PATHOLOGY AI (Artificial Intelligence)

Holger Lange[1], Cris Luengo[2]
[1]Chief Technology Officer, Flagship Biosciences, Westminster, CO, USA, email: holger@flagshipbio.com,
[2]Director of Image Analysis, Flagship Biosciences, Westminster, CO, USA, email: cluengo@flagshipbio.com

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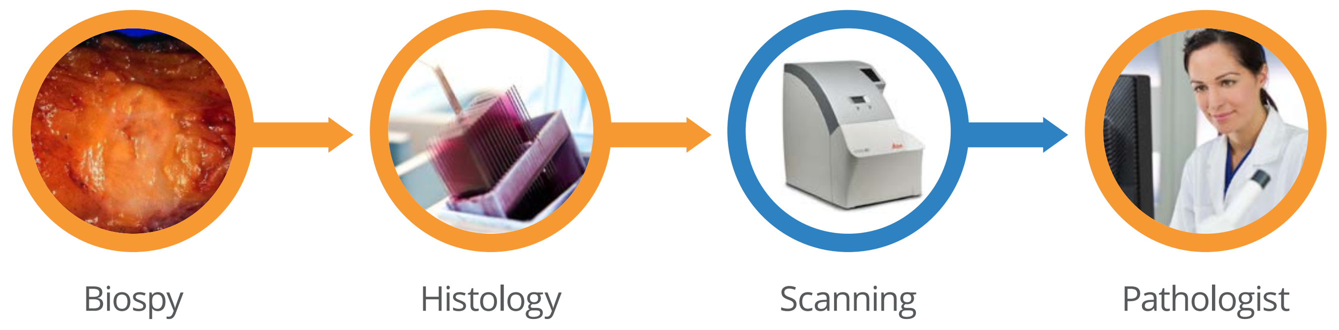
Background

Pathology (standard of care)

- Pathologists examine histology slides under a microscope, and provide either a single diagnosis (e.g. cancer/no cancer) or a single score (e.g. 0, 1+, 2+ or 3+).

Digital Pathology



- Digital pathology only replaces the microscope with a computer monitor.
- There is no tangible business case for digital pathology (unlike radiology), just convenience.
- Digital pathology enables pathology AI.

Deep learning has created a hype about artificial intelligence (AI) and healthcare AI.

Flagship Biosciences has been developing a pathology AI system over the last 8 years to solve the most challenging real-world tissue analysis problems across the entire pharmaceutical industry.

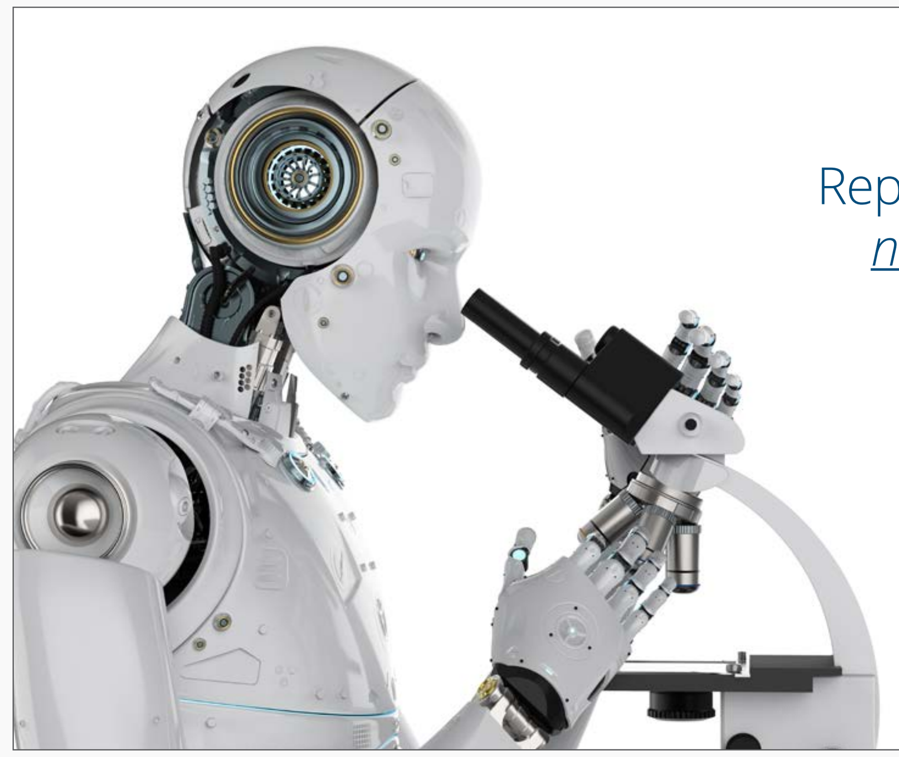
We share our experience and vision in the following key concepts and aspects around pathology AI.

References

LinkedIn article series engaging the community with in-depth discussions about the different aspects around Pathology AI: https://www.linkedin.com/in/drholgerlange/detail/recent-activity/posts

YouTube lecture series about Pathology AI:
Part I: https://youtu.be/ISAJBhBFOfA
Part II: https://youtu.be/sIc_yJEZ1l4
Part III: https://youtu.be/muFYjOnUGGs

Key Concepts



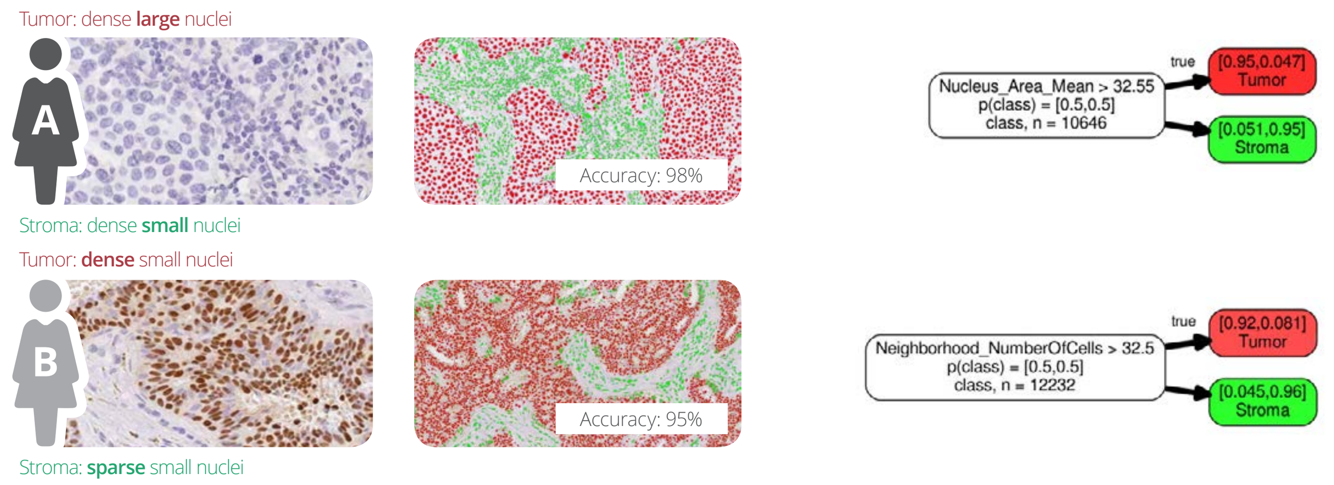
Replace the microscope,
not the pathologist!

WATCH YOUTUBE DEMO

A Pathologist-centric System Design

- Pathologists provide their expertise for each patient by identifying the different cell types and provide the proper controls for the cell detection and classification across the whole slide.
- Rich information data measurements can be verified properly during software verification.

Patient-type-specific Cell Classification



- Solves the key problem for any pathology AI system: the variations between different patient types.
- Simple decision trees provide excellent performance and transparency into the decision process.
- No need for training data and no need for deep learning.

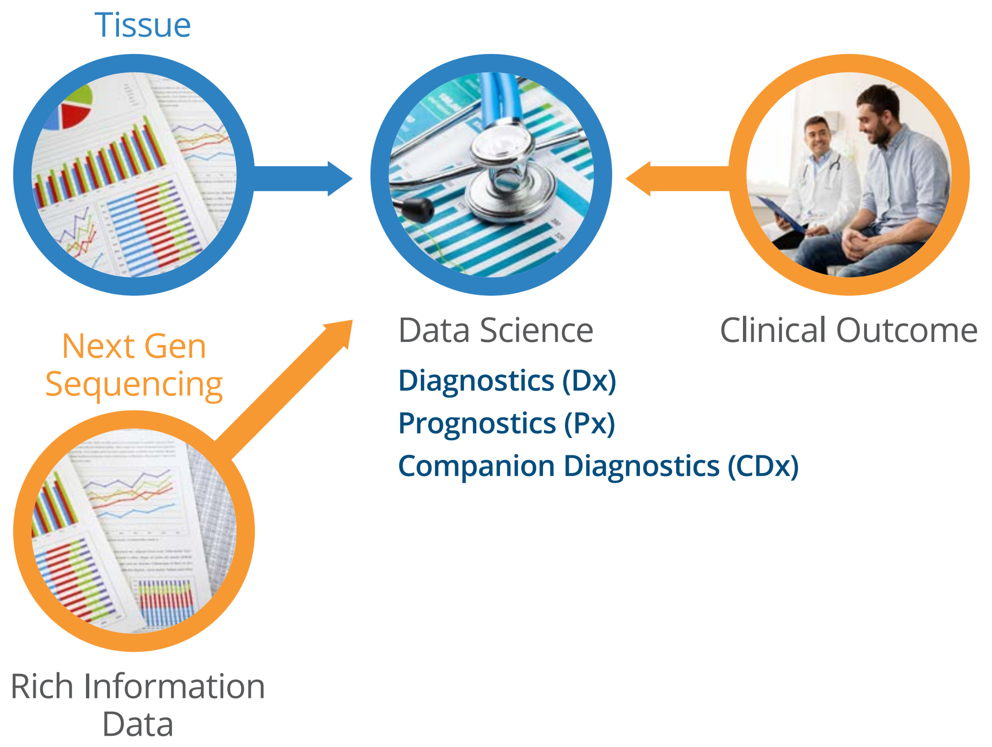
Full control and transparency into the decision process!

Conclusion

Pathologists using the right tools can perform high-performance, high-complexity tissue analysis!

- Pathologists provide their unique expertise about the tissue.
- Computers provide computational tasks that are impossible for humans.
- Pathology AI systems that replace pathologists will have a hard time achieving the performance of pathologists assisted by computers.

Healthcare Big Data



Diagnostics (Dx)
Prognostics (Px)
Companion Diagnostics (CDx)

- Requires moving from single-purpose, single-value pathology data to general-purpose, rich information data for tissue: cell type-specific cell distributions with biology-based features.
- 2-step approach:
  a. Single standard test that provides rich information data for a tissue type.
     - Simple regulatory clearance (only measurements, no clinical outcome).
  b. Diagnostics (Dx), Prognostics (Px) and Companion Diagnostics (CDx) are created by simply correlating the rich information data to clinical outcome.
     - Now it is just a scoring scheme.
     - All available (and future) drugs can be tested on the same test.
     - Clinicians in the field can develop their own tests.
- Integration with Next Generation Sequencing (NGS), radiology, etc.

Business Model

- The true barrier for pathology AI is the business model, not the technology.
- Barriers include a myriad of "tissue type" – "stain" – "indication" tests, each having only a $11 million market with < $10 per test, based on CMS reimbursement.
- Pathology AI requires a value-based business model (see pharmacogenomics): Single test saves thousands of dollars.
- Killer app: immuno-oncology (IO), providing a microscope-impossible test.
- Healthcare big data is a huge opportunity to save lives and lower healthcare costs.
- Pathology AI will drive the adoption of digital pathology.

Central Lab Model

- Cost-effective alternatives and smart intermediate steps for risk mitigation of a distributed medical device:
  - Lab Developed Test (LDT)
    - QMS to include digital pathology and pathology AI under CAP/CLIA.
    - Use any slide scanner and any 3rd party software.
  - Single-site Medical Device
    - QMS to include design controls.
    - Obtain FDA approval based on site-specific study.

- Digital pathology enables a very simple global service model:
  - No shipping of tissue or slides.
  - No extra IT at local sites.

Distributed Medical Device

- A pathology AI system needs to be manufactured as a medical device according to QMS compliant with ISO 13485, ISO 14971, IEC 62304 and FDA QSR.
- Obtain FDA approval based on multi-site studies conducted following good clinical practices for clinical trials.
- A global distribution channel is possible through partnership with IVD manufacturers.