

Improving Biometrics Processes with Six-Sigma

Andrew York, Covance, Crawley, UK

ABSTRACT

Since 2005, Covance Clinical Development Services has deployed Six Sigma as part of its process improvement culture. The aim being to measure, improve and monitor process efficiency leading to an increase in quality and a reduction in the cost and time associated with running a clinical trial. In 2008, Biometrics completed its first Six Sigma green belt project aimed at reducing the work time for writing medical writing narratives, achieved through a SAS® based programmatic approach. In 2009 we initiated further projects aimed, for example, at reducing the time it takes to write a SAP or to reduce the work required to QC Tables, Figures and Listings. This paper examines impact of Six Sigma within Biometrics, the time commitment, the challenges faced. It will then present an overview of some of our completed and ongoing projects and finally will look to the future and the lessons learnt along the way.

INTRODUCTION

Six-Sigma was first introduced into Covance in 2002 within our Early Development business. The success of this programme led to its introduction into our Late Stage (Clinical Development Services) business in 2005. Although Six-Sigma came into being within a manufacturing environment, it was felt that there was sufficient potential as a process development tool to adopt it for something other than the manufacture of “widgets”.

Adopting Six-Sigma was a complete culture change for Covance, processes needed to be analyzed and evaluated statistically using applicable data and robust statistical method. Six-Sigma introduced an entire new language into the company, as well as to introduce statistical methods to many staff who were not qualified statisticians.

Many departments volunteered their best staff to become black belts, committing them to a minimum of two years as a Black Belt during which they had to complete many weeks of training, three Black Belt projects and also to pass an exam before they were fully accredited as a Black Belt. These staff were all given a guarantee of a position with the company at the end of their ‘stint’ as black belts and indeed many have gone on to critical roles with the company.

Green Belts likewise had to undergo three weeks of training, complete two Green Belt projects and pass an open book exam before they were accredited as Green Belts. Additional project team members, Process Owners and Project Champions complete this list again with a significant training investment in these staff.

Figure 1 (overleaf) demonstrates how a Six-Sigma process can lead to fewer process failures (or defects) even when compared to a marginally less robust process.

Note: This paper will mostly focus on the DMAIC (Define, Model, Analyze, Improve, Control) model for Six-Sigma.

SIX-SIGMA METHODOLOGY

There are numerous references to Six-Sigma methodologies including LEAN and DMAIC models (the two used at Covance), and some of these references can be found at the end of this paper for further reading. As stated, Six-Sigma requires some knowledge of statistical inference and analysis and depending upon the type of data analyzed can require fairly complex analysis. At Covance it is the role of the Black Belts under the guidance of the Master Black Belt to guide the Green Belts and Project Team Members through the analysis steps.

One way to describe Six-Sigma is that it is a measurable process which compares the Voice of the Process (VOP) to the Voice of the Customer (VOC). Process improvements occur to (a) achieve the desired quality outcome and (b) reduce variability in the VOP until it is at least as good as the VOC.

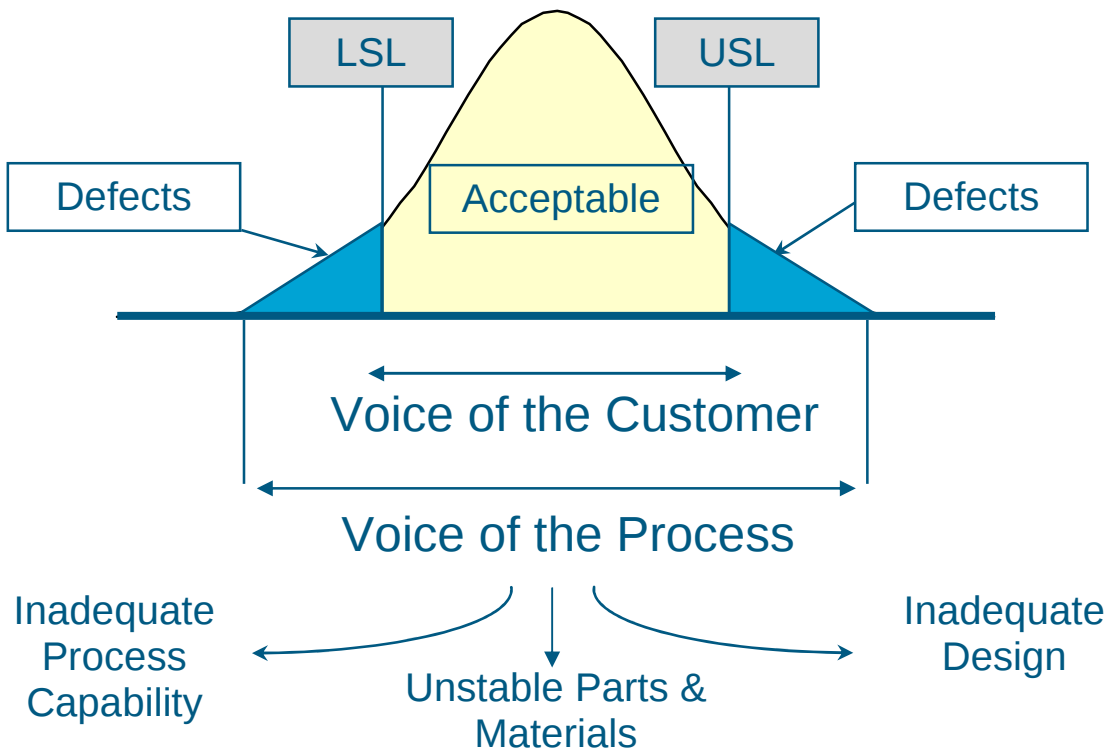
Figure 2 (overleaf) graphically illustrates and compares the Voice of the VOP versus the VOC. Although not shown in this case, ideally the VOP should be contained within the VOC.

PhUSE 2009

Figure 1 – The difference between processes that are 99% effective vs 99.99966%

99% Good (3.8 Sigma)	99.99966% Good (6 Sigma)
20,000 lost articles of mail per hour	Seven articles lost per hour
Unsafe drinking water for almost 15 minutes each day	One unsafe minute every seven months
5,000 incorrect surgical operations per week	1.7 incorrect operations per week
Two short or long landings at most major airports each day	One short or long landing every five years
200,000 wrong drug prescriptions each year	68 wrong prescriptions per year
No electricity for almost seven hours each month	One hour without electricity every 34 years

Figure 2 – Comparing the Voice of the Process vs Voice of the Customer



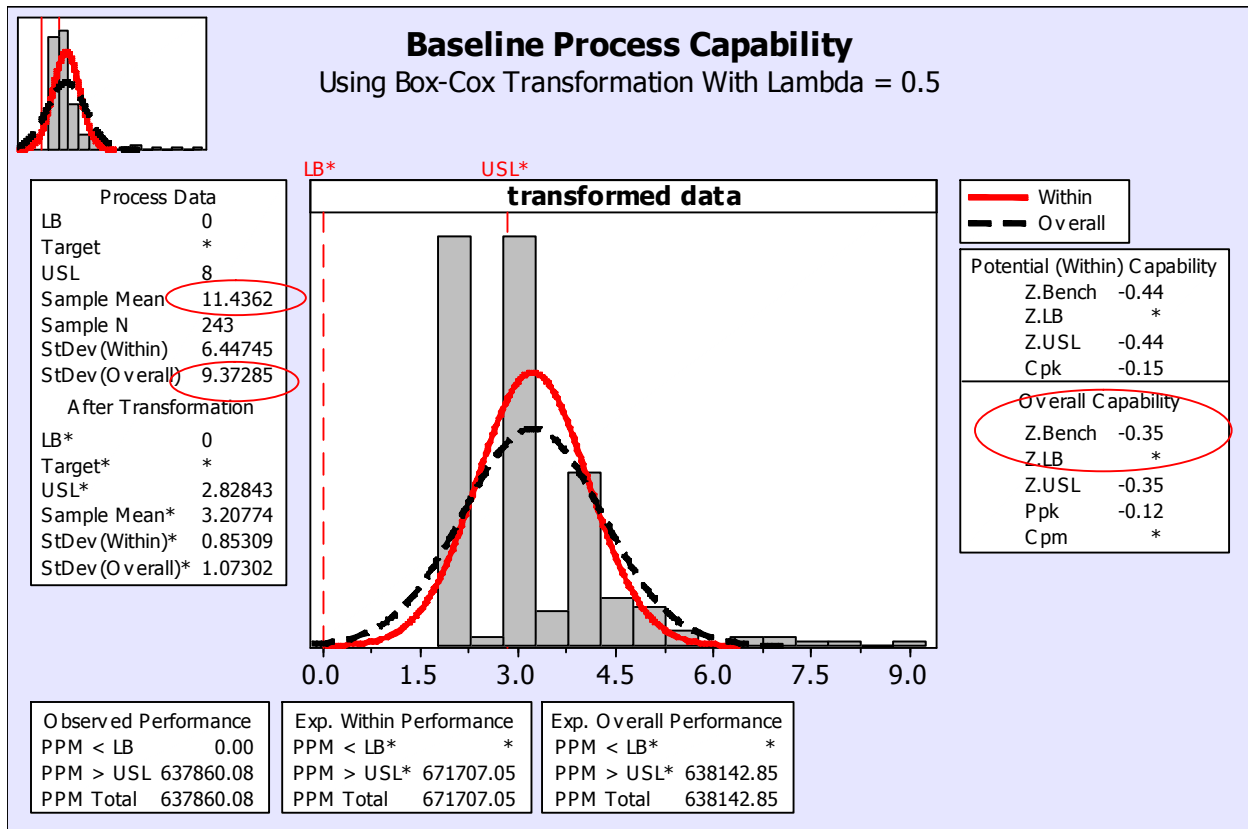
DEFINE, MEASURE AND ANALYSIS PHASES

The Six-Sigma Charter describes the aims of the project in ways that can be measured statistically (figure 3). Baseline data hopefully already exists but if not this must be collected such that the current state of the process (or VOP) can be measured and analyzed statistically (figure 4).

Figure 3 : Project Charter for the Medical Writing Narratives Project

Project Objective:
Y: Reduce work time to header completion for Draft 1 narrative by 50%
y1: Decrease work time variability of header completion for Draft 1 narrative by 50%.
Project Metrics:
Y: time to data entry of standard patient information in Draft 1 narrative header
y1: work time variability of header completion for Draft 1 narrative
Defect Definition:
Y: time to enter data for header exceeding 8 min/header
y1: work time variability of header completion for Draft 1 narrative std dev. of >5 minutes

Figure 4 : Baseline Analysis of Work Time for Narratives Header Completion



In addition to the baseline analyses, six-sigma tools such as the SIPOC (Suppliers, Inputs, Process, Outputs, Customers), Process Maps, Cause and Effect (C&E) Matrix, Fishbone Diagrams are employed to determine and evaluate cause of variability within the data. In statistical parlance these would be your independent variables (e.g. the x's in when expressed in a regression format: $y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_n X_n$).

In the case of the narratives project, factors such as European vs US or Internal vs External medical writers were amongst those considered when modeling the variables that contributed most towards the writing of medical writing headers.

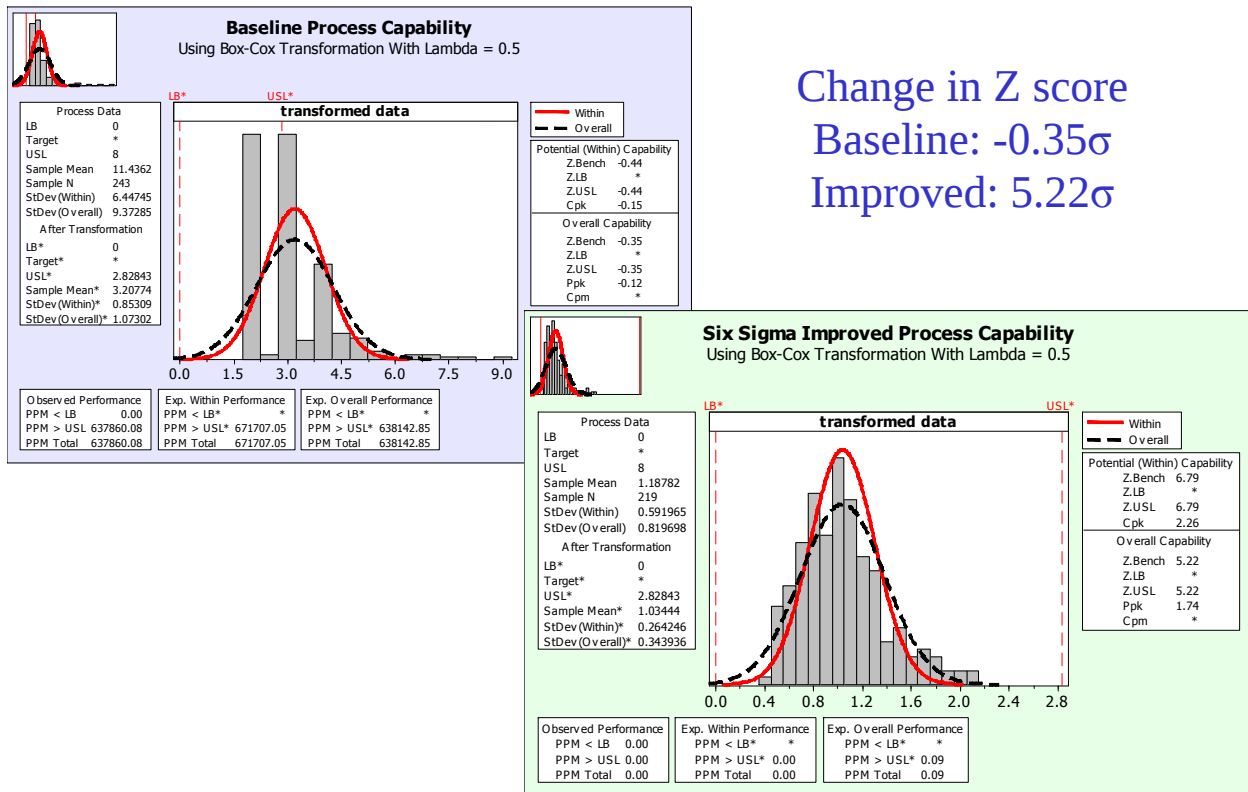
IMPROVE AND CONTROL PHASES

Once the core process has been analyzed, the project then moves into its Improve Phase. The project team should by now have some ideas for process improvements, helped by the statistical analysis of the independent variables as part of the baseline analysis. Part of this process is to involve the Project Champion to assist with the ranking of those factors which are most considered to be under the influence of the business to change or control (termed High-Level and Mid-Level C&E).

In the case of the Narratives project, a SAS® based solution was determined to be the optimum solution and was subsequently put in place to replace the manual process of header creation. Further data was collected to assess the performance of the new process in comparison to the baseline process. The data was compared statistically to assess if the process had been improved and in fact if the goals of the charter had been achieved (figures 5 and 6 - overleaf).

Once the process improvement has been established, the project enters its long-term control phase. Responsibility for tracking the control metrics falls to the nominated Process Owner who will monitor the process until either it falls out of control or else further improvements are conducted. Such improvements could be as the result of a new Six-Sigma project or a “just do it” (i.e. no-brainer) project.

Figure 5 : Assessing the Process Improvement



OUTCOME

For the narratives project, both of the charter objectives were met and exceeded and the project was hailed as a success by the senior management at Covance. In addition the project is now cited as part of the Six-Sigma training at Covance. Financially the project was also a success leading to savings for our Medical Writing department that exceeded the investment due to increased programming time. Finally and importantly our medical writers could spend more time focusing on the medical writing aspects of the narratives instead of manually entering header data into the individual narratives.

Figure 7 (overleaf) illustrates the control chart for the Narratives project, the process improvement can clearly be seen.

Figure 6 : Analyzing the Improvement

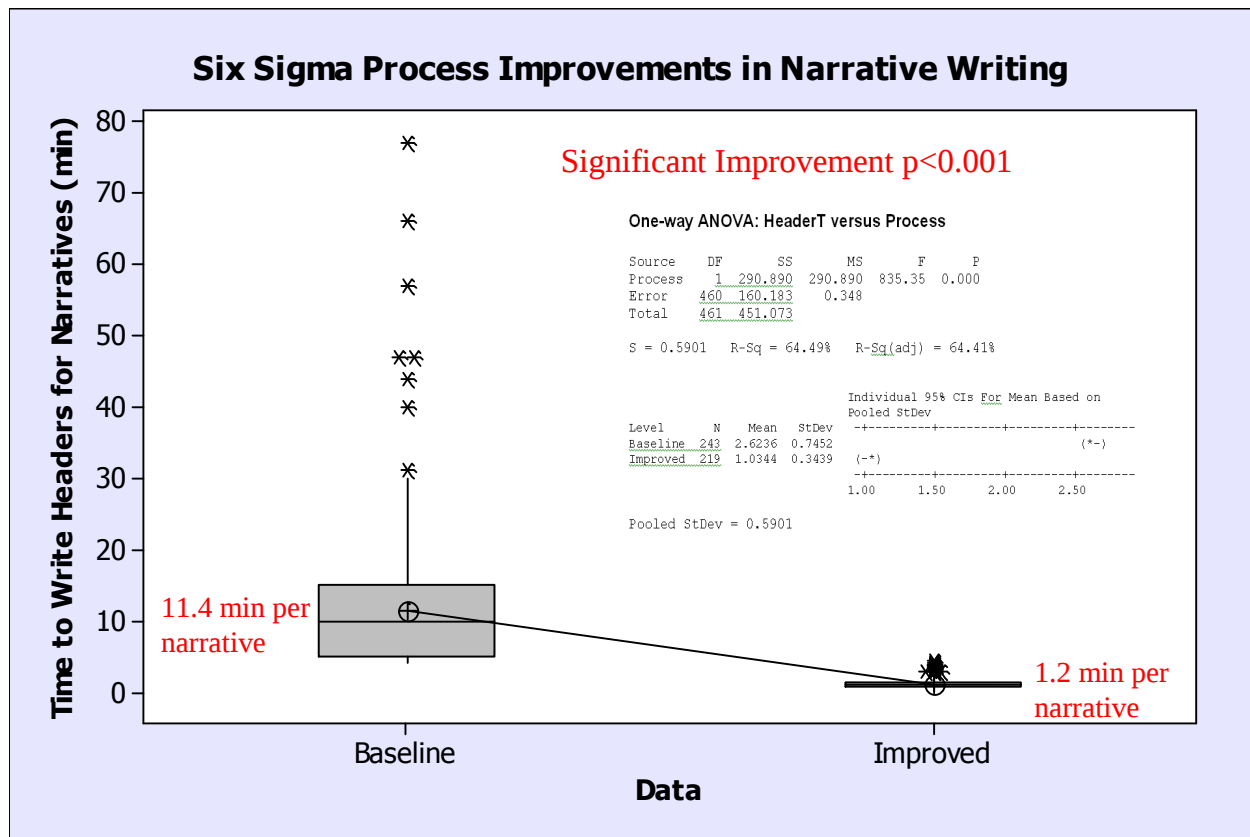
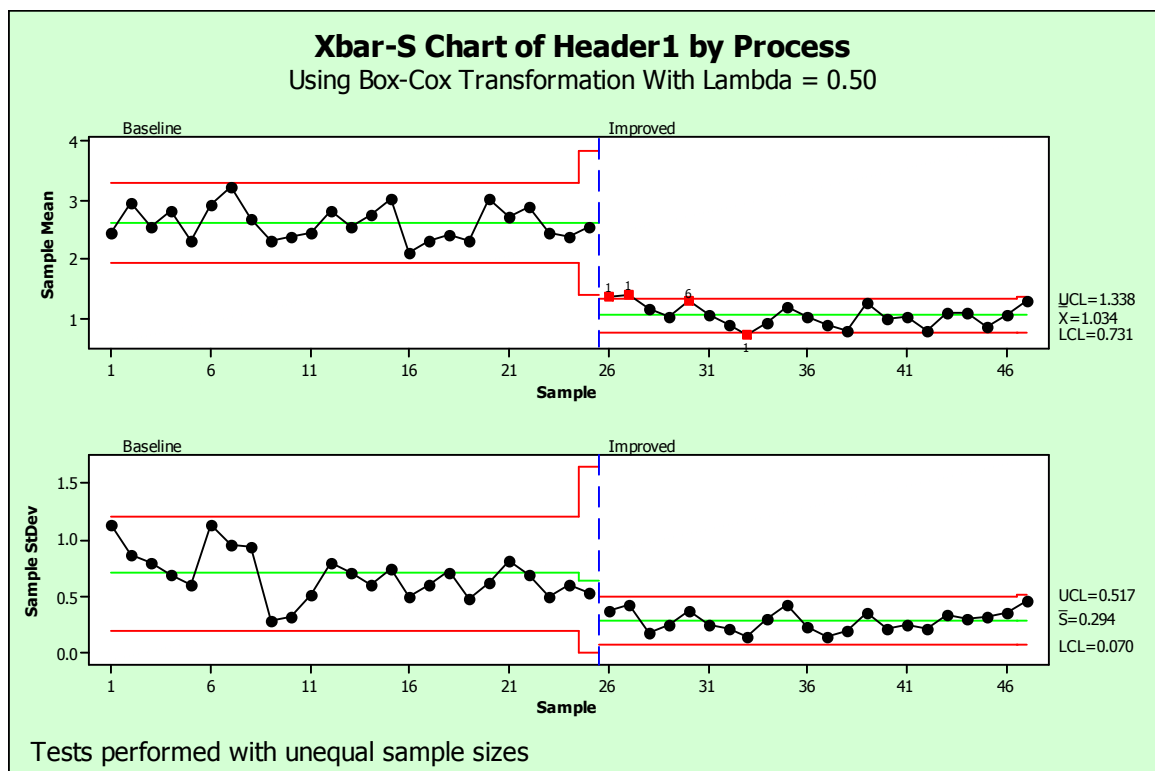


Figure 7 : Control Chart for the Narrative Project



FURTHER PROJECTS

The above is an example of just one project; Covance is currently running or has completed dozens of such projects. Within Biometrics examples of new ongoing projects includes:

- Reducing work time on SAP production
- Reducing the work time for QC of Tables, Figures and Listings
- Reducing the work effort for data transfers

Additional cross-functional projects are also being considered, including collaborations with Data Management and Medical Writing. In total we have contributed to this effort with one Black-Belt, five Green Belts and perhaps a dozen Project Team members.

CONCLUSION

Six-Sigma represents a valuable tool for driving and measuring process improvements within Covance Biometrics and across functions. Covance has prioritized Six-Sigma as a major engine for change and as even in this years' harsh economic climate has prioritized the Six-Sigma efforts around the globe.

Challenges and roadblocks to Six-Sigma of course exist and these include alignment of resources, resistance to change, having to retrospectively collect historical data from non-optimal systems. Of course most Green Belts are not trained statisticians and so Black Belt support is a crucial success factor.

However a natural result of implementing Six-Sigma is an inherent ability to define and collect meaningful performance metrics for those processes utilizing a six-sigma control plan. Needless to say both Covance and our Clients will all benefit from improved processes in the long run.

REFERENCES

- **The Power of Six Sigma** - Subir Chowdhury (Dearborn Trade Publishing) 117pgs, \$17.95: A good introduction that uses a fictionalized tale of 2 individuals to explain how Six Sigma works.
- **What Is Six Sigma** - Pete Pande and Larry Holpp (McGraw-Hill) 86pgs, \$12.00: Easy read, provides basics
- **Six Sigma For Dummies** - Craig Gygi, Neil DeCarlo and Bruce Williams (Wiley) 318 pgs, \$21.99: Contrary to the title, the book is a thorough attempt to provide more detail on the DMAIC process, some good examples, links methodology to tools.
- **Six Sigma and Minitab** - Quentin Brook (www.qsbc.co.uk) 180pgs, ~\$35.00: A more in depth link between DMAIC and Minitab, (similar to the Minitab cheat sheet idea), with good flow diagrams to point you to the right tools.
- **Lean Six Sigma Pocket Toolbook** – Michael L. George, David Rowlands, Mark Price, John Maxley, 282pgs, McGraw-Hill (\$15) – Excellent in-depth guide to the tools and methodology.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Andrew York
Covance CAPS Limited
Manor Royal
Crawley
RH10 9PY
Email: Andrew.york@covance.com
Web: www.covance.com

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