



Science For A Better Life

Managing the Change

Evolving from Statistical Programmers to
Clinical Data Scientists

October 14th 2014 *Sascha Ahrweiler*



Agenda

- Evolution of Statistical Programmer
- Next Step in the Evolution
- Manage the Change to the Skill Set Required
- Conclusion



Forward-Looking Statements

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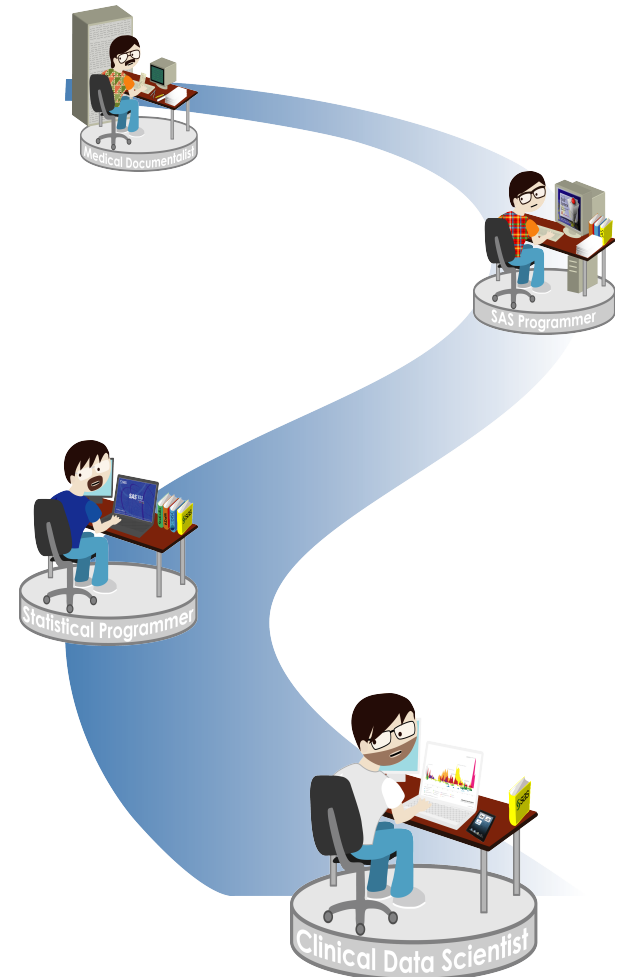
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Evolution of Statistical Programmer

Working in the **Pharmaceutical Industry** =
Working in a **rapidly changing environment**

- Evolutionary Phylogenesis of Statistical Programmer in the past four decades
- From cavemen era to highly advanced and skilled species
- Scientific advances
- Increased regulatory need

Let's take a look back into history





Medical Documentalist

Why

Randomized clinical trials embodied in regulation as government recognized need to control medical therapies

When

Early 20th Century

What

Role of Medical Documentalist created
Support Biostatistician

Often direct reporting line
Tables, Figures, Listings for CSR

How

Mainframe based computer centers
Batch programs in Fortran, PL1, Basic
Copy and Paste of Graphics





SAS Programmer

Why

Breakthrough of PCs and SAS
Increased support Biostatistician

When

Early 1980s

What

Role of SAS Programmer created

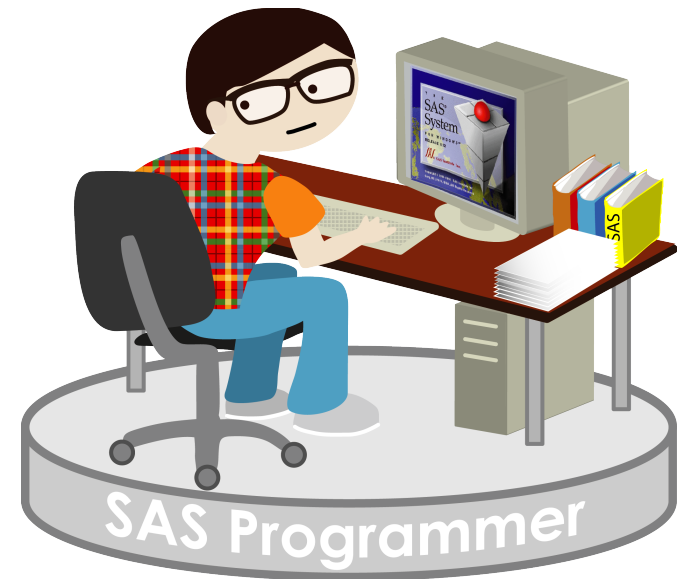
- Tables, Figures, Listings for CSR
- Integrated Analysis
- Safety
- More output generated with SAS

How

SAS79 released

PC based

User interface



Statistical Programmer

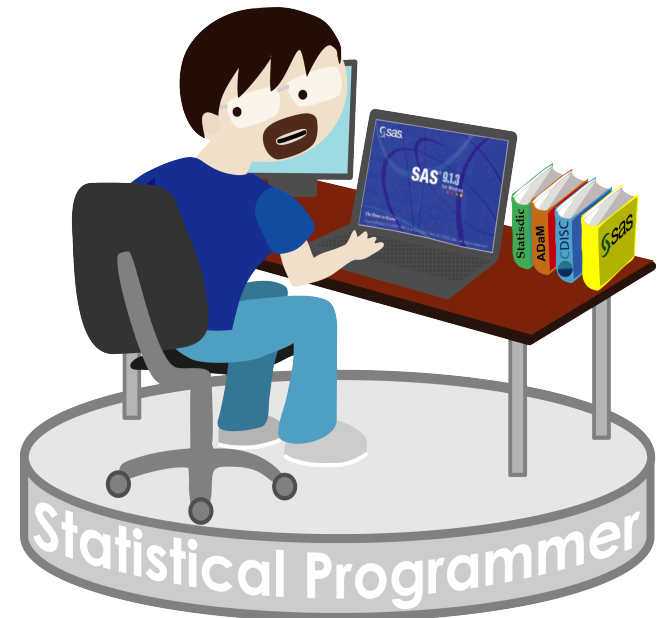
Why
New Statistical Methods and Requirements
Increased Statistical Knowledge

When
Late 1990s / Early 2000

What
Biostatistician focus on Statistics
Statistical Programmer translates SAP into SAS

- Tables, Figures, Listings for CSR and IA
- Safety and Efficacy
- CDISC compliant

How
Server based





Next Step in the Evolution

Until now

Future

Study

Integrate Data for Submission

Changing Guidelines

Huge amount of treatment and outcome data

Changes in Reimbursement

CT.gov
EMA Data Transparency
...

CPRD
Patients Like Me
Patient Registries
...

German IQWiG
British NICE
US Private Health Insurance
...

Think beyond Approval



Clinical Data Scientist

Why

Increased Need for handling and analyze all kind of data
Less thoroughly specified tasks

When

Late 2010s

What

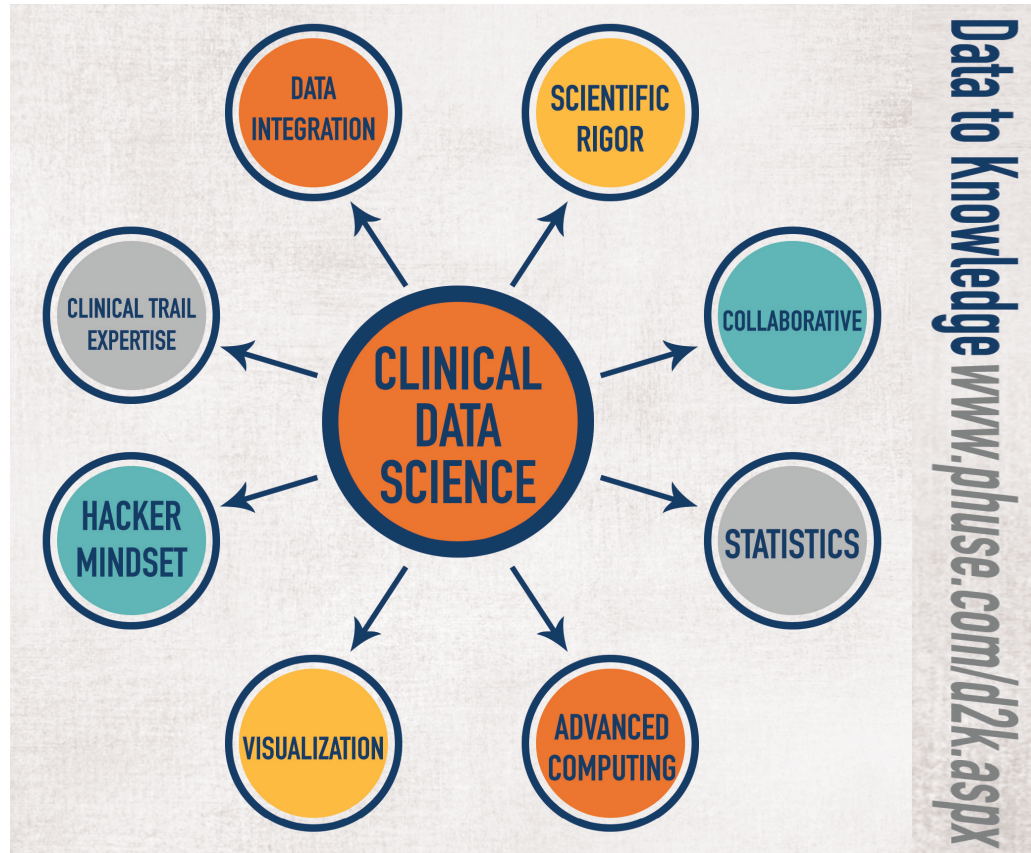
Role of Clinical Data Scientist created
Understands data wrt structure and content
Works collaboratively across functions
Multiple data handling, analysis and reporting tools

How

Server based
Cloud computing
Big Data



Required Skill Sets



Statistical Programmers have the right mix of skills to quickly adapt

Manage the Change to the Skill set required



Basics of Change Management

- Identify early adoptors
- Convey the message
- Will be a journey

Clear Commitment needed from Mgmt

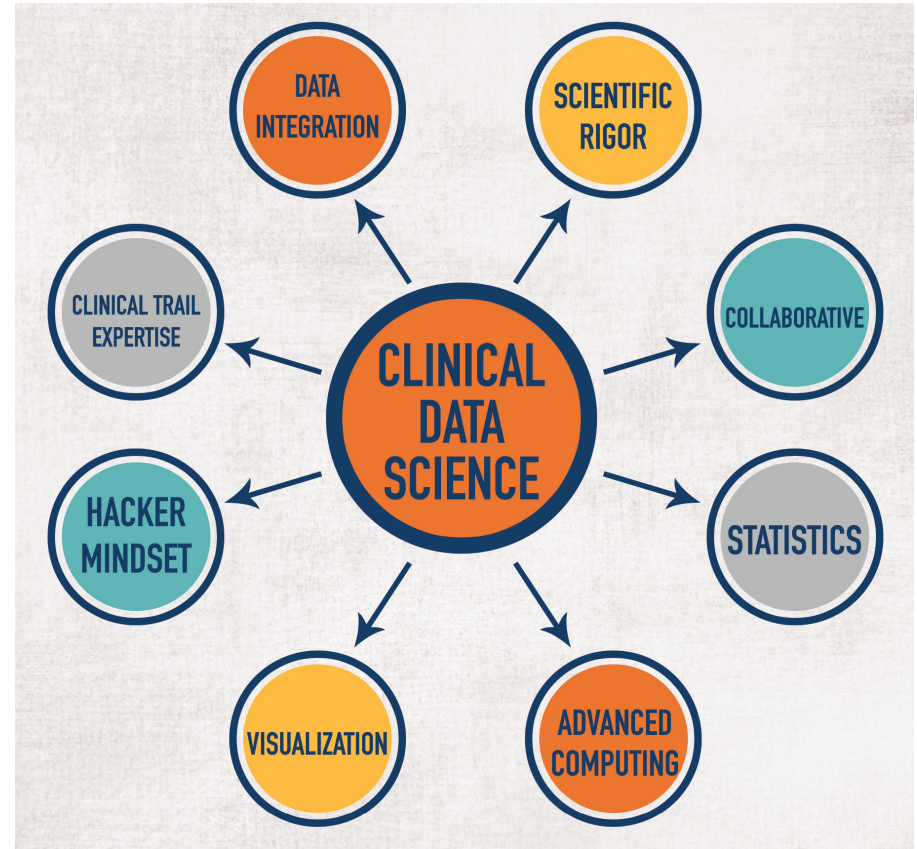
- Time and Financial

Clear Vision and Strategy

On the job / Workload neutral

Knowledge Sharing

Out of comfort zone



Manage the Change



What

CDS **understands drug development** process from R&D to approval

- Trial designs, data collection, analysis and reporting of clinical trials
- CDISC SDTM and ADaM usage

How

Share knowledge amongst colleagues to shorten duration of “experience”

Team presentation of study results



Create knowledge library

Manage the Change



What CDS prepares integrated analysis for various purposes (ISS, ISE, Value Dossier, economic models, ...)

CDS needs to know how to setup and analyze databases

CDS understands data wrt structure and content

CDS has Therapeutic Area knowledge

How Presentation from SMEs: Follow through **parameter from end to end**



Understand the end to end process

Share Knowledge

Build Knowledge Library

Manage the Change



CDS analyzes and reports data to regulatory and reimbursement agencies

- Agencies review thoroughly

CDS is an expert on data he transforms, analyzes and reports

Mathematical/Computer background **usually comes with scientific rigor**

Gap of specific TA knowledge

Read Protocols

Read and Understand IB

Accompany Proj Mgr at Site Initiation Visit

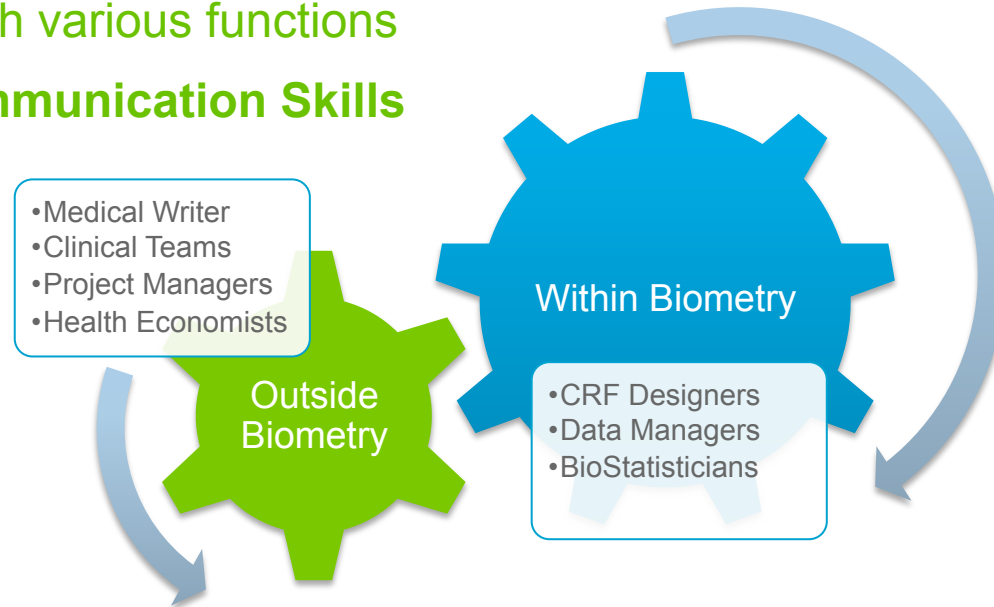
Attend Sales Forces Training



Manage the Change

CDS collaborates with various functions

CDS has strong **Communication Skills**



Presentations

Customized Communication Trainings

Don't be afraid to ask to understand each other

Meet&Greet to **Listen and Understand each other**

Participate in short Internships

Manage the Change



CDS understands Statistical Methods used in Clinical Trials

CDS applies Statistical Analysis methods to analyze data and report information

Should have a **basic understanding of Statistics**

- TLF programming => Basic Statistics (Mean, SD, etc.)
- More sophisticated Statistical Modeling requires advanced knowledge

PhUSE library from annual conferences

- Usually theoretical introduction combined with practical implementation

Mentoring by experienced colleague with SAP review

- Proactively think prior to programming

Manage the Change



What

Use **various tools** to handle, analyze and report data

- Not limited to a single tool (eg. SAS®)
- Use the best tool for each task

How

Programmer should have **natural interest** in computer science

Openness to learn new things

Workshops on new tools

Webinars

Platform independent conferences (eg. PhUSE) and learn about R, Spotfire, JMP, etc.

Talk to Exhibitors at these conferences



Manage the Change

What

CDS visualizes all kind of data

CDS has a good understanding of creation and interpretation of informative graphs

CDS summarizes results visually for various purposes

- Clinical Trial Results, Integrated Analysis or Data Mining.

How

On the job development of good understanding of visuals used Clinical Studies, Integrated Analysis and Meta Analysis

Mean and Individual Plots

Scatter Plots, Boxplots, Regression, Kaplan Meier

Graphic Library

Forrest Plots, Tree Maps, Word Clouds

Periodic Elements of Visualization

Literature

Dashboards

Manage the Change



What

Solving difficult data derivation challenges

Finding appropriate solutions for every problem drives them

How

Programmer have an innate Curiosity to solve data problems

Like solving a puzzle which contains of data and their relationship

Requires LM with people skills, time and personal interaction to find out what kind of puzzles still challenge a programmer

Acknowledge Situations when Challenges were solved

Acknowledge hard work and success to keep people engaged



Conclusion

Evolution of Statistical Programmer

Role of Statistical Programmer has evolved and will continue to evolve

Next Step in the Evolution

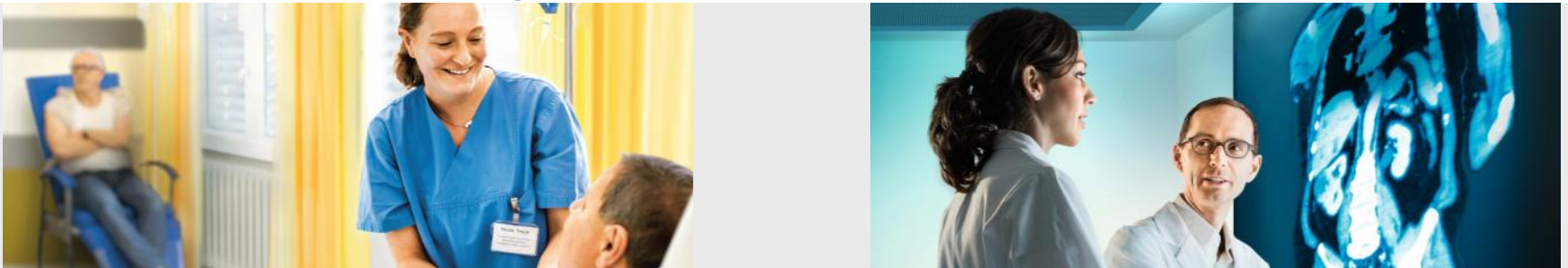
Think beyond Submission and Approval

Manage the Change to the Skill Set Required

Slight Evolutionary Change still requires steep Learning Curve

Integrate Development of new Skills into daily work

Be open for change and elevate to the next level





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Thank you!

ProgrammingBros: designed by Telse Ahrweiler