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Martha Brady
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Population Council

CONSTRUCTING A CRITICAL PATH FOR PRODUCT DEVELOPMENT, COMMERCIALIZATION, AND ACCESS

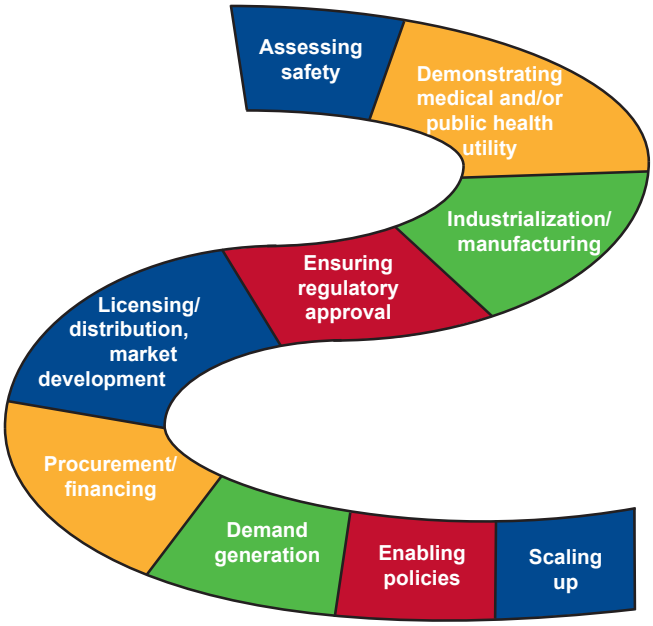
Martha Brady, Senior Associate

The Population Council is an international nonprofit, nongovernmental organization that conducts biomedical, social science, and public health research on HIV and AIDS; poverty, gender and youth; and reproductive health (RH). Our work cuts across disciplines, geographies, and the public and private sectors. The Population Council develops and tests the effectiveness and acceptability of new and improved health technologies, including contraceptives and microbicides, which are designed to benefit women and men in developing countries. Our work includes user's perspectives throughout the development and introduction process. In addition, we encourage licensing, registration, manufacturing, and distribution of contraceptive and other RH technologies developed by the Council.

Council's work on product development

The Population Council has developed and licensed some of the most widely used long-acting, reversible contraceptives in the world. Our work includes basic research directed toward fundamental understanding of biology and disease processes, providing the foundation for product development, as well as translational research which employs novel techniques and tools in the lab, and innovative approaches in field programs to ensure that our scientific discoveries translate into improving the lives of women and men around the globe.

As a product developer we know what is required to take an innovation to a viable product. Product developers must negotiate scientific and technical dimensions along the critical path from innovation to commercial product. Whether working with drugs, devices, or biologics—or some combination thereof—our experience suggests that this pathway encompasses scientific, technical, programmatic and policy dimensions.



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The critical path

The focus of the FDA's Critical Path initiative includes:

- Assessing safety.
- Demonstrating medical and/or public health utility.
- Industrialization.

Equally important elements in delivering the product to the user include:

- Ensuring regulatory approval.
- Establishing licensing and distribution channels.
- Seeding and developing markets.
- Negotiating financing and procurement mechanisms.
- Generating demand among potential users, providers, and policymakers.
- Developing service delivery guidelines and training.
- Creating an enabling policy environment.
- Planning for scaling up.

FOR MORE INFORMATION, VISIT WWW.POPCOUNCIL.ORG
OR CONTACT MARTHA BRADY, MBRADY@POPCOUNCIL.ORG

Population Council One Dag Hammerskjold Plaza New York, New York 10017
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SCIENTIFIC, TECHNICAL, PROGRAMMATIC, AND POLICY DIMENSIONS OF A CRITICAL PATH

Dimension	Definition	Illustrative Activities
Assessing safety*	Show that the product is adequately safe for each stage of development	• Pre-clinical ▪ Show that product is safe enough for human testing ▪ Eliminate products with safety problems • Clinical ▪ Show that product is safe enough for use in humans ▪ Identify potential issues with labeling
Demonstrating medical and/or public health utility*	Show that the product benefits people who will eventually use it	• Pre-clinical: Select appropriate design (devices) or candidate (drugs) with high probability of effectiveness • Clinical ▪ Show effectiveness in people ▪ Evaluate acceptability among users
Industrialization/ manufacturing*	From lab concept or prototype to a reliably manufactured product	• Design a high-quality product: physical design, characterization, specifications • Develop production capacity for: ▪ Manufacturing scale-up ▪ Quality control ▪ Transfer of technology
Ensuring regulatory approval	Approval of product by regulatory authorities (e.g., FDA, EMA, SRAs)	• Determine regulatory pathway; engage regulatory bodies • Work with manufacturer to submit dossiers
Licensing/distribution, market development	Establish licensing arrangements	• Identify suitable licensing and distribution entities • Conduct market seeding activities • Strengthen supply chain
Procurement/ financing	Mechanism for bulk purchasing and financing	• Establish public sector pricing and financing arrangements • Engage donors around procurement • Conduct strategic demand forecasting
Demand generation	Transform unmet need into user demand	• Create awareness among users, providers, and policymakers • Engage advocacy, civil society, and women's groups • Identify market segments, advertising and pricing strategies • Document user perspective
Fostering an enabling policy environment	Incorporate into international guidelines and national norms	• Issue WHO guidelines • Develop country service delivery protocols • Identify and train providers and key opinion leaders • Conduct implementation research to identify best ways to expand access and improve quality
Scaling up	Take product to mainstream	• Prepare introduction strategy with local stakeholders • Assess acceptability under routine service conditions • Conduct implementation research and measure and evaluation