

Best Practices for Multi-Site Compliance

By: Aaron Plante, Product Manager, TOPAZ Technologies (Former IACUC Compliance Specialist for Wyeth Research)

The biomedical research industry is experiencing its next evolution. Pharmaceutical companies are undergoing mergers and acquisitions, academic institutions are increasing to collaborate and government research organizations are partnering to push biomedical research forward. The biomedical research world is growing smaller as globalization increases. As organizations continue to globalize, they are faced with new challenges. One of these challenges is managing compliance requirements across multiple locations (both foreign and domestic).

Challenges of Multi-Site Compliance Management. Managing strict compliance requirements for experimental studies is a difficult task that requires dedicated staff, sound management practices and attention to detail in an environment fraught with regulatory requirements, multi-site studies and inter-institutional collaborations. Faced with high volumes of disparate data, compliance managers need to rethink

ways to efficiently and effectively manage compliance requirements.

Best Practices in Multi-Site Compliance Management. While multi-site compliance management may seem overwhelming at first, there are steps organizations can take to simplify compliance management and ensure continued compliance. Discussed in this article are a few proven best practices to help an organization successfully manage compliance across multiple locations:

Centralize Data Management. First and foremost, multi-site compliance managers need a 360 degree view of all compliance-related operations and access to critical research information including: study protocols, committee review information, research subject metrics, and review/renewal/approval dates and deadlines. By collecting each site's siloed information in one central location, institutions can efficiently store, update and track their research activities. This centralized data increases management's awareness of research activities while reducing the potential for administrative noncompliance.

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Recent News

TOPAZ Technologies Introduces Biosafety Software Solution

Solution Automates IBC Protocol Operations and Addresses Research Compliance Requirements

TOPAZ Technologies recently introduced the latest software addition to its product line, the Biosafety Solution. Our new software is a web application that automates the protocol process from inception to approval. Like our other software, the Biosafety application helps prevent regulatory compliance violations by compiling, tracking, and managing complex research data while creating audit trails and comprehensive reports on demand.

Key features include:

- Customizable Biosafety protocol forms
- Automated protocol monitoring, tracking, and management
- Regulatory reports and audit trails
- Collaborative review environment
- User-defined role and access control
- Meeting agenda scheduler
- User-defined templates for recording meeting minutes

Learn more at www.topazti.com

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Standardize Data Captured Across Sites and Studies. While centralizing disparate location data is important, it can be difficult to maintain without standardization.

To help standardize data and maintain consistency across locations institutions must create and leverage standardized templates. To accomplish this, first define key data components required across every study at every site (e.g., regulatory-mandated information) and then define site/study specific requirements. As templates are defined, seek multi-site feedback and actively consult with study management to ensure necessary data is captured.

Developing these standardized templates will help drive global initiatives, manage end-user expectations and gain site buy-in; reducing resistance to change and ensuring new operational expectations are met. In addition to uniform metrics, institutions must allow appropriate site-specific processes to remain intact to ensure relevant processes are maintained. Finding the right blend of standards, harmonization and location-specific processes is key to the success of multi-site data management.

Automate Compliance Management. One of the largest challenges for managing compliance across multiple locations is keeping up with the overwhelming amount of data and making sure important deadlines are met. By automating operations, institutions can leverage automated alerts to ensure research needs are being met while maintaining study time lines and ensuring all requirements are in place to keep the organization operating in compliance. Automatically tracking key expiration dates,

deadlines and usage information virtually eliminates human error, providing valuable assistance in removing potential non-compliance weak points.

Monitor Activities Frequently for Each Site. To ensure compliance requirements are being followed at every location, it is important to implement a consistent reporting regimen to closely monitor the day-to-day activities. In addition to reviewing reports on a regular basis, compliance managers should maintain detailed audit trails of every study, for both regulatory and internal tracking needs.

Appoint An On-site Compliance Specialist For Each Location. While it is important to have a central compliance manager that oversees institutional compliance procedures, it is equally important to have site-specific compliance specialists. A compliance specialist on location will have more hands-on contact with the site's operating environment and the specifics of the study and will be more in-tune with compliance procedures. This onsite expertise and additional enforcement will provide an extra level of protection to help ensure compliance requirements are being met.

Successfully Managing Multi-Site Compliance. As the biomedical research industry continues to change and the regulatory burden continues to increase, it is important that institutions have an efficient process in place to maintain compliance across the organization. The growing pains of multi-site compliance management can

be minimized by following the best practices mentioned in this article. Following these will not only simplify compliance management and protect your organization; it will provide a scalable environment and structure for future growth.

Technology Tip

GRANITE™ Training Module Helps Regulate Compliance Requirements

Tracking employees' qualifications manually can be time intensive and risky when trying to achieve compliance. Did you know that GRANITE can help with that? Its training module can simplify training and certification tracking to ensure staff qualifications are met and up-to-date. Using the training module you can track training and certification compliance requirements, including:

- Orientation Training
- Occupational Health Training
- Certifications

With staff members directly linked to protocols, you can select any individual and gain full access to their training records, certifications, and expiration dates. Additionally, by using dynamic filtering, you can automatically identify qualified individuals for new or upcoming studies based on procedural qualification requirements. Simply enter a procedure or species and a qualified match is made.

Moreover, by adding these features to the web based protocols software, you can access this information anywhere, at anytime, to ensure ongoing compliance.

To learn more about the GRANITE Training Module, contact customer support or call 800.250.9090

Upcoming Events

TOPAZ Technologies International Conference

When: August 29 – September 4

Where: Santa Cruz, California

Chaminade Resort & Spa

Discover best practices, participate in timely discussions, and network with peers, all while enjoying the California coast. Plus, stay a little longer and participate in two days of educational seminars focused on user development and application training led by TOPAZ software experts.

Register today, or download our conference brochure at www.topazti.com

Live Webcast: Effective Approaches to Maintaining Federal Compliance for Research Protocols

Date: Tuesday, July 28, 2009

Time: 11:00 AM – 11:50 AM CST

Join us for a free webcast that will showcase an electronic compliance system that standardizes information and provides the ability to share and manage research information between internal and external personnel.

Key Topics Include:

- Integrating IACUC, IRB, and IBC committee work spaces to simplify and streamline collaboration
- Leveraging existing management and information systems for increased effectiveness
- Strengthening security and compliance management through automation

Register Today! Visit:

www.topazti.com/SummerNewsletter.html

Customer Spotlight

Company: Texas Southern University

Experienced Results:

- Improved processes ensuring compliance, reduced redundancies, improved data accuracy and increased staff efficiency
- Heightened confidence levels in human and animal research programs
- Reduced negative factors affecting compliance
- Enhanced communication with researchers

Customer Overview:

After a phased implementation and training program led by the TOPAZ Technologies team, Texas Southern University went live with TOPAZ Technologies Protocols for Animal and Human Studies in February of 2009. Since that time TSU has experienced heightened compliance confidence levels, increased efficiency and improved data accuracy in its animal care and use programs and in the program for the use of human subjects in research.

“Our experiences with TOPAZ Technologies automated protocol solutions thus far have given us the confidence that we will achieve our overall goals to increase efficiency and efficacy of our compliance programs, ensuring compliance adherence by the TSU research community,”

- Linda Gardiner, Ph.D.

Director of the Department of Research Enhancement and Compliance Services
Office of Research
Texas Southern University

Client Support

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Key benefits include:

- Web based solution enabling remote access, from anywhere at any time
- Centralized location to store and track data for multi-site management
- Custom protocol form builder with drag and drop simplicity
- Full-featured meeting management for agenda building and sharing, tracking meeting minutes and electronic review, approval and storage
- Collaborative environment with version compare features for tracking edits to protocols

Why wait? Schedule your upgrade today at 800.479.2498.

Employee Spotlight

Willkommen (Welcome) Dr. Gabriel N. Schenker

TOPAZ welcomes the newest member of our team, Gabriel N. Schenker, Ph.D. as Senior Software Architect. Located in Dättlikon, Switzerland, Gabriel's position includes designing and developing new software applications for TOPAZ Technologies. With over 12 years of experience, Gabriel will focus on the expansion and continuous improvement of the TOPAZ software architecture to meet our customers' needs now and in the future. Prior to joining TOPAZ, Gabriel held positions as an independent consultant, trainer, and developer for several large organizations in Switzerland.

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Quarterly

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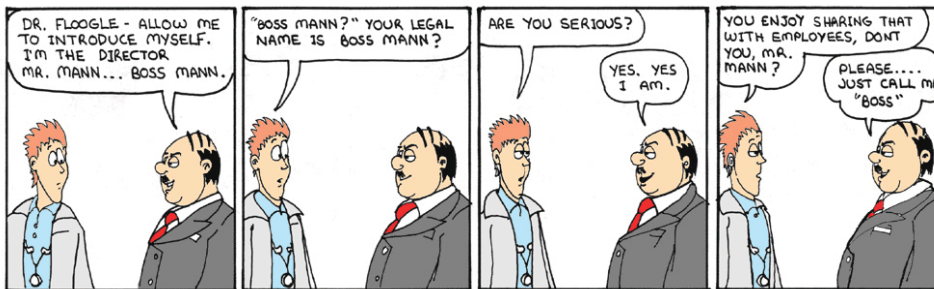
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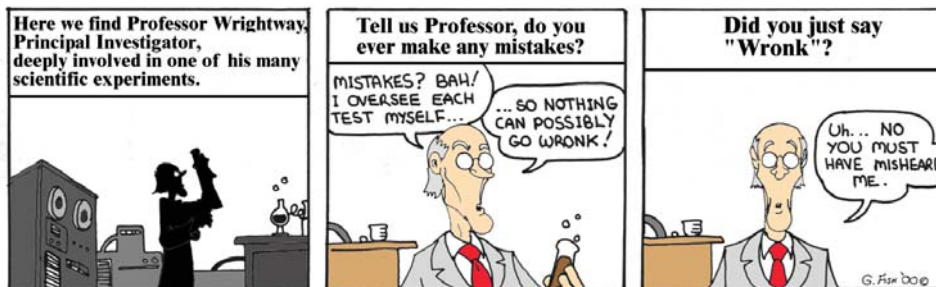
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... and the Professor ...



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