Column headings in these first three rows are from TRWG Imaging Modality (IM) Pathway		*Statement of Value to stakeholders: patients, manufacturers, Pharma, etc. What are alternatives?*	Discovery of potential imaging biomarker	Do tools exist or do new assays or other supporting tools need to be developed?*		Test / refine imaging performance, PK/PD, toxicology, etc. in preclinical setting				Optimize acquisition and analytic parameters in preclinical or Phase 0 setting				Test / refine imaging performance, PK/PD, toxicology, etc. in Phase I/II setting		Phase II+ trials for specific clinical utilities				
	Column headings in this row are from TRWG IM, specific to imaging agents			Current scanners can perform desired function?		Establish GMP production for agent if necessary		Submit IND if necessary		Establish GMP manufacturing if necessary									
	Column headings in this row are from TRWG IM, specific to devices				Develop necessary new imaging platform or function? (iterative with development of technique)		Pre-IDE meeting for platform if necessary	separate image acquisition and image analysis?	File IDE if necessary; If optimized platform available for clinical testing, file 510(k) if necessary										
Column headings in this row are from QIBA Pathway			Pre-QIBA (though IB Roundtable may address these)							Define and iteratively refine acquistion, analysis, interpretation, QC, etc. (UPICT) for specific clinical utility (also define "gaps")	Technical Characteristics and Standards Groundwork (systems engineering analysis of sources of variability)			Clinical Performance Groundwork (Sensitivity and specificity for expert readers)		Clinical Efficacy Groundwork ("real world" imaging conditions)				
											Phantom development	Assessment of intrinsic scanner variability / minimum detectable change	Assessment of intra- and inter-reader (human and/or computer) bias and variance across scanners and centers	intra-reader	Inter-reader (Multiple image analysts)	Correlation between new biomarker and "accepted-as-standard" method	Value from new imaging biomarker in clinical trials	Value from new imaging biomarker in clinical practice	
Row headings below are biomarkers of interest.										Iterative refinement of UPICT during the row 4 and 5 activities for the specific clinical utilities						Implement the refined UPICT protocols during these Phase II+ trials and develop / merge databases from the trials to support validation and qualification of imaging biomarkers			
Emphysema		progression	lung density	DONE	DONE	DONE	DONE	DONE	?	?	?	not done	problem established; solutions pending						
		phenotype																	
AIRWAY																			
VENTILATION																			
OA																			
STROKE																			
ONCOLOGY																			