Data Interchange Standards: Relevance for the Lab Professional

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No topic has been so frustrating, contentious, and yet so tedious as the subject of data standards…

Jules Berman, Bioinformatics

A different type of “standards talk”

HL7 and DICOM

Goals

- Stop thinking of DICOM and HL-7 as tools and plumbing.
- Stop thinking of them as “standards” that at forced on you
- Think of them as organizations. Global organizations of people.
- Organizations of people very dedicated to integration of clinical information and images between disparate clinical systems in the real world
- Smart people, some of whom have worked on clinical data integration of twenty years
- People nonetheless

Goals

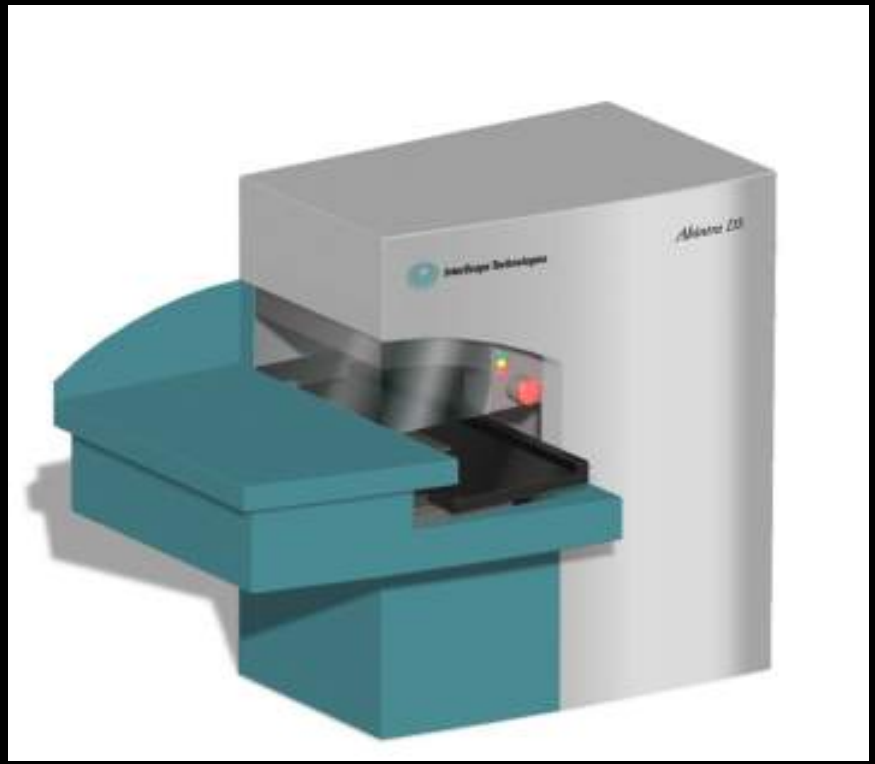
- Begin to think of HL-7 and DICOM as organizations that you can impact and make better
- Begin to think of HL-7 and DICOM as interesting and cutting edge organizations
- Begin to think of HL-7 and DICOM as strategic
- I will do this through two stories. One about DICOM and one about HL-7
- The stories might become technical, but don’t focus on that, Focus instead on the idea that these are organizations of people that you can work with, influence for your practice and your field

The story of DICOM WG 26

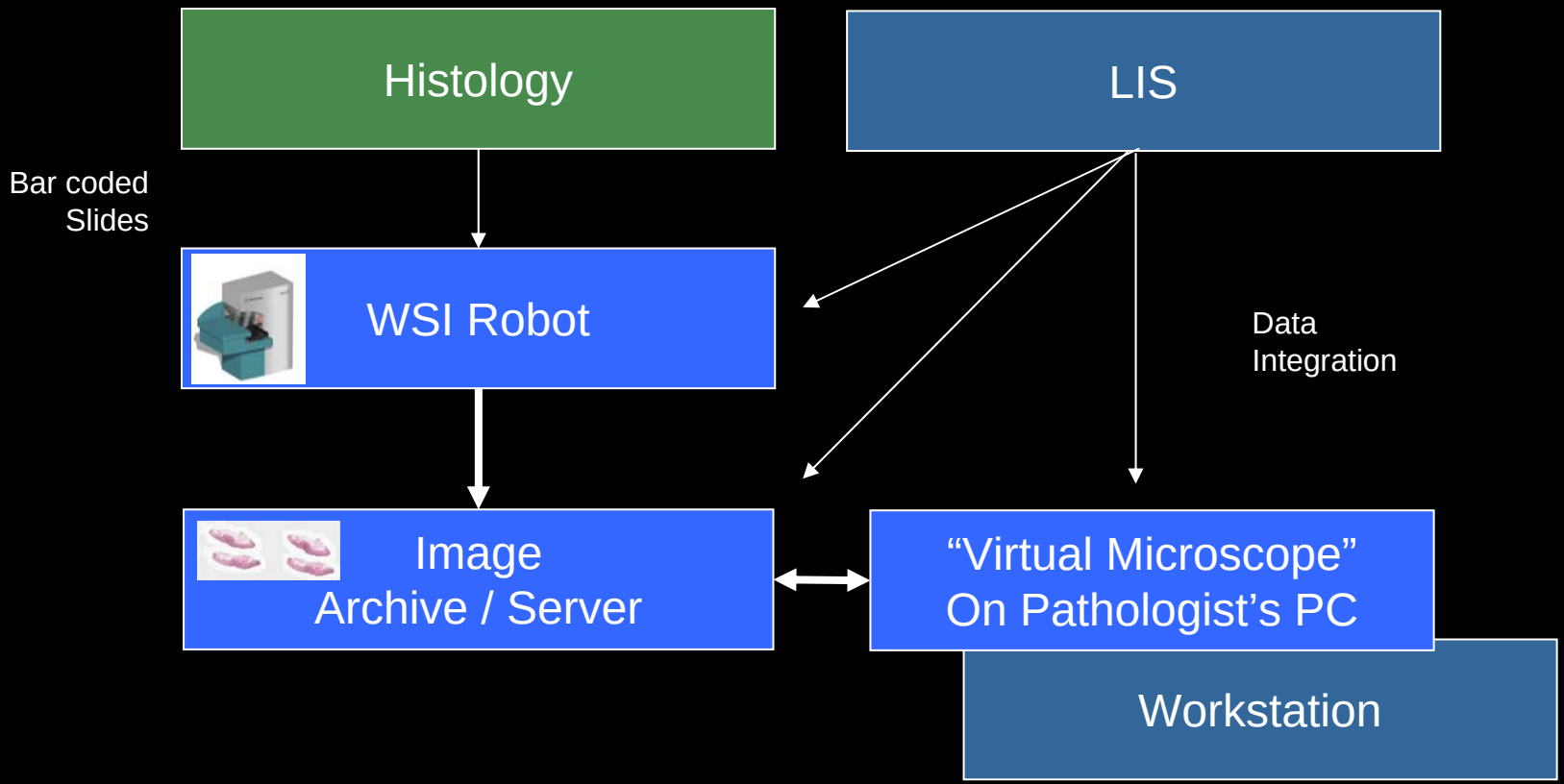
- We are about to enter a period of great change in Pathology. In the relatively near term, we will be able to digitize all of our slides, at high resolution and multiple focal planes as the slides as they come out of histology

- This capability might be transformational, maybe even disruptive. If we can image, we should be able to apply computational power and network connectivity to study of morphology and the practice of pathology

Imaging Robots



- The engine of this change will be the Automated, high speed, high resolution whole slide imaging robots
- Automated – give the robot a slide, press a button and walk away
- Read Bar Codes
- Full Sampling
- High Resolution (large image sizes)
- Fast


Histology
LIS
Bar coded
Slides
WSI Robot
Data
Integration
Image
Archive / Server
“Virtual Microscope”
On Pathologist’s PC
Workstation

Tasks
- Work List
- Case (S01-00104)
- Conference
- Search

Tools

Resources

Support

InterScope Technologies
Intelligent tools for pathology™

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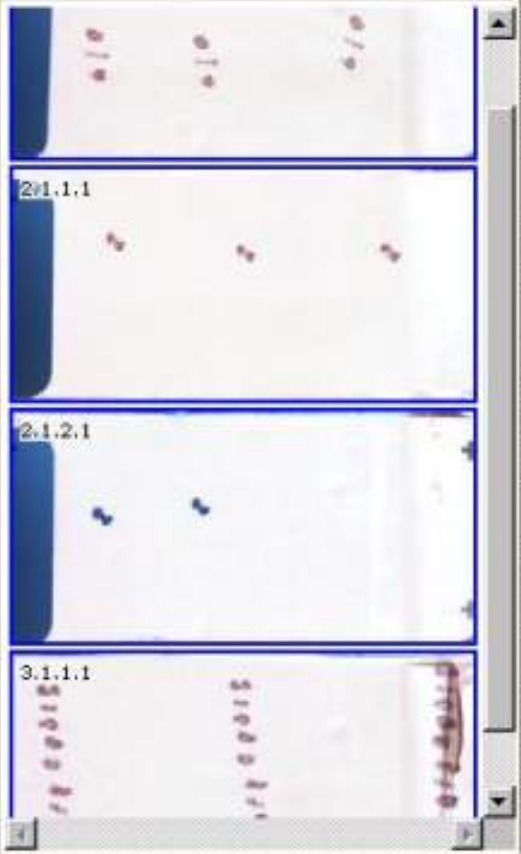
Patient Name:
Madison, Dolley

Accession #:
S01-00104



Accession Date:	**10/19/2000**	MRN:	**999820372**
Procedure Date:	**10/18/2000**	DOB:	**6/19/1948**
Signout Date:	**Not Signed Out**	Sex:	**Female**
Attending MD:	**Walter Brown, DR**		

PATIENT HISTORY:

Polyps

GROSS DESCRIPTION:

1. Esophagogastric Junction, Biopsy: A formalin container is received labeled with the name "D. Madison" and "bx E-G Junction". It contains three 0.1 cm. diameter items of tan soft tissue that are submitted in toto as #1.

2. Stomach, Not otherwise specified, Biopsy: A formalin container is received labeled with the name "D. Madison" and "gastric bx". It contains a 0.1 cm. diameter item of tan soft tissue that is submitted in toto as #2.

3. Colon, Sigmoid, Polypectomy: A formalin container is received labeled with the name "D. Madison" and "sigmoid colon polyp". It contains multiple fragments of tan soft tissue that in aggregate are 0.4 cm. in diameter. They are submitted in toto as #3.

☐ Flag Case

*Patient Demographic *Patient History
*Gross Description

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Log Off
Full Scree
Where Are
Show Text
Compare
Related Case
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Measure
Patient Name:
Dolley Madison
Accession #:
S01-00104
Viewing Slide #:
1.1.1.1
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2.1.1.1
2.1.2.1
3.1.1.1
0.39%
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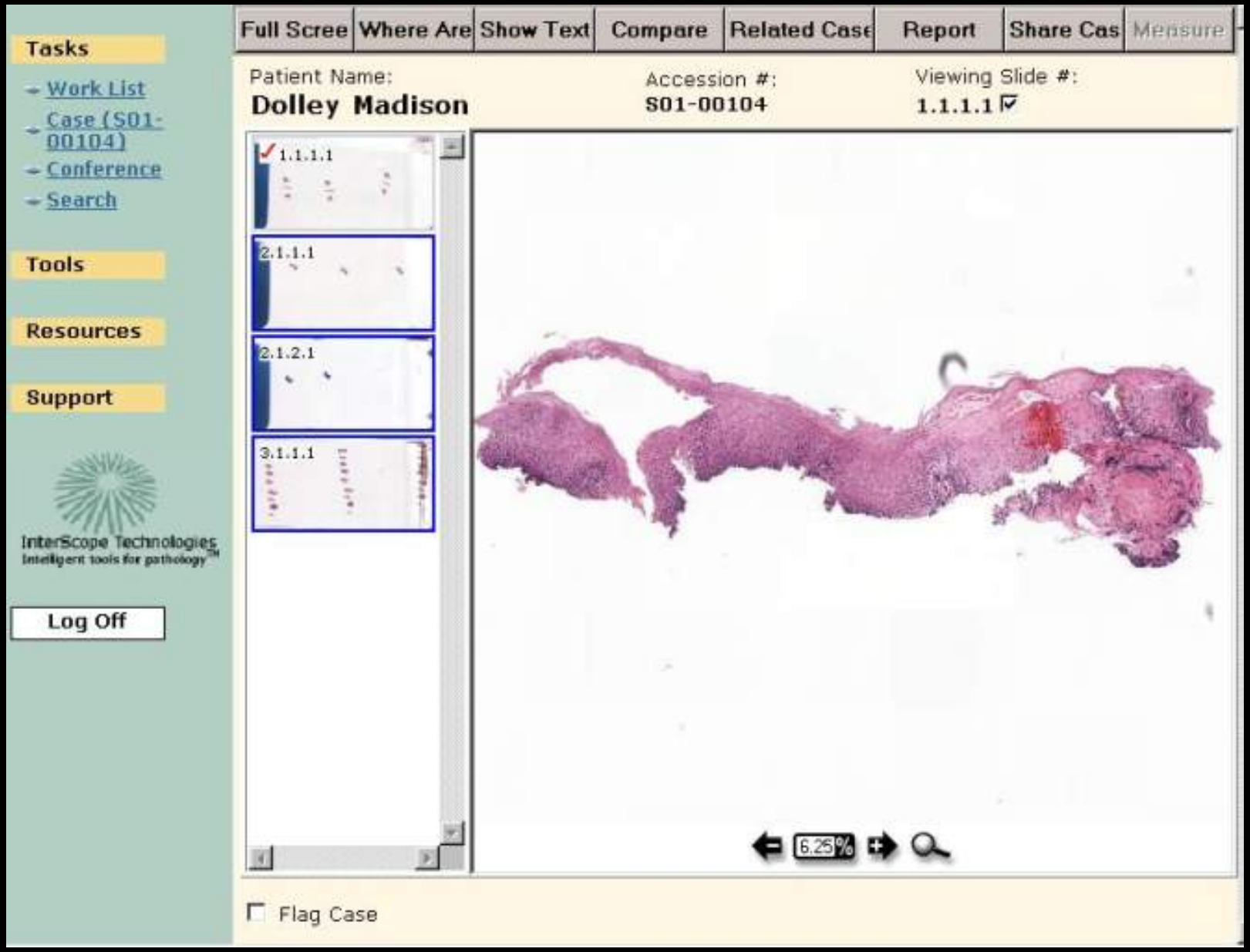
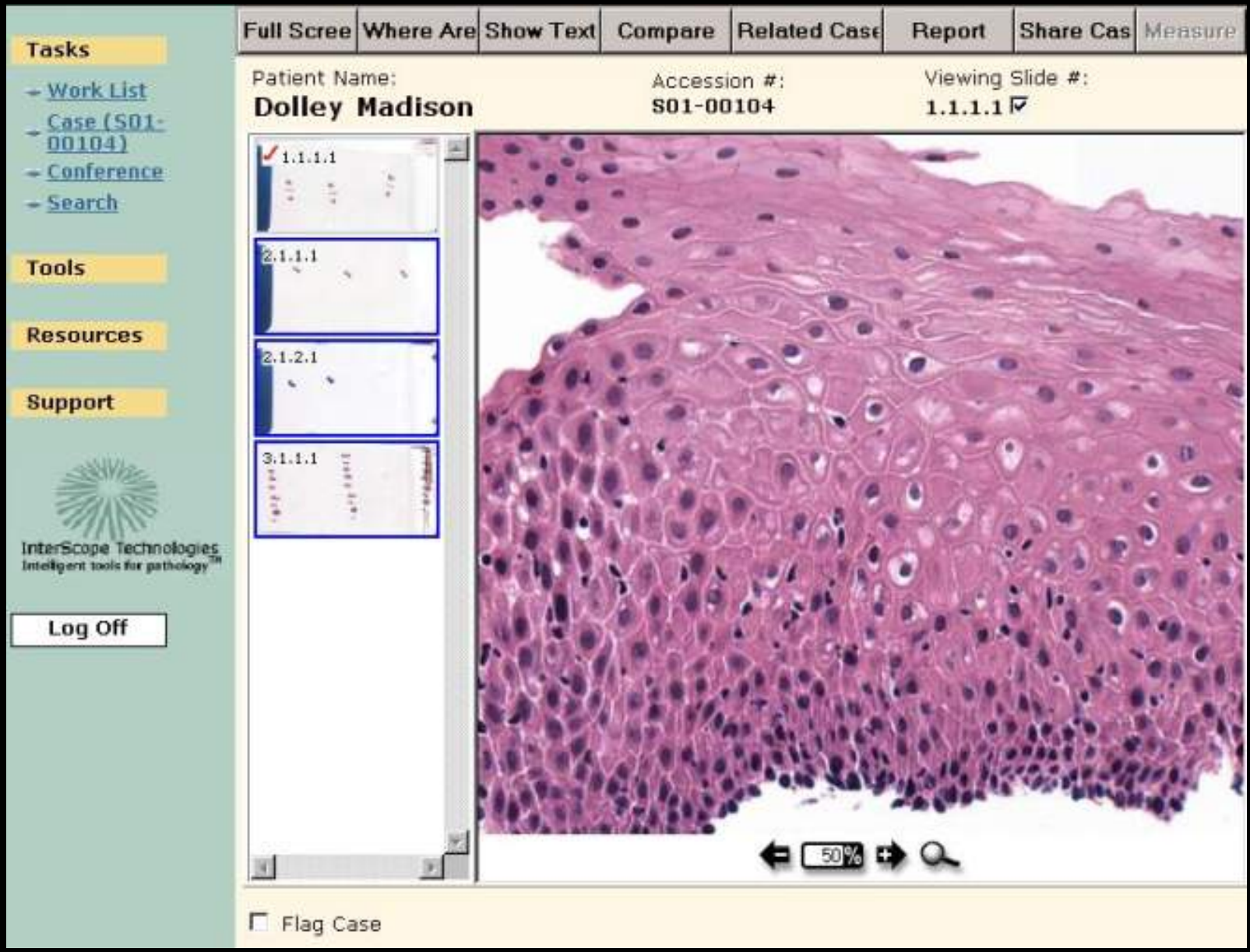


Case Western Reserve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Viewing Slide #:
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3.1.1.1
50%
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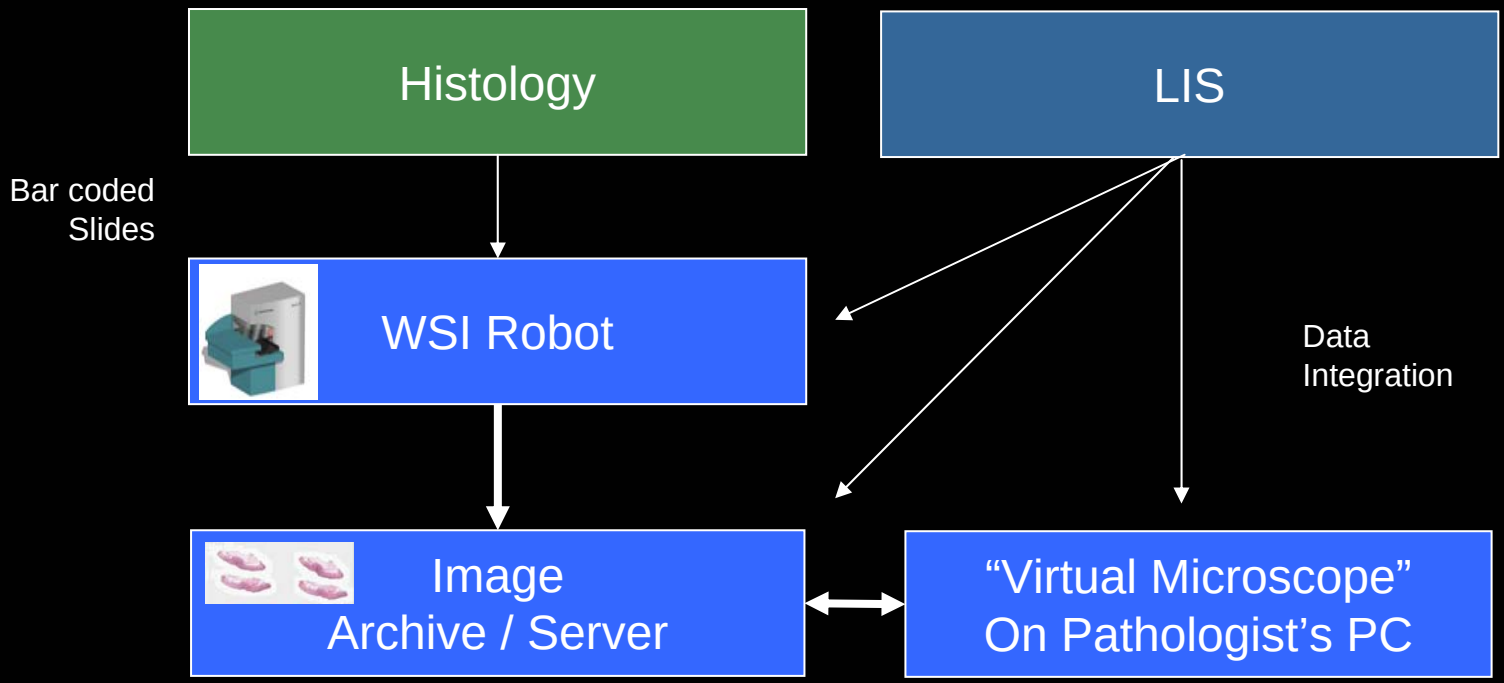
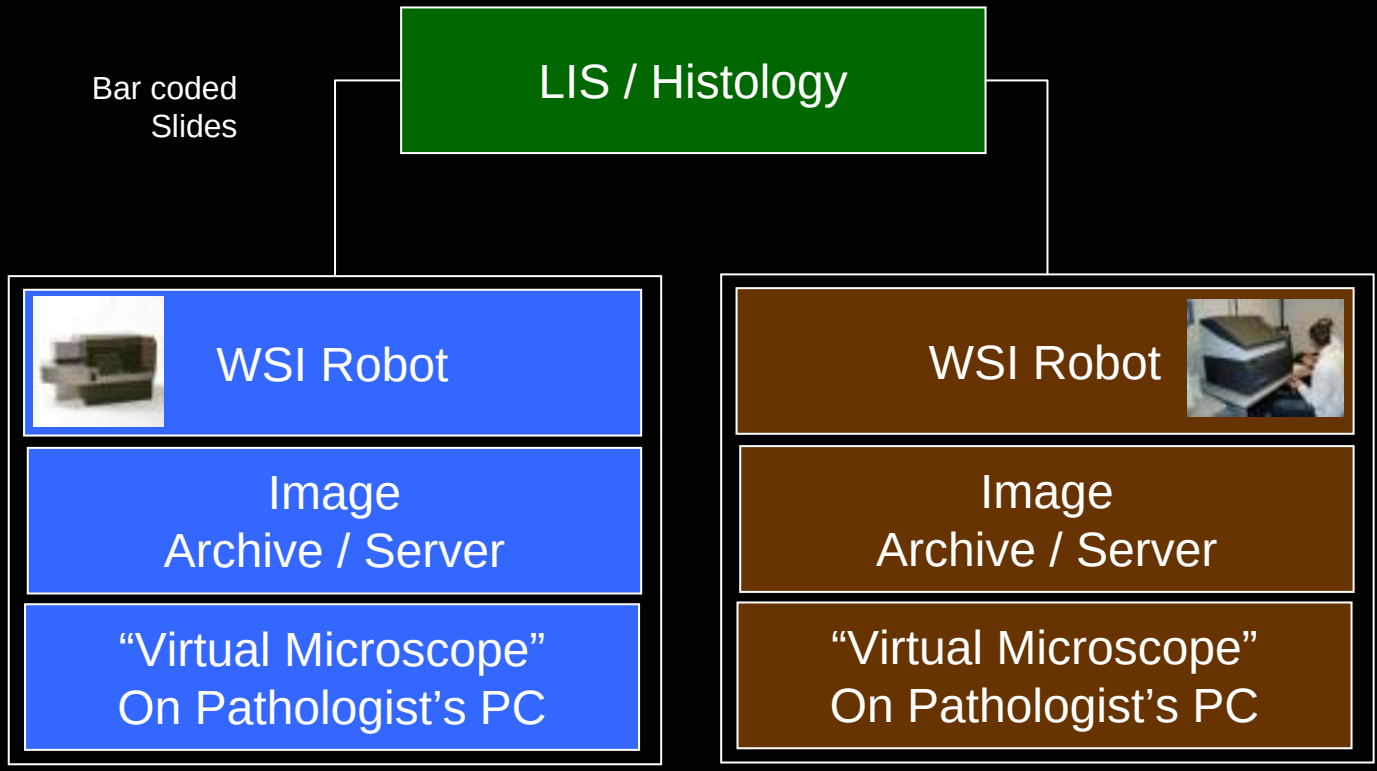


Looks like a flexible environment

System Semi-integration in Pathology



Imaging systems are not compatible

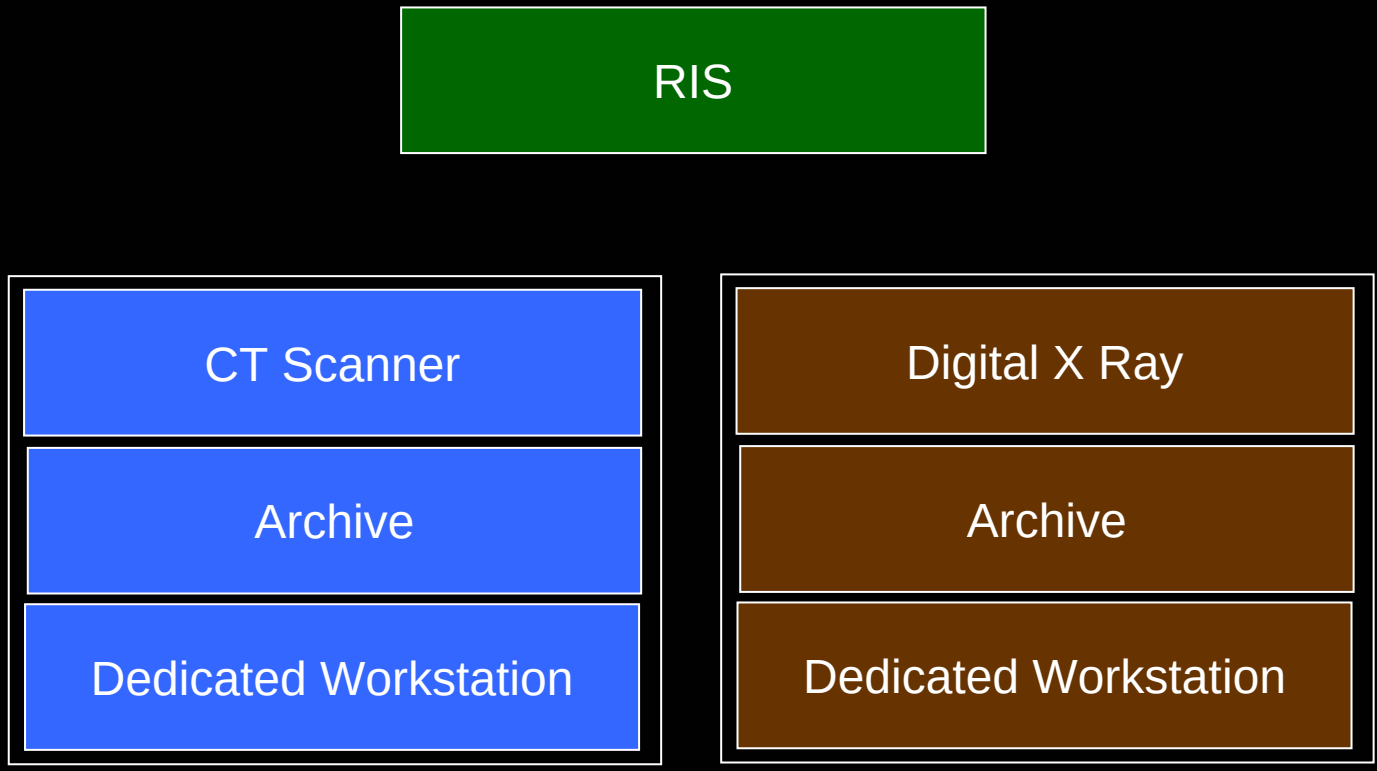
With silos, we will lose much of the efficiency and power of digitization

It just gets worst…

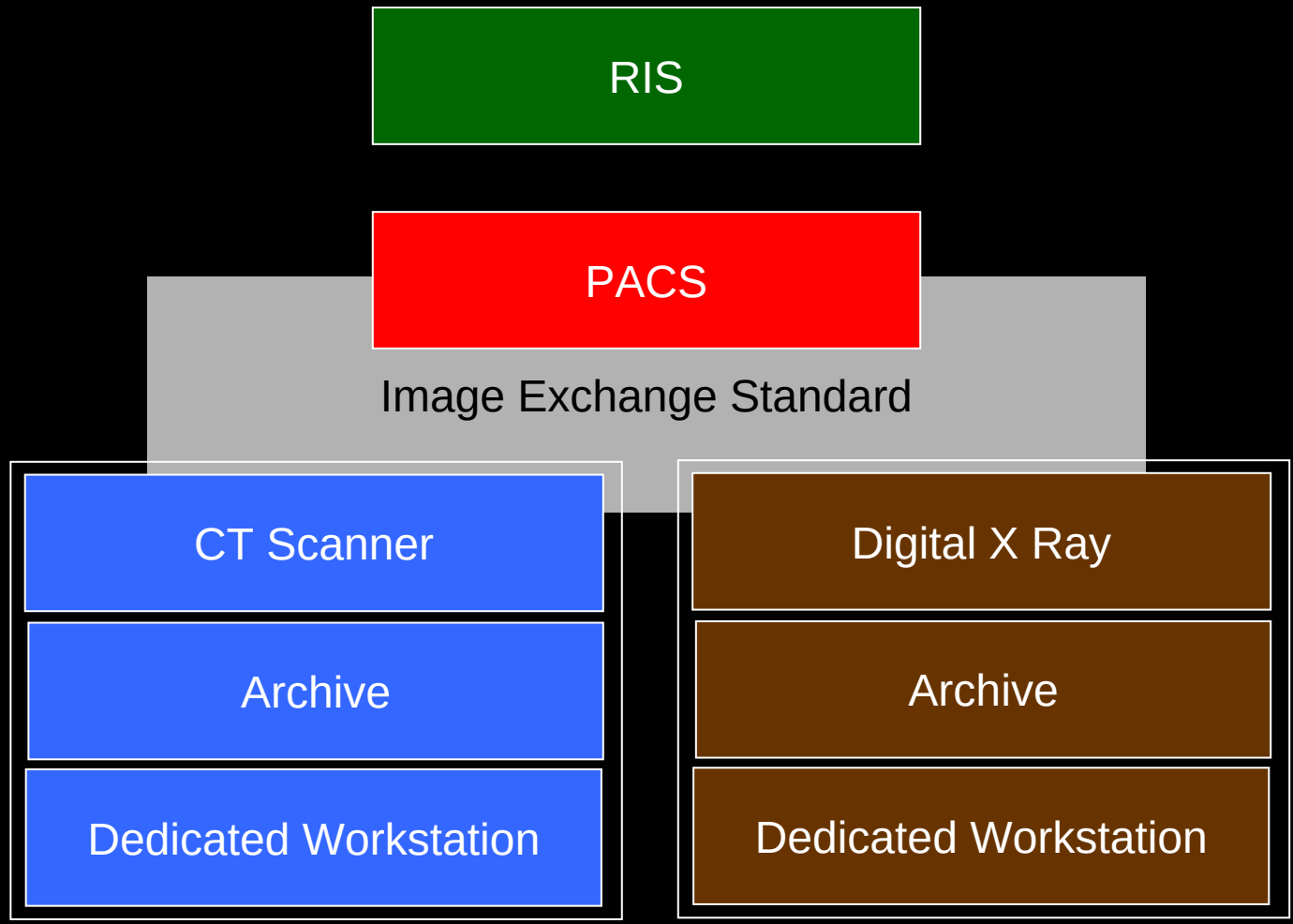
- The WSI industry continues to expand and specialize
  - High Speed (sub-minute) v High Resolution (oil immersion) v multi-spectral
  - Workstation providers, Archive providers, PACS providers, Robot providers
  - Image analysis vendors
  - Clinical systems, Research systems, Educational systems
- We will likely have multiple imaging system in our practices, they need to integrate at the case level

But this had happened before

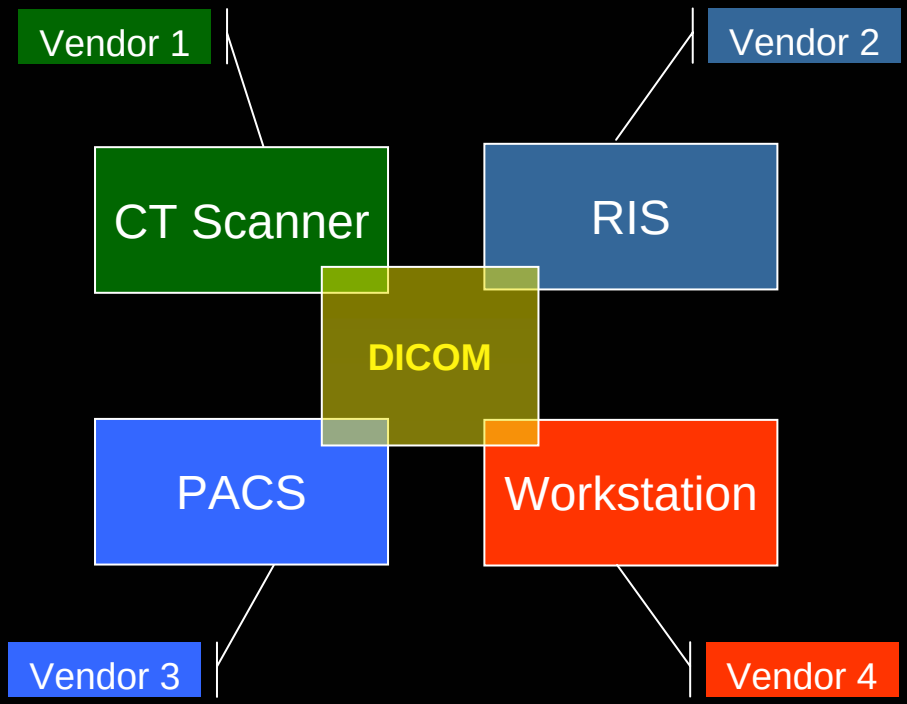
Radiology had the same issue in the 1980s



Two Important Inventions

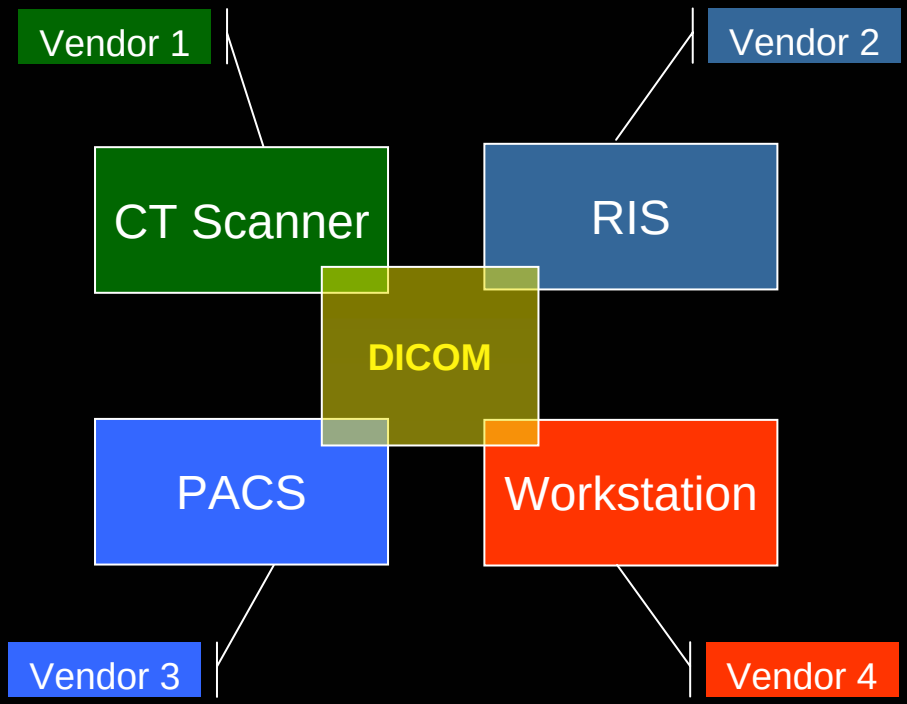


DICOM – an Image Exchange Standard:



- Radiology had different devices (and different PACS) made be different vendors couldn't integrate images and image related data
- 1985: ACR (American College of Radiology) and NEMA (National Electrical Manufactures Association) published the first ACR-NEMA standard for radiology
- 1993: DICOM published with scope over all of clinical medicine

Standards are strategic:



- ACR → Device makers should build devices, but when devices have to communicate, they will communicate through in a standard way (DICOM) and we will be part of that standard
- Organizing the diagnostic imaging portfolio of a hospital is part of our professional responsibilities...We cannot allow proprietary information models or protocols to limit our capability
- Vendors bought in from the beginning

DICOM

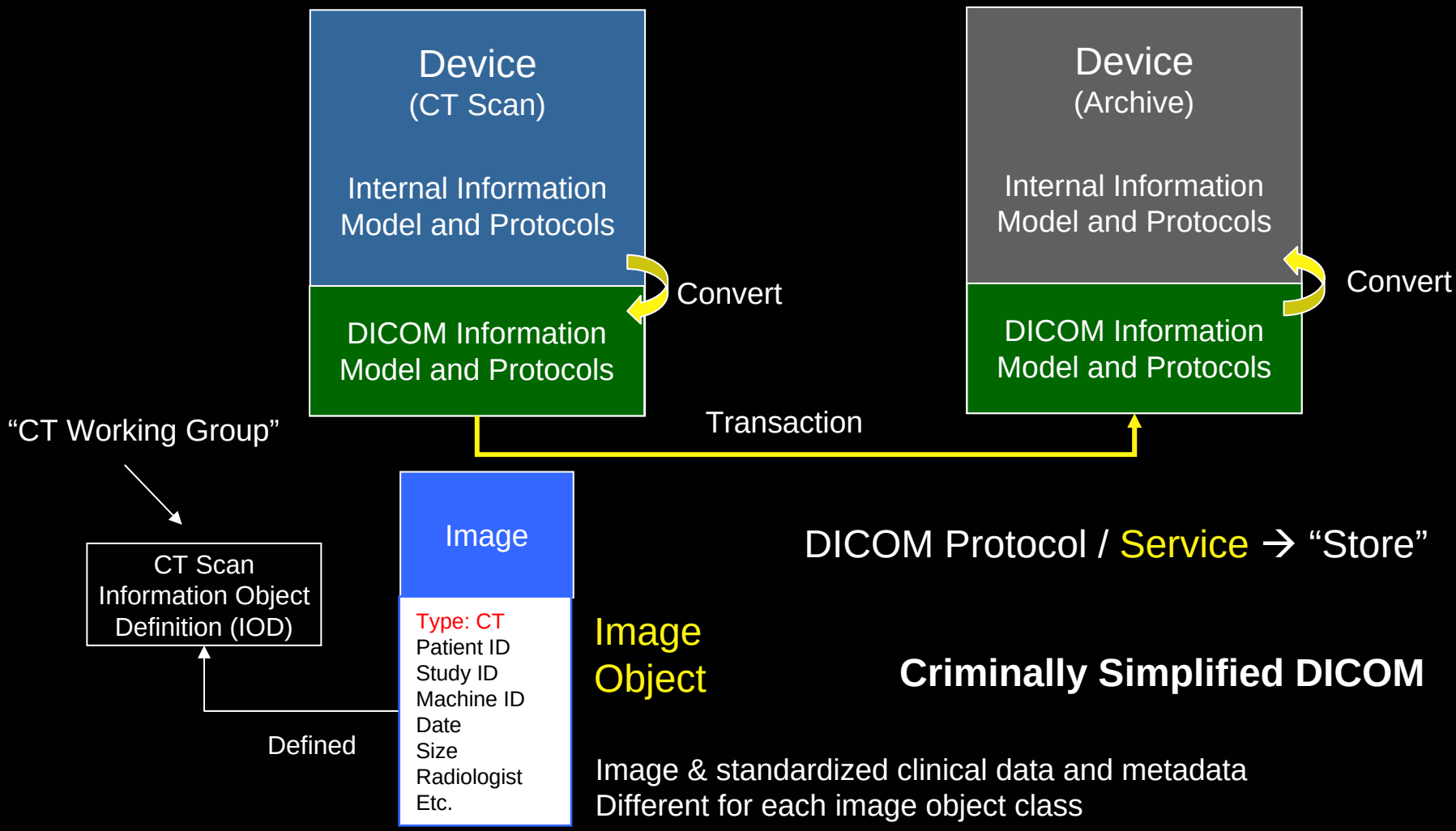
- Remarkably successful → Is the basis for virtually all PACS and multi-specialty Clinical Image Archives…

- Very large client community
- Very strong vendor community
- Over time, it has been responsive to technical and practice changes

- It managed by NEMA through open, collaborative, international working groups

- Working Groups maintain and extend different parts of the standard

- It was designed to be used by other (non-radiology) specialties and many have done so


Device
(CT Scan)
Internal Information Model and Protocols
DICOM Information Model and Protocols
Convert
Device
(Archive)
Internal Information Model and Protocols
DICOM Information Model and Protocols
Convert
Transaction
"CT Working Group"
CT Scan Information Object Definition (IOD)
Defined
Image
Type: CT
Patient ID
Study ID
Machine ID
Date
Size
Radiologist
Etc.
Image Object
DICOM Protocol / Service → "Store"
Criminally Simplified DICOM
Image & standardized clinical data and metadata
Different for each image object class
Working groups from different specialties can define IODs as needed…

- From ~ 1995 to the present, many specialties established a DICOM domain with the appropriate IODs for their specialty
- Vendors built DICOM based PACS for those specialties

People began thinking about a Pathology PACS
and a Pathology version of DICOM as early as 2000

WG 26

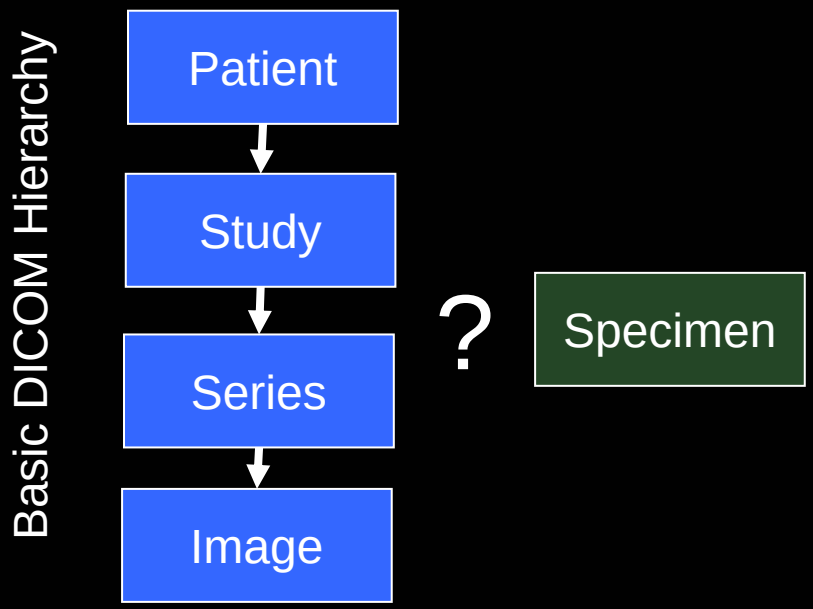
- Numerous discussion over several years (Bruce Beckwith, Yukako Yagi, Ed Smith and others)
- *This is normal and should be expected*
- October 2005: DICOM Strategic Planning Working Group invited a number of pathologist to Budapest to discuss the possibility a Pathology Working Group in DICOM
- December 2005: DICOM WG 6 established WG 26, with scope over all of pathology imaging

DICOM and Pathology

- It is made up of pathologists, the WSI industry and senior members of DICOM who act as mentors
- Five formal meetings - Phoenix January 06, Madrid, Vancouver, Chicago, DC. (plus conference calls)
- For DICOM to work in Pathology, three main issues had to be solved…

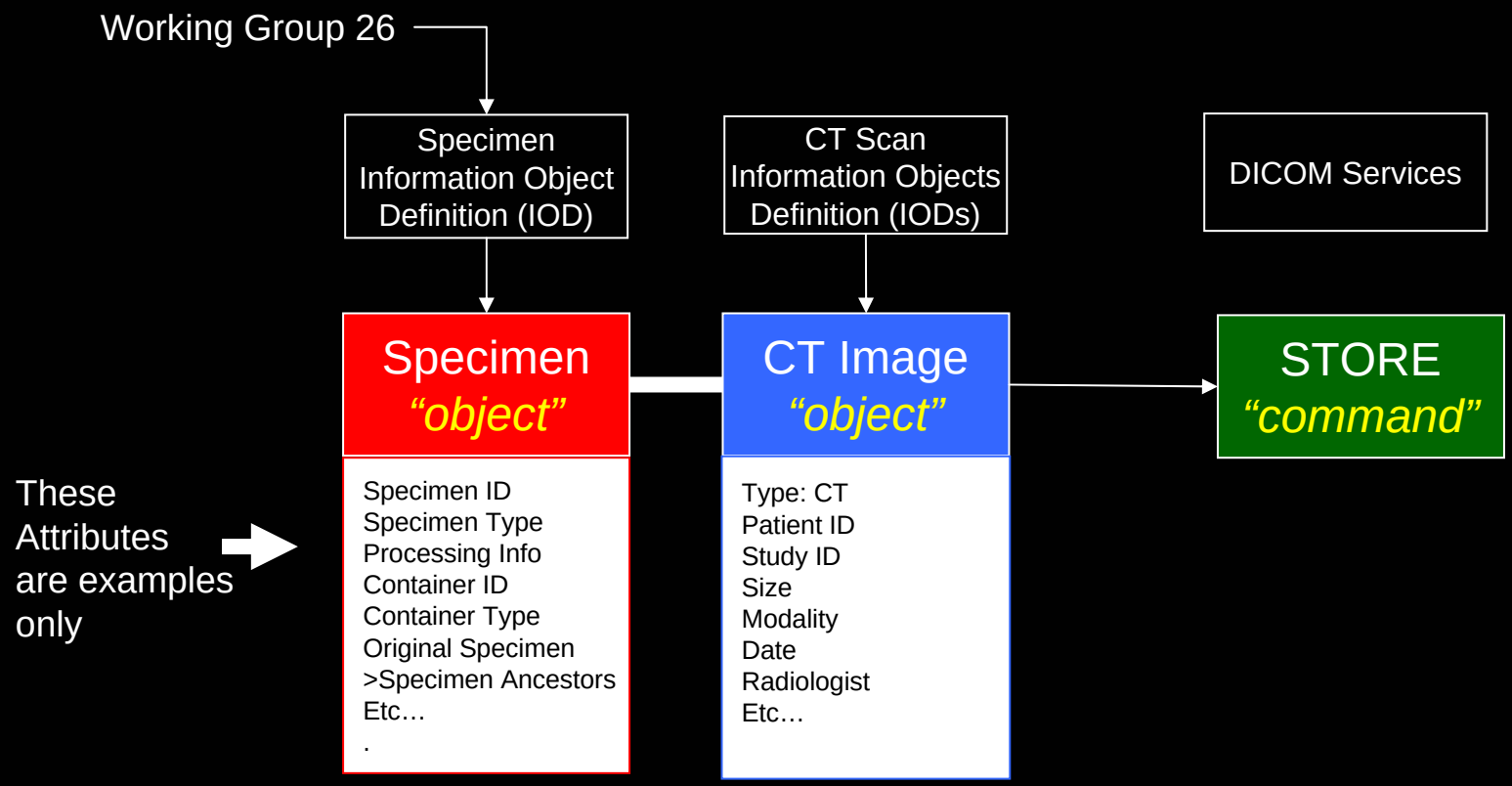
Specimens

Specimens in DICOM



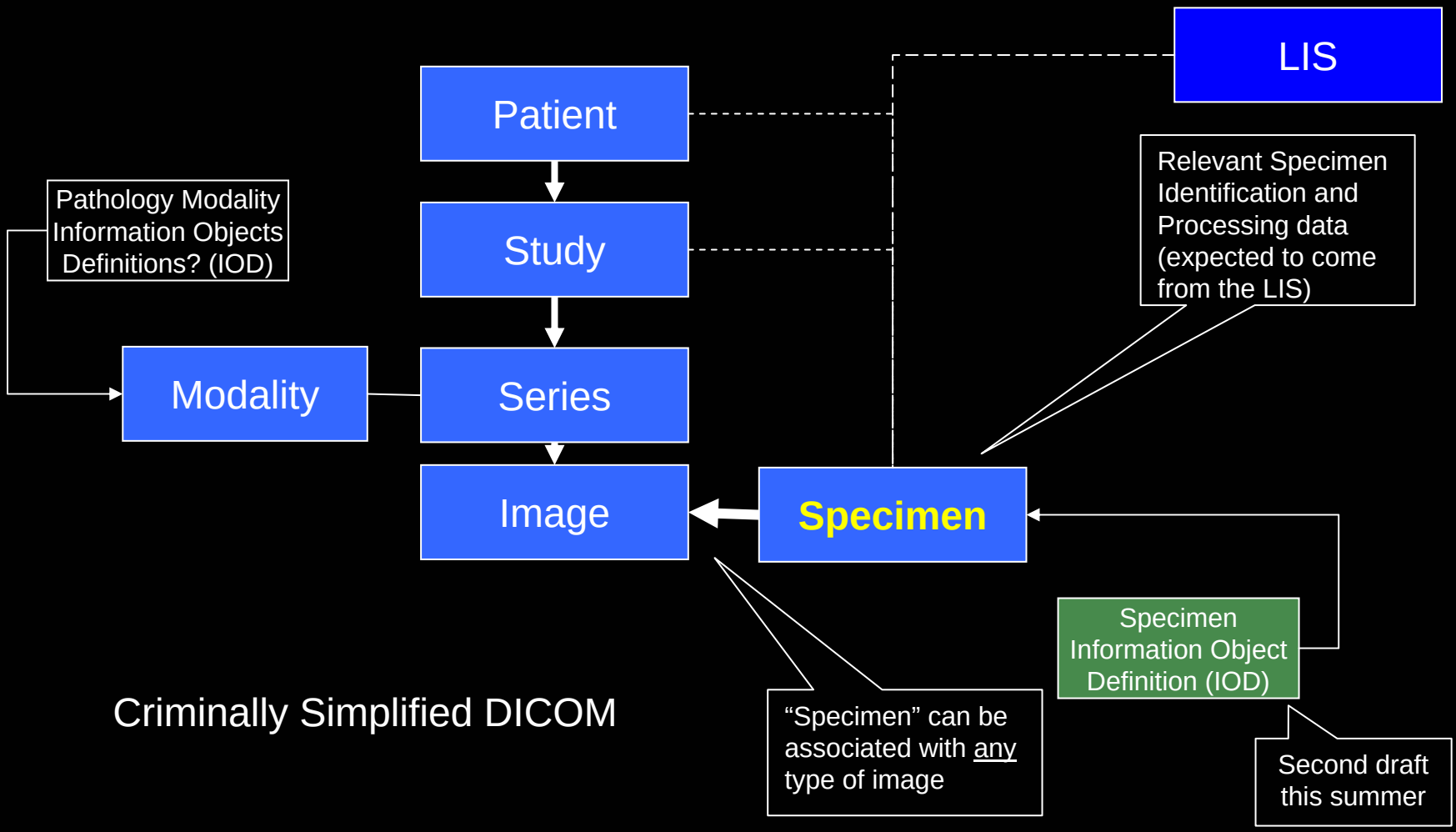
Criminally Simplified DICOM

- DICOM expects a Patient to be the subject of every image
- In pathology a Specimen is the subject of an image
- In pathology, imaging begins in the cutting room / histology. Information on identification, ancestry, collection, processing, staining, etc needs to be associated with the image



Criminally Simplified DICOM

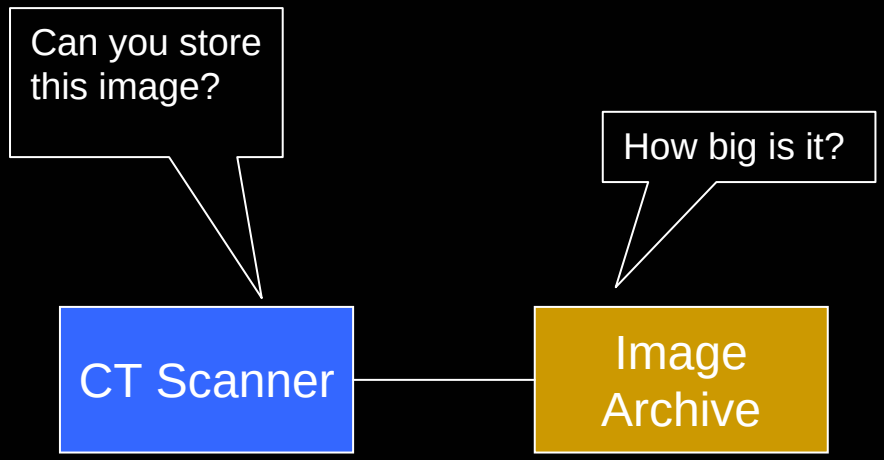
WG 26 Status: The Specimen Object



Criminally Simplified DICOM

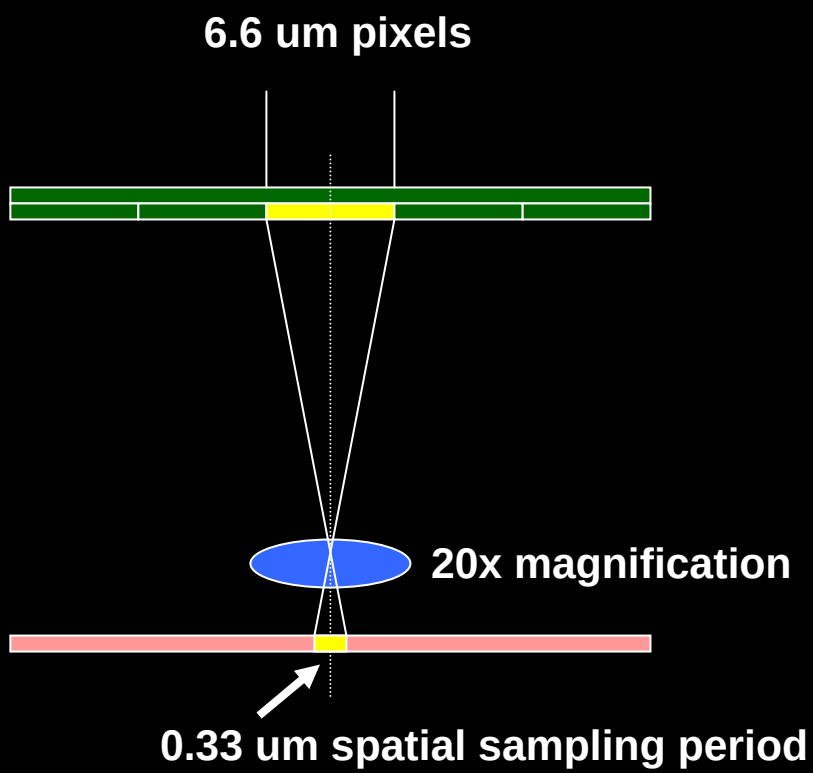
Image Size

WSI are “too big” for DICOM:



- The DICOM field that held the size of image was an unsigned 16 bit integer
- Maximum uncompressed size of an image 64K x 64K ~ 4 GB

How big is a WSI?



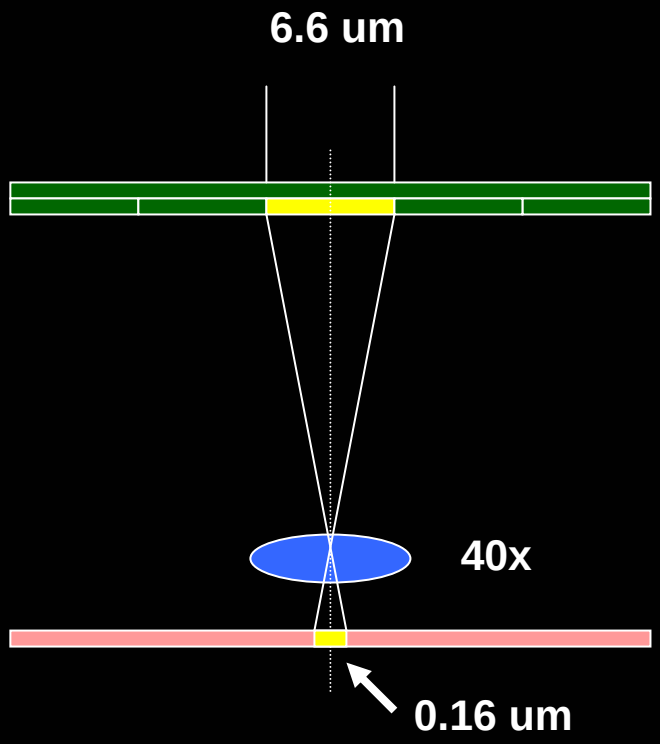
- Consider a WSI system:

- 0.6 NA, 20x Primary Magnification
- 8.8 x 6.6 mm CCD
- 6.6 um pixels

- 0.33 um/pixel
- 900 million pixels / square cm
- 3 bytes / pixel (24 bit color)
- ~ 3 GB of data / square centimeter of tissue per focal plane

- "sampling period" is used rather than "resolution" because of the effect of focusing on real resolution

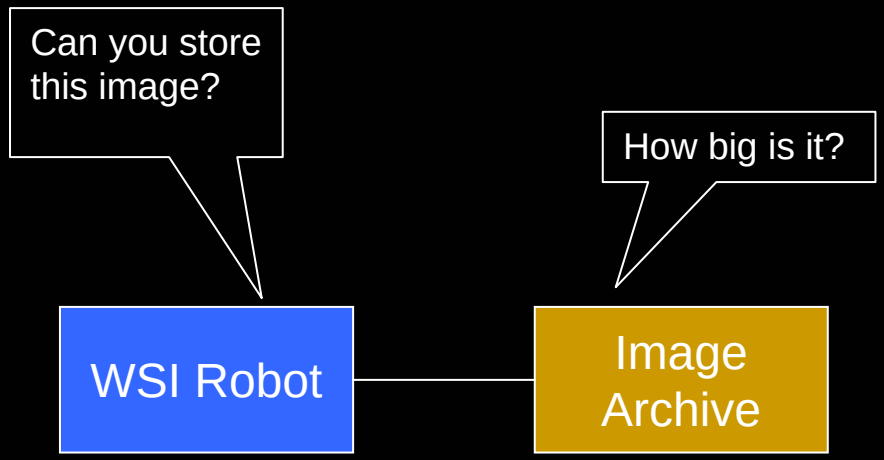
Very Large Datasets



- 3 GB per centimeter at 20x and one focal plan
- 12 GB per centimeter at 40x and one focal plan
- 60 GB per centimeter at 40x and 5 focal planes

- WSI robots compress all images (JP2000 ~ 30x compression, JGP ~ 15x)

WSI are “too big” for DICOM:

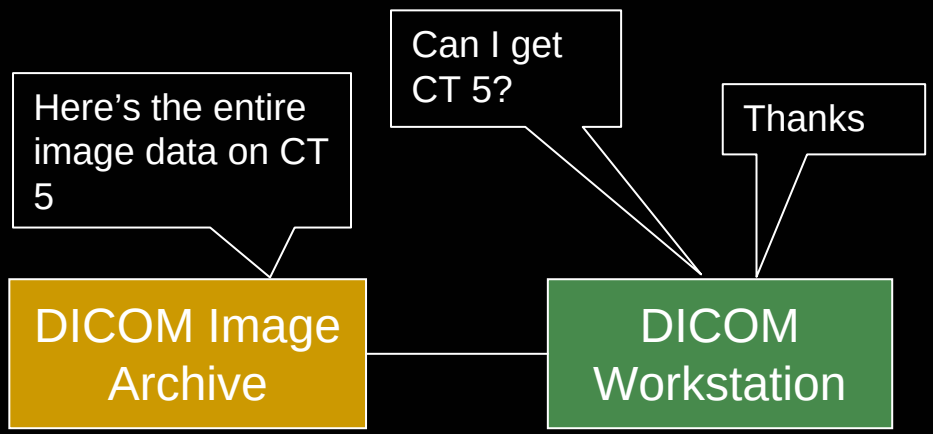


- The DICOM field that held the size of image was an unsigned 16 bit integer
- Maximum uncompressed size of an image 64K x 64K ~ 4 GB
- The “simple” solution (increasing the size of the field) was not simple…

Dynamic Client – Server Interaction

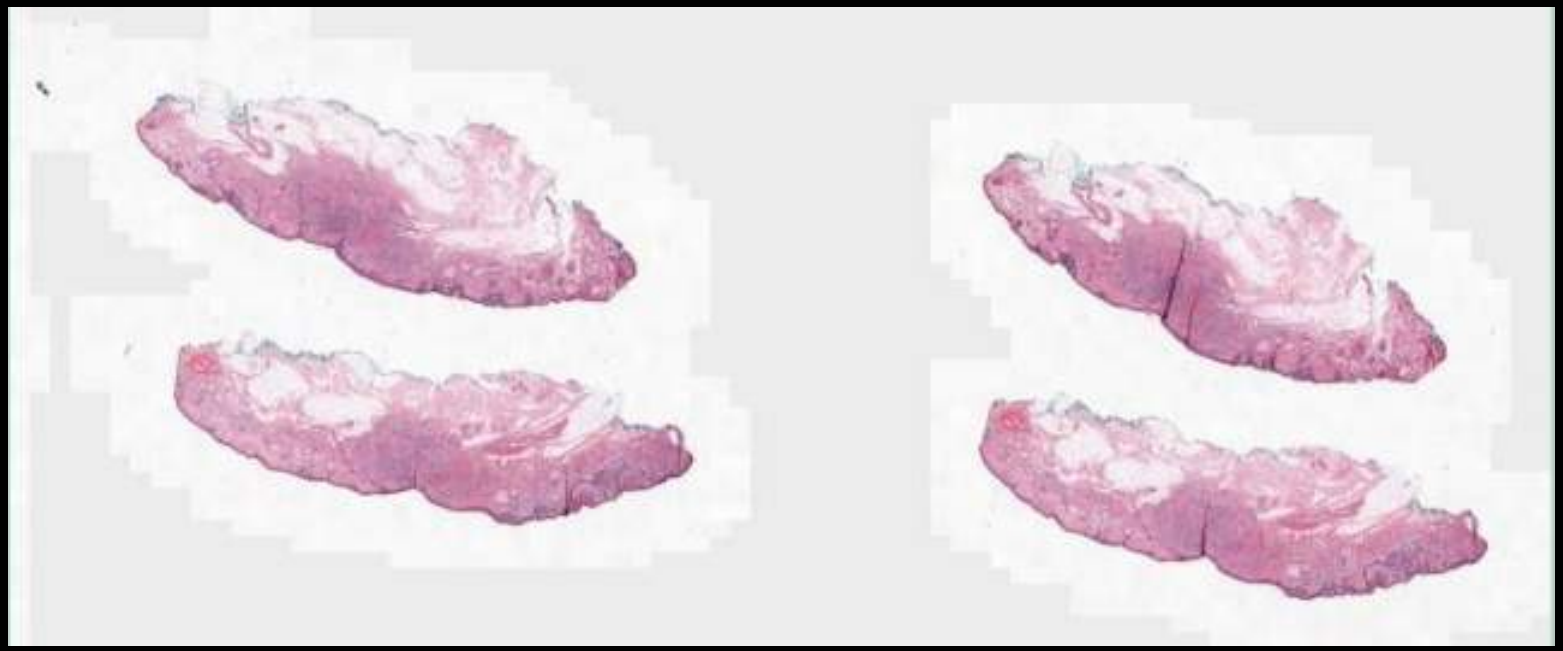
“Sub-image Access”

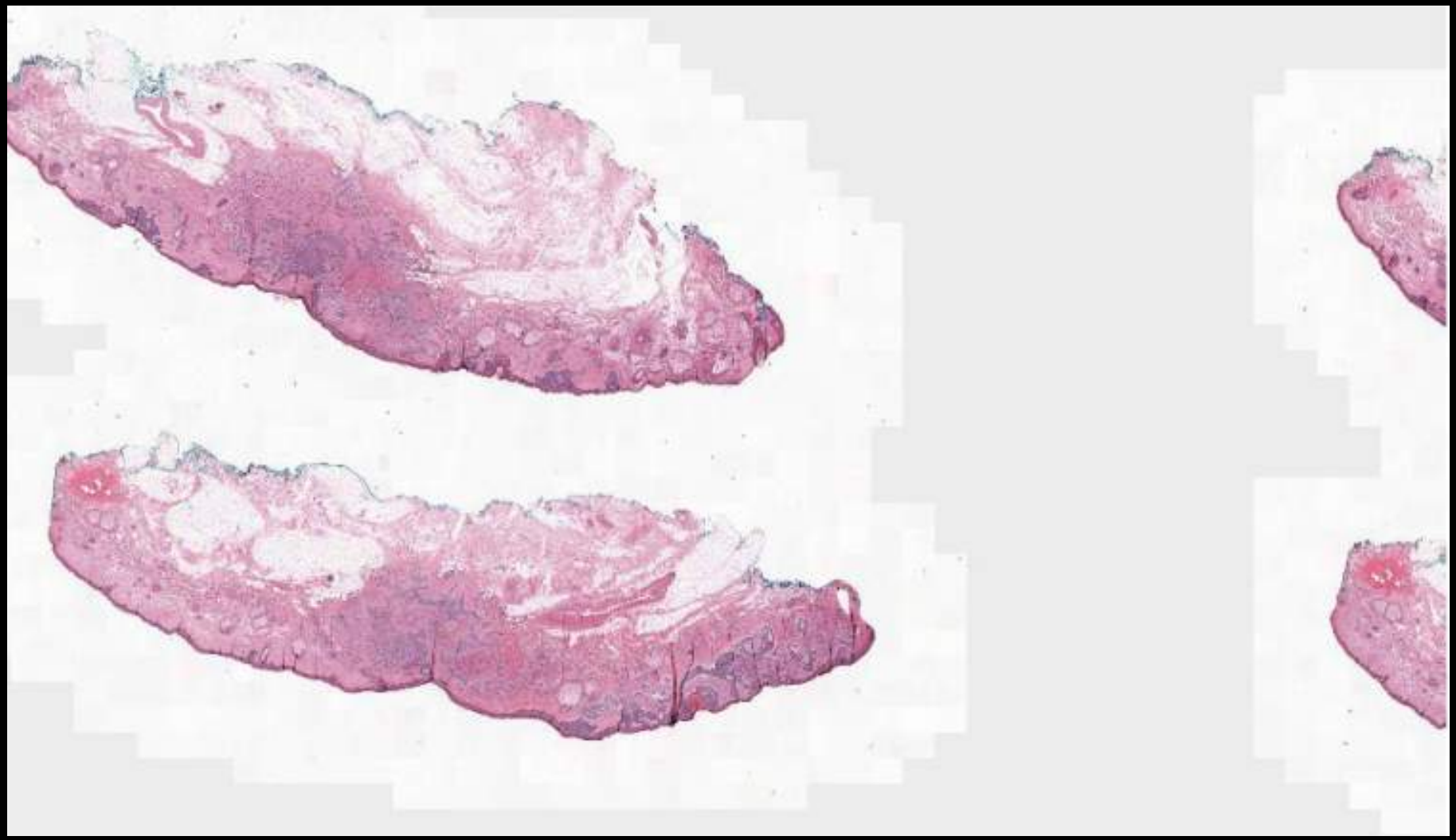
“Sub image access”

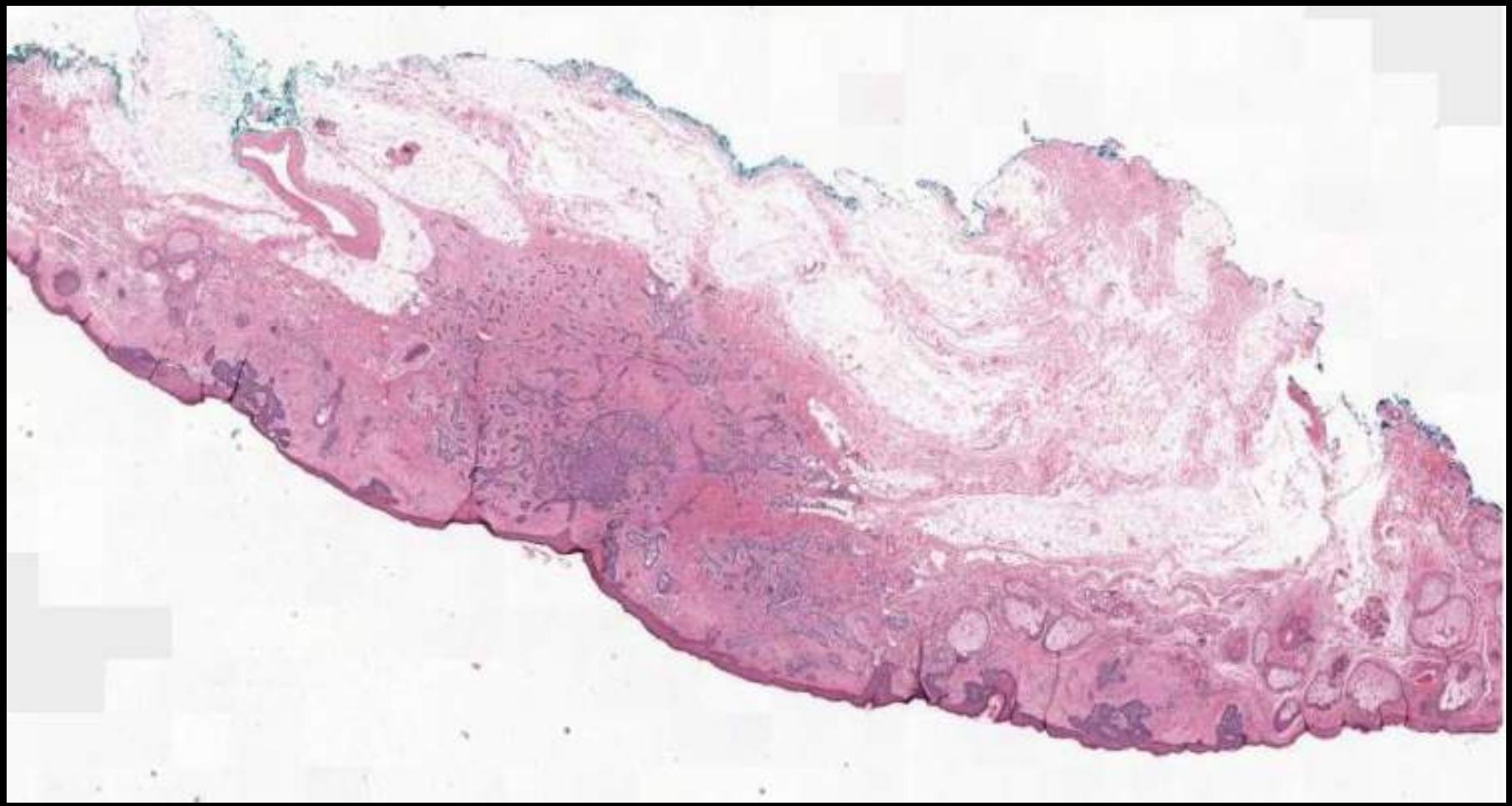


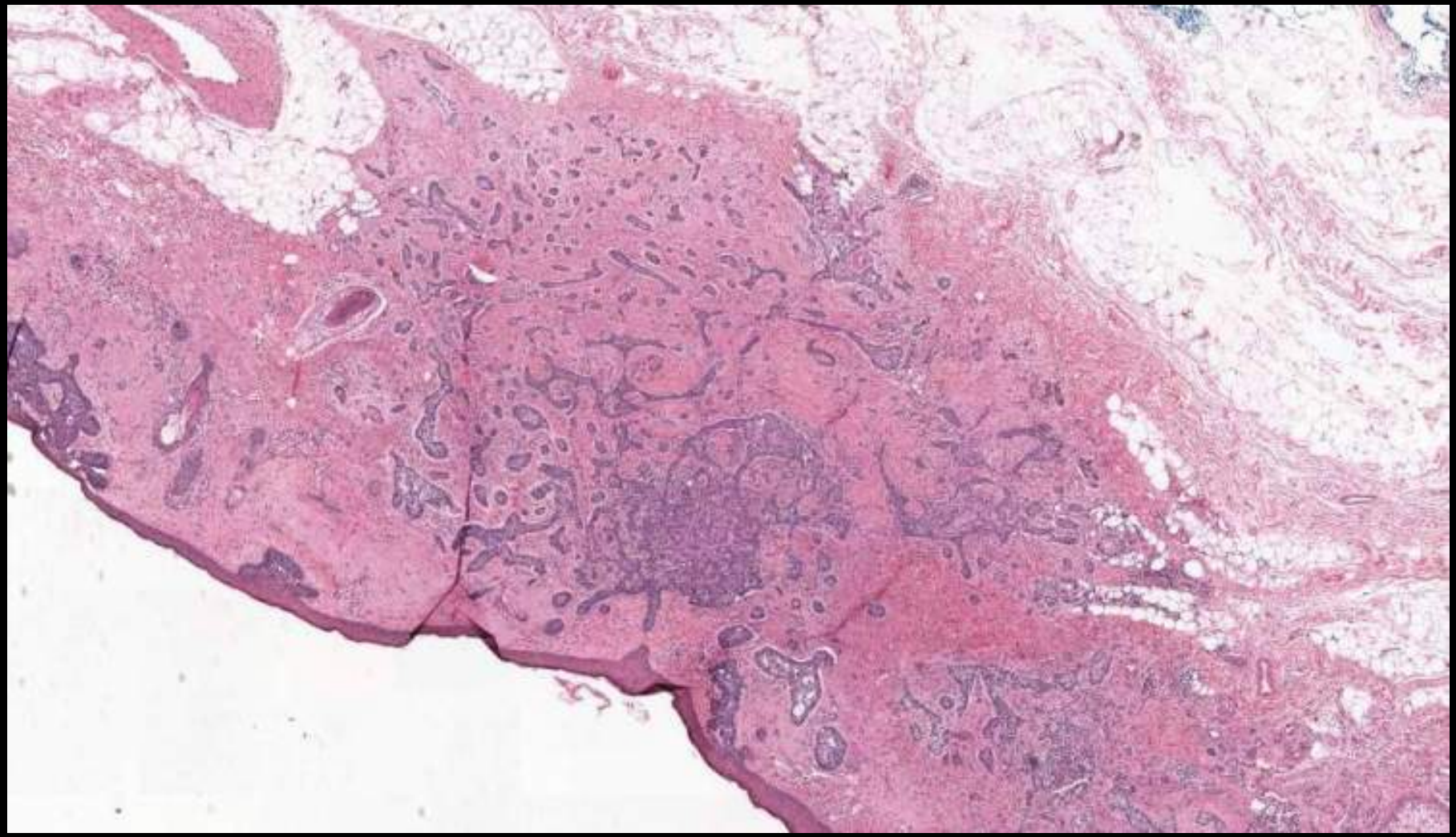
- DICOM had no good mechanism to implement dynamic client server interactions required for the “virtual microscope”
- Normal DICOM operation is that when a client wants an image, the entire image data set is sent to client.
- WSI can’t work that way – this has become known as the “access pattern” issue

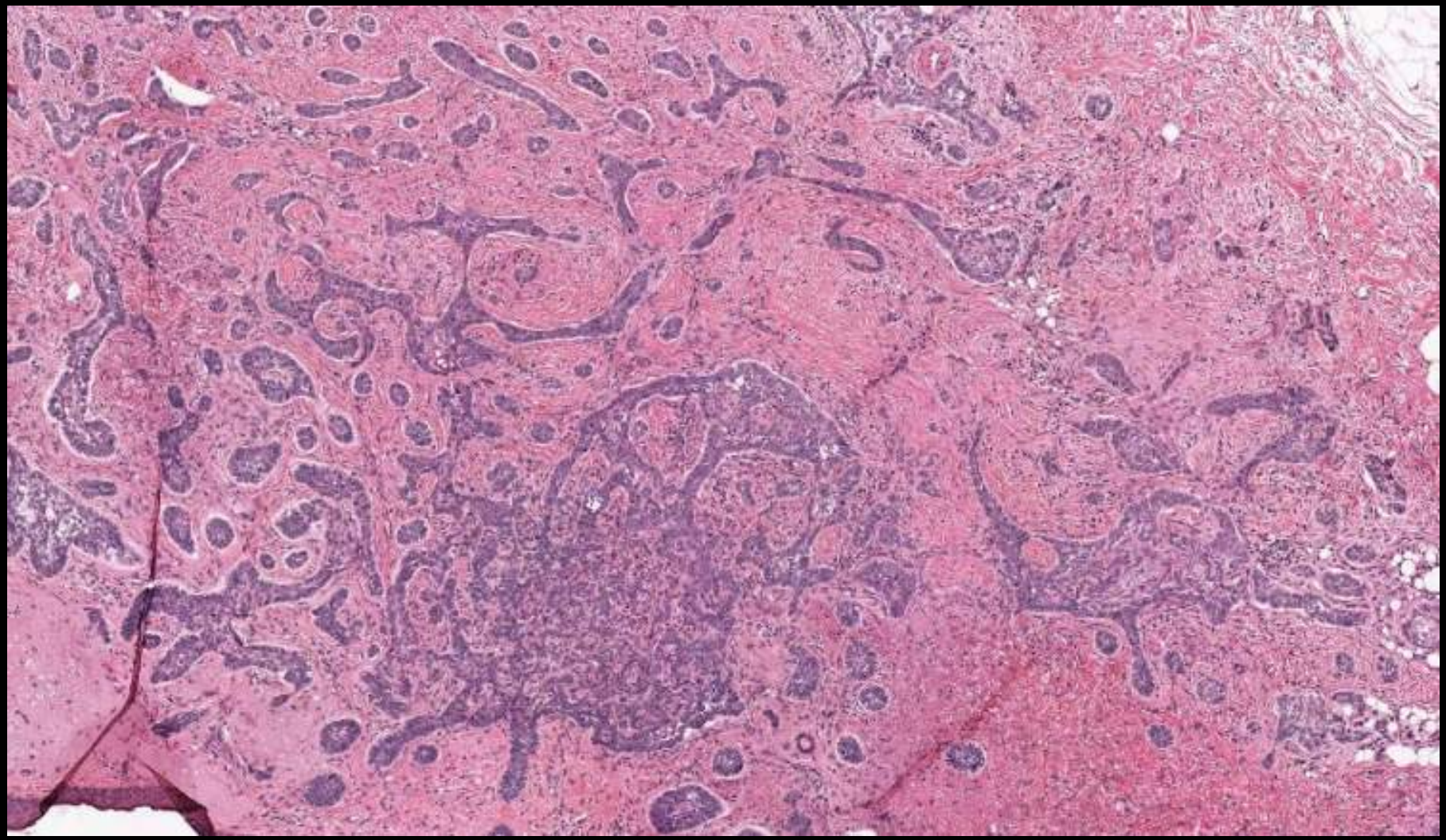
In virtual microscopy, we never send the entire digital slide data set to the client

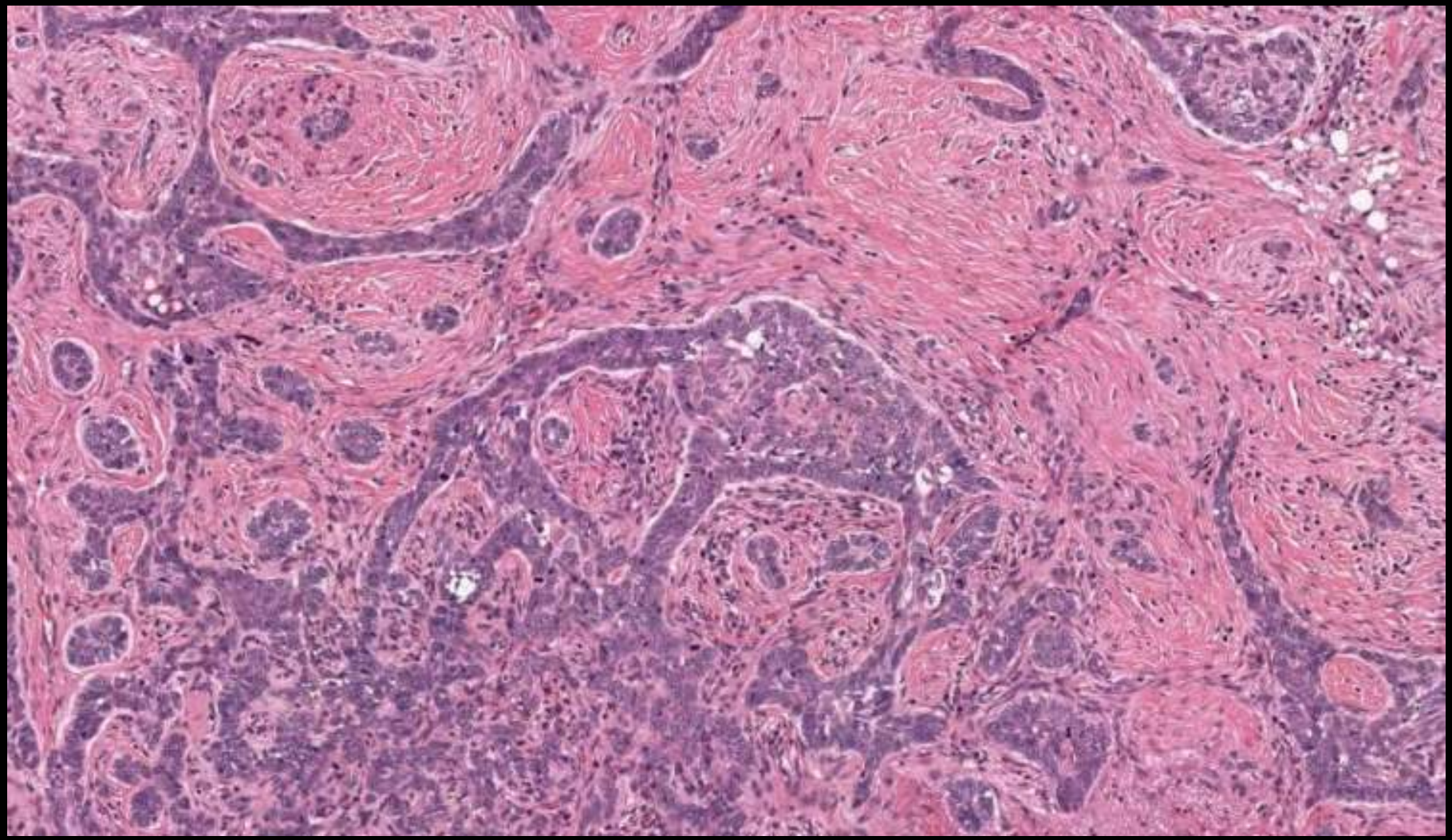


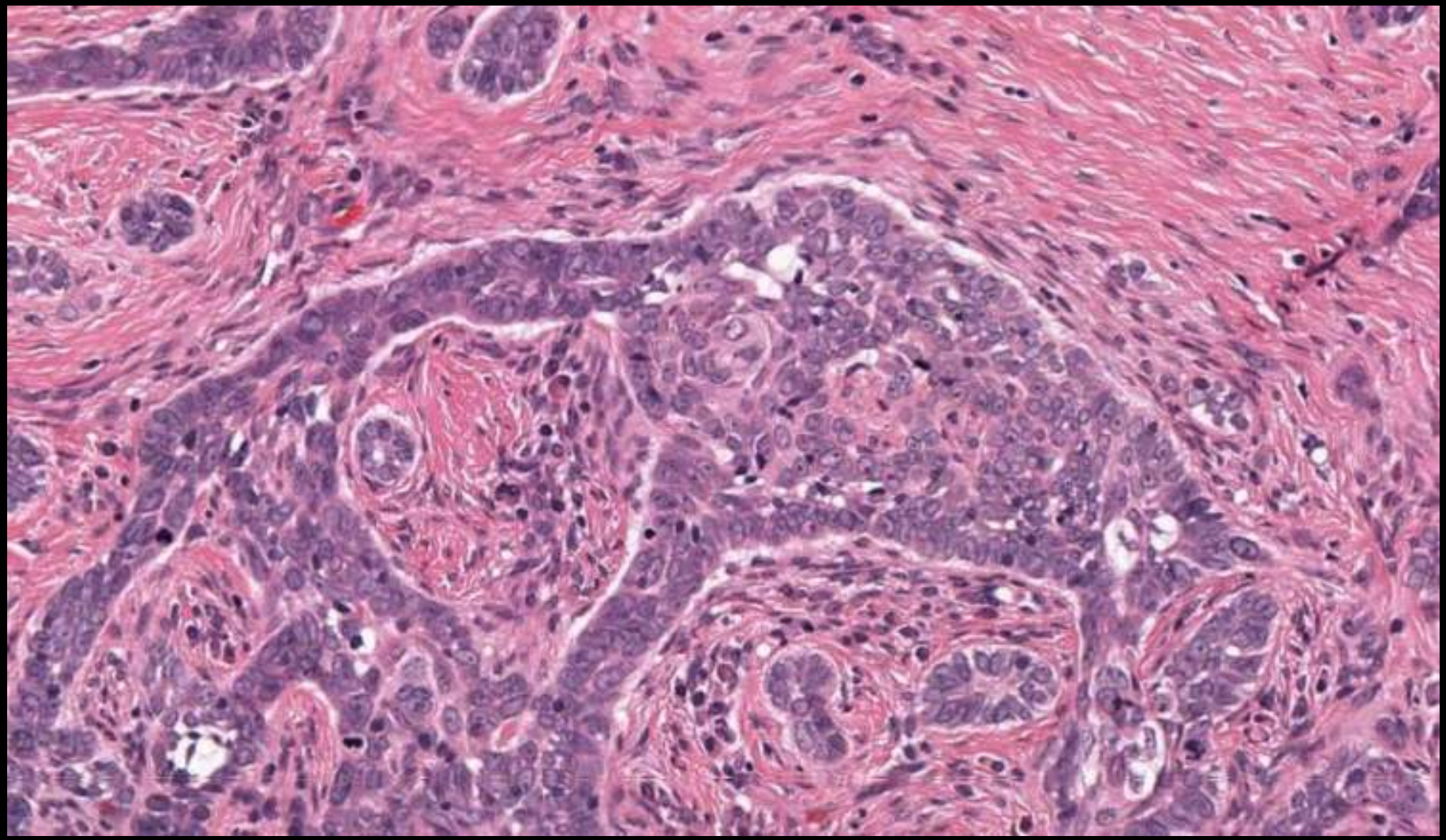












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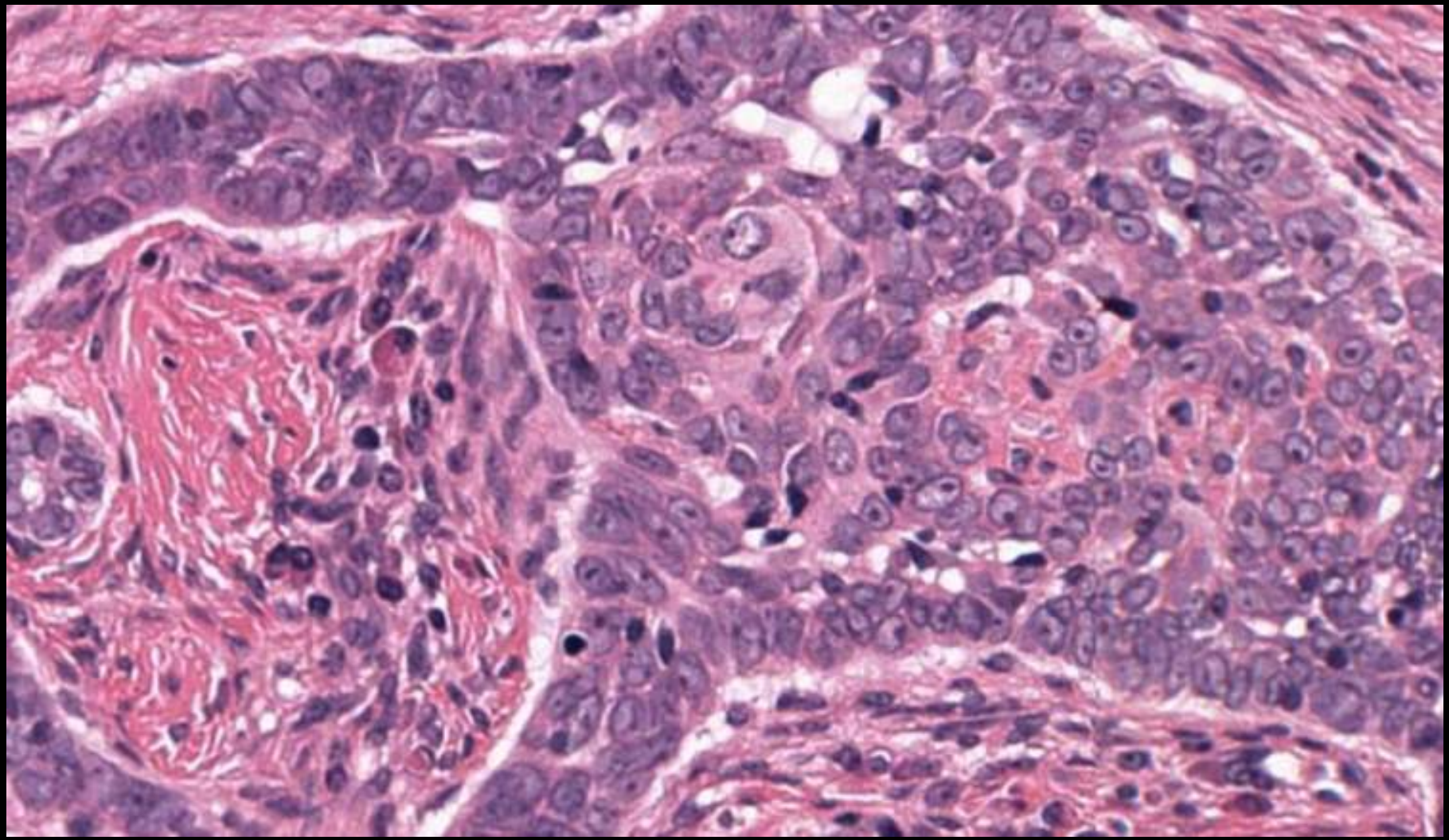
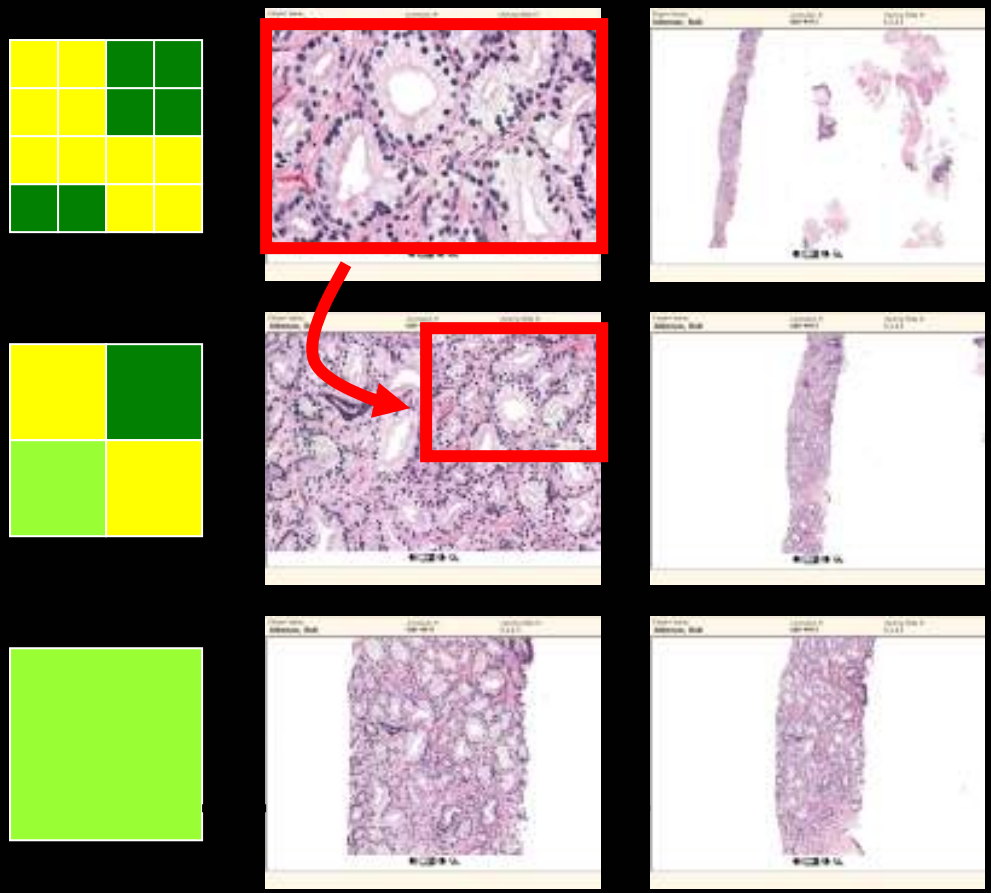
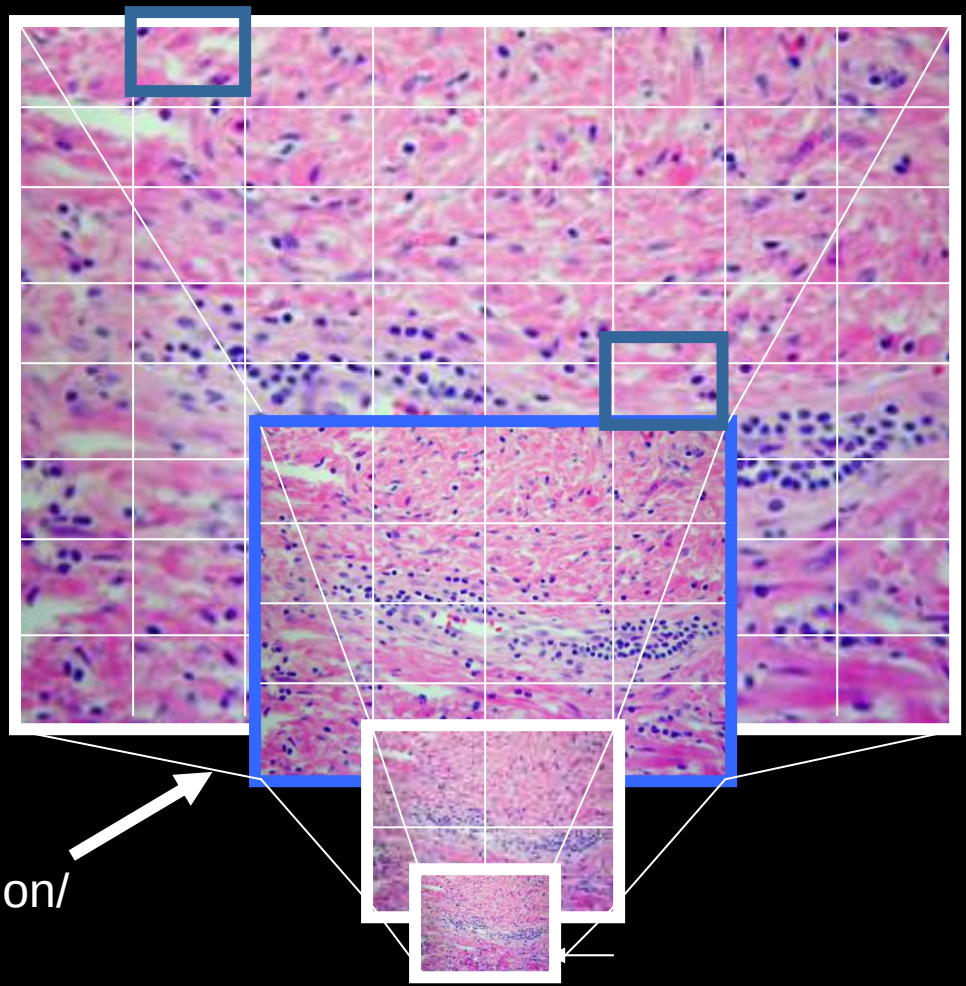


Sub-image access



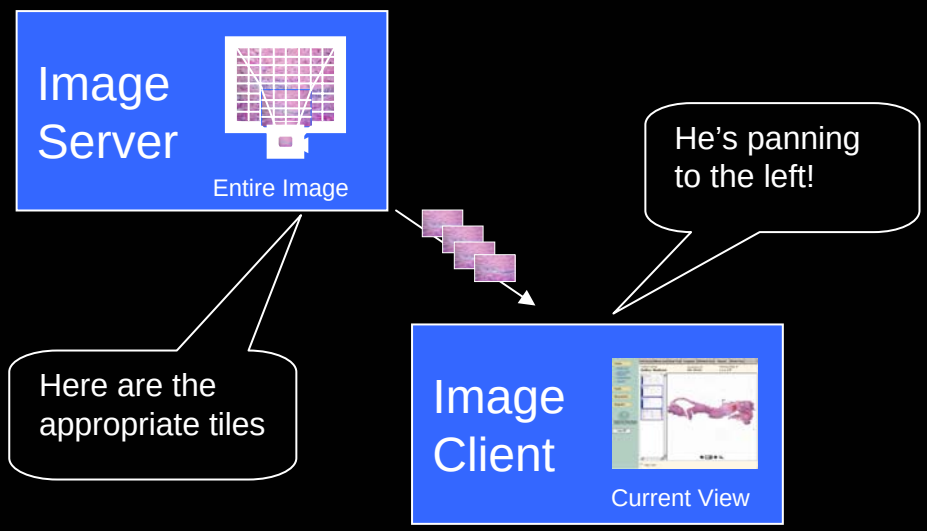
- How is a data set that big displayed on a monitor
- Multi-resolution data representations
- Data is a “pyramid tif”
- Each layer of the pyramid is divided in to “tiles”

One the server, a WSI exists as a multi-resolution “pyramid tiff”
Each layer of the pyramid is a different resolution
Each layer is made up of little “tiles”
The tiles are units that are sent from server to client



Courtesy Yukako Yagi

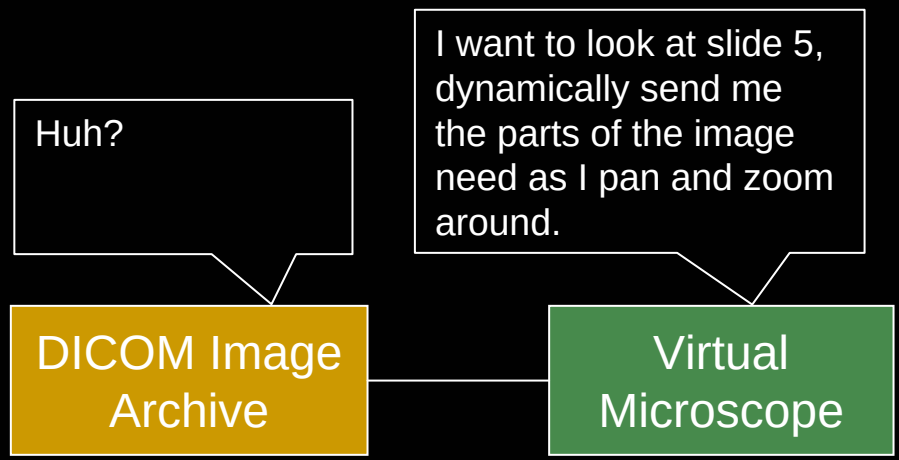
Pathologist – Image Interaction



"Sub-image level access"

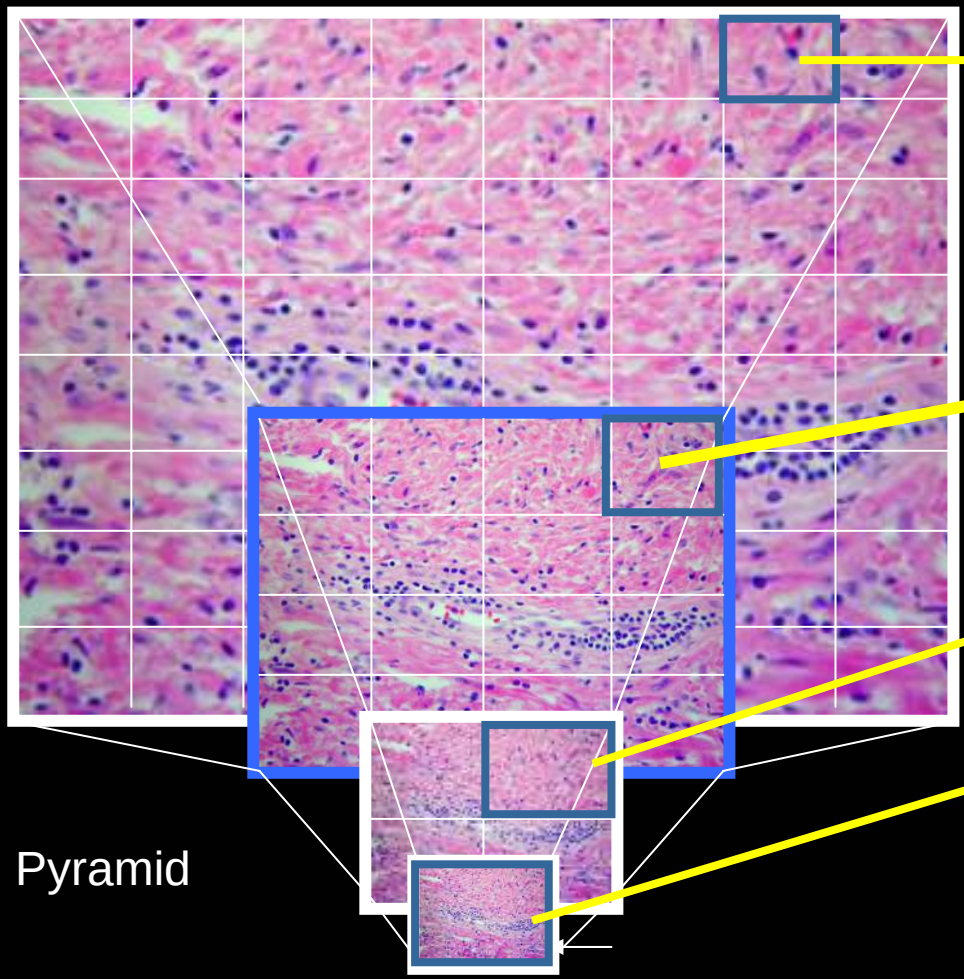
- A Virtual Microscope is software that allows the user to "pan and zoom" across a Digital Slide just as if one was examining a physical slide under a physical microscope
- A virtual microscope is a client-server application in which the server sends only the demanded by the client
- The client requests (and the server sends) only the tiles needed to render the field requested by the pathologist

Sub image access is not yet supported in DICOM:

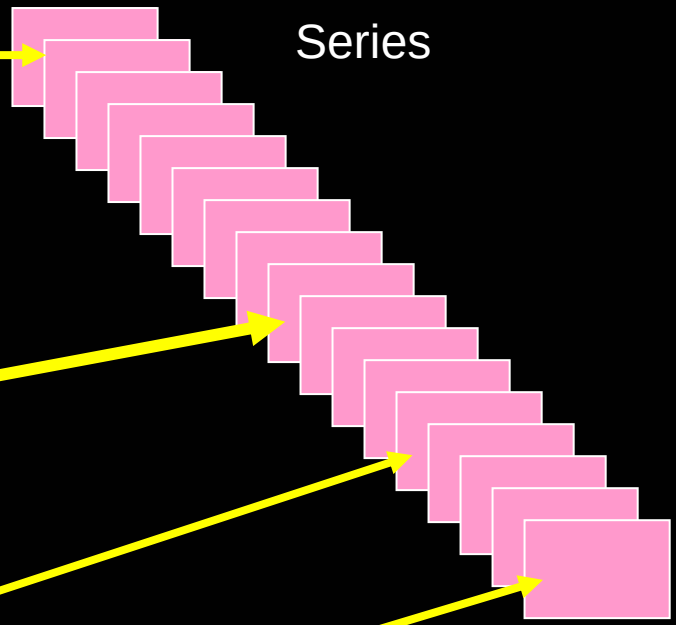


Proposed Solution

Ole Eichhorn (Aperio)
Kemp Watson (Objective Pathology)
Andy Lowe (DMetrix)
And many others…



Pyramid

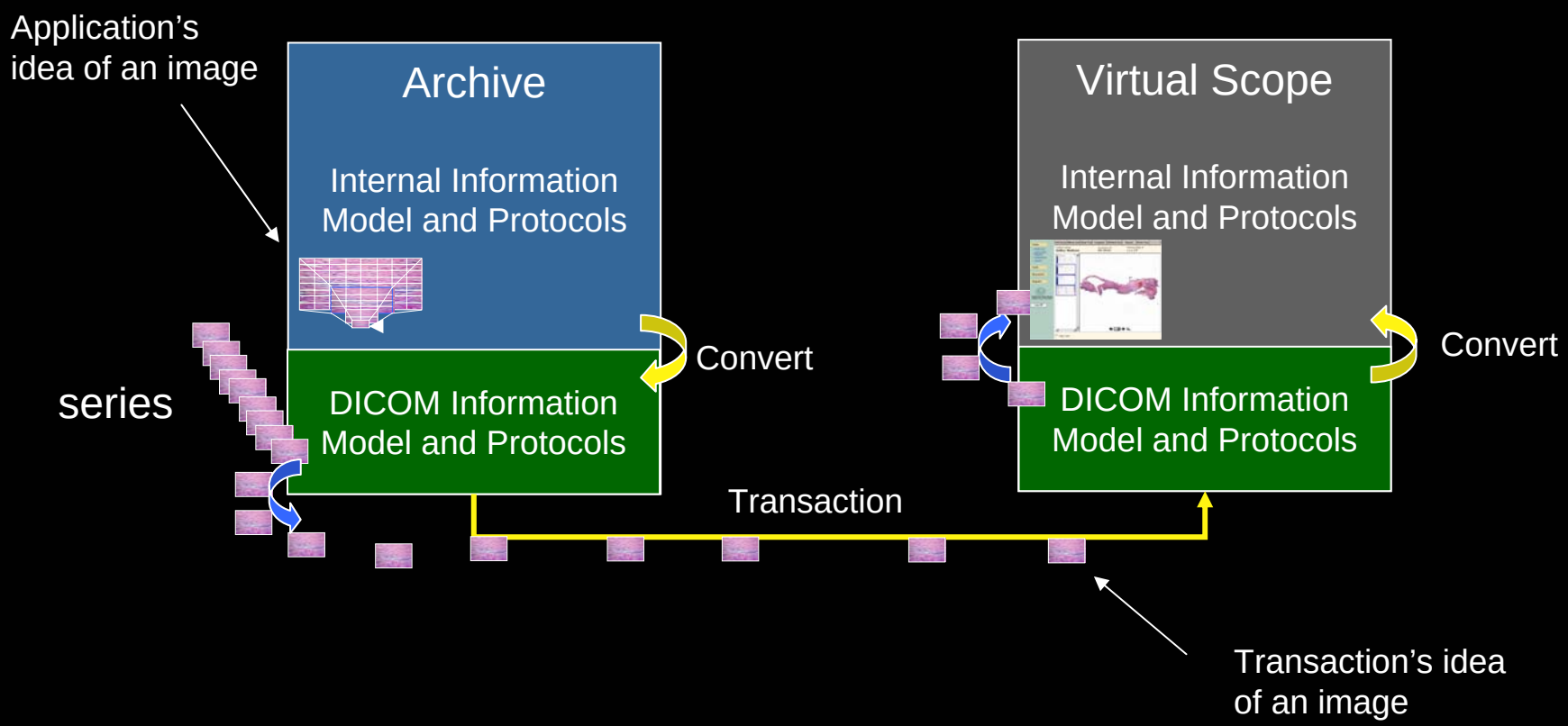


Series

Image

WSI is made up of a series of tiles…
Each tile is a DICOM image…

Proposed Solution



The Point

- DICOM is a mysterious organization for most pathologist, but it need not be
- Like any other else, it took time and patience (and humility) to make the initial connections
- But so far, it has worked well
- It has not required special knowledge on the part of the Pathologists involved

The Point

- We are DICOM

  Pathology has a working group

- Pathology “owns” specimen imaging

- WSI vendors have experience in deeply important areas - large images and rapid “sub-image access”

- Who knows what the future brings, but it looks good know

Strategic Leverage

- It is important to be associated with DICOM even if Pathology decides not to use DICOM
- Key step in the clinical collaboration of Pathology and Radiology
- Key step in the integration of Pathology and Radiology into Diagnostic Departments

HL-7 and Messaging Models

This is not HL-7:

MSH | ^~\& | QUEST | LAB | REPOSITORY | REGENSTRIEF | 200504031656 | | ORU^R01 | 9999 | P | 2.1 | 9999999 |
PID | | | 9999999^^^MET | ^ | DOE^JOHN^X | | 19450101 | M | | | | | | | | | | 000099999999 | 999999999 |
PV1 | | | OPSUR^ | | | | | | | | | | | 000000 | | 000099999999 |
OBR | 1 | 870930010^OE | CM3562^LAB | L132^LYTES^L | | | 19870329080 0 | | | | | | | SER | | | | | | 198703311400 | | | F |
OBX | | NM | 2951-2^sNa^LN | | 150 | mmol/L | 136-148 | H | | A | F |
OBX | | NM | 2823-3^sK^LN | | 4.5 | mmol/L | 3.5-5 | N | | N | F |
OBX | | NM | 2075-0^sCl^LN | | 102 | mmol/L | 94-105 | N | | N | F |
OBX | | NM | 2028-9^sCO2^LN | | 27 | mmol/L | 24-31 | N | | N | F |

This is an example of an HL-7 Version 2.x message

Courtesy Dr. Gunther Schadow

Health Level 7 (HL-7)

- HL-7 is an organization
  - Founded in 1987 by HIS and LIS community in the USA
  - Mission is Interoperability of disparate clinical information systems
  - 20+ SIGS and Technical Committees (Laboratory, Anatomic Path)
  - Thousands of members with affiliates in 27 countries
  - ANSI Accredited Standards Development

HL-7

- HL7 is an organization of smart people
- Dedicated to clinical data integration in the real world
- It just continued to work and innovating
- I expect HL7 to be here in 20 years
- I expect HL7 to be that group who first implements “today’s cool stuff” in a major way

We are not going to talk about Version 2 today

MSH | ^~\& | QUEST | LAB | REPOSITORY | REGENSTRIEF | 200504031656 | | ORU^R01 | 9999 | P | 2.1 | 9999999 |
PID | | | 9999999^^^MET | ^ | DOE^JOHN^X | | 19450101 | M | | | | | | | | | | 000099999999 | 999999999 |
PV1 | | | OPSUR^ | | | | | | | | | | | 000000 | | 000099999999 |
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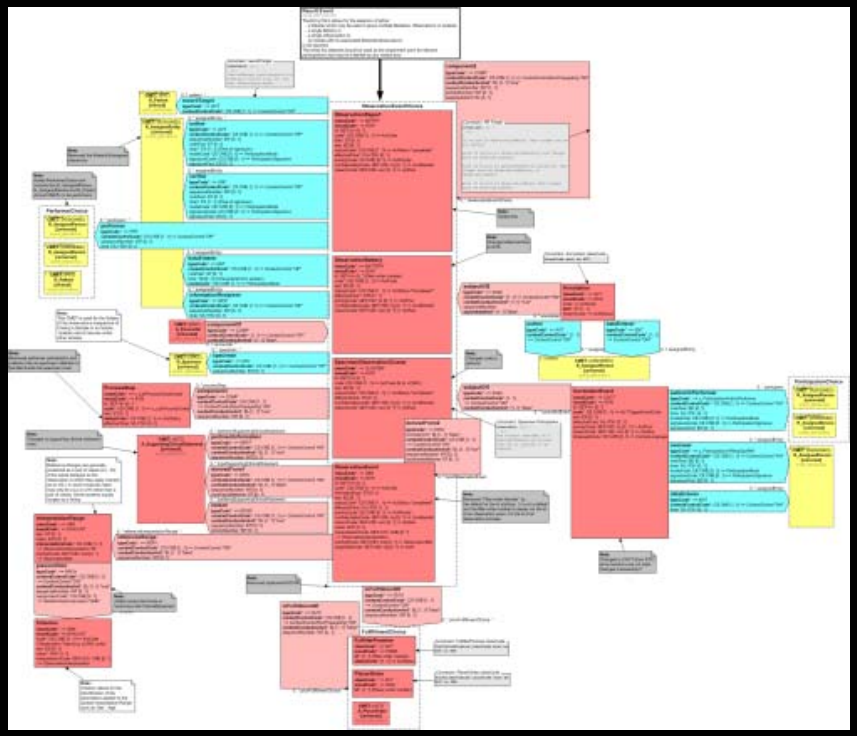
Version 2 is a successful standard appropriate for the 1990s when There was a need for a “highly flexible standard” for systems to talk

Version 3



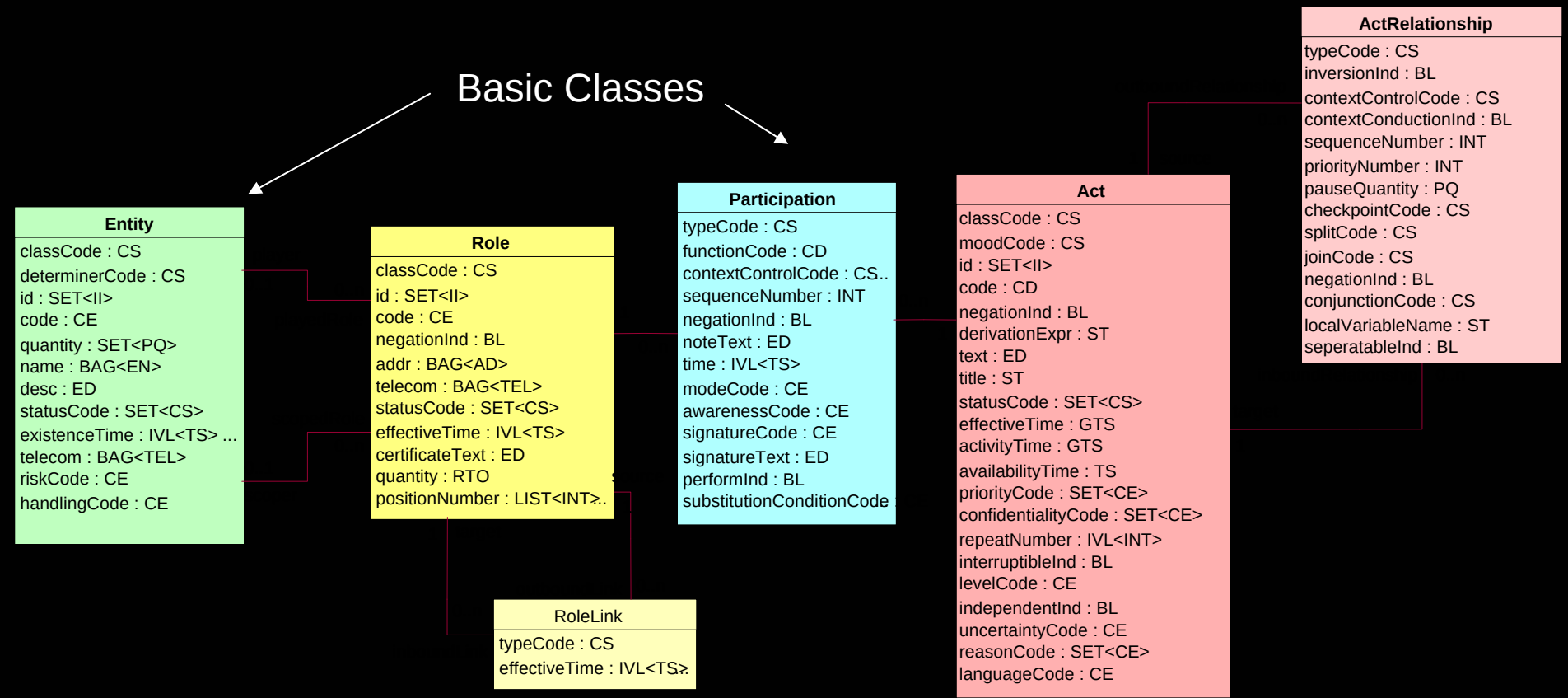
- Interoperability, not flexibility
- International
- Vocabularies and Data Types
- Technologies (UML, XML)
- A model base standard
- Version 3 messages are defined in and flow from a UML model of medicine

Models

- The world is more than vocabularies and data elements
- If the lab and the pharmacy want to communicate it is important that they have a consistent vocabulary and data elements but the also need a consistent view of the world
- The reason the financial world can be so integrated is because there is a consistent, well understood, financial model

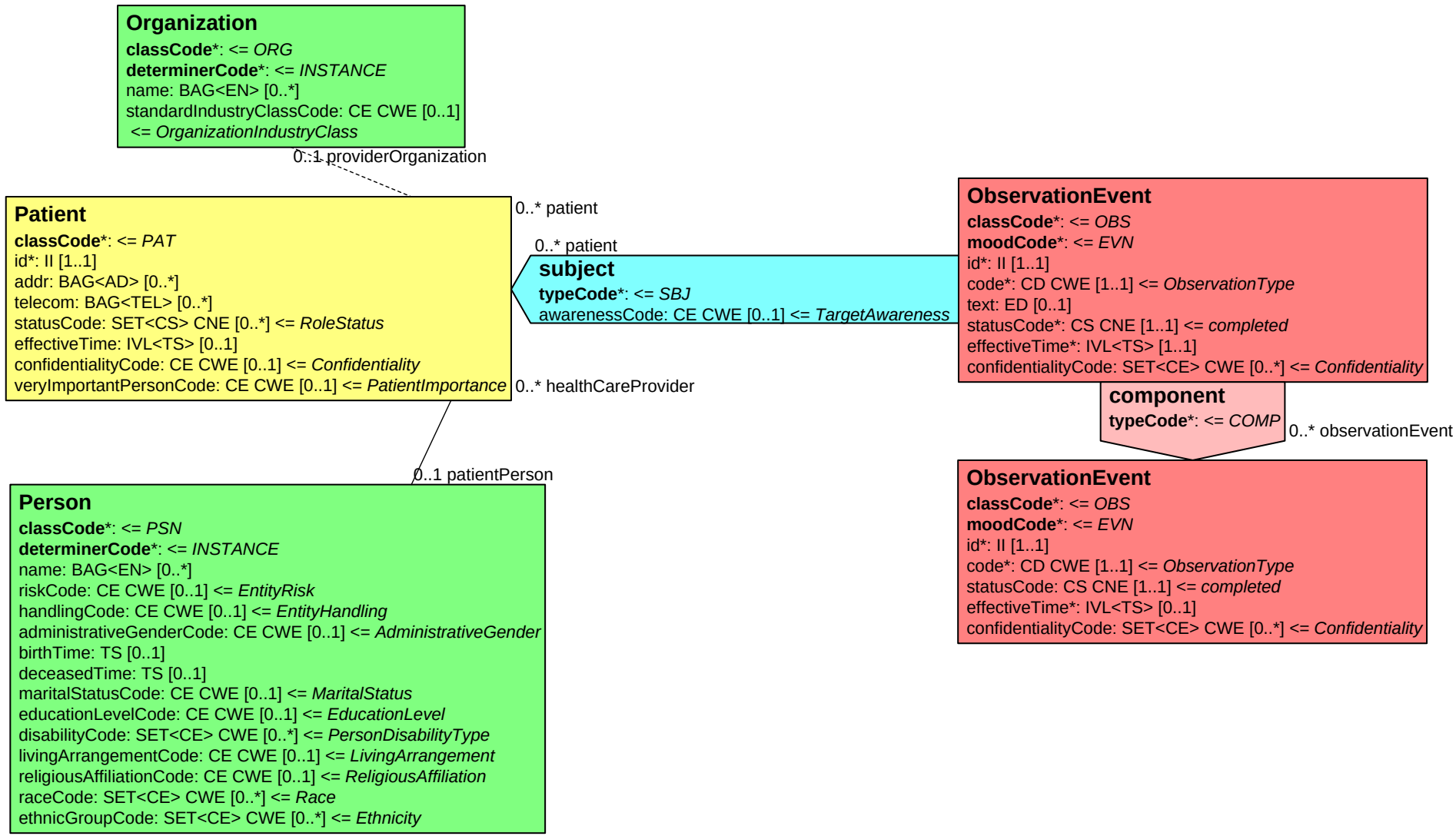
Where are our (agreed upon, well documented) models of data and data flows in heath systems?

The RIM Backbone

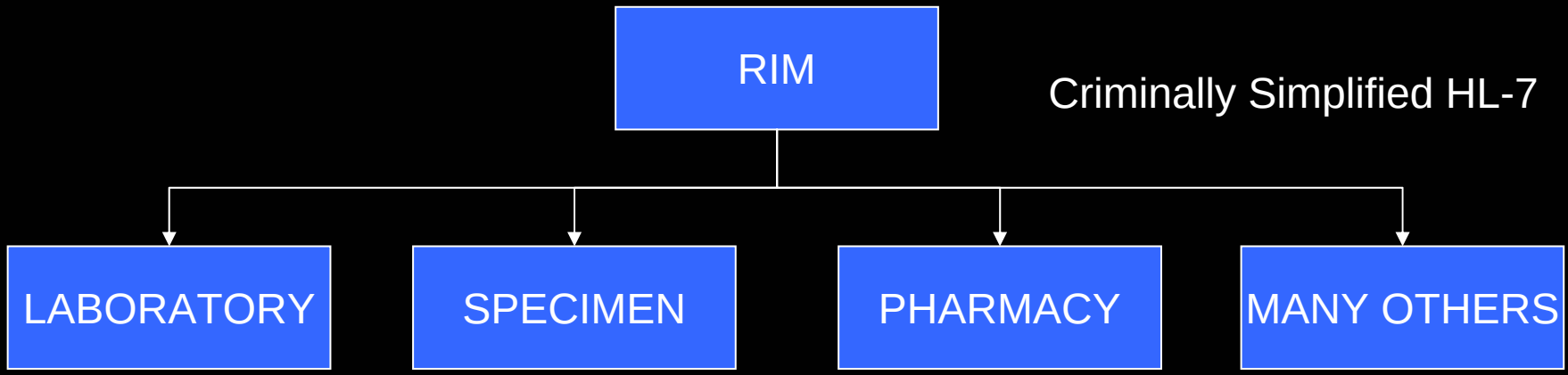


Entities play Roles that Participate in Acts

Courtesy Dr. Gunther Schadow

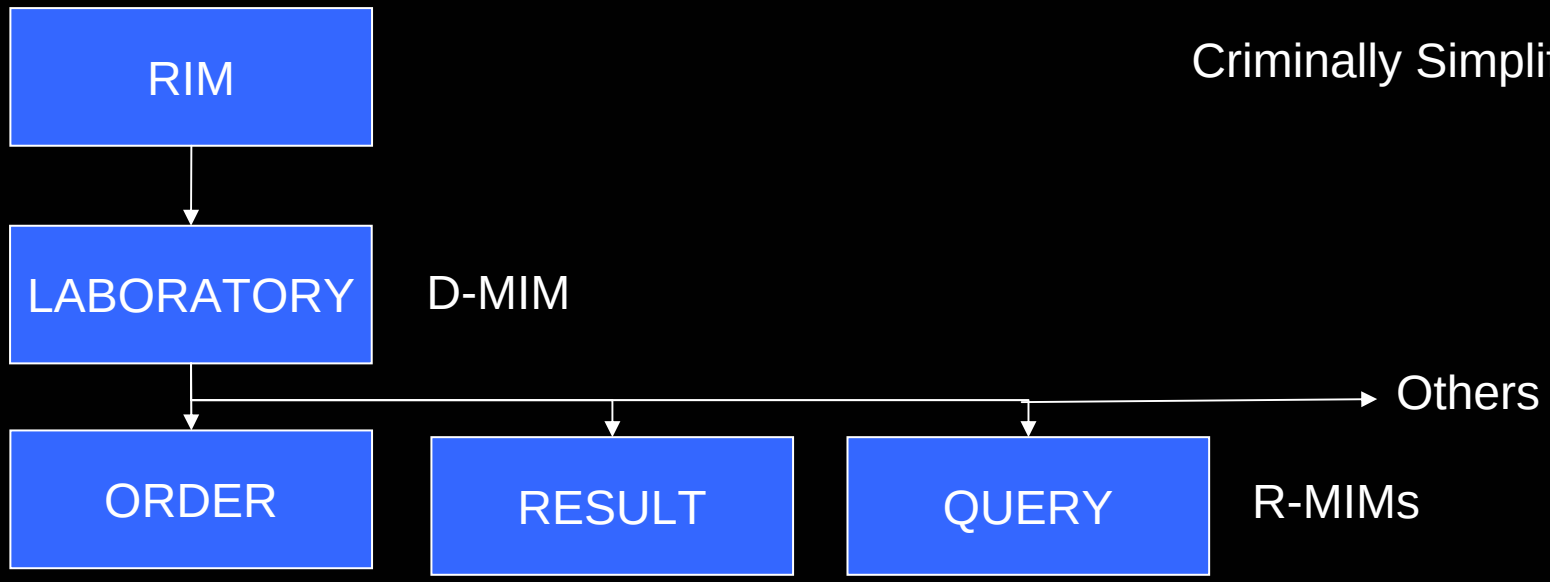

Organization
classCode*: <= ORG
determinerCode*: <= INSTANCE
name: BAG<EN> [0..*]
standardIndustryClassCode: CE CWE [0..1]
<= OrganizationIndustryClass
0..1 providerOrganization
Patient
classCode*: <= PAT
id*: II [1..1]
addr: BAG<AD> [0..*]
telecom: BAG<TEL> [0..*]
statusCode: SET<CS> CNE [0..*] <= RoleStatus
effectiveTime: IVL<TS> [0..1]
confidentialityCode: CE CWE [0..1] <= Confidentiality
veryImportantPersonCode: CE CWE [0..1] <= PatientImportance
0..* patient
0..* patient
subject
typeCode*: <= SBJ
awarenessCode: CE CWE [0..1] <= TargetAwareness
ObservationEvent
classCode*: <= OBS
moodCode*: <= EVN
id*: II [1..1]
code*: CD CWE [1..1] <= ObservationType
text: ED [0..1]
statusCode*: CS CNE [1..1] <= completed
effectiveTime*: IVL<TS> [1..1]
confidentialityCode: SET<CE> CWE [0..*] <= Confidentiality
0..* healthCareProvider
component
typeCode*: <= COMP
0..* observationEvent
0..1 patientPerson
Person
classCode*: <= PSN
determinerCode*: <= INSTANCE
name: BAG<EN> [0..*]
riskCode: CE CWE [0..1] <= EntityRisk
handlingCode: CE CWE [0..1] <= EntityHandling
administrativeGenderCode: CE CWE [0..1] <= AdministrativeGender
birthTime: TS [0..1]
deceasedTime: TS [0..1]
maritalStatusCode: CE CWE [0..1] <= MaritalStatus
educationLevelCode: CE CWE [0..1] <= EducationLevel
disabilityCode: SET<CE> CWE [0..*] <= PersonDisabilityType
livingArrangementCode: CE CWE [0..1] <= LivingArrangement
religiousAffiliationCode: CE CWE [0..1] <= ReligiousAffiliation
raceCode: SET<CE> CWE [0..*] <= Race
ethnicGroupCode: SET<CE> CWE [0..*] <= Ethnicity
ObservationEvent
classCode*: <= OBS
moodCode*: <= EVN
id*: II [1..1]
code*: CD CWE [1..1] <= ObservationType
statusCode: CS CNE [1..1] <= completed
effectiveTime*: IVL<TS> [0..1]
confidentialityCode: SET<CE> CWE [0..*] <= Confidentiality

Behind the RIM lie the D-MIMS



Criminally Simplified HL-7

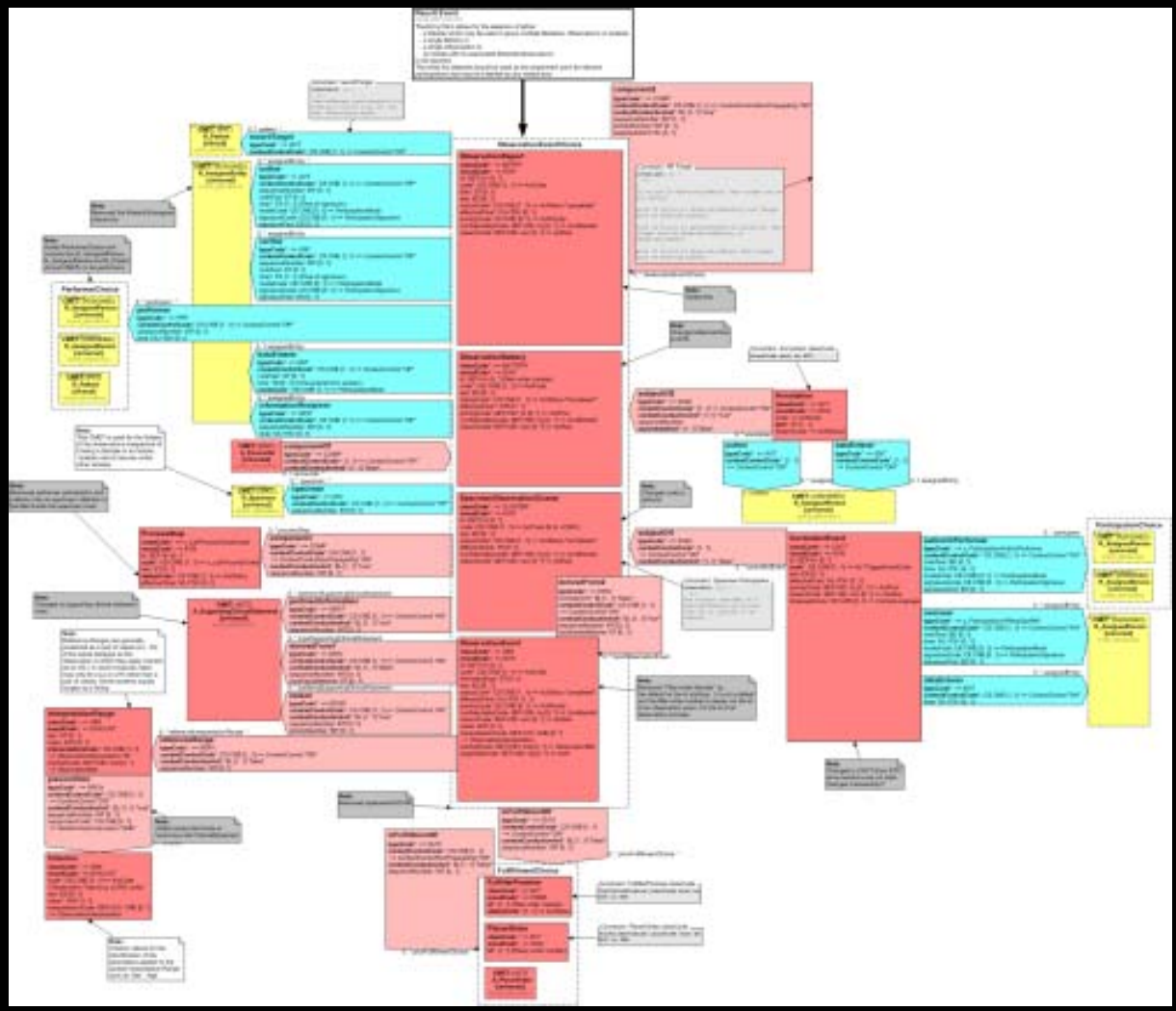
- D-MIMS (Domain Message Information Models) are specializations of the classes in the RIM
- They are models of medical domains
- The contain all the classes (and their relationships) necessary to construct all message needed within that domain
- They are developed an maintained by working groups (SIGs)



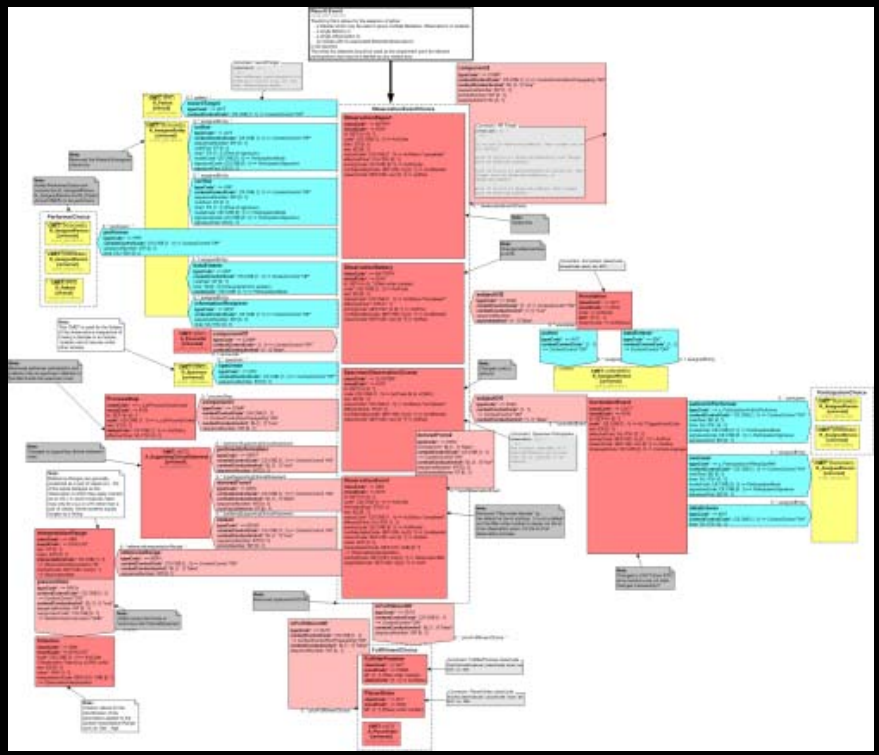
Criminally Simplified HL-7

- Because D-MIMS can get very complicated, they can be “specialized” in R-MIMs (Refined Message Information Model)
- From the R-MIMS, UML* tools build “Hierarchical Message Definitions” and the messages themselves (which and be in XML)

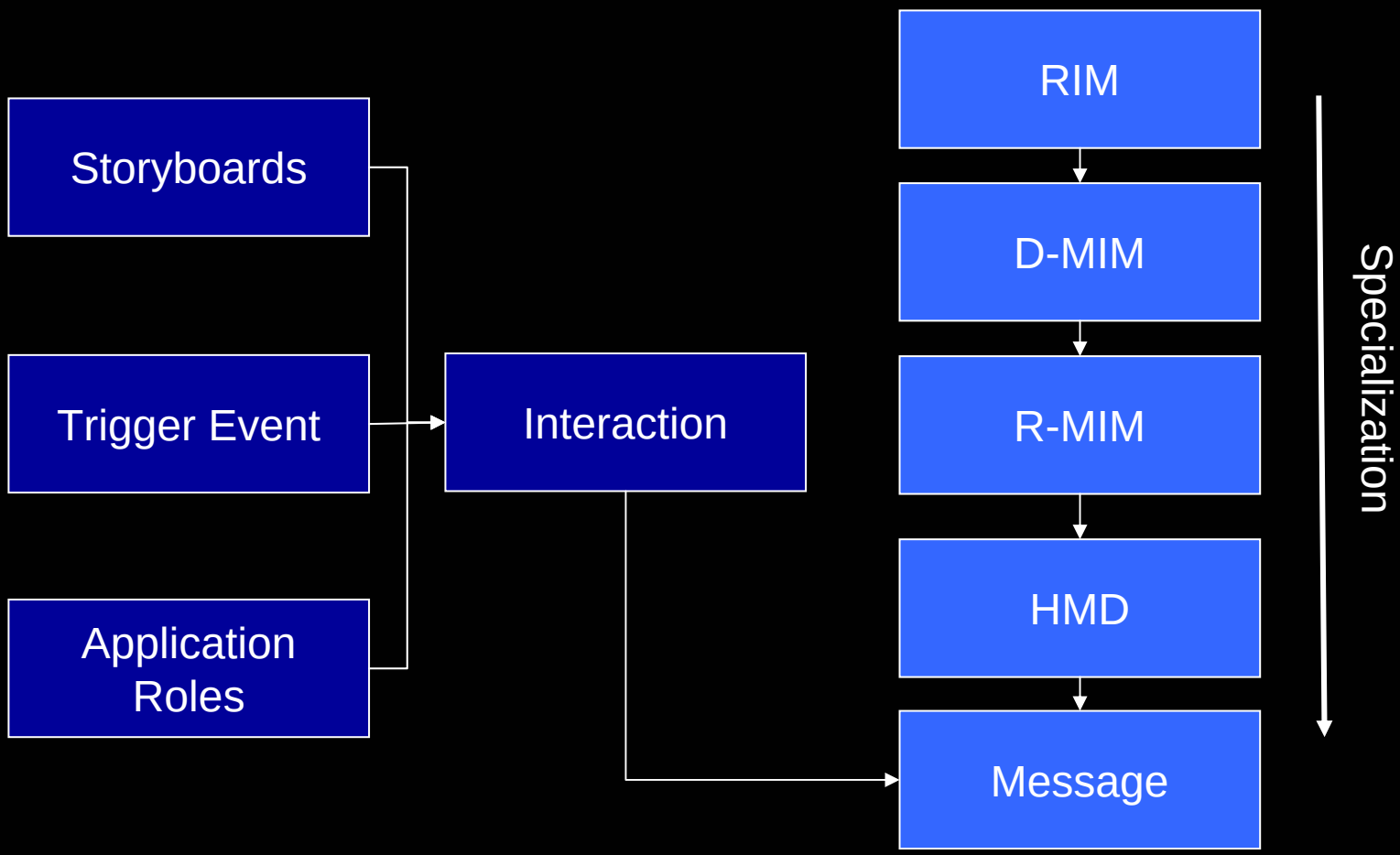
Laboratory Results R-MIM



Why



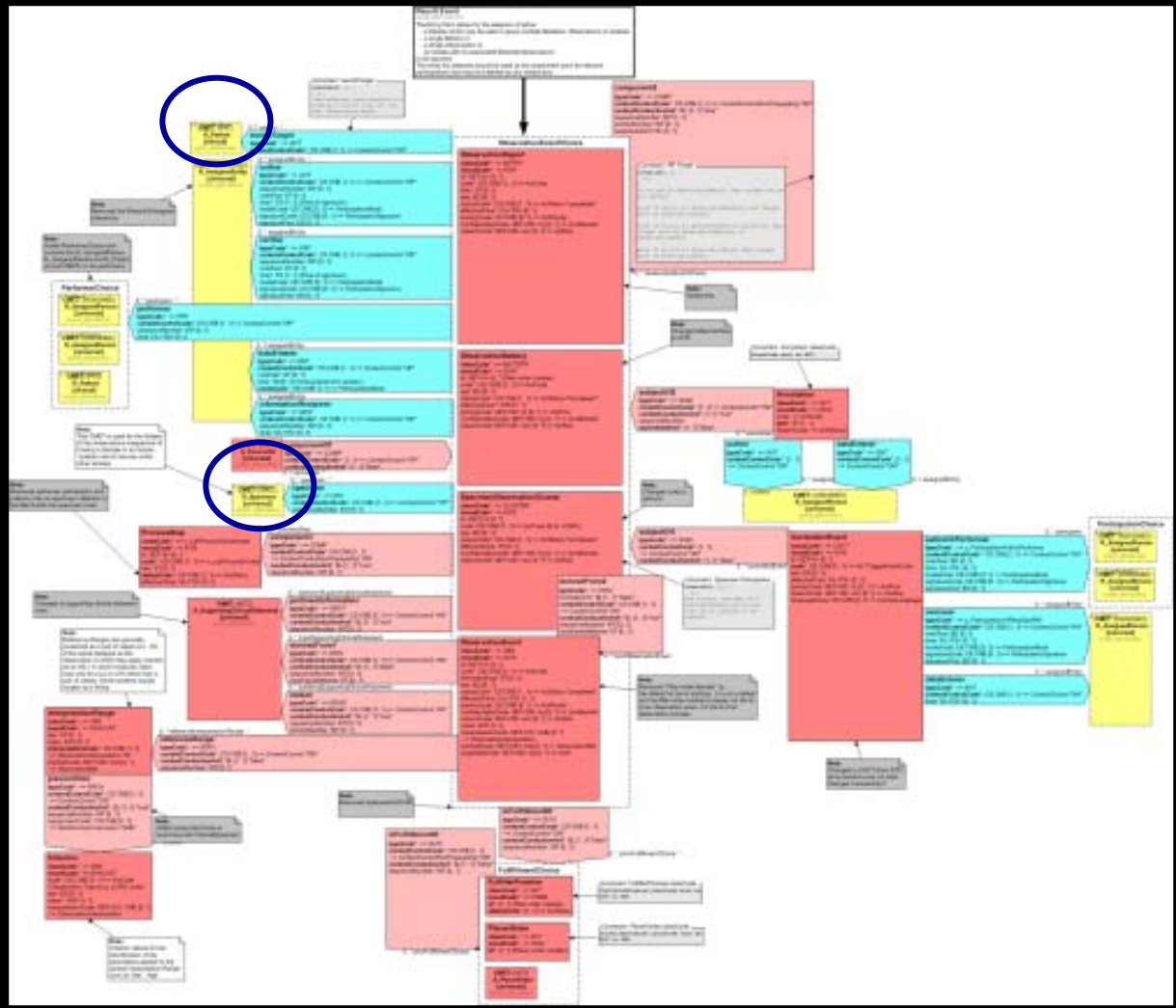
- Detailed UML model of the messaging (things and events) in a generalized lab
- Developed over many months by practitioners and developers around the world
- “Validated” in real implementation
- The complete documentation includes “storyboards”, trigger events and “application roles”


Storyboards
Trigger Event
Application Roles
Interaction
RIM
D-MIM
R-MIM
HMD
Message
Specialization

Models as building blocks

- D-MIMs are harmonized against the RIM
- Models can (and do) incorporate other models (other parts of the HL-7 model)
- CMETs (Common Message Element Types)
- Provides consistency between different parts of the model
- Allows for building complex structures based on simpler, “validated” building blocks

Laboratory Results R-MIM



Implications

- The HL-7 V3 (or DICOM) Messaging Information Models are not be the only possible models for clinical data flow
- The D-MIMs are developed in an open, collaborative way, are documented in UML. Working groups are highly diverse and anyone can join
- Real world “labs” should be specializations of the model
- Messages are document in and flow from the model
- As HL7 V3 becomes implemented (especially overseas), will be “validated” or modified by real world experience
- Complex structures can be build by combining simple structures

Implications

- The world is not just a collection of data elements
- The HL-7 models should have value to lab managers and pathologists
- The should also have value to those trying to integrate different specialties (Laboratory – Radiology – Pharmacy)
- The information models at the heart of the standard can provide important insights, and institutional understanding, into the way data flows in health systems. Such information models should be intellectual valuable for informaticians and those tasked to create large, complex (federated) clinical information systems

Conclusions

- You can make a difference
- “The secret of success is consistency of purpose”
- HL7 is not going away

Learn More

- Join DICOM WG 26
- Join HL7 Lab or Anatomic Pathology SIG - www.hl7.org
- Books
  - Understanding Version 3 by Andrew Hinchley (www.hl7.org)
- Next meeting is in Cologne at the end of April
- GilbertsonJR@gmail.com