Annual Review of MHRA GCP Referrals: 2017

Period covered: January – December 2017

Cumulative Summary:

Total Referrals				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Total	47	101	1	149

Type of Notifying Organisation				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Sponsor	40	95	1	136
CRO	2	3	0	5
Trust	0	2	0	2
Investigator	0	0	0	0
HRA	1	0	0	1
Whistleblowers	1	0	0	1
Other	3	1	0	4
Grand Total	47	101	1	149

Impact/Reason for Serious Breach				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Approval issues	4	9	0	13
IMP	6	15	0	21
Other non-compliances	9	14	0	23
Patient confidentiality	0	6	0	6
Patient safety	8	42	1	51
Scientific value / data credibility	11	14	0	25
N/A	9	1	0	10
Grand Total	47	101	1	149

Outcome/Action				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
In-house Follow-up	12	57	0	69
None	31	30	0	61
Recommend Routine Inspection	3	11	0	14
Recommend Triggered Inspection	0	1	0	1
Transferred	1	1	0	2
Pending	0	1	1	2
Grand Total	47	101	1	149