

Research Compliance Activity Summary Report
Quality Improvement Office (QIO)
 Fiscal Year 2018 (7/1/2017 to 6/30/2018)

Clinical Research Billing Compliance					
Area Activities					
	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Research Billing - Scheduled Reviews					
• Number of Departments Reviewed	n/a	n/a	n/a	n/a	0
• Number of PI's Reviewed/Education Sessions	n/a	n/a	n/a	n/a	0
• Number of Studies Reviewed	n/a	n/a	n/a	n/a	0
• Number of Dates of Service Reviewed	n/a	n/a	n/a	n/a	0
Area Training Activities					
Presentations (# of events)	n/a	n/a	n/a	n/a	0
Human Subjects Research Quality Assurance (QA)/Quality Improvement (QI)					
Area Activities					
	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Research QA - Scheduled Reviews					
• Number of PI's Reviewed	7	7	12	12	38
• Number of Studies Reviewed	10	8	12	12	42
Research QA - Directed Reviews					
• Number of PI's Reviewed	1	0	0	1	2
• Number of Studies Reviewed	1	0	0	2	3
Area Training Activities					
Presentations (# of events)	2	1	2	2	7
Sponsor-Investigator Meetings	0	0	3	2	5
External Inspections Attended	1	3	1	1	6

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Clinical Trials (CT.gov)					
Area Activities - Registration, Monitoring and Auditing	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Total # of Records	543	563	587	591	2284
Total # of Records - Overall Status	119	84	134	133	470
• Completed	18	7	18	12	55
• Active/Not Recruiting	16	9	17	10	52
• Active/Recruiting	54	34	54	23	165
• Not Yet Recruiting	14	13	25	11	63
• Enroll by Invitation	5	5	8	4	22
• Terminated	9	7	11	1	28
• Withdrawn	1	0	1	0	2
• Blanks	2	0	0	0	2
Problem Records	33	33	47	23	136
• Not Recently Updated	6	11	3	1	21
• Update Not Released/Never Released	6	11	32	13	62
• Entry Not Completed	5	8	18	10	41
• PRS Comments	6	9	4	4	23
• Late Results	6	2	9	5	22
• Record has 1 Error	4	11	8	6	29

*Single record may have more than one problem; bulleted breakdown not inclusive and identifies only those problems monitored and audited as part of the IU ClinicalTrials.gov Compliance Program.

**Not inclusive of those records with posted results reporting

Area Training Activities	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Presentations (# of events)	1	0	0	0	1
• Interactive, Computer Lab Training	0	0	0	0	0
• Departmental Training	0	0	0	0	0
• Coordinator Training	1	0	0	1	2

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Clinical Trials (CT.gov)					
Area Activities - Results Reporting In-Progress	Q1 (Jul-Sep)	Q2 (Oct-Dec)	Q3 (Jan-Mar)	Q4 (Apr-Jun)	TOTALS
Results Reporting - PI IU Status	94	67	101	62	324
• In Progress	5	7	10	16	38
• Public	76	55	81	42	254
• In PRS Review	2	0	0	0	2
• Released	3	0	1	3	7
• Completed	8	4	9	1	22