Report of Classification, Analysis, and Trending of GCP Inspection Data and Findings

1- **No of inspections conducted in 2022**: 24 GCP inspections
2- **Type of inspection:** Of the 24 conducted GCP inspections, 19 (79%) were routine inspections, 4 (17%) were follow up inspections, and 1 (4%) was Triggered inspection.
3- **Type of Product:** Of the 24 conducted GCP inspections, 12 (50%) were for Pharmaceutical IMP related trials, 11 (46%) for Biological IMPs related trials, and 1 (4%) for Medical Device related trial.
4- **Timing of inspection in relation to Stage of Clinical Trial Conduction:** Of the 24 conducted GCP inspections, 21 (88%) were during the conduction of the trial, 2 (8%) were after the end of the trial, and 1 (4%) was before the initiation of the trial.
5- **Type of Inspected Facility:** Of the 24 conducted GCP inspections, 23 (96%) were at the clinical trial site, and 1 (4%) was at the laboratory.
6- **Geographical Region:** Of the 24 conducted GCP inspections, 19 (79%) were inside Cairo, and 5 (21%) were outside Cairo.
7- **Finding Category:** Of the 95 findings recorded, 42 (44%) belonged to (Quality of Data/Records and Reports Category), 22 (23%) belonged to (Facility and Equipment Category), 8 (9%) belonged to (IMP Category), 8 (9%) belonged to (Trial Quality Management Category), 6 (6%) belonged to (Regulatory Issues Category), 2 (2%) belonged to (Informed Consent Category), 1 (1%) belonged to (IRB category), 1 (1%) belonged to (Subject Safety and Rights Category), and 5 (5%) belonged to (General and Others Category) specifically Protocol Compliance and Personnel.
8- **Finding Grade:** A total of 95 findings, comprising 3 (3 %) critical, 20 (21%) major, and 72 (76%) minor were recorded during the inspections conducted in 2022.
9- **Finding Responsibility:** Fifty Five (58%) of the findings responsibility rests with the Principal Investigator/Institution, 24 (25%) rests with the sponsor, and 16 (17%) rests with the CRO.
10- **Mode of Finding Category:** The most frequently recorded findings belong to the (Records and Reports Category) (44%).
11- **Mode of Finding Category for Critical Grade:** For critical findings, the category (Regulatory Issues) was the most frequently recoded (67%).
12- **Mode of Finding Category for Major Grade:** For major findings, the category (Facility and Equipment) was the most frequently recorded (20%).
13- **Mode of Finding Category for Minor Grade:** For minor findings, the category (Records and Report) was the most frequently recorded (51%).
14- **Number and Percentage of Critical Grade for each Category:** The category (Regulatory Issues) included 2 (33%) critical finding, and the category (Subject Safety

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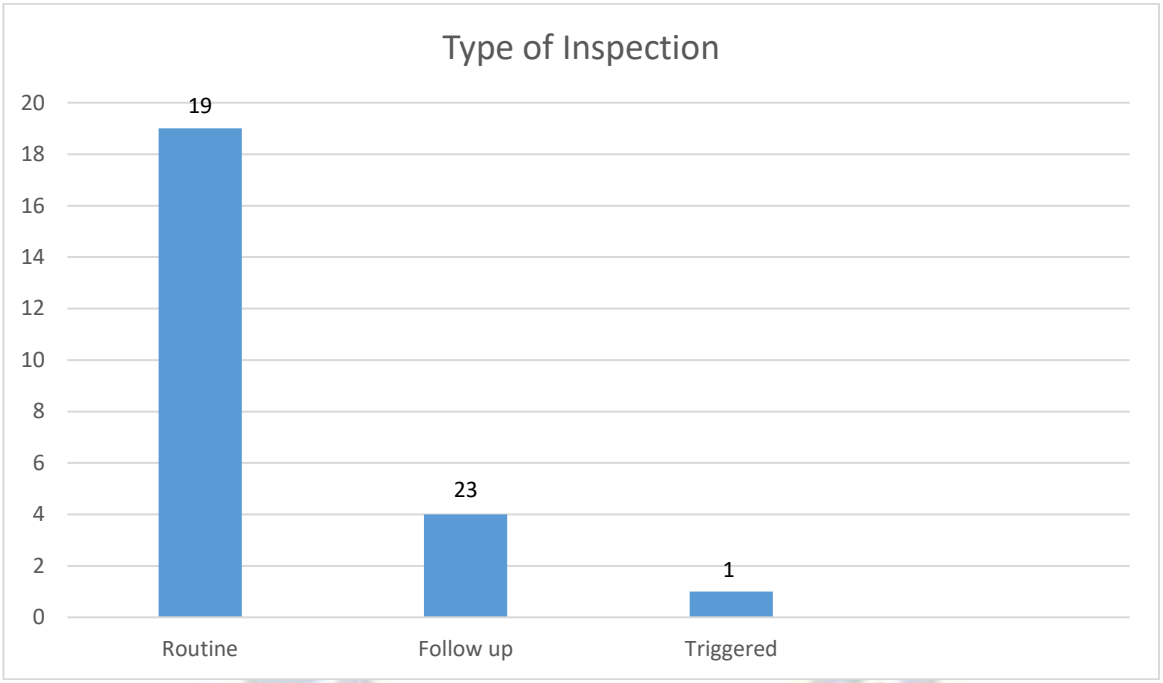
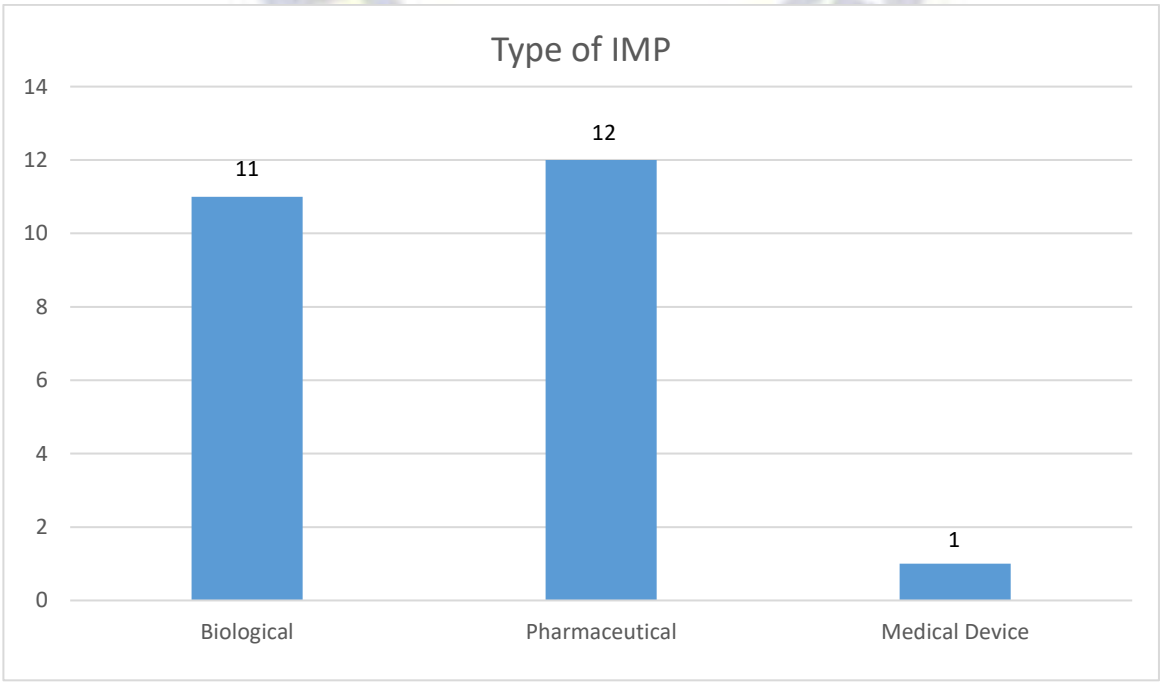
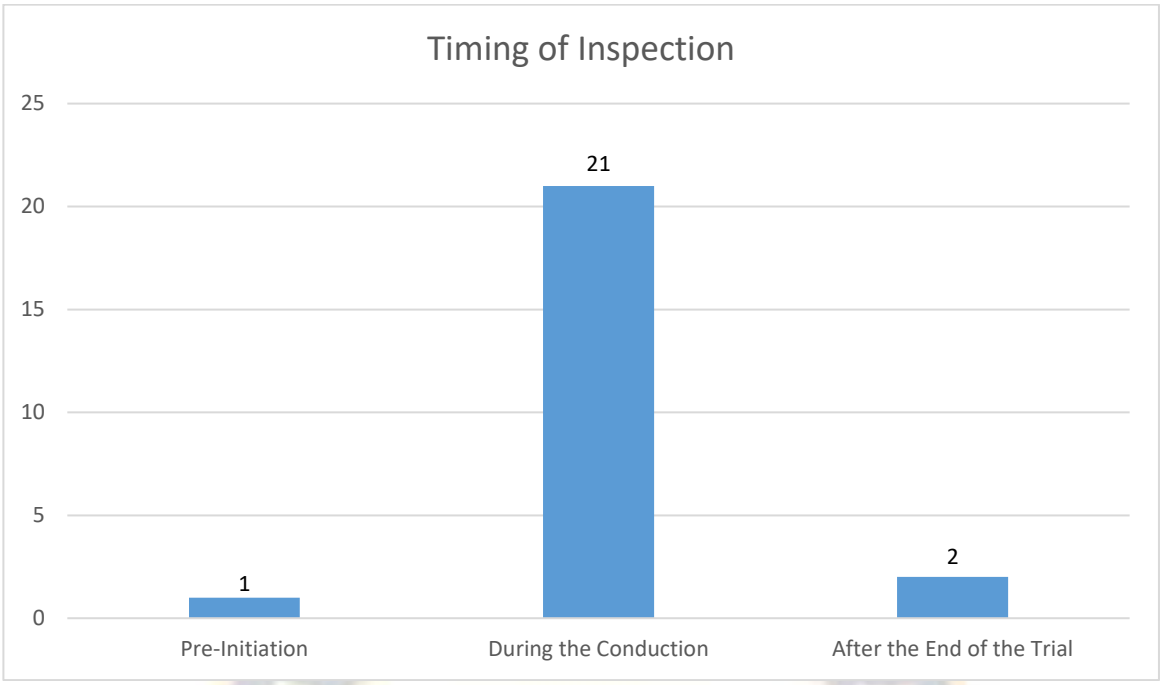
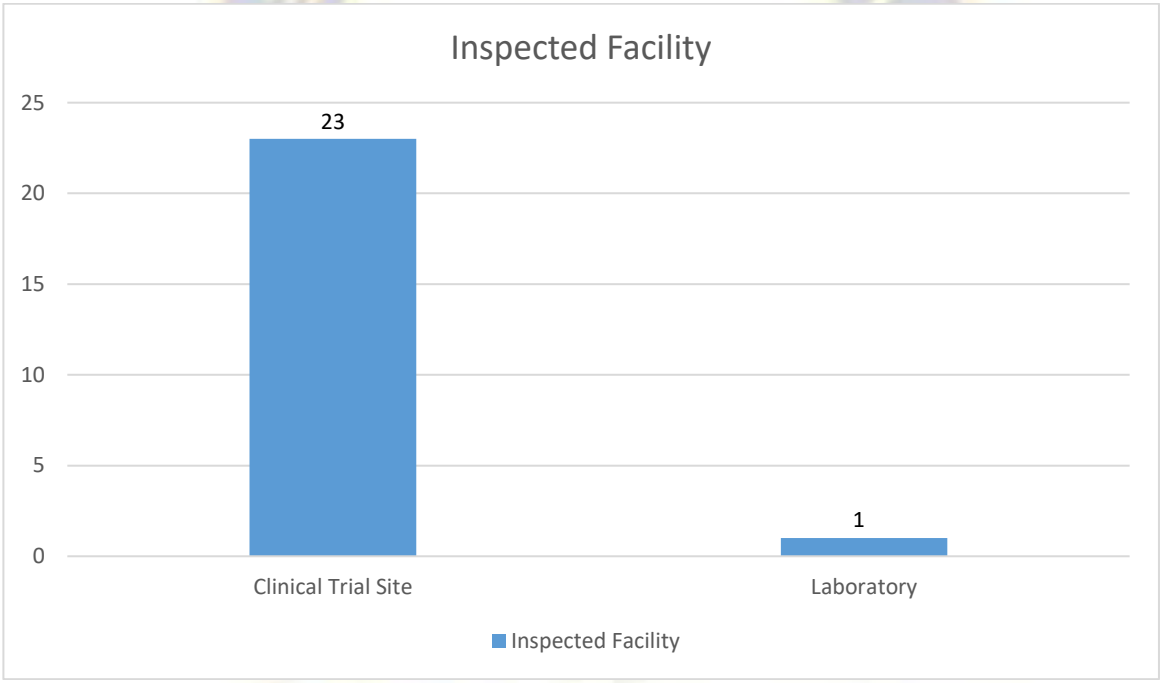
and Rights Category) included 1 (100%) critical finding. No critical findings were recorded for other identified categories.

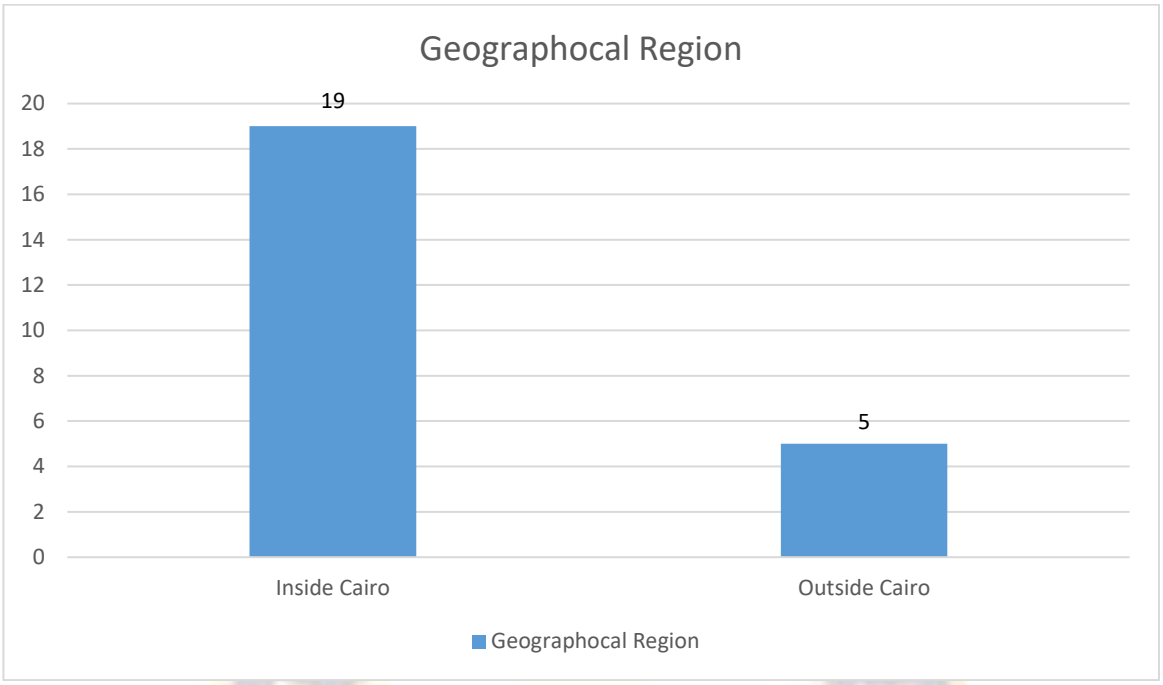
15- **Number and Percentage of Findings' Grades for each Inspected Facility:** All inspection findings were identified at the clinical trial sites, no findings were identified in the inspected laboratory.

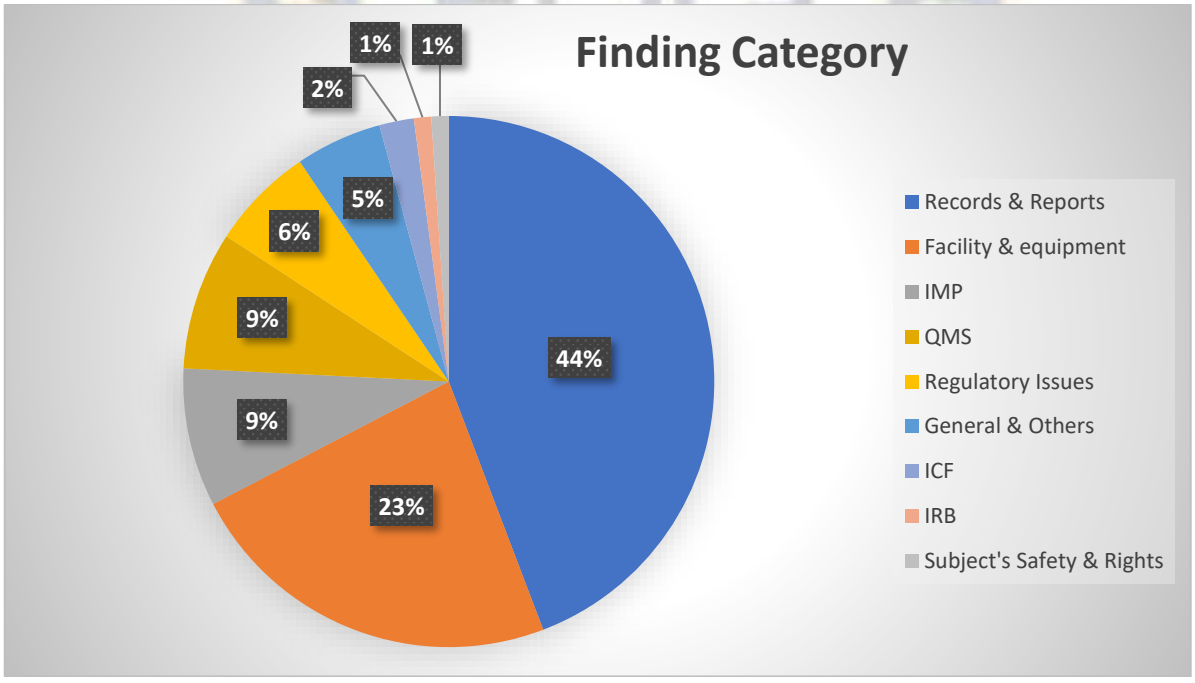


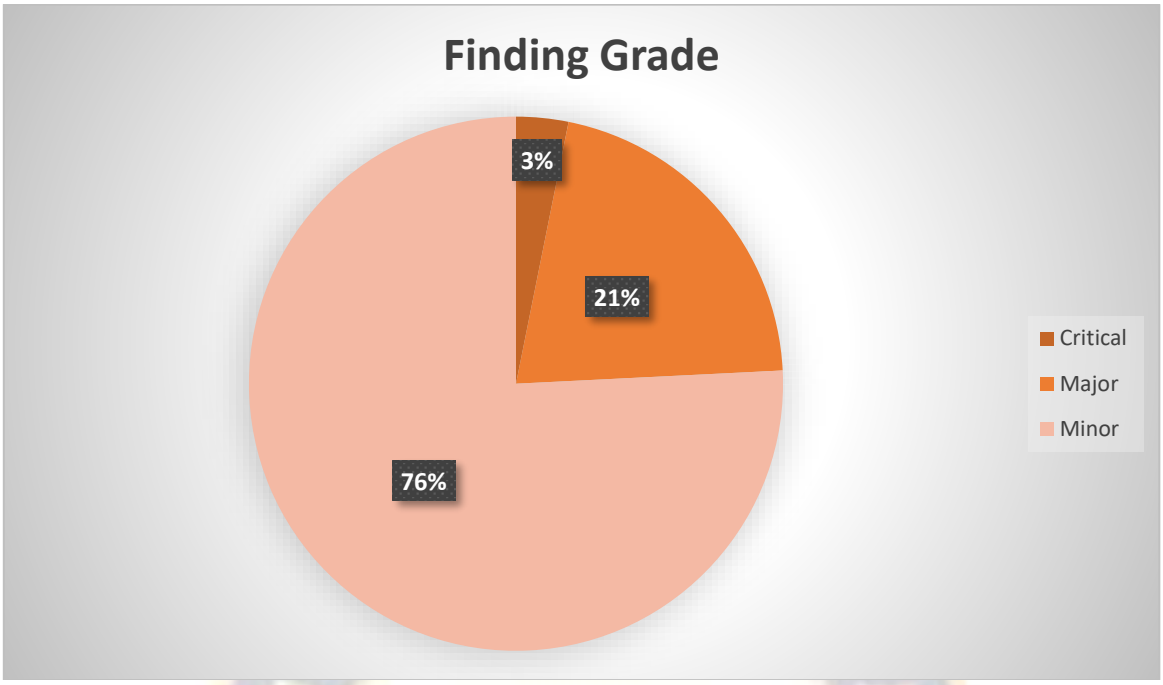


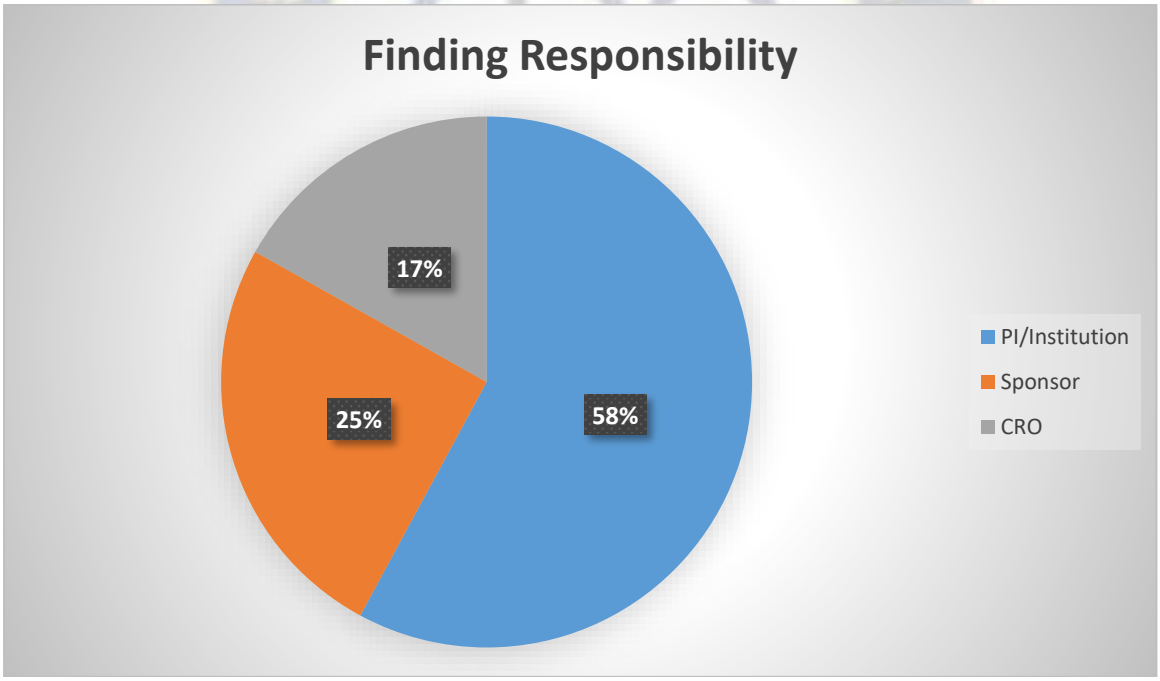

Timing of Inspection
25
20
15
10
5
0
21
1
2
Pre-Initiation
During the Conduction
After the End of the Trial


Inspected Facility
25
20
15
10
5
0
23
1
Clinical Trial Site
Laboratory
Inspected Facility


Geographocal Region
20
18
16
14
12
10
8
6
4
2
0
19
5
Inside Cairo
Outside Cairo
Geographocal Region


Finding Category
1%
1%
2%
5%
6%
9%
9%
44%
23%
Records & Reports
Facility & equipment
IMP
QMS
Regulatory Issues
General & Others
ICF
IRB
Subject's Safety & Rights


Finding Grade
3%
21%
76%
Critical
Major
Minor


Finding Responsibility
17%
25%
58%
PI/Institution
Sponsor
CRO

Conclusion:

- Most of the inspections were conducted at the clinical trial site, only one inspection was conducted at laboratory (related entity). However, it is planned to increase the share of inspection on other related entities in next years based on risk –based approach.
- Critical findings accounted only for 3% of the total findings, and the majority were graded as minor which indicates acceptable level of compliance to GCP principles.
- Most of the critical findings belonged to the category (Regulatory Issues) which may be explained by the relatively recent issuance of regulations. This concern is being covered by continuous awareness of applicants through workshops and answering of all regulatory questions asked by the applicants via email.
- The trend of deficiencies comes from the category (Records and Reports), although most of findings in this category are graded minor, however; it represents an area of concern for attention in all planned inspections.
- The majority of findings' responsibility rests with the Principal Investigator, for this the General Administration of Clinical Trials is heading for providing a unified GCP training and certification for all involved PIs.