NIH (NIAID) Activities on *Candida auris*

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National Institute of Allergy and Infectious Diseases

NIAID Antimicrobial Resistance Approach

- **Basic Research**
- **Translational Research/ Product Development**
- **Clinical Research**

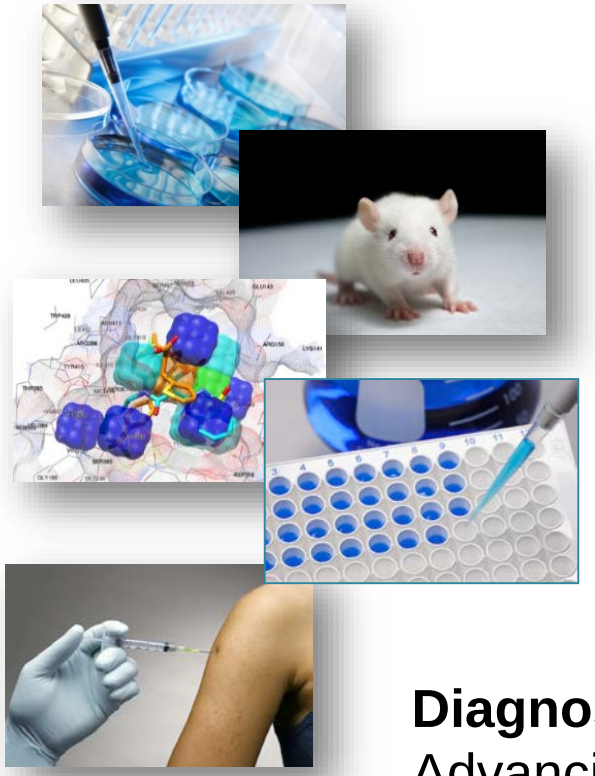
Diagnosis, Prevention and Treatment

Basic Research

- ~34% of the basic mycology portfolio dedicated to *Candida* spp ($18M FY18)

- *Candida auris* specific research:
  - develop genetic tools
  - determine evolution of drug resistance
  - identify druggable pathways using gut and cellulitis animal models
  - analyze host-pathogen interaction

Translational Research



Therapeutics

- ~60% of the antifungal therapeutic portfolio dedicated to *Candida* spp ($6.6M FY18)
- *Candida auris* specific research:
  - Library screening
  - Lead optimization
  - Pre-IND studies
  - Host-based immune therapy

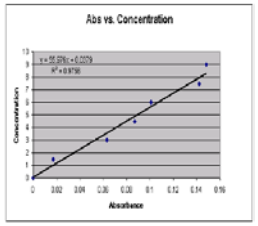
Diagnosis (New Opportunities)

Advancing Development of Rapid Fungal Diagnostics

- R01 (PA-19-080) & R21 (PA-19-081) options
- Open until 2022
- First set of applications still under review

Translational Research

***In Vitro* Assessment of Antimicrobial Activity**

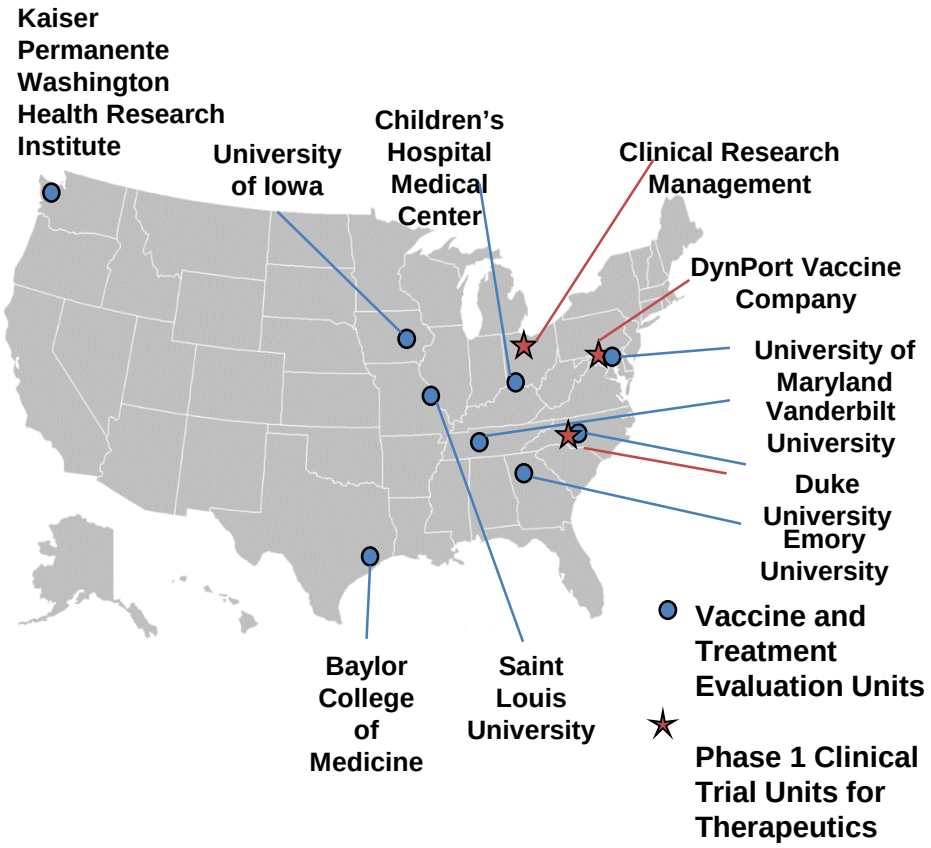


Animal Models

NIAID preclinical services have supported antifungal agents at all stages of development.

- Most clinical stage antifungals targeting *Candida* spp. indications have utilized NIAID preclinical services
- Testing specific to *C. auris* efficacy
  - In 2017, NIAID developed a *C. auris* systemic candidiasis model of infection in mice.
  - Since 2017, tested four products versus *C. auris in vivo*.
  - Since 2017, tested fifteen products versus *C. auris in vitro*.

Clinical Trial Support



General Capabilities

- Contracts provide services, not direct funding, for all aspects of the clinical trial

Phase I Clinical Trial Units for Therapeutics

- Support Phase I clinical trials of new drugs

Vaccine and Treatment Evaluation Units (VTEUs)

- Phase I-IV clinical trials
- Prevention and treatment of DMID pathogens

NIAID is supporting two Phase I clinical trials on two products that have anti-*C. auris* activity. One is a First-in-Human study.

NIH Intramural Support

NIH Clinical Center participated in a study about the first seven reported cases of *C. auris* in the United States

- The third patient in the US infected with *C. auris (*already colonized) was transferred to the NIH, and identified at the NIH Clinical Center in 2016. NIH CC alerted CDC.

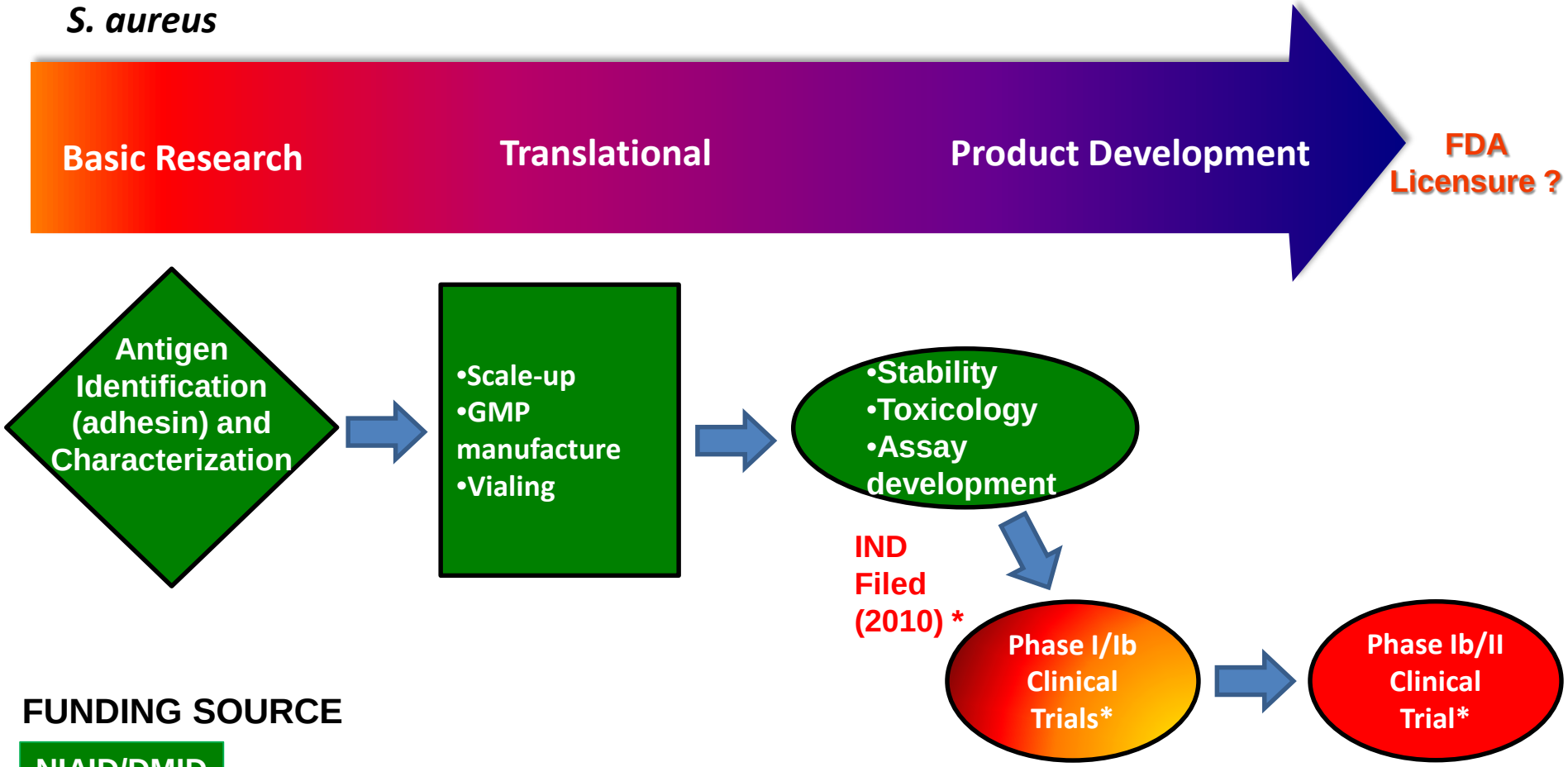
NIAID and National Human Genome Research Institute (NHGRI) are establishing a mouse model of cutaneous *C. auris* colonization and infection to understand colonization and infection with a systems biology approach

- Skin biology and immunity
- Bacterial-fungal microbiome on the skin
- Decolonization strategies in mice

NIH Clinical Center

Vaccine Candidate NDV-3: Active Against *Candida and S. aureus*

Problem: Growing number of healthcare-associated infections due to *Candida* and *S. aureus*



FUNDING SOURCE

- NIAID/DMID
- Company
- DoD

*NovaDigm Therapeutics, Inc.

EFFORT: ◇ Investigator ▭ DMID Service Contracts ⬭ Company/PPP

Thank you

…for your interest