Feature

Best Validation Practices for Multi-Layered IVR Systems - PART 1

In a previous article[1] which appeared in an earlier issue of Quasar, a detailed insight into the issues which need to be considered when providing a robust and validated IVR system were discussed. Building on that article, this and a further paper will describe the basic validation methodology employed by IVR suppliers in an attempt to clarify the issues surrounding the validation of multi-layered IVR systems.

Introduction

The pharmaceutical industry is becoming increasingly dependant upon IVR (Interactive Voice Response) and IWR (Interactive Web Response) systems for the management of clinical trials. Using IVR systems enables study managers to readily access current information, while also allowing patients to enter their own data directly. In addition, IVR systems ensure that valuable information is available in real time, including the numbers of patients screened or randomised, patient diary compliance and the number of medication packs available at any given site. The availability of this information allows study managers to achieve the most efficient and timely clinical trials possible.

Due to their significant importance to the success of clinical trials, IVR systems need to be carefully validated in order to ensure accurate results are achieved. Basic validation methodologies dictate that IVR suppliers should firstly define the system model. This will enable them to identify any generic validation issues and their associated risks, impact and assumptions. Based on this analysis, IVR suppliers will then be in position to provide clear guidance for the project, platform and infrastructure levels of the system so that an appropriate documentation set is created and validation stages are clearly defined.

Defining the system model

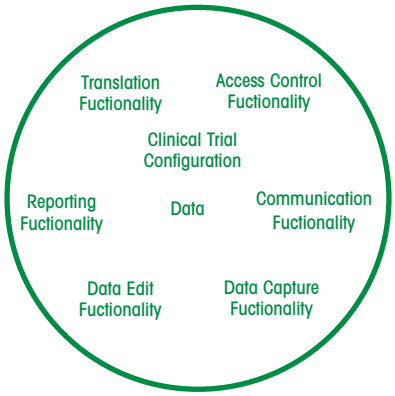
There are many factors to consider when defining a system model. Firstly, it should be identified if the system is stand alone or part of a network, and whether it is comprised of one or multiple pieces of hardware. It is also important to establish where the data resides, whether it is within the system or outside it, and what use the system will make of the data (adding, manipulating, modifying, reporting etc.). If a system is linked, it needs to be made clear which the dominant system is and why and where the data are. Finally, when looking at the system's overview documentation any assumptions which have been made must be made clear.

All these factors greatly determine the validation process to be followed and the structure of the overall documentation, both of which need to be controlled by a Quality Management System.

IVR and IWR System Models

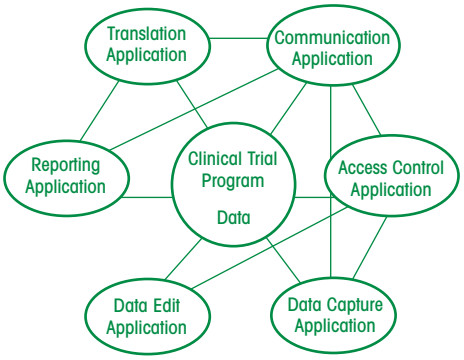
There are several models that can be employed to produce and run IVR and IWR systems (see Fig 1). Model 1 involves an all-encompassing system that contains all the functionality needed, which allows individual client studies to be specified and configured. This system is simpler to provide, validate and control, but it usually requires a long development period and upgrades take correspondingly longer to build and validate. However, this example generally allows for the client project to be standard built onto the platform allowing for more rapid validation, configuration, testing and release.

Fig 1 - *Model 1*



Model 2 is the other extreme, where both the client-specific code and the applications used to support the IVR process provide the total functionality. All of the components are stand alone but are networked together as a larger system. In model 2, there is a great deal of piece-meal validation and change control, but this model allows for the system to be modified on demand with shorter development times. Furthermore, it requires that the client project has its own programme to control the underlying functionality required. While this results in a flexible design, it requires a greater level of validation meaning that it takes longer to programme, test and release to the client.

Fig 1 - *Model 2*



There are also systems available which are hybrid models that use different proportions of larger components supported by stand alone applications.

General Validation Issues

For the daily use of the IVR software, most of the issues are the same as for any pharmaceutical company computer system, with the notable exception of the data flow to and from external sources and key process stages where the client is the gatekeeper. However, unlike pharmaceutical companies, IVR suppliers are often in the unique position of creating as well as using their own software, as opposed to purchasing off-the-shelf systems. As a consequence, the distinction between developing and testing software becomes rather blurred, challenging the more traditional validation roles of the developers and users. This can result in the validation of the client project being largely performed by the development team, with support from the supplier groups at critical stages.

When supplying a computerised service as part of a clinical trial, the involvement of the clients at the three key stages (specifying the requirements, testing and change control) needs to be considered. This is especially important when the platform changes could affect current and future client projects.

IVR systems are made up of component layers each one of which presents its own challenges for validation.

Validation Rules of the Component Layers

Platform Layer

The platform layer is usually the one with the least number of changes. Mostly, any changes are to provide additional functionality, which can be developed with reasonable timelines and altered according to specific needs. In a few exceptional cases, the process might need to be compressed to meet urgent timelines. These timelines often allow for the generation of a comprehensive set of documentation that fully details all aspects of the system.

Client Project Layer

The time taken to create and test a client project is usually measured in weeks. In addition, the project is required to have input from the client who may not be familiar with describing the IVR functionality required. These factors are outside the control of the IVR provider. However, once the project has been released into the production environment, the only changes to the functionality are those made at the request of the client. When dealing with client specific codes, IVR suppliers need to explain the functionality to clients in such a way that their acceptance is obtained. However, this can often cause delays because of misunderstandings and the difficulty in obtaining authorisation signatures. Therefore, this may result in more changes occurring within the client project layer. A key advantage for clients is to use the same supplier, as having more familiarity with specifying their projects reduces the amount of change.

Infrastructure Layer

This is the part of the system that usually experiences the largest number of changes due to the modern trend of having an infrastructure made up of many components. Most suppliers upgrade components frequently, and as these items are purchased off-the-shelf the infrastructure only requires qualification. In addition, there is a constant need to change the requirements of the system and expand its processing power, communication links and data storage capacity. Therefore, a documentation process that meets the challenges of recording additions and modifications is needed. Consequently, much of the documentation resides in supporting documents such as overviews, standards and a rapid assemblage of system specifications.

Within the scope of the entire IVR system, the same validation principles apply but not the same documentation principles. The level of documentation must be tailored to meet the needs of regulations, processes and business. This requires each component to be risk assessed equally across the system whether the components are bought-in or bespoke.

Risk Assessment/Impact Analysis

The scope of the assessment should encompass each individual software and hardware component. The documented assessment will cover the use and significance of each component, in order to determine which level of validation is required. There are three levels of validation that can be applied depending on the result of the assessment, namely Validation, Qualification and Installation. These three levels also correspond to the perceived risks resulting from the system. Systems perceived as high risk are validated, those with a medium risk are qualified and those with a low risk only require installation.

When specifying the requirements or functionality of a system individually or collectively, another risk assessment is performed. These risk assessments can be either scheduled for key points during the validation process or be continually assessed, dependant upon each component. Validation of any of the component layers will have to follow the same basic validation methodology irrespective of the system's development lifecycle.

Conclusion

This article has looked at the issues to be considered in developing a validation approach for an IVR system and the level of perceived risk associated with the system and components. The next and final article will build on this to assess the key steps in the validation process and identify specific forms of documentation associated with the validation.

References

1. M. Wright. 'Providing a Robust and Validated Interactive Voice Response System', QUASAR, 93, pp16-20. Oct 2005.

Mark Wright

Mark Wright is currently Validation Consultant at ClinPhone Group Ltd., a company specialising in providing electronic trial management solutions. He has been involved in pre-clinical research, Quality Assurance and computer systems validation since 1980 in the pharmaceutical industry and CROs.