

## Annual Review of MHRA GCP Referrals: 2015

Period covered: January – December 2015

### Cumulative Summary:

<b>Total Referrals</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
Total	34	71	105

<b>Type of Notifying Organisation</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
CRO	9	3	12
MHRA	0	1	1
Public	0	0	0
Sponsor	23	65	88
Trust	1	1	2
HRA	1	1	2
Whistle-blowers	0	0	0
Grand Total	34	71	105

<b>Impact/Reason for Serious Breach</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
NA	1	0	1
Scientific value / data credibility	5	11	16
Patient safety	16	45	61
Other Non-compliances	4	10	14
IMP	4	1	5
Approval Issues	3	2	5
Patient confidentiality	1	2	3
Grand Total	34	71	105

<b>Outcome/Action</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
In-house Follow-up	6	38	44
Urgent Triggered Inspection	0	2	2
Recommend Triggered Inspection	0	4	4
Recommend Routine Inspection	0	6	6
None	28	21	49
Transferred	0	0	0
Grand Total	34	71	105