Session III – Key Points

Illuminate novel ways to apply genetics to clinical development

- Useful review of gene families that have been frequent fliers for pgx = ADME, HLA, drug targets and their pathways. Does this suggest that we can focus our attention and be more efficient?
- Role of genomics late in development or post-marketing—> it's late, but the N is big! (GWAS on phase III, Post-market study of clopidogrel to answer clinical question). Early indications associated with strong effects may be discoverable early.

Survey innovative ways to engage participants

- Importance of discovery and clinical studies on diverse populations (often from disease-driven groups, like Alzheimer's, who can run the show) —> real limitations in European populations (who are a bottleneck) and generalization into other populations. Many reasons to be alarmed about continued focus on bottleneck populations.
- Importance of patient alignment with/influence on research goals & study design, patient control of data. Difficulty in getting to this.
- ASHG offer: create templates for patient education and recruitment for use in rare (and common) disease studies

Additional logistical challenges (timelines, stratification, risk scores)

- Trial efficiencies are within reach (ISPY e.g.). Time is clearly a huge issue in limiting cycle of innovation.
- Single platform as an attractive way to do this effectively, efficiently. Barriers to developing this platform (economics, competition, etc…)