

**PharmaSUG 2018 - Paper LD-01**  
**The Statistical Programming Summit**  
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**ABSTRACT**

On September 14, 2017 eighteen Statistical Programming leaders from twelve Bio/Pharma companies in the Boston area met and discussed topics endemic to work we are all involved with, including: CDISC standards, Quality Control (QC) and Quality Assurance (QA) of Statistical Programming deliverables, Metadata-driven solutions (e.g. specifications to generate data and define-xml) and Submission Experience.

**INTRODUCTION**

The Statistical Programming Summit was an all-day event with solicited, pre-selected topics, as follows: (1) "CDISC, Challenges to Implementation and the Future of Standards", (2) "QC/QA Process[es]", (3) "Submission Experience" and lastly (4) "Metadata-driven Solutions [e.g., Specifications]".

The Programming Summit also served as a venue for leaders of Statistical Programming groups in the Boston area to discuss and think about solutions to challenges we all face (e.g., the four topics).

**THE ORIGIN AND EMERGENCE OF A COLLABORATIVE PROGRAMMING SUMMIT**

To act on an idea – this was the seed that flowered into the all-day event. This seed was planted during the course of an ongoing discussion about process improvement within the Statistical Programming group at Vertex, particularly my manager. Years ago, she (now the Head of our Department) had been involved in an informal gathering of statisticians across 'big pharma' that met periodically to discuss statistical designs and methods, agnostic of any proprietary information or specific or ongoing clinical trials. She had been inspired at that time by the participants who made time to engage so deeply with both their work as well as their peers (or, perhaps future peers).

The Programming Summit created from that idea was, for the most part, a desire to create that same type of collaborative, non-proprietary meeting within the Statistical Programming Community. The aim was to discuss ideas that focused on improved and more efficient processes that would ultimately lead to higher quality deliverables.

**THE DEFINITION OF SUCCESS**

In order to hold this event it had to be justified, with clear outcomes and goals. The only way to make this happen was to ensure that we had enough invitees that felt they could come to Vertex and participate in this type of discussion - and were passionate about quality and sharing ideas that would lead to better deliverables. Also, everyone had to be ensured a voice at the table and feel welcome, so there were ground rules (i.e., what we could take away from the event in the case that no one wanted to share or discuss information), as follows:

- (1) Don't talk about proprietary information,
- (2) Have fun,
- (3) Participate,
- (4) Meet someone new,
- (5) Take what you want from this meeting and
- (6) Decide what the next steps, as a result of this meeting, would be (e.g., when there will be a Next Meeting).

Those six points were the definition of success heading into the meeting.

While the format and logistical issues of this event are the topic of, and deserve, an entirely different paper this paper will focus on why an event like this has the power to make progress across the industry and lends a forum to thinking and developing ideas and follow-up action items that can't be done working in an office all day long. In other words, it had to be worthwhile for so many leaders to take a day off from the 'day jobs' and make time to focus on ideas that would shape a better future for the Statistical Programming Community. To elaborate more, each definition of success is further clarified, below:

### **1 - DON'T TALK ABOUT PROPRIETARY INFORMATION**

This was easy to avoid, as the topics had no company-specific information. As mentioned previously, the topics were solicited and had been agreed-upon by the time the summit started. Also, with so many programmers there, with long tenures in the industry at different employers, our collective experience was much more valuable than any company-specific tools, technology, etc.

### **2 - HAVE FUN**

This may sound easy, but having very senior members of programming groups from the local area meant that they were using their valuable time - and expected some information and specific ideas about improvements they could take away. So we set some ground rules about letting everyone have an opportunity to speak, not to discuss or try to sell anything, to talk about what was possible as opposed to expressing objections to the ideas participants provided, etc.

### **3 - PARTICIPATE**

This took a bit of pre-planning. It's very difficult to anticipate who is going to say what during a meeting like this! There are bound to be people who want to talk more than others, especially managers who are used to having to communicate a great deal of time during their workday! So, while we sent out an open invite, the selection process of people essentially boiled down to those who were truly interested in participating, engaging and learning – all while listening as much, or more, than talking!

### **4 - MEET SOMEONE NEW**

As programmers we don't always get the opportunity or, even when we do, we don't always see it as an 'opportunity' to talk with others about our ideas, questions, etc. Many of us think as programmers it's our job to solve problems (it is), but it's also our job to always search for better processes, programming techniques, industry trends. It's also in our own benefit to reach out, network and discuss industry-wide challenges - both to grow our knowledge base as well as our networking group.

### **5 - TAKE WHAT YOU WANT FROM THE MEETING**

This was perhaps the easiest measure of success and also a great way to get the conversation started. As we had agreed upon the topics ahead of the meeting, each person most likely had interest in all four of the topics but there were some topics that all attendees were interested in and a couple that a few attendees were very interested in. Among these most popular, as a bit of surprise, was the Quality Assurance (QA) topic – there was discussion about what this role looks like (of course it differs upon who is asked), whether it needs/deserves a place within industry as the Quality Control (QC) process is very robust and well-documented throughout the industry. However, as mentioned, even though it was of broad interest to everyone, there wasn't any great desire or plan on how this could be implemented at each company.

### **6 - NEXT STEPS**

This was the most challenging aspect of the Summit – as the host we were successful in getting attendees to the table, facilitating very useful and productive discussions and, as we said we were going to follow up, now was the challenge: we had to follow up on a meeting that generated a lot of interest (as demonstrated by the topics and discussion above).... In order to follow up effectively the following framework was used:

### Step 1: Review Action Items

There was a lot of lively discussion around all four topics. The depth and interest of the conversation changed during the course of the day, with a lot of interest in QC/QA but not a lot of experience implementing it to a particularly lively discussion about metadata driven solutions - where each person seemed to be on a different page about what the desired outcome was and, perhaps more critically, where we are right now in terms of the industry adopting new technology. However, a PhUSE Single Day Event this year (Collegeville, PA on 17May2018) is entirely dedicated to “Artificial Intelligence and Data Automation – Game Changer on Data Analysis and Decision-Making”, so perhaps we are more prepared [to adopt new technology] than we think!

### Step 2: Prioritize Action Items

It was clear after reviewing what was discussed that the *intersection of interest and implementation* was greatest for “Submission Experience”.

### Step 3: Make Specific Follow-up Plans

- a. **PhUSE Project:** After discussing with other attendees, a few of us decided to keep the ball rolling by seeing whether an existing PhUSE working group or sub team/project was looking into ‘Practical Submission Experience’ - specifically in terms of how questions about data submission packages are being communicated to regulatory agencies. In addition, we also looked into whether there existed a forum about where to address gray areas in terms of eSubmissions. We were not surprised to find out that information sharing and question asking/sharing, while of great interest, did not exist on the scale we were looking for.

As a result of the question we asked and the answers we received, two of us decided to meet at the CDISC Conference in Austin (about two months after the Programming Summit) to propose to PhUSE the creation of a project to be called “Industry Experiences Submitting Standardised Study Data to Regulatory Authorities”. We slowly accumulated members in the remainder of November and December, and, by the PhUSE 2018 Computational Science Symposium (CSS) on March 4-6, 2018, we had over 50 members who participated in the breakout session! The project now has a clear goal and deliverable of writing a white paper and information sharing platform by Q4, 2018.

- b. **PhUSE Single Day Event:** In addition to the PhUSE project, we put our heads together and consulted with PhUSE to see whether this theme, ‘Practical Submission Experience’ would be of enough interest to have a Single Day Event dedicated to it. The answer was a resounding yes, so we set the wheels in motion and the PhUSE Single Day event dedicated to ‘Practical Submission Experience’ will occur in Boston on April 26, 2018 with a great panel of speakers and topics ranging from Sponsor regulatory guidance to implementation of CDISC standards based on existing regulations, guidance from industry, and recommendations (e.g., white papers) from groups such as PhUSE.
- c. **Next Programming Summit:** In addition to both the PhUSE project (“Industry Experiences Submitting Standardised Study Data to Regulatory Authorities”) and Single Day Event (“Practical Submission Experience”) we also decided to host another Programming Summit, again at Vertex, to occur in the fall of 2018. In order to make this happen, I submitted an abstract for PharmaSUG 2018 on the Programming Summit, which was approved in the Leadership Section, and we will ask for volunteers to attend as well as get feedback and questions from those in the audience.

This is especially important, as there can be a lot of excitement at the end of the meeting but, after the meeting, as we all fall back into our routines and familiar patterns, it’s easy to say ‘that was useful, but much, much more difficult to actually instill this kind of action in others. If that’s the case, do it again at your company!

## **CONCLUSION**

The purpose of this paper is to help the reader engage with peers and network in the name of improving data quality and efficiencies. It's one thing to aspire to greatness within your group, or even better within your organization, but how can this be compared to greatness across the industry? .

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## **CONTACT INFORMATION**

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