Building a National Framework for the Establishment of Regulatory Science for Drug Development

Opportunities for Enhancing Regulatory Science

A Blueprint to Benefit Patients

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IOM Drug Forum | Feb 26, 2010 | Washington, DC

A Model for Enhancing Regulatory Science

Cancer as a Case Study:

1. Scientific Priorities
2. Consolidation of Expertise Aids Regulatory Science
3. Partnership Between Government and Academic Centers
4. Training & Scientific Exchange

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Scientific Priorities to Focus Regulatory Science

The oncology community has identified key areas where emerging scientific opportunities could advance cancer care:

- Validation of Biomarkers
- Clinical Trial Design
- Quality of Life/ Symptom Management
- Evaluation of Combination Therapies
- Chemoprevention
- Stem Cells

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Consolidation of Expertise Aids Regulatory Science

Model: Office of Oncology Drug Products (OODP)

- Elevated from a division to an office in July 2005 to consolidate oncology regulation and house cancer expertise in a central location
- Includes small molecules, drugs and biologics
- Improves consistency in review standards and policies
- Allows for routine scientific interactions
- FDA Cancer Program: Could further advance regulatory science by:
  - Enhancing intra-agency collaboration between FDA Centers
  - Increase interactions with other health related federal agencies
  - Expanding on external advisory capacity
  - Harmonization with international regulatory bodies

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Partnership Between Government and Academic Centers

Model: The NCI Cooperative Groups

- 12 clinical trials cooperative groups.
- Each institution operates independently, but also co-operatively.
- Institutions can share data and infrastructure while simultaneously addressing disparate areas of cancer research.
- Perform crucial research on post-market approved drugs such as assessing toxicity as well as additional uses for these drugs.
- Could serve as a model for centers of regulatory science to aid FDA by answering product specific questions, research methodologies, guidance development etc.
- IOM study underway that examines cooperative group role in FDA regulation.

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Training & Scientific Exchange

Model: The FDA-NCI Interagency Oncology Task Force (IOTF)

- Joint Fellowship Training Program allows exchange of FDA and NCI staff
- Expanding program to allow FDA staff to take sabbatical to conduct research at academic institutions
- Research Input: I-SPY 2; the FDG-PET biomarker trials; chemoprevention biomarkers; input into the exploratory IND etc.

Other Scientific Exchange Opportunities

- Collaborative problem solving through workshops and exchanges with professional societies and external stakeholders.

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Need for Infrastructure Support at FDA

"First and foremost, the FDA will establish an intramural Center of Excellence that will catalyze the development of regulatory science at the FDA"

- Funding Science within FDA is crucial.
- Regulatory Science cannot take place in isolation.
- A lack of resources and personnel within FDA should be addressed.
- FDA needs an investment in resources to accept findings from regulatory science and implement them.

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