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Pharmaceutical R&D Outsourcing: Best Practices, Trends, and Predictions

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Agenda

- The state of the RDO market
- Service delivery models – determining the best one for your organization
- Regulatory outsourcing – benefits, considerations, and risks
- How to safely optimize RDO through controls and risk mitigation
- Evolution of the R&D market – what's next?

PHARMA INDUSTRY SOURCING TRENDS

Pharma Industry – Challenges

- Patent cliff- pharma industry is set to lose \$78 billion between 2009-2014
- US Prescription sales expected to decline over next 5 years with non-US markets sales to increase and offset reduction
- US Healthcare Reform
 - Payers' cost containment measures (price and reimbursement cuts) impact pharma through:
 - *Shrinking profit margins*
 - *Heavier competitive pressures*
- Growing regulatory pressure
 - Continued focus on drug safety and restrictions of pharma marketing
- **European/US Budget Deficits – cost containment of Healthcare**

Pharma Industry – Actions being taken today

- Industry consolidation via M&A and Joint Ventures
 - Leverage economies of scale
 - Capitalize on synergies
 - Expand pipeline or other ‘lacking’ areas
 - Expand into new markets
 - Expand into new product categories (e.g., pharma + biotech)
- Increased partnering in areas that were previously considered proprietary
- Redefinition of the corporate strategy via diversification vs. specialization
- Revisiting what is considered core vs. non-core
 - Leads to additional outsourcing and establishment of multifunctional shared services organizations
- Deliberate focus on improving collaboration

Pharma Industry – Actions being taken today (cont)

- Continued implementation of ‘across the board’ cost reduction programs to grow profits and offset slowing sales growth
 - R&D Restructuring
 - Reduce clinical phase and early-stage R&D costs
 - Additional sales force reductions
- R&D cost cutting goals include improved profit margin without impacting drug development programs
 - Outsourcing is a key strategy for R&D and all SG&A functions
- Revisiting what is considered core vs. non-core
 - Leads to additional outsourcing and establishment of multifunctional shared services organizations

Pharma Industry – Next 18 Months

- Emerging market expansion- growth potential of 12% year on year
- Biologics market expansion- grow \$41billion between 2009-2014
- Continued and accelerated consolidation through M&A activity
 - Includes spin-offs to allow increased focus on corporate strategy and core competencies
- Cost reduction programs will become more rigorous and ‘closer to the bone’
- Creative alliances and significant outsourcing relationships will evolve in areas like Real estate and facilities, Regulatory, R&D and Legal
- Providers establishing greater experience in dealing with multiple regulatory regimes but regulations will continue to evolve
- Increased emphasis on the role of governance for these new (and modified existing) contracts
- Will seek expert assistance from an operational level with how to bring together or tear apart existing outsourcing contracts due to these forecasted mergers and spin-offs
- Expansion of use of third party service providers in both operational and strategic (e.g., R&D) process areas
- Collaborations and joint ventures between pharma companies will increase and evolve
 - Looking at ways to share data and technology
 - Sharing of outsourcing providers/services

Pharma Sourcing Landscape

Company	Processes Sourced											
	IT	F&A	S2P	OTC	HR	CDM	Research	Real Estate & FM	Legal	Salesforce	Regulatory	
Pfizer	●	●	○	◐	◐	●	◐	◐	◐	◐	◐	●
GlaxoSmithKline	●	●	◐	◐	●	●	◐	●	○	◐	◐	◐
Sanofi-Aventis	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
AstraZeneca	●	◐	◐	◐	●	●	◐	◐	◐	◐	◐	◐
Merck	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Novartis	◐	◐	◐	◐	○	◐	○	●	◐	◐	◐	◐
Johnson & Johnson	●	◐	◐	◐	●	●	◐	◐	◐	◐	◐	◐
Roche	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Eli Lilly & Co.	●	●	◐	◐	◐	◐	◐	●	◐	◐	◐	◐
Wyeth	●	●	◐	◐	◐	●	◐	○	○	◐	◐	◐
Bristol-Myers Squibb	●	●	●	●	●	●	◐	●	◐	◐	◐	●
Abbott Laboratories	◐	○	◐	◐	◐	○	◐	◐	◐	◐	◐	◐
Schering-Plough	●	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Bayer Schering	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Boehringer Ingelheim	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Takeda	●	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Astellas*	●	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Daiichi-Sankyo*	○	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
Eisai*	○	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐	◐
UCB Group*	●	●	◐	●	◐	●	◐	◐	◐	◐	◐	◐

None	○	Unlikely or Unknown	◐	Evaluating/ In Process	◐	Some	◐	Most	●
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Sourcing Timeline



Regulatory BPO

eNDA standard						eCTD standard			BMS Purdue*	Allergan Pfizer Purdue* UCB	Abbott Boehringer Ingelheim GSK TBD (2)
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CDM/Data Management Clinical BPO

				Wyeth		Pfizer Novo Nordisk	Lilly Sequenom Merck Novartis	GSK BMS Merck Biogen Roche	Pfizer GSK Solvay J&J Roche AZ Amgen	UCB	J&J
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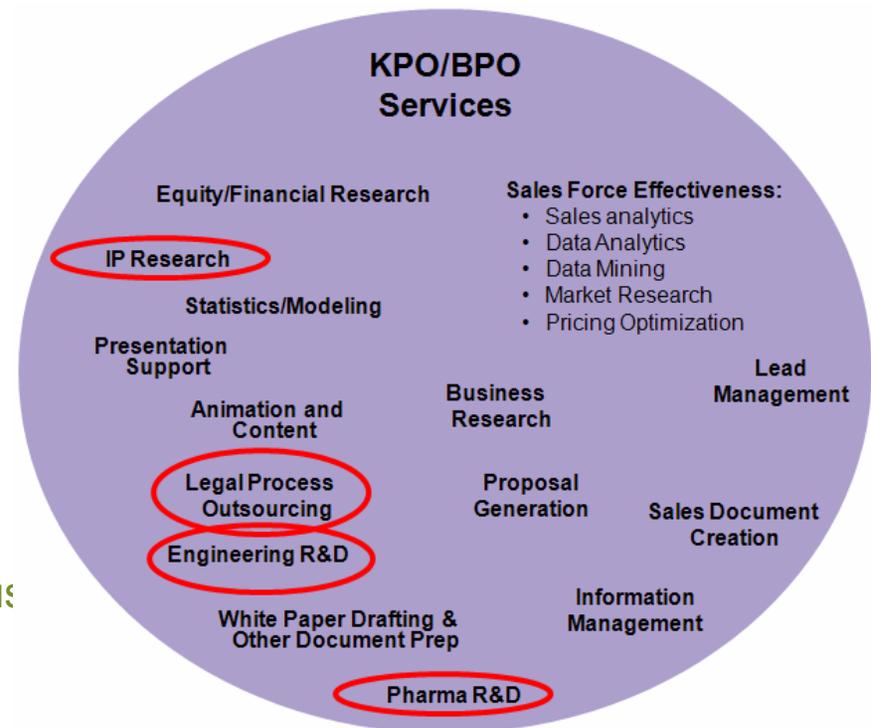
Research Outsourcing

							Pfizer		Wyeth Novartis		
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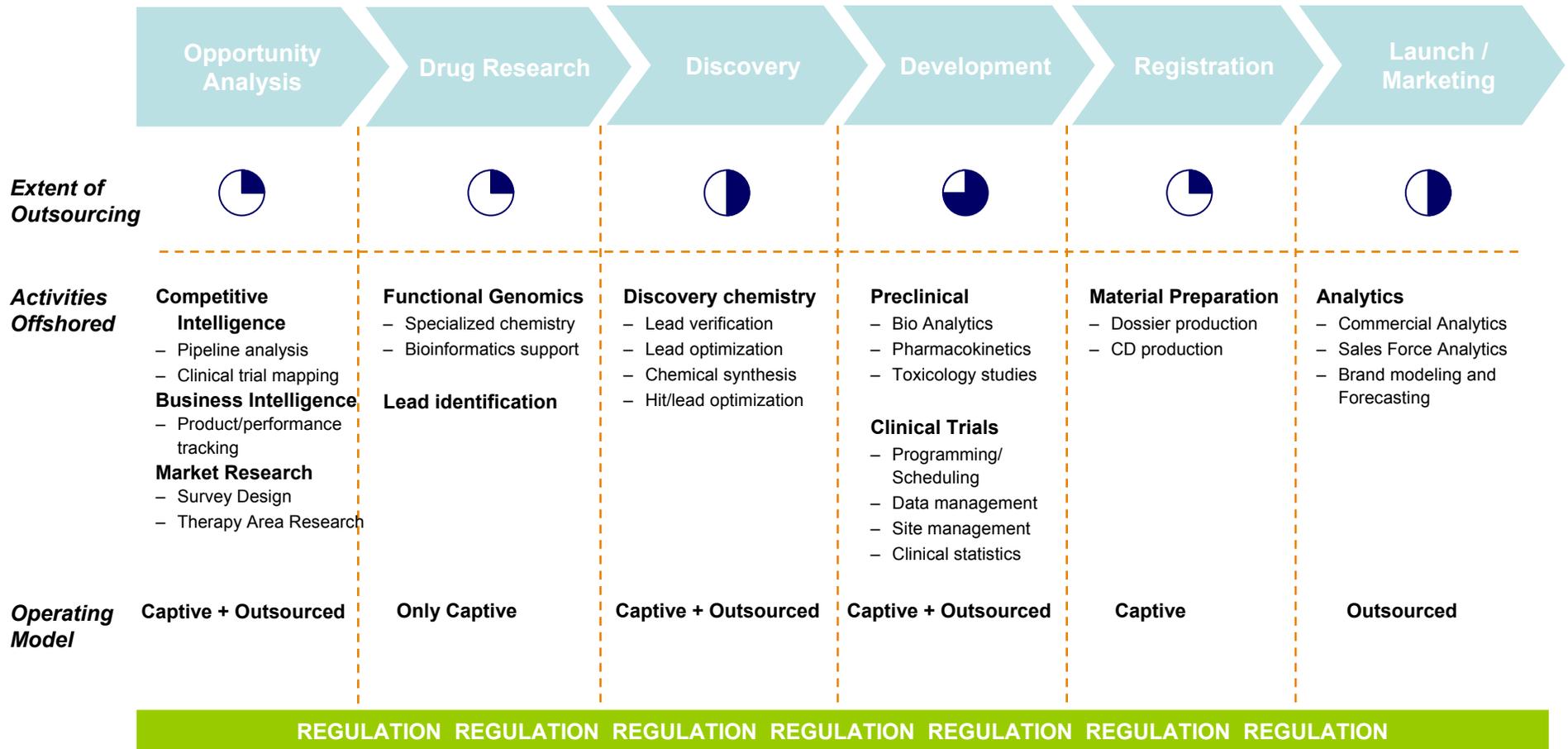
TRENDS IN PHARMA R&D OUTSOURCING (RDO)

Pharma BPO/KPO Covers a Full Range of Still Evolving Services

- Pharma is of the most experienced industries when it comes to outsourcing
 - Very mature in preclinical/clinical trials RDO work
 - Still exploring drug research/registration RDO work
- Common RDO approaches
 - Lots of RDO dabbling
 - Engaging tactically while defining a strategic direction
 - “Visions” are clearer than strategies due to competing priorities, numerous decision makers, and uncertainties over RDO maturation pace
 - Are not progressing monolithically across the organization; different areas have different agendas, goals and risk profiles



Outsourcing Opportunities Exist Across the Pharma Value Chain... Specifically within R&D



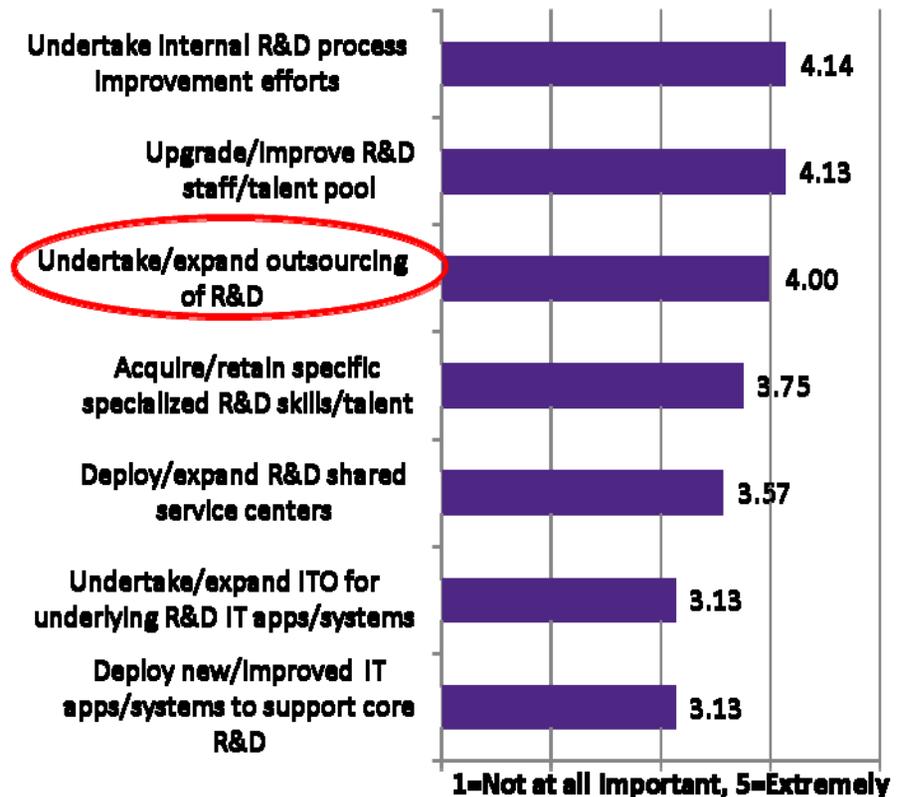
Most Outsourced
 Least Outsourced

Drivers for Pharma RDO

Pharma R&D Challenges/Trends

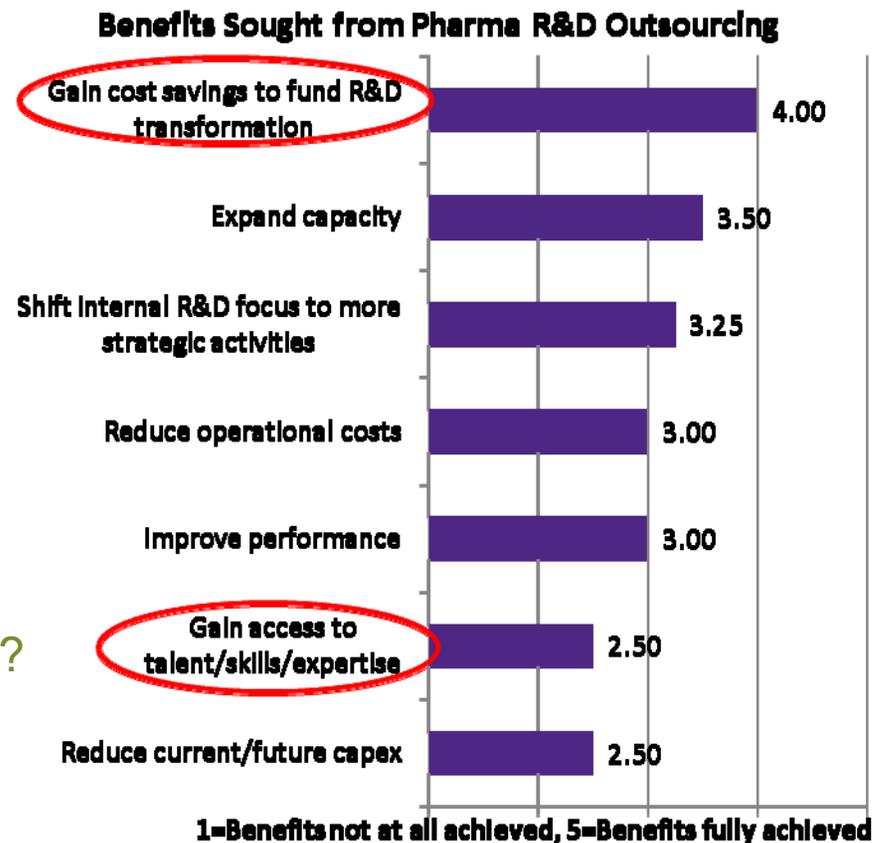
- Lots of M&A but efficiencies still elude R&D
- Capex requirements to invest in R&D enabling technologies
- Overall cost pressures
- Skills shortages, protectionist immigration policies
- Emerging market competition/needs to get into emerging markets
- Lessening differentiation from commoditized R&D activities
- Improving “supply side” pharma R&D capabilities/offerings

Means to Improve Pharma R&D Capabilities

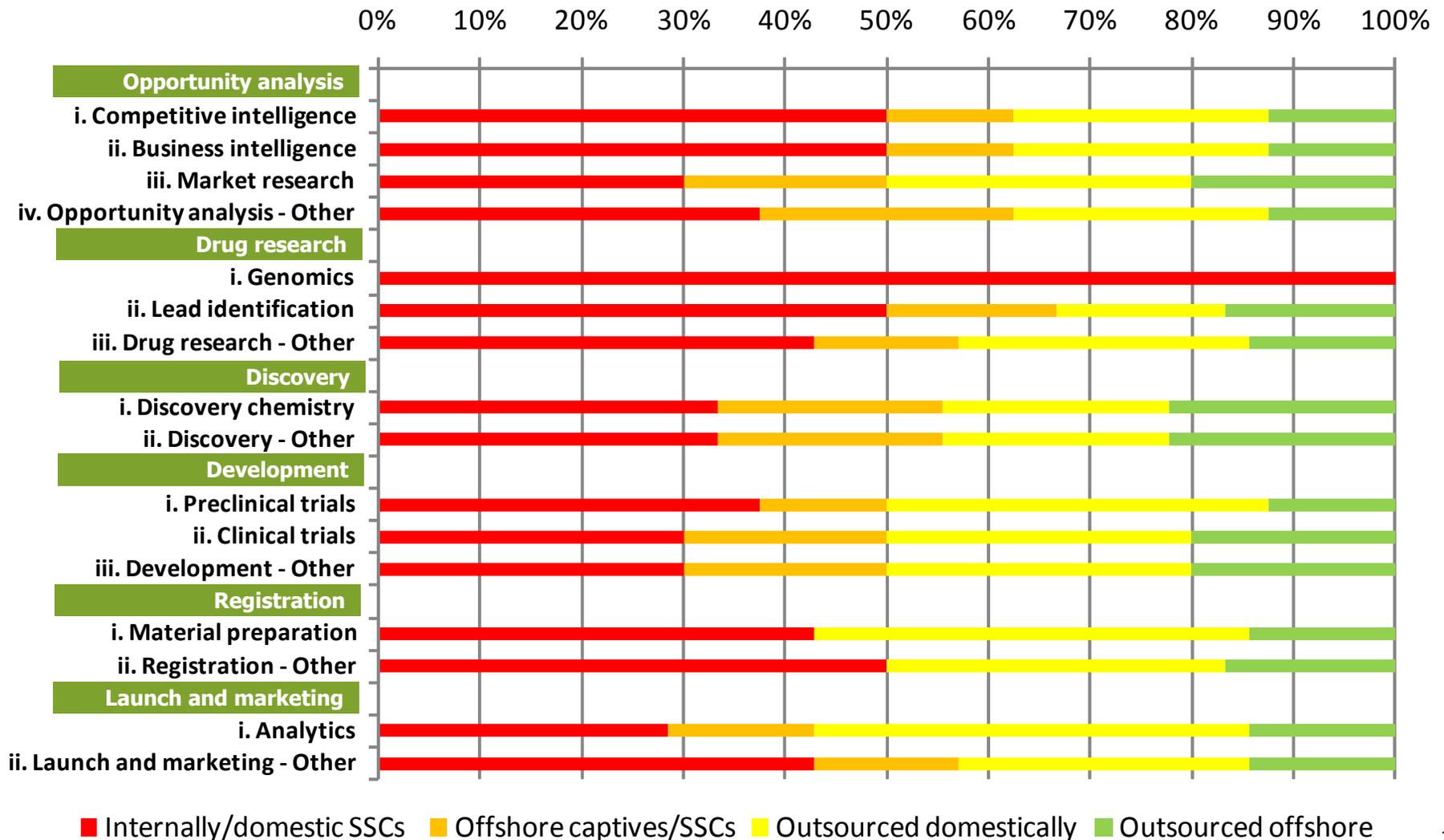


Benefits Sought & Achieved from RDO

- Access to skills is cited....
- But reducing costs is paramount
- But not an either/or scenario
- Benefits sought vary across firms and stakeholders within firms; clear definitions and stakeholder alignment key
- While benefits sought are similar to other type outsourcing, measuring success is more challenging
 - What constitutes R&D “innovation”?
- Important to balance aspirations with abilities to source and manage efforts



Representative Pharma R&D Service Delivery Model



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