

**Applying the Agile Mechanism in the Clinical
Trails Domain for Drug Development**

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Abstract

The current speed of economic growth has greatly affected the means of pharmaceutical organizational operations in the establishment of clinical trials. Pharmaceutical organizations are looking for ways to increase customer experience and reduce costs of production in the process. The customer experiences can be increased by creating a forum for active participation during the processes of the establishment. Equally, the costs of production and conducting research study can be ensured through the reduction of reworking chances. Through the creation of this experience, the effectiveness of the clinical trials needs to be properly created. Traditionally, organizations used waterfall methodology in the development of the clinical trials. The linear processes did not allow for proper correction of the processes and how the customers could understand the progress unless the developments were at certain milestones. The system of operation is still in use today because of the strong traditional background. As a result, organizations are forced to rework certain operations because of the reduced client satisfaction. These reworks force the organizations to spend more on the processes hence reducing the effectiveness of the processes. The introduction of the agile methodology has played a crucial role in the development of cost effective and efficient processes of clinical trials. This paper proposes the effectiveness of agile methodology in the establishment of clinical trials.

Keywords: Clinical trials, agile methodology, waterfall methodology

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Chapter One: INTRODUCTION

Background of Research

Agile framework for software development, including the Scrum structure, have become universal since the 2001 Declaration for Agile Software Development. Many organizations, for example, Amazon, Yahoo, Marriott, and even SAS have exhibited the progressive effect of Agile on data innovation development and usage. Inside the government, the Government Accountability Office (GAO) in a multi-office contemplate recognized particular development of Agile as a best practice, while offices including the Federal Bureau of Investigation (FBI) and the Department of Defense (DoD), Department of Veterans Affairs, Department of Homeland Security (DHS), and others have approved the part of Agile in emphatically changing upcoming and innovative short IT projections (Azanha, Argoud, Camargo Junior & Antonioli, 2017).

While the advantages of Agile are clear and persuading, its application and selection over the product development group have not been without inclination. Agile-related terminology, preparing, writing, and business postings regularly delineate a romanticized "developer" original who codes unremittingly in at least one object-oriented programming (OOP) dialects, whose value is estimated by the product he makes, and who might possibly have an undesirable dependence on Zombie-related legend, legend, and eBay barter. Truly, programming engineers and developers speak to a significantly more extensive fragment and incorporate many experts who will not grasp the developer group or title. Biostatisticians, factual developers, information examiners, monetary investigators, clinical analysts, information scientists, doctors, clinicians, and a wealth of different experts rather regularly see programming development not as endpoint, but instead as a way keeping that in mind-an instrument to help the observational journey for truth (Rauchenberger, Little & Montana, 2013).

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Along these lines, these experts while containing both essential and auxiliary developer parts might be more unconvincing than supposed traditional developers to incline toward the product driven, pointlessly limit clarifications of Agile that sadly continue. Since SAS developers optimize such a various cluster of parts in similarly assorted associations and ventures, they frequently get business value not from code they make but instead from subordinate information items - including informational collections, investigations, systematic reports, and information driven choices.

Acquired from the Software Industry, Agile Product Development Methodology holds incredible guarantee for use in Adaptive Clinical Study Development (Aziz & Abdullah, 2015). Agile, is best portrayed as having two essential properties—soundness and dynamism, that enables associations to react and quickly adjust to changes in the earth. Accordingly, Agile tries to standardize three basic transformative standards, the 3 E's that applies to associations and venture management association inside them (Aziz & Abdullah, 2015). The first E is envisioning; which includes making noteworthy, straightforward, and key direction concentrated on partner fulfilment, empowered by solid sponsorship at the basic levels in the association. The second E is engaged; which entail making groups with a common reason and vision, an end to end responsibility and a feeling of proprietorship; as well as to create a culture that empowers group interdependency. The third E is empowering, which involves characterizing clear, level structures/parts, consider vigorous groups of training, energize dynamic association, give cutting edge innovation bolster, and release the creative soul (Aziz & Abdullah, 2015). These three basic standards empower agile preparation inside associations, and thusly, help set the foundational structure for venture management workplaces to help agile undertakings. In this regard, the aim

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of the current study is to examine the agile methodology to define its feature and relate them to applications in the clinical trials area of research.

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Problem Statement

The modern society has been undergoing significant changes due to the economic, social and technological advancements. In the business scope, customers are demanding better services and efficiency, and organizations are competing in a position of better efficiency and value for customers (Kettunen, 2017). All these dynamics are based on the pursuit of reducing costs while optimizing quality and efficiency. For company teams to deliver high levels of customer value, they utilize various project management and implementation tools, with the traditional one being the waterfall methodology.

Before the introduction of agile methodology, the waterfall methodology had the widest application. This methodology cost more because of the sequential way of handling the processes which had to be followed for its effectiveness. The waterfall methodology is characterized by sequential and overlapping phases that are linked to one another. The defined method of operations made the process more expensive. Equally, the testing points of the waterfall methodology were in the later stages. From this development, it becomes hard to make changes during the stages of application.

Clinical trials need that the stakeholders get a chance to evaluate the product before the actual mass production. Unfortunately, the current methodology allows for testing only in late stages of development because of this overall development increases the overhead costs and time for the development. In the current methodology, the stakeholders are denied the chance to make their evaluations and only to hope that the product will come out fine at the point of testing. The costs become high when there is a fault in a product. The product must be redone, and more time is spent on one product.

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More recently in 2001, the agile methodology was introduced, and although it has not found universal applications, it remains an attractive methodology, which many agencies have already adopted (Juricek, 2014). In the clinical research, the researchers and scientists are working to optimize processes, such as drug development and medical devices design and development. The clinical trials on drugs and equipment, as well as IT tools such as programs also need improved levels of efficiency, to cut costs and complete the projects more efficiently. The present situation is that the clinical trials can benefit from agile methodologies if it is more efficient and applicable.

However, the reality is that there are many inefficiencies in the clinical trials, which lead to many of the trials failing. On this note, it is assumed in the current study that the agile methodology could have beneficial features which can benefit the clinical trials (Azanha et al., 2017). It is on that note that the present investigation set out to examine the agile methodology of research and project management, to define its features in view of the waterfall or traditional approaches in the application and determine if it is applicable and beneficial to the clinical trials. On that note, the underlying question answered is: can the agile methodology be applied in the clinical trials domain to boost efficiency and, performance and cost-effectiveness?

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Project management Justification

Adopting a clinical trial is a project. This is because there is an initiation, where the current systems are studied and marked. Then there is planning. This is the stage where adequate plans are laid in place on how to adopt new systems, and ensure the agile methodology is adopted in clinical trials. In the execution phase, the real plans are implemented, and tested to ensure that they work. Then there is closure where the systems will have been tested, and if found advantageous, the process is closed. By having all these components, then this qualifies as a project.

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Literature Review

Clinical trials are very complex especially when it comes to the need to reduce time and cost. The clinical trials must be done through multidisciplinary teams and within the required times. The economic situations keep fluctuating and because of this, there is a need to come up with the most economic and effective approach in the development of clinical products. The processes through which the products are made are determined through the quality of the product, the reliability, safety and the efficiency of the processes used. As clinical trials need to make some of the highest quality products in the market today, the current selection of approach is based on the historical views of the product development. Agile methodology is one of the latest concepts in the clinical trials and because of the benefits linked to the methods; its implementation process needs to be hastened. As different organizations focus on waterfall methodology, this section relies on the previous research works done on the agile methodology. The section is divided into a couple of topics based on the findings of the researchers.

Palmquist et al., (2013) established that traditionally, clinical systems established randomization process to help in randomly allocating patients to a trial. As the methods progressed, the clinical trials established the application of electronically supported plan models and this model was perfected using the conventional waterfall method. With the use of this model, after the product had successfully gone through the first stage of development, it would automatically go to the second stage. Through this establishment, it has been hard for an error created in the first step to be addressed. Because of this difficulty, there is a need for the clinical trials to embrace the introduction of the agile methodology because of the flexibility in application.

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Development of high quality clinical trial software (CTS)

Serrador & Pinto, (2015) believes agile methodology is crucial in the reduction of time spent during the development of the clinical product. In this research, it was equally proven that the methodology does not only come up with ways of reducing the time spent on the development but the sustainability of the processes play an important role. Through this methodology, high quality clinical trial software is salient. Through this software, the agile methodology works within a system that has a proper budget. Unlike the waterfall methodology, the clinical trial software that comes with an agile methodology is crucial because its application does not require additional resources (Serrador & Pinto, 2015). For example, the steps that are involved in product development using the methodology can be corrected without having to skip the least of them. As the first step leads to another, the faults in the product can be seen. The corrections are ensured when the product is in the process and from this advantage; there is a reduction in the chances of rework.

For clinical trials, the accuracy of the collected data is salient. The development of the drugs through these experimental designs requires data accuracy so that the recurrence of the problems may be prevented. The clinical trial software used in the agile methodology developed a properly designed study protocol. Clinical trials come with trial questions which need to be answered. From the development of the questions, the variables and the measures of the products to be developed are created. The accuracy and the quality of the determined results are dependent on the quality of data to be collected for the trial. The software plays an important role in managing the data and this is an aspect that is not addressed in the waterfall methodology. In the normal process of data analysis, a lot of time is spent in the process. When the given data is not accurate, the whole process becomes futile (Thiemich & Puhlmann, 2013). The inaccuracy of the

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data would lead to time wastage. This problem is addressed by agile methodology through the application of clinical trial software. The errors that enter the database are minimized and the management of the data is increased.

Reduced waiting time between steps

The study protocol design needs a couple of steps for an effective development of products. Each step needs distinct roles within the establishment. In agile methodology, the steps between the product developments are done in a quicker way. The product moves from one step to another at a comparatively faster rate than in waterfall methodology. Because of the accompanying technology in agile methodology, the assessment of the products tends to be faster (Thiemich & Puhlmann, 2013). The stakeholders in an organization using waterfall methodology will have to spend more time in examining the quality of the products at each step of development. More time is spent in the micromanagement of the protocol designs and this makes waterfall methodology less efficient especially when it comes to time (Thiemich & Puhlmann, 2013). Agile methodology on the other hand does not focus on the micromanagement of the protocols but the research team can focus more on the means of solving specific problems instead.

The agile methodology focuses on the establishment of flexible and stable systems which can be sustainable in the clinical trials. The methodology is characterized by time-boxed iterations. The time boxed iterations create a dependable system which can support both adaptive planning and evolutionary delivery (Serrador& Pinto, 2015). Clinical trials usually have certain rapid changes and needs for alterations. The fact that these changes are rapid creates the need for a stable and supportive system that can adjust to these requirements without an alteration on the expected delivery time. Agile methodology has technologies that encourage both flexible and

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rapid responses towards the needed alterations. The efficiency of the operations is measured based on the time of production and the delivery.

Rauchenberger, Little & Montana, (2013) confirm that in the traditional manufacturing systems, organizations depended on steps for effective follow up on the quality of the product. Waterfall methodology provided a way through which the defection of the product could be traced to a step of operations. As the system led to proper product development, the duration of coverage was longer. The current pharmaceutical industries still trust in the waterfall methodology for the development of the pharmaceutical products. Both in the traditional and modern manufacturing means, the steps were to be completed sequentially. The processes were developed at the expense of time. The numbers of steps are to be determined before the processes are initiated so that the sequence can be followed during the manufacturing process. This methodology consumed a lot of time and the numbers of products to be manufactured were greatly reduced.

For a clinical study, Mahadevan, Kettinger&Meservy, (2015) opines that the duration for completing a project is shorter. From this research, it was established that a project that can take eight weeks to be completed using a waterfall methodology could only take five weeks on agile. This difference is created from the steps used in the process.

Consistency in communication and updates

Lodha, (2016) established that in as much as there are several organizations using waterfall methodology in their clinical trials. Very few have come to the realization of the accompanying shortcomings. Some of the organizations that have noticed the shortcomings of the methodology are shifting from its application. The waterfall methodology offers a linear

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means of communication. There is no chance of check-ins that can be done by the patients or other stakeholders. The possibility of adjusting is controlled at specific milestones and this reduces the chances of effectiveness. The methodology depends more on the hope of quality rather than assurance. The communication signals can only be gathered at the milestones developed by the methodology and this created a huge gap in its application.

Glaiel, Moulton & Madnick, (2014) furthered the study on the importance of communication in agile methodology. As opposed to the waterfall methodology, agile creates an understanding of communication before the commencement of the project. The agile methodology reduces the chances of redesigning the product because of the ease in communicating with the established technologies such as the clinical trial software. The methodology creates a check in tracking progress where the quality of operation can be tracked and, therefore, reducing the chances of rework. The communication channels are created sequentially so that when there is an adjustment to be made, the rates of success become higher.

Newer projects and designs require creativity which enhances the communication between team members towards achieving the desire goals (Vijayasathy& Butler, 2016). Agile methodology is not designed specifically. After the methodology has been understood, it becomes easy for different clinical trials to be established. The data to be used is not specific. Because of this flexibility, organizations can create some of the best practices in the clinical trials. The fact that the output is constantly reviewed during the production processes improves the chances of correction and this creates a good relationship between the product to be developed and the developer. The methodology allows for prioritization at any stage of development and this makes it easy for the final product to be of a very high quality.

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Standardization of the protocols

Mahalakshmi&Sundararajan, (2013) established that patients have different needs and expectations. The clinical trials have different focuses which should be attained. During clinical trials, the focuses of the trials are diverse. The methodology allows for easier development of standardization protocols. Within a uniform clinical trial or a study, patients have diverse needs and expectations. The agile methodology allows for the standardization of the methods, but it allows for creating differences so that too much customization can be avoided. The agile approach makes it easy for the standardization of the protocols. Standardization, in this case, includes the creation of a common system that can be used by all patients. In such a case, it would be hard to determine the needs of a specific clinical trial (Mahalakshmi&Sundararajan, 2013). The agile methodology creates a solution to this barrier by allowing for flexible adjustments of the method. At the same time, the methodology allows for a controlling mechanism such that the flexibility cannot be designed for a specific clinical trial hence blocking out the other possible study tests.

Changing consumer responsibilities

Moniruzzaman&Hossain, (2013) claims that to be able to understand the effectiveness of agile standardization, understanding the influence of the methodology on how the roles of consumer responsibilities are affected is crucial. This concept can be easily understood if the responsibilities of the consumers are considered alongside the expectations in a waterfall methodology. Firstly, a single individual can play a pivotal role in the creation of a link between the development team and the organization. In most cases, clinical trials have a couple of tests and studies involved. In these studies, how the programs are handled should be understood by the patients and the consumers of any form. The organizations need a link between the

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production processes and the operations of the entire company. The creation of this link explains the concept of standardization as there are different products that can be accomplished using the same processes.

The agile methodology creates an opportunity for specificity. As the methodology allows for product or processes standardization, the consumers can be involved in the process (Palmquist et al., 2013). The involvement of the patients in the processes improves the developmental processes of the product and the chances to make mistakes are reduced in the process. The inclusion of the customers in the process of clinical trials should not be underestimated as through this process, it would become easy not to redo a task that had been done. The patients can see the progressive development of the processes and this improves the chances of improvements in the successive stages. The iterative nature of agile methodology makes it easy for the development of a proper product (Moniruzzaman&Hossain, 2013). One of the major advantages of agile methodology is that fact that the process of a clinical trial can be altered in the duration of the development. The product can be altered during the processes. The clients can find it easy to make their preferences at each stage and this is the importance of the existing flexibility.

Patwardhan et al., (2016) opined that for the agile methodology to be successful, progressive feedback is necessary. Through this feedback, the development of the product can be corrected or improved if there is a need. Because agile methodology allows for iterative improvements, coming up with ways of increasing the nature of the product is easy. This is one of the reasons why the agile methodology is cost effective especially in the current economy. The clients can give their feedbacks at each stage of development and as a result, an appropriate method can be established. Waterfall methodology only allows for improvements at specific

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milestones. A client cannot change the preferences after the process has started. This stiffness in the application of waterfall methodology makes it less attractive for flexible processes. Being that the approach has been used for ages because of the norms of the organizations, it has become hard for the effective development of flexible products over the years. There are times when clinical trials require flexibility and adjustments. These adjustments can easily be made through agile methodology and, therefore, making it possible for organizations to attract more clients (Patwardhan et al., 2016). The involvement of the patients in the processes increases their trust hence establishing a means for higher profitability. Equally, this establishment makes the customers be available at the right time. as compared to the traditional waterfall methodology, clients do not need to appear only at the end of the product, but the involvement will allow for continued processes and client participation.

Agile methodology and cost effectiveness

The introduction of agile methodology has largely influenced the clinical trials. These influences can be linked to the cost reduction and effectiveness of the processes Kettunen, 2(017) confirms that all the occurrences in an organization are directed towards the reduction of costs of production. When the costs are high, the value of the products would be high and the chances of making proper profits are reduced. The means through which agile methodology has influenced the cost of production has placed its advantage at a higher level.

Agile methodology is faster, and this is an aspect of cost effectiveness. When the process is faster, a large volume of clinical trials can be ensured. Clinical trials require faster developments so that a large volume of products can be affected. The waterfall approach is expensive because when a product is faulty, it can only be detected at specific milestones. Correcting the product would mean that it must be taken through several processes back

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(Kettunen, 2017). Such inconveniences cause difficulty in financial planning as they lead to higher production costs.

Clinical trials require quality research with small data developments. For example, when a new medical product is to be developed, the sample to be used is just small. The standardization of the research requires that each patient should have specific data and information that is customized to them. In as much as agile methodology prevents intensive chances of customizing data, it allows personalization of information especially when a data sample is a small group (Losada et al., 2013). For clinical trials, the aspect of smaller data is crucial. It is easier for smaller data to be used with agile methodology because of the progressive inspection. It is cheaper to use smaller data because the chances of errors are reduced (Papadopoulos, 2015). Waterfall methodology is appropriate for large projects which require reduced accuracy in the analysis. Because of the accuracy of smaller data, the agile methodology reduces the chances of mistakes as the data is protected and properly analyzed in the process.

Stoica, Mircea & Ghilic, (2013) confirm that traditionally, the waterfall methodology focused on the expectations of the stakeholders. The customers could only see their products at certain milestones. In case the clients were not satisfied with the quality of the developed product, the organization had to incur extra costs to correct the systems. The satisfaction of the clients was uncertain, and, in several cases, additional costs would be incurred in the process. Agile methodology has brought about a process that focuses on the needs of the clients (Palmquist et al., 2013). The clinical trials are done with the customer in mind. Because of the flexibility of the operations, organizations that do clinical tests can invite different clients for process confirmation. This allowance makes it easier for the clients to come in and make certain adjustments (Saltz, 2015). In these adjustments, the involvement of the clients minimizes the

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chances of reworking hence saving on the operational costs. Certain defects can be corrected at the early stages of the processes hence saving on costs. The involvement of the clients makes it easy to satisfy their needs hence saving on the correction costs.

In the normal project management triangle used in waterfall methodology, the focus of the operations involves time, cost and scope. Cost is a factor of time. From the project management triangle, the cost of a product was determined by the length of time taken in its production (Lotz, 2013). Through this understanding, clinical trials used to take longer and cost higher in the process. This triangle opened an avenue for making more profits from simple tests. The introduction of agile methodology came with a different triangle of project management. In this triangle, the focuses of operation are on value, quality and constraints. The costs of the operations and the clinical trials are determined by the quality of the final product. When the quality is low, the costs are high because the product must be done again (Papadopoulos, 2015). The agile methodology makes the process flexible since the costs of operation are reduced. The quality is the focus of production and the chances of the clients being satisfied are very high.

Rahman, Rutz & Akhter, (2013) believe agile methodology reduces the risks that are linked to production. This is so because the approach first reduces the volume of production. When the volume is low, the risks that are linked to the cost of production are low. The involvement of the clients in the production processes reduces the chances of making mistakes during the clinical trial processes. Different organizations have various trials of focus. The trials are varied and depending on the client, the involvement would save a lot of resources in the process. The risk of rejection is reduced to nil. The products are released to the clients in small quantities but early enough. Being that clinical trials only require smaller data, chances of errors

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are reduced. The costs of doing the clinical trials are equally reduced and this makes agile methodology appropriate in the processes of clinical trials.

The effectiveness of the Agile framework

Vijayasathy & Butler (2016) established that agile technology has made it easier for smaller teams to come up with very large projects and ensure that they are effectively managed. Big projects require big teams for considerations. When the teams are smaller, it became hard for the organizations to work with smaller groups in the process of wanting to clear them. Clinical domains are very complex to deal with. When there are complications in the process of research, it becomes hard for the for the teams to work on them. Bigger teams were preferred to work on the projects so that there would be better delivery processes. With this approach, clinical domain projects used to be handled but their effectiveness was not guaranteed. The large numbers of the professionals handling the projects are usually less effective because of constant problems and disagreements. Through the agile methodology, smaller and more efficient groups can be easily used in the processes of clinical tests and the results would be much better and more efficient in the end. The agile methodology makes the work of the teams easier and the quality of delivery is high in the process. The technology equally ensures that the teams are given the opportunity to work together under the guidance of operational principles that would place them on course.

Most projects in clinical trials are long term. Mahadevan, Kettinger, & Meservy (2015) established that trials and domains can take a duration of between six to eight months of testing. The duration is linked to the fact that the testing durations must be involved with the processes of prediction and requirement addition so that there can be ease in operation. Using agile technology, Mahadevan, Kettinger, & Meservy (2015) believed projects that could take eight months can be done in only four weeks and very effectively. The agile methodology uses a

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technology called the iterations of ideations. In this technology, the processes involved with the product development are deeply considered. The testing durations are reduced, and the processes are made to be worked with shorter times which can be easily handled. Agile methodology equally uses the processes of coding, iteration and testing which are done as the processes are established to create effectiveness in the product quality. The development cycle as created by the agile technology ensures that time is saved. The methodology focuses on the aspects of time and quality so that there can be a balance between the two. Clinical domains can be handled in a faster way with the highest quality of operation. The efficiency of time in the operations of the technology does not affect the quality of operations. The processes are made more efficient to up to more than 25% and this confirms the effectiveness of the process(Kettunen, 2017).

Vijayarathy & Butler (2016) opined that humans are prone to mistakes in different projects and these cannot be avoided. The fact that humans make mistakes makes it hard for the project developments to be effective. In waterfall methodology, when the mistakes are made, it becomes hard for the projects to be continued. The mistakes affect the developments of the projects and as a result, it becomes an impossibility to ensure that there is a high quality process. With this ideology, the chances of ensuring that the quality of clinical processes is maintained are slim. The agile technology allows for corrections of these mistakes during the processes of the establishment. There are a couple of things that can be changed especially when they happen as mistakes, but the changes can be effectively made in the development cycle and the processes are made better. Vijayarathy & Butler (2016) established that agile methodology has a provision of teams where there is a frequent inspection of the processes and this allows for changes to be made in the development cycle. The processes are aimed at minimizing the cost of

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productivity. Wastes are equally minimized with the same processes since they defect of clinical trials would be realized before they affect the quality of the trials.

According to Papadopoulos (2015), the agile methodology provides for engagement of the stakeholders and this reduces the chances of dissatisfaction in the processes. Clinical trials are always unique. The qualities of operations are necessary, and they need to be very high for the effectiveness of the developments. To ensure that there is a high quality, the specifications of the stakeholders must be held to a higher degree. The clinical trials are based on the requirements and the adherence to the specifications this ensures that the project team and the stakeholders collaborate in an appropriate way. Through this collaboration, it becomes easy for the for the trials to avoid unnecessary corrections. The corrections that are avoided come with the reduction in the costs of production and process establishment. Through this organization, the satisfaction of the stakeholders increases the marketability of the series and this offers an opportunity for future development and market. There are different clients that are interested in the processes of clinical trials. Agile methodology ensures that there is transparency and the stakeholders are involved in all the processes of the development and the establishment of the appropriate research processes.

A research was done by Mahadevan, Kettinger, & Meservy (2015) on the effectiveness of agile technology established that the methodology is salient in the early predictions of the appropriate delivery periods. The methodology uses a time boxed and fixed schedule sprints to come up with an organized process of how the deliveries can be made more effective. The agile methodology seeks to create better operational effectiveness. The predictability of the results is one of the most important aspects of the operations. The prediction is ensured through the establishment of the application of beta test which is a software used specifically for the

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predictions of the processes. The predictions are done earlier so that there can be planned operations to create a sufficient business value. The operations of the processes as established by the agile methodology focus on the early predictions for the correction processes to be done easily.

The research done by Flora & Chanda (2014) established that agile methodology allows the clients to determine the features and the processes to be used in the project management. This allowance is very relevant to the processes of clinical trials since it is from these trials that the processes can be determined where the needs of the clients can be understood. Agile methodology insists on the specifications of the clients because it is through this establishment that the quality of the tests and productions can be realized. Organizations need to ensure that they create a strong business value. The value of the business is established when there is adherence to the requirements of the clients. The focus of the methodology is on the users and not the operations of the organizations. Because of the flexibility of the technology, it becomes easy for the users to effectively change the required steps and therefore, ensuring the quality of the processes involved.

Agile methodology and quality improvement

The information put forth by Rauchenberger, Little & Montana (2013) opined that agile methodology allows for handling bigger projects in smaller steps. The projects are broken down into smaller operational units which can be easily managed by the processes to be used. The projects teams can focus on the aspects of the project that guides the direction of project completion. Because the mistakes can be found early in the project processes, it becomes easy for corrections to be made. The project teams can focus on the iterations and this improves the focus of the development and the operations hence ensuring that there is a high degree of

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customer satisfaction. The cost of production, the schedules of operations, the scope and predictability of operations can be dealt with in time hence improving the effectiveness of the technologies to be used. Rauchenberger, Little & Montana (2013) further added that the operations of the agile methodology are crucial in the development of the processes and this allows for better focus on an iteration. The steps play a crucial role in the establishment of the processes. When these steps are considered, the agile methodology ensures that the objectives are achieved in a more organized way which focuses more on the business operations.

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Research methodology

The research methods are involved in the processes that the researcher took to handle the research process. The methodology process informed the researcher the steps which that were necessary towards reaching the desired goals of the research.

Research Worldview

The structural thinking approach was the most appropriate research method used in the process. The structural thinking approach involves a phenomenon analysis with the hope of creating an understanding out of the existing information. The researcher equally focused on the constructivism mature of worldview in the process of handling the research. Historically, the use of waterfall technology has been widely spread. Agile technology has not been fully embraced and the clinical domains are not conclusively using in their trials. The processes involved in the constructivism approach involve the application of proper systems that can be used to create an understanding of the subject matter. The research works, and development is crucial for the establishment of a new knowledge. The constructivism worldview approach intends to establish an understanding from a nonexistent information. The researcher seeks to create a new knowledge both from the research works done in the past and the information received from the respondents used for the study. The research was done under the assumption that the healthcare organizations were not aware of the effectiveness of the agile methodology and the researcher was trying to establish the knowledge for the first time.

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Research design

Being that the research does not consider quantities for the analysis processes, it becomes easy for the researcher to establish the procedures and the processes that would be appropriate in the process of analysis. The nature of the research requires a deep and conclusive analysis of the information gathered. To ensure that this is possible, the researcher used the primary qualitative research process that engaged the respondents in a more direct manner. The researcher required the proper establishment of quality information. The topic of research needed deep analysis. The information required open discussions from the respondents and the experts that understood the subject matter in a deeper way. From this consideration, the researcher settled for the qualitative research methods as a means of data collection.

Research strategy

The topic of study needed deep analysis. The researcher used several resources in coming up with conclusive information about the effectiveness of using the agile methodology in clinical trials. With this focus, the literature review focused on the direct information from a couple of researchers where the information required proper capturing for analysis. The researcher equally sought to the use of qualitative research methods where the information to be used was linked to the understanding of the respondents. The researcher then used the information from the literature review to complement the findings from the respondents. The responses were first compared for similarities and disparities. In the process of research handling, there were chances that certain gaps could not be filled during the research process. The resources used in the literature review process were not sufficient to address all the questions that were raised by the research. The researcher depended on the respondents through the research processes to fill the

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gaps that were created by the study. Through this comparison, the desired research quality was effectively established.

Research Population

Agile methodology technique is an area that has not received a deep attention. The researcher needed respondents with good knowledge on the topic. Because it was not easy to tell the level of knowledge of the respondents on the subject matter, the researcher resorted to the use of a few respondents that understood the clinical trials domains and the natures of the technology that can be appropriate for them. The researcher used IT professionals in the healthcare organizations to participate in the research process. The researcher equally selected a few clinical officers who have had years of experience in clinical processes. This combination was necessary for understanding the most commonly used methodologies and the most appropriate ones that could be used. The selection process was done randomly.

Research Sample

There are several healthcare organizations that could be approached. The researcher minimized the use of resources so that only a few people could be used for the sake of the volume of the study and the resources that could be used in the process. The researcher settled on 22 respondents who would be appropriate in handling the research process. Equally, the researcher selected 10 quality questions that could be easily handled by the researchers so that the quality of the research could be maintained. At the same time, the researcher needed to ensure that all the areas of the researcher were covered so that the chances of gap development could be reduced.

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Data collection Methods

The data collection method followed the pattern of the research design developed for the study. For the data collection, the use of structured questions was appropriate. The selected respondents were given the questions survey via email, so they could prepare for the responses in time. The healthcare organizations are among the busiest organization in the world. The professional selected for the research process was hard to find because of their work schedules. The researcher equally depended on the literature review for the establishment of data reality for effective conclusions.

Data Analysis Method

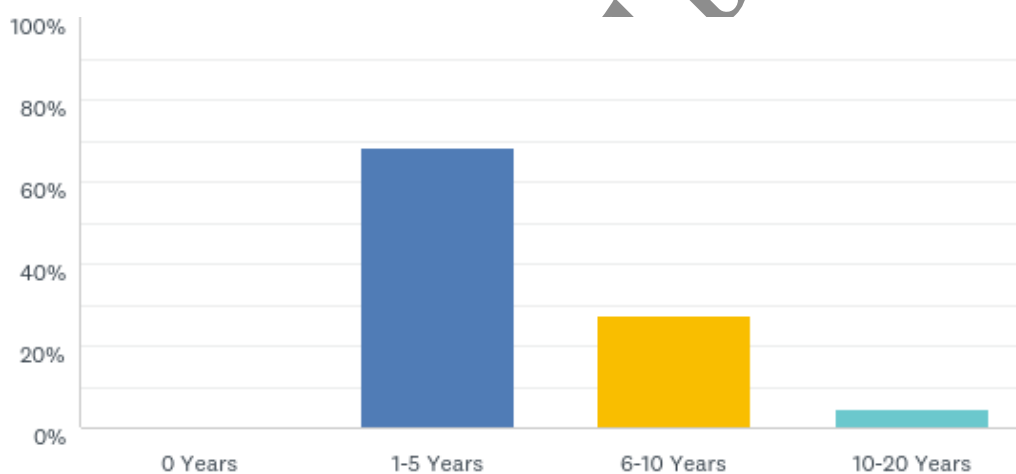
Because of the schedule of the research, it was necessary that some of the mails were saved for future reference. The researcher could not remember all the responses put forth by the respondents and for this reason, the researcher was forced to record the responses with the permission of the respondents. The mails were useful for the period of the research process and after the research was completed, the researcher was compelled to do away with them for the purposes of security and safety of the organizational operations. Equally, the researcher used tables and charts to come up with figures in the representation of the general opinions of the research works. The researcher came up with certain themes under which the responses of the respondents were to be grouped. These themes were represented in tabular forms and charts so that the quality of the research could not be lost.

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RESULTS AND FINDINGS

Q1: How many years of clinical trial experience you have?

All the respondents gave their thoughts on the needs of this question. The respondents selected were people who had been in the clinical trial for a couple of years. 15 respondents confirmed that they have been in the clinical trial professions for one to five years. The number of the respondents in this category constituted 68.18% of the total respondents. Six respondents were between six to ten years of experience and this constituted 27.27% of the respondents and only one respondent had an experience of above ten years. The results are shown in the graph and the table below.



Graph 1

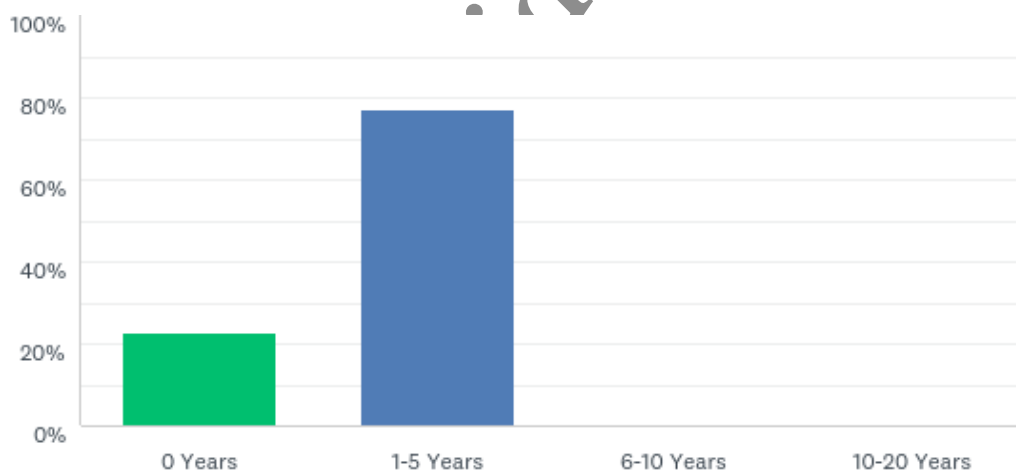
ANSWER CHOICES	RESPONSES
0 Years	0.00% 0
1-5 Years	68.18% 15
6-10 Years	27.27% 6
10-20 Years	4.55% 1
Total Respondents: 22	

Table 1

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Q2: How many years of agile developments experience you have?

The second question was based on the understanding of the respondents on the experience on the application of agile technology in clinical trials. From this question, five respondents confirmed that they have no experience with the use of the agile methodology in clinical trials. These respondents had never used the technology in their lives before since they started their clinical trial practices. The respondents that had never used the agile methodology in clinical trials constituted 22.73% of the total respondents. 17 respondents confirmed that they have used the agile methodology for at least one year in their experiences with clinical trials. This percentage constituted 77.27% of the total respondents used for the study. The representations of the results above are expressed in the graph two and table two below.



Graph 2

APPLYING THE AGILE MECHANISM IN THE CLINICAL TRIALS DOMAIN

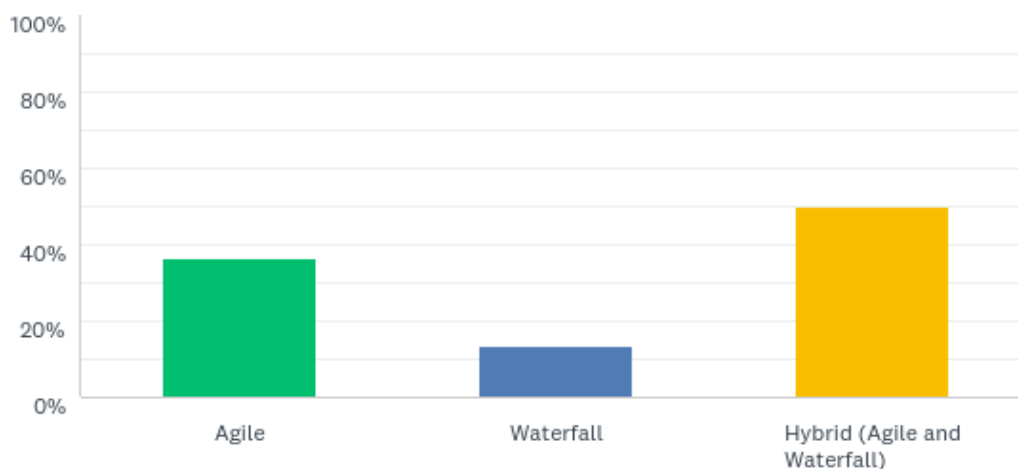
ANSWER CHOICES	RESPONSES	
0 Years	22.73%	5
1-5 Years	77.27%	17
6-10 Years	0.00%	0
10-20 Years	0.00%	0
Total Respondents: 22		

Table 2

Q3: What is the nature of project management methodology used in your organization today, specifically for clinical trial projects?

This question tested on the nature of technologies used by different organizations in their processes of project management. Eight respondents, who constituted 36.36% confirmed that they use the agile methodology as their project management methodology. Three respondents which constitute 13.64% confirmed that their organizations use waterfall methodology as a method of project management. The remaining respondents used a hybrid methodology which is a combination of both agile and waterfall methodologies as their selected technologies in project management. The results of this question are presented in graph 3 and table 3 below

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Graph 3

ANSWER CHOICES	RESPONSES	
Agile	36.36%	8
Waterfall	13.64%	3
Hybrid (Agile and Waterfall)	50.00%	11
Total Respondents: 22		

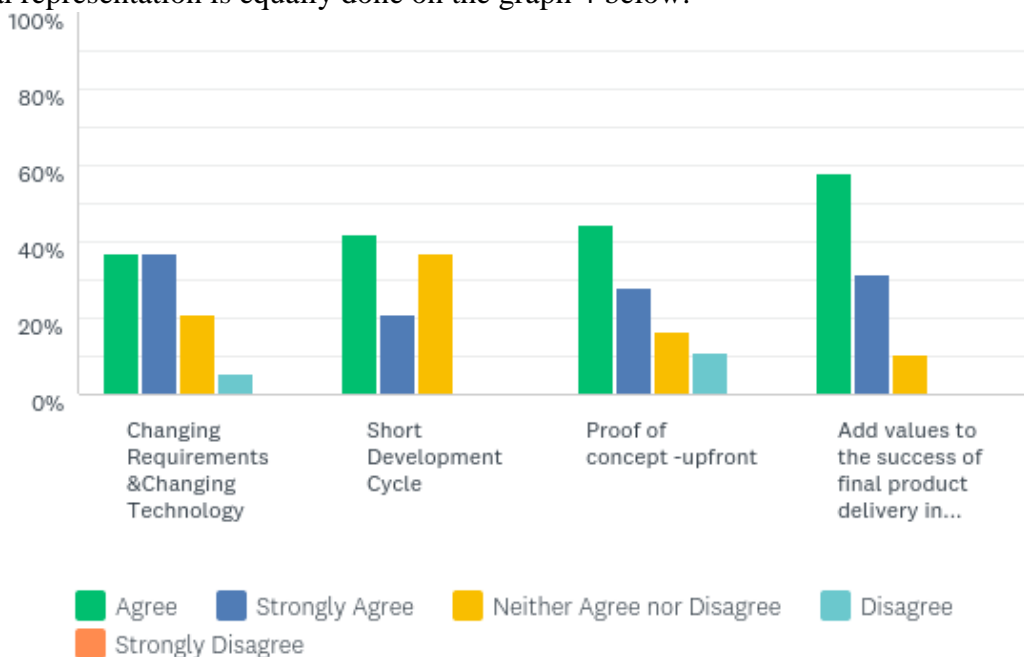
Table 3

Q4: How would you following reason to opt for agile methodology in the clinical trial?

This question as specific on the expectations of the respondents and how they planned to use the agile methodology in the project management processes. The question as closed where the respondents were only supposed to say whether they agree or not. Three respondents skipped this question and this means that only 19 respondents were in a position to respond to the questions effectively and completely. The question tested on the role of agile methodology in changing requirements and changing technology, the short development cycle, proof of concept upfront and how agile methodology could add value on the final product delivery in the clinical trials. The respondents reacted to the claims evenly and the results are tabulated in table 4 below. The

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graphical representation is equally done on the graph 4 below.



Graph 4

	AGREE	STRONGLY AGREE	NEITHER AGREE NOR DISAGREE	DISAGREE	STRONGLY DISAGREE	TOTAL
Changing Requirements & Changing Technology	36.84% 7	36.84% 7	21.05% 4	5.26% 1	0.00% 0	19
Short Development Cycle	42.11% 8	21.05% 4	36.84% 7	0.00% 0	0.00% 0	19
Proof of concept -upfront	44.44% 8	27.78% 5	16.67% 3	11.11% 2	0.00% 0	18
Add values to the success of final product delivery in clinical trial	57.89% 11	31.58% 6	10.53% 2	0.00% 0	0.00% 0	19

Table 4

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Q5: For how long has the organization used the above project management methodology in the clinical trial domain?

This question tested on the application of the agile methodology in the organizations today. The question targeted the application of agile methodology in project management in different organizations. One respondent skipped the question and only 21 respondents were in a position to respond to the requirements of the question appropriately. Two respondents confirmed that they have used agile technology for less than six months. The respondents constituted 9.52 percent of the total respondents. Six respondents, which constituted 28.57% of the total respondents, confirmed that they have used the methodology for between six months to one year. Nine respondents, which made a total percentage contribution of 42.86% of the total respondents confirmed that they had used the methodology for more than two years and for a maximum of five years. Four respondents confirmed to have used the methodology for not less than three years. This made about 19% of the total respondents used in the study. The tabulated results are shown in table 5 below. The graphical representation is equally shown in graph 5 below.



Graph 5

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ANSWER CHOICES	RESPONSES	
Less than 6 months	9.52%	2
6 months to 1 year	28.57%	6
2 to 5 years	42.86%	9
More than 3 years	19.05%	4
Total Respondents: 21		

Table 5

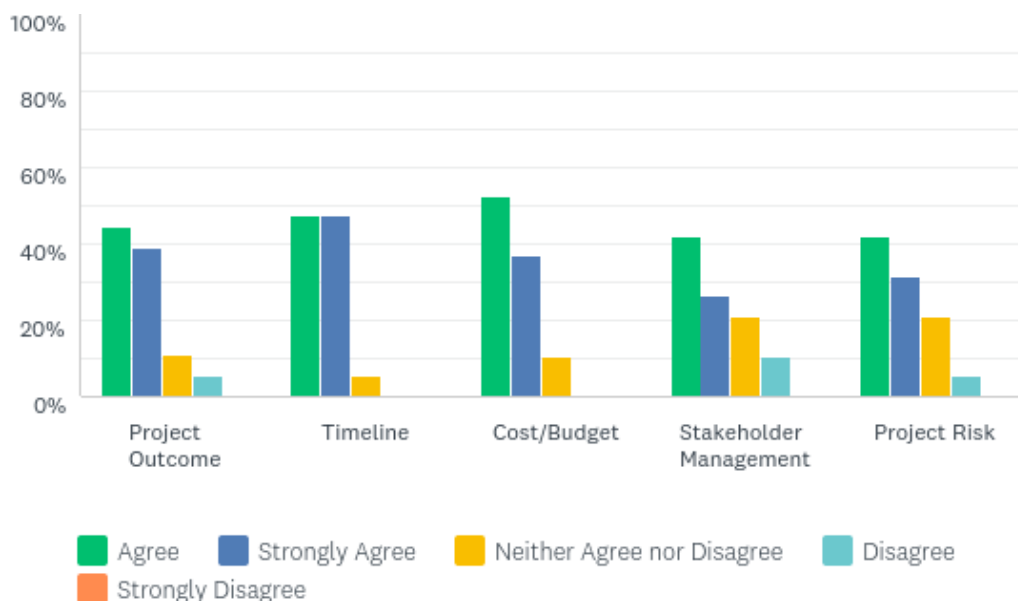
Q6: How likely is the agile adoption in the clinical environment going to affect the following factors?

1. Project Outcome
2. Timeline
3. Cost/ Budget
4. Stakeholder Management
5. Project Risks

The question tested on the effects of agile technology on the different operational units of project management. The respondents were supposed to give their views on each operational unit. The highest number of respondents agreed that project management processes can be affected by different managerial units. The agile methodology has a role to be played in each managerial unit and the effects of these considerations could be positive. 44% percent of the respondents acknowledged that agile methodology would affect project outcome. 47% of the respondents acknowledged that agile methodology would affect the timelines of the project managements, 52% of the respondents confirmed that the technology would affect the budgeting of the projects, project risks and stakeholder management would be affected equally as confirmed by 42% of the

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respondents. Three respondents skipped the question as 19 out of the 22 respondents gave their different views on the agile methodology and the project management units. Table 6 shows the detailed response and graph 6 gives an illustration of the responses based on the data collected on this question.



Graph 6

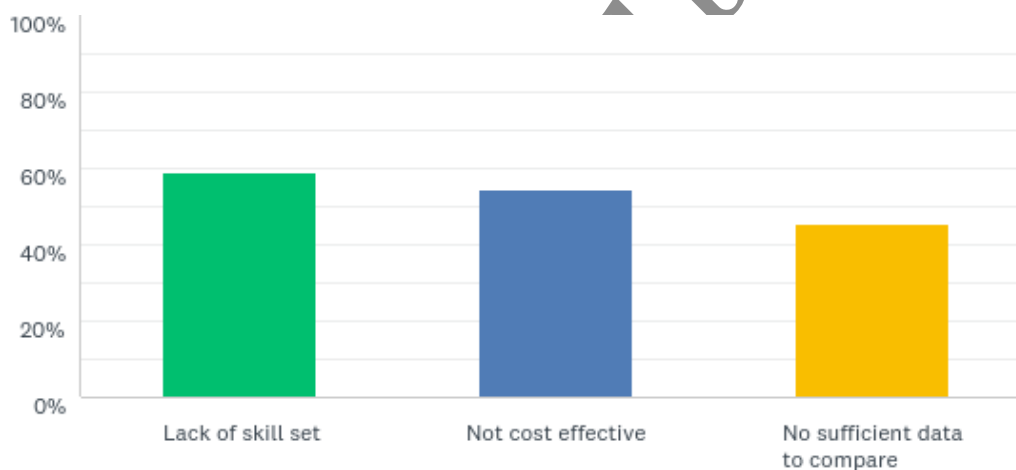
	AGREE	STRONGLY AGREE	NEITHER AGREE NOR DISAGREE	DISAGREE	STRONGLY DISAGREE	TOTAL
Project Outcome	44.44% 8	38.89% 7	11.11% 2	5.56% 1	0.00% 0	18
Timeline	47.37% 9	47.37% 9	5.26% 1	0.00% 0	0.00% 0	19
Cost/Budget	52.63% 10	36.84% 7	10.53% 2	0.00% 0	0.00% 0	19
Stakeholder Management	42.11% 8	26.32% 5	21.05% 4	10.53% 2	0.00% 0	19
Project Risk	42.11% 8	31.58% 6	21.05% 4	5.26% 1	0.00% 0	19

Table 6

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Q7: While implementing the agile method in clinical trial projects in your organization, what were challenges in training workforce?

All the respondents responded to this question. 13 respondents cited lack of skills to be the main challenge affecting the implementation of the agile methodology. This response constituted 59.09% of the total respondents. 12 respondents cited the cost of implementing an agile methodology as the major challenge facing the implementation process. The respondents constituted 54.55% of the total respondents. 45% of the respondents cited data insufficiency as the major problem affecting the implementation of the agile methodology. Table 7 and graph 7 below illustrate the results of the question.



Graph 7

ANSWER CHOICES	RESPONSES	
Lack of skill set	59.09%	13
Not cost effective	54.55%	12
No sufficient data to compare	45.45%	10
Total Respondents: 22		

Table 7

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Q8: How did you tackle the above challenges while implementing the agile method in clinical trial projects in your organization?

73% of the respondent said that they a hired agile coach to help with the implementation of the agile methodology. The 73% was a total of 16 respondents. All the respondents were comfortable with responding to this question. Ten respondents who constituted 45% of the total sample used in house projects as a means to maneuver through the challenges facing the implementation of the technology. Seven respondents confirmed that they used study groups to tackle the accompanying challenges in the implementation process. The table 8 and graph 8 below illustrate the response in this section.



Graph 8

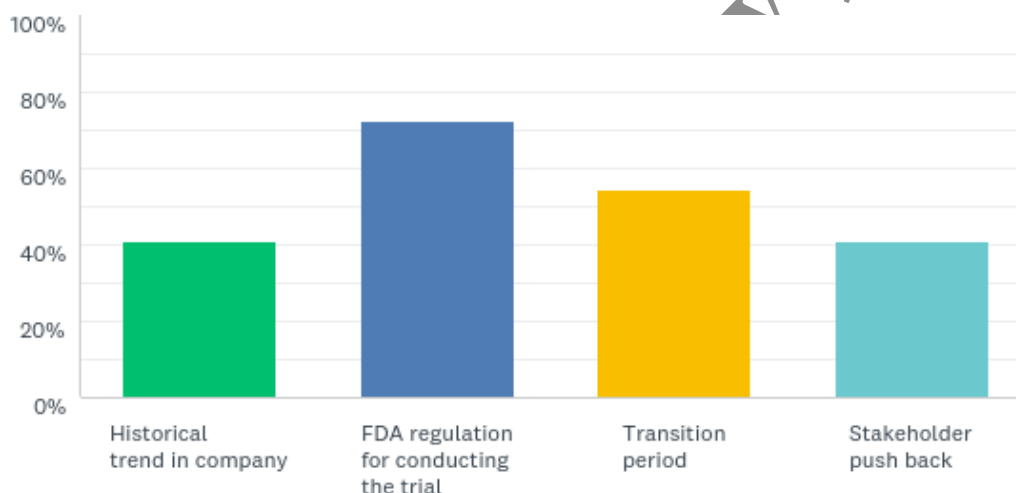
ANSWER CHOICES	RESPONSES
In house project	45.45% 10
Hired agile coach	72.73% 16
Study groups	31.82% 7
Total Respondents: 22	

Table 8

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Q9: What are the challenges do you see in implementing the agile method in clinical trial projects?

All the respondents gave their views on this subject. Nine respondents cited that historical trends could be a challenge in the implementation process. 16 respondents cited the FDA regulations to be a major problem in the implementation process. 12 respondents were of the opinion that the transition period of the implementation would be a challenge in the process. Nine respondents feared stakeholders push back as a means of reducing the chances of implementing the technology. Table 9 and graph 9 illustrates the responses gathered on this question.



Graph 9

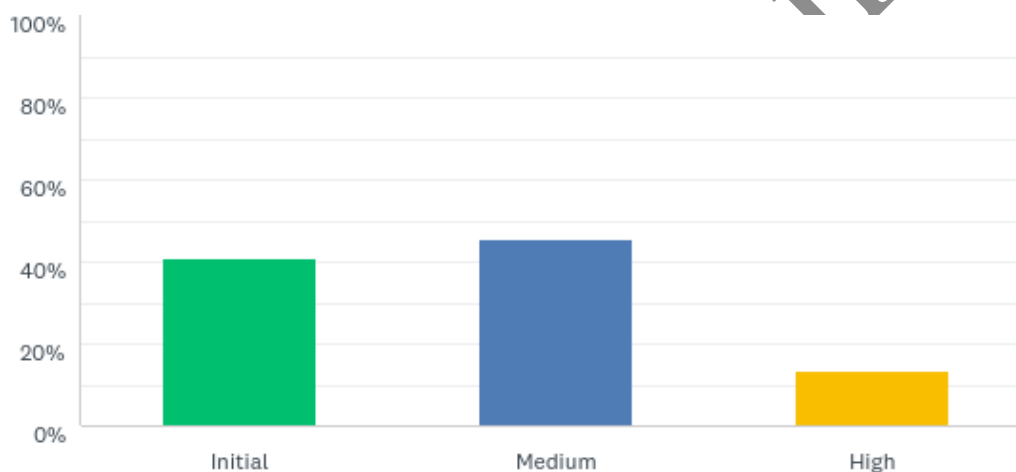
ANSWER CHOICES	RESPONSES
Historical trend in company	40.91% 9
FDA regulation for conducting the trial	72.73% 16
Transition period	54.55% 12
Stakeholder push back	40.91% 9
Total Respondents: 22	

Table 9

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Q10: What is the maturity level of agile implementation in clinical trial projects?

45.45% of the total respondents confirmed that agile methodology implementation process is on the medium level of implementation. 40.91% confirmed that the implementation phase of the agile methodology is still on the initial stages and 13.64% of the total respondents believed the implementation process of the methodology was at the highest stage. From the results, only three out of the 22 respondents confirmed that the implementation of the technology is on a high level. Table 10 and graph 20 illustrates responses received on this question.



Graph 10

ANSWER CHOICES	RESPONSES	
Initial	40.91%	9
Medium	45.45%	10
High	13.64%	3
Total Respondents: 22		

Table 10

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Summary of the findings

In summary, the research questions were specific to the use of the agile methodology in clinical trials and drug development. The research questions were systematic. The questions first intended to understand the nature of the respondents from the number of years that they have been working in the organizations. From the number of years, the research questions narrowed down to the number of years that the respondents had in experience with the application of the agile methodology. This understanding was salient in establishing a standard of research. The research questions then narrowed further to the application of the agile methodology in the specific organizations. The questions tested on the specific applications of the technology, the challenges facing its full implementation and the future of application in the development of clinical trials.

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Conclusion

Agile methodology is appropriate in the clinical trials domain. The clinical processes require consistency and good quality in the development. The tracking processes should support the desired quality of the end product. From the research, healthcare and pharmaceutical organizations have been constantly dependent on the traditional means of making the trials. The waterfall technology has been used directly and consistently in the process and through this understanding; it has been hard for the pharmaceutical organizations to keep track of the processes of the drug developments. The waterfall methodology is not very flexible. The methodology does not support a systematic review of the drug development processes. The mistakes that are made at one point must affect the entire process and since the correction mechanisms cannot be effectively established, the qualities of the trials are lowered.

The research established the salience of the clinical trials and the application of the agile methodology in the process. The advantages of the application of the agile methodology are more than those of the traditional systems. The time of operation, the cost of working on the clinical trials, the quality of the end products and the ease in making corrections when there is need prove the need of the agile methodology in the clinical trials. The research questions were specific in getting firsthand information from different professionals on the need for agile methodology in the clinical trials. Through the questions, the salience of the methodology was established and the gaps that currently exist in the clinical trials filled.

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Recommendations for future study

The research considered the need for agile methodology in clinical trials. The researcher focused on the advantages and the positive contributions of the methodology on clinical trials. The agile methodology has disadvantages or the limitations of its application. For future research study, the disadvantages that are aligned with the methodology should be included. The clinical trials need to be done in perfection and with the knowledge of the challenges; it would be easy for the processes to be improved and the qualities to be effectively established.

Secondly, from the research development, the application of agile methodology in clinical trials was the focus. The results of the interviews indicate that most of the companies dealing with the pharmaceutical developments apply both agile and waterfall methodologies. The effectiveness of the mixed methods should be compared with the application of the agile methodology for appropriate implementation. Future research should the indication of the organizational advantage when the only agile methodology is employed for the clinical trials in the pharmaceutical companies.

The research focused on establishing the advantages of applying the agile methodology in clinical trials. From the literature review and the results, several advantages were drawn. The research did not cover the reliability of the methodology. Future research should consider addressing the reliability of the agile methodology alongside the advantages. The application of the agile methodology is dependent on both the advantages and the reliability of the technology.

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