Annual Review of MHRA GCP Referrals: 2016

Period covered: January – December 2016

Cumulative Summary:

Total Referrals				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Total	33	78	1	112

Type of Notifying Organisation				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Sponsor	21	61	1	83
CRO	6	9	0	15
Trust	1	3	0	4
Investigator	1	3	0	4
HRA	1	1	0	2
Whistleblowers	2	0	0	2
Other	1	1	0	2
Grand Total	33	78	1	112

Impact/Reason for Serious Breach				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
NA	6	0	0	6
Scientific value / data credibility	6	13	0	19
Patient safety	16	39	0	55
Other Non-compliances	1	11	0	12
IMP	4	8	1	13
Approval Issues	0	4	0	4
Patient confidentiality	0	3	0	3
Grand Total	33	78	1	112

Outcome/Action				
Serious Breach?	**No**	**Yes**	**Pending**	**Grand Total**
Pending	0	0	1	1
In-house Follow-up	7	55	0	62
Urgent Triggered Inspection	0	0	0	0
Recommend Triggered Inspection	0	2	0	2
Recommend Routine Inspection	2	5	0	7
None	24	16	0	40
Transferred	0	0	0	0
Grand Total	33	78	1	112