

PROJECT MANAGEMENT FOR DRUG DEVELOPMENT

Training and Consultancy to Release Your Potential

Threats, Challenges and Opportunities

In many ways, drugs are typical of high-technology products in the challenges they present to the developer. There is a high level of technical risk, especially at the early stages, compensated by high returns for a minority of marketed products. The environment within which this development takes place could however be considered bizarre by other comparable industries. For example, just when we are ramping up the cost as we enter clinical trials (especially phase III), we are forced to lose control by delegating critical work to external clinical investigators - so we are adding severe operational risks to the technical ones. Recent evidence provides little comfort for pharmaceutical senior executives:

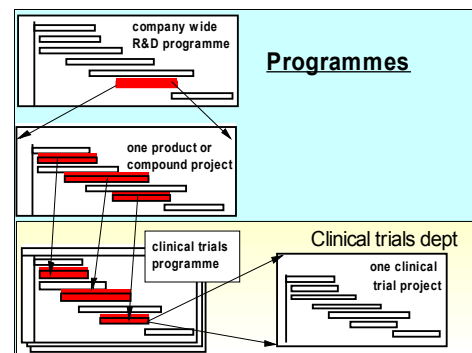
“Although scientific innovation can only be sustained if it is commercially viable, the time period between the discovery of any novel medicine and its commercial application is lengthening as development times increase.

“The Centre for Medicines Research estimates that it is now taking an average of twelve years from the identification of a suitable drug target to first market launch.”
(CMR International – www.cmr.org).

All this is despite massive effort and highly-publicised business change programmes. It is getting more difficult to launch simultaneously in all major markets, because of problems with co-ordinating international regulatory submissions. Fewer new drugs are being brought to market, and the success of these is being badly eroded by ‘fast-followers’ – similar competitors taking away market exclusivity.

Vertical Project Integration

Project management in pharmaceuticals is well established at the top level, where the compound is the project. Thus the beginning of the development project is when the drug comes out of discovery and is selected for development, and the project scope is everything needed to bring the product profitably to market. The problem here is that only one drug in every five marketed actually makes a profit at all – the other four fail to recoup their R & D costs.



At the other end, a project would be (for example) an individual clinical trial, and although at this level the uptake of project management techniques has been much slower, it is happening. The question then arises – how did top level project management happen at all without proper planning and progress control at the level where the work is actually done? In other words, how did strategic project managers make decisions in the absence of real-time data on what was happening at the ‘coal face’?

Solutions for Pain-free Outsourcing

The contracted-out R & D model is now well established, but it is still in its adolescence compared with industries such as engineering. Problems such as the following still occur:

- ‘Scope creep’ – escalating cost because of project changes
- Disputes over workloads and resources
- Lateness
- Quality failures, and deviations from specifications

All these and many other problems between sponsors and CROs can be avoided by a results-orientated planning approach. It is actually quite a simple process and leads into a clear contract virtually automatically. Of course, project changes always occur, and then a structured process for managing change is essential. Such a process can only work with a clear plan, otherwise the change cannot be defined.

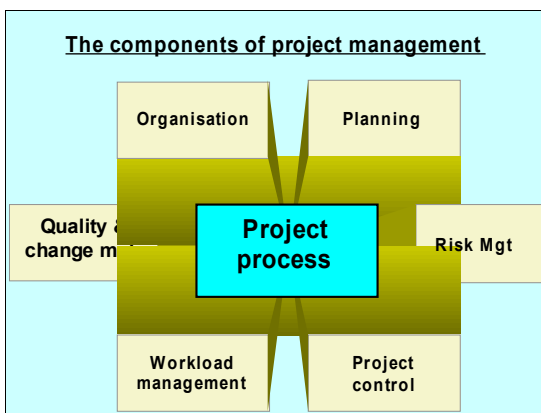
Getting the Right Skills in Place

Project management is not just for managers – it is for everyone in the project team, and also for those supporting them. The latter includes top management, suppliers, contractors, and service departments. The techniques enable people to:

- Get requirements, development plans and protocols right – to minimise mid-project changes.
- Organise and lead teams to success.
- Plan in enough detail to enable good control.
- Make plans achievable by using sensible planning data.
- Foresee problems and make contingency plans.
- Keep projects on track and give intelligible progress reports.
- Manage heavy workloads by prioritising and scheduling multiple projects.

...and where to get those skills

Les Rose has worked in the pharmaceutical industry since 1974, mostly in clinical research and related areas, and his main professional interest is clinical trial project management. Previous companies include Pfizer, May & Baker, and Bristol-Myers. He established himself in consultancy in 1987, and more recently led a venture in the use of the Internet in clinical project management.



He has trained and advised many drug companies in R & D management, and has been active as a committee member of the Pharmaceutical Industry Project Management Group. A graduate biologist, Les has served on the Biomedical Sciences Committee of the Institute of Biology, and is a chapter author in 'Pharmaceutical Project Management' (Marcel Dekker Inc). He now practices as a consultant via his company **Pharmavision Consulting Ltd**, working as an interim project manager, as well as helping clients to develop their own project management systems and processes.

Associates

Pharmavision Consulting's extensive network of associates enables related disciplines to be integrated with your needs. These include:

- Strategic project management for R & D
- Decision analysis
- Cost modelling
- Portfolio management
- Establishing the product profile
- Project remediation

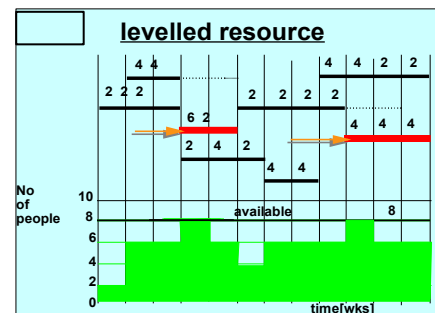
We can help you to ensure that your top level project plans do not suffer because of gaps in your clinical development management. There are two complementary components to the help we can give you – training and consultancy.

Training

Techniques Covered

Our standard three-day course in project management for clinical research can be customised to your requirements. The modules available are:

- Critical Issues in Clinical Projects
- The Project Management process
- Project Organisation & Roles
- Project Planning – time/resource
- Project Planning – budget & cost control
- Matching Workload to Capacity
- Estimating & Risk Management
- Progress Control and Reporting
- Computers in Project Management
- Delegation, Teams and Communication for Projects
- Managing Contractors and Suppliers
- Building Quality into Clinical Projects
- Action Plan workshop



Course Format

There are three modes:

1. Lecture – mainly divided into essential skills covered in detail, and advanced skills which are optional and covered in less detail (although full lecture notes are provided for both).
2. Case exercise – including role-play and simulations where techniques learned are actually used. Some exercises are competitive games, in which project problems are measurable in cash terms.
3. Syndicate discussion – where groups evaluate what they are currently doing and discuss implementation of skills, and generate new ideas to solve their own problems.

Custom Programmes

Materials can be customised by (for example)

- Relating new techniques to your own SOPs and documents
- Using your real project plans for syndicate work
- Expanding or condensing (or even deleting) topics according to your present skill levels
- Originating new lecture material to meet special needs
- Writing new case exercises to integrate with your practices

Consultancy

Once trained, people want to implement new skills quickly. However, developing the items required falls outside the scope of training, and is within the remit of consultancy. We can work with you on an individual basis, to develop such essential tools as:

- Project planning templates using your project management software. The categories of data could include:

Standard task dependency networks	Activity codes
Work breakdown structure	Resource tables

- Tools for collecting tracking data
- Progress report formats
- SOPs for project planning and management

...and most importantly, we can develop with you an action plan and monitor your progress.

Getting Started

We offer you a no-risk way of making a start. It works like this.

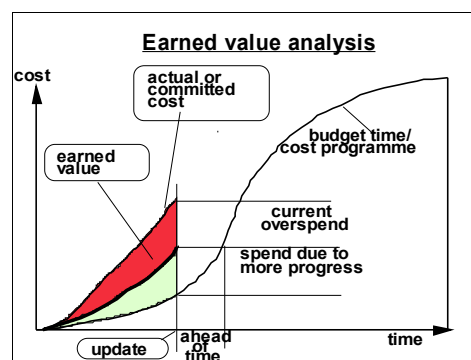
1. We visit your office to carry out a structured analysis of where you are now. For most companies this normally takes a working day. We would need to talk to people face to face, usually individually, each interview taking about 20 minutes.
2. At the end of the day we give you verbal feedback on the findings, and discuss the next steps.
3. We write up the findings and submit our recommendations – which may include training and consultancy to meet your specific needs.
4. We then agree a schedule to implement the chosen solution.

The evaluation day is at our risk. If you choose not to commission any work from us, then we will not charge you a fee for the day. If you do commission some work, then we will include the day's fee in the billing for the main package. This approach has the following advantages for you:

- There is minimal staff time requirement to get things started – only 20 minutes for each person we interview.
- You will avoid the internal conflicts which often arise when someone internal is asked to set up systems and practices.
- People usually listen more carefully to external people, whom they see as independent.
- You will not have to spend any time in briefing us on what you want – we will get this from the interviews.
- You will get some useful information at zero risk to you.
- We don't recommend anything until we know what you want.

Cost-effectiveness

Properly-implemented project management will typically achieve a saving in total project duration of at least 10%. If clinical development time is five years, then you should be able to launch onto the market six months early, which could mean for major products eventual extra sales of over £100m. Your clinical research staff could well be costing your company over £500 per day to employ and support, but even at that



rate the time spent on training is extremely cost-effective. If performance does not improve, you will be wasting some of the £500/day.

A Final Message....

Most people can see the sense of all this immediately, and resolve to do something about it 'when we have time'. The problem is that you never do. **It is almost certainly costing your company £1m for each day you are late to market, so set yourself a target and contact us today.**

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"A project gets a year late one day at a time"

from "Project Management Truths" at
<http://www.project-training-uk.freeserve.co.uk/>