company's top 3 when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top driver? Note that by "driver," we mean a factor that actually contributed to decisions about whether or not to adopt an innovative approach, and not simply a perceived (incidental) benefit.

Use of Non-traditional Study Designs and Endpoints

Top 3 Challenges to Adoption and Effective Use

N: Sponsor=90-104, Provider=39-50

Q: Out of these potential issues, what would you say are your company's top 3 challenges when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top challenge?

Innovations by Type

Decentralized Trial Activities and Patient Engagement Technologies

Innovations by Type: Decentralized Trial Activities and Patient Engagement Technologies

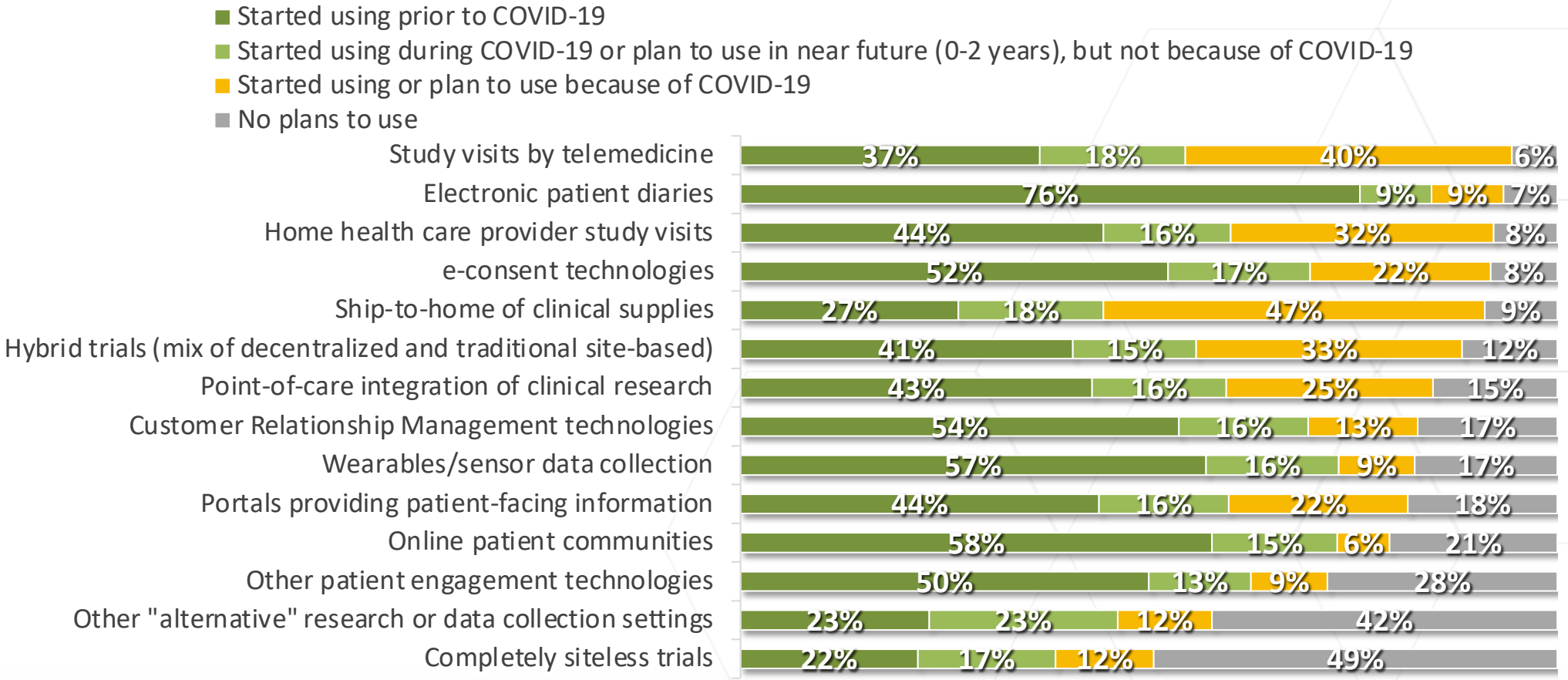
- With respect to the use of decentralized trial activities and patient engagement technologies, many respondents reported that their companies had deployed or planned to deploy these innovations independent of COVID-19. However, responses varied widely by specific innovation. Innovations most likely to have already been adopted prior to COVID-19 included electronic patient diaries (76%), online patient communities (58%), and use of wearable sensors (57%). Innovations most likely to have been adopted because of COVID-19 included ship-to-home of clinical supplies (47%), study visits by telemedicine (40%) or home health care providers (32%), and hybrid trials (33%). Ninety-four percent had already adopted or planned to adopt study visits via telemedicine, but 49% had no plans to move toward completely siteless trials.
- Respondents' perceptions of the impacts of innovations in this category on clinical trial quality varied considerably depending on the aspect of quality in question. Most respondents felt that decentralized activities benefitted retention and diversity of study participants, as well as the streamlining of clinical development programs, including the sparing of required human resources. However, approximately one-quarter felt that decentralization presented substantial risks to protocol compliance, study participant safety, and study participant privacy.

Innovations by Type: Decentralized Trial Activities and Patient Engagement Technologies

- Among respondents whose companies had deployed decentralized trial activities and patient engagement technologies, the primary drivers for doing so most commonly included increasing study participant retention and protocol compliance, and necessity due to COVID-19.
- Among all respondents, including those whose companies had not yet deployed innovations in this category, the primary challenges associated with adoption and effective use involved operational and process integration, followed closely by regulatory concerns, unclear value propositions, and a wide variety of other challenges. Responses to this question were quite a bit more variable than they were for challenges related to other innovation categories. Although both sponsor and provider respondents were concerned about operational and process integration and regulatory challenges, sponsors were much more likely to feel limited by lack of understanding of the innovations (26% cited it as a Top 3 challenge) compared to providers (11%). (Slightly different numbers than appear in figure are due to rounding.)

Decentralized Trial Activities and Patient Engagement Technologies

Please rate your company's plans for use of each of the following clinical trial tools, using the below scales:

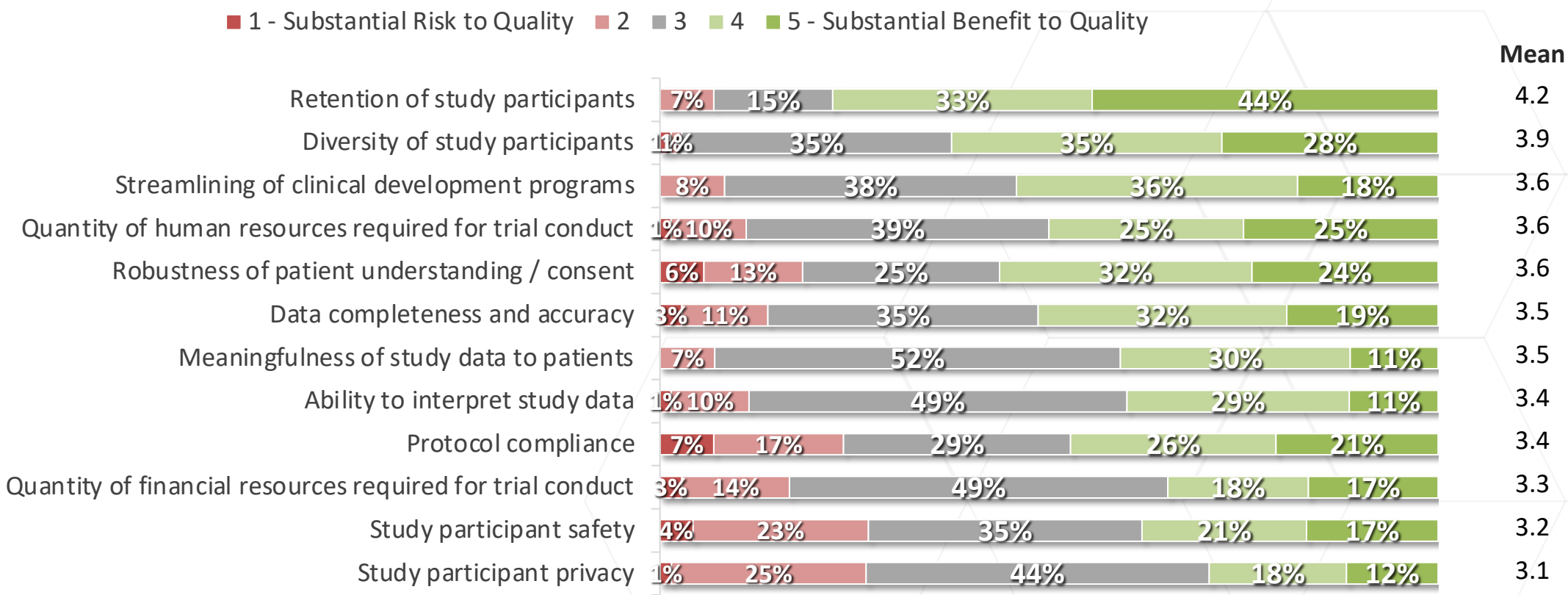


N: 26-91

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Decentralized Trial Activities and Patient Engagement Technologies

Perception of Innovations' Impacts on Clinical Trial Quality

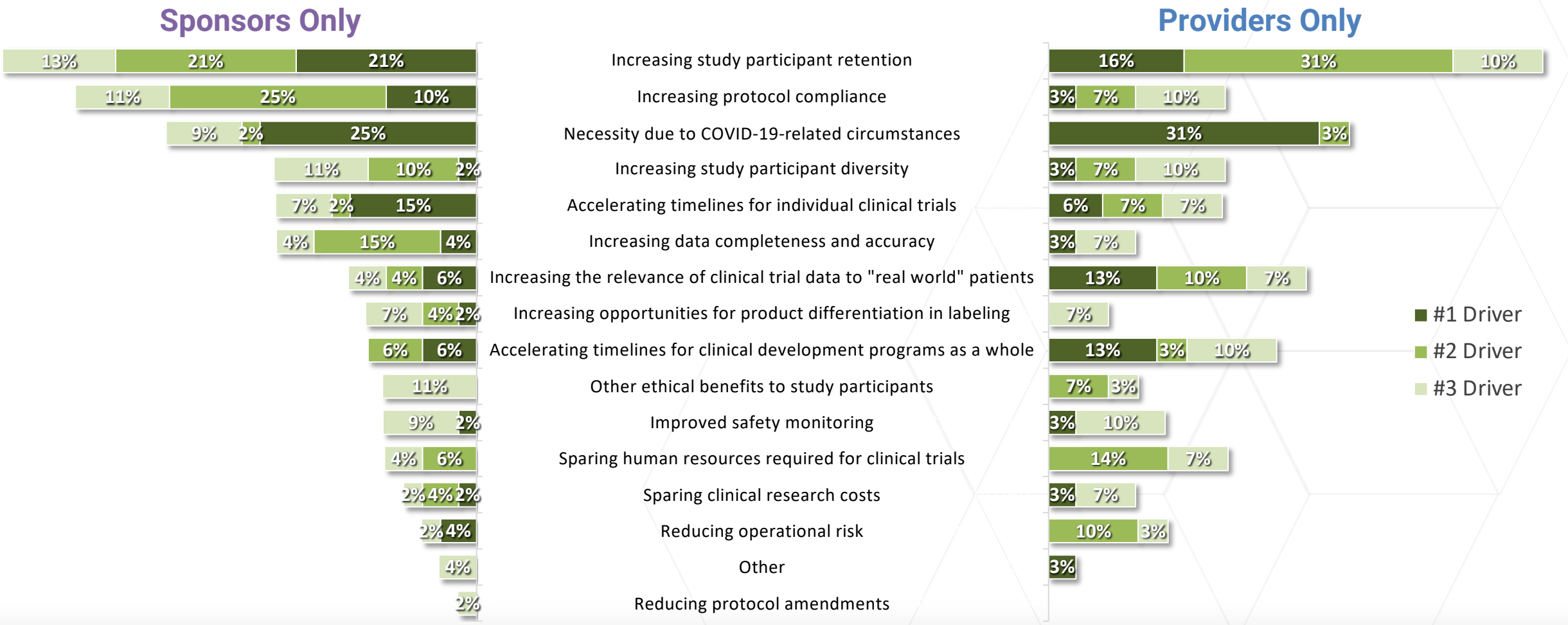


N: 68-72

Q: On a scale from 1 (substantial risk to quality) to 5 (substantial benefit to quality), with a rating of 3 being neutral, how do you perceive each of the below innovations to impact clinical trial quality in each of the following areas?

Decentralized Trial Activities and Patient Engagement Technologies

Top 3 Drivers for Adoption and Effective Use

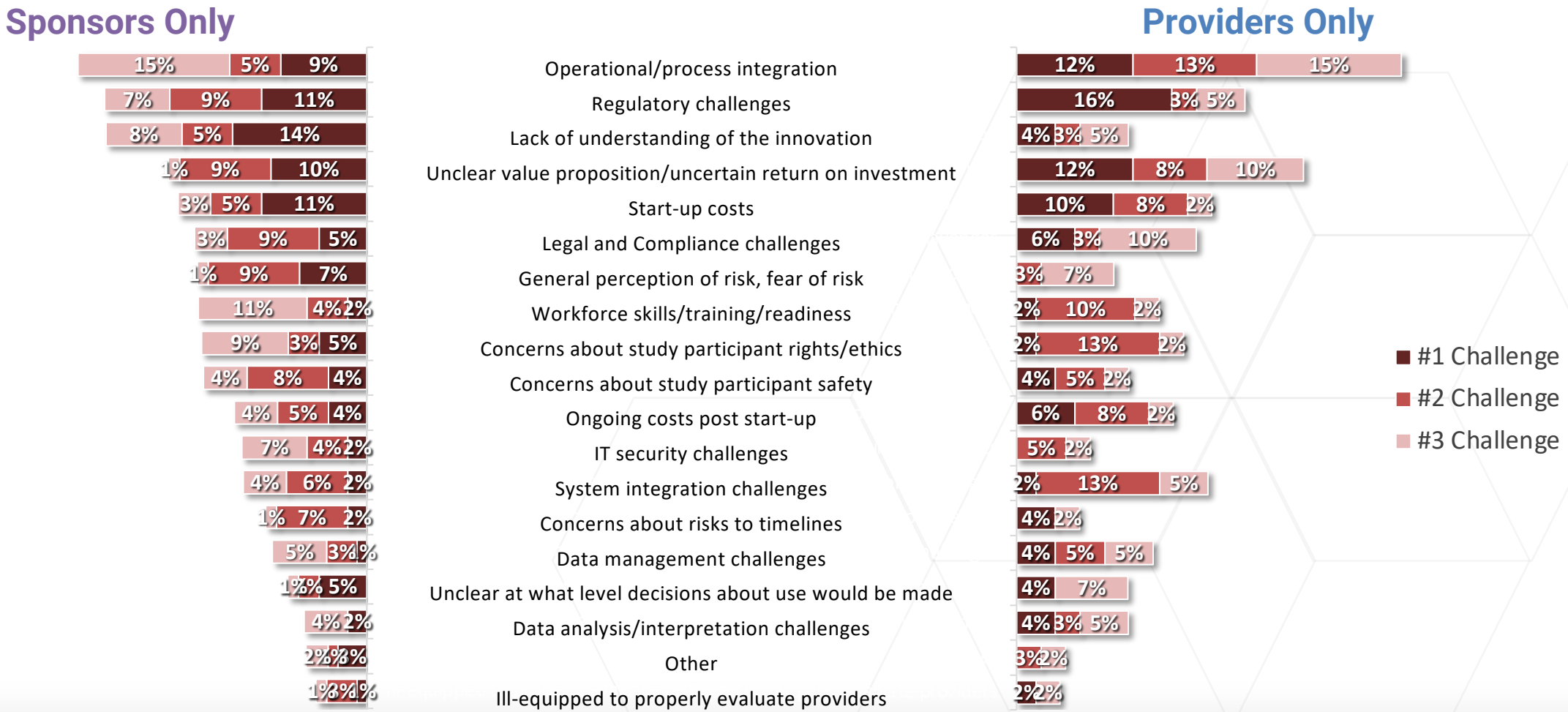


N: Sponsor=46-48, Provider=29-32

Q: Out of these potential drivers, what would you say are your company's top 3 when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top driver? Note that by "driver," we mean a factor that actually contributed to decisions about whether or not to adopt an innovative approach, and not simply a perceived (incidental) benefit.

Decentralized Trial Activities and Patient Engagement Technologies

Top 3 Challenges to Adoption and Effective Use



N: Sponsor=91-103, Provider=40-51

Q: Out of these potential issues, what would you say are your company's top 3 challenges when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top challenge?

Innovations by Type

Data Management, Risk Management, and Monitoring

Innovations by Type: Data Management, Risk Management, and Monitoring

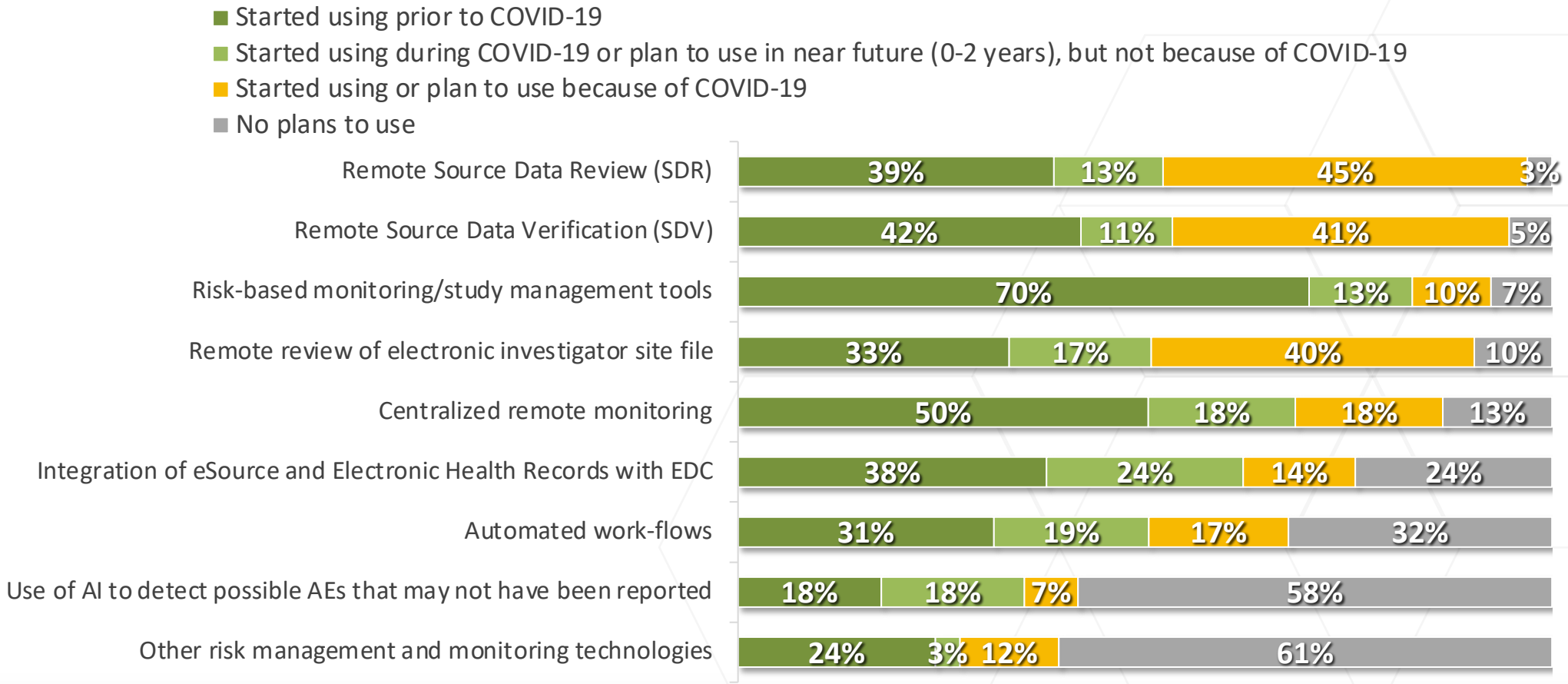
- With respect to the use of data management, risk management, and monitoring innovations, many respondents again reported that their companies had deployed or planned to deploy these innovations independent of COVID-19. However, responses once more varied widely according to the specific innovation. Innovations most likely to have already been adopted prior to COVID-19 included risk-based monitoring and study management tools (70%) and centralized remote monitoring (50%), whereas innovations most likely to have been adopted because of COVID-19 included remote source data review (45%), remote source data verification (41%), and remote review of the electronic investigator site file (40%). Ninety-seven percent had already adopted or planned to adopt remote source data review, but 58% had no plans to utilize AI to detect possible AEs that may not have been reported.
- Respondents' perceptions of the impacts of innovations in this category on clinical trial quality again varied considerably depending on the quality aspect. Most respondents felt that innovations in this category benefitted data completeness and accuracy, protocol compliance, the ability to interpret study data, and study participant safety. Feelings about impacts on other aspects of quality tended toward neutral, but more than 15% of respondents were concerned about risks to study participant privacy and to the quantity of human and financial resources required to conduct trials.

Innovations by Type: Data Management, Risk Management, and Monitoring

- Among respondents whose companies had deployed data management, risk management, and monitoring innovations, the primary drivers for doing so most commonly included increasing data completeness and accuracy, reducing operational risk, increasing protocol compliance, and necessity due to COVID-19. The general pattern of top drivers was the same across sponsors and providers, though improved safety monitoring was more likely to be a Top 3 driver for provider respondents (35%) than for sponsor respondents (20%).
- Among all respondents, including those whose companies had not yet deployed innovations in this category, the primary challenges associated with adoption and effective use related to operational and process integration, followed by data management challenges, lack of workforce readiness, system integration challenges, and a wide variety of other concerns. Responses to this question were again more variable than they were for challenges related to some of the other innovation categories, but overall patterns were similar for both sponsors and providers.

Data Management, Risk Management, and Monitoring

Please rate your company's plans for use of each of the following clinical trial tools, using the below scales:

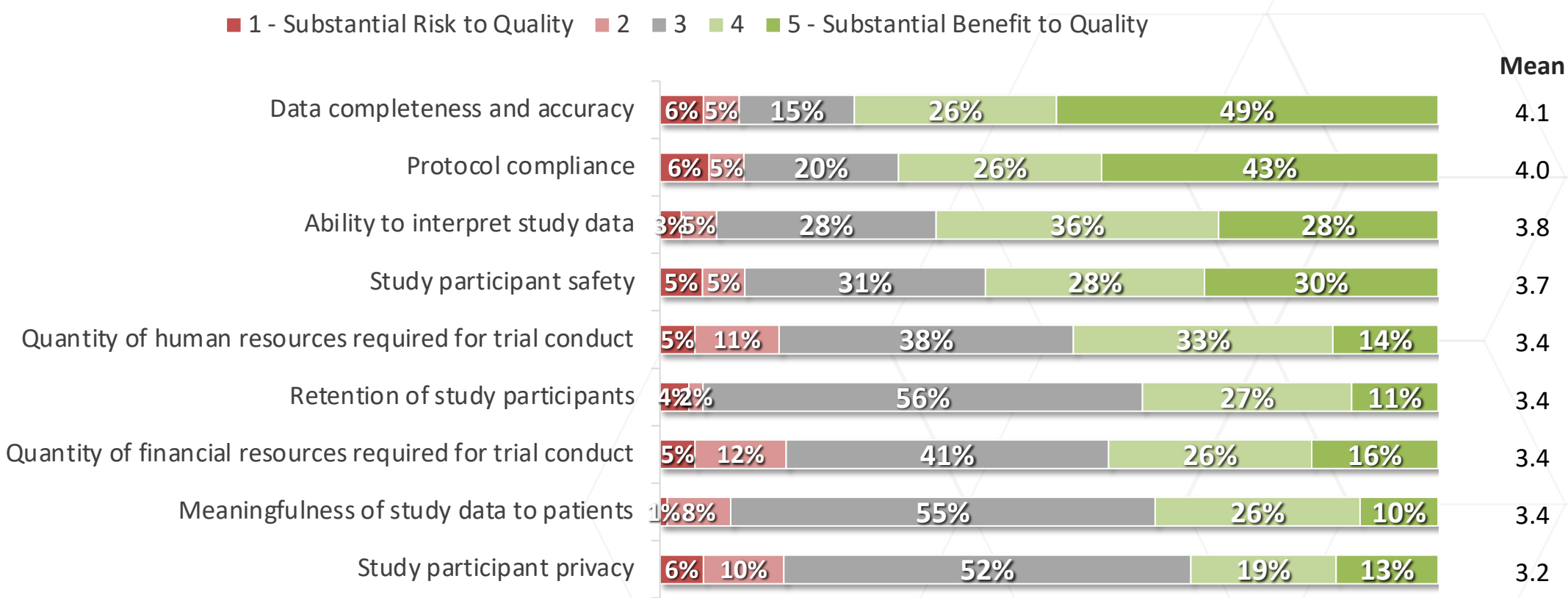


N: 33-134

Q: Please rate your company's plans for use of each of the following clinical trial tools, using the below scales.

Data Management, Risk Management, and Monitoring

Perception of Innovations' Impacts on Clinical Trial Quality

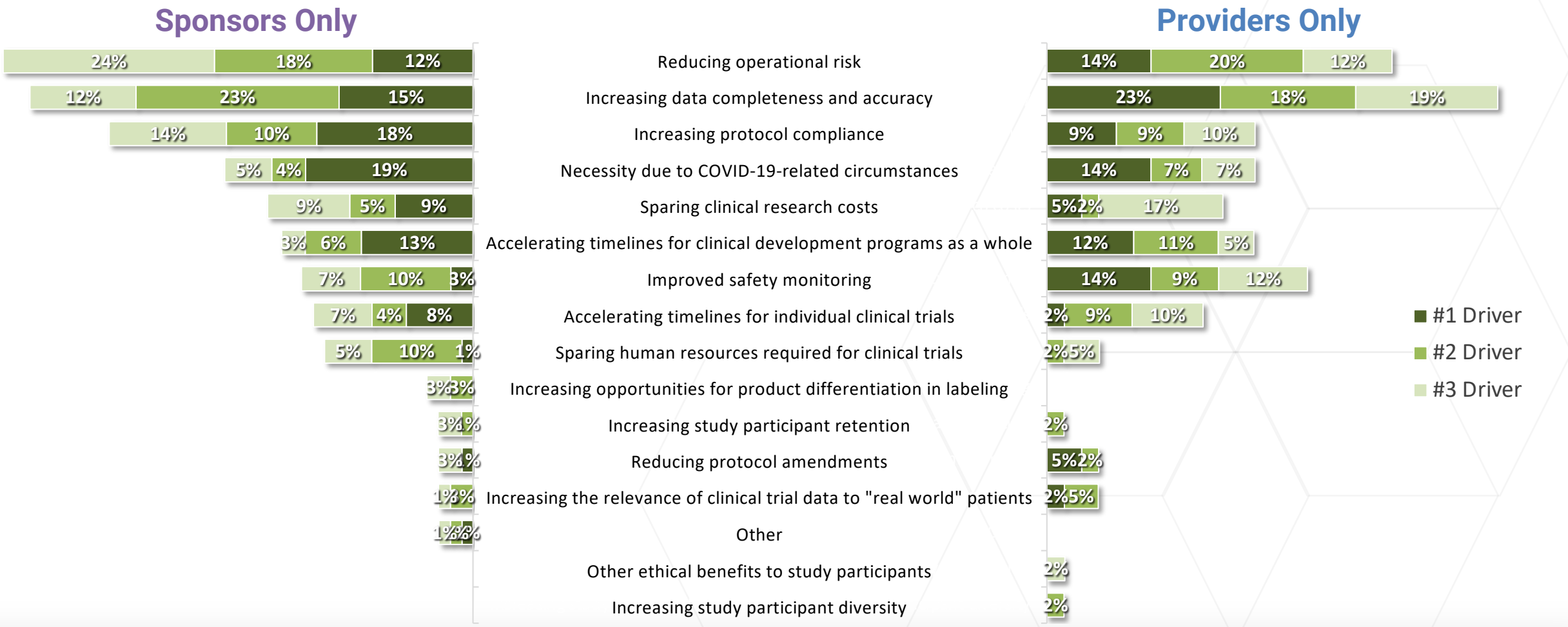


N: 107-111

Q: On a scale from 1 (substantial risk to quality) to 5 (substantial benefit to quality), with a rating of 3 being neutral, how do you perceive each of the below innovations to impact clinical trial quality in each of the following areas?

Data Management, Risk Management, and Monitoring

Top 3 Drivers for Adoption and Effective Use

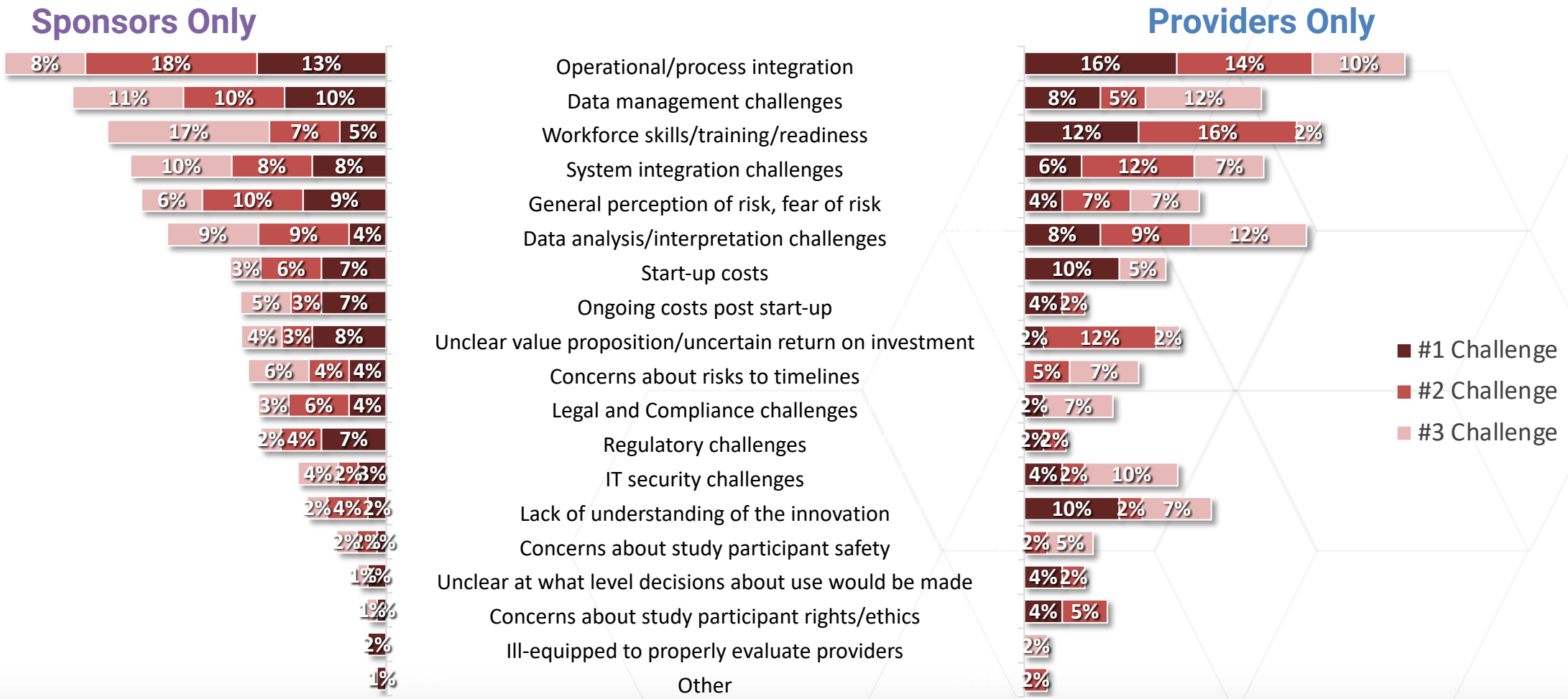


N: Sponsor=74-78, Provider=42-44

Q: Out of these potential drivers, what would you say are your company's top 3 when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top driver? Note that by "driver," we mean a factor that actually contributed to decisions about whether or not to adopt an innovative approach, and not simply a perceived (incidental) benefit.

Data Management, Risk Management, and Monitoring

Top 3 Challenges to Adoption and Effective Use



N: Sponsor=96-105, Provider=42-51

Q: Out of these potential issues, what would you say are your company's top 3 challenges when it comes to effectively using innovations in each of the following areas, ranked in order with 1 representing the top challenge?

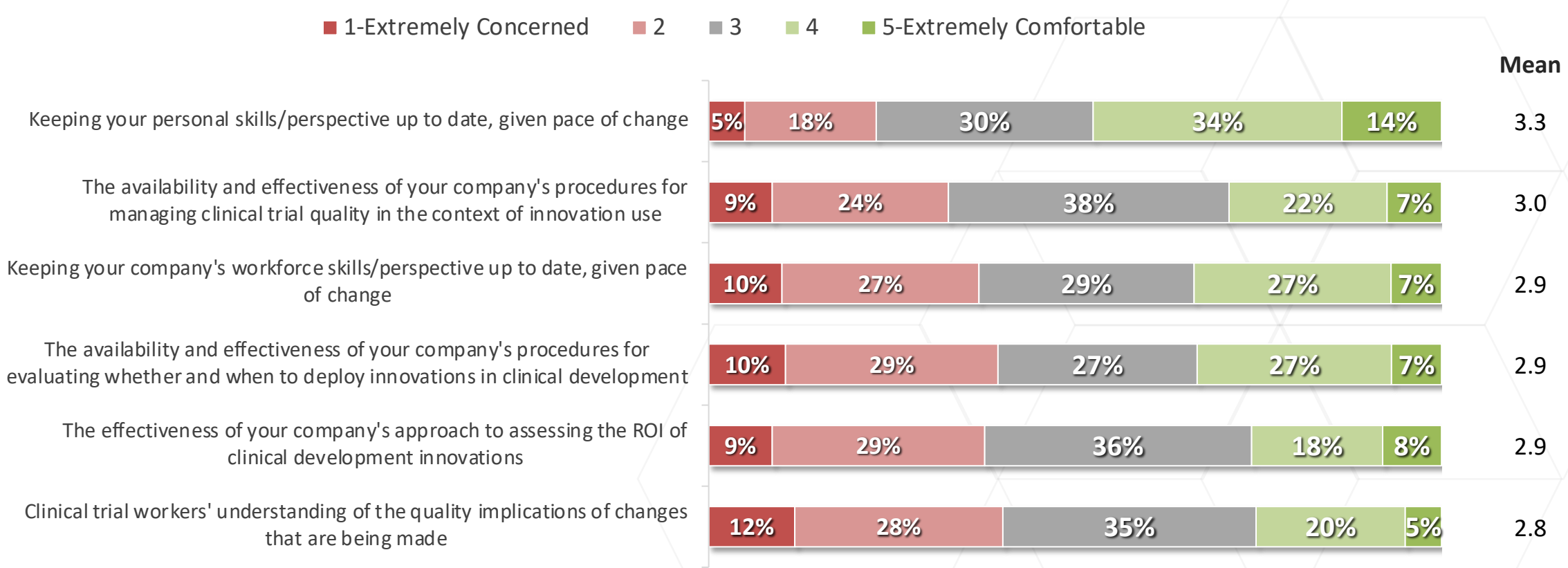
Workforce Considerations in Clinical Research Innovation

Workforce Considerations in Clinical Research Innovation

- When respondents were asked about their levels of concern regarding various aspects of workforce and corporate readiness for innovations, their responses varied widely. Nearly half were comfortable about keeping their own personal skills and perspectives up to date, but only one-third were comfortable about their companies' workforces as a whole in this respect, and more were uncomfortable.
- Many were also concerned about their companies' readiness in other respects. At least one-third were uncomfortable with their companies' procedures for managing clinical trial quality in the context of innovation use and for evaluating whether and when to deploy innovations in clinical development; more were uncomfortable than were comfortable in these respects.
- Even greater percentages were uncomfortable with the effectiveness of their companies' approaches to assessing the ROI of innovations (38%), and with clinical trial workers' understanding of the quality implications of the changes being made (40%). Again, these fractions were higher than the fractions who were comfortable in these respects (26% and 25%, respectively).

Concerns about Workforce and Corporate Innovation Readiness

Please rate your level of concern about each of the following:



N: 160-162

Q: Please rate your level of concern about each of the following on a scale of 1 (extremely concerned) to 5 (extremely comfortable).

Thank You

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