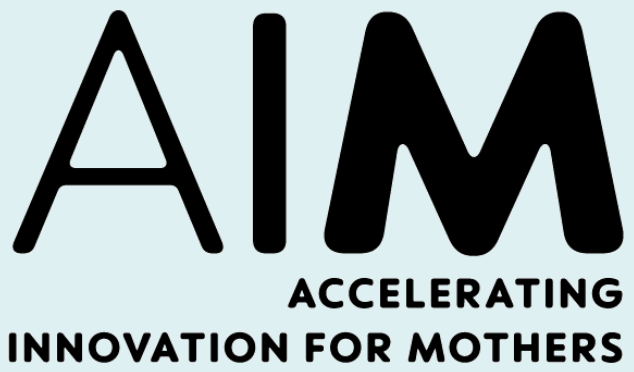




AIM-GENDER: Understand and address barriers to pregnant women’s participation in clinical trials



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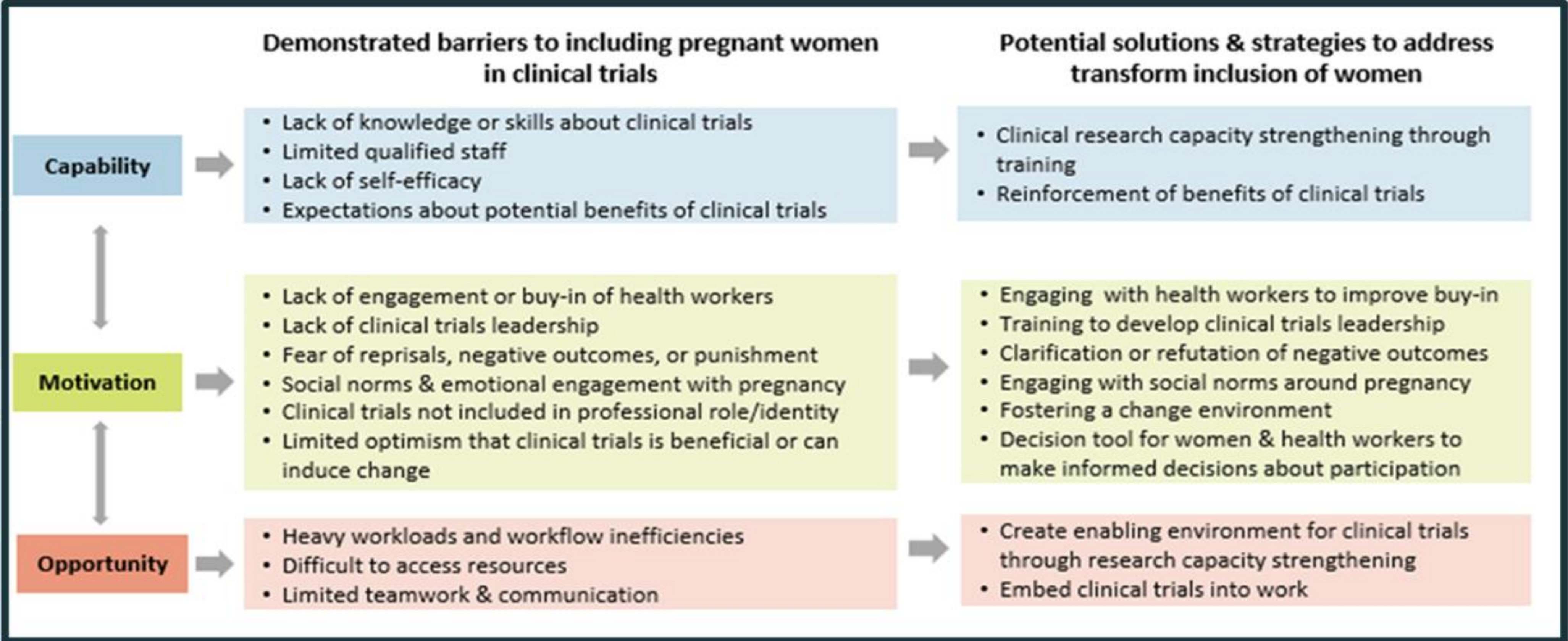
Background

The findings from the ongoing broader Accelerating Innovation for Mothers (AIM) project demonstrated the glaring exclusion of pregnant women from drug and vaccine trials. There is a long history of this exclusion, and where women are included, they tend to be underrepresented compared to men. In the context of global health, the exclusion of pregnant women in low-and-middle income countries (LMIC) from clinical trials and development represents an intersectional ‘double disadvantage’, as both their gender and country of residence result in reduced agency and opportunity for participation in research that impacts their lives. We aim to explore the extent of gender bias related to the participation of pregnant women in clinical trials, at the intersection of the health system, health facility, health workers, and women through conducting a scoping review in addition to primary research in LMIC . Our objective is to identify and describe the “downstream” challenges and opportunities affecting the participation of pregnant women in clinical trials operating at the intersection of health systems and communities to inform strategies that can promote meaningful engagement of pregnant women at scale.

Methodology of Scoping Review

We searched Medline, CINAHL, PsycINFO, Scopus, Web of Science, Embase and grey literature from inception to 2023 to identify primary research, commentaries, case reports, short communications and editorials on the participation of pregnant women in clinical trials. Eligibility for inclusion required an article to report on the views, perceptions, perspectives or behaviours of individuals at any level (leadership to service delivery) within health systems, and/or those of pregnant women, their family or community members in relation to this topic. Relevant data is being extracted using a theoretically informed systematic charting process. Our analysis of the barriers and opportunities is underpinned by the *Capability, Opportunity and Motivation Behavior* (COM-B) model, and are also applying a “gender lens” to the data to understand how gendered divisions of labour, access to and control over resources, and decision-making power contribute to the problem.

Figure 1:



The research in this poster are supported by funding from MSD, through its MSD for Mothers initiative and is/are the sole responsibility of the authors. MSD for Mothers is an initiative of Merck & Co., Inc., Rahway, NJ, U.S.A.

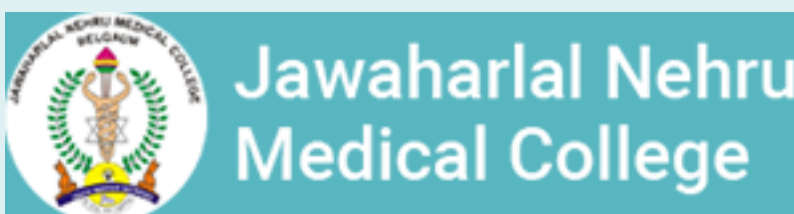


Figure 1: Potential barriers to the participation of women in clinical trials in maternal health

Figure 2:

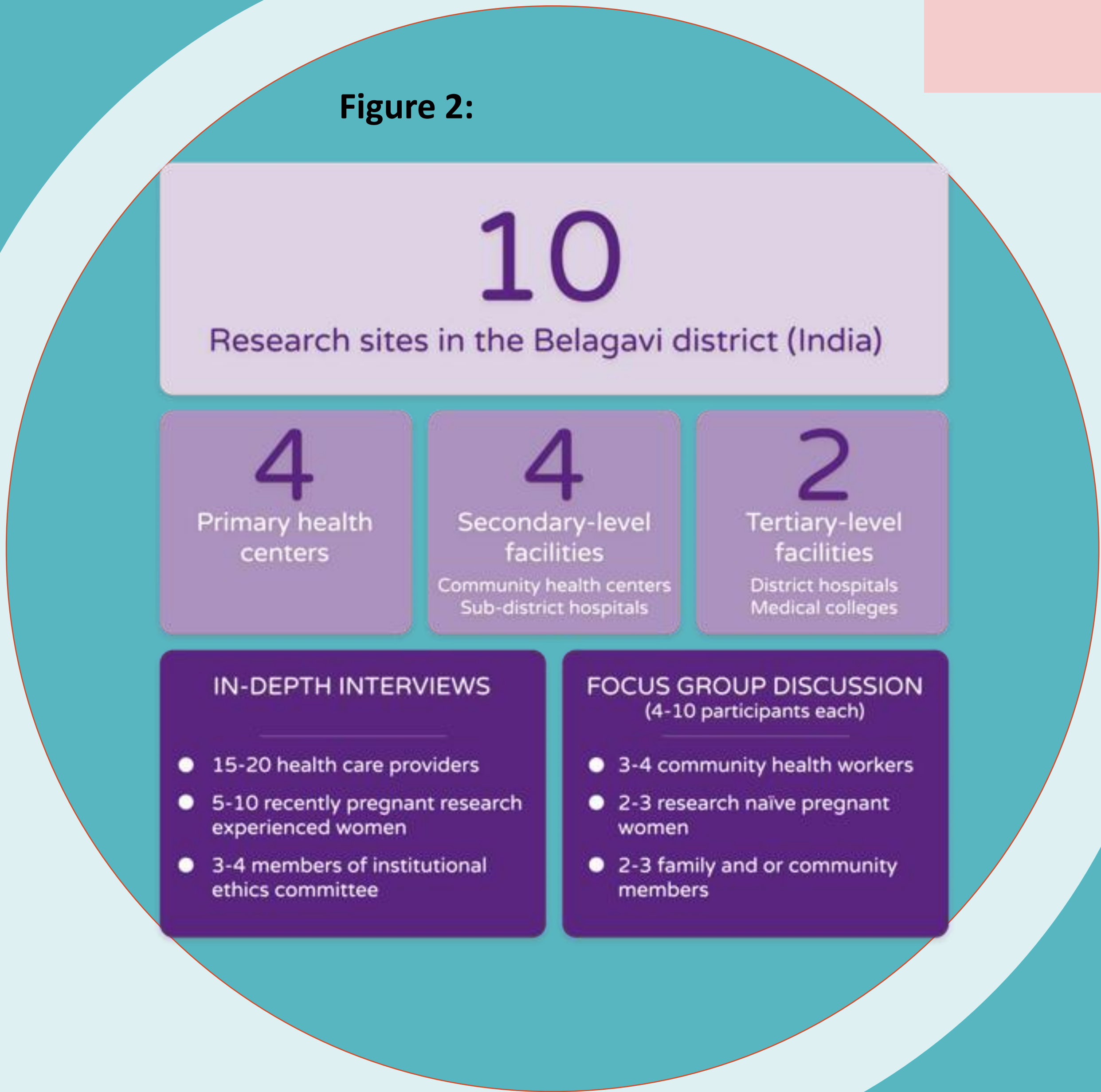


Figure 2: Summary of study sites and participants for AIM-GENDER 1.0 primary research study in India (first LMIC study site)

Figure 3:

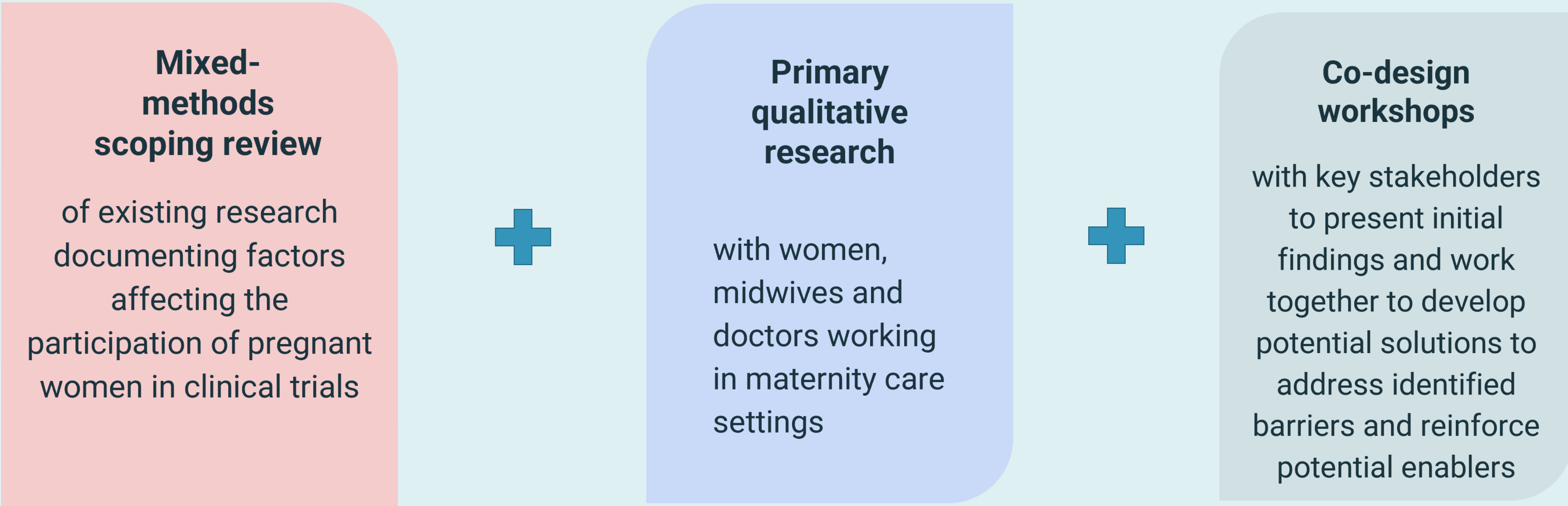


Figure 3: Summary of AIM-GENDER scope of activities

Results

At the service-delivery level, preliminary findings suggest that providers’ negative attitudes may stem from an inadequate awareness and knowledge about the value of clinical trials (psychological capability) and accompanying concerns regarding perceived risks and accountability to pregnant women and their families (reflective motivation). In the context of a traditional doctor to patient model of care, some providers felt that they had a duty to “protect” the safety of their obstetric patients and enact decisions on their behalf. Heavy workloads, staffing concerns and low institutional priority for research were environmental constraints (physical opportunity) affecting provider motivation. Among pregnant women, a perception of potential benefit to the health of the foetus or infant and access to diagnostic services or clinical treatments served as motivating factors for participation, whereas extended time requirements, negative perceptions regarding certain procedures (like blood draws) and husbands’ refusal were some inhibitory factors affecting participation.

Conclusion

This scoping review synthesises data, generating valuable new evidence on the challenges to overcome and opportunities that can be leveraged to address under-representation of pregnant women in clinical research. Research gaps identified will inform the design of the next phase of this project involving primary qualitative research.