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DRAFT AGENDA: Developing vaccines for fungal diseases: Coccidioidomycosis/Valley fever

August 13-14, 2024

5601 Fishers Lane, 1D13, Rockville, MD

Website registration: https://cvent.me/kDvG4z

Objectives and background:

This joint workshop between the FDA, NIH, and CDC will bring together a diverse group of stakeholders to summarize progress toward developing vaccines against fungal diseases, with an emphasis on our current understanding of the epidemiology, biology, and immunology of Valley fever; discuss current vaccine programs, essential diagnostics, and regulatory pathways; and identify remaining gaps and opportunities to support the successful development of a vaccine against Valley Fever and other fungal infections.

Valley fever, also called coccidioidomycosis, is one of the most common endemic fungal infections in the United States with over 20,000 cases reported to the CDC annually and over 200,000 estimated symptomatic infections. Due to similarities with other respiratory illnesses and nonspecific symptoms, Valley fever is often misdiagnosed. The course of infection may be self-limited, but in some cases, Valley fever can affect previously healthy individuals, cause severe or life-threatening illness, and require prolonged antifungal therapy. Natural infection confers protection against future disease, suggesting that a vaccine is possible. Several vaccine strategies and platforms are in early stages of development, but more research and support are needed to realize the goal of a Valley fever vaccine.

Day 1

Time	Session/Topic	Speaker/Moderator
Welcome, introductions, opening address		
7:30-8:30	Registration	
8:30-8:40	**Opening Remarks, workshop objectives FDA/NIAID**	David Kaslow, MD, FDA & TBD, NIAID
8:40-9:10	**Valley fever vaccine: past, present, and future** **A Patient Perspective on Valley Fever** *25 min + 5 min questions*	Royce Johnson, MD Rob Purdie Kern Valley Fever Institute
Session 1: Epidemiology and burden of Valley fever		
9:10-9:30	**Valley fever epidemiology** *20 min*	Tom Chiller, MD CDC
9:30-9:50	**Incidence and geographic distribution of Valley fever** *20 min*	Mitsuru Toda, PhD CDC
9:50-10:10	**California populations at high risk of infection or severe coccidioidomycosis based on surveillance, hospitalization, death, and outbreak data** *20 min*	Gail Cooksey, MPH California Department of Public Health
10:10-10:25	Coffee Break *15 min*	
10:25-10:45	**Modeling the future of Valley fever epidemiology** *20 min*	Jennifer Head, PhD University of Michigan
10:45-11:05	**Moderated Discussion** *20 min*	Tom Chiller & Mitsuru Toda, CDC

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Session 2: Immunology and correlates of protection		
11:05-11:25	**A clinical overview of Valley Fever** *20 min*	Fariba Donovan, MD University of Arizona College of Medicine
11:25-11:45	**The innate and adaptive immune response to Valley Fever** *20 min*	Manish Butte, MD UCLA
11:45-12:05	**T cell epitopes for a Valley Fever Vaccine** *20 min*	Erik Settles, PhD Northern Arizona University
12:05-12:25	**Moderated Discussion** *20 min*	Dona Love, PhD, NIAID
12:25-1:10	**Lunch** *45 min*	
Session 3: Challenges of Valley fever Diagnostics		
1:10-1:30	**Valley fever diagnostics: an overview of current strategies** *20 min*	GR Thompson, MD University of California, Davis Medical Center
1:30-1:50	**Valley fever diagnostics: testing guidance** *20 min*	Janis Blair, MD Mayo Clinic, Arizona
1:50-2:10	**Valley fever diagnostics: cell-mediated immune assays** *20 min*	Neil Ampel, MD University of Arizona
2:10-2:30	**Considerations for a rapid Coccidioides diagnostic** *20 min*	Sean Baumann, PhD IMMY
2:30-2:50	***Moderated Panel Discussion*** *20 min*	Paul Eder, PhD, NIAID Judith Anesi, MD, FDA
2:50-3:05	Coffee Break 15 min *15 min*	
Session 4: Current Valley fever vaccine candidates		
3:05-3:35	**Current Valley fever vaccine candidates: Live-attenuated vaccines from the dog model to human vaccine** *30 min*	John Galgiani, MD University of Arizona
3:35-4:00	**Current Valley fever vaccine candidates: Recombinant & mRNA platforms** *25 min*	Chiung-Yu Hung, PhD University of Texas, San Antonio
4:00-4:25	**Current Valley fever vaccine candidates: mRNA & DNA platforms in NHP models** *25 min*	Deb Fuller, PhD University of Washington
4:25-4:45	***Moderated Panel Discussion*** *20 min*	Kim Taylor, PhD, NIAID Lanling Zou, PhD, NIAID
End of Day 1		

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Day 2

Session 5: Regulatory considerations FDA		
Time	**Session/Topic**	**Speaker/Moderator**
9:00-9:25 am	**Reaching Phase I: Chemistry, Manufacturing, and Controls Regulatory Considerations** *25 min*	Scott Stibitz, PhD FDA
9:25-9:50 am	**Development and Licensure of Preventive Vaccines: Clinical Regulatory Considerations** *25 min*	Judith Anesi, MD FDA
9:50-10:15 am	**Clearance, approval, validation: Regulatory considerations for novel diagnostics** *25 min*	Ribhi Shawar, PhD FDA
10:15-10:35 am	***Moderated Panel Discussion***	Scott Stibitz, PhD, FDA Judith Anesi, MD, FDA
10:35-10:55 am	Coffee break *20 min*	
Session 6: Breakout sessions with FDA and NIAID		
11:00-12:00pm *(Each room running concurrently)*	**Room 1: How to file an Investigational New Drug Application**	Cara Fiore, PhD, FDA Claudia Wrzesinski, PhD, FDA
	Room 2: eCTD Details – What Goes Where?	Sheila Dreher-Lesnick, PhD, FDA
	Room 3: Meetings with FDA – What to Expect	Susan Lehman, PhD, FDA Judith Anesi, MD, FDA
	Room 4: Practical Tips on Clinical Trial Design	Rachel Zhang, MD, FDA
	Room 5: NIAID preclinical support, clinical trial mechanisms, regulatory support	NIAID Staff
Session 7: Wrap up and next steps		
12:00-12:30 pm	**Town Hall with FDA, NIAID, CDC** -	FDA, NIAID, CDC moderators
12:30 pm	**End of meeting**	
End of Meeting		