Confessions of a Former Executive Officer

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Role of the Executive Officers

- Physician with Oncology Expertise
- Interface with the study team & Alliance Operations
  - to guide a study through the NCI's scientific and regulatory committees
  - Works with Budgeting Contracts team
  - Ultimately, facilitates study's implementation and its successful completion

During Study Development

- Works closely with protocol team to review protocol (scientific review)
  - Review I/E, schema, treatment section, dose mods consistent with Alliance trials
- Coordinates pieces:
  - Pathology, Imaging, QOL (CCP)
- Funding and Contracts:
  - Pharma, NIH (BIQSFP)
  - **Study Chairs NOT authorized to negotiate on behalf of Alliance**

While Study Enrolling

- Assistants and reviews amendments
  - Trouble Shoots issues with protocol
- Accrual Enhancement Efforts
  - Patient Materials vs. Site Interventions
- Queries from sites (backup, vacation coverage for SC)
- Emergency Unblinding for placebo controlled studies

Post- study Closure

- Gather the troops to respond to DSM action
  - CTEP, pharma notifications
  - Site and Patient Notifications
- Post-study actions:
  - Requests for Pharma
  - Secondary Analysis: Funding, logistics

In General……

- A great resource to help make your study a success
- Goal is to help support and further the scientific vision of group
- Within the Alliance, collaboration between scientific team and ‘operations’ team is crucial.
  - Neither can succeed independently

Study Design and Budget Considerations:

- Real World Examples

AMBASSADOR: Adjuvant Pembro vs. Observation in UCC

- PDL-1 testing required for stratification
  - Integral Biomarker
    - Funding – Pharma vs. BIQSFP
- Observation Arm vs. Pembro q3weeks
  - Balance of arms (MD visits, toxicity assessments, labs)
- Interval of Restaging Scans for DFS endpoint
  - Frequency stats(FDA) desired vs. NCCN guidelines

National Coverage Analysis Considerations

- **RC** = Routine care for QCT and billable to Medicare
- **S** = Sponsor paid/provided per study funding sheet
- **NB** = Non-billable item
- **M** = Likely billable to Medicare. Must document medical necessity.

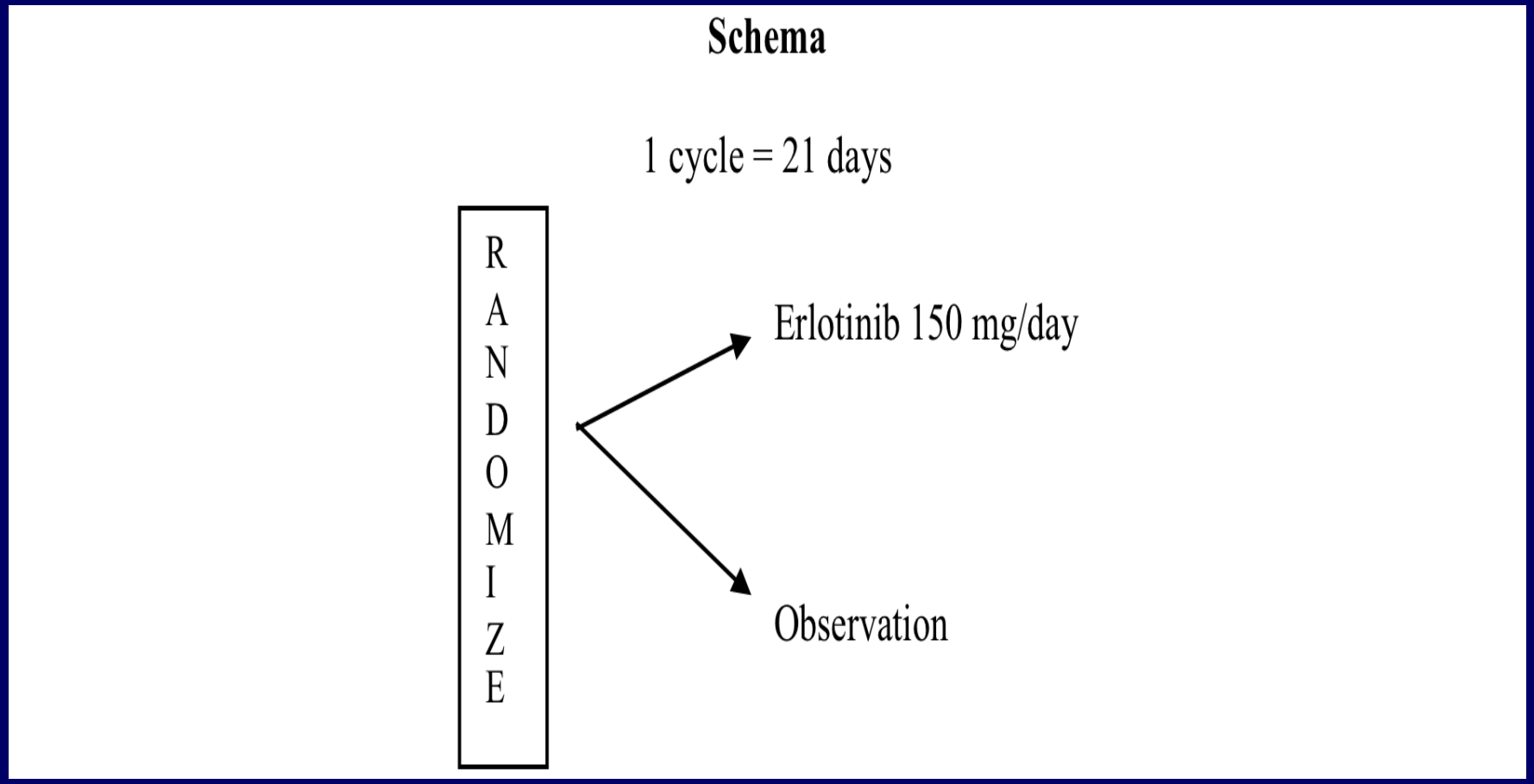
Phase III ASA vs placebo for adjuvant therapy breast cancer: the ABC trial

- Does the investigational item or service fall into a Medicare benefit category?
  - NO!: does not fall into one of the 72 Medicare benefits categories. ASA is OTC
  - **LABORATORY :** Platelet count
    - NOT BILLABLE

NCA: Tests performed to determine eligibility

- Ie FACT blood panel, lipid panel
- May be ruled as 'Not Billable'
- Appears to be for screening for clinical trial participant eligibility, so likely not billable. If medical necessity is documented in the medical records, then may be billable to Medicare/third party payors.

ALCHEMIST: Erlotinib vs. Placebo (now Observation)



Questions?