Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

ADOPTION OF INNOVATIVE TECHNOLOGIES WITHIN PHARMACEUTICAL R&D

Tufts Center for the Study of Drug Development | May 2020

Innovative technologies that generate big data and use advanced analytics such as artificial intelligence (AI) are expected to have a huge effect on the health care system and result in a market that could potentially generate $100 billion in annual sales.[1] In addition, the impact of AI enabled technologies on biopharma companies is projected to lead to improvements in operational efficiency, performance and cost reduction across the entire value chain.[2] Organizations are implementing new technologies in a number of ways, including for example the use of AI and machine learning (ML) for drug discovery, within pharmacovigilance and safety, and managing regulatory intelligence. Clinical trial innovations are also being implemented and include virtual or decentralized trials, mobile nursing networks, telemedicine, mobile health technologies and patient wearable devices. Digital innovation, however, continues to pose challenges and in a recent industry survey biopharma companies were found falling behind in digital transformation (use of innovative technologies) compared to other industries.[3] The research noted that the industry received a middling ranking for use of newer technologies among a number of other industries including manufacturing, insurance, government, IT and telecommunications. The findings indicated that only about 20% of biopharma companies are achieving digital maturity. In other research conducted with C-suite executives across 13 different business sectors at 3,000+ companies, the health care sector represented one of lowest adoption rates of AI technologies.[4]

Given the impact of innovative technologies on the pharmaceutical industry and barriers to adoption, Tufts CSDD and Saama Technologies, Inc. collaborated on a study investigating how the industry best uses automation, IT technologies and applications, including advanced analytics (such as AI or machine learning) to support R&D. The research also provided insights into what areas the industry views as most easily automated and where these innovations are being applied and having the greatest impact. The level of impact of a number of factors on adoption were also assessed including regulatory concerns, company resources and culture, leadership, trust and risk. In addition, the greatest challenges to implementation were identified as well as the role of partners in supporting the adoption of new technology and analytics.

METHODOLOGY

The study used a dual methodology comprised of a Roundtable discussion with industry experts to examine best practices using technology and automation and a web survey of biopharmaceutical executives.

- The Roundtable was held with 19 participants from pharmaceutical and biotech companies; technology companies; and other company types including non-profit and consulting. The discussion gathered perceptions and insights from participants across a broad range of areas including biopharmaceutical industry challenges and barriers to adopting new technologies and innovations; and areas where innovations

are currently being piloted or implemented. In addition, other factors that present adoption challenges were examined including the impact of global regulatory issues, organizational structure and culture and staffing roles and functions. The insights from the Roundtable were incorporated into a web survey developed collaboratively by Tufts CSDD and Saama.

- The online survey gathered perceptions about technology adoption and factors leading to implementation and organizational impact. Other areas explored included the role of partnerships, regulatory influence on adoption, trust in AI and advanced analytics, and resources and staffing expertise.

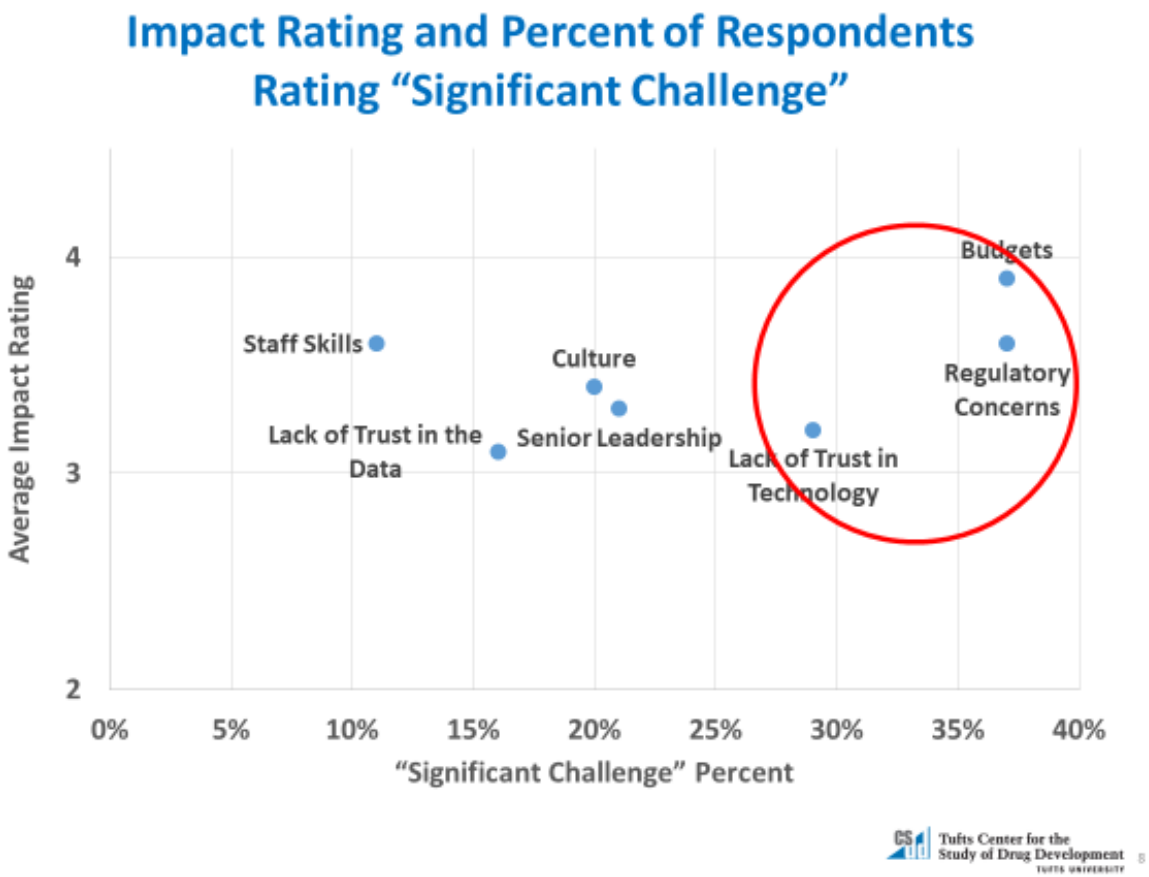
- The survey was distributed via a link to an e-mail invitation using Qualtrics survey software to pharmaceutical and biotech industry executives and responses were collected between November 2019 and January 2020. A total of 114 responses were collected.

- Respondents represented a mix of companies with over one-third (35%) from large companies, less than one-third (32%) from small companies and 14% from mid-sized companies. Two in 10 (22%) did not specify company size. More than half (53%) worked in clinical development or clinical operations roles and the majority were vice presidents or directors in their organizations.

KEY FINDINGS:

ADOPTION OF INNOVATIVE TECHNOLOGIES IS DRIVEN BY A MULTITUDE OF FACTORS

Adoption is driven by a complex combination of factors with budgets and regulatory concerns perceived as the largest factors hindering adoption. Budgets and regulatory concerns were rated significant challenges to technology implementation more often than expected and viewed as top factors impacting adoption. Lack of trust in technology was also a key area in preventing adoption (Chart 1).



LARGE COMPANIES HAVE MORE RESOURCES AVAILABLE TO SUPPORT INNOVATIVE TECHNOLOGIES

Adoption in large companies is perceived as more mature due to greater availability of resources and more staff expertise and knowledge. The survey revealed significant differences in a number of areas between large and small companies.

- Respondents from large companies rate their company's knowledge of advanced analytics such as AI or ML significantly higher than small companies. (Chart 2) On average, respondents from large companies report one-third of their staff have the skills and knowledge to use advanced analytics while small companies report, on average, only 12% of their staff have the skills and knowledge. (Chart 3)

- Staff at large companies also report being better prepared for the use of advanced analytics compared to small companies and are also more likely to offer training.

"On a scale of 1 to 10, with 1 as the lowest and 10 as the highest, how knowledgeable is your company about Advanced Analytics technologies such as AI/ML?"

Company Size	Mean (CoV)
Large	7.0 (.27)*
Mid-sized	6.0 (.45)
Small	5.0 (.48)*
Overall	5.8 (.42)

*Tukey's HSD indicates significant difference between large and small companies.

Tufts Center for the Study of Drug Development

"What percentage of your staff possess the skills and knowledge to use Advanced Analytics technology?"

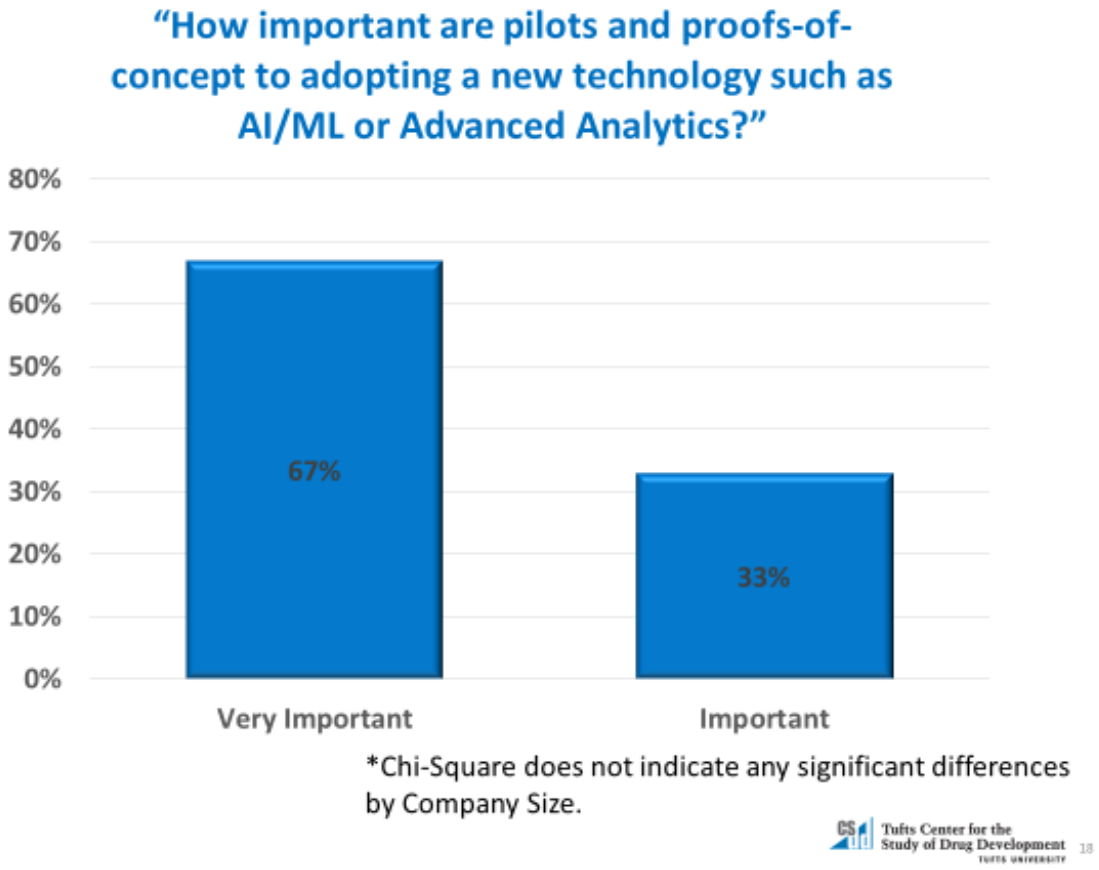
Company Size	Mean (CoV)
Large	33.1% (.68)*
Mid-sized	25.4% (.47)
Small	12.2% (.75)*
Overall	23.7% (.81)

*Tukey's HSD indicates significant difference between large and small companies.

Tufts Center for the Study of Drug Development 14

COMPANY INVESTMENTS IN PILOTS AND POCS ARE LIKELY TO RESULT IN GREATER ADOPTION

Pilots and proof of concepts (POCs) are essential to adoption and increase the likelihood of acquiring a new technology with 100% of companies rating pilots and POCs as important to adopting a new technology. (Chart 4)



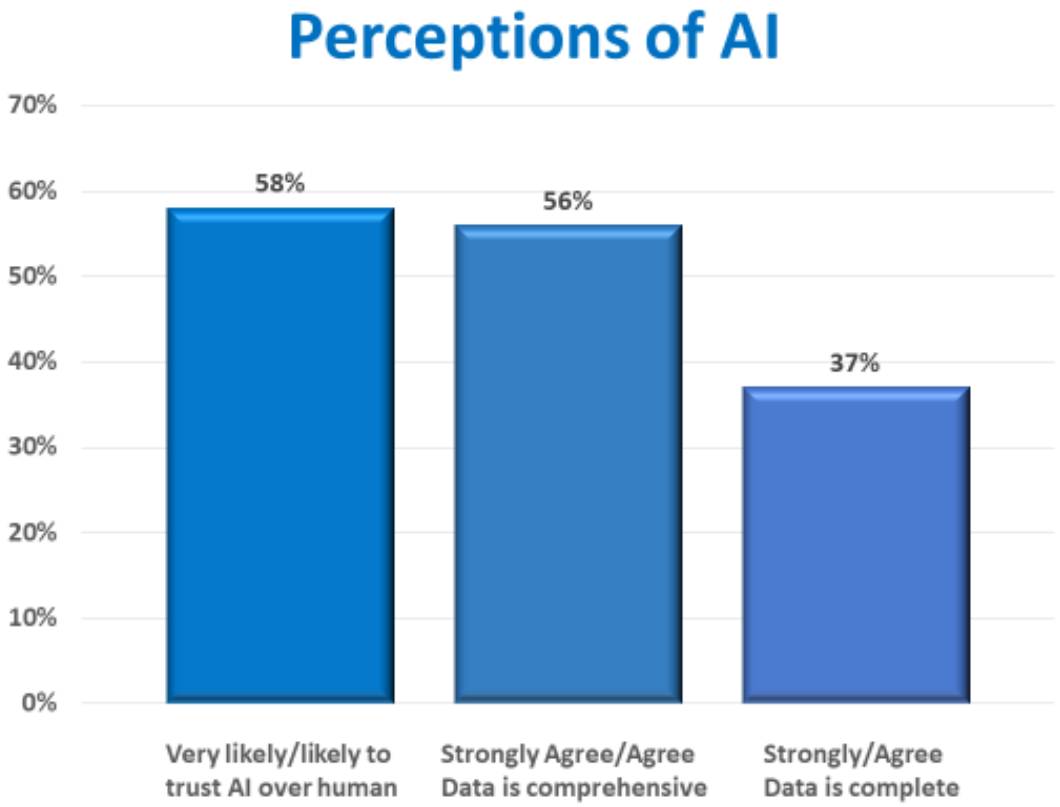
- A majority of companies (84%) revealed that the chances of acquiring a new technology increases with the completion of additional pilots or POCs.

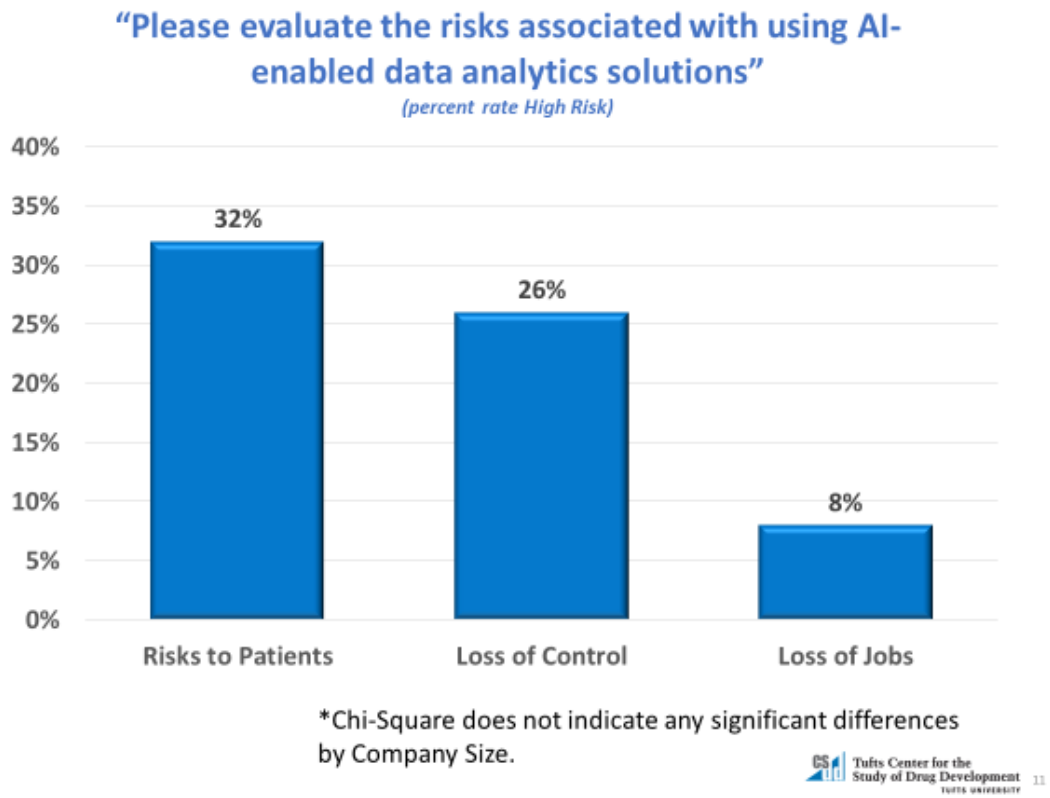
- On average, 2.3 pilots and 1.9 POCs are completed in order for an organization to acquire a new technology and more than ¾ indicated that the probability was high that their organization would acquire a new technology after a pilot or POC.

PERCEPTIONS ABOUT DATA AND ANALYTICS AI SOLUTIONS REVEAL THE IMPORTANCE OF TRUST IN TECHNOLOGY

Although respondents had mixed views about the underlying data used to train an analytics solution, nearly 3/5 were likely to trust the recommendations or outcomes of an analytics AI solution over a human. Nearly 6 in 10 (56%) indicated that they agreed that the underlying data used to train an analytics solution is comprehensive, however there was more dissent about the completeness of data as less than 4 in 10 (37%) agreed that the underlying data of an advanced analytics solution is complete (Chart 5).

- Only about one-third of respondents assessed risks to patients with using AI solutions as high, and just over one-quarter perceived loss of control as a significant risk. Only 8% perceived loss of jobs as a large risk factor (Chart 6).





A FEW KEY CAPABILITIES INCREASE TRUST IN TECHNOLOGY SOLUTIONS

Technical competence was identified as the top capability needed to increase trust in an advanced analytics solution. Demonstrating domain knowledge was also considered to build trust. Nearly 2/3 of respondents felt that having a solution that is very easy to use was the primary capability to mitigate an organization's lack of resources.

- Colleagues and key opinion leaders were identified as the top external resources that help organizations leverage vendor selection offering advanced AI and analytics. Over three-quarters (76%) of respondents reported colleagues were influential, and over half (55%) relied on key opinion leaders. A low percentage of respondents (8%) reported not using any external resources.

PARTNERSHIPS WITH CROS, TECHNOLOGY AND DATA PROVIDERS, AND OTHERS REVEAL OVERALL SATISFACTION

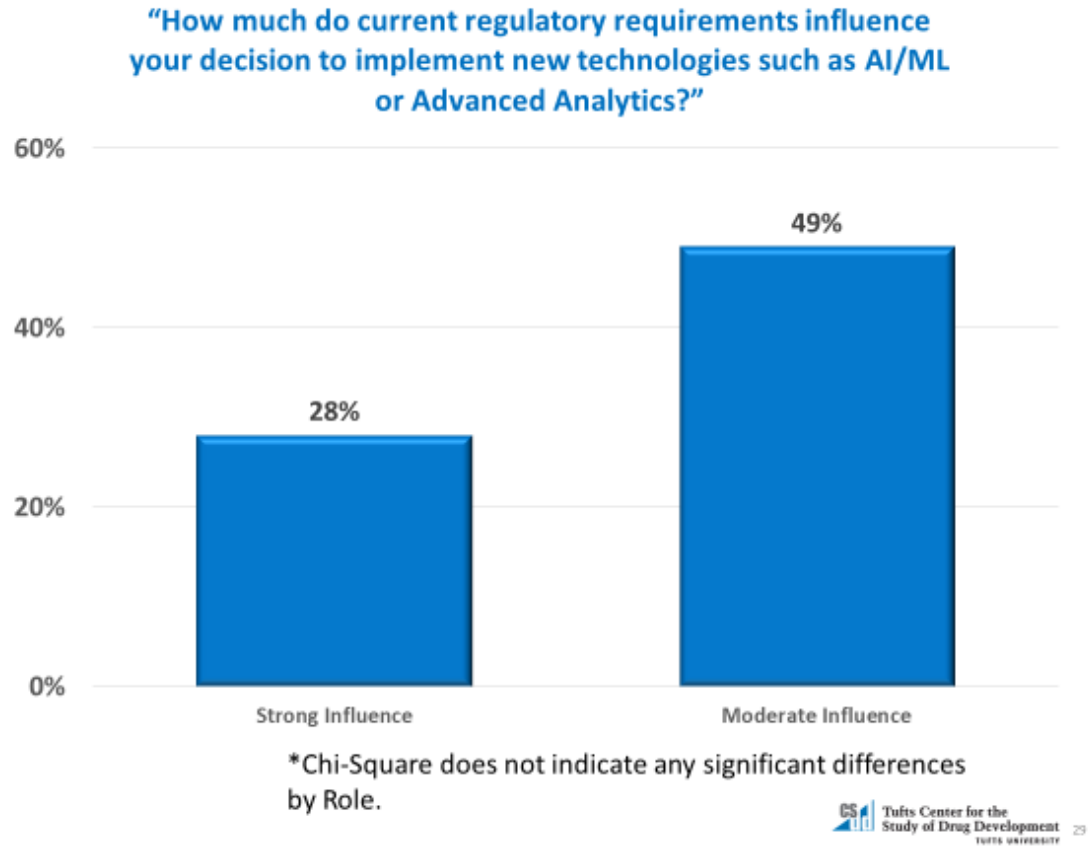
A total of 36 respondents reported that their organization has partnered with vendors or service providers and more than three-fourths of respondents expressed overall satisfaction with their partnerships. The largest group (n=30) reported partnering with contract research organizations (CROs), while 20 had partnered with technology companies and 20 with data providers. 8 companies reported government partnerships and 6 engaged with other company types.

- An overwhelming majority of respondents (97%) rated their relationships with data providers as satisfied, while nearly 3 in 4 (73%) respondents in partnerships with technology companies were satisfied, and more than 2/3 (68%) of respondents with CRO partners were satisfied.

- Respondents estimate on average that their partnerships would increase from 2018 to 2020, from 7 to 10.3.

REGULATORY REQUIREMENTS ARE VIEWED AS MODEST CHALLENGES

Although regulatory concerns are perceived as a top factor hindering adoption, regulatory requirements are viewed as modest challenges. Nearly half (49%) indicated that current regulatory requirements have a moderate influence on their organization's decision to implement new technologies such as AI/ML or advanced analytics, while 28% reported a strong influence. (Chart 7)



- Half of the respondents estimated that it would take from 1-2 years to adopt a new technology if it were mandated by the FDA, with nearly one-fourth (23%) indicating 1 to 11 months and 18% report adoption taking 3 to 5 years. A small percentage (8%) was unsure of the length of time to adoption. No respondents indicated that it would take more than 5 years.

KEY TAKEAWAYS

- Technology adoption is driven by a complex combination of factors with budgets and regulatory concerns perceived as the largest factors hindering adoption. Lack of trust in technology was also a barrier to implementation.
- Adoption in large companies is perceived as more mature both in terms of expertise and knowledge and greater availability of company resources such as skilled staff and training.
- Pilots and proof of concepts (POCs) are essential to adoption and increase the likelihood of acquiring a new technology.
- Respondents offered mixed views on data comprehensiveness and the completeness of advanced analytics solutions but tended to trust the outcomes of an analytics AI solution over a human.
- The top capabilities that increase trust in advanced analytics solutions are technical competence and domain knowledge and organizations primarily rely on colleagues and key opinion leaders to facilitate vendor selection.
- Ratings of partnerships with CROs, technology and data providers, and other company types reveal overall satisfaction and expectations for increasing numbers of partnerships in two years.
- Although regulatory concerns are perceived as a top factor hindering adoption, regulatory requirements are viewed as modest challenges in implementing new technologies.

This research study was funded by Saama Technologies, Inc.

REFERENCES

1. Cattell J, Chilukuri S, Levy M. How big data can revolutionize pharmaceutical R&D. Accessed February 12, 2020 https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/how-big-data-can-revolutionize-pharmaceutical-r-and-d.
2. Steedman M, Taylor K, Properzi F et al. Deloitte Insights: The rise of artificial intelligence across biopharma; 2019. Accessed February 10, 2020 https://www2.deloitte.com/us/en/insights/industry/life-sciences/rise-of-artificial-intelligence-in-biopharma-industry.html
3. Standing M, Reh G. Deloitte Insights: Survey finds biopharma companies lag in digital transformation: It is time for a sea change in strategy 2018. Accessed February 10, 2020 https://www2.deloitte.com/content/dam/Deloitte/br/Documents/life-sciences-health-care/Biopharma-companies-lag-in-digital-transformation.pdf
4. Bughin J, Hazan E, Ramaswamy S. Artificial intelligence: The next digital frontier. June 2017, McKinsey Global Institute. https://www.mckinsey.com/~/media/McKinsey/Industries/Advanced%20Electronics/Our%20Insights/How%20artificial%20intelligence%20can%20deliver%20real%20value%20to%20companies/MGI-Artificial-Intelligence-Discussion-paper.ashx

ADDITIONAL SAAMA PUBLICATIONS (AND LINKS):

Clinical Operations In The Age Of A Pandemic

What will Clinical Research Look Like in 5, 10, 20 Years? Are We Heading to Heaven, Hell or Purgatory? Part 1 of 4

What will Clinical Research Look Like in 5, 10, 20 Years? Are We Heading to Heaven, Hell or Purgatory? Part 2 of 4

What will Clinical Research Look Like in 5, 10, 20 Years? Are We Heading to Heaven, Hell or Purgatory? Part 3 of 4

What will Clinical Research Look Like in 5, 10, 20 Years? Are We Heading to Heaven, Hell or Purgatory? Part 4 of 4

AUTHOR

Mary Jo Lamberti, PHD - Associate Director of Sponsored Research and Research Assistant Professor, Tufts CSDD

Dr. Mary Jo Lamberti is a Research Assistant Professor at Tufts University School of Medicine and Associate Director of Sponsored Research at Tufts CSDD. She is an internationally recognized expert on benchmarking drug development operating practices. Her research focuses on a variety of areas including outsourcing and partnerships; clinical supplies; investigative site initiation and management; patient recruitment and retention; and the use of technologies and digital solutions in clinical trials. She has published extensively and is a frequent speaker at global conferences. Dr. Lamberti holds a BA from Wellesley College and a PhD in psychology from Boston University.

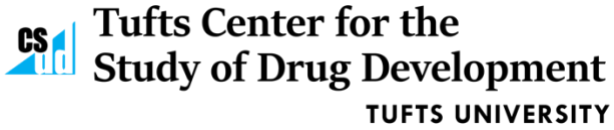
Zachary Smith, MA – Research Analyst, Tufts CSDD

Zachary is a Research Analyst on the Sponsored Research team where he has worked on projects focusing on a variety of topics including patient recruitment, patient diversity in clinical trials, and benchmarking clinical trial durations and costs. He received a BS in Psychology from Florida Southern College and earned his MA in Psychology at Brandeis University. He previously worked as a research assistant at a variety of labs including the Etter Lab at the University of Massachusetts, and the Evolutionary Psychology Lab at Harvard University.

About Tufts Center for the Study of Drug Development:

The **Tufts Center for the Study of Drug Development** (Tufts CSDD) is an independent, academic, non-profit research center at Tufts University School of Medicine in Boston, Massachusetts. Our mission is to provide data-driven analysis and strategic insight to help drug developers, regulators, and policy makers improve the quality, efficiency and productivity of pharmaceutical R&D.

Established in 1976, Tufts CSDD conducts scholarly analyses addressing the economic, scientific, political, and legal factors that affect the development and regulation of human therapeutics. For over four decades, Tufts CSDD has been a prominent and influential voice in national and international debates on issues pertaining to biomedical innovation and the development of drugs and biologics. In addition, the Center hosts symposia, workshops, courses, and public forums on related topics, and publishes the *Tufts CSDD Impact Report*, a bimonthly newsletter providing analysis and insight to critical drug development issues.



Tufts University School of Medicine:
The Tufts Center for the Study of Drug Development
75 Kneeland Street, Suite 1100 | Boston, MA 02111
csdd.tufts.edu | **csdd@tufts.edu** | 617-636-2170