

# **GCP INSPECTION QUESTIONNAIRE**

## **Analysis of Returns**

### **1. Introduction**

Questionnaires were drawn up to seek feedback from sponsors and CROs and separately from investigators at investigator sites concerning the conduct of GCP inspections. The questionnaires comprised fifteen and thirteen questions respectively of a non-technical nature, regarding pre-inspection activities, the opening meeting, conduct of the inspection, the closing meeting and the inspection report. An additional question asked whether the organisation or investigator site felt that they had benefited from the inspection.

A total of thirty completed questionnaires were returned to the undersigned for analysis. These comprised eighteen from sponsors and CROs and twelve from investigators. The respondents were invited to assign a score to each question ranging from 1 (totally dissatisfied) to 4 (totally satisfied) or to indicate if the question was not applicable. Respondents were invited also to add comments after each section of the questionnaire. The inspections covered by the questionnaire took place in 2007 and 2008.

### **2. Method**

The number of responses per question in each score category from 1 to 4, including the “not applicable” scores, were tabulated against the question numbers for each of the questionnaire types (Tables 1 and 2). An additional table was drawn up for the eleven questions common to both types (Table 3). The numbers of responses for each question were multiplied by the relevant score and the total score for each was used to calculate the perceived performance level as a percentage of the maximum possible score, taking the “not applicable” scores into consideration.

### **3. Results**

#### **3.1 Sponsors and CROs**

Table 1 shows that out of a possible 266 scores, taking into account the number of “not applicables”, only eight scores (3%) were in the dissatisfied category, with none in the totally dissatisfied category. Eighty-three scores (31%) were in the satisfied category and 175 scores (66%) were in the totally satisfied category. The overall satisfaction rate was 93%. The lowest satisfaction rate (79%) was for question 1.4 (Do you consider that completion of the SCTS will be of value to your organisation’s quality system for clinical trial activities?). Four of the eight “dissatisfied” scores resulted from one inspection, but the respondent and his/her organisation wished to remain anonymous.

#### **3.2 Investigators**

Table 2 shows that out of a possible 142 scores, taking into account the number of “not applicables”, only four scores (3%) were in the dissatisfied category, with none in the totally dissatisfied category. Forty scores (28%) were in the satisfied category and 98 scores (69%) were in the totally satisfied category. The overall satisfaction rate was 91%. The lowest satisfaction rate (85%) was for questions 3.1 (Did the inspection start punctually each day and at the times agreed?) and 5.1 (How well did the sponsor/CRO work with you post-inspection to

address the deficiencies identified during inspection?). The comparatively large number of “not applicable” scores are attributable to respondents who were not able to attend the closing meeting or to intended respondents who had left the organisation and for whom substitute respondents were unable to answer particular questions.

### 3.3 Common questions for sponsors, CROs and investigators

Table 3 presents data for those questions that are common to both questionnaires. The combined overall satisfaction rate was 93% with lowest (87%) for question 1.1 concerning communication between the GCP Inspectorate and the site/organisation before the inspection.

## 4. **Comments from respondents**

### 4.1 Sponsors and CROs

Twenty nine comments were recorded on the returned questionnaires. Twelve of these described the helpfulness and professionalism of the inspectors. Nine comments amounted to major or minor criticism, five of which concerned the time between the inspection and the receipt of the report. One concerned an unexpected GMP inspector participation in the inspection. Of the remaining comments, two suggested that positive comments might be included in reports.

### 4.2 Investigators

Seventeen comments were recorded on the returned questionnaires. Eight of these described the courtesy and professionalism of the inspectors. Four comments amounted to criticism, three of which concerned the time between the inspection and receipt of the report.

NOTE: The GCP Inspectorate only send reports directly to sponsors/CROs and therefore cannot influence how sponsors interact with investigators, the impact on investigators' clinical works and their perceptions on the timeliness of the reports

## 5 **Observations**

The results of the exercise reflect well on the competence and professionalism of the GCP inspectors. The overall satisfaction rates of sponsors, CROs and investigators were high; only three percent of the questions resulted in a “dissatisfied” score. There was no particular pattern associated with the low scores, except that 50% of those from sponsors and CROs were recorded by one organisation which wished to remain anonymous.

The lowest satisfaction rate concerned the usefulness of the summary of clinical trial systems (SCTS) although it is difficult to view this as a problem with the inspection process. Lower satisfaction rates were also seen concerning the inspection report and the comments recorded by the respondents concerning the time between the inspection and receipt of the inspection report is a reflection of this. It must be noted that although rates of 82% and 85% in this regard do not indicate a critical situation, there is a strong suggestion that action is needed in this area.

In conclusion, the results of the exercise indicate that there is a high degree of satisfaction with the conduct of GCP inspections as seen by sponsors, CROs and investigators and with the performance of the inspectors themselves.

**Table 1**

**GCP questionnaire for sponsors and CROs: number of scores per category**

Question	SCORE					Percentage of maximum possible score
	N/A	1	2	3	4	
Was there adequate communication between the MHRA and your organisation before the inspection?			1	8	9	85
Were the requests for information contained in the pre-inspection letter clearly put?				7	11	90
Do you consider that completion of the pre-inspection letter aided the inspection process?				13	5	82
Do you consider that completion of the Summary of Clinical Trial Systems (SCTS) will be of value to your organisation's quality system for Clinical Trial activities?	1		3	8	6	79
Was the purpose of the inspection clearly explained?	1			2	15	97
Was an outline of the inspection plan presented?	1			2	15	97
Did the inspection start punctually each day and at the times agreed?				3	15	96
Was the inspection carried out efficiently, professionally and courteously?				2	16	97
Were the inspection questions clearly put?				6	12	92
Did the inspection team acknowledge any constraints in obtaining requested documents or access to personnel?	1			6	11	91
Was the classification system for deficiencies (i.e. critical, major and other) explained clearly?			1	2	15	94
Were the actual inspection deficiencies presented clearly?			1	6	11	89
Were you informed about the next steps in the inspection process?				5	13	93
Were the deficiencies (and any examples/evidence cited) accurately and clearly presented?			2	9	7	82
Do you feel that your organisation has benefited from the inspection?				4	14	94

**Table 2**

**GCP questionnaire for investigators: number of scores per category**

Question	SCORE					Percentage of maximum possible score
	N/A	1	2	3	4	
Was there adequate communication between the MHRA GCP Inspectorate and your site before the inspection? (if appropriate)	1			4	7	91
Was there adequate communication between the Sponsor/CRO and your site before the inspection?	3			3	6	92
Was the purpose of the inspection clearly explained?				3	9	94
Was an outline of the inspection plan presented?				3	9	94
Did the inspection start punctually each day and at the times agreed?			1	4	7	85
Was the inspection carried out efficiently, professionally and courteously?				1	11	98
Were the inspection questions clearly put?				2	10	96
Did the inspection team acknowledge any constraints in obtaining requested documents or access to personnel?				3	9	94
Was the classification system for deficiencies (i.e. critical, major and other) explained clearly?	2			3	7	93
Were the actual inspection deficiencies presented clearly?	2		1	3	6	88
Were you informed about the next steps in the inspection process?	2		1	2	6	88
How well did the sponsor / CRO work with you post-inspection to address the deficiencies identified during inspection?	2		1	4	5	85
Do you feel that your investigator site has benefited from the inspection?	2			4	6	90

**Table 3****GCP questionnaire, common questions for sponsors, CROs and investigators: number of scores per category**

Question	SCORE					Percentage of maximum possible score
	N/A	1	2	3	4	
Was there adequate communication between the MHRA and your organisation before the inspection?	1		1	12	16	87
Was the purpose of the inspection clearly explained?	1			5	24	96
Was an outline of the inspection plan presented?	1			5	24	96
Did the inspection start punctually each day and at the times agreed?			1	7	22	92
Was the inspection carried out efficiently, professionally and courteously?				3	27	98
Were the inspection questions clearly put?				8	22	93
Did the inspection team acknowledge any constraints in obtaining requested documents or access to personnel?	1			9	20	92
Was the classification system for deficiencies (i.e. critical, major and other) explained clearly?	2		1	5	22	94
Were the actual inspection deficiencies presented clearly?	2		1	8	19	91
Were you informed about the next steps in the inspection process?	2		1	8	19	91
Do you feel that your organisation has benefited from the inspection?	2			8	20	93