



Focus

- Programmers have the chance to work on multiple Therapeutic Areas/ Indications simultaneously giving broader experience
- Defer to Pharma counterparts as TA experts
- Work with multiple clients using variety of standards
- Potentially bigger programming departments as all work is 'in-house'
- More time spent on detailed timesheeting (and focus on financial aspects)

- Likely to be assigned to one TA and indication for prolonged period becoming expert in specific endpoints and datatypes
- Greater opportunity for engagement with a variety of stakeholders internally from Statistics/ Clinical/ Regulatory Affairs/ DM/ Patient Safety giving a wider view of the industry and ability to follow the science
- More control of work-life balance
- Greater exposure to patient stories and emphasis on helping patients reminding us 'why' we do this work

- Programmers more likely to be individual contributors (more hands-on tasks)
- Programming Leads may also have greater focus on financial management of project
- Likely to only be involved from FSI to final TLF delivery



Study Role

- Could have large proportion of outsourced studies so need to learn smart ways of execution of Sponsor oversight over CRO: quality assurance checks as starting point and then risk & criticality based review of deliverables
- More accountability rather than responsibility.
- Leads have greater focus on quality of deliverable and outcome of trial
- Earlier involvement in study as part of pre-investment decisions

What's the difference?!

Deliverables

- Generally focussed on core deliverables as part of the CSR:
- Data imports, SDTM, ADaM, TLFs and submission package
- Production and validation of deliverables
- Generally following well defined and developed processes
- 100% validation as almost everything is a formal deliverable

- Often more adhoc analysis to support internal decision making, regulatory responses or/and publications
- Depending on TA, likely to be more exposure to Exploratory/Novel endpoints
- Support for project level deliverables like BIMO/DSUR/PBRER
- More complete insight into submissions to regulatory bodies and experience which goes beyond FDA/PMDA/EMA
- Risk based approach to validation

- As deliverables from CROs are focused on SDTM/ADaM/TLF there are more opportunities to specialize in those areas - especially helpful for people new to the industry
- Usually not TA-aligned so more focus on centralization of tools
- More work done in-house so more chances for developing novel tools for efficiency in generating deliverables
- More diversified development opportunities (multiple TAs/indications)



Opportunities

- Greater visibility of impact on Patients.
- One of career paths allows for becoming Programming expert for set of medicines
- Opportunity to work with multiple functions in very natural way.
- Opportunity to work with other functions and/or business units through secondments.
- Entrepreneurial use of new technologies not only to develop TFLs but also to support all processes related to drug development



Tom Ward, Biometrics, Late-stage Development, Respiratory and Immunology (R&I), BioPharmaceuticals R&D, AstraZeneca, Cambridge, UK
tom.ward1@astrazeneca.com;

Piotr Karasiewicz, Biometrics, Late-stage Development, Respiratory and Immunology (R&I), BioPharmaceuticals R&D, AstraZeneca, Warsaw, Poland
piotr.karasiewicz@astrazeneca.com

