Key Conclusions

25th meeting of the roundtable – the field has come a long way in terms of understanding of systematic clinical integration.

- Evidence generation
  - Still very much in the mode of evidence generation – important to make clear what is research and what is clinical.
  - Numbers and diversity of participants is very important for multiple types of knowledge.
  - Clinical utility data will be key to broader adoption and ongoing maintenance – key to (clinical and economic) value is use of information with evidence based interventions.
  - Ignoring personal (dis)utility for all participants in this space risks misadventure .
- Genomic screening programs
  - Multiple avenues to funding program can work.
  - Financial sustainability remains a work in progress – currently organizational leadership buy-in is key.
- Data sharing
  - Data sharing critical given needed sample sizes, but much infrastructure needs to be developed.
  - Models for data sharing exist and might be adapted to purpose.
  - Not entirely clear what to share (outcomes), or how.

Considerations for programs considering launch:

- Population
  - Engagement/inclusion of 'population' early and often
  - Active management of inclusiveness of work is key
- Intervention
  - Careful consideration of what technology, what to test for and report (and for how long)
  - Smaller high-yield panels based on population prevalence
  - Managing expectations (negative results) very important
  - Multidisciplinary approach key – meet non-genetics providers where they are
  - Integrate research teams with clinical infrastructure
- Comparison
  - How will outcomes be attributed to genomic result return?
- Outcomes
  - Purposeful pre- set outcomes/metrics implementation study/evaluation – not limited to traditional trial metrics (financial for example)
  - Electronic infrastructure lags and needs attention

Action steps? - Near

- What data do we collect and share?
  - Establishing process for identification and development of common outcomes and metrics for data sharing that are agreed upon by researchers and participants – Population health AC?
- Who participates?
  - Convene group to identify and develop tools to ensure early engagement, entry, and long-term meaningful participation of typically under-included population groups in developing clinical genomics programs.

Action steps? - Far

- Evidence needs
  - Engage key decision makers (including employers?) in discussions of value and process of developing models that meet their decision making needs.
- Infrastructure
  - Authoritative multi-stakeholder organization providing guidance to field?
  - Common data model, test coding and result
- Incentives
  - Work on process to help ensure that payment for testing requires data sharing/ deposition into ClinVar or similar
  - Coverage with evidence development/risk-sharing agreements