

**FRIENDS**  
of CANCER  
RESEARCH

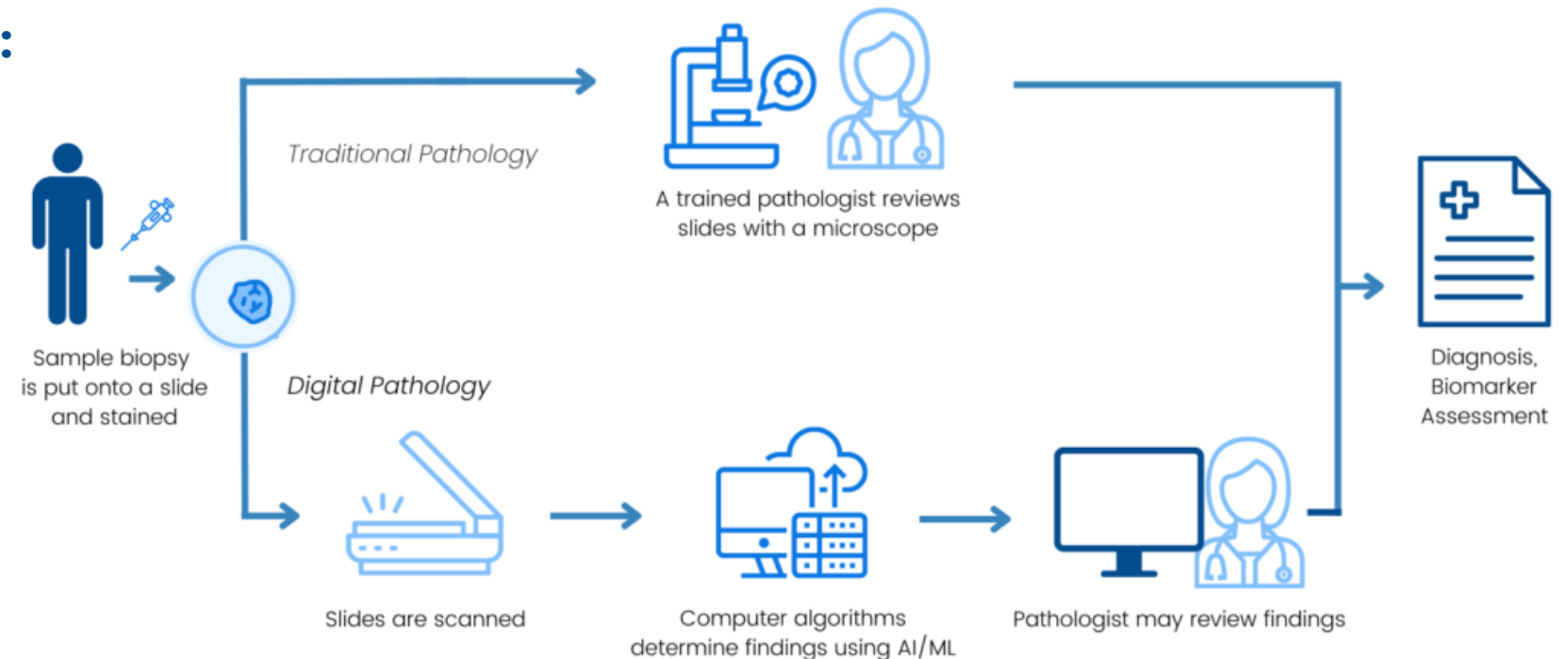
# **The Digital and Computational Pathology Tool Harmonization Project**

**The Digital PATH Project**

# Digital and Computational Pathology

## Challenges in Computational Pathology:

- Lack of standardization in image acquisition, analysis, and interpretation can lead to variability in biomarker results and difficulty comparing data across different studies
- Limited guidelines and need for a framework to guide evidentiary needs



# Digital PATH Project

## Landscape Assessment

## Demonstration Project

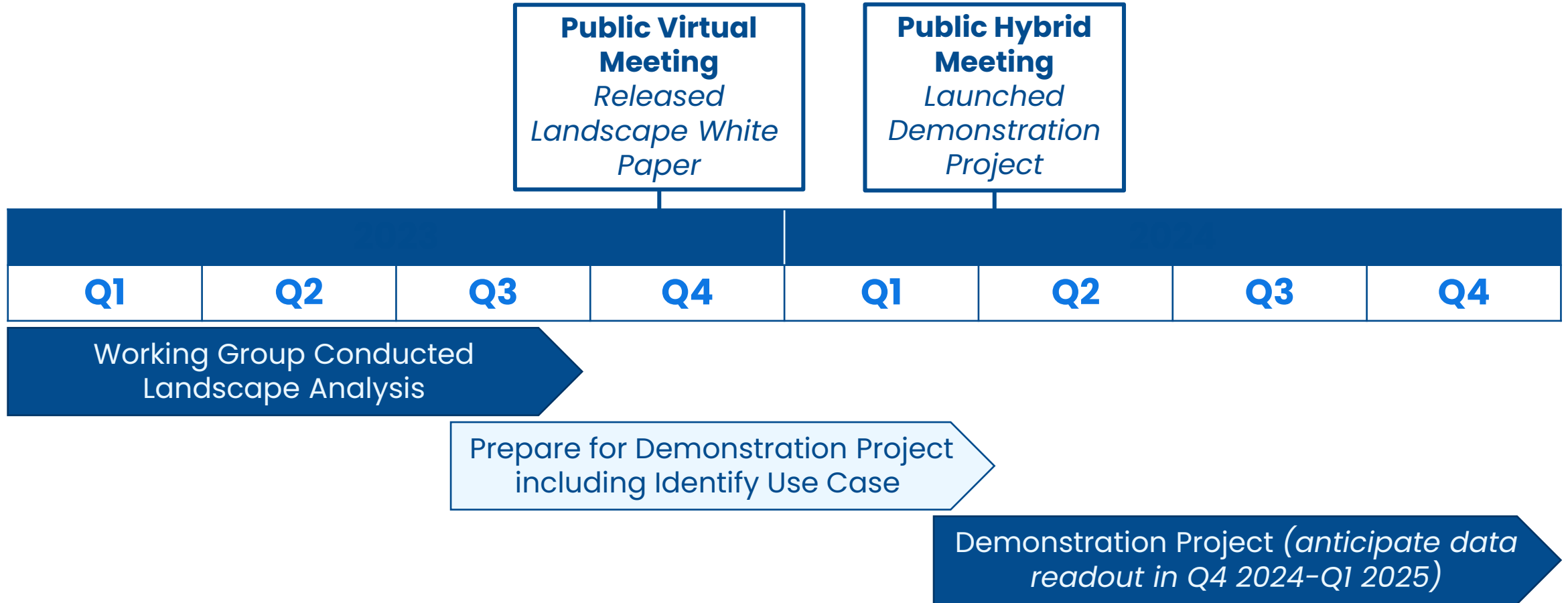
### Objectives

- Characterize uses of computational pathology in oncology
- Provide proposals to facilitate robust development of computational pathology platforms
- Assess concordance of biomarker measurements across different algorithms and compared to pathologists
- Identify opportunities for alignment and propose best practices

### Approach

- Assemble a multi-stakeholder working group to develop a white paper to provide a landscape assessment of challenges and opportunities
- Develop a demonstration project to identify variability among algorithms in HER2 scoring in breast cancer and support opportunities for harmonization

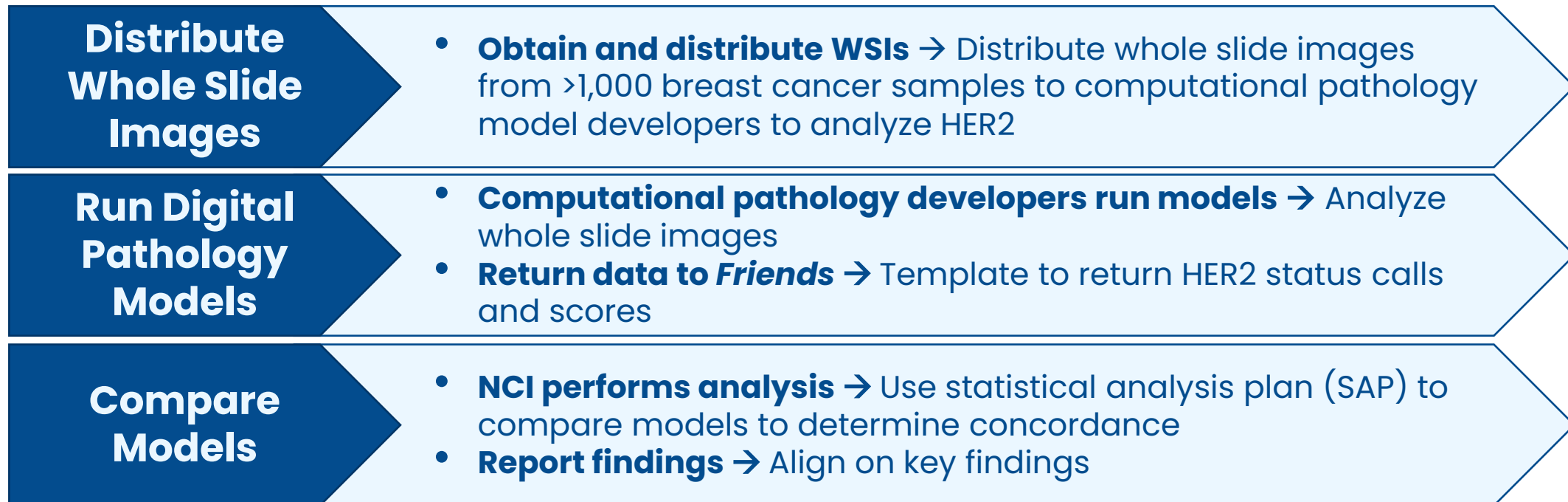
# Project Timeline



# Digital PATH Project

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

**The Use Case:** HER2 assessment in breast cancer



# Analysis Strategy Overview

## Primary Analysis

### Descriptive analysis describing concordance

HER2 categorical scores: 0, 1+, 2+, 3+

## Secondary/ Exploratory Analysis

### Factor Associations

Association of patient, specimen, and model attributes with HER2 categorical scores

### Pathologist Concordance

Concordance between models and pathologists

### Quantitative Measurements

Concordance between models providing quantitative biomarker measurements

### Additional Categorical Scores

Concordance between models that provide ultra-low, low, and other categories