

# Advancing Translational R&D: Clinical Image Management

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# Agenda

- The Value of Imaging
- The Need for a Medical Image Management System (MIMS)
- The Value of MIMS
- Defining The Pieces
- Putting The System Together (the life of MIMS)
- Key Learnings
- Vendor Acknowledgements
- Questions

# The Value of Imaging

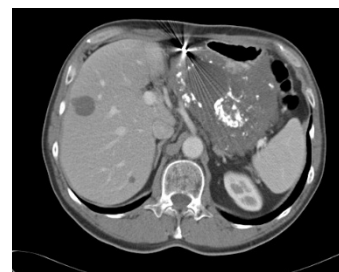
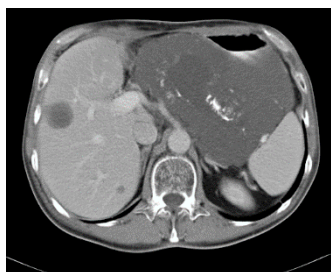
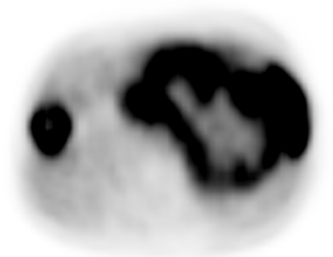
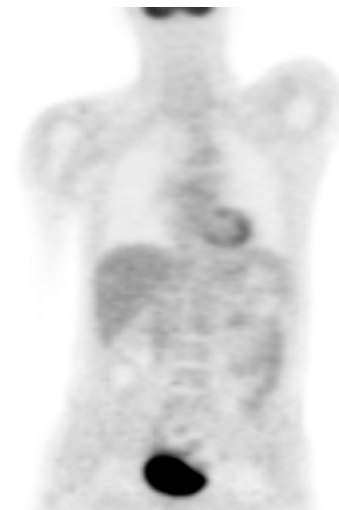
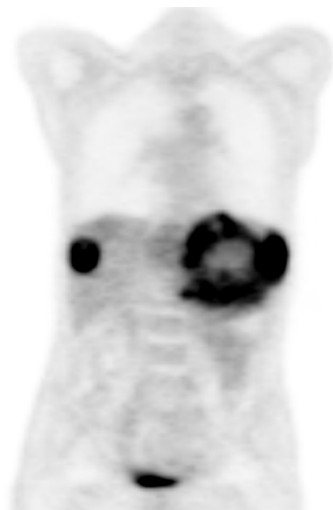
“Leveraging imaging can dramatically impact the success rates of new therapies across therapeutic areas”

Wendy Hayes, Executive Director, Bristol-Myers Squibb

# The Value of Imaging

- Imaging as a Biomarker in Drug Development
  - Imaging may maximize the full potential of assets across current target indications
  - Imaging may support the strategic expansion of assets to additional indications
  - Predictive imaging biomarkers may lead to patient stratification, patient selection and personalized medicine
  - Imaging may allow for the translation from pre-clinical studies to early and late phase clinical trials
  - Imaging may offer the ability to predict an early indication of response

# Patient with GIST Pre- and Post-Treatment (GastroIntestinal Stromal Tumor)



Baseline

1 month

1 year



Courtesy of Annick D. Van den Abbeele, MD, DFCI



Bristol-Myers Squibb

# The Value of Imaging

Imaging offers fast, reproducible, accurate methods to assess response to oncologic therapies.....

*Prostate cancer clinical trial end points: "RECIST"ing a step backwards*

Scher HI<sup>1</sup>, Morris MJ, Kelly WK, Schwartz LH, Heller G

Clinical Cancer Research Journal, July 15, 2005 11:5223

PubMed – NCBI, 2005 Jul 15;11(14):5223-32

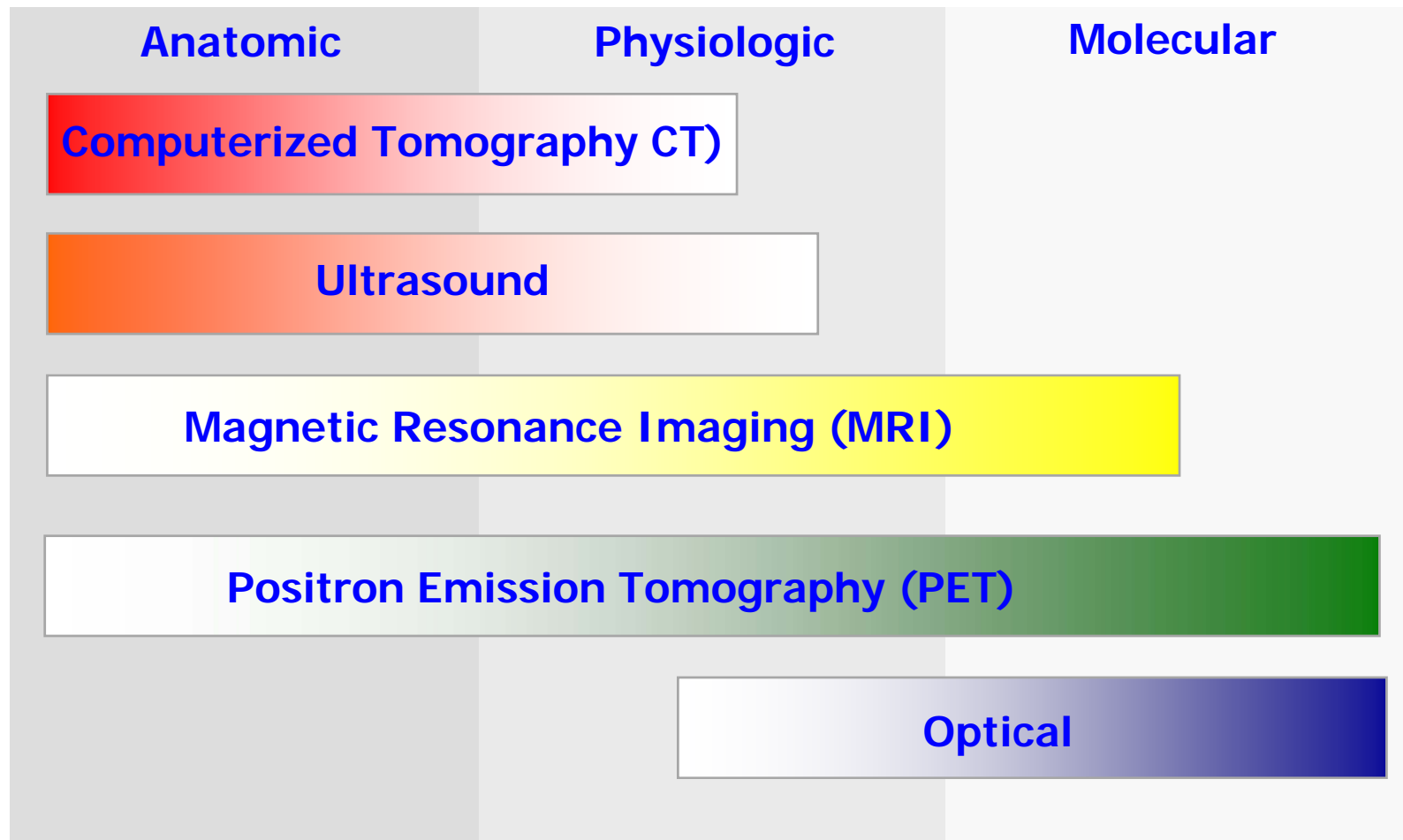
# The Value of Imaging

- FDA Guidance for Industry, Standards for Clinical Trial Imaging Endpoints\*
  - The purpose of this guidance is to assist sponsors in the use of endpoints that depend on the results of imaging tests in clinical trials of therapeutic drugs and biological products.
  - This guidance focuses on the imaging standards that we regard as important when imaging is used to assess a primary endpoint, or an endpoint component, in a clinical trial intended to confirm a drug's efficacy.
  - These standards can be used by sponsors to ensure that the imaging data are obtained in a manner that complies with a trial's protocol, that the quality of imaging data is maintained within and among clinical sites, and that there is a verifiable record of the imaging process.
  - By considering the topics highlighted within this guidance, sponsors can obtain clinical trial imaging data in a manner that minimizes variability and enhances data quality and the ability to detect drug treatment effects.

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\*U.S. Department of Health & Human Services, FDA, August 2011

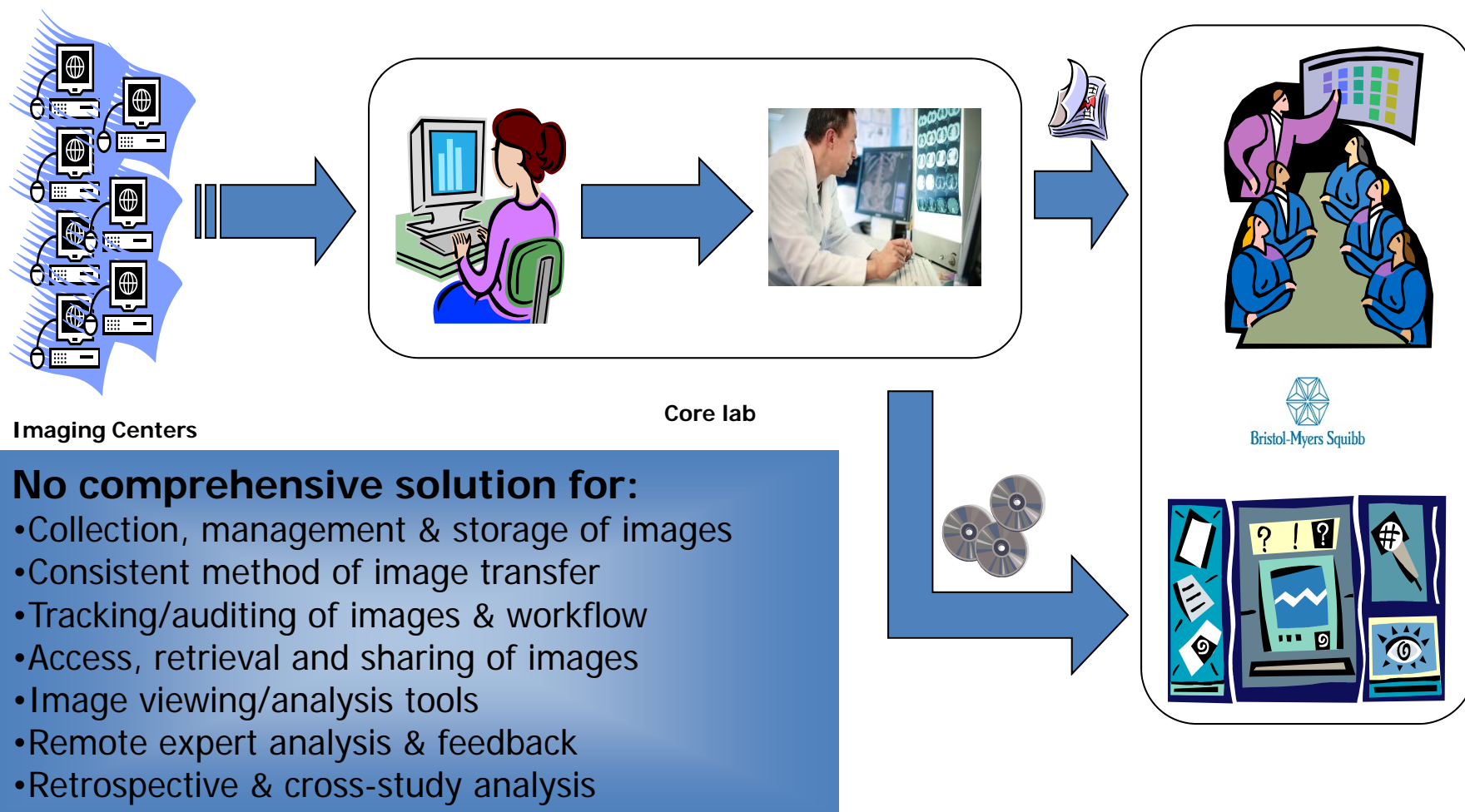
# Spectrum of Imaging Technologies



*Hoffman, J. M. et al. Radiology 2007;244:39-47*



# The Need for a Medical Image Management System (MIMS)



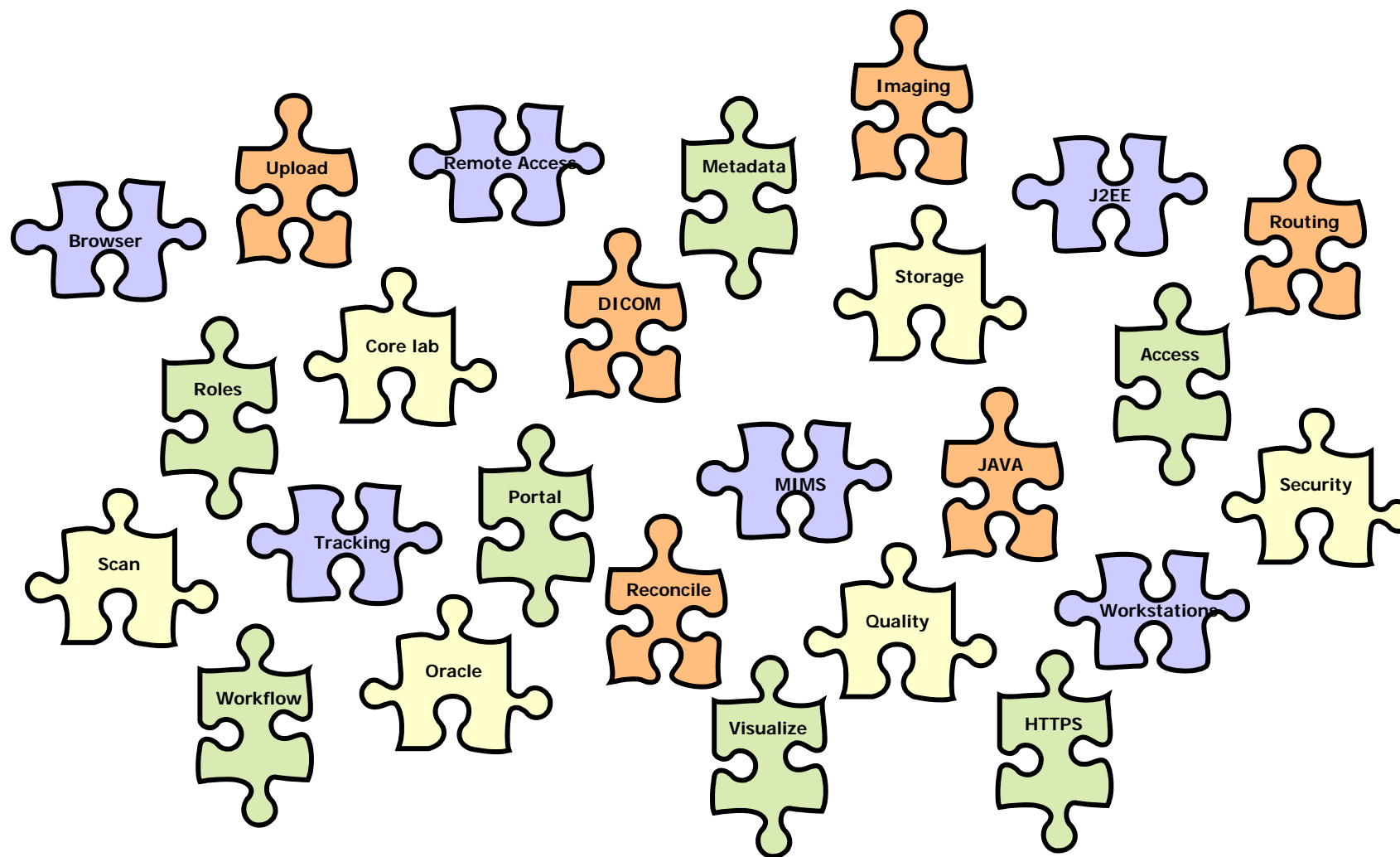
# The Value of MIMS

- Single storage solution for clinical trial images (21 CFR Part 11 and HIPAA compliant)
- Image-centric transport using industry standard technology provides status and statistics specific to imaging studies (not just “computer files”)
- Industry standard DICOM\* image set format allows analysis using commercially available & open source imaging software
- Flexible de-identification tools guarantee patient anonymity
- Ability to associate trial-centric metadata (user defined) with imaging data
- Searching/sorting results can be downloaded to a user (local or remote)
- Expert analysis “results” can be uploaded and linked to original image sets
- Role-based functionality simplifies user interface and provide inherent security

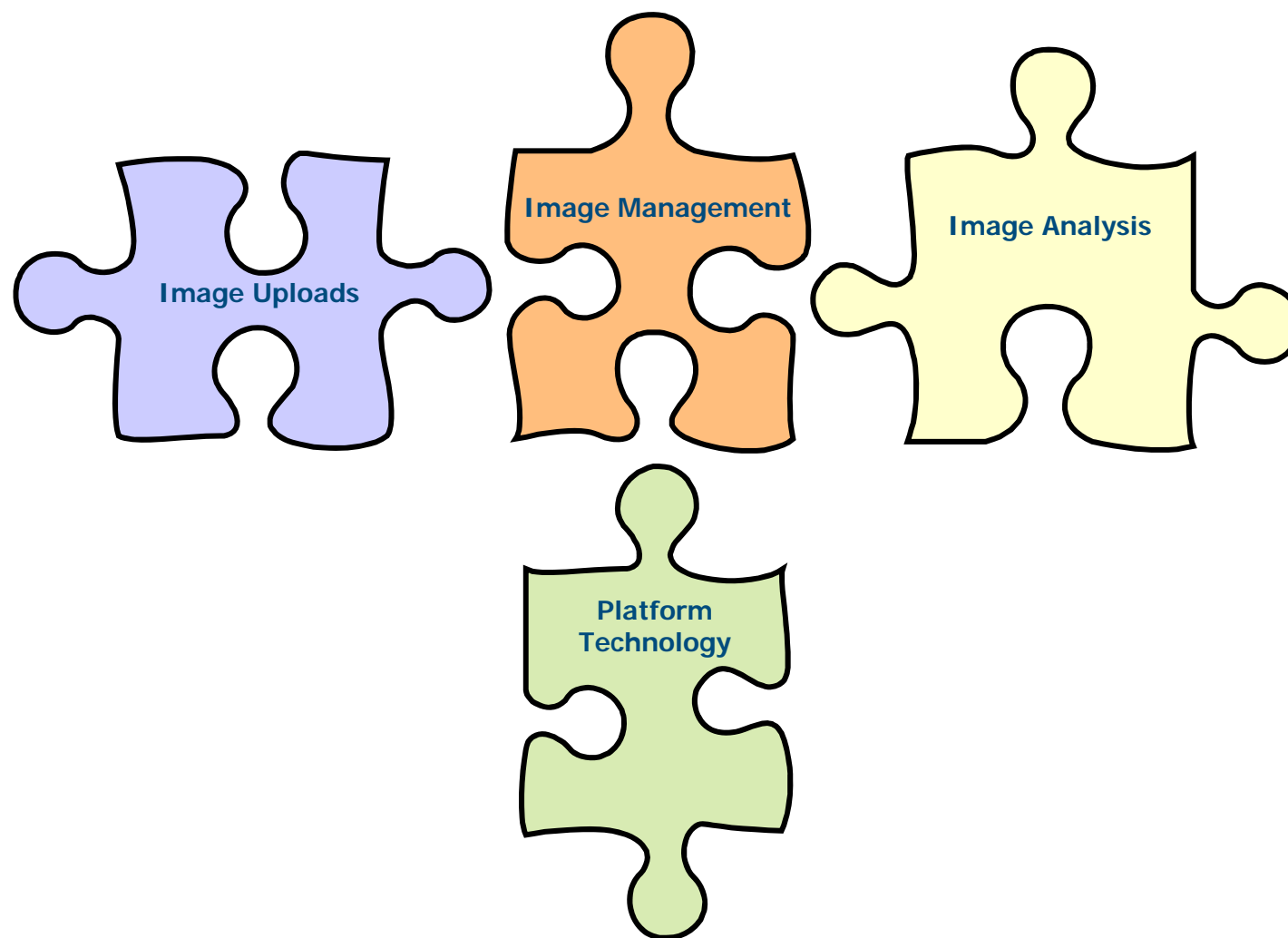
\* Digital Imaging and Communications in Medicine



# Defining The Pieces



# Putting it Together



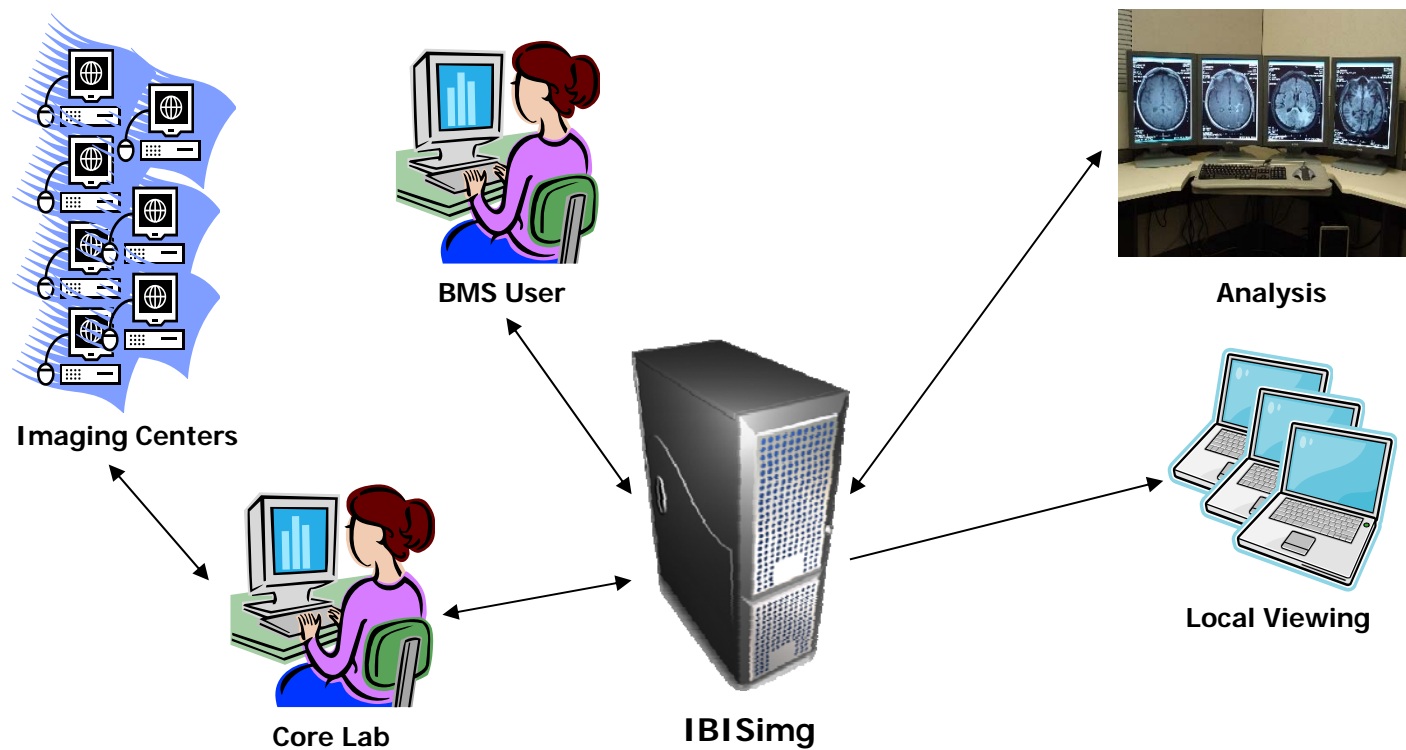
# IBISimg Image Management System

The Image Management System from Impact Business Information Solutions (IBISimg) provides a robust set of secure, easy-to-use capabilities designed to streamline and automate the receipt, validation, storage, management, review and analysis, and export of DICOM images and associated metadata. IBISimg is a pure Web-based application with a browser-based user interface, which facilitates centralized deployment, use and administration.

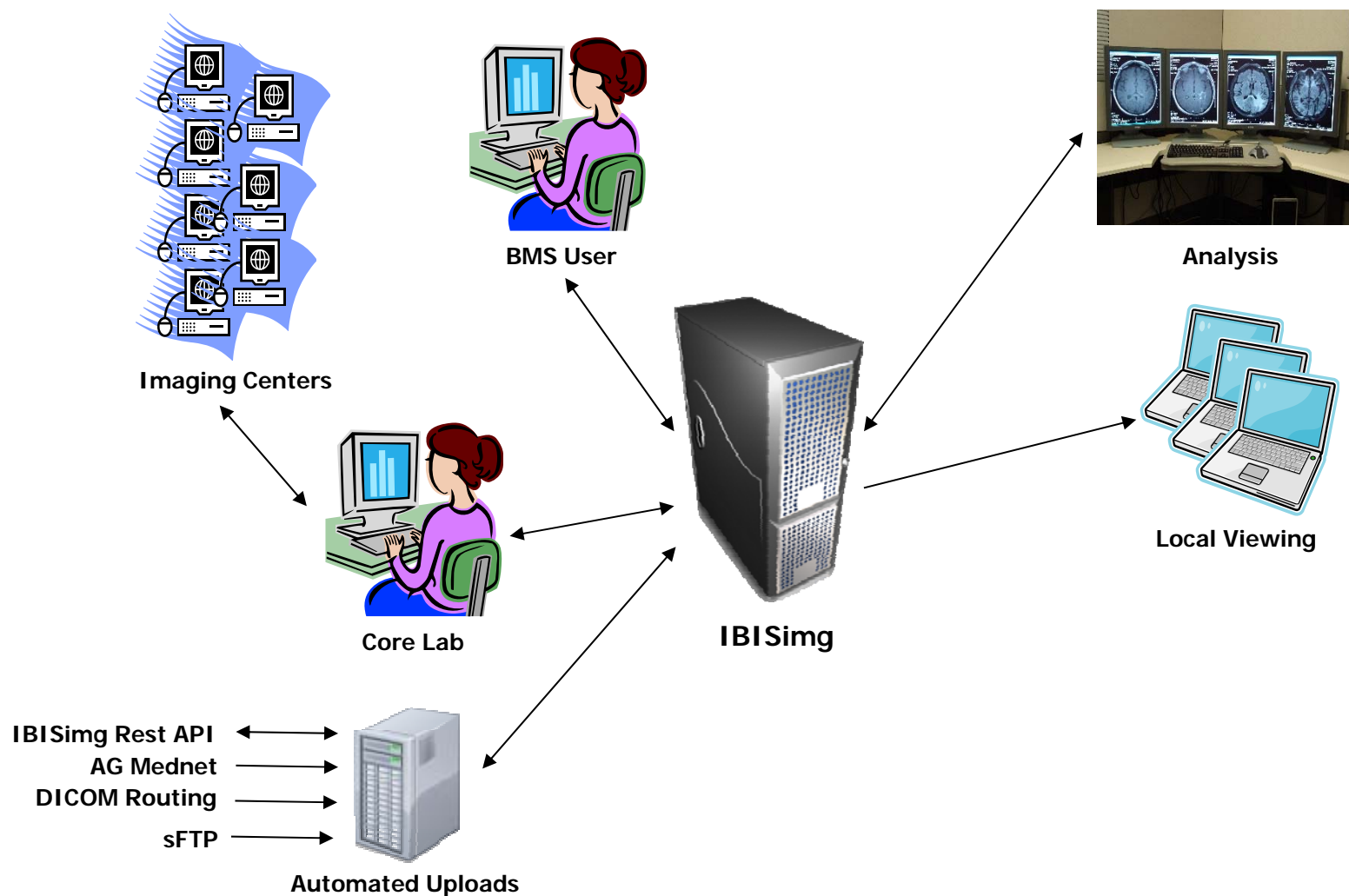
IBISimg capabilities include the ability to:

- Receive DICOM image data, validate the image data, assign metadata attributes to the datasets and store them in a single, central repository
- Filter/export image data for review and retrospective analysis
- Provide a variety of reports covering operational details and audit logs
- Configure user role-based functionality and manage audit trail tables to provide robust system security
- Provide context-sensitive online help

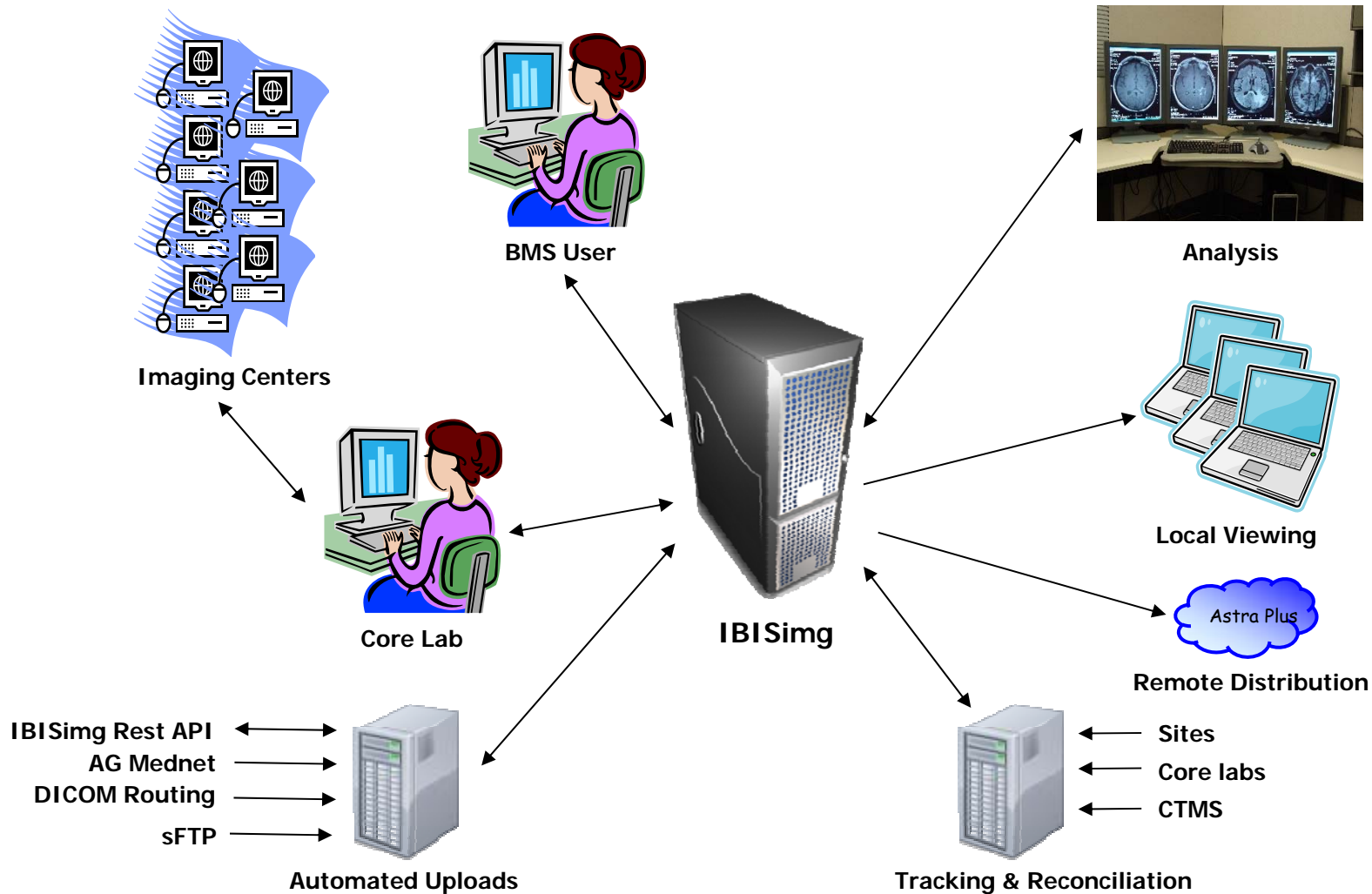
# The Life of MIMS - Initial System



# The Life of MIMS – Automated Uploads

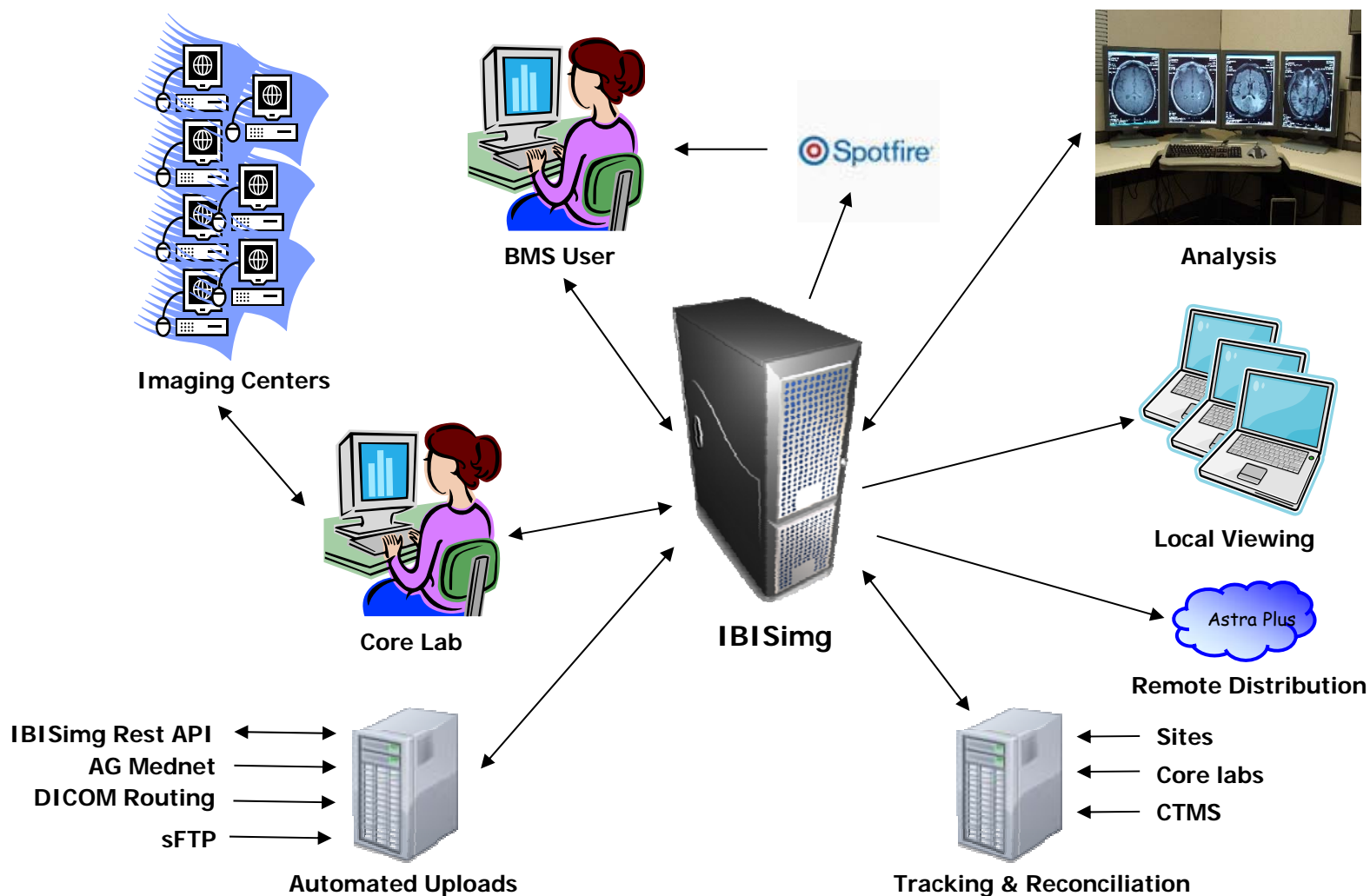


# The Life of MIMS – Tracking, Reconciliation & Distribution





# The Life of MIMS – Quality & Operational Visualization



# Key Learnings

- Image Data Quality

- The DICOM standard is good, but...
  - Ensure DICOM data conformity requirements early in the clinical trial setup
  - Confirm site de-identification / anonymization processes
  - Assess imaging data quality asap after uploads from core labs to reduce downstream “surprises”

- Imaging Upload Capabilities

- A variety of upload capabilities enables a “best fit approach” for individual core labs
  - Confirm core labs ability to export images from their internal systems
  - Incremental and bulk upload capabilities are needed
  - Internet upload clients (core lab and 3<sup>rd</sup> party) are still popular
  - DICOM Routing and sFTP are gaining acceptance
  - IBISimg Rest API supports automated / integrated synchronization between core lab and sponsor systems

# Key Learnings

- Imaging Upload Performance
  - Multiple factors can affect upload performance
    - Internet access bandwidth
    - Selection of what to upload
    - Workflow processes (priority?) at sites and core labs
- Imaging Upload “Costs”
  - Automated / improved workflow capabilities reduce subject/visit upload costs
    - Improved workflows, minimizing human interaction, reduces transfer costs and improves image metadata quality
    - Automated /synchronized uploads improves sponsor access to images

# Key Learnings

- **Imaging Data Reconciliation**
  - Reconciling imaging metadata with other information systems (IVRS, CTMS, core lab portals, etc.)
    - Provides additional sanity check on imaging data
    - Minimizes multiple system access by downstream users
- **Image Viewing**
  - Reading room workstations for additional / retrospective analysis
  - Virtualization provides open source viewing platform via remote access
- **Image Distribution**
  - Automated distribution across internet a big improvement over courier based delivery of CDs, DVDs and USB drives

# Vendor Acknowledgements

- Impact Business Information Solutions
  - IBISimg Image Management System
- Laurel Bridge
  - Compass DICOM Image & HL7 Router
- AG Mednet
  - AG Mednet Site Upload Network
- Candelis
  - Astra Cloud Hosted Services
- Merge Healthcare
  - eFilm Workstation
- Synaptive Medical
  - Clear Canvas Workstation

# Questions?

