



## ARCHIVED 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)

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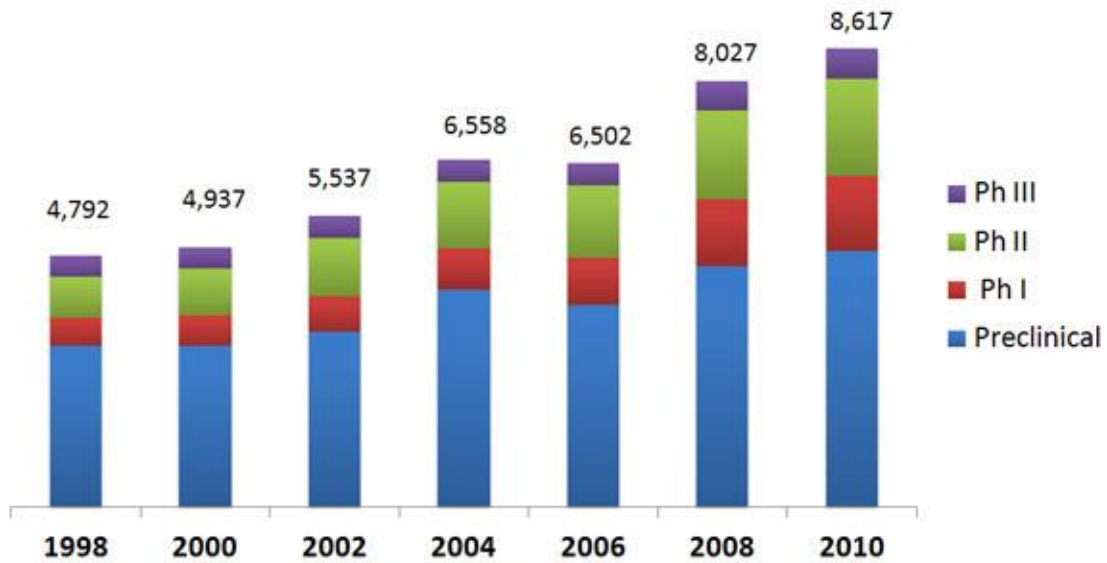
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**The Center for Information and Study on Clinical Research Participation (CISCRP)**

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

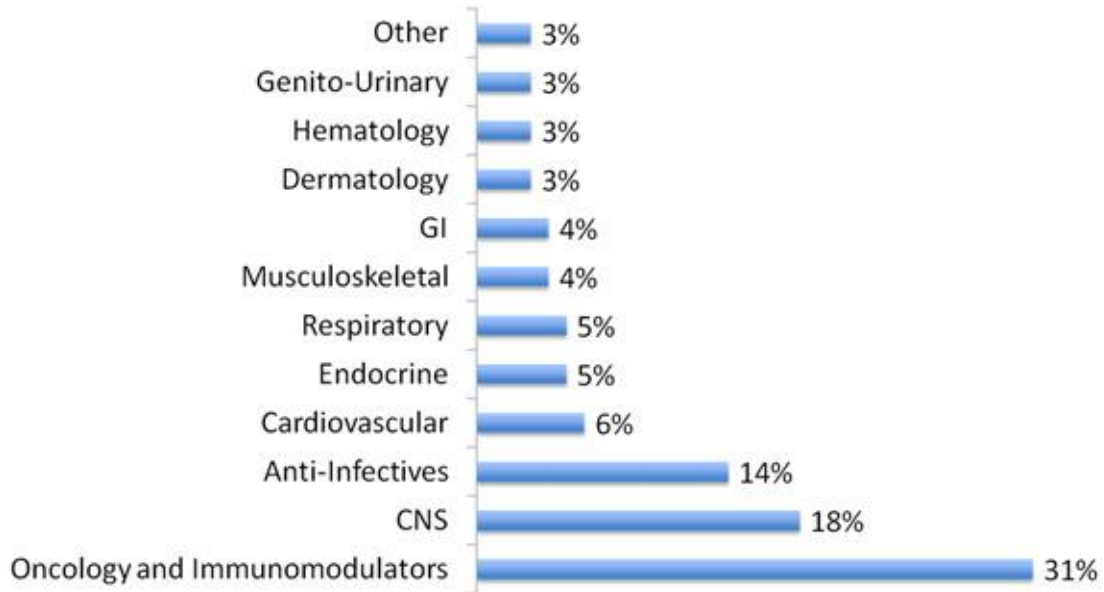
**Support our mission to educate and inform on clinical research participation!**

# Total Number of Drugs in Research and Development World Wide



Source: Pharmaprojects

## Distribution of Active Global R&D Projects by Therapeutic Area



Source: EvaluatePharma 2010

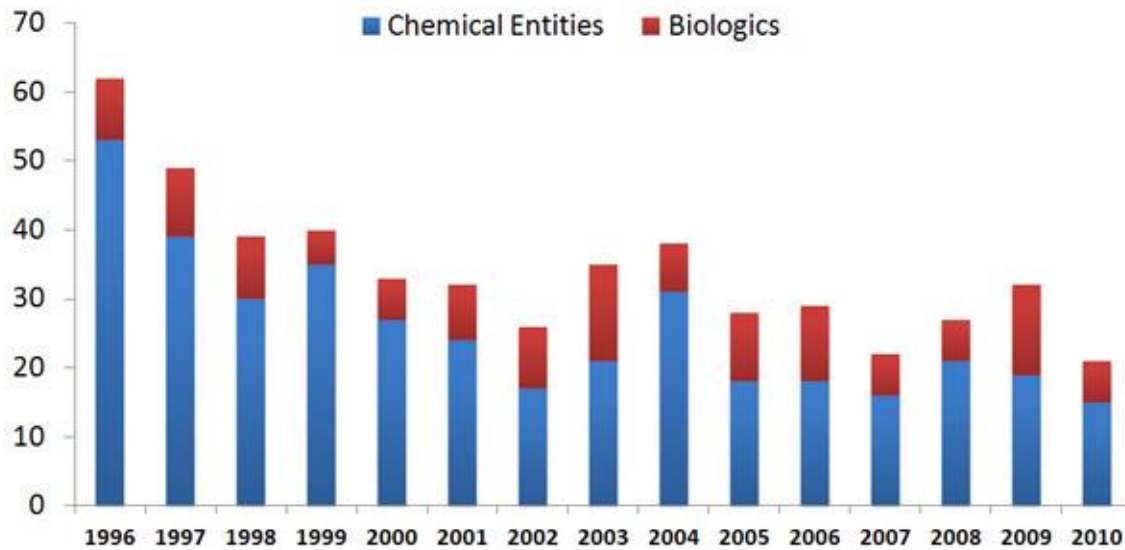
## **Industry-Funded Clinical Development Activity Targeting Diseases that affect Diverse Populations**

- 800 medicines for diseases that disproportionately affect American women in 2010; up from 348 in 2000
- 581 medicines for diseases that disproportionately affect Hispanic Americans in 2009; up from 245 in 2001
- 709 new medicines for diseases that disproportionately afflict African Americans in 2009; up from 156 identified medicines in 1999

Sources: FDA; PhRMA

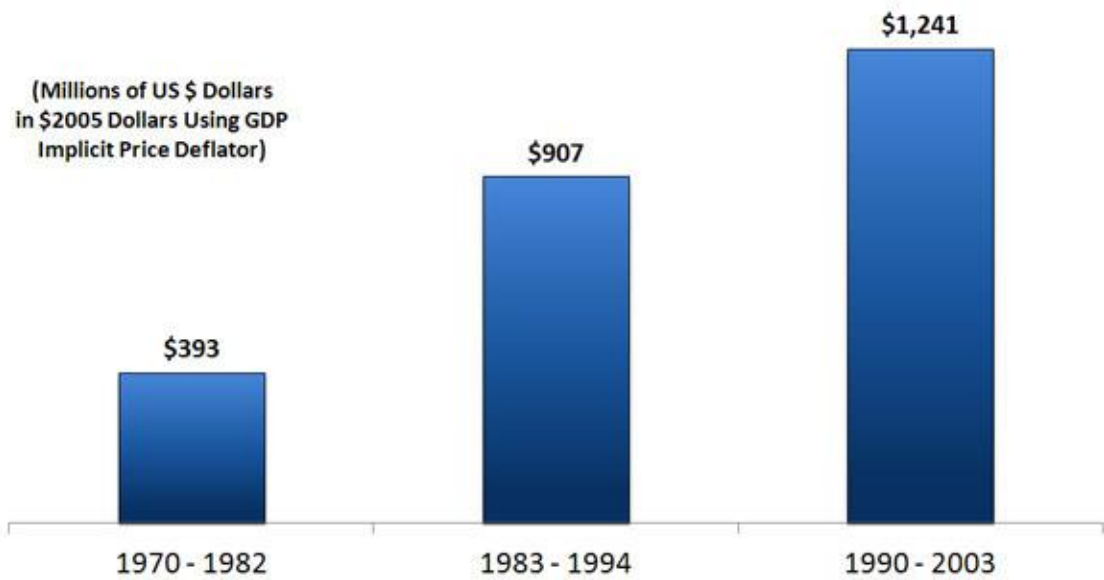
# NME Approvals by Molecule Type

Number of Approvals



Source: Food and Drug Administration

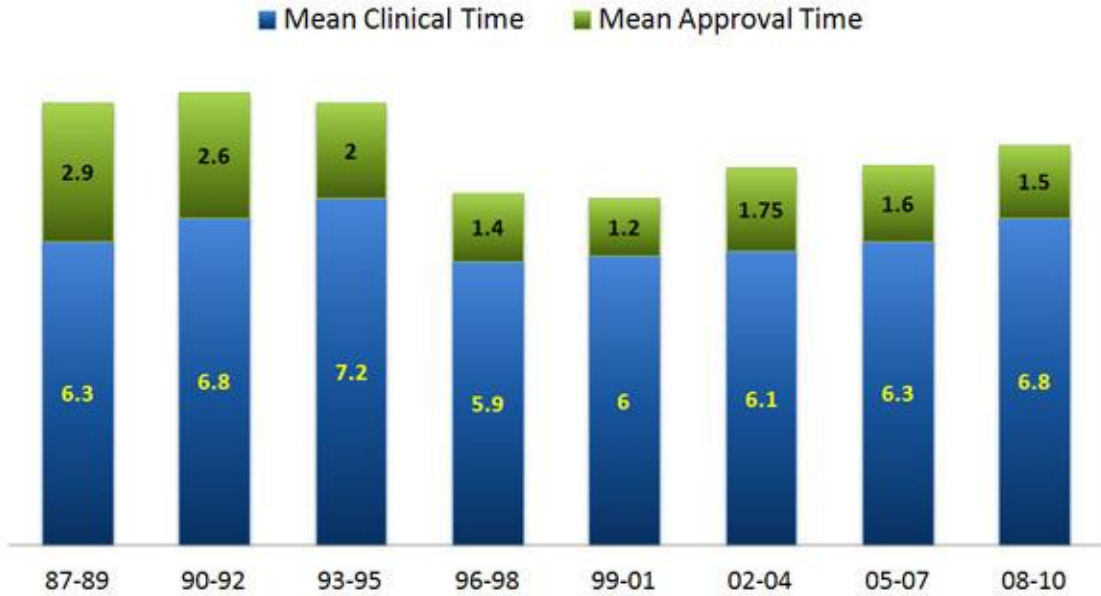
## Total Cost to Develop a single Approved Drug (Direct plus Capitalized Costs)



Source: Tufts Center for the Study of Drug Development

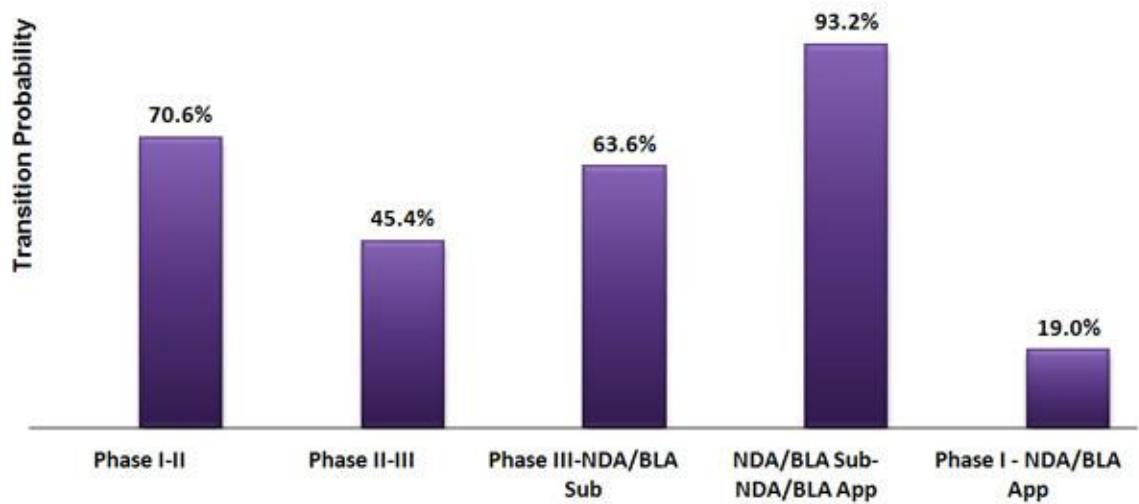
# Drug Development Durations

(Cycle Time in Years from IND Approval to NDA Approval)



Source: Tufts Center for the Study of Drug Development

## Phase Transition Probabilities for All Drugs (1998-2008)



Source: Tufts Center for the Study of Drug Development



## Examples of the Size and Scope of Clinical Trials Leading to Approved Drugs

Drug Name	Treatment for	Years in Clinical Trials	Number of Study Volunteers
Allegra	Seasonal allergies	2	3,600
Celebrex	Rheumatoid Arthritis	3	13,000
<u>Prilosec</u>	Ulcers, GERD	4	4,000
Viagra	Erectile Dysfunction	2.5	3,000
<u>Vioxx</u>	Osteoarthritis	4	10,000
<u>Gleevec</u>	Leukemia	3	2,500
Lipitor	High cholesterol	5.5	15,000
<u>Lunesta</u>	Insomnia	3.5	2,100

Source: Getz, The Gift of Participation, 2010

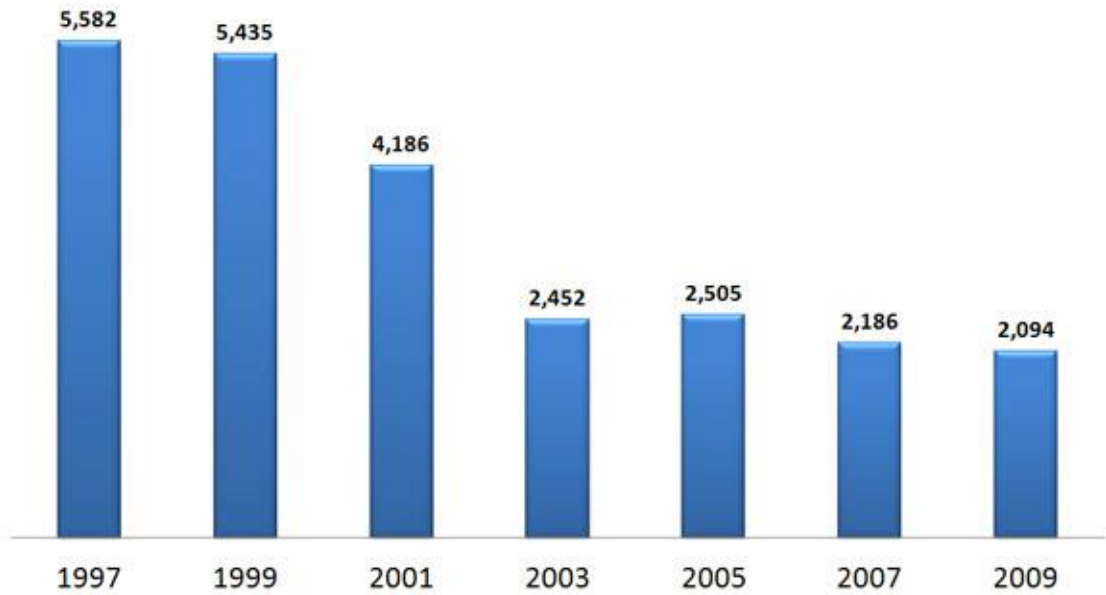
# Protocol Complexity and Administration Burden

(All TAs, All Phases)

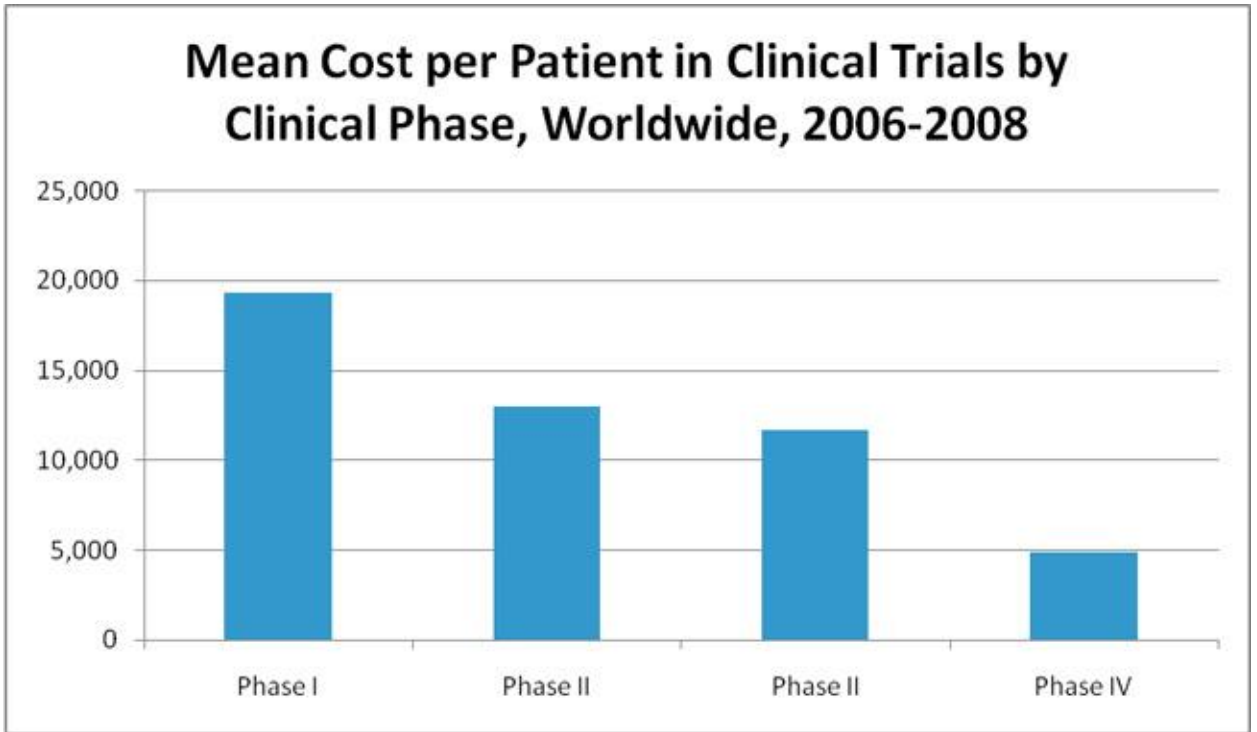
	00 – 03	04-07	08-11
Unique procedures per protocol (median)	20.5	28.2	30.4
Total procedures per protocol (median)	105.9	158.1	166.6
Total investigative site work burden (median units)	28.9	44.6	47.5
Total eligibility criteria	31	49	N/A
Median number of CRF pages per protocol	55	180	N/A

Source: Tufts Center for the Study of Drug Development

## Average Number of Patients Enrolled per Approved Drug



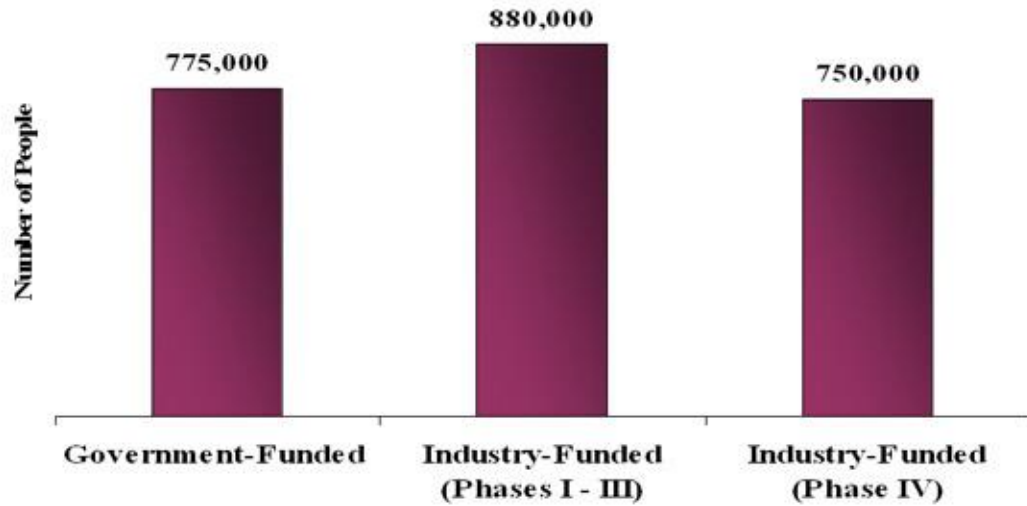
Source: Tufts Center for the Study of Drug Development



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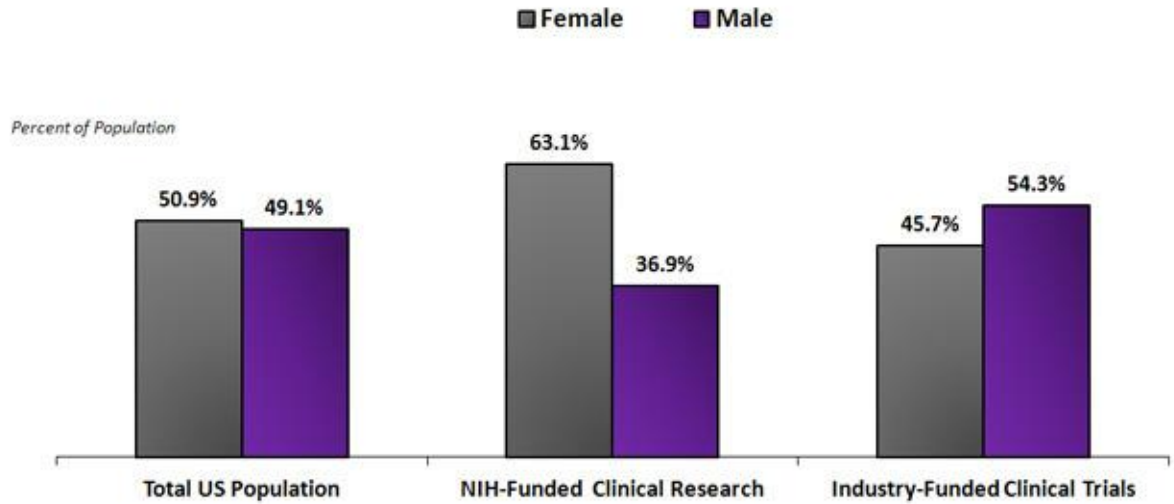
Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010

## Estimated Total Number of Volunteers Completing Clinical Trials Annually



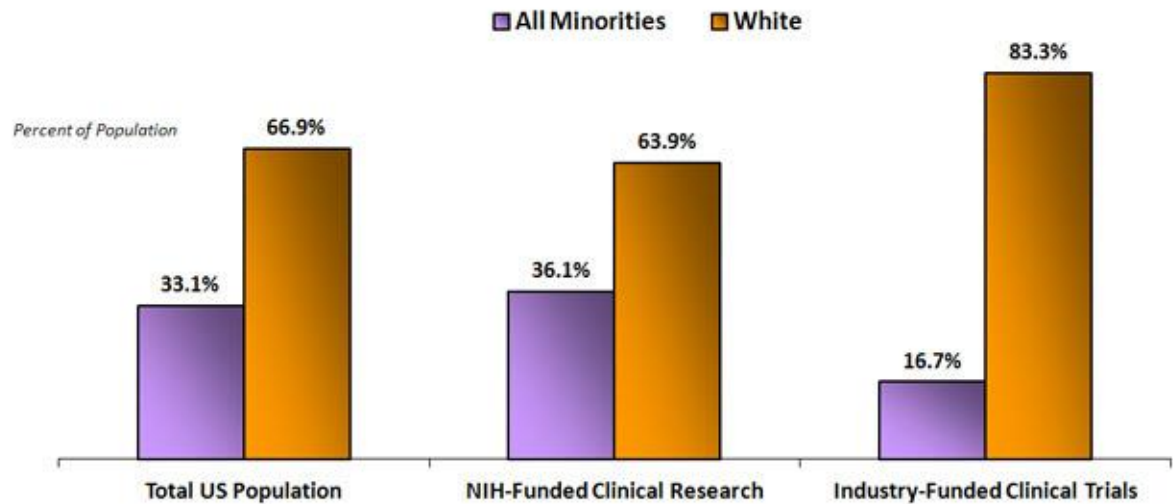
Source: CISCRP

# Proportion of Volunteers in Clinical Research by Gender



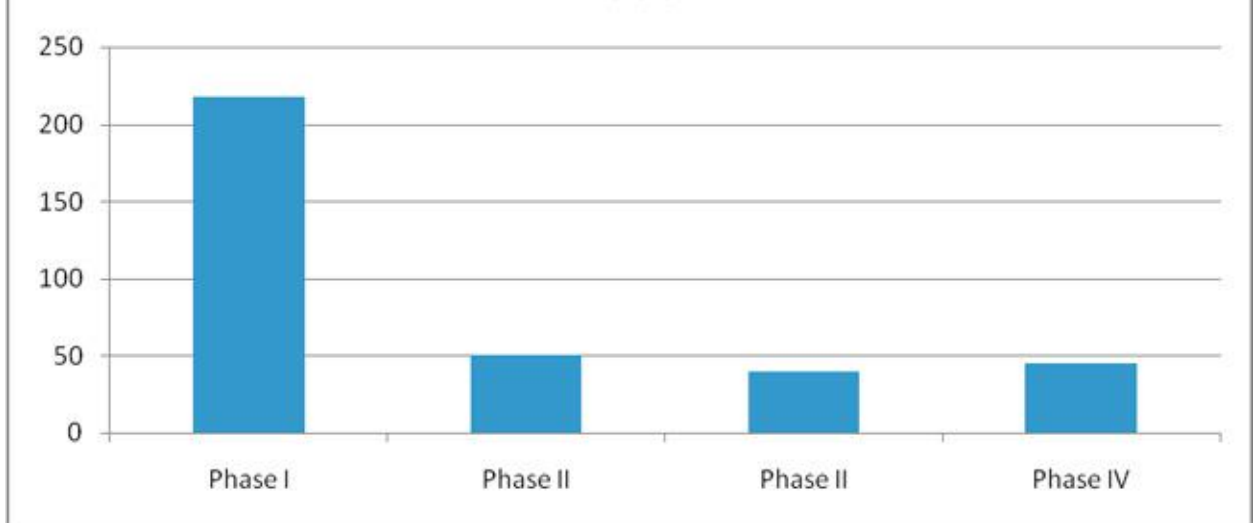
Sources: US Census Bureau; NIH; Tufts CSDD 2010

# Proportion of Volunteers in Clinical Research by Race and Ethnicity



Sources: US Census Bureau; NIH; Tufts CSDD 2010

## Mean Patient Reimbursement Per Visit in Clinical Trials by Phase, Worldwide, 2006-2008

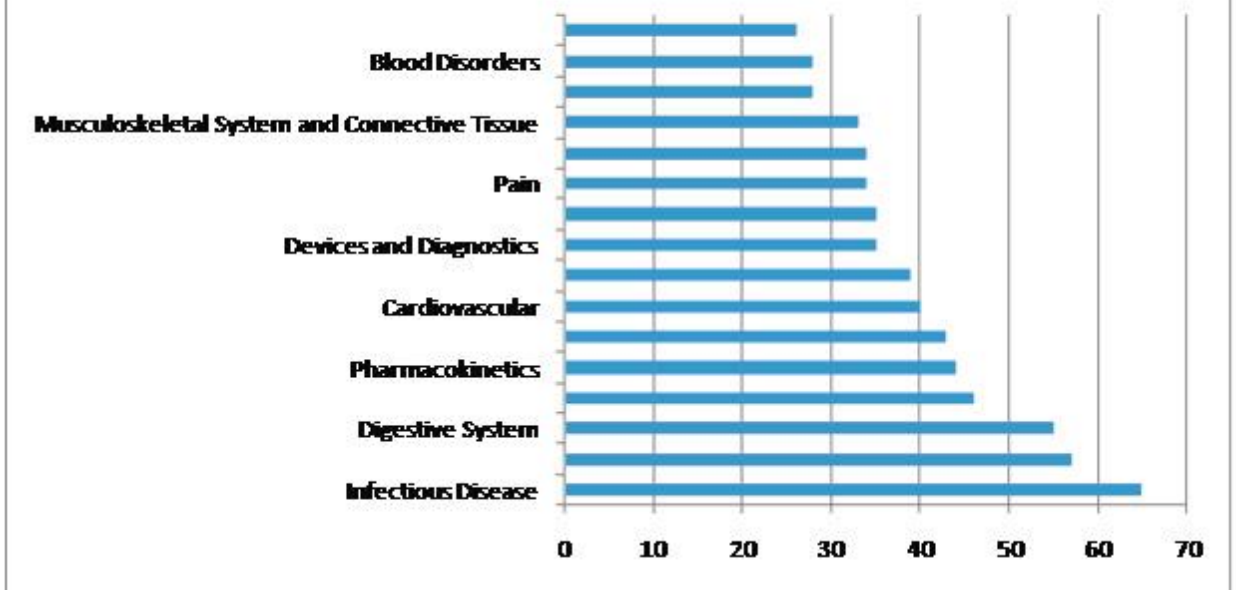


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Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010



## Mean Patient Reimbursement Per Visit in Clinical Trials by Therapeutic Area, Worldwide, 2006-2008



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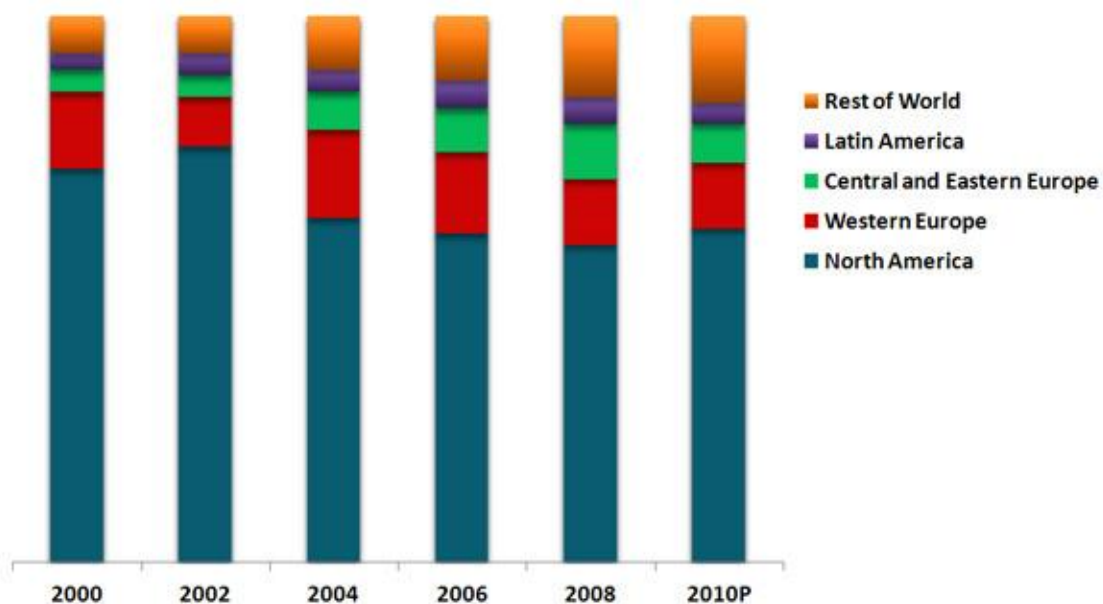
Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2009/2010

## Average Number of Countries Participating in a Single Clinical Trial by Phase

	<b>2002-2006</b> <b>(Mean # of Countries)</b>	<b>2006-2010</b> <b>(Mean # of Countries)</b>
<b>Phase I Clinical Trial</b>	<b>2</b>	<b>2</b>
<b>Phase II Clinical Trial</b>	<b>11</b>	<b>18</b>
<b>Phase III Clinical Trial</b>	<b>19</b>	<b>34</b>

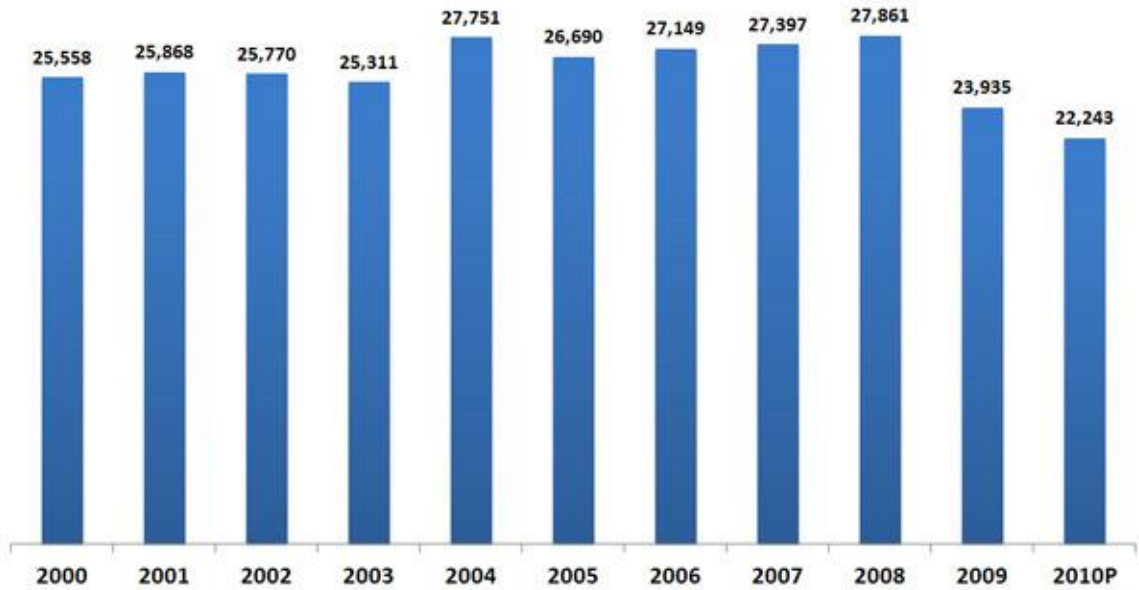
Source: Tufts Center for the Study of Drug Development

## Distribution of FDA-Regulated Investigators World Wide



Source: Tufts Center for the Study of Drug Development

## Active Number of Unique Principal Investigators Filing Form 1572s World Wide



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