MSL@UNC Regulatory Affairs Event

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CATO SMS

Partnering from Strategy to Approval

About me

- Ph.D. in bioengineering from Penn State in 2015
  - Overqualified for many entry-level industry positions
  - Underqualified for many established industry positions
- Joined Cato Research (now CATO SMS) through the Fellows program
  - No practical drug or device development experience required
  - Crash course and hands-on experience in all aspects of product development, from preclinical to postmarketing stages, over 1 year.
- Stayed at CATO SMS after my Fellowship in the Regulatory Affairs group
  - Work on projects involving drugs, biologics, and devices
  - Often in a consultant (for strategic advice) or project manager/director (for regulatory meetings and applications) role

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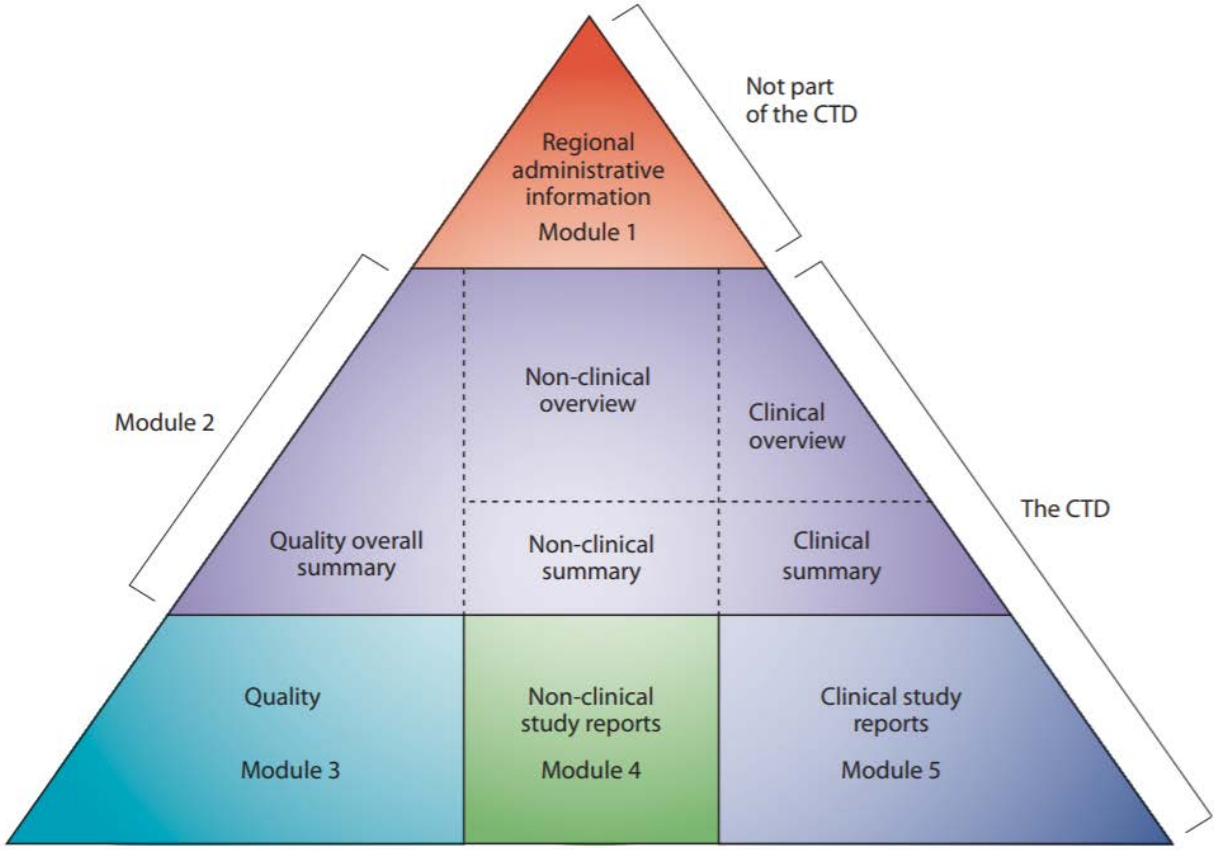
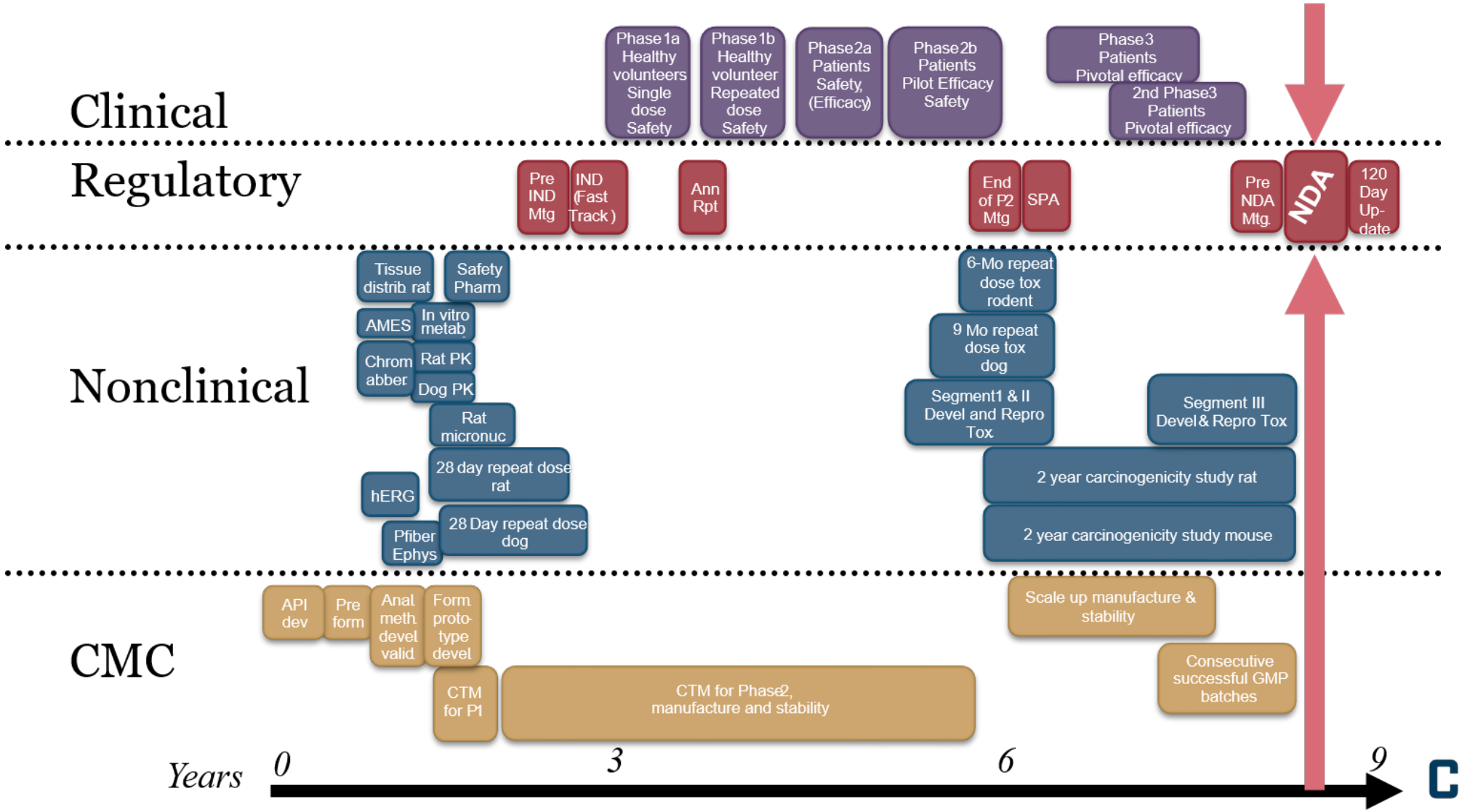
Regulatory Affairs Covers Multiple Disciplines

- Many worldwide regulatory submissions for drugs and biologics conform to the Common Technical Document (CTD) format.
  - Quality (chemistry, manufacturing, and controls [CMC])
  - Nonclinical
  - Clinical
- A good regulatory professional understands the various disciplines and can provide input and oversight on the entire development program.
  - Subject matter experts support individual sections
  - Often 3rd party vendors perform and/or support the manufacturing, nonclinical testing, and clinical trial activities.
- Medical device submissions are organized differently, but still require a multidisciplinary approach.



Source: ICH.org

An Integrated Approach Leads to Product Approval



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Regulatory Professionals Need a Diverse Skillset

- Disclaimer: These skills are those I've found helpful in my own experience or that I've noticed in successful regulatory colleagues. You will get a different list from every regulatory professional.
- What skills are helpful in regulatory affairs?
  - Strong written and oral communication and comprehension
  - Capable of distilling complex topics into concise and informative summaries
  - Willingness and desire to continually learn
  - Ability to handle competing deadlines and stress
- How to prepare for regulatory positions?
  - Sign up for FDA and industry email lists to stay abreast of current developments
  - Attend a few local seminars/events (e.g., NCRAF) or online webinars from national or international organizations (many are free).
  - Read FDA guidance documents, or those from other regulatory bodies, that align with your research or personal interests

CATO SMS

How to Get Involved at CATO SMS

- Internship program through UNC
  - Typically 10-12 weeks, with 2-2.5 days each week spent at CATO SMS
  - Activities typically include medical writing, research to support business development or regulatory strategy, and internal infrastructure projects.
  - Includes opportunities to sit in on CATO SMS project meetings
- CATO SMS Fellows Program
  - 1-year program to introduce PhD and post-doc students to product development (no defined start/stop date each year)
  - Includes all activities from the intern program, plus long-term project assignments and Assistant Project Manager roles.
  - Fellows are offered a scientist position (typically in Regulatory Affairs or Clinical Strategy) at CATO SMS after completing the 1-year program.

- Laura DiMichele, PhD, RAC, CCRP
  - Vice President, Clinical Strategy
  - Oversees the Fellows and Internship programs at CATO SMS
  - Laura.Dimichele@cato-sms.com
- Joshua Taylor, PhD, RAC
  - Director, Regulatory Affairs
  - Joshua.Taylor@cato-sms.com
- Fellows Job Posting

- Questions?

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