WHAT YOU NEED TO KNOW ABOUT CLINICAL TRIALS

Joe Ramsdell, M.D.
Director, UC San Diego Airways Research Center
The Challenges Of Clinical Research In COPD and Asthma: Time and Money

Traditional approached by individual pharmaceutical companies or grants to single investigators from the NIH, other agencies or foundations
Clinical Research Timeline*

- Drug Discovery
  - Screening based on understanding of disease mechanisms or existing treatments

- Preclinical studies
  - Proof of concept trials before exposure to humans
  - Perhaps one in 140 candidate drugs reach this phase
  - Up to 10 years

- Clinical trials
  - One in 2000 candidate drugs reach this phase
  - Human tests (closely regulated)
  - Up to 10 years

- FDA review
  - Up to two years

- Ultimate release....sometimes over 20 years!
- Postmarketing studies

*Timelines roughly similar for devices
Research Networks Offer An Important Public Alternative To Pharmaceutical Company Drug Development

• Able to study drugs or combinations of drugs that may not be practical for financially feasible for industry
• Able to study populations that may be less attractive to industry (e.g., asthmatics who smoke)
• Able to study underlying mechanisms in a way that industry cannot (e.g., COPDGene)
• Able to quickly initiate protocols based on existing network expertise
• Existing networks relevant airways disease
  • COPD (ALA/ACRC network, COPDGene and others)
  • Asthma (ALA/ACRC network, AsthmaNet and others)
The ALA/ACRC Network:

The American Lung Association Airways Clinical Research Centers Research Program is a clinical network of prominent adult and pediatric asthma and COPD specialists who seek to answer important questions about asthma that directly benefit the patient.
UC San Diego ACRC
Director: Joe Ramsdell, M.D.
Codirector: Julie Ryu, M.D.
Codirector: Steve Wasserman, M.D.
Lead coordinator: Amber Martineau
American Lung Association ACRC Sites

- Baylor College of Medicine, Houston, TX
- University of Arizona, Tucson, AZ
- University of California at San Diego, San Diego, CA
- National Jewish Health and Mt. Sinai Icahn School of Medicine, Denver CO and New York, NY
- The Nemours Children’s Clinic, Jacksonville, FL
- The Illinois Consortium (Northwestern University, University of Chicago, Rush University, University of Illinois at Chicago), Chicago, IL
- New York Consortium (Columbia University, Weill Cornell Medical College, NYU Medical Center), New York, NY
- St. Louis Asthma Clinical Research Center, St. Louis, MO
- Duke University Medical Center, Durham, NC
- St. Vincent Hospital and Health Care Center, Inc., Indianapolis, IN
- University of South Florida, Tampa, FL
- The Northern New England Consortium, Colchester, VT
- Data Coordinating Center, Johns Hopkins University, Baltimore, MD

**New Centers:**

- University of California, San Francisco, San Francisco, CA
- University of Washington, Seattle, WA
- Temple Lung Center, Philadelphia, PA
- University of Alabama, Birmingham, Birmingham, AL
- University of Michigan, Ann Arbor, MI
ACRC is a Unique Network

- The ACRC network conducts large clinical trials that will have a direct impact on patient care and asthma treatment.
- The large number of subjects enable researchers to answer important questions in which a result may be “no difference” between alternative treatment groups.
Changing the Face Of Asthma Medical Practice

- Study of Inactivated Influenza Vaccine in Asthmatics (SIIVA) (NEJM)
- Effectiveness of Low Dose Theophylline As Add-On Therapy In Treatment of Asthma (LODO) (AJRCCM)
- The Leukotriene Modifier or Corticosteroid or Corticosteroid Salmeterol (LOCCS) Trial (funded by GSK) (NEJM)
- Trial of Asthma Patient Education (TAPE) (funded by NHLBI) (JACI)
- Sinusitis and Rhinitis in Asthma (SIRNA) (funding by Schering Plough) (CHEST)
- Study of Acid Reflux in Asthma (SARA) in Adults and Children (funded by NHLBI) (NEJM, JAMA)
Practical Impact of ALA/ACRC Research: Since SIIVA was published in NEJM, the percentage of asthma patients receiving a flu shot increased 20%
During its first 12 years the American Lung Association has contributed only half of the total research dollars expended by the ACRC ....

Remainder is from corporate and NIH grants.

This is equivalent to raising $25 million from external sources.
During its first 12 years for every dollar invested in the 
American Lung Association 
Awards and Grants Program, 
more than $37 in external support of 
lung disease research has been generated.

Why is that important?
DOM Research Trend
Federal Competitive Awards
(excludes continuations, supplements, subawards & clinical trials)
Can this approach work? --We are turning the corner in the fight against the asthma epidemic

In the first half of the 21st-century, we have seen various improvements in mortality and health care use associated with asthma.

However, there is still work to be done in the area of COPD where the trends are going in the other direction.
THE CRITICAL ROLE OF CLINICAL TRIALS IN RESEARCH

Monitored research studies under the direction of experts

Enrolling can give patients access to cutting edge treatments

Tests how new medical approaches work compared to best known therapies...

Without clinical trials, asthma and COPD treatment would always remain the same
RESEARCH PROVIDES HOPE FOR ASTHMA AND COPD...

Volunteer!

UC San Diego Clinical Trials Center/Airway Research Center
UC San Diego Airways Research Center Team

UC San Diego Clinical Trials Center/Airway Research Center