

Integrated approach to portfolio management

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Why Integrating? - Global vaccine development challenges are mostly addressed within partnerships, rather than within individual organizations

Examples:

- Innovation challenges: partnerships between funding organizations, government, academia, biotech, industry
- Vaccine formulation challenges: collaborations between more than one biotech, academia/biotech, academia/industry, industry/biotech, industry/industry, etc.
- Clinical development challenges: partnerships between funding organizations, clinical research organizations, government, industry
- Challenge of poor anticipated return on investment: partnerships between funding organizations, industry, government

Several diseases associated with high global health burden share many of these challenges (HIV included)

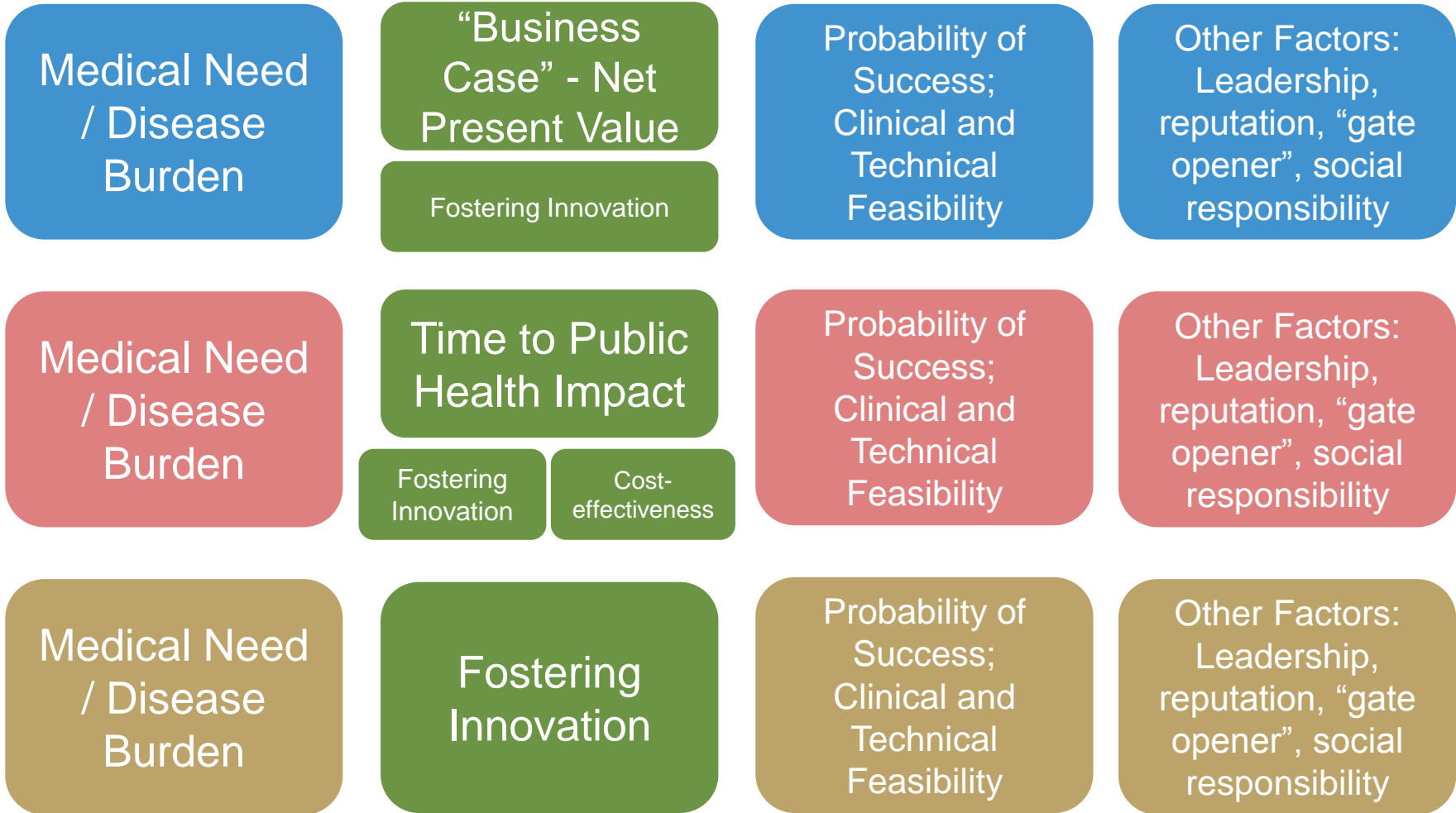
Vaccine development targeting these diseases generally requires PARTNERSHIPS (added/synergistic value, shared risk/benefits)

Integrated Portfolio within Partnerships – General Features

- Generally “focused” approach, rather than “comprehensive” – Examples:
 - Aeras/Sanofi/Government for TB vaccine
 - PATH/BMGF/GSK for Malaria Vaccine
 - WHO/PATH/Serum Institute of India, Limited (SIIL)/Government for Meningococcal A vaccine
 - P5 partnership for HIV Vaccine
- Generally limited number of candidates evaluated
 - Attempt to leverage one or a few promising candidates towards licensure for timely public health impact
- Partnership portfolios generally have “short” life
 - Once milestones are reached (or failed), partnership may dissolve
 - Life of partnerships generally shorter than life of its members
- Partnership portfolios may be highly fluid as dictated by frequent changes in partner composition, priorities, governance, etc.
 - What seems a robust integrated portfolio today may not hold tomorrow

Drivers of Integrated Portfolios within Partnerships (1/3)

INDUSTRY
FOUNDATION
GOVERNMENT



Drivers of Integrated Portfolios within Partnerships (2/3)

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Medical Need
/ Disease
Burden

Probability of
Success;
Clinical and
Technical
Feasibility

Other Factors:
Leadership,
reputation, “gate
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Drivers of Integrated Portfolios within Partnerships (3/3)

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Medical Need
/ Disease
Burden

Probability of
Success;
Clinical and
Technical
Feasibility

Other Factors:
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Example of Integrated Portfolio

Pox Protein Public Private Partnership (P5)

- Addresses challenges: formulation challenge (vectors, proteins, adjuvants); clinical development challenge (public/community perceptions, cost, infrastructure, operations/logistics), poor anticipated return on investment challenge
 - Medical Need: HIV preventive vaccine
 - Candidates: ALVAC-HIV, DNA, gp120 proteins (adjuvanted with MF59, AS01, or others)
 - Probability of Success: built on RV144 results and supportive correlates of protection work.
 - Clinical Feasibility: assumed high given sustained funding, infrastructure built in targeted geography, and historical lessons from RV144 and Thailand development
 - Technical Feasibility: assumed moderate-to-high, given experienced industrial partners
 - Other factors: committed upper management from different partners; potential “reputational blockbuster”
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An out-of-the-box Partnership: GHVCI (Global Health Vaccines Center of Innovation) as a model for partnership focused on innovation

- Partners: Infectious Disease Research Institute (IDRI), Sanofi Pasteur (SP) and the Bill & Melinda Gates Foundation (BMGF).
 - Builds on Vaccine Discovery Partnership signed in 2013 between SP and BMGF
- Focus: Global-Health, Open-Innovation, Vaccine Research & Development
 - Open innovation R&D model--to provide antigens, adjuvanted formulations, funding, and expertise to allow development of needed vaccines.
- Portfolio: variety of adjuvant/formulation platforms and a pipeline of candidate antigens to address a range of infectious diseases.
- Funding: BMGF and SP under a tripartite agreement allowing other parties to participate for specific projects and ensuring training for project-participating scientists.
- SP and BMGF to work together to ensure access of infectious diseases solutions to countries most in need

Thank you!