CHAPTER ONE

THE DRUG DEVELOPMENT PIPELINE

» The R&D Continuum
» Clinical Trial Phases
» Drug Pipeline Activity
» Drugs in Worldwide Clinical Development
» Distribution of Global Drug Pipeline by Research Phase
» Drugs in Development for Age-related Illnesses
» Drug Development Timelines During Three Decades
» The Fastest Drug Developers
» Fastest and Slowest Companies
» Drug Development Durations
» Annual NME Approvals
» Drug Submissions and Approvals
» Variability in Clinical and NDA Approval Duration
» CDER New Molecular Entity (NME) and New Biologic License Application (BLA) Filing and Approvals
» New Drug Approvals
» Proportion of Expanded Access IND Requests Approved
» Expanded Access INDs Submitted
» Worldwide Active R&D Projects in Development
» R&D Projects by Current Phase

» Comparing Study Size by Phase
» Distribution of Global Pipeline by Molecule Type
» Biosimilars Clinical Pipeline
» Biologic Medicines in Development
» First-in-Class Medicines in the Pipeline
» Worldwide Clinical Trials First Entered in Each Calendar Year
» Active Clinical Projects Worldwide
» Worldwide Clinical Trials Volume
» New Clinical Trials Started
» Most Active Clinical Pipelines
» Active Projects in Global Phase I Clinical Trials
» Top Five Largest Pharmaceutical Company Pipelines
» Drugs in Preclinical Testing
» Registered Studies in Specific Locations
» New Active Substances Launches by Therapeutic Area
» Drugs in Clinical Development by Therapeutic Area
» Most Active Therapeutic Areas in Clinical Testing
» Therapeutic Area Growth
» Global Compounds in R&D by Therapeutic Area (1 of 2)
» Global Compounds in R&D by Therapeutic Area (2 of 2)
CHAPTER ONE
THE DRUG DEVELOPMENT PIPELINE

» R&D Projects Allocated by Therapeutic Area
» R&D Products by Therapeutic Area (1 of 5)
» R&D Products by Therapeutic Area (2 of 5)
» R&D Products by Therapeutic Area (3 of 5)
» R&D Products by Therapeutic Area (4 of 5)
» R&D Products by Therapeutic Area (5 of 5)
» Vaccine Drugs in Development
» Growth in the Vaccines Development Pipeline
CHAPTER TWO

DRUG DEVELOPMENT PERFORMANCE

» Productivity as Measured by Annual Approvals
» A Robust R&D Engine
» Drug Development Durations
» Cycle Time by Setting Type
» Cycle Time by Global Region
» Actual Study Enrollment Cycle Times
» Distribution of Direct Procedure Costs
» The In-Direct Cost of Collecting Non-Core Data
» Study Enrollment Cycle Times
» High and Rising Development Risk
» Charting a Surge in ALS Donations
» Health Charity Research Budgets
» Rates of Digital Giving by Sector
» Online Fundraising: #Giving Tuesday Results
» Commercial IND Activity
» Commercial IND Activity
» Historical Sources for Comparator Drugs and Co-Therapies
» Total Number and Distribution of New Phase II and III Clinical Trials Registered on Clinicaltrials.gov
» Annual Volume of Investigator-Initiated Studies
» Investigator-Initiated Study INDs as a Percent of all INDs Submitted
» Investigator-Initiated Study Grants and Contracts
» Proportion of Drugs in R&D Relying on Biomarker Data
» Sharp Growth in Scientific Publications on Biomarkers in Diabetes Type-II Research
» Top Cancer Diseases in R&D Using Biomarker Data for Patient Selection/Stratification
» Top Sponsors of Oncology Trials in R&D Using Biomarkers to Select or Stratify Patients
» Section Slide: Cycle Time
» Traditional Development Duration
» Drug Development Duration
» Clinical Approval Times for Drugs and Biopharmaceuticals
» Phase Lengths for Biotech Products Approved
» Cycle Time Acceleration Targets
» Traditional Clinical Development Scope, Purpose and Duration
» Overall Drug Development Timelines During Three Decades
» The Fastest Drug Developers
» Comparing the Fastest and the Slowest Companies
CHAPTER TWO

DRUG DEVELOPMENT PERFORMANCE

» Wide Variability in Clinical and NDA Approval Duration
» Section Slide: Success Rates
» Success Rate Variation by Molecule Size
» NCE Approval Success Rates by Therapeutic Class
» Success Rates by Therapeutic Area and Phase
» Success Rates in Oncology
» Average Cycle Time from Site Initiation to First Patient Randomized
» Are Global Trials Really Faster?
» NME Review Time Ranges
» Priority/Standard NME Review Gap
» Section Slide: Comparator Drugs
» Distribution of Comparator Drugs by Sourcing Method
» Incidence of Comparator Drug Use in Clinical Trials
» Mean Number of Full-time Staff Dedicated to Obtaining Comparator Drugs and Co-Therapies
» Distribution of Comparator Drugs by Type
» Section Slide: Investigative Site Performance
» Site Initiation Timeline
» Site Initiation Timeline by TA
» “First Patient-In” Cycle Time
» “First Patient-In” Cycle Time Breakdown
» “First Patient-In” Cycle Time Breakdown by TA (1 of 2)
» “First Patient-In” Cycle Time Breakdown by TA (2 of 2)
» Benchmark Cost Per Patient by Major TA
» Average Number of Patients Per Study for the Major Therapeutic Areas
» Median Number of Patients Per Phase Study
» Median Site Startup vs. Cycle Time by Phase, 2010-2012, (n=#studies)
» Growth of Active Global Development Projects by Phase
» Top Perceived Challenges by Medical Device Executives
» Distribution of Protocol Procedures by Endpoint Type
» Unprecedented Commercial Performance
CHAPTER THREE

DRUG DEVELOPMENT ECONOMICS

» Commercial Performance
» Global Clinical Study Grant Spending
» Impact on Performance and Amendments
» Cost per NME
» Total Spending on Cloud Computing in the Global Healthcare Market
» Benefits of Cloud Computing Platforms
» Cost to Develop an Approved New Drug has more than Doubled
» Industry-Sponsored Clinical Trial Grants by Phase
» Global Clinical Trial Grant Spending
» Growth in Clinical Trial Grant Spending
» Size of the U.S. Gamification Industry
» Growth in Spending on Contract Services and Overall R&D
» Outsourcing Spend as a Proportion of Total R&D Spending
» Average Cost to Develop One New Approved Drug
» Total Estimated Global Spending on Select Contract R&D Services Markets
» Global R&D Spending All Pharmaceutical and Biotech Companies

» R&D Spending
» Biopharmaceutical Company Investment in R&D PhRMA Member R&D: 1999-2014E
» Pharmaceutical R&D Expenditure Annual Growth Rate Percentage
» Eroding Contribution from Launched Innovations
» Benchmark R&D Spend as a Percentage of Sales
» Global R&D Spending
» Benchmark R&D Spending and Annual Growth
» Global R&D Spending by Clinical Trial Phase
» Estimated Cost to Develop New Drug
» Cost of Developing a New Drug
» Clinical Services Outsourcing
» Percentage of Annual R&D Budget Spent on Outsourcing
» Global CRO Market Model
» Percentage of Total Work Outsourced by Phase, by Company Type
» Growth in Global Phase I-III Clinical Trial Grant Spending
» Total Clinical Trial Grant Spending
» Median Percentage of Cost Per Patient by Phase
CHAPTER THREE

DRUG DEVELOPMENT ECONOMICS

» Median Percentage of Cost Per Patient by Therapeutic Area
» Screen Failure Costs as a Percentage of Total Cost per Patient
» Median Percentage of Per Patient Costs Relative to North American Rates
» Median Outpatient Reimbursement Per Visit Worldwide
» Median Outpatient Reimbursement Per Visit by Therapeutic Area, Worldwide
» Clinical Trials Laboratory Services Market

» Comparing Annual Growth Rates
» Clinical Lab Test Market Segments
» Private Equity Participation in Study Conduct Market
» Estimated Revenue of the Largest Investigative Sites
» Contract Services Adoption Rates in Drug Development
» Medical Technology R&D Spending Worldwide
» Comparing R&D Spending
» Medical Device Market Segments
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

Copyright © 2017 CenterWatch.
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

» Investigator Databank
» Total Active Principal Investigators Worldwide
» Active Investigators Worldwide
» Global Distribution of Investigative Sites
» Principal Investigators in Southeast Asia
» Principal Investigators in South Asia
» Principal Investigators in East Asia
» Regional Growth Rates
» Top Growing andDeclining Global Investigative Site Markets
» New Clinical Trials Starts and their Distribution by Global Region
» Growth and Decline in the Number of Active Global Clinical Trials
» Global Distribution of Studies Registered on ClinicalTrials.gov
» Number of Studies Registered on ClinicalTrials.gov
» Number of New Phase II and III Clinical Trials Registered on ClinicalTrials.gov
» NIH Research Project Grant Applications, Awards and Success Rates
» Baby Boomer Generation

» Baby Boomer Household Expenses
» Section Slide: Global Site Relationships with Sponsors and CROs
» Comparing Average Overall Sponsor Ratings
» Average Site Ratings of Sponsors by Region
» Top Performing Sponsors
» Top Performing Next-tier Sponsors
» Sponsors Receive ‘Excellent’ Rating from Global Investigative Sites
» Site-Sponsor Relationship Attributes
» Improvement Areas for Sponsors
» Relationship Attributes Rated
» Average CRO Rating Across Relationship Attributes
» Top Performing CROs
» CROs Receive High Ratings from Global Investigative Sites
» CROs are Strong Performers on Specific Attributes
» CROs Receive Low Ratings from Global Investigative Sites
» Largest CRO Performance Gaps Across Attributes
» CRO Performance Gaps
» Site Ratings of Sponsor and CROs Relationship Attributes
CHAPTER FOUR
CLINICAL RESEARCH PARTNERS

» Site Ratings of Sponsor and CRO Study Conduct Support Attributes
» Attribute Category Performance
» Section Slide: Contract Clinical Outsourcing
» Growing Penetration of Outsourcing
» Growing Reliance on Outsourcing
» Global R&D Spending by Segment
» Largest Global Drug Development Contract Service Providers
» Global Clinical Laboratory Services Market Size and Forecast
» Global Market Share for Contract R&D Services
» Global Demand for CRO Services
» Medical Affairs Teams Support
» Adoption of Integrated Alliances
» Function Managing Relationships with External Providers
» Expanding Services and Outsourcing Models
» Outsourcing Model Usage by Primary Function
» Outsourcing Models for ‘Less Core’ Functions
» Proliferation of Pre-Competitive Alliances
» The Incidence of Change Orders
» Collaboration and Risk-Sharing

» The Impact of Collaboration and Risk-Sharing
» Innovative Development Ideas
» CROs with Internally Developed CTMS Systems
» EDC Platforms Used by Select Leading CROs
» CRO Acquisitions of Clinical Trial Technologies
» Acquisitions by Technology Solutions Providers
» eClinical Trial Technology Solutions
» CRO Acquisitions of Investigative Sites/Site Networks
» CROs Gaining Site Conduct and Patient Recruitment Capabilities
» Consolidation in the Market (small and mid-sized CROs)
» Consolidation in the Market (large CROs)
» Industry Acquisitions (1 of 6)
» Industry Acquisitions (2 of 6)
» Industry Acquisitions (3 of 6)
» Industry Acquisitions (4 of 6)
» Industry Acquisitions (5 of 6)
» Industry Acquisitions (6 of 6)
» Private Equity Acquisitions of CROs
» CRA-reported Days per Month Spent Visiting Sites, by Region
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

» Incidence of Pre-study Visits Performed by Sponsors
» Ratio of Fully Loaded CRO Staff Salaries to Comparable Pharmaceutical Staff Salaries
» Pharma CEO Compensation
» Pharma Industry Job Cuts: U.S.
» Section Slide: Investigative Site Landscape
» Identification to Activation: One-Year Cycle
» Active & Newly Initiated Clinical Trial Volume
» Sizing the Investigator Landscape
» No Change in Site Landscape Fragmentation
» Investigative Site Financial Health
» Revenue of the Largest Investigative Sites
» Site Infrastructure and Scale
» Comparing Site Infrastructure Supporting Industry-funded Clinical Trials
» Comparing Part-time and Dedicated Site/Site Network Infrastructure
» Distribution of Investigators by Site Type
» Study Start-Up Disadvantages at AMCs and Hospitals
» Site Organizations Supporting Industry-Funded Clinical Trials
» Clinical Trial Grant Spending
» Level of Burden Associated with Clinical Trial Operations
» Sponsor/CRO Payment Frequency
» Sponsor Payment Promptness
» Accounting Method Used by Investigative Sites
» Site Payable and Receivable Cycles
» Investigative Site Expenses as a Percentage of Study Grant Revenue
» Allocation of Clinical Trial Grant Expenses
» Comparing Operating Expenses
» Investigative Site Expenses and Profit
» Site Perceptions of Profit per Study Grant
» Site Operating Profit: Topline and Adjusted for Hidden Costs
» Hidden Cost Recovery
» Examples of Uncompensated Study Costs
» Protocol Ready to Site Activation
» Average Per-Patient Clinical Trial Costs by Selected Medical Condition
» Change in Annual Study-Related Costs by Select Regions
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

» Site Performance by Global Region
» Cycle Time by Global Region
» Activation and Achievement by Global Region
» Clinical Trial Performance Measures by Site Type
» Activation and Enrollment Achievement Rates by Site Type
» Average Number of Randomized Patients per Trial per Investigative Site
» Volunteers Completing Clinical Trials: 2013
» Aggregate Patient Recruitment Success Rates
» Comparing Dropout Rates
» Community Hospital Setting and U.S. Location
» More Than Half of Community Hospitals are Part of a Larger Health System
» Community-Hospital Planned Investment Areas to Grow Clinical Research Programs
» Benefits of Supporting Clinical Research Programs at Community Hospitals
» Challenges of Supporting Clinical Research Programs at Community Hospitals

» Growing Proportion of Global Community-based Principal Investigators
» Warning Letters to Clinical Investigators
» Complaints Received for Non-Compliance and Fraud
» Investigator Non-Compliance and Fraud
» Sponsorship Ratios of Clinical Trials
» Reasons for Delay in Improving eCT Compatibility at Sites
» Major Site Networks and Their Owners/Investors
» CROs Acquiring Investigative Sites/Site Networks
» Private Equity Participation in the Study Conduct Market (1 of 3)
» Private Equity Participation in the Study Conduct Market (2 of 3)
» Private Equity Participation in the Study Conduct Market (3 of 3)
» Section Slide: Risk Based Monitoring
» Risk-Based Monitoring
» Management of Risk-Based Monitoring
» Management of Risk-Based Monitoring by Active Trial Volume
» Risk-Based Monitoring Impact on Staff
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

» Preparing Staff for Risk-Based Monitoring
» Section Slide: Clinical Research Coordinators
» Number of Employees Supervise
» Company Policy on Education & Training
» CRC Salary
» CRC Salary by Site Type
» Factors Behind Supplemental Income
» Supplemental Income as a Result of Certification
» CRC Supplemental Income as a Result of Certification
» Supplemental Income as a Result of Certification—By Major Certifications
» Best Path to Increase Salary & Upward Mobility
» Best Sector for Upward Mobility
» State of the Economy
» Satisfaction with Current CRC Position
» Job Security with Current Employer
» Overall Job Security
» Workload Changes
» Challenges of a CRC Professional
» Significant Changes in the CRC Role

» CRC Career Benefits
» CRC Career Challenges
» Section Slide: Clinical Research Associate
» Number of Employees Supervise
» Company Policy on Education & Training
» CRA Salary
» CRA Salary by Company Type
» Factors Behind CRA’s Supplemental Income
» Supplemental Income as a Result of Certification
» Supplemental Income as a Result of Certification
» Supplemental Income as a Result of Certification—By Major Certifications
» Best Path to Increase Salary & Upward Mobility
» Sectors for Opportunity and Upward Mobility
» State of the Economy
» Satisfaction with Current CRA Position
» Job Security with Current Employer
» Overall Job Security
» CRA Workload Changes
» Challenges as a CRA Professional
CHAPTER FOUR

CLINICAL RESEARCH PARTNERS

» Significant Changes in the CRA Role
» Section Slide: Patients/Study Volunteers
» Adoption of Patient Centric Initiatives
» Patient Centric Initiatives
» Sponsors Plan to Seek Input from Patient Panels
» Methods of Contacting Patients for Clinical Trials
» Study Start-Up Cycle Time by Site Type
» Study Start-Up Cycle Time by Region
» Factors Contributing to Delays in Enrolling the First Patient
» Study Volunteer Attrition Rates
» Reasons to Not Participate in a Clinical Trial
» Study Volunteers Require Special Attention
» Patients Search for Clinical Trial Information
» Methods Patients Use to Identify Clinical Trials
» Internet Resources Patients Use for Clinical Trials Information
» Search Methods Used by Patients to Identify Clinical Trials
» Technology Devices Used by Patients to Search for Clinical Trials
» Methods to Contact Research Centers to Participate in a Clinical Trial
» Patients Receive Decision-making Help Regarding Clinical Trial Participation
» Individuals Helping Patients in Deciding to Participate in a Clinical Trial
» Social Media Contributes in the Decision-making Process of Clinical Trial Participation
» Patients Reviewed the Informed Consent Form
» Evaluation of the Informed Consent Process Before the Start of the Clinical Trial
» Patients Evaluation of the Electronic Informed Consent Form Experience
» Professional Responding to Informed Consent Process Queries
» Patient’s Understanding of the Benefits and Risks of Participating in a Clinical Trial
» Study Participant Concerns
» Evaluating the Overall Quality of Care Received During the Study
» Clinical Trials Inclusion/Exclusion Criteria too Strict for Participation
CHAPTER FIVE

CLINICAL RESEARCH PRACTICES

» Identification to Activation: A One-Year Cycle
» Median Site Startup vs. Cycle Time by Selected Countries
» Number of Registered Studies with Posted Results
» Clinical Trials Registered for Recruitment as it Relates to Country Income
» Number of Clinical Trials Registered for Recruitment Globally
» Average Number of Countries per Study by Designed Study Duration by Year
» The Burden of Study Startup
» Median Number of Active Clinical Trials
» Median Number of Patients Enrolled
» Active and Newly Initiated Trial Volume
» Investigative Site Activity
» Investigative Site Enrollment Performance
» Plan to Actual Enrollment Performance
» Clinical Trial Performance Measures by Site Type
» Activation and Enrollment Achievement Rates by Site Type
» Financials by Investigative Site Type
» Distribution of Study Budget Direct Costs by Procedure Type
» Profit Expectations for Investigative Sites

» Investigative Site Operating Margins
» AMC Share of Phase I-III Industry Funded Clinical Trials
» Study Start-up Challenges at AMCs and Hospitals
» Investigative Site Enrollment Achievement
» Actual Study Enrollment Cycle Times
» Study Enrollment Cycle Times
» Greatest Causes of Delays
» Investigative Site Perceived Causes of Delays
» “First Patient-In” Cycle Time by Region
» Investigator Turnover Rates by Region
» Average Number of Randomized Patients per Trial per Site
» Physician-Patient Referrals: Challenges
» Sites Randomizing One or More Patients per Trial
» Number of Clinical Studies Involving Risk-Based Monitoring
» Volume of Studies Involving Risk-Based Monitoring
» Sponsor/CRO Payment Frequency
» Sponsor and CRO Payment Frequency
» Familiarity with the Physician Payment Sunshine Act
» Familiarity with the Sunshine Act
CHAPTER FIVE
CLINICAL RESEARCH PRACTICES

» Sunshine Act and Impact on Investigator’s Participation in Clinical Trials
» Potential Conflicts of Interest
» Total Dollar Value by Nature of Payment
» Classifying Procedures by Endpoint Type
» Distribution of Procedures by Endpoint Type
» Distribution of Direct Procedure Costs
» In-Direct Cost of Collecting Non-Core Data
» Incidence and Impact of Facilitated Review Mechanisms
» Adoption of Adaptive Trial Designs
» Variable and Inconsistent Usage
» Facilitated Review Mechanism Impact
» Feasibility Review Mechanism Effectiveness Perceptions
» Comparing Operating Expenses
» Incidence of Subjective Outcome Assessments in Clinical Trials
» Incidence of Adjudicated Endpoints
» Contrasting Expanded Access and Right to Try Programs
» Annual Volume of Investigator-initiated Studies
» Investigator-initiated Study INDs as a Percent of all INDs Submitted

» Investigator-initiated Study Grants and Contracts
» Regulatory Staffing
» Factors Contributing to Increased Regulatory Cost/Burden
» Primary Manager of Regulatory Compliance Tasks
» Physical Office Space Dedicated to Regulatory Document Storage
» Increase in Cost Burden by Site Type
» Regulatory Tasks
» DCRI’s Portfolio: Clinical Trials Scope
» DCRI Clinical Trials Portfolio
» Actual CRO Performance Relative to Plan
» Contribution of Innovative Ideas from CROs
» The U.S. Gamification Industry
» Gamification Conducted in Clinical Trials
» Gamification Market Segments
» Therapeutic Areas with Clinical Trials Involving Gamification
» Planned Staff Increases at Investigative Sites
» Certified Clinical Research Staff
» Level of Change in Workload During the Past Three Years
» Job Security with Current Employer
CHAPTER FIVE

CLINICAL RESEARCH PRACTICES

» Company Policy on Education and Training
» Career Challenges
» Approach to Obtaining a Promotion and Increasing Salary
» Median Salary Growth for Select Positions
» CRA Professionalism
» Section Slide: Protocol Complexity
» Protocol Amendments
» Protocol Complexity and Execution Burden
» Complexity and Work Burden by Phase
» Protocol Complexity Impact on Cycle Time
» Impact on Performance and Amendments
» Amendment Prevalence by Therapeutic Area
» Protocol Amendment Prevalence by Phase
» Amendment Occurrence by Phase
» Impact of Implementing an Amendment on Study Cycle Times
» Direct Cost to Implement a Substantial Amendment
» Impact on Study Timelines
» Impact on Baseline Planning
» Distribution of Deficiency Areas
» Prevalence and Avoidability of Amendments

» Distribution of Avoidable and Unavoidable Amendments
» Distribution of Protocol Procedure Types
» Distribution of Protocol Procedures by Endpoint Type
» Distribution and Cost of Procedures by Endpoint Classification and Phase
» Distribution of Changes Made to the Protocol
» Primary Reasons for Amending Protocols
» Distribution of Procedures by CSR/Analysis Plan Classifications
» Distribution of, and Total, Direct Cost per Classified Protocol Procedures
» Section Slide: Patient Recruitment
» Sponsors Investment of Adopting Patient-centric Initiatives
» Patient-centered Practices
» Outreach Strategies to Improve Patient Recruitment
» Organizations’ Experience with Patient Recruitment Strategies
» Patients Participate in Clinical Trials
» Preferred and Actual Sources for Information about Clinical Research Studies
» Preferred and Actual Sources for Information about Clinical Research Studies
CHAPTER FIVE

CLINICAL RESEARCH PRACTICES

» Patient Recruitment Strategies
» Patient Recruitment Challenges
» Diseases with the Highest Screen Failure Rates
» Section Slide: Development Technology Solutions
» Digital Healthcare Investment Activity
» Total Spending on Cloud Computing in the Global Healthcare Market
» Global eClinical Solutions Market
» Global EMR/EHR Market Growth
» Physicians Using EHR by Specialty
» Investigative Sites Evaluate Technology Solutions
» Physicians Respond to New Digital Solutions
» Top Physician Information Sources
» Technology Use Among IRBs
» The mHealth Boom: Wearable Devices and Smartphones
» Distribution of mHealth Apps by Category
» Industry-Sponsored Mobile Health Trials by Device
» Growth in Healthcare-related Wearable Devices Sold Annually
» Wearable Devices Worldwide Forecast
» eClinical Trial Technology Solutions

» External Forces Vendors Expect will Impact eCT Innovations
» Barriers to Sponsor Adoption of eCT Solutions
» Sponsors Reported Use of eCT Solutions
» Adoption of Electronic-TMF Document Capture by Activity Type
» eTMF Adoption Drivers for Sponsor Companies
» eTMF Adoption Drivers for CROs
» Benefits Attributed to an eTMF
» Benefits of Mobile Health in Clinical Research
» Mobile Devices Used to Collect Health Information
» Challenges of Mobile Health in Clinical Trials
» Apple’s ResearchKit Apps Developed
» Global Smartphones Shipped Annually
» Frequency of Mobile Device Usage
» Growth of Routine Usage of Social Networks by Adult Internet Users
» Social Media Website Usage
» Millennials Highly Interested in Telemedicine
» Cloud Computing Pain Points for Managers
CHAPTER SIX
THE GLOBAL PHARMACEUTICAL MARKET

» Commercial Performance
» Global Pharmaceutical Sales
» Global Pharmaceutical Sales by Region
» Top Global Pharmaceutical Companies by Sales
» Next Top Global Pharmaceutical Companies by Sales
» Worldwide Conventional and Biotech Drug Sales
» Top Global Pharmaceutical Companies by Sales
» Next Top Global Pharmaceutical Companies by Sales
» Top 10 Prescription Products by Global Sales
» Next 10 Prescription Products by Global Sales
» U.S. Prescription Sales by Therapeutic Classes
» U.S. Prescription Sales for the Next Therapeutic Classes
» Worldwide Prescription and OTC Sales
» Worldwide Prescription and OTC Sales
» Growth in Worldwide Prescription and OTC Sales by Therapeutic Area (1 of 2)
» Growth in Worldwide Prescription and OTC Sales by Therapeutic Area (2 of 2)
» Generics and Branded Generics
» U.S. Prescriptions Filled with Generics

» Distribution of Global Medicine Spending
» Forecasted Growth of Global Medicine Spending
» Largest Therapeutic Areas by Spending (1 of 2)
» Largest Therapeutic Areas by Spending (2 of 2)
» Global Biologics Spending
» Top Global Medical Device Manufacturers
» Radiopharmaceutical Regional Markets Expands
» Patent Expirations: Worldwide Sales At Risk
» Level of Trust in Pharma
» Comparing Industry Reputations
» Total Active Investigators Worldwide
» Global Distribution of Investigative Sites
» Investigator Databank Global Site Distribution
» Top Growing and Declining Global Investigative Site Markets
» Regional Growth Rates
» Growing Proportion of Community-Based Principal Investigators Worldwide
» Global Distribution of Studies Registered on ClinicalTrials.gov
» Growth and Decline in the Number of Active Global Clinical Trials
CHAPTER SIX
THE GLOBAL PHARMACEUTICAL MARKET

» Number of New Clinical Trials Starts and their Distribution by Global Region
» Cycle Time by Global Region
» Activation and Achievement by Global Region
» Change in Annual Study-Related Costs by Select Regions
» Countries Where New Clinical Trials were Conducted
» Consolidation in the Market (Small and Mid-sized CROs)
» Consolidation in the Market (Large CROs)
» Private Equity Acquisitions of CROs
» CRO Acquisitions of Investigative Sites/Site Networks

» IRB Mergers & Acquisitions
» M&A in the U.S. and Europe by Year
» Operating Challenges for Medical Device Companies
» Top Perceived Challenges by Medical Device Executives
» Top Therapeutic Areas with Clinical Trials Involving Gamification
» Global EDC Market Size
» Market Share of Global Wearable Device Sales
» Global Distribution of Wearable Devices
» Wearable Devices by Body Location
CHAPTER SEVEN
DRUG DEVELOPMENT REGULATION
CHAPTER SEVEN

DRUG DEVELOPMENT REGULATION

» Publicized Infringements Harming the Industry’s Reputation
» Contrasting Expanded Access and Right to Try Programs
» Distribution of Deficiency Areas
» Complaints Received for Non-Compliance and Fraud
» Potential Conflicts of Interest
» Proportion of Companies with Facilitated Review Mechanisms
» Date Feasibility Review Mechanism Established
» Facilitated Review Mechanism Impact
» Feasibility Review Mechanism Effectiveness
» FDA Guidance on eSource Data Impact Plans for Adoption/Development of eClinical Trial Tools
» Incidence of Adjudicated Endpoints
» Evaluable Patients per NDA
» Average Number of Pages per Investigator Brochure
» Section Slide: IND and NDA Submissions and Approvals
» Number of IND Submissions
» NDA Submissions by Filing Status
» NDA Submissions and Approvals
» NDA Priority Approvals
» NME and NBE Submissions to CDER

» CDER NME and NBE Approvals
» NMEs/NBEs First-Cycle Review Outcomes
» CDER NME NDAs/BLAs
» CDER First-Cycle NDA/BLA Approved Rates
» NDAs and NMEs Approved
» Approved NDAs and NMEs Receiving Priority Designations
» NMEs Approved with Postmarketing Requirements and/or REMs
» NBA/BLA Priority Approvals
» New Biologic Approvals
» FDA Orphan Drug Approvals
» FDA Orphan Drug Approvals and Designations
» FDA Orphan Drug Designations

» Section Slide: Regulatory Review and Approval Cycle Time
» Total Review in Time for all Original NDAs/BLAs
» Mean NME Approval Times
» EMAs Median Approval Time of New Active Substances (NAS)

» Section Slide: FDA Inspection Results
» FDA, CDER Inspections of Sponsors and CROs
» BioResearch Monitoring Inspections Overseen by FDAs CDER
CHAPTER SEVEN

DRUG DEVELOPMENT REGULATION

» CDER Inspections of Clinical Investigators
» Foreign and Domestic Clinical Investigator Inspections Conducted by OSI
» International Clinical Investigator Inspection Results
» Referral-Related Clinical Investigator Inspections
» Clinical Investigator Deficiencies
» Investigator Deficiencies: Final Classification of OAI
» FDA Inspection Results
» Warning Letters Issued to Clinical Investigators
» BIMO Warning and NIDPOE Letters
» Clinical Investigator Regulatory Actions
» Volume of Physician-filed INDs
» Investigator-Initiated Trials as a Proportion of Active INDs
» Section Slide: IRB Landscape
» Number of Commercial IRBs Operating in the U.S.
» Institutional Review Boards in Academic Settings
» Comparing IRB Protocol Review Times
» Incidence and Level of Commercial IRB Use by Institutional IRBs
» Median IRB Review Times by Type of Review
» IRB Staffing and Funding Levels
» Annual Reported Change in Workload and Resources Required
» Technology Use Among IRBs
» IRB Services Market Consolidation
CHAPTER EIGHT
PATIENT ENGAGEMENT

» The Cycle of Engagement
» The Critical Need for Public Education and Outreach
» Industry is Implementing Patient-centered Practices
» Sponsors Using Patient Advisory Boards for Clinical Studies
» Advisory Board Feedback on Primary Endpoints for an Investigational Prostate Cancer Treatment
» Patient Organizations Funding Clinical Research
» Public Views About Clinical Research
» General Knowledge About Clinical Research
» Understanding the General Term: ‘Clinical Research Study’
» Public Perceptions
» Evolving Public Perceptions
» Public Willingness to Participate in Clinical Trials
» Willingness to Participate in a Clinical Research Study
» Willingness to Participate
» Clinical Research Studies Conducted at Various Medical Settings
» Important Factors Influencing the Decision to Participate in a Clinical Trial
» Protocol Design is an Important Decision to Participating in a Clinical Trial
» Reasons for Not Participating in a Clinical Trial
» Reasons for Not Participating
» Reasons for Not Participating in a Clinical Trial
» Benefits and Risks of Clinical Trial Participation
» Understanding the Informed Consent Form
» Difficulty in Understanding the Informed Consent Form
» Willingness to Participate After Reading the Informed Consent Form
» Participant Experiences Around the Informed Consent Form Process
» Individuals Consulted with Prior to Participating in a Clinical Research Study
» Motivating Factors to Continue Clinical Trial Participation
» Individual Motivating to Continue Clinical Trial Participation
» Participant Experiences on the Expectations of Clinical Trial Participation
» Participant Experiences
» Factors Causing Stress for Study Volunteers During Participation
» Study Volunteers Require Special Attention
» Actions of Ineligible Volunteers
» Participants Who Dropped Out of Participating in a Clinical Trial
» Attitudes and Experiences by Severity of Disease
» Participation in a Future Clinical Trial
» Study Volunteers’ Sources for Clinical Research Information
» Information Sources for Clinical Trial Participation
» Information Sources for Clinical Trial Participation
» Patients Use Internet Resources for Clinical Trials Information
» Internet Usage Statistics
» Growth of Routine Usage of Social Networks by Adult Internet Users
» Social Media Website Usage
CHAPTER EIGHT

PATIENT ENGAGEMENT

» Social Media Usage to Learn About Clinical Research Studies
» Distribution of mHealth Apps by Category
» Industry-Sponsored Mobile Health Trials by Device
» The mHealth Boom: Wearable Devices and Smartphones
» Market Share of Global Wearable Device Sales
» Growth in Healthcare-related Wearable Devices
» Global Distribution of Wearable Devices
» Wearable Devices by Body Location
» Section Slide: Public Perceptions of Clinical Trials and Participating
» Level of Trust in Clinical Research Study Information Sources
» Level of Trust in Clinical Research Study Information Sources: Regions
» Level of Trust in Clinical Research Study Information Sources: Racial Origins
» Level of Trust in Clinical Research Study Information Sources: Ethnicity
» Level of Trust in Clinical Research Study Information Sources: Education
» Level of Trust in Clinical Research Study Information Sources: Income
» Level of Trust in Clinical Research Study Information Sources: Age
» Level of Trust in Clinical Research Study Information Sources: Severity of Disease
» Safety of Clinical Research
» Safety of Clinical Research: Regions
» Safety of Clinical Research: Racial Origins
» Safety of Clinical Research: Ethnicity
» Safety of Clinical Research: Education
» Safety of Clinical Research: Income
» Safety of Clinical Research: Age
» Safety of Clinical Research: Severity of Disease
» Perceived Risks and Benefits of Clinical Trial Participation
» Perceived Risks of Clinical Trial Participation: Regions
» Perceived Risks of Clinical Trial Participation: Racial Origins
» Perceived Risks of Clinical Trial Participation: Ethnicity
» Perceived Risks of Clinical Trial Participation: Education
» Perceived Risks of Clinical Trial Participation: Income
» Perceived Risks of Clinical Trial Participation: Age
» Perceived Risks of Clinical Trial Participation: Severity of Disease
» Perceived Benefits of Clinical Trial Participation: Regions
» Perceived Benefits of Clinical Trial Participation: Racial Origins
» Perceived Benefits of Clinical Trial Participation: Ethnicity
» Perceived Benefits of Clinical Trial Participation: Education
» Perceived Benefits of Clinical Trial Participation: Income
» Perceived Benefits of Clinical Trial Participation: Age
» Perceived Benefits of Clinical Trial Participation: Severity of Disease
» Public Perceptions of Clinical Trials
CHAPTER EIGHT

PATIENT ENGAGEMENT

» Public Perceptions of Clinical Trials: Regions
» Public Perceptions of Clinical Trials: Racial Origins
» Public Perceptions of Clinical Trials: Ethnicity
» Public Perceptions of Clinical Trials: Education
» Public Perceptions of Clinical Trials: Income
» Public Perceptions of Clinical Trials: Age
» Public Perceptions of Clinical Trials: Severity of Disease
» Clinical Research Study Participation Drivers
» Clinical Research Study Participation Drivers: Regions
» Clinical Research Study Participation Drivers: Racial Origins
» Clinical Research Study Participation Drivers: Ethnicity
» Clinical Research Study Participation Drivers: Education
» Clinical Research Participation Drivers: Income
» Clinical Research Study Participation Drivers: Age
» Clinical Research Study Participation Drivers: Severity of Disease
» Willingness to Participate in a Clinical Research Study
» Willingness to Participate in a Clinical Research Study: Regions
» Willingness to Participate in a Clinical Research Study: Racial Origins
» Willingness to Participate in a Clinical Research Study: Ethnicity
» Willingness to Participate in a Clinical Research Study: Education
» Willingness to Participate in a Clinical Research Study: Income
» Willingness to Participate in a Clinical Research Study: Age
» Willingness to Participate in a Clinical Research Study: Severity of Disease
» Importance of Clinical Research to Discovery and Development of New Medicines
» Importance of Clinical Research to Discovery and Development of New Medicines: Regions
» Importance of Clinical Research to Discovery and Development of New Medicines: Racial Origins
» Importance of Clinical Research to Discovery and Development of New Medicines: Ethnicity
» Importance of Clinical Research to Discovery and Development of New Medicines: Education
» Importance of Clinical Research to Discovery and Development of New Medicines: Income
» Importance of Clinical Research to Discovery and Development of New Medicines: Age
» Importance of Clinical Research to Discovery and Development of New Medicines: Severity of Disease
» Section Slide: Evaluation of the Public’s Knowledge & Understanding on Clinical Trials
» Knowledge of Clinical Research
» Knowledge of Clinical Research: Regions
» Knowledge of Clinical Research: Racial Origins
» Knowledge of Clinical Research: Ethnicity
» Knowledge of Clinical Research: Education
» Knowledge of Clinical Research: Income
CHAPTER EIGHT
PATIENT ENGAGEMENT

» Knowledge of Clinical Research: Age
» Knowledge of Clinical Research: Severity of Disease
» Understanding of Clinical Research
» Understanding of Clinical Research: Regions
» Understanding of Clinical Research: Racial Origins
» Understanding of Clinical Research: Ethnicity
» Understanding of Clinical Research: Education
» Understanding of Clinical Research: Income
» Understanding of Clinical Research: Age
» Understanding of Clinical Research: Severity of Disease
» Clinical Research Considered as an Option When Discussing with your Doctor
» Clinical Research Considered as an Option When Discussing with your Doctor: Regions
» Clinical Research Considered as an Option When Discussing with your Doctor: Racial Origins
» Clinical Research Considered as an Option When Discussing with your Doctor: Ethnicity
» Clinical Research Considered as an Option When Discussing with your Doctor: Education
» Clinical Research Considered as an Option When Discussing with your Doctor: Income
» Clinical Research Considered as an Option When Discussing with your Doctor: Age
» Clinical Research Considered as an Option When Discussing with your Doctor: Severity of Disease
» Confidence in Finding Appropriate Clinical Research Study
» Confidence in Finding Appropriate Clinical Research Study: Regions
» Confidence in Finding Appropriate Clinical Research Study: Racial Origins
» Confidence in Finding Appropriate Clinical Research Study: Ethnicity
» Confidence in Finding Appropriate Clinical Research Study: Education
» Confidence in Finding Appropriate Clinical Research Study: Income
» Confidence in Finding Appropriate Clinical Research Study: Age
» Confidence in Finding Appropriate Clinical Research Study: Severity of Disease
» Section Slide: Patient’s Decision to Participate
» Sources of Information for Clinical Research Studies
» Sources of Information for Clinical Research Studies: Regions
» Sources of Information for Clinical Research Studies: Racial Origins
» Sources of Information for Clinical Research Studies: Ethnicity
» Sources of Information for Clinical Research Studies: Education
» Sources of Information for Clinical Research Studies: Income
» Sources of Information for Clinical Research Studies: Age
» Sources of Information for Clinical Research Studies: Severity of Disease
» Sources of Information for Clinical Research Studies: Regions
CHAPTER EIGHT
PATIENT ENGAGEMENT

» Sources of Information for Clinical Research Studies: Racial Origins | Ethnicity
» Sources of Information for Clinical Research Studies: Education
» Sources of Information for Clinical Research Studies: Income
» Sources of Information for Clinical Research Studies: Age
» Sources of Information for Clinical Research Studies: Severity of Disease

» Important Information When Deciding to Participate
» Important Information When Deciding to Participate: Regions
» Important Information When Deciding to Participate: Racial Origins | Ethnicity

» Important Information When Deciding to Participate: Education
» Important Information When Deciding to Participate: Income
» Important Information When Deciding to Participate: Age
» Important Information When Deciding to Participate: Severity of Disease

» Factors Influencing Participation Decision
» Factors Influencing Participation Decision: Regions
» Factors Influencing Participation Decision: Racial Origins | Ethnicity
» Factors Influencing Participation Decision: Education
» Factors Influencing Participation Decision: Income
» Factors Influencing Participation Decision: Age
» Factors Influencing Participation Decision: Severity of Disease

» Prior to Participating, Individuals Consulted
» Prior to Participating, Individuals Consulted: Regions
» Prior to Participating, Individuals Consulted: Racial Origins
» Prior to Participating, Individuals Consulted: Ethnicity

» Prior to Participating, Individuals Consulted: Education
» Prior to Participating, Individuals Consulted: Income
» Prior to Participating, Individuals Consulted: Age
» Prior to Participating, Individuals Consulted: Severity of Disease

» Learning About A Clinical Research Study
» Qualified to Participate in a Clinical Research Study
» Qualified to Participate in a Clinical Research Study: Regions
» Qualified to Participate in a Clinical Research Study: Racial Origins | Ethnicity

» Qualified to Participate in a Clinical Research Study: Education
» Qualified to Participate in a Clinical Research Study: Income
» Qualified to Participate in a Clinical Research Study: Age
» Qualified to Participate in a Clinical Research Study: Severity of Disease

» Volunteers Ineligible to Participate
» Volunteers Ineligible to Participate: Regions
» Volunteers Ineligible to Participate: Racial Origins

» Volunteers Ineligible to Participate: Ethnicity
» Volunteers Ineligible to Participate: Education
» Volunteers Ineligible to Participate: Income
» Volunteers Ineligible to Participate: Age
CHAPTER EIGHT
PATIENT ENGAGEMENT

» Volunteers Ineligible to Participate: Severity of Disease
» Reasons for Participating in Clinical Trials
» Reasons for Participating in Clinical Trials: Regions
» Reasons for Participating in Clinical Trials: Racial Origins | Ethnicity
» Reasons for Participating in Clinical Trials: Education
» Reasons for Participating in Clinical Trials: Income
» Reasons for Participating in Clinical Trials: Age
» Reasons for Participating in Clinical Trials: Severity of Disease
» Unwillingness to Participate
» Unwillingness to Participate: Regions
» Unwillingness to Participate: Racial Origins
» Unwillingness to Participate: Ethnicity
» Unwillingness to Participate: Education
» Unwillingness to Participate: Income
» Unwillingness to Participate: Age
» Section Slide: Patient’s Experiences on Participation
» Clinical Research Study Participation
» Comparing Patient Care and Attention to Standard Care: Regions
» Comparing Patient Care and Attention to Standard Care: Racial Origins
» Comparing Patient Care and Attention to Standard Care: Ethnicity
» Comparing Patient Care and Attention to Standard Care: Education
» Comparing Patient Care and Attention to Standard Care: Income
» Comparing Patient Care and Attention to Standard Care: Age
» Comparing Patient Care and Attention to Standard Care: Severity of Disease
» Clinical Research Study Participation Meeting Overall Expectations
» Clinical Research Study Participation Meeting Overall Expectations: Regions
» Clinical Research Study Participation Meeting Overall Expectations: Racial Origins
» Clinical Research Study Participation Meeting Overall Expectations: Ethnicity
» Clinical Research Study Participation Meeting Overall Expectations: Education
» Clinical Research Study Participation Meeting Overall Expectations: Income
» Clinical Research Study Participation Meeting Overall Expectations: Age
» Clinical Research Study Participation Meeting Overall Expectations: Severity of Disease
» Clinical Research Study Participation
» Clinical Research Study Participation: Completing versus Not Completing: Regions
» Clinical Research Study Participation: Completing versus Not Completing: Racial Origins
CHAPTER EIGHT
PATIENT ENGAGEMENT

» Clinical Research Study Participation: Completing versus Not Completing: Ethnicity
» Clinical Research Study Participation: Completing versus Not Completing: Education
» Clinical Research Study Participation: Completing versus Not Completing: Income
» Clinical Research Study Participation: Completing versus Not Completing: Age
» Clinical Research Study Participation: Completing versus Not Completing: Severity of Disease
» Motivating Factors to Complete a Clinical Research Study
» Motivating Factors to Complete a Clinical Research Study: Regions
» Motivating Factors to Complete a Clinical Research Study: Racial Origins
» Motivating Factors to Complete a Clinical Research Study: Ethnicity
» Motivating Factors to Complete a Clinical Research Study: Education
» Motivating Factors to Complete a Clinical Research Study: Income
» Motivating Factors to Complete a Clinical Research Study: Age
» Motivating Factors to Complete a Clinical Research Study: Severity of Disease
» Clinical Study Participation Experience
» Level of Stress Encountered in Study Participation: Regions
» Level of Stress Encountered in Study Participation: Racial Origins
» Level of Stress Encountered in Study Participation: Ethnicity
» Level of Stress Encountered in Study Participation: Education
» Level of Stress Encountered in Study Participation: Income
» Level of Stress Encountered in Study Participation: Age
» Level of Stress Encountered in Study Participation: Severity of Disease
» Positive Experiences Participating in a Clinical Research Study
» Positive Experiences Participating in a Clinical Research Study: Regions
» Positive Experiences Participating in a Clinical Research Study: Racial Origins
» Positive Experiences Participating in a Clinical Research Study: Ethnicity
» Positive Experiences Participating in a Clinical Research Study: Education
» Positive Experiences Participating in a Clinical Research Study: Income
» Positive Experiences Participating in a Clinical Research Study: Age
» Positive Experiences Participating in a Clinical Research Study: Severity of Disease
» Challenges in Participating in a Clinical Research Study
» Challenges in Participating in a Clinical Research Study: Regions
» Challenges in Participating in a Clinical Research Study: Racial Origins
» Challenges in Participating in a Clinical Research Study: Ethnicity
CHAPTER EIGHT
PATIENT ENGAGEMENT

» Challenges in Participating in a Clinical Research Study: Education
» Challenges in Participating in a Clinical Research Study: Income
» Challenges in Participating in a Clinical Research Study: Age
» Challenges in Participating in a Clinical Research Study: Severity of Disease
» Recommend and Discuss Participation
» Recommend and Discuss Participation: Regions
» Recommend and Discuss Participation: Racial Origins
» Recommend and Discuss Participation: Ethnicity
» Recommend and Discuss Participation: Education
» Recommend and Discuss Participation: Income
» Recommend and Discuss Participation: Age
» Recommend and Discuss Participation: Severity of Disease
» Information Interested in Receiving After Study Participation Ends
» Information Interested in Receiving After Study Participation Ends: Regions
» Information Interested in Receiving After Study Participation Ends: Racial Origins
» Information Interested in Receiving After Study Participation Ends: Ethnicity
» Information Interested in Receiving After Study Participation Ends: Education
» Information Interested in Receiving After Study Participation Ends: Income
» Information Interested in Receiving After Study Participation Ends: Age
» Information Interested in Receiving After Study Participation Ends: Severity of Disease
» Study Updates After Participation Ended
» Study Updates After Participation Ended: Regions
» Study Updates After Participation Ended: Racial Origins
» Study Updates After Participation Ended: Ethnicity
» Study Updates After Participation Ended: Education
» Study Updates After Participation Ended: Income
» Study Updates After Participation Ended: Age
» Study Updates After Participation Ended: Severity of Disease