CLINICAL INFORMATICS STRATEGY

Summary of strategic goals, tactics, and implementation plan recommended by the informatics strategy working team

Prepared for general distribution to CAP members and other interested parties

August 2013

Focusing CAP’s commitment to clinical informatics in support of pathology
ACKNOWLEDGMENTS ................................................................. 3
EXECUTIVE SUMMARY .............................................................. 3
DEFINITION OF CLINICAL INFORMATICS ................................. 7
CHANGING PARADIGMS IN THE EVOLVING HEALTHCARE ENVIRONMENT ......................................................... 8
PERSPECTIVE ON THE FUTURE .................................................... 10
CI STRATEGIC FOCUS AND TACTICS ........................................... 12
RISKS ASSOCIATED WITH INACTION ......................................... 15
STRATEGIC IMPLEMENTATION PLAN ........................................... 16
ACKNOWLEDGMENTS

This Clinical Informatics strategy ("the CI strategy," "the strategy") results from an iterative process with significant input and review by members and professional staff of the College of American Pathologists ("CAP"). The effort began in Q3, 2012, but builds on experience and insights developed over a number of years. We would like to acknowledge and thank those who participated in this project, including:

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- Diagnostic Intelligence and Health IT (DIHIT) Committee
- Transformation Program Office Steering Committee
- Strategy Management Committee
- Risk Management Committee
- CAP Consulting Steering Committee
- Council on Government and Professional Affairs / DIHIT Workgroup

EXECUTIVE SUMMARY

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CAP is committed to helping catalyze the transformation of pathology. Over the last several years, CAP built a case for change, describing why the specialty needs to evolve, how change might occur, and what benefits would result. Clinical informatics (CI) will be key to transformation. We define clinical informatics as “the application of information management in healthcare to promote safe, efficient, effective, personalized, and responsive care. Clinical informatics benefits individuals, institutions, populations, and communities.”

CI will help pave the way to context-driven pathology, improve clinical quality and reduce cost downstream, and enable the establishment of new channels for communication with clinical colleagues, hospital administrators, and patients.

The proposed strategy rests on three aspirations:

- Broaden CI experience and skills among practicing pathologists
- Strengthen the influence of practicing pathologists by helping them use CI to meet health information management needs of their practices
- Provide guidance on the CI standards and best practices that affect pathology

This strategy will guide CAP in helping members and their practices meet their CI needs. It defines where and how CAP should focus effort and investment in CI to support transformation, why that is valuable, and how to assess progress.

The CI strategy will:

- Enhance the capabilities of pathologists and pathology practices to deliver measurable value in the evolving healthcare environment
- Support members in making scalable, sustainable change at multiple levels—individual, practice, healthcare
- Enable interaction, collaboration, and knowledge-sharing across the CAP membership
- Fulfill the goals defined in the Transformation Strategy and provide guidance for CAP’s CI efforts
- Enhance CAP program integration and knowledge-sharing to meet prioritized CI needs
- Strengthen CAP’s commercial functions

CAP already conducts many activities related to CI, including efforts on standards, CAP Learning offerings, DIHIT Committee projects, and advocacy and policy efforts in Washington DC. Rather than defining one-off initiatives to implement this enterprise strategy, we envision collaborative efforts to weave CI into the fabric of CAP.

We recommend that the DIHIT Committee, or an appropriate successor group, assume a central role in implementing the CI strategy, serving as:

- Architect—translating the CI strategy into initiatives, measures, and targets
- Integrator—working with other CAP committees/functions (e.g., CAP Learning and Advocacy) to build and use resources and expertise most effectively
- Custodian—providing ongoing oversight of strategy implementation

DIHIT will coordinate the efforts of CI experts and others in CAP to achieve the strategic goals and execute the strategic implementation plan.

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1 Andrew E. Horvath MD, FCAP, Walter H. Henricks MD, FCAP

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Developing the clinical informatics (CI) strategy

CAP leadership identified the development of a CI strategy as key to ensuring optimal patient care and maintaining a competitive edge in a changing healthcare environment. Based on research and interviews with thought leaders and subject-matter experts, we defined clinical informatics and secured BOG approval of that definition. We developed a comprehensive list of CI needs for pathology and laboratory medicine, including test utilization, analysis, and reporting; understanding of laboratory information systems (LIS) and electronic health record systems (EHR); “-omics” interpretation and storage; and clinical decision support. Based on these needs, we defined six CI goals linked to CAP’s transformation goals (see chart below). The BOG, XCOM, and TPOSC have all endorsed these goals.

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<td>2.3 Enable the specialty’s sustainable advantage</td>
<td>Focus CAP on CI standards and guidelines</td>
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<td>Support development of CI best practices</td>
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The CI strategy also outlines tactics for achieving each strategic goal:

**Build visibility for CI roles and contributions**
- Make practicing pathologists aware of value-creating roles that require CI capabilities
- Increase awareness of the CI sub-specialty among pathology residents and residency programs
- Make healthcare stakeholders (CXOs, payers, and others) aware of the impact that quality lab and pathology information and the pathologist’s information management role have on improving patient care and cost-effectiveness

**Ensure pathology (and by extension CAP) is seen as the leading authority on integrating lab and pathology information into CI**
- Develop a portfolio of positions/policies to support pathology’s role in information management
- Ensure that sufficient economic incentives and a sustainable regulatory environment exist and reflect pathology’s interests
Build basic knowledge of CI among practicing pathologists

- Infuse CI basics throughout CAP’s learning portfolio
- Explore alternative methods of knowledge-sharing among practicing pathologists

Foster development of access to practice-level CI capabilities

- Facilitate design of and access to information management tools that help practicing pathologists integrate lab data across enterprise systems, ACOs, HIEs, and EHRs
- Monitor and intervene selectively in vendor development of information technologies to ensure that information management capabilities are built into lab systems
- Facilitate the integration and interpretation of clinical, diagnostic, and therapeutic information in pathology and lab reporting

Focus CAP on CI standards and guidelines

- Monitor and intervene selectively in developing standards to ensure inclusion of the functional requirements needed to manage lab and pathology data
- Define or endorse CI quality standards for accreditation, quality management, and other practice needs
- Monitor evolving practices and standards to identify emerging trends in healthcare information technology and their potential impact on lab and pathology practices

Support development of CI best practices

- Ensure that best practices for the assimilation, analysis, and communication of lab and pathology data stored in the EHR are developed, implemented, and communicated to practices and practicing pathologists
- Equip pathologists to be the stewards of lab information in EHRs by building understanding of the way that EHRs view and store data.

The CI strategic goals and high-level tactics provide the basis for the strategic implementation plan.
DEFINITION OF CLINICAL INFORMATICS

"Informatics is the science of information management" – John Sinard MD, PhD, FCAP

- The CI strategy focuses on a subset of informatics.
- CI will be key to transformation.
- We define clinical informatics as “the application of information management in healthcare to promote safe, efficient, effective, personalized, and responsive care. Clinical informatics benefits individuals, institutions, populations, and communities.”

The term informatics is broad, with many similar definitions used across industries. We define informatics as the “science of information management.” The strategy focuses on a subset of informatics – clinical informatics, which we define as “the application of information management in healthcare to promote safe, efficient, effective, personalized, and responsive care. Clinical informatics benefits individuals, institutions, populations, and communities.”

CI sits at the intersection of three domains of activity:

- Clinical care provided to an individual patient
- The health system — the structures, processes, and incentives that shape the clinical care environment, including such major health domains as public health, population health, personal health, health professional education, and clinical research, as well as clinical care
- Information and communications technology – tools that enable capturing, delivering, transmitting, and using data, information, and knowledge efficiently and knowledge of how to use those tools effectively

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CHANGING PARADIGMS IN THE EVOLVING HEALTHCARE ENVIRONMENT

“No one has to change. Survival is optional.” - William Edwards Deming

- Unsustainable costs trends are driving healthcare reform, creating alternative payment models to the fee-for-service model.
- The emergence of a value-based setting will place greater emphasis on effective information management to enable efficient high-quality care, patient safety, effective resource utilization, and better health outcomes. New reimbursement models, along with electronic health records (EHRs), are changing the way pathology will contribute to optimal patient care.

Over the past several decades, pathologists have practiced in a healthcare environment where volume determined payment (fee-for-service), encouraging focus on maximizing productivity (units of service) while reducing unit cost. This environment did not encourage pathologists to address value more broadly. Unsustainable cost trends are driving healthcare reform, creating alternative payment models to fee-for-service. While we do not believe fee-for-service will disappear, we see a value-based setting emerging, placing greater emphasis on effective information management to enable efficient high-quality care, patient safety, effective resource utilization, and better health outcomes.

New reimbursement models, along with electronic health records (EHRs), are changing the way pathology will contribute to optimal patient care. With the launch of the Medicare and Medicaid Electronic Health Record Incentive Programs and the Office of the National Coordinator (ONC) for Health IT (HIT) Certification Program, requirements for standards-based health information exchange (HIE) across providers and care settings are increasing. As government programs develop, requirements will increase to enter, communicate, and store pathology and laboratory information in structured formats to support optimal care of individual patients and analysis of population health across the country.

As the basis for healthcare payment shifts from volume to value, pathologists will have to demonstrate true, differentiated value, and CI will be critical to their success. Pathologists stand to play a substantive role in CI management. They will need to combine their unique domain knowledge and diagnostic expertise with CI tools in order to improve clinical outcomes and generate cost savings for patients, institutions, and payers.

In order to use CI effectively, pathologists will need to:
- Understand that they engage with CI issues every day
- Build competence in CI to support evolving practice needs
- Understand emerging areas where the application of CI (“managing information in a new way”) creates new sources of value, including the use of information to improve diagnosis, prognosis, and treatment decisions and outcomes for individual patients and populations
- Embrace standards and best practices for incorporating CI into daily practice
- Connect with other pathologists “making their way” in this space

The Head of Hematology and Oncology contacts you for data on the number of lung cancer cases that had positive lymph nodes on resection over the past 2 years. She also informs you that their new clinical trials system has fields for various pathologic staging elements (e.g., number of nodes) and asks if you can provide these data as discrete elements.

- How do you respond to this request?
- What are the main issues/challenges?
- Secure access to CI experts, a shared knowledge base, and capabilities, tools, and resources to support daily practice
- Acquire solutions to:
  - Improve the ordering of pathology and laboratory tests
  - Enhance specimen analysis and interpretation
  - Manage and correlate vast amounts of data from genomic analysis (in the LIS and EHR)
  - Ensure accurate and effective results reporting
- Explore business model options and start-up approaches that include CI capabilities.

Practices will need:
- Guidance on business model options and start-up approaches, most of which cannot succeed without effective information management strategies and resources
- Examples of other practices “making their way” in this space
- Practical guides, tools, and advice on building CI capabilities

Today CAP addresses some, but not all, of these issues. The CI strategy counts on current capabilities and recommends changes to fill gaps.
PERSPECTIVE ON THE FUTURE

“The goal is to turn data into information, and information into insight.” - Carly Fiorina, former CEO, HP

- We envision pathologists and practices leveraging CI capabilities to transform healthcare.
- The strategy rests on three aspirations for pathologists: Broaden CI experience and skills among practicing pathologists, strengthen the influence of practicing pathologists by using CI to meet health information management needs, and provide guidance on CI standards and best practices for pathology.
- The CI strategy does not envision all pathologists becoming informaticists or informatics experts, but transformation will require more to become significantly more sophisticated in their knowledge and use of CI.

We envision a future where CI delivers significant benefits to pathologists, as well as their customers:

- Paving the way to context-driven (real-world) pathology data management
- Improving clinical quality and outcomes downstream
- Generating clinical cost savings downstream
- Establishing new channels for communication with clinical colleagues, hospital administrators, and patients

We envision pathologists and practices using CI capabilities to “…transform healthcare by analyzing, designing, implementing, and evaluating information and communication systems that enhance individual and population health outcomes, improve patient care, and strengthen the clinician-patient relationship.”\textsuperscript{5}

We believe those who know most about diagnosing disease should combine that knowledge with understanding of informatics concepts, approaches, and tools to:

- Assess the information and knowledge needs of healthcare professionals and patients
- Characterize, evaluate, and refine clinical processes
- Develop, implement, and refine clinical decision support systems
- Lead or participate in the procurement, customization, development, implementation, management, evaluation, and continuous improvement of CI systems

These beliefs translate into three aspirations that guide the CI strategy:

\textsuperscript{5} (Reed M. Gardner, 2009) – multiple quotes (italicized)
• Broaden CI **experience** and skills among practicing pathologists
• Strengthen the **influence** of practicing pathologists by using CI to meet health information management needs
• Provide **guidance** on CI standards and best practices for pathology

The CI strategy does not envision all pathologists becoming informaticists or informatics experts. As David Booker, MD FCAP, puts it, “Most pathologists will need to know only a few things about clinical informatics: What tools are available? Which should I use? How do I use them?”

Certainly, some pathologists are already CI specialists, and successful transformation will require more to become significantly more sophisticated in their knowledge and use of CI, possibly specializing or dedicating part of their day to this work. But the CI strategy does not envision this as the broad future of the specialty.

Nevertheless, pathologists should begin to position themselves at the intersection of the three domains (clinical care, the health system, and information and communications technology). Besides possessing deep medical knowledge, this will require understanding, at a minimum:

• The field of clinical informatics
• The healthcare environment, including the influence of business processes on healthcare delivery and the flow of data among the major components of the health system
• The impact of information systems and processes (positive and negative) on the decision making and actions of healthcare team members
• The re-engineering of healthcare processes
• Fundamental information system concepts, including the life cycle of systems, the constantly evolving capabilities of information technology and healthcare, and the technical and nontechnical issues involved in system implementation
• The impact of CI systems on users and patients, clinician users’ support requirements, and ways to promote clinician adoption of systems
• The evaluation of information systems to enable system improvement
• The leadership of organizational change, especially fostering collaboration and communicating effectively.6

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6 (Reed M. Gardner, 2009)
CI STRATEGIC FOCUS AND TACTICS

“The CI strategy defines where CAP should focus effort and investment in CI to support transformation.
The CI strategy describes six areas of strategic focus and tactics for achieving each of them.”

The CI strategy defines where CAP should focus effort and investment in CI to support transformation. The strategy defines focal areas that, taken together, would enable pathologists to develop the capabilities needed to use CI effectively, positioning pathologists to become the primary champions for appropriate management of lab and pathology information in:

- Selecting and ordering laboratory tests
- Analyzing and interpreting test results (including outsourced tests)
- Reporting and applying results in clinical care and treatment decisions
- Understanding laboratory information systems (LIS) and electronic health records (EHRs)
- Understanding molecular, genomics, and imaging modalities and use of relevant databases
- Using data/information for better decisions on diagnosis, prognosis, and treatment and better outcomes for individual patients and populations

The strategy sets six strategic goals, selected for the reasons outlined below:

Build visibility for CI roles and contributions. In a coordinated healthcare system, using CI to improve performance offers a way for pathologists to reassert their role as valued members of the patient care team. Success will require pathologists to understand the potential of these new roles and non-pathologists, such as CXOs, to understand the value pathologists bring to the team.

Ensure pathology (and by extension CAP) is seen as the leading authority on integrating laboratory and pathology information into CI. Supporting CAP members in maintaining their economic viability is core to CAP’s mission. Positioning pathology (and by extension CAP) as the leading authority on lab and pathology information creates opportunities to influence policies and the regulatory environment.

Build basic knowledge of CI among practicing pathologists. CAP members require at least basic knowledge of CI. While not all pathologists need to become informatics specialists, all do need to have a basic knowledge of CI management in order to deliver measurable value in the evolving healthcare environment.

Foster development of access to practice-level CI capabilities. Even the most critical tests and procedures cannot ensure pathology’s criticality in coordinated care settings. Pathologists and pathology practices must become better able to prosper in a competitive space, and they will need CI capabilities for competitive advantage.

Focus CAP on CI standards and guidelines. Standards and guidelines add considerable value to the diagnostic process. With Meaningful Use pushing the adoption of EHRs, CI standards and guidelines
become essential. Participation in developing clinical standards is integral to CAP’s mission of improving patient care.

**Support development of CI best practices.** CI best practices in pathology reporting and EHR information handling facilitate the delivery of high-quality care that achieves the best outcomes. CAP must be a leading authority in ensuring developing and disseminating appropriate best practices.

The CI strategy outlines specific tactics for achieving each strategic goal.

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2.3 Enable the specialty's sustainable advantage

**Focus CAP on CI standards and guidelines**
- Monitor and intervene selectively in developing standards to ensure inclusion of the functional requirements needed to manage lab and pathology data
- Define or endorse CI quality standards for accreditation, quality management, and other practice needs
- Monitor evolving practices and standards to identify emerging trends in healthcare information technology and their potential impact on lab and pathology practices

**Support development of CI best practices**
- Ensure that best practices on assimilation, analysis, and communication of lab and pathology data stored in the EHR are developed, implemented, and communicated to practices and practicing pathologists
- Equip pathologists to be the stewards of lab information in the EHR by building understanding of the way that EHRs view and store data

Effective execution of these tactics would:

- Enhance the capabilities of pathologists and pathology practices to deliver measurable value in the evolving healthcare environment
- Support members in making scalable, sustainable change at multiple levels—individual, practice, healthcare
- Enable interaction, collaboration, and knowledge-sharing across the CAP membership
- Fulfill the goals defined in the Transformation Strategy and provide guidance for CAP’s CI efforts
- Enhance CAP program integration and knowledge-sharing to meet prioritized CI needs
- Strengthen CAP’s commercial functions.
RISKS ASSOCIATED WITH INACTION

“There are risks and costs to a program of action, but they are far less than the long-range risks and costs of comfortable inaction” - J.F. Kennedy

- Failure to act would put pathologists’ success in the future healthcare environment at risk.
- Failure to support pathologists’ CI needs would diminish CAP’s reputation as thought leader and advocate.

We recognize several risks associated with failure to implement the CI strategy:

- Failure of pathologists to take a CI leadership role could limit success in the future healthcare environment.
- Other specialties could assume a pivotal role in areas where pathologists could lead (e.g., CI management), reducing the pathologist’s role as a physician.
- Pathologists could lose the opportunity to shape their economic future in the changing environment.
- Pathologists could lose the opportunity to be at the forefront of the rapid progress in genomics and molecular pathology, which use of CI facilitates.

CAP failure to support the CI needs of pathologists in transformation would diminish CAP’s reputation as thought leader and advocate. Lack of CAP guidance and advocacy would disappoint members who already understand the importance of CI in transformed roles. This would have lasting negative impact on CAP’s ability to achieve the OPEN goals.

Other respected professional organizations, including the American Society of Clinical Oncology (ASCO) and the Radiological Society of North America (RSNA), are playing active roles in innovating and partnering with others on CI. This includes developing CI standards and working to understand what their members need from HIT and HIT vendors.
CAP’s current involvement in activities related to the CI strategy, including efforts in standards development work, CAP Learning offerings, DIHIT Committee projects, and advocacy efforts in Washington DC, provides a solid foundation for strategically enhancing our informatics efforts.

To develop a comprehensive implementation plan, we analyzed current and proposed CI initiatives across CAP. We reviewed objectives, strategic focus, timelines, staffing, budget constraints, and requirements for member volunteer time. Central to the analysis were the DIHIT Committee’s current and proposed initiatives, as well as other CAP initiatives. DIHIT Committee members participated in developing and reviewing prioritization criteria. The review paid particular attention to the links between initiatives and the six strategic CI focus areas, transformation goals, and XCOM and TPOSC guidance on priorities. In parallel, we similarly analyzed baseline activities to ensure appropriate prioritization of initiatives and baseline activities.

The analysis generated a comprehensive landscape of initiatives, including synergies, overlaps, and dependencies. We mapped the correlation of current or proposed initiatives with strategic goals to identify gaps.

Then we developed criteria for prioritizing initiatives, based on guidance from leaders and members of the CI working group, the XCOM, and the TPOSC. The prioritization of initiatives has four dimensions:

1. Impact of initiatives on:
   - Patient care and safety
   - Pathologists and practices
   - The specialty of pathology
   - The general healthcare environment

2. Alignment with transformation mission and vision
   - Roadmap and tools to catalyze the transformation
   - Distribution of initiatives among pathologist, practice, and environment

3. Timing / urgency
   - Initiative timelines/overlaps
   - Dependencies on other projects

“However beautiful the strategy, you should occasionally look at the results.” - Winston Churchill

- CAP already conducts many activities related to the CI strategy.
- The strategic implementation plan outlines CI activities and initiatives and CAP investment scenarios focused on environmental and pathology practice needs.
- The plan includes success criteria and measures for all prioritized initiatives and basic activities.
- We recommend increasing investment levels for maximum impact on the transformation goals.
• Need to participate in government discussions of policies
• Impact on delay of projects

4. Investment requirements
   • Staff resources
   • Member expertise and participation
   • Financial investment.

Achieving the six goals of the CI strategy will require CAP investment over a number of years. The level, focus, and timing of that investment will affect the pace and degree of achievement. To monitor progress toward achieving the strategic goals, we defined three dimensions of impact on which we based our recommendations for priority initiatives:

• Environment — participating in developing standards, public policies, laboratory and EHRs, and software tools that support practice strategies to fit the healthcare environment
• Pathology practices — providing informatics capabilities and tools for use in a practice setting where one or more members can handle technical issues
• Individual pathologist — creating opportunities to develop informatics understanding and skills.

The XCOM and TPOSC recommended making initiatives that affect the environment the highest priority and those that enable pathology practice capabilities the second priority. These initiatives, especially those focused on environmental factors, promise the greatest short- and medium-term impact on members and the specialty. Initiatives focused on the individual pathologist are also important but will have less impact on the membership, though they will benefit pathology practices. The recommended initiatives reflect this prioritization.

The final prioritization of the initiatives will be set among the relevant committees, management and subject matter experts after the budget allocation and available staffing are determined. The intended content and components of each initiative will be refined and finalized at the time of project initiation.

Most of the 11 recommended CI initiatives originated in the DIHIT Committee. We matched these initiatives, along with TPO-led initiatives, with the desired impact and specific objective.

**Overview of recommended informatics initiatives**

**Top Priority: Accreditation-related initiatives**

Accreditation Standards Revision: Review of LAP checklists in light of Meaningful Use requirements and proposed CLIA guidance in this area, as well as overall review of LAP checklists in an electronic reporting environment

**Second Priority: Vendor-related initiatives**

Vendor Collaboration: Facilitation of change in pathology informatics through an implementation mechanism to see CAP-generated guidance and practices realized in the vendor marketplace

EHR Error Repository: Creation of a repository of real-world errors and patient safety risks that occur in managing laboratory information in the EHR

Data Interoperability and Flow: Development of an infrastructure for implementation of an integrated disease report. Built on the data elements in the DIHIT Integrated Disease Report project (TPO Initiative #23)
Decision Support Informatics Rules: Development of an open access library/database of existing clinical decision rules relevant to pathology, with a probable focus on test utilization, to provide the basis for further development and evaluation of new decision rules

Lower Priority (Final priority dependent on Learning)

Lab Technology Case Reviews: Creation of a library of pedagogically useful case studies in pathology informatics that communicates fundamental knowledge in informatics using a hands-on approach, depicting future informatics practice patterns, and making a convincing case using a story-telling strategy that informatics is a component of pathology practice

Other Initiatives

Knowledge Base Platform (options currently in discussion): Originally proposed as a CI initiative; TPOSC recommended consideration as an independent proposal that is broader, and has implications beyond, CI

PHC Case Study (joint with Center): TPOSC recommended this initiative as more appropriately considered in connection with the Genomics and Center strategies

GME Curriculum Revision: Improvement of graduate medical education for pathology to provide a sufficient pipeline of residents and fellows trained in the new knowledge and skills required now and in the future particularly in the topic of Informatics

Pathology Competency Model: Maintenance of the pathologist competency model as a key foundational element of the learning strategy and learning portal

Learning for Enhanced Pathology Services: Identification of informatics and genomics competency gaps limiting pathologists from providing transformational services, and provide learning solutions to address those gaps