Before we begin

Tech Support

If you are experiencing technical difficulties, please contact WebEx Tech Support at +1.866.779.3239.

Q&A

The Q&A tab is located near the bottom right hand side of your screen; choose "All Panelists" before clicking "Send."

CLE

We will mention a code at some point during the presentation for attendees who requested CLE. Please make note of that code, and insert it in the pop-up survey that will appear in a new browser tab after you exit out of this webinar. You will receive a Certificate of Attendance from our CLE team in approximately 30 to 45 days.

Audio

The audio will remain quiet until we begin at 9 AM PT/12 PM ET.

You will hear sound through your computer speakers/headphones automatically. Make sure your speakers are ON and UNMUTED.

To access the audio for by telephone, please click the "phone" icon below your name on the Participants Panel for teleconference information.

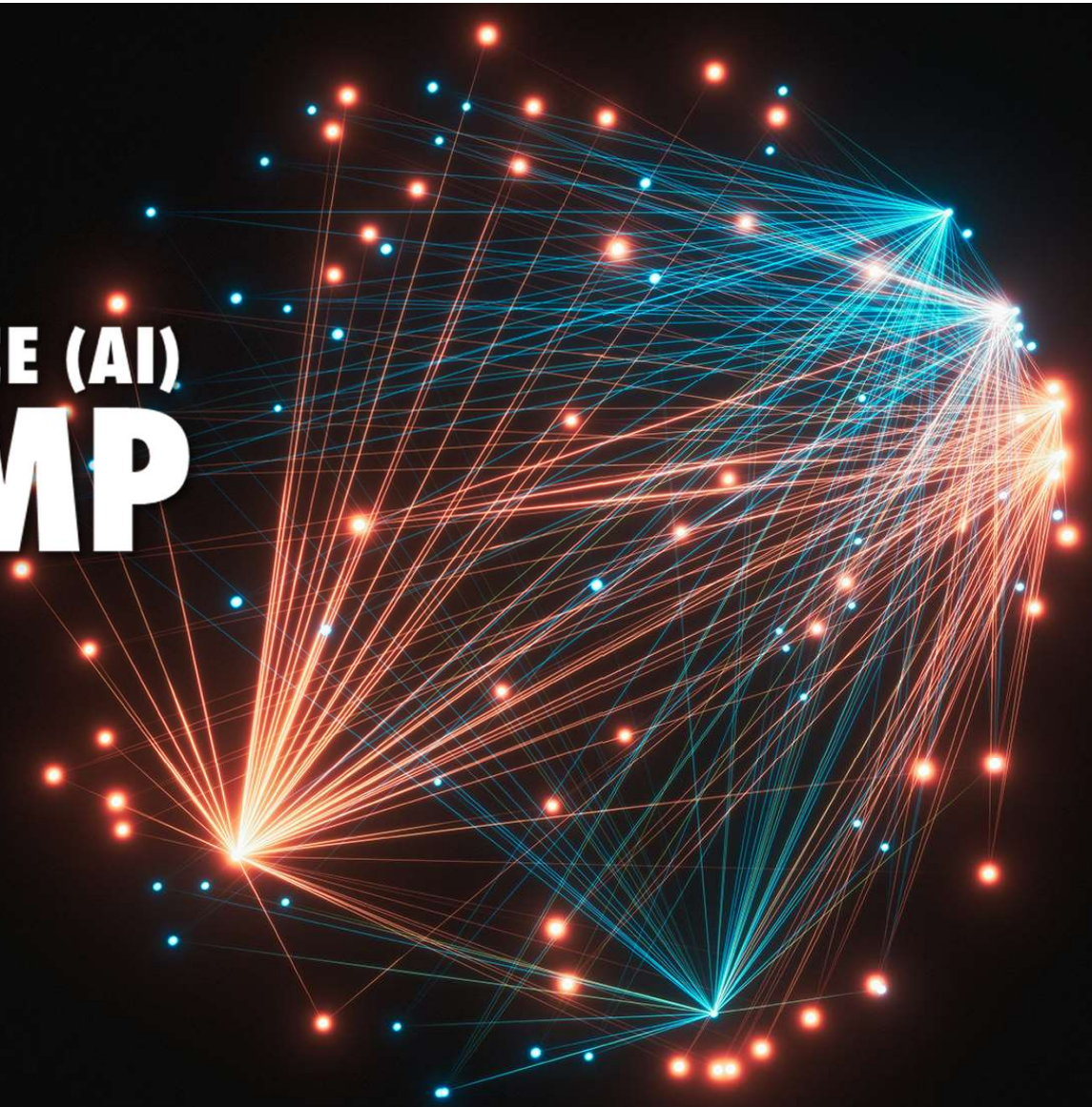
Morgan Lewis

ARTIFICIAL INTELLIGENCE (AI) BOOT CAMP

Digital Health Update

January 11, 2023

Michele L. Buenafe and Jacob J. Harper



Host

Andrew J. Gray IV

Presenters

Michele L. Buenafe

Jacob J. Harper

Morgan Lewis

Digital Health Update: What's New in 2023

Topics to be discussed today include

FDA Regulatory Developments

Healthcare and Reimbursement Developments

FDA Regulatory Developments

Morgan Lewis

How Do FDA Developments Impact AI/ML?

- AI/ML software and other digital health technologies may be regulated by FDA as medical devices

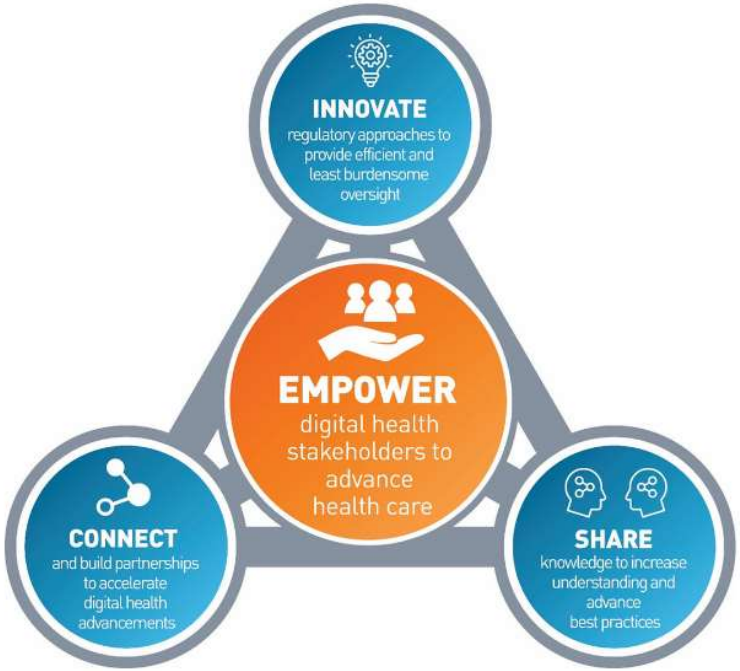
- AI/ML software also may be used for the development and/or production of medical devices and other FDA-regulated products

- FDA regulations, policies, and guidance affect AI/ML when used for medical purposes or otherwise used in the healthcare space

FDA Programs Impacting AI/ML Technologies

- Digital Health Center for Excellence
- Good Machine Learning Practices
- Guidance Documents
- COVID-19 Updates

Digital Health Center for Excellence



- Established September 22, 2020
  - "[C]reated to empower stakeholders to advance health care by fostering responsible and high-quality digital health innovation. The DHCoE is part of the planned evolution of the Digital Health Program in CDRH."
  - Key Goals:
    - Develop/Issue Guidance Documents
    - Increase Number and Expertise of Digital Health Staff
    - Develop the Software Precertification Pilot

FDA Discussion Paper – AI/ML Software

- Proposed framework to address how FDA would handle postmarket modifications to AI/ML software devices
  - Existing model requires sponsors to evaluate all device software changes to determine whether the change requires a new submission to FDA
  - May not work for AI/ML software, because such software is intended to continuously evolve
- Under the proposed framework, AI/ML software developers would include in their initial FDA submissions a predetermined change control plan:
  - SaMD pre-specifications (SPS), which define the types of software algorithm changes that are covered/permitted under the plan
  - Algorithm change protocol (ACP), which defines methods to control risks for the permitted changes and how the changes may occur
- May require statutory changes to fully implement proposed framework

Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD

- Changes that fall within the agreed upon SPS + ACP could be documented to file
- If outside the SPS + ACP and the change leads to a new intended use, change is subject to FDA premarket review
- If outside the SPS + ACP and no new intended use, change is subject to "focused FDA review"

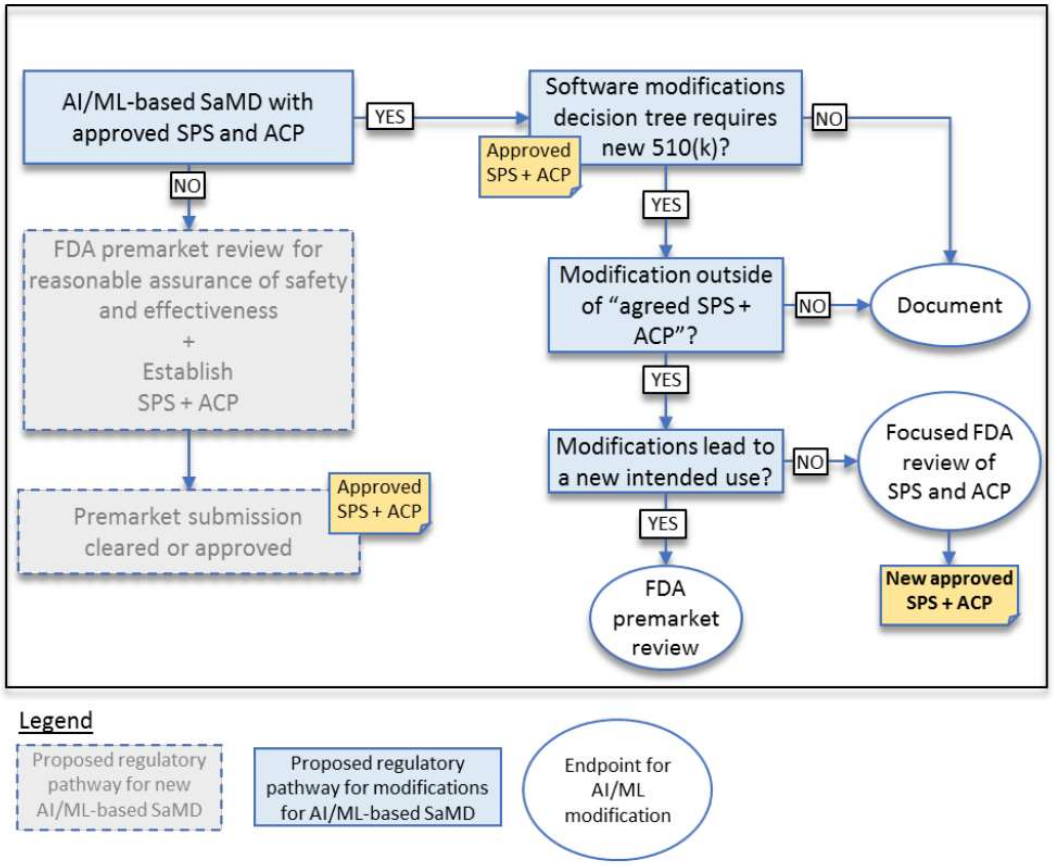


Figure 5: Approach to modifications to previously approved SaMD with SPS and ACP. This flowchart should only be considered in conjunction with the accompanying text in this white paper.

Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD

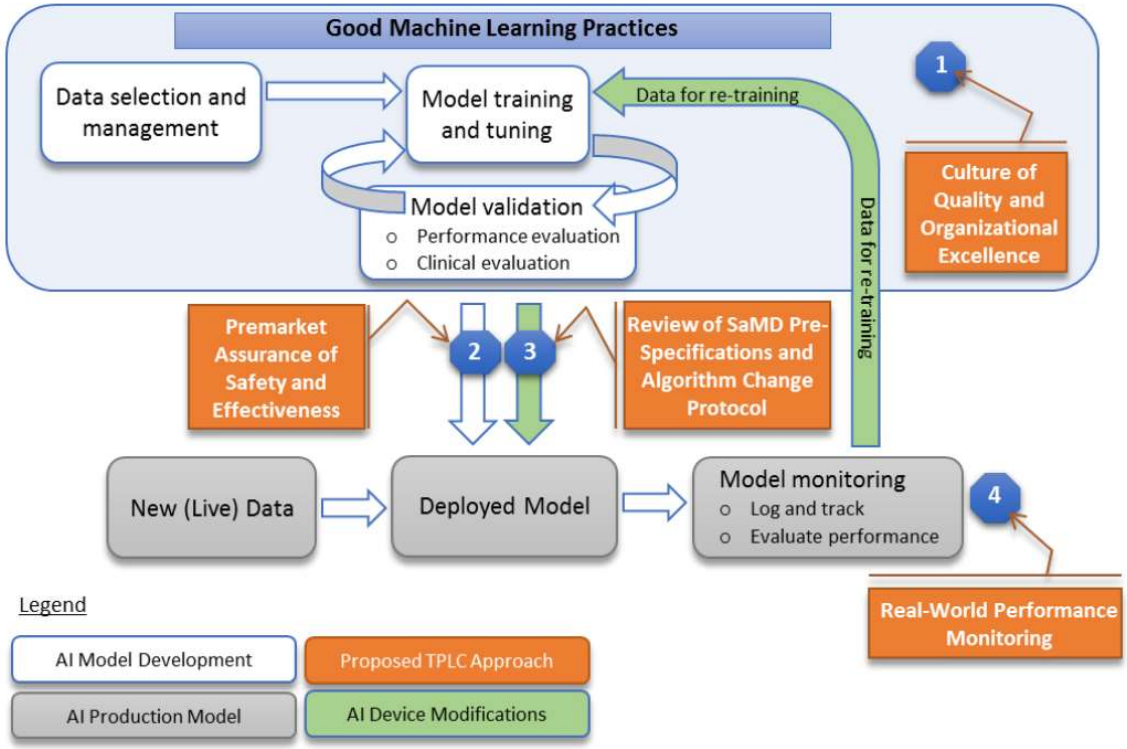


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

- Discussion Paper also proposes establishing clear expectations for good machine learning practices as part of the TPLC approach for AI/ML-based SaMD

5-Point Action Plan For Artificial Intelligence/Machine Learning-Based SaMD

Commitment	"Action"	Feedback from 2019 Paper Driving Action
1. Further develop the proposed regulatory framework	Issue draft guidance document (maybe 2021) that will discuss the use of predetermined change control plans (for software learning over time)	• Feedback received showed "strong community interest" in the Predetermined Change Control Plan • Types of modifications to AI/ML software devices proposed in Paper were relevant; however, feedback suggested additional types of modifications that should fall under this framework
2. Support the development of good machine learning practices (GMLP) to evaluate and improve machine learning algorithms	FDA will "deepen" its work in communities in order to encourage consensus outcomes GMLP efforts will be pursued in close collaboration with the Medical Device Cybersecurity Program	• Feedback received generally provided strong support for the idea and importance of GMLP • Request for FDA to encourage harmonization of GMLP with consensus standards efforts, leveraging already-existing workstreams, and involvement of other communities focused on AI/ML

5-Point Action Plan For Artificial Intelligence/Machine Learning-Based SaMD

Commitment	"Action"	Feedback from 2019 Paper Driving Action
3. Foster a patient-centered approach, including device transparency to users	Hold a public workshop to share learnings and to elicit input from the broader community on how device labeling supports transparency to users	• Feedback received indicated concerns with labeling content for AI/ML-based devices: – How to describe the data used to train the algorithm, the relevance of its inputs, the logic it employs (when possible), the role intended to be served by its output, and the evidence of the device's performance • Feedback received indicated that FDA should clarify its position on transparency of AI/ML technology in medical device software
4. Develop methods to evaluate and improve machine learning algorithms.	"Support" regulatory science research efforts to develop methods to evaluate bias in AI/ML-based medical software	• Feedback received described the need for improved methods to evaluate and address algorithmic bias and to promote algorithm robustness

5-Point Action Plan For Artificial Intelligence/Machine Learning-Based SaMD

Commitment	"Action"	Feedback from 2019 Paper Driving Action
5. Advance real-world performance (RWP) monitoring pilots	Work with stakeholders on a voluntary basis to support RWP monitoring pilots	• Feedback indicated that additional clarity is needed as to the type and nature of RWP data needed to monitor product performance and mitigate risks. • Questions asked: – What type of reference data are appropriate to utilize in measuring the performance of AI/ML software devices in the field? – How much of the oversight should be performed by each stakeholder? – How much data should be provided to the Agency, and how often? – How can the algorithms, models, and claims be validated and tested? – How can feedback from end-users be incorporated into the training and evaluation of AI/ML-based SaMD?

Good Machine Learning Practice for Medical Device Development: Guiding Principles

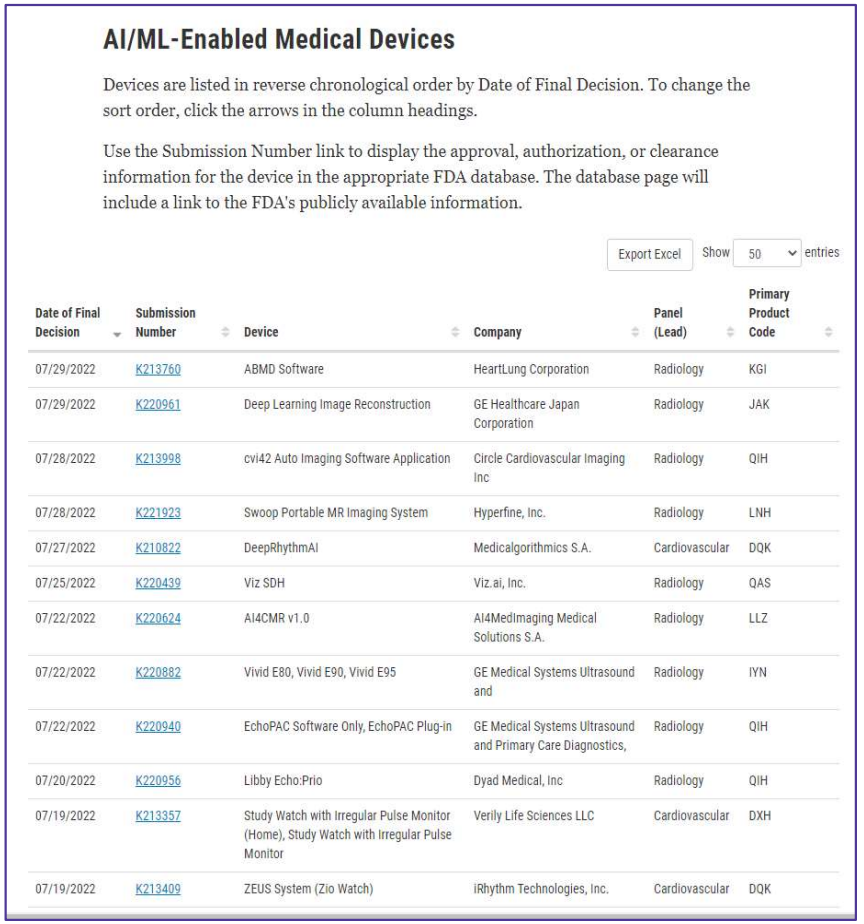
10 "Guiding Principles" developed jointly by FDA, Health Canada, and MHRA

1. Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle
2. Good Software Engineering and Security Practices Are Implemented
3. Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population
4. Training Data Sets Are Independent of Test Sets
5. Selected Reference Datasets Are Based Upon Best Available Methods
6. Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
7. Focus Is Placed on the Performance of the Human-AI Team
8. Testing Demonstrates Device Performance during Clinically Relevant Conditions
9. Users Are Provided Clear, Essential Information
10. Deployed Models Are Monitored for Performance and Re-training Risks are Managed

AI/ML-Enabled Medical Devices

- Current FDA list includes over 500 devices
  - Vast majority cleared via 510(k) process
  - 18 *de novo* submissions
  - 3 premarket approval applications (PMAs)

- Review Branch
  - Significant majority in Radiology, followed by Cardiovascular, Hematology, and Neurology



AI/ML-Enabled Medical Devices

Devices are listed in reverse chronological order by Date of Final Decision. To change the sort order, click the arrows in the column headings.

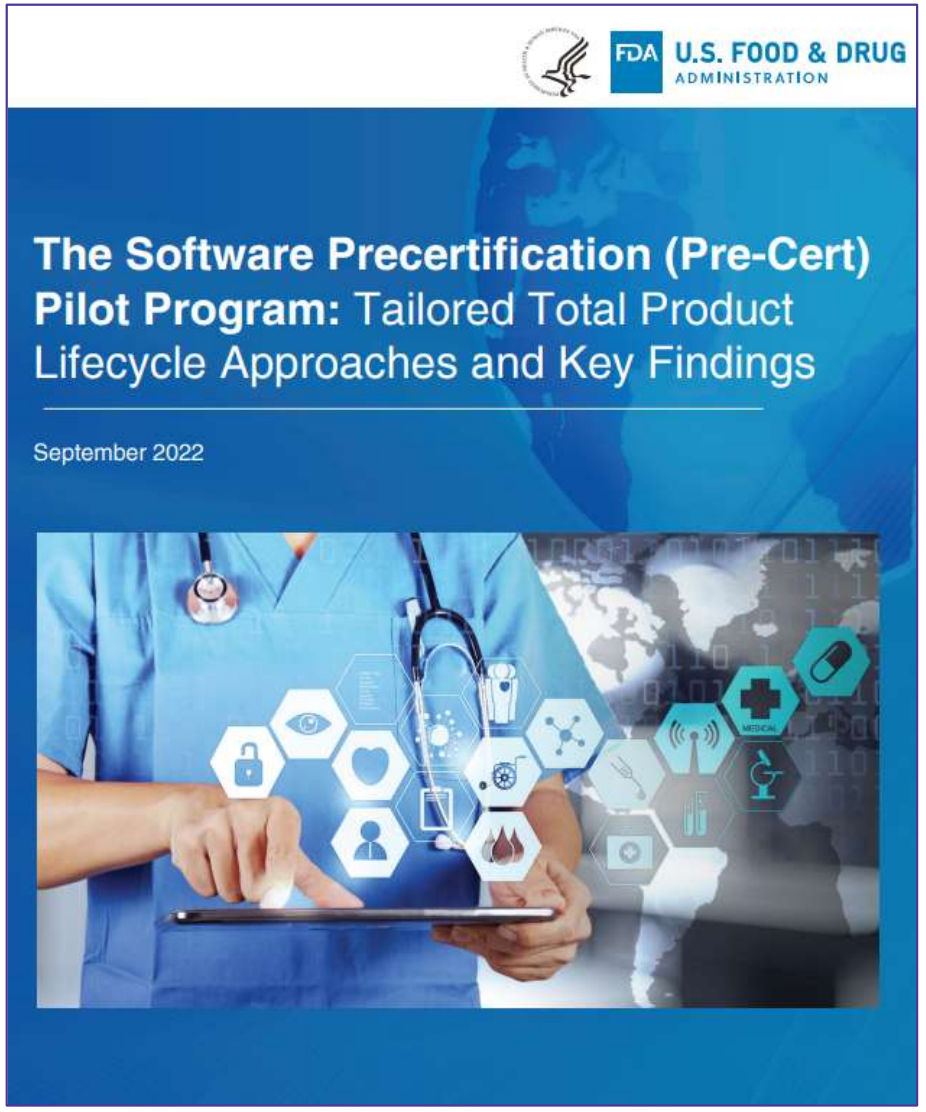
Use the Submission Number link to display the approval, authorization, or clearance information for the device in the appropriate FDA database. The database page will include a link to the FDA's publicly available information.

Export Excel Show 50 entries

Date of Final Decision	Submission Number	Device	Company	Panel (Lead)	Primary Product Code
07/29/2022	K213760	ABMD Software	HeartLung Corporation	Radiology	KGI
07/29/2022	K220961	Deep Learning Image Reconstruction	GE Healthcare Japan Corporation	Radiology	JAK
07/28/2022	K213998	cvi42 Auto Imaging Software Application	Circle Cardiovascular Imaging Inc	Radiology	QIH
07/28/2022	K221923	Swoop Portable MR Imaging System	Hyperfine, Inc.	Radiology	LNH
07/27/2022	K210822	DeepRhythmAI	Medicalgorithmics S.A.	Cardiovascular	DQK
07/25/2022	K220439	Viz SDH	Viz.ai, Inc.	Radiology	QAS
07/22/2022	K220624	AI4CMR v1.0	AI4MedImaging Medical Solutions S.A.	Radiology	LLZ
07/22/2022	K220882	Vivid E80, Vivid E90, Vivid E95	GE Medical Systems Ultrasound and	Radiology	IYN
07/22/2022	K220940	EchoPAC Software Only, EchoPAC Plug-in	GE Medical Systems Ultrasound and Primary Care Diagnostics,	Radiology	QIH
07/20/2022	K220956	Libby Echo:Prio	Dyad Medical, Inc	Radiology	QIH
07/19/2022	K213357	Study Watch with Irregular Pulse Monitor (Home), Study Watch with Irregular Pulse Monitor	Verily Life Sciences LLC	Cardiovascular	DXH
07/19/2022	K213409	ZEUS System (Zio Watch)	iRhythm Technologies, Inc.	Cardiovascular	DQK

Software Pre-Certification Program

- Key findings from Working Model and Pilot:
  - "FDA has found that rapidly evolving technologies in the modern medical device landscape could benefit from a new regulatory paradigm, which would require a legislative change"
  - "Given the challenges faced during the pilot, FDA has determined that the approach described in the Working Model is not practical to implement under our current statutory and regulatory authorities. However, the pilot informed what new statutory authorities could support a future regulatory paradigm that builds on these concepts."



Recently Issued Guidance Documents Affecting AI/ML

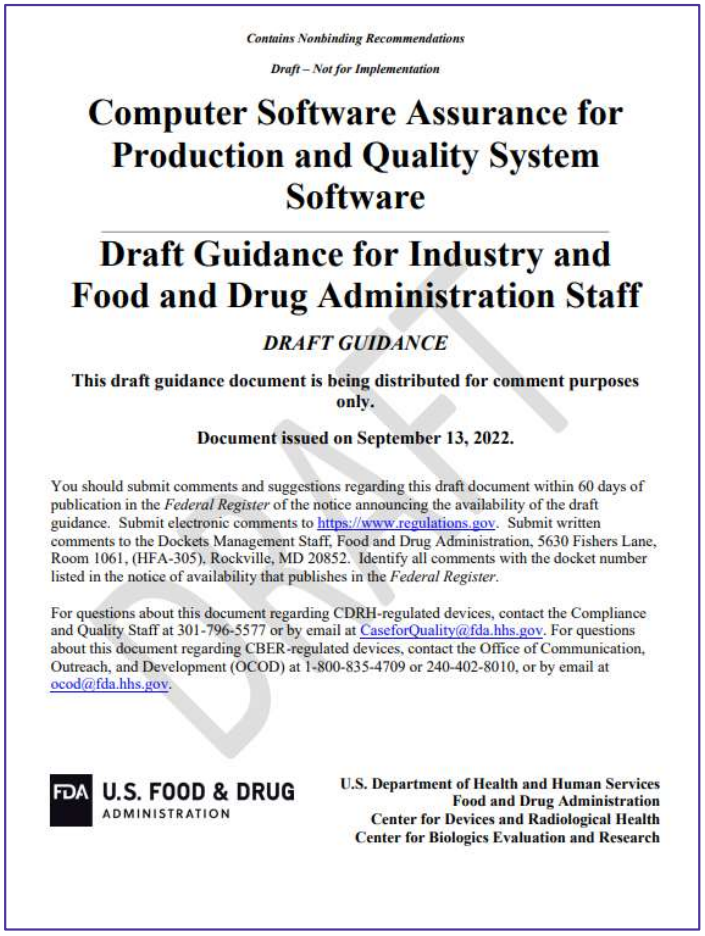
- Clinical Decision Support Software – Final Guidance (Sept. 28, 2022)
- Computer Software Assurance for Production and Quality System Software – Draft Guidance (Sept. 28, 2022)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Draft Guidance (April 8, 2022)
- Digital Health Technologies for Remote Data Acquisition in Clinical Investigations – Draft Guidance (Jan. 21, 2022)
- Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions – Draft Guidance (Dec. 23, 2021)
- Updates to existing final guidance:
  - Policy for Software Functions and Mobile Medical Applications
  - Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices

Clinical Decision Support Software – Final Guidance

- Exemption for *clinical decision support* (CDS) functions that meet the following criteria:
  1. Is not "intended to acquire, process, or analyze a medical image or a signal from an *in vitro* diagnostic device or signal acquisition system"
  2. Is intended for the purpose of "displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines)"
  3. Is intended for the purpose of "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition"
  4. Is intended for the purpose of "enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient"

The CDS exemption only includes software *intended for use by a health care professional* – not for consumer use

Computer Software Assurance for Production and Quality System Software – Final Guidance



Contains Nonbinding Recommendations

Draft – Not for Implementation

Computer Software Assurance for Production and Quality System Software

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 13, 2022.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the Compliance and Quality Staff at 301-796-5577 or by email at CaseforQuality@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

DRAFT

- New draft guidance provides recommendations for "computer software assurance" for software and automated systems used for medical device production or quality
- Describe various methods and testing activities to establish "computer software assurance" and ensure compliance with QSR (including software validation) and other regulatory requirements.

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

- Cybersecurity as part of QSR requirements
- Use of a Secure Product Development Framework
- Transparency
  - Labeling Recommendations
  - Vulnerability Management Plans

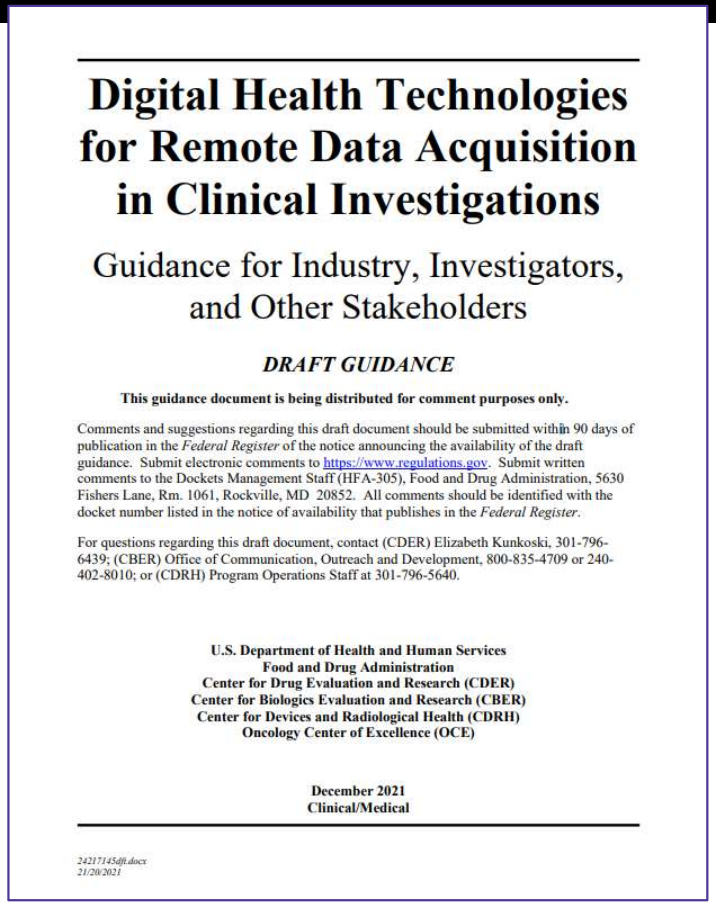
Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions

- Sets forth a proposed 9-step process to assess the credibility of computational modeling and simulation (CM&S) used to support a medical device premarket submission

1. Describe the question(s) of interest to be addressed
2. Define the context of use (COU) of the computational model
3. Determine the model risk
4. Identify and categorize the credibility evidence
5. Define credibility factors for the proposed credibility evidence and set prospective credibility goals
6. Perform prospective adequacy assessment
7. Generate the credibility evidence by executing the proposed study(ies) and/or analyzing previously generated data
8. Determine if credibility goals were met and perform post-study adequacy assessment
9. Prepare a report on the credibility of the CM&S

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

- Applies to ALL types of clinical investigations utilizing a digital health technology (DHT) for remote data acquisition
- A DHT defined as "a system that uses computing platforms, connectivity, software, and/or sensors, for healthcare and related uses."
- Guidance covers considerations when using DHTs in clinical investigations
  - Selection of a Digital Health Technology and Rationale for Use in a Clinical Investigation
  - Digital Health Technology Description in a Submission
  - Verification, Validation, and Usability of Digital Health Technologies
  - Evaluation of Clinical Endpoints From Data Collected Using Digital Health Technologies
  - Statistical Analysis
  - Risk Considerations When Using Digital Health Technologies
  - Record Protection and Retention
  - Other Considerations When Using Digital Health Technologies During a Clinical Investigation



Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Guidance for Industry, Investigators, and Other Stakeholders

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Elizabeth Kunkoski, 301-796-6439; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Program Operations Staff at 301-796-5640.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)

December 2021
Clinical/Medical

24217145dft.docx
21/20/2021

Guidance Document Priorities FY 2023 – A-List

- Final Guidance Priorities –
  - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
  - Content of Premarket Submissions for Device Software Functions
  - Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
  - Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance Document Priorities FY 2022 – B-List

- Draft Guidance:
  - Marketing Submission Recommendations for A Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions
  - Removed from Priority List:
    - Risk Categorization for Software as a Medical Device: FDA Interpretation, Policy, and Considerations

FDA COVID-19 Policies for Digital Health

2020 COVID-19 Guidance Documents - Title	Date Issued	Status
Enforcement Policy for Remote Digital Pathology Devices During the COVID-19 Public Health Emergency	04/24/2020	Final
Enforcement Policy for Imaging Systems During the COVID-19 Public Health Emergency	04/23/2020	Final
Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices During the COVID-19 Public Health Emergency	04/23/2020	Final
Enforcement Policy for Telethermographic Systems During the COVID-19 Public Health Emergency	04/16/2020	Final
Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency	04/14/2020	Final
Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the COVID-19 Public Health Emergency	04/06/2020	Final
Enforcement Policy for Clinical Electronic Thermometers the COVID-19 Public Health Emergency	04/04/2020	Final
Enforcement Policy for Non-Invasive Remote Monitoring Devices During the COVID-19 Public Health Emergency	03/20/2020	Final

Transition Plan for Devices That Fall Within COVID-19 Enforcement Policies

- Proposes a 180-day transition period for manufacturers of devices covered by a COVID-19 enforcement policy, which would start from the "implementation date"
- Three phased transition plan:
  - Phase 1 begins on the implementation date
    - Requires compliance with Part 803 for MDRs
  - Phase 2 begins 90 days after the implementation date
    - Requires compliance with Part 806 (corrections/removals reporting) and Part 807 (registration/listing)
    - Premarket submission must be filed and accepted for review *prior to* start of Phase 3
  - Phase 3 begins 180 days after the implementation date
    - FDA withdraws the enforcement policies
    - Requires compliance with all applicable regulatory requirements (including QSR, labeling, UDI, etc.)

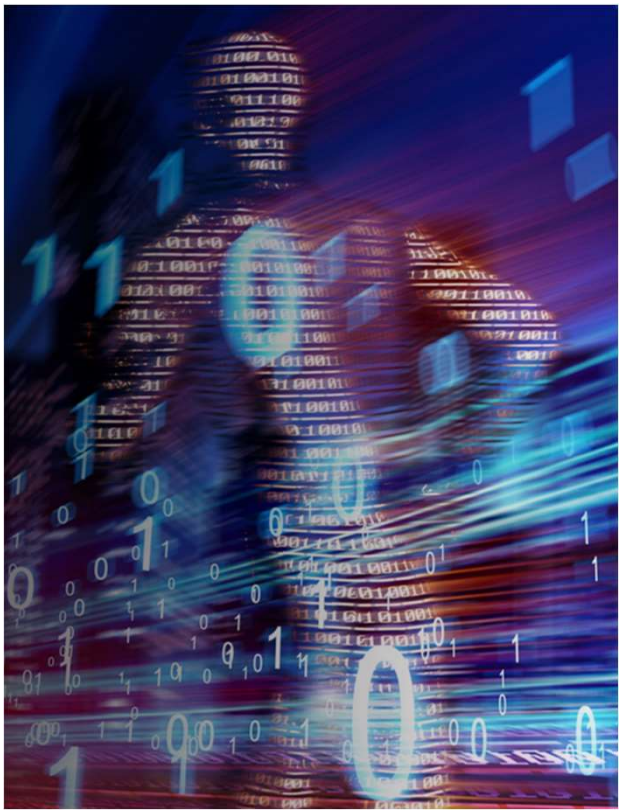
Healthcare and Reimbursement Developments

Morgan Lewis

Reimbursement for AI/ML Technologies

- Reimbursement framework for AI/ML not advanced
  - Limited opportunities to realize direct reimbursement
  - Healthcare system remains focused on physician as decision-maker and source of reimbursable service

- Some limited exploration of AI/ML reimbursement
  - American Medical Association (AMA) in December 2021 released its AI Taxonomy framework
  - Centers for Medicare & Medicaid Services (CMS) soliciting comments on AI/ML reimbursement mechanisms



AMA Taxonomy Framework

Service Components	AI Category: Assistive	AI Category: Augmentative	AI Category: Autonomous
Primary objective	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically ~~relevant~~ meaningful conclusions
Provides independent diagnosis and/or management decision	No	No	Yes
Analyzes data	No	Yes	Yes
Requires physician or other QHP interpretation and report	Yes	Yes	No
Examples in CPT code set	Computer-aided detection (CAD) imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Continuous glucose monitoring (CGM) (95251), external processing of imaging data sets	Retinal imaging (92229)

- 3 overall categories of AI devices based on the "work performed by the machine" in delivering an overall service
- Within the 3rd category ("Autonomous"), there are 3 sub levels describing the level of professional involvement associated with the machine
  - **Level I** – AI offers diagnosis/treatment but physician must implement
  - **Level II** - AI initiates diagnosis/treatment with override option and may need physician implementation
  - **Level III** – AI initiates diagnosis/treatment and physician must contest

CMS Interest in AI/ML Increasing

- CMS has explored reimbursement for certain limited procedures utilizing AI since 2018
  - Initial focus was on HeartFlow, a device that utilizes AI to better visualize arteries
    - While the procedure is not reimbursable under the Physician Fee Schedule (PFS), it is included in the Outpatient Prospective Payment System (OPPS) APC framework

- In 2022, CMS continues to explore payment for CPT code 92229 (described by AMA as an "autonomous" service) in both the OPPS and the PFS and requests public comment about SaaS, analytics, and payment for new technologies and clinical software.

CMS Interest in AI/ML Increasing

- CMS explained:

"Rapid advances in innovative technology are having a profound effect on every facet of health care delivery. Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program. In some cases, these innovative technologies are substituting for more invasive care and/or augmenting the practice of medicine."

87 Fed. Reg. 72027 (Nov. 23, 2022).

- CMS also sought comment on the impact of AI in the Physician Fee Schedule Practice Expense methodology:

"[Previously,] we wrote that as the data used in our PE methodology have aged, and more services have begun to include innovative technology such as software algorithms and AI, these innovative applications are not well accounted for in our PE methodology. . . . increasingly, stakeholders have routinely expressed concerns with our policy to consider analysis fees as indirect costs, especially for evolving technologies that rely primarily on these fees with minimal costs in equipment or hardware."

86 Fed. Reg. 65037 (Nov. 19, 2021).

AI/ML Impact in Value-Based Care

- While direct reimbursement of AI/ML technologies remains elusive and limited, AI can nevertheless be successfully integrated into other existing payment models
- Increased efficiencies and better outcomes that certain AI/ML technologies can foster will ultimately result in greater payment and shared savings opportunities for healthcare providers involved in value-based care models or other alternative payment models
- Further, private insurers have flexibility to reimburse for services in a variety of ways, including through pilot programs that may attempt to test the clinicial and financial ROI of AI/ML-assisted services.

State Laws Impacting AI/ML

- Irrespective of payment, AI/ML in healthcare quickly abuts the practice of medicine and state regulation of licensed professionals

- State medical boards are considering the impact of telehealth, AI, and the use of other technologies on the standard of care and regulating the practice of medicine
  - For instance, in 2018, the Federation of State Medical Boards passed a resolution (introduced initially by the Pennsylvania Board of Medicine) to establish a workgroup on "AI and its Potential Impact on Patient Safety and Quality of Care in Medical Practice"
  - Though the workgroup has not issued formal guidance, it highlights the focus of professional licensing agencies in identifying whether AI can improve patient safety and care

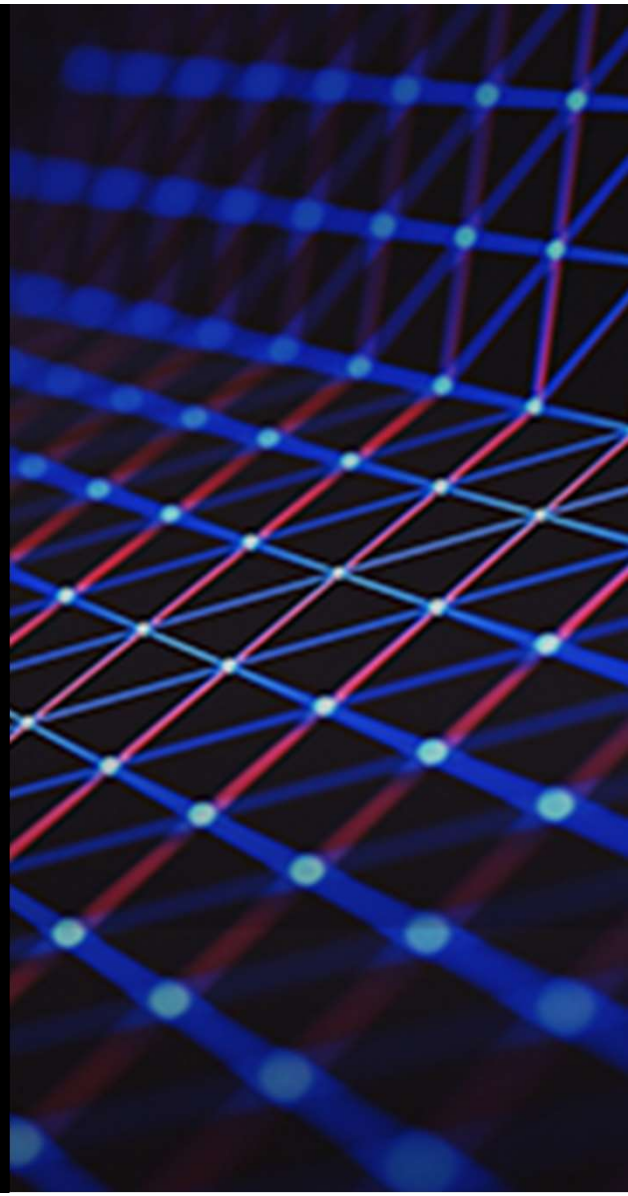
Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

Morgan Lewis

To help keep you on top of developments as they unfold, we also have launched a resource page on our website at **www.morganlewis.com/topics/coronavirus-covid-19**

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to **subscribe** using the purple "Stay Up to Date" button.



Biography

Michele L. Buenafe
Washington, DC
+1.202.739.6326
michele.buenafe@morganlewis.com

Michele L. Buenafe counsels clients on US Food and Drug Administration (FDA) compliance and enforcement matters related to medical devices, combination products, and digital health technologies, such as software as a medical device (SaMD), telemedicine systems, clinical decision support software, wearable devices, artificial intelligence systems, and mobile medical apps. She also advises on US Drug Enforcement Administration (DEA) and state regulatory issues for controlled substances and medical products, including both drugs and devices. Michele serves as the leader of the firm's digital health team and as co-leader for the firm's cross-practice healthcare industry team.

Biography

Jacob J. Harper
Washington, DC
+1.202.739.5260
jacob.harper@morganlewis.com

Jacob Harper advises stakeholders across the healthcare industry, including hospitals, health systems, large physician group practices, practice management companies, hospices, chain pharmacies, manufacturers, and private equity clients, on an array of healthcare regulatory, transactional, and litigation matters. His practice focuses on compliance, fraud and abuse, and reimbursement matters, self-disclosures to and negotiations with OIG and CMS, internal investigations, provider mergers and acquisitions, and appeals before the PRRB, OMHA, and the Medicare Appeals Council.

Biography

Andrew J. Gray IV
Silicon Valley
+1.650.843.7575
andrew.gray@morganlewis.com

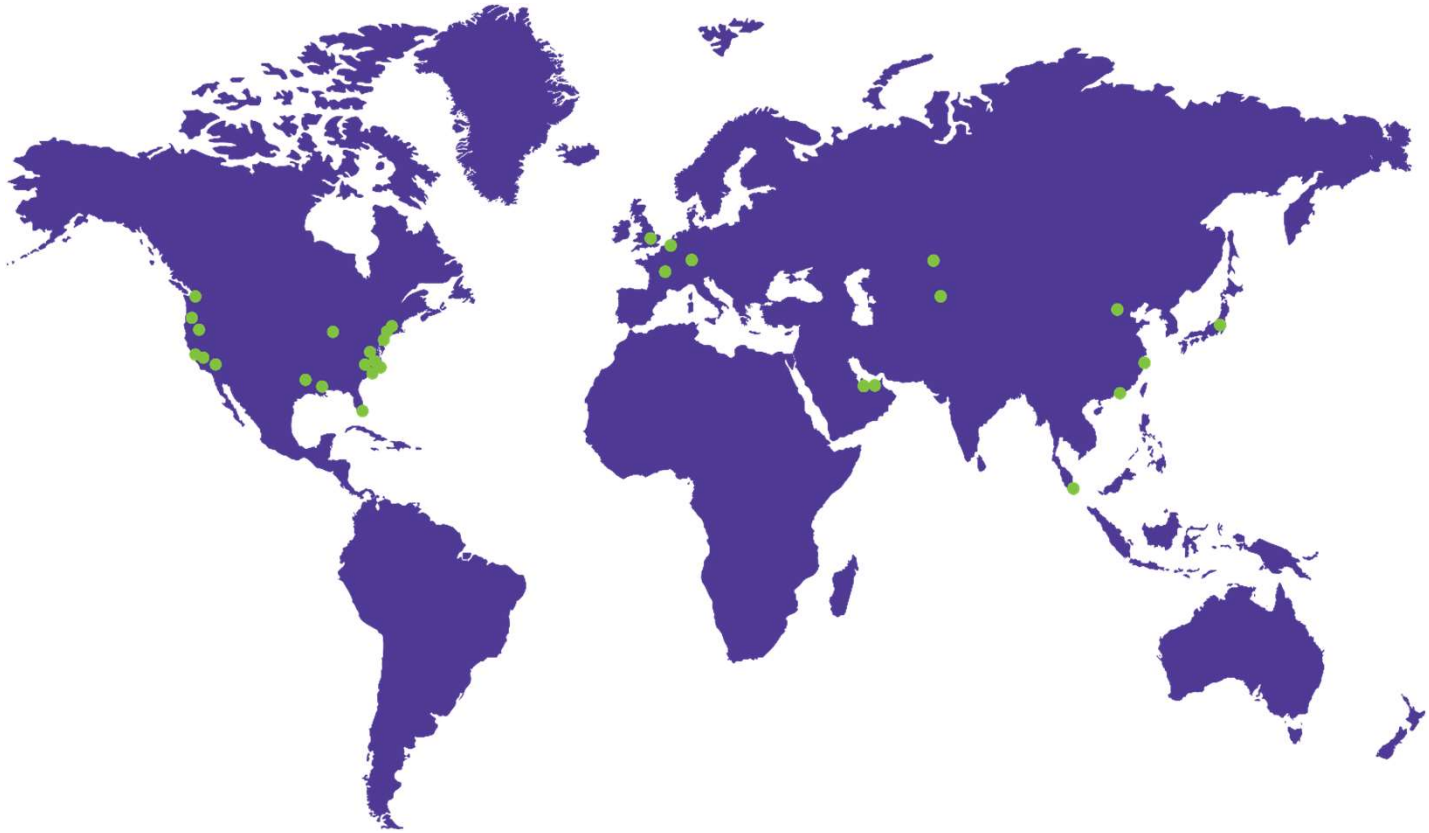
Serving as the leader of the firm's semiconductor practice and as a member of the firm's fintech and technology industry teams, Andrew J. Gray IV concentrates his practice on intellectual property litigation and prosecution and on strategic IP counseling. Andrew advises both established companies and startups on AI, machine learning, Blockchain, cryptocurrency, computer, and Internet law issues, financing and transactional matters that involve technology firms, and the sale and licensing of technology. He represents clients in patent, trademark, copyright, and trade secret cases before state and federal trial and appellate courts throughout the United States, before the US Patent and Trademark Office's Patent Trial and Appeal Board, and before the US International Trade Commission.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Astana
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
New York
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Seattle
Shanghai*
Silicon Valley
Singapore*
Tokyo
Washington, DC
Wilmington



Morgan Lewis

THANK YOU