

Third Party Involvement and DICOM in Medical Imaging

Prepared by

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**Inzight Consulting, LLC
for ADSA07 May 16, 2012**

Background, Objectives, and Methodology

Background

- This work is funded by DHS, but I am not an employee
- I do not speak for or represent DHS or TSA
- Work is ongoing; findings are subject to revision

Objectives

- Is 3rd party involvement (and DICOM) good for medical vendors? (esp. CT)
- Is 3rd party involvement (and DICOM) good for other stakeholders?
- What role does DICOM play in third party involvement?
- What are the implications for security imaging?

Methodology

- Primary and secondary research (emphasis on CT)
- > 24 interviews re: medical imaging (vendors, academics, etc.)
- Next step: Interviews with security vendors
- Thank you! To all who have helped

Not
complete

Just beginning

Summary: Third Parties and DICOM in Medical Imaging

- 3rd party involvement helps *advance the field* and it is *good* for incumbent vendors and other stakeholders. Magnitude varies by modality (e.g. MRI > CT)
- Medical vendors engage various third parties in a variety of ways and, while doing so, strive to protect their IP and commercial interests
- Several things motivate medical vendors to work with third parties
 - Hospitals have incentives to upgrade equipment and vendors have a “carrot” and “stick” incentive improve offerings. Third parties can help.
- DICOM plays a role in 3rd party involvement (for images, not for raw data)
- DICOM benefits customers and vendors
- DICOM was adopted voluntarily, but pressure from users played a key role
- DICOM is neither necessary nor sufficient for interoperability
- These findings from medical imaging are relevant to security, but there are also important differences between the two domains

Medical Market Characteristics (Possible Differences vs. Security)

- **Large vibrant ecosystem of MD, PhD, Vendors (e.g. RSNA)**
- **Large and growing market, with proven ability to absorb new advances**
- **Thousands of customers: different niches, buying criteria, and timelines**
- **Potential for serendipity → innovation → new applications and markets**
- **Third Parties in medical imaging have**
 - **Common understanding of goals and close relationships with vendors**
 - **Access to MDs, images, cutting-edge problems, and feedback loops**

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Ads for New:

- Lower dose CT
- 3D mammog.
 - +CAD
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Relevance

- 3rd Parties
- DICOM
- Market dynamics and incentives

Agenda/Contents

- **Background, Objectives and Methodology**
- **Caveats**
- **Summary**
- **Medical Market Characteristics**
- • **Types of third parties; types of involvement**
- • **Is 3rd party involvement good for vendors? Other stakeholders?**
- **How do vendors protect their interests?**
- **MRI versus CT**
- **Government role in third party funding**
- **Role of DICOM in medical imaging and third party involvement**
- **Summary**

Distinguish Among Different 3rd Parties, Different Funding

- **Academic third parties**
 - Hired by vendor as a consultant, on own time (1099)
 - Hired by vendor as Principal Investigator, through the university (PI)
 - Working independently (i.e. funded by government or university)
- **Commercial Third parties**
 - Competitor (potential or actual)
 - Not a competitor
 - Hired or engaged by current vendor(s)
 - Self-funded or funded by government
- **Other**

Medical Vendors Engage Academic 3rd Parties in a Range of Ways

Funded and Controlled by Vendor

Not Funded by Vendor

**Narrow Engagement,
Specific Issue**

**Long-term, Broad
Area (Often MRA)**

**Follow the lit, attend
conf's, etc.**

As Consultant

As PI thru U.

As PI through U.

Vendor Control Declines ----->

1

2

3

4

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Predictable

**Solve
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**Incremental
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**Role for serendipity
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**Wide range of
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no direct**

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**Incremental
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**Wide range of
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**application
Potential big
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Do Vendors Make Money from Engaging with 3rd Parties? (Silver box)

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Potential big
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**Low cost, + ROI
only benefits 1**

**+ ROI, may
help # not just 1**

**ROI: ? presume +
on avg. May help #**

**Free: + ROI. But
may help #, not 1.**

Relative Role of Government Funding (Blue box at bottom)

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Govt \$: low/no

Govt \$: low/no

Gov't \$: medium

Gov't \$: high

To Whom Do Benefits Accrue, from Academic 3rd Party Advances?

	Benefits to		
	Vendor #1	Other Vendors	Other Stakeholders
Advance unique to vendor #1	++	-	+
All vendors have access to advance.	+	+	++

Advance unique to vendor #1

All vendors have access to advance.

- • There is a tension between the best outcome for Vendor 1 and the best outcome for other stakeholders (e.g. hospitals or government)

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Advance unique to vendor #1

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- There is a tension between the best outcome for Vendor 1 and the best outcome for other stakeholders (e.g. hospitals or government)
- • Assuming the market can grow (in units or price), or if the upgrade cycle can be accelerated, then vendors can benefit from an advance that they all share. (Cross-licensing in medical imaging, etc.)

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Vendors Protect Their Interests with Research Agreements, etc.

- **NDA and data restrictions**
- **Publication review (NDA Issues; IP issues) (Not always observed)**
- **IP provisions**
- **May use Master Research Agreements (MRA)**
 - **Can take 3 to 6 months to negotiate**
- **Non-compete agreements**
- **Relationships and Trust**

One Possible Model for University/Vendor Agreements: NERFOE

Vendor gets

- **Non-exclusive royalty free (NERF) license to any IP and an option to negotiate exclusive license (NERFOE)**

University gets

- **Right to license IP to others for \$, unless exclusivity option is exercised**

Outcome

- **Vendor cannot be “held hostage” or locked out of advance**
- **University may extract additional value if advance is truly significant**

MRI vs. CT

- **Academics have greater access to MRI “secrets” than they do for CT**
- **Academic third parties have contributed more to MRI than to CT**
- **Both society and vendors have both benefited**

Why is MRI different than CT?

- **Partly an accident of history**
- **MRI grew out of NMR (academic field)**
- **A “borderline irresponsible” gamble by “visionaries” paid off**
- **Feedback loop: Easier to demonstrate new ideas in clinic (no radiation)**
- **Greater barriers to entry (on hardware side)**

- **Despite easier access, research agreements are still required**

Government Funding Plays a Role in Third Party Efforts

Academic Funding (NIH, NSF, NCI, etc.)

- Work done without vendor involvement
- Work done in partnership with vendor

Commercial Entities (NIH, NCI, Military, SBIR, etc.)

- Army grant to Imatron to develop new CT scanner
- AS&E's 4th Generation CT scanner funded by NCI
- PET/CT prototype funded by NCI
- SBIR

Accelerating Third Party Involvement and Deployment

- **Clarify objectives**
- **Reduce Barriers**
- **Increase Incentives**

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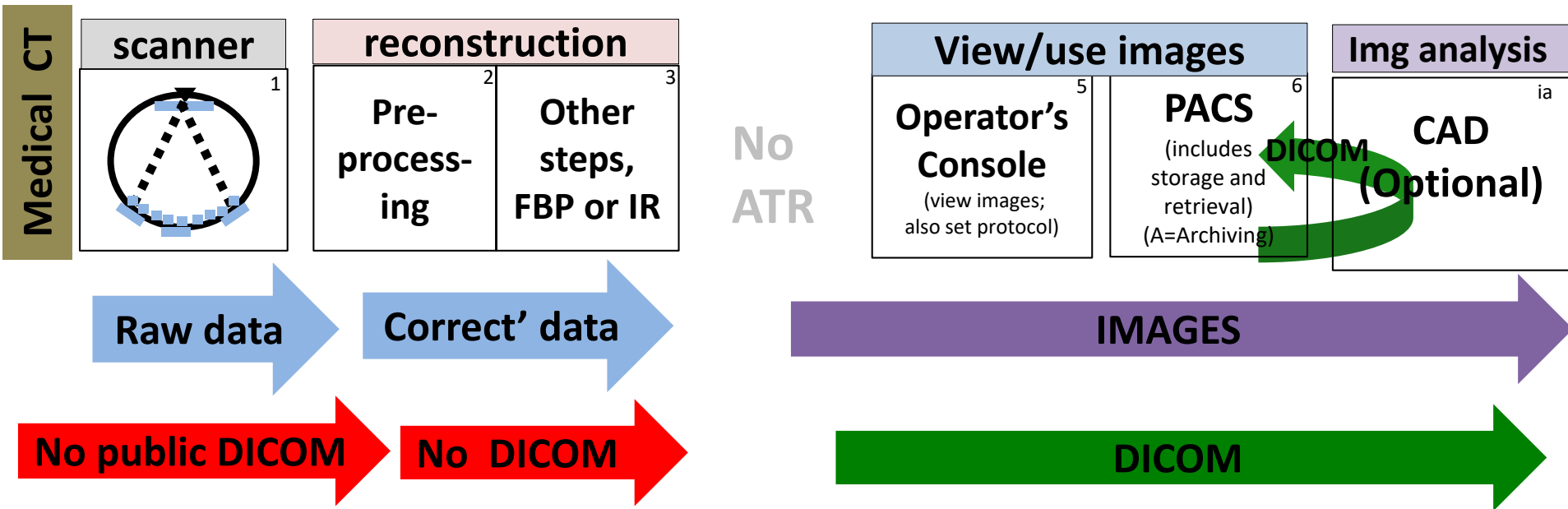
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Role of DICOM in Medical CT

DICOM is a standard for formatting and transmitting images

Simplifying slightly: DICOM exists “to the right of the image” (green arrow)

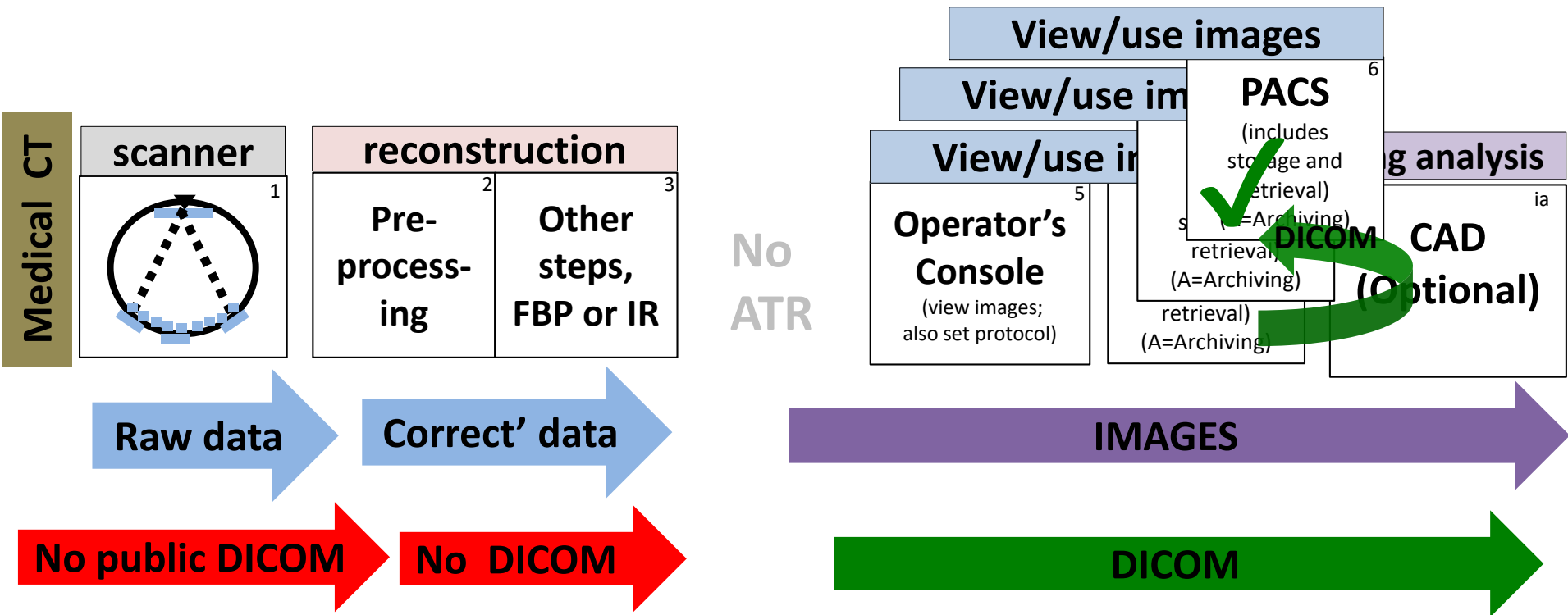
There is no DICOM “to the left of the image” (red arrows)



PACS Systems are ~Plug'n'Play, With a High Level of Interoperability

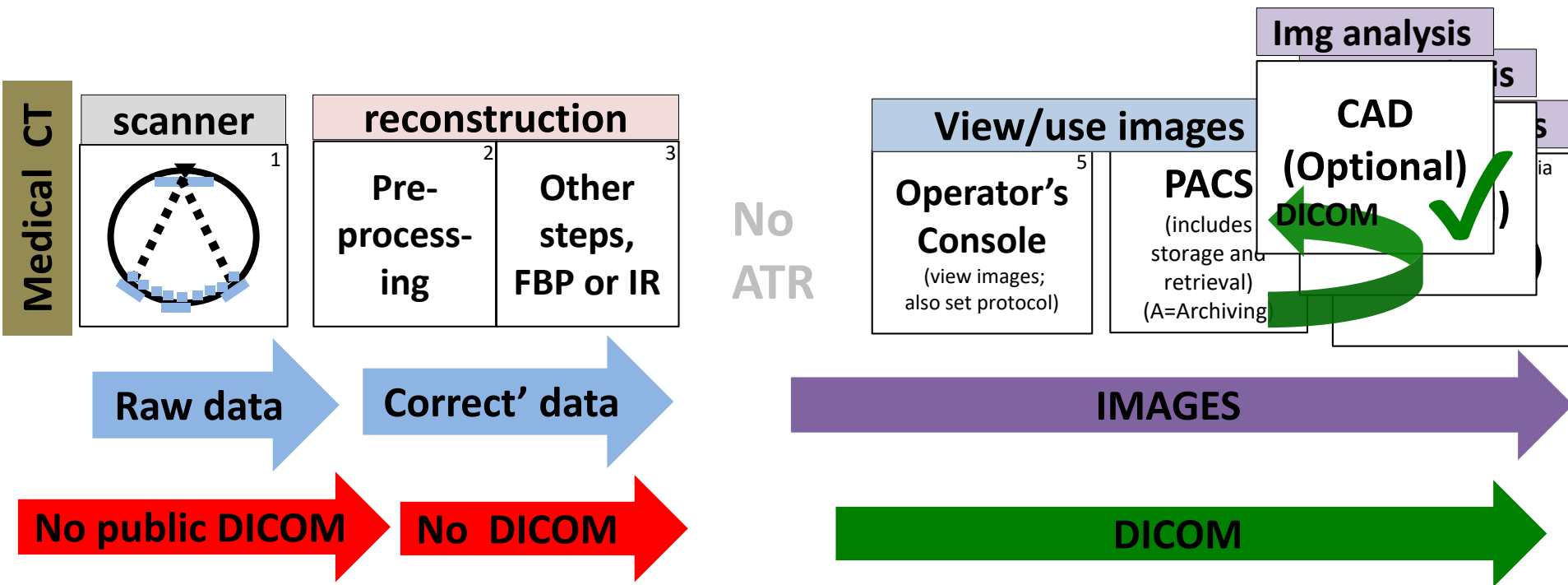
Before DICOM, medical imaging systems were proprietary

Since DICOM, PACS and their various components are (for the most part) interoperable



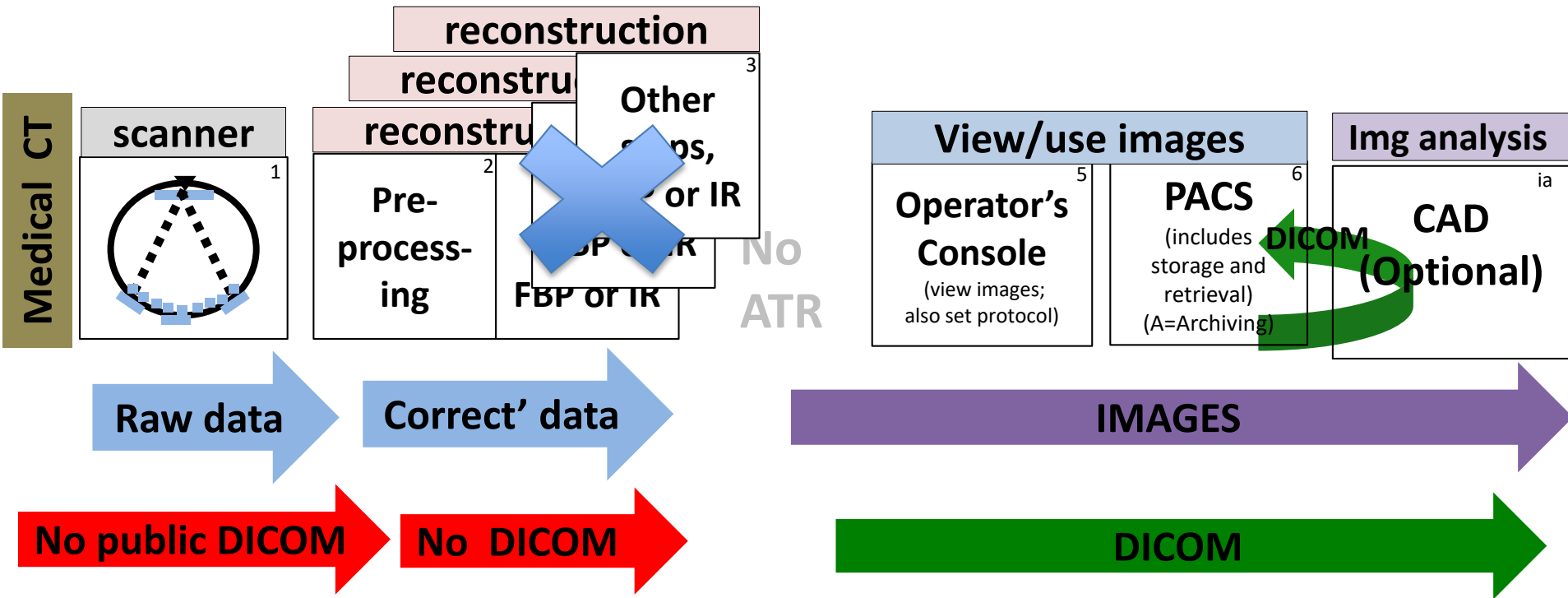
DICOM Facilitates Image Analysis R&D and Deployment (e.g. CAD)

Image Analysis or CAD from multiple vendors can be implemented on one CT system, since this is done “to the right of the image” using DICOM images



DICOM has Not Been Important to CT Reconstruction and There are no Deployed Examples of Plug'n'Play Reconstruction in CT

There are no deployed examples of multiple reconstruction algorithms from multiple vendors (or from academics) running on one medical CT scanner



DICOM Benefits Vendors and Other Stakeholders

Benefits to Customers from Adopting DICOM Standard

- Create PACS industry and remote reading
- Enable interoperability
- Reduce “vendor lock in”
- Increase competition; reduce barriers to entry
- Commoditize products and related services
- Reduce costs, including custom integration

Some of these “benefits” for customers might be “negatives” for vendors.

However, vendors report that the benefits to them outweighed the potential loss of negotiating power *vis a vis* their customers. None interviewed would give up DICOM.

Benefits to Suppliers from Adopting DICOM Standard

- Create PACS industry and remote reading
- Grow imaging market (new users, new applications, more scans, more equip.)
- Interoperability → Reduce barriers to acquiring new customers
- Encourage focus on areas of “core competence” and “competitive advantage”
- Reduce costs (design, engineering, workforce training, acquisition integration)

Summary: Third Parties and DICOM in Medical Imaging

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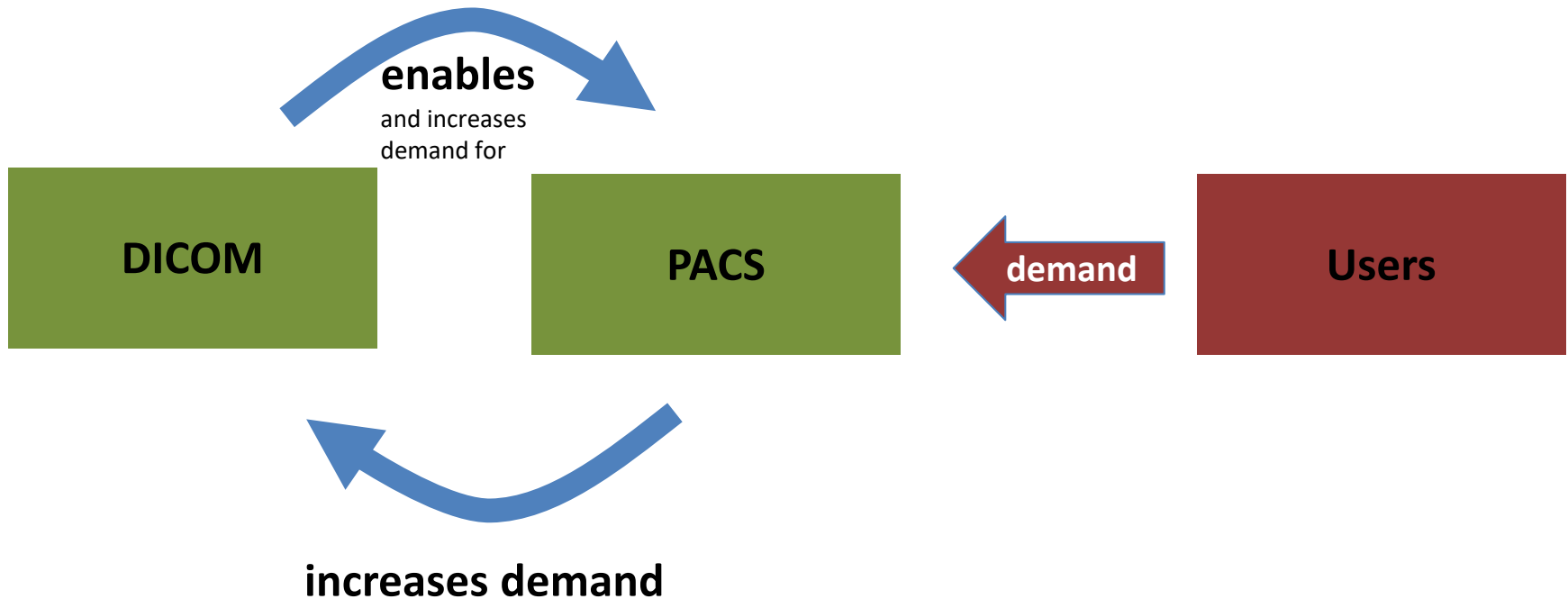
End

Backup

DICOM and PACS Created a Virtuous Circle of Increased Demand

One vendor pointed out: “People say DICOM enabled PACS. But you can also say that the market demand for PACS created demand for DICOM. The two were ‘chicken and egg.’ ”

Also note that the User Demand (red arrow) is Demand in three overlapping senses: 1) Market Demand (users will buy it), 2) Users insist on it, and 3) there is a compelling logical use or "need" for it.



DICOM History: Selected Key Dates

- 1982. PACS conference. Need identified. MD complain to ACR, FDA.
- • 1982. FDA tells industry: choose voluntary or expect regulatory
- Next 10 years: slow progress, some resistance, foot dragging
- 1990. Implementations “other than prototype” available for 1st time
- 1992-1994 RSNA demos; sense of possible → sense of inevitable
- 1994-5 DICOM at RSNA on commercial floor. 30% → 80% products
- Ongoing: Connect-a-thons continue; needed to demonstrate interoperability

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- 1982. First PACS conf. Radiologists complain to ACR, FDA
- • 1982. FDA tells industry: choose voluntary or expect regulatory
- 1983. ACR and NEMA form Committee
- 1985. ACR-NEMA 1.0 is released. Point-to-point
- 1988. ACR-NEMA 2.0 is released. Limited networking
- 1988. Siemens and Philips publish specs for their own joint networking standard (SPI)
- 1990. Implementations of ACR-NEMA “other than prototype” available for 1st time
- 199x. Parts of SPI incorporated into ACR-NEMA
- 1992. First Connect-a-Thon (to demonstrate that interoperability works in real world)
- 1992 RSNA demo of ACR-NEMA. (Software funded by RSNA and vendors)
- 1993. ACR-NEMA or DICOM 3.0 released at RSNA. Networked. Not on commercial floor
- 1994. DICOM at RSNA on commercial floor 1st time. 30% of products have DICOM opt.
- 1995. DICOM “productized.” 80% of relevant products have DICOM option
- 1997/8. IHE founded. 1998/9. VA required IHE in RFP’s
- 2001. Horii testifies vendors still produce DB incompatibilities; “weakness” or not?

Examples of Academic 3rd Party Contributions to Medical Imaging

Small Problems, Funded by Vendors

- Usually not public; may not be published
- Examples we heard: reconstruction (CT, PET); motion artifacts, etc.

Long-Term MRA, Funded by Vendor: Hire Smart People, See What Happens

- Various advances in MRI
- MBIR (~10 years until GE's Veo product)

Independent of Vendors (Funded by government grants or by university)

- Fan beam and Xenon detectors for CT (Boyd; Stanford to GE to wide license)
- Dual energy CT (Alvarez and Mocovski; Stanford)
- Mistretta's DSA; (licensed broadly by WARF--\$1B in end-user revenue)
- Cone beam CT (numerous advances; some with vendors)
- CAD (Doi at Chicago; founded R2; sold to Hologic for \$220M; widely licensed)

Third Party Contributions to MRI

According to a IP Manager for major Medical Vendor

- **Most MRI Research Agreements are not “outsourced research.” Rather, it’s “we like your work, here’s some seed money. Go get more grant money from NIH, do good work, and keep us posted and give us annual updates.”**
- **“It is recognized that we in industry don’t know what the right questions are.” Typically the best advances come from centers where Medical Physicists work closely with MD; they are “tightly coupled” and therefore “know what questions to ask.”**
- **This approach has made MRI “5x to 10x bigger” than it would have been without academic contributions, he says**
- **Examples of academic advances in MRI: Fast-Spin Echo (BWH); FLASH; GRASS; TRICKS**
- **Note, however, that he says that this model is less useful in CT.**

DICOM: Things That Reduced Vendor Resistance Over time

- **Pressure from users (KOL and ACR) and regulators (FDA)**
- **An increasing sense of “the possible”**
 - **Engineers began to see the goal as a “solvable problem” and a challenge**
 - **Early PACS installations at military hospitals showed “the future”**
- **An increasing sense that real-world users would actually buy DICOM and PACS**
 - **Early on, some in marketing were skeptical that customers would actually pay for DICOM and PACS. Why build it before customer will actually want to buy it?**
 - **PACS installations at military hospitals in the '80's and RSNA demonstrations in 1992 and 1993 helped convince industry that customers would want to buy**
- **An increasing sense of “the inevitable”**
 - **The RSNA demonstrations in 1992 and 1993 contributed to a sense of excitement and inevitability around DICOM & PACS. So did military PACS.**
- **More user pressure**
 - **By 1994-1995 when DICOM was available in products, KOL & ACR recommended to radiologists that they should require it in any RFP**