

# Critical Path Initiative

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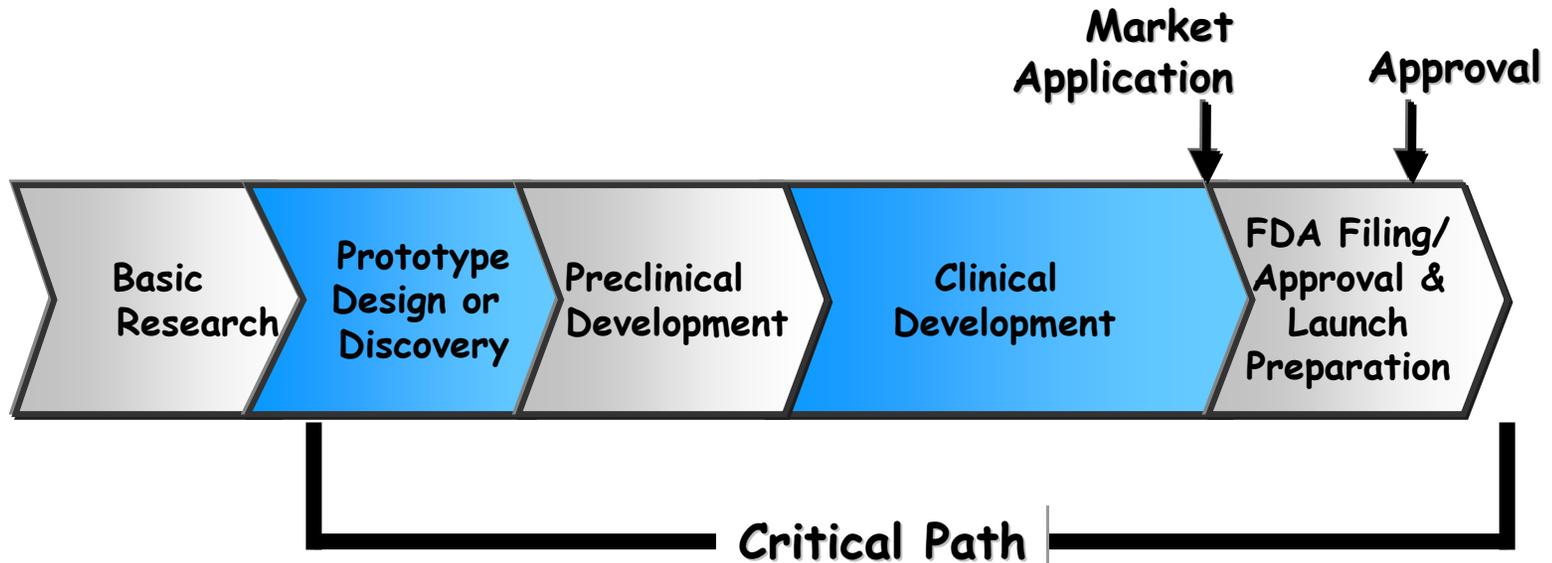
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# What's the FDA Critical Path Initiative?

**A serious attempt to modernize the medical products' Critical Path and 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 FDA?

- **Because of the tremendous benefit of bringing innovative products to the public faster**
- **Because our unique perspective understanding 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 companies, patient groups, academic researchers, and other stakeholders  
to

## **Modernize, Develop and Disseminate solutions (tools)**

to the science hurdles affecting product development industry-wide

# 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 consistently high 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>Malfunction</b>
<b>Wrong Drug / Dose</b>	<b>User Error</b>
<b>Clinically studied</b>	<b>Bench studied</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

- **New hepatitis assays**
  - Serum panel to assess sensitivity and specificity
- **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

- **Surrogate markers**
  - Pathways for the statistical validation
- **Permanently implanted devices**
  - Practice guidelines for appropriate monitoring -- with Medical Specialty Organizations
- **Neural tissue contacting materials**
  - Extent of neurotoxicity testing

# Are you interested?

## FDA Critical Path Docket and Opportunity List Update

- **We are reviewing the comments send through the public docket**
  - Areas that benefit from research and development of critical path evaluative tools
- **We are compiling the National Critical Paths Opportunities List**
  - Almost there!

# Are you interested?

## Contact us

- **Web Address**

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

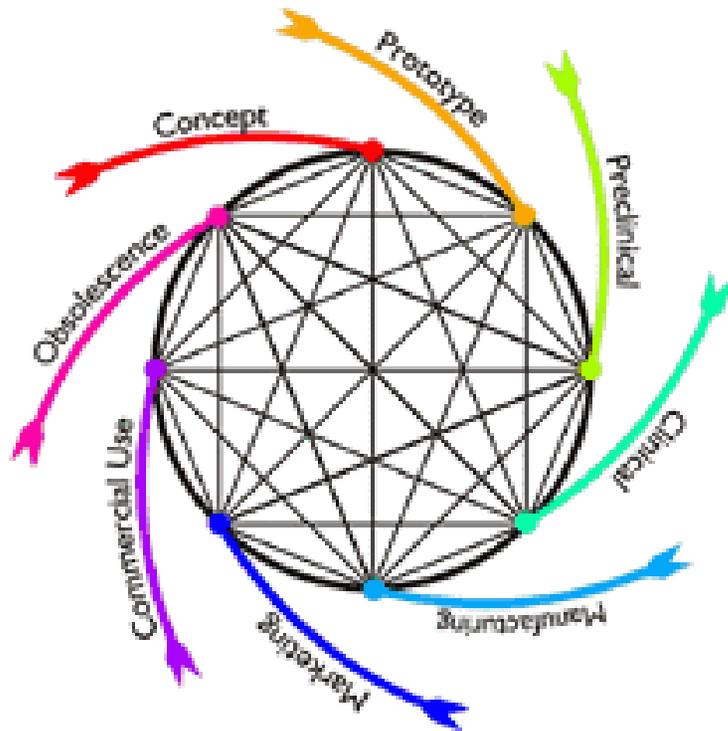
- **Open Docket**

<http://www.fda.gov/dockets/ecomments>

Docket # 2004N-0181

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

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



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Public Throughout the  
Total Product Life Cycle --  
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