Medicines & Healthcare products Regulatory Agency

Annual Review of MHRA GCP Referrals: 2021

Period covered: January – December 2021

Cumulative Summary:

Total Referrals				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Total	25	80	1	106

Type of Trial				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Commercial	18	59	0	77
Non-Commercial	7	21	1	29
Grand Total	25	80	1	106

Type of Notifying Organisation**				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
CRO	5	15	0	20
HRA	1	2	1	4
Investigator	0	0	0	0
MHRA	0	2	0	2
Public	1	0	0	1
Sponsor	17	58	0	75
Trust	1	0	0	1
Other	0	3	0	3
Grand Total	25	80	1	106

Actual impact				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Patient Safety/physical/mental integrity	4	18	0	22
Data Integrity	3	11	0	14
Both Patient Safety and Data Integrity	3	5	0	8
No significant impact***	15	46	0	61
Awaiting Final Determination*	0	0	1	1
Grand Total	25	80	1	106

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Area of Non-Compliance				
Serious Breach?	**No**	**Yes**	**Awaiting Final Determination***	**Grand Total**
Archiving	1	0	0	1
Clinical Sample Analysis	0	1	0	1
Clinical Sample Management	1	0	0	1
Competent Authority	1	6	0	7
Computer Systems Validation	1	3	0	4
CRF Data / Source Data	1	0	0	1
Data Integrity	0	4	0	4
Data Integrity Control Processes	2	2	0	4
Data Management	0	1	0	1
Dose Escalation	1	0	0	1
Facilities and Equipment	0	1	0	1
False and Misleading	2	0	0	2
GCP Compliance	0	3	1	4
IMP Management / Pharmacy	6	15	0	21
Informed Consent	1	10	0	11
Laboratory Results Reporting	0	2	0	2
Medical Oversight by the Principal Investigator	0	2	0	2
Pharmacovigilance	0	10	0	10
Project/Trial Management	0	2	0	2
Protocol Compliance	2	6	0	8
Research Ethics Committee	1	3	0	4
Staff Delegation & Responsibilities	0	1	0	1
Subject Confidentiality	1	1	0	2
Subject Eligibility	2	5	0	7
Subject Identification & Recruitment	2	0	0	2
Subject Safety	0	2	0	2
Grand Total	25	80	1	106

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	1	20	0	21
Urgent Action	0	2	0	2
Non-urgent Action	0	0	0	0
Request further information for Serious Breach determination	3	5	0	8
In-house Follow-up	8	35	0	43
None	13	18	0	31
Awaiting Final Determination*	0	0	1	1
Grand Total	25	80	1	106

* Awaiting final determination of serious breach following 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.