Inclusive Innovation

How Product Development Partnerships contribute to Gender Equality, Disability and Social Inclusion

December 2024

Strategic input on health to the Australian Government

Specialist Health Service

Acknowledgment

This report would not have been possible without the generous contribution of time and insights from representatives of the Product Development Partnerships (PDPs) and funding organisations who participated in our consultations. We are particularly grateful to the 11 PDPs and five funding organisations that shared their experiences, challenges, and best practices in integrating gender equality, disability equity, and social inclusion into their work.

Special thanks to the Australian Department of Foreign Affairs and Trade (DFAT) for commissioning this analysis and for their commitment to advancing GEDSI principles in global health innovation. In particular, we'd like to thank Larissa Burke and Dr Klara Henderson for their leadership and expertise.

Authors

This report is researched and produced by Dr Marie Lamy, Director, Just Consult Pte. Ltd and Dr Wesley Pryor, Nossal Institute for Global Health, University of Melbourne.

Disclaimer

This publication has been funded by the Australian Government through the Department of Foreign Affairs and Trade. The views expressed in this publication are the author's alone and are not necessarily the views of the Australian Government.

Acronyms

Acronym	Definition
AI	Artificial Intelligence
BMGF	Bill and Melinda Gates Foundation
CAB	Community Advisory Board
CTTI	Clinical Trials Transformation Initiative
CRO	Clinical Research Organisation
DE	Disability Equity
DEI	Diversity, Equity, and Inclusion
DFAT	Department of Foreign Affairs and Trade (Australia)
DNDi	Drugs for Neglected Diseases initiative
EDA	Federal Department of Foreign Affairs (Switzerland)
ESG	Environmental, Social, and Governance
EVI	European Vaccine Institute
FDA	Food and Drug Administration (United States)
FCDO	Foreign, Commonwealth and Development Office (UK)
FGS	Female Genital Schistosomiasis
GARDP	Global Antibiotic Research and Development Partnership
GE	Gender Equality
GEDSI	Gender Equality, Disability, and Social Inclusion
GPP-EP	Good Participatory Practice for Emerging Pathogens
HSI	Health Security Initiative
IAVI	International AIDS Vaccine Initiative
IDS	Investment Design Summary
IVCC	Innovative Vector Control Consortium
IVI	International Vaccine Institute
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex, Asexual, and others
LMIC	Low and Middle-Income Country
MDGH	Medicines Development for Global Health
MiMBA	Malaria in Mothers and Babies Initiative
MinBuza	Ministry of Foreign Affairs (Netherlands)

Acronym	Definition
NIMICT	Neurological Clinical Trials Project
NTD	Neglected Tropical Disease
OPD	Organisation of Persons with Disabilities
PBPK	Physiologically based Pharmacokinetic
PDAP	Product Development and Access Program
PDP	Product Development Partnership
PHR	Partnerships for a Healthy Region
PopCouncil	Population Council
R&D	Research and Development
SAGER	Sex and Gender Equity in Research
SI	Social Inclusion
SOGI	Sexual Orientation and Gender Identity
SRHR	Sexual and Reproductive Health and Rights
STEM	Science, Technology, Engineering, and Mathematics
Swiss EDA	Swiss Federal Department of Foreign Affairs
TB	Tuberculosis
TPP	Target Product Profile
USAID	United States Agency for International Development
US FDA	United States Food and Drug Administration
WHO	World Health Organization

Contents

Executive Summary

This report examines the integration of Gender Equality, Disability, and Social Inclusion (GEDSI) principles within Product Development Partnerships (PDPs) and the product innovation and development continuum. GEDSI is recognized as fundamental to achieving effective and inclusive development outcomes in global health, acknowledging that social norms, power dynamics, and intersecting identities significantly impact individuals' access to health resources and services. By integrating GEDSI considerations throughout their work, PDPs can better identify, and address barriers faced by underrepresented groups, develop more appropriate and accessible products, and ultimately improve health outcomes for women, people with disabilities, and other socially marginalised communities. This analysis, based on a mixed method approach including a literature and document review and primary data from 11 PDPs and five funders, captures best practices and provides actionable recommendations to support PDPs in their journey to improve GEDSI integration.

Key Findings

The findings are structured along six themes that emerged from the data and form the basis of the evaluation framework for this report. Most of the 11 PDPs interviewed, are making considerable effort to update their internal governance structures and policies to frame their engagement towards more gender equality and diversity. Disability inclusion, however, is not directly considered. All PDPs expressed a desire to learn more about disability inclusion within their organisations.

Organisational policies and governance

- Gender equality is often reflected in governance structures, but disability inclusion receives less consideration.
  - Many PDPs have established gender (or what is also often labelled Diversity, Equity and Inclusion) working groups, steering committees and diverse leadership initiatives, that generally focus on promoting gender equality.
  - Gender balance on boards is still a work in progress with noticeable efforts to encourage diversity of representation across genders as reported in the Global Health 50/50 Gender and Health Index.
  - Disability inclusion receives considerably less attention due to an admitted lack of understanding, research, expertise, and guidance.
- GEDSI integration and mainstreaming is influenced by funding, resources, and organisational mandate.
  - The level of available funding specifically earmarked for improving gender equality and further social inclusion significantly impacts the extent of implementation of specific gender equality or social inclusion policies implementation.
  - Organisational size and staff capacity affect the ability to support gender equality and social inclusion efforts. Larger teams with more human resources are more likely to find dedicated champions to lead on these efforts. Work tasks can be re-assigned among team members to dedicate time to lead a gender equality working group, for example.
  - To ensure that PDP activities are designed to reduce gender inequities, improve disability and social inclusion, the availability of quality, disaggregated data is acknowledged as essential.

Data collection and utilisation

- There is a growing recognition across PDPs of the need for sex-disaggregated, gender-disaggregated and disability-disaggregated data. We noted an increased focus on obtaining data disaggregated by sex, gender, and an interest in expanded this disaggregation to age, disability, and geographic location.

- We noted a lack of contextual data that could inform a disability inclusion approach or strategy and a lack of disability data in PDP monitoring plans.

  - There is limited information on disability, contextual information, data on disability prevalence and how it relates to disease areas and to PDPs' programs.

  - There is a need for more research on the intersection of disability and product development or innovation, beyond the prevention of disability.

- PDPs recognise the importance of understanding local contexts and socio-cultural barriers. Inequities are best understood locally, and therefore, local research is crucial for informing programs, from clinical trial design to access programs.

Partnerships and community engagement

- Community Advisory Boards (CABs) are effectively used among close to a third of the PDPs consulted to integrate diverse perspectives from priority populations across the product development continuum:

  - Almost all PDPs engage to some extent with underrepresented groups as well as groups with lived experience of the disease in their therapeutic area of research.

  - These groups include religious or ethnic minority group leaders, youth, and women's organisations to inform and guide programming.

- There is a noticeable gap across the 11 PDPs in engagement with Organizations of Persons with Disabilities (OPDs) and LGBTQIA+ advocates.

PDPs' ability to instigate transformative change is specific to activities under their direct control and within their mandate and spheres of influence. Among those are product design and designing inclusive clinical trials.

Product development and clinical trials

- There is an increased focus on developing inclusive Target Product Profiles (TPPs). Some PDPs explicitly call for products that meet the needs of pregnant and lactating women and women of childbearing age.

  - Some PDPs are calling for more guidance from the World Health Organization (WHO) to ensure focus on gender and disability inclusion in TPPs.

  - Some PDPs hold consultation with communities to ensure product acceptability and suitability.

- There are still barriers and challenges to ensuring diversity, and the inclusion of pregnant and lactating women, LGBTQIA+ individuals, as well as people with disabilities in clinical trials.

- PDPs are not yet adequately addressing the historical underrepresentation of women in clinical trials.
- PDPs acknowledge the complexity of issues around safety concerns and ethical considerations for including women in pregnancy and lactating women and clinical trials.
- Designs of trials and implementation can both intentionally and inadvertently exclude persons with disabilities.

- Efforts are being made to support clinical trial sites to be more inclusive and accessible.
  - Some PDPs are already considering trial sites and measures to ensure trials sites are accessible for people with reduced mobility.
  - Some PDPs are offering home visits for participants who may not be able to travel to trial sites.
  - PDPs are moving towards 'adaptive'[1] rather than merely 'inclusive' clinical trial protocols [see page 36]

- PDPs recognise that there are several barriers to diverse participation in trials.
  - This includes literacy issues, domestic responsibilities, work and income pressures, and discrimination.
  - Some of these barriers are being addressed through strategies like cultural competency training, community partnerships, honorariums and compensation, and other adaptive approaches

- Two of the11 PDPs consulted mentioned artificial intelligence (AI) and emerging technologies as a tool to improve diversity in clinical trials
  - AI could support increased efficiency in disaggregated data and trends analysis or to optimise patient recruitment and enhance participation, however this is a nascent area that should be considered carefully.

Programs and access

- While recognising that downstream accessibility is not in scope for all PDPs, there is still a role for PDPs to play in ensuring affordability and accessibility and acceptability of new innovations for all.
  - Some PDPs are developing innovative distribution methods for hard-to-reach areas in support of social inclusion.
  - We note there isa missed opportunity on the provision of clear, understandable information about medicines in various formats, including those suitable for people with disabilities.

[1] This approach involves adapting processes to be more inclusive and efficient at reviewing gender or sex-disaggregated data to inform decisions that lead to product development benefiting multiple communities. It also involves identifying context-suitable approaches that match the needs of participants and the requirements of the trial.

- There is a gap when it comes to consulting underrepresented communities to inform access plans.

- PDPs are not all systematically conducting thorough cultural assessments to ensure products are culturally appropriate and respectful of diverse beliefs and practices.

- A noted opportunity is to explore formulations and treatment protocols that may be more suitable and acceptable for people with disabilities.

Health systems impact and resilience

- There is a growing focus on localisation efforts and ensuring the promotion of diversity at the local level for a sustainable approach to product innovation.

  - Some PDPs are offering training and coaching for women in STEM to access leadership positions and recruiting Principal Investigators from countries with high disease burdens.

- A need for increased sharing of GEDSI best practices among PDPs was observed.

  - There is emerging collaboration between PDPs on GEDSI issues, but room for improvement.

  - The importance of training programs and capacity development efforts focused on gender, disability, and social inclusion for health workers and researchers was noted.

Recommendations

Integrating GEDSI principles into the product innovation and development continuum is crucial for developing equitable and effective global health solutions and ensuring those solutions are relevant to all, including unrepresented populations. While progress has been made, particularly in gender equality, there is significant room for improvement in disability inclusion and broader social inclusion. Both PDPs and their funders play critical roles in advancing GEDSI integration, from organisational policies to product development and access strategies. By implementing the recommendations outlined in this report, PDPs and funders can contribute to more inclusive and impactful health innovations that truly leave no one behind.

Incremental steps toward disability and gender inclusion

The following two diagrams encapsulate key recommendations PDPs and funders can take to identify and make progress towards disability inclusion and gender equality. They are followed by detailed recommendations.

Figure 1: Steps to support progress on disability inclusion across the Product Development Curriculum

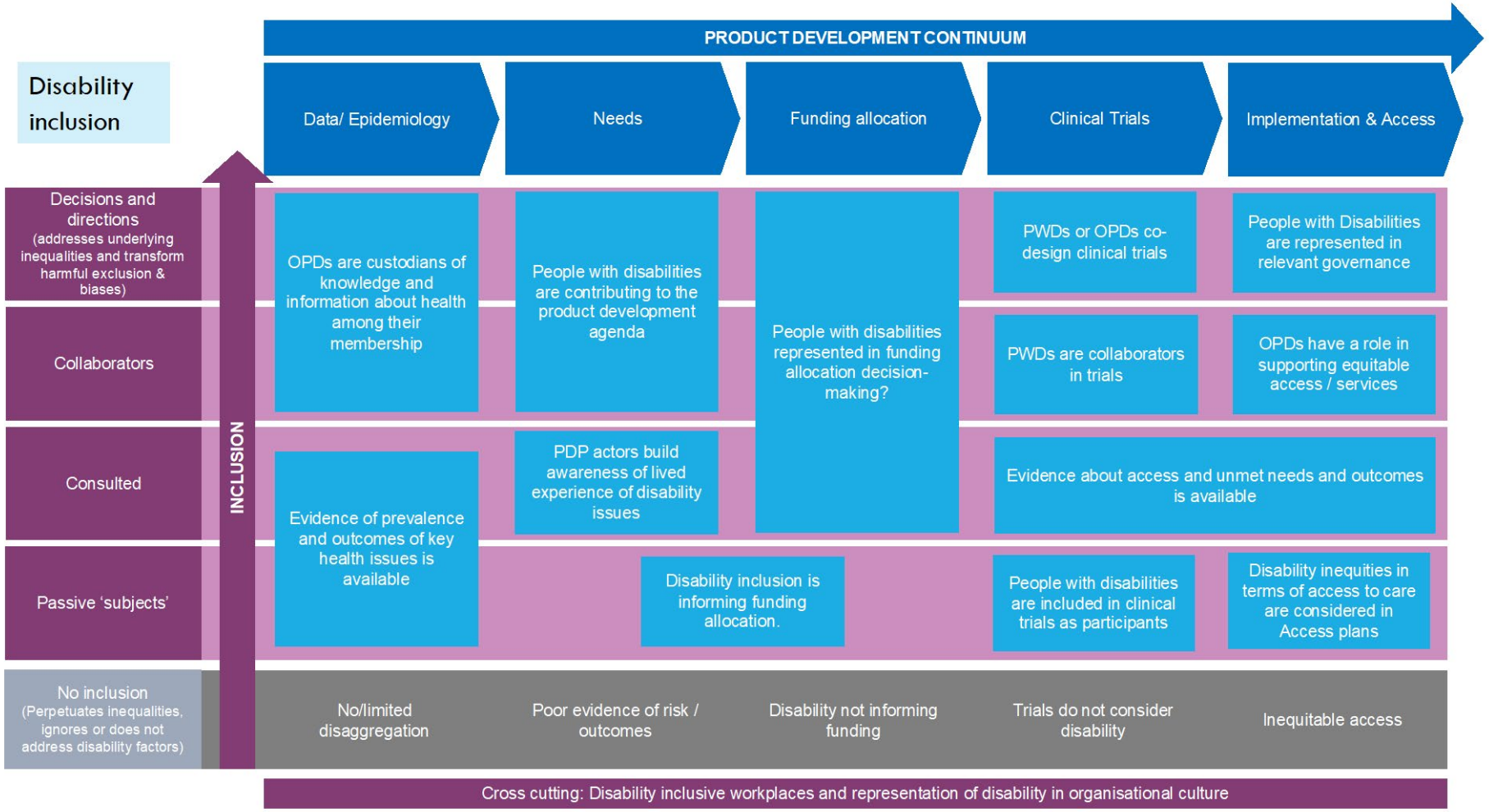
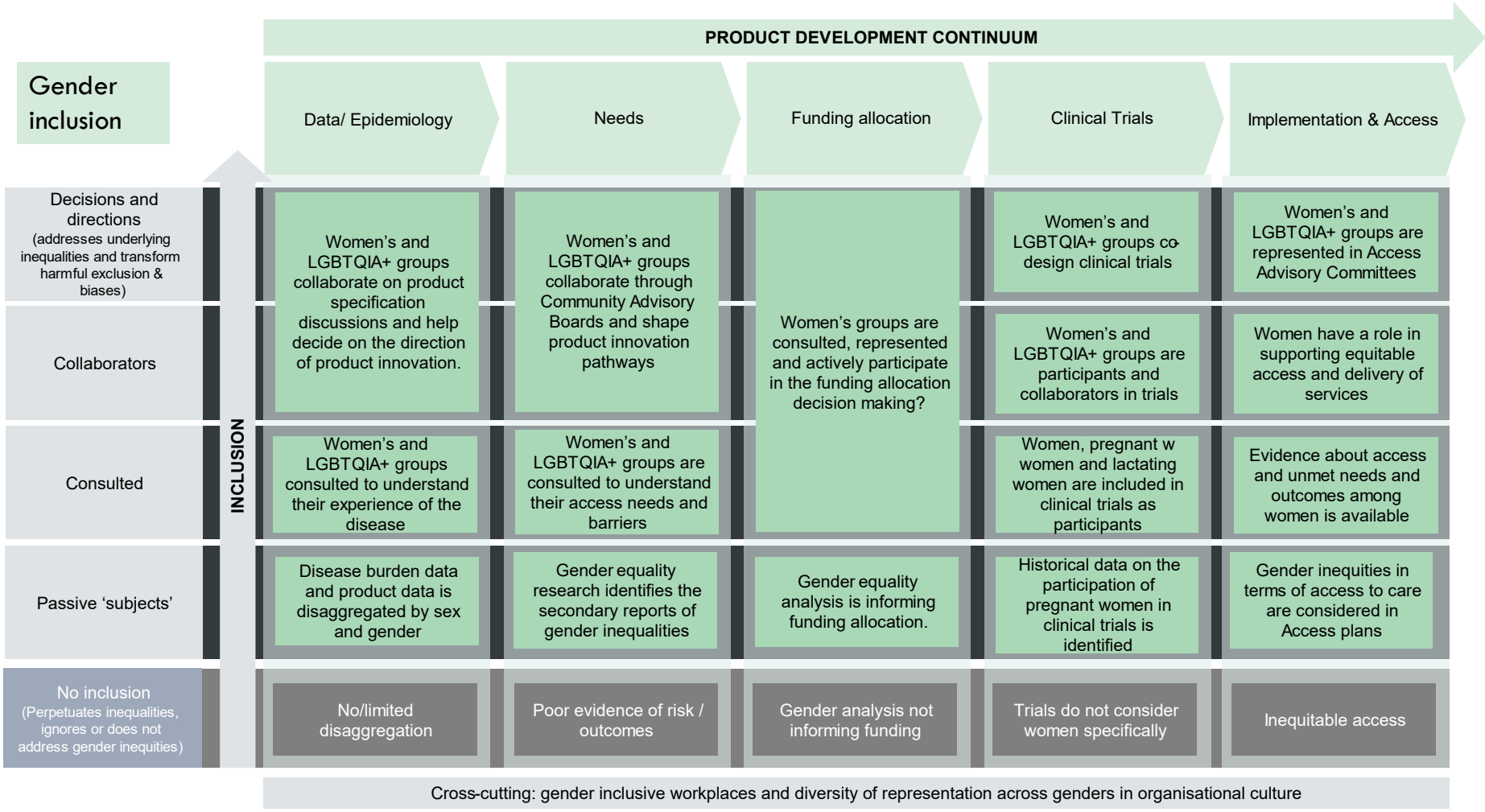


Figure 2: Steps to support progress on gender equality across the Product Development Curriculum



The recommendations are colour coded for ease of references as follows:

Colour	GEDSI category
Green	GEDSI - Gender Equality, Disability and Social Inclusion
Pink	GE - Gender Equality
Blue	DE - Disability Equity
Grey	SI - Social Inclusion

Recommendations For PDPs

Theme	GEDSI category	Recommendations
Organisational policies and governance	GE	Use the Global Health 50/50 self-assessment tool to measure progress along gender equality integration within the organisation.
	DE	Use the CBM organisational self-assessment tool to measure progress along disability inclusion within the organisation.
	GEDSI	Develop GEDSI strategies that encompass not only gender equality but also disability equity more intentionally.
	GEDSI	Establish task forces or working groups to work on gender equality, disability rights and inclusion of other groups who experience social disadvantage.
	GEDSI	Offer GEDSI training for staff.
	DE	Co-develop basic disability awareness and guidance among PDPs as a joint responsibility, through a secretariat or joint working group.
	GEDSI	Implement inclusive recruitment practices.
Data	GEDSI	Collect disaggregated data by sex, gender, age, disability, etc.
	DE	Invest in research on disability and product development intersection.
	GEDSI	Conduct research on access barriers in target countries for unrepresented populations including women, persons with disabilities, LGBTQIA+ communities and other socially marginalised groups.
	GE	Adopt and publicly commit to the Sex and Gender Equity in Research (SAGER) SAGER guidelines.
	DE	Adopt and publicly commit to RDI's Research for All guidance which is about making research inclusive of people with disabilities.
	GEDSI	Package available evidence to support advocacy efforts on promoting GEDSI mainstreaming among partners organisations.

Theme	GEDSI category	Recommendations
		This will serve to maximise the impact of your efforts on GEDSI beyond the product innovation space.
	DE	PDP grantees of DFAT should adhere to DFAT's inclusive and accessible communication guidelines.
Partnerships	GEDSI	Conduct a stakeholder mapping exercise of locally based representative organisations and associations of underrepresented groups and communities.
	GEDSI	Engage more directly with women's groups, women rights organisations, youth groups, and Indigenous People's organisations, organizations of people with disabilities (OPDs), disability rights organisations, and LGBTQIA+ advocates.
	GEDSI	Establish and work actively through *Community Advisory Boards* (CAB) to integrate diverse perspectives in product development and clinical trial design, at the community level.
	GEDSI	Collaborate with local universities and research institutes for a better understanding of local contexts, challenges, barriers and inequities and to support diversity in clinical trials.
	GEDSI	Establish regular exchange forums for PDPs on GEDSI priorities or establish a formal cross-PDP working group on GEDSI in product innovation.
Products and clinical trials	GEDSI	Improve diversity and inclusion within clinical trials, working with and through *Clinical Research Organisations* (CROs) by adopting and publicly committing to WHO's Guidance for best practices for clinical trials.
	GE	Actively look for pathways to include pregnant and lactating women in clinical trials and provide clear and safe measures to reduce gender bias in clinical trials by identifying opportunities for improved safe inclusion of women, pregnant women and lactating women, especially for diseases where they carry increased risks.
	DE	Engage with CROs and clinical trial sites that have linkages to local OPDs, prioritise access for people with disability or who are willing to make such changes to do so.
	SI	Train staff on how to conduct inclusive clinical trials, share resources on respectful engagement and set benchmarks for inclusion in clinical trials. Ensure that clinical staff are familiar with local customs cultural sensitivities, and inclusive communication and have access to local sign language interpreters.
	DE	Address the needs of people with disabilities in product formulation and treatment protocols to facilitate uptake and drive demand for all.
Programs	GEDSI	Establish an Access Advisory Committee with GEDSI experts, including members with from priority populations: women

Theme	GEDSI category	Recommendations
		organisations, ethnic minority groups and OPDs to advise on access plan for new innovations.
	DE	Conduct acceptability consultations as an entry point by fostering engagement with locally based advocacy organisations including OPDs, in community engagement during trials and/or implementation to inform access plans and ensure that innovations are accessible to all, including priority and marginalised populations
	SI	Identify innovative distribution methods and identify local partners to support access to medical products for hard-to-reach remote areas and marginalised communities.
Health System Impact	GEDSI	Support localisation efforts that improve diversity and inclusion; including training local partners in GEDSI principles, training and empowerment women in Science, Technology, Engineering, and Mathematics (STEM).
	GEDSI	Share GEDSI-related findings through various channels for advocacy and capacity building in country.

Recommendations For Funders

Theme	GEDSI category	Recommendations
Investment Design	GEDSI	Establish permanent, funded teams or divisions to continuously support investments in GEDSI that include experts (in-house, or external) on disability equity and rights as well as gender equality. Support grantees with high level, general guidance on intersections of disability and public health / product development.
	GEDSI	Develop and make publicly available a GEDSI in PDP investments strategy that is reviewed regularly (e.g. at least every five years) to adjust to a rapidly evolving landscape.
	DE	Increase focus on disability inclusion in product innovation and access by setting aside funding for disability inclusion research and supporting consultations between PDPs and OPDs.
	DE	Funders facilitate roundtable discussions jointly with OPDs, focusing on disability and health and disability product innovation. These roundtables should be specifically targeted to PDP staff members and their partners.
	GE	Encourage PDPs to use the Global Health 50/50 self-assessment tool to measure progress on gender equality within global health organisations, as a funding requirement. Progress can be re-assessed and measured year on year.

Theme	GEDSI category	Recommendations
	DE	Encourage PDPs to report into the CBM organisational self-assessment tool to measure disability inclusion as a measuring tools on disability inclusion, as a funding requirement.
Data and program design	GEDSI	Request gender, disability and social inclusion analyses as a deliverable under funding agreements and eventually, as a pre-requisite for funding.
	GE	Request the integration of sex and gender data reporting in preclinical phases and early-stage development. Encourage grantees to refer to historical data from clinical trials where women may have fallen pregnant (where available) to support early data analysis of efficacy of product among women.
Product category selection	GEDSI	Ensure diversity in product category selection across investments.
	GEDSI	Develop a strong rationale for focusing an investment on specific disease categories only so as not to leave other vulnerable groups behind. Ensure collective funding covers all critical disease categories.
	GE	Request PDPs to identify pathways for the inclusion of pregnant and lactating women in clinical trials.
Programs and access	GEDSI	Fund access pathways through PDPs, that reflect the needs of all communities, including underrepresented and socially marginalised groups.
	GEDSI	Request more research and attention from PDPs on local community needs, specifically among, women, people with disabilities, and socially marginalised groups, to drive demand and navigate socio-cultural, political landscapes, and to inform access plans.
Partnerships	GEDSI	Ensure adequate funding envelopes for PDPs to run extensive, inclusive and adequate community engagement activities along the full product development continuum.
	GEDSI	Share best practices, guidelines and recommendations on GEDSI mainstreaming for PDPs through the PDP Funders Group Discussions.
	DE	Convene disability representatives and foster dialogue between OPDs and the PDPs.
Monitoring & evaluation	GEDSI	Require specific GEDSI indicators into each program's monitoring and evaluation framework.
	GEDSI	Develop and implement a *Joint Reporting Mechanism* with common GEDSI reporting measures across PDP Funders.

1. Introduction

The purpose of this analysis is to both reflect on how Gender equality, disability equity, and social inclusion (GEDSI) intersects with product development and access, capture best practices and issue recommendations for both PDPs and funders of PDPs, based on the literature and collected primary data from PDPs and their funders. This report will serve to inform the sector – both PDPs and donors on actions to support PDPs in the journey to improve GEDSI.

1.1 GEDSI in global health: definitions

GEDSI is fundamental to achieving effective and inclusive development outcomes in global health. GEDSI analysis recognises that social norms, power dynamics, and intersecting identities significantly impact individuals' access to health resources and services[2]. By addressing barriers faced by women, people with disabilities, and other socially marginalised groups, health programs can better target interventions and improve overall population health[3]. In the context of Product Development Partnerships (PDPs) in global health, integrating GEDSI considerations ensures that new health technologies and interventions are designed to meet the diverse needs of all populations, including those often overlooked in traditional research and development processes[4]. This approach not only promotes equitable access to health innovations but also enhances the effectiveness and sustainability of global health initiatives by understanding the root causes of health disparities[5]. Ultimately, centring GEDSI in global health efforts aligns with the principle of "leaving no one behind" and contributes to more comprehensive, rights-based health outcomes[6].

GEDSI, Diversity Equity and Inclusion (DEI), and Environmental Social Governance (ESG) are frameworks addressing various aspects of social responsibility, diversity and inclusivity, each with distinct focuses and contexts.

- GEDSI, used predominantly in the development space and adapted by Australia's Department of Foreign Affairs and Trade, specifically targets gender equality, disability equity, and social inclusion in foreign aid investments. It aims to ensure that development projects consider and benefit diverse groups, particularly focusing on gender and disability.

- DEI, commonly used in organisational contexts, addresses workforce and workplace issues. Diversity encompasses various human differences, equity ensures fair treatment and access, and inclusion fosters a sense of belonging for all employees.

- ESG, primarily used in the corporate and investment world, has a broader scope. Environmental factors consider a company's impact on nature, social factors address relationships with employees, suppliers, and communities, while governance relates to leadership, audits, and shareholder rights.

While these frameworks overlap, they differ in their primary applications and specific areas of focus.

For the purposes of this report, we refer to GEDSI as *gender equality, disability equity, and social inclusion*, aligning with DFAT's definition and guidance as elaborated in DFAT's

2 DFAT. (2024). Gender Equality, Disability and Social Inclusion Analysis Good Practice Note.

3 World Health Organization. (2021). Gender and health. https://www.who.int/health-topics/gender

4 Theobald, S., et al. (2017). The importance of gender analysis in research for health systems strengthening. Health Policy and Planning, 32(suppl_5), v1-v3. [4] Hawkes, S., & Buse, K

5 Gender and global health: evidence, policy, and inconvenient truths. The Lancet, 381(9879), 1783-1787

6 United Nations. (2015). Transforming our world: The 2030 Agenda for Sustainable Development.

GEDSI Analysis Good Practice Note[7]. This term focuses specifically on broader social inclusion, which is crucial in development contexts. This terminology is also most consistent with existing GEDSI frameworks and policies within the development space and among Product Development partners included.

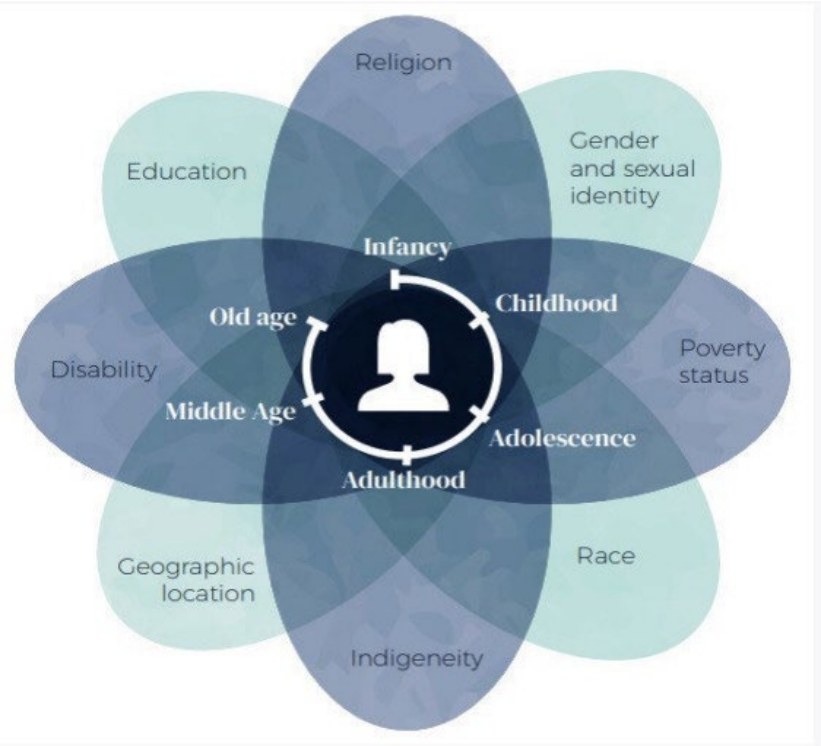


Figure 3: Identity and different forms of discrimination. Source: DFAT's Good Practice Note on GEDSI analysis

The Australian Government prioritises GEDSI across development programs, recognising these as core to achieving equitable impact[8]. DFAT's approach to GEDSI recognises that power structures are influenced by multiple factors including gender, disability status, and other social markers. The approach emphasises intersectionality, acknowledging that individuals' identities have many layers affecting their access to resources and power. It aims to inform more effective and inclusive programming.

Product Development Partnerships (PDPs) in global health will significantly enhance their impact and effectiveness by integrating GEDSI considerations throughout their work. GEDSI analysis helps PDPs identify and address barriers that different groups face in accessing health technologies and interventions, ensuring more equitable and inclusive health outcomes[9]. By considering diverse needs and experiences, PDPs can develop products that are more appropriate, accessible, and effective for a wider range of users, including women, people with disabilities, and other marginalised groups[10]. This approach can lead to increased uptake and adherence to health interventions, ultimately improving their overall impact and improved health outcomes[11]. Furthermore, incorporating GEDSI perspectives can uncover innovative solutions and market opportunities that might otherwise be

7 Australia's Department of Foreign Affairs and Trade (DFAT), 2023, Gender Equality, Disability and Social Inclusion analysis - good practice note.

8 The Australia's International Development Policy, 2023, highlights as one of its core priorities, to "**support** all people to fulfill their potential, including through new international strategies for gender equality, and disability equity and rights" and "**enhance** support for gender equality by ensuring that 80 per cent of investments address gender equality effectively, and all new investments over $3 million include gender equality objectives".

9 DFAT. (2024). Gender Equality, Disability and Social Inclusion Analysis Good Practice Note.

10 Theobald, S., et al. (2017). The importance of gender analysis in research for health systems strengthening. Health Policy and Planning, 32(suppl_5), v1-v3.

11 Hay, K., et al. (2019). Disrupting gender norms in health systems: making the case for change. The Lancet, 393(10190), 2535-2549.

overlooked[12]. By engaging with diverse stakeholders and end-users throughout the product development process, PDPs can also build trust and legitimacy within priority populations, facilitating the eventual adoption and scale-up of new health technologies[13]. Ultimately, prioritising GEDSI in PDP work aligns with global commitments to universal health coverage and the principle of leaving no one behind in health innovation[14] [15].

1.2 Method

To explore how PDPs incorporate GEDSI in their work, we used mixed methods in four distinct phases:

- Phase 1 - Literature and document review
- Phase 2 - Stakeholder consultations
- Phase 3 - Analysis and framework development
- Phase 4 - Thematic analysis and validation

1.2.1 Phase 1: Literature and Document Review

The initial phase involved an extensive review of relevant documents and academic literature to establish a solid foundation for the study:

a. **DFAT Documentation Review**: we examined documents provided by the Australian Department of Foreign Affairs and Trade (DFAT)[16] relating to GEDSI and their International Development Policy. This review helped us understand DFAT's perspective and priorities regarding GEDSI in the context of international development.

b. **PDP Documentation Review**: we analysed documents provided by PDPs operating globally, including PDP grantees of the PDAP program. This review offered insights into how PDPs currently approach and implement GEDSI principles in their work.

c. **Academic Literature Review**: we conducted a scoping review of academic literature focusing on gender equality, disability equity, and social inclusion in the context of medical product development, and access to medicines.

Keywords used: gender equality / disability inclusion / social inclusion + medicine development / medical product / development clinical trials / access to medicines.

1.2.2 Phase 2: Stakeholder Consultations

The second phase involved extensive consultations with key stakeholders to gather first-hand information and insights:

a. **Consultation Scope**: we conducted 40 consultations with PDPs, including both DFAT grantees and PDPs beyond the current investment portfolio.

b. **Participating Organisations**: Consultations were held with representatives from the following 11 PDPs:

12 Perez, C. C. (2019). Invisible Women: Exposing Data Bias in a World Designed for Men. Abrams Press.

13 Packed, R., et al. (2020). Unpacking power dynamics in research and evaluation on gender equality and women's empowerment: Lessons from a meta-evaluation. Evaluation, 26(4), 437-457.

14 DFAT. (2024). Gender Equality, Disability and Social Inclusion Analysis Good Practice Note.

15 World Health Organization. (2019). Delivered by women, led by men: A gender and equity analysis of the global health and social workforce. Human Resources for Health Observer Series No. 24.

16 This included PDP partner plans submitted to DFAT for the 5 grantees of DFAT.

- Drugs for Neglected Diseases (DNDi)
- European Vaccine Institute (EVI)
- FIND
- Global Antibiotic Partnership (GARDP)
- Innovative Vector Control Consortium (IVCC)
- International Vaccine Institute (IVI)
- Medicines Development for Global Health (MDGH)
- Medicines for Malaria Venture
- PATH
- Population Council (PopCouncil)
- TB Alliance

c. **PDP Funders**: Consulted with key five funders of PDPs to understand their perspectives on GEDSI integration:
   - Bill & Melinda Gates Foundation (BMGF)
   - Foreign, Commonwealth and Development Office (FCDO)
   - Netherlands, Ministry of Foreign Affairs (MinBuza)
   - Swiss Federal Department of Foreign Affairs (Swiss EDA)
   - United States Agency for International Development (USAID)

These consultations provided valuable insights into the practical implementation of GEDSI principles, challenges faced, and innovative approaches adopted by various organisations.

1.2.3 Phase 3: Analysis and Framework Development

The third phase focused on synthesising the information gathered and developing an evaluation framework:

- **Review of Findings**: We conducted a comprehensive review of the information collected from the document analysis and stakeholder consultations. This review helped identify key themes, patterns, and gaps in GEDSI implementation across PDPs.
- **Evaluation Framework Development**: Based on the review, we developed a custom evaluation framework. This framework was designed to guide the analysis of how GEDSI is mainstreamed across the work of all PDPs, ensuring a consistent and comprehensive approach to our assessment.

1.2.4 Phase 4: Thematic Analysis and Validation

The final phase involved detailed analysis and validation of our findings:

- **Thematic Coding Analysis**: we conducted a thematic coding analysis across the pillars of GEDSI. This involved systematically categorising and analysing the data collected to identify recurring themes, best practices, and areas for improvement in GEDSI implementation.

- **Cross-checking Findings**: to ensure the validity and reliability of our analysis, we cross-checked our findings against multiple sources of information. This process involved comparing insights from different PDPs, funders, and literature sources to identify consistencies and discrepancies.

1.3 Limitations

We acknowledge the following limitations as part of our research method.

- **Limited Sample Size and Representation**

    - Analysis was restricted to 11 PDPs out of approximately 25 operating globally. This represents less than half of the global PDP landscape. Sample limitations prevent broader generalization across PDPs with different mandates, operational models, and therapeutic focus areas. Findings should be interpreted within this context of limited representation.

- **Scope of Stakeholder Engagement**

Consultations were exclusively conducted with PDP organisations. Key stakeholder groups were not directly consulted, including:

    - Persons with disabilities and their representative organisations
    - Women's rights organisations
    - Other priority population groups and their advocates

One key recommendation is to establish formal mechanisms for engagement between PDPs and these essential stakeholder groups.

- **Depth of Analysis**

The evaluation provides a high-level snapshot of GEDSI integration across participating PDPs. This approach differs from comprehensive single-PDP GEDSI evaluations which would:

    - Examine organisation-specific integration opportunities in greater detail.
    - Provide deeper analysis of therapeutic area-specific GEDSI considerations.
    - Allow for more targeted and contextual recommendations.

The breadth of the multi-PDP approach necessarily limited the depth of analysis for individual organisations.

- **Documentation Availability**

Several key documents were not reviewed during the analysis period:

    - Some monitoring and evaluation frameworks.
    - Some PDP's Risk assessment and mitigation plans (some were still in development).

- External funders' monitoring and evaluation templates for PDPs.

These limitations may impact the comprehensiveness of certain findings. The current findings are not intended to inform a comparative analysis of PDPs.

2. Findings Part 1: GEDSI in medical product innovation

The intersection of gender equality, disability, and social inclusion (GEDSI) with product development and access to medicines presents a complex landscape of challenges and opportunities. Product Development Partnerships (PDPs) play a crucial role in addressing these intersecting issues, particularly in the context of Neglected Tropical Diseases (NTDs) and other health conditions that disproportionately affect socially marginalised populations. Gender, disability, and other social determinants of health can significantly impede access to medical products and health services. Recognising this, PDPs are increasingly focused on addressing these inequities through their work. The development of drugs for NTDs, which often lack commercial investment, inherently positions PDPs to tackle existing health disparities. NTDs predominantly affect Lower Middle-Income Countries (LMICs), particularly in rural and hard-to-reach areas, exacerbating inequalities in access to health and economic opportunities, especially for women, children, and people with disabilities.

The focus on NTDs by PDPs represents an intentional effort to rectify long standing inequities in access to effective diagnostic and treatment options. With NTDs impacting 1.62 billion people globally and associated with significant morbidity, physical and mental harm, and socio-economic burden, the work of PDPs in this area is critical [17]. These diseases reflect and reinforce existing inequities, costing developing countries billions of dollars annually in direct health costs, lost productivity, and reduced socio-economic and educational attainment. PDPs are uniquely positioned to address socio-cultural barriers where gender plays a role in impeding access to medicines and health services. They can provide vital information about the safety and efficacy of new products for underrepresented patient groups, including those who may face high levels of stigma in certain disease areas.

2.1 Disease burden among priority populations

For PDPs, it is critical to understand the nuanced distribution of disease burden and how these impact populations based on sex, gender, age, and disability differently. Understanding who is most at-risk from a particular disease is paramount, necessitating a deep dive into epidemiological data that is representative, and disaggregated by sex, gender, disability, geographic location and age. In addition, further qualitative analysis into the gender barriers and other social factors that negatively influence access to diagnosis or treatment need to be understood and taking into consideration when evaluating who the priority populations at risk are.

Ensuring attention to sex and gender diversity in the development of medicines and medical products is crucial. Firstly, with regards to sex, biological differences between sexes can lead to variations in drug responses. Secondly, gender norms affect risk and access and intersect with other social determinants of health, requiring a nuanced approach [18] [19]. Gender and sex significantly influence individuals' vulnerability to certain diseases, due to biological, socio-cultural or even political factors. There is growing recognition of certain diseases' disproportionate impact on girls and women, particularly in cases of some NTDs such as female genital schistosomiasis (FGS)[20] for example. When it comes to Tuberculosis (TB) in pregnant women, the disease significantly increased risks of adverse outcomes including maternal and foetal mortality rates. TB in pregnancy is associated with a ninefold increase in miscarriage, a twofold increase in preterm birth and low birthweight, and a six-

17 World Health Organization (2024) Global report on Neglected Tropical Diseases – stronger together, towards 2030 – available here.

18 Palmer-Ross, A., et al. (2021). BMJ Global Health, 6:e004997.

19 Peppin, P., et al. (2008). International Journal of Feminist Approaches to Bioethics, 1(2):100-124.

20 Access & Development Partnership (2019) Discussion Paper: The Gender dimensions of NTDs, available here

fold increase in perinatal death.[21] Gender not only affects how people experience symptoms and severity but also shapes the social consequences of diseases based on sociocultural expectations. Additionally, certain health conditions affect genders differently or are unique to specific genders [22] [23]. The influence of gender extends to healthcare access and treatment, with various social, economic, and cultural factors creating differential impacts across genders. Healthcare-seeking behaviour is notably affected by gender, suggesting distinct patterns and barriers in seeking medical assistance[24]. A poignant example is found in leprosy, where "*women patients are more severely affected by stigma than male patients. This phenomenon is thought to be due to male dominance in patriarchal societies, socioeconomic dependency on men as primary income providers, gender-based violence and constant responsibility for the care of others*".[25]

2.2 Lack of diversity in clinical trials

Recent literature emphasises the importance of diversity in clinical trials to ensure generalisable results and to address the specific health needs of various populations[26] [27] [28]. Clinical trials have historically lacked diversity, leading to significant gaps in medical knowledge and potentially inequitable healthcare outcomes. The WHO guidance for best for clinical trials (2024) highlight several groups that have been historically underrepresented in trials: demographic groups (such as children, older persons, women of childbearing age, and ethnic minorities), socioeconomic groups (including remote populations, socially marginalised people, refugees, and LGBTQIA+ individuals), and those with varying health statuses (including people with disabilities, rare diseases, or multiple health conditions)[29]. The exclusion of these groups from clinical trials significantly limits the generalisability of research findings, particularly problematic when these same populations often bear the highest disease burden. This lack of representation not only impedes evidence-based decision-making but can also reduce trust in medical interventions among underrepresented communities, potentially perpetuating health inequities.

Historically, women have been underrepresented in clinical trials, leading to a lack of sex and gender-specific data on drug efficacy and safety[30]. The systematic exclusion of pregnant and lactating women from clinical trials is rooted in past tragedies (e.g., thalidomide). The literature adds that pregnant, lactating women and women of reproductive age may also be excluded from clinical trials due to cultural barriers, limited acceptance of their participation by the community,[31] [32]. The presumption of exclusion has led to significant gaps in medical knowledge about drug safety and efficacy for mothers and babies. This in turn, limits treatment options for certain illnesses than can be of greater risk for pregnant women. To date, data for medical product use in pregnant women and lactating women is mostly generated from non-clinical developmental and reproductive animal toxicity studies, with

21 Miele K, Bamrah Morris S, Tepper NK. Tuberculosis in Pregnancy. Obstet Gynecol. 2020 Jun;135(6):1444-1453. doi: 10.1097/AOG.0000000000003890. PMID: 32459437; PMCID: PMC7975823.

22 Palmer-Ross, A., et al. (2021). BMJ Global Health, 6:e004997.

23 Yakerson, A. (2019). International Journal for Equity in Health, 18:56.

24 Access & Development Partnership (2019) Discussion Paper: The Gender dimensions of NTDs, available here

25 Access & Development Partnership (2019) Discussion Paper: The Gender dimensions of NTDs, available here

26 Kelsey, M.D., et al. (2022). Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemporary Clinical Trials, 116, 106740.

27 das Neves, J., & Ensign, L. (2022). Advances in drug delivery for women's health: A matter of gender equity. Advanced Drug Delivery Reviews, 182, 114132.Overview of how sex, gender norms, social norms and inequalities affect product needs, products and the product development pathway R&D (broader literature review, latest clinical trial guidelines)

28 Wolter et al. (2022) Transgender Youth Inclusion in Healthcare in Southeast Asia: Insights from Indonesia, Thailand, and the Philippines

29 WHO (2024) Guidance for best practices for clinical trials, https://www.who.int/publications/i/item/9789240097711

30 Yakerson, A. (2019). International Journal for Equity in Health, 18:56.

31 Boulougoura et al, Phase I, Randomized, Controlled Clinical Study of CC-11050 in People Living With HIV (APHRODITE), 2019; ICHGCP, CC-11050 Trial in Nepalese Patients With Erythema Nodosum Leprosum, 2020

32 J.G. Malundo, Responsiveness of Offshored Clinical Trials among Women in the Philippines, 2019 Kelsey, M.D., et al. (2022). Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemporary Clinical Trials, 116, 106740

limited human data. However, without trial data, healthcare providers and pregnant and lactating women lack evidence-based guidance they need to support decision making, often leading to either the discontinuation of necessary treatments or the use of medications without adequate safety data. Addressing these gender-specific aspects in medical product development is essential for achieving gender equality in global health and ensuring that women and girls have access to effective, tailored healthcare solutions[33] [34].

Key barriers to inclusion and effective strategies for improving representation of under-represented and therefore under-served groups in clinical trials include complex historical and ethical dilemmas, language and communication issues, lack of trust, limited access to trials, restrictive eligibility criteria, attitudes and beliefs, lack of knowledge about clinical trials, and logistical challenges[35]. Other societal and gender barriers have limited the participation of pregnant and lactating women in clinical trials; from mobility restrictions, childcare needs, and complex consent requirements that disproportionately affect women in some societies.

Special considerations are now being made for pregnant and lactating women as there is a growing recognition of the need to consider sex-specific biological differences in drug development, including pharmacokinetics and pharmacodynamics[36] [37]. The historical practice of 'protection by exclusion', particularly for pregnant and lactating women, is being challenged, with a move towards safe inclusion to generate more comprehensive data. Evidence-based strategies for improving inclusion include cultural competency training, community partnerships, personalised approaches, multilingual materials and staff, communication-specific strategies, efforts to increase understanding and trust, and addressing logistical barriers[38].

Recent guidance from the WHO and from the United States Food and Drug Administration (US FDA) on more inclusive clinical trial designs[39] [40]reflects a shift towards building more diversity in clinical trials, with greater consideration towards removing biases in trial design. The fair inclusion of pregnant and lactating women in clinical trials is essential for ensuring that medical interventions are safe and effective for this population. The ethical dilemma on the inclusion of pregnant women in clinical trials is complex and ongoing but, in this report, we emphasise the importance of striving for the fair inclusion of pregnant and lactating women in clinical trials by following the available recommendations from WHO and US FDA guidance.

The inclusion of persons with disabilities in clinical trials still faces significant challenges:

33 Kelsey, M.D., et al. (2022). Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemporary Clinical Trials, 116, 106740.

34 das Neves, J., & Ensign, L. (2022). Advances in drug delivery for women's health: A matter of gender equity. Advanced Drug Delivery Reviews, 182, 114132.Overview of how sex, gender norms, social norms and inequalities affect product needs, products and the product development pathway R&D (broader literature review, latest clinical trial guidelines)

35 Bodicoat, D.H., Routen, A.C., Willis, A. et al. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials 22, 880 (2021). https://doi.org/10.1186/s13063-021-05849-7

36 das Neves, J., & Ensign, L. (2022). Advances in drug delivery for women's health: A matter of gender equity. Advanced Drug Delivery Reviews, 182, 114132.Overview of how sex, gender norms, social norms and inequalities affect product needs, products and the product development pathway R&D (broader literature review, latest clinical trial guidelines)

37 das Neves, J., & Ensign, L. (2022). Advances in drug delivery for women's health: A matter of gender equity. Advanced Drug Delivery Reviews, 182, 114132.Overview of how sex, gender norms, social norms and inequalities affect product needs, products and the product development pathway R&D (broader literature review, latest clinical trial guidelines)

38 Bodicoat, D.H., Routen, A.C., Willis, A. et al. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials 22, 880 (2021). https://doi.org/10.1186/s13063-021-05849-7

39 US Food and Drug Administration, Guidance documents, various, available here and here.

40 WHO (2024) Guidance for best practices for clinical trials, https://www.who.int/publications/i/item/9789240097711

1. Exclusion criteria in research is an example of a persistent structural barrier to inclusion. One study found that 34% of registered trials explicitly exclude people based on hearing, motor, visual, or cognitive impairments.[41]

2. This underrepresentation results in an inadequate evidence base for clinical care of individuals with disability.[42]

3. Barriers include risk assessment, recruitment protocols, consent issues, and systemic factors.[43]

4. Many studies fail to provide or describe accommodations that could enable participation of people with disabilities.[44]

5. With simple accommodations, most persons with intellectual disabilities could participate in many studies.[45]

The literature suggests that efforts are needed to increase inclusion (including of people with disabilities) through research policy initiatives, education, and more thoughtful study design that considers the needs of people with disabilities.[46] [47]

2.3 Key considerations

Examining the role of GEDSI in PDPs, therefore, several other key considerations emerge from a review of the literature:

1. Ensuring fair representation of underrepresented priority populations in decision-making processes within organisations and across programs.

2. Developing gender-responsive and disability-inclusive innovation that considers the diverse needs of all groups.

3. Moving beyond binary approaches to gender to include transgender and non-binary individuals in product development considerations.

4. Being aware of and understanding local contexts to better address the needs of different groups within specific cultural settings[48].

5. Implementing multi-pronged approaches to improve diversity in clinical trials, including diverse research teams, improved trial design, better access to trial sites, and education on sex, gender, and disability differences in medicine.

As PDPs continue to evolve, their role in promoting GEDSI through product development and access to medicines will be crucial in shaping a more equitable global health landscape,

---

41 Schwartz, J. K., & Unni, E. (2021). Inclusion of People with Disabilities in Research to Improve Medication Adherence: A Systematic Review. Patient Preference and Adherence, 15, 1671–1677

42 Shariq, S., Cardoso Pinto, A.M., Budhathoki, S.S. et al. (2023). Barriers and facilitators to the recruitment of disabled people to clinical trials: a scoping review. Trials, 24, 171.

43 Shariq, S., Cardoso Pinto, A.M., Budhathoki, S.S. et al. (2023). Barriers and facilitators to the recruitment of disabled people to clinical trials: a scoping review. Trials, 24, 171.

44 Schwartz, J. K., & Unni, E. (2021). Inclusion of People with Disabilities in Research to Improve Medication Adherence: A Systematic Review. Patient Preference and Adherence, 15, 1671–1677

45 Schwartz, J. K., & Unni, E. (2021). Inclusion of People with Disabilities in Research to Improve Medication Adherence: A Systematic Review. Patient Preference and Adherence, 15, 1671–1677

46 Schwartz, J. K., & Unni, E. (2021). Inclusion of People with Disabilities in Research to Improve Medication Adherence: A Systematic Review. Patient Preference and Adherence, 15, 1671–1677

47 Feldman M. A. et al. (2013). Where are persons with intellectual disabilities in medical research? A survey of published clinical trials. Journal of Intellectual Disability Research, 58(9), 800-809

48 Bodicoat, D.H., Routen, A.C., Willis, A. et al. Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials 22, 880 (2021). https://doi.org/10.1186/s13063-021-05849-7

one that is responsive to the diverse needs of all populations, regardless of gender, disability status, or social background.

3. Findings Part 2. Current integration of GEDSI within PDPs

This section presents an overview of current best practices and key insights from our research and analysis, on GEDSI integration within PDPs. Thematic coding analysis revealed six distinct yet interconnected categories of reflection, along which we have organised the presentation of findings below. Specifically, we delve into the mainstreaming of GEDSI within organisational policies and governance structures, data collection and utilisation for inclusion, partnership engagement, product identification and development processes, programs to facilitate uptake and access while leaving no one behind, and the broader health systems impact that PDPs can achieve. By exploring these themes, we aim to offer a holistic understanding of the current state of GEDSI integration in PDPs, serving as a baseline for the recommendations targeted to PDPs and their funders.

3.1 Organisational policies and governance

The first theme that emerged from our analysis touched on organisational policies and the governance structures in place within PDPs, and how these incorporate GEDSI principles. Before GEDSI can be incorporated in global health programming, global health organisations should reflect an internal commitment to GEDSI, incorporating these commitments in their institutional and governance framework. Essentially, GEDSI needs to be reflected in the 'DNA' of the organisation so that the organisation is better equipped to exemplify GEDSI commitments, and these commitments can be translated to and mainstreamed to external programs with greater impact.

One observation is that gender equality is a more prominent area of reflection among PDPs than disability or social inclusion. Gender equality is mainstreamed across most PDPs' governance structures and processes within most cases, a gender working group or point of contact, and across more than half of PDPs consulted, a specific committee tasked with reporting on progress. This commitment to gender equality is reflected in gender equality strategies, approaches or organisation-wide public commitments to support gender equality, equal opportunity, representation and participation. Disability inclusion on the other hand, is less of a priority at the organisational level, mainly due to unclear definitions of disability in the context of different therapeutic areas and in the context of product innovation, a lack of guidance and limited access to people with disabilities and to disability inclusion expertise to guide PDPs' approaches.

The way that PDPs actively integrate GEDSI within their organisational structures and program design appears to be influenced by several factors:

1. The level of funding available to support GEDSI strategy development and GEDSI activities.
2. The resources available: among larger PDPs where there is more staff available it appears to be easier to identify champions that can lead a GEDSI working group.
3. The amount of time available: in larger organisations, it is easier to re-distribute and share responsibilities for dedicated staff to contribute to GEDSI working groups.
4. The mandate: meaning that if there is a clear strategic direction towards GEDSI internally, staff members are more inclined to dedicate time and resources. In addition, it was acknowledged by most respondents that PDPs are only able to instigate transformative change along the activities that are under their direct spheres influence: product profile development, product development clinical trials, access programs. For some PDPs, this does not encompass downstream access to a medical product.

PDPs have made strides in integrating GEDSI principles into their own governance frameworks, human resources practices and leadership structures. Most PDPs consulted report having implemented diverse leadership initiatives, established gender equality working groups or task forces, and adopted inclusive recruitment practices. These changes are reported for some in the Global Health 50/50 Report [49] [50] (seven out of the 11 PDPs consulted). Organisations are increasingly incorporating gender metrics into performance evaluations and setting targets for gender equality and for diversity of representation at all levels of leadership[51]. Some also consider social inclusion metrics to set targets on the participation of communities with lived experience of the diseases that their product innovation covers.

The 2020s have been a turning point for many PDPs in terms of building more diversity within organisations, intentionally, as evidenced in the Global Health 50/50 Gender and Health Index Data (2018-2024). The Global Health 50/50 report offers a used benchmark against which to monitor progress on incorporating gender equality in their governance structures (see Appendix A for a detailed overview of the methodology used by the Global Health 50/50 initiative). Two PDPs reported that their yearly assessments through the Global Health 50/50 report have helped to move the needle internally and led to establishment of gender equality working groups. This has helped to drive change internally in those organisations when it comes to leadership and board structures, ensuring diversity of gender, age, disabilities, background and cultures. Despite these encouraging examples, progress remains uneven, and sustained efforts are needed to achieve full GEDSI integration across the sector[52]. Board diversity is still a work in progress across PDPs with only three of the seven PDPs captured in the Global Health 50/50 Gender and Health Index with specific strategies in place to promote diversity and inclusion and representation publicly (through targets, dedicated seats, and monitoring of these targets). Because of the nature of the partnerships, other PDPs mentioned that nomination of board members is often not exclusively in their hands, underpinning the importance for PDPs of working hand in hand with its closest stakeholders and collaborators to streamline GEDSI in their organisational policies.

While several PDPs have gender strategies in place, their focus is primarily on the promotion of gender equality, and they fail to adequately cover reflections and solutions to improve disability inclusion or broader social inclusion. Disability inclusion has received less consideration in general. This disparity stems from a reported lack of understanding, expertise, guidance, and general awareness surrounding disability inclusion in this context. The intersection of disability and product development is characterised by perceived technical complexity, especially concerning the definition of disability. This complexity, coupled with limited guidance on how to approach disability inclusion in product development, has resulted in a less mature integration compared to gender mainstreaming efforts. Despite these challenges, there is a growing appetite for change and a desire to better understand the intersection between disability inclusion and product development.

The lack of emphasis on disability inclusion is proportional to the amount of available guidance, highlighting a critical gap in resources and expertise. Disability inclusion practitioners often possess specialised knowledge in particular sectors, but there is a scarcity of professionals with comprehensive understanding of both disability issues and product development processes. This shortage of expertise is further compounded by a

49 Global Health 50/50. (2023). Gender equality: Flying blind in a time of crisis. 2023 Global Health 50/50 Report.

50 Dhatt, R., et al. (2017). The role of women's leadership and gender equity in leadership and health system strengthening. Global Health, Epidemiology and Genomics, 2, e8

51 Talib, Z., et al. (2019). Promoting gender equity in global health leadership in academic and professional institutions. Global Public Health, 14(3), 390-403.

52 Hawkes, S., et al. (2020). The global movement for gender equality in global health. The Lancet, 395(10229), 1021-1022.

general lack of community awareness among the biomedical sphere regarding disability issues. The absence of prominent voices advocating for disability equity in health and medical product development has contributed to misconceptions and insufficient attention to disability-related considerations in this field.

To address these challenges, there is an expressed need to identify relevant entry points for disability inclusion in specific product development contexts and to strengthen expertise and guidance in this specialized nexus. The demand for 'high level' or 'overview' type training and workshops underscores the necessity for broader education on this topic. Additionally, investments in developing evidence-based and rights-based guidance at the intersection of disability and product development could significantly enhance the integration of disability considerations in future partnerships. By addressing these areas, the field can work towards more comprehensive and effective inclusion of disability considerations in product development partnerships, aligning with broader GEDSI principles and practices. [see recommendations 5.1.1]

In the context of social inclusion, the intentional effort to actively engage Indigenous and hard-to-reach communities is deeply influenced by the culture and history of the organisation and its location. For example, ethnic minority groups in mountainous regions of Vietnam are at greater risk of malaria than urban populations in Vietnam, and across the regions malaria in pregnancy still poses significant risk of mortality with limited treatment options. Most of the PDPs consulted engage communities with lived experiences of the diseases in their portfolio's focus areas, but to varying degrees. In most cases, affected communities are consulted but not actively engaged in the program design.

3.2 Data

Our conversations suggest that there is widespread recognition of the importance of understanding the nuances in disease burden, and to recognise, through data disaggregation, how certain diseases disproportionately affect women, pregnant or lactating women, persons with disabilities, or other socially marginalised groups. This is understood as a prerequisite to identifying therapeutic areas in need of innovation and to gather needed resources to develop these innovations. Two PDPs mentioned the role of AI in supporting with disease burden mapping at a more granular level. However, while AI offers significant opportunities for analysing disease trends and processing disaggregated data, its implementation requires careful consideration as regulatory frameworks continue to develop alongside this rapidly evolving technology.

3.2.1 Disaggregated disease burden data

While most PDPs acknowledge that sex-disaggregated data is needed to better inform equitable product design and innovation, few of the PDPs consulted acknowledged the importance of obtaining data that is also disaggregated by gender, age, disability, and geographic location. This more granular approach to data collection can better inform the product development pathway and program design. Understanding the varying needs of patients regarding medicine formulation and treatment regimens is crucial. Such information is invaluable in designing clinical trials, product formulations, and access programs, as well as in developing engagement strategies.

Across all the PDPs consulted, we noticed that there were no indicators concerning disability monitoring and evaluation plans used in reporting to donors. Only a select few PDPs (three out of 11) have explored how disability inclusion is considered within the product innovation space and within the therapeutic area of interest and included some data and reflections within a GEDSI strategy. While the most appropriate disability data depends on contexts and the specific products, in general, disability data could include:

i. estimates of relative prevalence of relevant disease among persons with disabilities,

ii. general estimates of disability in the overall population or specific catchments, and

iii. estimates of persons with disabilities who can access (or who have an unmet need) for products.

Another perspective at the intersection of basic data to guide analysis is the long-term disabling consequences of disease. Many of the PDPs consulted took a disability lens from the perspective of consequences of disease rather than considering the rights-based or strengths-based approach to disability inclusion within product innovation. Understanding the need for specific health services arising from long-term needs are essential 'determinants' of inclusion but are not currently an adequate part of the discourse in the PDPs or other perspectives explored in this analysis.

3.2.2 Understanding local context

Understanding the local context, including socio-cultural and political barriers related to gender and disability inclusion, is critical for informing the design of clinical trials and access programs. This localised approach ensures that PDPs can tailor their efforts to the specific needs and challenges of the communities they serve. While most of the PDPs consulted do conduct local research to understand local perspectives with regard to disease burden, access to diagnostics, vaccines or treatments, most do not yet use the opportunity to gather specific local perspectives that can better inform their understanding of gendered barriers or their understanding of the needs of people with disabilities. Local perspectives on gendered barriers to access, or on the accessibility to or acceptability of products for among women, pregnant or lactating women, gender-diverse groups, or among people with disabilities would support better tailoring of product innovation activities and access programs.

3.2.3 Publication guidelines

Heidari et al (2016) recognised the need for guidelines to ensure that published research reflects and promotes inclusion, particularly in terms of sex and gender considerations. The Sex and Gender Equity in Research (SAGER) guidelines are slowly gaining traction among PDPs. The guidelines represent a comprehensive approach to reporting sex and gender information in study design, data analyses, results, and interpretation of findings[53].

These guidelines aim to address the historical oversight of sex and gender differences in research design, study implementation, and scientific reporting. By providing a systematic approach to reporting on sex and gender, SAGER guidelines aim to enhance the generalizability of research findings and their applicability to clinical practice, benefiting both women and men. The SAGER guidelines were developed through an extensive process involving a panel of 13 experts from nine countries, teleconferences, conference presentations, and a two-day workshop. Additionally, an internet survey of 716 journal editors, scientists, and other members of the international publishing community was conducted, along with a literature search on sex and gender policies in scientific publishing. These guidelines are a great tool to ensure diversity in research and publications, but not all PDPs consulted mentioned specifically adopting and using these to guide their work. Additionally, while about a third of the PDPs consulted mentioned the SAGER guidelines, none mentioned the Research for Development Impact Network's "Research for All guidance"[54] - a handbook of guidelines aimed at making research more inclusive of people with disabilities. [see recommendation see recommendations 5.1.2]

53 Heidari, S., Babor, T.F., De Castro, P. et al. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Res Integr Peer Rev 1, 2 (2016). https://doi.org/10.1186/s41073-016-0007-6

54 RDI Network (2020). Research for all: Making Development Research Inclusive of People with Disabilities. Authored by CBM-Nossal Partnership for Disability-inclusive Development and Research for Development Impact Network

Through the consultations of PDPs, we have captured some notable efforts at accommodating diversity and acknowledging contributions from researchers, including local researchers that are directly affected by the research. While these examples are too few, one is illustrated below.

Case Study: Population Council's Approach to Inclusive Publishing

The Population Council provides an exemplary model for ensuring diversity and inclusion in scientific publishing. Managing two peer-reviewed journals, the Council implements several strategies to promote inclusivity, including ensuring diversity in editorship, authorship, and among reviewers. Supporting authors with disabilities or neurodiverse conditions, for example, by arranging calls to discuss feedback and encouraging open conversations about needs. And promoting transparency and accessibility in the peer review process.

This approach not only enhances the quality and relevance of published research but also contributes to building a more inclusive scientific community.

The integration of GEDSI considerations in data collection, analysis, and publication is crucial for PDPs. By focusing on disaggregated data, understanding local contexts, and adhering to inclusive research and publication guidelines, PDPs can enhance the effectiveness and equity of their interventions, ultimately contributing to improved health outcomes for diverse populations affected by neglected diseases. [see the set of recommendations A.2]

3.3 Partnerships and community engagement

A critical third theme emerging from this evaluation relates to PDPs' approaches to community engagement, particularly engaging marginalised or underrepresented groups to inform product development and study design. Community engagement forms a cornerstone of many PDPs' strategies for inclusive development. Several PDPs work through *Community Advisory Boards* to integrate diverse perspectives into their work. For instance, the International Vaccine Institute (IVI) engages *Community Advisory Boards* comprising of young adults and older persons, religious and leaders of ethnic minority groups. Similarly, Population Council, given the focus of its products on women's sexual and reproductive health, primarily engages with women-centred civil society organisations, including those representing youth, sex workers, and women with disabilities. These multifaceted groups of women and advocates in the civil society space provide invaluable insights into the needs and concerns of diverse populations.

3.3.1 Diversity in community engagement

The involvement of community leaders at the clinical trial stage is considered by some PDPs as crucial to ensure that diverse, locally anchored views are represented in the design and delivery of clinical trials. These leaders can effectively explain and inform potential participants about the trial's purpose and procedures. In some cases, the engagement of community leaders occurs through smaller local sessions in villages, typically attended by 5-20 people, and should be an integral part of clinical trial design and implementation. PDPs also engage communities through partnerships with local universities and research institutes, leveraging their established networks and trust within the community. A deeper reflection is needed across PDPs on identifying and engaging with other groups that do not necessarily hold power, in the countries where the clinical trials are held [see recommendation 5.1.3]

Community engagement in some cases extends beyond the trial phase to include sharing results of clinical trials with clinical trial participants and community representatives.

Population Council, for example, employs the WHO's Good Participatory Practice[55] framework to ensure that all key stakeholders are mapped out and informed about the potential of trials and their outcomes. This offers an opportunity to map out underrepresented groups that should be included both in consultation, clinical trial design, participation and follow up.

PDPs may also learn from each other about successful and innovative ways to engage communities and share information about the innovations in development. For instance, to overcome literacy barriers in sharing information about cholera in Mozambique, IVI has utilized song and dance to communicate about the disease, its consequences, and how vaccines work to prevent it.

Case Study: IVI's Innovative Community Engagement in Mozambique

IVI's work in Mozambique demonstrates an innovative approach to overcoming literacy barriers in health communication. To share information about cholera and its prevention, IVI, in collaboration with the local government stakeholders, utilised song and dance performances at the launching ceremonies of preventive mass OCV vaccination campaign in 2018. These creative methods effectively brought community members together for vaccination and awareness raising on multisectoral approach towards cholera prevention including proper hand washing and hygiene practice. In most developing nations, literacy levels tend to be lower among women compared to men. In Mozambique, more than half of the female population cannot read or write. For this reason, identifying innovative ways to share health information to overcome illiteracy is part of a series of efforts to overcome gender barriers to access to health. This case study highlights how PDPs can adapt their engagement strategies to local contexts, ensuring that vital health information reaches all community members, regardless of literacy levels.

3.3.2 Fostering dialogue between OPDs and product development actors

A notable gap across almost all of the PDPs' (10/11) engagement strategies, however, is the inclusion of persons with disabilities. PDPs do not yet engage directly with Organisations of Persons with Disabilities (OPDs), to support truly inclusive product development and deployment. Many PDP stakeholders reflected that their work focuses less on disability than on other issues. In their view, this partly arises from a lack of opportunities to learn from or work together with persons with disabilities. Poor emphasis on disability in health arises from a mix of structural barriers to disability inclusion. For example, persons with disabilities are denied opportunities for higher education and are less likely to be represented in biomedical or research workforces, reinforcing a cycle of exclusion. When people with disabilities are under-represented, the cultural and organisational shifts required for meaningful integration of disability into practice will lag behind other issues. This negative cycle affects disability equity in many ways along the product development continuum. To break this cycle, a starting point is to raise the voice of persons with disabilities among PDPs. DFAT for example has long championed OPDs, and disability inclusive development 'cross cuts' all DFAT's investments. This is a promising entry point for funders to improve on their leadership and support of disability rights in global health. [see recommendations 5.1.4]

3.3.3 Engaging with healthcare providers

PDPs have also reported engaging with healthcare service providers as another crucial aspect of their work. These interactions can help PDPs better understand the needs of underrepresented priority populations, and the barriers to diagnosis or access to treatments that they face. For instance, IVI works with antenatal clinics to test vaccines in pregnant women and build a database on their efficacy in this population. In this specific case, IVI engages with service providers that directly serve women, as a specific, and often

55 WHO's Good Participatory Practice for Emerging Pathogens (GPP-EP) is WHO's principle-based framework for ensuring meaningful stakeholder engagement throughout clinical trials, particularly during public health emergencies. Based on principles of respect, fairness, integrity, transparency, accountability, and autonomy, it emphasises building sustained relationships between trial sponsors, researchers, and communities to enhance trial acceptance, improve recruitment, and ensure research is both ethical and contextually appropriate.

marginalised community. This ensures that gender specific data is collated to inform future product innovation that are better adapted to the needs of pregnant women.

3.3.4 Advocacy and exchange of best practices

Advocacy activities are reported as another important facet of PDPs' efforts to promote GEDSI. These activities aim to build awareness and educate partners and stakeholders on GEDSI matters to improve health impact and ensure no one is left behind. PDPs participate in global meetings, external communications, campaigns, and publications that address issues of gender equality in product innovation or access to medicines.

Collaboration between PDPs on GEDSI issues is also emerging. Several PDPs are part of the *Global Health Technologies Coalition* - a coalition that explores issues related to representation, gender equality, and North/South equity, primarily through collaborative communication activities. While not all PDPs consulted were aware or engaged in this coalition, it is reported to be a useful platform for exchange on best practices for example, when it comes to making clinical trials more inclusive.

IVCC mentioned the application of a sub-award policy to external partners. This sub-award policy encourages a commitment to diversity, equity, inclusion as well as to safeguarding as part of any new partnerships and collaborations with IVCC. When initiating a dialogue with a potential partner to establish a project, IVCC does not solely review the technical aspects of a partnership or proposal but also assesses the governance structure of the partner organisation and initiates an open dialogue on diversity and inclusion with its partners.

In conclusion, while PDPs are making significant strides in community engagement and partnerships to promote gender equality and social inclusion to some extent, fewer PDPs engage with OPDs. PDPs need to ensure more diversity across their engagement strategies at all stages of the product development continuum [see recommendation 5.1.3]

3.4 Products

PDPs play a crucial role in addressing health inequities through their product selection and development processes. The product development process follows several steps from Target Product Profile development and defining the desired characteristics of medical products, to pre-clinical studies on animals, and clinical trial Phases I, II and II (small to large sale trials to confirm the effectiveness and monitor side effects).

The development of Target Product Profiles (TPPs) is a critical stage where gender and disability considerations can be integrated into product development. PDPs are increasingly recognising the importance of reflecting these considerations in TPPs, with some calling for greater involvement from organisations like the WHO to issue guidance and ensure a focus on gender and disability inclusion. Most of the PDPs mentioned the importance of co-developing TPPs in consultation with communities to ensure product acceptability and suitability and acknowledged the importance of considering the needs of pregnant and lactating women specifically in product design.

There are common misconceptions of the intersections of disability and products. As mentioned previously, most PDPs emphasise the prevention of disability as a consequence of the products being developed. Most PDPs do not consider disability inclusion within product innovation or organise structured consultation and active participation of OPDs in the product design phase. This may arise due to a mix of reasons (relative to gender and other sectoral issues):

- Less ‘exposure’ to persons with disabilities than other groups
- Less awareness about social models of disability and how disability, health, and health outcomes are related

- Less guidance
- Less technical expertise
- Less policy guidance
- Less scrutiny or incentivisation of disability inclusion in funding
- Less evidence and data

3.4.1 Lack of diversity in clinical trials

Clinical trials represent another crucial area where PDPs can promote inclusivity and equity. Several barriers prevent diverse participation in trials, including literacy issues, domestic responsibilities, work and income pressures, and discrimination. Recognising these challenges, some PDPs are moving towards 'adaptive' rather than merely 'inclusive' clinical trial protocols. This approach involves adapting processes to be more inclusive and efficient at reviewing gender or sex-disaggregated data to inform decisions that lead to product development benefiting multiple communities. It also involves identifying context-suitable approaches that match the needs of participants and the requirements of the trial.

PDPs have to balance the health needs of all, including the differentiated needs of sexes or across genders. The inclusion of pregnant, lactating women and women of reproductive age in clinical trials remains a complex issue and ethical dilemma. Due to historical evidence of safety concerns, the default for medical product innovators is to exclude women from clinical trials, to avoid risks of testing medicines on pregnant women (with the exception of PDPs that specifically chose to develop innovations for malaria in pregnant women (MMV) or women's sexual and reproductive health for example PopCouncil.

On one hand a commitment to equity means that PDPs should develop new products that are proven safe for use for pregnant and lactating women. On the other hand, PDPs need to adhere to safety guidelines for conducting clinical trials. At present, a number of PDPs, including DNDi, require women to use contraceptives to participate in clinical trials. However, this is not a sufficiently inclusive solution to product innovation. The growing demand for new products suitable for pregnant/lactating women in the neglected disease field means that more research is needed to identify better research methods and clinical trial methods to balance these risks and health goals. These could include focusing on early toxicology studies, analysing historical registers of women in clinical trials that fell pregnant, and others. [see recommendations 5.1.4]. There is some awareness of the FDA draft guidance (2018) advises that pregnant and lactating women can be included in clinical trials if strong evidence of safety has been established in early toxicology studies or previous trials. None of the PDPs consulted mentioned the recently published guidance for best practices for clinical trials by the WHO (2024).

Case Study: MMV's Malaria in Mothers and Babies (MiMBa) Initiative

Recognising that malaria disproportionately affects the poor and socially marginalised as well as underrepresented populations, particularly pregnant women and adolescent girls, MMV has developed the MiMBa initiative to address this specific health inequity. Key aspects of this initiative include:

- Targeting a high-risk group: Globally, 130 million women and girls are at risk of malaria during pregnancy.
- Addressing a critical need: Prevention of malaria in the first trimester of pregnancy is crucial, as pregnant women are three times more likely to suffer from severe disease.
- Product development: MMV is focusing on the clinical development of a prophylaxis that can be used in pregnancy to prevent malaria, including a Phase II study of pyronaridine–piperaquine in healthy women and a pivotal Phase III study in pregnant women.
- Preclinical considerations: MMV uses preclinical reproductive safety screening for the prioritisation of compounds to improve access to appropriate medicines for pregnant or lactating women.
- Physiologically based pharmacokinetic (PBPK) modelling is part of the MiMBa development strategy. PBPK use mathematical modelling and combines information on human physiology and drug properties to understand drug concentration change over time in the body after administration, drug-drug interactions and optimal dosing in special populations. For example, MMV and partners recently published a position paper summarising the clinical and PBPK modelling data, which indicates that the benefits of primaquine in breastfeeding women outweigh the potential risks.

This initiative demonstrates MMV's commitment to addressing gender-specific health needs and reducing health inequities in malaria prevention and treatment.

Beyond considerations on the inclusion of women, PDPs are also grappling with how to make trials more inclusive for LGBTQIA+ individuals and people with disabilities. Gender-binary protocols can make LGBTQIA+ individuals uncomfortable with treatment. While sex assigned at birth is often a scientific requirement in studies, forms with only binary options for gender/sex may alienate non-binary individuals. Moreover, in some regions, it may be unsafe for non-binary and transgender patients to share their gender identity due to fear of discrimination or legal ramifications.

For persons with disabilities, certain trial eligibility criteria can lead to exclusion, particularly for those with intellectual disabilities who may have difficulty accessing or interpreting trial information. There is a general recognition among the PDPs consulted that too little attention is placed on making clinical trials more inclusive of people with disabilities. Some PDPs are already implementing measures to make clinical trial sites more disability-inclusive, such as working with *Clinical Research Organisations* on site to identify and select wheelchair-accessible venues for clinical trials and by offering home visits. Additional measures being explored include providing trial information in braille and sign language. More guidance and evidence on best practices is needed in this field. The *Clinical Trials Transformation Initiative* (CTTI) has identified key motivations for implementing diversity and inclusion practices, including ethical imperatives, institutional culture, leadership support, and funder requirements[56].

The literature suggests that key strategies for enhancing inclusion in medical product development and clinical trials, including the decentralisation of research sites, and the use of digital tools to improve accessibility[57]. For instance, Artificial Intelligence (AI) solutions and other emerging technologies are being explored to support clinical trials by bringing

56 Clinical Trials Transformation Initiative National Action Plan for Achieving Diversity in Clinical Trials - see here.

57 Kelsey, M.D., et al. (2022). Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemporary Clinical Trials, 116, 106740

efficiency in disaggregated data analysis, optimising patient recruitment, and enhancing participation experience[58]. The use of AI however should be considered carefully to ensure that solutions are working to improve the inclusion and diversity of participation in clinical trials rather than perpetuate existing power structures.

As PDPs continue to evolve their approaches to product development and clinical trials, the integration of GEDSI considerations remains crucial. By addressing these issues throughout the product development process, from initial selection to clinical trials and beyond, PDPs can play a significant role in creating more equitable and inclusive health solutions for diverse populations worldwide.

3.5 Programs and access

GEDSI principles also apply to PDP's access plans, ensuring the equitable distribution, adequate uptake, accessibility and acceptance of products, including among socially or geographically marginalised groups. This section speaks to the inclusion of all marginalised and unrepresented groups in the development of access plans, acknowledging the intersectionality between socially and geographically marginalised groups.

We do recognise the fact that not all PDPs incorporate within their mandate the downstream access planning. This is sometimes covered by other partners or funded complementarily. As a first step, all PDPs consulted recognised the importance of understanding barriers that impact access among specific gender groups, age groups, or due to disability, socio-economic background or geographic location. Research and community engagement activities, cited in the previous sections, can provide more granular information on what access barriers exist among affected groups, and thus help shape adequate access plans and programs. We do note however, that barriers to access for persons with disabilities have not been explored by most PDPs.

Case Study: MDGH supports accessibility by establishing an Access Advisory Committee

MDGH's Access Advisory Committee involves civil society organisations of patients with lived experience of the disease, disease alliances for leprosy for example as well as health professionals to provide strategic support and community engagement pathways to inform access plans. This Advisory Committee can also be a vehicle through which MDGH shares new learnings about clinical trial outcomes and efficacy of the medical product in development. Such an Access Advisory Committee offers a platform for diverse and underrepresented groups to have a say in shaping access plans to improve relevance and uptake among priority, marginalised populations.

As a first theme, PDPs mentioned the theme of *affordability*. Several key considerations noted within access programs include a focus on cost reduction and the imperative of working to develop affordable treatments, for NTDs in particular, that affect mostly poorer populations. Most PDPs already explore affordability by developing cost-effective production methods, negotiating preferential pricing for low-income countries, and by advocating for policies that promote financial access to essential medicines.

58 Hutson M (2024) How AI is being used to accelerate clinical trials, Nature, Nature Index, Available here.

Case Study: The Global Antibiotic Research and Development Partnership (GARDP) exemplifies how PDPs can integrate affordability considerations into their R&D process

GARDP prioritises product affordability from the early stages of development, aiming to ensure access to antibiotics for those most in need, regardless of economic status. They do so by considering the cost factors in Research and Development (R&D) to develop affordable antibiotics, and by exploring strategic licensing agreements with pharmaceutical partners to enable wide production and distribution. By embedding affordability into their core approach, GARDP works to bridge the gap between innovative antibiotic development and accessible treatment options, particularly for marginalised, or poorer populations in low- and middle-income countries.

A second consideration relates to *accessibility* to medical products or the physical and logistical aspects of obtaining medical products. This includes geographic accessibility or ensuring medicines are available in both urban and rural areas, addressing transportation and logistical challenges. PDPs referred to efforts in providing clear, understandable information about medicines in various formats (including those suitable for people who face communication barriers or are illiterate) to ensure inclusion in access programs.

A third theme discussed refers to *acceptability* or the extent to which healthcare products and services align with cultural, social, religious or individual preferences. For PDPs to ensure inclusion of the needs of diverse priority populations, products and treatments need to be culturally appropriate and adapted to specific needs and requirements. Respondents mentioned that medicines and healthcare interventions should be acceptable to all genders, considering factors such as stigma, privacy concerns, and cultural norms. Products should be designed with consideration for various impairment types, ensuring they are acceptable and usable by people with different disabilities. For example, exploring formulations that may be more suitable for people with dysphagia or swallowing impairment.

3.6 Health systems impact and resilience

PDPs have a crucial role not only in developing new health technologies but also in strengthening global health systems, prioritising local knowledge, building on existing local capacity, and supporting diversity at the local level. A key aspect of this work on supporting localisation, is to continue to emphasise the importance of diversity and inclusion. This ensures the sustainability of product innovation and access work in countries and drives momentum for innovation locally. PDPs recognise the responsibility to harness local expertise and skills-set.

Training is reported as a key component of PDPs' capacity-building efforts. This includes not only training their own staff on GEDSI but offers the potential of extending training to support access to leadership positions for women in STEM, for example. These training programs could incorporate a focus on gender, disability, and social inclusion, ensuring that these critical aspects of health equity are integrated into all levels of product development and healthcare delivery [see recommendations 5.1.6]

Case Study: Empowerment of female scientists in Africa

IAVI, with funding support from USAID, started a woman in leadership program to support women scientists' pursuit of leadership positions as Principal Investigators in research projects and research institution leads. The intention was to both empower female scientists and build on their capacity to ensure the sustainability of programs in HIV biomedical research in the long run with their leadership. This project also aimed to address the lack of women in higher level positions and incorporated skills-building in conflict management, negotiation, and managing office policies through a robust coaching system. A cohort of 20 women benefited from six months coaching sessions and has received positive feedback. The ambition is to renew this program, contingent on funding.

4. Findings Part 3. Funder Approaches to Inclusive Innovation

Funders play a crucial role in supporting GEDSI mainstreaming within PDPs. This section evaluates how government agencies, donor organisations, and other funding bodies have been incorporating and supporting GEDSI considerations in the PDP space to date. Some funders such as DFAT and Bill and Belinda Gates Foundation (BMGF) have taken a strong stance on the integration of gender equality in product innovation, with DFAT also prioritising considerations for disability equity (as exemplified by the commissioning of this report). A summary of these early reflections is shared below.

4.1 Governance

Funders' internal structures and policies play a significant role in promoting GEDSI. There is a growing recognition among funding organisations consulted, that funders should be held to the same GEDSI standards as their grantees, with delineated GEDSI strategies. Several donors have established teams in-house, primarily to support gender analysis and mainstreaming with limited attention to disability rights and health equity. The FCDO Research directorate's dedicated team focusing on gender and women's issues is one notable example of institutional commitment. The BMGF has a team of five gender equality specialists supporting 28 vertical program teams.

Disability inclusion, however, is not yet a prominent consideration among PDP funders, except within DFAT. There is growing interest in changing this and receiving guidance on how to consider disability inclusion in the product innovation space; so that funders are better equipped to inform and guide PDPs grantees in return. Most funders we interviewed acknowledge that they are not doing enough to address disability inclusion in product innovation and access. Funders are taking different approaches on this topic; while some are keen to provide hands-on guidance and consultation support, others consider this beyond their mandate and leave it up to the PDP grantees.

4.2 Data and program design

Our analysis shows that funders impose varying levels of requirements on PDP grantees when it comes to their considerations of GEDSI. Of the funders we spoke to, very few request a gender analysis as a prerequisite for funding to PDPs. Similarly, none of the funders consulted currently request a disability inclusion analysis from their grantees.

BMGF has made strides in gender equality program design, supporting disease burden modelling efforts with a gendered lens for cost-benefit analysis. They acknowledge that determining disease burden and analysing trend differences across genders, is still an underdeveloped area that may impact the evidence base for promoting medical product (including vaccine) adoption and informing delivery. In analysing those trends, BMGF teams looks beyond sex-disaggregated disease burden data to consider the gender dimensions of diseases, as well as gendered barriers to access to medical products and health service.

While funders acknowledge that a shift in thinking has occurred, they recognise that there is still a long way to go in fully mainstreaming gender equality considerations into funding decisions and PDP program designs. They also acknowledge a lack of data on the intersection of disease burden with disability, that could adequately inform ways of making product innovation more disability inclusive.

4.3 Product category selection

Funders' priorities in product selection reflect varying degrees of gender equality consideration: Some funders, such as the Netherlands Ministry of Foreign Affairs (MinBuza) and Foreign, Commonwealth and Development Office (FCDO), prioritise funding for product

categories that address diseases particularly affecting women, such as NTDs among women working in water-related occupations, or placental malaria. Some funders, like FCDO, have specific investment focuses, such as Sexual and Reproductive Health and Rights (SRHR). BMGF is working to reinforce the integration of sex and gender lenses in preclinical phases and early-stage development to predict differences in outcomes and adverse events, which could inform subsequent phases of product development. Disability inclusion does not at present inform product selection.

4.4 Programs and access

Some funders view access programs as critical elements of the PDP continuum. There is ongoing discussion among some funders about whether market access strategy fits within PDPs' portfolios or if PDPs should focus on their expertise in science, innovation, drug discovery, development, clinical trials, and formulations. Regardless, funders emphasise that inclusive access pathways cannot be neglected and should be funded and addressed, reflecting the needs and wants of all to ensure no one is left behind.

In the program logic of the DFAT Product Development and Access Partnerships Program, the requirement of grantees is to consider access to final products for all, including women, persons with disabilities and First Nations communities (or Indigenous Peoples and ethnic minority groups). The emphasis on access programs takes an inherently inclusive lens to ensure that all priority populations are considered in the access planning. Other funders request more research and attention from PDPs on local community needs to drive demand and ensure pathways for innovations to reach priority and marginalised communities.

4.5 Monitoring & evaluation

Funders recognise the importance of accountability in gender equality commitments: Some funders believe there is insufficient follow-up on gender equality commitments from PDPs until specific indicators are incorporated into each program's monitoring and evaluation framework. The PDP Funders Group developed a Joint Reporting Mechanism for PDPs, although this does not currently include GEDSI reporting measures to standardise and enhance accountability across the sector.

In conclusion, while progress has been made in incorporating gender equality considerations into PDP funding and governance, there remains significant room for improvement, particularly on disability equity and social inclusion. Funders are increasingly recognising their role in driving these changes, but consistent application of GEDSI principles across all aspects of PDP work – from governance to product development to access – is still a work in progress. The development of standardised reporting mechanisms and increased emphasis on GEDSI in funding requirements are positive steps towards more inclusive and equitable global health innovations.

5. Recommendations

Integrating GEDSI principles into the product innovation process is crucial for developing equitable and effective global health solutions. While progress has been made, particularly in gender equality, there is significant room for improvement in disability inclusion and broader social inclusion. Both PDPs and their funders play critical roles in advancing GEDSI integration, from organisational policies to product development and access strategies. Building on the findings of this analysis, several recommendations are proposed, addressed to both PDPs and funding organisations. By implementing the recommendations outlined in this section, PDPs and funders of PDPs can contribute to more inclusive and impactful health innovations that truly leave no one behind.

The recommendations below are sectioned in six categories and are colour coded for ease of references. To ensure that the coding of recommendations is accessible, we also include a reference to each category code listed below.

Colour	GEDSI Category
Green	GEDSI - Gender Equality, Disability and Social Inclusion
Pink	GE - Gender Equality
Blue	DE - Disability Equity
Grey	SI - Social Inclusion

Recommendations are ordered in incremental steps. The first recommendation listed in each section is considered a first incremental step towards progress in mainstreaming GEDSI.

5.1 Recommendations for PDPs

PDPs should prioritise GEDSI to ensure their innovations respond to the needs of all priority populations. By engaging diverse perspectives and ensuring an in-depth understanding of the needs of women (including pregnant and lactating women), persons with disabilities and ethnic or minority groups into research and development processes, PDPs are better positioned to develop medical products and access plans that better address the needs of all. For instance, considering disability accessibility in clinical trials and product design ensures treatments are tested by all patients, while gender-responsive approaches help account for how diseases and treatments may affect women differently. An inclusive approach to product innovation supports improved health outcomes across all population groups, helping to address historical healthcare disparities and ensure equitable access to life-saving treatments and preventive measures.

5.1.1 Organisational policies & governance

Organisational change plays an important role in anchoring a culture of diversity and inclusion in the organisation and in maintaining progress towards inclusive programs.

Creating an inclusive organisational culture and driving systematic change to embrace diversity is fundamental to effective GEDSI mainstreaming across programs. An inclusive culture fosters innovative thinking by bringing together diverse perspectives, experiences, and approaches to problem-solving.

Ensuring the meaningful inclusion of women, people with disabilities and minority groups in the decision-making structures and processes of an organisation is key to mainstreaming GEDSI across the organisation. This diversity of thought leads to more comprehensive

solutions that better serve varied community needs. Furthermore, when staff at all levels feel valued and represented, they are more likely to champion GEDSI principles in their work, identify potential barriers or biases in program design, and advocate for inclusive practices. Organisations should invest in ongoing staff training on GEDSI, establish clear accountability mechanisms, allocate adequate resources, and ensure diverse representation in decision-making positions. This can help break down systemic barriers, challenge unconscious biases, and create an environment where GEDSI considerations become second nature rather than an afterthought in program planning and implementation.

While most PDPs surveyed have established guidance or standards to promote gender diversity within the organisation, the practical implementation of these frameworks sometimes falls short of the intended goals and deserves more scrutiny and attention. Beyond ensuring active engagement of all genders, including equitable access to leadership positions, it is critical to consider how organisations recognise and adapt to the needs of individuals with disabilities. Additionally, it is important to consider how organisations ensure a diversity of perspectives and contributions from all social groups including Indigenous groups and other marginalised communities.

Below are some of the basic recommendations to consider to ensure organisational and governance backing for GEDSI within PDPs:

Table 1: Organisational policies and governance

Number	Category	Recommendation
1.1	GE	If not already done so, use the Global Health 50/50 self-assessment tool to measure progress along gender equality integration within the organisation.
1.2	DE	Use the CBM organisational self-assessment tool to measure progress along disability inclusion within the organisation.
1.3	GEDSI	Develop a comprehensive strategy that address all three elements: gender equality, disability inclusion, and broader social inclusion. Currently, many GEDSI strategies have a stronger emphasis on gender equality than on the whole range of inclusivity considerations
1.4	GEDSI	Establish a formalised and permanent task force or working group within the organisation. Nominate at least two designated representatives internal to the team and consider expanding the composition of this body with one representative for each department. If a gender working group exists, consider expanding the scope of this working group to encompass disability equity and broader social inclusion.
1.5	GEDSI	Offer training for staff, including on gender equality and inclusion, including specialised training on responsive program design, inclusive community engagement, and on inclusive clinical trials. Use the resources developed by the Neurological Clinical Trials (NIMICT) Project which include toolkits, manuals, educational videos, and online training modules to guide investigators through the process of designing inclusive clinical trials.

Number	Category	Recommendation
1.6	DE	Co-develop basic disability awareness and guidance with other PDPs to align on the 'definition' of disability in the context of PDPs, utilising a rights-based approach to disability.
1.7	GEDSI	Human Resources: Implement inclusive recruitment practices and set targets for equal representation of genders at all levels, as well as targets for representation of persons with disabilities and affected populations.

5.1.2 Data

Data plays a crucial role in advancing GEDSI within PDPs. By implementing comprehensive data collection and analysis strategies, PDPs can better understand the diverse needs of their target populations and develop more inclusive solutions. This section outlines key recommendations for strengthening data practices, from collecting disaggregated disease burden data to conducting targeted research on access barriers. These data-driven approaches enable PDPs to make evidence-based decisions, measure progress, and advocate for meaningful change in product development and healthcare delivery. The following recommendations provide practical guidance for PDPs to enhance GEDSI initiatives through improved data collection, analysis, and utilisation practices.

Table 2: Data recommendations

Number	Category	Recommendation
2.1	GEDSI	Collect and disaggregate data by sex, gender, age, disability, ethnicity, socio-economic status, location, where possible. For gender, refer to the Sexual Orientation and Gender Identity (SOGI) data best practices where it is safe to do so[59]. Use language and terminology that everyone can understand and that is sensitive to the cultural and legal context and include 'prefer not to say' as an option. Consider where disaggregation could be applied retrospectively to historical datasets available.
2.2	DE	Invest in research on the intersection of disability with product development and access to medical products. This is to address a recognised gap for several PDPs. Specifically, generate new, or synthesise existing evidence on disproportionate risk and key disability issues for disease areas relevant to PDPS. Explore joint formative research initiatives on disability inclusion between PDP grantees.
2.3	GEDSI	Conduct desk and in-country research on access barriers for women, LGBTQIA+ populations, socially marginalised groups,

59 In some countries, same-sex relationships and gender diversity are criminalised, making the explicit use of LGBTQIA+ terminology potentially risky for the safety of local communities. When working in these contexts, PDPs should prioritise the security of LGBTQIA+ communities by using locally appropriate and culturally sensitive language, while still ensuring their health needs are considered through careful program design and discrete engagement strategies that don't put individuals at risk.

Number	Category	Recommendation
		hard-to-reach or minority ethnic groups, as well as persons with disabilities, to understand country-level access. This will serve to better inform access plans. Consider country-level regulations that may restrict access in hard-to-reach places.
2.4	GE	Adopt and publicly commit to the Sex and Gender Equity in Research (SAGER) SAGER guidelines.
2.5	DE	Adopt and publicly commit to RDI's Research for All guidance which is about making research inclusive of people with disabilities.
2.6	GEDSI	Identify experts on gender equality and disability equity, as well as local representative group to include in a shared database for PDPs to consult for regional or in-country contextual information on GEDSI.
2.7	GEDSI	Package available evidence to support advocacy efforts on promoting GEDSI mainstreaming among partner organisations. This will serve to maximise the impact of your efforts on GEDSI beyond the product innovation space.
2.8	DE	PDP grantees of DFAT should adhere to DFAT's inclusive and accessible communication guidelines.

5.1.3 Partnerships

Effective partnerships and inclusive community engagement are fundamental to ensuring that product innovation truly serves all populations. In the next section we outline several recommendations to guide PDPs on how to expand engagement strategies beyond traditional stakeholders to actively involve underrepresented communities throughout the entire product development lifecycle - from initial design to implementation. This means intentionally seeking out and building relationships with OPDs, women's organisations, LGBTQIA+ advocates, and community groups that may not typically have a voice in healthcare innovation. Additionally, strengthening collaboration between PDPs themselves creates valuable opportunities to share best practices, learn from collective experiences, and accelerate GEDSI mainstreaming across the product development landscape. Through these enhanced partnership approaches and inclusive engagement strategies, PDPs can better develop and deliver health solutions that effectively meet the diverse needs of all populations, while building sustained momentum for GEDSI integration across the broader product innovation ecosystem.

Table 3: Partnerships recommendations

Number	Category	Recommendation
3.1	GEDSI	Conduct a stakeholder mapping exercise of locally based representative organisations and associations of underrepresented groups and communities including women's organisations, LGBTQIA+ groups, OPDs, and ethnic minority group representatives that can be consulted to support the product innovation phase (as well as the development of access plans).

Number	Category	Recommendation
3.2	GEDSI	Engage more directly with women's groups, women rights organisations, youth groups, Indigenous Peoples' organisations, OPDs, and LGBTQIA+ advocates. For example, by creating formal partnerships with these organisations and through their involvement in Community Advisory Boards (see Recommendation 3.3 below).
3.3	GEDSI	Establish and work actively through *Community Advisory Boards* (CAB) to integrate diverse perspectives in product development and clinical trial design, at the community level. Membership of the CAB should be specifically inclusive of local women's organisations, people with disabilities, youth and LGBTQIA+ advocates.
3.4	GEDSI	Collaborate with local universities and research institutes to better understand socio-cultural barriers and inequities that could impact access to clinical trials, and to leverage established networks to maximise diversity in clinical trials and to support access plans.
3.5	GEDSI	Establish a regular exchange forum for PDPs to discuss GEDSI priorities along the product development and access to medical products continuum. This forum can be a mechanism through which PDPs can share experiences and best practices and jointly participate in external advocacy to push the GEDSI in product innovation agenda globally.
3.6	GEDSI	Implement a sub-award policy for all partnerships that institutionalises joint commitments, with new partners, on diversity equity and inclusion (following IVCC's model).

5.1.4 Product selection and clinical trials

Inclusive and equitable clinical trials are essential for developing medical products that effectively serve all populations affected by neglected diseases. To achieve this, PDPs must implement innovative approaches that actively promote diversity in trial participation, with particular attention to the inclusion of women - including pregnant and lactating women - and people with disabilities. Presumptive inclusion of pregnant and lactating women should be a default based on a careful benefit-risk analysis. The WHO guidance for best practices for clinical trials recommend several approaches to enable their inclusion: evaluating pre-existing evidence of similar interventions' safety in this population, expediting reproductive toxicology studies where necessary (especially for high-fatality diseases), monitoring drug excretion in human milk where applicable and tracking any effects on breastfed infants. Such options demonstrate a comprehensive approach to safety monitoring that benefits both mother and child.

Building more diversity within clinical trial designs requires close collaboration with *Clinical Research Organisations* and a focus on creative recruitment strategies, comprehensive training programs for trial staff in cultural competency and inclusive practices, and intentional study designs that address historical biases in clinical research. By generating safety and efficacy data that truly represents diverse populations, PDPs can better guide their product development processes to create innovations that meet the distinct needs of all priority populations, ultimately reducing gender and disability disparities in health outcomes.

Table 4: Products and clinical trials recommendations

Number	Category	Recommendation
4.1	GEDSI	Improve diversity and inclusion within clinical trials, working with and through *Clinical Research Organisations* (CROs) by: Adopting and publicly committing to WHO's Guidance for best practices for clinical trials. Considering multiple trial sites closer to residential areas, or home visits to support inclusivity in clinical trials for participants that may not be able to travel. Providing compensation for replacement of home caretaking responsibilities to encourage more women (traditionally in caretaking roles) to participate. Ensuring trial sites accommodate accessibility, from the physical environment (e.g., ramps, wide doorways to accommodate wheelchairs, signage in different formats, etc.), to information that is available in local sign language, or access to local interpreters. Embedding inclusive communications techniques and approaches on clinical trial design by using audio, visual, large print and braille communication alternatives, to facilitate the participation of people with sensory impairments and persons with low literacy.
4.2	GE	Actively seek pathways to include pregnant and lactating women in clinical trials and provide clear and safe measures to reduce gender bias in clinical trials by identifying opportunities for improved safe inclusion of women, pregnant women and lactating women, especially for diseases where they carry increased risks. These include: Conducting thorough benefit-risk analysis of inclusion, exploring the specific burden of the disease on pregnant women, and availability of other treatments, to determine the urgency of inclusion. Generating reproductive data in pre-clinical toxicology animal studies as a pre-requisite. Using historical data from pregnancy registries, and past clinical trials where women became pregnant to generate preliminary results on safety and efficacy. Enhancing post approval safety evaluations and observational studies to generate data among pregnant women.
4.3	DE	Engage with CROs and clinical trial sites that have linkages to local OPDs, prioritise access for people with disability or are willing to make such changes to do so.
4.4	SI (including DE)	Train staff on how to conduct inclusive clinical trials, share resources on respectful engagement, and set benchmarks for inclusion in clinical trials. Ensure that clinical staff are familiar with local customs and cultural sensitivities and are familiar with inclusive communication strategies including having access to local sign language interpreters.

Number	Category	Recommendation
4.5	DE	Address the needs of people with disabilities in product formulation and treatment protocols to facilitate uptake and drive demand for all by: Gathering insights and perspectives from OPDs on medicine formulation and treatment protocols and how these could be improved. Considering ways to adapt drug formulations to accommodate the needs of people with physical disabilities such as dysphagia or difficulty swallowing. Using accessible formats for product information. E.g. Use visuals, easy read formats and appropriate language for diverse audiences, use of audio or braille).

5.1.5 Programs and access

We recognise that not all PDPs focus on downstream access and building access plans, however ensuring that new innovations are accessible to all, including to women, people with disabilities or other socially marginalised populations is critical to leave no one behind. PDPs should build acceptability for new innovations by engaging diverse communities in the product development processes, conducting thorough cultural assessments, and incorporating feedback from various stakeholder groups along the product design process. PDPs should also consider developing more accessible product information formats to deliver information about their products in a way that is suitable to the needs of persons with disabilities, or for populations with low literacy. PDPs need better guidance and examples, on accessible information materials, adequate communication methods, and specific formulation requirements. Some PDPs can also improve downstream accessibility to new innovations by collaborating with local health systems, and organisations that represent priority populations, developing innovative distribution methods, and ensuring that communities living in more remote areas or marginalised groups experiencing specific barriers to access to health services have means of obtaining the medical product.

Table 5: Programs and access recommendations

Number	Category	Recommendation
5.1	GEDSI	Establish an *Access Advisory Committee* with GEDSI experts, including members with from priority populations: women organisations, ethnic minority groups and OPDs to advise on access plan for new innovations.
5.2	DE	Conduct acceptability consultations as an entry point by fostering engagement with locally based OPDs in community engagement during trials and/or implementation to inform access plans and ensure that innovations are accessible to all, including priority and marginalised populations.
5.3	SI	Identify innovative distribution methods and identify local partners to support access to medical products for hard-to-reach remote areas and marginalised communities.

5.1.6 Health system impact and resilience

Beyond product innovation PDPs have a role to play in engendering change and encouraging diversity at the local health system level, and among the partners along the product development continuum. We have seen in the findings section that some PDPs dedicate time and resources in sharing best practices, knowledge, and building on the skills set of local partners, particularly to facilitate access to leadership positions for women in STEM. Through similar initiatives, PDPs can play a play in fostering greater inclusion through localisation efforts.

PDPs should also share their learnings and best practices when it comes to GEDSI mainstreaming with partners in the product innovation, development and access space and with partners in countries, through advocacy activities and training programs that incorporate a focus on gender, disability, and social inclusion. This is to ensure that these critical aspects of health equity are integrated into all levels of product development and healthcare delivery.

Table 6: Health system impact and resilience recommendations

Number	Category	Recommendation
6.1	GEDSI	Support localisation efforts that improve diversity and inclusion, including training local partners in GEDSI principles, training and empowerment women in STEM and as Principal Investigators
6.2	GEDSI	Share GEDSI-related findings through various publication channels; publish research papers, give presentations, and participate in external working groups or conferences to share these findings and advocate for greater update of GEDSI across product innovation pathways

The journey toward comprehensive GEDSI integration in PDPs is necessarily progressive, building upon existing foundations to facilitate the meaningful inclusion of all underrepresented groups in product innovation processes. While many PDPs have already made public commitments to gender equality, similar explicit commitments to disability equity and social inclusion are essential next steps. Although various tools exist to guide PDPs in enhancing diversity and inclusion, there remains a particular need to develop and share best practices around disability equity within the PDP community. To illustrate how we see the progressive steps towards full inclusion of persons with disabilities and gender inclusion, we present two complementary diagrams that map out the incremental steps toward both disability inclusion and gender inclusion. These diagrams illustrate how PDPs can systematically progress from basic compliance to transformative inclusion, acknowledging that organisations may be at different stages of their GEDSI journey and that sustained, deliberate effort is required to advance through each phase

Figure 4: Steps to support progress on disability inclusion across the Product Development Curriculum

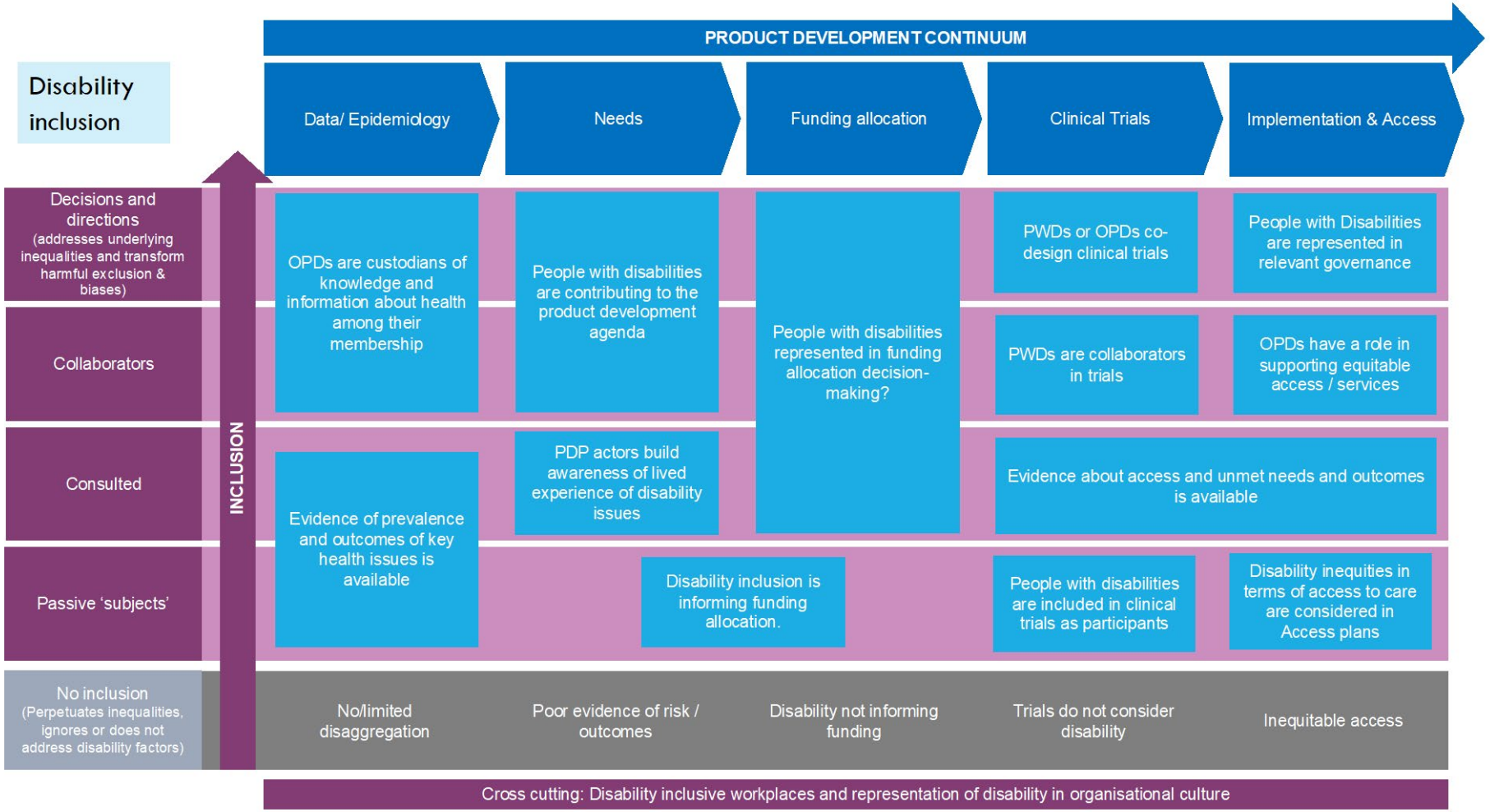
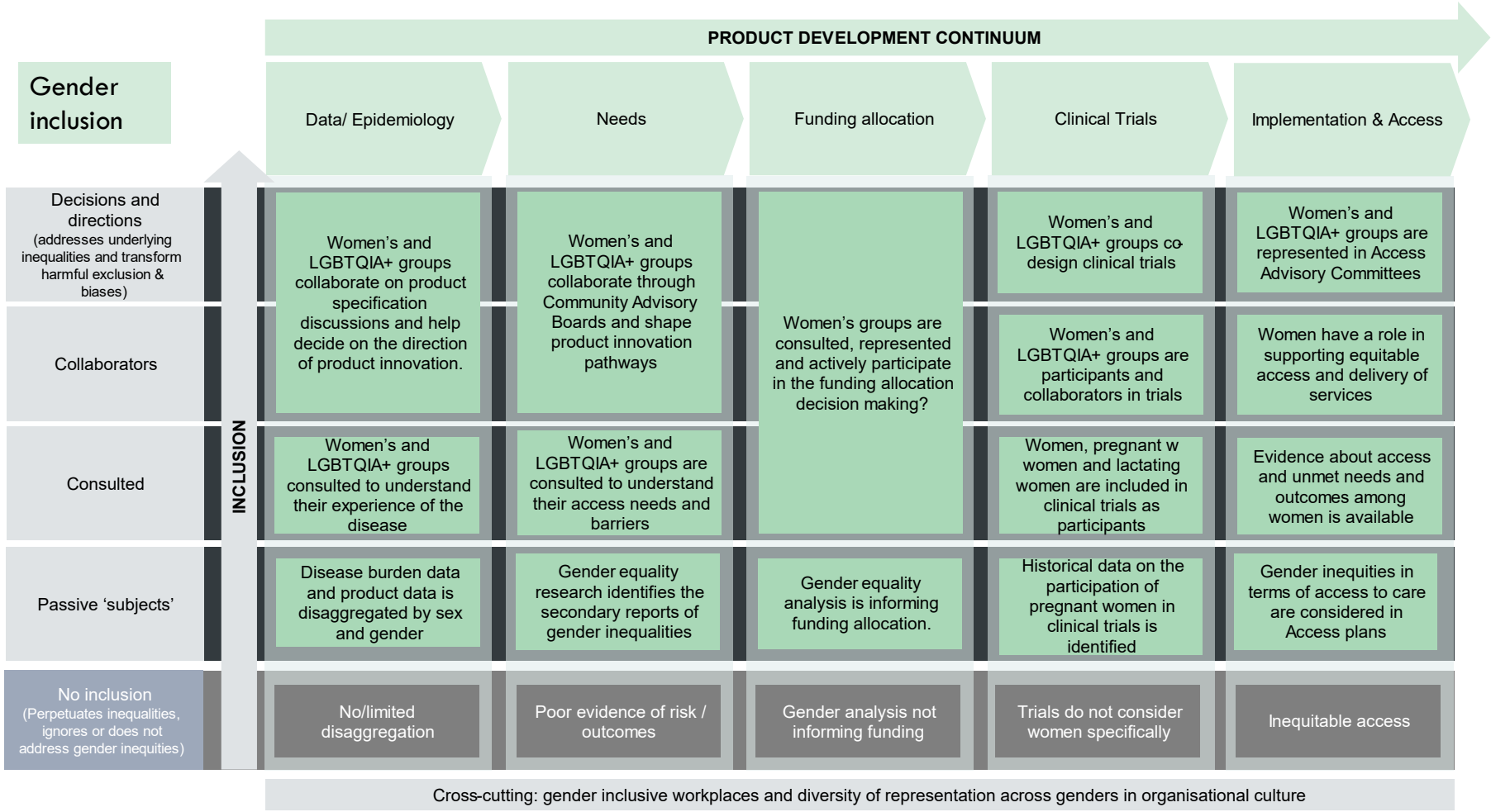


Figure 5: Steps to support progress on gender equality across the Product Development Curriculum



5.2 Recommendations for Funders

Considerations for GEDSI should be an integral part of each program design, ideally mandated by funders. This could be supported either through core funding or targeted funding to PDPs. Funders may also be guided by the evaluation tool, summarised in Appendix B and developed from our analysis, to evaluate PDP's current integration of GEDSI within their organisational structures, policies and program work.

5.2.1 Investment design

Funders play a critical role in embedding GEDSI principles within product development partnerships through strategic investment decisions and accountability measures. By developing comprehensive GEDSI strategies, and providing dedicated funding for disability inclusion research, funders can create sustainable frameworks for inclusive product development. This section outlines key recommendations for structuring investments to promote GEDSI, including the importance of engaging with OPDs and participating in global measurement tools to track progress.

Table 7: Investment Design

Number	Category	Recommendation
1.1	GEDSI	Establish permanent, funded teams or divisions to continuously support investments in GEDSI that include experts (in-house, or external) on disability equity and rights as well as gender equality. Support grantees with high level, general guidance on intersections of disability and public health / product development
1.2	GEDSI	Develop and make publicly available a GEDSI in PDP investments strategy or guidance document that is reviewed regularly (e.g. at least every five years) to adjust to a rapidly evolving landscape. The strategy or guidance document should delineate how, as a funder, you plan to contribute to improving gender equality, disability equity and social inclusion and keep PDPs accountable. Embed GEDSI considerations into each program design and monitoring and evaluation frameworks.
1.3	DE	Increase focus on disability inclusion in the product innovation and access by setting aside funding for disability inclusion research and to support consultations between PDPs and OPDs.
1.4	DE	Funders facilitate roundtable discussions jointly with OPDs, focusing on disability and health and disability product innovation. These roundtables should be specifically targeted to PDP staff members and their partners.
1.5	GE	Encourage PDPs to use the Global Health 50/50 self-assessment tool to measure progress on gender equality within global health organisations. Progress can be re-assessed and measured year on year.
1.6	DE	Encourage PDPs to report into the CBM organisational self assessment tool to measure disability inclusion as a measuring tools on disability inclusion.

5.2.2 Data and program design

Strong data foundations and analytical frameworks are essential for advancing GEDSI in product development. Funders should require comprehensive gender, disability, and social inclusion analyses as prerequisites for funding, while supporting disease burden modelling that incorporates GEDSI perspectives. This approach ensures that evidence-based decision-making guides program design, with particular attention to sex- disaggregated data in preclinical phases and targeted research on the burden of disease on people with disability, and access barriers for people with disability.

Table 8: Data and program design

Number	Category	Recommendation
2.1	GEDSI	Request gender, disability and social inclusion analyses as a deliverable under funding agreements and eventually, as a pre-requisite for funding. This analysis should include the following elements: • disease burden-modelling efforts with a gendered lens • disability and social inclusion lens for cost-benefit analysis • targeted set of evidence summaries / evidence gap maps of disability for priority diseases/issue.
2.5	GE	Request the integration of sex and gender data reporting in preclinical phases and early-stage development[60]. Encourage grantees to refer to historical data from clinical trials where women may have fallen pregnant (where available) to support early data analysis of efficacy of product among women.

5.2.3 Product category selection

Funders must take a balanced and strategic approach to product category selection, ensuring their investment portfolios address the diverse health needs of all populations. While maintaining focus on critical areas like sexual and reproductive health, decisions should be guided by comprehensive disease burden data and evidence of access barriers facing groups who experience inequities This strategic approach helps prevent gaps in funding across disease categories while ensuring appropriate attention to conditions that disproportionately affect marginalised communities.

Table 9: Product category selection

Number	Category	Recommendation
3.1	GEDSI	Ensure diversity in product category selection across investments, as guided by disease burden data and data on barriers to access for vaccines, diagnostics or treatments for these diseases, particularly on inequity barriers the negatively impact groups who experience increased inequities include women, children, marginalised communities and people living with disabilities.

[60] See indicator no. 9 in PDAP Program logic and monitoring and evaluation framework: Number of products in trials in the last year with Australian Government support that have been informed by GEDSI analysis. Reporting a positive change from previous year on reporting of disaggregated data by preclinical, clinical phase 1, 2 and 3 and Chemistry and Quality Control.

Number	Category	Recommendation
		Consider specific investments in maternal health, women's sexual and reproductive health and treatments for women in pregnancy.
3.2	GEDSI	Develop a strong rational for focusing an investment on specific disease categories only so as not to leave other groups behind. Sexual and reproductive health products and maternal and child health commodities are critical, but beyond that, funders should ensure, collectively, that all disease categories that disproportionally impact underrepresented populations, including women, pregnant women, lactating women, people with disabilities or socially marginalised communities, are adequately funded.
3.3	GE	Request PDPs to identify pathways for the inclusion of pregnant and lactating women in clinical trials.

5.2.4 Programs and access

To ensure equitable access to health innovations, funders should prioritise support for access pathways that reflect diverse community needs. This includes providing resources for in-depth research on local community requirements, cultural contexts, political landscapes and research into the specific needs and access barriers for underrepresented or marginalised groups including women, people with disabilities, and ethnic minority or Indigenous groups. Understanding these factors is crucial for developing effective access strategies that reach all populations, particularly those traditionally underserved by healthcare systems.

Table 10: Programs and access

Number	Category	Recommendation
4.1	GEDSI	Fund access pathways through PDPs, that reflect the needs of all communities, including underrepresented and socially marginalised groups.
4.2	GEDSI	Request more research and attention from PDPs on local community needs, specifically among, women, people with disabilities, and socially marginalised groups, to drive demand and navigate socio-cultural, political landscapes, and to inform access plans.

5.2.5 Partnerships

Effective partnerships require adequate funding for comprehensive community engagement throughout the product development process. Funders should ensure PDPs have sufficient resources to conduct inclusive stakeholder engagement activities and foster collaboration across the sector. By facilitating the sharing of best practices through mechanisms like the PDP Funders Group Discussions, funders can accelerate the adoption of effective GEDSI practices across the field.

Table 11: Partnerships

Number	Category	Recommendation
5.1	GEDSI	Ensure adequate funding envelopes for PDPs to run extensive, inclusive and adequate community engagement activities along the full product development continuum.
5.2	GEDSI	Share best practices, guidelines and recommendations on GEDSI mainstreaming for PDPs through the PDP Funders Group Discussions.
5.3	DE	Convene disability representatives and foster dialogue between OPDs and the PDPs, so that people with disabilities themselves can share knowledge and expertise with PDP stakeholders, explore issues that affect them directly, and determine the most effective ways forward with PDPs. Persons with lived experience of disability can openly share their thoughts on reflections on how they can be included in the product design, clinical trial design and development process. (See our section on - Fostering dialogue between OPDs and product development actors. page **Error! Bookmark not defined.**)

5.2.6 Monitoring & Evaluation

Robust monitoring and evaluation frameworks are essential for tracking progress and ensuring accountability in GEDSI implementation. Funders should require specific GEDSI indicators across all funded programs and work together to develop standardised reporting mechanisms. This coordinated approach to measurement and evaluation helps track collective progress while identifying areas requiring additional attention or resources.

Table 12: Monitoring & Evaluation

Number	Category	Recommendation
6.1	GEDSI	Require specific GEDSI indicators within each program's monitoring and evaluation framework.
6.2	GEDSI	Develop and implement a *Joint Reporting Mechanism* with common GEDSI reporting measures across PDP Funders.

By implementing these recommendations, PDPs and their funders can significantly advance GEDSI in product development, leading to more equitable and effective global health innovations.

5.3 Conclusion

The integration of GEDSI principles within PDPs represents both a significant opportunity and an ongoing challenge in global health innovation. This analysis has revealed that while progress has been made, particularly in gender equality initiatives, there remains substantial work to be done in comprehensively incorporating disability equity and broader social inclusion considerations across the product development continuum.

The findings demonstrate that PDPs have made notable strides in establishing gender-responsive organisational structures and policies, with many organisations implementing gender working groups and developing targeted strategies. However, disability inclusion and broader social inclusion often receive less attention, primarily due to limited guidance,

expertise, and awareness within the biomedical sphere. This disparity highlights the need for a more balanced and comprehensive approach to GEDSI integration.

A key insight emerging from this analysis is the critical importance of data disaggregation and community engagement in driving meaningful GEDSI integration. While sex-disaggregated data collection has become more commonplace, there remains a significant gap in disability-specific data and comprehensive social inclusion metrics. The engagement of diverse communities, particularly OPDs and other marginalised groups, in product development processes remains inconsistent across PDPs.

Clinical trials represent another area where significant progress is needed. While there is growing recognition of the importance of diverse participation, barriers persist in including pregnant and lactating women, LGBTQIA+ individuals, and people with disabilities. Some PDPs have begun implementing innovative approaches to make trials more inclusive, but these efforts need to be systematised and scaled across the sector. A noticeable opportunity is around the presumptive inclusion of women in pregnancy and lactating women in clinical trials.

The role of funders in advancing GEDSI integration cannot be overstated. Through strategic funding requirements, dedicated resources for GEDSI initiatives, and robust monitoring and evaluation frameworks, funders can create powerful incentives for PDPs to prioritise inclusive practices. The development of standardised reporting mechanisms and increased emphasis on GEDSI in funding requirements are positive steps toward more equitable global health innovations.

Looking ahead, the recommendations outlined in this report provide a roadmap for both PDPs and funders to enhance GEDSI integration. Key priorities include:

- Strengthening organisational policies and governance structures to better reflect GEDSI principles.
- Improving data collection and analysis practices to inform inclusive product development.
- Expanding partnerships with diverse community organisations and stakeholders.
- Implementing more inclusive clinical trial designs and practices.
- Ensuring equitable access to medical products for all populations.
- Building capacity for GEDSI integration through training and knowledge sharing.

The incremental recommendations proposed outline a practical pathway for PDPs to move from basic compliance to transformative inclusion. This journey requires sustained commitment, adequate resources, and collaborative effort across the product development ecosystem. As the global health community continues to work toward the goal of leaving no one behind, the integration of GEDSI principles in PDPs becomes increasingly crucial. Success in this endeavour will require ongoing commitment from PDPs, sustained support from funders, and active engagement with diverse communities to ensure that health innovations truly serve the needs of all populations.

6. References

1. Australia's Department of Foreign Affairs and Trade (DFAT). (2023). Gender Equality, Disability and Social Inclusion analysis - good practice note.

2. Bodicoat, D.H., Routen, A.C., Willis, A. et al. (2021). Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. Trials, 22, 880. https://doi.org/10.1186/s13063-021-05849-7

3. Boulougoura et al. (2019). Phase I, Randomized, Controlled Clinical Study of CC-11050 in People Living with HIV (APHRODITE).

4. das Neves, J., & Ensign, L. (2022). Advances in drug delivery for women's health: A matter of gender equity. Advanced Drug Delivery Reviews, 182, 114132.

5. DFAT. (2024). Gender Equality, Disability and Social Inclusion Analysis Good Practice Note.

6. Dhatt, R., et al. (2017). The role of women's leadership and gender equity in leadership and health system strengthening. Global Health, Epidemiology and Genomics, 2, e8.

7. Ellis, E., et al. (2017). Assessing the Feasibility of Asking About SOGI in the Current Population Survey.

8. Federal Committee on Statistical Methodology. (2016). Measures of SOGI in Federal Surveys.

9. Feldman M. A. et al. (2013). Where are persons with intellectual disabilities in medical research? A survey of published clinical trials. Journal of Intellectual Disability Research, 58(9), 800-809.

10. Global Health 50/50. (2023). Gender equality: Flying blind in a time of crisis. 2023 Global Health 50/50 Report.

11. Hawkes, S., & Buse, K. (Year not provided). Gender and global health: evidence, policy, and inconvenient truths. The Lancet, 381(9879), 1783-1787.

12. Hawkes, S., et al. (2020). The global movement for gender equality in global health. The Lancet, 395(10229), 1021-1022.

13. Hay, K., et al. (2019). Disrupting gender norms in health systems: making the case for change. The Lancet, 393(10190), 2535-2549.

14. Heidari, S., Babor, T.F., De Castro, P. et al. (2016). Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. Research Integrity and Peer Review, 1, 2. https://doi.org/10.1186/s41073-016-0007-6

15. Hutson M. (2024). How AI is being used to accelerate clinical trials. Nature, Nature Index.

16. Kelsey, M.D., et al. (2022). Inclusion and diversity in clinical trials: Actionable steps to drive lasting change. Contemporary Clinical Trials, 116, 106740.

17. Malundo, J.G. (2019). Responsiveness of Offshored Clinical Trials among Women in the Philippines.

18. Medina, R., et al. (2022). Collecting Data About LGBTQI+ and Other Sexual and Gender-Diverse Communities.

19. Miele K, Bamrah Morris S, Tepper NK. Tuberculosis in Pregnancy. Obstet Gynecol. 2020 Jun;135(6):1444-1453. doi: 10.1097/AOG.0000000000003890. PMID: 32459437; PMCID: PMC7975823.

20. Packed, R., et al. (2020). Unpacking power dynamics in research and evaluation on gender equality and women's empowerment: Lessons from a meta-evaluation. Evaluation, 26(4), 437-457.

21. Palmer-Ross, A., et al. (2021). BMJ Global Health, 6:e004997.

22. Perez, C. C. (2019). Invisible Women: Exposing Data Bias in a World Designed for Men. Abrams Press.

23. RDI Network. (2020). Research for all: Making Development Research Inclusive of People with Disabilities. Authored by CBM-Nossal Partnership for Disability-inclusive Development and Research for Development Impact Network.

24. Schwartz, J. K., & Unni, E. (2021). Inclusion of People with Disabilities in Research to Improve Medication Adherence: A Systematic Review. Patient Preference and Adherence, 15, 1671–1677.

25. Shariq, S., Cardoso Pinto, A.M., Budhathoki, S.S. et al. (2023). Barriers and facilitators to the recruitment of disabled people to clinical trials: a scoping review. Trials, 24, 171.

26. Talib, Z., et al. (2019). Promoting gender equity in global health leadership in academic and professional institutions. Global Public Health, 14(3), 390-403.

27. Theobald, S., et al. (2017). The importance of gender analysis in research for health systems strengthening. Health Policy and Planning, 32(suppl_5), v1-v3.

28. United Nations. (2015). Transforming our world: The 2030 Agenda for Sustainable Development.

29. United States Food and Drug Administration (USFDA). (2018). Draft Guidance, Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry. https://www.fda.gov/media/112195/download

30. Wolter et al. (2022). Transgender Youth Inclusion in Healthcare in Southeast Asia: Insights from Indonesia, Thailand, and the Philippines.

31. World Health Organization. (2019). Delivered by women, led by men: A gender and equity analysis of the global health and social workforce. Human Resources for Health Observer Series No. 24.

32. World Health Organization. (2021). Gender and health. https://www.who.int/health-topics/gender

33. World Health Organization. (2024). Global report on Neglected Tropical Diseases – stronger together, towards 2030.

34. World Health Organization (WHO). (2024). Guidance for best practices for clinical trials. https://www.who.int/publications/i/item/9789240097711

34. Yakerson, A. (2019). International Journal for Equity in Health, 18:56.

Appendix A. Global Health 50/50 Report Methodology explained

Global Health 50/50 is an independent, evidence-driven initiative to advance action and accountability for gender equality in global health. The goal of the Global Health 50/50 initiative, the Global Health 50/50 report and its Gender and Health Index is to measure progress across organisations on how they are driving gender equality in organisational and leadership structures and how this commitment is reflected in their strategic approaches. The initiative provides 'how to guides' offering actionable guidance to improve gender equality within organisations. Global Health 50/50 researchers assess publicly available information on global health institutions, including PDPs, to self-reported/self-assessment – Global 50/50 team do their own research and post information on their online tool. They then consult the organisations reviewed so that they have a chance to assess the data and fill the gaps where required. Global 50/50 explores five core variables illustrated below looking at the presence of a gender equality strategy of public commitment, workplace gender equality policies, workplace diversity and inclusion policies, board diversity and inclusion policies, gender parity in senior management, and sex-disaggregated monitoring and evaluation frameworks.

Figure 6: Global 50/50 initiatives' variables for assessing gender equality integration in global health organisations

The figure above represents the four areas of inquiry within the Global Health 50/50 report. The figure shows four different boxes entitled:

- Commitments to redistribute power
- Policies to tackle power & privilege imbalances
- Who holds power and enjoys privilege

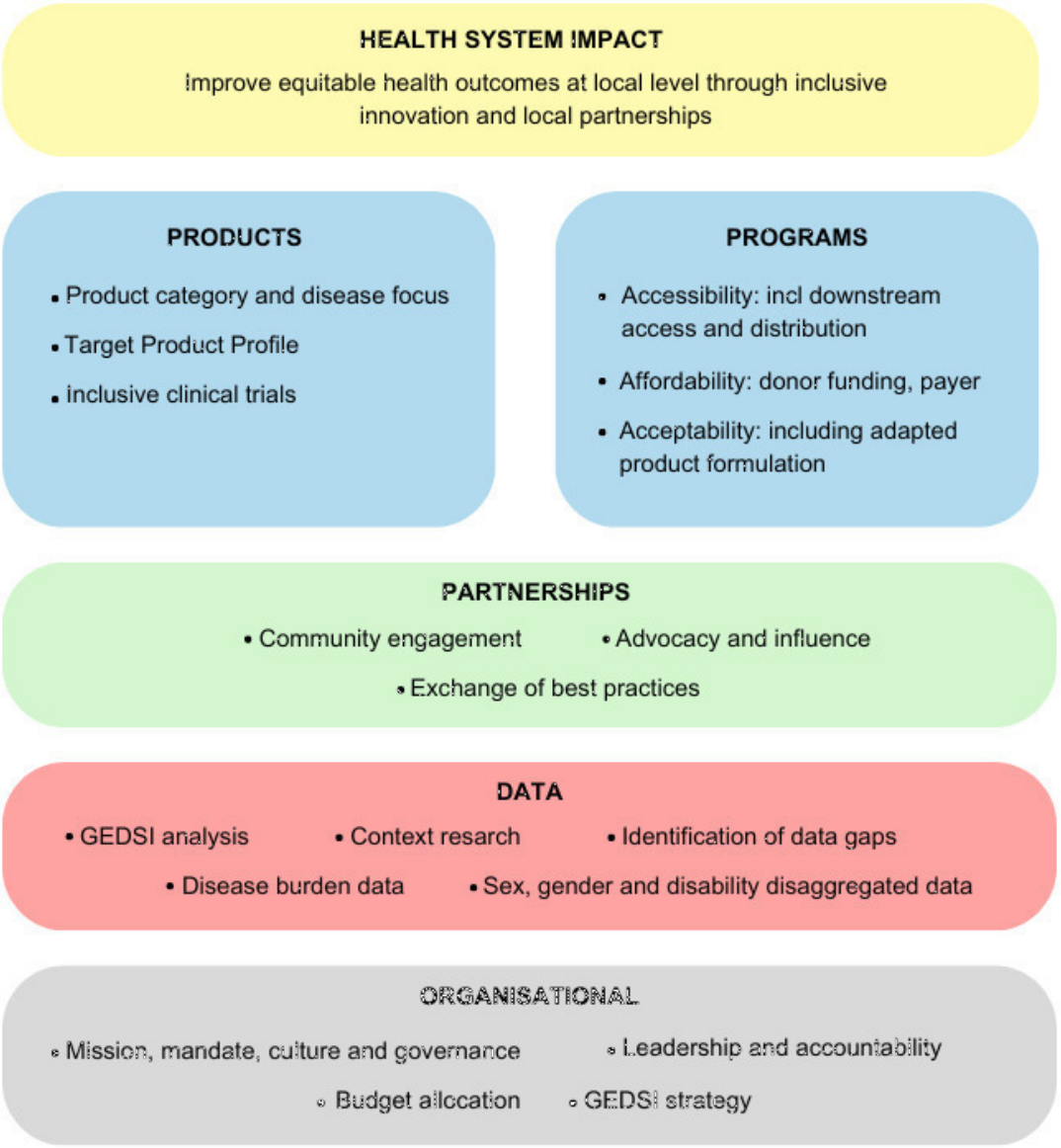
- Gendered power dynamics driving health inequities

Each category is assessed on a yearly basis. Every two years, Global Health 50/50 also looks into sexual harassment policy updates, parental leave and support to new parents, flexible working arrangements and the gender pay gap in each organisation assessed.

Appendix B. Evaluation tool for GEDSI integration in PDPs

Our thematic analysis of the document, literature and consultations held in the context of this research project yielded six different categories of inquiry that are captures in the framework illustrated below. This framework may be used to evaluate the incorporation of GEDSI within PDPs.

A scoring system may be developed in conjunction with the categories proposed to evaluation the level of mainstreaming of GEDSI considerations across PDPs' organisational structures and activities e.g. Levels 1-4 where 1 is Low, 2 is Medium, 3 is High and Transformative[61].



Organisational

Internal policies of the PDP and the allocation of resources, time and money, according to the organisations' mandate and mission.

61 PATH's Equity in Programming Tool is a useful reference to exploring scoring options.

Sub-categories:

- **Gender Lens**: Assess how the organisation integrates a gender perspective in its policies and operations.
- **Disability Inclusion**: Evaluate how the organisation considers the needs of individuals with disabilities.
- **Social Inclusion**: Review how the organisation addresses social equity and ensures marginalised groups are considered.

Indicators:

- **A GEDSI strategy** exists - accountability & reporting mechanism on set goals (WG?),
  - Social inclusion is considered specifically
  - Disability inclusion is considered specifically exists
- **Accountability mechanism** is in place to measure organisation's progress against strategy.
- **Progress is reported** publicly either e.g. through website
  - Organisation progress on gender equality is reported through Global 50 50 for benchmarking and year on year measurement of progress.
  - Organisation uses the CBM organisational self-assessment tool to measure progress along disability inclusion within the organisation.
- **Governance structure** reflects diversity and equity commitment and ensures gender parity and racial, geographic diversity at senior leadership levels (including at organisational and board level) as well as transparent career progression, work life balance, and safeguarding mechanisms.
- **Risk identification and mitigation plan** is in place that takes into consideration gendered risks to ensure the investment does no harm and addresses gender gaps
- **Budget** is allocated to GEDSI specific as a % of grant funding allocation
- **Expertise** (in-house or externally hired) is available on Gender Equality and on Disability and or social Inclusion.

Data

PDP's understanding of the intersectionality between gender, disability, social marginalisation and the disease area or product profile that the products in development are intended to tackle.

Indicators:

- **Research** was conducted to understand **intersectionality** with disease burden and gender, disability or vulnerability in general.
- **A GEDSI analysis** was conducted to ensure the investment is relevant and to support decision-making on product category selection

- **A data collection approach** or system is in place or planned to understand barriers faced by **persons with disabilities**
- **Data gaps** on intersectionality are identified and a plan is in place to address these gaps
- **Research** was conducted to understand local context, and access barriers to inform market access strategy
- **Sex & gender disaggregated data** is collected as part of the programs in place to inform product development, and access. A baseline exists and reporting against baseline is in place as a next step.
- **Data is further disaggregated** by disability, age, geographic, socio-economic status for a more granular understanding of the burden of disease within society.

Partnerships

How the PDP engages externally and partners with other entities.

Sub-categories:

- **External Engagement**: Assess the organisation's approach to engaging underrepresented communities in decision making processes
- **Community Organisations**: Evaluate how the PDP includes and empowers community organisations in program design and delivery.

Indicators:

- **Diversity representation** is ensured across advisory or expert committees, involved in the co-creation of product development pathways and solutions
    - Specific evidence of how the program has supported an active role of people with disabilities and/or organisations of persons with disabilities
- **Community Engagement** mechanisms are in place to inform product development pathways
    - Diverse stakeholders, from marginalised and vulnerable communities, are engaged in the decision-making process.
    - Disability Organisations of persons with disabilities, women's organization, other CSO player, patient groups are engaged in shaping product priorities?
- **Advocacy and exchange of best practices** takes places through informal exchanges with other PDPs and global health organisations
- **Partnership agreements** are structured to reflect and highlight organisation's commitment to GEDSI as a best practice

Product

Determine how gender, disability and other social factors (e.g., ethnicity, age, geographic location) are considered in the selection, design and development of products and evaluate how equity and inclusion principles are integrated into clinical trials, ensuring diverse and representative participation. Sub-categories:

- **Product Selection**: Evaluate the inclusivity of the criteria used for product selection.
- **Development**: Assess whether product development incorporates equity and inclusion principles.
- **Clinical** Trials: Review whether clinical trials are inclusive and equitable, considering diverse participants.

Indicators:

- **Target Product Profiles (TPPs):** the gender and disability lens reflected in the TPPs.
    - **TPPs** are co-developed with underrepresented communities to ensure product acceptability and suitability.
    - **TPPs** consider pregnant, lactating women.
- **Selected disease focus** for product development targets women, or other vulnerable groups to ensure their needs are met and informs product selection.
- **Clinical Trials** are shaped with provisions in place for the safe inclusion of women, pregnant and lactating women, people with disability.

Programs [*where applicable and if in scope*]:

This category focuses on how GEDSI is applied in programs to ensure the affordability equitable access, and acceptability of products.

Sub-categories:

- **Affordability**: Review if pricing strategies ensure products are affordable to low-income communities, for a broader focus on social inclusion of poorer, marginalised groups.
- **Acceptability**: Assess if communities find the products culturally and contextually acceptable.
- **Accessibility**: Determine how accessible the products are to various populations, especially women, people with disabilities or socially marginalised groups.

Indicators

- Priority communities are collaborating on the supply and distribution plans for product, to ensure downstream availability.
- Priority communities are actively engaged in advising on the formulation and packaging to ensure acceptability.
- Pricing and distribution strategies are designed to ensure equitable access. Communities are consulted to inform access strategies

Health Systems Impact

This category is to assess whether the PDPs contribute to the long-term strengthening of inclusive local health systems and build local capacity (localization).

Sub-categories:

- **Training on GEDSI**: Assess the PDP's contribution to training healthcare workers, researchers, and partners on gender, disability, and social inclusion.

- **Capacity Building**: Evaluate how the PDP strengthens local health systems, including building infrastructure and providing technical assistance to improve and support diversity and inclusion at the local level.

Indicators

- Training activities are in place to support localisation, employ and build capacity among local women in STEM, for example.

- Training is offered to local partners on GEDSI based on PDP's learnings of how it applies to the research, development and production of essential medicines.