



## Is an Evolving Chart Audit Plan Necessary in a Long-Term Multi-Center Trial?

Brenda K. Brewer, MMSc

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### Who Am I?

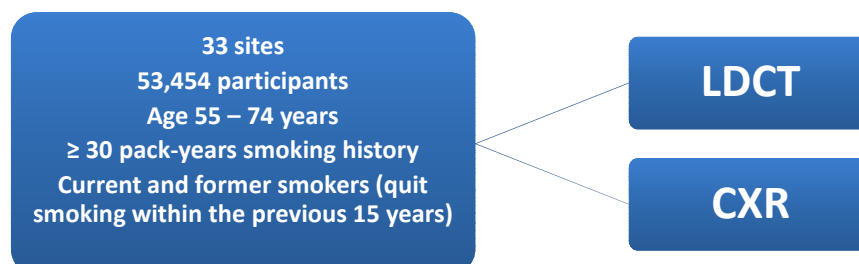
- Westat is the Coordinating Center (CC) for the National Lung Screening Trial/Lung Screening Study (NLST/LSS)
- CC Project Director for the NLST/LSS

## Presentation Objectives



## National Lung Screening Trial (NLST)

Randomized controlled trial designed to determine whether screening with low-dose helical computed tomography (LDCT) reduces lung cancer mortality relative to screening with conventional chest x-ray (CXR) in persons at elevated risk of lung cancer.



## NLST Overview: Organization

NCI-sponsored with two collaborative administrative components

**LSS**

Lung Screening  
Study

10 sites

34,614 participants

**ACRIN**

American College  
of Radiology  
Imaging Network

23 sites

18,840 participants

## NLST Overview: LSS Sites

- Georgetown University Medical Center  
(Washington, DC)
- Henry Ford Health System  
(Detroit, MI)
- Marshfield Clinic Research Foundation  
(Marshfield, WI)
- Pacific Health Research and Education Institute  
(Honolulu, HI)
- University of Alabama at Birmingham  
(Birmingham, AL)
- University of Colorado Denver  
(Aurora, CO)
- University of Minnesota School of Public Health  
(Minneapolis, MN)
- University of Pittsburgh Medical Center  
(Pittsburgh, PA)
- University of Utah Health Science Center  
(Salt Lake City, UT/Boise, ID)
- Washington University School of Medicine  
(St. Louis, MO)



## Challenges

- Operationalize monitoring requirements
- Efficiently capture/document audit results
- Accommodate various approaches at each site

## Special Challenges

- Continue monitoring over a long-term
- Keep audit form relevant to the trial focus
- Ensure selection of relevant cases
- Incorporate and capture protocol changes

## Our Approach

### Before each site visit cycle:

Meet internally to discuss  
general issues

Obtain client agreement on overall  
focus, chart selection, and reports

Identify and make necessary revisions  
to the audit selection and form

## Our Approach

### Before each site visit:

Prepare annual site status report

Review previous site visit and data  
monitoring reports to identify issues

Add targeted audits to focus on  
site-specific issues

## Chart Audit Focus

### Start Up

- Recruitment
- Eligibility
- Consent

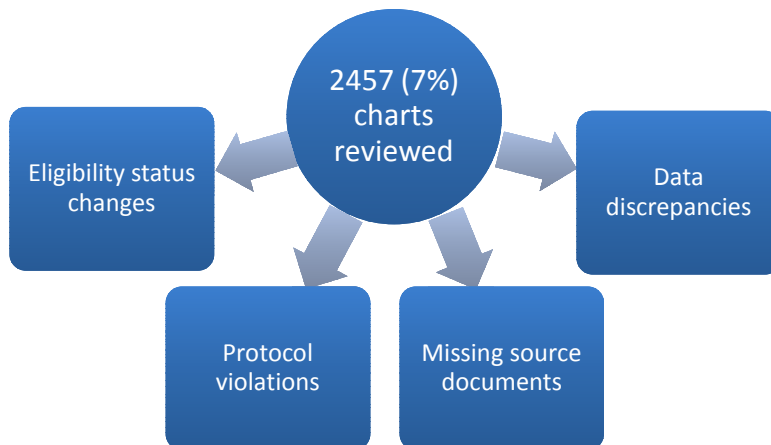
### Follow Up

- Screening
- Retention
- Cancer and vital status ascertainment

### Close Out

- Final form accounting
- File archival

## Quantitative Outcomes of Chart Audits



## Qualitative Outcomes of Chart Audits

- Learned how procedures were implemented
- Discovered systemic issues
- Disseminated ideas at meetings and trainings
- Modified data form to capture additional information
- Modified the data QA plan
- Modified the data management system
- Established rapport with site staff

## Hawaii Site Visit



## Lessons for Future Trials

Review site visit and monitoring reports regularly to determine general issues

Work with client to agree on site visit focus plan

Assess audit form regularly and modify as needed to ensure capture of useful information

Re-evaluate chart selection criteria in consideration of trial outcomes

Standardize chart management across sites

## Conclusion

In this long-term, multi-year trial, an evolving chart audit plan became an integral part of the total monitoring plan that allowed the CC to respond to ongoing issues and ensure high quality data.



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