



Working with offshore providers of MedDRA Coding
@ 2011 EU MedDRA User group meeting, Geneva

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Pharma & CRO – Setting the scene

- Mrs Farmer
 - Decision to outsource/Off-shore MedDRA coding
 - Accountability for the project remains in-house

- Mr Crow
 - In charge of Off-shore Coding function
 - Works on many projects for many different sponsors
 - Bottom line is important – speed and efficiency is key

Pharma & CRO – Setting the scene

PERCEPTIONS!

This is what I imagine my offshore CRO to be...



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This is what I imagine my Sponsor to be...



Pharma Perspective

- How are things going?

- I feel frustrated: the only way I can contact you is via email because you aren't available for team meetings.
- When we do speak you agree to do something but then the timelines are missed
- I've worked with 3 different coding leads in 6 months
- Why don't you use our project coding conventions
- The reports you produce don't contain the HLT that I need for my review
- The consistency and assignment of LLT's & PT's is poor
- You now tell me that the MedDRA version in the clinical DB doesn't match the Safety DB and you are going to charge "€£\$€£\$" to upversion?

Off-Shore/CRO Perspective

- How are things going?
 - I feel frustrated that the only way I can talk to you is via email because you always have team meetings in the afternoon – it's 10pm here in India!
 - You keep changing the timelines and then DM forget to inform me
 - I've had 3 different coding leads in 6 months. 1 Left for better money elsewhere, 1 was promoted and the other had to be moved to another one of your prioritized projects.
 - Your conventions were confusing to us. We are working on many different conventions for different sponsors. Sorry...
 - The coding tool we used was not set up to capture HLT or HLGTT so we can't report this....
 - Unless you pay us more to customize the report?
 - We review for accuracy and consistency and are confident the PT is appropriate for all terms. We rely on you to approve.
 - We were unaware that we needed to upversion MedDRA in the Clinical DB during the trial.

Problems / Work-arounds

- Cultural Differences
 - Working in different time zones
 - Schedule meetings at time-zone friendly time-slots
 - No last minute meetings outside standard hours
 - Language
 - I can't understand your accent
 - I can't understand your accent
 - We may not understand their accents, but it works both ways!
 - OK - We should put that on the back burner for now until we've done some blue sky thinking
 - What are you talking about?
 - Need to be very clear in communication and avoid colloquial expressions

Problems / Work-arounds

- Cultural Differences

- Company loyalty

- We all stay late and work weekends to meet our new database lock deadline
 - Why do the CRO not understand the timelines have changed?
 - The CRO personal are paid to do the job and don't have “ownership” of the Drug
 - Are they are expected to do extra work for “free”?
 - Clear and understood expectations, configurations, specifications in advance within scope of work

- Staff turn-over

- Off-shore offices / CROs have a higher staff turn over
 - Moved to other projects
 - Move to other companies
 - Career progression
 - Standardise and fully document the processes

Problems / Work-arounds

- Processes
 - Process and standards must be clearly documented up front
 - All studies should work to the same coding standards
 - Avoid Project specific coding guidelines or conventions
 - Timelines and priorities for coding must be agreed & Coding teams kept in the loop – not just DM contact.
 - Process for review of coding
 - Accountabilities
 - Define Process for upversioning and timelines for upversioning
 - Accountabilities
 - Define data required on the reports

Problems / Work-arounds

- Training
 - Who is responsible for training?
 - Are the coders adequately trained
 - MedDRA certification?
 - Training and mentoring of new staff
 - Dilution of experience with staff turnover
- FDA have noticed more “soft coding” of MedDRA terms from outsourced studies
- Need to review data on ongoing basis
 - Agree accountabilities – who will sign-off? (Pharma or CRO?)

Problems / Work-arounds

- Communication
 - Ongoing communication is essential
 - Communication is a two way thing
 - Don't assume the CRO are mind readers and know your idiosyncrasies
 - Use effective communication styles / tools
 - Meetings for information sharing / teams / planning
 - Telephone for urgent issues and 'discussions'
 - E-mail follow up for clarification / minutes / actions / timelines
 - Clear written communication of decisions post meetings

Summary

- Off-shoring of coding does work
- Clear processes need to be defined
- No project specific coding requirements
- Requirements for upversioning agreed
- Cultural understanding
- Agreed and clear forms of communication
- Avoid remote contract management – full details to be agreed by both parties before the start of the project
 - Avoids misunderstandings of accountabilities
 - Avoids scope creep
 - Avoids unbudgeted charges

Pharma & CRO Relationship

So what PERCEPTIONS
should we have?

This is how we should work together:



**This is what I imagine my
off shore CRO to be...**



**This is what I imagine my
Sponsor to be...**



Thank you!

