

# NIAID/NIH – CBER/FDA TB Vaccine Regulatory Workshop

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US Department of Health and Human Services (DHHS)



National Institutes of Health (NIH)



National Institute of Allergy and Infectious Diseases (NIAID)



# NIH



Supports and Conducts Research to Strengthen the Foundation of Scientific Knowledge and its Translation into New Health Care Interventions.

# NIAID



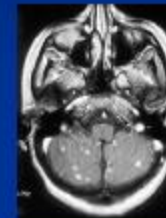
Has the Lead within NIH in Research on Tuberculosis

([www.niaid.nih.gov/dmid/tuberculosis/](http://www.niaid.nih.gov/dmid/tuberculosis/)).

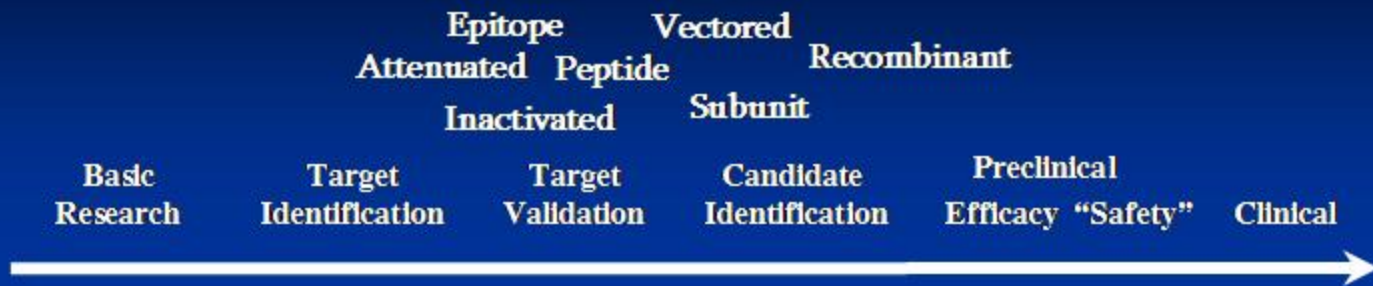
Encourages Submission of Applications in all Aspects of TB Science, as well as Vaccine, Drug and Diagnostic Development.

Provides contract resources to support:

- basic research
- development of candidate drugs, vaccines, diagnostics
- clinical testing of new candidates



# Goals of the Workshop.....



- Overview of the Regulatory Process for Vaccines in the US
- Focus on preclinical development and Phase I/II trials
- Identify issues in TB vaccine development

.....Provide opportunities to discuss regulatory issues for TB vaccines



## **NOT Covered Today.....**

- ▶ **NO** detailed discussion of individual vaccine candidates
- ▶ **NO** discussion of merits or shortcomings of a candidate
- ▶ **NO** discussion of science of vaccine development
- ▶ **NO** discussion of Phase III trials



# Agenda Topics.....

## **Session I. Overview Of The USFDA Regulatory Process**

IND “enabling” studies and the IND

## **Session II. Vaccine Development: From The Laboratory To FDA**

Practical issues in getting to an IND - two perspectives

## **Session III. Clinical Trial Issues**

Issues to consider for Phase I/II TB vaccine trials

## **Session IV. Specific Vaccine Issues**

What to consider for specific CLASSES of TB vaccines

## **Session V. Open Discussion**

..... and now, let talk about this.....

## **Session VI. Meeting Summary**

What are outstanding issues in TB vaccine development?

.....and over lunch: A TB vaccine study in the UK

How are our colleagues in Europe dealing with TB vaccine development?

