OpenClinica P20 WIN Software Development Lifecycle (SDLC) Methodology

Document Summary

This document outlines the Software Development Lifecycle (SDLC) Methodology that will be used by the P20 WIN OpenClinica team. The team will be fully committed to ensuring that the project is well managed, staffed with the appropriate team members, and that the work products in the SOW are delivered on time and to the specifications required. The project will receive the proper oversight from the executive team at OpenClinica.

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Revision History

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1 Software Development Lifecycle (SDLC) Methodology

OpenClinica will complete the project using the methodologies of the Agile Unified Process (AUP) framework. AUP is a well-established and highly-regarded management and software development methodology and is particularly well-suited to this initiative given the nature of the tasks in the SOW.

With AUP, the development process occurs along four serial phases: Exploration (Inception and Elaboration), Construction, and Transition. Each phase is organized into a series of short, fixed-length, mini-projects called iterations, with each iteration including its own set of requirements analysis, design, implementation, and testing activities. The outcome of each iteration is a tested, integrated, and executable system.

In AUP, the following principles are used to shape and define the project schedule and development cycle:

- Tackle high-risk and high-value issues in early iterations
- Continuously engage users for evaluation, feedback, and requirements
- Build a cohesive, core architecture in early iterations
- Continuously verify quality; test early, often and realistically
- Manage requirements carefully
- Practice change request and configuration management

This approach to the software engineering process delivers the following benefits:

- Early rather than late mitigation of key risks (technical, requirements, objectives, usability)
- Early visible progress
- Early feedback, user engagement, and adaptation leading to a refined system that more closely meets the real needs of the stakeholders
- Better management of complexity. The development team is not overwhelmed by “analysis paralysis” or very long and complex steps.
- Lessons learned in an iteration can methodically be used in subsequent iterations to improve the overall development process.

In our view, AUP provides an ideal framework for rapid progress on the project. Using this methodology, the team will be able to productively tackle multiple activities in parallel. The high quality of the products we produce using this methodology will be ensured by the following:

- Ongoing stakeholder involvement
- Availability of concrete work products for evaluation and feedback
- Adherence as a core principle to test-driven design
- Use of appropriate strong project management tools and controls
Effective project management is a vital ingredient of the AUP process, and will be critical in this case to ensuring the success of the project. Accordingly, OpenClinica will assign an experienced, qualified project manager to this effort.

The project manager is responsible for ensuring on a daily basis that the development and adopter teams have the resources, tools, and information needed to perform their work effectively. The project manager’s aim here is to address vital (but non-core) institutional issues and to ensure that any obstacles to progress that can be addressed are addressed and removed. In this capacity, the project manager is able to reduce most of the accidental complexity inherent to projects and in this way to free team members to focus the bulk of their attention and time on core business, functional, and technical issues. This approach, we believe, leads to higher productivity, quality, and morale, and is an effective method for controlling costs and risks.

In addition, the project manager will be responsible for conducting the full range of standard project management activities. In particular, the project manager will take the lead on the following tasks:

- Developing and updating the project management plan, tracking the team’s progress against this plan, and reporting on progress and variances to the stakeholders.
- Developing an effective communications plan, ensuring that the plan is being followed, and taking any additional required steps to ensure that all relevant project matters and issues have the necessary visibility and are receiving the requisite attention from project members and stakeholders.
- Using a structured risk management plan to identify and address project risks and issues.
- Overseeing staffing and ensuring strong and productive team dynamics.
- Reviewing work products and ensuring that all deliverables meet the required quality standards.

1.1 Communications

Full and open communications is vital to the success of this project. Upon contract award, OpenClinica will establish clear liaison channels between our team, the pP20 WIN leadership and other key stakeholders. In addition, as one of top priority tasks, we will develop a communications plan and will submit this plan for review and approval. In developing our comprehensive communications plan we will consult closely with the key project stakeholders to determine the best schedule, approach, and media for communicating project information. We anticipate using a combination of face-to-face meetings, teleconferences, web and email-based communications methods.

1.2 Stakeholder Involvement

Managing stakeholder involvement is critical throughout the course of the project, particularly so in the processes of requirements gathering and analysis, adopter implementation, and user acceptance testing. This work encompasses activities such as collection of requirements and needs from the stakeholders, provision of draft design artifacts for review and comment by the Client, and correspondence related to Review and Delivery activities.

The two most critical factors of success in the area of Stakeholder Involvement are 1) Making sure communication is open, engaging, and efficient; and 2) balancing the need for comprehensiveness and consensus with a bias for action that will enable for on-time delivery. In both cases, proactive engagement of the community will be critical. The team will combine broad requests for information/feedback with involvement of specific individual stakeholders who have shown the capability and willingness to contribute meaningfully to solving challenges in the health information problem domain. In all cases, the team will produce correspondence that includes specific action items and a timeline for those items to be fulfilled. The stakeholder communications approach will allow measurable progress while still enabling open, stimulating discussion of the problem domain and exploring innovative solutions with the stakeholders.
The stakeholder involvement process benefits from conceptualization of the domain in use cases, UML models, and working prototypes. These initial models serve to quickly identify the boundaries of the system, the stakeholders, the key use cases, and any assumptions about the proposed solution. These early concept models are not necessarily considered system specifications, but serve as the basis for effective discussions with team members and stakeholders to iteratively refine the software requirements and risks.

A key early product of stakeholder involvement will be a Vision and Scope document, which will serve as a brief introduction to the system, a synopsis of key features, and to define the short-term and anticipated long-term capabilities of the system. A key reason we utilize an Agile methodology is that it allows us to put fully functioning versions of the system in the hands of the stakeholders very early in the development lifecycle. We will deliver a fully functioning version of the system, a release to verify that the project manager, developers and stakeholders agree on the solution. A release will typically happen at the end of each development iteration or a group of iterations. During the Construction phase, releases will be maintained and updated as needed, such that the stakeholders and developers can review progress and changes, thereby mitigating risk and fostering involvement and awareness.

1.3 Risk Management

Risk management is critical to the successful execution of every project, since risk is inherent to all projects. Recognition of this fact and development of appropriate mitigation strategies can minimize the impact of known risks and moderate unexpected risk to the project. During this project, the team will use a standard risk management model. The key elements of this model include the following steps:

- Identifying risks
- Qualifying risks
- Quantifying risks
- Developing a risk response plan
- Monitoring risks
- Communicating the project risk list and response plan to the appropriate stakeholders.

The project manager will lead the risk identification, qualification, quantification, monitoring, mitigation, and control effort for the project. As part of this update task, appropriately identified risk mitigation and risk contingency activities will be incorporated into the Project Management Plan as necessary for risks that meet thresholds that are along the project critical path to completion.

1.4 Quality Assurance and Delivery

The OpenClinica team is committed to delivering high quality work products. We will prepare and submit a comprehensive Testing Strategy Plan and Quality Assurance Plan designed to meet the needs of this project as supplements to our Project Management Plan.