



GCP INSPECTORATE

GCP INSPECTIONS METRICS REPORT

METRICS PERIOD: 1st April 2016 to 31st March 2017

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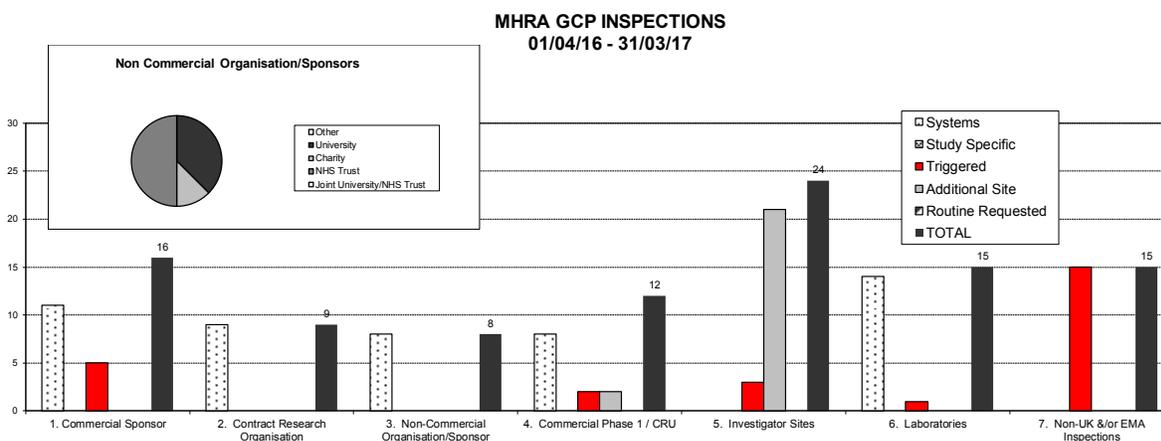
1. INTRODUCTION

This report covers the metrics period 1st April 2016 to 31st March 2017.

2. GCP INSPECTIONS UNDERTAKEN

During the Metrics Period a total of 99 GCP Inspections were undertaken by the MHRA GCP Inspectorate. The types of inspections are presented below.

The number of inspections of non-commercial organisations was 8, of commercial sponsors was 16, of Contract Research Organisations (CROs) was 9, of investigator sites there were 24 and finally there were 12 phase 1 unit inspections. GCP inspections of UK laboratory facilities conducting clinical trial sample analysis are generally conducted by the MHRA Laboratories Inspectorate and there were 15 inspections. The number of non-UK bio-equivalence (BE) and European Medicines Agency (EMA) inspections was 15, all were triggered inspections. There was one inspection where the organisation opted to host the inspection outside of the UK, but this was part of the UK risk based domestic inspection programme and has not been classed as a non-UK inspection for this report. Triggered inspections were carried out because of information received by the GCP Inspectorate, for example in response to a serious breach report, or in relation to a centralised Marketing Authorisation Application. Triggered inspections were undertaken of different types organisations. Of the 26 UK triggered inspections, 5 were for commercial sponsors, 1 was for a GCP laboratory, 2 were for phase 1 units, 3 were for an investigator site and 15 were non-UK BE/EMA inspections, with 7 triggered by the EMA Committee for Medicinal Products for Human Use (CHMP) with 8 foreign bioequivalence inspections triggered by MHRA.



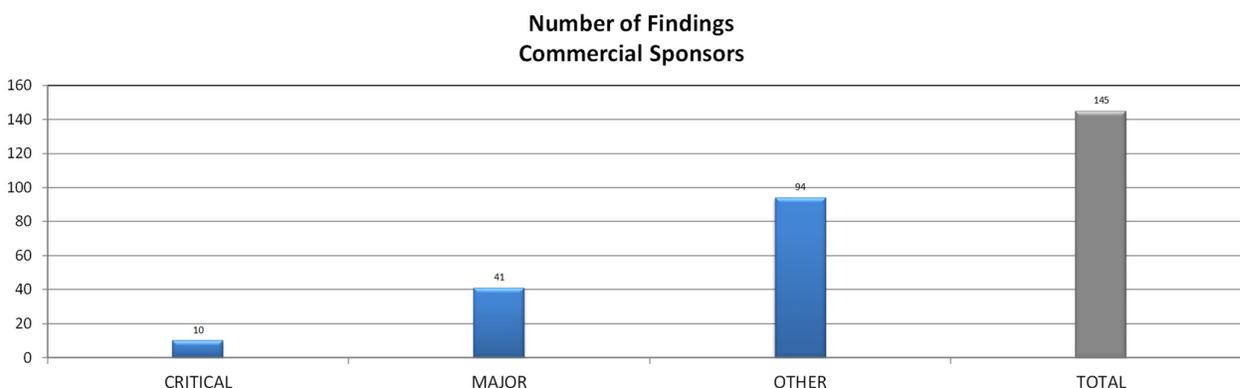
3. INSPECTION REPORTS AND FINDINGS

Reports relating only to the inspections carried out and completed in the Metrics Period were reviewed. It is important to note that multiple inspections can be reported in one GCP Inspection Report, for example, a commercial sponsor GCP Inspection Report may consist of the sponsor inspection and associated investigator site inspections. There are also occasions where there are two separate visits to the same organisation to complete the inspection. Where an inspection was conducted before 1st April 2017 and the other inspections (e.g. associated investigator site or further visit) were conducted after 1st April 2017 (e.g. sponsor site then the investigator site(s)) the findings from the inspections conducted/completed after 1st April 2017 will not be included in this metrics report, as these were inspections conducted/completed during the 2017-2018 Metrics Period. There were 2 inspections where an additional visit was necessary (a commercial sponsor and a CRO), but both inspections took place in this reporting period. There was one inspection of a commercial sponsor where it was the additional visit, the previous inspection was undertaken in the 2015-2016 reporting period, as such the

inspection report was issued in the current reporting period. Metrics from inspections requested by the EMA are produced by the EMA. Findings from inspections of GCP laboratories and UK triggered BE inspections are reported by the GCP/GLP Inspectorate. The findings are those that were contained in the inspection reports and do not consider any inspection responses, apart from in the explanatory text for critical findings. The metrics data entry had an independent sample Quality Control (QC) check.

3.1 Commercial Sponsors (Routine Systems, Study Specific and Triggered)

A total of 16 commercial sponsors were inspected and all have been reported. For 1 of these inspections, it was a repeat visit to the same organisation to complete the inspection, and there was only one report generated, so the total reported is 15. Of these inspections, 10 were systems inspections and 5 were triggered. Of the 15 inspections, 7 (46.7%) had at least one critical finding and all (100 %) had at least one major and/or critical finding. The total number of findings and findings per inspection are represented on the figures below.



Number of Findings Per Inspection (Commercial Sponsors)

	Mean	Median	Mode	Maximum	n
Critical	0.7	0.0	0.0	2	15
Major	2.7	3.0	3.0	5	15
Other	6.3	7.0	9.0	10	15

There were 10 critical findings from 7 organisations.

Critical Finding 1

A critical finding was given to a commercial sponsor for Pharmacovigilance. There were three areas to this finding.

The first concerned the use of an unapproved updated Reference Safety Information (RSI) as there was a failure to comply with regulations because an updated RSI for adverse drug reaction (ADR) expectedness assessment was used without it being approved by MHRA. The internal process was that the RSI, internally comprising a “synonym/preferred terms/ list” (SPTL) and investigator brochure; would be implemented as soon as it was finalised within the company and prior to receiving a substantial amendment approval from the MHRA.

The second was the use of an unapproved RSI (not using the RSI that was submitted and approved by MHRA, but use of a separate, more extensive SPTL). The conduct of the trial pharmacovigilance activities was not undertaken in accordance with the clinical trial authorisation. This was because the RSI (IB section) approved by the MHRA was not being used for ADR case assessment. Instead the non-submitted and therefore unapproved SPTL was being used and this expanded greatly and inappropriately the expected terms compared to the approved RSI. The IB had the high level MedDRA dictionary terms and just a few lower level terms, whereas the SPTL had all the lower terms resulting in an extensive list of expected events. This was systemic across investigational medicinal products and inconsistencies were seen between the RSI and the SPTL (predominantly many additional preferred terms in the SPTL).

The third was the use of the SPTL for expectedness assessment at the start of the reporting period for Development Safety Update Reports (DSURs), resulting in potentially erroneous (incorrect/misleading data) reports submitted to the MHRA. The SPTL is programmed to generate a listing of SARs with any unexpected events identified which meant the preparation of the DSUR was undertaken by assigning expectedness based on an unapproved RSI (i.e. SPTL) in place at start of reporting period. Because of using the SPTL, events that should be SUSARs may be not be identified as such, which would have been the case if they had been assessed against the approved RSI.

During the inspection, examples of inappropriate assessment of expectedness were seen due to using an unapproved RSI and unreported SUSARs. There were also issues with the quality and version control of the SPTL and the IB. Because of these findings, the sponsor was required to conduct an extensive and detailed review to identify unreported SUSARs and erroneous DSURs, providing the reports to MHRA.

Critical Findings 2 and 3

There were 2 critical findings for a commercial sponsor for Pharmacovigilance (Reference Safety Information) and Record Keeping/Essential Documents (Trial Master File [TMF]).

Pharmacovigilance

The MHRA approved Reference Safety Information (RSI) in effect at the time of occurrence of a Serious Adverse Event (SAE) was not being used for expectedness assessments as required by CT-3 guidance. As a result, there was confirmed under-reporting of SUSARs to the competent authority and inaccurate information being submitted in DSURs. This was illustrated by the document being used during case processing to assess expectedness assessments of SAEs containing further guidance and detail than the Reference Safety Information (RSI) submitted and approved by the MHRA. Several systemic issues were identified with the process for the development and use of the RSI resulting in the under-reporting of 110 SUSARs for all active UK trials up to 23 February 2016.

Record Keeping/Essential Documents

The TMF was presented as a paper TMF for inspection. However, the TMF did not contain all the essential documents required to enable the reconstruction of trial events and demonstrate compliance with the regulations and the organisation's own quality system. Several essential documents were retained within different electronic systems which were not defined to be part of the TMF and to which inspectors were not provided direct access (even with a guide user). The TMF had not been fully defined to include all the ancillary systems and the documents located within them. Where the TMF

maintenance had been contracted out to a third-party contractor, there was limited information available in the organisation's own files to demonstrate effective oversight of clinical trial activities to fulfil its obligations as a sponsor.

Critical Finding 4

A critical finding was given to a commercial sponsor for Clinical Trial Authorisation as the pharmacovigilance processes used by the sponsor were flawed as there was a failure to comply with the terms of the Clinical Trial Authorisation (CTA). It was evident that the Reference Safety Information (RSI) submitted and approved by the MHRA was not being used to perform expectedness assessments for Serious Adverse Drug Reactions (SAR) in the 2 clinical trials that had their TMF reviewed. In general, whilst a Summary of Product Characteristics (SPC) or Investigator Brochure (IB) (or both) had been submitted to the MHRA and Research Ethics Committee (REC) it was not made explicit by the sponsor which of these would be used for expectedness assessments, i.e., which contained the RSI. This was irrelevant in any case, because the pharmacovigilance processes would not necessarily involve referral to these documents. Instead, internal documents would be used that had not been submitted and approved; these being the Company Core Safety Information (CCSI), the Company Core Data Sheet (CCDS) and the Expected Preferred Terms List (EPTL). These documents had more expected SARs than the submitted and approved documents as the sponsor had a policy of using "medical concepts", whereby any MedDRA preferred term (PT) under the higher-level term that may be in the SPC/IB would be considered expected, even though there was no direct match to the RSI.

Furthermore, updated documents containing new expected adverse reactions were used for expectedness assessments which were not submitted and approved as substantial amendments by the MHRA and REC prior to implementation. Finally, there was a lack of control of the submission of the RSI to the REC and the MHRA as evidence was seen that there was no consistency between the RSIs that were submitted to them.

As a result, there were examples of unapproved RSIs being used to perform expectedness assessments and therefore there was a risk of inaccurate reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs) in the sponsor's clinical trials.

Because of these findings, the sponsor was required to conduct an extensive and detailed review to identify unreported SUSARs and erroneous DSURs, providing the reports to MHRA.

Critical Finding 5

A critical finding was given to a commercial sponsor for Data Management due to processes relating in particular to data generated through electronic patient reported outcome (ePRO) devices. The following issues were identified:

- There was incorrect data in the eDiary that could not be changed, but was used for the analysis. Data Change Forms (DCFs) had been submitted by Investigators to change entries for data entered by both site staff and subjects that which had been identified as incorrect. These requests were denied as it was explained that changes to the data could not be made and the investigator would need to document the response in the source.
- The eDiary devices used by subjects did not have an audit trail to verify when entries were being made and by whom. Whilst the data provided to the investigators contained a form "save time" this was not reflective of when data was actually entered and there was no way to verify who entered the data as user name and login were not captured in the audit trail.
- There was lack of information provided in DCFs regarding what the query was. It was explained that data could only be changed via a DCF. However, examples were seen where the DCF lacked detail

and information and referenced a helpdesk ticket number. These were not available in the eTMF nor were they provided to investigators to reconstruct changes to source data.

- It was explained that data from different devices could be merged (e.g. for replacement devices) and an auto-merge code generated. However, as there was no list of device IDs demonstrating who had been assigned the device (in the TMF), it was not possible to reconstruct which devices had been merged.
- The portal used to manage DCFs did not have an audit trail, so if changes were made to a request after it was submitted by the investigator these could not be identified.
- There was no overall list or tracking of users to the system and their access rights when they were granted and revoked to verify who was managing and making data changes in the portal.
- There was a loss of PI control of data between database lock and pdfs being sent to the site. The pdfs returned were also only the final version of the data and did not contain all meta data.

Critical Finding 6 and 7

There were 2 critical findings for a commercial sponsor for Data Integrity and Monitoring.

Data Integrity

The questionnaires that were to be completed for the trial for eligibility and primary endpoint data contained language and medical terms that were not easily understood by patients. The questionnaires should have been completed by a health care professional. There was no clear instruction or training provided to sites on how these should be completed. It could not be confirmed that a Health Care professional/delegated investigator staff member had completed or overseen the questionnaire completion. Therefore, the accuracy and quality of the data could not be confirmed.

It was found during the site inspection that the Electronic Health Records (EHRs) and the paper source data used on the trial had several significant deficiencies, for example; it was not possible to verify who completed them, when they were completed, who had been making changes and why. Entries into the EHRs could be deleted and amended. The EHR audit trails had not been reviewed by the monitor or sponsor prior to the trial start and there was only evidence that the monitor had logged onto the EHR on one date. The audit trail provided for the EHR was limited and deficient as it did not show what type of changes were being made, i.e. if the entries were new, deletions or amendments. Due to these deficiencies integrity of the data could not be confirmed.

Monitoring

The Sponsor failed to ensure sufficient and robust monitoring of the two trials reviewed leading to data integrity issues on both trials selected for review. Extensive issues and GCP non-compliances were observed on both trials and at both sites due to deficiencies in the Sponsor's oversight and monitoring processes.

Critical Finding 8 and 9

A critical finding was given to a commercial sponsor for Record Keeping/Essential Documents as the Trial Master File (TMF) had a number of issues with finding and accessing documents in the eTMF, as evidenced below:

- The inspector requested documents that could not be located in the eTMF. Despite the assistance of the study team and the eTMF experts, not all these documents could be found over the 4-day inspection, and those that were provided took two days to locate.
- Documents were not filed consistently or correctly with documents at the inappropriate level of the TMF (e.g. Product Level vs Study Level.)
- There were many documents missing from the eTMF, for example, signature sheets, correspondence, emails and previous versions of documents.

- The eTMF was incomplete and unreliable with emails incomplete, duplicate documents, blank/incomplete documents, the same name for many different documents, same document under different names and in different locations and missing documents.
- The eTMF management SOP required that there be monthly QC of all eTMFs at a study level, but this was not occurring.
- The audit trails for all 5 eTMFs reviewed during the inspection showed there was a large number of documents uploaded following the inspection notice prior to the inspection showing the eTMFs were not being updated regularly and therefore were not being kept in an inspection ready state.

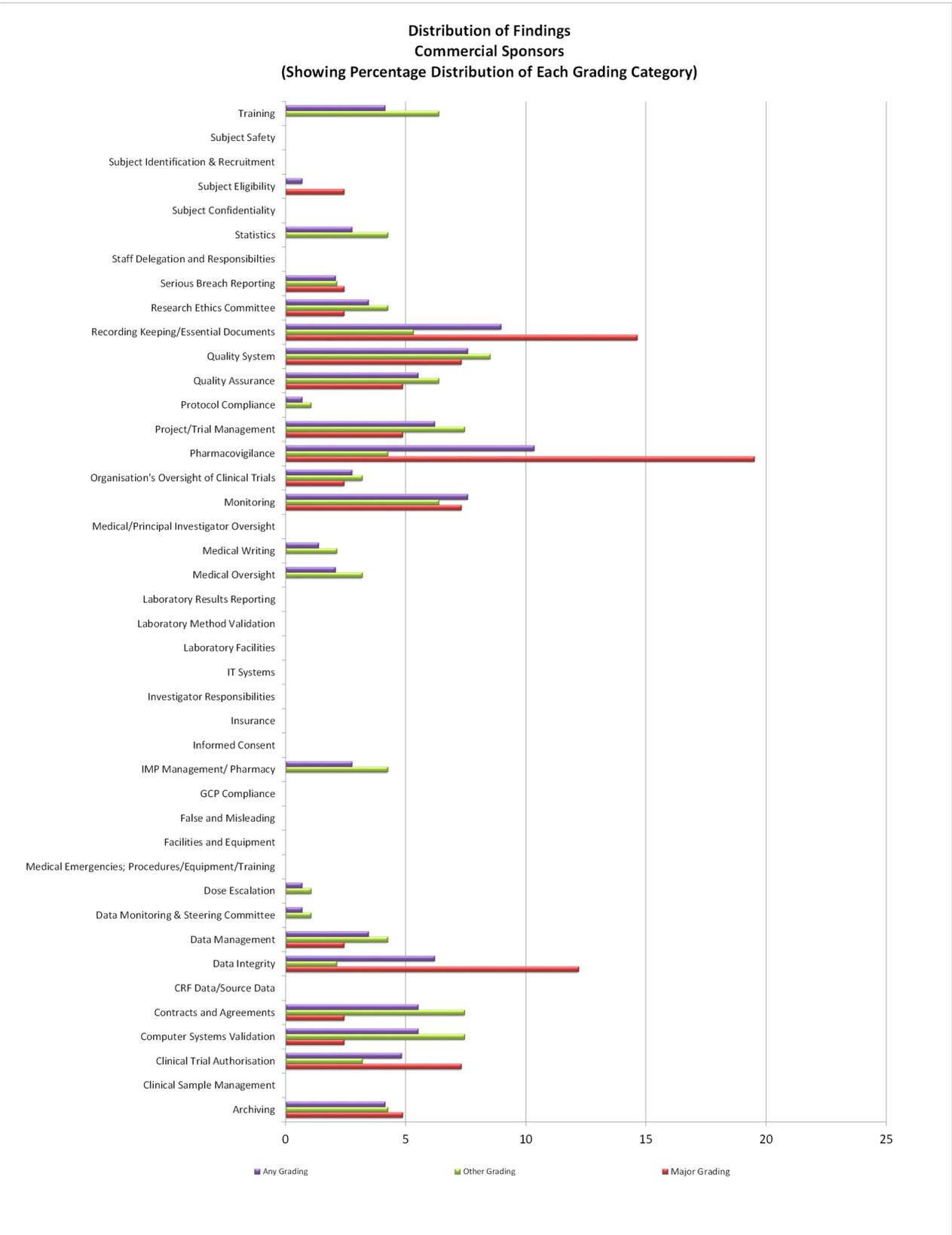
A second critical finding was given for Pharmacovigilance as there was significant potential for Suspected Unexpected Serious Adverse Reactions (SUSARs) to go unreported through several failing processes that included:

- Expected terms from IBs were pre-loaded into a database to be used as RSI before MHRA approval. This was identified in a previous MHRA Pharmacovigilance (PV) inspection in 2016, but the CAPA and assessment focuses had been on trials of marketed products and not those in development.
- Synonym lists used as the RSI were not the listed in IBs.
- There was scope for medical reviewers to use clinical interpretation instead of just the RSI when identifying SUSARs.
- There was over reporting due to programmed reporting rules for clinical trials being matched to that for post marketing PV requirements.
- Incorrect down grading of follow-up reports after new RSI is approved as the sponsor was not using the RSI in place at the time of the event.
- Over reporting of cases due to a manual functionality bug error in the system that auto submits reports that have been correctly down-graded.
- IBs were available to investigators in a portal prior to regulatory approval, but there was no check of the audit trail to see if they were being downloaded. If the IB was not approved there was no formal procedure to remove it from the portal.
- There was no notification sent by the eCRF system when SAEs were entered relying instead on the pharmacovigilance software to identify and capture the SAEs from the clinical database. This was also not checked by monitors, because there was no check by the monitor to ensure that SAEs have been reported via the eCRF in a timely manner and therefore no way of knowing if the automated reporting was functioning correctly.

Critical Finding 10

A critical finding for Monitoring was given to the sponsor of the trials conducted by an investigator site that was subject to a triggered GCP inspection. The monitoring undertaken by the sponsor failed to identify the recruitment of patients who were ineligible for participation within the range of trials reviewed during the triggered inspection. The reasons for ineligibility included previous medical history, prohibited medication and required prior treatment.

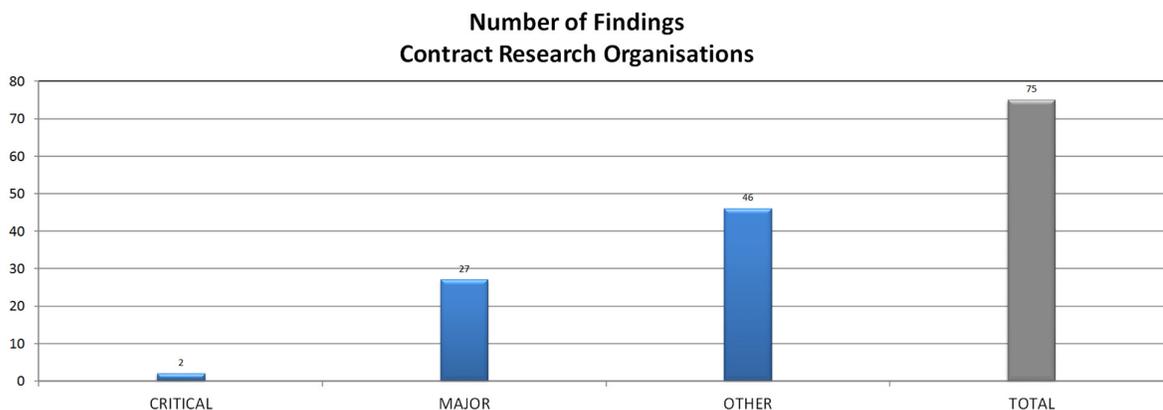
The figure on the following page shows the distribution of Major, Other and any grade of inspection findings. This identifies the areas where GCP inspectors have been making observations of non-compliance with GCP.



3.2 Contract Research Organisations (CRO) (Routine Systems and Triggered)

A total of 9 Contract Research Organisations were inspected, one of these was a return visit so 8 inspections have been reported. All 8 were systems inspections. It should be noted that vendors of electronic systems and niche providers of services used in clinical trials (aside from clinical conduct of a trial) are and have always been included in this category.

Of the 8 inspections, 2 (25.0 %) had critical findings and 7 (87.5%) had at least one major finding. The total number of findings and the findings per inspection are represented on the figures below.



Number of Findings Per Inspection (Contract Research Organisations)

	Mean	Median	Mode	Maximum	n
Critical	0.3	0.0	0.0	1	8
Major	3.4	4.0	5.0	6	8
Other	5.8	6.0	6.0	8	8

There were 2 critical findings from 2 organisations.

Critical Finding 1

A critical finding was given to a niche service provider for Computer System Validation (CSV) due to lack of validation documentation of a key eCRF software release. There was insufficient documentation to be able to reconstruct the design, build, testing and release of the version and so it was therefore not possible to confirm that the software release was in a validated state currently and prior to its release. At the time of the inspection the following key documentation was not available:

- Final version of the User Specification
- Final version of the Design Specification
- The Traceability Matrix
- Complete set of populated tests scripts and re-tests scripts to show all functionality had been tested and passed

Specific functionality requirements that were categorised as business critical were selected from the design specification document that was available, but it was not possible to determine if these had been included in the build and if so, if they had been tested prior to its release.

A version of the User and Design Specifications were available, but these were not the version quoted in the validation report. It was not possible to identify which functionality was and was not included in the final build. Two change of scope documents were presented relating to the build, but neither of them specified what the specific changes were in relation to functionality, just that it had changed.

The functional design specification that was available contained a column “Existing Functionality Y/N”, it was not defined in any SOP or work instruction what this column meant and how it should be populated.

The process to determine which functionality would be added in updated releases was done through steering group and SPRINT meetings. This process which was used to create the User Specification was not formally captured in the validation documentation and there was no formalised record keeping of the decision to select or exclude functionality from builds.

Critical Finding 2

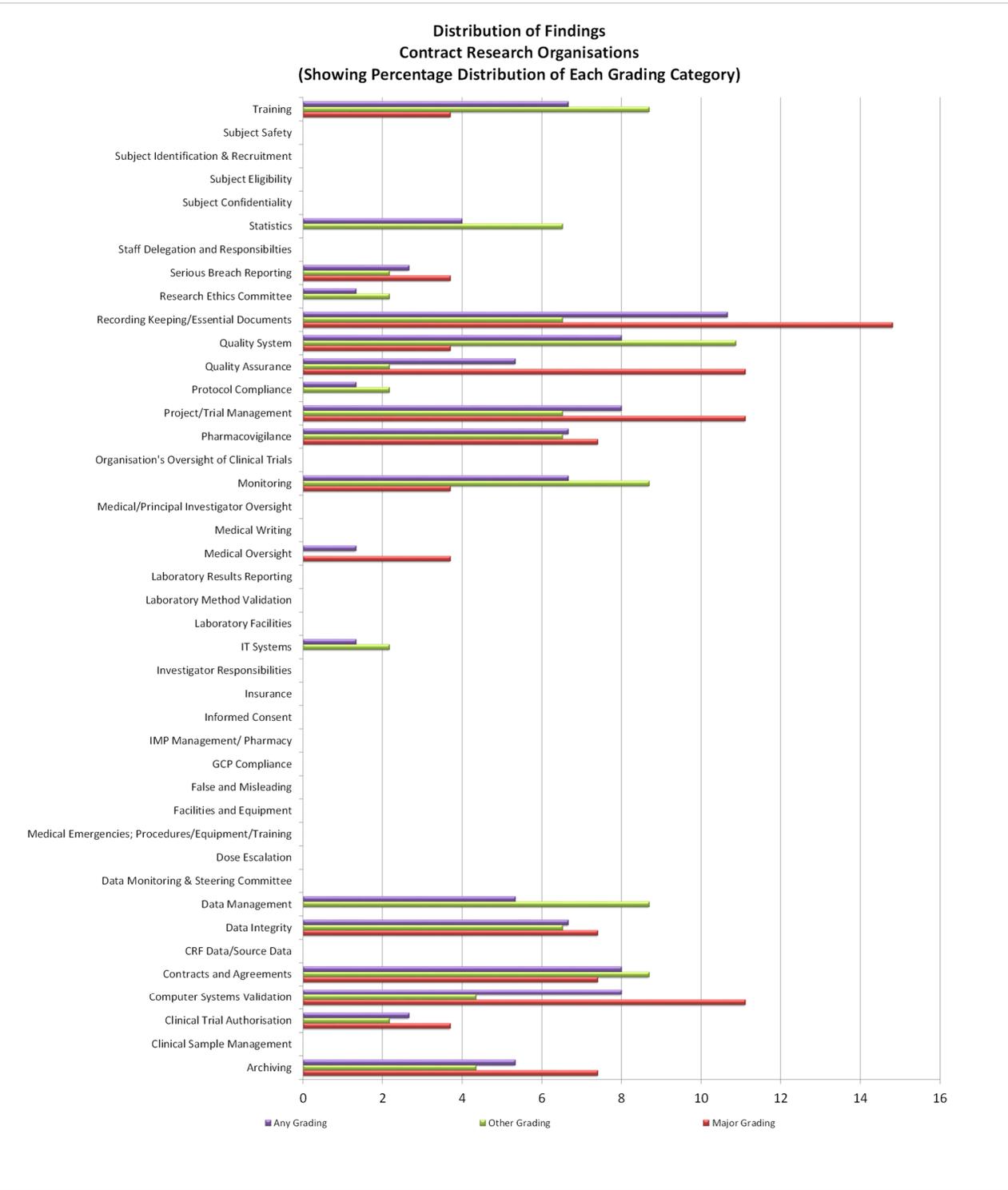
There was one critical finding given to a CRO for Record Keeping/Essential Documents (Trial Master File).

The Trial Master File (TMF) presented for inspection did not meet the requirements of the legislation for it being the basis of the inspection, readily available, directly accessible and complete, to the extent that the TMF impeded inspectors from assessing GCP and legislative compliance.

The inspection was extended as it required the Inspectors to return after four months to enable review of clinical trial compliance. In the interim period, the CRO were required to undertake significant work to ensure the three selected TMFs were complete for inspection. It took the full four months to ensure the completeness of the three selected TMFs. Over 3000 documents had been created/uploaded in to one of the trial TMFs and over 5000 documents had been uploaded in to another of the selected TMFs. Although this ensured that the selected TMFs could be inspected during the extended part of the inspection the following issues were required to be assessed across trials and a robust CAPA plan implemented.

- It was not clearly defined in agreements with the trial Sponsors the scope of the Trial Master File (TMF) that was required to be held by the CRO i.e. the whole TMF or parts of the TMF in relation to the activities delegated to the CRO.
- The TMFs selected for inspection were found to be significantly incomplete, to such an extent that the trial conduct could not be reconstructed, and the inspection had to be extended. This was found to be a systematic issue, with the eTMF being considered and used as a final document repository rather than a contemporaneous system used to manage the trial.
- The eTMF lacked essential functionality.
- The TMFs had not been maintained to a sufficient standard and therefore issues were found with the accuracy and reliability of the TMFs. For example, documents being named incorrectly, misfiling, duplication etc.

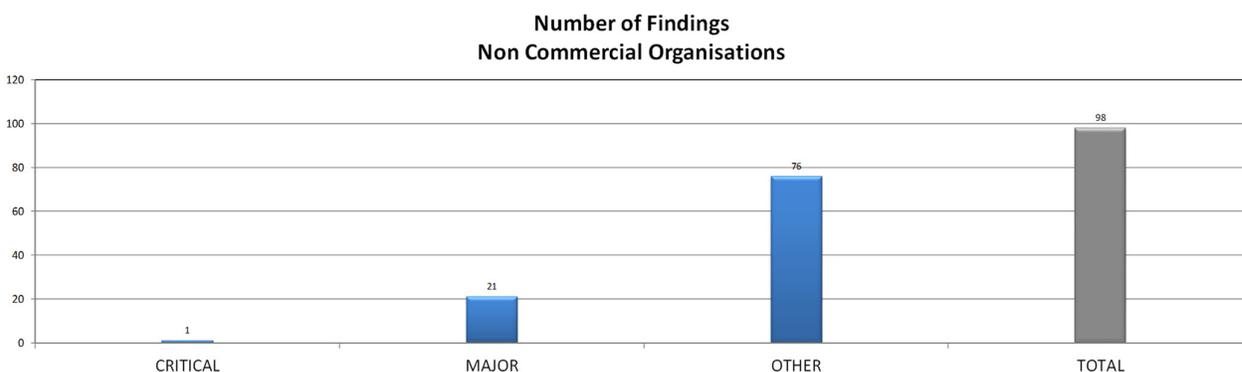
The figure on the following page shows the distribution of Major, Other and any grade of inspection findings. This identifies the areas where GCP inspectors have been making observations of non-compliance with GCP.



3.3 Non-Commercial Organisations (Routine Systems and Triggered)

A total of 8 non-commercial organisations were inspected. Of the 8, 3 were of universities, 4 were of NHS Trusts and 1 was an inspection of a charity. Two of the non-commercial organisations were clinical trial units (CTU), which are inspected in their own right; and one organisation was a non-commercial niche provider of data management and statistical services. All have been reported. None of the inspections were triggered inspections.

Of the 8 inspections, 1 (12.5%) had at least one critical finding and 7 (87.5%) had at least one major and/or critical finding. The number of findings and findings per inspection are represented on the figures below.



Number of Findings Per Inspection (Non-Commercial Organisations)

	Mean	Median	Mode	Maximum	n
Critical	0.1	0.0	0.0	1	8
Major	2.6	2.5	2.0	5	8
Other	9.5	10.0	2.0	14	8

There was 1 critical finding identified from 1 organisation.

Critical Finding 1

A critical finding was given to an NHS Trust relating to the Organisation's oversight of CTIMPs as there was a lack of adequate Corrective and Preventative Action (CAPA) following the last MHRA GCP Inspection (in 2013). The issues identified during this inspection that had a confirmed impact on patient safety, as well as potential for further impact so the finding was graded as Critical.

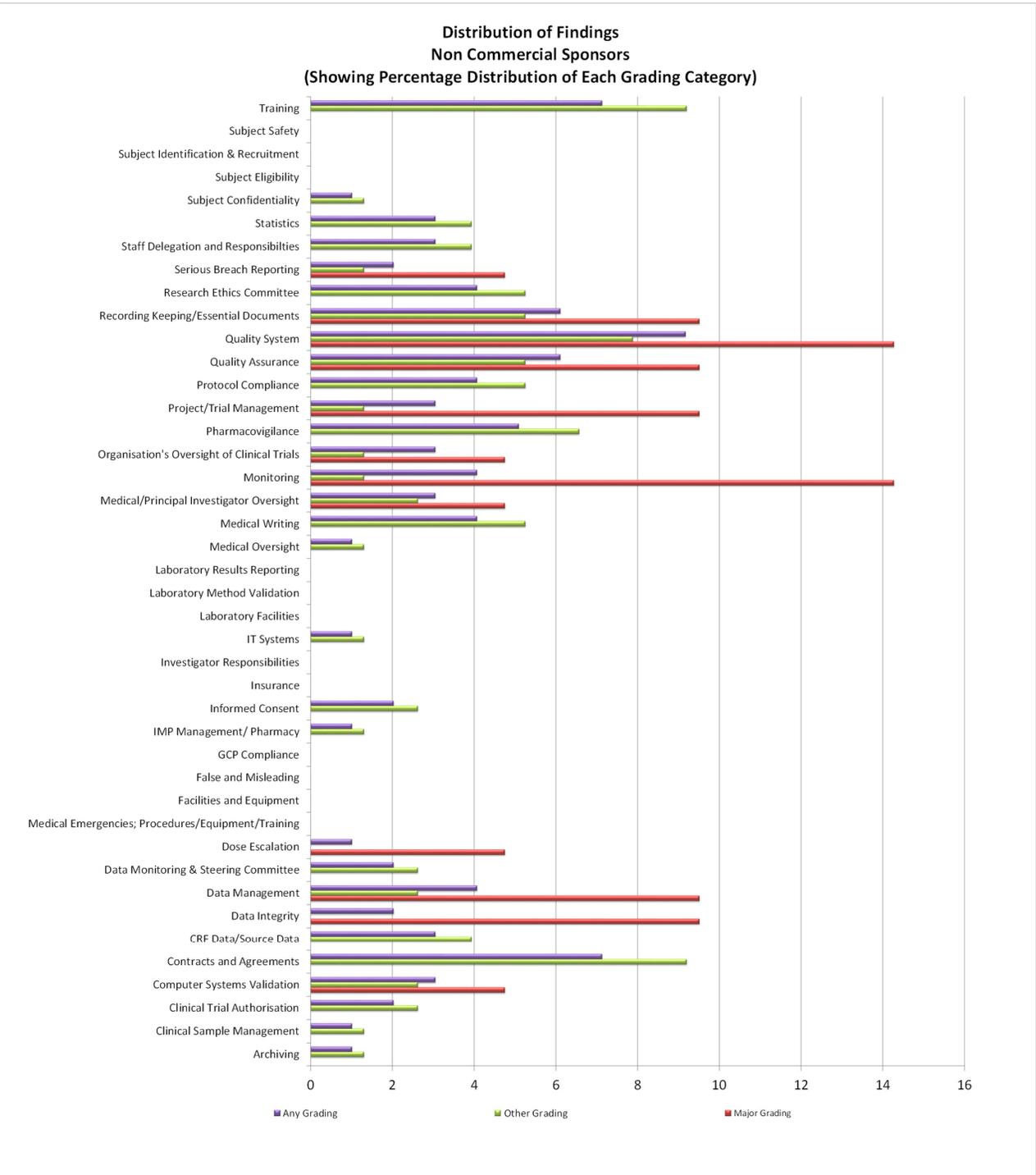
For example: Oversight of pharmacovigilance responsibilities by the Trust was considered inadequate to ensure compliance with Part 5 of the Regulations, and to ensure the ongoing safety of patients participating in Trust sponsored trials, as described below.

There was no copy of the Reference Safety Information (RSI) held on file by R&D for sponsored trials, which is used to determine expectedness and therefore potential need to report SUSARs. Therefore, prior to SUSAR reporting, there was no process for the Trust to check that expectedness assessments had been made appropriately, or that the correct version of the RSI had been used prior to SUSAR submission. The Trust retains responsibility for submission of SUSARs, but delegates expectedness assessments to the Chief Investigator/ Principal Investigator, therefore oversight of compliance by delegated parties was necessary by the sponsor. This lack of oversight was demonstrated in a trial,

where following the first SAE for a subject, the Trust QA Manager emailed the Investigator to ask what the RSI for the trial was.

The Trust was unaware of the critical compliance issues with pharmacovigilance in one of their sponsored trials, prior to the MHRA inspection of the CTU (which were contracted to perform safety reporting on the trial). The RSI version used for expectedness assessments was not the same as that submitted and approved by the MHRA for the trial, resulting in missed SUSAR reports. There was no assessment of the updated information in the RSI versions on the conduct of the clinical trial and safety of trial subjects, which related to potential for congenital anomalies / birth defects for subjects taking one of the IMPs on the trial. Missed SUSARs were found that related to pregnancies during the trial. Furthermore, issues regarding incomplete SAE reports and DSURs were also identified during the CTU inspection relating to this trial, which had not been picked up by the sponsor through mechanisms for oversight.

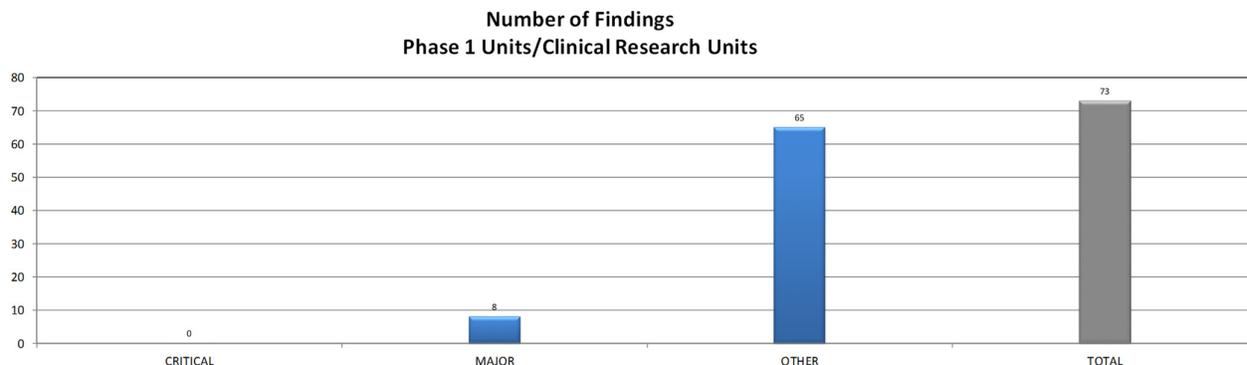
The figure on the following page shows the distribution of Major, Other and any grade of inspection findings. This identifies the areas where GCP inspectors have been making observations of non-compliance with GCP.



3.4 Phase 1 Units/Clinical Research Units (Routine Systems and Triggered)

A total of 12 inspections were done of Commercial Phase 1 Units/Clinical Research Units. Eight of the inspections were routine inspections for the MHRA voluntary phase 1 accreditation scheme, 2 inspections were undertaken as an associated site of a sponsor/CRO inspection and 2 inspections were triggered. Note that findings reported here relate to GCP and not those related to the accreditation scheme.

Of the 12 reported inspections, none (0%) had a critical finding and 5 (41.7%) had at least one major finding. The number of findings and findings per inspection are represented on the figures below.

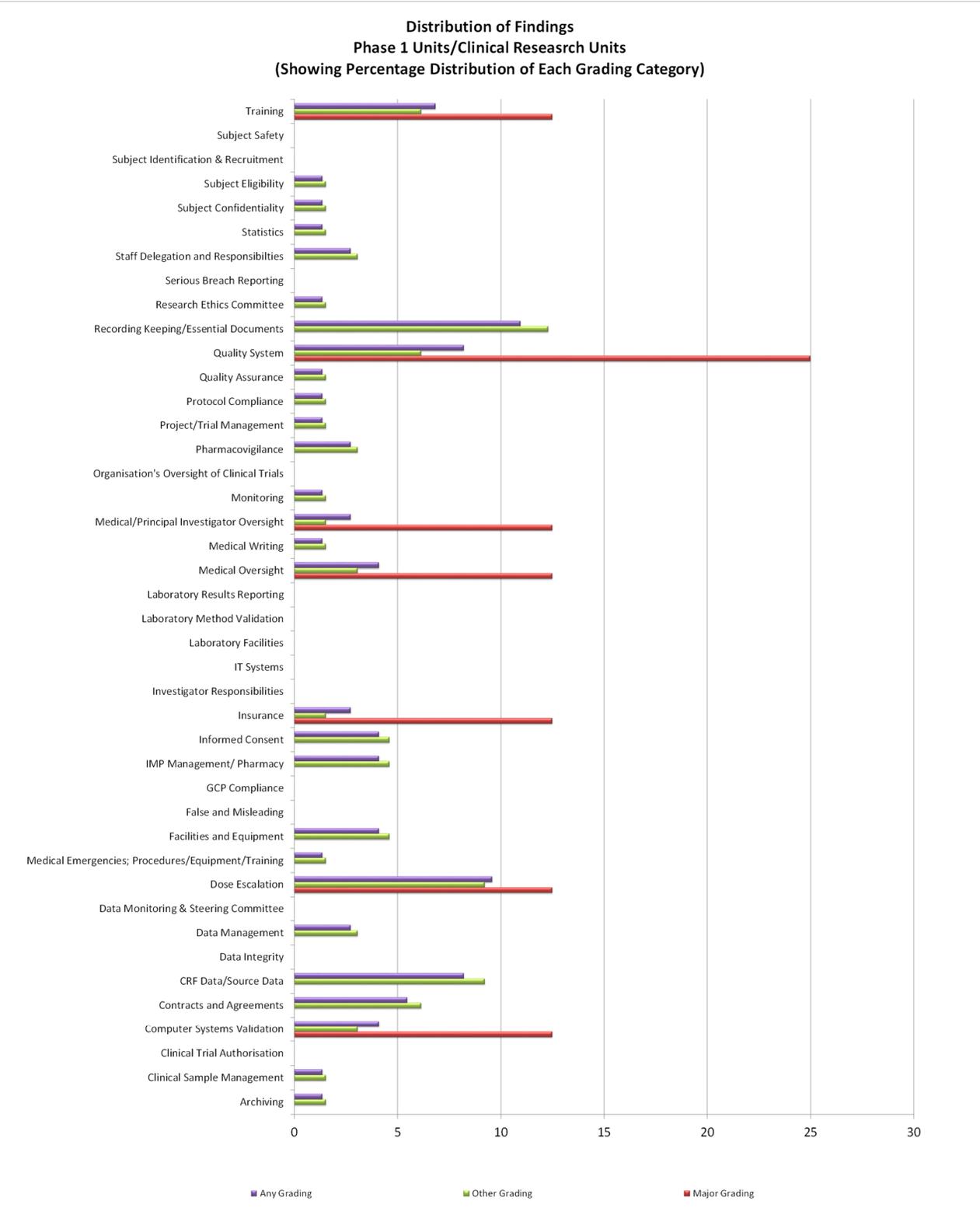


Number of Findings Per Inspection (Phase 1 Units/Clinical Research Units)

	Mean	Median	Mode	Maximum	n
Critical	0.0	0.0	0.0	0	12
Major	0.7	0.0	0.0	3	12
Other	5.4	5.5	6.0	12	12

There were no critical findings.

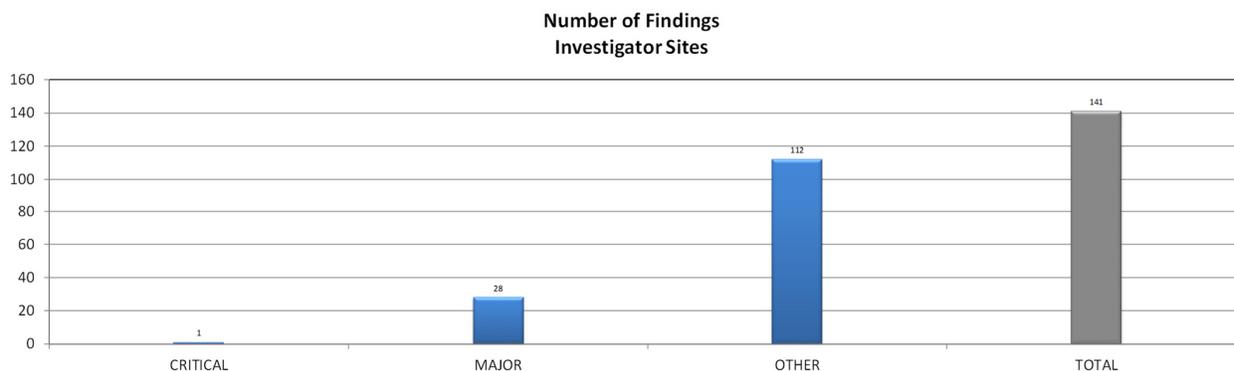
The figure on the following page shows the distribution of Major, Other and any grade of inspection findings. This identifies the areas where GCP inspectors have been making observations of non-compliance with GCP.



3.5 Investigator Sites (as part of Commercial/Non-commercial/CTU/CRO (Routine Systems & Study Specific and Triggered))

A total of 24 investigator sites in the UK were inspected, 21 were as an associated site with a sponsor/CRO/non-commercial/CTU inspection and 3 were triggered inspections. For 2 of the 3 triggered inspections, the trigger was following the sponsor inspection as there were concerns about how the trial had been managed. The third triggered inspection was the second inspection at the same site, the first being undertaken in the reporting year 2015-2016. These 2 inspections resulted in a critical finding.

Of the 24 inspections, 1 (4.2%) had a critical finding and 14 (58.3%) had at least one major finding. The number of findings and findings per inspection are represented on the figures below. It should be noted that as associated sites, the emphasis of the inspection was on how the investigator site had been overseen by the sponsor/contracted CRO.



Number of Findings Per Inspection (Investigator Sites)

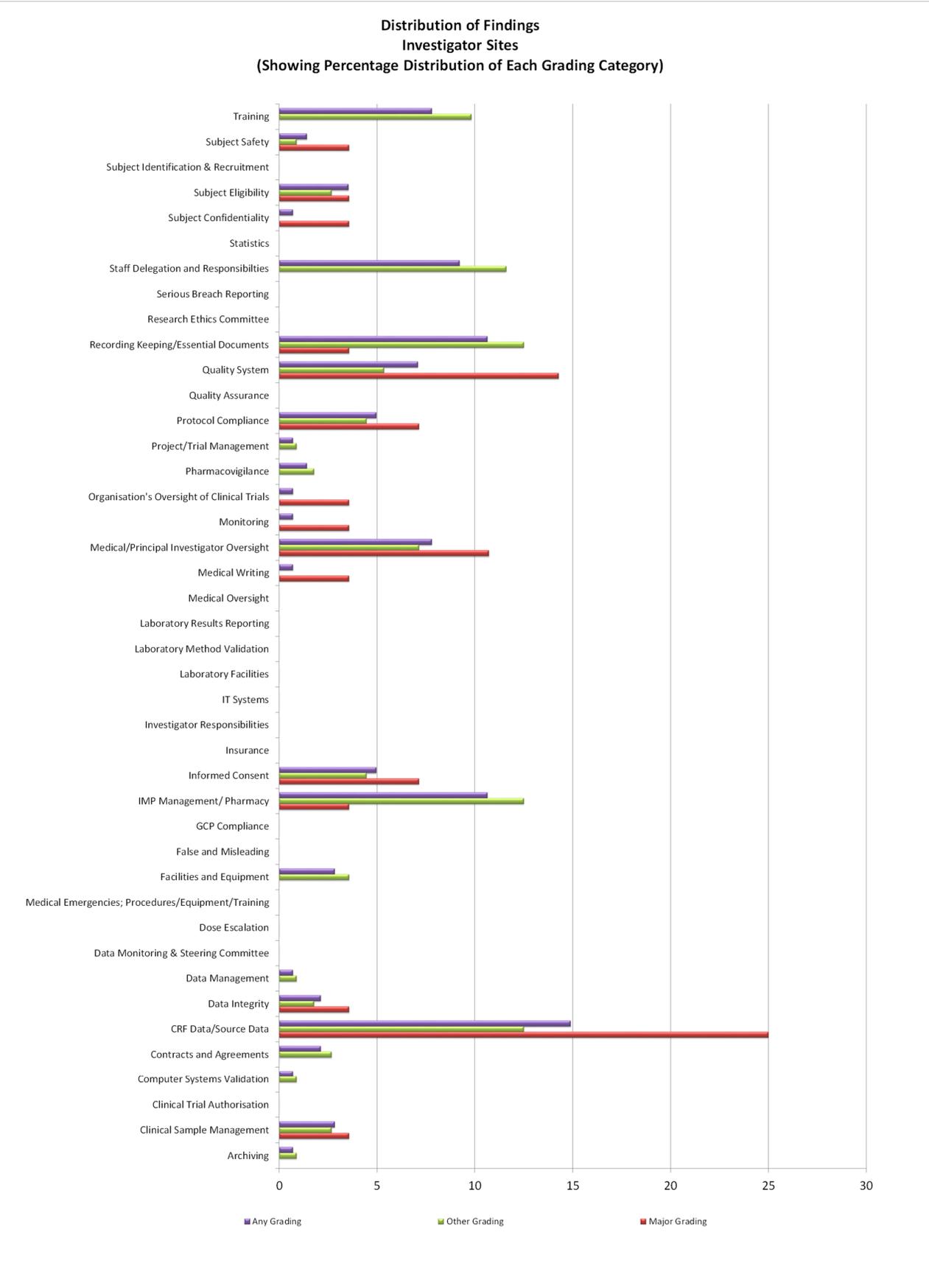
	Mean	Median	Mode	Maximum	n
Critical	0.0	0.0	0.0	1	24
Major	1.2	1.0	0.0	4	24
Other	4.7	5.0	5.0	8	24

There was 1 critical finding for 1 investigator site.

Critical Finding 1

Following a serious breach notification, two triggered inspections of trials conducted by this Principal Investigator (PI) identified systemic inclusion of patients who were ineligible for the studies that the PI had deemed them eligible resulting in a critical finding for Subject Eligibility. The reasons for ineligibility included previous medical history, prohibited medication and required prior treatment. Approximately 20% of subjects enrolled by this investigator (16/78 across several studies) were deemed ineligible.

The figure on the following page shows the distribution of Major, Other and any grade of inspection findings. This identifies the areas where GCP inspectors have been making observations of non-compliance with GCP.



3.6 Inspection Finding Trends Since Statutory GCP Inspections Implementation

The following figures show the data from previous metrics reports and earlier unpublished data to illustrate the changes in the number of findings for different organisations. This shows a general improvement following the introduction of statutory GCP inspections, however, for some types of organisations, recent years have shown general increase in the severity of inspection findings.

