



21 CFR Part 11: Electronic Records. An Interactive Voice Response System. Case Study for Success

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Summary

A large full-service clinical research organization in the US needed to replace their legacy interactive voice response system which did not provide 21 CFR Part 11 compliant audit trails. They chose to custom-build the new software using C++ component architecture, eXtensible Markup Language (XML), Hypertext Markup Language (HTML), and Microsoft web telephony engine. The case study described in this article illustrates that when systems developers read, study, understand, and embrace 21 CFR Part 11 before designing and validating their product, the regulations are easily met. Copyright © 2002 John Wiley & Sons, Ltd.

Key Words

21CFR Part 11; electronic records; interactive voice response (IVR) system

Case Study Situation and Problem Analysis

The existing interactive voice response (IVR) system delivery time at a large full-service clinical research organization was 8–10 weeks for each clinical study, and sometimes longer. Set-up

of the IVR system was on the critical path to study start-up, which made set-up time visible to the sponsors, project leaders, and all other stakeholders. Study leaders demanded improvements in the cycle time for study start-up and, at the same time, competition in the industry was dictating a requirement for faster cycle time for IVR system delivery.

Most staff members at the clinical research organization stated that the reason for the lengthy configuration time for the study system delivery was due to a documentation burden created by validation and quality assurance (QA). The organization saw validation as an 'add on' of 'documentation for documentation's sake'. The organization's management stated that validation was unnecessary bureaucratic overhead. Systems users often quoted documentation as major factor in delays in the delivery of any system. However, management saw the underlying root cause problem was not the documentation itself, but the inconsistent and constantly changing requirements.

The systems users did not understand the systems life-cycle and the importance of requirements specifications in software development and test processes and thus did not devote the necessary time to develop a stable set of specifications and requirements before the system was implemented for the first time. Each change to the specifications required revisions to the systems documentation and subsequent approvals by all the stakeholders. The systems developers began to feel that they were in a recursive loop which prevented them from constructing the system solutions the studies required.

Multiple changes to the system and system requirements were occurring after the implementation of the IVR system. Over the course of time,

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inconsistent and changing requirements created a situation in which the legacy system became unreliable and unstable. The legacy system architecture did not support the number of frequent changes. Further, when investigators complained of problems occurring during the calls, the problems could not be reproduced or easily diagnosed. The legacy system did not provide any type of call log and did not provide 21 CFR Part 11 compliant audit trails. Thus the legacy system did not provide the ability to track, recreate or research problem calls from study sites. The legacy system required replacement, as remediation would not achieve 21 CFR Part 11 compliance.

Background and Approaches to the IVR Replacement Project

The targeted use of the new IVR system was primarily investigator study sites for acute care trial enrollment. There was a high need for system stability, reliability, and responsiveness due to safety considerations for patient enrollment in acute care trials. The need for data security, integrity and accuracy was also high.

Before the new software development project began, software validation training was provided to the Information Technology (IT) staff and to the key users (i.e. pharmacists, clinical project managers and data managers). The entire IT staff attended extensive training in software validation, but not all the key users chose to participate in the training due to other priorities. In addition, a new software developer was hired for the development project and the developer was instructed to read the applicable guidelines and regulations in-depth and was formally trained on 21 CFR Part 11 before the system project was initiated.

The software development team consisted of an experienced project manager and one software developer. The choice for a small team was a deliberate choice because, management felt with a small team, the personal accountability would be high resulting in a high-quality product. The team studied the documentation concerns and determined that the following life-cycle docu-

ments were required for the delivery of each study-specific IVR system:

- script branches for voice responses,
- text to be recorded for voice messages,
- study specific randomization scheme,
- requirements specifications,
- design specifications,
- test plans/scripts,
- test execution results,
- training guides for investigator study sites.

The project manager felt that it was critical to consider whether there would be some gain in efficiency if the new system aided in the automated generation documentation of the IVR system requirements and specifications, thus speeding the delivery time of the IVR application. After understanding the requirements for each of the validation methodology and system development life-cycle documents, the team set a goal to automatically generate the key documents from the system if possible.

Goal for New System

The organization's goal was simply to deliver a high-quality validated system on time and under budget for each clinical study. Each system would be also required to handle study data such as project, site, and subject identifiers, etc. Further, the new system would need to provide the capability to handle voice files in various specified languages, and interactive interface components for handling call-flow during patient enrollment.

New System Design Characteristics

The resulting system exceeded the organization's expectations, as the new XML system was self-documenting, self-describing, and interactive. The developers chose technology which would allow the user to interface with the system via the phone or web-browser. The system permitted either voice-recorded messages or computer-generated voice

messages. Future releases of the system were targeted to support voice recognition and automated language translation.

Requirements

You may wonder, in what way was the system self-documenting? The system provided visual interactive script creation via XML, which permitted the users to create specifications for the script interactively and graphically. The IVR system generated a diagram of the call flow process and a detail specifications report outlining each step of the IVR process for storage, archival, printing and review.

The visualization of the script was essential in reducing the time it took for the users to settle upon the final specifications of the system, as it reduced the number of iterations required for the user to understand and conceptualize how the system would perform the call flow. When IVR call flow changes were required, the changes were tracked within the system. Prior versions of script were accessible and retrievable in human readable form. Telephone calls using prior call flow models could be retrieved and reproduced. At the end of the creation of a new call flow process, an HTML specifications document was generated to meet QA requirements.

Testing

A test plan builder was designed into the system. The test plan builder aided the user in the generation of test plans and testing call flow processes. The user created the test plan interactively and XML generated the IVR call flow based on already captured user specifications. The test plans were then executed as the user pointed and clicked through the test plan step by step. The system automatically tracked all test paths and the test execution. The system created an HTML test plan and an executed test report document for QA to include in the validation package.

System change control

Changes to the IVR system were tracked within the system with the audit control function. The

old and new versions of the system were both preserved so that at any point in time one could research the exact version of the system which was in use in a particular call scenario.

Electronic records

Audit trails provided in the system met requirements for 21 CFR Part 11 compliance for electronic records, capturing date and time stamps, user ids, and a record of the user's action. The system provided audit trails which tracked the design of the call flow, audit logs which tracked any changes to the call flow through version control, and a call log that captured each of the users actions within a specific call to the IVR.

Results

The new IVR system was placed into production for a 500-patient clinical trial. No problems were reported or experienced during the installation phase. With the new IVR system in place, the expected cycle time for future study IVR system delivery is expected to be 1–2 weeks, depending upon the study complexity and the number of language translations required for the callers. This represents a cycle-time savings of 8–9 weeks during a critical time in most studies.

Other benefits were observed. The clinical research organization's staff no longer complained about documentation or validation. The software developers began to concentrate on the work of building the study-specific call flow processes and solving business problems instead of solving day-to-day legacy system problems. The users became involved in the specification and test stage of the life cycle. The quality of the overall validation effort was improved through the innovative and creative use of technology and the appropriate application of the regulations to that technology.

The new IVR system produced change control records which recorded all system changes, and met the quality assurance requirements for a validated and compliant system. The overall quality of the study IVR system was greatly improved.

The new system offered the organization a competitive advantage. The integrity, accuracy, and validity of the records within the system are preserved in a Part 11 compliant system for electronic records.

The system enforced good systems change control. XML allows for the archival and retrieval of historical system and data records. XML preserves the content, context, and meaning of the data. The new IVR system exceeded expectations in its adherence to the regulations because the developers embraced the electronic records rule to ensure that the systems design took into account the necessary requirements for CFR 21 Part 11.

Soon, management began to realize they had a powerful multi-purpose tool in the new IVR system. Some proposed uses of the system included; patient diary, quality of life and outcome studies, patient satisfaction surveys, site activation, drug-supply requests and tracking, and electronic data capture. In summary, the IVR system could be used in any study data collection process in which the investigator site, the coordinating center, the sponsor, or patient was

required to interact with a series of questions either by the phone, via web-browser, or hand-held device.

Conclusion

When systems developers read, study, understand, and embrace 21 CFR Part 11 before designing and validating their product, the regulations are easily met. The validation effort of new technologies can be streamlined when the system design itself aids in the system validation, documentation, and change control. Successful implementation of 21 CFR Part 11 is within the reach when teams are trained, innovative, creative and ready to work within the regulations.

References

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