Assessment in Rapid Acting Antidepressants Workgroup:
The inaugural meeting of this workgroup was co-chaired by Drs. Mark Opler and Dawn Ionsecu.
The workgroup began with an overview of the assessment methods commonly utilized in clinical trials of rapid acting antidepressants (RAADs). These included:
(a) traditional clinical rating scales;
(b) clinical rating scales with adaptations/modifications to permit assessment at abbreviated time points (e.g. 24 hours, 1 hour, etc.);
(c) novel methods, such as actigraphy, ecological momentary assessment, and passive remote evaluate through smartphones.
After this initial presentation and review of data from publications by Elizabeth Ballard and others, an open discussion was held to gather input and information from attendees. Several key themes emerged from this discussion.

- Novel endpoints were of great interest. These were seen as having the potential to be more sensitive to early effects of treatment than traditional measures, being more feasible to implement on a large scale, and being less burdensome to the patient than frequent administration of traditional clinical interviews.
- While novel endpoints were a topic of significant interest, there was a general consensus that traditional measures (MADRS, HAMD) were going to continue to be utilized for multiple reasons.
- Some question/debate was raised around how novel measures would be validated and how such validation work might be funded. Points were raised about the lack of opportunity for development of new measures/tools.
- The example of development of new measures for suicidal ideation and behavior was raised as a possible framework for development.
- Another topic of discussion was that of functional recovery; the use of Goal Attainment Scaling was presented as an avenue for development. Comparisons to prior efforts to develop "patient's chief complaint" scales were made.
- The meeting was closed by the co-chairs with a statement that one of the critical next steps would be solicitation of workgroup members time/effort for active participation in preparation for the next meeting. Dr. Ionescu counseled the group to strive for "simplicity" in seeking solutions. Dr. Opler further recommended some effort to move beyond traditional avenues.

The following figure was used to help frame the discussion of the workgroup – additional notes from the discussion are incorporated:

Domain	**Current Status**	**Challenge**	**Notes/Suggestions**
Speed of onset of action	Clinical rating scale with modified time frame, e.g. one hour evaluation (MADRS/HAMD)	How do we evaluate more efficiently/effectively? How to we break the current â€œspeed limitâ€• (approx. <1 hour)? Are continuous methods possible? Can smartphone based/wearable evaluations help move this forward?	Streamlined/Optimized Clinical Interview Actigraphy (e.g. Ballard et al) EMA?

Phenomenology	Core depression symptoms (e.g. MADRS/HAMD) Transdiagnostic phenomena, e.g. Anhedonia (SHAPS)	Domains that may be â€œtractableâ€• to new MOAs may not currently be under evaluation. Can we gain any insights from the recently completed global trials?	Clinical Interview PRO EMA?
Patient experience / Patient centricity	PROs	Novel endpoints beyond traditional PROs may be required to better understand how RAADs are experienced by patients. Is Goal Attainment Scaling or â€œpatientâ€™s chief complaintâ€• approach practical or useful?	
Clinical Meaningful Change	Î” in MADRS/ HAMD? Remission cutoff?	Does the MADRS or HAMD translate into meaningful change? Can a Clinically Meaningful Change Score (e.g. S-STS-CMCM) be a model for future efforts	