VIEW

- **Virtual Imaging Evaluation Workspace (VIEW) in Cooperative Groups**
- **Collaboration:**
  - **ACRIN**
  - **CALGB Image Core Lab**
  - **QARC**

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.

VIEW Aims

- 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.

VIEW Status

• First annual VIEW Meeting: Chicago, June, 2008.

• First protocol utilizing VIEW: NCCTG (N0723 the MARVEL Trial-A Phase III biomarker validation study Second-Line Therapy in Patients With Advanced Non-Small Cell Lung Cancer (NSCLC) Randomized to Pemetrexed vs Erlotinib) opened on November 1, 2008 with an expected accrual of 1197 patients. Coordinated by NCCTG and available to all groups on CTSU.

• First VIEW meeting with FDA: November, 2008.

• Second protocol utilizing VIEW: RTOG – 0825 A phase III double blind placebo controlled trial of conventional concurrent Chemoradiation and adjuvant Temozolomide plus Bvacizumab versus conventional concurrent Chemoradiation and adjuvant Temozolomide in patients with newly diagnosed glioblastoma is under discussion.

VIEW Status

NCCTG N0723

- The plan is to collect all of the baseline and response CT's so that if needed a central review can be orchestrated quickly.
- No enrollment yet
- QARC will collect imaging and upload to ACRIN to perform QA of the images.

VIEW Status

NCCTG N0723 – Responsibilities to be divided as follows:

- E-Mail notification of enrollment sent to QARC and ACRIN
- Participating center submits baseline imaging to QARC
- QARC does basic QA: study is viewable, correct study and modality, correct date
- QARC staff completes baseline form in NCCTG RDC
- Imaging is imported into MAX and transferred to ACRIN (transfer via FTP initially)
- ACRIN performs QA for image quality
- ACRIN returns QA assessment to QARC; QARC enters into NCCTG RDC
- Process is repeated for follow-up imaging

VIEW Status

RTOG 0825

- The study is scheduled to accrue 720 participants at the rate of 40 participants per month.
- each case will generate approximately 8 imaging series (MR/CT) per participant.
- ACRIN will collect MR Perfusion images from a subset of the participating sites.

VIEW Status

RTOG 0825 – Responsibilities to be divided as follows:

- ACRIN will collect MR/CT and perfusion MR images from each of the institutions that agree to perform perfusion imaging - expected to represent about 30% of the accrued cases.
- QARC will collect MR/CT images from each of participating institutions not submitting images to ACRIN – estimated to represent 70% of the total accrual.
- CALGB will serve as the image archive and will receive images from both QARC and ACRIN.
- QARC and ACRIN will perform QC review of all image sets upon receipt
- CALGB will conduct QC on a sample of cases (10% +/-)
- Registration data will be provided to ACRIN and QARC by RTOG
- Interoperability to be demonstrated between QARC, ACRIN, and CALGB.
- No funding at this point for a central read of the images being collected and archived.