COLLEGE of AMERICAN PATHOLOGISTS

Justifying the Introduction of Emerging Technologies into a Pathology Department

How to Develop a Business Plan

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Disclosure

- **No financial disclosures**

Introduction

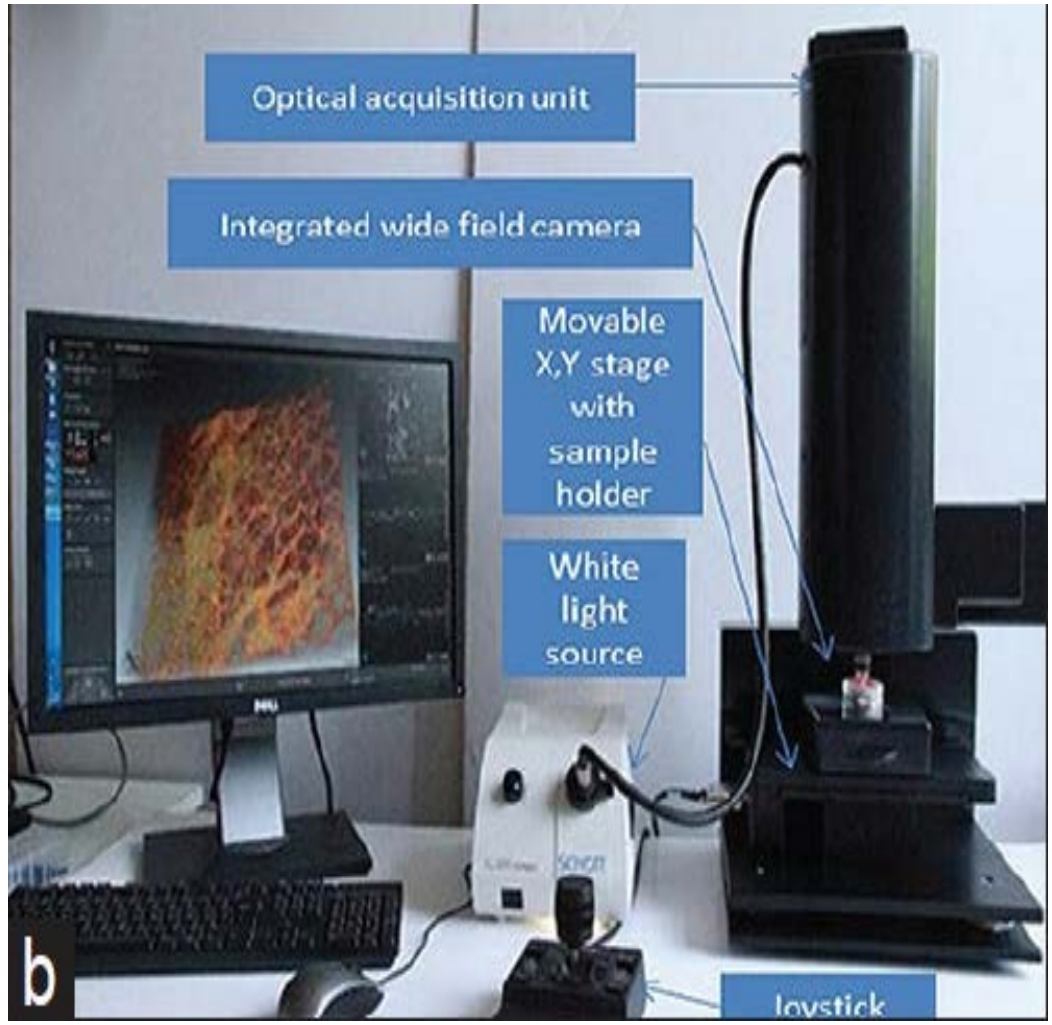
- **New technologies often, initially, do not have their own reimbursement codes.**
- **In many institutions, it can be very difficult to adopt new technologies with no obvious revenue stream.**
- **Financial arguments often justify inertia.**
- **Trying to convince people to give something new a try while apparently losing money doing so is not likely to win many converts.**
- **Pushing for this new technology requires a sound Business Plan.**

What do most pathologists know about a **Business Plan**?

- **Very little!**
- **Requires strategic vision and team-work (with administrative partners)**
- **Disciplined way of making sure you have thought about all of the ramifications**
- **Considers reductions in current expenses as much as potential increased revenue**
- **Considers replacement technologies as well as additional**
- **Considers the 1-3-5 year build-up**
- **Considers significant changes in workflow, space, capital, efficiency and personnel**
- **Considers the impact on other departments (cost reduction, improved productivity)**

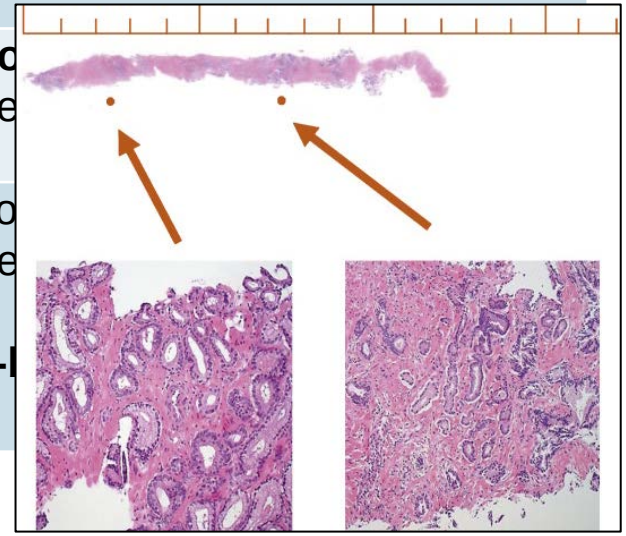
What is the new technology of Ex Vivo Microscopy (EVM)?

- **Rapid assessment of ex-vivo tissue without the usual processing, sectioning and staining:**



Applications of Ex Vivo Microscopy (EVM)

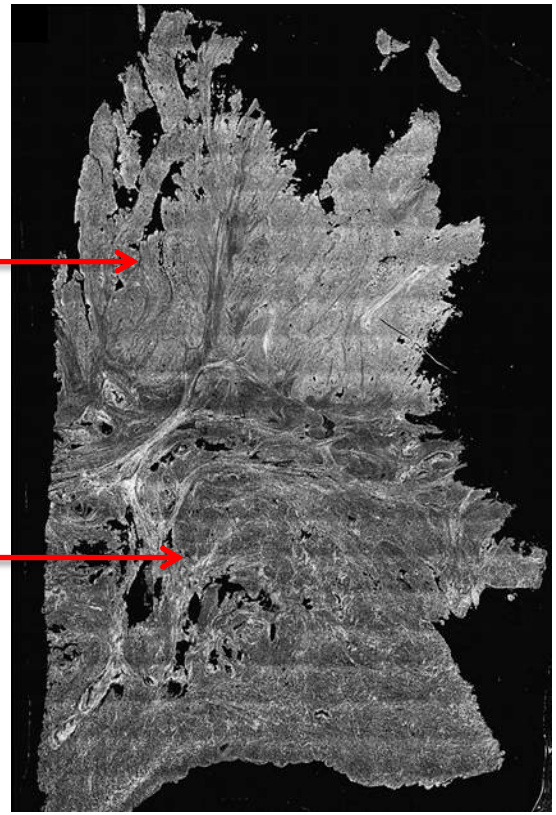
Setting	Pathology Application	How pathologists can use EVM
Intra-operative	Tumor margin assessment Sentinel LN assessment	Breast resections Identify metastases for frozen section or touch preparation
Intra-procedural	Needle biopsies & aspirates Transplant assessment	**Assess adequacy** of needle biopsies and aspirates Assess suitability of donor tissue for transplant – **no need for frozen** or permanent sections
Gross examination	Block selection	Identify highest grade lesions in resections
Genomic-molecular studies	Tissue triaging-selection	Select tumor or **co** frozen or permane
Bio-banking	Tissue triaging-selection Tissue documentation	Select tumor or co frozen or permane **Histology of bio-**



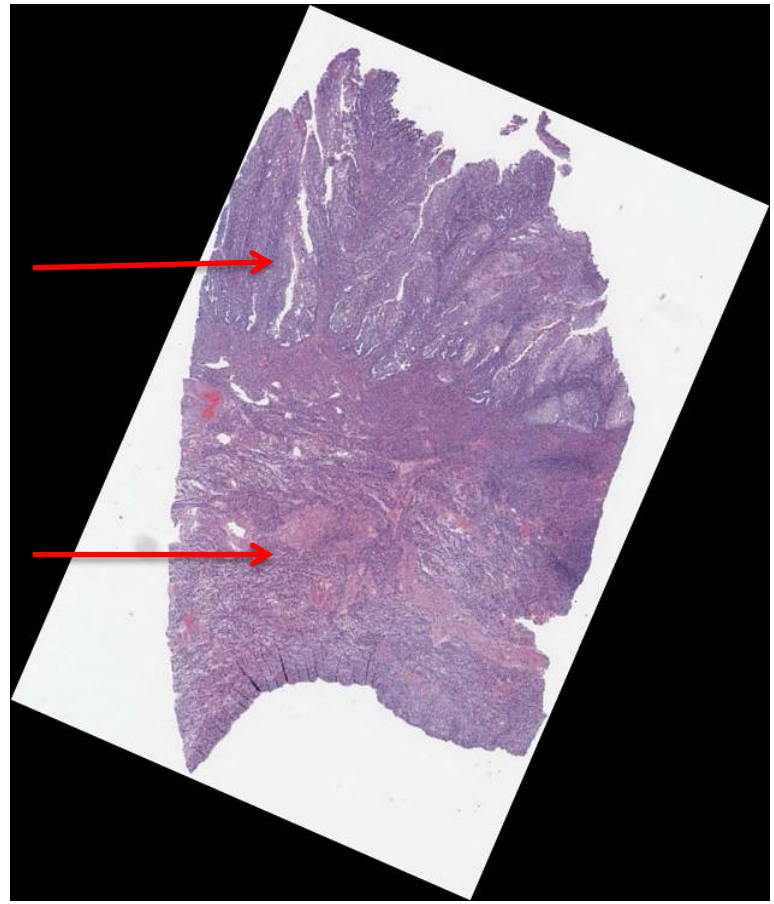
Ex Vivo Microscopy– endometrial Ca (OCT* technology)

Endometrial adenocarcinoma (superficial invasion)

Myometrium



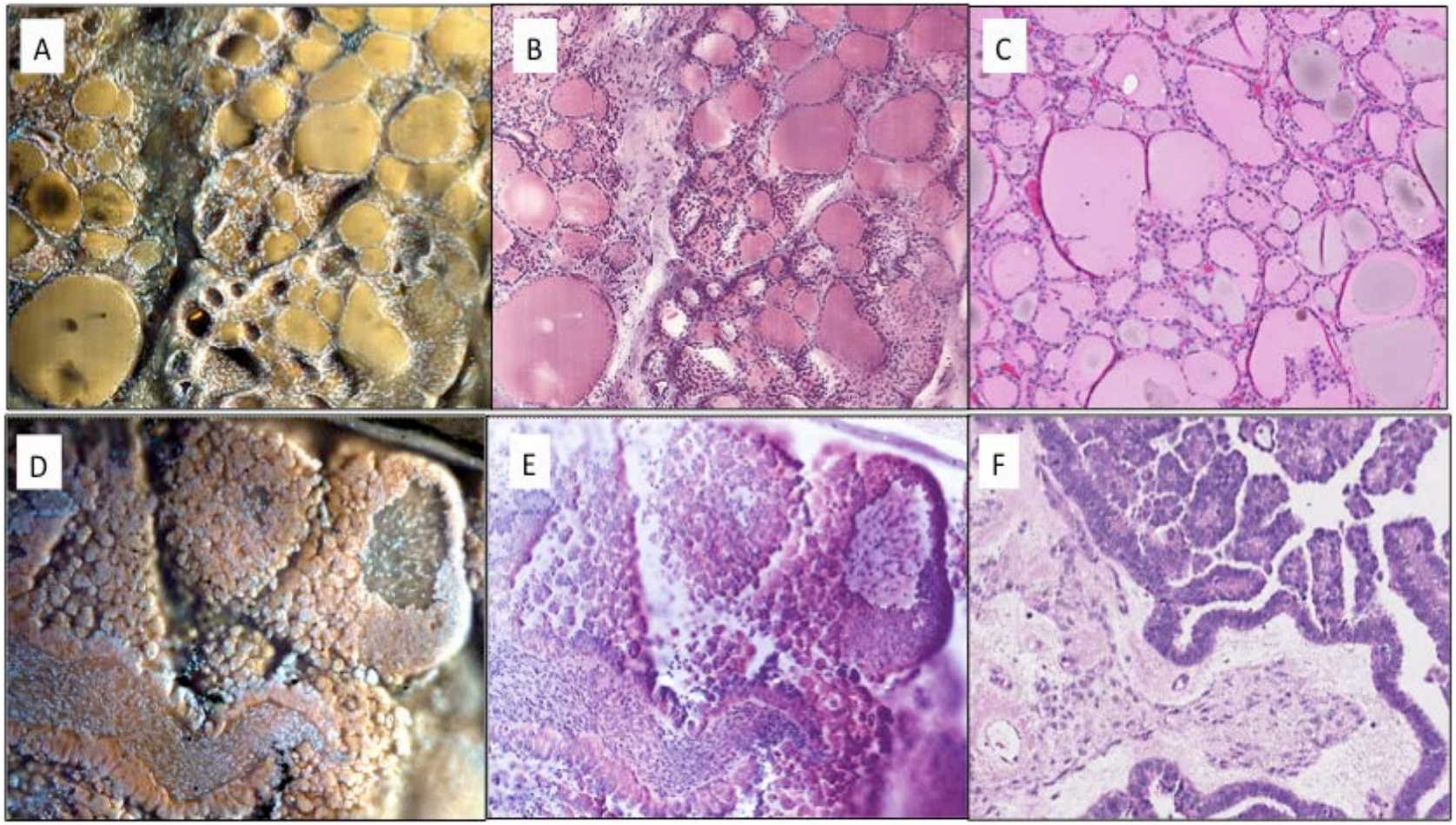
*Optical Coherance Tomography (OCT)



H&E

* Courtesy of Jeffrey Fine MD

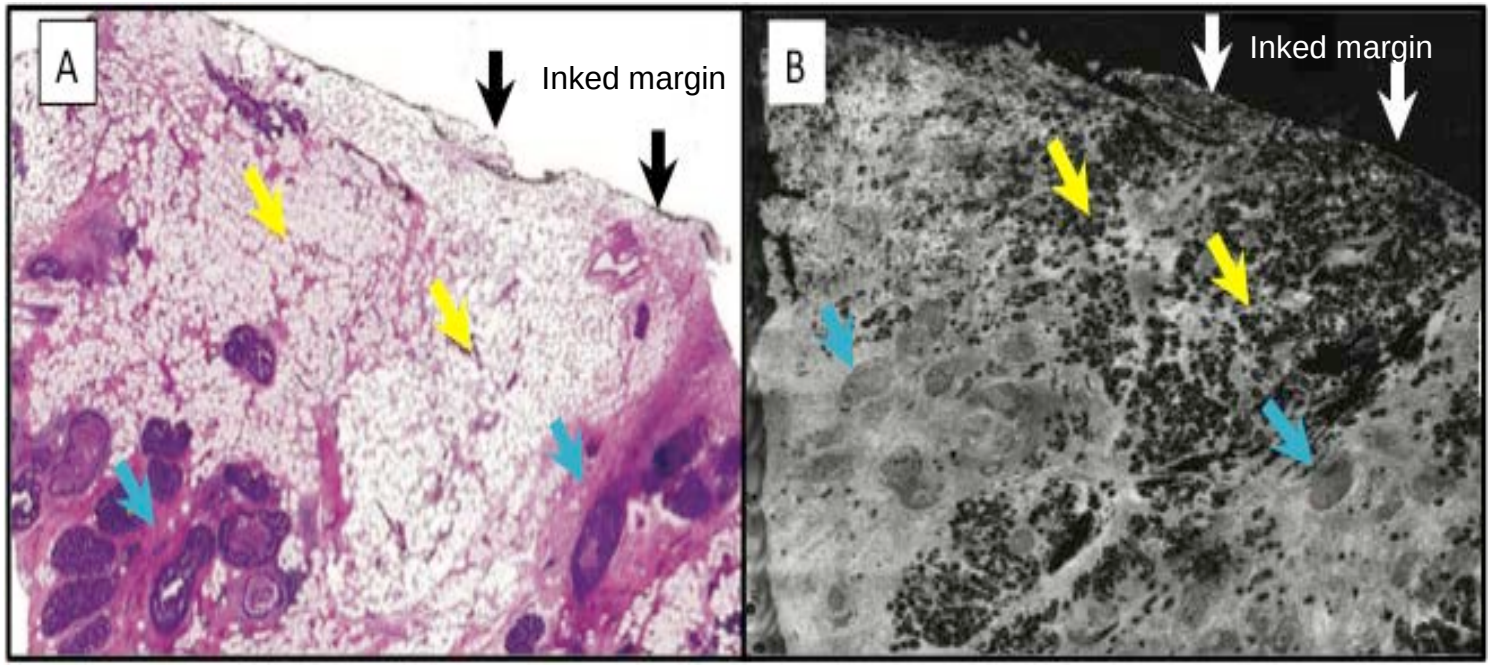
Ex vivo microscopy – normal thyroid (A-C) and serous papillary ovarian Ca (D-F) using MUSE™ (Microscopy with Ultraviolet Sectioning Excitation) technology



EVM (MUSE) image | Pseudo-colored MUSE image | Conventional H&E

*Courtesy of Richard Levenson, MD

Ex vivo microscopy – Breast tissue (fresh) with DCIS close to black-inked margins (using *OCT technology in B)



H&E stained frozen section

*Optical Coherance Tomography (OCT)

*Courtesy of Maria Shevchuk, MD

Business Plan components

- **Executive Summary**
- **Strategic Congruence**
- **Statement of Goals**
- **SWOT analysis**
- **Market plan**
- **Operation plan**
- **Administrative/Managerial Org. Chart**
- **Implementation / verification plan**
- **Financial plan**

Executive Summary – for EVM (1)

- **First page but written last when all information available**
- **One page succinct summary (may be the only thing read)**
  - **What is EVM?**
  - **Why are you asking for this technology now (*Goals*)?**
  - **What are the pros and cons of introducing this technology (*SWOT*)?**
  - **Why should the institution support this (*Strategic Congruence*)**
  - **Why can your clinical lab successfully implement EVM (*Operational and Implementation Infrastructure, Validation Skills*)?**
  - **What will be the impact on care costs, quality, safety, productivity and outcomes (*Financial Plan*)?**

Executive Summary – for EVM (2)

- **The emerging technology of EVM is clinically relevant, independently informative, and adds value to patient care by:**
  - **Improving disease detection**
  - **Better predicting prognosis and response to treatment (tissue adequacy for additional studies)**
  - **Reducing the cost of repeat procedures**
  - **Improving patient satisfaction (less biopsies, OR time, cost)**
  - **Improving clinician productivity (pathologists, surgeons, radiologists)**

Executive Summary – for EVM (3)

- **Its clinical usefulness depends on the validation and standardization of:**
  - **The chosen technology**
  - **Image acquisition**
  - **Nomenclature and image classification schemes**
  - **Reproducibility of interpretation**

- **Pathologists, with adequate training and documented competency, are crucial to such new technology validation**

Strategic Congruence - for EVM

- **Invoke the Mission, Vision and Goals of the institution:**
  - **Serving patients, quality, safety, value, fair costs, innovation, research**

Clinical Laboratory Improvement Amendments

- **Invoke the role of the clinical laboratories:**
  - **Providing a standardized infrastructure in a CLIA / CAP accredited lab environment for the development of clinically relevant, quality and cost-effective specimen testing**

- **Explain the emerging technology (EVM):**
  - **Introduce new imaging techniques into Surgical/Anatomic Pathology to enhance rapid and more cost-effective diagnoses, physician productivity and patient satisfaction**

Statement of Goals – for EVM:

- **Improved patient-centered care and physician productivity:**
  - **Less procedures/biopsies/margin re-excisions/cost/ time**
- **More cost-effective health care delivery:**
  - **More directed tissue biopsies**
  - **Less frozen sections, less specimen sampling**
  - **Improved triaging for treatment-related molecular studies to avoid repeat procedures**
- **<u>Potential</u> for improved clinical outcomes:**
  - **Improved disease detection, treatment response, prognosis prediction**

SWOT Analysis - for EVM (Strengths, Weaknesses, Opportunities, Threats)

- **STRENGTHS:**
  - **Pathologists are already tissue imaging experts**
  - **Subspecialist pathologists are already working with subspecialist clinicians who can help validate the new technology**
  - **Pathologists must be involved in the validation process (how and what tissues) and new workflows**
  - **Pathologists can incorporate new physiologic correlates (vascularity patterns, water content, tumor oxygenation) for additional diagnostic or prognostic "value"**

SWOT Analysis - for EVM (Strengths, Weaknesses, Opportunities, Threats)

- **WEAKNESSES:**
  - **Pathologists are currently not trained in optics or spectroscopy**
  - **It can be difficult for busy pathologists/trainees to embrace and educate themselves in a new technology**
  - **Workflow changes may require coordinating schedules within the Pathology Department, and OR, endoscopy suites, outpatient clinics**
  - **Pathologist reluctance to embrace digital images being sent to desk-top workstations for rapid interpretation and reporting templates**

SWOT Analysis - for EVM (Strengths, Weaknesses, Opportunities, Threats)

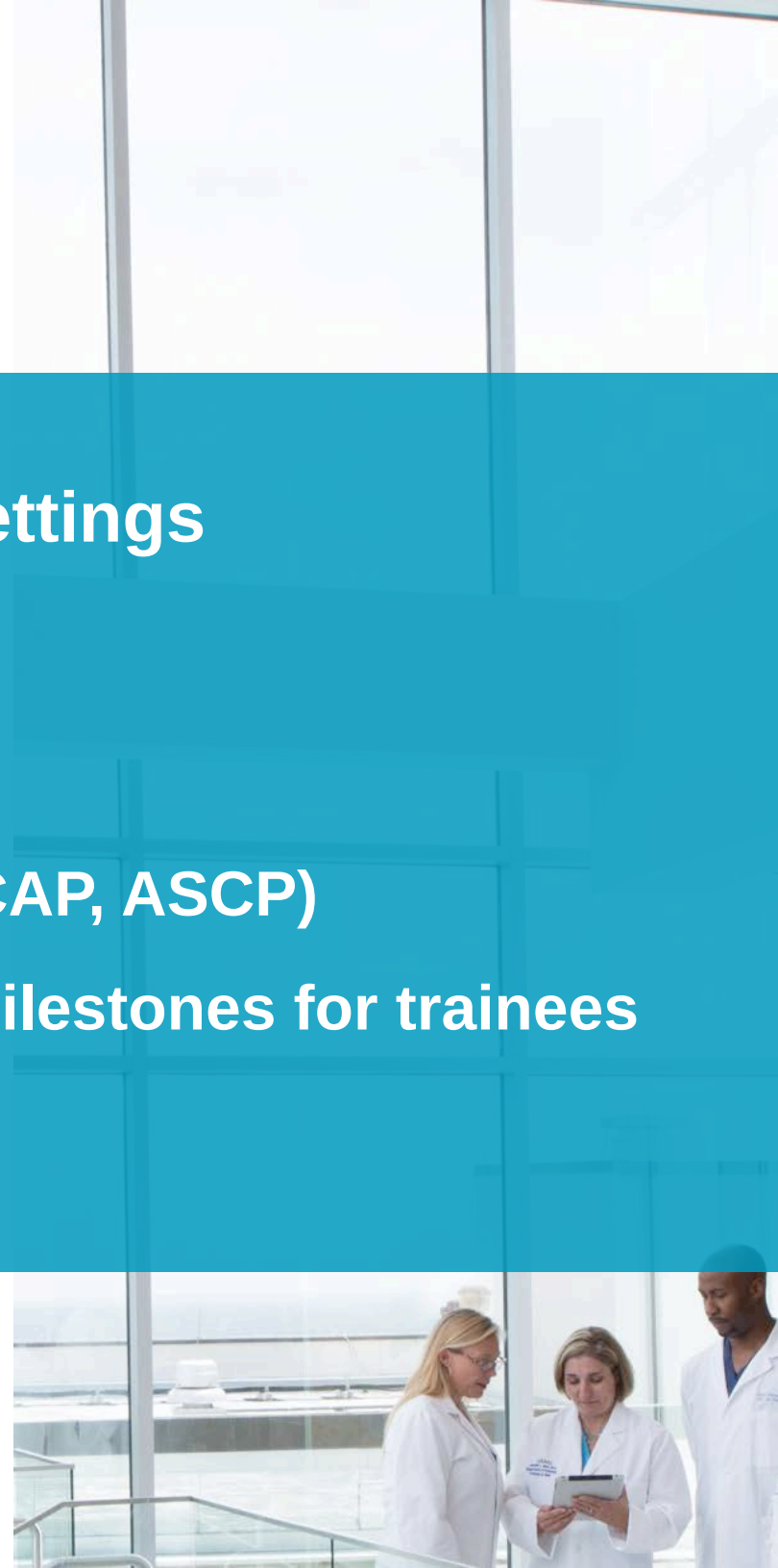
- **OPPORTUNITIES:**
  - **Reduced surgical volumes (move from fee-for-service to bundled payments) can be balanced with IVM/EVM technology?**
  - **Advantages to patients – less time in OR, fewer repeat biopsies, less inadequate tissue for diagnostic ancillary studies**
  - **Replacement of other labor-intensive procedures with poor sensitivity/specificity (eg: frozen sections)**
  - **Encourage instrument development by vendors (especially for EVM); become involved in validation studies and early adoption**

SWOT Analysis - for EVM (Strengths, Weaknesses, Opportunities, Threats)

- **THREATS:**
  - **Faster movement towards the "non-biopsy diagnosis", supplanting the diagnostic biopsy "gold standard" (resect and discard)**
  - **Other clinicians (GI, dermatologists, surgeons) will "claim" expertise**
  - **Attitude impediments from clinicians and pathologists**
  - **Perceived increased costs of new technologies (capital outlay, no immediate reimbursement)**

Market Share – for EVM (Opportunities and strategies to gain market share)

- **Academic vs private practice settings**
- **All pathologists, all trainees**
- **Education plan:**
  - **Professional society resources (CAP, ASCP)**
  - **Conferences, proficiency tests, milestones for trainees**



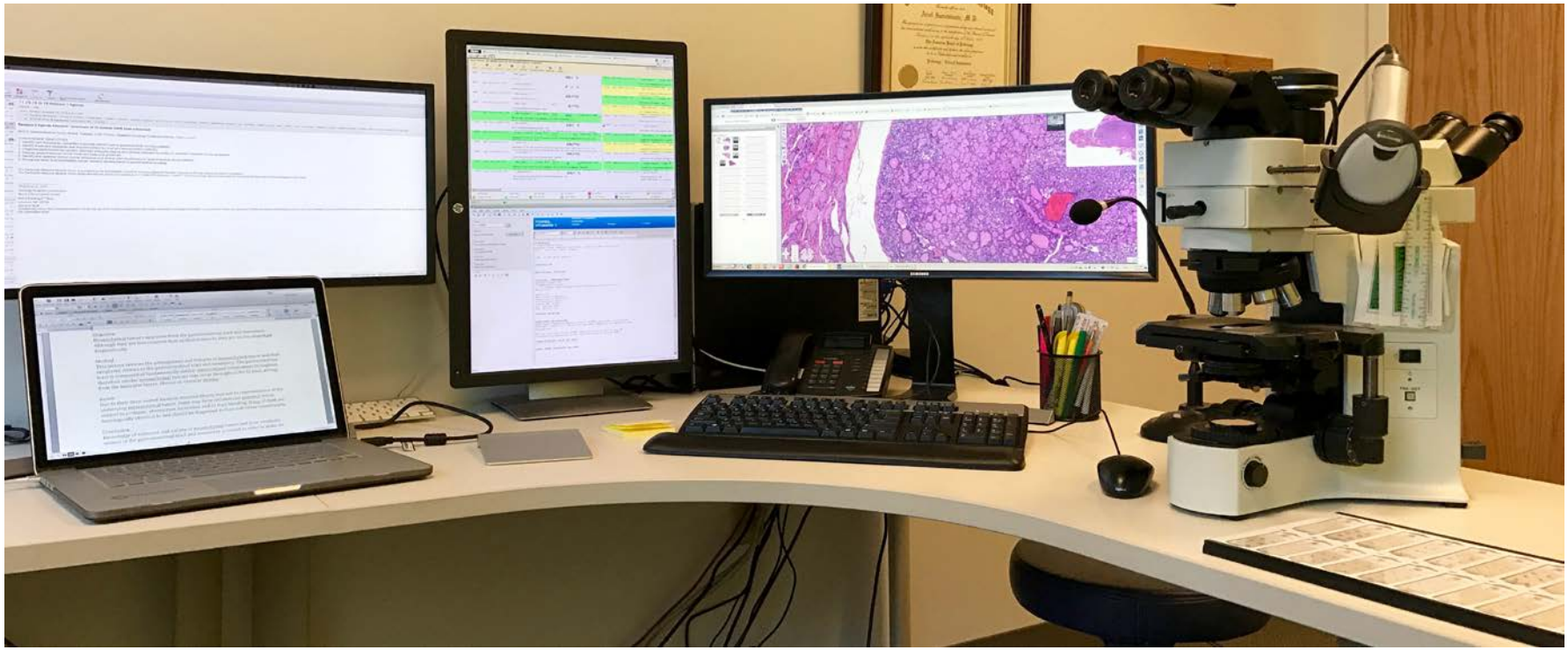
Operational Plan (1): implications of the venture

- **Space:**
  - **Instrumentation proximity to endoscopy suite/clinics)**
  - **Grossing room (dirty versus clean space)**
  - **Pathologist office space (clean space) for workstations**
- **Staffing:**
  - **Professional, technical, support (more? less? re-deployed?)**
  - **Training (pathologists, trainees, PA's)**
- **Workflow changes in the department**
- **Staff scheduling:**
  - **Endoscopy/ outpatient clinics, ORs, pathologist notification**

Operational Plan (2): implications of the venture

- **Equipment:**
  - **EVM instrumentation (beta-testing, purchase, lease)**
  - **Pathologist workstations (monitors, lap-tops)**
- **IT Capabilities:**
  - **Telepathology infrastructure**
  - **LIS report formatting (template reports, image display in reports, billing)**
- **Customer Service:**
  - **Patients - time, cost, comfort due to reduced/shortened procedures**
  - **Clinical colleagues - establish standardized clinical indications, diagnostic thresholds, clinical trials**

Pathologists and Offices of the Future – (Extra Monitors for Telepathology Including IVM / EVM)



- **IVM and EVM have the potential to revolutionize pathology practice:**
  - **Interventional pathologist?**
  - **Real-time pathologic interpretations?**
  - **Delayed interpretations of recorded images?**
- **What would the reports look like?**
- **How would we manage QA/QC, storage, billing?**

Administrative/Management Plan

- **Leadership management structure:**
  - **Current Org. Chart and reporting structure if unchanged**
  - **New Org. Chart and reporting structure if changed**
- **Operating budget as part of department:**
  - **Financial planning discussed later**

Implementation/verification plan

- **Industry choice for equipment**
- **Discuss financial implications with different departments**
- **Validation team and timeline:**
  - **Surgeons, PAs, faculty, trainees prepare protocol**
  - **Protocol validation**
- **Budget - to purchase, validate and standardize instrument**
- **Workflow modifications finalized**
- **Education component – to train faculty, trainees, PAs**
  - **Seminars on technology**
  - **Conferences**
  - **Publish the validation study**

Business Plan Components

- **Executive Summary**
- **Strategic Congruence**
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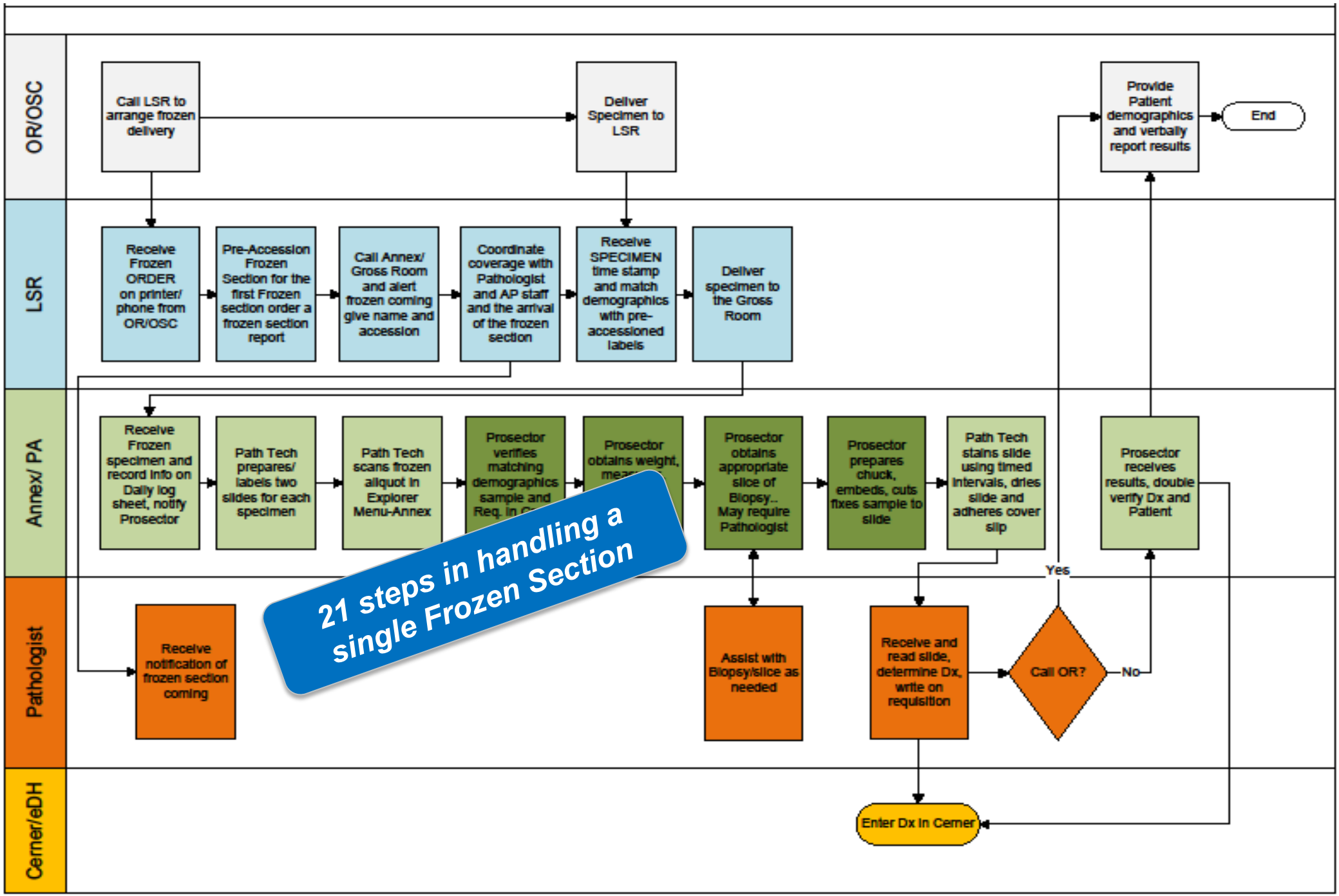
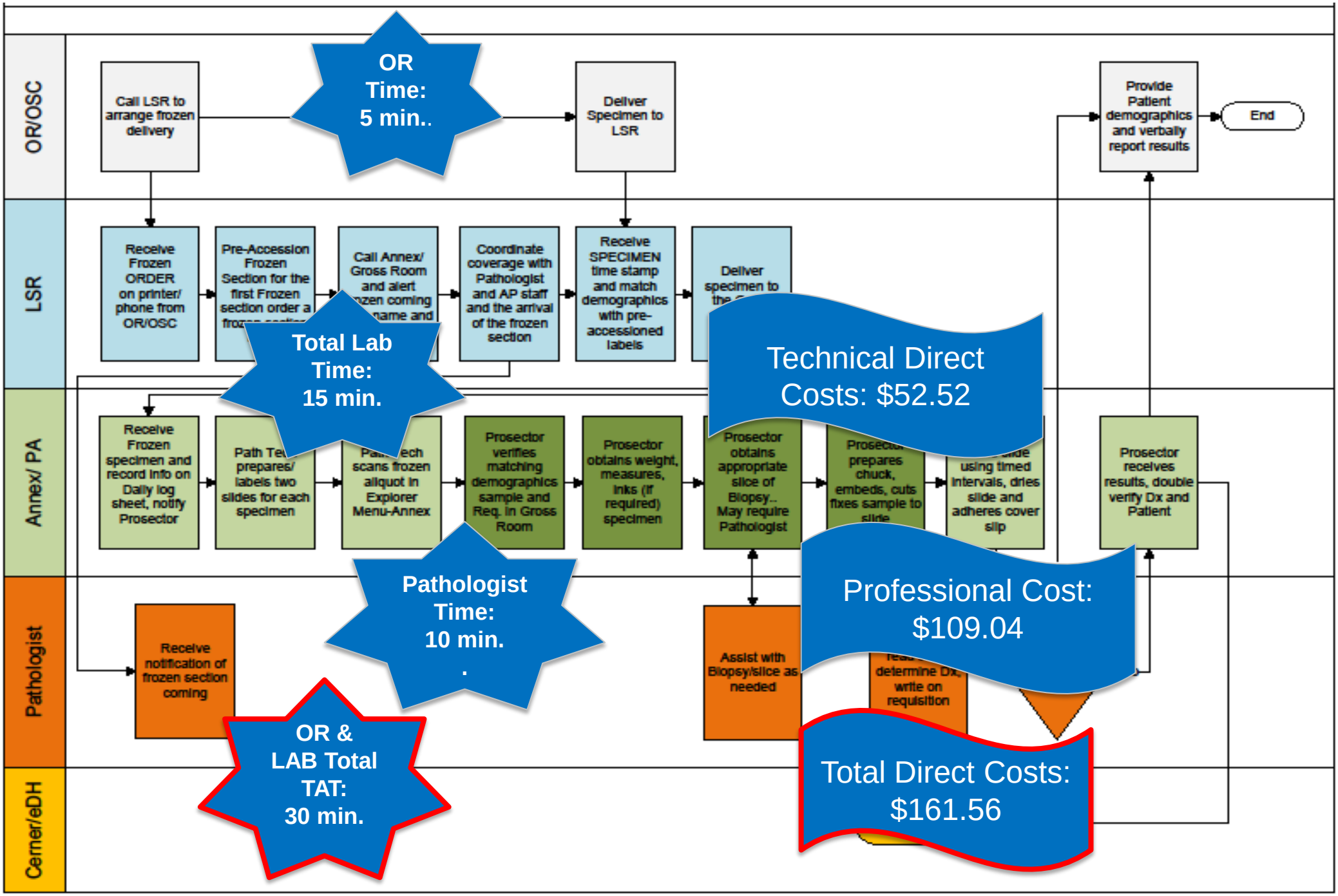
How a sound financial justification can be made if there are no approved CPTs for reimbursement?

- **Revenue projections – increased billing; no or capped reimbursements**
- **Labor costs (frozen sections versus EVM)**
- **Technical time: PA / trainee / histotech**
- **Professional time:**
  - **Faculty time and effort signing out frozens**
- **Personnel freed up to do other things**
- **Supplies at gross bench/ histology:**
  - **Less sampling/processing, less blocks/slides**
- **Capital outlay**
- **Space for instruments – Gross room, reporting office**
- **Start-up requirements - Training (faculty, trainees, PAs), courses, confs.**

Frozen Section Process Flow Map



Frozen Section Process Flow Map



Frozen Section Financial Summary

Frozen Section, Single Pro & Tech	CPT	List Price	Net. Rev.	Direct Costs	Full Costs	Margin
TECHNICAL FROZEN SECTION, SINGLE	88331	$177.00	$74.34	$52.52	$121.58	-$47.24
PROFESSIONAL CONSULT (with frozen section and 1 block)	8833126	$591.00	$118.20	$109.04	$109.04	-$9.16
	Total:	**$768.00**	**$192.54**	**$161.56**	**$230.62**	**-$56.40**

Definitions

Net revenue: 42% and 20% allowance rate for technical and professional components respectively

Direct costs: Technical - Time and costs of labor plus supplies
Professional – Cost/RVU for CPT code 88331

Full costs: Allocated overhead (space rental, lights, cleaning etc) per CPT code (the professional area is nearly all labor)

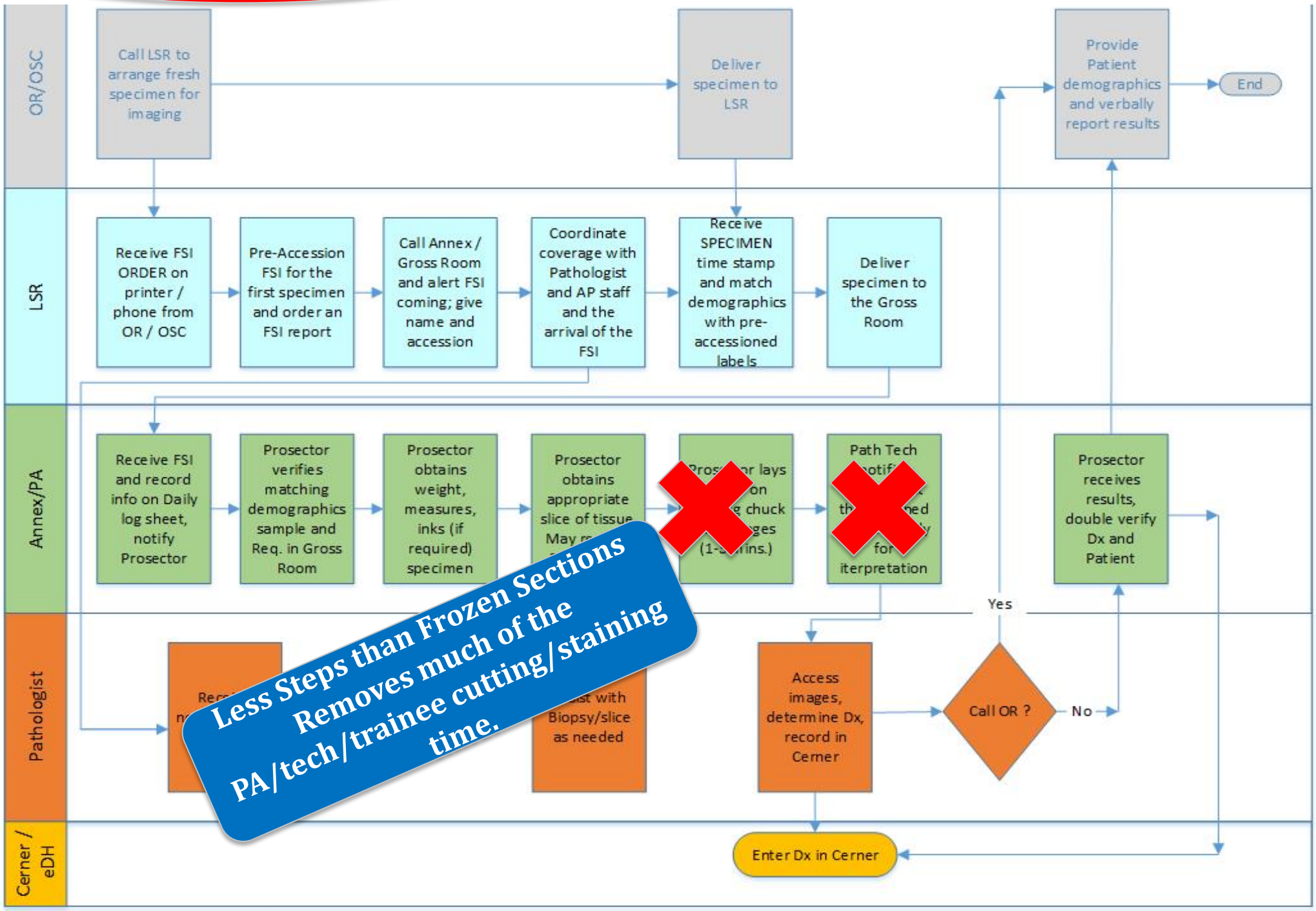
Margin: Net revenue minus Full costs

Dartmouth-Hitchcock Performs over 1,400 frozens/year

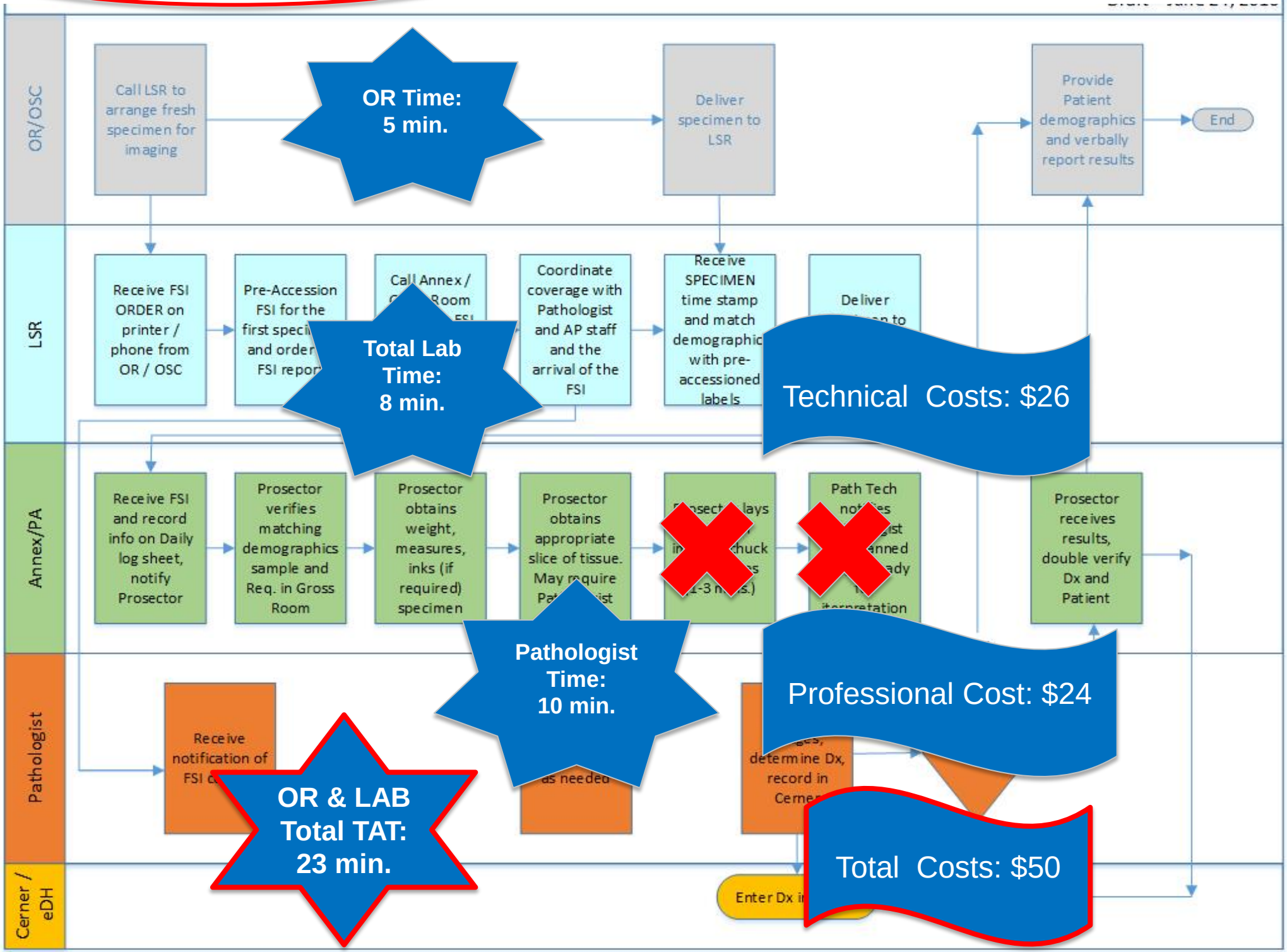
Loss of $85,000/year (56.4*1400)

Majority of loss in the Technical Component

Ex Vivo Microscopy Process Flow Map



Ex Vivo Microscopy Process Flow Map



EVM Imaging Financial Summary

Fresh Specimen for Imaging	CPT	List Price	Net. Rev.	Direct Costs	Full Costs	Margin
TECHNICAL: Fresh Specimen for Imaging	88399	$177.00	$0.00	$26.00	$26.00	-$26.00
PROFESSIONAL CONSULT (Fresh Specimen for Imaging)	8839926	$591.00	$0.00	$24.00	$35.00	-$35.00
	Total:	**$768.00**	**$0.00**	**$50.00**	**$61.00**	**-$61.00**

Definitions:

Net revenue: Use unlisted Surg. Path. CPT code (88399), therefore assume ***no net revenue***.

Direct costs: Technical - lower for EVM (less steps, no frozen sections to be cut and stained)
Professional – no CPT for RVU's generation so cannot look at cost/RVU.
Instead, look at time to interpret images (10 mins at $145/hr)

Full costs: Low estimate, given the absence of a CPT code

Margin: Net revenue minus Full costs

EVM Imaging: Financial Summary

Other considerations:

- **The decreased RVU's (because no CPT code) will increase the overall cost/RVU.**
- **Margin loss is similar comparing Frozen Section to Specimen Imaging by EVM.**
- **Processing of Fresh Specimen is faster, may be of higher quality and have other quality and cost considerations:**
  - **EVM reduces technical time to prepare image.**
  - **EVM may reduce surgical re-excisions for positive margins, boosting surgeon and OR productivity.**
  - **EVM may require less space, supplies and equipment (gross stations, cryostats) than frozen section.**

EVM Imaging: Breast re-excision costs

- **Breast tissue is difficult to evaluate by frozen section**
- **We rely extensively on gross evaluation and x-ray scans (Faxitron) as a result**
- **160,000 breast conserving surgeries performed annually for non-palpable breast cancer or DCIS:**
  - **If 30% (48,000) need re-excision, at $11,000 each, the US spends $500 million annually for re-excisions**
  - **If EVM can reduce the rate to 10%, $330 million could be saved annually**
  - **Patient satisfaction would increase**
  - **Surgeons and other health professionals would be able to do other treatments**

In Vivo Microscopy Imaging: Barrett's Esophagus Dysplasia Surveillance

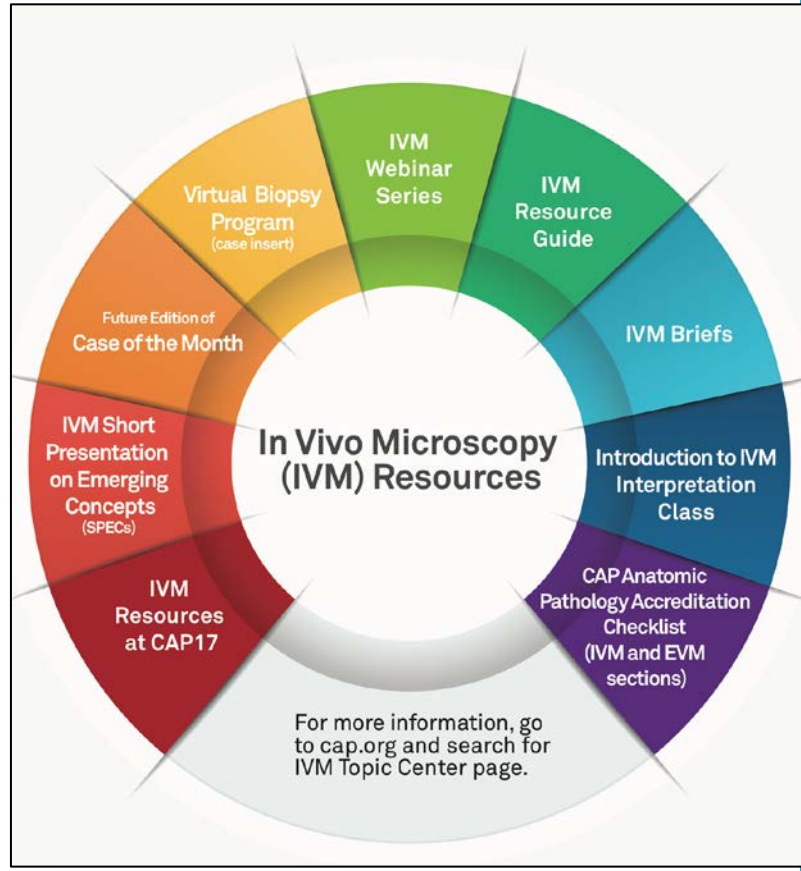
Barrett's esophagus surveillance costs for repeat procedures				
Findings	Frequency of scoping procedure	Tech CPT	Prof CPT	Biopsy # (processed and read separately)
No dysplasia	3-5 years	$2,316	$1,855	NO DYSPLASIA: 4-quadrant biopsies every 2 cm of BE segment.
Low Grade	6-12 months	$2,316	$1,855	DYSPLASIA: 4-quadrant biopsies every 1 cm of BE segment
High Grade	Every 3 months (unless treated with radioablation)	$2,316	$1,855	DYSPLASIA: 4-quadrant biopsies every 1 cm of BE segment

Why pathologists need to be involved in the development and validation of emerging technologies

- **Pathologists are already experts in interpreting microscopic images, as they relate to a specific diagnosis.**
- **Pathologists must be open to learning about new technologies that could improve clinical outcomes, add quality measures and increase productivity.**
- **Pathologists must continue to provide reproducible, clinically relevant and standardized diagnoses. To do this, they must participate in the rigorous validation of new technologies against their current diagnostic gold standards.**
- **The introduction and interpretation of new technologies may require different workflows, adapted pathologist schedules and coordination with other clinical groups. Pathologists must be open to these changes.**
- **As well as Faculty, residents and fellows should be part of a validation team so that the information can be disseminated throughout the Pathology community.**

Educational and course resources available for pathologists

- **National Societies with IVM focus areas:**
  - **International Society for Optics and Photonics**
  - **The Optical Society of America**
- **Conferences with IVM topics:**
  - **CAP 2018; Molecular Med TriCon 2018; USCAP 2018; Pathology Informatics Summit 2018; Pathology Visions 2018**
- **In vivo microscopy fellowships, combined with informatics Fellowships (also 2-4 week Mini-fellowships)**



Justifying the Introduction of Emerging Technologies into a Pathology Department: How to Develop a Business Plan

- **Learned the components of a Business Plan and how to use them to financially justify an emerging technology**
- **Discussed why pathologists need to be actively involved in the development and validation of emerging technologies**
- **Better understand how to document the "value" of new technologies in terms of reduced costs, better quality, and improved clinical outcomes**
- **Better understand how and why pathologists and trainees need to be engaged and educated about emerging technologies**

Upcoming IVM Webinars

Date	Topic	Speaker
July 10 11 AM CT	Incorporation of In Vivo Microscopy (IVM) into Pathology Practice	Gary Tearney, MD, PhD, FCAP

Register for these upcoming webinars as well as archived webinars:
cap.org > Calendar > Webinars

The CAP In Vivo Microscopy Resource Guide – see handout

- **The IVM resource guide highlights current IVM articles and other resources that assist in understanding and potentially adopting IVM and EVM**
  - **Printed guides are available for members ($39) and non-members ($69)**
  - **The digital copies of all four Resource Guides are a complimentary member benefit**
  - **Access them www.cap.org > Resources and Publications**

IVM Short Presentations on Emerging Concepts (SPECs) – see handout

- **IVM SPECs are:**
  - **Short PowerPoints, created for pathologists**
  - **Useful for educating colleagues about IVM and GI specialist on the role and value of pathologists in IVM**
- **IVM SPEC Topics:**
  - **In Vivo Microscopy (IVM): A New Role for Pathologists**
  - **IVM of the GI Tract**
  - **Ex Vivo Microscopy (EVM): A New Tool for Pathologists**
  - **Access them www.cap.org > Resources and Publications**

IVM Introduction to Interpretation Course

- **An IVM interpretation seminar designed for pathologists**
- **June 2 in Washington DC; 8:00AM–5:00PM**
- **Faculty include:**
  - **Lida P. Hariri, MD, PhD, FCAP, Massachusetts General Hospital**
  - **Savitri Krishnamurthy, MD, FCAP, The University of Texas MD Anderson Cancer Center**
  - **Greg Lauwers, MD, FCAP**
  - **Jonathan L. Myles, MD, FCAP, Cleveland Clinic Foundation**
  - **Babar K. Rao, MD, FAAD, Rutgers University**
  - **Gary J. Tearney, MD, PhD, FCAP, Massachusetts General Hospital**
- **Registrate now: email ivminfo@cap.org or https://cap.az1.qualtrics.com/jfe/form/SV_50BmcZCh0kf40jX**

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- **Check the IVM Topic Center for continued updates and for all your IVM resources**

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THANK YOU!

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