

# Report to the Science Board

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Deputy Commissioner / Chief Medical Officer  
June 2007*

# Topics Covered Today

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FDA Fellowship Program

Bioinformatics

# Current Fellowship Program

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- Cross Agency
  - Scientific
  - Administrative
- 100 fellows
- Center administered

# Future FDA Fellowship Program

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- Cross Agency
- Administered through foundation
- Target specific areas of need
  - Centers could nominate
  - Outside parties could target funds
- 2-year duration
  - Includes formal didactics
  - Fellows do “real work”

# Expectations for Fellowship Program

- Expose recently trained scientists and clinicians to FDA regulatory science: they will learn and we will benefit also
- Some outstanding scientists will choose to make a career at the Agency
- Those who don't stay may serve as "Ambassadors" to academia, industry, health professionals & other government organizations
- Bring in more senior people for sabbaticals, etc.
- Offer opportunities for FDA scientists to stay up to date, gain new skills, and teach others

# Goals for New Program

*(cont.)*

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- Have robust FDA-wide program in place by next year
- Target areas of emerging science or areas hard to recruit
  - Clinical imaging
  - Nanotechnology
  - Datamining

# Update on FDA Automation/Bioinformatics Strategy

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- FDA data management needs are extremely challenging
- Massive amounts of data on regulated products but very difficult to utilize systematically
- FDA implementing multifaceted improvement strategy

# Examples of Existing Problems

- Data ACCESS
  - Data on movement through commerce not always available
  - Marketing applications are paper based
  - Adverse event reports paper based
  - Electronic documents are unstructured
- Data STANDARDS
  - No widespread adoption/use of information exchange standards or terminology standards
- Data INTERFACE
  - Analytic review tools are outdated
  - Tools for safety signal detection are inadequate
  - Lack tools for cross-product analyses

# Strategy for Improvement

- Additional resources: both \$\$ and human capital
- Changes in regulations
- Strategy for governance, planning, and implementation
- Transparency to allow synchrony with FDA stakeholders
- Incremental Projects as resources become available
  - Each new project leverages accomplishments of previous projects
- New systems built to align with enterprise Service Oriented Architecture
- Partnerships with external organizations to leverage resources:
  - NIH, AHRQ
  - DOD, VA
  - Public-Private Partnership

# FDA Bioinformatics Board (BiB)

- February 21, 2006, Senior Management approved formation of the BiB to achieve the Agency's goal for information infrastructure that is
  - Modern
  - Well-integrated
  - Reliable
  - Efficient
  - Affordable

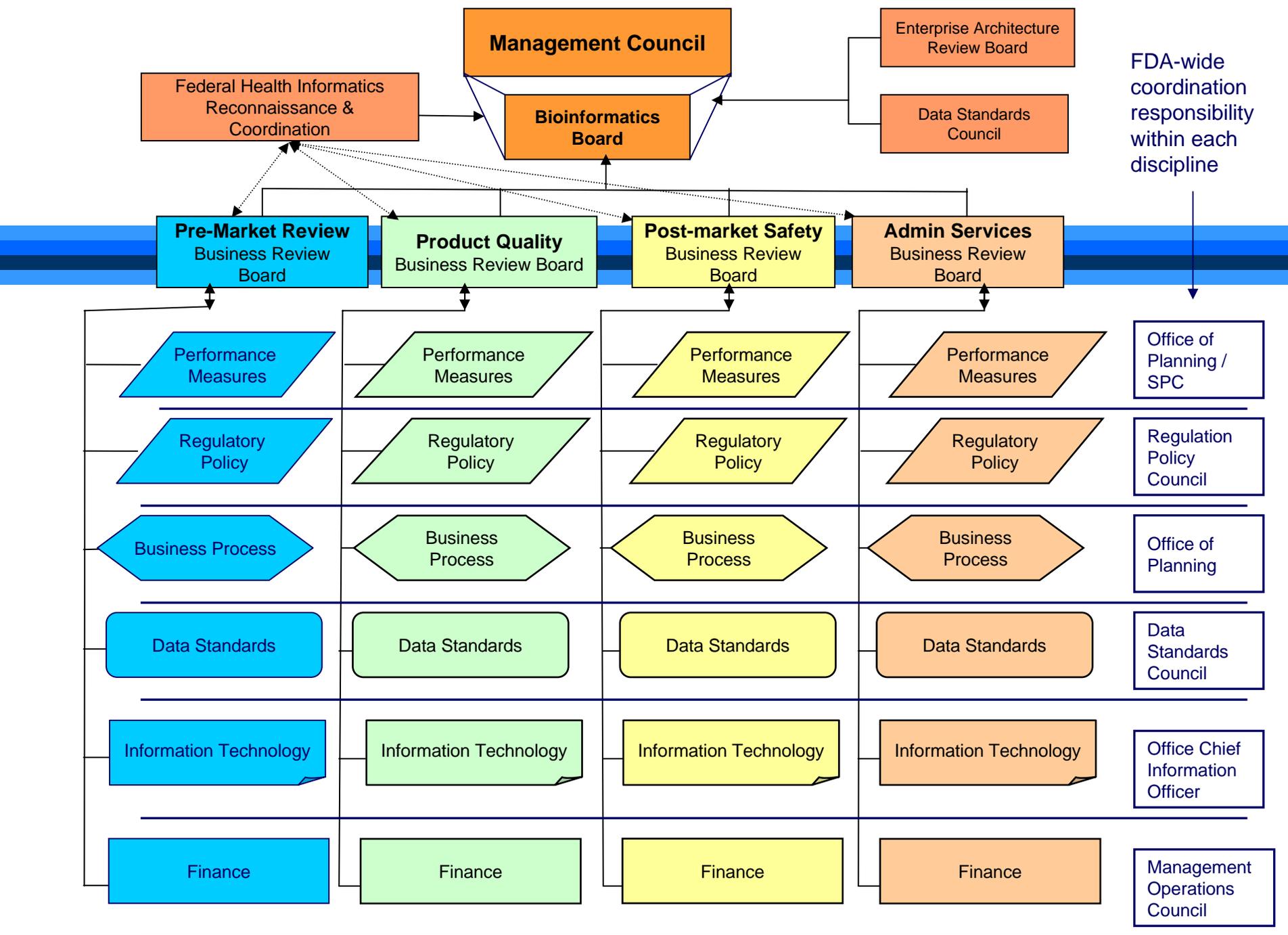
Agency approach based on premise that oversight of the design, building, and maintenance of such an infrastructure must be both business-driven, business-owned, and enterprise-wide

# BIB

- FDA using term “bioinformatics” to describe the thrust and direction of this business planning function
  - Because the FDA business of public health protection involves regulatory decision making using biological, medical, behavioral, and health data
- Scope includes coordination and oversight of all activities related to
  - Business automation planning including scientific activities
  - Acquisition
  - Implementation decisions throughout FDA

# Business Review Boards (BRBs)

- One BRB for each strategic business area
- Each BRB responsible for the following:
  - Support the BIB in area of expertise
  - Act as Agency-wide “business sponsor” of new systems development
  - Provide oversight and direction of the work being performed on IT systems and projects within defined area
  - Review at a high level recommended new data standards, revisions to current regulations, changes in business processes, software application design requirements, etc.
  - Communicate plans back to Centers/Offices to facilitate consistent and efficient implementation



# BRB Project Teams

- The Business Review Boards (BRBs) establish project teams to investigate and make recommendations on major cross-agency initiatives within/across core strategic areas
- Initial projects
  - Postmarket BRB – Medwatch Plus
  - Premarket BRB – Electronic Document Room
  - Quality BRB – Harmonize FDA process for identifying and tracking regulated establishments & products
  - Admin BRB – Beginning work mid July
  - Scientific BRB—under development

Chair: Janet Woodcock  
Co-Chair: Jonn Dyer

# Management Council

## Bioinformatics Board

**Post Market Safety Business Review Board**  
Chair: Janet Woodcock

**Product Quality Business Review Board**  
Chair: John Gardner

**Pre-Market Business Review Board**  
Chair: Malcolm Bertoni

**Administrative Business Review Board**  
Chair: Open

Program Mgr: Open  
Project Mgr: Daryl Allis

**Support Members Group**

- Data Standards
- Policy
- Business Process
- Performance Mgmt.
- Information Technology
- Finance
- Enterprise Architecture

Lise Stevens

Eric Mettler

Don Lipkey & Malcolm Bertoni

Linda Smale

John Gentile

Lamin Jeng

Data Standards Council

Regulatory Policy Council

OPI & Ctr./Office Business Owners

IT Panel  
CBER – CDER  
CDRH – CFSAN  
CVM – OC

External Stds. Development Organizations

Office of Management

Enterprise Architecture Review Board

Randy Levin

Gary Washington

**Legend**

- Post Market Safety Example
- Other Business Review Boards

# Ongoing Projects

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- Registration and listing: FURLS;  
Standard = HL7 SPL
- Adverse event reporting:  
MedWatch Plus. Standard =  
HL7 ICSR
- Product labels: ELIPS.  
Standard = HL7 SPL (“Daily  
Med” now populated with

# Ongoing Projects

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- Study reports and other submissions  
Standard = HL7 RPS
- Study data Standard = CDISC, HL7  
Systems= JANUS, Web SDM,  
ToxVision (JANUS database  
currently being piloted by NCI/FDA)
- ECGs Standard= HL7 annotated ECG  
Waveform data; system= ECG  
warehouse

# Ongoing Projects

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- Clinical investigator information: system = FIREBIRD
  - Developed by NCI/CA-BIG and FDA
  - Repository for investigator forms, and IRB information, etc
  - File in one place rather than repeated submissions
  - Being piloted now at FDA

# Ongoing Projects

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- Clinical data interchange project (with NIH)
  - Had FDA Part 15 hearing on this matter
  - FDA/NIH published RFI on concept
  - Reviewing responses
  - Seek public private partnership for data interchange

# Ongoing Projects: Genomic Data

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- Nov/06: workshop on submission of genomic data to FDA
- Publication of concept paper on data elements
- NCTR: ArrayTrac software for analysis

# Summary

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- FDA taking an enterprise-wide approach to information management at all levels: from business process information to regulatory submissions to scientific data
- Focus on standards development; process standardization, and modular system parts
- Working with HHS AHIC effort and many Federal and private partners