

OVERVIEW

The Vaccine Product Development Center at IAVI is designed to serve the Collaboration for AIDS Vaccine Discovery (CAVD) and the broader field, with the primary goal of accelerating the development and testing of novel HIV vaccine candidates.

In essence, this program provides a methodology by which Principal Investigators, currently supported through the CAVD, could rapidly and confidently access additional HIV vaccine development expertise that helps to ensure the success of their project in reaching first in human studies. Done in a timely fashion, this results in an efficient way of taking the vaccine candidate(s) forward to clinical development with full regulatory support. Potential issues with the development of the candidate product will be identified and expertise provided in ways to address such issues.

RESEARCH OBJECTIVES

- 1.) Provide an expert range of development services from which the CAVD PI can select appropriate support (depending on their particular needs), specifically:
 - a.) Product development planning, including supporting development of Product Development Plan and Target Product Profile and provision of tools for monitoring of objectives vs. deliverables.
 - b.) Development of regulatory strategy and preparation of related filings, e.g. pre-IND, IND (USA and International).
 - c.) Design and management of preclinical studies, e.g. Toxicology.
 - d.) Identification, commissioning, and management of manufacturing partners and distribution of clinical materials.
 - e.) Clinical development planning and execution through Phase I/II.
 - f.) Continuous project management assistance/support.
 - g.) Quality assurance support across entire process.
- 2.) Work with the PI to identify their specific needs and then provide a proposal on how the grantee's needs may be met, including specific work recommended, internal and external resources that would be utilized, deliverables and timelines.
- 3.) Grantee determines which of the recommended services they would like to accept and liaise with CAVD Program Officers on overall plans to discuss likely impacts of any suggested modifications to the project (e.g. additional activities and associated costs).
- 4.) Assuming agreement, specific projects will commence with agreed upon plan, timing, milestones, and monitoring.
- 5.) Request feed-back from the CAVD PI on the success of their project, lessons learned and implement process of continuous improvement.

PROGRESS

A total of 15 CAVD PIs have been supported to date through this mechanism, with 18 individual projects, multiple cGMP campaigns, tox studies, and regulatory filings and 17 Phase I clinical studies launched through December of 2018.

Grant at a Glance

Principal Investigator

Thomas Hassell,
PhD



Grantee Institution

International AIDS
Vaccine Initiative, New York, USA

Project Title

Vaccine Product Development Center

OPPID

1153692

Grant Award

Up to \$29.4 Million, awarded
August, 2016