

# Using an Innovative Public-Private Partnership Model to Increase Access to Affordable Implants: Lessons Learned from the 5-Year Sino-implant (II) Initiative

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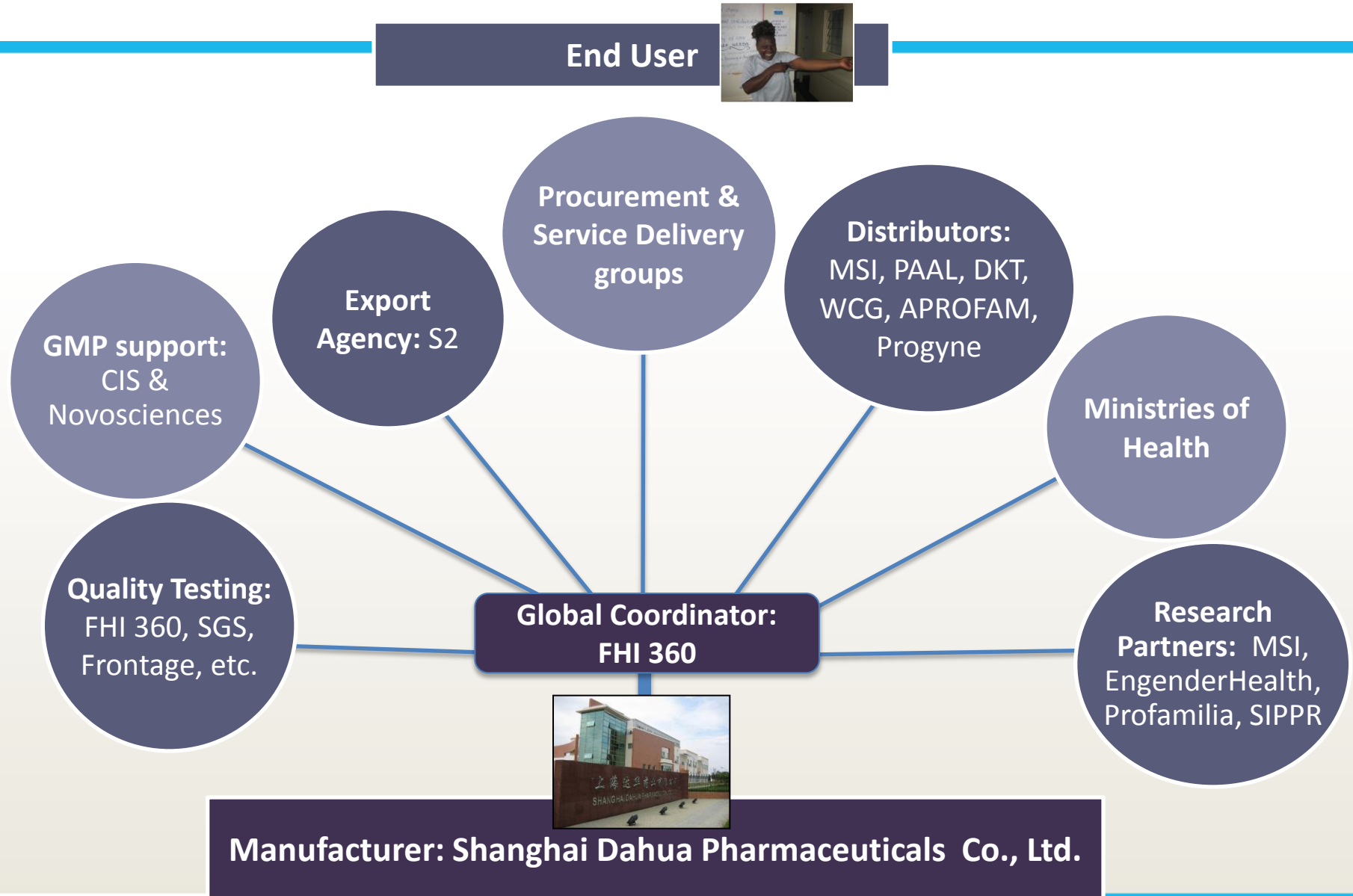
RHSC Membership Meeting



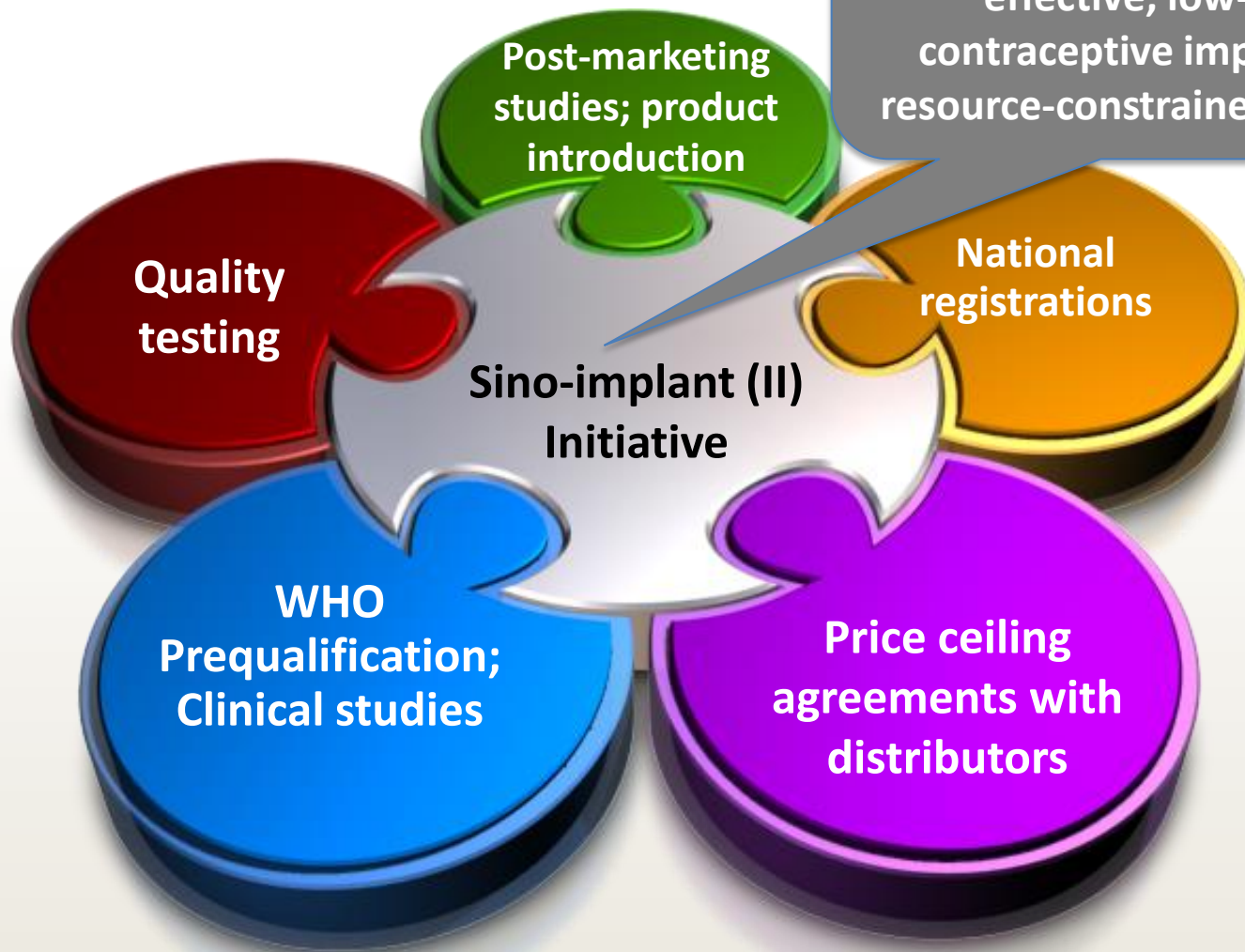
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# The Power of Partnerships

# Dahua's Global Business Platform with Current Partners



# Overview: Sino-implant (II) Initiative



**Shared Goal:**  
To increase access to highly effective, low-cost contraceptive implants in resource-constrained settings

Funding for the Sino-implant (II) initiative comes from the Bill & Melinda Gates Foundation

# Ongoing product quality evaluation

- **Lot-Release Testing:** Every Sino-implant (II) lot tested by Dahua and independent, internationally recognized company (SGS)
- **Annual Evaluation:** API, metal impurities, sterilization residue, endotoxins, cytotoxicity, and package integrity



**2008-2012:  
Product met all  
international  
quality standards  
evaluated**

- **CpK Analysis** of three test parameters (dissolution, content and tube thickness) showed manufacturing process is stable & well-controlled
- **Explant study** compared levonorgestrel in Sino-implant (II) rods removed after different periods of use to published data for Jadelle

# WHO Prequalification Process Ongoing



- Application compiled and submitted to WHO by Dahua with technical assistance from FHI 360
- Application accepted for formal review in Oct 2010
- Process includes clinical dossier review, CMC dossier review, and GMP inspection
- Additional clinical data requested; studies in the Dominican Republic and China ongoing

## **WHO GMP Status Achieved Jan 2013**

- Dahua determined to be operating in compliance with WHO Good Manufacturing Practices (GMP)





## Sino-implant (II) Registration Status

# Sept 2013

Registered under  
multiple trade names:  
**Zarin, Femplant, Trust, Simplant**



### Registered (n=25)

**Bolivia<sup>†</sup>**  
**Burkina Faso<sup>†</sup>**  
**Cambodia<sup>†</sup>**  
**Chile\***  
**China**  
**Ethiopia\*\***

**Fiji<sup>†</sup>**  
**Ghana<sup>†</sup>**  
**Guatemala<sup>¥</sup>**  
**Indonesia**  
**Jamaica**  
**Kenya<sup>‡</sup>**

Madagascar<sup>†</sup>  
Malawi<sup>†</sup>  
Mali<sup>†</sup>  
Mongolia<sup>†</sup>  
Mozambique<sup>‡</sup>  
Nepal\*

**Nigeria<sup>‡</sup>**  
**Pakistan<sup>†</sup>**  
**Senegal<sup>‡</sup>**  
**Sierra Leone<sup>‡</sup>**  
**Uganda<sup>‡</sup>**  
**Zambia<sup>‡</sup>**  
**Zanzibar<sup>‡</sup>**

**Under review in over 10 additional countries**

†Distributed by Marie Stopes International (MSI);

‡ Distributed by Pharm Access Africa Ltd. (PAAL)

\* Distributed by WomanCare Global

**\*\* Distributed by DKT International**

¥ Distributed by APROFAM

# Pre- & Post-Marketing Studies in Four Countries

## Over 2,500 women enrolled across four studies: Bangladesh\*, Kenya, Madagascar, and Pakistan

- Findings contribute to understanding of safety profile
- Desire from Ministries of Health for local data
- Research partners: EngenderHealth, MSI
- Funding from USAID and Gates Foundation

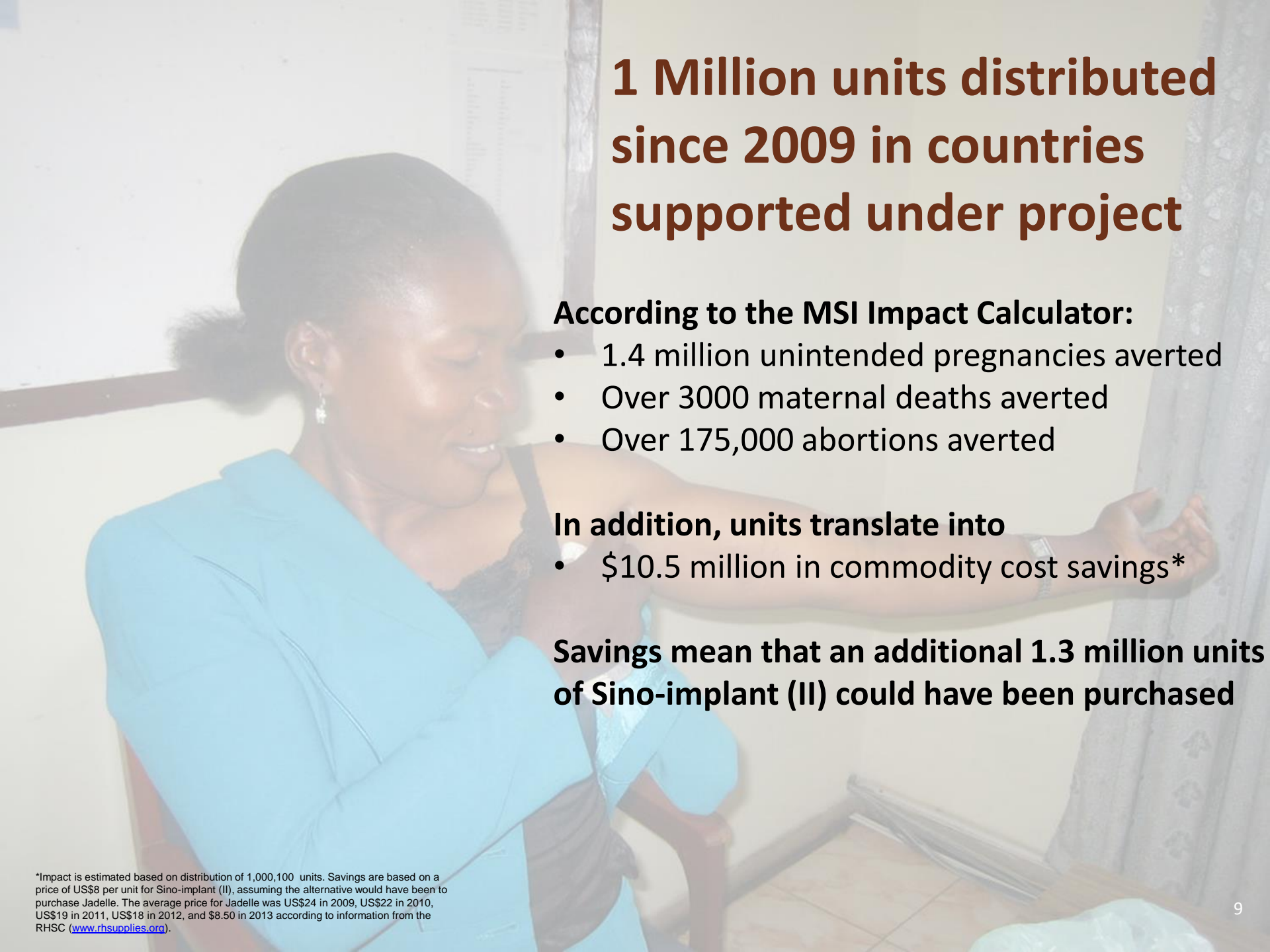
## Studies completed with 12 months of follow-up data available. Key findings:

- Bangladesh & Madagascar: no pregnancies
- Kenya & Pakistan: pregnancy rate below 1%
- Insertion problems rare
- High satisfaction and continuation rates
- 1 Serious Adverse Event (SAE) reported that was possibly related to product: pregnancy in Kenya was ectopic



\* Study in Bangladesh led by Engenderhealth under RESPOND project



A woman with dark hair tied back, wearing a light blue button-down shirt, is seated and holding a baby wrapped in a light blue cloth. She is looking down at the baby with a gentle smile. The background is a simple room with a window and some papers on the wall.

# 1 Million units distributed since 2009 in countries supported under project

## According to the MSI Impact Calculator:

- 1.4 million unintended pregnancies averted
- Over 3000 maternal deaths averted
- Over 175,000 abortions averted

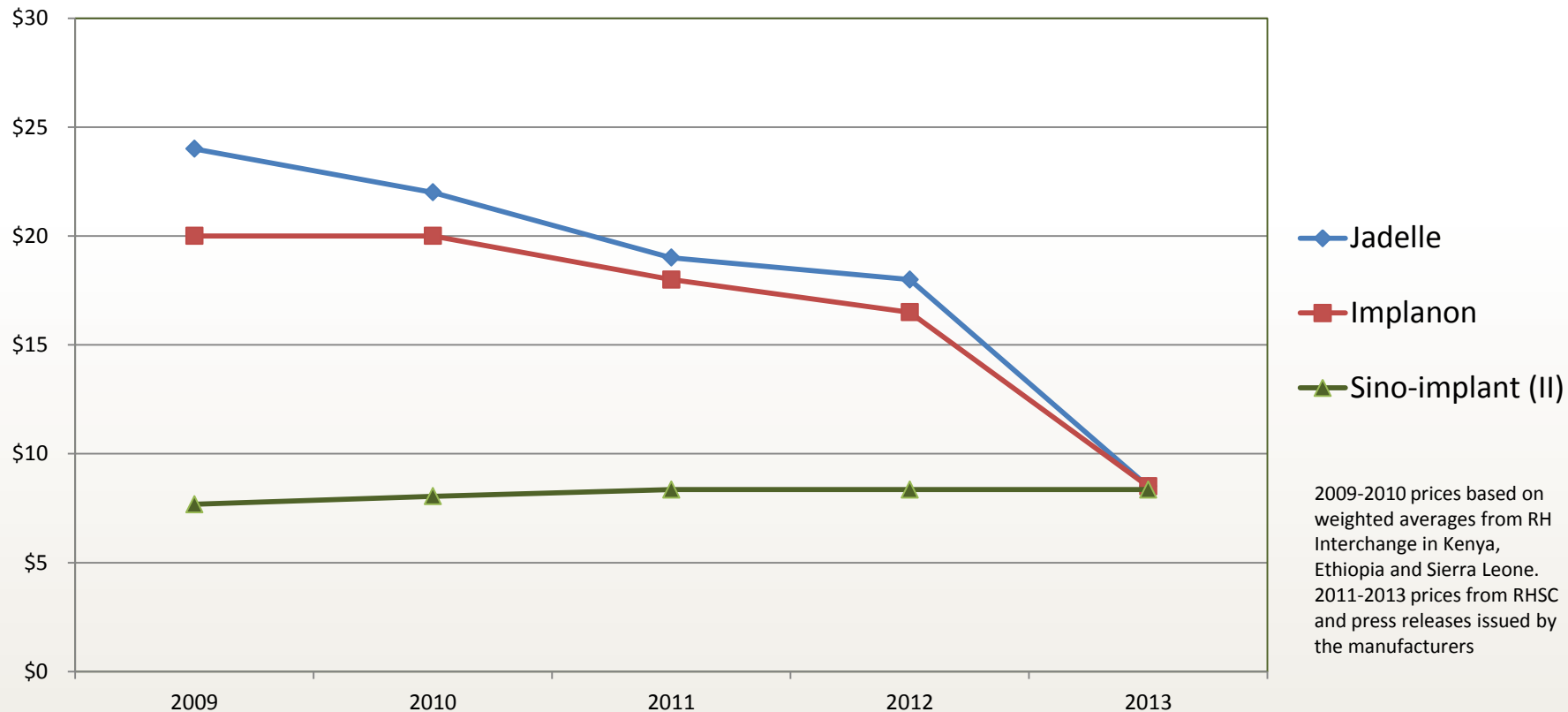
## In addition, units translate into

- \$10.5 million in commodity cost savings\*

**Savings mean that an additional 1.3 million units of Sino-implant (II) could have been purchased**

\*Impact is estimated based on distribution of 1,000,100 units. Savings are based on a price of US\$8 per unit for Sino-implant (II), assuming the alternative would have been to purchase Jadelle. The average price for Jadelle was US\$24 in 2009, US\$22 in 2010, US\$19 in 2011, US\$18 in 2012, and \$8.50 in 2013 according to information from the RHSC ([www.rhsupplies.org](http://www.rhsupplies.org)).

# Contraceptive Implant Prices 2009-2013: Changes Since Global Introduction of Sino-implant (II)



## Key Milestones

**2009:** Sino-implant (II) registered in Kenya under trade name Zarin; first registration outside of Asia

**2011-2012:** Under agreement with partners, Merck/MSD reduces price of Implanon to \$18/unit, with retro-active reduction to \$16.50 when volume thresholds reached in Dec 2012

**2011-2012:** Bayer HealthCare reduces price of Jadelle to \$19/unit and then subsequently to \$18/unit

**2012-2013:** Bayer HealthCare and Merck/MSD lower the prices of Jadelle and Implanon to US\$8.50 per unit as part of volume guarantees

**2009-2013:** Over 1 million Sino-implant (II) units procured in countries under Gates initiative since 2009, resulting in over \$10 million in commodity savings

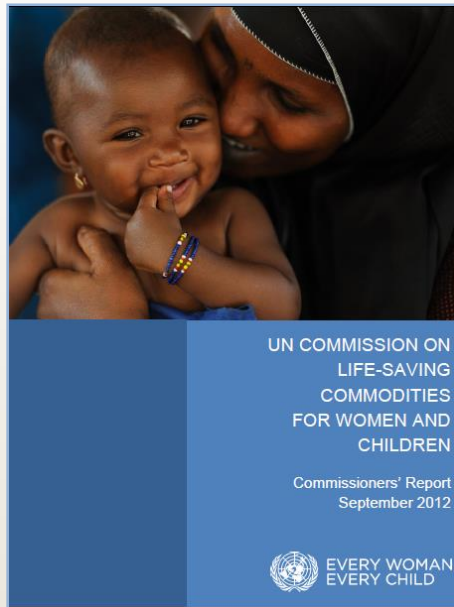
# Key Take-Aways and Lessons Learned (1 of 2)

- ✓ **Three highly effective, low-cost contraceptive implants are now available**
  - Dahua played direct role in this effort by being the first to market with a low-cost (<US\$9/unit) contraceptive implant
- ✓ **Support to Dahua from global coordinating entity facilitated dossier submissions, quality testing, and international introduction**
- ✓ **WHO Prequalification remains critical milestone**
  - Process lengthy and costly; ongoing technical assistance will be required
- ✓ **For all implant programs, ensuring high quality service provision, informed choice, and timely access to removals is essential**
  - Will require commitment and involvement of multiple partners

# Key Take-Aways and Lessons Learned (2 of 2)

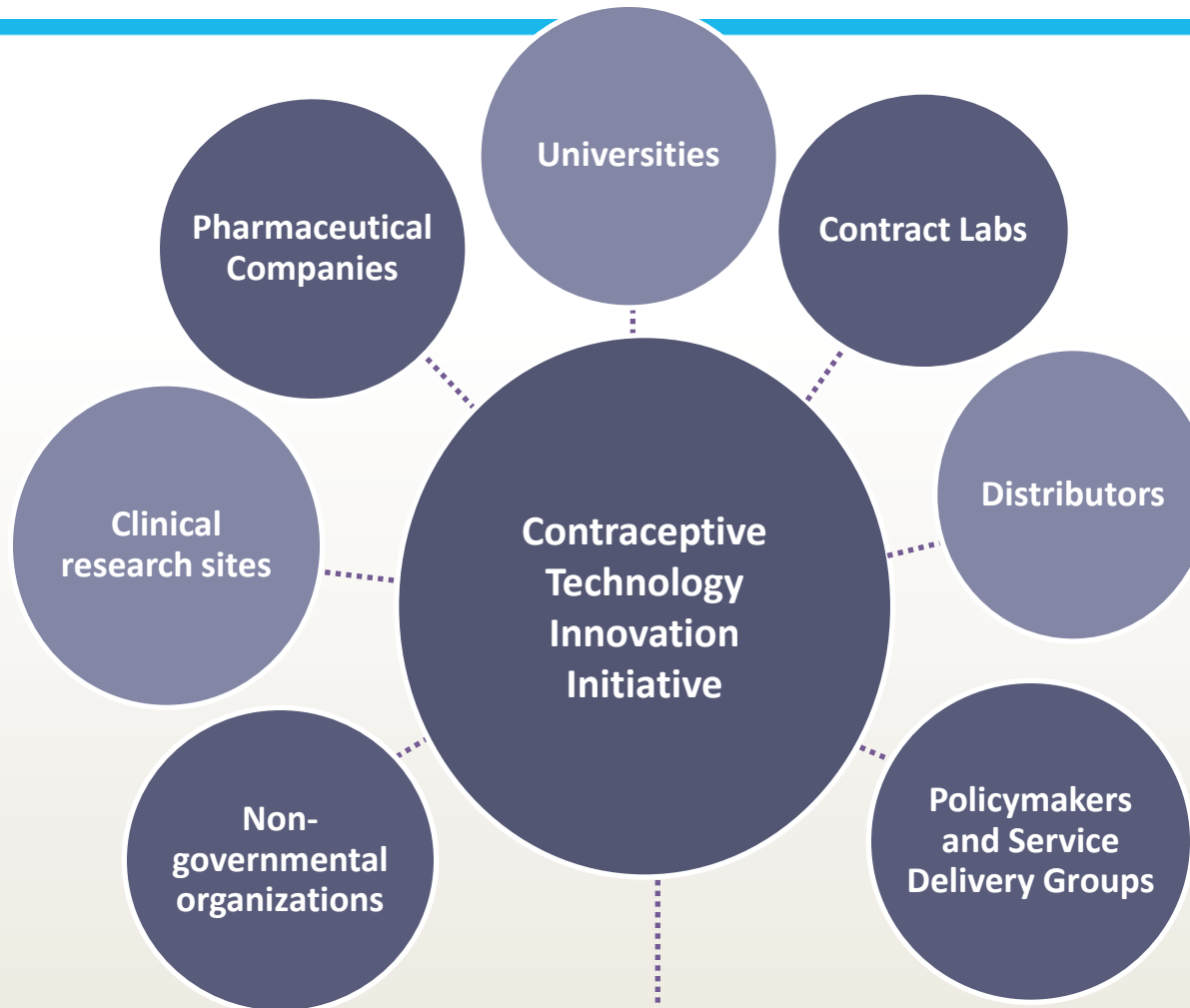
## ✓ Sustainability remains priority

- Southern manufacturers may not have capacity for all activities including product registrations and renewals. Partnerships important moving forward
- Size of total implant market unknown
- New landscape may require modified business model for Dahua

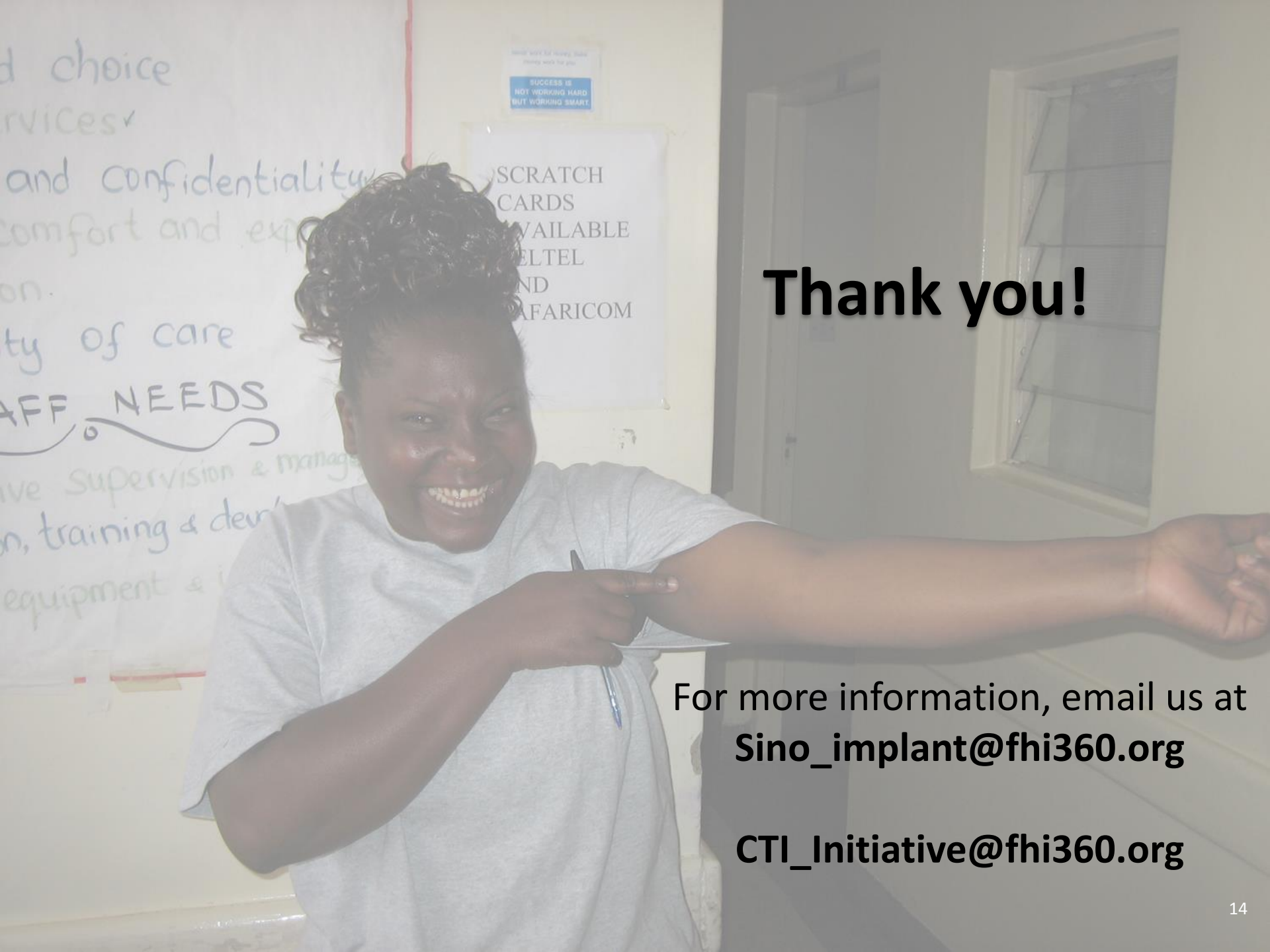


The UN Commission on Life-Saving Commodities for Women and Children recognizes that to strengthen quality and ensure accessibility, it is essential that **“at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products.”**

# Under New Contraceptive Technology Innovation Initiative, Strengthening and Building Strategic Partnerships is Priority



**GOAL: To develop strategically important, long-acting contraceptives with a strong focus on global partnerships to ensure access to affordable and acceptable quality products for those most in need**



# Thank you!

For more information, email us at  
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