

## Annual Review of MHRA GCP Referrals: 2019

Period covered: January – December 2019

### Cumulative Summary:

Total Referrals				
Serious Breach?	No	Yes	Awaiting Final Determination *	Grand Total
Total	36	75	1	112

Type of Trial				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
Commercial	21	43	0	64
Non-Commercial	15	32	1	48
Grand Total	36	75	1	112

Type of Notifying Organisation **				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
CRO	8	16	0	24
HRA	0	0	0	0
Investigator	1	0	0	1
MHRA	2	0	1	3
Public	0	0	0	0
Sponsor	25	58	0	83
Trust	0	1	0	1
Grand Total	36	75	1	112

Impact/Reason for Serious Breach				
Serious Breach?	No	Yes	Awaiting Final Determination *	Grand Total
Approval Issues	4	5	1	10
IMP	3	6	0	9
N/A	3	0	0	3
Other	5	4	0	9
Patient Confidentiality	2	1	0	3
Patient Safety	12	44	0	56
Scientific Value/Data Credibility	7	15	0	22
Grand Total	36	75	1	112

Outcome/Action				
Serious Breach?	No	Yes	Awaiting Final Determination *	Grand Total
In-house Follow-up	20	54	0	74
None	16	9	0	25
Recommend Routine Inspection	0	11	0	11
Recommend Triggered Inspection	0	1	0	1
Awaiting Final Determination	0	0	1	1
Grand Total	36	75	1	112

\* 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)