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Research Project Management on Clinical Trials-1

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ABSTRACT

The scenario of this project came from amalgamation of both good clinical practice (GCP) the project management for professional (PMP); since all research studies and clinical trials are considered as research project then we have to prepare and formulate a "Research Manager" for research projects with specific job description for what are the steps to follow to get a successful and completed clinical trials. In-fact, writing this book depends on two main references articles namely: "A guide to the project management body of knowledge: (PMBOK guide)" project management for professional and "Clinical Trials Requirement Guideline (version 1.3)", Drug sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia.

INTRODUCTION

Clinical researchers may be characterized with someone who has a clinical background and is able to apply his/her knowledge, skills, and technique to manage clinical research activities. They are individuals who can lead the research team to complete the process of a research project in the right direction. Compromising project management skills together with good clinical practice will meet stakeholder needs, wants and expectation. More importantly, they should possess the knowledge and skills to identify project management processes with information needed to initiate, plan, execute, monitor and control and close a single research project in a timely manner that will enhance the success over a wide range of research projects.

METHODS AND MATERIALS

Clinical research is systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the object of ascertaining their efficacy and safety. Projects may include industries, information technology, and businesses, such as product manufacture, transport and infrastructure, and building and construction. While research project for clinical studies involved human subject to discover or verify the pharmacodynamics and pharmacokinetic of a pharmaceutical product or the effect of a medical device. Subjects involved in clinical trials may be patients or healthy people, or both.

Project management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements. The primary challenge of project management is to achieve all specific goals and objectives and meet specific success criteria; while the primary constraints are **scope,** time, quality and **budget.** Project management is accomplished through the appropriate application includes a number of elements, which are categorized into five process groups.

These five Process Groups

There are several types of research management (RM) structures in organizations, each varying in the degree of control and influence they have on projects within the organization, such as:

Supportive RM provide a consultative role to projects by supplying templates, best practices, training, access to supportive information and lessons learned from other projects. This type of RM serves as a project repository. The degree of control provided by the RM is low.

Controlling RM provides support and requires compliance through various means. Compliance may involve adopting project

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Controlling management frameworks or methodologies, using specific templates, forms and tools, or conformance to governance. The degree of control provided by the RM is moderate.

Directive directive take control of the projects by directly managing the projects. The degree of control provided by the RM is high.

Project management is aimed at producing an end-product that will effect some change for the benefit of the organization that instigated the project. It is the initiation, planning and control of a range of tasks required to deliver this end product, which could be a physical product, it could be new software or something less tangible like a new way of working. The control imposed by a formal approach is essential when there are complexities such as new technology, inter-dependent tasks, teams spread across several departments or companies, or where teams are located in different parts of the world; all common occurrences in many business projects.

A key factor that distinguishes project management from just management is that it has this final deliverable and a finite timespan, unlike management which is an ongoing process. Because of this, a project manager needs a wide range of skills; often technical skills, certainly people management skills and good business awarenes

Typical components of project management

Identifying requirements.

Defining the reason why a project is necessary.

Addressing the various needs, concerns, and expectations of the stakeholders in planning and executing the project.

Capturing project requirements, specifying quality of the deliverables, estimating resources and timescales.

Preparing a business case to justify the investment.

Securing corporate agreement and funding.

Developing and implementing a management plan for the project.

Leading and motivating the project delivery team.

Managing the risks, issues and changes on the project.

Monitoring progress against plan.

Managing the project budget.

Setting up, and carrying out communications among stakeholders that are active, effective, and collaborative in nature.

Maintaining communications with stakeholders and the project organization.

Managing stakeholders towards meeting project requirements and creating project deliverables;

Balancing the competing project constraints.

Closing the project in a controlled fashion when appropriate.

There are standard project management processes used to plan and control tasks, budgets and schedules, to communicate between the different people involved and deal with risks. These processes are usually ongoing throughout the project. Also, there are various phases of a project that will have a defined start and end within the overall project lifespan. For instance, the requirements gathering phase often occurs in the early part of the project. So a project has a range of processes that occur throughout it life (monitoring, controlling, communicating etc.) and a range of phases (initiation, requirements, planning etc.) that occur roughly chronologically.

Research manager should know the strategies to manage research project and how to facilitate relationships between the research team and others in all phases of the research projects from writing proposal to publication. Also to know and describe every step in the project life cycle in depth, so the research project manager will know exactly which tasks to complete, when and how. Whether they are experts or novices, it helps to complete tasks faster than before.

Research Project Managers should have overall understanding of all aspects of clinical research and how is the research team familiar to their jobs. This understanding helps sponsors and funding agencies to communicate seamlessly with the clinical researchers and project team members to ensure that project objectives, work plans, and priorities are met.

Effective project managers require a balance of ethical, interpersonal, and conceptual skills that help them analyze situations and interact appropriately.

The ability of a Clinical Research Project Manager (CRM) to manage all aspects of a clinical trial significantly impacts the time and cost taken to develop a drug or medical device. It is important that a Research Project Manager is a well-rounded individual. These CRMs will be required to have a high set of skills, tools and knowledge that is proficient in clinical research. This allows research project management to efficiently lead the trial outcome from the start of the project. A Project Manager must also have the ability to appropriately act, respond and adapt to developing situations during a clinical trial. The project manager is the person assigned by the performing organization to lead the team that is responsible for achieving the project objectives.

Feasibility assessments for a research study is likely to be with potential benefit. That is if the investigator achieve the goals of the clinical study represent a common sense that will be converted in sharing the development and innovation. The second choice that if the investigator identify possible problems in the worst case scenarios that will be another achievement to keep away from this treatment. The feasibility assessment focuses on the degree significant of the clinical research technically, within the budget, and on the planned time frame.

RESEARCH LIFE CYCLE

Some combination materials of good clinical practice or clinical research requirement and project management for professional.

Most of the universities and research institutions have similar approach (more or less) for the steps of life cycle such as:

Write a research proposal (initial concept)

Brainstorming to formulate a research question.

Literature review.

Start to write a research protocol.

Write a research methodology

Identify the research team

Identify research location(s)

Identify the research support team

Get consultation(s)

Distribute the work load

Plan on how startup, using work breakdown structure and Ghant chart.

Project Start Up

Create a data management plan or a case report form (CRF)

Make plan on how to document

Conduct a feasibility study to assess the methodology

Data Collection, analysis and sharing

Organize files, backups & storage, QA for data collection

Document analysis and file manipulations

Manage file versions

Determine file formats

Contact Archive for advice

Further document and clean data

End of Clinical Research Project

Close all financial issues

Write manuscript(s)

Final Remarks

Deposit data in data archive (repository)

In this study, Research life cycle has similar concept with more orientation to project management for professional. Research life cycle is clinical project management and how to achieve all of the project aims and objectives and to find alternative plan for constrains and obstacles. The objective is similar to research project manager where the research life cycle is an overall meaning for the preparing the initial concepts, planning, research methodologies and analysis until closing. The appropriate application and integration of a research project management processes are categorized into five Process Groups.

These five Process Groups have called steps of research cycle identified as

Initiation:Those processes performed to define a new research project or a new phase of an existing clinical trial or project by obtaining authorization to start the project or phase.

Define as writing a research proposal for a new idea provides a detailed description to meet the standards.

Ensure the commitment of the sponsor, IRB concerns, and/or Good Clinical Practice standards.

Ensure the submission of all essential documents for the conduct of a clinical trial.

Identify research team.

Define and provide details on a scientific research methodology and deals specifically with the manner in which data is collected, analyzed and interpreted.

Ensure all equipment and supplies availability.

Ensure that the site of conducting the clinical research is appropriate.

Create work break down structure.

Assign duties for the research team.

Perform the research methodology as plan to produce results according to the GCP and international standards.

This phase is to ensure that the research methodology is executed according to the plan. Executing phase involves proper co-ordination and management of human resources, equipment, supplies and any other resources such as material and budgets. Moreover, this phase will include data collection, organize files, backups & storage, data analysis and file manipulations. It is consider the longest phase and the most productive phase.

Identify variance to the planned methodology.

Identify changes (if any).

Identify the corrective or preventive actions.

Initiate the corresponding changes.

Conclude all results in a discussion format.

Complete the project as a conclusion.

Complete the final touches of the budget processing and close it.

Submit for publication.

PROJECT and OPERATION

Project

Project is a temporary endeavor design undertaken to create a unique product, service or result. Temporary means having a definite beginning and end (usually time-constrained, and often constrained by funding or **deliverables)** undertaken to meet unique goals and objectives. The end is reached when the

project's objectives have been achieved, or if the project is terminated for any reason.

Operation

An ongoing work effort is generally a repetitive process because it follows an organization's existing procedures. The ongoing execution of activities that produce the same result or product repetitively is what operations is all about.

Table 1: Table showing the difference between project management and operational management.

Project Manager	Operational Manager
Role ends with project	Routine
Temporary team	Stable organization
Many different skills	Specialist skills
Work not done before	Work repeatable
Time, cost and scope constraints	Annual planning cycle
Unique goals and objectives	Multiple purposes
Difficult to estimate time and budget	Budgets set and fixed events
Protects the deliverables (time, cost, Quality)	Protects the Service (capacity, budget, availability
Tasks are specific for that for that project and have never been done before	Tasks are repetitive, routine and cyclical
Implement revolutionary change	Implement evolutionary change
Teams are formed to implement projects and then disbanded once the project is completed	Teams are consistent
Teams consist of team members from different departments , different skill sets	Teams frequently consist of team members with similar technical skill sets
Examples:	Example:
A university hospital designs and constructs a new clinic (s).	Caring for patients at the bedside in a hospital or prolongation of hospital stay.
A diabetic structured selfmanagement program using monitoring devices that electronically send blood sugar level and blood pressure directly to physician. In the beginning it is a project after implementing the program it will be an operation because it will be a routine activity.	Day to day follow-up activities that a physician and his/her patients engage in on a daily basis for the purposes of providing a good care.
Clinical Trials	Ongoing research

CASE REPORT FORM (CRF)

A printed, optical, or electronic document designed to record all of the protocol required information specifically used in clinical research to be reported to the sponsor on each trial subject. The sponsor is responsible for designing a CRF that accurately represents the protocol of the clinical trial, as well as managing its production, monitoring the data collection and auditing the content of the filled-in CRFs. There is no specific size for a CRF so that it can range from a handwritten one-time 'snapshot' for one participant in the clinical trial to hundreds of pages. CRFs can be electronically captured data obtained over a period of weeks or months. It can also include required check-up visits months after the patient's treatment has stopped.

WORK BREAKDOWN STRUCTURE (WBS)

It is a tree structural view that shows a subdivision or breaking elements to a deliverable-oriented decomposition of a project into smaller components. It is an essential tool for planning and executing the project. A work breakdown structure is a key project deliverable that organizes the team's work into manageable sections. The work breakdown structure can be displayed in two forms one in form of a table with subdivision of tasks two in form of an organizational chart.

GHANT CHART

It is a diagram to illustrate the start and finish dates of the terminal elements. This diagram shows the process of analyzing research activity sequences, durations, and resource requirements. It summarizes the relationship of planning and work breakdown structure (duration and responsibilities) of the research project.

DISCUSSIONS

INITIATION

The process being formally accepting to perform a new research project by obtaining authorization to start the research study. It is sort of commitment to conduct a clinical research study with the following steps for initiation process:

Define and writing a research proposal for a worthwhile idea provides a detailed description to meet the standards.

Ensure the commitment of the sponsor regarding financial aspects such as:

How to provide budget cost.

The way of payment to the research team, research support team and others.

The way of payment for training and other commitments from the sponsor.

Ensure the commitment of the sponsor and/or IRB concerns to perform the research with Good Clinical Practice standards.

Ensure the submission of all essential documents for the conduct of a clinical trial.

Ensure communication with other sections regarding research support team.

Identify research team.

Select the project manager if not already assigned.

Select the site area to conduct the clinical trial.

WRITE A RESEARCH PROPOSAL

Clinical researchers must undertake sufficient detail for an assessment of the followings:

The feasibility the research study and its applicability.

Description for the benefits and limitations of the proposed setting for the study.

The team of investigators incorporate the range of disciplines and experience needed to carry out the study.

The proposed recruitment rate realistic.

BRAINSTORMING

Brainstorming is a well-known tools of creative thoughts that involves ideas to get a conventional approach. In clinical research, group or interactive brainstorming, group ideation is involving where it requires a facilitator. The facilitator's responsibilities include guiding the session, encouraging participation and writing ideas down.

Clinical research started with a formation of research question with as aim and objective; this research question developed to have more than aim and so many objectives to achieve these aims to end up with a proper research methodology.

PROJECT SUMMARY

Like the abstract of a research paper, the project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

GENERAL INFORMATION

Protocol title, protocol identifying number (if any), and date.

Name and address of the sponsor/funder.

Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.

Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research

RATIONALE and BACKGROUND INFORMATION

References (of literature cited in preceding sections)

Study Design

Methodology

Safety Considerations

Follow-Up

Data Management and Statistical Analysis

Quality Assurance

Expected Outcomes of the Study

Dissemination of Results and Publication Policy

Duration of the Project

Problems Anticipated

Project Management

Ethics

Informed Consent Forms

Budget

Other support for the Project

RESEARCH PROJECT MANAGER

A research project manager must be appointed to sort out and management of the following responsibilities:

Responsibility for clinical research project manager (CRM) with PI and Research team

Review protocol(s) for investigational drug trials (could be a new medical device or new procedure), as required.

Liaise with principal investigators and/or research team to distribute responsibilities.

Define the scope of work, then create work breakdown structure (WBS).

Determine sequence of activities.

Estimate activity duration.

Draw a work plan.

Define how to monitor the quality of the output and closing remark.

Responsibility for clinical research project manager with regard finance processes

Draft a budget for the clinical trial includes the following aspects: Honorarium for PI, co-PI, sub-investigators, as a research team.

Compensation for the research technologists, phlebotomists, nurses, pharmacists, data collection, secretaries and other research support team. iii. Compensation for consultant, biostatistician and other consulting team.

Equipment such as "instrument", "machine", "device," or "apparatus" to aid in the **diagnosis,** monitoring or treatment of **medical conditions.**

Supplies (if it is not provided by the sponsor).

Others (specific)

Miscellaneous (nonspecific)

Determine sheet for income and expenditure (a financial report)

Responsibilities for clinical research project manager with other sections/ department to assign members for research supporting team (Pharmacy, Laboratory, other sections such as radiology, Information technology, Administration etc..).

Pharmacy

Liaise with principal investigators and/or research team to establish pharmacy's role, and to implement dispensing, and compounding procedures (if any).

Although it is the responsibility of the PI for investigational drug availability, storage and accountability at the trial site, yet the CRM should share this responsibility.

Together with the PI, they should be ensure that the code is disclosed only in accordance with the protocol (in case of blind randomized trials).

Communicate with, and trains staff from pharmacy anticipated to

participate in any aspect of the clinical investigational drug trial.

Maintain a pharmacy binder which contains a study summary, protocol, dispensing procedures, completed samples of required paperwork, dispensing checklist, fee schedule, and any other relevant materials for each investigational trial.

Maintains responsibility for the management of the inventory for clinical investigational drug trials; orders, replaces and returns study materials, as required.

Laboratory

Establish the role of the laboratory in the study.

Responsibility regarding blood withdrawn (phlebotomist)

Conducting biochemical tests

Ensure privacy of results.

Other section such as radiology, information technology, administration etc..

Arrange subject's appointments

Retrieve and collect data for analysis

Other support concerning research process.

Describe communication regarding IRB required documents

Check all documents before the clinical phase of the trial commences (listed in Clinical Trials Requirements Guidelines (GCP)).

The essential documents are:

Signed protocol and amendments, if any.

Informed consent form (Including all applicable translations).

Sample of case report form (CRF).

Investigator's brochure to document that relevant and current scientific information about the investigational product has been provided to the investigator.

Financial aspects of the trial to document the financial agreement between the investigator/institution and the sponsor for the trial.

Curriculum vitas and/or other relevant document evidencing qualifications of investigator(s) and sub investigators to document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects.

Communicates any concerns regarding ethical issues or deviation from established policies and procedures to the Ethics Committee or IRB

Before recruiting any patient for the clinical trial, PI and CRM should have written and dated approval from the IRB for the trial protocol, written informed consent form, inclusion and exclusion criteria, subject recruiting procedure, and any written information to be provided to subjects.

During the trial, the PI and CRM should provide to the IRB/IEC all documents subject to review.

The PI and CRM should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies). The PI and CRM and the sponsor should sign the protocol, or an alternative contract, to confirm agreement.

The PI and CRM should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/ favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

The PI and CRM should document and explain any deviation from the approved protocol.

The PI and CRM may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favorable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

i. to the IRB/IEC for review and approval/favorable opinion, ii. to the sponsor for agreement and, if required, iii. to the regulatory authority(ies).

Initiate a review checklist for all responsibilities of the project manager

Clinical research contracts concern to provide public assurance with the rights, safety and well-being of trial subjects protection. It also concerns about the financial aspects, therefore, it must be in writing to be legally binding and enforceable by law. Unification of clinical research contracts will simplify and accelerate the processing of the initiation of a research to be conducted.

There are several types of research contract (often referred to as agreements) associated with research. They vary according to the funder and the nature of the research.

Confidentiality Non-Disclosure Agreement (CDA or NDA)

This type of agreement could be initiated by sponsor or a contract research organization where all the investigational drugs and pharmaceutical products are under investigation. It could be also initiated from the PI, if the research study initiated from the PI. This agreement to be signed and considered as the first step ever in the clinical research.

Research Service Agreements

The purpose of a research service contract will:

Define scope of work to be conducted

Define the associated budget/ payment terms.

Define the contribution of each part from technical, commercial and economical.

Set out the right of the results, who will own it, the right to use the results and the right of publications.

Set out agreed liability and indemnities.

Clinical Trial Agreement

This is the master agreement in any clinical research institution, it is an agreement governing the terms and obligations of all parties in conducting a clinical trial. It must be fully recognized from all parties involved in the research and should be fully executed accordingly. Each pharmaceutical company or a CRO have their own unified agreement with very minor changes. This type of agreement would be managing the relationship of sponsor, principle investigator and the research institution. This agreement could be involved in multicenter clinical research studies or in a center performing clinical research study.

Duties of Site and Investigator

Table 2: The Duties are mentioned in the table.

Inspections	Financial Disclosure	Sub-investigators and Other Personnel
Compliance Adverse Events		Debarment and Disqualifications
Enrollment Study Initiation		Protocol Violations/Deviations
Test Article Study Documents		Genetic Data & Specimens
Facilities Conduct of Study		Electronic Data and Signatures
IRB Informed Consent		Communication of Results to Subjects
CRF Conflict of Interest		Return of Study Materials

The principle investigator should be capable to fulfill a list of the following duties:

Compensation

Confidential Information

Protected Health Information and Use of Data

Intellectual Property

Data Publication and Copyrighting

Subject Injury

Indemnification

Insurance and Liability

Effective Date, Term & Termination

Notice

General

References

Table 3: Nurse, technician or interviewer is not limited for one person, the PI could meet contracts with unlimited number of research support team within the same budget.

RESEARCH FUND APPLICATION	
Principal Investigator: __Xxx Yyy Zzz	Protocol Number: __Res Prot. No. 2___
Duration: __Two (2) Years (24 months)	Expected Starting Date: ____1/1/2020
Sample Size: __200 Patients (4 visits)___	Expected Completion Date: _31/12/2022_

Budget Category	First Year		Second Year		Total	Remarks
	Quantity	Unit Cost	Quantity	Unit Cost		
Principal Investigator	1	20,000	1	20,000	40,000	
Sub-Investigator(s)	4	50,000	4	50,000	100,000	
Scientific Consultant	1	25,000			25,000	
Biostatistician	1	15,000			15,000	
Research Nurse	200x2	50	200x2	50	40,000	No limit*
Technician	200x1	50	200x1	50	20,000	No limit*
Interviewer	200x12	10	200x12	10	48,000	No limit*
Continuous Glucomonitor	20	10,000			200,000	
Laptops	4	5,000			10,000	
Glucometers	200	free				Donation
Strips	200x12	50	200x12	50	240,000	
Travelling					30,000	
Accommodation					20,000	
Advertisement					10,000	
Publication cost					10,000	
					50,000	
			GRAND TOTAL		858,000	

Table 4: CHECKLIST FOR CRM RESPONSIBILITIES

Yes	No	Na	Checklist	Comments
1.Responsibility for CRM with PI and Research team				
			Review protocol(s) for investigational drug trials, as required	
			Liaise with PI and/or research team to distribute responsibilities.	
			Define the scope of work, then create work breakdown structure.	
			Determine sequence of activities.	
			Estimate activity duration.	
			Draw a work plan.	
			Define how to monitor the quality of	

	the output and closing remark.
2. Responsibility for clinical research project manager with regard finance processes	
	Draft a budget for the clinical trial
	Honorarium for PI, co-PI, sub-investigators, and research team
	Compensation for research support team
	Compensation for research consulting team
	Equipment (if it is not provided by the sponsor).
	Supplies (if it is not provided by the sponsor).
	Others (specific)
	Miscellaneous (nonspecific)
	Determine sheet for income and expenditure
3. Responsibility for clinical research project manager with Other sections	
	Liaise with PI and/or research team to establish pharmacy's role, and to implement dispensing, and compounding procedures (if any).
	Share the PI the responsibilities for investigational drug availability.
	Together with the PI, ensure that the code is broken only in accordance with the protocol and GCP standards.
	Communicate with, and trains staff from pharmacy staff.
	Maintain a pharmacy binder contains the protocol and fee schedule.
	Maintains responsibility for the management of the inventory.
	Arrange with phlebotomist to withdraw blood (if any)
	Conduct chemical reagent control tests
	Arrange for subject's appointment and visits
	Other communication
4.Describe communication regarding IRB required documents	
	Signed protocol and amendments, if any.
	Informed consent form
	Sample of case report form (CRF)
	Investigator's brochure
	Financial aspects of the trial with the sponsor for the trial
	CV of PI and research team.

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