# Executive Summary

One of the primary goals of the Innovation Pathway is to transform the experience for innovators working with FDA and for FDA working with innovators. In designing the Collaboration Phase we asked ourselves: Can a more collaborative culture lay down a new foundation for FDA's internal business processes? What would happen if FDA and the applicant worked cooperatively during the total product life cycle to create a shared understanding of both the developmental and regulatory processes?

Innovation Pathway 2.0 experiments with a different model of interaction and engagement between innovators and FDA. The Collaboration Phase, one of IP2.0's key features, is a mostly unstructured period that lays the ground work for deeper knowledge and a shared view of the benefits and risks of the product, allowing both parties to chart a regulatory pathway that is sensitive to time, and therefore indirectly cost. The amount of time spent in the Collaboration Phase is agreed upon by the applicant and the FDA at the outset (with a120-day maximum), giving flexibility for both sides to strive for agreement, and allowing a customized approach for each company. While FDA retains responsibility for regulatory decision-making, the intent is to arrive at these decisions in a collaborative way.

The guiding principles behind the Collaboration Phase include creating a **shared understanding of product success** including its **benefits and risks**, creating solutions that **facilitate forward progress**, allowing **experimentation, prototyping, and learning**, and striving for greater **transparency**.

Successful components of the Collaboration Phase are expected to drive the business processes used by FDA and are intended to be supported and enhanced by the information technology infrastructure.

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# Case Studies of the Collaboration Phase

The following three case examples are used to illustrate the philosophies, features, and processes of the Collaboration Phase.

## Case 1:

"GemMedix" is a start-up company that has developed an innovative monitoring system intended for consumers, and has been accepted onto the Innovation Pathway. A venture-funded company, they are early in the prototype phase and have performed engineering and animal testing that demonstrates proof of principle. They are unclear whether certain features of the product are regulated by the FDA. For the features that are regulated by the FDA, there does not appear to be a predicate.

For the Collaboration Phase, GemMedix and FDA agree to bi-weekly interactions over a 60-day period, with the goal of getting clarity on the regulatory pathway. Since the company is based in Seattle, meetings are conducted through videoconferencing with the FDA team. Organized and facilitated by the FDA case manager using best-practices for meetings, the early interactions serve to educate both FDA and the company, peer-to-peer, on both the device and various regulatory approaches which could lead to device marketing. GemMedix ships two prototype devices to the FDA team and shows a video demo of how the product will be used by consumers. Subsequent meetings include FDA's program operations staff and a policy analyst to tackle issues related to product classification. Over the course of several meetings, a regulatory pathway is established along with a rough estimate of the timeline for future interactions.

GemMedix remains concerned that one part of the proposed regulatory pathway will considerably delay market entry. Recognizing this is a critical

decision point, the FDA or GemMedix review team can request higher level FDA review at this time.

Using a prototype collaborative workspace, GemMedix and FDA create the documents that will serve to capture the key decisions reached during collaboration. At the end of the Collaboration Phase, FDA converts components of these into a completed pre-IDE application for the purpose of documenting and archiving the material, and the appropriate reference letter is sent to the company. The collaborative workspace remains open for future interactions and linking of key documents among team members.

The GemMedix and FDA team members answer a satisfaction survey at the end of the Collaboration Phase, which results in constructive suggestions to both sides.

## Case 2

"Spectrum" is developing an implantable technology for patients with autism. They have conducted extensive safety studies on animals and previously submitted a pivotol IDE to FDA that had been disapproved. Because this technology represents medical device innovation addressing clinical needs and improved patient care, and alternative treatments are unavailable, Spectrum is accepted onto the Innovation Pathway.

Spectrum and FDA agree to a 45-day Collaboration Phase during which there will be extensive discussion of initial clinical insights and the data necessary to support an early feasibility study. The FDA case manager suggests consultation with the Network of Experts to propose a device evaluation and trial evaluation strategy to best describe the device and procedure-related attributes and also to address the potential failure modes.

Working together, patient and caregiver needs are identified and tied to the possibility of technology addressing them. There is a shared concern and discussion about the risks of this technology, as well as the benefits it could bring.

The Spectrum and FDA team members use a prototype "decision tool" that steps them through the expected risks and benefits for the device when used in patients with autism. Previous discussions with caregivers and patients help to establish clinically relevant trade-offs between risks and benefits and become part of the decision framework. This exercise helps the team generate a common understanding of the minimum evidence FDA needs to make decisions at key stages: 1) at the time of IDE submittal for the first in human trial; 2) at the time of IDE submittal for the pivotal trial; and 3) at the time of premarket submission to support the approval decision. Should the PMA be approved, the decision framework would then be incorporated into the published Summary of Safety and Effectiveness, making public the basis on which FDA's benefit-risk determination was made.

## Case 3

In response to an Innovation Challenge, several companies developing similar technologies are accepted on the Innovation Pathway, each at different stages of development. Each company is working separately with FDA during their respective Collaboration Phases. However, because they will share similar regulatory challenges, FDA opens a public collaboration workspace to post questions and answers. With permission from each company, specific regulatory issues are converted into generic questions for open discussion, allowing applicants to contribute to the developing opinions.

During the course of the Challenge, FDA hosts a virtual workshop for all participants. The virtual workshop is a public, moderated conversation with subject matter experts both inside and outside the agency.

# Guiding Principles for the Collaboration Phase

The following guiding principles, which are used in the case examples, serve to define the "rules of engagement" among the participants and FDA.

## Principle 1: Share an In-Depth, Common Understanding of Success

The Collaboration Phase is intended to provide sufficient unstructured time between the applicant and FDA to allow experiential learning about the product, including hands-on interaction through manufacturing and health care facility site visits, in-person demonstrations of the new device, and/or video demonstrations, etc. Using best practices in idea exchange, such as IT tools that promote collaboration, document sharing, conversations, and peer-to-peer interactions, this period drives toward the goal of generating a shared understanding of the product. Leveraging outside experts through FDA's Network of Experts can enrich the dialogue and more quickly identify and resolve important scientific questions.

## Principle 2: Apply Best Practices in Framing Benefit and Risk

To assure that decisions are based on an appropriate balance of benefit and risk, teams will work from a number of guidance documents, including the following (which currently exist in draft form, and therefore will be implemented when finalize):

- "*Draft Guidance for Industry and Food and Drug Administration Staff – Factors to Consider when Making Benefit-Risk Determinations in Medical Device Premarket Review*,"
- "*Draft Guidance for Industry and Food and Drug Administration Staff – Investigational Device Exemption (IDE) for Early Feasibility Medical*

*Device Clinical Studies, Including Certain First in Human (FIH) Studies*,"

- "*Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations*," and
- "*Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff - Design Considerations for Pivotal Clinical Investigations for Medical Devices*."

In addition, teams will work with a decision support tool at appropriate points in the regulatory pathway. To understand the product in the context of current clinical practice, and to the evaluation of benefits and risks, teams will incorporate patient, caregiver, and physician perceptions of the benefit-risk trade-offs into decision-making.

## Principle 3: Create Solutions that Facilitate Forward Progress

During the Collaboration Phase, the team shares responsibility for developing a pathway that is least burdensome and predictable while allowing for some measure of flexibility, understanding that some issues are within FDA's control to address, some can only be influenced, and others are not within FDA's sphere of influence. Regardless of FDA's level of control we proactively commit to share with innovators the responsibility to reduce the cost and time from development to market without changing our approval standard of reasonable assurance of safety and effectiveness or our evidentiary standard of valid scientific evidence. Critical decision points are approached in a way that permits re-examination of past precedents and allows new approaches. Critical decision points might include: device classification, de Novo versus PMA, significant risk versus non-significant risk clinical trials, and pre-market versus post-market evidentiary requirements.

## Principle 4: Improvise, Experiment, Prototype, Test, and Learn

The Collaboration Phase results in a pathway that is customized based on an on-going discussion with the company. The charted pathway is allowed to "fail fast" by promoting frank assessment of it as it is traversed, and allowing adjustments to be made as necessary. Surveys of the participating innovator and FDA staff conducted at critical points are intended to provide more regular feedback to both sides, helping to de-stigmatize the feedback process and encouraging the team to learn.

## Principle 5: Full Transparency in Decision Making

Because of the collaborative nature of this phase, the innovator should have a clear picture of how FDA intends to make critical decisions about the product's trajectory through the regulatory process. By allowing critical decisions to receive higher level FDA review, the process is intended to reduce uncertainty about future decisions. Prior to market approval, documents supporting the decision-making framework can be viewed and discussed between the innovator team and FDA. At the time of approval, portions of these documents will be incorporated into the published Summary of Safety and Effectiveness (for PMA devices) to allow transparency of process. The team will also work collaboratively with other experts to develop new guidances or update existing guidances, providing a more predictable pathway for future applicants.

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# CDRH INNOVATION INITIATIVE

February 2011
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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## EXECUTIVE SUMMARY

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or the Center) is responsible for advancing public health and facilitating innovation to help bring novel technologies to market and make the medical devices that are already on the market safer and more effective. As part of this Medical Device Innovation Initiative, CDRH is outlining additional actions the Center might take to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients.

The Innovation Initiative proposes actions CDRH could take to help accelerate and reduce the cost of development and regulatory evaluation of innovative medical devices safely and based on sound science. These actions include:

- **Facilitate the development and regulatory evaluation of innovative medical devices by:**
  - Establishing the Innovation Pathway – a priority review program for pioneering medical devices; and
  - Streamlining the *de novo* pathway.
- **Strengthen the U.S. research infrastructure and promote high-quality regulatory science by:**
  - Establishing a voluntary third-party certification program for U.S. medical device test centers;
  - Creating a publicly-available core curriculum for medical device development and assessment;
  - Leveraging device experience and data collected outside the United States; and
  - Advancing regulatory science for medical devices through prioritizing scientific research, establishing public-private partnerships, collaborating with other government agencies, and holding public workshops.
- **Prepare for and respond to transformative innovative technologies and scientific breakthroughs by**:
  - Enhancing CDRH's current horizon scanning process by adopting emerging horizon scanning methods, seeking public input to identify important and innovative medical device technologies as they arise, and periodically reporting its horizon scanning findings to the public; and
  - Developing a Network (or Networks) of Experts to serve as a resource to assist in addressing scientific questions about emerging technologies with which our reviewers might not be immediately familiar.

CDRH is seeking public comment on all of the above actions and the proposals set out in the Medical Device Innovation Initiative through an open public docket and will be hosting a public meeting to solicit stakeholder feedback at our White Oak, Maryland, campus on March 15, 2011.

## BACKGROUND

The United States is the global leader in medical device innovation and CDRH is committed to assuring that American patients have timely access to important new technologies and next-generation products without compromising their safety. Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

CDRH is responsible for advancing public health by facilitating innovation to help bring novel technologies to market and make the medical devices that are already on the market safer and more effective. Recently, the Center announced 25 actions it will take in 2011 to strengthen its most widely-used premarket review process – the 510(k) program – and reduce uncertainty in its use of emerging science to foster innovation and improve the predictability, consistency and transparency of its decision making.[1] These actions will not only improve the safety and effectiveness of medical devices but also increase the ability of innovating companies to attract investors, estimate costs, and more quickly bring products to market.

As part of this Medical Device Innovation Initiative, CDRH is proposing additional actions the Center could take to encourage innovation, streamline regulatory and scientific device evaluation, and expedite the delivery of novel, important, safe and effective innovative medical devices to patients. Because improving the predictability of our premarket review programs is our number one priority, CDRH will proceed in a manner that does not delay the implementation of critical actions to reduce uncertainty and that does not adversely impact our premarket review performance. Instead, we will implement the Innovation Initiative to the extent practical given current resources, and would consider expanding the Initiative should additional resources become available.

In light of our commitment to meeting our Medical Device User Fee Act performance goals and improving the predictability of our current regulatory processes, expending significant resources to implement the Innovation Initiative is a luxury we cannot afford. Although, given current resources, we cannot yet make a radical overhaul of our review processes; we can lay the foundation for the new paradigm we are proposing herein.

CDRH is seeking public comment on the proposals contained in this report through an open public docket and will be hosting a public meeting to solicit stakeholder feedback at our White Oak, Maryland, campus on March 15, 2011.

### Innovation and Medical Device Development

New scientific discoveries or novel ideas are often at the root of innovative medical device development – whether the product is a transformative technology, a modified version of an already marketed model, or a novel application of existing tools or scientific approaches. The

[1] *See* "510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps." Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf, and "Plan of Action for Implementation of 510(k) and Science Recommendations." Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf.

regulatory process affects a significant portion of the device development pathway. To the extent it is feasible, regulatory pathways should accommodate and facilitate the iterative, cyclical nature of device design and development. They should also account for the inevitable cycles of design-prototype-test-redesign that are inherent to the development process.

CDRH has used a total product life cycle model (see **Figure 1**) to illustrate the iterative nature of medical device design and development and to highlight the importance of incorporating user needs and device experience into next-generation device development.

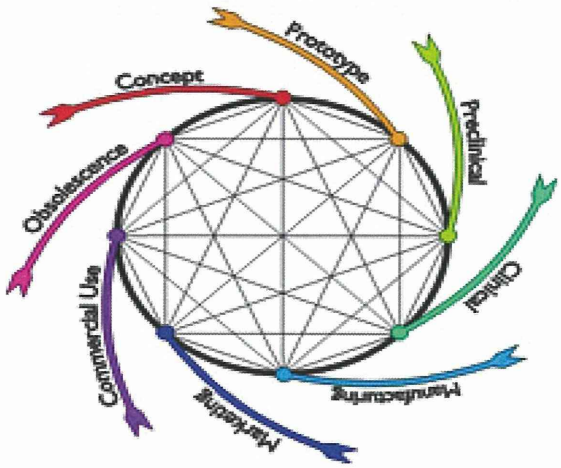


**Figure 1.** *The Total Product Life Cycle approach to medical device development and regulation is shown. Medical device development is an iterative process that rapidly incorporates preclinical, clinical, and manufacturing experience into next-generation concept and design.*

A large portion of a device's total product life cycle is occupied by product development from concept to marketing. The pathway to successful device development is cyclical and iterative as ideas are prototyped, tested, improved, re-tested, optimized and finalized. The device development pathway is a continuum with feedback loops and device modifications (**Figure 2**). Although portrayed as a compartmentalized process with distinct phases – such as pre-clinical and clinical – steps in device development overlap and portions may need to be repeated as testing and user experience are incorporated into product modifications and the device moves closer to its marketed form. And, product evaluations and modifications continue to occur even after a product reaches the market.

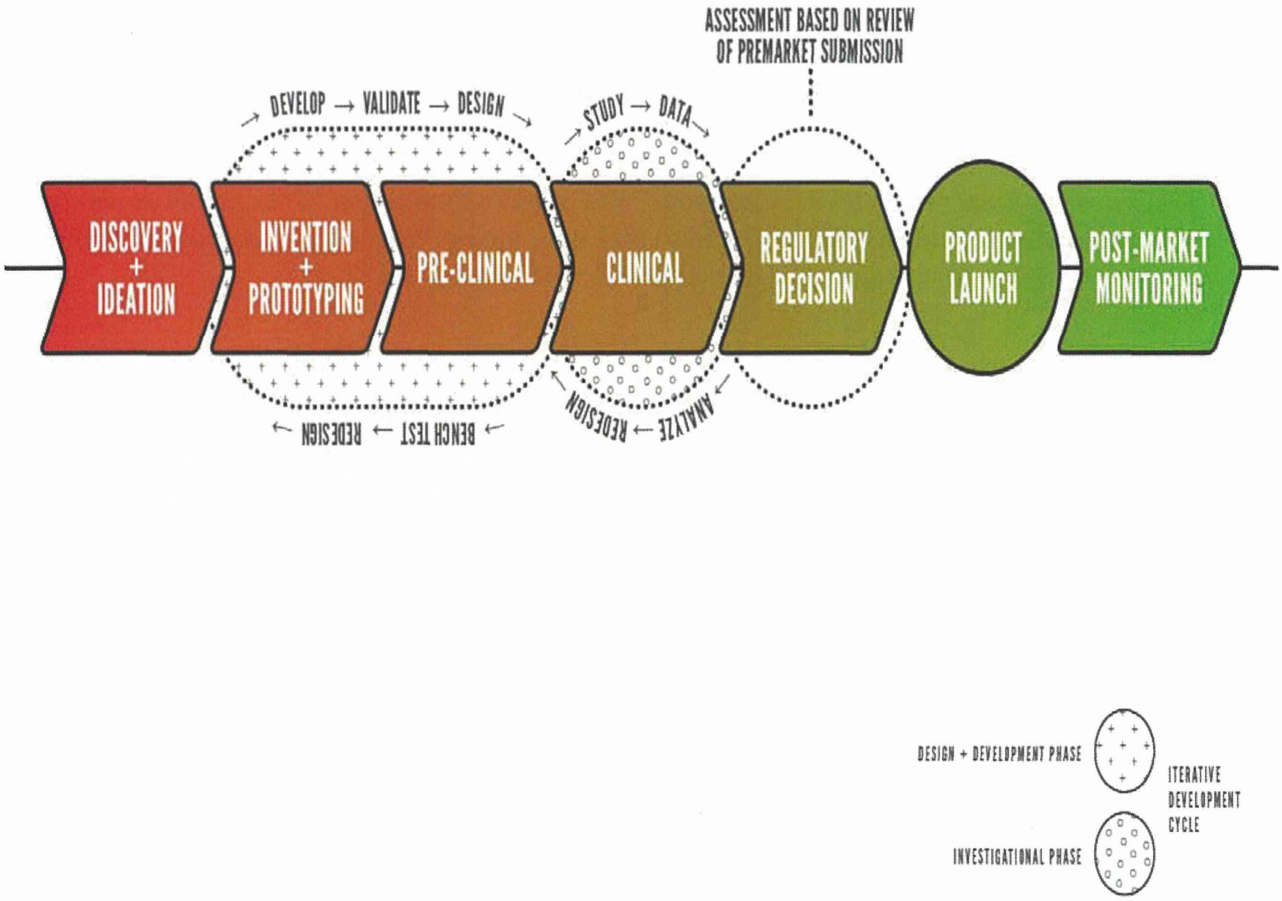


**Figure 2.** *The medical device development pathway from discovery and ideation to product launch and post market monitoring is shown. The regulatory process affects a significant portion of the device development pathway and should accommodate the iterative, cyclical nature of device design and development.*

CDRH's current regulatory pathways are designed to accommodate the incremental improvements manufacturers make to their marketed devices. The regulatory process allows manufacturers to modify existing devices and submit supporting data for regulatory review on a shortened timeframe. The 510(k) process facilitates access to modified versions of marketed lower-risk products by providing a streamlined review pathway for new devices proven to be "substantially equivalent" to legally marketed "predicate" devices. This pathway promotes evolutionary enhancements by providing a quicker pathway to market for newer versions of legally marketed lower-risk devices. Similarly, manufacturers may submit certain changes to devices approved under the premarket approval (PMA) process as PMA supplements that leverage previous device testing and experience where appropriate. The Center has also created certain resource-intensive review processes to reduce Agency decision times while still allowing for adequate assessment of an application. These programs include "real-time review", wherein CDRH will issue a decision on a PMA supplement generally within five business days of meeting with the sponsor, and "interactive review", which facilitates the efficient and timely review and exchange of regulatory and scientific information between CDRH and the sponsor.

## CDRH's Innovation Initiative

CDRH recognizes that transformative innovative devices typically present new scientific and regulatory challenges. The Innovation Initiative supports the development of innovative products by addressing some of the barriers that can impede a product's timely progress to market.

The Innovation Initiative proposes actions CDRH could take to help accelerate the development and regulatory evaluation of innovative devices safely and based on sound science. These actions are:

- Facilitate the development and regulatory evaluation of innovative medical devices;
- Strengthen the U.S. research infrastructure and promote high-quality regulatory science; and
- Prepare for and respond to transformative innovative technologies and scientific breakthroughs.

## 1. FACILITATE THE DEVELOPMENT AND REGULATORY EVALUATION OF INNOVATIVE MEDICAL DEVICES

### 1.1 Create a Priority Review Program for Pioneering Technologies (the Innovation Pathway)

Recognizing the important benefits truly innovative medical devices have on the public health of Americans, CDRH proposes to establish a priority review program – the Innovation Pathway – for eligible innovative products.

CDRH has long recognized the importance of facilitating innovation and expediting the review of important new technologies. The expedited review process for medical devices was first established in 1994, and most recently described in a 2008 FDA Guidance entitled "Expedited Review of Premarket Submissions for Devices", which incorporated changes under the Food and Drug Administration Amendments Act of 2007 (FDAAA)(Public Law 110-85).[2]

A device is considered appropriate by FDA for expedited review if it:

1. is intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition, and
2. addresses an unmet medical need, as demonstrated by any one of the following:

[2] As described in the Expedited Review guidance, *see* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089643.htm, FDA is required by statute (section 515(d)(5) of the Federal Food, Drug, and Cosmetic Act) to review only PMAs meeting certain conditions on an expedited basis. FDA, however, uses the criteria as guidelines for expedited review of product development protocols, 510(k)s and *de novo* classifications.

a. The device represents a breakthrough technology[3] that provides a clinically meaningful advantage over existing technology;
b. No approved alternative treatment or means of diagnosis exists;
c. The device offers significant, clinically meaningful advantages over existing approved alternative treatments; or
d. The availability of the device is in the best interest of patients.

In the six-year period beginning with 2005 and ending with 2010, approximately 7% of PMA submissions, representing 23 out of 314 applications received, were granted expedited review status. Expedited review times are typically longer than standard review times and have not reliably met the targets FDA agreed to as part of Medical Device User Fee Act (MDUFA) negotiations, primarily due to the unique regulatory and scientific challenges presented by devices that are granted expedited review status. Nevertheless, compared to what would have occurred under the standard review program, expedited review has shortened the time to market for a number of important innovative technologies including drug-eluting coronary stents, implantable pacemakers, vision and hearing systems, and continuous glucose monitors.

The Innovation Pathway (**Figure 3**) is intended to provide earlier investment of Center time and resources in devices that are truly pioneering technologies and that have the potential to revolutionize patient care or health care delivery. We anticipate that the devices reviewed under this pathway may raise scientific and regulatory questions that are novel, challenging and resource-intensive. While it is critically important to take steps to facilitate the development of transformative innovative devices, we also recognize the importance of meeting our commitments under MDUFA. Therefore, the number of devices that we would be able to accommodate under the Innovation Pathway would depend on available resources. We would closely monitor our resources so that our performance and commitments for the review of other devices are not adversely affected, thus avoiding unintended consequences for devices reviewed under other pathways.

[3] Breakthrough technologies should be demonstrated to lead to a clinical improvement in the treatment or diagnosis of the life-threatening or irreversibly debilitating condition.

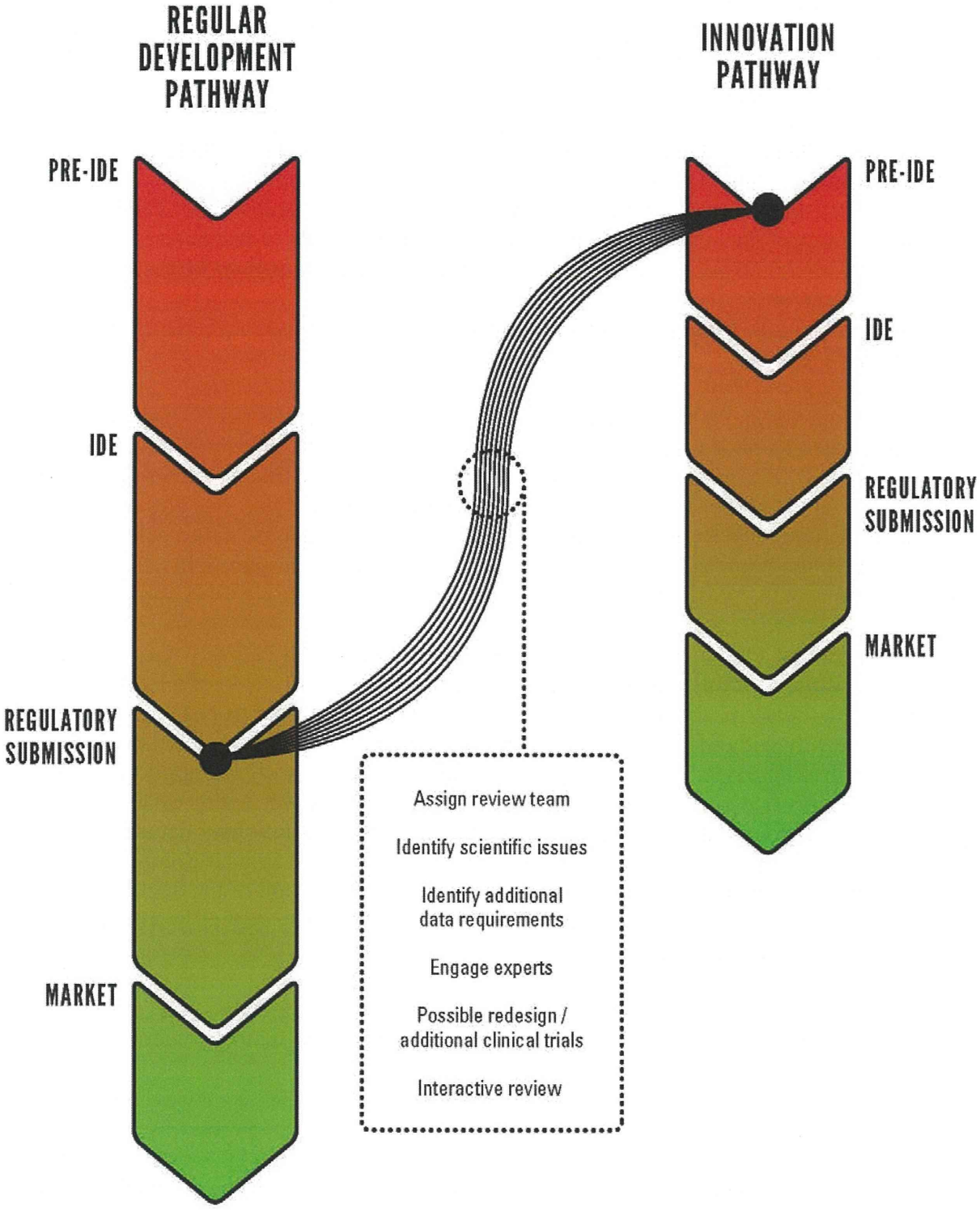


**Figure 3.** *The Innovation Pathway recognizes the unique nature of transformative innovative product development. By front-loading critical aspects, such as identifying appropriate clinical endpoints and key scientific questions, and seeking advice from external experts, we can provide a more timely and efficient regulatory review process.*

CDRH proposes that, to be eligible for consideration for the Innovation Pathway, the Center would have to determine that the device is radically different from any legally marketed medical device in the United States in its underlying technology or manner of use, and is designed to meet at least one of the following criteria:

1. significantly improve upon currently available treatments or diagnostics for life-threatening or irreversibly debilitating diseases or conditions;
2. treat or diagnose a life-threatening or irreversibly debilitating disease or condition for which no approved or cleared alternative treatment or means of diagnosis exists;
3. address an unmet public health need as identified by the Council on Medical Device Innovation; or
4. address an issue relevant to national security such as vaccine development and medical counter measures.

Although the Innovation Pathway is a proposal for which CDRH seeks public comment, the Center has accepted a pilot submission into the program: a revolutionary brain-controlled upper-extremity prosthetic designed to restore near-natural arm, hand and finger function to patients suffering from spinal cord injury, stroke or upper-extremity amputation. The arm system, funded by the Defense Advanced Research Projects Agency (DARPA), will use a microchip implanted on the surface of the brain to record neuronal activity and decode the signals to actuate motor neurons that control the prosthesis.

CDRH proposes that additional candidate devices for the Innovation Pathway may be identified in one of two ways: 1) at the request of the sponsor; or 2) at the suggestion of a CDRH employee or manager with the permission of the sponsor. No submissions would be considered for the Innovation Pathway without the explicit consent of the sponsor. The Center Science Council, which is described in greater detail below, would meet regularly to evaluate applications to the Innovation Pathway and would communicate a decision to the sponsor within 30 days of the application submission date. Decisions would be based on the revolutionary nature of the device, how well the submission meets the criteria listed above, and available and anticipated Center resources. Because of the innovative and transformative nature of the devices eligible for this pathway, it is expected that devices reviewed under this pathway generally will be PMA, PMA supplement, and *de novo* submissions.

The Innovation Pathway would have the following key features designed to meet the unique requirements of transformative medical device development and regulatory review:

- **Oversight by the Center Science Council (CSC)**[4] – The CSC, a new oversight body currently being developed within CDRH, will be comprised of a cross-disciplinary group of CDRH senior managers and experienced review staff. The CSC would monitor the device development and review processes from the date of acceptance into the Innovation

[4] *See* Footnote 1. *Also see* "CDRH Preliminary Internal Evaluations – Volume I: 510(k) Working Group Preliminary Report and Recommendations." and "CDRH Preliminary Internal Evaluations – Volume II: Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations." Available at http://www.fda.gov/FDAgov/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220272.htm.

Pathway until the date of regulatory approval (or removal from the Innovation Pathway). As for other submissions, a primary review team would be assigned; however, under the Innovation Pathway, the primary review team would be assigned earlier in the development process and the team and management would regularly update the CSC on the progress of the submission, unresolved regulatory or scientific challenges, or proposed changes to prior policies or decisions. Early CSC involvement should lead to quicker resolution of difficult scientific issues, early recognition of the need for additional expertise outside the Center, and a reduction in unnecessary delays. In addition, the Center created a new position – Associate Director for Technology and Innovation – to work with the CSC and oversee the Center's innovation activities;

- **Early Identification of Needed Expertise** – Early in the Innovation Pathway process, the specific subject matter experts needed for scientific and regulatory evaluation of the submission would be identified. When the required expertise does not exist in CDRH, CDRH would seek to locate the appropriate expertise outside the Center, including from CDRH's Network of Experts (see below);

- **Assignment of a "Case Manager"** – Each product accepted into the Innovation Pathway would be assigned a case manager. Case managers would help sponsors navigate the Innovation Pathway process by coordinating Center actions for review of their device submissions, ensuring timely information exchange, and reporting directly to the CSC;

- **Development of an Innovation Pathway Memorandum** – The memorandum, developed through an interactive assessment process with the sponsor, would describe a proposed roadmap and timeline for device development, clinical assessment, and regulatory review. Delays and uncertainty would be minimized by identifying and addressing difficult, unresolved regulatory science questions (such as appropriate clinical trial endpoints) during the early Innovation Pathway stages. The Innovation Pathway Memorandum would generally be completed within 120 days from acceptance into the Innovation Pathway;

- **Frequent Communication with the Sponsor** – The sponsor and review team would communicate regularly throughout the development process to address questions or issues that arise, develop the clinical trial protocol, engage during premarket review or discuss other scientific or regulatory challenges along the way. The sponsor and review team would also meet periodically in person or via teleconference as needed;

- **Creation of Flexible Clinical Trial Protocols** – Clinical trial protocols developed through an interactive assessment process would anticipate the need for iterative device testing and redesign, as appropriate, and may employ tools to best leverage available data and minimize delays. For example, multiple stages of clinical evaluation (such as feasibility and pivotal trials) may potentially be performed under a single protocol that allows for a phased-in approach. Iterative clinical trial designs may be employed when treatment effects are uncertain given the novelty of the technology; and

- **Established Timeframes for Regulatory Review** – Once the device completes the preclinical and clinical stages of development, it would be submitted for regulatory review. Given significant senior management and review team involvement throughout the device development process, CDRH proposes that reviewers would have 150 days to complete their review – which is approximately half the time they take to review most PMAs.

The proposed Innovation Pathway is designed to facilitate the scientific and regulatory evaluation of transformative innovative products and invest Center time and resources in these products earlier in the review process. Enrollment in the Innovation Pathway would not change the scientific or regulatory standards that CDRH would use to evaluate device submissions and determine their appropriateness for marketing. Instead, the Innovation Pathway would recognize the challenges of developing transformative innovative devices and increases the commitment of Center resources to their development and evaluation.

### 1.2 Streamline the *de novo* Pathway

The *de novo* classification process was created[5] to provide a mechanism for the classification of certain lower-risk devices for which there is no predicate. The de novo classification process is intended to apply to lower-risk devices that are classified into class III through the 510(k) process. The *de novo* process is most applicable when the risks of a device are well-understood and appropriate special controls can be established to mitigate those risks.

As outlined in the 510(k) Working Group Report,[6] current implementation of the *de novo* pathway is inefficient, unpredictable, and underutilized. From 2005 to 2009, CDRH reviewed 59 *de novo* submissions out of the more than 20,000 510(k) submissions received. In January 2011, CDRH recommended steps it will take to streamline implementation of the *de novo* process including issuing draft guidance by September 30, 2011.[7]

CDRH intends for this guidance to:

- Streamline 510(k) submissions and *de novo* petitions for eligible devices;
- Clarify the criteria for *de novo* eligibility; and
- Provide a more efficient process for *de novo* review.

Importantly, the development of *de novo* guidance and streamlining the *de novo* process is intended to increase the efficiency and predictability of regulatory review for low- and moderate-risk devices that lack an appropriate legally marketed predicate.

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[5] The *de novo* process was created by the Food and Drug Administration Modernization Act through an amendment to section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act.
[6] *See* Footnote 4.
[7] *See* Footnote 4.