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

<table>
<thead>
<tr>
<th>Role in advancing women’s health R&amp;D</th>
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<tbody>
<tr>
<td><strong>Communities and Community Organizations</strong> 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.</td>
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<td><strong>Researchers and Academia</strong> 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.</td>
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<td><strong>Health Care Workers and Systems</strong> 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.</td>
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<td><strong>Public and Philanthropic R&amp;D Funders</strong> 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.</td>
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<tr>
<td><strong>Private Sector</strong> 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.</td>
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<tr>
<td><strong>Payors and Insurers</strong> are third party entities that pay for women’s healthcare, such as single payer public programs, socialized care, or private insurance providers. They may be organized at the national or subnational level.</td>
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<td><strong>Regulatory and Standard-Setting Agencies</strong> 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.</td>
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The full Women's Health Innovation Opportunity Map can be found here: [https://bit.ly/3PEcL20](https://bit.ly/3PEcL20)

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Improving women's health unleashes a powerful engine for change

By prioritizing resources and efforts along five criteria...

<table>
<thead>
<tr>
<th>Potential for impact</th>
<th>Readiness</th>
<th>Innovation</th>
<th>Matters to women</th>
<th>Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving the underserved</td>
<td>Sex and gender influences</td>
<td>Life course perspective</td>
<td>Quality of life and well-being</td>
<td></td>
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</tbody>
</table>

...With four lenses in mind...

...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).
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 strategies, screening, diagnostics, monitoring, and treatments 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