**Rotavirus**
- Rotavirus is the most common cause of severe diarrhea among children.
- Over 500,000 deaths annually worldwide.
- Hospitalization of approximately 55,000 children annually in the United States.
- 90% of deaths of children occur in poor countries.

**Meningitis**
- Meningitis is an infection of the fluid of a person’s spinal cord and the fluid that surrounds the brain.
- Neisseria Meningiditis is the leading cause of Meningococcal disease.
- Bacterial Meningitis can have devastating effects resulting in death or permanent brain and hearing damage.
- Some 10-20 percent of survivors develop permanent pathological damage such as epilepsy, hearing loss, or mental retardation.

**Principles of the Rotavirus Partnership**
- Continuous interaction between all parties.
- Leadership of PATH.
- Agreement of all parties to resolve technical issues.
- Preclinical and clinical agreements.
- Intellectual property (IP) in the context of scale-up.
- Patent agreements with the NIH.
- Funding support to NIH licensees.
- IP rights in US, Europe, Japan, Canada, Australia, Brazil, China, India, and South Korea.

**Meningitis Vaccine Project**
- NIH inventor: Dr. Albert Kapikian
- License Agreement with the NIH.
- Manufactures the vaccine.
- SII (Serum Institute of India)
- IP directed towards Scale-up process.
- Efficient conjugation procedure of bacterial polysaccharides to a carrier protein, using dihydrazide.
- Conjugated vaccine.
- Does not decrease transmission of the organism in the population.
- Does not protect very young children.

**Role of Partnership Components**
- Provides expertise regarding clinical trials.
- Clinical trials.
- Funds and manages the project.
- License Agreement with the NIH.
- IPV.

**Role of PATH-VMP**
- Provides expertise regarding scale-up processes.
- Provides leadership.
- Provides expertise regarding preclinical and clinical agreement.
- Provides leadership.

**Role of Partners**
- WHO: World Health Organization
- FDA: Food and Drug Administration
- PATH-MVP
- SII (Serum Institute of India)

**Meningitis Vaccine for Sub Saharan Nations: Partnership between WHO and PATH with IPV from FDA**

**Meningitis Vaccine Project**

**Meningitis Vaccine Program**

**Role of Partnership Components**
- NIH inventor continued involvement with licensees through consultation and advice.
- Discuss and resolve technical issues.
- Reporting progress.
- Annual meetings with the participation of all parties including consultants.
- Scale-up agreement with PATH.
- Scale-up production of virus strains and production of vaccines.
- Provide scale-up materials to NIH licensees for clinical studies.

**License Agreement with the NIH**
- Financial support of the global partnership.
- A component of Bill and Melinda Gates Foundation.
- A global charitable organization.
- Provides continuous advice to licensees.

**Partnership for Global Vaccine Development**
- Partnerships for Global Vaccine Development.
- PATH – Program for Alternative Technology in Health.
- Murdoch Children Research Institute (Australia).
- Brazil.
- India.
- China.

**Rotavirus**
- Hexavalent Human-bovine reassortants viruses: G1-G4; G8, G9.
- Regional Exclusive licenses. Non-exclusive for rest of the world.

**Meningitis**
- Meningitis is inactivation of the fluid of a person’s spinal cord and the fluid that surrounds the brain.
- Vaccines for Meningitis can have devastating effects resulting in death or permanent brain and hearing damage.
- Meningitis (MVP) is the leading cause of Meningococcal disease.
- Worldwide, the vast majority of meningococci are caused by 5 meningococci (A, C, Y, W-135) of the bacterium.

**Pathologip**
- PATH provides the technology.
- Provides expertise regarding scale-up processing.
- Provides leadership.
- Provides expertise regarding clinical trials.

**Technology**
- Comprised vaccine.
- Efficient conjugation procedure of bacterial polysaccharides to a carrier protein, using dihydrazide.
- IPV directed towards scale-up processes.

**Meningitis Vaccine Project**

**Meningitis Belt in Africa**

**Meningitis Vaccine Program**

**Partnership**
- Under the terms of the license agreement, NIH-PATH, SII of India was granted sublicense rights.
- SII of India was granted sublicense rights to scale-up the procedure and to manufacture the vaccine.
- The project is now in Phase III clinical trials.

**Funding**
- $19.1M; 2006-2011
- Bilateral Agreement between WHO and PATH with IP from FDA

**Role of PATH**
- Provides expertise regarding clinical trials.
- Clinical trials.
- Funds and manages the project.
- License Agreement with the NIH.
- IPV.

**Role of Partners**
- WHO: World Health Organization
- FDA: Food and Drug Administration
- PATH-MVP
- SII (Serum Institute of India)

**Partnership for Global Vaccine Development - Meningitis Vaccine Project (MVP) for Sub Saharan Africa**

**Kevin Chang, Ph.D.; Peter Soukas, J.D.; Susan Ano, Ph.D, Uri Reichman, Ph.D.**