



Malaria Research Program at CBER

Sanjai Kumar, Ph.D.

Chief, Malaria Research Program

Division of Emerging and Transfusion-Transmitted Diseases

Office of Blood Research and Review

CBER, FDA

Rockville, MD



FMVCC Meeting, January 7, 2011



FDA Mission Oriented Research: Science Based Regulation

- **Blood safety from infectious agents**
- **Assays of vaccine safety and efficacy**



CBER Malaria Research Program

- **Blood safety from malaria**
 - **Direct parasite detection: DNA tests**
 - **Surrogate of infection: Antibody tests**
- **Applications:**
 - **Diagnostics**
 - **Donor screening**
 - **Efficacy of vaccines and drugs**



CBER Malaria Research Program

- **Assays of vaccine safety and efficacy**
 - **Biomarkers of attenuation and virulence of malaria sporozoites**
 - **Biomarkers of attenuation and virulence of blood stage parasites**



CBER Malaria Research Program

- **Assays of vaccine evaluation**

- A quantitative Western Blot that can detect a single *P. falciparum* sporozoite

- A quantitative Western Blot for the detection of antibodies to mosquito salivary gland in serum



CBER Malaria Research Program

- **Biomarkers of attenuation and virulence in irradiation-attenuated *P. falciparum* sporozoites**
 - Comparative expression profiling in non-irradiated and different doses of γ -irradiation exposed *P. falciparum* sporozoites
 - Unique biomarkers of attenuation and virulence are identified that belong to important biological pathways
 - Search for association between biomarkers of attenuation and infectivity and growth in liver cell cultures.



CBER Malaria Research Program

- **Biomarkers of attenuation and virulence in irradiation-attenuated *P. falciparum* blood stage parasites: Building a model to study the effect of γ -irradiation on a cell**
 - **Effect of γ -irradiation on survival and growth in cultures**
 - **Ultrastructural changes**
 - **Microarrays**



CBER Malaria Research Program

- **γ -irradiated *P. berghei* parasites**
 - Optimal dose to achieve attenuation
 - Vaccine studies: Anti-parasite and anti-disease effects
 - Mechanisms of immunization-induced immunity



CBER Malaria Research Program

- **Molecular mechanisms of experimental cerebral malaria**
- **Immunological mechanisms that induce protection in the *P. yoelii* model**