

Developing Exploratory Programmers Based in India

Jan Stefanek

PhUSE 2014



Inspired by **patients.**
Driven by **science.**



Developing Exploratory Programmers Based in India

Introduction and overview

Successful collaboration between the Statistical Programming groups at UCB (Monheim) and Accenture (Mumbai) for study work

Extension of collaboration into „exploratory work“

- What is Exploratory Programming ?
- What skills are needed for Exploratory Programming?
- How do we develop these skills?
- How this was accomplished at UCB
- Ongoing lessons learned and conclusion

Developing Exploratory Programmers Based in India

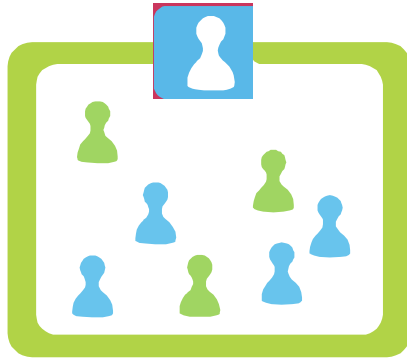
Exploratory programming at UCB

Support for

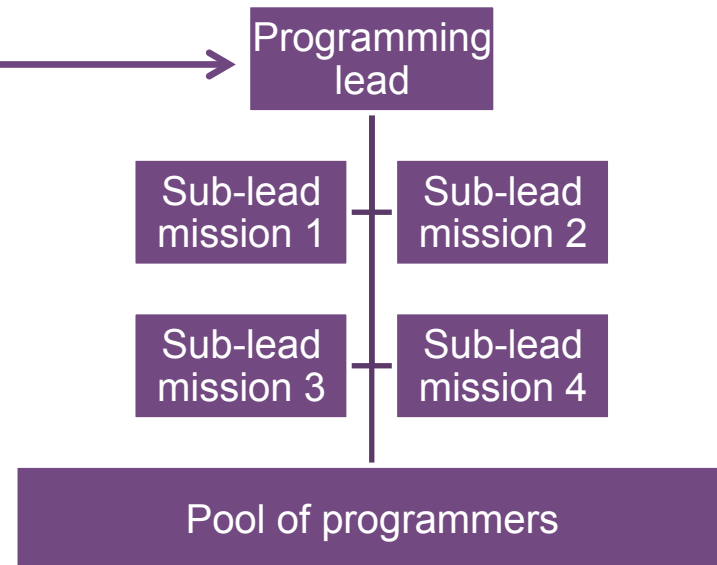
- Congress contributions
- Scientific manuscripts
- Advisory boards
- Data mining initiatives
- Validation of new methods of measurement such as questionnaires
- Health economic analyses
- Value added dossiers
- Health technology assessment projects
- Study planning

Developing Exploratory Programmers Based in India

Data Generation Team (DGT) structure



Chair
Medical representatives
Publication manager
Biostatistician
Programming lead
Market access representative
Ad-hoc members



Developing Exploratory Programmers Based in India

Preliminary considerations about the training

Training concept for programmers from Accenture in Mumbai

- Long-term perspective
- Train the trainer approach
- Cultural differences and collaboration in a global team
- Common understanding to conduct the training in Monheim for several weeks
- Possible issues of such a long absence from home
- Skills to be trained best assessed by comparing exploratory work with study work

Developing Exploratory Programmers Based in India

DGT programming compared to study programming 1

	Study work	DGT work
Quality of evidence	Hypothesis testing	- Hypothesis generating - Weaker evidence
Workflow	Pre-determined with respect to scope of work, priorities, and timelines	- Rollercoaster with peaks and troughs - Reprioritization, urgent requests - Requests are related to research questions that can change over time resulting in several cycles with time gaps without work in between

Developing Exploratory Programmers Based in India

DGT programming compared to study programming 2

	Study work	DGT work
Versatility	• One study • One biostatistician • One programming environment • Limited range of statistical models • Programming specifications: SAP (Statistical Analysis Plan) • Lead programmer is gate keeper to the study team	• Several studies • Several biostatisticians • Several (legacy) programming environments • Broad range of statistical models • Programming specifications: Broad scope ranging from SAP-like to One-liner • Programmer can be in contact with requesters

Developing Exploratory Programmers Based in India

Skillset of Exploratory Programmers

SKILLS

Ability to work in a global team

Understanding of drug development process, scientific and experimental thinking

Understanding the “big picture” of the compound

Knowledge about the compound and its studies

Knowledge of the DGT workflow

Ability to quickly understand study designs

Ability to make sense of purely specified requests

Advanced knowledge of statistical methods

Ability to deal with legacy structures and content

Developing Exploratory Programmers Based in India

Skills and corresponding learning modules 1

SKILLS	TRAINING MODULES
Ability to work in a global team	• Using “Focussed discussions” as training method • Experience of collaboration and interpersonal relations among colleagues in Monheim • Attendance at DGT meetings as guests • Focussed discussion with trainer about expectations on DGT programmers where cultural differences are involved (critical thinking; speaking up; contributing to team discussions; etc.)

Developing Exploratory Programmers Based in India

Skills and corresponding learning modules 2

SKILLS	TRAINING MODULES
Understanding of drug development process, scientific and experimental thinking	• Focussed discussions with trainer about basic scientific concepts (e.g. scientific terms; definition; operationalization; objectivity, reliability, validity) • Focussed discussions with trainer about the drug development process with anecdotic information • Presentations by Accenture programmers about goals, design, and results of selected studies important for DGT work with discussion • Presentations by Accenture about proposals for the design and analysis of studies they would develop with discussion

Developing Exploratory Programmers Based in India

Skills and corresponding learning modules 3

SKILLS	TRAINING MODULES
Understanding the “big picture” of the compound	• Presentations by Accenture programmers about the diseases which are treated by the compound with discussion
Knowledge about the compound and its studies	• Presentation by Accenture programmers about the compound and the indications where it is administered • Presentations by Accenture programmers about goals, design, and results of selected studies important for DGT work. Subsequent discussion with expert programmers.

Developing Exploratory Programmers Based in India

Skills and corresponding learning modules 4

SKILLS	TRAINING MODULES
Knowledge of the DGT workflow	• Presentation by trainer about DGT structure and process as well as it's environment • Discussions with UCB internal experts of the content areas DGTs cover • Passing a DGT e-learning course • Study work (Operational Procedure about scientific publishing at UCB)
Ability to quickly understand study designs	• Study work about the compound in general (Investigator Brochure, e-learning courses about the compound, etc.)

Developing Exploratory Programmers Based in India

Skills and corresponding learning modules 5

SKILLS	TRAINING MODULES
Ability to make sense of purely specified requests	• Focussed discussions with trainer with real life examples from the past
Advanced knowledge of statistical methods	• Internal training in Mumbai • Presentations by Accenture programmers about results of analyses with advanced statistical methods they had not used before (e.g. longitudinal modelling) with discussion
Ability to deal with legacy structures and content	• Presentation by trainer

Developing Exploratory Programmers Based in India

Implementation of trainings

Characteristics of trainees

- Fluent English
- Solid hands-on experience in clinical study work
- Good statistical knowledge

Trainings

- 3 trainings so far; 2 in Monheim, 1 in Mumbai
- 6 programmers in Monheim for 3 and 2 months, 3 in Mumbai for 2 months
- Additional trainings in statistics in Mumbai
- Some modules were conducted sequentially, others when an occasion arose.
- In Monheim 3 to 4 sessions of 1 to 2 hours each week
- Actual DGT work started after about half of their stay
- UCB planned for every endeavour to make the stay of Accenture programmers in Monheim to be comfortable

Developing Exploratory Programmers Based in India

After the trainings and challenges

After the trainings

- Programmers in Monheim on average on the same level as a newly hired expert contractor
- Trainings could not fully compensate hands-on experience
- Fully integrated into the global team
- Integration of programmers trained in Mumbai not as seamless
- Establishment of weekly meetings to discuss issues and conduct additional training modules
- Trainer will visit Mumbai in November

Challenges

- Improvement of trainings in Mumbai
- Turnover of staff

Developing Exploratory Programmers Based in India

Conclusion and summary

Conclusion

- Training concept first time in the industry
- Ambitious objective to develop Accenture programmers to exploratory programmers fulfilled
- 6 of the 18 DGT programmers are from Accenture
- Considerable cost savings

Summary

- Insight into exploratory programming work at UCB
- Requirements of exploratory programming
- Training concept for the development of the skill set needed
- Implementation of training and experiences at UCB so far

Developing Exploratory Programmers Based in India

Acknowledgments

Thanks for comments, suggestions, and reviews to

- My colleagues at UCB
- Sascha Ahrweiler, Bayer
- Sathish Thota, Accenture
- John Salter, PhUSE

Questions?

Thanks!