

Off Shored, 5 years on (PP17)

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Roche

1 – Background

Emerging PD bottlenecks

- Drug safety activities
- Data processing
- DDE
- SPA

Goals of Global Capacity Building Initiative

1. Increase overall **capacity**
2. Increase **resourcing flexibility**
3. Realize **cost benefits** by optimizing external resourcing strategy
4. Improve **efficiency** through process improvements

Constraints at the existing HQ sites

- Resourcing gaps in several areas
- Infrastructure constraints in most HQ sites

Rapidly evolving global sourcing landscape

- Emerging strong vendor base in Asia

Likely variability in the pipeline growth

- Internal FTEs alone cannot match entire resourcing needs in our current pipeline growth scenario
- Variability negatively affects work-life balance for internal FTEs

Roche engaged into a global capacity building initiative to meet its long-term strategic goals. The objective was to increase capacity, obtain resource flexibility, improve efficiencies and gain cost benefits. The decision was to look for an Off Shore partner. After a rigorous selection process, a BPO (Business Process Outsourcing) was selected in India.

Partnership & Growth

ROC-I Partnership
(Roche Operations Centre-India)

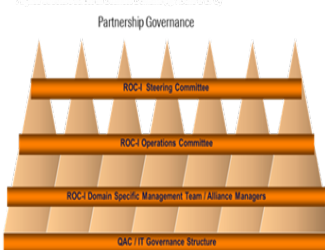
Service Excellence

- Additional Processes and delivery centers (India & US)
- Increased Volumes and activities
- Continuous Improvement

Scale Depth & Breadth of Scope, Add New services

- Regulatory Publishing
- Clinical Documentation
- Clinical Trial Monitoring System

Partnership Governance



Partnership Beginnings

- Clinical Data Management
- Statistical Programming
- Clinical Programming
- Drug Safety

2007-2008
(Establish Base)
~150 FTEs

2008-2009
(Build Scale)
~300 FTEs

2009-12
(Partner to Excel)
~600 FTEs

The partnership started with 4 functions where there were perceived resource gaps.

Once the foundations were set, additional functions were included and the resource scaled.

As the partnership has matured there has been increased focus on widening the scope of work including non-transactional work.

The governance structure has also evolved to ensure that each function is adequately represented and the functional strategies implemented

2 – Statistical Programming & Analysis Group, 5 years on

2007-2008
(Establish Base)

Scope

- Validation Programming Team
- Independent working environment
- Follow BPO Defined Process

Operating Model

- Work Packages

Training

- Systems & Programming (Roche)

Group Size

10-20

Sites supported

UK,
Switzerland

2008-2010
(Build Scale)

- Validation Programming Team
- Safety Reporting Team
- Common working environment
- Use Safety Reporting Tool (MARS)
- Follow BPO Defined Process

- Work Packages (validation)
- Project based (safety)

- Systems & Programming (BPO)
- MARS application (Roche)
- Competency Building (Roche)

20-50

UK,
Switzerland, USA
(east), Australia

2011-12
(Partner to Excel)

- 1 BPO SPA Team
- Use Safety Reporting Tool (MARS)
- Programming Development
- Safety & Efficacy Programming
- Specification Writing
- Data Mapping
- Electronic Submissions
- Eliminated BPO Defined Process
- Greater Flexibility of resource utilisation

- Integrated
(BPO SPA members part of Roche teams)

- All training (BPO)
- Cross Training (BPO)
- Competency Building (BPO)

30-40

UK,
Switzerland, Asia
Pacific

The past 5 years have seen big changes within the Statistical Programming & Analysis group in the operating model, scope of work & interactions with the off shored group. The diagram above represents how the activities with the shored group has evolved to meet the business needs. As confidence has grown over the years so has the scope of work and integration with the Roche programming teams.

3 – Challenges faced

Reducing the attrition rates and retaining the experience is a continually challenge

Systems challenges around the creation of accounts, granting access, speed & connectivity

Challenge requirements & specifications, pro-activeness, ownership



Focus often shifts to minimizing the impact on delivery whilst replacing FTEs when attrition occurs

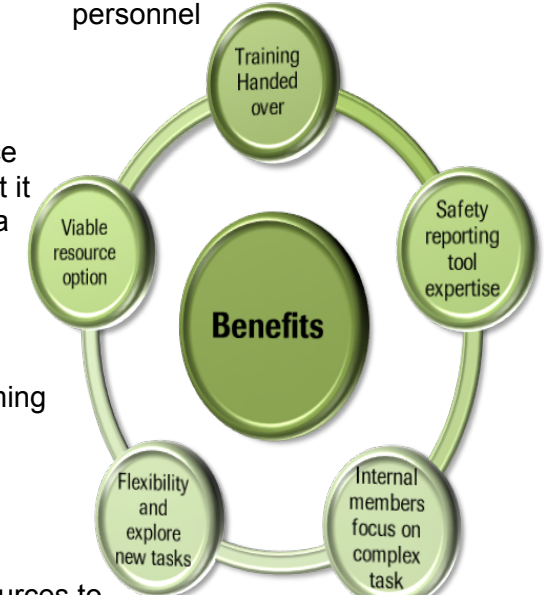
Obtaining SAS programmers with good experience in Pharma seems to be a challenge that is faced across the BPO industry

Lack of confidence in internal teams in using external groups

4 – Benefits gained

All training has been handed over and conducted by the BPO personnel

With the experience being built it provides a good resource option to support programming work



Most of the standard safety reporting is now handled by this group

Use resources to perform any tasks has meant we are better able to optimize the resource utilization

Internal staff able to focus on more complex and interactive tasks

5 – Learning's from the partnership

