

Annual Review of MHRA GCP Referrals: 2013

Period covered: January – December 2013

Cumulative Summary:

Total Referrals			
Serious Breach?	No	Yes	Grand Total
Total	39	76	115

Type of Notifying Organisation			
Serious Breach?	No	Yes	Grand Total
CRO	1	9	10
MHRA	1	0	1
Public	4	0	4
Sponsor	23	62	85
Trust	2	3	5
NRES	2	0	2
Other	0	1	1
Whistle-blowers	5	0	5
EMA/EU inspectorate	1	1	2
Grand Total	39	76	115

Impact/Reason for Serious Breach			
Serious Breach?	No	Yes	Grand Total
NA	4	0	4
Scientific value / data credibility	5	24	29
Patient safety	13	36	49
Other Non-compliances	8	12	20
IMP	4	0	4
Approval Issues	2	2	4
Patient confidentiality	3	2	5
Grand Total	39	76	115

Outcome/Action			
Serious Breach?	No	Yes	Grand Total
In-house Follow-up	8	44	52
Urgent Triggered Inspection	0	3 (10)*	10
Recommend Routine Inspection	3	3	6
None	27	19	46
Transferred	1	0	1
Grand Total	39	76	115

* A total of 10 breaches led to triggered inspections as follows:

3 triggered inspections were performed in 2013, one in relation to 6 breaches, the other 2 in relation to one breach per inspection. One remaining triggered inspection is to be performed in January 14 in relation to 2 breaches.