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Research Article

Research Project Management on Clinical Trials-2

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ABSTRACT

INVESTIGATOR shall perform each Project in accordance with the terms and conditions of this Agreement.

The financial support given by SPONSOR to the INVESTIGATOR pursuant to this Agreement shall not be exclusive.

INSTITUTION shall assume the legal responsibility attached to the SPONSOR capacity as it results in particular from Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001, and from national laws and regulations, with respect to patients and the Saudi Arabia health authority (SFDA) for trials carried out by INVESTIGATOR.

The Investigator's work is essential to the Study to be performed under this Agreement. INSTITUTION shall notify SPONSOR of any proposed change of the Investigator. If Investigator decides to leave Institution, SPONSOR may either consent to the designation of a new Investigator, or arrange for the transfer of the Study to Investigator's new institution. Other investigators may not be substituted nor can substantial changes in the level of effort be made without the prior written approval of SPONSOR.

INSTITUTION and the INVESTIGATOR agree to grant SPONSOR certain rights to the data (or samples) and the results generated under the Study as provided for herein.

INTRODUCTION

INVESTIGATOR

set-up and maintain a Trial Master File (TMF) containing documents and written communications essential to the management of the study. All documents to be filed in the TMF according to ICH GCP requirements must be clearly identifiable. The TMF must be kept in a secure location for the duration of the study and archived after completion or premature termination of the study in a secure fire-proof facility for a minimum of 15 years.

be responsible for the data management of the Study, including collection and analysis of the Study Data, its inclusion in the INVESTIGATOR's database and its retention as required by ICH-GCP, in accordance with the Declaration of Helsinki and with the principles of good clinical practice as laid down by the ICH topic E6: 'Good Clinical Practice: Consolidated Guideline', and all applicable local regulations.

Obtain all required preliminary legal authorizations from the local health authority, including required approval of any competent ethics committee or similar administrative body and conduct the Study strictly in accordance with the terms of any such approval.

Be responsible for and comply with safety reporting obligations and their related activities as required and in accordance with the Protocol and any amendments to the Protocol as approved by all Parties.

Provide SPONSOR with information on the progress of the Study, quarterly.

Provide SPONSOR with a copy of the final Clinical Study Report within an estimated period of 6 months] after the final data lock of the Study.

Provide SPONSOR with a copy of the Health Authorities and Ethics Committee authorizations.

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Treat any information provided by SPONSOR according to the confidentiality provisions within this Agreement.

With patients selected in accordance with, and who meet, the criteria specified in the Protocol.

Only after all necessary legal, regulatory or other approvals have been granted including, without limitation, those of any Institutional Review Board/Independent Ethics Committees at the Institution and strictly in accordance with the terms of any such approval.

INVESTIGATOR shall be entitled to make changes to the Protocol and shall notify SPONSOR in writing of any such change immediately after having made such change.

INVESTIGATOR will ensure that sub investigators and personnel who participate in the conduct of the Study are informed of and abide by all applicable terms of this Agreement.

INSTITUTION

INSTITUTION agrees to perform the above titled Study in accordance with the Protocol. INSTITUTION shall

Ensure that such study is performed in compliance with all applicable federal, state, and local laws and most importantly according to the GCP standards and regulations and with all protocol requirements, including those relating to documentation and submission of reports to SPONSOR.

The Protocol is considered as a final copy after it is signed by the SPONSOR and the Investigator and approved by Institution's Institutional Review Board (the "IRB"). Thereafter, the Protocol may be amended only by written agreement between INSTITUTION and SPONSOR, and, if required, any such amendments must be approved by the IRB and SFDA.

SPONSOR and INSTITUTION agree to abide by the terms of, and fulfill their respective obligations under, any final informed consent form covering the Study (including any modification thereto) that is approved by both SPONSOR and Institution's IRB.

INSTITUTION shall submit written reports to SPONSOR according to the schedule mutually agreed upon between INSTITUTION and SPONSOR.

INSTITUTION and SPONSOR shall agree on a form of informed consent to be used in the conduct of the Study.

The expected number of patients per institution will be up to 50. Further adjustments in the number of patients may be made upon ability to enroll patients in a timely manner.

INSTITUTION agrees that SPONSOR will have access to any source documents from which case report forms have been generated.

If the INSTITUTION is conducting a blinded trial it agrees to maintain the blinding of the subject. Investigator understands that the randomization codes will be released upon the completion of the Study and finalization of the database by SPONSOR. For multi-center studies, data from all centers are required before the Study is completed. Should a medical emergency occur requiring Investigator to break the code for a specific patient, Investigator agrees to notify SPONSOR immediately.

INSTITUTION agrees that no subject in the Study may participate concurrently in any ancillary study (other than those set forth in the Protocol, if any) without the prior written approval of SPONSOR. If a subject participates in such ancillary study pursuant to this section, Investigator agrees that all such ancillary studies will be conducted in accordance with all federal and state laws, rule and regulation, including without limitation IRB approval and informed consent.

INSTITUTION shall allow (Name of the Company), the SPONSOR, to visit the facility where the Study is performed during regular business hours to assure of the quality standards used.

INSTITUTION shall be responsible for the management and payment of all those who participated in this project including the research team and research support team.

It is the responsibility of the INSTITUTION to ensure that all work performed by the research team is done in compliance with this Agreement.

TERM AND TERMINATION

This Agreement shall become effective on the date of the last signature of this agreement and expires (one (3) year). Thereafter, the term of this Agreement shall automatically renew for successive one year periods unless either party provides prior written notice to the other party of its desire not to renew the term hereof, which notice must be given at least 60 days prior to the then current term of this Agreement.

In the event that either party commits any breach of or default in any of the terms or conditions of this Agreement, and fails to remedy such default or breach within thirty (30) days after receipt of written notice thereof from the other party, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party. Such termination shall be effective as of the date of the receipt of such notice.

This Agreement shall remain in effect until all work under this Agreement has been completed, unless it is terminated earlier in accordance with the terms of this agreement, therefore, No termination of this Agreement, however effectuated, shall release the parties from their rights and obligations accrued prior to the effective date of termination.

Upon termination of this Agreement or any Project, other than for breach of the terms hereof, SPONSOR shall reimburse INVESTIGATOR for any amounts SPONSOR is otherwise obligated to provide INVESTIGATOR under the terms hereof, for work on each terminated Project performed by INVESTIGATOR up to the effective date of termination and for non-cancellable pre-paid expenses reasonably incurred by INVESTIGATOR in anticipation of its work on each Project.

GOVERNING LAW

This Agreement shall be construed, and legal relations between the parties hereto shall be determined, in accordance with the laws of (specify). Both parties agree that any disputes in connection with this Agreement that cannot be resolved by mutual agreement.

Quality Assurance

INSTITUTION warrants that an internal research quality assurance through which the INVESTIGATOR will have the assurance that the work is performed in compliance with ICH topic E6: 'Good Clinical Practice: Consolidated Guideline', and all applicable laws, rules, regulations. The INVESTIGATOR's quality assurance group will perform periodic audits to ensure the adequacy of INVESTIGATOR ' s performance and implement quality control procedures. Relevant reports detailing the results of audits may be inspected by SPONSOR.

INVESTIGATOR is responsible for ensuring direct access to all trial related sites, source data/ documents, and reports for the purpose of monitoring and auditing and inspection by domestic and foreign regulatory authorities. INSTITUTION retains the sole responsibility as legal SPONSOR and has such oversight for trial conduct, regulations, patient privacy and source data access. Source data verification can be granted to monitors and auditors of INVESTIGATOR, to Ethics Committees and to Regulators. Access to original patients' charts and dossiers cannot be granted to SPONSOR unless appropriate approvals according to national applicable laws and Ethics committees have been obtained. In case of a retro-acquisition of the Clinical Trial Database, the necessary steps will be undertaken to allow audit of site files and source data within the applicable laws and regulations. Should any local and/or national government authority conduct, or give notice of intent to conduct, an inspection or take any other regulatory action with respect to the Study, the INVESTIGATOR shall promptly give SPONSOR notice thereof, supply all information pertinent thereto and SPONSOR shall have the right, but not the obligation, to be present at any such inspection or regulatory action.

PLANNING

Planning is the process on how to achieve a goal. It is the basic management function to formulate within the available resources. Planning for conducting a clinical research study could be concluded within the following steps:

Identify the aims and objective of a clinical research study.

State the methodology within the available resources.

Create a vision or work plan to solve the research question.

Implement, direct and monitor the research process.

The main objectives of a research project plan is to define the needs and **scope** of the research study. Guidelines for specifying needs include the following rules:

State in simple words the requirements explicitly of your research subjects

Assume any variation for these requirement.

Recognize that there will be changes to your research project and the scope of the work will not go on precisely as anticipated.

Be transparent as possible, include pictures, graphs, physical models and other nonverbal exhibits in the formulation of requirements.

Establish a system carefully to monitor any variables made to requirements.

Educate project staff and customers to the problems of specifying requirements.

In order to make a plane for a classic research project, a similar stages for a research protocol project should put in one frame with the following steps:

Define a frame as the scope of the research.

Identify a research problem.

Refine and define aims and objectives.

Design a research tools

Identify how to process the research methodology.

Work Breakdown Structure (WBS):

Reporting Systems

Reporting systems for a research project could be referred to those data gathering efforts which get information on clinical trials. Reporting systems should constitute procedure for gaining reliable and valid information about what is happening in each segment of the research.

(CRF) consist of:

Section 1: Cover page and instructions

Section 2: Screening (Screening No. can be added to the header in this section if required instead of Subject No.)

Section 3: Post randomisation/enrolment visits

Section 4: Adverse events and concomitant medication(s)

Section 5: PI sign off

Reports and communication is also a main task for the CRM, reporting in clinical trial such as

The investigator should submit written summaries of the trial's status to the institution, IRB, regulatory authorities annually, or more frequently, if requested by the IRB.

The investigator should promptly provide written reports to the sponsor, the IRB and, where required by the regulatory requirements, the institution

On any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects.

All serious adverse events (SAEs) should be reported immediately. The immediate and follow-up reports should be with more detail. The investigator should also comply with the applicable regulatory requirement(s) related to the reporting of

unexpected serious adverse drug reactions to the regulatory authority and the IRB.

Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to the sponsor according to the reporting requirements and within the time periods specified by the sponsor in the protocol.

For reported deaths, the investigator should supply the sponsor and the IRB with any additional requested information (e.g., autopsy reports and terminal medical reports).

If the trial is terminated prematurely or suspended for any reason, the investigational institution should: o Promptly inform the trial subjects,

o Assure appropriate therapy and follow-up for the subjects, and, o Where required by the applicable regulatory requirement(s),

Upon completion of the trial, the investigator should, where required by the applicable regulatory requirements, inform the institution, and the IRB with a summary of the trial's.

METHODOLOGY/ EXECUTION

The Project methodology or project execution phase is the third phase in clinical research project management and it is the longest phase in the research life cycle. During this phase, the principle investigator together with clinical research manager will execute the tasks described in the plans, processes, and implement procedures. Both PI and CRM will oversee and manage the research resources as the detailed in the research protocol including all tasks deliverables which was decomposed by WBS.

General consideration in methodology and execution

Select site area for patient recruitment.

Performs education responsibilities.

Provides accurate and efficient dispensing of medication.

Performs administrative responsibilities.

Provides direct and/or functional supervision; maintains overall responsibility for other section(s) operations such as pharmacy, laboratory etc. in assigned area.

Performs communication responsibilities.

Performs cross-functional duties including Intra-venous admixture pharmacist, staff pharmacist, patient care, as assigned.

Arrange for scientific gathering for the whole research team.

Distribute responsibilities among research team.

Three elements in the concept "professional responsibility", these are:

The effective use of knowledge, experience and technology of the researcher,

The suitability of the professional's attitudes and actions, and

The propriety of the professional's conduct in view of the profession's selfimage and defined interests.

Level				
1	Introdcution			
1.1		Project Summary		
1.2		Background information		
1.2.1			Reason for conducting Research	
1.2.2			Current Situation	
1.2.3			Definition of Key Concept	
1.3		Litrature Review		
1.3.1			Problem that basis of the Project	
1.3.2			Cause of the problem	
1.3.3			Possible Solution	
1.4		Study Goals		
1.4.1			Aims	
1.4.2			Objective	
1.4.3			Purpose	
1.5		List of References		
2	Methodology			
2.1		Method (procedure)		
2.1.1			Information on the intervention	
2.1.2			State hypothesis or theory	
2.1.3			Procedure measurement	
2.1.4			Observations	
2.1.5			Instrument to collect information	
2.1.6			Laboratory Investigation	
2.1.7			Equipment needed	
2.2		Work plan		
2.3		Study Design		
2.3.1			Type of the Study	
2.3.2			Population	
2.3.2.1				Participant Recruitment process
2.3.2.2				Safety consideration (Ensure reporting ADR)
2.3.2.3				Incusion Criteria
2.3.2.4				Exclusion Criteria
2.3.3			Sampling frame	
2.3.4			Expected Duration	

Figure 1: Work Breakdown Structure for writing a Research Protocol ½.

2.4		Select Site area		
2.5		Follow-up (provide indicator)		
3	Data Management			
3.1		Data Collection		
3.2		Data Handling and Coding		
3.3		Statistical Analysis and Statistical Method		
3.4		Monitoring		
3.5		Verification		
4	Finance and Insurance			
4.1		Budget Details with Justification		
4.2		Insurance Coverage for Participants		
4.3		Procurement		
4.4		Human Resources		
5	Other			
5.1		Quality Assurance		
5.2		Expected Outcomes of the study		
5.3		Duration of the project in each phase		
5.4		Problem anticipated		
5.5		Ethics Consideration		
5.6		Informed Consent		
5.7		Link with other Projects (if any)		
5.8		Curriculum Vitae for investigators		
5.9		Editing		
5.9.1			Maintain clear structure proposal	
5.9.2			Gramtic Mistake	

Figure 2: Work Breakdown Structure for writing a Research Protocol 2/2.

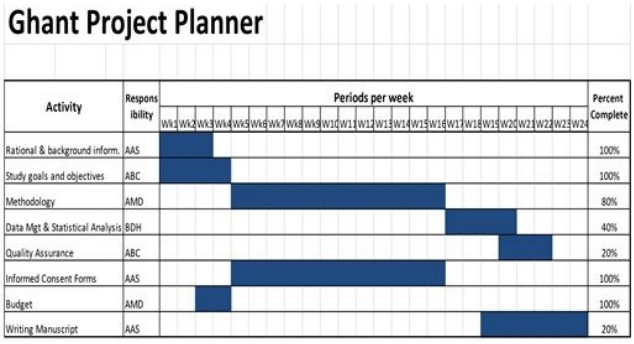


Figure 3: Ghant Project Planner.

Research Integration Management

Research project integration management processes are as follow:

Collect all essential documents: Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements. All of the documents addressed in the clinical trials are subjected for inspection by the SFDA or any regulatory authority.

Develop project management plan: The process of defining, preparing, and coordinating all subsidiary plans and integrating them into a comprehensive research project management plan. The project's integrated baselines and subsidiary plans may be included within the project management plan. The research plan may be presented in a Gantt chart to illustrate professional research project plan.

Research scope management

Project Scope Management includes the processes required to ensure that all the work required to be accomplished successfully in terms of clinical and/or technical services, products and results. "Scope" may refer to:

Product scope—the features and functions that are to be included in a product or service.

Project scope—the work that must be done in order to deliver a product with the specified features and functions

Research quality management

Research Quality Management include the following processes:

Research Plan Quality Management: The process of define the scope of quality requirements for a research project and its deliverables and documenting how the project will demonstrate compliance with quality requirements and/or standards.

Research Communications Management include the following processes:

Plan Communications Management: The process to find how and when the research team receive information, and communicate with each other based on research team needs and requirements. Plan Communications process involves determining what kind of information should be shared with or between the whole research team. The standard methods of communication that are widely used across the world are either written or oral methods.

The communication activities involved in these processes may often have many potential dimensions that need to be considered, including, but not limited to:

Internal (within the research team) and external (customer, vendors, other research org);

Formal (reports, minutes, emails, memos) and informal (briefings, ad-hoc discussions);

Vertical (up and down the organization) and horizontal (with peers);

Official (newsletters, annual report) and unofficial (off the record communications); and

Written and oral, and verbal (voice inflections) and nonverbal (body language).

Manage Communications: The process of creating, collecting, distributing, storing, retrieving and the ultimate disposition of research information. Communication between research team should be continuous, particularly during periods of change in the research process or adverse drug reaction.

Control Communications: The process of monitoring and controlling communications throughout the entire research life cycle to ensure the exchanged information of the research team are met. Effective management is to document the issues and monitor its resolutions

Research team management

Research Team Management includes the processes required to be able to administer and organize the whole research team. CRM should have the impact to analyze research team expectations and their impact on the research project, and to how develop appropriate management strategies for effectively engaging research teams in research project decisions and execution.

Identify Research teams: The process of identifying the people, groups, or organizations that could impact or be impacted by a decision, activity, or outcome of the research project; and analyzing and documenting relevant information regarding their interests, involvement, interdependencies, influence, and potential impact on research success.

Plan Research team Management: The process of developing appropriate management strategies to effectively engage research teams throughout the research life cycle, based on the analysis of their needs, interests, and potential impact on research success.

Manage Research team Engagement: The process of communicating and working with research teams to meet their needs/expectations, address issues as they occur, and foster

appropriate research team engagement in research activities throughout the research life cycle.

Control Research team Engagement: The process of monitoring overall research team relationships and adjusting strategies and plans for engaging research teams.

Research Project Monitoring and Controlling

The Monitoring and Controlling is the process to confirm that all tasks of the research project that was approved by the IRB and regulatory authorities and getting authorized for conduction should be within scope, on time, and on budget so that the research project proceeds with minimal risk. This process encompasses comparing tangible performance with planned performance baseline and taking corrective action to get the desirable research. Monitoring and Controlling process is continuous assessment throughout the life cycle of the research project. It aims to provide the sponsor with early detailed information on the progress or delay of the clinical research.

Project monitors should ensure that the clinical trial is conducted and documented properly, including laboratories. Project monitors should also ensure that equipment are adequate to safely and properly conduct the trial throughout the trial period. Moreover, verifying that the investigational product(s) are supplied and stored in acceptable conditions. Project manager on the other hand, pays particular attention to unacceptable variances in the protocol and those that cannot be tolerated, such as in case adverse drug reaction for an investigational drug. Important question(s) should always be asked in clinical trials involving drugs, such as: Can we live with a side effect of a medication? Or: Can we live without this medication? This is exactly similar to the argument of the IRB committee to make their decision to eliminate an immediate hazard(s) to trial subjects in case of clinical trials.

Responsibility of the Project Monitor

Assessment of the trial site

Staff education and compliance

Data management

Case-report forms

Investigational product

Communication

Notification of the trial or submission to the drug regulatory authority

Reports

Common reasons that a researcher might want to bypass Feasibility Findings

Founders or entrepreneurs know the new venture is feasible based on their own experience or on a similar business model that is currently successful.

You're still confident in the results from your most recent study and don't think there have been enough changes to warrant a new one.

The costs in both money and time prohibit completing a full feasibility analysis.

At a global or regional level, feasibilities are often managed by the global study teams but the actual execution is done by the country offices (sponsor) or contract research organizations (CRO) as the case may be.

Components of a Feasibility Study

Description

Technical

Economic

Legal

Operations

Scheduling

Types of feasibility studies

There can be three broad types of feasibilities:

Program level: this relates to the entire program of studies planned e.g. a program on antibacterial in a variety of infections.

It has two aspects:

Ethical and Regulatory: which aim towards finding overall time for clinical trial approval, particular regulatory requirements which can affect decision related to placing of the study etc.

Medical: Disease frequency, prevalence of program-specific patient population, nature of existing treatment patterns or guidelines, presence of alternative drugs and treatments.

The broad objective of program level feasibilities is to identify which regions can be considered for the more-specific study level feasibilities.

Study level: this is very specific to a particular study e.g., an antibacterial in skin and soft tissue infections.

It has four aspects:

Clinical: This relates to the epidemiological data on the study specific population (more specific in terms of stage of disease, protocol based definition of study disease and population), availability of standard care (in terms of background therapy and comparators), specific agreement with inclusion and exclusion criteria and acceptance of study specific procedures in line with existing medical practices.

Regulatory: This is one of the most important pieces of information in a study level feasibility. This would include the overall approval timelines to get the study ongoing, understanding specific regulatory requirements (e.g., translated protocol, export of biological materials, special requirements in case of biological samples etc)

Technical: The usage of technology in clinical trials has increased significantly in recent times. This includes e-CRFs, tools for randomization, clinical supplies shipments, etc. Feasibilities can assess prior experience of usage of tools, any problems which are anticipated and exploring possible options to overcome these challenges

Operational: As clinical trials are becoming more global, some countries (e.g., Eastern and Central Europe, Korea, Taiwan, India etc) have emerged as major destinations for clinical trials across therapeutic areas. This increases the chance of studies with similar patient population being conducted in the same country and actually competing with each other for recruitment affecting overall study and country performance. It is necessary to identify such a risk. Similarly assessing a general estimate of sites and numbers of patients helps in resource allocation and study planning. From a recruitment point of view, identifying recruitment strategies and exploring various options also helps in planning of the study.

Site or Investigator level: this is most specific related to conducting the study in a particular hospital / clinic.

It is actually the micro- feasibility – deciding whether to work with an investigator or not and identifying challenges and probable solutions. Given the challenges above, selecting the right site is of paramount importance. While country offices have greater responsibility in this case, study teams provide overall oversight and guidance.

It consists of the following:

Clinical aspects: Assessing the investigator's readiness in terms of standard care (e.g., type of drugs, dosage), actual study population vs. the patient population treated or seen by the potential investigator, readiness and acceptance of background and comparative therapy and familiarity with use of tools and technology is done in investigator level feasibility.

Site demographics: Site demographics help us in assessing the type of clinical practice (hospital vs. out-patient), prior experience in clinical trials, and availability of study coordinators, pharmacists and nurses. This helps in assessing the 'competency' of the investigator/ site to conduct the clinical trial, not necessarily in terms of medical knowledge but more in terms of protocol related knowledge, personnel availability etc.

Recruitment and retention: This is the most important section of the site feasibility. It helps us in finding the recruitment potential, specifically in anticipated subjects per month and in the entire trial. On one hand, it helps in deciding whether we want to explore other sites, on the other it helps in tracking site performance during study conduct. Other information collated includes ethical considerations, presence of competitive studies, prior experience in conducting similar studies etc.

Reporting Adverse Event

1. Adverse Event (or Adverse Experience

2. Adverse Drug Reaction (ADR)

3. Unexpected Adverse Drug Reaction

4. Serious Adverse Event or Adverse Drug Reaction

Miscellaneous Issues

Reactions Associated with Active Comparator or Placebo Treatment Products with More than one Presentation or Use Post-study Events .

ADVERSE DRUG REACTION PROBABILITY SCALE (NARANJO)

The Naranjo Algorithm, or Adverse Drug Reaction Probability Scale, is a method by which to assess whether there is a causal relationship between an identified untoward clinical event and a drug using a simple questionnaire to assign probability scores.

Table 1: Represented the total score.

Question	Yes	No	Do Not Know	Score
1. Are there previous conclusive reports on this reaction?	+1	0	0	
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	
3. Did the adverse event improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	
4. Did the adverse event reappear when the drug was readministered?	+2	-1	0	
5. Are there alternative causes that could on their own have caused the reaction?	-1	+2	0	
6. Did the reaction reappear when a placebo was given?	-1	+1	0	
7. Was the drug detected in blood or other fluids in concentrations known to be toxic?	+1	0	0	

8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0
9. Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0
10. Was the adverse event confirmed by any objective evidence?	+1	0	0
		Total Score:	

Table 2: Represented the Interpretation score.

Score	Interpretation of Scores
Total Score >9	Definite. The reaction (1) followed a reasonable temporal sequence after a drug or in which a toxic drug level had been established in body fluids or tissues, (2) followed a recognized response to the suspected drug, and (3) was confirmed by improvement on withdrawing the drug and reappeared on reexposure.
Total Score 5 to 8	Probable. The reaction (1) followed a reasonable temporal sequence after a drug, (2) followed a recognized response to the suspected drug, (3) was confirmed by withdrawal but not by exposure to the drug, and (4) could not be reasonably explained by the known characteristics of the patient's clinical state.
Total Score 1 to 4	Possible. The reaction (1) followed a temporal sequence after a drug, (2) possibly followed a recognized pattern to the suspected drug, and (3) could be explained by characteristics of the patient's disease.
Total Score ≤0	Doubtful. The reaction was likely related to factors other than a drug.

CLOSING RESEARCH PROJECT

Principal Investigator is responsible for timely submission of the final technical reports and the final fiscal reports are due within 60-90 days after the expiration date of the research project. Closing clinical research processes showing research closeout which include the following steps: Ensure that all obligations described in the contract have been met.

Closing financial report

Discontinue any charges to the project

Reporting to IRB

Reporting to sponsor

Write a manuscript

Final remarks

Project closeout includes the following key elements:

1. Financial report showing that

2. Submitting to the IRB the followings

3. Reporting to Sponsor

4. Writing manuscript(s)

5. Final remarks

The minimum list of essential documents that has been developed for every phase during the research processes. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated:

Before the clinical phase of the trial commences,

During the clinical conduct of the trial, and

After completion or termination of the trial.

Clinical trial where the use of human as subjects are prone to adverse drug reaction or events that could be endanger the health of the subjects, therefore it is important to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial. Efficient monitoring, controlling, auditing, reviewing, approving, and providing continuing review of trials is essential. "The Closing Process Group consists of those processes performed to conclude all activities across all Project Management Process Groups to formally complete the project, phase, or contractual obligations." –A Guide to the Project Management Body of Knowledge (PMBOK Guide) Fifth Edition.

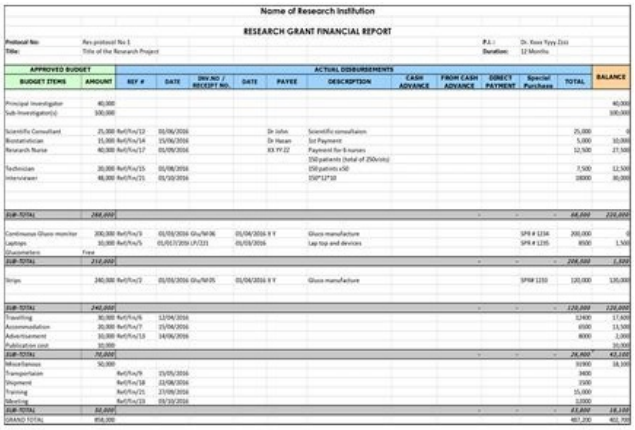
Table 3: Work Breakdown Structure for writing a manuscript ½.

	Manuscript title
	Authors and affiliations

Level				
1	Abstract			
1.1		Introduction		
1.2		Method		
1.3		Result		
1.4		Conclusion		
2	Introduction			
2.1		Project Summary		
2.2		Background information		
2.2.1			Reason for conducting Research	
2.2.2			Current Situation	
2.2.3			Definition of Key Concept	
2.3		Litrature Review		
2.3.1			Problem that basis of the Project	
2.3.2			Cause of the problem	
2.3.3			Possible Solution	
2.4		Study Goals		
2.4.1			Aims	
2.4.2			Objective	
2.4.3			Purpose	
3	Methodology			
3.1		Study Design and Participant		
3.1.1			Type of the Study	
3.1.2			Population	
3.1.2.1				Participant Recruitment
3.1.2.2				inclusion criteria
3.1.2.3				exclusion criteria

Table 4: Work Breakdown Structure for writing a manuscript 2/2.

3.2		Study outcomes		
3.3		Study instrument		
3.3.1			Observations	
3.3.2			Instrument to collect Information	
3.3.3			Laboratory investigation	
3.3.4			Equipment needed	
3.4		Data Collection		
3.5		Etical Considerations		
3.6		Data analysis		
4	Results			
4..1		Participants demographic characteristics		
4.2		Outcomes		
4.2.1			tables	
4.2.2			figures and graphs	
5	Discussion			
5.1		Summary of results		
5.2		comparison with similar literatures		
5.3		strengths and limitations		
5.4		implication in practice		
5.5		recommendations		


Name of Research Institution

RESEARCH GRANT FINANCIAL REPORT

Figure 4: Research Grant financial Report.

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