National Institute of Allergy and Infectious Diseases

NASEM workshop: Impact and Control of Valley Fever

Update on the NIAID Strategic Plan for Research to Develop a Valley Fever Vaccine

November 17-18, 2022

NIAID

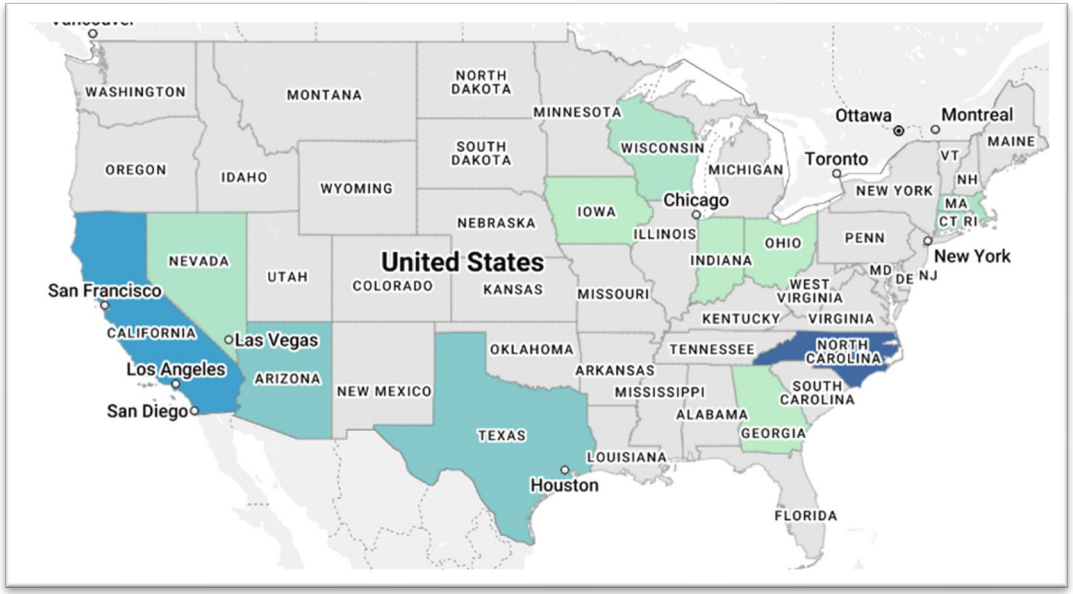
National Institute of Allergy and Infectious Diseases

Dona Love, PhD
Mycology Program Officer
NIAID, National Institutes of Health

Coccidioidomycosis—Research Portfolio

- >30 projects
- > $30M funding
- 7 R01s
- 12 R21s
- 4 U19s

Location of NIH Cocci research grants

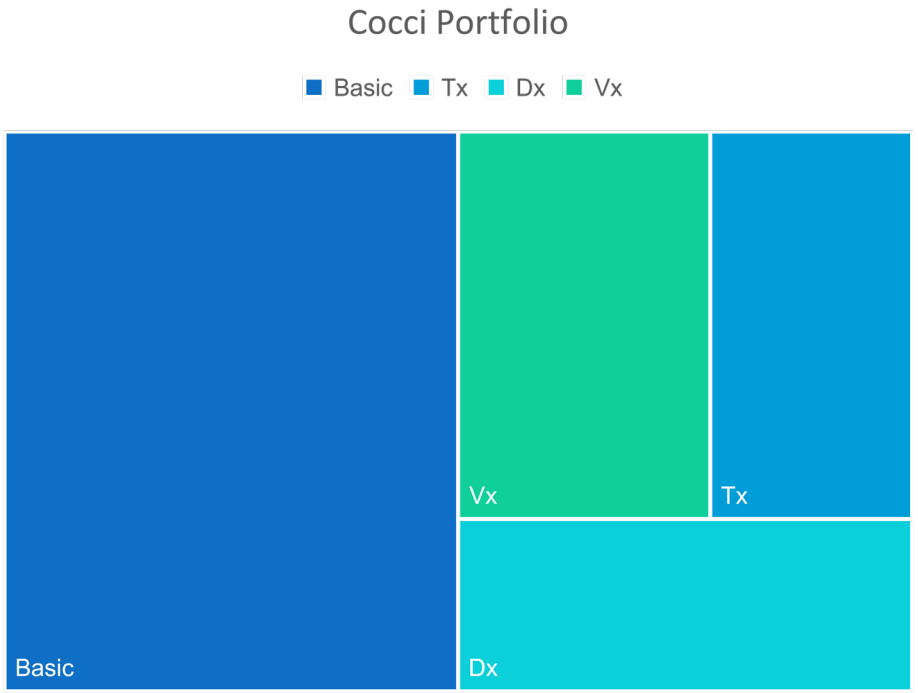


-data from NIH Reporter

Coccidioidomycosis—Research Portfolio

- >30 projects
- > $30M funding
- 7 R01s
- 12 R21s
- 4 U19s

- NIAID utilized special Program announcements and RFAs to increase applications and grants



-data from NIH Reporter

Advance Research and Vaccine Development for Coccidioidomycosis

- NIAID established a **Strategic Plan** for Research to Develop a Coccidioidomycosis Vaccine
- Published a Request for Information to solicit community comments & suggestions (NOT-AI-22-026)
- Structured around three areas of research vital to developing a vaccine for coccidioidomycosis:
  - *Understand Coccidioides Pathogenesis and Host Responses*
  - *Develop Tools and Resources to Support Coccidioides Research*
  - *Advance Strategies to Prevent or Treat Valley Fever*

Advance Research and Vaccine Development for Coccidioidomycosis

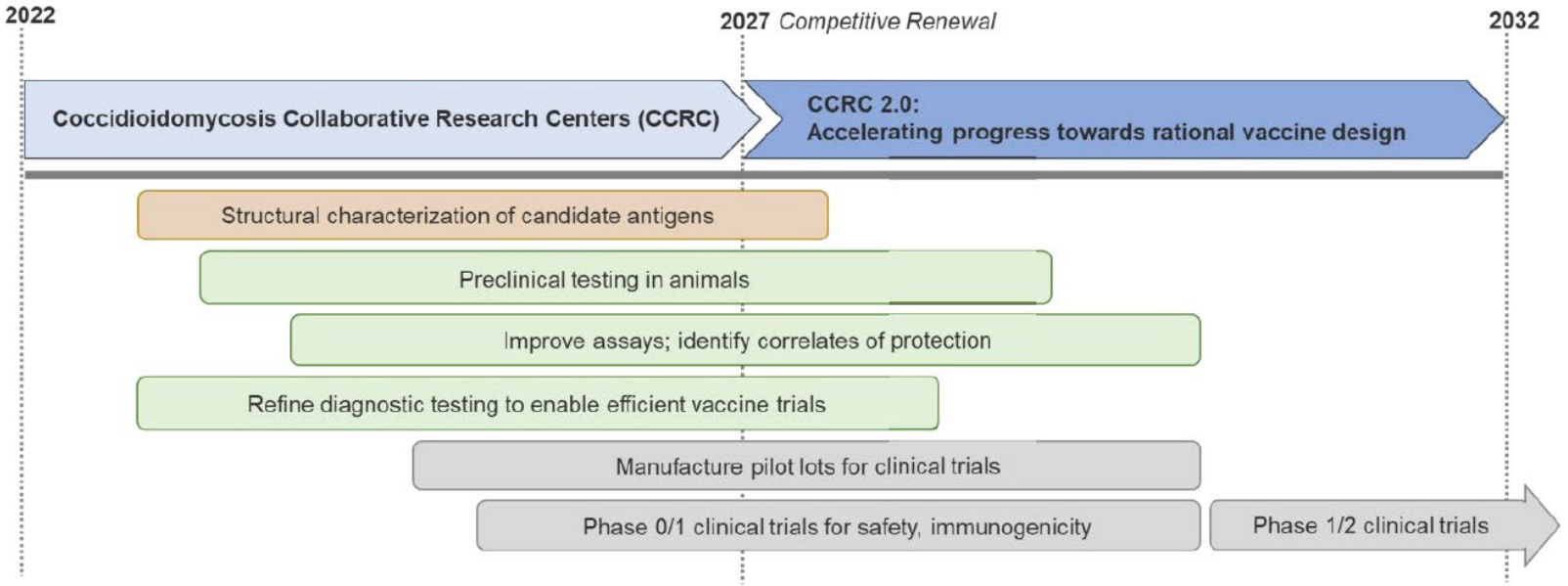
- Received 13 responses from academia/industry
- NIAID Working Group
- Published September 15, 2022

Advance Research and Vaccine Development for Coccidioidomycosis

Target Product Profile (TPP) Characteristics

	Minimal	**Optimal**
Goal	Prevent disease	Prevent infection
Age range	All adults	All ages
Special populations	Safe and effective in immunocompromised	Safe and effective in all populations
Species covered	*C. immitis* and *C. posadasii*	*C. immitis* and *C. posadasii*
Durability of protection	Lifelong with yearly boosters	Lifelong after priming regimen
Vaccine platforms	Suitable for use in immunocompromised people (i.e., recombinant protein, mRNA)	Suitable for use in immunocompromised people (i.e., recombinant protein, mRNA)

10-year Benchmarks towards a Valley Fever Vaccine



Appendix Figure 1: Benchmarks in the Valley fever vaccine development process.

NIAID-Supported Valley Fever Research Resources

- Appendix 4 lists resources for Valley fever research

Resource Name	Description
	vaccines to treat allergies, autoimmune diseases, and cancer
NIH Tetramer Core Facility	Produces and distributes major histocompatibility complex tetramers and related reagents to the research community
Phase I Clinical Trial Units for Therapeutics	Support design, development, implementation, and conduct of Phase I clinical trials against viral (other than HIV), bacterial, parasitic, and fungal pathogens
Preclinical Models of Infectious Disease Program	Provides development, screening, and efficacy testing in preclinical infectious diseases models, including traditional lab species, nonhuman primates, and non-traditional models
Structural Genomics Centers for Infectious Diseases	Applies state-of-the-art technologies/methodologies to characterize 3-D atomic structures of molecules to support infectious disease research
Therapeutic Development Services: Biopharmaceutical Product Development Services	Offers services for biotechnology products, such as planning, product characterization, process development, formulation, Good Manufacturing Practice, and Chemistry, Manufacturing and Control documentation
Therapeutic Development Services: Interventional Agent Development Services	Facilitates development of therapeutics, including lead identification and development, chemistry and manufacturing, toxicology, and pharmacokinetics

Resources for Researchers

Synthesis & Manufacturing

- Medicinal chemistry synthesis
- Small molecule manufacturing
- Vaccine manufacturing
- Biopharmaceutical manufacturing (for products containing monoclonal antibodies, recombinant proteins, peptides, and nucleic acids)
- Diagnostics reagent production or procurement

Non-clinical Studies

- *In vitro* ADMET profiling
- Screening pharmacokinetics (mouse, rat, hamster)
- Bioanalytical method development and qualification
- Non-GLP and GLP pharmacokinetics
- Non-GLP and GLP safety and toxicology
- Assay development for non-clinical and clinical samples
- Immunogenicity

Efficacy Studies

- *In vitro* MIC
- Hollow fiber infection models
- Validated animal infection models
- Developing new animal infection models

Documentation and planning support

- Product development plan production
- Support for regulatory activities and documentation

Interested in PCS? *Email: erin.zeituni@nih.gov, erica.raterman@nih.gov* ***Interested in more information on PCS and contacts?*** *See: https://www.niaid.nih.gov/about/dmid-preclinical-clinical-services-contacts*

NIH

NIAID

Thank You

Contact Information:

Dona Love
Dona.Love@nih.gov
Text/Call: 240-695-7097

NIH National Institute of Allergy and Infectious Diseases

NIAID

Additional support for researchers

www.niaid.nih.gov/research/resources

www.niaid.nih.gov/research/therapeutic-development-services

NIAID

NIAID Early Phase Clinical Trial Units (EPCTUs)

EPCTUs will:

- Support: implementation of Phase 0 to Phase 2 clinical trials in healthy and diseased populations in an expeditious manner; and include bioanalysis.
- Support: licensed and investigational therapeutics (including small molecules and monoclonal antibodies), vaccines, diagnostics, and adjuvants.

Additional support for researchers

b|e|i RESOURCES

SUPPORTING INFECTIOUS DISEASE RESEARCH

NTCF NIH TETRAMER CORE FACILITY

Vaccine Adjuvant Compendium

NIAID

Career Development Awards for Clinicians

K08

- Mentored Clinical Scientist Research Career Development Award
- 3-5 years “protected time”
- 75% effort
- Clinical trial not allowed
- Citizen/permanent resident
- $100K salary; $50K support

K24

- Midcareer Investigator Award in Patient-Oriented Research
- Mentor young physicians in clinical research
- Up to 5 years
- 1 renewal of 5 years
- 25-50% effort
- Clinical trial allowed
- Citizen/permanent resident

K23

- Mentored Patient-Oriented Research Career Development Award
- ≤5 years “protected time”
- 75% effort
- Clinical trial not allowed
- Citizen/permanent resident
- $100K salary; $50K support

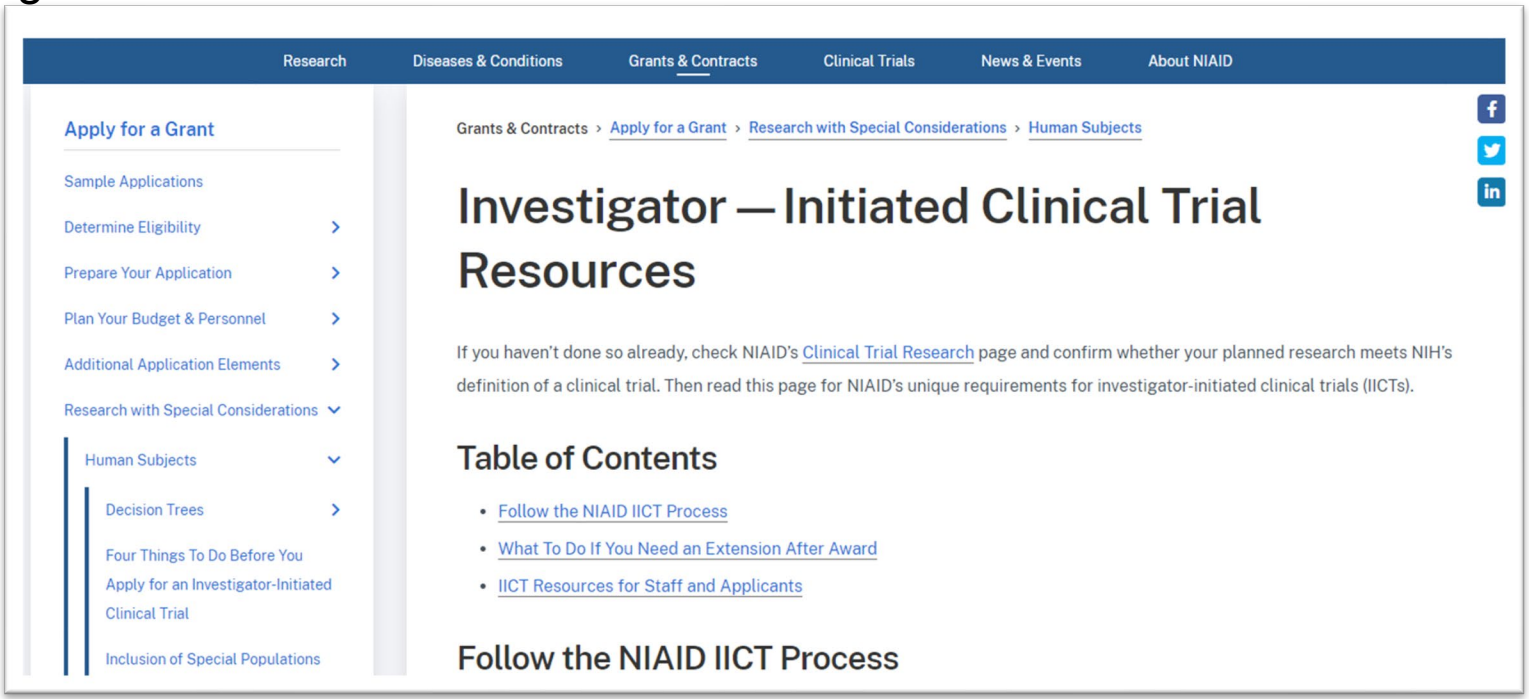
K99/ R00

- Physician-Scientist Pathway to Independence
- ≤2 years K99; ≤2 years R00
- 25-50% effort
- Clinical trial allowed
- No citizenship requirement
- K99: $75K salary; $25K support
- R00: $249K total costs

NIAID

Investigator-Initiated Clinical Trial Awards

Considering a clinical trial? Go here first:



IICT awards—getting started

- Start with NIAID's Investigator—Initiated Clinical Trial Planning and Implementation Awards SOP, then read the following:
  - Investigator-Initiated Clinical Trial Awards—General Questions and Answers and other IICT Questions and Answers
  - Four Tips for Investigator—Initiated Clinical Trial Applications
- Decide which IICT FOA best suits your research
- At least 10 weeks before your application's due date, speak to the scientific/research contact listed on the FOA to request a prior consultation
- All grant applications >$500K direct costs require prior consultation