Clinical Studies Initiative Overview

Presented at the

ADC Education Core Leaders Meeting

September 19, 2008

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Why a Clinical Studies Initiative?

- Of 9,380 interventional trials under way at over 50,000 sites in the US, **80% are delayed** because of enrollment shortfalls
- Among trials that do not complete recruitment on time, **80% are delayed more than 1 month**
- In the past 20 years, the average number of patients needed per trial **increased from 1,700 to as many as 4,000**
- These grim statistics are worse for the 70 Phase II and III Alzheimer’s trials currently (or due to begin) recruiting in the US

Recruitment more challenging for AD

Why?

- Healthcare decisions often **made by proxy** and /or committee
- **Caregiver participation is almost always required** and many caregivers are already over-burdened, stressed & often in poor health themselves
- Physicians function as **gatekeepers**
- Trial design typically excludes both the very elderly as well as early onset populations when inclusion criteria specifies **ages 65-80**
- AD patients often have **exclusionary comorbidities**

Recruitment more challenging for AD

Healthcare decisions typically made by **proxy**

- A patient able to **understand informed consent is** often not considered at appropriate level of dementia for most studies
- Decision regarding clinical trial enrollment is understandably daunting and involves **weighing risks**, possible randomization to a **placebo** vs. **“benefits”**
- **Extended family** often involved in decision-making
- **“Payback”** is perceived differently compared to enrollment in a study for cancer
- **Decision by committee** in a slow process

Recruitment more challenging for AD

Enrolling a loved one in a clinical trial increases a caregiver’s burden because...

- 98% of all studies **require caregivers** to observe and evaluate the participant
- **Transportation** to and from study site often an issue
- Patients are often **agitated by changes** in routine
- Caregivers also fear that any change in medication or randomization to a placebo may trigger **behavioral changes** such as **agitation** or **aggression**

Recruitment more challenging for AD

Physicians function as gatekeepers

- Caregivers and family rarely exclude patient’s physician from decision-making process and his/her **opinion holds significant weight**
- Based on market research conducted by the Alzheimer’s Association in 2007, nearly 75% had referred patients to clinical trials but **only 25% had referred patients to AD trials**. WHY?
- **Lack of awareness / information** cited as #1 reason

Recruitment more challenging for AD

Physicians function as gatekeepers

- **No idea how to find information** about trials in / near their practice area
- Majority of respondents **could not name a single clinical trial database**
- Those who did refer patients to clinical studies cited a **preference for colleague-to-colleague communication and conference attendance** as favored sources of information about research and clinical study opportunities

Situation assessment in a nutshell

There is a critical shortage of volunteers for Alzheimer’s disease studies because…

- **More trials under way for AD** than ever before; need for the largest number of participants ever
- Prospective participant pool reduced by numerous **comorbidities** in an elderly population
- Caregivers and additional decision-makers represent target market for **recruitment messaging**
- As the cost of conducting clinical trials has risen, many **sponsors have reduced funding** for recruitment
- **Few physicians** are **referring patients** to Alzheimer’s clinical trials

The Alzheimer’s Association’s response

The Clinical Studies Initiative

- **An Association-wide commitment** to investigate, understand and address the factors contributing to a recruitment bottleneck
- A **campaign to raise awareness** of AD clinical trial opportunities **(without publicizing specific studies)** within the medical community and the general population
- An **opportunity to promote awareness of the Association** and **its local chapters** as a resource for patients, caregivers and physicians

Methodology

Pilot program began 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 population

Why a pilot program?

Need to **substantiate assumptions**

- Metrics would determine future of initiative
- Potential existed for future roll out to additional chapters in additional markets
- The sooner we could show a positive outcome, the sooner we could share results with donors and potential partners

Smaller scale **facilitated faster start**

Pilot program components

- Market Research
- Creation of a Clinical Studies Initiative Advisory Council
- Outreach to physicians
- Outreach to patients, caregivers, and the public
- Utilization of healthcare marketing agency specializing in patient recruitment
- Evaluation of metrics and feedback

Review of initial market research results

- **Lack of awareness / information cited** as #1 deterrent to referrals
- Respondents had **no idea how to find information** about trials near their practices
- Majority of respondents (79%) **could not name a single clinical trial database**
- Physicians cited a **preference for colleague-to colleague communication**
- **Research shaped our initial physician outreach program** as it will with the design of the Initiative’s next phase

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.

- Implemented **Web site enhancements** and online promotions
- Implemented a centralized **toll-free Clinical Studies Hotline** to provide general and specific information on clinical studies
- Developed marketing materials that recognized **diversity**
- Implemented comprehensive **grassroots campaign** executed by specialists

Outreach to patients, caregivers, etc.

Public Relations

- **Interviews** with Alzheimer’s Association chapter executives, Task Force Members, patients and caregivers

Advertising

- Print
- Radio
- Television

Pilot program physician outreach results

Post pilot program site survey response

Compared to last year, has the number of referrals from physicians increased? PS 23% YES NPS 7%

Currently, is it very difficult for your site to enroll participants into Alzheimer’s research studies?
PS 12% YES NPS 50%

Compared to this time last year, has the number of calls about Alzheimer’s research participation increased? PS 38% YES NPS 7%

Compared to this time last year, has the number of people you screened for AD studies increased?
PS 54% YES NPS 14%

PS = 26 Responding sites **NPS = 14 Responding sites**

Next Steps

Based on the success of the pilot program…

- We are **adding 10 chapters** to the original five and will make an official announcement shortly
- We are implementing **alternatives to outsourcing** for several key aspects of Phase 1 of the full scale Initiative including adding a full time public relations practitioner and bringing call center screening and fulfillment in house
- The next phase will focus even more heavily on **outreach to the medical community** and **minority and under-served populations**

Next Steps

Market research

- Will focus on the roles played by patients, caregivers, families and medical professionals with regard to **making decisions about study enrollment**
- Research may also **target individuals who chose NOT to enroll** although they were eligible to do so
- Because retention is also major issue in AD trials, we are considering interviews with **individuals who voluntarily dropped out** during the study