FDA Centers of Excellence in Regulatory and Information Sciences

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novasano HEALTH AND SCIENCE

Discussion Topics

- Drivers for evolution in regulatory science
- Trends in discovery domain and lessons for the regulatory domain
- Centers of Excellence in Regulatory Science (COERS) Network
  - Activities
  - Structure
  - Function

Drivers for Evolution of Regulatory Science

- Close current gaps and deficiencies
  - Methods, e.g. development of new modeling capability
  - Capability and capacity development through collaboration and training
- Keep pace with discovery
  - Emerging sciences
  - New innovation strategies, e.g. distributed collaborative networks
- Adapt to rapidly evolving environmental challenges
  - Globalization
  - Accelerated emergence of digital information assets

COERS Network Activities

- Research and innovation: The FDA, in collaboration with the centers of excellence, designs a comprehensive long term research and innovation agenda that will inform the advancement of the scientific tools, methods, and information requirements to progress regulatory science.
- Regulatory services: Outreach by the FDA on an ad hoc basis for specific issues to get immediate support to perform an assessment on a regulated product. Potential activities include scientific, methodological or technical consultations/collaborations or for guidance document development.
- Education: Potential activities include development of regulatory science training programs, in academic centers, scientist exchange programs, and regulatory science fellowship programs at the FDA that may leverage the network.

Open Innovation

- Closed innovation fosters a mind-set that is siloed and the dominance of individual institutions over ideas, technologies, and economies, with all the benefits and risks of an undiversified portfolio.
- Open innovation, however, is not some extraordinary ideal or concept. It is happening right now because today's information-empowered flat world makes for a ripe landscape.
- We believe open innovation will fuel the intellectual entrepreneurship and novel collaborations across institutions and geographies needed to develop solutions to some of the world's most critical healthcare challenges and to directly address patient needs in both developed and emerging economies.

  Dr. Paul Stoffes, company group chairman of pharmaceutical research and development at Johnson & Johnson. Boston Globe, February 2, 2009

- "building networks where together with a number of different groups you come up with solutions to solve medical needs."

  Paul Stoffels, WSJ Health Blog (Jan 29 09)

Collaborative Innovation
Real World Examples

- Innocentive – collaborative problem solving through a global network of scientists
- CollabRx - collaborative activities for the diagnosis and treatment of cancer patients
- Lilly Chorus platform - supports distributed collaborative discovery efforts
  - A More Rationale Approach to Drug Development, HBR, March 2008
- Disease-based associations are driving communities and collaborative science
- Informatics enabling collaborative discovery - a call to standardize data and information that describe drug assets. This need applies to all regulated products.
  - Getting the drugs we need, HBR, Jan-Feb 2010
- TrialX - leverages patients enrolled in personal health records to participate in communities and to enroll in clinical trials. Leverages social networking and semantic web tools.
- OMOP – a public-private partnership to collaboratively develop infrastructure, processes and ultimately statistical methods for safety science

Collaborative Innovation
A Solution and a Science

- Daniel Chin, Senior Principal Research Scientist, Roche, said a major Informatics challenge is how to retrieve all the data for a compound for scientists globally. Scientists today are feeling overwhelmed with data, but not feeling like they are getting all the insights and perspectives they could about the properties of a compound or its reactants.
- Chris Waller, Senior Director, Pre Competitive Collaborations, Pfizer, outlined the Pistoia Project focus on pre-competitive partner standards, open innovation amongst its members and individual projects for collaboration such as Electronic Lab Notebooks and simplifying a cross industry architecture.
- Susie Stephens, Director, Biomedical Informatics, Johnson and Johnson, noted how open innovation models are becoming the key way to meet the challenges that innovation require in the industry.
- **Collaboration, Open Innovation and Semantic Web Highlight - Molecular Medicine Tri Conference, February 10th, 2010**

Open/collaborative innovation is itself an 'emerging science'

Collaborative Discovery Reward and Risk

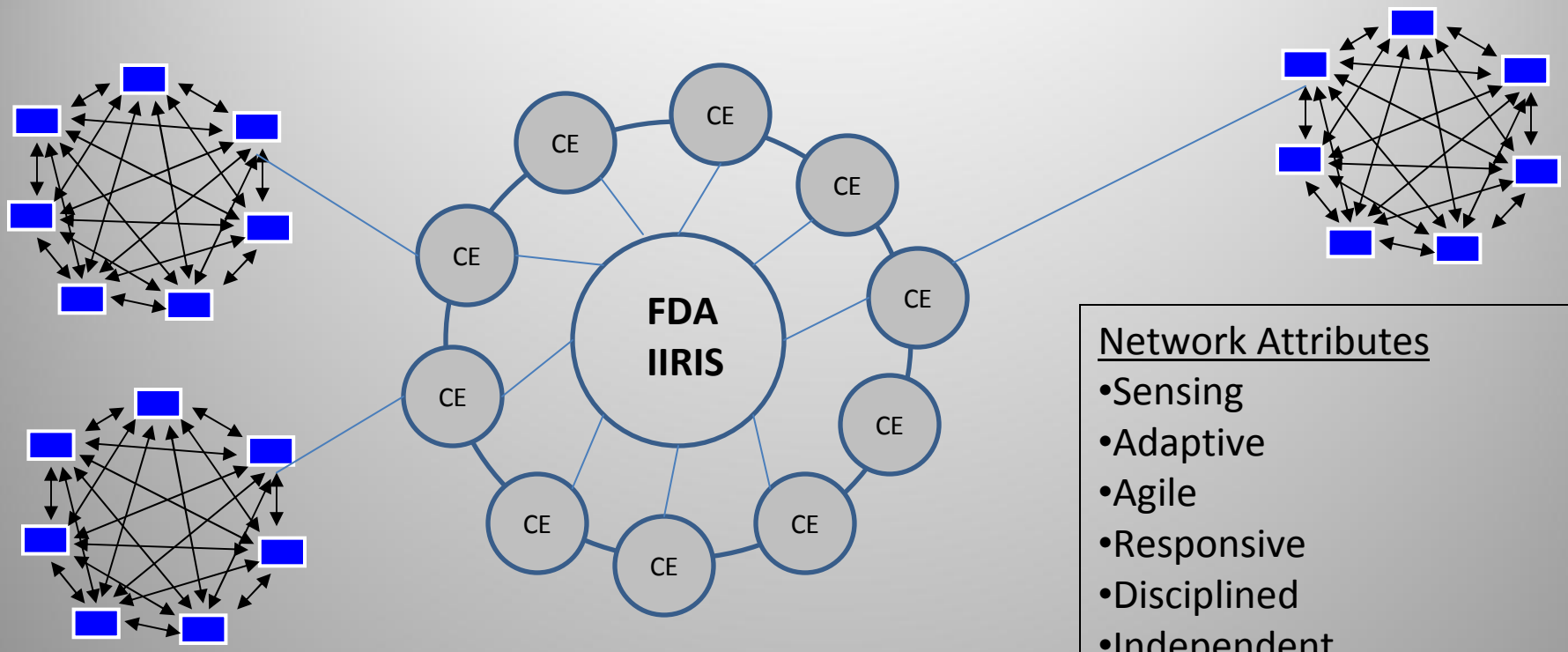
- Successful efforts to accelerate innovative product discovery bring critical new therapies to market
- At the same time, these successes will further challenge product regulation

There is a critical need to adopt distributed and collaborative innovation strategies to the development of more robust regulatory capability – the people, methods, tools, information assets, etc.

Key Network Components

- Intramural center
- Extramural centers
- Network
- Network of networks
- Open/collaborative innovation in regulatory and information sciences
- Innovation of the ‘innovation network’

COERS Network
FDA Led, Advisory Board(s) and Community Enhanced



- The FDA must have the capability to respond to emerging regulatory challenges due to emerging science, information assets, and globalization.
- Collaborative innovation that is being applied in the discovery realm must be applied in the regulatory science domain.

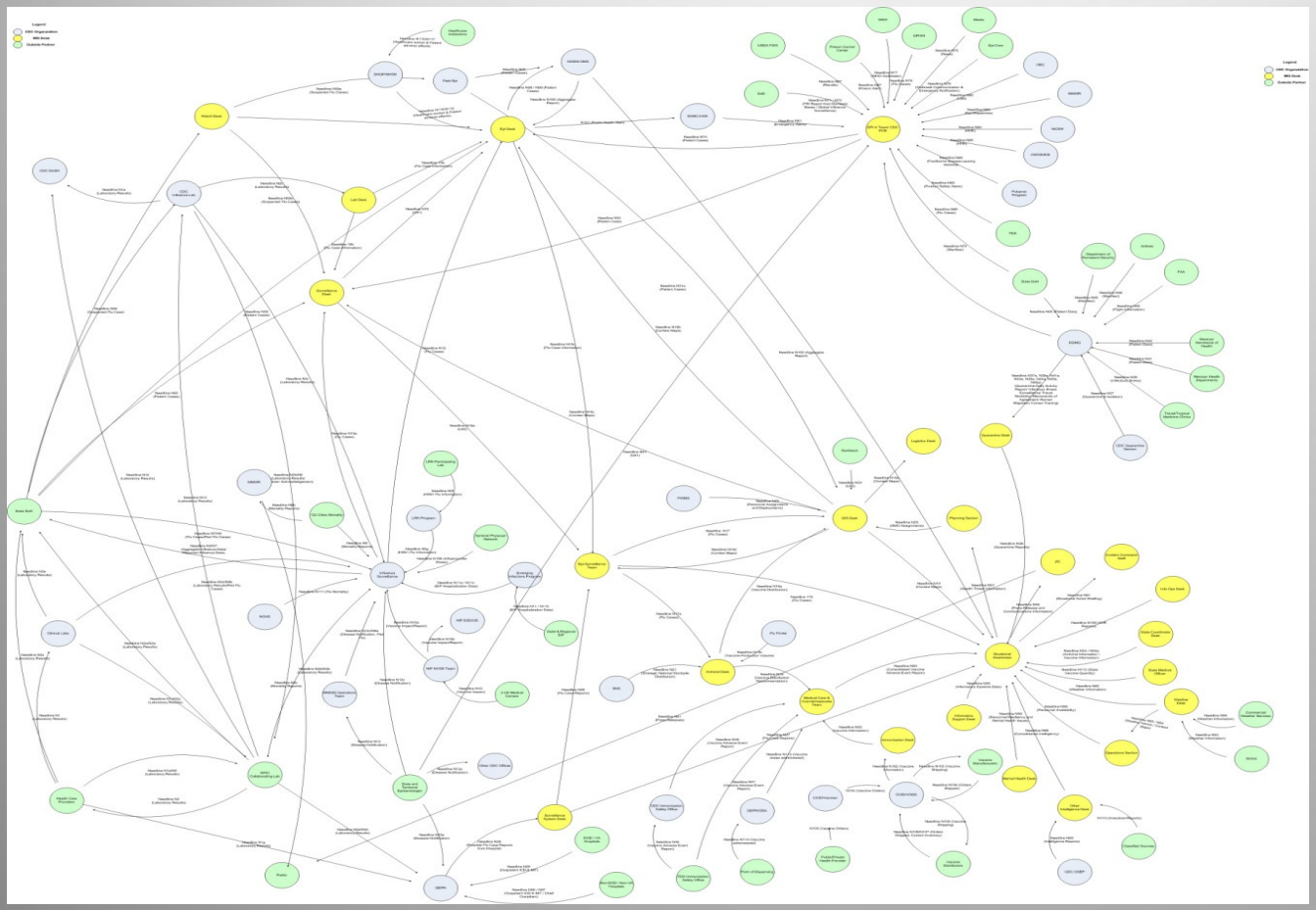
IIRIS – Institute for Innovation in Regulatory and Information Sciences

<u>Network Attributes</u>

- Sensing
- Adaptive
- Agile
- Responsive
- Disciplined
- Independent
- Collaborative
- Shared platforms, processes, infrastructure, methods, etc

…….a collaborative network that is more than the sum of its parts

Event Response Information Supply Chain
Usually, at best, a vague idea in a person's mind



An innovation or sensing-response network is really a network of networks

The lesson for a FDA COE network is that it will be most effective as a network of networks versus a hub with 10 siloed academic centers

A subset of data and information flow for Pandemic Influenza

Collaborative Networks Information Dependent

- The emergence of large and very large information assets should be systematized
- There will be requirement for many of these in order to cover all diseases, medical products, other regulated products, patient demographic subpopulations, etc.
- Independent of need, these assets are emerging 'because innovators can' and because these resources can be leveraged for work and money

It is critical need to create a framework for describing these data assets that will be used for clinical trials, safety surveillance, comparative effectiveness. Many stakeholders will want to leverage these access and a way to describe, certify, and inventory these assets will improve access, utility, and safe use of these data assets.

COERS Outcomes

- Process outcomes; development of best practices – e.g. informatics platforms, predictive algorithms to improve efficiency of inspection process, development of guidance documents (determined by FDA leadership and FDAAA)
- Health outcomes; e.g. elucidation of mechanism and risk factors for adverse effects or insights into mechanisms of efficacy facilitating more personalized strategies of drug development and administration.
- Economic outcomes; e.g. comparative effectiveness assessments as generics and biosimilars emerge for consideration. Reduced cost., conduct of drug development and regulation through leaner more efficient drug development and regulatory review procedures

COERS Outcomes

(con't)

- Talent development outcomes; e.g. training of modern drug development and regulatory scientists and experts for service in industry, academia, FDA and other government agencies
- Unmet national medical needs achievement outcomes; e.g. Acceleration of development and approval of medical countermeasures against bioterrorism threats
- Transparency and confidence building outcomes; e.g. Academic involvement in improvement of drug development and regulatory procedures and decisions will enhance public trust and willingness to support both drug/device development and government regulation

COERS Outcomes

(con't)

- Academic outcomes; e.g. Invention and innovative concepts are a byproduct of awareness of scientific challenges in the drug development and regulatory domains
- Collaborative network development outcomes; e.g. Creation of academic-FDA collaborative networks to solve drug development and regulatory challenge

Summary

- A Centers of Excellence Network is an unique and critical opportunity to progress regulatory science
- COERS addresses critical challenges
  - Chronic resource shortages
  - Deficiencies in regulatory science and informatics
  - Requirement for ability to sense emerging sciences, trends, capabilities, risks and opportunities and then respond
- The structure and operational model for the COE is an important enabler of innovation, outcomes, and ultimately public health impact