Review Article

Latest Trends of Interactive Voice Response System (IVRS) Health Care Systems

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ABSTRACT

The integration of telephony with computers has created interactive voice response technology that has begun to have many applications for healthcare. This technology has to turned touch-tone phones into virtual computer terminals. A number of IVRT applications have been developed with nursing involvement. Research on IVRT use shows major applications dealing with chronic disease management, medication management and the care of special populations. . It will be up to Nurse Informaticists to develop and test creative uses for IVRT that will both leverage technology and improve patient care. Use of the IVRT provides opportunities to educate as well as to monitor individuals on their self-management behaviors. As an understanding of the uses of IVRT in patient care grows, it will offer added value to healthcare services. Emerging technologies in computer and telecommunication industry has eased the access to computer through telephone[1]. An Interactive Voice/Web Response System (IVRS) is one of the user friendly systems for end users, with complex and tailored programs at its backend. The backend programs are specially tailored for easy understanding of users. Clinical research industry has experienced revolution in methodologies of data capture with time. Different systems have evolved toward emerging modern technologies and tools in couple of decades from past, for example, Electronic Data Capture, IVRS, electronic patient reported outcomes, etc [2].

Keywords: IVR (Interactive Voice Response) Prescriptions Telecommunications Touch-tone telephone, HIPAA, HIPAA compliance Clinical data management, Interactive Voice Response System, Interactive Web Response System.

INTRODUCTION

Healthcare has moved from the Industrial Age to the Information Age. In the Industrial Age care was episodic, provided in a traditional setting and was provider centric. Clinical data was interpreted by providers based on memory, intuition and pattern recall. New knowledge was developed in research settings. In the current Information Age, care is ongoing, customized and centered around the patient. Clinical data is supported by clinical decision support systems, alerts, reminders and evidence. New knowledge is often a by-product of patient care. Healthcare has moved from the translation of research into practice to translating practice into research. One of the tools supporting these changes is Interactive Voice Response Technology (IVRT) that automates interactions with telephone callers and communication systems[2]. IVRT is a type of telephone system that interacts with most users through voice commands. Interactive voice response (IVRT) is a technology of the Information Age. This technology has to turned touch-tone phones into virtual computer terminals. Initially IVRT was used for automated telephone interactions using prerecorded voice prompts and touch-tone keypad menus. Advances in technology using voice recognition now allow for input and responses gathered from the spoken word and IVRT has become a method of patient communication and data collection increasingly recognized as advancement in health information technology [3].

What is an IVR?

Interactive voice response (IVR) is a technology that allows a computer it interacts with humans through the use of voice and DTMF tones input via a keypad. Intel communications, IVR allows customers to interact with a company's host system via a telephone keypad or by speech recognition, after which services can be inquired about through the IVR dialogue. IVR systems can respond with pre-recorded or dynamically generated audio to further direct users on how to proceed. IVR systems deployed in the network are sized to handle large call volumes and also used for outbound calling, as IVR systems are more intelligent than many predictive dialer systems.IVR systems can be used for mobile purchases, banking payments, services, retail orders, utilities, travel information and weather conditions. A common misconception refers to an automated attendant as an IVR. The terms are distinct and mean different things to traditional telecommunications professionals—the purpose of an IVR is to take input, process it, and return a result, whereas that of an automated attendant is to route calls[1].

History

Despite the increase in IVR technology during the 1970s, the technology was considered complex and expensive for automating tasks in call centers. The first commercial application of IVR was an order entry inventory control system designed and developed by Steven Schmidt in 1973. Early voice response systems were DSP technology based and limited to small vocabularies. In the early 1980s, Leon Ferber's Perception Technology became the first mainstream market competitor, after hard drive technology (read/write random-access to digitized voice data) had reached a cost-effective price point [2].

At that time, a system could store digitized speech on disk, play the appropriate spoken message, and process the human's DTMF response. As call centers began to migrate to multimedia in the late 1990s, companies started to invest in computer telephony integration (CTI) with IVR systems. IVR became vital for call centers deploying universal queuing and routing solutions and acted as an agent which collected customer data to enable intelligent routing decisions. With improvements in technology, systems could use speaker-independent voice recognition of a limited vocabulary instead of requiring the person to use DTMF signaling. Starting in the 2000s, voice response became more common and cheaper to deploy. This was due to increased CPU power and the migration of speech applications from proprietary code to the VXML standard [4].

Technology

DTMF decoding and VOICE recognition are used to interpret the caller's response to voice prompts. DTMF tones are entered via the telephone keypad.

An IVR can be deployed in several ways:

- Equipment installed on the customer premises
- Equipment installed in the PSTN (public switched telephone network)
- Application service provider (ASP) / hosted IVR
- An automatic call distributor (ACD) is often the first point of contact when calling many larger businesses. An ACD uses digital storage devices to play greetings or announcements, but typically routes a caller without prompting for input. An IVR can play announcements and request an input from the caller. This information can be used to profile the caller and route the call to an agent with a particular skill set. (A skill set is a function applied to a group of call-center agents with a particular skill)[5].

Usage

[IVR systems are used to service high call volumes at lower cost. The use of IVR allows callers' queries to be resolved without a live agent. If callers do not find the information they need, the calls may be transferred to a live agent. The approach allows live agents to have more time to deal with complex interactions. When an IVR system answers multiple phone numbers, the use of DNIS ensures that the correct application and language is executed. A single large IVR system can handle calls for thousands of applications, each with its own phone numbers and script. Call centers use IVR systems to identify and segment callers. The ability to identify customers allows services to be tailored according to the customer profile. The caller can be given the option to wait in the queue, choose an automated service, or request a callback. The system may obtain caller line identification (CLI) data from the network to help identify or authenticate the caller. Additional caller authentication data could include account number, personal information, password and biometrics (such as voice print). IVR also enables customer prioritization [2]. In a system wherein individual customers may have a different status, the service will automatically prioritize the individual's call and move customers to the front of a specific queue. IVRs will also log call detail information into its own database for auditing, performance report, and future IVR system enhancements. CTI allows a contact center or organization to gather information about the caller as a means of directing the inquiry to the appropriate agent. CTI can transfer relevant information about the individual customer and the IVR dialog from the IVR to the agent desktop using a screen-pop, making for a more effective and efficient service. Voice-activated dialing (VAD) IVR systems are used to automate routine inquiries to a switchboard or PABX (Private Automatic Branch exchange) operators, and are used in many hospitals and large businesses to reduce the caller waiting time. An additional function is the ability to allow external callers to page staff and transfer the inbound call to the paged person. IVR can be used to provide a more sophisticated voice mail experience to the caller [6].

Medical Edit

IVR systems are used by pharmaceutical companies and contract research organizations to conduct clinical trials and manage the large volumes of data generated. The caller will respond to questions in their preferred language and their responses will be logged into a database and possibly recorded at the same time to confirm authenticity. Applications include patient randomization and drug supply management. They are also used in recording patient diaries and questionnaires. IVR systems allow callers to obtain data relatively anonymously. Hospitals and clinics have used IVR systems to allow callers to receive anonymous access to test results. This is information that could easily be handled by a person but the IVR system is used to preserve privacy and avoid potential embarrassment of sensitive information or test results. Users are given a pass code to access their results.

Healthcare Edit

In the context of tuberculosis, patients need to adhere to the medicine daily basis for a period of few months to completely heal. In public sector, there is a scheme called DOTS (Directly Observed Therapy Short Course which was the most effective source for poor population. However, this method requires the patient to commute to the clinic everyday which adds financial and time constraints to the patient.99DOTSis a project that uses good ICTD principles to use IVR technology to benefit TB patients. Patients have a customized packet of tablets that they receive from the healthcare official who trains them to take the medicine in the sequence daily. Opening the packet in a sequence reveals a phone number that the patient needs to dial to acknowledge that they have taken the medicine. This research project was based out of Microsoft Research India by Bill the is and who received MacArthur Fellowship for the project. The project has spun off as ever well Technologies which now work closely with the Government of India to scale this technology to patients throughout India.

Because most patients are familiar with and have access to telephones, IVRT is an enabling technology that is likely to transform the provider-patient relationship. Consumers and providers have accepted this technology. Use of the IVRT provides opportunities to educate as well as to probe individuals on their self-management behaviors.

Spoken messages may be more effective with individuals who have low literacy levels since statements and questions can be repeated as often as necessary. Calls may be conducted in other languages such as Spanish. Some patients may perceive a computer-generated language as less threatening than a personal discussion. The technology provides consistency in interviews. Data can be collected and stored on a 'real-time' basis. Healthcare systems face the challenge that to provide services to patients in a simple, easy to use, accessible way. Economic pressures and accountability for performance require the use of information technology in the provision of quality cost-effective and value-based care. As an understanding of the uses of IVRT in patient care grows, it will offer added value to healthcare services. Consumers will be empowered to be an active participant in their own healthcare. IVRT has the potential to provide added value in the transformation of healthcare systems [8].

IVRS Used in Clinical Trials

Clinical research and pharmaceutical industry have been exponentially grown during the first decade of 21st century in terms of drug discoveries, their development, various medical devices, and other technologies to serve community better in healthcare. This rapid boom has put pharmaceutical industries under tremendous pressure to win the race of getting their drugs in market and getting them patented. This is a key milestone for the sponsors to start getting returns for their huge research investment. Pharma companies are profound from the drug discovery, Investigational New Drug Application, and New Drug Application till the different phases of clinical trial to accelerate the entire process and achieve the key milestones well in advance vis-a-vis the competitors. In an event to accelerate the drugs' journey to market and the regulatory guidelines becoming more stringent such as data submission in specific formats (Clinical Data Acquisition Standards Harmonization/Study Data Tabulation Model), adverse event reporting on stipulated timelines, notification of adverse events to specific regulatory bodies in expected timelines; there were instances observed which often led to incorrect randomization/drug dispensation, incorrect recordings of adverse events. These instances put trial subject's safety under risk, also affected the safety and efficacy analysis. Over the period, there was an obvious rapidity seen in the growth of clinical trials along with technological innovations and integration of tools. This included increase in the number of molecules getting registered for new trials, several therapeutic area trials, medical device trials, bio-similar and bio-betters coming to market which led to increase in the complexity and the global recognition and advancement. In addition, stringent regulatory requirements in terms of safety of patients, data collection/modification, drug supply, submissions to regulatory authorities, have in turn increased the scope of data collection, randomization, safety monitoring, data formatting, documentation, reporting, and analysis. With the growing rate of clinical trials containing massive data and patient pool across the globe, the sponsors have been involuntarily forced to recalibrate their conventional way of conducting trials and to opt for new innovative and more normalized way of conducting clinical trials. Telecommunication industry along with information technology came up with various innovative technologies to cater to the needs of different industries [6].

An Interactive Voice Response System (IVRS) is one of the technologies developed and customized to enhance the quality of healthcare services. Tailored programs in computer (Information Technology) can be accessed through telephone (Telecommunication) by user around the clock. Computer-based applications such as randomizer and drug inventory management system used for kit generation are easily accessed through telephone with the use of IVRS. Moreover, as a backup, the web-based Interactive Web Response (IWR) system was developed. IVR was more commonly used in healthcare viz. IWR as it could be accessed from any corner of the world without internet and computer. Thus, this innovative e-Clinical solution, IVRS, from telecommunication industry was acquainted with healthcare and clinical research industry. Being a potential innovative technology, IVRS has proven its efficiency in clinical research. In the early first decade of 21st century, the use of IVRS was limited only with few government services such as railway in India. This was

because of lack of technology and infrastructure within interior parts of the country [8].

During the last 15 years, the various new technologies such as mobiles and internet reached beyond metro cities and into interior part of India such as small towns and developing cities. IVRS has been implemented by different industries such as telecom service providers, banking, and customer care services for product-based companies to capture the market. Over the period of time, IVRS has evolved to great extent and helped in overcoming many challenges, some of the challenges that were addressed are

Adaptive trial design

In prospectively planned events of amendments in clinical trials, IVRS can be customized to implement the dynamic randomization and complex dosing algorithms efficiently. Automated randomization through IVRS eases process of assigning subjects to different treatment arms and proper dispensation of drug per treatment arm following the dosing algorithm.

Global trials

IVRS extends major contribution in the success of Global clinical trial in addition to adaptive trials challenges encountered by industry due to globalization of clinical trials such as remote recruitment, randomization, and drug dispensation.

Clinical Outcome Assessments and Patient-Reported Outcomes

Successful collection of Patient-Reported Outcomes (PRO) can be governed by IVRS. PRO or Clinical Outcome Assessments is modern technique of data collection from patients and physician against their response to diary questionnaires. IVRS along with handheld electronic patient reported outcomes device is used to capture data and store it in databases for analysis prior to regulatory submission.

Randomization/stratification

Randomization of subjects in various strata is based upon predefined criteria. Stratified randomization refers to situation in which strata are constructed based on the values of prognostic variables, and a randomization scheme is performed separately within each stratum.

Multiple dosing/weight based dosage

For pediatric studies, complex dosing algorithm is considered and here dosing is based upon different criteria such as weight of subject, age in months, and special consideration toward vaccination schedules. In pediatric age group, dosing is given based on body weight or body surface area. It is based on an understanding of drug pharmacokinetic (PK) that is directly proportional to body size, i.e. PK parameters increases in proportion with increasing body size. These complex dosing algorithms can be implemented in IVRS and used in studies for proper drug dispensation.

Product inventory management

Product inventory management includes product supply/re-supply to site, electronic proof of receipt, product status/condition (damaged and on-hold), etc. Implementing IVRS for product inventory management overcomes challenges faced during shipment of drugs such as drugs not reaching respective sites on time, their condition on arrival at site (s), special consideration to injectable as they need to be shipped and stored at specific temperature throughout their transfer/transport till it can be administered to patient, and automated product resupply at respective sites (s) [6].

As a general practice, IVRS is not implemented in all clinical research studies. The sponsor takes decision on the implementation of Electronic Data Capture (EDC) system, IVRS, and other eClinical systems in a particular study based upon several parameters. The sponsor identifies the implementation of IVRS in a study after considering some of the points outlined below.

- ✓ Consulting with study team members such as clinical study manager, study biostatistician, clinical supply chain management representative
- ✓ Complexity of randomization, including stratification
- ✓ Complexity of product management
- ✓ Integration with other systems
- ✓ Number of geographical regions or clinical sites
- ✓ Study budget
- ✓ Timelines.

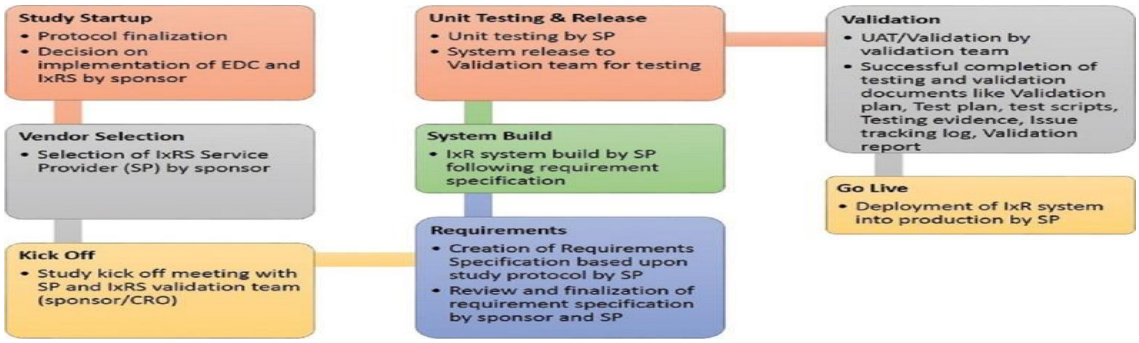

Figure 1: Interactive Voice/Web Response System generic process [9]

Clinical Study Modules Covered

Leading eClinical solution providers from biopharmaceuticals with innovative technologies and integrations have enhanced the implementation of IVRS. This in turn is assisting in improving the efficiency of data collection and management of this data when it comes to final analysis and submission. Different modules listed below can be implemented effectively through IVRS. Choice of selection of modules may vary from sponsor to sponsor.

Site management

This module can be used to activate or deactivate the sites, to set a predefined drug supply to sites. This module is accessed by the sponsor.

Cohort management

This module is used to open or close cohorts based upon the set conditions defined in protocol. In addition, the sponsor can update the cohort target based on the requirement.

Product management

Using this module, the sponsor can update expiration date of product that will be shipped to sites.

Enrolment/randomization

Randomization is the process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments to reduce bias. IVRS with the help of randomizer tool deployed by service provider, to enroll/randomize the patients into different treatments arms as defined in protocol, generates the unique enrolment/randomization number for each patient. Based on randomization number, the patient receives appropriate treatment in the trial as per the randomization plan.

Dosing/drug dispensation

Dosing algorithms are built in IVRS to dispense investigational drug to patients as per the protocol defined dosing schedule and treatment arm. The patient receives a unique kit number or box number after drug dispensation call. Earlier Investigators had to assign kits manually to subjects while performing drug dispensation.

Electronic proof of receipt

Receipt of drug at sites can be confirmed through this module. In addition, the condition of drug received and its timeframe can be mentioned during this call.

Emergency unblinding

This module is used for unblinding of subjects in case of any serious adverse event either by subject number or by kit number assigned. This module can only be accessed by sponsor and statistician.

Product inventory adjustment

Drug supply management to sites can be governed through this module. Once quantity of drug goes beyond defined number at site, required quantity will be automatically shipped to respective site (s) to make sufficient availability of drugs at site [12].

IVRS acts as central hub for other systems used in clinical research. IVRS can be integrated with various eClinical systems such as Clinical Trial Management System, EDC, and Drug Supply Management System to automate data transfer process for key variables/data points which are collected through IVRS such as screening ID, randomization number, and kit number.

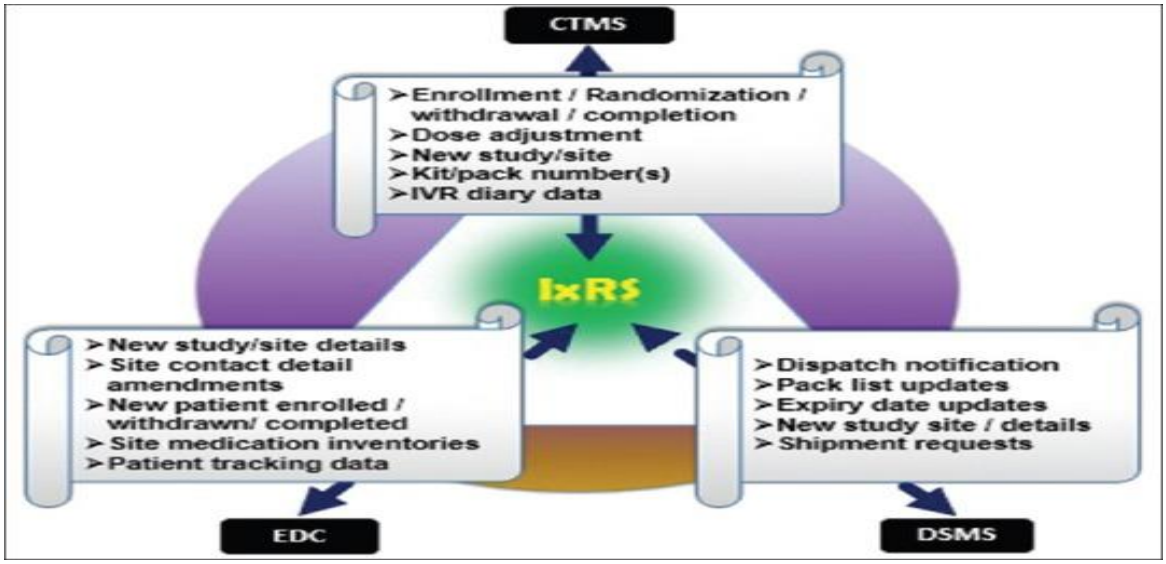

Figure 2: Interactive Voice/Web Response System integration with eClinical systems[7].

Currently most sponsors perform randomization using an Interactive Voice Response System (IVRS) so that treatment codes for individual patients are no longer available at the sites for inspection.

The IVRS utilizes a dynamic randomization system using an adaptive minimization technique for pre-specified stratification variables. The randomization algorithm evaluates previous treatment assignments across the different strata to determine the probability of treatment assignment. There are no fixed randomization lists available prior to enrollment of patients and there are no pre-determined randomization schedules. The randomization algorithm is the source document and is supposed to be signed and dated prior to the time when the first patient is randomized into the study. An external vendor is used to manage the treatment allocation codes][10]. Once a subject is found to be eligible for a trial, the investigator contacts the IVRS vendor and provides details about the subject including their stratification factors. Typically sites receive confirmation faxes from the IVRS vendor that include relevant patient information such as the date of randomization, the date of last visit and the date the last medication was assigned.

In emergencies, investigators must call the IVRS vendor to break the treatment code since there are no longer envelopes with patient numbers and treatment codes for investigators to open at the sites. Treatment codes may be released to external vendors prior to the final analysis in order for plasma concentration analyses or PK modeling to be performed in patients receiving the new investigational treatment. Treatment codes may also be released or partially broken up to the code level (e.g. treatment A, B) for the Data Safety Monitoring Board (DSMB) and may be completely unblinded if the chairman of the DSMB requests it. Treatment codes are released to the sponsor or contract research organization after the official analysis database lock [11].

Nowadays, the IVRS moves to the web-based system. The term is also becoming IWRS (interactive web response system). It could be the situation, when we use the term IVRS, it actually means IWRS.

The utility of the IVRS/IWRS is not just limited to the randomization. It can be used in other areas as well:

- ★ Collecting the clinical efficacy outcome. For example, in IBS (Irritable Bowel Syndrome) study, the IVRS is used to collect the information about the presence or intensity of several IBS related symptoms daily (such as satisfactory relief, Abdominal discomfort or pain, Bloating, Stool frequency, Stool consistency...)
- ★ Patient Reported Outcome (ePRO)
- ★ Outcome research
- ★ Cohort management (open/close a cohort) in dose-escalation studies
- ★ Patient registry / registry studies
- ★ Drug supply management / Study drug inventory tracking [13].

IVRS Data Destruction by HIPAA Guidelines

The Health Insurance Portability and Accountability Act were first instituted in 1996 as a way to federally mandate and monitor the health care industry's use of data. That said, technology has advanced considerably since 1996. In the late 2000s, HIPAA was altered to reflect the digital age. The term "protected health information," otherwise known as PHI, was introduced and a set of strict rules was established to ensure its confidentiality.

Data destruction is an important consideration in any sector, but health care has some of the highest stakes. Permanent identifying data is stored in almost every health care office, from small local practices to large medical insurance companies. Preserving this data is crucial and HIPAA sets forward a very specific mandate. Data needs to be properly sanitized. However, health care is different in that its information is valuable, not just to hackers but to scientists.

This makes health care a unique industry with its own special conditions. Data must either be de-identified for academic use or properly and completely destroyed.

The Rules Regarding PHI

PHI data fully identifies an individual and his or her relationship to a health care organization (insurance, hospital or related business). The HIPAA Journal identifies PHI as possessing 18 specific identifiers. These factors range from general identifiers such as name, telephone number and email address to more permanent identifying data like a social security number. The rule for determining what data is PHI is simple. If the data can be attained on its own from a public source i.e. – a telephone book holding a name and number, that data by itself is not PHI. It is only when the data is combined with private information that it becomes PHI. Obviously, information such as social security numbers are always confidential and protected by HIPAA and common law, whether fully defined as PHI or not.

When HIPAA was altered to incorporate PHI, the government established a set of laws governing its disposal. All PHI data must be disposed of properly from any decommissioned device with data storage. Proper PHI disposal reports that incorrectly destroyed data will be punishable by fines ranging from $25,000 to over $1 million. In addition to these fines, a mandatory investigation will be held into the health care company responsible for the initial data mishandling. Patients and authorities will have to be informed and it will be up to the state's Attorney General to decide whether or not further discipline/legal action is needed.

The Justification for De-Identification:

Health care data is not like normal data. It is no exaggeration to say that patient data can save lives by

helping doctors and other medical staff properly understands the diseases that they are fighting. Health care is a unique industry in this way, with data that is life-destroying and live-saving at the same time.

The government understands this and so HIPAA's guidelines created the potential for de-identifying PHI data for academic use. According to the U.S. Department of Health and Human Services, de-identification is accomplished in two ways: through either expert determination or safe harbor methods. Each must ensure that the identifying nature of the PHI is obscured beyond the doubt of recovery. It is highly unlikely that an outside force looking at this information will be able to trace the information back to identify a particular patient. The safe harbor method operates by directly removing the 18 identifying factors of PHI data. Once this is done, the data can be used by an academic party without fear of an individual's privacy being exposed.

The Dangers of De-Identification

Of course, neither method is flawless. The PHI data is still there and, in some cases, re-identification practices can be ordered to return the data to PHI status. This data is typically retrieved through a code, meaning that the de-identification is only as secure as this code is.

De-identification should only be done when it is necessary to increase medical knowledge. It should never be done for the process of archiving data for private records or corporate archives. Regardless of its usage, all devices that use PHI or other confidential data must be properly sanitized before being decommissioned. Any improperly sanitized device code lead to the unlawful re-identification of PHI data. Any improperly sanitized device code lead to the unlawful re-identification of PHI data.

Properly Destroying PHI Data

In order to maintain HIPAA compliance and make sure all data is properly sanitized; health care operators need to follow a comprehensive three-step method. The first two steps of this method apply only to devices with data storage media, but all devices that use flash memory and have been exposed to confidential data should undergo step three before decommission is complete.

Deleting and overwriting data

All hard drives should be fully wiped with all confidential information being deleted. Once this is done, new, benign programs should be written to the hard drive. This helps make sure that the confidential data has been overwritten. Preferably, this step is repeated several times to make sure the original confidential data have been completely removed from the hard drive.

Degaussing traditional hard drives

Any and all traditional hard drives should be degaussed. Traditional hard drives work through magnetic fields, and degaussing alters these fields in a way that makes the data completely unreadable. Once a traditional hard drive is degaussed, it can never be read again. Solid state drives do not work by using magnetic fields, so this process does little to affect their data.

Shredding the physical data storage

Once the data has been overwritten (and degaussed when possible) it should be fed into a specialized hard drive/ SSD shredder. This final step is enough to remove all reasonable doubt of data recovery. It is important that IoT-enabled smart devices with flash storage also be destroyed to guarantee the safeguarding to PHI and other classified data [17].

Health care is a targeted industry for cybercrime, and all operators within the space need to be very conscious of their responsibilities to data security. The life-saving potential of its information provides positive avenues for improving humanity while opening up new potential windows for cyber attacks. HIPAA enforces strong guidelines for preserving confidentiality, and health care providers must make sure they are not on the wrong end of those repercussions [17].

HIPAA Compliance

In short, the Health Insurance Portability and Accountability Act, or HIPAA, is a federal law that was enacted to keep health care information private and confidential. There's a lot more to it & more of the details can be found here.

Call Tracking's Role In HIPAA Compliance

In case you're not familiar, call tracking is the process of attaching a unique phone number to individual marketing channels to help collect data. This helps improve lead generation and proving ROI.

Protecting Patients While Growing Your Practice

As an organization in the healthcare industry, you have to consider more than just providing exceptional patient care. While providing exceptional patient care should be a major focus, you also have to consider how to grow your business.

Call tracking provides a pretty foolproof way for any business in any industry to collect the data needed to make better investments and earn new business. It will help you determine how to best market your healthcare organization to new customers and patients.

Developing A Call Tracking Strategy

However, the decision to add call tracking into your business development strategy can't compromise your ability to meet HIPAA's minimum standards. Your organization still has an important obligation to keep protected health information secure and confidential. Healthcare organizations have to be sure that they choose a call tracking provider that understands the details of HIPAA compliance and have their own processes in place to help their customers achieve compliance.

Picking A Provider

To ensure your call tracking is meeting HIPAA requirements, look to work with a provider that minimally offers the following:

Business Associate Agreement

Any business providing HIPAA compliant call tracking should work with you to complete a business associate agreement. A business associate agreement is a contract between a HIPAA-covered entity and a HIPAA business associate. Essentially, the document ensures that the third party safeguards your data in the same way you would as a HIPAA compliant organization.

Data Encryption

All data should be protected via SSL encryption. This establishes an encrypted link between your server and another server, allowing for the secure transfer of information. All of your call records, web visitor sessions, and call routing records should also be stored in an encrypted environment.

Secure Transfers

Your call tracking provider should not transfer any protected information to a non-compliant external system.

Information Accessibility

Each user should have a unique set of login credentials that grant them individual access to all reporting or call details. Sessions should be timed out after a period of inactivity.

Access/Modification Detail Reporting

HIPAA mandates that records be kept of any time protected information is accessed or modified. Reporting should be secure and accessible 24/7.

Maintaining HIPAA compliance is an absolute necessity for organizations in the healthcare industry. Achieving it should be viewed as an asset & an accomplishment, not a deterrent to business growth. By working with an organization that is capable of providing HIPAA compliant call tracking, you can meet your federal obligations while still taking advantage of the tools that help you grow your business strategically &smartly [18].

Benefits of IVRS

Beyond its ease to access, operate, and round the clock availability, IVRS has many other advantages which recommends its deployment into complex clinical trials, clinical trials with large number of patients, with different treatment arms, and with complex dosing schedules. Few of them are listed below:

- Its scalability enables to recruit and manage large number of patients
- Its robustness helps to have multiple studies ongoing at single time point
- Real-time response from systems enables assigning unique numbers to patients, for example, enrollment/randomization and dispensation
- With technological evolution, easy integration with other eClinical systems enabling key data points flowing from multiple systems into one.
- Easy deployment irrespective of trial type, number of subjects, number of sites, therapeutic areas [15].

IVRS and IWRS have gained wide acceptance because they provide real-time benefits in Patient Randomization, drug assignment and inventory management, study blinding, reporting, systems integration and low costs:

- Randomization. Real-time feedback from a centralized database allows a researcher to dynamically allocate treatments to subject groups to better aid statistical analysis.
- Drug Assignment. Knowing where and when to allocate expensive trial drugs saves valuable resources.
- Study Blinding. IVRS/IWRS helps improve the blinding process by allocating treatment groups in a controlled and unbiased manner.
- Reporting. Through automated system reports, real-time information can be made available to the study manager via fax and email.
- Systems Integration. The IVRS/IWRS and the initial study preparations and documentation fit into the familiar manual processes of organizations running clinical trials.
- Low Cost. Provided as a hosted service there is no capital expenditure required - you only pay an initial study setup fee and a low monthly fee for the provision of Services for the duration of the study [12].

CONCLUSION

Pharma companies need to opt for emerging and innovative technologies in clinical research to compete in global competition to utilize maximum benefits for patent filed before its expiry. Implementation of IVRS into clinical studies can accelerate trial by remote recruitment, appropriate randomization, and automated product management. With evolving technologies, IVRS can be easily implemented into studies and can be accessed remotely through telecommunicating devices such as phone, mobile, and I Pad even from the areas where

internet facilities are not available. Hence, IVRS can become indistinct choice for most flexible, user-friendly, and robust tool for the pharma companies. IVRS has boomed pharma industry and clinical trials started implementing IVRS to large extent. IVRS service providers were dreaded by other technological innovations such as EDC systems which were likely to replace the IVRS. However, today we can see rapid growth in the use of IVRS in clinical trials.

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