

# THE LITTLE STUDY THAT COULD

## Meeting the Challenges of Multi-Site Studies in Diverse Populations



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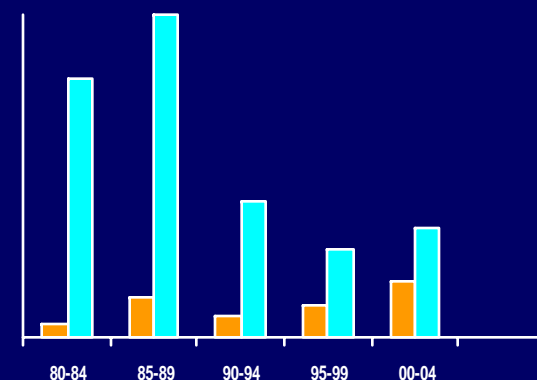
**for the Tuberculosis Epidemiologic Studies  
Consortium**



# Changing Research Needs

- Increase in multi-site studies

- ✓ McWilliams R, et al. JAMA 2003; 290: 360-36



- U.S. population is increasingly diverse

- ✓ 9.5% born in another country

- ✓ Studies need to reflect U.S. population



# Challenges

- Institutional Review Boards (IRBs)
- Enrollment barriers
- Maintaining data quality
- Operational consistency among diverse sites



# Missed Opportunities for Prevention of Tuberculosis in Foreign-Born Persons

- Majority of TB cases in U.S. now in foreign-born
- Insufficient data on the epidemiology of TB in the foreign-born population
- Study: Interviewed and collected clinical data on 1,695 foreign-born persons with TB



# Elements of the Study

1

In-person  
interview  
(1 hour)



2

Arrival screening  
information from  
CDC's Division of Global  
Migration and Quarantine

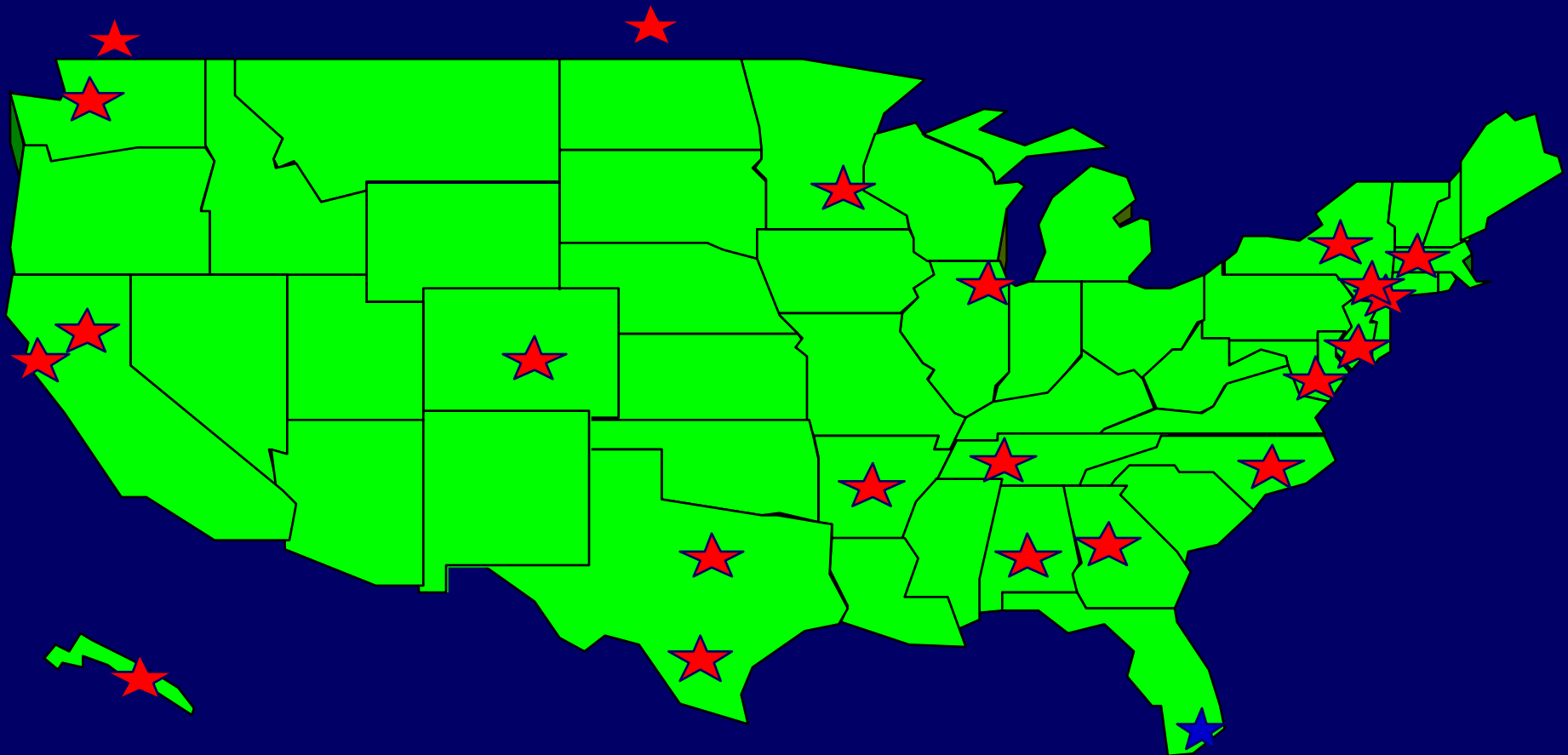


3

Clinical data  
from surveillance  
report



# Missed Opportunities for Prevention of Tuberculosis in Foreign-Born Persons



- ★ = TBESc site
- ★ = Subcontracting site



# Meeting the Challenges: *IRB Review*

- Approval from 35 IRBs
  - ✓ 490 reviews over life of study
- Simple process for using central IRB
- A third of IRBs ceded oversight
- Agreement for no changes to central IRB-approved consent forms



# Meeting the Challenges:

## *Enrollment (Recruitment)*

- Participants spoke 35 different languages
- Questionnaire and consent forms translated into 10 languages
- Short Form translation
  - ✓ turnaround for new forms: 1 week
- 9 persons not enrolled because of language





# Meeting the Challenges: *Enrollment (Interviewing)*



- A single phone interpretation company
  - ✓ Access to questionnaire electronically
- Adapted interviews to participants' needs
  - ✓ Convenient locations – home, library, etc.
  - ✓ Convenient times – weekends, after hours



# Meeting the Challenges: *Training*

- **Simulated patients, remote observers**
- **3 in-person trainings**
- **Remote training program for new site hires and refresher**



# Meeting the Challenges:

## *Maintaining Data Quality*

- Enrollment at 22 U.S. and Canadian sites
- Site specific implementation and quality assurance plans
- Weekly recruitment logs
- Biweekly conference calls
- Site monitoring visits
- Web-based documentation system



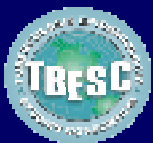
# Meeting the Challenges: *Maintaining Data Quality*

- **Web-based secure data entry system**
  - ✓ Remote access for all sites
  - ✓ Built in quality assurance checks
  - ✓ Remote trainings and refreshers



# Conclusions

- Multi-site epidemiologic studies require flexibility, innovation, adaptation
- Study exceeded enrollment goal of 1,500
- 8 initial papers in preparation
- Approaches may help other investigators contemplating multi-site studies



# Acknowledgements

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  - ✓ Katz, Davidow, Reves
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*Thank you*

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