CDDF WORKSHOP

27 - 28 September 2021

ONLINE WORKSHOP

Digital Tools and Artificial Intelligence in Oncology Drug Development

Digital Diagnosis

Digital Pathology and AI

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Roche Tissue Diagnostics

Disclaimer

- Roche Employee

Roche Digital Pathology Portfolio

Establishing a platform ecosystem and delivering a superior pathologist interface is a key focus of our strategy

Scanning

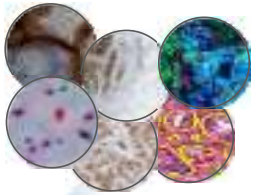
Roche DP 200 and
DP 600* Slide Scanners

Interoperable with DICOM images and other open formats from third party scanners

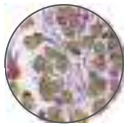
Pathologist Interface

NAVIFY Digital Pathology platform (uPath) manages the full pathologist workflow

Image Analysis



Roche Image Analysis Apps
PD-L1 (SP263) lung, Her2 Dual ISH, Her2, Ki-67, ER, PR*



Open API to support third party image analysis algorithms

** In development*

Roche’s approach to developing algorithms

End to end solution through uPath image analysis algorithm suite

VENTANA assay

Fully automated assay

+

VENTANA DP 200 slide scanner

High-quality images with accurate, fast, easy-to-use scanners

+

Roche uPath enterprise software

Pathologist interface offers seamless workflow for analysis

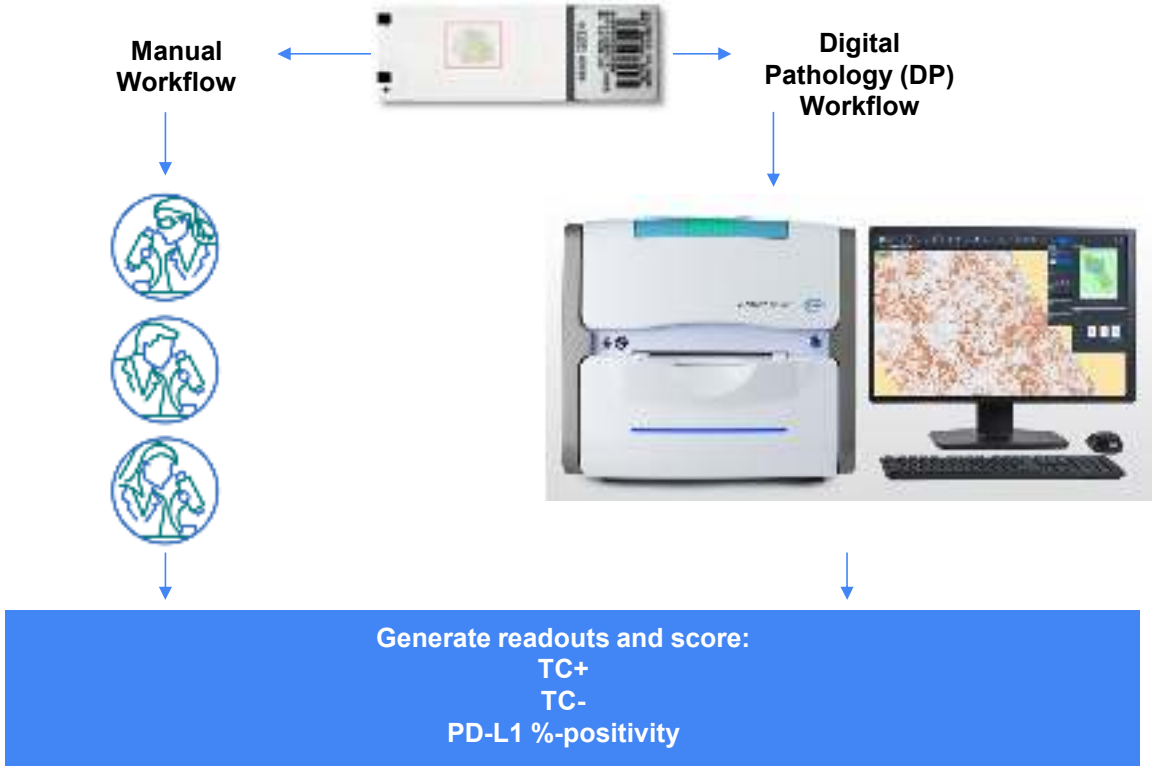
+

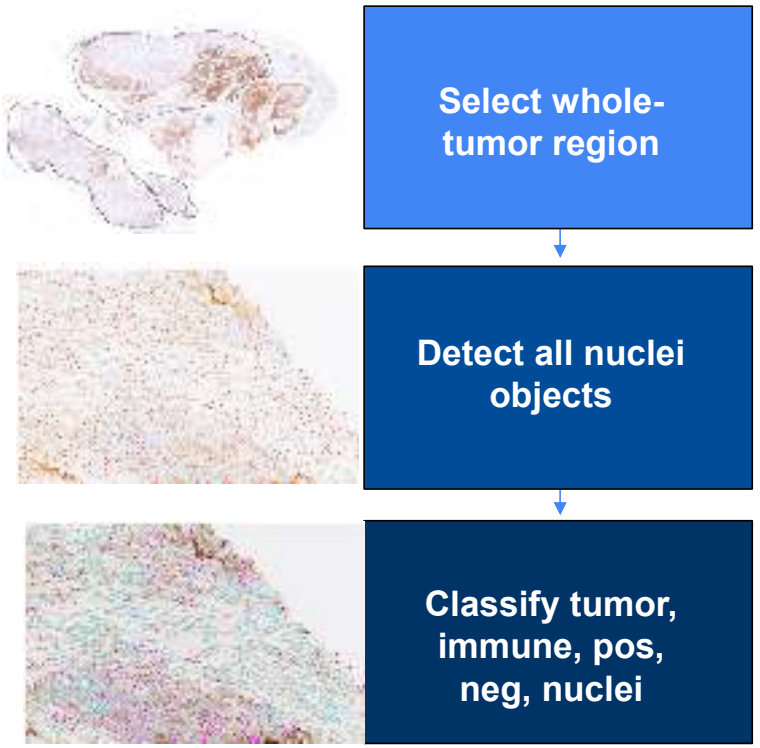
Image analysis

Analyze confidently with algorithms

Approach to developing algorithms

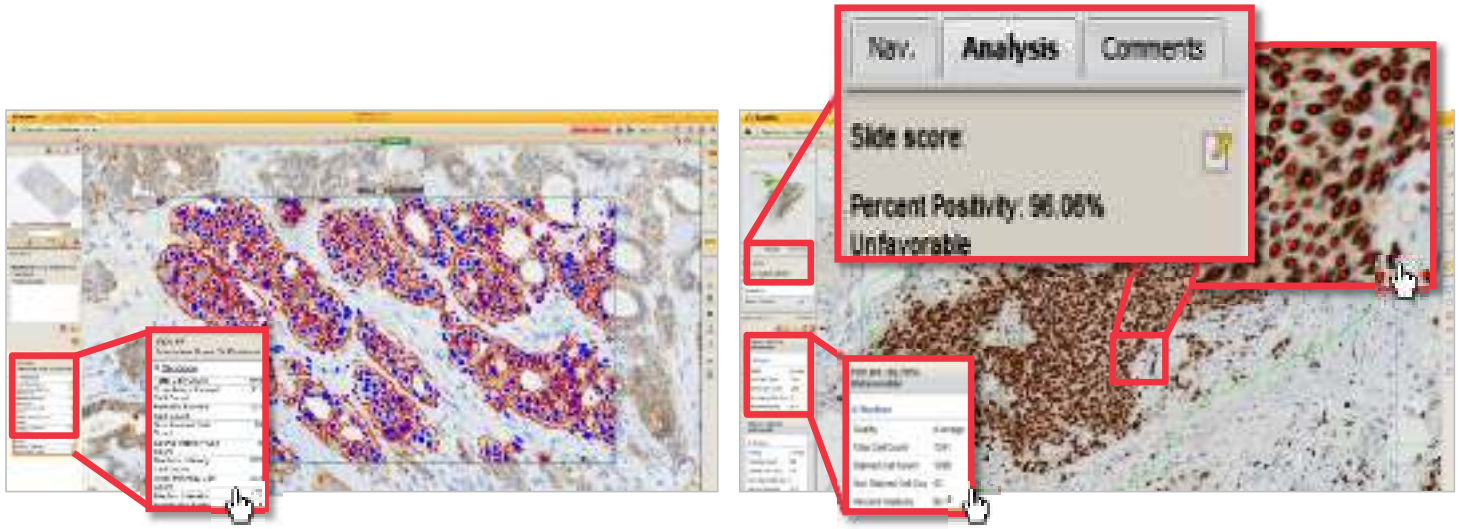
Objective: Replicate clinical workflow at highest accuracy





IVD Product: Learning-based Companion Algorithms

Mature technology & products (ER, PR, Ki67, p53, HER2)



Breast Panel algorithms (Her2, ER, PR, Ki67)

ER, PR and Ki67 use machine learning to identify cells

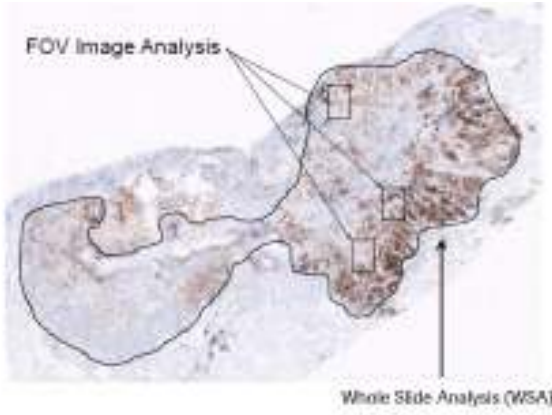
FDA 510(k) Cleared and CE-IVD Breast Panel Algorithms

AI technology used for ER, PR, Ki67 Algorithms:

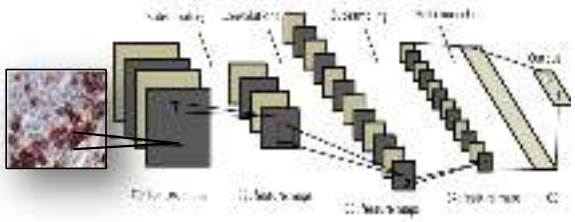
- Support Vector Machines (Supervised Learning)

Next Generation Digital Pathology Algorithms

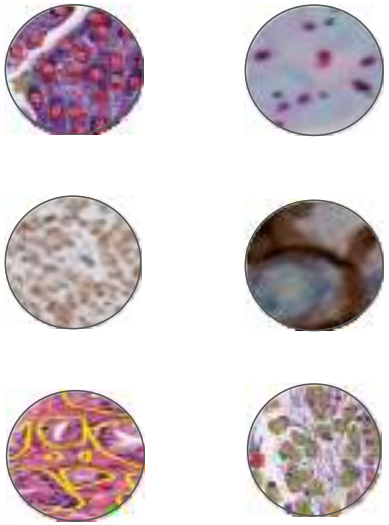
Whole Slide Analysis



Artificial Intelligence/Deep Learning Algorithms

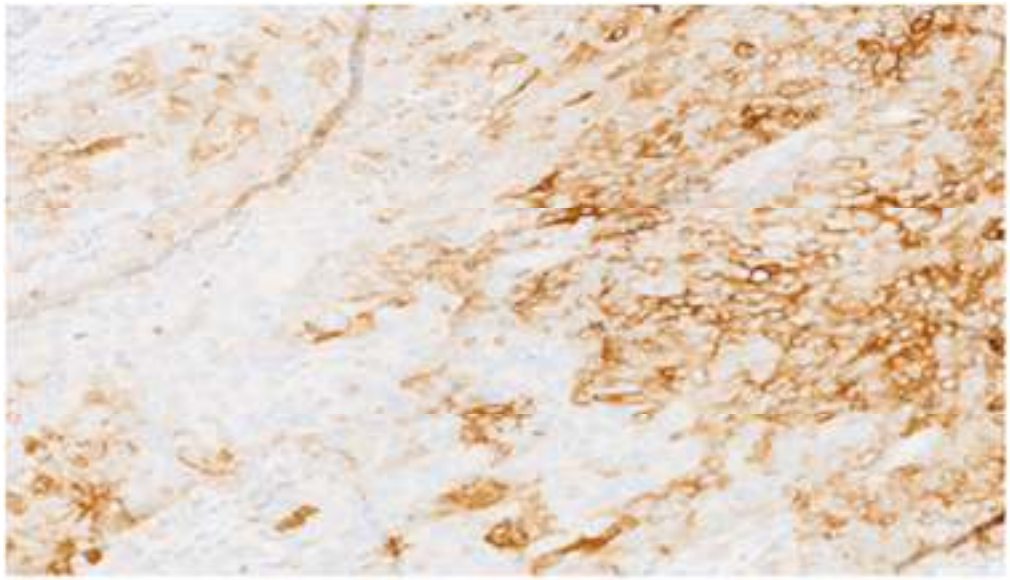


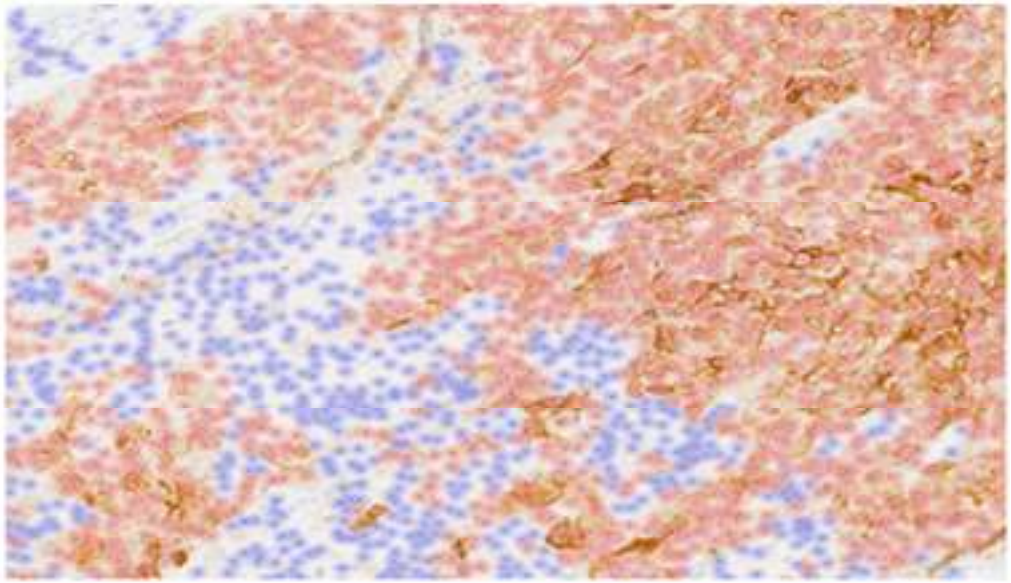
Algorithms for IHC, H&E, ISH



Roche uPath Digital Pathology Algorithm Portfolio

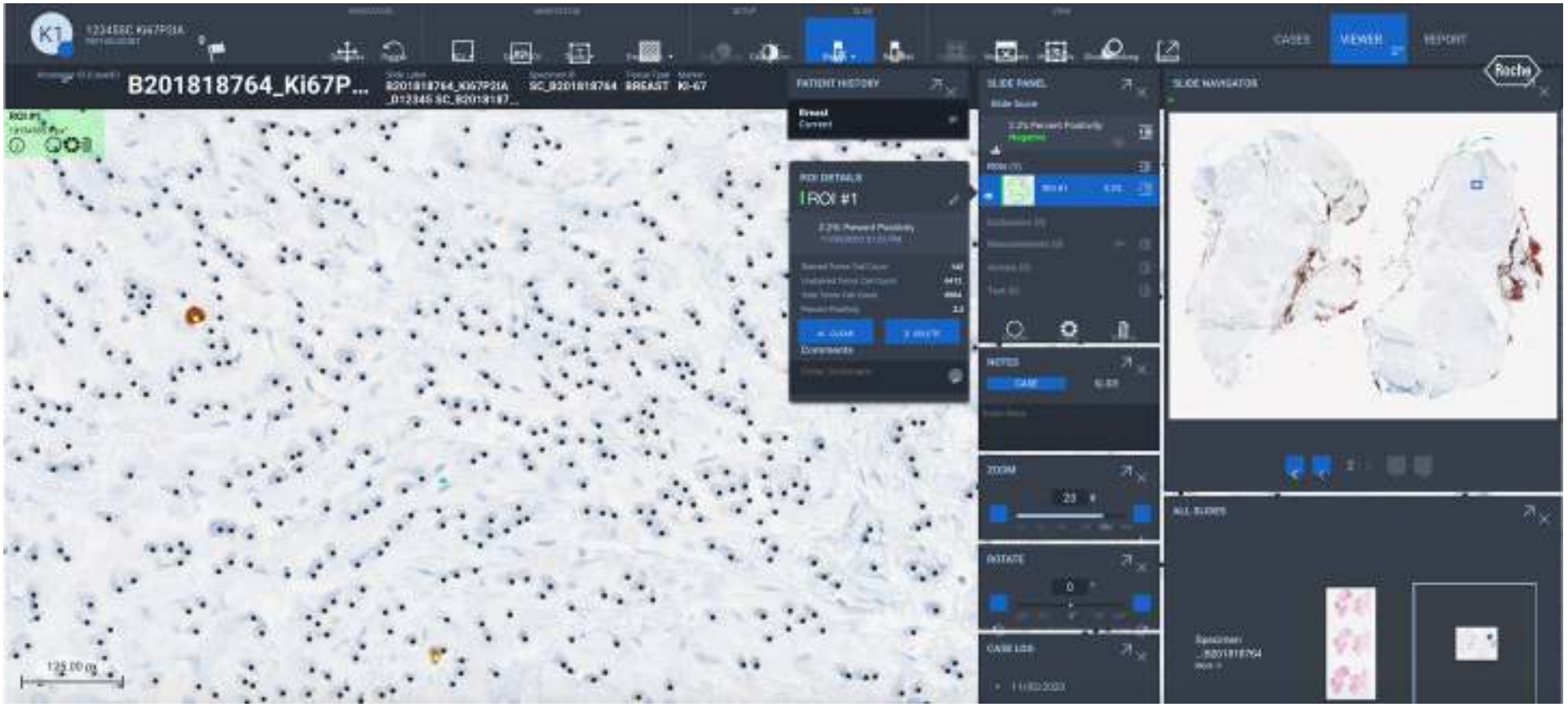
PD-L1 (SP263) Lung decision support algorithm



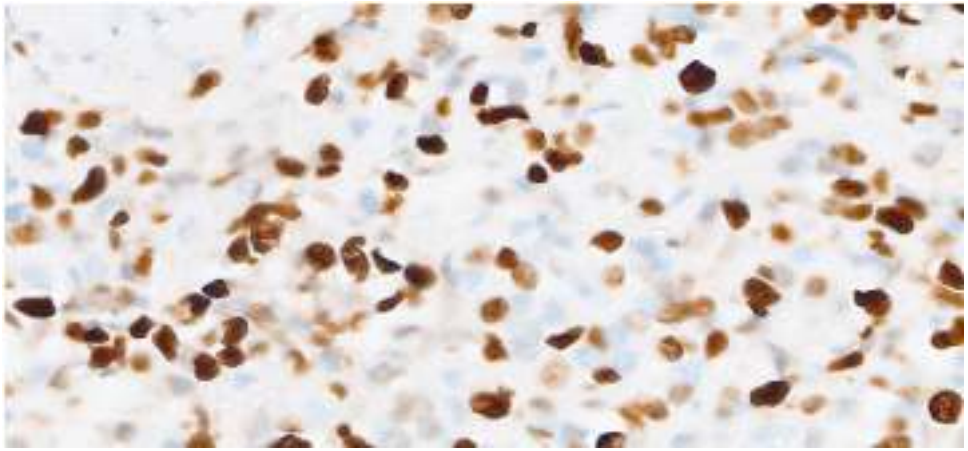


$$\frac{\text{Positive Tumor Cells}}{\text{Total Tumor Cells (Positive + Negative Tumor Cells)}} = \text{TC\%}$$

ER Algorithm



ER Algorithm

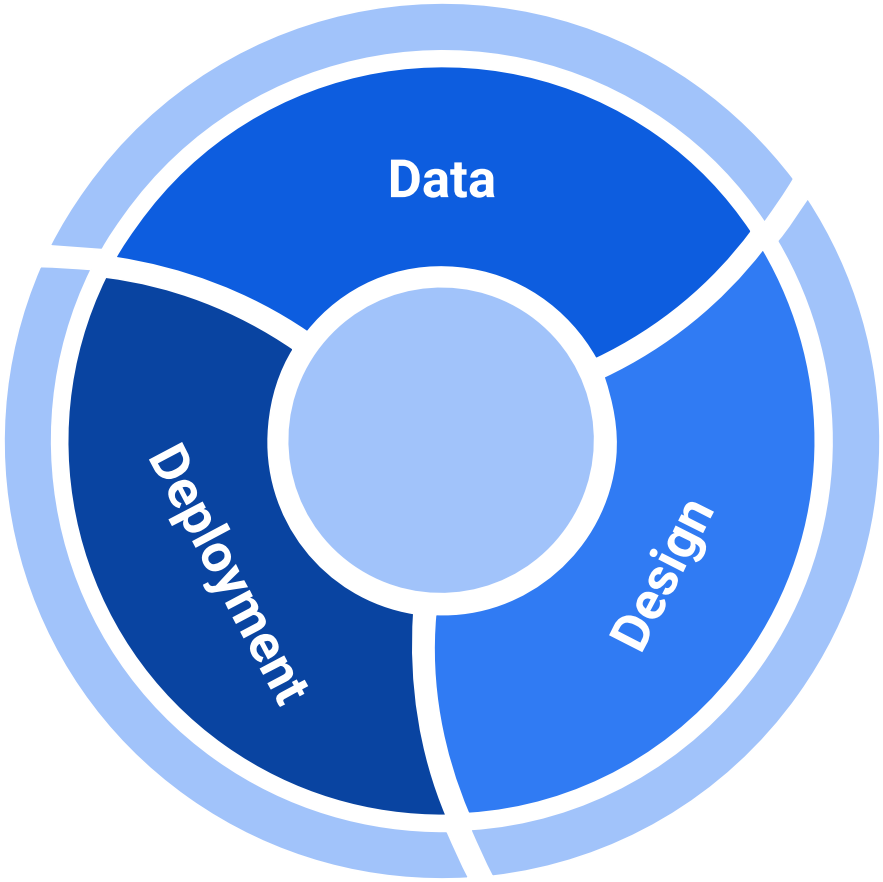


Tumor with nuclear staining (Yellow overlay)

Tumor without nuclear staining (Black overlay)

$$\frac{\text{ER Positive Tumor Cell Nuclei}}{\text{Total Tumor Cell Nuclei (Positive + Negative)}} = \text{ER Percent Positivity}$$

Critical Components of DP Algorithm Development



Good Machine Learning Practice (GMLP)

Currently under discussion

GMLP considerations as applied for SaMD

- Relevance of available data to the clinical problem and current clinical practice;
- Data acquired in a consistent, clinically relevant and generalizable manner that aligns with the SaMD's intended use and modification plans;
- Appropriate separation between training, tuning, and test datasets; and
- Appropriate level of transparency (clarity) of the output and the algorithm aimed at users.

GMLPs are the best practices which are aligned with good software engineering practices.

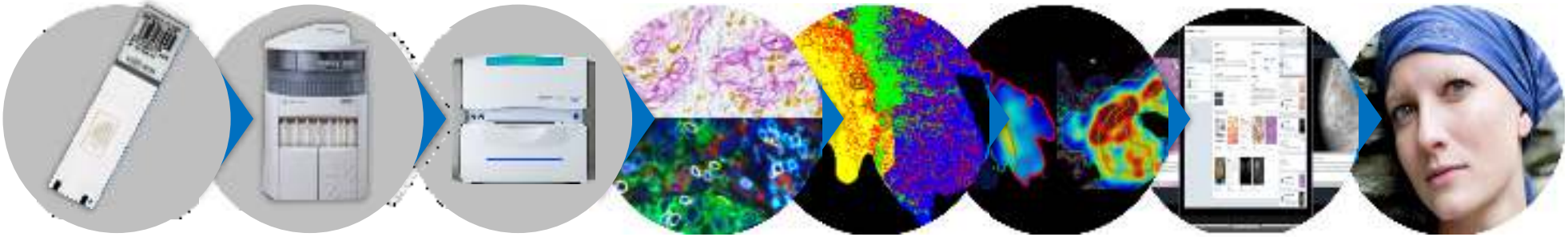
DP AI Algorithms: a Tool for Oncology Drug Development

- Algorithms for IHC, ISH and H&E slides
- Data collection through algorithms along the development of new treatments
- Digital biomarkers

The Future Anatomic Pathology Lab

Superior clinical lab workflow enhanced by NAVIFY Digital Pathology

1. **Patient specimen arrives for analysis**
2. **Automated staining**
3. **Whole slide scanning (BF**, FL**)**
4. **Automatic whole slide image analysis with NAVIFY Digital Pathology**
5. **Digital scoring algorithm**
6. **Result interpretation**
7. **NAVIFY portfolio and platform of decision support solutions**
8. **Diagnostic and/or treatment decision**



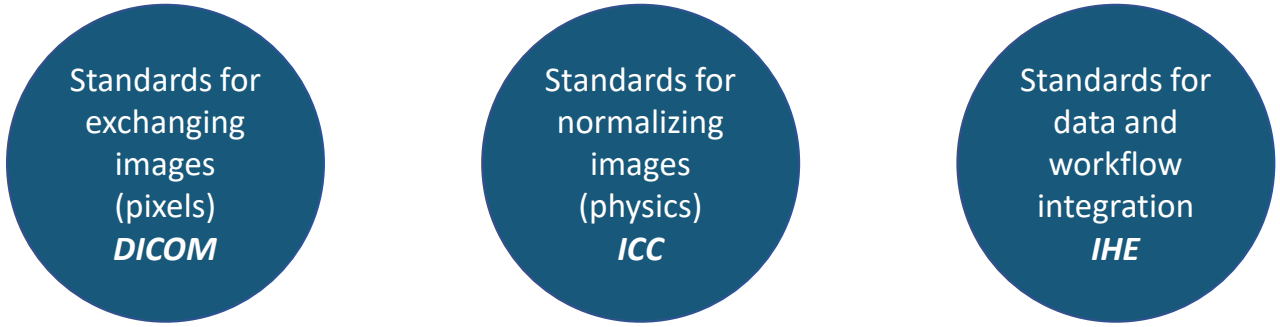
* IHC = Immunohistochemistry

** BF = brightfield; FL = fluorescent; TILs = tumor-infiltrating lymphocytes

Standardization in Digital Pathology

Standards are critical for AI

- DICOM WG26
- PaLM/IHE
- Digital Pathology Association (DPA) Task Force on Regulatory and Standardization
- Alliance for Digital Pathology/Pathology Innovation Collaborative Community (Picc) – A regulatory science initiative



Doing now what patients need next