


# Building A High Performing Industry Research Portfolio

Lynne A. Armiger, MSN, CRNP,  
JHCRN Network Coordinator

# Trial Acquisition Strategies

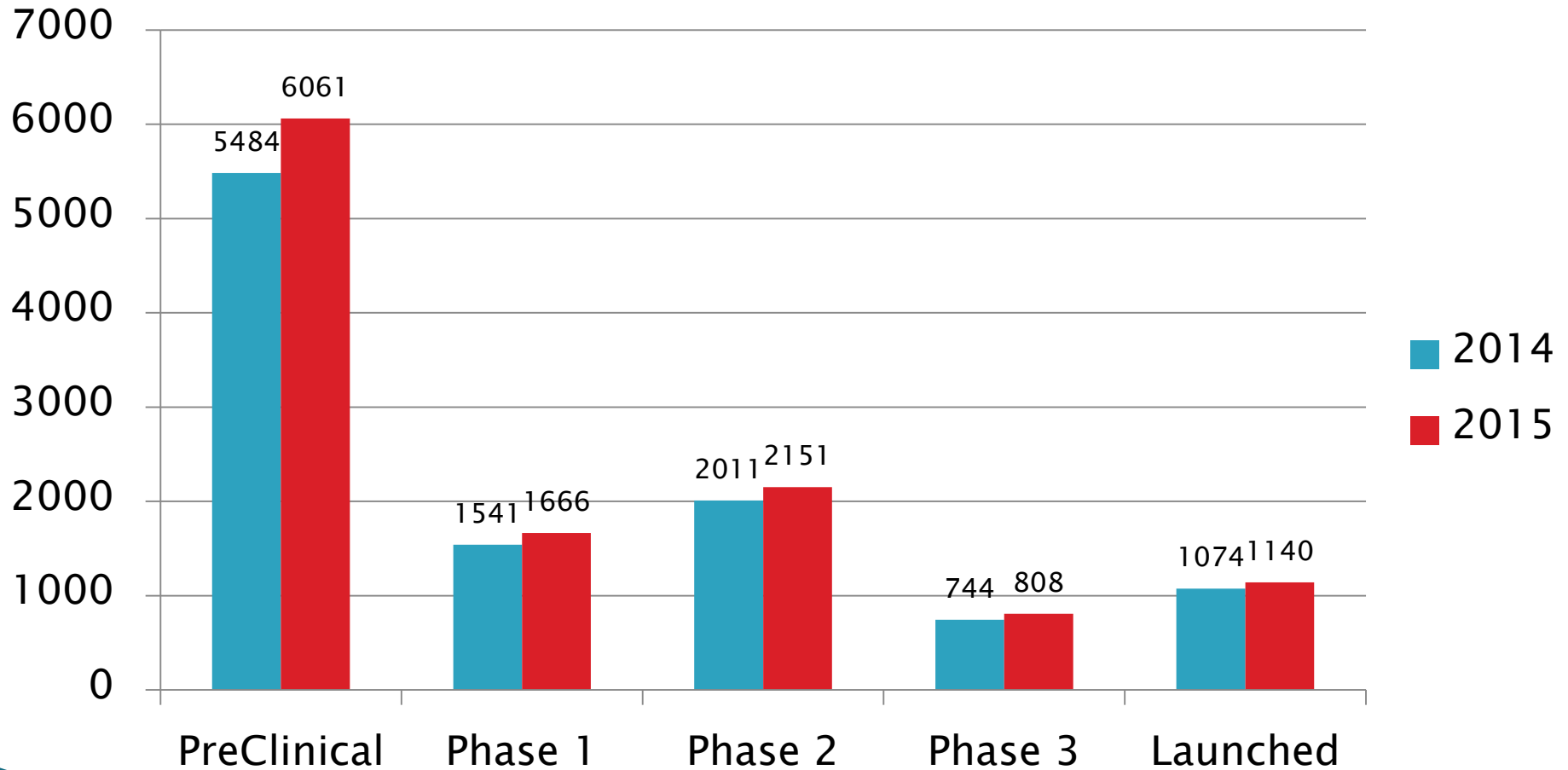
- ▶ **Networking**
    - Colleagues
    - Pharmaceutical & Device Representatives
  
  - ▶ **Internet-Based Resources**
    - CenterWatch
    - CRO / Sponsor Websites
- 

# Trial Acquisition Strategies

- ▶ **Investigational Databases**
    - CROs
    - Sponsors
    - Study Brokers
  
  - ▶ **Preferred Partner Relations**
    - JHCRN / CRO Partnerships
    - JHCRN / Sponsor Partnerships
- 

# What & Where Are the Trial Opportunities

# Pipeline by Developmental Phase



# Top 20 Pharma Companies by Pipeline

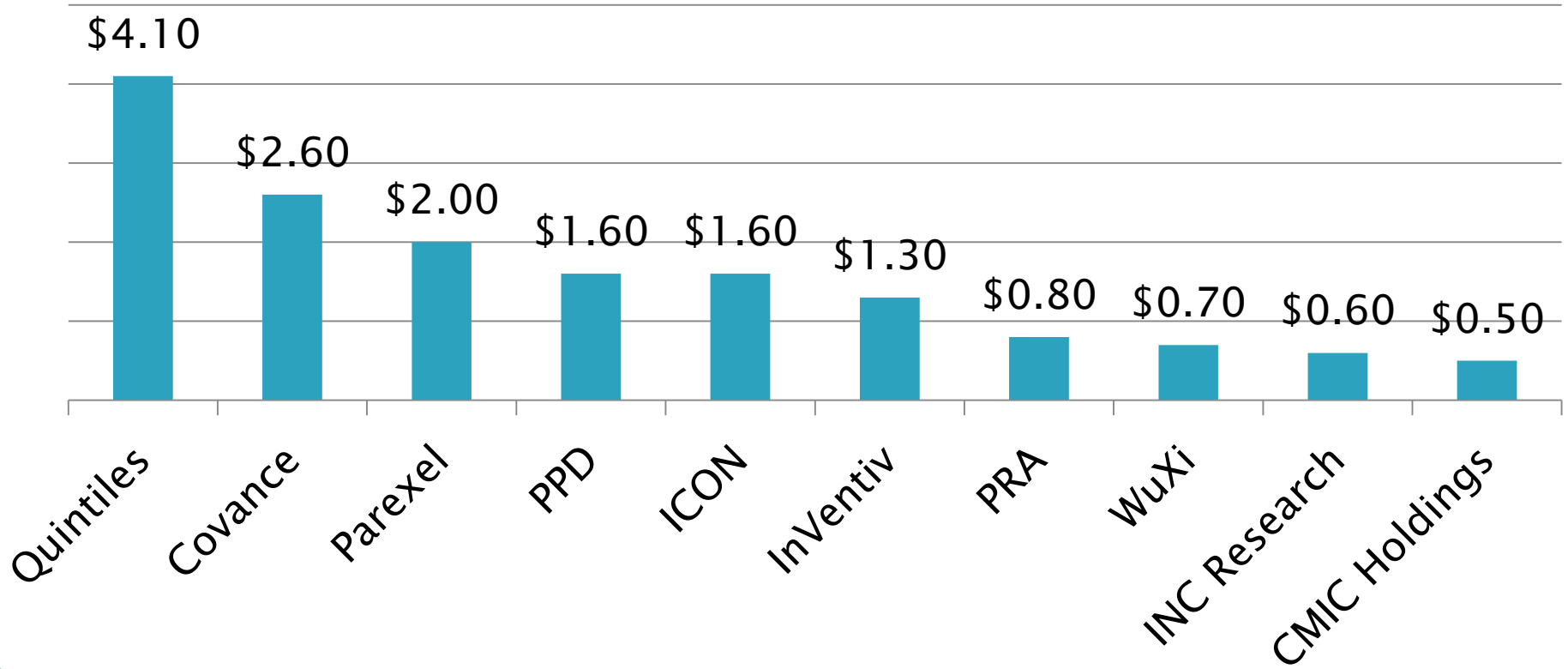
Position	Company	No. of Drugs in Pipeline	No. of Drugs Originated 2015
1	GlaxoSmithKline	258	163
2	Novartis	245	182
3	Roche	234	158
4	AstraZeneca	222	121
5	Johnson & Johnson	204	100
6	Merck & Co	199	130
7	Pfizer	199	132
8	Sanofi	184	84
9	Takeda	130	68
10	Eli Lilly	119	93

# Top 20 Pharma Companies by Pipeline

Position	Company	No. of Drugs in Pipeline	No. of Drugs Originated 2015
11	Bristol-Myers Squibb	118	88
12	Daiichi Sankyo	104	60
13	Bayer	99	43
14	Amgen	94	72
15	Teva	92	43
16	AbbVie	85	16
17	Actavis	84	34
18	Astellas	83	44
19	Eisai	82	47
20	Boehringer Ingelheim	82	56

# Largest Contract Service Providers

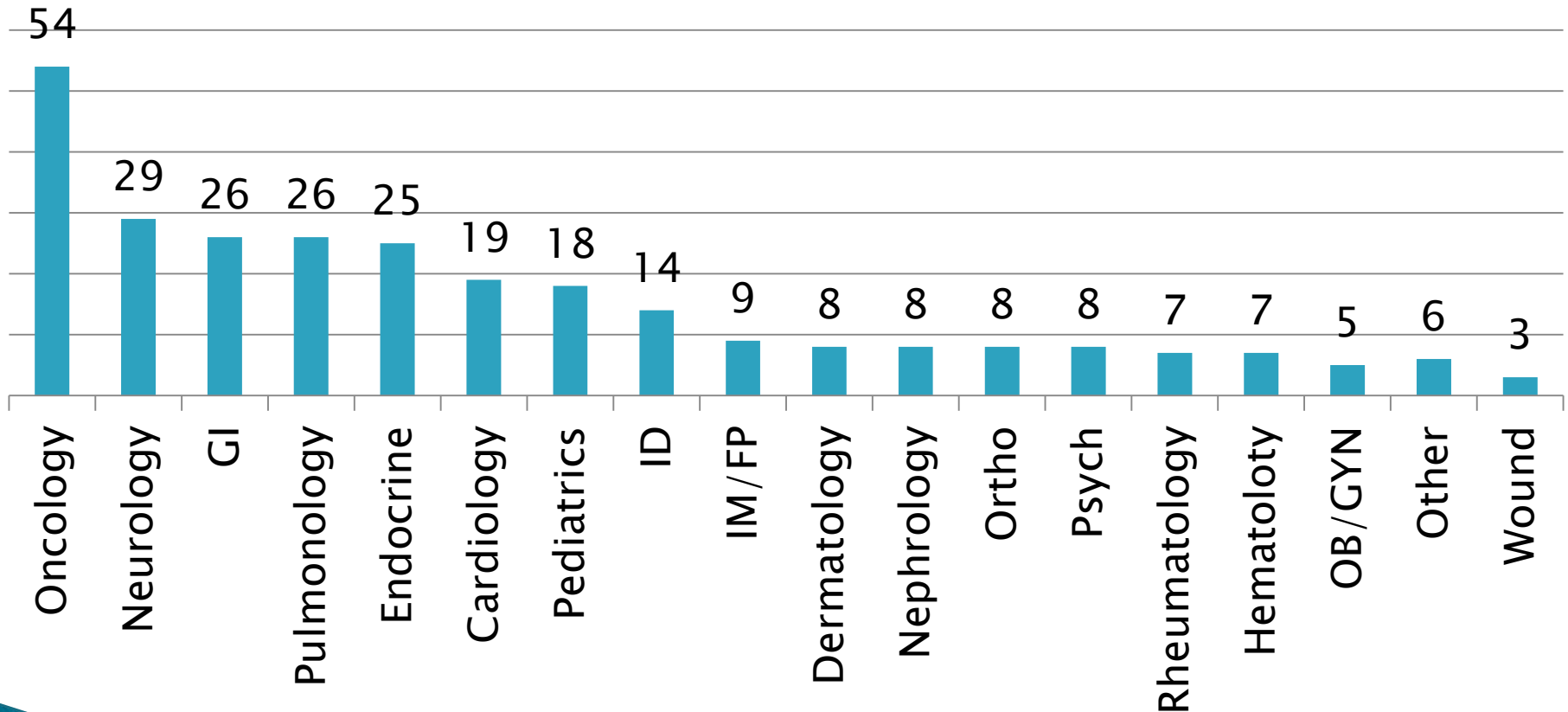
## 2014 Revenue in U.S. Billions





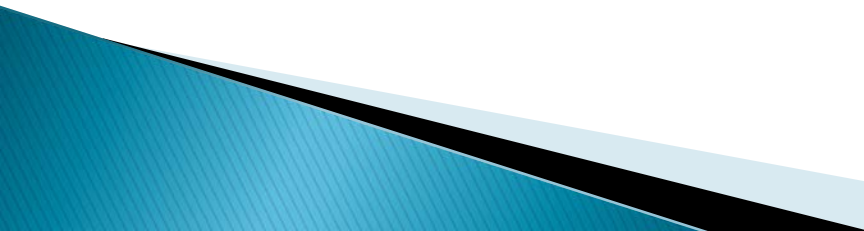
# JHCRN Trials by Indication

2014 Trials = 284 Opportunities

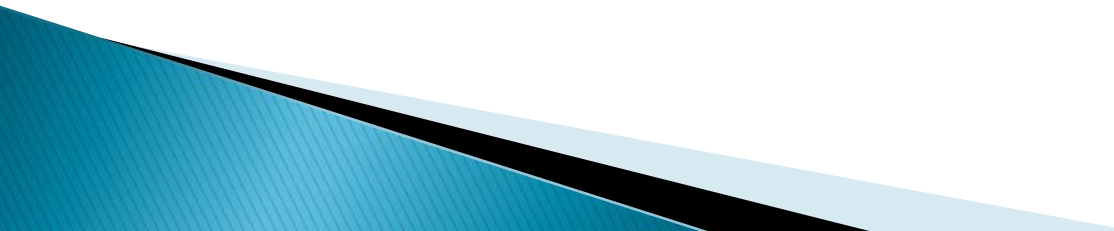


# Study Start-Up & Industry Expectations

# Current State = Opportunities

- ▶ **70% Site Start-Up Delays**
    - \$50,000 CRO/Sponsor Costs
    - \$13,000 Site-Level Costs
  - ▶ **45% Studies Completed Late**
  - ▶ **20% Sites Recruit Zero Patients**
- 

# What Are CROs /Sponsors Looking For In A Site

- ▶ **Experience**
  - ▶ **Patient Population**
  - ▶ **Investigator Interest**
  - ▶ **Process & Capabilities**
  - ▶ **Historical Performance**
- 

# Quintiles Partner Goals

## ▶ Increase Utilization

- Active Trials – Goal  $\geq 20$  (JHU = 30)
- Subjects Contributed – Goal  $\geq 100$  (JHU 2014 = 47)

## ▶ Reduced Cycle Time

- CDA < 20 Days (JHU 2014 = 36)
- CTA – < 133 Days (JHU 2014 = 212)

## ▶ Quality Metrics – Site and Study Specific

- JHU Overall Trending 94%
- Partner Site Trending 96.3%
- Non-Partner Site Trending 94.2%

# Quintiles Site & Study Metrics

Elibility & Entry Criteria Deviations	Patients with ICF Deviations	Patients with IP Deviations	Patients with Source Doc Criteria Deviation	Patients with SAE Deviations
1	1	0	0	0
0	1	0	0	0
0	0	7	0	0
0	1	2	0	0
0	0	2	0	0
0	0	8	0	0
0	0	1	0	0
0	1	4	0	0

# Quintiles Site & Study Metrics

No. of Pts Randomized	No. of Pts Screened	No. of Pts Complete	No. of Pts Enrolled	Avg. GCP & Protocol Compliance
1	1	0	1	0.6
1	1	0	1	0.8
7	10	0	7	0.829
4	4	0	4	0.85
3	3	0	3	0.867
13	13	1	13	0.877
2	2	0	2	0.9
13	18	12	13	0.933

# Parexel Site Alliance – 2015 Goals

- ▶ 300 Alliance Sites Globally
    - 100 – US/Canada
  - ▶ 10% “Better” Start-Up
  - ▶ 20% Better Patient Enrollment – Than Country Avg.
- 



# Supporting Investigator Interest

- ❖ JHCRN Investigator Database Handout
- ❖ Research Resources Handout

Header section for the Johns Hopkins Institute for Clinical & Translational Research. It features the logo on the left, navigation links for "ABOUT US" and "CONTACT US" on the right, and a search bar with a "GO" button.

- CLINICAL RESOURCES
- CONSULTING SERVICES
- FUNDING OPPORTUNITIES
- COLLABORATION, MENTORING & TRAINING

# INFORMATION FOR INVESTIGATORS

Browse: [Home](#) / [Clinical Resources](#) / [Human Subjects Research Core](#) / [Johns Hopkins Clinical Research Network \(JHCRN\)](#) / Information for Investigators

## Welcome Investigators

Capitalize on a dynamic community of investigators, institutional collaborations, rapid access to industry-sponsored studies, and a

## News

- [Successful Pharmaceutical Study Start-Up: Key Steps for...](#)
- [New Investigator Training Bootcamp: October 30th](#)
- [SMARTT Program: Speeding the Translation of Discoveries to...](#)
- [CTSA Tool Shop Webinar July 18: The](#)

# JHCRN Investigator Registration

- ▶ <http://ictrweb.johnshopkins.edu/ictr/jhcrn/investigator.cfm>
- ▶ The JHCRN intends to share your information with external research entities (i.e. pharmaceutical sponsors and/or their associates) when a potential opportunity matches your specialty area(s) and/or research interests. \*

You agree to allow the JHCRN to share your information with entities external to JHCRN sites.

Yes    No

# THANK YOU

---

