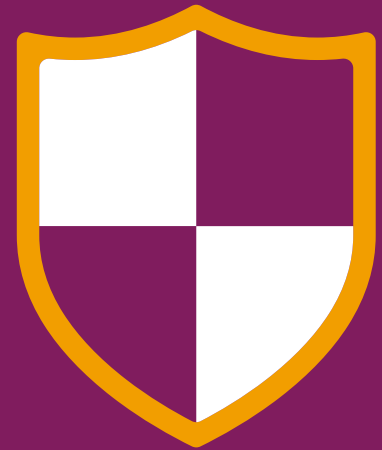# PSIXCHANGE
MAKE YOUR DATA WORK

AN ITERATIVE APPROACH TO SAFETY SYSTEM IMPLEMENTATION (OR HOW TO AVOID HAVING ALL THE GEAR AND NO IDEA)

You may have read in a previous blogpost[1] that Right-sizing the implementation of a system can be accomplished by utilising industry experts in technology, validation and processes to achieve the Holy Grail of system implementation: *Do it quicker, cheaper and better.*

In addition, similar benefits can be realised throughout the Maintenance phase of the system lifecycle by Right-sourcing the non-billable, administrative tasks.

To build on the theme of Right-sizing, we want to introduce the idea of Iterative Implementation.

1 Right-sizing for Safety Database Implementation, 18-Jan-2019,
Right-sizing for Safety Database Implementation
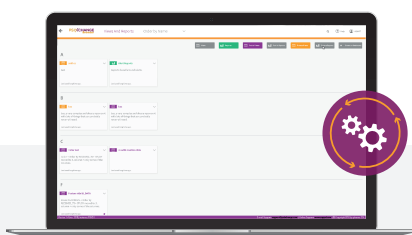
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WHAT IS ITERATIVE IMPLEMENTATION?

Put simply, *Iterative Implementation* breaks the overall system delivery into smaller pieces that can be released to users over a period of time. It is the opposite of Waterfall, where the system is released in one Big-Bang.

The benefits of delivering a system in an iterative manner is that by having multiple smaller delivery cycles the project team can take advantage of what has been learned in the earlier stages and adapt the future iterations accordingly. In addition, the requirements can be adjusted to align with the current business processes rather than relying on requirements developed 12+ months ago. Finally, Return on Investment (ROI) is typically seen sooner as implementation is generally quicker when delivered through iterative cycles when compared to a Waterfall delivery.

THAT SOUNDS VERY SENSIBLE, SO WHY DO WE NOT SEE IT OFTEN IN COMMERCIAL OFF THE SHELF (COTS) IMPLEMENTATIONS?

Well, there are many reasons driving that decision with one of the biggest being the internal investment approval process which often dictates that all of the investment (and therefore all of the computerized system) must be budgeted for up front. Executive Management often will not accept continuous investment requests for the same product.

Another is that software vendors often wish to implement their products in as many parts of your organization as possible. This both generates additional revenue for them and develops new opportunities and potential for more work throughout your organization. So, where PV may be seen in isolation as a vertical business unit, which has limited growth potential, by embedding horizontally to other areas such as Medical Writing, Risk Management, etc., the broader overall project is very attractive to a vendor.

There are of course many other valid reasons for wanting the implementation of a COTS systems to be in one go, including continuous change management and commercial reputation. However, it can often be advantageous to focus on what benefits can be gained from implementing an iteration of a computerized system right now based on the current operational procedures, internal capacity and organizational capabilities and less on the perceived perfect system.

Once the core product is in productive use, we can look at what makes sense to focus on next. "Rome wasn't built in a day," as they say.

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HOW CAN AN ITERATIVE APPROACH BE APPLIED TO THE COTS SYSTEM?

We can look at Iterative Implementation in 2 ways: Iterative Skills & Resources and Iterative Functionality.

ITERATIVE FUNCTIONALITY

Iterative Functionality is probably the most recognized approach to Iterative Implementations and is seen commonly across the commercial software industry where the Basic product is less costly and comes with basic functionality to satisfy your initial needs, while the Premium product has the full suite of functionality and usually costs more. An example of this is Adobe Acrobat which offers its basic product (Reader) for free and its premium products (Standard and Pro) at an increasing price based on functionality.

In terms of how this works for the implementation of a COTS safety database, the aim is to define a set of business requirements that provide a basic yet robust foundation for the processing, reviewing and reporting of data. Once the core product is deployed it may then be time to look at any additional functionality that could enhance your business processes and develop your client offerings (analysis of the data, electronic reporting, etc.) and implement those in the next phase of the system.

This cycle then continues as iterations become established, your organization becomes more adept at using the system, and you identify new requirements and opportunities. This allows you to start benefiting from using the system sooner, gets you to full utilisation quickly, and shortens the overall time for ROI.

FIGURE 1: COMPARING AVAILABLE FUNCTIONALITY OVER TIME BETWEEN ITERATIVE AND WATERFALL IMPLEMENTATIONS. NOTE: ALL NUMBERS ARE FOR ILLUSTRATIVE PURPOSES ONLY.
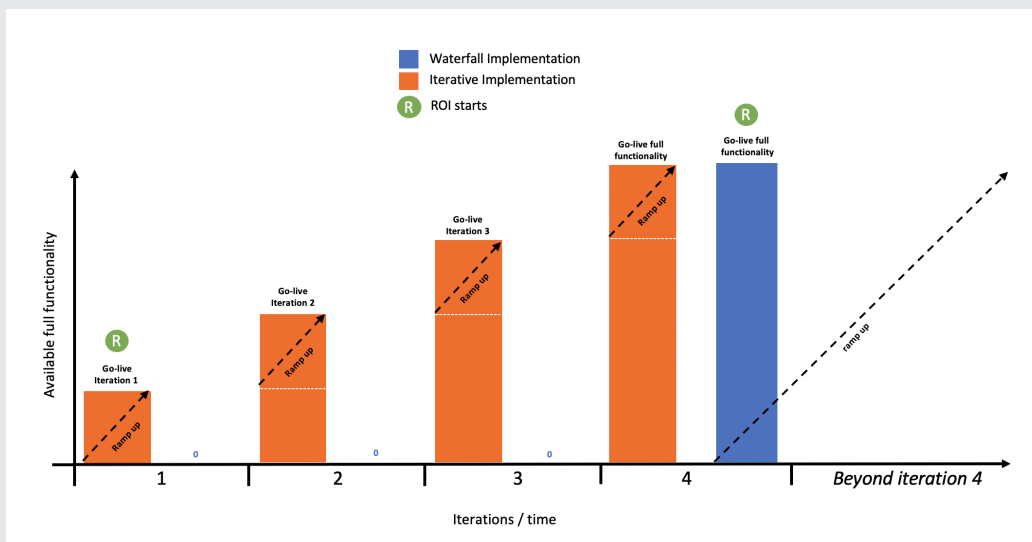
Thankfully, for the first iteration, a combination of well-defined guidelines and regulations within the computerized system validation area and safety systems being well established within the PV arena means that most COTS systems' basic offering provides the functionality to be both compliant with the pertinent regulations and to meet the core needs of your PV business (that is not to say that these systems should be introduced into your company without first defining your requirements of course!).

We can take Oracle Argus Safety as a prime example.

Argus Standard Edition is the core offering that provides for the entry, processing, review and reporting of case data. It additionally has aggregate listings based on defined templates and some basic metrics. Argus Interchange is also included as standard for electronic reporting via a gateway. Argus Standard Edition is used throughout the industry and across companies of all sizes to deliver the required functionality for supporting PV processes.

Argus Enterprise Edition provides a more comprehensive offering that builds on the core Argus Standard Edition with additional functionality that allows deep dive into the data (Argus Analytics), along with customization and design of listings and reports (BI Publisher).

Furthermore, there are **additional modules** which can be introduced (at the beginning or at a later stage) to support other defined business areas such as: remote data entry **(Argus Affiliate)**, periodic report writing and publishing **(Argus Dossier)**, Japanese language **(Argus Safety Japan)**, and Signal Detection and Signal Management **(the Empirica suite of products)**

But do you need all of that functionality in place at the same time? Is there value in investing time, resources and money in, say, implementing Argus Affiliate if your initial release is restricted to a central processing hub?

What are the benefits of having functionality to create custom listings when the native listings meet your initial needs?

These are some of the questions that we must consider when looking at implementing a *Right-sized* safety database into an organization and determining whether an iterative approach is best.

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ITERATIVE SKILLS & RESOURCES

Iterative Skills and Resources is probably a less recognized strategy for system implementation. Whereas Iterative Functionality is driven primarily by the core business processes that must be supported by the system and is focused in the Implementation Phase of the system lifecycle, Iterative Skills and Resources recognises the capacity and capabilities of the organisation's workforce and is focused on the Maintenance Phase of the system lifecycle.

Traditionally, training is used as the main tool to ensure that the customer has the necessary skills to use the system. This focuses primarily on the main business users; Data Processing, Medical Review, and Regulatory Reporting.

You may have read in a previous blogpost, there are some specific hurdles in identifying and utilizing administrative staff. For example, they are hard to find, expensive to employ, may not have enough work to be fully utilized and there may not be an identified backup.

"Right-sourcing" is the partnering of your organization with a vendor specifically to undertake business-led tasks, thereby reducing the operational and financial risks.

This can be made iterative by tapering the support from the vendor over time, for example by initially providing all the administrative support, to then providing administrative support at times of high volume only and then finally providing no administrative support at all.

This facilitates a quick ramp-up to go-live without the additional burden of identifying and onboarding administrative employees at a time when your organisation is already going through a big change (with the implementation of a new system) whilst outlining a mechanism by which this role can eventually be handed back, once your organization has established an internal resource for these tasks. The added benefit of this approach is that training is provided over a longer period of time and within the real-world.

IN SUMMARY

Applying an iterative approach to all aspects of a drug safety safety database implementation project can help your organization right-size the internal effort, maximizing the benefit at each stage of implementation and contributing to an efficient and effective journey along your safety system roadmap.

FIGURE 2: COMPARING EFFECTIVENESS OF ADMINISTRATIVE SUPPORT FOR TAPERED RIGHT-SOURCE ADMIN VERSUS CUSTOMER-ONLY ADMIN. NOTE: ALL NUMBERS ARE FOR ILLUSTRATIVE PURPOSES ONLY.
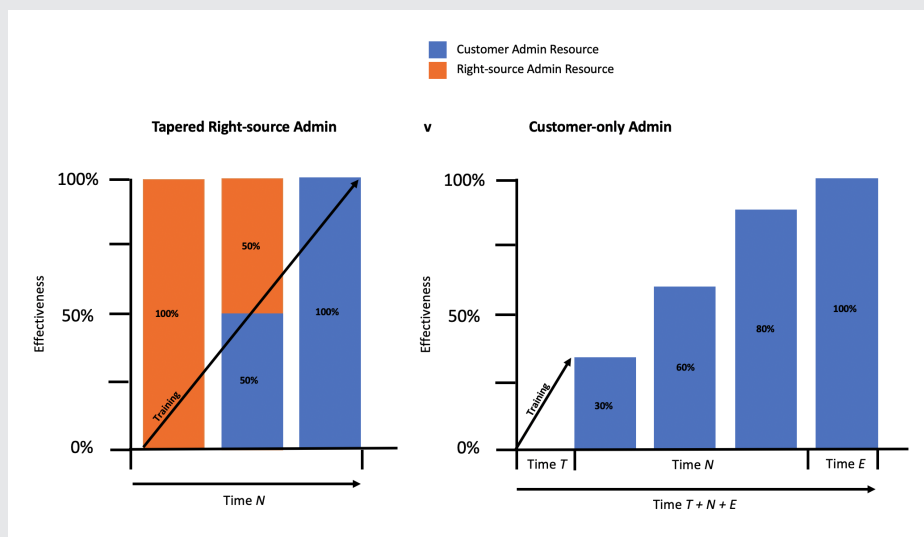
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FIND OUT MORE

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www.psixchange.com

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