Session IV Summary
Regulatory Science Career Paths

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Key Findings

• **Regulatory Science** is inherently multidisciplinary; can be viewed as
  • “Translational Science with a Regulatory Twist” (DeMets)
    – Clinical Pharmacology includes incl. regulatory science
    – “Part of Translational Medicine and Therapeutic Sciences” (Giacomini)

• **Employers include FDA, industry & academia**
  – Functional roles (not discussed) may broaden career opportunities

• **Opportunities – Reinvigorating Clinical Pharmacology, CTSA’s, NCATS*, BIG RESEARCH CHALLENGE’S LIST**

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* National Center for Advancing Translational Sciences
Regulatory Science Career Paths & Opportunities

• Regulatory Agencies (FDA, EMA, sFDA et al; HHS, FTC, Congressional staffs, et al; state health agencies; journal editors)

• Biopharmaceutical Industry (biotech’s, PHARMA, CRO’s, consultants)

• Academia (undergraduate & graduate teachers, researchers; clinical trialists, IRB’s, NIH)

• Healthcare System Decision Makers (payors, formulary committee’s)

• Investors (institutional, venture)
Training in Regulatory Science

Career Path

FDA

Industry

Academia

Adapted from IOM presentation “Regulatory Science Career Paths in Academia”, William Chin, M.D., Executive Dean for Research, Harvard Medical School, Sept 20, 2011

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Academia is currently not receptive to regulatory scientists

• Barriers
  – definition of discipline
  – Lack of appreciation of research challenges and potential for innovative research
  – academic respect
  – academic home/career progression pathways
  – lack of role models
  – Sustained, respectable sources of research funding,
  – BIG QUESTION RESEARCH CHALLENGES – (include biostatistical, bioinformation methodologies, quantification of risk benefit, implementation of Animal Rule, predicting cardiovascular (QT), hepatotoxicity & other toxicities, career opportunities; COI/IP, data sharing)
  – Too few candidate regulatory scientists

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Opportunities for Advancing Regulatory Science Career Paths

• Reinvigorate, expand research fellowships in clinical pharmacology

• Imbed regulatory science research fellowships in translational medicine – e.g. CTSA’s

• Incorporate as significant component of NCATS
  – Populate BIG RESEARCH CHALLENGE’S LIST for RFP’s

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