



Contraceptive Technology Innovation



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





A global leader in contraceptive technology innovation

Throughout our 40-year history, FHI 360 has helped to increase access to family planning by evaluating and introducing a range of contraceptive methods that meet the needs of women and men worldwide. FHI 360's research and development programs have contributed to the introduction of more than 10 contraceptive products in over 30 countries. 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, including barrier methods, intrauterine devices (IUDs), implants, injectables and permanent contraception.

WHY DEVELOP AND INTRODUCE NEW CONTRACEPTIVE METHODS?

Despite the availability of various contraceptive products, more than 200 million women living in developing countries want control over their fertility and yet are not using effective contraception. For some of these women, access to contraception is limited. For others, currently available methods do not meet their needs or preferences or are unaffordable. Innovative solutions for product development, registration, pricing and introduction are needed to address these barriers. FHI 360 has a proven track record as a global leader in these areas.

CURRENT PORTFOLIO

FHI 360 develops, evaluates and introduces new contraceptives with an emphasis on mid- to long-acting methods. Our portfolio includes:

» **Contraceptive Technology Innovation Initiative:**

The goal of this project is 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. Launched in 2013 with funding from the Bill & Melinda Gates Foundation, the project spans multiple stages of research and development.



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

» **Development of a biodegradable implant:**

With funding from the U.S. Agency for International Development (USAID), FHI 360 is supporting the development of a new biodegradable contraceptive implant that would eliminate the need for implant removal. Although current implants are safe, highly effective and popular, the need for removal services can be problematic for women in resource-limited settings who might not have access to trained personnel or be able to afford the procedure.

FHI 360 is evaluating options for a biodegradable implant that would be effective for at least 18 months and would have a predictable return to fertility. Early proof-of-concept testing is under way.

» **Development of a longer-acting injectable:**

With support from the Bill & Melinda Gates Foundation, FHI 360 is evaluating innovative approaches to the development of an injectable contraceptive that lasts for six months. Current injectables — used by more than 40 million women worldwide — are effective for up to three months. Reinjection intervals require women to return to their health provider four to 12 times a year, which can be challenging in resource-limited settings. Longer intervals between injections would likely lead to higher compliance and continuation rates. Several approaches to developing a longer-acting injectable are currently being evaluated in collaboration with U.S. and international partners.

» **Sino-implant (II) initiative:** Sino-implant (II) is a low-cost, highly effective contraceptive implant manufactured by Shanghai Dahua Pharmaceuticals Co., Ltd and is currently labeled for four years of use.

The Sino-implant (II) initiative, funded by the Bill & Melinda Gates Foundation and led by FHI 360, has been at the forefront of helping to increase access to affordable, high-quality contraceptive implants globally. The product has been registered in more than 20 countries worldwide. More than 1 million units have been distributed since 2009 in countries included in the initiative. This distribution has translated into a cost savings of US\$10.5 million.

Additional FHI 360 work includes supporting the early introduction in low- and middle-income countries of a new levonorgestrel intrauterine device (LNG20 IUD) developed by Medicines360, providing regulatory support for a new postpartum IUD inserter, conducting clinical testing of a novel device for removing subdermal contraceptive implants, and assessing the potential uptake and benefits when long-acting, reversible contraceptives are made more widely available.

ONLINE CLEARINGHOUSE

Through the Contraceptive Technology Innovation Initiative, FHI 360 is developing a new web portal that will expand global access to resources on contraceptive research, development and introduction. The website will bring together resources created by FHI 360 and our partners, including information about early- and late-stage contraceptive technologies from a variety of groups, information about Active Pharmaceutical Ingredients that can support product testing and quality assurance, international regulatory resources and effective product introduction strategies focused on low-resource settings.

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CUTTING-EDGE LEADERSHIP IN FAMILY PLANNING

FHI 360 uses a multidisciplinary approach to advance innovation in contraceptive product development and introduction. Our team has expertise in reproductive physiology, drug development, formulation science, obstetrics and gynecology, clinical trials, epidemiology, product quality testing and biostatistics. In addition, we leverage FHI 360's expertise in the following areas:

» **Regulatory affairs and quality assurance:**

FHI 360 has more than 40 years of experience in supporting regulatory activities for product development, clinical trials, registration and post-approval activities. Our expertise spans all stages of product development, including drug formulation and pre-clinical, clinical and quality assurance activities.

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



HARNESSING THE POWER OF PARTNERSHIP

FHI 360 seeks and 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 partners to ensure affordability of final products is a priority across all of our activities.

» **Health services and social and behavioral**

health research: FHI 360's researchers study the feasibility and acceptability of integrating new contraceptive methods into service delivery systems. Activities include evaluating provider and client understanding and knowledge of contraceptive technologies, as well as documenting health system barriers to the successful introduction and scale-up of new methods. FHI 360 uses behavioral research to understand user preferences for new technologies and the sociocultural, institutional and individual factors that affect use of contraceptives within different populations and geographic settings worldwide.

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



FHI 360 HEADQUARTERS
359 Blackwell Street, Suite 200
Durham, NC 27701 USA
T 1.919.544.7040
F 1.919.544.7261

WASHINGTON DC OFFICE
1825 Connecticut Avenue NW
Washington, DC 20009 USA
T 1.202.884.8000
F 1.202.884.8400

www.fhi360.org