

# State of the Clinical Trials Industry

A Sourcebook of Charts and Statistics

**2009**



100 N. Washington St., Ste. 301  
Boston, MA 02114  
[www.centerwatch.com](http://www.centerwatch.com)

# Table of Contents

ix	□	LIST OF FIGURES AND TABLES
xxxv	□	FOREWORD
1	□	INTRODUCTION
		<b>2008 in Review</b>
41	□	CHAPTER ONE
		<b>Industry Sales</b>
		■ Pharmaceutical Markets and Sales
		■ Top 10 Pharmaceutical Companies by Revenue
		■ Top 10 Biotech Companies by Revenue
		■ Biologics Markets and Sales
		■ Medical Device Markets and Sales
		■ Generic Drug Markets and Sales
75	□	CHAPTER TWO
		<b>R&amp;D Expenditure</b>
		■ Research and Development Growth Rates
		■ BioPharma Research and Development Spending
		■ Spending on Development
		■ Sources of Clinical Trial Funding
		■ Industry Sponsorship of Trials
		■ National Institutes of Health (NIH) Budgets and Grant Distribution

109	□	CHAPTER THREE
		<b>Clinical Development</b>
		■ Clinical Trial Initiations
		■ Pipeline Growth
		■ Success Rates
		■ Causes of Delays
		■ Investigational New Drug Applications (IND)
		■ Development Pipelines
		■ Development and Approval Times
		■ Numbers of Subjects in Clinical Trials
		■ Clinical Trials by Phase
		■ Clinical Trial Complexity
		■ Clinical Trial Costs per Subject
		■ Pediatric Development
157	□	CHAPTER FOUR
		<b>Eye Ons and Pipelines</b>
		■ Allergies
		■ Breast Cancer
		■ Cardiovascular Disease
		■ Eye Disorders
		■ HIV/AIDS
		■ Hormone Deficiencies
		■ Juvenile Arthritis
		■ Muscular Dystrophy
		■ Osteoporosis
		■ Ovarian Cancer
		■ Prostate Cancer
		■ Tropical Diseases
223	□	CHAPTER FIVE
		<b>Sponsors</b>
		■ CenterWatch U.S. Investigative Site Survey-Sponsors

	<ul style="list-style-type: none"><li>■ CenterWatch European Investigative Site Survey-Sponsors</li><li>■ CenterWatch Latin American Investigative Site Survey-Sponsors</li><li>■ Small Company Layoffs</li></ul>
257	□ CHAPTER SIX <b>Contract Research Organizations</b> <ul style="list-style-type: none"><li>■ Contract Research Organization (CRO) Market and Usage</li><li>■ Contract Research Organization Acquisitions</li><li>■ CenterWatch U.S. Investigative Site Survey-CROs</li><li>■ CenterWatch European Investigative Site Survey-CROs</li><li>■ CenterWatch Latin American Investigative Site Survey-CROs</li><li>■ Site Management Organizations (SMO)</li></ul>
289	□ CHAPTER SEVEN <b>Outsourcing</b> <ul style="list-style-type: none"><li>■ Outsourcing Penetration and Expenditures</li><li>■ CenterWatch Vendor and Outsourcing Survey</li><li>■ Institutional Review Boards (IRB): Total and OHRP-registered</li><li>■ Electronic Data Capture (EDC)</li><li>■ Clinical Trial Laboratory Services</li><li>■ Electronic Health Records (EHR)</li><li>■ E-Diaries Market and Uptake</li></ul>
331	□ CHAPTER EIGHT <b>Investigative Site Infrastructure and Operations</b> <ul style="list-style-type: none"><li>■ Investigators and Study Initiations</li><li>■ CenterWatch Survey of Physicians</li><li>■ Employment in Clinical Research</li><li>■ Site Productivity</li><li>■ CenterWatch Site Financials Survey</li><li>■ Payments to Clinical Trial Subjects</li><li>■ CenterWatch Investigator Meeting Survey</li><li>■ CenterWatch Training Survey</li></ul>

383	□	<b>CHAPTER NINE</b> <b>Study Volunteers</b> <ul style="list-style-type: none"><li>■ Subjects per New Drug Application (NDA)</li><li>■ Finding Health Information Online</li><li>■ CenterWatch Patient Experience Survey</li><li>■ Clinical Trial Participation by Race and Gender</li><li>■ Disease Demographics</li><li>■ Health Care Expenditures</li></ul>
429	□	<b>CHAPTER TEN</b> <b>U.S. Regulatory</b> <ul style="list-style-type: none"><li>■ New Drug Approval (NDA) Submissions and Approvals</li><li>■ New Molecular Entities (NME) Approvals</li><li>■ Orphan Drug Designations and Approvals</li><li>■ Combination Products Review and Assignments</li><li>■ Post-marketing Commitments</li><li>■ Investigational New Drug Applications (IND) Submissions</li><li>■ Generic Drug Submissions and Approvals</li><li>■ Fast Track Designations</li><li>■ Investigational Device Exemption (IDE) Submissions and Approvals</li><li>■ Humanitarian Device Exemptions (HDE)</li><li>■ Premarket Notification (510(k)) Classifications</li><li>■ Premarket Approval (PMA) Submissions</li><li>■ FDA Inspections, Warnings, Withdrawals, Adverse Events</li><li>■ Prescription Drug User Fee Act (PDUFA) Fees</li></ul>
471	□	<b>CHAPTER ELEVEN</b> <b>Worldwide View</b> <ul style="list-style-type: none"><li>■ Ongoing Clinical Trials</li><li>■ Analysis of Investigators from FDA-1572</li><li>■ Regional Locations for Clinical Trials</li><li>■ Canadian Clinical Trials</li><li>■ Japanese Clinical Trials</li></ul>

	■	Korean Clinical Trials
	■	Singapore Clinical Trials
	■	Australian Clinical Trials
	■	EU Clinical Trials
	■	Russian Clinical Trials
	■	Indian Clinical Trials
	■	Latin American Clinical Trials
	■	Country Attractiveness for Clinical Trials
	■	Global Health Care Expenditures
539	□	I N D E X
544	□	A B O U T C E N T E R W A T C H