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The Implication of Agile & Traditional Method as a Practice in Pharmaceutical Industry

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PROGRAM: ISEM, PROJECT MANAGEMENT, LEARNING TECHNOLOGIES

PROPOSAL FOR MASTER THESIS OR APPLIED PROJECT

**TITLE: THE IMPLICATION OF AGILE & TRADITIONAL METHOD AS A PRACTICE
IN PHARMACEUTICAL INDUSTRY**

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Date:

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ABSTRACT

Traditional Project Management theory followed by Pharmaceutical industry since decades needs to be revitalized with implication of some modern ideas and techniques. Macro economy parameters such as government rules, regulation and economic stability is been changing the outset of the industry from time to time. Project Management approach followed by pharmaceutical industry needs to be revitalize, more adaptive and more agile to counter fit the changing needs.

Effective pharmaceutical project management enables new medical discoveries to reach us sooner and, perhaps, at less cost. To that extent, researchers and practitioners of project management art and science influence the treatment of disease and maintenance of health worldwide. Their process, therefore, deserves our close attention

KEYWORDS:

Few Keywords: Examples -- Pharmaceutical Project Management, Agile with Traditional.

1. INTRODUCTION (2-4 PAGES)

Pharmaceutical industry has provided many valuable break through, such that their presence can be felt in everyday life. Life saving drug are being developed but the time to the market has its own definition. New Drug Development is a process that goes through various stages proper management with right direction and right resources will prove to be more beneficial and will help to reach out to it end users more quickly and more effectively.

The adaptation in the mid-1960s of some of these “new” project management philosophies, organizational forms, procedures and tools by some leading health-care companies marked the beginning of the current era of pharmaceutical R&D project management, Staples, et al., 1989.

Projects usually involve a high volume of manpower, financial and emotional investments. According to the old business rule efficiency multiplied by effectiveness leads to excellence. This paper will give an insight of newly adopted Agile methodology and how it can be incorporated within pharmaceutical industry that is so versatile and diverse which in turn can increase the productivity and minimize the cost, reduce overhead of unwanted processes. There are many instances where pharmaceutical industry does need this agility to be incorporated into traditional approach especially during development of new drug.

Agile method has proven its value and has contributed to the success of software industry to roll out software projects on the fly. Fundamental concept of Agile describes the agility of an organization and its process to adapt to changes. The aim is to encounter the defects at early stages and to concentrate on possible areas of improvement during the development which accelerates the product development by eliminating defects and

enhances product delivery time and quality to the market. Pharmaceutical industry has always been striving to keep up the product quality.

Pharmaceutical drug development is combination of various functional sections or groups within the pharmaceutical organization. Diagram portrays overview of high level organizational structure of overall development team.

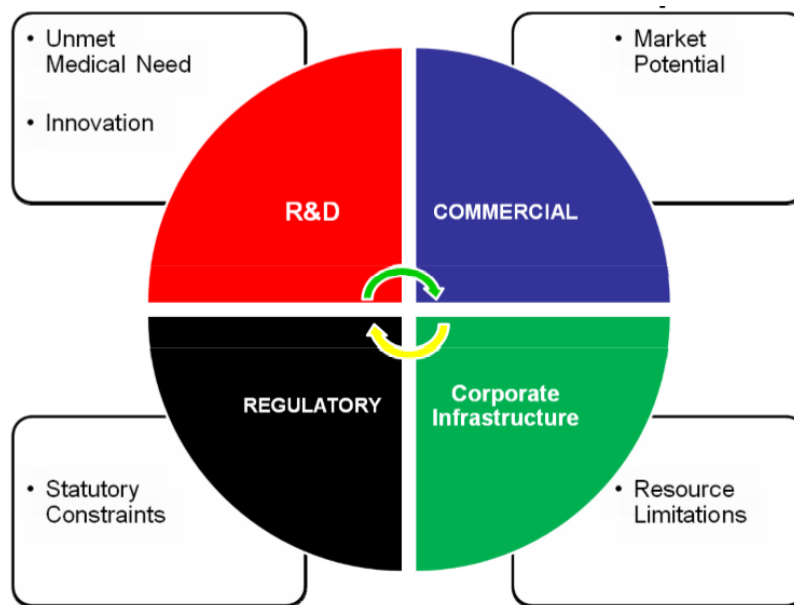


Figure: 1 Organizational Over view of pharmaceutical development, Christopher D. Breder, 2012

Pattanaik Asima (2014) underlines challenges involved in project management in the pharmaceutical industry; she identifies key players involved in project management which are Project Manager, Functional Manager, Upper Management and Project team members. Paper highlights challenges encountered by project manager in pharmaceutical industry which are resource limitation, cross-functional team management, institution processes, cultural differences and customer management. Pattanaik, Asima (2014) underlines that resource limitations are one of the major concerns in project execution.

The basic process of pharmaceutical drug development is a long process that stretches across the time of 15 years and can be visualized as under. At various stages there are various groups of people involved and with traditional project management it becomes difficult to keep track of all activities and areas of focus

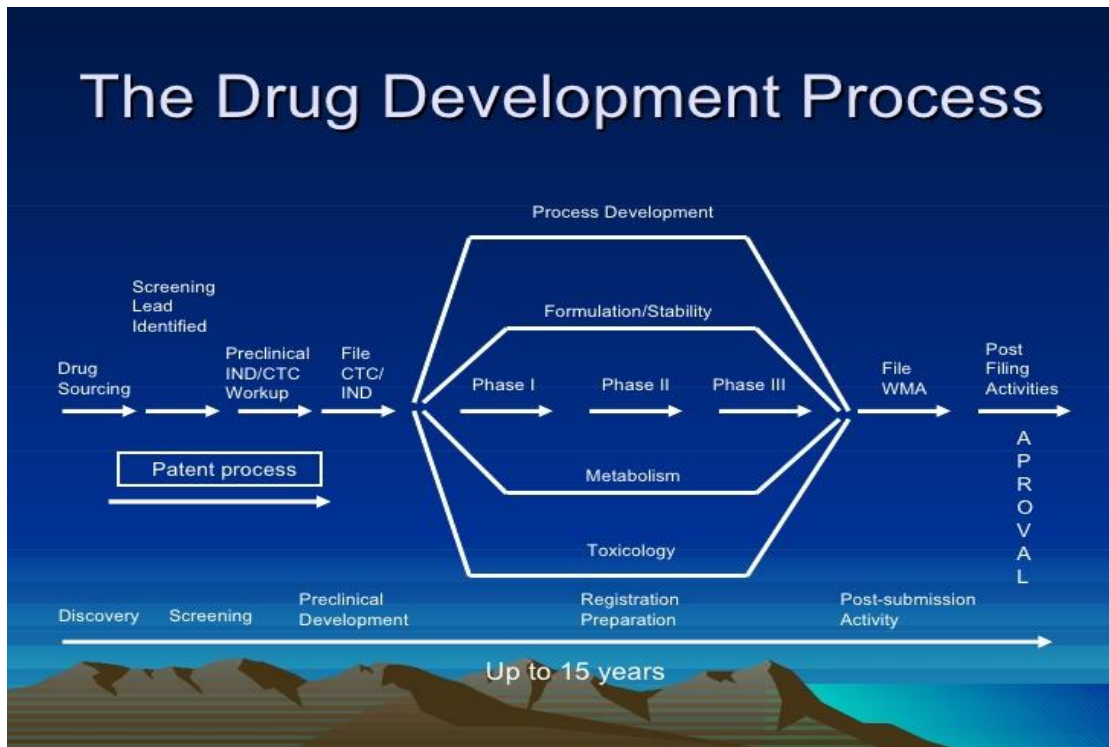


Figure: 2 Outline of various activities and phases of New Drug Development,

The PMI Pulse of the profession capturing value of project management in their February 2015 publication have outlined that organization with agility have more success rate and have achieved their business goal with project outcomes. Their research concluded the numbers as shown in picture below.



Figure: 3 Agility and Project Outcomes, PMI Pulse, 2015

PMI Pulse publication of February 2015 indicates that Agility may also be linked to profitable growth: Research conducted at the Massachusetts Institute of Technology suggests that agile firms grow revenue 37 percent faster and generate 30 percent higher profits than non-agile companies PMI Pulse, 2015. This further extends the interest of research reach area.

The paper describes how the use of agile project management (APM) in accordance with traditional project management enables enhancement the new drug development in pharmaceutical industry. Tools and practices from APM such as iterative development; the use of artifacts such as boards, panels and sticky-notes, (Highsmith, 2004; Chin, 2004; Augustine, 2005, Boehm & Turner, 2004) in conjunction with traditional approach proves to reduce the time and enables to concentrate on focus area.

2. PROBLEM STATEMENT AND JUSTIFICATION (1-3 PAGES)

2.1 Clear statement of the problem

Project management methodology that has been vastly followed through decades by many industries along with pharmaceuticals industry has been traditional approach. Since traditional

methodology has proven its success in the past its essence are been found in modern day project management as well. But rapid and drastic changes in the surrounding does call for revamp of the ancient methodology by introduction of modern day philosophy of successful mantra. It has been said that old experience with new thinking is always a right mantra for success; hence modern day winning team combines people with vast old school experience people with modern day computer savvy less experienced people. Hence to reflect this mantra in pharmaceutical project management current thesis will enlighten our thought process on revamping of traditional methodology by introduction of modern day agile project methodology.

2.2 Why it should be solved (justification)

Pharmaceutical project management is quite challenging. There is a vital uncertainty that prevails internally and externally, at macro level and at micro level. Every pharmaceutical company either big or small, brand or generic are striving hard to bring new drug to the market which are beneficial to patient and can prove profitable to the drug manufacturing company. Delivering Quality product safely, quickly and cheaply is mantra for pharmaceutical firm to be successful.

The drug manufacturing processes involves lot of complexes from laboratory to market shelf. Process involves technical development team using quality by design, drug evaluation and regulatory process team, clinical studies team and supply chain team. Project proves to be successful if all these teams communicate and coordinated among themselves during drug manufacturing process. Normally it takes more than 5 – 10 years for successful manufacturing of new drug, during this time frame inherent uncertainty during drug evolution and many circumstantial factors change the course of the project which may lead to failure if not tackled in an appropriate timely manner. Coordination between many internal functional group such as R&D,

regulatory, legal, finance, supply chain, sales, and marketing, as well as external partners. The efficiency in coordination between different functional groups is crucial.

Uncertainty in pharmaceutical industry has been vital key player that contributes to the fact and increase the gap since most of the new invention are based on the assumption, it requires a continuously evolving, knowledge-based ecosystem utilizing user feedback to improve. Assumption changes as and when information becomes available which changes the course of the project and the management of that project as new hurdles are been encountered. Hence to have prevailing team that compromises of expert from various streams under single roof becomes more relevant. AGILE philosophy enables the team to act together on any obstacle or hurdle during their small sprint and resolve it much quicker obsoleting the condition of project or product failure.

Project management becomes challenging due to known and unknown risks. Traditional project management technique where Program Evaluation and Review Technique (PERT), Gantt chart techniques help in identifying risk and develop plan for mitigating of known risks. Unknown risk which can staggered your entire project can be crucial at time; it can be handled through formation of proper team of right members, addressing it at each and every stage and building it into the product. This is possible through inclusion of AGILE methodology along with traditional methodology.

According to a survey of the Standish Group, \$80 -145 billion per year is spent on failed and cancelled projects ^[1]. Forrester Research indicates a 66% project failure, costing U.S. businesses at least \$30 billion every year ^[1]. According to the Meta Group, 60% - 80% of project failures can be attributed directly to poor requirements gathering, analysis, and management ^[1] . Improving these performance records is essential for any organization. However, if traditional

project management is ineffective, it is necessary to research other methods of managing and delivering projects. This is where agile methods come into play^[2].

2.3 What will be the deliverables?

The purpose of this thesis is to show that agile project methodology when used in conjunction with traditional project management can prove to be more effective in accomplishment of the new drug development in pharmaceutical industry.

Thesis will mainly focus on using agile tool to revamp traditional project management practices that is been followed by pharmaceutical industry to avoid any project failure in development of new drug.

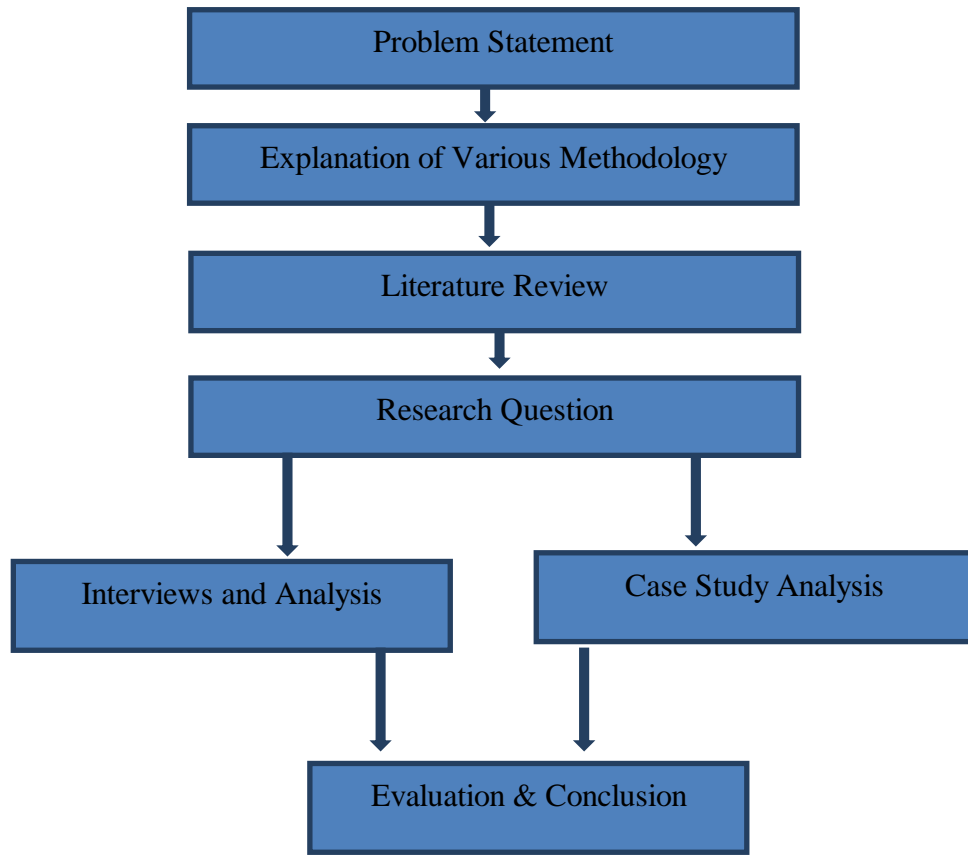
Our research objectives are

- To understand the new product development cycle/stages in pharmaceutical industry and important area of project management.
- To understand main characteristic and differences between Traditional and Agile project management Methodologies
- To understand WBS involved during the new product development and club agile tools during various stages of traditional project management.
- Thesis will also discuss the success of HYBRID project management in various industry along with pharmaceutical industry.
- Thesis will also conclude some observation from daily life pharmaceutical industry.

2.3 Type of work: behavioral research, building an artifact, applied study

Thesis will present Qualitative research on agile methodology being implemented with traditional project management often called as hybrid. It will include literature review, interviews,

Case study analysis followed by evaluation and conclusion. The outlay of the research foundation will be:



Figur: 4 Research Over view Chart.

Limitation of Research

The research paper will be limited to defining various agile methodology tools that can be included within traditional project management to improve the current traditional project management practices. Projects will not emphasis on adoption of AGILE methodology by a pharmaceutical organization or implementation of AGILE methodology to replace current traditional methodology. Thesis will be limited to define some methodologies from Agile that can be easily implemented into traditional format for better project management within pharmaceutical

3. LITERATURE REVIEW -- ANALYSIS OF RELATED WORK (4-5 PAGES)

3.1 Conducting further Literature review

Literature review will help us to understand the existing area of research. Literature review will emphasis on some of the work and ideas that has been conducted by experts in the field of pharmaceutical project management. The literature review will be focused on the following aspect:

- Pharmaceutical Project management.
- Traditional and existing Pharmaceutical project management and its approach in new drug development
- Challenges of traditional project management methodology during new product development in pharmaceutical industry, this will help us to understand some of the major setback that are been encountered and calls in for solution.
- Success & failures of agile product management methodology in pharmaceutical new drug development.
- Prospects of hybrid methodology in pharmaceutical new drug development.

3.2 Pharmaceutical Project Management

New drug development is a process which involves multiple resources. As per, Pharmaceutical Manufacturers Association (PMA) estimates that current cost to develop a drug in US is between 97-125 million dollars, Murphy, P. L. (1989). Traditional Project management has flourished in highly regulated environment of pharmaceutical industry where predominantly black and white documentation has been a key feature. Regulated environment refers to the law and regulation that has been developed by various countries federal, state and local government body in

order to control and protect business trades and practices to protect people. It also establish certain norms that should be followed in best interest to keep quality of the product intact and establish a standard procedure called as GxP (Good manufacturing practices) which is trade secret of being best in pharmaceutical industry.

Pharmaceutical new drug development project team consists of four major group Clinical, Non-Clinical, Regulatory, Chemistry Manufacturing and Controls.

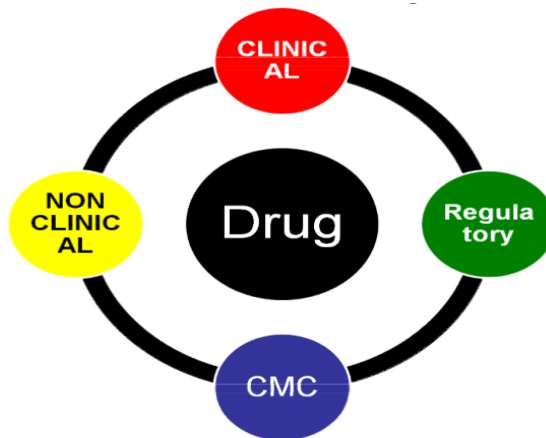


Figure: 5 Pharmaceutical Project Team, Christopher D. Brede 2011

Each of these groups is further divided into diversified sub-groups which are focused on individual functionality areas of new drug developmental studies. Figure: 6 explain functionality of these individual groups in area of new drug development.

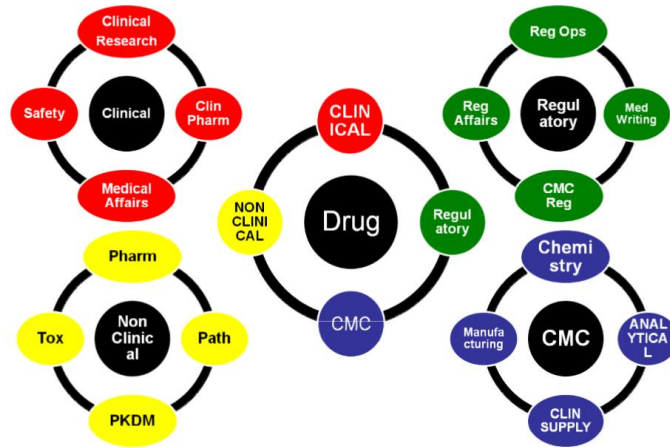


Figure: 6 Team at First Level, Christopher D. Breder, 2011

Each of these subgroups are further divided into individual functional teams which work on day to day project activities for new drug development project, activity of one of such functional team is highlighted below.

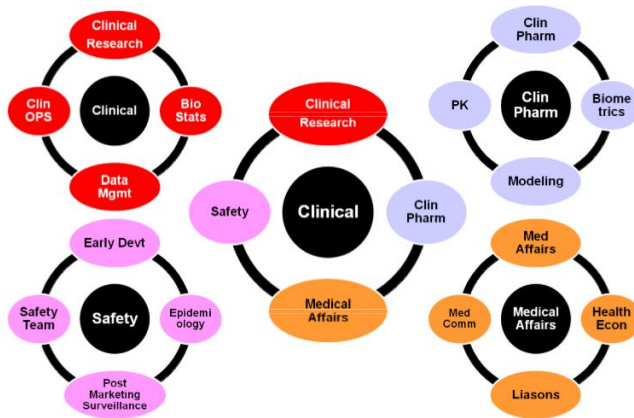


Figure: 7 Clinical Development Project Team, Christopher D. Breder, 2011

Research paper by Tanzeena Sara(2012), explains that Pharmaceutical project management emphasizes on six elements of project management, Project definition, Project team and organization, Project planning, scheduling and control, Problem solving and decision making using proto-type, Senior management review and control, Proactive and real time change management.

Paper further explains core objective of pharmaceutical project management are management/authority, development, registration, supply chain, QA, patent, market. Figure:8 is visualization of pharmaceutical project management core objective.

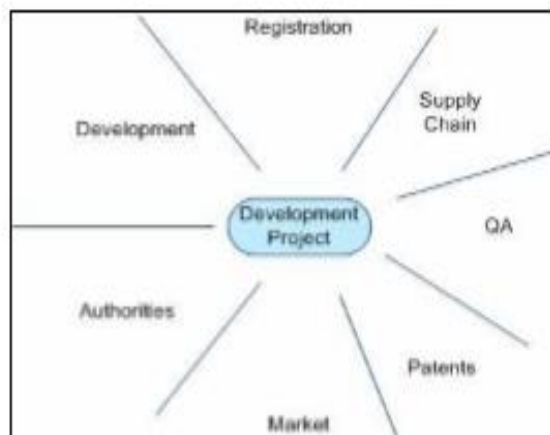


Figure: 8 Objects of a Pharmaceutical Project Management, Tanzeena Sara2012

Tanzeena Sara (2012) in her work described role of each above objects Management/ Authority will run the project, development department develop the product through galenical, analytical, clinical study etc, registration is required for the launching of the product which will do the respective department, supply chain department will provide raw material necessary for the development through active and excipient sourcing, QA will assure the quality of the product according to marketing authorization and marketing department will deal with the market to launch the product. To make product successful all objects of management have to be performed within time frame & budget.

3.3) Comparing existing methods that address the general area of thesis problem statement:

Traditional, water fall methodology has been followed since the evolution of project management methodology. The term Waterfall refers to the sequential nature of project phases, with each phase starting as another ends. There are supporters and critics of this approach to Project Management. PMBOK [4] defines the traditional project management as 'a set of techniques and tools that can be applied to an activity that seeks an end product, outcomes or a service'.

Pharmaceutical industry had adopted project management since early 1960s but scope of its practice extended during mid of 1960s. One of the classic example of traditional project management explained in article by Staples, et al., 1989 was breakthrough of VAS-OTEC hypertension drug in 1979 by one of the leading drug manufacturing company MERCK, was remarkable. The history of this drug dictates that it was first marketed in United States six years after drug initiation of the development cycle. The article by Staples, et al., 1989 further describes how MERCK laid emphasis on waterfall methodology with more comprehensive approach to project management with which it was able to meet and at time surpass its project goal.

Article by Staples, et al., 1989 further explains that the massive development effort that transformed the active new chemical entity into a FDA-approvable New Drug Application (NDA) was accomplished in just over four years, about 20-40% faster than the industry average, and project costs were within 10% of original projections was result of a project management process conceived within the culture and executed within a framework based on good communications and highly-coordinated teamwork. The Gantt chart highlighted the progress of the drug during this

development phase of VAS-OTEC helps in underlining the success of traditional system within pharmaceutical new drug development.

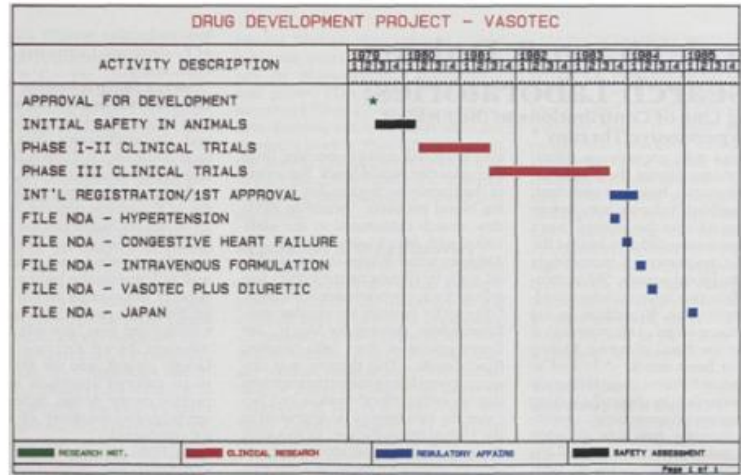


Figure: 9 Drug Development Project Gantt chart, Staples, et al., 1989

The above figure represents the waterfall approach followed by MERCK during their successful new drug development.

Traditional approach of project management focuses on strategic development plan, scheduling and control. Tools used for planning involves Work Breakdown structure (WBS), Project evaluation and review technique (PERT) and Critical Path Management (CPM). WBS is typically tree structure which shows subdivision of efforts. Another most commonly used tool for scheduling is Gantt Chart, which typically uses MS project management software to outlay task and sub task, providing a time frame to accomplish common project goal. Critical path is identified based on task duration. PERT technique use three estimates, most likely, worst case and best case estimates which proves to be cumbersome process is explained by Tanzeena Sara (2012).

Typical Gantt chart for new drug development using traditional project management will look as follow:

GANNT Chart

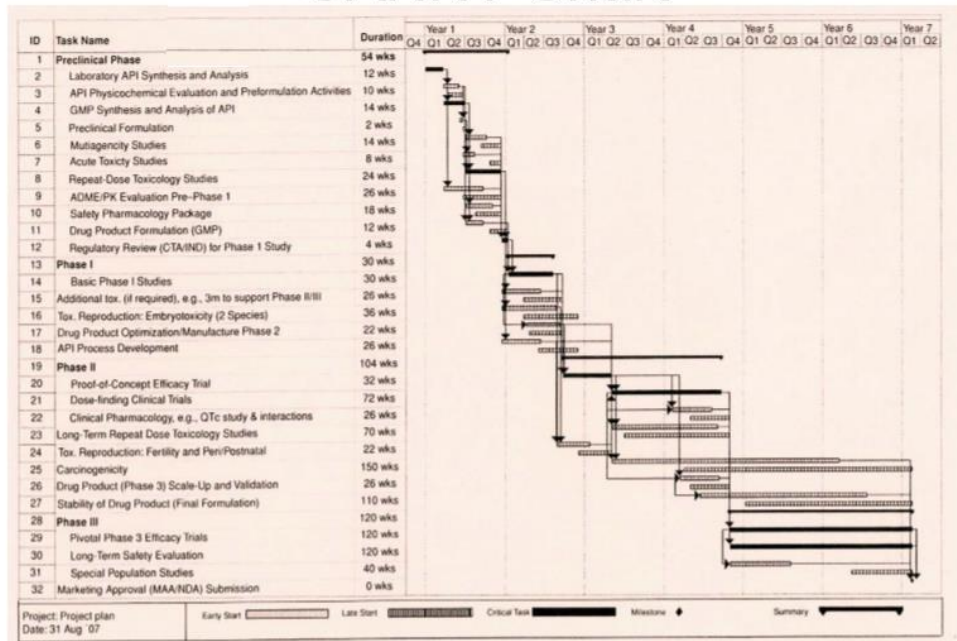


Figure: 10 Gantt chart for New Drug Development, Christopher D. Breder 2012

Some of the drawback of traditional involves

- Waterfall methodology is built in to it, Lalit Ashok, 2015.
- It needs lot of careful planning
- Any small changes in the project during later stage of project are uncontrollable and can lead to major setback.
- Risk management plan needs to be developed and maintained during the planning phase.
- Budgetary approvals are made to the projects to the extent that they can be projected.
- Waterfall methodology phase challenges to with changes in internal and external forces of pharmaceutical industry.

Drawback of traditional project management and modern day Pharmaceutical project management breeds on Agility as key requirement to sustain and absorb unknown uncertainty in today market. Stephen Denning (2015) explains that changes can be encountered if approached using right method he further explains that if organization developed and implemented a set of goals, practices and values that were best suited for changing and emerging market, those organization developed cultural agility. He explains that organization with agility approach can imbed agile approach to their formal project management can and do co-exist successfully.

Agile is a method that allows team members to deliver project piece by piece and make quicker adjustment as needed. Stephen Denning (2015) also explains that “Agile is frequently introduced as a way to speed up phases of a project”. He further defines characteristic of agile organization to be “flexible and adaptable, open communication, openness to change, empowered team members, experiential learning, rapid decision making and strong customer focus”, (Stephen Denning, 2015). Organization these days are concentrating more on agility as organizational strategy rather than using agile as tool or template.

Stephen Denning (2015) paper concentrates more on organizational agility; he recognizes organization that uses agile tool and techniques such as scrum or DevOps to be smart which indicates their speed and flexibility. He outlines the organization with adoption to agile are more likely to use combination of various different project management practices. Stephen Denning (2015) paper further justifies the topic of selection for our project topic selection by indicating that today’s organization are blending methods or using hybrid approach by adapting aspects of proven models to satisfy need of project, organization, industry and market. Report also highlights case study of departments of Veterans Affairs (VA) and statistical data of high organizational responsiveness with agility. Conclusion that is been derived from Stephen Denning (2015) report

is that to “thrive in uncertain business world organization must create culture of agility and to become agile organizations will need to make changes in how they work towards establishing frame work strategy, culture, leadership, people and process, Stephen Denning (2015).

According to Conforto et al., 2014 indicates in his research that “project planning and control is a great challenge for companies engaged in developing new product or technologies” the research article further presents an exploratory survey that was carried out within 19 medium and large sized companies operating in different sector, with respect to practice of agile management approach to new product development projects. The outcome of their study were favorable in indicating that major sectors had most required factors needed to establish agile project management. This research paper published under project management journal further summarizes the adaptation of agile methodology for new product development as a path forward practiced by many industries apart from software industry which gives a strong foundation for current research topic.

Based on the finding of Stephen Denning (2015) report, Conforto et al., 2014 we conclude that successful pharmaceutical organization should adopt agility culture to improve its approach toward better project management, risk management and to succeed in new product development to lead by an example.

Failure of Agile method in pharmaceutical described in paper by Hajou et al., 2014 describes in his paper about research done by Takashi et al., 2006 describing that agile methodology by itself will be failure in pharmaceutical industry just because creation of documentation is against principle of agile and hence it call s for minimal use or outside of development team. Hajou et al., 2014 concluded with systematic literature review that the pharmaceutical industry is an unattractive and unpopular industry to practice agile methodology or

agile frame work it is therefore in need for a novel methodological approach to embrace the need for quality control, strive for regulatory compliance and utilize the strong features of agile development.

A comparison between traditional and agile methodology from Rami Hansenne and Allan Hibner, 2011 will help us to better understand both the methods and will help us to justify the requirement of new approach i.e. combination of method HYBRID methodology, Which will evolve as a successful proposed methodology of recent era for pharmaceutical drug development.

	Traditional Project Management	Agile Project Management
Principles and Context	<ul style="list-style-type: none"> Project scope is known in advance and will not change significantly^[20] Events affecting the project are predictable Processes must be well defined, repeatable and their execution rigidly controlled 	<ul style="list-style-type: none"> Complete project scope is not known at start and will evolve during the project^[49] Unpredictable events may affect the project Processes must be lightweight and easily adaptable to the project context
Origin and Theory	<ul style="list-style-type: none"> Scientific Management^[20] Process based approach 	<ul style="list-style-type: none"> Adaptive management and chaos management^[20] Iterative approach
Focus	<ul style="list-style-type: none"> Quality^[50] Cost/Earned value^[50] Planning/timing^[50] 	<ul style="list-style-type: none"> People and teamwork^[39] Customer value^[39] Execution^[39]
Key characteristics	<ul style="list-style-type: none"> Full in-depth upfront planning Continuous command and control Management by Exception Formal hierarchy Disciplined adherence to processes 	<ul style="list-style-type: none"> Incremental refinement and re-planning Self-organizing expert teams Flat hierarchy Active client participation
Key strengths	<ul style="list-style-type: none"> Controls scope creep through rigid control over requirements^[20] Strongly emphasizes and controls the quality of deliverables Deviations in terms of cost or planning are detected in an early stage Easily teachable and repeatable Efficient monitoring and resource control through incremental project lifecycle 	<ul style="list-style-type: none"> Thrives in dynamic environments with strong client participation^[20] Very reactive to changes^[49] Strong team involvement and collaboration Improved customer satisfaction and team motivation^[53] Quick and easy to learn Low start-up time
Key weaknesses	<ul style="list-style-type: none"> Poorly suited to dynamic and uncertain project environments^[20] Any changes in the later project stages may have a significant impact on the overall project Initial plan often falls quickly out of touch with reality and requires constant revision Inappropriate for small projects due to overhead of formal deliverables Less frequent interaction with stakeholders 	<ul style="list-style-type: none"> Susceptible to scope creep as clients have the luxury of changing requirements on an on-going basis^[53] Overall cost and planning cannot be determined upfront Less efficient for large teams due to daily stand-ups Not usable for fixed price projects

Figure: 11 Comparison between Traditional and Agile Methodology, Rami Hansenne and Allan Hibner, 2011

4) Development of any detailed design or requirements analysis that support thesis study

Hybrid method where traditional method can still be leveraged along with new ideas can be implemented in highly regulated industry. Research presented by Sommer et al., (2015) [3] provided an impressive insight of stage gate/Agile combo termed as hybrid methodology that offers industrial companies a promising alternative. The paper explains that new product development (NPD) of pharmaceutical industry observed a significant change when they implemented scrum methodology (Agile Umbrella) in accordance with their existing methodology. It showed significant improvement in the performance, better allocation of resources and improved project efficiency among development projects.

Major firms are revamping their project management strategy from olden days traditional approach to modern day more collaborative approach under banner of “HYBRID” where “blending Agile and Traditional method can provide flexibility, speed, and improved communication in new product development” Cooper(2016). Stage-Gate project management focuses on macro planning process whereas Agile is a micro planning project management methodology. Paper further highlights difference between agile and stage gate and further emphasis that stage gate provides guidance for what projects to do and then what to do within project, Cooper (2016). Paper concludes that Stage-Gate- Agile hybrid methodology is feasible for physical product developers and may yield high returns.

According to Lodha (2016), “hybrid models, where agile and traditional methods are combined, must be integrated into the Quality Management System when used in a regulated

industry to add special sprints for covering formal documentation requirements” lays strong foundation for our further research for the topic.

5) Conducting experiments

In the research study conducted by Sommer et al., (2015) [3] was an experiment where Agile/Stage-Gate hybrid process using scrum was implemented within new product development team in pharmaceutical industry. According to the paper scrum tools such as Scrum boards, burn-down chart, daily Scrum, product backlog and value chain model were used during product design stage. The results were recorded and transcribed using various interviewing, group discussion, questionnaire, email tracking and observation. The result enlisted as “In Pharmaceutical, NPD had experienced significant project overruns and issues with resource allocation. The company chose to implement Scrum to support project execution, since some project managers had heard positive reports from their peers. After implementation, the company maintained Stage-Gate for steering committee meetings and portfolio coordination but used Scrum within most projects. The management team also implemented a value chain coordination process that includes a daily meeting, held at a centrally placed whiteboard picturing the company value chain. This meeting is attended by department and project managers, who share progress and, when necessary, work together to reallocate resources. Performance improvements were documented through an internal evaluation report. The report showed significantly improved project efficiency across development projects. Our qualitative post-implementation study supported those findings and showed that efficiency was enhanced through three practices: continuous resource reallocation, enhanced process visibility through the use of visual tools, and enhanced communication and knowledge sharing within and across projects”

6) Conducting statistical analysis

Study conducted by PMI's Pulse of Profession enlisted under document Capturing the value of project management through Organizational Agility, Stephen Denning, 2015 highlights that blend approach enables organizational Agility through "agile" project management approach which has been practiced by industries since last decades. Paper further explains that organizations have now realized that using agile techniques, such as Scrum or DevOps, is not an indication of an organization's speed or flexibility. Finding of the report suggest that most agile organizations are more likely to use several different project management approaches.

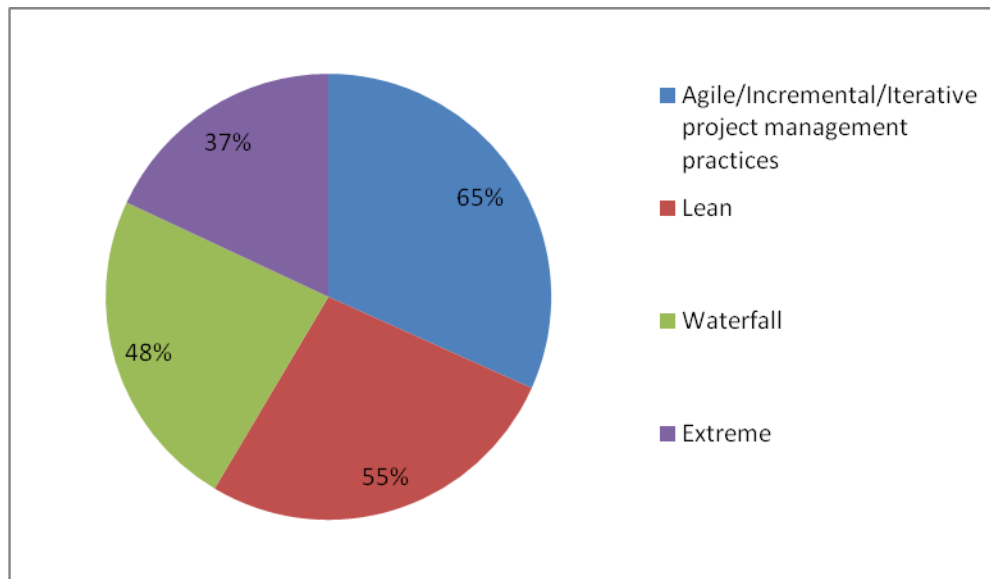


Figure: 12 Agile organizations are more likely to use several different project management approaches, Stephen Denning, 2015

The numbers suggests that organizations are blending methods or using a hybrid approach unique to the needs of the project, the organization, its industry, and the market.

Report by Stephen Denning, 2015 also suggests that Organizations using more than one approach are capable to reconfigure their processes and combine different techniques to cope with their own

distinctive challenges. In today's fast-moving, perpetually changing market, a culture of organizational agility that enables flexibility and the use of the right approach for the right project is an essential strategic competence.

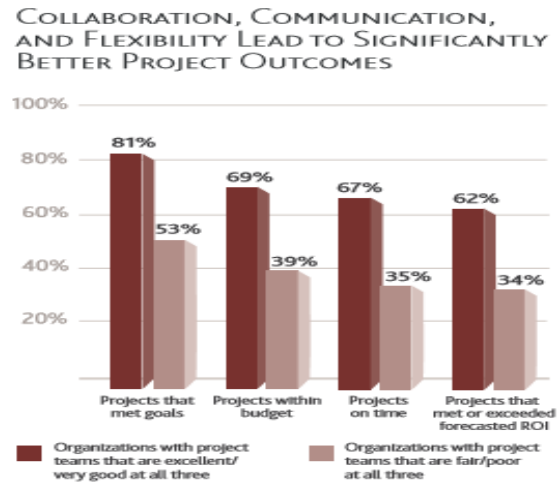


Figure: 13 Collaboration, communication, and flexibility lead to significantly better project outcomes for Stephen Denning, 2015

Stephen Denning, 2015 reported the above graph that shows 81% projects succeed to meet original goal Vs 53% of the team do not. Based on this numbers he further concluded that organization where teams are more collaborative, communicative and flexible have shown significant project outcomes. These findings reinforce how increased agility contributes to higher revenue, lower costs, and faster time-to-market, while also improving customer and employee satisfaction levels.

8) Writing up results

The result that can be transcribed from the literature is dictates that traditional project management technique i.e. waterfall methodology dominated initial phase of pharmaceutical project management during 1960s where internal and external forces did not impact project as they

do impact in modern era. Agile methodology by itself will not be able to succeed to find its roots in pharmaceutical project management as it emphasis on less documentation and more stringent quality parameters. Hybrid methodology comes along with agility and methodology that can lead to more successful path forward.

9) Generating conclusions

Hence we can concluded from the literature review that modern era of project management asks for strong agility along with the virtues and aspect of traditional project management in pharmaceutical industry, Hence we can conclude that our topic for research “**THE IMPLICATION OF AGILE & TRADITIONAL METHOD AS A PRACTICE IN PHARMACEUTICAL INDUSTRY**” will prove to be an enlighten the path of modern day project management in pharmaceutical industry. We will further perform Qualitative Analysis and present some case study that will help us to justify our topic of research and its importance in modern day.

REFERENCES

- [1] Hass, K. B., the Blending of Traditional and Agile Project Management. *PM World Today*, May 2007. IX(V): p. 1-8.
- [2] Rami Hansenne and Allan Hibner Overcoming Organisational Challenges related to Agile ..., June 2007.
- [3] Murphy, P. L. (1989). Pharmaceutical project management—is it different? *Project Management Journal*, 20(3), 35–38.
- [4] Project Management Institute, A Guide to the Project Management Body of Knowledge (PMBOK® Guide). Fourth Edition. 2008,Project Management Institute. 459

- [5] Staples, R. G., Engelhart, J. E., Malkin, M. F., & Rhodes, R. R. (1989). Project management in the pharmaceutical industry. *PM Network*, 3(6), 11–28.
- [6] Edivandro Carlos, C. Fabian, Daniel C, A. Luis Fernando, M, & Sergio Luis, D (2014, June). Agile Project Management Adopted by Industries. Retrieved February 06, 2017, from <http://www.pmi.org/learning/library/agile-project-management-adopted-industries-3789>
- [7] Hajou, A., Batenburg, R., Dr, & Jansen, S., Dr. (2014). How the Pharmaceutical Industry and Agile Software Development Methods Conflict A Systematic Literature Review. Retrieved February 5, 2017, from <https://pdfs.semanticscholar.org/7e6a/b8644867b5de3b16cac9818d582efc64bbce.pdf>
- [8] Sommer, A. F., Hedegaard, C., Dukovska-Popovska, I., & Steger-Jensen, K. (2015, Jan. & feb.). Improved Product Development Performance through Agile/Stage-Gate Hybrids. Retrieved February 5, 2017, from https://www.projectmanagement.com/content/attachments/jwoolcott_260515093635.pdf
- [9] Pattanaik, A. (2014). Complexity of project management in the pharmaceutical industry. Retrieved March 21, 2017, from <https://www.pmi.org/learning/library/project-management-complexity-pharmaceutical-industry-1487>
- [10] Denning, S. (2015, September). Capturing the Value of Project Management Through Organizational Agility. Retrieved March 21, 2017, from <http://www.pmi.org/-/media/pmi/documents/public/pdf/learning/thought-leadership/pulse/pulse-of-the-profession-2015.pdf>
- [11] Robert G. Cooper (2016) Agile–Stage-Gate Hybrids, *Research-Technology Management*, 59:1, 21-29
- [12] Guarino, R. A. (2004). *New drug approval process: accelerating global registrations* (3rd ed.). Chapter -3, *Basic Project Management* (Gus Cicala); New York: M. Dekker.

- [13] Sara, T. (2012). Project Management in Pharmaceuticals. *International Journal of Pharmaceutical and Life Sciences*, 1(1). doi:10.3329/ijpls.v1i1.12949
- [14] Concepts in Pharmaceutical Development Project Management. (n.d.). Retrieved June 19, 2017, from https://www.bing.com/cr?IG=70A6BDC1DEA14596BB74521DA0F13AFD&CID=12B14437FD7D620420BE4E91FC7B6313&rd=1&h=OGtYp7_sXjIX0udNam_ifh5zFS9UdU2WgaTc tbDRIt0&v=1&r=https%3a%2f%2fippcr.nihtraining.com%2fhandouts%2f2011%2fBreder_508.pdf&p=DevEx,5061.1
- [15] Hansenn, R., & Hibner, A. (n.d.). Overcoming Organisational Challenges related to Agile Project Management Adoption (Unpublished master's thesis). Supervisor: Dr. Urban Ljungquist 2011-06-07
- [16] Capturing the Value of Project Management Through Organizational Agility. Retrieved June 19, 2017, from <http://www.pmi.org/-/media/pmi/documents/public/pdf/learning/thought-leadership/pulse/pulse-of-the-profession-2015.pdf>

APPENDICES

Any extra materials, sample data, etc