NRG Oncology Quality Assurance Audits

John A. Blessing, PhD
Deputy Group Statistician

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NRG Oncology Quality Assurance Audits

Structure

- Larry Copeland MD, Deputy Group Chair – Audits
- John Blessing, PhD, Deputy Group Statistician
  - -Administration/Information Technology
  - -Oversight of Quality Assurance Audit Program
- Sally Bialy, MA
  - -Director of Administration/Operations – Buffalo
  - -CTMB Liaison/NRG Audit Coordinator
- Audit Working Group
  - -Experienced members of Pittsburgh, Philadelphia, and Buffalo Offices

NRG Oncology Quality Assurance Audits

Purposes

- Assure quality of clinical trials execution
- Verify the accuracy of submitted data
- Document adherence to regulatory requirements
- Enhance education

Scientific Misconduct

NRG Has Zero Tolerance

- Immediate reporting
- Intentional misrepresentation of data
- Intentional disregard for regulatory safeguards
- Essential that institutional misconduct procedures are also followed

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Audit Components

- Regulatory
  - IRB
  - Informed Consent
- Drug accountability and storage
- Patient case review

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Patient Case Review

- Informed consent execution
- Eligibility
- Treatment
- Disease outcome
- Toxicity
- Data Quality

NRG Oncology Quality Assurance Audits

Overview

- Clinical Trials Monitoring Group Guidelines
- Experienced Legacy Group auditors
- Harmonization of Procedures
  - Similarities
  - Differences

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What May Be Different

- Most affiliate audits conducted at main member
- Audit timeframe for initial cycle
- Duration of audit
- Requests prior to audit
  - IRB approvals
  - Informed consents
  - DARFs

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Audit Location

- Affiliates and Components are audited with Main Member
  - Communication through Lead Research Associate
  - All materials are audited at the Main Member
  - Pharmacy review off-site for Affiliates
- Each affiliate will receive an individual Final Audit Report
- CCOPs will continue to receive one comprehensive Final Audit Report including all components

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Audit Due Date

- Governed by earliest due date for involved Legacy Groups
  - Some institutions will have a Legacy Group component audited "early"
    - Last RTOG audit on 06/12/13
    - Last GOG audit on 11/12/12
    - Last NSABP audit on **10/09/11**
  - Next audit due on 10/09/14
- Audit of IRB/Pharmacy/Data since individual last audit date
- Regular schedule if only one Legacy Group involved

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Scheduling

- Working Group conference calls
- Determination of "Lead Office" for each audit
  - Typically based upon case load
    - Staggered prior audit dates
    - Former affiliates have become new main members
  - Does not signify importance
    - NRG institution
    - NRG Office

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Scheduling

- Lead office may change from audit to audit
- Lead office will interact with institution
  - Lead RA is institutional contact
  - Lead RA interacts with other institutional staff
- Audit team may have representation from multiple Legacy Groups

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Harmonization

- Regulatory review
  - Off-site prior to audit vs on-site
  - Protocols being audited vs all protocols
- Pharmacy review (essentially unchanged)
  - On-site: complete review
  - Off-site: limited review (security and storage not possible)

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Harmonization

- Patient Case review
  - Case selection across NRG Legacy Groups
  - 10% of accrual required
    - Main Member
    - Each Affiliate
    - Not 10% of combined total accrual

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Major vs. Lesser Deviations

- Major
  - "Variance from protocol-specified procedures that make the resulting data questionable"
- Lesser
  - Generally no impact on outcome or interpretation
- The cumulative effect of multiple lesser deviations may constitute a major deviation

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Exit Interview

- Preliminary discussion of results
- Recommendations
- Feedback
- Education

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Rating Classifications

- Acceptable
  - No major deviations noted
  - Major deficiency noted and corrected prior to audit
    - Single instance
    - Prior to case list distribution
  - Re-audit within three years
- Acceptable, follow-up required
  - Requires written corrective plan
  - Consideration given to early re-audit
- Unacceptable
  - Requires written corrective plan
  - Requires re-audit within 12 months

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Institutional Preparation

- Schedule adequate audit space and time
- Notify key personnel
  - Must be available for Exit Interview
- Inform pharmacy (if applicable)
- Organize patient records
  - Obtain medical records
  - Highlight or tab key data elements (on source docs)
  - Provide x-rays and viewing box
- Review IRB folder for each audited protocol
- Provide copy of each audited protocol

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Helpful Hints

- Download model consent if allowed
- At minimum, download model risk section
- When submitting protocol amendment, request IRB to provide written documentation regarding need for reconsent
- Include Performance Status on assessments
- Use carboplatin calculator; print for documentation
- Note restrictions on drug orders
  - Do not change carboplatin dose for routine changes in creatinine
  - Do not change bevacizumab dose for weight change < 10%

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Helpful Hints

- Develop tumor measurement worksheet
  - Each assessment column must be signed and dated
- Before submitting data, request physician review
  - Tumor measurements
  - Response
  - Progression
- Use comment boxes to provide explanations
- Print electronic medical records in flow sheet format (drug doses , interim counts, CA-125, etc.)