

# lyrs in risked based monitoring



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## IVRS in Risked Based Monitoring

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As per current trends in clinical trial industry and upcoming technology, Integration of data from IVRS to Risked Based Monitoring Portal will help in efficient tracking of patient participation in study, drug dispensing and supply management. Occurrence of errors and risk in a clinical trial drug management can be controlled using the predictive analytic model and trigger mechanism. This will enhance patient safety, ensure good quality data and retain the integrity of clinical trial in this high complex environment.

### Introduction

The last two decades have seen a rapid increase in drug development department of pharma industries with major focus on developing new drugs which intend to improve the quality of human life. However with this there is also an increase competition amongst the pharmaceutical companies to be the first to develop the drugs. In order to develop and achieve the intellectual rights over drugs the pharmaceuticals need to first patent the drug by seeking the relevant regulatory and government licensing approval. It is expected that the pharmaceutical industry conducts the clinical trials on these new discoveries to evaluate the efficacy and the side effects on actual human projects.

The competition among the pharmaceutical industries has increased the complexities in management of clinical trial like maintaining high integrity

data, ensuring the patients well-being is safeguarded, minimizing the errors generated. <sup>1</sup>

In order to have the best quality data from the clinical trials the FDA emphasis on —

*“ Increased use of electronic systems and improvement in statistical assessments, present opportunities for alternative monitoring approaches that can improve the quality and efficiency of sponsor oversight of clinical trials” <sup>2</sup>*

This led to development of tools of technology like Interactive Voice Response System (IVRS) designed to reduce errors and simplify the clinical trial management process.

This paper is to understand the use of IVRS in Risked Based Monitoring.

Pharmaceuticals are putting a lot of efforts in introducing new drugs in market. However the process has become more complex due to the following factors:

1. Diverse regions of the world leading to increase in the number of sites
2. High patient population

In order to tackle the above complexities, IVR systems are developed to facilitate overall drug management – manage the flow of drug at sites, patient randomization, dose titration, unblinding and expiry date updating. IVRS is a technology where in a telephone is used to gather information from database or enter in the database. IVR system also provides the facility to

integrate it with other management solutions and applications to improve the management of clinical trials by identifying early risk indicators. Thus, IVRS technology has helped in effective management of clinical trials by reducing the cost to clinical trial and introduction of faster technology. <sup>5, 6</sup>

Several factors are driving the globalization of clinical trials. Commercially, sales of pharmaceuticals in 2009 grew at 3-5% in Europe and the United States, compared to 13-15% in Asia, Africa, and Australia, and 10.6% in Latin America. Moreover, IMS has forecasted sales growth of 3-6% for United States and Western Europe, and 12-15% for Latin America, Asia, Africa, and Australia annually through 2014. <sup>7</sup>

With focus now moving to Emerging countries for patient recruitment as well as the burden on pharmaceutical companies to reduce clinical trial cost, most of the service providers have developed IVRS which will provide Pharmaceutical companies with a study-wide view of patient and drug supply activity which will help monitor progress, anticipate problems, and ensure preventive actions are in place. It is observed that the EDC developing companies have started developing IVRS services and vice versa which has further reduced the clinical trial cost by 40%. The advantage of collaborating these services has reduced the number of systems required to access the data, reduced the data entry and duplication errors across the systems and ensured sequential flow of information.

Biopharmaceutical companies have started adopting clinical technology to help improve their R&D productivity. Today, sponsors are executing complex global studies efficiently through use of new technology to help collect safety

and efficacy data for submission to the health authorities. To accomplish this, they need access to real time data to conduct analysis and provide decisions with respect to the clinical trials hence the need for technologies like IVRS

IVRS is widely use in global clinical trials for patient management, and drug supply management.

Patient level: IVRS is used in real time tracking of patient recruitment – screening and randomization, assigning of study drug, managing patient visit schedules and collect trial data. Some of the features of IVRS in remote monitoring are automated access of information, 24 /7 availability with cost effectiveness. *IVR* s system provides a faster and flexible way in the registration of a patient and integrating the same into EDC system. <sup>3</sup>

- Integration of the subject screening data from IVRS and other vendor portals like EDC, CTMS, Labs with Risk Based Monitoring Portal can help generation of proactive triggers to the site by Central Monitor with respect to patient eligibility for the study.
- On recruitment of first subject at site, Central monitor can raise trigger for an onsite visit to assess risk. This will help minimize the eligibility deviation as well as proactively predict the enrollment rate for the study.
- Integration of visit data received from IVR system in RBM portal will also predict the subject level compliance to the study medication, missed visit and predict the retention rate for the study.

Making the enrolment and retention predictable and efficient will be a major quality benefit to pharmaceutical industry.

Study Level: Proper drug accountability management is essential to ensure patient safety, maintain study timelines and protect integrity of the clinical trial data. Advances in technology have rendered paper-based drug accountability records obsolete. Electronic drug accountability is a function that can be added to an existing IVR system. IVRS is ideal for drug accountability because it tracks drug dispensing units by warehouse, depot, and site location, and by batch, bulk lot, packaging step, label group, expiration date, temperature excursion and patient allocation. <sup>4</sup>

Sophisticated technologies are now built into IVRS to calculate and administer complex dose titrations.

Integration of data from IVRS for site level drug supply and patient level with Risk Based Monitoring portal can help central monitor to predict the drug supply needed at the site. The feature will include:

- Triggers for acknowledging the resupply received at site,
- Return of study drug based on the expiry date.
- RBM can also enable study level visualizations to help clinical trial management to plan and track the drug supply on an ongoing basis.

Trials involving Patient Related Outcomes (PROs), IVRS is used to collect data directly from patient like effects of study medicines on a patient's quality of life, including adverse effects, this helped sponsor manage patient safety and timely submission of data to health authority..

In studies involving blinded lab results, IVRS is used to collect real time data directly from sites, patients and labs and provide real time lab results and reports. Using IVRS, alert system can be organized for medication dosing and visit reminders for trial patients.

IVRS is well suited for adaptive trials as they are simple to implement and use and provide flexibility to implement adaptive modification.

IVRS has gained wide acceptance among sponsor because they provide real-time benefits in patient management, study drug management, blinding, reporting, systems integration and low costs. Some of the benefits of IVRS are:

- It provides real time feedback from centralized database which help researcher allocate the right treatment and help better aid statistical analysis
- It improves blinding process by allocating treatment group in controlled and unbiased manner
- Robust and automated system provide real time reports to study manager which enable proper study planning, ensure site compliance
- Low cost – initial study set up fee with low maintenance fees is the expenditure to the sponsor

However certain challenges seem to persist in implementation of IVRS in clinical trials:

- Providing technical and study-related support to sites and patients throughout a trial in regional languages for global studies

- IVRS set-up timelines on an average are 3 months, hence can impact study start-up timelines
- Redundancy in vendors with the experience, capabilities, resources, and expertise to manage global trials
- Proactive management of study supplies to avoid delays
- Reducing duplication in data entries, and resulting errors using IVRS may cause costly delays before data lock and statistical analysis.

Skill set used in development of IVRS technology are IT software specialist, Clinical data management, supply chain experts, statistician, and operations manager.

IVRS also plays a key role in Risk based monitoring. As aware that FDA has recently published guidance which suggests reduction of onsite monitoring visit to be replaced with alternative approaches to monitoring, with specific support for centralized and risk-based monitoring. The guidance states, “ Several publications suggest that data anomalies (e. g. fraud, including fabrication of data and other non-random data distributions) may be more readily detected by centralized monitoring techniques than by on-site monitoring.”

There is growing evidence that using centralized monitoring the detection of non-compliance and data fabrication is more than using the traditional 100 % SDV model. Real time integration of data from IVRS, EDC, CTMS and other data portals in centralized monitoring portal help early detection of fraudulent, noncompliant, erroneous data, hence facilitates immediate preventive and corrective at site, ensures good quality data and patient safety

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- In today's Internet-savvy world, Interactive Web Response Services (IWRS) are quickly replacing outdated and time consuming Interactive Voice Response System. IWRS provides increased efficiency and productivity with lower rates. There is also a dramatic reduction in development cycles compared to IVRS. Sponsor company based on the study design, sites, logistic and budget decide upon the use of IVRS / IWRS technology for the studies.

Thus integration of IVRS / IWRS technology with centralized and risked based monitoring model will help the pharmaceutical industry manage the clinical trial efficiently by proactively reducing the risks concerning the drug supply management at patient and site level, ensure efficient patient tracking and retain patient safety.

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