

7:10	<p>Welcome and brief review of workgroup rationale, and plan for tonight</p> <p>Gary Sachs reviewed history of the group, plans for a publication, etc.</p>
7:15	<p>Lessons from Successful 'Engineering' Industries - Hugo Geerts</p> <p>What we can learn from engineering industries: formalize "collective knowledge"; embrace complexity; make output actionable for pharma. Examples taken from schizophrenia, Alzheimer's</p> <p>Virtual simulation can be a valuable tool. Barriers: limited knowledge of biology; human variability; complex non-linear interactions; modeling post-hoc only;</p> <p>Recommendations: Extensive modeling of failed trials; post-hoc analysis of individual conditions; control for comedications &amp; genotypes. Virtual patient trial simulations.</p>
7:35	<p>Innovation in Cancer and Psychopharmacology - Dan Rossignol</p> <p>Delivering the right dose – in cancer, use MTD; in CNS, fear of inverted U. Extended release or depot earlier in development? Can we exploit exploratory INDs?</p> <p>Patients enrolled are much different; in cancer, subjects are well-diagnosed, highly motivated, very adherent to medication, with no "professional patients". Reduce the stigma of CNS disorders?</p> <p>Cancer survivors considered heroes.</p>
7:50	<p>Designs For Improving Efficient Drug Development – John Travers</p> <p>Enrichment designs: placebo lead-in; randomized withdrawal; SPCD; two-way enriched design</p> <p>Non-enrichment designs: adaptive; crossover.</p>
8:05	<p>Indication Finding - Mike Detke</p> <p>Given limited knowledge of pathophysiology &amp; validity of animal models, consider more strongly the value of serendipitous clinical observations.</p> <p>Consider multiple small phase 2a studies, using innovative trial designs. Consider crossover designs because of greater statistical power.</p> <p>Consider areas of great unmet need, such as substance use disorders.</p>
8:20	<p>Innovation as a discipline - Gary Sachs</p> <p>Factors influencing speed of innovation spread: source, incumbent traditions, execution burden, complexity, contradiction of common beliefs, lag time to see results, who sees the results, distribution of rewards, narcissistic injury, incentives to overcome barriers.</p> <p>Approaches to overcoming these barriers proposed.</p>
8:35	<p>Summary of consensus recommendations: to focus on completing publication by next ISCTM meeting.</p>
8:50	<p>Should this workgroup Persist or Pivot? To be determined at upcoming teleconference meetings.</p>