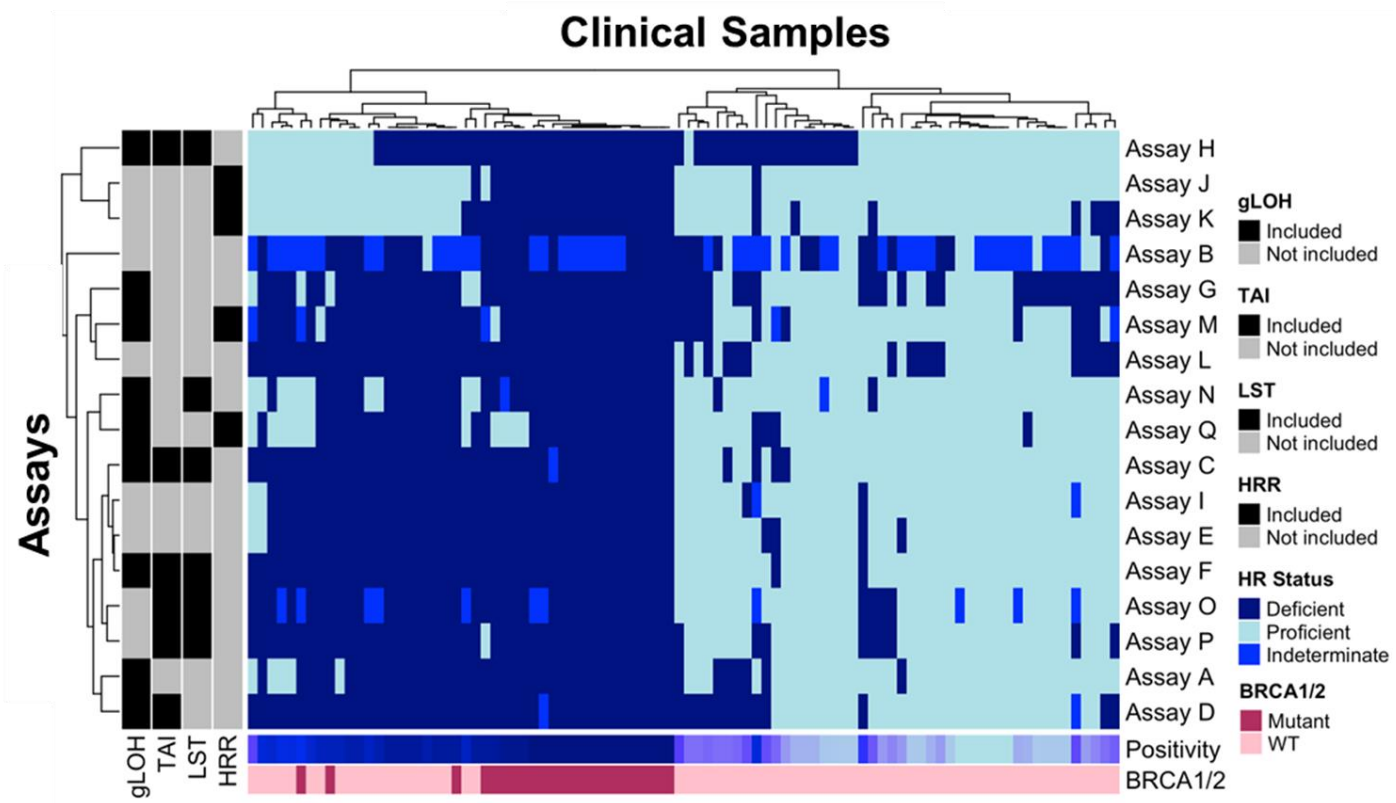
The HRD Harmonization Project

The Homologous Recombination Deficiency (HRD) Harmonization Project supports the use of assays that measure the HRD biomarker for treatment decision-making. With our project partners, *Friends* examined sources of variability across HRD assays to identify areas for alignment and propose solution to improve assay development.

Approach: *Friends* partnered with key stakeholders to assess the variability in HRD assay outputs. Assay developers received freshly extracted nucleic acids from archival ovarian cancer samples (n=90) and reported HRD status. Statisticians from NCI assessed concordance and the group discussed assay, clinical, and sample characteristics as potential sources of discordance to provide recommendations for future HRD assay development.



gLOH: Genomic Loss of Heterozygosity; TAI: Telomeric Allelic Imbalance; LST: Large-scale State Transitions; HRR: mutations in HR Repair pathway genes other than *BRCA1* and *BRCA2*; WT: Wild-type

Variability in HRD calls across assays appeared to be primarily driven by assay characteristics rather than sample and patient clinical characteristics

Who Is Involved? *Friends* is proud to partner with ACT Genomics, AmoyDx, AstraZeneca, Bayer, Bionano Genomics, Inc., BostonGene Corporation, Bristol Myers Squibb, Burning Rock, Diagnostic Laboratory Services, Inc., DNAnexus, EMD Serono, Inc., European Organisation for Research and Treatment of Cancer (EORTC), Foundation Medicine, Inc., Genentech, Inc., Guardant Health, Inc., Illumina, Inc., Invitae Corp., Laboratory Corporation of America (Labcorp), MD Anderson Cancer Center, Merck & Co., Inc. (MSD), Molecular Characterization Laboratory (MoCha) at Frederick National Laboratory, the National Cancer Institute (NCI), Neogenomics Laboratories, Inc., PathAI, Pfizer, Pillar Biosciences, SOPHiA Genetics, Tempus, Thermo Fisher Scientific, the FDA, University of Alabama at Birmingham, and the University of Heidelberg.