



Paper LI05

Statistical Programming in the Future – Our Mindset, Data FAIRness, and the Importance of Stakeholder-Relationships

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ABSTRACT

Going towards the future, not only continuous interest and training in new techniques, skills (e.g. new programming languages, data visualization, data science) and knowledge improvement is important. Because, in order to enable all this, the right statistical programming mindset needs to be in place. This presentation / paper will talk about the statistical programming mindset of the future and outline why it is essential and needed going forward. Equally important is our approach how to deal with data when it comes to data FAIRness (findable, accessible, interoperable, reusable). Besides this, good and fruitful stakeholder-relationship are important and to lift statistical programming to the next level in order to become an equal partner with clinical teams and stakeholders. This presentation /paper will discuss and outline why these three aspects are important moving forward and show best practices.

INTRODUCTION

Leadership and innovation is dealing with our future, short- and long-term. This presentation / paper focuses on three important topics when thinking about the (our) statistical programming future:

- 1) Our mindset (the most important aspect)
- 2) Data FAIRness (findability, accessibility, interoperability, reusability)
- 3) Stakeholder relationships (fruitful and successful)

Data are the statistical programmers oil, but other aspects are equally important in order to succeed. There are many, and this presentation / paper focuses on three of them.

THE THEME – BACKGROUND AND CONTEXT

Where are we as statistical programmers in 2019 and where do we go in 2020 and beyond?

Common questions circulating in the industry around statistical programming are:

- o Is our job generally still safe?
- o Will we, statistical programmers, only be project managers in the future?
- o Can even project managers without statistical programming background do our job?
- o What type of statistical programmer are you? Programmer (hands on) or project manager (no hands on)?
- o What do you want to do in the future?
- o Do you prefer to work in small teams where you can still do some programming or do you prefer large teams where only project management skills count?
- o Who is teaching us project management skills?
- o Why are we just thrown into the cold project management water when only having a programming background?
- o Why do students learn R® only?
- o Will there still be SAS® in e.g. 5 years?

There are a lot of unknowns developing towards the future with unknown answers but this presentation / paper will outline the complexity developing towards the future and focus on three important aspects as outlined above.

The statistical programming work environment is rapidly evolving and it is important to gain new skills and technical knowledge going forward. Also data visualization, data science, artificial intelligence, data architecture and machine learning will increase in importance. However, necessary soft-skills (beside technical upskilling) and the right mindset



need to be in place in order to enable the full potential. New programming languages and technical skills can be learned, easier than having the right mindset.

DOING NOW WHAT PATIENTS NEED NEXT

The most important aspect is to focus on the patient, doing now what patients need next. What does statistical programming need to do now in order to help patients? On a high level, speed, agility and change is needed because the world / industry evolves, patients are waiting and everyone wants to be faster (filings for example). We as statistical programmers need to be more agile and faster when it specifically comes to

- Understanding the data
 - We have more and more external data and “special” data like biomarkers, data from handheld devices etc.
- Decision making
 - Often study reporting and conduct is slowed down by slow and wrong decision making)
- Delivery of tables, listings and figures (TLFs) or outputs incl. interactive data displays (IDD)
 - These are the products that statistical programming delivers in order to allow decision making and to file

SOFT-SKILLS VS TECHNICAL SKILLS

Getting fit for the future it is often regarded equal to technical upskilling of statistical programmers. However, the so-called “business skills” are equally important. Statistical programmers need to do more than just technical upskilling.

We cannot and should not only look at the technical competencies but also at the business (soft) skills.

STATISTICAL PROGRAMMING EVOLUTION

In the last couple of years, statistical programming underwent a huge transformation.

- a) From the service-providing „cellar“ job.....
 - Statistical programmers just received requests for analyses and numbers and statistical programming did it
 - Handed it up to the “main floor” to the statistician
- b)To the actual office,
 - Statistical programming got a little bit more visible but had their own office on the “main floor”
 - Statisticians at least came in and brought the request...
- c)Talking with Statisticians
 - Statistical programmers started to talk to statisticians and worked together on the analysis plan
 - There were more and more discussions
- d)And to being an equal partner with the whole clinical study team
 - Going forward, statistical programmers are or want to be equal partners in the clinical study teams / filing teams
 - ...and statistical programmers want to be equal partners with all stakeholders and a valuable team member

THE CONTEXT

Technical upskilling is just one aspect among many others going forward. More skills are needed than just being technically on top of the industry. This paper only focuses on three of these.

- **Stakeholder relationships** - We want to have functioning teams and statistical programming should be an equal and influencing partner going forward.
- **Data FAIRness** - Our data is our oil and we need to make it FAIR, enhanced data insights and sharing is important, audit readiness is needed and “cook books” as well as documentation needs focus.
- **The statistical programmers mindset** - The most important aspect, what is the statistical programmers mindset we need to have?



Other aspects are:

- **External business partners** - The foundation of many companies are external business partners. We need to think about the right work for the right people and also strengthen these partnerships. Service providers and external business partners should be regarded as full team members.
- **Tools and processes** – In order to keep up with new tools and processes, proper change management is needed. Also upskilling and the will to adapt.
- **Working groups** – We as statistical programmers are all in working groups, internal and external. These are key in order to move departments forward and to initiate change.
- **Project management** (a huge topic) – Project management fills multiple day trainings, all soft skills like e.g. negotiation skills, delegation etc. are key to success.
- **Centers of excellence** – centers of excellence should be/ are created in order to drive automation forward and to automate certain processes.
- **Speed** - Everyone wants statistical programming to be faster (especially when talking about filings), ultimately especially patients are waiting for new drugs. Also with the upcoming of e.g. new processes like real time oncology review (RTOR).
- **Knowledge** - In order to be an equal partner with stakeholders knowledge is important. Statistical programming needs to understand the experiment, the study, the disease and the project.
- **Recruitment and onboarding** – Often statistical programming is not good with onboarding, defining backups. In order to avoid teams failing, retaining and recruitment of talent is important.
- **Changing teams** – All statistical programmers are confronted with changing. This topic is also related to onboarding and knowledge transfer.
- **Different roles** – Within statistical programming we take different roles like e.g. submissions lead, or study management team representative. The state of the study, early development vs. late phase and different working models contribute to different roles within statistical programming.

The question arises do we actually still have time for hands on programming? The answer is that we need to focus on many aspects, not only on technical up-skilling in order to be fit for the future.

THE STATISTICAL PROGRAMMING MINDSET – FUTURE

As statistical programmers, we need to leave our “cellar”, the service provider mentality way of thinking, our comfort zone. In order to achieve that, the right statistical programming mindset needs to be in place. Being genius in programming only is no longer enough.

ASPECTS

In order to get the right mindset, learning (not only technical) and knowledge transfer is essential. For a new starter in statistical programming it usually takes a couple of months in order to be fully productive. All the aspects mentioned below need to be learned in order to be fit for the future. Statistical programming needs to get away from the service provider mentality, i.e. starting to program one day after joining a clinical team based on requirements. Statistical programming needs to look outside the box, e.g. the meaningfulness and the interpretation of tables / numbers produced. Also one needs to look into the future, e.g. interactive data displays (IDDs) that already start to replace static outputs. In order to be ready for the future, we also need to change the way we think in terms of submissions: We need to be ready at study read-out instead of only starting thinking about the submission once the read-out is positive. Statistical programming also needs to put further efforts into automation and standardization. In order to bringing new medicines to patients, statistical programmers need to successfully interact with stakeholders, e.g. medical writers and the science team. To achieve faster filings, frontloading of activities (clinical study reports), unplanned analyses after study read-out and fruitful relationships are needed with stakeholders. This includes the analytical strategy, i.e. do all outputs still need to be static? We as statistical programmers need to find the best solution, the smartest solution. We also need to get better with code sharing and code collaboration (even across pharmaceutical companies).

Here are the aspects we need to focus on in the future in order to build the right statistical programming mindset:

- **Passion & commitment** - We need to show passion and engagement in what we are doing.
- **Curiosity / learning** - We need to stay curious and learn (learning when we need it, on time).
- **Fixed vs. growth mindset** – We need to change from a fixed mindset to a growth mindset.



- **Challenging the status quo** – We need to be curious, challenging tools and processes we use and anything else.
- **Taking risks** - We don't need to be perfect and also try to do things in a different way. We need to take smart risks.
- **Understand the landscape we are in** - We need to be aware of what is going on around our function (stakeholders and teams).
- **Agility & planning** - We need to get better in planning instead of fire-fighting, i.e. avoid emergency
- **Speed** - We are asked by everyone around us to be faster and we can only be faster when having the right mindset.
- **Being smart** - We need to be smart, we need to drive things as statistical programmers.
- **Pro-activity** - We need to be able to propose solutions, e.g. interactive data-displays (IDDs) and also for planning with stakeholders together.
- **Empowerment** - We need to have the trust from our leaders, we need to be empowered making decisions.
- **Value generation** - We need to know what we are doing in order to contribute and to add value.
- **Flexibility** - We need to be agile and flexible in the way we work in statistical programming.
- **Data citizens (F.A.I.R.)** - We need to document and stick to the FAIR principles.
- **Critical thinking** - We should raise our voice and think critical.
- **Being an equal partner** - We want and need to be a good partner with all functions around us.
- **Automation** - We need to move automation forward in order to be faster and to feed “speed”, e.g. center of excellences. We are not where we want to be yet.
- **Analytical strategy** - We need to plan and think how we analyze clinical data, e.g. IDD from IMCs
- **Engagement with stakeholders** - We need to build fruitful and successful relationships with our stakeholders.

FIXED VS GROWTH MINDSET

Statistical programmers need to change their mind from a fixed mindset to a so-called growth mindset including the underlying aspects that come with this new way of thinking.

When having a fixed mindset, one is static, whereas with a growth mindset, one develops and progresses – With intelligence, behaviors and the general way of thinking.

FROM..... TO..... **

Our behaviors and our mindset are key to enable change, up-skilling and going towards a successful future. Certain aspects that need to change and in place are as follows:

Fixed Mindset:

A fixed mindset is generally static, with a tendency to these behaviors:

Problems & challenges

- The tendency is to avoid problems and challenges.

Effort & time investment

- Time investment and efforts taken are seen as useless and without adding value.

Feedback & criticism

- Feedback is something positive, but with the fixed mindset useful negative feedback is ignored.

Obstacles & hurdles

- The tendency to resign, to give up and to become defensive.

Outcome & results

- Outcomes and deliverables are not fully seen as something positive and strengthening.

Success of team members

- The feeling of looking at others that are more successful, which is seen as a threat.

Growth Mindset:

A growth mindset is generally learning- focused and future / curiosity-driven , with a tendency to these behaviors:

Problems & challenges

- The tendency to taking on challenges and to see these as something positive.

Effort & time investment



- Effort and time spent is seen as positive, the will to get better.
- Feedback & criticism
- To listen to feedback (also negative) and to absorb it, i.e. to grow with it.
- Obstacles & hurdles
- To stay strong and to overcome these.
- Outcome & results
- See even small steps as positive and seek for better results and achievements.
- Success of team members
- See inspiration and food for thought in the success of stakeholders and team members.

Our behaviors are key to enable agility and to drive change

From..... inclusive & pleasing	→ To trusting others to take the right decision(s)
From being conservative	→ To being courageous
From perfectionism	→ To being pragmatic and intuitive
From rewarding performers	→ To rewarding collaborators and fast decision makers

We have to embrace ambiguity and feel comfortable with “failing forward“.

DATA F.A.I.R.NESS

In order to be fit for the future and to meet stakeholders needs, data needs to be FAIR. Also when thinking about other departments and functions who might / will look at the data in order to gain further insights and to perform further analyses (also in a pooled way). This might / will be years later.

DEFINITION

This is subtopic for the above. The term FAIR stands for

Findability	☐ Where are our data?
Accessibility	☐ How can I get the data?
Interoperability	☐ How can I connect or integrate the data?
Reusability	☐ Can our data be easily shared and used again?

Findability is important because different people and functions look for our data and the documentation, even years after. As documentation is often seen as overhead and unnecessary, it is in fact extremely important. It is often very difficult to find information (documentation, programs, data) – this need to change going towards the future.

Accessibility is key as well, as our data is not our data. We actively need to open it up for other functions after read-out of studies / projects and after embargos are lifted.

Interoperability is often connected with pooling of data. Often statistical programmers struggle to pool data, even within a project / molecule. Going towards the future, studies need to be more harmonized and standardized.

Reusability is an important aspect. Data without the necessary specifications / documentation is useless. Any data sharing needs to contain data and the necessary documentation and metadata.

Data FAIRness should bring structure and should make data re-usable to others in order to support e.g. personalized healthcare and to gain further insights. It needs to be applied when planning, acquiring, processing and releasing data.



WHAT CAN STATISTICAL PROGRAMMERS DO?

In order to implement Data FAIRness within biometrics and our departments, the question, what statistical programmers can do on a daily basis, usually immediately comes up.

Planning: Already at the planning phase, statistical programmers need to focus on and pay attention to:

- Data standards that are used in the study / project
- Terminologies and adherence to global company data standards
- Selection of the right vendor(s)
- Focusing on the requirements
- Definition of the necessary metadata, having the end (analysis) in mind

Acquisition: In the data acquisition phase, statistical programming needs to be involved in these discussions:

- How to store the data, how to tag it, how to catalog it
- Thoughts on conformance and documentation

Processing: At the data processing phase, which is probably closest to statistical programming, key elements are:

- The documentation of any workflow, e.g. project / study landing pages including all necessary links etc.
- Thoughts on reproducibility, e.g. writing “cookbooks”, where other statistical programmers need to be able to execute the same task
- Thoughts about standards and formats

Release: At the data release phase, the following points need to be taken care of:

- All stakeholders and even wider communities need to have access to results and the actual data (incl. documentation)
- Correct versioning, audit trails and transparency needs to be ensured
- Compliance and adherence to global data standards needs to be in place

By doing all this and following certain rules, we as statistical programmers ensure, that the data we analyze and process can be re-used. One might think that lots of these aspects relate to other functions, but in the future (and already now) we have data architects with end-to-end data processing in mind.

STAKEHOLDER RELATIONSHIPS

Stakeholder relationships are important for statistical programming and will even become more important in the future. They need to be good, close and fruitful in order to be set up for success.

THE WORLD AROUND US

Who are our stakeholders? In fact, there are lots. Statistical programmers are surrounded by a great variety of different functions with different “languages”, needs and background.

- Safety Science
- Clinical Science
- Statistics
- Medical Writing
- Managers
- Company-internal standards groups
- Submission / filing teams
- Regulatory
- Study management teams
- Tools/ processes / systems expert groups and super users
- Modelling and simulation / pharmacokinetics
- Data acquisition (external data)
- Independent data co-ordination centers (IDCCs)



- Other companies (e.g. vendors)
- Statistical programming project leads
- Data management
- Independent data monitoring committees (IDMCs)
- Business partners
- Real world data science
- Biometrics teams
- Health authorities
- ...and even more...

PARTNERSHIP

This is subtopic for the above. Given all these stakeholders and functions around us, a fruitful partnership is needed in order to be successful as statistical programmer and as a team. The statistical programmers vision should be that we are a curious and trusted partners and the emphasis here is on partner, being an equal partner, being a valuable team member. The vision is that we drive and continuously evolve analytics to generate insights from healthcare data to ultimately improve patient lives. In order to be able to do that, a pro-active collaboration-approach is needed with our stakeholders. We as statistical programmers need to think ahead as influential partner to drive analytics / analyses that advance drug development and in order to gain meaningful insights from data.

KEY ELEMENTS

In order to shape and to have fruitful, successful and good stakeholder relationships, the following key elements are essential:

- Being an equal partner → It is important to be on the same level with our stakeholders, to speak the same language and to understand them.
- Knowing the disease / molecule → In order to be on the same level statistical programmers need to understand the “experiment”, the disease / molecule to a certain extent.
- Being proactive → Pro-activity means that statistical programmers should offer analytical possibilities / alternative ways and smart solutions (e.g. interactive data displays) to stakeholders.
- Communication → Communication is key for any good relationship with any stakeholder and statistical programmers should continuously work on communication skills..
- Discussion → Statistical programmers should discuss on the same level with our stakeholders and various partners around us.
- Understanding → Understanding the “language” of our partners is essential in order to be able to communicate successfully and to understand requirements, wishes and discussions.
- Planning together → Planning is key to be successful and fast / agile when it comes to analyses and deliveries.
- Making statistical programming visible → Pro-activity, showing expertise and curiosity should ultimately lead to more visibility for our stakeholders.
- Being curious and asking questions → Stakeholders are usually happy to answer all our questions and answers will lift statistical programming to the next level in terms of understanding and knowledge.
- Driving seat → Statistical programmers should be in the driving seat instead of having a service provider-mentality.

CONCLUSION

The future for statistical programming is much more than just technical up-skilling. Statistical programmers need to be aware that there is much more that we need to upskill on. Data FAIRness, our mindset and stakeholder relationships are just three aspects. Being an equal partner with the necessary skills will enable us to drive and shape analytics / analyses and ultimately drug development.

REFERENCES

**The Mindsets, from the research of Carol Dweck, Ph. D.



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