Defining a Discipline of Regulatory Science: Academia

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“The Food and Drug Administration (FDA) protects and promotes the health and safety of all Americans through enhancing the availability of safe medical products and foods and promoting innovation that addresses unmet medical and public health needs.”

“…rapid advances in innovative science have provided new technologies to discover, manufacture and assess novel medical products,…”
FDA’s Science Priorities

• Modernize toxicology
• Innovation in clinical evaluation and personalized medicine
• Improve product manufacturing
• Evaluate innovative technologies
• Improve health outcomes through Information Science
• Improve prevention-focused food safety systems
• Improve medical countermeasures against threats to health and security
• Strengthen Social and Behavioral Science regarding decisions about regulated products
Core Missions of Academic Health Centers

• Three-legged stool
  ➢ Education
  ➢ Research
  ➢ Clinical care

• Overarching Societal Mission
  ➢ Developing and implementing new and improving models of care
Science and Medicine

1900s
Germ Theory
Chemistry
Physiology
Pathology
Physics

2000s
Genomics
Proteomics
Metabolomics
Systems Biology
Informatics
Micro/Nano Processing

Find It
Fix It

Predict It
Personalize It

Understanding Disease

Understanding Health, Disease and Complexity

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Development of Disease

Baseline Risk → Earliest Molecular Detection → Earliest Clinical Detection → Typical Current Intervention

Time

Initiating Events

Disease Burden

Cost

1/reversibility

Personalized Medicine Tools

- Quantify Baseline Risk
- Monitor Progression
- Refine Risk Prediction
- Define Disease
- Monitor
- Personalize Therapy

Personalized Health Planning

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# Emerging Medical Capabilities

## Personalized Medicine Tools
- Health Risk Assessments
- Genomic Predictors (e.g.)
  - SNPs
  - Gene Sequencing
  - Haplotype Mapping
- Biomarkers
- Gene Expression Tests
- Proteomics Tests
- Metabolic Profiles
- Clinical Risk Models
- Clinical Decision Support
- Adverse Outcome Models
- Drug Metabolism Indicators
- Companion Diagnostics
- Targeted Therapies

## Applications
- Quantify Baseline Risk
- Enable Disease Prevention
- Define Disease Mechanisms
- Monitor Disease Progression
- Select Therapies
- Targeted Therapies

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Types of Research in Academic Health Centers

- Basic discovery
  - Non disease-oriented
  - Disease-oriented
- Translational research
- Clinical trials
- Outcomes research
- Classical epidemiology
- Health policy
- Regulatory sciences
What Do Physician-Investigators Need?

- Recognition and role models
- Financial aid
- Funds for training
- Research training programs
- Appropriate tenure tracks
- Appropriate research infrastructure in medical schools and teaching hospitals
- Stable federal funding for clinical research
Needs for Regulatory Sciences in Academia

- Recognize as a discipline(s)
- Define qualifications
- Define educational needs
- Create academic homes
- Define career pathways
- Identify sources of support
- Define APT