The Tortoise and the Hare – Lessons Learned in Developing ADaM Training

Alyssa Wittle, Covance by Labcorp, Inc.

ABSTRACT

A challenge: increase the number of outstanding ADaM spec writers and programmers. The reasons are obvious for why this is an essential part of our business. More outstanding ADaM programmers and spec writers mean less QC issues, more time & money saved, less Pinnacle21 findings, less time in review cycles, and more. Plus, outstanding programmers tend to make outstanding spec writers and eventually become subject matter experts who provide invaluable education and information to the rest of a team. There are a few routes to take in determining the most effective approach with the highest level of effectiveness. About a year into the redesign of our ADaM Mentoring Program, a few strategies have been applied and shown to have success. This paper will discuss the options considered, the strategy for picking candidates for training, and the key training aspects which have shown improvement and positive feedback from every trainee who has gone through the program. Spoiler alert: slow and steady wins the race!

INTRODUCTION

A race is set – a tortoise versus a hare. The outcome seems very obvious – is this even a competition? A hare can run circles around a tortoise any day! The race begins and the hare takes off down the race track, with the tortoise chugging along behind, slow and steady. But, suddenly, the hare leaves the race track due to something that looks more interesting...all the while the tortoise is still focused on the finish line. Who wins? You know the story – the tortoise wins due to his focus and persistence while the hare loses what seemed like a sure thing.

After years of trying multiple training methods in ADaM, we were given a task to develop more outstanding ADaM spec writers and programmers. This is an entirely understandable goal, and one which is likely an underlying goal for every company working with ADaM. We were faced with a choice: provide our team members with a refresher training using our existing training materials for ADaM or try something new. While creating something new would be time consuming on the front end, it was an approach we strongly believed would be more effective overall. Our team decided to shoot for something new and see if it was as effective as we anticipated. We have now taken several different types of trainees through this new and improved program, and we collected overwhelmingly successful feedback from each of them. In order to refine and adjust to be the most effective as possible, we asked our trainees about what additions and training formats would make our program even better. We believe our approach has shown a slow and steady approach will win the race.

TRAINING FORMAT OPTIONS

There are a variety of options to consider when preparing for an ADaM training program. There are pros and cons to each, both from an education and business perspective – and sometimes picking one single option is not the right answer either.

LARGE GROUP MULTI-DAY TRAINING

This is frequently the go-to training style for many companies. It requires one presentation that is generally reusable, is easy to record, has as few as one trainer for hundreds of participants, and is delivered in a matter of a couple days. However, this style of training has some drawbacks in effectiveness. It is difficult for so many people to get longer periods of time (from 4 up to 8 hours per day), typically multiple days in a row, away from their projects to be able to focus on training which inevitably leads to multi-tasking. Also, for many people, sitting in a training all day long makes it hard to pay attention – especially when so many throughout our industry are virtual now rather than in-person. Even if a trainee managed to stay focused through the entire training, the likelihood that all of the material will be retained is minimal due to the sheer volume of details needed in a full ADaM training. Finally, the

larger the group, the less likely it is that someone who has a question will be willing to speak up and ask it.

RECORDING SELF-PACED TRAINING

Recording trainings makes a lot of sense from a business perspective because it requires less hours from a trainer and it also allows flexibility for a trainee to squeeze the training in around their other responsibilities. It also allows a trainee to have an easy reference to compare back to. This sounds great in theory, but the issues with a recording-only style is that the if a trainee misunderstood a topic, they have no one to ask for clarification. Even if a mentor is provided for that purpose outside of the recording, some trainees will not remember or will not be willing to take the initiative to ask a question outside of the training, and the mentor may not have the availability to adequately answer the question. Also, when a training is given via recording there is very little chance for accountability to ensure the training is actually being watched –the video may be playing to a multi-tasker or even to an empty room.

LARGE GROUP SHORT TRAININGS

Eliminating the long trainings is a step in the right direction for focus and retention compared to a large group, long session per day, multi-day training. However, the problem remains that many people will be completely unwilling to ask any questions in a large group setting.

MENTORING SMALL GROUP SHORT TRAININGS

Short, small group trainings with a dedicated mentor might not seem to make the most business sense on the surface, but in fact they appear to be the most effective approach to training for the most people. Short training sessions allow the most material retention and focus for the trainees, plus due to the short duration it is easy to fit into a busy schedule. The small group size and *mentor*-led training allows a comfort level to form over time so that most trainees will be comfortable and willing to ask questions as they come up both during and after the training session. This option is more demanding on a mentor since their role will continue for a longer period of time than a one-time long training format. However, if the trainings are split out effectively, the overall duration between the long, multi-day training sessions will be approximately the same as the cumulative short training sessions. This is the method we have found to be most effective for increasing understanding, retention and performance.

CHOOSING TRAINING CANDIDATES

Implementing a new training technique, especially one requiring a small group, means you have to carefully select your initial trainee groups. A few clear groups became evident to pick from for our first several groups of mentees to go through our ADaM Mentoring Program.

The first group we wanted to target was pulling from our group of outstanding SDTM spec writers who expressed an interest in learning ADaM, based on employee request and management nomination. This allowed us to test our initial material on mentees who were completely new to ADaM requiring a unique combination of being basic enough to be understood to mentees who may have never considered some of the requirements of analysis (such as windowing or DTYPE), while being detailed enough to give them all the tools they need to become an effective ADaM programmer.

Next, we brought in some statisticians who allowed us to determine what extra material we needed for a mentee who was not necessarily familiar with SDTM. This group was a challenge in its own way as the statisticians frequently considered CDISC as a "necessary evil." However, over the course of the training sessions they were able to see that rather than being an annoyance, CDISC actually allows projects to move more efficiently; a solid understanding of ADaM helped them to accomplish their work faster, with less review comments, and they could more easily and independently identify issues in a dataset. This group also allowed us to have examples which were complex enough to answer any analysis-specific questions a statistician might have such as how to apply imputation methods in ADaM.

Outstanding analysis programmers who needed to gain ADaM expertise were the next group to go through the mentoring. This group is ideally found through employee request and nomination of line managers or project leaders. The goal of this group is not only to teach general ADaM strategy to

mentees who have analysis experience, but also to be able to have material which helps programmers to see how common analysis methods/concepts that are unrelated to ADaM (such as performing change from screening and change from the visit's pre-dose value on the same set of records) will appear in the ADaM (needing to use BASETYPE).

Next, ADaM spec writers who were having frequent review issues were given the mentoring training as a remediation tool. The purpose of this was to make sure we had enough detail and examples to explain why certain approaches were CDISC compliant, and how to avoid common pitfalls in ADaM spec writing. The mentor could then assess if an improvement in understanding and quality was seen following training; if any areas still seemed to be less than perfect, we were able to refine the training technique to ensure the mentees were understanding the concepts.

Finally, the last essential group to go through the mentoring program was candidates who were suggested from their managers and project teams to be ADaM experts. This group had a two-fold purpose. First, we were able to ensure that those who were defined as experts actually *were* experts. If they were – fantastic, then we prepared them to be able to be a mentor for this program and familiarize them with all training sessions and materials. If they turned out not to have as much expertise as anticipated, then having them go through the training would hopefully clarify any misunderstandings they had, and rather than progressing them to be a mentor they are instead reassigned to get more experience before being re-considered for a mentor role.

KEY FINDINGS

Over some trial-and-error plus being intentional in obtaining feedback from mentees, we gained some good insight into what details were successful for the most amount of people in our trainings. Every mentee is different, every group is different, and every business is different, so the emphasis on feedback is essential during and after your trainings. We used two surveys – one given at the half-way point of our mentoring program and the other after completion. We asked for brutal honesty so that we could alter and perfect things in our approach as needed – let us look at the key findings we had.

SHORT AND SWEET TRAININGS

Overwhelmingly, the feedback from our mentees was that shorter training sessions helped them far more than longer sessions. In our program, there were four trainings which lasted about 45 minutes, while most trainings were in the 15-20 minute range with time for questions to fit nicely into a 30 minute window. These were helpful for retention because the mentees could concentrate on one item at a time and let that information really sink in before moving to the next topic. It also helped with scheduling because even in a busy schedule it is easier to find 30 minutes every few days to dedicate to ADaM training than it is to carve out entire days or even half days. We also found it was easier for the mentees to concentrate on the smaller trainings too – they could afford to step away from their project work for 30 minutes and be fully-focused on these shorter trainings, whereas multi-tasking was almost guaranteed to occur during the longer training sessions. Our trainings were topic specific: Date Imputation, Windowing, Analysis Flags vs Criterion Flags, etc. which allowed for a very focused training and conveniently the Implementation Guide divides out these variables in individual tables already to help determine the topics.

FREQUENCY

In order to keep the "easy to squeeze in" philosophy, what we heard from the mentees most often is that training sessions twice per five-day work week was the best fit of often enough but not too much. Obviously, around holidays they must be rearranged. We found having country specific training groups was helpful in scheduling both at a functional time of the day for everyone and also arranging trainings around country-specific holidays.

SMALL GROUPS

Every single participant in our various mentoring programs thus far have reported back to us that they found the small group format to be more effective for them. Specifically, we found that about 7 mentees per mentor was the upper limit, with 5 being an ideal size. This was determined both from mentee feedback regarding group size as well as considering the amount of work for the mentor when the group

got too large. Smaller groups worked better for a variety of reasons, however the primary reason is that there was far more willingness to ask questions in a small group setting. Programmers specifically said that if a group was even over 10 people they would be less willing to ask questions or ask for clarification. Also, the time commitment of a mentor in our program extends past the training itself – they are a true mentor: there to guide, answer questions and ensure understanding. With too many people this eventually becomes too much for a single person and less effective.

THE RIGHT MENTOR

Everyone has had that college professor who was a genius and yet put you to sleep or did not communicate well. The same holds true here – what good is a trainer if they do not engage well with the audience. We have very specific expectations of the trainer, foremost being that they are an expert in what they are training. Following that, communication skills are essential. A mentor is more than a lecturer, they need to form a level of rapport with their mentees so that when a question comes up the mentee is willing to ask the mentor. In addition, the mentor needs to have available time for this – a big part of it being that the mentees should never feel as if they are a burden for contacting their mentor. Questions should be able to be answered in a timely and friendly manner rather than being pushed off or as a last priority. Mentees do not want to be a burden to anyone and are far less likely to ask questions if they get the impression they are adding stress or chaos to their mentor's day. Finally, a mentor should ideally be able to answer any questions a mentee might ask – in this case, the mentor should be an ADaM expert.

TRAINING GEARED EXERCISES

One big question we had to solve was how to determine if the mentees were actually understanding the information. The answer we found was training exercises sent immediately after the training session which contained generally 3-5 questions based directly on applying what they just learned. These exercises ideally should be able to hit at multiple levels of thinking through the topics in how to program, how to spec, and simply how to apply the topic. Surprisingly, even with the added time it took to complete the exercises, most of the trainees found the exercises extremely helpful to reinforce their understanding of the topic. A big part of the exercises being effective is in the hands of mentor to review and "grade" all the responses. This program is not a pass/fail situation, but we found that if the exercises were required, reviewed and the mentees were given thoughtful responses, that the understanding level and retention increased even more. These responses were perhaps explaining other options that could have been used (since ADaM has so many compliant approaches which can be used and everyone has their own style), where their logic went wrong, or just sending it back with some tips and asking them to try again. We also found that the mentees who were intentional about completing the exercises prior to the next training had much better results and retention than those who delayed completing the exercise.

APPLICABLE ASSIGNMENTS

Resourcing is always a challenge, but we found that the ideal approach for any ADaM Mentee is to have the opportunity to apply what they are learning to their project work immediately. This means, if an employee is going through an ADaM mentoring program then they should simultaneously have at least one ADaM assignment on a project. Ideally, the QC programmer paired with them should be aware of the newly trained programmer and able to help their development by giving thoughtful QC comments explaining why the issue is wrong if it has to do with the application of an ADaM concept.

CONTENT ACCESSIBILITY

An organized structure for training content to make it as accessible as possible is very important. Generally, within the exercise email the training itself was attached – potentially with some extra examples for more advanced groups. Then, the full training spectrum was saved by topic, in order, with all materials available for the mentors to access for future mentoring groups and for the mentees to use as an easy reference point and to spot-check their mapping and programming work.

EXAMPLES

One frequent request was examples – all the examples possible. This was a request which we divided out in various places, but still probably did not include as many examples as were requested particularly in programming. This is because we do not want mentees to use examples in programming as requirements in how something must be programmed. However, we did include examples in each training which were descriptive of different parts of the ADaM process – what the TFL analysis might look like, what the specs could be, how the dataset could look, how programming might look, etc. It was very important to include each of these various types of examples because it pieces together the whole picture of an ADaM and that it is not simply a stand-alone step but the *essential* step joining the data to the analysis and to help the ADaM mentees to start viewing the entire process rather than one single variable or dataset.

EXPLAIN THE WHY

When designing trainings, it is straightforward to describe What you need to have, Where it needs to go and How one might get it there – these are the logical parts of the ADaM training. However, the glue that holds all of this together on a project, which really ensures the understanding of a topic is the WHY. Without knowing why something is correct or incorrect, a programmer will repeat the incorrect method. Without knowing why they need a particular variable, they will not know which variable to use when faced with the same situation again. Explaining to a programmer *why* we have SRCSEQ for traceability will help them remember to maintain their traceability rather than overlooking a variable that is not actually printed on a TFL. Explaining why it might be simpler to make a new record than to make a new flag for the table to display will encourage the spec writer and the programmer to start their analysis dataset work with considering the analysis itself and the format of the output that their ADaM dataset is used to create. This step is crucial and cannot be skipped.

FUTURE PLANS

Our mentoring program is up and running, but that does not mean all the important work is complete. We asked our mentees for feedback regarding how we can improve the program and generally considering how we can continue to work towards the most effective program for our employees.

A huge request from our mentees was a "Playground" area: a space which is not project-specific which has a variety of ADaM specs, datasets, programs, along with sample analysis plan sections and TFL shells which applied to the ADaMs so that they can investigate, recreate, find examples, get ideas, and learn from strategies that are guaranteed to be 100% CDISC compliant. The key to making this area work is to have a large variety of formats and approaches for different types of analyses. The goal is not to provide a one-size-fits-all approach, it is to demonstrate the flexibility of ADaM to analyze anything with multiple, equally compliant ways to get there. The advantage of this is very evident and it is on our list to compile in the future.

As a way to ensure comprehension for topics which a mentee struggled with in the training exercises, we have been developing some additional follow-up exercises for each training session. The pro of this is that exercises are the best tool we have (aside from their assignments) to determine of a mentee is understanding a concept. So, if they struggle with the initial exercise, read the feedback, ask some questions, and get a bit more clarification, then these additional exercises will be able to show if they can correctly apply what they learned. The con is the exercises are the hardest to keep track of for the mentor – particularly for participants who do not focus on returning exercises in a timely manner. Extra exercises, while encouraging understanding, also means more administrative work.

CONCLUSION

There are many effective ways to train, however when the subject matter is as involved as the ADaM Implementation Guide there are ways to make the process more effective for everyone involved. Better retention and understanding results in less time spent in spec reviews, in QCs, in Pinnacle21 reviews and eliminates rework at every stage. Utilizing a program like this can encourage your employees to meet their career development objectives. Trainings accomplished all at once may be the hare in the race, but

the slower, spread out training meets more of the goals of a training in the long run – slow and steady wins the race!

CONTACT INFORMATION

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

Alyssa Wittle
Covance by Labcorp, Inc.
Alyssa.Wittle@Covance.com
https://www.linkedin.com/in/alyssa-wittle-a922638b