



The Business Case for a Software Solution

Executive Summary

The need for software to enable the management of compliance and vivarium operations can be perceived as a luxury that makes the jobs of researchers and administrators easier. However, most organizations eventually reach a threshold at which either current productivity or regulatory compliance or both cannot be sustained without some kind of automation.

Software solutions not only improve productivity; they also reduce errors, diminish the probability of compliance violations, and improve billing accuracy, all of which contribute to sustainable and efficient research.

This paper provides some potential business justifications for the implementation of a software system within research operations of any size. Effective and efficient research compliance protects the institutions, researchers, and the research subjects. The regulatory landscape and many institutions' organizational needs require comprehensive research management software that is more than a simple electronic submission system

Alternatives

The alternatives to not acquiring a software solution for growing institutions are to either: (1) create a collection of PDF smart forms, databases, and spreadsheets or (2) continue the current status quo. Both of these options hinder the growth of burgeoning research institutions, significantly contribute to their administrative burden, and increase their regulatory risk.

Costs & Financial Analysis

In the last 10 years, research compliance has become a profession and is no longer the realm of lower level administrators. Entry level research compliance positions prefer masters level education and individuals to fill this role are hard to find. Research management software fills a crucial Fulltime Employee (FTE) void in many research institutions, while the annual cost of typical systems is less than the cost of an additional FTE.

Benefits

A good software solution has substantial benefits, including

- Reducing the administrative burden of researchers and staff
- Technology security, organizational metrics and reporting
- Increased compliance with regulatory requirements leading to decreased risk
- Improved communication between committees, facility and researchers
- More efficient and more satisfied staff
- More accurate cost management and billing



Reducing or Eliminating Administrative Burden

In the most recent FDP Faculty Workload Survey, researchers estimated that they spend almost half of their research time on meeting administrative requirements rather than conducting active research. For researchers to engage in research with human or animal subjects, administrative requirements are some of the most time consuming.

The right software solution enables the reduction of the administrative overhead of IACUC, IRB, or IBC submission through the use of smart technology. The forms are often long and complex and do not leave much room to provide guidance requiring researchers to call senior or administrative staff for assistance. With smart technology, the number of forms can be reduced by employing branching logic to streamline the questions a researcher sees. Further, by replacing text boxes with drop down lists, data entry time is decreased allowing more time for actual research.

Organizational Metrics and Reporting

Reporting is a critical aspect to the business and administration of any research institution. Understanding your animal inventory in the context of specific protocols, animal acquisition, billing and veterinary care, is absolutely vital.

USDA audits and AAALAC accreditation require that research facilities not only remain in compliance; they also require that the institution can demonstrate that compliance, which can only be performed with proper reporting.

Increased Compliance with Regulatory Requirements Leading to Decreased Risk

From a regulatory perspective, an institution is either in compliance or it is not, but understanding whether the institution is operating at 100% compliance can be difficult to ascertain. This organic uncertainty is a risk factor that must be mitigated if a research institution is to continue growing.

By capturing evidence of rigorous review of protocols, and providing a variety of tools to assist both compliance staff and the researchers themselves, staff members can avoid transgressions such as working beyond protocol expiration, exceeding authorized animal counts etc. A software solution can greatly reduce risk and provide easily reported evidence in the event of an audit.

Animal Facility Efficiencies and Per Diems

Except in the smallest of facilities, keeping accurate animal census counts and billing accurate per diems is not feasible without a software system. Many systems employ barcode scanning, for example, so that census data can be efficiently and accurately loaded into the system rather than recording it longhand. This enables accurate per diem rates, which in turns enables institutions to keep rates low, and that leads to more satisfied researchers.

New Common Rule

Using a software solution, you can more easily support the operation as rules change. All the necessary adjustments can be made with simple form changes and additions to master pick lists. For example, software would make the compliance processes easier to bring into line with the New Common Rule, because the protocol forms can be more easily changed to reflect and to help enforce the new requirements, both among the researchers and the committee members.

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Dynamic Reviews

Software can also provide a centralized reviewer portal in which reviewers can perform work with a specific focus **together**. This approach promotes collaboration among reviewers, which in turn promotes a more prepared team for review meetings. It helps create a more productive work environment because of the improved focus it fosters.

Regulatory Training Compliance

Ensuring the maintenance of research and administrative credentials becomes both more critical and more difficult to manage. Greater staffing numbers creates more opportunity for individuals to lose track of specific training requirements, and a diminished ability to manage those requirements.

Software can also enable administrators to configure required competencies and courses for specific individuals. Both administrators and individuals can centrally track these requirements, through reports and viewable data, and intervene as necessary to ensure training compliance.

Conclusion

There is no question that when your organization reaches the paper tipping point, a software solution can return the productivity that administrative overhead inevitably consumes. All research institutions strive for both efficiency to keep costs low and effectiveness to reduce risk. As these institutions experience growth, software is often the only solution for minimizing both cost and risk.

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About Topaz Technologies

TOPAZ Technologies, LLC provides animal and human research software solutions for the medical research industry. With almost 40 years in the industry, TOPAZ is the established leader in delivering software-based solutions for complex regulatory environments.

We provide regulatory compliance and operations software for human and animal research facilities. TOPAZ Elements is an integrated application suite that facilitates protocol approvals, ordering animals, tracking animal census and billing, and veterinary care.

TOPAZ was founded in 1979 in Oklahoma. We've been in beautiful Austin, Texas for the last 35 years, and as of June 2016, we're part of the CSI family of companies. We provide compliance (IACUC, IRB, IBC management) software and animal facility management software to universities, pharmaceutical and biotech companies, hospitals and government agencies to assist with protocol management, animal facility operations, AAALAC compliance, animal health records, animal ordering, census and per diems and PI billing.



Main: 512.249.8080 | Fax: 512.249.8780
Email: info@topazti.com | Support: 800.479.2498

