Navigating the "7-Cs"of Clinical Outsourcing: There be Dragons!

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GENSTAR CAPITAL

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The View of Dragons Vary…

Navigating the 7-Cs

Where are the Dragons?

Navigating The 7-C's of Clinical Outsourcing:

1. **Change:** New approaches to outsourcing, FDA, and healthcare reform ….
2. **Complexity:** "Big data", genomics, and personalized medicine…
3. **Consolidation:** Biopharma, CROs, technology companies, labs, public to private conversions…
4. **Continuity:** Industry consolidation can lead to significant turnover in both sponsor companies and service providers. The ability to minimize development disruption is an important success factor…
5. **Consistency:** "You're only as good as your last project", the key to success is minimizing inconsistent delivery of services and products…
6. **Competency:** Essential skills and knowledge in the outsourced areas, but also understanding the customers' strategy and goals for the product…
7. **Collaboration:** Essential to any customer - supplier relationship …

Environmental Factors Driving Pharma Change

Market Forces Shaping the Healthcare Continuum….Which are the Dragons?

Drivers & Disruptors

Cost of Healthcare & Impact of New Models

Longevity & Chronic Diseases

Patient Engagement & Advocacy

Tele-Medicine & Digital Health

Clinical Innovation

Diagnostics, Robotics & AI

Policy & Regulatory Reform

Value Chain Integration

New Technology Entrants into Healthcare

Genomics, Big Data & Analytics

There Will be Healthcare Reform….

- Continued pressure to reduce healthcare costs, improve access and make drugs more affordable
- Lack of transparency and significant misinformation leading to distrust of all parts in the healthcare continuum and value chain
- Extreme Left favors universal healthcare or Medicare for all, single payer system, control of drug prices, and improved quality and patient outcomes
- Moderates and the Right also view a need for healthcare reform and improved access with a reduction in drug prices, but take a more measured approach….

The Debate is Front and Center among Voters….

Drug Pricing: *Perception Versus Reality*

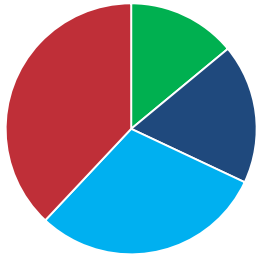
- A Politico/Harvard poll finds that a majority of lawmakers across both parties believe lowering drug prices should be the top priority for Congress in 2019, with 90% of democrats and 82% of republicans saying this is "extremely important."[1]
- The majority of Americans favor actions to reduce drug prices such as increased access to generics, price transparency and government intervention to more tightly regulate pricing and penalties of excessive pricing…[2]
- One in four people taking prescription drugs report difficulty affording their medication.[2]
- "The issue is not what drugs cost, but what patients pay out of pocket."
- The Wholesale Acquisition Cost (WAC) is based on what pharmaceutical companies believe the market will bare and will maximize profits rather that what price will cover prior investment and increase access to consumers.[3]
- Pharmaceutical companies rarely receive the WAC as there are a number of discounts and rebates as negotiations are made with wholesale distributors, PBMs, Medicare, and Medicaid.[3]

[1] https://www.politico.com/tipsheets/prescription-pulse/2017/09/25/congress-should-focus-on-drug-prices-politico-harvard-poll-finds-222465
[2] Kamal, Cox, and McDermott, What are the Recent and Forecasted Trends in Prescription Drug Spending? Peterson-Kaiser Health System Tracker, February, 2019.
[3] Rosenthal and Graham, Price and Affordability of Direct-acting Antiviral Regimens for Hepatitis C Virus in the United States, Infectious Agents and Cancer, 2016, 11-24.

What are the Facts Regarding Drug Prices vs Overall Healthcare Spend….?

- National spending on retail prescription drugs grew just 0.4% in 2017, which was slower than spending growth in hospital services (4.6%), physician services (4.2%) and overall health expenditures (3.8%).[1]
- The average net price for brand name drugs grew less than 2% in 2017 (after discounts and rebates totaling $153 billion).[2]
- One of the largest Pharmacy Benefits Managers (PBMs), Express Scripts, recently reported that net drug prices had dropped by 0.4% and drug prices for Medicare plans declined by 1.4% in 2018.[3]
- For every $1.00 spent on healthcare in the U.S., just 14¢ is spent on drugs.[4]

Healthcare Spend in the U.S.

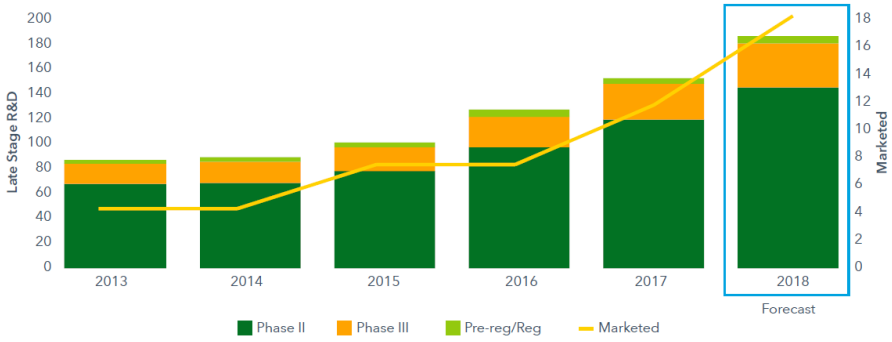


- Prescription Drugs
- Physicians and Clinical Services
- Hospital Services
- Other Services (Home Healthcare, Nursing Care, Facilities, Etc.)

[1] https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures
[2] https://www.drugchannels.net/2018/04/the-gross-to-net-rebate-bubble-topped.html
[3] https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022
[4] https://www.drugcostfacts.org

Shift in Biopharma Drug Pipelines Focused on Higher-Priced Biologics…

Number of Next Generation Biotherapeutics Currently in Late Stage Development or Marketed



Source: IQVIA Institute, IQVIA R&D Insight, Jan 2018
Notes: Reg = Registered.

PhRMA's Response… It is the Cost of Innovation!

America's biopharmaceutical industry invests **$90 BILLION** in research and development

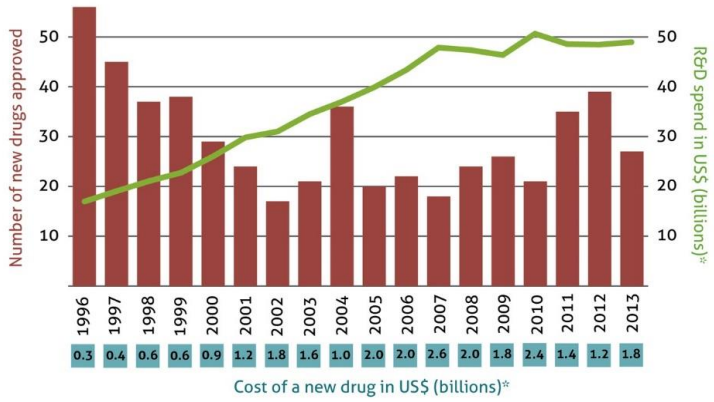
In 2016, the U.S. Food and Drug Administration (FDA) approved **27 NEW MEDICINES,** including 22 new medicines approved by the FDA Center for Drug Evaluation (CDER)

More than **7,000 MEDICINES** and treatments are in development globally right now

Roughly **3,500 COMPOUNDS** are currently being studied in the United States alone—more than in any other region

2018 Cost of Biopharma Innovation: > $2.6 Billion Per Drug and 59 Drugs Approved

2018 was a banner year for the US Food and Drug Administration (FDA), with 59 new drugs approved by the Center for Drug Evaluation and Research (CDER), including 19 first-in-class agents, 34 novel drugs for rare diseases, and a record seven biosimilars.[2]



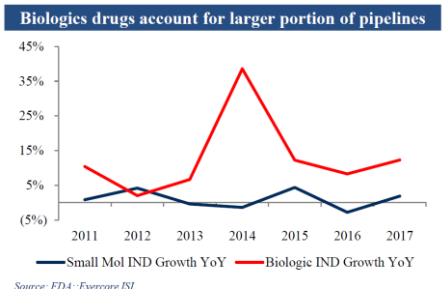
Data: USFDA, PhRMA

Akshat Rathi | theconversation.com

** New drug cost and R&D spend could be 30% higher if non-PhRMA members are included*

[2] Medscape, January 2019

New Therapeutic Targets Creating More Complex Trials



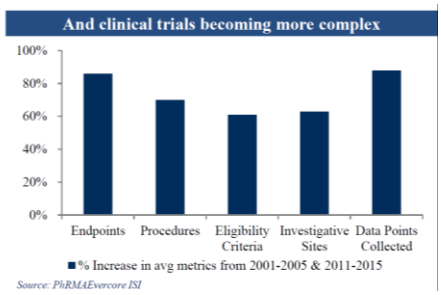


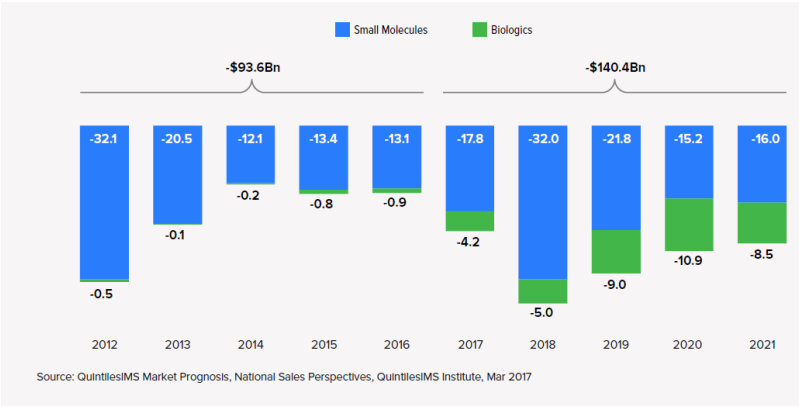
Figure 14: Trial complexity has increased

	2001-2005	2011-2015	% Growth
Number of distinct procedures[1]	24	36	52%
Total number of procedures performed[1]	135	220	62%
Cost per study volunteer[1]	$949	$1,412	49%
Number of patients[2]	729	597	(18%)
I/E criteria[2]	31	50	61%
Countries[2]	5	10	102%
Sites[2]	124	196	58%

Source: 1. Getz, K.A. "Trends in clinical trial design complexity" Sup. Bos 01, 2017 [Simple average across Ph I/II]; 2. IQVIA 2017 analyst day presentation. Numbers are average per trial

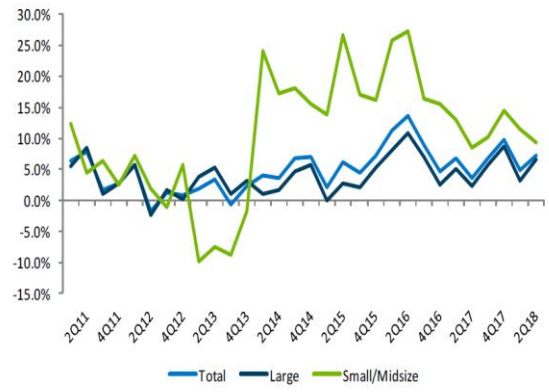
Drives increased R&D cost and increased outsourcing

Drug Sales at Risk From Patent Expiries…



Historical R&D Growth

Total vs. Large vs. S/Mid Average Weighted R&D Growth, 2011 to Present



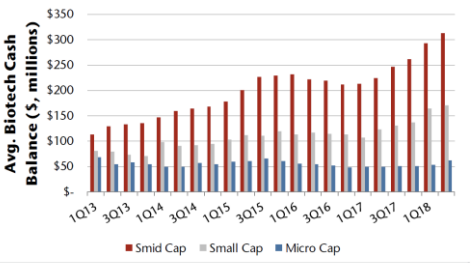
Note: Consists of 217 companies, a majority of which are included in the NYSE DRG and Nasdaq Biotechnology indices
Source: FactSet and William Blair estimates

…Recently Driven by Strong Biotech Funding

Biotech funding at all time highs…

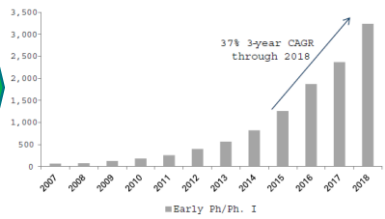
Source: BioCentury. Note: Includes venture, follow-ons, and IPOs; as of 12/10/18

…and so are cash balances

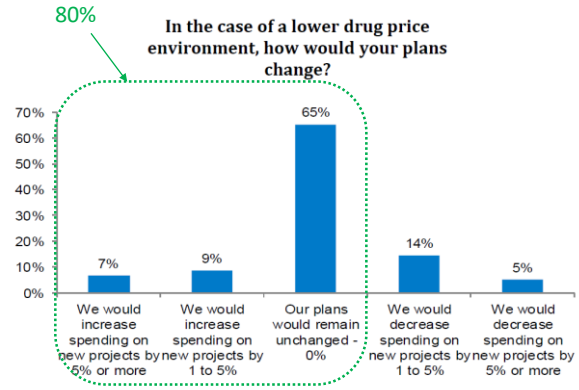


Source: Factset and Jefferies

Unprecedented pre-clinical and Phase I trial starts



Optimism for Continued R&D Growth; However, …



Note: 138 respondents (Large:56, Midsize: 26, Small: 56)
Sources: Life Science Strategy Group, LLC and William Blair

A recent survey conducted by the law firm of Manatt, Phelps and Phillips, LLP reveals that 70% of America's Pharmaceutical companies would likely have to make significant cuts to cancer R&D if certain Medicare Part B proposals go forward. Half of responding companies reported that 20% or more of their current projects could be reduced or terminated.[1]

[1]https://innovation.org/about-us/commitment/innovation-fragility/washington-considering-policy-changes-that-could-threaten-innovation

Biopharmaceutical Industry Trends

- Pharma companies significantly investing and bringing to market 'orphan' drugs
  - Orphan drugs target smaller populations with unmet needs; only 40% of known diseases are currently treatable!
  - FDA encouraging/fast-tracking novel drugs
  - Less competition protects pricing
  - Significant price of drugs compensate for continued patent expiries and price pressure from PBMs
- Political headline risk related to drug pricing; recent legislation proposed
- Increasing R&D costs (cost per marketed drug has doubled since 2010!)
- Increasing need for real-world evidence to prove efficacy of drug to support reimbursement
- Increased discounts to PBMs to get included on formularies (significant pressure on generics, including list price decreases in high single digits)
- Unprecedented levels of Biotech funding – Hubs for externalizing innovation
- Next round of consolidation and biotech-pharma mergers? BMS/Celgene ($75B!)

Change at the FDA, EMA & Healthcare Reform

FDA News

- Resignation of FDA Commissioner Scott Gottlieb in March 2019 was a Shock
- What does it mean for drug development and healthcare regulatory policy?
  - In 2018, drug approvals increased 28% over the prior year supporting accelerated drug development
  - New improved PDUFA VI, GDUFA II and BsUFA II Regulations (2017)

Dr. Gottlieb was respected by the agency's career staff, which enabled him to push them "to do more and to do things differently. That combination is hard to find."

Laurie McGinley and Lenny Bernstein, The Washington Post, March 2019.

Dr. Ned Sharpless, who was supported by Dr. Gottlieb and is coming from his post as Director of the NCI, will likely stay the same course set by Dr. Gottlieb, focusing on clinical trial optimization in targeted patient populations

FDA Areas of Focus

- Focus on driving increased competition to lower drug prices
  - FDA Commissioner Gottlieb is strong champion of generic industry
    - Record amount of generics approved in 2017
  - Increase in speed, and number, of drug approvals to accomplish goal
  - Use of real word evidence to accelerate drug approval
- Focus on reducing regulatory burden and increasing innovative products
- FDA approving record amounts of new drugs
  - Meaningful increase in new drug filings since 2011, which signals a strong pharma pipeline
- FDA providing fast-track approvals for orphan drugs (targeting rarer diseases with smaller patient populations)
- FDA focus on Real World Evidence (RWE), "patient-centricity" and a new more relevant model for drug development: Moving clinical research and clinical care more in line with patient needs

EMA and European News

- Move of the EMA from the UK to Amsterdam in progress:

Christa Wirthumer-Hoche
Chair of EMA Management Board

- Focus on driving increased competition to lower drug prices across EU member states
- Like the FDA, the EMA is carefully examining how to incorporate RWD/RWE into regulatory decision making: A taskforce was created: the "HMA-EMA Joint Big Data taskforce" which issued a key summary report in February of this year.
- The EU's Innovative Medicines Initiative (IMI) is pursing the development of machine learning and digital clinical trials and have created a Centre of Excellence Project on Remote Decentralized Trials.

EMA and European News

- The ICH released the E8(R1) for public consultation: Topics include adopting a quality-by-design framework for clinical studies and expanding the guideline's scope to include a broader range of study designs and data sources.
- Rising drug prices, access and reimbursement continue to be major issues across EU member states.
  - Strict price controls and annual reviews by government health plans
  - New innovative drugs to treat cancer, rare diseases and neurodegenerative disorders have led to large increases in drug prices relative to historical levels
- Major focus on "Relative Effectiveness" and evidence generation of new medicines in order to demonstrate cost effectiveness, value and to stimulate competition and innovation.

Pharma Services Landscape

Pharma Services Landscape

Discovery & Preclinical	Clinical & Reg.	Mfg. & Packaging	Supply Chain	Commercial & Comm.	Med. Affairs
Primary Services: • Target identification / validation • Screening and lead generation • Candidate prioritization / optimization • Drug metabolism / pharmacokinetic analysis **Support Services:** • Biological / diagnostic tools development • Animal research models • Informatics • Imaging services • Analytical sciences • Pathology services • Toxicology services • Supply management / distribution • Sample storage	**Primary Services:** • Clinical trial management • Regulatory consulting services • Safety and efficacy data management • Health economics and outcomes research **Support Services:** • Clinical trial optimization / enhancement • Patient / investigator enrollment • Site management • Supply management / distribution • Patient monitoring • Analytic and imaging services • Electronic data collection • Biometrics / biostatistics • eClinical • Clinically observed outcomes • Site management organizations • CTMS • RTSM	• API process development • API manufacturing • Formulation development • Dose form manufacturing • Fill / finish manufacturing • Process development and scale-up • Quality control / quality assurance • Analytical laboratory services • Packaging solutions • Labeling solutions	• Primary distribution services • Specialty product application / dosing • Specialty distribution • Specialty pharmacy • Home infusion	• Contract sales / field force • Patient services / case management • Hub services / patient access • Market access services • Marketing & communications • Marketing services • Multi-channel marketing • Adherence programs • Adherence / compliance services	• Market access services • HEOR • Real-world evidence • Scientific publishing and communications • Publications planning and management • Medical writing • Regulatory writing and submission • Medical education

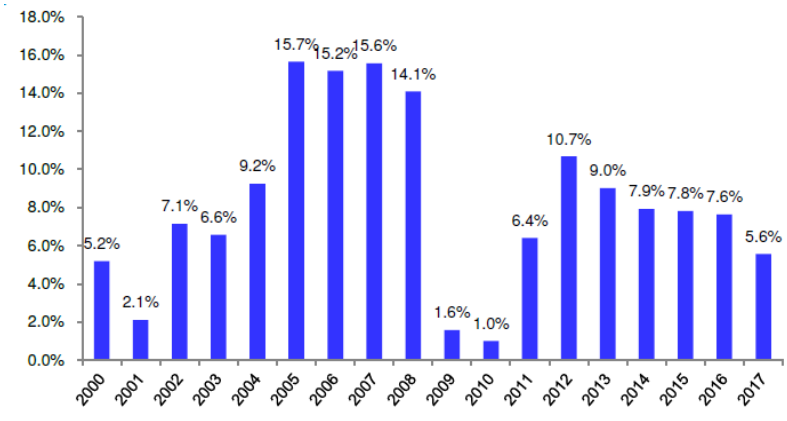
Contract Research Organizations (CRO)

How Well do You Know Your CRO History?

- What was the first CRO acquired by a company outside the CRO industry?
  - Corning Glass Works acquired Hazelton Labs in 1987 (preclinical testing)
  - Corning Inc. acquired G.H. Besselaar Associates in 1989
- What mega-CRO resulted from this initial consolidation?
  - Lab Corp - Covance

CRO Historical Organic Growth

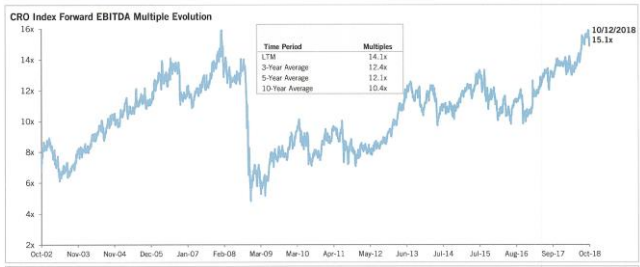
2018 growth of approximately 7% with optimistic projections of 9.1% and 10.3% in 2019 and 2010, respectively, shows confidence in outsourcing fundamentals.[1]



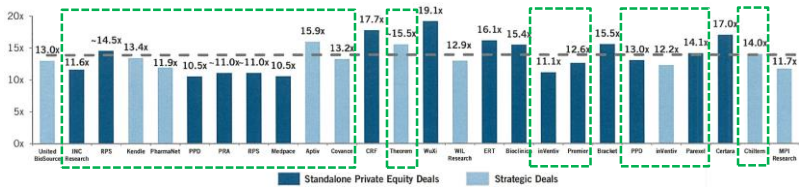
Source: Company filings, Deutsche Bank estimates

[1]D. Windley and D. Yan, Annual Survey Says CRO Outlook is Encouraging: Upgrade IQV, Jefferies Equity Research, Pharmaceutical Services, January 2019.

CRO Trading & Precedent Comps Show Healthy Valuations



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018 YTD
Yearly Average	7.3x	9.3x	11.0x	12.7x	12.5x	11.8x	7.2x	8.5x	8.6x	8.5x	11.2x	11.1x	12.1x	10.9x	12.7x	14.2x
Forward EPS Growth Rate	21%	20%	20%	23%	23%	22%	15%	23%	24%	32%	19%	15%	16%	17%	17%	29%
R&D Spend Growth	13%	16%	7%	17%	13%	9%	(6%)	5%	1%	3%	4%	4%	2%	5%	3%	3%
CRO O/S Penetration	35%	34%	35%	35%	35%	36%	37%	37%	38%	40%	41%	43%	44%	46%	47%	48%



CRO Merits & Considerations

Merits

- Accelerating R&D spend
- Proven CRO value proposition drives outsourcing
- Biopharma cash balances at all-time high
- Increasing trial complexity favors outsourcing
- Surge of interest and growth in Phase IV/post-approval
- Trends toward consolidation having positive impact on sector valuation

Considerations

- Biotech spending if sustained contraction in financing markets
- How much outsourcing penetration is left to drive growth? 10+ points?
- Potential large pharma mergers
- Political rhetoric on pharma pricing
- Margin pressure from move to FSP (functional service providers) and large strategic partnerships

Contract Development & Manufacturing Organizations (CDMO)

CDMO Overview

- Outsourced market of ~$40 billion, growing high-single-digits
- Significant amount of fragmentation (top 5 players control ~25% of CDMO market)
- Increased focus of pharma companies to reduce manufacturing footprint
- Significant supply/demand imbalance for biologics manufacturing

Merits

- Accelerating R&D spend / strong global demand for drugs
- CMOs offer superior operational efficiency for both large and small molecules
- Greater product complexity adds to manufacturing challenges for pharma companies
- ~30% of CDMO work outsourced; good penetration runway left
- Significant M&A given fragmentation of suppliers and pharma site sales (650 manufacturing sites @ big pharma)
- Trends toward consolidation having positive impact on sector valuation

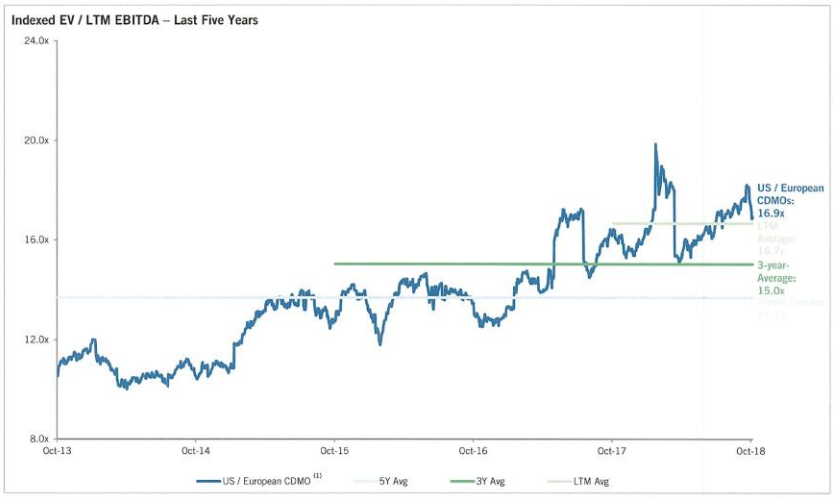
Considerations

- Overcapacity in certain areas driving margin pressure?
- Conventional manufacturing techniques lack differentiation
- Capital intensity; need to find businesses with acceptable R.O.I.C.
- Long sales cycles

CDMO/Packaging & Logistics Landscape

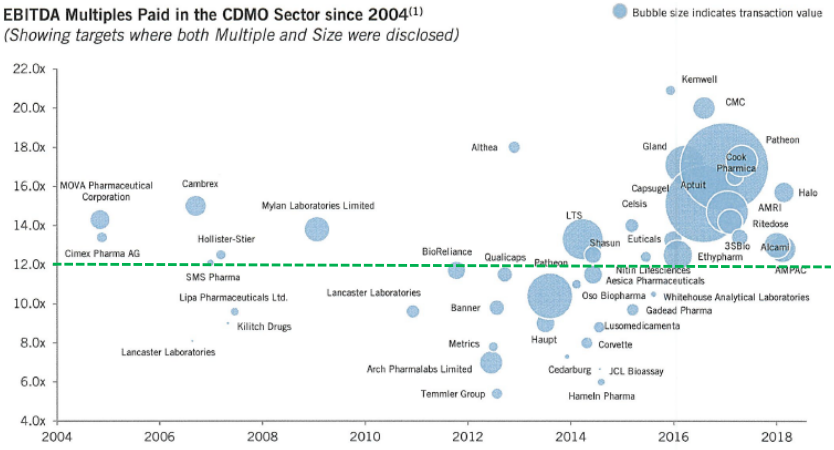
Pharma Value Chain	Research	Development/Clinical			Commercial				
Out-sourced Services	**Research/ Discovery** Research for new therapeutic molecules **~35% outsourced**	**Development** Pre-clin / Clin -Develop/assess new molecules -Design, execute and monitor clinical trials **20-35% outsourced**	**Manufacturing** API / Drug prod Synthesize API and DP, including PD **20-50% outsourced[1]**	**Pack./Distr.** Pack / Distr Prim. + sec. packaging and clinical trial logistics **20-40% outsourced**	**Manufacturing** API / Drug prod Synthesize API and DP, including PD **20-50% outsourced[1]**	**Packaging** Prim. / Sec. **Prim.**: Place DP into prim. contai-ner (e.g. vials) **Sec.**: Apply sec. packag. (cartons..) **15-30% outsourced**	**Distribution** Sto-rage / Tran-sport -Warehouse and maintain drugs -Deliver drug products to end customers **n/a**	**Sales & Marketing** -Sales staff -Marketing activities **5-10% outsourced**
Mkt size outs. ($)	~9B	~20B	~7B	~3B	~4B	~35B	~14B	~5B	n/a	5-6B
CAGR (15-20)	7-8%	5-7%	6-7%						n/a	8%[2]
EBITDA margin	15-20%		~20%+	10-15%	~20%	~15%			n/a	n/a

CDMO Trading Comps



CDMO Precedent Transactions

EBITDA Multiples Paid in the CDMO Sector since 2004(1)
(Showing targets where both Multiple and Size were disclosed)



Change in Outsourcing

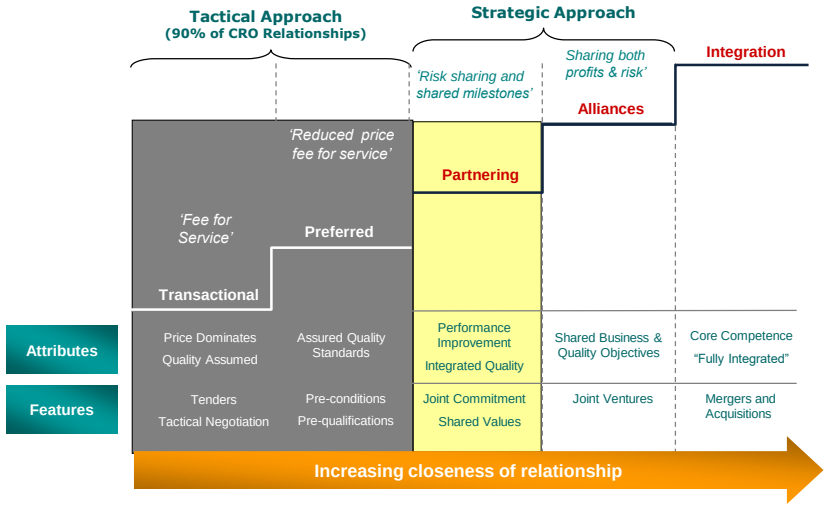
A brief historical perspective

Functional, BPO and Full Service Outsourcing

March 8, 2004

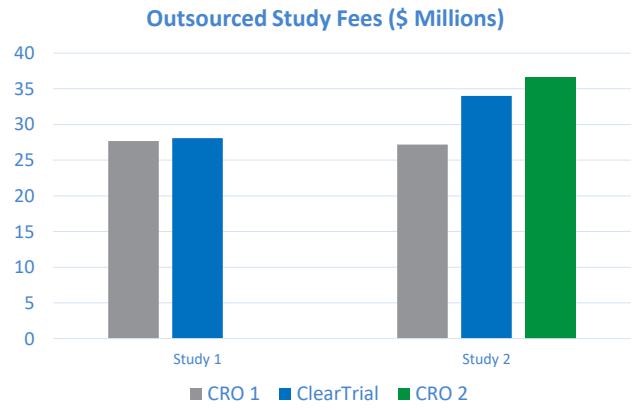
Evolving Outsourcing Models: FSP, Full Service, Hybrid…

Sourcing Approaches & Options: Where do Most CRO Relationships Exist?



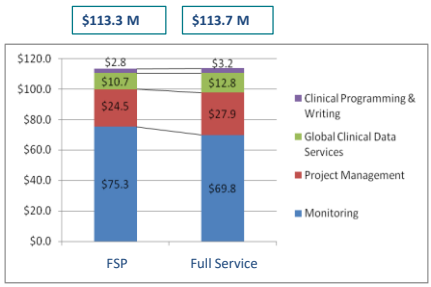
Direct CRO Fees: FSP vs Full Service

	CRO 1	Clear Trial	CRO 2
Study 1	$27.7 M	$28.1 M	-----
Study 2	$27.2 M	$34.0 M	$36.7 M



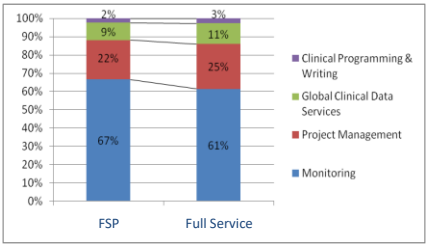
Analysis Shows Cost Comparability Between Full Service and FSP Models

Total by $



- Largest costs are in Clinical Monitoring, Project and Study Management accounting for up to 89% of the total budget

By % Allocation



- Comparing the relative percentage of each cost type, monitoring had the biggest difference of only 6%

6 Compounds, 14 Protocols

Is One Model Better than Another?

- No significant differences between FSP and full service models with regard to total costs and costs by function.
- A general view of greater control in the FSP model by sponsors (both resources and systems).
- Internal fixed costs to oversee and manage FSP providers is higher than full service model when tasks are fully delegated.
- Quality and performance are generally comparable between models.
- Most models have settled into a “preferred vendor” and partnering approach, regardless of model type.

Industry Outsourcing Trends

- Shift to fewer suppliers
- Dedicated vendor management functions
- Risk sharing and annual savings targets
- Mix of FSPs, full service providers and BPOs
- Acceptance of outsourcing advantages with regard to cost, time and quality
- CROs evolving from tactical resource to strategic service providers
- Consolidation among providers and the formation of “mega” CROs
- Impact of PE firms and privatization from the public environment

CRO Industry Tail Winds…

- Accelerated R&D spending
- Increasing outsourcing penetration
- Larger global CROs appear to be gaining share, but the "rising tide lifts all ships"
- Increased appreciation of the value of "Big Data" to enhance the speed of clinical development
- Resurgence in Asia-Pacific capabilities as large biopharma expands in these markets
- Re-balancing of resources: In house, FSP and Full Service in Strategic Partnerships
- Improved cooperation between Transcelerate, CTTI and ACRO fueling innovation across the clinical development ecosystem
- Increased customer satisfaction with partnerships compared to 2017, but still below the peak in 2016

[1]D. Windley and D. Yan, Annual Survey Says CRO Outlook is Encouraging: Upgrade IQV, Jefferies Equity Research, Pharmaceutical Services, January 2019.

Private Equity Investment, New Models and What's Next?

Private Equity Investment Drivers

- Strong market position with a sustainable competitive advantage
- Multiple avenues for organic and inorganic growth
- Stable recurring cash flows
- Low capital expenditure requirements
- Favorable industry trends
- Experienced leadership
- Multiple areas to create value:
  - Divest underperforming assets
  - Improving efficiency of operations
  - Pricing optimization
  - Organizational delayering
  - Expanding the customer base
  - Globalization

Private Equity Concepts

- Investment Funds: Combination of debt (leverage) and equity
- Buy low and sell high: Creating excitement in the industry can fuel valuations (e.g., ERT transaction)
- Investment period of 3-5 years on average
- Target industry consolidation and economies of scale
- Upscale management if needed (generally CEO, CFO and Head of Business Development)
- Partner with management to create value and growth
- Focus on the end game and exit vs quarter to quarter performance
- Exits can be IPO, sale to a strategic buyer or sale to another PE firm

Consolidation and New Models, Some Examples….

- Jaguar Holdings Company (U.S. firm) acquires PPD in 2011 (private transaction ≈ $4 billion
- PPD (Jaguar Holdings, PE firm) acquires Acurian and Radiant Research to create a more integrated value chain
- Lab Corp acquires Covance in 2015 (transaction ≈ $6 billion)
- IMS acquires Quintiles in 2016 to form IQVIA (transaction ≈ $9 billion)
- Nordic Capital (EU PE firm) acquires ERT in 2016 (transaction ≈ $1.8 billion)
- Cinven (EU PE firm) acquires Bioclinica in 2016 (transaction ≈ $1.4 billion)
- Pamplona (EU PE firm) acquires Parexel in 2017 (transaction ≈ $9 billion)
- Genstar Capital (U.S. PE firm) acquires CRF Health (merged with Bracket Global) in 2018

State of Healthcare PE Investments

- Healthcare private equity activity remains at historically high levels
  - Deal count increased significantly from 2016 to 2018, with a CAGR of 21.4%
  - Value of worldwide Healthcare PE deals in 2018 was $103.7 Billion, primarily led by the U.S.-based firms, a 17% increase over 2017 values.
  - Total disclosed value increase driven by more megadeals ($4.5+), four in 2018 compared to only one in 2017
  - Deal count increase driven by more activity in the APAC region
- Most active region was North America, and provider was the most active sector, consistent with prior years
  - Funds relied on expanded deal approaches in order execute deals due to rising valuations
  - 8 of top 15 deals executed by consortium of financial sponsors and/or alongside corporate partners
  - The four largest deals of 2018, totaling $27.1 billion, were public to private conversions
  - Investors continued buy and build strategies signaling intentions to make follow-on investments in more than 25% of deals
  - Buyout funds increased growth and other earlier stage investments
  - Increased focus on portfolio add-ons (“double plays”, “tuck ins”, and “adjacency expansion”)
- Going forward, the consensus is that the pace of investment in Healthcare will continue
  - Healthcare is historically a good investment area for PE investors, particularly during recessions
  - While valuations are arguably high, many funds are taking different approaches to support them (e.g. follow on M&A, commercial excellence, operational improvement)…

Summary and Conclusions

Executive Summary/Key Takeaways

- **Health of biopharma companies remains strong:**
  - Robust drug research pipeline of high-value drugs
  - Significant funding and cash balances with Biotech
  - Overall favorable FDA environment leading to increase in drug approvals
- **Pharma outsourcing levels continue to increase with future runway**
- **From an investment perspective, a number of actionable opportunities in 2019/2020 will become available for consolidation:**
  - CROs, Packaging/Logistics, Specialty Clinical Services, Post Approval/Commercial, Technology/Clinical Software, and CDMOs
- **Areas of continued focus impacting industry dynamics and change:**
  - New paradigms in the healthcare system affecting drug pricing could be a significant factor
  - Biotech funding affecting R&D spending
  - Pharma sponsor M&A affecting drug development pipelines
  - Generic penetration for biologics
  - New regulatory pathways and guidance
  - New models and entrants in global drug development leading to disruption
- **Private Equity investment continues to increase in Healthcare and Biopharma Services**

Thank You