



WG-16 Update fMRI & QIBA

2010 Nov 08

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Outline

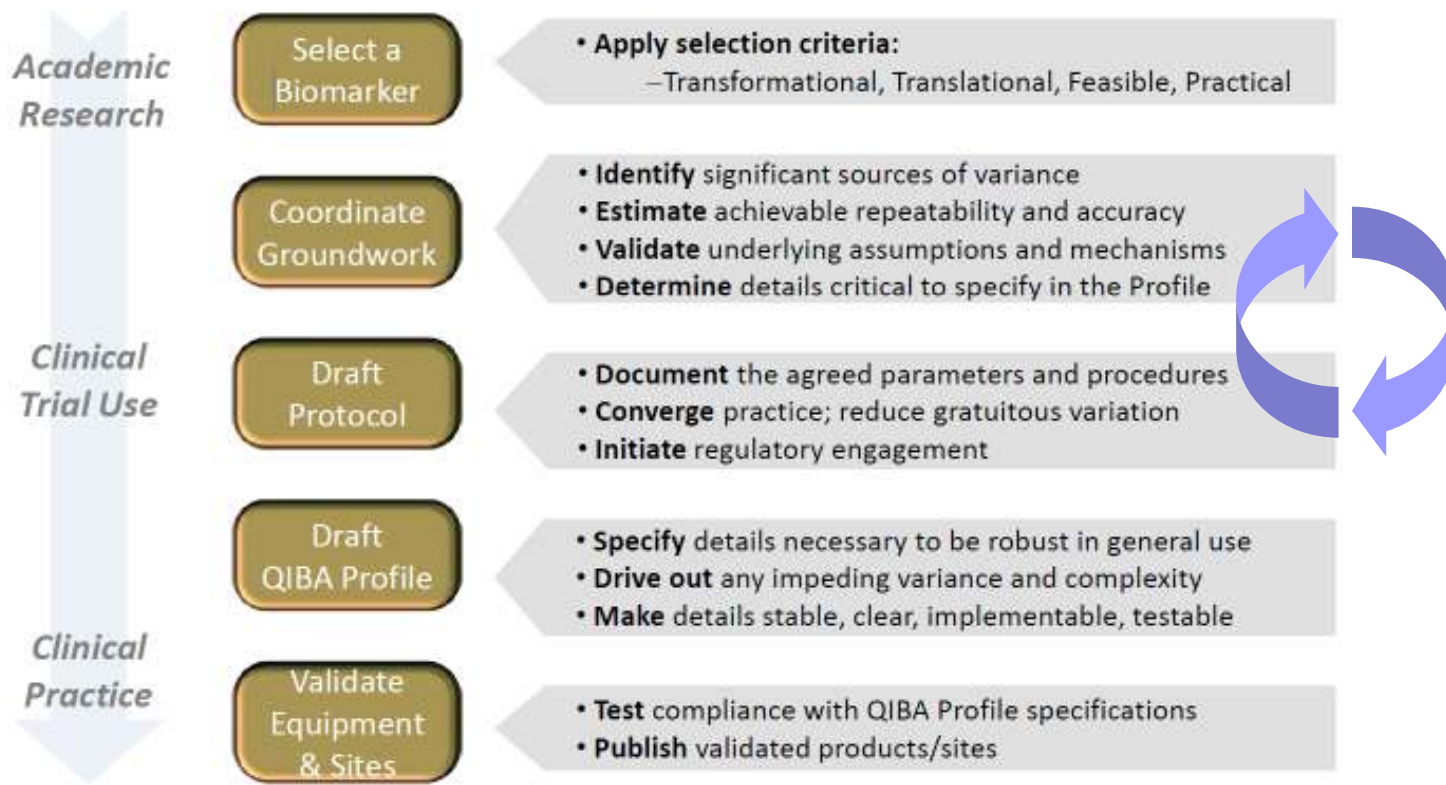
- **QIBA Background**
- **QIBA fMRI**
- **fMRI Workflow**

Q I B A B a c k g r o u n d

- Quantitative Imaging Biomarkers Alliance
- Wiki: <http://qibawiki.rsna.org>
- Mission: **“Improve the value and practicality of quantitative biomarkers by reducing variability across devices, patients and time.”**
- Organized into 4 working areas (Committees):
 - Quantitative-MR
 - DCE-MRI subcommittee
 - fMRI subcommittee
 - Quantitative-PET
 - Quantitative-CT
 - COPD-Asthma

How does QIBA 'work'

QIBA "Industrializes" QI



What is a Profile?

- A Profile is a document.
- It tells a user what can be accomplished by following the Profile. ("Profile Claims")
 - E.g. you will be able to detect volume changes of greater than <20%> in Stage IV Lung Nodules which are <5mm> in diameter or greater.
- It tells a vendor what they must implement in their product to state compliance with the Profile. ("Profile Details")
 - E.g. to comply, the scanner must be able to:
 - scan a <Mark-324> Chest Phantom, identify the smallest resolvable target, display the diameter of that target
 - demonstrate resolving targets at least as small as <2mm> diameter on the Mark-324 phantom
 - scan patients according to the ACRIN NLST acquisition protocol
 - E.g. to comply, the quantification application must be able to:
 - segment a nodule (automatically or manually), derive the volume, store it in a DICOM object
 - run a user through a set of test data with known volumes and at the end display an accuracy score
- It may also tell the user staff what they must do for the Profile Claims to be realized. ("Profile Details")
 - E.g. to comply, the site CT techs must be able to:
 - scan the patient within 10 minutes of contrast injection
 - E.g. to comply, the radiologist must be able to:
 - achieve a score of <95%> or better using their segmentation application on the <Lung Invaders> test set.

What about the IHE Process?

■ How do Profiles fit in the IHE Process?

- The Profile concept and process has been borrowed from IHE
 - Users identify a high priority multi-system problem.
 - Vendors & Users collaborate to document a standards-based solution (a Profile).
 - Vendors confirm it works by testing their implementations with other vendors (a Connectathon)

■ How does QIBA differ from IHE?

- IHE mostly profiles engineering problems. QIBA also tackles scientific problems.
- When a profile claim is unvalidated or a profile detail cannot be defined until further research is done:
 - IHE declares the profile premature and sets it aside until such groundwork is completed
 - QIBA locates, encourages, and if necessary coordinates, getting the research completed

QIBA fMRI Subcommittee

- Formed at RSNA 2009
- Chairpersons:
 - Cathy Elsigner – NordicNeuroLab, Inc
 - Jeff Petrella – Duke University
 - Joy Hirsch – Columbia University
- Organization
 - Committee with two working groups:
 - fMRI-DICOM (DTucker)
 - Reproducibility (JVoyvodic)
- Participants from both academic and commercial backgrounds:
 - Avotec, Inc
 - BioClinica, Inc
 - Buckler Biomedical LLC
 - CHOP
 - Columbia University
 - Duke University
 - GE Healthcare
 - Harvard-Brigham and Women's Hospital
 - Johns Hopkins University
 - Lehigh Valley Diagnostic Imaging
 - MAC
 - MD Anderson Cancer Center
 - Medical College of Wisconsin
 - NordicNeuroLab, Inc
 - Prism Clinical
 - Roche
 - Siemens
 - Temple
 - University of California, San Diego
 - University of Texas Health Services Center at San Antonio

What is the QIBA fMRI Committee working on?

Example drill down: PreSurgical Mapping using BOLD fMRI

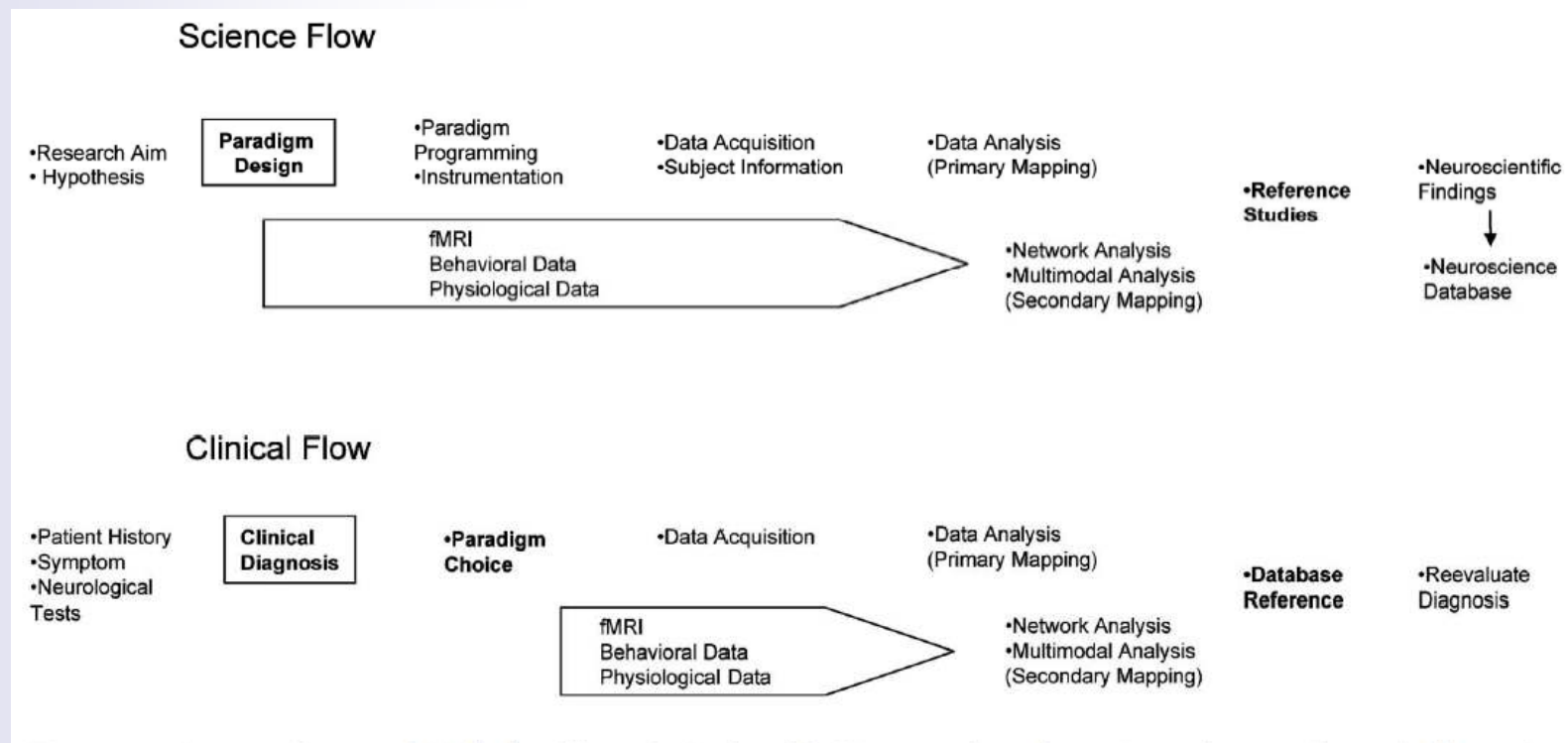
- BOLD fMRI: quantitative analysis of EPI image sequences used in conjunction with functional imaging stimulus paradigms
- Use cases:
 - Clinical routine
 - UC1: diagnostic assessment in surgical and/or treatment planning (e.g. tumor, epilepsy)
 - UC2: risk assessment in decision making
 - UC3: therapeutic progress assessment in a clinical environment (e.g. stroke recovery, TBI)
 - Clinical trials (future)
 - UC4: biological effect assessment as predictive biomarker, therapeutic progress

- BOLD fMRI is not standard of care in clinical practice but employed increasingly
- CPT codes introduced (2007) – positive growth in reimbursement and adoption
- Methodology evolved via neuroscientists, neuropsychology – relatively new to radiology practice
- Current radiological practice is not quantitative
- fMRI not yet used in clinical trials

- Manufacturers provide technical solutions for implementation - variability in defining parameters (# volumes and TR)
- Required peripheral equipment not routinely provided by MR vendor – requiring integration of 3rd party technical solutions (stimulus presentation)
- Variability in analysis protocols – QC measures available from manufacturers (MR and SW)
- Economic challenge to manufacturers – volume is not there

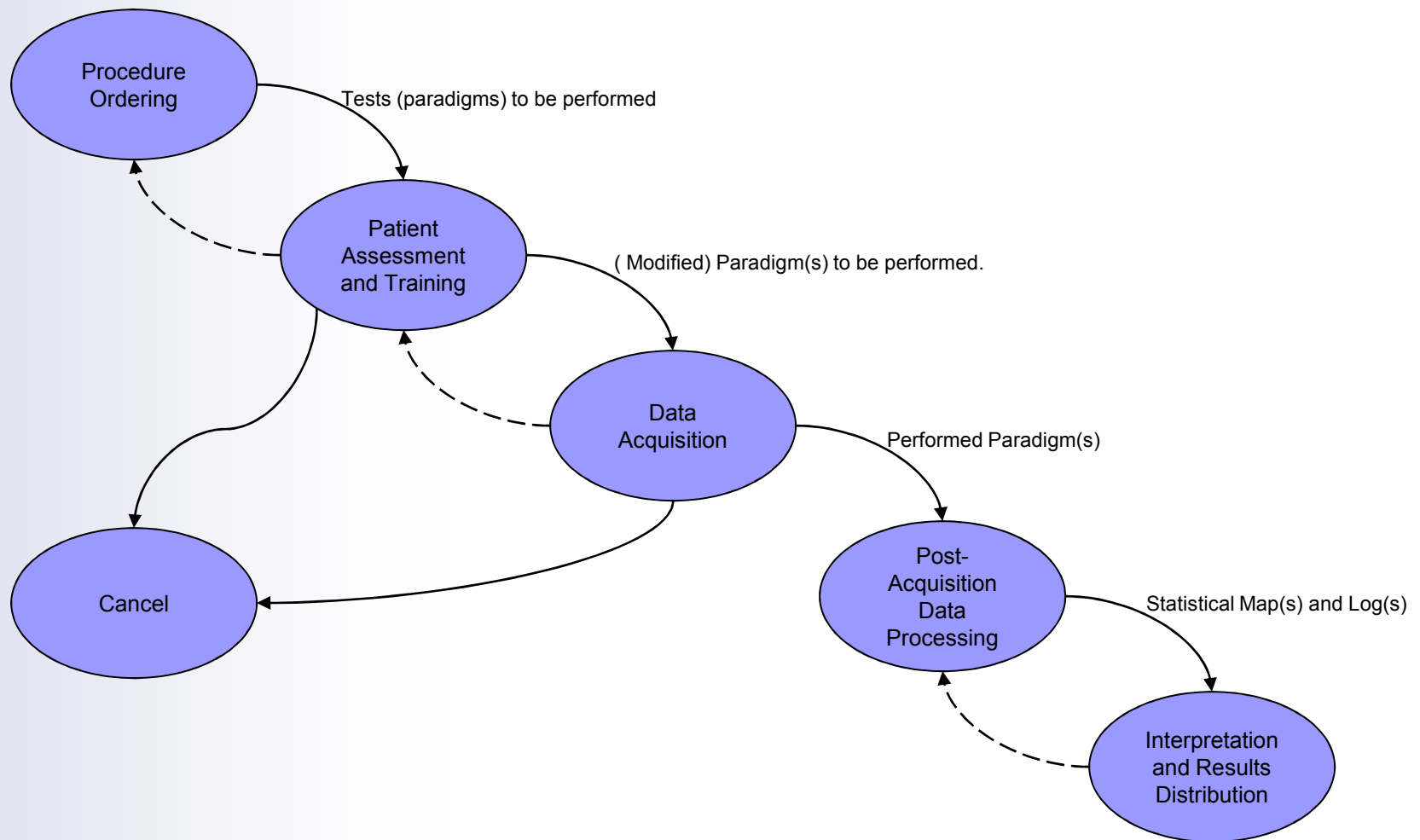
Scientific vs Clinical Neuroimaging workflow¹

‘Although scientific and clinical neuroimaging will share the majority of resources, the annotation of concepts and instances will be slightly different, which can be explained by the contrast of “research flow” and “clinical flow” (see figure).’



1. From: Nakai T, Bagarinao E, Tanaka Y, Matsuo K, and Racocceanu D. Ontology for fMRI as a Biomedical Informatics Method. Magn Reson Med Sci, 7:3, 141-155, 2008.

Workflow Model (proposed by me)



Methodology

- fMRI-DICOM working group asked members of the QIBA fMRI Committee to describe their current clinical practice
 - 6 respondents
 - 3 Academic
 - Duke
 - Johns Hopkins
 - Medical College of Wisconsin
 - 3 Manufacturers
 - Medical Numerics, Inc
 - NordicNeuroLab, Inc
 - PRISM Clinical Imaging
- Evaluation of responses to determine if model works to describe data, or if a new model is needed.

Ordering Step

- Respondents referenced the ordering process:
 - “The patient’s initial entry into the workflow ... through conventional methods established at each institution.”
 - “... mapping is ordered as part of more comprehensive suite of brain imaging data...”
 - “... the ordering physician initiates the fMRI workflow by making a choice of one or more fMRI tasks ...”
- One respondent provided indications for use:
 - ‘indicated either to assist diagnosis or to guide treatment planning and delivery’
- Most respondents alluded to a set of pre-existing tests (paradigms):
 - “...general purpose paradigms such as visual field mapping and functionally specific tests...”
 - “... language paradigms include: - auditory presentation of stimuli ... -combined visual and auditory ... - a picture naming task...”
 - “... provide stimulus paradigms embedded within paradigm guidance software ...”
- One respondent described the content of the fMRI task (paradigm)
 - “... include patient instructions, acquisition parameters, and data processing parameters”

Assessment & Training

- All workflows described some patient training and assessment step.
 - Input to this step includes the patient, the trainer and the list of paradigms to be performed
- Rational:
 - "... assessment should be made of the patient's alertness, cognitive ability, and behavioral capabilities in order to flag any factors that could compromise ..."
 - "Patient training should be conducted ... to familiarize the patient with the fMRI tasks ... and to confirm patient's ability to perform the task"
- Changes to paradigms:
 - "changes in paradigm selection and/or instructions may be required"
 - "Tune or replace paradigm selection as needed; may change difficulty, length, etc"
- Caveats:
 - One respondents noted that for certain types of tasks (e.g. memory) the practice stimuli should be unique in order to avoid habituation.
- Output or work products:
 - Trainer assessment
 - "Trained paradigms == worklist"
 - "If changes are required ... should be noted ... and remain part of the patient record."

Data Acquisition

■ Typical scan include

- Preparatory QA/QC activities
 - Augmented by additional equipment used to conduct fMRI examination include stimulus delivery hardware, response devices and synchronization devices
 - Need to ensure patient can see and hear stimuli
- One respondent described their imaging protocol in depth:
 - Structural Imaging
 - 3-plane localizer
 - Calibration scan for parallel imaging
 - Whole-brain T1 (1mm³ voxels)
 - T2 FLAIR
 - Shim scan
 - Functional mapping scan (continuing on previous example)
 - Vary by paradigm
 - Prescribed using the same slices as the T2 images
 - DTI
 - Axial 15 direction centered to match fMRI scan

■ Most respondents described

- short training / refresh performed prior to each task
- Real-time patient monitoring for alertness, compliance and task-related physiological changes :
 - Responses to tasks (typically hand or foot movement),
 - Eye tracking
- Use of real-time fMRI analysis
 - Evaluate patient motion
 - QA / QC check of data
 - Evaluate fMRI activation

■ Post-scan evaluation for alertness, etc.

- Part of QA/QC record
- One respondent uses a 1 to 5 rating scale (both technician and self-assessment).
- One respondent specifically indicated that this should be done during the scan

Post-Acquisition Data Processing

■ Steps described include:

- Multiple reads/write cycles of data
- Reconstruction of time-series
- Corrections for warping and misalignment
- Data smoothing and normalization
- Evaluation for artifacts, data rejection, overall data quality measures
- Clustering of regions of interest
- Image segmentation
- Computation of metrics and statistical measures

■ Computational environments

- Respondents described performing processing:
 - both on the acquisition device and on dedicated processing stations
 - Using a combination of software tools (some FDA cleared, other research tools).

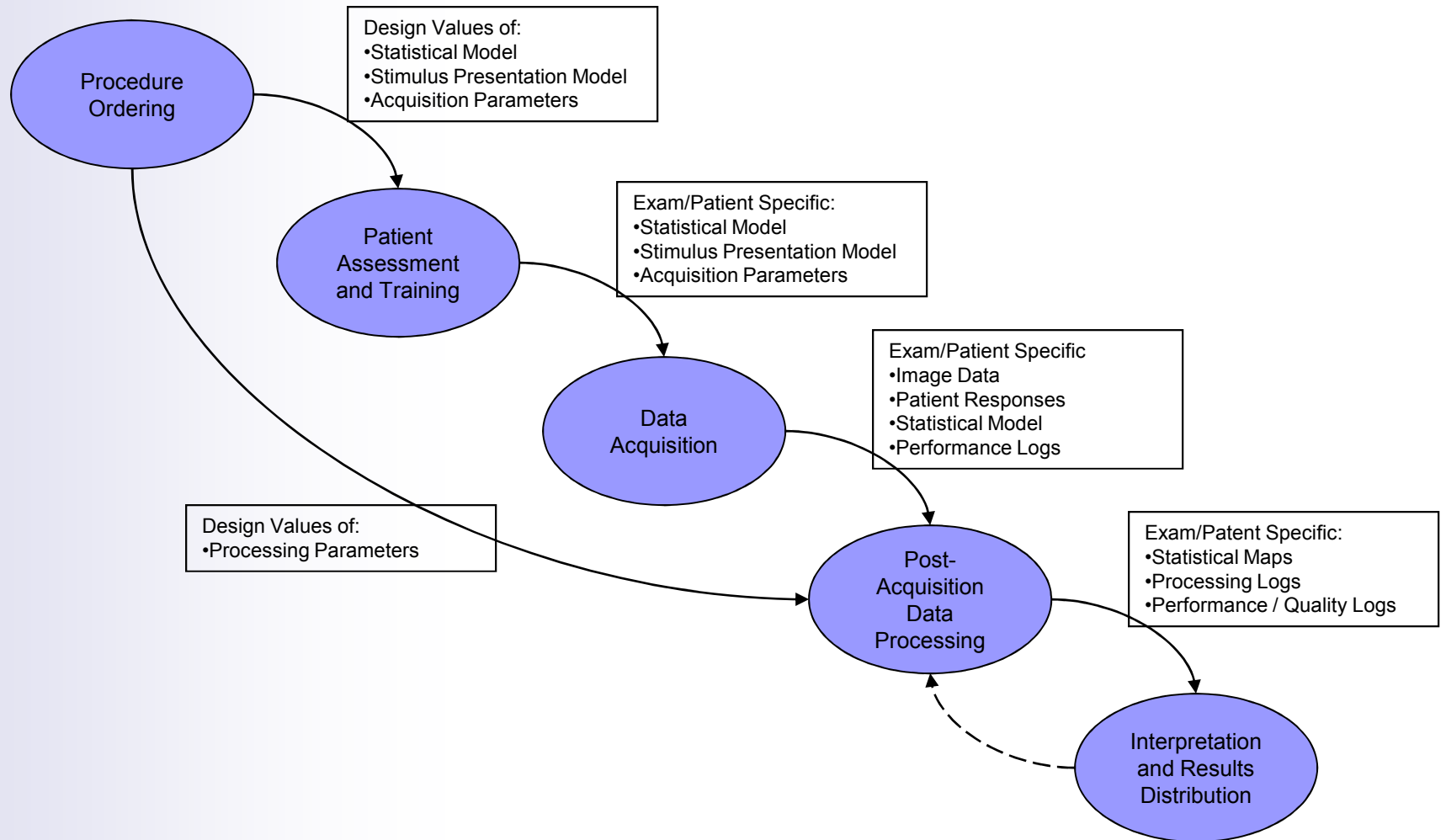
■ Output

- Documentation of processing including technical QA and evaluation
 - One respondent described a standard multipoint evaluation of quality control protocol – evaluation of outliers
- 3D images
 - Overlaying structural and functional data
 - Color-coded activation
 - Multiple orientations
 - Variety of image formats
 - Proprietary
 - JPEG
- Integration of results onto PACS is important

Display / Reporting / Interpretation

- Results become part of patient record
- Need for annotation and markups
 - Referring physicians may not understand what they are looking at or for
- Integration into departmental image management systems (PACS) seen as important
- Respondents indicated they use standardize or template reports that include:
 - Demographic information
 - Indications
 - Techniques
 - Structural image finding
 - Functional image finding
 - Impressions
 - Annotations
 - May include references to DTI and Perfusion results if also performed.
- Export of images to other departments
 - Surgical planning systems

Workflow Model (Augmented)



Next Steps & Discussion

- Open invitation to all to visit QIBA posters RSNA
- Initial Profile Development
 - ETA – 6-9 months (??)
 - Narrowing in on a set of claims for the first profile:
 - fMRI activation is a valid indicator of the functional status of the associated brain tissue
 - Presence of fMRI activation indicates that the brain tissue is responsive to the stimulus/task used.
 - Absence of a BOLD response should indicate damaged, non-functioning tissue.
 - One might even hope that graded response amplitude could be an indicator of partial function.
 - fMRI activation evoked by a specific task (sensory, motor, or cognitive) indicates that the associated brain tissue is a necessary component of the brain network responsible for the tested function
 - If the task is finger flexion, then resulting fMRI activation indicate those brain regions that contribute to the ability to flex the fingers.
 - Caveats:
 - Neurovascular uncoupling
 - Disconnection
 - Functional specificity
 - Performance variability
- Parallel work to define parameters, representation, etc.
 - What needs to be store, when it needs to be stored, where it gets stored..
- Special thanks to
 - Andrew Buckler – for contributing QIBA slides
 - Bob Haworth – for reviewing slides and contributing ideas