Vaccine Case Studies

New Vaccine Landscape and Market Introduction Assessment

Situation

Many new life-saving vaccines will be available to developing countries between now and 2012. Global donors want to ensure they are available to the world's poorest countries as quickly as possible. However, the introduction of these vaccines will be hindered by the lack of information to support vaccine adoption decision-making, limited country finances, competing country health care priorities, and global funding uncertainty.

Applied Strategies was commissioned by the Global Alliance for Vaccines and Immunization (GAVI) and the World Bank to determine whether opportunities exist for the global community to improve the speed with which 72 of the poorest countries supported by GAVI are provided with the data they need to be ready to make vaccine adoption decisions and to assess the financial implications of introducing six new vaccines into their countries.

Contribution

- Worked across sectors of the global health community (BMGF, GAVI, WB, WHO, UNICEF) and vaccine teams (human papillomavirus, Japanese encephalitis, malaria, meningococcal, pneumococcal, and rotavirus)
- Developed and validated inputs leveraging key global community experts
- Derived 10 key decision-making criteria for new vaccine adoption
- Assessed the decision-making readiness of 72 GAVI-eligible countries across six new vaccines
- Analyzed the financial implications of various future vaccine adoption scenarios
- Leveraged analysis results to develop new vaccine introduction frameworks and strategies for 2007–2010
- Supported recommendations with an innovative software solution

Results

- A current vaccine portfolio for each GAVI-eligible country
- The earliest date when key data will be available for an adoption decision on each vaccine by each country
- Cost to each country of its existing vaccine portfolio and potential new vaccines
- Cost to GAVI of existing and new vaccines given various financial scenarios
- Potential acceleration interventions for country's readiness for adoption
- Insights into strategies that may be required to support the introduction of new vaccines into GAVI-eligible countries

Vaccine Case Studies

TB Global Market Assessment & Profitability Analysis

Situation

Aeras sought to do an in-depth vaccine landscape analysis examining all the vaccine candidates in its pipeline to gain increased transparency of analysis inputs, to estimate the market size and profitability impact, and to assess eligibility for global health donor funding.

Aeras asked Applied Strategies to leverage its expertise in vaccine global market assessments and its rigorous decision analytic frameworks to determine whether the market was sufficiently attractive to preclude push-pull funding.

Contribution

- Delivered a comprehensive and independent TB vaccine global market assessment
  - Vaccine need and potential market size and value
  - Potential and forecast demand
- Performed risk-adjusted NPV analyses for vaccines to determine market segment profitability
  - BCG replacement vaccines
  - Both initial vaccinations for BCG replacement and boosts for infant and adolescents vaccinated with BCG

Results

- Increased transparency of inputs and a better understanding of complexities of forecasting a developing-world vaccine
- Set the stage for more specific discussions between Aeras, BMGF, and suppliers on push-pull strategies

Vaccine Case Studies

Malaria Vaccine: R&D Portfolio Analysis & Investment Strategy

Situation

The Malaria Vaccine Initiative (MVI) is a public-private partnership formed in 1999 to accelerate the development of promising malaria vaccine candidates and ensure their availability and accessibility in the developing world. MVI faced challenges in how to leverage key learning from historic and ongoing malaria vaccine projects to shape a long-term R&D strategy for its portfolio of vaccine candidates. This was important in building a case for its Core Grant Renewal.

Applied Strategies worked with MVI to develop a five-year R&D strategy for proactively and successfully managing a portfolio in a highly uncertain development environment.

Contribution

- Portfolio approach to R&D
  - Transparent and consistent portfolio characterization
  - Clinical Trial outcome identification and follow-on activity planning
  - Go/no-go investment decision criteria
- Ensuring Execution
  - Comprehensive strategy implementation plan to ensure a successful rollout, completion of key design activities, and ongoing system monitoring and refinement
  - Facilitate effective and credible reviews with key stakeholders (donors, suppliers and countries)

Results

- Laid the foundation for MVI to create its Core Grant Renewal proposal
- Defined the metrics for and tracking accountability for their R&D strategy
- Designed and implemented a more effective project and portfolio management system
- Developed transparent and robust decision-making processes

Vaccine Case Studies

MVI Portfolio Management Process (Public-Private Partnership)

Situation

The Malaria Vaccine Initiative (MVI) was founded in 1999 to accelerate the development of promising malaria vaccine candidates and ensure their availability and accessibility in the developing world. MVI has partnered with many academic, government, and industry research and development organizations to support dozens of vaccine trials, including several endemic population trials in Africa. MVI's R&D portfolio contains 11 ongoing vaccine candidate programs, including the first malaria vaccine to move into Phase III trials.

MVI had some of the same issues as a medium-size biotech, in particular, a large product portfolio that needed to be prioritized and managed. The pharmaceutical industry has developed best practice management processes that help maximize the potential value of the R&D portfolio. In the global health community, however, portfolio management is not routinely practiced, even though maximizing the return on these investments could be measured in lives saved.

Applied Strategies management has been playing a key role in bringing some of these best practices to global health vaccine teams, and MVI initiated a project with us to design and implement a comprehensive portfolio management process.

Contribution

- Established a management committee and program teams with clearly defined decision-making processes and charters
- Defined team member roles and responsibilities and selecting the required team membe rs consistent with these defined roles
- Designed team and cross-team processes that ensure efficient use of MVI resources
- Developed a comprehensive implementation plan to ensure a successful rollout, completion of key design activities, and ongoing monitoring and refinement

Results

- R&D management driven by a portfolio, rather than an individual project, perspective
- All vaccine projects managed consistently and rigorously
- More consistent and transparent vaccine investment and development decisions
- Decision-making responsibility placed at the appropriate levels
- More effective and credible reviews with external stakeholders
- Enhanced return on MVI R&D investments

Vaccine Case Studies

HIV Vaccine Global Vaccine Need & Market Potential Assessment

Situation

The world's largest philanthropic foundation wanted a rigorous, credible global assessment to better understand demand if and when the first vaccine is successful.

Applied Strategies was hired to conduct a global market assessment for HIV vaccines. Our team is currently forecasting global demand for HIV vaccines. This is to be followed by determining forecasted demand given supply and financing scenarios and the potential supplier return on investment.

Contribution

- Developed a base line market assessment that can be used as comparison to third-party assessments and referenced in key stakeholder discussions
- Acquired deep understanding of how to analyze the market potential for HIV

Results

- Generated additional insights regarding demand assessment based on market segmentation
- Unique assessment that accounted for uncertainty of vaccines in clinical development providing prevention and/or transmission and all combinations thereof

Vaccine Case Studies

Launching the First Advance Market Commitment (AMC)

Situation

Advance Market Commitments (AMCs) are a new mechanism for creating an economically attractive low-income country market for vaccine suppliers. The objective is to accelerate the availability of vaccines to these regions of the world and thereby save the lives of millions of children annually.

For the World Bank and Global Alliance for Vaccines & Immunization (GAVI), Applied Strategies led an effort to model and analyze the financial and risk implications of an AMC to determine AMC investment level and AMC vaccine price. We achieved buy-in to the model design and analysis results from a community of diverse stakeholders, including the G8 Finance Ministers, World Bank, GAVI, Center for Global Development, multinational and emerging vaccine suppliers, government finance ministries, and six vaccine-focused public-private partnerships. Our work was instrumental in convincing government donors to raise $1.5 billion to support a pilot AMC for pneumococcal vaccines.

Contribution

- Provided an industry best practices framework to understand the financial implications and risks of the AMC to suppliers, donors, and countries
- Developed a software model to address interdependent decisions on vaccine development, global financing, and country adoption
- Performed analyses to determine AMC size and price for six vaccines in support of the G8 pilot AMC decision-making process
- Educated donors, GH organizations, and suppliers on AMC analysis methodologies, inputs, and results
- Participated in pilot AMC supplier consultations
- Achieved buy-in from diverse stakeholders

Results

- Consistent and transparent analyses across six vaccines, enabling the G8 to decide on a pilot AMC on merit
- $1.5 billion raised for the first pilot AMC for pneumococcal vaccines
- Expected to accelerate developing-world pneumococcal vaccine introduction up to 50%
- Approximately 300,000 children per year are expected to be saved, or a total of 5 million lives by 2030

Vaccine Case Studies

Advance Market Commitment (AMC) Vaccine Supplier Consultations

Situation

The Pneumo AMC was launched in February 2007 after development for several years. Discussions with industry representatives after the announcement indicated that a range of issues still exist about designing and implementing potential AMC agreements. Industry discussions to date have helped shape the framework, but further details are needed on a bilateral basis with individual manufacturers.

Applied Strategies was engaged to facilitate gathering industry input on key financial terms and to structure and create the documents that form the basis of the AMC.

Contribution

- Developed and implemented a consultation strategy between Global Health and Vaccine Suppliers
- Developed and managed key consultation materials (agendas, attendees, & presentations)
- Chaired and presented at supplier consultations
    - With the five major suppliers—Merck, GSK, Wyeth, Novartis-Chiron and Sanofi-Pasteur
    - With six emerging suppliers including manufacturers in India, Brazil, and China
- Translated and compiled supplier feedback for dissemination to donors and suppliers

Results

- Better clarification and categorization of supplier support and concerns
- Data for a donor-chartered expert committee to use to finalize AMC pilot terms
- Greater understanding of AMCs across a broad supplier community