



# Can Agile Methodology Improve Clinical Management?



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## Introduction

Can an old theory and a new technology help redefine a new way for pharmaceutical companies to undertake complex drug development project management? It turns out this potent combination can provide a more efficient manner to provide oversight of issues with manufacturing formulations and drugs, not to mention opportunities to realize areas for acceleration in all phases of clinical development

## Challenge

Typically, today most biopharma companies utilize traditional project and clinical management processes that are elaborate and time consuming to manage for day-to-day operations. They utilize MS Project, Excel, SharePoint and other systems to design, forecast, store data and report the progress of the project, and they are only as transparent as the systems allow.

It takes an enormous amount of time to gather, calculate and report the data to many levels of management. The cost to develop a drug for full regulatory registration and marketing in the traditional paradigms is immense; usually the cost is in the hundreds of millions of dollars (if not more) over the course of minimum 5 – 7 years.

It is safe to say that much of this cost can be realized very early on in molecule discovery, formulation, and API manufacturing bulk quantities for scale up in preparation for conducting clinical trials and subsequent marketing the product. There are many issues the team must resolve at each step of development. The traditional drug development paradigms are slow when the time arises for teams needing data for decision making.

The goal of the company is to be either first to market or be best in class with each new drug developed. It is the key number one goal of the development team to meet one of these criteria if possible in the most cost and time efficient manner. To have both goals met is the ultimate prize, but teams usually have to compromise just to be sure at least one if possible.

Some teams get hung up on the traditional hierarchical development process, which slows development down and introduces unnecessary delays. Being first to market can mean huge revenues; being best in class enjoys the same benefit but also allows the company to set the industry standard for that class of drug, realizing even greater revenue and earning potential while cornering the market share.

As you will see below, there are ways to utilize an old IT technique to enhance your team's chances of hitting one of these goals.

## Overview

Agile methodology is traditionally used by IT teams to roll-out and test new software on the fly. It enables the IT team to discover bugs early on and allows teams to fix during development, thereby accelerating the time from application to market. But can Agile Project Management (APM) practices and the presence of APM enablers in the pharmaceutical industry enhance the clinical management of a drug?

APM theory requires the use of certain practices and tools, such as the concept of product vision, and iterative development; the use of visual artifacts such as boards, panels, and sticky-notes, and so forth (Highsmith, 2004; Chin, 2004; Augustine, 2005, Boehm & Turner, 2004). Past experience shows that most companies are struggling to use their current management practices in the face of solving different or very complex project challenges. Additionally, the presence of some APM enablers indicates opportunities to adapt the APM theory for different sciences or companies other than those in traditional software development.

In most cases, you'll see that APM enablers exist in every project regardless of the industry, so in that context, clinical project management and manufacturing or CMC functions lends themselves to Agile Methodology management practices. Multidisciplinary teams, project manager experience, project team experience, suppliers, and partners are just a few enablers named as each can have an impact on the project in various ways.

## Agile Methodology

Agile Methodology, at its core, promotes full team inclusion. It stresses the importance of individuals and interactions over processes and tools, customer collaboration over contract negotiation, and allows responding to change over following a plan.

Agile methods were developed to overcome perceived and actual weakness in a conventional engineering process; Agile development can provide important benefits, but remember that the old school thinks it is not applicable to all projects, all products, all people, and all situations. However, in our experience it can have a huge impact on clinical management team task completion and deliverables.

In the modern economy, it is often very difficult or nearly impossible to predict how a clinical management project will evolve as time passes. As stated earlier, market conditions change rapidly and clinical teams need to evolve as new competitive threats emerge without warning. In many situations, i.e. traditional clinical management, you can't expect teams to define all the requirements fully before the project begins, but your team must be able to respond as the development issues change and must remain fluid to a point.

To maintain fluidity, the team must be responsive to change. Most process management models can deal with common problems but sometimes fail miserably with really complex issues.

Agile management is much more than an effective response to change; It encompasses the philosophy espoused in the Agile manifesto. Agile encourages team structures and attitudes that make *communication* more facile and emphasizes *rapid delivery of operational tasks* and deemphasizes the importance of intermediate work. Agile methods adopt the customer as a part of the development team and work to eliminate the "us and them" attitude that continues to pervade many clinical projects and

teams, and recognizes that planning in an uncertain world has its limits and realizes that a project plan must be flexible.

An Agile team is one that is an effective (*rapid and adaptive*) response to change. These teams are *effective communicators* among all stakeholders which draws the *customer* onto the team thereby organizing a team so that it is in control of the work performed. Early, incremental but accurate data and results can be achieved for team development decisions, possibly saving the company much time and millions of dollars, not to mention putting in place a new clinical management process that can be used repeatedly.

## Benefits

As an experienced PMs of drug development and clinical project management, our teams are always looking for the 'Holy Grail' clinical management tool to make our teams function better and be more efficient. Time is money, and making early decisions with timely, quality data can save lots of money for the company or sponsor.

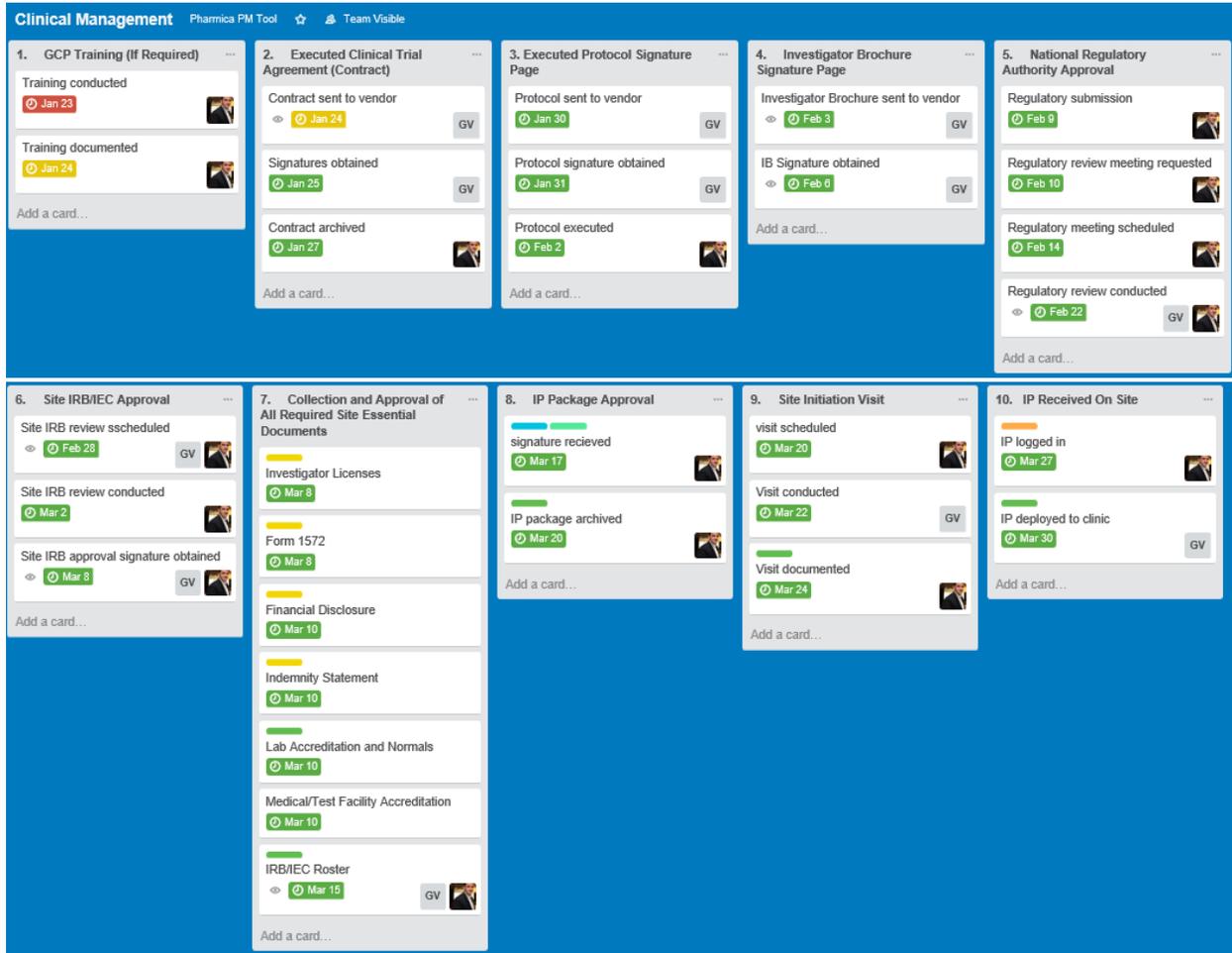
One of the new tools that embraces the Agile manifesto is Trello (<https://trello.com/>). It is a tool that was designed back when the Deming philosophy of quality work management was in vogue.

Trello uses the Kanban paradigm for managing projects, originally popularized by the Japanese and Toyota in the 1980s for supply chain management. (Kanban is a method for managing knowledge work which balances demands for work with the available capacity for new work. Work items are *visualized* to give *team participants* a view of *progress* and *process*, from *task definition* to *customer delivery*. Team members "pull" work as capacity permits, rather than work being "pushed" into the process when requested)

In Trello, Projects are represented by *interactive* boards (sort of like a whiteboard) which contain lists (*corresponding to task lists*). Lists contain cards (*corresponding to tasks*). Cards are supposed to progress from one list to the next (via drag-and-drop), for instance mirroring the flow of a feature from idea to implementation. Users can be assigned to cards. Users and boards can be grouped into organizations, and everyone on your team has access to interactions and tasks at hand and *work due* with *dates* and *responsibilities*.

This management system is not meant to replace the full-blown, all-encompassing Microsoft Project Plan, but it can give your team a big upper hand in managing very difficult parts of a plan or project to help prevent delays in the big picture. It is meant to bring your team out of the traditional silos in an extremely collaborative way and share the success together.

This will provide the transparency that is required for any team, or for any level of management and enables a tremendous amount of efficiency with less complexity by enabling each team member to look at and complete any task that they are assigned to without having to wait to be reminded of the task or deadline.



By utilizing tools such as Trello along with an Agile approach to clinical project management, you can gain the advantage over your competitors in the clinical development arena. Given what's at stake, even a small edge can mean a lot a few years down the road.

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