

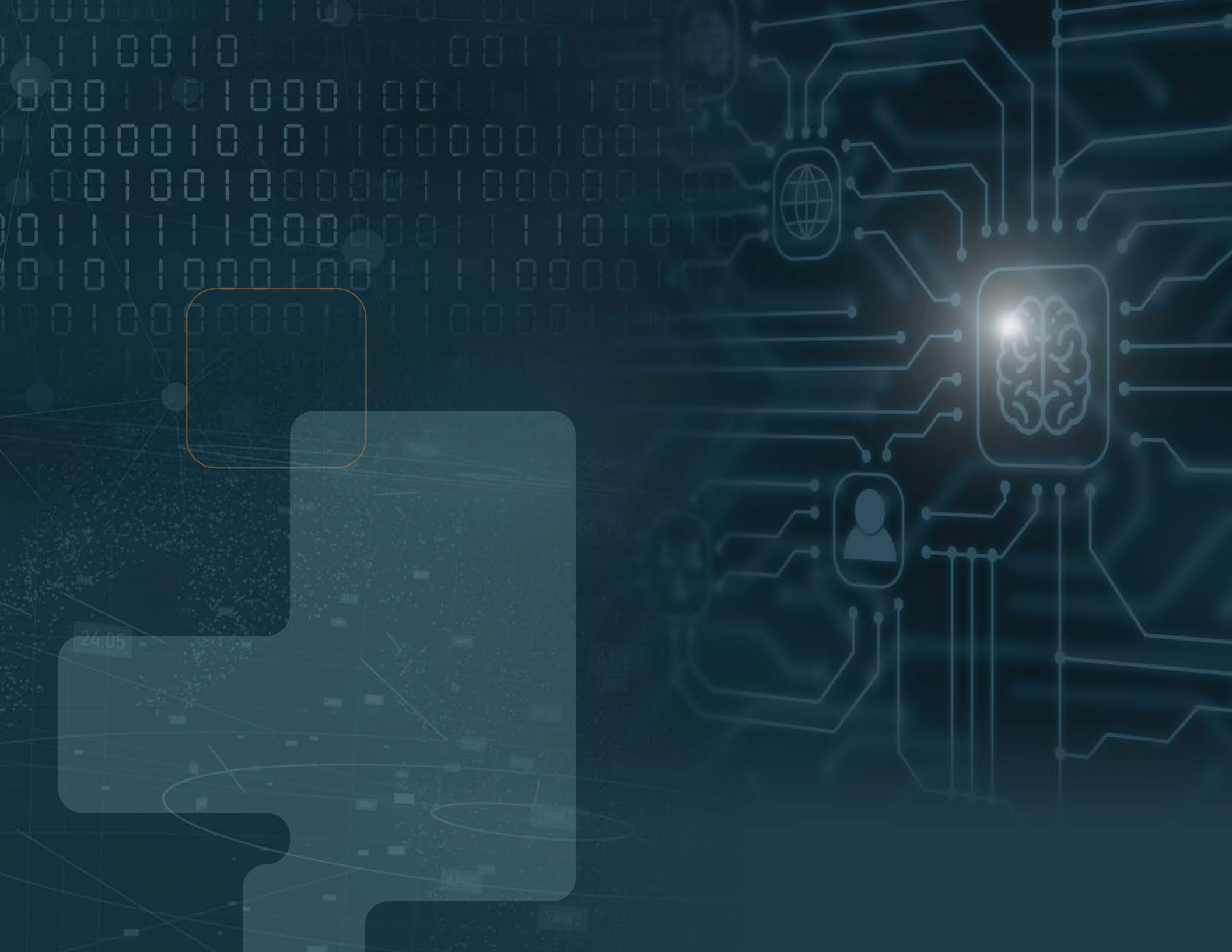
June 2023

Optimizing Clinical Trials at Health Systems

The Role of Artificial Intelligence
and State of the Market



Center for **Connected** Medicine



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Forward

The pharmaceutical and biotech industries have made tremendous strides in developing new therapeutics to treat rare diseases and chronic conditions in recent years. However, a critical component of bringing new treatments to market is facing many challenges. Carrying out successful clinical trials requires the identification and enrollment of the appropriate patients. But finding those patients is often a costly and laborious process for academic medical centers and health systems that typically must perform manual chart reviews to identify qualifying patients.

This cumbersome process is expensive and often leads to delays and higher costs to study sponsors. In fact, around 80% of trials fail to meet the initial enrollment target and timeline, according to a 2020 study published in the Journal of Medical Internet Research.

Artificial intelligence may hold some promise in addressing this challenge. As AI use in health care captures more attention for its potential to streamline operations, unburden physicians, and help analyze large data sets, this report addresses the emerging use case of using AI for clinical trial patient matching. Natural language processing (NLP) is already being used to harness and analyze the vast quantities of unstructured data often siloed in clinical notes. The application of NLP for patient matching could be a game changer for health systems, industry, and patients.

While it's early days for this use of AI, the Center for Connected Medicine (CCM) is committed to exploring the future of innovation at health systems, especially where it intersects with digital technology and medical and scientific breakthroughs. Optimizing clinical trials with AI is an ideal focus area as we carry out our mission and call attention to opportunities for health care to improve.

Alex Nixon
Senior Research Analyst, CCM



Introduction

Health care organizations that participate in clinical trials can help advance innovation in health care while offering patients access to cutting-edge treatments not yet widely available. However, participating in such trials comes with a variety of challenges, most notably the costly, highly manual process of identifying and recruiting participants as well as the need to manage each study's specific regulations and requirements.

This report explores organizations' interest in leveraging more sophisticated, automated technology—including artificial intelligence (AI) capabilities—to improve the efficiency and efficacy of clinical trial processes. While development of AI-powered tools for clinical trial participant recruitment and retention is still early, more than half of respondents agree that the technology has potential for addressing challenges.

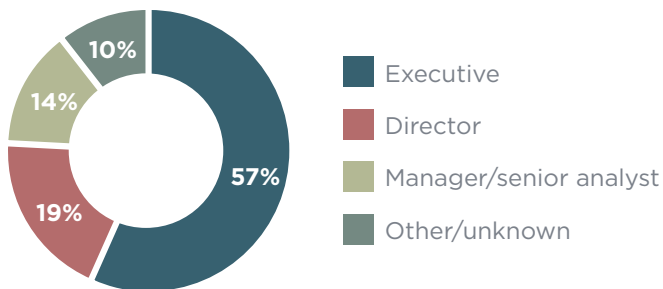
Additionally, outside the specific use case of clinical trials, this report explores respondent perspectives on the current state of AI in the health care market at large. Respondents to the Center for Connected Medicine's Top of Mind research have consistently identified AI as a top-of-mind technology with significant potential to impact the future of health care. Prior to the COVID-19 pandemic, adoption of AI solutions in health care was slow and often narrowly focused on specific areas, such as value-based care and population health management. During the pandemic, implementation of AI was limited mostly to capabilities that could help reduce the burden of the pandemic. Now, there is renewed interest in the technology's potential to improve operational efficiency amid financial pressures, staffing challenges, and other concerns.



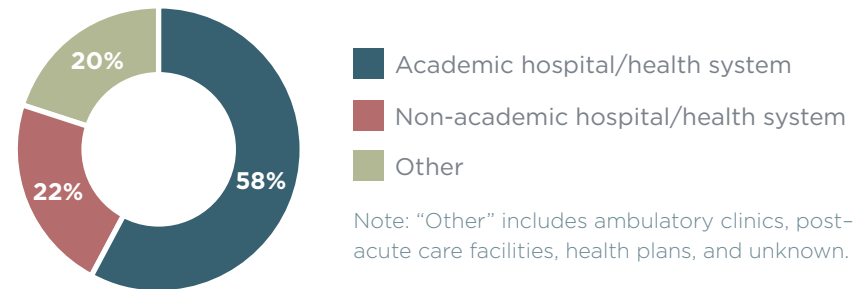
Respondent Demographics

Data for this report was collected from 58 executives and other senior-level contacts at payer and provider organizations, many of whom specialize in AI and analytics. Over half of the respondents represent large acute care organizations (>500 beds). Respondents were asked a series of qualitative and quantitative questions about (1) their organizations' participation in and challenges with clinical trials, and (2) their organizations' current and future utilization of AI capabilities. Data was collected from December 2022 through February 2023. The demographics of survey respondents are summarized below.

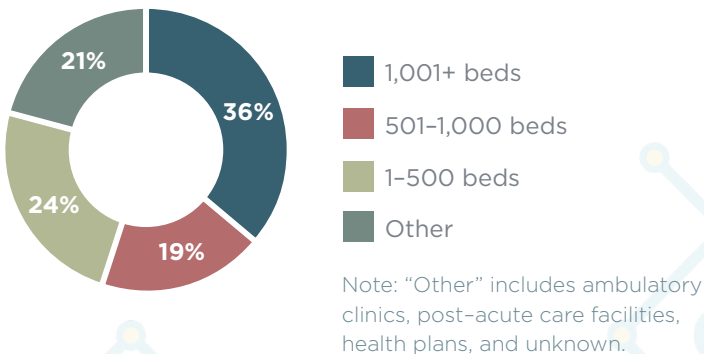
Job Level (n=58)



Academic Status (n=58)



Organization Size/Type (n=58)



Clinical Trials

Clinical trials continue to push health care to new levels of innovation and treatment. However, participation in these trials comes with many administrative challenges for health care organizations, especially early in the enrollment phase. This section of the report looks at why health care organizations choose to participate in clinical trials along with the challenges they face. It also shares respondent perspectives on using technology solutions to make the clinical trial process less resource heavy.



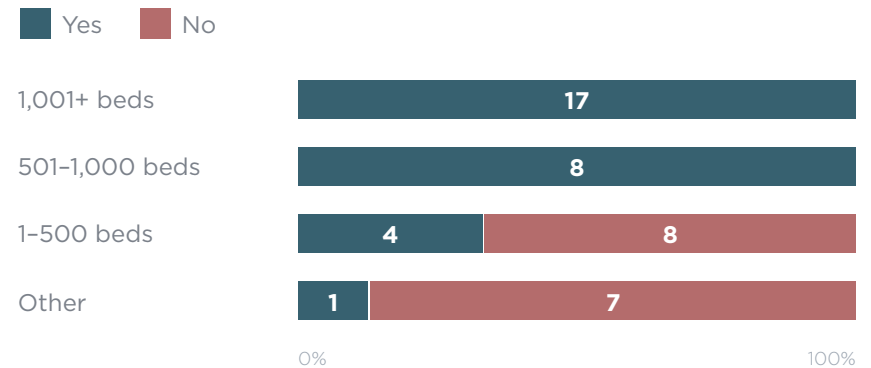
Key Terminology

- **Clinical trials:** Studies that identify and measure the health-related effects of targeted interventions on human subjects
- **Prescreening:** Steps conducted prior to enrolling a participant in a clinical trial that check to make sure the participant meets all the required qualifications
- **Clinical trial matching solution:** Technology that helps organizations find and match patients to appropriate clinical trials
- **Clinical trial management solution:** Software that helps organizations manage all operational aspects of a clinical trial

Patient Treatment Options and Researcher Recruitment Provide Motivation for Clinical Trials

The majority of interviewed respondents reported that their organization participates in clinical trials, including all 25 of the largest (i.e., organizations with >500 beds). Their top two reasons for participation (both cited by 72% of respondents) are to offer alternative treatment options to patients and to attract researchers and clinicians. In this consumer-based market, the ability to offer cutting-edge care can help organizations stay relevant. A far less commonly cited driver of participation is the desire to diversify revenue sources. Because it requires significant financial, human, and other resources to support a clinical trial, revenue diversification is rarely an initial motivator. However, once organizations have created the infrastructure necessary to support clinical trials, they might begin looking for ways to achieve a financial ROI.

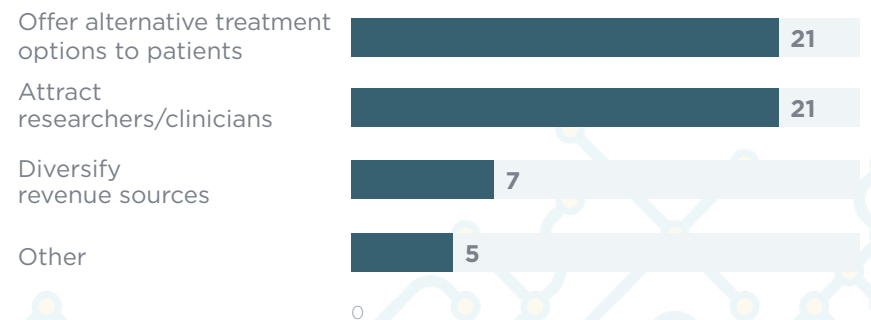
Does Your Organization Participate in Clinical Trials for New Drugs, Treatments, and Devices? (n=45)



Note: Chart does not include respondents who chose “unsure” or did not answer this question.

Note: “Other” includes ambulatory clinics, post-acute care facilities, health plans, and unknown.

Why Does Your Organization Participate in Clinical Trials? (n=29)



Note: “Other” includes having ownership in future therapeutic technologies and innovation.

Timely Identification of Patient Cohorts a Challenge for Two-Thirds of Respondents

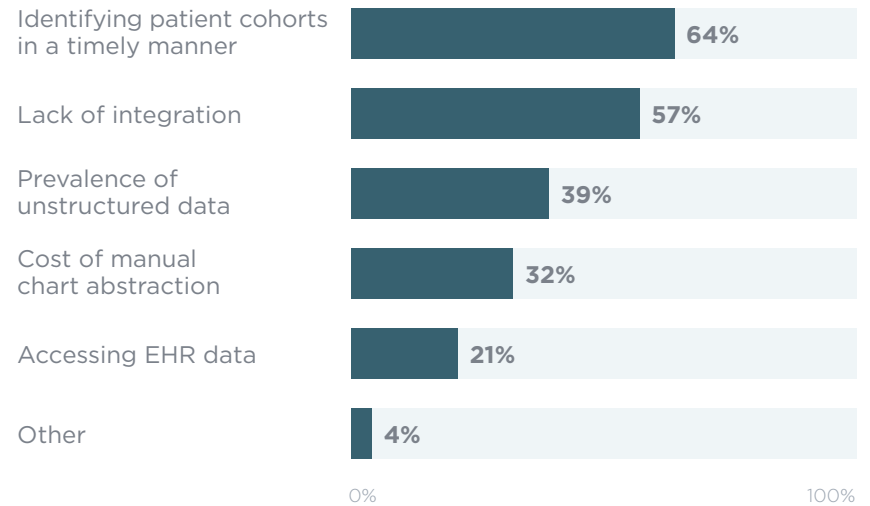
Organizations that participate in clinical trial research face a number of difficulties. The biggest challenges are the inability to identify patient cohorts in a timely manner and a lack of integration between clinician workflows and the trial management workflows.

Low awareness among patients and providers, lack of adequate representation of minority or underserved populations, and demanding study criteria can make it a struggle to identify and enroll participants. With diseases such as pediatric cancers, both parents and providers are likely to be highly engaged in patient care, resulting in higher participation rates. However, for studies that involve rare diseases or have vigorous protocol designs, it can be significantly harder to identify and enroll patients. When technology is lacking, organizations often hire coordinators to manually sift through patient charts to find potential matches. This is especially challenging for large organizations that have numerous trials and significantly more providers to keep informed.

Lack of integration between clinician workflows and trial management workflows is also a common problem. The pharmaceutical companies or other sponsors running the studies often use their own clinical trial management solutions, leading to duplicate data entry between these systems and an organization's own IT solutions. Additionally, to access the required treatment protocols, clinicians may have to switch between programs, making the care and documentation process inefficient and time consuming. This administrative burden can also dissuade providers from having patients participate in trials. Lack of integration is particularly a challenge for larger hospitals (>500 beds), but some respondents share steps their organizations have taken to target this issue. A clinical research information officer shared, **“To date, one of the gaps for us has been lack of integration for clinical trial management, but we are in the process of implementing Epic research functionality, and we have integrated a FHIR-enabled 21 CFR Part 11-compliant EDC (OpenClinica) with our EHR, so that gap is narrowing as we speak.”**

The other challenges less commonly reported are closely tied to the inability to identify patient cohorts and the lack of integration. For example, the prevalence of unstructured data is partly the result of poor integration and makes it difficult to identify patients. Unstructured data is a particular challenge for the smallest hospitals in this research sample. Larger organizations also report this as a challenge but are more likely to have resources to help them interpret and utilize the data. Other less commonly reported challenges include the cost of manual chart abstraction and the difficulty of accessing electronic health record (EHR) data.

Biggest Challenges with Meeting the Needs of Clinical Trial Sponsors (n=28)



Note: “Other” includes institutional review board requirements and overall lack of resources.

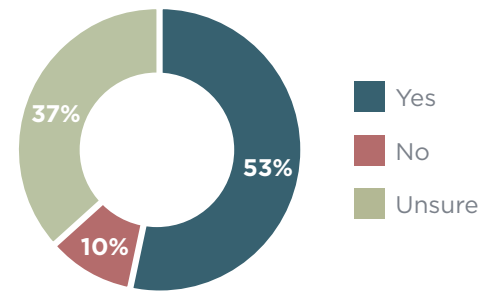
Many Recognize the Importance of Prescreening at Point of Care

During the prescreening process, organizations determine whether a patient meets the inclusion and exclusion criteria, and patient information is sent to the clinical trial sponsor to determine whether the patient should be enrolled. Abstracting the necessary data from the patient's chart is typically a very manual process. Implementing workflow solutions to help with this and to capture the responses of potential enrollees at the point of care could improve the timeliness of enrollment.

Respondent interest in such technology is mixed. Though more timely identification of patient cohorts is a top priority, nearly half of respondents disagree or are unsure whether a prescreening solution at the point of care is highly important. Variation in study participation rates may account for some of this lack of interest. It is easier to find participants for studies with less stringent criteria or for which there is high patient and provider interest, making a point-of-care prescreening tool less vital for success. However, types of studies for which it is much more challenging to find qualified participants would benefit more from technology that helps providers identify potential candidates at the point of care.

About one-third of participants—mostly executive-level contacts—are unsure whether it is highly important to have a prescreening workflow solution at the point of care. It may be that these respondents feel such information would be more helpful for clinicians to access before they are interacting with the patient. Clinicians typically have very little time with patients, so having the information prior to the patient visit could help them better prepare for the conversation.

Are Prescreening Workflow Solutions at the Point of Care Highly Important? (n=30)



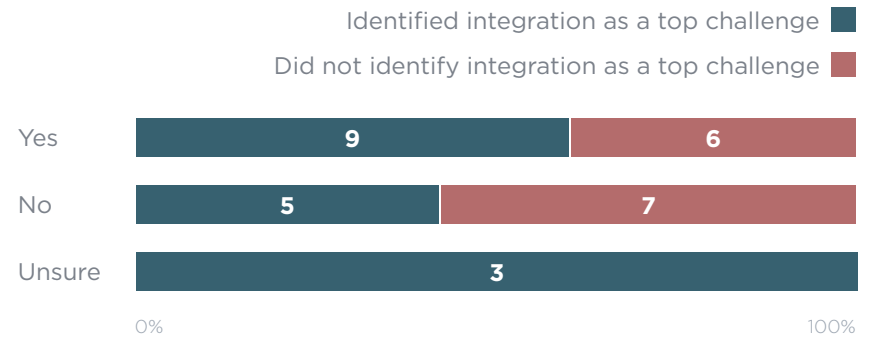
Only Half of Organizations Say Direct Integration between Matching Solution and Management Solution Is of Strategic Importance

Not surprisingly, respondents that identify integration between clinical trial management solutions and clinical workflows as a challenge are more likely to also view direct integration between clinical matching tools and clinical trial management solutions to be of strategic importance. However, overall, nearly half of respondents do not view direct matching tool/management solution integration as vital. One such respondent noted that the current technology is not advanced enough, though they are optimistic for the future. Even respondents who do agree with the importance of such integration emphasize that it would be beneficial only if it came with robust technology and high accuracy.

More often, respondents are interested in integrating the clinical trial management solution directly into the clinician EHR workflow. The current lack of such integration leads to time-consuming duplicate data entry.

Is Direct Integration between Matching Solution and Management Solution of Strategic Importance?

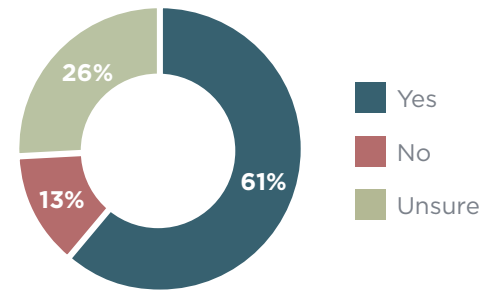
(n=30)



Most Organizations Agree That AI Solutions Could Play Critical Role in Clinical Trials

The majority of respondents, especially those representing larger organizations, agree that AI data science solutions have the potential to play a critical role in identifying and recruiting participants for clinical trials. AI is seen as having the potential to allow organizations to complete matching, identification, and recruitment tasks at scale, enabling them to participate in more trials. Smaller organizations are more likely to be unsure what role AI technology will play. Respondents who don't see AI as playing a critical role in the future mention that existing analytics capabilities could potentially provide the same outcomes.

Are AI Data-Science Solutions Critical to Patient Matching, Identification, and Recruitment? (n=31)



Some IT vendors offer AI capabilities for clinical trials, though perceptions of the market readiness of these solutions are mixed. A clinical research information officer shared, **“I have worked in the trial-matching space, and my experience has been that high-fidelity matching benefits greatly from structured data, and a significant amount of needed data is currently in the EHR as unstructured data. This is a significant gap.”** However, according to respondents, some vendors that are focused specifically on AI for clinical trial matching have seen early positive results, and some research has shown that AI can positively impact safety, efficacy, and cost when used in clinical trials.

Artificial Intelligence: State of the Market

Artificial intelligence (AI) has been a buzzword in health care for years. In the Center for Connected Medicine's 2018 Top of Mind report, 63% of health care organizations reported that implementation of AI solutions was a low priority. However, interest in the technology has been growing recently. In the past two Top of Mind surveys, health system leaders identified AI as the emerging technology generating the most excitement. This is partly due to easier accessibility of AI tools and more potential for health care use cases. Many organizations employ at least one data scientist, and solutions such as R and Python are free, making it easier for organizations to explore ways to utilize AI. The following section examines the areas in which health systems currently use AI as well as where they plan to invest in the future.

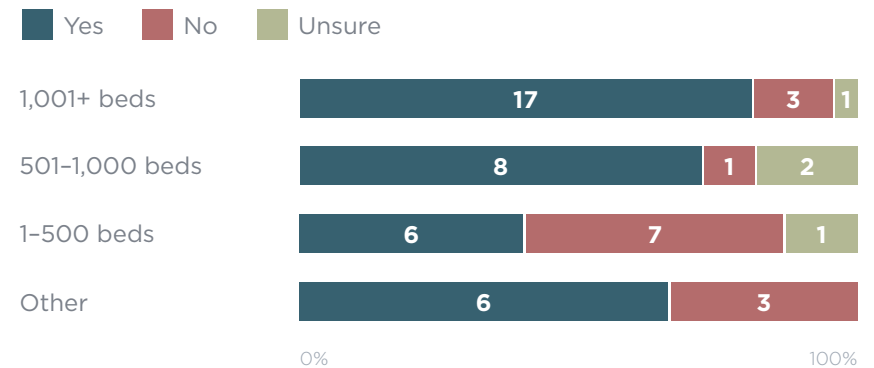
Key Terminology

- **Artificial intelligence:** Software that provides machine learning (ML) or natural language processing (NLP) capabilities for health care-related clinical, operational, or financial areas
- **Machine learning (ML):** Tools for structured data that study and learn computer systems' algorithms and statistical models to effectively perform tasks without requiring explicit instructions, relying instead on patterns and inference to determine results
- **Natural language processing (NLP):** Tools for unstructured data that enable software solutions to understand, process, and analyze natural language, whether speech or text

Most Responding Health Care Organizations Are Utilizing AI

An increasing number of health care organizations are dipping their toes in the water with AI capabilities. Two-thirds of respondents in this research are utilizing a health care AI solution at their organization. Several factors are influencing the increase in adoption. AI platforms have continued to evolve, and some health care IT solutions now come with built-in AI capabilities. Additionally, given the buzz around AI, organizations may adopt the technology in order to ensure they aren't falling behind competitors. The largest organizations in this research are the most likely to report some form of AI use. These organizations are more likely to have the resources needed to maintain, utilize, and operationalize AI solutions.

Is Your Organization Using Any Health Care AI Data-Science Solutions? (n=55)



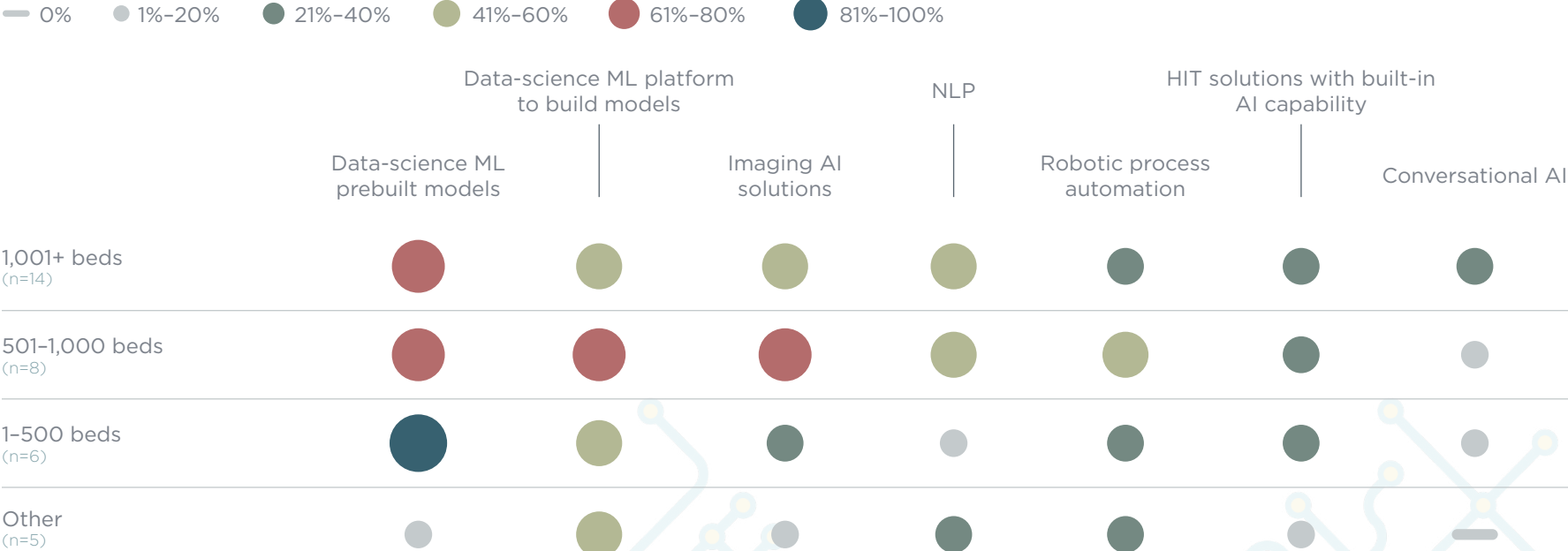
Note: "Other" includes ambulatory clinics, post-acute care facilities, health plans, and unknown.

While it can be a challenge to derive actionable insights from AI, [separate research recently conducted by KLAS](#) found that organizations are successful in operationalizing AI when they focus on use cases related to value-based care and population health management. Successful organizations focus on first identifying the right problem to solve, and then they are able to manage change and derive actionable insights from the data. Simply implementing an ML model won't produce the desired ROI if the model isn't operationalized throughout the organization.

Prebuilt ML Models the Most Common Type of AI in Use; RPA and Conversational AI Beginning to Be Adopted

Across organization sizes, data-science machine-learning models are the most common type of AI solution being leveraged, with prebuilt models being more common as they are generally easier to get up and running. Multiple respondents specifically reported using Epic’s prebuilt models. About half of respondents report using a data-science machine-learning platform to build their own models, and many organizations use both prebuilt models as well as models built by internal resources. Proper implementation of ML models is critical since the quality of the data that populates the model will determine its accuracy and success.

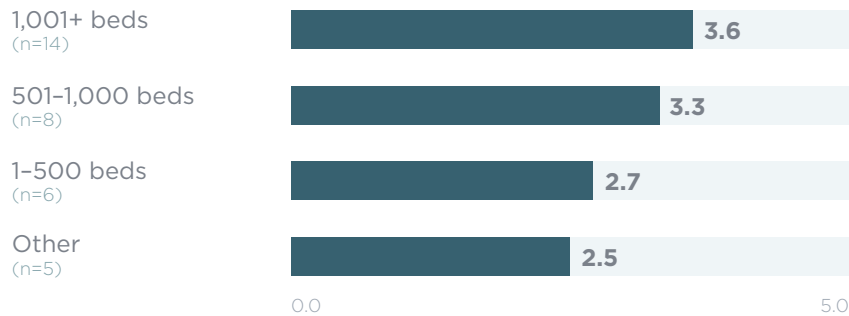
Which of the Following Types of AI Solutions Is Your Organization Using? (n=33)



Note: Respondents could report more than one type of AI solution.
 Note: "Other" includes ambulatory clinics, post-acute care facilities, health plans, and unknown.

Artificial Intelligence: State of the Market

Average Number of AI Solutions in Use (n=33)



Note: "Other" includes ambulatory clinics, post-acute care facilities, health plans, and unknown.

Many of the largest organizations in this research report are using three or more types of AI. However, this usage is likely limited to specific use cases or specific areas of the organization. The respondents who report that their organization has achieved good results with AI often attribute this success to the efforts of their own data scientists in building out models rather than to deep adoption of HIT solutions with AI capabilities.

Outside of data-science machine-learning models, the other types of AI solutions respondents were surveyed about—including imaging AI solutions, NLP, robotic process automation (RPA), and conversational AI—are most likely to be adopted by larger organizations. There is particular interest in newer solutions, such as RPA and conversational AI, and what they will be able to do for health care. RPA has shown early promise—nearly all participants in a recent KLAS report on RPA adopters reported results such as improved financial outcomes and staff efficiency. Given its ability to mimic human conversations and interactions, conversational AI is seen to have promising health care applications and the potential to improve operational efficiency and patient experiences. Able to learn and adapt, conversational AI is much more sophisticated than chat bots, which have been more widely adopted.



Disease Management and Prediction the Most Common Use Case Today; Operational Optimization Top of Mind for Now and Future Investment

Across organization sizes, health/disease management and prediction is the top use case for which organizations are currently leveraging AI capabilities, and it is also a top area for future investment (see next chart). Disease management and prediction enables identification of at-risk patients within a given population and also enables early detection of diseases such as sepsis—one of the most common use cases for AI. Such information is often used as a foundation for organizations' population health management (PHM) and value-based care (VBC) initiatives. Separate KLAS research on health care AI similarly found that health care organizations are using disease management and prediction models for a variety of PHM or VBC efforts, including preventing readmission in post-acute care patients, identifying patients who could most benefit from care management, and targeting patients most at risk for cancer or heart disease. With these models, organizations are able to make sure the most at-risk patients receive the care they need.

Operational optimization is the second most common use case and the number-one area for future investment (see next chart). One-third of organizations not currently using AI for operational optimization are considering future investment, and most current users are planning deeper adoption. While operational optimization does not have direct clinical or patient-facing applications, it is one of the most pragmatic AI use cases, and the high interest is no surprise given the cost pressures and thinning margins many health care organizations face. Though AI can be expensive and resource heavy, it can also create many operational efficiencies, particularly for revenue cycle and command center use cases. AI predictions have been shown to help improve patient flow management in command centers and provide decision makers with better information.

Imaging is the third most common use case. Imaging AI solutions and models require FDA clearance and must prove a high level of accuracy. The technology can improve radiologist efficiency by identifying the images most likely to have problems or abnormalities, allowing specialists to focus on the most urgent cases. Given the staffing shortages that many organizations face, such technology could help organizations do more with less. Studies have even found that certain ML models are better than physicians at predicting life expectancy for cancer patients as the AI removes subjectivity from the analysis. Additionally, using ML models with imaging and clinical data has shown promise in being able to predict heart attacks.

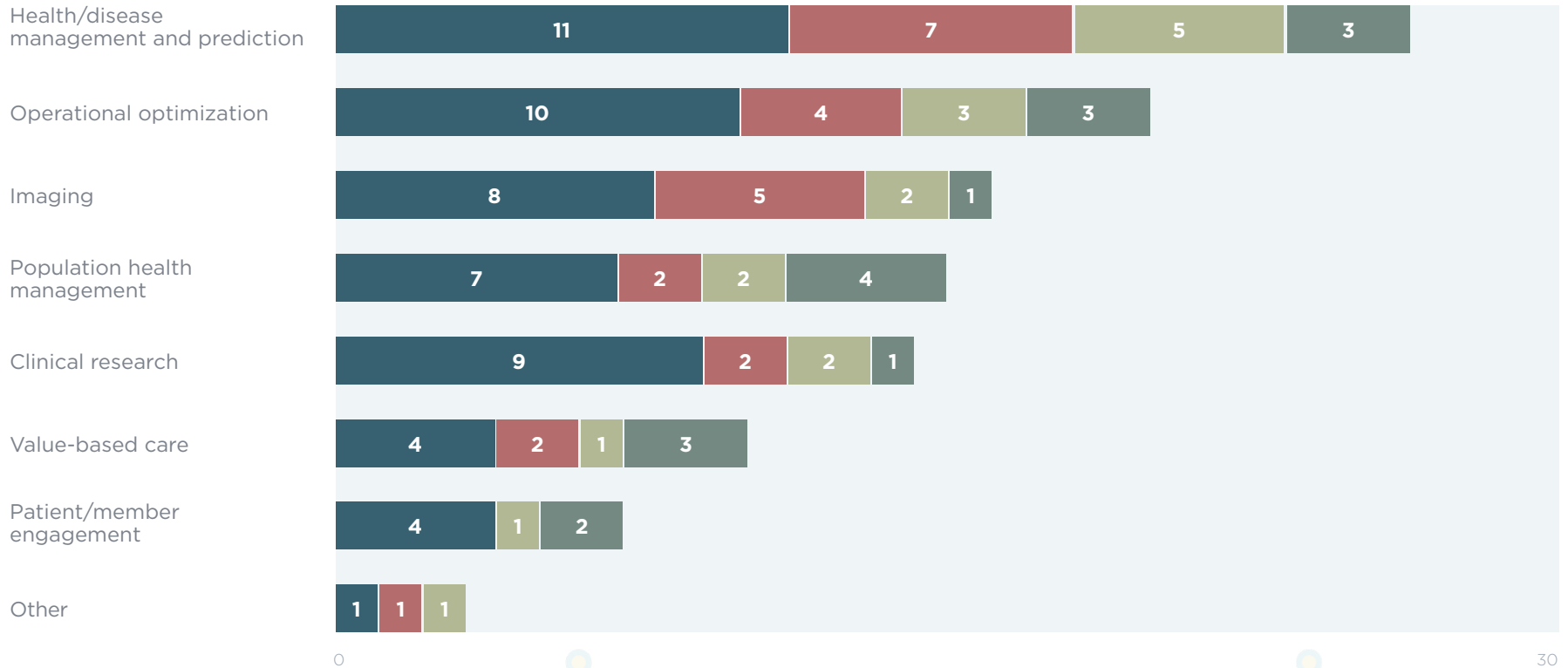
A majority of interviewed organizations plan to continue investing in multiple AI use cases over the next two years. Operational optimization is the most common area of focus given its potential to demonstrate a more immediate ROI. Other areas with less easily proven financial benefits will likely see less investment. Only a few organizations have no plans to invest in AI over the next two years. Some of these respondents question AI's maturity and efficacy, especially in comparison to other types of technology.



Artificial Intelligence: State of the Market

Current AI Use Cases (n=34)

■ 1,001+ beds
 ■ 501-1,000 beds
 ■ 1-500 beds
 ■ Ambulatory clinics, post-acute care facilities, health plans, and unknown

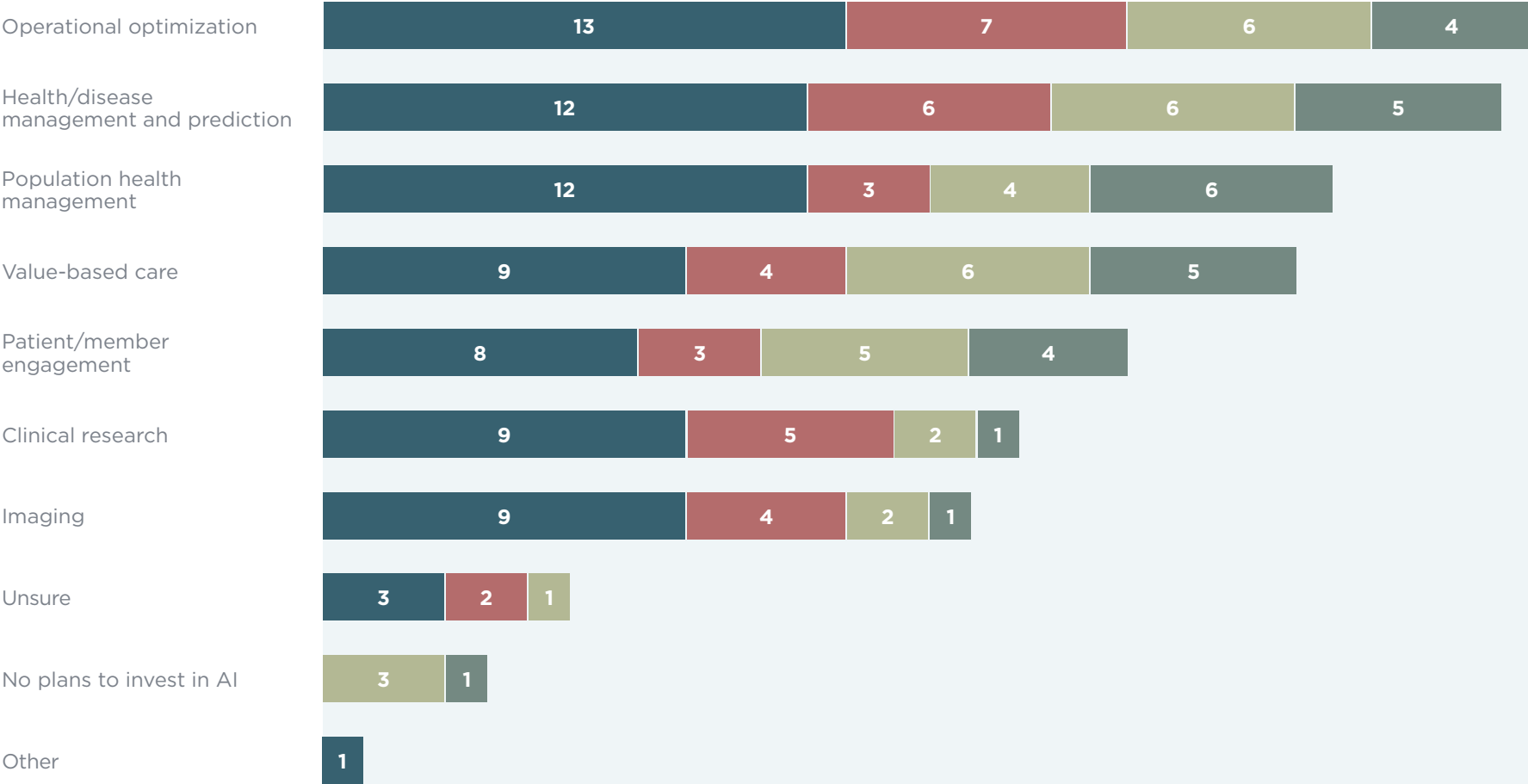


Note: "Other" includes cognitive computing models and analytics embedded within EHR, coding and documentation improvement, revenue cycle robotic process automation, and surgery.

Artificial Intelligence: State of the Market

What AI Use Cases Does Your Organization Plan to Invest in Over the Next Two Years? (n=49)

■ 1,001+ beds
 ■ 501-1,000 beds
 ■ 1-500 beds
 ■ Ambulatory clinics, post-acute care facilities, health plans, and unknown



Note: "Other" includes drug diversion.

A Message from Realyze Intelligence

AI Offers Solution to Improving Clinical Trial Matching

Every year in the United States there are nearly 2 million new cancer cases diagnosed and more than \$6 billion spent on research to uncover a cure, with roughly \$2 billion of the overall research spending dedicated to running clinical trials to evaluate the tests, treatments, and tools being developed to cure cancer. Clinical trials, which represent approximately one third of all cancer research spending, can only be successful if clinicians are able to find patients to participate in the trials. But this can be an immense challenge. While more than 50% of patients report being interested in joining clinical trials to treat their cancer, only 6.5% end up enrolling in a trial.

Part of the reason for the lag in enrollment is that the current process for matching patients with clinical trials is extremely time and labor intensive. It can take clinical staff members one to two hours per patient to manually review complex files and cross-reference patients with available clinical trials that may provide them with lifesaving medicine. This inefficient and ineffective process can cost a hospital system millions of dollars annually. Cancer cures are desperately needed and there is no shortage of clinical trials being run every year or patients interested in being matched to them.

That is where AI and natural language processing can offer a solution. As this survey research from the Center for Connected Medicine highlights, AI can be used to more quickly and efficiently match patients to appropriate clinical trials. Realyze Intelligence, a UPMC Enterprises portfolio company, was launched to match patients to clinical trials using AI and natural language processing. “Realyze Intelligence is a software as a service company that integrates with patient records, applies a combination of artificial intelligence technology and clinical

expertise to understand the complexities of patient histories, and matches patients with clinical trials,” Co-founder Aaron Brauser says. Cancer patients have extremely long and complicated histories, much of it captured in unstructured data in the form of notes from doctors, pathologists, and other clinicians. Further, patient conditions are changing over time and new information is being added to their records constantly.

Realyze Intelligence technology reads, analyzes, and summarizes all of a patient’s complex records containing large volumes of both unstructured and structured data. “But that’s only half the story, because once you have that data, you need to normalize it and then understand clinically what that means. And that’s where we use our clinical expertise and modeling on top of that to extract all the details about those patients at that specific time before their cancer progresses,” Mr. Brauser points out. Once patients are matched to clinical trials Realyze Intelligence software provides the clinicians with an easy-to-read summary of a patient’s history, a list of clinical trials they may be well matched to, and notes to discuss in the next appointment.

AI has many potential applications in health care. Specifically in oncology, perhaps one of the most powerful will be matching patients to clinical trials. Using AI and natural language processing to read, analyze, and uncover insights from large volumes of structured and unstructured data could be the next big step toward curing cancer.

Learn more about [Realyze Intelligence](#).



About the Center for Connected Medicine and KLAS

Center for Connected Medicine

The Center for Connected Medicine (CCM) at UPMC is defining the future of the modern health system through programming that informs, connects, and inspires leaders and innovators in health care. Collaborating with a network of experts from across the health care ecosystem, the CCM focuses its research and events on consumer-centered solutions, digital transformation, and scientific and medical innovation. Learn more at connectedmed.com.



KLAS Research

Driven by a mission to improve the world's health care, KLAS is a health care-focused research firm whose data helps provider, payer, and employer organizations make informed software and services decisions. Powered by insights and experiences discovered in the 25,000+ interviews with health care organization leaders and end users that KLAS conducts each year, KLAS' work creates transparency in the health care market and acts as a catalyst for software vendors and services firms to improve their offerings.



Contributors to This Report

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