

## ISCTM Innovative Technologies for CNS Clinical Trials Working Group

Meeting Minutes; February 21, 2020; 7:30-9:15am

Attendees: Ariana Anderson, Peter Annas, Steve Brannan, Raimund Buller, Jim Cassella, Bob Dagher, Mike Davis, Stephanie Duhoux, Walter Dunn, Carlos Forray, Corey Fowler, Morten Grunnet, Bill Horan, Rich Keefe, Nicole Kwoh, Shaheen Lakhan, Jessica Lipschitz, Hilda Maibach, Steve Marder, Aurelia Mittoux, Michael Sand, Peter Sorantin, Jane Tiller, Katherine Tracy, Vinita Uttamsingh, Joop van Gerven, Christoph von der Goltz, Glen Wunderlich, Robert Yolken

1. Mike and Rich welcomed the workgroup attendees, and Rich summarized the group's activities over the past year. Over the course of a series of teleconferences and a meeting at the ISCTM autumn meeting in Copenhagen, the group has identified three challenges in CNS clinical trials that could potentially be addressed by novel technological strategies: identifying and recruiting the right patients, demonstrating superiority of an investigational drug to placebo in the context of a high placebo response, and demonstrating clinically meaningful change.
2. The workgroup participants divided into three subgroups (one for each identified challenge) for discussion and writing planning. Ariana Anderson and Bill Horan led the subgroup on placebo response, Shaheen Lakhan led the subgroup on patient recruitment, and Steve Marder led the subgroup on clinically meaningful change. The subgroups were asked to consider issues identified at the Copenhagen working group meeting for their topic and identify potential novel technology-based strategies to address the issues. For each strategy, subgroups should consider potential promises, pitfalls, unintended consequences, and impacts on different stakeholders (e.g., subjects, site staff, study investigators, sponsors, regulators, etc.)
3. After ~60 minutes of subgroup-based discussions, the larger workgroup reconvened, and a leader from each subgroup presented a summary of their discussion to the larger group.
4. Before concluding for the morning, subgroup leaders identified volunteers who were interested in writing for the first workgroup manuscript. Subgroup leaders were asked to draft a summary/outline of their discussions by 3/15/2020 and enlist help from subgroup members as needed.

Plan: After draft summary/outlines have been received from each of the three subgroups, Mike and Rich will work with subgroup leaders and writing volunteers with a goal of completing the first workgroup manuscript.