Original Research

A Study on the Application and Use of Artificial Intelligence to Support Drug Development

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ABSTRACT

Purpose: The Tufts Center for the Study of Drug Development (CSDD) and the Drug Information Association (DIA) in collaboration with 8 pharmaceutical and biotechnology companies conducted a study examining the adoption and effect of artificial intelligence (AI), such as machine learning, on drug development. The study was conducted to clarify and understand AI adoption across the industry and to gather detailed insights into the spectrum of activities included in the definition of AI. The study investigated and identified analytical platforms and innovations across pharmaceutical and biotechnology companies currently being used or planned for in the future.

Methods: A 2-part method was used that comprised in-depth interviews with AI industry experts and a global survey conducted across pharmaceutical and biotechnology organizations. Eleven in-depth interviews focused on use and implementation of AI across drug development. The survey assessed use of AI and included perceptions about current and future use. The survey also examined technology definitions, assessment of organizational and personal AI expertise, and use of partnerships. A total of 402 responses, including data from 217 unique organizations, were analyzed.

Findings: Although 7 in 10 respondents reported using AI in some capacity, a wide range of use was reported by AI type. Patient selection and recruitment for clinical studies was the most commonly reported AI activity, with 34 respondents currently using AI for this activity. In addition, identification of medicinal products data gathering was the top activity being piloted or in the planning stages, reported by 49 respondents. The study also revealed that the most significant challenges to AI implementation included staff skills (55%), data structure (52%), and budgets (49%). Nearly 60% of respondents noted planned increases in staff within 1−2 years to support AI use or implementation.

Implications: Despite the challenges to AI implementation, the survey revealed that most organizations use AI in some capacity and that it is important to the success of an organization's workforce. Many organizations reported expectations for increasing staff as implementation of AI expands. Further research should examine the changing development landscape as the role of AI evolves. (*Clin Ther*. 2019;41:1414−1426) © 2019 Elsevier Inc. All rights reserved.

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INTRODUCTION

Artificial intelligence (AI) has been identified as a transformational influence on drug development. According to a recent report, big data and machine learning could profoundly affect the health care system and potentially result in a market that generates $100 billion in annual sales.[1] Industry experts predict that drugs developed using AI methods may be 2–3 years from launch but in the longer term will be critical to compete in the pharmaceutical industry.[2–4]

Although there is no globally accepted definition for AI, it is typically used as a general term to encompass all methods that the pharmaceutical industry is implementing, such as machine learning (including deep learning), natural language processing, and computer or machine vision. All these innovations, despite being labeled AI, reflect differing analytical approaches. AI depicts machines or systems that have the ability to perform independent decision making and can be described as "an entity (or collective set of cooperative entities), able to receive inputs from the environment, interpret and learn from such inputs, and exhibit related and flexible behaviors and actions that help the entity achieve a particular goal or objective over a period of time."[5]

Much of what is labeled AI in the pharmaceutical industry is closer to machine learning, which is characterized by an algorithmic process whereby computers provide improved feedback. Machine learning is described as "an application of artificial intelligence (AI) that provides systems the ability to automatically learn and improve from experience without being explicitly programmed. Machine learning focuses on the development of computer programs that can access data and use it to learn for themselves."[6] More specifically, "machine learning refers to algorithms that can be designed to evaluate and make predictions on the basis of new and complex features."[7]

Machine learning is being applied to a broad range of areas across health care. Some of these areas include disease identification and diagnosis, developing personalized treatments, drug discovery and manufacturing, clinical trial research, radiology and radiotherapy, smart electronic health records, and epidemic outbreak prediction.[8] Within clinical trials, machine learning and natural language processing have been applied to patient recruitment and selection as well as clinical trial design and optimization.

Natural language processing is another area that is being applied to drug development. This method extracts meaning from text using machine learning approaches.[9] An additional AI approach, computer or machine vision, is the use of algorithms to enable computers to understand the content of images. These images can be used to understand the anatomy of cells and find new treatments for disease.[10]

Use of AI has been most prevalent within drug discovery, and many companies have established in-house initiatives or partnerships with AI companies. Some companies are now using AI approaches for repurposing drugs and finding new uses for existing drugs or late-stage drug candidates. Another use is through AI platforms for phenotypic drug discovery "where compounds are screened in cells or animal models for compounds able to cause a desirable change, without any knowledge of the biological target."[2]

Pharmaceutical and biotechnology companies are using machine learning in various ways: for discovery and biomarker identification; within pharmacovigilance activities, including adverse event case processing or gathering regulatory intelligence; and with real-world data, which can involve the use of large data sets of claims or electronic health data. In a recent survey, the top pharmaceutical uses for AI were identified as pharmaceutical research and discovery and regulatory intelligence.[11] In addition, a report examining spending for AI found that the field of pharmaceutical research and discovery was second in terms of fastest spending growth forecast for 2016 to 2021, second to public safety and emergency response.[12] Machine learning has been used in numerous disease areas within drug discovery. One area is cancer research and has been used to distinguish normal cells from tumor cells and to decode cancer pathology images. Machine learning has also created huge efficiencies when compared with traditional drug discovery methods in repurposing high-throughput imaging assays to predict biological activity of compounds in other assays.[13]

To implement AI, there is a need for sufficient quality data to train systems. Access to data is another challenge.[14] Because systems are trained through supervised learning, massive amounts of data are required to perform complex tasks accurately. Access to data can also incur costs if companies partner with technology or data providers. In addition, the data must be of high quality because bad data can affect the results. Currently, although industry-wide data standards exist for several uses, they may not be currently applied. In addition, there is a great deal of effort required to integrate data into organizational systems, so it can be used for AI, such as machine learning.[15] There are also challenges with access to patient-level data and concerns about data privacy. In addition, other barriers include a shortage of workers with appropriate technical skills and fear of a changing culture, which may threaten employee jobs.

Aside from spending estimates and forecasted use, there are little published data that quantifies the current uptake and adoption of AI technologies across the pharmaceutical industry. A recent survey of 1600 business executives across 7 markets found that the pharmaceuticals and life sciences industry was the most mature in AI adoption. In addition, 40% of life science respondents indicated that their organization had deployed AI and it was working as expected compared with 25% overall for all industries.[16]

Evaluation of the adoption and effect of AI, such as machine learning, is warranted not only to identify any gaps in our understanding of adoption but also to gather additional detailed insights into the spectrum of activities included in the definition of AI. The Drug Information Association (DIA) and the Tufts Center for the Study of Drug Development (CSDD) conducted a study to identify analytical platforms and innovations currently being used or planned for the near future. The study was conducted in collaboration with 8 pharmaceutical and biotechnology companies, including Amgen, Bayer, Eli Lilly, Genentech/Roche, Johnson & Johnson, Merck & Co, Novartis, and Pfizer. The objectives were to identify, define, and benchmark new technologies being applied to each major research and development function, including regulatory, clinical operations, medical affairs, and pharmacovigilance. The study also explored the latest technological and digital strategies being deployed by peer companies to determine which are the most effective and meaningful.

METHODS

Study Design and Participants

The Tufts CSDD, the DIA, and the 8 companies in the working group collaborated on the methods and design of the study. The study consisted of a 2-part project to identify the use and application of AI and its components within the drug development industry. The first phase was composed of a series of 11 semistructured interviews with identified AI experts working at or contracting with pharmaceutical or biotechnology companies. The questions asked during these interviews were developed with input from the working group supporting this project. Areas examined in the interviews included respondent demographic characteristics, interviewee opinions and perceptions about technology definitions, organizational technology capabilities, organizational and industry AI investment, effect of AI, as well as challenges, attitudes, and expectations. The results from these interviews were analyzed using the NVivo qualitative data analysis software (Provo, Utah) to identify key issues and ideas.

The second phase consisted of a survey that was designed and implemented to gather metrics on AI and several subcategories of AI, including general algorithms that augmented human cognitions, machine learning, natural language processing, and computer vision. The survey aimed to capture AI use within the respondent's organization and their current perceptions of AI in drug development. The survey was created using key findings from interviews conducted in the first phase and with input from the working group. The final survey consisted of 33 questions divided into 6 sections: respondent demographic characteristics, technology definitions and assessment of expertise, general organizational AI use, AI partnerships, specific organizational AI utilization, and AI realities and future use.

The data collection instrument was designed and distributed using the online survey software Qualtrics (Provo, Utah). The survey was distributed to a list of individuals who had attended DIA events in the past and indicated interest in AI. The incentive for respondents to complete the survey was an offer of a summary copy of the survey results after the final analysis. The survey was open for 6 weeks from the middle of October to late November.

Statistical Analysis

Data cleaning was performed in Excel (Microsoft Inc, Redmond, Washington) and SAS (SAS Institute Inc, Cary, North Carolina), and analysis was conducted in SAS. Respondents who did not complete the entire demographic characteristics section were excluded, but other submitted responses were factored into the analysis. Respondents were taken to the end of the survey if they indicated no knowledge or familiarity with AI or component technologies. They were also not allowed to answer questions beyond the first 3 sections of the survey if they reported that their organization did not use AI or component technologies and had no plans for implementation. This logic was applied to ensure that the population of respondents had some understanding in this area and that specific questions about organizational AI use could be answered.

To identify the practices in which companies were engaging in the field of AI, responses to a subset of questions were aggregated by respondent company rather than by respondent. Respondents identified their organization at the end of the survey, and if they failed to do so, other information they provided (eg, e-mail address) was used to identify their organization. Responses were excluded from these analyses if the organization could not be discerned.

Subgroups analyzed included organization type (pharmaceutical or biotechnology vs contract research organization [CRO]) and company size evaluated by research and development budget (small [<$100 million], medium [$100 million to $1 billion], and large[>$1 billion]). Basic descriptive statistical analyses were used.

RESULTS

The final survey instrument was distributed to 15,000 individuals who had indicated to the DIA that they were interested in the drug development technology. Respondents were excluded from the final analysis for not answering enough questions or were not knowledgeable or experienced with this topic.

The survey received 634 responses, and ultimately 402 were included in the final analysis. Many of the analyses performed in this study were conducted to identify the number of unique companies who were engaging in an AI practice. This data set included information from 217 unique organizations after aggregating responses from the same organization and excluding those for which an organization could not be identified. Most organizations (57%) were small, with research and development budget of <$100 million. Midsized companies, with research and development budgets between $100 million and $1 billion, represented 19% of respondents, and large companies with research and development budgets >$1 billion comprised 24% of respondents.

Respondents primarily worked at pharmaceutical or biotechnology companies (55%) followed by CROs (15%), technology or data providers (11%), or other research-based organizations (20%). The highest proportion of respondents occupied clinical development or clinical operations roles (33%). An additional 15% represented pharmacovigilance, tolerability, or risk management functions; 13% were information technology, computer science, or data science or analytics professionals; 11% focused on legal or regulatory; 8% on strategy or business development; 5% on medical affairs or postmarketing; 1% on drug discovery or preclinical; and 11% on other. Geographically, 61% of respondents were based in North America, 23% represented Europe, 11% Asia Pacific, 2% Latin America, and 3% were from the rest of world. The country with the highest representation was the United States, with 58% of respondents working in US locations. Each other country represented at most 5% of the final sample.

Pharmaceutical AI Use vs Perceptions

The literature made clear that AI is a general term that subsumed many distinct applications. Through discussion with the members of the working group, we decided that this study would examine 4 technologies that used aspects of AI: algorithms augmenting human cognition, machine learning, natural language processing, and computer vision. AI experts were asked to provide definitions that they believed were appropriate during interviews, and throughout this process, the definitions used to inform survey respondents were refined until there was general agreement that these buckets were appropriate and overlap was minimal (Table I).

Table I. Artificial intelligence technology definitions provided in the survey.

Technology	Provided Definitions	Examples
Algorithms augmenting human cognitions	A method in which machines identify complex patterns, trends, and relationships Systems or computational models meant to augment human cognitions	Autonomous robots or vehicles Curated advertisements, news, or internet searches Fraud protection Optimized travel predictions
Machine learning	Process that enables machines to provide improving feedback Mimics human judgment The code that enables a machine to both absorb data and compute an answer and to provide output based on predetermined answers Continuous and repetitive learning	Automated regulatory review Support vector machines Neural networks Modeling techniques
Natural language processing	Programs with the ability to extract meaning from text or voice Application of machine learning Restricted by a set of rules	Alexa, Siri, or Cortana Social listening Skype translator Customer reviews
Computer vision	Machines that can process, analyze, and understand images	Image recognition Video tracking Object recognition

Table II. AI use by organization.

	Organizations, %			
Variable	Overall (N = 174)	Large Companies (n = 43)	Midsized companies (n = 35)	Small companies (n = 95)
General AI				
Use within the organization	68	88	74	57
Personal use	39	58	43	28
Use within the organization	55	86	57	41
Algorithms augmenting human cognitions				
Personal use	27	51	29	16
Use within the organization	53	86	60	37
Machine learning				
Personal use	26	47	26	18
Use within the organization	53	86	43	42
Natural language processing				
Personal use	26	49	20	18
Use within the organization	44	81	43	28
Computer vision				
Personal use	11	16	9	11

AI = artificial intelligence.

Respondents were asked whether they personally used these technologies within their roles at their respective organizations; if their organization made use of these technologies, but they personally did not; or if their organization did not use the technology. By evaluating valid responses provided by 174 unique companies, a range of potential industry AI technology use was established (Table II). Any company at which the respondent personally used AI or AI technology according to the definitions provided was measured as personal use. The respondents indicating that their organizations used this technology but they did not were added to those indicating personal use to calculate organization use. Any use of the composite 4 technologies was considered to constitute some general AI use. Therefore, it was estimated that 68%–39% of the pharmaceutical industry used some form of AI. This number was much higher when examining only large companies (88%–58%), slightly higher than average for midsized companies (74%–43%), and lower than average among small companies (57%–28%). This trend continued throughout all the composite technologies, with algorithms augmenting human cognitions generally being the most used, closely followed by machine learning and natural language processing, with computer vision consistently being the least used.

Perceptions of the maturity of AI technology were gathered. Respondents were asked to rate the level of maturity of AI in the pharmaceutical industry in general and across various functional groups (Figure 1). In general, overall maturity and maturity in functional groups were perceived to be very low. Ratings of ≥7 were considered mature, whereas those rated ≤4 were nascent. Only the drug discovery, pharmacovigilance or tolerability, and supply chain management functions were estimated as beyond nascent by >50% of respondents. The 75%–100% highest ratings for overall AI and regulatory maturity were evaluated by respondents at the nascent level.

Organizational AI Implementation

Participating organizations varied in their allocation of functions or departments with responsibility for AI (Figure 2). Four in 10 companies indicated that they had no centralized responsibility, that various functions or departments were responsible, or that individual business units managed these areas. An additional 9% of companies indicated that they were not sure who filled this role. Other selected options were the research and development department (20%), the chief information officer role (12%), and the chief digital officer role (8%).

Respondents were also asked whether they were currently using, planning or piloting, or not considering a variety of AI innovations (Table III). Current rates of use were highest for clinical patient selection and recruiting (31%), AI enhanced literature review (30%), and chat bots or virtual engagement

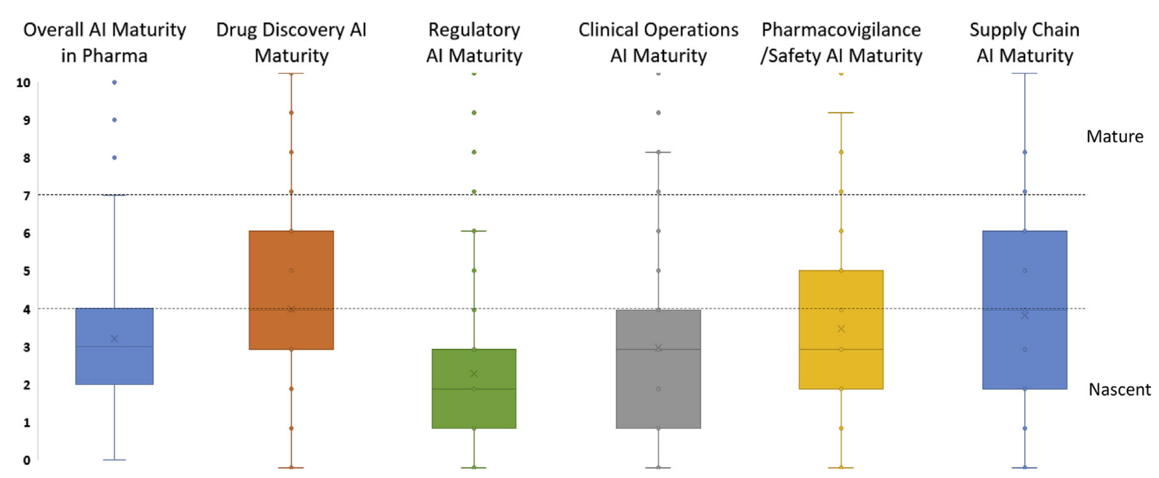

Figure 1. Perceived AI Maturity by Function.

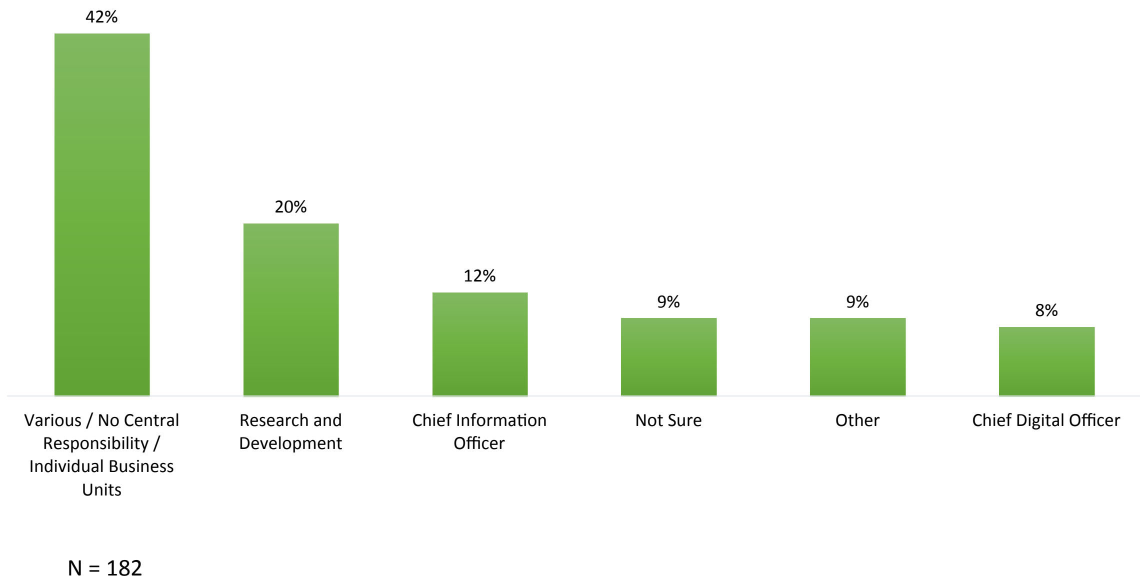

Figure 2. Functions and Departments Responsible for AI and New Technologies.

Table III. AI innovation implementation.

AI Innovation	Organizations, No. (%)		
	Currently Using	Piloting or Planning	Not Considering
Clinical patient selection and recruiting	34 (31)	48 (44)	28 (25)
AI enhanced literature review	33 (30)	35 (32)	43 (39)
Chat bot or virtual engagement	26 (24)	39 (36)	44 (40)
Social listening for adverse events	23 (22)	46 (43)	38 (36)
Personalized treatments or genetic data analysis	20 (19)	46 (43)	42 (39)
Target identification pipelines	19 (18)	38 (36)	49 (46)
Drug repurposing	17 (16)	36 (34)	53 (50)
Shipping or manufacturing accountability	16 (15)	36 (34)	55 (51)
Generation of small molecule leads	15 (14)	32 (31)	57 (55)
Drug and product order authenticity	13 (12)	37 (35)	57 (53)
IDMP data gathering	12 (11)	49 (46)	46 (43)

AI = artificial intelligence; IDMP = identification of medicinal products.

(24%). However, for every innovation, the percentage of companies planning or piloting the innovation was higher than those currently using it. Most notable among the technologies to be implemented in the future were identification of medicinal products data gathering (46%), clinical patient selection and recruiting (44%), social listening for adverse events (43%), and personalized treatments and genetic data analysis (43%). Identification of medicinal products data gathering is the innovation currently used the least (11%) but most often planned for future use. Finally, small molecule leads (55%), drug and product order

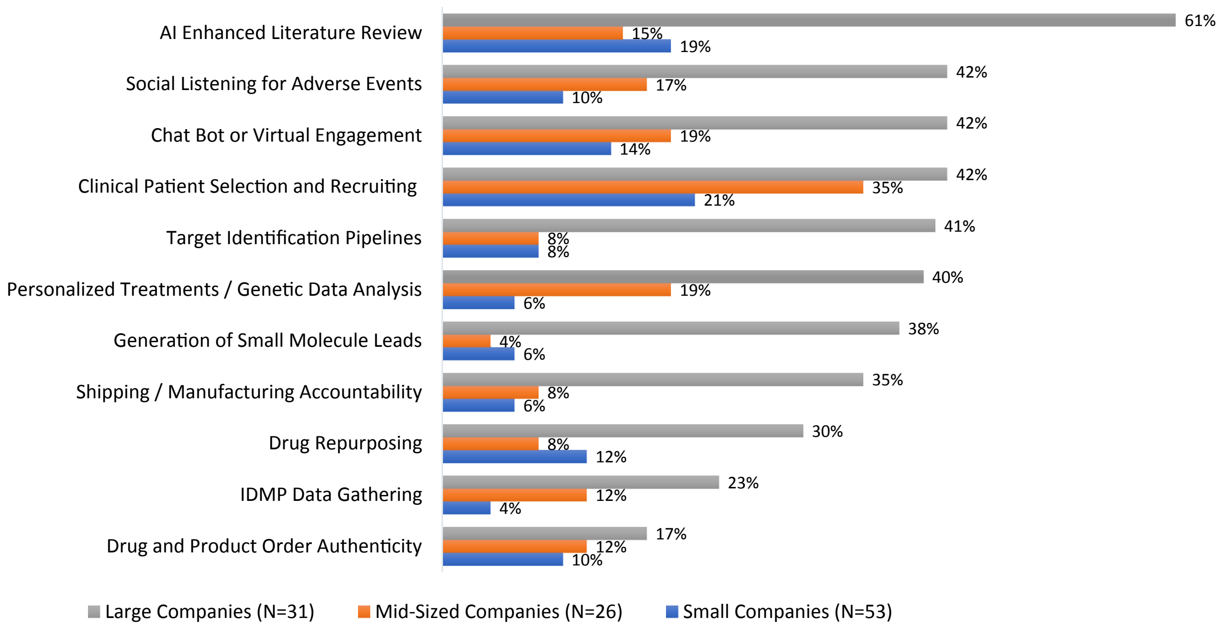

Figure 3. AI Innovation Utilization by Company Size.

authenticity (53%), and shipping or manufacturing accountability (53%) were the innovations most often not being considered by the organizations in this sample.

When examining the companies that are currently using these innovations by the size of their research and development budgets, large companies are using all these technologies more often than midsized and small companies (Figure 3). More than a third of large companies are using 8 of the 11 offered innovations, whereas midsized companies are only

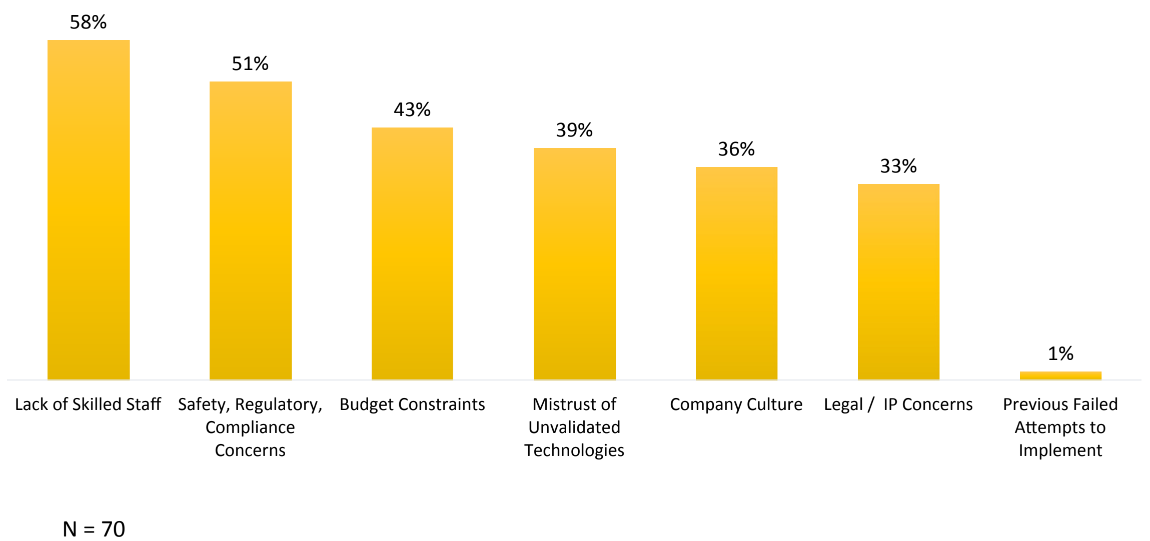

Figure 4. Major Factors for not Utilizing AI Technologies.

using clinical patient selection and recruiting more than a third of the time (35%) and there are no innovations that a third of small companies report using currently.

When respondents who indicated that their companies were not using the 4 AI technologies were asked what the reasons for this were, the most commonly cited major factor was the lack of skilled staff (58%) (Figure 4). Other reasons cited were safety, regulatory, and compliance concerns (51%), budget constraints (43%), and mistrust of unvalidated technologies (39%). Notably, only 1% of organizations who were not using AI attributed previous failed attempts at implementation as a major factor.

AI Staffing and Challenges

Most respondents (59%) reported that their organization was planning to increase staff for AI use or implementation within the next 1–2 years (Figure 5). An additional 19% indicated that they were planning staff increases for this purpose in the next 2–5 years, and 7% predicted that staffing increases would take place in >5 years. Only 15% of respondents said that there was no increase to AI staff planned. Of those reporting that they would be increasing their staff, 61% indicated that this would be a small increase, 28% a moderate increase, and 11% a large increase.

More than 60% of companies reported that they currently partner with another AI organization. The top partnerships were technology or data providers (95%), academic organizations (58%), and CROs (56%). The most commonly selected partnership areas were clinical operations (71%), pharmacovigilance or tolerability (68%), and drug discovery or preclinical (56%).

Finally, respondents rated the common AI challenges in terms of how significant they had been for their organization (Figure 6). The areas most commonly rated as significant challenges were staff

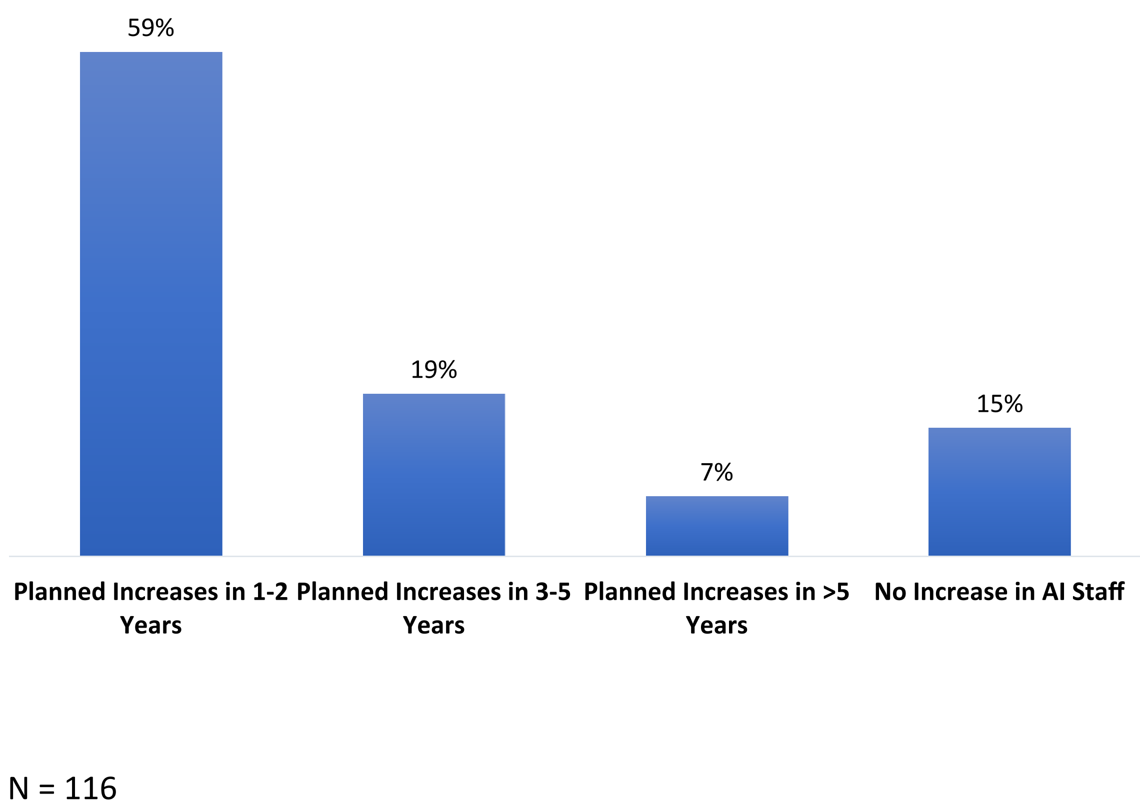

Figure 5. AI Staffing Predictions.

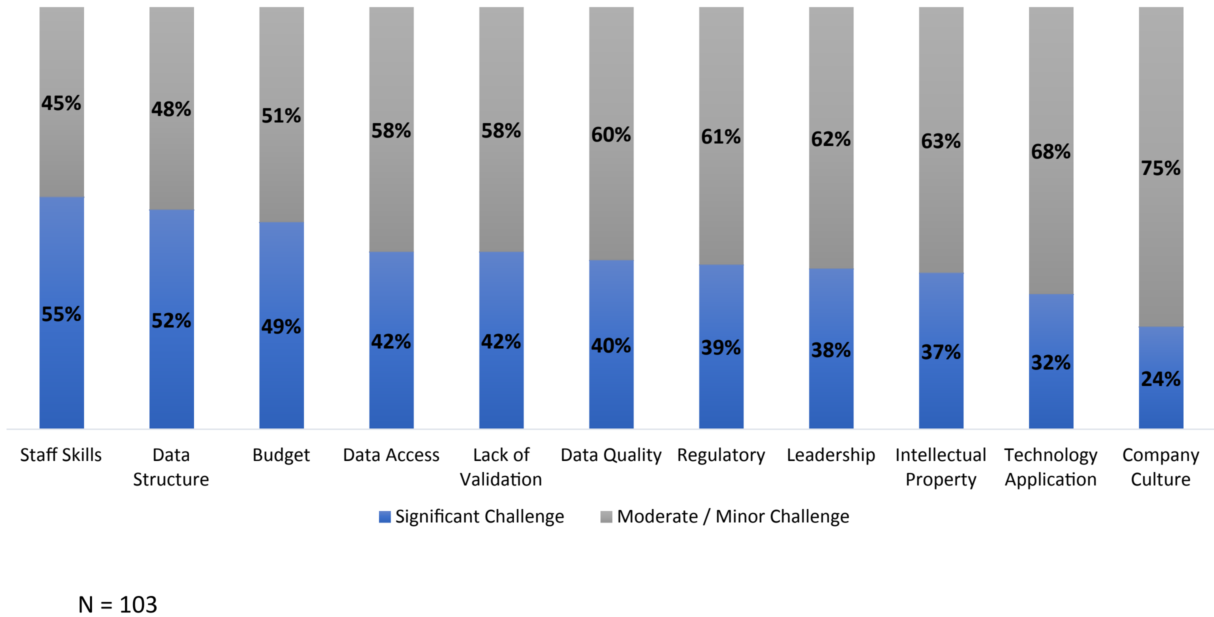

Figure 6. AI Implementation Challenges.

skills (55%), data structure (52%), and budget (49%). The areas least commonly cited were company culture (24%), technology application (32%), and intellectual property (37%).

DISCUSSION

One of the key findings from the study is that nearly 7 of 10 respondents report that their organizations use AI in some capacity. We also found that nearly 4 of 10 respondents report that they personally are using some form of AI in their roles at their organizations. Larger companies (defined as having research and development budgets >$1 billion) tend to use AI more than midsized or small companies, which is not surprising given their budgets and staffing. In addition, larger companies also seek innovation and new approaches to drug development given the high cost of development and the desire to differentiate treatments in increasingly competitive disease areas. Large companies also report greater use of AI enhanced literature review, social listening for adverse events, chat bots or virtual engagement, and patient recruitment than midsized and small companies. Another finding was that departments responsible for implementation of AI varied by organization and were managed by individual business units or various departments or decentralized. Some respondents were also unaware of which departments had oversight of AI. These results reflect the broad application and siloed use of AI across organizations. Patient selection and recruitment for clinical studies was the most commonly reported AI activity. Because 61% of respondents represented clinical departments, this finding may in part reflect recruitment bias. In addition, identification of medicinal products data gathering was the top activity being piloted or in the planning stages. This finding has been corroborated in other research and is an area for which new technology and assessments are being developed because AI could potentially facilitate regulatory information and management.[17] With data that are typically housed in multiple systems and reports across functions and departments, implementing AI or machine learning could greatly expedite this process.[18]

Respondents revealed that the top factors preventing use were lack of skilled staff; tolerability, regulatory, and compliance concerns; and budget constraints. Similarly, the major implementation challenges were staff skills, data structure, and budgets. Not having staff with appropriate skill sets and lack of budgets are common challenges across all industries. However, influence of regulatory constraints and data that are unstructured or too siloed, requiring excessive effort to adapt to AI use, are significant issues for the pharmaceutical industry. Access to data was also reported as a barrier to implementation and has been a pervasive issue cited in much of the published literature.[13] Pharmaceutical staff may harbor some skepticism of AI methods because 39% of respondents cited a mistrust of technologies that were not validated as a factor in not using AI. The challenge remains, although perhaps this phenomenon is not as great as 10 years ago as evidenced by the AI partnerships and activity in the pharmaceutical industry. Another issue is mistrust of newer automated methods that do not include human intervention. Much of this work requires more research to educate staff and validate the methods used and to gain trust from all stakeholders involved. In addition, as health authorities and industry develop standard policies and a regulatory framework to address concerns, such as ethical use, the black box phenomenon, bias, and validation, the use of AI technologies will undoubtedly be more openly accepted and increase at an exponential rate.

Despite the challenges to AI implementation, we expect to see increased use to hedge against development risk. With the increase of precision medicines and treatments for rare diseases, access to data and AI-driven analytics will intensify.[4,19,20] Nearly 60% of respondents noted planned increases in staff within 1–2 years, and approximately the same (61%) anticipated small increases in overall staffing. Most acknowledge that AI is important to the success of their workforce despite the barriers to use. Many respondents reported forming partnerships, most typically with technology or data providers, and many of the larger companies are already working with companies that specialize in AI or startups as evidenced by the frequency of company press releases.

This study had several limitations. The first is sampling bias. Respondents were extracted from DIA contact lists of individuals who had indicated an interest in the AI topic. This interest alone increases the likelihood that those receiving invitations to complete the survey would be employed in companies using AI or occupy roles in which they deal with AI when compared to their peers. In addition, those contributing the time to answer this survey may have been even more motivated to produce a response because of the summary report incentive. These factors may have caused the estimate of companies in the drug development industry using AI and AI technologies to be inflated.

Another limitation is low response rates to the survey. Given that this survey was a web survey with no incentive provided to respondents, in addition to being sent to busy pharmaceutical and biotechnology executives, it is typical to expect lower response rates.

Another limitation with the industry use figure is the range of values produced. Because respondents were asked to respond to multiple questions based on the practices their organization adopted, it is likely that there was some uncertainty in this area. This assumption was partially addressed by collecting multiple responses from many companies and aggregating them into a single, company-wide response. The approach to aggregate responses was taken as respondents reflected disparate functions and various uses of AI in their survey responses. However, we are aware that when asking about company practices, some employees may not have complete clarity on practices being implemented across other functions and departments. Some may have reported that their organizations used AI when, in fact, they did not or vice versa. In addition, because large companies are so fragmented, perhaps we may have underestimated adoption for this group. Thus, we calculated ranges to approximate AI industry use.

Finally, a further limitation is the lack of precision around defining AI. When interviewing experts on the topic of AI in drug development, we gathered disparate opinions about how true AI was defined and about how many organizations were using it. The interviews revealed that the existence of AI according to the computer science definition was rare and that many organizations claimed they used AI when, in fact, they were using techniques that supported human decision making rather than supplanting it. On the basis of our interviews, we formulated definitions for the 4 composite AI technologies (algorithms augmenting human cognitions, machine learning, natural language processing, and computer vision) and inquired about whether companies were using these. Had we merely asked respondents whether they were using general AI, there might have been more uncertainty regarding expert versus organizational definitions. However, the issue of incomplete organizational knowledge combined with definitional overlap may have influenced the percentage of respondents who reported their company use of AI. Given the limitations, further study is needed to provide insights into which technologies are being implemented and their specific focus.

CONCLUSION

AI technologies are in use today, most commonly in patient selection for studies and in data management. Use is increasing and expected to continue to increase. Future research will examine specific use cases and their effect on drug development performance and efficiency as well as identifying areas of greatest value from the case examples.

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CONFLICTS OF INTEREST

The authors have indicated that they have no conflicts of interest regarding the content of this article.

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