Biomarkers – Minimum Standards Initiative: Chaired by S. Potkin & D. Goff

Further work groups:

Focus was on Non-imaging Biomarkers:
- FDA is interested in several categories of biomarkers—most relevant are predictors of treatment response and biomarkers that change with treatment and are closely associated with therapeutic response, which can serve as surrogate markers for endpoints. Surrogate markers may allow smaller subject samples or studies of shorter duration (e.g., blood pressure & lipids vs. heart disease). In Psychiatry, we don’t have validated predictive or surrogate markers. What is needed to validate these markers: standardization of phenotypic characterization and biomarkers with sharing of data. Types of biomarkers include predictive, continuous treatment vs. limited time, relapse markers, functional outcome, resilience, or diagnosis. Different biomarkers may be involved at different phases of illness (prodrome, first-episode, relapse, etc.). The potential value of composite markers, e.g. DNA, gene expression, blood proteins/metabolites with phenotypes. While genetic markers are most commonly employed, markers for environmental stress or the interaction between genes and environment may be important.
- Identify surrogate markers that can be correlated with clinical outcome. For example, DLFPC inefficiency. Is it correlated with cognitive domains? If DLPFC efficiency is improved does it result in symptom improvement? Can imaging markers predict the halting of progression from prodrome to schizophrenia or the prevention of long-term decline in functioning as endpoint for new treatments?

Minimum Dataset
- As a society, the ISCTM can interact with the FDA on determining what the minimum dataset should be for Phase II, III trials.
- Find out how other organizations that deal with big data (e.g., Google, Kaiser) are collecting their data with respect to reliability and standardization by TransCelerate Biopharma, Inc (cross industry-wide effort to standardize rater training). Can the negative symptom consensus report serve as a model?

- Challenges: lack of pathophysiological understanding, clinical symptom-based nosology, heterogeneity of schizophrenia
- Opportunity: the ACA (Affordable Care Act) can spread the standardization and minimum phenotype data set throughout the systems