

Guilty as Charged!

ALIAS: “Micro Manager Mickey”

CRIME:

- Spends too much time communicating the status of the project (e.g. via tracking sheets) rather than getting on with the work
- May assume that the Study Team assigned are not up to the task
- Requests intermediate deliveries (often unQC'd) to check on progress and then reviews and provides comments on incomplete work (“self-fulfilling prophecy”) – see point above)



PUNISHMENT:

- Crucial time wasted that could be spent on study work; more likely to miss deadlines if status tracking is too intense.
- Demotivated Study Team (feel like progress and quality are constantly scrutinised)
- Study Team waste time reviewing Customer comments on incomplete work when mistakes highlighted have already been rectified by following internal QC process.

SPOILS:

- Easily contactable
- Willing to discuss questions regularly
- In-depth study knowledge

PAROLE CONDITIONS:

- At the study start up meeting the whole Study Team should discuss and agree the level and frequency of information they require; try communicating study progress via a monthly status report/email. At the study start up meeting, explain to your counterpart the rationale for requesting for this information.
- Hold an open discussion regarding when and why intermediate deliveries are required and how much QC your counterpart will be carrying out at this time. Agree to only provide/ receive consolidated comments upon receipt of final version of deliverable.

ALIAS: “Ad hoc Annie”

CRIME:

- Requests instant resource with very little or no notice
- Has an unrealistic expectation of delivery timelines
- Does not give clear scope of a task
- Makes small requests which quickly spiral into larger tasks



PUNISHMENT:

- Study Team unable to produce work within short timelines
- Required resource not immediately available
- First draft deliverable is not as expected; misinterpretation due to lack of documentation

SPOILS:

- Study statisticians motivated by interesting pieces of work e.g. submissions or sensitivity/ journal analyses

PAROLE CONDITIONS:

- Consider using a Dedicated Study Team working on a Fee for Service basis. Benefits of this include:
 - Higher level of understanding of the project needs
 - Same customer and CRO team lead pairing
 - Customer only pays for the time spent on a task
 - CRO gets paid for the time billed to the study.
- When timelines are tight be as flexible as possible
- Ensure that sufficient detail is available for the Study Team to complete the task; organise a teleconference to discuss the technicalities - this often works better than multiple emails.

ALIAS: “Panicking Pete”

CRIME:

- Is prone to overreacting as soon as something is not quite as expected
- Does not think through a situation or check that a mistake has been made before claiming that something is incorrect
- Considers everything urgent (“this MUST be done this week”) even when there is no impact on the overall study
- Sometimes appears rude and/or unreasonable



PUNISHMENT:

- Embarrassment of realising error in initial judgement
- “Cry Wolf” situation occurs where actual emergencies are not perceived as genuine
- Relationship between Study Team and Customer may break down - counterparts become reluctant to communicate with each other

SPOILS:

- Nothing!

PAROLE CONDITIONS:

- If you think there is an issue, just pick up the phone and talk to each other!
- Always think before “flying off the handle”; if mistakes are made, these are genuine and everything will be done to rectify the situation.
- Always be polite: insulting your colleagues isn't going to help the relationship!
- Study Team Leaders should ensure there is always someone available to discuss any questions with the Customer.
- If possible, the Customer should make Study Team aware of internal pressures relating to the work being carried out (i.e. priority of study and the flexibility around timelines – are these “set in stone”?).
- Study Team should do all they can to understand the pressures the Customer is under.

ALIAS: “Mind Changing Mo”

CRIME:

- Makes numerous last minute requests but is unwilling to re-negotiate timelines
- Cannot understand how “small” changes can impact on ability to meet deadlines
- Provides unconsolidated conflicting comments from different departments following review of a deliverable



PUNISHMENT:

- Cost implications (changes scope of work must be paid for)
- Changes to agreed methods of analysis once work is underway will increase overall time spent and may affect quality
- Lack of internal communication slows finalisation of Statistical Analysis Plan (SAP) etc. as consolidated views need to be reached

SPOILS:

- Nothing!

PAROLE CONDITIONS:

- Where changes are necessary, provide with as much notice as possible and be realistic about delivery expectations (consider agreeing to deliveries in batches)
- Aim to sign off SAP as early as possible (for Phase III Studies we recommend 6 months prior to DBL) and make sure all requirements are reviewed thoroughly
- Encourage clinical colleagues to review the shells with the SAP; this will minimize the need for updates to outputs at a later stage
- At the start-up meeting the Study Team should discuss the processes they are using (this will highlight why “small” changes may take longer than expected)
- Provide consolidated comments in one document (or organise a TC with all key reviewers to make any final decisions).

ALIAS: “Hands-Off Harry”

CRIME:

- Does not respond to communications
- Will not provide clear timelines for the stages of delivery
- Does not feed back on deliverables in a timely manner



PUNISHMENT:

- Final milestone takes longer for Study Team to reach: they are often held back waiting for decisions to be made
- Study Team have to make numerous assumptions to allow work to continue
- When comments are finally received, the original Study Team may not be available to make any updates (as they will have moved onto new projects)

SPOILS:

- Study Team can progress with the work without interruptions/changes to plans
- CRO given full responsibility for statistical input and decision making (this can be very motivating for the Study Statistician)

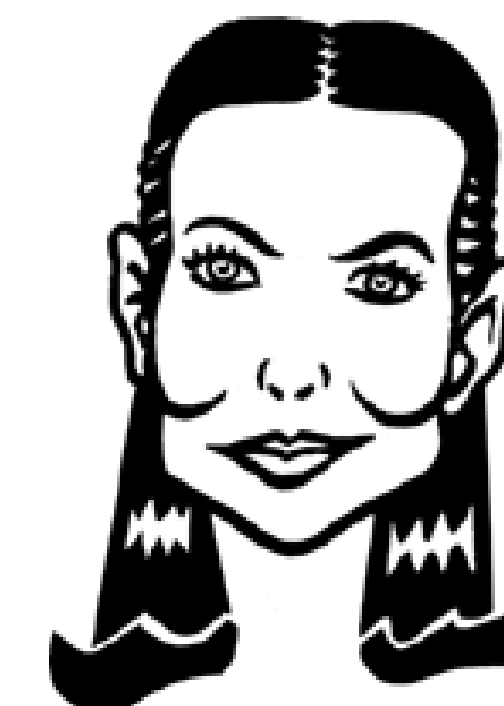
PAROLE CONDITIONS:

- Make sure that responsibilities, including the levels of involvement required from all key team members, are stated up front.
- Agree timelines for all deliverables and stick to them. If the timelines have to change, make sure you agree some more!
- Agree a communication method that suits your way of working to ensure progress. Set-up regular calls or send the Quintiles QandA_Tracker to address any questions/issues.

ALIAS: “The Perfectionist”

CRIME:

- Expects that all deliverables will be “perfect”!
- Does not understand or is unwilling to pay for QC procedures but expects no errors
- Has an unrealistic expectation of working with “real” data (e.g. assumes there will be no unresolved partial dates or incorrectly completed diary entries remaining at database lock)



PUNISHMENT:

- Disappointed with quality of deliverable as expectations are unrealistic
- Study Team are unable to meet unrealistic expectations which can lead to low morale
- Need to spend time creating rules for dealing with data issues at critical stage of delivery

SPOILS:

- Knowledgeable about their Studies (makes key decisions)
- High level of communication
- Good at meeting deadlines

PAROLE CONDITIONS:

- Discuss and agree QC procedures for all deliverables - ensure that expectations from Customer and Study Team are clearly stated prior to starting work (including specific details relating to DSMBs, Interims etc). Write and agree a QC and Senior Biostatistical Review Plan for the work.
- Agree up front with DM colleagues which data and key variables are critical for the study and the error rate acceptable for each of these (e.g. % of AEs expect to see coded at 6 month DSMB).