

## One Vision, Many Interpretations?

Todd Case, Biogen Idec, Cambridge MA, USA

### ABSTRACT

As we all know, Programmers come in all shapes and sizes - with varying backgrounds, talents, educations, communication skills, interpersonal savvy and interests (among many other potential characteristics). That said, it's not surprising when digging into the details to find individual team members will almost universally employ different programming techniques (sometimes equally as efficient and effective) than their peers to achieve the same result. This works in 'one-off' cases (such as urgent regulatory requests, some types of QC where the code should be as independent as possible from the source code) but definitely not for consistency and efficiency! Often, however, if the group of programmers is large enough, the *means* to the end need to be consistent in order to be efficient and scalable (e.g., use code that is well re-usable, documented, easy to read, etc.).

### INTRODUCTION

The goal of this paper is to discuss how to work together to try and make One Vision, *Minimal* Interpretations - which potentially increases [most important] quality, time to results and ensures that programmers are working on the less mundane, routine work and more on the meaningful and interesting work! It should be noted that this paper does not advocate specific programming techniques or even that there should be agreement about what techniques are used – the main goal of the paper is to understand how and why consistency is important. Whether its template programs or custom built software for the generation of common tables – these are examples of code that can be easily used, re-used and hopefully QC'd consistently as well.

More specifically, the intent of this paper is to focus on ways that sometimes prevent our best intentions (e.g., consistently mapping SDTM domains [particularly 'non-standard' domains], selecting standard tables for inclusion in our planned analyses, etc.) from being implemented in a consistent way – even if there is consensus on the concept to be implemented! I wrestled with the title of this paper, debating back and forth between 'One Vision, Many Interpretations' or 'One Vision, One Interpretation'. While wrestling with this title, I realized that 'One Vision, Many Interpretations' was already occurring in a number of ways, some examples were how different vendors: (1) map SDTM domains, (2) create eSUB deliverables (in the US), (3) selection criteria that partners use when choosing vendors, etc. Knowing as many programmers as I do, I thought the 'Many Interpretations' would attract more interest while still tackling the main topic of this paper – consistent implementation of programming deliverables when there are a 'million and one ways to program the same thing in a software language'.

### REVISITING THE TITLE - IN THE TIME OF GOOGLE

After deciding on the title of this paper I 'googled' it to see if it had already been used in any context. The first (and 3 out of the top 10) link I saw were lyrics of the song '*One Vision*' from the rock band Queen (I doubt any member of Queen was a Programmer), part of which are as follows: "No wrong no right, I'm gonna tell you there's no black and no white ...All we need is one worldwide vision". There was even one link to exploration risk, which, I felt is somewhat applicable to this paper. Risk is inherent in the work we do. For example, does it make sense to QC every page of 1,000+ page listings? Or, does it make sense to create a dataset of that listing and just compare that dataset to one created by the developing programmer? Or does it make sense to review *n* number of patient's records for that listing. Or....? Risk is a large topic and, just from its context within this paper, it too can be employed consistently. If we purposefully choose an approach to dealing with risk (e.g., different types of QC for different types of deliverable) it inherently ensures a consistent level of quality (again, always the most important trait of a deliverable).

### WAIT, WHY GOOGLE AND NOT YAHOO?

This is a great example of 'One Vision, Many Interpretations'. There are a lot of internet search engines out there, why did I choose Google? At this point it's worth looking at Table 1, below:

Table 1:



|                                        |
|----------------------------------------|
| when did google                        |
| when did google <b>start</b>           |
| when did google <b>buy youtube</b>     |
| when did google <b>come out</b>        |
| when did google <b>buy motorola</b>    |
| when did google <b>buy android</b>     |
| when did google <b>go public</b>       |
| when did google <b>maps start</b>      |
| when did google <b>chrome come out</b> |
| when did google <b>become a verb</b>   |
| when did google <b>plus launch</b>     |
| Google Search    I'm Feeling Lucky     |

I used Google because it has engrained its way into our languages, our dictionaries – it exemplifies ‘One Vision, One Interpretation’. Google was introduced as an English word after I graduated from college – helping reinforce the fact that a couple of generations have entered the workforce since I did! Why do I bring this up in a paper? Because, when we talk about ‘consistency’ and ‘one vision’ we need to take into account that for those of us who started programming more than ten years ago there many different versions of the software we use (and even software) have emerged since that time, which ultimately has an impact on how we program, what we think is important, and even how we define consistency. And that is only for those who have been programming more than ten years. For those who have been programming more than say, twenty years, they may be thinking there is nothing better than programming in FORTRAN.

Is consistency defined by creating SDTMs for all of your studies (for Phase I studies that were performed decades ago)? Is it defined by mapping SDTM consistently across all projects in a company? What if vendors are creating SDTMs and contracts have already been signed to map SDTMs based on ‘their’ standards? What if a vendor is being used and creates SDTMs differently (even between branches within the same company). The reader will have already noted there are a lot of questions here with many definitive answers.

### **CEMENTING THE CONCEPT (DO WE STILL HAVE ONE INTERPRETATION?)**

The thesis of this paper is to discuss how to consistently deliver (or receive) a type of deliverable. There have been several examples discussed, but for purposes of simplicity we will focus on two deliverables produced consistently within the industry: SDTM mapping and patient profiles. Having had the opportunity to work across several biotech/pharmaceutical companies over the course of the last 12 years, I’ve noticed that, at the minimum, these can differ to quite an extent between companies, and to a lesser extent, even within the same company. Sure, there are always the ‘exceptions’, such as (for patient profiles) ‘the selection criteria are different’ or, better yet, ‘the therapeutic area is special’ and for (SDTMs) it could be a plethora of misunderstanding, but one I’ve heard commonly is “You mapped it like that?!?”.

### **“BUT IT’S TRULY DIFFERENT...”**

This kind of thinking (i.e., not considering the fact no matter how ‘different’ or ‘special’ a project is) is often what stymies consistency across projects. True- there are times and situations where there is a need to perform work as fast and high quality as possible (e.g., maybe at a start-up where there is only one therapy, an unmet medical need, and patient advocate groups and regulatory agencies clamoring to get that therapy on the market); however, even in this case there are almost certain to be similarities, or similarities that will benefit the future, for example, the next indication this miracle therapy is going to work for!

Regarding the patient profile example, across companies and probably virtually universal in the industry, Demographics, Adverse Events and Concomitant and Rescue medications are consistent and probably included in patient profiles. The thesis and presentation of this paper will be to challenge the reader/attendee to think about

## PhUSE 2013

writing code or templates that are consistent enough to incorporate differences among studies, therapeutic areas, etc. Highlighting this will almost certainly prove that, time after time, making things 'simple' is much more difficult and more rewarding than 'doing things different because the study/therapeutic area is 'special' or 'different'.

Regarding the SDTM example, it could get a little trickier (but keep in mind there will always be the most current version of the Implementation Guide) because the number of novel endpoints and new data being collected will always continue to grow. The recommendation would be to always map SDTMs (even for legacy studies that are being marketed), to work with your vendor (if they are being received from Data Management or a vendor) to ensure that the domains are mapped as expected (if your work place does not have standards than a close review of the Implementation Guide is necessary), and to perform a QA that ensures (1) all data collected on the CRF are mapped into a domain, and (2) all CRF forms are mapped as expected.

### ONE VISION, ONE INTERPRETATION.

The purpose of this paper was to discuss how to consistently program and deliver deliverables – whether they be SDTM mapping, QC, patient profiles, 1000 page listings, etc.. The reader may still be thinking that 'One Interpretation' may sound stifling, unimaginative and uncreative. However, this paper has mentioned several challenges to consistency that actually take a lot of creativity to overcome! It should be stressed that it's critical and the time is now to recognize why there are challenges to consistency and how to address them and recognize that addressing any type of deliverable should boil down to accessing the issue from a fundamental perspective- one consistent interpretation and implementation.

### CONCLUSION

This paper has discussed the vast array of different styles that programmers use (even within a single programming language), that each style has its own merits and limitations and there is no 'silver bullet' in terms of a specific programming technique. We also realized that here are generations of programmers with different backgrounds, degrees and experiences as well as risk. Further, with all of these 'differences' we also recognized that each protocol and related Statistical Analysis Plan are different as well. We then discussed some examples of types of deliverables in which there is (or could be) much consistency across the industry – SDTMs, Patient Profiles, Safety analyses, etc. In sum, while there are many reasons and ways that programming deliverables can be different, the argument of this author is that consistent presentations (whether it be safety tables, patient profiles, etc.) and SDTMs (at least consistent mapping strategy conceptually) will ultimately reap exponential rewards in terms of both quality and efficiency, and leave the more novel and exciting programming for the rest of us!

### REFERENCES

[www.google.com](http://www.google.com)

<http://www.merriam-webster.com/dictionary/google>

Queen® Lyrics <http://www.songlyrics.com/queen/one-vision-queen-single-mix-lyrics/>

### ACKNOWLEDGMENTS

Thanks to my team members at Biogen Idec and my manager Greg Silva for the significant support and effort contributed.

### DISCLAIMER

The views expressed in this paper are solely those of the author.

### CONTACT INFORMATION

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

Todd Case  
Biogen Idec  
14 Cambridge Center  
Cambridge, MA, USA / 02142  
Phone: 201 650 1260:  
Email: [todd.case@biogenidec.com](mailto:todd.case@biogenidec.com)  
Web: [www.biogenidec.com](http://www.biogenidec.com)

Brand and product names are trademarks of their respective companies.