Digital PATH Project:
Digital and Computational Pathology Tool Harmonization Project
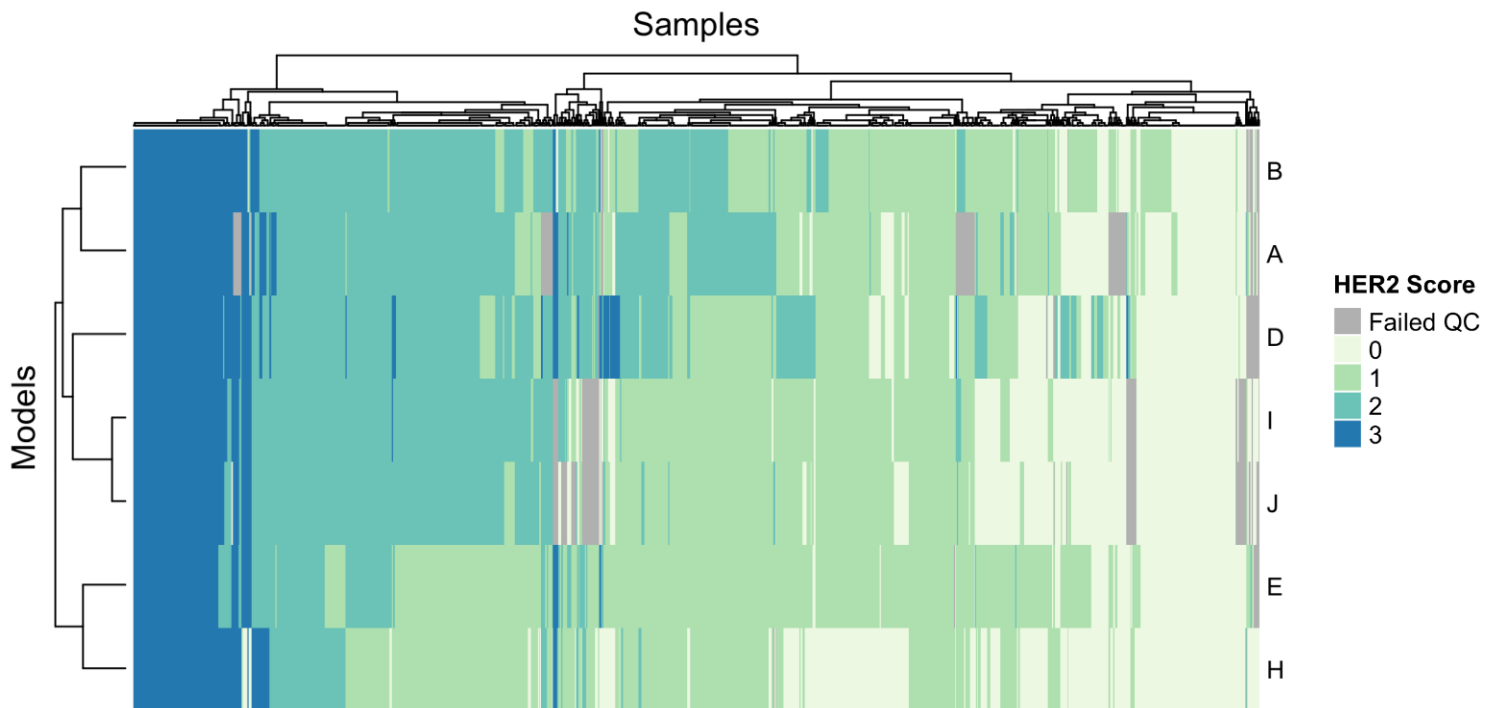
The Digital and Computational PAthology Tool Harmonization (Digital PATH) Project explores the variability in biomarker assessment across computational pathology platforms. With our project partners, *Friends* examined variability and potential sources of discordance across models to inform alignment and propose solutions to improve model development and validation.

Approach: Over 1,000 whole slide images from patients diagnosed with breast cancer were distributed to model developers (n=10) who reported HER2 status. In coordination with project partners, statisticians from the NCI Biometrics Division assessed the level of agreement across models and considered clinical and sample characteristics, as well as model development attributes, as potential factors contributing to discordance to support future alignment.

Heatmap titled "Samples" (top) and "Models" (left axis) with dendrograms. Legend — HER2 Score: Failed QC (gray), 0, 1, 2, 3. Model rows labeled B, A, D, I, J, E, H.

Observed variability in HER2 biomarker assessment across models providing predicted ASCO/CAP HER2 scores.

There is high agreement in assigning HER2 3+ across the seven models, as well as assigning samples as HER2 0, with larger variability in assigning 1+, 2+.

Who Is Involved? *Friends* is proud to partner with 4D Path Inc., Amgen, AstraZeneca, BostonGene, Bristol Myers Squibb, Caris Life Sciences, Daiichi Sankyo, EMD Serono, Inc., Emory University, the U.S. Food and Drug Administration (FDA), GA Green Consulting LLC, GSK, Indica Labs, Johnson and Johnson Innovative Medicine, Karolinska Institute, Kulig Consulting, Loxo@Lilly, Lunit, MD Anderson Cancer Center, Merck and Co., Molecular Characterization Laboratory (MoCha) at Frederick National Laboratory, National Cancer Institute (NCI), Nucleai, Panakeia, PathAI, Patient Advocates, Roche Diagnostics, Sanofi, Tempus AI, Inc., University of North Carolina, and ZAS Hospitals Antwerp.