

Strawman

- Minimal: baseline, agreed upon measures of suicidality. All CNS-active
- For discussion: Treatment arms, efficacy data, more refined patient characteristics (comorbidities, etc), genes

Suggested Next Steps

- RCT: need longitudinal data; response to Rx a mediator?
 - Need efficacy data (but rigorous blinding procedures)
- Compromise may be to know PBO, Drug 1, Drug 2, etc (don't need specifics about what drug from what company)
- Need to find out what companies are willing to do
- ? Use existing data – retrospective, spontaneous vs prospective – what does the extant data suggest may have greater utility. Refine prospective data collection accordingly
- How much data has already been collected with appropriate standards? Could it “launch” the prospective initiative?
- How to merge datasets across FDA Divisions? (T Laughren: can be done)
- Instrument – need refinement?
- Potential issues with mapping onto C CASA? Is it sensitive enough?
- Add additional instrument(s)?

Next Steps

- Follow up on straw person
- Needs refinement – discussion with various NIH institutes? (NIMH, NINDS, NIAID, NIDA, NIAAA)?
- Maybe discuss at IOM Neuroscience Forum if they wish to take it on