

Linear v. Unified Approach to the Drug Study Process

A Linear Approach to the Drug Study Process

We all know how an assembly line works. A physical object (widget) moves along and has its value “enhanced” at various stops along the way. Each “stop” involves some activity which adds to the cumulative value of the manufactured widget (the outcome). This linear approach has been so successful for widgets the methods have been applied in many corners of the business world.

One such place within the pharmaceutical industry is in drug study design and reporting. Consider the impact of applying this approach to the drug study process.

The Drug Study Process as it is Today

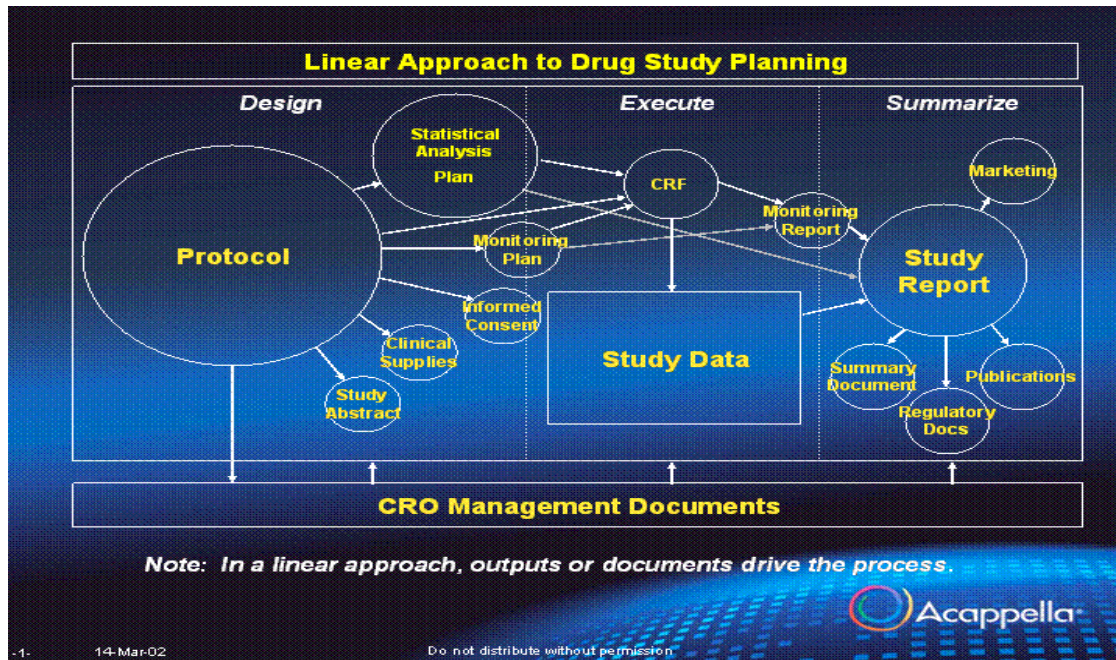


Figure #1 – A Linear Approach to Drug Study Design and Reporting

The following statements look at key elements of a linear approach to the conduct of a drug study process.

1. In Figure #1 a multitude of activities which compose a drug study move along in a sequential manner. Each circle is a business activity that usually results in the “manufacture” of an object, usually a document, report, form, a data structure etc.
2. An activity usually must wait for the outcome of a preceding activity (i.e., the manufacturing of its object) in order to begin or be finalized. Each activity therefore can slow down or stop the progress of a drug study. The effect of these bottlenecks is cumulative, ultimately pushing out submission timelines.

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3. The Protocol, which is the critical path process and document, moves along under the assumption it is error-free and quality assured. Unfortunately, in a later activity, problems are detected that put the drug study at risk. More likely, opportunities are identified that if realized earlier, could have improved the study.
4. The linear approach typically results in high-level business/clinical objectives being implemented without exposure to the realities of execution. Furthermore, shared experiences and observations are rarely recorded, much less exploited for gains in productivity.

A Unified Workspace for Drug Development

Is this process broken? Perhaps not broken, but it could benefit from further engineering. But where does one start? Let's try at the beginning. Note that a drug is not a widget (or "physical asset"). Drugs and drug studies are in fact "intellectual assets" where data and information about safety, effectiveness, market opportunity, etc. are the key contributors to a successful drug study or drug launch. Furthermore, drug value is enhanced, not through physical activity but through intellectual activity.

This should be no surprise to anyone. So let's return to roots and conceptualize the drug study process not as a series of activities whose goal seems to have become the manufacture of objects but as a series of intellectual activities that must be documented.

If this subtle but important re-emphasis in perspective can be reclaimed, what else follows? Can seemingly distinct intellectual activities be more tightly integrated? Can the exchange of information between them be more dynamic? If the exchange is more dynamic, can documentation still be properly and correctly executed? Figure #2 illustrates what this new world might look like.

The Drug Study Process as it Can Be

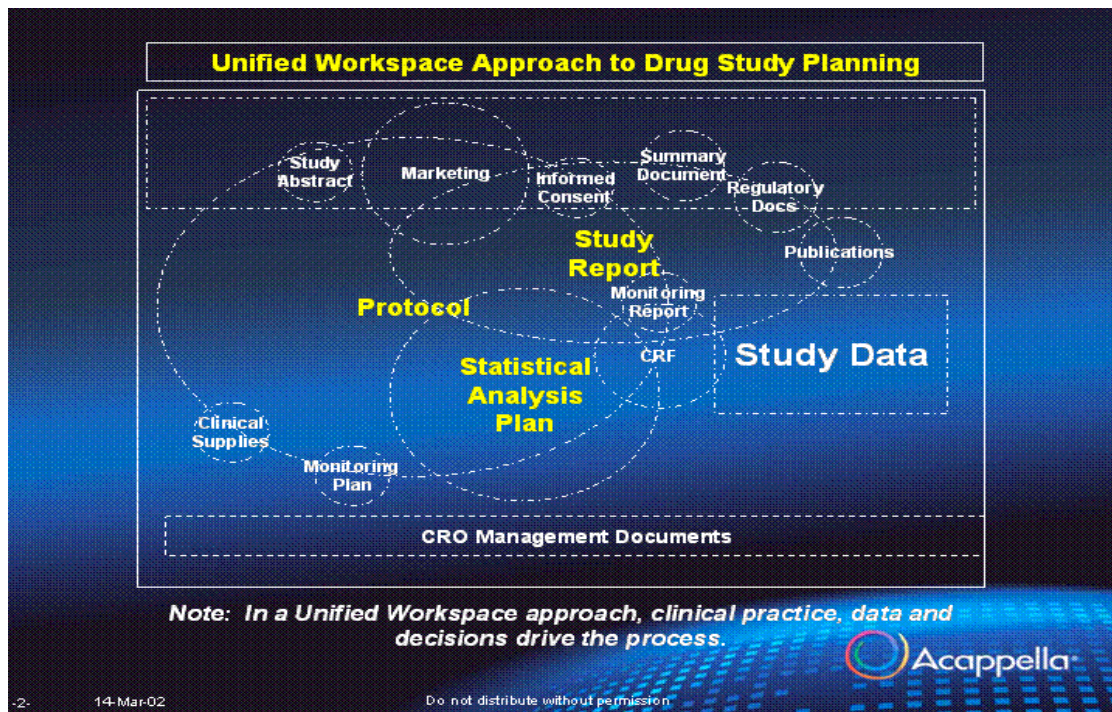


Figure #2 – A Unified Workspace Approach to Drug Study Design and Reporting

The drug study process in Figure #2 is seen from a data/information perspective, capitalizing on data common across activities. In fact, speeding information to activity owners and participants in the drug study is elevated to highest priority. The following statements therefore look at key aspects of this unified workspace approach to the conduct of a drug study process:

1. The requirement is for data/information sharing in “real-time”, breaking down the barriers between the activities. Boundaries between activities are more porous and open to dynamic exchange. For instance, once a clinician completes a Protocol, common data points within the Statistical Analysis Plan (SAP) and Study Report are automatically populated. Protocol information is passed along to the other corollary activities such as Informed Consent, Study Abstract or Summary, Clinical Supplies, Monitoring Plans and the Case Report Form.
2. As information is populated and reviewed, anyone can flag their discomfort with the plan or its execution. This “quality control” event causes the team to deal with the questions in real-time. Fundamentally, the process is allowed to loop back before moving forward. This form of collaborative effort ensures the effectiveness of every activity in the drug study without compromising efficiency.
3. At the appropriate moments throughout, data/information is captured and then used to “manufacture” the foundations for the documents, forms, etc. Documentation is relegated to an administrative act that can be executed at the selected, appropriate time.
4. With clinicians, scientists, and supporting staff freed from administrative functions (object manufacturing), they can focus more intently on the science necessary to create better, more effective drug studies and drugs.

In a process where timelines to production are lengthy and related costs are enormous; 1) for an early error that is propagated, or 2) when the final product fails because of limitations in the feedback loops – it is important to integrate activities as closely as possible and ensure they are aligned with the desired outcome(s).

Within the unified workspace, these issues are addressed. Collaboration is inherently facilitated; the quality of the final output – the drug study is improved; and business velocity is accelerated. The data/information of each activity is also mine-able. As such, the lessons learned in a constantly changing market and regulatory environment are available for continual improvement in drug study design and execution.

The patented Telamon™ Platform is the technology for establishing and supporting this unified workspace approach. It alone can relocate the drug study center of gravity from document-centric to information/analysis-centric.