2013 Winter Group Meeting

November 7, 2014 / Chicago, IL

PI Perspective
Why should we be involved?

Michael Collins, MD, FACS

Audit Preparation Workshop, November 7, 2014

Clinical Trials

- From a clinician standpoint, why should we want to be involved in clinical research programs?
  - Let alone be a PI
  - Time factor: consents, meetings, audits
  - Extra personnel
  - Interfacing with IRB
  - Cost involved

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Clinical Trials

- Must deal with the following concepts
  - Responsibility
  - Evaluation
  - Treatment
  - Integrity of patient care and soundness of the research data
  - Ethics
  - Scientifically sound principles (evidence based)

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Clinical Trials

- Why?
- Reasons for participation can be summed up by one letter---"Q"
- Query: an inquiry or a form of questioning
- Edward Derrick and Q Fever
- "Query" as it applies to Clinical Trials
  - A form of questioning about clinical topics where we don't know the answer similar to the "query" of Derrick's fever

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Clinical Trials

- I have since related Dr. Derrick's methodology of the "query" to the rationale for performing Clinical Trials
  - Query: a form of questioning
  - That question then becomes the Clinical Trial
  - Participation in Clinical Trials then programs us to look at *all* clinical questions from Dr. Derrick's view of….Query

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Clinical Trials

- When all patients are treated as if they are in a Clinical Trial, not only does patient care benefit but the entirety of the clinical experience improves
  - We become better physicians
  - Patient care improves

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Clinical Trials

- Why do I participate in Clinical Trials
  - Passion for the “query”
  - Patient outcomes are improved
  - Definite benefit in applying protocol workup and treatment to all patient care
  - Surveillance
    - Better QoL and Survival because patients are seen and evaluated at regular intervals

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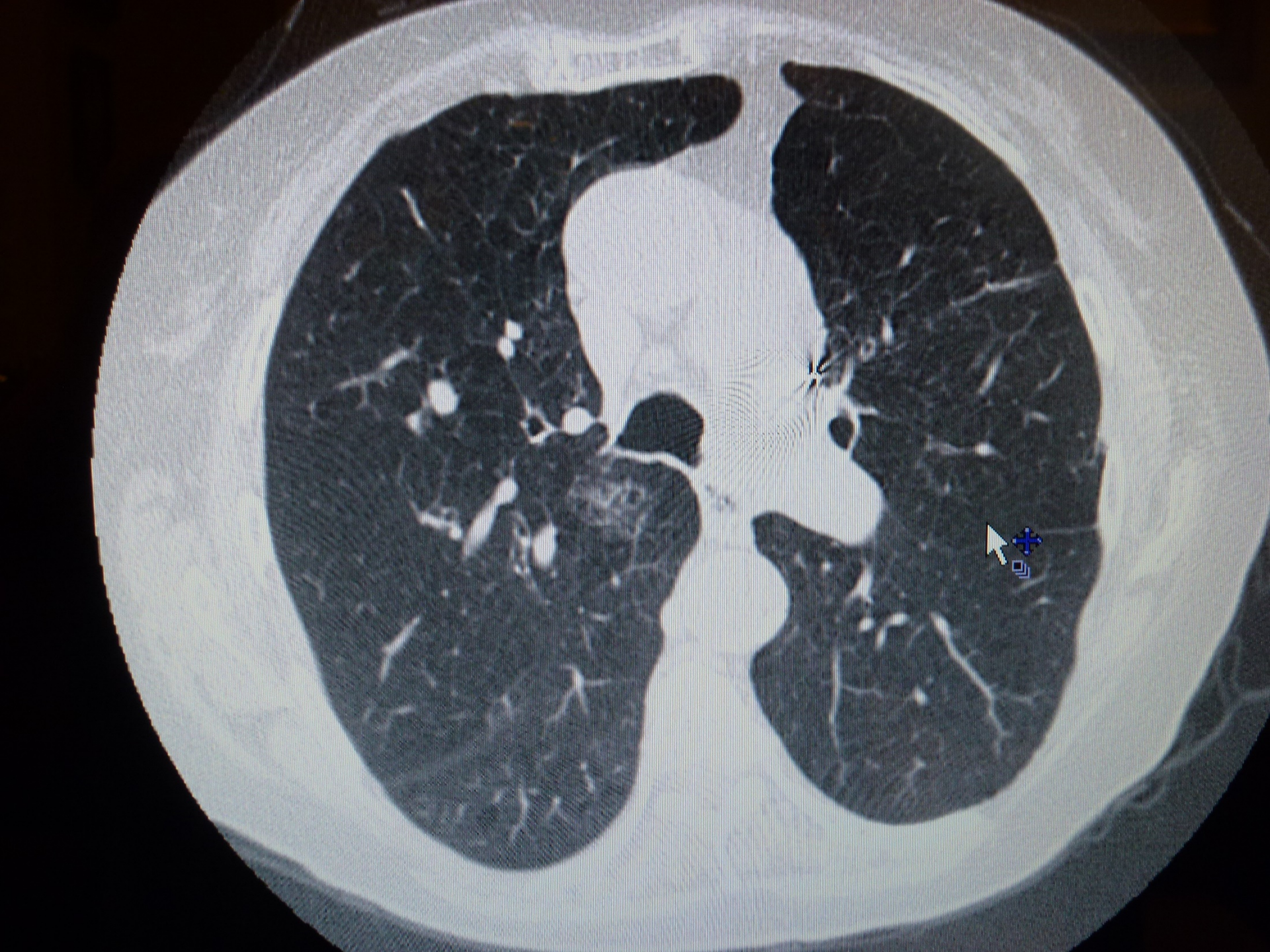

Principal Investigator's Role for Alliance Audits

- [An investigator is] … a physician who assumes full responsibility for the treatment and evaluation of patients on research protocols, as well as the integrity* of the research data.

- The investigator assures CTEP that the clinical trial will be conducted according to ethically and scientifically sound principles."

*integrity: 1. Unimpaired condition; soundness. 2. Adherence to a code; 3. State of completeness.

ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

Principal Investigator's Role for Alliance Audits

Prior to Audit

- Treat each patient as if he/she will be audited.
- Make the treatment program, dose modifications, and schedule of tests an obvious portion of the patient's chart.
- Provide complete documentation of clinical care and the rationale for protocol deviations.
- Demand compulsivity from other medical personnel.

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Principal Investigator's Role for Alliance Audits

Prior to Audit

- Perform periodic mock-audits of your institution and affiliates. Don't assume that everything is fine--- ***assure yourself!***
- Be certain that IRB and Pharmacy policies conform to Alliance standards; negotiate compliance, if necessary!

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Principal Investigator's Role for Alliance Audits

Preparation for Audit

- Recognize stress level and "clear the decks."
- Be available for last-minute data resolution.
- Provide audit correspondence and information to all personnel involved with the audit, especially affiliates/components.
- Impress ancillary departments with the importance of cooperation and support.

Be available for introductions and exit interview.

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Principal Investigator's Role for Alliance Audits

Post Audit

- Share results with other investigators and departments that are involved in Alliance research.
- Re-examine strengths and weaknesses in the structure of the research office/program.

Principal Investigator's Role for Alliance Audits

Post Audit

- Address clinical and organizational issues in a written response to the audit findings, including findings that may have been erroneous or require clarification.
- Use the critique of the extramural reviewers to help improve the research/overall cancer program.

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Clinical Trials

- I have come to appreciate the concept of looking at all of my patients through Derrick's "Q"—adopting it to the Clinical Research setting of constantly questioning…..
- Participating in Clinical Trials undoubtedly takes extra time, work, effort, planning, etc.
  - Answers to critical clinical questions
  - Benefit of overall better patient care surely justifies the input

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