PREMIER TRANSFORMING HEALTHCARE TOGETHER®

August 8, 2023

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Attention: FDA-2023-N-0743

Submitted electronically to: http://www.regulations.gov

Re: Discussion Paper on Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products (Docket Number FDA-2023-N-0743)

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) regarding the discussion paper titled *Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products (FDA-2023-N-0743).* As described, this discussion paper presents the FDA with the opportunity to support innovation, accelerate and enhance the development of novel therapies, and elucidate regulatory gaps and procedural pitfalls at a commensurate pace with evolving artificial intelligence (AI) and machine learning (ML) technology.

Premier supports the development of this discussion paper as a positive step towards recognizing the ways in which technology can be leveraged to reduce costs, improve data quality and access, expedite processes and advance health equity. Specifically, Premier applauds the FDA's efforts to incorporate emerging technologies into drug development and provide clarity for clinical trial innovators. In our comments, Premier recommends that the FDA consider the following:

- Issue clear guidance on patient consent and data-sharing requirements in clinical trials, particularly with the rise of promising technology applications for real-world data in decentralized clinical trials and synthetic control arms;
- Clarify applicability of anti-kickback statute in certain situations that may arise in innovative trial designs and recruitment processes;
- Clearly specify a minimum cybersecurity standard for the transmission and storage of participant health data using digital health technology;
- Incentivize continued innovation by protecting intellectual property while holding developers to high standards of accountability for reliable, valid and unbiased outcomes; and
- Take steps to capture, monitor and manage pre-specification activities in drug development.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company and national supply chain leader, uniting an alliance of 4,400 hospitals and approximately 250,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier's sophisticated technology systems contain robust data gleaned from nearly half of U.S. hospital discharges, 812 million hospital outpatient and clinic encounters and 131 million physician office visits. Premier is a data-driven organization with a 360-degree view of the supply chain, working with more than 1,400 manufacturers to source the highest quality and most cost-effective products and services. Premier's work is closely aligned with healthcare providers, who drive the product and service contracting decisions using a data driven approach to remove biases in product sourcing and contracting and assure access to the highest quality products. In addition, Premier

operates the nation's largest population health collaborative, having worked with more than 200 accountable care organizations (ACOs).

A Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with healthcare providers, manufacturers, distributors, government and other entities to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, North Carolina, Premier is passionate about transforming American healthcare.

Premier also has several AI assets, including but not limited to:

- Stanson Health, a subsidiary of Premier, designs technology to reduce low-value and unnecessary care. Stanson leverages real-time alerts and relevant analytics to guide and influence physician's decisions through Clinical Decision Support technology, providing higher-quality, lower-cost healthcare. Stanson's mission is to measurably improve the quality and safety of patient care while reducing the cost of care by enabling context-specific information integrated into the provider workflow.

- Premier's PINC AI™ Applied Sciences (PAS) is a trusted leader in accelerating healthcare improvement through services, data and scalable solutions, spanning the continuum of care and enabling sustainable innovation and rigorous research. These services and real-world data are valuable resources for the pharmaceutical, device and diagnostic industries, academia, federal and national healthcare agencies, as well as hospitals and health systems. Since 2000, PAS researchers have produced more than 1,000 publications which appear in 264 scholarly, peer-reviewed journals, covering a wide variety of topics such as population-based analyses of drugs, devices, treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.

- Conductiv, a Premier purchased services subsidiary, harnesses AI to help hospitals and health systems streamline contract negotiations, benchmark service providers and manage spend based on historical supply chain data. Conductiv also works to enable a healthy, competitive services market by creating new opportunities for smaller, diverse suppliers and helping hospitals invest locally across many different categories of their business.

II. COMMENTS ON HUMAN-LED GOVERNANCE, ACCOUNTABILITY, AND TRANSPARENCY

Premier offers the following comments in response to questions concerning human-led governance, accountability, and transparency in the use of AI/ML in drug development.

In what specific use cases or applications of AI/ML in drug development are there the greatest need for additional regulatory clarity?

Premier has identified several key areas where the FDA could offer regulatory clarity that would accelerate the pace of innovation and the use of AI/ML technology in drug development.

Innovation in Clinical Trials: As technology development and its application in clinical trials accelerate, Premier anticipates questions will arise at the intersection of patient privacy and digital innovation. Given the availability of quality real-world data (RWD) through electronic health records, claims data, home health devices and other sources, new clinical trial models such as synthetic control arms may soon become standard practice. Synthetic control arms can increase the power of trial populations by eliminating the need for a control population and can help increase trial enrollment by easing patient fears that they will receive a placebo. The FDA has already recognized the value of RWD to support development of drugs and biologics. To uphold that commitment and continue to advance the use of RWD in clinical trials, the

FDA should include guidance on proper informed consent for the use of RWD for a synthetic control arm. Premier requests clarification on the following topics:

- **Consent Procedure**: Premier requests clear guidance from the FDA on the process for properly gathering consent from patients for the use of their RWD to construct a synthetic control arm. As one premise of decentralized clinical trials is the ability to gather data from a wide or disparate patient population, the incorporation of RWD should be included in the FDA's guidance around collecting and managing data during decentralized clinical trials.

- **HIPAA Consent Waivers**: Premier urges the FDA to issue clear guidance for the use of HIPAA consent waivers to incorporate RWD into clinical trials. Specifically, the HIPAA Privacy Rule waivers that may be granted under 45 CFR section 164.512 for the purposes of "recruitment" may be essential to identifying and recruiting patients across the country for a decentralized clinical trial. However, Premier would like the FDA to clarify whether this same process is sufficient to include de-identified patient data in a synthetic control arm for a trial. Premier acknowledges that the FDA's requirements for informed consent for participation in clinical trials under 21 CFR 50.20 are separate from HIPAA Privacy Rule waivers; however, Premier believes the FDA can and should clarify whether trials incorporating HIPAA waivers into recruitment or for a synthetic control arm will be in compliance with FDA requirements.

- **De-identified Data**: If the FDA believes that the HIPAA consent waiver process is not sufficient to include RWD in a synthetic control arm, Premier requests clarification about the recommended procedure to re-identify and obtain consent from all patients selected for the control arm.

The FDA should address the aforementioned questions in its final guidance in order to facilitate the effective design and administration of decentralized clinical trials, including those with synthetic control arms. Patient privacy and informed consent are crucial components of clinical trials, and it is critical that the FDA pre-empt questions that will arise from the incorporation of digital health technology and RWD into decentralized trial models.

Kickbacks and AI Technology: Premier believes that the FDA has the opportunity to issue clarification on how anti-kickback statute will be applied to the use of AI technology in drug development, particularly in the identification and recruitment of clinical trial participants, in the following contexts:

- When patients are referred to local healthcare providers on a fee-for-service basis under the process described in this draft guidance, it raises the question of whether this represents a "kickback" for physicians who identify and enroll patients from their clinic in trials. Of course, the availability and involvement of non-trial providers is essential to protecting patient safety and ensuring participants receive medical attention as necessary, as the FDA notes in this draft guidance. Premier urges the FDA to clarify that this interaction would not be viewed as a violation of anti-kickback statute.

- In the context of clinical trials and drug development, the provision of digital health technologies to trial participants could be construed as a kickback or a violation of the "Civil Monetary Penalties Law" or the "False Claims Act." Legislation addressing the provision of digital health technologies to patients in order to promote geographic or socioeconomic diversity has included an explicit safe harbor from anti-kickback statute provision prosecution. Premier recommends that the FDA include language clarifying this exception in its final guidance.

- Decentralized clinical trial designs may promote the use of synthetic control arms and explore the potential value of synthetic data in trial design and innovation. Within this context, Premier requests clarification about whether payment-per-patient or data point would violate anti-kickback statutes. Premier strongly recommends that the FDA provide a clearly defined exception for this use of data science and cutting-edge healthcare technology to safely develop new drugs through a more cost-effective and efficient process.

In each of these scenarios, innovation in trial design and execution with demonstrably positive effects may be hindered by a conservative interpretation of existing statutes. These uses of AI technology to enhance clinical trial diversity, reduce prohibitive costs, and accelerate the development of crucial new drugs and devices do not conflict with the spirit of anti-kickback statutes, but uncertainty is anathema to innovation. The FDA should clarify the applicability of relevant statutes and, where necessary, include explicit safe harbor exceptions for these critical interests.

Protecting Patient Data: The baseline standards currently proposed by the FDA to govern data storage and cybersecurity are inadequate to ensure patient data is protected and secure. The provisions of 21 CFR part 11 are valuable to ensure the integrity and validity of patient records, but do not adequately establish best practices for confidentiality, privacy or cybersecurity. These crucial components of patient protection should not be left up to trial administrators to determine. Premier strongly recommends that the FDA provide guidance on key cybersecurity concerns arising during decentralized clinical trial design and execution:

- **Cybersecurity**: The FDA should lay out a minimum cybersecurity standard for the transmission and storage of participant health data on or using digital health technology. In addition to the standards for authentication and access control contained in 21 CFR part 11, these standards should include a requirement for end-to-end encryption for data-in-transit and encryption standards for data-at-rest. The FDA could even consider bolstering the access control requirements of 21 CFR part 11 to include a zero-trust architecture mandate. The FDA should also require that all data collected during a decentralized clinical trial should be stored in a secure centralized repository to mitigate cybersecurity and privacy risk. Administrators of a decentralized clinical trial should also be required to develop a cybersecurity plan that covers each of the digital health technologies that will access patient health information during the trial.

By clarifying and bolstering these standards, the FDA can ensure that the privacy and confidentiality of participant health data is prioritized even as trial administrators explore which models and digital health technologies best facilitate decentralization. Premier expects a period of innovation in trial design as decentralized clinical trials become the norm, and the FDA should take care to ensure participant privacy is not an unintended casualty of digitization.

Data Sharing: If the FDA intends to build on its domain-specific expertise in data science, informatics, statistics and mathematics to help ensure the appropriate application of AI technology in the context of digital health technologies used for drug development, Premier has the following comments:

- ***When appropriate, Premier suggests a requirement for structured communication layers such as Predictive Model Markup Language (PMML)***. This would allow for system interoperability in a fashion similar to FHIR.

- ***The FDA should provide open-source client libraries in Python, R, or other important languages***. Python and R are important data science tools, and a client library would allow researchers to interact directly with the data elements in the fashion the FDA intends them to be used rather than each vendor making their own access decisions. In addition, it is essential for FDA to provide support (ideally financial and at a minimum technical) to vendors who create these libraries.

- ***The FDA should consider a federally hosted private cloud for communicating with clinical trial sponsors***. This would facilitate health information exchange (HIE) activity and can be used to train and evaluate the data.

What does transparency mean in the use of AI/ML in drug development (for example, transparency could be considered as the degree to which appropriate information about the AI/ML model—including its use, development, performance, and, when available, logic—is clearly communicated to regulators and/or other stakeholders)?

Premier strongly believes that transparency is a key component of responsible AI and is an essential element of any trustworthy AI system used in drug development. Premier has identified two key themes around appropriate transparency requirements and the complex relationship between transparency and explainability.

Promoting transparency. Trust – among patients, providers, payers and suppliers – is critical to the development and deployment of AI tools in healthcare settings. In order to earn trust, AI tools must have an established standard of transparency. Recent policy proposals, including those proffered by the Office of the National Coordinator for Health Information Technology (ONC), suggest transparency can be achieved through a "nutrition label" model. This approach seeks to demystify the black box of an AI algorithm by listing the sources and classes of data used to train the algorithm and/or used as an input. Unfortunately, some versions of the "nutrition label" approach to AI transparency fail to acknowledge that when an AI tool is trained on a large, complex dataset, and is by design intended to evolve and learn, the initial static inputs captured by a label would not provide accurate insights into an ever-changing AI tool. Further, overly-intrusive disclosure requirements, around either data inputs or algorithmic processes, that would force AI developers to publicly disclose their intellectual property or proprietary technology may stifle innovation. Premier recommends that AI technology in healthcare should be held to a standardized, outcomes-focused set of metrics, such as accuracy, bias, false positives, inference risks, recommended use and other similarly well-defined values. Outcomes, rather than inputs, are where AI technologies hold potential to drive health or harm. Thus, Premier believes it is essential to focus transparency efforts on the accuracy, reliability and overall appropriateness of AI technology outputs in healthcare to ensure that the evolving tool does not produce harm.

End-User Specific Explainability: Premier has commented repeatedly about the importance of ongoing testing to determine accuracy and prevent bias in AI applications. Additionally, Premier has advocated for transparency into when information or recommendations are generated by an AI system. However, the concept of transparency cannot be completely disentangled from the concept of explainability. The PCAST Working Group on Generative AI will likely receive many comments urging them to incorporate explainability; however, Premier urges the members of the Working Group to carefully tailor explainability requirements to the end user of the AI system. While Premier's recommendations for a "nutrition label" or "model label" represent the type of explainability that might be valuable to a patient or healthcare system, it's important to remember that different uses of AI, such as for clinical decision support or clinical trial design, have different end users who may need a higher degree of visibility into how the AI system reaches a decision and the factors it considers.

In your experience, what are the main barriers and facilitators of transparency with AI/ML used during the drug development process (and in what context)?

Premier strongly believes in the importance of transparency in the use of AI/ML in drug development, and we have identified the following drivers and barriers to consensus transparency practices.

Proprietary Algorithms and Intellectual Property (IP): The developers of AI/ML systems that can be used for drug development derive value from the proprietary algorithms they create and train. Transparency should not be anathema to innovation – it is crucial that transparency requirements allow innovators bringing value to the drug development process to retain the rights to their intellectual property. **Therefore, *Premier believes that transparency requirements should focus on transparency of quality, process and outcome tailored to the appropriate audience*.**

- **Quality**: Transparency measures, such as the "nutrition label" model suggested above, should provide insights into the accuracy, reliability and any bias in the results from AI/ML systems. Nutrition labels should include a cursory overview of the results of the latest round of model validation, building assurances that the technology is reliably achieving high-quality, accurate results. Premier has also supported guidelines for data quality to ensure that AI systems are trained and tested on data that will not introduce bias.

- **Process**: There should be some visibility into how an AI system uses data to arrive at a result or recommendation. This should not require disclosure of proprietary algorithms, but should instead focus on giving drug developers or clinical trial administrators the information they need to determine whether their use case is appropriate and whether the technology can comport to any guidelines or procedural requirements imposed on the drug developer.

- **Outcome**: As the FDA has acknowledged, the unique challenge presented by AI/ML systems stems from the evolving nature of the algorithms involved. Therefore, ***Premier believes that the most important element of transparency, particularly as applicable to the principles above, is transparency of outcome.*** Most AI systems contain model validation and ongoing testing; Premier urges the FDA to issue guidance on a clear and understandable series of measures – including ongoing disparity testing, accuracy and bias measures, quality metrics and potentially other values – that will be used to assess the outcomes of AI systems in a transparent manner that is useful to drug developers. This is accompanied by a corollary component of transparency - transparency of use. By emphasizing outcome when devising transparency metrics and guardrails, Premier believes that these standards will remain focused on a key element of the burgeoning use of AI – the importance of knowing when and how AI will be used in drug development.

Data Transparency: Some academic thought around transparency in AI has emphasized the potential value of making test and training data for AI/ML systems fully transparent, i.e., public. While there is undeniable value in sources of open data and open-source AI, this is a value-add service (much like federated health data networks being examined by the CDC) that can be used to improve public health and economic growth. ***Fundamentally, Premier believes that requirements for fully open training and test data will prove a substantial barrier to industrywide acceptance of AI transparency practices.*** There is a place for open data, and drug developers may benefit from it in some contexts, but any wide-reaching requirements for disclosing test and training data will discourage innovation and heavily reduce the incentive to develop novel AI systems.

Promoting Innovation & Transparency: Premier recommends that agencies within the federal government pursue public-private partnerships to develop standards and regulations that support U.S. AI innovation and ensure that American workers, businesses and the economy benefit from AI development. Premier and other private companies at the cutting edge of AI technology development can offer real-world insights into the ways AI is being used drug development and healthcare settings across America, as well as the challenges that drug developers face with implementation, financing and regulation. One of the most significant challenges the federal government faces while developing AI regulations for the life sciences is understanding how drug developers and trial administrators actually use AI technology and the processes providers are using on the ground to implement new AI systems and procedures**. *In order to effectively regulate AI and incorporate effective transparency guidelines, Premier believes the government must be responsive to real-world challenges and be strategic about which stages of the implementation and operations process regulations target*.** Partnerships with industry experts can help ensure that regulations are effective, promote patient safety and value of care, and help tackle some of the biggest challenges facing the American healthcare and life sciences sector.

What are some of the good practices utilized by stakeholders for providing risk- based, meaningful human involvement when AI/ML is being utilized in drug development?

Premier believes that human involvement in AI/ML should begin with workforce training and meet three key standards.

Workforce Training: Premier believes technology can work alongside and learn from healthcare professionals, but current technology will not and should not replace the healthcare workforce. Premier would reiterate the importance of comprehensive risk assessments, recommended use and trainings that combat automation bias and incorporate human decision-making into the use of AI technology in healthcare.

- **Risk Assessments**: The risks and safety concerns around AI technology are unique to each use case, and Premier supports the requirement of a risk assessment and mitigation plan specific to the level of risk associated with the use case. For example, the use of AI systems to identify potential patients involves different concerns, such as privacy and confidentiality, and carries a different level of risk than the use of AI to develop a dosing regimen for a trial.

- **Recommended Use**: Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design. Whether the intended use of a technology is ongoing safety and quality monitoring, digital endpoint analysis, trial design, or patient identification, the training protocol and appropriate data set will have several key differences. Therefore, it is crucial that drug developers know the intended context, such as condition, applicability and use case, of each AI system.

- **Automation Bias & Workforce Enablement**: Finally, Premier acknowledges the risks of automation bias and fully automated decision-making processes. To reduce these risks, promote trust in AI technologies used in drug development and achieve the goal of supporting the healthcare and life sciences workforce through AI, Premier recommends that federal workforce training programs provide comprehensive AI literacy training for the healthcare and drug development workforce. These workers deal with high volumes of incredibly nuanced data, research, and instructions – a growing percentage of which may be supplied by AI.

By ensuring our healthcare workers understand how to evaluate the most appropriate AI use cases and appropriate procedures for evaluating the accuracy or validity of AI recommendations, we can maximize the advisory benefit of AI while mitigating the risk to patients. Additionally, clear, risk-based guidance on which uses of AI technology in healthcare require human review and decision-making, similar to the principles discussed in section five of the OSTP's AI Bill of Rights, is essential.

What processes are in place to enhance and enable traceability and auditability?

Premier believes that watermarking, a form of provenance system for AI-generated content or recommendations, is a crucial process to enable traceability and auditability for AI involvement in drug development.

Watermarks: Watermarking or provenance data/systems for AI-generated content were a component of the voluntary commitments recently announced by the White House. Premier generally supports the development of similar metrics for scientific research or clinical decision support recommendations produced by AI technology. It is important that patients, scientists, and medical professionals understand when decisions or recommendations are made by AI so they can consciously respond and evaluate the new information accordingly.

Specifically, watermarking is one potential strategy to combat automation bias, a risk especially pertinent to the use of AI technology in healthcare. Automation bias refers to human over-reliance on suggestions made by automated technology, such as an AI device. This tendency is often amplified in high-pressure settings that require a rapid decision. The issue of automation bias in a healthcare setting is discussed at length by the FDA in guidance on determining if a clinical decision support tool should be considered a medical device. Premier suggests that future guidance or standards for the use of AI should consider automation bias in risk assessments and implementation practices, such as workforce education and institutional controls, to minimize the potential harm that automation bias could have on patients and vulnerable populations, including to mitigate any potential risk of AI used in unintended settings or built on biased datasets.

How are pre-specification activities managed, and changes captured and monitored, to ensure the safe and effective use of AI/ML in drug development?

In recent years, the FDA has taken important steps to consider how AI/ML-driven medical devices should be treated during the clinical trial and approval process. The resulting guidance and action plan introduced a new strategy for handling the evolving nature of AI algorithms in Software as a Medical Device (SaMD). One core component of this model involves outlining SaMD Pre-specifications (SPS), a collection of potential changes that the device manufacturer intends to incorporate into the device over its lifetime. Types of pre-specifications include retraining for performance improvement, new data acquisition systems, and changes related to the intended use. While this discussion draft specifically asks about how SPS can be managed within drug development, the corollary Algorithm Change Protocol (ACP) – which details how changes in the SPS will be performed and validated – provides an equally important guide to navigating evolving algorithms in drug development. Premier has identified the following opportunities to capture, monitor and manage SPS activities in drug development:

- **Pre-specification**: Premier suggests that the FDA can use this model to acknowledge and address the evolving nature of algorithms, but any application of this model to drug development must first acknowledge that the AI/ML systems used are not SaMD and are not themselves subject to approval. It is necessary to adjust the purpose of Pre-Specification reporting and logging from approval to the appropriate drug development use case. For the use cases highlighted in this discussion draft, Premier suggests that three principles can guide management:

    - **Predictability**: Pre-specification activities should be predictable. Changes to intended use or the introduction of new data acquisition systems should be done outside of the finite period of a clinical trial use case. For example, if an AI system is being used to identify trial participants or to optimize a dosing regimen, the trial administrators should be able to predict the timeline for an update or new feature to ensure consistency across the trial. Premier suggests that all developer-driven updates detailed in Pre-Specification should be implemented on a publicly available timeline that allows trial administrators to build in consistency across the use of the tool, with the goal of ensuring that the use of different AI tools does not introduce variability into trial procedure. For Pre-specification activities driven by a continuously adaptive algorithm, such as the incorporation of new data for retraining or enhancement, the process used should be predictable, consistent and technically explainable to trial administrators.

    - **Reliability**: Pre-specification activities should not affect the reliability of an AI tool. Elsewhere in these comments, Premier has argued the importance of ongoing disparity testing and evaluation. Pre-specification activities should be no exception. Premier supports the implementation of a standardized format for reportable, continuous model evaluation to ensure that the overall accuracy and reliability of the AI system does not change after any update, either developer-driven or as the result of an adaptive algorithm. This could take the form of regular tests or a method to flag irregular results, either of which would provide indicators that a pre-specification activity fundamentally changed the AI system.

    - **Attributability**: Premier believes that the recommendations above should be logged and tracked. Any form of update to the AL/ML system should be recorded in a log available to drug developers currently using the system, should be attributable to either a developer update or continually adaptive algorithm feature, and should be trackable over time.

- **Algorithm Change Protocol**: The Algorithm Change Protocol (ACP), as described in this FDA presentation, provides a roadmap to implementing the principles outlined above. Premier urges the FDA to issue guidance on a similar procedure that AI/ML technologies designed for use in drug development would provide to trial administrators. As the FDA cannot directly regulate the technologies used as a resource by drug developers, Premier suggests that they instead establish minimum reporting standards for sponsors based on the information above, which must be provided to the FDA as part of pre- and post-trial submissions. These could detail the information that trial

administrators and drug developers should require from the AI tools they use, as well as require pre-specification plans and ACPs for the technology used to ensure those standards will be met.

III. COMMENTS ON QUALITY, RELIABILITY, AND REPRESENTATIVENESS OF DATA

Premier offers the following comments in response to questions about quality, reliability and representativeness of data.

What additional data considerations exist for AI/ML in the drug development process?

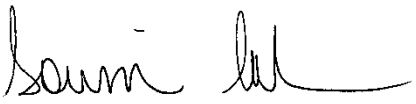
Premier firmly believes that training and test data quality are fundamental to the reliability and effectiveness of AI systems. Premier has identified several key considerations for data quality and recommendations for data standards and guidelines.

Data Standards: Premier understands the importance of data standards, responsible data use and data privacy in the development and deployment of AI technology. Data standards should specifically focus on objective assessment of potential sources of bias or inaccuracy introduced through poor dataset construction, cleaning or use. These may include, but are not limited to, appropriately representative datasets, bias in data collection (e.g., subjectivity in clinical reports) or introduced by instrument performance or sensitivity (e.g., pulse oximetry devices producing inaccurate measurements of blood oxygen levels in patients with darker skin), bias introduced during curation (e.g., datasets with systemically introduced nulls and their correlation, such as failure to pursue treatment due to lack of ability to pay), and training and test data that is appropriately applicable to various patient subpopulations (e.g., data that sufficiently represents symptoms or characteristics of a condition for each age/gender/race of patient that the tool will be used to treat). Premier also supports the establishment of guidelines for proper data collection, storage and use that sufficiently protect patient rights and safety. This is particularly important given the sensitivity of health data.

IV. CONCLUSION

Premier appreciates the opportunity to comment on the FDA's draft discussion paper, "Using Artificial Intelligence & Machine Learning in the Development of Drug & Biological Products." If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Administration in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com or 334.318.5016.

Sincerely,



Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.