PROJECT SCOPE STATEMENT

PROJECT TITLE: Developing an application to report Adverse Drug Events (ADEs) to health regulatory authority of USA by practitioners	
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PROJECT JUSTIFICATION:	Adverse Events Reporting System is critical for recognizing, assessing, and reporting medication and supplement-related adverse events. Therefore organizations in the healthcare and life sciences industries must clearly outline how adverse events will be tracked and reported. Our idea allows reporting of ADEs to United States Food and Drug Administration (USFDA) MedWatch program, by integration of the application with an in-house EHR system to make it easier for healthcare providers to report adverse events. USFDA relies on ADE reports as one important way to help identify and better understand the risks associated with the medical products. Receiving higher-quality reports in timely manner allows USFDA to immediately detect and respond to warning signals and public health issues. These reports, when combined with data from other sources, can give vital information that contribute to greater patient safety.
PRODUCT DESCRIPTION:	The mobile application for reporting ADEs is developed to create documentation of the adverse drug reactions (ADR) reported by the patients to the clinicians. This app facilitates ease of reporting ADRs to USFDA by the clinicians instead of wasting copious amount of time of the patient filling forms to report ADRs. The documented proofs are utilized in future to take precautionary measures to minimize the occurrence of these ADRs while prescribing the treatment regimens. In addition to this, the software used in the application is user friendly as it can be integrated with the available in house EHR systems. The convenience and compliance of reporting ADEs is made comfortable to physicians with the help of this application as it can be accessed through mobile phones and electronic tablets as well.
PROJECT DELIVERABLES:	• Designing and development of mobile application which is both compatible for IOS and Android for reporting the ADEs to USFDA MedWatch program. • This mobile application help healthcare professionals to report ADEs quickly and efficiently. • It also helps in measuring ADE incidence by creating a database with all the ADEs reported in specific time.
OUT-OF-SCOPE ITEM:	• This application is only for the use of physicians and not for

	the usage of other hospital staff, patients, and other personnel. • This mobile application is developed only to report ADEs following drug administration, and which are reportable to MedWatch program of USFDA. Other ADEs related to vaccine, medical devices and veterinary products are out of scope as of now.
PROJECT OBJECTIVES:	• To design, develop, and release an IOS & Android compatible mobile application to report ADEs to MedWatch program of USFDA by 19th of April 2022. • In the next 10 days, educate and encourage HCPs to use the application, thereby reducing the burden of work by 70% with the use of new application instead of regular paper-based reporting. • Improving the regulatory compliance of ADR reporting to 95% by Apr 29th, 2022.
COST OBJECTIVES	• The cost of planning and collection of information required for developing a mobile UI is estimated at 8000$. • Designing and Development of mobile application costs 25000$. • Integrating the application with EHR and communication platforms costs 15000$. • Testing the mobile application for total of 7 cases costs 9000$. • Troubleshooting and production deployment of the app in both IOS and Android platforms costs 5000$ • Training the physicians on the usage of mobile application costs 3000$. • Monitoring the usage of app by using cloud watch, Splunk, and Nagios tools costs 10000$.
SCHEDULE OBJECTIVES	• To identify data fields required for reporting from MedWatch form and in-house EHR system by 23 Feb 2022 for designing app User Interface (UI). • Building backend, front end, and UI elements of app by 06 Apr 2022 to develop an application. • Integration of the app with EHR and communication platforms Gmail and Outlook by 13 Apr 2022. • Testing the performance of mobile app by reporting one dummy report for each type of case (7 reports) and

	troubleshooting errors, if any by 17 Apr 2022. • Launching the application on IOS and Android platforms on 19 Apr 2022. • Training provided to physicians at IU hospitals on how to use the app by 21 Apr 2022. • Monitoring the ease of use and time taken by physicians to report an ADE using mobile app and comparing it with the previous process of paper submission. • Closure of the project by 29 Apr 2022.
ACCEPTANCE CRITERIA	• Quality of the application should be at least 98% i.e., it should work as expected for 98 cases out of 100 without any huddles. • Procuring required resources, planning, implementing followed by testing and production within the time of 3 months. • The project fall under the cost budget provided.
CONSTRAINTS:	• A time restriction is the completion of scheduling, as well as the deadlines for each project and its phase. The final delivery date must be determined. To overcome the time limitation, adequate planning and scheduling of time-bound tasks is required. • The scope limitation relates to particular goals, deliverables, features, and functions in addition to the activities necessary to complete the project. • The project's budget covered all the financial resources needed to complete it on time. You must evaluate not just the cost of materials, but also labor, suppliers, quality control, and other factors.
ASSUMPTIONS:	Resources: • Access to IU Health care patient and drug database should be guaranteed with the respective legal restrictions. • Access to in-house EHR to keep a digital copy of the patient's details over time. • Stakeholders will be able to test the mobile app while (but not limited to) Phase 2 and Phase 3 are in progress. • Access to licenses and tools such as Cloud watch, Splunk and Nagios are guaranteed. Legal: • All documentation to be able to access all databases will be

	provided by IU Health with all restrictions and limitations this includes before the start of the project. Delivery: • Project servers arrive configured as expected. • The mobile app will be designed to link with internal and external databases but no changes on the databases themselves will be handled within this project. Budget: • Project costs will stay the same as initially budgeted. • 10% of the cost of the original budget will be considered for unexpected changes on the project itself. • Training will be conducted internally with no additional training costs incurred. • Maintenance and customer support should be provided internally after project completion. Finances: • Funding for all licenses, training and deployment will be provided by IU Health and sponsors. • Funding for inspection on a regular basis will be provided. Scope: • The project scope will not change once stakeholders sign off on the scope statement Schedule: • All phases included on the project will be conducted as planned within the project schedule. Methodology: • Project will follow waterfall methodology throughout execution. • Project will follow team governance guidelines and requirements. Architecture and design: • The solution will utilize REST API architecture • The solution will reside in an offsite cloud • App will be available for iOS and Android