

MAMEF Clinical Trial in Karachi, Pakistan, August – December 2012.

The IoF, in Partnership with the CVD at the University of Maryland School of Medicine, is to under take a clinical trial of its Non-Typhoidal Salmonella MAMEF Assay in Karachi, Pakistan, August through December 2012.

The goal of this project is to “test the feasibility of the IoFs rapid and sensitive diagnostic assay platform which downstream will be developed into a hand-held point-of-care device that detects Salmonella in blood”, which is in keeping with the funding agencies mission, *The Bill and Melinda Gates Foundation*, which aims to support new technologies that can improve diagnosis of diseases that disproportionately affect developing countries. This clinical trial will test the efficacy of the IoFs MAMEF assay / technology on whole blood drawn from 5-15 yr-old children.

Salmonella enterica serovar Typhi and S. enterica serovars Paratyphi A and B, the causative agents of typhoid and paratyphoid fever (known as enteric fevers), are human-restricted pathogens that remain important causes of morbidity and mortality in many countries with poor sanitation and water and food contaminated by human fecal waste. In addition, in sub-Saharan Africa systematic blood culture-based surveillance in various research sites has unexpectedly revealed that the burden of non-typhoidal Salmonella (NTS) invasive disease was as high as the burden of invasive bacterial disease caused by Haemophilus influenzae type b (Hib) and Streptococcus pneumoniae in infants and toddlers and was associated with case fatality rates of 20-30%. Notably, two serovars, S. Typhimurium and S. Enteritidis, account for 80-95% of all invasive NTS in sub-Saharan Africa. Invasive Salmonella bacteremia is currently detected by standard blood culture techniques which requires multiple hours (or even days) before detection occurs. Additional hours are required for bacteria to be confirmed as Salmonella; yet further delay ensues until the serovar is elucidated. *Thus, there is a pressing urgent need for a sensitive and specific rapid diagnostic test to detect Salmonella bacteremia.*

The goal of this work is to field test in clinical trials the IoFs Microwave-Accelerated Metal-Enhanced Fluorescence (MAMEF)-based diagnostic device that is at least as sensitive as blood culture in detecting Salmonella in blood but does not require any bacteriologic culture step (such as enrichment in broth culture) and is extremely rapid, confirming the presence of Salmonella at very low DNA copy numbers in < 2 minutes. Ultimately, we have configured our MAMEF technology to detect any Salmonella serovar, but also to identify specifically S. Typhi, S. Paratyphi A, and the NTS serovars S. Typhimurium and S. Enteritidis. Our approach particularly targets use in settings lacking blood culture capability and where Speed, Sensitivity and low cost testing is paramount.

For more information on our latest clinical trial, contact Professor Dr Chris D. Geddes, Geddes@umbc.edu