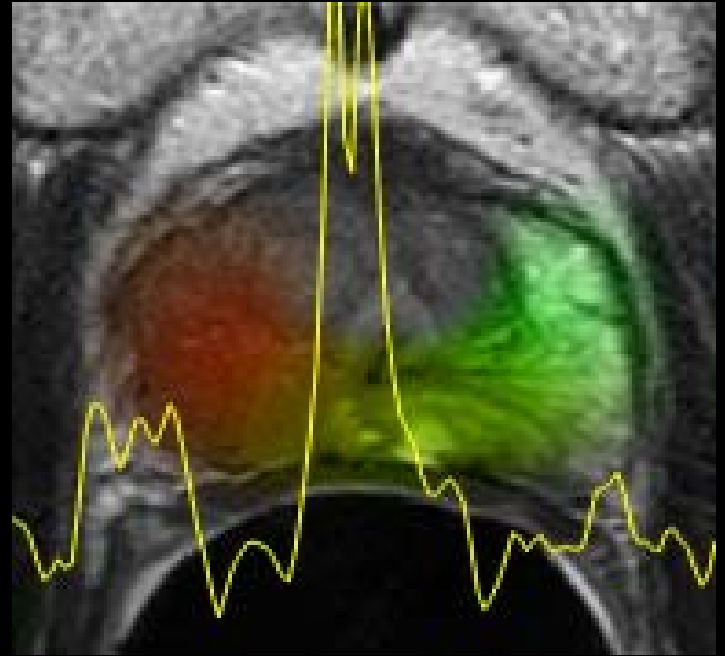
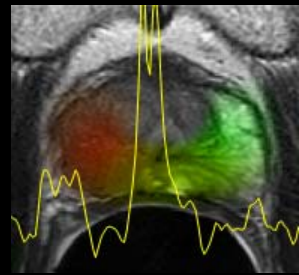


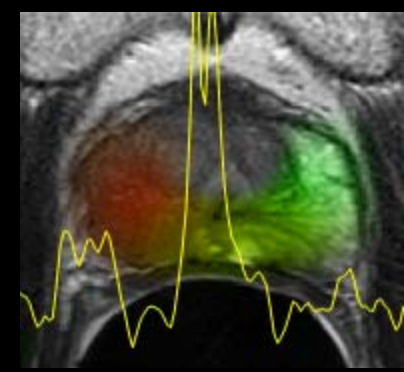
Virtual
Imaging
Evaluation
Workspace



NCI RFP

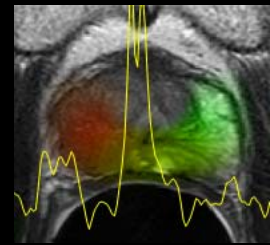


- Establish a consortium to provide imaging core laboratory services to the NCI-sponsored cooperative groups, and, if necessary, other NCI-sponsored clinical trial programs
- Develop an inter-operative IT infrastructure across the network for collection, distribution and archiving of images obtained on NCI-sponsored trials that utilize VIEW. This IT infrastructure will be 21 CFR Part 11 compliant and caBIG compatible.
- Develop standard operating procedures for acquisition and assessment of imaging endpoints in cancer clinical trials and an approach to standardizing newer imaging markers. This includes the development of standardized quality assurance approaches and the establishment of quality performance metrics.

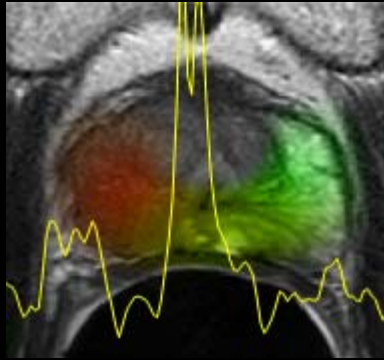


- Develop a standardized approach to credentialing facilities that perform imaging exams according to the VIEW standards.
- Assist clinical trial organizations in the development of an imaging charter that is acceptable to the trial sponsors and FDA.
- Advance the science of imaging biomarker development: explore alternative imaging analysis, alternative imaging approaches, and establish databases that can be mined for testing new approaches.

The Consortium



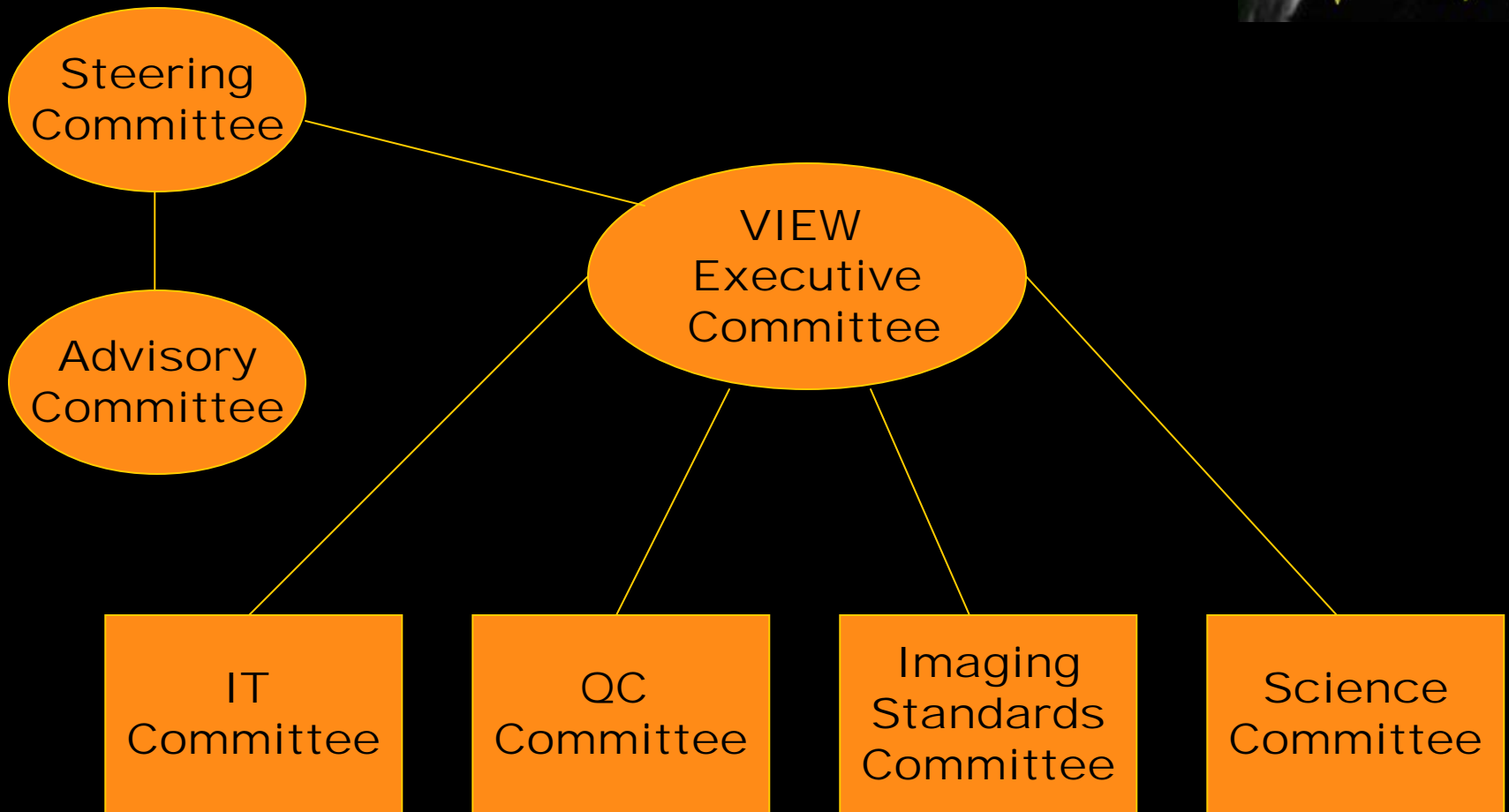
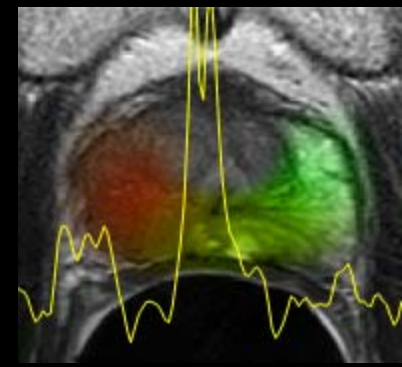
- ACRIN's entire mission is dedicated to imaging clinical trials and has developed a comprehensive imaging core laboratory
- QARC has been providing imaging core laboratory support to cooperative groups for radiation therapy planning and more recently imaging core services for 25 years
- CALGB has a strong imaging committee with expertise in functional anatomic imaging and has an imaging core laboratory at Ohio State University



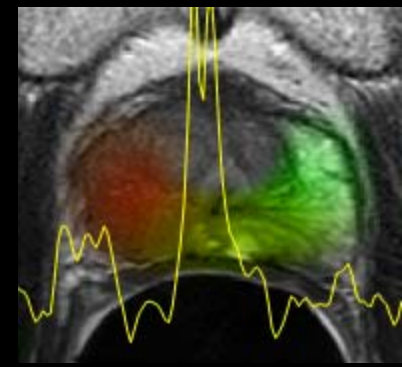
ALL HAVE WELL-DEVELOPED IMAGING
CORE LABORATORY STANDARD
OPERATING PROCEDURES



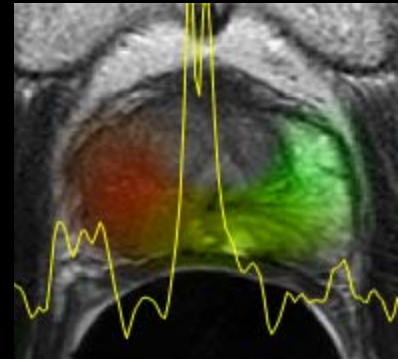
Organizational Structure



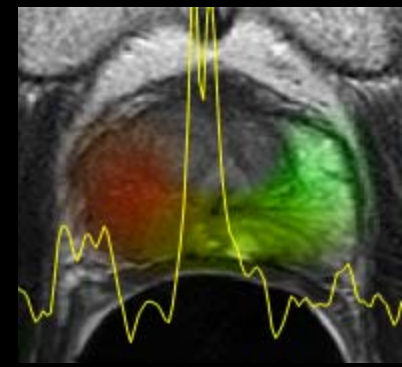
- Consortium is the VIEW operational model
- Services offered by the different member groups will be bundled to satisfy the needs of a particular trial



- VIEW Consortium members will alternate taking the lead on a proposed trial provided interest is there to provide services:
 - Imaging Charter
 - Operational model
 - Budget
 - FDA interactions

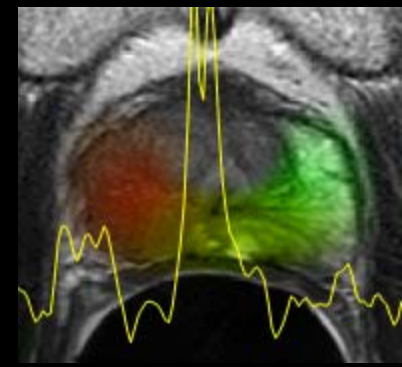


IT Infrastructure



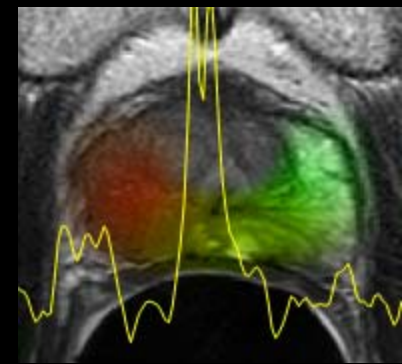
	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
Demonstrate transfer of images btw. VIEW members					
Develop process to establish 21 CFR Part 11 compliance					
Migration of VIEW to Part 11 compliant systems					
Develop strategy for caBIG adoption					
Implement caBIG compliance program					

Imaging Standards Development



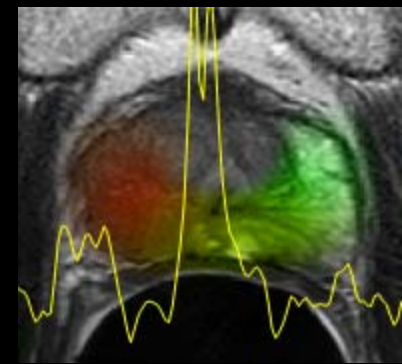
	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
Establish VIEW standards for RECIST endpoints					
Establish VIEW standards for PET-FDG endpoints					
Establish VIEW standards for DCE-MRI endpoints					

QC Process Implementation



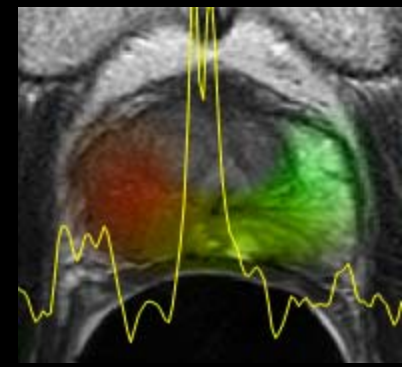
DEVELOP HARMONIZED APPROACHES TO QC AND CASE SETS FOR TESTING REPRODUCIBILITY OF:	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
Cross-sectional imaging					
PET Imaging					
RECIST reproducibility					
PET FDG endpoint reproducibility					

QC Process Implementation



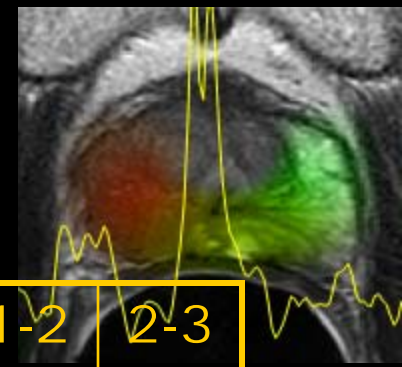
TEST REPRODUCIBILITY :	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
RECIST within each lab					
RECIST across member labs					
Establish standards of RECIST reproducibility					
PET within each member lab					
PET across member labs					
Establish standards of PET reproducibility					

Credentialing Standards Development



	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
Develop credentialing standards for RECIST					
Develop credentialing standards for PET					
Develop database of sites credentialed according to imaging endpoint					

Develop and Execute Imaging Charter



	0-3 M	3-6 M	6-12 M	1-2 Y	2-3 Y
VIEW members available to offer core laboratory services					
VIEW accepting formally limited request for RECIST endpoints					
VIEW offering RECIST endpoint credentialing, central QC, and review					
Accept limited requests for PET FDG endpoints					
Perform PET FDG credentialing, central QC, review					



The VIEW

