

U.S. Clinical Study Protocol (Updated – Task 4)

Study Overview

This is a virtual, observational, non-diagnostic study designed to evaluate agreement between application-based assessments and physician evaluations of visible facial characteristics. The study is appearance-based and does not provide medical diagnoses or treatment recommendations.

Study Design

The study evaluates predefined facial indicators across three imaging stages. Each stage represents an independent assessment context.

Imaging Stages

- Stage A: Front facial image only
- Stage B: Front and side (phi-angle) images
- Stage C: Front and side images with video

Participant Flow

Participants provide consent and are guided through standardized facial image capture. Prior to image capture, participants are shown a brief message instructing them to ensure their face is clean and free of makeup or skincare products. This instruction is informational only and does not collect data.

Demographic Data Collection

Age is collected as a categorical age range during initial registration for demographic stratification purposes only. Age is not collected during scan or assessment flows.

Age Ranges

- Under 20
- 20–39
- 40–59
- 60 and above

Data Explicitly Not Collected

The study does not collect information related to sleep, hydration, lifestyle behaviors, or gender. Such data are not required to meet the study objectives and are intentionally excluded.

Physician Review

Physicians independently review facial images by imaging stage and record appearance-based observations. Physicians are blinded to application outputs and to other physician reviews.

Ethical Considerations

Participation is voluntary. All data are handled in accordance with applicable ethical and regulatory standards. This study does not involve diagnosis, treatment, or medical decision-making.

Regional Note

This study follows U.S. regulatory and ethical guidelines.

Status

This document reflects the completed updates under Task 4 and is aligned with current study decisions.