

## Re-energising late-stage drug development

### Background

- Late-stage drug development is complex, expensive and uncertain. In 2004/05 a high profile programme in a leading global pharmaceutical company, sought to develop a class-leading anti-retroviral treatment for patients with HIV/AIDS. This development broke new ground in approaches to the treatment of HIV in people for whom other treatments no longer work, but was struggling to gain momentum in a combined Phase 2b and Phase 3 development programme.

### Challenges

- A 2003 consultancy project in the Global R&D organisation noted weaknesses in the culture centred on direction setting, accepting responsibility and getting things done. In general terms, the relative sophistication of planning and objective setting processes was not matched by effective execution. People found it difficult to focus on what mattered and organisational complexity was paralysing. Many were reluctant to be held accountable. Morale and engagement was low, and cynicism widespread.

### Objectives

- Our team climate review indicated that the situation was consistent with the global diagnosis. The reality was that the team, whilst individually committed, had issues with role clarity, performance expectations, open communications and decision-making. Senior management were frustrated that productivity and engagement was not higher on such a worthwhile, innovative programme with clear patient value. The Development Team Leader (DTL) had responsibility, but little power, over colleagues assigned to the team.
- The project consultant (now a Director of Leading Change) recommended that the team focused on developing a 'winning culture' by adopting a solution based on the principles of Mission Command. Working with the DTL we set objectives to re-energise highly able but weary and de-motivated people, focusing them around a single goal (drug approval) and freeing up their ability to make decisions in line with the project's intent.

### Specific consultancy interventions

- Our initial workshops in July 2005 clarified the Team's strategic objective (to gain approval of the drug product in the second quarter of 2007 in order to launch the first product in its class in US and EU). The workshops focused on what was required to achieve the strategic objective and aligned people around their roles in the plan. Through this highly interactive event we created:
  - A high level of clarity about what people were trying to achieve;
  - Alignment up and down the team and between sub-teams and individuals;
  - Defined team and individual areas of accountability for delivering results;
  - Clear boundaries for decision-making.
  - A higher level of engagement and high performance behaviours
- A follow-on workshop in September 2005 integrated US-based colleagues who had been unable to attend the earlier workshops due to events in London on 7 July 2005. The workshop focused on re-planning the End-Game (the final phase of collating the

submission to Regulatory Authorities) and taking as many activities as possible off the critical path.

- Six months downstream we facilitated a 'stop and think' review with the development team and their Contract Research Organisation (CRO) partner. We addressed a number of operational challenges at this highly successful meeting which marked the start of the final phase of the project as the team prepared for filing later that year.
- Over the project lifecycle we held regular 'check-in' meetings with the team's leadership where we reviewed and explored performance, discussed alternative approaches, challenged assumptions and provided coaching and support where necessary. Team leaders used us as a confidential sounding board about the leadership challenges they faced throughout the project.

### Programme Impact

- In July 2005 two of the pivotal studies were in significant difficulties with slow patient recruitment. An empowered Development Operations mission-leader, working closely with their CRO turned the situation around by developing innovative approaches to amend protocols and flex budget in order to open new study centres with better recruiting prospects. Against the odds the team fully recruited the studies in sufficient time, whilst the End-Game team reduced their timeline to in order to give the studies the best possible chance of success. In the words of the team leader:

*"... the study teams believed in mission command and were 'up for' the challenge ... traditional roles became less important. Individual skills, creativity, enthusiasm and belief of team members became more important than job descriptions. We would not have responded in this way without mission command" (now Therapeutic Area Head of Clinical Operations)*

- Specific changes resulting from the mission command programme included support and trust from the programme leadership team who loosened budgetary constraints to allow the studies to develop novel approaches to recruit.
- In mid 2006 this programme was one of several subject to an independent academic-led survey into the effectiveness of the mission command programme. This review posited that there was an overwhelming agreement that the basic ideas and principles which comprise the concept of Mission Command were useful and applicable to the company's challenges. It concluded that the programme had created real value for the company.

*"To summarize, the concept is highly valued and appreciated; people who declared themselves as sceptics before the presentations and training said they were transformed and became believers and supporters after the training."*

- The mission command programme was assessed to have clear, tangible and immediate benefits:

*"All those who were interviewed, regardless of position, indicated the high utility of the training... Two areas that were constantly mentioned as the main areas of contribution **were team building and goal setting**. Other areas included: **improved team communication, opportunity to reflect, improved work atmosphere and increased motivation**"*

## Results

- This project was an organisational success story during a period characterised by cost inflation in drug development, greater regulatory burdens and field force reductions in big pharmaceutical companies.
- The development team leader attributes their success, in no small part, to the change in attitudes and behaviours brought about by the mission command programme. Specific examples of change were:
  - The way that the sub-teams took accountability for delivering project outcomes
  - The openness, honesty and efficiency of team conversations around the mission
  - The proactive way that US, UK, India based functional teams and CROs pulled together to manage their inter-dependent timelines and deliver the project filing goal
- In February 2007 both U.S. and EU regulatory agencies granted the product an accelerated review.
- In April 2007 the U.S. Food and Drug Administration advisory panel unanimously recommended approval. The drug received full FDA approval on 6 August 2007.
- In September 2007 the EC approved the treatment for treatment experienced patients. The registration process for treatment-naïve patients concludes in 2008.
- Analysts estimate that sales for this product will be \$120 million in 2008 rising to \$591 million in 2010.

*"This project is an outstanding example of rapid development and continuous innovation through which company researchers quickly translated a scientific hypothesis into a promising compound in this area of great medical need." Senior Vice President, Global R&D.*

## About Mission Command

- Mission Command is a leadership philosophy, targeted at empowering teams or individuals to achieve goals through clear understanding of a leader's intent in defining those goals. It is a proven and integrated solution that improves an organisation's ability to get things done.

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