

Breakout group 3A - **Monitoring Assays for Solid Tumors**

Session leaders: Drs. Pennello, Lively and Sullivan

morning

Definition of clinical utility of monitoring assays

- *In what clinical settings will monitoring assays for solid tumors be useful?*
- *Are treatment options a prerequisite for utility of an assay?*
- *Is affordability? If so, how is affordability measured?*

Evidence needed

- *Is it sufficient to show harmonization with other assays for the same indication?*
- *Is it sufficient (or necessary) to show outcomes improve when the test is used?*
- *Does evidence always have to be generated in the same organ or context it will be used?*

Relevant endpoints

- *Are the endpoints for monitoring assays different than for predictive or prognostic assays?*
- *Does what constitutes a clinically relevant endpoint depend on the disease?*

afternoon

Evidence generation

- *Randomized controlled trials are the standard. Are there any cases in which nothing less can be considered?*
- *It is not feasible to perform RCTs for every assay in every context. What are other options?*
- *When are the other options appropriate and when are they not?*
- *How to deal with rapidly changing technology??*

Role of NCI

- *What are the other interested agencies and organizations unable to do?*
- *Are there opportunities in that gap that NCI could appropriately fill?*
- *Could the clinical trials network be utilized differently to generate the evidence?*

Please review the following articles and websites. They will be used to illustrate the challenges faced in trying to answer the questions above.

Example 1: Use of the CellSearch® assay to monitor breast cancer

S0500 Trial (insert link to schema)

<http://www.cancer.gov/clinicaltrials/featured/trials/swog-s0500>

<http://clinicaltrials.gov/show/NCT00382018>

http://www.accessdata.fda.gov/cdrh_docs/pdf10/K103502.pdf

Example 2: A new contrast agent for FDG-PET to detect recurrence of prostate cancer

<http://prostatecancerinfolink.net/2012/09/13/fda-approves-specialized-imaging-agent-for-pet-scans-in-recurrent-prostate-cancer/>

http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203155Orig1s000SumR.pdf (Summary Review)

Example 3: Use of an assay for circulating tumor cells to detect emergence of drug-resistance in lung cancer

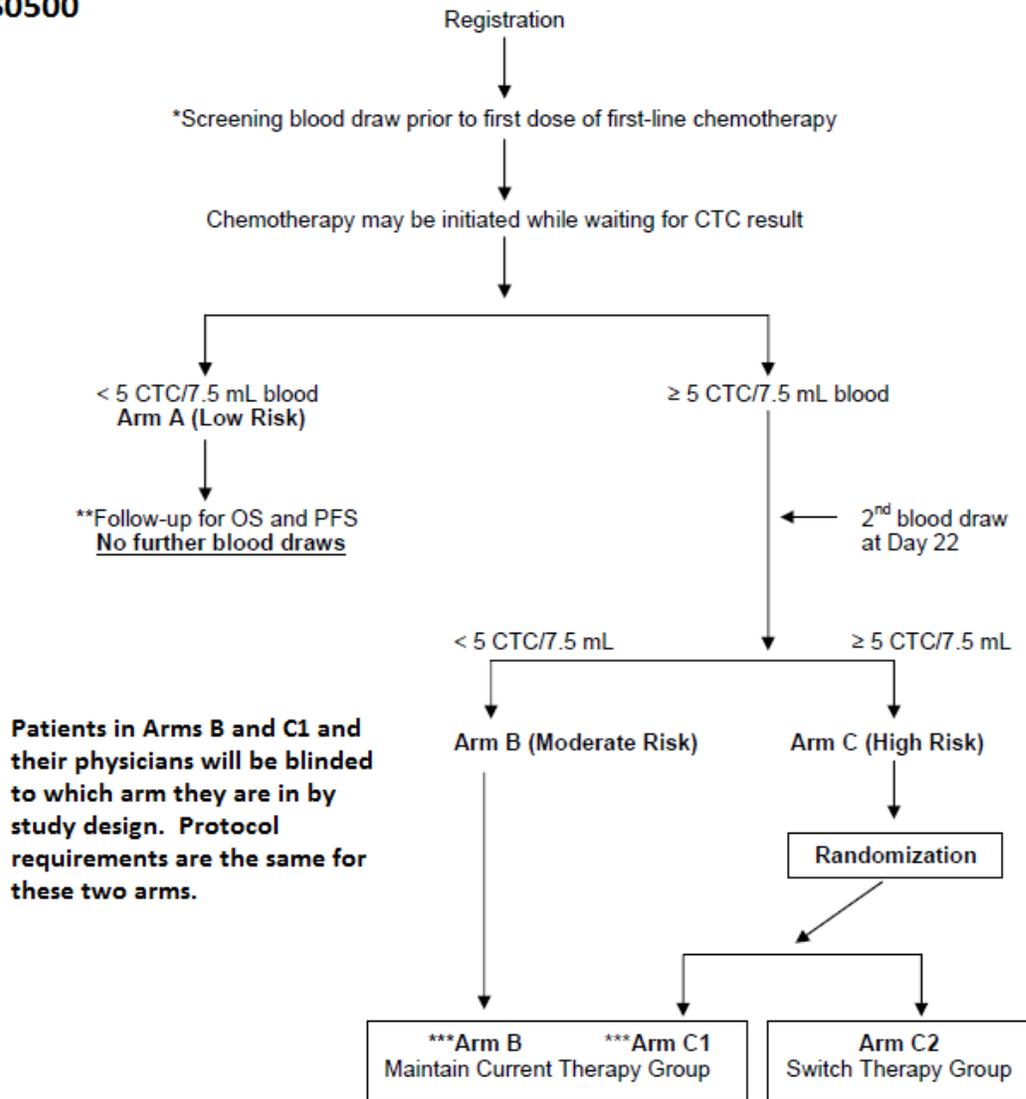
Maheswaran, S. et al., (2008) Detection of Mutations in EGFR in Circulating Lung-Cancer Cells, [New England J. Med. 359:366-77](#).

See also:

Mandrekar, S.J. et al., (2005) Clinical Trial Designs for Prospective Validation of Biomarkers, [Am. J. Pharmacogenomics 5:317-325](#).

S0500

SCHEMA



Patients in Arms B and C1 and their physicians will be blinded to which arm they are in by study design. Protocol requirements are the same for these two arms.