FRIENDS of CANCER RESEARCH

Digital PATH Project:

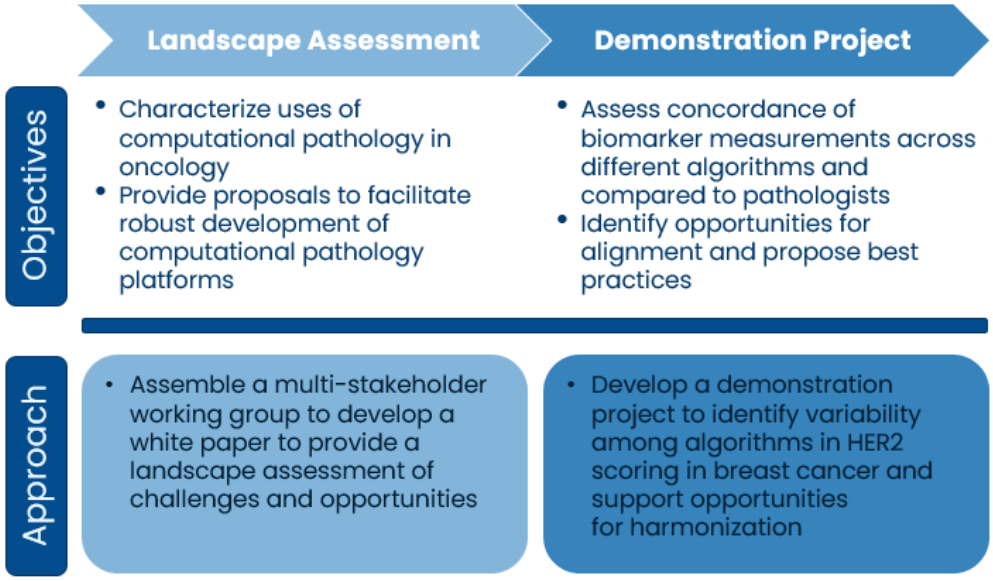
Digital and Computational Pathology Tool Harmonization Project

The Definition: Digital pathology is an emerging application which creates whole-slide images for storage, viewing, analyses, and interpretation. Digitized images support the development of computational pathology platforms that use techniques such as artificial intelligence (AI) and machine learning (ML) to measure specific biomarkers. This technology can aid pathologists to provide greater accuracy, reproducibility, and expediency of biomarker assessment.

The Problem: Currently, the absence of standardized approaches for image acquisition, analysis, and interpretation of biomarkers across computational pathology platforms can lead to variability of biomarker results, leading to difficulties in comparing across different studies. Without alignment, regulatory review processes may be challenging to establish and implement, potentially impeding uptake and use of these platforms in oncology drug development and clinical care.

The Solution: **Friends of Cancer Research (*Friends*)** assembled a multi-stakeholder group to identify opportunities for use of digital and computational pathology in oncology drug development and develop proposals to support robust development of these emerging technologies. *Friends* launched the Digital PATH research partnership to assess biomarker measurements across computational pathology platforms. This work will identify factors that may contribute to variability across platforms, propose areas for alignment in the field, and provide insights for shaping regulatory frameworks and processes.

The Research Question: What factors contribute to variability in biomarker assessment across computational pathology platforms and what performance metrics support improved evaluation and alignment?



Why Is This Important? It is critical to have regulations and standards in place to ensure these technologies help to appropriately identify patients for treatment. The Digital PATH Project will identify opportunities for improved alignment of computational pathology platforms for future development and validation.

Who Is Involved? *Friends* is proud to partner with 4D Path Inc., Amgen, AstraZeneca, Bristol Myers Squibb, EMD Serono, Inc., the U.S. Food and Drug Administration (FDA), GSK, Indica Labs, Johnson and Johnson Innovative Medicine, Loxo@Lilly, Lunit, Massachusetts General Hospital, MD Anderson Cancer Center, Merck and Co., National Cancer Institute (NCI), Nucleai, PathAI, Patient Advocates, Roche Diagnostics, Sanofi, Tempus AI, Inc., University of North Carolina, ZAS Hospitals Antwerp, and Verily.