Spotlight: Digital Health Regulatory Science Research Opportunities

FDA

Medical Extended Reality

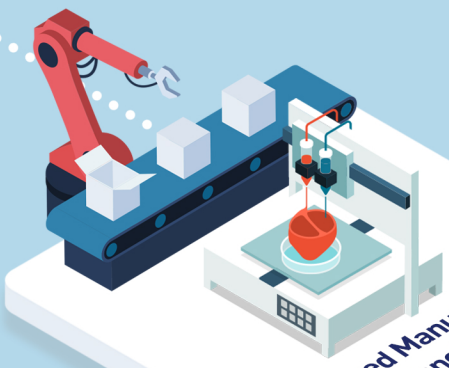
Digital Imaging

Wireless Connectivity

Cybersecurity

Patient Generated Health Data

Artificial Intelligence / Machine Learning



Advanced Manufacturing Technologies

Interoperability

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Contents

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Introduction

Digital health is enabling the rapid evolution of the health care system towards an increasingly patient-centered model where care is available outside of traditional hospital and clinical environments. This is blurring the lines that used to separate episodes of care from daily life. The coronavirus disease 2019 (COVID-19) pandemic and associated public health emergency accelerated the adoption of innovative digital health technologies (DHTs)[1] and health care delivery models, further establishing telecare as a staple in modern health care that is supplementing—and disrupting—existing care delivery paradigms. DHTs are increasingly ubiquitous, with many individuals using one or more consistently through the day. DHTs can include both medical devices and consumer products. The power and ubiquity of DHTs and general-purpose computing platforms that enable telecare continue to increase, providing more opportunities for evidence-based digital health products with the potential to support more equitable access to health care, improve patient outcomes, and promote public health.

Digital health encompasses many components critical to the future of health care. To enable connected care and improved public health, stakeholders should carefully consider the importance of wireless connectivity, cybersecurity, and interoperability. DHTs can help real-world data (RWD) and real-world evidence (RWE)[2] facilitate regulatory, health care, and other types of decision-making. With this, however, comes the need for further exploration into the potential impact of using DHTs, taking traditional human factors a step further and examining the cognitive and neurological effects on users like patients and health care providers. Furthermore, digital health offers the potential to reach many underserved populations and improve the health care individuals receive. Stakeholders across the digital health ecosystem should approach development, implementation, and advancement of digital health solutions thoughtfully to promote health equity[3] and user trust in new technologies.

The U.S. Food and Drug Administration (FDA) is committed to continuing to play an integral role in the health care ecosystem as it evolves, helping assure that DHTs that meet the definition of device[4] are safe and effective. The FDA issues appropriate requirements and develops policies for areas of great importance to public health, like medical device software as well as DHTs used in clinical studies, healthcare and wellness. To foster responsible and high-quality innovation in digital health, the FDA's Center for Devices and Radiological Health (CDRH) established the Digital Health Center of Excellence (DHCoE) in September 2020. The DHCoE works to empower digital health stakeholders by promoting awareness, transparency, and consistent application of digital health statutory and regulatory policies; pioneering the development and enhancement of digital health regulatory paradigms; and fostering

[1] FDA-NIH Biomarker Working Group. BEST (Biomarkers, EndpointS, and other Tools) Resource [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2016-. Glossary. 2016 Jan 28 [Updated 2021 Nov 29]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK338448/ Co-published by National Institutes of Health (US), Bethesda (MD).

[2] Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices. U.S. Food and Drug Administration (2028). Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices.

[3] Center for Devices and Radiological Health 2022-2025 Strategic Priorities. U.S. Food and Drug Administration (2022). Available at https://www.fda.gov/media/155888/download.

[4] See section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the definition of a device.

digital health-focused collaborations. In alignment with CDRH's regulatory science priorities[5] and the FDA's focus areas of regulatory science[6], efforts within the DHCoE are focused on improving the safety, effectiveness, and quality of medical products. CDRH is an active contributor in the digital health space, hosting multiple public meetings[7,8,9,10], listening sessions[11,12], and Patient Engagement Advisory Committee meetings[13], as well as providing resources[14,15] for the stakeholder community. Current CDRH research programs[16] focus on the areas highlighted in this document. CDRH's involvement in the digital health ecosystem extends into collaborative communities as well, where the FDA participates in a variety of communities with digital health focus areas.[17]

This document is intended to advance digital health regulatory science by encouraging discussions and stakeholder collaborations throughout the health care ecosystem and beyond. Patients, researchers,

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[5] CDRH's Regulatory Science Priorities. U.S. Food & Drug Administration (2017). Available at https://www.fda.gov/medical-devices/science-and-research-medical-devices/cdrh-regulatory-science-priorities.

[6] Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science (FARS). U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/science-research/advancing-regulatory-science/focus-areas-regulatory-science.

[7] Public Workshop - Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-medical-extended-reality-toward-best-evaluation-practices-virtual-and-augmented.

[8] Public Workshop - Evolving Role of Artificial Intelligence in Radiological Imaging. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-evolving-role-artificial-intelligence-radiological-imaging-02252020-02262020.

[9] Virtual Public Workshop - Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-workshop-transparency-artificial-intelligencemachine-learning-enabled-medical-devices.

[10] Virtual Public Meeting – Patient-Generated Health Data Throughout the Total Product Life Cycle of Medical Devices. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-meeting-patient-generated-health-data-throughout-total-product-life-cycle-medical.

[11] Webinar – Digital Health Center of Excellence Listening Session #1. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-digital-health-center-excellence-listening-session-1-10192020-10192020.

[12] Webinar – Digital Health Center of Excellence Listening Session #2. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-digital-health-center-excellence-listening-session-2-11122020-11122020.

[13] CDRH Patient Engagement Advisory Committee. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/cdrh-patient-engagement-advisory-committee.

[14] Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/media/145022/download.

[15] Guidances with Digital Health Content. U.S. Food & Drug Administration (2020). Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content.

[16] Medical Device Regulatory Science Research Programs Conducted by OSEL. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-regulatory-science-research-programs-conducted-osel.

[17] Collaborative Communities: Addressing Health Care Challenges Together. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together.

health care providers, medical product manufacturers, technology companies, standards organizations, and others play integral roles in advancing digital health. Collaborations can take many forms, with various levels of involvement by individual stakeholders, which can include the FDA. Alignment and partnerships can help focus efforts on the research and application of DHTs. Innovation in digital health can continue, with the goal of promoting the use of safe and effective medical products that have the potential to improve patient outcomes and public health.

This document does not initiate a call for proposals or carry funding implications. Instead, it is meant to highlight important scientific research areas identified by stakeholders internal and external to the FDA. These areas are divided into three categories: advancing patient engagement, leveraging connectivity, and improving health care through software (although these are not intended to be exhaustive). Topic areas are further broken down into near-term and longer-term categories depending on whether there are longer-term efforts that may help to advance the field. We anticipate that advances in digital health will continue to occur rapidly and prompt new areas of interest for regulatory science research in the future.

Advancing Patient Engagement

DHTs can help seamlessly integrate individuals as proactive agents of their health care and wellness, potentially expanding access to and quality of care. Thoughtful and consistent engagement with patients can help fully realize the potential of this technology. DHTs can collect patient-generated health data (PGHD) to help provide critical information on personal behavior, physiology, and preferences. The information gleaned from patients can help shape future medical products and care paradigms. Ongoing FDA efforts in patient science & engagement[18], human-device interactions[19], and medical extended reality[20] have highlighted the importance of the patient voice in medical product development.

Patient-Generated Health Data

PGHD can be used to complement data collected during clinical visits to form a more complete picture of a person's health status.[21] DHTs, including wearable consumer products or medical devices, mobile applications, software, and patient-led registries, are common sources of this type of RWD. PGHD, including biometric data, symptoms, and patient-reported outcomes, can be used in patient monitoring, diagnosis and prognosis, shared decision-making, and assessment of patient

[18] CDRH Patient Science and Engagement Program. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-science-and-engagement-program.

[19] Human-Device Interaction Program: Research on Human Interaction with Medical Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/human-device-interaction-program-research-human-interaction-medical-devices.

[20] Medical Extended Reality Program: Research on Medical Extended Reality-Based Medical Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/medical-extended-reality-program-research-medical-extended-reality-based-medical-devices.

[21] Conceptualizing a data infrastructure for the capture, use, and sharing of patient-generated health data in care delivery and research through 2024. Office of the National Coordinator for Health Information Technology (2017). Available at https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf.

safety. PGHD can be used not only to improve the quality of clinical care, but also to evaluate innovative medical products and treatment paradigms, especially in decentralized clinical investigations.

PGHD-Related Research Areas

Near-Term	Longer-Term
• Consumer-grade DHTs verification and validation in specific clinical and regulatory applications • Novel digital biomarkers validation in relevant contexts of use • Platform usability requirements for patients • Data characteristics/requirements to be used in clinical, regulatory, and other decision making • Privacy and security, along with other cybersecurity considerations • Data sharing and governance • Maintenance and management of large volumes of PGHD • Integration into existing health care systems' workflows	• Standardization of PGHD from different sources • Data synchronization and interoperability of multiple sources of PGHD • Performance specifications for use when considering interchangeability of wearables (for example, "bring-your-own wearable" approaches to clinical investigations) • Clinically meaningful and patient-relevant composite endpoints derived from multiple data sources • Integrated analytical tools • Visualization tools to advance transparency • Reliable metrics to compare standard disease outcomes (for example, sleep quality, performance status) as measured by DHTs to traditional collection methods

Medical Extended Reality

Advances in computing and display technologies have fostered rapid growth in the availability of augmented reality (AR), virtual reality (VR), and mixed reality technologies. Accompanying these advances is the increased interest in the use of this technology outside of the gaming and entertainment industries, moving into the development of medical extended reality (MXR) devices. Both health care professionals and patients may be primary users of MXR devices, with applications in surgical, diagnostic, and therapeutic spaces.

MXR-Related Research Areas

Near-Term	Longer-Term
• MXR device (hardware and software) image quality characterization/evaluation across the MXR application space, including spatial and temporal resolution and noise characteristics • Consumer-grade sensors commonly used by MXR devices validation for the desired clinical contexts of use • Visual, physical, and cognitive load, motion sickness, and other effects users may experience with MXR devices which could affect their ability to use the device safely and effectively	• Registration/localization accuracy of the virtual models to patients for preoperative planning, surgery, and image-guided interventions • Recommended dosage and/or impact of content on therapeutic effect when used as a medical therapy (such as chronic/acute pain treatment or cognitive behavioral therapy) • Appropriate outcome measures to evaluate effectiveness of using MXR devices compared to standard-of-care

Leveraging Connectivity

Intrinsic to DHTs is connectedness—to the Internet, health care networks, and other DHTs. This connectedness can improve access to care, quality of care, and system efficiency. Wireless connectivity can enable remote patient monitoring, remote operation of medical devices (for example, telesurgery or device programming), and data sharing between platforms. These functions are critical in underserved areas where they can help expand access to care. The exchange and potential use of information across connected systems warrants coordination across systems to minimize risk to an individual and the ecosystem, as well as to ensure efficiency within the system. With the ever-increasing connectedness in health care comes cybersecurity and interoperability concerns. The FDA is actively engaged in both internal and external efforts to help mature cybersecurity[22], interoperability[23], and wireless connectivity[24] efforts.

Cybersecurity

With the connected nature of digital health, increased exposure to cybersecurity threats is introduced. Management and prevention of cybersecurity threats is important to maintain patient safety with this increasing level of connectedness. Establishing and maintaining cybersecurity is a collective undertaking between manufacturers, patients, health care facilities, providers,

[22] Cybersecurity. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.
[23] Medical device interoperability. U.S. Food & Drug Administration (2018). Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/medical-device-interoperability.
[24] Wireless medical devices. U.S. Food & Drug Administration (2018). Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices.

government agencies, and other stakeholders.[25,26] Cybersecurity deficiencies could result in technology malfunction or failure, potentially putting a patient's safety at risk.

Cybersecurity-Related Research Areas

Near-Term	Longer-Term

• Threat modeling approaches to identify risks across the environment of use and the appropriate controls to mitigate the risks
• Cyber-incident response strategies, tactics, and tools, including:
  ○ Security controls and features
  ○ Rapid deployment of solutions
• Cybersecurity risk assessment approaches to increase consistency in the identification, evaluation, and responses to cybersecurity vulnerabilities throughout the total product lifecycle
• Security controls and legacy devices
• Threat detection and prevention methods
• Cybersecurity and cybersecurity vulnerabilities across the supply chain (for example, in manufacturing processes)
• Cybersecurity considerations for cloud domains
• Software Bill of Materials (SBOM) creation and assessment techniques.
• Cybersecurity considerations for artificial intelligence and machine learning (AI/ML) technologies
• Cybersecurity considerations for remote control of devices
	• Cybersecurity standards development
	• Enhanced approaches to identify, evaluate, and respond to cybersecurity vulnerabilities throughout the total product lifecycle
	• Best practices for cybersecurity considerations in cloud domains
	• SBOM utilization and usability

Interoperability

As innovative wearable technologies and other digital platforms are developed and adopted into the daily lives of patients, interoperability becomes more critical throughout the total product

[25] Content of premarket submissions for management of cybersecurity in medical devices. U.S. Food & Drug Administration (2018). Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices.
[26] FDA fact sheet: the FDA's role in medical device cybersecurity. U.S. Food & Drug Administration. Available at https://www.fda.gov/media/123052/download.

lifecycle, from development through post-market applications.[27] Interoperability not only applies to DHTs, but laboratory and electronic health record data and semantics as well.

Research focused on interoperability can catalyze innovation to address many health care issues from public health emergencies to monitoring of patient safety. Rapid integration of data from different sources can help during the development and deployment of novel health care solutions with applications like remote medical device control and intelligent interaction between patient monitoring devices, all working to improve clinical outcomes and patient safety.

Interoperability-Related Research Areas

Near-Term	Longer-Term
• Interface specifications to capture complexity of interactions for safe interoperable systems • Interoperability considerations for personalized patient monitoring and control platforms • Validation for systems with common consumer electronics • Software as a medical device (SaMD) running on interoperable platforms • Clinical scenarios to drive standards and test methods development • Electronic clinical data semantics (for example, laboratory data, imaging data) harmonization	• Governance structures and management of ecosystems to support a community of interoperable systems • Metrics for benchmarking domain-specific progress in interoperability • Non-clinical and clinical "test beds" to verify interface specifications and assess performance • Open interfaces to enable sharing of accurate data amongst shared applications • Global application development to improve the quality of data, instantiate medical knowledge at bedside, and reduce risks to patients, thereby improving patient care

Wireless Connectivity

Medical devices increasingly rely on wireless connectivity, including Wi-Fi, Bluetooth, and 5G, especially as health care shifts from the clinic to the patient. Wireless technologies that can be used in medical devices have diverse characteristics, including the communication range, access-right type to the radiofrequency spectrum (for example, licensed vs. unlicensed), support for mobility, and network management mode (for example, 5G network centrally controlled by a network operator vs. user-controlled Wi-Fi network).

[27] Design considerations and premarket submission recommendations for interoperable medical devices. U.S. Food & Drug Administration (2017). Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.

Connectivity-Related Research Areas

Near-Term	Longer-Term
• Engagement throughout the 5G-health care ecosystem (for example, device manufacturers, network operators, health delivery organizations) • Medical device 5G use-cases and associated network key performance indicators • Design considerations and recommended practices for integrating 5G and beyond communication technologies in medical systems • In the case of 5G-enabled connectivity, mechanisms for documenting the roles and responsibilities of involved stakeholders throughout the connected device lifecycle • Wireless coexistence profile characterization and wireless coexistence test signal development for emerging wireless technologies in the unlicensed spectrum including Wi-Fi 6, Bluetooth Low Energy 5, and 5G New Radio-Unlicensed	• Risk-based evaluation methods to support safe and effective use of 5G and beyond communication technologies in medical devices ○ Evaluation inputs and assessment criteria ○ Generalized test methods that can be applicable to multiple 5G-enabled use cases • Consensus standards development for integrating, assessing, and maintaining pervasive medical device wireless connectivity

Improving Health Care through Software

As the reliance on connected and smart products increases, the role of software is also growing. It is a critical component of the digital world, especially within digital health where consumer software and medical device software functions support the evolving health care ecosystem. Innovative uses of software in the manufacturing of medical products can help improve quality and efficiency. Further applications of novel software include the integration of artificial intelligence and machine learning (AI/ML)[28] into medical imaging and diagnostics. Contributing to the advances within the field, ongoing FDA efforts have included additive manufacturing[29,30], AI/ML[31], and digital imaging[32,33].

Advanced Manufacturing Technologies

Innovative technologies or the innovative application of existing technologies and processes is gaining traction in the manufacturing of medical products. When applied, advanced manufacturing offers the opportunity to improve quality, performance, and compliance of medical products while encouraging innovation in the medical technology space.

Typical methods of advanced manufacturing include additive manufacturing and intelligent manufacturing (for example, automation and the use of AI when streamlining production). Successful implementation of advanced manufacturing techniques can potentially aid in addressing medical product shortages, improve medical product supply chain resilience, and enhance domestic medical product production agility.[34]

[28] Machine Learning-enabled Medical Devices: Key Terms and Definitions. International Medical Device Regulators Forum (2022). Available at https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20AIMD%20WG%20Final%20Document%20N67.pdf

[29] Additive Manufacturing Program: Research on Additive Manufacturing for Medical Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/additive-manufacturing-program-research-additive-manufacturing-medical-devices.

[30] Case for Quality. U.S. Food and Drug Administration (2020). Available at https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/case-quality.

[31] Artificial Intelligence and Machine Learning Program: Research on AI/ML-Based Medical Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/artificial-intelligence-and-machine-learning-program-research-aiml-based-medical-devices.

[32] Medical Imaging and Diagnostics Program: Research on Medical Imaging and Diagnostic Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/medical-imaging-and-diagnostics-program-research-medical-imaging-and-diagnostic-devices.

[33] Digital Pathology Program: Research on Digital Pathology Medical Devices. U.S. Food and Drug Administration (2021). Available at https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/digital-pathology-program-research-digital-pathology-medical-devices.

[34] Advanced Manufacturing. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing.

Advanced Manufacturing-Related Research Areas

Near-Term	Longer-Term
• Integrated program lifecycle management to maximize the reuse of design and development assets, adaptive planning, and concurrent execution to optimize design and production performance • Product design excellence enhancement through Model-Based Systems Engineering (MBSE) which integrates the reliability, availability, maintainability, and safety (RAMS), various types of failure mode and effects analyses (xFMEA), and system modeling directly onto the 3D models • Manufacturing simulation, digitally integrated supply chain data, and automation to enable flexible, agile, and automated manufacturing operations and continuous production • AI/ML technology as an adjunct to production and quality system processes, such as complaints management • Edge computing and smart manufacturing technologies • Good cybersecurity practices integration when adopting digital technologies (for example, edge computing, manufacturing execution systems, and data integration systems) across the enterprise lifecycle, manufacturing operations, or the supply chain • Interoperability and communication standards to facilitate integration of advance manufacturing technologies	• Digital thread to enable closed-loop quality that automates and error-proofs the quality system regulatory requirements enabling improved safety and compliance • Modeling and simulation with a “digital twin” to optimize processes and production and digital evidence to support regulatory decisions • Continued understanding of regulatory considerations that impact the application of edge computing and smart manufacturing technologies • AI/ML technology autonomous integration into production and quality management processes using validated algorithms with strong knowledge of critical quality attributes

Artificial Intelligence and Machine Learning

DHTs harnessing the power of AI/ML have the potential to transform health care, from optimizing workflows to improving diagnostic capabilities.[35] When used as a medical device or in a medical device, this rapidly progressing field can assist health care providers and improve patient care. AI/ML can also be implemented to improve the production and quality system processes in medical product manufacture or the performance of medical devices (for example, optimizing the acquisition of medical imaging data). The nature of the design process of many AI/ML algorithms gives them the capability to learn from real-world experience to improve their performance or to adapt to changing clinical conditions.

AI/ML-Related Research Areas

Near-Term	Longer-Term

• Transparency of AI/ML-enabled medical devices
• AI/ML algorithm training for clinical datasets, including RWD, that may be scarce, sparse, or imperfectly labeled
  ○ Methods for data collection and verification when constructing clinical datasets, including development of standards
  ○ Novel approaches to enhance AI/ML training and testing for small clinical datasets including data augmentation, transfer learning and synthetic datasets
  ○ Methods related to identification and mitigation of algorithmic bias and uncertainty related to clinical data sources due to observable and unobservable confounders in training datasets
• Robustness and resilience of algorithms to withstand changes in patients (for example, demographics, symptoms), data sources (for example, data acquisition
	• Improved explainability of AI/ML algorithms outputs to users
	• Assessment criteria and techniques for adaptive and autonomous AI/ML algorithms employed in medical devices
	• Real-world performance monitoring for AI/ML software

[35] Artificial intelligence and machine learning in software as a medical device. U.S. Food & Drug Administration (2021). Available at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device.

methods), and clinical contexts (for example, standard of care, diagnostic tests) • Well-controlled study designs and statistical methods for the evaluation of new uses made possible by AI/ML, including triage and multi-modality prognosis • Challenges with assessing AI/ML-based image reconstruction and denoising techniques • Quality system approaches to AI/ML development and implementation, including developing a consensus on AI/ML best practices for data management, feature extraction, training, and evaluation	

Digital Imaging

Digitization of medical imaging in diagnostic and therapeutic applications across many clinical areas has the potential to improve the quality and efficiency of care. Traditional radiology modalities are currently harnessing the power of AI/ML to enhance tasks like lesion detection, computer-aided-diagnosis, and image reconstruction or segmentation. Digital pathology is an emergent area within digital health that visualizes, analyzes, and interprets digitized specimen slides, typically in a diagnostic application. Additionally, clinical areas like ophthalmology and dermatology are also rapidly integrating AI/ML into workflows to enhance tasks like informing diagnoses. Overall, digital imaging is an important component of health care of the future. Since digital imaging relies heavily on AI/ML, many of the research gaps presented in the AI/ML section of this document are also relevant.

Digital Imaging-Related Research Areas

Near-Term	Longer-Term
• Technical and clinical verification and validation of a digital imaging modality • Simulation and/or phantom development to assist with digital imaging modality characterization • Reproducibility evaluation across different systems, operators, or sites • Generalizability of AI/ML algorithms across multiple manufacturers, models, or versions of a digital imaging modality	• Performance standards and assessments for different clinical applications • Interoperability of components of digital imaging modalities • Digital imaging modalities integration into existing clinical workflows to optimize efficiency