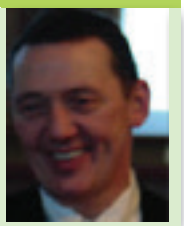
OVERVIEW

To further product advancement within the CAVD, the Foundation has worked with the International AIDS Vaccine Initiative (IAVI) to create a specialized Central Service Facility titled the Vaccine Product Development Center (VxPDC) that acts to support a series of CAVD Principal Investigators (PIs). The VxPDC works with PIs to progress their preventative projects (vaccines and antibodies) through a translational stage and into clinical studies. An appreciable fraction of this work is funded through the VxPDC Core Grant, whereas this specific grant is a companion module. Specifically, it became apparent that a more efficient and effective support of investigators could be achieved by further centralizing that support with funds to cover:

- the costs associated with the cGMP manufacture of the vaccine through a variety of Contract Manufacturing Organizations (CMOs);
- the associated toxicology study(ies) necessary for regulatory filings typically carried out at specialist Clinical Research Organizations (CROs);
- and the subsequent clinical data analyses on completion of clinical studies.

Giving IAVI the flexibility to contract directly with third-party service providers will allow IAVI to utilize both the expertise of their specialists and their portfolio of development projects, both considerable advantages vs. having individual CAVD PI institutions pursue negotiations where they may lack such expertise or the leverage of larger portfolios. In such a centralized context, a number of advantages should be realized. The costs and time involved in setting up contracts with these companies will be reduced, again as specialists will be used to set up the contracts and since IAVI has been in a position to negotiate favorable rates with multiple suppliers. Similarly, savings in cost and time can be realized by having IAVI implement master service agreements with key CMO and CRO's. The number of errors (setbacks for time and costs of a project) will be reduced. When errors do occur with a particular project, management by a single team ensures that lessons from the events furnish expertise that can be applied to other projects, thereby improving performance and quality.

Grant at a Glance



Principal Investigator
Thomas Hassell, PhD

Grantee Institution
International AIDS Vaccine, Initiative, New York, USA

Project Title
Vaccine Product Development Center: GMP Manufacturing, Toxicology, and Clinical Data Management

OPPID
1147661

Grant Award
Up to $57.6 million, awarded in May 2016

One key point to highlight is that the overall governance of the process has been designed to ensure the CAVD PI (and colleagues) are kept fully aware of the work conducted with the CMOs and CROs in support of their program, and to provide clarity over the PI's key decision making role in the final selection of the vendors/suppliers.

This grant is led by Thomas Hassell, PhD at the International AIDS Vaccine Initiative (IAVI). The majority of costs are allocated to contracted services provided by third parties. The CMOs and CROs selected will primarily be based in the U.S.A. However, in some instances selection of overseas groups will be considered, and these are most likely to be based in Europe to be proximal to particular CAVD grantees. The award was made in May, 2016 and then further supplemented through an amendment in October of 2017 with an anticipated end date of 12/31/2021.

RESEARCH OBJECTIVES

Initial objectives include:

1.) Production of MPER peptides in liposomes
2.) Production of BG505 SOSIP.664
3.) Production of selected monoclonal antibodies
4.) Production of eCD4-Ig
5.) Production of a CMV vectored HIV/AIDS vaccine.