



## Regulatory assurance through effective business information governance

A small pharmaceutical research company discovered that an excel-based solution, implemented along with the right governance protocols, delivered better regulatory assurance to their international enterprise than could have been delivered by simply moving to the big-price-tag software solutions they'd been looking to purchase.

A small international pharmaceutical research company – let's call them DrugCo – operates in various countries – Australia, New Zealand, North America, South America, Europe, Ireland and Great Britain. Safety monitoring and reporting regulations require that all adverse events be reported to regulatory agencies.

Adverse events constitute a significant business, legal and regulatory risk for companies conducting clinical trials and selling drugs. DrugCo was highly concerned with their current system that involved a paper-based report of each event being entered into Microsoft Excel. As a new trial was underway in the USA, DrugCo also needed to ensure compliance with the US FDA requirements for their trial, which impacted what was considered effective management of adverse events.

## History

Larger pharmaceutical companies tend to use customised, full-service software systems that are pharmacovigilance (PV) compliant, in order to mitigate risk and ensure all regulatory requirements are met. DrugCo didn't have the budget of their huge global peers, and weren't sure the investment in such a system could be justified by the size of their trials.

DrugCo engaged Intraversed to see if an alternative solution to their business and regulatory assurance needs could be found.

# Understanding the problem first

After undertaking a thorough evaluation of DrugCo's business processes, including the protocols for data capture, quality assurance, data entry and issues management, we realised DrugCo's primary risk wasn't a lack of expensive software.

The official processes for handling the data, from capture to end-reporting, were DrugCo's biggest risk. This included inconsistent definitions of what needed to be reported and conflicting management accountability. Both these problems could lead to missing information, which could ultimately result in legal risk for DrugCo, but also incorrect assessment of the drug being trialled, which could equate to lost revenue and business growth, as well as pose a danger to life.

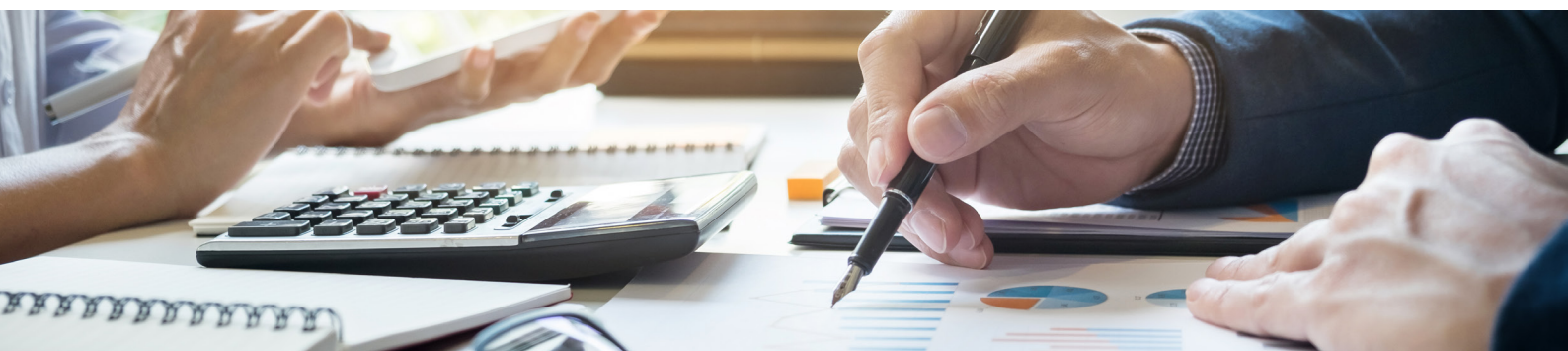
## A business information-focused solution

Intraversed were able to develop a plan for DrugCo that established solid and effective business information management processes, which included:

- organisation-wide definitions of key data terms & metrics,
- requirements for data capture and validation on entry,
- implementation of reliable security measures,
- establishing an audit trail and cross-checking process,
- establishing a backup and recovery process and
- upgrading their excel-based system to ensure all necessary information
- was recorded according to the regulatory requirements across all countries.

## The result

The bottom line for DrugCo was a saving of over \$700K on software they didn't need, and confidence in establishing subsequent clinical trials knowing their systems were robust and compliant.



# What can you learn from DrugCo's experience?

While software companies work hard at developing custom-systems suited precisely to the needs of certain industries, they're not always the best solution for every business operating in that space.

The secret to knowing whether such a software package will solve the business problems your company is facing is having a thorough understanding of all the business terms, rules, processes and systems that are involved and seeing exactly what is contributing to the problem. Only then can you determine if a software package can resolve the problem.

In our experience, the real cause of the problem is rarely lack of effective core-process software. The problems are more likely to be the result of ineffective business information resource management.

Managing your business information resources well has four key elements:

- define your key business terms,
- ensure your resources are catalogued,
- develop a thorough and effective issues management process, and
- establish a governance environment to ensure ongoing effective management.

If you're struggling with attaining the level of business assurance you want and you'd like to find out how business information resource management could help, why not [take our free assessment at intraversed.com.au](https://www.intraversed.com.au) and let us help you find areas you can address for early benefits.



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S-DE-2020-0064