

# THE WALTER REED ARMY INSTITUTE OF RESEARCH

## *Translational Medicine Branch*

### **Mission**

The Translational Medicine Branch at the WRAIR serves as a centralized resource for regulatory compliant activities, product development, and validated assay development. The Branch further serves as the focus for active FDA communication and proactive discovery of FDA requirements and changes in coordination with sponsors and their designees. The Branch comprises three departments: the Department of Clinical Trials led by MAJ(P) James Moon, the Pilot Bioproduction Facility led by Dr. Ken Eckels, and the Department of Regulatory Affairs led by Ms. Lisa Ware.

### **Scope of the Problem**

The Department of Clinical Trials executes Phase I, II, and III human clinical trials to the highest ethical and safety standards– fully compliant with GCP, FDA, and DoD regulations. The department operates with maximum efficiency, multitasking functional areas among job descriptions, new metrics for recruiting efficiencies, and FDA part 11 CRF compliant electronic databases. Dedicated staffing includes licensed nurses who are also certified clinical coordinators, data managers, a phlebotomy team and administrative personnel to assist investigators in all trial related activities.

The Pilot Bioproduction Facility (PBF) manufactures clinical grade material for clients. The PBF is a multi-use facility designed and operated for production of vaccines in compliance with current Good Manufacturing Practices (GMP) regulations. Compliance with cGMP ensures that products prepared in this facility will be safe, potent, and producible. The PBF follows all federal regulations that apply to biological products and has expertise in the development and production of vaccines for the prevention of a variety of infectious diseases. Additional capabilities include viral diagnostics and GLP testing.

The Department of Regulatory Affairs provides regulatory guidance and promotes compliance for all product development activities. Professional regulatory services ensure that submissions are suitable and effective in order to accelerate the development process. The regulatory affairs team includes medical writers, database managers, regulatory affairs scientists, archivists and biostatisticians. This team prepares, reviews and maintains regulatory documentation (IND applications, Investigator's Brochures) to ensure efficient review and approval.

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# WRAIR

Walter Reed Army  
Institute of Research

Soldier Health • World Health



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Bringing Value...Inspiring Trust

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### Major Accomplishments

- The Department of Clinical Trials initiated, continued, or completed seven critical studies to develop effective protections from multiple forms of malaria, infectious diarrhea, H1N1, and Plague.
- Branch personnel authored six manuscripts published online or in peer-reviewed literature during FY2011.
- Dr. Kenneth Eckels, along with other scientists at WRAIR, recently received an award for his contributions in the research, development and clinical testing of the newly licensed Japanese encephalitis (JE) vaccine. Intercell recognized the scientists at WRAIR who initiated the vaccine project and contributed to numerous aspects of vaccine development up to licensure. As a result of this public-private partnership, military personnel, dependents and civilians will be protected against the serious and growing risk posed by JE when travelling to many countries of the world.
- The Department of Regulatory Affairs has incorporated biostatisticians into the team to provide in house FDA part 11 and STIG compliant statistical analyses to clinical trials. The department has been instrumental in developing electronic data capture for the MRMC. The department has initiated one new Investigational New Drug (IND) application, maintained eight active INDs and three master files with the FDA.

### Future Challenges/Directions

- Sustain robust leadership within each department and develop highly experienced deputy personnel to ensure stability and growth of technical capabilities
- Grow and nurture a stable customer base to solidify funding streams and workloads
- Continue to attract, train and maintain talented and capable product development investigators and staff.

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