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Automation & AI in Digital Pathology

Edinburgh, Nov 2018

Darren Treanor BSc (Computing) MB BCh PhD FRCPath
Consultant Liver Pathologist, Leeds Teaching Hospitals NHS Trust, UK,
Honorary Clinical Associate Professor, University of Leeds, UK,
Guest Professor, Linköping University, Sweden

www.virtualpathology.leeds.ac.uk

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Things you need to know about Digital Pathology

Edinburgh, Nov 2018

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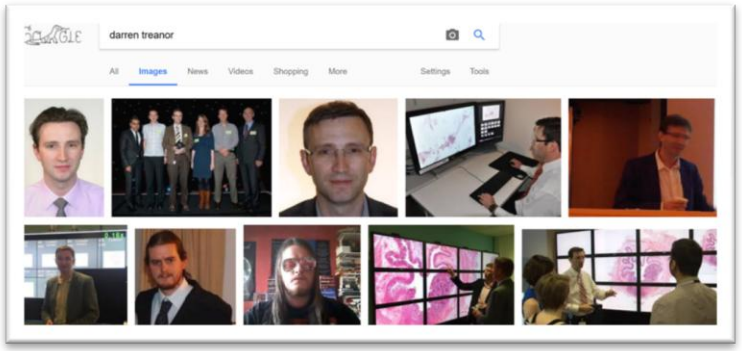
Disclosures

- Advisory board: Leica, Sectra AB
- Research funding: FFEI, Roche, Leica



Overview

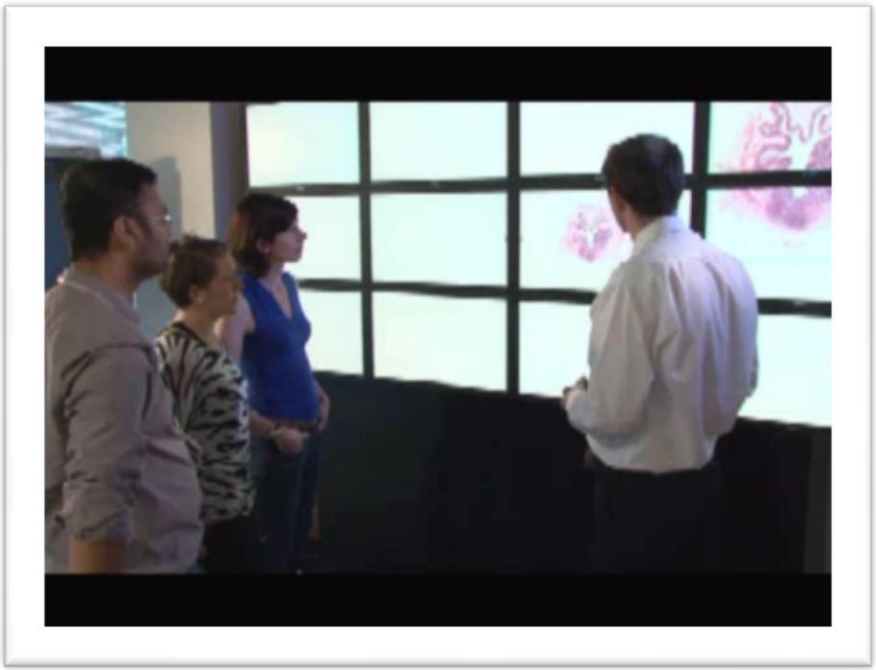
- Background
- Leeds Leica Digital pathology partnership
- Going digital
  - Preparation
  - Scanner capacity
  - Laboratory issues
  - Validation
- Where we are today

Background

Leeds: Context

- Leeds Teaching Hospitals NHS Trust
  - Single site laboratory
  - Fully sub-specialised
  - 45 consultant pathologists
  - 30 trainee pathologists
  - ~ 250,000 H&E slides/ year in “histopathology” (i.e. cellular pathology excluding cytopathology)
  - UKAS (ISO) accredited
- Leeds University department on same site
  - 7 senior academic pathologists
- Scanning since 2003
  - 6 Leica/ Aperio scanners
  - > 250,000 slides
  - 160TB of image data
  - All online

www.virtualpathology.leeds.ac.uk



***Website**: 10,000 + virtual slides, slide library, e-learning, QA materials, papers, videos and more*

***Powerwall**: 48 megapixels, size 3.5m x 1.5m, 2 on site at Hospital, 2 in University*

Innovation into practice: Leeds virtual microscope

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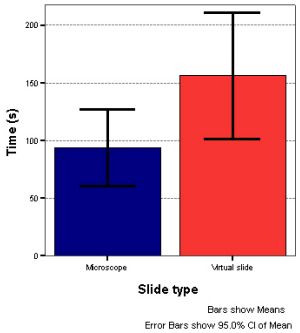
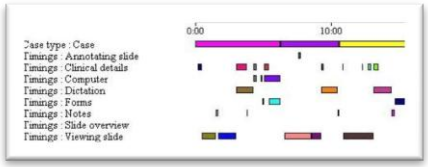
Identified the problem

- *DP is 60% slower than glass slides*



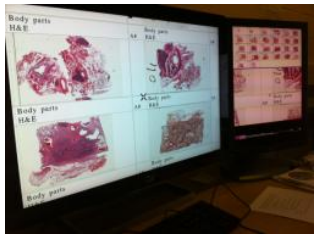
Studied it

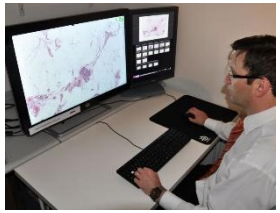
- *Time & motion studies*
- *Workflow analysis*

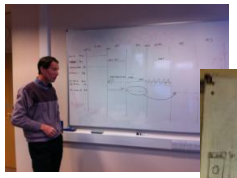


Solved it

- *Fastest DP viewer*
- *Ultra high resolution displays*





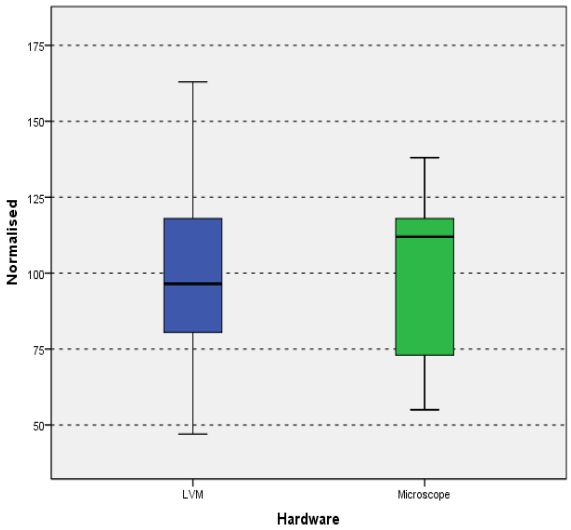


Licenced to Roche

- *Protected IP & know-how*
- *Basis of 2018 Virtuoso DP product*

VENTANA
a member of the Roche Group
Roche

Leeds virtual microscope



Normalised time to complete task
Error bars show 95% confidence interval (CI)

Innovation into Practice: Colour calibration target

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Identified the problem

- *No colour control in digital pathology*

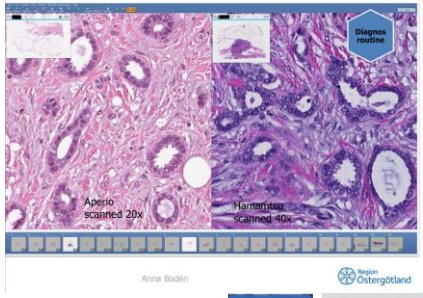
Studied it

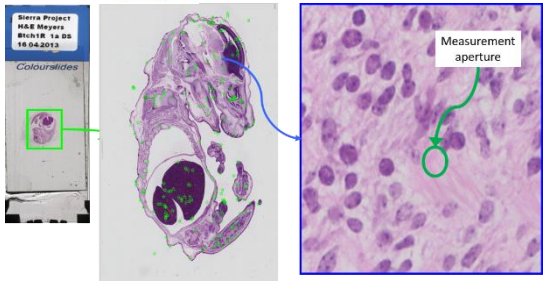
- *Spectral analysis of tissue*
- *Developed tissue mimicking substrate*

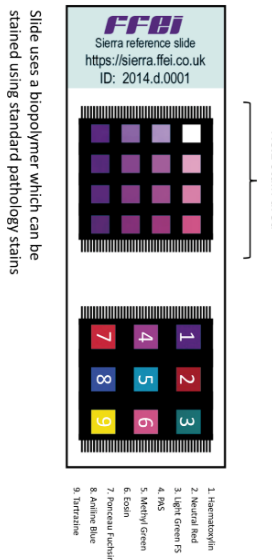
Solved it

- *Manufactured prototype slide*
- *Clinical utility proved*

FFEI marketing 2017







Innovation into Practice: 3D pathology

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Identified a need

- *3D tissue imaging for research*

Studied it

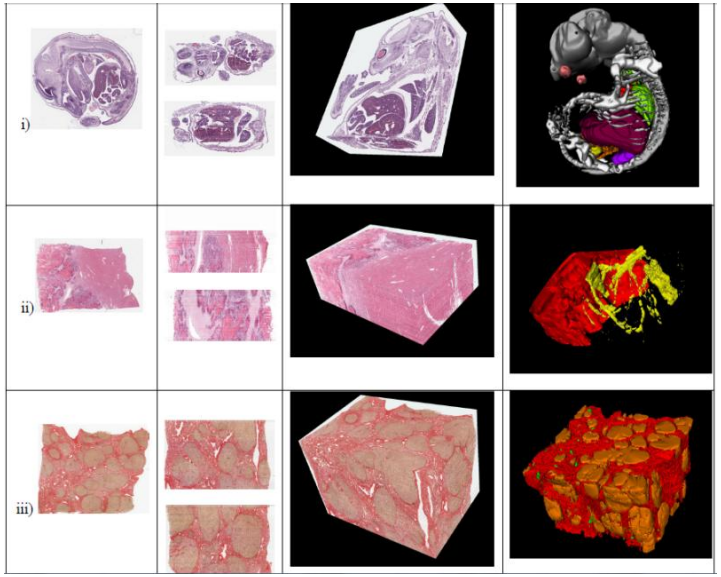
- *Tissue variation*
- *Multiple modalities*

Solved it

- *Iterative multi-scale non-rigid 3D registration*

On the market

- *Heterogenius Ltd*



Evidence based digital pathology

The Diagnostic Concordance of Whole Slide Imaging and Light Microscopy

A Systematic Review

Edward Goacher, BSc; Rebecca Randell, PhD; Bethany Williams, MBBS; Darren Treanor, MB, PhD, FRCPath

• *Context.*—Light microscopy (LM) is considered the reference standard for diagnosis in pathology. Whole slide imaging (WSI) generates digital images of cellular and tissue samples and offers multiple advantages compared with LM. Currently, WSI is not widely used for primary diagnosis. The lack of evidence regarding concordance between diagnoses rendered by WSI and LM is a significant barrier to both regulatory approval and uptake.

Objective.—To examine the published literature on the concordance of pathologic diagnoses rendered by WSI compared with those rendered by LM.

Data Sources.—We conducted a systematic review of studies assessing the concordance of pathologic diagnoses rendered by WSI and LM. Studies were identified following a systematic search of Medline (Medline Industries, Mundelein, Illinois), Medline in progress (Medline Industries), EMBASE (Elsevier, Amsterdam, the Netherlands), and the Cochrane Library (Wiley, London, England), between 1999 and March 2015.

Conclusions.—Thirty-eight studies were included in the review. The mean diagnostic concordance of WSI and LM, weighted by the number of cases per study, was 92.4%. The weighted mean κ coefficient between WSI and LM was 0.75, signifying substantial agreement. Of the 30 studies quoting percentage concordance, 18 (60%) showed a concordance of 90% or greater, of which 10 (33%) showed a concordance of 95% or greater. This review found evidence to support a high level of diagnostic concordance. However, there were few studies, many were small, and they varied in quality, suggesting that further validation studies are still needed.

(*Arch Pathol Lab Med.* doi: 10.5858/arpa.2016-0025-RA)

Evidence based digital pathology

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A Systematic Analysis of Discordant Diagnoses in Digital Pathology Compared With Light Microscopy

Bethany J. Williams, MB, BS, BSc; Philip DaCosta, MBBS, MRCS, LRCP, FRCPath; Edward Goacher, BSc; Darren Treanor, MB, BSc, PhD, FRCPath

• *Context.*—Relatively little is known about the significance and potential impact of glass-digital discordances, and this is likely to be of importance when considering digital pathology adoption.

Objective.—To apply evidence-based medicine to collect and analyze reported instances of glass-digital discordance from the whole slide imaging validation literature.

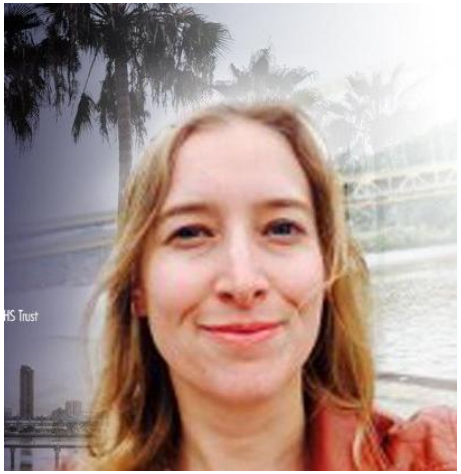
Design.—We used our prior systematic review protocol to identify studies assessing the concordance of light microscopy and whole slide imaging between 1999 and 2015. Data were extracted and analyzed by a team of histopathologists to classify the type, significance, and potential root cause of discordances.

Results.—Twenty-three studies were included, yielding 8069 instances of a glass diagnosis being compared with a digital diagnosis. From these 8069 comparisons, 335 instances of discordance (4%) were reported, in which glass was the preferred diagnostic medium in 286 (85%), and digital in 44 (13%), with no consensus in 5 (2%). Twenty-eight discordances had the potential to cause moderate/severe patient harm. Of these, glass was the preferred diagnostic medium for 26 (93%). Of the 335 discordances, 109 (32%) involved the diagnosis or grading of dysplasia. For these cases, glass was the preferred diagnostic medium in 101 cases (93%), suggesting that diagnosis and grading of dysplasia may be a potential pitfall of digital diagnosis. In 32 of 335 cases (10%), discordance on digital was attributed to the inability to find a small diagnostic/prognostic object.

Conclusions.—Systematic analysis of concordance studies reveals specific areas that may be problematic on whole slide imaging. It is important that pathologists are aware of these to ensure patient safety.

(*Arch Pathol Lab Med.* doi: 10.5858/arpa.2016-0494-OA)

The capacity to digitally capture, view, analyze, store, share, and view whole slide pathology images has led used increasingly in Europe and North America for secondary diagnosis (eg, for second opinions or frozen



www.archivesofpathology.org/doi/pdf/10.5858/arpa.2016-0494-OA

2003-2015

- We know quite a lot about digital pathology – 80+ publications, several inventions
- We didn't *need* to use digital pathology (e.g. pathologist vacancies)
- We actively *decided not to use* digital pathology for primary diagnosis

Case study: Skåne, 2011

- Highly motivated
- Well funded
- Ambitious
- Chose leading suppliers of scanners, storage, and display
- Linked DP to lab transformation and new LIS

SKÅNE 8 november 2013 00:45

System för miljoner används inte

Cancerdiagnostiken skulle revolutioneras med ny teknik. Dyra datorskärmar används nu som anslagstavlor för post-it-lappar.

Av: Nina Nord FÖLJ SKRIBENT

Martina Glimberg FÖLJ SKRIBENT

Frightened yet?

Leeds going digital

The challenge as we see it

- Digital pathology adoption is not widespread adoption - early majority phase
- Pathologists don't understand it, find it daunting
- We need maintain patient safety, and prove it
- Digital pathology systems are maturing

Leeds-Leica Strategic Partnership

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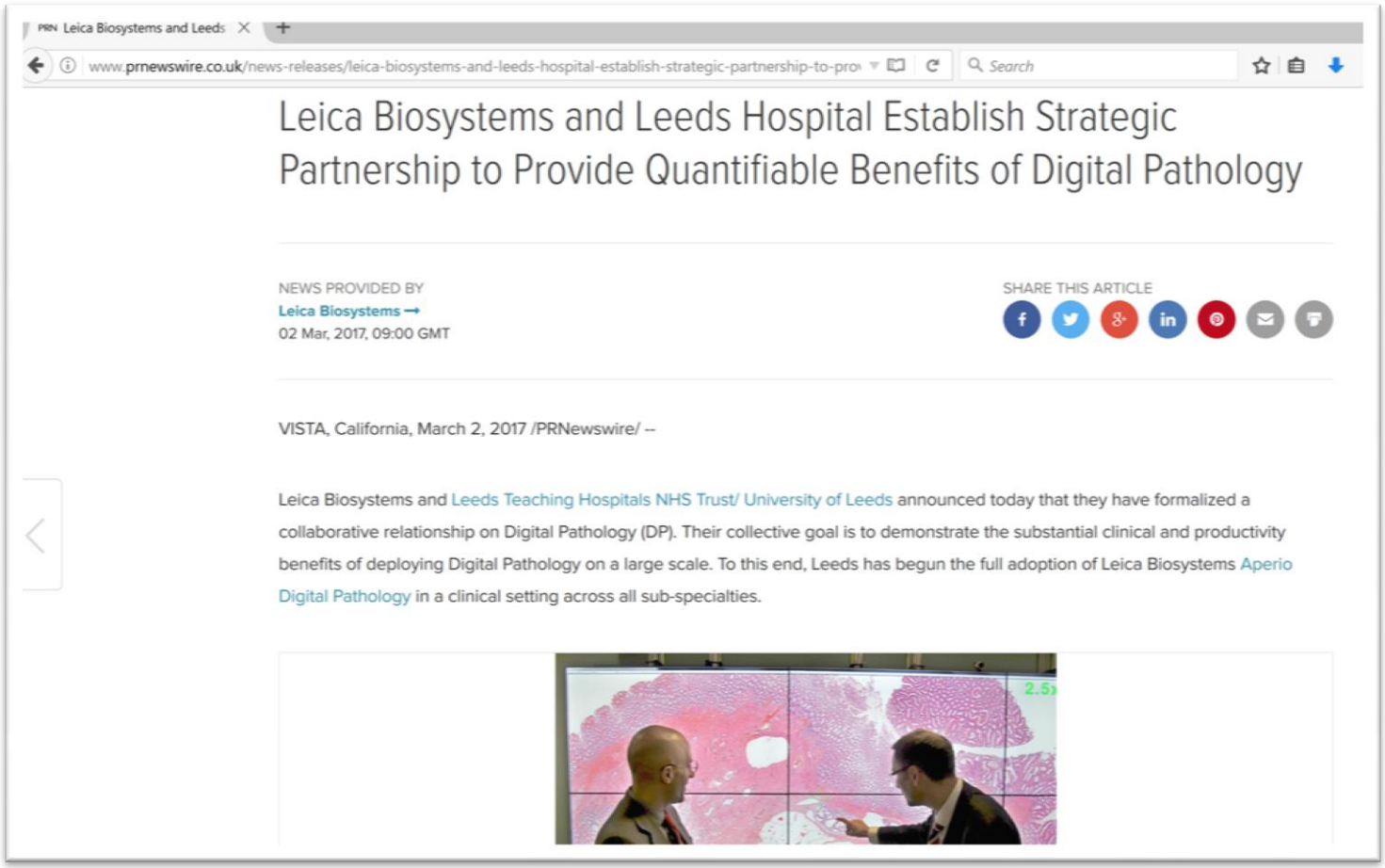

Leeds-Leica Digital pathology partnership: Aims

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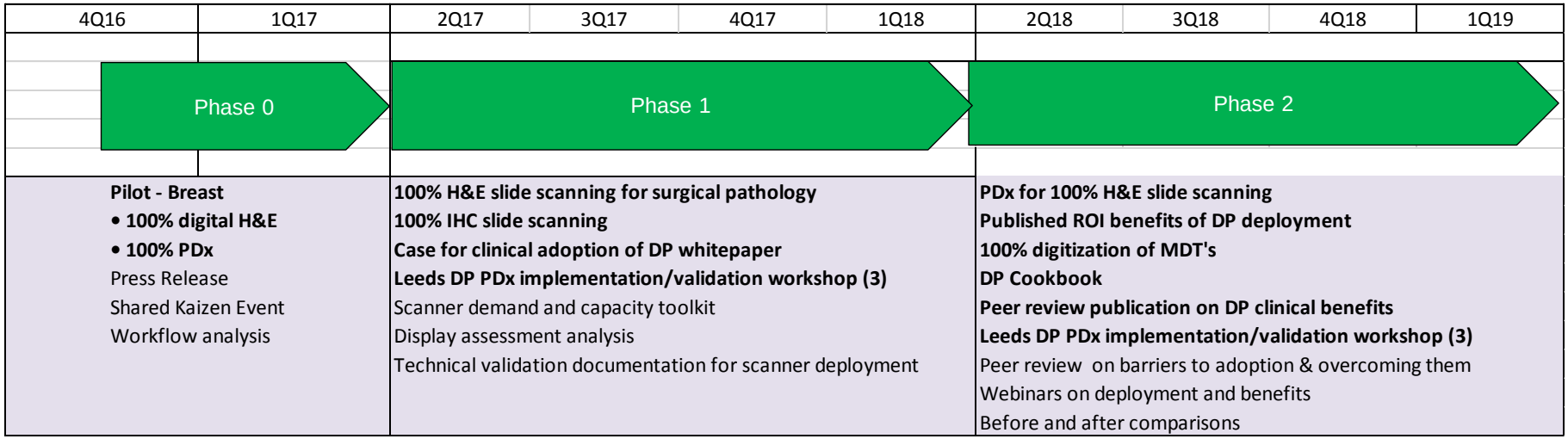
- Digital pathology deployment at Leeds
- Centre of excellence in clinical use of digital pathology
- Research-driven deployment
    - Lean process engineering
    - Quantify benefits vs costs
    - All surgical pathology slides scanned;
        - All MDTs digital;
        - All IHC reviewed digitally
    - All pathologists able to diagnose digitally – and helped to validate safely
    - Outputs
        - Validation procedures
        - Scan capacity calculation
        - Display assessment
        - Business case/ ROI
- Reference centre & Workshops

Overview Gantt



Project team

- Darren Treanor — Clinical lead
- Basharat Hussain — Project manager
- Bethany Williams — Medical validation
- Chloe Lockwood — Laboratory lead, technical validation
- Dharshana Jaydewarne — Lean engineer





Going digital: General advice

Implementation

To err is human, to really foul things up requires a computer.

William E Vaughan

- Digital pathology is
  - A big IT project
  - A new(ish) technology
  - A big laboratory transformation
  - A big medical change

Health warning #1

- It’s not possible to tell you everything you need to know in 25 minutes

What we did at Leeds

- We have a perfect laboratory
- We have perfect staff
- We have a perfect digital pathology system and a perfect LIS
- We know everything there is to know about digital pathology
- We planned the project perfectly
- We ran the project perfectly
- Everything worked perfectly, first time
- Do what we did, and you'll be fine

What we did at St Elsewhere

- We have a perfect laboratory
- We have perfect staff
- We have a perfect digital pathology system and a perfect LIS
- We know everything there is to know about digital pathology
- We planned the project perfectly
- We ran the project perfectly
- Everything worked perfectly, first time
- Do what we did, and you'll be fine

Health warning #2

- Labs are rarely perfect, especially underfunded understaffed labs
- Staff are not perfect, especially if they're over-stretched
- The perfect digital pathology system and LIS is yet to be developed
- There are lots of unanswered questions about digital pathology
- Projects don't run perfectly, especially complex IT projects with novel technology and multiple interfaces

- We need to work as a team and learn together

Going digital

Going digital: Preparatory work

Preparation: Use cases

- Think about
  - What you want to achieve
  - How much you want to spend
- Do a pilot
  - A *meaningful* pilot
- Consider a phased roll-out
  - Breast → IHC → Full digital

Preparation: Case for adoption and business case

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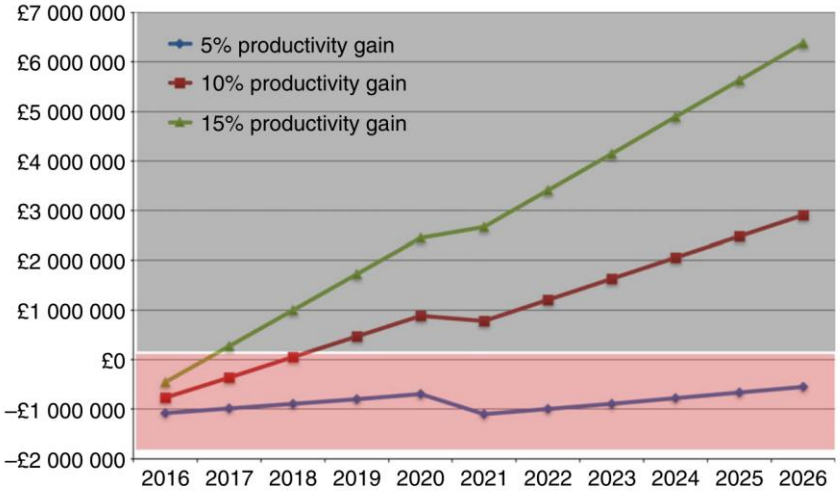
- Case for adoption
- J Clin Pathol 2017

- Optimised business case
- J Clin Pathol 2018



Preparation: Culture

- Openness to change and improve
- Willingness to try the new technology
- Community effort, collaborative
- Nobody feels threatened or coerced

A preliminary survey of pathologists at Leeds showed strong support for digital pathology in general, with 88% of pathologists interested or very interested in digital pathology.

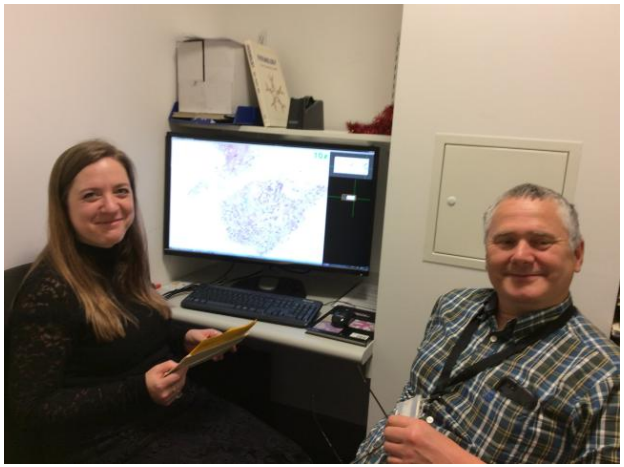
Not at all interested	Uninterested	Neutral	Somewhat interested	Very interested
0	1	4	11	25
0%	2%	10%	27%	61%

Looking at consultants only, there was very strong support for MDT review, IHC review and second opinions (over 84% neutral or positive), and strong support for use in primary diagnosis (71% neutral or positive)

	Not at all likely	Unlikely	Neutral	Likely	Very likely
MDT review	0	2	3	5	21
IHC review	1	2	4	7	17
Second opinion	2	3	4	7	15
Primary diagnosis	3	6	6	7	9

Preparation: Meaningful pilot

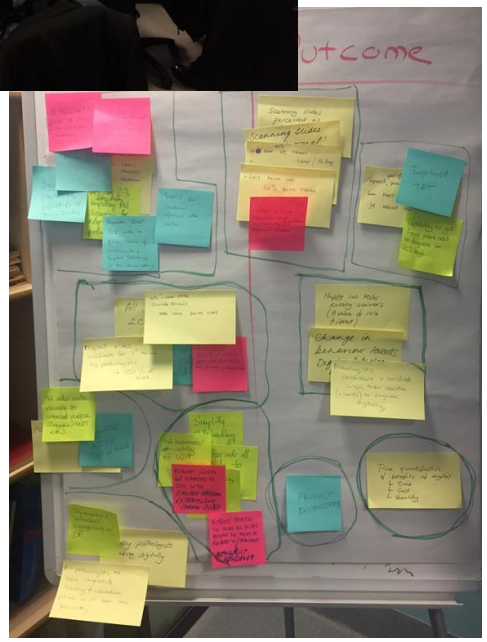
- 100% scanning of all breast cancer slides
- Leica CS2 scanner deployed
- 4 pathologists fully validated
- Doing 99% of their work digitally
- >3000 cases now

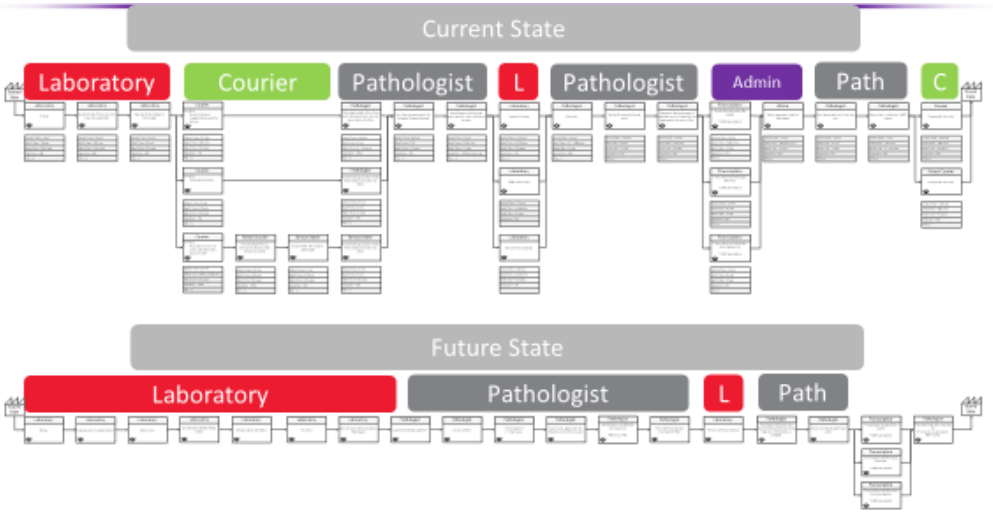


- 4 Evangelists for digital
- Many issues found & solved

	Pathologist 1	Pathologist 2
True discordance	0.7%	0.9%
Deferral rate	1.8%	0.5%

Planning the full deployment: Kaizen event

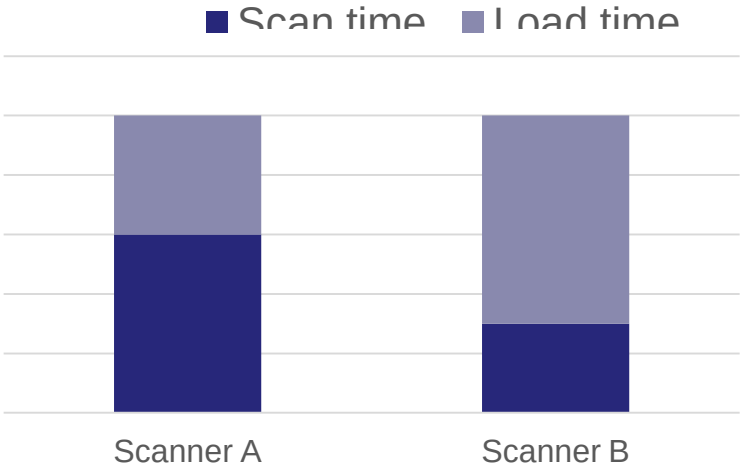




Future state expected to reduce touchpoints (and likely potential errors) while improving TAT and resource dedication

Scanner capacity...

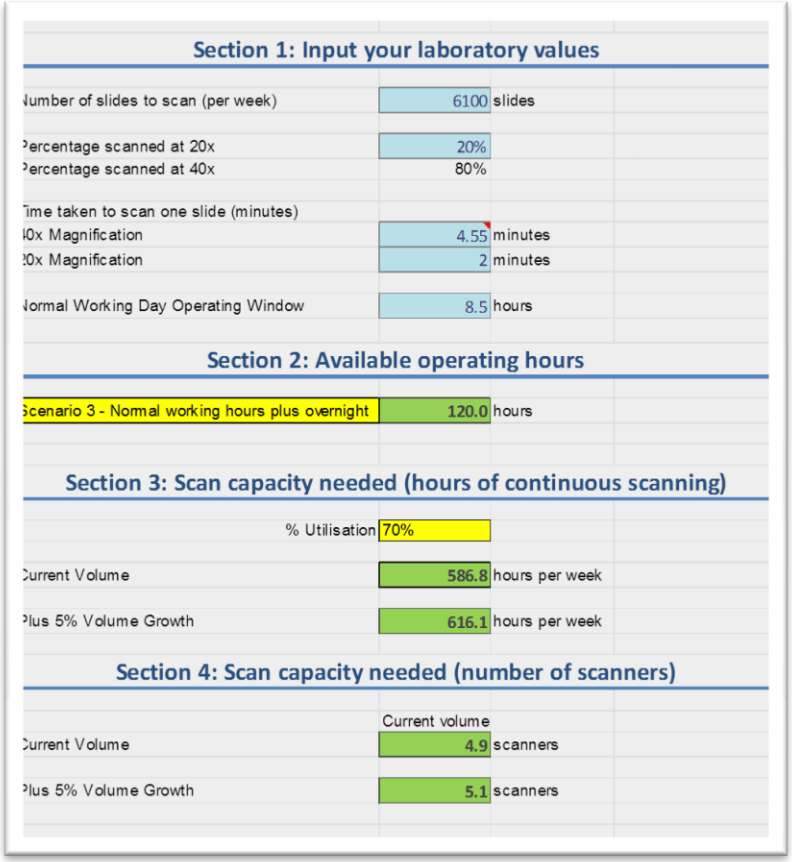
- Nobody gets this right, as far as I can see
- You need to match capacity and demand
- Every vendor has the fastest scanner in the world



Scanner B is twice as fast acquiring the image, but twice as slow to load – overall speed is the same

Scanner capacity at Leeds

- 150 Breast slides per day
  - One Leica AT2 and one CS2 is barely enough to run smoothly
- For full lab digitisation (1200 slides, 100 urgent, 100 IHC)
  - 6 AT2 scanners (400 slide capacity)
  - 3 CS2 scanners (2 large slides)
  - Load all day
  - Scan 24/7



Section 1: Input your laboratory values

Number of slides to scan (per week)	6100	slides
Percentage scanned at 20x	20%	
Percentage scanned at 40x	80%	
Time taken to scan one slide (minutes)		
40x Magnification	4.55	minutes
20x Magnification	2	minutes
Normal Working Day Operating Window	8.5	hours

Section 2: Available operating hours

Scenario 3 - Normal working hours plus overnight	120.0	hours

Section 3: Scan capacity needed (hours of continuous scanning)

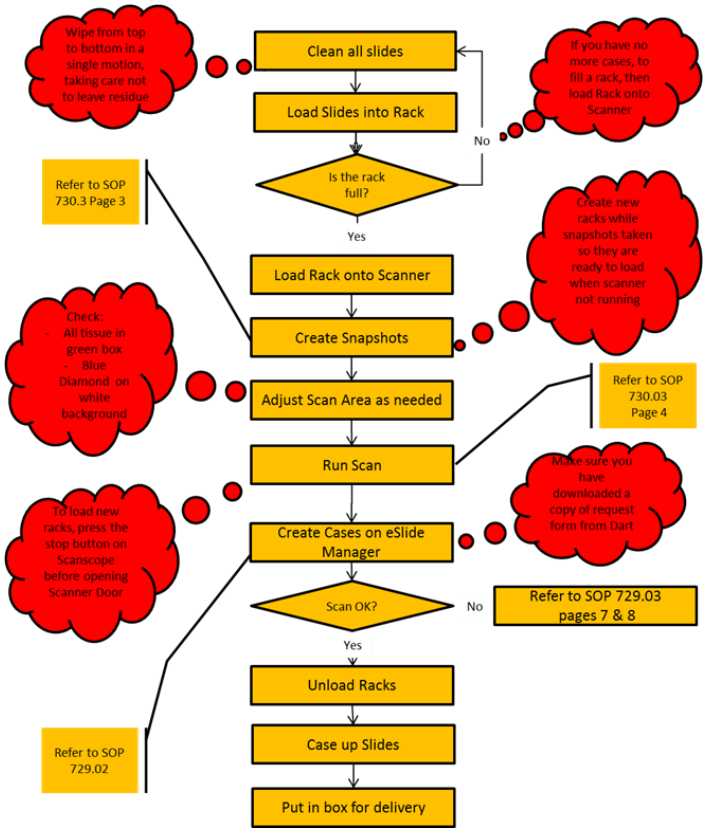
% Utilisation	70%	
Current Volume	586.8	hours per week
Plus 5% Volume Growth	616.1	hours per week

Section 4: Scan capacity needed (number of scanners)

	Current volume	
Current Volume	4.9	scanners
Plus 5% Volume Growth	5.1	scanners

Staff to run the scanner

- Map the process
  - Complex operation, including QA/QC steps
- Time each step
- Decide what skills needed at each point



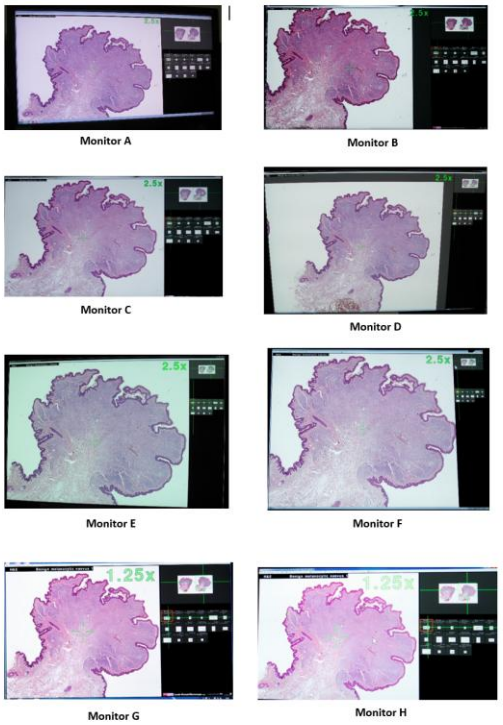
- Leeds

Breast only	0.4 FTE
Breast & IHC	0.8 FTE
100% digital	2.2 FTE

Display assessment at Leeds

- Not all displays are equal
- Nobody knows the minimum specification for a digital pathology display
- Displays are getting better all the time

- For primary diagnostic use, every day, every case , you need to ensure your display is consistent
- In a brightly lit room, you need a bright display



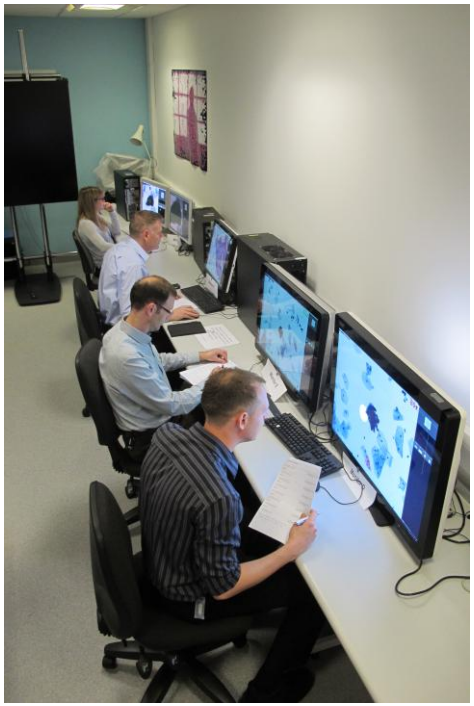
Display choice at Leeds

- Primary diagnosis
  Barco 6MP medical grade and Eizo 8MP medical grade (Currently)
  Jusha 6MP medical grade (2018-)

- MDT use
  Standard NHS display (Iiyama 2MP)

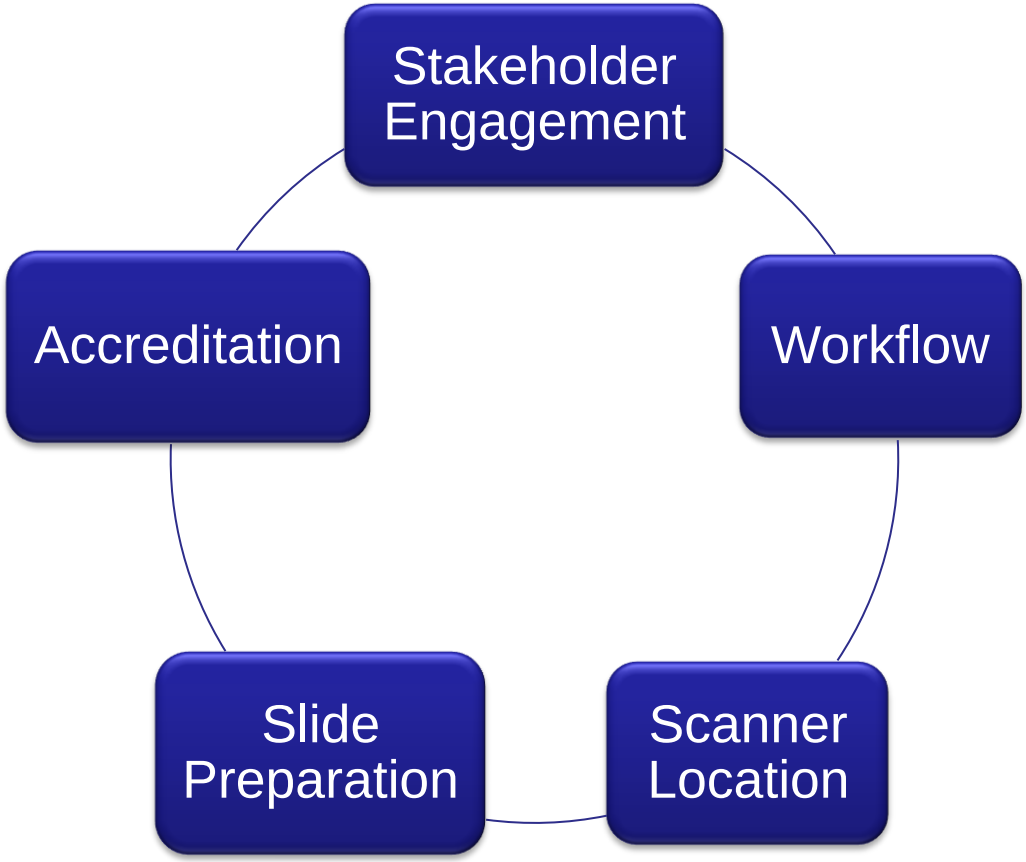
- IHC
  ? Fairly low spec display may be OK

- Paper in preparation



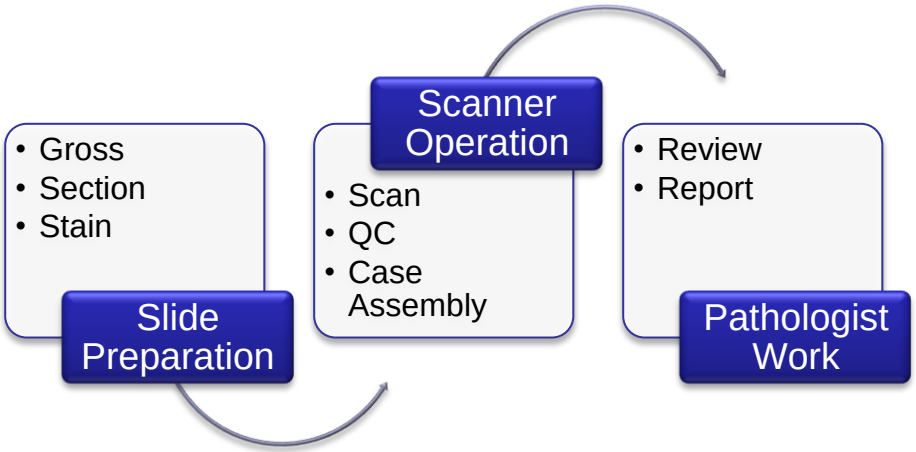
Going digital: Laboratory issues

Top 5 lessons in the lab



End to end workflow

- Consider the entire process from start to finish- specimen arrives at laboratory to pathologist viewing image
- Invest time incorporating digital pathology into the current laboratory workflow
- **Make digital pathology the end of the laboratory workflow process**



Scanner Location

- Formal options appraisal
- 10 possible locations
- 6 criteria
  - Dedicated scanning room, or in the main laboratory?
  - Is it LEAN, and does it fit in with the existing lab workflow?
- Chose central bench adjacent to cells

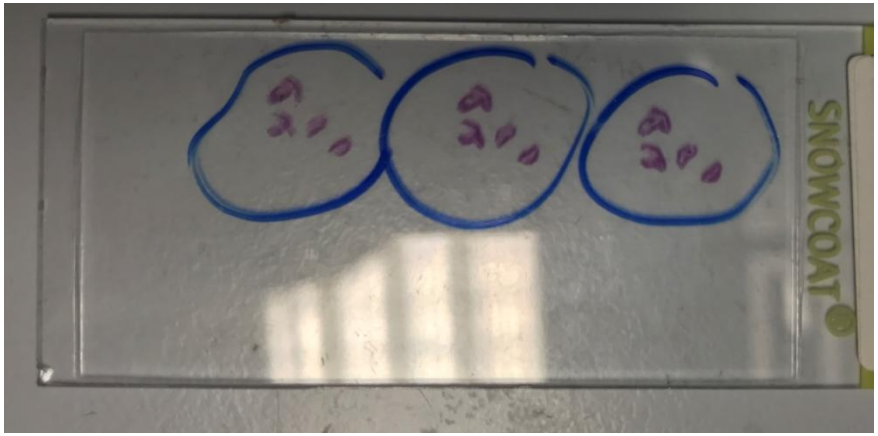
Option	Centralised Approach	Walk around Time	Existing Infrastructure	Suitable Bench / Building Work	Supports Existing Lab workflow	Scanner Maintenance
Option 1 – Seniors Room						
Option 2 – Wash Room						
Option 3 – Temporary Slide Storage						
Option 4 – Back Wall						
Option 5 – Equipment Storage Room						
Option 6 – Slide Storage Room						
Option 7 – Spare Bench						
Option 8 – IHC Area						
Option 9 – IHC QA Area						
Option 10 – Additional Work Area						

Slide Preparation- Microtomy and Coverslipping

- Thin sections - 3µm.
- Section should be free of folds, creases and bubbles.
- Section should be in the middle of the slide away from the edges.
- No overhanging/broken coverslips.
- Free from excess mountant around the edges.

Slide Preparation- Scanning

- DRY- 10 minutes at 60°c.
- CLEAN - No dirt, wax, pen or fingerprints on the slide or coverslip
- Clean slides with microscope lens cloth, and 70% alcohol (if necessary).



Stained → Dried → Cleaned → Scanned

Accreditation to ISO15189

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Quality

- Risk assessments
- Conformity
- Calibration
- External Servicing
- Internal Maintenance
- Continuous Improvement
- Audits
- External Quality Assurance Programmes
- IT Infrastructure

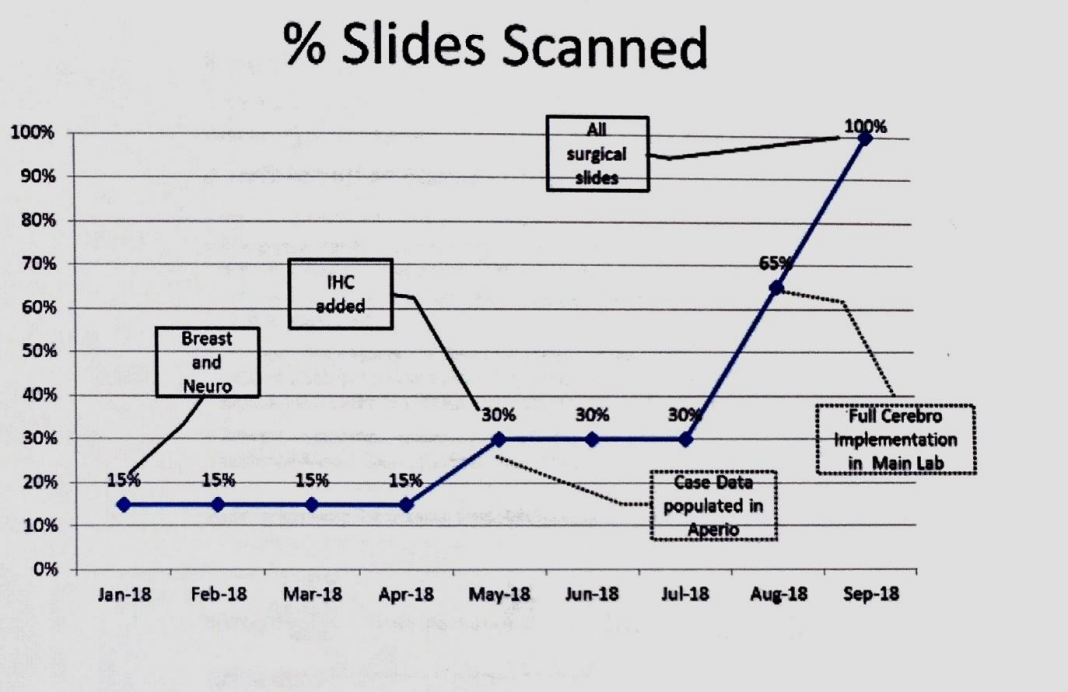
Responsibility

- Laboratory Manager
- Health and Safety Management
- Quality Manager
- Training Officer
- Laboratory Seniors
- All Lab staff

Documentation

- Standard Operating Procedures
- Risk Assessments
- Certificates of Conformity and Installation
- Non-conformances
- Calibration and Maintenance
- Internal and External Quality Assurance
- Training and Competency Records

The end result



- 100% scanning
- 1000 slides/ day
- 1GB/ minute

‘ the process we have for digital pathology is fantastic’

- Laboratory Technician

Going digital: Clinical validation

How are we validating digital pathology?

- Novel validation protocol
- Evidence based
- Minimise risk
- Pathologist training
- Pathologist led self validation
- Rigorous enough to convince external assessors, pathologists and patients that we are safe

Validation summary

Training

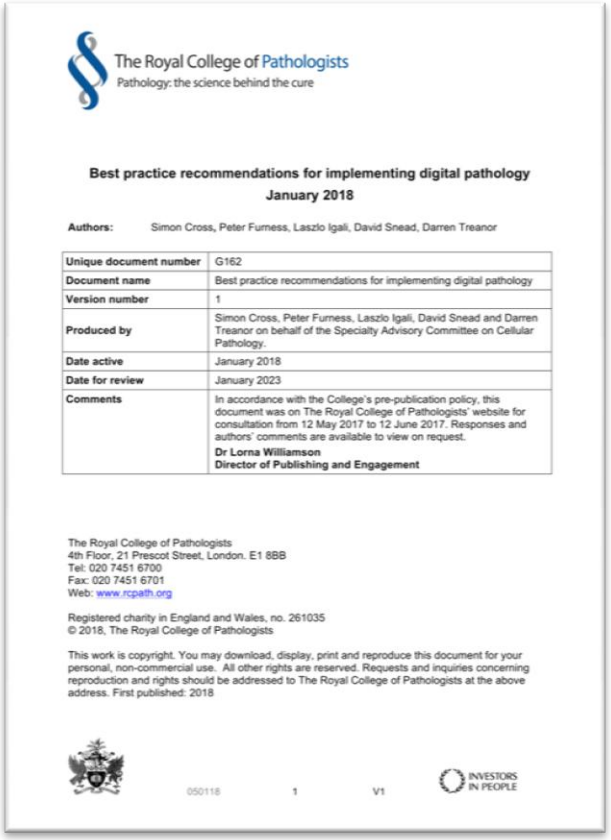
- 1:1 formalized training in digital microscope use
- Observed practice with feedback

Validation 1
Training set

- Test set of 20 challenging and informative specialty specific cases
- View on digital, make notes, compare with glass immediately

Validation 2
Live cases

- Entire workload scanned (2 months)
- Diagnosis made on digital immediate glass check before sign out



The Royal College of Pathologists
Pathology: the science behind the cure

Best practice recommendations for implementing digital pathology
January 2018

Authors: Simon Cross, Peter Furness, Laszlo Igali, David Snead, Darren Treanor

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The Royal College of Pathologists
4th Floor, 21 Prescot Street, London. E1 8BB
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

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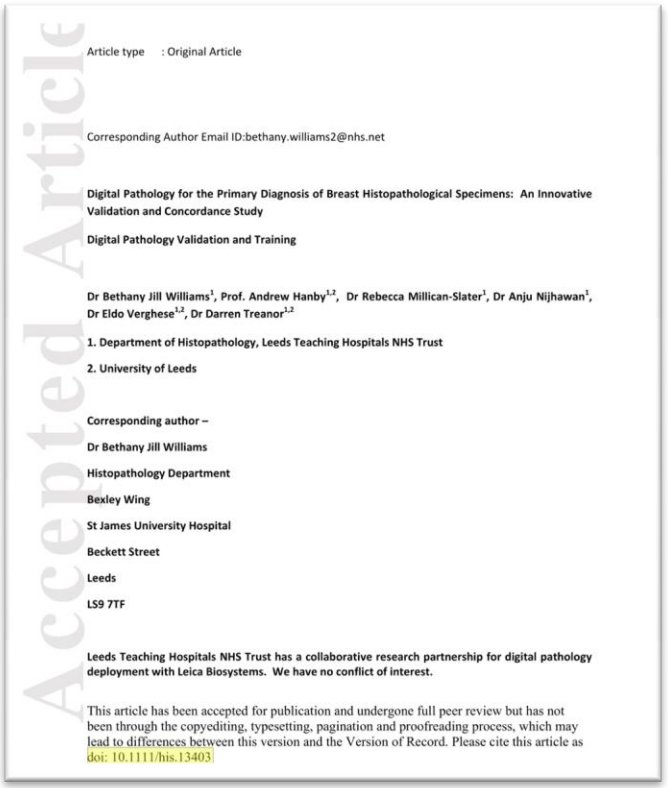

Accepted Article

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Corresponding Author Email ID:bethany.williams2@nhs.net

Digital Pathology for the Primary Diagnosis of Breast Histopathological Specimens: An Innovative Validation and Concordance Study

Digital Pathology Validation and Training

Dr Bethany Jill Williams[1], Prof. Andrew Hanby[1,2], Dr Rebecca Millican-Slater[1], Dr Anju Nijhawan[1], Dr Eldo Verghese[1,2], Dr Darren Treanor[1,2]

1. Department of Histopathology, Leeds Teaching Hospitals NHS Trust

2. University of Leeds

Corresponding author –

Dr Bethany Jill Williams

Histopathology Department

Bexley Wing

St James University Hospital

Beckett Street

Leeds

LS9 7TF

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http://www.rcpath.org/resourceLibrary/best-practice-recommendations-for-implementing-digital-pathology-pdf.html

Histopathology Sep 2017 doi: 10.1111/his.13403

It all went perfectly

This is the best thing that has ever happened in pathology

I have no slides now in my room for any of the cases which I will show at our next MDT. Seriously I was thinking, do I really need the microscope anymore?!

I tell my husband that every day I'm changing the world when I go to work

This is the worst project ever

It all went perfectly…

- Background environment
  - Worst squeeze on NHS funding in recent times
  - Stretched IT and management capacity
  - Many other changes (Managed lab service, genomics)
- Hardware
  - Scanners were very reliable
- Software
  - Interfaces LIS-Digital-Tracking
  - Immature workflows in dig path & LIS software
- Change in the lab
  - Tracking system installation & configuration – main dependency/ delay
  - Process changes – not right first time, still evolving
  - Ethos – *Digital as the final product*, not an add on

It all went perfectly…(2)

- People
  - Expectations
  - Communication
    - *Nobody told me!*
- Handover from project team to business as usual
- Validation/ medical side seems more straightforward (early adoptors?)

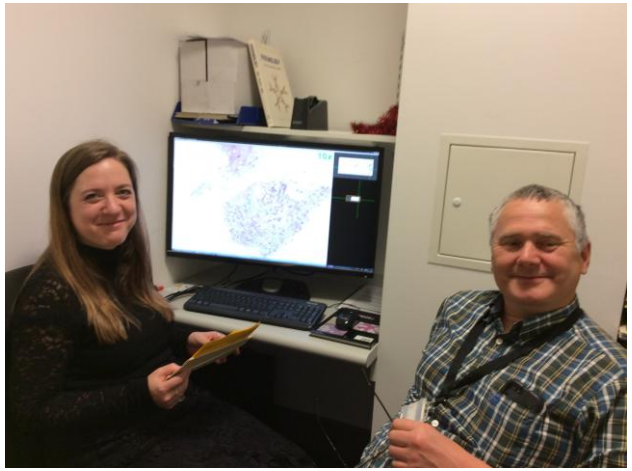
Beware the intermediate state

- No barcodes = manual case assembly
- No interface => Dual data entry
- During validation => Shipping & viewing glass and digital

- Transition phases of weeks/ months – be ready
- We often chose to use workarounds/ intermediate states rather than wait for the perfect system

Primary diagnosis using digital pathology

- 100% scanning of all breast and neuropathology slides
- 6 pathologists fully validated
- 2 pathologists validating
- We are confident that it is safe



- << 1% deferral rate

→ They love it!

What next?

2018

- Start validation for 30+ other pathologists

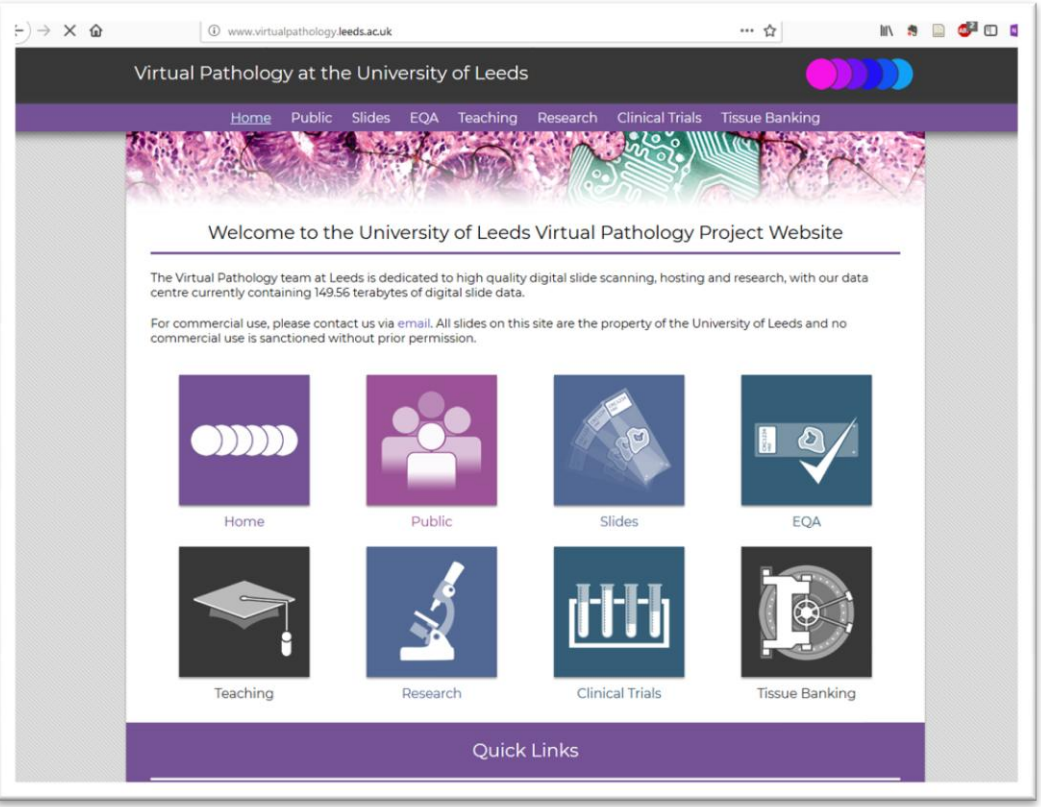
2019

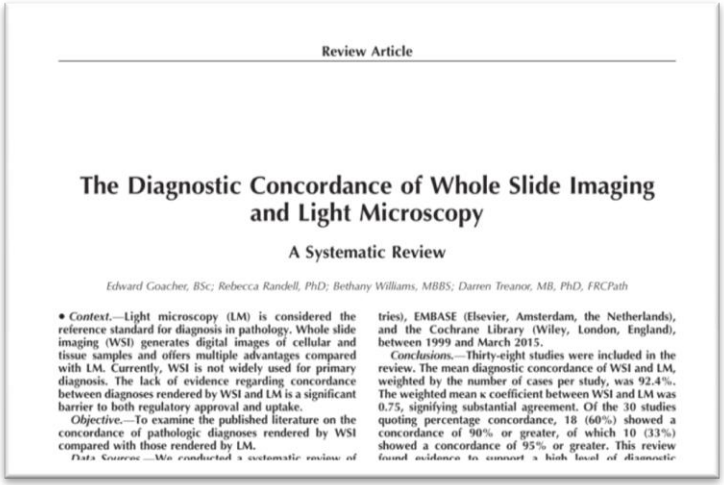
- Complete validation
- MDT adoption
- Benefits realisation

Next

- Regional expansion to 6 hospitals
- Image analysis in clinical use

Notices





Review Article

The Diagnostic Concordance of Whole Slide Imaging and Light Microscopy

A Systematic Review

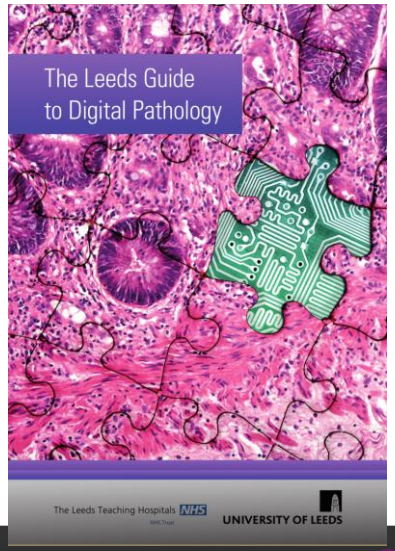
Edward Goacher, BSc; Rebecca Randell, PhD; Bethany Williams, MBBS; Darren Treanor, MB, PhD, FRCPath

• *Context.*—Light microscopy (LM) is considered the reference standard for diagnosis in pathology. Whole slide imaging (WSI) generates digital images of cellular and tissue samples and offers multiple advantages compared with LM. Currently, WSI is not widely used for primary diagnosis. The lack of evidence regarding concordance between diagnoses rendered by WSI and LM is a significant barrier to both regulatory approval and uptake.

Objective.—To examine the published literature on the concordance of pathologic diagnoses rendered by WSI compared with those rendered by LM.

tries), EMBASE (Elsevier, Amsterdam, the Netherlands), and the Cochrane Library (Wiley, London, England), between 1999 and March 2015.

Conclusions.—Thirty-eight studies were included in the review. The mean diagnostic concordance of WSI and LM, weighted by the number of cases per study, was 92.4%. The weighted mean κ coefficient between WSI and LM was 0.75, signifying substantial agreement. Of the 30 studies quoting percentage concordance, 18 (60%) showed a concordance of 90% or greater, of which 10 (33%) showed a concordance of 95% or greater. This review



2019 events...

- ECDP
  Warwick 11-13 April
- Nordic DP
  Linkoping 16 May
- Pathological Society
  Harrogate 2-4 July
- ESP Computational pathology
  Nice 7 Sep

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