Adaptive Design

• Ibrahim Turkoz presented a Phase IIIB/IV pragmatic randomized adaptive design in schizophrenia comparing a novel antipsychotic to treatment as usual
  – incorporating two real world endpoints in the primary
  – executed in an EMR system (less expensive, quicker data access)
  – using a population enrichment adaptation.
• Tom Parke showed his simulation work exploring
  – combining/addressing 2 endpoints (hospitalization and treatment failure
  – statistical power associated with the subgroups (SUD and early in disease patients
• Dinner group provided excellent feedback which will comprise next steps
  – Address bias introduced by the investigator and patient agreeing to the trial that will limit the ability to detect the endpoints
  – statistical power associated with the subgroups (SUD and early in disease patients