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PART 11 BUSINESS CASE SHOULD DRIVE SMART COMPLIANCE EFFORTS

Regulations aside, the business case for complying with the erecord and edata rules in 21 CFR Part 11 is clear and compelling, says Len Grunbaum, with The Practical Solutions Group.

"The most important thing the FDA is looking for is edata quality and integrity," he told EDIR June 11. "The FDA relies on that to make its go/no go decisions on approving the marketability" of regulated drugs and devices, he noted. "We look at Part 11 as [a collection of] best business practices and less as a regulation."

From a Contract Research Organization (CRO) to any drug or device manufacturer, most companies understand the importance of edata quality and integrity, he notes. "These are just good business practices....Part 11 is common sense" where it calls for sufficient training, audit trails to reconstruct the process, validation that computer systems are doing what they were intended to do, and esignatures that are inviolable, he adds.

"We firmly believe [Part 11] codifies good business practices and if you adopt those for business reasons you'll comply as a byproduct," Grunbaum said.

However, even if a company adopts that philosophy, addressing Part 11 is not always easy, he admits. "Everybody takes [compliance] seriously, but if you ask five people what Part 11 means you'll get seven answers."

Inside this issue:

GUTHRIE: IT CRUCIAL IN BATTLE AGAINST PUBLIC HEALTH THREATS

Benjamin Guthrie, a noted expert and frequent lecturer on health IT topics, recently discussed the critical role IT can and must play in the nation's public health surveillance requirements. "Unique IT systems are critical to attain a proper response" to the public health threat posed by bioterrorism-related and emerging pathogens. Guthrie brings nearly ten years experience in Department of Defense Management including Research and Development efforts, clinical IT projects, medical logistics, clinical assessments and engi

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Did You Hear?...

"If you ask five people what Part 11 means you'll get seven answers," Len Grunbaum, Partner, The Practical Solutions Group

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neering tasks for services provided to the US Army Medical Research and Materiel Command. Currently he is a Program Manager with the Anteon Corporation, responsible for technology planning, research and development, and medical initiatives with several Army and Navy programs.

EDIR: Define IT and analysis systems and discuss the strengths and weaknesses of each.

Guthrie: It is important to define our public health surveillance needs – the crux of the problem before embarking on this difficult challenge of addressing and eradicating emerging disease threats. In the 1992 US Institute of Medicine Report (IOM), academicians defined "emerging infections" as apparently newly recognized infections or reappearance of previously controlled infections, or worsening trends in antimicrobial resistance. The IOM stated that emerging infectious diseases stem from many sources and can be associated with many contributing factors. This report recognized that their frequency of occurrence, severity and potential for impacting ever larger numbers of people are increasing. And, because of this, the report called for the US to take countermeasures and undertake multidisciplinary approaches to detect, control and if possible prevent the emergence of infectious diseases of global public health significance.

Hence, the military and civilian agencies have undertaken an aggressive stance on disease monitoring and eradication of emerging infectious disease (EID) threats that may harm human populations. Because of the apparent threat posed by EIDs, military and civilian agencies have independently established several IT and analysis systems to address surveillance capabilities.

EDIR: Is our current system overwhelmed? Talk about the threat that EIDs pose and what kind of IT systems are in place today to monitor them.

Guthrie: Yes, in my opinion, the current system is not only overwhelmed, but disjointed and not centralized into compatible IT systems that foster information sharing. There is a wide variety of systems that currently exist, and clearly some IT systems have advantages and limitations, but there is not one reportable system that captures all real time data on EID threats. The main rationale for the establishment of medical disease surveillance, data collection, and analysis systems is to be able to detect early public health problems and facilitate their control by implementing effective response measures. The accurate capture of medical infor-

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mation data by these systems is necessary in order to effectively counteract EID and biowarfare threats to the population's health and well-being. This capability exists, but is not centralized, nor has the ability to respond effectively to EIDs.

Threats that EIDs Pose –

EIDs pose a major threat to a population's health and well being. There are five such significant biological threats, which if not closely monitored, can cause major global catastrophes of major proportion. Avian influenza, current emerging and re-emerging of diseases (AIDS, TB, SARS, Malaria), bio-safety lapses, bioterrorism and biowarfare, and multi-drug resistant pathogens all pose serious global threats. EIDs, such as Ebola, drug-resistant tuberculosis, and HIV/AIDS present one of the most significant health security challenges facing the global community. Deaths from infectious disease have risen sharply, and contributing factors, such as climate change, ecosystem disturbance, public transportation systems, and the deterioration of public health infrastructures, have contributed greatly to the spread of EIDs. Furthermore, the US is vulnerable to a release of biological agents by rogue nations and terrorists, which could significantly increase the worldwide dispersal of EIDs.

Existing Systems in Place to Monitor EIDs-

Existing surveillance systems are characterized by the routine, systematic collection, analysis, interpretation and reporting of standardized, population-based data, which is based on already established CDC and WHO promulgated guidelines for disease surveillance. Existing systems rely on the following -

- Hospitalization and outpatient visit information, which is coded in a standardized fashion (i.e. ICD-9) and which provides diagnostic, treatment and laboratory data outcomes. These systems have provided reliable information on common and severe EID problems, such as severe respiratory conditions, which have been critical for the early detection of problems such as avian influenza and SARS in humans. However, there is a need for standardization of such systems across government health agencies internationally.
- Reportable diseases or conditions used to monitor trends in illnesses. Such systems have facilitated detection of EID outbreaks, such as epidemics of enteric illness (cholera), malaria, and dengue in developing countries around the world where these diseases are endemic. This system is the most commonly utilized, given its ease of establishment and standardization, however, it is limited in terms of scope (some diseases are not reportable) and the fact it depends on already-established diagnostic algorithms which are defined for existing known agents (i.e. new, unrecognized EID agents/syndromes are not reportable).
- Specimen-based systems, such as blood and serum repositories, are often used to assist in specific investigations of disease outbreaks for which biologic markers of detection are available (i.e. a diagnostic serum or blood test). These systems are very limited in that they are not real-time based and also require the development of agent-disease specific study protocols which are hypothesis-driven, and which require human use clearance (i.e., can take months to years to conduct).
- Targeted medical threat, epidemiologic and testing data for specific pathogens in native populations (such as research-oriented investigations in HIV, malaria and diarrheal diseases). These systems are

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LabPas, Phoenix Data Systems Collaborate on Etrials

LabPas's Phase I Clinical Trial Software and Phoenix Data Systems (PDS), a firm specializing in Electronic Data Capture (EDC) just announced they have agreed to interface their products for Phase I clinical trials.

This interface will allow Phase I operations to automate the aggregation of a wide range of clinical trial information. LabPas CT will export validated electronic data including subjects and samples, direct equipment feeds and clinical lab results directly to PDS Express, improving trial time, reducing queries, and speeding data lock. Integration will also improve trial management accuracy and speed by unifying scheduling, tracking and study events with clinical data.

"The powerful combination of LabPas CT's cutting edge trial management software and the ability of PDS Express to effectively provide EDC for Phase I trials will provide unmatched insight, speed and efficiency to early drug development," said Bill Claypool, M.D., CEO of Phoenix Data Systems.

Nextrials CTO Honored

Nextrials, a company engages in clinical research software and services, recently said that its co-founder and chief technology officer, Robert F. Lyons, has been selected as a winner in the annual "Top 25 Chief Technology Officers for 2007" competition by IDG's *InfoWorld*. This award showcases IT executives that have shown leadership within their companies and their respective industries.

"This year's CTO 25 award winners are true visionaries who believe that leading edge technology equals leading edge business," said Steve Fox, *InfoWorld* editor-in-chief. "Their constant invention and reinvention of strategic tools, coupled with an eagle eye for business opportunity, provide a blueprint for IT success."

Lyons has more than 20 years of experience in software programming and web application development. He is the chief architect of Prism, Nextrials' flagship electronic data capture and clinical trial management product for the pharmaceutical and biotechnology research industries. He also shares his expertise through active membership in the Drug Information Association (DIA) and the Clinical Data Interchange Standards Consortium (CDISC), where he was an original member of the team that developed CDISC's Operational Data Model XML standard.

ICM Unveils Elearning Module

ICM has released an electronic learning module for VIZYX; it says it is the only integrated compliance management software suite developed exclusively for life sciences companies. Integrated with the VIZYX platform, VIZYX.els enables FDA-regulated companies to automate the process of employee training as well as managing training records.

"Companies are under increased pressure to keep costs down, even as regulatory compliance demands, risks and costs associated with non-compliance increase," said Ramon J. Dempers, ICM President and CEO.

"VIZYX.els is an efficient way to train users on anything from the use of an SOP, a laboratory instrument or sales and marketing content," he added. "The training is performed quickly and without the normal scheduling headaches experienced when trying to manage training manually. This leaves the training department free to develop effective training materials while providing employees with 24/7 access to the VIZYX Training Center."

Agilent Boosts Compliance Tool

Agilent Technologies just announced new FDA-compliance features for its MassHunter Workstation, a software that provides intuitive instrument control, data acquisition, qualitative and quantitative data analysis and reporting for the Agilent 6410 Triple Quadrupole liquid chromatography/mass spectrometer (LC/MS) system. Customers in regulated environments can now leverage MassHunter software to help them comply with 21CFR Part 11, the company said.

Guthrie on Military, Civilian Surveillance

Expert Ben Guthrie provided a brief listing of military and civilian surveillance capabilities –

Military-

There is a broad array of surveillance system capability within the Department of Defense (DoD) to include Army, Navy, and Air Force surveillance systems to detect and combat infectious disease agents. These include IT systems within the DoD-Global Emerging Infectious Surveillance and Response System (DoD-GEIS), the Armed Forces Health Surveillance Center (AFHSC), the Armed Medical Surveillance Activity (AMSA) to include the Defense Medical Surveillance System and the Defense Medical Epidemiology Database, the DoD Serum Repository, the Armed Forces Health Longitudinal Technology Application (AHLTA), the Medical Protection System (MEDPROS), and the Defense Medical Mortality Registry. These represent major systems within DoD for surveillance activity, and assist with the detection and eradication of EIDs.

Civilian -

There is a broad array of surveillance system capability within civilian agencies as well to include the CDC, USDA, WHO, HHS, and the USGS. These IT systems include the Epidemic Information Exchange (Epi-X), the Public Health Information Network (PHIN), the World Health Organization's Communicable Disease Global

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- mostly specimen- and research-based, and more costly, requiring the establishment of state-of-the-art laboratory facilities which can provide a rapid diagnostic testing and response capability.

EDIR: What kind of future IT requirements do we need? Talk about surveillance systems that could be responsive to EID threats.

Guthrie: Over the past years, disaster preparedness has become an area of intense national focus. The threat of disease outbreaks, from naturally occurring pathogens or those maliciously introduced, has provoked a major response from the biomedical, public health, defense, and intelligence communities. A new information infrastructure and methods to support real-time detection and monitoring of diseases, as well as their diagnosis and treatment, has rapidly emerged. In order to better direct the development of medical policies and directives, joint, medical EID surveillance systems need to integrate central data sharing IT/analysis systems with state-of-the-art laboratory diagnostic testing and response capabilities in critical regions of the world. We need::

- Development of joint, multi-agency network(s) of collaborating USG and academic centers in the US and other developed countries, united through common, web-based enabled, data entry and sharing systems, and which work on a 24/7 basis. Operationally efficient systems which provide timely user feedback, and access to health experts' opinions and recommendations are urgently needed.
- Establishment of a network of new, state-of-the-art, EID reference laboratories, established in strategically important, and politically stable, areas of the world. Such laboratories would enable the early detection, characterization and containment of EID epidemics by providing much-needed accurate diagnostic and response capabilities now lacking in most developing countries. Such laboratories would need to be supported multilaterally by donor countries and organizations in each region in order to avoid funding fluctuations/cuts while at the same time meeting country-specific medical surveillance needs.

Guthrie: Military, Civilian Capabilities (From Page 5)

Atlas, the Electronic Laboratory Exchange Network (eLEXNET), the USGS's National Wildlife Health Center's EPIZOO, and the National Animal Health Surveillance System.

Advantages of IT Systems –

Many of these systems, both military and civilian, have marked advantages in IT surveillance of EIDs. Numerous DoD-level and civilian registries, repositories, and surveillance systems are already established and operational. Most are linked and integrated to provide summaries of data and several models exists that capture comprehensive surveillance systems. These advantages must be expanded upon because health surveillance is critical to medical readiness and force health protection within the DoD; while concurrently effecting domestic and civilian populations in the US.

Limitations of IT Systems -

Despite the advantages, several limitations do exist that hamper disease surveillance and the ability to respond to EID threats. Within DoD, the tri-Services (Army, Navy, AF) have separate surveillance programs/standards/philosophies with limited sharing, and availability of programs optimized to address Service-specific needs. In addition, some EID threats in the military are classified, so information sharing to civilian agencies is impossible. Of course, this does not even address the technical challenges associated with information sharing between DoD and civilian agencies to address EID threats. What the military may know, civilian agencies may not know, until long after a crisis is addressed, or vice versa.

Next Issue: Guthrie's recommendations.