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Establishing a strong data skills training approach for your commercialisation statistics function:

Tips, Tricks, and Experiences

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Introduction

When I started in the industry, the word 'training' didn't trigger any associations with work. Instead, it made me think of going to the gym or for a run.

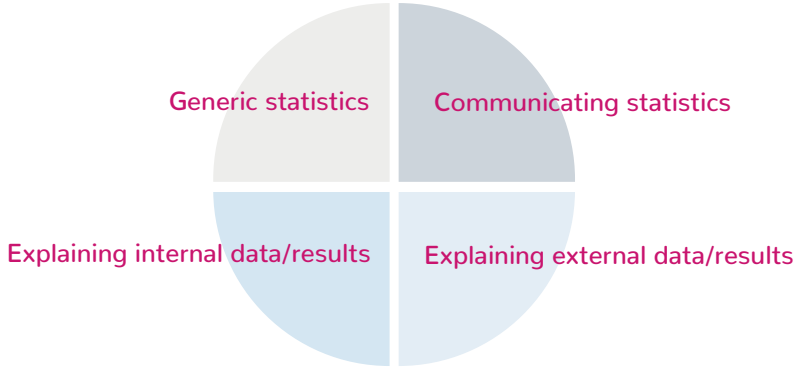
After just a couple of months on the job, I learned why many colleagues had negative thoughts about training. Whenever this topic would come up, people would start to glaze over, look bored or even frustrated and cynical.

Why is this? Well, unfortunately, for many people, training means reading pages of SOPs, guidance and other dull documents. Even worse, it might mean watching endless boring videos and answering questionnaires.

The same is true for the typical statistics training for non-Statisticians. I've learnt from non-Statistician colleagues how much they hated these modules during their school or university days. For them, statistics is the epitome of dry material delivered in an incomprehensible way.

As Statisticians, we must work hard on our approach to combat this poor reputation and provide effective training to our non-statistical colleagues that will help the organisation achieve greater commercialisation and product launch success. After all, disseminating statistical results and data knowledge is integral to the commercialisation process.

Over 2 decades of work in the analytical field, I have delivered countless training sessions to non-Statisticians about statistical topics, spanning four distinct areas:



In this guide, I'll share my tips, hints and learning about delivering statistical training in these areas to better support launch and commercialisation goals. I'll also discuss how we can overcome pitfalls to ensure that we deliver sessions that our colleagues can feel positive about. After all, delivering training is an important way for us to increase our influence and leadership in the commercial organisation - but it needs to be effective and well-tailored to the audiences.

Delivering generic statistics training

Nearly every company has some generic 'statistics 101' training available for non-statistical colleagues. Either it is still regularly offered, the slides are available on demand (or sleeping somewhere), or someone considers starting it again.

It usually covers the basics of:

- Descriptive statistics
- Inferential statistics
- Design of studies
- Common topics of interest for the indications of the company like:
  - Time to event
  - Rare disease topics
  - Longitudinal data

Statisticians often like developing and delivering these training types as they follow exactly how they have been trained themselves. The slides are distributed for everyone to pick up and teach, making it straightforward for the teachers to scale the solution.

Unfortunately, this type of training has some downsides. First, people find it hard to prioritise such training among all the other activities they have. The calendars of most people are crowded with activities and meetings and adding yet another in-person training (or even pre-recorded training) leads to lots of pushback. More senior people don't prioritise the material, scheduling it for a day in the future that never comes.

Second, non-Statisticians find it hard to relate to the content when the examples do not come from their specific field or therapy area. Non-Statisticians often find it hard to transfer problems from one area to the other based on abstract concepts like continuous random variables.

Third, and this is probably the most important reason, the audience does not get an emotional connection to such a generic training. We know from learning theory that emotions play a crucial role in being both able to understand and follow the training and to retain the learned content.

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If people don't care, they won't learn and certainly won't remember the training.

We need to meet people where they are. When I changed my approach from giving a one-size fits all training to therapy-specific training like statistics in diabetes, statistics for neuroscience, statistics for oncology etc, I was able to anchor the problems I was speaking about in the world of my audience.

I started to incorporate publications and studies relevant to their field, which also allowed me to use their terminology – for example, speaking about toxicity in oncology rather than safety.

The engagement with the content and among the attendees improved dramatically and registration and show-up rates increased. It was much more fun to conduct these training sessions and feedback at the end of the training was very positive.

Of course, this increased the time needed to deliver the training but the time to prepare the training was only marginally changed. I only adapted the motivating examples and left all the theory unchanged.

While perhaps less influential than the other training types, it's well worth investing a little extra time to get it right.

Top tips:

1. Be specific to your audience
2. Use the right domain terminology
3. Meet people where they are using relevant examples

Data Communication Training

In the first years of working as a Statistician in the affiliate of a large pharma company, one particular day stands out very vividly in my mind. At the time, we had a new General Manager joining us at the affiliate. This new manager felt that there was a lack of understanding in the non-sales organisation of how the business actually works and what it means to speak with customers, i.e., prescribing physicians, on a day-to-day basis. He asked everybody in the office to spend a day with a sales representative on the road.

So, on this memorable day, I was assigned to an experienced sales rep in Munich and shadowed him on 12 different customer visits. Sometimes we would have a lot of time to speak but usually the conversations were very short – maybe just a minute in front of the welcome desk. Nevertheless, the sales rep was able to make his point and get a specific aspect of the data across.

I observed 2 reasons for his effectiveness. First, he was good at explaining in simple terms what the results meant for the physician. Second, the data was presented in a very impactful way using great data visualisations.

On this day I learned more about compelling data communication than in each of the other days of my career. Most importantly, I learned about the power of data visualisation.

I was very proud that one of the sales rep's figures – a Kaplan-Meier Curve – came directly from my desk. But I was also embarrassed that it didn't look as awesome as the figures produced by professional marketing agencies. At that moment, I committed to improving my data visualisation and general data communication skills.

If we as Statisticians don't help our colleagues to communicate our results effectively, they will rely on other sources to do so. These people may have no statistical training and limited understanding of the strengths and limitations of the data.

It is critically important for Statisticians to become involved in the flow of information from end to end: from the raw data to the end customer. Naturally, information flows via lots of different functions and hierarchies across the company. The bigger the company, the more people and functions will be involved, and the more sophisticated and complex the network of people involved in preparing/updating/customizing the information will be.

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The goal is to have everybody touching or working with the data knowing how best to communicate about it.

The first vital part of communication training is to help translate statistical wording, like "no treatment by subgroup interaction", into easily understandable wording appropriate for the different audiences. I'll discuss precisely how we approach this in the next section on 'training on internal data'.

The other fundamental aspect of the training is about how to best display the data or how to engage with the statistics team to request new ways to visualize the data. Depending on the needs of the organisation, the goals of this visualisation training might include:

- Increase the awareness of the organisation on the capabilities of the statistics function to provide high quality data visualisations
- Showcase more advanced data visualisations which include patient level data and allow for interactions with the data (e.g., filtering, sorting, highlighting).
- Provide ways to appropriately communicate variability within the data and consistency across different ways to analyse the data.

The content of such trainings could cover:

- Data visualisation theory including:
  - Gestalt principles
  - Pre-attentive attributes
  - Colour theory
- Design principles:
  - Use white space
  - Alignment of objects
  - De-cluttering
- Effective annotation of data visualisations (labels, titles, footnotes, etc)
- Tools for effective data visualisation (e.g., colour choices, collection of graph types, ...)
- Best practices regarding the process to generate data visualisations.

The topic of data communication is perhaps one of the most critical in our modern drug development paradigm. As such, we must give it proper attention in our training stack.

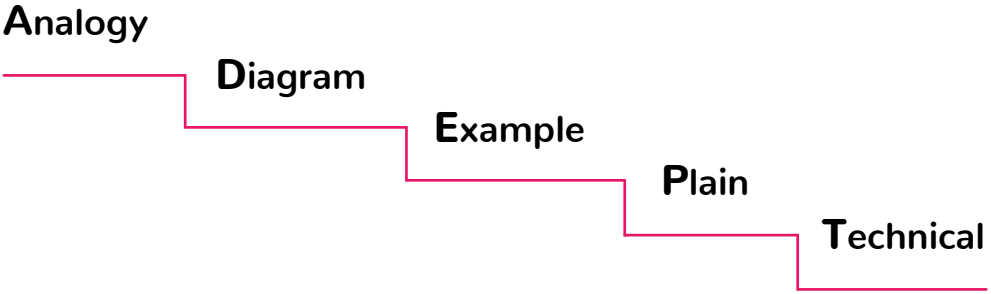
Top tips:

1. Consider the goals of your data communication training
2. Make sure your colleagues know how to request visualisations from your team
3. Showcase advanced visualisations and how they can help

Internal data/results training in advance of or during a product launch

It's obvious that internal data or study results training belongs to standard services offered by statistics organisations. However, it is often done only reactively and not sufficiently leveraged strategically to improve the impact of the statistics organisation to all levels of the company and beyond.

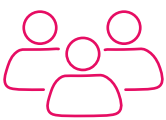
Every experienced Statistician will have been asked to explain more complex aspects of the design or analyses of the internal data. Good Statisticians have built skills to translate such complex statistical concepts into plain language. An effective way to communicate such topics is the ADEPT approach:



Imagine you want to explain the concept of interaction between 2 factors – e.g., treatment (new and old) and gender. You may start by moving into an analogy of comparing a formula 1 race car and a typical family car. Which car is faster depends on the nature of the road. On the highway, the race car will be faster. On a muddy farm track, the family car will be faster. You may then show this using a diagram sketching the speed of the cars for different roads and highlighting the different directions of the difference of speed depending on the road. As a third step, you may use the example from your clinical data of comparing treatment and gender explaining in plain language that the effect of the drug depends on the gender and thus the overall effect in a study depends on the proportions of the different genders in the study. Finally, you can write down the mathematical formula of how the proportion of the gender impacts the overall study result.

For internal training to be successful, we need to consider three different factors:

Timing



Audience

Scalability

Timing the training correctly is of utmost importance.

I once worked on a launch where the study team had changed the primary analyses based on some unexpected data. During the data communication process, there was misunderstanding about why the analysis had been changed, resulting in a lack of trust in the organisation on the appropriateness of the approach.

It took a lot of meetings, additional communication and training to explain the background and the reasons for changing the analysis.

Still a lack of trust remained. This story shows that training on the methodological aspects of data needs to be done at least in parallel with the corresponding data being distributed.

In some instances, it might even be possible to train in advance on anticipated problems. For example, if a study uses a new approach for estimands, combines historical data for the comparator arm, or uses advanced methods for adjusting for multiplicity, Statisticians should expect questions about these novel or non-standard design and analyses approaches.

Training key people in the organisation early – even before the study results are available – will help to decrease misunderstandings later. This strategy is called "first mover advantage" in communication theory. As we set the frame of the discussion, we control the situation and improve the consistency of the message.

Preparing training upfront belongs to the overall communication plan and should be done in a timely fashion.

The second factor is the audiences. Internal and external audiences differ in terms of:

- Their prior statistical knowledge or data literacy
- Their understanding of clinical data
- The format through which they will consume the training
- The time they will be able to invest in training

It is therefore advisable to segment the different internal and external audiences such as:

- Other Statisticians
- Clinical/medical/health outcome researchers and medical writing professionals
- PRA and medical affairs representatives (globally and locally)
- Upper management and governance boards
- Marketing (globally and locally) and sales
- KOLs
- PR and media
- Physicians and other healthcare providers
- Patients, patient advocacy groups, and other caregivers

This segmentation will allow you to better tailor your educational tools and communications.

The last factor is scalability. It's usually possible to train the global team and a global advisory board with KOLs intensively via in-person training by a Statistician. These stakeholders typically include people with a high level of medical education, background knowledge and a relatively large amount of time available for training. When we need to train an entire global sales team on the other hand, it is simply not feasible to conduct the training face to face as it would expend impractical levels of time and resources.

In these scenarios, Statisticians should provide scalable training formats. Three approaches are commonly used:

Train the trainer

Webinars

Asynchronous trainings

In the **train the trainer** approach, Statisticians train key multipliers in the organisation to explain further statistical concepts around the data. These typically include physicians in the local affiliates of the organisation. Further key people might be selected medical scientific liaisons, local PRA, and marketing representatives. Individuals with a high affinity of methodological approaches, a good peer network, and good communication/ teaching skills will be optimal for this approach.

Train-the-trainer sessions can also easily be combined with other meetings/conferences where the relevant people come together for other reasons. Such events can be:

- Business planning meetings
- Key global conferences
- Large functional meetings

During the launch of a new product, key people from around the globe usually need to come together to learn about the product, the indication, the strategy, etc. Such meetings provide the optimal environment to explain the data together and answer any questions about it.

Webinars offer an easy solution to explain the data and associated questions. They are easily scalable and can be recorded for use in other time zones and for people joining later. They also can be easily customized for specific audiences and set up ad-hoc for new data becoming available. However, the interactivity is much more limited compared to in-person events and many people face a higher emotional hurdle to speak up in such events. Including smaller break-out groups or follow up meetings helps to improve the interactivity.

Finally, there are many forms of **asynchronous training**. These include FAQ documents, reports, slide sets, videos, and more. Having a central place for these trainings with managed access to various parts helps to keep things updated. As obvious as this sounds, many companies – especially large ones – struggle to have such a place. Due to local regulations around the world and potentially differing labels of the product, different employees need to have different levels of access to information.

In practice, all 3 approaches will be used in combination to train the different parts of the organisation.

Top tips:

1. Segment your training audiences
2. Consider how different training formats would meet your needs
3. Pick the right training format to suit the needs of your audience

External evidence training for product launch/commercialisation launch

Many of the points mentioned for training on internal data also hold true for the training on external evidence. The key difference to the internal data lies in the lowered ability to prepare for such data.

Even though companies will have an awareness about key competitor studies currently running and approximate timelines for disclosure, which often fall in-line with major conferences, they rarely plan for managing these events pro-actively.

External data will travel through the organisation very fast and become hot topics, especially if they are seen as threats to the company-owned assets. Such "bad news" can create a lot of tension or even panic in organisations.

Proactive and fast communication around the assessment of the data, the impact on the company's strategy, and follow-up actions, provides the only way to manage "bad news".

It is advisable to have, for example, indirect comparisons in place to put the new data into perspective against the company-owned product. Furthermore, comparing design features between studies and evaluating which impact these will have on outcomes will help to avoid false conclusions. For example, if the competitor study included easier to treat patients it might result in larger treatment effects.

Explaining such effects will help to put results in perspective and provide a structured and understandable narrative for use by people meeting external customers. Especially for customer facing teams working with KOLs, it will be very advantageous to be well informed and have the opportunity to address such data prospectively in meetings with KOLs rather than being surprised about it and not being able to confidently address questions about it.

Top tips:

1. Expect the unexpected with emerging external evidence and have a process in place for handling it
2. Be agile and provide a structured narrative for use by customer-facing teams
3. Apply learning from your experience on training on internal data

The process of developing a strong training framework takes time and effort, but will result in stronger influence, better data communication, and ultimately better results for your Launch and Commercialisation team.

To learn more about our Launch and Commercialisation statistics services, click below.

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