

Single Day Events

Managing Clinical Programming Outsourcing

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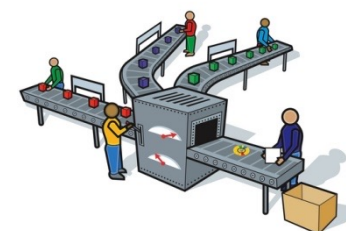
Outline

- Introduction
- A Few Cases
- Other Common Challenges
- Summary

Introduction: Two Waves

Manufacture Focused

- 1960s Semiconductor
- 1970/80 Other industries
- Lower wage, lower skilled



Service/Research Area

- 1990 Start with Call Center
- “Y2K” Led to IT
- Expand to Financial, Pharmaceutical industry



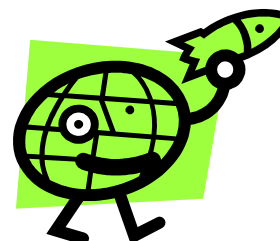
Introduction: Why?

General Agreement on Tariffs and Trade (GATT) and Later World Trade Organization (WTO)

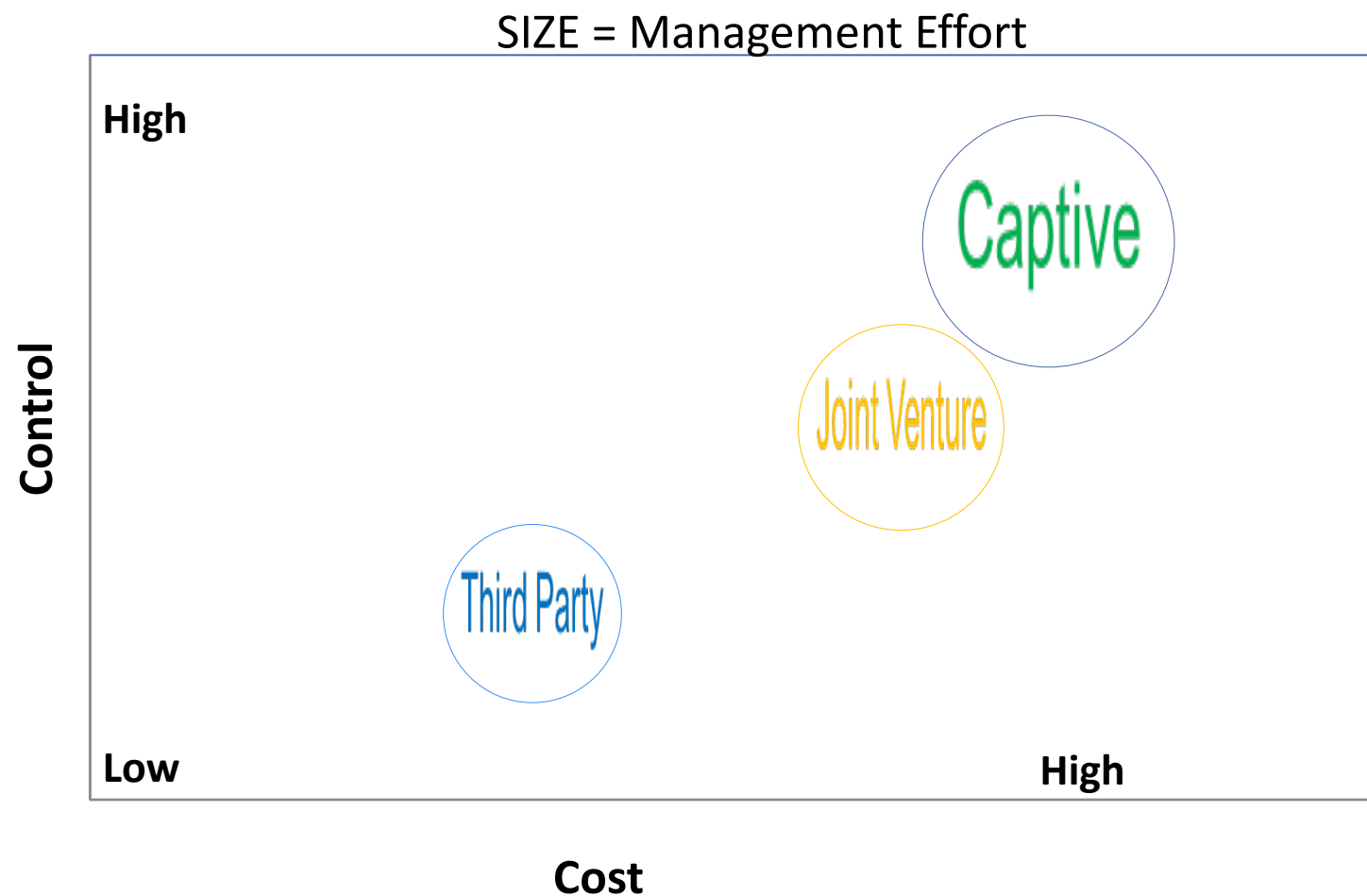
Technology Available

Cost Saving Pressure

The Desire to Serve Global Market



Introduction: Common Models



Case I

- Small Marketing Research Organization
- Semi-Annual Marketing Survey Product for Pharmaceutical Client
- Outsource Data Collection and Reporting
- Java and DHTML Based Application
- Projected Savings of 1/2-2/3

Case I

- Do Not Fully Understand Business
- Cut Corner and Hidden Cost
- No Real Relationship Between Company and Offshore Provider
- Poor Planning, No Long Term Vision
- Not All Responsible Party Involved and Engaged
- Under Estimate Communication and Interaction Need
- Product Received from Offshore Shelved

Case II

- Large Pharmaceutical Company
- Global Application Development Team to Build Analysis and Reporting Platform
- Outsource Data Mapping and Reporting Interface
- Java and DHTML Based Front End Application
- Offshore Company Had Prior Engagement in Other Areas

Case II

- Lack of Clinical Experience
- Poor Knowledge on CDISC SDTM or ADaM
- Timeline Behind

- Fully Supported by Business
- Update and Provide More Detailed Specification
- Sponsor Send Develop Team Members to Offshore
- Additional Trainings Provided

- Overall Projects Timeline Delayed
- Finally Delivery Was Satisfactory

Case III

- Medium Sized Pharmaceutical Company
- Pilot Functional Service Provider Model for 1 Year
- Strategic Partner Relationship
- Primary to Support Safety Ad hoc

Case III

- Provider Programmers Worked Hard But Less Experienced
- Training/Coaching Pressure on Sponsor
- Lack of Ownership/Knowledge to Make Decision/Solution
- For Urgent Request, Often Delayed Delivery Due to Time Constraint

- Programmer Worked Better on Tasks Involves Longer Deliver Time

Case IV

- Medium Sized Pharmaceutical Company
- Legacy Studies SDTM Conversion Outsourced to Niche Vendor
- Offshore Vendor Knowledgeable on CDISC SDTM
- Vendor Implemented Similar Conversion Project Before

Case IV

- Vendor Newly Established Offshore Team in Tunisia
- Concern on Patient Data Privacy
- Concern on Data Transfer Requirements of EU Directive

- Further Discussion Clarified that Tunisia Team Would Only Access SAS Server in EU Country Remotely
- Measure Was Taken to Ensure Data Cannot Be Down Loaded to Local Laptop
- Provider Inter-Company Agreement
- Local Addendum

Other Common Challenges:

- Language Barrier
- Culture Differences
- Legal
- Time Difference
- Lack of SMEs
- Quality of Delivery

Summary:

- Research Your Need
- Long Term Vision
- Laws and Regulations
- Compliance and Security
- Choose Your Path
- Start Setup When You Are Ready



Summary:



Further Information



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