Title: **DEVELOPMENT OF A DNA VACCINE FOR VISCERAL LEISHMANIASIS**

Acronym: LEISHDNAVAX
Coordinator: Professor Simon Croft

Summary:

This project is focused on preclinical development of a safe and efficient prophylactic and therapeutic DNA vaccine ready for clinical trials against different forms of leishmaniasis. The immunogenicity of our T cell-directed vaccine LEISHDNAVAX, will be evaluated in human cell culture systems, its efficacy will be determined in animal models for visceral and cutaneous leishmaniasis, and we will establish its safety in standardised preclinical studies. The vaccine will be based on the Minimalistic Immunogenically Defined Gene Expression (MIDGE) vector developed for efficient induction of T-cellular immune responses and, if required, adjuvanted with Double Stem Loop Immunomodulator (dSLIM). These technologies have been developed by Mologen AG (www.mologen.com), our SME partner. Based on preset criteria, we will select 3-5 known protective antigens from a predefined shortlist and incorporate their genes into MIDGE vectors. To complete the preclinical requirements, efficacy and safety studies will be conducted for prophylactic as well as therapeutic indications. The prototype vaccine will be produced under GMP conditions. While all this is being done, we will identify and prepare sites to conduct clinical trials at ICH-GCP standards against different forms of leishmaniasis. This includes training in preclinical and clinical development, and establishing all required components and infrastructure to conduct trials at the highest international standard. The consortium includes partners with extensive experiences in *Leishmania* research and vaccine development in India (IICB & RMRI), Tunisia (Ins. Pasteur, Tunis), Israel (HUJI), Germany (Charite & Mologen AG) and United Kingdom (LSHTM).