

## **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.