

## Annual Review of MHRA GCP Referrals: 2012

**Period covered:** January – December 2012

### Cumulative Summary:

<b>Total Referrals</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
Total	29	53	84 (2 unassigned)

<b>Type of Notifying Organisation</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
CRO	4	4	8
MHRA	0	0	0
Public	0	0	2 (unassigned)
Sponsor	18	36	54
Trust	4	11	15
Investigator	0	1	1
NRES	2	1	3
Other	1	0	1
<b>Grand Total</b>	<b>29</b>	<b>53</b>	<b>84 (2 unassigned)</b>

<b>Impact/Reason for Serious Breach</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
Not Applicable	3	0	3
Scientific value / data credibility	5	14	19
Patient safety	8	24	33 (1 unassigned)
Other Non-compliances	3	5	8
IMP	5	6	11
Approval Issues	3	2	6 (1 unassigned)
Patient confidentiality	2	2	4
<b>Grand Total</b>	<b>29</b>	<b>53</b>	<b>84 (2 unassigned)</b>

<b>Outcome/Action</b>			
<b>Serious Breach?</b>	<b>No</b>	<b>Yes</b>	<b>Grand Total</b>
<i>Still to be determined</i>	0	1	3 (2 unassigned)
In-house Follow-up	4	19	23
Urgent Triggered Inspection	0	3	3
Recommend Triggered Inspection	0	2	2
Recommend Routine Inspection	1	4	5
Transferred	1	0	1
None	23	24	47
<b>Grand Total</b>	<b>29</b>	<b>53</b>	<b>84 (2 unassigned)</b>