

## 2018-2020 STRATEGIC PRIORITIES ACCOMPLISHMENTS

Through our [2018-2020 Strategic Priorities](#)—*Employee Engagement, Opportunity, and Success; Simplicity; and, Collaborative Communities*—CDRH continued to improve our performance and our programs to assure CDRH is an employer of choice, a high-performing organization, and a best-in-class model for excellent customer service, actively collaborating with our customers, and engaging as a true partner with and on behalf of patients.

This document includes CDRH’s accomplishments through December 2020 in meeting, and in most cases exceeding, our strategic goals. In light of CDRH’s significant work in the fight against COVID-19, CDRH is continuing to focus on the 2018-2020 strategic priorities through 2021. We plan to leverage the lessons learned from the COVID-19 public health emergency to help inform where we go in 2022 and beyond.

### MEASURE OF SUCCESS - NOVEL TECHNOLOGIES

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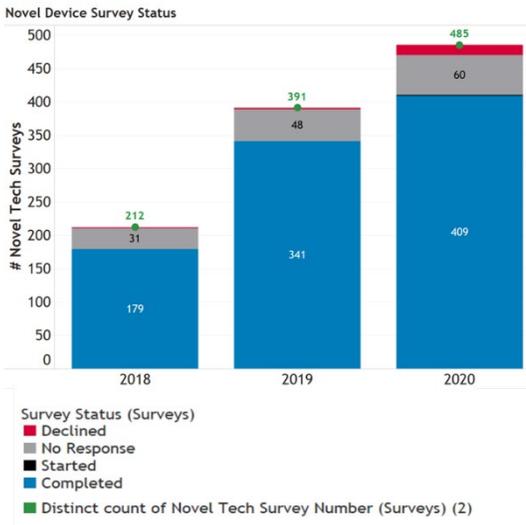
Our measure of success on novel technologies aligns with and helps us benchmark progress toward achieving our vision that patients in the United States have access to high-quality, safe, and effective medical devices of public health importance first in the world.

Novel technologies include those brought to market through the Premarket Approval (PMA), humanitarian device exemption (HDE), and De Novo pathways, as well as a subset of those brought to market through Emergency Use Authorization (EUA), or through the [Breakthrough Devices Program](#). They address an unmet need or may be safer or more effective than currently available alternatives. CDRH contacted manufacturers of novel technologies to determine their intent to bring their devices to the United States.

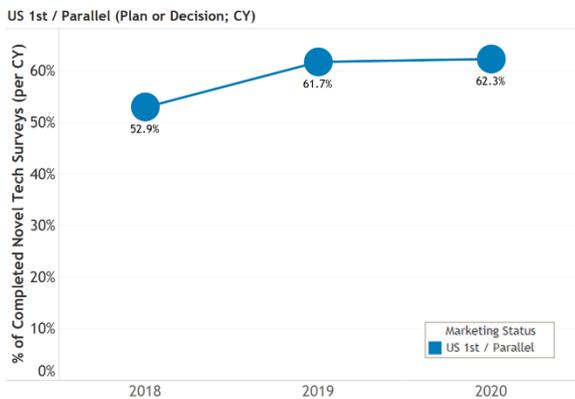
# Novel Technologies –Manufacturers’ Intent to Market in the United States Metric

2020 Target	Result
<p><b>50% of novel technology manufacturers intend to bring their devices to the United States</b></p> <p>By December 31, 2020, more than 50% of manufacturers of novel technologies for the U.S. market intend to bring their devices to the United States first or in parallel with other major markets.</p>	<p><b>62% of novel technology manufacturers intend to bring their devices to the United States</b></p> <p>Based on an 87% response rate from companies contacted about novel technology devices between 2018 and 2020, 62% of companies intended to bring their devices to the United States first or in parallel with other major markets by December 31, 2020.</p>

## Highlights



Between January 2018 and December 2020, CDRH identified 1,090 manufacturers of novel technology. As of May 2021, more than 900 of these manufacturers shared with CDRH their plans for bringing their device to market (87% response rate).



Calculated yearly based on the year of first interaction between CDRH and the manufacturer, the percentage of manufacturers intending to bring their device to the U.S first or in parallel to other major markets increased every year, from about 53% to 62%, exceeding the established 50% goal.



## STRATEGIC PRIORITY: EMPLOYEE ENGAGEMENT, OPPORTUNITY, AND SUCCESS

*Employee Engagement, Opportunity, and Success* recognizes the connection between taking care of our employees and achieving our vision. Engaged employees are the most productive, creative, loyal, and motivated; they are less likely to leave and more committed to the mission and vision. However, engagement requires work-life balance, open dialogue, and opportunities to succeed.

### Employee Engagement, Opportunity, and Success Metric

2020 Target	Result
<p><b>80% employee engagement level</b></p> <p>By December 31, 2020, achieve at least an 80% employee engagement level.</p>	<p><b>81% employee engagement level</b></p> <p>CDRH’s 2020, Federal Employee Viewpoint Survey results engagement index was 81%, increasing 4% since 2019 and 15% since 2015.</p>

### Highlights

#### Engage Recommendations

Since 2018, led by the CDRH Engage Council, CDRH has implemented programs and completed engagement projects, increasing engagement across CDRH and accomplishing many of the Engage Recommendations. These include:

- Launch *CDRH Careers* platform to support career and professional development
- Revamp CDRH’s internal communication tools and infrastructure and acquire tools to promote open and two-way-communication
- Establish the use of “360 feedback” mechanisms to give staff the opportunity to provide feedback on their managers
- Develop and implement CDRH’s Guiding Principles
- Launch wellness initiatives to support work-life balance.

#### CDRH Guiding Principles



Using employee feedback and the CDRH Shared Values and Customer Service Standards as the foundation, the CDRH Engage Council led the development of a set of Guiding Principles that reflect and support the behaviors, beliefs, and values that create a collaborative workplace. The Guiding Principles describe the behaviors for which CDRH employees hold each other accountable and foster a collaborative environment in which Center employees at all levels feel valued and heard. They were formally adopted in December 2018. All Center employees have received training on the Guiding Principles. To monitor progress, a survey was developed, and since October 2020, has been conducted at least twice a year.

## **CDRH Diversity and Inclusion Program**

One of the Center priorities is ensuring that CDRH is an organization where everyone feels safe, welcome, and heard.

- In 2019, CDRH established a Diversity, Inclusion and Belonging (DI&B) Program and began taking steps to assure a Center 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 the CDRH Inclusion Council, to assist and give CDRH staff a voice for DI&B efforts across CDRH. That same year the Center began conducting a climate assessment with the goal of identifying areas for improvement and metrics to further promote and sustain DI&B.

## **CDRH Wellness Center**

In 2020, CDRH hired a Wellness Specialist to develop the CDRH Wellness Center. Launched in 2021, the online Wellness Center is a psychologically safe space that supports individual employees, teams, and the organization as a whole by housing wellness resources designed to empower employee wellness and to foster a holistic wellness culture.

Through interactive communication channels, on-demand webinars, virtual group exercises, mental health trainings, podcasts, blog posts, and specialist referrals, the Wellness Center is intentional in promoting employee wellness, morale, and quality of life by providing easily accessible and meaningful wellness resources to CDRH's multigenerational, multidisciplinary, and multicultural workforce.

## **Digital Transformation**

CDRH's Digital Transformation Initiative focuses on ensuring employee success by giving staff better tools to do their jobs efficiently and effectively and achieve our public health mission. The systems deployed as part of this initiative will improve user experience for customers both inside and external to the FDA and enhance the Center's ability to accept, store, analyze, and distribute data. The governance and processes supporting CDRH's digital transformation promotes standardization of best practices, access to more comprehensive and integrated device information, and enhanced decision support.

Since 2018, CDRH has:

- Established CDRH's Technology and Data Services Group to provide staff with improved IT services
- Delivered new and improved internal search capabilities, along with user learning resources, to staff
- Established IT and Data Governance to drive IT implementations
- Acquired technology and data management tools and services.



## STRATEGIC PRIORITY: SIMPLICITY

Simplicity is about how CDRH addresses the challenges achieving our mission and vision present to us—the issues are often complex; the solutions and processes do not necessarily have to be.

### Simplicity Metric

2020 Target	Result
<p><b>Improve 80% of CDRH’s processes</b> By December 31, 2020, lean at least 80% of CDRH’s core processes.</p>	<p><b>Improved 86% of CDRH’s processes</b> As of December 31, 2020, CDRH has leaned 87% of its core processes.</p>

### Highlights

#### Process Improvement Program

The CDRH Process Improvement Program, launched in 2019, uses Lean Six Sigma as its foundational methodology and works with CDRH staff to improve and simplify processes. Since 2019, the program has engaged in over 48 improvement projects, leaning 44 out of 51 identified “core” processes. Over 20% of CDRH employees, more than 400 people total, have participated in process improvement efforts so far.

#### Horizontal Harmonization and the Intake, Triage, Review, and Action (ITRA) Approach

To further promote simplification, CDRH took a holistic view of its processes and engaged in harmonizing horizontal process steps and activities that are similar across functional areas. CDRH successfully established a concise and standardized pre- and post-market model that focuses on Intake, Triage, Review, and Action, shifting towards a more harmonized and modular review approach. Staff participating in two large 2019 and 2020 process improvement teams successfully aligned all core pre- and post-market processes to the ITRA approach.

#### Simplified Process Operations

CDRH employees working on process improvement projects delivered simplified process operations.

- A team led the harmonization of the De Novo process across the Center and removed 20% of its administrative process steps.
- A solution piloted by the project team delivered simplified process operations for CLIA waiver by application submissions that reduced the number of submissions under review by the FDA for more than 30 days to just 6%.
- In record time, another team developed an intuitive Device Shortages System (DeSSy) to capture information in support of CDRH’s COVID-19 response.
- A team harmonized and simplified policy development processes internal to CDRH.
- Lastly, a team working on Advisory Committee Panel Meetings greatly simplified internal panel preparation activities by developing a series of templates to collect “static information” that can be cascaded into required forms and templates, greatly reducing rekeying of information and duplication.



## STRATEGIC PRIORITY: COLLABORATIVE COMMUNITIES

The Collaborative Communities priority acknowledges that the FDA serves the American public better and achieves its vision when stakeholders in the medical device ecosystem, including CDRH, proactively work together to address both shared problems and problems unique to others.

### Collaborative Communities Metric

2020 Target	Result
<p><b>Participate in 10 communities</b></p> <p>By December 31, 2020, participate in at least 10 collaborative communities.</p>	<p><b>Participating in 12 communities</b></p> <p>By December 31, 2020, CDRH was a participant in 10 collaborative communities. As of August 2021, CDRH is a participant in 12 collaborative communities.</p>

### Highlights



#### Collaborative Communities Toolkit

CDRH developed a toolkit as a resource for stakeholders interested in forming collaborative communities. The [Collaborative Communities Toolkit](#) provides a collection of helpful ideas to foster strong collaborative communities that are well-prepared to take on health care challenges. To complement the Toolkit, CDRH created a Staff Guide and delivered training to help address common questions CDRH staff might have about collaborative communities. CDRH also held a [webinar](#) to encourage interested stakeholders to learn more about collaborative communities.

#### CDRH Participation in Collaborative Communities

CDRH currently participates in these collaborative communities, which have been established and are managed and controlled by external stakeholders:

- Collaborative Community on Ophthalmic Imaging
- National Evaluation System for health Technology Coordinating Center (NESTcc) Collaborative Community
- Standardizing Laboratory Practices in Pharmacogenomics Initiative (STRIPE) Collaborative Community
- International Liquid Biopsy Standardization Alliance (ILSA)
- Xavier Artificial Intelligence (AI) World Consortium
- Case for Quality Collaborative Community
- Heart Valve Collaboratory (HVC)
- Wound Care Collaborative Community
- Pathology Innovation Collaborative Community (PICC)
- REducing SuiCide Rates Amongst IndividUals with DiabEtes (RESCUE) Collaborative Community
- MedTech Color Collaborative Community
- Digital Health Measurement Collaborative Community (DATAcc)

## Examples of Early Impacts

The Collaborative Community on Ophthalmic Imaging held a virtual, public workshop in September 2020 with over 1000 registrants from across the globe to discuss artificial intelligence in the imaging of the retina. Most notably, patients were an integral part of the program and the proceedings are being published in *Ophthalmology*, a peer-reviewed journal.

The ILSA Collaborative Community published a white paper in *Critical Reviews in Oncology/Hematology* highlighting the contributions to liquid biopsy in oncology.