Contraceptive Technology Innovation Initiative

HEALTH

SUMMARY

Funded by the Bill & Melinda Gates Foundation, the Contraceptive Technology Innovation (CTI) Initiative aims to develop innovative mid- to long-acting contraceptives that are of high-quality and are acceptable and affordable to women in need in low-resource settings. The five-year grant (2013-2018) has four objectives:

1) Spearhead research and development of strategically important mid- to long-acting female contraceptive technologies.

2) Implement innovative problem-solving approaches to facilitate and accelerate regulatory approvals.

3) Create partnerships to strengthen development, low-cost production, registration, and distribution of new products, with a focus on collaborations with manufacturers in emerging markets.

4) Share experience and knowledge with the global community.

As part of the CTI Initiative, FHI 360 scientists collaborate with private- and public-sector partners to address gaps in the current contraceptive method mix. Our research portfolio includes the following research:

- ✓ Developing a biodegradable implant to eliminate the need for implant removals. Women in resource-poor settings may not have easy access to health professionals trained in implant removals. Research teams are evaluating options for a biodegradable implant system that would release a contraceptive steroid at a slow, constant rate for at least 18 months, with a short return to fertility.

- ✓ Advancing a novel, longer-acting contraceptive injectable that would last six months, substantially extending the effectiveness of existing products. Longer intervals between injections could lead to higher compliance and continuation rates. We are engaging with partners to evaluate multiple drug delivery technologies that would slowly release etonogestrel, levornorgestrel, or Nesterone® over a six-month time span.

- ✓ Extending use of depot medroxyprogesterone acetate (DMPA) to provide six months of pregnancy projection. DMPA is currently marketed as an injectable contraceptive offering three months of protection when applied intramuscularly (IM). FHI 360 is leading a Phase I clinical study in the United States and the Dominican Republic to evaluate whether DMPA can provide six months of pregnancy protection when injected subcutaneously. Our researchers are also collaborating with Teva Pharmaceutical Industries Ltd. to develop and evaluate a new formulation of MPA that would be effective for six months.

- ✓ Incorporating etonogestrel-filled microspheres into microneedles. Affixed to a patch the size of a coin, hundreds of microneedles would break off upon permeating the skin. The needles would biodegrade rapidly, leaving behind microspheres that release etonogestrel slowly over several months. A contraceptive microarray patch could potentially be self-administered and would offer supply chain advantages, especially key in remote, resource-constrained settings.

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- ✓ Conducting comparative Phase II/Phase III trials of the Copper-T 380A intrauterine device (IUD) and newer copper alternatives available only in limited markets. A U.S. trial will be conducted in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Human Development. A trial in Kenya will generate additional product feedback from providers and users. Findings on acceptability, side effects, and continuation rates could support new product introduction and scale-up of additional copper IUD methods, expanding choice for women.

- ✓ Expanding access to a new, more affordable levonorgestrel-releasing IUD (LNG-IUS) in low-resource settings. Uptake of the LNG-IUS in developing countries has been low, primarily due to its high cost. FHI 360 is conducting market assessments and supporting product introduction strategies for a new, more affordable LNG-IUS in Kenya, Nigeria, and Zambia.

- ✓ Studying the acceptability of novel methods under development among potential users to ensure their perspectives are incorporated into research, development, and introduction efforts. Studies are underway in Uganda and Burkina Faso to identify user preferences for product attributes, explore key factors influencing potential acceptability, and estimate potential demand.

- ✓ Evaluating new contraceptive leads, by conducting comprehensive literature reviews and participating in consultations and site visits to identify and evaluate novel materials, manufacturing methods, and drug delivery modes. Our current watch list of "blue sky" contraceptive leads includes male non-hormonal methods and on-demand, user-controlled options.

STRATEGIC PARTNERSHIPS

FHI 360 maintains strategic partnerships with product development scientists, universities, contract laboratories, pharmaceutical companies, clinical research sites, regulatory groups, manufacturers, distributors, and service delivery organizations to advance contraceptive research and introduction activities. CTI Initiative partners commit to facilitating global access to project results, which means that knowledge and information gained from research is promptly and broadly disseminated and that any resulting contraceptive products are made available and accessible at reasonable costs to people in need in developing countries.

KNOWLEDGE SHARING

The CTI Exchange (http://ctiexchange.org) is a web platform providing global access to resources on contraceptive product research, development, registration, and introduction. It includes:

- ✓ A resource library of more than 145 useful tools and resources to help scientists, manufacturers, distributors, and service delivery providers navigate the entire product development process, from early-stage research to product registration and introduction
- ✓ Exchanges, a blog for stakeholders and experts to share news, write commentary, and announce events
- ✓ Calliope, the Contraceptive Pipeline Database, a resource that provides data about more than 190 contraceptive leads and products under development, along with information on contraceptives currently available only in limited markets.

CONTRACEPTIVE TECHNOLOGY INNOVATION EXCHANGE

CONTACT US

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