



## Clinical Research Charts and Statistics

The charts and statistics below have been collected through CISCRP studies, surveys and research.

If you have any questions about these charts and statistics, or would like to suggest useful information to include, please contact us at [info@ciscrp.org](mailto:info@ciscrp.org)

Visit [www.ciscrp.org](http://www.ciscrp.org) for news and updates about our nationally recognized programs and events.

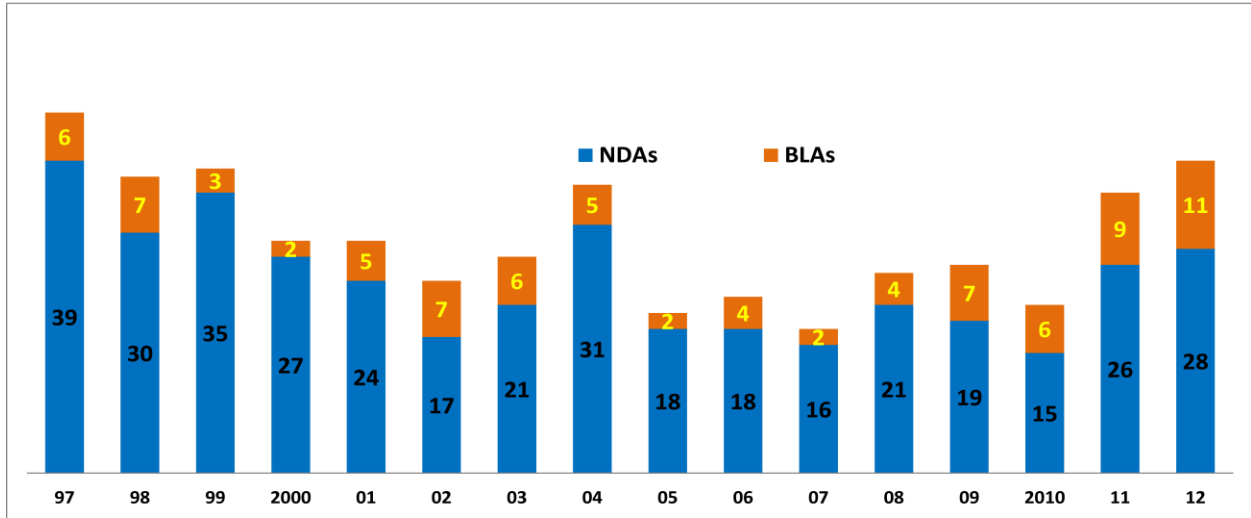
---

**The Center for Information and Study on Clinical Research Participation (CISCRP)**

**501(c)(3) nonprofit organization**

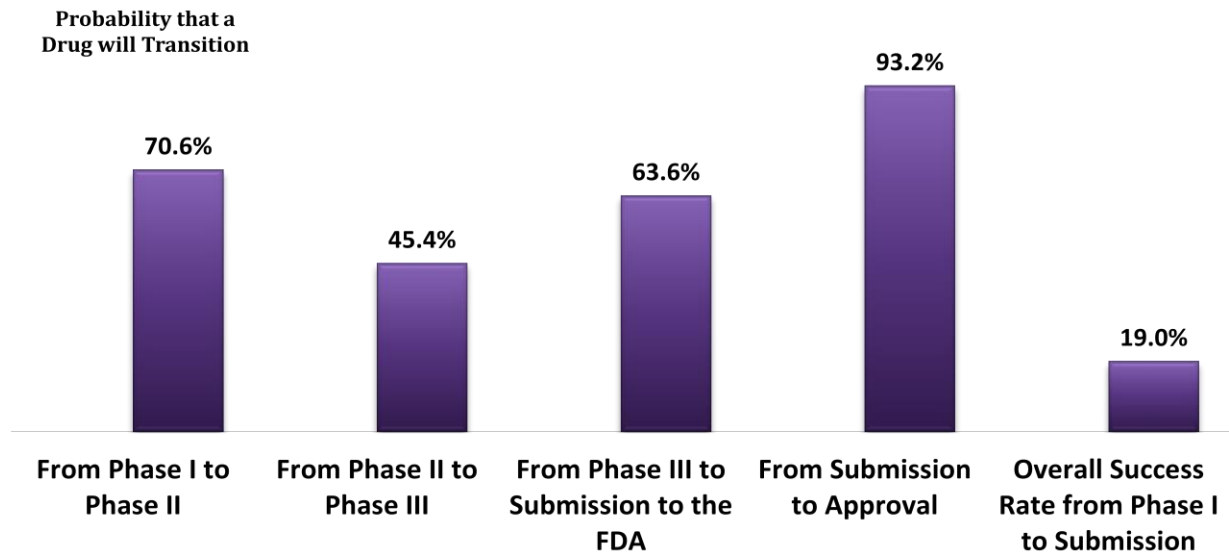
**Support our mission to educate and inform on clinical research participation!**

# Annual FDA Approvals of New Drugs and Biologics



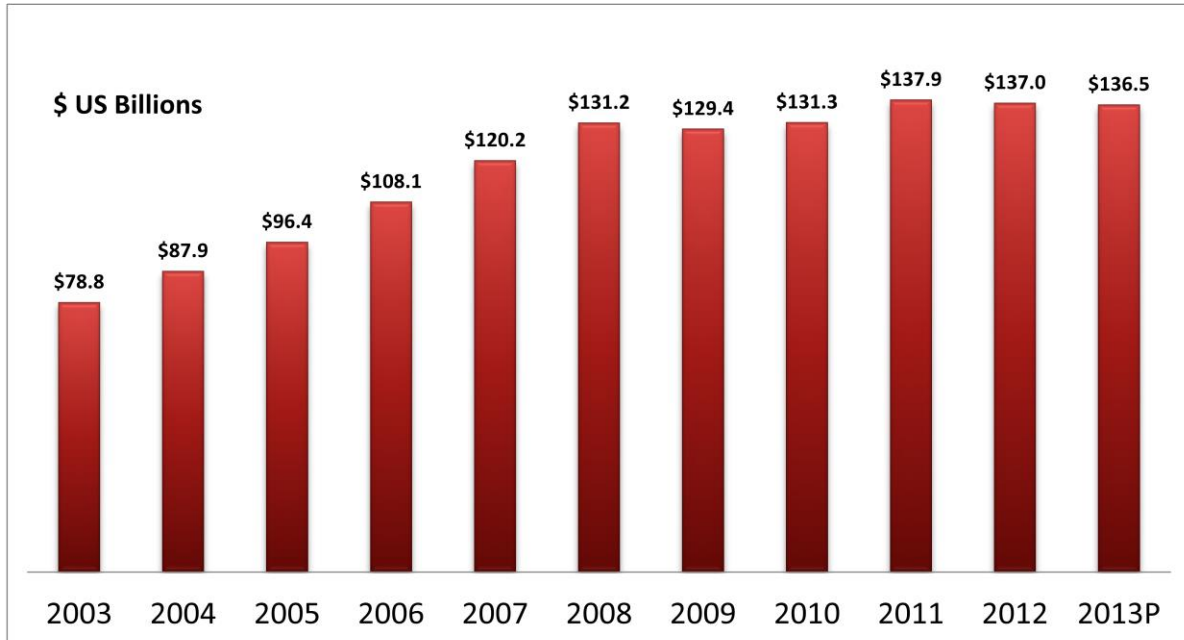
Source: FDA

# Success Rates by Phase for Investigational Drugs



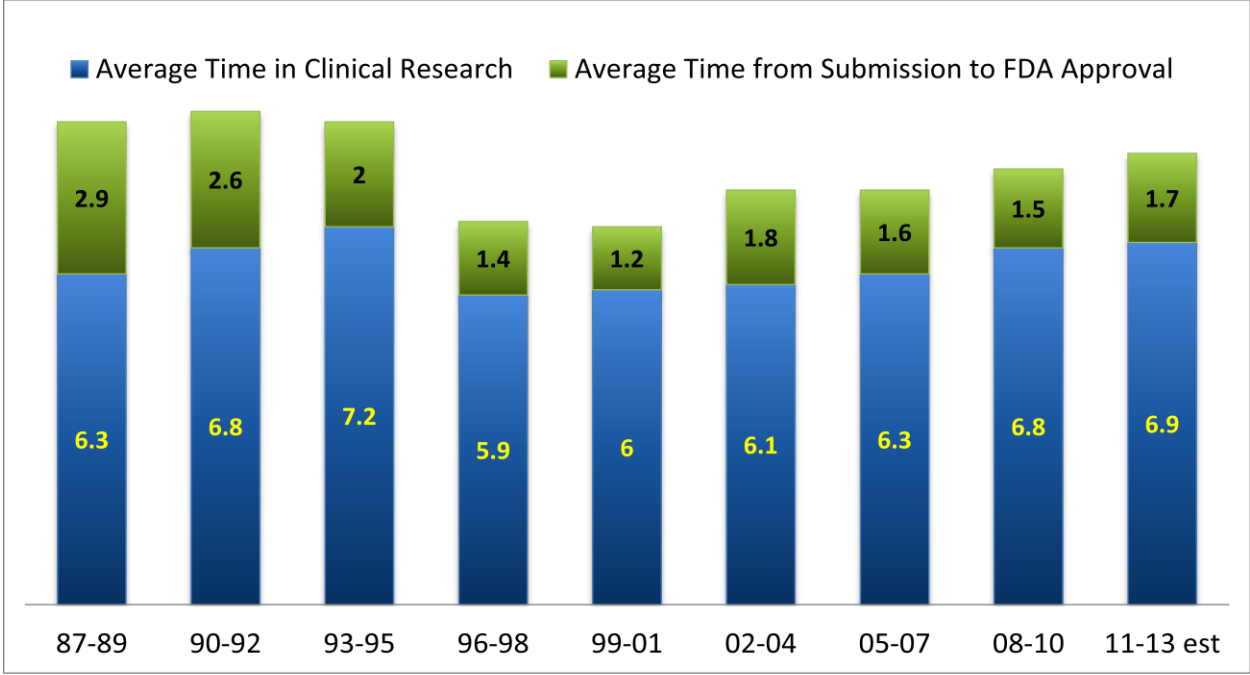
Source: Tufts CSDD

# Growth in Global Spending on Drug Development



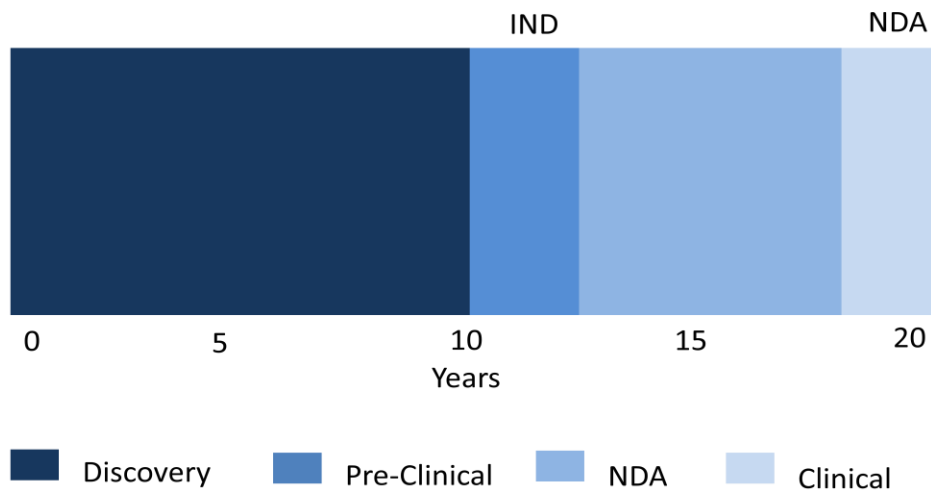
Source: EvaluatePharma

# Time in Years from the Beginning of Clinical Research to FDA Approval



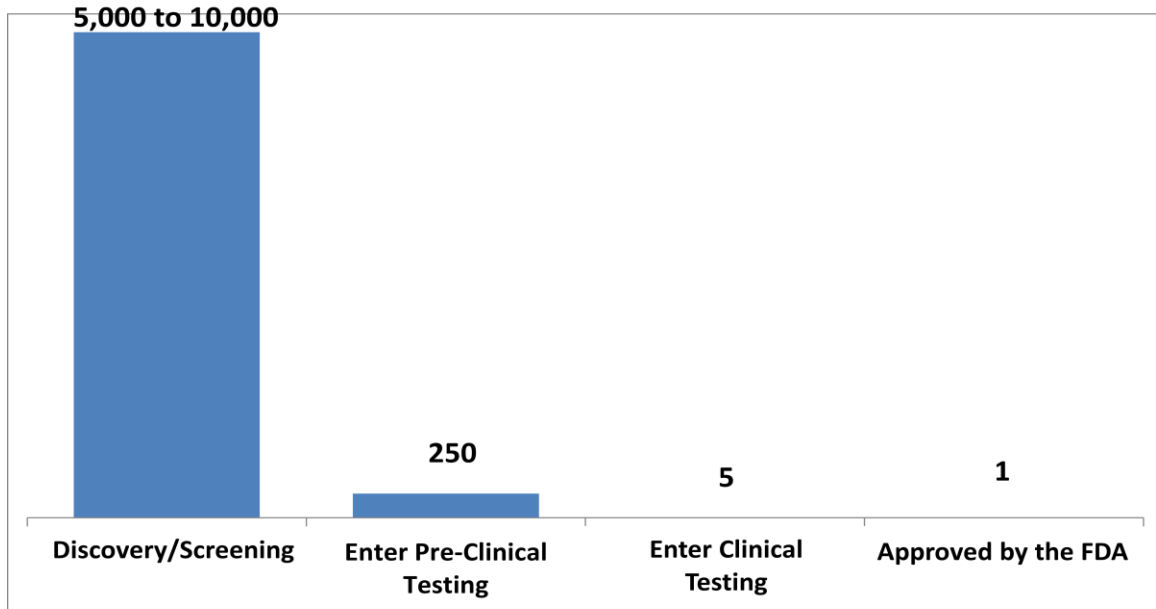
Source: Tufts, CSDD

# A Long and Complex Process



Source: Food and Drug Administration

# Very Few Investigational Drugs Reach the Final Approval Stage



Source: PhRMA,  
CSDD

## Examples of the Duration and Size of Drugs Successfully Completing Clinical Trials

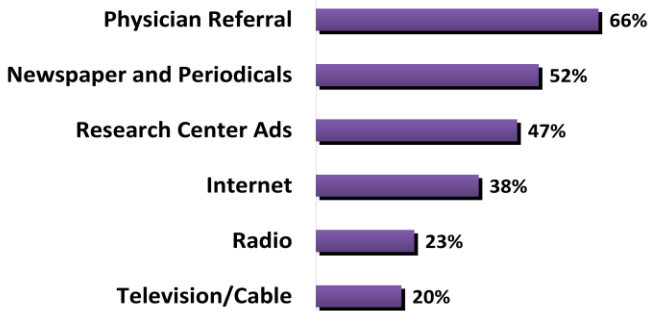
Drug Name	Treatment for	Years in Clinical Trials	Number of Study Volunteers
Allegra	Seasonal allergy relief	2	3,600
Celebrex	Rheumatoid arthritis	3	13,000
Lipitor	High cholesterol	2.5	20,000
Prilosec	Ulcers, GERO	4	4,000
Viagra	Erectile dysfunction	2.5	3,000
Vibativ	Skin infection	7.2	1,794
Vioxx	Osteoarthritis	4	10,000
Zocor	High cholesterol	2.5	20,000
Zytiga	Prostate cancer	5.3	1,195

Source: CISCRP



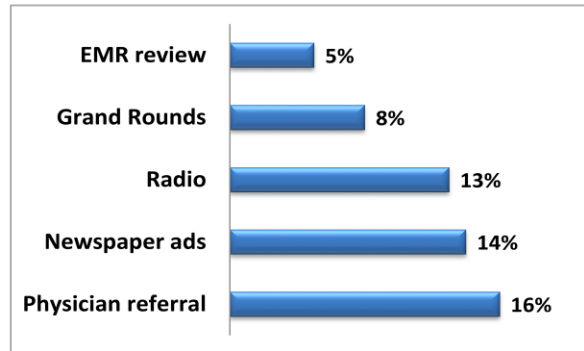
# \$1.2 billion Spent on Patient Recruitment

## Decentralized Recruitment Approaches



~ \$750 million (US) spent in 2012

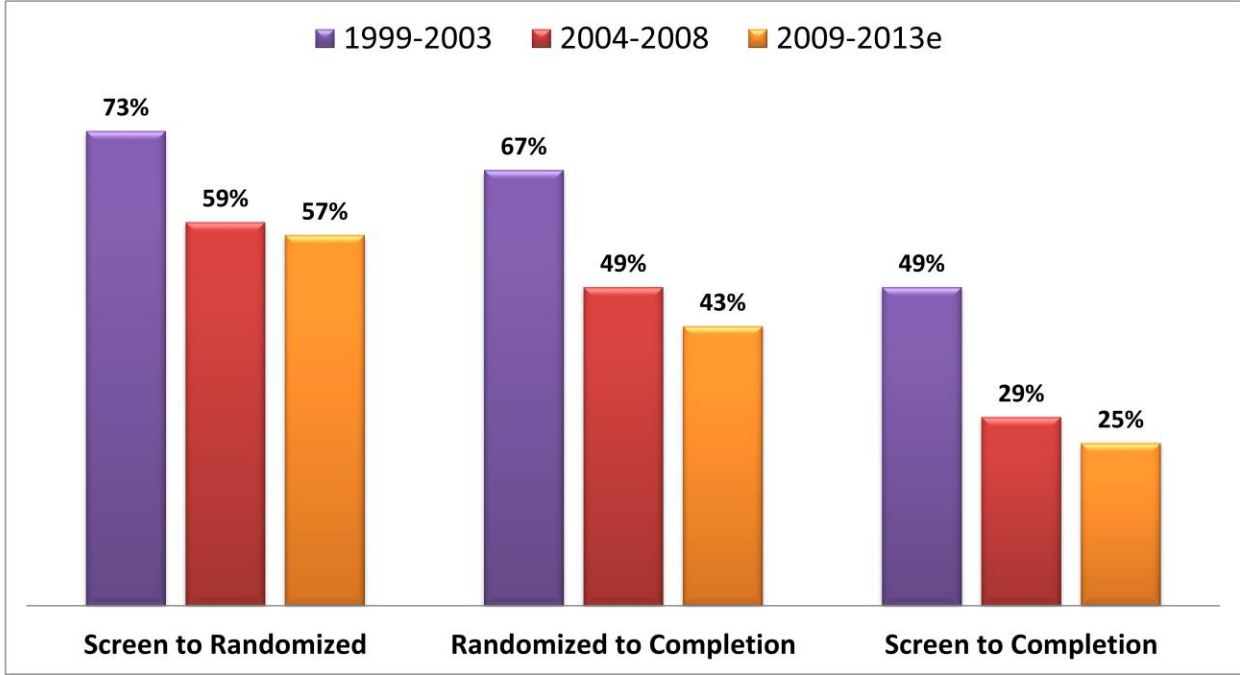
## Centralized Recruitment Approaches



~ \$400 million (US) spent in 2012

Source: Tufts CSDD, 2010 Survey of 3,516 Global Sites and 2012 survey of 48 sponsors and CROs

# Aggregate Patient Recruitment Success Rates



Source: Tufts CSDD; N=3,534 phase II-IV protocols

# Study Enrollment Cycle Times

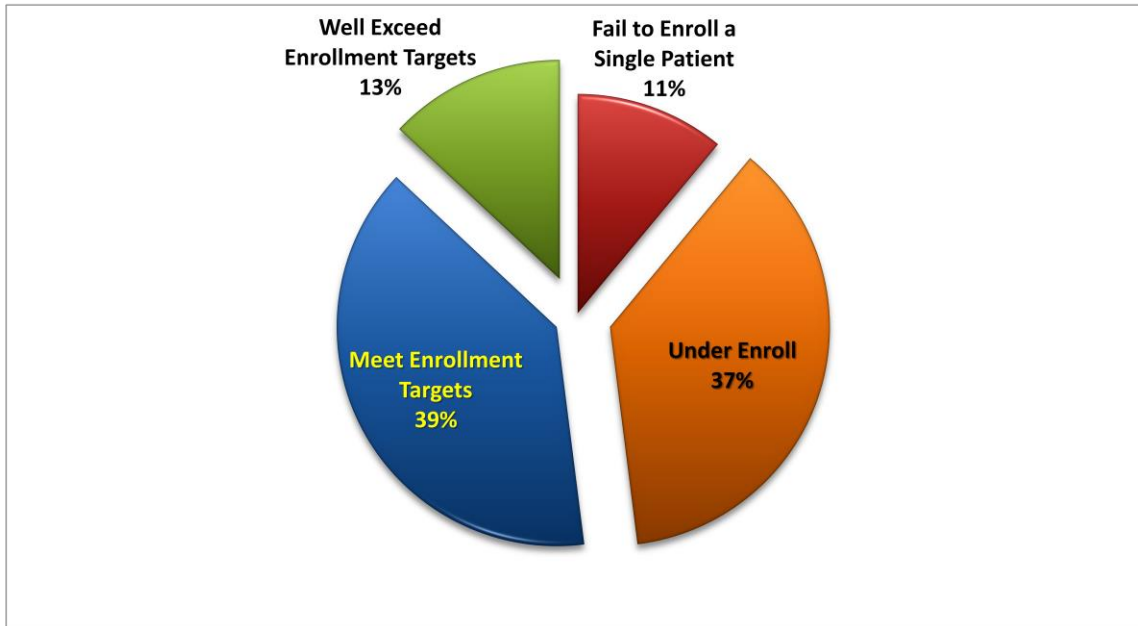
	2012 Screen to Completion Rates	Increase in Planned Study Duration to Reach Target Enrollment
Overall	56%	94%
Cardiovascular	59%	99%
CNS	61%	116%
Endocrine/Metabolic	41%	113%
Oncology	78%	71%
Respiratory	59%	95%

\* Does not include screen failure rates

Source: Tufts CSDD, 2012

# Investigative Site Enrollment Performance

(N= 15,965 sites participating in 153 global phase II and III clinical trials)



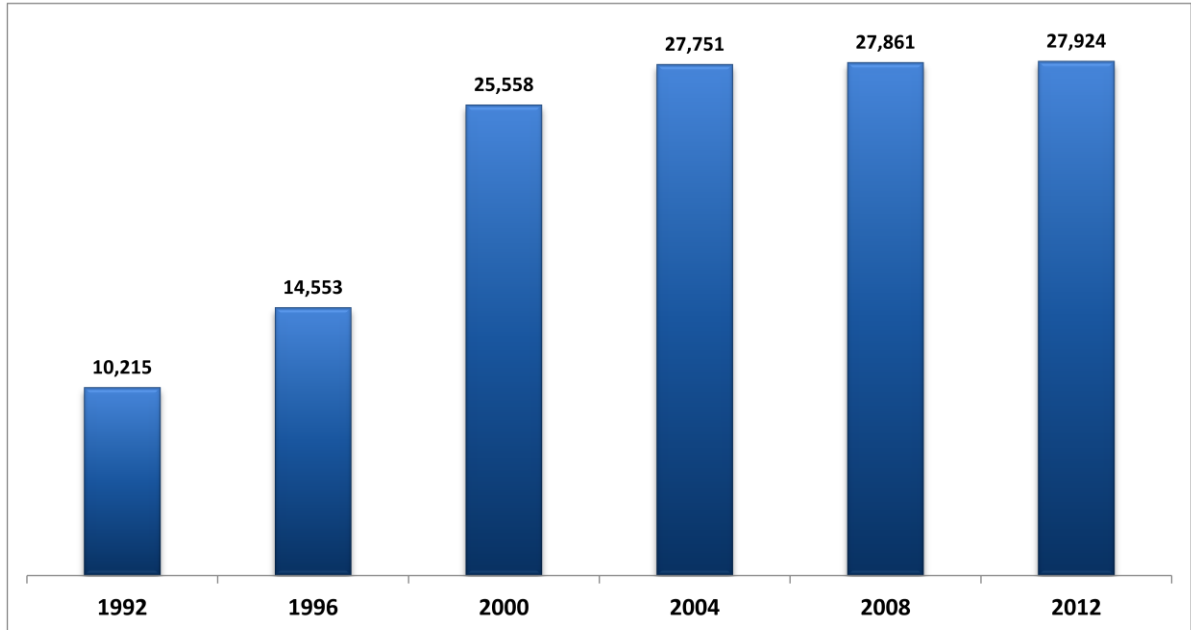
Source: Tufts CSDD, 2011

# A 'Typical' Phase III Protocol

	2002	2012
Total Number of Endpoints	7	13
Total Number of Procedures	106	167
Total Number of Eligibility Criteria	31	50
Total Number of Countries	11	34
Total Number of Investigative sites	124	196
Total Number of Patients Randomized	729	597
Total Number of Data Points Collected*	N/A	929,203

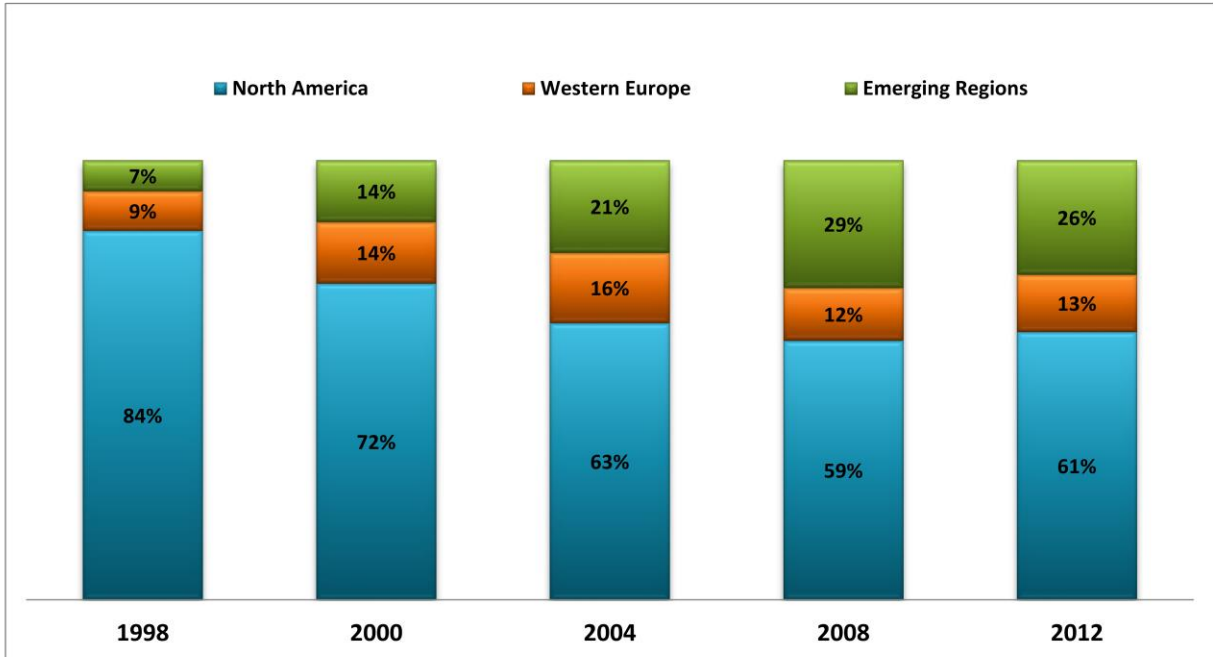
*Source: Tufts CSDD; \*Medidata*

# Unique Investigators Filing Form 1572s World Wide



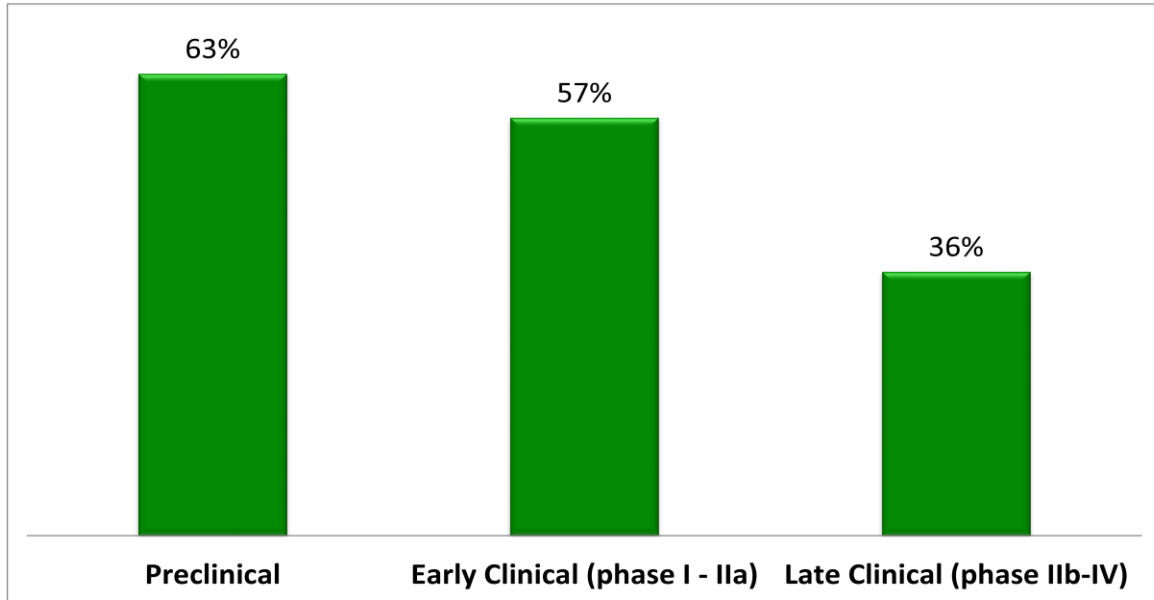
Source: FDA's Bioresearch Monitoring Information System File (BMIS)

# Global Distribution of FDA-Regulated Investigators



Source: Tufts CSDD

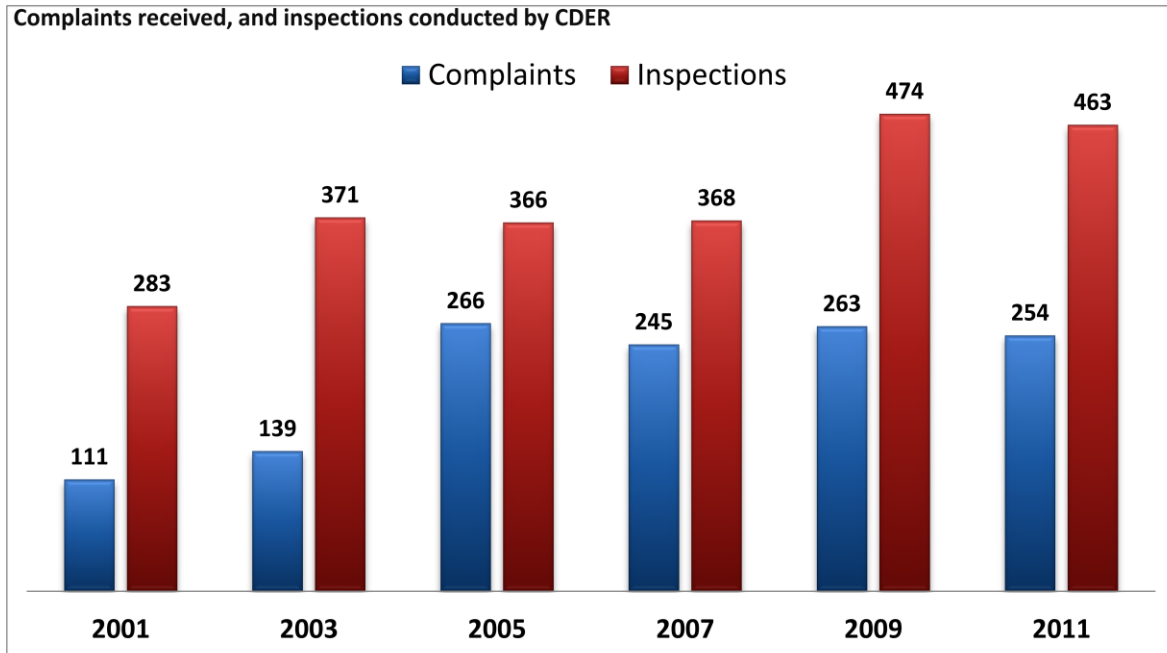
# Average Proportion of Drugs per Company Pipeline Relying on Biomarker Data



Source: Tufts CSDD

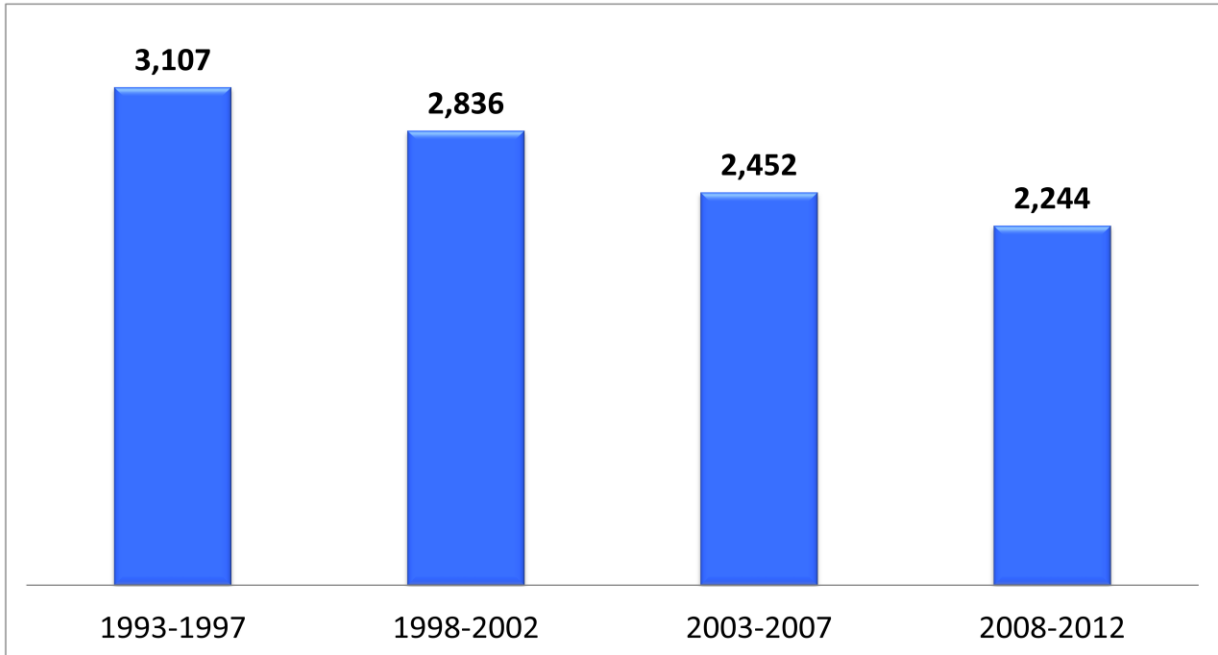


# High Volume of Complaints and Inspections



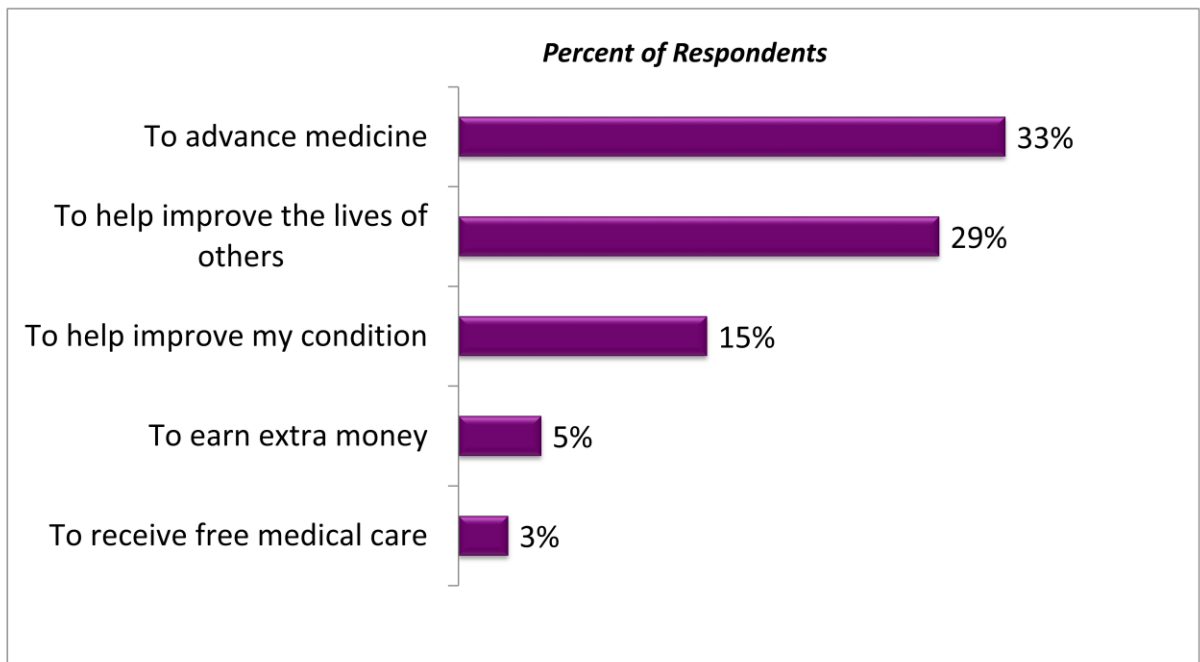
Source: FDA Office of Compliance

# Decreasing Average Number of Patients per NDA



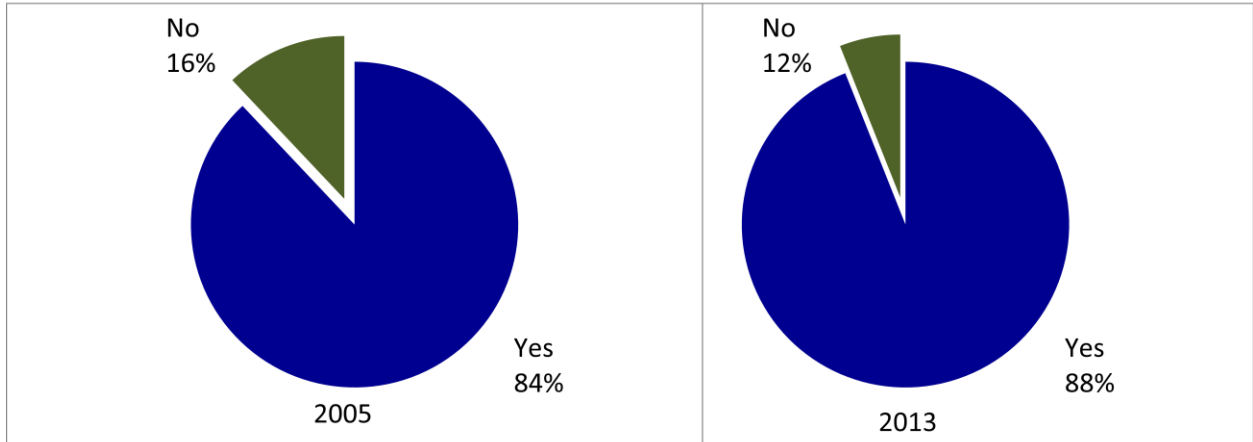
Source: CenterWatch, 2012

# Top Reasons People Choose to Participate in Clinical Trials



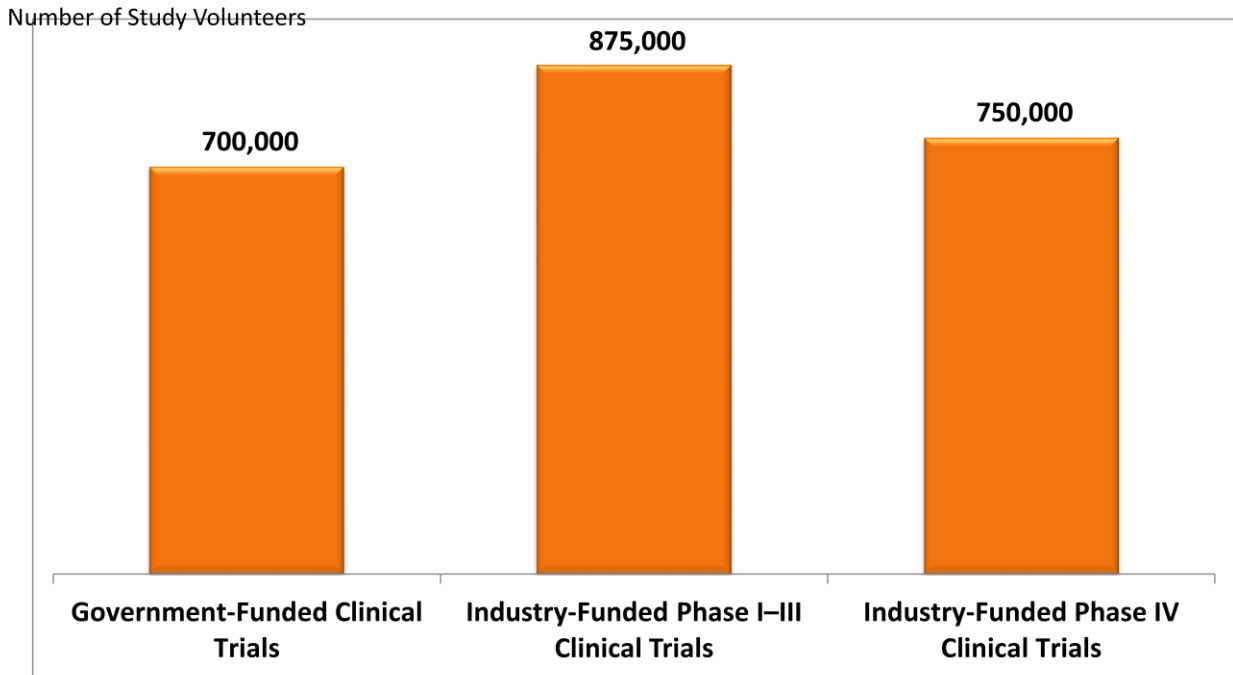
Source: CISCRP, 2013; N=5,701 people worldwide

## The Majority of Volunteers Would Participate in a Clinical Trial Study Again



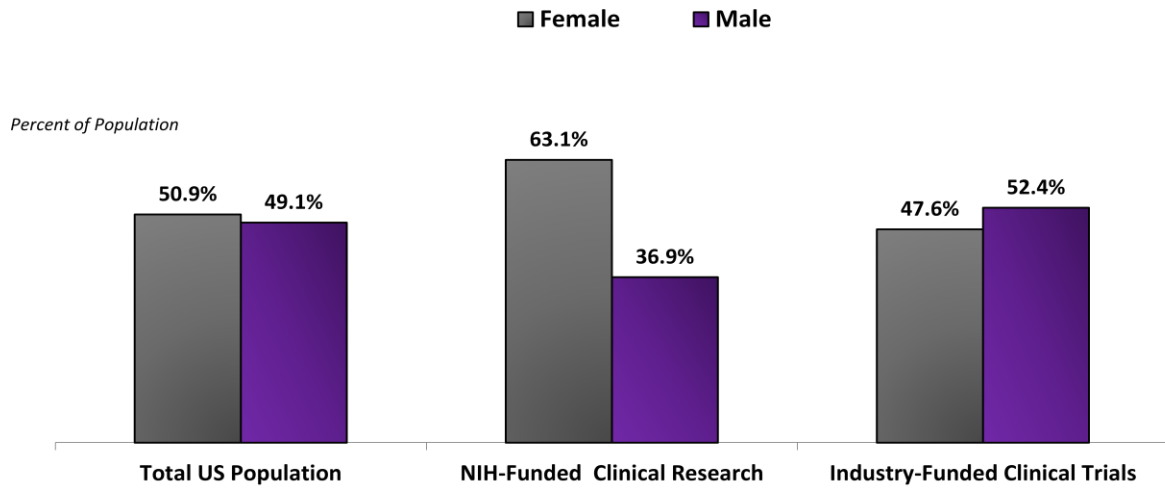
Source: CISCRP, 2013; N=5,701; HarrisInteractive, 2005; N=2,261 2005

# Estimated Total Volunteers Completing Clinical Trials in 2013



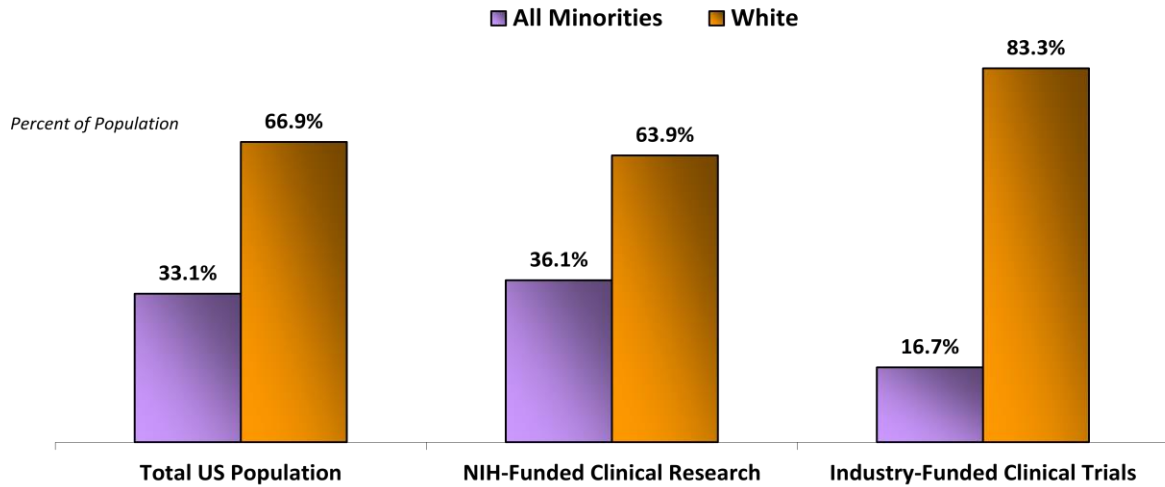
Source: CISCRP, 2014

# Proportion of Study Volunteers by Gender in Clinical Research Studies



Sources: US Census Bureau; NIH; Tufts CSDD 2012

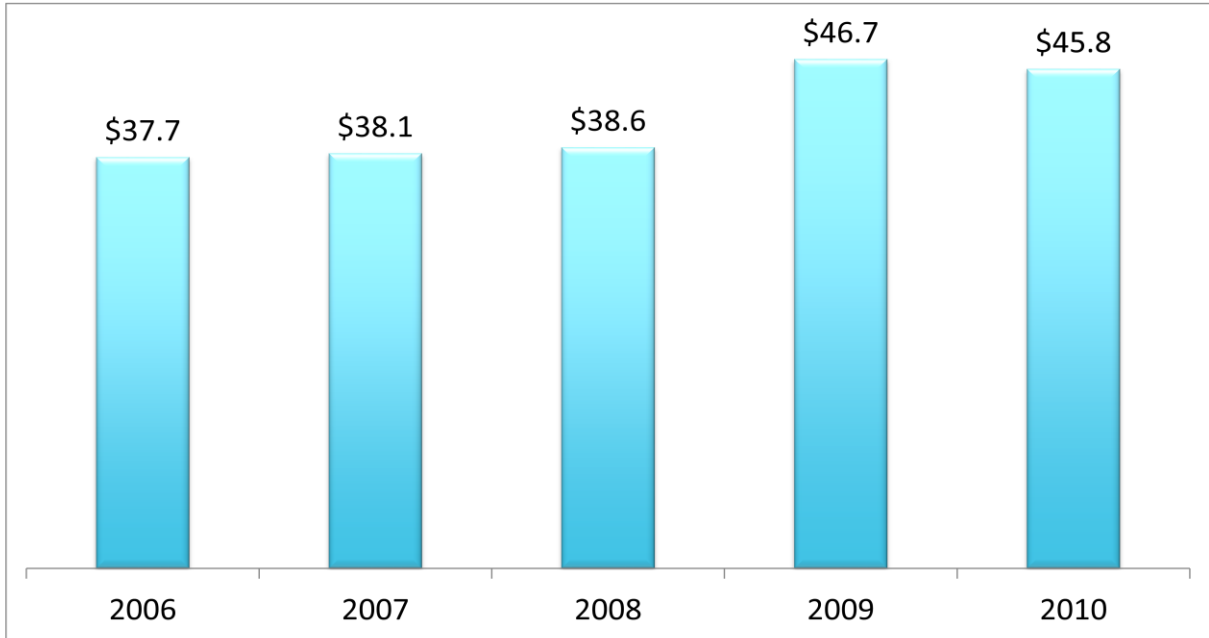
# Proportion of Study Volunteers by Race and Ethnicity in Clinical Research Studies



Sources: US Census Bureau; NIH; Tufts CSDD 2012

## Total US Government Spending on Health Related Research

(Dollars in \$US Billions)



Source: Research!America



# US Clinical Trial Grant Spending

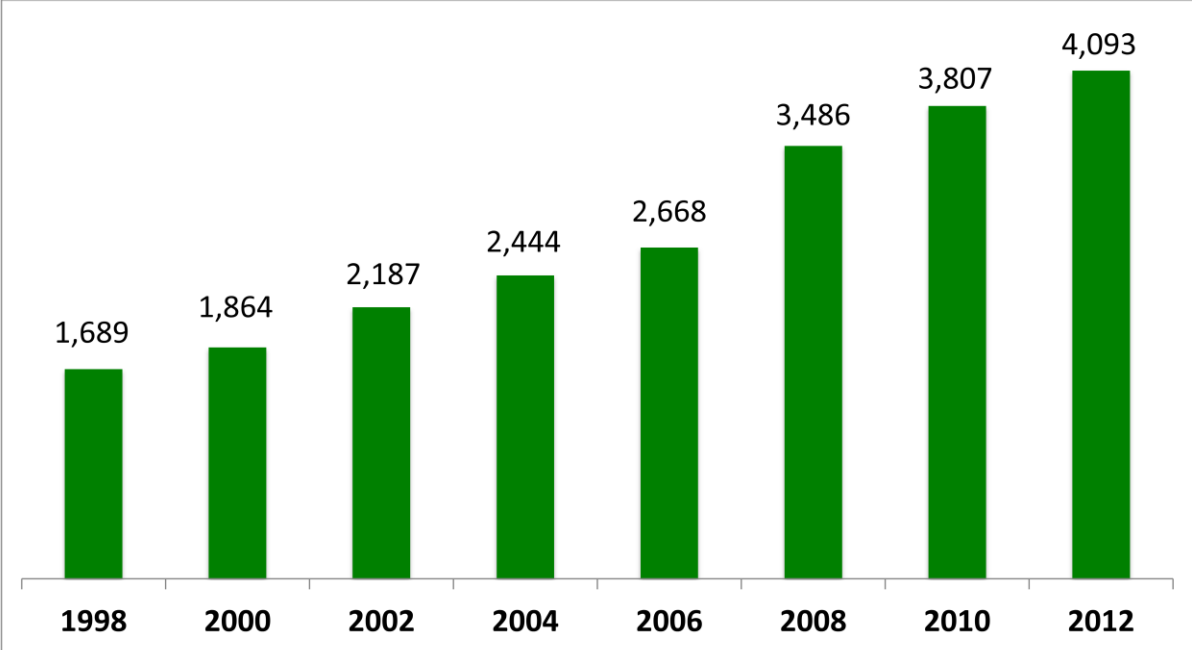
Dollars in \$US Billions	2000	2004	2008	2012	Annual Growth 00-12
NIH/Other Federal Spending	\$1.6	\$2.5	\$3.0	\$3.2	6.0%
Industry*	\$3.8	\$6.1	\$8.3	\$9.6	8.0%
TOTAL	\$5.4	\$8.6	\$11.3	\$12.8	7.5%

\* Does not include global study monitoring costs and medical device trials

Source: Tufts CSDD



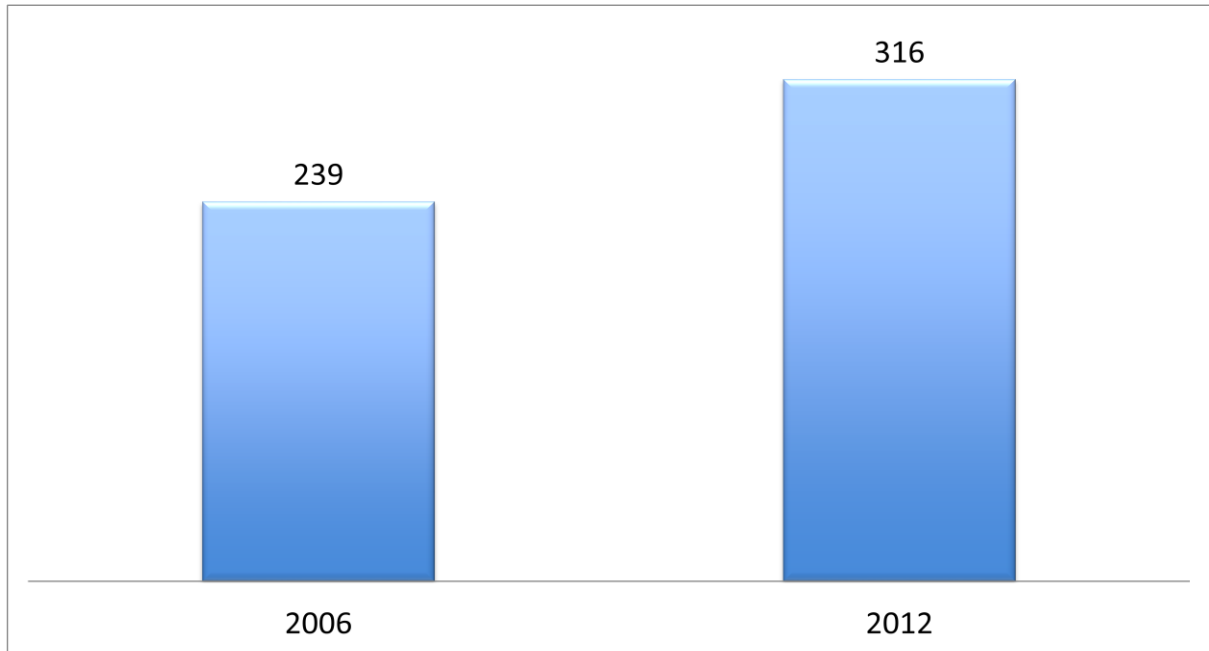
# Number of Drugs in Clinical Development Phases I–III Worldwide



Source: *Pharmaprojects*



# Total Number of Drugs in Clinical Trials for Children



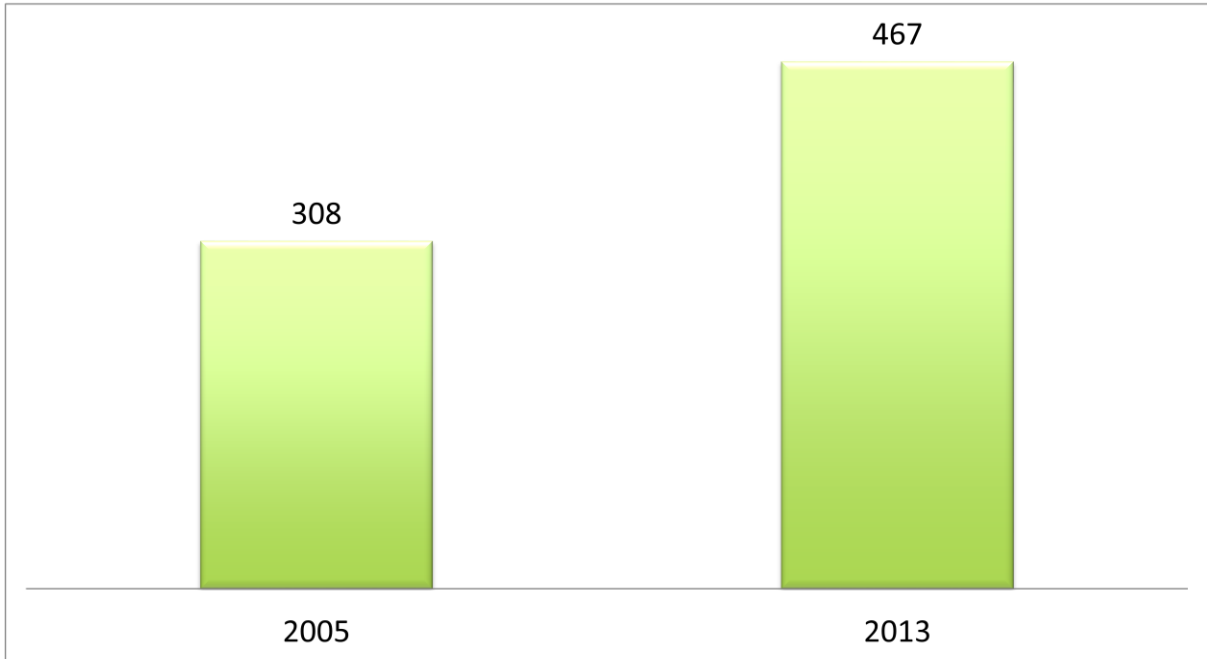
Source: Pharmaceutical Research & Manufacturers of America

# Top Areas Where Drugs Are in Clinical Trials Specifically for Children

	Number of Drugs
Infectious Diseases	55
Cancer	53
Genetic Diseases	52
Neurological Disorders	29
Respiratory Disorders	26
Cardiovascular Diseases	18
Skin Disorders	15
Psychiatric Illnesses	14
Diabetes	11
Arthritis	7

Source: Pharmaceutical Research & Manufacturers of America, 2012

# Total Number of Drugs in Clinical Trials for Adults 65+



Source: Pharmaceutical Research & Manufacturers of America

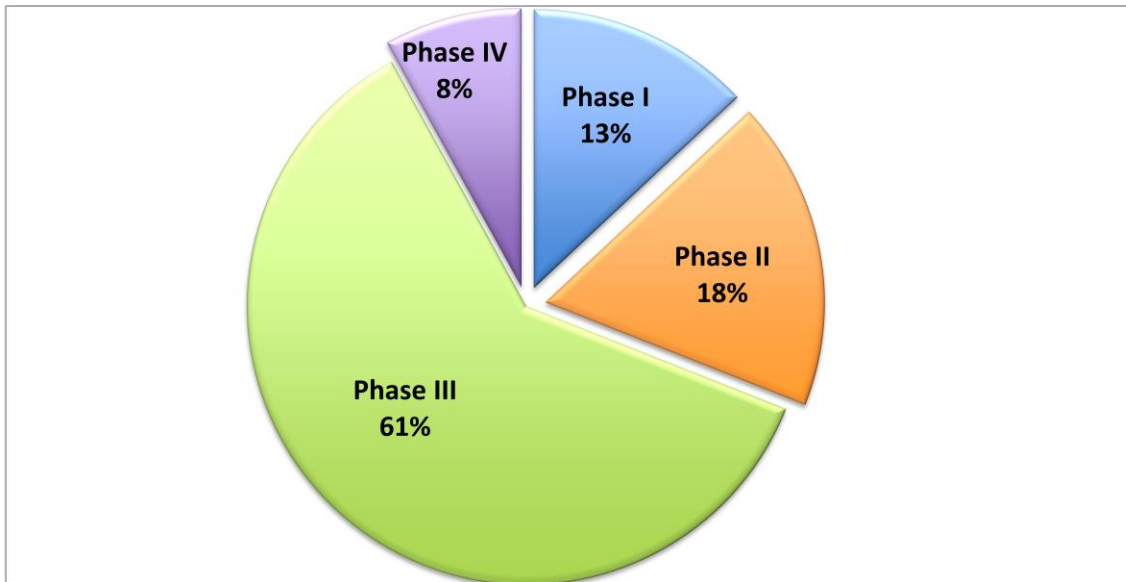
# Top Areas Where Drugs Are in Clinical Trials Specifically for Adults 65+

	Number of Drugs
Diabetes	142
Rheumatoid Arthritis	92
Alzheimer's Disease	82
Heart Disease	48
Chronic Obstructive Pulmonary Disease	40
Depression	34
Chronic Kidney Disease	20

Source: *Pharmaceutical Research & Manufacturers of America, 2013*

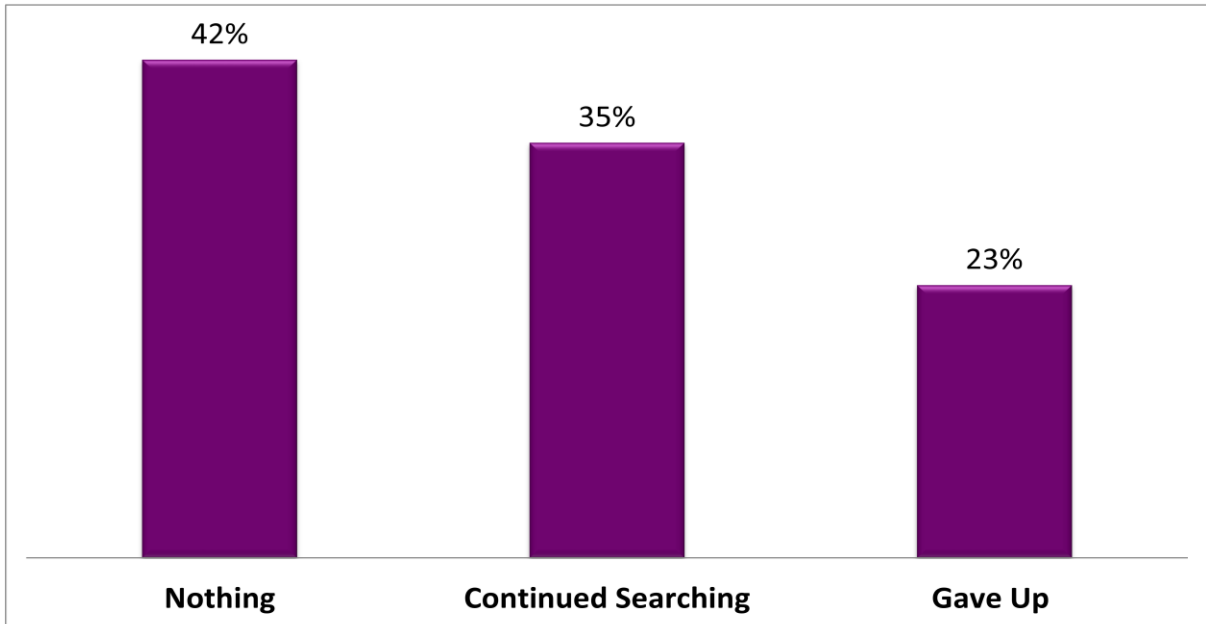


# Proportion of Total Volunteers Participating in Clinical Research by Phase



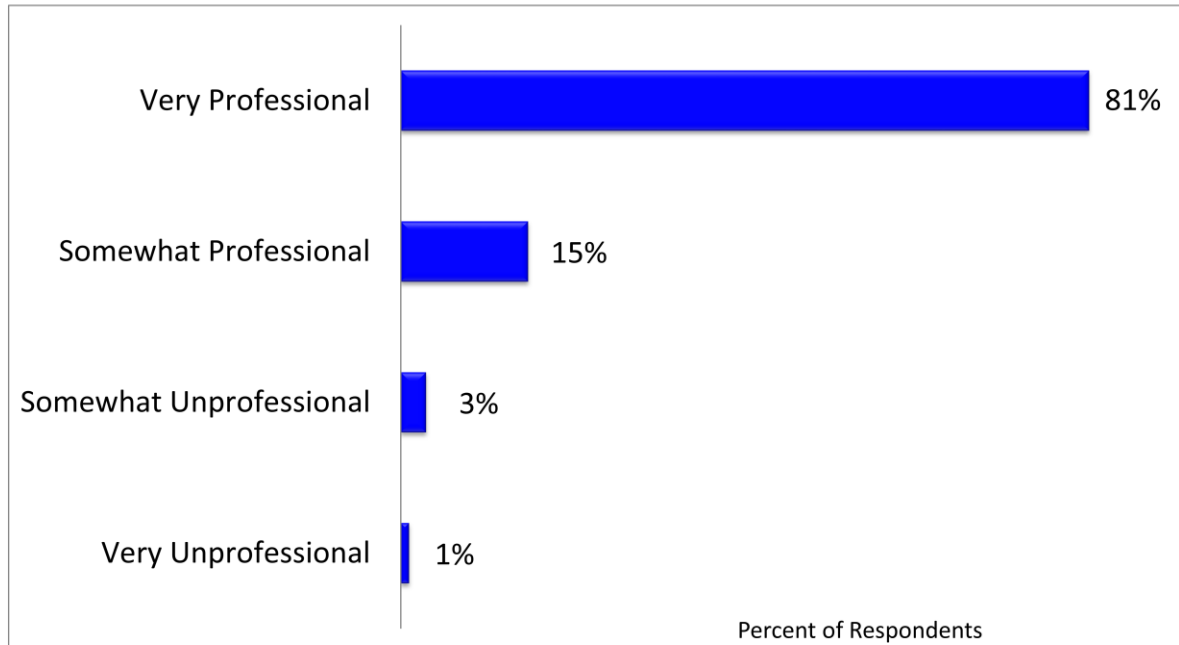
Source: CISCRP, 2012

# Most Volunteers Who Are Ineligible for a Clinical Trial Don't Search for Another



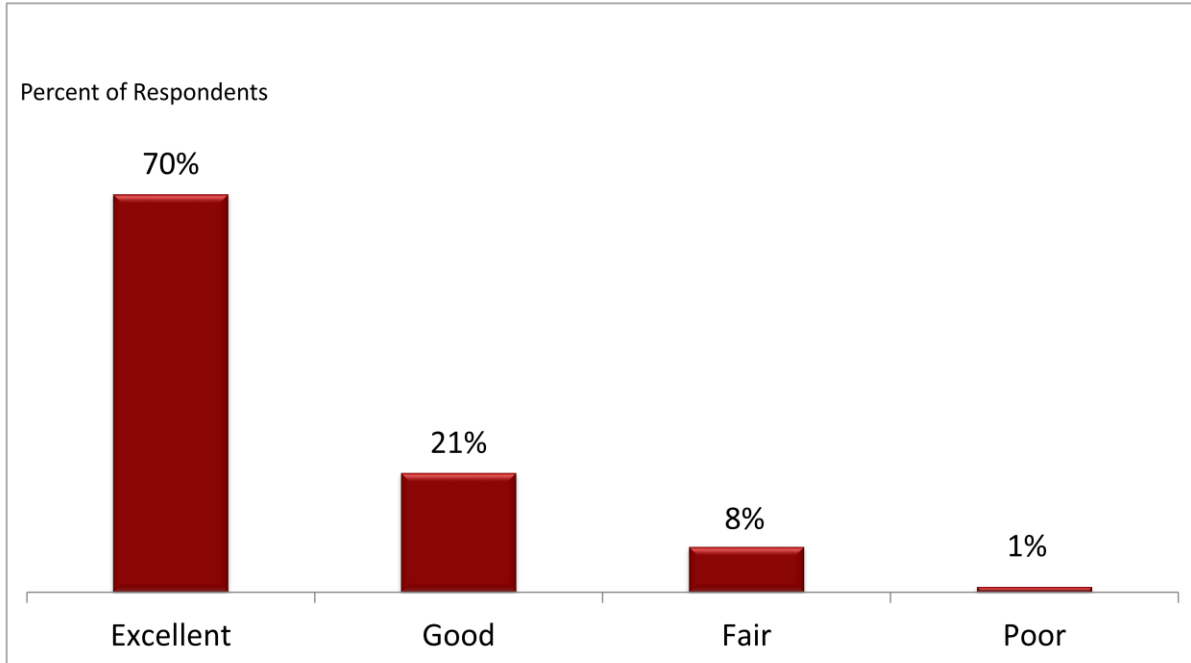
Source: CISCRP, 2013; N=4,425 people worldwide

# Study Volunteer Ratings of Clinical Research Staff Professionalism



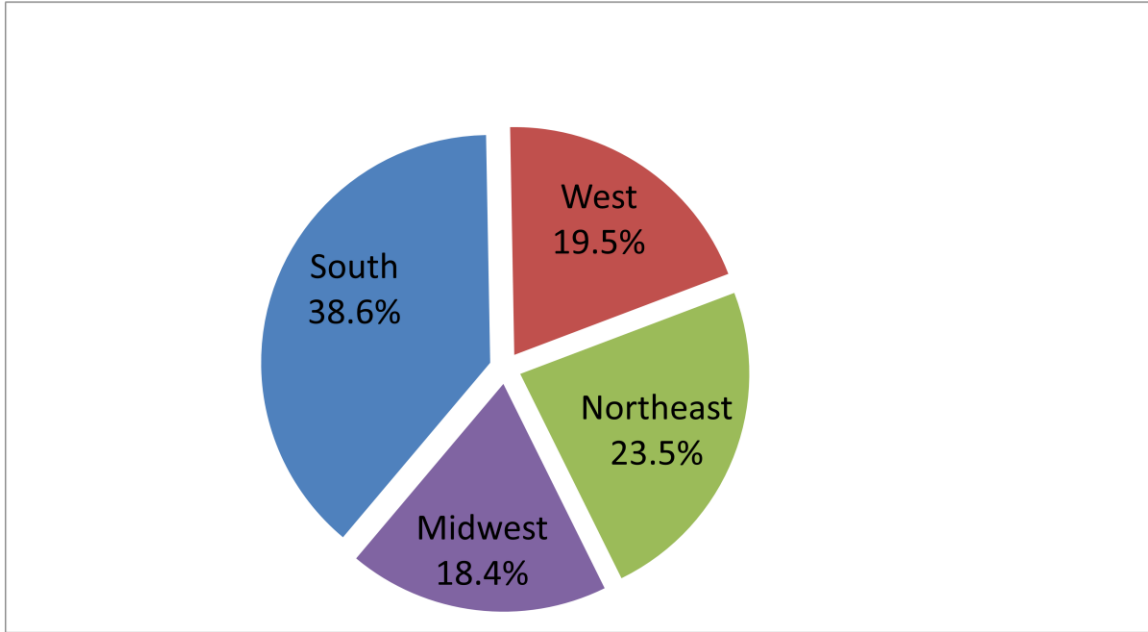
Source: CenterWatch Survey of 1,063 study volunteers, 2012

# Study Volunteer Ratings of the Quality of Care that They Received in a Clinical Trial



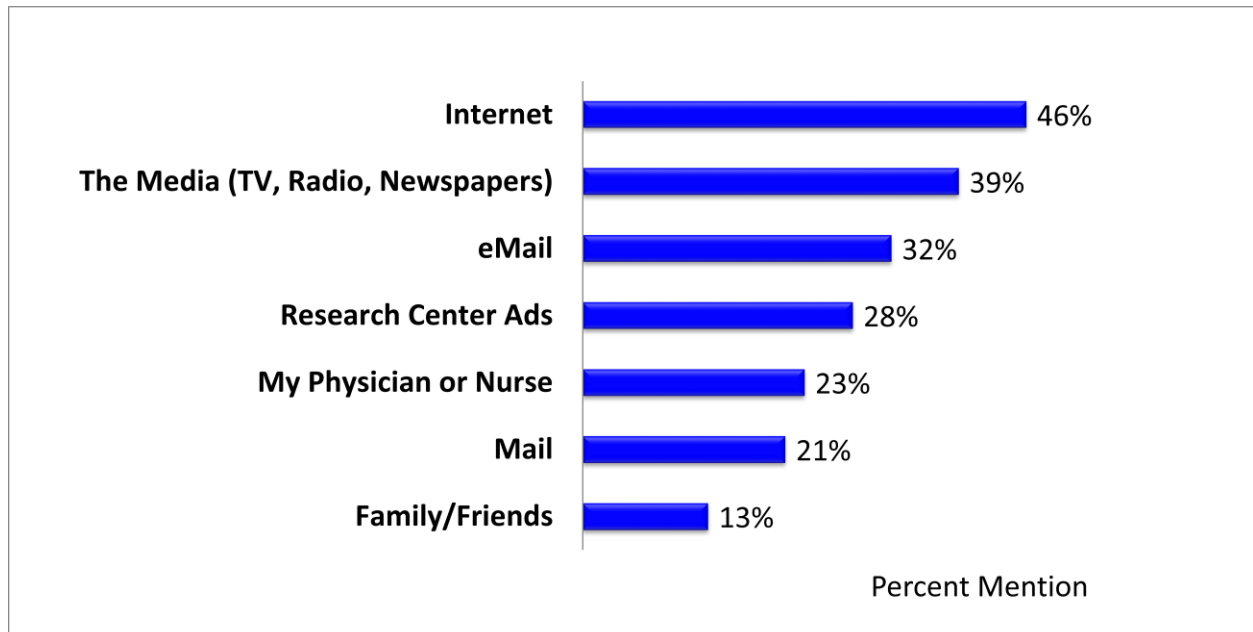
Source: CenterWatch Survey of 1,063 study volunteers, 2012

## Distribution of Active Clinical Trials by Geographic Regions in the US



Source: Tufts CSDD, 2012

# Top Ways that People Report Finding out About Clinical Trials



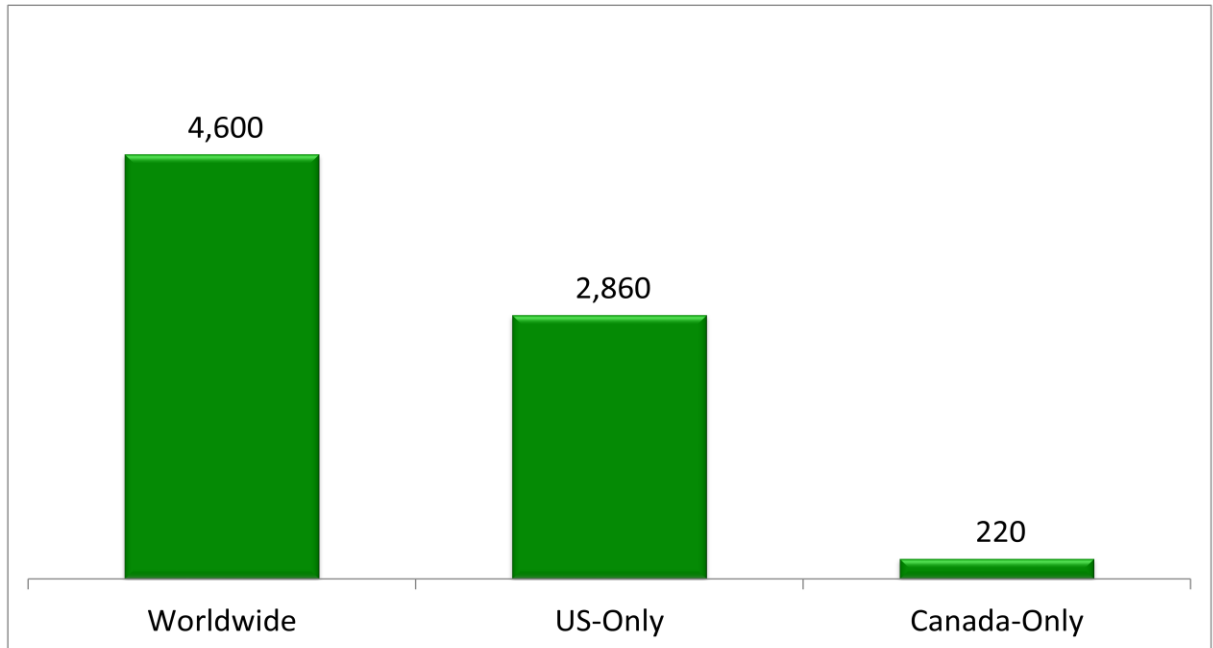
Source: CISCRP, 2013; N=5,701 people worldwide

# Examples of Compensation Levels Offered to Study Volunteers

Condition	Number of Visits	Compensation Range
Arthritis	1-24	\$100- \$1,450
Breast Cancer	5-45	\$150 - \$1,350
Depression	1-50	\$200 - \$1,036
Type II Diabetes	2-28	\$50 - \$1,300
HIV	4-16	\$50 - \$1,160

Source: CISCRP, 2013

## Number of Institutional Review Boards/Ethical Committees Operating in the US, Canada, and Worldwide in 2013



Source: Department of Health and Human Services, 2013