digital imaging

and anatomic pathology's care delivery model

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Chief Executive Officer
BioImagene

Executive War College
New Orleans, April 27-29, 2010

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1 disruptive innovation

what differentiates it from sustaining innovation?

2 digital pathology

just how disruptive is it? what trends will it trigger?

2 10 trends for 2020

how will the delivery model change? and why?

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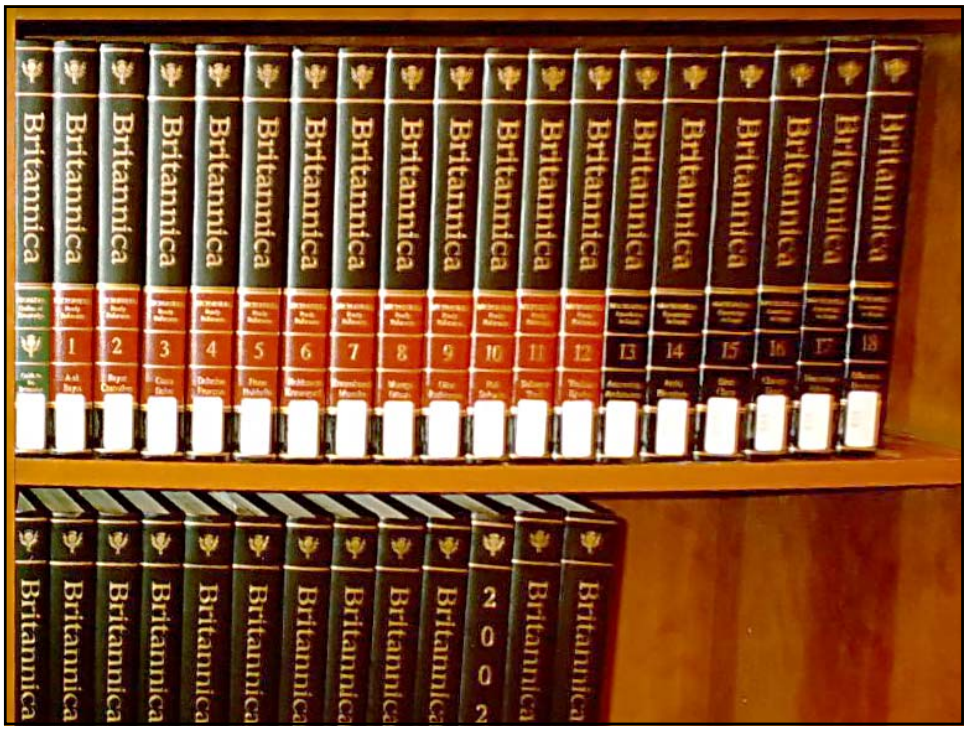
what is a
disruptive
innovation?

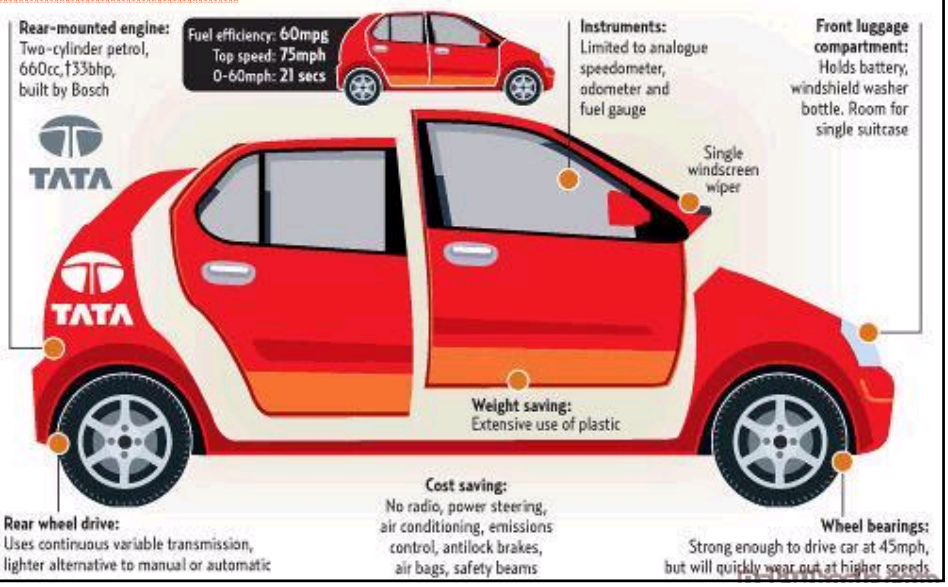


what is
this?

a low-end
car?

Building the world's cheapest car

The cheapest car in the world, set to sell for just $2,500, is being unveiled at the Delhi Auto Expo by the Indian car manufacturer Tata Motors. The "one lakh" – slang for 100,000 rupees – people's car is aimed at the country's 65 million scooter riders currently unable to afford a car



a high-end
motorcycle?

what is
this?

a low-end
ultrasound?

a high-end
stethoscope?

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what is
this?

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another

disruptive

innovation

These innovations were all disruptive for a single reason:

When they were introduced, their performance was initially much lower than that of the existing technologies…

But, they were able to bring the cost down so dramatically that their adoption became inevitable… sometimes in an alternative market segment (to start with)

Eventually, their performance caught on, and led to their mass dissemination.

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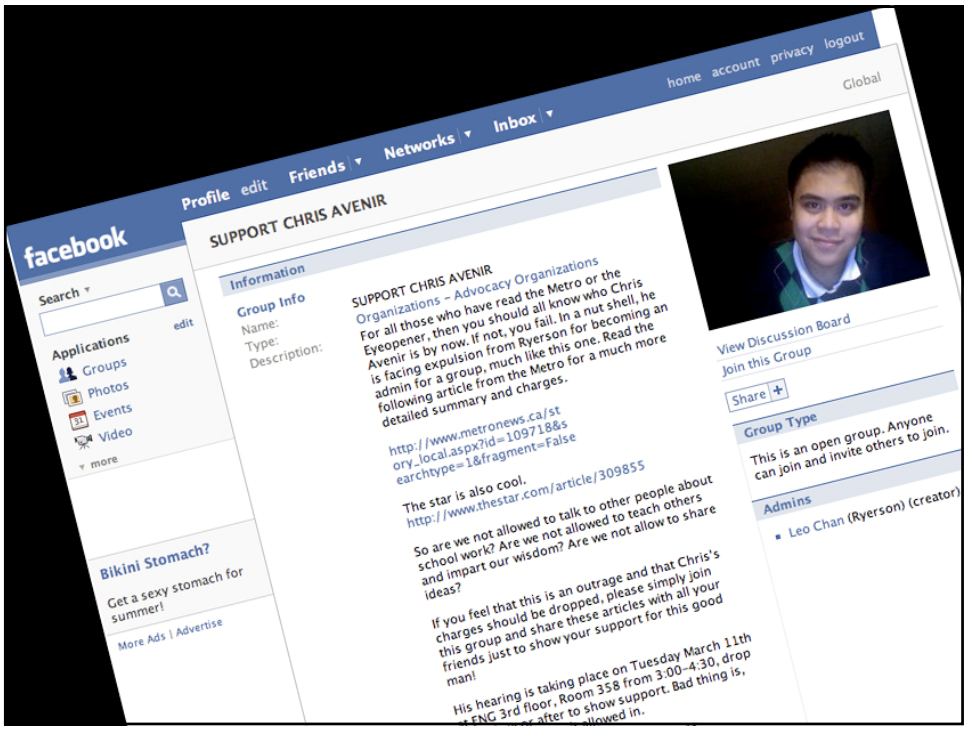
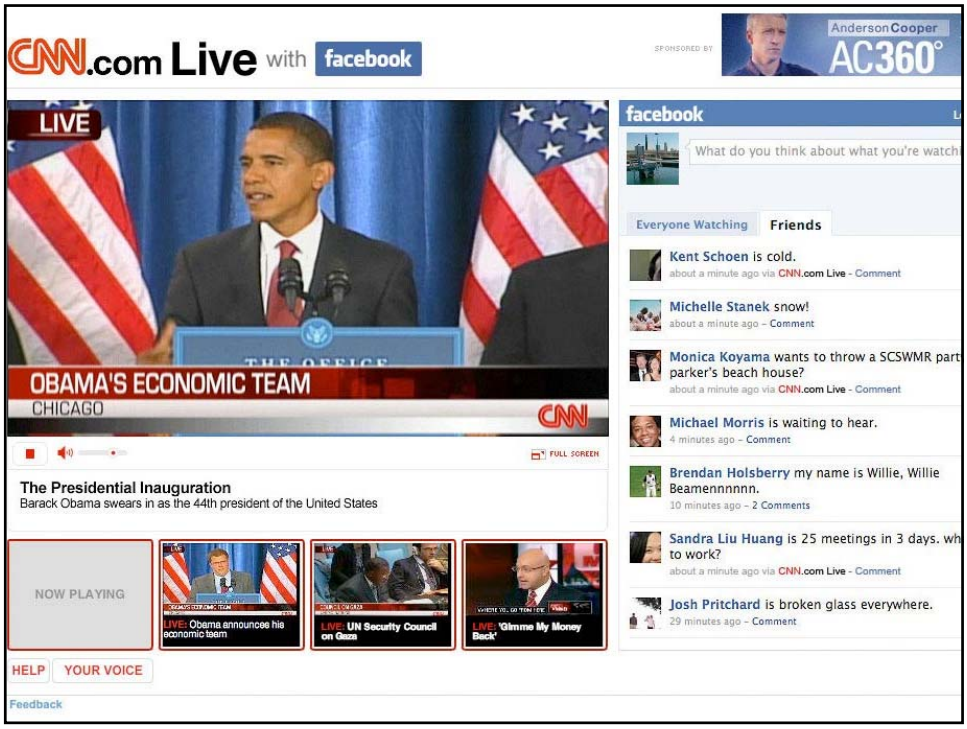
now, another type of

disruptive

innovation

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Barack Obama swears in as the 44th president of the United States
NOW PLAYING
LIVE: Obama announces his economic team
LIVE: UN Security Council on Gaza
LIVE: 'Gimme My Money Back'
HELP
YOUR VOICE
Feedback
facebook
What do you think about what you're watch
Everyone Watching
Friends
Kent Schoen is cold.
about a minute ago via CNN.com Live - Comment
Michelle Stanek snow!
about a minute ago - Comment
Monica Koyama wants to throw a SCSWMR part
parker's beach house?
about a minute ago via CNN.com Live - Comment
Michael Morris is waiting to hear.
4 minutes ago - Comment
Brendan Holsberry my name is Willie, Willie
Beamennnnnn.
10 minutes ago - 2 Comments
Sandra Liu Huang is 25 meetings in 3 days. wh
to work?
about a minute ago via CNN.com Live - Comment
Josh Pritchard is broken glass everywhere.
29 minutes ago - Comment


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Subjects

These innovations were also disruptive, but for a different reason:

They were able to "deconstruct" the existing value chain of a business…

They were able to "dis-intermediate" the value chain of a business…

They were able to "re-configure" the value chain with a different set of players.

Their adoption was set off by some "tipping point"

all great examples of

disruptive

innovation

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but, in order to see why,

we had to look

unconventionally

In the conventional world of "looking",
it is easy to see what is going on,

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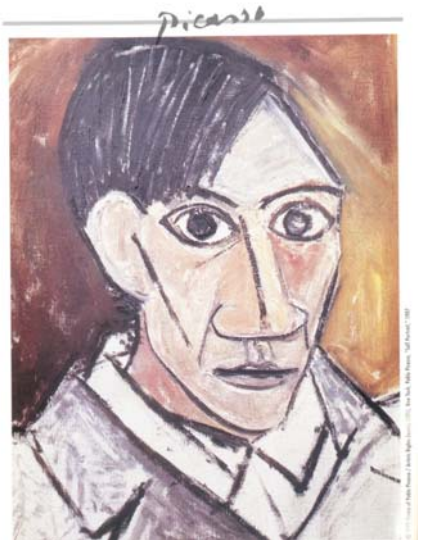
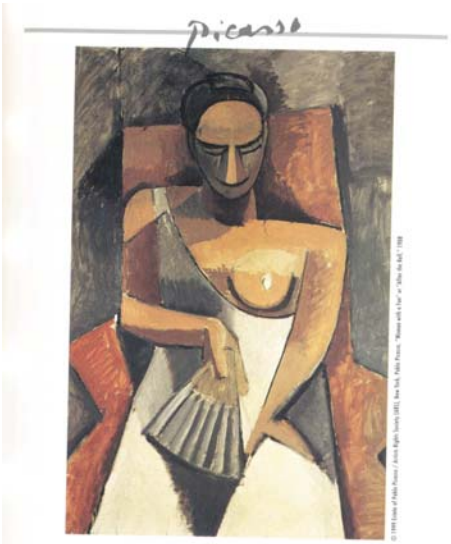
reality is recognizable,

even though sometimes fuzzy, the picture is understandable .

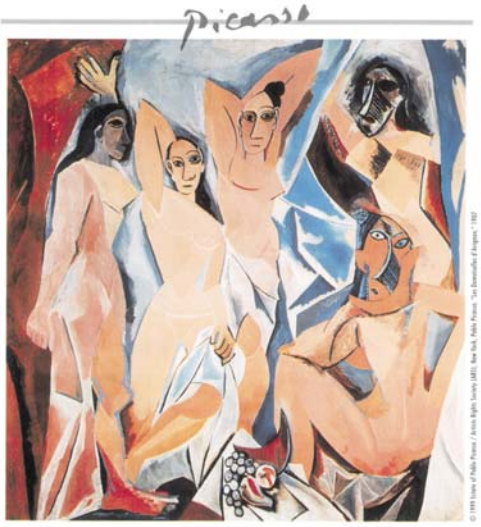
Then things start to look funny …



they become harder to recognize



… and disjointed,



… but you can still tell what is going on.

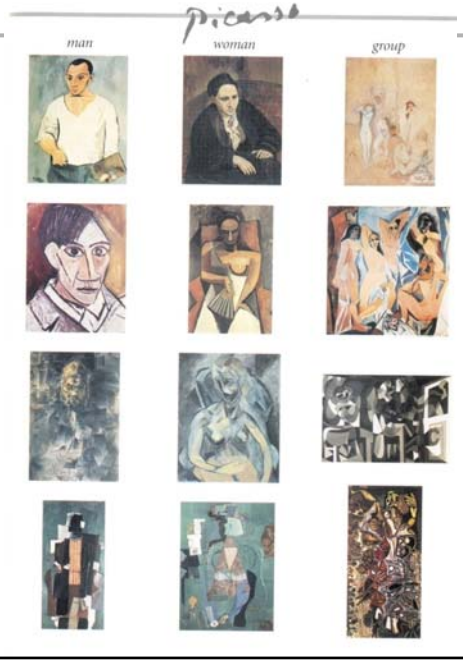
However, it gets harder…

… and harder

and finally it becomes impossible

to see what is going on…

... by looking at things the conventional way.



our onus is to figure out the pattern

that lies hidden underneath the apparent chaos on the surface

to see through Picasso's outer shell and uncover…

the Velazquez that lies behind it.

our onus is to figure out the pattern

space :: pattern

time :: ?trend

trends

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two trends tiggered by

disruptive

innovation

2 things

you simply could not do at all before

1 things

you can do at a significantly lower cost

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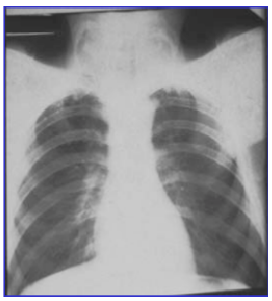
what did digital-ization

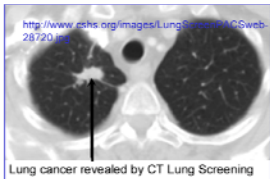
transform

in radiology?

ca 1900
X- Ray



ca 2000
CT

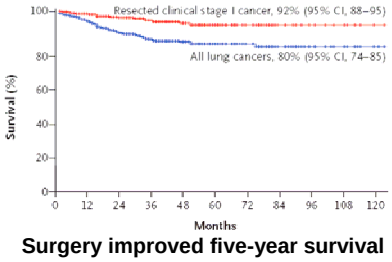


Lung cancer revealed by CT Lung Screening

31,567 asymptomatic persons at risk for lung cancer using low-dose CT identified 484 with stage I lung cancer

The NEW ENGLAND JOURNAL of MEDICINE

Survival of Patients with Stage I Lung Cancer Detected on CT Screening



Surgery improved five-year survival

15 years of digital radiology

2

New: 3D Visualization
New: Quantitative analysis (Cardiology, Oncology)
New: Fusion – anatomy and physiology
New: Contextual access to anatomy atlas at POC
New: Contextual access to "similar cases" at POC
New: Contextual access to expert opinion at POC

1

Productivity up by 20%
Report turn-around time down from 3 days to 3 hours
Radiology study availability up from 60% to nearly 100%
"Handling errors" down – undocumented

Clinician viewing up by a factor of 2
Comparison with prior studies up by a factor of 5
Screening (breast, lung, colon) up by a factor of 10

2 **things**

you simply could not do at all before

1 **things**

you can do at a significantly lower cost

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2 **redefine**
standard of care

1 **automate**
standard of care

what did digital-ization
transform
in radiology?

what can digital-ization transform in pathology?

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Potential Clinical Use Cases… inventoried

quantitative comparison

improve report turnaround time

case sharing and collaboration

pathology 2.0

education

archiving and retrieval

tumor boards

remote case review

reporting

improve slide “availability”

efficient primary diagnosis

research and clinical trials

consultation and second opinions

data mining for decision support

reduce handling errors

QA

quantification

CME and proficiency testing

remote frozen sections

image analysis

improve slide “availability”

personalized medicine

companion algorithms

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Potential Clinical Use Cases… organized

quantitative comparison
improve report turnaround time
case sharing and collaboration
pathology 2.0
education
archiving and retrieval
tumor boards
remote case review
reporting
improve slide “availability”
efficient primary diagnosis
research and clinical trials
consultation and second opinions
data mining for decision support
reduce handling errors
QA
quantification
CME and proficiency testing
remote frozen sections
image analysis
improve slide “availability”
personalized medicine
companion algorithms

Potential Clinical Use Cases… organized

2

Quantitative comparison
Case sharing and collaboration
Image analysis
Remote frozen sections
Data mining for decision support
Personalized Medicine

1

Improve report turn-around time
Archiving and retrieval
Tumor boards
Remote case review
Efficient primary diagnosis
Reduce handling errors
Improve slide availability
Quantification

2 **things**

you simply could not do at all before

1 **things**

you can do at a significantly lower cost

2 **redefine**

standard of care

1 **automate**

standard of care

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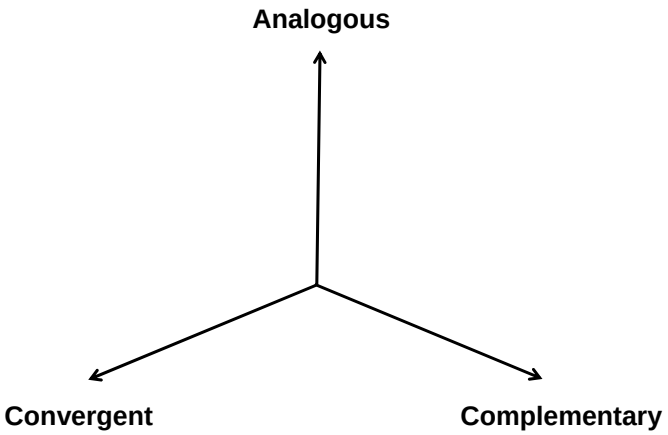
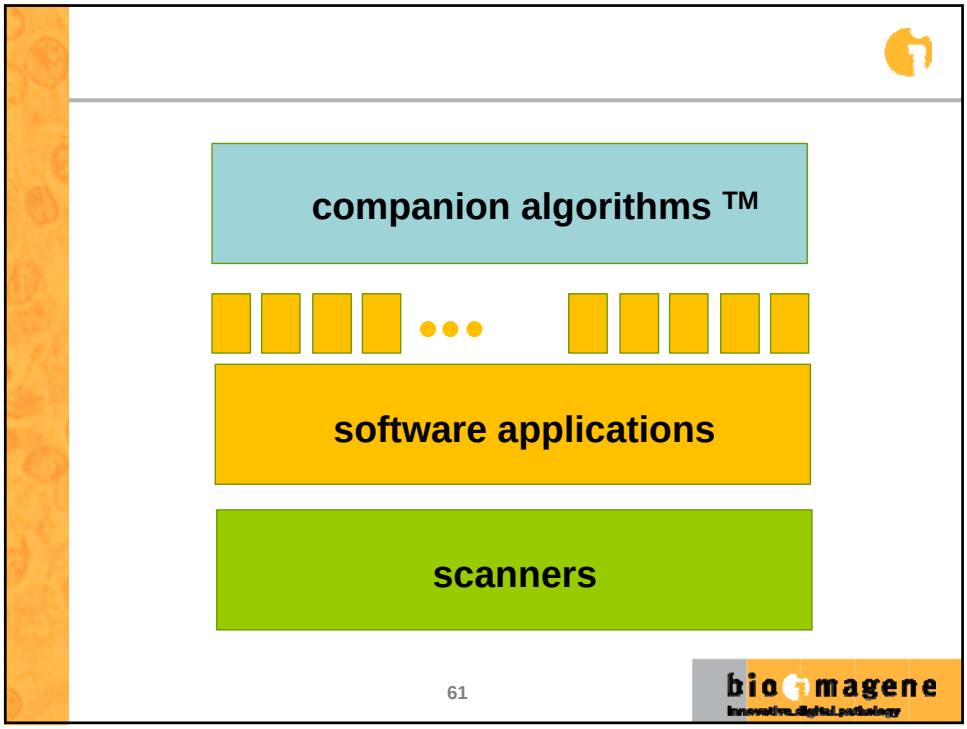
Radiology – Pathology Juxtaposition



how do we

implement

digital pathology?


companion algorithms ™
software applications
scanners
61
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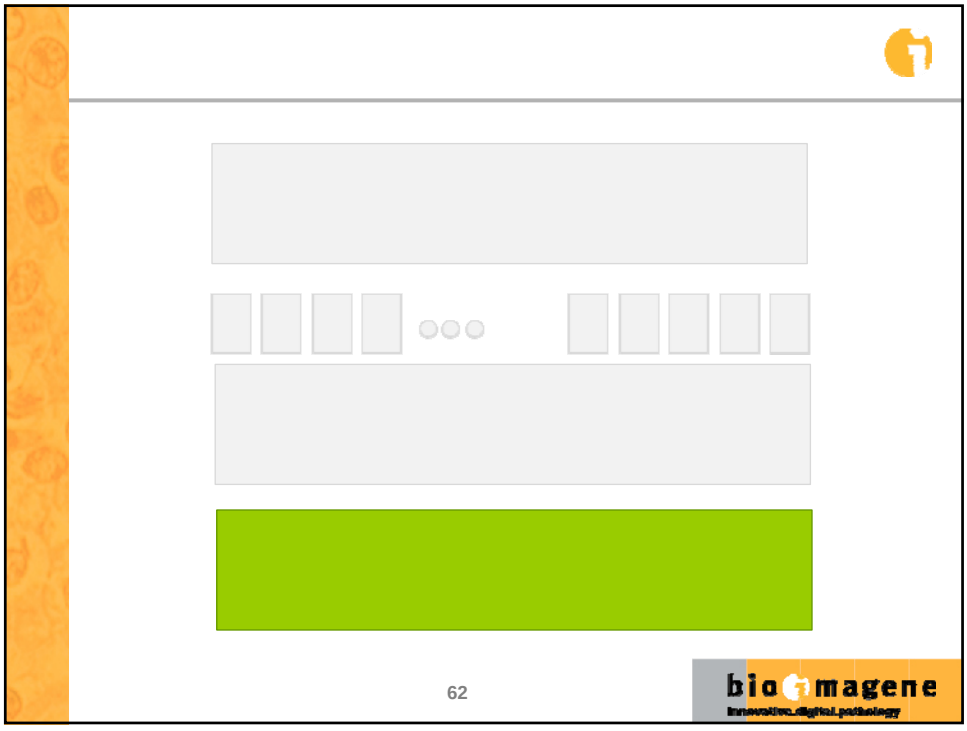
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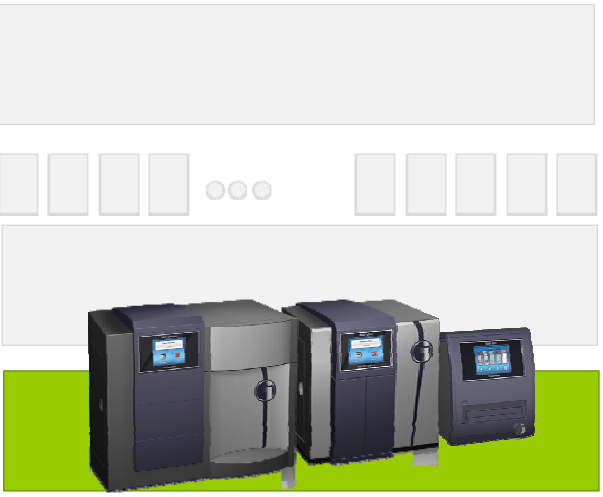
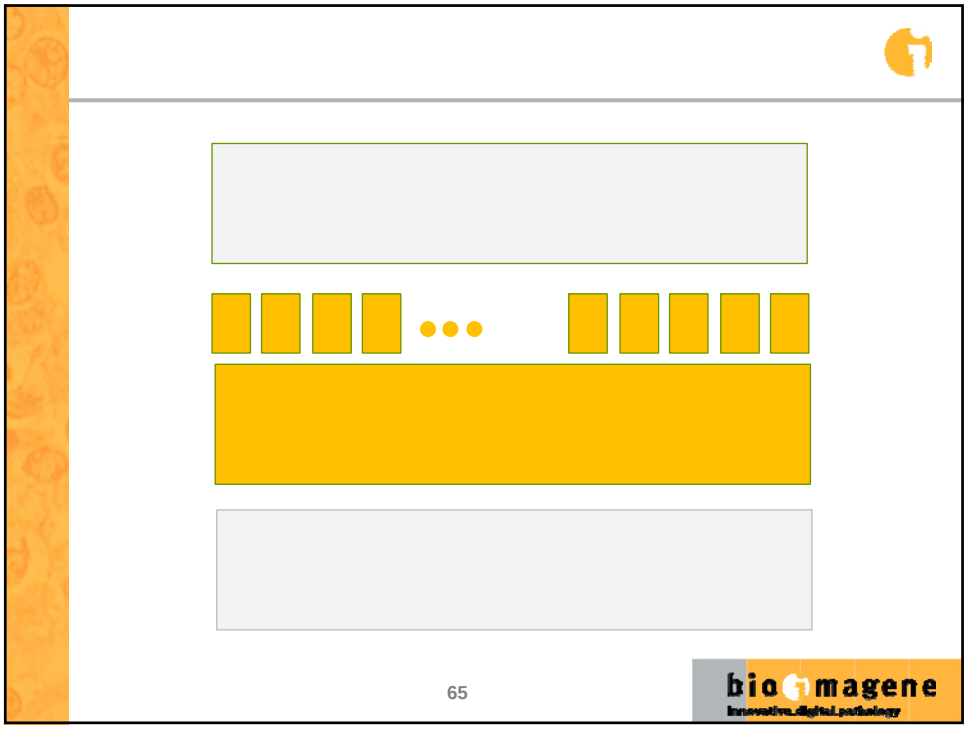


companion algorithms ™

software applications

scanners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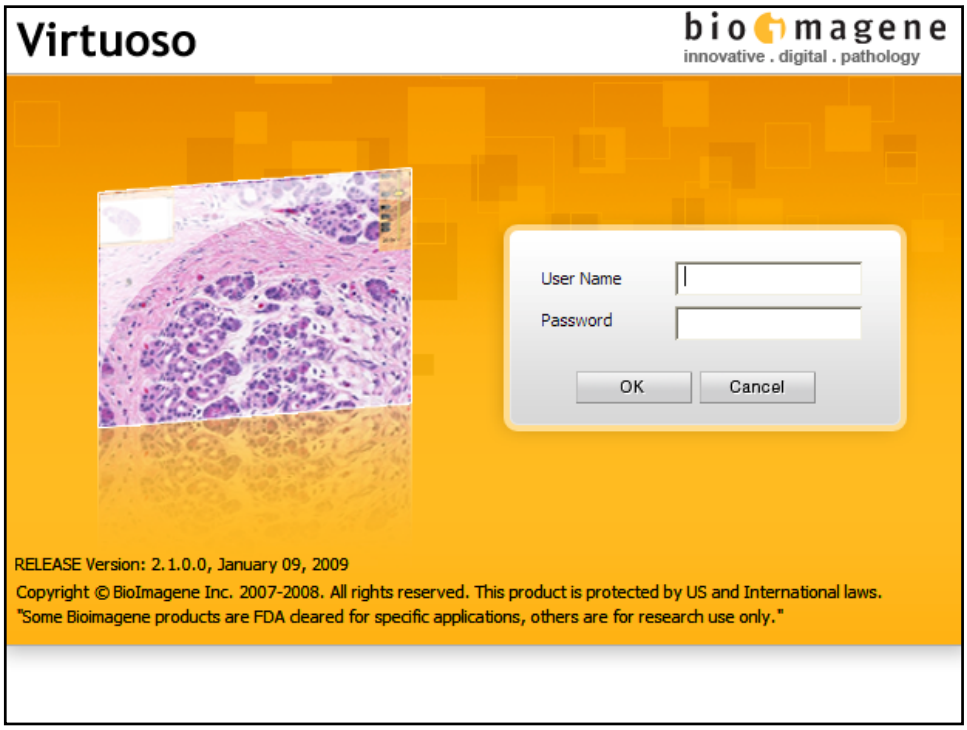
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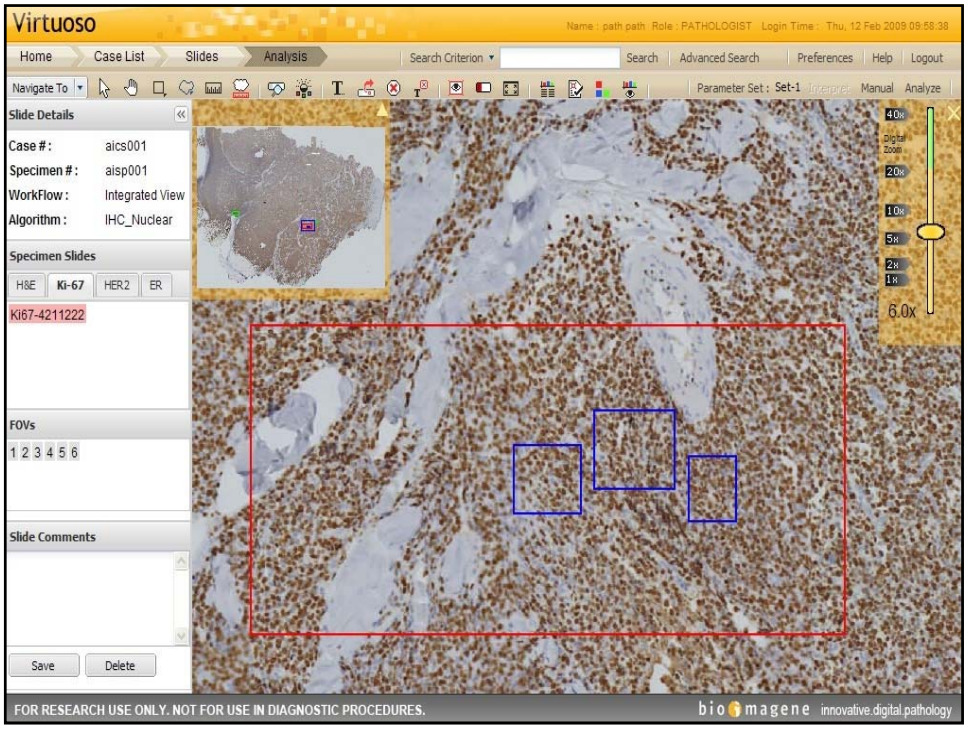
Virtuoso
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Case List
Slides
Analysis
Search Criterion
Search
Advanced Search
Preferences
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Navigate To
Parameter Set : Set-1
Manual
Analyze
Slide Details
Case # : aics001
Specimen # : aisp001
WorkFlow : Integrated View
Algorithm : IHC_Nuclear
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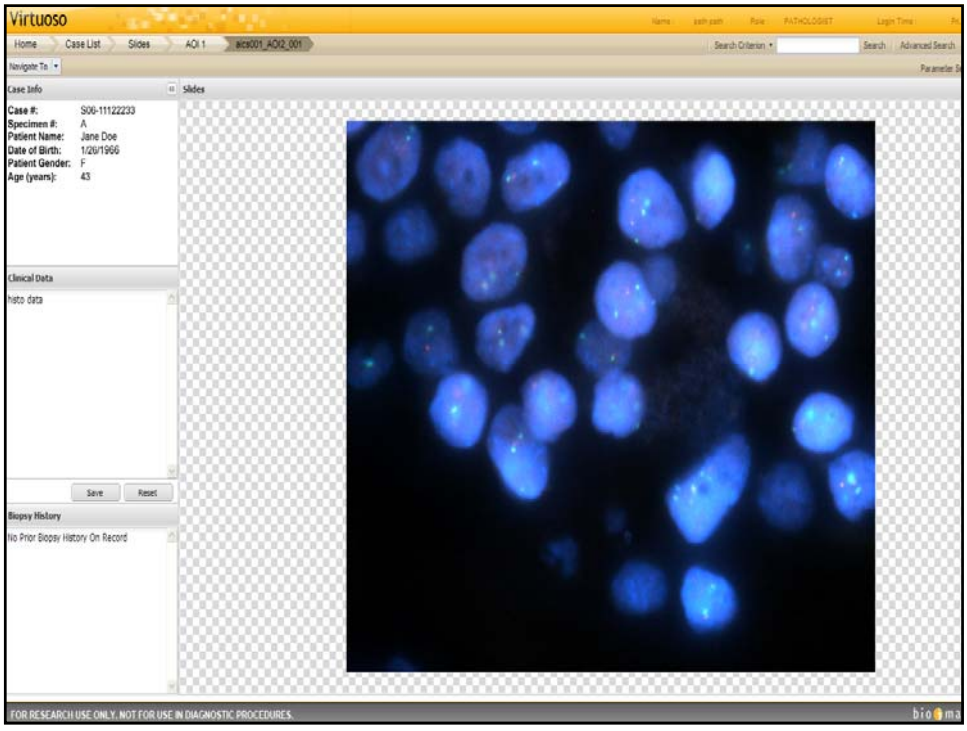
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Home
Case List
Slides
AOI 1
aics001_AOI2_001
Search Criterion
Search
Advanced Search
Navigate To
Case Info
Slides
Case #: S06-11122233
Specimen #: A
Patient Name: Jane Doe
Date of Birth: 1/26/1966
Patient Gender: F
Age (years): 43
Clinical Data
histo data
Save
Reset
Biopsy History
No Prior Biopsy History On Record
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Digital Pathology?

companion algorithms ™

software applications

scanners

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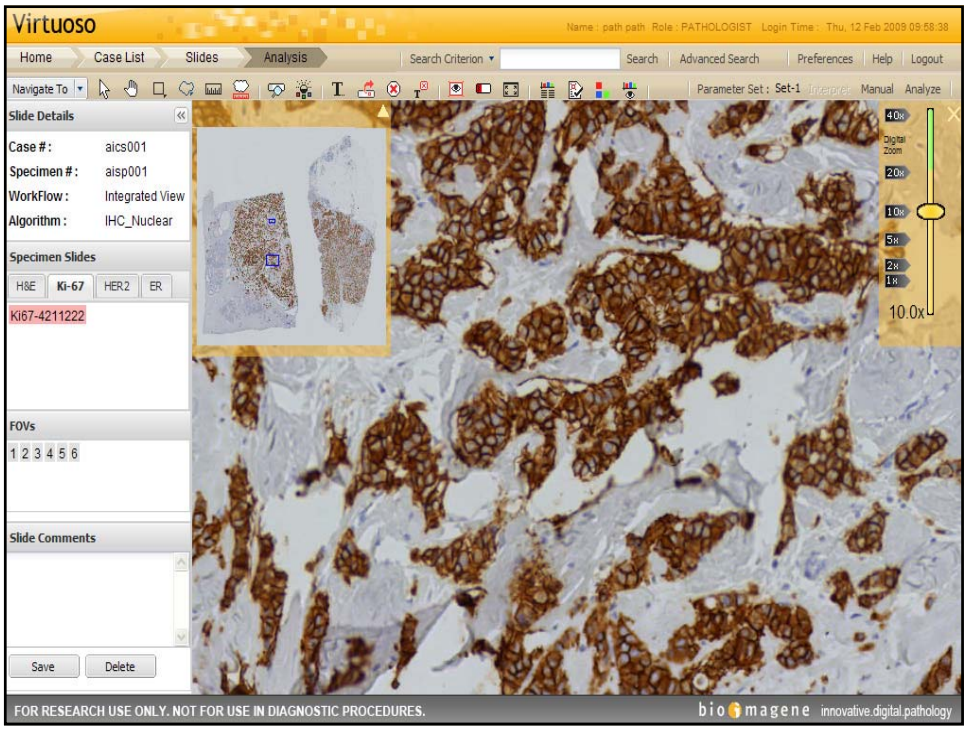
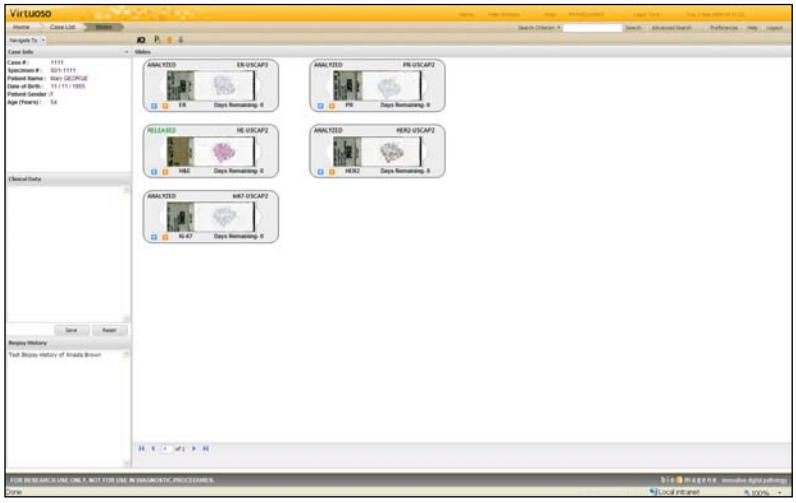
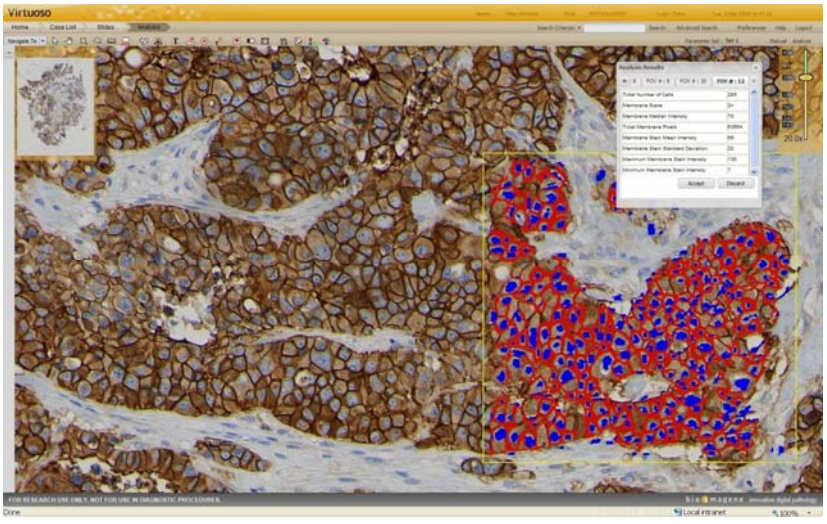


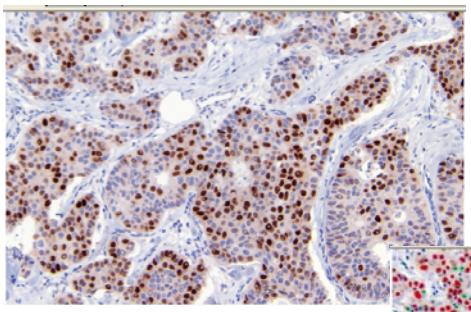
Breast Panel – Image Analysis for IHC

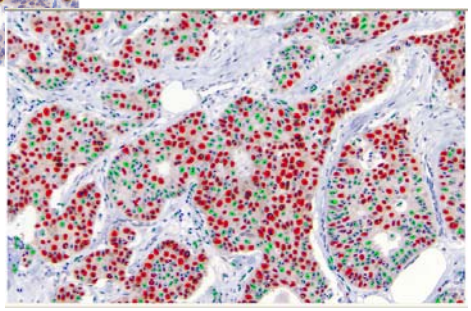


Her2-neu IHC: Membrane Algorithm



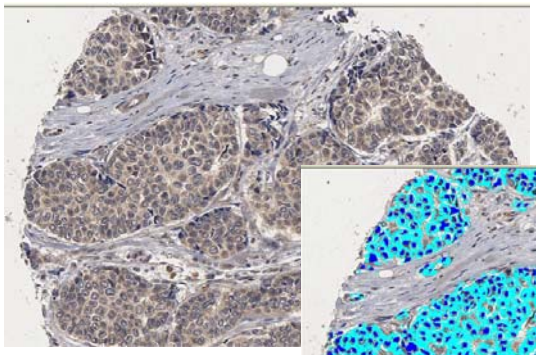
ER/PR IHC: Nuclear Algorithm

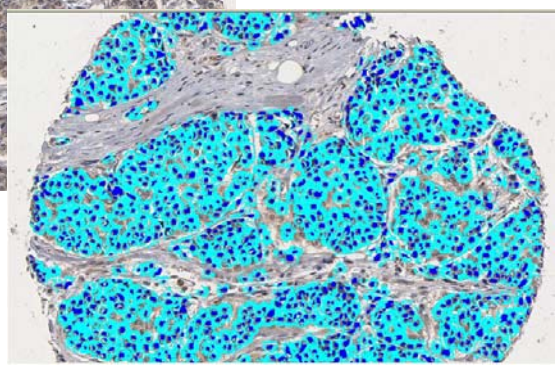




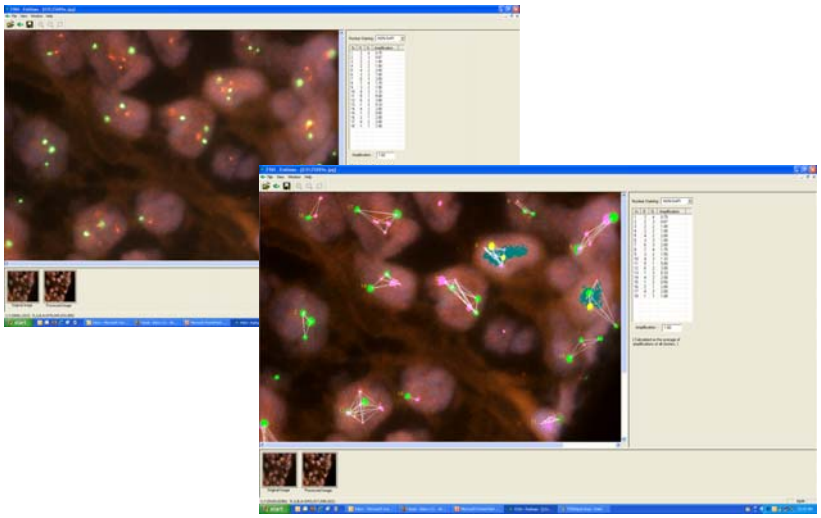
Results	Nuclear
Non Stained Cell Count	95
Stained Cell Count	314
Percent Positivity	77

Cytoplasmic Algorithm

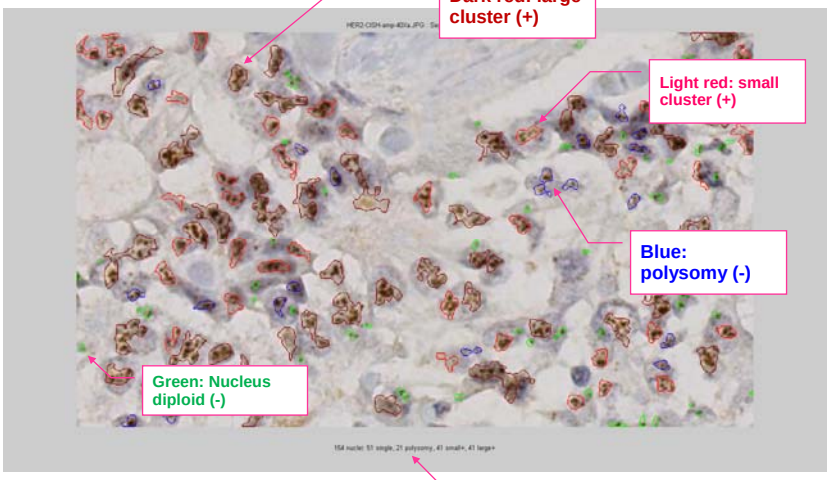




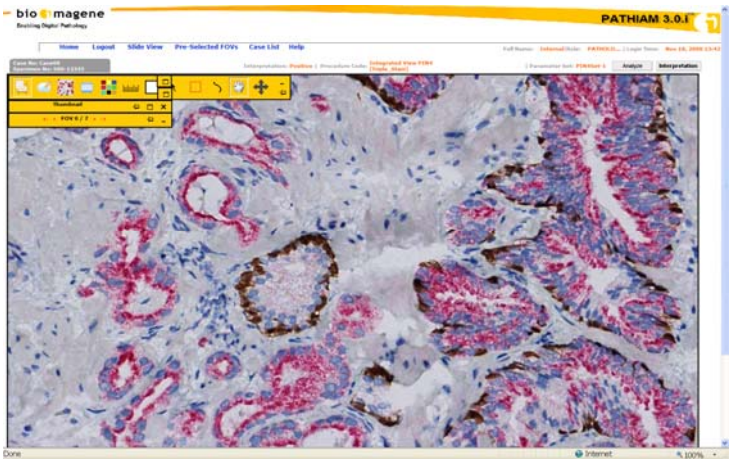
Digital Scoring of Her2-neu FISH



Digital Scoring of Her2-neu CISH



Prostate Panel: IHC triple stain algorithm



P504s (red, cytoplasmic stain)

K903 (brown, cytoplasmic stain)

p63 (brown, nuclear stain)

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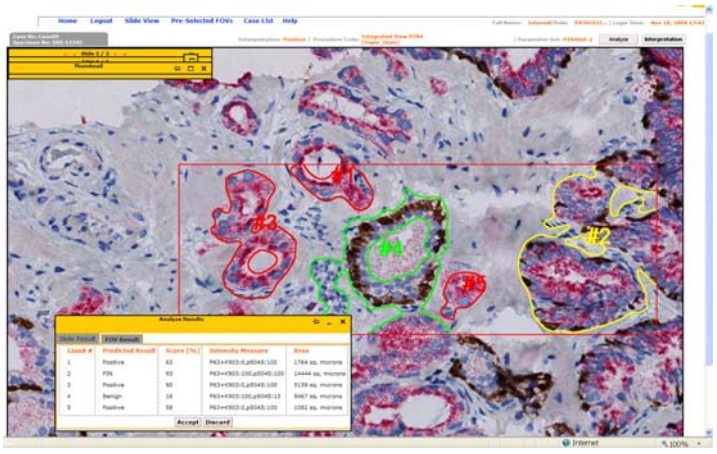
Prostate Panel: IHC triple stain algorithm



Red glands (Red only): Adenocarcinoma

Green glands (Brown only): Benign

Yellow glands (Red + Brown): HGPIN

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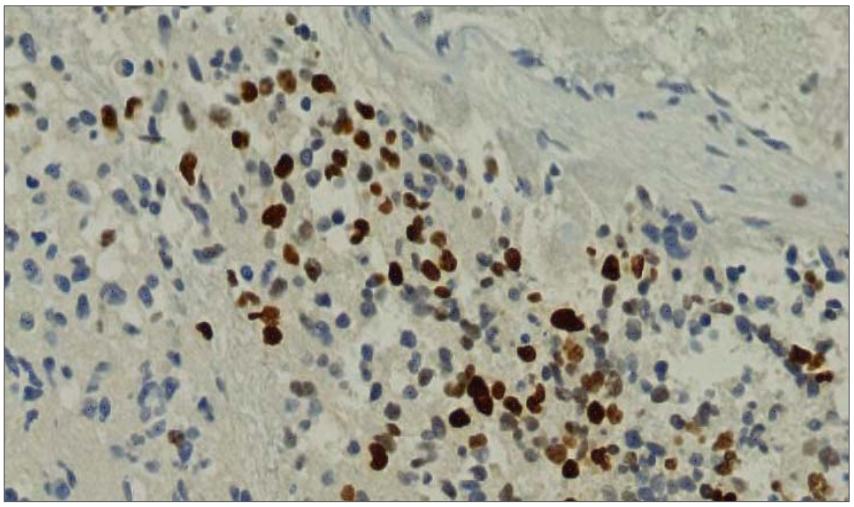
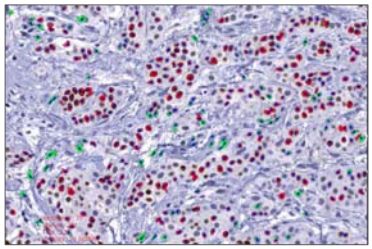
Ki67 Scoring in CNS Glial Tumors



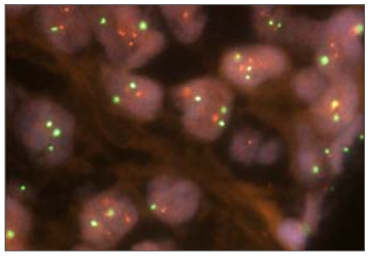
56%

Companion Algorithms: Breast Cancer

Her2-neu IHC, FISH,and CISH: selection of patients for Herceptin®



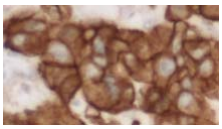
ER/PR scoring selection of patients for anti-estrogen therapy

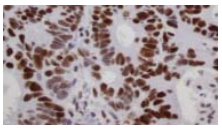


Companion Algorithms: Colon and Lung

Colon Cancer

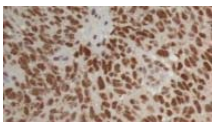
- EGFR testing (IHC/FISH) for selection of patients for Erbitux®
- Thymidylate synthase testing for selection of patients for anti-folate based chemotherapy
- MLH/MSH testing for identification of patients with hereditary nonpolyposis colorectal cancer (HNPCC)





Lung cancer

- EGFR testing (IHC/FISH) for selection of patients for Tarceva® and Iressa®
- ERCC1 and RRM1 testing (IHC) for selection of patients suitable for chemotherapy drugs - prediction of response to cisplatin and gemcitabine



Companion Algorithms: Other Cancers

Prostate Cancer

- Therapy selection - AR IHC for selection of patients for anti-androgen therapy
- Prognostic FISH markers - 21q22 Rearrangements (*TMPRSS2*)

Gastrointestinal Stromal Tumors

- CD117 testing for diagnosis and selection of patients for Gleevec® therapy

Oligodendrogliomas

- FISH testing for deletions at chromosomes 1p and/or 19q for predicting response to chemotherapy

Lymphomas/leukemias – variety of tests (including IHC and FISH) crucial for diagnosis, prognosis, and treatment decisions

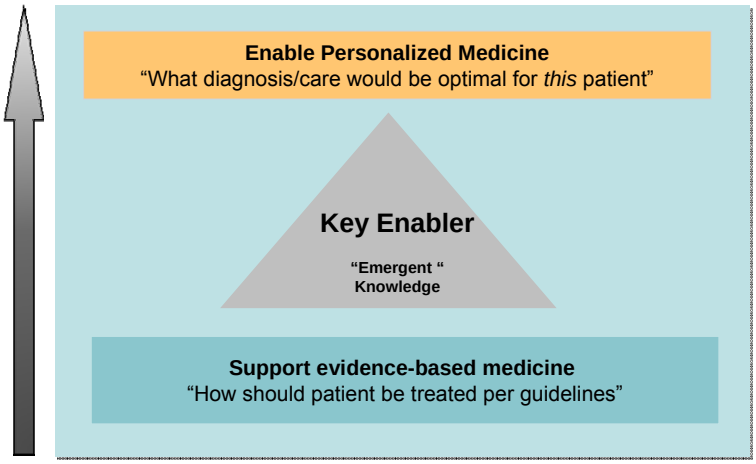
companion algorithms ™

enable companion diagnostics

companion algorithms ™

enable personalized medicine

Personalized Medicine: What?



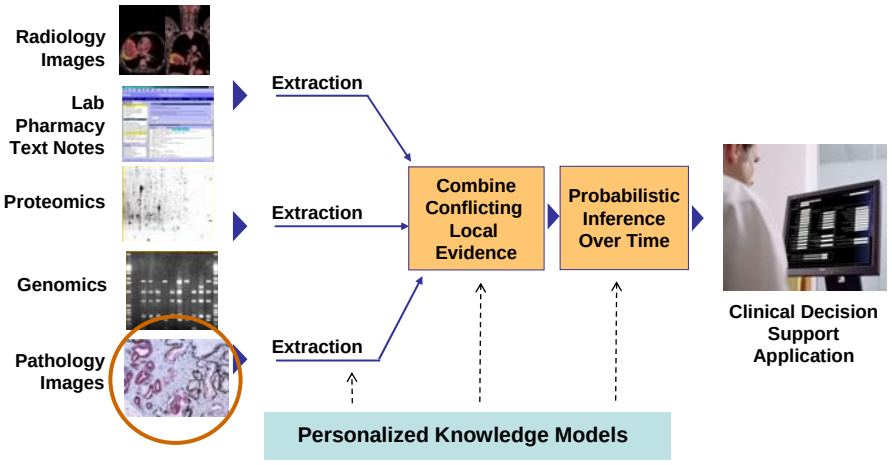
Personalized Medicine: How?

1. **<u>Collection</u> of large databases of patient data and external medical knowledge**

2. **<u>Creation</u> of personalized knowledge models**

3. **<u>Application</u> of personalized knowledge models in clinical workflow**

Personalized Medicine: How specifically?



digital

pathology…

… is a key “missing piece”

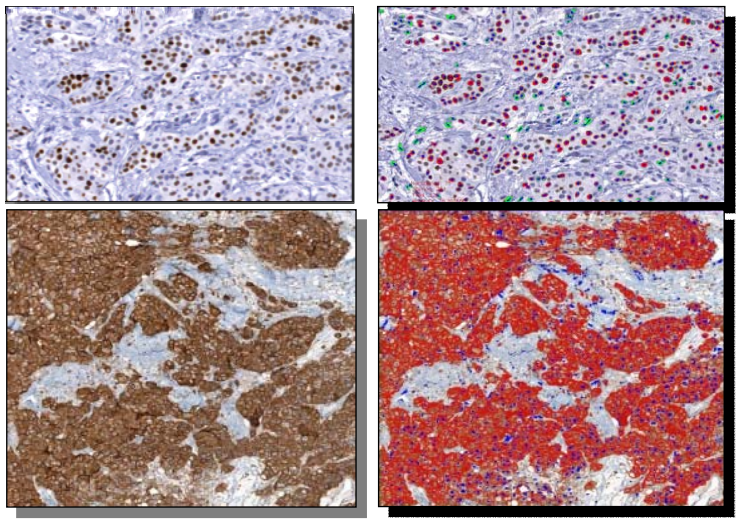
With discovery of new biomarkers….

Identification of biomarkers whose expression correlates with:

1.Behavior of disease (for prognosis)

2.Response of disease to specific therapeutic agents

… the role of quantification will increase

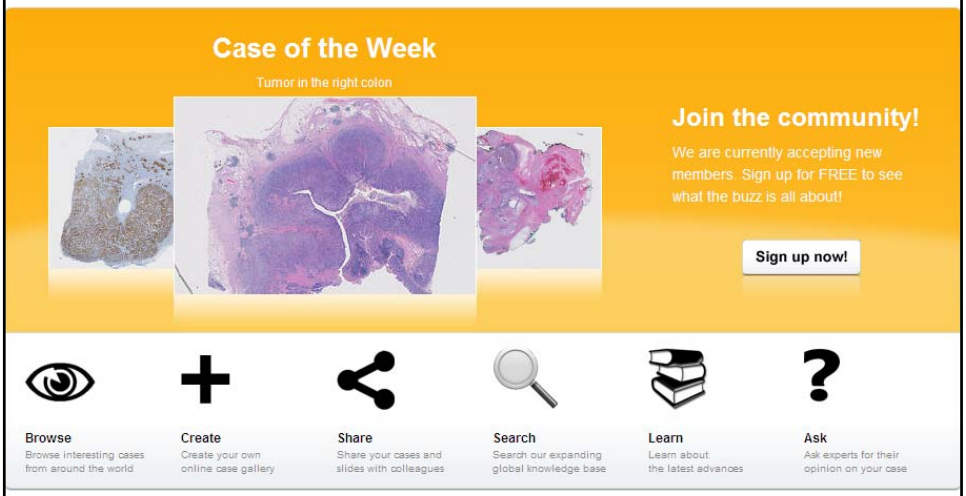


companion algorithms ™

will redefine standards of care

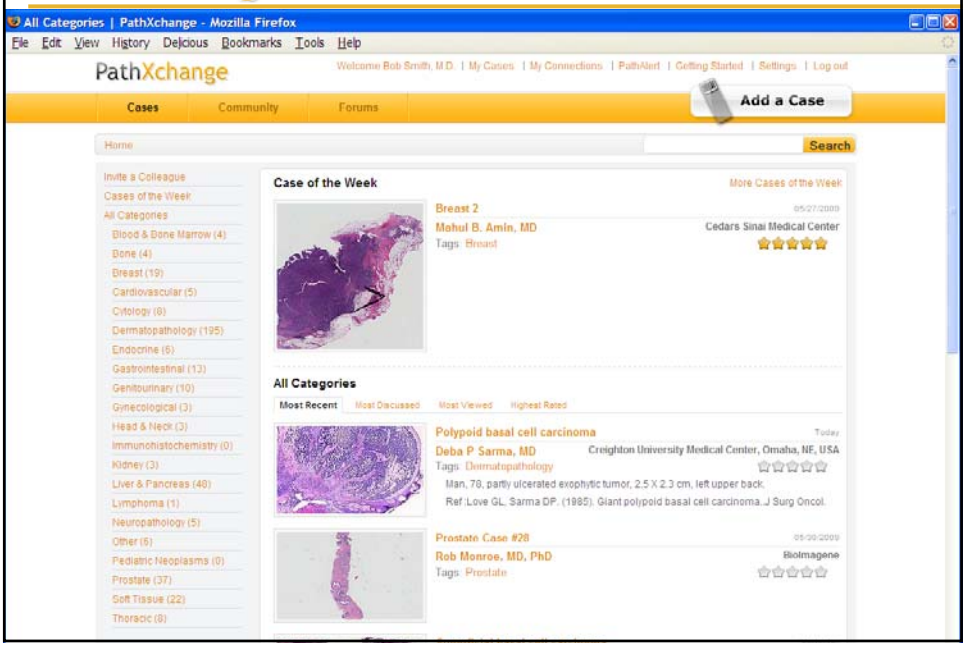
how do we accelerate adoption?

PathXchange



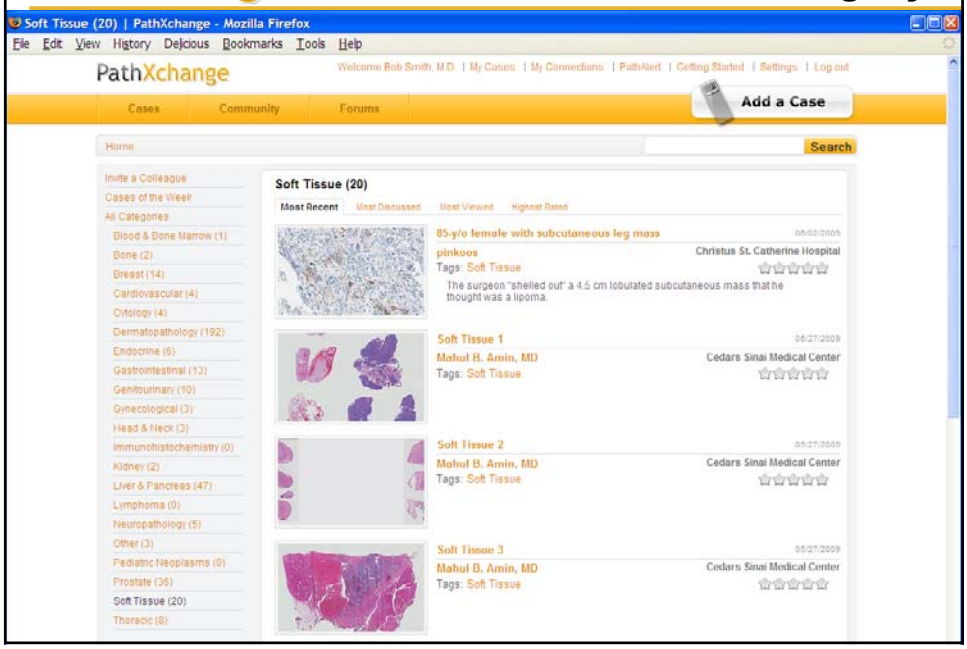
PathXchange

Browse case gallery



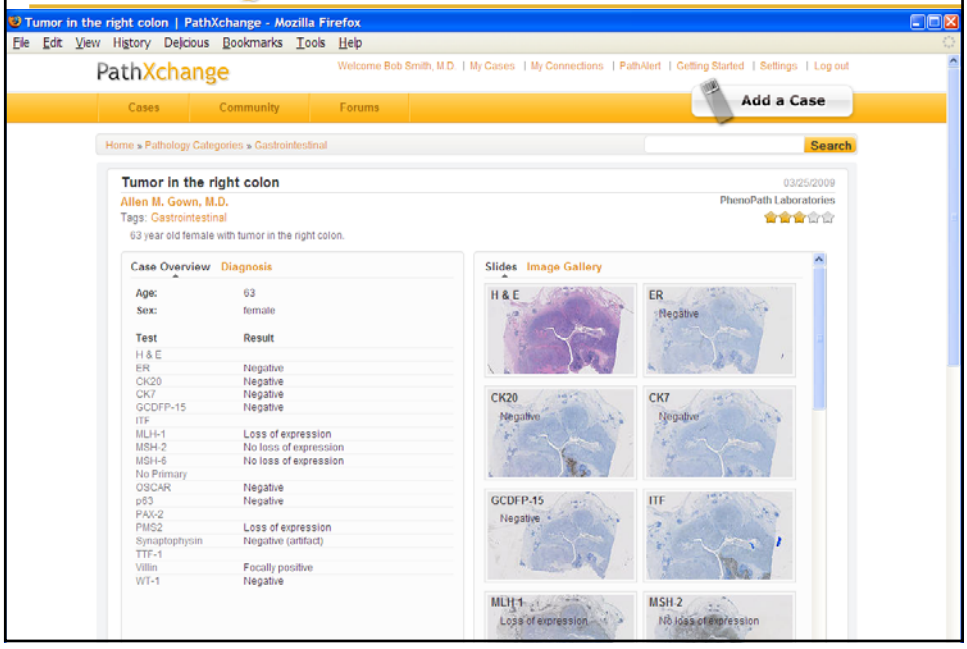
PathXchange

Browse cases in a category



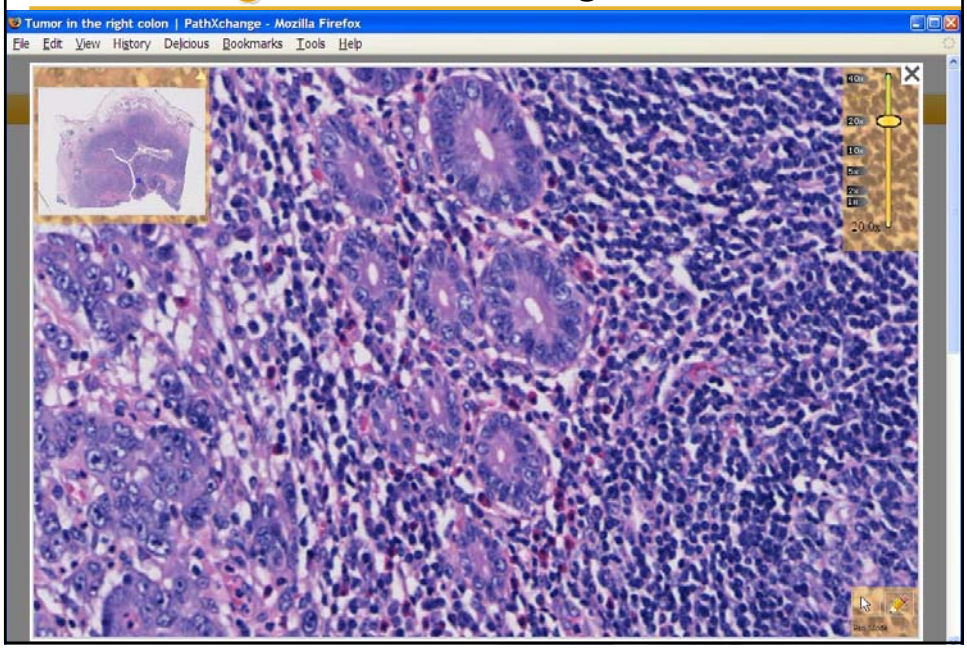
PathXchange

Browse a case



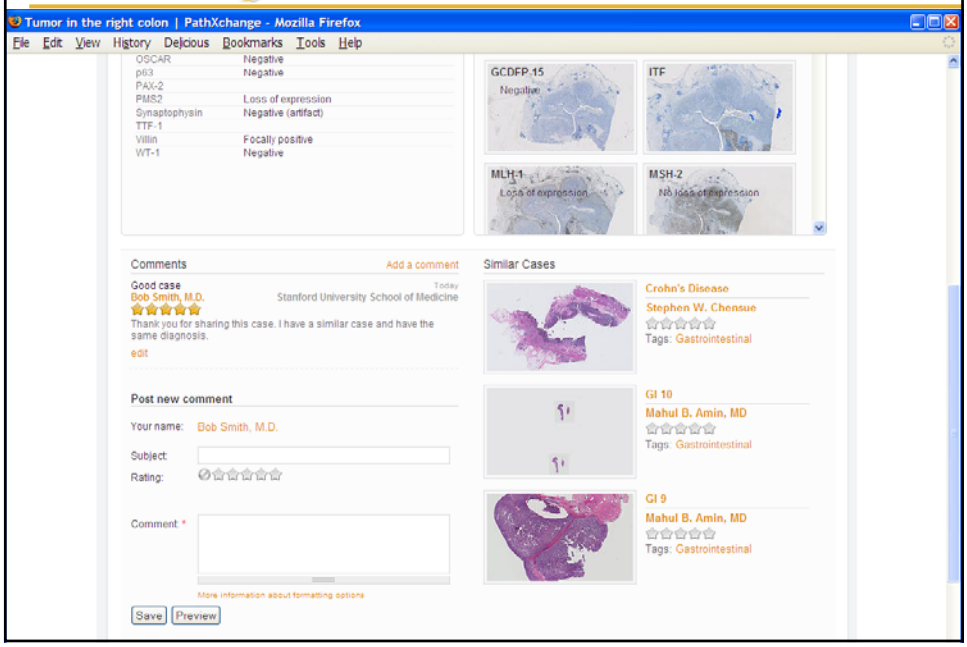
PathXchange

Browse digital slides



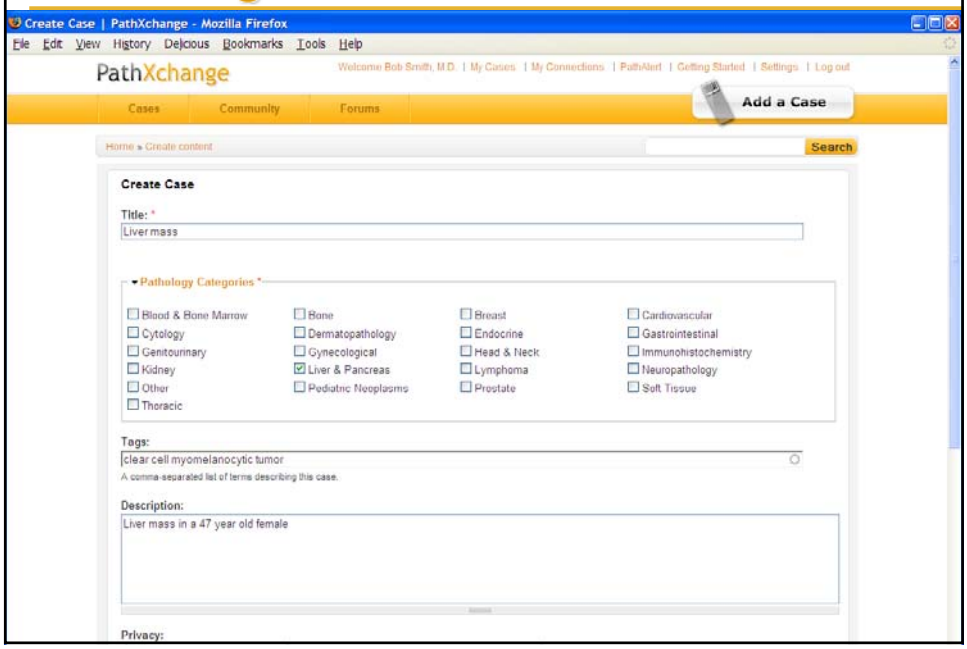
PathXchange

Browse similar cases



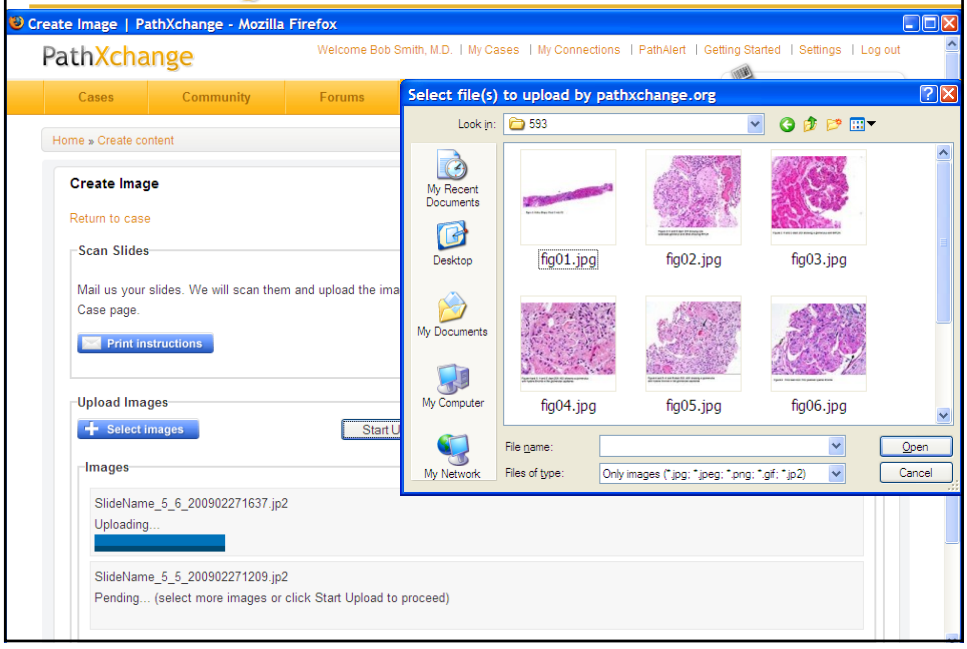
PathXchange

Create a case



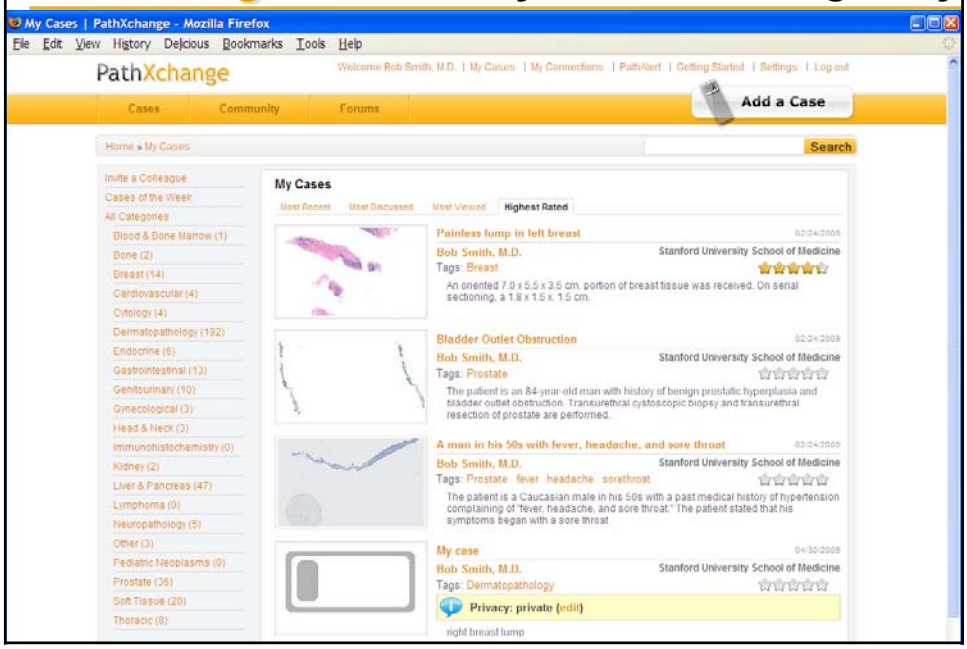
PathXchange

Scan slides and upload



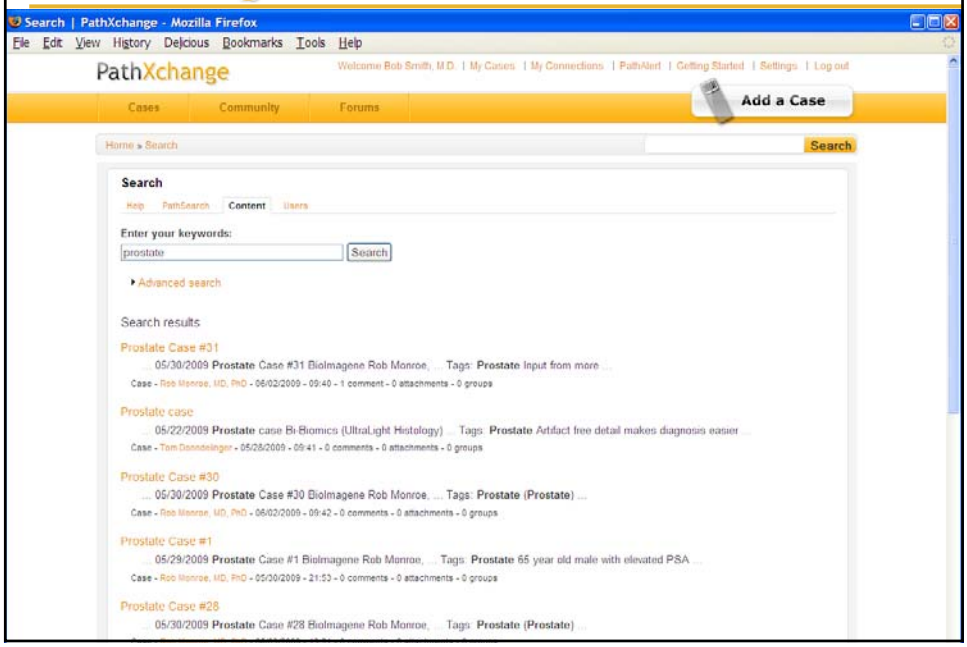
PathXchange

Create your own case gallery



PathXchange

Search for cases, users…



PathXchange

250 days... since launch

4000 pathologists... online

8000 cases... uploaded

120 countries

what is our

compass?

biomagene
innovative digital pathology

Our compass for the industry….

1. … from acquisition thru image analysis, to decision support to report
2. … from “off-time” to real-time, from single-modality to multi-modality
3. … from morphology to molecules (….morphology AND molecules)
4. … from “information” to “diagnostic confidence”

5. … to personalized medicine, enabled with companion algorithms ™

What does that mean?

“from pathologist to diagnostician”

… an INTEGRATOR!

what

trends

will this trigger...

... for the

delivery

model

1

integration

across the value chain

bio magene
innovative digital pathology

2

disintermediation

of the value chain

3

personalization

of therapeutic decisions

4

super-specialty

based delivery model

5

integration

of morphology and molecules

6

integration

radiology and pathology

7

integration

across the medical record

8

efficiency

will remain a key driver

9

informatics

will emerge as a “practice”

10

education

will change dramatically

Digital Pathology will….

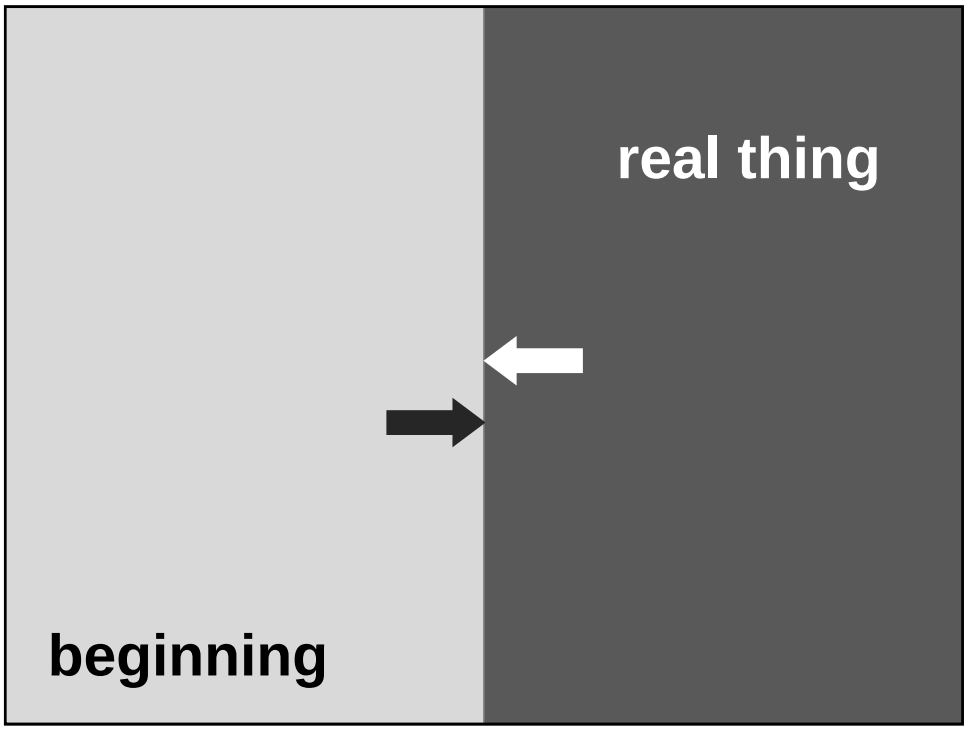
2 **redefine**
standards of care

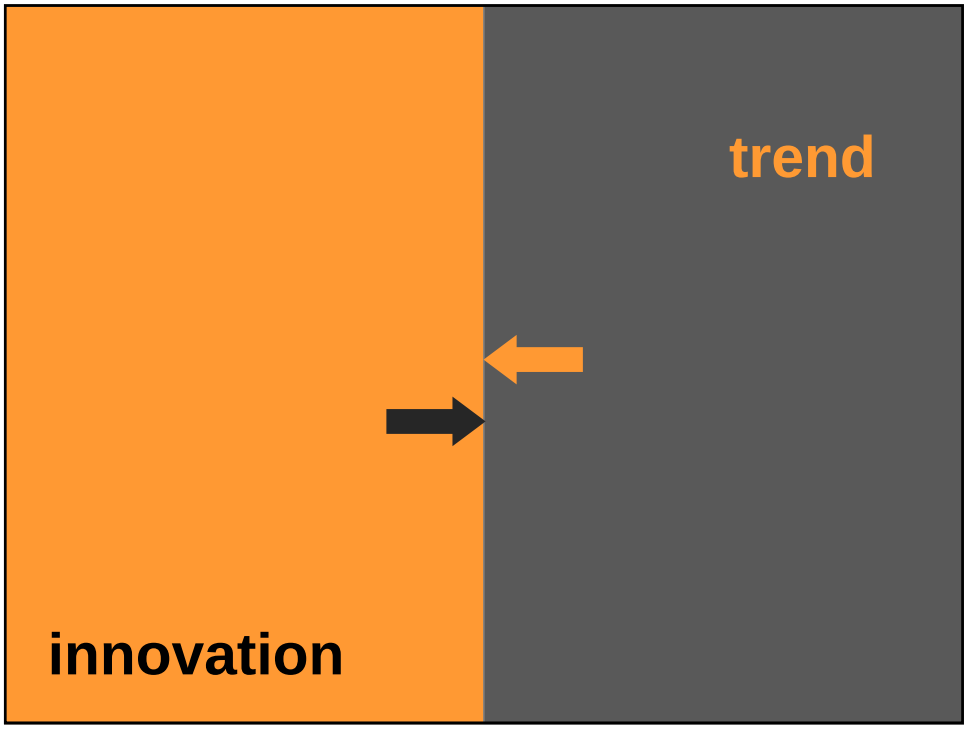
1 **automate**
standards of care

bio magene
innovative digital pathology

And we are at….

the end of the beginning





digital pathology

an enabler for a disruptive change

biomagene

digital pathology

the beginning of a trend