UNIVERSIDAD PARA LA COOPERACION INTERNACIONAL
(UCI)

FINAL GRADUATION PROJECT:
Project Management Methodology for APHINN: a company that invests and sells health related services and new technologies.

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APPROVAL PAGE

UNIVERSIDAD PARA LA COOPERACION INTERNACIONAL
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This Final Graduation Project was approved by the University as partial fulfillment of the requirements to opt for the Master in Project Management (MPM) Degree

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DEDICATION

To my loving parents, for always believing in me.

To my dear sister, for keeping my feet on ground and my dreams in the sky.

To my greatest teacher, who walks this earth on four paws.

ACKNOWLEDGMENTS

I am deeply thankful with my tutor Jorge Trejos, who inspite of my lack of confidence always cheered me, helped me and turned what was supposed to be a stressful period into a wonderful and enriching experience. *Pura vida!*

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ABBREVIATIONS AND ACRONYMS

- **APHINN:** Accelerator Platform for Health Innovation
- **DSDM:** Dynamic System Developmental Method
- **IT:** Information Technologies
- **MoSCoW:** Must Have, Should Have, Could Have and Won´t Have
- **NDA:** Non-Disclosure Agreement
- **OTC:** Over the Counter
- **PIS:** Primary Information Sources
- **PMBOK:** Project Management Book of Knowledge
- **PMI:** Project Management Institute
- **PMM:** Project Management Methodologies
- **PMO:** Project Management Office / Project Management Officer
- **R&D:** Research and Development
- **SIS:** Secondary Information Sources
- **TRL:** Technology Readiness Level
- **UCI:** Universidad para la Cooperación Internacional

EXECUTIVE SUMMARY (ABSTRACT)

In Mexico health related R&D and innovation is funded almost exclusively by government sponsors, threatening researchers due to a lack of ability to procure private investment and a constant reduction in federal budget. The subyacent ramains that this inventions and innovation never reach the market or generate profit, making the current model unsustainable.

Public and private fundings now lean towards research that has potential to generate income. For this reason it is necessary to create a model within health innovation where private funds and business are put into place, in an effort to create a sustainable business environment into health research.

APHINN is a company that has created an integral ecosystem that accelerates health innovation processes by integrating a value chain with company building, funding, networking, research and development, manufacturing and commercialization of current health technology efforts. This value chain provides private funding and has the objective to ensure that health innovation and research are conducted with the quality and necessary characteristics to reach the global market.

APHINN will be managing different projects in the near future and therefore it is of the utmost importance to establish a Project Management Methodology (PMM) within the company that leads to successful projects. A PMM brings a lot of benefits to the organization because it unifies criteria, controls scope, improooves efficiency implementing, promotes effective decision making, saves time and money, mitigates risks, and improooves chances of project success.

The general objective of the project is to elaborate a project management methodology framework for a better development of health innovation and technology projects at APHINN. The specific objectives were to analyze with a matrix current management methodologies to asses and identify which

methodology characteristics best suited APHINN's needs, to create a document for PMM to be used in all of future KHELE's projects and to establish a document with the work flow for the PMM to simplify its understanding and application.

This research was conducted using a descriptive methodology with primary information sources such as expert interviews, speeches and original methodology papers, as well as secondary information sources such as methodology reviews and peer reviews for health projects.

1. INTRODUCTION

1.1. Background

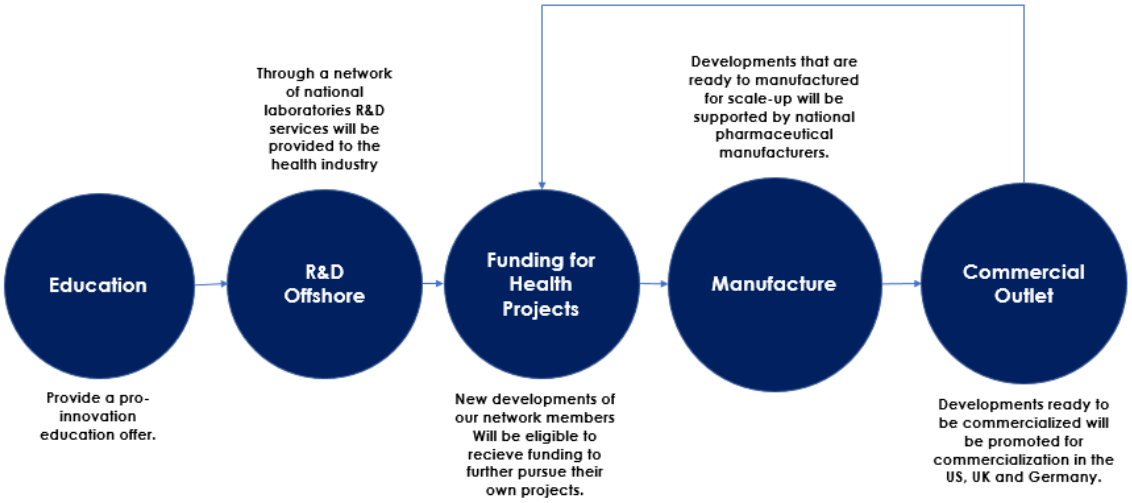
Health research has advanced greatly in the last decades, but a lot of the proposals responsible for this advance do not reach their full development. Only 5% of new health developments reach the market as a consecuence of slow and costly validation channels and lack of resources.

Mexico falls behind when it comes to productive research and development (R&D) health plataforms, which constantly alienates national talent to search for opportunities beyond borders.

The R&D health system in the country is currently threatened due to a constant reduction in federal budget for non-profit research. The funding apparatus is leaning towards research that has potential to generate income. For that reason it is necessary to create a model where private funds and business are put into place, in an effort to create a sustainable business environment into health research.

APHINN is a start-up company that accelerates health innovation processes by integrating a value chain with education, funding, networking, research and development, manufacturing and commercialization of current health technology efforts. APHINN provides services to researchers, public institutions, private institutions, pharmaceutical industry, hospitals, biotechnology companies and other health innovation companies.

Figure 1-1: APHINNs Business Model



Source: APHINN's Business Model, 2017

1.2. Statement of the problem

Project management methodologies (PMM) are a set of processes, tools and techniques that are used when developing a project. A structured PMM will help deliver projects successfully by minimizing uncertainties. That being stated, every company should have a methodology that suits the needs of its core business.

APHINN is a start-up that poses issues and opportunities. One of the issues is that other management processes and information are still lacking and have not been put into place. The main opportunity is that it provides the freedom to develop something that suits your needs and keeps the process simple. Our main business is to accelerate health scientific developments by putting together the right resources, in the right time, at the right place, doing things right. That is the main reason it is of the utmost importance to establish a PMM that advances the probabilities of leading successful projects within our company.

1.3. Purpose

Accelerating health innovation processes makes new technologies more affordable and rapidly availabe in an environment that is constantly changing. APHINN's goal is to democratize access to health technologies by accelerating the innovation processes.

APHINN's business model is based on a lean methodology that uses external existing capacities installed in laboratories funded by the government to provide outsourcing services to the global health industry. The income that the laboratories generate from the services provided helps fund their own projects, creating a sustainable business environment within the health tech industry.

This integrative and lean bussiness model implies that project success relies on a range of providers that must be effectively managed to reach a common goal. For this particular reason it is a priority for APHINN to develop a custom project management methodology that ensures effective and efficient project management that leads to succesful completion of projects.

Putting in place a PMM on an early stage can set the grounds of how APHINN's projects will be initiated and planned, which brings a lot of benefits to the organization such as the following:

- Unifies criteria to manage projects: Defines and unifies tools, techniques, templates and processes to be followed.
- Project scope is controlled: an effective method helps manage scope.
- Improoves efficiency of project implementation.
- Effective decision making: Roles and responsibilities enable decision taking.
- Helps manage client: establishing a methodology ensures client expectations are in agreement with what will be delivered.

- Saves time and money: having a clear path to follow saves time and money in the initiation process.
- Helps mitigate risks.
- Improoves team work.
- Improoves chances of project success.

1.4. General objective

To elaborate and document a project management methodology framework by the end of 2017, that is suitable to particular project characteristics of a health innovation and technology company for a better development of projects at APHINN.

1.5. Specific objectives

1. To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.
2. To create and document a Project Management Methodology Framework to be used in future APHINN's projects.
3. To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.

2. THEORETICAL FRAMEWORK

2.1 Company/Enterprise framework

2.1.1. Company/Enterprise background

APHINN is a platform whose focus is the acceleration of health innovation through knowledge and technology promotion. Our purpose is to generate channels that land in effective solutions to help Latin-American population.

2.1.2. Mission and vision statements

Mission:

Support, promote and offer the best health technologies available at a global level, with scientific alliances in three continents to save at least one million lives in the next 10 years through our efforts.

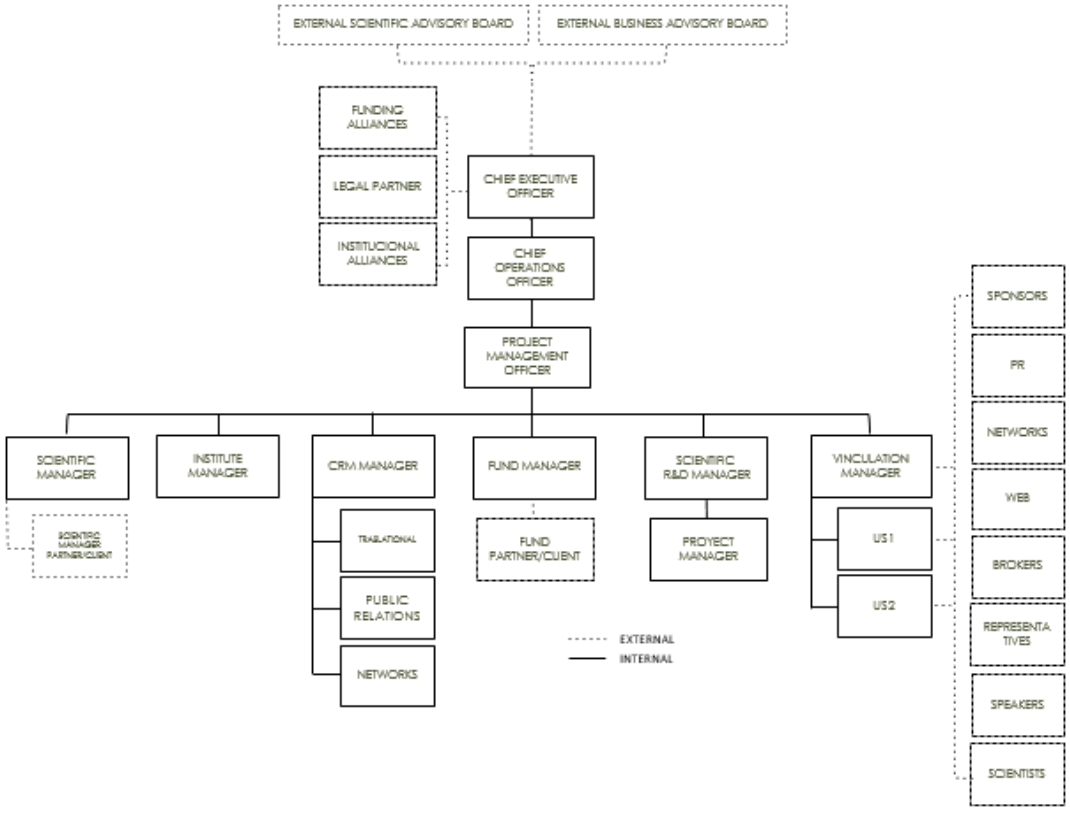
Vision:

To become the most important platform, leader in disruptive health innovation business in Latin America.

To accomplish our mission and vision it is crucial to implement a project management methodology that improves our chances of success. To lead the health innovation business, we must ensure that all projects are conducted in the best way possible every time a new project arises. A PMM unifies criteria, controls scope, mitigates risks, improves teamwork and makes project implementation more efficient. For that matter it is necessary to generate a PMM for APHINN.

2.1.3. Organizational structure

Figure 2-1: APHINN's organizational structure



Source: APHINNs Business Model, 2017

It is important to mention that based on our business model, all areas will be overseen by the PMO. For that reason, the PMM will impact all areas in APHINN.

2.1.4. Products offered

APHINN aims to make the health innovation ecosystem financially sustainable by offering:

- **R&D Service Outsourcing**

  Research institutes in Mexico have a great capacity in infrastructure. Nonetheless, they are constantly lacking in financial resources to conduct their research because they rely solely on federal grants. By offering R&D

services offshore, we can monetize their expertise and infrastructure creating an important income that will help them continue their research interests.

- **Funding Program for Scientific Developments**

Mexican research institutes produce a great number of scientific papers, but they barely produce new technologies. These institutes lack commercialization departments that actually help scientists commercialize their developments. The funding program will help scientists structure their creations (Intellectual Property (IP), patents, etc.) to take them to their end-stages and commercialize them.

- **Commercialization**

APHINN has established alliances with the global pharmaceutical industries and public health platforms in Mexico. The pharmaceutical industry is the biggest consumer of new technologies while public health institutes are the biggest spenders. The aim is to create a virtuous cycle that supports the use of innovative Mexican developments and technologies.

In spirit of helping propel Mexican health innovation throughout the world, instead of burdening our clients with upfront fees, a small percentage of the business created is kept by APHINN. Interaction with clients can be as follows:

- Company building: 10% of the company's equity is taken.
- Research and Development: 10% of the total value of the R&D project is charged.
- Service Outsourcing: 10% of the total value of the services provided is charged.

- Funding a technology: 10% of the total investment landing we help to acquire is charged as well as 10% of the equity.
- Licensing a technology: 10% of the value of the licensing contract and royalties is charged.
- Selling a technology: 10% of the value of the sell is charged.

This structure means that the way APHINN makes money is when projects succeed. Taking that into account, choosing the best fit for a PMM is critical for the company's financial sustainability and overall success.

2.2. Project Management concepts

2.2.1. Project

PMBOK defines a project as a temporary endeavor that is undertaken to create a unique product, service or result. Because of the unique nature of projects, there might be uncertainties that is important to manage through a good PMM (PMI, 2013)

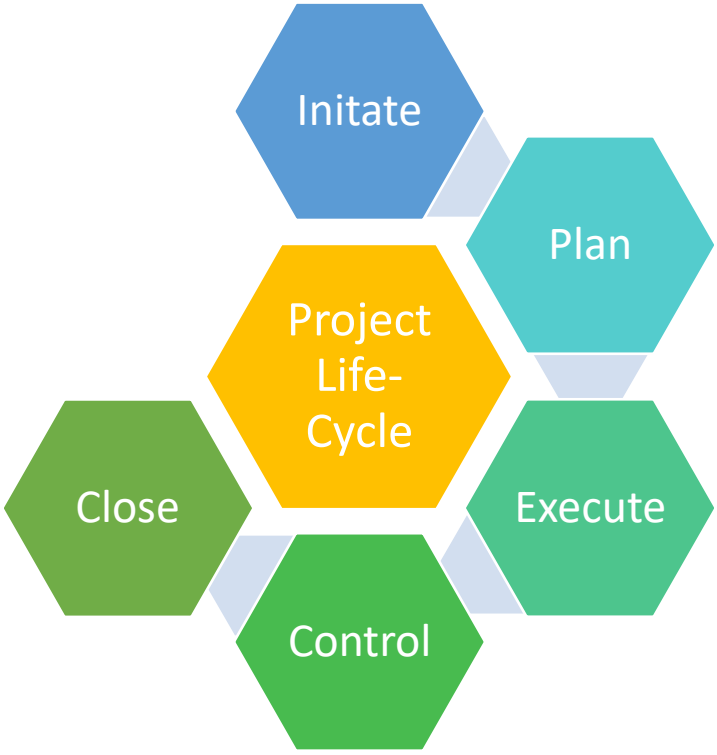
2.2.2. Project management

Project management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements (PMI, 2013).

2.2.3. Project life cycle

The PMBOK defines the project lifecycle is a series of phases that a project goes through form its initiation to its closure, these phases are generally sequential and determined by the management and control need of the organization involved, the project and its area of application (PMI, 2013).

Figure 2-2: Project Life Cycle



Source: PMI, 2013

2.2.4. Project management processes

A process is a set of actions and activities performed to create a product, service or result. The project management processes ensure the effective flow of the project activities through its life cycle. The PMBOK describes five process groups:

- Initiation: Processes performed to define a new project or phase of an existing project by obtaining authorization to start the project or phase.
- Planning: Processes required to establish the scope of the project, refine the objectives and define the course of action required to attain the objectives that the project was undertaken to achieve.
- Executing: Processes performed to complete the work defined in the project management plan to satisfy the project specifications.
- Controlling: Processes required to track, review and regulate the progress and performance of the project.
- Closing: Processes performed to finalize all activities across all process groups to formally close the project or phase.

  (PMI, 2013)

2.2.5. Project management knowledge areas

- Project Integration Management
- Project Scope Management
- Project Time Management
- Project Cost Management
- Project Quality Management
- Project Human Resource Management
- Project Communications Management
- Project Risk Management
- Project Procurement Management
- Project Stakeholder Management

Figure 2-3: Project management process groups and knowledge areas.

Knowledge Areas	Project Management Process Groups				
	Initiating Process Group	Planning Process Group	Executing Process Group	Monitoring and Controlling Process Group	Closing Process Group
4. Project Integration Management	4.1 Develop Project Charter	4.2 Develop Project Management Plan	4.3 Direct and Manage Project Work	4.4 Monitor and Control Project Work 4.5 Perform Integrated Change Control	4.6 Close Project or Phase
5. Project Scope Management		5.1 Plan Scope Management 5.2 Collect Requirements 5.3 Define Scope 5.4 Create WBS		5.5 Validate Scope 5.6 Control Scope	
6. Project Time Management		6.1 Plan Schedule Management 6.2 Define Activities 6.3 Sequence Activities 6.4 Estimate Activity Resources 6.5 Estimate Activity Durations 6.6 Develop Schedule		6.7 Control Schedule	
7. Project Cost Management		7.1 Plan Cost Management 7.2 Estimate Costs 7.3 Determine Budget		7.4 Control Costs	
8. Project Quality Management		8.1 Plan Quality Management	8.2 Perform Quality Assurance	8.3 Control Quality	
9. Project Human Resource Management		9.1 Plan Human Resource Management	9.2 Acquire Project Team 9.3 Develop Project Team 9.4 Manage Project Team		
10. Project Communications Management		10.1 Plan Communications Management	10.2 Manage Communications	10.3 Control Communications	
11. Project Risk Management		11.1 Plan Risk Management 11.2 Identify Risks 11.3 Perform Qualitative Risk Analysis 11.4 Perform Quantitative Risk Analysis 11.5 Plan Risk Responses		11.6 Control Risks	
12. Project Procurement Management		12.1 Plan Procurement Management	12.2 Conduct Procurements	12.3 Control Procurements	12.4 Close Procurements
13. Project Stakeholder Management	13.1 Identify Stakeholders	13.2 Plan Stakeholder Management	13.3 Manage Stakeholder Engagement	13.4 Control Stakeholder Engagement	

Source: PMI, 2013

3. METHODOLOGICAL FRAMEWORK

3.1 Information sources

Information sources are specific persons, things or places from where information comes, arises or is taken. They may come in many forms such as: magazine articles, interviews, speeches, data bases, newspapers, research papers, peer reviews, etc..

3.1.1. Primary sources

Primary Information Sources (PIS) are those that allow the researcher to get as close as possible to original ideas, these sources may include original publications, firsthand accounts of events, speeches and empirical observations or research.

The PIS that will be used for this project will be interviews, empirical observation or research magazine articles of actual cases and original publications of established methodology.

3.1.2. Secondary sources

Secondary Information Sources (SIS) analyze, review or summarize information in primary resources in PIS or SIS. These are sources that rely on the ideas of original publications and provide the source where they were taken from.

The SIS used in this project will be reviews made from other Project Manager Professionals on Project Management Methodologies.(Virginia Tech University Libraries, 2017)

Chart 3-1: Information Sources

Objectives	Information sources	
	Primary	**Secondary**
To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.	▪ PMBOK 5th Ed. ▪ Original Project Management Methodologies Papers. ▪ Speeches	▪ Peer reviews of project management methodologies ▪ Reviews of methodologies used in health projects.
To create and document a Project Management Methodology Framework to be used in future APHINN's projects.	▪ PMBOK 5th Ed.	▪ Other Project Management Methodologies ▪ Peer reviews of project management methodologies
To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.	▪ PMBOK 5th Ed.	▪ Other project management methodologies work flow.

3.2. Research methods

Research is defined as any kind of investigation that intends to uncover interesting or new facts about a particular subject. In that context, research methods are the range of tools and techniques used for collecting and analyzing data in a way you can come to reliable conclusions. Using the right research methods for the projects helps your conclusions have more validity and the new knowledge created to have a solid basis.

Research can be conducted under various designs that are enlisted below:

3.2.1. Historical

Historical research aims at a systematic and objective evaluation and synthesis of evidence in order to establish new facts and draw conclusions about past events. As a source, it uses primary historical data.

3.2.2. Descriptive

Descriptive research relies on observation as a means of collecting data, examining situations in order to establish a norm.

3.2.3. Correlation

This design establishes relationships between two concepts where there is assumed to be some kind of influence of one over the other.

3.2.4. Comparative

Compares distinct parallel situations, particularly when the researcher has no control over events.

3.2.5. Experimental

This design attempts to isolate and control every relevant condition that can determine the events that are being investigated, and then observes the effects of the manipulated conditions.

3.2.6. Simulation

It devises a representation in a small and simplified form of a system that can be manipulated to create effects. It provides an artificial environment in contrast with the experimental design.

In research data can be presented in two different ways that can be qualitative and quantitative, which are defined below:

3.2.7. Quantitative

This kind of research deals with data in the form of numbers and uses mathematical operations to investigate their properties.

3.2.8. Qualitative

This type of research is based on data expressed in the form of words and descriptions. It is common when people are the focus of the study.

For this research a descriptive design with qualitative data will be used. (Walliman, 2011)

Chart 3-2: Research methods used for this paper.

Objectives	Research Methods		Rationale
	Design Type	Data Type	
To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.	Descriptive Comparative	Qualitative	APHINNs usual projects to be managed will be described and PMMs will be defined to understand their main characteristics. Then the PMM's will be assessed and compared to APHINN´s project description to choose the characteristics that best suit the company's needs.
To create and document a Project Management Methodology Framework to be used in future APHINN's projects.	Descriptive	Qualitative	The specific PMM to be used in APHINN will be defined and described to understand its main characteristics, as well as the possible constraints and how to manage them.
To establish a document with a flowchart that describes the proposed Project Management Methodology to	Descriptive	Qualitative	The specific PMM to be used in APHINN will be defined and described in a work flow manner.

provide future team members with a quick methodology reference guide.			

3.3. Tools

A tool is something tangible that helps to better conduct activities in order to produce the desired product or result. The PMBOK uses a wide range of tools for conducting project management processes.

For this project the following tools will be used: Software Project MS and Microsoft Office 2016 to elaborate electronic copies of the documents, data bases for research, meetings, expert judgement and document analysis.

Objectives	Tools
To nalyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs	Data bases, expert judgement, document analysis.
To reate and document a Project Management Methodology Framework to be used in future APHINN's projects.	Microsoft Office 2016, meetings, expert judgement.
To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.	Microsoft Office 2016, document analysis.

Chart 3-3: Tools used to conduct this paper.

3.4. Assumptions and constraints

3.4.1. Assumptions

An assumption is defined by the PMBOK as a factor in the planning process that is considered to be true, real or certain without proof or demonstration. Assumptions for this project by stakeholder are described below in Chart 3-4.

Stakeholder	Assumptions
Internal Stakeholders: Company CEO, Company PMO, Project Director, Project Managers, Company Advisory Board	• APHINN will develop health innovation and technology projects. • A PMM will help better develop successful projects. • APHINN will collaborate with the current project of developing a PMM framework. • APHINN will put the PMM developed in practice. • Information to develop the PMM framework will be available. • Final product of this project will be applicable to all or most projects at the company. • PMM Framework will need further development for Executing, Evaluation and Controlling phases.
External Stakeholders: Government Institutions, Company clients, Company business partners, Health system users	• A PMM will help better develop successful projects in APHINN. • APHINN knows how to manage a health innovation and technology projects. • APHINN manages to the best of their abilities health innovation and technology projects.

Chart 3-4. Project assumptions by stakeholder.

3.4.2. Constraints

A constraint is a factor that affects the execution of a project, program, portfolio or process. In project management they can affect scope, quality, schedule, budget, resources, and risks. (PMI, 2013)

For this project, we considered the constraints to be primarily fall under the category of time and resource and are described below in chart 3-5.

Constraint	Constraint Description
Information	• Lack of information on management could make the process of developing a PMM harder and more extensive.
Experience	• Lack of experience in Project Management can result in having to procure expert advice (that might have to be paid for).
Budget	• There is little to none financial resources to support the project of developing an FGP. • Lack of financial resources can affect the possibility to acquire the necessary tools and bibliography to conduct the project.
Time	• Advice from UCI faculty to develop the PMM is limited to dates and time periods established by the university.

Chart 3-5: Constraints and their description.

In chart 3-6 assumptions and constraints applicable for each objective are described.

Chart 3-6: Assumptions and constraints associated to specific objectives.

Objectives	Assumptions	Constraints
To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.	• It is assumed that APHINN will colaborate with the current project. • Information to develop the PMM framework will be available. • A PMM will help better develop successful projects in APHINN. • APHINN knows how to manage a health innovation and technology projects. • APHINN manages to the best of their abilities health innovation and technology projects.	• Lack of information on management could make the process of developing a PMM harder and more extensive. • Lack of experience in Project Management can result in having to procure expert advice (that might have to be paid for). • Lack of financial resources can affect the possibility to acquire the necessary tools and bibliography to conduct the project.

Objectives	Assumptions	Constraints
To create and document a Project Management Methodology Framework to be used in future APHINN's projects.	• It is assumed that the required information to develop the Project Management Methodology Framework will be available. • It is assumed APHINN will put the Project Management Methdology in practice. • PMM Framework will need further development for Executing, Evaluation and Controlling phases. • It is assumed that the final product will be applicable to all or most projects at the company. • APHINN will develop health innovation and technology projects.	• Lack of experience in Project Management can result in having to procure expert advice (that might have to be paid for). • Advice from UCI faculty to develop the PMM is limited to dates and time periods established by the university.
To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.	• It is assumed APHINN will put the Project Management Methdology in practice. • It is assumed that the final product will be applicable to all or most projects at the company.	• Lack of experience in Project Management can result in having to procure expert advice (that might have to be paid for). • Advice from UCI faculty to develop the PMM is limited to dates and time periods established by the university.

3.5. Deliverables

A deliverable is a product, result or capabilities produced by a specific project that must, in the best scenario be accepted and validated by the project customer or sponsors as to meeting their specified needs.

In management literature there is a vast variety of project management methodologies, it is the goal of this paper develop and document a project management methodology framework by the end of 2017 that is suitable for

company that invests and sells health related services and new technologies in order to advance the probabilities of having successful project outcomes.

The PMM that results of this project include initiating and planning process groups as well as all knowledge areas (integration, scope, time, cost, quality, human resources, procurement, communications, risk and stakeholders). The company where the methodology is to be executed is still on a planning phase, making it impossible to carry out the rest of the process groups (executing, monitoring & controlling and closing). The outcome of this project pretends to provide a simple yet sufficient guide to successfully initiate and plan health related projects.

Based on bibliographic research and expert judgement, the deliverables of this project are described below and related to specific objectives in chart 3-7.

1. Document with characterization of projects managed in APHINN – Describes the main characteristics of APHINN's projects to set a basis from which to judge and assess the addecuacy of PMMs.
2. Document with description of relevant project management methodologies – Defines and set a baseline for the comprehension of already established PMMs.
3. Document with project management methodologies analysis matrix and assessment – Describes the main characteristics of previously described PMMs to analyze, assess, compare and choose the most suitable methodologies.
4. Document proposing a framework project management methodology for APHINN's projects.
5. Document with a flow diagram describing proposed project management methodology – General reference guide of the proposed PMM.

Chart 3-7: Deliverables

Objectives	Deliverables
Analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.	▪ Document with characterization of projects managed in APHINN. ▪ Document with description of relevant project management methodologies. ▪ Document with project management methodologies analysis matrix and assessment.
Create and document a Project Management Methodology Framework to be used in future APHINN's projects.	▪ Document proposing a framework project management methodology for APHINN's projects.
Establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.	▪ Document with a flow diagram describing proposed project management methdology.

To better understand what comprises each deliverable, chart 3-8 describes with more precision what each deliverable will contain.

Chart 3-8: Deliverable description of work, resources required and quality requirements.

ID	Name	Description of Work	Resources Required	Quality Requirements
1.1.1.	Document with characterization of projects managed in APHINN.	Describes the main characteristics of APHINN's projects to set a basis from which to judge and assess the addecuacy of PMMs.	▪ Bibliography ▪ Internet Access ▪ Office Software	▪ APA Bibliography
1.1.2.	Document with description of relevant project management methodologies.	Defines and sets a baseline for the comprehension of already established PMMs.	▪ Bibliography ▪ PMI membership for access. ▪ Internet Access ▪ Office Software	▪ APA Bibliography
1.1.3.	Document with project management methodologies	Describes the main characteristics PMMs in 1.1.2. to analyze,	▪ Bibliography ▪ Document from 1.1.2.	▪ APA Bibliography

	analysis matrix and assessment.	assess, compare and choose the most suitable methodologies	▪ Office Software	
2.1.1.	Document proposing a framework project management methodology for APHINN's projects.	Describes a Framework PMM initiation and planning processes.	▪ Bibliography ▪ Document from 1.1.3. Office Software	▪ APA Bibliography
3.1.1.	Document with a flow diagram describing proposed project management methodology.	Schematizes the proposed PMM in a flow chart.	▪ Bibliography ▪ Document from 2.1.1. Office Software	

4. RESULTS

4.1. Management methodologies assessment matrix

Objective: Analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.

4.1.1. Project Characterization

The choice of PMM in a company determines how projects will be planned and executed. Choosing an appropriate PMM has a lot of weight in overall project success. In order to begin the process of methodology selection it is necessary to know the type of projects that will be undertaken in the specific company by describing the projects' general attributes. For this paper the characterization attributes suggested by Grushka-Cockayne, Holzmann, Weisz, and Zitter (2015) will be used to better describe APHINN's projects. Attributes and levels to be assessed can be seen in chart 4.1. Project Characterization Attributes.

Chart 4-1: Project Characterization Attributes

Project Characterization Attributes		
Attribute	**Description**	**Levels**

Budget	Sum of funds authorized for project execution. Including direct and indirect costs, as well as project management reserves.	• Fixed • Variable • Flexible
Commitment	Feeling of duty that people have to achieve for completion of project goals and objectives that translate into project success.	• High • Medium • Low
Contract Type	Terms and conditions for administrating the business relations.	• Fixed Price • Cost Plus • Hybrid
Customer Type	Customer focus in the project planning, implementation and service user.	• Single internal • Single external • Market
Duration	Total number of work periods required to complete a scheduled activity or work breakdown structure.	• Long • Medium • Short
Goals	Desired achievements, outputs and outcomes.	• Well Defined • Estimated • Unclear
Pace	How critical the time frame is. Where time frame defines project success or failure.	• Fast • Regular
Procedures and Regulations	Organizational or regulatory infrastructure within which the project is operated.	• Non-specific • Standard • Specific Regulations
Project Characterization Attributes (Continued)		
Attribute	**Description**	**Levels**
Resources	All material required to carry out project activities.	• Versatile • Standard • High-Expertise
Scope	The work performed to deliver a product, service or result with specified features and functions.	• Rigid • Multiple-delivery units

		• Modular
Team Availability	Degree to which team members are able to start a task when it is called for, weather planned or unexpected.	• Fully available • Partially available • Very Limited available
Team Distribution	Spatial and temporal distance, also implying culture.	• Single location • Multiple locations • Globally
Team Size	Number of team members, understood in terms of communication and performance complexity.	• Small • Medium • Large
Uncertainty	Situations where the established facts are questioned and the impact of strategic planning on the project performance is raised.	• Ambiguous • Predictable • Highly predictable
Sponsorship	The entity funding the project.	• Owner • External to the company • Internal to the company

Source: Grushka-Cockayne, Holzmann, Weisz, and Zitter, 2015

Based on these project characterization attributes and the kind of projects to be undertaken, attribute levels that best describe the projects managed at APHINN have been selected as can be seen in Chart 4.2. APHINN's Projects Characterization

Chart 4-2: APHINN'S Projects Characterization

APHINN'S Project Characterization		
Attribute	**APHINN'S Level**	**Rationale**
Budget	Fixed	Budgets for the projects of our company are fixed and linked to milestones. Each milestone unlocks the budget needed to accomplish the next milestone.
Commitment	High	Team commitment to fulfill projects success is high, due to the fact that we are dealing with providing health. Financial and R&D services for developing new health technologies, as well as all results and processes must be 100% accurate and reliable, so high commitment is crucial.
Contract Type	Fixed-price	Contracts are fixed-price, with a 10% success fee in the cases stated before and a fixed fee in case a client fails to complete the project acceleration process.
Customer Type	Market	All of the projects final deployments will be marketed.
Duration	Long	Projects will have a long duration, due to established government processes and regulations.
Goals	Well Defined	Each service, R&D project or investment will need to have very well defined goals before entering APHINN'S portfolio in order to minimize ambiguity and risk.
Pace	Fast	In the health tech industry time is very important (patent life-span, cost-opportunity, etc) because it is all about saving lives, the faster you can move, the faster you get return of investment and the faster people can benefit from it.

APHINN'S Project Characterization (Continued)		
Attribute	**APHINN'S Level**	**Rationale**
Procedures and Regulations	Specific Regulations	Health related products, especially those like new molecules, OTC, IT, devices and supplements must undergo specific procedures and regulations in order to be launched into the market.
Resources	High-Expertise	All resources to undertake projects will include highly specialized human and technical resources that have to be managed accurately.
Scope	Modular	The product or service we provide allows projects to be divided in units to work in several steps at a time and put together at the end, although these individual units might be rigid.
Team Availability	Partially Available	Since all projects are different and will slightly vary in the kind of resources needed team availability to start is partial. To minimize delay and optimize time teams will be identified before project launching and be notified a start date and delivery by contract.
Team Distribution	Globally	Teams will be globally allocated but kept simple for our philosophy is putting together high-efficiency teams to accelerate health technology innovation processes.
Team Size	Small	Teams must be small sized, structured like a start-up with a leader for each module/unit/task.
Uncertainty	Highly Predictable	Uncertainties in the projects we undertake are highly predictable, which helps minimize those risks.
Sponsorship	External	All sponsors or investors will be external to our company and to the technology owner.

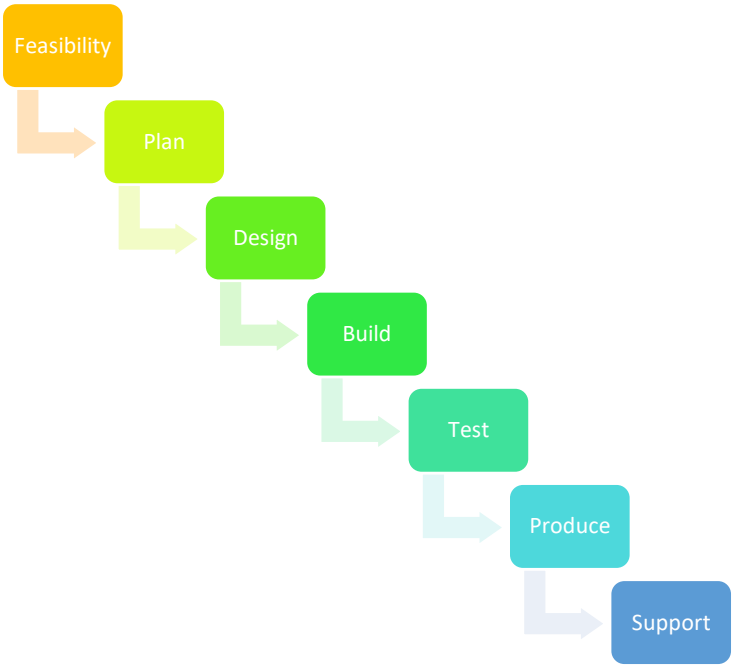
4.1.2. Description of Project Management Methodologies

Project Management Methodologies can be subdivided in two large branches: Waterfall and Agile. It is essential to briefly review their conceptual basis to select the kind of methodology that best suits APHINN's projects.

4.2.2.1. Waterfall

Described for the first time in the 70s, this methodology consists of sequential phases in which each phase of the project must be completed before moving to the next one. This methodology is highly used in construction and manufacturing industries for simple and unchanging projects. The waterfall approach assumes that all requirements can be defined from the beginning of the project and can remain unchanged (Hughey,2009).

Figure 4-1: Waterfall methodology stages and workflow



Source: Hughey, 2009.

4.2.2.2. Agile

The guidelines for Agile methodologies were first described in the Manifesto for Agile Software Development in 2001, but the need and the development of such frameworks had been described in papers since the 1970's

Agile values individuals and interactions over processes and tools, working software over comprehensive documentation, customer collaboration over contract negotiation and responding to change over following a plan. (Manifesto for Agile Software Development, 2001)

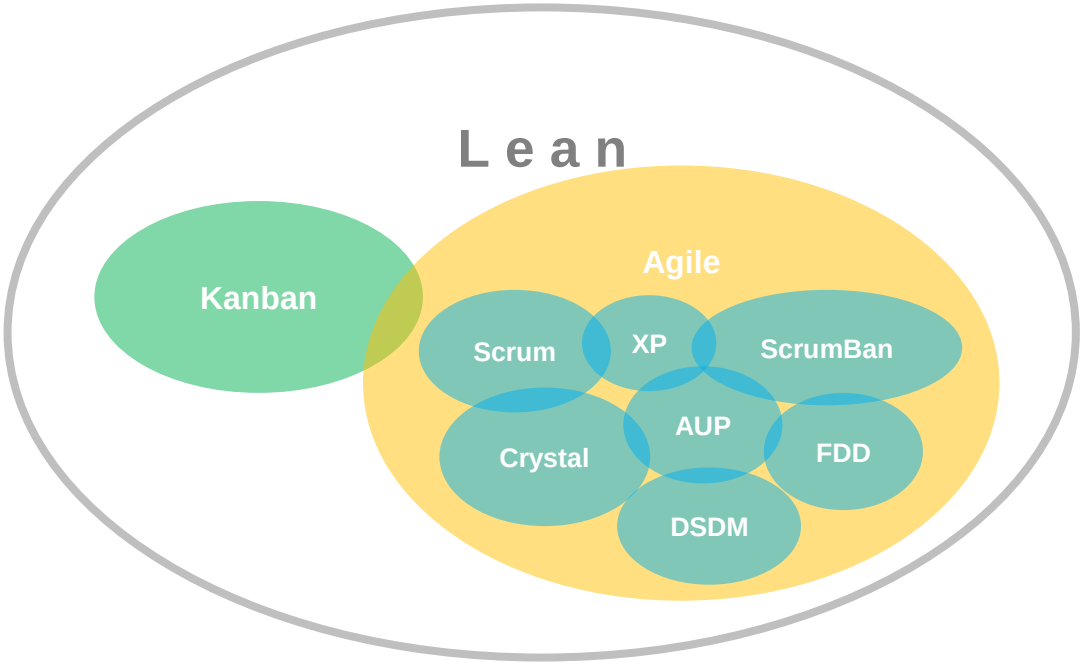
Agile twelve guiding principles under which this methodology must be conducted are (Manifesto for Agile Software Development, 2001):

- Our highest priority is to satisfy the customer through early and continuous delivery of valuable software.
- Welcome changing requirements, even late in development. Agile processes harness change for the customer's competitive advantage.
- Deliver working software frequently, from a couple of weeks to a couple of months, with a preference to the shorter timescale.
- Business people and developers must work together daily throughout the project.
- Build projects around motivated individuals. Give them the environment and support they need, and trust them to get the job done.
- The most efficient and effective method of conveying information to and within a development team is face-to-face conversation.
- Working software is the primary measure of progress.

- Agile processes promote sustainable development. The sponsors, developers, and users should be able to maintain a constant pace indefinitely.
- Continuous attention to technical excellence and good design enhances agility.
- Simplicity--the art of maximizing the amount of work not done--is essential.
- The best architectures, requirements, and designs emerge from self-organizing teams.
- At regular intervals, the team reflects on how to become more effective, then tunes and adjusts its behavior accordingly.

Agile Software Development (ASD) is a term used to define a set of practices and methods based on the values and principles of the Agile Manifesto, where solutions evolve through collaboration of self-organizing, cross-functional teams by using practices that are appropriate for their own context (PMI, 2017).

Figure 4-2: Agile Project Management Approaches or Frameworks



XP: Extreme Programming, AUP: Agile Unified Process, FDD: Feature Driven Development, DSDM: Dynamic System Development Method.
Source: Agile Practice Guide, 2017

For the purpose of this paper, the agile approaches selected to be analyzed were Scrum, Kanban and DSDM, based on their simplicity of implementation and adaptability to a variety of industries.

4.2.2.3. Scrum

This methodology, based on Agile approach, is a framework for developing and sustaining complex products. The SCRUM guide defines it as a framework within which people can address complex adaptive problems, while productively and creatively delivering products of the highest possible value. SCRUM is lightweight, simple to understand and difficult to master. This framework uses an iterative and incremental approach with a cross-functional and self-organizing teams to deliver a “potentially finished product” on a determined amount of time that can range between two weeks and thirty days, this is called a sprint. Every project will go through several sprints before accomplishing the finished product that meets the requirements established by the Product Owner.

SCRUM methodology is based on small teams that must have three main roles:

> **Product Owner:** Is the person who is responsible for Return on Investment (ROI) and the final decision maker on product requirements. This person must have clear vision of the product, and is usually focused more on what the product should be and not on how it will be done.

Scrum Development Team: Is a cross functional team responsible for self-organizing in order to produce a potentially shippable product increment every sprint.

Scrum Master: This role has no management authority, it acts as a facilitator that protects the team from distractions, impediments, enforces time boxes and provides visibility.

SCRUM uses two main tools to organize the order, time and way the work must be done: Product Backlog and Sprint Backlog.

Product Backlog: This is a ranked list of customer-centric features that are prioritized by the product owner, it contains everything the team might ever do. Anyone in the team can add items to this backlog that must be prioritized by the Product Owner.

Sprint Backlog: Contains what must be done to fulfill the goals of the current sprint. It has an end date, the committed Product Backlog items that describe what must be done and a list of tasks that state how will it be done.

The main technique used in SCRUM are meetings. They divide in five kind of meetings that have very specific goals.

Sprint Planning Meeting: Team and Product Owner define which items will be committed to the sprint, usually done by using the top priorities from the Product Backlog. Then they plan what tasks will be done in order to achieve those items.

Daily Scrum: It consists on a daily 15-minute meeting of the Scrum Development Team where team members report to each other what has been done, what they will be doing and if they are having any obstacles.

Sprint Review Meeting: In this meeting a demonstration of the potentially finished product is presented to the Product Owner and to other important stakeholders. They will be in charge of providing feedback.

Sprint Retrospective Meeting: The team meets together to inspect and adapt their working process during the last sprint with feedback.

Backlog Refinement Meeting: SCRUM team comes together to add new items to the Product Backlog, break existing items into smaller pieces or modify their priority. (Sutherland J, 2016)

4.2.2.4. Kanban

Kanban Method is a tool to design, manage and improve flow systems for knowledge work. It can be applied to existing workflows to drive evolution and change. Its goal is to improve services to be delivered by collaborating teams, meeting customer requirements.

This method is value led, motivated by respect to lead collaborative work between all individuals. It is based it in nine specific values to ensure success:

- Transparency: Sharing clear, straight-forward and accurate information openly improves flow.
- Balance: Understand the balance of different aspects, viewpoints and capabilities.

- Collaboration: Working together.
- Customer Focus: Knowing the goal for the system.
- Flow: Work is a flow of value.
- Leadership: Inspire by example.
- Understanding: Self-knowledge to move forward.
- Agreement: Commitment to move together towards goals.
- Respect: Value and show consideration for people.

Kanban has six foundational principles that are divided in two groups:

- Change Management Principles:
    - Start with what you do now.
    - Pursue improvement through evolutionary change.
    - Encourage leadership at every level.
- Service Delivery:
    - Understand and focus on customer needs and expectations.
    - Manage the work, let people self-organize around it.
    - Evolve policies to improve outcomes.

There are six basic practices that are essential to implement the Kanban Method:

- **Visualize:** Visualize your work and the way it flows.
- **Limit Work in Progress:** Respecting limits of work in progress (WIP), where new tasks cannot be started until work is completed.
- **Manage Flow:** Flow of work should maximize delivery of value and minimize leads.
- **Make policies explicit**: Explicit policies articulates and defines processes beyond workflow definition.
- **Implement feedback loops:** These loops improve strategy alignment, operational coordination, risk management, service improvement, replenishment, continuous workflow and customer

deliveries. They are seven established cyclical meetings that ensure feedback is happening.

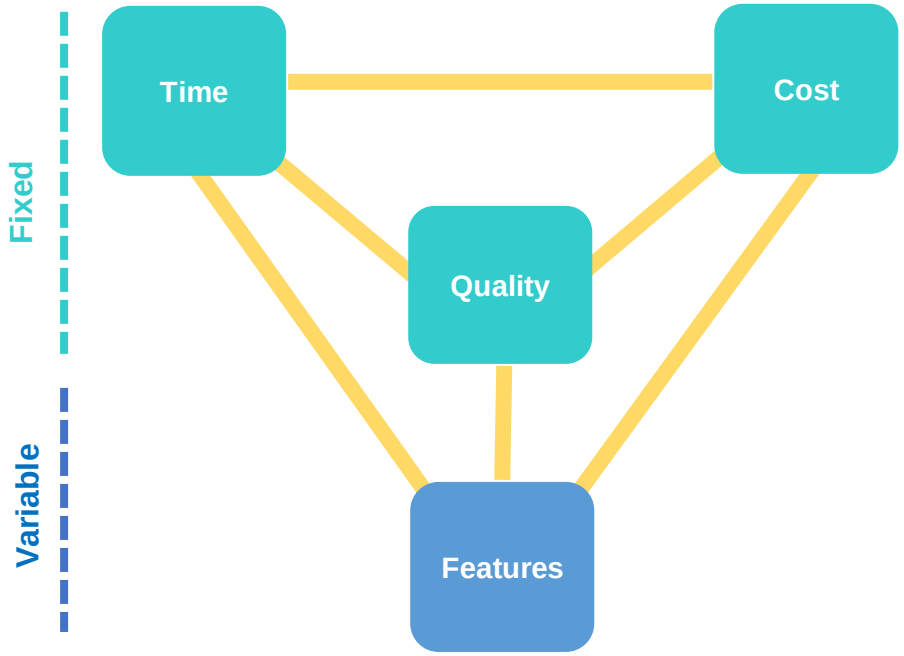
- **Improve collaboratively, evolve experimentally:** Kanban is an improvement method.

4.2.2.5. Dynamic Systems Development Method (DSDM)

The DSDM philosophy is that “best business value emerges when projects are aligned to clear business goals, deliver frequently and involve the collaboration of motivated and empowered people” (Agile Business Consortium, 2014).

DSDM was initially designed to add more structure to existing agile approaches. This framework has emphasis on constraint-driven delivery, setting project constraints (time, cost, quality) as fixed and product features as variable aiming to provide the right solution at the right time.

Figure 4-3. Dynamic Systems Development Method (DSDM) Approach



Source: The DSDM Agile Project Framework (2014 Onwards)

To achieve this approach, the DSDM framework requires the project to be broken down into focused and fixed duration project increments, called timeboxes, lasting two to four weeks. The goals set for each timebox should always be business driven and worked on collaboratively, never compromising quality (Agile Business Consortium, 2014).

This framework is based on eight principles which are (Agile Business Consortium, 2014):

- **Focus on the Business Need:** Deliver what the business needs and when it needs it. To fully comply with this principle teams should understand business priorities, establish a valid business case, ensure sponsorship and commitment and guarantee delivery of the Minimal Usable Subset.
- **Deliver on Time:** Considers time is one of the most important success factors. To fulfil this principle, teams need to timebox the work, focus on business priorities, always meet deadlines and build confidence through predictable delivery.
- **Collaborate:** Active cooperation and commitment is viewed as a synonym for best performance practices. This principle is based on involving the right stakeholders at the right time, encourage pro-active involvement from business representatives, ensure member empowerment on decision making and building team culture.
- **Never Compromise Quality**: The level of quality should be established and agreed upon from the beginning and all work should aim for that exact quality level. To achieve this teams must agree on the level of quality before start, ensure quality is

never a variable, test early and continuously to the appropriate level, constant quality review and make sure to design and document appropriately.

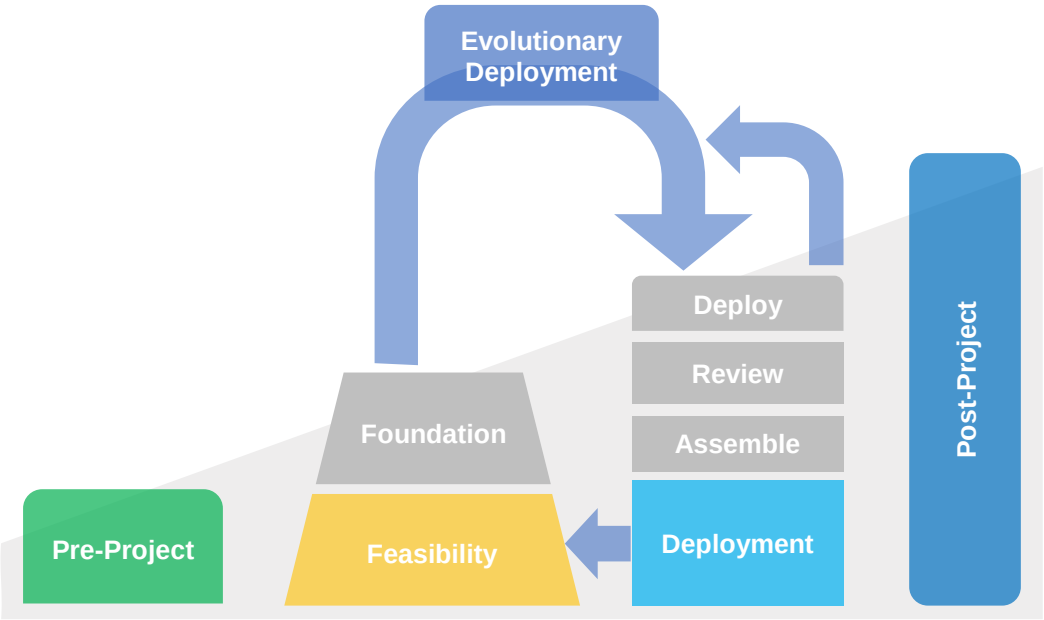
- **Build Incrementally from Firm Foundations:** It is essential to understand the scope of the project but not in such detail that causes delays. This ensures firm foundation upon which to act in order to deliver real business benefit as early as possible. To comply with this principle teams need create strong foundations with appropriate analysis and design, as well as formally re-asses project priorities with each delivered increment.
- **Develop Iteratively:** This framework combines iterative development, frequent demonstrations and comprehensive review for timely feedback. Business feedback, recognizing that detail will emerge on later stages, embracing change and encouraging creativity through iterative development are necessary to fulfil this principle.
- **Communicate continuously and clearly:** Poor communication can lead to project failure. DSDM is design to improve communication for teams and individuals by encouraging informal face to face communication, daily stand-up team sessions, workshops, visual communication practices, early solution demonstrations, managing stakeholder expectations and full transparency at all times.
- **Demonstrate Control:** To ensure project control and transparency is essential to have reference to a plan for the work being performed. In order to meet this principle Project Manager and Team Leader need to make plans and progress visible to all, measure progress focusing on delivery, manage proactively, and evaluate continuing viability based on

business objectives and use formal tracking/reporting methods.

The DSDM process model consist of six lifecycle phases aligned with the previous principles (Agile Business Consortium, 2014). These phases are:

- **Pre-project Phase:** Ensures the right projects are started and set up correctly based on a defined objective.
- **Feasibility Phase**: Establishes feasibility from a technical and financial perspective.
- **Foundations Phase:** It intends to establish an understanding of the business rationale, the potential solution to seek, how to develop the project and the delivery of the solution. In this phase low levels of detail must be respected in order to be developed in the next phase.
- **Evolutionary Development Phase:** The purpose of this phase is to evolve the solution. Evolving the solution is achieved through team applying practices such as iterative development, timeboxing, MoSCoW prioritization and workshops.
- **Deployment Phase:** The deployment phase has three main activities: Assemble, Review and Deploy. The objective of this phase is to bring the evolving solution into use and asses if it meets all the requirements of a final solution. After the last deployment, the project is formally closed.
- **Post-project:** This phase evaluates how well the business requirements or benefits have been met. This phase may be used after every deployment.

Figure 4-4: Dynamic Systems Development Method (DSDM) process



Source: Dynamic System Developmental Method, 2014

When defining the requirements that the final product should meet, DSDM uses the MoSCoW technique. MoSCoW is utilized to prioritize requirements, it stands for Must Have, Should Have, Could Have and Won't Have this time. It provides a clear description of that item and expectations of its completion. The rules for each classification are described below (Agile Business Consortium, 2014).

Chart 4-3: MoSCoW prioritisation Rules

Must Have	Should Have	Could Have	Won't Have
No point delivering on target date without it. Not legal without it. Unsafe without it. Cannot deliver viable solution without it. No more than 60% of effort.	Important but not vital. May be painful to leave out. May need some kind of workaround.	Wanted or desirable but less important. Less impact if left out in comparison with Should Have. Typically 20% of effort.	Requirements agreed will not be delivered within the current time frame. Not within the scope for the current timeframe.

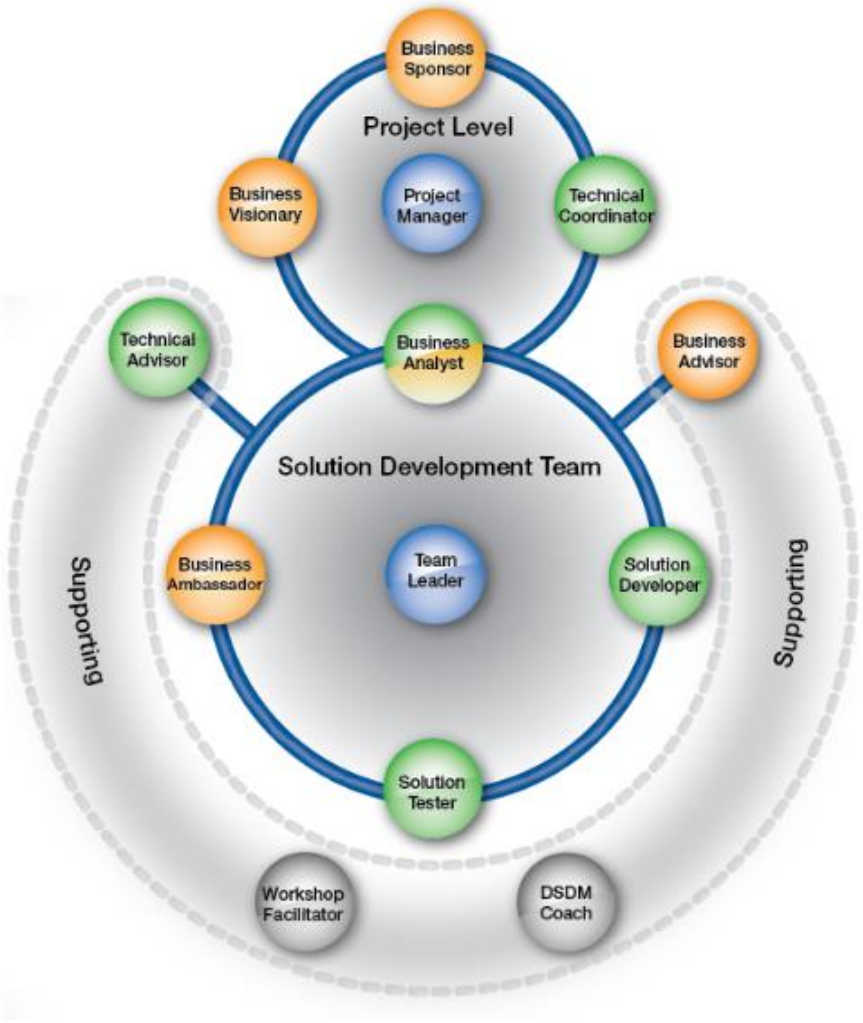
Source: Dynamic System Developmental Method, 2014

Agile frameworks are characterized by iterations, in DSDM iterations are called timeboxes. The DSDM Handbook defines a timebox as a fixed period of time at the end of which an objective has been met, ensuring the deliverable is complete and meaningful. The optimum length of a timebox is two to four weeks, but can be modified to be as short as a day or as long as six weeks, longer timeboxes tend to lose team focus (Agile Business Consortium, 2014).

DSDM has defined roles and responsibilities within the project team, although it is clear that agile methodologies promote self-organizing DSDM sustains that each person within the team must actively take responsibility for their empowerment. Roles are classified in business interest roles, technical solution roles, management interest roles and process interest roles (Agile Business Consortium, 2014).

- **Business Interest Roles:** Business sponsor, business visionary, business advisor, business ambassador, business analyst.
- **Technical Solution Roles:** Technical coordinator, technical advisor, business analyst, solution developer, solution tester.
- **Management Interest Roles**: Project manager, team leader
- **Process Interest Roles:** Workshop facilitator, DSDM Coach.
  (Agile Business Consortium, 2014)

Figure 4-5: DSDM team model



Source: Dynamic System Developmental Method, 2014

4.1.3. Analysis matrix of Project Management Methodologies

For the purpose of the present matrix is to facilitate contrast between different methodology aspects, which are shortly described in Chart 4-4, aspects that apply to APHINN´s projects are contrasted with blue.

Chart 4-4 Analysis Matrix of Project Management Methodologies

Project Management Methodologies				
	Waterfall	**Scrum**	**Kanban**	**DSDM**
Life-cycle	Sequential hand-down phases.	Lifecycle iterations until product meets requirements.	Associated to goal completion.	Pre-project, feasibility, foundations, evolutionary development, deployment and post project.
Iterations	No iterations, sequential work.	2-4 week sprints. Incremental iterations.	Associated to goal completion.	Incremental iterations.
Limit Work in Progress	No, WIP determined by schedule and WBS.	Indirectly limited by sprints.	Limited by WIP limits.	Indirectly limited by iterations.
Communication	Push	Interactive	Pull	Interactive
Time Estimation	Critical Path Method	Sprint Planning	Optional	Timeboxes
Meetings	None required. Recommended, not specified goals.	Established: Daily Scrum, Sprint Planning, Sprint retrospective, Backlog Grooming.	None established.	Workshops recommended as needed.
Team size	Any size	Small	Any size	Any size
Team members	Departmental	Cross-functional	Cross-functional or specialized.	Cross-functional

Project Management Methodologies (Continued)				
	Waterfall	**Scrum**	**Kanban**	**DSDM**
Roles	Not defined. Created as needed.	Defined. Product Owner, Scrum Master and Development Team.	Not defined. Created as needed.	Executive sponsor, visionary, ambassador user, advisor user, project manager, technical coordinator, team leader, solution developer, solution tester, scribe, facilitator, specialist roles.
Ownership	Multiple team ownership.	Single team.	Multiple team ownership.	Single team.
Task size	Any size	Limited to sprint.	Any size.	Any size, timeboxes are adjustable.
Team work	Departmental. Hand-down process.	Collaborative.	Collaborative, based on achieving team goals.	Collaborative, based on achieving team goals.
Changes to work scope	Not possible without delay.	Should wait until next sprint and must be prioritized by Product Owner	Added as needed when capacity is available.	Added and classified in every iteration.
Workflow visualization	Done by analysis.	Partial, visualized in every sprint.	Full visualization.	Not specified.
Work visualization	None.	Burn-down chart in every sprint.	Permanent board throughout project.	Pre-project planning.

Project Management Methodologies (Continued)				
	Waterfall	**Scrum**	**Kanban**	**DSDM**
Task management	Schedule, Estimation and Interrelations. CPM.	Sprint planning.	Workflow and limited WIPs	Timebox planning.
Task priorization	Only as by CPM.	Done by Product Owner.	Optional.	Work is prioritized according to business needs, MoSCoW.
Project predictability	Highly predictable projects.	Highly unpredictable project features.	Unpredictable workflow projects.	Unpredictable projects.
Focus	Following a determined process.	Constant and incremental deployments.	Improvement of workflow.	Constraint-driven delivery

4.2. Project Management Methodology Framework for APHINN

Objective: Create and document a Project Management Methodology Framework to be used in future APHINN's projects.

4.2.1. Typical projects to be managed

APHINN participates within the health industry by acceleration and innovation of new health technologies that are being developed inside public universities. A typical project to be managed within this company would include:

- Regulations: All health technologies need to go through several testing and clinical stages to be cleared for public use. These specific regulations are to be considered.
- Small and cross-functional teams with different geographical allocations: Our business is based on the Lean philosophy, so teams must remain small and cross-functional to deliver results in the swiftest way possible without compromising quality.

- Investor: All projects will have an external investor to the technology owner and to our company.

A more detailed characterization of typical projects to be managed can be found in Chart 4-2 of this paper.

It is important to highlight that APHINN is a company who has not yet been launched and this constitutes a plan to be executed in the future.

4.2.2. Methodology Selected

On chart 4-2 typical projects to be managed were characterized and current PMMs were analyzed as well as compared with the goal of selecting the most suitable methodology.

Based on the evidence presented it is clear to say that APHINN's project best fit with Agile Methodologies. DSDM seems to be the best fit for the company's needs, but SCRUM and Kanban have several aspects and techniques that are already used in APHINN and have been found to be very effective.

That being stated, a hybrid methodology is thought to be fittest for APHINN's projects. In the chart below, desired characteristics from each of the analyzed methodologies are briefly described.

Chart 4-5: Agile desired characteristics for APHINNs projects.

Scrum	Kanban	DSDM
Cross-functional small sized team. Sprints. Meeting dynamic. Iterations.	WIP Limits Work visualization in board. Iterations.	Philosophy Phases Overall and lightweight project planning. Constraint-driven delivery Focus on quality MoSCoW prioritization method. Project Manager/Team Leader roles. Focus on business value.

4.2.3. Justification

Agile methodologies first emerged for the software development industry, even now most current methodologies are created for IT projects. Although using agile concepts and techniques in a variety of industries has been proven to work successfully, no methodology has been adapted to use on an industry that has to comply with strict regulations. Choosing to apply a hybrid methodology on APHINNs projects is the result of putting together different elements of agile frameworks to best serve the health industry and its constraints (Conforto, 2014).

4.2.4. Methodology Description

4.3.4.1 Philosophy

Best business value emerges when projects are aligned to clear business goals, delivered frequently in a timely manner and involve the collaboration of motivated and empowered people. (Agile Business Consortium, 2014)

4.3.4.2. Values

- Honesty: Transparency and respect for others in all forms of communication is essential to healthy business and smoother processes.
- Empathy: The capacity to understand and respect someone else's experience from its frame of reference will enable the team to take on every project as something that can potentially save lives.
- Quality: Ensuring the best product possible with the available resources ensures client satisfaction and ultimately society's wellbeing.

- Creativity: Always incentivize lateral thinking and freedom of ideas within business and team environment seeking for disruptive, innovative and improved products or methods.
- Tenacity: Thrive and persist in all our actions for improvement of individual and public health.
- Freedom: Speech, thoughts, ideas, methods and culture should be always respectful of others and free to be expressed in secure environments.
- Joy: Tasks taken on should enable a feeling of pride, happiness and fulfillment to team members, maintaining moral motivation high.

4.3.4.3. Roles

- **Sponsor:** Is the project champion who is committed to the project, to the proposed solution and the approach to delivering it. Must be able to resolve business issues and make financial decisions to ensure fast progress. The sponsor may be represented by a single person or an advisory investment board. Responsibilities include:

  - Resolve business issues and financial decisions.
  - Hold project budget and ensure funds.
  - Empower roles within the project.
  - Be informed of progress and issues to inform external stakeholders such as investors.

- **Project Manager:** Provide agile leadership with a facilitative style to the team, focusing on managing the working environment. Responsibilities include:

  - Communication between sponsor, team and external stakeholders.
  - Accurate delivery from the technical team and the business team.

- High level planning, but not detailed sprints or task planning.
- Enable collaboration with project team to agree on a Delivery Plan.
- Team empowerment and effective communication amongst them.
- Escalating issues that need sponsor or external involvement.
- Attending daily stand-up meetings.

- **Project Owner**: Acts as a servant-leader for the Technical Team ensuring that it functions as a whole and meets objectives. Responsibilities include:

  - Ensure iterative development process is focused.
  - Manage risks and issues at sprint level.
  - Monitor day-to-day progress of the Technical Team.
  - Facilitate daily stand-ups.
  - Communicate progress to Project Manager.
  - Facilitate reviews and retrospectives with the team.

- **Technical Advisor:** Ensures that the project is technically coherent and meets desired technical standards, advises on technical decisions and innovation. The technical advisor is in charge of:

  - Advising on projects essential requirements.
  - Advising on team's technical activities.
  - Advising on the feasibility of non-essential requirements.
  - Promote high-level practice standards.
  - Approve solution prior to deployment.
  - Approving and advising changes in requirements that directly or indirectly impact business.
  - Empower roles within technical team.
  - Reviewing deployments.

- **Technical Team:** Working full-time on the project to translate business requirements into technical solutions that meet functional and non-functional needs, empowered by the Technical Advisor to make decisions in their expertise area. Responsibilities include:

  - Develop product in increments.
  - Integrating advice from Technical Advisor into solution increments.
  - Testing the deployment.
  - Follow technical constraints and requirements.
  - Adhere to standards and best practices.
  - Recording changes.
  - Escalating project issues with the Project Manager.
  - Monitor Technical Risks.

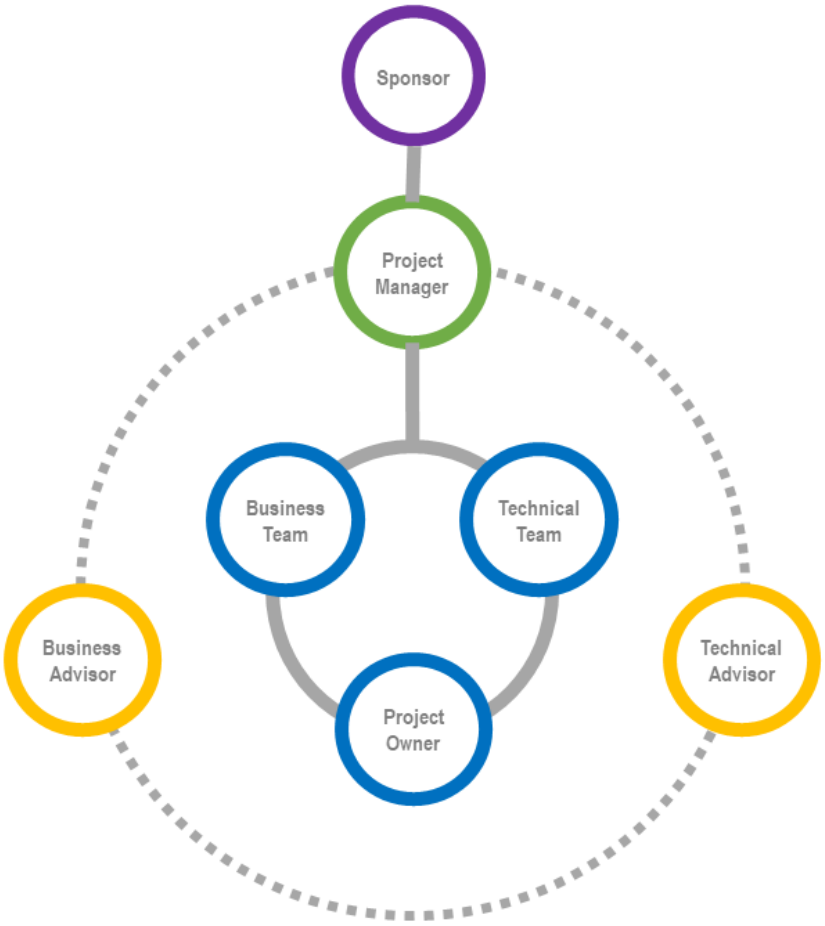
- **Business Team:** Facilitates the project needs for legal, financial and market information and pipelines to sell, transfer of license the developments. Responsibilities include:

  - Monitoring budget expenditure.
  - Generate project dossier.
  - Provide legal documentation necessary to business transactions.
  - Insert deployments into business.
  - Conduct financial feasibility study
  - Monitor business risks.

- **Business Advisor:** Provides the team with strategic direction, ensuring that the final product will deliver the promised benefits. Responsibilities include:

  - Defining and promoting the business vision.
  - Monitoring progress that aligns with business vision.
  - Approving and advising changes in requirements that directly or indirectly impact business.
  - Quality vote when business team cannot reach decision.
  - Empowering roles within business team. (Agile Business Consortium, 2014).

Figure 4-6. APHINN team model



4.3.4.4. Methodology Stages

Pre-Project

It ensures only the right projects that are in line with business scope and based on clearly defined objectives are started. (Agile Business Consortium, 2014)

Chart 4-6: Methodology Stages

Inputs	Tools and Techniques	Outputs
Project Proposal	Expert Judgment Decision Making	Project Asessment

- **Project Proposal**: Brief description of the project that includes, but is not limited to: Description of product, objectives, Technology Readiness Level (TRL), target group and broad assessment of market size.

- **Expert Judgement:** Judgment provided based upon expertise in an application area that is appropriate for the activity being performed (PMI, 2017).

- **Decision Making:** The technique recommended for this stage is multicriteria decision analysis, which uses a matrix to provide a systematic analytical approach for establishing criteria (PMI, 2017). Criteria to be assessed can vary, for this particular stage it should include but is not limited to: defined objectives, TRL, target group size, public health relevance, scalability, and market size.

- **Project Assessment:** Results from expert judgement on the Project Overview and it establishes if the project delivers a solution for health issues that is innovative, solves a problem and can be scaled up. It

determines if the project will advance and be studied to a greater detail in the feasibility phase. (Agile Business Consortium, 2014)

- **Recommendations:**
  This stage must not take more than three working days.

Feasibility Phase

The main goal of the phase is to conduct a study that establishes the feasibility of the proposed project from a technical, regulatory and financial perspective to decide if further exploration of the project is justified. (Agile Business Consortium, 2014)

Chart 4-7: Feasibility Phase

Inputs	Tools and Techniques	Outputs
Project Proposal	Expert Judgment Data Gathering Data Analysis Decision Making	Feasibility Study

- **Expert Judgment:** Judgment provided based upon expertise in an application area that is appropriate for the activity being performed. For this phase, expertise from individuals with special knowledge in the following topics must be considered: organizational strategy, technical knowledge in focus area and risk identification (PMI, 2017).

- **Data Gathering:** Data gathering technique for the feasibility phase can include but is not limited to:
- Focus groups
- Market research

- **Data Analysis:** Document analysis consists of reviewing and assessing relevant documented information, it **is** used to help elicit relevant information and support decision making (PMI, 2017)

- **Decision Making:** Techniques that can be used in this stage can be multicriteria decision making, autocratic decision making or voting.

- **Feasibility Study**: The study must include but is not limited to:

    - Technical feasibility: Must be proven with a scientific project that includes validated reports made with Good Laboratory Practices and supporting bibliography.
    - Regulatory feasibility: Country, regional and global health regulations must be explored to recognize the capability of reaching market from a legal point of view. If faced with determining regulatory difficulties ending the project must be seriously considered as an option.
    - Financial feasibility: Brief market exploration, amount of money needed to take the project to completion and expected return of investment.
    - Risk Register: Risks detected on each of the feasibility study sections must be included.
    - Go or No Go: Technical, regulatory and financial experts should make a recommendation based on the feasibility study to decide if further exploration is worthy. Usually done by a board of experts.

- **Recommendations:**
    - This phase must not last more than five working days.

Foundations Phase

The purpose of this phase is to establish a clear and brief business rationale, the solution created by the project and how development and delivery will be managed.

Chart 4-8: Foundations Phase

Inputs	Tools and Techniques	Outputs
Project Proposal Feasibility study	Expert Judgment Data gathering Requirement Meeting MoSCoW prioritization	Project Charter Requirements Log

- **Expert Judgment:** Expertise should be considered from people with specialized knowledge and training relevant to project business analysis, requirement analysis, documentation, regulatory requirements, as well as from people who have participated in previous similar projects (PMI, 2017).

- **Data gathering:** Data gathering techniques used for this phase can be benchmarking, brainstorming and focus groups.

- **Requirement meeting:** One meeting must be held with the project team to establish project's requirements and prioritize them.

- **MoSCow prioritization:** MoSCoW stands for Must Have, Should Have, Could Have and Won't Have. It comprises a method to order requirements by relevance to the project (Agile Business Consortium, 2014).

Chart 4-9: MoSCoW prioritization

Must Have	Should Have	Could Have	Won't Have
No point delivering on target date without it. Not legal without it. Unsafe without it. Cannot deliver viable solution without it. No more than 60% of effort.	Important but not vital. May be painful to leave out. May need some kind of workaround.	Wanted or desirable but less important. Less impact if left out in comparison with Should Have. Typically 20% of effort.	Requirements agreed will not be delivered within the current time frame. Not within the scope for the current timeframe.

Source: Dynamic System Developmental Method, 2014

- **Project Charter:** Document that formally authorizes the existence of the project and the ability to assign organizational resources to project activities (PMI, 2017). It must include but is not limited to the following sections:
  - Project purpose.
  - Objectives and success criteria.
  - Low-level of detail requirements,
  - Low-level project description, boundaries and key deliverables.
  - Sprint duration.
  - Pre-approved financial resources.
  - Key stakeholder list.
  - Project approval requirements.
  - Roles and responsibilities.
  - Low-level Budget

- **Requirements Log:** Document with a low-level list of requirements ordered with MoSCoW prioritization tool.
- **Recommendations:**
  - This phase should not last longer than two weeks.
  - This phase may be revisited after deployment to modify requirements.
  - This phase determines sprint duration, sprints longer than a month are not recommended.

Evolutionary Development Phase

This phase comprises the creation of project increments iteratively exploring the low-level detail of the previously stated requirements.

Chart 4-10: Evolutionary Development phase

Inputs	Tools and Techniques	Outputs
Project Charter Requirements Log	Work Board Meetings	Project Increment

- **Work Board:** A permanent work board is a work and workflow visualization tool that helps optimize the flow of work by communicating status, progress and issues. Simple processes are laid out in vertical lanes where tasks or activities are placed depending on their progress. It can be done in a physical board with sticky notes or electronic format. It is flexible enough for teams to add or remove processes. Color codes are useful to differentiate tasks and highlight issues. The suggested format can be seen below in Figure 4-7.

Figure 4-7. Work Board Template

- **Meetings:** Meetings will be a fundamental tool for this phase. The meetings listed below must happen during each iteration or sprint.

  - **Sprint Planning Meeting:** Project team defines which items will be committed to the sprint, usually done by using those best ranked in the MoSCoW prioritization tool from the Requirements Log. Then they plan what tasks will be done to achieve those items.

  - **Daily Stand Up:** Consists is a daily 15-minute meeting of the Project Team where team members report to each other what has been done, what they will be doing and if they are having any obstacles.
  - **Sprint Review Meeting:** In this meeting a demonstration of the potentially finished product is done to the Product Owner and to other important stakeholders, and give feedback.

  - **Sprint Retrospective Meeting:** Team meets together to inspect and adapt their working process during the last sprint with feedback.

  - **Backlog Refinement Meeting:** Project Team comes together to add new items to the Requirement log, break existing items into smaller pieces or modify their priority. (Sutherland J, 2016)

- **Project Increment:** Is the product resulting from the work done in the sprint, it may consist of a usable or functional product or a module of the work completed that must later be assembled to other modules to be functional.

- **Recommendations:**
  - This phase will last until a finished product is deployed.
  - After first iteration Requirements Log revision may be necessary.

- If any problem should arise during this phase, encourage using Design Thinking ™ for innovative and user centered problem solving.

Deployment Phase

The deployment phase is the release of the project increments or the final solution. It consists of three main activities:

a) **Assemble**: The activities that must take place to bring together all the elements, ensuring the deployment is coherent.
b) **Review:** A final review before deployment to ensure it meets the appropriate standards and its complete enough to be viable.
c) **Deploy:** Putting what has been created into operational use or submitting it to revision to go on the next stage.

Chart 4-11: Deployment phase

Inputs	Tools and Techniques	Outputs
Project increment	Assemble	Product Deployment

Closing Phase: This only happens after the final deployment and it must end with a retrospective performance meeting.

- **Retrospective Performance Meeting:** In this meeting, the EVM tool can be used to assess the final performance of the project. Lessons learned should be recorded, so they can later be used to adjust and update the PMM.

4.3.4.5. Integration Management Plan

The Integration Management Plan includes the processes and activities to identify, define, combine, unify and coordinate the various processes and project management activities within the process groups. The main documents to be developed are:

- **Project Charter:** Document that formally authorizes the existence of a project and provides the project manager with the authority to apply resources to project activities. It establishes a direct link between project and strategic objectives (PMI,2017). The project charter must include but is not limited to:
    a. Project purpose.
    b. Objectives and success criteria.
    c. Low-level of detail requirements,
    d. Low-level project description, boundaries and key deliverables.
    e. Sprint duration.
    f. Pre-approved financial resources.
    g. Key stakeholder list.
    h. Project approval requirements.
    i. Roles and responsibilities.
    j. Low-level Budget

- **Project Management Plan:** Is the process of defining, preparing, and coordinating all plan components and consolidating them into an integrated management plan (PMI, 2017). See 4.3.4.4. Methodology Stages.

4.3.4.6. Plan Scope Management

Plan Scope Management documents how the project and the scope will be defined, controlled and validated (PMI,2017). The scope management plan will include:

- **Scope Statement:** Formally states project requirements, deliverables and non-goals.
- **Scope Baseline:** Defined with the deliverables stated on the Project Charter and Statement of Work, as well as the Requirements log and the MoSCoW prioritization. Development of a WBS is recommended as part of the Requirements log. Approved by the Technical Advisor and Business Advisor.
- **Scope Control:** To avoid scope creep, requirements added on subsequent iterations must be reviewed and approved by Technical Advisor and Business Advisor. Project Manager is responsible for updating documents.

4.3.4.7. Plan Schedule Management

This process establishes the procedures and documentations for planning, developing, managing, executing and controlling the project schedule (PMI,2017). This process will be performed in the Foundations Phase and may be revisited if any requirements added throughout iterations impact the schedule. It must include:

- **The Schedule Management Plan**: It is baselined with the number and length of iterations defined in the Project Charter, monitored and controlled with the EVM tool at the end of each iteration at the review meeting.

- **Rules of performance measurement:** They should be established and defined for each project, but should include definition of percent complete and EVM techniques to be used.

4.3.4.8. Plan Resource Management

Plan Resource Management is the process of defining how to estimate, acquire, manage and use team and physical resources (PMI, 2017). This process must be done in the Foundations Phase and can be revisited if requirements are added during iterations.

- **Human Resources:** Project team will be structured according to team model and roles in section 4.3.4.3. Since most of APHINN's project team is external to the organization, any training needs and staffing must be integrated in the SOW and considered in the Cost Management plan.

- **Physical Resources:** All material resources needed must be integrated into the SOW and considered in the Cost Management Plan. Any additional resources that come up in iterations because of additional requirements must be reviewed and approved by the Sponsor.

- **Recognition Plan:** Recognition and rewards given to team members if project ends successfully in being sold, licensed or transferred. Team members possess a success fee that varies in percentage but is based on the final project profit. Specific team members with their assigned success fee must be defined in the contract addendum for each project with the help of contractors.

- **Team Charter:** Establishes the team values, agreements and operating guidelines. See section 4.3.4.1. Philosophy, 4.3.4.2. Values, and in chart

4-12 Communication Matrix. Conflict resolution will be mediated with Design Thinking technique.

4.3.4.9. Cost Management Plan

Project cost is primarily concerned with the cost of the resources needed to complete project activities. The Cost Management Plan describes how the project costs will be planned, structured and controlled alongside with the necessary tools to conduct it and includes but is not limited to:

- **Units of measure**: All cost estimates must be done in US dollars, considering most inputs used by contractors are of US origin and the variant exchange rate between the US dollar and Mexican peso. Units of measurement should be according to the service provided, negotiated and finally established in contract addendum.
- **Level of precision:** All cost estimates must round-up the unit to the nearest whole number. Example: $ 996.8 to $ 997.
- **Level of accuracy:** For determination of realistic cost estimates +/-15% should be considered including contingency costs.
- **Control threshold:** Deviations allowed are 10% from stage baseline or 7.5% from overall project cost baseline. If deviations surpass the allowed threshold, it must be notified to project manager.
- **Organizational basis for cost estimates:** Cost estimates must be based on all resources needed to comply with the SOW requirements.
- **Cost estimates:** Each contractor is responsible of estimating the costs of the services they will be providing, but it must be ensured contractors are following consistent and good estimating practices such as:
  - **a.** Use all resources needed to comply with SOW requirements as the basis for cost estimates.
  - **b.** Bottom-Up Estimating Method where the cost of individual work packages or activities is estimated to great level of detail.

c. Inflation: 6% average annual inflation rate should be considered according to Mexican average inflation rates.

- **Cost Performance:** Earned Value Management (EVM) is to be used as performance measurement in electronic format.
- **Reporting format:** Cost reporting must be presented with EVM indicators at the end of each sprint at the Sprint Retrospective Meeting or if any contingency arises at a called for Backlog Refinement Meeting.
- **Cost Recording:** All costs of services, goods or professional consultations must be recorded by an electronic receipt according to Mexican Department of Treasury and submitted to APHINN by secure e-mailing service.

4.3.4.10. Plan Procurement Management

Procurement refers to the necessary processes to purchase or acquire products, services or results needed from outside the project team (PMI, 2017).

APHINN is a crowdsourcing company with a lean philosophy, an ecosystem built with the best teams to execute different stages of each project or different services. These teams are external pre-approved contractors, so collaborations must be strengthened and secured by planning procurement.

- **Pre-approved contractors:** Pre-approved contractors must comply with a series of documents and legal requirements that ensure they have the capacity to fulfill the services they claim to offer. These include but are not limited to: Service Catalog, Technical Capacity, ISO compliance and regulatory compliances. Pre-approved contractors must sign a Non-Disclosure Agreement (NDA) and the Framework Collaboration Contract.

- **Identify Clients:** It is APHINN's responsibility to identify clients and offer the eco-system services catalog available. If there is interest of

collaboration with APHINN, a standard NDA must be signed with the potential clients before continuing to share sensible information.

Once the client shows interest to request specific services from APHINN's eco-system, a Framework Collaboration Contract must be signed with the client.

Once specific services are requested by a client, the following steps must be conducted:

1. Ask client for a procurement statement of work.
2. Ask client for budget.
3. Identify a short list of pre-approved and qualified partners/sellers.
4. Request proposals and quotations.
5. Sellers submission of proposals.
6. Technical evaluation of proposals and cost.
7. Select winning proposal taking into account Selection Criteria.
8. Finalize negotiations and sign Contract Addendum with seller and client.

Selection Criteria: The criteria to be considered when selecting a pre-approved contractor are:

a. Capability and capacity
b. Technical expertise
c. Adequacy with SOW
d. Product cost
e. Delivery dates
f. Financial stability

Procurement Documents:

1. Non-Disclosure Agreement (NDA): The NDA is a legal binding document that defines confidential information, states the way information must be

used, distributed and managed between two parties. It must include but is not limited to the following clauses:

a. Confidential Information
b. Confidentiality
c. Confidential Information Property
d. Non-disclosure
e. Non-reproduction
f. Protection and Defense of Confidential Information
g. Information Devolution
h. Validity
i. Material and Industrial Property
j. Sanctions
k. Jurisdiction

This document must be presented to a potential contractor when there is interest of collaboration with APHINN, but sensible information must be shared before making a binding decision. It is the first document to be signed with the contractor before continuing any further collaboration.

Copies: Contractor and APHINN must sign two copies in original of the NDA.
Archive: One copy will be kept by the contractor and the second copy will be filed in APHINN in physical and digital form.
Authorized Signature: NDA must be signed by the legal representative of each party.
Organizational Project Asset: Standard NDA template

2. Framework Collaboration Contract: The Framework Contract is a legal binding document that defines general collaboration rules among

APHINN and a contractor to become a pre-approved contractor. It must contain but is not limited to the following clauses:

a. Legal description of both parties
b. Ethical guidelines
c. Objective
d. Scope
e. Services catalog and qualifications (For Contractors)
f. Addendum Definition
g. Costs, payment and interests.
h. Documentation and communication.
i. Contact Information
j. Intellectual Property and Publications
k. Non-Competition Clause
l. Validity
m. Contract Termination
n. Contract Change Control
o. Damages
p. Jurisdiction

This document must be presented to the third party once there is a clear path for collaboration, opportunities, or contracting services have been identified.

Copies: Contractor and APHINN must sign two copies in original of the Framework Collaboration Contract.
Archive: One copy will be kept by the contractor and the second copy will be filed in APHINN in physical and digital form.
Authorized Signature: Must be signed by the legal representative of each party and two witnesses.
Organizational Project Asset: Standard Framework Collaboration Contract template.

3. Contract Addendum: This document must clearly state deliverables and results that must be obtained from any service APHINN is providing or requesting from the third party. It must include but is not limited to:

g. General objectives
h. Specific objectives
i. Regulatory guidelines
j. Ethical guidelines
k. Quality guidelines
l. Scope
m. Schedule
n. Deliverables
o. Results
p. Budget
q. Cost
r. Sanctions
s. Change requests
t. Jurisdiction
u. Responsibility
v. Success fees for team members.

This document must be developed by the business team, reviewed by the team Advisors as well as the Project Owner before being presented to the third party.

Copies: Third party and APHINN must sign two copies in original of the Contract Addendum.
Archive: One copy will be kept by the third party and the second copy will be filed in APHINN in physical and digital form.
Authorized Signature: Must be signed by the legal representative of each party.

4. **Statement of Work (SOW):** Document that defines the portion of the project scope that is to be included within the related contract. It describes the procurement item in such detail that it allows sellers to determine if they can provide services. (PMI, 2017) The SOW must contain:
    a. Detailed description of the item/service required
    b. Specifications
    c. Average volume consumed
    d. Quality requirements and performance metrics
    e. Collateral services (logistics, transportation, certifications)
    f. Coordination requirements

g. Acceptance methods and criteria
h. Performance data
i. Period of performance
j. Payment schedule, currency
k. Warranty

4.3.4.11. Plan Quality Management

Planning Quality Management is the process of identifying quality requirements and standards for the project and its deliverables, as well as documenting compliance with the requirements and standards (PMI,2017).

Quality management standards related to APHINN's projects and activities can include but are not limited to:

a. **ISO-9001:2015 Quality Management System**: This norm sets the criteria for a quality management system (ISO, 2015).
b. **Good Laboratory Practices (GLP)**: They are the recognized rules governing the conduct of non-clinical safety studies and are based on the Organization for Economic Cooperation and Development (OECD) principles to ensure the quality, integrity and reliability of the study data. (UNDP, WB, WHO, 2001)
c. **World Medical Association Declaration of Helsinki**: It is a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. (WMA, 2017)
d. **Good Clinical Laboratory Practice (GCLP):** It is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects (WHO, 2009).
e. **ISO 13485:2016 Medical Devices:** Specifies requirements for quality management system where an organization needs to demonstrate its

ability to provide medical devices and related services that consistently meet customer needs and applicable regulatory requirements (ISO, 2017).

All projects must comply with applicable quality standards and additionally should include the following components:

a. Quality objectives
b. Deliverables subject to quality reviews
c. Quality control and quality management activities
d. Tools used for the project
e. Quality metrics

4.3.4.12. Plan Communications Management

Communications management plan is the process of developing an appropriate approach for project communication activities based on the project information needs. This plan includes methods of distribution, storage, retrieval and ultimate disposition of the project information (PMI,2017).

The communication management plan must include:

a. Communication Management Approach: Interactive Method is recommended for all APHINN's projects.
b. Identify Communication Constraints: Standards, regulations, legislation or organizational policies must be considered.
c. Identify Stakeholder Communication Requirements: Normally, communication must be delivered formally through meetings or memos according to the communications matrix, but may be delivered upon special request.
d. Language for communications must be Spanish when it is the native language, and English when stakeholders have a native language other than Spanish.

e. Communication Technologies used typically are e-mail, telephone, videoconferences, face-to-face, and storage cloud where all project documentation must be archived.
f. Resources for communication available at all times are meeting rooms, Internet access, Mobile phones and laptops.

Communication requirements must be described in a communication matrix, the standard matrix for APHINN's methodology is shown in Chart 4-12. More communication types can be added if needed.

Chart 4-12 Communication Matrix

Communication Type	Objective	Medium	Frequency	Audience	Owner	Deliverable	Format
Project Assessment	Determine if proposed project delivers an innovative solution.	E-mail	Once	Project sponsor Project Owner	Technical Advisor	Memo with Project Assessment	Soft copy archived in cloud.
Feasibility Study	Determine project financial, technical and regulatory feasibility.	E-mail	Once	Project sponsor Project Owner	Technical and Business Advisor	Feasibility study with Go or No Go	Soft copy archived in cloud.
Requirement Meeting	Introduce project team and determine requirements	Face to face	Once	Project Manager Project Team Stakeholders	Project Owner	Requirement log Sprint duration	Soft copy archived in cloud
Sprint Planning Meeting	Define which items will be committed to the sprint and tasks.	Face to face	At beginning of each sprint.	Project Team Project Owner	Project Manager	Items and tasks to be achieved from sprint.	Soft copy archived in cloud
Daily Stand-up Meeting	Communicate what as been done, what they will be doing and obstacles	Face-to-face Conference (video or phone)	Daily	Project Team	Project Manager	None	None
Work Board	Show work flow and work status	Electronic.	To be modified continuously.	Project Team	Project Manager	Work Board actualization.	Soft copy in established software.
Sprint Review Meeting	Review, assembling or final deployment of project.	Face-to-face Conference (video or phone)	End of each Sprint.	Project Advisors Project Manager Sponsor *Stakeholders	Project Team	Project status sent to all stakeholders.	Soft copy archived in cloud
Sprint Retrospective Meeting	Inspect and adapt working process during the last sprint with feedback.	Face-to-face Conference (video or phone)	End of each Sprint.	Project Advisors Project Manager	Project Team	Project Updates (Risk) if applies.	Soft copy archived in cloud and sent to all stakeholders .
Requirement log Refinement	Add new items to the Requirement	Face-to-face Conference	When required	Project Team	Project Manager	Requirement log update if	Soft Copy archived in

Meeting	log, break existing items into smaller pieces or modify their priority	(video or phone)				applies.	cloud and sent to all stakeholders .

To ensure an adequate flow of information, a communication flowchart must be put into place. A standard flowchart can be seen in Figure 4-8.

Figure 4-8 Communication Flowchart

4.3.4.13. Risk Management Plan

Planning risk management defines how to conduct risk management activities for a project. It ensures that risk management is proportional to risks and project's importance (PMI,2017). The risk management plan should have the following elements:

a. **Risk Strategy**: Strategy must be defined within each project.
b. **Roles & Responsibilities:** Both Technical Team and Business Team each should assign a responsible team member to perform risk management activities.
c. **Timing:** Risk management processes should be performed throughout the Evolutionary Development Phase.
d. **Risk Categories**: Risk categories should include at least the following categorizations: technical risks, business risks, market risks, regulatory risks, external risks.
e. **Stakeholder Risk Apetite:** Stakeholder risk apetite will be recorded in the stakeholder register according to the risk probability and impact scale.
f. **Risk probability and impact scale:**

Chart 4-13. Risk definitions of probability and impact.

Scale	Probability	Impact		
		Time	Cost	Quality
High	>51%	>3 months	Defined according to project budget	Very significant in overall functionality
Medium	26-50%	1-3 months	Defined according to project budget	Some impact in key functional areas
Low	1-25%	1-4 weeks	Defined according to project budget	Minor impact on functionality
None	<1%	No change	No change	No change

g. **Risk Register:**

Chart 4-14. Risk Register Template

Category	Risk	Risk Owner	Probability	Impact Time	Impact Cost	Impact Quality	Triggers	Timing	Potential Risk Responses
Technical Risk									
Business Risk									
Regulation Risks									
External Risks									

h. **Risk Report:** A report must be emitted and sent to project team members when the status of a risk changes and must include risk register information, as well as threats and opportunities posed by the risk.

4.3.4.14. Plan Stakeholder Management

Stakeholder register contains information about identified stakeholders that should include:

a. **Identification:** Name, organization, position, contact and project role.
b. **Assessment:** Requirements, expectations, influence potential, direction of influence, phase of most influence.
c. **Classification:** Internal/External, impact, influence, power and interest.
d. **Current and Desired engagement level:** unaware, resistant, neutral, supportive or leading.

e. **Stakeholder Engagement:** Once stakeholders have been properly identified, strategies and actions required to promote the desired involvement must be put into place depending on their status.

Chart 4-15. Stakeholder register template

	Stakeholder 1	Stakeholder 2	Stakeholder 3
Name			
Organization			
Position			
Contact			
Project Role			
Internal/External			
Requirements			
Expectations			
Power			
Impact			
Interest			
Current Influence			
Influence Potential			
Direction of Influence (Upward, Downward, Lateral)			
Phase of most Influence			
Engagement (unaware, resistant, neutral, supportive or leading)	Current: Desired:	Current: Desired:	Current: Desired:
Engagement Strategy			
Required Actions			

4.3. Diagram for the Project Management Methodology

Objective: Establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.

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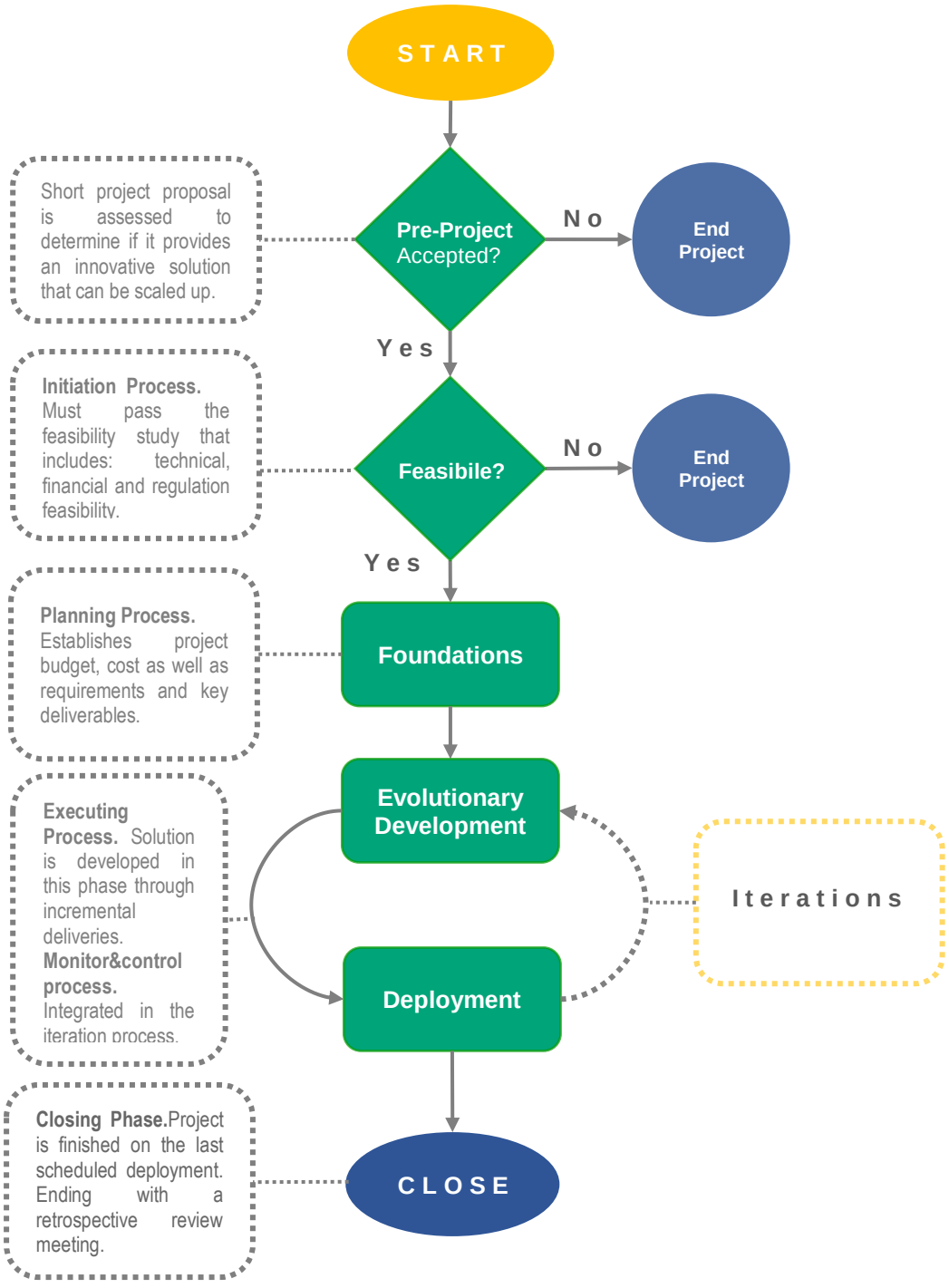

5. CONCLUSIONS

5.1. General Objective: To elaborate and document a project management methodology framework by the end of 2017, that is suitable to particular project characteristics of a health innovation and technology company for a better development of projects at APHINN.

The development of a tailor-made project management methodology is a complex task that requires a lot of time an effort to get from initiation to a working implemented methodology. In accordance to the scope of this project, only initiation and planning process groups have been developed. There is still a lot of work to be done. The Project Management Methodology must continue to be developed and expanded to all process groups, as well as implemented and evaluated. On the other hand, all the work that implies developing your own project management methodology has its benefits. It can leverage existing intellectual property, accommodate organizational culture and seek in-puts from the project management team to constitute an appropriately tailored methodology (Whitaker, 2012).

5.2. Specific Objective 1: To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.

The characterization of APHINN's projects and the matrix analyzing different project management methodologies were done based on research, bibliography and relevant information to the project. The process of analyzing, documenting and selecting the right project management methodology is complex but worth it, assuming the correct PMM has been chosen. When implementing the proposed Project Management Methodology, an issue log must be kept and later recorded into lessons

learned. Performing this task will allow, if needed, continuous improvement of the PMM.

5.3. Specific Objective 2: To create and document a Project Management Methodology Framework to be used in future APHINN's projects.

The proposed PMM was made to be specific but simple enough to allow easy implementation in different organizations. For that reason, templates and excess documents were reduced to a minimum, trying to merge the functionalities into a more specific document.

5.4. Specific Objective 3: To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.

Flowchart provides a quick reference guide of the methodology stages, but still fails to have enough detail to be a tool that aids PMM implementation. The flowchart should be broken down into stages and described in greater detail.

6. RECOMMENDATIONS

6.1. Specific Objective 1: To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.

For the purpose and scope of this project, the waterfall approach and three agile frameworks were chosen to be analyzed. The main recommendation for this objective is to continue to learn, research and integrate useful aspects of other approaches or frameworks.

6.2. Specific Objective 2: To create and document a Project Management Methodology Framework to be used in future APHINN's projects.

The main recommendation to take this objective to the next level is to further develop the process groups not covered by this project's scope. Execute, Monitor and Control, and Close process groups development will generate a lot of inputs for the proposed methodology. It is suggested that the methodology must be implemented for initiating and planning, so that issues with the proposed PMM arise and can be corrected in a timely manner. Nonetheless, it cannot be fully implemented until all the process groups have been developed.

To ensure an effective PMM implementation, based on the experience of Plewinsky (2014) for a tech company, there are several crucial steps prior to implementing. The first thing he did was to evaluate the methodology with key stakeholders and refine it with their inputs, then simulation workshops were put into place to test the PMM, which leads to a formal approval and implementation. When trying to implement, it is important to keep in mind that a training program must be offered for project managers and a PMO must support project managers in implementation. Lastly, it is very important to evaluate project methodology performance to continue to refine the processes and continuous methodology improvement.

6.3. Specific Objective 3: To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.

The recommendation for the flowchart as a quick reference guide is to establish additional flowcharts with a higher level of detail for each project phase. A complete and detailed flowchart reference guide of the proposed PMM can be a very important tool for effective implementation of a new and tailored methodology.

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APPENDICES

Appendix 1: FGP Charter

PROJECT CHARTER **Formalizes the project start and confers the project manager with the authority to assign company resources to the project activities. Benefits: it provides a clear start and well defined project boundaries.**	
Date	**Project Name:**
June 26, 2017	Project Management Methodology for APHINN –a company that invests and sells health related services and new technologies.
Knowledge Areas / Processes	**Applicacion Area (Sector / Activity)**
Knowledge areas: Integration, Scope, Time, Cost, Quality, Human Resources, Procurement, Communications, Risk, Stakeholders. **Process groups:** Initiation, Planning.	**Innovation in Health Project Management**
Start date	**Finish date**
June 26, 2017	December 22nd, 2017

Project Objectives (general and specific)

General objective:

To elaborate and document a project management methodology framework by the end of 2017, that is suitable to particular project characteristics of a health innovation and technology company for a better development of projects at APHINN.

Specific objectives:

1. To analyze with a matrix different project management methodologies to assess which characteristics best suit APHINN's needs.
2. To create and document a Project Management Methodology Framework to be used in future APHINN's projects.
3. To e
4. To establish a document with a flowchart that describes the proposed Project Management Methodology to provide future team members with a quick methodology reference guide.

Project purpose or justification (merit and expected results)

APHINN is a start-up company that accelerates health innovation processes by integrating a value chain with investment, networking, research and development (R&D), manufacturing and commercialization. APHINN's goal is to democratize access to health technology by accelerating the innovation processes. APHINN provides services to researchers, public institutions, private institutions, pharmacology industry, hospitals, biotechnology companies and other health innovation companies.

Our business model is based on a lean methodology that uses external existing capacities to provide services and generate a sustainable business environment within the health industry. This bussiness model implies that project success relies on a range of providers that must be effectively managed. For this particular reason it is a priority for APHINN to develop a project management methodology that ensures effective and efficient project management that leads to succesful completion of projects.

Description of Product or Service to be generated by the Project – Project final deliverables

1. Document with characterization of projects managed in APHINN.
2. Document with description of relevant project management methodologies.

3. Document with project management methodologies analysis matrix and assessment.
4. Document proposing a framework project management methodology for APHINN's projects.
5. Flow diagram describing proposed project management methdology.

Assumptions

It is assumed that APHINN needs a Project Management Methodology.
It is assumed that APHINN will colaborate with the current project.
It is assumed APHINN will put the Project Management Methdology in practice.
It is assumed that all the required information to perform the Project Management Methodology Framework will be available.
It is assumed that the final product will be applicable to all or most projects at the company.

Constraints

Resources: Being a startup, we are lacking of a lot of magagement information and financial resources to support the project.
Time: The methodology is limited to comply with the dates and time periods established by the UCI faculty.
Quality: Lack of project management experience could result in lower quality of the result. A limited budget could result in not being able to procure the necessary tools to conduct the project, affecting the overall quality of it.

Preliminary risks

If team lacks experience, it might not fully cover what the company needs, impacting in product quality.
If there is unexisting information, it might delay achievement of milestones, impacting in time.
If experience is lacking, we might not choose the best methodology for the company, impacting in product quality.
If product quality is poor, we might not choose to use the methodology, impcting in future time and cost for the company.

Budget

$ 100 USD
As a start-up we are working on no salary and with no budget, so it is my belief that this specific project could be done with a small budget. With the lack of information and lack of expert advice I suggest this budget considering that it might be necessary to obtain bibliography and/or payed expert advice.

Milestones and dates

Milestone	Start date	End date
Bibliographic Research of current methodologies	July 5th, 2017	August 5th, 2017
Definititon of methodology characteristics to be assessed in matrix	August 6th, 2017	August 19, 2017
Matrix elaboration	August 20, 2017	September 9th, 2017
Matrix analysis and evaluation	September 10th, 2017	September 23rd, 2017
Definition of characteristics that best suit APHINNs needs.	September 24rd, 2017	September 30, 2017
Developing methodology	October 1st, 2017	October 21st, 2017
Definition of methodology work flow	October 22nd, 2017	November 1st, 2017

Relevant historical information

APHINN is a start-up company that accelerates health innovation processes by integrating a value chain with education, funding, networking, research and development (R&D), pharmacologic manufacturing and commercialization. APHINN's goal is to democratize access to health technology by accelerating the innovation processes. APHINN provides services to researchers, public institutions, private institutions, pharmacology industry, hospitals, biotechnology companies and other health innovation companies.

There are no previous similar projects being conducted in México, but it is a developed sector in India, China and Russia.

The company is located in México and its main clients are prospected to be located in México, United Kingdom, Germany and United States.

Stakeholders

Direct stakeholders:

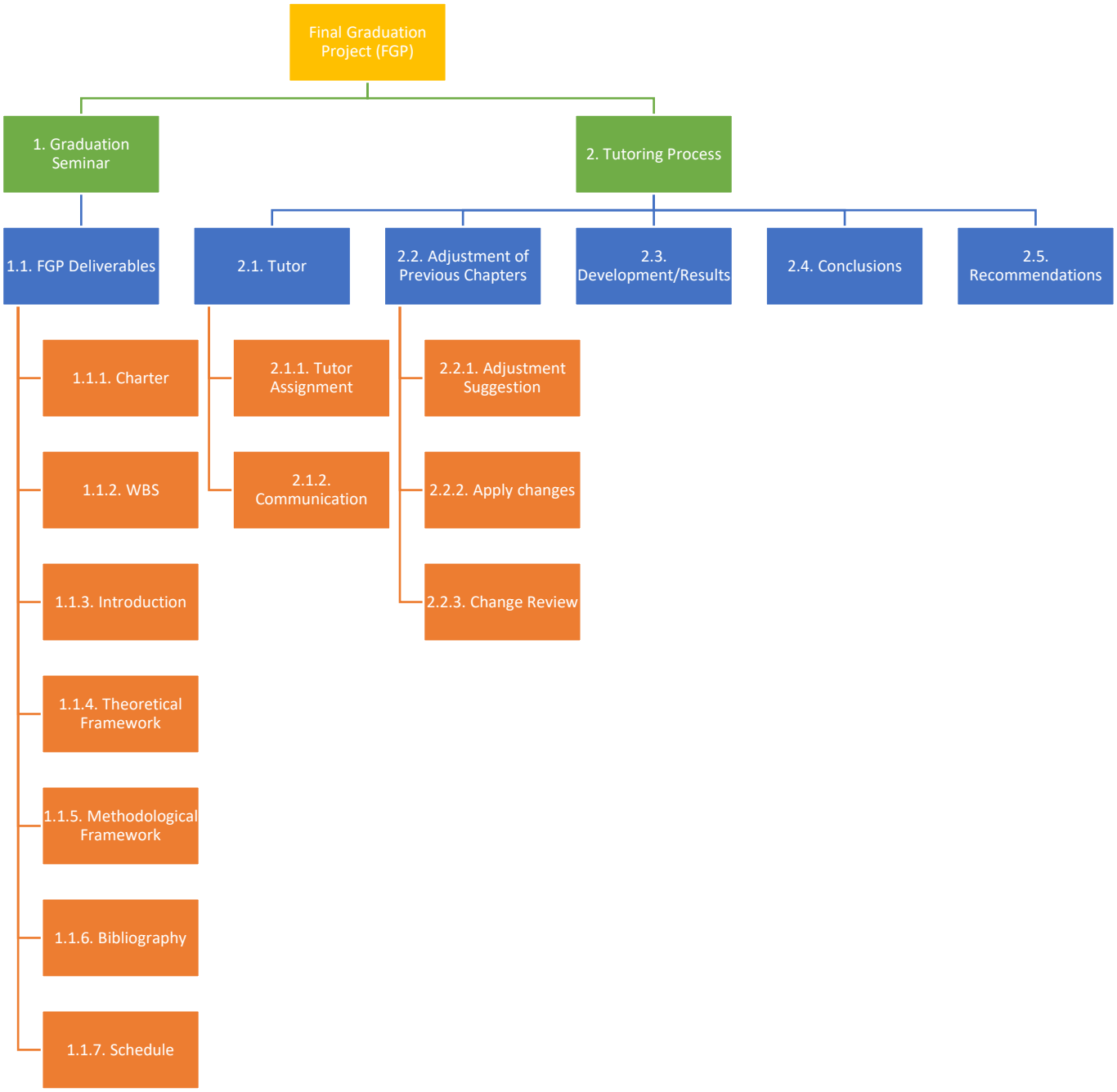
- Company CEO
- Company Project Director
- Company PMO
- Company Advisory Board

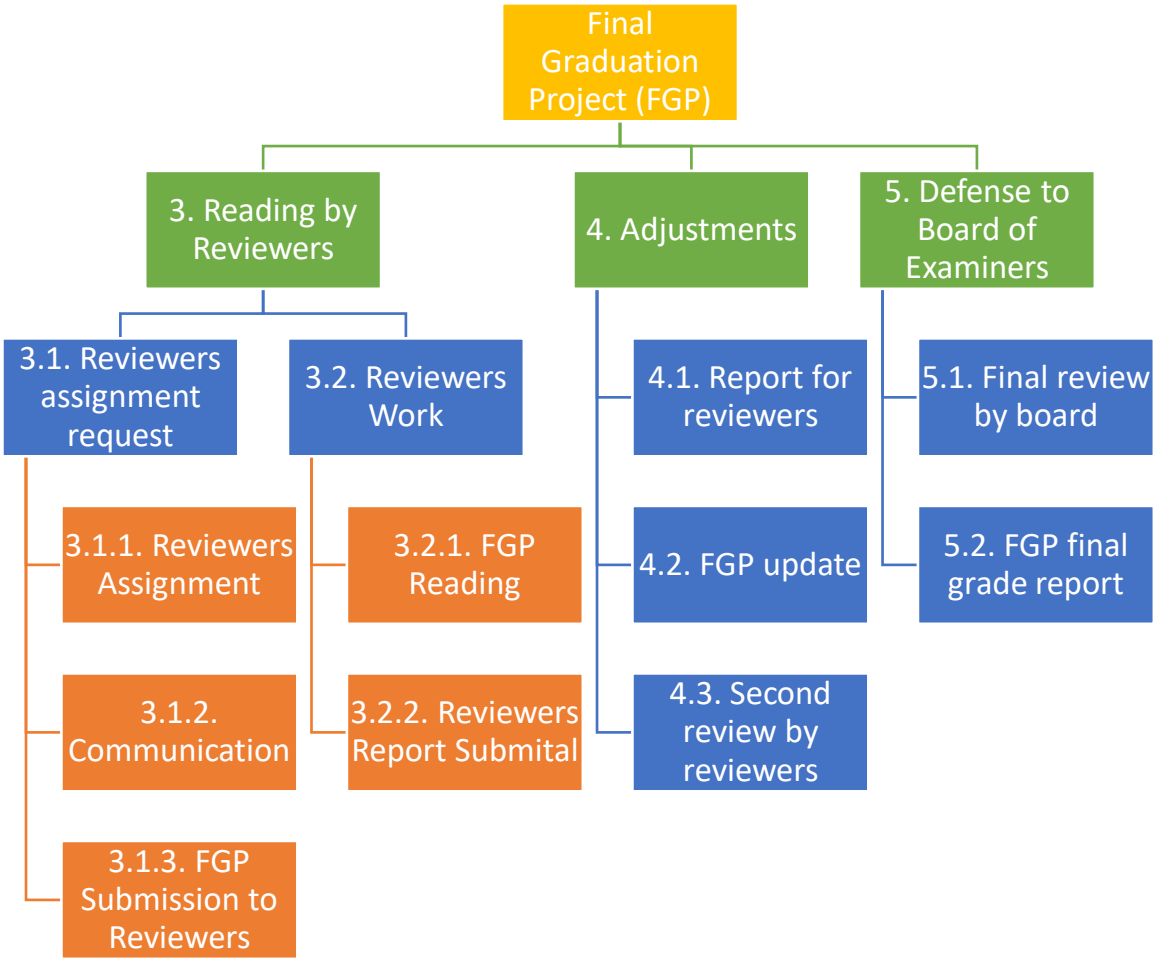
Indirect stakeholders:

- Government institutions
- Company employees
- Company project managers
- Company providers
- Company clients
- Company business partners.
- Health system users

Project Manager: **Patricia Carolina Campa Moya**	**Signature:** 
Authorized by:	**Signature:**

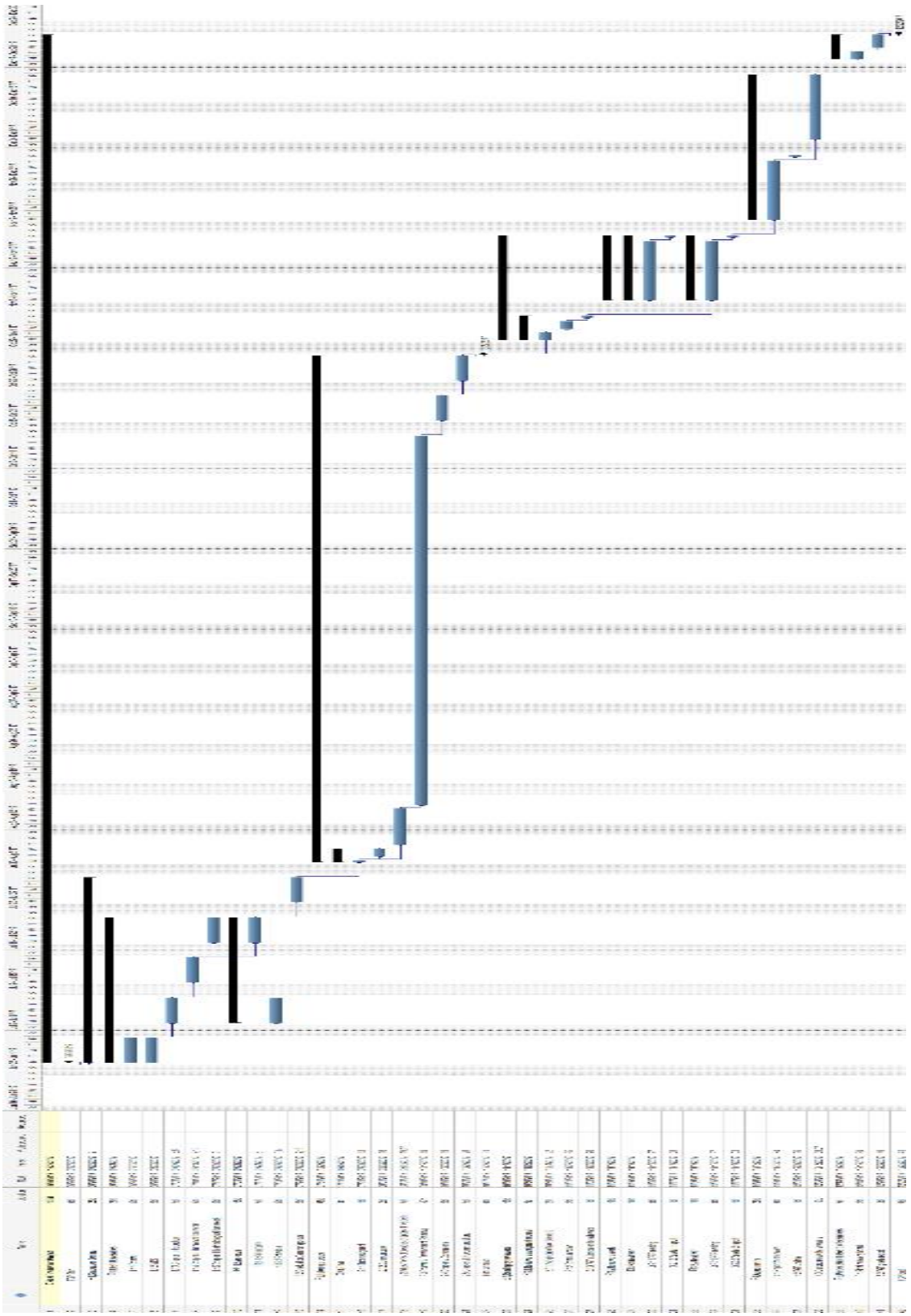
Appendix 2: FGP Work Breakdown Structure




Final Graduation Project (FGP)
3. Reading by Reviewers
4. Adjustments
5. Defense to Board of Examiners
3.1. Reviewers assignment request
3.2. Reviewers Work
4.1. Report for reviewers
5.1. Final review by board
3.1.1. Reviewers Assignment
3.2.1. FGP Reading
4.2. FGP update
5.2. FGP final grade report
3.1.2. Communication
3.2.2. Reviewers Report Submital
4.3. Second review by reviewers
3.1.3. FGP Submission to Reviewers

Appendix 3: FGP Schedule

	Name	Duration	Start	Finish	Predecessors
1	**Final Graduation Project**	**130d**	**06/26/2017**	**12/22/2017**	
2	FGP Start	0d	06/26/2017	06/26/2017	
3	**1,Graduation Seminar**	**25d**	**06/26/2017**	**07/28/2017**	**2**
4	**1.1,FGP Deliverables**	**20d**	**06/26/2017**	**07/21/2017**	
5	1.1.1,Charter	5d	06/26/2017	06/30/2017	
6	1.1.2,WBS	5d	06/26/2017	06/30/2017	
7	1.1.3,Chapter I. Introduction	5d	07/03/2017	07/07/2017	5,6
8	1.1.4,Chapter II. Theoretical framework	5d	07/10/2017	07/14/2017	7,12
9	1.1.5,Chapter III. Methodological framework	5d	07/17/2017	07/21/2017	8
10	**1.1.6,Annexes**	**15d**	**07/03/2017**	**07/21/2017**	
11	1.1.6.1,Bibliography	5d	07/17/2017	07/21/2017	8
12	1.1.6.2,Schedule	5d	07/03/2017	07/07/2017	5,6
13	1.2,Graduation Seminar approval,	5d	07/24/2017	07/28/2017	9,11
14	**2,Tutoring process**	**65d**	**07/31/2017**	**10/27/2017**	
15	**2.1,Tutor**	**3d**	**07/31/2017**	**08/02/2017**	
16	2.1.1,Tutor assigment	1d	07/31/2017	07/31/2017	13
17	2.1.2,Communication	2d	08/01/2017	08/02/2017	16
18	2.2,Adjustments of previous chapters (If needed)	5d	08/03/2017	08/09/2017	16,17
19	2.3,Charter IV. Development (Results)	47d	08/10/2017	10/13/2017	18
20	2.4,Chapter V. Conclusions	5d	10/16/2017	10/20/2017	19
21	2.5,Chapter VI. Recommendations	5d	10/23/2017	10/27/2017	20
22	Tutor approval	0d	10/27/2017	10/27/2017	21
23	**3,Reading by reviewers**	**15d**	**10/30/2017**	**11/17/2017**	
24	**3.1,Reviewers assigment request**	**5d**	**10/30/2017**	**11/03/2017**	
25	3.1.1,Assigment of two reviewers	2d	10/30/2017	10/31/2017	22
26	3.1.2,Communication	2d	11/01/2017	11/02/2017	25
27	3.1.3,FGP submission to reviewers	1d	11/03/2017	11/03/2017	26
28	**3.2,Reviewers work**	**10d**	**11/06/2017**	**11/17/2017**	
29	**3.2.1,Reviewer**	**10d**	**11/06/2017**	**11/17/2017**	
30	3.2.1.1,FGP reading	9d	11/06/2017	11/16/2017	27
31	3.2.1.2,Reader 1 report	1d	11/17/2017	11/17/2017	30
32	**3.2.2,Reviewer**	**10d**	**11/06/2017**	**11/17/2017**	
33	3.2.2.1,FGP reading	9d	11/06/2017	11/16/2017	27
34	3.2.2.2,Reader 2 report	1d	11/17/2017	11/17/2017	33
35	**4,Adjustments**	**20d**	**11/20/2017**	**12/15/2017**	
36	4.1,Report for reviewers	9d	11/20/2017	11/30/2017	34
37	4.2,FGP update	1d	12/01/2017	12/01/2017	36
38	4.3,Second review by reviewers	10d	12/04/2017	12/15/2017	36,37
39	**5,Presentation to Board of Examiners**	**5d**	**12/18/2017**	**12/22/2017**	
40	5.1,Final review by board	2d	12/18/2017	12/19/2017	38
41	5.2,FGP grade report	3d	12/20/2017	12/22/2017	40
42	FGP End	0d	12/22/2017	12/22/2017	41



Appendix 4: Revision Dictum

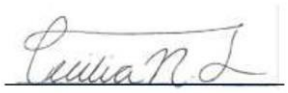
Certificate of Accuracy

México City, México

December 16, 2017

To whom it may concern:

I, Cecilia Noriega Trujillo, have thoroughly reviewed and edited the **Final Graduation Project** written as a partial requirement for the **Master in Project Management (MPM) Degree** at Universidad para la Cooperación Internacional by **Patricia Carolina Campa Moya**. I have been awarded the degree of Bachelor of Arts in English Language Teaching by Universidad de Sonora (ID number: 10647473), and being proficient in the English language, I hereby attest that to the best of my knowledge, ability, and belief, this is an accurate document in terms of grammar, spelling, and punctuation.



Cecilia Noriega Trujillo
B.A. in English Language Teaching

Certification Credentials may be verified online.

https://www.cedulaprofesional.sep.gob.mx

La Universidad de Sonora

Otorga a

Cecilia Noriega Trujillo

el título de

Licenciada en Enseñanza del Inglés

en virtud de haber cumplido con los requisitos establecidos en la reglamentación respectiva, según documentación que obra en los archivos de la Universidad.

Firma del Interesado

Hermosillo, Sonora, México, 2 de noviembre de 2014

"El Saber de mis Hijos hará mi Grandeza"

Dr. Heriberto Grijalva Monteverde
Rector

M.C. María Magdalena González Agramón
Secretaria General Administrativa

Dra. Armida Guadalupe García de León Peñúñuri
Vicerrectora, Unidad Regional Centro

La Dirección de Servicios Escolares de la Universidad de Sonora hace constar que;
el presente título esta basado en el Acta elaborada el.
16 de octubre de 2014

misma que quedó registrada en el libro 2, foja 261.

Hermosillo, Sonora, 7 de noviembre de 2014

"El Saber de mis Hijos Hará mi Grandeza"

Dra. Amina Marín Martínez