

Developing a novel PRO measure in multiple global regions and languages for key contraceptive side effects

Amelia Mackenzie¹, Jenni Smit², Marija Miric³, Alison Edelman⁴, *Mags Beksinska², Vivian Brache⁵, Angely Catano³, Stephanie Chung^{1,6}, Leila Cochón⁵, Eunice Cuevas³, Maddison Delacerda⁴, Marci Messerle Forbes⁴, Emily Hoppes¹, Leah Ingeno⁴, Laura Jacobson⁴, Mbali Khomo², Elena Lebetkin¹, Thandiwe Majola², Melissa Matos³, Mbali Mavundla², Sarah McCaffrey¹, Alicia Mendez³, Massiel Mendez³, Nothando Mhlaba², Nzwakie Mosery², Lungelo Ndlovu², Bongeka Qiya², Kayla Stankevitz¹, Bongive Zulu²

1. FHI 360, United States; 2. University of the Witwatersrand Maternal, Adolescent, and Child Health Research Unit, South Africa; 3. Two Oceans in Health, Dominican Republic; 4. Oregon Health & Sciences University, United States; 5. Profamilia, Dominican Republic; 6. University of North Carolina at Chapel Hill, United States; *After PIs, authors appear in alphabetical order.

BACKGROUND

- Contraceptive **side effects** and **non-contraceptive benefits** can influence:
 - Sexual and reproductive health,
 - Wider health and overall wellbeing, and
 - Daily functioning and lives in both **positive** and **negative** ways.
- Menstrual changes** impact healthcare decision-making and quality of life as both a side effect and non-contraceptive benefit of contraception.

OBJECTIVE

- Despite the importance and regulatory requirement for data collection, **no measure of menstrual changes exists with evidence of validation** for use across contraceptive products.
- Our research collective aims **to develop a PRO measure of menstrual changes** for use in contraceptive clinical trials.

RESULTS

Figure 3. Conceptual model of user experiences with contraceptive-induced menstrual changes (CIMCs).

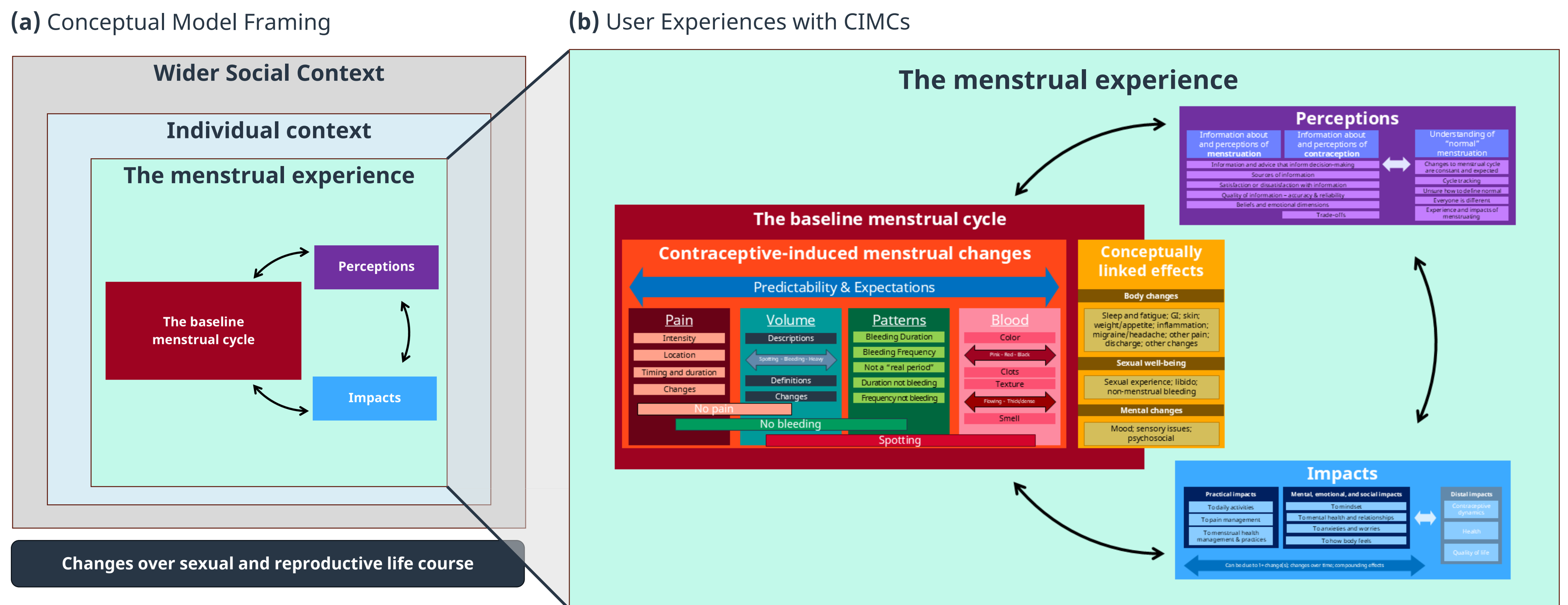
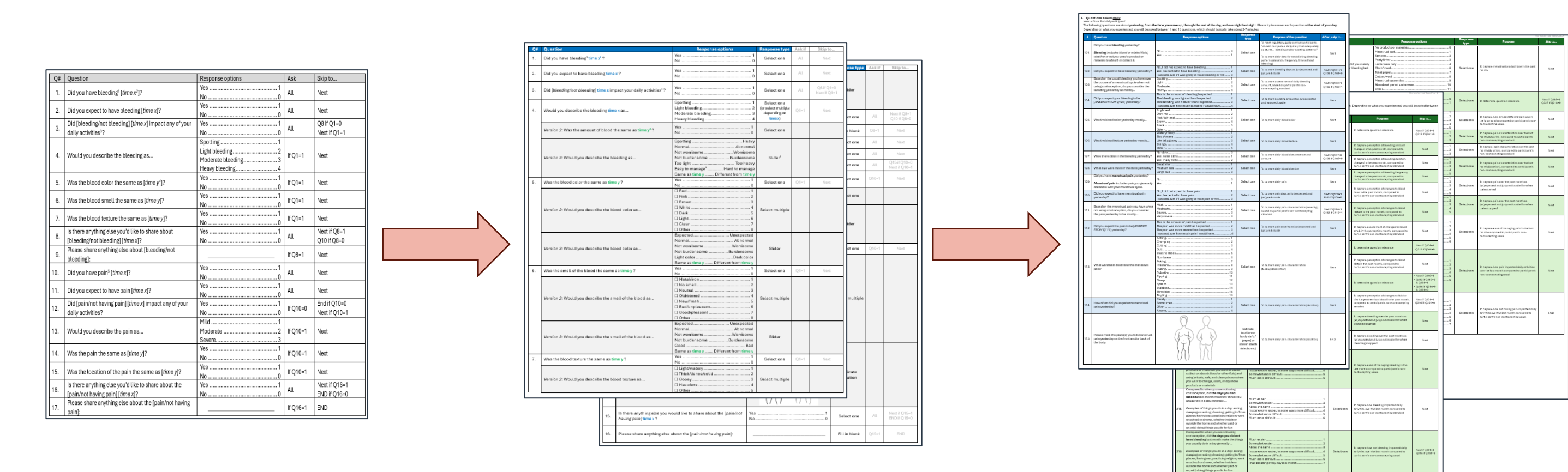


Figure 4. PRO drafting from conceptual model and revisions.



- Current draft PRO measure** for cognitive debriefing:
 - 4 to 10 items asked **daily** to assess CIMCs
 - 5 to 27 items asked **monthly** to assess perceptions & impacts of those CIMCs
- Cognitive debriefing
 - 2-3 round of 6 cognitive interviews per site (i.e., 18 total per round) with revisions between rounds
 - First round of interviews completed, revisions underway

METHODS

Formative work

- Global convenings
- Key informant interviews
- Systematic review
- Formal consensus-building

Multi-part study

- Concept elucidation (Fig 1-3)
- PRO drafting (Fig 4)
- Expert feedback (Fig 4)
- Cognitive debriefing (now)
- Pretesting (next)

Three global regions & languages

- South Africa (isiZulu)
- Dominican Republic (Spanish)
- United States (English)

Figure 1. Affinity mapping analysis during concept elucidation

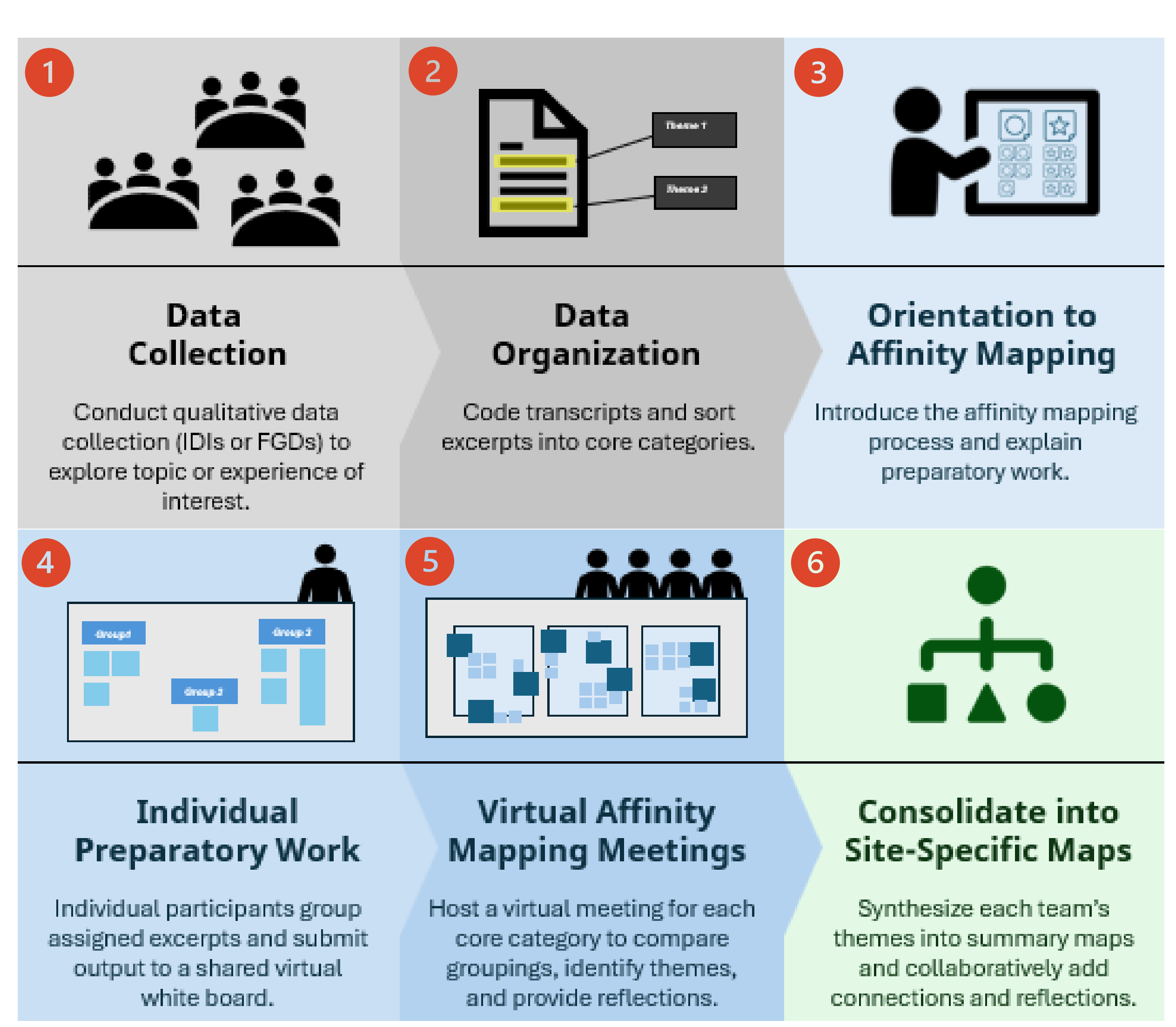
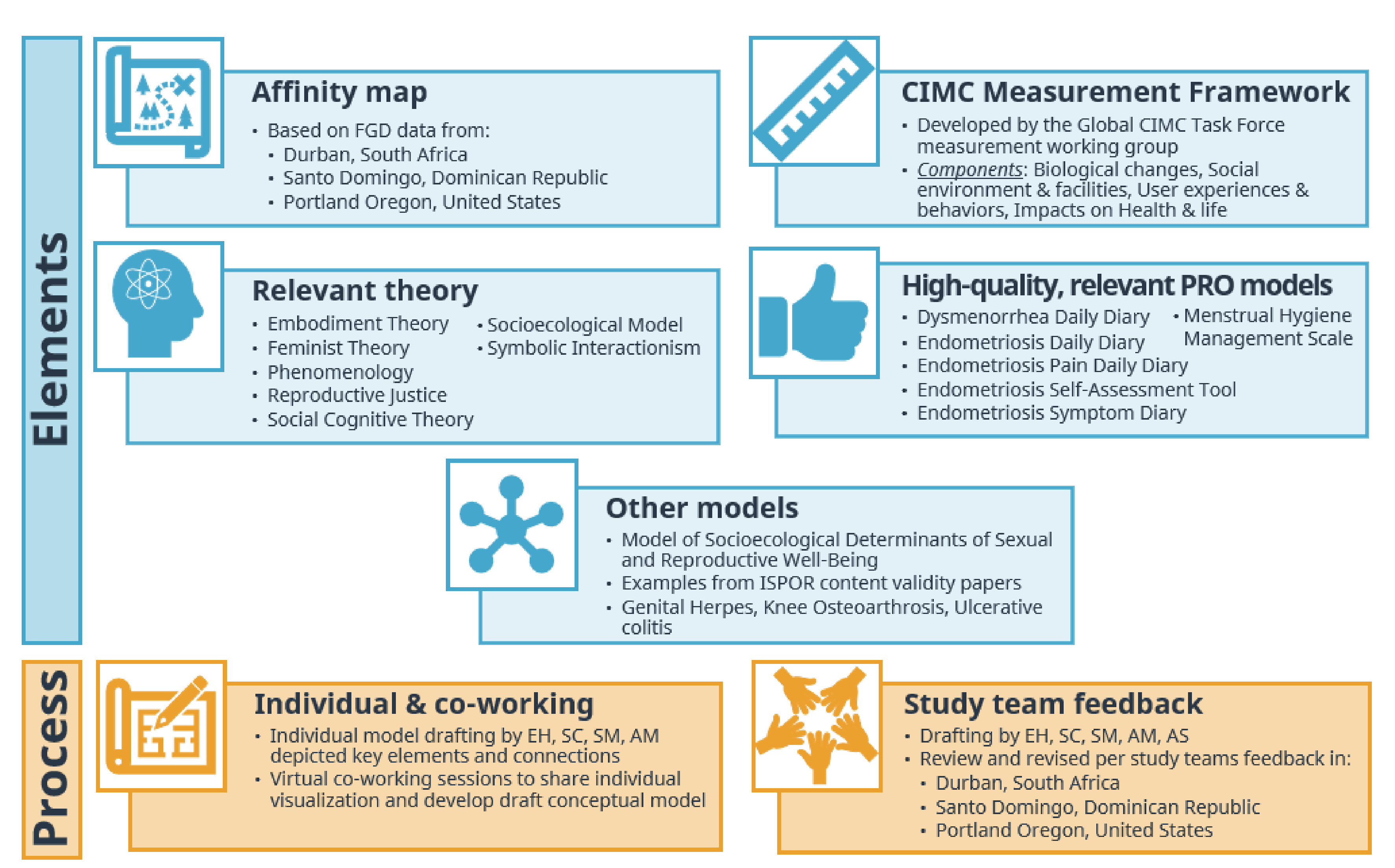


Figure 2. Conceptual model development



CONCLUSIONS

- Our approach, based in measurement best practices and regulatory methodological guidance, of creating an **evidence-informed conceptual model** to inform the development of a **person-centered PRO measure** is largely unique in the field of contraceptive development.
- Measurement of CIMCs—as well as other side effects and non-contraceptive benefits—using a **standardized, person-centered measure with evidence of validation across contexts** can help inform **improved healthcare decision-making** by people, providers, payers, & regulators.

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