

Statistical Programming, Novartis Pharma S.A.S, Rueil-Malmaison,

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Once the transition is done, it is not always easy to act in this new role and stick to it under certain circumstances. On the other hand it is also possible to use your new skills to help your old role: a programming procedure can save hours of data management review! Some tips will be given to combine the experience obtained in both roles and get the most from them.

The diagram features a black winding road with white dashed lines, curving from the bottom left towards the top right. The year '2006' is positioned at the start of the road on the left, and '2015' is at the end on the right. Five orange rounded rectangular boxes are connected to the road by thin orange lines, representing career stages:

- 2006 (Start):**
 - Biology and computing background
 - 5 years
- Mid-Left:**
 - Trainee/Junior data manager
 - 1 year
 - Internship abroad in clinical trials field, in a large company
- Mid-Right:**
 - Trial programmer
 - 2 years
 - Project leading, involvement in clinical team. Still programming !
- 2015 (End):**
 - Support programmer
 - 2 years
 - Lots of programming on many different data types

Trainings		
Gaps	Solution	Tips
SAS	Trainings	Read existing programs before building your own coding style
Biostatistics	Exchanging with programmers and biostatisticians	Questions on stats from programmers is not unusual. There is no stupid question.
Statistical programmer role	Learning from mentor Personal experience	Attend higher level meetings and try to be involved in various activities.

The figure displays three pie charts representing the distribution of activities for three different roles: DM trainee, Support programmer, and Trial programmer. The activities are categorized into five groups: Programming, Documentation, Interacting with other functions, Other (trainings, reading ...), and Coordinating programming team.

Role	Programming	Documentation	Interacting with other functions	Other (trainings, reading ...)	Coordinating programming team
DM trainee	~45%	~25%	~15%	~10%	~5%
Support programmer	~55%	~15%	~10%	~10%	~10%
Trial programmer	~35%	~20%	~20%	~10%	~15%

CRF Form #	CRF Item	Evaluable Question/Discrepancy	Condition to generate	Query text
TREAT % (corresponds to any Treatment cover panel) PRSC	ELCHGIC, SWSTTIO	ELCHGIC = No at visit N and VISIO at visit N-1	The dose level change is "No" but a new dose prescription is reported. Please update	

Identification
of issues
impacting
analysis

```

1 | Bring PHEM and INSD together and reconcile data |
2 |-----|
3 data pchem plainly dmpgonly;
4 script plain (comp 3
5     dmg (l1:=ind) ;
6 by dmpgacct;
7
8 if ind and pk then output pchem;
9 if pk and not ind then do;
10     Put "WASH INSD: Data Issue 1: FF records not in clinical DB Record number=" _a _staysid= mpin= phkzrel=;
11     output plainly;
12 end;
13 if (not pk and ind) or (ind and mpstels eq "Not Received") then do;
14     Put "WASH INSD: potential Data Issue 2: subject no FF records and need to verify. Record number=" _a _staysid=
15     output dmpgonly;
16 end;
17 run;

```

SAS to manipulate data

Scatter plot showing Analysis value (Y-axis, ranging from 100 to 180) versus Visit number (i) (X-axis, ranging from 0 to 80). The data points are categorized by group (flag): 0 (blue circles), 0+1 (green circles), and 1 (red crosses). The plot shows a general upward trend in analysis values across visits for all groups, with group 1 consistently having the highest values and group 0 the lowest.

Understanding
of site
behavior with
queries

This move is not standard, generally you « are born » statistical programmer or data manager. There is no standard transition package. But nothing between the 2 roles is unbridgeable. A good sense of adaptability is primordial to overcome role differences. People will not mind your lack of biostatistics knowledge if you show other qualities.

After acquiring confidence in the statistical programming field, the combination of experiences is possible and it can save time to the whole clinical team when it comes to data cleaning specifications and data review tools. It also helps yourself understanding data you analyze and how it is structured.

It was a challenge for me at the beginning to enter the world of SAS programmers but the transition went even better than I had expected. This kind of life change, despite the efforts that it takes, is possible and profitable.

Clichés



“it shouldn’t take them long...they just have to press a button. “

“looking forward to the test run of outputs to complete my data cleaning.”

- Test runs are often made of dummy data and the purpose is to verify the layout.
- Unfortunately not just a press button, each study is specific and programs are adapted.



“I have spotted this issue a hundred times, why isn’t it resolved? “

“it’s bad quality data...as usual.”

- Sites can have different reactions to queries. Sometimes they will confirm values that do not look correct to the programmer.
- A precise review of edit checks allows better data quality throughout the conduct of the study and avoids manual review.