"Building a Career in Clinical Research"

April 12, 2011

Keith C. Ferdinand, MD FACC, FAHA

Clinical Professor, Cardiology Division, Emory University
Adjunct Morehouse School of Medicine
Chief Science Officer
Association of Black Cardiologists, Inc.
Atlanta, GA
Agenda

• The Importance of Clinical Research

• Diversity in Clinical Trials

• Opportunities for Clinician Participation

• Participant Recruitment and Retention
Importance of Clinical Trials
The Importance of Clinical Research

- The only direct method to evaluate risks and benefits of given exposure / intervention
- Balanced distribution of potential confounders
The average number of studies conducted for a new drug prior to market approval is 64!
Diversity in Clinical Trials/Research
## African Americans in Statin Clinical-Event Trials

<table>
<thead>
<tr>
<th>Trial</th>
<th>Statin</th>
<th>Total Patients, n</th>
<th>African Americans, n or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>4S</td>
<td>Simvastatin</td>
<td>4444</td>
<td>N/A</td>
</tr>
<tr>
<td>WOSCOPS</td>
<td>Pravastatin</td>
<td>6595</td>
<td>N/A</td>
</tr>
<tr>
<td>CARE</td>
<td>Pravastatin</td>
<td>4159</td>
<td>Others, 7-8%</td>
</tr>
<tr>
<td>LIPID</td>
<td>Pravastatin</td>
<td>9014</td>
<td>N/A</td>
</tr>
<tr>
<td>AFCAPS/TEXCAPS</td>
<td>Lovastatin</td>
<td>6605</td>
<td>206</td>
</tr>
<tr>
<td>HPS</td>
<td>Simvastatin</td>
<td>20536</td>
<td>N/A</td>
</tr>
<tr>
<td>ALLHAT</td>
<td>Pravastatin</td>
<td>10355</td>
<td>3491</td>
</tr>
<tr>
<td>ASCOT</td>
<td>Atorvastatin</td>
<td>10305</td>
<td>Others, 5-5.5%</td>
</tr>
</tbody>
</table>

Comparison of Efficacy and Safety of *Rosuvastatin* Versus *Atorvastatin* in African-American Patients in a Six-Week Trial

- Keith C. Ferdinand, MD, Luther T. Clark, MD, et al

ARIES: African-American Rosuvastatin Investigation of Efficacy and Safety

- The effects of statins in African-Americans had not been well differentiated

- African Americans generally undertreated with lipid-modifying therapy, both in receiving treatment and achieving recommended goals

- The ARIES trial first prospective, large-scale, comparative trial of statin therapy in African-Americans

Median % Change in CRP at Week 6
(Patients with baseline CRP \( \geq 2.0 \) mg/L: \( n = 510 \))

*\( P < 0.01 \) versus baseline (within-treatment change from baseline)

Median baseline CRP (interquartile range): 5.4 mg/L (3.4–9.7 mg/L)
Opportunities for Clinician Participation
Clinical Research for Practitioners

- Major scientific contribution - proposing & conducting Investigator Initiated Study (generally postmarketing)

- Serving as an overall/site Primary Investigator in Phase III or Phase IV study/Government Cohorts (e.g. CDC, NHLBI)

- Physicians with large practices – subject recruitment within practice.
How Do Sponsors Identify Potential Investigators?

- Academic Center Affiliation
- Key Opinion Leaders
- Authors of publications in a related field or with a similar compound
How Do Sponsors Identify Potential Investigators?

- Community-based physicians
- Regional and local Thought Leaders
- Recommendations from sales reps
- Medical specialty lists/directories
- High prescribers in the same therapeutic
- Practices with diverse patient populations
General Investigator Responsibilities

• Protecting the rights, safety, and welfare of patients under the investigator’s care

• Obtaining written informed consent of each patient prior to administration of study drug

• Ensuring investigation conducted according to regulations: FDA Form 1572
Specific Investigator Responsibilities

- Adequate documentation
- Record keeping and record retention
- Investigator Reports
- Prompt reporting of Adverse Events
- Immediate reporting of Serious Adverse Events
- IRB compliance with initial and continuing reviews
- Protocol compliance
- Drug accountability
Video/Education Area

What Do You Need to Begin Clinical Trial Research?

- Positive attitude and interest in research
- Access to subject population
- Research infrastructure (especially for Phase III studies)
  - Study Coordinator and adequate number of staff
  - Adequate office space
  - Secure, locked storage for investigational drug and study supplies
What Do You Need to Begin Clinical Trial Research?

• Appropriate equipment (base on protocol)

• Thorough understanding of regulations governing clinical research

• Ability to fulfill regulatory requirements
Participant Recruitment and Retention
Patient Recruitment

- From investigator’s own practice:
  - Chart review
  - Appointment log
  - Waiting room advertising
  - Word of mouth
- Media advertising
  - Newspaper, Magazines
  - Radio
- Referrals from other physicians
Minority Recruitment Issues

- Economic Barriers
  - Funds for minority patients
  - Access to healthcare, quality of healthcare

- Individual Barriers
  - Geographic issues
  - Educational issues
  - Patient Preferences
Minority Recruitment Issues

- **Sociocultural Barriers**
  - Mistrust, fear of conspiracy (e.g.: “Tuskegee Experiment”)
  - Specific educational materials designed for minorities

- **Research Barriers**
  - Communication between referring physician and research team
  - Number of minority investigators and recruiters
  - Communication with participant
So What Can We Do?
THANK YOU!