

Capability Statement

Catalyst Global is a US-based 501(c)(3) committed **to increasing access to critical sexual and reproductive health (SRH) products and services in low- and middle-income countries**. Our team of experts in the public health, social marketing, pharmaceutical, and medical device industries provide comprehensive technical assistance to product developers, manufacturers and implementing partners to enable access to high quality health products in global markets. Our credentials in product introduction, global regulatory affairs and quality assurance have made Catalyst Global a preferred partner of organizations seeking to move products from laboratories and manufacturing plants to the girls and women who need them.



Our Approach

Catalyst Global increases access to key sexual and reproductive health products and services to girls and women living in low- and middle-income countries by supporting **go-to-market strategies** for product introduction, and by building partner capacity in **pre- and post-market support** for the introduction of new products. Catalyst Global has five main focus areas, as outlined below.

01. Designing and Coordinating Go-to-Market Strategies



Catalyst Global acts as a product-neutral convener, designing and coordinating go-to-market strategies, and building teams that work at different levels along the value chain (e.g. manufacturing, distribution, marketing etc.) to introduce new technologies for women's health. We conduct assessments to gain an understanding of the market for new products, and implement formative research to better understand girls and women's needs and perspectives. We use this data to develop and improve tailored strategies to maximize impact. To date, we have supported a wide variety of reproductive health commodities, from the manual vacuum aspiration device for surgical abortion, to emergency/oral contraception to a smartphone app that tracks fertility, among others.

Catalyst Global Impact

- Catalyst Global has increased access to 16 reproductive health products in over 90 countries, including 4 self-care methods.
- In partnership with PSI, Catalyst Global introduced the hormonal IUD to over 4,800 women in Zambia and Madagascar; the Caya® Diaphragm to over 2,400 women in Niger and Benin; and the Woman's Condom to more than 137,000 women in Malawi and Zambia.
- Catalyst Global's regulatory support ensured the continued availability of the manual vacuum aspiration (MVA) device for safe surgical abortion to women in 25 countries.
- In collaboration with the University of California, San Francisco and Harvard University, Catalyst Global supports one clinical trial for a biotherapeutic gel for HIV prevention.
- Catalyst Global supports the Population Council's acceptability study for a multipurpose technology, the dual-prevention pill (contraception and HIV prevention).

02. Ensuring Manufacturing Quality



Catalyst Global works closely with manufacturers to improve their quality management systems. This includes supporting manufacturers and suppliers to improve their processes to meet international best practice, conducting quality system assessments to verify current regulatory status, and performing onsite Good Manufacturing Practice audits. For example, Catalyst Global recently conducted internal quality audits for Medintim and its suppliers in preparation for distribution of its products, the Caya® Diaphragm and Caya® Gel, in Benin and Niger. Catalyst Global can also identify new manufacturing options and assist with tech transfers. For new products, Catalyst Global verifies compliance to product specs for each lot and issues corrective action requests to address nonconformities; assists with the establishment of pharmacovigilance policies and procedures between manufacturers and distributors; and monitors distributed products for post-market safety issues.

03. Providing Strategic and Practical Support for Regulatory Compliance



Catalyst Global specializes in conducting landscape assessments to provide strategic guidance for manufacturers, product developers and implementing partners on the most impactful and cost-effective regulatory compliance strategies. We also provide practical technical assistance in a number of key areas—compiling, reviewing and submitting applications to local, regional and WHO prequalification and or Stringent Regulatory Approval authorities; trademark support; scientific advice and clinical trial oversight; maintaining regulatory status of products; and building capacity of national regulatory authorities. Some recent examples of Catalyst Global activities include supporting Medicines360 with national-level registration of its product in Nigeria, and regionally through the East African Community regional harmonization initiative in Tanzania, Uganda and Rwanda; collaborating with Mann Global Health and Evofem Biosciences to develop and implement strategic regulatory pathways for a new, hormone-free contraceptive gel; and collaborating with MSI Reproductive Choices on regulatory compliances for 7 products in 11 countries. Since 2010, Catalyst Global's strategic and practical technical assistance to partners has resulted in over **160 registrations of health commodities in over 90 countries** in Africa, Asia and Latin America.

Expanding Effective Contraceptive Options (EECO)

Catalyst Global leads the \$21M, USAID-funded EECO project (2013–2023) in partnership with Population Services International (PSI) and a number of other collaborators. EECO is designed to address women's method-related reasons for non-use of contraception by piloting innovative contraceptive technologies in low- and middle-income countries that better meet the needs of girls and women. Catalyst Global produces roadmaps for the successful introduction of new and underused commodities globally.

Catalyst Global's role is to act as a product-neutral convenor, identifying and coordinating a skilled team of partners, linking upstream product developers and suppliers with downstream marketing and distribution partners; lead regulatory and quality assurance efforts; troubleshoot and mitigate supply chain vulnerabilities; and work through both public and private sector channels to bring essential reproductive health commodities to the girls and women who need them. Examples of products that Catalyst Global and partners have successfully introduced include the Caya Diaphragm and gel in Niger and Benin; the hormonal intrauterine device (IUD) in Zambia and Madagascar; and the Woman's Condom in Malawi and Zambia. In collaboration with the Population Council, EECO has also supported the introduction of the progesterone vaginal ring in Nigeria, and is supporting an acceptability study of the dual prevention pill, a multipurpose prevention technology that combines oral preexposure prophylaxis (PrEP) and oral contraceptives, in South Africa.



04. Supporting Quality of SRH Service Delivery



Catalyst Global provides technical assistance to local stakeholders through guidance and tools that facilitate capacity building and training of health workers to support new products and services. Catalyst Global is currently co-leading a technical sub-group with AVAC to develop provider counselling messages for the dual prevention pill. In Malawi, Catalyst Global designed a medical detailing program to educate and train providers to offer the Whisper Woman's Condom in order to reduce provider-related barriers to access. More than 137,000 Woman's Condoms were distributed through pilot introductions in Zambia and Malawi. In Kenya and South Africa, Catalyst Global collaborated with health care providers and with leadership at the local, provincial, and national levels, to identify and address barriers to the provision of comprehensive abortion care (CAC). The team introduced tailored strategies that included the development of a benchmarking tool for evaluating the quality of services at the facility level; connecting health care providers to training and mentorship opportunities; updating guidelines and policies to ensure public sector health care providers had clear guidance on providing safe CAC, and establishing data feedback loops with providers and managers to support evidence-based decision making. Catalyst Global provided capacity-building support to over **600 health care providers**, and **more than 230,000 women** accessed safe, high-quality services through these providers.

05. Strengthening the Knowledge Base for New Product Introduction



Catalyst Global seeks to increase knowledge about sexual and reproductive health product introduction, in particular of new and underused technologies, by sharing our experience with partners through publications, presentations and webinars. Our most recent publications can be found [here](#).

Catalyst Global Strategic Priorities

Launch the Market Access Accelerator

Catalyst Global will continue to leverage its experience as a strategic convener, identifying and bringing teams together to increase access to new and innovative women's health products. The Market Access Accelerator will offer an expanded set of go-to-market services to commercial partners, including market assessments, regulatory and quality support, distribution partnerships, and formative research.



Photo by: Alexandra Angel, PSI.



Diversify product portfolio and partnerships to include new innovative technologies

Catalyst Global will expand its partnerships to include other high-impact products and services in focus areas that include HIV prevention, abortion, emergency contraception, maternal health, menstruation and multi-purpose technologies.

Provide support to partners in low- and middle-income countries

Catalyst Global is committed to strengthening the capacity of partners that are closest to the girls and women that are at the heart of our work. This includes building the capacity of and supporting the transfer of technologies to manufacturers to reduce the distance between production and user; supporting regulatory authorities to streamline processes and apply best practices; and reinforcing the capacity of government agencies and local organizations that are overseeing and supporting service delivery.



Recent Publications

A New Contraceptive Diaphragm in Niamey, Niger: A Mixed Methods Study on Acceptability, Use, and Programmatic Considerations, available [here](#). Feb 2022

Introducing the hormonal Intrauterine Device in Madagascar, Nigeria, and Zambia: results from a pilot study, available [here](#). Jan 2022

20 Essential Resources: Contraceptive Product Introduction, available [here](#). Sep 2021

“Donation of Contraceptive Products Through Special Import Permits: A Case Study in Zambia and Nigeria,” published in the International Journal of Drug Regulatory Affairs (IJDR), available [here](#). Dec 2020

Expanding Effective Contraceptive Options: Introducing the Caya Diaphragm in Niger, available [here](#). Jun 2020

Expanding Effective Contraceptive Options: Lessons Learned from the Introduction of the Levonorgestrel Intrauterine System (LNG-IUS) in Zambia and Madagascar, available [here](#). Apr 2019

Introducing New Contraceptive Options: Product Registration Basics for Global Health Program Managers, available [here](#). Mar 2019

Learning about Expanded Access and Potential of the Levonorgestrel Intrauterine System (LEAP LNG-IUS), available [here](#). Nov 2018

Expanding Effective Contraceptive Options: Lessons Learned from the Woman’s Condom Introduction in Zambia and Malawi, available [here](#). Oct 2018

Assessing the Total Market for Female Condoms in Malawi and Zambia, available [here](#). Sep 2018

Product Registration Toolkit, available [here](#). Jul 2022



Photo by:
Alexandra Angel, PSI.