Medicines & Healthcare products Regulatory Agency

Annual Review of MHRA GCP Referrals: 2022

Period covered: January – December 2022

Cumulative Summary:

Total Referrals				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Total	37	84	1	122

Type of Trial				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Commercial	32	62	0	94
Non-Commercial	5	22	1	28
Grand Total	37	84	1	122

Type of Notifying Organisation**				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
CRO	9	19	0	28
HRA	2	4	0	6
Investigator	1	1	0	2
MHRA	0	1	0	1
Other	0	2	1	3
Sponsor	23	54	0	77
Trust	2	3	0	5
Public	0	0	0	0
Grand Total	37	84	1	122

Actual impact				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Both Patient Safety and Data Integrity	0	2	0	2
Data Integrity	0	9	0	9

Actual impact				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Patient safety / physical / mental integrity	1	14	0	15
Awaiting Final Determination*	0	1	1	2
No significant impact***	36	58	0	94
Grand Total	37	84	1	122

Area of Non-Compliance				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Archiving	0	1	0	1
Clinical Sample Analysis	1	1	0	2
Clinical Sample Management	2	1	0	3
Competent Authority	2	3	0	5
Computer Systems Validation	0	2	0	2
Data Integrity	2	2	0	4
Data Integrity Control Processes	3	0	0	3
Data Management	1	0	0	1
GCP Compliance	0	2	0	2
IMP Management / Pharmacy	6	21	0	27
Informed Consent	1	4	0	5
IT Systems	1	1	0	2
Laboratory Facilities and Equipment	0	1	0	1
Laboratory Results Reporting	1	0	0	1
Medical Oversight by the Principal Investigator	2	4	0	6
Project/Trial Management	1	4	0	5
Protocol Compliance	4	6	0	10
Record Keeping/Essential Documents	1	1	0	2
Research Ethics Committee	2	5	0	7
Statistics	1	0	0	1
Subject Confidentiality	3	10	0	13
Subject Eligibility	0	4	1	5
Subject Identification & Recruitment	1	1	0	2
Subject Safety	1	10	0	11
Training	1	0	0	1
Grand Total	37	84	1	122

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Action/Outcome				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Urgent Triggered Inspection	0	0	0	0
Recommend Triggered Inspection	0	0	0	0
Recommend Routine Inspection	0	0	0	0
Review at next scheduled inspection	6	15	0	21
Urgent Action	0	0	0	0
Non-urgent Action	0	1	0	1
Request further information for Serious Breach determination	2	2	0	4
In-house Follow-up	11	35	0	46
No action required	18	31	0	49
Awaiting Final Determination*	0	0	1	1
Grand Total	37	84	1	122

* Awaiting final determination of serious breach following completion of investigation by reporter
** Sponsors are required to report serious breaches but other parties, who have a concern that a breach has occurred, are also able to report (e.g., if the sponsor refuses to report)
***As per Regulation 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 [Statutory Instrument 2004/1031 and subsequent amendments], the definition of a serious breach includes that which is likely to effect to a significant degree the safety or physical or mental integrity of the subjects of the trial; or the scientific value of the trial. Therefore, a reported breach can still meet the definition of a serious breach if it has significant potential to affect these aspects, despite ultimately having no significant impact.