

Annual Review of MHRA GCP Referrals: 2014

Period covered: January – December 2014

Cumulative Summary:

Total Referrals			
Serious Breach?	No	Yes	Grand Total
Total	36	68	104

Type of Notifying Organisation			
Serious Breach?	No	Yes	Grand Total
CRO	5	4	9
MHRA	0	0	0
Public	6	0	6
Sponsor	23	62	85
Trust	0	1	1
HRA	1	0	1
Whistle-blowers	1	1	2
Grand Total	36	68	104

Impact/Reason for Serious Breach			
Serious Breach?	No	Yes	Grand Total
NA	5	1	6
Scientific value / data credibility	4	12	16
Patient safety	11	32	43
Other Non-compliances	8	11	19
IMP	2	9	11
Approval Issues	4	2	6
Patient confidentiality	2	1	3
Grand Total	36	68	104

Outcome/Action			
Serious Breach?	No	Yes	Grand Total
In-house Follow-up	9	35	44
Recommend Triggered Inspection	0	1	1
Recommend Routine Inspection	1	11	12
None	24	20	44
Transferred	2	1	3
Grand Total	36	68	104