In collaboration with the Global Alliance for Women's Health, Kearney and the Gates Foundation

WORLD ECONOMIC FORUM

Prescription for Change: Policy Recommendations for Women's Health Research

WHITE PAPER

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Contents

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Foreword

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The World Economic Forum's Global Alliance for Women's Health, in partnership with Kearney and the Gates Foundation, is pleased to present this white paper proposing key policy recommendations to protect improvements already made in women's health science and innovation and to promote further progress.

Addressing the women's health research gap is not only an ethical imperative but also a critical step towards transforming global health outcomes. Women's health has historically been under-researched and underfunded, leading to gaps in knowledge and innovation. Despite comprising half the world's population, women have also been under-represented in clinical research, resulting in significant disparities in the understanding of men's and women's physiology. These disparities have far-reaching implications, influencing diagnosis, treatments and ultimately health outcomes for women.

This existing gap in women's health research is in line with the fact that women live in poor health for 25% more of their lives compared to men, according to a 2024 report.[1] Closing this gap could yield 75 million disability-adjusted life years annually – the equivalent of adding seven healthy days per year per woman – and unlock $1 trillion in annual global GDP by 2040. While the economic benefits are impressive, improving women's health is the real win, with lasting positive repercussions for society. The time has come for stakeholders to address the drivers of this gap, improving the lives of women while strengthening communities and economies worldwide.

This paper addresses the policy changes needed to establish a more robust, safe and inclusive approach to women's health science and innovation. We strongly believe that driving innovation in women's health can improve the statistics and lead to more women-focused clinical research. Furthermore, it makes the case for including women from diverse racial, ethnic and age groups in clinical trials to ensure such trials better reflect the populations they aim to serve.

The policy recommendations presented in this paper aim to address the gap in women's health research. By promoting a more inclusive approach to research, society can advance science through a deeper understanding of women's physiology, thereby improving safety and outcomes for women while advancing knowledge on health and medicine for all.

Looking to the future, it is imperative that policy-makers, healthcare leaders and other stakeholders join forces to uphold women's health as a cornerstone of medical progress. The vision outlined in this white paper provides a strategic path to closing the women's health research gap and advancing sex-specific medicine.

Executive summary

Women's health research represents a vital opportunity to drive innovation, improve outcomes and boost economic growth.

Despite living an average of five years longer than men, women spend 25% more of their lives in poor health or with some degree of disability.[2] Addressing this burden could improve the length and quality of life for millions of women while also boosting the global economy by at least $1 trillion annually by 2040. Despite the potentially high economic return, the most meaningful impact of these policy changes is improving women's health and, in turn, their lives.

Currently, however, only 7% of healthcare research focuses on conditions that exclusively affect women.[3] In addition, women remain under-represented in clinical trials, especially in early clinical trials and in key therapeutic areas such as cardiology and oncology, particularly women of colour and post-menopausal women.[4] Meanwhile, only 5% of available medications have been adequately monitored, tested and labelled with safety information for use in pregnant and breastfeeding women.[5] Furthermore, sex-disaggregated data is not necessarily reported. For example, only 7% of migraine trials and 17% of ischaemic heart disease trials have published sex-disaggregated data.[6]

These disparities contribute to the significant physical and social burden that many women face during their lifetimes. The opportunity – and need – for change is undeniable and imperative.

Charting the way forward

The objective of this white paper is to highlight issues in clinical research that are relevant to women's health, to communicate the importance of solving the problem to key decision-makers and to promote practical policy recommendations that can drive coordinated action. Implementing these recommendations would create a more supportive environment for women's health science and innovation and improve health outcomes for women.

Throughout 2024 and early 2025, the Global Alliance for Women's Health convened a working group of more than 45 organizations from industry, regulators and beyond to work jointly on transforming the policy landscape in women's health science and innovation. Driving change using the five levers of healthcare policy outlined below will facilitate an improved understanding of critical physiological differences between men and women and promote better health outcomes for everyone.

The white paper's recommendations are as follows:

1 **Unlock innovation in women's health.** Regulatory changes, such as priority review vouchers, paired with financial incentives such as tax credits, research funding and public–private investment matching, can encourage a wide range of stakeholders to invest in women's health and ultimately stimulate innovation. The adoption of a new pricing and reimbursement value proposition can also help address funding gaps, accelerate research and drive the development of new treatments.

2 **Expand the inclusion of women in clinical trials.** To ensure that new treatments are safe and effective in women, it is essential to improve their enrolment in clinical trials, especially in early clinical trials and in key therapeutic areas, such as cardiology and oncology, as well as the enrolment of often excluded subpopulations, such as women of colour and post-menopausal women. For pregnant and lactating women, the paper recommends introducing a maternal investigation framework, requiring research to be conducted, if possible, in those populations and offering targeted research incentives to support the collection of more representative data. Creating awareness among regulators and clinical trial staff as to the importance of inclusion and how best to design inclusive clinical trials can accelerate the alignment of efforts to achieve shared goals.

3 **Enhance disaggregation of clinical trial data.** Standardizing terminology and data collection and requiring comprehensive sex-specific benefit-risk assessments will provide better identification of unique sex-specific effects. Particularly while improving data collection, it will be important to adopt flexible methodologies for analysis and global data sharing to maximize insights from limited datasets.

4 **Design clinical trials with women in mind.** Educating investigators, developers, clinical trial staff and patients, along with improved clinical trial access, especially for women from underserved populations, is essential for advancing women's health research. Clinical trials must also be designed to account for sex-based differences in physiological mechanisms and treatment responses.

5 **Deepen insights on sex-specific differences.** To account for sex differences and ensure transparency about safety and efficacy for all patients, clinical guidelines as well as product package inserts and patient information leaflets need to be updated. Lastly, implementing the SAGER guidelines in scientific journals will improve transparency when reporting sex-specific differences – clearly a quick win.

Women have waited long enough to live in better health; the time for change is now. Prioritizing innovation and inclusion can break down the barriers hindering progress in women's health research while driving global economic growth. Uniting industry leaders, regulators, other experts and patients is a decisive step towards reshaping the landscape of women's health science and innovation one policy at a time. These policies will drive more robust science that not only improves health outcomes for women but also promises far-reaching economic benefits for all.

Introduction: The case for women's health policy transformation

Sex characteristics have a fundamental effect on health and diseases, yet current research does not adequately account for this.

For far too long, women's health has been treated as a niche issue rather than a fundamental pillar of public health policy. The consequences of this oversight are profound, including delayed diagnoses, inadequate treatments and preventable suffering, even death, that affects half the world population. Despite advances in medicine, healthcare systems continue to overlook the unique biological and social factors influencing women's health. Transforming women's health policy is not just a moral imperative, it is a necessary step towards better, more robust science leading to improved outcomes, reduced healthcare costs and a healthier, more successful society.

BOX 1 **Terminology**

Definition of women's health

Women's health – which includes conditions that affect women exclusively, differently and disproportionately to men – is often simplified to include only sexual and reproductive health. This report defines women's health as covering conditions that affect women exclusively, such as endometriosis and menopause, but also conditions that affect women differently such as cardiometabolic conditions or disproportionately such as bone health, brain health and autoimmune diseases.

Focus of this white paper

The focus of this white paper is on sex-associated biological variables as an initial step, even though its authors recognize the importance of gender as a cross-cutting issue. Throughout this white paper, the term "sex" is used to mean sex-associated biological variables. Furthermore, the terms "women" and "men" are used to mean individuals with female- and male-typical biological variables, respectively. It is important to acknowledge the complexity of sex and gender and the need for more research into the challenges facing transgender, genderfluid and non-binary communities.

Definitions of sex and gender:[7]

Definition	Examples
Sex refers to the biological variables that differentiate females and males, and which can include variations of what are considered female-typical and male-typical characteristics (sometimes known as "variations in sex characteristics" or "intersex").	Sex chromosomes Gene expression Hormone profile Secondary sex characteristics Internal and external reproductive organs
Gender refers to an aspect of a person's identity. A person is subjected to a range of social forces (both constraints and privileges) based on their gender, which may influence their behaviours, their perception of themselves and how they are treated by others. All these influences may be relevant for biomedical, health and care research. When accounting for gender, it is worth keeping in mind that an individual's gender exists on a spectrum, can change over time and intersects with other aspects of their identity such as age, ethnicity and sexual orientation. There is considerable diversity in how people experience and express gender within and between societies.	Gender identity (the gender with which a person identifies) Gender expression (how a person outwardly presents themselves in relation to gendered forces) Gender modality (whether a person's gender identity is the same as their sex assigned at birth or not, i.e. whether they are cisgender or transgender) Perceived or presumed gender (how a person's gender is typically understood by those around them, which may differ from their gender identity and/or gender expression)

Research shows that medicines are three and a half times more likely to be withdrawn for safety risks in women, and, since 2000, adverse events from approved medicines in the United States have been reported 52% more frequently in women than men, with serious or fatal events 36% more common for women.[8] However, the effects of the research gap in women's health are not just physical, they have also had a profound psychological impact in society. In a 2022 health survey, nearly 30% of women report having their health concerns dismissed by a provider and 15% say their provider did not believe they were telling the truth.[9] The disparities continue, with research showing that women are 13–25% less likely than men to receive opioid analgesia when reporting acute abdominal pain.[10] Another study showed that women have longer emergency department throughput and process times than men.[11] Despite these issues, women's health remains under-researched, under-represented and underfunded, and available data is patchy at best, leaving critical gaps in prevention, diagnosis and treatment of conditions.

Investing in women's health is an investment in a better future for all

Increasing the investment in women's health will not only improve the quality of life for women, which is essential in its own right, but presents an opportunity to boost the global economy by more than $1 trillion annually by 2040.[12] This estimate is supported by a 2025 survey which found that 70% of about 1,000 respondents globally reported losing one to five days of productivity in the previous month due to women's health issues. Furthermore, 61% of respondents indicated that they had taken time off due to women's health conditions, yet many shared that this metric did not fully capture their experience. They felt pressured to continue working even when sick to avoid falling behind.[13]

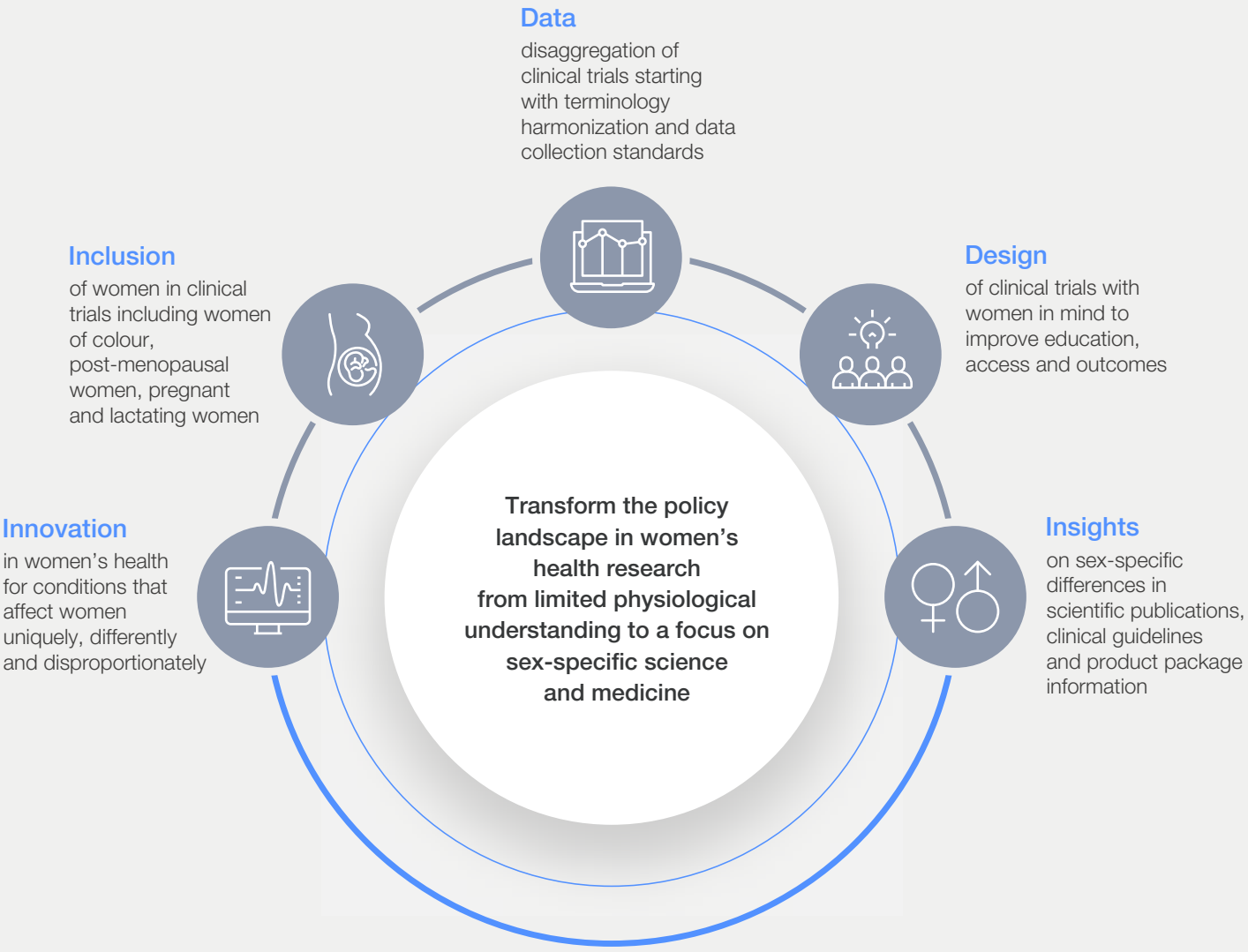
Going forward, it is important that improvements already made in women's health science and innovation are protected and further progress is promoted – from in-vitro systems to animal models to human studies. This begins with driving research into women-specific conditions while also advancing the understanding of women's physiology in conditions that affect women differently or disproportionately. To achieve this, the inclusion of women in clinical trials should be expanded, accounting for race, ethnicity and age and disaggregating clinical trial data accordingly. In addition, clinical trials should be designed to account for meaningful sex-based differences. Finally, sex-specific insights should be deepened to better inform both physicians and patients (Figure 1).

Without funding and regulatory changes to support and advance sex-specific clinical research, women will not be able to fully reap scientific advances to the same extent as men – despite their unique health needs and despite their explicit right to science and technology as outlined 30 years ago in the Beijing Declaration and Platform for Action.[14] Incentives, requirements and the representation of women in research leadership are key enablers for progress with proven track records.

The Global Alliance for Women's Health, in partnership with Kearney and the Gates Foundation, is pleased to share this white paper with the objective of guiding advocacy and policy changes protecting and promoting women's health in clinical research.

> **When women spend 25% more of their lives in poor health, the problem isn't just clinical – it's systemic. Transforming women's health research isn't optional; it's critical to unlocking smarter science, stronger economies and fairer futures. Now is the moment for us to turn that possibility into policy – and policy into progress.**
>
> Sanjana Bhardwaj, Deputy Director, Program Advocacy and Communications, Gates Foundation

Focus areas



Source: World Economic Forum

1 Unlock innovation in women's health

Innovation in women's health research is urgently needed to improve condition prevention, diagnosis and treatment.

At a time when regular advances in precision medicine are transforming condition prevention, diagnosis and treatment, many conditions that exclusively affect women or affect women differently and disproportionately remain understudied.

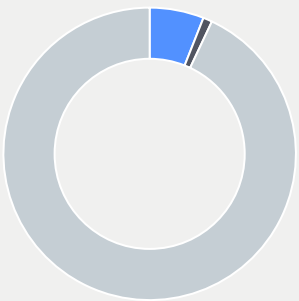
Innovation in women's health research can deliver a better understanding of the differences in the underlying physiology between men and women and address these unmet needs.

1.1 Women's health is underfunded and under-researched

Maternal hypertensive disorders – pre-eclampsia, for example – account for 70,000 maternal deaths worldwide each year, but with few early symptoms they are often diagnosed too late or even go undiagnosed.[15] Endometriosis, an oestrogen-linked condition that affects 10% of reproductive-age women and girls globally – a total of more than 190 million women – lacks an effective treatment despite its prevalence and often debilitating symptoms.[16] Meanwhile, there is also insufficient research into menopause, a normal and expected transition for almost every woman in mid-life, despite its having a profound impact on women's health and quality of life. These are just a few examples of how a lack of investment in clinical research can negatively affect women, with a larger impact on those from low and middle-income countries (LMICs), where access barriers push available solutions even further out of reach.

These numbers are just the tip of the iceberg. A major lack of funding for women's health directly limits research, creating a ripple effect throughout society. For example, only 7% of biopharma innovation is invested in women-specific conditions, with not even 1% invested in conditions beyond women's cancer (Figure 2).[17] Furthermore, there is a global "drought" of medicines that are in the pipeline for maternal health, with only two drugs since the 1950s having been developed and registered for pregnancy-specific conditions.[18] Additionally, the US National Institutes of Health (NIH) allocates only 11% of its budget to women's health research, and, despite women having a 50% higher mortality rate in the year following a heart attack, only 4.5% of the NIH's budget for coronary artery disease supports women-focused research.[19] On the global health stage, women's health is equally underfunded. Within LMIC-applicable research and development (R&D) for sexual and reproductive health – arguably a women-centric health area to begin with – investment in conditions that exclusively affect women accounts for only 8% of the total and represents only a small proportion of what is spent on other global health issues such as malaria.[20]

FIGURE 2 **Investment in women-specific conditions**



2024 Pharma R&D spend (%)

- Women's cancers 6%
- All other women-specific conditions <1%

Source: Evaluate Pharma. (2025). Kearney analysis. https://www.evaluate.com/

1.2 Success in orphan and paediatric diseases: Incentives drive investment and innovation

History shows that well-designed incentives drive innovation in under-represented areas of research. The US Orphan Drug Act was introduced in 1983 to accelerate innovation in treatments for rare, or "orphan", diseases by providing strong incentives for drug development. Since its passage, the US Food and Drug Administration (FDA) has approved more than 600 orphan drug indications from more than 450 distinct drug products compared with only 10 such product approvals in the decade prior to enactment.[21] The Act grants the FDA authority to designate orphan drugs, offering sponsors key benefits such as market exclusivity for seven years, tax credits of up to 25% for clinical trial expenditures and waived prescription drug user fees.[22] Comparable incentive structures have been introduced across the globe to drive innovation in rare diseases. For example, in 1993, Japan launched the Orphan Product Development Support Program to promote the development of therapies for rare diseases by providing various incentives for developers, such as financial subsidies for research, market exclusivity and prioritized scientific consultations.[23]

Similarly, even though the US Congress has not renewed the FDA's Rare Pediatric Disease Designation and Priority Review Voucher Program recently, the programme's success demonstrates how strong incentives can lead to scientific innovation.[24] Between 2012 and 2024, the programme drove innovation by accelerating treatment development for rare paediatric diseases, with more than 560 designations, 53 priority review vouchers, 47 awarded for indications that had no approved treatment prior to the programme and 39 new treatments – 36 of which previously had no approved options.[25] These incentives have driven investment and innovation in previously neglected areas of medicine and can serve as a blueprint for advances in women's health research.

Finally, antimicrobial resistance (AMR) is another example of how incentivization can affect global health. AMR is a pressing global health threat, yet the development of new antibiotics has lagged due to limited financial incentives.[26] To address this, policy-makers in some jurisdictions introduced market entry rewards, priority review vouchers and extended market exclusivity, which successfully spurred investment in antibiotic innovation. These incentives, which began in 2012, encouraged pharmaceutical companies to develop novel treatments despite high research costs and uncertain returns. The AMR model demonstrates that targeted incentives can drive innovation and bring life-saving advances to market, offering a valuable blueprint for accelerating progress in women's health research.

1.3 Policy recommendations to unlock innovation in women's health

Regulatory as well as financial incentives are critical to accelerating innovation in women's health. Streamlined approval pathways, tax incentives and public–private partnerships can encourage R&D. Past successes, such as the orphan drug and paediatric research incentives, as well as the AMR initiatives, have demonstrated the power of incentives in driving investment and scientific breakthroughs. Aligning policy, investment and innovation can drive meaningful improvements in women's health outcomes globally.

The following policy recommendations address the underfunding to drive innovation in women's health (Figure 3):

- **Introduce regulatory incentives to drive innovation in women-specific conditions.** Innovation in women-specific conditions should be incentivized through the introduction of programmes such as female disease designation and priority review vouchers. Like the Rare Pediatric Disease programme, this would grant sponsors priority review vouchers for developing treatments for women-specific conditions. These vouchers could be redeemed for expedited approval of another product. Additional incentives, such as extended data or market exclusivity – for example, through a transfer exclusivity voucher – can further encourage investment in research.

- **Create financial incentives to drive innovation in women's health.** Increased government funding can be achieved through grants, prizes and dedicated women's health research initiatives. Tax credits, deductions and exemptions can further incentivize innovation. Together, these financial incentives can address the significant funding gaps reported by agencies such as the NIH. Additionally, public–private funding matches can heighten the impact of philanthropic and private-sector contributions, driving investment in innovative treatments and technologies.

– **Adopt a new pricing and reimbursement value proposition to drive innovation in women-specific conditions.** Implementing new pricing structures such as price premiums for underinvested women-specific conditions or even guaranteed payment structures before product development can incentivize the creation of treatments. These pricing strategies reduce the financial risks for manufacturers, encourage innovation and prioritize conditions that exclusively affect women. Additionally, ensuring equality in cost coverage for reproductive procedures addresses the fact that women have disproportionately more out-of-pocket expenses than men.

To drive meaningful progress in women's health research, a combination of three incentives is needed: regulatory, such as disease designation and priority review vouchers; financial, including tax credits; and pricing and reimbursement, such as price premiums. Past experiences show that a strategic blend of these incentives has the power to improve innovation and investment in women's health research. However, achieving this requires collaboration at every level, including working with: regulatory bodies to establish effective legislative and policy frameworks; governments to secure financial support; and payers to ensure sustainable market incentives. These policies can provide the structural framework needed to implement effective changes.

> **Innovating in women's health is key to addressing unmet needs and ensuring that all women receive the comprehensive care they deserve for a healthier future.**
>
> Kelle Moley, Global Vice-President of Clinical and Translational R&D, Reproductive Medicine and Maternal Health, Ferring

FIGURE 3 **Women's health research policy recommendations**

Innovation

Unlock innovation in women's health

- **Introduce regulatory incentives** to drive innovation in women-specific conditions
- **Create financial incentives** to drive innovation in women's health
- **Adopt a new pricing and reimbursement value proposition** to drive innovation in women-specific conditions

Inclusion

Expand the inclusion of women in clinical trials

- **Create awareness with regulators and investigators** to generate women-specific data earlier
- **Improve enrolment** of women in clinical trials to drive new and effective treatments
- **Introduce a maternal investigation plan** to support research for pregnant and lactating women
- **Require research on pregnant and lactating women** to close critical data gaps
- **Incentivize research on pregnant and lactating women** to advance maternal and infant health

Data

Enhance disaggregation of clinical trial data

- **Standardize terminology and data collection** to improve women's health research
- **Require comprehensive sex-specific benefit-risk assessments** to close critical gaps in clinical research
- **Adopt flexible methodologies for analysis and global data sharing** to maximize insights from limited data

Design

Design clinical trials with women in mind

- **Employ sex-specific biomarkers** to understand differences in disease mechanism and manifestation
- **Design clinical trials to account for sex-based differences** in physiological mechanism and manifestation
- **Educate investigators, developers, clinical trial staff and patients** to improve research quality and outcomes
- **Ensure access to clinical trials** through proactive strategies to recruit and retain women, particularly those from underserved communities

Insights

Deepen insights on sex-specific differences

- **Report sex-disaggregated data in scientific publications** to improve transparency on insights
- **Update clinical guidelines** to ensure safe and effective treatments for all patients
- **Ensure transparency in product information** for safer, more effective treatments

Source: World Economic Forum

2

Expand the inclusion of women in clinical trials

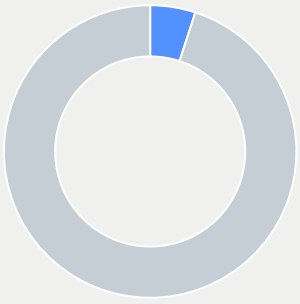
The appropriate representation of women in clinical trials should be the top priority to improve women's health outcomes.

Despite women experiencing various medical conditions differently and disproportionately compared to men, sex-specific research is lacking. In the 1950s and early 1960s, thalidomide was prescribed to pregnant women to treat morning sickness, but it led to severe birth defects including children being born with missing or malformed limbs.[27] This prompted the exclusion of women of childbearing age from clinical trials for almost four decades and is one of the main reasons for a gaping hole in clinical research focused on women and their unique health outcomes. Additionally, females are often ignored and only seen as small males in both animal and human studies – another reason for the huge gap in women's health research.

2.1 Women remain under-represented in clinical trials

It was not until 1993, when the NIH mandated women's inclusion in trials, that women began to be more widely represented in clinical trials. However, even though the representation of women in clinical trials has been increasing in recent years, women remain under-represented in early clinical trials, potentially creating significant gaps on dosing accuracy and consequently safety and efficacy, and in important therapeutic areas such as cardiology and oncology, despite the high disease burden in those areas.[28] Further to this, key subpopulations such as women of colour and post-menopausal women remain under-represented in clinical trials.[29,30] Meanwhile, only 5% of available medications have been adequately monitored, tested and labelled with safety information for use in pregnant and breastfeeding women, and as such more than 80% of pregnant patients are routinely prescribed therapies that have never been studied during pregnancy or lactation.[31,32] All of these discrepancies highlight a critical oversight in women's health science and innovation (Figure 4).

FIGURE 4 **Inclusion of pregnant and lactating women in clinical trials**



Drugs labelled for use in pregnant and lactating women

→ 5%

Source: Innovative Medicines Initiative. *Background. IMI ConcePTION.* https://www.imi-conception.eu/background/

The consequences of this research gap are significant, but when studies are designed to account for sex differences, the benefits are clear. For example, Novartis discovered that its heart failure drug Entresto, launched in 2015, was particularly effective for women, who are twice as likely as men to develop heart failure with preserved ejection fraction – also known as diastolic heart failure, in which the left ventricle, the organ's main pumping chamber, becomes stiff and is unable fill properly.[33] After conducting clinical trials on target subgroups, a 2019 Phase 3 trial revealed that the drug reduced hospitalizations for women by 33%. This finding led to expanded FDA approval, allowing more than 2 million additional patients to benefit and underscoring the urgent need for research that prioritizes sex-specific data.

2.2 Success in paediatrics: Requirements and incentives drive inclusion

Two decades ago, the United States implemented policies to drive paediatric drug development. In 2002, the Best Pharmaceuticals for Children Act (BPCA) provided marketing exclusivity incentives for sponsors that voluntarily conducted paediatric studies; the following year, the Paediatric Research Equity Act (PREA) introduced a requirement for paediatric studies using appropriate formulations to obtain paediatric labelling with the option to request a waiver if, for example, evidence strongly suggests that the drug is unsafe in paediatrics. This regulatory requirement proved significantly more effective than just incentivization, leading to 475 drug approvals, compared to 199 approvals under the BPCA's voluntary approach.[34] Additionally, an initial paediatric study plan was established to ensure that paediatric considerations were incorporated early in drug development. The European Medicines Agency (EMA) has put similar requirements in place with the EU Paediatric Regulation and the Paediatric Investigation Plan.[35,36] The success of these policies highlights that requirements have a far greater impact on approvals than incentives alone. Applying this approach to pregnant and lactating women – by requiring research on medication safety, efficacy and dosing, paired with targeted incentives to overcome increasing costs – can ensure that this demographic of women is no longer excluded from essential clinical trials.

2.3 Recent guidelines and initiatives start to focus on inclusion

Although the United States has recently made changes to broaden clinical research to include more women, a global push to improve policies that promote better representation is still needed. In 2024, the FDA Diversity Action Plan was put in place to improve enrolment of participants from under-represented populations in clinical trials.[37] In the same year, the National Academies of Science, Engineering, and Medicine released the report *Advancing Clinical Research with Pregnant and Lactating Populations: Overcoming Real and Perceived Liability Risks* to improve representation of pregnant and lactating women in clinical trials.[38] Other regulatory bodies such as the EMA, Health Canada and the United Kingdom's Medicine and Healthcare products Regulatory Agency (MHRA) initiated similar guidelines and projects. Most recently, the FDA introduced draft guidance on studying sex differences in the clinical evaluation of medical products highlighting the need to include women in clinical trials, particularly pregnant and lactating women, and to conduct sex-specific data analysis.[39] Further, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) currently develops a guideline on the inclusion of pregnant and breastfeeding individuals in clinical trials.[40] Finally, the 2024 Access to Medicine Index is a testament to this shifting landscape. It highlights early progress within the pharmaceutical industry in addressing this issue, with some companies taking steps to include pregnant and lactating women in HIV clinical trials.[41]

This lack of sex-specific research is contributing to a major absence of data and thus knowledge regarding the treatment safety and efficacy in women throughout their lives. Policy changes requiring and incentivizing the inclusion of diverse women in clinical trials are necessary to address these gaps and better understand sex-specific differences in treatments.

2.4 Policy recommendations to expand the inclusion of women in clinical trials

The following policy recommendations are intended to address disparities in representation and expand the inclusion of women in clinical trials, including pregnant and lactating women (Figure 3):

- **Improve enrolment of women in clinical trials to drive new and effective treatments.** Building on the FDA Diversity Action Plan, regulatory bodies should have the authority to mandate the inclusion of women in clinical trials. Enrolment goals should be based on sex, race, ethnicity and age – from 18 to post-menopausal women – aligned with the prevalence in the intended use population. Additionally, women of childbearing age must be presumed eligible for participation rather than routinely excluded, with clear justification required for any exceptions. Further, contraception guidelines should be harmonized based on actual reproductive risks rather than broad, inconsistent requirements, while ensuring the availability of highly effective contraceptives and appropriate education, to avoid unnecessarily excluding women from research.

- **Introduce a maternal investigation plan to support research for pregnant and lactating women.** Modelled on the FDA's Pediatric Study Plan and the EMA's Paediatric Investigation Plan, this structured approach integrates reproductive health considerations early in clinical trials, potentially even using non-animal models (such as organ-on-a-chip). By the time Phase 3 clinical trials are being undertaken, at the latest, thorough benefit-risk evaluations should guide the inclusion or exclusion of pregnant and lactating women. Additionally, collecting global pregnancy outcome data using national and international registries, including from LMICs, can help promote inclusion and inform evidence-based clinical guidelines.

- **Require research on pregnant and lactating women to close critical data gaps.** In an intervention modelled on the PREA, mandating studies on the safety, efficacy and dosing of medications in pregnant and lactating women will help address the long-standing absence of data – first in preclinical research and, depending on safety outcomes, also in clinical research. Post-authorization safety studies should be considered the absolute minimum. The routine inclusion of available data on pregnant and lactating women in periodic benefit-risk evaluation reports and risk management plans should also be required, with systematic investigations triggered when a concern is identified. Additionally, when benefit-risk assessments are incomplete, establishing post-market registries, such as Medication Safety in Pregnancy (EUROmediSAFE), can generate real-world evidence to refine clinical guidelines and improve maternal and infant health outcomes.[42]

- **Incentivize research on pregnant and lactating women to advance maternal and infant health.** In an intervention modelled on the BPCA, offering incentives for studies on both on- and off-patent drugs as well as other bioactive substances (e.g. nutraceuticals) will help fill critical knowledge gaps and ensure safer treatment options. Additionally, making clinical trial insurance more affordable for research involving pregnant and lactating women will help remove financial barriers for investigators and sponsors, supporting and encouraging greater inclusion in clinical studies and ultimately improving healthcare outcomes for these populations.

BOX 2 | **Quick win: Regulator and investigator awareness education**

Create awareness with regulators and investigators to generate women-specific data earlier. Creating awareness with regulators and investigators – particularly on the inclusion of pregnant and lactating women – can improve study design and promote better representation in clinical trials. Educating on the importance of inclusion is an easy policy to implement that can immediately drive clinical research towards better health outcomes for women.

The results are clear: better representation leads to better science. Inclusion mandates – particularly for female subpopulations – should be seriously considered as they have proven to be more impactful than incentives in driving progress. The successful implementation of such requirements, as seen in past best practices, has led to tangible improvements in diverse representation and outcomes. Regulatory agencies play a critical role in driving these changes. Focusing on these tried-and-tested strategies, along with quick wins such as a regulatory and investigator awareness education to guide study design, will accelerate the necessary shifts in research practices and policies, ultimately improving the safety and effectiveness of treatments for all women.

> **Expanding the inclusion of women in clinical trials is crucial for advancing medical research. Through better representation of women, we can develop treatments that are safer and more effective for everyone.**
>
> Catharina Boehme, Assistant Director-General for External Relations and Governance, World Health Organization

3 Enhance disaggregation of clinical trial data

Data collection on conditions that affect women differently or disproportionately to men must be improved.

Women face a wide spectrum of health conditions that affect them differently or disproportionately to men, yet critical gaps in data collection continue to marginalize or even exclude them. A recent report found that of 52 migraine trials, 29 published data, of which only two (7%) published sex-disaggregated results, and of 320 ischaemic heart disease trials, 153 were open to both sexes and published data, of which only 26 (17%) published sex-disaggregated results despite that condition being the leading cause of death in women worldwide.[43,44] Another systematic review and meta-analysis showed that only 13% of Alzheimer's articles reported sex-stratified results.[45] As a result, the physiology of women is still not well understood, and knowledge of how conditions present and respond to treatment in women is limited; hence, wrong conclusions on the safety and efficacy of drugs in women are being drawn.

The first step in addressing this issue is to harmonize the terminology – especially by making a clear distinction between sex and gender – and establishing standardized data collection practices that go beyond common factors such as sex, race, ethnicity and age and include the socioeconomic status typically computed based on several factors such as income level, education and home postal code. The recently published Medical Science Sex and Gender Equity (MESSAGE) policy framework from the United Kingdom provides a strong foundation by defining sex and gender distinctions clearly.[46] According to its policy framework, sex refers to biological differences between females and males, while gender is an aspect of identity that influences behaviour, self-perception and social interactions. A fundamental policy shift towards more inclusive research and data collection can help ensure that women's health is much better understood and appropriately protected and promoted.

The policies outlined in this paper aim to rectify this imbalance by focusing on inclusive data collection practices and requiring sex-specific metrics in research to ensure women's health is no longer marginalized in the broader healthcare landscape. Bridging this data gap can pave the way for more targeted interventions, improved health outcomes and a healthcare system that better serves women.

3.1 Policy recommendations to enhance disaggregation of clinical trial data

The following policy recommendations are intended to enhance disaggregation of clinical trial data, including terminology and data collection standardization (Figure 3):

- **Standardize terminology and data collection to improve women's health research.** Harmonizing ICH terminology – for example, sex vs. gender – and implementing consistent data collection standards, including post-marketing surveillance with sex-specific indicators, will enhance clarity and comparability in clinical research. These measures are a critical first step towards improving data disaggregation, ensuring that sex-specific differences in health outcomes are accurately captured, analysed and disseminated globally.
- **Require comprehensive sex-specific benefit-risk assessments to close critical gaps in clinical research.** Requiring comprehensive sex-specific benefit-risk assessments, along with an intersectional analysis by race, ethnicity and age for regulatory approval, but also for journal submissions, can ensure that differences in the safety, efficacy and dosing of drugs

and other bioactive substances are properly evaluated – for all populations investigated. Applications should not advance without this analysis unless scientifically justified. Regular updates based on real-world evidence will keep clinical guidelines relevant, while standard statistical reporting with confidence intervals and controls for confounding variables can improve data reliability.

– **Adopt flexible methodologies for analysis and global data sharing to maximize insights from limited data.** Using advanced statistical approaches, such as Bayesian methods, or synthetic data for in-silico modelling to power sample sizes while integrating real-world evidence will enable more accurate and timely evaluations of treatment safety and efficacy, particularly for under-represented populations. Additionally, sharing existing and future clinical trial data among regions and countries will enhance transparency, accelerate innovation and ensure that medical decisions are based on diverse, comprehensive datasets, ultimately improving global health outcomes.

Improving data disaggregation will take several steps. The first is to harmonize terminology and define standardized data collection practices, ideally in collaboration with ICH. Once a clear framework is in place, regulators must establish concrete requirements for data analysis, ensuring that sex-specific differences are consistently assessed. Finally, addressing gaps in the limited data will require a coordinated effort among industry, regulators and other key stakeholders to implement flexible statistical approaches and incorporate real-world evidence. In taking these steps, a more inclusive and data-driven foundation for women's health research can be built.

> **Generating data that accurately represents the individuals receiving medicines is essential for making evidence-based decisions. We are committed to ensuring clinical research reflects the diversity of the populations we serve, thereby improving health outcomes for all.**
>
> Alison Cave, Chief Safety Officer, Medicines and Healthcare products Regulatory Agency (MHRA) UK

4 Design clinical trials with women in mind

Clinical trials should be designed to capture sex-based differences between men and women.

For decades, clinical research has largely been overseen by men and designed with men as the default subjects; women's health, if addressed at all, has been an afterthought. Even when women are included in clinical trials, sex-based differences are frequently overlooked in data analysis, obscuring critical insights into how hormonal fluctuations, metabolism and genetics influence disease progression and treatment efficacy. This male-centric approach to research has led to a significant gap in medical knowledge that is impeding advances in women's health.

Medical devices, for instance, have historically been designed with men's physiology as the standard, despite clear anatomical and biomechanical differences between men and women. Some hip implants, for example, fail at nearly twice the rate in women due to differences in bone structure and load-bearing mechanics.[47] Similarly, drug trials that fail to account for sex-specific variations in body mass, metabolism and hormone fluctuations may lead to incorrect dosing recommendations or increased risks of adverse effects for women. These examples underscore the critical need for clinical trials designed to capture meaningful sex-based differences, rather than relying on generalized findings that overlook half the population and – as seen with medical implants – often lead to higher failure rates in women.

While little progress has been made in addressing these issues, the NIH policy on Sex as a Biological Variable provides an excellent framework for improving study design.[48] This policy mandates that researchers consider sex as a critical factor in study design, ensuring that both male and female subjects are adequately represented and analysed in clinical research. Expanding on this, it asserts that clinical trials should be designed to account for known sex differences, with separate analyses for each sex when significant variations exist. Lastly, it encourages inclusion of both men and women when differences are uncertain, and broad participant representation when the data is inconclusive.

Relying on men's physiology and pathology as the foundation for treatment guidelines for both men and women does a profound disservice to women's health. Designing clinical studies with women's health not just in mind but at the forefront is a scientific necessity. Without research that accounts for sex-specific differences, medical advances will continue to be skewed towards the physiology of men, perpetuating inadequate care for women and inaccuracies in results.

4.1 Policy recommendations to design clinical trials with women in mind

The following policy recommendations are intended to design clinical trials with women in mind (Figure 3):

- **Employ sex-specific biomarkers to understand differences in physiological mechanism and manifestation.** Prior to designing clinical trials, requiring robust preclinical in-vitro and animal data on sex-specific biomarkers in lab testing and imaging will help to clarify the differences in the physiological mechanism and manifestation in men and women. These detection sources are the foundational indicators that prompt further enquiry and define how to design clinical trials, especially in the case of sex-specific differences.

- **Design clinical trials to account for sex-based differences in physiological mechanism and manifestation.** When prior research confirms significant sex differences, clinical trials should be structured to answer separate primary questions for men and

women, ensuring adequate sample sizes based on the intended use population and appropriate (novel) clinical endpoints and assessment scales. In cases where the data is inconclusive, trials must include sufficient participants from both sexes to allow for meaningful analysis. Additionally, adaptive trial designs can improve efficiency by enabling real-time adjustments, reducing the patient burden while ensuring diverse populations are adequately studied.

- **Educate investigators, developers, clinical trial staff and patients to improve research quality and outcomes.** Requiring an education plan ensures that investigators, developers and clinical trial staff receive proper training, and that patients and their families are well-informed through accessible formats such as videos rather than dense text. Programmes such as the University of Maryland School of Pharmacy PATIENTS Professors Academy exemplify this approach, enhancing patient comprehension and compliance to promote more effective and inclusive research participation.[49]

- **Ensure access to clinical trials through proactive strategies to recruit and retain women, particularly those from underserved communities.** Requiring a recruitment-and-retention plan that addresses barriers – such as childcare, transport and financial security – can significantly improve the participation of women in clinical trials, particularly from low- and middle-income backgrounds. Remote access options and partnerships with community organizations can further build trust and engagement. Additionally, analysing clinical trial dropout rates by sex and underlying causes can provide valuable insights to refine study designs and enhance not only recruitment but also retention of diverse populations in future research.

Education and access are essential for meeting ethical standards and for ensuring informed consent but also for making clinical trials more inclusive, thereby advancing medical research. Achieving this requires a multistakeholder approach that brings together investigators, industry leaders and other experts to drive change. However, better study design is what ultimately ensures that research produces meaningful, achievable results. When prior preclinical and clinical studies reveal sex-based differences, clinical trials must be designed to address them, with regulators setting clear requirements for sex-specific analyses. Only once these differences are understood and integrated into clinical research can more effective, personalized treatments be achieved.

> **Embedding sex-based biological differences into clinical trial design is a scientific and ethical imperative – policy must lead the way to make this the norm, not the exception.**
>
> Victor Dzau, President, National Academy of Medicine

5 Deepen insights into sex-specific differences

The inclusion of sex-specific insights in publications, guidelines and product information presents a major opportunity for improved outcomes.

Most medications today come with a leaflet or product insert that provides important information about a prescribed medication. Key details such as dosing information and adverse side effects are included to provide transparency for the patient and the physician. Consider this, however: for a pregnant Hispanic woman managing anxiety or a 49-kilogram postmenopausal Asian woman with high blood pressure, it cannot be presupposed that the safety, efficacy and dosing of a product in a white man is comparable. In these scenarios, the dosing recommendations, side-effect profiles and efficacy data may be completely misaligned with these women's unique physiology. Asthma, for example, is a common respiratory condition that affects men and women at similar rates and is often treated with inhaler therapy, bronchodilators and corticosteroids. However, studies indicate that during acute exacerbations, this form of treatment is about 20% less effective in women than in men.[50]

To address these discrepancies, the SAGER (Sex and Gender Equity in Research) guidelines were introduced almost 10 years ago. They represent a comprehensive procedure for the reporting of sex and gender information in study design, data analyses, results and interpretation of findings, designed primarily to guide scientific journal authors but also useful for editors.[51] Adding sex-specific insights, where available, to scientific publications, clinical guidelines and product package information, could provide women and their medical teams with more accurate and supportive information. These details are not superfluous; they are essential to proper treatments and positive outcomes.

5.1 Policy recommendations to deepen insights into sex-specific differences

The following policy recommendations are intended to provide insights into sex-specific differences for both patients and physicians (Figure 3):

- **Update clinical guidelines to ensure safe and effective treatments for all patients.** Revising clinical practice guidelines once information is available to account for sex-specific clinical presentations and social determinants of health, such as age, will help refine drug choice and dosing recommendations. Resources such as the Janusmed Sex and Gender database in Stockholm, Sweden, can provide critical insights, particularly for pregnant and lactating women, whose unique physiological and hormonal factors affect drug safety and efficacy.[52] Strengthening these guidelines will lead to more personalized and ultimately better healthcare.

- **Ensure transparency in product information for safer, more effective treatments.** Requiring timely updates to product package inserts and patient information leaflets with sex-specific data will help patients and providers make more informed decisions. Including details on human vs. animal evidence, dosing variations and potential differences in benefit-risk assessment ensures that women and their providers have access to the critical information needed for safer, more personalized care.

BOX 3 | **Quick win: Reporting in scientific publications**

Report sex-disaggregated data in scientific publications to improve transparency on insights. Implementing the SAGER guidelines in scientific journals will ensure that sex differences are properly considered and reported. These changes are relatively easy to implement and a quick win. By improving accountability in research, it will lead to more transparent and complete reporting of findings and encourage industry-wide adoption of those practices.

Laying a stronger foundation for sex-specific research is an essential first step for meaningful progress. It begins with making sure women are properly and widely included in clinical trials and then continues with collecting comprehensive sex-specific data. With this foundation in place, clinical guidelines can be refined, drug labelling updated and essential sex-specific information integrated into product inserts and leaflets. Finally, quick-win strategies such as implementing the SAGER guidelines in scientific journals will help accelerate the adoption of these changes, leading to better transparency and outcomes in women's health.

> **To truly advance women's health in Africa and globally, sex-specific data must be non-negotiable – from clinical trials to journal publications. Holding the scientific ecosystem accountable is a critical step towards inclusive, evidence-based care that reflects the realities of women's lives.**
>
> Fara Ndiaye, Co-Founder and Deputy Executive Director, Speak Up Africa

Conclusion

Achieving meaningful transformation in women's health requires a fundamental shift in how clinical research policies address the unique considerations of physiology.

Despite progress in recent decades, critical gaps remain in research funding, clinical trial representation and data disaggregation, leaving women underserved across the globe. To bridge these gaps, the proposed policies can drive innovation and ensure that research truly represents the diverse experiences of women around the world.

The inclusion of diverse populations – particularly women of colour and post-menopausal women, as well as pregnant and lactating women – is not just an ethical imperative but a scientific necessity. Without robust representation, practitioners will continue to operate in a system where women experience higher rates of misdiagnosis, delayed treatments and serious or even fatal adverse reactions due to data derived primarily from clinical trials on men. Addressing these disparities requires a transformation in clinical research.

The urgency of the need for change has never been greater, nor has the opportunity. Implementing the proposed policies to drive innovation in women's health, expand the inclusion of women in clinical trials, enhance data disaggregation, design clinical trials to account for sex-based physiological differences and update clinical guidelines to provide better insights on leaflets and packaging will provide a strong starting point to close the knowledge gaps that have long hindered progress, creating an opportunity to stimulate a new era of medical advances.

Real transformation, however, necessitates more than just policy requirements. Sustained collaboration among governments, regulatory bodies, industry leaders, funders, research institutions, patient groups and others will be needed for long-term success. The World Economic Forum's Global Alliance for Women's Health aims to unite stakeholders around a common vision of robust, safe and inclusive science and is committed to encouraging the structural changes needed to progress clinical research, ensuring that innovation meets women's diverse needs, preferences and lifestyles.

The policies outlined in this paper mark an essential step towards reshaping the future of women's health research. When focusing on women's health, the benefits ripple throughout communities, economies and future generations. Bold new healthcare policies, collaborative action and a focus on developing safe and effective treatments can create lasting change that transforms women's health and creates a stronger and more vibrant global future for all.

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