Alzheimer’s Association
Clinical Studies Initiative

Presented at the October 4, 2007 meeting on

*Recruitment and Retention Challenges and Opportunities For the Alzheimer Disease Centers*

By
Paula Moore
Director, Clinical Trials
Alzheimer’s Association
What is the Alzheimer’s Association’s Clinical Studies Initiative?

- A response to a crucial shortage of volunteers needed for current and future Alzheimer’s disease studies
  - 80% of all clinical trials fail to enroll on time
  - Statistics are often worse for AD studies
- An Association-wide commitment to investigate, understand and address the factors contributing to a purported recruitment bottleneck
What is the Alzheimer’s Association’s Clinical Studies Initiative?

- A campaign to raise awareness of all AD clinical trial opportunities (without publicizing specific studies)
  - Within the medical community
  - Among the general population
- An opportunity to promote awareness of AD and of the Association as a resource for patients, caregivers and physicians
Background

- Growing concern about recruitment challenges and slow enrollments in all sectors
  - Unprecedented number of AD studies underway
  - Many promising compounds in research pipeline and especially in Phase III studies
- Many investigators approached the Association with requests to "do something"
Rationale

- We had sought and were continuing to seek donations for research within the context of our vision of “a world without Alzheimer’s”
- We were funding research and had always positioned research as the means to this end
- We were uniquely positioned to make a difference
  - Existing infrastructure already in place
  - Connections to the research community
  - Established Web site
  - Toll-free help line
Methodology

- Pilot program with five chapters
  - Rhode Island (Providence)
  - Georgia (Atlanta)
  - Northern California / Northern Nevada (San Francisco)
  - Greater Indiana (Indianapolis)
  - Oklahoma/Arkansas (Tulsa)

- Seeking variety in size and type of market
  - All had research under way
  - All had pockets of aging populations
Why a pilot program?

● Need to substantiate assumptions
  ➢ Metrics will determine future of initiative
  ➢ Potential for roll out to additional markets
  ➢ Results will pave way for donors and partnerships

● Smaller scale facilitated faster start
What we knew. . .

- AD trials among most difficult to enroll
  - Healthcare decisions by proxy
  - Caregiver participation required
  - Some require “washout” period
  - Many are placebo-controlled
  - Physicians function as gatekeepers
  - Elderly target population frequently present with exclusionary co-morbidities.
Market Research

- Need to validate assumptions about PCPs
  - 100 physicians, 20 from each market
  - 42 family practice; 58 internal medicine
  - 70% Caucasian
  - 12% Asian
  - 8% African American
  - 2% Hispanic
  - 7% Other or refused
- 20 minute interviews by clinicians
Estimated Alzheimer's Disease Prevalence by County

- 13,860 - 113,541 (53)
- 4,409 - 13,766 (158)
- 1,074 - 4,393 (531)
- 390 - 1,069 (875)
- 1 - 390 (1524)

© 2007, P.K. Data, Inc.
Market research interviewees

- Percent of AD patients in practice > age 65
  - Providence – 10%
  - Tulsa – 10%
  - Indianapolis – 8%
  - Atlanta – 11%
  - San Francisco – 12%

- Average – 10%
Who typically diagnoses AD?

<table>
<thead>
<tr>
<th>City</th>
<th>Self</th>
<th>Both</th>
<th>Refer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providence</td>
<td>55</td>
<td>35</td>
<td>10</td>
</tr>
<tr>
<td>Tulsa</td>
<td>35</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Indianapolis</td>
<td>75</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Atlanta</td>
<td>60</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>San Francisco</td>
<td>45</td>
<td>40</td>
<td>15</td>
</tr>
</tbody>
</table>

Full Sample

- Both: 41%
- Self: 54%
- Refer: 5%
Awareness of current AD research

- Very aware
- Somewhat aware
- Generally unaware

<table>
<thead>
<tr>
<th>Location</th>
<th>Very Aware</th>
<th>Somewhat Aware</th>
<th>Generally Unaware</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providence</td>
<td>20</td>
<td>70</td>
<td>10</td>
</tr>
<tr>
<td>Tulsa</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indianapolis</td>
<td>25</td>
<td>65</td>
<td>10</td>
</tr>
<tr>
<td>Atlanta</td>
<td>30</td>
<td>55</td>
<td>15</td>
</tr>
<tr>
<td>San Francisco</td>
<td>20</td>
<td>55</td>
<td>25</td>
</tr>
</tbody>
</table>

Full Sample
- Very aware: 19%
- Somewhat aware: 69%
- Generally unaware: 12%
Referred patients to ANY clinical trial?

- Providence: 65 Yes, 35 No
- Tulsa: 70 Yes, 30 No
- Indianapolis: 85 Yes, 15 No
- Atlanta: 80 Yes, 20 No
- San Francisco: 70 Yes, 30 No

Full Sample:
- Yes: 74%
- No: 26%
Referred patients to a trial for AD?

- Providence: 23 Yes, 77 No
- Tulsa: 43 Yes, 57 No
- Indianapolis: 29 Yes, 71 No
- Atlanta: 12 Yes, 88 No
- San Francisco: 100 No

Full Sample:
- Yes: 22%
- No: 78%
Market Research

- Only 2% of PCPs expressed skepticism with regard to drug research.
- Only 11% of referring PCPs expressed any concern about losing a patient to another practice.
- Nearly 75% had referred patients to clinical trials but only 25% had referred patients to AD trials. WHY?
Market Research

● Lack of awareness / information cited as #1 reason

● No idea how to find information about trials in / near their practice area

● Fear of side effects, risks
Aware of trials under way in your area?

Full Sample

Yes 21%

No 79%

<table>
<thead>
<tr>
<th>Location</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providence</td>
<td>25%</td>
<td>75%</td>
</tr>
<tr>
<td>Tulsa</td>
<td>30%</td>
<td>70%</td>
</tr>
<tr>
<td>Indianapolis</td>
<td>25%</td>
<td>75%</td>
</tr>
<tr>
<td>Atlanta</td>
<td>5%</td>
<td>95%</td>
</tr>
<tr>
<td>San Francisco</td>
<td>20%</td>
<td>80%</td>
</tr>
</tbody>
</table>
Market Research

- Majority of respondents could not name a single clinical trial database.
- Those who did refer patients to clinical studies cited colleague-to-colleague communication and conference attendance as primary sources of information about research and clinical study opportunities.
Pilot Program Components

- Outreach to physicians
- Outreach to patients, caregivers, social service providers and the public
- Utilized healthcare marketing agency specializing in patient recruitment
- Recruited a Clinical Studies Initiative Advisory Council
Outreach to Physicians

- Market research findings gave shape to the physician outreach component of the pilot program
  - Continuing Medical Education dinner presentations offered 1.5 CME units; 155 PCPs attended
  - Provided physician “Toolkits” containing brochures, flyers, posters
Outreach to patients, caregivers, etc.

- Mobilized volunteer task force of prominent researchers in each pilot city
  - Featured on brochures to provide local connection
  - Each recorded a radio spot appealing to patients and caregivers to learn about local clinical studies underway
  - Served as spokespersons with the media
Outreach to patients, caregivers, etc.

- Developed marketing materials that recognized diversity
  - Posters and brochures targeting Asians, African Americans and Hispanic populations
- Implemented comprehensive grassroots campaign executed by specialists
  - Recruited 76 partners, many with minority and/or faith-based affiliations
  - Attended hundreds of community events, varying in size from 25 to 5,000 participants
Outreach to patients, caregivers, etc.

- Implemented Web site enhancements and online promotions
  - Created user-friendly overlay of Clinicaltrials.gov
  - Implemented targeted search word promotions with Google, Yahoo and MSN, which linked to banner advertisements by searcher’s Zip code
  - Advertised on relevant Web sites including WebMD, e-medicine, Caregiver.com
Outreach to patients, caregivers, etc.

- Implemented a centralized toll-free Clinical Studies Hotline to provide general and specific information on clinical studies
  - Callers are asked about their familiarity with Association programs and services and are offered the option of a live transfer to the nearest chapter or a call-back at a more convenient time
Outreach to patients, caregivers, etc.

- Non-emergency calls to the Association’s 24-hour toll-free Helpline are closed with an inquiry as to whether the caller would like to learn about clinical study opportunities
  - Callers answering affirmatively are offered the option of a live transfer to the Clinical Studies Hotline or a call-back at a more convenient time
Outreach to patients, caregivers, etc.

- Public Relations
  - Interviews with Alzheimer’s Association chapter executives, Task Force Members, patients and caregivers
- Advertising
  - Print
  - Radio
  - Television
Current status and next steps...

- Six week advertising blitz
- Collection and analysis of metrics
- Evaluation of specific strategies and tactics
- Hopefully, roll out of Clinical Studies Initiative to additional markets
- Exploration of potential partnership opportunities