



**Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research
(SCEPTER-III)**

**Clinical Trials to Evaluate Patient-Centered Outcomes of Sedation in Mechanically Ventilated Patients in the
Adult ICU**

Westin Georgetown Hotel – Washington, DC

MEETING AGENDA

| Thursday, March 28, 2019 | | |
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| 7:30 – 8:00 AM | Continental Breakfast | Washington Ballroom |
| 8:00 – 8:30 AM | Welcome and Introductions | Bob Dworkin, |
| 8:30 – 8:45 AM | Procedural Sedation – SCEPTER 1 & 2 Goals for SCEPTER 3 | Denham Ward |
| 8:45 – 10:00 AM | Panel Discussion: Current Clinical Guidelines SCCM PADIS guidelines: Pain, Agitation/Sedation, Delirium, Immobility and Sleep Impairment | Douglas Coursin (moderator) John Devlin, Yoanna Skrobik |
| 10:00 – 10:30 AM | Break | |
| 10:30 – 11:00 AM | Patient and family perspective | David Brown |
| 11:00 – 11:30 AM | Establishing core outcome measures and instruments: A case study in evaluating post-discharge status of ICU survivors | Dale Needham |
| 11:30 – 12:00 PM | Q&A and Panel Discussion: How to incorporate the patient's and families' perspective | Pam Flood (moderator) David Brown, Dale Needham, Ingrid Egerod |
| 12:00 – 1:00 PM | Lunch | Mayfair Court |
| 1:00 – 1:30 PM | SEDCOM, MENDS, MIDEX & PRODEX – Lessons learned for study design, outcomes and measures | Richard Riker |
| 1:30 - 2:00 PM | Evaluating efficacy in ICU sedation clinical trials: a regulatory perspective | Martha Van Clief |
| 2:00 - 2:30 PM | Q&A and Panel Discussion: Current controversies, and unmet needs | Gil Fraser, Douglas Coursin (moderators) Yoanna Skrobik, Mervyn Maze, Richard Riker, Martha Van Clief |
| 2:30 -3:00 PM | Break | |
| 3:00 - 3:30 PM | Design issues for clinical trials of ICU sedation | Daniel Sessler |
| 3:30 - 4:00 PM | Clinical Trials for new ICU Sedation Protocols | Leanne Aitken |
| 4:00 - 4:30 PM | Statistical issues in clinical trial design for ICU sedation | Elizabeth Colantuoni |
| 4:30 – 5:00 PM | Q&A and Panel Discussion: Clinical trial design | Steve Shafer(moderator), Daniel Sessler, Leanne Aitken, Franklin Dexter, Elizabeth Colantuoni, Yahya Shehabi |
| 7:00 – 9:00 PM | Dinner | Mayfair Court |

| Friday, March 29, 2019 | | |
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| 7:30 – 8:00 AM | Continental Breakfast | Washington Ballroom |
| 8:00 – 8:30 AM | Defining and measuring light vs moderate sedation / analgesia | Pratik Pandharipande |
| 8:30 – 9:00 AM | Case Study: Approval of Dexmed for ICU sedation | Mervyn Maze |
| 9:00 – 10:00 AM | Panel Discussion: Who should be studied and how? <ul style="list-style-type: none"> • Patient inclusion / exclusion criteria • Sedation / analgesia prior to enrollment • “Rescue” medications • Controls (placebo vs active vs usual) • Multicenter vs single center • Informed consent • Enrollment size; allocation ratio; stopping rule • Adaptive trial design; interim analysis • Primary vs secondary end points; composite outcomes • Subgroup enrollment and analysis • Planned statistical analysis; properties of proposed measurement instruments • Phase 2, Phase 3, seamless Phase 2/3, Phase 4 study designs | Avery Tung (moderator) |
| 10:00 – 10:30 AM | Break | |
| 10:30 – 12:00 PM | Panel Discussion: Evaluating acute use of ICU sedation/analgesia <ul style="list-style-type: none"> • Sedation level measure and frequency of measurement – RASS, Ramsay sedation scale, Sedation-Agitation Scale, Glasgow Coma Scale, BIS, etc. • Pain assessment and frequency of measurement – Behavioral pain scale, CPOT, NVPS, VAS, Faces, FLACC, COMFORT other? • Delirium measurement (CAM-ICU, ICDSC, other?), frequency of measurement and treatment, interaction with sedation level • Use of “wake-up” • Efficacy outcomes <ul style="list-style-type: none"> ○ % time within RASS target ○ Use of rescue medications ○ Days alive without delirium or coma ○ Sleep states (polysomnography) • Safety outcomes (during sedation) <ul style="list-style-type: none"> ○ Mortality ○ Unplanned extubations during sedation ○ Length of sedation / mechanical ventilation ○ Over-sedation (coma) criteria | Yoanna Skrobik (moderator) |
| 12:00 – 1:00 PM | Lunch | Mayfair Court |
| 1:00 – 2:30 PM | Panel Discussion: Acute, Subacute and chronic outcomes after ICU sedation <ul style="list-style-type: none"> • Mortality - ICU, Post ICU (how long after ICU D/C?) • ICU days and Hospital days • Cognitive function and memory measurement (IQCODE, MMSE, Trials-B, etc.) and frequency (28, 180 days, 1 year?) • Physical functioning (6MWT, other?) • HRQOL (EQ-5D, SF-36v2, ADL, other?) • Pain and PTSD (CAPS, long term opioid use, other?) | Tim Girard (moderator) |
| 2:30 – 3:00 PM | Group Discussion: SCEPTER-III next steps | Denham Ward |

