

# A Critical Look Down the Critical Path to MPT Development

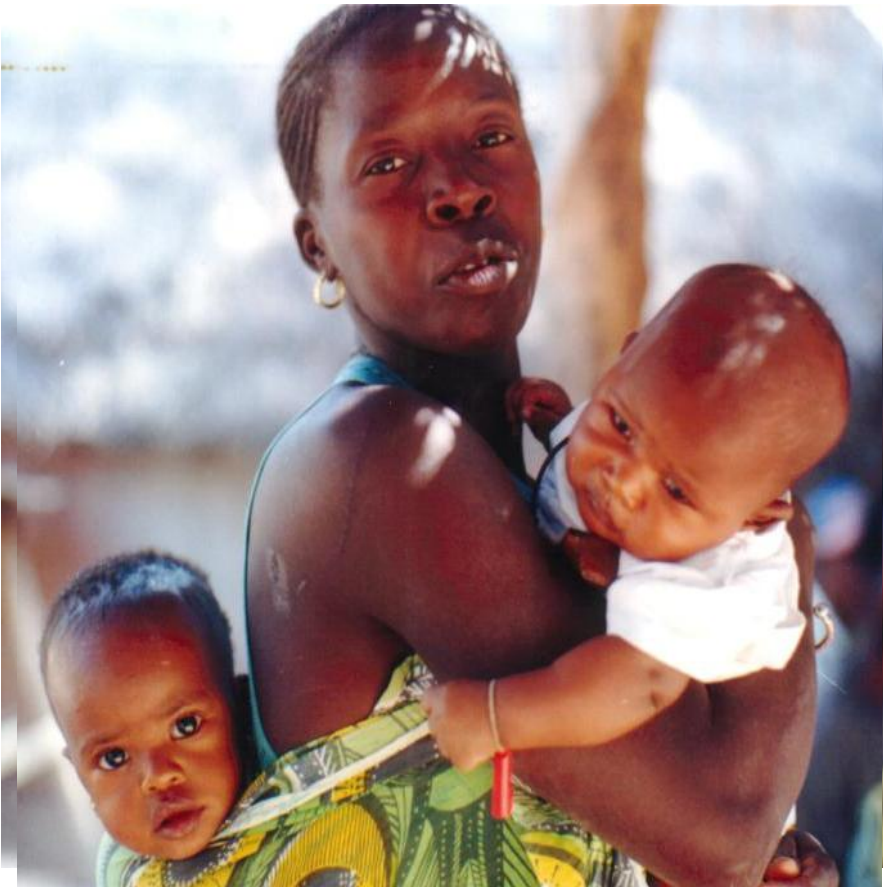
**Martha Brady, Senior Associate  
Population Council**

**MPT Product Development Workshop  
February 20-21, 2013  
CONRAD**

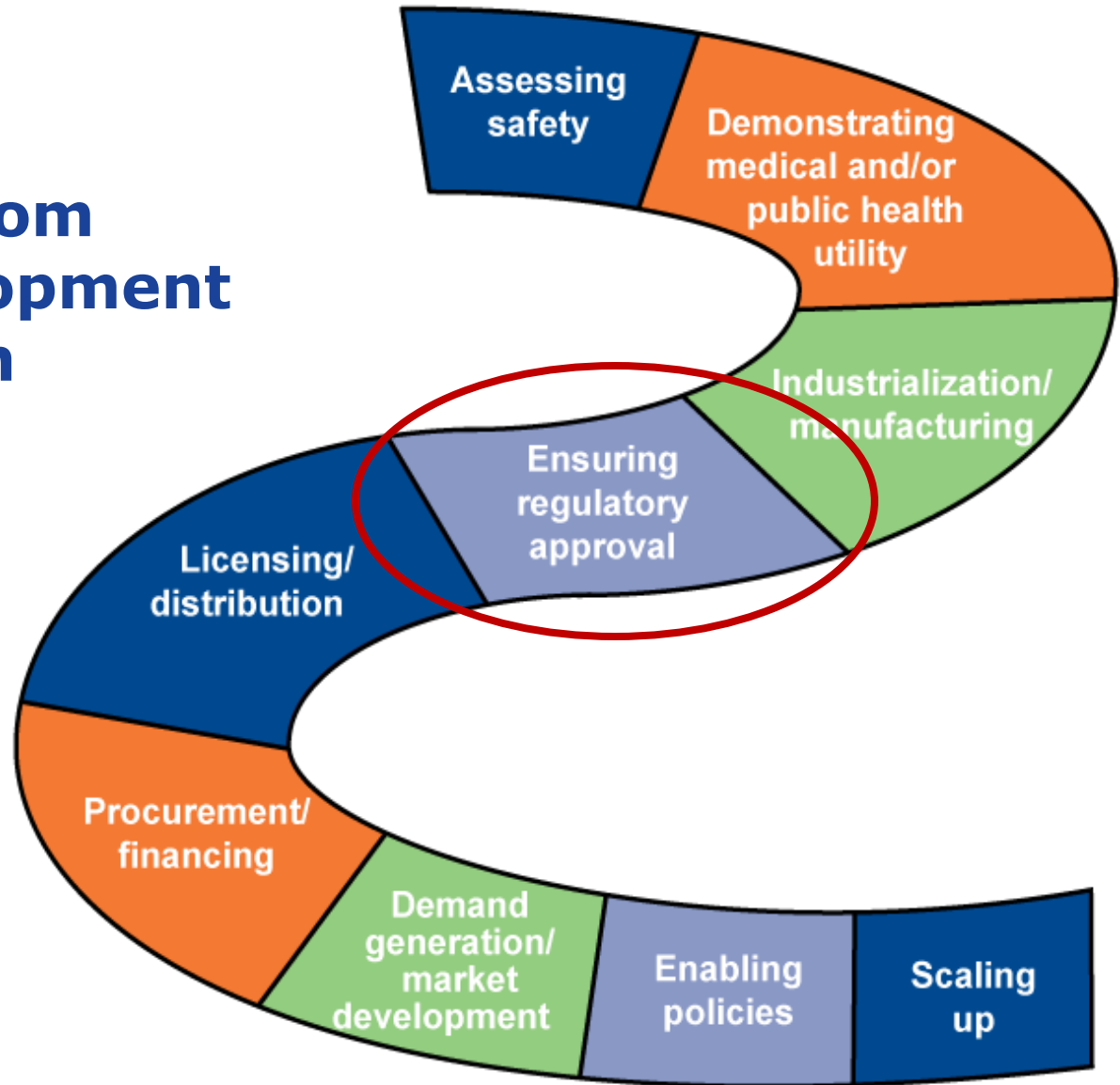


# Who Needs MPTs?

**Diverse groups of women across geographies, ages, cultures**



# Constructing a Critical Path from Product Development to Introduction



Brady, M., Critical Path Framework © 2011 Population Council

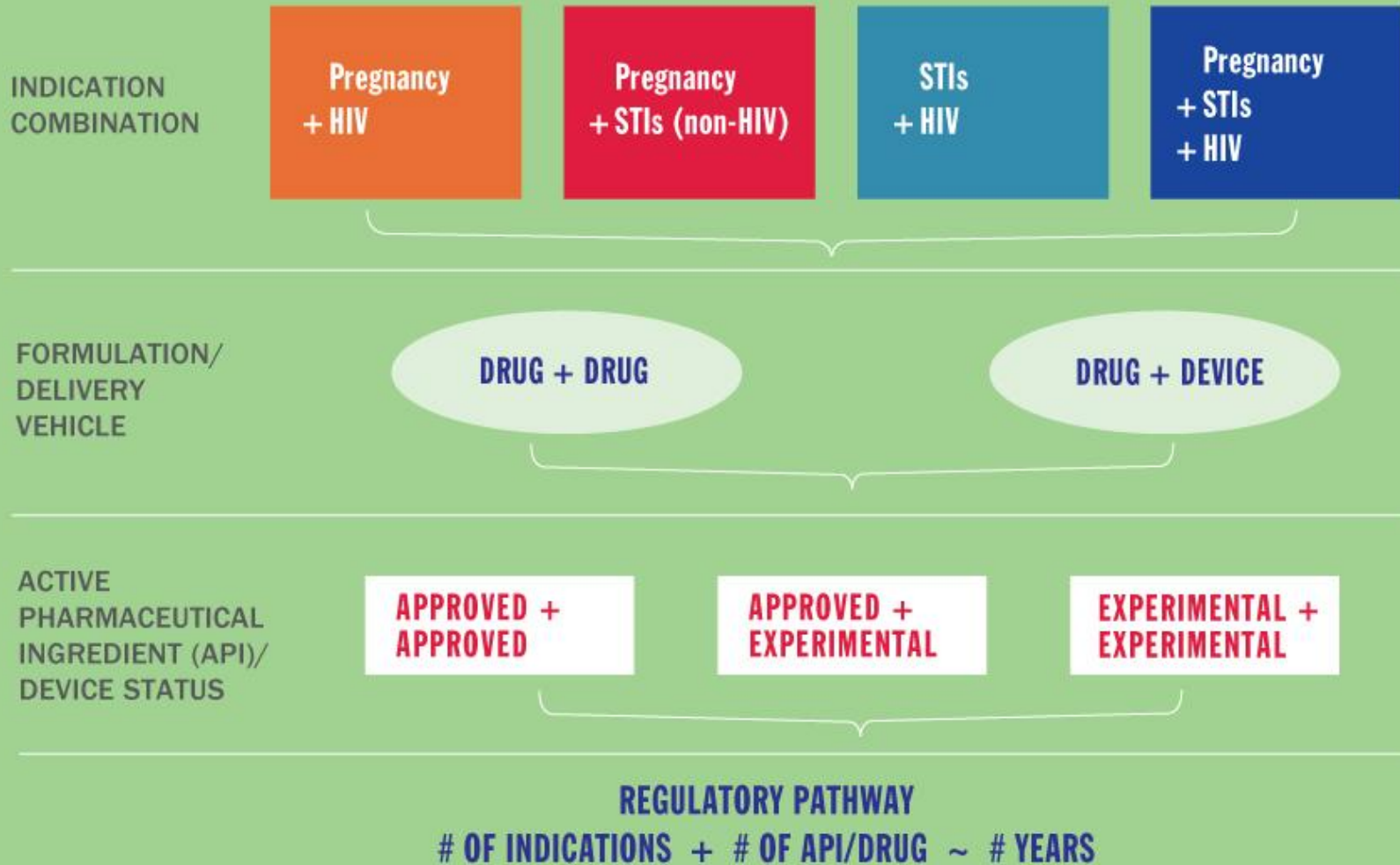


Ensuring  
regulatory  
approval

## Critical Activities

- **Clarify regulatory pathway(s) for MPTs**
- **Engage regulatory bodies at global and local levels**
- **Work with product developers and/or manufacturers to submit dossiers**

# MPT Pathway: A Typology



Martha Brady  
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# MPT Regulatory Puzzle



Specific regulations will vary with each MPT,  
*however*

the following perspectives provide a basis:

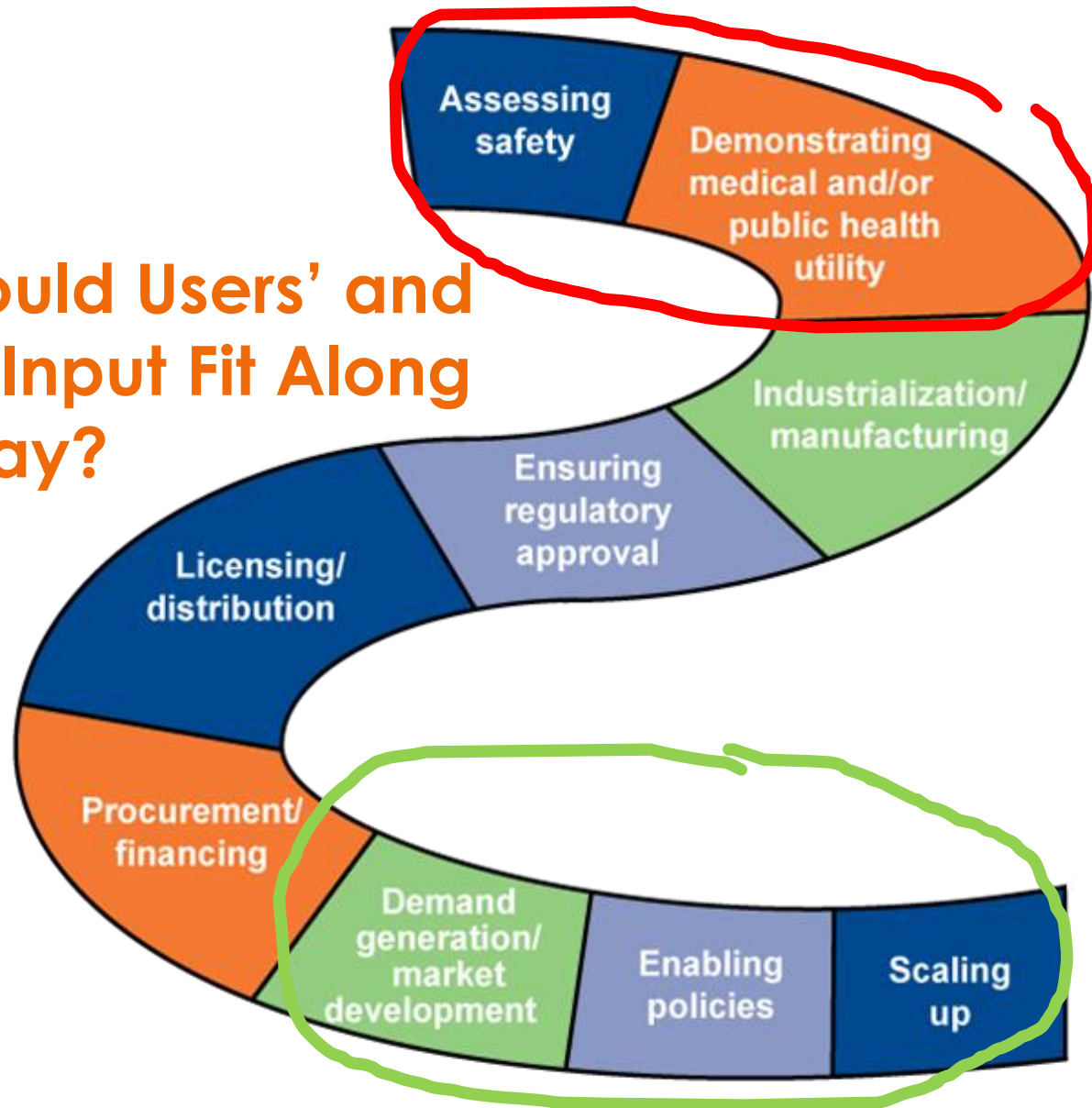
- ✓ Experimental versus approved
- ✓ Drug versus device
- ✓ Systemic versus topical delivery

# Tailored MPT Guidance and Policy Could Help to:

- Clarify pathways for regulatory review and licensure of MPTs within key regulatory authorities
- Set overall regulatory and development strategy
- Determine resource requirements and research approaches (assessments, algorithms)
- Inform intellectual property arrangements
- Define options for pricing, manufacturing, and ultimately availability of future MPT



## Where Should Users' and Providers' Input Fit Along the Pathway?



Brady, M., Critical Path Framework © 2011 Population Council



# Weighing and Balancing

Product attributes, efficacy, safety, “ease” of use, locus of control, effects on fertility, social cost, perception, pleasure, price



Brady, M. Population Council, 2008

# MPTs and the End User: Shaping a Research Agenda

- Understanding women's motivations to use MPTs (what indication trumps, why, and in what contexts?)
- Marketing and product positioning (how should a specific MPT be pitched; what is the USP)?
- Financing mechanisms (funded via FP or HIV?; in US issue of reimbursement)
- Access and Acceptability (AA) Working Group

# Access and Acceptability Working Group

- Newly forming; soft launch 2013
- Inter-agency effort, chaired by Martha Brady
- Virtual meetings; work towards consultation in late 2013
- Will adapt *access frameworks* and modify for MPTs
- Learn from the past to inform the future

More to follow.....

# Too early? Too late? Time to get started!!

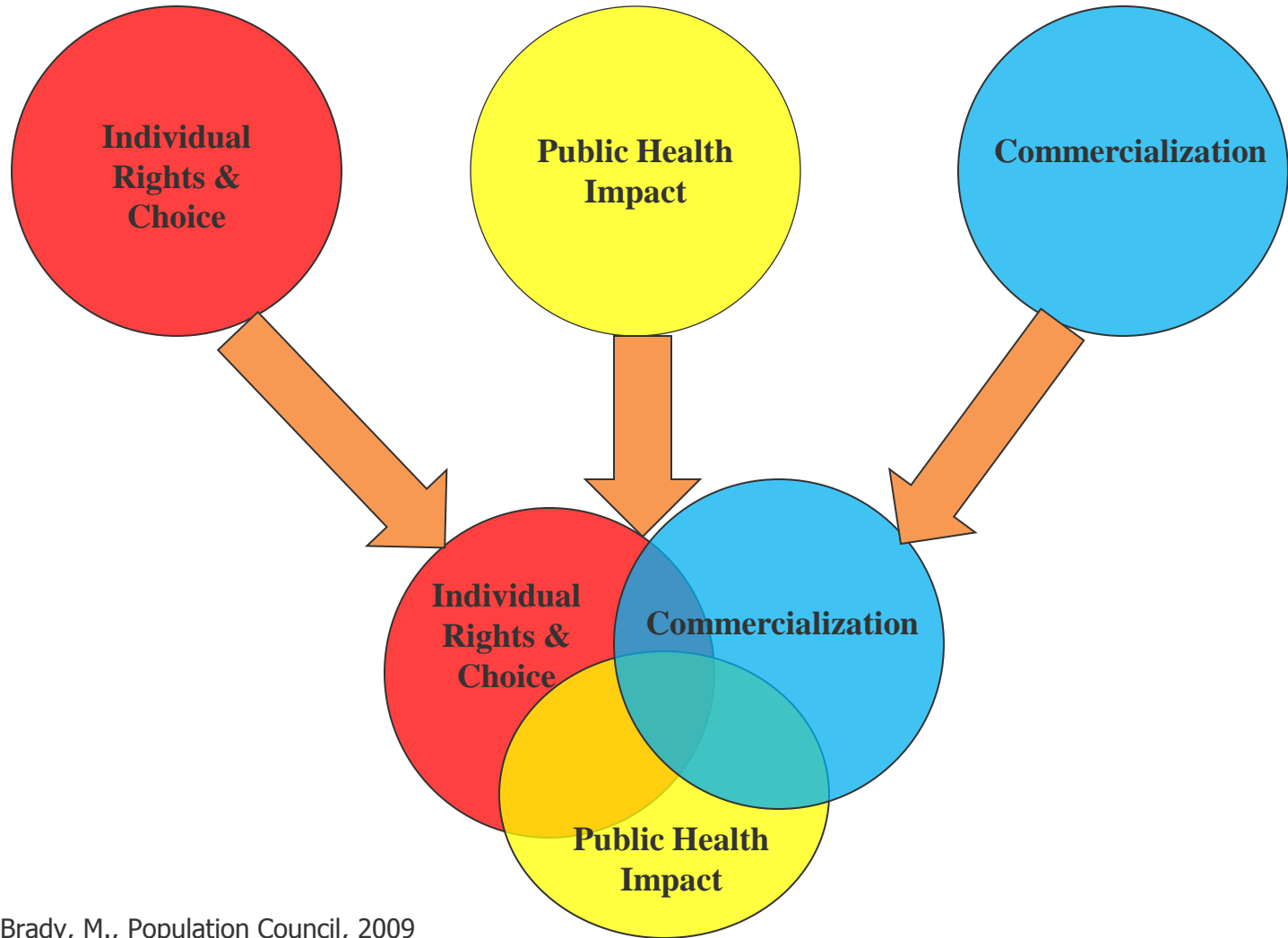


courtesy of [www.cartoonstock.com](http://www.cartoonstock.com)



"Sure, St. Luke's has a heart-lung machine, but we have a heart-lung-kidney-liver-spleen machine."

# Aligning Goals

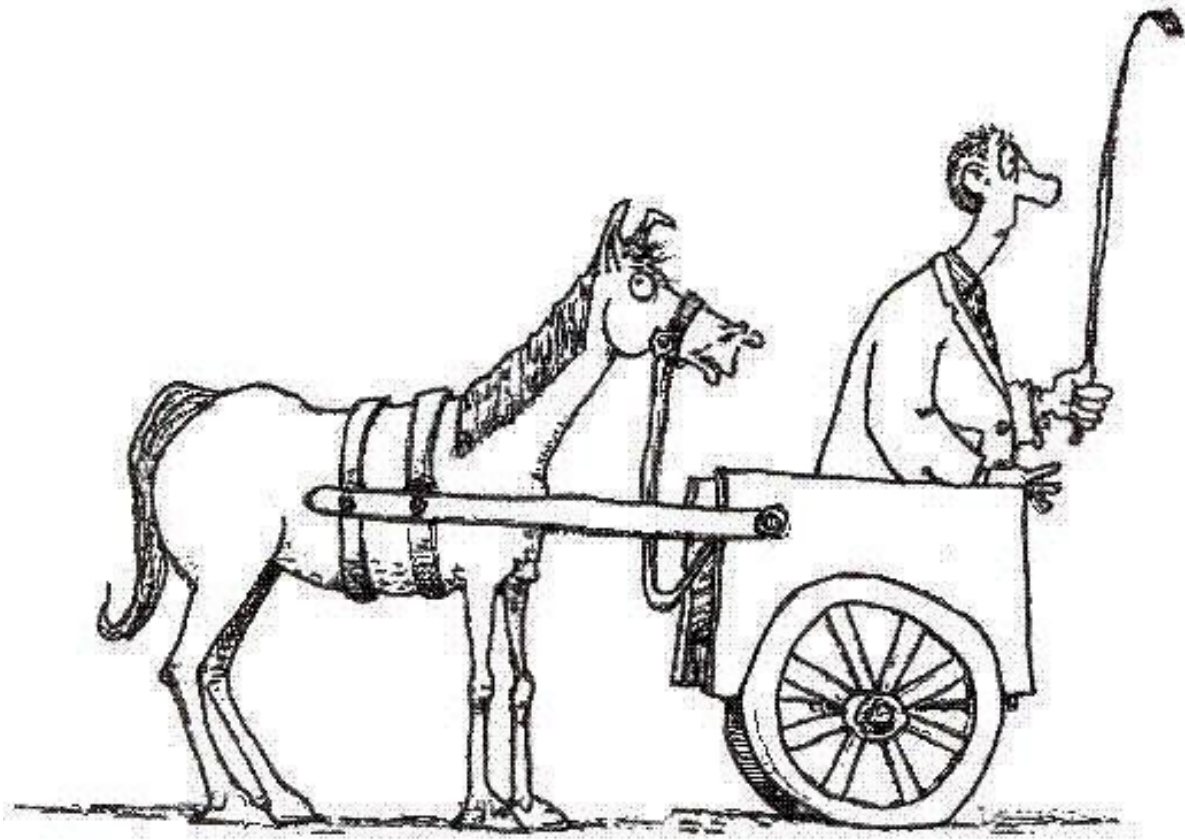


Brady, M., Population Council, 2009



# Building an Investment Case





## Dimensions Along Critical Path where Users' and Providers' Perspectives Key

Dimension	
Assessing Safety	<p><b>Preclinical:</b> Show product safe enough for human testing. Eliminate products with safety concerns.</p> <p><b>Clinical:</b> Show product safe. Identify potential issues with labeling.</p>
Demonstrating Medical and/or Public Health Utility	<p><b>Preclinical:</b> Select appropriate design or candidate with high probability of effectiveness.</p> <p><b>Clinical:</b> Show effectiveness in people. Evaluate acceptability among users.</p>
Demand Creation Market Development	<p>Create awareness among policymakers, providers, users. Engage civil society. Build champions. Train providers. Identify advertising and pricing strategies.</p>
Enabling Policy	<p>Develop introduction plan with key stakeholders. Integrate product into service delivery norms and guidelines. Conduct implementation research.</p>

# Population Council's "Bench to Bedroom" Research

