

Outsourcing R&D Stability Studies- Successes and Lessons Learned

Anwar Hussain, MS, MBA
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Outline

BMS- Decision to Outsource Stability Studies, Models Used, Work Outsourced

Assessing Success and Lessons Learned- Quality, Performance, Cost

Summary, Closing Thoughts

BMS Decision to Outsource R&D Stability Work

➤ Main Driver- Cost Efficiencies

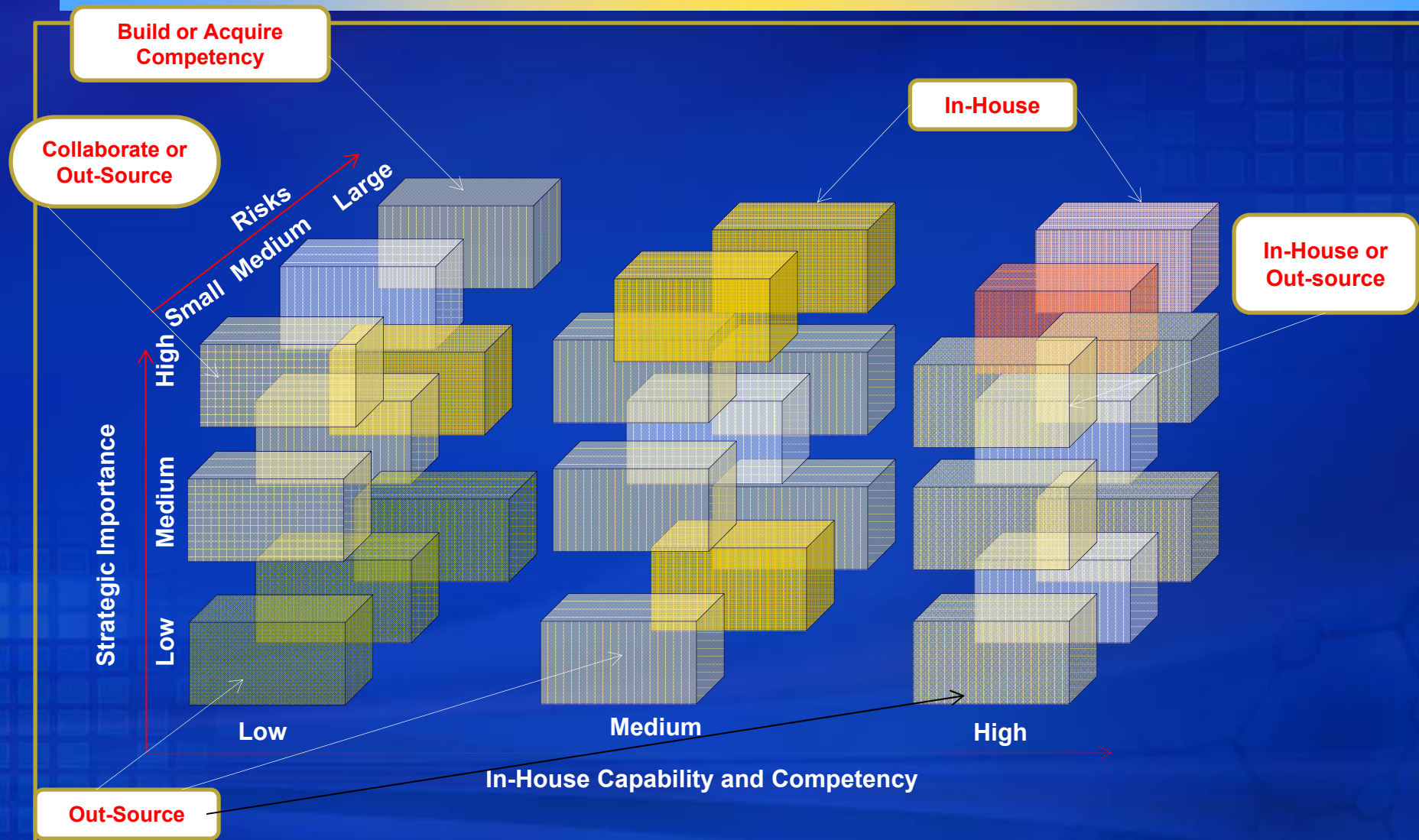
- Costly to conduct all aspects of drug development in-house
 - rising investment required to develop new medicines
 - personnel and capital resources have become increasingly constrained

➤ Affords best use of available in-house skills

- Outsourcing many of the traditional functions enables existing in-house resources to focus on activities which provide proprietary knowledge

Outsourcing is a critical strategy for dealing with resource challenges, escalating internal costs and gaining efficiencies in the overall drug development process.

BMS PD Outsourcing and Selective Integration Strategy



Reference: TCS Healthcare Whitepaper

Outsourcing Models Used by BMS

- **Fee for Service**
 - Work performed at CRO
- **“On-Site” Leased Scientific Workers**
 - CRO staff nested in laboratories and plants of sponsor company
- **FTE**
 - **Dedicated facility, equipment and personnel with on site BMS presence**
 - Technical Manager
 - Project Manager
 - Quality

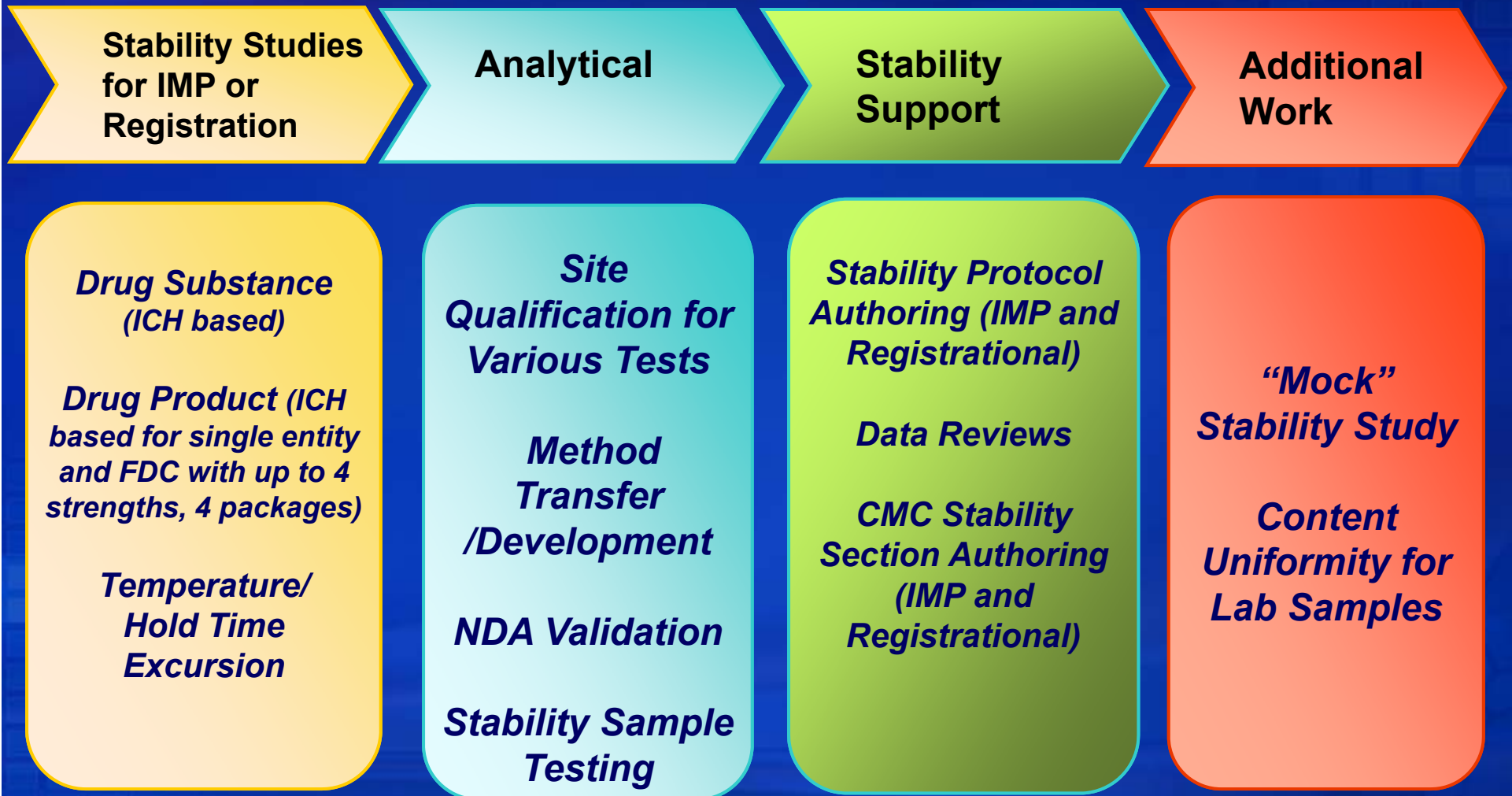
Develop Strategic Relationship with CRO

Forging of agreements with select partners that can result in broader strategic business alliances with BMS



One vendor for many project activities allows for increased efficiency as experience is gained and practices are well established

Work Outsourced in Stability Function



Assessing Success of Outsourcing

- **Maintaining robust Quality Systems**
- **Establishing key performance indicators for**
 - testing (method execution, turnaround time)
 - quality of data generated
 - efficiency of the study execution
 - collect, review and monitor metrics
- **Meeting cost savings goals**

Quality- Lessons Learned/Successes

Lessons Learned

- **Partner with CRO on all Quality related matters**
 - Don't assume or take for granted, know their processes, procedures
 - Share knowledge, teach/train, help them
- **SOPs**
 - Tailoring to the sponsors needs

Successes

- **On-site Quality Manager**
- **Held regular Quality Council Meetings**
- **Built up to "right first time" quality index of 99.9%**
- **Connected CRO with external Quality Consultants**
- **Successful HA audits with no 483s, minimal major audit observations**

Quality- Successes and Lessons Learned



Logistics/Performance- Lessons Learned/Successes

Lessons Learned

- **Close partnering is essential to achieving optimum productivity**
- **Set clear expectations for data turnaround time**
- **Use the same data acquisition and LIMS systems**
- **Ensure solid IT systems and support**
- **Time zone differences can work in favor of or against the timeline**

Successes

- **On-site Technical and Project Managers**
- **Maximize opportunities for lab automation**
- **Assist in streamlining lab operations (use of simple pre-printed lab notebooks)**
- **In the FTE model having a dedicated staff builds knowledge and expertise**
- **Dedicated facility and equipment reduce logistics and scheduling challenges**
- **Up front investment in teaching the partner how we do something translated into gains over time**

Logistics/Performance- Lessons Learned/Successes



Achieving Cost Savings Goals- Lessons Learned/Successes

Lessons Learned

- BMS staff spent considerable time and effort training and guiding CRO staff
- Until CROs were fully functional, BMS staff had to step in and assist
- Time zone differences meant that BMS staff had to put in extra time for meetings with CRO or preparing assignments to keep CRO staff fully engaged

Successes

- Considerable savings, >50% of in-house expenditure, realized by outsourcing to ex-US CROs
- Compared to local, US CROs, savings are approximately 25% when outsourced to Ex-US CROs

Cost Comparison For Registrational Stability Study

Activity	Ex-US FTE Model	US CRO 1 FFS	US CRO 2 FFS
Sample Shipment	\$2,185	\$0	\$0
Sample Storage	0	124,440	134,000
Set-up Charges	0	14,000	47,000
Chamber Management	4,000	0	0
Sample Management	4,000	0	0
FTE Lab Work + Documentation	143,182	327,600	258,888
Stability Management Fee	0	9,000	0
Tech Transfer Fee from CRO	0	40,000	23,500
BMS Management Costs (Travel, BMS On-Site Employees)	28,000	0	0
Total Fully Loaded Cost	181,367	515,040	463,388
Inflation Rate Factor Applied (4% annually in US)	181,367	602,524	542,098
Total Fully Loaded Cost/Sample	\$1,080	\$3,586	\$3,227
Percent Cost Savings/Sample	Compared with CRO 1: 70% Compared with CRO 2: 67%		

Closing Thoughts

Sound Quality Systems are the foundation of successful outsourcing experiences

FTE Model allows for optimum partnering opportunities

Commitment and open communication between the Sponsor and the CRO are essential

Outsourcing Stability Studies takes effort and careful planning, but the desired benefits can be achieved

Many BMS Departments Helped Make the Concept a Reality



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