Regulatory Pathways for MPTs: Distilling and Clarifying the Process

Presented by
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Population Council

The Population Council Changes the Way the World Thinks about Critical Health and Development Issues

- **Discovery**, **development**, and **delivery** of contraceptive, reproductive health, and HIV-prevention products and services.
- **Path-breaking programs** to enhance girls' health, education, financial skills, and wellbeing.
- **Building the next generation of scientists and researchers** to address health and development challenges in their countries.

Three programs, multiple disciplines

HIV and AIDS

Reproductive Health

Poverty, Gender, and Youth

Basic research

Product development

Clinical trials

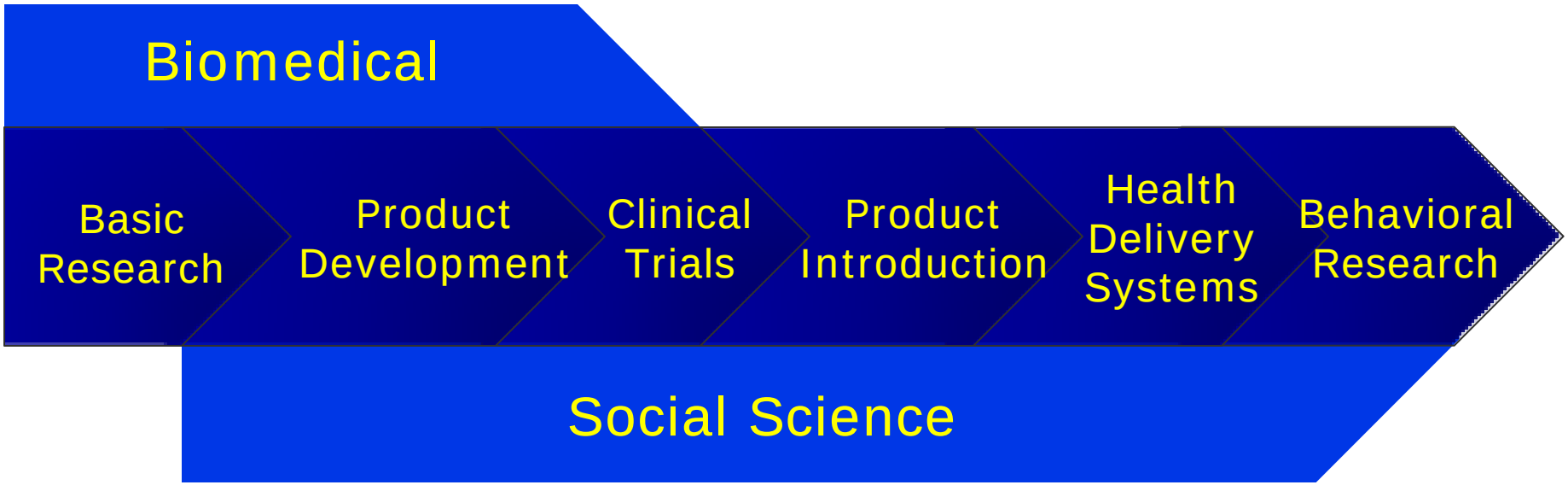
Product introduction

Operations research

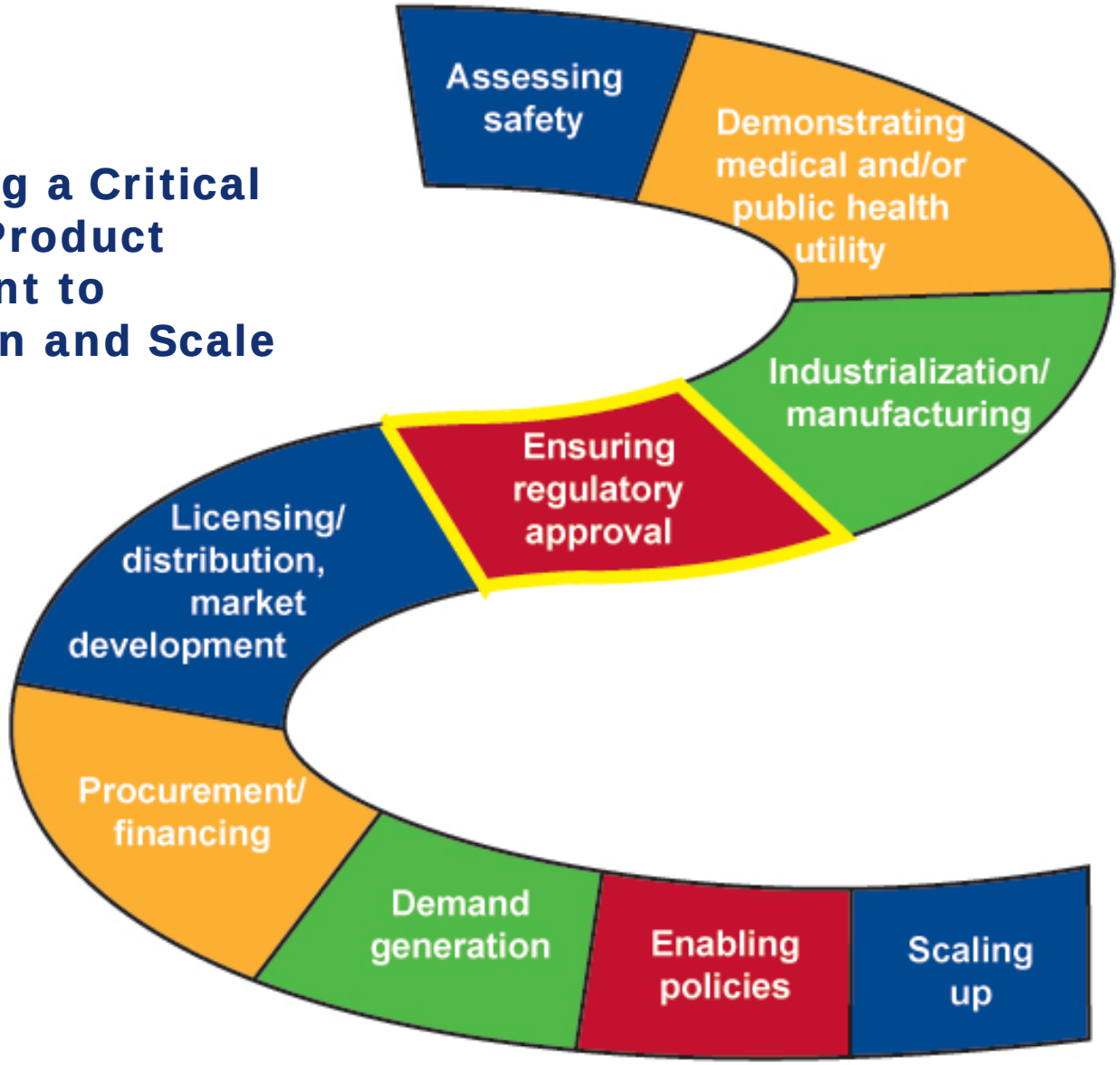
Policy research

Demographic analysis

“Bench to Bedroom” research



Constructing a Critical Path from Product Development to Introduction and Scale



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Key Guidance Documents Related to Combination Products

1. [FDA/CDER] Guidance for Industry: Co development of Two or More Unmarketed Investigational Drugs for Use in Combination (draft Dec. 2010)
   http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM236669.pdf

2. [FDA/OCP] Guidance for Industry and FDA Staff: Early Development Considerations for Innovative Combination Products (Sep. 2006)
   http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126054.pdf

3. [EMEA] Guideline on Clinical Development of Fixed Combination Medical Products (Feb. 2008)
   http://www.tga.gov.au/docs/pdf/euguide/ewp/024095enfin.pdf

Application of Key Guidance Documents to MPTs

Source of guidance	Includes info on "combination products"?	Refers to both therapeutic and prevention products?	Includes info about multi-indication?	RH-related mentioned?
1 - CDER	YES	Therapeutic only	NO	NO
2 - OCP	YES	Therapeutic only	NO	NO
3 - EMA	YES	**Both**: however prevention is only mentioned in dosage proposal	**YES, but only** for "two closely related diseases such as hyperglycemia & hypertension…."	NO

Key Regulatory Authorities

- EMA (European Medicines Agency)
- SRA (Stringent Regulatory Authorities)
- NRA (National Regulatory Authority)
- US FDA (United States Food and Drug Administration)
- MHRA (Medicines and Healthcare products Regulatory Agency)

*WHO pre-qualification process

Some Regulatory Challenges for MPTs

- MPTs do not fit into discrete category of *drug, device*, or *biologics,* though they may involve any/all of these.
- Applicability of existing guidance unclear.
- Knowledge about safety and/ or efficacy of one of the MPT components may be inadequate.
- Others?

Tailored Guidance for MPTs Needed to:

- Set overall regulatory and development strategy.
- Determine resource requirements and research approaches (assessments, algorithms).
- Clarify pathways for regulatory review and licensure of MPTs in US and other regions (FDA and EMA).
- Inform intellectual property arrangements; identify incentives; define options for pricing, manufacturing, and availability of any future MPT.

Advancing the MPT Agenda: Challenge and Opportunity

The Challenge: Complexity in product development requires innovative approaches to trial designs, and guidance on regulatory requirements for development and licensure.

The Opportunity: Combination and/or multi-indication products represent cutting-edge science, a promising area for health improvements, possibly larger markets, and potentially cost savings.

What do We Mean by….. Combination Products? Multipurpose?

Combination Products

- A product comprised of two or more regulated components—any combination of a drug, device, and biological product— produced as a single entity.*
- Intended to address single indication.

*(Code of Fed Reg. 21 CFR 3.2)

Multipurpose Prevention Products

(FDA has not published a definition)

- A single agent intended to address more than one indication.
- A combination product intended to address more than one indication.

What Goes Where at FDA? Designation and Division

- Drugs → CDER (Center for Drug Evaluation and Research)
- Biologics → CBER (Center for Biologic Evaluation and Research)
- Device and radioactive therapy → CDRH (Center for Devices and Radiological Health)
- Combination products* → OCP (Office of Combination Products)

*In cases where the primary mode of action is not obvious or easily determined