

# Women's Health Innovation Opportunity Map 2023



50 High-Return Opportunities to Advance Global Women's Health R&D

The Women's Health Innovation Opportunity Map identifies 50 opportunities that are critical for catalyzing innovation to improve the health of women. We, the Innovation Equity Forum, urge stakeholders across the research and development ecosystem to draw inspiration from and act on these highlighted opportunities to advance equitable, high-return innovations for women's health.

## Background

Women's health is an underserved area for innovation, facing disproportionately low research and development (R&D) funding relative to its burden. A misconception predominates that women's health is restricted to women's reproductive years—disregarding the full life course and whole body; this must change. While stakeholders are beginning to address innovation gaps in women's health, including advancing sex- and gender-based training and gendered medicine, no coordinated agenda across sectors with a global focus exists to align their efforts.

To address this need, the Bill & Melinda Gates Foundation and the National Institutes of Health initiated an inclusive, consultative, cross-sector effort to generate a Women's Health Innovation Opportunity Map as a collaborative framework to advance women's health innovation. The Opportunity Map focuses on unmet needs in women's health, including female-specific health conditions, conditions that affect women disproportionately or differently, and conditions that are under-studied or under-resourced for women.

This Opportunity Map has three key components. First, it lays out nine broad **topics** of women's health innovation with unique challenges, needs, and objectives. For each topic, leading **opportunities** were identified based on their potential for impact, readiness to scale, innovation feasibility, focus on women's unmet health needs, and ability to improve health equity. Finally, specific **solution strategies** articulate actionable ways to realize each opportunity and create impact within the next 15 years. As such, the Opportunity Map provides a guide that stakeholders across the women's health ecosystem—from researchers to entrepreneurs, investors, government bodies, biopharmaceutical companies, civil

society, and more—can use to advance high-impact investments and initiatives to improve women's health, ultimately reducing morbidity and mortality and increasing well-being.

## Methodology

A Forum of over 250 experts and stakeholders—representing over 50 countries and diverse perspectives across various geographic regions and sectors that work in women's health—gathered to develop the Opportunity Map. Members convened monthly from January to July 2023 and were organized into 11 sub-committees that identified and developed opportunities within each topic. They evaluated these opportunities against five criteria (PRIME), generating scores that the members compared by scorer demographics. This consultative process culminated in July with the Innovation Equity Forum (IEF) convening, where Forum members and special guests gathered in-person and virtually for a hybrid meeting. During this event, participants engaged in information exchanges and participatory decision-making discussions. In topic-focused breakout groups, they delineated leading opportunities for inclusion in this report and formulated actionable solution strategies to realize each opportunity.

## Call to action

This Opportunity Map outlines a bold and actionable plan to address critical priorities for advancing women's health innovation. Publishing the Opportunity Map marks the first step to gather stakeholders in the R&D ecosystem and coalesce around impactful investments or important steps and opportunities needed to improve women's health.

**We call all innovators, influencers, and advocates from across the women's health R&D ecosystem to work together to realize the opportunities presented in this report, including:**







**1 | Commit to equitable inclusion, participation, and funding of women** across the R&D continuum, including embedding sex and gender considerations at all stages.

**2 | Invest in the areas of women's health innovation** highlighted in this report that address critical needs for diverse groups of women and have high return on investment potential, including financial returns and health and social benefits.

**3 | Create a partnership** with the objective to strengthen the R&D ecosystem across the full scope of women's health.

## Stakeholders in the women's health R&D ecosystem

The women's health innovation landscape includes stakeholders with diverse motivations and skillsets, representing different geographic regions, and possessing different forms of power and influence. Engaging them collectively as partners, and leveraging their individual strengths, will be key to building a robust and equitable R&D ecosystem for women's health.

Each opportunity in the report calls one or more of the following groups to action	Role in advancing women's health R&D
 <p><b>Communities and Community Organizations</b> represent patients, advocates, and healthcare professionals who are passionate about women's health. Health-focused civil society, non-governmental and advocacy organizations, implementing agencies, and media platforms often rally around specific diseases or conditions.</p>	Elevate the needs of diverse and underrepresented groups of women
 <p><b>Researchers and Academia</b> include a wide range of stakeholders, including academic researchers and institutes, public and private research centers, organizations that monitor the R&amp;D pipeline, journals and publishers, and entities responsible for establishing standards for R&amp;D professional education.</p>	Advance sex- and gender-informed research and practices throughout the R&D life cycle
 <p><b>Health Care Workers and Systems</b> include the stakeholders within health systems who contribute to the delivery of care such as frontline professionals, pharmacies, and support staff, as well as health system managers and professional associations. It also includes organizations dedicated to strengthening health systems, including program implementers, financiers of delivery and commodities, and others.</p>	Elevate R&D needs and opportunities tailored to specific service delivery settings, and work with partners to co-create solutions
 <p><b>Public and Philanthropic R&amp;D Funders</b> are the government, multilateral, and philanthropic institutions and financing mechanisms that fund women's health R&amp;D. Given their financial power, the strategies of these institutions have tremendous influence on the market for innovations.</p>	Invest in under-resourced areas, and work with partners to harmonize funding efforts
 <p><b>Private Sector</b> includes pharmaceutical and medical device companies, venture capital firms, startups, trade associations, and other businesses innovating for women's health R&amp;D. The fast-growing FemTech sector funds consumer products, digital health applications, and medical products and technologies designed for women's needs.</p>	Invest in untapped but high-return areas of women's health R&D, and elevate needs for de-risking innovation
 <p><b>Payors and Insurers</b> are third party entities that pay for women's healthcare, such as single payor public programs, socialized care, or private insurance providers. They may be organized at the national or subnational level.</p>	Prioritize the availability of solutions that address women's health needs
 <p><b>Regulatory and Standard-Setting Agencies</b> include institutional, national governmental, and multinational bodies responsible for regulating pharmaceuticals and medical products, establishing policies that influence healthcare purchasing and access for women, and providing R&amp;D oversight.</p>	Ensure sex- and gender-explicit frameworks are in place to guide other stakeholders toward a stronger pipeline of solutions that improve women's health

The full Women's Health Innovation Opportunity Map can be found here: <https://bit.ly/3PEcL20>

The Innovation Equity Forum was sponsored by the Bill & Melinda Gates Foundation and National Institutes of Health. The findings and conclusions contained within this document are those of the authors and do not necessarily reflect the positions or policies of the Bill & Melinda Gates Foundation, National Institutes of Health, or other participating organizations.

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# Improving women's health unleashes a powerful engine for change



By prioritizing resources and efforts along five criteria...

Potential for impact

Readiness

Innovation

Matters to women

Equity

...With four lenses in mind...

Serving the underserved

Sex and gender influences

Life course perspective

Quality of life and well-being

...We can advance opportunities to lay stronger foundations for equitable innovation...

## 1 | Data and modeling



1. Collect, harmonize, utilize, and **report granular data (qualitative and quantitative) for health elements and determinants** to inform prioritization, develop models, and innovate products for women's health across the life course.
2. Support **capacity to collect, harmonize, utilize, and report granular data** (qualitative and quantitative) for health elements and determinants to inform prioritization, develop models, and innovate products for women's health across the life course.
3. **Update and expand burden of disease metrics** to better account for sex and gender-related conditions, long-term sequelae, and socio-cultural gender biases (including input data gaps, disability weighting, and duration assumptions).
4. Identify and **fill data gaps related to calculating return on investment (ROI)** in women's health R&D, including economic models and ROI for disease-specific areas.
5. Develop approaches for **incorporating qualitative information and proxy indicators into models**, including unstructured narrative data.

## 2 | Research design and methodologies



1. Advance **sex- and gender-intentional research design and analysis** during all stages of research (including preclinical and clinical) to generate endpoints, outcome measures, and evidence relevant for women across the life course, and to evaluate heterogeneity of treatment effects by sex and gender.
2. Promote knowledge- and resource-sharing on the **preclinical and clinical research landscape in LMICs and other under-resourced settings** to strengthen research activities and promote collaborations that advance women's health.
3. Strengthen the use of **computational and bioinformatics modeling** (reducing the use of animal models) and machine and deep learning approaches to better understand the biological basis of diseases affecting women and inform product development, risk identification, and treatment approaches—including by leveraging existing datasets and unbiased common data elements.
4. Support **in vitro translational model development**—such as organoids and organ-on-a-chip systems—to ensure more extensive clinical and translational characterization of diseases, conditions, and differences by sex and gender.

## 3 | Regulatory and science policy



1. Ensure the implementation of **sex- and gender-intentional science policy frameworks** that cover all aspects of the R&D lifecycle for medical products and healthcare innovations—including ethical, legal, and societal implications—with harmonization and collaboration mechanisms to accelerate their development.
2. Require **legal and/or regulatory frameworks** covering all aspects of the R&D lifecycle for medical products and healthcare innovations to systematically apply **sex- and gender-intentional approaches and evidence at all stages of development** to drive sex- and gender-specific interventions (e.g., ensuring clinical studies capture relevant differences in disease trajectory and outcomes across sex and gender, including novel endpoints).
3. Require reporting and timely updates of **sex- and gender-specific outcomes in healthcare product labeling and package inserts**.
4. Advance data harmonization and standardization efforts to drive **sex-, gender-, and age-disaggregated post-market surveillance** with common indicators specific to women's health.
5. Assess and implement **regulatory and policy incentives** that will promote investment and address barriers and disincentives, to accelerate the pace and volume of development, de-risk R&D in women's health, ease market authorization, and improve access to innovations that improve women's health.

## 4 | Innovation introduction



1. Create robust and ongoing **data repositories to catalyze women's health product development** and accelerate the successful introduction of these products into new markets.
2. Establish **centralized innovation hubs** specifically focused on the design and commercialization of solutions for women's health and well-being.
3. **Improve pathways to market** for women's health solutions by accelerating commercialization, regulatory review, reimbursement, and access.
4. Create **new pathways to fund innovation**.
5. Support **market shaping approaches** that enable suppliers to develop innovations accessible in LMIC settings by incentivizing payors and market entry and addressing demand and scale issues.

## 5 | Social and structural determinants



1. Ensure that **women's needs and voices guide national and global research agendas** through broad representation and reflection of different communities.
2. Conduct a **global review of social determinants of health interventions** with an emphasis on those that focus on vulnerable populations of women; based on review, develop equitable standards for inclusion of social determinants of health considerations for women's health research.
3. Research the **intersectional impacts of gender roles, power dynamics, and economic agency** (e.g., decision-making, unpaid work) on women's health.
4. Increase **representation of women, sexual and gender minorities, and other marginalized populations in the review of research grants** in women's health R&D.
5. Research **traditional and cultural practices** that promote women's health outcomes and well-being.

## 6 | Training and careers



1. Create and implement resources for **educating the current and future research and healthcare workforce on women's health and sex and gender influences** on health.
2. Advocate among educational policymakers and institutional decision-makers for the **integration of women's health and sex and gender considerations into education and training**.
3. Investigate **barriers and enablers for the participation, progression, and leadership of women** in R&D, entrepreneurship, and healthcare careers, and use successful practices to create reference tools.
4. Establish **safeguards for women's rights** within countries globally to receive STEMM education and pursue STEMM, R&D, and entrepreneurship careers and leadership positions.
5. Enhance **men's allyship** to activate opportunities for women to pursue STEMM, R&D, and entrepreneurship careers and leadership positions.

...To benefit women across the spectrum of conditions that affect them uniquely, differently, or disproportionately...

## 7 | Communicable diseases



1. **Assess the burden of disease** and costs resulting from infections that affect women disproportionately or differently, including reproductive tract infections, infections in pregnancy, and pathogens with outbreak potential.
2. Stimulate R&D to explore **associations between microbes (pathogens, commensals) and conditions that primarily or disproportionately affect women**.
3. Develop and evaluate **vaccines and other prevention interventions** for infections that disproportionately impact women and evaluate maternal immunization to protect the mother-infant dyad.
4. Develop **improved diagnostic tests for STIs and other reproductive tract infections**, including affordable point-of-care and self-testing products.
5. **Expand therapeutic options for infections in women**, including during pregnancy and breastfeeding.

## 8 | Non-communicable and chronic conditions



1. Evaluate **sex- and gender-related differences in the evolution and presentation of cardiometabolic diseases** and responses to available therapies to inform the development of optimal prediction, prevention, screening, diagnosis, monitoring, and treatments for women, with a specific focus on ischemic heart disease, diabetes, and obesity.
2. Evaluate **sex- and gender-related differences in outcomes and responses to medications** (including chemoprevention, chemotherapy, immunotherapy, and targeted therapy) to inform the development of prevention strategies, screening and diagnostic tools, and treatments for lung, colorectal, and gynecological cancers.
3. Evaluate **sex- and gender-related differences in the evolution and presentation of neurological disorders** and responses to available therapies to inform the development of prevention strategies, screening, diagnostics, monitoring, and treatments for women, with a specific focus on dementia, migraine, and pain.
4. Develop prevention interventions, screening and diagnostic tools, and treatments that account for **sex- and gender-specific elements in mental health disorders** across diverse settings and across the life course, with a specific focus on post-traumatic stress disorder (PTSD), depression, and anxiety.
5. Evaluate **sex- and gender-related differences in the evolution and presentation of autoimmune disorders** and responses to available therapies to inform the development of prevention, screening, diagnosis, and treatment options for women, with a specific focus on systemic lupus erythematosus (lupus), rheumatoid arthritis, osteoporosis, and autoimmune thyroid diseases.

## 9 | Female-specific conditions



1. Investigate the **biological and external mechanisms of female gynecological health conditions** and develop tools and therapies for prevention, diagnosis, treatment, and non-invasive monitoring of conditions, including normal menstruation and disorders such as polycystic ovarian syndrome, endometriosis, adenomyosis, and fibroids.
2. Stimulate R&D on the **role of the vaginal microbiome** in health and illness and develop interventions to address vaginal dysbiosis and foster a low-risk vaginal microbiome.
3. Increase research on **prenatal, intrapartum, and postpartum conditions and risk factors associated with adverse maternal health outcomes** to enable the development of diagnostics, treatments, and prevention, including artificial intelligence/machine learning tools.
4. Investigate evidence gaps in understanding the **role of micronutrients**, including iron and folic acid, and their formulation for improving maternal outcomes.
5. Create and support **biobanks with diverse, linked milk and blood samples** that can be accessed for research, including assessing the safety of prescription and over-the-counter medication use during pregnancy and breastfeeding.
6. Develop **improved, accessible contraceptive technology** with fewer side effects and more prolonged efficacy.
7. Understand **how policies that influence reproductive care impact women's health** to support the development of new modalities for the full range of reproductive care.
8. **Optimize fertility potential**, including in males, by developing new, affordable diagnostic tools and treatments.
9. Develop **self-administered solutions and new biomaterials** such as mesh products and stem cells to support safe and effective treatment options for conditions such as urinary incontinence and prolapse in women.
10. Develop novel, evidence-based, and specific **diagnostics and treatments for symptoms of menopause**, such as hot flashes, insomnia, joint pain, mental health disorders, and genitourinary syndrome.



...Powered by global collaboration, knowledge sharing, and mutual commitment.



## 10 | Partnership for Women's Health R&D



1. Create a **partnership with the objective to strengthen the R&D ecosystem** across the full scope of women's health.



### Current State:

Nascent, under-resourced, and siloed field(s)

A partnership that spans the full scope of women's health R&D could unify fragmented approaches to addressing barriers across the R&D ecosystem:

1. Convene stakeholders across women's health R&D to advance the opportunities laid out in this report
2. Position women's health R&D as a priority within existing R&D partnerships and the broader health ecosystem
3. Define, implement, and share models, incentives, and accountability approaches for equitable R&D partnerships



### Future State:

Robust, well-funded, and equitable ecosystem