Breast Imaging Integration Working Group
ECOG-ACRIN Fall 2012 Group Meeting
November 10, 2012, Hollywood, FL

Agenda

1. Education Session: Current Status and Progress in Clinical Trials of Optical Breast Imaging

2. Developing Studies with Planned Imaging Aims

3. Developing Studies with Possible Imaging Aims

4. Selected Active or Developing ACRIN Breast Trials

5. Open Discussion
Breast Imaging Integration Working Group

Moderator: David A. Mankoff, MD, PhD (U of Pennsylvania)
Christopher Comstock, MD (Memorial Sloan-Kettering Cancer Center)
Jennifer Harvey, MD (University of Virginia)
Nola M. Hylton, PhD (U of California San Francisco Diller Cancer Center)
Lale Kostakoglu, MD, MPH (The Mount Sinai Hospital)
Constance Lehman, MD, PhD, FACR (U of Washington School of Medicine)
Brian Leyland-Jones, MD, PhD (Emory Winship Cancer Institute)
Kathy D. Miller, MD (Indiana U, Simon Cancer Center)
Savannah Partridge, MD (University of Washington)
Melinda L. Telli, MD (Stanford Women’s Cancer Center)
Bruce J. Tromberg, MD (University of California Irvine)
Heidi Umphrey, MD (University of Alabama at Birmingham)

The Breast Imaging Integration Working Group facilitates collaboration between the Breast Subcommittee of the Early Detection and Diagnosis Committee (Cancer Control and Outcomes Program) and the Breast Committee (Therapeutic Studies Program) for the development of science that involves imaging as a primary or secondary aim.
Breast Imaging Integration Working Group Summary
1. Education Session: Current Status and Progress in Clinical Trials of Optical Breast Imaging

ACRIN 6691 – B. Tromberg

- Looking at sensitivity of optical imaging for therapy “Functional Oncologic Imaging”.
- Clinical role, portable and individualized therapy
- Goal is to standardize the DOSI measurements and analysis
- Primary aim is to correlate DOSI TOI measurements with pathological complete response from baseline to mid-therapy time point
- The instrument is a handheld, single point spectroscopic imager that combines discrete frequency-domain and broadband steady–state spectrometers, with a schematic of the device
- Limited number of NTR approved institutions- 5 sites, adding 2
- Accrual status: 30/60
- Also see accompanying overview of ACRIN 6691
Breast Imaging Integration Working Group Summary

2. Developing Studies with Planned Imaging Aims

1. **E4112 - C. Lehman** and DCIS Working Group
   - Lumpectomy ± / MRI / ± RT
   - Use of MRI to advance and modify therapy
   - Incorporation of DCIS score to differentiate low and high risk radiated
   - Awaiting DCP review; pending response to 9/19/12 bold review

2. **E2112 - K. Miller, D. Mankoff**, Connolly and Sparano
   - Randomized Phase III trial of Endocrine Therapy plus entinostat / placebo in patients with Hormone Receptor-Positive Metastatic Breast Cancer.
   - Subset: FES, FDG-PET and blood sampling prior to therapy, Correlative endpoint to see if FES PET can function as both a predictive or prognostic marker
   - Response and call 11/13. Awaiting CTEP approval

3. **E3112 HER2 - B. Leyland-Jones, D. Mankoff** and Andreopoulou
   - TDM-1 + pertuzumab +/- bevacizumab. Imaging component will combine more or less SOC pre and post therapy with both MRI and PET
   - C. Lehman and D. Mankoff to work with B. Leyland-Jones on implementing serial FDG PET and MRI
   - Bold review on 9/19/12, comments received
Breast Imaging Integration Working Group Summary
3. Developing Studies with Possible Imaging Arms

M.Telli, Lipson, Ford and Mankoff

• Triple negative neoadjuvant proposal: AC-paclitaxel vs carbo/gem in TNBC, with HRD marker interaction study
• Prospective trial design – BRCA mutated patients
• Study allows for an early read out and pCR comparison between treatment groups
• Planned MRI for response evaluation should be reviewed with ACRIN expertise (Hylton, Partridge)
• Awaiting thoughts on additional imaging
• Estimated sample size 486
• Targeting Executive Review Committee review end of 1Q13
Breast Imaging Integration Working Group Summary

4. Selected Active or Developing ACRIN Breast Trials

1. **ACRIN 6702 - S. Partridge** and H. Rahbar
   - Diffusion-weighted imaging (DWI) for improved detection and diagnosis
   - Addressing NCI Imaging Committee Steering Review comments
   - Revised exploratory concept to be submitted in early January
   - Also see accompanying overview of ACRIN 6702

2. **ACRIN 6694 - C. Comstock** and I. Bedrosian
   - The effect of pre-operative MRI on surgical outcomes, recurrence rates, cost and QOLY for those planning BCS
   - Primary endpoint changed from in breast reoccurrence to local-regional occurrence
   - Identifying sites, finalizing forms and statistical plan for data sharing with Alliance through RAVE

3. **ACRIN 6698 (formerly 6693) - S. Partridge** and N. Hylton
   - MR imaging biomarkers to assess response to neoadjuvant treatment ISPY-2
   - Trial is open to accrual
   - 6698 adds the diffusion-weighted MRI and has an option for the test re-test
   - Also see accompanying overview of ACRIN 6698
4. **ACRIN 6688 - D. Mankoff, L. Kostakoglu and Jolles**
   - Correlate the percentage change in SUV between baseline (FLT-1) and early therapy (FLT-2) with pathologic complete response
   - Planned 54 eligible patients to yield 49 patients to evaluate primary aim
   - Secondary aim: correlate FLT uptake with Ki-67 score
   - Accrual completed September 2012
   - Also see accompanying [overview of ACRIN 6688](#)

5. **NSAPB-RTOG - H. Umphrey** and Baski, De Los Santos and Julian
   - Diagnostic tool to assess pathological response
   - Awaiting comments from ACRIN breast committee, December 19, 2012

6. **UVa Mammography Project - J. Harvey**
   - Breast Density Risk Model
   - 3 years, 4000 women
   - Also see accompanying [overview of UVa Mammography Project](#)
Breast Imaging Integration Working Group Summary
5. Open Discussion

• Evolution of ECOG-ACRIN
• Biomarker Sciences Program and Breast Imaging Integration Working Group Interactions
• Integration Working Group Future Discussions
• Meetings currently held at Fall and Spring ECOG-ACRIN group meetings