Considerations for the Regulatory Approval of Multipurpose Prevention Technologies (MPTs)

Cara Chrisman, PhD, AAAS Fellow, USAID

~and~

Martha Brady, M.S., Senior Associate, Population Council

USAID
FROM THE AMERICAN PEOPLE

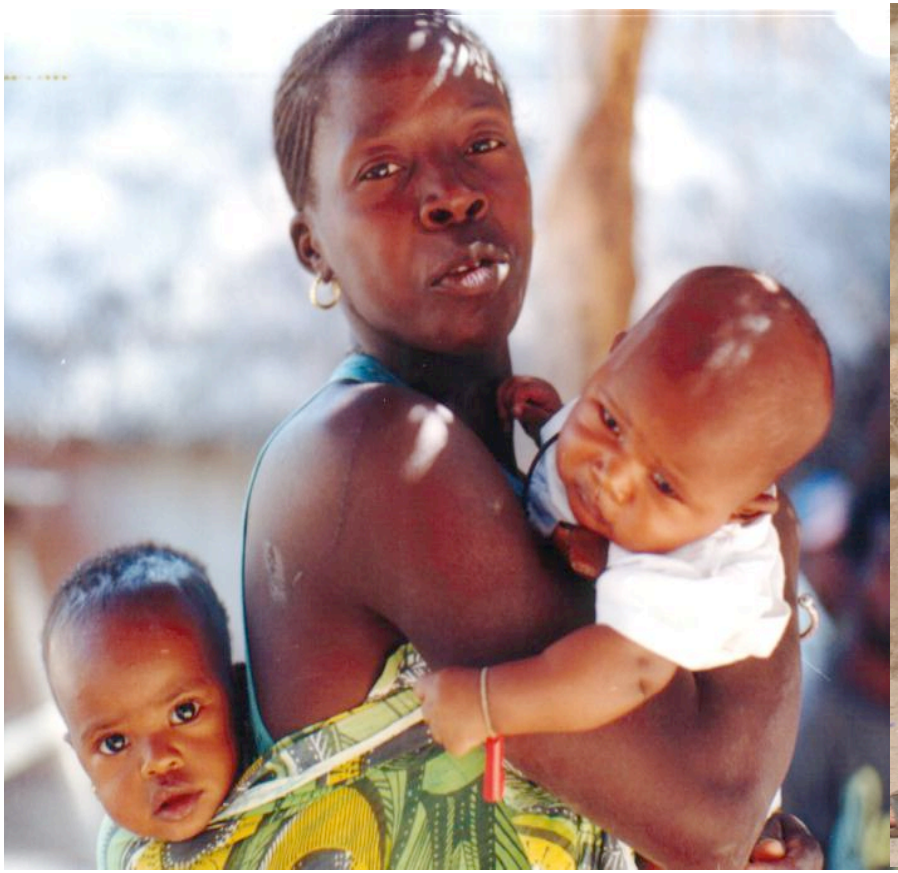
Multipurpose Prevention Technologies for Reproductive Health
Accelerating Research on Multipurpose Prevention Technologies for Reproductive Health

11-12 December, 2012
India Habitat Centre - New Delhi, India

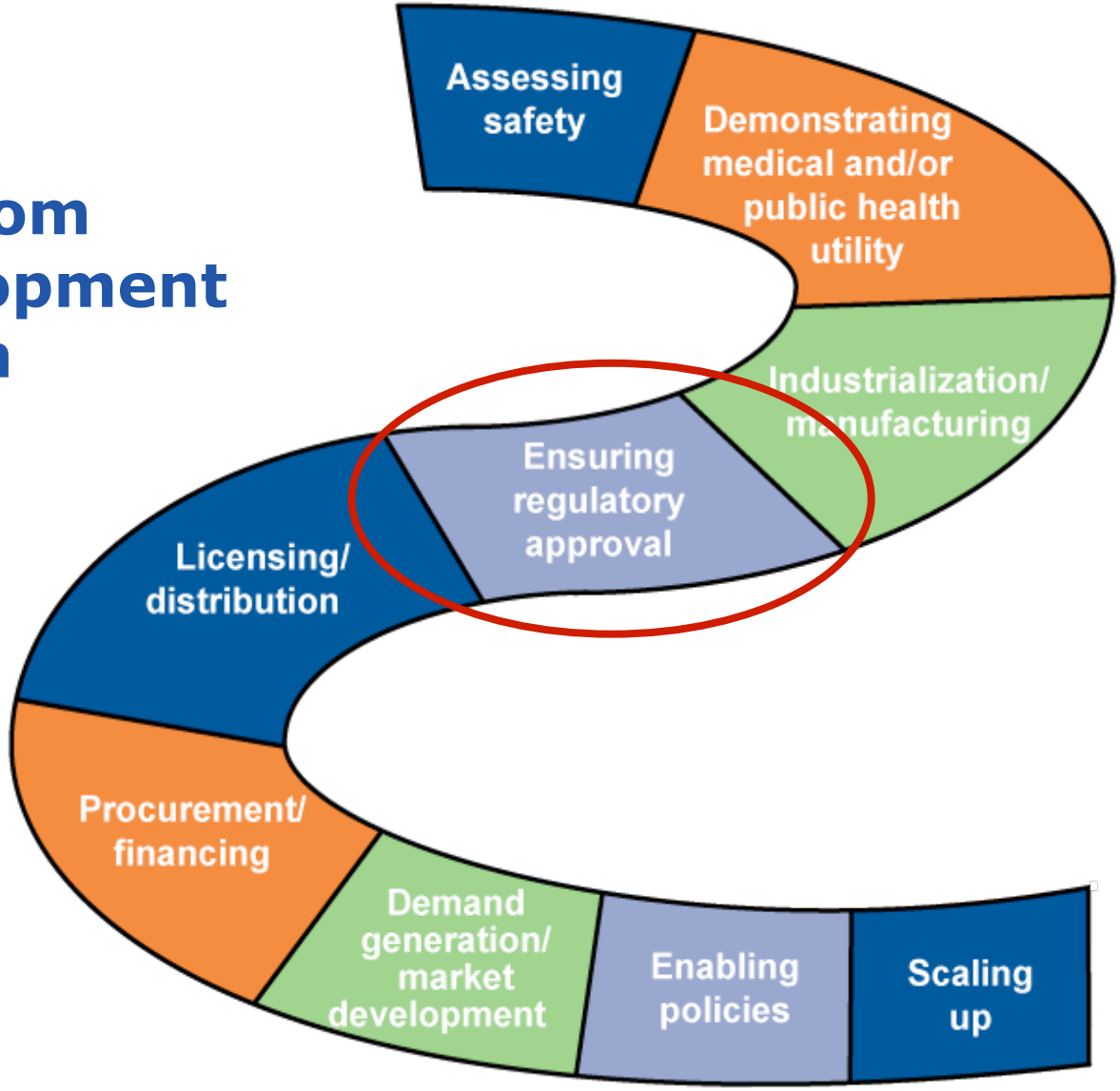
Population Council

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

CRITICAL ACTIVITIES

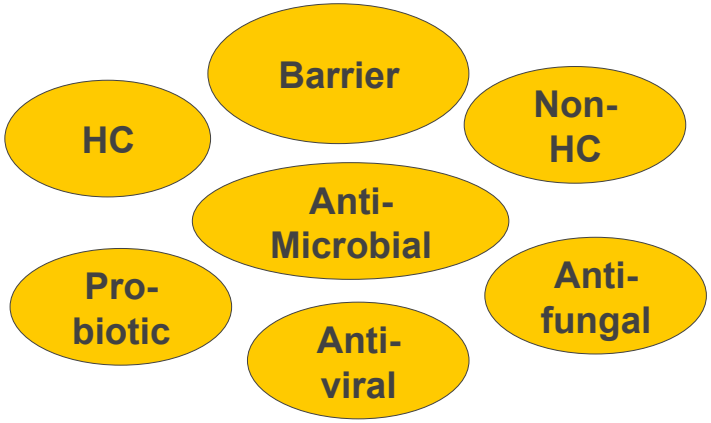
- **Clarify regulatory pathway(s) for MPTs**
- **Engage regulatory bodies at global and local levels**
- **Work with product developers and/or manufacturers to submit dossiers**

Complexities of developing MPTs:

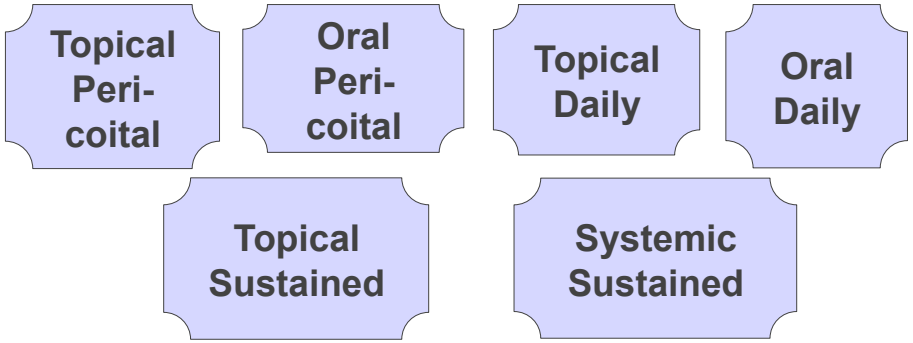
INDICATION

- Pregnancy
- HIV
- HSV
- HPV
- Gonorrhea
- Syphilis
- Chlamydia
- BV
- Candida
- Trichomonas

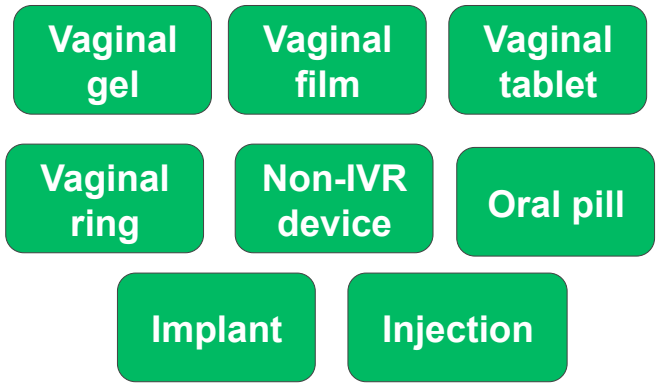
MECHANISM OF ACTION



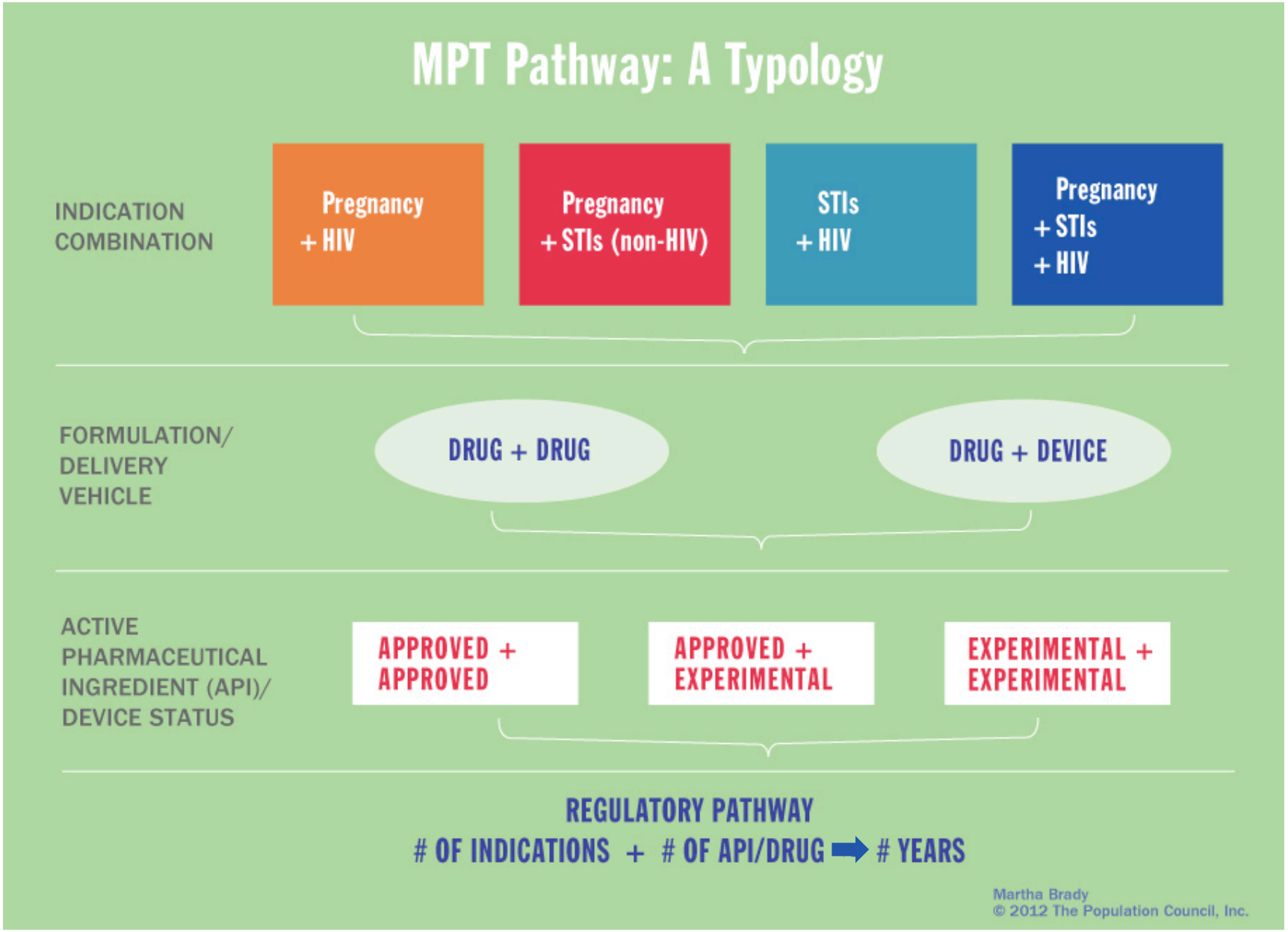
DOSAGE & ADMINISTRATION



FORMULATION & DELIVERY



Adapted from J. Romano presentation, *Multipurpose Prevention Technologies for Reproductive Health 2011 Symposium,* Washington, DC



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

Thank you!