Safeguarding public health

GCP INSPECTORATE

GCP INSPECTIONS METRICS REPORT

METRICS PERIOD: 1st April 2009 to 31st March 2010

DATE OF ISSUE: 4th March 2013

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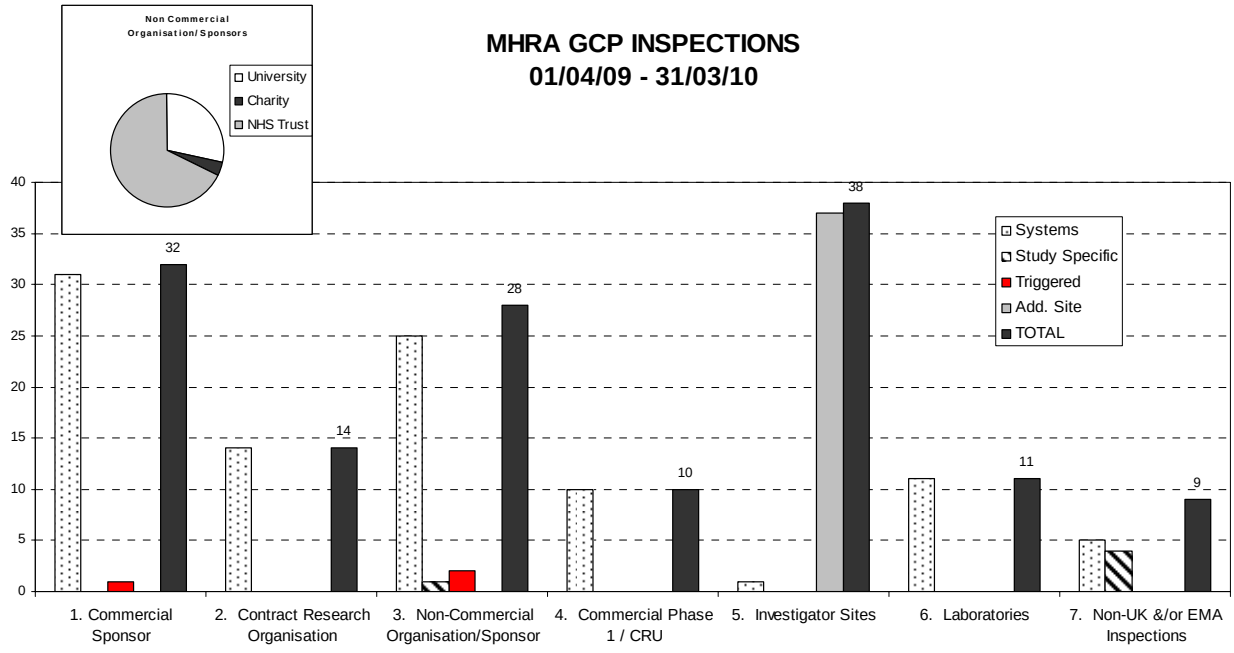
1. INTRODUCTION

This report covers the metrics period 1st April 2009 to 31st March 2010.

2. GCP INSPECTIONS UNDERTAKEN

During the Metrics Period a total of 142 GCP Inspections were undertaken by the MHRA GCP Inspectorate. The types of inspections are presented below. For the 28 non-commercial sponsor inspections, 8 were of Universities, 18 were of NHS Trusts and 2 were of a charitable organisation. The predominant type of inspection was that of investigator sites, due to them being associated with inspections of other non-commercial and commercial sponsors and contract research organizations (CROs). Triggered inspections were carried out as a result of information received by the GCP Inspectorate, for example in response to a serious breach report or whistleblower, and two of these were undertaken.



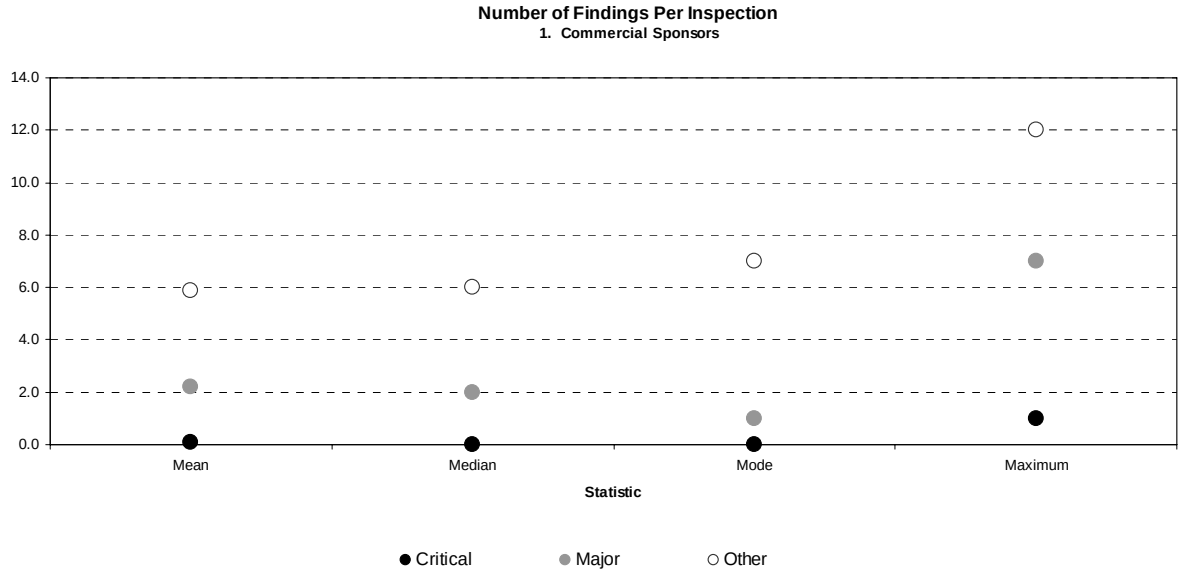
3. INSPECTION REPORTS AND FINDINGS

Reports relating only to the inspections carried out 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. Where an inspection was conducted before 1st April 2009 and the other associated inspections were conducted after 1st April 2009 (e.g. sponsor site then the investigator site(s)) the findings from the inspections conducted after 1st April 2009 (e.g. investigator site(s)) will be included in this metrics report, as these were inspections conducted during this Metrics Period. The findings reported in this document cover UK site inspections only. The findings are those that were contained in the inspection reports and do not take into account any inspection responses, apart from in the explanatory text for critical findings. The metrics data entry had an independent QC check.

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

A total of 32 commercial sponsors were inspected and 32 have been reported.

Of the 32 inspections, 3 (9.4%) had at least one critical finding and 26 (81.3%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.



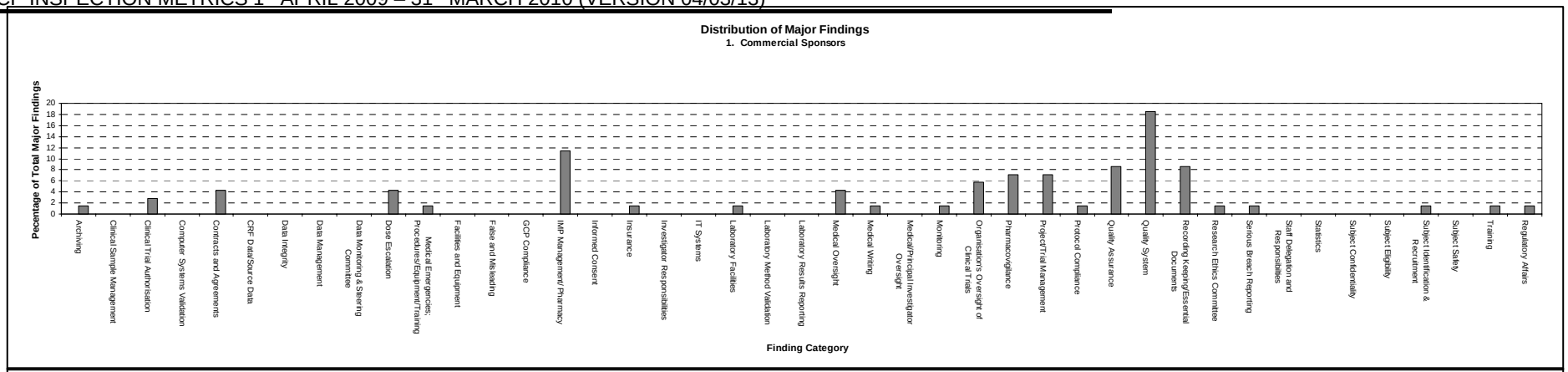
There were 3 critical findings from 3 separate organisations.

The first finding relating to IMP management concerned a sponsor organisation that had conducted IMP labelling activities on an IMP for an investigator-initiated study, without a valid Manufacturer's Authorisation for Investigational Medicinal Products (MIA IMP) to do so. In addition, there was no Qualified Person batch certification to ensure that the final product was manufactured according to EU Good Manufacturing Practice, the Clinical Trials Authorisation and the product specification file.

The second finding was for Protocol Compliance, as there was a failure to comply with the approved protocol. The sponsor applied for a protocol amendment following a Grounds for non-acceptance letter from the MHRA which required that women of childbearing potential should not be included in the study even if using contraceptive measures, due to the absence of toxicology studies. The amendment was approved by the MHRA but was not implemented by sponsor and consequently women of childbearing potential were included into the study.

The third critical finding was for Subject Confidentiality and concerned a sponsor organisation that did not have a robust process for handling confidential patient identifiers. Consequently several examples of confidential patient details were identified on the sponsors copy of the case report forms (CRFs) reviewed by inspectors for a number of studies indicating a systematic confidentiality issue which resulted in this finding being graded as critical. Please note that in February 2011 the classification for a critical finding was changed to remove "confidentiality" from the definition, therefore confidentiality issues would no longer always result in critical findings.

The figures on the following page show 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.


Distribution of Major Findings
1. Commercial Sponsors
Pecentage of Total Major Findings
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Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
CRF Data/Source Data
Data Integrity
Data Management
Data Monitoring & Steering Committee
Dose Escalation
Medical Emergencies; Procedures/Equipment/Training
Facilities and Equipment
False and Misleading
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IMP Management/ Pharmacy
Informed Consent
Insurance
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IT Systems
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Laboratory Results Reporting
Medical Oversight
Medical Writing
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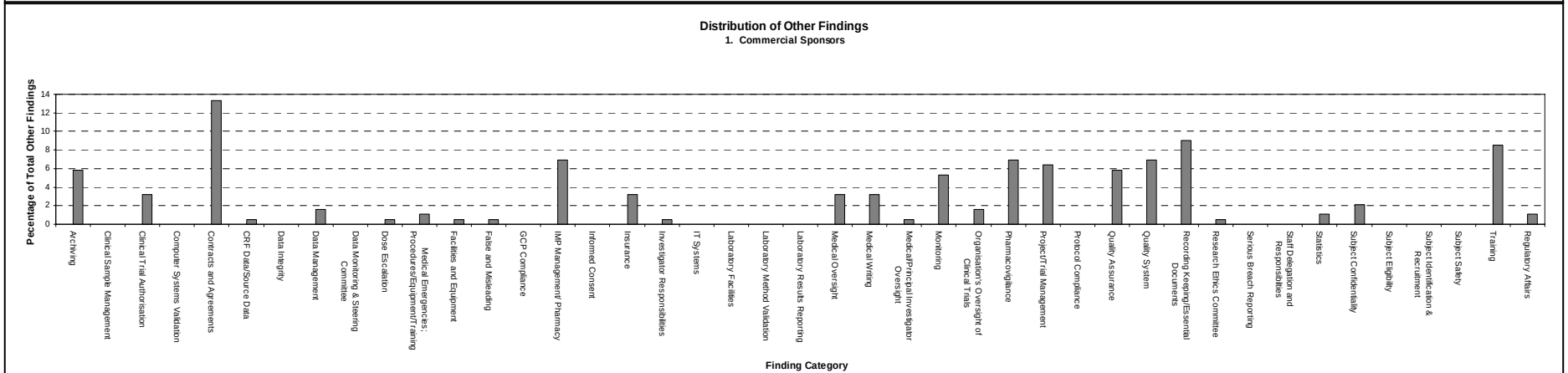
Pharmacovigilance
Project/Trial Management
Protocol Compliance
Quality Assurance
Quality System
Recording Keeping/Essential Documents
Research Ethics Committee
Serious Breach Reporting
Staff Delegation and Responsibilities
Statistics
Subject Confidentiality
Subject Eligibility
Subject Identification & Recruitment
Subject Safety
Training
Regulatory Affairs
Finding Category


Distribution of Other Findings
1. Commercial Sponsors
Pecentage of Total Other Findings
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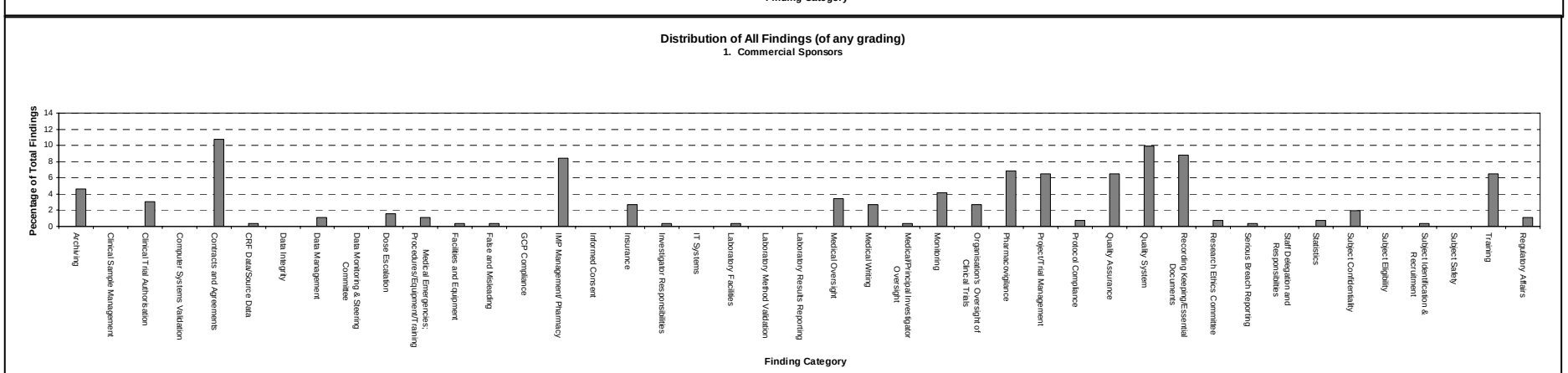
Distribution of All Findings (of any grading)
1. Commercial Sponsors
Pecentage of Total Findings
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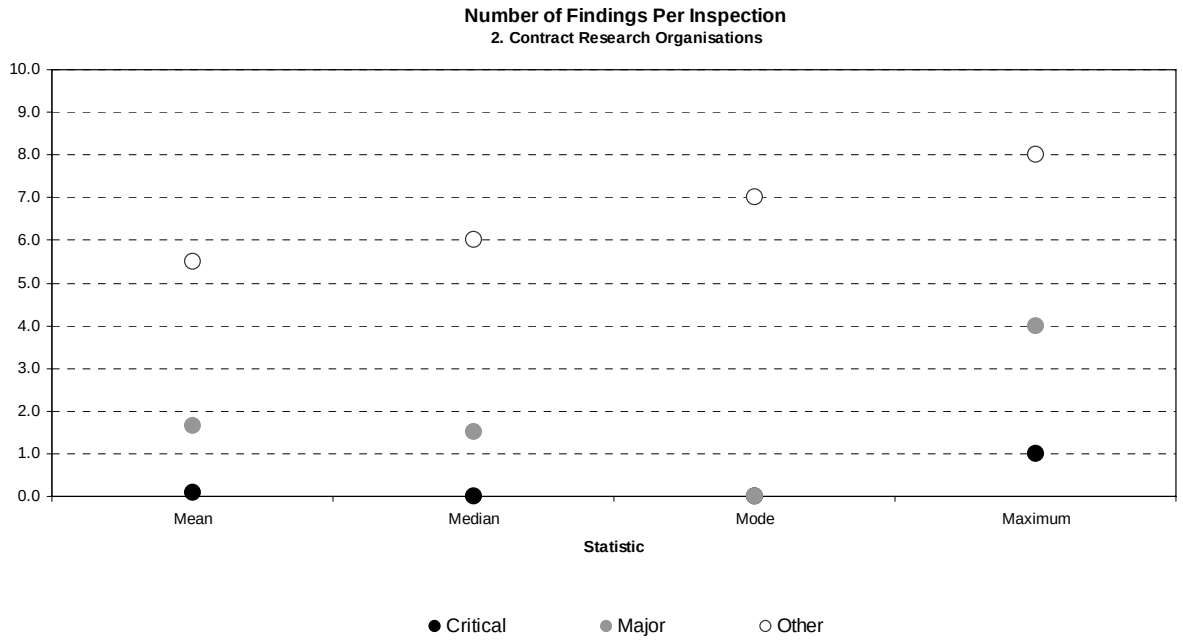
3.2 Contract Research Organisations (CRO) (Routine Systems and Triggered)

A total of 14 Contract Research Organisations were inspected and 14 have been reported.

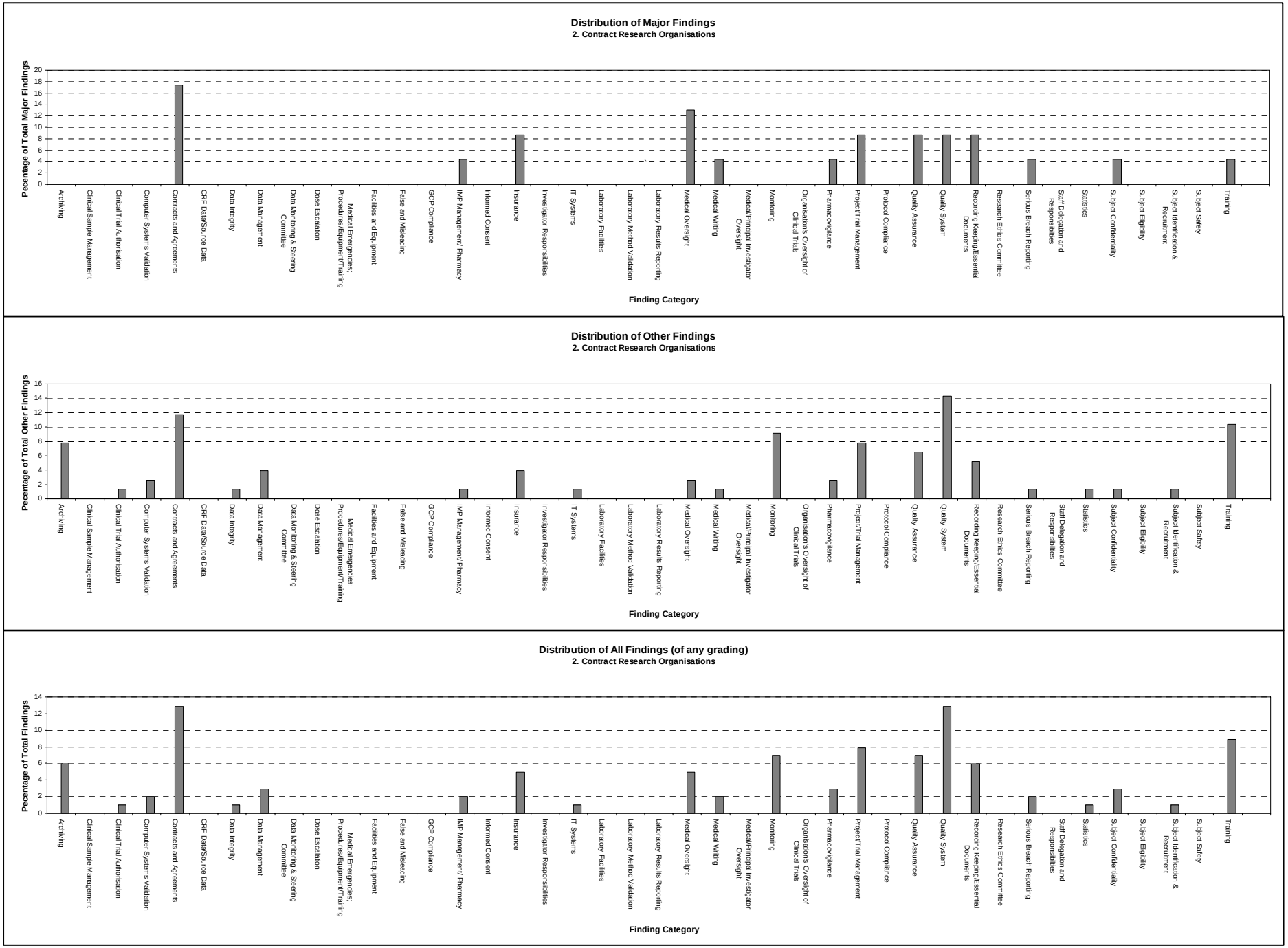
Of the 14 inspections, 1 (7.1%) had at least one critical finding and 10 (71.4%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.



There was one critical finding from one CRO organisation:

There was one critical finding from one organisation for Subject Confidentiality as the CRO had routinely collected subject sensitive information which was stored in the CRO database without prior written consent of the subjects. Subjects routinely underwent telephone pre-screening interviews to ascertain eligibility, and this information was retained on the database. However these subjects had not been asked to sign a written consent for this information to be retained nor to allow the access of their records by regulators. This was a systematic issue which potentially violated the right of the subjects consequently resulted in this finding being graded as critical.

The figures on the following page show 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.


Distribution of Major Findings
2. Contract Research Organisations
Pecentage of Total Major Findings
Finding Category
Distribution of Other Findings
2. Contract Research Organisations
Pecentage of Total Other Findings
Finding Category
Distribution of All Findings (of any grading)
2. Contract Research Organisations
Pecentage of Total Findings
Finding Category
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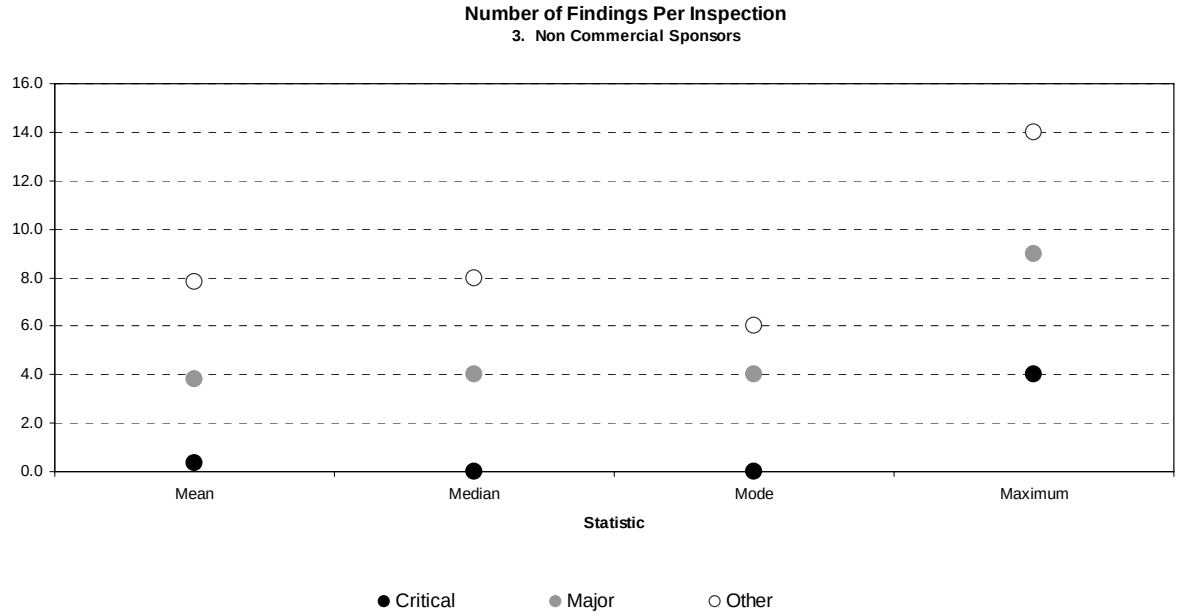
3.3 Non Commercial Organisations (Routine Systems and Triggered)

A total of 28 Non Commercial Organisations were inspected. 18 were NHS Trusts, 8 were Universities and 2 were Charities. All have been reported.

Of the 28 inspections, 6 (21.4%) had at least one critical finding and 27 (96.4%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.



A total of 10 critical findings were identified from 6 organisations inspected. Four organisations had 1 critical finding each (2 NHS Trusts and 2 Universities), 1 University had 2 critical findings and 1 University had 4 critical findings.

There were 2 critical findings given to 2 organisations for Informed Consent. Issues raised as evidence within the critical findings included, for example; missing consent forms, consent not taken as per the protocol, unapproved version of the consent form used to take consent, registrar taking consent not on the delegation log, failure to obtain informed consent from the subjects, failure to obtain informed consent prior to enrollment into the study and incomplete informed consent forms.

There were 2 critical findings given to 2 organisations for an organisation's (sponsor) oversight of clinical trials. Evidence within the critical findings included, failure to implement the corrective and preventative actions from previous inspection findings so non-compliance continued for example the CAPA required monitoring systems to be set up in December 2007, however no monitoring processes were in place at the time of the inspection. In addition there were insufficient levels of sponsor oversight, for example a lack of arrangements for oversight and monitoring of investigator sites, no review of informed consent forms and failure to rapidly deal with non-compliance with the protocol relating to consenting procedures.

There were 2 critical findings given to 2 organisations for Subject Confidentiality. Evidence to support these critical findings included lack of detail in the patient identifiers procedure to cover what would

happen in the event of patient identifiers being sent to the Sponsor, process for removing patient identifiers not robust and evidence of patient identifiers found during inspection and trial documentation containing patient identifiers held outside the hospital Trust.

One organisation was given 3 further critical findings for Clinical Trial Authorisations, Investigational Medicinal Products and Pharmacovigilance. Evidence within the critical finding for Clinical Trial Authorisation (CTA) was that there was no formal procedure to manage CTA applications or ensure that conditions of CTA approval had been addressed. This was identified at a previous inspection, however the action resulting from the inspection was insufficient and therefore this finding was upgraded to a critical finding. Evidence within the critical finding for Investigational Medicinal Product (IMP) included that there was insufficient action following the critical IMP finding from the previous inspection, for example procedures to cover contracting and managing of IMP had not been implemented, the labeling procedure had not been amended to comply with Annex 13 requirements and there was no evidence that issues with QP certification had been addressed. Evidence for the critical finding for Pharmacovigilance included that corrective actions from the previous inspection had not been sufficiently implemented, for example there was no evidence of auditing of existing protocols to ensure that they contained adequate instructions for recording and reporting adverse events, and no processes were implemented to ensure and monitor compliance of SUSAR reporting and ASR submissions.

One organisation was given a single critical finding for GCP Compliance, due to a failure to comply with the conditions and principles of GCP in the following areas;

- Protocol Non-Compliance including evidence that there had been a systematic failure to perform randomisation, take consent, give treatment and report adverse events as per the protocol.
- Investigational Medicinal Product Management including evidence that expired IMP stock had been dosed to patients, there was no QP certification for the studies reviewed and no formalised procedure for regulatory green light and release of IMP.
- Pharmacovigilance, such that SAEs were not reported to sponsor despite 4 deaths occurring, general failure or lateness to submit Annual Safety Reports to the authorities and an overall lack of procedures to govern key pharmacovigilance activities.
- Clinical Trial Authorisations which included evidence that 1 study commenced prior to MHRA approval and another study had been conducted without any CTA approval.
- Data Credibility, due to a lack of documentary QC evidence to confirm the allocation of IMP and dosage to the subjects was as per the randomization schedule for 2 of the studies reviewed.
- Insurance with evidence that one study had no insurance cover by the policy that was in place.
- Essential Documents resulting from a general lack of required essential document to enable the reconstruction of the trial.

Each was given as a major finding, but due to the number of areas involved it was given as a critical finding for GCP non-compliance.

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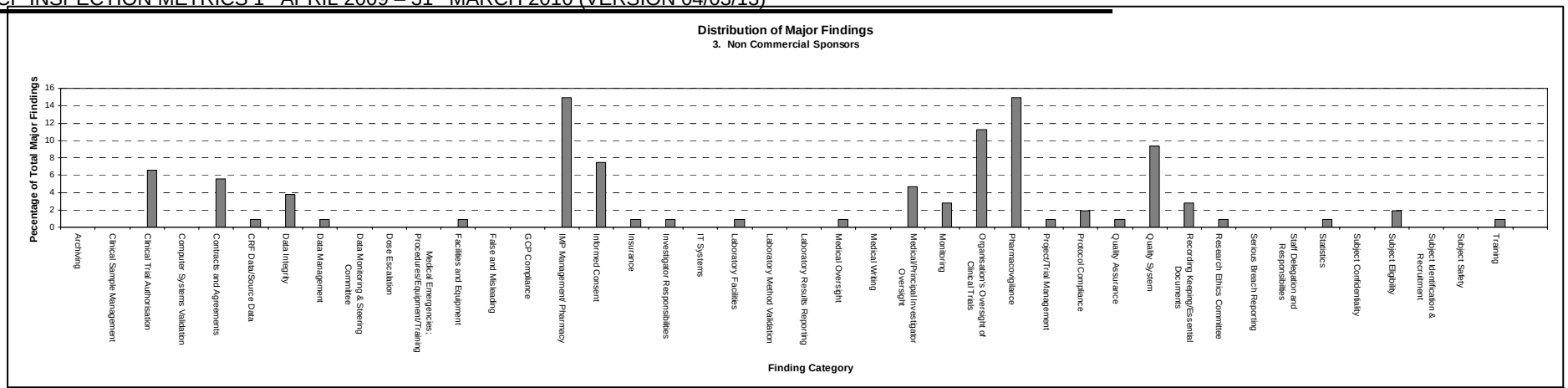
Distribution of Major Findings
3. Non Commercial Sponsors
Pecentage of Total Major Findings
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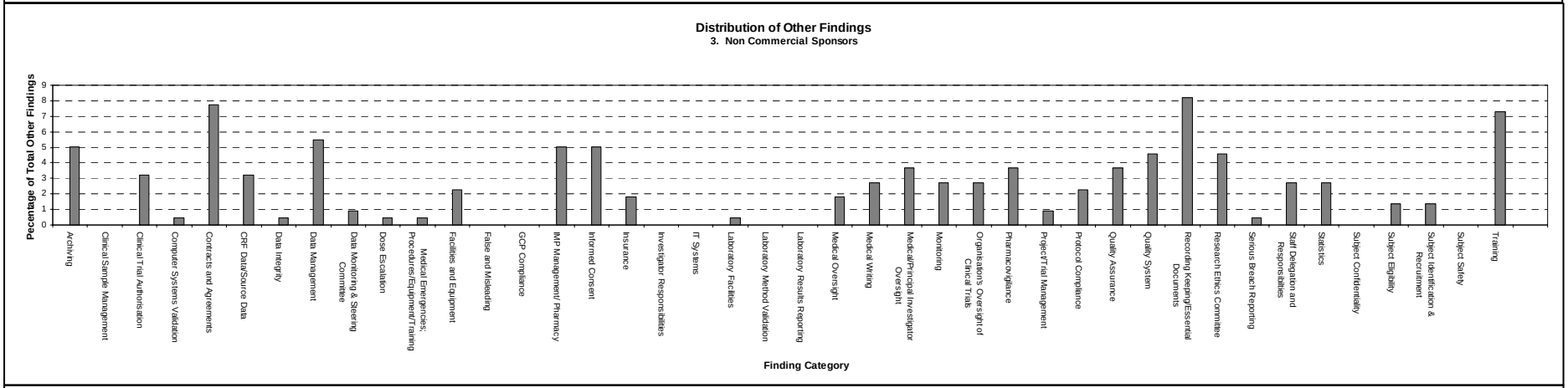
Distribution of Other Findings
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Pecentage of Total Other Findings
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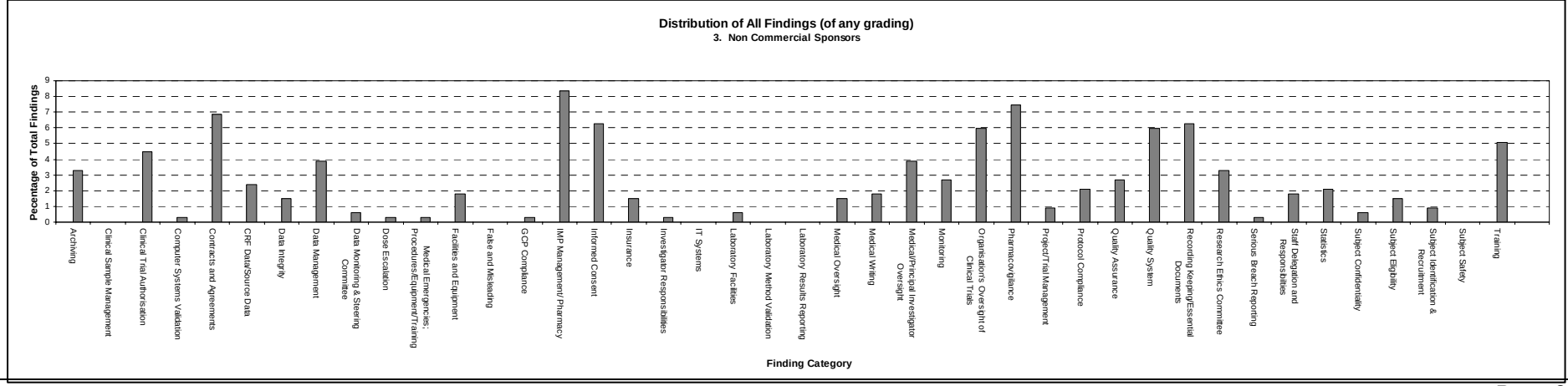
Distribution of All Findings (of any grading)
3. Non Commercial Sponsors
Pecentage of Total Findings
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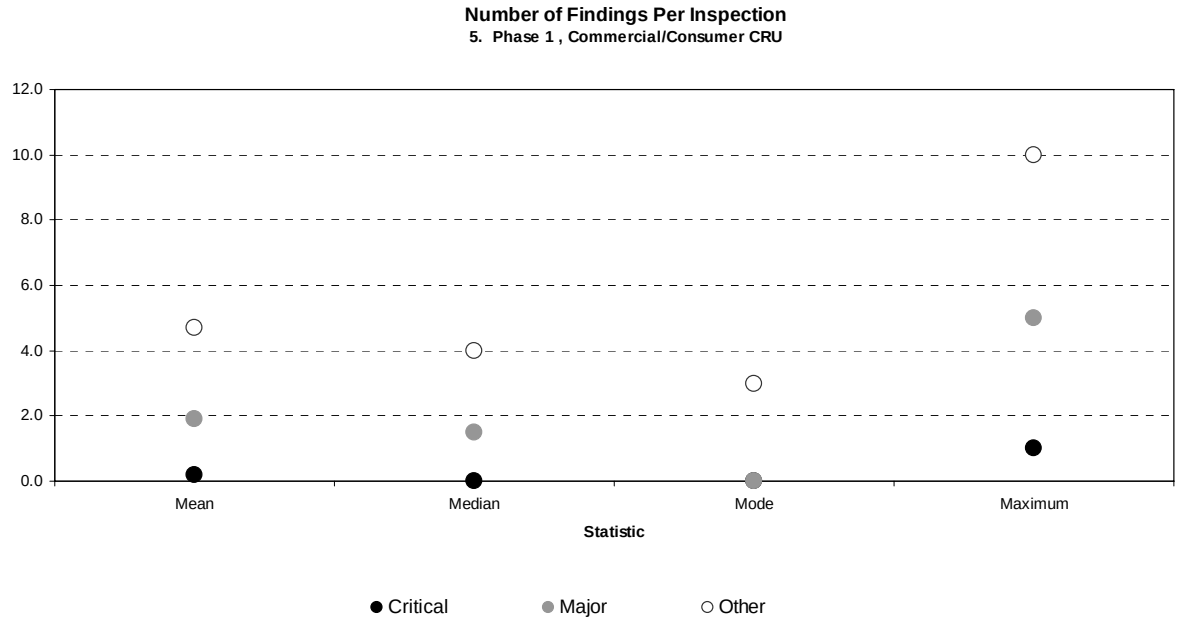
3.4 Commercial Phase 1 Units/Clinical Research Units

A total of 10 inspections were done of Commercial Phase 1 Units/Clinical Research Units. 1 of these was a triggered inspection, seven were inspections for the voluntary phase 1 accreditation scheme and 2 were systems inspections. All of the inspections have been reported. The findings reported here concern GCP issues and not those solely related to the requirements of the MHRA phase 1 accreditation scheme.

Of the 10 reported inspections, 2 (20%) had a critical finding and 6 (60%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.

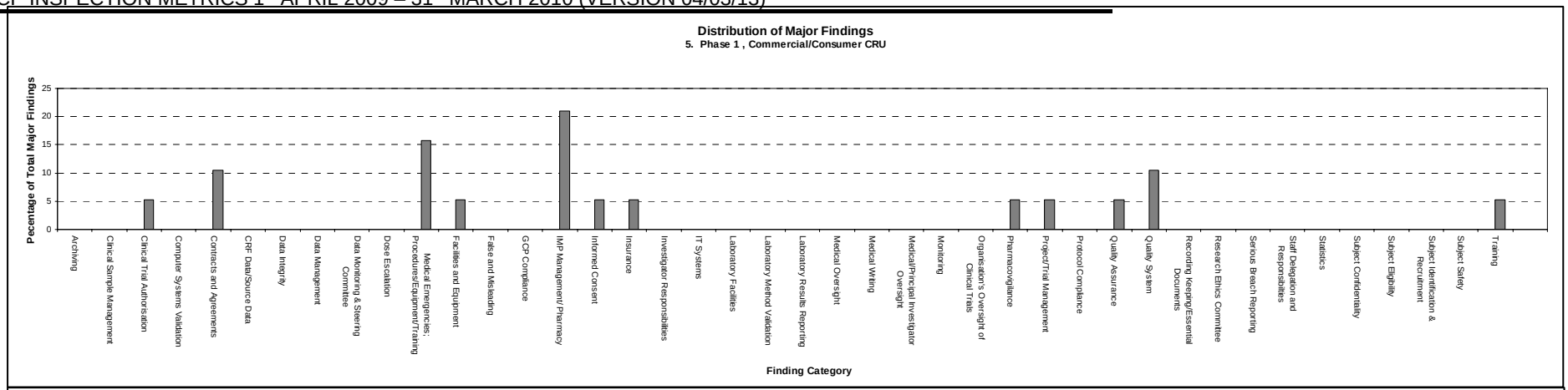


There were 2 critical findings from 2 separate organisations

The first critical finding was for Protocol Compliance due to the systematic failure to comply with the directions of the protocol which had the potential to jeopardize the safety and well-being of the trial subjects and the integrity of the trial data. These protocol non-compliances included two subjects who were entered into the study 3 times and received 3 doses of IMP despite the protocol stipulating that a subject was permitted entry a maximum of twice in non-contiguous cohorts. This was not reported as a serious breach, nor was an assessment made of the impact of this on data integrity or patient safety. In addition, the protocol required cohorts of 3 subjects, however 4 subjects were entered into one of the cohorts, and an ineligible subject was entered into the study using a non-compliant protocol waiver.

The second critical finding was for Pharmacovigilance and included evidence that the safety of a trial subject had the potential to be jeopardised following a failure to manage a Serious Adverse Event and ensure it had been reported and recorded appropriately. In addition, due to poor record keeping practices, it was not possible to verify the activities from the trial data.

The figures on the following page show 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.


Distribution of Major Findings
5. Phase 1 , Commercial/Consumer CRU
Pecentage of Total Major Findings
0
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Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
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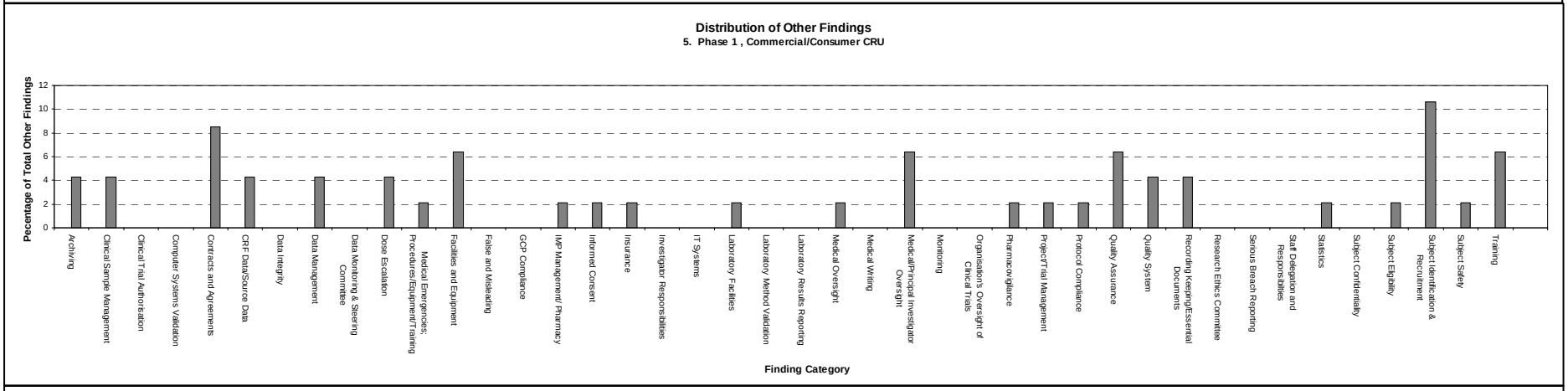
Finding Category


Distribution of Other Findings
5. Phase 1 , Commercial/Consumer CRU
Pecentage of Total Other Findings
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Clinical Sample Management
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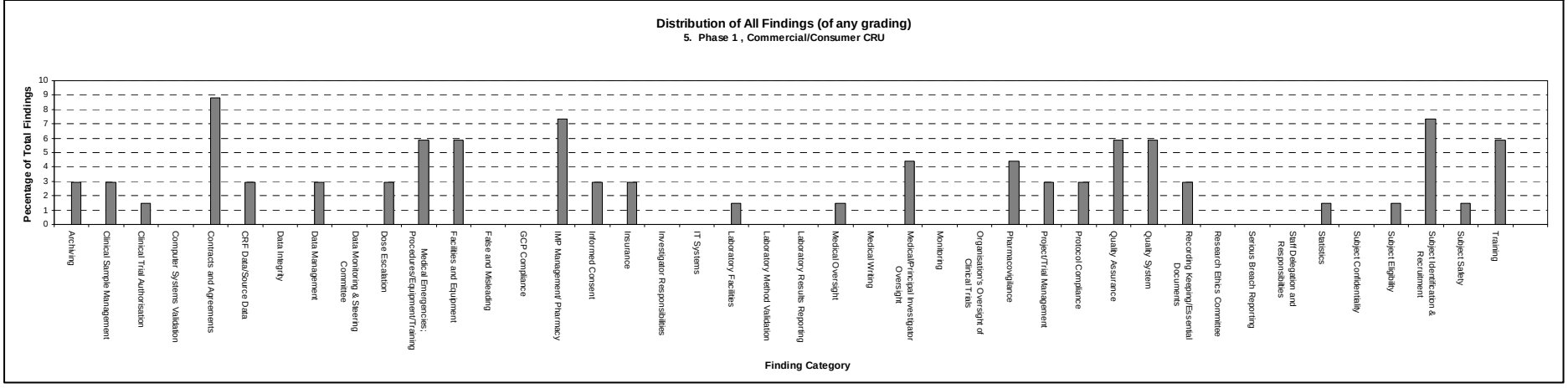
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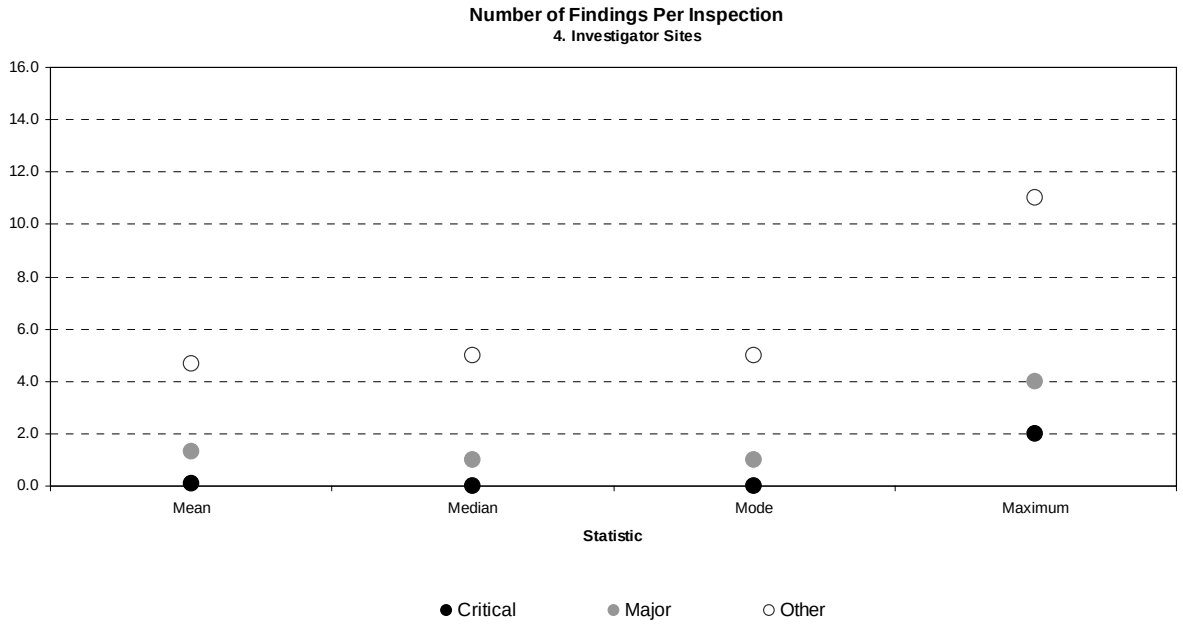
3.5 Investigator Sites (as part of Commercial/Non-commercial/CRO Routine Systems & Study Specific and Triggered)

A total of 38 investigator sites in the UK were inspected. One of these was a pilot systems inspection of an investigator site that was hosting many trials and this required its own report rather than an associated site of a sponsor/CRO inspection.

Of the 38 inspections, 2 (5.3%) had at least one critical finding and 29 (76.3%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure 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.

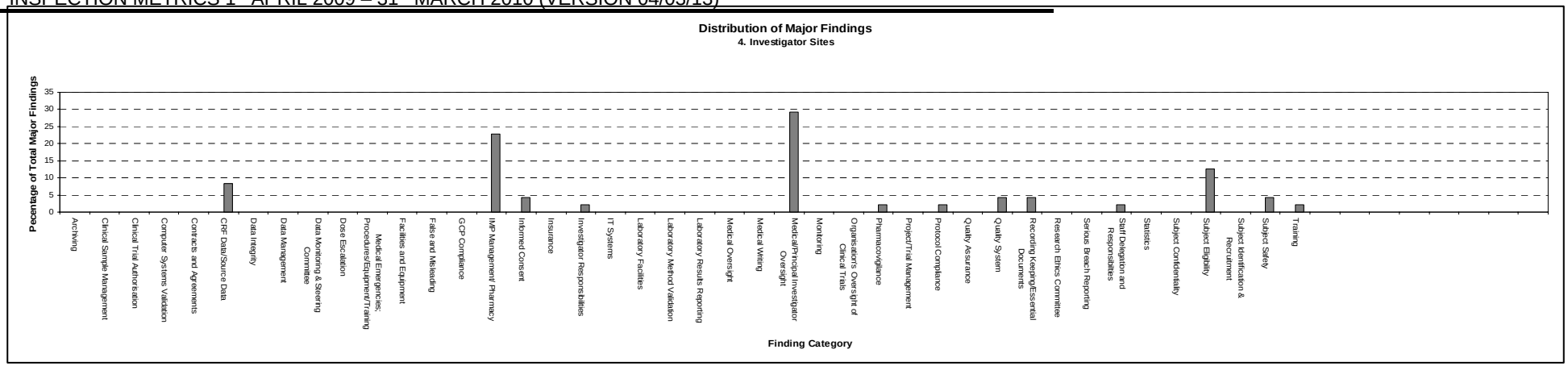


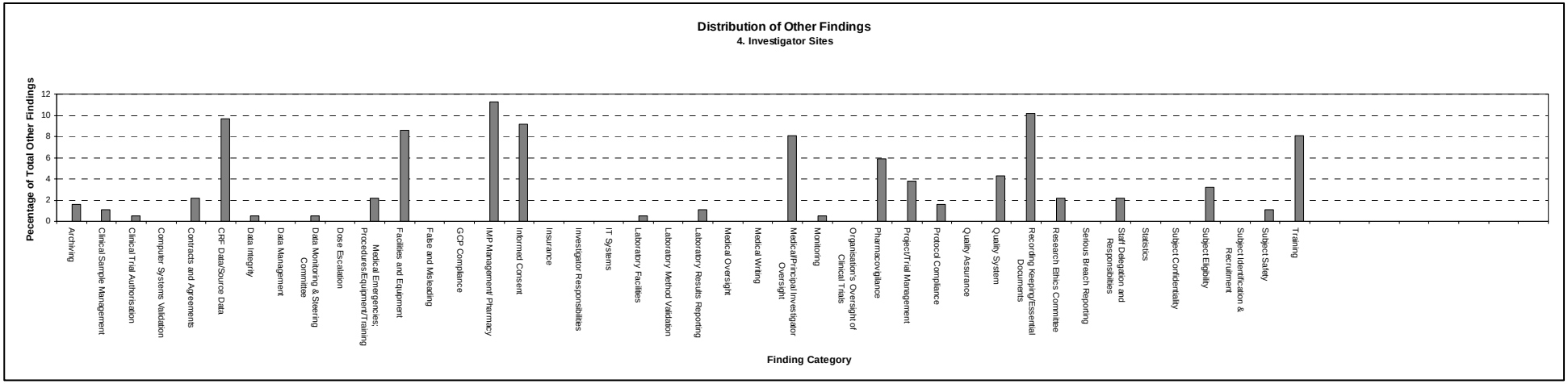
There were 3 critical findings, reported from 2 investigator sites.

The first was a critical finding given concerning Subject Safety and included the following issues; a number of serious adverse events had not been reported to sponsor adequately and within the required timeframes, compliance with the protocol for blood pressure monitoring and hypertension management had not been done and there had been a delay in reporting of notable hypertensive episodes to the sponsor as required by the protocol, due to the side effect profile of the IMP which consequently put subjects at risk. The second critical finding for the same site was in relation to Data Integrity. There was no requirement to verify the CRF data for dosing compliance against the pharmacy records and consequently there were a number of discrepancies between the CRF entries and the actual pharmacy pill counts resulting in the CRF dosing compliance data for the IMP being misleading due to the lack of reconciliation against the actual pharmacy pill count. As a result, the use of the CRF data concerning protocol compliance as part of the analysis may be biased as the protocol violators would not be identified.

A critical finding was given for the other investigator site for Investigational Medicinal Product (IMP) management due to trial subjects being dispensed medication that would expire during the period prescribed for use. Consequently 4 subjects took expired stock which had the potential to jeopardise their safety.

The figures on the following page show 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.


Distribution of Major Findings
4. Investigator Sites
Pecentage of Total Major Findings
0
5
10
15
20
25
30
35
Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
CRF Data/Source Data
Data Integrity
Data Management
Data Monitoring & Steering Committee
Dose Escalation
Medical Emergencies; Procedures/Equipment/Training
Facilities and Equipment
False and Misleading
GCP Compliance
IMP Management/ Pharmacy
Informed Consent
Insurance
Investigator Responsibilities
IT Systems
Laboratory Facilities
Laboratory Method Validation
Laboratory Results Reporting
Medical Oversight
Medical Writing
Medical/Principal Investigator Oversight
Monitoring
Organisation's Oversight of Clinical Trials
Pharmacovigilance
Project/Trial Management
Protocol Compliance
Quality Assurance
Quality System
Recording Keeping/Essential Documents
Research Ethics Committee
Serious Breach Reporting
Staff Delegation and Responsibilities
Statistics
Subject Confidentiality
Subject Eligibility
Subject Identification & Recruitment
Subject Safety
Training
Finding Category


Distribution of Other Findings
4. Investigator Sites
Pecentage of Total Other Findings
0
2
4
6
8
10
12
Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
CRF Data/Source Data
Data Integrity
Data Management
Data Monitoring & Steering Committee
Dose Escalation
Medical Emergencies; Procedures/Equipment/Training
Facilities and Equipment
False and Misleading
GCP Compliance
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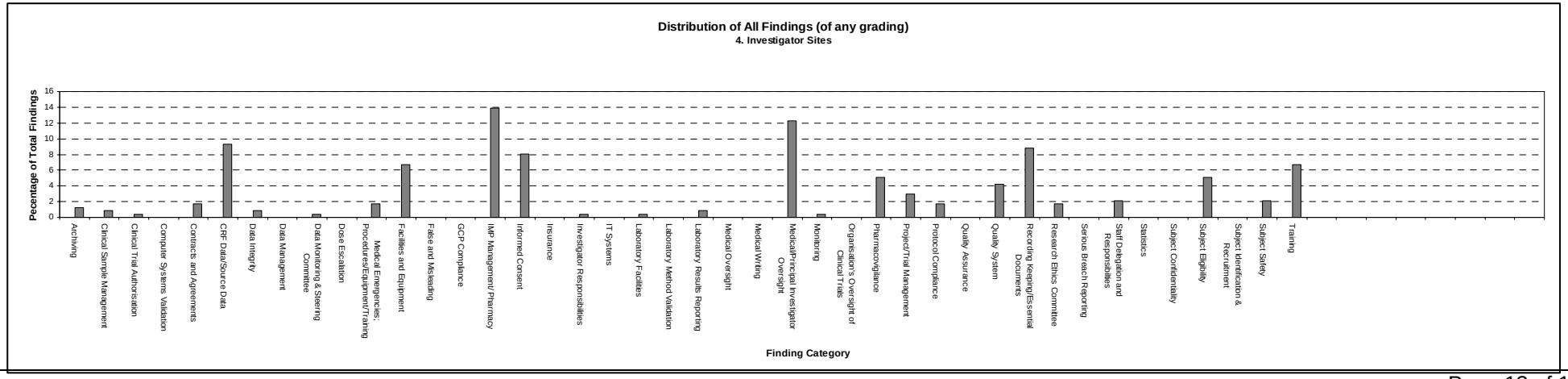
Recording Keeping/Essential Documents
Research Ethics Committee
Serious Breach Reporting
Staff Delegation and Responsibilities
Statistics
Subject Confidentiality
Subject Eligibility
Subject Identification & Recruitment
Subject Safety
Training
Finding Category


Distribution of All Findings (of any grading)
4. Investigator Sites
Pecentage of Total Findings
0
2
4
6
8
10
12
14
16
Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
CRF Data/Source Data
Data Integrity
Data Management
Data Monitoring & Steering Committee
Dose Escalation
Medical Emergencies; Procedures/Equipment/Training
Facilities and Equipment
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