



# Male Contraception: Where We Stand and What's Ahead

The Quest for a More Equitable Contraception for All







**CTI** Exchange





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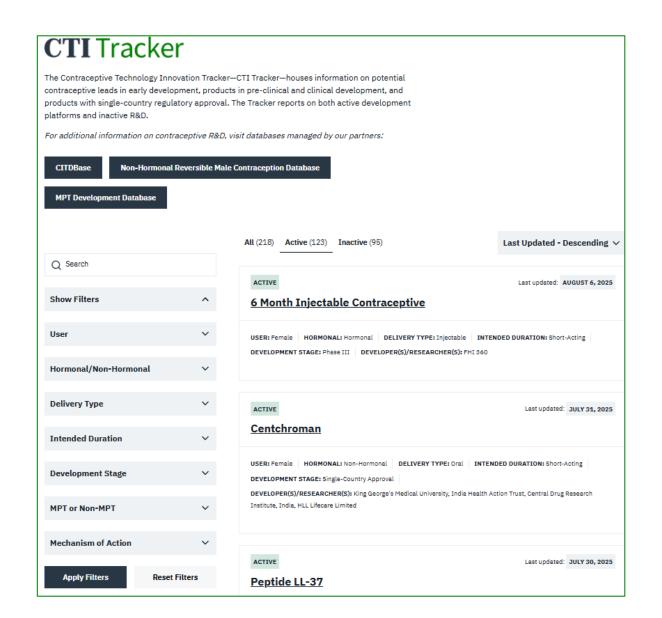




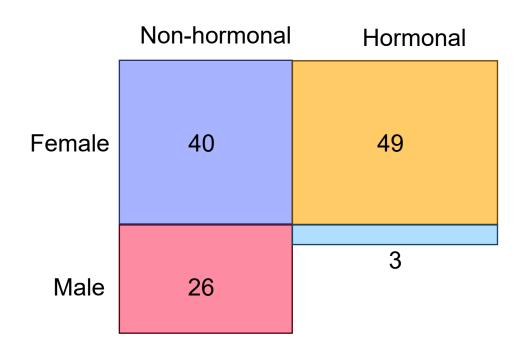
# The Contraceptive Product Pipeline

Where We Are and What We've Learned





# There are 123 active products in the pipeline.

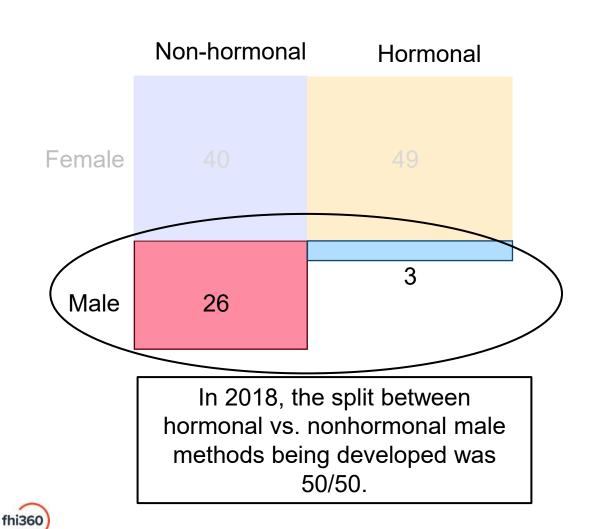


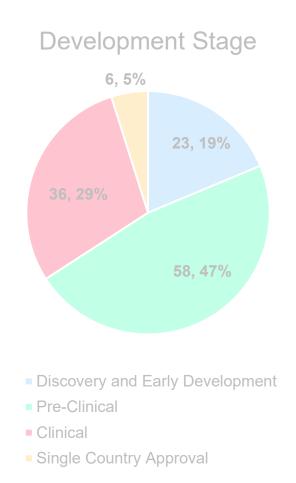
\*Note: 5 products do not fall neatly within these categories

# **Development Stage** 6, 5% 23, 19% 36, 29% 58, 47% Discovery and Early Development Pre-Clinical Clinical Single Country Approval

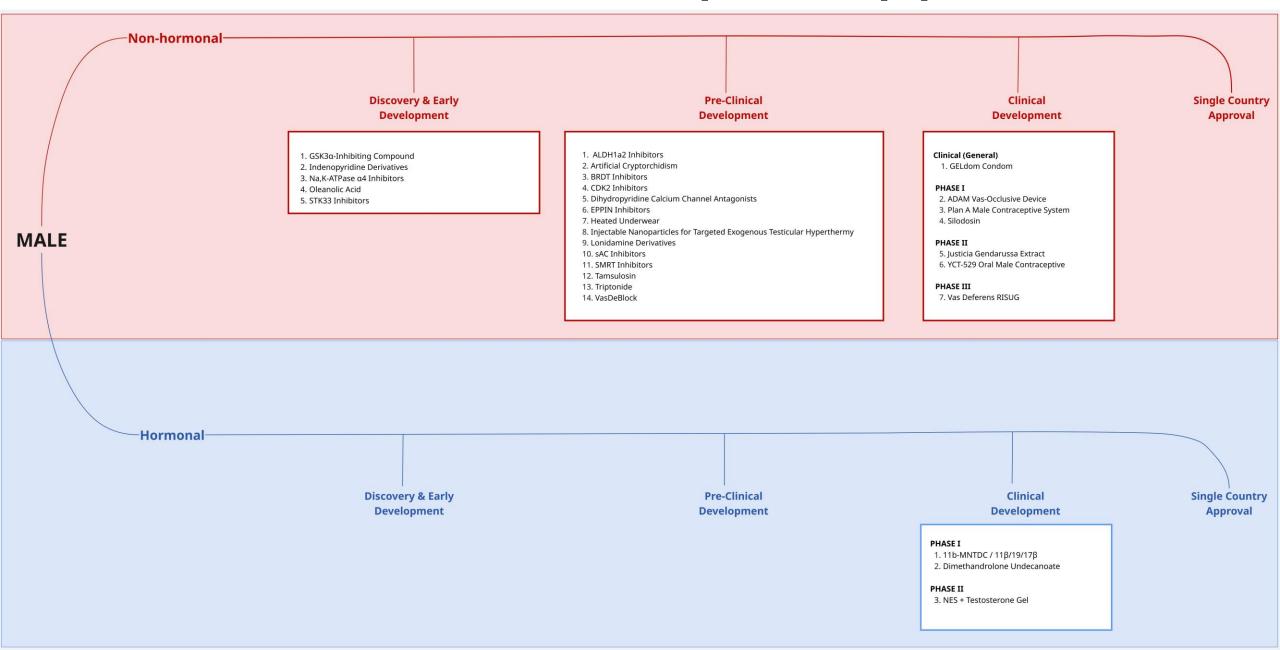


# There are 123 active products in the pipeline.





# Overview of the male product pipeline



# **Hormonal** male methods reaching clinical development

Non-hormonal  Discovery & Earl	у	Pre-Clinical  Development Dev	Clinical Single
PRODUCT	PHASE	PAST & PRESENT DEVELOPERS	DELIVERY TYPE
11b-MNTDC / 11β/19/17β	Phase I*	BIOQUAL, Inc, NICHD & NIH Contraceptive Development Program Sites, Health Decisions	Injectable <i>or</i> Oral
Dimethandrolone Undecanoate	Phase I**	BIOQUAL, Inc, NICHD, Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center, NIH Contraceptive Development Program Sites	Injectable <i>or</i> Oral
NES + Testosterone Gel	Phase II	Population Council, Global Clinical Sites, Health Decisions, NICHD, Contraline	Transdermal



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<sup>\*</sup>Product has reached Phase I clinical development but last published in 2020

<sup>\*\*</sup>Product has reached Phase I clinical development but returned to non-clinical in vitro evaluation as of 2022

# Nonhormonal male methods reaching clinical development

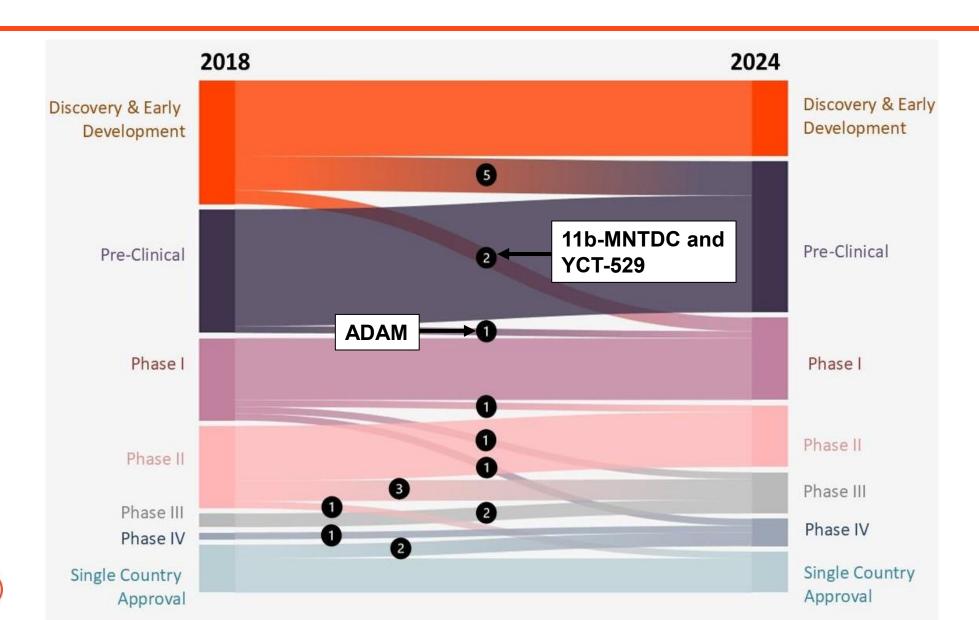
PRODUCT	PHASE	DEVELOPERS	DELIVERY TYPE
ADAM Vas-Occlusive Device	Phase I	Contraline, LLC	Vas Deferens
Plan A Male Contraceptive Syste	Phase I	NEXT Life Sciences	Vas Deferens
Silodosin	Phase I	TSS Shripad Hegde Kadave Institute of Medical Sciences	Oral
Justicia Gendarussa Extract	Phase II	Airlangga University	Oral
YCT-529 Oral Male Contraceptive	e Phase la/IIb	YourChoice Therapeutics, University of Minnesota	Oral
Vas Deferens RISUG	Phase III*	Indian Council for Medical Research, Indian Institute of Technology, Kharagpur, University of Rajasthan	Vas Deferens
GELdom Condom	Phase II	Eudaemon, University of Wollongong, Australia	Barrier

\*Product has 40+ year development pathway. Developers have indicated Phase III research pursued, not confirmed

3. NES + Testosterone Gel



# **Progression of Contraceptive Products through Development**





# **Key Observations & Challenges**

#### Volatility in Product Development

- Among inactive products, development stalled during early development for 30%, pre-clinical stage for 28%, and clinical stages for 42%
- 27 products changed developers or teams over the course of the review

#### Shifts in R&D Landscape

- Decline in large for-profit company involvement
- Rise of smaller reproductive health start-ups

#### Systemic Challenges

- Chronic underinvestment slows progress
- Scientific and regulatory complexity adds barriers



# Thank you!

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# Heather Vahdat Executive Director Male Contraceptive Initiative (MCI)

Logan Nickels, PhD
Chief Research
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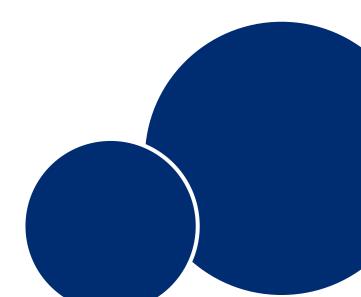


# Reproductive Autonomy for All.

Male Contraceptive Initiative RHSC NURHT Meeting

Heather Vahdat, MPH Logan Nickels, PhD 25 September 2025



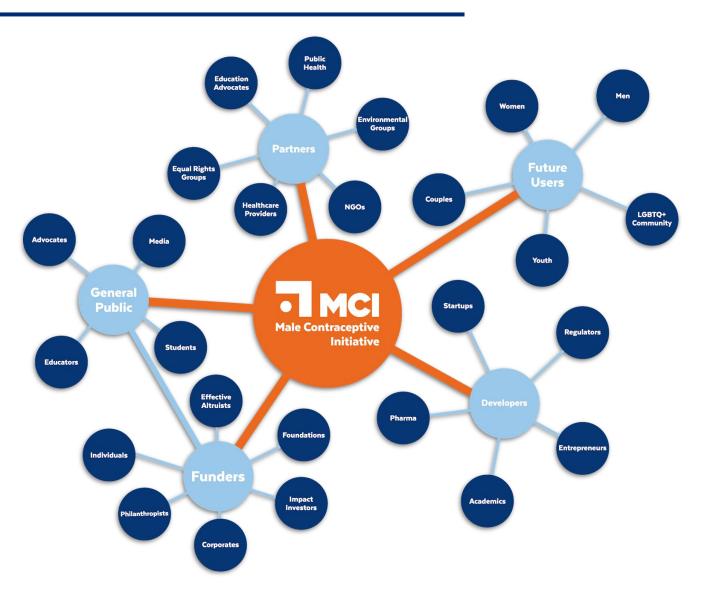




# About Male Contraceptive Initiative

Male Contraceptive Initiative (MCI) is a global hub and ecosystem facilitator for the entire non-hormonal, reversible male contraception industry.







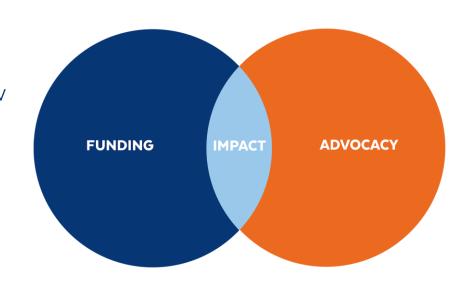
# MCI's Approach

# 1. Funding and Supporting Research and Development

We commit the majority of our funding to activities supporting researchers in their work. These funds support the development of new male methods and provide professional training and mentoring opportunities for scientists.

#### 2. Advocating for Male Contraception

MCI supports global-level advocacy activities to ensure that products developed in the space are supported for success beyond the bench. This includes supporting the elucidation of regulatory pathways, market research activities, and working with governments, ministries of health and other key partners to build awareness and financial support for male contraceptive product development.





# There is High Global Demand

#### Significant interest in USA / LMICs

All countries have >75% interest in trying a novel male method within 5 years.

Form/product route of administration is the top decision-making criteria in all countries

#### High female partner trust

50-86% would trust their partner if told their partner was taking a contraceptive

#### **Post-Dobbs Supreme Court Decision**

Data at right show pre-Dobbs survey results - Post-Dobbs survey show now about half (49%) of men interested within 12 months of availability

#### **Interest in Novel Male Birth Control Methods**

Time to trial by Men for Male Contraceptive Technologies, Cumulative.







# Status of Male Contraceptive Development

#### Fundamental And Technical Advances Enable Multiple And Diverse TPPs

- An early-stage, but emerging pipeline.
- Improved understanding of male reproductive biology has enabled the identification of multiple promising sperm-based contraceptive targets
- Modern computational modeling, drug screening, and medchem allows for faster and more efficient drug R&D efforts
- Clinical advances
  - A recently completed phase 11b study on a male-use hormonal gel (NES/T, Ph 2b) provides a regulatory roadmap and a likely first-in-class product
  - Two biotech companies with non-hormonal male contraceptive programs have advanced to clinical stages and a group of nonclinical programs are in pursuit



# Mechanisms of Male Contraception

#### **Spermatogenesis**

- Stopping new sperm from developing
- Time for onset and return to fertility

Includes hormonal, nonhormonal, and thermal methods

#### **Sperm Transport**

- Blocking the exit of sperm
- Possibility of drugbased approaches

Small field outside of vasocclusive devices, includes barrier methods

#### **Sperm Function**

- Directly hampering sperm function
- Male AND / OR female delivery
- Possibility of ondemand contraception

Innovative, exciting, and difficult sector













# Contraceptive Products in Development

#### **Hormonal Contraception**

A daily gel rubbed on the shoulders, a daily oral pill, and a longer-term injectable formulation are all in clinical trials.\*\*

#### **Reversible Vasectomy\***

These medical devices can be effective for years and require an outpatient administration procedure. As medical devices, they can have a shorter time-to-market.

#### **Non-Hormonal Contraception\***

An exciting research field with hundreds of possible targets. Products can be short-acting, on-demand, long-acting, or even unisex.



<sup>\* -</sup> Visit <a href="https://www.malecontraceptive.org/the-pipeline.html">https://www.malecontraceptive.org/the-pipeline.html</a> to learn more about our focus areas!







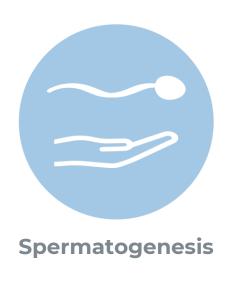




<sup>\*\* -</sup> Visit https://www.malecontraception.center/ for more information on clinical trials!



# Hormonal Male Contraception



#### **NES/T**

Nestorone® / Testosterone

Daily transdermal gel, rubbed on shoulders

- Population Council
- Phase IIb, clinical efficacy

~3-4 years from approval

#### **Additional hormonal products**

(early-stage clinical development from Population Council)

- Daily oral pill: 11β-MNTDC
- Daily oral pill & ~3-monthly injectable: DMAU









## Reversible, Non-Hormonal Vas-Occlusive Devices





#### **ADAM**

Contraline

Hydrogel polymer, injected into vas deferens

Early clinical studies

~3 years to approval



#### Plan A (RISUG)

NEXT Life Sciences

Hydrogel polymer, injected into vas deferens

- Pre-clinical US
- Clinical India (RISUG)

~5 years to approval



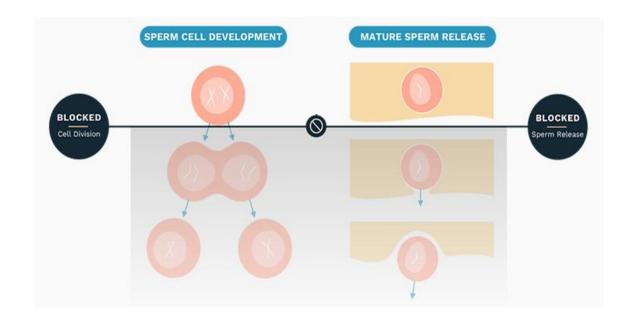


# Non-Hormonal Once Daily Male Pill - YCT-529

#### **Spermatogenesis**

 Prevents sperm cell development AND mature sperm release

YourChoice Therapeutics
YCT-529: ~5
years to approval









# YourChoice Therapeutics YCT-259

- Daily oral pill
- Advancing to Phase II clinical studies
- Developed by California based biotech



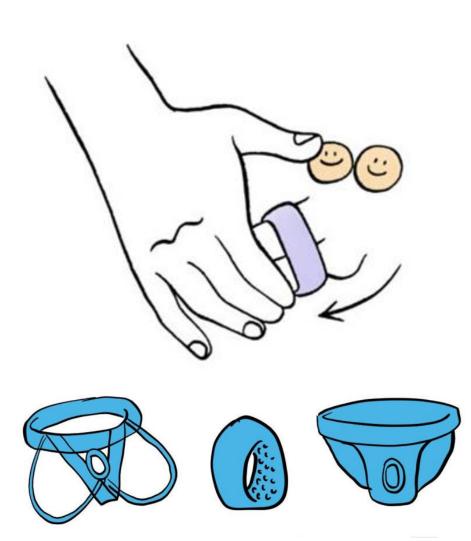
### Non-Hormonal Wearable Methods - Thermal

#### **Spermatogenesis**

- Causes sperm cell apoptosis
- Mechanism not well understood

Androswitch:
Unclear market
timeline







- Medical Device
- Largely EU / French setting
- Seeking first approval for clinical studies
  - Safety, efficacy, reversibility unproven

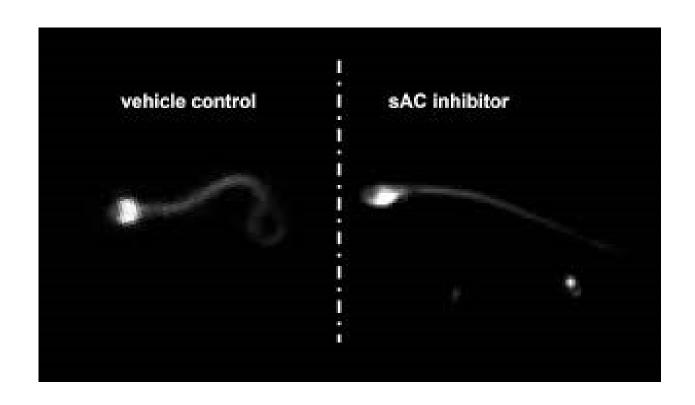


# Non-Hormonal On-Demand Pill - Sacyl

#### **Sperm Function**

- Preventing the ability of sperm to "swim"
- Potential unisex contraceptive

Sacyl Pharmaceuticals~7-10 years toapproval









# Sacyl Pharmaceuticals **SAC Inhibitor**

- On-demand oral pill
- Optimizing timing and potency
- Seeking approval for human studies 2025-2026



# MCI-RHSC Collaborative Opportunities

- Continued collaboration with NURHT to keep members apprised of pipeline progress
- Consider potential for joint advocacy efforts through A&AWG
- Facilitate conversations between RHSC manufacturers/other members and MCI grantees (i.e. product innovators) to share information and develop strategies to support parallel introduction of products in LMICs
- Share information regarding local/regional production capacity, regional regulatory harmonization efforts, and product registration processes.
- Shared advocacy to address myths and misperceptions about the demand for male contraceptive methods and to promote their inclusion in the mix of reproductive health supplies



# Reproductive Autonomy for All.

Meaningful relationships
Stronger families
Improved health / educational / economic outcomes
Equity in contraceptive burden and opportunity
Male engagement in reproduction
Broad improvement in men's health
Better sex education
A new model of healthcare
Contraception for anyone who wants it

We can create a better world for everyone.



# **THANK YOU!**

# Q3-A