

## Annual Review of MHRA GCP Referrals: 2020

Period covered: January – December 2020

### Cumulative Summary:

Total Referrals				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
Total	26	51	2	79

Type of Trial				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
Commercial	19	36	1	56
Non-Commercial	7	15	1	23
Grand Total	26	51	2	79

Type of Notifying Organisation**				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
CRO	3	5	1	9
HRA	0	2	0	2
Investigator	0	1	0	1
MHRA	1	1	0	2
Public	1	1	0	2
Sponsor	19	39	1	59
Other	2	2	0	4
Grand Total	26	51	2	79

Impact/Reason for Serious Breach				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
Approval issues	1	3	0	4
IMP	0	2	0	2
Patient Confidentiality	0	3	0	3
Patient Safety	0	17	1	18
Data Integrity	1	8	0	9
Both Patient Safety and Data Integrity	0	4	1	5
No significant impact***	20	13	0	33
Other	1	1	0	2
N/A	3	0	0	3
Grand Total	26	51	2	79

Outcome/Action				
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	9	0	9
Review at next scheduled inspection	0	4	0	4
Urgent Action	0	1	0	1
Non-urgent Action	0	0	0	0
Request further information for Serious Breach determination	1	0	0	1
In-house Follow-up	9	27	0	36
None	16	10	0	26
Awaiting Final Determination	0	0	2	2
Grand Total	26	51	2	79

\* 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.