

Annual Review of MHRA GCP Referrals: 2018

Period covered: January – December 2018

Cumulative Summary:

Total Referrals				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
Total	24	76	15	115

Type of Notifying Organisation				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
CRO	3	7	1	11
MHRA	1	0	0	1
Public	0	0	0	0
Sponsor	20	65	14	99
Trust	0	4	0	4
HRA	0	0	0	0
Whistle-blowers	0	0	0	0
Grand Total	24	76	15	115

Impact/Reason for Serious Breach				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
NA	2	0	1	3
Scientific value / data credibility	4	7	2	13
Patient safety	9	35	5	49
Other Non-compliances	6	16	2	24
IMP	2	8	4	14
Approval Issues	0	4	0	4
Patient confidentiality	1	6	1	8
Grand Total	24	76	15	115

Outcome/Action				
Serious Breach?	No	Yes	Awaiting Final Determination*	Grand Total
In-house Follow-up	10	45	5	60
Urgent Triggered Inspection	0	1	0	1
Recommend Triggered Inspection	0	5	0	5
Recommend Routine Inspection	0	9	0	9
None	14	16	9	39
Transferred	0	0	0	0
Grand Total	24	76	15	115

*Awaiting final determination of serious breach following investigation by reporter.