Figure 1: Evaluation framework for genomic test development. Tests should be evaluated within a given clinical context (i.e. specify disease or health condition, type of patient, proposed test role, desired outcomes, and current practice or clinical alternatives)

Phase 0: Marker identification & Assay Development
- Discovery, establish association between biomarker(s) and outcome(s) of interest
- Develop assay based on identified biomarker(s)

Phase 1: Initial Test Performance and Assay Refinement
- Determine test performance of defined assay in targeted population
- Refine assay based on initial test performance

Phase 2: Test Validation & Generalizability
- Determine test performance and feasibility in intended population

Phase 3: Clinical Test Performance & Health Impacts
- Determine effects (benefits and harms) on important decision making and health outcomes

Phase 4: Comparison with Existing Tests
- Determine comparative effectiveness (benefits and harms)

Phase 5: Population Impacts
- Determine health, cost effects at a population or health systems level
- Determine feasibility of implementing testing programs, and legal/ethical implications for society

Clinical Phases (Includes clinical validity/utility)
Pre-Clinical Phases (Includes analytic validity)