Expanding the use of digital pathology to drive revenue and create a competitive advantage
Disclosure

I am a consultant for Dermatopathology Laboratory of Central States (DLCS- ClearPath LLC. DLCS owns 100% of Clearpath™ LIS and digital pathology product.
Compexity Made Simple
Background

30 years in diagnostic lab industry

- Nichols Institute, Specialty Labs, Large regional lab, Start up molecular lab
- Founded and sold 2 start-up cloud based lab software products
- Extensive experience in Molecular, NGS, AI and digital pathology

Consulting Specialties

Business development, Marketing, New Test Development, and LIS Optimization
Variables of a Successful Revenue-focused DP Program

- Digital Scanner
- User Simplicity
- Workflow efficiency
- Outreach Marketing
- LIS Integration
Digital Pathology Revenue Opportunities Today

- Biorepository $$
- Image Analysis Interpretation $$
- Workflow improvements $$
- Secondary consults $
- TC/PC Reads $$
- Assisted Dx (AI) $$
- “Pull through” $$$
A Clinical Lab Case Study: Using DP for Outreach

• **Goal**: Take current DP technology and create an easy to use tool to drive revenue to laboratory
  – Midwest regionally-focused Dermatopathology lab doing ~ 800 cases a day
  • Dermatologists trained in Dermpath
  • CLIA allows derms to read own cases
  • Derm has few difficult diagnoses
  • Easy learning curve of technology
  • Allows Dermatologists to use digital slides as teaching tool for colleagues or patients

**CORE Differentiator** - Functionality tied to user workflow. Takes out the “Clunkiness” of current DP systems through lab integration
Timeline of Product Evolution

2012- Midwest Lab develops IPAD based digital pathology EDUCATIONAL app to help residents prepare for Derm boards
   - Rated best teaching app in 2014 by derm residents
2015- Image viewer technology on tablet extended to working prototype for pathologists at lab
   - Technology also used to build out LIS for complete integration
2016- First clients start using for TC/PC, internal concordance/efficiency study completed and presented at DPA.
2017- Concordance paper published in JAMA Dermatology. Began next evolution of DP data mining with AI company Proscia
2018- Proscia and DLCS-Clearpath LLC announce plans to create first dermatology-specific DP computational pathology suite
General Workflow – Once Validation Complete

- Client sends in biopsy for processing
- Lab accesses sample, creates slide(s), scans slide at 20X or 40X
- Digital images placed in client’s password protected workbox on-line
- Glass slides mailed to client (for confirmation)
- Client has control over diagnosis and additional help
Key Features of Clearpath™
Product from a User Perspective

Remote user can read cases from anywhere using a touch enabled digital scope
- Image has rotation, measurement and magnification tools
- Image can be shared with patient if desired

All patient information incorporated into one view extending LIS features for diagnosing cases
- CPT and ICD10 codes
- Canned Diagnostic Comments
- Interfacing to EMR

Interaction with processing lab seamless for additional stain orders or push for global reads
- Difficult cases
- Vacation coverage
Set-up Process for New Clients

- Lab sells or counsels client on approved tablets and monitors for viewing images (IPAD Pro most popular)
- Client performs CAP recommended validation study to show concordance between glass and digital
- Lab creates customized reports for client
- Remote training for first cases
- Lab bills TC and Client bills PC
Typical Early Adopters

• Education-oriented Derms/Dermpaths

• Rural and Remote clinics where one derm/dermpath reads for many doctors

• Tech-savvy Dermatologist looking to integrate more parts of their practice

• Clients looking to make extra income through TC/PC split
Accretive to the Business

Revenue per slide  $26*
Variable Expense
- Technical Preparation  $8.57
- Delivery  $4.28
- Billing  $0.78
- Sales  $0.97
- Scanning  $0.50
- Other  $1.75
**Total Costs**  $16.85

- Gross Profit $9.15 or 35% GM

*Higher margin increases come from additional global work, consults and recuts (revenue side) and efficiencies on expense side. Logistics costs come down with volume and removal of slide return in future

NOTE: Lab increased revenue run rate by 10% first year
Expense plan for managing system and growth

• Slide scanning instrument maintenance and service
  – $25-50K/yr.

• Implementation team for set up and training
  – 1-2 FTEs

• IT support
  - 1 FTE

• Optional
  – Marketing
  – Sales
Adoption Drivers of Growth

- Insurance contracts for lab
- Continued FDA Approval for Systems and Segments
- Broader experience using Digital images in practice
- Integration into EMRs/LIS
- Positive word of mouth and networking of existing customers
- Consultative features of product
- Addition of image analysis tools accessible through viewer (ex. Derm Identification Algorithm)
Implementing AI into workflow

- Partnered with Proscia Inc, an AI pathology software company
- Expanding validation study in 2018
- Pilot deployment in late 2018 as a part of digital workflows

Where AI operates - Diagnosis

Sample Intake → Accession → Grossing → Histology → Scanning → AI Software → Pathology Confirmation → Transcription
AI- The new Paradigm of Software-driven diagnosis

BEYOND THE IMAGE
- Drives workflow efficiency
- Objective and standardized
- Increases read consistency

Dx: Basal Cell Carcinoma
Variant: Nodular
Tumor: 86%

REVISE CONFIRM
Final Take-Aways

- This Case Study shows the potential to grow revenue and differentiate by applying DP as an outreach option
- Pathologist ease-of-use via image viewer and report generation a critical element in planning
- Certain TC/PC specialties make sense for DP including Dermatology, GI, GU, and general AP
- Integration into existing LIS functionality an important consideration
- Stored images have biorepository potential
- AI for triaging and aid in diagnosis
QUESTIONS?