Follow The Fellow Brick Road: The Journey To A Career In Clinical Investigation

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Clinical Research: NIH Definition

• **Patient-oriented research**: Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects.
  – Mechanisms of human disease
  – Therapies or interventions for disease
  – Clinical trials

• **Epidemiological and behavioral studies**: Examine the distribution of disease, the factors that affect health, and how people make health-related decisions.

• **Outcomes and health services research**: Seek to identify the most effective and most efficient interventions, treatments, and services.

http://www.nichd.nih.gov/health/clinicalresearch
Somewhere Over The Rainbow

Year 1
- August: Began MSCI coursework
- July: IRB Submission

Year 2
- August: Identified mentor and research question
- February: Fellowship Award Application to PIDS: NOT FUNDED
- February: Fellowship Award Application to IDSA: NOT FUNDED
- October: Began enrolling study participants
- November: Began writing KL2 application

Year 3
- June: Began writing KL2 application
- September: Submitted KL2 Application: FUNDED

Year 4
- May: Completed MSCI

Year 5
- July: KL2 Program began
- May: Began writing K23 application

Year 6
- February: Submitted K23
Identifying a Research Question

• Decide what excites you
  – Driven by clinical research questions or fundamental biological processes?

• Develop a niche
  – Passion = Success
  – Choose an area that’s moving forward

• READ, READ, READ
  – Become the expert
  – Find what has been done already
    • NIH Research Portfolio Online Reporting Tools (RePORT)
  – Ascertain the gaps in what is known about the topic
    • Determine which of these gaps is FEASIBLE to study and EXCITING to you

• Plan a logical progression of studies
Inspiration: Identify a Clinical Challenge

- **EMERGING EPIDEMIC**
  - Skin abscesses and invasive infections caused by methicillin-resistant *Staphylococcus aureus* (MRSA) in otherwise healthy children

Orscheln RC et al., *Clin Infect Dis* 2009
Choosing A Research Mentor

• Never too early
  – Meet with prospective mentors
  – Attend seminars

• Peer reviewed funding, stable research program

• Record of research productivity

• Track record of training mentees
  – Accomplishments of prior trainees
Choosing A Research Mentor

• Career stage

• Availability and time to mentor
  – Regular interactions

• A mentor should:
  – Assist with navigating the institutional infrastructure
  – Provide guidance regarding grant applications
    • Funding mechanism
    • Timing
  – Facilitate networking and collaborative opportunities
  – Allow you to branch off
Advisory Team

• Advisors may be outside of your specialty
  – Multiple perspectives
  – Advocate for you

• Advisory Team Meetings
  – Set short-term and long-term goals
  – Develop a career development plan and timeline
  – Assess needs
  – Evaluate progress every 6-12 months
  – Adjust or revise career path as needed
Multidisciplinary Team

• Multidisciplinary Collaborators: bring different expertise together
  – Infectious Diseases Specialists (Adult and Pediatric)
  – Molecular Microbiologists
  – Biostatistician
  – Epidemiologist
  – Primary pediatricians
    • Practice based research network
  – Genome Center
  – CDC

• Clinical Team
• Colleagues (peer mentoring)
• Institutional Resources
Building Your Research Team

• Research Assistant/Coordinator/Nurse
  – Intelligence and past success
    • You can provide the experience
    • “Some people without brains do an awful lot of talking.”
      - Scarecrow
  – Interest in clinical interactions
    • Important for participant recruitment and retention
  – Be explicit about expectations of position
  – Focus on whether they will fit the culture of your team
    • Work ethic
    • Team player
Leading Your Research Team

• Communication
  – Develop and retain your key people
  – Consider their career development, too
  – Help them see the importance of the big picture
  – Be open to their ideas
– Delegate
  • Train well and empower them to do their job
Formal Training in Clinical Investigation

• **Formal Degree**
  – Master’s in Public Health
  – Master’s of Science in Clinical Investigation

• **Coursework**
  – Study Design
  – Epidemiology
  – Biostatistics
  – Ethics for Clinical Research
  – Scientific Writing
Other Skills Needed

• Marketing skills, creativity
• Financial planning
• Questionnaire design
• Database management
  – Microsoft® Access
  – REDCap: Research Electronic Data Capture
• Reference management program
• People management (supervisor)
• Time management
• Handling rejection
• Work-life balance
Plan Ahead: Clinical Research Takes TIME and PATIENCE

• Participant recruitment and retainment
  – No mouse colony
  – Uncertainty about participant compliance
  – Attrition

• Talk to a statistician while designing the study
  – Collect and enter data in a manner that can be easily analyzed
Challenges of Clinical Research

• Institutional Review Board
  – Talk with the IRB: Choose the correct forms and wording to make the process go smoothly
  – Some committee members are lay people
  – Demonstrate that you are thinking good science AND participant safety
  – Be straightforward about research risks
    • Outline measures to minimize risks
Challenges of Clinical Research

• Other Administrative Applications
  – Federal Drug Administration
    • Investigational New Drug (IND) application or exemption
  – Certificate of Confidentiality
  – Institutional Clinical Research Center
  – Radiation Safety
  – Data Safety and Monitoring Board

• Disappointments along the way
  – Wrong hypothesis
  – Grants and manuscripts rejected by reviewers
Why would I EVER want to do clinical research???
Rewards of Clinical Research

• Moving science forward
• Answering a clinical question
• Identifying solutions
• Working with patients (playing with kids)
• Making an impact in the health of children
Development Package

• Protected time
  – Clinical service
  – Lectures
  – Committees
• Personnel: human capital
• Research space
• Equipment and supplies
• Participant remuneration
Final Pearls

• Present your research at every available opportunity

• Submit abstracts to meetings

• Be committed to finish what you start
  – Every abstract should become a manuscript

• Apply for funding: apply early, apply often!

• Watch and listen to successful people

• Focus, focus, focus
  – But be willing to branch out if a good opportunity arises

• Persevere
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The End