Just Don't Rely on Processes: Support Local Subject Matter Expertise

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ABSTRACT

Since the dawn of time (or at least since we started analyzing data from clinical trials) companies engaged in clinical research have developed processes designed to ease the burden of programmatic data review, data standardization and data analysis tasks. These processes typically include standards for input data, standards for outputs and code to get from one to the other. In many cases people who have a limited understanding of the process (or the subject matter) can quickly generate outputs that are right most of time.

But how can we efficiently manage cases where the process does not produce accurate results? And how can we be sure that people following the process are able to evaluate if the results are accurate? A big part of the answer is ensuring that process users have sufficient subject matter expertise. If users understand (in detail) how the process works, and what it is designed to accomplish, they will be able to address most cases where the process does not work or produces inaccurate results. We will share a few representative examples of where subject matter expertise is needed to ensure a process works as intended and produces accurate results. We will also suggest training methods designed to help process users gain the subject matter expertise they need to be successful.

INTRODUCTION – A BRIEF HISTORY OF THE UNIVERSE, THE EARTH AND CLINICAL TRIALS

In the beginning there was nothing.
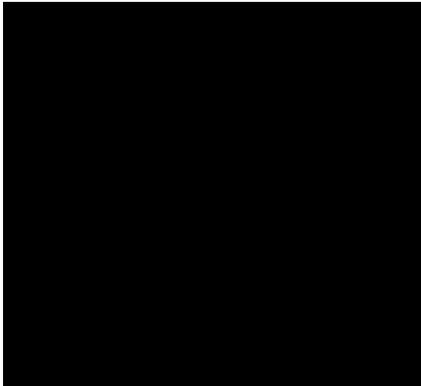
Then there was something.

Then there was the earth.

The earth was populated by plants then dinosaurs and then by humans.

Humans started working to live longer, healthier lives. At first we focused on avoiding dangerous animals that wanted to eat us (and on having enough to eat). Once we were fairly safe and well fed, we learned how to live longer and better lives by observing and guessing. Eventually, we designed clinical trials to systematically evaluate whether investigational drugs were safe and effective.
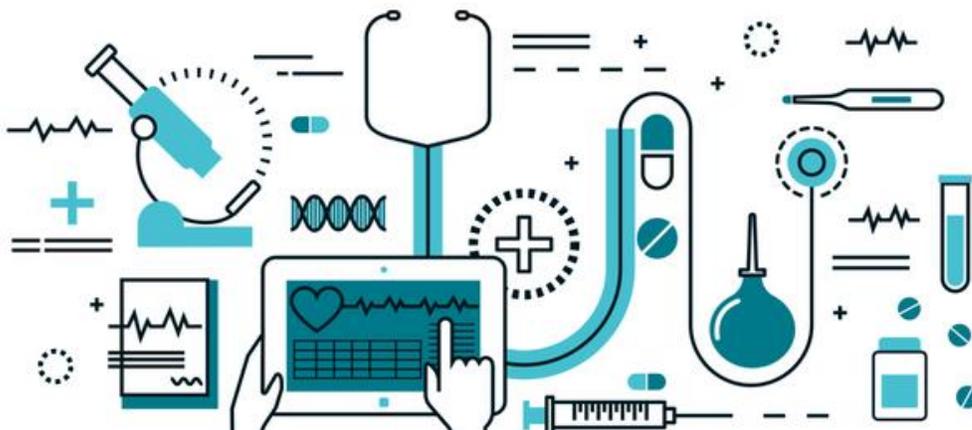
THE WONDERS (AND RISKS) OF AUTOMATED PROCESSES

And now, we are all working to make clinical trials more efficient. One key to efficient clinical trials is automation. Automated processes (when designed, or at least vetted, by experts in the area to be automated) can save time and money and result in better quality. And with more comprehensive automation, even more time and money can be saved.

But as automation becomes more and more useful and user-friendly, the need for human understanding can often be discounted to the point that users are not able to understand how to leverage the process and cannot even evaluate whether the process is working as it should. To quote Hamlet: "There's the rub. " The better the process, the more useful it is; and the more useful (and user-friendly) a process is the more likely it is that user groups will lose track of exactly how it works and how to evaluate whether it is working exactly as intended.

There are many circumstances where mostly right is all that is needed; clinical research is not one of them. We suggest that companies take care to ensure that they have (and maintain) the subject matter expertise they need to use processes correctly, fix any problems or gaps that surface and be able to conclusively confirm that any outputs are exactly as they should be. What follows are simple process examples designed to highlight both the risks and benefits of automation along with some general steps companies can take to ensure processes are used as intended and have the Subject Matter Expert (SME) support they need.

AUTOMATED PROCESS EXAMPLE

Controlled Terminology (CT). Everybody loves it if it can be easily controlled. To accurately apply all those standard terms, a process is needed to support to creation, maintenance and review of how collected terms are mapped to their controlled term counterparts. SMEs are needed to ensure that the process is functioning correctly and terms are all (and we do mean all) appropriately mapped.

Consider this example of a CT mapping process.

1. The SME develops a list of collected terms used on the CRF and creates a spreadsheet to match the collected terms to SDTM CT.
2. The SME then creates a macro to read in the CT mapping.
3. The macro is used in multiple projects to support creation of SDTM domains.
4. The macro has been written to support ongoing SME review. One example: Any collected terms which are not matched to a CT value will be output into a report for review and will result in a warning in the log file.
5. The SDTM programs are re-run by a (non-SME) generalist on a monthly basis.
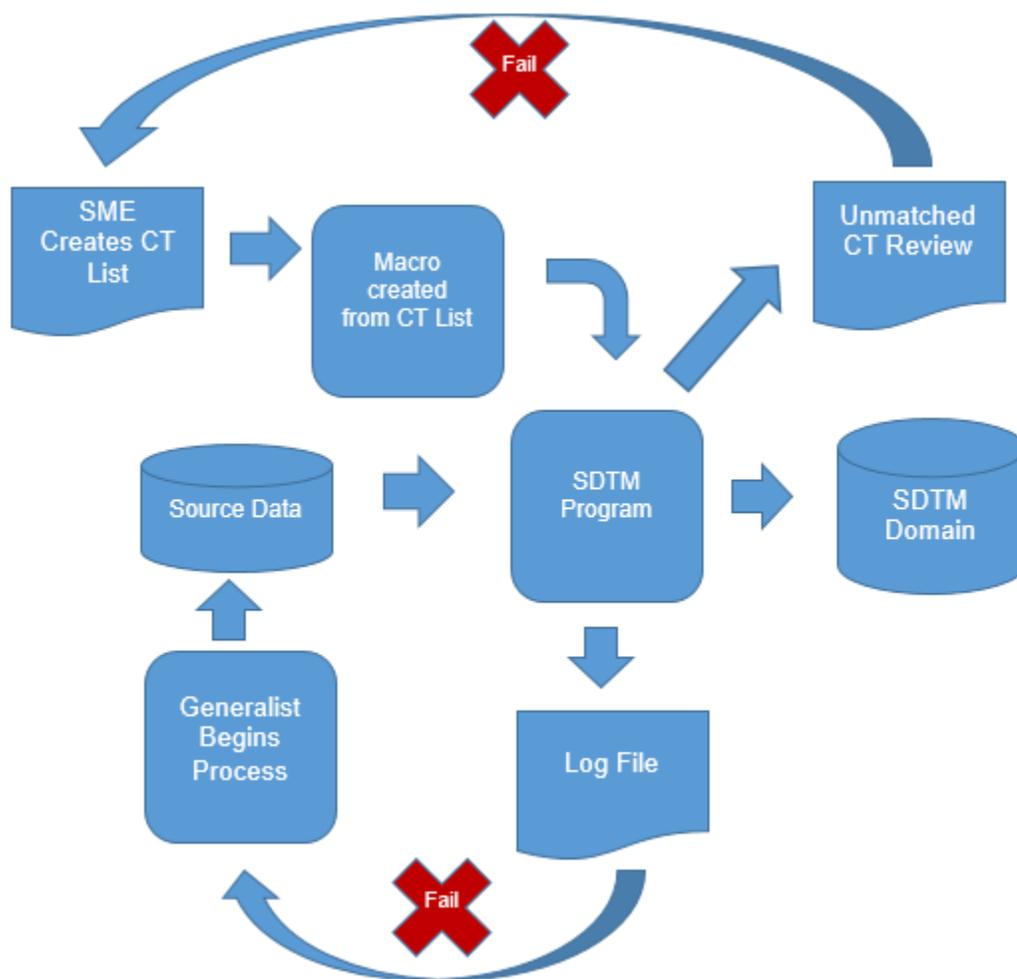
See Figure 1, below.

Figure 1. Example CT Process

How could this process fail when it has built in checks and balances? Let's throw a recently hired SME into the mix. When the SDTM programs are re-run by a generalist, a warning appears in the log file. A new collected term is now in play.

AUTOMATED PROCESS EXAMPLE – SME SUPPORT REQUIRED

The generalist reviews the log but does not know where the warning is originating. The new SME is not familiar with the company's process for mapping to CT and does not review the unmatched CT report. The process has now failed in two ways: 1) The generalist does not know (based on the log warning alone) to go back to the SME and ensure the CT spreadsheet is updated; and 2), the new SME does not know that the CT report exists or where to account for the new collected term. The process has flagged the data for updates; but with little or no training on the process, and limited information in the log, the monthly maintenance runs will lead to increasingly non-conformant SDTM. And even worse, management will likely be sleeping soundly knowing that CT mapping has process support, blissfully unaware that no one understands how to leverage the process.

Several steps can be taken to correct the process. These include better training for the generalist and SME and better process documentation. Automated processes are great. But if no one knows how to use them properly there is no benefit to the staff or company and they may even lead to worse results.

AUTOMATED PROCESS EXAMPLE – ASSOCIATED TRAINING AND CONTROLLED DOCUMENTS

When a new process is developed, we council companies to take the time to thoroughly go over the process as applied in a training session. This might need to be several sessions (one for each functional group) for large scale processes that operate across functional areas (perhaps impacting Clinical Data Management, Database Design, Standards Implementation and Statistical Programming). In this day and age of technology, do not underestimate the value of live, interactive training. Without an attentive, engaged audience, little will be retained.

Training must be supplemented by documentation. Plan to give SMEs sufficient time to establish process documentation that can be utilized by SMEs and generalists alike. Whether the documentation is a working procedure, SOP, or warning note in the log, it should be clear and concise and include the "who, what, when, and where" of the process or issue. Quick reference guides with links back to the full documentation are also useful for staff to keep on their desktops. And as an added bonus, processes often get improved if SMEs find they are challenging to explain to a general audience.

ANOTHER AUTOMATED PROCESS EXAMPLE

Evaluating whether mapped data conforms to the applicable CDISC (SEND, SDTM or ADaM) standard is best done multiple times over the course of a study. So developing an automated process to support that repeated need is ideal. One approach that we have put in play is to build a process around a VBA macro that facilitates the management of Pinnacle 21 (P21) report findings over the life-cycle of a study. The VBA macro is supported by a curated list of standardized explanations and update notes for all possible issues. A pictorial representation of the process (sourced from Crockett, Widel, 2017) is below in Figure 2. VBA tool support areas are enclosed in the yellow box.
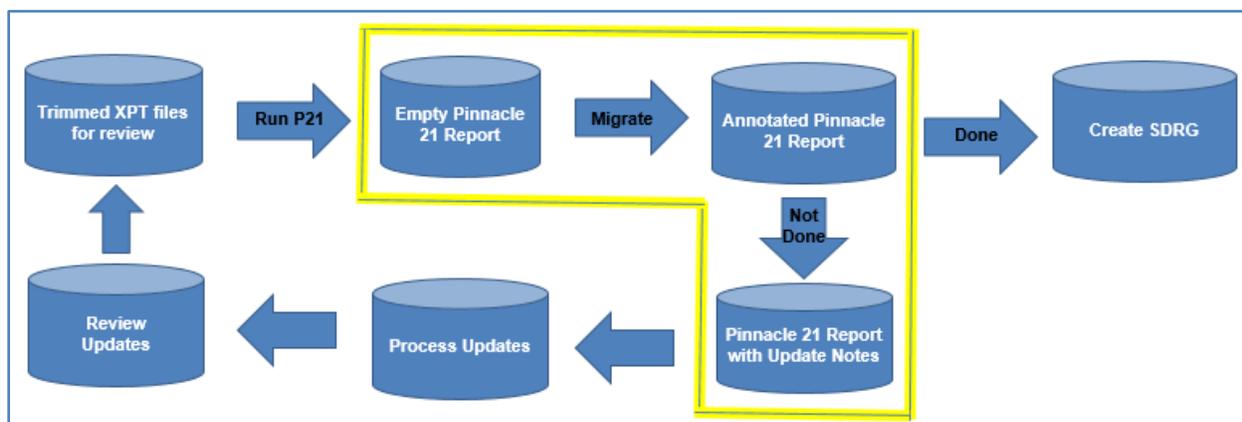

Figure 2. P21 Conformance Management Process Overview.

This automated process starts with running Pinnacle 21 Community. Once the issue report is generated, the VBA macro is used to automatically migrate issue explanations and update notes from the curated list of standardized explanations (for the first run) or from an existing Pinnacle 21 report (for later runs) to the newly generated report. The VBA macro also flags changes in the number of individual issues found from one report to the next. As an added bonus, the annotated report can be used to facilitate resolution of data and mapping issues by the study team (via update notes). After updates are completed and reviewed, the xpt files are recreated and the process starts again.

Sounds great, right? Quick questions. What skills are needed to ensure that P21 issues are appropriately addressed? What groups will receive feedback on the data based on this process? Who should manage/maintain the curated list of standardized issue explanations? We could go on for quite a while with this, but best to get back to our main theme and rephrase: Where is SME support needed? What training and documentation is needed to support continuing (and accurate) use of this process?

ANOTHER AUTOMATED PROCESS EXAMPLE – SME SUPPORT REQUIRED

Quite a bit. ☺

To be more precise, expertise is needed in multiple areas of the P21 report review process: developing and maintaining the VBA macro; understanding, documenting and correcting P21 report issues; creating and maintaining SDTM mapping processes (including local standards for issue documentation); and knowledge of company data collection and query processes.

These areas of expertise go across departments and functional areas. No one person can master all of these areas as each requires extended study and consistent practice. Keeping and maintaining the knowledge and expertise across groups needed for this process to thrive takes time, coordination, training and documentation.

ANOTHER AUTOMATED PROCESS EXAMPLE – ASSOCIATED TRAINING AND CONTROLLED DOCUMENTS

Just like every good organization has a president and a vice president, so should processes. Every SME needs a SME in-training to ensure durable SME support for the process and to provide expert review of process documentation. With an SME succession plan in place and solid documentation, a process is likely to have a long, successful and uninterrupted run. Without that support, an automated process will likely have a short and troubled existence.

Automated processes that are cross-functional are best documented by the associated SMEs from each function. The documentation can then be reviewed by all SMEs across functions. That cross-functional review can help ensure that process documentation is easily read and understood by a broad audience and often can to help to build more effective cooperation across groups.

CONCLUSION

Automated processes (when designed, or at least vetted, by experts in the area to be automated) can save time and money and result in better quality. But they need our support. When working to make a task more efficient, make sure to document how the process works and highlight where humans (often SMEs) need to step in and ensure everything is (and remains) accurate.

REFERENCES

Crockett, E. and M. Widel. 2018. "Automating CDISC Conformance Issue Management." Proceedings of the 2018 PhUSE/CSS Conference, PP05, Raleigh, NC. Available at http://phusewiki.org/docs/2018%20US%20CSS/posters/PP05.pdf

ACKNOWLEDGMENTS

RECOMMENDED READING

- *Discover Your CliftonStrengths*

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