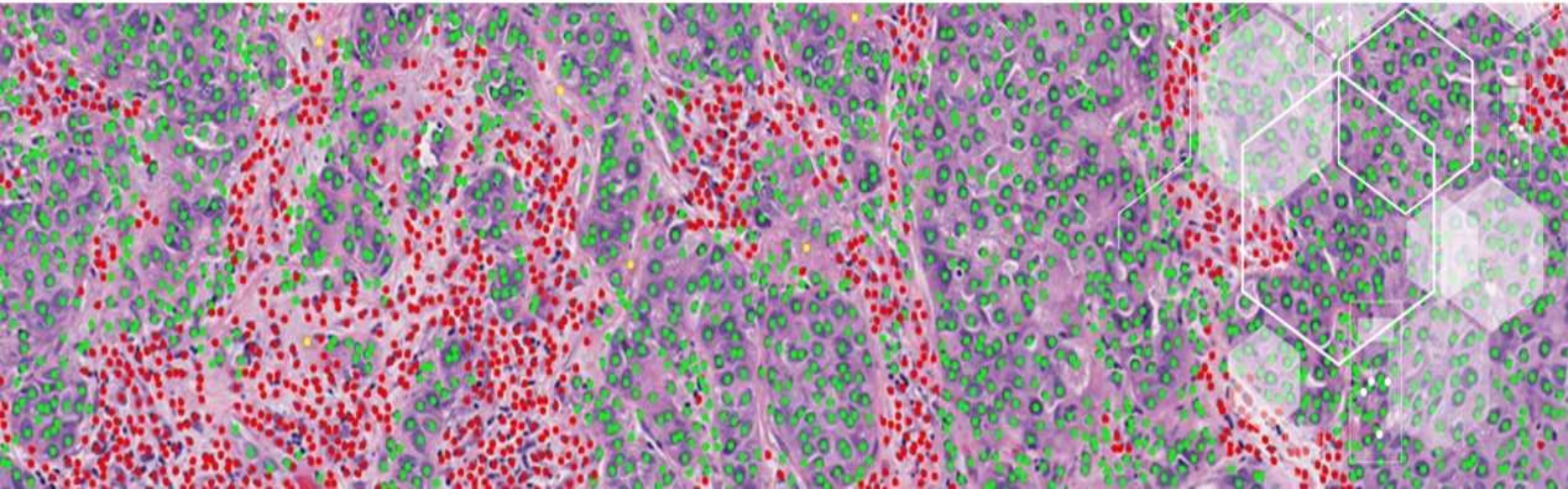


Digital Pathology Current Status and Future Directions

Ehab A. ElGabry, MD



Disclosures

- I, Dr. Ehab A. ElGabry am the Senior Medical Director Of Personalised Health Care Solutions (PHCS) and Head of Companion Diagnostics Pathology for Roche Tissue Diagnostics

Objectives:

- Define the scope of digital pathology and provide the rationale for why Digital applications will continue to expand and transform the pathology practice .
- Describe whole slide image technology and the concepts of digitizing pathology workflow.
- List current and future digital pathology applications and highlight their benefits for pathology practice

Presentation overview

- Digital Pathology Historical Milestones
- Challenges of current practice model and the need for digital pathology solutions
- Definition of DP
- Digital pathology LAB infrastructure essentials
- Current and future digital pathology applications

Historic Milestones

- 1968 : Black and white photos of Blood smears sent via video from Logan airport
- 1980 : Remote Tele Pathology
- 1986 : Robotic Telepathology system
- 2000 : WSI comes to market
- 2009 : FDA panel meeting addresses the use of digital pathology for primary diagnosis
- 2017: FDA approval of the first WSI platform for primary diagnosis.

Adoption Barriers



- Digital solutions technology infrastructure challenges
- Regulatory Issues
- Payers evidence for reimbursement
- learning curve
- Regional specific challenges : regulatory, reimbursement, and technology infrastructure
- Silos
- Skepticism by the medical community (Academics, hospitals, community labs)

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Global state of cancer today

Cancer continues to be one of the leading causes of death worldwide

14 million

people worldwide
develop cancer¹

And will rise to more than

21 million

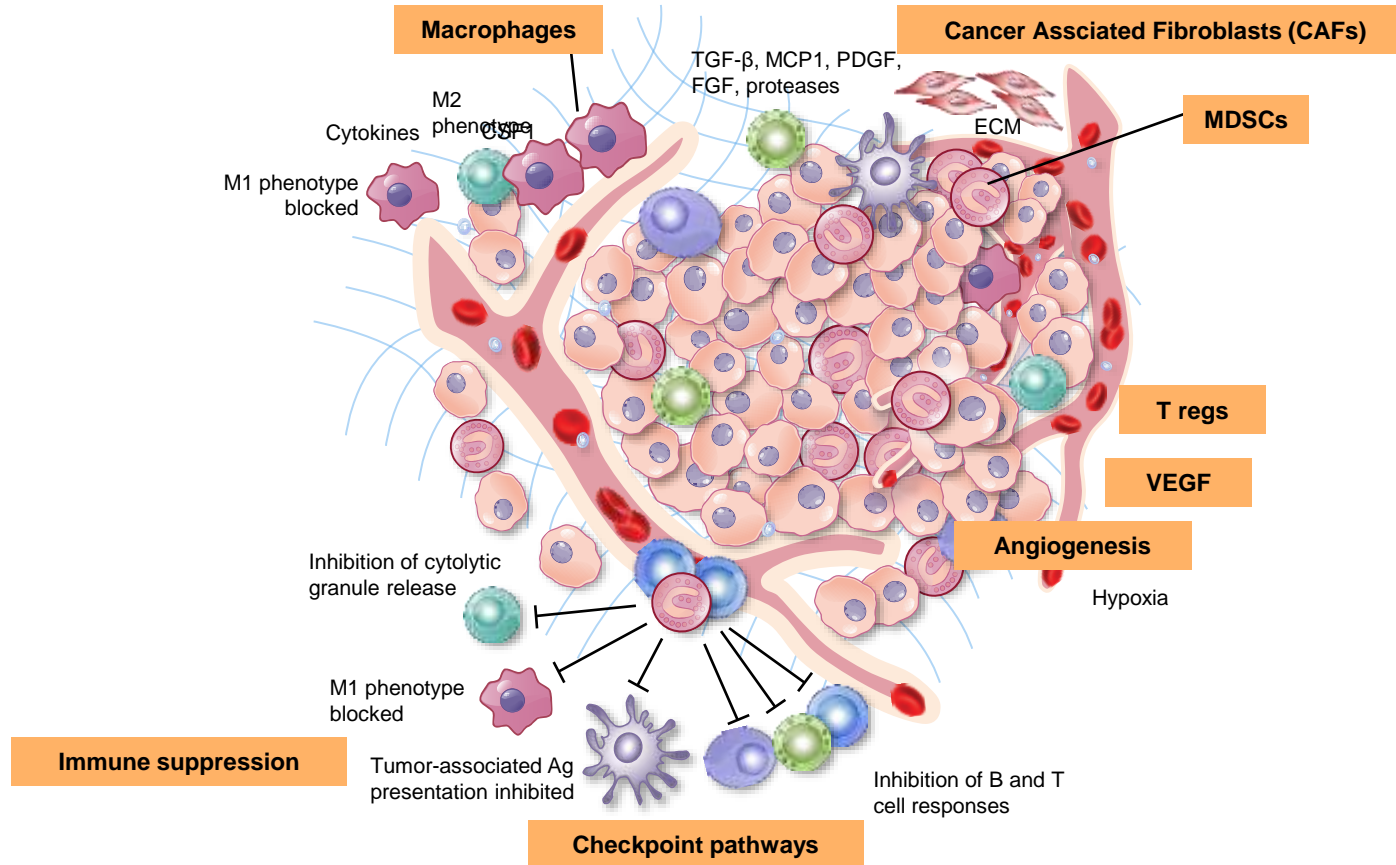
by year 2030¹



¹World Health Organization Cancer Key Facts, 2017 (<http://www.who.int/cancer/media/news/cancer-key-facts/en/>, accessed on 27 June 2018)

Tumors Are Developing Ecosystems

Critical Interactions Between Cancer Cells and the Tumor Microenvironment



Increasing number of approvals for PD-1/PD-L1 inhibitors*

Challenging for pathologists to assess PD-L1 across multiple tumor types/indications

Squamous Cell Head & Neck Cancer

1L/2L nivolumab after platinum chemotherapy
1L/2L pembrolizumab after platinum chemotherapy

Malignant Melanoma

Adjuvant/1L ipilimumab
1L nivolumab ± ipilimumab
Adjuvant nivolumab
1L pembrolizumab

Merkel Cell Carcinoma

2L avelumab

Hepatocellular Carcinoma

2L nivolumab after sorafenib

Adv. Renal Cell Carcinoma

1L nivolumab plus ipilimumab
2L nivolumab after anti-angiogenic therapy

MSI-H or dMMR Cancers

2L nivolumab in CRC
2L nivolumab plus ipilimumab in CRC
2L pembrolizumab in any MSI-H/dMMR cancer

Cervical Cancer

2L pembrolizumab CPS ≥ 1



Non-Small Cell Lung Cancer

1L pembrolizumab TPS ≥ 50%
1L pembrolizumab + pemetrexed/carboplatin in non-squamous NSCLC
2L pembrolizumab TPS ≥ 1%
2L nivolumab
2L atezolizumab NSCLC
Maintenance durvalumab after chemoradiation

Small Cell Lung Cancer

3L nivolumab

Gastric & GEJ Carcinoma

3L pembrolizumab after fluoropyrimidine- and platinum-chemotherapy +/- HER2 therapy & CPS ≥ 1

Classical Hodgkin Lymphoma

4L pembrolizumab
3L nivolumab after auto-HSCT and BV
4L nivolumab and after auto-HSCT

PMBCL

3L pembrolizumab

Locally Adv. or Met. Urothelial Cancer

1L/2L nivolumab after platinum chemotherapy
1L/2L pembrolizumab
1L atezolizumab in cisplatin ineligible IC ≥ 5%
2L atezolizumab after platinum chemotherapy
1L/2L avelumab after platinum chemotherapy
1L/2L durvalumab after platinum chemotherapy

*U.S. FDA Approved Immune Checkpoint Inhibitors as of 20-Jul-2018

Scoring Methods

TPS ?

CPS ?

?

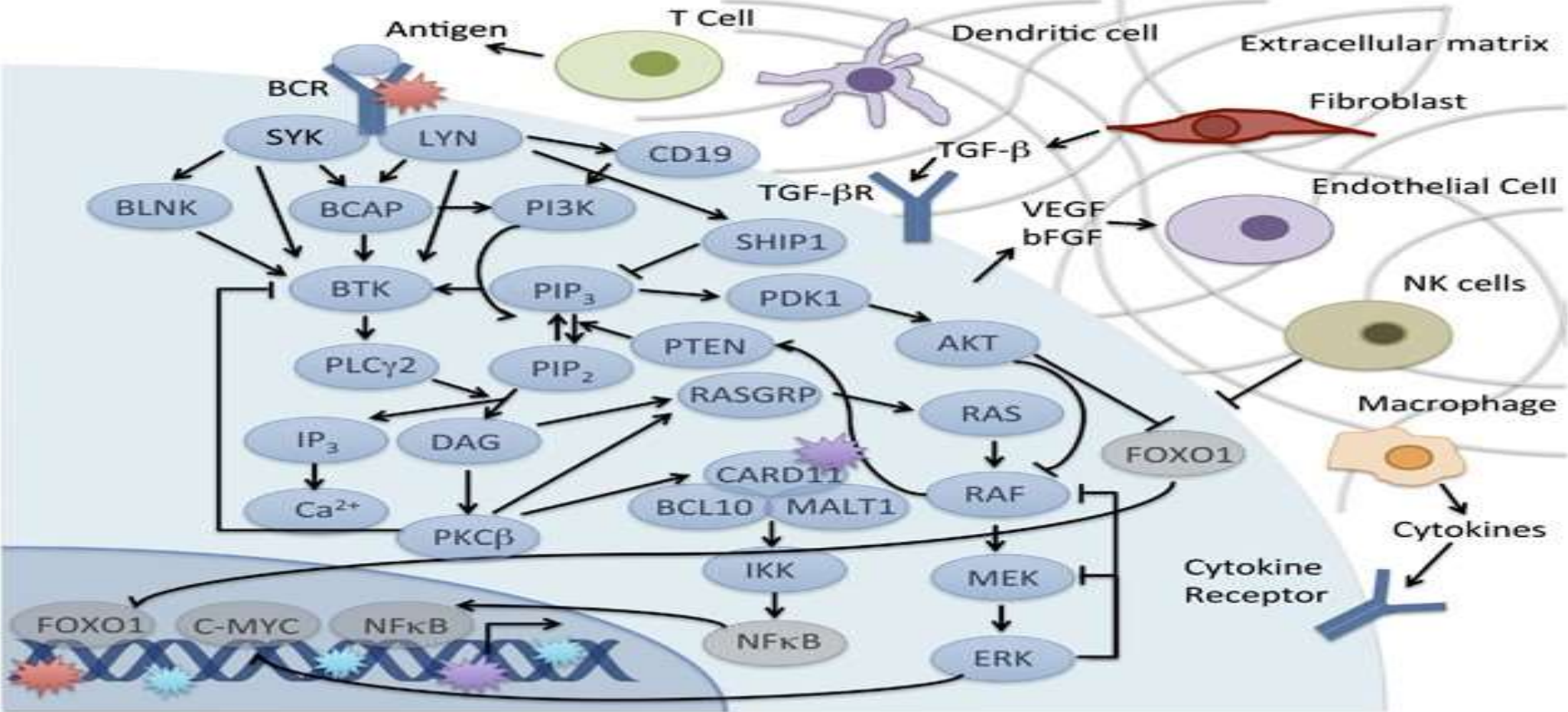
H-score?



Tils?

ICP ?

Embracing Complexity To Develop Better Diagnostic Strategies

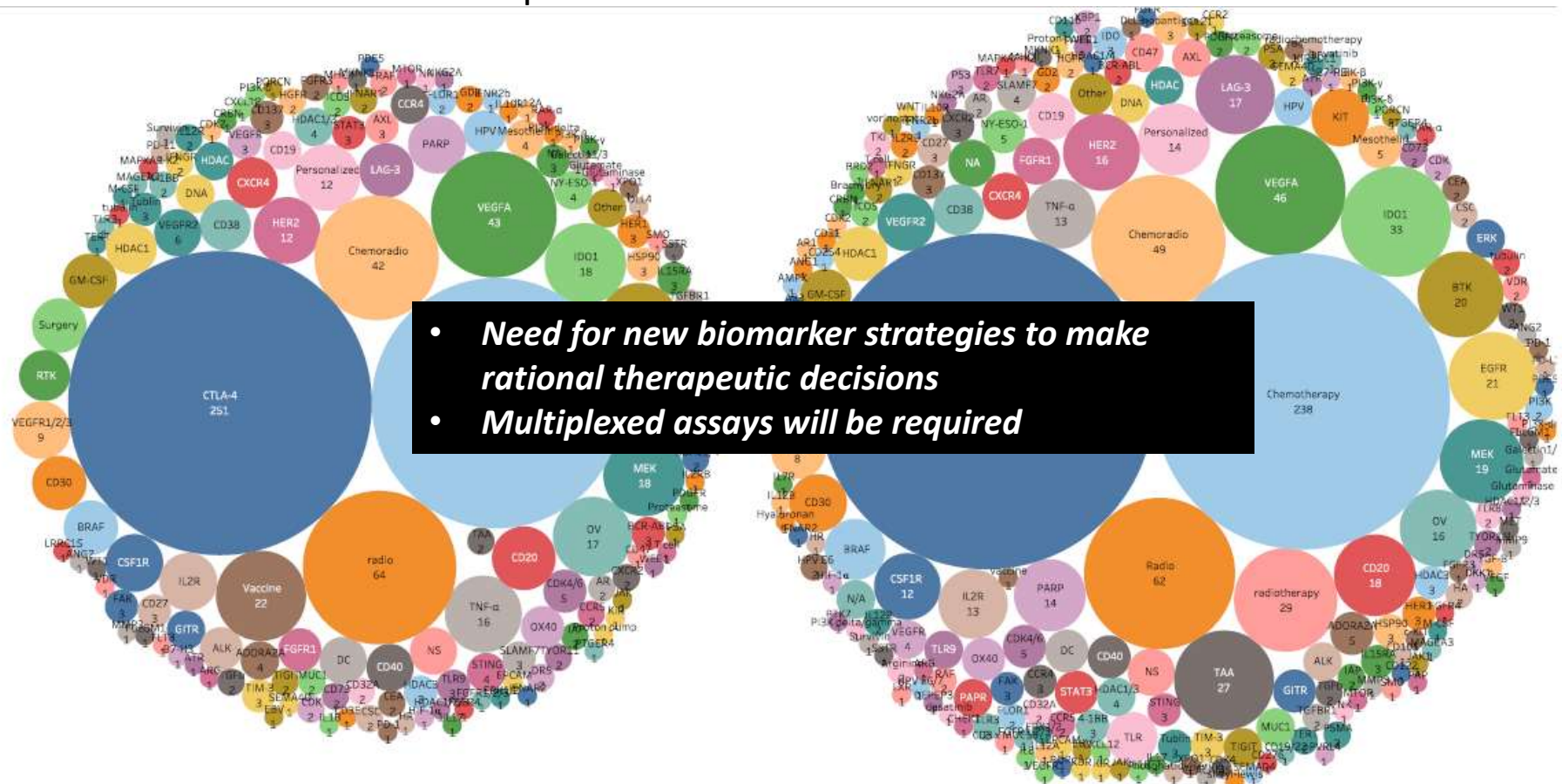


Challenges increase with combination therapies

334 new immunotherapy combo trials have started in 9 months

1105 combo trials as of September 2017

1449 combo trials as of June 2018



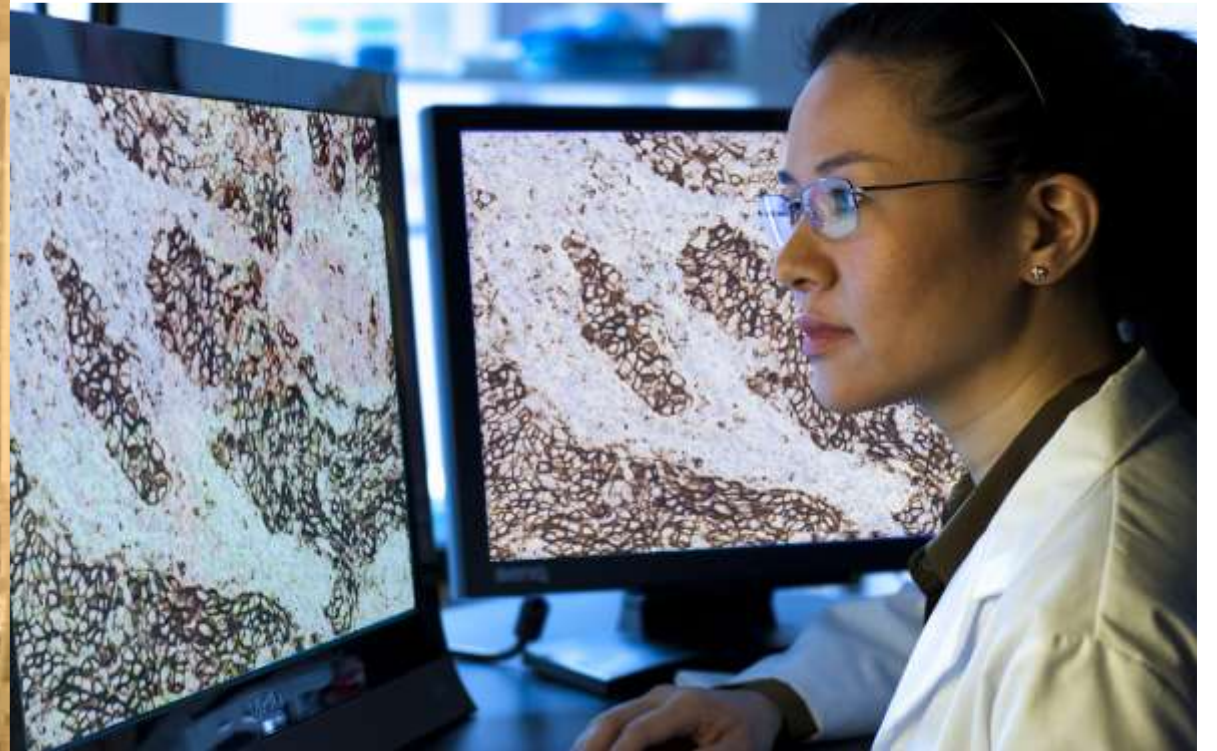
Too few pathologists to meet demand

Growing problems fuel new solutions



¹www.clpmag.com/2017/10/digital-pathology-gives-rise-computational-pathology/

Paradigm Shift



Welcome To The Era Of Digital Pathology



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DP Definition :

- Digital pathology is a dynamic, image-based environment that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide.

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Digital Pathology Workflow Essential Components

Pathologist Interface

Scanning



LIS