**Formative study for developing patient-reported outcomes (PROs) for measuring contraceptive-induced menstrual changes (CIMCs) – Part 1**

**DATA DOCUMENTATION**

# Introduction

The use of contraception can cause changes in uterine bleeding patterns, uterocervical fluid, and uterine cramping, and it can impact how users experience menstrual and gynecologic disorders and symptoms. Collectively, these changes can be referred to as contraceptive-induced menstrual changes (CIMCs). Although there is wide agreement among clinical researchers and contraceptive developers on the importance of CIMCs to the future users of contraceptive products under development, how to best assess CIMCs during contraceptive clinical trials has remained an area of contention with the field.

CIMCs are largely measured via reports from trial participants—referred to as patient-reported outcomes (PROs). Developing new and improved ways to measure CIMCs in contraceptive clinical trials has potential for wide impact on meeting the contraceptive needs of users and couples. Such improvement can permit more accurate contraceptive product labeling, including data on CIMCs that are most relevant to users, which can enable providers to offer better counseling and allow users to make informed decisions.

# Study Goal and Objectives

The broad goal of our research is to improve and standardize CIMC measurement in contraceptive clinical trials, with this two-phase formative study as the first step towards developing a PRO measure (PROM) with evidence of validation to measure CIMCs in contraceptive clinical trials.

The primary study objective is to develop a conceptual model for CIMCs to identify measurement domains for drafting the initial version of the CIMC PROM, and the primary outcome is a conceptional model and a draft version of the PROM.

# Study Design

We conducted phase 1 of a two-phase formative qualitative study to develop and refine a PROM to measure CIMCs for future contraceptive clinical trials.

The multisite study was conducted in three countries in three global regions: Durban, South Africa in Africa; Santo Domingo, the Dominican Republic in Latin America and the Caribbean; and Portland, United States in North America.

The target population was adults of reproductive age who reported experiencing CIMCs.

Inclusion criteria were:

- Adults of reproductive age (i.e., 18-49 years old), and
- Users of hormonal or intrauterine contraception who report experiencing CIMCs with their current method, or
- Recent users of hormonal or intrauterine contraception within 3 months of discontinuation at time of recruitment who report experiencing or having experienced CIMCs.

Exclusion criteria were:

- Not an adult of reproductive age (i.e., under 18 years old or over 49 years old), or
- Pregnant, breastfeeding, or less than 12 months postpartum, or
- Users of hormonal or intrauterine contraception who report not experiencing CIMCs with their current method, or
- Users of hormonal emergency contraception, or
- Users exclusively of contraception that does not cause CIMCs, or
- Recent users of hormonal or intrauterine contraception beyond 3 months of discontinuation at time of recruitment, or
- Recent users of hormonal or intrauterine contraception within 3 months of discontinuation at time of recruitment who do not report experiencing or having experienced CIMCs, or
- Anyone using gender affirming therapy or other hormonal treatment.

For Phase 1 of this non-experimental formative qualitative research, we conducted FGDs using open-ended discussion questions and participatory activities.

The study protocol, informed consent documents, and data collection instruments were approved by the ethical review by the University of Witwatersrand's Human Research Ethics Committee (HREC) in South Africa, the Two Oceans in Health internationally accredited independent IRB (IRB FWA00031272) in the Dominican Republic, the OHSU IRB (IRB00000471, FWA00000161) in the United States, and FHI 360's Protection of Human

Subjects Committee (PHSC) in the United States before initiating data collection for that site.

## Data Collection

18 FGDs (6 per country) were conducted with 102 women (4-7 per group) from 21 November 2024 – 18 September 2025.

- 21 Nov 24 to 28 Feb 2025 in South Africa
- 24 Jan 25 to 6 Feb 25 in Dominican Republic
- 28 Aug 25 to 18 Sept 25 in United States.

Data were collected by trained research assistants. FGDs were audio recorded. Each participant was administered a quantitative screening questionnaire. The responses were recorded on a paper questionnaire. Data were then entered into REDCap or Excel prior to conducting the FGD.

## Data Management

FGDs were transcribed verbatim. The FGDs in South Africa were conducted in iZulu and in Dominican Republic in Spanish. The FGDs in the United States were conducted in English. The transcripts were transcribed directly into English in South Africa, in Spanish in the Dominican Republic, in English in the US. The Spanish transcripts were translated into English prior to analysis. The local investigators conducted quality checks on the translations for completeness and quality prior to submitting to the rest of the study team for review.

The quantitative data were stored on a secure server and exported for analysis.

The data in this open data package are as follows:

- Full transcripts with any identifying information redacted. All names in the transcripts are pseudonyms.
    - C101-C106 – South Africa transcripts
    - C201-C206 – Dominican Republic transcripts (English and Spanish)
    - C301-C307 – United States transcripts
- Quantitative screening questionnaire:
    - CIMC Demographics_COMBINED.csv

Additional documentation included in the open data package are as follows:

- Data documentation (this document)
- Data collection forms
    - Pre-FGD form (quantitative screening)
    - FGD guide
- Informed consent form
- Codebook

## Limitations

These data are primarily qualitative and are not representative of the general population in either of the three countries. These data were generated solely for the purpose of developing a CIMC PROM which will be pretested with new users of existing contraceptive methods that cause CIMCs (i.e., hormonal or intrauterine contraception) to establish additional evidence of its validity in later phases of this study.