

# Critical Path Initiative in Medical Devices

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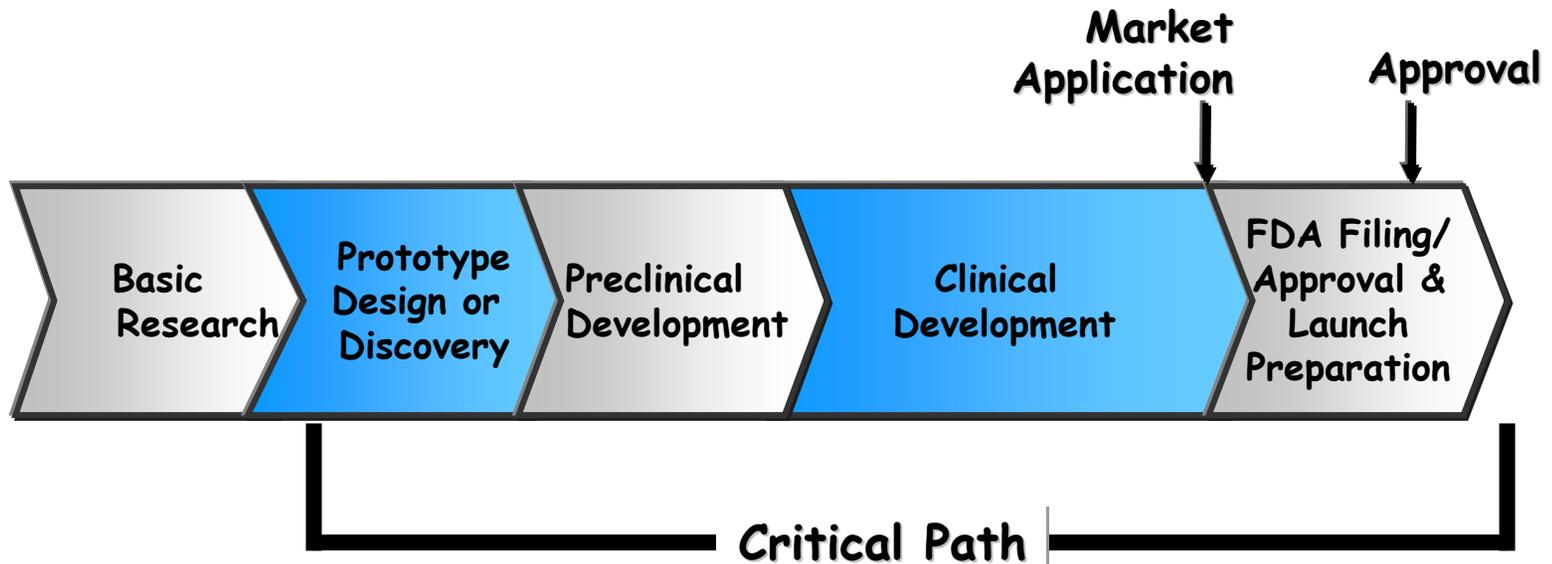
# Overview

- **What is the FDA's Critical Path Initiative?**
- **Why is the FDA interested?**
- **What are the critical path tools?**
- **What are medical device areas of interest?**
- **What are medical device Critical Path projects?**
- **How can you get involved in FDA's Critical Path Initiative?**

# What's the FDA Critical Path Initiative?

**A serious attempt to make product development more predictable and less costly**

# What's the Critical Path?



The journey from medical product candidate to full-scale production and marketing



# Why is FDA interested?

- **Because of the significant benefit of bringing innovative products to the public faster**
- **Because of our unique perspective on product development -- we see success, failure and missed opportunities**
- **Because it will help us to develop guidance and standards that foster innovation and improve chances of success**

# What do we want to do?

## **Work together**

with industry, academia and patient care  
advocates  
to

## **modernize, develop and disseminate solutions (tools)**

to address scientific hurdles impacting  
industry-wide product development



# What are the Critical Path tools?

## The methods and techniques used for:

- **Assessment of Safety** – how to predict if a potential product will be harmful?
- **Proof of Efficacy** - how to determine if a potential product will have medical benefit?
- **Industrialization** – how to manufacture a product at commercial scale with consistent quality?

# Some Critical Path Tools...

- **Biomarkers**
- **Bayesian statistics**
- **Animal models biomarkers**
- **Clinical trials design**
- **Computer simulations**
- **Quality assessment protocols**
- **Post-market reporting**
- **Suggestions???**

# Medical Device Critical Path Opportunities



# Medical Device Critical Path

## Medical devices are different

<b>Drugs</b>		<b>Devices</b>
<b>Pure molecules</b>		<b>Complex components</b>
<b>Toxicology</b>		<b>Biocompatibility</b>
<b>Short half-life</b>		<b>Durable Equipment</b>
<b>Long market life</b>		<b>Rapid product cycles</b>
<b>Drug interactions</b>		<b>Device Malfunction</b>
<b>Wrong Drug / Dose</b>		<b>User Error</b>
<b>Clinical studies</b>		<b>Bench and Clinical studies</b>
<b>Good Manufacturing Practices (cGMP)</b>		<b>Quality Systems (ISO 9000)</b>

# Medical Device Areas of Interest

## Device SAFETY tools

- Biocompatibility database
- Effects of products on diseased or injured tissues

# Medical Device Areas of Interest

## Device **EFFECTIVENESS** tools

- Surrogate endpoints for cardiovascular device trials
- Computer simulation modeling for implanted devices

# Medical Device Areas of Interest

- **Device mass manufacture or INDUSTRIALIZATION tools**
  - Practice guidelines for follow-up of implanted devices
  - Validated training tools for devices with a known learning curve

# Medical Device Critical Path Projects of Interest

- **Validation of biomarkers**
  - markers for diagnosis, therapy, and product purity
- **Peripheral vascular stents**
  - Computer models of human physiology to test and predict failure (before animal and human studies)
- **Intrapartum fetal diagnostic devices**
  - Clear “Regulatory Path” -- with consensus from the Obstetrics community)

# Medical Device Critical Path Projects of Interest

- **Pharmacokinetics and image-guided interventions**
  - Collaboration between NIH and CDRH
- **Identifying barriers to drug/diagnostic device co-development**
- **Surrogate markers**
  - Pathways for the statistical validation

# Medical Device Critical Path Projects of Interest

- **Accelerating the Availability of an Artificial Pancreas**
  - Developing a system using the continuous glucose sensors and insulin pumps linked by a control-algorithm.
- **Compromised Health Models**
  - animal models to improve prediction of toxic effects of medical products

# Are you interested?

## FDA Critical Path Opportunity List Update

- **We have compiled the National Critical Path's Opportunities List and released it in March 2006**
  - [http://www.fda.gov/oc/initiatives/criticalpath/reports/opp\\_report.pdf](http://www.fda.gov/oc/initiatives/criticalpath/reports/opp_report.pdf)
  - [http://www.fda.gov/oc/initiatives/criticalpath/reports/opp\\_list.pdf](http://www.fda.gov/oc/initiatives/criticalpath/reports/opp_list.pdf)

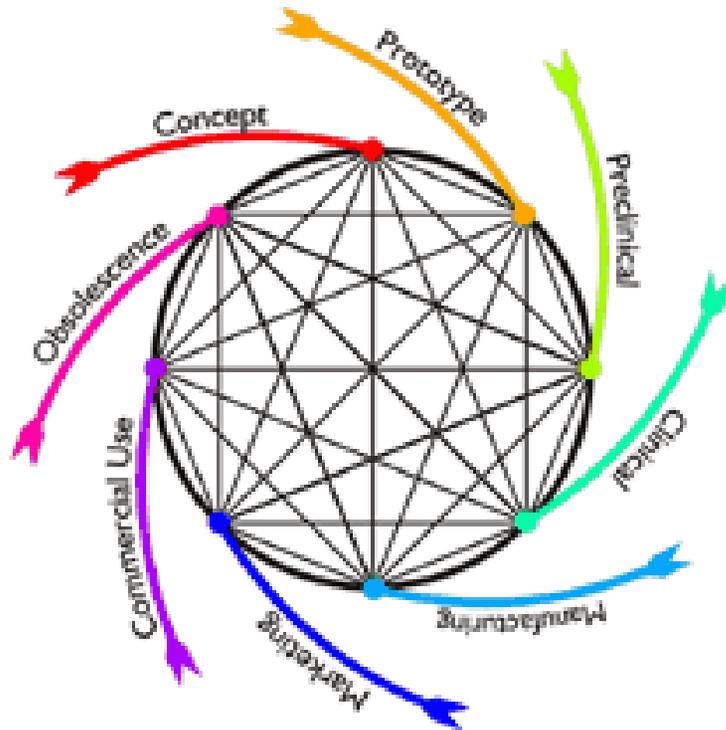
# Are you interested?

- **Web Address**

<http://www.fda.gov/oc/initiatives/criticalpath>

- **CDRH webpage (under news and events) provides links to the critical path white paper**

<http://www.fda.gov/cdrh>



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Public Throughout the  
Total Product Life Cycle --  
It's Everybody's Business*

**Center for Devices and  
CDRH  
Radiological Health**