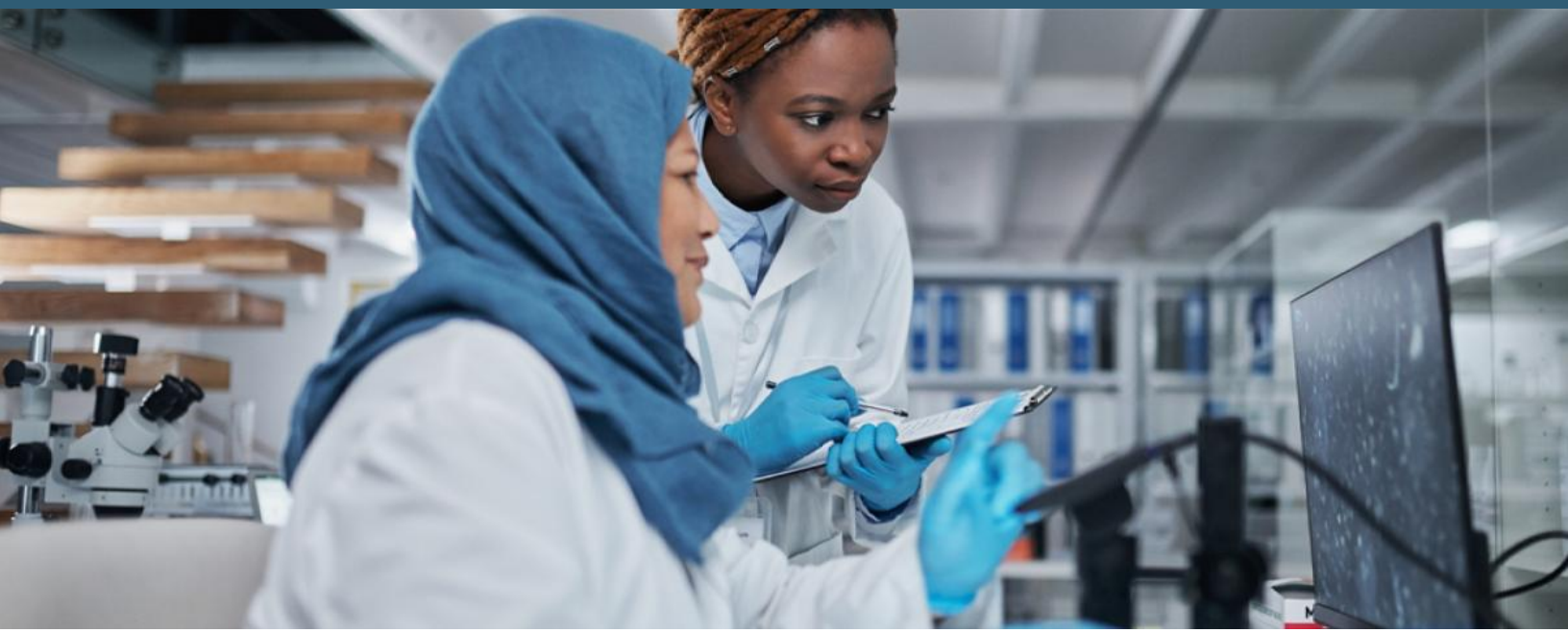


Women's Health Innovation Opportunity Map

2024 Progress Report

A report by Camber Collective, commissioned by the Innovation Equity Forum (IEF)

Executive Summary

Momentum for women's health innovation grew in 2024, fueled by increased advocacy, new partnerships, and growing funding commitments. However, persistent barriers in the cross-cutting systems that enable innovation continue to hinder progress.

Substantial strides were made in 6 of 50 high impact opportunities identified in the *2023 Women's Health Innovation Opportunity Map*: Innovation hubs expanded in both HICs and LMICs to accelerate solutions to improve women's health. Burden of disease and cost estimates improved through sex- and gender-intentional data practices, alongside ROI data that supported the case for investment. Breakthroughs in vaccines, diagnostics, and preventive measures addressed several communicable diseases, including STIs, RSV, and GBS, and the inclusion of pregnant and lactating individuals in tuberculosis clinical trials marked a pivotal step toward equity in research. Progress in female-specific conditions included new drug approvals for uterine fibroids and PCOS, while advancements in maternal health research delivered tools to improve outcomes for mothers and infants. In non-communicable diseases, a deeper understanding of sex- and gender-specific differences in cardiometabolic conditions has paved the way for more precise prevention, diagnosis, and treatment strategies.

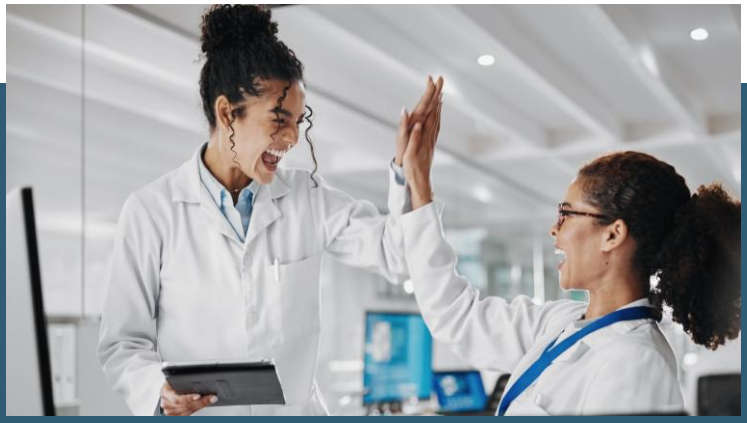
More modest progress was made across 33 additional opportunities, such as the medical institutions in some regions incorporating gender considerations into training curricula, improvements in sex- and gender-intentional research and regulatory frameworks, and discrete advancements in contraceptive technology, fertility optimization, menopause, autoimmune diseases, neurological disorders, and mental health. The remaining 11 opportunities stalled or experienced setbacks.

While 2024's advances give reason to celebrate, barriers in the cross-cutting systems that enable innovation continue to impede more significant progress toward developing solutions that improve the health of women. Notably, a lack of accountability for the systematic collection, analysis, and reporting of sex- and gender-specific data limits understanding of the true burden of women's health issues and the impact of interventions, impeding evidence-based decision-making. Gaps in ecosystem indicators prevent visibility into the breadth of the women's health R&D pipeline, particularly for conditions beyond sexual and reproductive health. Pathways to market remain a critical obstacle, particularly in LMICs, where barriers to accessing innovations are most pronounced. Compounding these challenges are deep-rooted societal and structural inequities that have historically limited women's participation and advancement in R&D careers. These inequities contribute to the ongoing attrition of women from the research field, stalling progress toward a more inclusive and representative research ecosystem. Finally, while promising funding commitments and partnerships have emerged, efforts remain fragmented.

Actionable Priorities for Key Stakeholders across the Women's Health Ecosystem

This progress report celebrates advancements made in 2024 and highlights areas where more concerted effort is needed. Four areas for immediate action stand out in their ability to accelerate progress for women's health innovation across conditions:

- **Close epidemiological and accountability data gaps**, including data on social and structural determinants and conditions beyond sexual and reproductive health to ensure innovations better address the diverse health needs of all women [*Opp. 1.2, 1.3, 5.2].*
- **Create new market pathways** and de-risk investment for women's health innovation *[Opp. 3.5, 4.3, 4.5].*
- **Enhance the participation and funding of diverse populations across the R&D continuum** to ensure that women's needs and voices guide national and global research agendas *[Opp. 5.1, 5.4, 6.3].*
- **Activate the IEF as an action and accountability engine** to translate opportunity areas to action and accelerate harmonized advocacy that unlocks new partnerships for women's health innovation *[Opp. 4.5, 10].*



The term "women" in the context of "women's health," is inclusive of both sex as a biological variable and gender as a social variable across the life course. This definition includes people assigned female at birth, transgender women and men, and non-binary people affected by the topics covered by the Opportunity Map. We recognize that not all people who identify as women have the same reproductive anatomy, and not all people assigned female at birth identify as women.

Ecosystem Progress

By strengthening the women's health innovation ecosystem, we can build on the momentum of the past year and build resilience to key challenges.

The last year has given us many reasons to celebrate. Substantial funding commitments have been made to women's health R&D, including $384 million invested in gender-equitable initiatives by Equity 2030 Alliance members,[1] the US ARPA-H Sprint for Women's Health allocating $110 million to innovation projects,[2] over $55 million pledged by members of the World Economic Forum's (WEF) Global Alliance for Women's Health,[3] and government actions like the UK FCDO's inclusion of women's health in research funding,[4] and Germany's establishment of a women's health research budget.[5] Interest in women's health innovation has steadily increased as private equity and venture capitalists recognize the potential in addressing unmet needs in women's health and there has been greater advocacy around the ROI for women's health innovation, including a new WEF report demonstrating the $1 trillion GDP opportunity of reducing the women's health gap by 2040.[6]

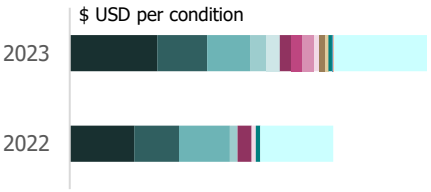
Despite this progress, significant hurdles remain. Only 1% of global healthcare R&D funding is allocated to female-specific conditions beyond oncology, and female-dominant conditions receive disproportionately low funding relative to their burden.[7] Data availability remains limited, and the innovation pipeline is hindered by gender biases throughout the R&D lifecycle, a lack of leadership diversity, and perceived market risk of women's health products. On the political stage there have been rollbacks in policies protecting women's rights.

To further strengthen the women's health innovation ecosystem and build resilience to these challenges, **future efforts will need to increase the visibility of women's health R&D within broader global and public health agendas, foster cross-sectoral and cross-discipline collaboration, and translate increased momentum into knowledge, solutions, and access.**

*Key indicators across the women's health innovation ecosystem (**Highlights**, **Lowlights**)*

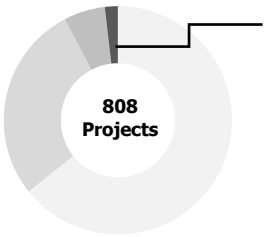
Product Development

$889 million in R&D funding dedicated to SRH globally in 2023 — an increase of $114M* from 2022[8]



**SRH funding was $656M in 2022. In 2023, $118M from 7 added SRH conditions was excluded to capture "real" growth.*

- STIs
- HPV
- Contraception
- Pre-eclampsia + eclampsia
- Preterm labour
- MPTs
- Menopause
- Endometriosis
- > one SRH issue
- Uterine fibroids
- PCOS
- PPH
- Maternal anemia
- Abortion
- SRH + another GH area

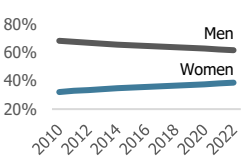


0.4% of pipeline R&D projects among 20 leading research-based pharmaceutical companies target reproductive, maternal, and neonatal health conditions — down from 0.9% in 2022[9]

- Non communicable diseases
- Communicable diseases
- Neglected tropical diseases
- Maternal & newborn conditions

Skills, Knowledge, and Networks

↑ **44% of organizations commit to regularly sex-disaggregate monitoring and evaluation** data in 2024 — up from 40% in 2023[10]

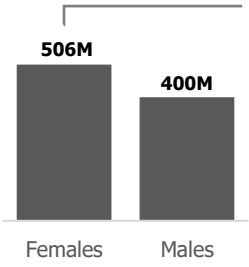


39% of STEMM researchers globally are women.[11]

Supply and Access

1 reproductive health product of 44 products added in 2024 to the WHO Prequalification List, used by international procurement agencies to guide distribution of safe, quality, effective products in resource-limited countries — down from 4 reproductive health products prequalified in 2023[12]

Health and Economic Impacts



- Years lived with disability, 2021

26% more time that women spend in poor health than men[13]

Opportunity Dashboard

Cross-cutting topic areas from the 2023 Women's Health Innovation Opportunity Map

1. Data and Modeling

New **reports on burden of disease and ROI, and new guidelines on data collection and reporting** but opportunities remain to harmonize efforts globally, expand burden of disease metrics, integrate SDOH into estimates, and leverage AI capabilities.

	Progress	Achievement
1.1. Granular data for health elements	▶	20%
1.2. Capacity to collect, harmonize, use data	■	0%
1.3. Updating burden of disease metrics	▶	20%
1.4. Filling data gaps for calculating ROI for WH	▶	20%
1.5. Incorporating qualitative info in models	■	20%

2. Research Design and Methodologies

Progress on **sex- and gender-intentional research globally and on translational model development** in the US, Europe, China, and India. Globally, there remains a lack of accountability and incentives to scale work long term or apply new technologies for WH.

	Progress	Achievement
2.1. Sex- & gender-intentional research design	▶	40%
2.2. Knowledge-sharing on pre-clinical and clinical research landscape in LMICs	▶	20%
2.3. Computational and bioinformatics modeling and machine learning	■	20%
2.4. In-vitro translational model development	▶	20%

3. Regulatory and Science Policy

Increased **application of sex- and gender-intentional policy and regulatory frameworks by select actors** but few standardized requirements for ensuring research diversity and reporting sex and gender outcomes in labeling.

Ensure consideration of sex and gender in:	Progress	Achievement
3.1. Science policy frameworks	▶	40%
3.2. Legal and regulatory frameworks	▶	20%
3.3. Product labeling and package inserts	■	20%
3.4. Post-market surveillance	▶	20%
3.5. Regulatory and policy incentives	▶	20%

4. Innovation Introduction

Emerging repositories, innovation hubs, increased funding, and government initiatives (e.g. Women's Health Index, Pakistan Innovation Hub, ARPA-H Sprint, etc.). Coordination and investment remain insufficient, and market shaping approaches are needed in LMICs.

	Progress	Achievement
4.1. Data repositories for product development	▶	40%
4.2. Centralized WH innovation hubs	⏭	40%
4.3. Pathways to market for WH solutions	■	20%
4.4. New funding for WH innovation	▶	20%
4.5. Market-shaping approaches for LMIC access	▶	40%

5. Social and Structural Determinants

Globally, efforts are underway to **incorporate SDOH and women's needs in research agendas** (e.g., MESSAGE project, PMNCH guidance on SDOH). Despite efforts, funding has not sufficiently supported research on SDOH and traditional and cultural practices.

	Progress	Achievement
5.1. Women's voices in research agendas	▶	20%
5.2. Standards for SDOH in WH research	▶	20%
5.3. Research on intersectional impacts on WH	▶	20%
5.4. Women and SGM in research grant review	■	0%
5.5. Research on traditional practices for WH	■	0%

6. Training and Careers

Advocacy, conversation, and research on the topic but limited implementation of training, mentorship, tools, and men's allyship beyond the US context. Some setbacks in female participation in OB/GYN field and in retention and longitudinal support for women in R&D.

	Progress	Achievement
6.1. Resources to educate workforce on WH	▶	40%
6.2. Integration of sex and gender in education	■	20%
6.3. Tools to support women's R&D careers	▶	40%
6.4. Safeguards for women's rights to STEMM	⏪	20%
6.5. Men's allyship for women's career paths	■	20%

Progress over the last year[1]

⏪ Set-backs ▶ Moderate ■ Unchanged ⏭ Substantial

Proximity to achieving opportunity[2]

0% 50% 100%

None Partial Fully

1 Defined as movement, conversations, and commitments that indicate the direction the field is moving within a given opportunity

2 Defined as the actual implementation and/or actualization of the opportunity area and/or associated solution strategies

Issue-specific topic areas from the 2023 Women's Health Innovation Opportunity Map

7. Communicable Diseases

Progress in the last year evidenced by **new guidelines and research on therapeutic and preventive options, inclusion of pregnant and lactating persons in trials, and improved, ready-for-market diagnostic tests**. However, outside HPV and maternal immunization, therapeutic options remain limited, especially for pregnant and lactating women.

	Progress	Achievement
7.1. Burden of disease and costs estimates	⏭	20%
7.2. Associations with microbes	▶	40%
7.3. Vaccines & prevention interventions	⏭	40%
7.4. Improved diagnostic tests for STIs	▶	40%
7.5. Expanded therapeutic options	▶	20%

8. Non-Communicable & Chronic Conditions

Advancements for conditions like diabetes, obesity, lung and ovarian cancer, migraines, and postpartum depression, continued progress in autoimmune conditions, neurological conditions, and PTSD, but less progress on colorectal cancer, anxiety, and menstrual migraines.

Evaluate sex- and gender-related differences in outcomes and responses to treatments for:

	Progress	Achievement
8.1. Cardiometabolic diseases	⏭	40%
8.2. Cancers	▶	20%
8.3. Neurological disorders	▶	40%
8.4. Mental health disorders	▶	40%
8.5. Autoimmune disorders	▶	20%

9. Female-Specific Conditions

Promising progress across opportunities, most notably:

Gynecological health: Approval of linzagolix for UF, evidence on artemisinin for PCOS, and development of single cell atlas for the human endometrium.

Vaginal microbiome: New publications on the vaginal microbiome and ongoing and new research on vaginal dysbiosis and the vaginal mucosa.

Ante/Intra/Postpartum conditions: New evidence on WHO intrapartum care model, treatment of PPH in LMICs, and use of AI-enhanced point-of-care ultrasound technology.

Contraceptive technology: Late-stage trials for male CT and notable commitments from governments, philanthropy, and the pharmaceutical industry around CT.

Fertility potential: Progress in HICs on endometrial biopsy technology, diagnostics, and AI, and new research to understand infertility in HICs and LMICs.

	Progress	Achievement
9.1. Mechanisms of female gynecological health	⏭	40%
9.2. R&D on the role of the vaginal microbiome	▶	20%
9.3. Research on pregnancy-related conditions	⏭	20%
9.4. Role of micronutrients on maternal health	▶	60%
9.5. Biobanks with milk and blood samples	▶	40%
9.6. Improved contraceptive technology	▶	60%
9.7. Reproductive care policy impact on WH	■	20%

9. Female-Specific Conditions (Cont.)

Menopause: Evidence on neurokinin 3 receptor antagonists as non-hormonal menopause treatment.

Despite advancements, significant challenges remain in scaling clinical trials to pregnant and lactating populations and LMICs, accelerating and addressing cost and access barriers for product introduction, and sustaining maternal and neonatal biobanks at a global scale.

	Progress	Achievement
9.8. Diagnostic tools and treatments for fertility	▶	40%
9.9. Self-administered solutions and new biomaterials	▶	20%
9.10. Novel diagnostics and treatments for symptoms of menopause	▶	20%

10. Cross-Sector Partnership

Globally, there are **several partnerships with some focus on women's health innovation and increased collective advocacy and momentum at global events**. However, there is no overarching partnership beyond the IEF with a remit to strengthen the women's health R&D ecosystem, and existing efforts remain uncoordinated, focus on problem identification over action, and lack equitable representation. While the IEF and GAWH are important conveners, they are not resourced to lead the field at a larger scale.

	Progress	Achievement
10.1. Partnership for strengthening WH R&D	▶	20%

Progress over the last year[1]

⏪ Set-backs ▶ Moderate

■ Unchanged ⏭ Substantial

Proximity to achieving opportunity[2]

0% — 50% — 100%

None — Partial — Fully

1 Defined as movement, conversations, and commitments that indicate the direction the field is moving within a given opportunity

2 Defined as the actual implementation and/or actualization of the opportunity area and/or associated solution strategies

Organization Highlights

The following examples, highlighted by the IEF, illustrate how stakeholders across the women's health R&D ecosystem are driving progress across Opportunity Map topic areas.

UK | The George Institute's Medical Science Sex and Gender Equity Project (MESSAGE) led a collaborative process to design a sex- and gender-intentional policy framework for UK biomedical funders and regulators.[1] The framework aims to ensure biomedical, health, and care researchers consider sex and gender throughout the research cycle. Aligned with the principles of the Women's Health Innovation Opportunity Map, the initiative prioritizes inclusivity and equity in health innovation. Four policy labs convened a diverse group of stakeholders — including researchers, people with lived experience, and medical regulators — to collaboratively tackle structural and methodological gaps in how sex and gender are factored into research. The effort has received broad support, with 32 public statements of support from UK medical research institutions holding ~£4.1 billion of medical research funding. MESSAGE plans to expand this work globally by working with local partners to adapt the framework within India's biomedical research sector and launching MESSAGE Publishing in partnership with Elsevier, BMJ, and other major journals.

Key stakeholder groups

- Community Organizations
- Researchers and Academia
- Regulatory Agencies

Opportunity Map areas

- 2. Research Design and Methods
- 3. Regulatory and Science Policy

Pakistan | Aga Khan University and Khyber Medical University are integrating sex and gender perspectives into medical training curricula in Pakistan.[2] The initiative will review pre-clinical and clinical curricula to identify gaps, develop a toolkit for incorporating sex and gender considerations into medical education, and pilot the toolkit, focusing on disease presentation, treatment, and decision making. The project will also create a resource to share lessons learned, enabling regional institutions to adopt best practices, enhance their curricula, and have a blueprint for more inclusive and equitable medical education in the region.

Key stakeholder groups

- Health Care Workers and Systems
- Researchers and Academia
- Private Sector

Opportunity Map areas

- 3. Regulatory and Science Policy
- 4. Innovation Introduction
- 6. Training and Careers

The Center for Economic Research in Pakistan and LUMS Centre for Entrepreneurship are launching a Women's Health Innovation Hub to address the gap in femtech startups in Pakistan.[3] The hub will foster partnerships with healthcare providers, government bodies, and investors, using human-centered design to develop culturally relevant, cost-effective solutions for women's health. Over a ~2-year cycle, the hub will support startups in achieving market readiness and sustainability and connecting entrepreneurs with mentors and partners to navigate the healthcare and startup landscapes.

US | GSK published a study on demographic diversity in their US-based interventional clinical trials.[4] The study revealed that epidemiologic data can provide more accurate benchmarks for enrollment than census data and found that women were well-represented in trials for female-specific conditions but underrepresented in trials for prevalent, non-female-specific conditions. The findings have prompted conversation within GSK and across the pharmaceutical industry on how to ensure representation of sex, gender, and race within clinical trials and how to prioritize the continued need not just for inclusion of women in trials, but analysis of data by sex and gender to enhance knowledge about women's health.

Key stakeholder groups:

- Private Sector

Opportunity Map areas:

- 2. Research Design and Methodologies

If you have organizational highlights you'd like to see featured in future reports, please share them with the corresponding authors.

The IEF co-sponsors advanced the Opportunity Map and reaffirmed their commitment to women's health, dedicating new funding to drive innovation in women's health products, technologies, and infrastructure.

NIH ORWH released two funding opportunities that prioritize research on Opportunity Map topic areas to address long-standing gaps in women's health research.

1. Notice of Special Interest (NOT-OD-24-079)[5] | This notice supports research that focuses on conditions that predominantly affect women, present and progress differently in women, or are female-specific.
2. Small Business Opportunities for Innovative Women's Health Research (SBIR/STTR)[6] | This program prioritizes investments in innovators and early-stage small businesses conducting research centered on women's health or on one of NIH's high priority topics, which correspond with the Opportunity Map. Small businesses with active SBIR and STTR awards can request supplemental funding (*PA-24-255*)[7] to enhance the diversity in the research and entrepreneurial workforce, further advancing equity and innovation in the field.

Key stakeholder groups

Public and Philanthropic R&D Funders

Opportunity Map areas

5. Social & Structural Determinants
7. Communicable Diseases
8. Non-Communicable Conditions
9. Female-Specific Conditions

In addition to committing $3.6 million to women's health innovation via the Global Grand Challenges mechanism,[8] the Gates Foundation developed an Upstream Sex and Gender Marker to better address biases across the R&D continuum.[9] This six-question learning tool is designed to help investment-makers identify and address sex and gender biases during the proposal design phase, complementing the Gates Foundation's existing Gender Integration Marker that focuses on service delivery. The new tool models the paradigm shift and best practices embodied in the Opportunity Map by advising that investments:

1. Are informed by gender-specific needs and preferences of end users.
2. Ensure sampling is representative of target populations.
3. Address gender barriers and promote equity in the R&D workforce.
4. Mitigate unintended gender-related consequences.

This new tool will standardize the integration of gender considerations into philanthropic R&D investments, making innovations more equitable and effective.

Key stakeholder groups

Public and Philanthropic R&D Funders

Researchers and Academia

Opportunity Map areas

1. Data and Modeling
2. Research Design and Methodologies

Acknowledgments

Much of the content included in this report was informed by Expert Advisory Groups (EAGs), who assessed progress and achievement for each of the 50 opportunities to accelerate women's health innovation. We extend deep gratitude to the EAG members, the IEF, and all dedicated researchers, innovators, advocates, and resilient women worldwide who champion health equity in their communities and beyond. This report was prepared by Camber Collective with grant support from the Gates Foundation. The findings and conclusions contained are those of the authors and do not necessarily reflect the positions or policies of the Gates Foundation, National Institutes of Health, or other participating organizations.

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The Opportunity Map issued a call to action in 2023, inviting innovators, influencers, and advocates from across the women's health innovation ecosystem to drive change within their organizations and fields:

- Commit to equitable inclusion, participation, and funding of women across the R&D continuum, including embedding sex and gender considerations at all stages.
- Invest in areas of women's health innovation highlighted in the Opportunity Map that address critical needs for diverse groups of women and have high potential for return on investment – and coordinate investment across government, industry, philanthropy, and others.
- Advance partnerships to strengthen the R&D ecosystem across the full scope of women's health.

This call remains as urgent as ever. The health and wellbeing of women everywhere is improved when we invest in sex- and gender-intentional R&D. The progress made since the launch of the Opportunity Map underscores the power of collaborative efforts in advancing women's health R&D — and only through such collaboration and intention can we realize equitable health outcomes for all.

Methodology

The Opportunity Map Progress Report was developed between August and December 2024. With an emphasis on learning and action, the report leverages a light-touch, efficient methodology to provide a snapshot of progress in the women's health innovation ecosystem and opportunity topic areas since the launch of the Opportunity Map in October 2023.

The goal of this report is to ensure that the Opportunity Map is not just a report, but an actionable guide for accelerating innovation that improves the lives of women everywhere

The report focuses on the following three objectives, each leveraging tailored data collection methods:

Women's Health R&D Ecosystem	Identify progress on key indicators across women's health R&D stages, aligned to the Opportunity Map results framework. Desk research of select data platforms (e.g., IHME, G-Finder) and IEF member survey
Opportunity Map Topics	Understand progress within and proximity to achieving each of the 50 opportunities in the Opportunity Map, including successes and challenges over the last year and remaining barriers. Survey and consensus-building meetings with Topic Expert Advisory Groups
Organizational Success Stories	Highlight case studies from selected partners that either demonstrate the adoption and use of the Opportunity Map or illustrate impactful efforts aligned with the Opportunity Map's ambition. IEF member survey to surface examples and qualitative interviews with selected partners

The process involved comprehensive consultation with over 100 experts across a diversity of geographic regions and industries within the women's health innovation field

Stakeholder Engagement Approach

The primary consultative body for this report was the Innovation Equity Forum (IEF), comprising over 250 diverse stakeholders from academia, healthcare, pharmaceutical companies, venture capital, startups, multilateral institutions, advocacy, and other sectors.

In August 2024, IEF members completed a survey to identify highlights and challenges in women's health innovation over the past year and recommend experts for advisory groups on each Opportunity Map topic area. From September to October 2024, Expert Advisory Groups (EAGs) were convened for each topic area. These groups consisted of 6-8 experts from various organizations, including the Gates Foundation, NIH, pharmaceutical industry, private sector, and non-governmental and community-based organizations from both HICs and LMICs. EAG members completed surveys assessing progress and achievement levels for each opportunity over the previous year. **Progress** is defined as commitments, guidelines, and other indicators of directional movement of the field for a given opportunity, while **achievement** is defined as the implementation of the opportunity and its associated solution strategies.

Following completion of the surveys, EAGs participated in 1-2 alignment meetings to review their collective responses, reconcile diverging opinions, and align on ratings for each opportunity. To address knowledge gaps and validate EAG inputs, supplemental desk review was conducted as needed. While this exercise leveraged a rating system, the process was ultimately a qualitative assessment of progress and achievement, with a quantitative scale (0 to 100%) used as an illustrative tool to facilitate the alignment discussions and understand progress relative to last year and to other opportunities.

The final stage involved sharing the progress report to the broader IEF to identify remaining gaps and validate EAG ratings.

What This Report is Not

An evaluation of the Opportunity Map. The purpose of this progress report is to better understand, build upon, and contribute to the knowledge base around concrete actions and opportunities within the field of women's health innovation — not to attribute progress directly to the Opportunity Map.

A comprehensive landscape of advancements in women's health innovation. This report did not include a systematic review of developments. Instead, it relied on the expertise and contributions of IEF members and partners, who represent a diversity of industries and geographies across the women's health innovation field.

Commitment to Adaptive Learning

This report represents an initial effort to identify and celebrate successes within women's health innovation, to maintain and build momentum, and to learn from one another about what drives success and where barriers remain. The methods used for any future progress tracking will continue to evolve to ensure that outputs meet the dynamic needs of the community and inspire action for lasting impact.

1 | Data and Modeling

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

1.1 | Collect, harmonize, utilize, and report **granular data for health elements and determinants** to inform prioritization, develop models, and innovate products for women's health.

- ✓ **Recognition of the need for more granular data is growing, as evidenced by new recommendations and data initiatives, especially in HICs,** including:
  - The World Bank Thematic Note on SOGI and Gender Equality in its Gender Strategy for 2024-2030[1]
  - EUI Widening Europe Programme-funded FEMETRICS project addressing gender data gaps across official statistics providers[2]
  - Release of the NASEM overview of research gaps in women's health research at NIH[3]
  - US government ARPA-H Sprint for Women's Health funding novel approaches to data collection, biomarker research, and diagnostic innovations,[4] and integration of SOGI into government data collection
- ❑ **More work is needed to standardize, collect, and integrate data on sex, gender, and social and structural determinants of health into routine and accessible data collection systems, especially in LMICs.**

1.2 | Support **capacity to collect, harmonize, utilize, and report granular data** for health elements and determinants to inform prioritization, develop models, and innovate products for women's health.

- ✓ Increasingly, **organizations are releasing RFPs and guidelines to collect more granular health data**, and numerous initiatives are collecting gender-informed health data. For example, the Department of Statistics Malaysia is institutionalizing gender data collection and analysis, including establishing interagency coordination mechanisms, improving data management techniques, and initiating a Gender Gap Index monitoring tool.[1]
- ❑ Overall, there **remains a lack of global coordination around sex and gender data harmonization** and a lack of resourcing for LMICs to build the capacity to collect and utilize granular data relating to women's health.

1.3 | **Update and expand burden of disease metrics** to better account for sex and gender-related conditions, long-term sequelae, and socio-cultural gender biases.

- ✓ In the last year, **IHME has undertaken a critical evaluation of the YLD framework for women's health conditions and is modeling proposed updates**, though none have been published or incorporated into the Global Burden of Disease Study yet. Additionally, new research sheds light on sex- and gender-related conditions and outcomes, including a Lancet systematic analysis of differences between females and males across the top 20 causes of global disease burden[1] and several publications in the last year highlighting the disproportionate burden of disease and costs for infections that affect women (see opportunity 7.1).
- ❑ **The current definition of DALYs continues to present challenges, as gender bias has historically informed definitions and data collection.** DALYs do not directly incorporate SDOH, and disability weights do not capture the full spectrum of social or emotional burdens.

1.4 | Identify and **fill data gaps related to calculating return on investment (ROI) in women's health innovation, including economic models and ROI** for disease-specific areas.

- ✓ **Recent work on ROI in women's health innovation** includes:
  - Impact Global Health G-FINDER project's expanded tracking of sexual and reproductive health R&D funding to include seven new conditions including maternal iron deficiency anemia, abortion, endometriosis, menopause, PCOS, uterine fibroids, and preterm labor[1]
  - WEF report on projected economic growth for investing in women's health[2]
  - UNFPA's WomenX Collective mobilizing US$100M for the adoption of advanced solutions, local capacity building, and evidence-based investment cases to scale women's health solutions[3]
  - UK NHS assessment of ROI for its women's health services[4]
- ❑ Despite progress, **current initiatives highlight the limitations of established databases and modeling tools.**

1.5 | Develop approaches for **incorporating qualitative information and proxy indicators into models**, including unstructured narrative data.

- ❑ Although generative AI capabilities have expanded broadly,[1,2] most research and initiatives in this field continue to be piecemeal and lack coordination. **Further efforts are needed to develop use cases, best practice guidelines, trainings, and templates** on how communities can leverage qualitative data for women's health applications, including in models.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

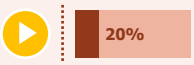
CIHR, Canadian Institutes of Health Research; **CPI, Center for Policy Impact; **EU**, European Union, **EUI**, European University Institute; **IHME**, Institute for Health Metrics and Evaluation; **MRC**, UK Medical Research Council; **NASEM**, National Academies of Sciences, Engineering, and Medicine; **NHLBI**, National Heart, Lung, and Blood Institute; **NHS**, NHS Confederation; **NIH**, National Institutes of Health; **VA**, Veterans Association; **WEF**, World Economic Forum*

2| Research Design and Methodologies

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

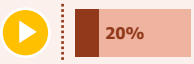
Progress | Achievement

2.1 | Advance **sex- and gender-intentional research design and analysis** during all stages of research 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.



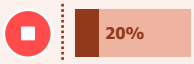
- ✓ **The WHO endorsed the Sex and Gender Equity in Research (SAGER) guidelines** and translated them into multiple languages, and endorsed the Guidelines for Accurate and Transparent Health Estimates Reporting (GATHER) — marking a major milestone in promoting sex- and gender-intentional research on a global scale.[1] Progress has also been observed from select actors across industries:
  - New guidance on diversity action plans to improve enrollment of underrepresented populations in clinical trials (US FDA)[2]
  - A new toolkit to increase recruitment of women veterans in large clinical trials (VA Health Services)[3]
  - Development of a business case for a women's health research institute (The Royal Women's Hospital)[4]
  - Development of a global multi-stakeholder collaborative to integrate the patient perspective throughout the R&D lifecycle (The Synergist)[5]
- ❑ Globally, there remains **insufficient education, advocacy, and resourcing for researchers to implement sex and gender analyses in research**. Select champions and cross-functional teams exist, but there are few pathways **to incentivize work globally at a broader scale.**

2.2 | 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 innovations.



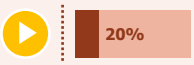
- ✓ **Some progress in sub-Saharan Africa,** including a Concept Foundation project mapping research sites that can conduct regulatory level trials in maternal health.[1]
- ❑ Despite concentrated efforts, **few initiatives focus on supporting LMICs over the long term** (e.g., helping train LMIC researchers, establishing regional hubs or negotiation platforms to support research funding, or incentivizing increased biotech presence). Furthermore, **some grants require principal investigators to be affiliated with institutions in North America, limiting resource opportunities**.

2.3 | Strengthen the use of **computational and bioinformatics modeling** 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.



- ✓ The Global Initiative on AI for Health, launched by WHO, ITU, and WIPO in 2023, produced **guidance on regulatory considerations, ethics, and governance** for using AI for health.[1] In Africa, The Human Heredity and Health in Africa (H3Africa) initiative has contributed substantial infrastructure and training since 2010, and though its projects concluded in 2023, other efforts are underway to **expand on genomics capacities on the continent**.[2] Additionally, the Gates Foundation announced $30 million to fun a new AI platform in Africa that will support scientists and innovators in developing safe, equitable technology.[3]
- ❑ However, achievement overall has been limited given **lack of infrastructure, coding and quality standards, and multi-country databases** globally to strengthen computational and bioinformatics modeling, particularly with women's health applications.

2.4 | 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.



- ✓ Advances in technology over the last year include:
  - **Advances in microfabrication, 3D bioprinting, tissue sensors, bioengineering, and biobanks**,[1] which have led to the development of human disease models with high clinical biomimicry and predictability to help unravel disease mechanisms, particularly infectious, genetic diseases, and cancer.
  - **Advancements in in-vitro translational model development across several organizations in the US, Europe, Asia, and South America,** particularly in organoids and organ-on-a-chip systems: Wyss Institute for Biologically Inspired Engineering (Harvard University),[2] The Institute for Stem Cell Biology and Regenerative Medicine in India,[3] and more.[4,5] Hospital Británico is creating an institutional biobank of tissues, liquid samples, and organoids to advance translational research.
- ❑ While technologies are advancing, they are **not consistently leveraging sex as a biological variable, and their use for female-specific conditions remains nascent**.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

**EMBL, European Bioinformatics Institute; FDA, Food and Drug Administration; NIH National Institutes of Health; VA, Veterans Administration*

3 | Regulatory and Science Policy

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

3.1 | Ensure the implementation of **sex- and gender-intentional science policy frameworks** that cover all aspects of the R&D continuum for medical products and healthcare innovations with harmonization and collaboration mechanisms to accelerate their development.

Progress: Moderate | Achievement: 40%

- ✓ In the last year, new international **guidelines and government policy frameworks** have been released that require consideration of sex and gender differences in medical products and healthcare innovations, including:
  - **Europe:** NIHR's statement of intent on integrating sex and gender in health and care research,[1] the proposed NHS constitution revision focused on sex and gender reassignment,[2] and Ireland DOH's inclusion of a gender lens for policy processes in its Women's Health Action Plan for 2024-2025[3]
  - **Australia**: The NHMRC's statement on improving representation and consideration of sex and gender throughout the research process[4]
  - **Africa**: 2024 International Women's Day policy dialogue hosted by the AU calling for inclusive policies, innovations, and research[5]
- ❑ Despite progress, more work is needed to **develop and implement frameworks in LMICs** and **HICs** to reduce the risks of rollbacks.

3.2 | Require **legal and/or regulatory frameworks** covering all aspects of the R&D continuum 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.

Progress: Moderate | Achievement: 20%

- ✓ There are existing legal and regulatory frameworks across major regulatory bodies that cover the R&D continuum for medical products and healthcare innovations. **Over the last year, only a few bodies in have attempted to apply sex- and gender-intentional approaches within their frameworks** (e.g., Swissethics' recommendations for including sex and gender in ethical review of research projects,[1] the FDA's update of their Women's Health Research Roadmap[2] and new Diversity Action Plans for Clinical Studies,[3] National Academies' report on the real and perceived risks of legal liability of conducting research with pregnant and lactating people,[4] and South Africa adding a special section on women in its 2024 update of its Ethics in Health Research Guidelines[5]).
- ❑ More efforts are needed on this opportunity from **major regulatory actors in LMICs**, and **there is a need globally to identify a committee or working group** that can focus explicitly on women's health R&D regulatory frameworks, tools, and guidance documents.

3.3 | Require reporting and timely updates **of sex- and gender-specific outcomes in healthcare product labeling and package inserts**.

Progress: Unchanged | Achievement: 20%

- ✓ There are **some efforts globally**, including IMI ConcePTION,[1] Gravitate Health,[2] and the CAMT guidelines on perinatal medication regimens.[3]
- ❑ Despite requirements on some products, and encouragement by some national regulatory bodies, there are **no known consistent national or global requirements for reporting sex and gender specific outcomes** in labeling.

3.4 | Advance data harmonization and standardization efforts to drive **sex-, gender-, and age-disaggregated post-market surveillance** with common indicators specific to women's health.

Progress: Moderate | Achievement: 20%

- ✓ Over the past year, **only a few major actors have attempted to advance data harmonization and standardization efforts to drive sex-, gender-, and age disaggregated post-market surveillance,** e.g., AMA Manual of Style's call for public review and comment on its "Draft Guidance on Reporting Gender, Sex, Gender Identity, Sexual Orientation, and Age in Medical and Scientific Publication,"[1] IMDRF's common data set for exchanging data on adverse events related to medical devices[2] and guiding principles to support medical device health equity,[3] funding from the FDA related to its OWH Women's Health Research Roadmap including strengthening post-market surveillance and labeling,[4] and the launch of the GAWH and its advocacy platform for policy and regulatory changes.[5]
- ❑ However, **harmonization is not occurring at a global level,** nor is there a mechanism for ensuring regulations and guidance are routinely amended to incorporate emerging best practices.

3.5 | 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.

Progress: Moderate | Achievement: 20%

- ✓ **There has been progress on implementation of incentives, particularly from the US government** (e.g., US federal commitments[1] to incentivize research across the R&D continuum and across an array of investigators). Globally, the biopharmaceutical industry recently produced an open letter to G20 health ministers in support of reimbursement policies for innovative treatments addressing women's health.[2]
- ❑ Despite progress there are **limited regulatory and policy incentives which ensure investment in diverse investigators, sponsors, and innovators,** including for research in LMICs.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

***AU**, African Union; **EFPIA**, European Federation of Pharmaceutical Industries and Associations; **FDA OWH**, Food and Drug Administration Office of Women's Health; **GAWH** Global Alliance for Women's Health; **IMDRF**, International Medical Device Regulators Forum; **JAMA**, Journal of the American Medical Association, **NHMRC**, The National Health and Medical Research Council; **NHS**, NHS Confederation; **NIH ORWH**, National Institutes of Health Office of Research on Women's Health; **NIRH**, National Institute for Healthcare Research; **SWHR**, Society for Women's Health Research*

4 | Innovation Introduction

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

4.1 | Create robust and ongoing **data repositories to catalyze women's health product development** and accelerate successful introduction of products in new markets.

Progress: Moderate | Achievement: 40%

✓ Over the past year, **new market research has underscored the importance of advancing women's health product development**, including the WHAM Report's case for funding women's health research[1] and the WEF's analysis of the women's health gap.[2] **Furthermore, several global repositories of representative data on women's health conditions are available** and routinely updated, including:

- WHO **Health Inequality Data Repository**, which shows how health is experienced by people of different sexes[3]
- Hologic's **Global Women's Health Index**, an index of key women's health metrics built on national-level surveys across 143 countries[4]
- Impact Global Health's **G-FINDER database**, which expanded its scope for tracking investments in sexual and reproductive health R&D[5]

❑ Despite these efforts, a **comprehensive global reporting platform specifically for healthcare professionals still lacking**. Additionally, there are **no established systems or tools for systematically collecting, quantifying, and publishing data** on the impact of diseases and conditions that disproportionately affect women's health **or for systematically capturing medical data,** including molecular (biobanks), clinical (hospital real-world evidence), and electronic medical records.

4.2 | Establish **centralized innovation hubs** specifically focused on the design and commercialization of solutions for women's health and well-being.

Progress: Substantial | Achievement: 40%

✓ Significant strides have been made in **establishing women's health innovation hubs globally**. Notable examples include:

- **Pakistan**: CERP and the LCE were recently awarded a WHI Grand Challenges grant to establish an innovation hub aimed at supporting startups that create accessible and effective health solutions for women in underserved, low-income communities[1]
- **India**: Since its launch in 2022, Femtech India, the country's leading platform for innovation and collaboration in the Femtech sector, has gained substantial momentum; key developments include partnerships with UNFPA and a new collaboration with Flo Health[2]
- **UK**: The UK government has outlined its strategy for implementing a £25 million investment to support commissioners, providers, and other partners to establish women's health hubs, particularly integrated care boards[3]
- **US**: The ARPA-H Investor Catalyst Hub connects researchers, entrepreneurs, and investors to accelerate healthcare solution development[4]
- **Germany**: Investments have been made in Center of Excellence Women in Science, laying the groundwork for more focused innovation[5]

❑ Despite progress, **several regions in LMICs have no established innovation hubs for women's health**. Additionally, while existing hubs have made progress, their **scope remains narrower than the broad vision outlined in the Opportunity Map**.

4.3 | Improve **pathways to market for women's health solutions** by accelerating commercialization, regulatory review, access, and reimbursement.

Progress: Unchanged | Achievement: 20%

❑ Globally, **progress in creating streamlined pathways for women's health indications has been slow.** Challenges remain in navigating regulatory, supply chain, and reimbursement systems, which continue to discourage investment and restrict access to new, innovative products.

4.4 | Create new pathways **to fund innovation**.

Progress: Moderate | Achievement: 20%

✓ There have been several **private and public funding commitments for women's health innovation over the last** year, such as:

- **Venture capital:** VC investments in women's health remained steady (2% of $41.2B) amid overall decreases in health investment[1]
- **Government funding:** $110 million for WH innovation projects via ARPA-H Sprint [2] and $8M awarded via NIH RADx for Maternal Health[3]
- **Philanthropic**: $3.6 million awarded via the Global Grand Challenges awards for women's health innovation[4]

❑ Despite advancements, **women's health remains underfunded**, with the available resources falling short of addressing unmet need. There is an urgent need to **mobilize existing commitments and explore innovative solutions** (e.g., tax incentives, pooled funding, etc.).

4.5 | Support **market-shaping approaches** that enable suppliers to develop innovations accessible in LMICs by incentivizing payors and market entry and addressing demand and scale.

Progress: Moderate | Achievement: 40%

✓ Several market-shaping successes have been achieved in recent years, particularly in FP and HIV. In the past year, key advancements include:

- **Gavi's launch of the AVMA** to support the sustainable growth of Africa's manufacturing base[1]
- **CHAI's expansion of affordable HIV/Syphilis dual rapid diagnostic tests** via partnerships with MedAccess and WHO[2]
- **MedAccess' support in increasing access to malaria testing** through a volume guarantee agreement with SD Biosensor[3]

❑ Despite advancements, globally there remains **no market-shaping strategy specifically for women's health solutions.**

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

***AVMA**, African Vaccine Manufacturing Accelerator; **ARPA-H**, Advanced Research Projects Agency for Health; **AVMA**, African Vaccine Manufacturing Accelerator; **CERP**, Centre for Economic Research in Pakistan; **FDA**, Food and Drug Administration; **FOGSI**, Federation of Obstetric and Gynecological Societies of India; **LUMS**, Lahore University of Management Sciences; **MOGS**, Mumbai Obstetric and Gynecological Society; **NICL**, National Incubation Center Lahore; **WEF**, World Economic Forum; **WHAM**, Women's Health Access Matters; **WHO**, World Health Organization*

5 | Social and Structural Determinants

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

5.1 | Ensure that **women's needs and voices guide national and global research agendas** through broad representation and reflection of different communities.

Progress: Moderate | Achievement: 20%

- ✓ Globally, **efforts are underway to increase women's needs and voices** in research agendas, such as:
  - NIH's Women's Health Awareness Community Engagement Program, which implements projects **prioritizing voices of U4 women (underrepresented, studied, reported, and served)**[1]
  - The commitment to **enhancing recruitment, enrollment, and retention of women in clinical trials** in the 2024 US White House Executive Order on Women's Health Research[2]
  - MESSAGE project inclusion of PWLE of different sexes and gender identities in design of a policy framework for UK biomedical research[3]
  - IDRC's call for research **proposals that focus on neglected SRHR conditions and populations** in sub-Saharan Africa[4]
  - **Prioritization of projects led by women/women-led organizations and LMIC institutions** in the Grand Challenges funding call[5]
- ❑ Despite this, **disparities in women's representation in research agenda-setting still exist** across and within regions and countries.

5.2 | 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.

Progress: Moderate | Achievement: 20%

- ✓ Attention and efforts over the last year to review and develop guidelines for SDOH include:
  - WHO PMNCH's **scoping review on how SDOH affect women's health outcomes** in LMICs[1] and **new guidance on monitoring SDOH**[2]
  - USAID's **literature review and brief** outlining how policymakers, health system practitioners, and development partners in LMICs can apply a SDOH lens in health systems strengthening efforts[3]
  - Royal Women's Hospital's new **Social Model of Health Research Centre** focused on SDOH research[4]
  - Four Clinical and Translational Science Award hubs in Texas aimed to **understand what contextual-level, centralized SDOH datasets are offered** and which individual-level SDOH are collected in structured fields in each electronic health record (EHR) system[5]
- ❑ Despite progress, **ongoing efforts are needed to convene partners and to develop widely accessible repositories** that support inclusion of SDOH more systematically in healthcare and research policies.

5.3 | Research the **intersectional impacts of gender roles, power dynamics, and economic agency** (e.g., decision-making, unpaid work) on women's health.

Progress: Moderate | Achievement: 20%

- ✓ New funding and research efforts have advanced in this area over the last year such as an NIH NOSI for research examining **health influences of gender as a social and structural variable**,[1] a Lancet analysis of **equity-informed interventions in maternal health,**[2] and review of multi-country **research programs focused on intersectionality**, gender norms, and adolescents.[3]
- ❑ However, there are **few longitudinal or comparative studies** on this topic in HICs and LMICs, **limited examination of digital advancements** in this area, and few efforts to **validate measures** of SDOH.

5.4 | Increase **representation of women, sexual and gender minorities (SGM), and other marginalized populations in the review of research grants** in women's health R&D.

Progress: Unchanged | Achievement: 0%

- ✓ **New research has advanced our understanding of the importance of increasing representation** of women, SGM, and other marginalized populations in grantmaking for healthcare research.[1]
- ❑ Despite acknowledgement and attention, very few research and funding agencies **convene review panels that include researchers from diverse backgrounds or provide sufficient training** for community members to participate in the review of research grants.

5.5 | Research **traditional and cultural practices** that promote women's health outcomes and well-being.

Progress: Unchanged | Achievement: 0%

- ✓ Within LMICs and certain communities in HICs, there is an understood importance of traditional and cultural practices, with growing recognition from the global community, evidenced by the **WHO holding the first global summit on traditional medicine in 2023**.[1]
- ❑ Despite increased awareness, **funding has not sufficiently materialized to support research** in this domain, and progress continues to be hindered by preference for the Western biomedical model.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

IDRC, International Development Research Centre; **NIH WHACEP**, NIH Women's Health Awareness Community Engagement Program; **USAID**, US Agency for International Development; **PMNCH**, Partnership for Maternal, Newborn, and Child Health; **WHO**, World Health Organization*

6| Training and Careers

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

6.1 | 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.

Progress: Moderate | Achievement: 40%

- ✓ Over the past year, there has been a **growing sense of urgency for expanding educational resources in women's health, with institutions in the US and Pakistan launching new programs over the last year,** such as: Mayo Clinic's Transforming Women's Health course, which provides education in women's health research and clinical practice[1]; UCSF's program addressing preventive care and reproductive health, and clinical approaches to diagnosing and treating common gynecologic and medical disorders[2]; NPACE's Women's Health Bundle, which includes seven essential courses for healthcare providers in women's health and primary care[3]; Texas Tech's Sex and Gender Specific Health Curriculum, which emphasizes the importance of considering sex and gender differences in healthcare[4]; Stanford's Women's Health & Sex Differences in Medicine Seed Grants, designed to support researchers to strengthen applications to major funding bodies like the NIH[5]; and the Grand Challenges award to AKU and KMU to integrate sex and gender perspectives into their medical training curricula.[6]
- ❑ Despite the urgency and the emergence of new initiatives, **funding for training and education in women's health remains scarce globally.** Additionally, there is a need to integrate sex- and gender-informed educational content into curricula and training across all healthcare and R&D-related fields and across the continuum of learners and develop metrics to track integration.

6.2 | Advocate among educational policymakers and institutional decision-makers for **integration of women's health and sex and gender considerations into education and training**.

Progress: Unchanged | Achievement: 20%

- ❑ Globally, there **remains an overall lack of teacher training, limited time allocated for teaching gender issues, insufficient financial incentives, and few medical school accreditation standards that incorporate women's health and sex and gender considerations**. Over the past year, there has been little progress in developing or implementing a comprehensive advocacy toolkit to integrate these critical issues into education and training. While some advocacy efforts are in motion, they remain fragmented, narrowly focused on specific conditions, and lack coordination, while the growing politicization of women's health — especially in the US and South America — further complicates efforts to gain support from educational policymakers and institutional leaders.

6.3 | 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.

Progress: Moderate | Achievement: 40%

- ✓ Significant progress has been made in addressing the structural inequities and barriers that limit women's participation, advancement, and leadership in healthcare and R&D fields. Key developments include **new publications that deepen the understanding of obstacles to women's career progression** across regions such as the US, Europe, SSA, and the Middle East (e.g., the WEF Global Gender Gap Report,[1] which highlights health-related gender disparities, and an Elsevier report on gender equality in research and innovation[2]). In addition, **new RFPs for women's health innovation** — such as those from Grand Challenges[3] and NIH NOSI[4] — explicitly target barriers and enablers of women's leadership in R&D, while **entrepreneurship programs** like the AWIDH in SSA,[5] the Africa Young Innovators for Health Award,[6] and emerging femtech hubs in India and Pakistan[7,8] are helping to mentor the next generation of women leaders in medicine and femtech.
- ❑ However, despite growing recognition of the intersectional impacts of gender roles, power dynamics, and economic agency, **progress has been limited in establishing baseline standards for re-entry and family leave policies and other structural barriers across countries**. Cultural norms and stereotypes about gender roles continue to impede efforts to create more inclusive and equitable policies.

6.4 | Establish **safeguards for women's rights** within countries globally to receive STEMM education and pursue STEMM, R&D, and entrepreneurship careers and leadership positions.

Progress: Set-backs | Achievement: 20%

- ❑ In many regions, there have been significant setbacks, including the **dismantling of key institutions** such as Argentina's Ministry of Women,[1] a marked **decline in female applicants to OB/GYN programs** in the US,[2] and a **drop in senior MD residency applicants in US states with abortion bans**.[2] Furthermore, progress in improving access and retention for women in R&D has been limited, with few laws or regulations in place to safeguard women's opportunities in STEMM fields. Even fewer laws exist that effectively support women's career advancement, and those that do remain inadequately aligned and enforced across national, state, local, institutional, and organizational levels.

6.5 | Enhance **men's allyship** to activate opportunities for women to pursue STEMM, R&D, and entrepreneurship careers and leadership positions.

Progress: Unchanged | Achievement: 20%

- ✓ There has been **growing awareness and introduction of male allyship initiatives in the US** (e.g., OSU's Advocates and Allies for Equity program[1] and inclusion of male allyship at the Big Ten Academic Alliance for Women in Medicine and Biomedical Science Conference[2]).
- ❑ However, on a global scale, there has been **limited adaptation of these programs to different contexts**.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

** **AYI,** African Young Innovators; **AKU**, Aga Khan University; **KMU**, Khyber Medical University; **NIH**, National Institutes of Health; **NPACE**, Nurse Practitioner Associates for Continuing Education; **UCSF**, University of California San Francisco; **WEF**, World Economic Forum; **WDHI**, Women in Digital Health Initiative*

7 | Communicable Diseases

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

7.1 | Assess the burden of disease and costs resulting from infections that affect women differently or disproportionately, including RTIs, infections in pregnancy, and pathogens with outbreak potential.

Progress: Substantial | Achievement: 20%

- ✓ In the past year, **several publications have highlighted the disproportionate burden of disease and costs for infections that affect women**, including: a forecasting analysis for the *Global Burden of Disease Study* covering 204 countries, projecting the impact of malaria, TB, STIs, and others (*Lancet*)[1]; a comprehensive analysis of disease burden in infections among pregnant women across 131 LMICs (*JGH*)[2]; a systematic review of the economic burden of UTIs (*JMIR*)[3]; evidence that women face greater exposure to AMR than men (*WEF*)[4]; and insights from the *Global Women's Health Index*, which highlights significant gaps in STI testing for women globally (*Hologic*).[5]
- ❑ Though additional research is underway in 2025 (see 1.3), more work is needed to strengthen and address gaps in routine data collection.

7.2 | Stimulate R&D to explore associations between microbes (pathogens, commensals) and conditions that primarily or disproportionately affect women.

Progress: Moderate | Achievement: 40%

- ✓ **Research over the past year has deepened our understanding of the etiology of pathogenic infections**, including:
  - **Autoimmune conditions:** Review of induced pluripotent stem cell-based research on mechanisms and therapeutic targets for autoimmune diseases,[1] evidence on DNA-sensing pathways,[2] advancements analyzing B-cell repertoire diversity,[3] deeper understanding of the gut microbiota's role in autoimmune diseases,[4] and the potential involvement of SREBPs in the development of RA and lupus[5]
  - **Gynecological conditions**: Advancements in the study of the vaginal microbiome (see 9.2), and enhanced understanding of the etiology of pregnancy-related infections,[6] the pathogenesis for PCOS and AUB,[7,8] and the role of the gut microbiota in endometriosis[9]
- ❑ More research is needed to elucidate mechanisms of pathogenic infection to develop targeted prevention and treatment options.

7.3 | Develop and evaluate vaccines and other prevention interventions for infections that disproportionately impact women and evaluate maternal immunization to protect the mother-infant dyad.

Progress: Substantial | Achievement: 40%

- ✓ Safe and effective vaccines are available for two STIs: HepB and HPV. In the last year, there has been **continued research on prevention measures for infections that disproportionately impact women and maternal immunization**, including:
  - **HIV and other STIs**: Evidence on use of cabotegravir during pregnancy in SSA,[1] evidence on safety of the Dapivirine vaginal ring during pregnancy,[2] progress on germline targeting strategies for HIV vaccines,[3] a review on the effectiveness of MenB vaccines for gonorrhoea prevention,[4] preclinical development of gonococcal vaccines,[5] and AVAC funding for African partners to identify a STI advocacy agenda[6]
  - **High-burden infectious conditions**: 15 TB vaccine candidates in clinical development[7]; updated guidelines from WHO on levofloxacin for TB prevention[8]; new evidence on a candidate malaria vaccine during pregnancy;[9] and evidence on vaccines for RSV[10] and GBS[11]
- ❑ Despite progress, **there is limited understanding of vaccine-induced protective immune responses** in the context of female physiology and hormonal influences on vaccine uptake. While maternal immunizations are becoming available, STI vaccines will take time, HIV vaccine studies have shown limited success to date, and preventive innovations for conditions like syphilis remain in much earlier development.

7.4 | Develop improved diagnostic tests for STIs and other reproductive tract infections, including affordable point-of-care and self-testing products.

Progress: Moderate | Achievement: 40%

- ✓ In the last year, there's been new R&D for diagnostic tests for STIs and RTIs, with several near-term products in the pipeline, including:
  - **Gonococcal/chlamydial infections (GC) and AMR**: Promising evidence of lateral flow rapid tests for detection of GC[1,2] and recognition of the role of whole genome sequencing for detecting AMR genes in bacterial strains[3]
  - **Syphilis**: FDA authorization of at-home, OTC diagnostic test[4] and new NIH grants for syphilis diagnostics[5]
  - **Cross-cutting:** New TPPs and guidelines from WHO for POC and self-testing technologies,[6,7] and new self-collection diagnostic for RTIs[8]
- ❑ Despite this, emerging **POC diagnostics remain invasive and costly,** and more research is needed on sustainably scaling them in LMICs.

7.5 | Expand therapeutic options for infections in women, including during pregnancy and breastfeeding.

Progress: Moderate | Achievement: 20%

- ✓ **New guidelines have been released and new studies are underway that will lead to more therapeutic options**. Examples include:
  - **STIs:** FDA approval of updated label for Biktarvy with data from pregnant adults with HIV,[1] updates to perinatal HIV clinical guidelines,[2] WHO toolkit to include pregnant and lactating persons in clinical trials for HIV and STIs[3]
  - **TB:** In South Africa, pregnant women have been included in a trial for new TB drug[4]
- ❑ Despite movement, **few new therapies have been released,** and therapies are limited for pregnant and lactating persons.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

FDA, Food and Drug Administration; **JGH, Journal of Global Health; **JMIR**, Journal of Medical Internet Research; **NIH**, National Institutes of Health; WEF, World Economic Forum; **WHO**, World Health Organization*

Issue-Specific Topics

8 | Non-Communicable and Chronic Conditions

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

8.1 | Evaluate **sex and gender differences in the evolution and presentation of cardiometabolic diseases** and responses to therapies to inform development of optimal prediction, prevention, screening, diagnosis, monitoring, and treatments for women, with a focus on heart disease, diabetes, and obesity.

Substantial | 40%

- ✓ Building on existing research in the US on sex differences in cardiometabolic disorders,[1] breakthroughs were seen over the last year in:
  - **Heart disease:** Finding that single blood test (C-reactive protein) can predict 30-year cardiovascular disease risk for women[2]
  - **Diabetes and obesity**: New evidence that semaglutide shows greater benefit among women living with heart failure and obesity[3]
- ❑ However, there is limited work on these conditions in LMIC populations or focus on leveraging AI in research.

8.2 | Evaluate **sex and gender differences in outcomes and responses to medications** to inform development of prevention strategies, screening and diagnostic tools, and treatments for lung, colorectal, and gynecological cancers.

Moderate | 20%

- ✓ Recent progress on lung and gynecological cancers in HICs includes:
  - **Lung**: Evidence on sex-differentiated responses to immunotherapy for NSCLC,[1] sex-specific differences in efficacy of targeted therapies for EGFR-mutated lung cancers,[2] and large-scale trials underway (Lung-MAP)[3] to collect disaggregated outcomes on treatments for NSCLC
  - **Gynecological**: Study on hormone-related factors influencing treatment response for ovarian cancer[4] and focus on ovarian cancer in ARPA-H Sprint for Women's Health[5] and DoD CDRDP program[6]
- ❑ However, more research is needed on colorectal cancer and across all conditions in LMICs.

8.3 | Evaluate **sex- and gender differences in the evolution and presentation of neurological disorders** and responses to available therapies to inform development of prevention strategies, screening, diagnostics, monitoring, and treatments for women, with a specific focus on dementia, migraine, and pain.

Moderate | 40%

- ✓ **Exploration of sex-differentiated pathology among neurological disorders is increasing**, including systematic reviews of sex and gender differences in treatment and cost of neurological diseases,[1] AI models that can distinguish between male and female brains,[2] and calls for neurological research agendas to focus on sex and gender to accelerate achievement of WHO IGAP targets.[3,4] Other advancements include:
  - **Migraines**: Breakthroughs in effectiveness of CGRP-targeting therapies, with outcomes examined by sex[5]
  - **Pain and dementia**: New research from the US VA on postpartum women veterans' pain[6]
- ❑ Women remain underrepresented in trials,[7] and more work is needed on conditions disproportionally affecting women.

8.4 | 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.

Moderate | 40%

- ✓ Attention to mental health has increased post-COVID-19 pandemic, with recent advancements in specific conditions such as:
  - **PTSD**: Large portfolio of ongoing research on PTSD by the US VA system with a specific focus on women[1]
  - **Depression and anxiety:** Approval of first postpartum depression pill in the US in 2023[2] and evidence on the effectiveness of community-based CBT on postpartum depression and anxiety in Ethiopia[3]
- ❑ **More attention is needed globally around sex- and gender-specific elements of mental health conditions and the contextual factors that impact screening, diagnosis, and treatment** (e.g., few studies examine the effects of menstruation on depression, include phenotypic considerations such as gender in precision medicine subtypes, or examine challenges to PTSD diagnosis in women).

8.5 | Evaluate **sex and gender differences in the evolution and presentation of autoimmune disorders** and responses to available therapies to inform development of prevention, screening, diagnosis, and treatment options for women, with a focus on lupus, arthritis, osteoporosis, and thyroid diseases.

Moderate | 20%

- ✓ In HICs, there has been increased investment and attention around autoimmune diseases, including:
  - Research from Sweden demonstrating the **role of sex hormones in regulating the immune system**,[1] research from the US on **why autoimmune diseases disproportionately affect women**,[2,3] and funding from NIH ORWH on autoimmune diseases in women[4]
  - **Rheumatoid arthritis and lupus**: New research on sex differences and gender-related outcomes in rheumatoid arthritis[5] and continuation of programs focused on these conditions from NIH (AMP-AIM program)[6] and CDMRP[7]
- ❑ More research is needed among LMIC populations. Globally, gaps remain in understanding sex and gender differences in **inflammation surveillance, precision approaches, disease management, early detection, and translational research**.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

***NIH ORWH,** National Institutes of Health Office of Research on Women's Health; **NIH AMP-AIM,** National Institutes of Health Accelerating Medicines Partnership Autoimmune and Immune-Mediated Diseases; **DOD CDRDP,** US Department of Defense Congressionally Directed Medical Research Programs; **WHO IGAP,** World Health Organization Intersectoral Global Action Plan; **VA,** Veterans Affairs*

9 | Female-Specific Conditions

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

9.1 | Investigate **biological and external mechanisms of female gynecological conditions** and develop tools and therapies for prevention, diagnosis, treatment, and non-invasive monitoring of conditions. ⏭ 40%

- ✓ There has been several advancements in gynecological health, including:
  - Attention and **coverage from NIH related to endometriosis and fibroids**[1]; SCHDUL P50 Centers' examination of health disparities in fibroids[2] and the launch of RADx Tech for ACT ENDO challenge for endometriosis[3]
  - Increased **awareness of the impact of menopause** on the risk of comorbidities in aging women[4,5]
  - **Approval of linzagolix for uterine fibroids** in EU in September 2024,[6] early evidence on **benefits of artemisin** for treating **PCOS**,[7] and publication of a **single cell atlas** for the human endometrium[8]
  - New research via GC awards which will:[8] 1) work on innovating **menstrual health management**, 2) study the acceptability of **quick-drying reusable menstrual SunPad** in Kenya, and 3) study the impact and **genetic landscape of endometriosis** in Africa
- ❑ Despite progress, **larger trials are needed globally for newer advancements**.

9.2 | 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. ▶ 20%

- ✓ There is increasing **interest and research on the role of the human microbiome on women's health,** including:
  - New publications on the **vaginal microbiome,**[1] and review of **vaginal microbiota transplantation** for key diseases and preterm birth[2]
  - Evidence on **ongoing or new therapies for vaginal dysbiosis,**[3] and a new lab at Harvard focused on the **vaginal mucosa** and its links to bacterial vaginosis, pregnancy, preterm birth, and more[4]
  - New research via GC awards[6] focused on: 1) **metal dependencies** and low-risk vaginal microbiome, 2) **anti-microbial antibody repertoires** in the female genital tract, and 3) preclinical development of **metabolite-based modulators** of microbiota
- ❑ Despite interest and new evidence, there is **no large-scale clinical trial on vaginal microbiome products**.

9.3 | 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. ⏭ 20%

- ✓ **There's been some improvement in genetics and fetal medicine and new research** in this area globally, such as:
  - **Prenatal conditions:** Increasing progress on AI-enhanced point of care ultrasound technology (e.g., PEARLS Trial)[1]
  - **Intrapartum conditions**: New evidence on effectiveness of the intrapartum care model endorsed by WHO[2]
  - **Postpartum conditions:** NEJM publication on the E-motive trial (PPH),[3] Lancet study on burden of postnatal conditions,[4] and evidence on prenatal interventions for reducing postpartum depression in Pakistan,[5] and use of tranexamic acid for PPH in women with anemia[6]
  - **Cross-cutting**: New research will:[7] 1) explore pharmacokinetics of primaquine in lactating mothers, 2) develop machine learning ultrasound tools to monitor women's nutrition in Ethiopia, and 3) evaluate effectiveness of a midwife-led birthing center in Ethiopia
- ❑ Despite progress, more **attention is needed around drug trial challenges during pregnancy and lactation**, understanding causes and treatment for **PIH or IUGR**, and addressing product QA concerns in LMIC contexts.

9.4 | Investigate evidence gaps in understanding the **role of micronutrients**, including iron and folic acid, and their formulation for improving maternal outcomes. ▶ 60%

- ✓ **There is enhanced understanding and emerging consensus on products and recommendations** in recent years,[1,2] multiple evidence syntheses further confirming the beneficial effects of MMS vs IFA on pregnancy and birth outcomes (e.g., 2024 evaluation of the WHO-recommended UNIMMAP-MMS),[3] and broader recognition of MMS as an effective life-saving intervention (e.g., the Lancet SVN series).[4]
- ❑ Additional **research efforts are underway to address global gaps related to the scale-up of MMS**. Multiple countries like Nigeria, Ethiopia, Rwanda, Pakistan, and Bangladesh are piloting introduction and scale up of MMS in ANC.[5]

9.5 | 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 ▶ 40%

- ✓ There are **existing efforts in Europe and Australia to establish breast milk biobanks** (e.g., IMI ConcePTION project[1] and RWH endometriosis sample biobank[2]); and **emerging recommendations** on maximizing and standardizing biobank data.[3,4]
- ❑ However, **resources are currently insufficient to develop and sustain maternal and neonatal biobanks** on a global scale.

Progress ⏪ Set-backs ⏹ Unchanged ▶ Moderate ⏭ Substantial **Achievement** 0% None Partial Full 100%

***EU**, European Union; **GC**, Grand Challenges; **IMI**, Innovative Medicines Initiative; **Lancet SVN**, Lancet Small Vulnerable Newborn Series; **NEJM**, New England Journal of Medicine; **NIH**, National Institutes of Health; **RADx Tech**, RADx Tech program at NIH; **RWH**, Royal Women's Hospital; **UNIMMAP**, United Nations International Multiple Micronutrient Antenatal Preparation; **WHO**, World Health Organization*

9 | Female-Specific Conditions

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

9.6 | Develop **improved, accessible contraceptive technology** with fewer side effects and more prolonged efficacy.

Progress: Moderate | Achievement: 60%

- ✓ **Researchers are conducting late-stage RCTs on male hormonal contraceptives,[1]** while the Gates Foundation, Pfizer, and Becton, Dickinson & Company have **expanded their decade-long collaboration to enhance access to injectable contraceptives** for women in LMICs.[2] National and subnational governments (e.g., the US[3],[4] and Germany[5]) and pharmaceutical companies (e.g., Bayer[6] and Organon[7]) have made **significant commitments to expanding male and female contraception** in both HICs and LMICs.
- ❑ Overall improved and accessible contraceptive options remain limited due to access gaps between HICs and LMICs, and **research is limited on nonhormonal options and addressing barriers to access for existing technologies**.

9.7 | 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.

Progress: Unchanged | Achievement: 20%

- ✓ Researchers and advocates are **advancing understanding of how policies impact reproductive care and women's health**. This includes publishing new analyses of policy impacts in LMICs[1] and HICs[2], raising awareness through advocacy in SSA[3], and making progress on policy implementation in the EU.[4]
- ✓ However, **restrictive laws against reproductive rights in some countries (e.g., US, Poland, El Salvador), pose challenges** for developing new modalities for pregnancy termination.[5]

9.8 | **Optimize fertility potential,** including in males, by developing new, affordable diagnostic tools and treatments.

Progress: Moderate | Achievement: 40%

- ✓ Over the last year, researchers have **advanced endometrial biopsy technology, diagnostics, and AI, and conducted new studies to understand the causes of and treatment responses to infertility** in both HICs and LMICs, including:
  - **Research on causes**: New studies on the use of stem cells to restore ovarian function and repair damaged testicular tissue and on epigenetic markers that predict response to fertility treatments;[1,2] recent investments from Gates Foundation supporting a large multi-country study to understand genetic associations of infertility and supporting various academic centers in Europe, US, and Africa to better understand the genomic etiology of infertility in males
  - **Expanding options**: Improvements in PGT,[3] use of AI to improve the accuracy of embryo selection,[4] and research on the use of NIPT to assess the genetic health of embryos before implantation
- ❑ Despite advancements, **existing options remain limited, costly, and difficult to access globally**.

9.9 | Develop **self-administered solutions and new biomaterials** like mesh products and stem cells to support safe and effective treatment options for conditions like urinary incontinence and prolapse in women.

Progress: Moderate | Achievement: 20%

- ✓ The cell therapy field has advanced, actively supporting innovations in development,[1] and embracing newer advancements over the past year, such as the **launch of the Berlin Center for Gene and Cell Therapies,[2] and new clinical trials exploring stem cells for female incontinence**.[3]
- ❑ Despite these advancements, **there remains inequity in access to these technologies, even in HICs, and there have been few efforts to globalize biomaterial guidelines** to enhance transparency and reporting of cell sex or safety profiles by sex.

9.10 | 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.

Progress: Moderate | Achievement: 20%

- ✓ In the last year, **individuals and organizations have increased awareness, conducted research, and generated greater demand for menopause solutions**, including:
  - The NIH ORWH's planned Pathways to Prevention (P2P) workshop to identify research gaps in the menopausal tradition and to promote wellbeing through midlife and beyond[1]
  - Evidence on **neurokinin 3 receptor antagonists**, a new class of non-hormonal menopause treatments[2]
  - One **approved compound** (fezolinetant)[3] and one compound (elinzanetant) with two successful Phase 3 trials[4]
- ❑ **Despite advancements, screening for comorbidities is not done routinely** in most women and modern **HRT and MHT regimens remain expensive and unattainable** for many women across the world, even in HICs.

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

***NIH ORWH**, National Institutes of Health Office of Research on Women's Health*

Cross-Sector Partnership

10| Cross-Sector Partnerships for Women's Health Innovation

The following examples inform progress and achievement ratings for each opportunity in the last year but do not represent a comprehensive list.

Progress | Achievement

10.1.1 | Convene stakeholders across the full scope of women's health R&D to advance the opportunities laid out in the Women's Health Innovation Opportunity Map 2023 report.

✓ Globally, organizations have made progress in the last year through partnerships strongly focused on women's health R&D, such as:

- The continuation of the **Innovation Equity Forum** (IEF), which includes 250+ experts in women's health R&D[1]
- The launch of the **WEF's Global Alliance for Women's Health** (GAWH), a multisectoral platform focused on elevating women's health on global agendas, unlocking more investments for women's health, and advancing women's health research and innovation[2]
- The launch of the **US Government's Women's Health Research Initiative**[3]
- The launch of **BCG's Innovate Her** strategy focused on innovating women's health and wealth solutions,[4] and of **Kearney's [w]Health** platform focused on improving gender equity across reproductive health, cancer, brain health, heart health, and immunology[5]
- The launch of **UNFPA's WomenX Collective**, which aims to leverage UNFPA's global footprint and expertise to close women's health gaps with solutions such as advanced products and process innovations[6]
- The launch of **WHAM and KPMG's Investment Collaborative**, which aims to increase funding for women's health research and investment, improve access and diversity in clinical trials, and drive evidence-based solutions that address the unique needs of women[7]
- The launch of the **Equity 2030 Alliance** at the 2023 World Health Summit which unites experts from business, academia, and government across 32 countries to champion equitable solutions, advocate for inclusive policies, drive investments in women-focused initiatives and advance gender equity in science, technology, and finance by 2030[8]

❑ Despite this progress, **no partnership has been able to convene stakeholders across the entire scope of women's health R&D to advance the opportunities laid out in the women's health innovation opportunity map.** Existing efforts remain uncoordinated, focus primarily on problem identification rather than action, do not sufficiently include LMIC voices, and lack implementation accountability (e.g., via measurable indicators). The GAWH and IEF have the potential to serve as a broader WH R&D field convener to address these gaps but are currently not structured or resourced to act in this capacity.

10.1.2 | Position women's health R&D as a priority within existing R&D partnerships and the broader health ecosystem.

✓ Globally, stakeholders within the women's health space have **intensified efforts to define collective advocacy approaches and increased attention and momentum around women's health R&D** at key global events. Examples include:

- A new **public-private coalition, "Investing in women's health," from the GAWH dedicated to strengthening the narrative around women's health prioritization** and building alignment for advocacy efforts around a set of impactful concrete actions[1]
- An **explicit focus on interdisciplinary collaboration** within the NIH ORWH's strategic plan for research on the health of women[2]
- Clear **regulatory advocacy goals** outlined within the SWHR 2023-2024 Federal Legislative Agenda[3]
- A statement on Prioritizing Women in Prevention and Control of NCDs during the **World Health Assembly**;[4] dialogue on Technology for Diagnostics, Development, and Treatment **at ICPD@30**;[5] NCD Alliance Forum spotlighting leadership and stimulating collective action ahead of 2025's UN High-Level Meeting on NCDs;[6] and a focus on women's health within the **Africa Women Innovation & Entrepreneurship Forum** (AWIEF)[7] and during the **NYSE Women's Health Investor Summit Annual Meeting**[8]
- The **WHAM and KPMG Investment Collaborative goals** around publishing a report on investment in women's health, synthesizing global funding publications to provide an annual state of the industry report, and creating WHAM Accountability Indexes[9]

❑ Despite increased momentum, advocacy efforts remain primarily concentrated within two communities: sex and gender advocates focused on broader women's health agendas and clinicians focused on female-specific conditions. **Cross-sector and cross-discipline stakeholder coordination remains a key gap that needs to be addressed in order to implement existing frameworks and increase visibility of women's health R&D within broader global health or disease-specific agendas.**

10.1.3 | Define, implement, and share models, incentives, and accountability approaches for equitable R&D partnerships.

✓ Globally, **stakeholders have raised awareness about the gaps and the importance of ensuring representation within women's health R&D**, with early efforts from HICs, such as the NAM's focus on equity in the innovation ecosystem.[1]

❑ Despite these early efforts, R&D partnerships continue to have limited representation from civil society, patient organizations, and LMIC stakeholders. **More efforts are needed to implement and share models, incentives, and accountability approaches that increase representation and foster equitable partnerships.**

Progress Set-backs | Unchanged | Moderate | Substantial **Achievement** 0% None | Partial | Full 100%

***BCG,** Boston Consulting Group; **KPMG,** KPMG International Limited; **NIH ORWH,** National Institutes of Health Office of Research on Women's Health; **NAM,** National Academy of Medicine; **SWHR,** Society for Women's Health Research; **UNFPA,** United Nations Population Fund; **WEF,** World Economic Forum; **WHAM,** Women's Health Access Matters*

References and Acronyms

Acronyms: AI Artificial Intelligence, **AMR** Antimicrobial resistance, **ANC** Antenatal care, **BV** Bacterial vaginosis, **CT** Contraceptive technology, **DALY** Disability-adjusted life year, **EHR** Electronic health record, **GBV** Gender-based violence, **GBS** Group B streptococcus, **GDP** Gross-domestic product, **GH** Global health, **HepB** Hepatitis B, **HICs** High-income countries, **HIV** Human immunodeficiency virus, **HPV** Human papillomavirus, **HRT** Hormone replacement therapy, **IUGR** Intrauterine growth restriction, **IFA** Iron and folic acid, **LMICs** Low- and middle-income countries, **MHT** Menopausal hormone therapy, **MenB** Meningococcal disease serogroup B, **MMS** Multiple micronutrient supplement, **NCD** Non-communicable disease, **NIPT** Non-invasive prenatal testing, **NSCLC** Non-small cell lung cancer, **NTDs** Neglected tropical diseases, **OTC** Over-the-counter, **PIH** Pregnancy-induced hypertension, **MPTs** Multipurpose prevention technologies, **PWLE** People with lived experience, **PCOS** Polycystic ovary syndrome, **PGT** Preimplantation genetic testing, **PoCTs** Point-of-care tests, **PPH** Postpartum hemorrhage, **PTSD** Post-traumatic stress disorder, **QA** Quality assurance, **RA** Rheumatoid arthritis, **RCT** Randomized controlled trial, **RFP** Request for proposals, **ROI** Return on investment, **RSV** Respiratory syncytial virus, **R&D** Research and development, **RTI** Reproductive tract infection, **SABV** Sex as a biological variable, **SGM** Sexual and gender minorities, **SDOH** Social determinants of health, **SOGI** Sexual orientation and gender identity, **SRH** Sexual and reproductive health, **SSA** Sub-Saharan Africa, **STIs** Sexually transmitted infections, **SREBPs** Sterol regulatory element-binding proteins, **TB** Tuberculosis, **TPPs** Target product profiles, **UF** Uterine fibroids, **VC** Venture capital, **WH** Women's Health **YLD** Years lived with disability

Opportunity Map

1. 2023. Gates Foundation & NIH. Women's Health Innovation Opportunity Map 2023: 50 High-Return Opportunities to Advance Global Women's Health R&D. https://bit.ly/42qUDkd

Ecosystem Progress

1. 2024. Equity 2030 Alliance. Equity 2030 Alliance: Collective Impact Report 2024 and Beyond.
2. 2024. ARPA-H Investor Catalyst Hub. ARPA-H Investor Catalyst Hub To Disburse $110 Million In Funding For ARPA-H Sprint For Women's Health Awards.
3. 2024. World Economic Forum. New Global Alliance for Women's Health Could Help Boost Global Economy by $1 Trillion Annually by 2040.
4. 2023. Gov.UK. Product development research for global health.
5. 2024. BMBF. Bundeshaushaltsplan 2025.
6. 2024. McKinsey Health Institute. Closing the women's health gap: A $1 trillion opportunity to improve lives and economies.
7. 2022. McKinsey. Unlocking opportunities in women's healthcare.
8. 2024. Impact Global Health. G-FINDER. ***Note**: Indicator is a modified version of G-finder's SRH filter and excludes funding for HIV and Hep B. In 2023, seven new conditions (pre-term labor, menopause, endometriosis, uterine fibroids, PCOS, maternal anemia, and abortion) were added to the SRH scope, accounting for an additional $118 million in funding in 2023.*
9. 2024. Access to Medicine Foundation. Access to Medicine Index 2024. ***Note**: Includes R&D activity for diseases, conditions and pathogens that the global health community considers most critical to address in LMICs, including 10 reproductive, maternal and newborn health conditions.*
10. 2024. Global Health 50/50. Gaining ground? 2024 Global Report.
11. 2024. ADS Elsevier. Progress Toward Gender Equality In Research And Innovation. ***Note**: Indicator is annual share of author count by gender for STEM publications.*
12. 2024. WHO. Prequalification of Medical Products. ***Note**: Includes the "reproductive health" and "Oncology" therapeutic areas.*
13. 2021. IHME. Global Burden of Disease Study 2021. ***Note**: Compares global YLDs for females and males.*

Organization Highlights

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2. 2024. Gates Foundation. Incorporating a Sex and Gender Lens into Medical Education in Pakistan.
3. 2024. Gates Foundation. Femtech Innovation Hub.
4. 2023. Reid et al. Demographic diversity of US-based participants in GSK-sponsored interventional clinical trials. *Clinical Trials.*
5. 2024. NIH. Notice of Special Interest: Women's Health Research.
6. 2024. NIH. Small Business Opportunities for Innovative Women's Health Research Webinar.
7. 2024. NIH. Supplemental Funding To Diversify The Entrepreneurial Workforce.
8. 2024. Gates Foundation. Opportunities to Advance Women's Health Innovation.
9. 2024. Gates Foundation. Upstream Sex and Gender Marker for Health.

Cross-cutting Topics

Topic 1. Data and Modeling

Opportunity 1.1.

1. 2023. World Bank. Sexual Orientation and Gender Identity (SOGI) Inclusion and Gender Equality.
2. 2024. EUI. FEMETRICS - Visible Women: Gender, Data, Social Europe.
3. 2024. NIH ORWH. National Academies of Sciences, Engineering, and Medicine Assessment of NIH Research on Women's Health.
4. 2024. The White House. FACT SHEET: Biden-Harris Administration Announces $110 Million in Awards from ARPA-H's Sprint for Women's Health to Accelerate New Discoveries and Innovation.

Opportunity 1.2

1. 2023. AVPN. The state of gender inclusion in Asia-Pacific's regulatory landscape.

Opportunity 1.3

1. 2024. Patwardhan et al. Differences across the lifespan between females and males in the top 20 causes of disease burden globally: a systematic analysis of the Global Burden of Disease Study 2021. *The Lancet Public Health.*

Opportunity 1.4

1. 2024. Impact Global Health. New data reveals what's happening in the funding of global health R&D.
2. 2024. McKinsey Health Institute. Closing the women's health gap: A $1 trillion opportunity to improve lives and economies.
3. 2024. UNFPA. WomenX Collective.
4. 2024. NHS Confederation. Women's health economics: investing in the 51 per cent.

Opportunity 1.5

1. 2024. Brandão et al. Revolutionizing Women's Health: A Comprehensive Review of Artificial Intelligence Advancements in Gynecology. *Journal of Clinical Medicine.*
2. 2024. NPJ Women's Health. Advances in AI for women's health, reproductive health, and maternal care: bridging innovation and healthcare. *NPJ Women's Health.*

Topic 2. Research and Design Methodologies

Opportunity 2.1.

1. 2024. Heidari et al. WHO's adoption of SAGER guidelines and GATHER: setting standards for better science with sex and gender in mind. *The Lancet.*
2. 2024. US. FDA. FDA Guidance Provides New Details in Diversity Action Plans Required For Certain Clinical Studies.
3. 2024. Goldstein. Recruiting women across the life of a study: A VA Cooperative Studies Program Process Improvement Project.
4. 2024. The Royal Women's Hospital. Research Centers.
5. 2024. PFMD. Patient-Focused Medicine Development.

Opportunity 2.2.

1. 2024. Concept Foundation. Accelerating Innovation for Mothers.

Opportunity 2.3

1. 2024. WHO. Global Initiative on AI for Health.
2. 2023. Lombard & Landouré. Could Africa be the future for genomics research? *Nature.*
3. 2023. Gates Foundation. Gates Foundation Celebrates 20 Years of "Grand Challenges" With New Investments and a Call to Make R&D Breakthroughs Available More Quickly and Equitably.

Opportunity 2.4.

1. 2023. Wang & Qin. Advances in human organoids-on-chips in biomedical research. *Life Medicine.*
2. 2024. Harvard University. Wyss Institute.
3. 2024. Institute For Stem Cell Science And Regenerative Medicine.
4. 2024. Li et al. Organoid modeling meets cancers of female reproductive tract.
5. 2024. Richards et al. Reproductive organ on-a-chip technologies and assessments of the fetal-maternal interface.

Topic 3. Regulatory and Science Policy

Opportunity 3.1.

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2. 2024. UK Government. NHS Constitution: 10-year review.
3. 2024. Ireland DOH. Women's Health Action Plan 2024-2025 Phase 2: An Evolution in Women's Health.
4. 2024. NHMRC and the Department of Health and Aged Care. Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research.
5. 2024. AU. African Union Commission Hosts 2024 International Women's Day Virtual Policy Dialogue on How Women's Leadership Strengthens Health Systems in Africa.

Opportunity 3.2

1. 2024. Swissethics. Sex And Gender In Research Involving Humans According To The HRA.: Recommendations for the Ethical Review of Research Projects.
2. 2024. FDA. Women's Health Research Roadmap.
3. 2024. FDA. FDA Guidance Provides New Details on Diversity Action Plans Required for Certain Clinical Studies.
4. 2024. National Academies. Advancing Clinical Research With Pregnant And Lactating Populations.
5. 2024. South African NDOH. South African Ethics in Health Research Guidelines: Principles, Processes and Structures.

Opportunity 3.3
1. 2024. IMI ConcePTION. ConcePTION data.
2. 2024. Gravitate Health.
3. 2024. CAMT. Perinatal Medication Use: Considerations for Health Care Providers

Opportunity 3.4
1. 2024. JAMA. Draft Guidance On Reporting Gender, Sex, Gender Identity, Sexual Orientation, And Age In Medical And Scientific Publication — Call for Review and Comment.
2. 2024. IMDRF. Common Data Set for Adverse Event Data Exchange Between IMDRF Regulators.
3. 2024. IMDRF. Guiding Principles To Support Medical Device Health Equity.
4. 2024. FDA. Extramural Women's Health Research.
5. 2024. The Global Alliance for Women's Health.

Opportunity 3.5
1. 2024. The White House. Biden-Harris Administration Announces $110 Million in Awards from ARPA-H's Sprint for Women's Health to Accelerate New Discoveries and Innovation.
2. 2024. IFMPA. Open letter from the biopharmaceutical industry to G20 Ministers in support of the G20 Health Agenda.

Topic 4. Innovation Introduction

Opportunity 4.1.
1. 2024. Women's Health Access Matters. The WHAM Report.
2. 2024. McKinsey Health Institute. Closing the women's health gap: A $1 trillion opportunity to improve lives and economies.
3. 2023. WHO. Health Inequality Monitor.
4. 2024. Hologic. Global Women's Health Index.
5. 2024. Impact Global Health. New data reveals what's happening in funding of global health R&D.

Opportunity 4.2.
1. 2024. Gates Foundation. Femtech Innovation.
2. 2024. Future Fem Health. Flo Health and FemTech India partner on 'Pass it on' project.
3. 2024. UK Department Of Health And Social Care. Women's Health Hubs: Core Specification.
4. 2024. ARPA-H Investor Catalyst Hub. ARPA-H Investor Catalyst Hub To Disburse $110 Million For ARPA-H Sprint For Women's Health Awards.
5. 2024. GESIS. Center Of Excellence Women In Science.

Opportunity 4.4.
1. 2024. Deloitte. Can investors help women's health break through the glass ceiling?
2. 2024. ARPA-H Investor Catalyst Hub. ARPA-H Investor Catalyst Hub To Disburse $110 Million In Funding For Women's Health Awards.
3. 2024. NIH. Release: NIH Announces Winners Of Prize Competition To Improve Postpartum Maternal Health And Health Equity Through Innovative Diagnostics
4. 2024. Gates Foundation. Opportunities to Advance Women's Health Innovation.

Opportunity 4.5.
1. 2024. Gavi. African Vaccine Manufacturing Accelerator (AVMA).
2. 2023. CHAI. All children can be born free of HIV, syphilis, and hepatitis B.
3. 2024. Medaccess. MedAccess Welcomes Rollout Of G6PD Testing And Tafenoquine In Brazil.

Topic 5. Social and Structural Determinants

Opportunity 5.1.
1. 2024. NIH. Women's Health Awareness Community Engagement Program.
2. 2024. The White House. Executive Order Advancing Women's Health Research and Innovation.
3. 2024. The George Institute for Global Health. Accounting for sex and gender in biomedical, health and care research.
4. 2024. IDRC. Call for letters of interest: Addressing neglected areas of sexual and reproductive health and rights in sub-Saharan Africa.
5. 2024. Gates Foundation. Opportunities to Advance Women's Health Innovation.

Opportunity 5.2
1. 2024. Bou-Karroum et al. Financing for equity for women's, children's and adolescents' health in low- and middle-income countries: A scoping review. *PLOS Global Public Health.*
2. 2024. WHO. Operational framework for monitoring social determinants of health equity.
3. 2023. USAID. Applying A Social Determinants Of Health Lens To Improve Outcomes.
4. 2024. Royal Women's Hospital. Social Model Of Health Research.
5. 2024. Craven et al. Toward standardization, harmonization, and integration of social determinants of health data. *Journal Of Clin. And Transl. Science.*

Opportunity 5.3
1. 2024. NIH. NOSI: Health Influences Of Gender as a Social And Structural Variable.
2. 2024. Bohren et al. Towards A Better Tomorrow: Addressing Intersectional Gender Power Relations To Eradicate Inequities In Maternal Health. *The Lancet Discovery Science.*
3. 2024. Banati et al. Intersectionality, Gender Norms, And Young Adolescents In Context: A Review Of Longitudinal Multi-country Research Programs To Shape Future Action. *Lancet Child And Adolescent Health.*

Opportunity 5.4
1. 2024. King et al. Promoting Diversity, Equity, Inclusion, And Justice In Grantmaking For Health Care Research: A Pragmatic Review And Framework. *Health Equity.*

Opportunity 5.5.
1. 2023. WHO. Traditional Medicine Global Summit.

Topic 6. Training and Careers

Opportunity 6.1.
1. 2024. Mayo Clinic. Transforming Women's Health.
2. 2024. UCSF. Controversies in Women's Health.
3. 2024. NPACE. Women's Health Bundle 2024.
4. 2024. Texas Tech University. Sex and Gender Specific Health Curriculum.
5. 2024. Stanford University. WHSDM Center Seed Grants 2024-2025.
6. 2024. Gates Foundation. Incorporating a Sex and Gender Lens into Medical Education in Pakistan.

Opportunity 6.3
1. 2024. World Economic Forum. Global Gender Gap Report 2024.
2. 2024. Elsevier. Progress Toward Gender Equality in Research & Innovation.
3. 2024. Gates Foundation. Opportunities to Advance Women's Health Innovation.
4. 2024. NIH. NOSI: Health Influences of Gender as a Social and Structural Variable
5. 2024. African Women in Digital Health.
6. 2024. IFPMA. Africa Young Innovators for Health Award.
7. 2024. Future Fem Health. Flo Health and FemTech India partner on 'Pass it on' project.
8. 2024. Gates Foundation. Innovation Hub.

Opportunity 6.4
1. 2024. Jaureguy. Government Shutters What Remained of Women, Genders, Diversity Ministry. *Buenos Aires Herald.*
2. 2024. Spong. OB/GYN Interest Endures in a Post-Dobbs World. *Contemporary OB/GYN.*

Opportunity 6.5
1. 2024. The Ohio State University. Advocates & Allies for Equity.
2. 2024. The Ohio State University. CommunityTEN Conference.

Issue-Specific Topics

Topic 7. Communicable Diseases

Opportunity 7.1
1. 2024. GBD 2021 Forecasting Collaborators. Burden of disease scenarios for 204 countries and territories, 2022-2050: a forecasting analysis for the Global Burden of Disease Study 2021. *Lancet.*
2. 2024. Qin et al. Trends and disparities of disease burden in infections among pregnant women in 131 low-income and middle-income countries, 1990-2019. *Journal Of Global Health.*
3. 2024. Zhu et al. Economic Burden Of Community-Acquired Antibiotic-resistant Urinary Tract Infections: Systematic Review And Meta-analysis. *JMIR Public Health and Surveillance.*
4. 2024. McKinsey Health Institute. Closing the women's health gap: A $1 trillion opportunity to improve lives and economies.
5. 2024. Hologic. The Hologic Global Women's Health Index: Year 3 Global Report.

Opportunity 7.2.
1. 2024. Ren et al. Research Progress Of Autoimmune Diseases Based On Induced Pluripotent Stem Cells. *Frontiers In Immunology.*
2. 2024. Dong & Fitzgerald. DNA-sensing pathways in health, autoinflammatory and autoimmune diseases. *Nature Immunology.*
3. 2024. Wang et al. B-Cell Receptor Repertoire: Recent Advances in Autoimmune Diseases. *Clin Rev Allergy Immunol.*
4. 2024. Mu et al. Gut microbiota and autoimmune diseases: Insights from Mendelian randomization. *The FASEB Journal.*
5. 2024. Xu et al. Research progress of SREBP and its role in the pathogenesis of autoimmune rheumatic diseases. *Frontiers in Immunology.*
6. 2024. Creisher & Klein. Pathogenesis of viral infections during pregnancy. *Clin Microbiol Rev.*
7. 2024. Hajam et al. A review on critical appraisal and pathogenesis of polycystic ovarian syndrome. *Endocrine and Metabolic Science.*
8. 2024. Leal et al. Abnormal uterine bleeding: The well-known and the hidden face. *Journal of Endometriosis and Uterine Disorders.*
9. 2024. Guo & Zhang. Role of the gut microbiota in the pathogenesis of endometriosis: a review. *Frontiers in Microbiology.*

Opportunity 7.3
1. 2024. Viiv Healthcare. Positive New Data For Apretude Use During Pregnancy At AIDS 2024.
2. 2024. Mascolini. Safety of dapivirine vaginal ring and oral PrEP for HIV prevention in the 2nd trimester.
3. 2024. ClinicalTrials.gov. Trial to Evaluate the Safety and Immunogenicity of Priming Regimens of 426c.Mod.Core-C4b and Optional Boost Regimen With HIV Trimer BG505 SOSIP.GT1.1 gp140, Both Adjuvanted With 3M-052-AF + Alum in Healthy, Adult Participants Without HIV.
4. 2024. Abara et al. Effectiveness of MenB-4C Vaccine Against Gonorrhea: A Systematic Review and Meta-analysis. *Journal of Infectious Diseases.*
5. 2024. García et al. Urgent Need to Understand and Prevent Gonococcal Infection: From the Laboratory to Real-World Context. *The Journal of Infectious Diseases.*
6. 2023. AVAC. Paving the Road for STI Prevention Advocacy.
7. 2024. WHO. Global Tuberculosis Report 2024: 6. TB research and innovation.
8. 2024. WHO. WHO releases updated guidelines on tuberculosis preventive treatment.
9. 2024. NIH. Candidate Malaria Vaccine Provides Lasting Protection In NIH-sponsored Trials.
10. 2024. Papazisis & Topalidou. Maternal Vaccination for the Prevention of Infantile RSV Disease: An Overview of the Authorized, In-Progress, and Rejected Vaccine Candidates. *Vaccines (Basel).*
11. 2024. Bjerkhaug et al. The immunogenicity and safety of Group B Streptococcal maternal vaccines: A systematic review. *Vaccine.*

Opportunity 7.4

1. 2024. Peters et al. Novel lateral flow assay for point-of-care detection of Neisseria gonorrhoeae infection in syndromic management settings: a cross-sectional performance evaluation. *The Lancet.*
2. 2023. Dighe et al. Highly-Specific Single-Stranded Oligonucleotides and Functional Nanoprobes for Clinical Determination of Chlamydia Trachomatis and Neisseria Gonorrhoeae Infections. *Advanced Science.*
3. 2024. Hassall et al. Limitations of current techniques in clinical antimicrobial resistance diagnosis: examples and future prospects. *NPJ Antimicrobials and Resistance.*
4. 2024. FDA. Marketing Authorization Enables Increased Access Syphilis Diagnosis.
5. 2024. NIH. NIH Awards Support Innovation In Syphilis Diagnostics.
6. 2023. WHO. The diagnostics landscape for sexually transmitted infections.
7. 2023. WHO. Point-of-care tests for sexually transmitted infections: Target product profiles.
8. 2024. Quest Diagnostics. Quest Diagnostics Introduces Specimen Self-collection For Genital Tract Infection Testing at Nationwide Network of Patient Service Centers.

Opportunity 7.5

1. 2024. Gilead. FDA Approves Biktarvy Label Update With Data For Pregnant Adults With HIV.
2. 2024. Clinicalinfo HIV.Gov. Updates To The Perinatal HIV Clinical Guidelines.
3. 2024. WHO. Antiretrovirals in Pregnancy Research Toolkit.
4. 2024. ClinicalTrials.gov. Building Evidence for Advancing New Treatment for Rifampicin Resistant Tuberculosis Comparing a Short Course of Treatment With the Current South African Standard of Care.

Topic 8. Non-Communicable and Chronic Conditions

Opportunity 8.1

1. 2019. Gerdts & Regitz-Zagrosek. Sex Differences In Cardiometabolic Disorders. *Nature Medicine.*
2. 2024. NHLBI. Single Blood Test Predicts 30-year Cardiovascular Disease Risks For Women.
3. 2024. Verma et al. Efficacy of Semaglutide by Sex in Obesity-Related Heart Failure With Preserved Ejection Fraction: STEP-HFpEF Trials. *Journal of the American College of Cardiology.*

Opportunity 8.2.

1. 2023. Sordo-Bahamonde et al. Chemo-immunotherapy: A New Trend In Cancer Treatment. *Cancers.*
2. 2024. Cohen et al. Sex influence on cancer immunotherapy efficacy and safety in advanced non-small cell lung cancer (NSCLC): A Canadian institution real-world experience. *Journal of Clinical Oncology.*
3. 2024. Lung-MAP. About Lung-MAP.
4. 2024. Zhao et. al. Sex hormones and immune regulation in ovarian cancer. *Discover Oncology.*
5. 2024. ARPA-H. Sprint for Women's Health awards aim to close gaps in women's health research.
6. 2024. DoD. Ovarian Cancer.

Opportunity 8.3

1. 2023. Bianco et al. Sex And Gender Differences In Neurodegenerative Diseases: Challenges For Therapeutic Opportunities. *International Journal Of Molecular Sciences.*
2. 2023. Ryali et al. Deep learning models reveal replicable, generalizable, and behaviorally relevant sex differences in human functional brain organization. *PNAS.*
3. 2023. Economist Impact. Sex, Gender, And The Brain: Towards an Inclusive Research Agenda.
4. 2024. Winter at al. National Plans And Awareness Campaigns As Priorities For Achieving Global Brain Health. *The Lancet Global Health.*
5. 2024. Porreca et al. Evaluation of outcomes of calcitonin gene-related peptide (CGRP)-targeting therapies for acute and preventive migraine treatment based on patient sex. *Cephalalgia.*
6. 2024. Kroll-Desrosiers. Exploring the Experience of Pain and Pain Management for Pregnant and Postpartum Veterans with Chronic Musculoskeletal Pain. *Women's Health Issues.*
7. 2022. Pinho-Gomes et al. Dementia Clinical Trials Over The Past Decade: Are Women Fairly Represented? *BMJ Neurology Open.*

Opportunity 8.4

1. 2024. US Department Of Veterans Affairs. PTSD: National Center for PTSD.
2. 2023. FDA. FDA Approves First Oral Treatment For Postpartum Depression.
3. 2024. Breakthrough ACTION. Mothers Time Tool For Community Health Workers.

Opportunity 8.5

1. 2024. Lakshmikanth. Immune system adaptation during gender-affirming testosterone treatment. *Nature.*
2. 2024. Dou et al. Xist Ribonucleoproteins Promote Female Sex-biased Autoimmunity. *Cell.*
3. 2024. Fairweather et al. Mechanisms Underlying Sex Differences In Autoimmunity. *JCI.*
4. 2023. NIH. NIH Supports Research on Autoimmune Diseases in Women.
5. 2023. Carmona et al. Tailoring Rheumatoid Arthritis Treatment Through A Sex And Gender Lens. *Journal Of Clinical Medicine.*
6. 2024. NIH. Accelerating Medicines Partnership® Autoimmune and Immune-mediated Diseases (AMP AIM) Program.
7. 2024. CDMRP. Lupus.

Topic 9. Female-Specific Conditions

Opportunity 9.1

1. 2024. NIH News. Spotlight: NIH Panel Explores Endometriosis Advances, Emphasizes Awareness.
2. 2023. Department of Health and Human Services. Specialized Centers for Research on Health Disparities in Uterine Leiomyoma (SCHDUL).
3. 2024. NIH Radx Tech. ACT ENDO Challenge.
4. 2024. World Economic Forum. What Is Menopause – And How Does It Impact Women's Health And Work Life?
5. 2024. Panay et. al. Menopause and MHT in 2024: addressing the key controversies – an International Menopause Society White Paper. *Climacteric.*
6. 2024. Kissei. Launch Of YSELTY for Uterine Fibroid Treatment in Europe.
7. 2024. Liu et al. Artemisinins ameliorate polycystic ovarian syndrome by mediating LONP1-CYP11A1 interaction. *Science*
8. 2024. Marečková et al. An integrated single-cell reference atlas of the human endometrium. *Nature Genetics*.
9. 2024. Gates Foundation. Global Grand Challenges.

Opportunity 9.2

1. 2024. Paduch-Jakubczyk et al. The Role Of Vaginal Microbiota In Women's Health. *Actual Gyn.*
2. 2024. Meng et al. Vaginal microbiota transplantation is a truly opulent and promising edge: fully grasp its potential. *Front Cell Infect Microbiol.*
3. 2024. Valeriano et al. Vaginal dysbiosis and the potential of vaginal microbiome-directed therapeutics. *Frontiers In Microbiomes.*
4. 2024. The Gonipath Lab. Research.
5. 2024. Gates Foundation. Global Grand Challenges.

Opportunity 9.3

1. 2024. Wistrom et al. Artificial Intelligence in Point-of-care Ultrasound. *Current Emergency and Hospital Medicine Reports.*
2. 2024. Abdolalipour et al. Effect of implementation of the WHO intrapartum care model on maternal and neonatal outcomes: a randomized control trial. *BMC Pregnancy And Childbirth.*
3. 2023. Gallos et al. Randomized Trial Of Early Detection And Treatment Of Postpartum Hemorrhage. *New England Journal of Medicine.*
4. 2024. Vogel. Neglected medium-term and long-term consequences of labour and childbirth: a systematic analysis of the burden, recommended practices, and a way forward. *Lancet Global Health.*
5. 2024. NIH News Releases. Intervention reduces likelihood of developing postpartum anxiety and depression by more than 70%.
6. 2024. WOMAN-2 Trial Collaborators. The effect of tranexamic acid on postpartum bleeding in women with moderate and severe anaemia (WOMAN-2): an international, randomised, double-blind, placebo-controlled trial. *The Lancet.*
7. 2024. Gates Foundation. Global Grand Challenges.

Opportunity 9.4

1. 2024. WHO. Antenatal Iron Supplementation.
2. 2022. Billah et al. Iron and Folic Acid Supplementation in Pregnancy: Findings from the Baseline Assessment of a Maternal Nutrition Service Programme in Bangladesh. *Nutrients.*
3. 2024. Kuche et al. The effect of UNIMMAP multiple micronutrient supplements versus iron-folic acid and placebo in anemia reduction among women of reproductive age in Kebribeyah Woreda, Somali Regional State, Ethiopia: a study protocol for a community-based individual RCT. *BMC Trials.*
4. 2023. Lancet. Small Vulnerable Newborn Series.
5. 2024. Gates Foundation, CIFF, ECF, and Kirk Humanitarian. Healthier Pregnancies and Brighter Futures for Mothers and Babies: A global investment roadmap for multiple micronutrient supplementation.

Opportunity 9.5

1. 2020. Innovative Medicines Initiative, Conception. Description of basic quality management structure for biobanking and pre-analytical handling of human breast milk specimens.
2. 2024. Gynaecology Research Centre - Rogers Group Royal Women's Hospital.
3. 2024. Alkhatib et al. Data Management in Biobanking: Strategies, Challenges, and Future Directions. *Biotech.*
4. 2024. Brancato et al. Standardizing digital biobanks: integrating imaging, genomic, and clinical data for precision medicine. *Journal Of Translational Medicine*.

Opportunity 9.6

1. 2024. Wang et al. Hormonal Male Contraception. *Andrology*
2. 2023. Gates Foundation. Gates Foundation, Children's Investment Fund Foundation, Pfizer and Becton, Dickinson & Company Expand Partnership for Greater Access to Injectable Contraceptive for Women in Low- and Lower-Middle-Income Countries.
3. 2024. Guttmacher Institute. The Right To Contraception In The United States.
4. 2024. US Department of Health and Human Services. HHS Secretary Xavier Becerra Announces New Actions to Increase Contraceptive Care Coverage on 51st Anniversary of Roe v. Wade.
5. 2024. Center For Reproductive Rights. New law proposed by German organizations and experts builds on recommendations from a government-appointed expert commission.
6. 2024. Bayer. Bayer´s Support To Access To Contraception.
7. 2024. Organon. Organon Launches US. Grant Programs And Listening Tour As Part Of "Her Plan Is Her Power," Reaching High-need Communities To Help Reduce Unplanned Pregnancies.

Opportunity 9.7

1. 2024. Cohen et al. National Policy Influences of Contraceptive Prevalence and Method Mix Strategy: A Longitudinal Analysis of 59 Low- and Middle-Income Countries, 2010–2021. *Global Health Science and Practice.*
2. 2023. Guttmacher. Reproductive Health Impact Study.
3. 2024. Center For Reproductive Rights. Addressing Policy And Legal Aspects Of SRHR At The Girl Up Kenya Leadership Summit 2024.
4. 2024. Center For Reproductive Rights. 10 Ways The EU Is Driving Progress On Gender Equality And SRHR.
5. 2024. Center For Reproductive Rights. The World's Abortion Laws.

Opportunity 9.8

1. 2024. Zhang et al. Research advances in the construction of stem cell-derived ovarian organoids. *Stem Cell Research & Therapy.*
2. 2024. Adore Fertility. Latest Innovations In Fertility Treatments.
3. 2024. Petch et al. Updates in preimplantation genetic testing (PGT). *Best Practice & Research Clinical Obstetrics & Gynaecology.*
4. 2024. Wang et al. A generalized AI system for human embryo selection covering the entire IVF cycle via multi-modal contrastive learning. *Patterns.*
5. 2024. Gallios et al. Defining ethical criteria to guide the expanded use of Noninvasive Prenatal Screening (NIPS): Lessons about severity from preimplantation genetic testing. European *Journal of Human Genetics.*

Opportunity 9.9

1. 2024. González Enguita et al. Cell Therapy In The Treatment Of Female Stress Urinary Incontinence: Current Status And Future Proposals. *Life.*
2. 2024. Bayer. Berlin Center for Gene and Cell Therapies kicked off in Berlin.
3. 2024. Womens Health. Phase 3 CELLEBRATE trial testing regenerative stem cell-based therapy to improve urinary control for women.

Opportunity 9.10

1. 2024. NIH ORWH. Advancing Women's Health Research: From Policy To Action.
2. 2024. Hager et al. Elinzanetant, A New Combined Neurokinin-1/-3 Receptor Antagonist For The Treatment Of Postmenopausal Vasomotor Symptoms. *Expert Opinion on Pharmacotherapy.*
3. 2023. USA FDA. FDA Approves Novel Drug to Treat Moderate to Severe Hot Flashes Caused by Menopause.
4. 2024. Bayer. Positive Topline Results From Phase III Long-term Study OASIS 3 Support Submissions For Marketing Authorization For Bayer's Elinzanetant.

Topic 10. Cross Sector Partnerships

Opportunity 10.1.1.

1. 2023. Gates Foundation. Women's Health Innovations | Innovation Equity Forum.
2. 2024. Global Alliance On Women's Health.
3. 2024. The White House. White House. Initiative On Women's Health Research.
4. 2024. BCG. A BCG X strategy and build effort to innovate women's health and wealth solutions.
5. 2024. Kearney. [W]Health.
6. 2024. UNFPA. WomenX Collective Launch to Transform Women's Health Globally.
7. 2024. WHAM And KPMG Announce $1.1 Million Partnership To Revolutionize Women's Health - WHAM Now.
8. 2023. UNFPA. Equity 2030 Alliance

Opportunity 10.1.2.

1. 2024. World Economic Forum. Commitments - The Global Alliance For Women's Health.
2. 2024. NIH. NIH-wide Strategic Plan For Research On The Health Of Women.
3. 2023. Society for Women's Health Research. 2023-2024 Federal Legislative Agenda 2023-2024.
4. 2024. WHO. Preparatory Process For The Fourth High-level Meeting Of The UN General Assembly On The Prevention And Control Of NCDs.
5. 2024. ICPD30. Global Dialogue On Technology.
6. 2024. Leadership on NCDs Towards 2025 & Beyond - 4th Global NCD Alliance Forum.
7. 2024. AWIEF. Fembiobiz Accelerator Programme.
8. 2023. Women's Health Investor Summit 2023 Takeaways | Modern Healthcare.
9. 2024. WHAM And KPMG Announce $1.1 Million Partnership To Revolutionize Women's Health - WHAM Now.

Opportunity 10.1.3

1. 2023. NIH. Toward Equitable Innovation In Health And Medicine.