Innovation Equity Forum

Data Harmonization Pilot

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The IEF, established through a collaboration between the Gates Foundation and the National Institutes of Health, brings together a global community of over 250 stakeholders committed to advancing women's health R&D. Our membership includes scientists, innovators, advocates, funders, implementers, and other women's health innovation ecosystem actors. Together, this diverse group is committed to advancing a more equitable, coordinated, and innovation-driven ecosystem for women's health.

From May to October 2025, IEF Working Groups worked across four action concepts—the Innovation Fund, Innovation Accelerator, Data Harmonization Pilot, and Knowledge Hub —to translate opportunities drawn from the Women's Health Innovation Opportunity Map into concrete initiatives. Each concept reflects deep ecosystem engagement, bringing together diverse stakeholders to co-design practical pathways that advance women's health innovation and equity globally.

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The Problem

To ensure that women receive evidence-based, tailored healthcare, accurate and accessible data are essential to understanding health conditions, informing diagnoses and treatment plans, and driving investment decisions and innovations. Women's health, however, is currently not accurately measured nor consistently understood. – Women's Health Opportunity Map (2023)

Women's health clinical research is weakened by the systematic and variable underreporting of critical data elements, starting with sex.[1] Women were excluded from research trials until the 1990s, or when included, their outcomes were not analyzed separately from those of men.[2] This omission in reporting masks important differences in disease presentation and treatment response, resulting in undetected sex-specific patterns, missed efficacy signals, and overgeneralized findings that ignore biological and social differences. These gaps have had tangible consequences: diagnostic delays when women's symptoms do not align with male-based criteria, treatment protocols that overlook differences in drug metabolism and efficacy[3] and blind spots in conditions that differently or disproportionately affect women, such as cardiometabolic disease, depression, and musculoskeletal disorders. Furthermore, no common evidence-based sex-specific guidelines currently exist. These gaps also undermine the accuracy of evidence more broadly, leaving research fragmented and harder to scale or compare across studies. This weakens published clinical evidence, as well as leading to poorer health outcomes for women.[4]

Standards like the SAGER Guidelines and the MESSAGE UK policy framework have been widely endorsed by clinical experts, reflecting growing recognition of the need for sex- and gender-intentional research.[5,6] Yet, implementation remains limited, with little enforcement to ensure consistent uptake.[7,8] Many studies are not designed to detect or interpret sex-related differences. When sex is collected and reported, it is often done so as a basic demographic variable, with results infrequently analyzed or disaggregated by sex. This results in evidence of sex-related differences being incomplete, inconsistent, and difficult to compare across studies.

Most existing efforts to improve data harmonization stop at sex and gender. Yet, women's health is shaped by life course, diversity dimensions, and social determinants of health—such as socioeconomic status and education—that influence exposure, resilience, and access to care across stages of life. Integrating these dimensions is essential to identifying periods of age-related heightened vulnerability and designing interventions that improve health outcomes for women throughout their lives.[9,10,11,12]

The Opportunity

Momentum is building to study, collect, harmonize, and report data across the life course to generate evidence that accurately reflects women's health needs.[13] The opportunity now is to shift from broad endorsement of sex- and gender-equitable research to including these variables in the performance of research, implementation of findings, and accountability through institutional practice.

The Innovation Equity Forum (IEF) proposes a pilot with a small number of funders requiring researchers to justify how and why sex is considered in research design, data collection, analysis, and reporting—supported by targeted trainings for funders, applicants, and reviewers. Other data elements, such as gender, age, or life stage, will be discussed and refined with pilot funders to provide a menu of considerations for applicants. The pilot will leverage established sex and gender standards (e.g., the SAGER Guidelines and MESSAGE Framework) and emerging global frameworks for intersectional analysis (e.g. GIST guidelines, DiMIS).[14,15,16] It will also draw lessons from national public funders such as the U.S. National Institutes of Health (NIH),[17] which mandates the inclusion of sex as a biological variable, and the Canadian Institutes of Health Research (CIHR),[18] which has embedded sex and gender integration across proposal review, scoring, and reviewer training.

By translating these precedents into a coherent, funder-facing model, the pilot will test a key hypothesis: that harmonized data standards—integrated from the outset into the research design process—will enable the collection of high-quality, sex-disaggregated and other equity-relevant data that can generate meaningful insights into sex and gender differences, improving research quality, comparability, and accountability.

In doing so, the pilot will generate data and insights to provide a proof of concept, thereby building a cumulative evidence base on sex differences and other diversity variables. It will also track changes in the number and quality of studies reporting sex-disaggregated outcomes, assess how these requirements influence research design, applicant composition, and question framing over time, and include metrics for representativeness (e.g., participation-to-prevalence ratios).[19,20,21]

The Approach

The IEF proposes a funder-led pilot focused on clinical research in four condition areas where sex and gender differences are significant but underexplored: cardiometabolic disease, musculoskeletal disorders, depression, and sexually transmitted infections (excluding HIV), selected by the IEF Data Harmonization Working Group. These conditions reflect categories outlined in the NIH *Chronic Debilitating Conditions in Women* framework: those more common in women and/or associated with greater morbidity in women (depression, STIs, osteoporosis within musculoskeletal disorders) and those representing high morbidity for women (cardiometabolic disease, including heart disease, stroke, and diabetes).[22] The Women's Health Opportunity Map developed by the IEF also highlights these conditions as priority areas with significant gaps in disaggregated evidence, reinforcing their selection for the pilot.[23]

The pilot will be ideally implemented with a small number of funders—organizations that help shape research design at the outset—to maximize leverage for institutional change. In later phases, the model could extend to journals to improve harmonization across the full research lifecycle.

Key Actors

Funders

Philanthropic and/or mission-driven funders with substantial clinical research portfolios across both high-income and low- and middle-income countries. They will:

- Co-design and test the pilot within their grantmaking systems, making the inclusion of appropriate data including sex and gender concepts an eligibility criterion for funding at the proposal stage
- Adopt staged funding—with an initial tranche released upon proposal approval and a subsequent tranche contingent on complete reporting of sex-disaggregated data during implementation
- Adapt reporting formats to ensure that sex-disaggregated reporting is undertaken across the variables monitored
- Participate in training and feedback sessions

Implementing group

A neutral organization or a group of subject matter experts (SMEs) with expertise in sex, gender, and intersectional analysis—and active engagement in global data harmonization efforts—will serve as the coordination and technical lead. The Implementing group will:

- Synthesize existing frameworks and best practices (SAGER, GIST, Gates Foundation Upstream Marker for Health, CIHR, DiMIS) into a funder-ready checklist
- Support the adaptation of the tool to each participating funder's systems
- Co-develop extensive training for funders, applicants, and reviewers
- Manage data collection, analysis, and learning outputs
- Co-produce an independent Learning Brief summarizing lessons/feedback, barriers, and recommendations for scale-up to other conditions and funders

Reference Committee

A small advisory group composed of IEF experts and representatives from participating funders, with balanced HIC-LMIC representation, will ensure global relevance and contextual sensitivity, provide technical guidance, review findings, and support dissemination.

Proposed Phases of Work

Phase 1 - Co-Design and Implementation (6 months)

Objective: Translate the concept into an operational pilot and implement it in at least one active funding cycle per participating funder.

- Synthesize existing frameworks into a harmonized funder checklist
- Co-develop training for funders, applicants, and reviewers, coordinating with existing materials (e.g., CIHR)
- Define monitoring and evaluation (M&E) framework
- Set up pilot processes within funder systems
- Develop a harmonized metadata schema aligned with SABV, SAGER, and DiMIS standards to ensure comparability across funder datasets
- Co-adapt application and reporting templates within each participating funder's system
- Funders implement the checklist in active calls or funding cycle

Phase 2 – Evaluation and Learning (24-36 months)

Objective: Assess the pilot's feasibility, institutional uptake, and scientific value, and synthesize lessons for broader adoption.

- Implementing group conducts mid-term evaluation and biannual follow-up with funders
- Aggregate data and qualitative feedback on checklist use, training relevance, and reporting completeness

Note: Given that most funder cycles span 2-3 years, the pilot will also capture mid-term learnings.

Expected Outputs:

- Harmonized templates and process notes for funders
- Aggregated dataset illustrating disaggregation patterns across portfolios
- A public-facing Learning Brief/Manuscript summarizing key findings and recommendations for scale-up

Design Principles

The pilot is designed as a learning system to build an evidence base that enables funders to adopt these tools as standard, sustainable practice.

Learning Objectives

- Demonstrate the feasibility of harmonized data standards in diverse funder contexts
- Build a cumulative evidence base on sex differences and intersecting factors
- Assess how harmonization shifts research design, applicant diversity, and portfolio composition

Sustainability Mechanisms

- A compact, open-access toolkit (checklist, training modules, templates) easily embedded in funder systems
- Capacity building for reviewers and program officers through peer learning and adaptation of CIHR's reviewer training model
- Inclusion of early-career and underrepresented researchers, especially women and LMIC-based scientists, as co-designers and contributors
- Flexible funding mechanisms—such as staged or lump-sum models with reporting gates—to reduce administrative burden while maintaining accountability

Evaluation Focus

The pilot will assess feasibility, scientific value, and institutional readiness through six key questions:

1. Does systematic disaggregation generate new insights into disease risk or treatment response?
2. Is the checklist practical and scientifically useful across research and funding settings?

3. What support or tools are needed for consistent adoption?
4. Which incentives (requirements, training, peer standards) are most effective?
5. Have we achieved harmonization? Does harmonization improve portfolio comparability, reproducibility, and accountability?
6. Does harmonization reduce data loss and improves visibility of underrepresented groups (e.g., women in low-resource settings or with comorbidities), thereby contributing to evidence equity?

These insights will inform iterative refinement and long-term scale-up. Even limited adoption, such as adding one or two checklist questions to funding templates, could represent meaningful progress. Over time, the checklist could evolve into a global reference standard for equitable data collection and reporting-scientifically rigorous, adaptable, and sustainable across regions and institutions.

Glossary of Terms

Sex. A biological variable—including anatomy, physiology, genetics, and hormones—that can influence health through a variety of pathways; for example, endocrine and immune system differences impact disease acquisition, presentation, and progression, and structural differences in the brain increase women's risk of concussion.[24,25]

Gender. A social and structural variable that includes identity, expression, roles and norms, relations, and power. Gender is considered separately from sex. Gender can influence health through a variety of pathways, such as care-seeking behavior and access, biased care provision, and differential exposures and protective factors as a result of gender norms (e.g., gender differences in sexual behavior and gender norms increasing the risk of depression).[26,27]

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Appendix

Draft - Funder's Research Outcomes Checklist

This tool is informed by and draws language from: the MESSAGE UK Funder Policy Framework, the Sex and Gender Equity in Research (SAGER) Guidelines, the Women's Health Opportunity Map, and the IEF Data Harmonization Working Group.

Eligibility Criteria:

- Applicants must answer **"Yes" with adequate justification** to all items below to be eligible for funding
- A **"No"** response is permitted only to help identify barriers and inform dialogue with applicants on how these challenges can be addressed

Purpose and adaptability:

This checklist provides a standard input for integrating equity-linked data elements into research proposals and reporting.

- **Required element:** *Sex* must be included as a minimum data requirement for funding eligibility.
- **Optional elements:** Funders may progressively add other variables—such as gender, age, life stage, socio-economic status, ethnic-racial identity, or physical health and disability—from an aligned menu based on international frameworks. Each funder must follow the same structure (design, collection, analysis, and reporting) and collect the same data to ensure consistency.
  This tiered design recognizes that system-wide adoption will take time while setting a clear, enforceable baseline and a pathway toward full intersectional data harmonization.

DESIGN	**Have you considered and accounted for sex when designing this study?** **If Yes:** • Specify which **sex-related characteristics** are relevant to your research question and why. • Identify which **participants** will be included and justify their inclusion/exclusion. • Identify any **potential equity risks or exclusions** (e.g., groups likely to be underrepresented or adversely affected) and describe how they will be mitigated. **If No:** Provide an **evidence-based justification** (i.e., non-applicability, limited capacity).
□ **YES** □ **NO**	*Please explain your response:*
COLLECTION	**Will you specify the target distribution and ensure adequate representation for sex?** **If Yes:** • Specify the **target distribution** (e.g., equal representation or proportional to population prevalence) and explain why it is appropriate to your research context. • Describe your **sampling or recruitment strategy** to achieve it. **If No:**

	Provide an **evidence-based justification** (e.g., single-sex condition, secondary dataset).
□ **YES** □ **NO**	*Please explain your response:*
ANALYSIS	**Will you analyze outcomes disaggregated by sex?** **If Yes:** • For **quantitative studies:** Describe how sex characteristics will be accounted for (e.g., stratified models, subgroup analyses, interaction terms). • For **qualitative studies:** Explain how gendered patterns or differences will be analyzed or interpreted in context. **If No:** Provide an **evidence-based justification** (e.g., sample size constraints).
□ **YES** □ **NO**	*Please explain your response:*
REPORTING	**Will you report and interpret sex-disaggregated results?** **If Yes:** • Confirm that results will be **presented separately by sex** in all outputs (tables, figures, publications) • Indicate how these results will be *clearly signaled in titles, abstracts, or summaries* to promote visibility and reproducibility • Describe how findings will be **interpreted and disseminated**, including implications for research, policy, and practice. • Indicate whether **disaggregated datasets** will be made available for transparency and secondary analysis. **If No:** Provide an **evidence-based justification** (e.g., preliminary data, confidentiality constraints).
□ **YES** □ **NO**	*Please explain your response:*

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