

A Critical Look Down the Critical Path to MPT Development

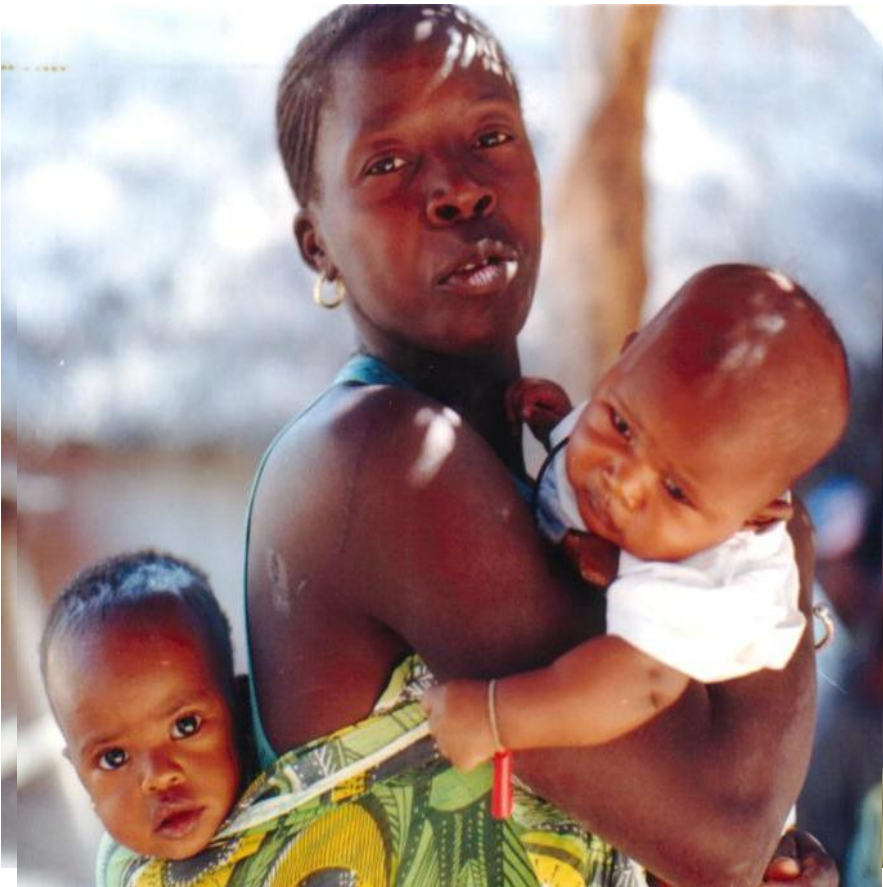
**Martha Brady, Senior Associate
Population Council**

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

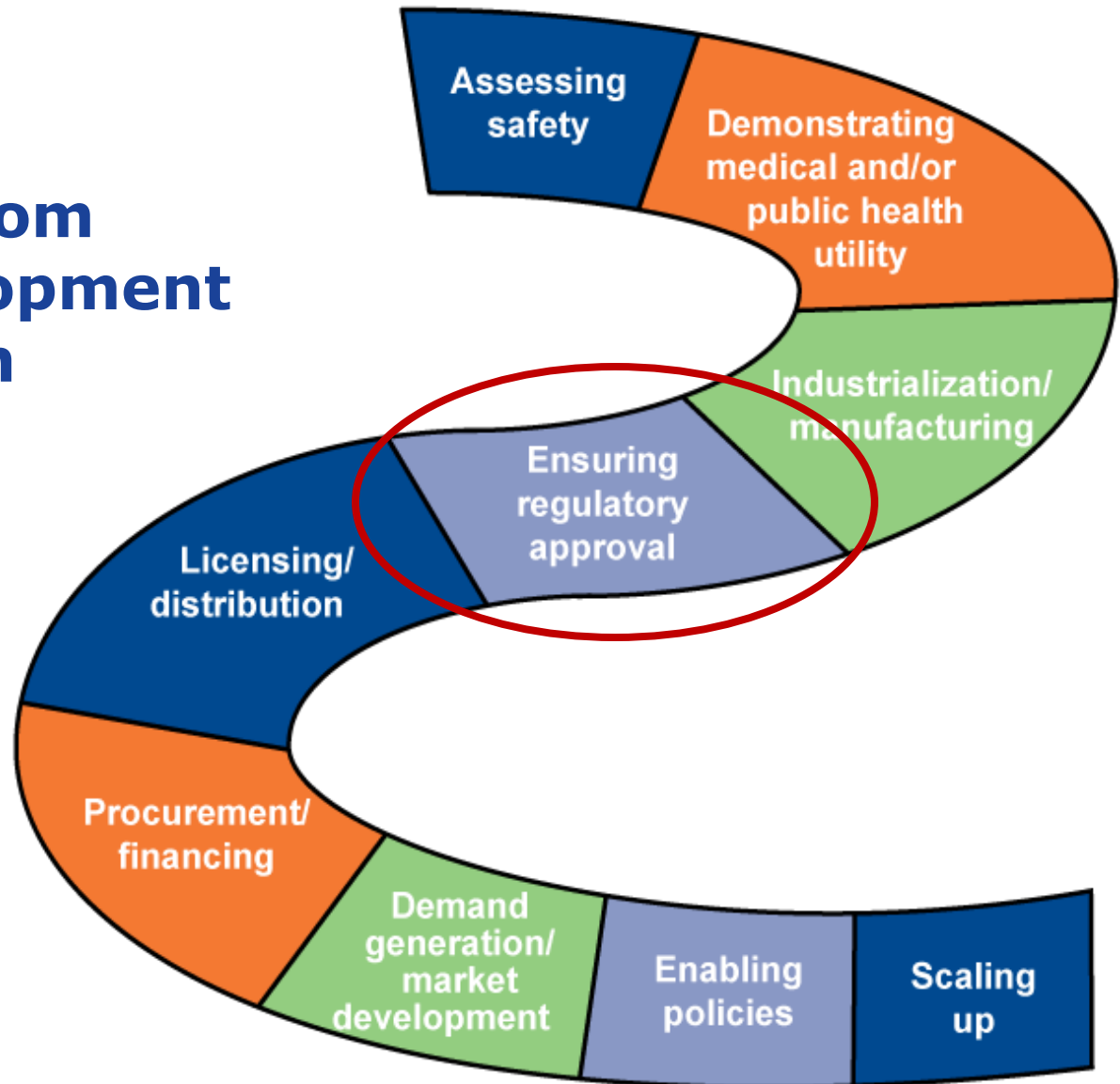


Who Needs MPTs?

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

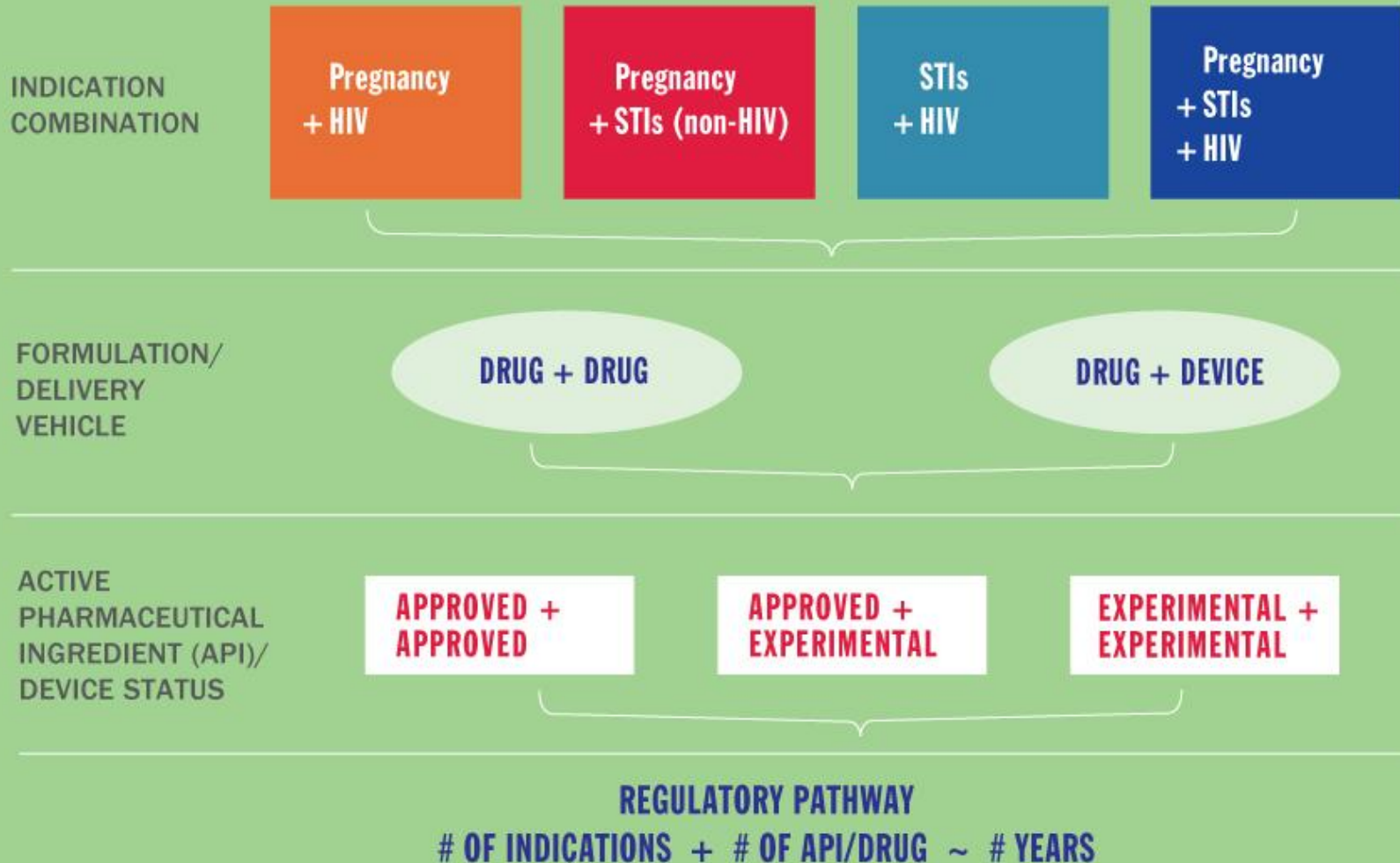


Ensuring
regulatory
approval

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

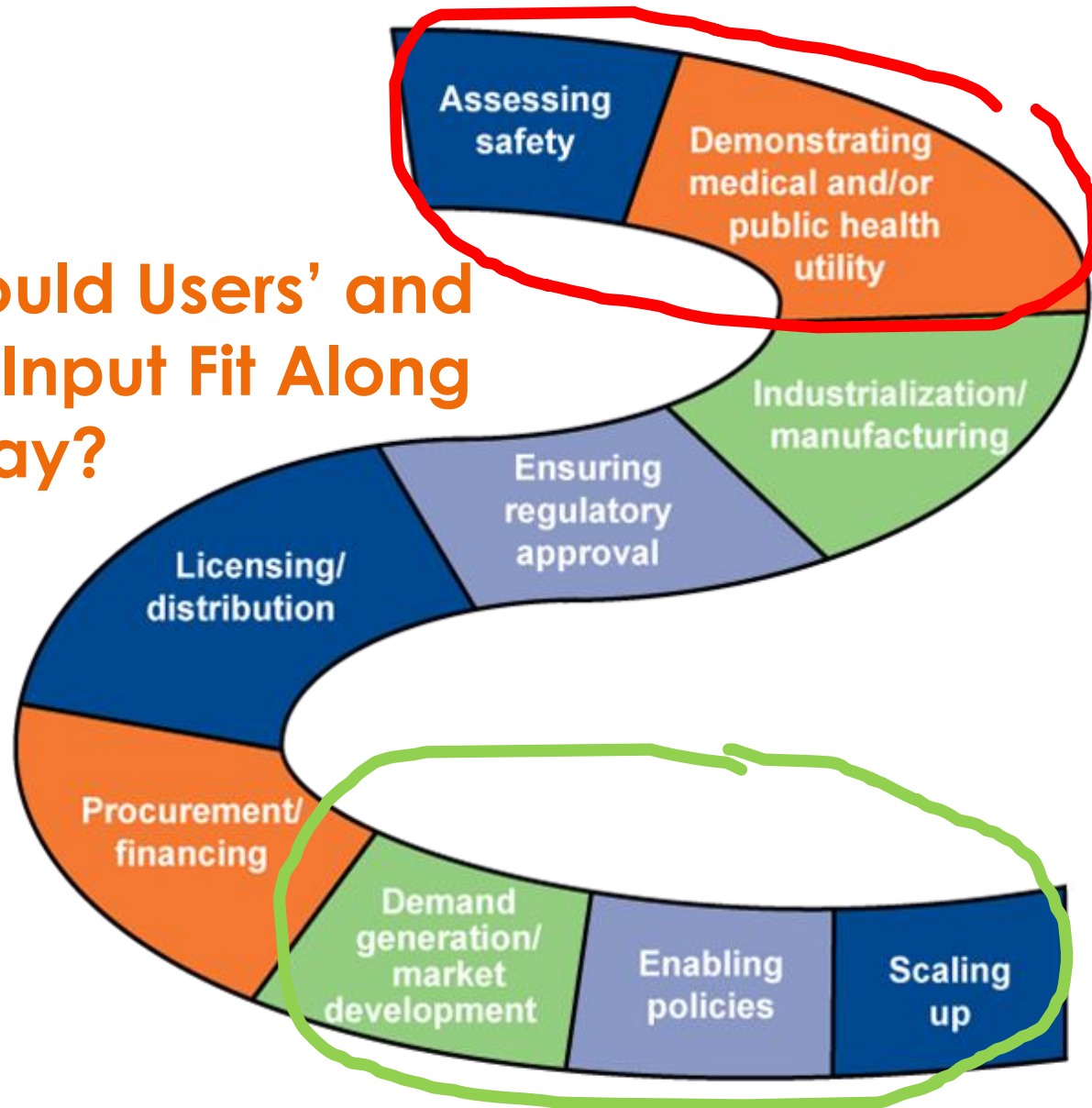
the following perspectives provide a basis:

- ✓ 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!!

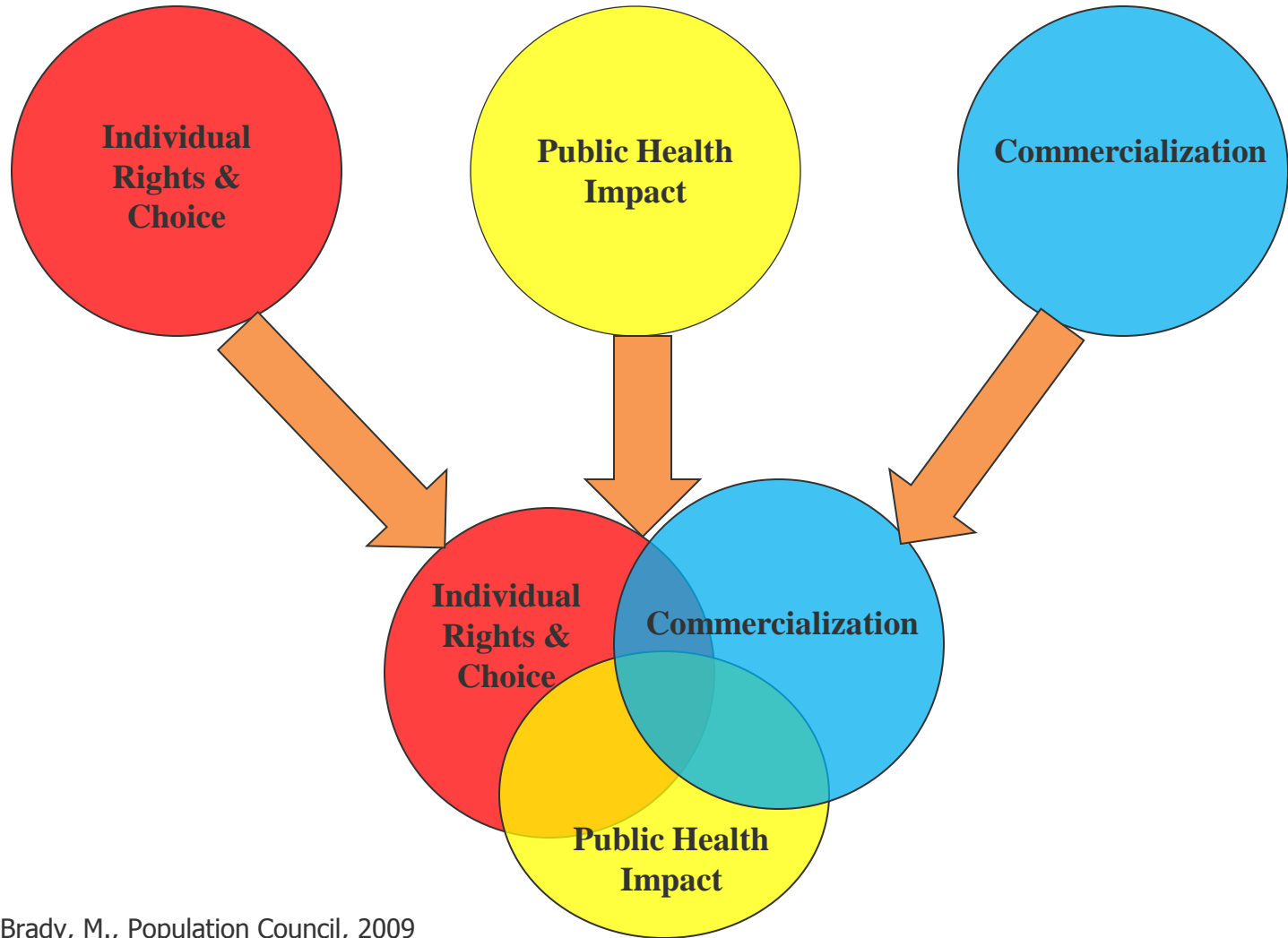


courtesy of www.cartoonstock.com



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

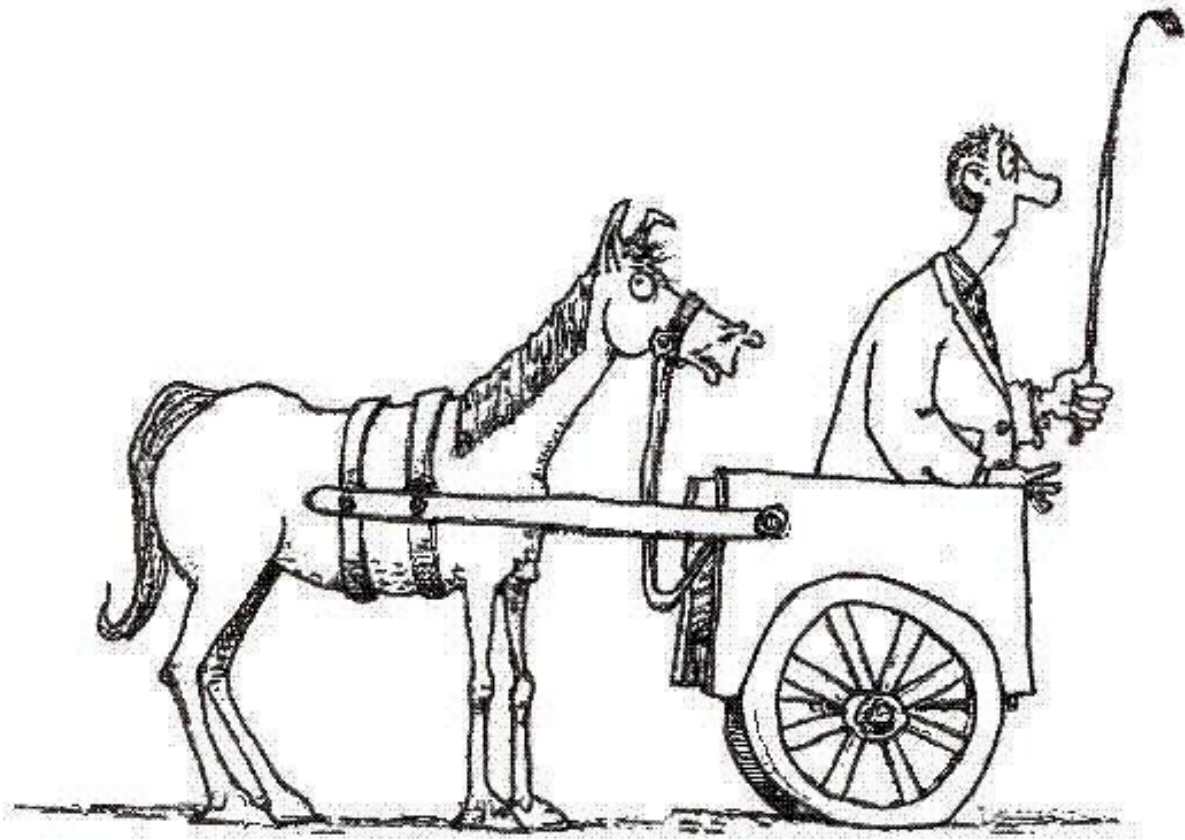
Aligning Goals



Brady, M., Population Council, 2009

Building an Investment Case





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

Dimension	
Assessing Safety	<p>Preclinical: Show product safe enough for human testing. Eliminate products with safety concerns.</p> <p>Clinical: Show product safe. Identify potential issues with labeling.</p>
Demonstrating Medical and/or Public Health Utility	<p>Preclinical: Select appropriate design or candidate with high probability of effectiveness.</p> <p>Clinical: 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

