

Draft SDB Workshop Questions

1. FDA is seeking to promote innovation and expedite the clinical development of devices intended for the diagnosis and treatment of Sleep Disordered Breathing (SDB). How should the following conditions (including their severity, e.g., mild, moderate, severe, if appropriate) be defined for the purpose of creating appropriate inclusion/exclusion criteria for a clinical study for SDB devices?
 - a. Apnea
 - b. Hypopnea
 - c. Sleep Disordered Breathing (SDB)
 - d. Obstructive Sleep Apnea Syndrome (OSAS)
 - e. Central Sleep Apnea Syndrome (CSAS)
 - f. Primary Snoring

2. Polysomnography (PSG) has been widely accepted as the “gold standard” test for the diagnosis of OSA and Primary Snoring. However, home sleep apnea testing (HSAT) has emerged in recent years as an alternative or complementary diagnostic tool for SDB.
 - a. Can HSAT be used for establishing a baseline diagnosis and for the collection of clinical performance data for device trials for OSA, CSA or Primary Snoring? If so, what are the recommended parameters which should be collected by an HSAT (e.g., nasal pressure, oximetry, chest and abdominal respiratory inductance plethysmography)?
 - b. What constitutes a technically adequate test (either PSG or HSAT, if appropriate) for establishing a baseline diagnosis of SDB for device studies (e.g., number of hours, number of nights).

3. FDA has received an increasing number of pre-market applications for devices intended to treat SDB. How should studies for the various technologies (e.g., intra-oral appliances, externally worn devices, electrosurgical devices for tissue reduction, and passive or active implantable devices of the upper airway) be designed with respect to the following factors (please consider whether your recommendations would vary if the device was an implant vs. an externally worn device):
 - a. What is the most appropriate control group (e.g., comparison to baseline measures, randomization to a concurrent control group)?
 - b. What is the minimum duration of the study? For implants and surgical procedures, how long after the intervention should the effectiveness endpoint be assessed?
 - c. What objective parameter or combination of parameters should be used for the primary effectiveness endpoints (e.g., AHI, ODI, T90 or other non-PSG/HSAT parameters)?
 - d. What would be a clinically meaningful difference for the above primary effectiveness endpoint(s) between/among study arms or within a study arm?
 - e. What patient-reported outcomes (PROs) are appropriate in the evaluation of SDB devices?

4. What are the safety and effectiveness concerns when a digital health device provides a diagnosis and monitoring of SDB?
 - a. What factors are important in developing a reference database (e.g., demographics, validation)?
 - b. What are the important safety and effectiveness concerns for SDB digital health devices used in the following settings?
 - i. A physician office or sleep center environment
 - ii. A non-clinical environment (e.g., at home or work)
 - iii. Prescription vs. OTC use?