



The company of specialists.

What are the global trends that we are seeing in Statistics and Programming? How does this impact our roles?

Gail Kniveton

I3 Pharma Resourcing

+44 1895 451 801

gail@i3pr.com

Considerations

- Approach
- Pressures from:
 - Health care
 - Drug pricing
 - Drug development
- Changes in the regulatory environment
- Outsourcing and offshoring strategies
- Changing technologies and e-patient records
- Trial designs
- How does this impact your roles?

Approach

- Qualitative review based on opinion
- Opinion leaders
- For discussion and your opinions

Pressures on Health care, drug pricing and generics

- Governments globally looking for cost effective healthcare
 - Drug pricing
 - More health economics and outcomes research
 - Patient recorded outcomes
 - E-patient records
 - How far is this away?
 - Use of generics companies
 - Lower cost drug production
 - Patent law differences
 - Medical ethics
 - Observational trials, metadata and epidemiology

Pressures on Health care, drug pricing and generics

- Impact on roles:
 - Looking for more cost effective research
 - More guidance via regulatory authorities
 - Use of new technologies/ processes
 - Use of lower cost resource
 - Outcomes based research
 - Epidemiology

Changes in the Regulatory Environment

- Regulatory authorities
 - Offer guidelines and regulations around design, management and assessment of clinical trials
 - Patient safety
 - Do they understand the statistical design and significance of results? (ref 1)
- Data Standardisation to facilitate review and reporting by regulatory authority e.g.
 - CDISC, CDASH, ADAM, SDTM
 - Alligning/ interpreting your company standards
 - CFR 21 part 11 for SAS applications (ref 2)

Changes in the Regulatory Environment

- FDAAA 2007 (US ref 3)
 - Registration of all trials
 - All results to be published within 1 year
 - Visibility of competitors drugs, endpoints, analysis and results
- Impact on roles
 - Must keep on top of regulatory changes
 - Engage experts
 - Internal
 - External
 - Consultancies
 - Training/ best practise forums
 - internal
 - via associations e.g. Phuse

Outsourcing and offshoring strategies

- Outsourcing historically was by project
- Big move to multi-project and longer term partnership deals
- Impact on roles
 - Improve communications skills
 - Project management skills
 - Working in or managing remote teams
 - Multi-timezone/ multi-cultural working
 - Lack of “junior” or “training” roles (US and Europe)

Changing technologies and e-patient records

- Technology version updates
 - Will SAS ever be challenged?
 - R, SPLUS, Winbugs, Winnonlin
- Merging data from different sources for analysis
- What impact will direct access to patients records have in future?
- Impact on roles
 - Constantly learning new systems, languages and formats
 - Technology/ software supplier training
 - Train the trainers
 - Version controls

Trial designs

- Regulatory updates
- Able to view competitors designs (e.g. FDAAA)
- Adaptive trials
- Health economics/ outcomes

- Impact on roles
 - Being informed about these updates
 - Understanding the methodologies
 - Applying this to your company standards and roles

Behavioural Competencies (stats programmers)

- Flexible
- Attention to detail
- Ability to work under pressure
- Starter/ Finisher
- Organised
- Logical thinking
- Problem solving
- Ability to simplify complex ideas to communicate to non-technical users

So, what are the important skills to have and how do you get them?

- Technical
 - SAS updates
 - Company training
 - , Phuse
- Regulatory
 - Review and interpret guidelines/ regulations
 - Use specialists (contractors or CRO)
 - Phuse, TOPRA

So, what are the important skills to have and how do you get them? Part 2

- Soft skills (behaviours)
 - Inhouse training
 - Face-to-face
 - Internet webinars
 - Phuse

References

- Ref 1 BMJ 2008;336:250 (2 February), Open letter, Sara Hughes
- Ref 2 Implementing CFR 21 part 11 D.J. Garbutt
- Ref 3
<http://www.fda.gov/oc/initiatives/advance/fdaaa.html>
- <http://www.cdisc.org/>
- <http://www.21cfrpart11.com/>