Research Compliance Activity Summary Report Quality Improvement Office (QIO)

Fiscal Year 2016-2017 (7/1/2016 to 6/30/2017)

Clinical Research Billing Compliance							
Area Activities							
	Q1	Q2	Q3	Q4			
Research Billing - Scheduled Reviews	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS		
Number of Departments Reviewed	0	0	0	0	0		
Number of PI's Reviewed/Education Sessions	0	0	0	0	0		
Number of of Studies Reviewed	0	0	0	0	0		
Number of Dates of Service Reviewed	0	0	0	0	0		

	Q1	Q2	Q3	Q4	
Area Training Activities	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS
Presentations (# of events)	0	0	0	0	0

Human Subjects Research Quality Assurance (QA)/Quality Improvement (QI)							
Area Activities							
Q1 Q2 Q3 Q4							
Research QA - Scheduled Reviews	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS		
Number of PI's Reviewed/Education Sessions	1	1	4	10	16		
Number of Studies Reviewed	3	1	4	10	18		
Number of Subjects Reviewed	22	6	29	102	159		

	Q1	Q2	Q3	Q4	
Research QA - Directed Reviews	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS
Number of PI's Reviewed/Education Sessions	2	3	0	0	5
Number of Studies Reviewed	2	8	0	0	10
Number of Subjects Reviewed	70	82	0	0	152

	Q1	Q2	Q3	Q4	
Area Training Activities	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS
Presentations (# of events)	1	3	2	2	8
Targeted Researcher Education/Guidance Sessions*	2	3	3	2	10

^{*}Includes PI held IND/IDE Education & FDA Audit Assistance/Liaison activities.

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Clinical Trials (CT.gov)							
	Q1	Q2	Q3	Q4			
Area Activities - Registration, Monitoring and Auditing	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS		
Determinations and Registrations	-	31	39	17	87		
ACT and NIH Determinatins	-	30	32	12	74		
New Record Registrations	-	1	7	5	13		
Results Reporting Monitoring	-	8	5	2	15		
Results Reporting for Departed Principal Investigator	-	6	1	0	7		
Results Reporting for IU Principal Investigator	-	2	4	2	8		
Maintenance Monitoring	-	25	59	28	112		
Update Not Released/Never Released	-	10	30	2	42		
Not Recently Updated	-	2	10	4	16		
• Other	-	13	19	22	54		

	Q1	Q2	Q3	Q4	
Area Training Activities	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS
Presentations (# of events)	-	8	3	0	11
Interactive, Computer Lab Training	-	1	0	0	1
Departmental Training	-	5	3	0	8
Coordinator Training	-	2	0	0	2

	Q1	Q2	Q3	Q4	
Area Activities - PRS Overview	(Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS
All Records Total	-	-	518	536	1054
Record Status = Enrolling by Invitation, Recruiting	-	-	128	127	255
Record Status = Active-Not Recruiting, Not Yet Recruiting	-	-	62	73	135
Record Status = Completed, Terminated, Withdrawn	-	-	325	333	658
Record Status = Suspended	-	-	3	3	6
Problem Records Total*	-	-	87	76	163
Late Results - per FDAAA	-	-	12	8	20
Update Not Released/Never Released	-	-	45	53	98
Not Recently Updated	-	-	16	27	43
Probable ACTs/Identified ACTs	-	-	163	167	330
Update Expected in Next 12 Months	-	-	58	56	114
Results Expected in Next 12 Months**	-	-	19	22	41

^{*}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

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Clinical Trials (CT.gov)							
		Q1	Q2	Q3	Q4		
Area Activities - Results Reporting In-Progress	((Jul-Sep)	(Oct-Dec)	(Jan-Mar)	(Apr-Jun)	TOTALS	
Results Reporting - Status		-		15	8	23	
Not Started		-	-	3	3	6	
Created		-	-	1	0	1	
• In PRS Review		-	-	9	1	10	
PRS Review Comments Issued		-	-	2	4	6	
Results Reporting - Department Total		-	-	15	8	23	
Results Reporting - PI IU Status Total		-	-	15	8	23	
Departed IU		-	-	7	1	8	
Remaining at IU		-	-	8	7	15	