AI Regulation Is Coming to Life Sciences: Three Steps to Take Now

To maximize the value of artificial intelligence and machine learning for patients, healthcare providers together with life sciences enterprises must gear up to meet the continually evolving regulatory landscape.

Executive Summary

Artificial intelligence and machine learning (AI/ML) have enormous potential to improve patient outcomes and drive new revenue streams for life sciences (LS) companies. Whether understanding the complexities of the human genome, assessing the effectiveness of treatments or modeling the spread of disease, AI/ML could help speed new treatments to market, make healthcare more efficient and effective, and better track and control pandemics. Insights from AI/ML solutions could be monetized as chatbots that can help patients manage their health, assist doctors as they diagnose and treat conditions, and guide robotic surgery.

Predictive algorithms, as well as AI/ML, can also improve and speed regulatory compliance by mining data from clinical trials and caregivers and surfacing potential issues before safety reports are submitted to regulators.

But the use of complex algorithms that improve themselves over time raises complex new regulatory issues. LS companies that understand, prepare for

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and help shape those regulations will be best positioned to use AI/ML to drive the maximum benefit for patients, healthcare providers and their shareholders. Read on to learn how LS companies should adapt their governance models, data management, and reporting, tracking and validation processes to meet the requirements of upcoming AI/ML regulations.

The regulatory challenge

Because AI/ML involves such new and rapidly changing computing technologies, and vast amounts of training data, it poses significant new regulatory challenges such as:

- Determining the accountability for providers of AI/ML-based solutions and assigning liability for harm caused by the "black box" of an AI/ML process.
- Assuring the quality and safety of products or therapies developed using AI/ML.
- Guaranteeing that the data and/or algorithms used in AI/ML solutions are not biased against underserved populations.
- Ensuring that the AI/ML solutions developed are sustainable and environmentally friendly, and that the recommendations are not in conflict with societal priorities such as social justice.
- Protecting the privacy of patients and their data. Existing patient privacy rules do not, for example, protect patient data when it is shared and used by technical or consumer marketing organizations rather than healthcare providers.

In response, regulators are working to create adaptive, real-time regulations, aided by next-gen-technology-enabled interventions, pre-certification programs and data-driven decision-making. The role of AI/ML

Current regulations governing AI/ML in life sciences

Regulator	Program and Link	Program Details	Program Type	Status
FDA	Developing a software pre-certification program: A working model (2018–2019).	Aims to provide tailored, pragmatic and least burdensome oversight to ensure organizations have a culture of quality and excellence. It includes streamlined pre-market review and post-market verification for continued safety, effectiveness and performance of software-as-a-medical-device (SaMD).	Evolving guidance documents.	Accepting applicants.
FDA	Proposed regulatory framework for modifications of AI/ML-based SaMD (April 2019).	Proposed framework to regulate iterative algorithms within AI/ML SaMDs to ensure patient safety. Assures ongoing algorithm changes are implemented according to prespecified performance objectives, follow defined protocols and use a validation process committed to improving the performance, safety and effectiveness of AI/ML software, including performance monitoring.	Discussion paper.	Currently accepting feedback.
UK Department of Health & Social Care	Code of conduct for data-driven health and care technology (July 2019).	Provides 10 principles in a code of conduct to enable the development and adoption of safe, ethical and effective data-driven healthcare technologies.	Guidance document/ code of conduct.	Active.
National Institute for Health and Care Excellence (NICE), Department of Health, UK	Evidence standards framework for digital health technologies.	Describes the types and levels of evidence needed to show the effectiveness and expected economic impact of a digital health technology.	Evidence standards and regulatory sandbox.	Active.

Figure 1

in life sciences is so new that only a few proposed regulations are industry-specific, with the rest addressing the cross-industry ethical, governance and social impacts of AI/ML.

Among the evolving regulatory frameworks are a voluntary pilot software pre-certification program developed by the U.S. Food and Drug Administration (FDA) for makers of software-based medical devices (see Figure 1, page 3), and an April 2019 discussion paper from the FDA seeking input from pharmaceutical companies on a proposed framework for regulating such devices.[1]

LS companies that work with regulators to help create these regulations can gain a competitive advantage by:

- Helping to shape the rules to provide the maximum value to patients, healthcare providers and the rest of the LS ecosystem.
- Understanding how AI/ML can add ongoing value to both their clinical and commercial operations.
- Identifying the skills they need to leverage AI/ML.
- Leveraging partners skilled in AI/ML to complement their own LS skills.

While the exact nature of forthcoming AI/ML regulations is still evolving, we have identified three areas – governance, data management and reporting/tracking/monitoring – that LS companies will likely need to address to stay ahead of the curve (see Figure 2).

The multiple dimensions of regulatory action

Governance model

- Apply existing quality, compliance and documentation processes to AI/ML-based medical solutions.
- Involve staff with regulatory experience as well as legal, risk, IT, security and analytics.
- Provide regulators with real-time updates; iteratively test AI/ML solutions for faster review and feedback.

Data management

- Create adaptable processes for collecting, organizing, maintaining, using, preserving and managing the security of data used in AI/MI solutions.
- Use data testing/analysis models and/or tools whose results can be submitted as evidence to support claims of safety assurance and provide audit trails to verify testing and results.

Reporting, tracking & validation

- Develop real-time reports, metrics and KPIs that evolve to meet changing AI/ML technological capabilities, as well as regulatory and market needs.
- Assure mature change and risk management, safety and audit, and quality assurance processes.

Figure 2

Solution developers will need to identify specific KPIs and targets for AI/ML solutions, explain outliers or anomalies in the data used in those solutions, and summarize actions planned or taken to address those outliers or anomalies.

GOVERNANCE MODELS

LS companies have long experience assuring their development, testing and manufacturing processes comply with complex regulations in multiple jurisdictions. But emerging regulatory, risk and ethical considerations associated with AI/ML require new governance models, implemented by staff with the proper skills who are empowered to resolve issues that could affect patient safety and privacy. Compared to the traditional development process for LS products, or the diagnostic process followed by a provider, it is often difficult or impossible to determine how an AI solution arrived at a conclusion. Governance models must be adapted to account for varying levels of risk tolerance and limits on the explainability and interpretability of AI/ML solutions.

In addition, AI/ML governance frameworks must allow for modifications in how the AI/ML solutions are measured as the algorithms, and their uses, change.

LS companies will need to demonstrate they already have or are acquiring the appropriate AI/ML tools, automation and test environments and have a centralized and transparent process to implement AI/ML solutions. Regulators will also expect evidence, perhaps in the form of third-party audits, of a robust and effective communication framework, reliable feedback and learning mechanisms, and multiple avenues of customer outreach. This information flow is essential to ensuring AI/ML solutions not only meet the needs of patients and caregivers but produce ethical and unbiased recommendations.

Solution developers will need to identify specific KPIs and targets for AI/ML solutions, explain outliers or anomalies in the data used in those solutions, and summarize actions planned or taken to address those outliers or anomalies. Their governance frameworks must also include mechanisms for changing the measurement criteria as the algorithms themselves evolve.

LS companies must also create and document appropriate decision-making evaluation frameworks for AI/ML solutions, backed by data analytics, as well as data governance models to ensure that the data used in AI/ML models is clean and reliable. Evaluation criteria should include the level of risk to patients, the criticality of the condition AI/ML is being used to diagnose or treat, the type of changes that have been made to the solution and the actual impacts of the AI/ML treatment.

Other requirements include protocols for premarket assurance, including change control mechanisms and documentation, as well as for determining acceptable risks and acting on those determinations. As regulators introduce premarket reviews of AI/ML solutions and changes to them, LS players can "self-regulate" with agile methods to manage risk and prove the safety and effectiveness of their solutions. This can be done, for example, by using controlled environments to iteratively test their products/services/models.

Proper experience will be critical to compliance success. The AI/ML governance task force should include staff with regulatory experience who can provide useful insights into the quality, format and other characteristics of the data required to prove compliance. It should also include C-level executives and experts in areas ranging from legal and risk to IT, security and analytics to evaluate and prioritize the risks of AI/ML solutions.

Depending on the type of solution, development staff should also include scientists and engineers who can help shape data generation, collection and maintenance techniques based on their domain and business knowledge.

DATA MANAGEMENT

Data is central in developing and refining AI/ML solutions, both to train the algorithms at the heart of AI and for use in those models to make potentially life-or-death decisions. The choice of data, its use and how it is protected to maintain patient privacy will be top of mind for regulators.

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To manage risk, LS companies will need to create data or information lifecycle management processes to collect, organize, maintain, use and preserve data. Data from clinical trials, pharmacovigilance, customer feedback or commercial sources should be gathered using validated or highly reliable methods with appropriate controls implemented by qualified experts. Those controls could include national or international standards or previously tested internal controls.

Producers of software-as-a-medical-device (or SaMD; software used to diagnose or treat conditions that is not part of a physical device) will need to demonstrate how they can leverage usage data to understand how their products are being used, identify opportunities for improvements, and respond proactively to safety or usability concerns.

Among the privacy and personalization requirements we expect for data used in ML/AI are the following:

- Any data used for training is accurate and has not been tampered with.
- If a training dataset is created in real time, the data within it should be anonymized in real time.
- Assurance that hidden biases or other defects in the algorithms do not result in the wrong diagnoses or treatment recommendations for the intended patient.
- Adaptive systems should ensure that new data and algorithms don't contain malware or other threats that could jeopardize patient data, the security of the AI/ML system or the functioning of other platforms with which the system shares data.

LS companies will need to prove that their AI/ML solutions give humans a substantial or even final say in patient care, preserve privacy, provide "effective redress" if they cause harm, and are auditable and understandable.

LS organizations should also utilize data testing/analysis models and/or tools whose results can be submitted as evidence to support claims of safety assurance. Capabilities to look for include robust document management and reporting, audit trails, content protection, integration with other information management and workflow systems, and the ability to present safety arguments through diagrams. We also recommend that proven processes to demonstrate the safety, effectiveness and performance of medical devices be extended to AI/ML solutions.

REPORTING, TRACKING AND VALIDATION

LS companies will need to prove that their AI/ML solutions give humans a substantial or even final say in patient care, preserve privacy, provide "effective redress" if they cause harm, and are auditable and understandable. They may also, depending on the political jurisdiction, need to prove their solutions do not harm society or threaten the democratic process, freedom of expression or freedom of identity.

Meeting these needs will require processes such as change and risk management, safety and audit, and quality assurance are well-established and maintained and can be leveraged for AI/ML solutions. Given the dynamic and unpredictable nature of AI/ML algorithms, companies will need to show they are investing in ensuring multistage verification and validation of AI/ML solutions. This could include engaging users in the verification process at various stages, measuring the quality of the output and ensuring the traceability of results.

Devices that rely on AI/ML must be validated using analytical and clinical data, and follow good machine learning practices (GMLP). These include the relevance of available data to the clinical problem and practice, that data is acquired in a consistent, clinically relevant and generalizable manner, and appropriate separation is maintained between training, tuning and testing of datasets.

Explainability, i.e., documenting the logic, decision methodology and data sources that influence the output of the AI/ML solution, is not an easy task as the algorithm(s) used are often highly complex. But such explainability helps assure data privacy and ethics as well as regulatory compliance. Explainable AI (XAI), itself a form of ML, can help describe how and why ML models made their predictions. For relatively straightforward models, decision trees or knowledge graphs used to make decisions can help provide such understanding. For more complex forms of ML, XAI uses methods such as highlighting which data played the greatest role in a decision. Defining ML uncertainty (describing questions the system cannot answer) can help determine when to trust it.

LS companies will need to develop frameworks to track and measure changes in the intended use of their AI/ML solutions, the algorithms used in them, the data used to train them or the output of the solution.

LS companies will also need to continually adapt their reporting to meet evolving AI capabilities and regulatory requirements. They will need to tailor the frequency of their reports, and the type of information in them, to the risk categorization of the device, the number and types of modifications made to it, and the maturity and reliability of the algorithms the solution uses to make decisions. For example, if an AI solution initially intended to assure patients receive the proper treatment by tracking their lifestyle habits evolves to the point it can also be used to diagnose disease, the KPIs used to measure its effectiveness must change as the potential risk of failures rises. In such a case, reports on the safety and effectiveness of the device might be done semiannually or quarterly rather than annually.

This continually evolving reporting will be provided by digital dashboards displaying data-driven and quality-focused KPIs measuring the explainability of the solution, how well it assures data quality and privacy, and its risk level.

SaMD manufacturers will need to create reporting frameworks, and choose reporting tools, that reflect the SaMD pre-specifications (SPS) and the algorithm change protocol (ACP) documents, which define the changes a manufacturer plans in a medical device and how it will implement those changes.[2]

Finally, LS companies will need to develop frameworks to track and measure changes in the intended use of their AI/MI solutions, the algorithms used in them, the data used to train them or the output of the solution. For example, the creator of a mobile app designed to monitor patient's exercise or eating habits for disease risk would need to validate predictions made by the app if the intended purpose evolved from monitoring to diagnosing by comparing against real-world data from diagnosed patients with similar lifestyles.

Collaboration and convergence are the keys to success for the future of AI/ML regulations. In order to gain advantage, the industry needs to proactively increase its engagement with regulators who will be converging at both national and global levels, adopting approaches like co-regulation and increased collaboration with patients, healthcare professionals, industry and payers.

Looking ahead: Help set the agenda

Collaboration and convergence are the keys to success for the future of AI/ML regulations. In order to gain advantage, the industry needs to proactively increase its engagement with regulators who will be converging at both national and global levels, adopting approaches like co-regulation and increased collaboration with patients, healthcare professionals, industry and payers. Even before the use of AI/ML becomes widespread in the LS field, industry players can position themselves to best meet emerging AI/ML regulations by:

- Preparing to "self-regulate" by proactively creating pathways that use agile and iterative methods to manage risk and ensure the safety and effectiveness of AI/ML solutions. This can be done in partnership with experts or in controlled environments to iteratively test products, services and models.
- Hiring and/or training staff who can work closely with regulators in understanding and helping to develop AI/ML regulations.
- Establishing, maintaining and refining quality systems that can validate their analytics and clinical outcomes, and adopting GMLP for data management, feature extraction, training and evaluation.

The power of AI/ML creates new challenges for regulators and the LS companies that must adhere to the emerging guidelines. Those who are "present at the creation" of these regulations can do the most to influence them and will be best prepared to meet them efficiently and effectively.

Endnotes

1 Guo, Elizabeth, et al., "FDA Outlines Proposed Framework for Regulating Artificial Intelligence Software," Covington Digital Health, April 10, 2019; www.covingtondigitalhealth.com/2019/04/fda-outlines-proposed-framework-for-regulating-artificial-intelligence-software/.

2 Singh, Jagmeet, "Preparing for the Regulatory Challenges Wrought by Software as a Medical Device"; www.ACS.com/whitepapers/preparing-for-the-regulatory-challenges-wrought-by-software-as-a-medical-device-codex2513.pdf.=

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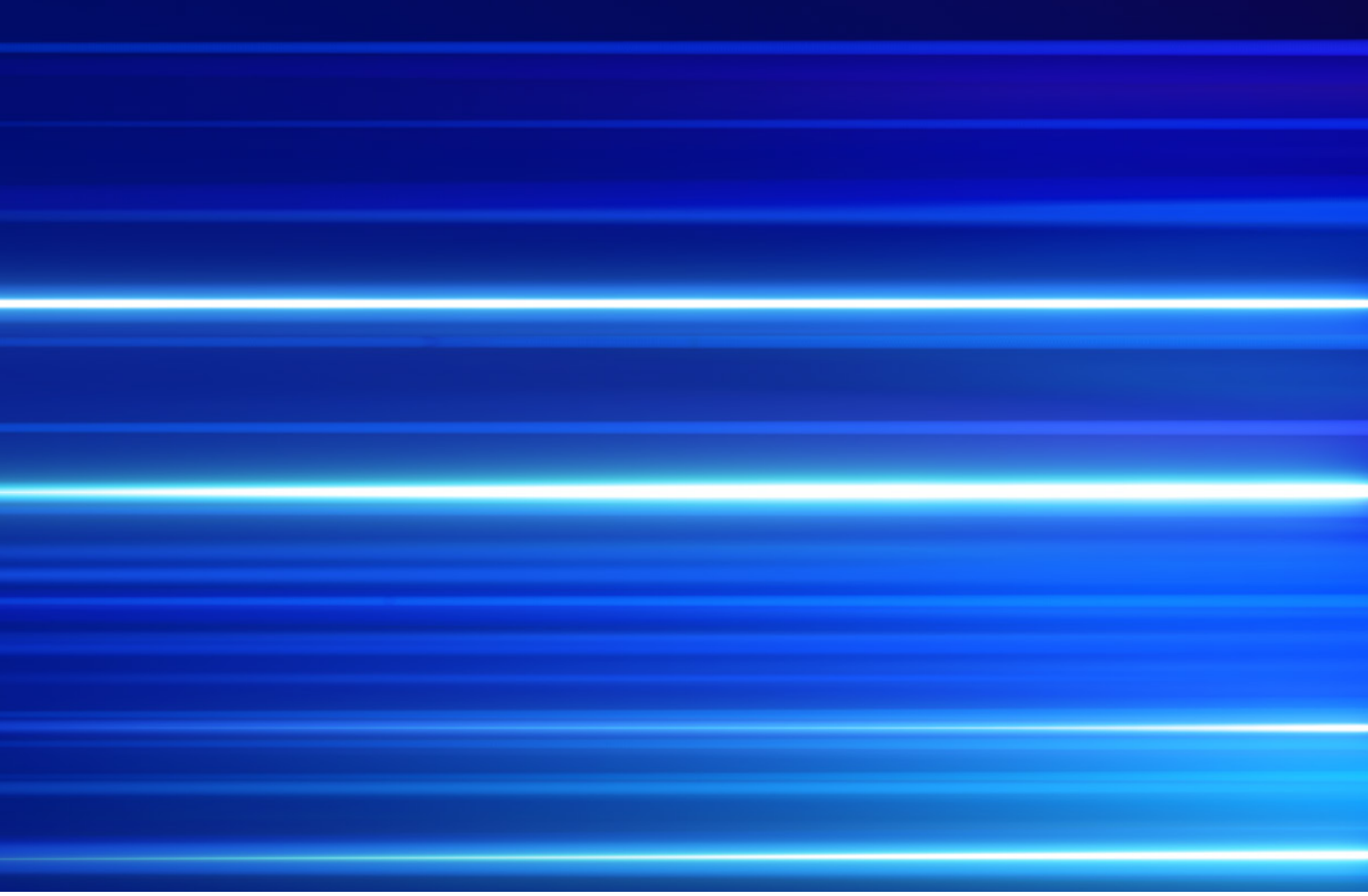

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