

Annual Review of MHRA GCP Referrals: 2011

Period covered: January – December 2011

Cumulative Summary:

Total Referrals			
Serious Breach?	No	Yes	Grand Total
Total	25	70	95

Type of Notifying Organisation			
Serious Breach?	No	Yes	Grand Total
CRO	1	2	3
MHRA	1	1	2
Public	2	0	2
Sponsor	15	50	65
Trust	4	16	20
Investigator	0	0	0
NRES	2	1	3
Other	0	0	0
Grand Total	25	70	95

Impact/Reason for Serious Breach			
Serious Breach?	No	Yes	Grand Total
Not Applicable	1	0	1
Scientific value / data credibility	2	15	17
Patient safety	11	29	40
Other Non-compliances	5	6	11
IMP	4	10	14
Approval Issues	1	7	8
Patient confidentiality	1	3	4
Grand Total	25	70	95

Outcome/Action			
Serious Breach?	No	Yes	Grand Total
<i>Still to be determined</i>	0	0	0
In-house Follow-up	5	30	35
Urgent Triggered Inspection	0	3	3
Recommend Triggered Inspection	1	3	4
Recommend Routine Inspection	0	5	5
None	18	29	47
Transferred	1	0	1
Grand Total	25	70	95