

Prevention Options for Women

Product Development PATH's Approach

PATH works to develop and introduce sustainable solutions to public health problems, particularly those in developing countries and low-resource settings. We believe that, to be effective, products must be “appropriate”—that is, affordable, accessible, and culturally acceptable to potential users.

A User-Driven Development Process

Women's and couples' perspectives are essential to the development of acceptable contraceptive and reproductive health technologies. Without their input, user compliance for a particular product may be poor. In contrast, when users' perspectives drive product development, the final product will likely be easier to obtain, easier to use, more comfortable, and more acceptable to both partners. In turn, couples will be more likely to protect themselves against HIV, sexually transmitted infections, and unwanted pregnancy.

When developing a new technology, PATH thoroughly explores users' needs and concerns to ensure that the design is culturally appropriate and acceptable. PATH conducts evaluations of prototype designs in countries representing the diverse range of cultures and user characteristics that ultimately will affect product acceptance.

Throughout the product-development process, we maintain a focus on advancing solutions that best meet the needs of end-users. In some cases, this means working with existing technologies developed by other groups; in other cases, it requires developing new technologies. PATH may develop technologies and license finished designs to manufacturing or commercialization partners, or may co-develop technologies with such partners. Regardless of the exact approach, we work to promote the entire class of products, and information on acceptability and use that we gain through our interactions with user groups is shared openly.

The Four Stages of Product Development

Emphasizing user feedback and collaboration with partners, PATH's product-development approach proceeds in four stages:

Discovery

PATH's qualitative research on users' perspectives begins with an assessment of the current context and existing solutions. We obtain information from women and couples to learn what works and what does not, and we identify the barriers to greater acceptability, access, and use. We conduct literature reviews, key informant interviews with decision-makers and stakeholders, and focus group discussions with relevant user audiences to further clarify potential improvements. In the discovery stage, we also conduct preliminary brainstorming and feasibility exercises.

Proof of Concept and Preliminary Design Assessment

We define preliminary product objectives and performance goals based on user needs and the current programmatic context. We develop preliminary prototypes in the PATH laboratories and perform bench testing for function, stability, and design safety. Users and potential users then evaluate the proposed design features through a variety of studies.

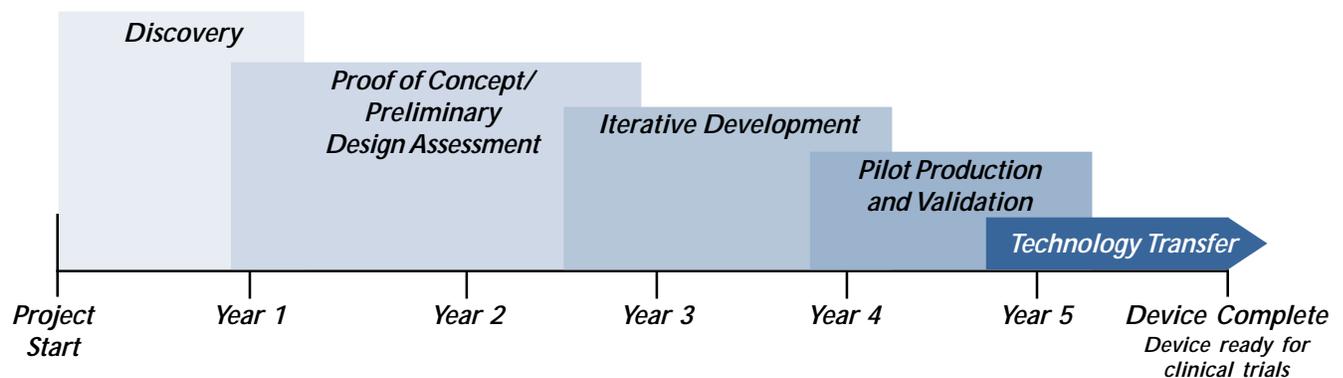
Iterative Development

PATH conducts increasingly refined cycles of development and user evaluation. The interactive process between the design team and potential users ensures that the proposed technology is evaluated through first-hand experience and that necessary modifications are identified. Because these user-evaluation studies are performed during the product development process, they are distinct from the clinical trials that are later used for registration and regulatory approval of the final product design.

Pilot Production and Validation

PATH researches production processes and manufacturing methods throughout the life of the design project. Once a prototype design has met its performance goals and has been validated in user populations, PATH identifies and works with a manufacturing partner who can produce the new device in larger-volume production runs. During this stage, PATH and its partners also plan for the clinical trials that will assess safety and efficacy, and meet with regulatory authorities to discuss strategy for registration and approval.

Typical Timeline for Product Development



Technology Transfer: Ensuring Sustainability for the Future

When transferring a technology to a commercial manufacturer, PATH works to protect product availability, access, and affordability for the public sector. Working within PATH's *Guiding Principles for Private-Sector Collaboration*, we carefully balance the needs of the public sector with the marketplace requirements of our commercial collaborators. Throughout our efforts, we strive to ensure that the products we develop will be safe, effective, and appropriate solutions for users throughout the world for years to come.

PATH is an international public health organization dedicated to improving the health and well-being of people living in developing countries and low-resource settings. For more information about PATH, please visit www.path.org.