

Introducing
Triangle Center of Excellence in Regulatory Science and Innovation

Triangle CERSI

Paul Watkins, Susan Halabi, Robert Mentz, Ehsan Samei

In cooperation with scientific communities of UNC, Duke, NCCU, NCSU



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Duke
UNIVERSITY



BURROUGHS
WELLCOME
FUND 

NC STATE
UNIVERSITY

Triangle CERSI PI's



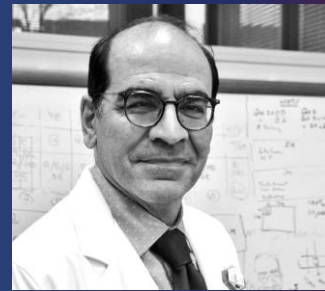
Paul Watkins



Susan Halabi



Rob Mentz



Ehsan Samei

- Regulatory science is **the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products.**

Strategic Areas for Regulatory Science



Modernize development and **evaluation** of FDA-regulated products



Strengthen post-market surveillance and **labeling** of FDA-regulated products



Invigorate public health preparedness and **response** of FDA, Patients & Consumers

BAA

Eligibility	all academic centers
Peer review	extensive
Initiator	academic
FDA collaborators	no

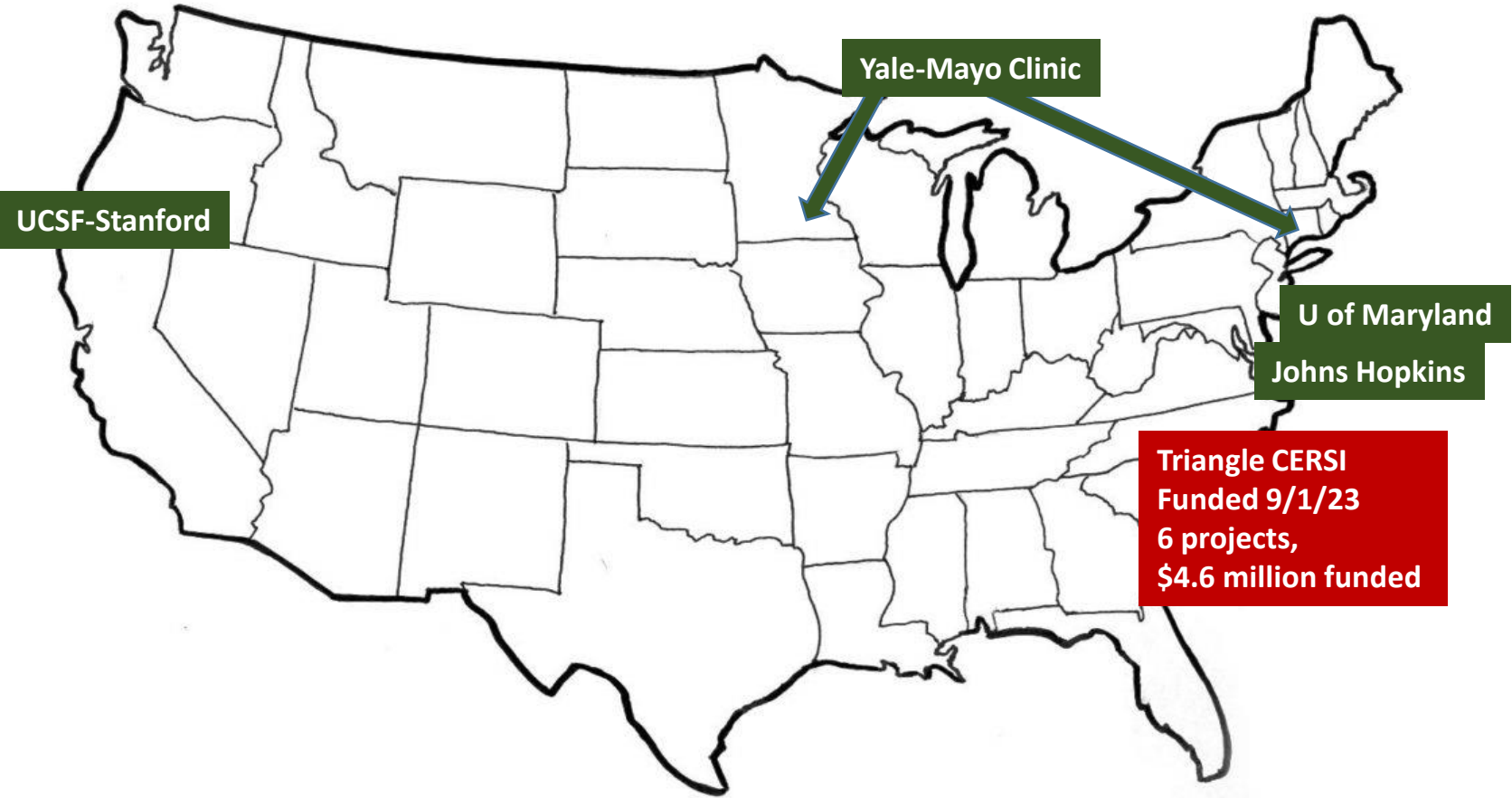
Funding through CERSI vs Broad Agency Announcement (BAA)



	BAA	CERSI
Eligibility	all academic centers	CERSI only
Peer review	extensive	limited
Initiator	academic	FDA
FDA collaborators	no	yes

Conclusion: CERSI is simpler path

Location of the five CERSIIs



Why Triangle CERSI?

- A unique scientific and industry community with deep expertise in regulatory science
- Physical proximity of 4 major universities, research foundations and industry
- Juxtaposition of synergetic connection of four MPIs
- Bringing unique and complimentary expertise to the CERSI network

What the Triangle CERSI has to offer ...

- 8 **health science schools** leading in research & education
- Innovation in **drug discovery and safety** assessments
- **Imaging** expertise – Center for Virtual Imaging Trials
- Expertise in **machine learning**, artificial intelligence and digital health
- Novel **statistical methods** – Bayesian, trial design/analysis, causal inference, real world evidence
- World's largest **full-service ARO** (study coordination, execution & dissemination) with cardiovascular, pediatric and data expertise
- Experience in **community engagement & recruitment** Innovation
- Medical countermeasures and preparedness for emerging **infectious disease**
- Individualized therapies and **precision medicine**
- Novel improved predictivity of **non-clinical studies as alternatives to** animal testing



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What triangle has to offer... NCCU, NCST, BWF



NC Central UNIVERSITY

- Expand ongoing training opportunities
- Exploring research opportunities

Research Center in Minority Institutions (RCMI) for Health Disparities Research

Julius Chambers Biomedical Biotechnology Research Institute,

Biomanufacturing Research Institute and Technology Enterprise

NC STATE UNIVERSITY

- Expertise in veterinary medicine
- Expertise in statistics
- The Biomanufacturing Training and Education Center (BTEC)
- Global “One Health” Academy

BURROUGHS WELLCOME FUND

- Centrally located 47,000 sq ft modern facility
- \$75K/year for NCCU student tuition for Reg Sci Masters and micro-credentials
- Opportunity to utilize Resident Scholar Program – \$125K awards

Triangle CERSI funded projects (*as of 10/25/23*)



CERSI PIs	Substance Use Disorders
PI: Ferreri-Hughes	Understanding the Provision of Opioid Overdose Harm Reduction in Community Pharmacies
PI: Dunn/Goldsack	Developing a risk prediction engine for relapse in opioid use disorder
PI: McElligott	Characterization of the impact of xylazine and dexmedetomidine: binding profile, addictive behaviors, physiology, and wound development
	Patient-Reported Outcomes and other Clinical Outcome Assessments
PI: Bennett/Coles	Recall of patient-reported symptoms and function in episodic disease/conditions including TMJ
	Complex Innovative Trial Design
PI: Li	Principal stratification methods and software for intercurrent events in clinical trials
	Use of Real-World Evidence to Support Medical Product Development and Regulatory Decision-Making
PI: CERSI -Cao	Using the UNC Clinical Data Warehouse to Evaluate the Benefit/Risk Ratio and Optimal Doses of Molecularly Targeted Therapies and Novel Biologics in Real World Patients

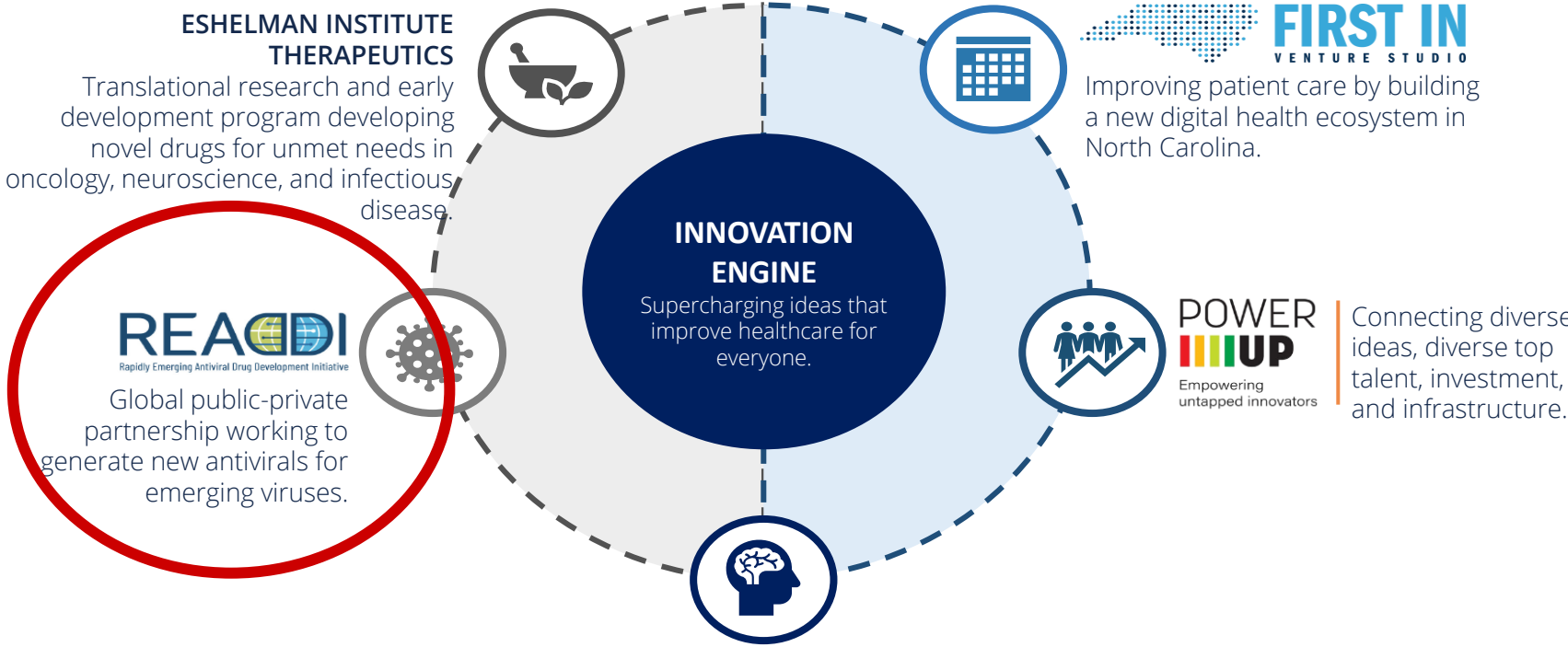
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What does Triangle CERSI mean to RTP

- 1). Help retain and recruit the top academic faculty
- 2). Opportunity to partner not-for profit entities
 - Burroughs Welcome Fund
 - Eshelman Institute for Innovation

PARTNER: ESHELMAN INSTITUTE FOR INNOVATION STRATEGY



TAKING ON OPIOIDS

Developing safe therapeutic alternatives to prevent opioid misuse from the onset.

Building a pipeline of venture concepts that address critical stages of the addiction cycle.

THERAPEUTICS

DIGITAL HEALTH

What does Triangle CERSI mean to RTP

- 1). Help retain and recruit the top academic faculty
- 2). Opportunity to partner not-for profit entities
- 3). Opportunities for engagement with for profit entities
 - “Information transfer”
 - Hotline to FDA?
 - RTP/NC Industry advisory board ?

Thank You!

Triangle CERSI PI's



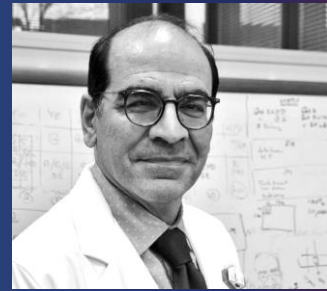
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