DEVELOPING AN APPLICATION TO REPORT ADVERSE DRUG EVENTS (ADEs) TO HEALTH REGULATORY AUTHORITY OF USA BY PRACTITIONERS
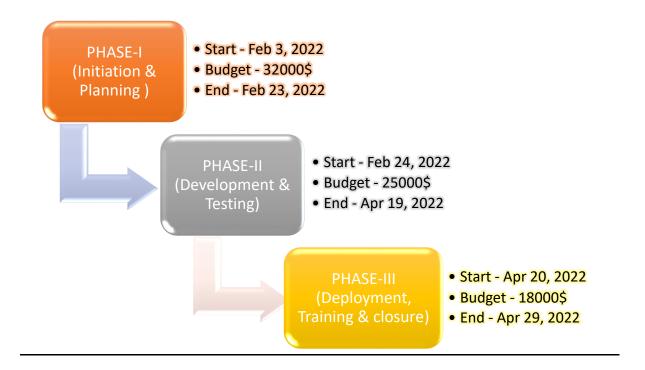
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Project Overview:

Adverse drug events (ADEs) are undesirable outcomes of pharmaceuticals that cause harm to patients. It's critical to keep track of ADEs on a regular basis in order to plan for their management. Pharmacovigilance, as defined by the World Health Organization, is the branch of science that studies ADE activities such as monitoring, evaluation, interpretation, and mitigation of adverse effects or any other medicine/vaccine-related concern. Even if a pharmaceutical product's safety profile is defined during its testing stage in clinical trials, some unwanted effects are impossible to detect unless the product is used by a broad group of people. As a result, every country's health authority, such as the United States Food and Drug Administration (USFDA) in the United States, the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, and others, requires that ADEs be monitored and reported within a certain time frame after finding. For accurate ADE reporting, regulatory authorities established various regulations and requirements that must be followed. Consumers were given the choice to opt out of reporting, but health care professionals were required to report. The ability to assess potential signals and plan for their prevention is made possible by efficient and accurate reporting of ADEs to regulatory authorities. This helps to improve public health.

With the aim to improve the reporting of ADEs by healthcare professionals of IU Health facilities to USFDA, we developed a mobile application that is compatible with both Android and IOS software. We integrated our new app with an in-house Electronic Health Record (EHR) system to cut down on the time it takes healthcare providers to enter the required information from patient data.

We divided the project into three phases and set aside money for each. The mobile application for ADE reporting was designed, created, tested, and eventually deployed by us. We gave healthcare personnel training on how to use the mobile app. Users of the app also gave us positive feedback. We were successful in completing the project on time and under budget.Finally, we completed the project by achieving our project aim of increasing ADE reporting compliance.

| PHASE-I (Initiation & Planning) | • Start - Feb 3, 2022
• Budget - 32000$
• End - Feb 23, 2022 |

| PHASE-II (Development & Testing) | • Start - Feb 24, 2022
• Budget - 25000$
• End - Apr 19, 2022 |

| PHASE-III (Deployment, Training & closure) | • Start - Apr 20, 2022
• Budget - 18000$
• End - Apr 29, 2022 |

Initiation:

Initiation is the preliminary stage toward successful project completion. The project's ultimate goal is to create a mobile app that allows doctors to report Adverse Drug Events (ADEs) to the US Food and Drug Administration. The project charter is critical because it outlines the stated objectives and aids in the formation of the appropriate team to work on the deliverable. The identification of appropriate stakeholders and teams to construct the mobile application is our initial deliverable. Following this, the requirements are described, the project budget is created, the milestones are defined, the challenges are identified, solutions are developed, and an effective communication strategy is established throughout the project. The importance of ADE reporting in reducing future complications and enhancing prognosis is undeniable. Clinicians can easily document adverse occurrences because of the initiative's connectivity with in-house EHR systems. IU Health has been highlighted as a significant client. Because the EHRs are well-organized and the patient base is big, the majority of people will profit from this effort. This clarifies the criteria we used to choose the stakeholders.

As there are interdependencies on each other to move the project forward in the appropriate direction, establishing a harmonious connection among the stakeholders and working team is crucial. Regular meetings to review progress and the next course of action are vital to the project's success. These tasks involve taking into account all stakeholders' ideas and opinions, determining scope, designing the project, devising strategies, scaling the project at various phases, and planning the release. We have reviewed and conducted meetings with US Food and Drug Administration to learn more about the MedWatch program and to better grasp the guidelines so that we could

draft and implement our application more effectively. Following all these streamlined steps, the strengths and weaknesses of the project are outlined along with the important milestones and dates to be accomplished. We aimed to develop and integrate the application with EHRs by April 29th, 2022.

Project Monitoring and control:

Keeping exact, convenient data in view of the projects result and related documentation. Keeping precise, optimal information considering the endeavor's outcome and related documentation.

Project Management programming for WBS Diagram-

WBS is one of the important project management tools that the board assists you with deciding the scope of work. This free device partitions the project work into individual parts which are really planned.

WBS is a tree-Liked and the general errands are on the top, and the different areas are displayed under it. The parts in WBS are connected to each other by using boxes and are categorized under appropriate headings like initiation, planning, predicting risk management etcetera. Management Software for WBS Diagram or Work Breakdown Structure.

Utilize a Work Breakdown Structure (WBS) to separate a project into little units of work, or sub-errands. This makes the work simpler to oversee and assess the work. This empowers more straightforward location of issues, monitors the task, and takes into consideration simpler advancement confirmation. It likewise keeps colleagues from feeling over working.

Concerning the extent of this interaction, checking and control is applied to yet not restricted to overseeing and controlling task works and risks, quality control measures, project execution in the whole lifecycle, controlling project, and the board of control of progress all through the project lifecycle. It's vital to figure out how a task's performing and whether it's on time, as well as carry out supported changes if necessary. This guarantees the project stays on target, on financial plan and on time. Using monitoring and assessment instruments gives you clear information that can be essential while distinguishing flaws in the project. It can likewise assist you with distinguishing amazing errors that could stop by. With the outcomes, additional opportunities can be experienced thus you ought to invest more energy zeroing in on the ongoing things and additional opportunities to try not to lose the newer upcoming projects that are yet to come.

Without appropriate monitoring and assessment, you can undoubtedly lose the trust of stakeholders.

Work execution information is a result of the direct and oversee project work process where the information is gathered, examined, and incorporated to deliver work execution data for giving a sound groundwork to pursuing task choices. With the presentation data, the task supervisor can acquire information on status expectations, execution status for change demands, and give assessed opportunity to finish.

Project Documents Updates

Project records that might require refreshing include:

•Timetable and Cost Forecast

•Work Performance Report
•Issue log
Monitor and control the project work process is crucial to meet the desired outcomes of the project
Cost Control
Without a doubt, project cost control is a significant checking and control part of any task. Also, acquired esteem the board technique works with simple appraisal of project cost execution. It principally utilizes Cost Variance (CV), Cost Performance Index (CPI) and Variance at Completion (VAC) to lay out cost fluctuations.
In any case, there are associations that don't carry out procured esteem the executives' procedures. In this way, these associations execute methods that track genuine expense set up for work bundles or on different projects market. Hence contrasting real expense planned priorly and supported spending plan gives the expense difference.

Project planning steps:

1. Make a business case and analyze it.
2. Stakeholders for Approval should be identified and met.
3. Define the scope of the project.
4. Determine the project's goals and objectives.
5. Determine the project's outputs
6. Make a timeline and milestones for the project.
7. Tasks are assigned.
8. Conduct a risk assessment

The business case explains why your company needs to complete the project. It should indicate how the problem will be remedied, such as a lack of return customers or a day longer supply line than competitors, and how much money will be gained by the business once the project is completed.
The scope of project is a description of what it is and isn't trying to accomplish. To avoid "scope creep," or resources flowing towards something that isn't in line with your project's aims, you must define the bounds of your project.
The goals and objectives for project will be based on the business plan's initial objectives. At this stage, you'll hone in on the original broad concepts and write them down in a project charter to serve as reference points as your project progresses.
The tangible outcomes of project are known as deliverables. Choosing what these deliverables will be and who will be accountable for both producing and receiving them is one of the most critical project planning steps.
Project schedule is a crucial document that details when certain project tasks will begin and end, as well as critical measurement milestones. It will be used to track the progress of the project. All stakeholders will have access to it, and it should be followed as closely as feasible.

Everyone on team should understand their responsibilities and who oversees project pieces. Any ambiguity about roles and duties on team should be eliminated by clearly assigning tasks.

A functional risk management plan necessitates a thorough review throughout the project's planning stage. All potential risks, as well as their potential impact on the project and chance of occurrence, should be assessed.

Project Execution:

They are the concrete outcomes and expectations that our efforts deliver. We ensure that the deliverables are thoroughly tested, satisfy the acceptance requirements, and are accepted by the customer and/or business sponsor as part of the execution process. In comparison to the other stages, this is the project's longest and most labor and resource-intensive stage.

The main goal of project execution is to create and generate the project's planned deliverables, which must be delivered on schedule and within budget, while also meeting the agreed-upon scope and meeting client quality standards. The significance of finishing the project execution phase successfully cannot be emphasized. The goal of the deliverables is to finish the tasks outlined in the project management plan to fulfill the deadline.the project's specifications the project deliverables are the main reason for the project's completion. The plans should be followed to the letter, with as little variation as feasible. Everything is the same. It all comes down to taking action and moving forward.

The project deliverables are the main reason for the project's completion. The plans should be followed to the letter, with as little variation as feasible. It all boils down to acting and moving forward. The chances of meeting the project's aim rise as you meet the deadlines for the deliverables.

Execution helps to start the project by kicking it off, forming a project team, and putting the plan into action. The execution phase includes holding progress meetings, updating project schedules, and management plans, quality control, approval of deliverables, and completion of the implementation phase evaluation. The project manager's job is to organize the project's many stages into deliverables that can be completed and measured at regular intervals to improve the final product's outcome.

The Work Breakdown Structure, which is a hierarchical breakdown of work tasks, was also used to define the app development stages, Gantt Charts were used to identify the project's start and end dates, as well as the task and durations, to comprehend the connections or interdependencies between all the tasks, and to see who is on each project's project team and who is working on each task separately. The Project Evaluation and Review Technique, or PERT, is a type of Network Diagram PM tool that is also used to determine the project's critical path. This method simplifies the scheduling of complicated projects while still generating realistic duration estimates for each task. Critical path management is a critical instrument that project managers rely on heavily. The goal of project documentation is to bring all of the work we've covered so far together in one

document. They were designed to eliminate any project-related ambiguity and to avoid any stakeholder conflict over the project's status.

What percentage of time was used for the execution phase of your project?

About 55% of our time was invested in the execution phase of the project.

Project Closing

According to the CDC, older adults are nearly 7 times more likely than younger persons to be hospitalized due to an emergency and that could be lowered if the drugs that they have been administered were monitored carefully (CDC, 2017). This project was born after these facts and as a result, this project summarizes a constant effort to provide a substantial and ground-breaking possibility for patients, authorities people in the field and our society to prevent people for being harmed by a medicine.

Allowing people from different backgrounds to come to a point where all the time and efforts were conducted into the same direction has been a challenge. But there is always this satisfaction about completing a project knowing that this would represent a change in the way doctors, patients, governmental agencies and people in the field can monitor Adverse Drug Events (ADEs) based on this project represents a great opportunity prevent diseases and potentially save lives in the future while making it easier to all stakeholders to contribute to the project and replicate the mobile application and submission in a digital format in other hospitals, states and potentially other places over the world. Having access to this kind of information shows that we are looking to make the world a better place for the people that surround us.

There is no other simpler system that represents this change on our field that we have record of. And even though some challenges have been faced, we are excited to see how the project has evolved to turn into the results that we can see at this point after six months of planning, analyzing risks, getting ideas and feedback from sponsors, experts on this field and people that will be using the app, we have concluded that the importance of working on people from different backgrounds, points of view, priorities and objectives has made this project stronger.

During this time, the goal of making a project with this relevance has implied having a significance for all the people involved, starting from The Sponsors, Team members, Contractors, Users, and people that have helped with their input, time, and effort to make sure that this project were going into the right direction. We can conclude that most of the deadlines were completed on time, that we did not overpasses the budget, and that the issues that we faced as a team were properly addressed on time with the expertise of our Management Team and the gentile observations of out sponsors and senior contributors.

Even though most of the goals of the project were adequately taken into account, It is expected for this project to grow in a second and maybe third phase with the help of the people involved in this project, contributing with issues on compatibility with other mobile devices, general maintenance of the platform to be sure that it keep working properly on the rest of the operating systems out there in the market (Android, iOS, Windows) and with the authorities involved in the

correct use, distribution, use and marketing of the information provided. All these goals were not considered into this phase, but they should be in the following stages to help with the correct application and development of the project for future acknowledgement.?

References:

Centers for Disease Control and Prevention. (2017). *Adverse Drug Events in Adults | Medication Safety Program | CDC*. Cdc.Gov. Retrieved April 29, 2022, from https://www.cdc.gov/medicationsafety/adult_adversedrugevents.html#:%7E:text=An%20a dverse%20drug%20event%20(ADE,as%20often%20as%20younger%20persons.