

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***

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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?

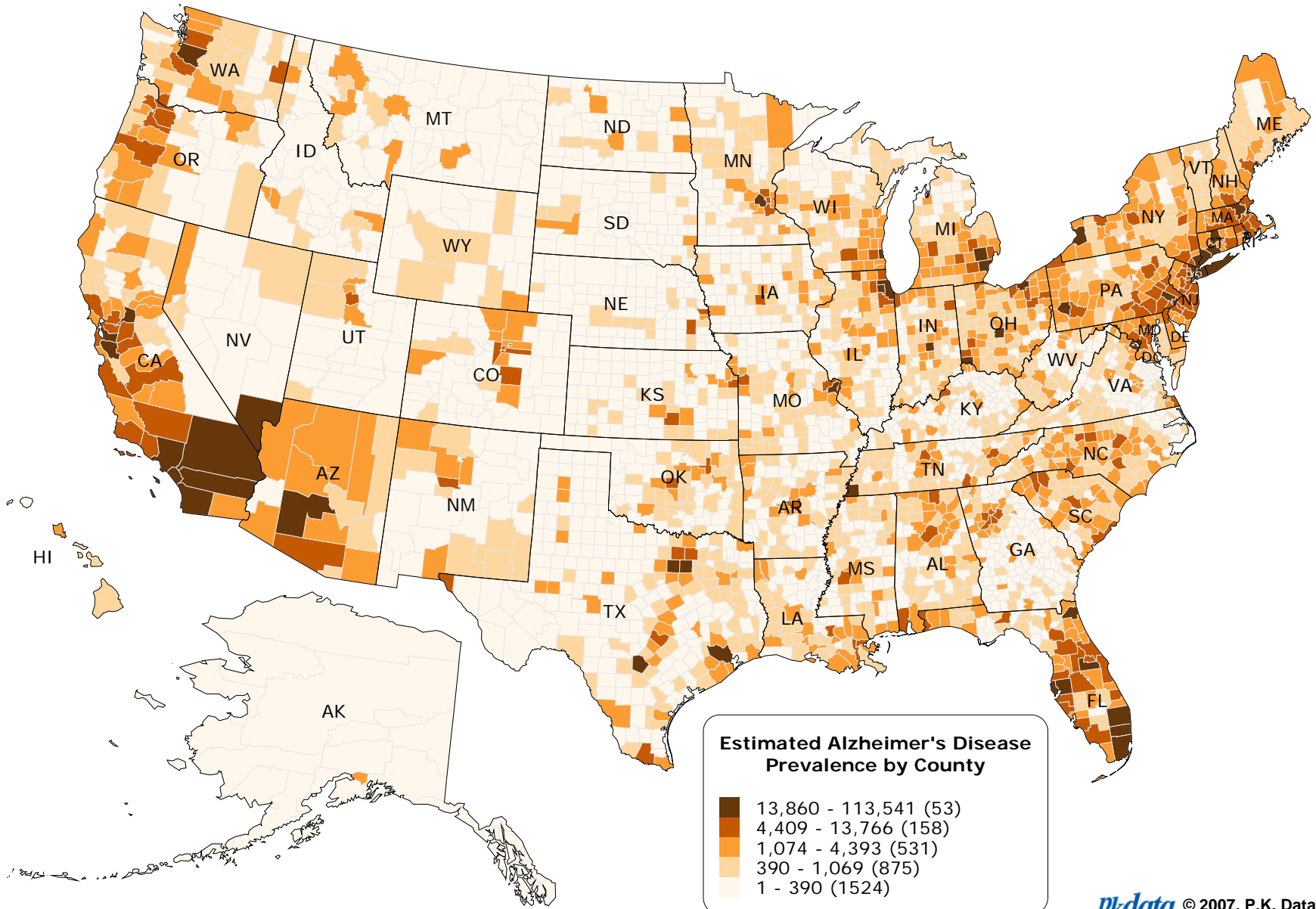
- Need to substantiate assumptions
 - Metrics will determine future of initiative
 - Potential for roll out to additional markets
 - Results will pave way for donors and partnerships
- Smaller scale facilitated faster start

What we knew. . .

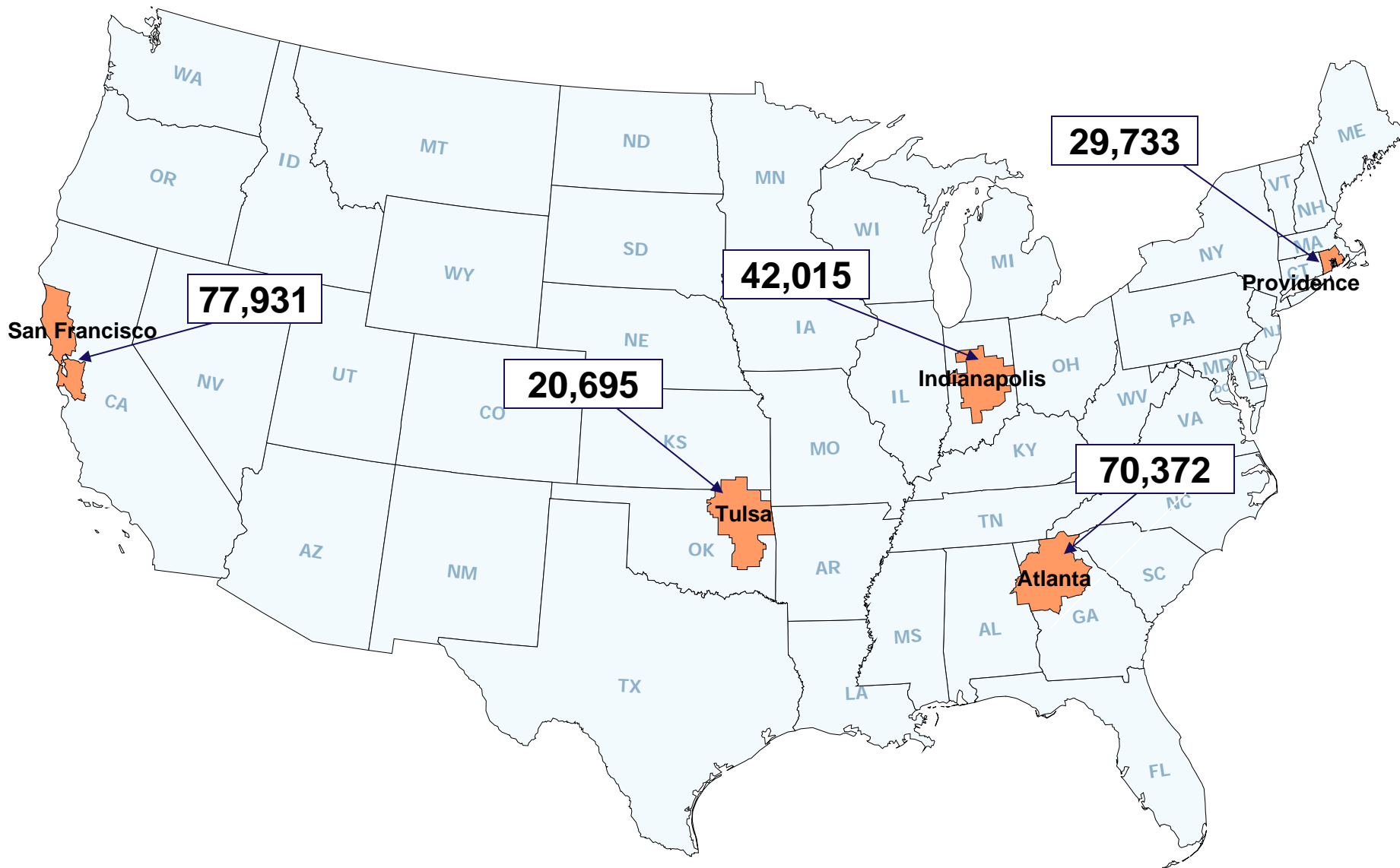
- AD trials among most difficult to enroll
 - Healthcare decisions by proxy
 - Caregiver participation required
 - Some require “washout” period
 - Many are placebo-controlled
 - Physicians function as gatekeepers
 - Elderly target population frequently present with exclusionary co-morbidities.

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



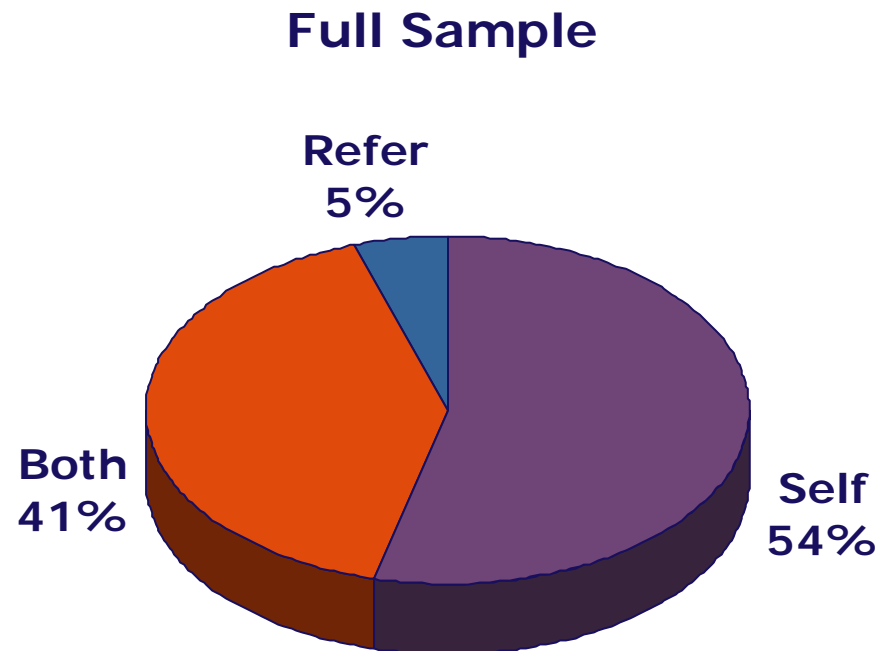
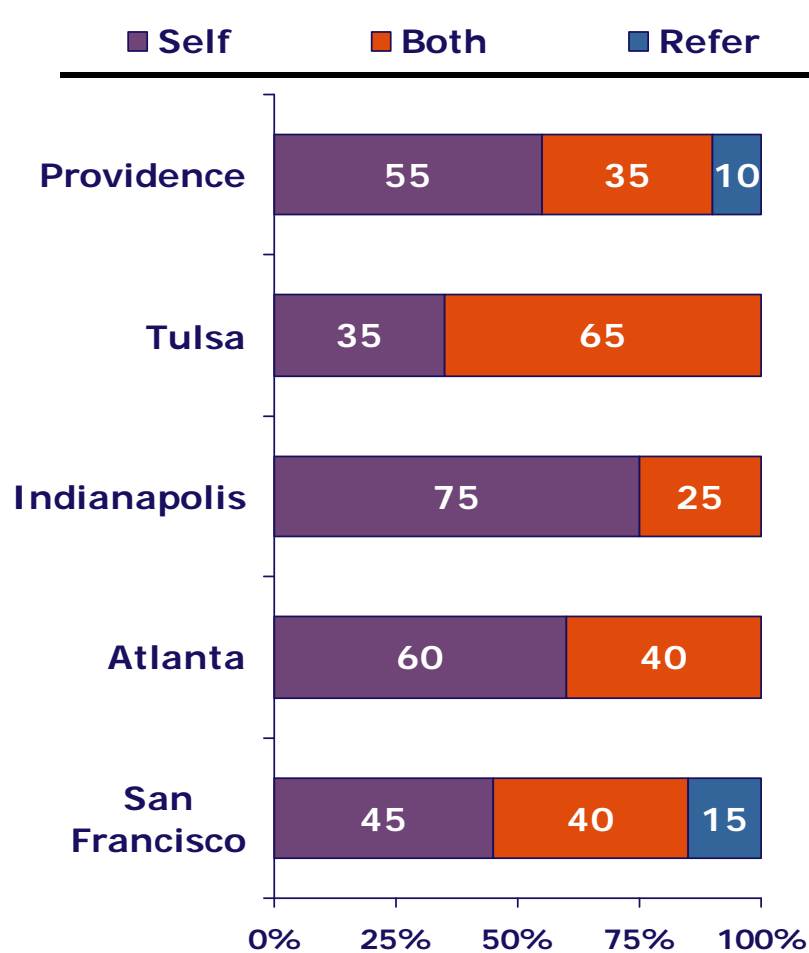
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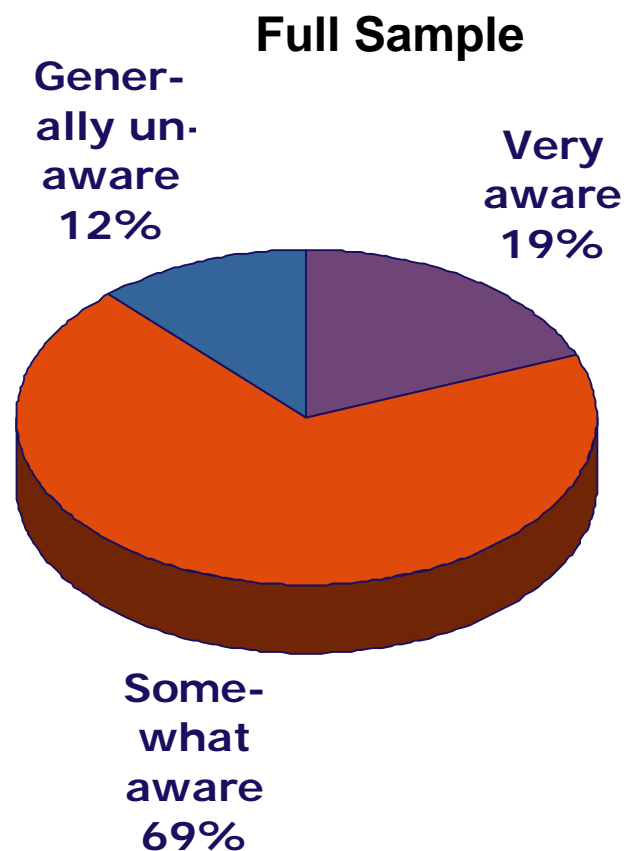
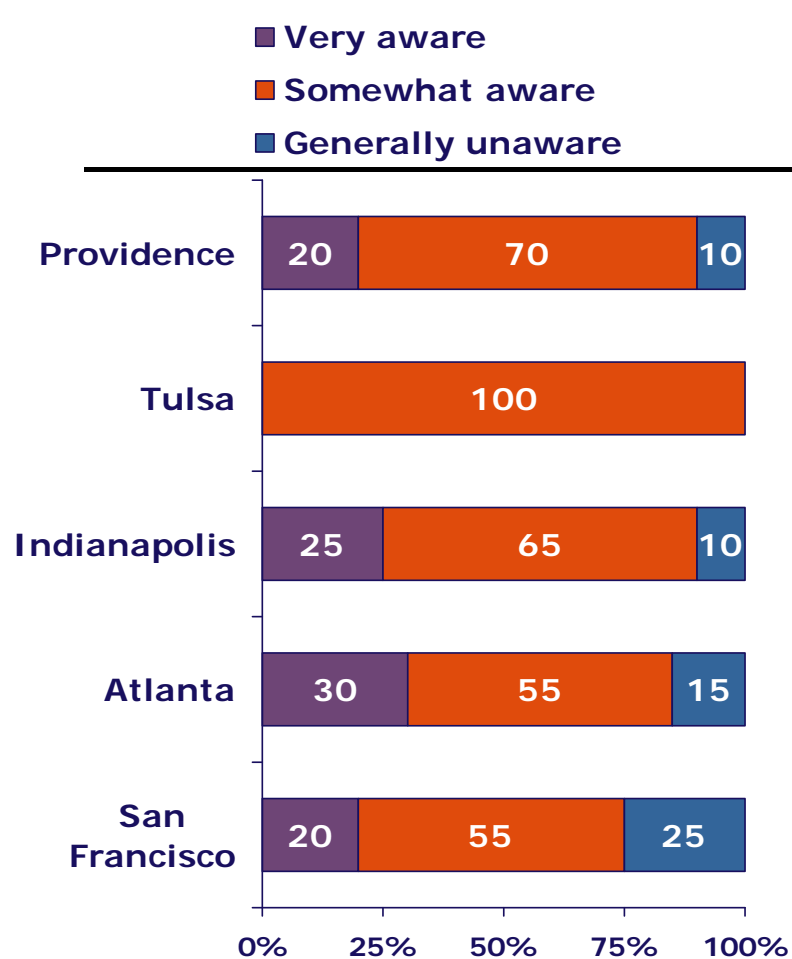
Market research interviewees

- 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?

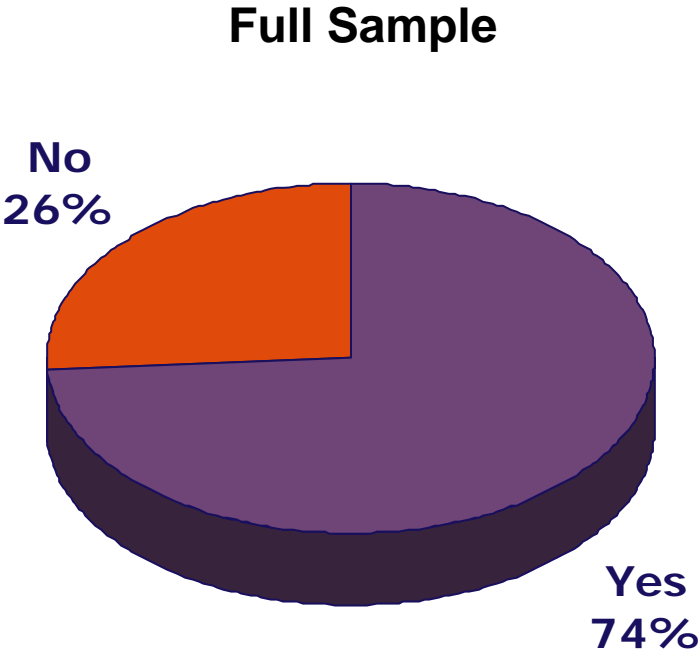
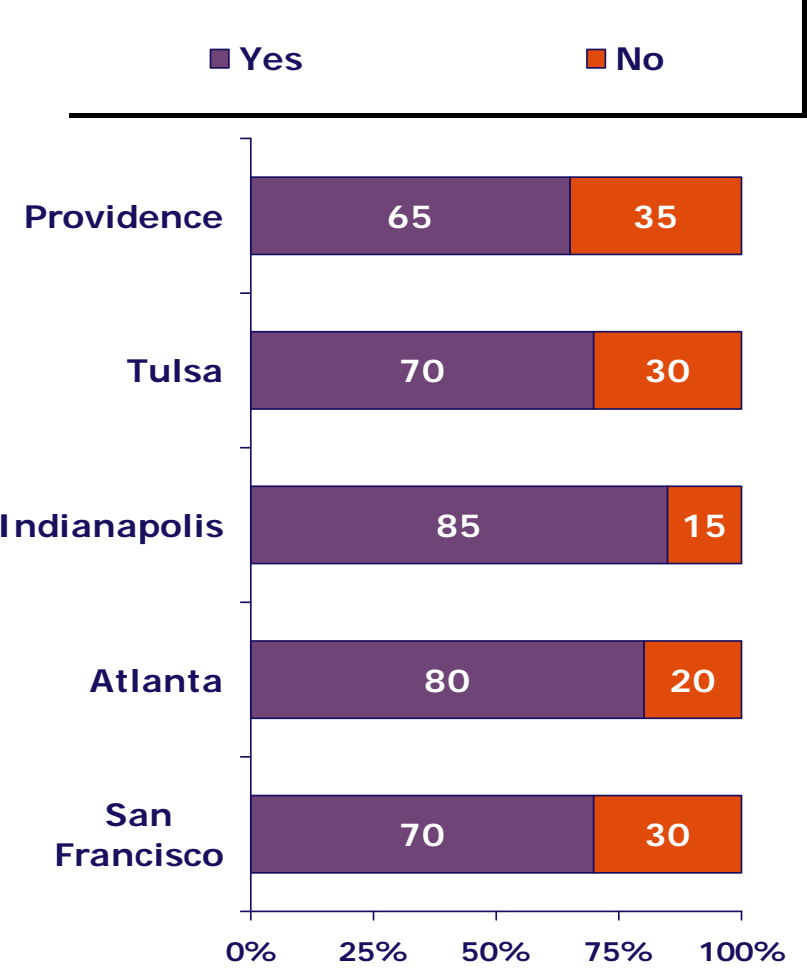


Awareness of current AD research

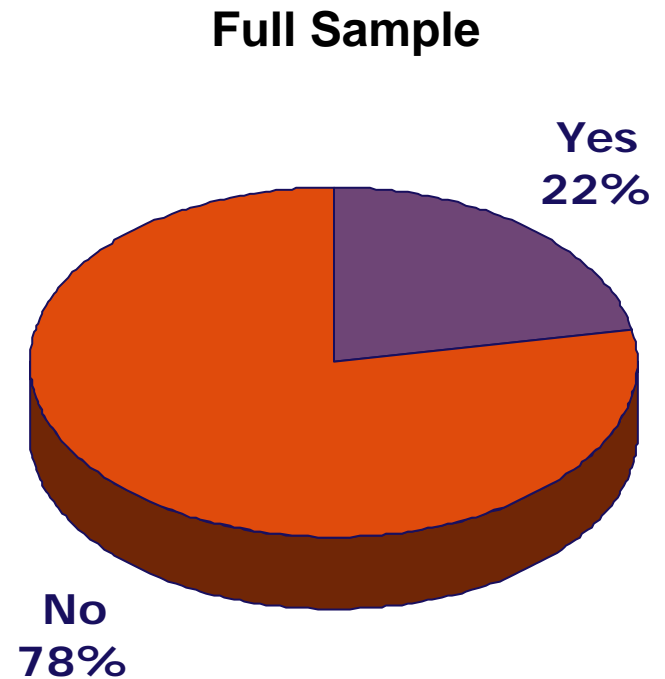
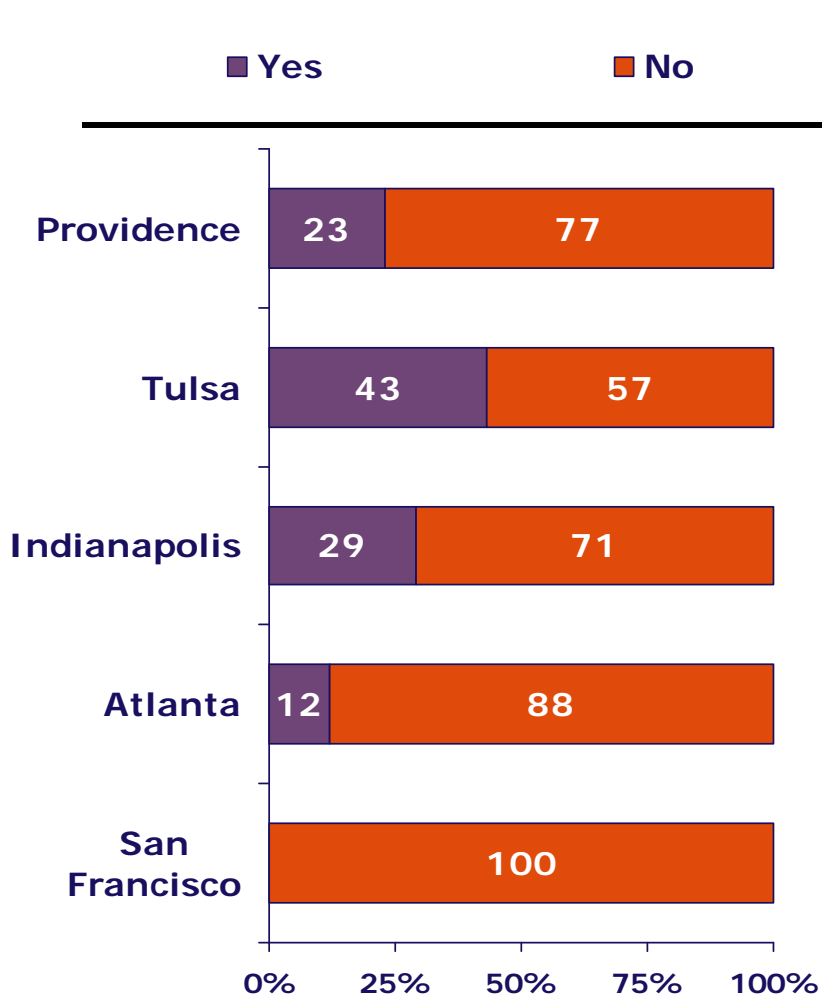


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Referred patients to ANY clinical trial?



Referred patients to a trial for AD?



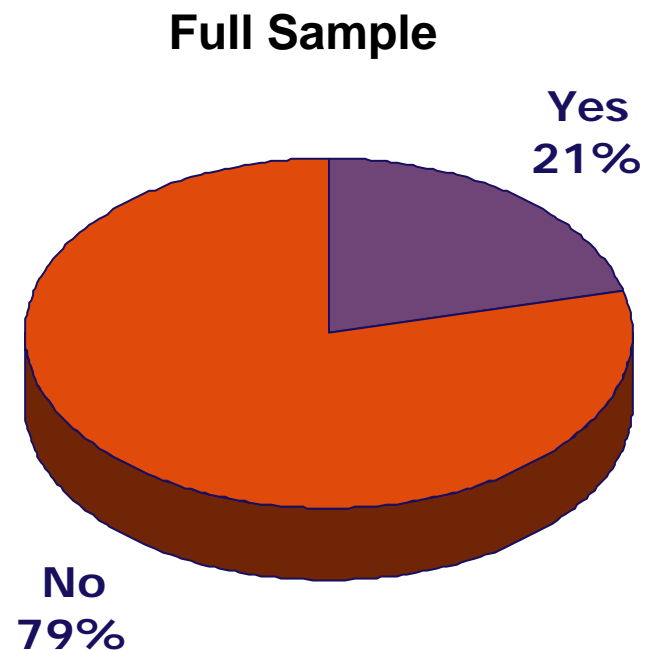
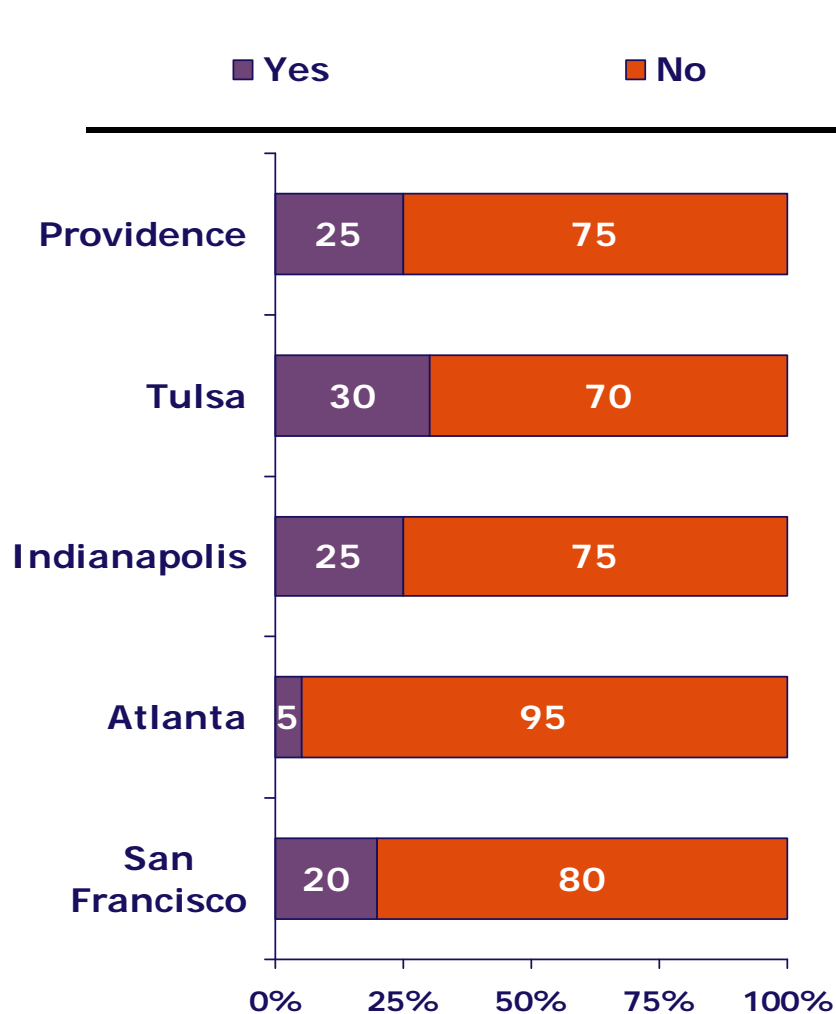
Market Research

- 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?



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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