
QIBA SPECT BIOMARKER COMMITTEE

22 JANUARY 2016



Agenda

- 1.Task Force updates
- 2.Profile Development/Writing
- 3.Timelines
- 4.AOB

SPECT BIOMARKER COMMITTEE TASK FORCE(S)

- ❖ Image Acquisition and Image Processing for DaTscan – Drs. Dewaraja and Frey
- ❖ Quantitative / Image Analysis – Drs. Miyaoka and Seibyl
- ❖ Phantoms / DRO Group – Drs. Dickson and Zimmerman
- ❖ Clinical / Literature Review – Dr. Seibyl

Draft Profile writing

- Title: "Quantifying dopamine transporters with 123 -Iodine labeled ioflupane in neurodegenerative disease"
- Review our m.o. for drafting components, assembly, & editing.
- Assign ownership of each component.

SPECT BC m.o. for writing profiles: “spiraling in”

- Write fast. Leave nothing blank. Use PET data when it’s handier than SPECT data. Use Technetium data if you find it before I-123 data.
- Highlight in yellow all scalar values that are not sound for this use case.
- Make comments in tracked changes mode about passages for which there is
 - No consensus
 - Unacceptable uncertainty
 - Known controversy
 - The information comes from another use case, e.g., PET
 - The information has been made up, i.e., fabricated out of thin air.
 - Etc.
- In summary, just get it done now; let us all obsess with you later.

Profile section assignments (first draft/next iteration/last check before public review)

- Executive Summary: Mozley/Seibyl/whole committee
- 3.1-3.2 (Pre-delivery, Installation) Device manufacturers/Cella
- 3.3 (Periodic QA) Dickson/Zimmerman, et al.
- 3.4 -3.5 (Subject selection, Subject Handling) Mozley/Seibyl
- 3.6 (Acquisition) Dewaraja
- 3.7 (Reconstruction) Frey/Dewaraja
- 3.8 (Image QA) Dickson/Zimmerman
- 3.9 (Image Distribution) ?Klein/Pierre
- 3.10 (Image Analysis) Miyaoka/Seibyl
- 3.11 (Image Interpretation) Seibyl, et al.

- Section 2 Nancy/?Anne

Timelines

- What is needed vis a vis support of claims and methodology, e.g. additional studies/phantoms/projects
- When shall this be initiated/completed?

		Biomarker Committee: SPECT			
		Profile Name: Quantifying dopamine transporters with 123-Iodine labeled ioflupane in neurodegenerative disease			
Category	Item	(Sub-Item) / Status	Date*	NIBIB Project**	
Profile Stage	Document Draft	Draft stage: now 33% completed	90% of sections by end of 2Q2016	none	
	Public Review version	NA (pending)	4Q2016		
	Literature Publication	UPICT Protocol : not started		start writing 4Q 2016	
		Article Draft / Submission / Publication /NA		2Q2017	
		If published, indicate citation or NA		NA	
	Technical testing (aka 'Feasibility Testing')	Prepare Checklist / Identify Trial & Sites		TBD	
		Perform Trial Data Gathering/Perform Analysis		TBD	
	Clinical testing (aka 'Field Testing')	Identify Trial to Assess		TBD	
		Define Protocol / Data Acquisition		TBD	
		Collect/Resolve Feedback		TBD	
Claim (Section 2)	Meta-analysis	Literature Aggregation	To be completed by end of 2Q2016		
		Perform Meta-analysis	not scheduled		
		Assess Findings Against Claim	not scheduled		
	ID Technical Characteristics	Assess Scanner Variability	In progress	will require ground work	
		Assess Image Analysis Variability	TBD	will require ground work	
		Assess Reader Bias	TBD		
Profile Details (Section 3)	Outline steps in processes	Draft text in progress	90% of sections by end of 2Q2016		
	Equipment Specifications	Draft text in progress	90% of sections by end of 2Q2016		
	Subject Preparation	Draft text in progress	90% of sections by end of 2Q2016		
	Image Acquisition	Draft text in progress	90% of sections by end of 2Q2016		
	Image Reconstruction	Draft text in progress	90% of sections by end of 2Q2016		
	Image Analysis	Draft text in progress	90% of sections by end of 2Q2016		
	Exam Interpretation	Draft text in progress	90% of sections by end of 2Q2016		
Phantoms	Physical Standard Traceable	In discussion	TBD		
	Physical Phantom	In discussion	TBD		
	Digital Reference Object	In active discussion	TBD	will require ground work	
Conformance (Section 4)	Testing Methods	Identify Activities Requiring Testing	TBD		
		Develop Testing Details	TBD		
	Device Version Tracking				

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 - 3.5. Subject Handling
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 - 3.7. Image Data Reconstruction
 - 3.8. Image QA
 - 3.9. Image Data Distribution
 - 3.10. Image Analysis
 - 3.11. Image Interpretation
- Section 4. Assessment Procedure

Wrap-up

Review action Items

Any other business