

Pre-meeting survey results showed that:

- Most attendees had some experience implementing innovations in CNS trials
- Most had no formal innovation training
- Many were interested in ongoing collaboration with the goal of a publication or learning more

Many barriers identified - Scannell publication circulated prior to the meeting<sup>1</sup>

Common Vocabulary reviewed:

- Adjacent possible
- Disruptive Innovation
- Prospect Theory
- Lean Development (minimal viable product)

<sup>1</sup>Scannell JW (2012) Nature Reviews: Drug Discovery, 11, 191-200

Case Studies / Examples were presented and discussed:

- Gahan Pandina – “disease area incubator” within J&J, without the usual big pharma structure. Application process, 2-4 year window with milestones, venture board, etc. High-risk. Novel areas. Some resources that only large companies have – stats, regulatory, etc.
- Another example was the long timeline to acceptance of superior statistical methods (e.g., MMRM) by FDA and other regulators.
- Framing questions appropriately for management is crucial
- Streamlining the process is essential to innovation
- Clinical examples with large effects can be illustrative, like the oncology model with initial open-label studies with small n’s that are gatekeepers for later controlled studies.
- There may be side benefits – improved workplace morale, etc.
- Important to look at examples from outside drug trials (psychotherapy, alternative medicine) and indeed even outside of health care.

Potential deliverables were discussed:

- What would a scholarly article on this problem look like? Identifying patterns and methods that seem to be consistently effective? Highlighting the questions, if not solutions? “Innovation for Dummies”?
  - Symposium – at ISCTM or elsewhere?
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