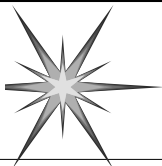


CALGB DATA AUDIT

POLICIES AND PROCEDURES

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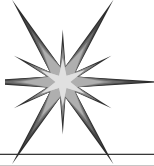


REGULATORY COMPLIANCE

- **IRB review/approval required before entry?**
- **Annual review at least every 12 months or <365 days?**
- **All updates reviewed as required within 90 days of implementation?**



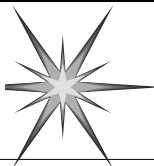
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REGULATORY COMPLIANCE

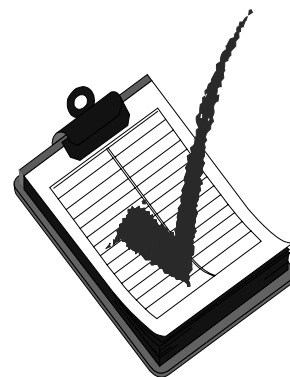
- Broadcast SAEs acknowledged by IRB within 90 days of distribution?
- Action Letters acknowledged by IRB within 90 days of distribution?
- Audit update and broadcast SAE list on web (resources → audit)

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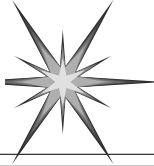


REGULATORY COMPLIANCE

- **Participant notification accomplished as indicated?**
- **IRB informed of local AERs?(C-804, Medwatch Addendum)**



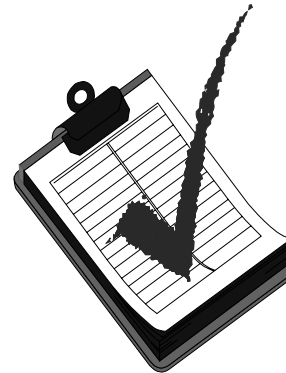
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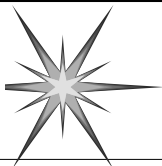
REGULATORY COMPLIANCE

Additional Reviews

- Companion studies
- Closed studies with patients still being followed – Expedited versus Full Board



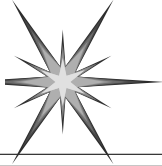
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INFORMED CONSENT

- All required content present (refer to NCI required consent elements checklist)
- One risk omitted → MAJOR
- *Original*, signed, witnessed, and dated on or before date of registration

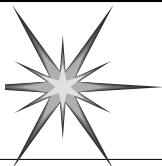
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INFORMED CONSENT

- **Evidence of understanding - interpreter if not mentally competent or non-English speaking**
- **All blanks completed (e.g., contact numbers, MD names, etc.) when patient signs the consent**

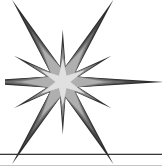
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ELIGIBILITY

- **Source documents for each eligibility criterion support the data submitted (including hx of prior Rx or disease; documentation of appropriate PS)**
- **Pre-Rx diagnostics accurate & obtained within required time frames; concurrence with path diagnosis if required**

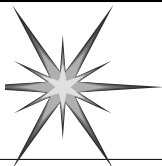
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ELIGIBILITY

- Pt declared ineligible if requirements not present
- Accurate ht/wt (ideal vs. real as specified per protocol) and BSA

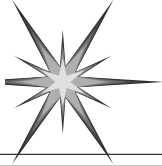
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TREATMENT

- BSA accurate; recalculated each cycle if specified in protocol
- Rx doses & dates accurate & in concordance with protocol; no prohibited medications/Rxs
- Documentation of Rx administration, including oral agents & protocol-specific supportive Rxs

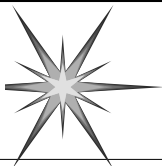
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TREATMENT

- ↗ **Dose reductions, escalations or delays justified by the protocol and documented in MD/RN notes and flowsheets**
- ↗ **Interim pt monitoring conducted according to protocol (labs, restaging diagnostics, etc.)**

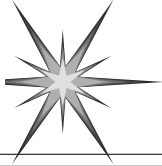
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TOXICITY

- ↗ **All toxicities recorded in chart reported on data forms; accurately graded**
- ↗ **Adverse event procedures followed as required (accurate, complete data provided to study officials; timeliness of reporting)**
- ↗ **Patient death within 30 days of Rx reported appropriately (even if *after* Rx completed)**

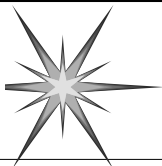
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RESPONSE

- **Measurements are verifiable & obtained at appropriate time points**
- **Same method of measurement at each interval**
- **Response/progression reported is accurate**
- **All *sites* of disease followed & recorded as required**

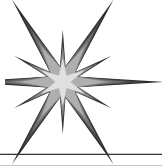
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FOLLOW-UP

- **Pts off-Rx but not off-study are followed at intervals required by protocol**
- **Required follow-up exams & diagnostics completed (e.g., annual mammograms, gyn exams, etc.) & reported as required**

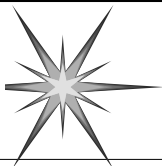
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FOLLOW-UP

- **Follow-up forms & reports are current (progression or other endpoint event not reported within 6 months is a Major deviation)**

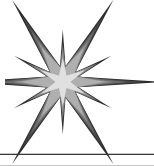
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RECORDS AND DATA QUALITY

- **Hospital/clinic charts in concordance with submitted data**
- **Treatment started within required time frame after entry (CALGB requires Rx to start within 7 days of registration)**
- **Flow sheets ,if required, complete and accurate reflection of records**

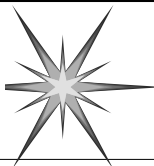
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RECORDS AND DATA QUALITY

- **Forms submitted within time frames**
- **Records are legible and reasonably well-organized**
- **Required submissions complete (e.g., slides, blocks, RT materials, serum samples) and utilized LabTrak**

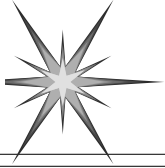
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LabTrak

- Verify sample submissions on all registered patients
- If checked periodically, then no surprises day of audit
- No path submission → MAJOR

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CTSU Audits

- Done by CALGB if CALGB given credit for registration
- Performed on all 3 areas –
 - IRB/Consent Content
 - Pharmacy
 - Patient Case Review