FDA U.S. FOOD & DRUG ADMINISTRATION

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee Meeting

Pulse Oximeters 2

February 2, 2024

Panel Questions

1. The Agency is proposing a more inclusive and representative clinical trial design to improve the quality of premarket studies to evaluate the performance of pulse oximeters taking into consideration a patient's skin pigmentation, and patient-reported race and ethnicity. Some of the key elements of this proposal are:
   - Inclusion of at least 24 participants that span the entire Monk Skin Tone (MST) scale. The MST has been validated to capture race and ethnicity diversity in pigmentations within the US. This will improve generalizability of study results.
   - An initial assessment of skin pigmentation with MST scale followed with an objective pigmentation measurement – Individual Typology Angle (ITA) - at the sensor site.

   a) Please discuss the advantages and challenges to the proposed clinical trial design, including specific consideration and discussion of the:
      a. pigmentation measurement approach and whether it will provide appropriate diversity of race, ethnicity and pigmentation in the clinical premarket study.
      b. proposed sample size and whether it will address appropriate diversity with respect to race, ethnicity, and skin pigmentation.

   b) What additional recommendations do you have to improve the evaluation of pulse oximeter performance, while taking into consideration race, ethnicity, and differences in skin pigmentation?

2. FDA is considering defining non-disparate performance as the estimate of the absolute difference in SpO_2 bias across ITA and MST levels if the difference is < 1.5% when SaO_2 > 85%, and < 3.5% when 70% < SaO_2 ≤ 85%.

   a) Please discuss the advantages and challenges to the proposed non-disparate performance definition.

   b) Please discuss alternate acceptance criteria for Agency's consideration.

c) Please discuss if there are specific SaO_2 thresholds (e.g., 90%, 88%) for which the accuracy of SpO_2 for detecting hypoxemia should be analyzed.

3. The Agency is considering the same premarket clinical trial design and definition of non-disparate performance for OTC pulse oximeters for medical purposes as for the prescription use devices.

a) Do you agree with this approach? If not, what do you recommend?

b) Please discuss what information about the premarket clinical trial design and the device's performance you recommend be included in the labeling for an OTC pulse oximeter for medical use?