

# Center for Devices and Radiological Health

## 2022 - 2025 STRATEGIC PRIORITIES





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# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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**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.

**Vision** Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

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# 2022 - 2025 STRATEGIC PRIORITIES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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## INTRODUCTION

Patients are at the core of our [mission](#) to protect and promote the public health. Our [vision statement](#) begins with our commitment to the American people that patients have access to high-quality, safe, and effective medical devices of public health importance first in the world. Access and timeliness—to technology and device safety information—are key to successfully providing American patients with high-quality health care.

Together, with congressional authorizations and user fee funding, our strategic priorities moved us closer to achieving our vision. Furthering our Total Product Life Cycle (TPLC)<sup>1</sup> approach, we reorganized to enhance cross-functionality, adopted the use of flexible, patient-centered benefit-risk paradigms, increased collaboration with our customers, streamlined our processes, and applied a least burdensome approach across all our products and services. We adapted policies and procedures to facilitate and streamline our reviews. We worked to strike the right balance between premarket and postmarket—obtaining the right data at the right time—creating incentives and programs that foster timely patient access to high-quality, safe, and effective technologies to improve health and quality of life.

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<sup>1</sup> TPLC is a holistic approach that takes into account all of the steps and processes in the evolution of a device from conception to obsolescence, integrating information and knowledge across premarket and postmarket activities. Applying the TPLC will increase information-sharing across the Center and enhance our collective decision-making.

## We made significant strides to meet the strategic goals we set in 2018.<sup>2</sup>

Our focus on our people, [customer service](#), process improvements, and organizational quality management allowed us to instill a culture of collaboration, quality, and continual improvement across the Center. Our internal and external customers consistently report high satisfaction in their interactions with CDRH, and our customer satisfaction ratings are routinely more than 90 percent. We adopted CDRH Guiding Principles that reflect and support the behaviors, beliefs, and values that create a collaborative workplace; launched a CDRH Wellness Center to support employee wellness and foster a holistic wellness culture; and, with participation of more than 400 employees, improved and harmonized about 90 percent of our core processes.

We improved the [digital user experience of internal and external customers](#) and radically improved programs and operations. Internal platforms like the new Decision Management Portal (DMP) will provide a single point of access to employee's work. We expanded our automated guided review templates or Submission Memo and Review Templates (SMARTs) and increased the efficiency and consistency of the premarket review process. We made available through the [Voluntary electronic Submission Template and Resource \(eSTAR\) Pilot Program](#), the 510(k) eSTAR, an interactive PDF form that closely follows the order and content of the 510(k) review as laid out in the SMART.

We continue to evolve our system based on a benefit-risk framework increasingly informed by patient input. We continue to work hand-in-hand with patients to incorporate their values and experiences into all aspects of the medical device total product life cycle. CDRH advances patient science through virtual education, collaboration on research projects, and leadership of the [Patient Engagement Advisory Committee \(PEAC\)](#). More than half of all Pre-Market Approval (PMA), Humanitarian Device Exemption (HDE), and De Novo submissions now incorporate Patient-Reported Outcomes (PROs) as a part of their clinical evidence to support device use.

We continue to seek creative and innovative approaches to our regulatory processes—doing business better and doing business differently. We made remarkable progress, continually innovating to meet new and evolving scientific advancements, patient needs, evolving societal values, emerging threats, and changes in our ecosystem.

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<sup>2</sup> 2018-2020 Strategic Priorities Accomplishments, <https://www.fda.gov/media/151423/download>

We launched the [Safer Technologies Program \(STeP\)](#), a new, voluntary program aimed to 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](#). STeP, an effort stemming from our [Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health](#), will help patients have more timely access to these medical devices and device-led combination products by expediting their development, assessment, and review, while preserving the statutory standards.

Through [the Medical Devices Development Tools \(MDDT\) program](#) we continue to qualify tools that medical device sponsors can choose to use in the development and evaluation of devices. When medical device sponsors use qualified tools in approved contexts, they know they will be accepted by CDRH without the need to reconfirm their suitability and utility. We also collated a [catalog of Regulatory Science Tools](#), providing a peer-reviewed resource for companies to use where standards and MDDTs do not yet exist so developers can focus their limited resources on technology development rather than method development. We provided support to the National Evaluation System for health Technology Coordinating Center (NESTcc) and, with more than [90 examples](#) of [leveraging real-world evidence \(RWE\)](#), we continue to bring real-world data (RWD) into regulatory decisions.

We accomplished so much because of the dedication, expertise, and innovative spirit of our staff—the reason behind our current and future successes. We put many of the key programmatic, policy, and process enhancements in place to achieve our vision in the next few years. Therefore, in 2022-2025, we will focus our efforts on ensuring our workforce and organization are well-positioned to fully achieve and maintain our vision for all patients. Putting patients first is an empty promise if it only applies to some and not all.

## 2022 – 2025 STRATEGIC PRIORITIES

We live in an ecosystem where technology and science evolve quickly. New problems and threats, like the COVID-19 pandemic, continually emerge. Societal needs, perspectives, and values change, as do the needs of our employees. We will continue to develop a CDRH that is prepared for innovations in technology and unanticipated national health challenges, while engaging with and continuing to serve the American public.

Our three 2022-2025 Strategic Priorities are a natural evolution of what we achieved through our 2018-2020 (and 2021) Strategic Priorities: Employee Engagement, Opportunity and Success; Simplicity; and Collaborative Communities. Through the 2022-2025 Strategic Priorities, we intend to:

- Promote a Modern and Diverse Workforce
- Enhance Organizational Agility and Resilience
- Advance Health Equity

**Promote a Modern and Diverse Workforce** aims to further enhance our incredible workforce, so it is exceedingly proactive, flexible, resilient, collaborative, and engaged. This priority also seeks to support our workforce to take full advantage of digital collaboration, technology and tools, and acknowledge and include diverse perspectives, experience, skills, and knowledge. Through this priority, we strive to prepare the organization for future disruptions, while maintaining work-life balance, maximizing flexibilities, promoting creativity, and supporting a culture of trust and empowerment. However, a modern and diverse workforce must be supported by an agile and resilient organization—one that is prepared for and can adapt quickly to avoid disrupting the operations of the Center and the work-life balance and wellness of our employees.

**Enhance Organizational Agility and Resilience** is about being able to rapidly adapt or redesign our business processes, approaches, and policies to leapfrog ahead of the needs of tomorrow. Organizational agility and resilience efforts will include fostering an enhanced learning and teaching environment; employee development and support; agile improvement and redesign of processes, policies, and programs; and capacity building. These efforts will support and help create the Modern and Diverse Workforce we aim to be.

**Advance Health Equity** is our priority that recognizes CDRH can advance the development of knowledge and safe and effective technologies to meet the needs of all patients and consumers. Technologies, including digital health technologies, can bridge that divide while advancing better health care, quality of life, and wellness for all; and should be designed and targeted to meet the needs of diverse populations. Putting patients first is an empty promise if it only applies to some and not all. No person should be left behind in health care.

## 2022 - 2025 MEASURES OF SUCCESS

Our measures of success will help measure progress toward our commitment to the American people that patients have access to high-quality, safe, and effective medical devices of public health importance first in the world. We have established clear and aggressive goals, including measures of success for the overarching device program as well as for each individual strategic priority.

- 1 By December 31, 2025, more than 50 percent of manufacturers of newly authorized novel technologies for the U.S. market brought their devices to the U.S. first or in parallel with other major markets.
- 2 By December 31, 2025, more than 75 percent of the time, FDA identifies and acts on significant safety signals related to medical devices marketed in the U.S. and other major markets first or in coordination with regulatory agencies of other major markets.

## PROMOTE A MODERN AND DIVERSE WORKFORCE

We live and work in an ecosystem where technology and science quickly evolve. New problems and threats continually emerge, like the COVID-19 pandemic. Societal needs, perspectives, and values frequently change, as do the needs of our employees.

To be successful today and get ahead of the technologies, challenges, and needs of tomorrow, we need to build on our earlier and current efforts to promote a modern and diverse workforce—one that is proactive, flexible, resilient, collaborative, and engaged. We also need to support our workforce to take full advantage of digital collaboration, technology and tools, and acknowledge and include diverse perspectives, experience, skills, and knowledge.

A modern and diverse workforce prepares us for future disruptions, while maintaining work-life balance, maximizing flexibilities, promoting creativity, and supporting a culture of trust and empowerment. The COVID-19 pandemic has reinforced the importance of flexibility—the ability to rapidly adapt and effectively address current and anticipated changes and challenges.

We recognize that while our workload will continue to be high, our experiences can still be rewarding and satisfying through personal and professional flexibilities, opportunities, and growth.

As OneCDRH, it is essential that our workforce represents the diversity of the American public at all levels of the organization including senior management. In 2019, CDRH established a Diversity, Equity, Inclusion, and Belonging (DEI&B) Program. We began taking steps to foster a workplace that is diverse, inclusive, and free of racism, biases, and disparities in the treatment of our colleagues or others because of their race, religion, gender, sexual orientation, age, physical capabilities, or beliefs. In 2020, CDRH established an Inclusion Council to assist and give CDRH staff a voice in these efforts across the Center. We conducted a climate assessment with the goal of identifying areas for improvement and metrics to further promote and sustain a culture where diversity, equity, inclusion, and belonging are essential to our Center's mission and continued excellence.

CDRH will continue to take steps to design an exceptional employee experience that leads to longevity, success, and increased engagement, and considers the entire employee lifecycle from initial interest in CDRH to onboarding and retention through eventual career transition. We will enhance the personal and professional CDRH experience through employee engagement programs that empower the employee

voice, promote wellness, foster an inclusive workforce, and support professional development programs that promote flexibility and professional growth, building on the work led by CDRH's Engage Council and the CDRH Engage Initiative that we launched in 2015.

## STRATEGIES AND ACTIONS

To accomplish this goal, CDRH will take several steps including the following:

- Implement CDRH's Diversity, Equity, Inclusion, and Belonging Road Map Action Plan.
- Continue to build and enhance employee engagement and wellness programs.
- Build on our hiring practices, including exploring the use of innovative recruitment practices, and expanding the reach of our recruitment efforts to broaden the diversity of our workforce.

## MEASURES OF SUCCESS

1

By December 31, 2025, CDRH employees across all represented groups will experience a greater sense of fairness and equity, as measured by a "very high" rating on the Inclusion Survey.

2

CDRH will achieve at least 90 percent of the annual Center-wide hiring targets for FY 2023-2025.

## ENHANCE ORGANIZATIONAL AGILITY AND RESILIENCE

The COVID-19 pandemic brought home the importance of agility and resilience. Our Mission and Vision depend on an organization that is situationally aware and attuned to the needs, concerns, and challenges of our customers. Moreover, a modern and diverse workforce must be supported by an agile and resilient organization. To be that organization, CDRH will focus on rapidly adapting and effectively addressing current and anticipated changes and challenges to avoid disrupting the operations of the Center, as well as the work-life balance and wellness of our employees. Additionally, we will focus on maximizing flexibilities, promoting creativity, and supporting a culture of trust and empowerment. We will radically simplify our processes on an ongoing basis, rapidly adapting or redesigning our business processes, approaches, and policies to address new challenges and leapfrogging ahead of the technologies and needs of tomorrow.

Over the past several years, we have taken many important steps to increase the Center's agility and resilience. These actions include reorganizing to enhance cross-functionality, creating internal programs such as the Minors Program and Communities of Practice, strengthening internal communications and collaboration, launching the Digital Transformation Initiative, and establishing a quality management system and program. Additionally, we focused on delivering outstanding customer service and implementing strategic priorities focused on Employee Engagement, Simplicity, and Collaborative Communities. Over the last two years we have taken many strategic actions to respond and adapt to the unprecedented workload demands of the COVID-19 pandemic.

We will develop a pipeline that supports a modern and diverse workforce. We will not only recruit and retain the best employees, but also take into account the long-term and evolving needs of the organization for technical and other skills that our Mission and Vision rely on to be successful. A key part of being agile means serving as a training ground for employees and rapidly developing them to be successful leaders, creators, and problem solvers within CDRH, as well as cross-training teams to have multiple skills so we can adapt to and embrace both short- and long-term changes.

In addition to focusing on how to better retain our employees, we also appreciate people increasingly see their career journey tied to experiences at multiple workplaces. Therefore, our growth opportunities should prepare people with skill sets they can apply in positions inside and outside CDRH. We should build employment opportunities that allow individuals interested in short-term positions to join our

organization while allowing us to leverage their expertise and experiences to rapidly meet new or growing needs. With a combination of employees who stay longer and those who come to CDRH as a stepping-stone in their career journey, we will build the growth opportunities best tailored to their and the Center's success, as well as create a network of alumni who can serve as a resource for our current employees, collaborators on projects, and ambassadors for the Center.

To be more agile, we will expand our efforts to leverage the expertise, skills, experiences, and resources of others outside of CDRH through partnerships and collaborations, building on such efforts as our [Network of Experts](#), public-private partnerships, and Collaborative Communities.

We will also embrace more flexible work schedules and continue to adapt to the virtual working environment. We will assist our workforce in taking advantage of the opportunities a virtual working environment can provide while addressing its challenges, such as the loss or minimalization of body language during virtual interactions and the greater likelihood of a sense of disconnection between employees.

We will communicate, engage, collaborate, and work with our internal and external customers in ways that best meet both of our needs through mutually rewarding experiences. We will be transparent in our decision making and communicate with our customers where they are, using multiple communication channels rather than only expecting them to seek information from us or major news outlets.

## STRATEGIES AND ACTIONS

To accomplish this goal, CDRH will take several steps including the following:

- Through collaborative Center-wide process, determine what work-life balance means to CDRH employees and take steps to achieve a work experience that is tailored and meaningful to our workforce.
- Enhance our professional and personal development programs to foster success of employees across their career, such as implementing the CDRH Careers Experiential Rotation Program (CERP).
- Significantly expand our efforts on Simplicity, through the incorporation of agile and design thinking.

## MEASURES OF SUCCESS

- 1 By December 31, 2025, CDRH will reduce the average amount of time spent on at least 10 core business processes without reducing performance or adversely impacting outcomes.
- 2 By December 31, 2025, more than 90 percent of CDRH employees experience a favorable and sustainable work-life balance as pre-defined through a collaborative Center-wide process.

# ADVANCE HEALTH EQUITY

## *Bridging the Health Technology Divide*

No person should be excluded from health care and no patient should be left behind. Putting patients first means all patients. However, historically under-resourced populations lack access to quality health care, and that gap continues to grow with the consolidation and centralization of health care services. Lack of access exists for a variety of reasons, including that necessary treatments and diagnostics are not available to the specific demographic groups, or treatments and diagnostics needed by those groups simply do not exist. Additionally, we sometimes lack the evidence to know whether an existing product benefits one demographic group (e.g., race, ethnicity, sex, and age) similarly to others. Innovation deserts persist for conditions that predominately affect diverse populations, particularly racial and ethnic minorities.

Unmet and unaddressed health conditions in diverse populations negatively impact the nation's overall health. Technology can bridge that divide while advancing better health care, quality of life, and wellness for all. Technology, including digital health technology, should be designed and targeted to meet the needs of diverse populations. Global and domestic populations that continue to suffer overall from the digital divide, such as those living in rural communities or in poverty, have often experienced better outcomes when digital health technologies are made available to them. Digital health technologies can help bridge the gap by bringing health care directly to patients wherever they are - at home, at work, in cities, and in rural communities - and can facilitate the participation of all populations in clinical studies and other opportunities for public health data collection. To enable the greatest public health benefit from these technologies, it is critical that patients and health care providers trust the information used to develop and evaluate them, as well as their output. Transparency, inclusivity, and engagement can foster better trust in technology.

The development of sophisticated algorithms that incorporate Artificial Intelligence/Machine Learning (AI/ML) can increasingly improve people's health, quality of life, and wellness. However, these algorithms may be biased or otherwise not fit for purpose if they are developed without the data or evidence to train and assess their performance in medically and demographically diverse populations, including racial and ethnic minorities, children, older adults, non-conforming gender, and women. That's why our Digital Health Center of Excellence issued a [Plan of Action for AI/ML](#) that, among other steps, would address bias in these technologies.

The performance of medical devices, including health technologies, needs to be well understood to mitigate negative unintended consequences on people's physical, cognitive, and emotional condition. CDRH is uniquely positioned to advance the development of high-quality, safe, and effective technologies to meet the needs of all patients and consumers and the information necessary for different populations to make well-informed decisions about whether and how to use them.

We will take actions to better understand the needs of different populations and the challenges they face in access to health care and health technologies. We will take actions to ensure the conceptualization, design, and evaluation of health technologies address the populations for which they are intended; strategies are undertaken to be inclusive of the demographic diversity in the U.S. in the design, evaluation, and surveillance of health technologies; and the evidence supporting a device's performance in different populations is transparent and accessible to the public. We will take steps to leapfrog the development of high-quality, safe, and effective health technologies, including digital health technologies, which provide significant improvements in health care, quality of life, and wellness to diverse populations, provide care in the home setting, increase efficiencies that lower overall health care costs, and help people take control of their health and wellness.

We will provide clear, accessible information in plain language that better informs people's decisions about their health care, quality of life, and wellness. We will advance the regulatory science necessary to achieve these objectives, including cognitive human factors, and harness innovation to make strides in conditions disproportionately affecting diverse populations. Instead of requiring these populations to proactively engage the health care ecosystem, CDRH will strive to meet patients where they are and cultivate the generation of health technologies, regulatory science tools, and communication products that can bridge the divide.

## STRATEGIES AND ACTIONS

To accomplish this goal, CDRH will take several steps including the following:

- Reduce barriers and increase opportunities for participation by diverse populations in evidence generation, including traditional clinical trials and real-world data studies.
- Develop a framework for when a device should be evaluated in diverse populations to support marketing authorization.

- Partner with patients, health care providers, industry, and payers to advance solutions that promote equity along the total product life cycle, including access to care.

## MEASURES OF SUCCESS

1

By December 31, 2025, 95 percent of publicly available premarket authorization decision summaries issued since December 31, 2024, will include available data stratified by demographic characteristics or include a statement that describes the performance associated with demographic characteristics.

2

By December 31, 2025, demonstrate year after year improvement from a 2023 baseline measure of consumer understanding of our patient/caregiver communications across diverse demographic groups.

## Contact Information

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