



Medicines & Healthcare products
Regulatory Agency



Discussion of RQA Inspection Feedback

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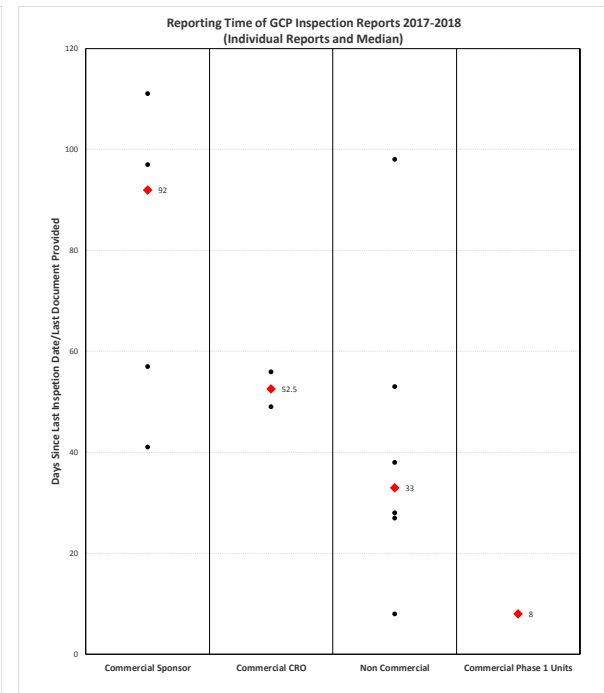
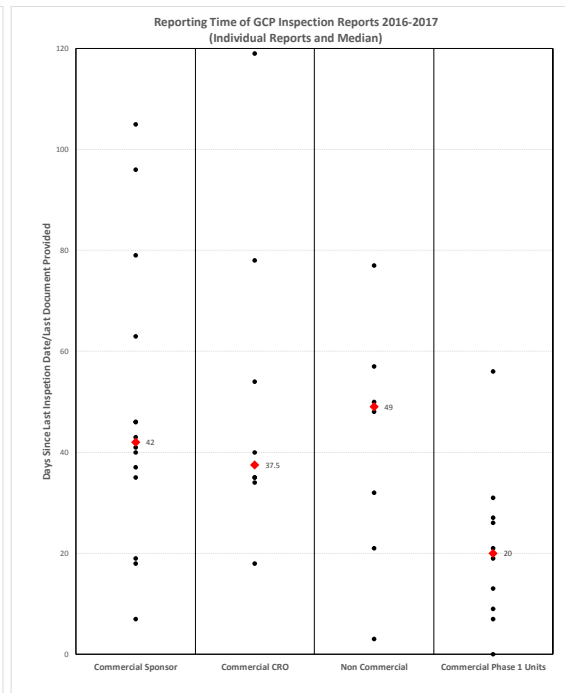
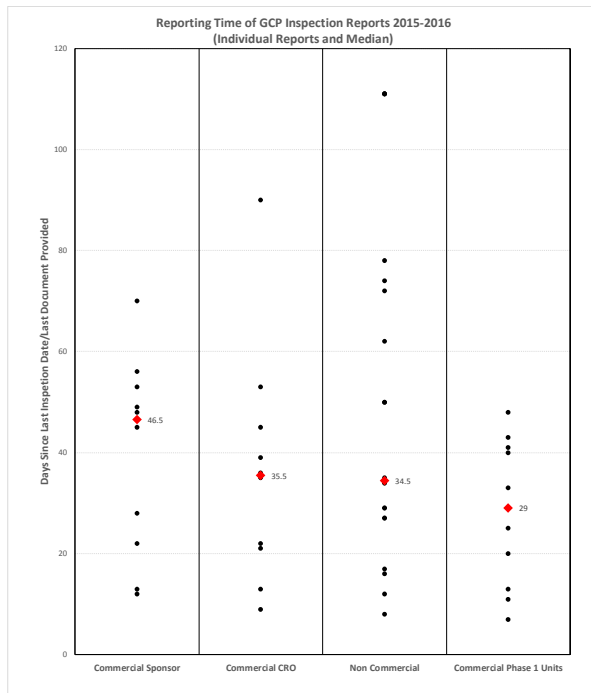
Dossier submission to Inspection

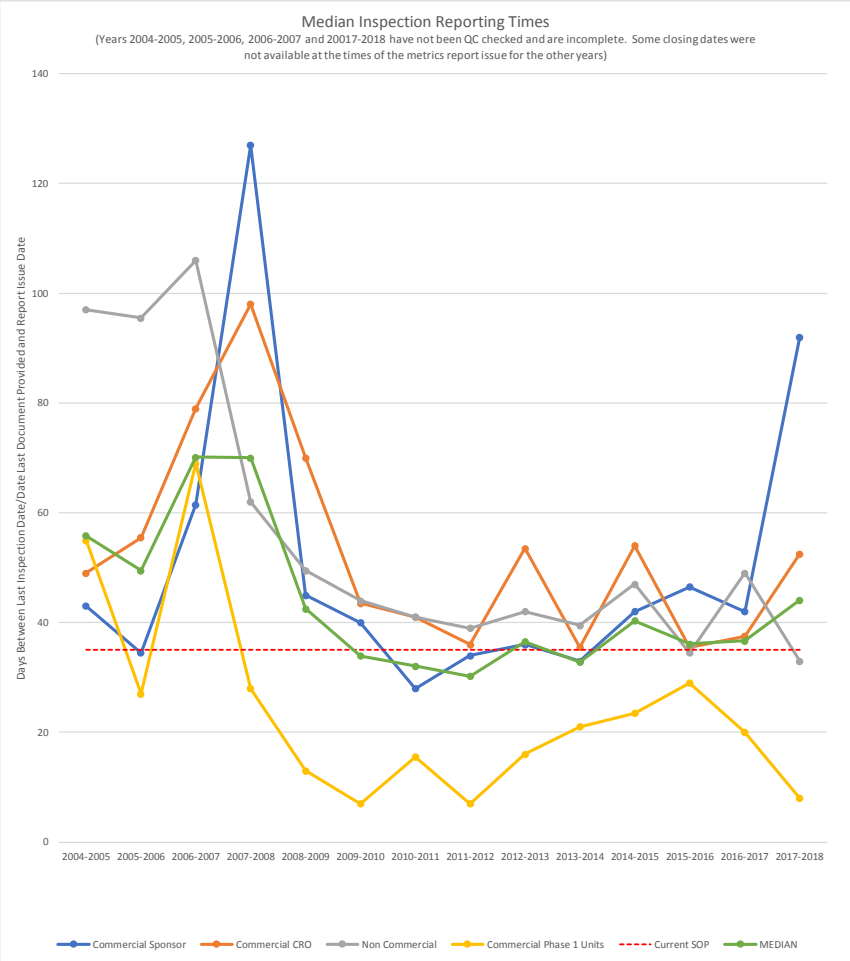
There are no processes that define that the inspection must take place within a certain timescale post receipt of dossier. Scheduling of inspections is based on risk, unplanned triggers etc.

We will look at ensuring that feedback to the organisation regarding the status of their inspection scheduling after a certain time has passed would be appropriate.

GCP Inspection Reports (2015-2018)

2017-2018 is incomplete/not QC checked

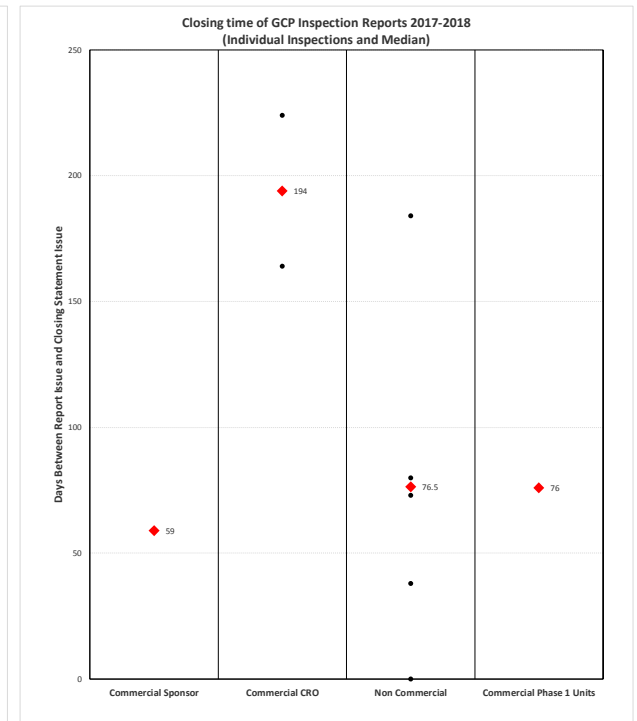
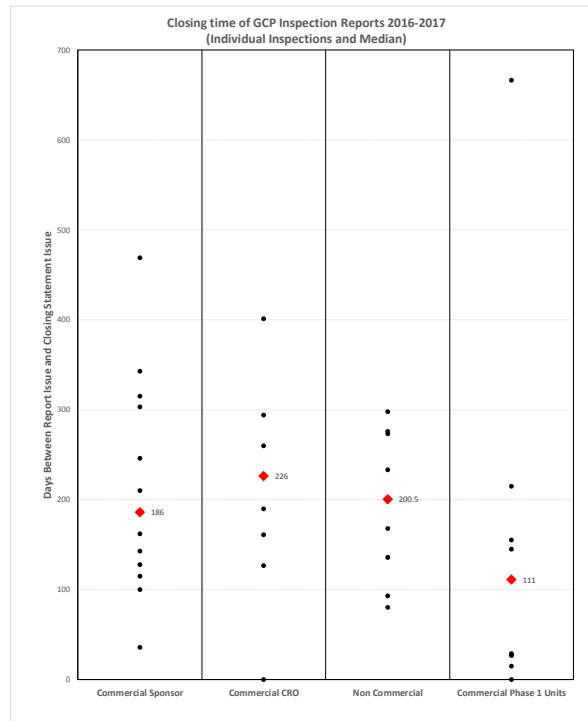
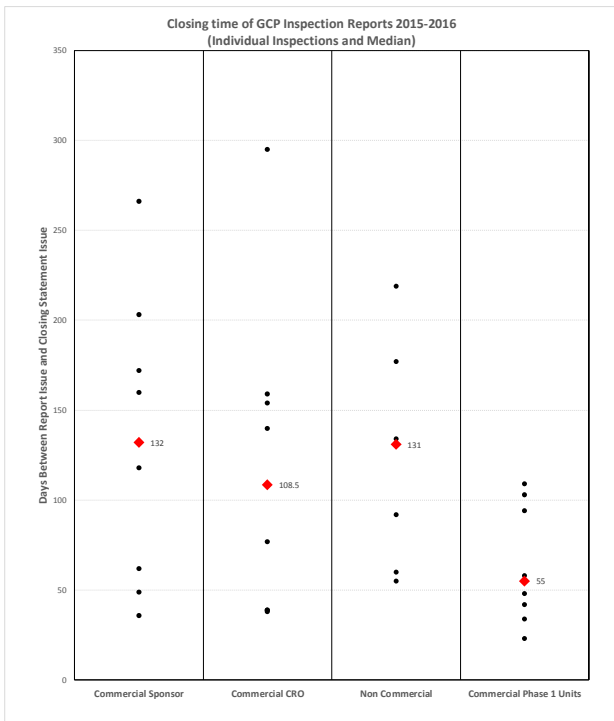


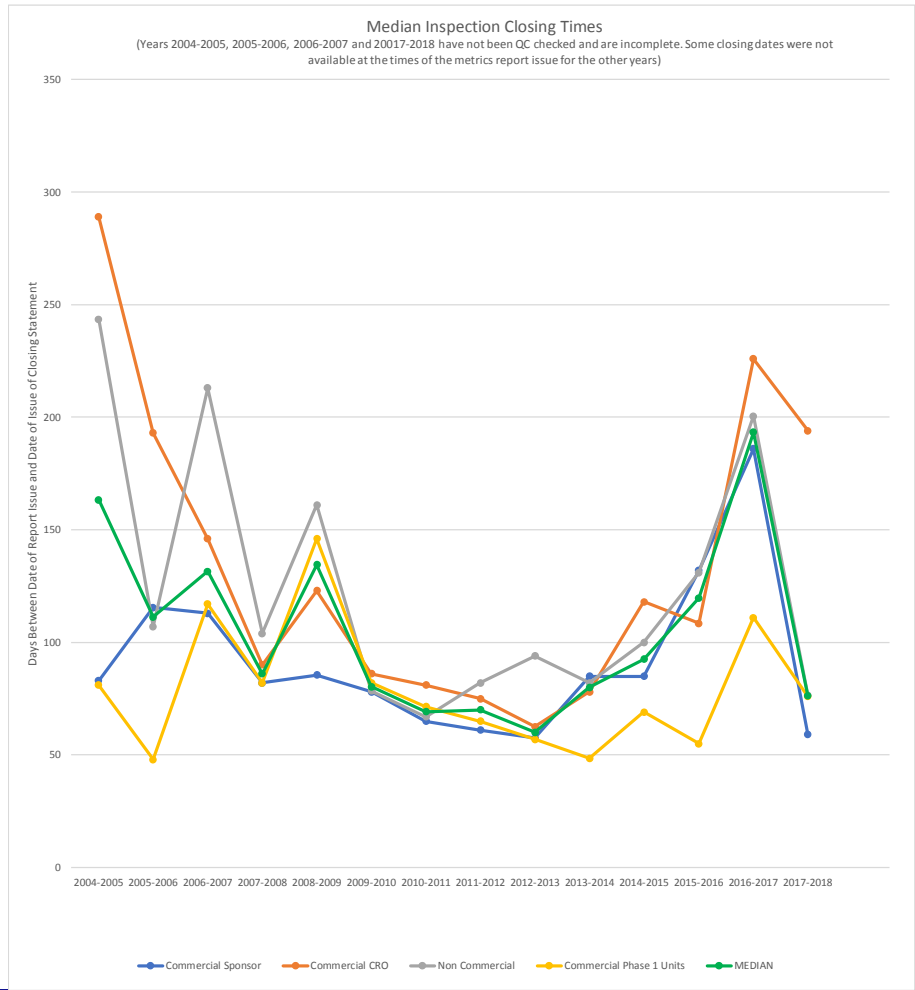


- Timescale for report is after last site inspection
- Full data for 2015-2017. 2017-2018 is on limited reports issued/data entered
- Increase in 2017/2018 – may be lowered once all data collected
- Median time is slightly beyond current target (35 calendar days) and slight trend to longer timescales
- Some late reports, but organisation is informed as is GCP Management

GCP Inspection Closure Times (2015-2018)

2017-2018 is incomplete/not QC checked

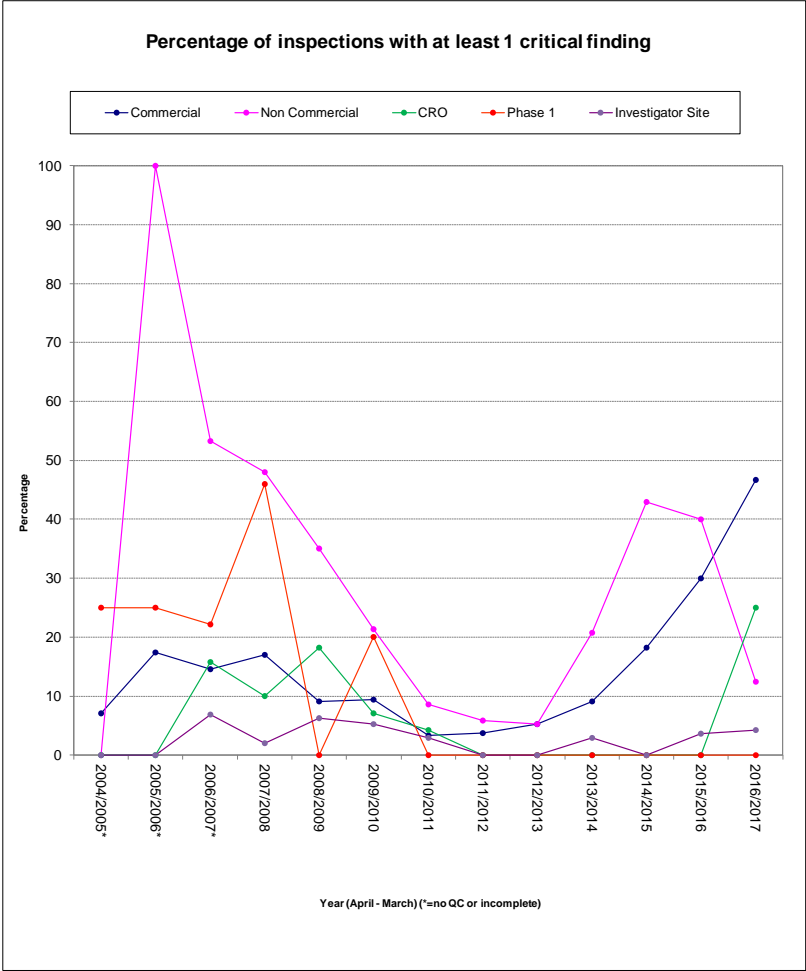


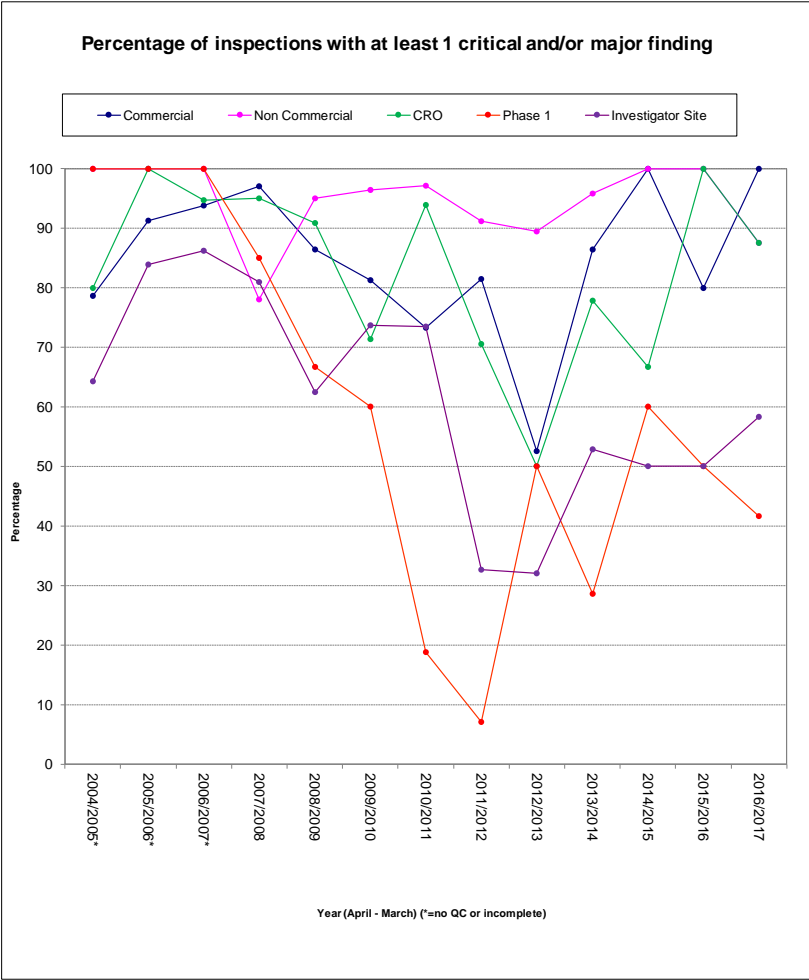


- Full data for 2015-2017. 2017-2018 is on limited reports issued/data entered
- Timescale is from final report to closing statement, response review times are not currently captured in our trackers
- Shows an increasing trend in time to close inspections – potential reasons:
 - Patience waiting for additional responses
 - Impact Assessments/Investigations
 - Multiple Responses received
 - Quarterly Reporting
 - Delay in issue of closing statement
- We will start to track MHRA GCP Inspectors response review times.

Does the time taken reflect that lengths/complexity of reports and subsequent responses review etc. increases with non-compliance?

- Metrics report 2016-2018 issued 11th May 2018.





Reasons for increasing non-compliance?

DISCUSSION?

Internal Audit Reports

MHRA GCP Inspectors continue only to request these where considered necessary to investigate serious non-compliance. Evidence of auditing is requested, but this does not need audit reports.

Remote Access to eCRF, eTMF

- Organisations will regularly offer remote access for eCRF.
- Set up of access to systems prior to inspection is required.
- Remote access and inspection of eTMF is NOT undertaken.
- Remote access to eCRF may be undertaken by inspectors as part of inspection planning.
- Access to eSystems is required during inspections.
- Sometimes access is sometimes requested to be left open to systems that can be remotely accessed post inspection as they may be useful to re visit as part of report writing (e.g. SOPs)
- No plans to do remote inspections.

Inspection Focus

eTMF

- Unless a previous critical in this area so there is CAPA to assess, the eTMF system itself and surrounding processes are not a focus of the inspection, it only becomes so once it has been seen to impede review
- Check audit trail to see if TMF up to date (compliance check)
- Organisation should be able to demonstrate compliance (that relates to subject safety and data integrity) – eTMF systems vary in how easy this is to assess and this is substantial when compared to paper. If an organisation wishes to maintain a poor system that does not facilitate review, inspection time on site will ultimately require to increase and critical findings issued.
- Numerous examples of engagement with stakeholders on eTMF, including entire day workshop in 2017.

Completed Trial for discontinued Development Programme

- Selection of trials to demonstrate processes too (e.g. Reporting, particular eSystem etc.) it is not just the nature of the trial.
- Any trial can be selected for compliance evaluation.

MHRA duplicated a finding (regarding RSI) from a PV inspection