Industry and Vaccine Development: Dispelling Some Myths

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Melinda, *Tree of Life*

Melinda's artwork reflects her journey living with HIV.

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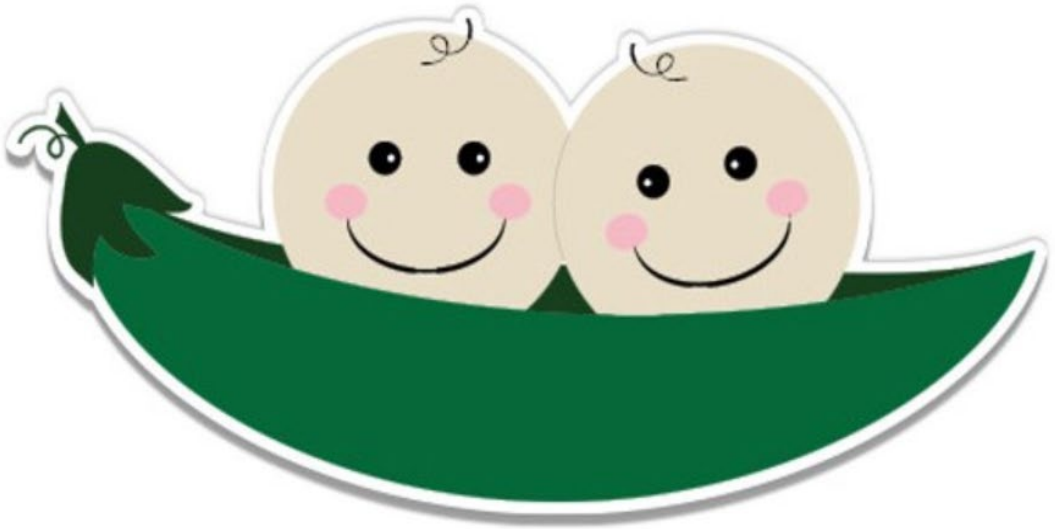
Why I joined the private sector

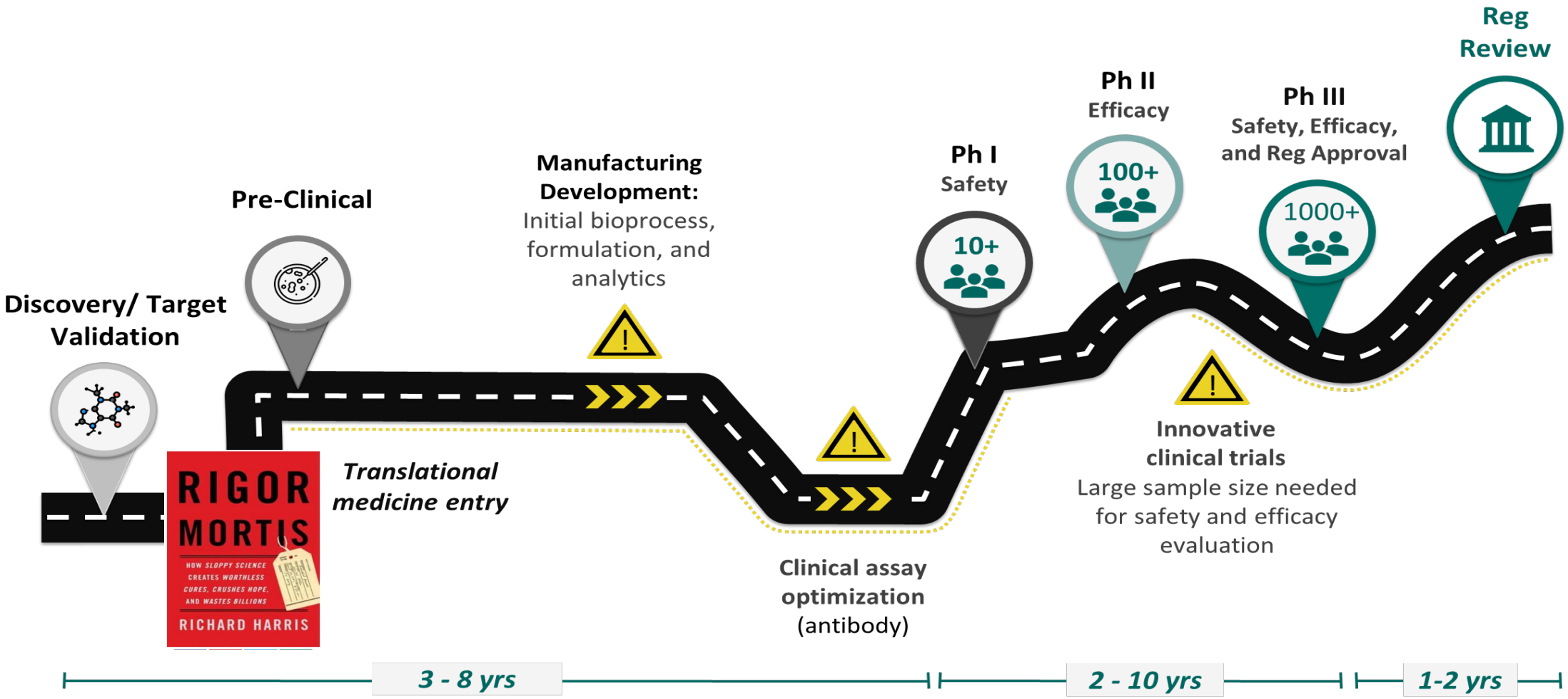
What was the same?

Collaborations with colleagues:

- Epidemiology of rotavirus including disease burden and serotypes
- Natural history of rotavirus
- Mechanisms of immune protection against rotavirus
- Epidemiology of intussusception



What was different? #1 R&R (Regulations and Rigor)



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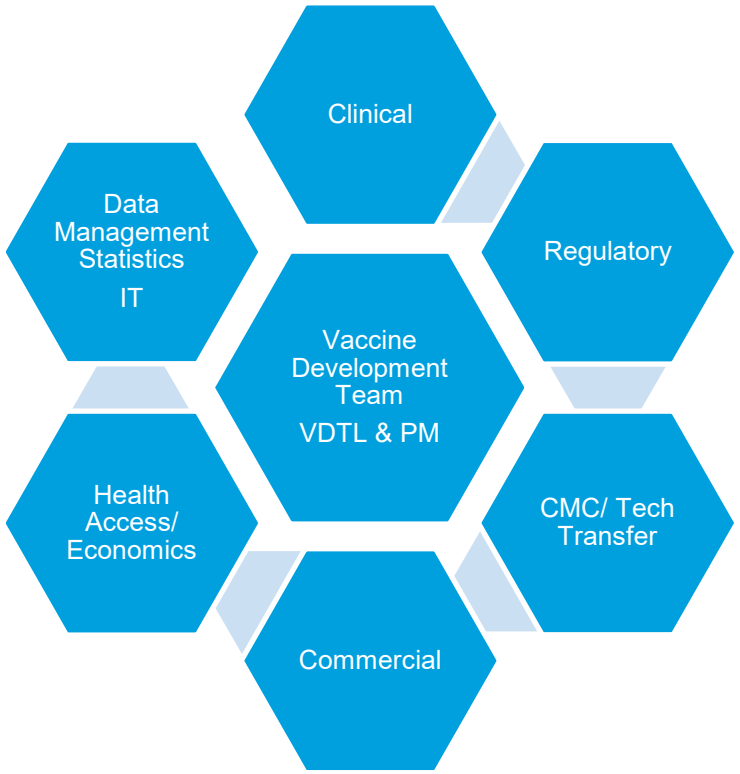
What was different? #2 TNT (Team and Teamwork)



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What was different? Portfolio and Priorities

- Vaccines are prioritized among other products, not just other vaccines (e.g., vaccines for low vs. high resource settings and/or dual market vaccines)
- Vaccines market is growing faster than other areas in pharma
- However, R&D costs are higher, and risk is perceived to be higher
  - Rare adverse events and changing disease burden may lead to changes in recommendations and uptake
- Thus, progressing development may be challenged even when there is a good business case.
- Vaccines are a commitment to improving health

It takes a village

Borrowed from Plotkin Vaccines

TABLE 4.4 U.S. Network Partners' Relative Contributions to Vaccine Research and Development

	Research			Development		
	Basic/Related	Targeted	Process	Clinical	Manufacture	Postlicensure Studies
NIH	+++	+++	—	++	—	—
CDC	—	—	—	—	—	++
FDA	—	+	+	+	—	+
DOD	+	+	+	+	—	+
USAID	—	+	—	+	—	—
Large company	+	+++	+++	+++	+++	+++
Small company	+	+++	±	±	±	—
Academia	+++	+++		+++	—	—
NGOs (PDPs)	—	+	±	+++	±	—

CDC, Centers for Disease Control and Prevention; DOD, Department of Defense; FDA, U.S. Food and Drug Administration; NGO, nongovernmental organization; NIH, National Institutes of Health; PDP, product development partnerships; USAID, U.S. Agency for International Development.
Relative contribution: +++, major; ++, intermediate; +, minor; ±, varies by company.
Modified from Marcuse EK, Braiman J, Douglas RG, et al, for the National Vaccine Advisory Committee. United States vaccine research: A delicate fabric of political and private collaboration. Pediatrics. *1997;100:1015–1020.*

In closing…

- Collaboration across all participants in the vaccine development ecosystem is vital to ensure the favorable impact of vaccines on health

My wish list?

- Better data on the natural history of infectious diseases connecting the evolution of the clinical presentation and immune response

- Better understanding of the mechanisms of protection with naturally occurring disease and vaccination
  - AND creating an approach for ***practical application*** of data generated from emerging immunologic technology and modeling to vaccine development

- Communication - collaboration across infectious diseases experts, social psychologists, communication specialists, and others on how to share information on natural disease and vaccination and its benefits and risks

The best way to predict your future is to create it… Abraham Lincoln

Thank you

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