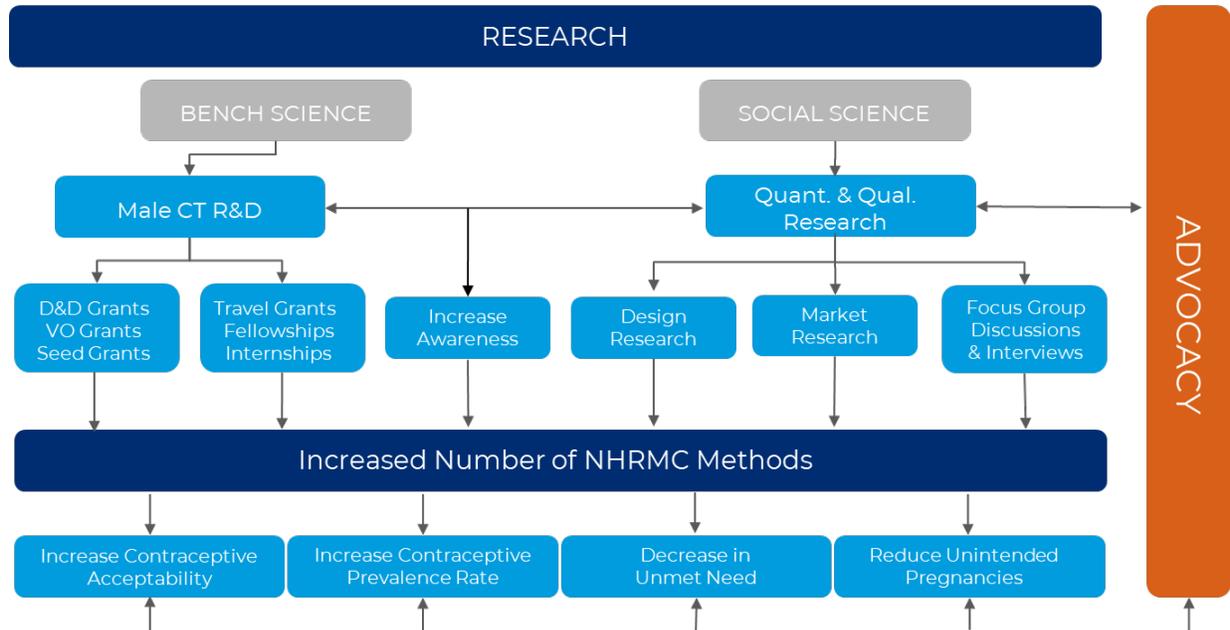


## MCI's Theory of Change



Note: D&D = Discovery & Development; VO = vas occlusive;

The following strategy is based on a theory of change model grounded in two core pillars of support, research and advocacy (pillars 1 & 2, respectively). These pillars work in concert to drive the product development pipeline forward while preparing the market, policymakers, and public for product introduction through advocacy and awareness building.

Activities supported by MCI are designed to address multiple facets of research and advocacy whenever possible. Examples include our trainee fellowship program, which engages students working in male contraception to contribute to R&D and quantitative/qualitative research outcomes while simultaneously building the next generation of researchers working in the field. Similarly, engaging the general public through social media and other communications channels allows us to educate, correct misperceptions, build champions, and attract new investors who can, in turn, demonstrate demand, invest funds, influence policy, and inform regulators.

In addition to these two core pillars, MCI is also thinking about future sustainability and how to best serve as leaders in the field. To that end, we have outlined two supporting pillars, 3 & 4, that focus on sustainability and leadership, respectively.

## Executive Summary

The purpose and mission of MCI for the next three years will be realized through a focused strategy based on four pillars:

**PILLAR 1 (Foundational Pillar: Research):** *Invest in research & development to support the development of non-hormonal reversible male contraceptive (NHRMC) methods.*

- Support MCI’s primary focus of supporting research & development efforts as a means of moving the field of NHRMC product development forward.
- Maintain our core areas of support (discovery & development grants, seed grants, and trainee fellowships)
- Support refinement of our investment strategies to sharpen our focus on promoting efficiency and measurable progress for methods in the product development pipeline.
- Level of Effort:
  - Director of Operations and Programs - 60%
  - Executive Director - 25%
  - Director of Communications - 15%

**PILLAR 2 (Foundational Pillar: Advocacy):** *Demonstrate the demand for NHRMC methods through community outreach and advocacy efforts.*

- Continue MCI’s efforts to demonstrate and project the demand for NHRMC through community outreach and market defining research.
- Efforts to date have resulted in tangible benefits to the NHRMC community so we will expand those aspects that have provided the greatest value, specifically:
  - supplement our domestic US market research results with new research from international settings.
  - maintain momentum towards a unified community of researchers working to identify product development efficiencies through collaboration (“team science”).
  - continue efforts to educate the general public and scientific community about NHRMC.
- Level of Effort:
  - Director of Communications - 60%
  - Executive Director - 25%
  - Director of Operations and Programs - 20%

**PILLAR 3 (Supporting Pillar: Sustainability):** *Establish a hybrid model of investment to support organizational sustainability.*

- Promote successful growth and sustainability of MCI and our programs through diversification of funding.
- Focus on identifying at least one additional major donor to provide core operating or research and development support to MCI.
- Explore a path to institutional sustainability through the cultivating investment-focused granting opportunities that offer the potential for down-stream returns to feed back into MCI's R&D pillar.
- Level of Effort:
  - Executive Director – 30%
  - Director of Communications – 10%
  - Director of Operations and Programs – 10%

**PILLAR 4 (Supporting Pillar: Leadership):** *Support alternative approaches to facilitating contraceptive product development by expanding MCI's role as a central resource focused on developing NHRMCs while maintaining flexibility/agility to respond to positive developments or other needs for course correction.*

- Build upon positive reception received at MCI's ideation event in July 2019 to move forward with efforts to modify/expand our operational model.
- Serve as a leadership hub for the field of NHRMC, presenting a cohesive voice for the research community as a means of increasing awareness of and support for the field. In addition, serve as a central point of contact and action for researchers to communicate needs and challenges to be addressed in the community as a means of reaching faster resolution.
- Level of Effort:
  - Executive Director – 20%
  - Director of Communications – 15%
  - Director of Operations and Programs – 10%

## MCI Strategic Plan 2020-22

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### **PILLAR 1: INVEST IN RESEARCH & DEVELOPMENT TO SUPPORT THE DEVELOPMENT NON-HORMONAL REVERSIBLE MALE CONTRACEPTIVE (NHRMC) METHODS.**

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**3-YEAR GOAL:** A minimum of two MCI-funded leads will demonstrate progress as indicated by a transition between phases of development. For example, from discovery to pre-clinical or pre-clinical to clinical.

**OUTCOME:** Demonstrated increase in momentum in the development pipeline will attract additional investors.

**PROGRAMS:** Research Grants; Advocacy: promoting grantees and other researchers; Raising awareness around the need for NHRMC.

### **ACTIONS**

#### **Program Year 2020:**

- 1. Prioritize one lead in 2020 to support and move into the next product development stage gate.**

**WHO:** Executive Director, Director of Operations & Programs, Research Committee

**STEPS:** Conduct a strategic review of the current known pipeline of leads; investigate 2-4 leads to use as case studies; select 1-2 most promising leads and create a pathway with estimated costs for each and identify a range at which to set the grant award.

**COST:** up to \$1M -- TBD

**2. Provide seed grant and discovery & development grant mechanisms to continue to support core research and development activities.**

WHO: Executive Director, Director of Operations & Programs, Research Committee  
STEPS: Review previous and current seed grant awardees and assess their potential viability based on our investment.  
COST: Staff time; Board volunteer time

**3. Offer  service grants to provide technical assistance to those working in the field of NHRMC such as consultant support for developing Product Development Plans and/or Target Product Profiles in an effort to increase fundraising potential.**

WHO: Executive Director, Director of Operations & Programs, Communications and Design Strategist, Board/Advisory Committee Members with Product Development/Business Expertise  
STEPS: Identify needs for TA and consultants with expertise in PDP/TPP development, preferably in the male contraceptive space; Conduct interviews with top three consultant candidates; Negotiate rates as non-profit; Contract consultant; publish grant mechanism  
COST: \$200K

**4. Continue to build and curate trainee fellowship program to support growth and sustainability of the research sector.**

WHO: Executive Director, Director of Operations & Programs, Communications and Design Strategist, Research Committee  
STEPS: Continue to support two open fellowships per year; Establish annual Frontiers in Reproduction-specific  Scholarship.  
COST: \$211K

**Program Year 2021:**

**1. Continue to provide balanced grant offerings that support a maturing pipeline**

**WHO:** Executive Director, Director of Operations & Programs, Research Committee  
**STEPS:** Conduct a strategic review of the current known pipeline of leads and MCI grantees; Identify 2-3 leads to use as case studies; Review development pathway and identify a range at which to set the grant award.  
**COST:** \$500K - \$1.5M -- TBD

**2. Offer service grant mechanism to those working in the field of NHRMC to provide other consultant support TBD based on need (e.g. Toxicology, CMC, regulatory, etc.).**

**WHO:** Executive Director, Director of Operations & Programs, Communications and Design Strategist, Board/Advisory Committee Members with Product Development  
**STEPS:** Identify potential consultants with expertise in the area; Conduct interviews with top three consultant candidates; Negotiate rates as non-profit; Contract consultant; publish grant mechanism.  
**COST:** \$200K

**3. Continue to build and curate trainee fellowship program to support growth and sustainability of the research sector.**

**WHO:** Executive Director, Director of Operations & Programs, Communications and Design Strategist, Research Committee  
**STEPS:** Continue to support two open fellowships per year; Establish annual Frontiers in Reproduction-specific Scholarship.  
**COST:** \$211K

**Program Year 2022:**

**1. Continue to provide balanced grant offerings that support a maturing pipeline of products.**

WHO: Executive Director, Director of Operations & Programs, Research Committee  
STEPS: Conduct a strategic review of the current known pipeline of leads and MCI grantees; Identify 2-3 leads to use as case studies; Review development pathway and identify a range at which to set the grant award.  
COST: \$750K - \$1.5M -- TBD

**2. Offer service grant mechanism to those working in the field of NHRMC to provide other consultant support TBD based on need (e.g. Toxicology, CMC, regulatory, etc.).**

WHO: Executive Director, Director of Operations & Programs, Communications and Design Strategist, Board/Advisory Committee Members with Product Development  
STEPS: Identify potential consultants with expertise in the area; Conduct interviews with top three consultant candidates; Negotiate rates as non-profit benefit; Contract consultant; publish grant mechanism.  
COST: \$200K

**3. Continue to build and curate trainee fellowship program to support growth and sustainability of the research sector.**

WHO: Executive Director, Director of Operations & Programs, Communications and Design Strategist, Research Committee  
STEPS: Continue to support two open fellowships per year; Establish annual Frontiers in Reproduction-specific Scholarship.  
COST: \$211K

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**PILLAR 2: DEMONSTRATE THE DEMAND FOR NON-HORMONAL REVERSIBLE MALE CONTRACEPTIVE (NHRMC) METHODS THROUGH COMMUNITY OUTREACH AND ADVOCACY EFFORTS.**

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**3-YEAR GOAL:** MCI is able to demonstrate demand for NRHMC at a global level.

**OUTCOME:** Increased recognition of the demand and market potential for NHRMC.

**PROGRAMS:**  Advocacy: Act as a coalition of biological and social scientists and communicators to raise awareness around the need for NHRMC; Research Grants

**ACTIONS**

**Program Year 2020:**

**1. Conduct an internationally-focused market research study.**

**WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs

**STEPS:** Post a request for quotes to determine estimated cost; Collaborate with stakeholders to identify target countries; Post a request for proposals and select a firm to conduct the research; Initiate research.

**COST:** \$250-500K est - TBD

**2. Debut  "Intended" podcast.**

**WHO:** Director of Operations & Programs, Communications and Design Strategist, Executive Director

**STEPS:** Complete storyboarding for all eight episodes; Conduct interviews; Research and write script; Record segments; Produce segments; Review and finalize segments; Publish, disseminate and promote series via multiple podcast channels.

**COST:** \$5,000

**Program Year 2021:**

**1. Complete international market research activities and disseminate findings.**

**WHO:** Communications and Design Strategist, Director of Operations & Programs, Executive Director

**STEPS:** Finalize research; Develop summary report; Correlate with previous market research efforts (2017 US market research report and 2019 youth research); Disseminate findings.

**COST:** \$50K - travel/meeting registration fees

**2. Produce a feature-length documentary film asset to advocate for NHRMC.**

**WHO:** Communications and Design Strategist, Director of Operations & Programs, Executive Director

**STEPS:** Develop a content strategy; Storyboard content and flow of the film; Film content; Produce content; Publish, disseminate, and promote.

**COST:** \$10K - travel, equipment - much of travel will leverage existing trips.

**Program Year 2022:**

**1. Conduct additional market research to explore product characteristics, user characteristics, and/or other information to support product development efforts.**

**WHO:** Communications and Design Strategist, Director of Operations & Programs, Executive Director

**STEPS:** Identify market research partner; conduct early market research; disseminate results.

**COST:** \$250K

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**PILLAR 3: ESTABLISH A HYBRID MODEL OF INVESTMENT TO SUPPORT ORGANIZATIONAL SUSTAINABILITY**

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**3-YEAR GOAL:** A minimum of two MCI-funded grants will include a clause to ensure downstream return on investment for MCI.

**OUTCOME:** MCI is supported through a hybrid funding model that is jump started but not fully reliant on philanthropic investment.

**PROGRAMS:** Social Enterprise; PRIs & other investments; Grants

**ACTIONS**

**Program Year 2020:**

**1. Identify at least one new major investor to achieve the match challenge.**

**WHO:** Executive Director, Board of Directors

**STEPS:** Continue to research potential organizations for outreach; Provide individual points of contact for targeted outreach; Engage consultant to provide training and assistance in fundraising techniques.

**COST:** \$20K

**2. Develop a strategic investment plan to identify timing and mechanisms by which MCI could realize returns on our grant investments.**

**WHO:** Executive Director, Director of Operations & Programs, Board/Advisory Committee Members with Business Expertise, Consultant(s)

**STEPS:** Identify comparable programs and identify approaches that could potentially align with the RMNCH field; Identify gaps in knowledge/operations that may need to be considered for implementation; Clarify ultimate goals for implementation; Develop a timeline and steps needed to achieve goals.

**COST:** \$25K

**3. Conduct meetings with select organizations to assess appetite for partnering with MCI as part of a modified investment model.**

**WHO:** Executive Director, Director of Operations and Programs  
**STEPS:** Identify teams that are in a position most likely to be able to seriously consider near term partnership agreements that include down-stream returns; Share strategic investment plan and determine which approaches appear to be most compelling; Incorporate results of conversations into strategic investment plan to further define planning efforts.  
**COST:** \$5K for travel costs

**Program Year 2021:**

**1. Release first funding opportunity to specifically include requirement of return on MCI investment in the funding agreement.**

**WHO:** Executive Director, Director of Operations & Programs, Research Committee  
**STEPS:** Identify appropriate mechanism for funding based on intelligence gathering in FY 2019-20; Draft RFP text; Communicate RFP.  
**COST:** \$1M - \$1.5M

**Program Year 2022:**

**1. Release second funding opportunity to specifically include requirement of return on MCI investment in the funding agreement.**

**WHO:** Executive Director, Director of Operations & Programs, Research Committee  
**STEPS:** Identify appropriate mechanism for funding based on intelligence gathering in FY 2019-21; Draft RFP text; Communicate RFP.  
**COST:** \$1M - \$1.5M

**2. Evaluate early success of the ROI grants/contracts and identify how the opportunities can be modified/expanded**

- WHO:** Executive Director, Director of Operations & Programs, Board/Advisory Committee Members with Product Development Expertise
- STEPS:** Review existing grant agreements for financial returns, progress against proposed goals, and opportunities to accelerate timelines.
- COST:** Staff time, Board volunteer time

**3. Develop investment recovery timeline to estimate time horizon for realization of investment returns.**

- WHO:** Executive Director, Director of Operations & Programs, Research Committee, Board/Advisory Committee Members with Business Expertise
- STEPS:** Identify potential time to recovery of investment returns as part of the evaluation of the ROI grants.
- COST:** Staff time, Board volunteer time

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**PILLAR 4: SUPPORT ALTERNATIVE APPROACHES TO FACILITATING CONTRACEPTIVE PRODUCT DEVELOPMENT BY EXPANDING MCI'S ROLE AS A CENTRAL RESOURCE FOCUSED ON DEVELOPING NON-HORMONAL REVERSIBLE MALE CONTRACEPTIVES**

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**3-YEAR GOAL:** MCI expands capacity to serve as a central hub to facilitate the development of NHRMC by receiving at least one investment specifically for organizational development.

**OUTCOME:** MCI becomes a central hub for investors and researchers for facilitating the development of NHRMC.

**PROGRAMS:** Social Enterprise; Advocacy: Promoting grantees and other researchers; Advocacy: Raising awareness around the need for NHRMC among policymakers, the general public, regulatory authorities, investors, and researchers, among other groups.

## ACTIONS

### Program Year 2020:

**1. Develop a proposal to seek investment in developing MCI as a novel business platform to support the development of NHRMC.**

**WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs, IDEO

**STEPS:** Initial framework of pitch deck developed by IDEO; MCI adds technical specifics and content; The combined team begins to shop the pitch to our respective networks to identify potential investors.

**COST:** \$4K for travel

**2. Continue success and momentum of collaborative approach initiated with 2019 Ideation event.**

**WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs, Australian collaborators, Other partners TBD

**STEPS:** Explore potential to host a follow-on ideation event in Australia to capture the momentum of on-going work in the region and to capitalize on annual Reproductive Biology conference to be held in New Zealand; Reach out to Moira O'Brian, Sab Ventura, Rob Gorkin, Simon Cook, Gianni Renda and others to determine best area of focus for a follow-on meeting; Coordinate with local partners to identify facility and other logistical needs.

**COST:** \$100K

**Program Year 2021:**

- 1. Conduct organizational research and development activities to inform how to expand the MCI business model to provide additional, targeted support to the field beyond our core grant-making efforts.**

**WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs, IDEO, Other collaborators TBD

**STEPS:** Identify appropriate mechanism for funding based on intelligence gathering in FY 2019-20; Draft RFP text; Communicate RFP.

**COST:** \$250 - \$500K

- 2. Continue success and momentum of collaborative approach initiated with 2019 Ideation event.**

**WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs, Other partners TBD

**STEPS:** Conduct collaborative working event to brainstorm around a critical issue in development pathway for RHNMC – tentatively proposed: regulatory pathway.

**COST:** \$100K

**Program Year 2022:**

- 1. Debut and implement MCI’s new business model based on collaboration with IDEO in 2020.**

**WHO:** Executive Director, MCI Staff, Board of Directors

**STEPS:** Conduct rebranding exercise; Develop key communication materials; Disseminate via webinar and at professional conferences.

**COST:** \$100K – travel and webinar costs

**2. Continue success and momentum of collaborative approach initiated with 2019 Ideation event.**

- WHO:** Executive Director, Communications and Design Strategist, Director of Operations & Programs, Other partners TBD
- STEPS:** Conduct collaborative working event to brainstorm around a critical issue in development pathway for RHNMC – tentatively proposed: manufacturing.
- COST:** \$100K