Autonomous Decision-making in Medical Devices - FDA Risk and Benefit Perspectives

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Non-Disclosure

- Heather Agler, Ph.D., has no conflicts to report.

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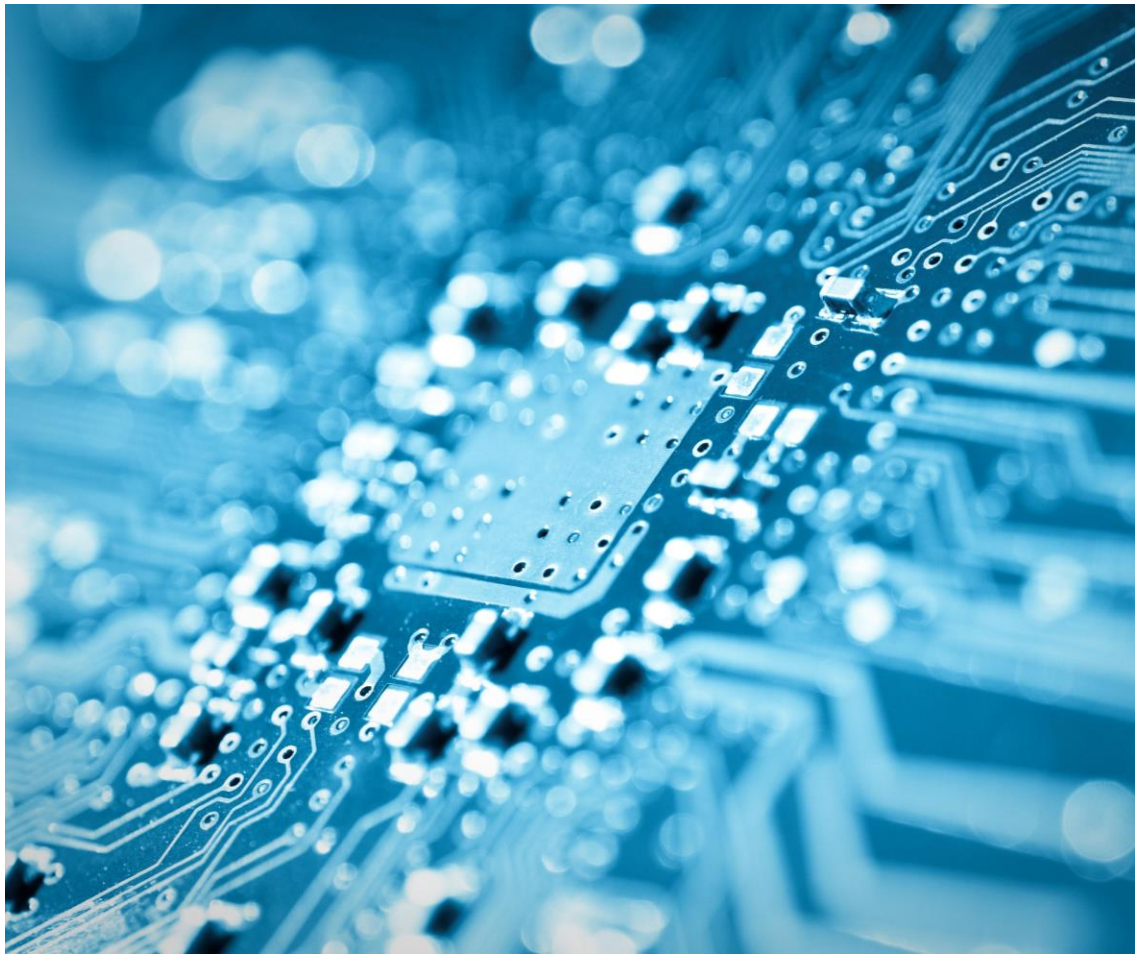
Agenda

1. **CDRH's Medical Countermeasure Innovation Program**
2. Autonomy in Medical Devices
3. Risks and Benefits
4. CDRH Programs to Support Innovation
5. Conclusion and Contact Information



Center for Devices and Radiological Health

- **MISSION**: The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health.
  - We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
  - We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.
  - We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.
- **SHARED VALUES:**
  - **Public Health Focus**
  - **Science-Based Decisions**
  - **Our People**
  - **Innovation**
  - **Transparency**
  - **Honesty and Integrity**
  - **Accountability**

Medical Countermeasure (MCM) Innovation Program

Supports the development of new innovative medical countermeasure devices and new innovative devices to support the warfighter

- **MCM Devices**: A medical device used in the detection, prevention, and management of a CBRNE, emerging infectious disease, or natural disaster event.

- Work with our federal partners including the DoW, BARDA, CDC, and others to get new medical countermeasure devices cleared or approved.
  - Outreach
  - Education
  - Collaboration

- **Our goal**: Shorten time it takes to develop safe & effective MCM devices, so they are available when needed.

MCM Innovation Program

- Point of contact for the DoW, BARDA, and other agencies on the medical device development needs.
- Provide high level informal feedback on medical device regulatory questions
- Connect agency partners with review teams to get simple questions answered when appropriate
- Work internally to educate CDRH on the special needs and special use environments for MCM medical devices.
- Continue to gather a group of CDRH SMEs to respond to agency questions
- Help determine the appropriate regulatory pathway.
- Manage FDA review/discussions of devices on MPAC List (Public Law 115-92)

Provide a POC to ask questions!!

Collaborations with DoW

- DARPA
  - Sepsis, TBI, Prosthetics, Robotic Devices,
- ONR
  - Automated / Autonomous Critical Care
- ARMY/MRDC
  - TBI, closed-loop control technologies, wearables
- Air Force
  - Closed-loop control ventilation
- Special Operations Command (SOCOM)

Types of Interactions: Medical Device Manufacturers

- Work with medical device companies that are developing needed medical devices.
  - Often have no prior experience with FDA and need help with understanding our processes and regulations.
  - Provide strategic help by educating companies on the various pathways available. (ex. Breakthrough Devices Program, HDE, De Novo…)
  - Provide information on the various resources FDA has available on our website

Provide a POC to ask questions!!

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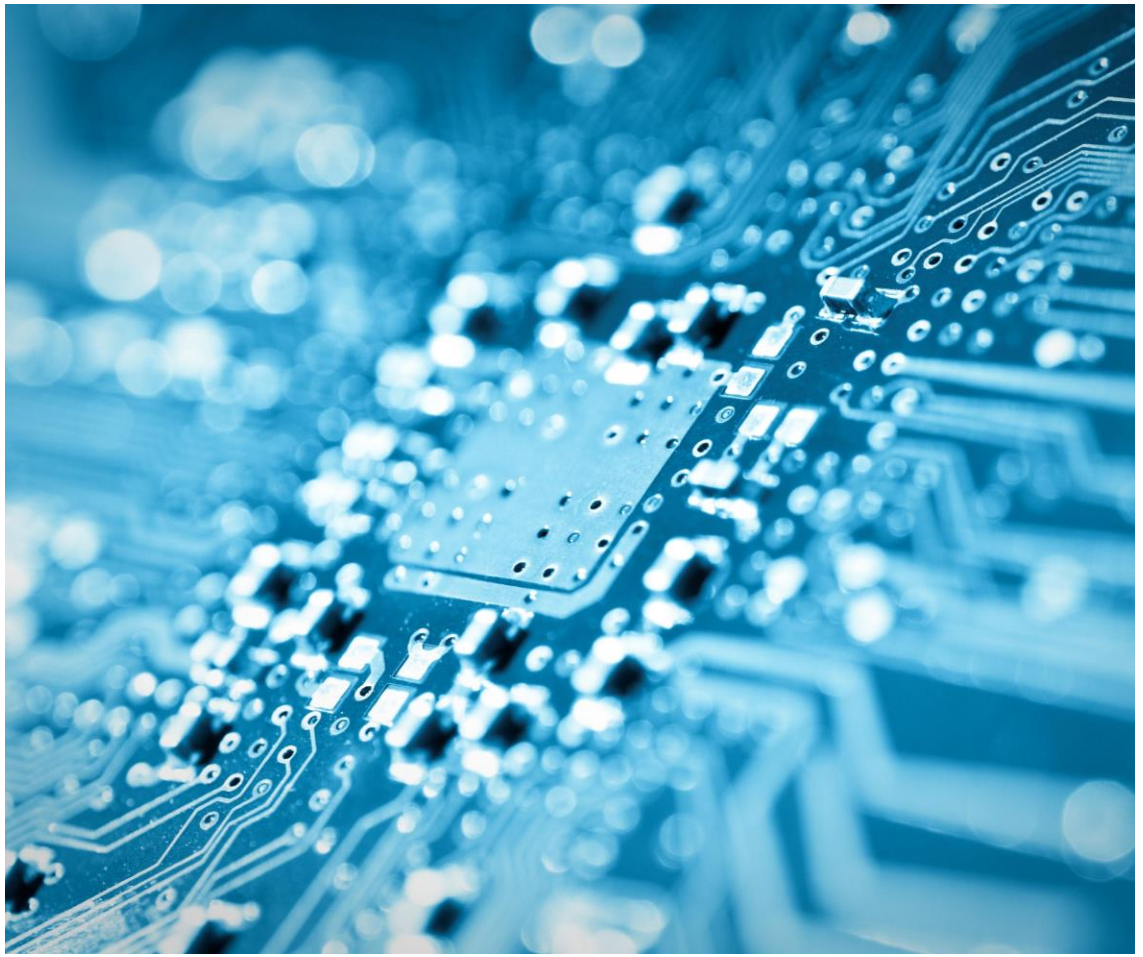


Autonomy in Medical Devices

- Autonomous medical devices are devices that can perform certain tasks or make decisions with limited or no human intervention.

- **Examples:**
  - Insulin pumps that automatically adjust insulin delivery.
  - Implantable cardiac devices that detect and correct abnormal heart rhythms.
  - AI-assisted imaging systems that help identify abnormalities.
  - Robotic surgical systems with autonomous assistance features.

Spectrum of Medical Device Autonomy

Full Human Control

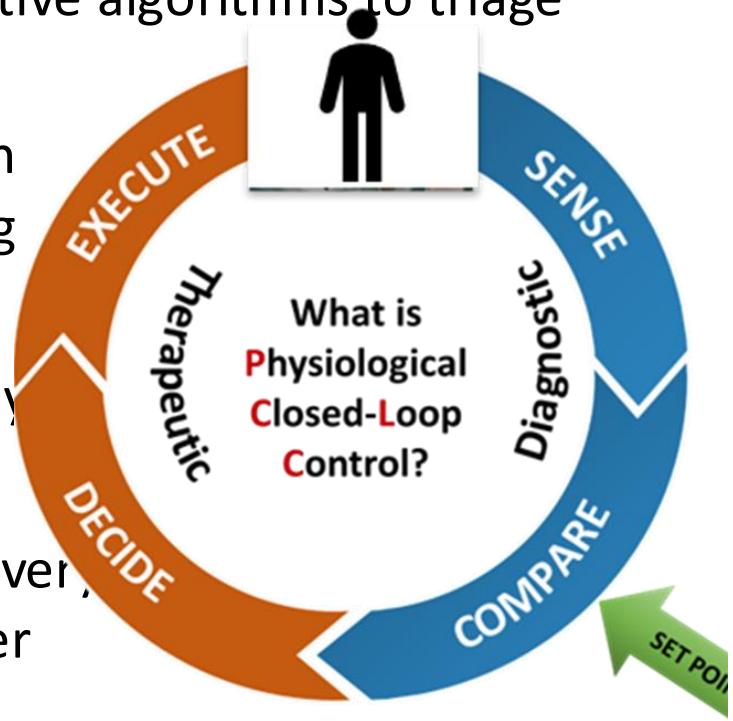
Full Autonomy

Examples of Autonomy

- AI/ML ultrasound diagnostics
- AI ECG interpretation
- Automated vascular access
- PCLC ventilators
- Closed-loop anesthesia
- Automatic insulin delivery
- Autonomous tasks in robotic surgery

Why Include Autonomous Decision Making in Medical Devices?

- Advances in artificial intelligence (AI) and machine learning (ML) have led to development of complex algorithms that have the potential to improve healthcare.
- COVID-19 demonstrated the need to develop smart and autonomous medical systems to manage patients when resources are strained. This can include predictive algorithms to triage patients.
- Autonomous closed-loop control (CLC) systems such as CLC ventilation have the potential to allow caregivers to manage more patients during resource intensive events such as a pandemic.
- Automated technologies streamline routine tasks, enhancing efficiency and reducing error.
- Innovation initiatives such as these demonstrated that healthcare delivery can be transformed by applying automation technologies used in other domains.



FDA Previous Involvement

GUIDANCE DOCUMENT

Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology

Guidance for Industry and Food and Drug Administration Staff

SEPTEMBER 2023

Download the Final Guidance Document | Read the Federal Register Notice

Docket Number: FDA-2021-D-0996

Issued by: Center for Devices and R

This guidance document provides
non-clinical testing, animal studie
medical devices with physiologic
the design and testing of a devic
technology. The design and test
limited to, the energy or article
training of the user population

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Physiological Closed-Loop Controlled Devices; Public Workshop; Request for Comments

A Notice by the Food and Drug Administration on 08/17/2015

PUBLISHED DOCUMENT

...HS.

...st for comments.

...on (FDA) is announcing the following public
...Closed-Loop Controlled (PCLC) Devices." Th
...s related to the design, development, and
...evices. FDA considers PCLC devices an
...hold a workshop focusing on design

A QUARTERLY PUBLICATION OF THE TELEMEDICINE & ADVANCED TECHNOLOGY RESEARCH CENTER

TATRC TIMES

TATRC Awards Projects to Accelerate Availability of Remote Controlled Ventilators and Infusion Pumps

"Virtual Hospital" Capabilities Extend Scale and Impact of Tele-Critical Care for COVID-19

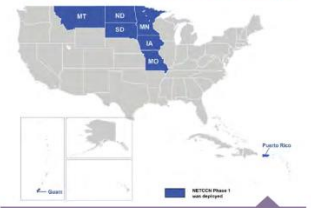
TATRC has awarded a total of approximately $2.8M in funding to three project teams to accelerate interoperability, remote control, and automation of mechanical ventilators and infusion pumps for integration into the National Emergency Tele-Critical Care Network (NETCCN) platforms in support of tele-critical care of COVID-19 patients. This effort will create and add "virtual hospital" capabilities to NETCCN and provide hospital-like functionality to the platform.

NETCCN consists of networks of critical care clinicians and providers that can deliver virtual care "from anywhere to anywhere" through the use of cloud-based, low-resource telemedicine platforms. Initial deployment of the NETCCN has supported several hospitals and other facilities in Guam, Puerto Rico, Iowa, Minnesota and the Dakotas and is expanding availability to assist wherever there is a lack of adequate critical care expertise and resources necessary to care for COVID-19 patients.

"The addition of 'virtual hospital' capabilities to NETCCN represent a key strategy to enhance the scope and impact of tele-critical care support to resource-limited environments. By accelerating development and inclusion of medical devices that utilize interoperable, remote control, and autonomous technologies, we can augment the knowledge, skills, and abilities of local caregivers," said TATRC Director, COL Jeremy Pamplin.

Currently, clinicians delivering critical care at a distance have limited ability to monitor, assess, and control the operation of essential medical devices like monitors, intravenous pumps, and ventilators used in the care of COVID-19 patients due to proprietary interfaces, absence of remotely controllable functions, and the need for custom licensing agreements.

NATIONAL EMERGENCY TELE-CRITICAL CARE NETWORK
NETCCN
VIRTUAL CRITICAL CARE ANYWHERE



Map of NETCCN Phase 1 deployment.

- Massachusetts General Hospital to develop a comprehensive framework for the safe, remote operation of high-acuity medical devices and to add the support for remote control data visualization for the Medtronic PB980 ventilator and NeuroWave AccuPump by passing patient and device data from these devices through DocBox to NETCCN systems.
- Nihon Kohden OrangeMed Inc. to develop, test, and implement the NKV-550 ventilator remote control function in collaboration with NETCCN performers, cybersecurity experts, and medical device interoperability experts.

Awarded teams will begin working with NETCCN teams and TATRC's Device Interoperability and Autonomy Coordinating Center (DIACC) to initiate these projects and make these

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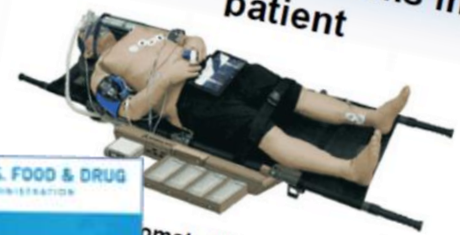
Automated Critical Care System (ACCS)
Treating multiple systems in a single patient



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Therapeutics
- Mechanical Ventilation
- Supplemental Oxygen
- Physiological Monitoring
- Casualty and Fluid Warming
- Analgesia/Sedation
- Therapy
- Fluid and Drug Infusion

U.S. FOOD & DRUG ADMINISTRATION

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

Examples: AI/ML-Enabled Medical Devices

FDA News Release

FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User

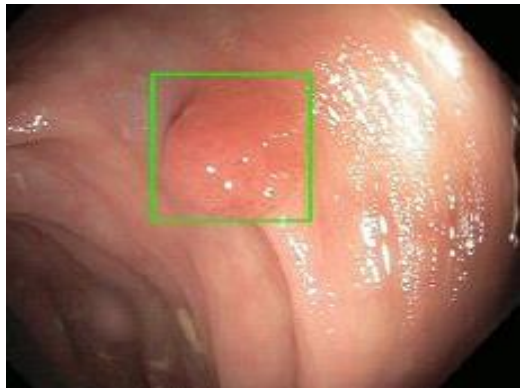
February 7, 2020

Caption Guidance

FDA News Release

FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer

April 9, 2021



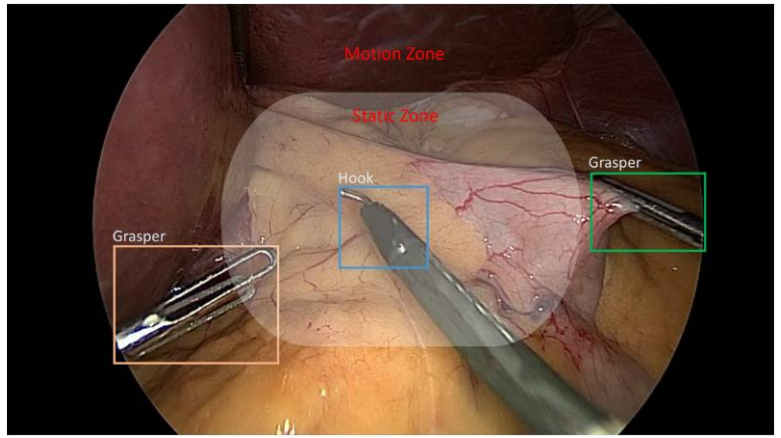
GI Genius

Caption Guidance™ (Caption Health, Brisbane AU). Figure from www.captionhealth.com
GI Genius™ (Medtronic Inc., Minneapolis, Minnesota, USA). Figure from Hassan C et al. Gut. 2019.

Examples: AI/ML-Enabled Medical Devices

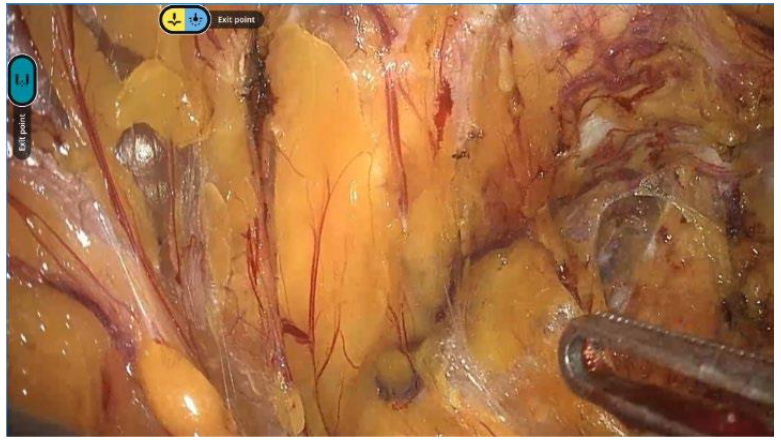
Moon Surgical, Maestro System (K242323)

ML algorithms to recognize and track surgical instruments in the camera visual field, autonomously moving the camera to keep the designated instrument centered in the visual field.



Covidien, Instrument Exit Point on Touch Surgery™ Aide (K253984)

ML algorithms to recognize and track surgical instruments in the camera visual field, autonomously indicating on the screen where the instrument exited view.



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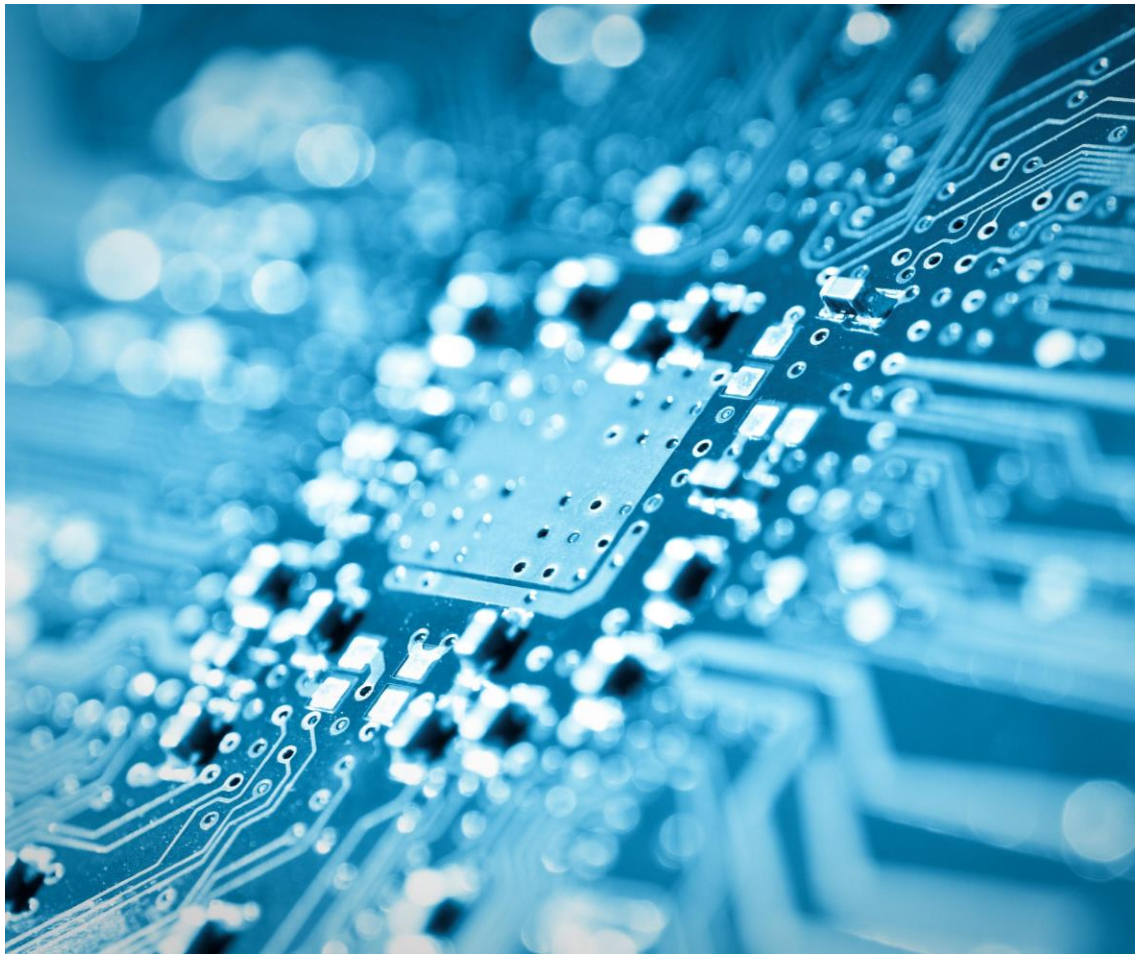
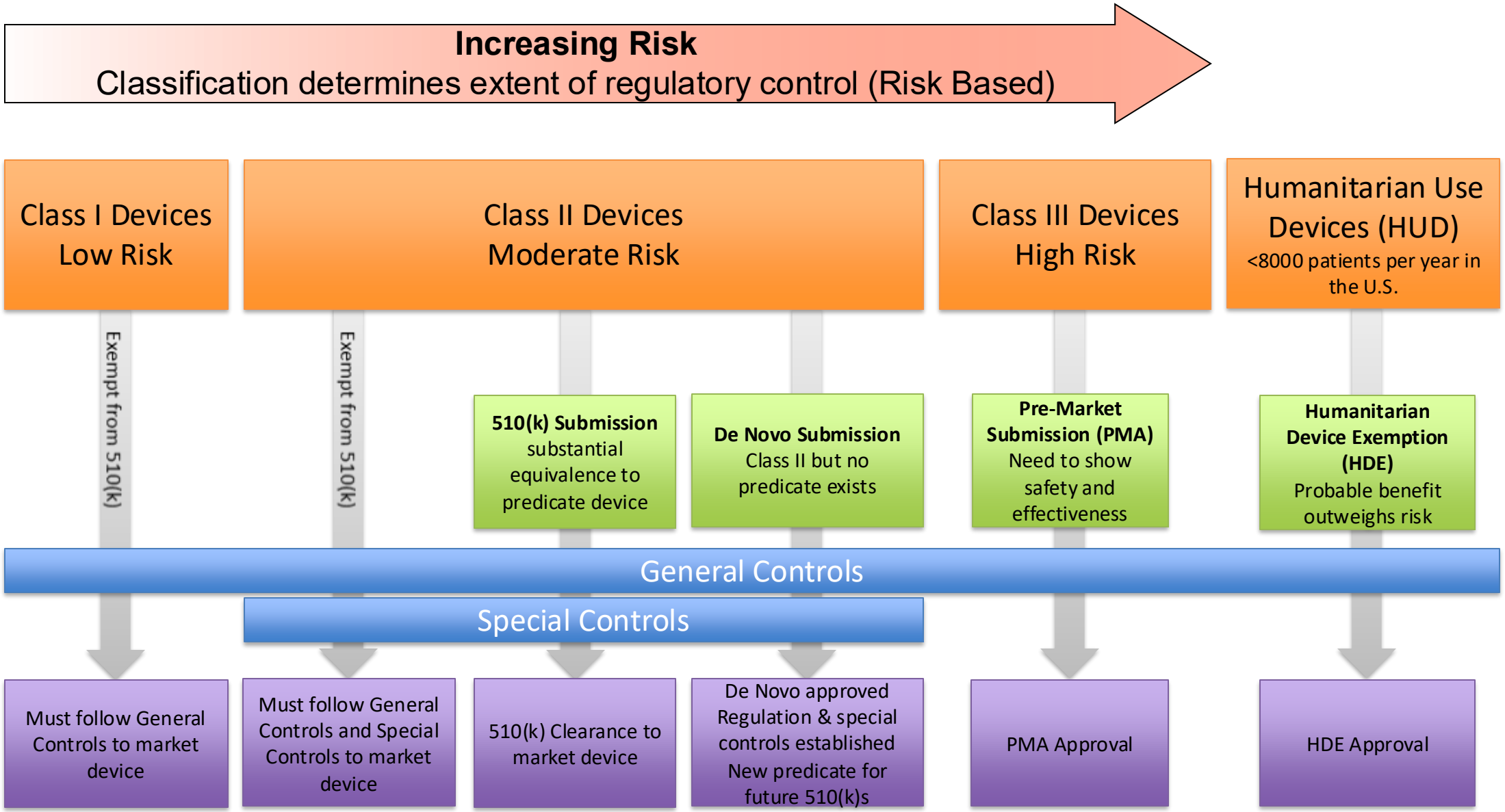


FDA/CDRH Regulatory Pathways



Potential Benefits

Enhanced Accuracy & Reproducibility	• Autonomous systems may perform procedural tasks with greater consistency, reducing variability between operators and potentially improving clinical outcomes.
Reduction of Errors	• Less degree of variability may reduce the risk of human errors, particularly in high-stress or resource-limited environments.
Improved Access to Procedures	• AI-guided devices (e.g., AI ultrasound) and telesurgery may extend specialized medical capabilities to austere environments, remote locations, and forward operating bases where expert clinicians may not be available.
Improved Workflow Efficiency	• Automation of routine tasks may free clinicians to focus on complex decision-making and direct patient care.
Reduced Cognitive and Physical Burden	• Autonomous systems may reduce the cognitive and physical demands on users, preventing fatigue-related errors in prolonged or high-intensity operational environments.

Potential Introduction of Risks

Inability to Correct Errors Before Execution	• A machine-generated error may be executed before the user can interrupt or override the system, reducing the window for human intervention.
Patient Harm	• Risk of misdiagnosis, uncontrolled bleeding, inappropriate drug delivery, or failure to achieve the intended clinical outcome.
Automation Rejection	• Users may distrust or reject autonomous recommendations or actions, potentially undermining the intended clinical benefit
Failure to Adapt	• Autonomous systems may not adapt to dynamic conditions, unique anatomical structures, or unexpected patient states.
Automation Bias	• Clinicians may defer to robotic or AI system direction over their own clinical judgment even when the system is wrong. Automation bias is well-documented across healthcare AI.
Loss of Situational Awareness	• Reduced user-device interaction may erode operator awareness of patient or device status, reducing ability to intervene appropriately when needed.

Low Risk Autonomous Devices

Not all autonomous technologies fall within FDA's device jurisdiction. Understanding these boundaries helps developers allocate resources appropriately and engage FDA early when needed.

General Wellness

CDRH does not actively regulate low-risk general wellness products. These must:

- Relate to maintaining or encouraging a general state of health
- Be low risk (non-invasive, non-implanted)
- NOT be intended to diagnose, cure, mitigate, prevent, or treat disease

Examples: fitness trackers, sleep monitors, stress management apps, caloric intake trackers

Autonomous functions in general wellness apps (e.g., AI coaching for sleep) may not require FDA review if they stay within wellness bounds.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices

Clinical Decision Support (CDS)

Certain CDS software is excluded from the device definition (21st Century Cures Act, Section 520(o)):

- Does NOT acquire/process medical images or physiologic signals
- Displays, analyzes, or prints medical information
- Provides recommendations to an HCP
- Enables the HCP to independently review the basis for recommendations

If all four criteria are met → Non-Device CDS (NOT regulated by FDA as a device)

If ANY criterion is not met (e.g., time-critical, specific diagnostic output) → Device and subject to FDA oversight
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

Mitigating Risks in Autonomous Medical Devices

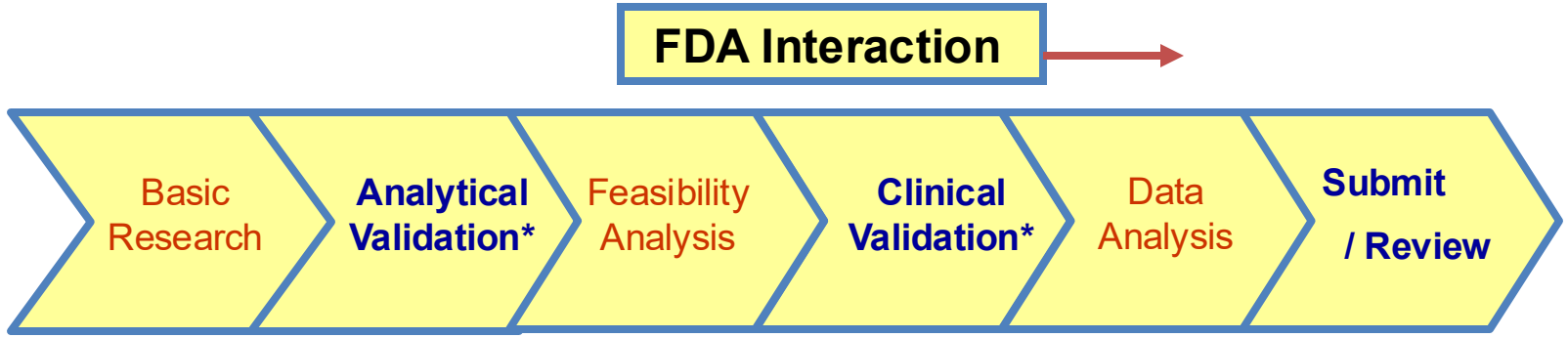
As new risks are introduced by adding autonomous function, mitigations should be identified to reduce risks to an acceptable level.

Possible Mitigations:

- Human Factors Testing
- Benchtop Performance Testing
- Animal Studies
- Clinical Studies
- Precision and Accuracy Testing
- Algorithm Validation

Medical Device Development Pathway

Recommend Early and Often FDA Interaction



Pre-submission interaction is one mechanism to receive review and feedback from CDRH

Never too early to seek FDA input

Why Engage Early on Autonomy?

- Classification may change when autonomy is added — what was a Class II device may require PMA
- Autonomous functions may introduce new risks that need to mitigated through specialized testing (human factors, AI/ML validation)
- FDA may have device-specific guidances that apply (e.g., PCLC guidance, AI/ML guidance)
- Early engagement prevents costly late-stage redesigns or regulatory surprises

Never too early to reach out!

Types of Feedback from CDRH

Informal Feedback

- Feedback through Division of Industry and Consumer Education (DICE).
- Feedback through the Digital Health mailbox
- Discussions organized by the MCM Innovation Program

Formal Feedback – obtained through official submissions

- **Q-submissions**
- Investigational Device Exemption (IDE)
- 510(k)
- Premarket Application (PMA)
- DeNovo

Q-Submissions

- FDA released a new guidance document on the Q-Submission Program and Meetings with FDA Staff http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

ıts / Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

GUIDANCE DOCUMENT

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

– Final Guidance for Industry and Food and Drug Administration Staff

MAY 2025

Download the Final Guidance Document | Read the Federal Register Notice

Final

Docket Number: FDA-2018-D-1774

Issued by: Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

The purpose of this guidance document is to provide an overview of the mechanisms available to submitters through which they can request interactions with the Food and Drug Administration (FDA) related to medical device submissions. These interactions can include written feedback or a meeting related to medical device Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, Humanitarian

Types of Q-submissions

Q-Sub Type	Method of Feedback	Timeframe for Sending Feedback or Scheduling Meeting (from receipt of submission)
Pre-Submission	Meeting (face-to-face or teleconference) with written feedback provided in advance	Written Feedback: 70 days or 5 days prior to scheduled meeting, whichever is sooner Meeting: Date based on mutual agreement (typically at 70-75 days)
	Written Feedback Only	70 days
Submission Issue Request (SIR)	Meeting or Written Feedback	If SIR is received within 60 days of FDA's marketing submission letter: 21 days as resources permit
		If SIR is received more than 60 days after FDA's marketing submission letter: 70 days as resources permit
Study Risk Determination	Formal Letter	90 days
Informational Meeting*	Meeting	90 days
PMA Day 100 Meeting	Meeting	100 days from the PMA filing date

*When used to track requests that do not meet the definition of a Q-Sub type, Informational Meeting timeframe and feedback mechanism can vary. Typically, informational meetings do not include FDA feedback

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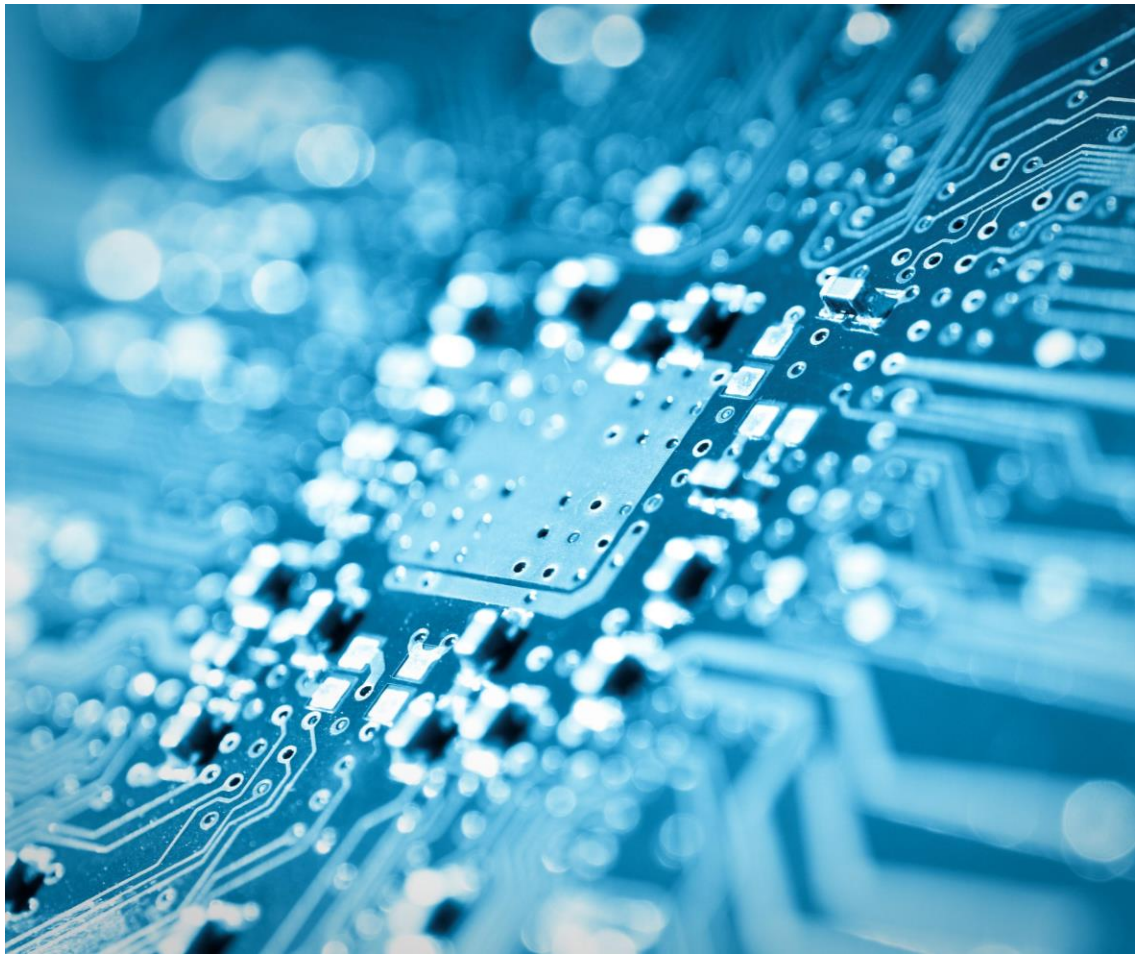


CDRH Programs and Initiatives to Support Innovation

- Collaborative Communities
- Breakthrough Devices Program
- STeP Program
- Total Product Life Cycle Advisory Program

Collaborative Communities

- A collaborative community is a continuing forum in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve common objectives and outcomes.
  - They bring together stakeholders to achieve common outcomes, solve shared challenges, and leverage collective opportunities.
  - If invited to participate, CDRH's decision to participate as a member is influenced by the public health impact of the community, its alignment with CDRH's regulatory mission, current priorities and resources.
  - Collaborative communities are not led by the FDA and do not exist to advise the FDA.
  - CDRH currently participates in 18 Collaborative Communities.

- Purpose of Collaborative Communities can be to:
  - Develop best practices and robust strategies for addressing challenges
  - Generate and evaluate evidence that supports novel approaches
  - Disseminate and implement solutions. The communities may also work to
  - Clarify ill-defined challenges
  - Generate consensus on the definition and scope of the challenges faced
  - Help address challenges and opportunities related to medical devices.

Further information on Collaborative Communities can be found at: https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challenges-together

Collaborative Communities – CDRH Participation

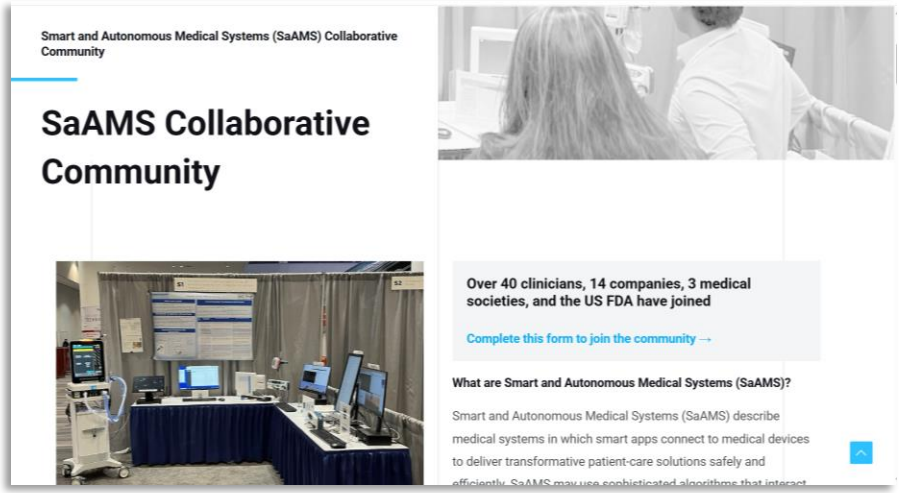
CDRH CURRENTLY PARTICIPATES IN 18 COLLABORATIVE COMMUNITIES

The FDA does not establish, lead, or operate collaborative communities. Nor are these communities intended to advise the FDA.

1. Collaborative Community on Ophthalmic Imaging
2. Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
3. International Liquid Biopsy Standardization Alliance (ILSA)
4. Case for Quality Collaborative Community
5. Heart Valve Collaboratory (HVC)
6. Wound Care Collaborative Community
7. Pathology Innovation Collaborative Community (PICC)
8. RESCUE (REducing SuiCide Rates Amongst IndividUals with DiabEtes) Collaborative Community)
9. Digital Health Measurement Collaborative Community (DATAcc)
10. Infection Management Collaborative Community
11. SHIELD Collaborative Community
12. OpenOximetry Collaborative Community
13. The Implantable Brain Computer Interface Collaborative Community (iBCI-CC)
14. **Smart and Autonomous Medical Systems (SaAMS) Collaborative Community**
15. Kilmer Community on Sterility Assurance
16. **Connected Health Collaborative Community**
17. **Robotics, Telesurgery, and Surgical AI Collaborative Community**
18. Electrphysiology Collaborative

CDRH_CollabCommunities@fda.hhs.gov

Collaborative Communities with Autonomous Medical Device Projects



https://mdpnp.mgh.harvard.edu/saams-cc/

https://robotelesurgaicc.org/

https://dimesociety.org/connected-health-collaborative-community/

Programs to Support Novel Devices

Breakthrough Device Program (BTD)

Expedites the development and review of devices that provide for more effective treatment or diagnosis of life threatening or irreversibly debilitating conditions

Safer Technologies Program (STeP)

Offers prioritized FDA interaction and review for devices that improve safety and reduce risks for conditions less serious than those covered under Breakthrough

- Enables Interactive & Timely Communication
- Promotes Pre/Post-market Balance
- Facilitates Flexible Clinical Study Design
- Engages Senior Management
- Qualifies for Priority Review

https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program
https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices

Breakthrough Device Program

Breakthrough devices go through a formal designation process which determines if the device meets the following eligibility criteria:

Subject to PMA, De Novo and 510(k) that:

- 1: “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; **and**

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
- 2D: the availability of which is in the best interest of patients.”

Devices on the DoW Priority List are treated as if they have Breakthrough Status

Safer Technologies Program (STeP) for Medical Devices

- The Safer Technologies Program (STeP) is a voluntary program for medical devices reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program.
- The goal of STeP is to provide patients and healthcare providers with timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards

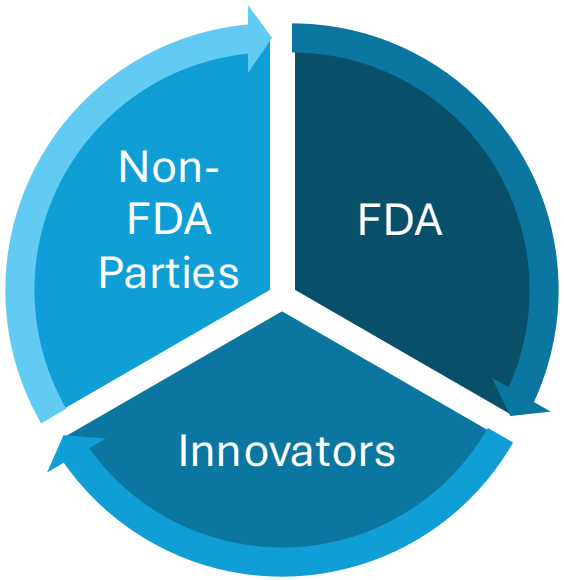
Criteria	Description	Reference Section of Guidance
First Eligibility Factor	Not eligible for the Breakthrough Devices Program due to the less serious nature of the disease or condition treated, diagnosed, or prevented by the device	Section IV.C.(1)
Second Eligibility Factor	Should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for **at least one** of the following	
	a. a reduction in the occurrence of a known serious adverse event	Section IV.C.(2)a
	b. a reduction in the occurrence of a known device failure mode	Section IV.C.(2)b
	c. a reduction in the occurrence of a known use-related hazard or use error	Section IV.C.(2)c
	d. an improvement in the safety of another device or intervention	Section IV.C.(2)d

https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices#what

Accelerating Innovation & Collaboration: Total Product Lifecycle Advisory Program (TAP)

- A voluntary program designed to expedite patient access to innovative medical devices.
- **Goal:** Help innovators navigate from concept to commercialization through early, frequent, strategic engagement
- **Mechanism:**
  - Provides a single point of contact (TAP Advisor)
  - “Sprint discussions" for timely feedback
  - Facilitates engagement with key stakeholders: **Patients, Providers, Payers**

Expanded to all of CDRH on July 1, 2026



https://www.fda.gov/medical-devices/total-product-life-cycle-advisory-program-tap/tap-overview

Traditional Process

Prolonged Sequential Process
Frequent Rework & Late Failures

https://dimesociety.org/connected-health-collaborative-community/

With TAP

FDA & Stakeholder Expertise

- **FDA**
- **Patients**
- **Payers**
- **Providers**

Better evidence strategy for faster commercialization

Patient access to high quality, innovative, safe, and effective medical devices

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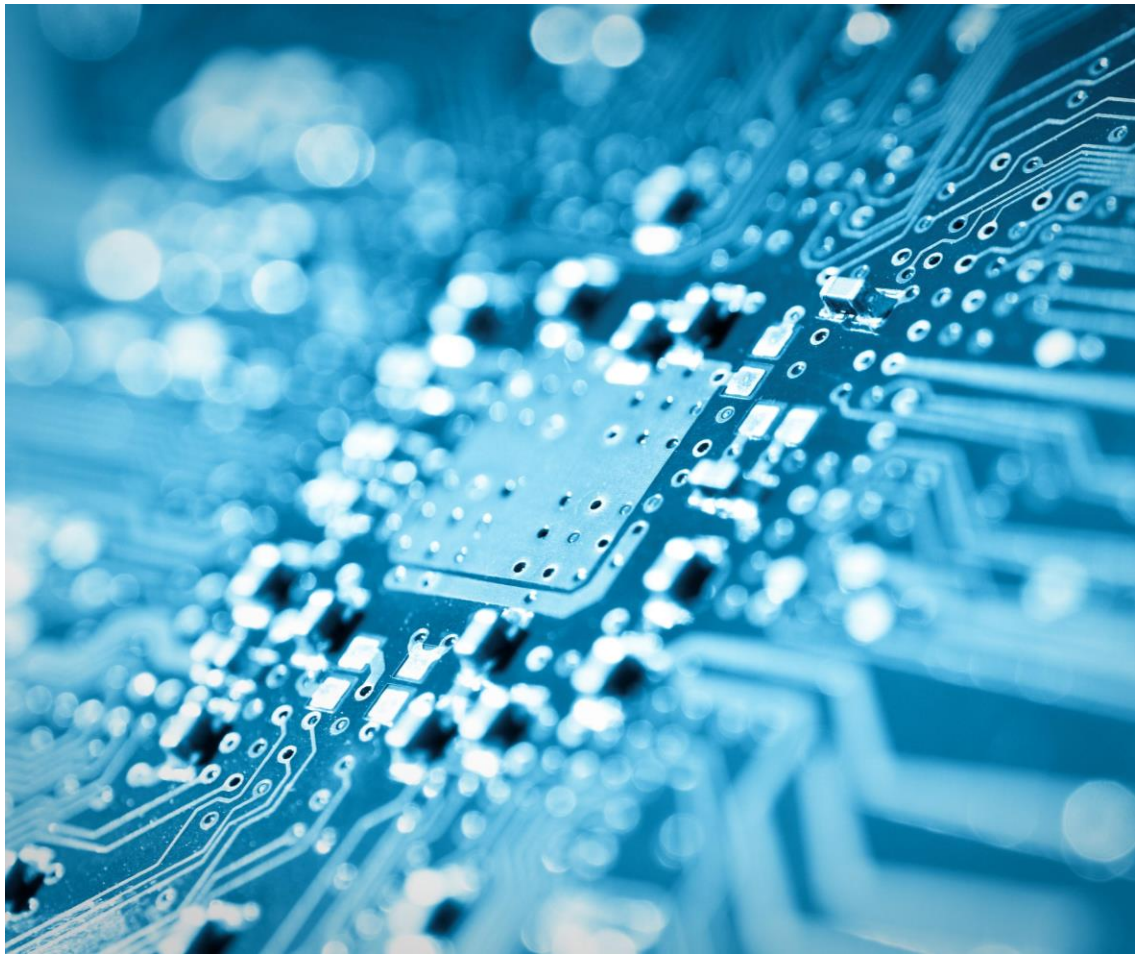
4. CDRH Programs to Support Innovation
5. **Conclusion and Contact Information**



Conclusions

- Regulation of autonomous medicals devices is based on risk.
- Talk to FDA early to understand the possible effects on regulatory pathway when autonomy is added or if a new type of autonomous device is created
- There are multiple ways to get feedback from the FDA including the MCM Innovation Program for devices that support the warfighter.
- FDA has created multiple programs to help medical device developers.

Thank you!

Contact Information: Heather.Agler@fda.hhs.gov

General CDRH Information:

- FDA Medical Device website (www.fda.gov/medicalDevices/)
  - Guidance Documents
  - Public information on cleared or approved devices
  - Regulations

Medical Countermeasure (MCM) Innovation Program

- Tracy Ulderich, Tracy.Ulderich@fda.hhs.gov – MCM Innovation Program Lead

Division of Industry and Consumer Education (DICE)

- If you have a question – Email: DICE@fda.hhs.gov
- Phone 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30pm EST)

Web Homepage:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm