Regulatory Science Career Paths Outside Academia

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Interagency Oncology Task Force (IOTF) Joint Fellowship Program

*Research and Regulatory Review Fellowships*

- NCI and FDA provide fellowship training programs in cancer-related scientific research and research-related regulatory review
- Federal fellowship program to encompass development and regulation of new medical products in a seamless way

http://iotftraining.nci.nih.gov
Fellowship Program Objectives

• Train a cadre of scientists in research and research-related regulatory review, policies, and regulations
• Build awareness of regulatory requirements into early stages of product development processes
• Improve planning throughout research and regulatory review
• Facilitate movement of drugs, biologics, and devices from basic bench science to commercialization and to the community
Fellowship Program: Four Types of Programs

- **Program 1** – Clinical Oncology Product Research/Review for Oncology Fellows
  
  *(MDs or MD/PhDs for up to three years)*

- **Program 2** – Clinical Oncology Product Research/Review for Board Certified Oncologists
  
  *(Board-certified oncologists for up to one year)*

- **Program 3** – Oncology Product Research/Review for Fellows
  
  *(MDs, MD/PhDs, or PhDs for up to two years)*

- **Program 4** – Cancer Prevention Fellows
  
  *(MDs, MD/PhDs, or PhDs for up to three years)*
NCI and FDA Responsibilities

• **NCI**
  - provides funding for the fellows
  - maintains fellows’ training plans
  - conducts fellows’ exit interviews

• **FDA**
  - provides mentors
  - identifies regulatory training opportunities
  - coordinates meeting travel

• **NCI and FDA**
  - require and provide ethics and appropriate safety training courses
Fellowship Program Training Courses

• Required courses:
  ✓ Drug law
  ✓ Reviewer training
  ✓ Statistics
  ✓ Clinical trial design

• Recommended courses:
  o Risk assessment
  o Risk management
  o GMP
  o GLP
  o Technical writing
  o Presentation skills
  o IND regulations
  o NDA regulations
Mentor Qualifications

• Programs 1 and 2:
  o Regulatory scientists/medical officers with active regulatory research program

• Programs 3 and 4:
  o Research-regulator PIs with active regulatory research programs

• Evidence of productivity
• Evidence of outstanding mentoring
• Approval of FDA Center/Division Director
Program Status

• Currently 12 fellows in the program and 22 alumni

• Current fellows:
  o Program 1: 1 fellow
  o Program 2: 1 fellow
  o Program 3: 8 fellows
  o Program 4: 2 fellows
Alumni Employment, by Sector

- Government - FDA, 12
- Center for Drug Evaluation and Research, 8
- Center for Biologics Evaluation and Research, 3
- Center for Devices and Radiological Health, 1
- Research & Program Management Services, 2
- Pharmaceuticals, 4
- Consulting, 1
- Healthcare, 1
- Government - NCI, 1
Thank You!
Program 1 - Clinical Oncology Product Research/ Review for Oncology Fellows

• To train:
  o in clinical trials methodology & analysis, epidemiology, medical product development, and regulation
  o in federal statutes, regulations, principles and practices of medical product and clinical review
  o and participate in product development research projects at both agencies

• Eligibility:
  o M.D. or M.D./Ph.D.
  o U.S. citizenship or U.S. permanent residency

• Fellowships up to 3 years and include up to 2 fellows/yr
Program 2 - Clinical Oncology Product Research/ Review for Board Certified (BC) Oncologists

- **To train:**
  - following an oncology clinical fellowship
  - in drug, biologic, or device development and related issues & standards for assessing medical product safety & efficacy
  - in federal statutes, regulations, principles and practices of medical product and clinical review

- **Eligibility:**
  - Board-certified oncologist
  - U.S. citizenship or U.S. permanent residency

- **1-year program up to 3 fellows/yr**
Program 3 - Oncology Product Research/Review for Fellows

- To train:
  - in research and review of medical product development process
  - in federal statutes, regulations, principles, and practices of medical product review
  - and participate in medical product development research
- Eligibility:
  - Ph.D., M.D., or M.D./Ph.D. degree
  - At least 3 years postdoctoral training in cancer-related topic
  - U.S. citizenship or U.S. permanent residency
- Program is up to 2 years and up to 6 fellows/yr
Program 4 – Cancer Prevention Fellows

• To train:
  o in cancer prevention
  o in drug, biologic, or device development and approval processes and application to study populations
  o in federal statutes, regulations, principles, and practices of medical product review
  o and participate in medical product development research

• Eligibility:
  o Ph.D., M.D., or equivalent degree
  o U.S. citizenship or U.S. permanent residency

• Program is up to 4 yrs and up to 2 fellows/yr