Safeguarding public health

MHRA

GCP INSPECTORATE

GCP INSPECTIONS METRICS REPORT

METRICS PERIOD: 1st April 2008 to 31st March 2009

DATE OF ISSUE: 12th March 2013

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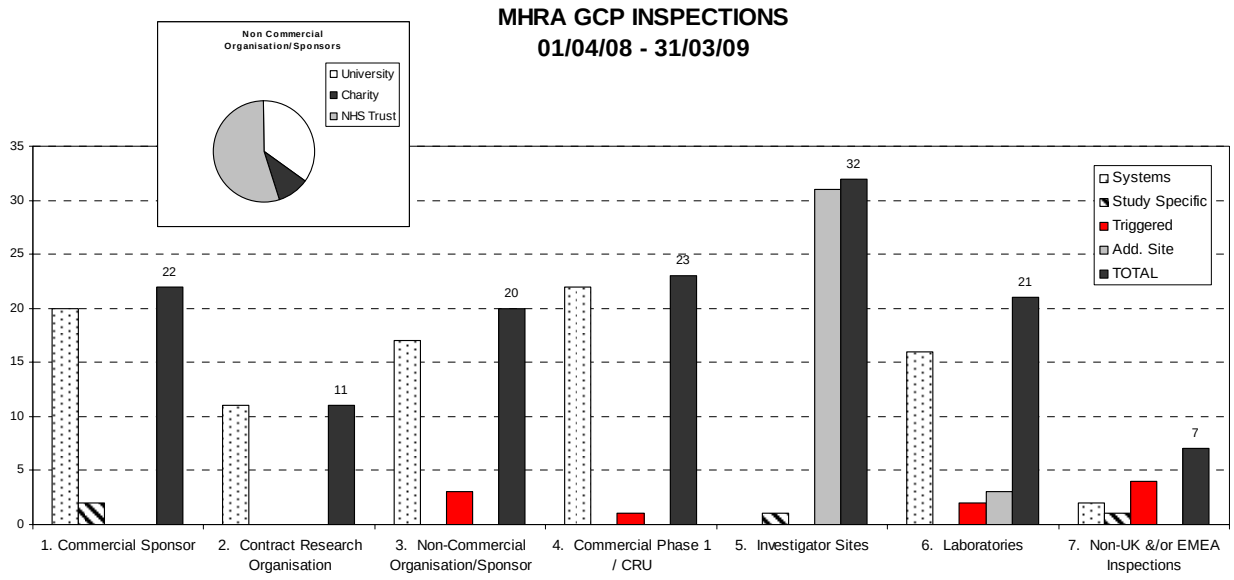
1. INTRODUCTION

This report covers the metrics period 1st April 2008 to 31st March 2009.

2. GCP INSPECTIONS UNDERTAKEN

During the Metrics Period a total of 136 GCP Inspections were undertaken by the MHRA GCP Inspectorate. This excludes 4 investigator sites which were inspected in this reporting year, but were previously reported in the 2007-2008 metrics report and so have not been included in this report. The types of inspections are presented below. For the 20 non-commercial sponsor inspections, 7 were of Universities, 11 were of NHS Trusts and 2 were of charitable organisations. 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 organisations. Triggered inspections were carried out as a result of information received by the GCP Inspectorate, for example in response to a serious breach report, and several of these were undertaken.



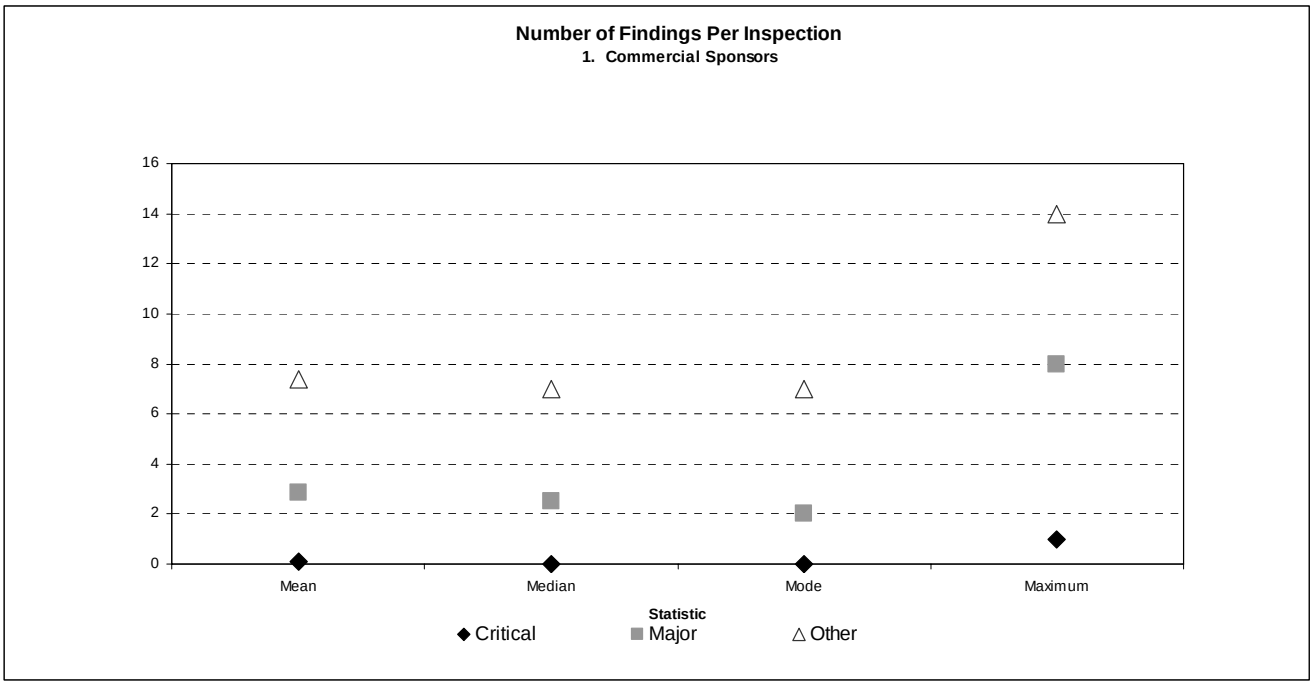
3. INSPECTION REPORTS AND FINDINGS

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 2008 and the other associated inspections were conducted after 1st April 2008 (e.g. sponsor site then the investigator site(s)) the findings from the inspections conducted after 1st April 2008 (e.g. investigator site(s)) will be included in this metrics report, as these were inspections conducted during this Metrics Period (however, note the comment regarding the 4 investigator sites above). 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 22 commercial sponsors were inspected and 22 have been reported.

Of the 22 inspections, 2 (9.1%) had at least one critical finding and 19 (86.4%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.

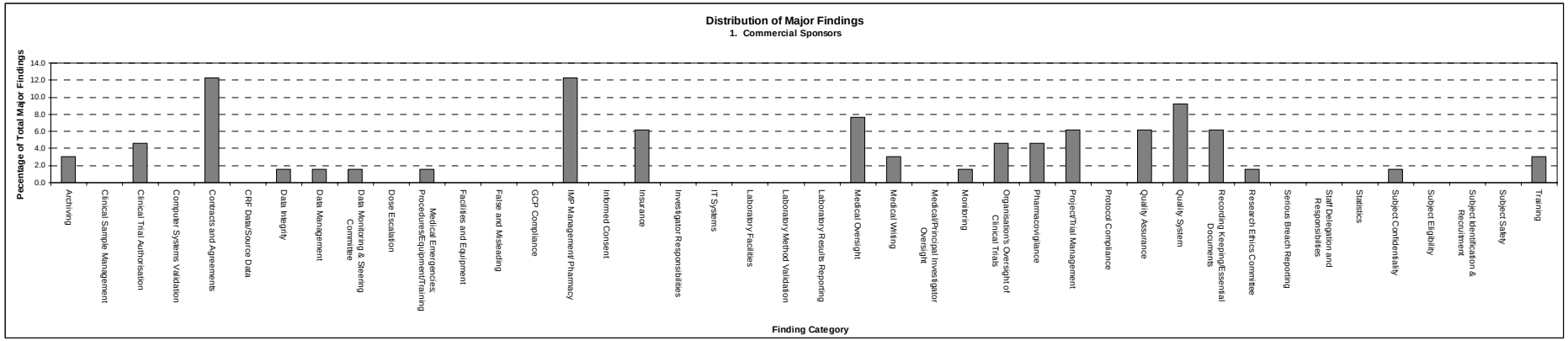


There were 2 critical findings from 2 separate organisations.

The first finding relating to IMP management concerned a sponsor organisation that had imported IMP from a third country into the UK without a MHRA licence to undertake such an activity.

The second finding was for data integrity and related to the failure of the eCRF to capture all of the data and the fact that changes to the database were made after the database lock, including those resulting from reconciliation with the pharmacovigilance database. At the time of the inspection, evidence indicated that there would be no impact on the primary object results based upon the missing diary card data, however, it was unclear what database changes had been made and what impact these may have. Following the inspection report being issued, the investigation undertaken by the sponsor also confirmed that the data changes did not affect the trial results and amended report documentation was provided by the sponsor to the EMA who were considering the data as part of a licence variation.

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
14.0
12.0
10.0
8.0
6.0
4.0
2.0
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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
GCP Compliance
IMP Management/ Pharmacy
Informed Consent
Insurance
Investigator Responsibilities
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Laboratory Facilities
Laboratory Method Validation
Laboratory Results Reporting
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Medical Writing
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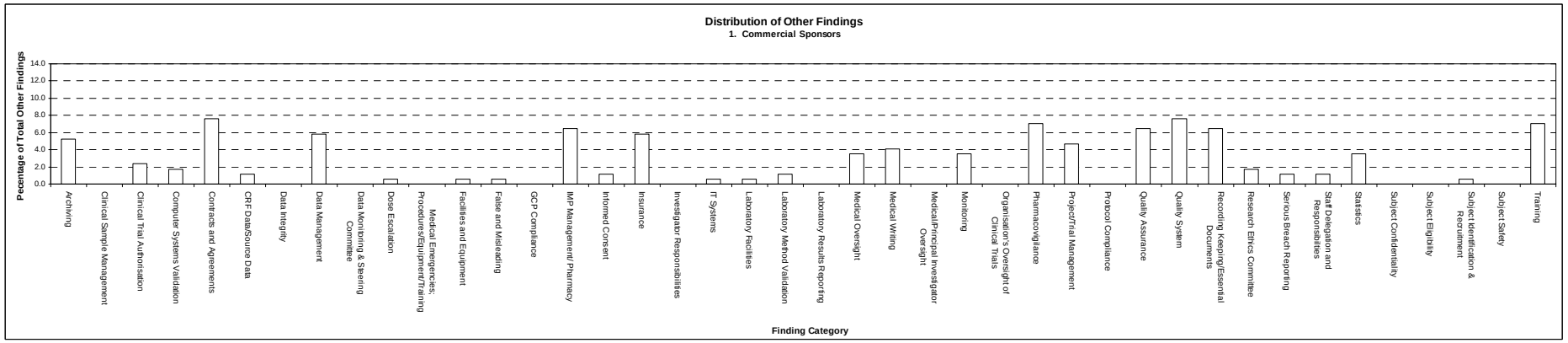
Quality System
Recording Keeping/Essential Documents
Research Ethics Committee
Serious Breach Reporting
Staff Delegation and Responsibilities
Statistics
Subject Confidentiality
Subject Eligibility
Subject Identification & Recruitment
Subject Safety
Training
Finding Category


Distribution of Other Findings
1. Commercial Sponsors
Pecentage of Total Other Findings
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12.0
10.0
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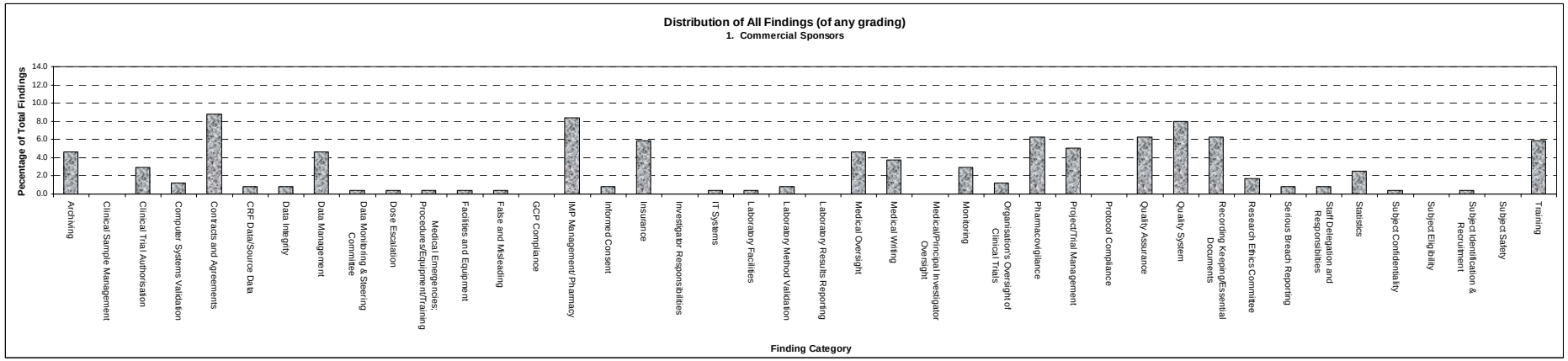
Distribution of All Findings (of any grading)
1. Commercial Sponsors
Pecentage of Total Findings
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Archiving
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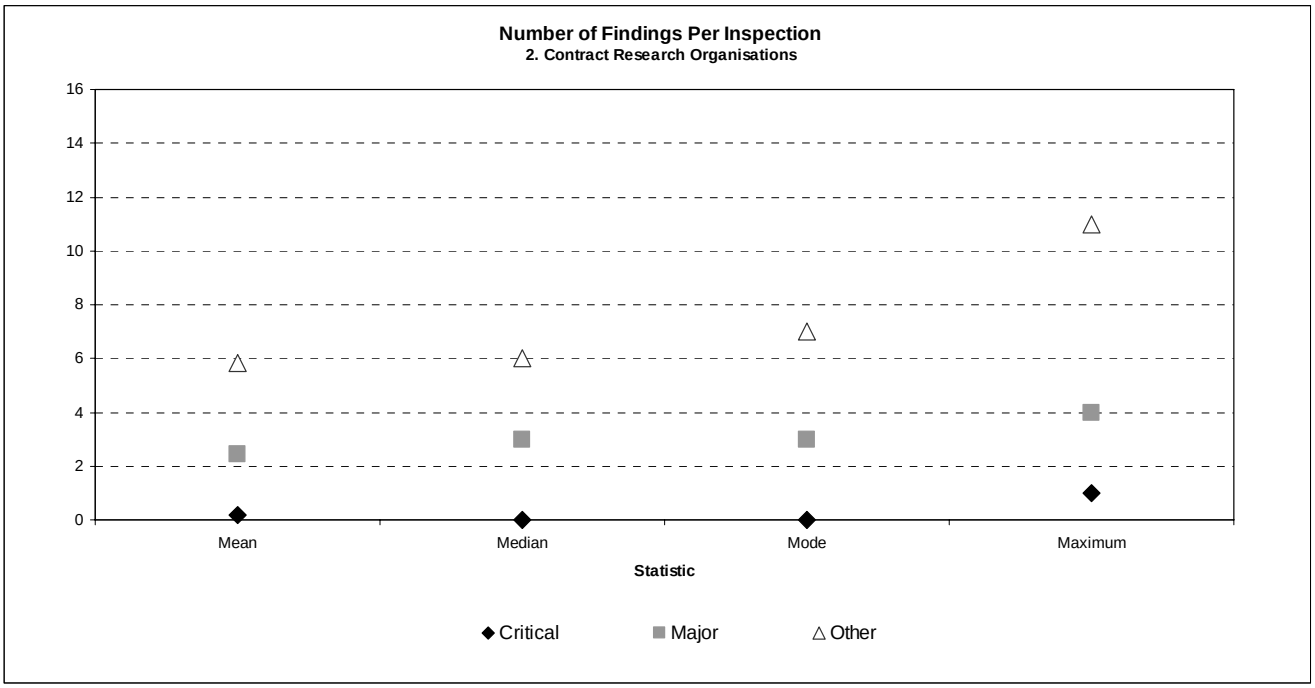
3.2 Contract Research Organisations (CRO) (Routine Systems and Triggered)

A total of 11 Contract Research Organisations were inspected and 11 have been reported.

Of the 11 inspections, 2 (18.2%) had at least one critical finding and 10 (90.9%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.

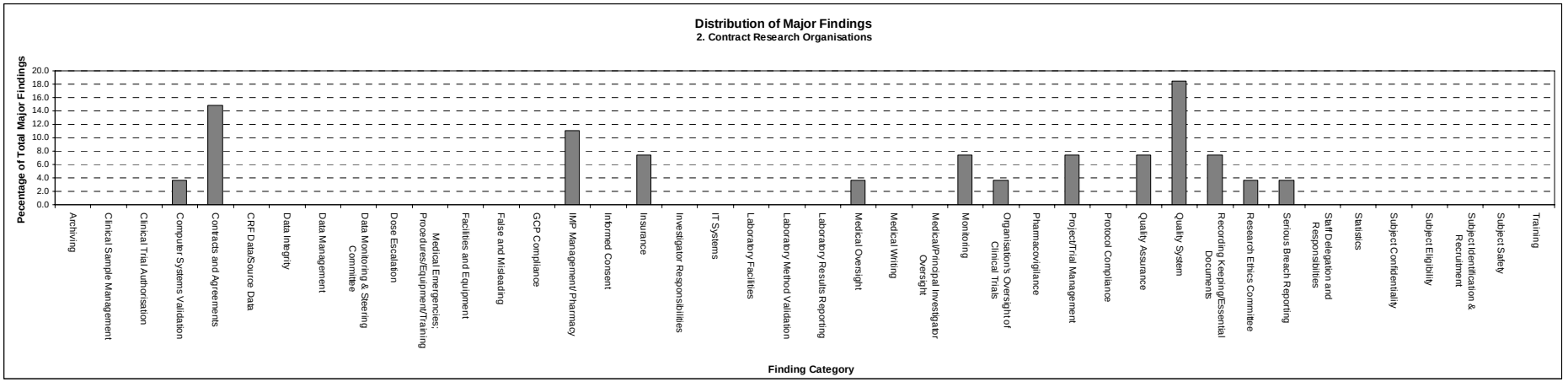


There were 2 critical findings from 2 CRO organisations:

There was one critical finding from one organisation for subject confidentiality as the CRO held the hospital numbers for several subjects and the address for one subject without their explicit. Note, however, that this finding is no longer routinely graded as critical. In addition, the CRO had no robust process for dealing with such information.

There was one critical finding reported from one organisation concerning Contracts and Agreements. The CRO had not got a formal contract in place with the trial sponsor until after subjects in the trial had been dosed. This was graded as critical due to the potential impact on the trial subject's access to compensation from the sponsor's insurance company, but as part of the investigation into the critical finding, the underwriters did confirm that the insurance was in place as a post inspection response.

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
20.0
18.0
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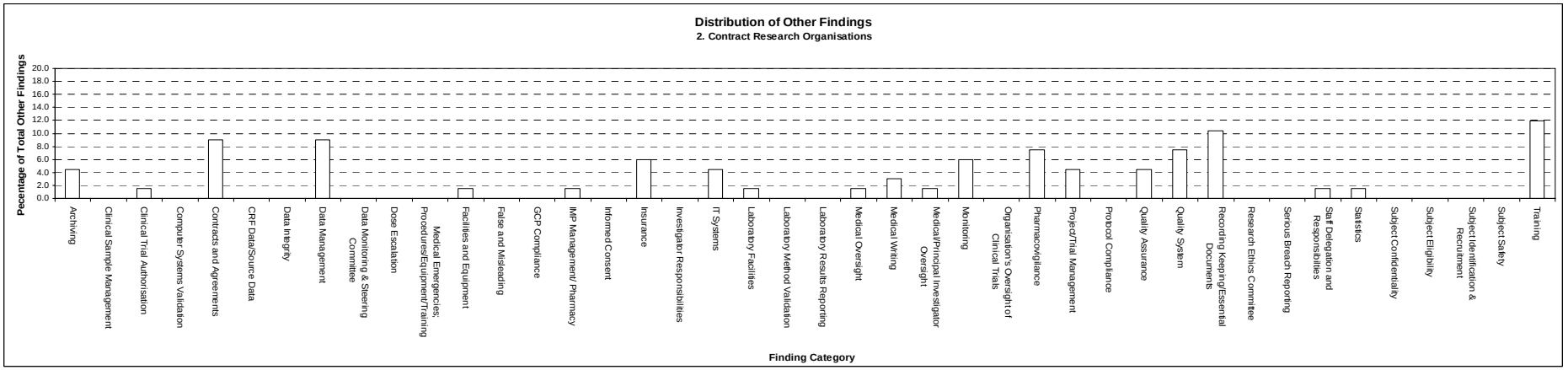
Distribution of Other Findings
2. Contract Research Organisations
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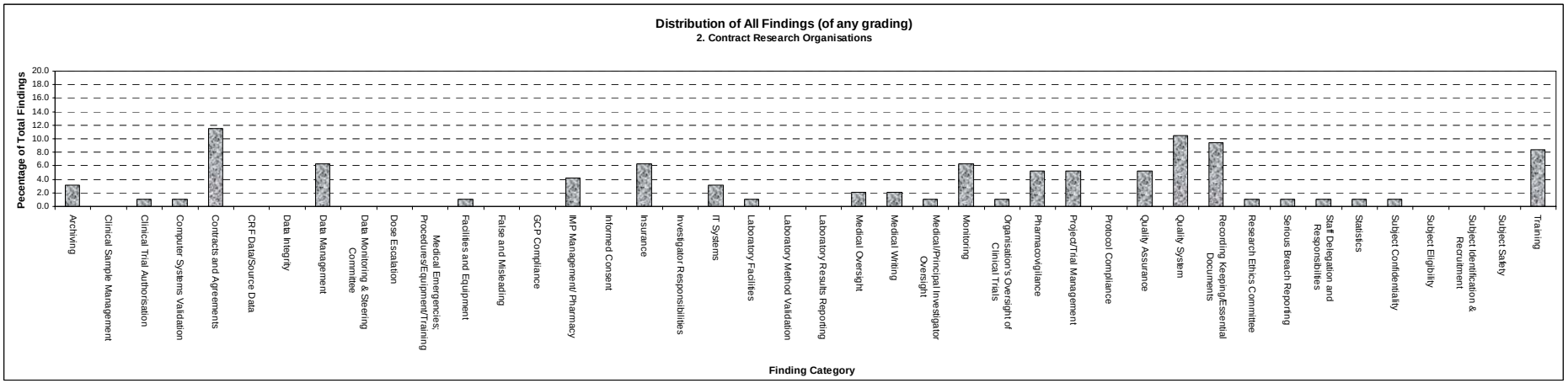
Distribution of All Findings (of any grading)
2. Contract Research Organisations
Pecentage of Total Findings
20.0
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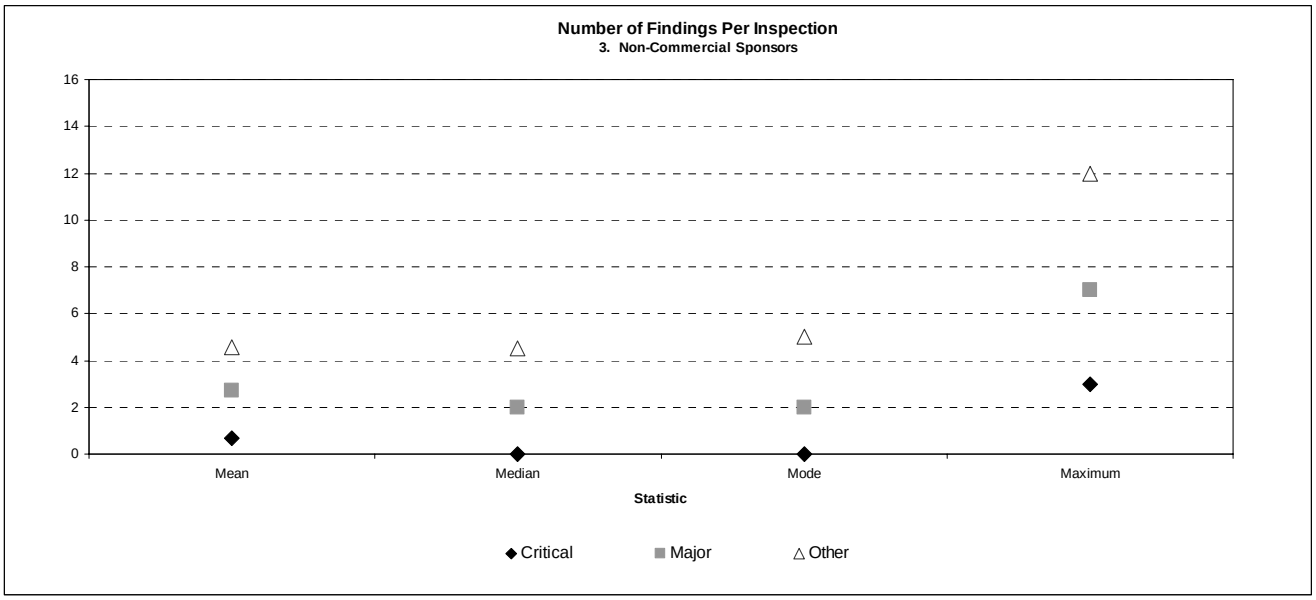
3.3 Non Commercial Organisations (Routine Systems and Triggered)

A total of 20 Non Commercial Organisations were inspected. Eleven were NHS Trusts, 7 were Universities and 2 were Charities. All have been reported.

Of the 20 inspections, 7 (35%) had at least one critical finding and 19 (95%) had at least one major and/or critical finding. The number of findings per inspection is represented on the figure below.



A total of 14 critical findings were identified from 7 organisations inspected. Two NHS Trusts had 3 critical findings each, 3 organisations (2 Trusts and a University) had 2 critical findings and the remaining 2 organisations (a Trust and a University) had 1 critical finding.

A common critical finding consisted of IMP management/pharmacy and a total of 4 critical findings were given to 4 organisations for this. Issues raised as evidence within the critical findings were varied, but included, for example; non compliance or issues with regulatory green light (in particular for multicentre trials), none or inadequate QP certification, lack of oversight and control of IMP storage areas and accountability & control of IMP, failure to implement GMP principles for IMP labeling by pharmacy, lack of quality systems and training, not implementing previous corrective action plan, non compliant labeling, lack of or incomplete contracts with and appropriate oversight of IMP subcontractors and finally a failure to report a medicine defect to the manufacturer.

A further critical finding was for an organisation's (sponsor) oversight of clinical trials, and a total of 5 critical findings were given to 5 organisations for this. Evidence within the critical finding included, lack of or poor systems to identify trials that fall under the legislation to confirm sponsorship and ensure R&D approval , ensuring CTA remarks/conditions are acted upon, protocol and CTA amendments undertaken appropriately, assessment and reporting potential serious breaches, confirming insurance is in place, approval & oversight of subcontractors and sponsor functions when delegated to the chief/principal investigator, lack of robust systems and procedures and finally failure to implement the corrective and preventative actions from previous critical inspection findings so non-compliance continued.

Two organizations had a critical finding each for pharmacovigilance, issues included as evidence in the critical findings included, inadequate procedures and protocols to comply with legislation, problems with documentation and assessment of expectedness and medical review of cases, no process for pregnancy reports, inadequate oversight of delegation of responsibilities to investigators and finally a failure to submit Annual Safety Reports

One organisation, was assigned its second critical finding for data integrity due to major non compliances for one trial in particular as it demonstrated a systematic quality control failure. The issues included: failure to take informed consent according to GCP principles; the IMP was imported from a third country and there was no QP certification; inability to verify the efficacy measures for the secondary endpoint of the trial; the blinding of the trial was compromised and no evidence of storage conditions of the IMP.

One organization was given a single critical finding for insurance, as it could not be established that adequate cover was in place.

One organization was given its one critical finding for Informed Consent as consent was taken from legal representatives and this had not been approved by the REC.

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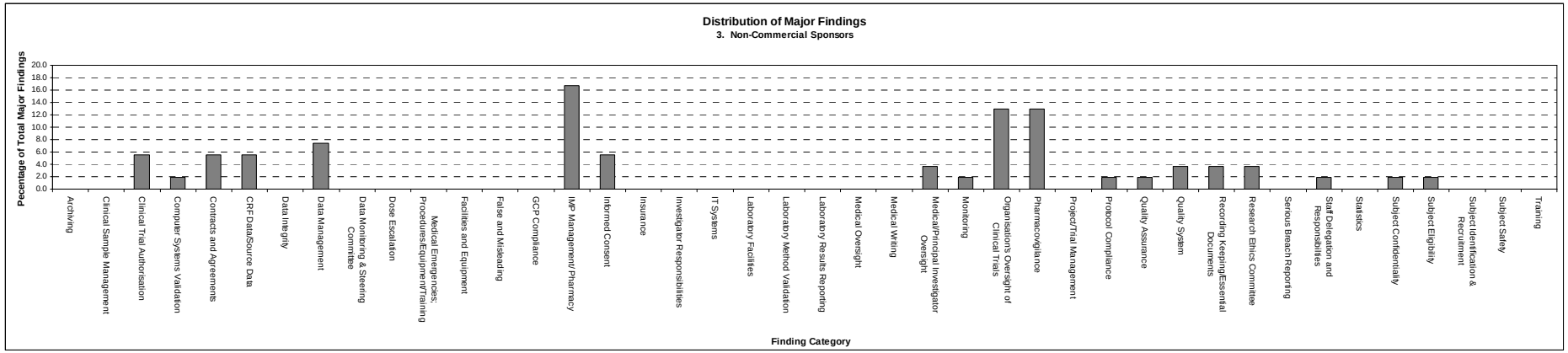
Distribution of Major Findings
3. Non-Commercial Sponsors
Pecentage of Total Major Findings
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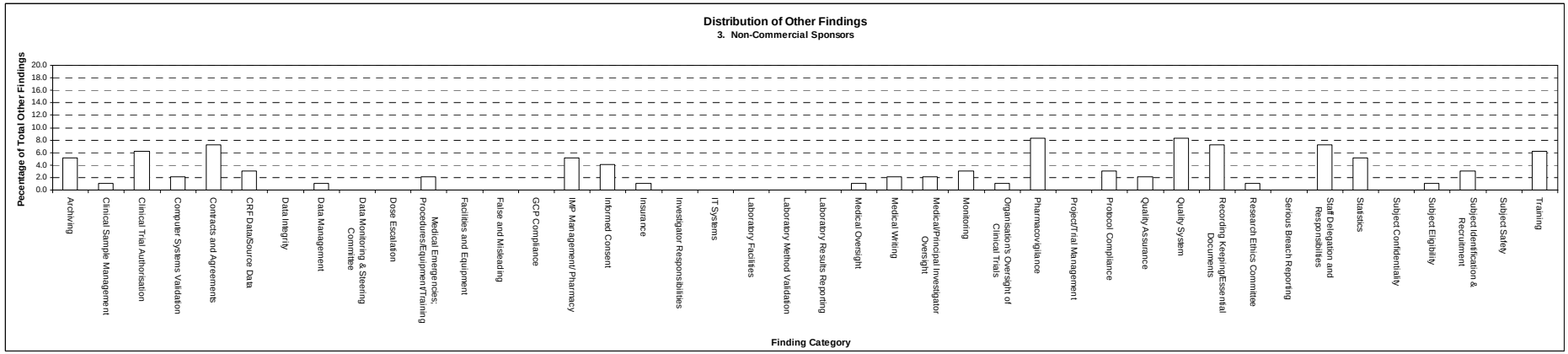
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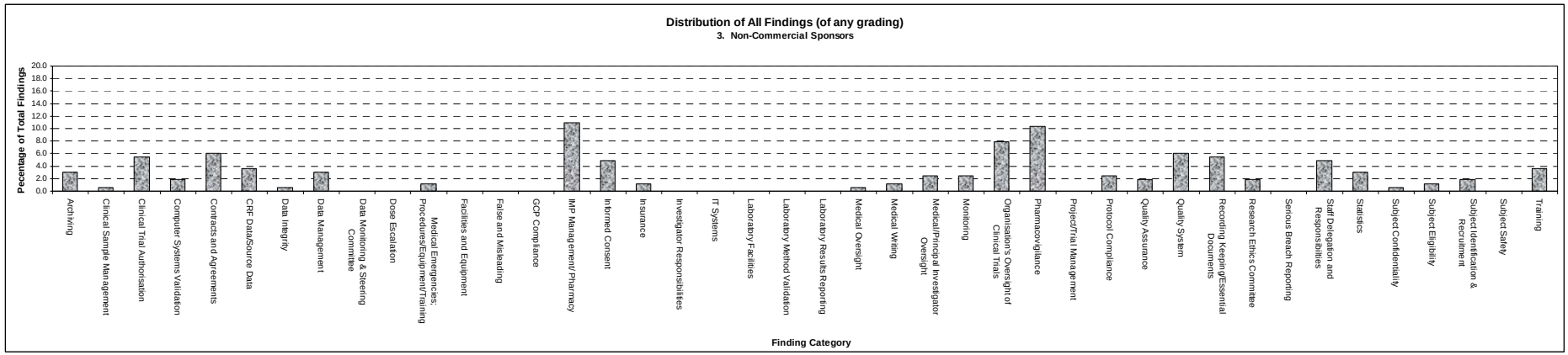
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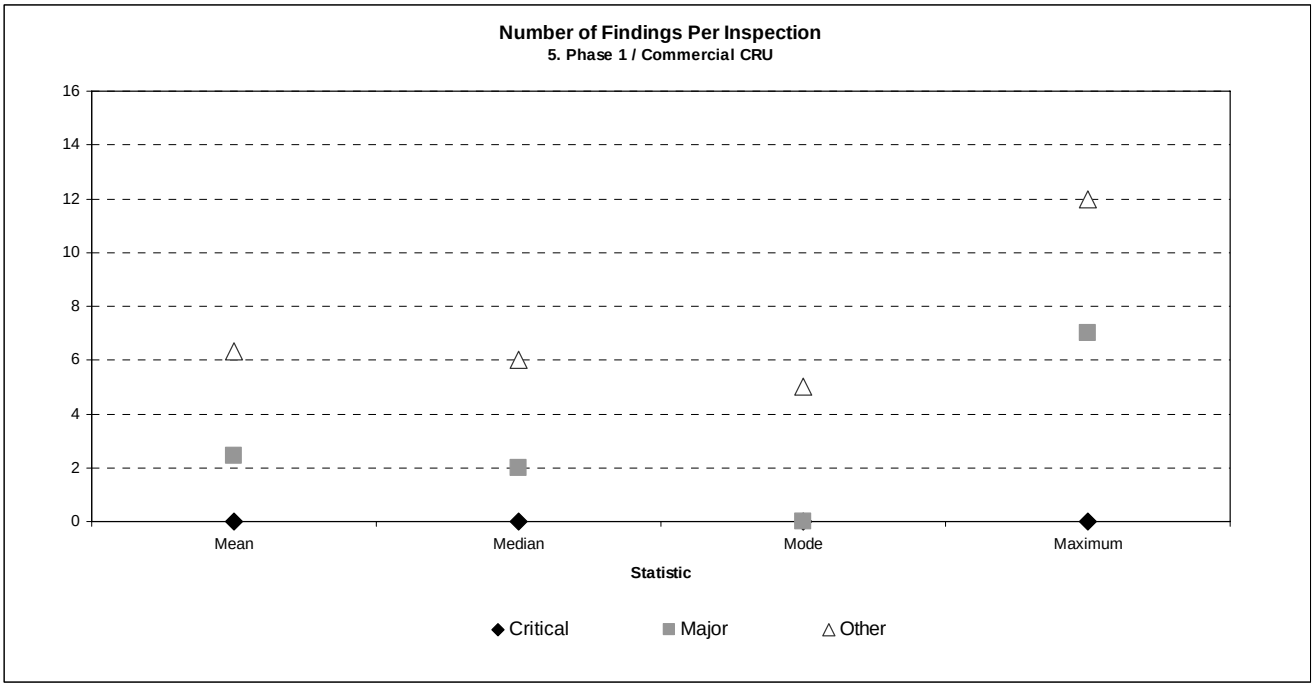
3.4 Commercial Phase 1 Units/Clinical Research Units

A total of 23 inspections were done of Commercial Phase 1 Units/Clinical Research Units and one of these was a triggered inspection. The majority (19) were inspections for the voluntary phase 1 accreditation scheme. All of the inspections have been reported, but in two cases, 2 inspection visits to the same organisation were included in one report, thus the number of inspections reports was 21.

Of the 21 reported inspections, none had a critical finding and 14 (66.7%) had at least one major finding. For two inspections there were no GCP findings, the only findings were those relating to the voluntary accreditation scheme (these are not included in this report). The number of findings per inspection is represented on the figure below.



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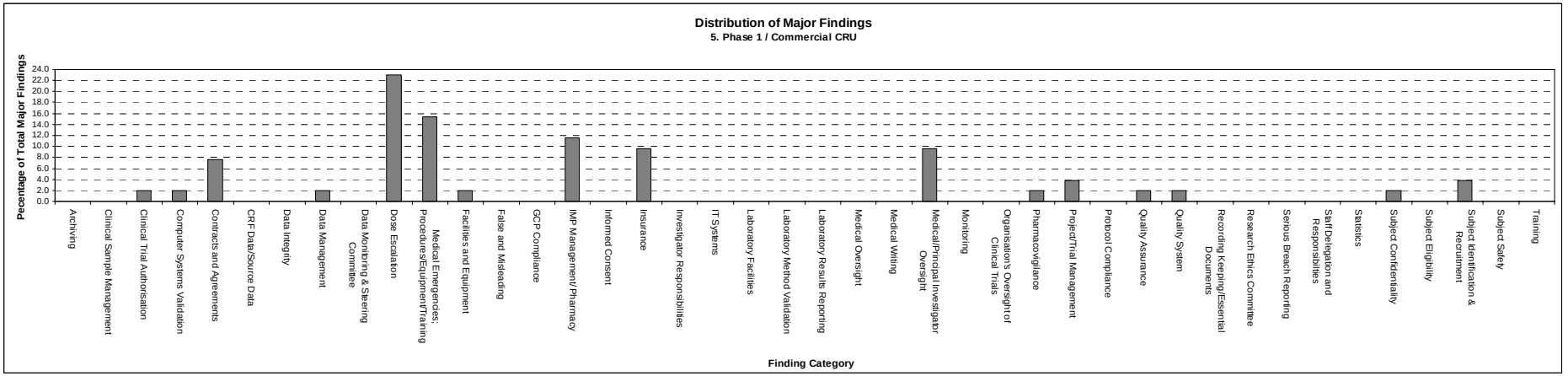
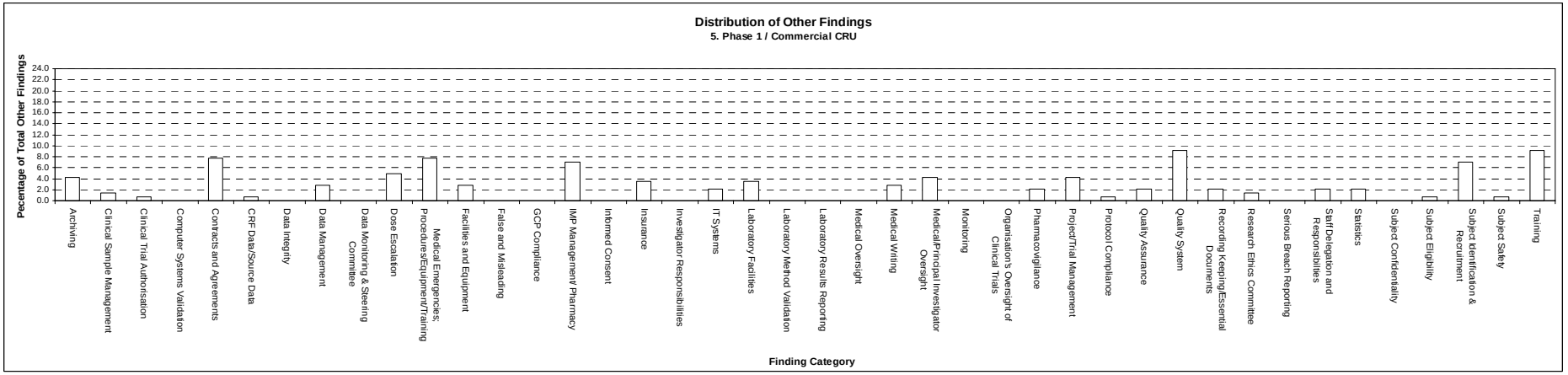
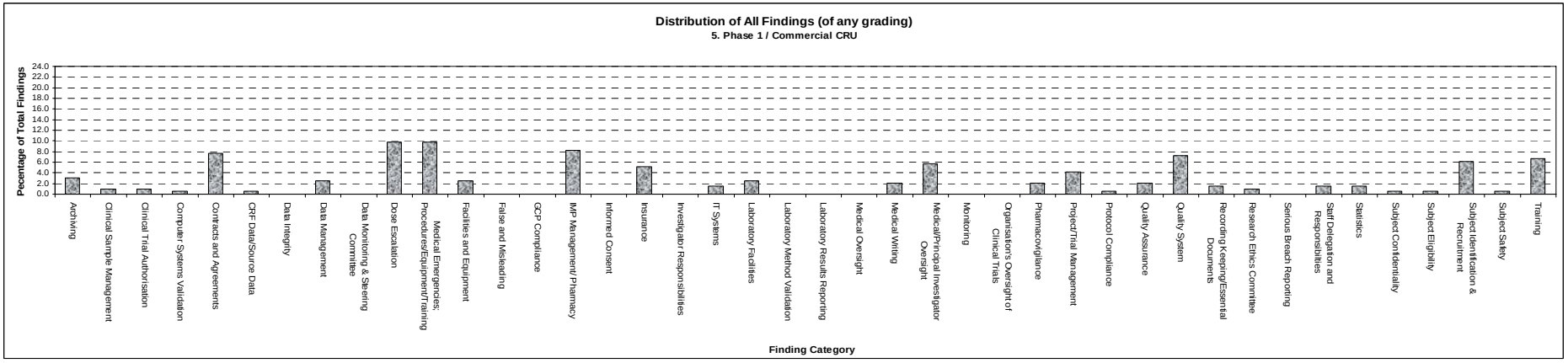

Distribution of Major Findings
5. Phase 1 / Commercial CRU
Pecentage of Total Major Findings
Finding Category

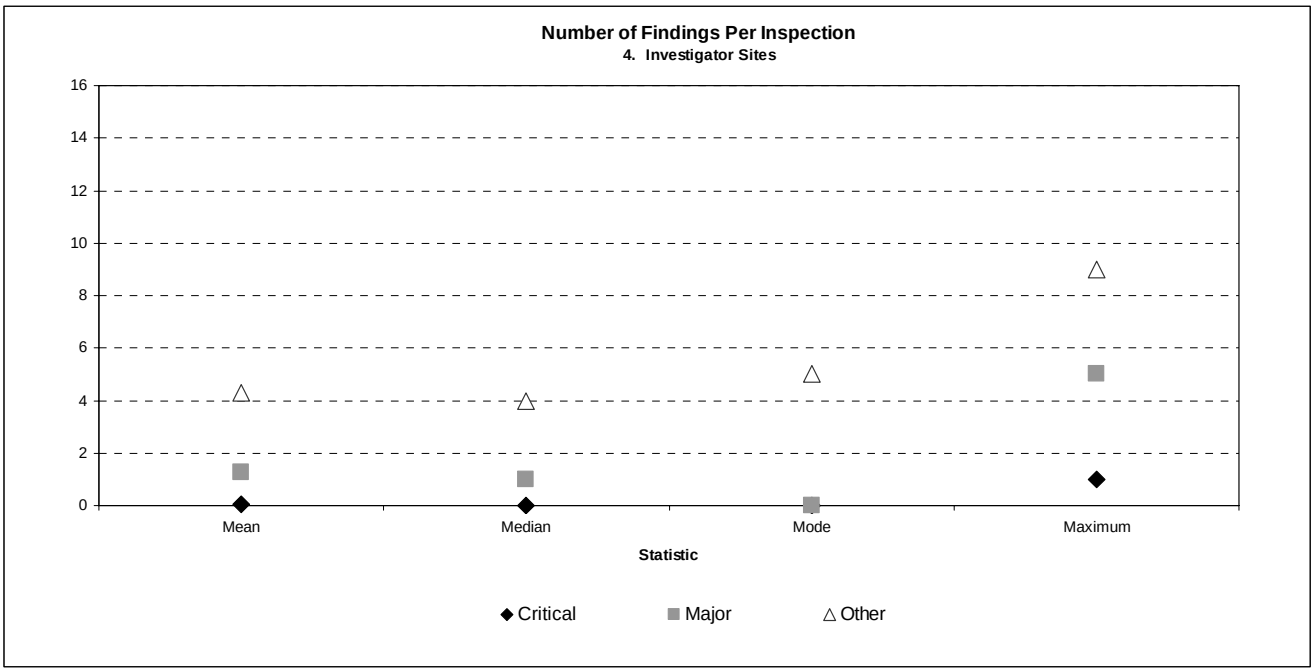

Distribution of Other Findings
5. Phase 1 / Commercial CRU
Pecentage of Total Other Findings
Finding Category


Distribution of All Findings (of any grading)
5. Phase 1 / Commercial CRU
Pecentage of Total Findings
Finding Category

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

A total of 32 investigator sites in the UK were inspected. One of these was a study specific inspection that required its own report rather than an associated site of a sponsor/CRO inspection.

Of the 32 inspections, 2 (6.3%) had at least one critical finding and 20 (62.5%) 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 2 critical findings, one each reported from 2 investigator sites.

The first was a finding given concerning accountability of Investigational Medicinal Products. There were inadequate and erroneous records of the preparation times of the intravenous infusions used as IMP. A high proportion of infusions given to patients (64%) showed serious errors in the documentation to prevent reconstruction.

A critical finding was given for a breach of subject confidentiality. A review of X-ray images sent from the investigator site to an external organisation indicated that subject confidentiality was breached as patient personal identifiers (including name, date of birth, hospital number) were in all x-ray images sent to the external organisation for centralised reading. This deficiency demonstrated the systematic failure for the sponsor and its representative to protect patient confidentiality.

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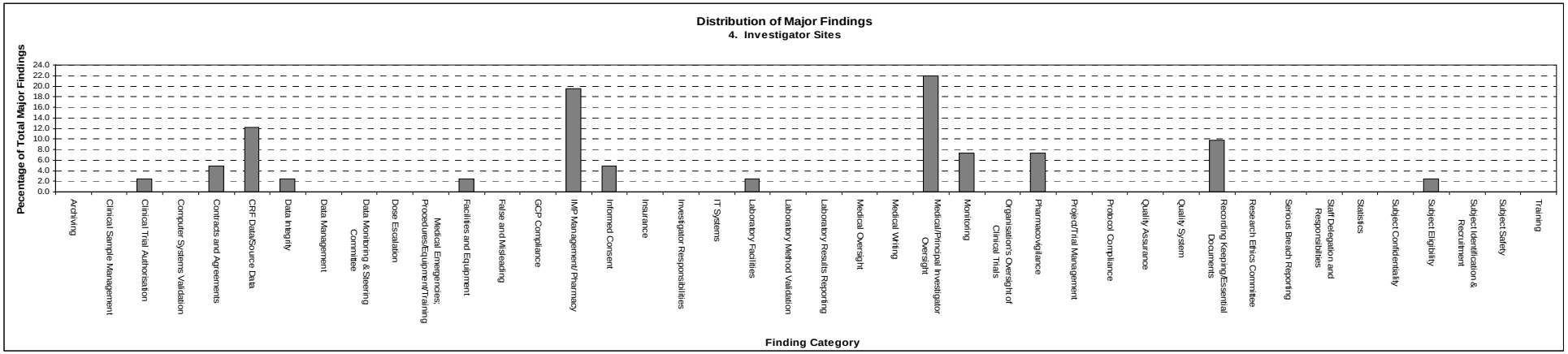
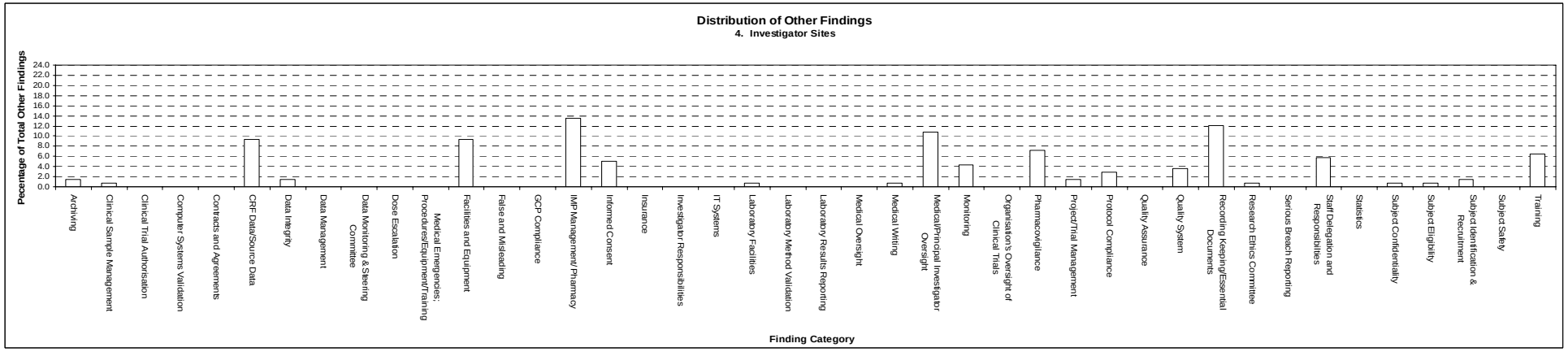

Distribution of Major Findings
4. Investigator Sites
Pecentage of Total Major Findings
24.0
22.0
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
Archiving
Clinical Sample Management
Clinical Trial Authorisation
Computer Systems Validation
Contracts and Agreements
CRF Data/Source Data
Data Integrity
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
24.0
22.0
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
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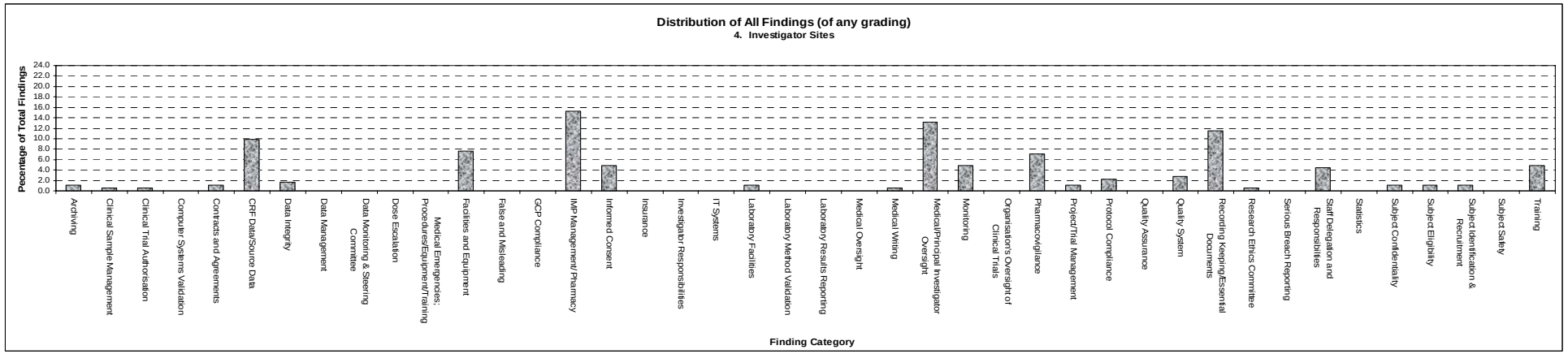
Distribution of All Findings (of any grading)
4. Investigator Sites
Pecentage of Total Findings
24.0
22.0
20.0
18.0
16.0
14.0
12.0
10.0
8.0
6.0
4.0
2.0
0.0
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