

**Malaria Vaccine R&D at NIAID:
Strategic Overview of
DMID-PIPB-MVDS
Portfolio & Activities**

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Framework for Malaria R&D at NIAID

NIAID Strategic Plan for Malaria Research

Efforts to Accelerate Control and Eradication of Malaria Through Biomedical Research

April 2008


 National Institute of Allergy and Infectious Diseases
National Institutes of Health




NIAID Malaria Working Group

NIAID Research Agenda for Malaria

April 2008

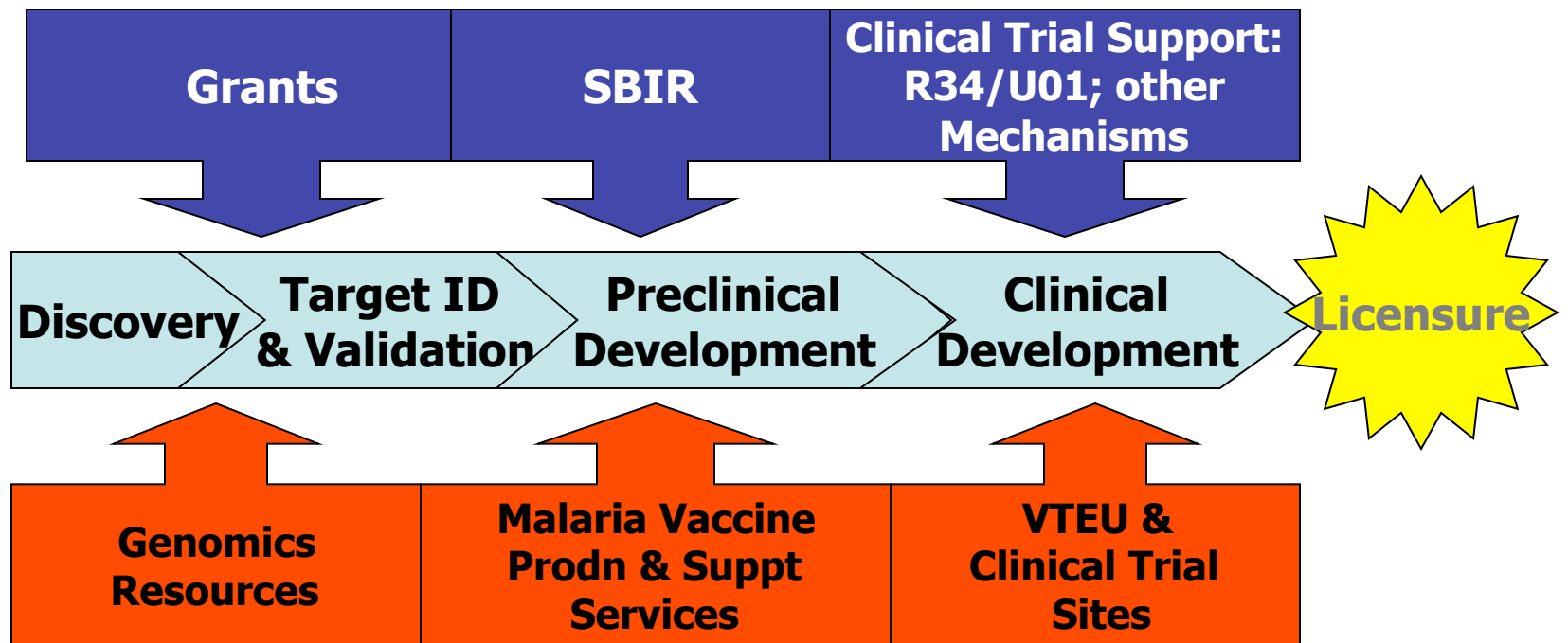
 National Institute of Allergy and Infectious Diseases
National Institutes of Health



Mission Statement: Malaria Vaccine Development Section (MVDS)/PIPB

- **The mission of the Malaria Vaccine Development Section (MVDS)/PIPB, is to identify, develop, validate and evaluate (both preclinically and clinically) promising malaria vaccine candidates. “Promising malaria vaccine candidates” includes not only the antigen(s) but also the platform(s).**

Supporting the Product Development Pipeline



Examples of Strategic Considerations

- **Rationale/Justification for Candidate/ Approach**
- **Indication & Public Health Utility/Niche**
- **Portfolio Balance**
- **Competitive Landscape**
- **Resource Requirements & Timeline**
- **Options for Collaboration & Hand-off**
- **Freedom to Operate**

Strategic Approaches: Overview

<i>Discovery</i>	<i>Target Identification & Validation</i>	<i>Proof of Concept</i>	<i>Preclinical Development</i>	<i>Clinical Development</i>
<ul style="list-style-type: none"> •Diverse portfolio & approaches 	<ul style="list-style-type: none"> •Diverse portfolio & approaches 	<ul style="list-style-type: none"> •Whole Parasite Vaccines •Diverse antigens & platforms (e..g., recombinant protein, VLP, nanotechnology, conjugates) •Combination vaccines 	<ul style="list-style-type: none"> •Ongoing efforts to support candidates in clinical development •Whole parasite vaccines 	<ul style="list-style-type: none"> •Ad35.CS •Polyepitope Pre-erythrocytic DNA vaccine •EBA 175 RII NG/AdjuPhos

Selected Strategic Approaches

<i>Clinical Development</i>	<i>Status</i>	<i>Future Plans</i>	<i>Future Directions</i>
Ad35.CS	Phase 1b in progress	<ul style="list-style-type: none"> •Phase 2a of Ad35.CS alone •Phase 1 studies of prime boost combinations 	Consider development alone and/or as prime-boost; consider inclusion of add'l Ags
Polyepitope Pre-erythrocytic DNA vaccine	Phase 1a in progress	If safety profile adequate, advance to Phase 2a	TBD; multiple options
EBA 175 RII NG / AdjuPhos	Phase 1b in progress	Pending identification of combination partner	Hub of multicomponent blood-stage vaccine