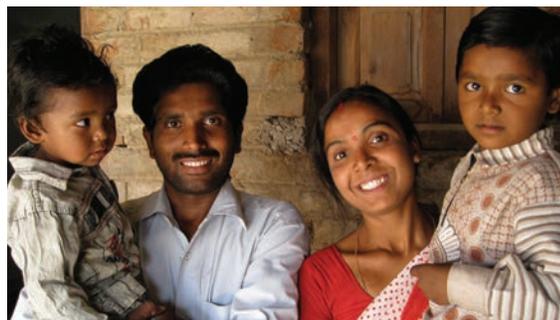




Contraceptive Technology Innovation



Developing and introducing innovative, high-quality and affordable contraceptives for the world





A global leader in contraceptive technology innovation

Since 1971, FHI 360 has helped to increase access to family planning by evaluating and introducing a range of contraceptive methods to meet the needs of women and men worldwide. We have conducted more than 500 clinical trials and pre- and post-marketing studies evaluating the safety, efficacy and acceptability of nearly every type of modern contraceptive method. Our efforts have contributed to the introduction of more than 10 contraceptive products in over 30 countries.

WHY DEVELOP AND INTRODUCE NEW CONTRACEPTIVE METHODS?

More than 220 million women living in developing countries want to control their fertility but do not use effective contraceptive methods. For some, access to contraceptive methods is limited. For others, current options do not meet their needs or are unaffordable. Innovative solutions in product development, country registration, pricing and market introduction are needed to address barriers that may impact contraceptive uptake. With a proven track record of more than 40 years, FHI 360 is a global leader in contraceptive technology innovation (CTI).

CURRENT PORTFOLIO

FHI 360 develops, evaluates and introduces new contraceptive technologies and refines existing methods with a target of increasing contraceptive access to women in low-resource settings. Our current CTI portfolio spans multiple stages of product development and is supported by three major awards:

- » **Envision FP:** Awarded by the U.S. Agency for International Development in 2015, *Envision FP* recognizes that family planning options must reflect the changing needs of women and couples during their reproductive lives. The goal of this project is



FHI 360's work spans multiple stages of research, development and introduction, targeting key opportunities for rapid expansion of the contraceptive method mix.

to develop, introduce and expand understanding of contraceptive technologies to enhance choice and reduce unmet need. Research focuses on developing new or improved contraceptives that are safe, affordable, and have fewer side effects.

Also under *Envision FP*, a rapid response team is in place to address technical and scientific queries related to field-generated concerns that could disrupt procurement, provision, uptake or use of methods. The team assesses the situation, offers informed recommendations to decision-makers and oversees post-incident monitoring.

» **Contraceptive Technology Innovation Initiative:**

Funded by the Bill & Melinda Gates Foundation, the CTI Initiative seeks to develop innovative mid- to long-acting contraceptives to provide high-quality, acceptable and affordable products for women most in need in low-resource settings. Under this award, FHI 360 researchers, in collaboration with private- and public-sector partners, are working to:

- **Develop a biodegradable implant** that would eliminate the need for implant removal. Research teams are evaluating options for an implant that would be effective for at least 18 months and provide a predictable return to fertility.
- **Develop a longer-acting contraceptive injectable** that would last six months. Currently marketed injectables only last one to three months. Longer intervals between injections could lead to higher compliance and continuation and could lower cost burdens on health care systems.

- **Evaluate and expand access to intrauterine device technologies:** FHI 360 is leading a comparative trial of the Copper-T 380A intrauterine device (IUD) and new, copper IUD alternatives. Findings on acceptability, side effects and continuation rates could support new product scale-up and introduction. FHI 360 is also working to expand access to a new, affordable levonorgestrel-releasing IUD in low-resource settings.

- » **Sino-implant (II) initiative:** Sino-implant (II) is a low-cost, highly effective two-rod contraceptive implant manufactured by Shanghai Dahua Pharmaceuticals Co., Ltd. Funded by the Bill & Melinda Gates Foundation and led by FHI 360, the Sino-implant (II) initiative has been at the forefront of increasing access to affordable, high-quality contraceptive implants globally since 2009. To date, Sino-implant (II) has been registered in over 20 countries. More than 1 million units have been distributed in countries included in the initiative; this translates to an overall procurement cost savings of US\$10.5 million.

KNOWLEDGE SHARING RESOURCES

FHI 360's CTI Exchange (<http://ctiexchange.org>) is a web portal offering a convenient single point of access for individuals wanting to find or share resources on contraceptive research, development, registration and introduction. In addition to providing a comprehensive resource library, the site houses *Calliope, the Contraceptive Pipeline Database* (pipeline.ctiexchange.org), which includes information on more than 170 contraceptive products either in various stages of development or offered only in limited markets.

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CUTTING-EDGE LEADERSHIP IN FAMILY PLANNING

FHI 360 uses a multidisciplinary approach to advance product development and introduction. Our CTI team has expertise in reproductive physiology, chemistry, chemical engineering, drug development, formulation science, obstetrics and gynecology, clinical trials, epidemiology, biostatistics and product quality testing. Additionally, we leverage FHI 360 competencies in the following areas:

» **Clinical regulatory compliance:**

FHI 360 provides regulatory operations management for clinical trials globally. Expertise includes regulatory submissions, development of country-specific regulatory profiles and regulatory strategies, drug shipment authorization, trial master file maintenance, recording of study progress in country-specific registries, review of research protocols for regulatory compliance, and audits for vendor qualification, good clinical practice (GCP) and site-inspection readiness.

- » **Product quality and compliance:** FHI 360 provides comprehensive quality assurance for global contraceptive procurement and distribution programs. Contraceptive products tested include male and female condoms, IUDs, injectables, implants and oral contraceptives. FHI 360 conducts good manufacturing practice (GMP) audits of facilities and suppliers, performs product quality investigations and participates in international standards committees.



HARNESSING THE POWER OF PARTNERSHIPS

FHI 360 maintains strategic partnerships with product development scientists, university and contract laboratories, pharmaceutical companies, clinical research sites, regulatory groups, manufacturers, distributors and service delivery organizations to advance contraceptive research and introduction activities. Working with these partners to ensure affordability of final products is a priority across all activities.

» **Health services and social and behavioral**

health research: FHI 360 researchers study the feasibility of integrating new contraceptive methods into existing health service delivery systems. Activities include evaluating provider knowledge and ability to deliver a wide range of contraceptive methods, and documenting health system barriers to the successful introduction and scale-up of new offerings. FHI 360 behavioral scientists seek to understand user preferences for new technologies and the sociocultural, institutional and individual factors that affect contraceptive use within different populations and geographic settings worldwide.

- » **Research utilization:** FHI 360 accelerates the uptake of research findings and evidence-based practices into governmental policies and country programs by developing practical tools (e.g., training curricula and job aids), building capacity of country policymakers and implementers to access and apply evidence, and supporting national scale-up of proven practices.

For more information about FHI 360's work in contraceptive technology innovation, email us at: cti@fhi360.org.