Strategies for integrating digital pathology into your business plans and workflow

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DISCLOSURE

In the past 12 months, I have had a significant financial interest or other relationship with the manufacturer(s) of the following product(s) or provider(s) of the following service(s) that will be discussed in my presentation.

Philips Digital Pathology Solutions, Consultation fees, Consultant and Member of Scientific Advisory Board
Goal of Presentation

• Present “Systems Thinking” approach for integrating Whole Slide Imaging into business plans and AP Workflow
Why are you attending this workshop?

• There has been an increased interest in DP for clinical use
  – FDA cleared the first system for primary diagnosis April 2017
  – Recent market research from multiple groups predict high annual growth rate in WSI and image analysis
  – There are increasing numbers of lectures workshops at national conferences, as well as publications on the subject.
What is “Systems thinking?”

• Systems thinking is interdisciplinary, and not IT specific

• It’s an approach to solving complex problems in real-world environments

• Evolved from systems engineering, which is an approach to constructing large and complex projects (NASA)
Framework for Systems thinking

• **Systems Architecture**
  – What are you trying to do?
  – At a high level, how are you going to achieve it?
  – Know the context of your system
  – How will you measure success?

• **Systems Engineering**
  – What components do you need to achieve your goal?
  – How will your entire process be integrated and connected?
  – How will feedback loops work to optimize your workflow?

• **Project Management**
  – Who needs to be at the table?
  – Who is championing the project?
  – What is your timeline?
  – How do you build flexibility to learn from your implementation?
STEP 1. DECIDE WHY YOU WANT TO USE DIGITAL PATHOLOGY IN YOUR CLINICAL WORKFLOW
Strategy should be your driver

• Define your strategy at the management level

• “How can my practice/business benefit from the use of Digital Pathology?”
  – Consolidate resources?
  – Expand outreach?
  – Further subspecialize your practice?
  – Provide new services?

• Does your strategy have enough buy-in from business and process owners to justify investment?
Understand your environment

Do a stakeholder analysis
Know your current constraints

- Pathologists’ attitudes toward DP
- Technical staff attitudes toward DP
- Regulatory boundaries and guidelines
- Timeline constraints on IT and/or business strategy
- What is the “intended use” of your scanning system
- What are the capabilities of your current LIS or workflow management system
Validate high level concept with stakeholders

• “Pathology is not an island”
• Know which stakeholders are needed for successful implementation
  – Facilities IT
  – IT (who will maintain these systems, who will interface the systems)
  – Compliance
  – Security
  – Legal
Know how you will measure success

• Suggestion: It’s still early. Do not rely on fiscal ROI alone
• Choose which properties are important
  – Ease of use
  – Improved communication
  – Pathologist satisfaction
  – Impact on physician experience
• Choose how to measure them
STEP 2. HOW, EXACTLY, ARE YOU GOING TO ACHIEVE YOUR VISION?
### What are the components of your "Digital Workflow" system?

- **Acquisition**
  - Biopsy
  - Triage
  - Glass
  - Process

- **Database**
  - Database Interface
  - Microscope
  - Quality

- **Scanner**
  - Embed
  - Machine Learning
  - Scan Speed
  - Resolution

- **Technicians**
  - Orders
  - Maintenance
  - Inspection

- **Modeler**
  - Pre-Condition
  - Decision Loop

- **Pathologists**
  - Knowledge
  - Slide Diagnosis

### Who will be operating within the system, and what will they be doing?

- **Acquisition**
  - Technicians
  - Modelers

- **Database**
  - Database
  - IT Network

### How are you going to connect it all together?

- **Scanner**
  - Digital Representation
  - Network Connection
  - Database

- **Database**
  - Server
  - Database
  - Slide Archival

- **Pathologists**
  - Code
  - Archival

- **Modeler**
  - Simulation
  - Pre-Condition

- **Technicians**
  - Inspection
  - Maintenance

- **Database**
  - Image System
  - Clean
Tip 1: Documentation for regulation

• Don’t forget the documentation as part of your system
  – System validation
  – Pathologist validation on system
  – Histotechnologist/scanner validation
Tip 2: Metrics are important

- Measure it, Understand it, Improve it
- Three areas of suggestion
  - Pathologist satisfaction/experience
  - Workflow efficiency
  - Scanning errors
Tip 3: Strengthen feedback loop processes

• Example: Histology/Scanning QC
  – Traditionally a paper process
  – Telepathology creates greater distance between pathologist and Lab
    • QC correction must be responsive to optimize benefits of telepathology

• How can you create feedback loops that enable responsive improvement?
STEP 3. PLANNING AND EXECUTING YOUR IMPLEMENTATION
“Big Bang” or gradual transition

• Few groups will be able to convert to an entirely digital workflow today

• How do you prioritize what goes digital and when?
  – Go back to your strategy
    • What work is most important?
## Protecting the Vision

### Risk Management and Mitigation

<table>
<thead>
<tr>
<th>Risks Log</th>
<th>Owner</th>
<th>Probability</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Loss of trust/interest by Champion Users</td>
<td>Medical Director of Digital Pathology</td>
<td>Likely</td>
<td>Critical</td>
</tr>
<tr>
<td>2. System functionality/benefits not as theorized</td>
<td>System Manager</td>
<td>Possible</td>
<td>Critical</td>
</tr>
<tr>
<td>3. Regulatory requirements erode financial benefits</td>
<td>FDA, Medical Director</td>
<td>Possible, but not likely</td>
<td>Critical</td>
</tr>
<tr>
<td>4. Scanner determined to be too manual to be feasible (&gt;3% rescans)</td>
<td>Lead Technician</td>
<td>Possible</td>
<td>Critical</td>
</tr>
<tr>
<td>5. User Interface/Experience is clunky</td>
<td>Project Manager</td>
<td>Very Probable</td>
<td>Medium</td>
</tr>
<tr>
<td>6. Transition is voluntary and not mandatory</td>
<td>Dept AP Leadership</td>
<td>Very Probable</td>
<td>Medium</td>
</tr>
<tr>
<td>7. System works, but doesn't interface well with other commercial systems</td>
<td>System Manager, Project Manager</td>
<td>Probable</td>
<td>Medium</td>
</tr>
<tr>
<td>8. Transition takes too long</td>
<td>Project Manager</td>
<td>Probable</td>
<td>Medium</td>
</tr>
<tr>
<td>9. System only applicable to MGH</td>
<td>Project Manager, System Manager</td>
<td>Low Probability</td>
<td>Medium</td>
</tr>
</tbody>
</table>

Note: Risk assessment and mitigation is addressed through risk management meetings in Project Schedule.
Summary

1. Engineer your workflow to enable your overall strategy
2. Design for the real world
3. Don’t forget the People that make your system work
4. Metrics and feedback loops are important
5. Approach your digital transition strategically
Gratitude

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Thank you

Any questions?
References


