

U.S. Food and Drug Administration

# 2018-2020 STRATEGIC PRIORITIES

Center for Devices and Radiological Health

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# CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

## Mission

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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.

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## Vision

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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. postmarket 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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## Shared Values

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**Public Health Focus**• We focus on activities and outcomes that protect and promote public health.

**Our People**• Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.

**Science-Based Decisions**• We make decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.

**Innovation**• We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.

**Honesty and Integrity**• We maintain the public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.

**Accountability**• We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them.

**Transparency**• We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.

# CDRH'S 2018-2020 STRATEGIC PRIORITIES: ACHIEVING OUR VISION OF TIMELY PATIENT ACCESS TO HIGH- QUALITY, SAFE AND EFFECTIVE MEDICAL DEVICES

## Introduction

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Patients are at the core of our mission – to protect and promote the public health. In our [2012 vision statement](#), we made a commitment to the American people that patients would have access to high-quality, safe and effective medical devices of public health importance first in the world. Good technology does not benefit patients if they do not have timely access to it. Access and timeliness are key to successfully providing American patients with high-quality health care – but we face challenges in meeting this commitment.

We have one of the most rigorous regulatory standards for protecting public health – reasonable assurance of safety and effectiveness. This bar can create disincentives for manufacturers to bring their technologies to the U.S. early, if at all, because to meet this standard often requires more evidence to bring a product to the U.S. marketplace, especially for high-risk devices and more innovative lower-risk technologies, than many other countries in the world. At the same time, we have been a historically underfunded center and we have not consistently operated our regulatory program as efficiently as we should, which can lead to a protracted regulatory process. Because of both our high regulatory standard and our funding and programmatic challenges, Americans have waited up to four or more years for access to life-saving devices. As important, we must

have robust scientific evidence that a device is safe and effective before approving that product for the U.S. market.

We chose our [strategic priorities over the past five years](#) to address this very problem – we’ve tried to reduce the time and cost required to bring a product to the U.S. market and support it throughout its life cycle while not compromising our reasonable assurance of safety and effectiveness standard, in part, by advancing a *total product life cycle approach* (TPLC)<sup>1</sup>, using flexible, patient-centered benefit-risk paradigms, collaborating more with our customers, streamlining our processes, and applying a least burdensome approach. Direction by Congress through legislation and increased funding through our [user fee](#) program have supported and advanced our efforts. In doing so, we’ve aimed towards helping innovators choose the U.S. marketplace, rather than be stymied by a complex and cumbersome regulatory process, while at the same time, we’ve preserved our safety and efficacy standard and the need for rigorous science, upon which American patients rely for quality health care.

Our strategic efforts, congressional direction, and user fee funding have produced remarkable results. However, our great progress and changes have been due in no small part to the dedication, expertise, and innovative spirit of our staff, who remain the bedrock of our current and future success.

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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.

## 2012-2017: Great Progress and Changes

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The impact of our strategic efforts can be seen in the steps we've taken to reduce the time and cost of generating clinical evidence, typically the most expensive and lengthy regulatory requirement for marketplace entry. We have adapted our policies and procedures to facilitate and streamline the development and [approval of clinical research protocols](#), as well as the initiation and conduct of clinical trials in the U.S.

Our focus and one of our key strategic priorities has been a more holistic view towards evidence generation, by trying to strike the [right balance between premarket and postmarket data collection](#)—in other words, asking for the least burdensome evidence necessary to approve or clear a device to enter the market versus what data could be appropriately gathered following market authorization. By striking the right balance between premarket and postmarket data collection we can help assure we get the right data at the right time, thereby creating incentives for timely patient access to high-quality, safe and effective technologies to improve their health and quality of life.

A strong example of our approach to efficient, timely, and robust evidence generation is the six-year investment we have already made to lay the foundation for the creation of the National Evaluation System for health Technology ([NEST](#)), to reduce the time and cost while increasing the value and use of evidence derived from clinical practice and the patient home setting. This is often called real-world evidence and includes leveraging data from digital technologies and electronic health information sources.

Our focus on [customer service](#), [organizational quality and quality management](#) has allowed us to instill a spirit of continuous improvement in the Center. Through more efficient daily work and more creative and innovative approaches to our regulatory processes—doing business better and doing business differently—in concert with increased funding from user fees and congressional direction through select changes in federal law, we have tangible evidence that we are moving towards meeting our commitment to the American people and our customers. For example, between 2009 and

2017 the annual number of novel devices approved by the FDA steadily increased almost 4-fold—from 24 to 95—to reach an all-time high during the user fee era.

Today American patients want to make decisions about their own care. They want devices to be high-quality, safe and effective and they want timely access to them. They want government to advocate for them, to take into account what matters most to them, and to be a gateway rather than a gatekeeper to innovative technologies while continuing to assure appropriate safeguards are in place. Through our [Partner with Patients](#) priority, we have already shifted our approaches to meet these needs, transitioning from a system based solely on risk, to a system based on benefit-risk tradeoffs informed by patient input.

We are actively qualifying new patient reported outcome measures, such as the [Kansas City Cardiomyopathy Questionnaire](#), and advancing the science of patient input to better assess the benefit-risk tradeoffs patients find acceptable and incorporate them into our decision making. Moreover, we established the [first FDA advisory committee comprised solely of patient representatives](#) and are working hand-in-hand with patients to incorporate their values and perspectives into all aspects of the medical device total product life cycle.

The health and quality of life of patients are dependent, at least in part, on the products that we review and we, therefore, have the clear responsibility to facilitate timely patient access to beneficial products. Because patients may not have access to an FDA approved or cleared device in the absence of adequate reimbursement, we have worked with the payer community on opportunities to streamline the pathway from FDA market authorization to payer coverage and reimbursement, such as the creation of the [Parallel Review Program](#) with the Centers for Medicare and Medicaid Services, and providing similar opportunities for private payers to participate in pre-submission meetings at a sponsor's request.

Now, with our foundation in place, we are ready to make our vision a reality. Although we will continually change to meet new and evolving scientific advancements, patient needs, evolving societal values, emerging threats, and changes in our ecosystem generally, our

new Strategic Priorities will focus on the enhancement and widespread application of three approaches we've already started to use, ultimately changing our role as a regulator from the traditional command-and-control gatekeeper to a true representative, participatory government entity that serves and enables rather than dictates to the public, fosters a spirit of community, and rewards responsible conduct.

## STRATEGIC PRIORITIES, 2018-2020

With a vision of timely patient access to high-quality, safe and effective medical devices and the recognition that our success depends on the people of CDRH, we will complete the work we have underway by December 31, 2020, through more systematic application of the following three strategic priorities:

- Employee Engagement, Opportunity, and Success
- Simplicity
- Collaborative Communities

**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, motivated, less likely to leave, and committed to the mission and vision. However, engagement requires work life balance, open dialogue, and opportunities to succeed. **Simplicity** is about how we address the challenges achieving our mission and vision present to us—our issues are often complex; our solutions and processes do not necessarily have to be. **Collaborative Communities** acknowledge that we serve the American public better and achieve our vision when stakeholders in the medical device ecosystem, including CDRH, proactively work together to solve both shared problems and problems unique to others.

## Our Measure of Success

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By December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets<sup>2</sup>.

Through the implementation of these Strategic Priorities, we will continue to improve ourselves and our program 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.

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<sup>2</sup> Novel technologies are devices subject to an original Premarket Approval ([PMA](#)) Application, panel-track supplements, [De Novo](#) classification requests, Humanitarian Device Exemption ([HDE](#)), or a premarket notification [510(k)] that is under our [Breakthrough Devices Program](#). Manufacturer intent could be measured using a survey tool. We selected this measure because it is directly tied to our Vision. We focused on manufacturer intent rather than the percent of new novel devices because we believe we can complete the steps we need to take to achieve our vision by December 31, 2020 but the full impact of our actions – U.S. patients having first access to high-quality, safe and effective medical devices of public health importance – may not be seen for a few more years. Even though a manufacturer may intend to bring their device to the U.S. first, it may take several more years to complete the data collection necessary to support market authorization, develop and submit an application for marketing authorization, and finish FDA review.

## Employee Engagement, Opportunity, and Success

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**“Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.”** This is one of our [Shared Values](#) and demonstrative of what makes CDRH great—our people.

Although we have long invested in our staff, within the boundaries of our available resources, and have included them in solving our collective challenges, we believe that making our employees a priority is just as important—if not more important—than any other priority we have undertaken now and in the past. Our 2018-2020 Strategic Priority **Employee Engagement, Opportunity, and Success** aims to improve our work life and work environment by reducing unnecessary burdens, promoting an environment of trust and mutual respect, facilitating open dialogue, fostering creativity and teamwork, providing a reasonable work life balance, and creating opportunities for professional growth and personal development.

An organization cannot be optimally successful unless its employees are fully engaged, the organization is fully invested in their professional and personal development and committed to their retention, they have the resources they need, and work in an environment that helps them succeed. CDRH is no exception. As we work to become the employer-of-choice, we better position ourselves to meet our vision.

### Our Current Work

In recent years, we have assessed the needs of our employees and developed recommendations to address them. From 2012 to 2013, our Employee Satisfaction Working Group engaged across CDRH, as well as assessed the actions of other Federal entities to develop recommendations to address the five areas where the Center scored the lowest on the annual Federal Employee Viewpoint Survey. These areas are the same as for other parts of the Federal government. Subsequently, we implemented their recommendations, including revamping and expanding our rewards and recognition program. In 2015, the Center launched the CDRH Engage initiative, a direct result of staff

feedback from the 2014 CDRH Customer Service Classes, CDRH's Customer Service Survey, and the 2014 and 2015 Federal Employee Viewpoint Surveys. From 2015 to 2017, our CDRH Engage Working Group reached out across the Center to develop recommendations to enhance engagement by all of our staff and managers. Currently, we are in the midst of implementing the recommendations, which include establishing and continually updating individual development plans, which address training and development needs for each CDRH employee.

Over the past two years, we have explored, piloted, and developed implementation plans to combine our Office of Compliance, Office of Surveillance and Biometrics, and Office of Device Evaluation into a single "super office." This re-organization, which will also include the Office of In Vitro Diagnostics and Radiological Health (OIR), will help us improve information sharing, decision making, and work efficiency by instituting a TPLC<sup>1</sup> approach to many of our core activities, similar to how OIR operates today. The opportunities that this new organization creates for our employees are significant. Under this new structure, we will do much more, including giving all of our employees more opportunities and greater predictability to grow personally and professionally without having to seek different jobs – to essentially grow in place rather than having to leave a job to advance, as they too often have to do. This will include managers and staff whose sole responsibility is the professional development of their Office colleagues.

An essential component of the TPLC transformation is ensuring that our management operations and administrative services are optimally aligned, structured, and delivered, not only in the new TPLC organization, but throughout the entire Center. Our CDRH Management Operations Review and Modernization (MORM) initiative aims to improve management operations and administrative services—recruiting and retaining our world-class workforce, securing the resources and facilities needed to operate, and having mechanisms to seek outside experts to inform our regulatory decisions and are critical to our organization's success. Like TPLC, MORM will create opportunities for career and professional development that do not exist today. The new methods we are test-driving

and refining through our new Office of Product Evaluation and Quality and MORM will serve as models for the rest of the Center.

An additional key success factor for the transformation is to continually ensure that barriers and silos become a thing of the past. The new teams that are formed as part of our modernization will engage colleagues across Offices in the Center, and with others outside the Center.

### The Next 3 Years

Over the next 3 years, we will complete our efforts to make the CDRH workplace one of trust, mutual respect and accountability, ongoing and open dialogue, and personal and professional growth. Our own research and results of the 2017 Federal Employee Viewpoint Survey show that over 70 percent of our workforce is engaged and our turnover rates best those in much of the public and private sectors but we know we can and we commit that we will do better. Our employees deserve no less than a best-in-class work life and work environment, and the American public deserve no less than a fully engaged, best-in-class workforce.

#### *Employee Engagement, Opportunity, and Success Metric*

By December 31, 2020, achieve at least an 80 percent employee engagement level.

#### *Implementation*

The CDRH Engage Council will oversee the implementation of this strategic priority.

## Simplicity

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**Simplicity** stems from our recognition that while the issues we deal with are often complex, our solutions and the processes we use to address them don't necessarily have to be.

Simplicity means that in everything we do, we continually streamline our policies, processes, programs, and approaches, as appropriate, to more effectively, efficiently, and quickly achieve our mission and vision. It means we stop doing or streamline what we determine is not sufficiently "value added" to the regulatory process and free our CDRH team to spend more time on what matters most to patients and staff. It means our policies are as straightforward as possible, including developing decision aids, when appropriate, to assure that anyone who would apply the policy in a given case, whether they be in the Center, industry or elsewhere, will arrive at the same outcome. And it means removing unnecessary burdens we impose on ourselves, such as through cumbersome processes, vague policies, and out of date information technology systems. It does not mean changing our regulatory standard of reasonable assurance of safety and effectiveness, our reliance on robust, valid scientific evidence, nor our dedication to our public health mission. To the contrary, it means improved decision making and better use of our resources to achieve our public health mission and vision. And it is consistent with, but is more than, the least burdensome provisions, the importance of which was further reinforced by the 21<sup>st</sup> Century Cures Act ([Cures Act](#)), and with our efforts to become the employer-of-choice and a best-in-class organization.

In applying an approach of simplicity, we must tackle the extent of uncertainty we and our customers encounter in a given circumstance. We almost always encounter uncertainty when making decisions, particularly regarding the benefits and risks of a device before it has been in widespread use, yet this cannot be a reason for delay or the imposition of unnecessary or not sufficiently value-added requirements on ourselves or our customers. For example, typically we will not know the full benefit-risk profile of a device before it is widely used in or on patients in routine clinical practice. Even very large premarket clinical trials generally do not reflect the true spectrum of benefits and risks but may impose

unreasonable costs and time delays that ultimately adversely affect patients. We must be *pragmatic* and *balance* an appropriate level of uncertainty as one of several factors in our decision making rather than as a determinative factor upon which we draw conclusions so that the desire for certainty is balanced against patient access and unmet clinical needs.

## Our Current Work

Our focus on continuous improvements, organizational excellence and quality management promotes simplicity. Quality and excellence require we engage in continuous improvement, *leaning* and improving our processes to better serve all our customers – internal and external, reducing unnecessary burdens, and increasing quality and predictability. We are working to reduce burden and improve the efficiency of CDRH core processes, in part through our implementation of a modern quality management system and further advancing our culture of quality.

We have already taken steps to simplify our policies and processes. For example, we continue to implement and expand the application of the least burdensome principle—the minimum amount of information necessary to address a regulatory issue through the most efficient manner, at the right time. In 2015, we [re-evaluated every device type under a PMA](#) to determine whether, based on the current state of the science, we should stop requesting certain data, shift some premarket data collection to the postmarket setting, down classify the device type, or not change how we regulate it. On the basis of our review, we concluded that we should change how we regulate 30 percent of the 210 device types then subject to PMA review. In 2017, we exempted more than [1,000 Class II devices from submitting a 510\(k\)](#) using a new process made available through the Cures Act.

Another example, is the just-in-time approach to product testing we implemented in our [Early Feasibility Clinical Study Guidance](#). Although a variety of testing must be completed and safeguards must be in place before patients can be enrolled in an early feasibility study, not all testing and safeguards must necessarily have been addressed to approve

or initiate the study. By reducing the time and cost for approving early feasibility studies, we have seen an increase in the number of such studies conducted in the U.S. Because device developers tend to seek product approval first in the countries in which they initially start their clinical trials, the growing number of early feasibility studies being conducted in the U.S. suggests that we will see earlier U.S. patient access to the technologies being evaluated if the evidence ultimately supports U.S. approval.

We also have developed flexible regulatory paradigms; pathways tailored to specific technologies. Instead of trying to fit devices into *one-size-fits-all* regulatory pathways, we believe regulatory pathways should be designed around the technology type and its unique evidence generation, innovation cycle, and patient access needs – while still meeting the U.S. standard of reasonable assurance of safety and effectiveness.

Our new approach to the oversight of direct-to-consumer genetic health risk ([DTC GHR](#)) tests serves as an example of a new flexible regulatory paradigm. For the first time ever, we implemented a firm-based framework. Unlike our traditional product-based framework in which each product and select modifications of those products are reviewed by CDRH prior to marketing, under this firm-based approach, the sponsor of DTC GHR tests only has to undergo a one-time premarket review of their test for a single claim. If the sponsor can demonstrate they do a good job on validating their test and performing consumer comprehension studies, they do not have to submit new claims and modifications to CDRH for premarket review, with a small set of exceptions. We implemented this new framework to best account for the rapidly developing science and lower risks to patients. Currently, we are piloting a similar firm-based approach for developers of lower-risk digital health technologies.

We also stopped expending human resources in areas we determined were not necessary to protect the public health. For example, in 2013, we issued our [Mobile Medical Apps Guidance](#). Through that guidance we exercised enforcement discretion for dozens of medical device functions we had previously actively regulated. We determined that patients could benefit from the innovation in digital health technologies we were

seeing if we de-regulated this space while not exposing patients to unnecessary safety problems given that these were lower risk functions with a good safety track record. The Cures Act codified and expanded this and other similar CDRH policies.

Simplicity requires that we remain agile. For industry to be innovative, government must be innovative. We must be well-positioned to try new things, fail fast, and get out ahead of where the science and technologies are going to be. For example, in our [Breakthrough Devices Draft Guidance](#), we proposed to employ what we call *sprints* in which the sponsor of a breakthrough technology identifies a regulatory challenge they need to solve and we then work interactively with the sponsor to address that challenge within a few weeks.

### The Next 3 Years

We will spend the next 3 years focused on applying the simplicity approach, as appropriate, in all that we do. The approach is consistent with the Continuous Improvement paradigm of our nascent quality system, and will become embedded in our day to day operations as we modernize our operations. The medical device ecosystem has become increasingly varied and complex, and we keep building on our existing policies and processes based on experiences and theory rather than redesigning them to better meet the changing needs of our customers today and reduce the additional workload unnecessary complexity creates for our employees and our customers. Although well intentioned, by adding new layers of requirements and processes without revisiting the value of these modifications in the aggregate, we may unintentionally create unnecessary hurdles and policies and processes that are so complex that there is a risk of incorrect and inconsistent implementation and adherence. Moreover, imposing new or expanded requirements on industry or new or expanded internal requirements or processes within CDRH can add additional burden on CDRH employees and/or our external customers without translating into a sufficient benefit for public health to warrant the added burden. In contrast, by applying the simplicity approach we can free up and better use our resources to focus on what has the biggest positive impact on public health.

We will continue to expand the application of simplicity and incorporate it into all that we do. For example, through the issuance of new policies and internal procedures we will complete the transition from a risk-based framework for medical device regulation to a benefit-risk framework that makes explicit the societal tradeoffs of the decisions we make and offers several regulatory options depending upon these tradeoffs. We also will explore international convergence of some of these pathways—but not change our regulatory standard for market authorization nor our reliance on valid scientific evidence—as we continue to work under the auspices of the International Medical Device Regulators Forum ([IMDRF](#)) to put in place the building blocks for creating a Medical Device Single Review Program. Under such a program, should it be established, the market authorization decision made by or on behalf of one participating jurisdiction would be relied on wholly or in part to support marketing authorization by other participating jurisdictions.

#### *Simplicity Metric*

By December 31, 2020, *lean* at least 80 percent CDRH core processes.

#### *Implementation*

CDRH's Leadership Team will oversee the implementation of this strategic priority. Tasks will include the development of principles for applying the simplicity approach.

## Collaborative Communities

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The hallmark of a Collaborative Community, is a continuing forum where public and private sector members proactively work together to solve both shared problems and problems unique to other members in an environment of trust and openness, where participants feel safe and respected to communicate their concerns. Members share a *collective responsibility* to help each other obtain what they need to be successful. Our early experience with developing and working with **Collaborative Communities** suggests that continuing to invest in building these cooperative relationships will improve the success of our meeting our commitment to public health and achieving our vision.

We will apply this approach to both domestic and international regulatory activities. The role of CDRH will be to foster a *community spirit* and *responsible choice* through the creation of Collaborative Communities with broad and fair representation to solve problems and proactively build for the future. We will enable our customers to take a more active role in the advancement of *smart regulation* and the rise of *Patient Scientists*—those scientists, health care professionals, engineers and others who focus on serving the unmet and developing needs of patients and who incorporate their own experiences as or with patients into their work in industry, health care, and government.

### Our Current Work

CDRH has applied the concept of Collaborative Communities in several instances. Our investment in [NEST](#) is a case in point of what could become a Collaborative Community. One of our most critical marks over the next 3 years will be to help establish and launch NEST. Established in 2017, the Governing Committee of the NEST Coordinating Center is made up of representatives of the key stakeholder groups in the medical device ecosystem and its objective is to drive down the time and cost of real-world data collection and analysis and to increase the value and use of real-world evidence to meet the various needs of the different member groups of the community, including timely patient access to beneficial medical devices, coverage and reimbursement, adoption of beneficial

technologies by patients and health care professionals, and more timely and effective postmarket surveillance. In this regard, NEST is being established as an entity of, by, and for the community.

The public-private forum established to create a competitive and transparent marketplace around device quality, as part of our [Case for Quality initiative](#), is another example of what could become a Collaborative Community, through its engagement of medical device purchasers, payers, patients, industry, and government. Through this on-going initiative, we are working to create a competitive marketplace for device quality, creating market-based and regulatory incentives to reliably and consistently manufacture high-quality devices.

The benefits offered by the Unique Device Identification System ([UDI](#)) can only be fully realized with the adoption and use of UDIs by the medical device ecosystem—manufacturers, distributors, payers, providers, patients, health care systems and other stakeholders with important roles to play throughout the medical device lifecycle. The Learning UDI Community ([LUC](#)), which is sponsored by the Association for Healthcare Resources and Materials Management (AHRMM), involves all members of the medical device ecosystem in developing a common understanding and approach to UDI adoption within the health care setting. Its work has significantly informed and accelerated UDI adoption.

The collaborative forums we proposed for [next generation sequencing tests](#) serve as a fourth example of the concept of Collaborative Communities. Under this proposal, representatives from the clinical community, working with other members of the ecosystem (e.g., test developers, patients) through existing or new entities, such as health care professional societies, would assess the evolving science to recommend when the state of the science adequately supports the association between particular genetic variants and specific diseases or conditions (clinical validity). CDRH would rely wholly or in part on these recommendations to support marketing authorization for these claims either through a premarket review process or in lieu of premarket review

altogether. These continuous forums also would help establish standards for analytical validity for the community that CDRH could adopt. We believe this approach could be applied to many types of tests and could become a principal framework for the smart regulation of diagnostic and predictive tests generally.

The [artificial pancreas](#), a revolutionary advance in diabetes care and a life-changing technology for people with type 1 diabetes, exemplifies the significant public health impact Collaborative Communities can have. This collaboration between diabetes patient groups, diabetes care providers, medical device manufactures, and CDRH resulted in the approval of the first automated insulin delivery system in the world.

### The Next 3 Years

We will make building Collaborative Communities our standard practice. In addition, we will consider whether a Collaborative Community approach could be adopted across two or more countries. IMDRF, whose mission is to advance the convergence and harmonization of medical device regulation and of which the U.S. is a co-founder and active member, could serve as a catalyst for the establishment of global Collaborative Communities.

#### *Collaborative Communities Metric*

By December 31, 2020, establish at least 10 new Collaborative Communities.

#### *Implementation*

CDRH will convene a cross-Center Steering Committee to oversee the implementation of this strategic priority. Tasks will include the development of a code of conduct and best practices for these communities.

## CONCLUSION

By fully and consistently implementing these priorities and thereby changing what it means for CDRH to be a modern-day regulator, along with continuing our ongoing efforts to transform the FDA's medical device program, we can make good on our commitment to U.S. patients that they will have access to high-quality, safe and effective medical devices of public health importance first in the world.

