

Vaccine Innovation and Adult Immunization Landscape

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Manufacturers Serve a Key Role in the Battle against Infectious Diseases

Manufacturers are best positioned to fully develop and produce vaccines

Extensive expertise and adaptability

State-of-the-art facilities

Capital independent of government grants

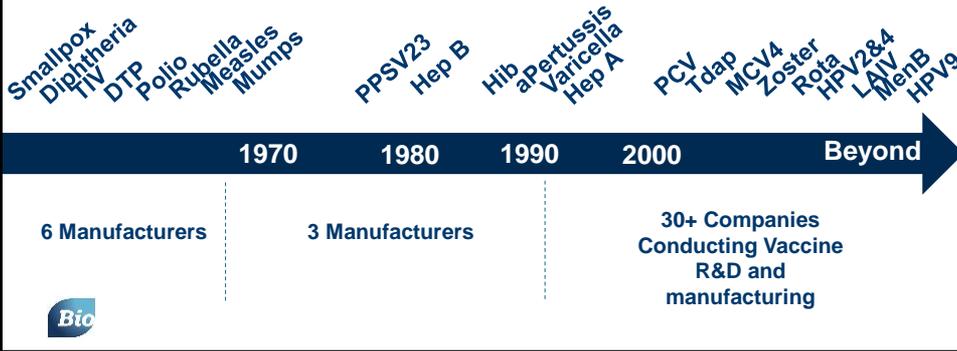


Future vaccines are dependent on a sustainable business and policy environment that recognizes and rewards innovation.

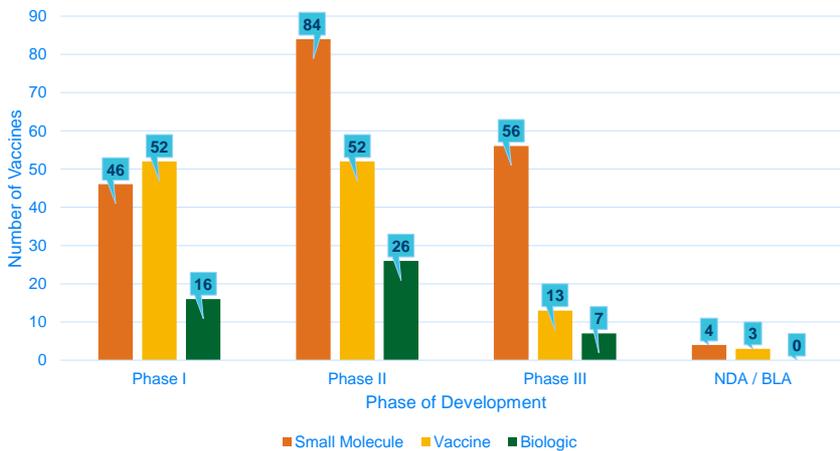


Changes to the Landscape Helped Stimulate New Company Entrants into Vaccine Development

- Over the last 2 decades, more than a dozen new vaccines have been introduced and the number of companies developing products has increased.
- Companies can increase investment in vaccines because new vaccines can often demonstrate comparable Returns on Investment (ROI) relative to new biologicals and pharmaceuticals.
- Large and small companies, as well as investors, are continually assessing the ROI and opportunity costs and making decisions on resource allocation priorities.



Infectious Disease Pipeline by Modality (type of product)

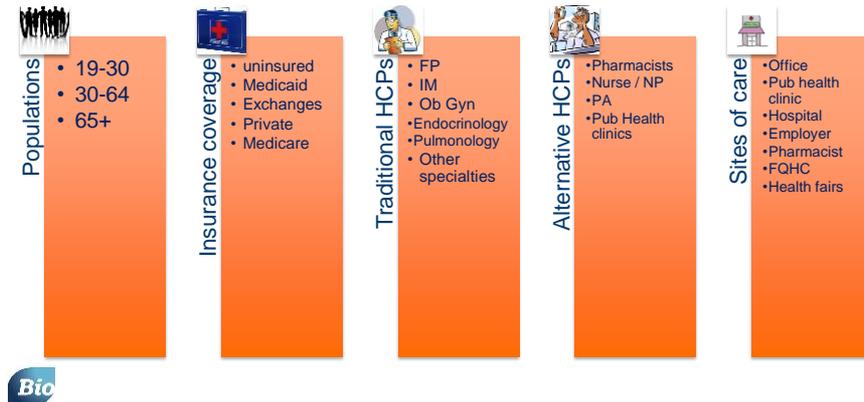


Source:

So what's next?

The Adult Immunization Environment Is Broader and More Complex than Pediatric

But it presents a unique opportunity for all stakeholders to work together to improve immunizations rates in diverse populations of adults.

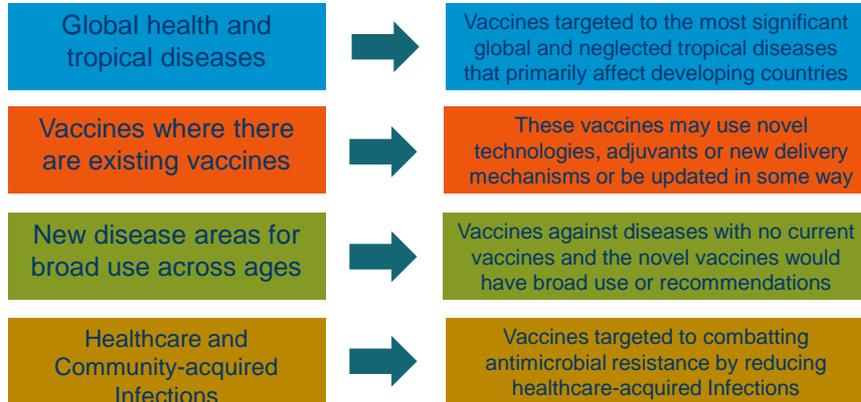


Decision to Pursue New Vaccines Has Numerous Criteria

- Vaccine companies assess new vaccine targets based on general criteria used for all bio-pharmaceutical investments:
 - Unmet medical and public health need
 - Scientific feasibility
 - Ability to scale up production to meet demand
 - Cost and time to develop
 - Global burden of disease
 - Treatment availability
 - Market size
 - Potential revenue
 - Fit with the company's existing portfolio or platform
 - Status of intellectual property

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Areas of Vaccine Development with Implications for Adult Immunization Programs



Global Health and Tropical Diseases

- Vaccines targeted to global diseases affecting many countries, primarily developing ones, although many of these vaccines can serve as travel vaccines in developed countries
- R&D for these vaccines is generally funded through global public-private partnerships, or Product Development Partnerships (PDPs) with the Bill & Melinda Gates Foundation, PATH, Wellcome Trust, the Global Fund and other global funding partners.
- In addition to long-standing neglected tropical diseases, emerging infectious diseases also fall into this category, such as Ebola and Middle East Respiratory Syndrome (MERS).
- These vaccines are considered high volume and would normally be made available through programs like UNICEF, PAHO and Gavi or US government programs.
- Investment is required in large scale manufacturing facilities in preparation for global demand.



Global Health and Tropical Diseases – Vaccines in Development

Target	Clinical-Stage Pipeline				BLA** or Licensed
	Ph 1	Ph 2	Ph 3	Total	
<i>Malaria</i>	1	1	1	3	
<i>Tuberculosis</i>	3	4		7	
<i>HIV</i>	6	4	1	11	
<i>Dengue</i>	2	1	2	4	
<i>Ebola</i>	4	1	1	6	
<i>Marburg / Plague (other hemorrhagic fevers)*</i>					
<i>Pandemic Influenza</i>	14	3		17	
<i>MERS</i>	1			1	
<i>Typhoid fever *</i>					
<i>Leishmaniasis</i>	1			1	
<i>Chikungunya *</i>					
				50	



Source: BioMedTracker from Sagient Research

* = preclinical research is underway

** = Biologics License Application

New Vaccines Where There Are Existing Vaccines

- Many vaccines in this category use novel technologies, such as novel adjuvants, in their development, production or delivery.
- Some of the vaccines will be targeted to specific populations or sub-sets of existing recommended populations, cover additional strains or help with an emergency response in the event of a pandemic / outbreak.
- This category could include clinical activities undertaken by vaccine companies in support of maternal immunization recommendations.
- In addition, this could include new ways to improve the way vaccines are stored or delivered, for example, improved heat stability, patches, use in multiple injection technologies, nasal spray delivery. etc



New Vaccines in Development Where There Are Existing Vaccines

Target	Clinical-Stage Pipeline				BLA or Licensed
	Ph 1	Ph 2	Ph 3	Total	
<i>Seasonal influenza</i>	3	8	2	13	1
<i>Herpes Zoster</i>			2	2	
<i>Hepatitis B</i>		1	1	2	
<i>Pertussis (generally included w DT)</i>	1			1	
<i>Human Papilloma virus (HPV)</i>		1		1	1
<i>Pneumococcal</i>		4		4	
				23	2

Source: BioMedTracker from Sagient Research

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New Disease Areas for Adult Vaccines

- Many vaccines in this category could potentially be indicated in multiple age categories based on the epidemiology of the disease and unmet medical or public health need
- Some of these vaccines also may be indicated as part of a maternal immunization platform



New Disease Areas with Vaccines in Development

Target	Clinical-Stage Pipeline				BLA or Licensed
	Ph 1	Ph 2	Ph 3	Total	
Norovirus		1		1	
Respiratory Syncytial Virus (RSV)	4	1		5	
Hepatitis C		3		3	
Herpes Simplex virus (HSV)	1	3		4	
Cytomegalovirus (CMV)	2		1	3	
Group B Streptococcal		1		1	
Escherichia coli		1		1	
				20	

Source: BioMedTracker from Sagient Research

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Healthcare and Community-acquired Infections - AMR Vaccines in Development

- Industry is actively pursuing vaccines as part of the solution to combatting antimicrobial resistant bacteria and other resistant pathogens.
- Resistance does affect whether there is an unmet medical need, which is an important consideration for companies.
- Vaccines are generally not developed specifically against the resistant strains of a pathogen, but rather against all strains.
- AMR vaccines are often designed to protect against pathogens for limited populations (e.g. healthcare-associated infections).



Healthcare and Community-acquired Infections (AMR) Vaccines in Development

Target	Clinical-Stage Pipeline				BLA or Licensed
	Ph 1	Ph 2	Ph 3	Total	
2013 CDC AMR Threat List & FDA Qualifying Pathogens List for GAIN Act:					
<i>Candida</i>		1		1	
<i>Clostridium difficile</i>		1	1	2	
<i>Escherichia coli</i>	1			1	
<i>Group B Streptococcus</i>		1		1	
<i>Pseudomonas aeruginosa</i>		1		1	
<i>Salmonella typhi</i>					2
<i>Staphylococcus aureus</i>	2	1		3	
<i>Streptococcus pneumoniae</i>	1	3	1	5	3
<i>Mycobacterium tuberculosis</i>	1	4		5	2
FDA Qualifying Pathogens List for GAIN Act:					
<i>Neisseria meningitidis</i>		1		1	5
<i>Vibrio cholerae</i>			1	1	
				21	12



Source: BioMedTracker, FDA & Industry Websites

Vaccines against Community and Healthcare-acquired Infections Face Some Unique Development Issues

- 79% of deaths reported in 2013 CDC AMR Report are due to HAIs

Challenges	Opportunities
Limited populations vs. routine vaccines	Prevention of infections can: <ul style="list-style-type: none"> - reduce morbidity & mortality - reduce hospitalizations - reduce antibiotic use - increase the effectiveness of hospital infection control programs - increase quality of life and productivity
Defining at-risk patients to vaccinate	
Target populations with high co-morbidities	
Level of immunocompetence may affect vaccine response	Durable protection
Rapid protection may be required	- reduce recurrent infections/readmission



Summary

- Vaccine companies are well-placed to act as partners with public health stakeholders to positively impact health in the U.S. and around the world
- Vaccine developers and manufacturers are already developing many vaccines to help prevent infectious diseases across the lifespan
 - There are over 120 vaccines in development between Phase I and licensure
 - Much of this work is done in partnership with global funders, governments, academic institutions and other vaccine developers
- The scientific, clinical and environmental issues affecting the development of novel vaccines can differ depending on the indications, populations, plans for global access, epidemiology and medical need.



Conclusion: The Future of Adult Immunization is Bright!

How can we work together to pave the way for these exciting vaccines?

- Increase cooperation and communication between the public and private sector
- Continue to improve coverage rates in the adult and maternal immunization platforms
- Communicate on the known benefits of vaccination for adults and pregnant women
- Improve access to vaccines for all – in-network providers, adult standards, policy goals
- Continue to encourage All providers to give strong recommendations to all patients



