

# Clinical Trial Outsourcing



Module 8 Topic 5

# What is Outsourcing?

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



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**“My husband and I are getting along much better now.  
We’re outsourcing our arguments to a couple overseas.”**



# What is Outsourcing?

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- 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

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- 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

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





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# Outsourcing - What

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- 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

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- 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

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- 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

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- 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

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- Process Optimization: Achieving the same objective in a less resource intensive way
- Resource Pooling: Achieving the same objective in a less resource intensive way
- Productivity Outsourcing: Maximizing return from a fixed investment





# Outsourcing - Why

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- 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

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**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

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**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

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- 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

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- 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

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- 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

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- 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

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## 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

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## 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

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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



# Outsourcing – need of the hour

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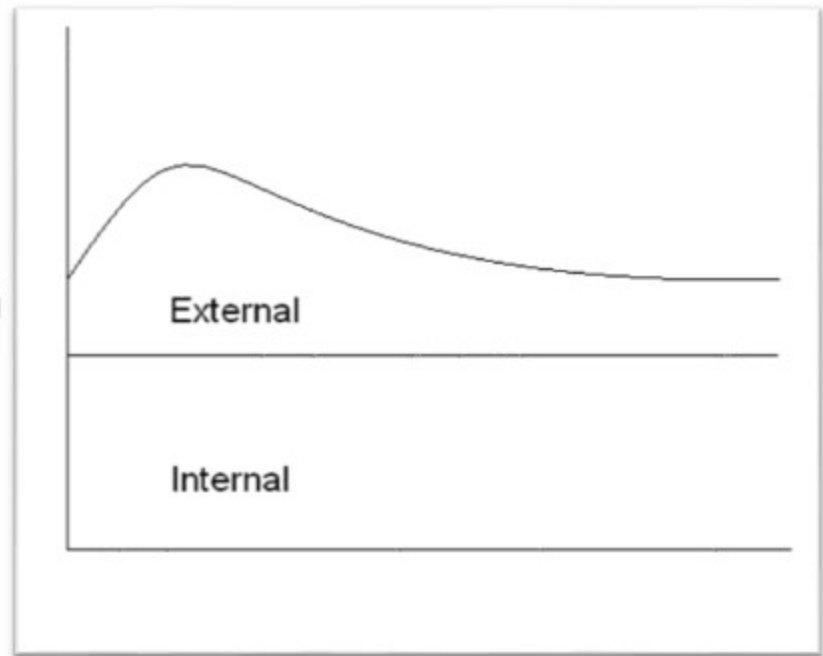
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# Outsourcing Types

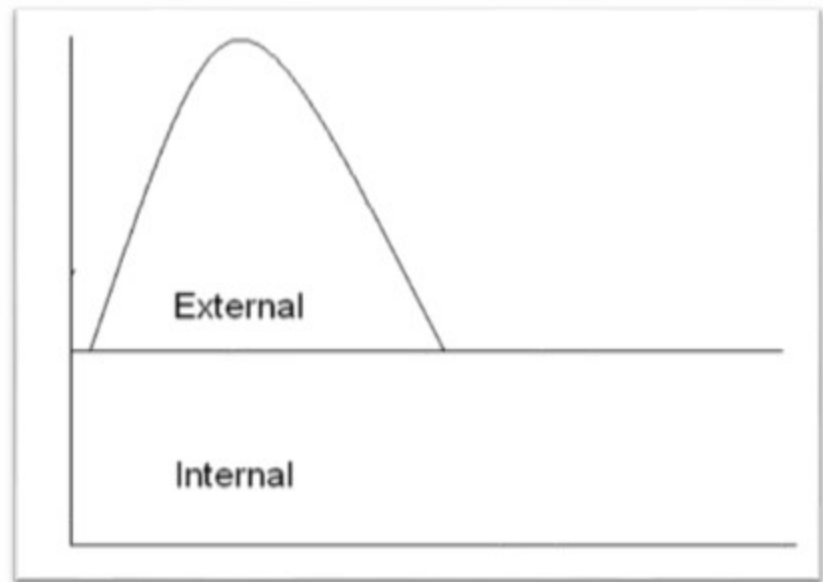
- Strategic outsourcing
- Preplanned and well organized
- Identified parties with competencies evaluated in advance
- More economical but availability could be a problem



# Outsourcing Types

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



# Sponsor Needs-based Outsourcing

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- 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)

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## 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

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- 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)

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- 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

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- 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

