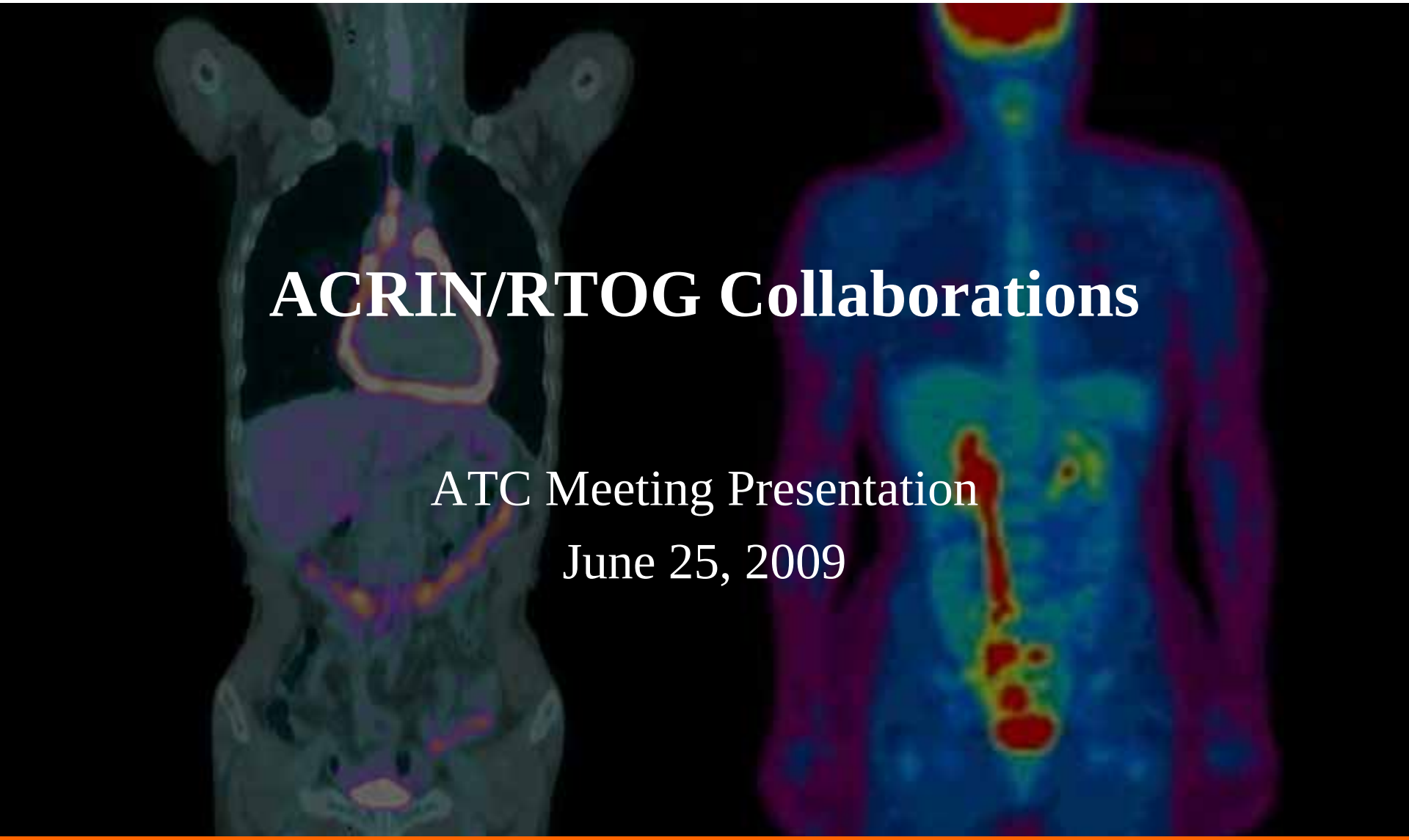

ACRIN/RTOG Collaborations

ATC Meeting Presentation

June 25, 2009

RTOG 0522

- A Randomized phase III trial of concurrent accelerated radiation and Cisplatin versus concurrent accelerated radiation, Cisplatin, and Cetuximab followed by surgery for selected patients for stage III and IV Head and Neck carcinomas
  - Study Accrual target: 945
  - Study Accrual: 942
- ACRIN participation:
  - Assess role of FDG PET/CT to assess disease status and the need for nodal dissection
  - PET qualification through ACRIN imaging core lab (no phantom)
  - Collect PET/CT images (optional), compare outcome based on CT only with CT and PET
  - Timepoints: pretreatment and 8-9 weeks post radiotherapy/pre-surgery
  - Image collection:
    - PET optional component: 129 participants
    - PET/CT Collection
      - Pre-treatment: 91 exams
      - Post –treatment (8-9 weeks): 75 exams

RTOG 0132/ACRIN 6665

- Phase II Trial of Neoadjuvant STI-571 (GLEEVEC) for primary and recurrent operable malignant gastrointestinal stromal tumors expressing the KIT receptor Tyrosine Kinase
  - Study Accrual target: 63
  - Study Accrual: 63 (Completed)

- ACRIN component
  - Assess role of FDG PET in predicting response to therapy
  - Site qualification by Wash. Univ.
  - Collect PET (mandatory) and diagnostic CT images on all participants
  - Qualitative and semi-quantitative tumor changes based on SUV (% decline SUV_{max} prior to surgery) and TBR as compared to size changes as defined by conventional cross-sectional imaging scans. Other measures: SUV_{avg}, SUV_{lean}, % change background subtracted SUV, % change TBR, post-therapy SUV, visual analysis
  - RECIST criteria for determining response
  - Four imaging timepoints: pre-treatment, within 1 week of treatment, repeat MR or CT at 4 weeks, PET and MR or CT just prior to surgery

RTOG 0132/ACRIN 6665

- **Image Collection:**
  - **PET: 175 exams**
  - **CT: 181 exams**
- Findings: ASCO 2009 abstract presentation, Annick van den Abbeele

RTOG 0235/ACRIN 6668

- PET pre- and post-treatment assessment for locally advanced non-small cell lung carcinoma
  - Study Accrual target: 250
  - Study Accrual: 251 (Completed)
  - 3 year follow up is in progress
- ACRIN component
  - Assess role of PET SUV shortly after treatment as a useful predictor of survival after chemoradiotherapy
  - Site qualification through ACRIN imaging core laboratory
  - Collect PET or PET/CT images and Diagnostic CT on all participants
  - Quantitative assessment of PET/CT in progress at ACRIN imaging core laboratory (SUV_{max}, SUV_{peak}, qualitative assessment of progression using the PET scan)
  - Timepoints: pre-treatment, post-treatment (14 weeks)
  - Image Collection:
    - PET or PET/CT: 217 exams
    - Diagnostic CT: 229 exams

RTOG 0625/ACRIN 6677

- A randomized control trial of Bevacizumab with Temozolomide in Recurrent Glioblastoma
  - Study Accrual target: 121
  - Study Accrual: 123 (Completed)

- ACRIN component
  - Selected Imaging aims
    - Central MRI review: assess agreement between local interpretation and central interpretation of standard MRI
    - Advanced MRI: assess potential role of perfusion MRI (DSC and DCE), diffusion MRI, and MRS as an early indicator of response to therapy after 2 weeks of treatment initiation
  - Site qualification through the ACRIN imaging core laboratory
  - Collect standard MRI images performed on all participants and advanced MRI as an optional component. Central read of all MRI exams with quantitative assessment from perfusion MRI and MRS.

RTOG 0625/ACRIN 6677

- Timepoints:
  - Standard MRI: baseline, 8 weeks, every 2 cycles
  - Advanced MRI: baseline, 2 weeks, 8 weeks, every 2 cycles
- Image collection:
  - Standard MRI: 310 exams
  - Advanced MRI: 73 exams

RTOG 0825/ACRIN 6686

- Phase II double-blind placebo-controlled trial of conventional chemoradiation and adjuvant Temozolomide plus Bevacizumab versus conventional concurrent chemoradiation and adjuvant Temozolomide in patients with newly diagnosed glioblastoma
  - Study Accrual target: 720
  - Study Accrual: none

- ACRIN component
  - Assess ability of perfusion MRI, diffusion MRI and MRS to predict response to treatment
  - Site qualification through ACRIN imaging core laboratory
  - Collect standard MRI on all participants and advanced MRI on all participants at qualified sites
  - RECIST to determine progression
  - Quantitative assessment of perfusion MRI, diffusion MRI and MRS in imaging core laboratory

RTOG 0825/ACRIN 6686

- **Timepoints:**
  - **DCE and DSC MRI 0-5 days prior to chemoradiation; 0-3 days prior to chemoradiation, 0-1 day after chemoradiation, post-chemoradiation (7 weeks)**
- **Imaging collection: Target 264 participants**
  - **Standard MRI: 0 exams**
  - **Advanced MRI: 0 exams**

RTOG 0837/ACRIN 6689

- A Phase II double-blind placebo-controlled trial of conventional chemoradiation and adjuvant Temozolomide plus Cediranib versus conventional concurrent chemoradiation and adjuvant Temozolomide plus placebo in patients with newly diagnosed glioblastoma
  - Study Accrual target: 177
  - Study Accrual: N/A

- ACRIN component
  - Selected imaging aims:
    - Assess ability of perfusion MRI and MRS to identify populations responsive to antiangiogenic therapy
    - Assess ability of FLT PET to evaluate response to chemotherapeutic agents when combined with radiation therapy
  - Site qualification through ACRIN imaging core laboratory
  - Collect standard MRI on all participants, advanced MRI on all participants at qualified sites, FLT PET on participants at qualified sites
  - RECIST to determine progression
  - Quantitative assessment of perfusion MRI, diffusion MRI, MRS and FLT PET in imaging core laboratory

RTOG 0837/ACRIN 6689

- Timepoints:
  - MR: MRI, MRS, DCE MRI, DSC MRI baseline, day 2 of treatment, week 4, week 10, week 16, week 24, progression
  - FLT PET/CT: baseline, repeat baseline (some), day 2, week 10
- Image Collection: Target 50 (25 with repeat baseline FLT PET)
  - Standard MRI: 0 exams
  - Advanced MRI: 0 exams