

**UNDERSTANDING THE TYPES AND
BENEFITS OF CLINICAL TRIALS**

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**WHAT DOES THIS NUMBER
REPRESENT?**

5,300,000

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5,300,000

The number of cases of Alzheimer's
Disease in the USA.

WHAT DOES THIS NUMBER
REPRESENT?

69

WHAT DOES THIS NUMBER
REPRESENT?

69 seconds

On the average, the amount of time that
passes before a new person is diagnosed
with Alzheimer's Disease in the USA.

WHAT DOES THIS NUMBER
REPRESENT?

15,000,000

WHAT DOES THIS NUMBER
REPRESENT?

15,000,000

The number of unpaid caregivers in the
USA.

WHAT DOES THIS NUMBER
REPRESENT?

\$202,000,000,000

WHAT DOES THIS NUMBER
REPRESENT?

\$202,000,000,000

The value of unpaid care for patients with
Alzheimer's Disease.

WHAT DOES THIS NUMBER
REPRESENT?

\$7,900,000,000

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REPRESENT?

\$7,900,000,000

Additional costs to the health care system
for caregiver health needs because of
their caregiver role.

WHAT DOES THIS NUMBER
REPRESENT?

\$183,000,000,000

WHAT DOES THIS NUMBER
REPRESENT?

\$183,000,000,000

Cost per year for Alzheimer's Disease.

WHAT DOES THIS NUMBER
REPRESENT?

\$630,000,000

WHAT DOES THIS NUMBER
REPRESENT?

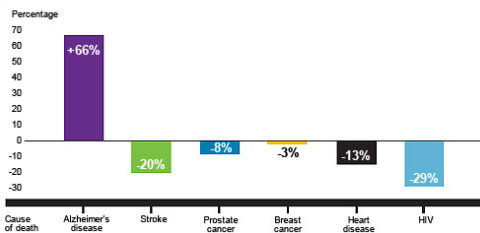
\$630,000,000

Annual research budget from the National
Institutes of Health.

\$183,000,000,000

\$630,000,000

Changes in Selected Causes of Death, 2000-2008



Benefits of Participation

- You can play a more active role in your own health care.
- You can gain access to potential treatments before they are widely available.
- You can receive expert medical care at leading healthcare facilities — often free of cost — while participating in important medical research.
- You can help future generations — your children and grandchildren — by contributing to Alzheimer research.

Risks of Participation

- There may be unpleasant or even serious side effects related to the potential treatments(s) being studied.
- The experimental treatment may not be effective.
- Consent form delineates the risks.

STAGES OF DRUG RESEARCH

- **Preclinical studies** in laboratories establish a scientific basis for believing a drug is reasonably safe and may be effective.
- **Phase I trials**, the first stage of human testing, typically involves fewer than 100 volunteers. These studies look at the risks and side effects of a drug. Participants at this phase are healthy volunteers.
- **Phase II trials** enroll up to a few hundred volunteers who have the condition the drug is designed to treat. These studies provide further information about safety and help to determine the best dosage of a drug. Phase II trials are generally too small to provide clear evidence about a treatment's benefit.

STAGES OF DRUG RESEARCH

- **Phase III trials** enroll several hundred to thousands of volunteers, often at multiple study sites worldwide. They provide the chief evidence for safety and effectiveness that the FDA will consider in deciding whether to approve a drug.
- **Phase IV trials**, also called post-marketing studies, are often required by the FDA after a drug is approved. During this phase, researchers continue to monitor the health of people taking the medication to gain further insight into its long-term safety and effectiveness.

FEATURES OF CLINICAL TRIALS

- Placebo-controlled
- Double-blind
- Cross-over
- Open labels

NON-DRUG CLINICAL TRIALS


- Effects of exercise on cognition, hippocampal perfusion.
- Effects of cognitive stimulation or training on clinical course of symptoms.
- Effects of caregiver education on costs of care, quality of life.

WHAT DOES THIS NUMBER
REPRESENT?

\$75,000,000,000

Annual savings to the health care system
with early diagnosis, caregiver education
and support.

TRIAL MATCH

- Make it easier to identify clinical trials for which one might qualify near their home.
- www.alz.org
- 
- 50 Clinical Trials active in Texas today.

UNT-HSC BRAIN BANK

- Need for normal samples
- Need for clinical data (including memory and other cognitive testing)
- A member of Texas Alzheimer's Research Consortium (TARC)
