Innovation in Contraceptive R&D Funding
Interpretation

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Sélectionnez "interprétation" dans votre barre d'outils Zoom pour passer à l’interprétation en Espagnol ou en Français

Selezione "Interpretación" en su barra de herramientas de Zoom para cambiar a interpretación en Español o Francés
Logistics

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

Remain on mute throughout the event.

Event is being recorded. Recording and slides will be sent to all registrants following the event.
<table>
<thead>
<tr>
<th>Session Title</th>
<th>Speaker</th>
<th>Time</th>
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<tbody>
<tr>
<td><strong>Welcome &amp; Logistics</strong></td>
<td>Kate Rademacher, MHA</td>
<td>5 Mins</td>
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<td></td>
<td>Independent Consultant</td>
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<tr>
<td><strong>Global Funding for Contraception R&amp;D:</strong></td>
<td>Cécile Ventola, PhD</td>
<td>20 Mins</td>
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<tr>
<td>Broadening Horizons to meet a Diversity of Needs</td>
<td>Policy Cures Research</td>
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<tr>
<td><strong>Private Investment in Contraceptive Innovation</strong></td>
<td>Stasia Obremskey, MBA</td>
<td>20 Mins</td>
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<td>RH Capital</td>
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<tr>
<td><strong>Discussion:</strong> Impact of Funder Strategy on</td>
<td>Rebecca Callahan, PhD, MPH</td>
<td>20 Mins</td>
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<td>Research Capability</td>
<td>FHI 360</td>
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<td><strong>Q&amp;A</strong></td>
<td>Moderated by Event Host</td>
<td>15 Mins</td>
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<tr>
<td><strong>Closing Remarks</strong></td>
<td>Dr. Samukeliso Dube</td>
<td>10 Mins</td>
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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
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

**LARC**s ($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

+$12m in device & combo cMPTs e.g., IVRs, MAPs, implants
At least +$32m in on-demand cMPTs e.g., vaginal gels, films and fast dissolve inserts
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.

<table>
<thead>
<tr>
<th>Funders</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>% of total</th>
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<tr>
<td>Gates Foundation</td>
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<td>45</td>
<td>49</td>
<td>47</td>
<td>40%</td>
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<tr>
<td>US NIH</td>
<td>26</td>
<td>35</td>
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<td>29</td>
<td>24%</td>
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<tr>
<td>Aggregate Industry</td>
<td>51</td>
<td>52</td>
<td>39</td>
<td>23</td>
<td>20%</td>
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<tr>
<td>Population Council</td>
<td>3.5</td>
<td>2.9</td>
<td>2.9</td>
<td>10</td>
<td>8.9%</td>
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<tr>
<td>USAID</td>
<td>5.4</td>
<td>4.3</td>
<td>11</td>
<td>4.1</td>
<td>3.5%</td>
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<tr>
<td>Male Contraceptive Initiative (MCI)</td>
<td>0.6</td>
<td>0.8</td>
<td>1.4</td>
<td>1.7</td>
<td>1.4%</td>
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<tr>
<td>EC</td>
<td>0</td>
<td>0.2</td>
<td>1.5</td>
<td>1.2</td>
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<td>Children’s Investment Fund Foundation (CIFF)</td>
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<td>&lt;0.1</td>
<td>&lt;0.1%</td>
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<td>Parsemus Foundation</td>
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<td>Vinnova</td>
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<td>&lt;0.1</td>
<td>&lt;0.1%</td>
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<tr>
<td>Brazilian FAPESP</td>
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<td>&lt;0.1</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
<td>&lt;0.1%</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>114</td>
<td>143</td>
<td>140</td>
<td>117</td>
<td>100%</td>
</tr>
</tbody>
</table>

*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 contraceptives averaging 60%+, but has also experienced **two consecutive years of decline** (+ much on reduced/ultra reduced hormones)
• Non-user-controlled contraceptives were the 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
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.

Entrepreneurs

- Self-funded
- Family & friends
- Philanthropic
- Gov’t program (SBIR, SBA)
- Loan
- Venture Capital

Innovation

VCs

(10 yr fund life)

Private Investors

Exit

- Acquisition
- Initial Public Offering (IPO)

Investment Bankers

Public Markets

Stock

- $
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)

"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

Backing companies such as

Facebook

Google

Uber

Amazon

Apple

Netflix
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
The role of VC in Contraceptive Innovation

Product Development Stage

Discovery → Pre-Clinical Research → Early Clinical Trials → Late Clinical Trials → Commercialization

Capital Stage

Non-dilutive funding (Grants via academic, Gov’t, Foundations) → Angels | Bootstrap → Venture Capital Funds

Pre-seed → Seed → Series A → Series B+

Pharma & Device Industry
Attracting Different Types of Capital

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

### Public v. Private Capital

<table>
<thead>
<tr>
<th>Risk / Impact</th>
<th>Low</th>
<th>High</th>
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<tbody>
<tr>
<td>Public Investment</td>
<td>Return Expectation</td>
<td>Private Investment</td>
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<tr>
<td>Corporate Investment</td>
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</table>

### 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

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

15-49 Yr Old Women (Millions in 2025)

United States & Canada

- Sexually Active Women: 68.5M
  - Non CT User: 49.0M
  - Current CT User: 19.5M
  - Target Market: 26.8M
    - Non CT User: 14.6M
    - Current CT User: 12.2M

EU

- Sexually Active Women: 116.8M
  - Non CT User: 80.0M
  - Current CT User: 36.8M
  - Target Market: 47.6M
    - Non CT User: 27.6M
    - Current CT User: 20.0M

Rest of World

- Sexually Active Women: 1,154.5M
  - Non CT User: 729.5M
  - Current CT User: 425M
  - Target Market: 394.9M
    - Non CT User: 212.5M
    - Current CT User: 182.4M

Source: Avenir LPPP project (www.lppp.avenirhealth.org); team analysis
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

- **Rest of the World**: $17.5B in 2030
- **North America & Europe**: $18B in 2030

Source: Global Market Insights, Contraceptives Market Report, 2023-2032
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

**Source:** Global Market Insights, Contraceptives Market Report, 2023-2032
## CT Products in US Market

<table>
<thead>
<tr>
<th>Pharma Company/Startup</th>
<th>IUD</th>
<th>Implant</th>
<th>OC Pills</th>
<th>Patch</th>
<th>Ring</th>
<th>Injectable</th>
<th>Vaginal Gel</th>
<th>Condom/ Diaphragm</th>
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<tbody>
<tr>
<td>Abbvie (prev. Allergan)</td>
<td>✔</td>
<td>✔</td>
<td></td>
<td>✔</td>
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<td>Bayer AG</td>
<td>✔</td>
<td>✔</td>
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<td>✔</td>
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<td>Agile</td>
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<td>✔</td>
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<td>✔</td>
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<td>Organon (prev. Merck)</td>
<td>✔</td>
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<td>✔</td>
<td>✔</td>
<td>✔</td>
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<td>Pfizer</td>
<td>✔</td>
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<td>Teva Pharmaceuticals</td>
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<td>Mylan</td>
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<td>Mayne Pharma</td>
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<tr>
<td>Perrigo (prev. HRA Pharma)</td>
<td>✔</td>
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<td>J&amp;J/Janssen</td>
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<td>Evofem</td>
<td>✔</td>
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<td>✔</td>
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<tr>
<td>Female Health Co/Veru</td>
<td>✔</td>
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<td>Various manufacturers</td>
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<td>✔</td>
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### 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).

Source: Global Market Insights, Contraceptives Market Report, 2023-2032; company websites
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**

- **Discovery Research**
- **Pre-Clinical Research**
- **Phase I Clinical Research**
- **Phase II Clinical Research**
- **Phase III Clinical Research**
- **Commercialization**

**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

- **Organon backing satisfies Danish startup’s funding needs for a new non-hormonal contraceptive**
  - A new deal with US-based Organon, valued at as much as USD 370m, is enough for two founders to retain ownership of women’s health firm Cingle Biomedical. No longer lacking funding, they can continue developing a non-hormonal contraceptive candidate.
Catalyzing Contraceptive Innovation

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

<table>
<thead>
<tr>
<th>Status</th>
<th>Private Investment Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>✔️</td>
<td>Large and/or Growing Market (revenue and demographics)</td>
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<tr>
<td>✔️</td>
<td>Technology protected by strong IP</td>
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<td>✔️</td>
<td>Commercial &amp; Reimbursement Potential</td>
</tr>
<tr>
<td>✔️</td>
<td>Path to Exit via IPO or Acquisition</td>
</tr>
</tbody>
</table>

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

Proof of Concept | Preclinical | IND enabling/GLP | Phase I/FIH | Phase II/Pilot | Phase III/ Pivotal

Sperm Motility/ Viability
- Obstruction w/ Sperm Viability
  - Contracept (CatSPER)
- Obstruction Only
- Fallopian Tube Occlusion
  - contraline (reversible)
  - Eclipse (perm.block)
  - Femiguard (reversible)
- Egg
  - Overa (ADC)

Post-Fertilization

Mifi50
Pipeline | Male Contraceptives

Hormonal & Non-Hormonal offerings

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

- **Sperm Transport**
  - (Vasalgel)
  - (NES/Tes gel)

- **Sperm Motility**
  - (sAC inhib.)

- **Fertilization**

**IND enabling/GLP**

**Phase I/FIH**

**Phase II/Pilot**

**Phase III/ Pivotal**

RH Capital Portfolio Company

FDA Submission & Approval

Confidential: RH Capital
Thank You
Discussion: Impact of Funder Strategy on Research Capability

Rebecca Callahan, PhD, MPH
FHI 360
Q&A
Closing Remarks

Dr. Samukeliso Dube

FP2030
Thanks for Attending

Questions: cti@fhi360.org