

INTRODUCTION

Male Contraceptive Initiative (MCI) was founded in 2014 as a 501(c)3 nonprofit dedicated to the advancement of long-acting, reversible, non-hormonal male contraceptive options. Since 2017, MCI has granted more than \$2M USD towards research and development of male contraception, and has championed advocacy efforts in the field to ensure public support and knowledge. MCI's approach ensures that a variety of contraceptive options have the opportunity to succeed, resulting in an eventual slate of birth control options to meet the varied needs of a diverse population.

Design thinking, or human-centered design, is a solutions-based problem-solving methodology rooted in empathizing with individuals or organizations (or, "stakeholders") most closely affected by a particular challenge. The approach utilizes qualitative research approaches and activities to identify pain-points in order to both articulate challenges and reposition them as opportunities. The intention is to first develop a holistic understanding of a challenge before collaboratively designing potential interventions to address it. Going through this process with those most impacted by the challenge ensures that potential solutions are practical, sustainable, and valued.

Though often expressed as a linear process, design thinking's effectiveness and value greatly increases with each application: it is at its most impactful when done in iterative cycles. The vernacular of design thinking varies, but the phases of the design thinking process are typically defined as:

- **Empathize**: Immersion in an issue or challenge to experience it from an enduser's perspective
- **Define**: Building off the empathic insights, structure both the problem and a solution
- **Ideate**: Take the problem statement and proposed solution and craft a viable intervention
- **Prototype**: Create a tangible or even physical manifestation of the arrived at intervention
- **Test**: Re-engage with end-users to evaluate the intervention's effectiveness



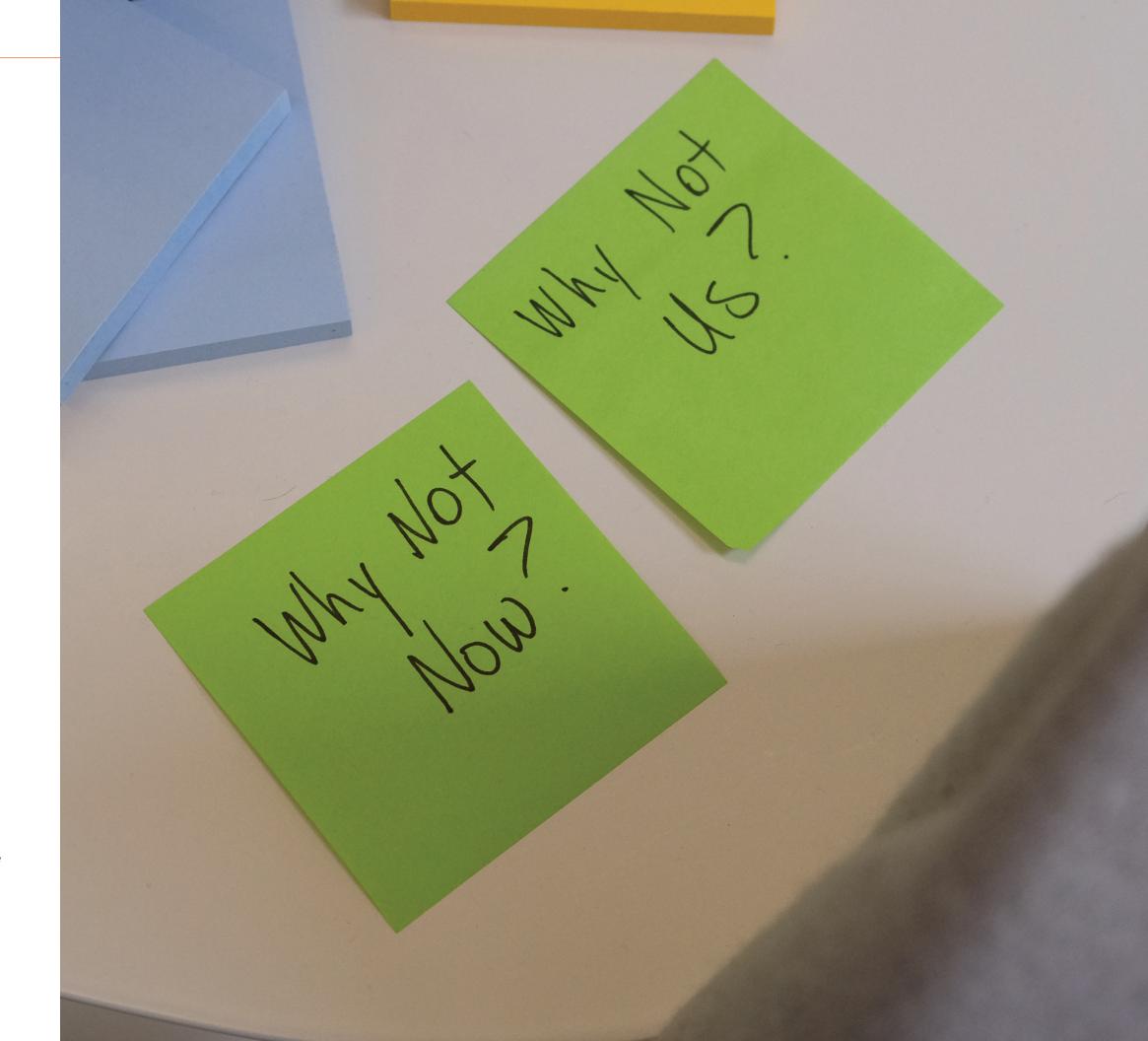
IDEO is a global design company committed to creating positive impact. From designing the first manufacturable mouse for Apple to advancing the practice of human-centered design, IDEO has long been at the forefront of creating change through design, and has tackled big problems across the spectrum of design and development.

Ideation allows the generation of different ideas in a short amount of time. By challenging smart, independent thinkers to approach problems collaboratively and with a mindset that discovers new direction, we can solve big problems with innovation.

Male contraception is a field with broad, reaching challenges that require a thoughtful cross-collaborative approach. From funding challenges to societal norms, male contraception faces hurdles that will require expertise both across and deep within the drug development pipeline. We also are mindful that some of the challenges the field is facing may have been addressed in other sectors.

For this reason, we wanted to invite leaders in male contraception, and from other fields of practice to contribute their knowledge and experience to make sure no time is wasted reinventing the wheel. Ideation is built around gathering diverse thoughts about how to address big challenges and we believe that it is this approach that will push the field of male contraception forward faster.

By bringing together experts in fields such as basic research, product development, pharmaceutical marketing, regulatory approval, design, and more, we hoped to gather unique insights into what some of the stumbling blocks might be for developing non-hormonal, reversible male contraception. Through this proactive approach, we can plan for how we might circumvent foreseeable challenges, ultimately accelerating the speed of development and getting male contraceptive products on the market sooner.





Participants

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Journey to Market

Drug development can be a confusing, opaque process - even to those that are in the process of developing new products. In identifying the ways that the male contraceptive field might overcome challenges before they arise, the group first tackled the Journey to Market in order to identify where challenges lay along the pathway a drug typically takes from discovery to market introduction. One immediate learning was that the journey isn't linear, and it isn't standardized. Many participants characterized it as a "swirling vortex" where each part of the process relies on previous steps while also informing future steps. Along the development pathway, each finding is equally likely to identify a need for iteration and improvement as it is to move the process forward.

Challenges

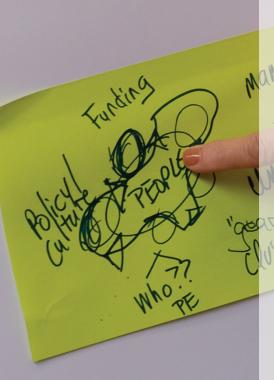
As participants thought their way through the development pathway, they identified hundreds of small challenges that would need to be addressed, including:

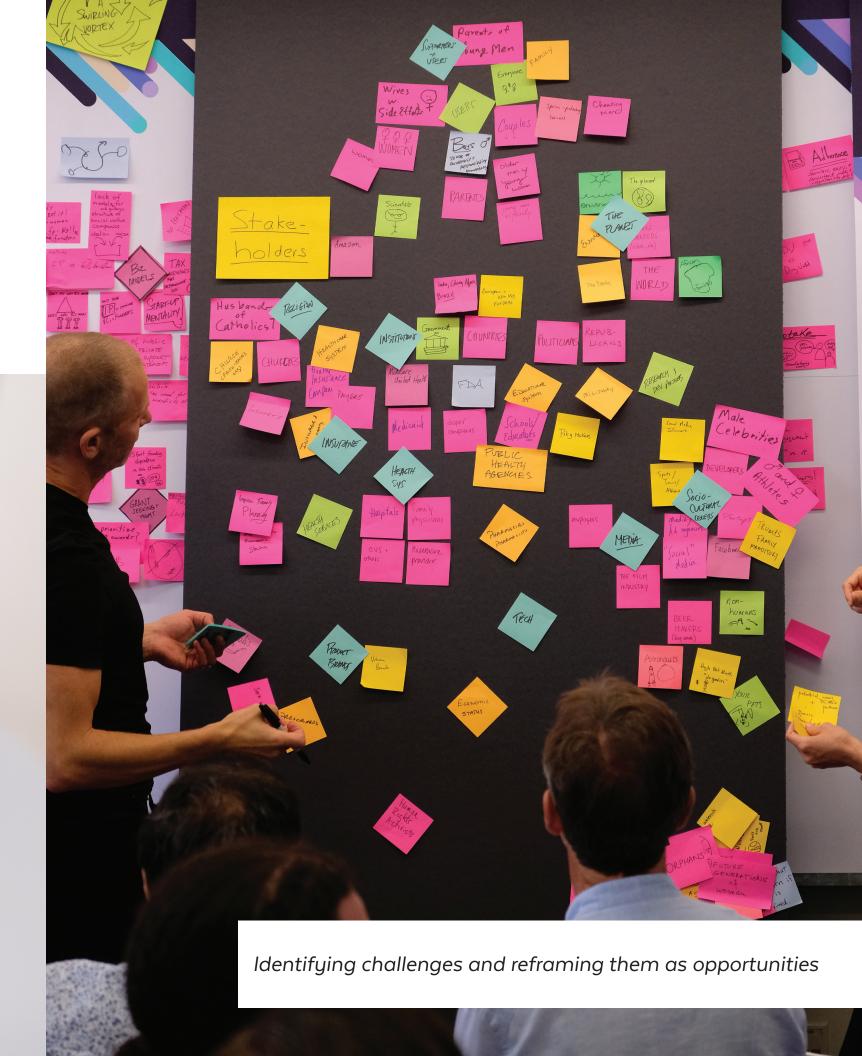
- scientific hurdles, such as understanding and overcoming the blood-testis-barrier
- regulatory challenges, like how there hasn't been a male contraceptive to set precedent for approval or process
- social stigmas that may impact uptake of eventual approved methods, including the fact that contraception has historically been viewed as a female responsibility

These challenges were grouped into larger categories, and themes began to emerge around challenges that impacted multiple steps of the pathway to market.

Stakeholders

Participants also took time to identify the stakeholders that need to be engaged in order to make male contraception successful. As with the challenges, stakeholders were sometimes specifically identified, such as the Catholic Church and the pharmacy chain CVS, but broader stakeholders were also identified such as environmentalists, female partners, and media outlets. These stakeholders were grouped into larger categories that also included venture capital, governmental institutions and health systems, as well as potential users and their partners.







North Stars

The North Star has been a means of direction and navigation for centuries. For the purposes of this event, we sought to identify our "North Star," or our guiding purpose. This meant having participants ask themselves two questions - "Which stakeholder is most important to me?" as well as "Which stakeholder is most important to get methods to market?" Here, participants began taking the first steps towards narrowing the focus of their purpose. Most participants selected "Users" as what was important to them, but then selected "Government and Foundation Funders / Venture and Investors." as being most important to get methods to market.



NORTH STAR





Fauxnique

Masculinity as a concept was a frequent discussion point throughout the workshop. Is contraception inherently a female concept, or is that a societal construction? What makes a man masculine, and would male contraceptives impact that narrative? An evening activity took participants to meet Monique Jenkinson, a performance artist who uses drag to explore the ideas of femininity and masculinity. Monique is a cisgender woman, who takes on the drag queen persona of Fauxnique to explore these concepts. Participants were able to watch Monique transform into Fauxnique as she explained the process and ultimate conversion between the two personas. Afterwards, participants explored their own ideas of masculinity and femininity through discussion and physical movement.







Roundtable: Taking Products to Market

The ultimate goal of male contraceptives is getting to market: where the average person has access to products that meet their unique contraceptive needs. Even though the pathway to market can look very different between healthcare sectors, there are lessons to be learned from past experiences. Christine Winoto of UCSF, Sherya Mehta of Zenflow, and Dennis Boyle of IDEO all joined for a roundtable to discuss the experience of bringing new healthcare products to market, and how to merge human need with clinical utility.



While the first day of the event was focused on identifying challenges, the second reminded us that every challenge is an opportunity. Day Two began by shifting the focus of activities towards identifying solutions by employing the How Might We approach. "How Might We" is a way to identify opportunities inherent in every obstacle by asking a simple question with three parts: How is the first section - it assumes there is a solution. It starts from a place of exploration. The next section, Might, encourages ambiguity and optimism - the solution doesn't have to be immediate or inside-the-box. The word also encourages the "yes, AND" mentality that fosters creativity. The final and most important piece is the We. The word "we" acknowledges that this is a team effort, and nobody has to go the road alone.



HMW Questions

To approach problems from a How Might We (HMW) standpoint, facilitators brought together outputs from the challenges and stakeholders activities, and with the North Stars in mind, began identifying how users might benefit from the opportunities inherent in the challenges presented. Then, facilitators began asking HMWs that could bring about concerted and sustained change that engaged key stakeholders. Some examples of HMWs included "How Might We create a support system for scientists so they can focus more on science," "How Might We position male contraceptives in the context of great and safe sex," and "How Might We give advocates of male contraception the quantitative and qualitative arguments for prioritizing male contraception."

After HMWs were grouped into categories, participants selected those that they felt were most important to answer, or that they felt could accelerate the time to market for male contraceptives.

How Might We? Outputs

HMW create a support system for scientists so they can focus more on science?

HMW align funders and grantees with shared goals and assessment to facilitate funding?

HMW separate

masculinity and

virility?

HMW help everyone in the male contraceptive community understand the lives, motivations and aspirations of target audiences?

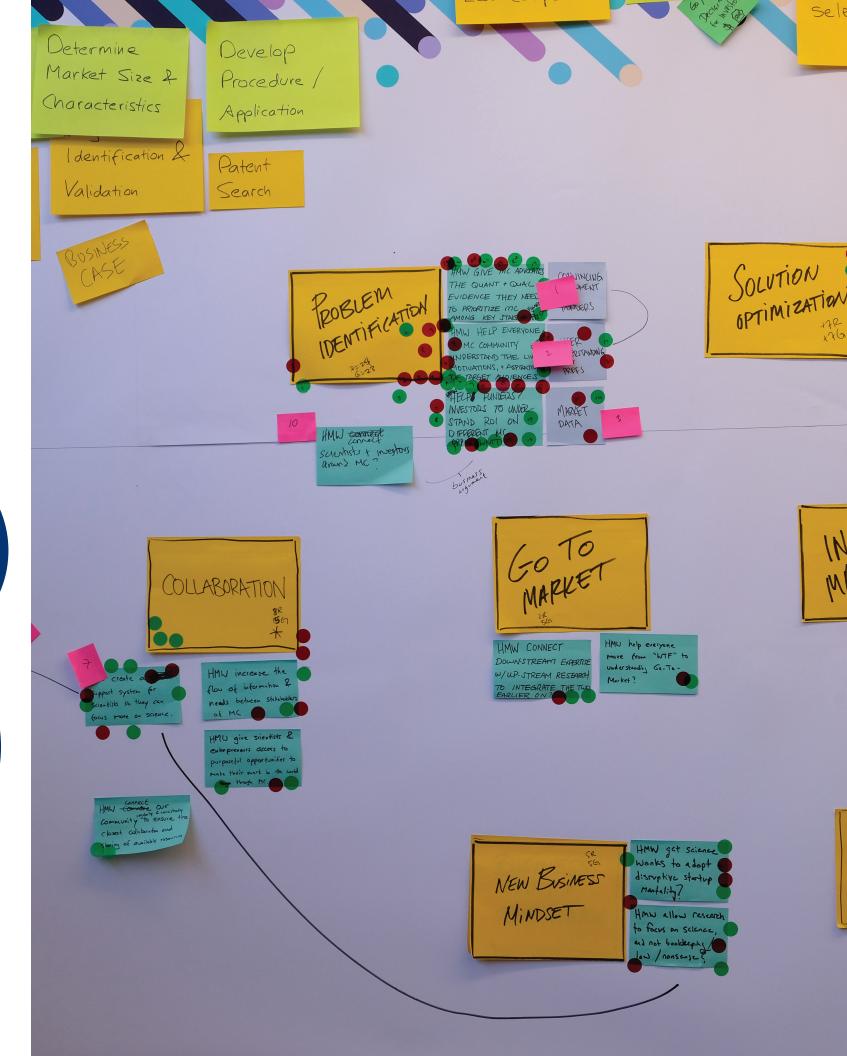
HMW give male contraceptive advocates the quantitative and qualitative evidence they need to prioritize male contraception among key stakeholders and funders?

HMW connect scientists and investors around male contraception?

HMW create and share a strategic vision for moving forward with male contraception? HMW position male contraceptives within the context of great and safe sex?

HMW help funders and investors to understand the return-on-investment in different male contraceptive opportunities?

HMW facilitate asynchronous, attributable "team science"?





Concept-ing

After formulating "How Might We" questions, participants were then asked to develop concepts as a means of addressing the identified challenges. Rough concepts were developed by brainstorming dozens of new ideas with a focus on speed and quantity as a starting point. This approach results in the generation of dozens of solutions, which are ultimately pared down but provide key insights into more refined concepts.

How might we position male contraceptives within the context of great and safe sex?

Some responses included branding of eventual products with pleasure and security, or combining non-contraceptive benefits such as multipurpose prevention technologies (MPTs) or Viagra within male contraceptives.

How might we give male contraceptive advocates the evidence they need to get male contraception prioritized among funders?

Some ideas brought together qualitative and quantitative data like peer surveys, economic analyses, and testimonials that placed the men at the center of the conversation and highlighted their needs and preferences.

These concept explorations were intended to be collaborative and exploratory. With a framework based on the concept that there is no such thing as a bad idea, the "yes, AND" mentality was apparent as other HMWs gathered ideas like partnerships with pornography distributors, male contraception TED Talk-like symposia, and petitioning for vasectomy coverage in the Affordable Care Act.

Basic concepts began to coalesce into general categories, which informed more actionable concepts to broad HMW questions. We might help everyone in the male contraceptive community to better understand the preferences, lives, and attitudes of target audiences by implementing social research programs like surveys, then communicating results with the researchers developing products, and building public outreach programs around the knowledge gained from these surveys.

Having brainstormed rough concepts and ways of tackling the HMWs, participants broke off into small groups and focused on some of the categories that were determined to be the most promising for the community to address. The concepts were intended to be descriptive, visual and to provide value to users.

Participants took these cleaned-up concepts and provided feedback as a group; improving, iterating, and adding features that would increase the value propositions for the target audiences. Ultimately, some of these concepts could see the light of day, and others provide a vision for how we might tackle big problems as a collaborative and unified group.

Two-way Survey

Data mining through social media channels to distribute virtual male contraceptive prototypes and get global feedback on the interest and profile of potential users.

"Little Black Book"

A dating app that verifies contraceptive use with both partners through gamification.

Sex & Vaccines

Using successful models of vaccine development to bring hormone-free contraceptives to market.

Male Contraception Stories

A campaign that increases public demand and support by communicating the motivations and desires of real men and their partners who want male contraceptives.

(S)teaming Ahead

A centralized grants administration that accelerates submission and access to critical research dollars for multi-disciplinary teams.

Impact Investment

Targeting investors seeking socially responsible opportunities through evidence that male contraception addresses issues such as overpopulation and simultaneously fills a market

MCI Global

A central, global NGO that coordinates male contraceptive stakeholders by connecting concepts and investors with advocacy and digital resources.

ROI Opportunity

A campaign that uses market research, public health engagement, market segmentation, as well as revenue models to engage funders and demonstrate the value of male contraceptives as a mid-range pharmaceutical product.

Connect & Align

A means of facilitating interactions between male contraceptive researchers, sharing goals and resources, and providing enhanced access to facilities and expertise for researchers that buy in to the system.

Statement Creation

A concise statement of a vision for hormone-free contraceptives that can be distributed for use with funders, grantors, and representative stakeholders.

Male Contraception Ubiquity

Using role modeling in media and pop culture to make male contraception aspirational and sexy.





Roundtable: Building a Platform

Concepts are a critical piece of the design process - they provide a jumping off point and allow thoughtful approaches to big problems that can be workshopped and modified. But eventually, concepts need to lead to action. Shalu Umapathy and Ridhi Arun of IDEO.org and Becca Carroll of IDEO's CoLab spoke with participants in a roundtable discussion about their experiences in building platforms for healthcare projects.



Collaborative Design (Platform Canvases)

Because getting male contraceptives to market is a collaborative effort, there has to be motivation for all stakeholders to remain engaged throughout path forward. Participants took thoughts from the roundtable, and built a Platform Canvas that imagined two participants – someone like them, and MCI – and designed a collaboration between them. What are the needs of each participant? What can they offer each other? What will they get out of the partnership? What are their hopes and fears? All of these items play into how MCI and others in the male contraceptive space can build collaborative relationships and encourage group thinking in a niche, small field.

Outputs

Broadly, there's a strong need for community in the male contraceptive space. Researchers are often siloed, working on projects with limited funds and time.

Bringing attention and organization to the field would allow collaboration, dissemination, and ultimately, progress.





Success Stories

A final exercise allowed participants to dream a little and get optimistic - a Mad-Libs-style activity told participants to dream of a time when one of their ideas took off. It asked them to detail when they knew a big moment in development was, and how they managed to make it happen. Optimism is key in solving any challenge, and the Success Stories gave participants a role and voice for impacting their own visions of success.

Reflection & Feedback

Before letting participants go and fly off into the world with new ideas, motivations, and relationships, they were asked to share some feedback from the event. What did they feel they got out of it? What concepts would they like to see come to life? Participants vocally asked for more networking and collaboration opportunities, and found the process of generating ideas using the HCD approach informative and useful.





Reflecting on a time well-spent together







Synthesis

While the workshop closed on Day 3, MCI and IDEO set to work on Day 4 to synthesize the results of the workshop. How might we implement some of these concepts? How can we build and impact the larger areas of opportunity within male contraception? A full day of synthesis and digestion resulted in the identification of target audiences that could be engaged in new ways, as well as action plans to address some of the concepts designed in Day 2 and maintain momentum towards addressing needs and challenges.







Key Takeaways & Learnings

Following the iterative process carried out by workshop participants, MCI and IDEO were able to identify nine focus areas to be addressed by the non-hormonal, reversible male contraceptive research and development community. Among these nine focus areas, six were identified as priorities. Among these six priority focus areas, three represented an overlapping theme of a need to develop a collaboration/support system for scientists.

Within these focus areas, ten specific needs for the field were identified. these needs were also narrowed down to four priority needs to address those that are most pressing, including:

- Connect MC scientists + investors
- Facilitate "Team Science"
- Create and share a strategic vision for moving forward with MC
- Give MC advocates the evidence they need to get MC prioritized among funders



Charting a Way Forward Together

MCI is working to address the identified priority needs through a mix of short-term programs and long-term implementations. Some pilot programs are in progress, such as a campaign that raises the long-term profile of male contraceptive awareness, "Team Science" communication programs, and shared resources to present the public and personal health benefits of male contraceptives to funders.

Harnessing the energy and collaborative engagement of an event like this is inspiring, and ensuring that the energy doesn't dissipate on return to the "real world" is an ongoing effort. MCI offered to take on the responsibility of being the centerpiece, and building a community to ensure momentum continues and facilitate continued collaboration. To support forward movement, the following distribution of roles is proposed:

MCI

- Brainstorm, track, and drive efforts to address the specific needs and focus areas identified during the workshop
- Serve as an administrative hub to establish a virtual community, disseminate information to the community, including TPPs, stock language for proposals, etc
- Work to identify key stakeholders that would benefit the community (e.g. entrepreneurs, donors, investors, etc
- Expand MCI's capability to serve as a central hub to the non-hormonal, reversible male contraceptive community and associated partners
- Coordinate meetings, webinars, and other events targeting specific areas of interest to the community
- Advocate for funding and support as a representative of the larger community of MC researchers

PARTICIPANTS

Continue to engage with the community in an open and collaborative manner
 Share experiences/learnings/documents via communication channels (Slack, shared online document storage, etc.) that are useful to others in the community (within comfortable limits with respect to proprietary information, of course).
 Share what hasn't worked -- these lessons are often more useful than knowing what has worked!

We believe that if we continue working together, we can facilitate change to move the development of non-hormonal, reversible, male methods of contraception forward faster!

- Heather, Logan, Kathryn, Kevin, and the MCI Board



About

MCI's mission is to facilitate research & development of male contraceptives for people around the world and to build awareness among researchers, donors and the general public about the demand for and status of novel male contraceptive methods.

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