

About the Institute for OneWorld Health

Founded in 2000, the Institute for OneWorld Health (iOWH) is the first non-profit pharmaceutical company in the US. Its mission is to develop safe, effective and affordable new medicines for people with infectious diseases in the developing world. The Institute for OneWorld Health was founded to address the wide gulf between human need, scientific effort, and the marketplace. In the spirit of partnership and collaboration, iOWH capitalizes on the specific talents and resources that our partners bring to this essential scientific endeavor. The Institute for OneWorld Health is headquartered in San Francisco, California with a field operation office in Bihar, India. We currently have three active drug development programs that include:

Visceral Leishmaniasis

Visceral leishmaniasis (VL or kala-azar) is a fatal systemic infection caused by various species of *Leishmania* parasites; transmission occurs through the bite of a sandfly. If left untreated, VL is nearly always fatal. Approximately 500,000 new cases of visceral leishmaniasis arise annually worldwide. Over 90% of visceral leishmaniasis cases occur in India, Bangladesh, Sudan, Brazil, and Nepal¹.

In its flagship program, iOWH completed a Phase 3 clinical study in India for Paromomycin IM injection as a new treatment for visceral leishmaniasis. In August 2006, Paromomycin IM injection received regulatory approval by the Drug-Controller General of India, and in May 2007, the drug was designated by the World Health Organization for inclusion on its Model List for Essential Medicines. In November 2007 iOWH initiated a major Phase 4 pharmacovigilance and access program of Paromomycin IM Injection for the treatment of VL in India.

Malaria

Malaria is a life-threatening disease transmitted by mosquitoes. More than 40 percent of the world's population lives in areas where malaria is transmitted. It is a preventable and treatable disease, but nonetheless kills at least one million people each year, primarily young children under the age of five.²

The Institute for OneWorld Health works in collaboration with synthetic biology innovator Amyris and leading pharmaceutical company sanofi-aventis to develop a semisynthetic form of artemisinin, whose derivatives are a key component in first-line malaria treatments. This partnership builds on technology originated by Professor Jay Keasling at the University of California, Berkeley. The collaboration, known as the Artemisinin Project, aims to create a complementary source of non-seasonal, high-quality and affordable artemisinin to supplement the current botanical supply, making them more accessible to the hundreds of millions of impoverished people who contract malaria each year.

Diarrheal Diseases

Every year, approximately two million children under the age of five die of diarrheal diseases³, mostly in resource-constrained developing countries. Since implementation in 1980, Oral Rehydration Therapy (ORT) has significantly and progressively reduced deaths due to acute diarrheal diseases. Yet there remains an urgent need to develop further safe, effective and affordable drugs to treat infants and children with diarrheal diseases.

Over the next five years, the Institute for OneWorld Health Diarrheal Disease Program will position itself to be the global leader in Diarrheal Disease Research & Development to discover, develop and deliver safe, effective and affordable therapeutics for the treatment of diarrhea in adults and pediatrics among neglected populations in developing countries. IOWH has received \$46M funding from the Bill & Melinda Gates Foundation to develop anti-secretory drugs that will leverage and complement ORT to prevent life-threatening complications of dehydration and malnutrition. To support this approach IOWH recently entered into a collaboration with Roche to access the Roche proprietary compound library to identify a potential new anti-secretory drug to be used as an adjunct to ORT for the treatment of diarrheal diseases.

¹ Centers for Disease Control and Prevention "Fact Sheet *Leishmania* Infection"
http://www.cdc.gov/ncidod/dpd/parasites/leishmania/factsht_leishmania.htm

² Centers for Disease Control and Prevention "Malaria Facts" <http://www.cdc.gov/malaria/facts.htm>

³ Bryce J, Boschi-Pinto C, Shibuya K, Black RE, 2005. WHO estimates of the causes of death in children. *Lancet* 365: 1147-52.