

# *The Biomarkers Consortium*

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Director, Center for Devices and Radiological Health

2007 Cardiovascular Biomarkers and Surrogate Endpoints  
Symposium  
October 2007



# *CDRH's Mission*

Getting safe and effective devices to market as quickly as possible...



... while ensuring that devices currently on the market remain safe and effective.

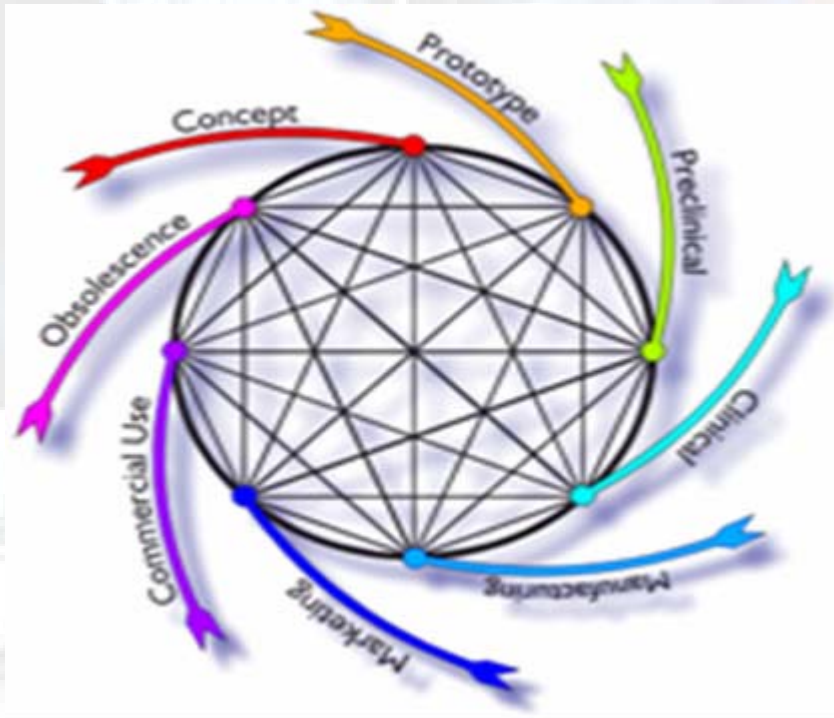
Helping the public get science-based accurate information about medical devices and radiological products needed to improve health



# *“Total Product Life Cycle” Vision*

**Efficient,  
Effective,  
and Predictable  
Product  
Development**

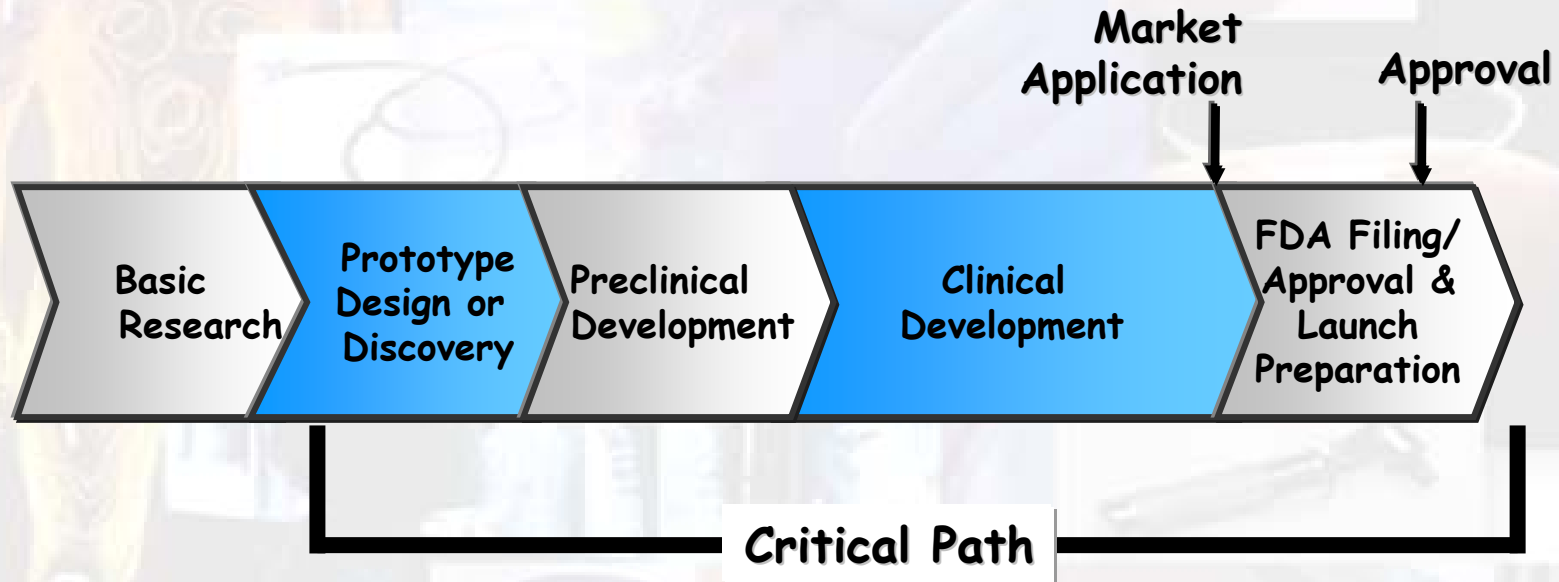
**Ensuring  
the Safety of  
Marketed  
Medical Devices**



**Enabling  
Technology  
and Innovation**



# *Critical Path Initiative*



The Critical Path Initiative is FDA's effort to stimulate and facilitate a national effort to modernize the sciences through which FDA-regulated products are developed, evaluated, and manufactured.



# *Critical Path Initiative*

- Development of biomarkers
- Clinical trial designs
- Bioinformatics
- Manufacturing
- Public health needs
- Pediatrics

- Critical Path Opportunities Report  
<http://www.fda.gov/oc/initiatives/criticalpath/>
- Critical Path Opportunities List  
[http://www.fda.gov/oc/initiatives/criticalpath/reports/opp\\_list.pdf](http://www.fda.gov/oc/initiatives/criticalpath/reports/opp_list.pdf)



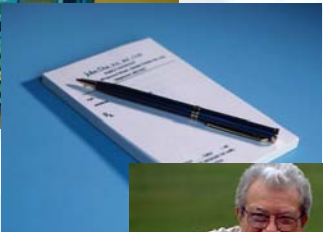
# *Moving towards personalized medicine...*



**The Right Dose of**



**The Right Therapy for**



**The Right Indication for**



**The Right Patient at**



**The Right Time.**

# *Genetic Biomarkers*

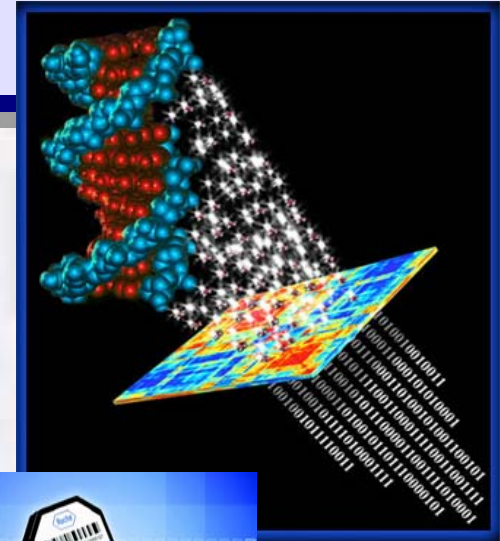


## ■ Genetic biomarkers

- Discovery and development of new drugs
- Refined clinical use of both old and new drugs
- Drug-Diagnostics Combinations -- Drug safety and efficacy may depend on diagnostic safety and effectiveness
- Personalized medical choices

## ■ Our role ensuring the quality of genetic testing:

- Comprehensive device authority -- Data and labeling thresholds prior to marketing of new diagnostics
- Quality system regulations
- Medical device reporting requirements





# *Nephrotoxicity Biomarkers*

- **Collaboration between CDRH, NCTR and CDER:**
  - **Develop animal models of subclinical and acute renal failure**
  - **Develop new and sensitive biomarkers of nephrotoxicity that detect renal injury and compromised function earlier than those that are currently available.**
- **The projects uses a multidisciplinary, systems biology approach to developing biomarkers that includes newer “-omics” technologies, like genomics and metabonomics, and traditional approaches.**

*The FDA Intercenter Renal Biomarkers Group received an FDA Outstanding Intercenter Scientific Collaboration Award at the 2006 FDA Science Forum*





# *The Biomarkers Consortium*

THE  
**biomarkers**  
CONSORTIUM

## **BMC's Goals**

- **Conduct research in “pre-competitive” areas by teams that share a vested interest in success**
- **Promote the discovery, qualification, development, and regulatory acceptance of biomarkers**
- **Speed the development of medicines and therapies for prevention, detection, diagnosis, and treatment of disease**
- **Make Consortium project results broadly available to improve patient care**

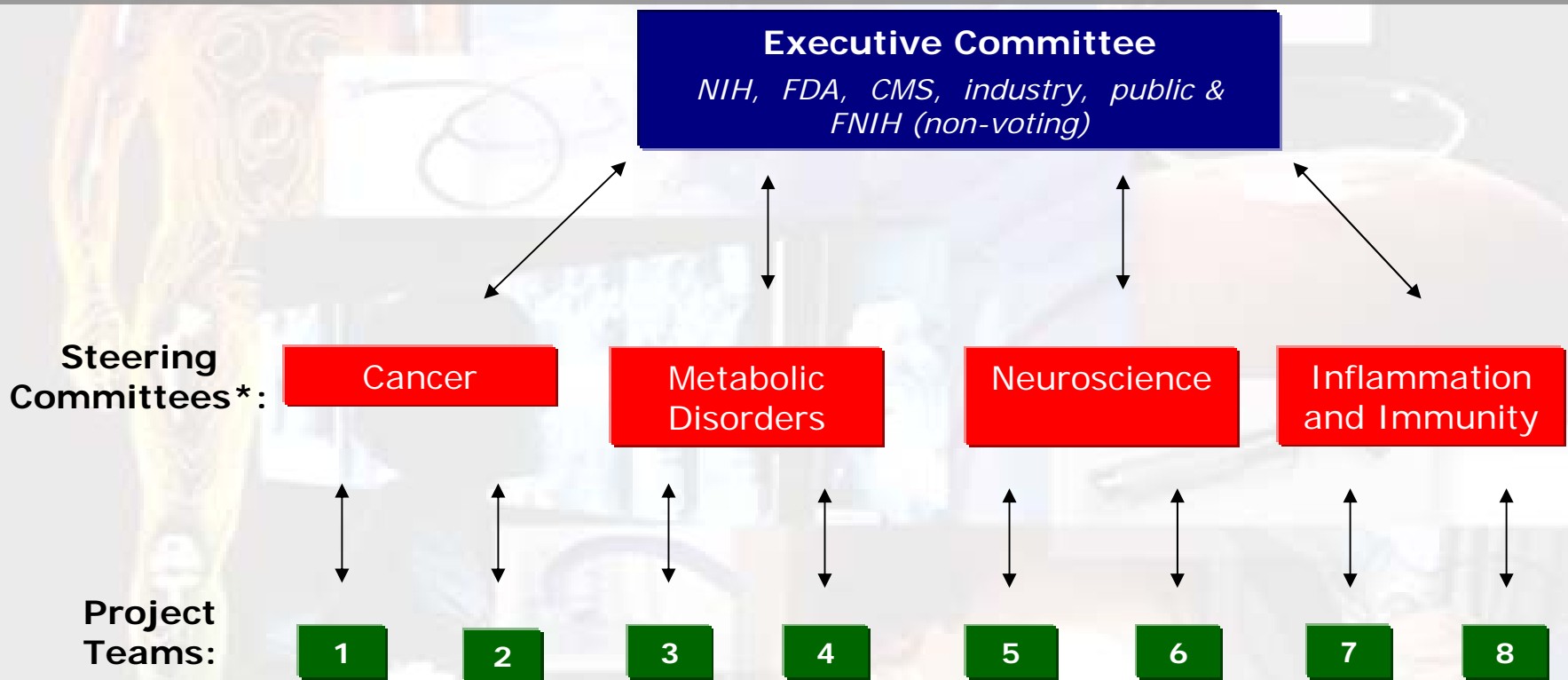


## ***FDA's Role in the BMC***

- **FDA's main role in this effort is as Federal Liaisons, providing scientific and strategic input particularly in those areas/projects that are related to our mission in public health.**
- **FDA has no fiduciary role in the BMC, but we are founding members and populate all committees, including the Exec Comm.**
- **Biomarkers figure prominently in FDA's critical path initiative**



# *BMC Governance*



\* New steering committees may be established in additional therapeutic areas (i.e., cardiovascular disease, infectious disease)



# *Executive Committee*

<b>Chairman</b>	Charles Sanders, Foundation for NIH (non-voting)
<b>NIH</b>	Thomas Insel, NIMH; John Niederhuber, NCI; Lawrence Tabak, NIDCR
<b>FDA</b>	ShaAvhree Buckman, Office of Translational Science; Daniel Schultz, Center for Devices and Radiological Health; Janet Woodcock, Office of the Commissioner
<b>Centers for Medicare &amp; Medicaid Services</b>	To Be Named
<b>Pharmaceutical/ Biotechnology Industries</b>	Garry Neil, Johnson & Johnson; Perry Nisen, GlaxoSmithKline; To Be Named
<b>Diagnostics/other industries (temporary representative)</b>	Sara Radcliffe, Biotechnology Industry Organization
<b>Public member</b>	Mary Woolley, Research!America
<b>Non-voting</b>	Steven Paul, Ellen Sigal (FNIH); Steven Hirschfeld (NICHD)



# *Executive Committee*

- **Establish and uphold policies and procedures**
- **Identify disease or scientific areas around which to establish Steering Committees**
- **Approve project concepts and plans for execution by the Consortium**
  - Project concepts: project summaries which, if approved, go to appropriate Steering Committee for further development
  - Project plans: detailed project descriptions to be executed by the Consortium
- **Advise FNIH Board of Directors on financial commitments**



# *Steering Committees*

- 4 Therapeutic areas (cancer, inflammation and immunity, metabolic disorders, neuroscience)
- Prioritize and refine project concepts proposed by the Executive Committee, the public, or themselves
- Recommend project concepts for Executive Committee approval
- Submit project plans for Executive Committee approval
- Assemble and oversee Project Teams to achieve each project's goals
- Convene advisory groups and workshops, engage consultants, etc. as needed to assist the planning process



# *Project Teams*

- **Develop detailed project plans for project concepts approved by the Executive Committee**
- **Submit completed project plans for Executive Committee approval, via the relevant Steering Committee**
- **With Executive Committee and FNIH Board approval and after funding is secured, develop project-specific guidelines and infrastructure and conduct the project**



# *Consortium Business Principles and Policies*

- **These policies have been negotiated with principals and legal counsel representing FNIH, NIH, FDA, PhRMA, and BIO:**
  - Intellectual property and data sharing
  - Antitrust
  - Selection/award of grants/contracts
  - Confidentiality
  - Conflict of interest
  
- **Policies available at [www.biomarkersconsortium.org](http://www.biomarkersconsortium.org)**



# ***BMC's 2007 Outlook***

- **Cancer, Inflammation and Immunity, Metabolic Disorders, and Neuroscience Steering Committees launched**
- **Develop approved project concepts**
  - Submit project plans to Executive Committee
  - Obtain funding and other agreements
  - Establish and convene project teams
  - Implement projects
- **Solicit, review, and act upon new project concepts**
- **Continue outreach to organizations about contributing membership**
- **The Biomarkers Consortium website launched (June 2007 at [www.biomarkersconsortium.org](http://www.biomarkersconsortium.org)) and members-only section (September 2007)**
- **Make The Biomarkers Consortium a center of excellence for biomarker discovery and their evaluation as surrogate endpoints**



# *Contact Information*

## **Foundation for NIH (FNIH)**

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*Director, The Biomarkers Consortium*

David Lee ([dlee@fnih.org](mailto:dlee@fnih.org))

*Contributing Membership/Partnership Development*

[www.biomarkersconsortium.org](http://www.biomarkersconsortium.org)



# Thank you!

[www.fda.gov/CDRH](http://www.fda.gov/CDRH)

