

Clinical Trial Outsourcing



Module 8 Topic 5

What is Outsourcing?

- Transfer in full or part of the business activities to an outside entity
- This may include transfer of
 - Business Processes
 - Procedures
 - Responsibilities



What is Outsourcing?

- Giving out work
- On the basis of need – absence of competence
- On the basis of wants – for convenience
- For luxury – Nobility



Outsourcing – need of the hour

- Who – entities that need outsourcing
- What – activities to outsource
- Why – the reasons
- When – in what conditions
- Whom – ideal partner
- How – the process
- Evaluation – did it help
- Strategize - can this be added in a format



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Outsourcing - Who

- Pharmaceuticals
- Biotech companies
- Medical device companies
- Diagnostic instrument companies
- Research institutes
- Virtual companies



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Outsourcing - What

- Pre-clinical
 - Lead identification
 - Lead optimization
 - Toxicity
 - Pharmacological studies
- Clinical
 - Monitoring
 - Site management
 - Recruitment services
- Project / program management
 - Study management
 - Full product development plan management



Outsourcing - What

- Data management & Statistics
 - Data entry
 - Data cleaning
 - Data analysis
- Safety services
 - Pharmacovigilance
 - Laboratory testing services
 - Special central evaluations such as ECG, MRI, CT
 - Drug level testing in biological fluids
- Regulatory Services
 - Creating dossier for regulatory submissions such as IND, NDA, aNDA, sNDA etc.



Outsourcing - What

- Documentation services
 - Research report writing
 - Study publications writing
 - Narratives for Adverse events
- Information technology related services
 - IVRS
 - Electronic data capture services
- Manufacturing packing services
 - Active ingredient manufacturing for testing and trials
 - Clinical trial packaging and QA services



Outsourcing - What

- Consultancy services
 - Regulatory consulting
 - Clinical expertise
 - Medical expertise
- Storage services
 - Study drug storage
 - Study sample long term storage
 - Study documentation storage and archival



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Outsourcing - Why

- Process Optimization: Using more resource efficient ways to achieve the same objective
- Resource Pooling: Achieving the same objective in a less resource intensive way
- Productivity Outsourcing: Maximizing return from a fixed investment



Outsourcing - Why

- **Process Optimization:** Using more resource efficient ways to achieve the same objective
 - Centralized study management (integrated CTMS)
 - Remote or supplemented monitoring services
 - Hybrid /EDC data capture services
 - Simplified investigator compensation
 - CRO selected sites



Outsourcing - Why

Resource Pooling: Achieving the same objective in a less resource intensive way

- Sponsor commits to a fixed head count for a fixed period of time
 - not necessarily physical heads – eg. different experience/locations
 - Generally PM, RCs and CRAs
- Projects time staggered to optimize resource use
- “Customer managed” time credited against project cost



Outsourcing - Why

Productivity Outsourcing : Maximizing return from a fixed investment

- CROs bid to provide most services for a fixed price
- Sponsor establishes a fixed price for a set of requirements
- CROs optimize study specs and timelines within specified parameters
- CROs present optimized study tactics



Outsourcing - Why

- Cost reductions
 - Does this really happens?

	Q1	Q2	Q3	Q4	Q5	Q6	Total	Cost / FTE	Total costs
Project time (FTE)	2.5	3.5	3	3	6	3.5	21.5		
CRO charges	2.5	3.5	3	3	6	3.5	21.5	215,000	8,250,000
Company costs	6	6	6	6	6	6	36	360,000	9,000,000



There are hidden costs of idle manpower which are not always considered in company as this is considered as fixed costs

Outsourcing - Why

- High work load
 - Present team almost completely busy
 - Permanent manpower can not be added
- Limited manpower
 - Require only for specific project, short term
- Limited or absence of expertise
 - Need special expertise, not internally available
 - No need (or permission) for permanent position



Outsourcing - Why

- Strategic objectives
 - Deferring high investments
 - Long term relationship establishment
 - Agreements for the specific services not available internally
 - Availability of better managed teams
 - Need of development partner
 - Previous agreement at merger / takeover
 - Cyclical requirement
 - Availability of all services from one provider



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Outsourcing - When

- Specific project requirement
 - Specific contract for single project
 - Only for the services required
- Frequent requirements
 - Long term contract for specific services
 - Assurance of minimum value per year
 - Better bargaining power – better terms, better teams
 - Better understanding of requirements from the partners



Outsourcing - When

- Strategic relationships
 - Sole / preferred service provider
 - Long term contract for specific services – can be with multiple providers
 - Availability of Industry best practice
 - Priority Availability of resources
 - Contractually obligated to perform
 - Transfer of department/ unit
 - Transfer of long term liability
 - Retention of expertise, process



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Outsourcing - Whom

Looking for Ideal partner

- Choose your goals & priorities
 - Costs
 - Timelines
 - Quality
 - Experience and Expertise
 - Coverage (countries)
 - Any strategic relationship to be honoured
 - Flexibility in achievement of above



Outsourcing - Whom

Looking for Ideal partner

- Process
 - Decide the way to go (elaborated in How)
 - Shortlist the entities that suit your requirement
 - Evaluate their credentials from the perspective of the present work
 - Make double sure they can comply to requirement
 - Choose the first winner and a back up that suits the most
 - Negotiate for a budget and requirements acceptable



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Outsourcing - How

- Define the specifications
 - Requirements such as number of sites, patients, countries, recruitment rates
 - Timelines – start of activity, first patient in, last patient completed, data cleaned, statistical analysis, final report etc.
 - Specifications of services required
 - Quality issues such as monitoring frequency, % of data verification, reporting requirements
 - Management issues such as whom to report, who is responsible for what activities



Outsourcing - How

- Decide the bidding process
 - Bidding – request from proposal from several vendors
 - Limited bidding – request for specific or pre-selected or short listed vendors to bid
 - Reverse bidding – Open bidding from short listed vendors for the lowest quote
 - Direct allocation – without bid



Outsourcing - How

- Decide the evaluation process
 - Who would participate in discussions and negotiations
 - Who will evaluate the proposals
 - What are the parameters to be evaluated and their importance and priority
 - Timelines for bid submissions and review and decision
 - Any strategic area need to taken into consideration



Outsourcing - How

- Processing the bids
 - Send the documents out to bidders and ask for response at a defined time
 - Define a process to answer queries (eg. telecon)
 - If necessary ask for presentations and discussions from short listed providers
 - Discuss and grade internally- based on team inputs.
 - Short list the preferred vendor and back up as required
 - Negotiate, if required and allot to the most suitable vendor
 - Define payment schedules



Outsourcing - How

- Post allotment activities
 - Complete the legal contract formalities for the project, if delayed define and interim process
 - Keep an eye on activities to confirm the agreed processes and timelines are being followed
 - Process any changes for contractual agreement with vendor and agree on modifications of terms and conditions and budgets



Outsourcing - How

- Post contract activities
 - Evaluate if the work was performed to the satisfaction – time, cost, quality
 - Confirm the contract completion and date of completion
 - Check if the payments are clear and there are no other obligations



Outsourcing - Evaluation

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Outsourcing - Evaluation

- Was the contract completed
 - On time
 - On budget
 - With quality
- Check if any changes need to be done in the process for future projects
- Ask feedback from your colleagues for any process changes and comments from the projects
- Convey your comments to the vendor
- Comment on the possible improvements and changes in the process, you would like to implement



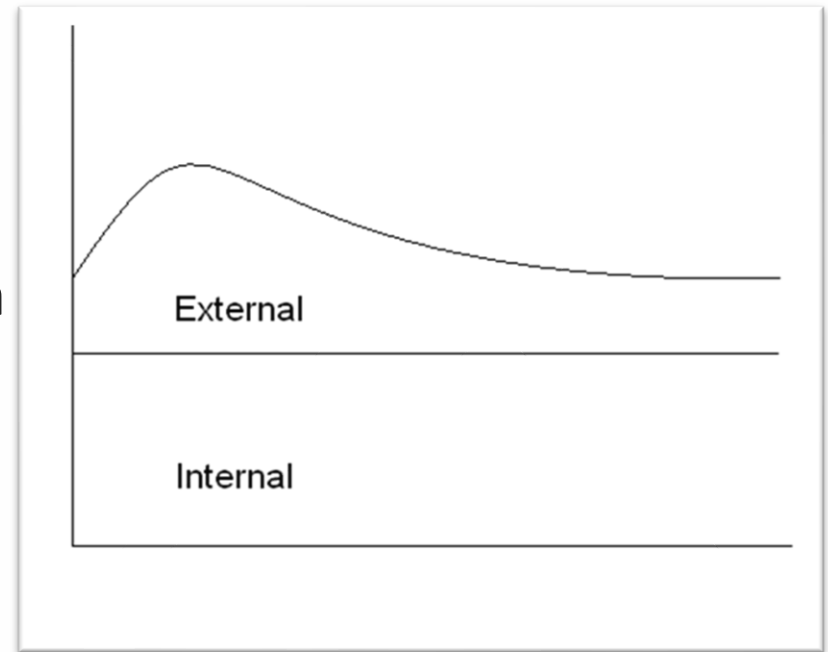
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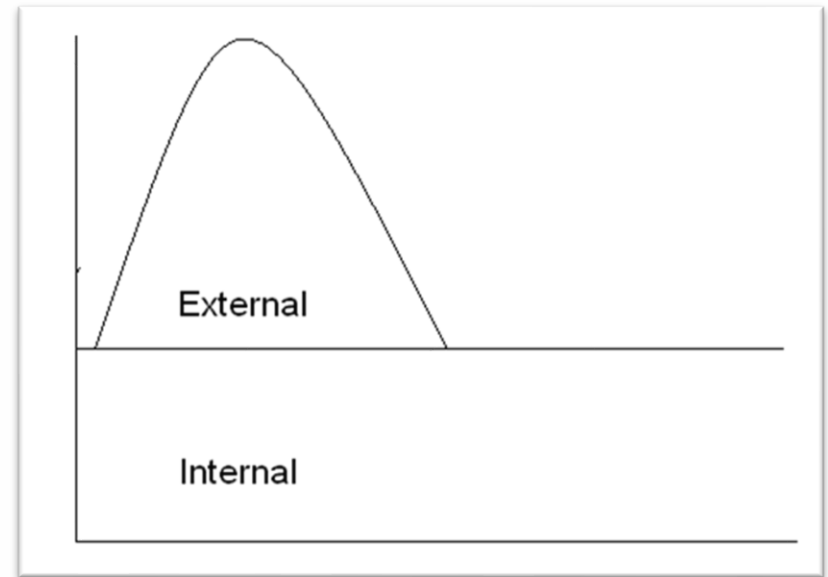
Outsourcing Types

- Strategic outsourcing
- Preplanned and well organized
- Identified parties with competencies evaluated in advance
- More economical but availability could be a problem



Outsourcing Types

- Need based Outsourcing
- Unplanned and as and when required
- Expensive & less efficient



Sponsor Needs-based Outsourcing

- Generally contract to contract (one contract to one protocol)
- Little CRO differentiation. All CRO's viewed as providing the same services
- Highly competitive and price sensitive. Pricing is a key decision factor
- Sponsor capacity constraints determine outsourcing need



Sponsor Needs-based Outsourcing (contd)

Advantages

- All Sponsor options remain open
- Significant pricing pressures (implied lower cost)
- Risk spread across multiple vendors

Disadvantages

- Little optimization of the CRO/Sponsor relationship
- High “business” efforts (implied higher cost)
- Sponsor does not differentiate CRO and CRO does not differentiate Sponsor



A Glance into India's Burgeoning Healthcare Sector

- On track to become world's most populous country by 2025
- 1.2 billion patients, with 64% between 15 and 64 years. Large, diverse and treatment naive
- Increasing patient numbers in lifestyle disorders segment with large chronic disease patient pool



A Glance into India's Burgeoning Healthcare Sector (contd)

- India's pharmaceutical sales saw double digit growth at 10.8% in 2016, the second highest among the BRIC nations
- By 2021, projected to be among top three pharmaceutical markets by growth and ninth largest by absolute market size
- India's disease burden is aligned with the new drug development focus of global pharmaceutical companies



India a preferred Outsourcing destination

- Consultative Regulatory Approach, Government Investments to Boost Regulatory Infrastructure
- Amended and Rational Compensation Guideline
- Shorter Approval Timelines, Industry Average of 6-7 Months in 2015
- Mandatory Site Accreditations Rollouts
- English speaking highly skilled investigators

