UNC | SCHOOL OF MEDICINE
North Carolina Translational and Clinical Sciences Institute

NC TraCS postdoctoral training program

MOTRD UP: Mechanisms of Translation, Realizing Discovery, and Understanding the Pipeline

June 2020

Funder: NC TraCS Institute

- North Carolina Translational and Clinical Sciences Institute
- Supported by a grant from NIH, the National Center for Advancing Translational Science (NCATS)
  - NCATS "strives to develop innovations to reduce, remove or bypass costly and time-consuming bottlenecks in the translational research pipeline in an effort to speed the delivery of new drugs, diagnostics and medical devices to patients"
  - TraCS has 3 components:

U:
Pilot awards, consultative services and programs

KL2:
Junior faculty career development program

TL1:
Postdoc program in translation

MOTRD UP: New Postdoctoral Program

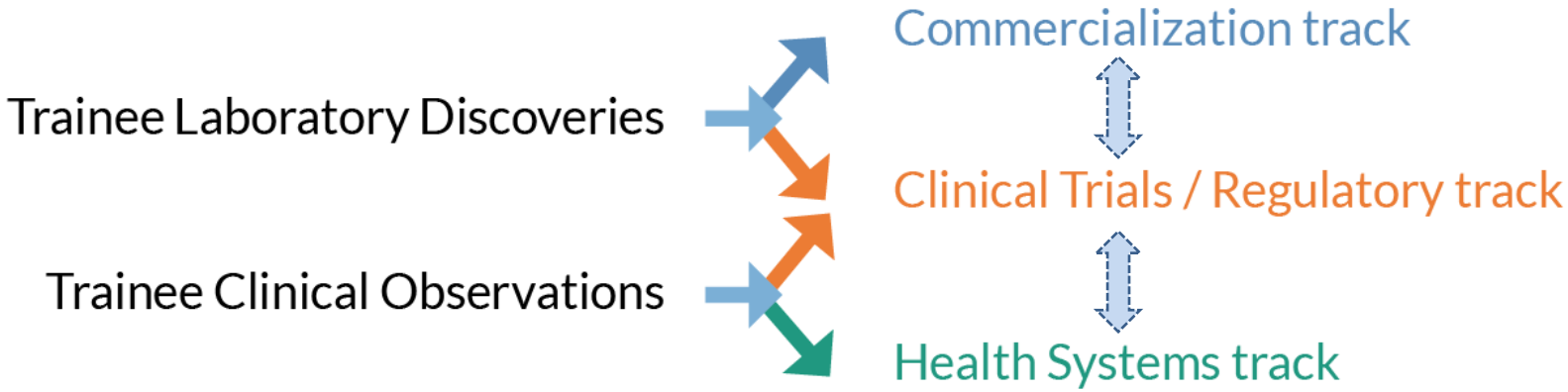
- Goal: Train a cadre of postdoctoral fellows to become translational scientists by immersing them in the actual translation of research products within one of three tracks in the translational pipeline:
- clinical trials/regulatory (CTR)
- entrepreneurship and commercialization (EC)
- health systems (HS)

What are the challenges to translation?

Clinical trials/regulatory (CTR)	Entrepreneurship and commercialization (EC)	Health systems (HS)
What steps do I take to bring a discovery from the lab into a clinical trial?	When is the right time to begin taking steps toward commercialization (i.e. patenting, development, startup formation)?	How do I know when there is enough evidence to support implementation of trial results into practice?
What permissions do I need and from what bodies- local, national?	How do I determine the right application/market for my technology?	How do I identify and interact with leaders of health systems?
How do I get funding?	What UNC and other resources are commonly used to advance technology development/commercialization?	What type of expertise do I need: clinical expert, local opinion leader, implementation scientist?
What are the functions of different members of clinical trial teams?	What types of advisors, consultants or collaborators should I seek out?	
	How should I develop a long-term development plan, given funding and market uncertainties?	

Examples of translation

MOTRD UP provides exposure to the full translational pipeline and applied training in 3 distinct tracks associated with the pipeline.



Unique mentorship structure

Scientific/content mentor: individual who will help you with the scientific direction of the project	You propose, can be a team
Resource experts: have extensive experience in overcoming regulatory, logistical, and other obstacles to conducting research activities, often the critical day-to-day individuals that expedite project implementation	TraCS or you can propose
Informatics experts: tailored to the needs of the project (e.g. CDW-H, “big data”)	TraCS or you can propose
Stakeholders: people/organizations who have an interest in the project	TraCS assistance and you can propose

Core Training Components for all Trainees

- Stakeholder
- Communication
- Informatics
- Leadership
- Strategic thinking
- Teamwork

Competency	Track 1: Commercialization/ Entrepreneurship	Track 2: Clinical Trials/ Regulatory	Track 3: Health Systems
Stakeholder Engagement	Venture capital, Angel investors; Stakeholder Advisory Board	The public, sponsors, industry, regulators	Public, payers, healthcare system leaders, providers
Communications (oral)	Business pitch	Informed consent process	Presenting data on effectiveness of quality improvement initiative to diverse team members
Communications (written)	Patent applications	FDA submissions, IRB applications	Developing 1-page brief on results of translational activity to health care system leaders
Informatics	mHealth, precision medicine applications	Use of i2b2, cohort discovery tools	Data linkage across sites

Examples of foundational skills training and tailoring to specific translational track

Foundational Skill	Track: Commercialization/ Entrepreneurship	Track: Clinical Trials/ Regulatory	Track: Health Systems
Stakeholder Engagement	Venture capital, Angel investors; Stakeholder Advisory Board	The public, sponsors, industry, regulators, clinicians, payors	Public, payors, healthcare system leaders, providers
Communications (oral)	Business pitch	Informed consent process	Presenting data on effectiveness of quality improvement initiative to diverse team members
Communications (written)	Patent applications	FDA submissions, IRB applications	Developing 1-page brief on results of research and policy/implementation for health care system leaders
Informatics	mHealth, precision medicine applications	Use of i2b2, cohort discovery tools	Data linkage across sites
Leadership/ strategic thinking	Planning for and launching start-up, interactions with academia	Responsibilities of clinical research team members, delegation	Forming and leading a team of health system leaders, providers and policy makers
Teamwork	Techniques for leading blended teams across academia/start-ups, industry	Increasing engagement of team members in translational research teams	Describing to health systems leaders and providers the “value statement” for research

Logistics: NIH T mechanism

- Stipends follow NIH guidelines
- Appointment period is 12 months with option for additional year
- NIH requirements for payback and electronic appointment processing, progress reports
- National TL1 meeting
- BUT- no tuition coverage (can audit relevant courses)

Eligible candidates

- Candidates must have something to translate, for example:
  - going into clinical trials
  - moving toward commercialization, or to obtain patent
  - data/policy ideas to implement in a health system
- Candidates will be asked to describe the “translational milestones” in the application process:
  - Patent, FDA IND, IRB approval, etc.
- Any questions about this, please ask!

Application Process

- Application consists of a description of the product/idea you want to translate, your scientific and other mentors (if you have them), your biosketch, preferred start date
  - We can help you find other mentors, but you must have a scientific mentor
- Applications taken on a rolling basis
- If you plan to apply, let us know: Allison_Rorie@med.unc.edu