

26 July 2023

Innovation in Contraceptive R&D Funding



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Logistics



Use the **Q&A feature** to ask questions at any time



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Event is being recorded. Recording and slides will be sent to all registrants following the event.

Overview

Welcome & Logistics	Kate Rademacher, MHA Independent Consultant	5 Mins
Global Funding for Contraception R&D: Broadening Horizons to meet a Diversity of Needs	Cécile Ventola, PhD Policy Cures Research	20 Mins
Private Investment in Contraceptive Innovation	Stasia Obremskey, MBA RH Capital	20 Mins
Discussion: Impact of Funder Strategy on Research Capability	Rebecca Callahan, PhD, MPH FHI 360	20 Mins
Q&A	Moderated by Event Host	15 Mins
Closing Remarks	Dr. Samukeliso Dube FP2030	10 Mins

**GLOBAL FUNDING FOR
CONTRACEPTION
R&D:
BROADENING HORIZONS TO
MEET A DIVERSITY OF NEEDS**

Policy Cures Research
26th July 2023

Cécile Ventola
Senior Technical Officer | Sexual and reproductive health

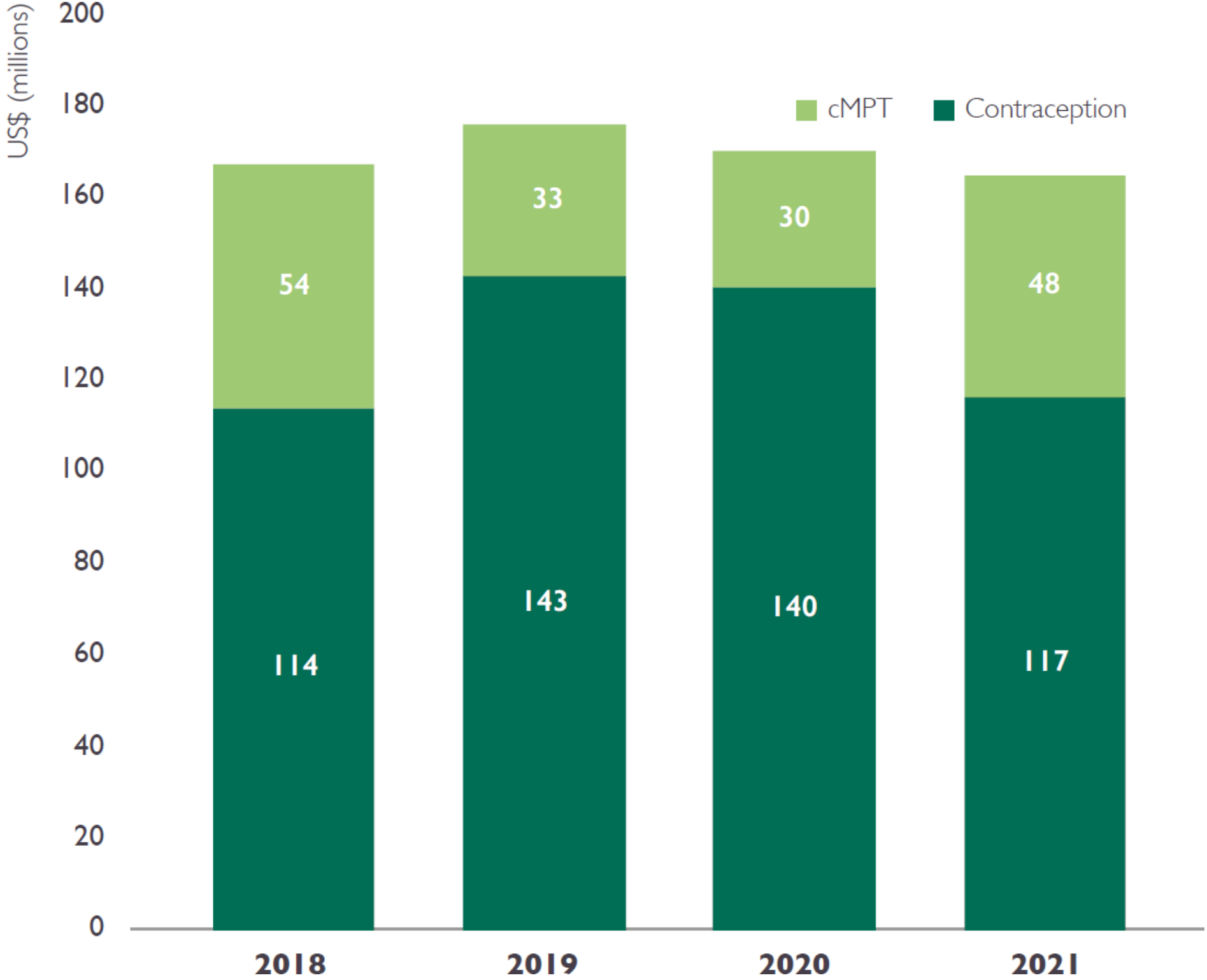
POLICY CURES RESEARCH.



The G-Finder survey

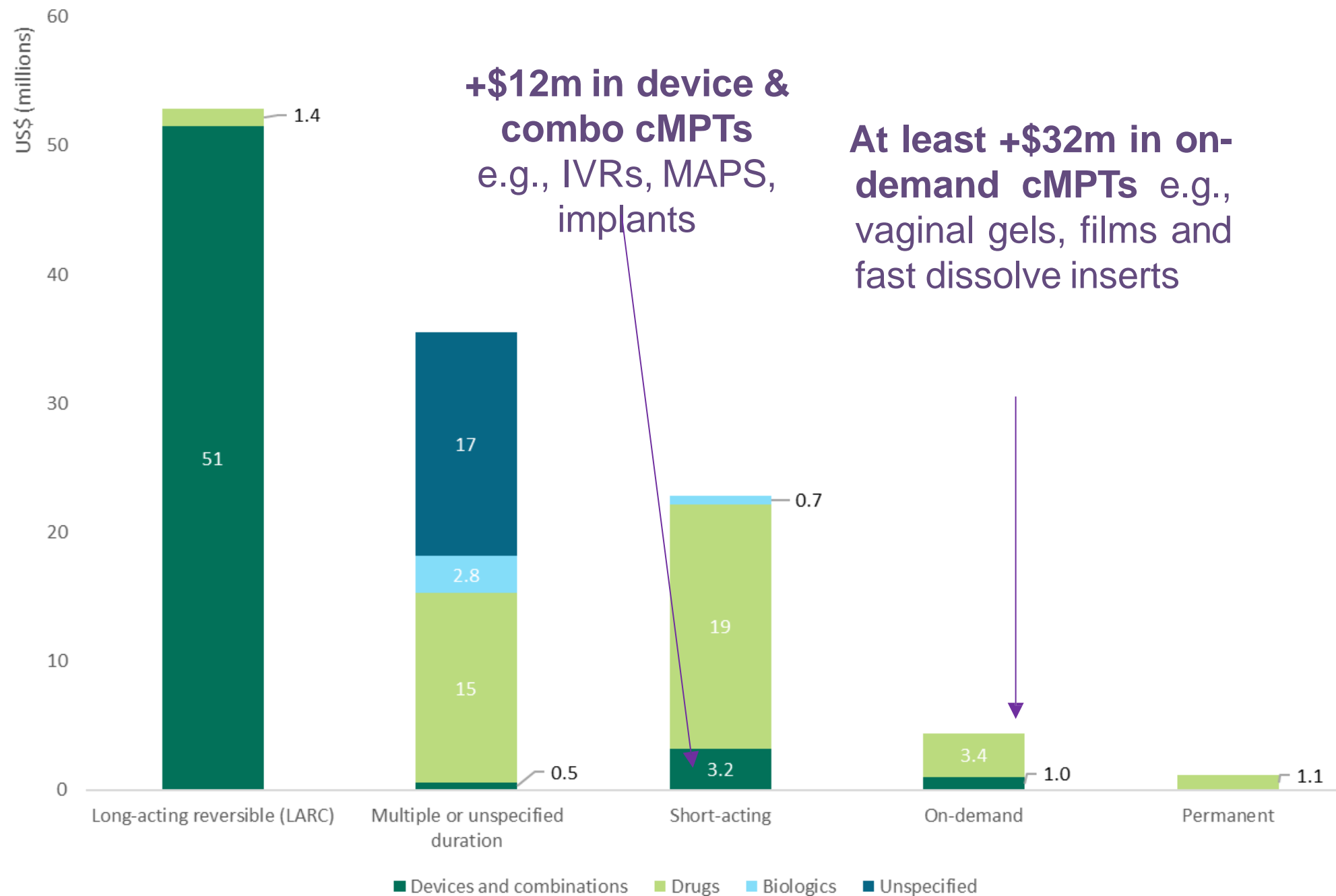
- tracks annual investment into R&D for new products and technologies to address priority global health challenges since 2007: annual survey with funders, grant recipients and industry (self-funded) and publicly available data (US NIH, Gates)
 - Neglected diseases, emerging infectious diseases, sexual and reproductive health
 - LMICs focused
- Sexual and reproductive health: data collected in 2013 and annually since 2018
- **Contraception:**
 - Scope: all contraceptive research from early stage to post-registration studies (drugs, vaccines, biologics, devices and combinations), LMIC applicable
 - Categories: LARCs (e.g. IUS, yearly IVRs), short-acting contraceptives (e. g. monthly OCP, micro-array patch, NES/T gel), on demand (vaginal capsules, oral pills, gels), permanent, multiple or unspecified duration
 - Multi-purpose technologies (MPTs) analyzed separately

Global investment in contraceptive R&D 2018-2021



It's been generally stagnant, and recently declined

Funding by contraceptive type: where is the focus? 2021 snapshot



LARCs (\$53m, 45%)

- almost **exclusively** invested in **devices & combination products** (97% of LARC funding)
- ▶ third consecutive decrease overall, but LARC devices still dominate

Multiple or unspecified duration (\$36m, 30%)

- focused on **unspecified product types and drug R&D** (91%) = largely multi-year/multi-method projects
- ▶ doubling since 2018, general (albeit fluctuating) focus on products the same

Short-acting (\$23m, 20%)

- concentrated on **drug R&D** (83%)
- Some \$ to device & combinations (14%) e.g., IVRs, MAPs
- ▶ halving from 2020, but similar drug focus across all years

On-demand (\$4.4m, 3.8%)

- mostly to **novel drugs** (\$3.4m, 77%)
- ▶ similar funding levels across years, largely same focus on drugs

Permanent (\$1.1m, 1.0%)

- via single drug R&D grant for fallopian tube-directed sclerotising polycloidal foam
- ▶ less than half as much as either 2020 or 2018, but more than the zero in 2019

Funders are few, and investment is concentrated

- Since 2018, **30 different funders** of contraception R&D.
- Just under **90% of all funding between 2018 and 2021 came from three sources**: the US NIH, the Gates Foundation and (aggregated) industry.
- While Gates supporter of **early-stage** R&D, US NIH has dominated funding for **clinical development & post-registration studies** (e.g. CCTN).
- Funding that **does not specify R&D stage** (40% of total) is nearly all from industry, covering undisclosed early and late-stage product development.

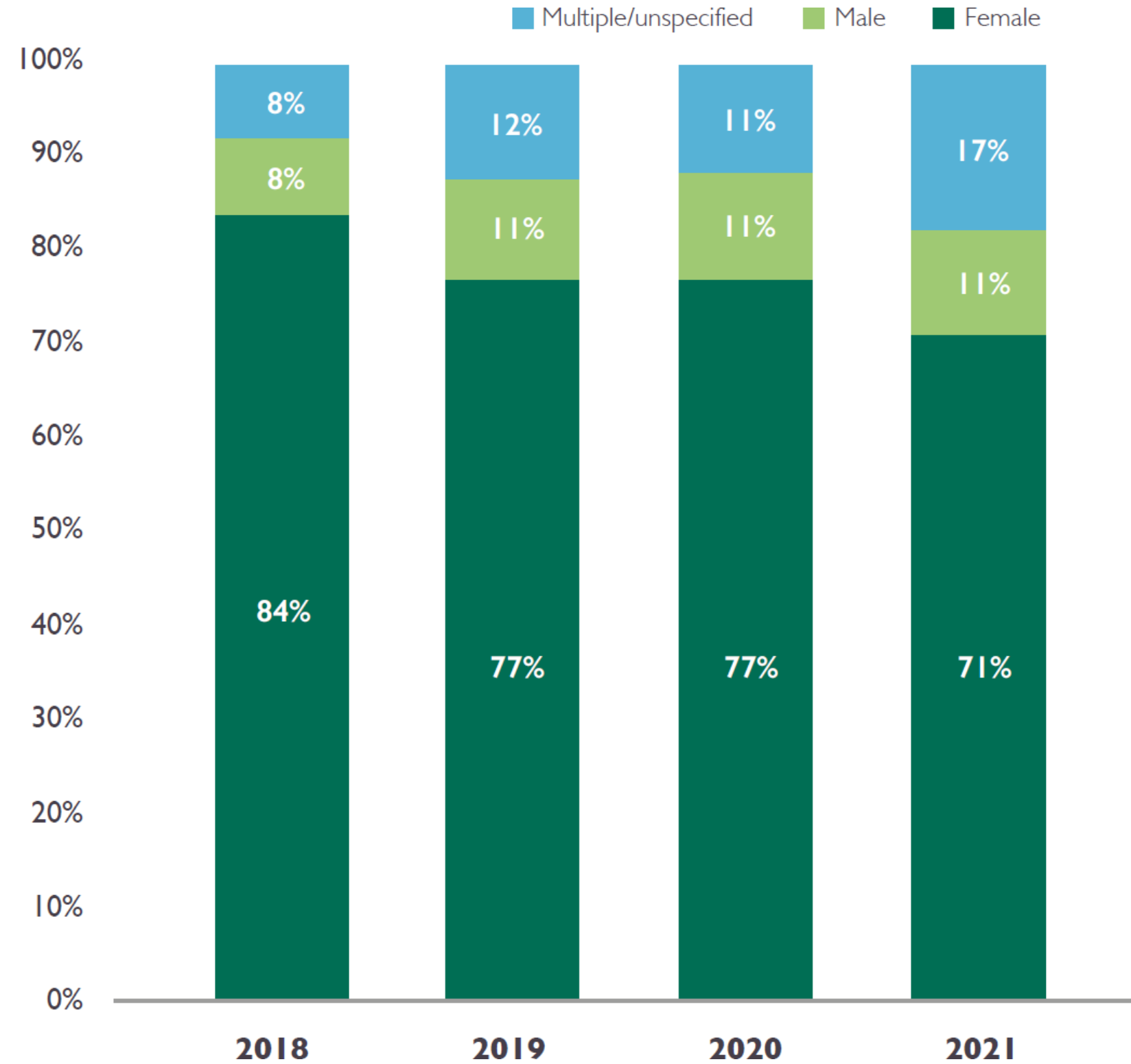
Funders	US\$ (millions)				% of total
	2018	2019	2020	2021	2021
Gates Foundation	26	45	49	47	40%
US NIH	26	35	33	29	24%
Aggregate Industry	51	52	39	23	20%
Population Council	3.5	2.9	2.9	10	8.9%
USAID	5.4	4.3	11	4.1	3.5%
Male Contraceptive Initiative (MCI)	0.6	0.8	1.4	1.7	1.4%
EC	0	0.2	1.5	1.2	1.1%
Children's Investment Fund Foundation (CIFF)			0.4	0.4	0.4%
Parsemus Foundation	<0.1	0.2	0.6	0.2	0.1%
Vinnova			<0.1	<0.1	<0.1%
Brazilian FAPESP		<0.1	<0.1	<0.1	<0.1%
TOTAL*	114	143	140	117	100%

*Totals in 2018-2020 reflect total funding for those respective years.

■ No reported funding.

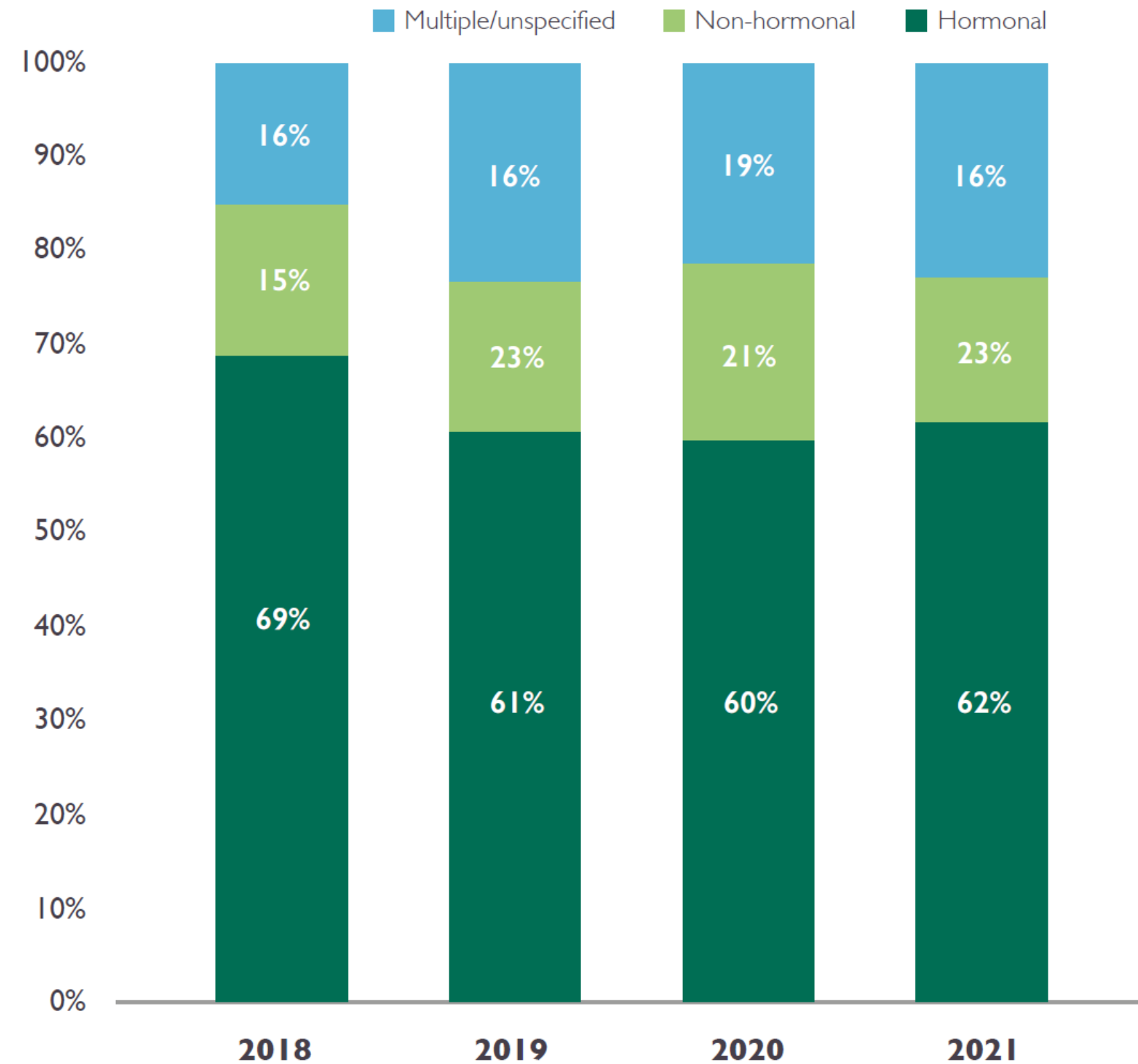
Female vs male end users

- Female end-user R&D dominates but **has gradually declined**
- Male end-users and multi/unspecified users **have risen**
- **Male contraceptives:** 57% short acting, and recent increase in LARCs and multiple/unspecified duration (from an average of 21% 2018-2020 to 42% in 2021)



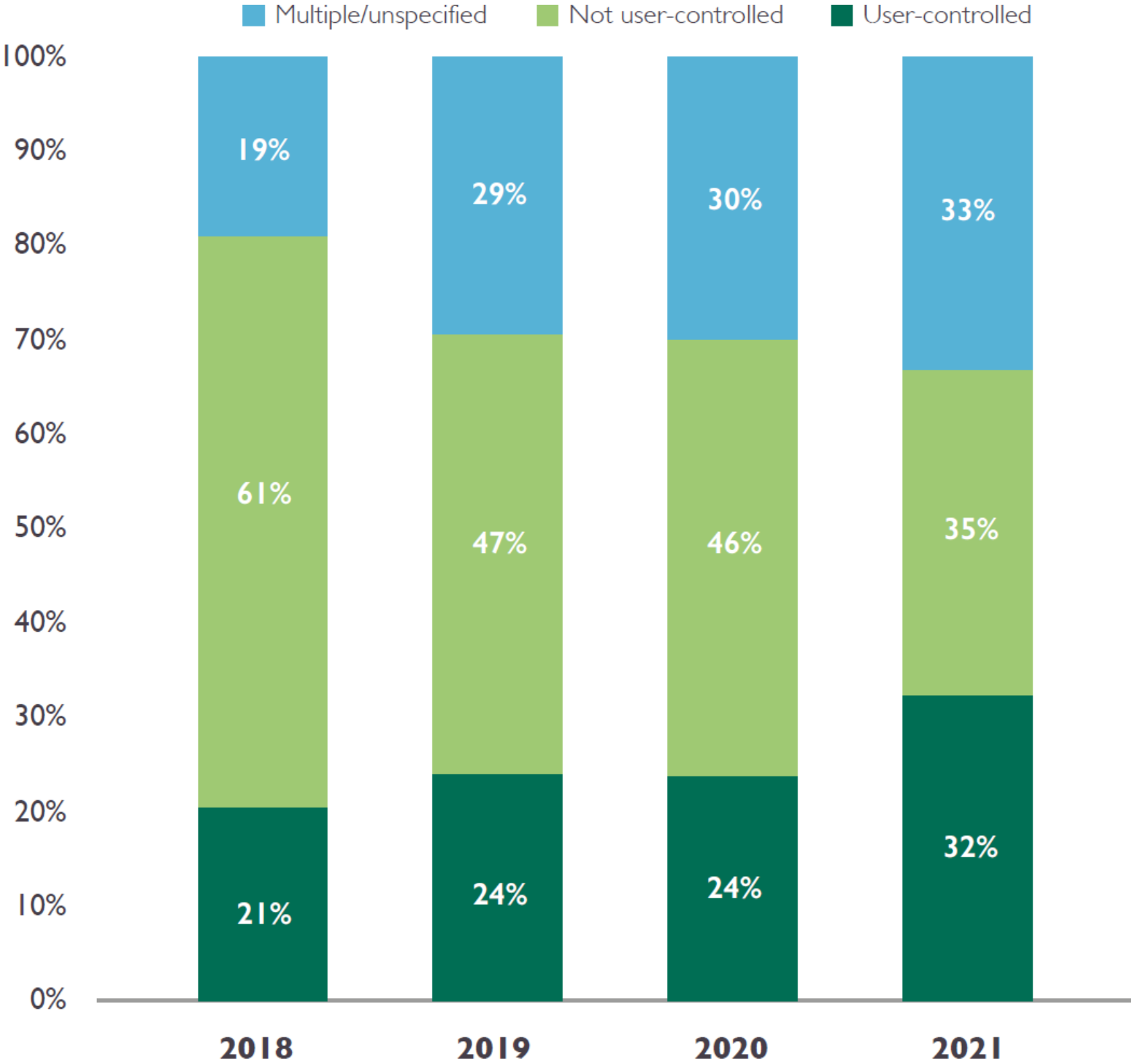
Hormonal vs non-hormonal

- Hormonal contraceptives averaging 60%+, but has also experienced **two consecutive years of decline** (+ much on reduced/ultra reduced hormones)

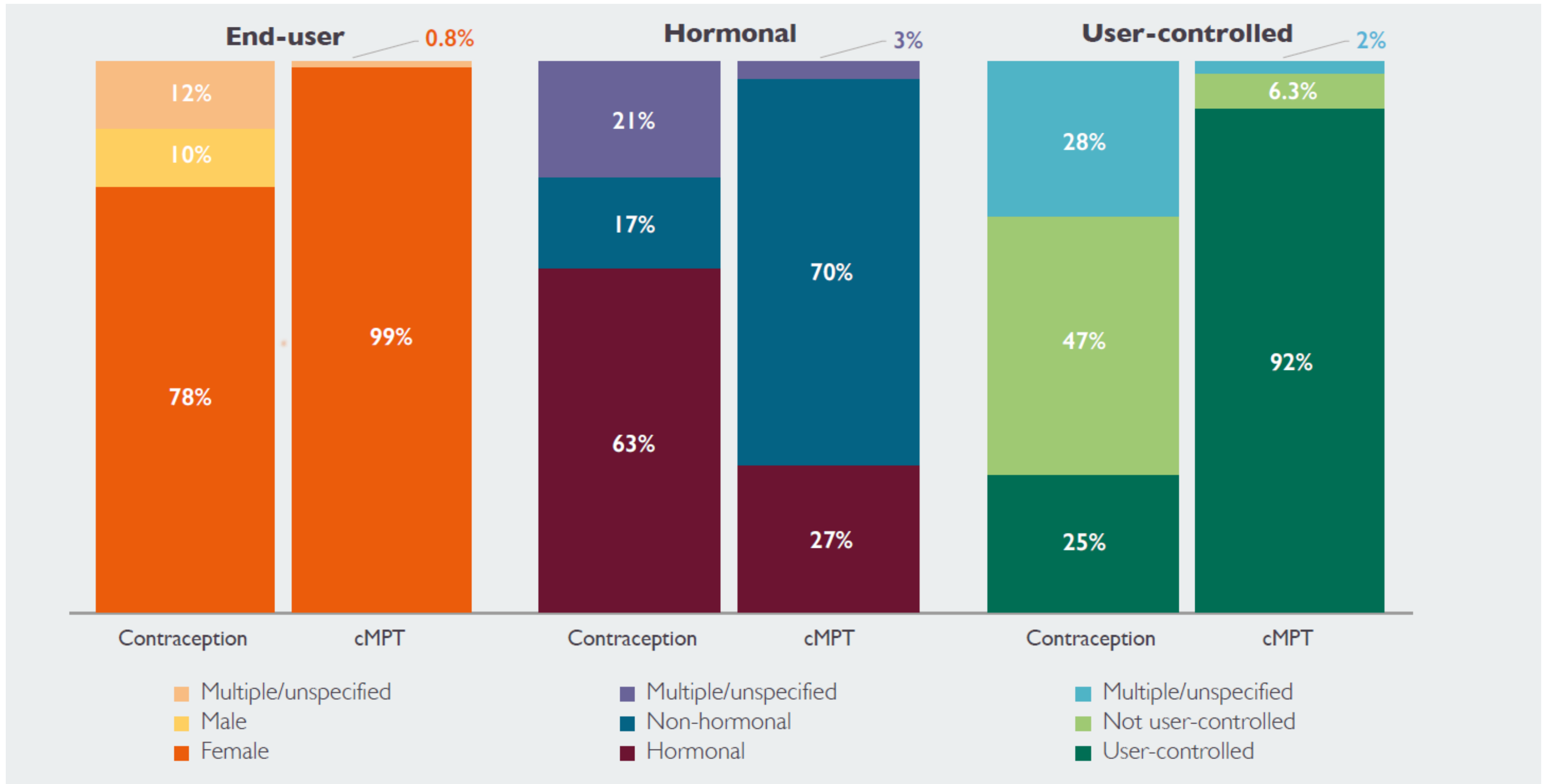


User-controlled vs non-user-controlled

- Non-user-controlled contraceptives largest, but this proportion **has decreased substantially** over the last four years (from 61% to 35%).
- User-controlled **has increased steadily**.



Contraception vs cMPTs (4-year average 2018-2021)



Conclusion

- Stagnating, slightly decreasing levels of investment: \$117m compared to \$1,466m for LMIC-relevant HIV/AIDS R&D or \$243m from just one global company for R&D expenditure for cosmetics and personal care in 2021
- Encouraging trends: towards **more human-centred, user-centric design in contraceptive innovation** with more non-hormonal, user-controlled and male focused products funded
 - although still in early development stages (91% of non-hormonal, 58% of user-controlled and 68% of male-only contraceptive research funding is for early-stage research vs. 38% for all contraceptives)
- **Limited pool of investors:** 90% from US NIH, Gates and the industry, no support from the public sector in LMICs or from public sector multilaterals ► **vulnerability**

Access to the data...

G-FINDER Contraception R&D report March 2023

www.policycuresresearch.org/analysis

G-FINDER SRH report

First: August 2020

Next: October 2023

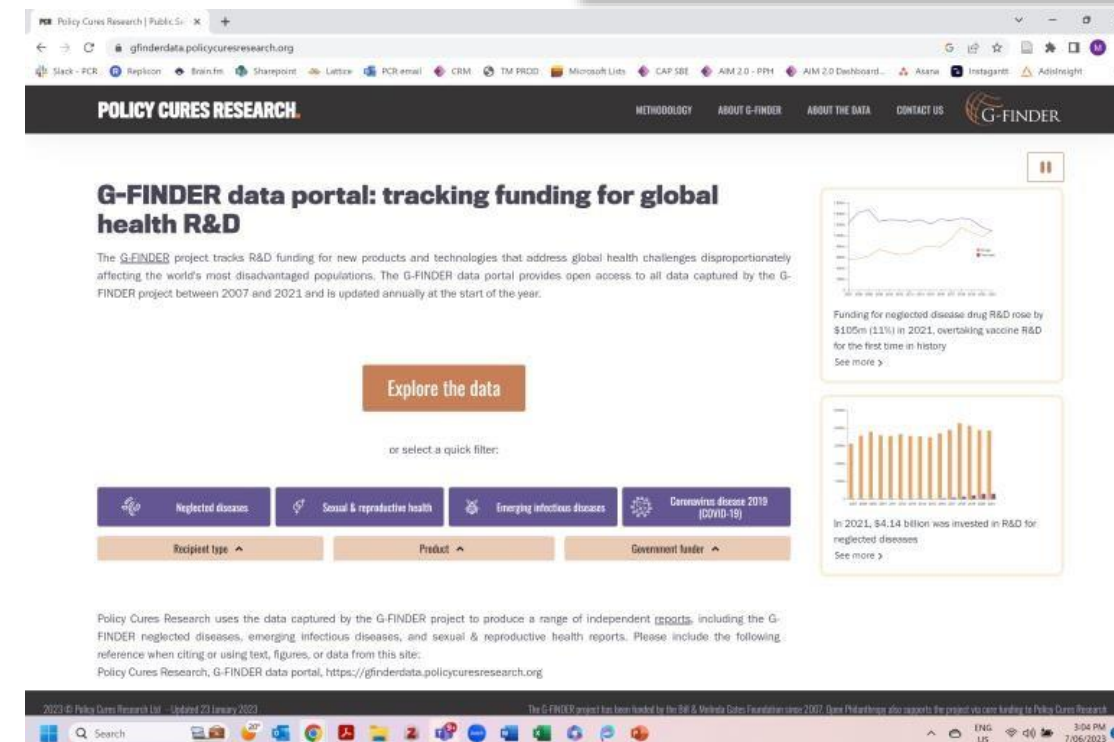
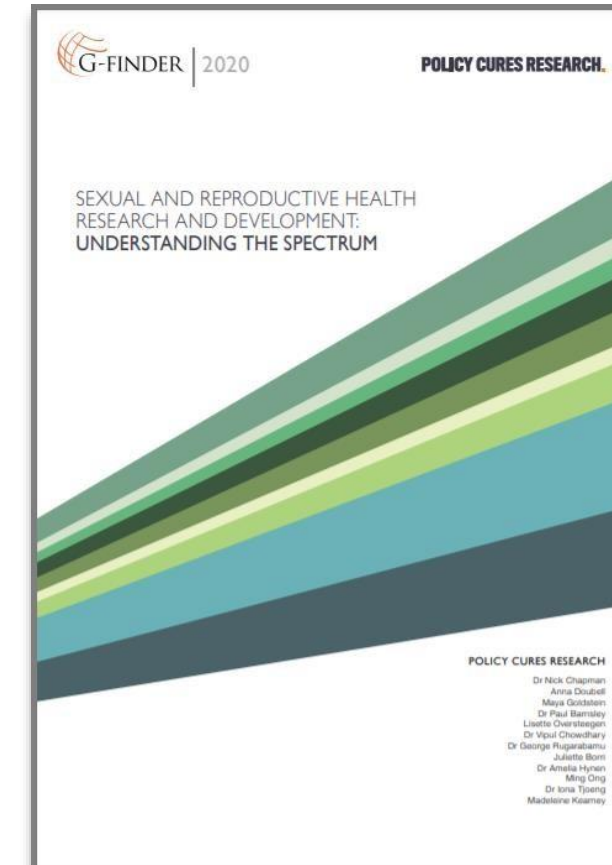
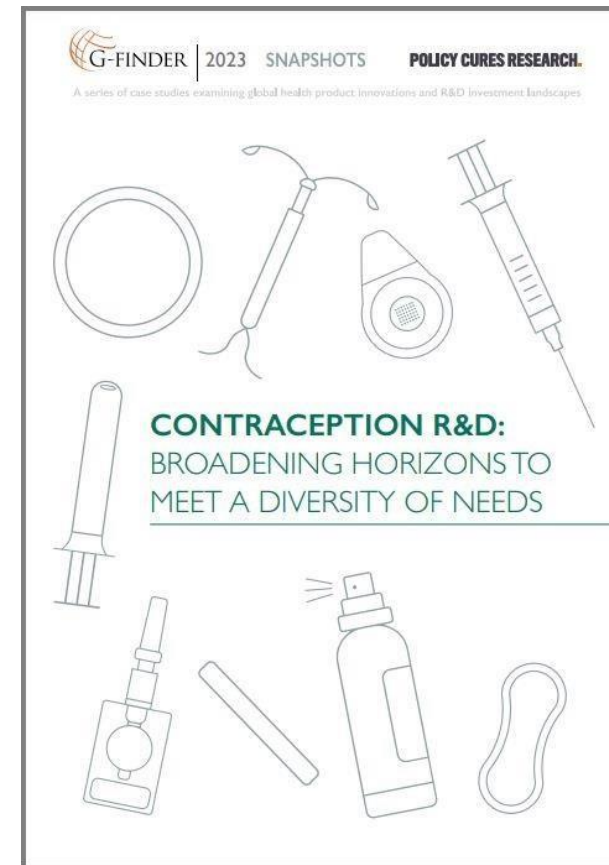
www.policycuresresearch.org/analysis

G-FINDER data portal

updated annually

www.gfinderdata.policycuresresearch.org/

Thank you! cventola@policycuresresearch.org



Private Investment in Contraceptive Innovation

July 26, 2023



47 Kearny St., Suite 600, San Francisco, CA

Agenda

Venture Capital Overview

RH Capital

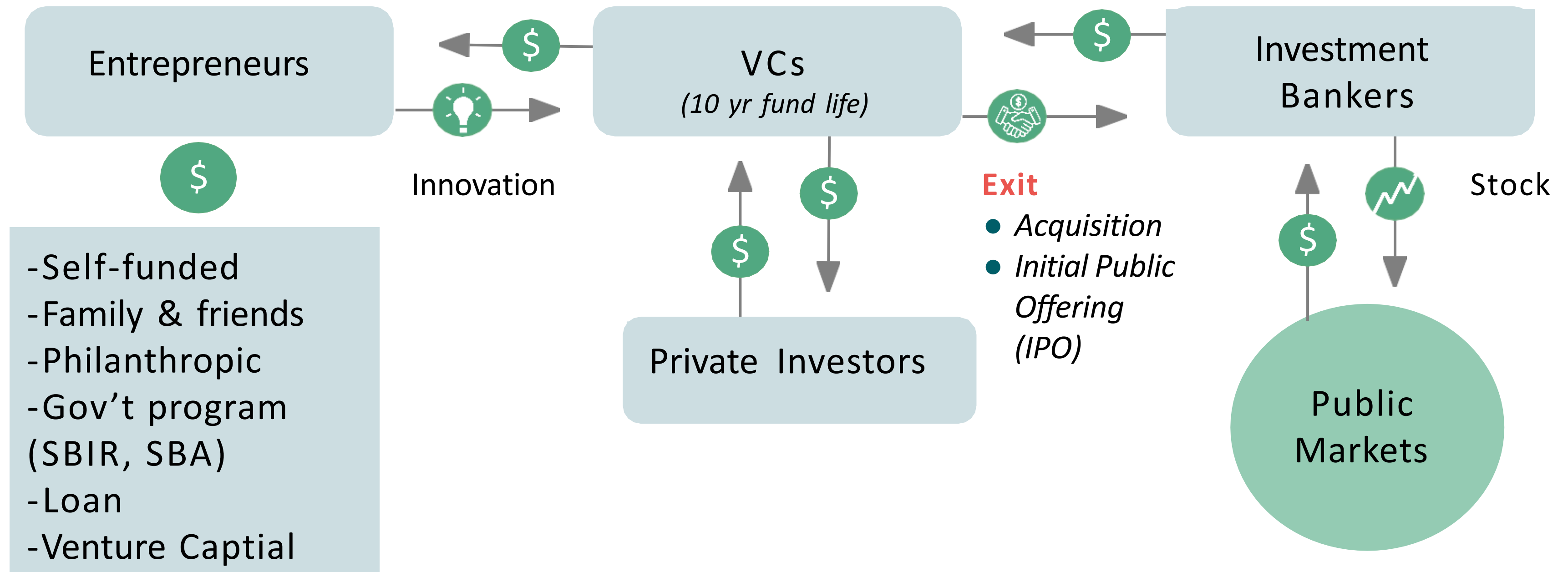
Attracting Private Investment in CT

Market Overview & Opportunities
Innovation Pipeline

Q&A

What is Venture Capital (VC)?

Private investment into early-stage companies for **equity** with expected **high long term growth** potential.



VCS role in the Economy

The #1 source of capital for the high-growth economy.

<0.25%

of companies receive VC
funding

~50%

of companies undergoing
IPOs are VC backed

\$65B

of VC capital invested in
healthcare in US and
Europe (2022)

Backing companies such as



"In recent decades, VC has generated more U.S. economic and employment growth than any other investment sector. Annually, venture investment makes up only 0.2% of GDP, but delivers 21% of it."

- Brookings Institution



An early stage, venture capital fund advancing innovation and health equity in reproductive health

Focus Areas:



Contraception



Maternal Health



**Other High Impact Areas
of RH**

\$40+M

Assets under Management (AUM)

18

Investments to date (~20 target)

**BILL & MELINDA
GATES foundation**

Strategic Partner



Contraceptive Strategy & Portfolio

De-Risking innovation to bring the next generation of contraceptives to market with the largest contraceptive portfolio in the world.

Seeking solutions which are:

- Highly Effective
- Non-hormonal focus
- Male and Female methods
- On Demand methods
- User-controlled vs. HCP controlled

Contraceptive Innovation Portfolio

contraline

Male
Contraceptive

CIRQLE

biomedical
Next Gen Female
Contraceptive



Spherical IUD &
Drug Delivery Platform



YourChoice
THERAPEUTICS

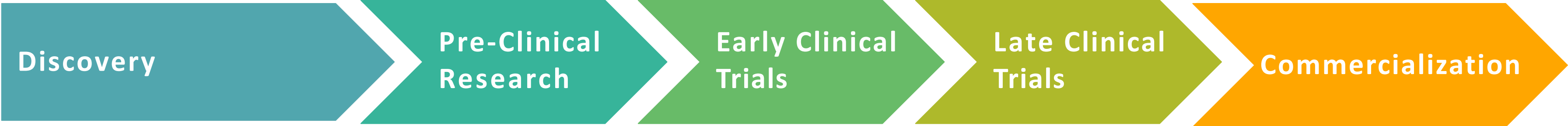
Next Gen Male & Female
Contraceptive

Contraceptive Access Portfolio

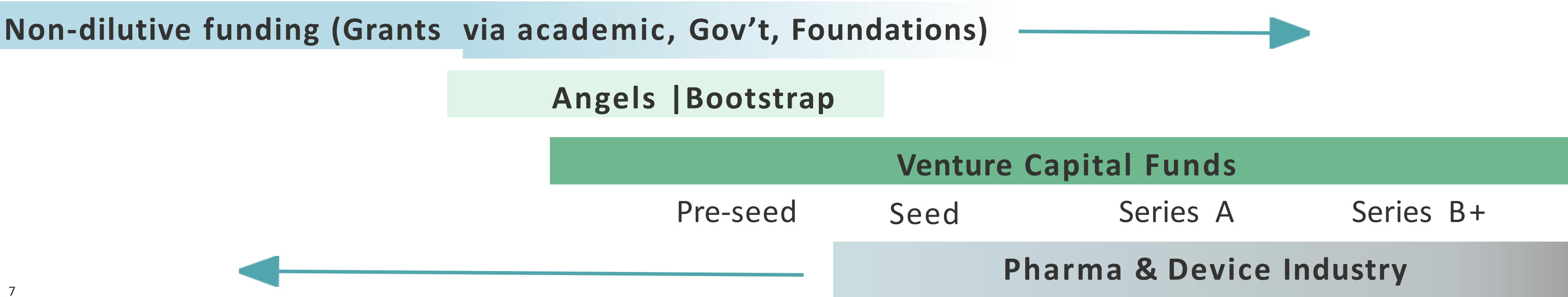


The role of VC in Contraceptive Innovation

Product Development Stage

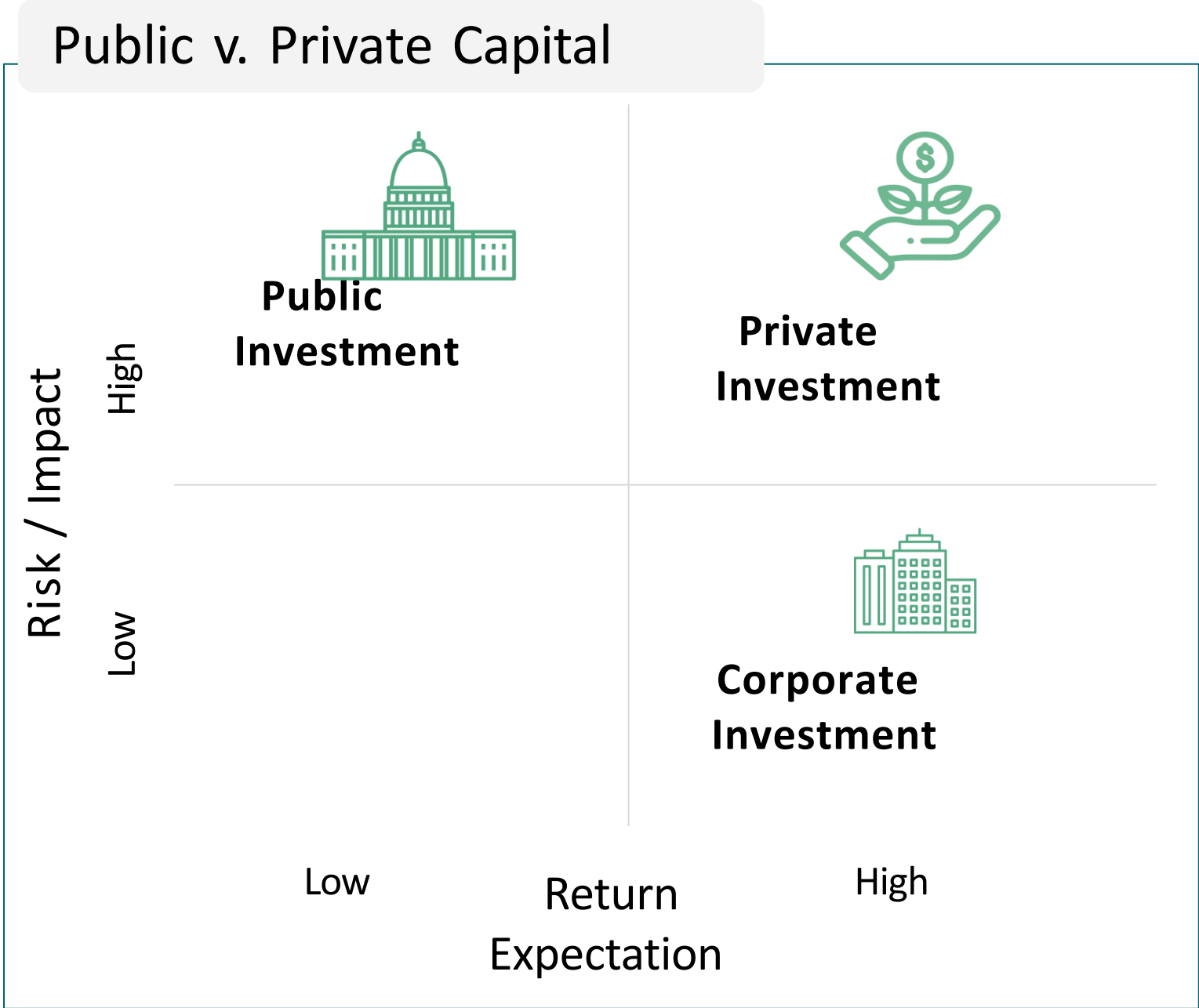


Capital Stage



Attracting Different Types of Capital

Capital sources for innovation have different criteria, including factors such as risk appetite and capital return expectations.



	Private Investment Criteria
✓	Large and/or Growing Market (revenue and demographics)
✓	Technology protected by strong IP
✓	Differentiated from Competitors
✓	Clear Regulatory Pathways
✓	Commercial & Reimbursement Potential
✓	Path to Exit via IPO or Acquisition

Attracting Private Investment

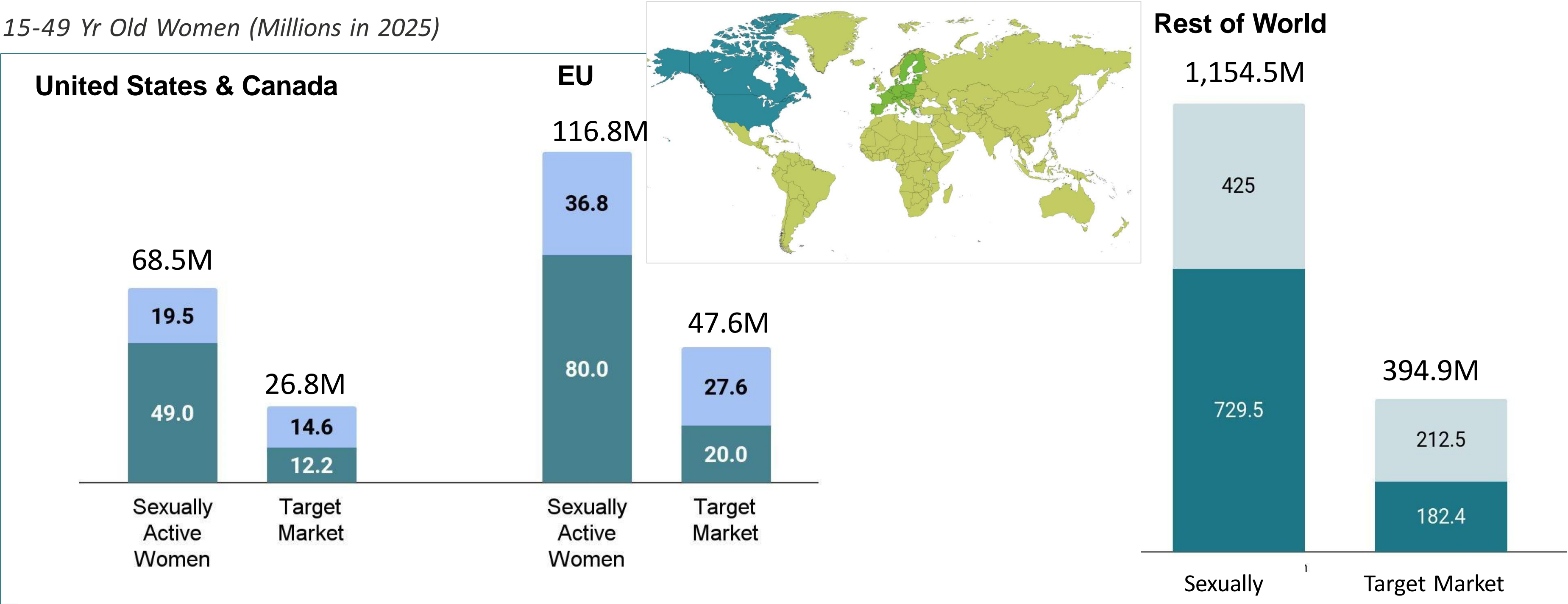
A New Era for Contraceptive Innovations

An Innovators Dream

Non CT User
 Current CT User

450M + women across the globe are potential users of new contraceptive technologies

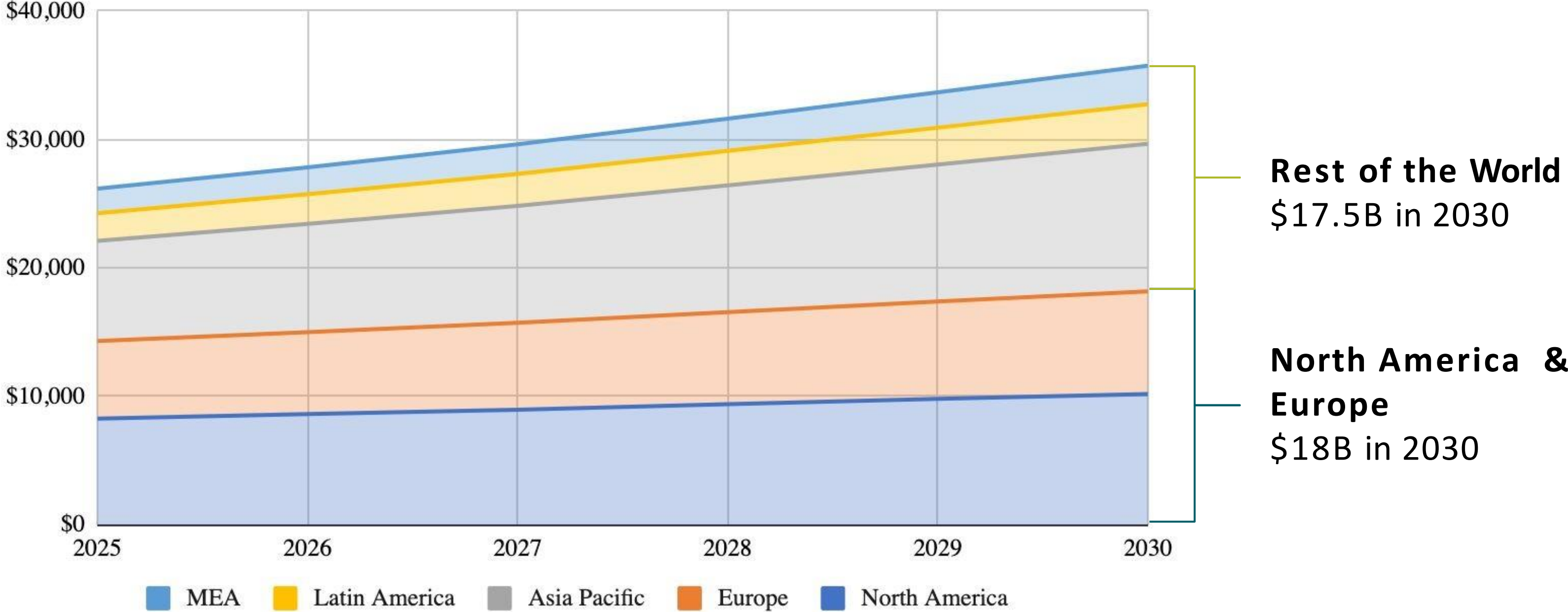
15-49 Yr Old Women (Millions in 2025)



Measured in Billions | Global Contraceptive Market

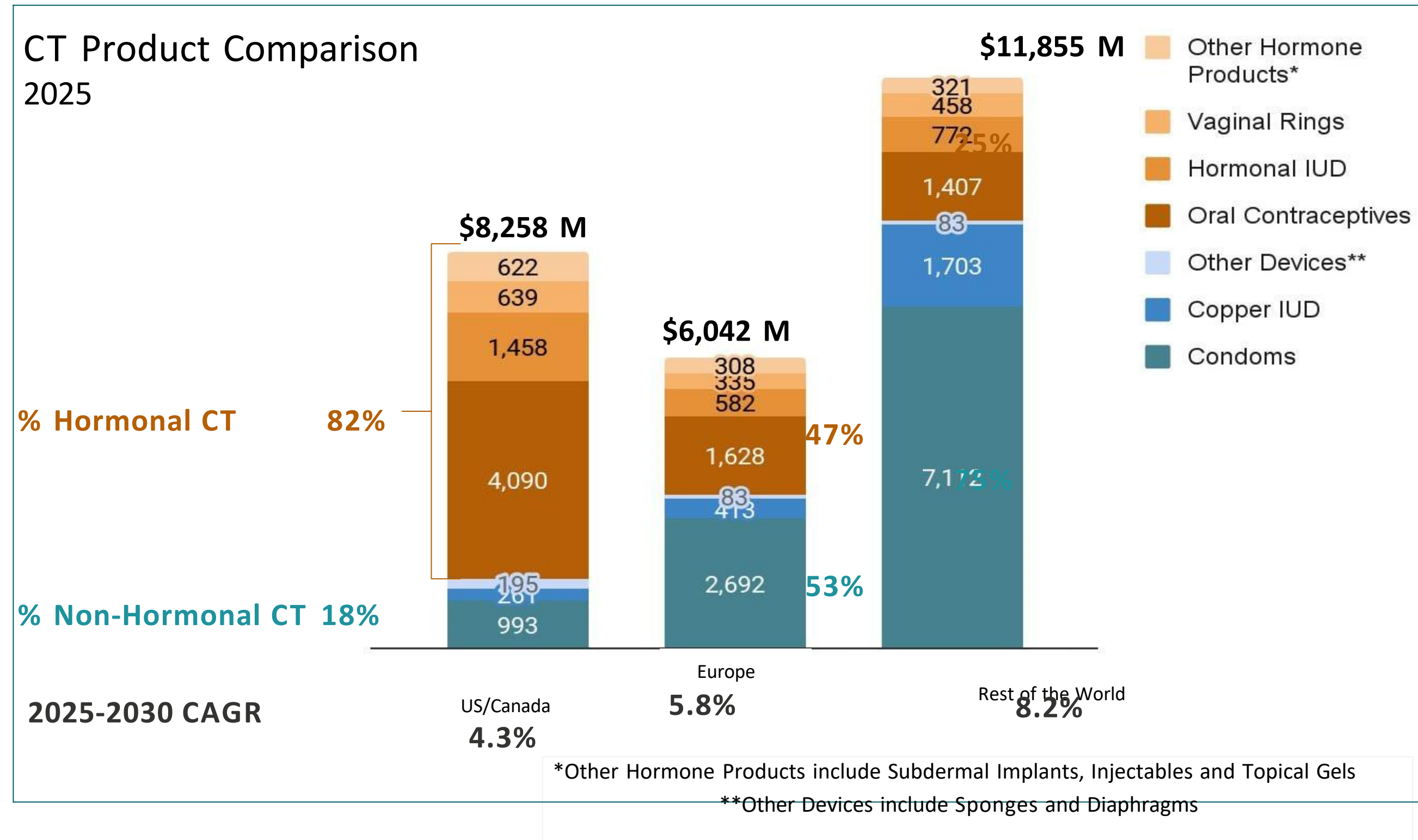
A large and growing market, with a projected 6% global growth rate through 2030

Global Contraceptive Market 2025-2030



Market Breakdown | Product Comparisons

Hormonal CT dominates North American market, but is less prevalent globally



- US/Canada market is larger than Europe, despite having ~60% of the population
- Both US/Canada and European markets are growing slowly compared to other regions
- “On-demand” methods represent only ~15% in the US/Canada but:
 - 45% of European market
 - 60% in other regions

CT Products in US Market

✓ = on the market

Pharma Company/Startup	IUD	Implant	OC Pills	Patch	Ring	Injectable	Vaginal Gel	Condom/ Diaphragm
Abbvie (prev. Allergan)	✓		✓					
Bayer AG	✓		✓					
Agile				✓				
Organon (prev. Merck)		✓	✓		✓			
Pfizer			✓			✓		
Teva Pharmaceuticals			✓		✓	✓		
CooperSurgical	✓							✓
Mylan			✓	✓				
Mayne Pharma			✓		✓			
Perrigo (prev. HRA Pharma)		✓						
J&J/Janssen		✓						
Evofem								✓
Female Health Co/Veru								✓
Various manufacturers								✓

Key Takeaways

- OCs, condoms, and IUDs have several large and small competitors; other categories have less representation
- R&D efforts are primarily focused on developing new varieties of existing products; very little R&D focused on “novel” methods
- Reasons for lack of R&D in women’s health include: concern over developing drugs for a healthy population, product liability risk, regulatory risk, and higher ROI opportunities (cancer, cardio)

Regulatory Guidance for Product Development

The hormonal CT regulatory pathway is well established, while non-hormonal and male products have the opportunity to work with regulators to develop new approval standards.

Regulatory pathway



Hormonal

Established regulatory standards: size of trials, number of cycles, and pregnancy as primary outcome measure

Non-hormonal

Working with regulators to develop **new standards.**

Reimbursement | US & Europe

Payment process and rates vary significantly by country, slowing commercialization.



Multi-payer system

- Affordable Care Act (ACA) passed in 2010 requires **insurance companies to pay for contraception** and counseling with no out-of-pocket costs to consumers
 - Applies to **all FDA approved products**, including male condoms but not vasectomies
- Many insurance companies were **not complying** with regulations, pushing women towards cheaper, generic products
 - In 2022, after consumer complaints, federal govt began to enforce ACA requirements

Resulting in lengthy process to get new products approved on insurance company's formularies



Single-payer system

- EU member state recognize a reproductive health and rights is a prerequisite for achieving gender equality and a **basic human right**
- Numerous EU Member States have **subsidized contraceptives** on the grounds of public health or to uphold fundamental rights
- Typically, **national health systems negotiate price and pay for contraceptive products** with some co-pay required

Early Market Validation

Momentum in the segment has increased with recent CT product launches and exit activity

New Products



Annovera
Hormonal Ring
August 2018



Twirla
Hormonal Patch
December 2020



Phexxi
Non-hormonal Gel
September 2020

Recent M&A Activity



Catalyzing Contraceptive Innovation

The business case for private investment: An underserved market with high-upside potential

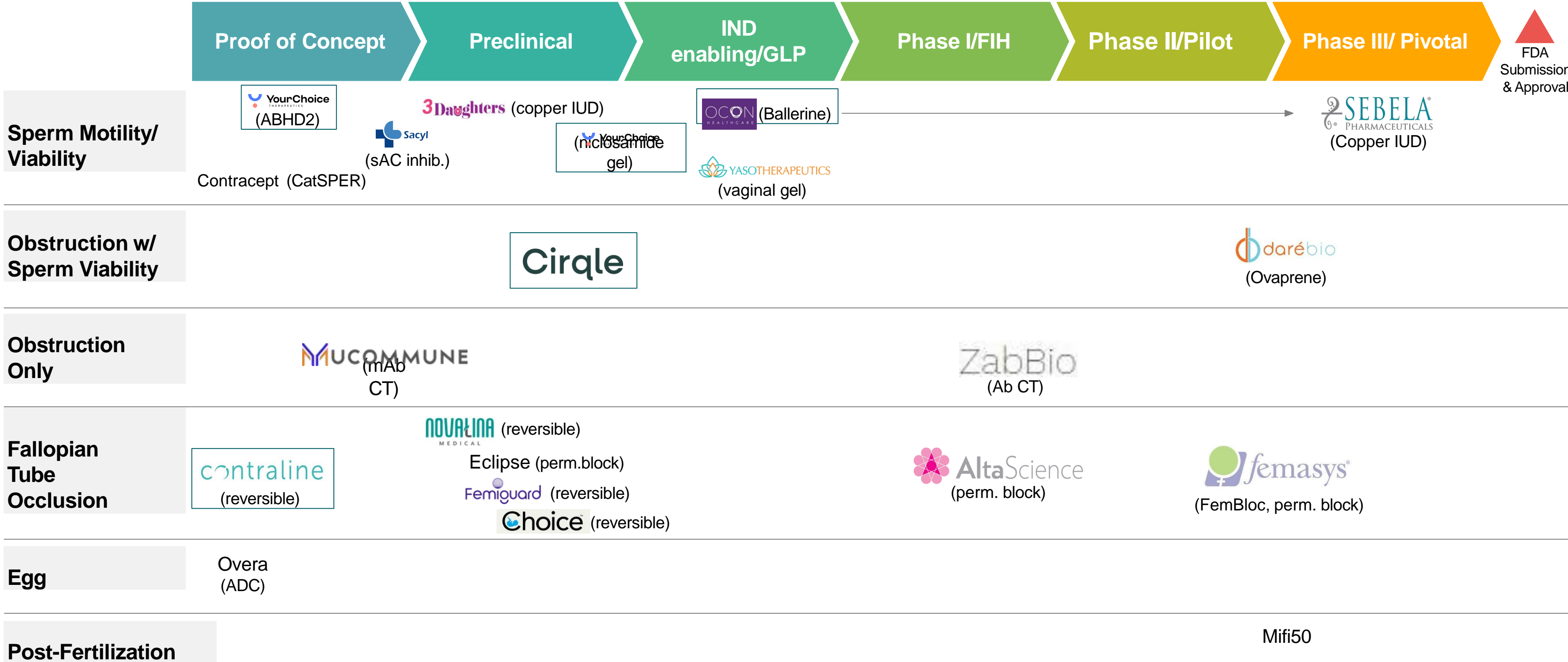
Status	Private Investment Criteria
	Large and/or Growing Market (revenue and demographics)
	Technology protected by strong IP
	Differentiated from Competitors
	Clear Regulatory Pathways
	Commercial & Reimbursement Potential
	Path to Exit via IPO or Acquisition

RH Capital's Value Add

- Masterclass series with technical expertise (scientific, regulatory)
- Support from BMGF
- Expertise in commercialization from existing CT portfolio
- Creating tools and resources to support the next generation of CT companies

Pipeline | Non-Hormonal Female Contraceptive

□ RH Capital Portfolio Company



Pipeline | Male Contraceptives

Hormonal & Non-Hormonal offerings

 RH Capital Portfolio Company



 FDA Submission & Approval


Spermatogenesis



Govt/Acad DMAU inj.
Govt/Acad DMAU pill
Govt/Acad 118-MNTDC pill



Sperm Transport

Sperm Motility



Epp'nPharma Inc

Fertilization

Thank You

Discussion: Impact of Funder Strategy on Research Capability

Rebecca Callahan, PhD, MPH

FHI 360

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Q&A

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Closing Remarks

Dr. Samukeliso Dube

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26 July 2023

Thanks for Attending

Questions: cti@fhi360.org

