



FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

IRB Work Activity

Q1 FY2014

Executive Summary

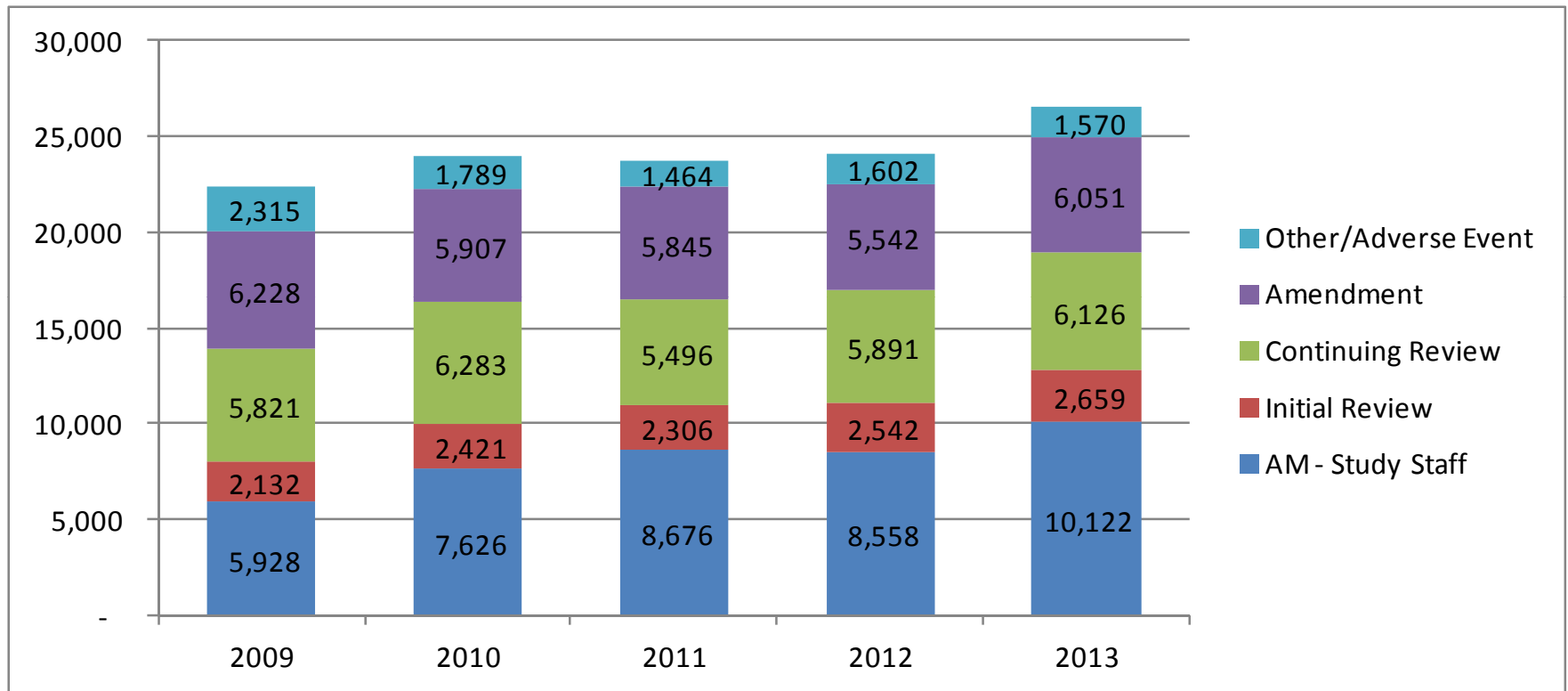
- Submissions received by the IRB were relatively flat from FY10 to FY12. Submissions increased 10% in FY13, due to an 18% increase in study staff amendments, a 9% increase in other amendments, a 5% increase in initial reviews, and a 4% increase in continuing reviews.
- Approved submissions with full board reviews accounted for 6% of all IRB approvals in Q1 FY14. Approval volumes declined in Q1 FY14 from the previous quarter, as study staff amendments declined due to seasonality. The volume of full board review approvals remain fairly consistent throughout the year.
- The turnaround times of expedited reviews have decreased substantially since April FY13 due to improved workflow automation that was accomplished upon implementation of Insight 3.2. Full board reviews have seen a slight decrease in turnaround time since the implementation of Insight 3.2.
- 99% of full board approvals in Q1 were on intervention/interaction protocols. Protocols with zero modifications typically had dramatically lower turnaround times than protocols with modifications, however, only 14% of protocols with full board reviews were approved with zero modifications. Continuing reviews and initial reviews had the lowest percentage of full board approvals with zero modifications (6% and 7%, respectively).
- In contrast to full board reviews, 77% of expedited reviews were approved with zero modifications (69% if study staff amendments are excluded), which helps to explain the lower turnaround times, along with the lower overall complexity of expedited reviews. 70% of expedited review approvals are on intervention/interaction protocols, while 15% are on health/medical records and 7% on secondary use protocols, with the remaining 8% encompassing excess human material, data repository, coordinating center/core labs, and tissue repository protocols.
- 61% of pending submissions at 1/22/14 were awaiting action from a PI/Submitter, 37% were awaiting action from the IRB, and 2% were awaiting action from an Ancillary Department. The majority of pending submissions awaiting IRB action relate to continuing reviews (39%), while initial reviews accounted for the majority of submissions awaiting PI/Submitter action (48%). Continuing Reviews (CRs) are not always reviewed on a first-come-first-serve basis by the IRB because CRs are prioritized based on expiration date.

Note: Turnaround Time Reporting parameters:

- Turnaround time begins when submission is received by IRB (HRO Intake workflow step) and ends when submission is complete and notification e-mail sent to PI
- All data is in calendar days

Received Submissions

Number of submissions received by year – FY09 to FY13

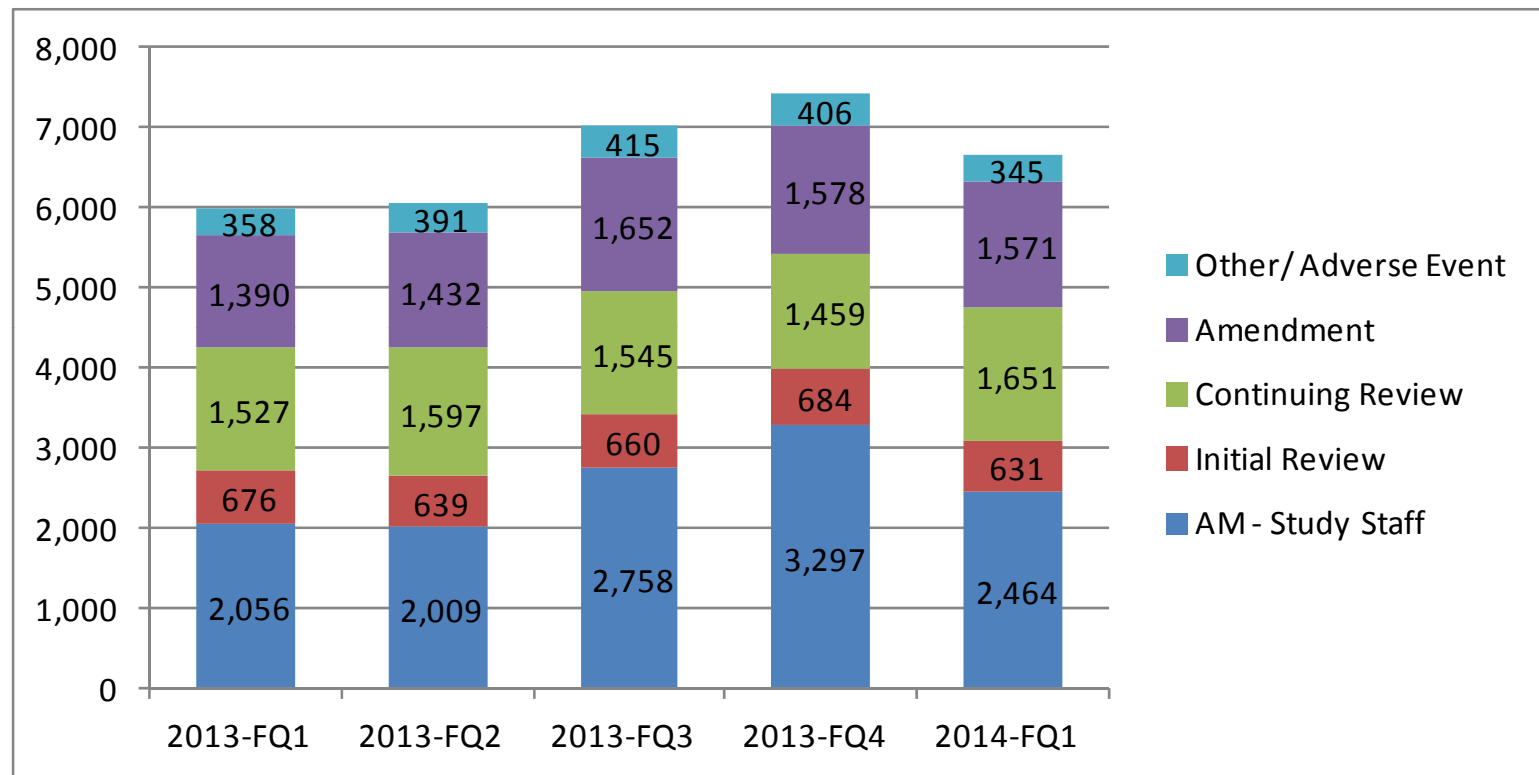


- Submissions received by the IRB were relatively flat from FY10 to FY12. Submissions increased 10% in FY13, due to an 18% increase in study staff amendments, a 9% increase in amendments, a 5% increase in initial reviews, and a 4% increase in continuing reviews.

Note: Includes all submissions received, regardless of outcome (includes completed/approved submissions, pending submissions, as well as submissions which were later withdrawn or disapproved). Received date is date submission received by IRB (i.e. first HRO intake workflow step).

Received Submissions

Number of submissions received by quarter - Q1 FY13 to Q1 FY14

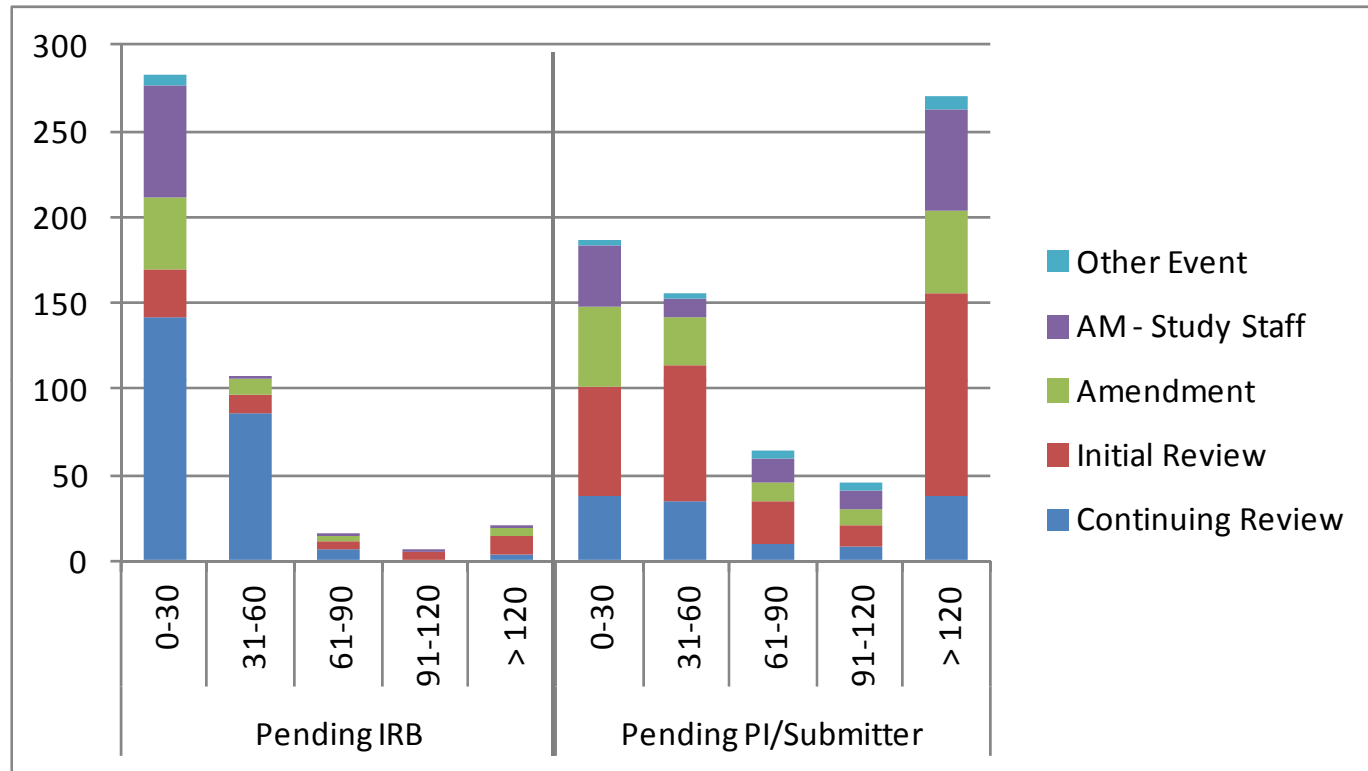


- Submissions received by the IRB increased in Q3 and Q4 FY13, mainly due to seasonality of study staff amendments. Although study staff amendments decreased 25% in Q1 FY14 from the prior quarter due to seasonality, study staff amendments were 20% higher in Q1 2014 than Q1 FY13. In addition, amendments and continuing reviews were up 13% and 8%, respectively in Q1 FY14, when compared to Q1 FY13, while initial reviews were down 4%.

Note: Includes all submissions received, regardless of outcome (includes completed/approved submissions, pending submissions, as well as submissions which were later withdrawn or disapproved). Received date is date submission received by IRB (i.e. first HRO intake workflow step).

Aging of Pending Submissions

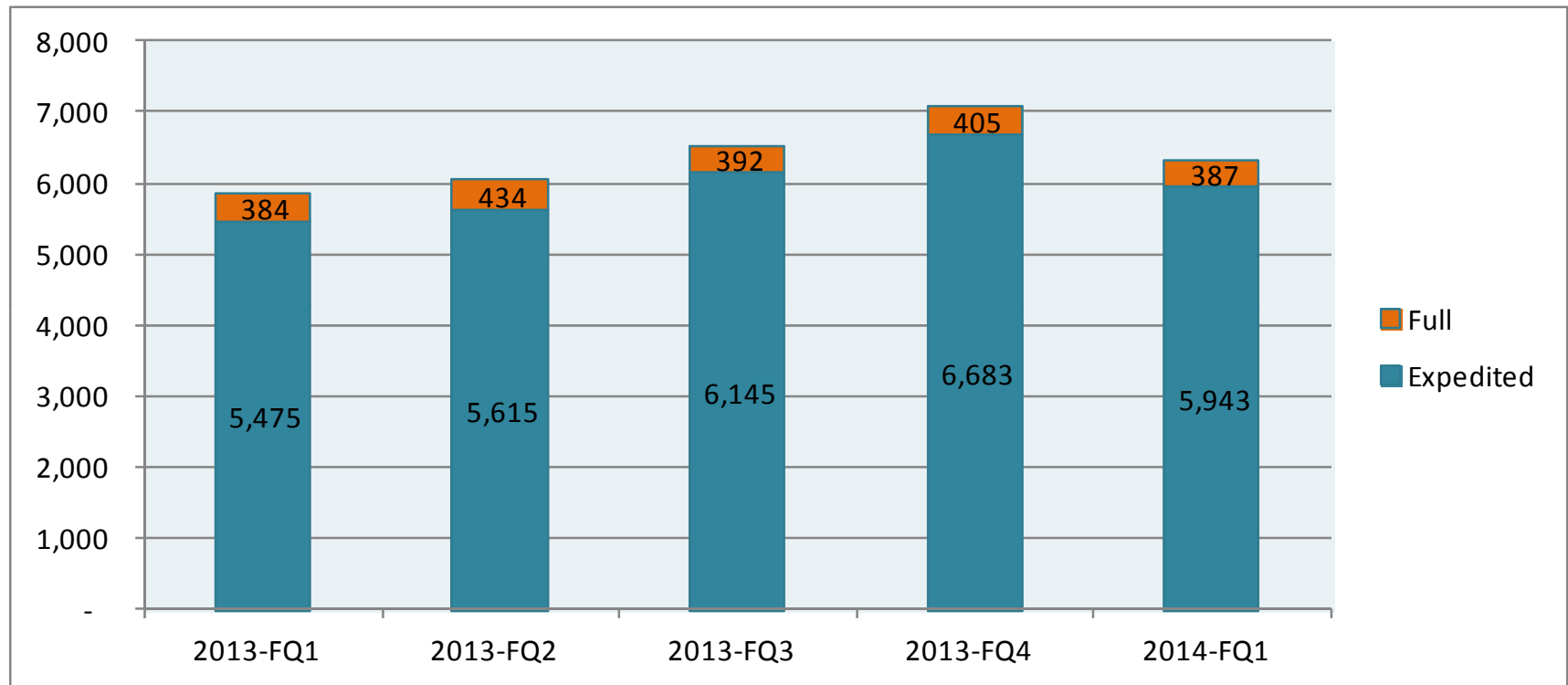
As of January 22, 2014



- The majority of submissions awaiting IRB action relate to continuing reviews (39%), while initial reviews accounted for the majority of submissions awaiting PI/Submitter action (48%). Continuing Reviews (CRs) are not always reviewed on a first-come-first-serve basis by the IRB because CRs are prioritized based on expiration date.

Volume of IRB Approvals by Quarter - Summary*

Number of Full and Expedited Reviews – Q1 FY13 to Q1 FY14

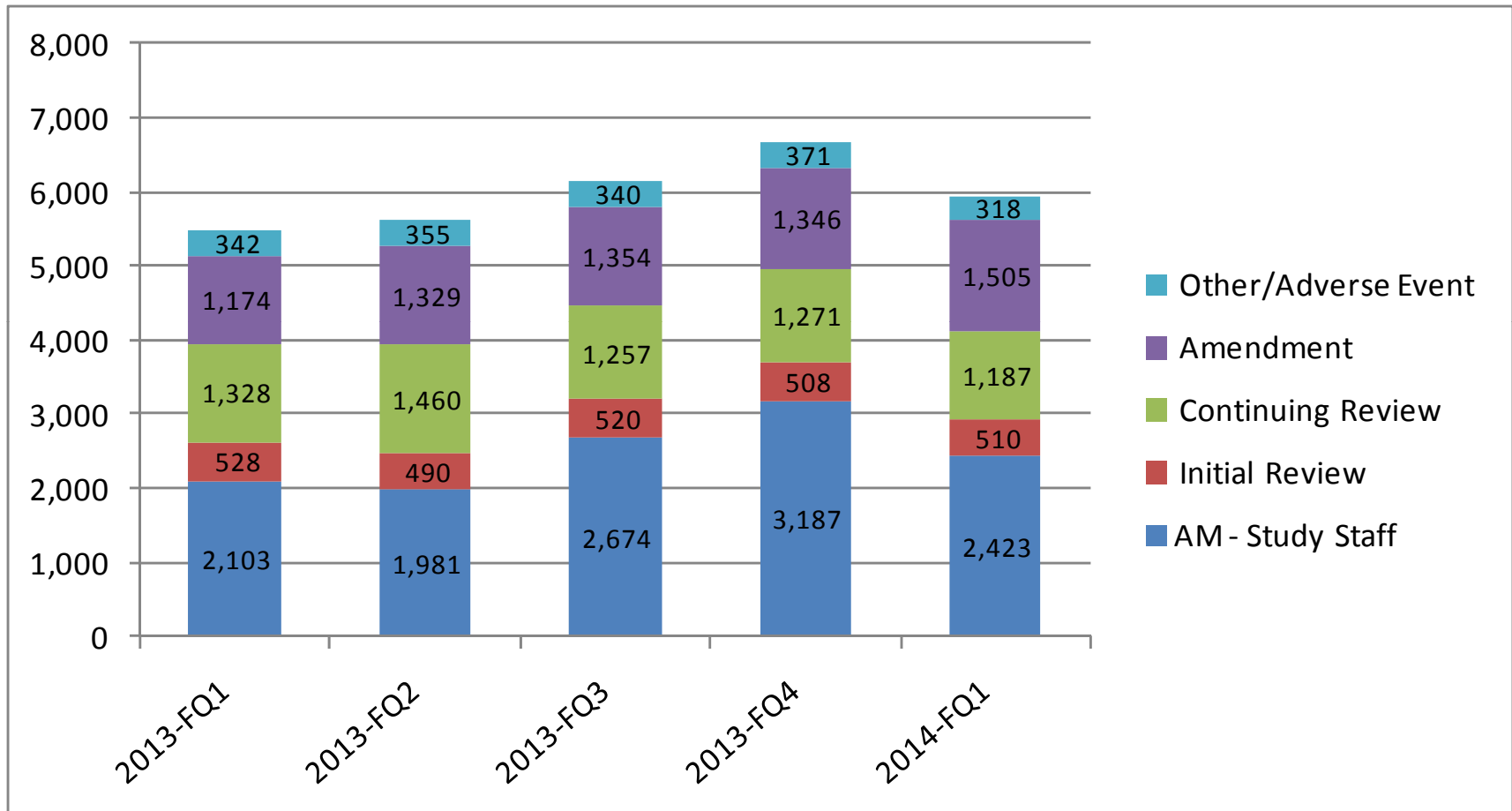


- Approved submissions with full board reviews accounted for 6% of all IRB approvals in Q1 FY14. Approval volumes declined in Q1 FY14 from the previous quarter, as study staff amendments declined due to seasonality.

*Includes all completed submissions (by quarter when submission was approved): Initial Reviews, Continuing Reviews, Amendments, Study Staff Amendments, and Other/Adverse Events

Expedited Reviews

Number of Completed/Approved Reviews by Quarter - Q1 FY13 to Q1 FY14

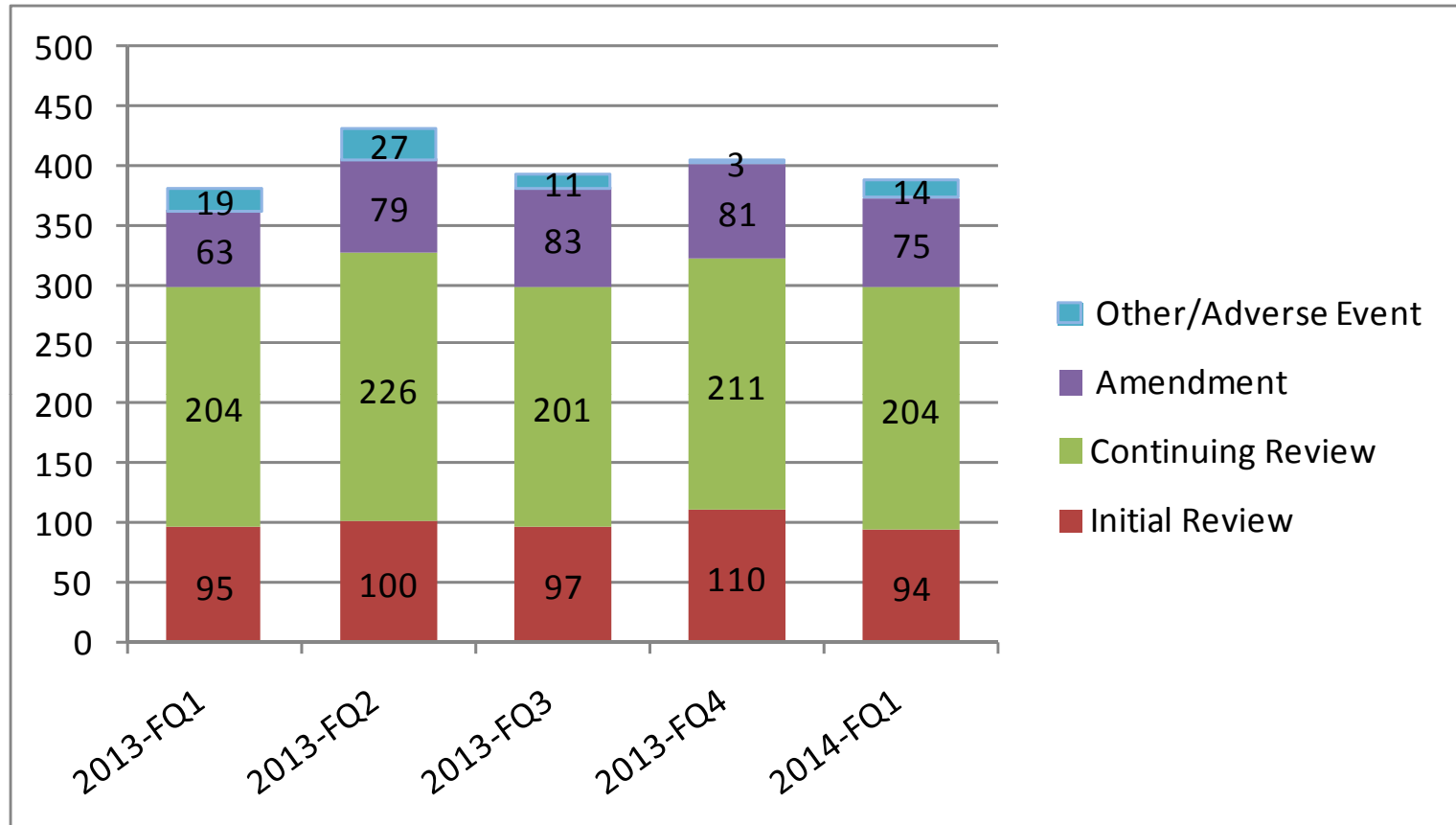


▪ In comparison to Q4 FY13, study staff amendments decreased 24% in Q1 FY14 due to seasonality and reviews of other/adverse events decreased 14% from Q4 FY13. Amendments increased 12% from Q4 FY13 and initial reviews remained constant.

-Includes all completed submissions with expedited reviews (by quarter when submission was approved).

Full Board Reviews

Number of Completed/Approved Reviews by Quarter- - Q1 FY13 to Q1 FY14

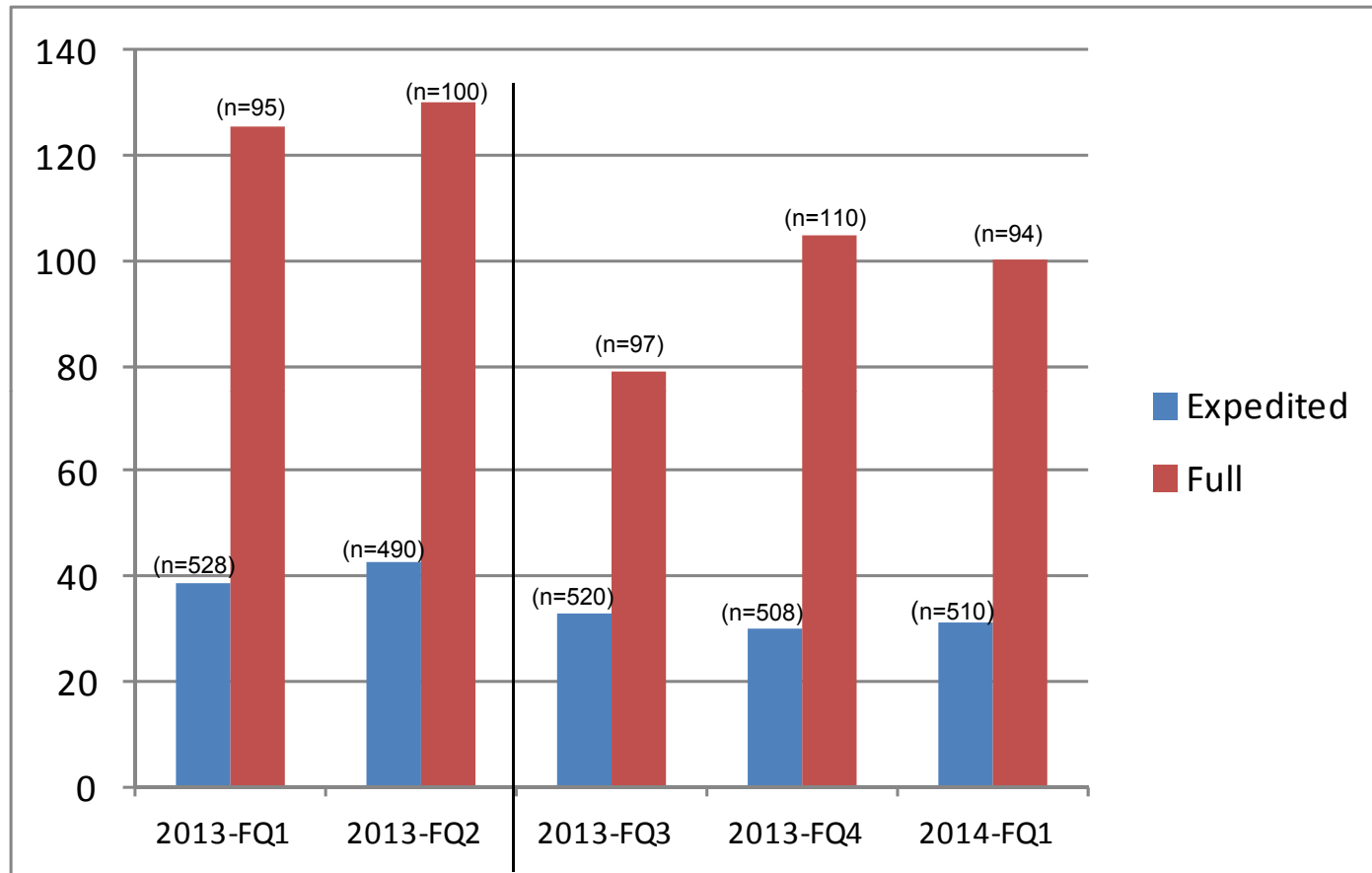


- The volume of full board review approvals remains fairly consistent throughout the year.

-Includes all completed submissions with full board reviews (by quarter when submission was approved).

Initial Review Applications (IR)

Turnaround Time by Quarter



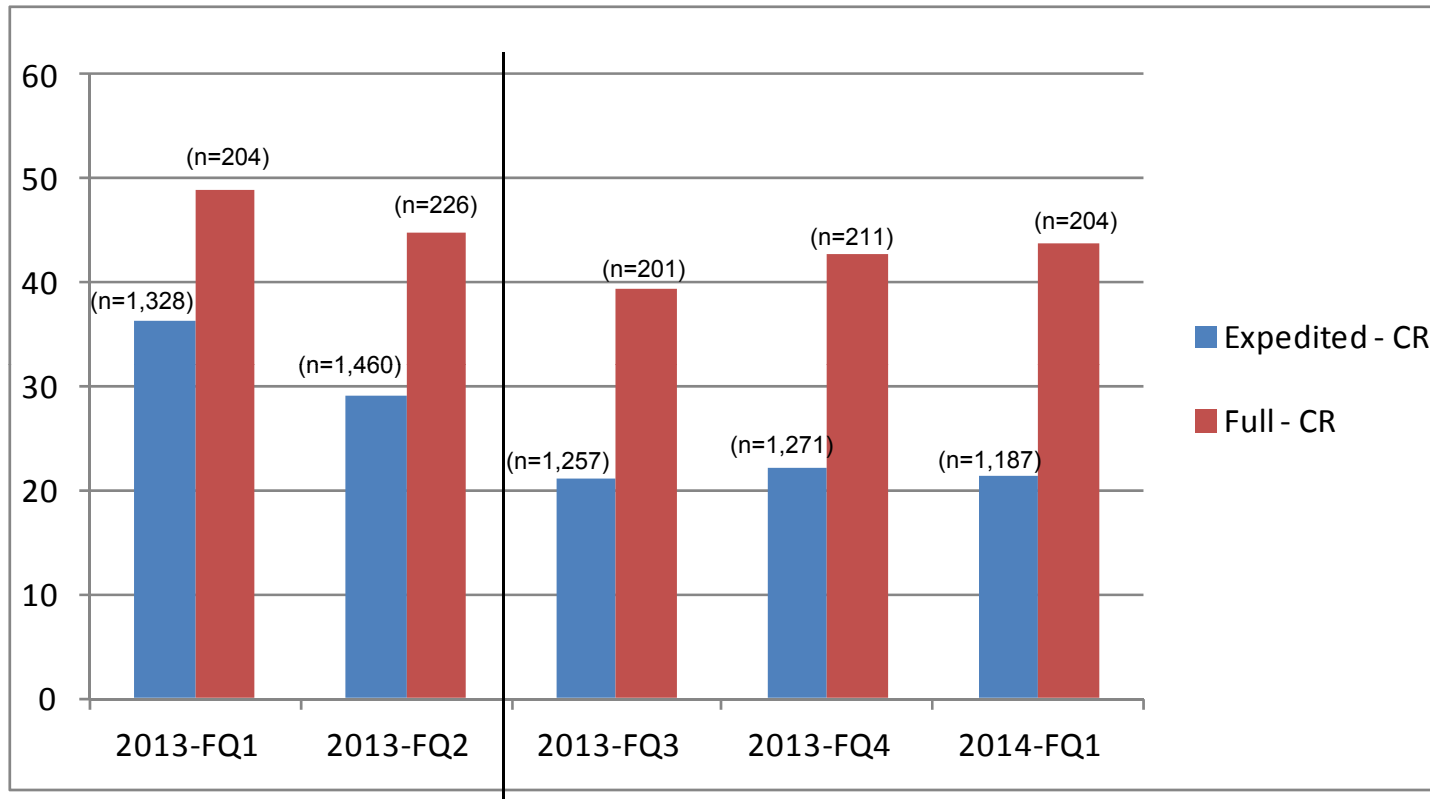
Insight 3.2
Implementation

- Improved workflow automation was accomplished for expedited reviews upon implementation of Insight 3.2 in April 2013. Turnaround times for full board reviews have also decreased since April 2013.

Note: Includes all completed initial review submissions (by quarter when submission was approved).

Continuing Reviews (CR)

Turnaround Time by Quarter



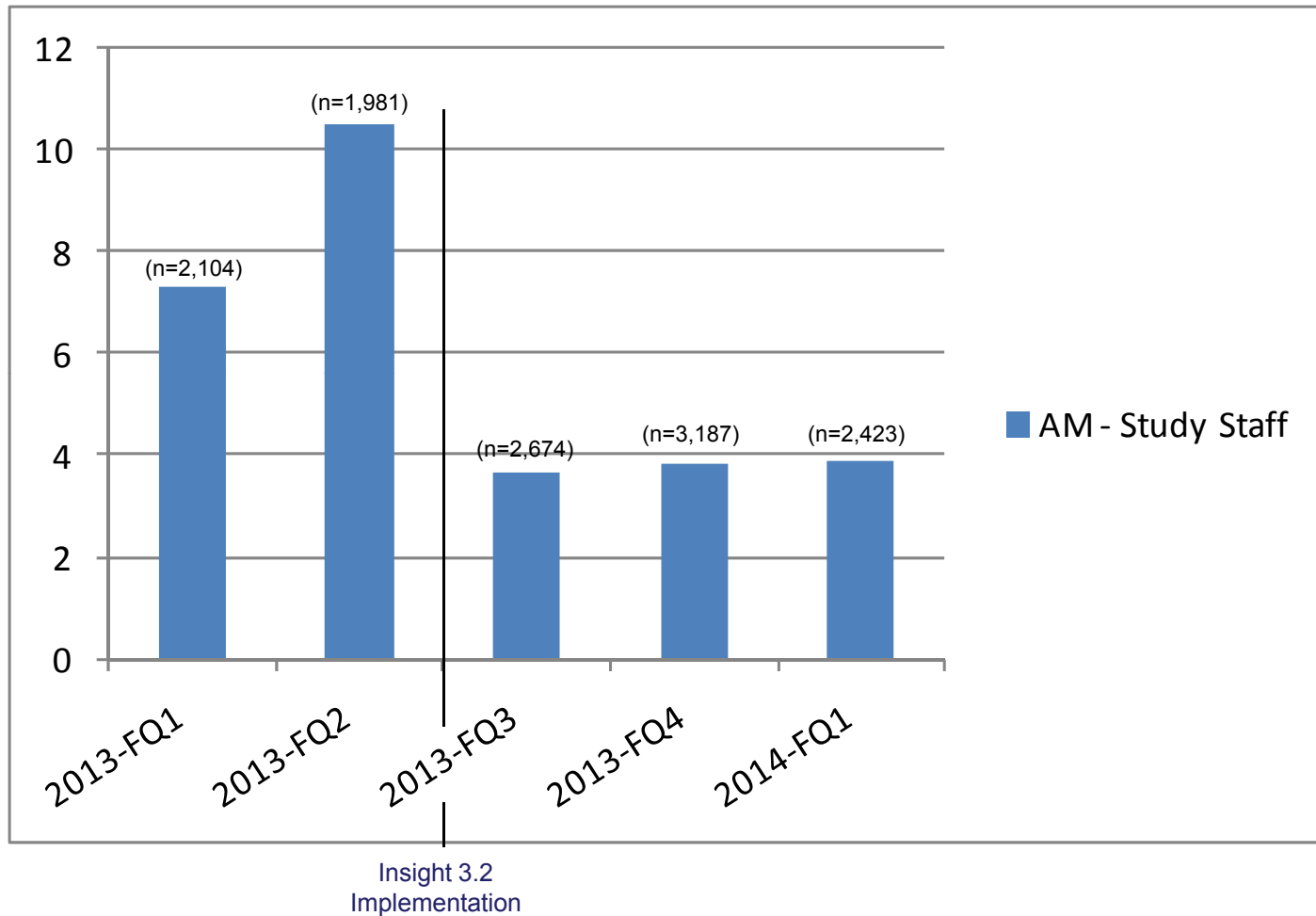
Insight 3.2
Implementation

- Improved workflow automation was accomplished for expedited reviews upon implementation of Insight 3.2 in April 2013. In addition, an IRB staff person was dedicated to expedited continuing reviews, which improved efficiency. Turnaround times for full board reviews have also decreased slightly since April 2013.

Note: Includes all completed continuing review submissions (by quarter when submission was approved).

Study Staff Amendments (SSAME)

Turnaround Time by Quarter

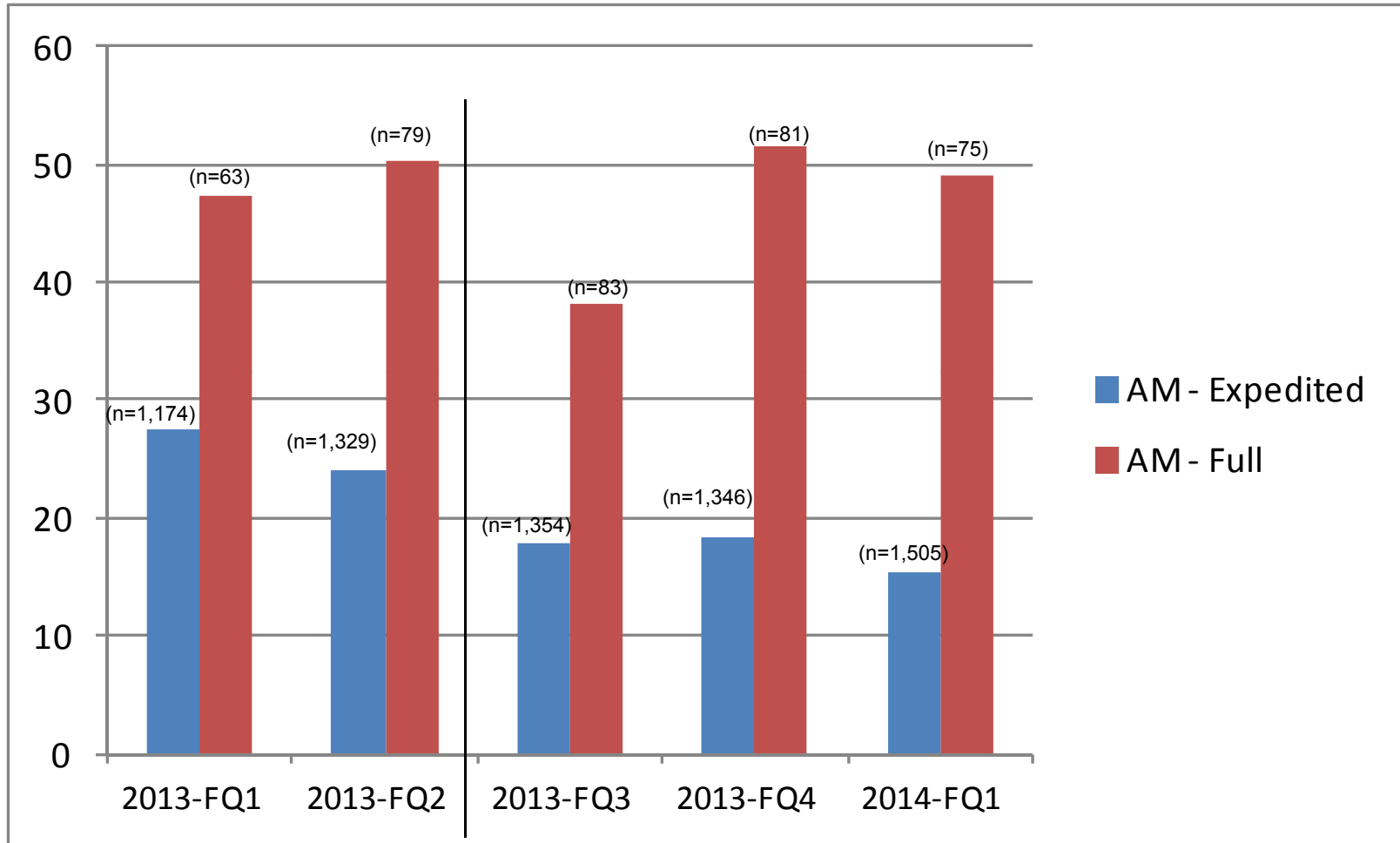


- Improved workflow automation was accomplished for expedited reviews upon implementation of Insight 3.2 in April 2013.

Note: Includes all completed study staff amendment submissions (by quarter when submission was approved).

Amendments (AME)

Turnaround Time by Quarter



Insight 3.2 Implementation

- Improved workflow automation was accomplished for expedited reviews upon implementation of Insight 3.2 in April 2013. The turnaround times for full board approvals of amendments has remained fairly consistent throughout the last 5 quarters (with the exception of Q3, when all full board reviews experienced lower turnaround times).

Note: Includes all completed amendment submissions (by quarter when submission was approved).



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Appendix

Turnaround Time (TAT) by Protocol Type and Number of Modifications for Full Board Reviews – Q1 FY14

IRB Board Type	Submission Type	Protocol Type	Number of Modifications on Submission	Number of Submissions	Average TAT Days from receipt by IRB to Approval	Average TAT Days - 1st IRB Review *
Full	Amendment	Intervention/Interaction	0 Total Mods	12	33.0	13.0
			1 Total Mods	42	42.6	17.1
			>= 2 Total Mods	21	71.4	15.8
Full	Continuing Review	Intervention/Interaction	0 Total Mods	13	27.1	14.5
			1 Total Mods	131	40.2	18.5
			>= 2 Total Mods	60	54.9	17.2
Full	Initial Review	Emergency Sgl Pt	0 Total Mods	4	23.5	15.5
		Intervention/Interaction	0 Total Mods	3	35.7	7.3
			1 Total Mods	17	86.0	18.4
			>= 2 Total Mods	70	110.8	19.9
Full	Other Event	Intervention/Interaction	0 Total Mods	11	29.4	9.1
			1 Total Mods	1	30.0	1.0
			>= 2 Total Mods	2	174.0	2.0
Total				387	58.7	17.4

- 99% of full board approvals in Q1 were on intervention/interaction protocols. Protocols with zero modifications typically had dramatically lower turnaround times than protocols with modifications, however, only 14% of protocols were approved with zero modifications. Continuing reviews and initial reviews had the lowest percentage of full board approvals with zero modifications (6% and 7%, respectively).

* The average turnaround time for the 1st IRB Review includes only the days to review the submission by the IRB Board during its first board review. Turnaround time starts when the submission is assigned to the IRB Board meeting and ends when the Board's first review is complete (on the meeting date).

Turnaround Time (TAT) by Protocol Type and Number of Modifications for Expedited Reviews – Q1 FY14

IRB Board Type	Submission Type	Protocol Type	Number of Modifications on Submission	Number of Submissions	Average TAT Days from receipt by IRB to Approval	Average TAT Days - 1st IRB Review *		
Expedited	Amendment	Coordinating Center / Core Labs	0 Total Mods	12	23.8	7.6		
			1 Total Mods	2	17.0	7.0		
			1 Total Mods	16	10.8	6.5		
		Data Repository	0 Total Mods	11	37.1	12.5		
			1 Total Mods	20	8.0	4.5		
			>= 2 Total Mods	12	44.4	8.6		
		Excess Human Material	0 Total Mods	4	69.5	8.5		
			1 Total Mods	56	8.6	4.0		
			>= 2 Total Mods	10	29.9	2.5		
		Health / Medical Records	0 Total Mods	3	96.0	4.7		
			1 Total Mods	862	9.8	5.8		
			>= 2 Total Mods	355	21.2	7.6		
		Intervention/Interaction	0 Total Mods	72	40.0	7.1		
			1 Total Mods	52	11.5	6.0		
			>= 2 Total Mods	10	30.8	6.0		
		Secondary Use	0 Total Mods	3	55.0	14.3		
			1 Total Mods	2	3.5	1.0		
			>= 2 Total Mods	2	12.5	6.0		
		Tissue Repository	0 Total Mods	1	61.0	20.0		
			1 Total Mods	10	0.5			
			>= 2 Total Mods	2	15.0			
		Expedited	AM- Study Staff **	Coordinating Center / Core Labs	0 Total Mods	1	26.0	
					1 Total Mods	82	0.9	
					>= 2 Total Mods	2	29.5	
Data Repository	0 Total Mods			1	7.0			
	1 Total Mods			96	3.8			
	>= 2 Total Mods			8	21.8			
Excess Human Material	0 Total Mods			1	118.0			
	1 Total Mods			409	1.3			
	>= 2 Total Mods			13	27.1			
Health / Medical Records	0 Total Mods			3	103.3			
	1 Total Mods			1,431	1.3			
	>= 2 Total Mods			187	16.2			
Intervention/Interaction	0 Total Mods			36	57.5			
	1 Total Mods			133	1.2			
	>= 2 Total Mods			3	19.3			
Secondary Use	0 Total Mods			2	80.0			
	1 Total Mods			2	1.5			
	>= 2 Total Mods			1	13.0			

- 70% of expedited review approvals are on intervention/interaction protocols, while 14% are on health/medical records and 7% on secondary use protocols, with the remaining 8% encompassing excess human material, data repository, coordinating center/core labs, and tissue repository protocols.
- In contrast to full board reviews, 77% of expedited reviews are approved with zero modifications (69% if study staff amendments are excluded), which helps to explain the lower turnaround times, along with the lower overall complexity of these reviews.

* The average turnaround time for the 1st IRB Review includes only the days to review the submission by the Expedited Reviewer during his/her first review of the submission (turnaround time starts when the submission is assigned to the expedited reviewer and ends when his/her first review is complete).

** The turnaround time of the first IRB review for Study Staff Amendments is not directly tracked in MicroStrategy due to the small amount of time normally allocated to these submissions.

Turnaround Time (TAT) by Protocol Type and Number of Modifications for Expedited Reviews – Q1 FY14 (continued from prior page)

IRB Board Type	Submission Type	Protocol Type	Number of Modifications on Submission	Number of Submissions	Average TAT Days from receipt by IRB to Approval	Average TAT Days - 1st IRB Review *
Expedited	Continuing Review	Coordinating Center / Core Labs	0 Total Mods	1	1.0	1.0
			1 Total Mods	38	20.9	2.9
		Data Repository	1 Total Mods	5	83.4	7.4
			0 Total Mods	73	15.7	0.1
			1 Total Mods	4	97.3	0.0
		Health / Medical Records	0 Total Mods	169	22.4	0.3
			1 Total Mods	6	67.5	11.8
			0 Total Mods	550	18.5	11.9
		Intervention/Interaction	1 Total Mods	136	28.8	10.0
			>= 2 Total Mods	41	50.6	9.8
		Secondary Use	0 Total Mods	153	13.2	0.4
			1 Total Mods	8	32.5	1.0
			>= 2 Total Mods	1	9.0	1.0
		Tissue Repository	0 Total Mods	1	5.0	1.0
			>= 2 Total Mods	1	58.0	20.0
		Expedited	Initial Review	Coordinating Center / Core Labs	0 Total Mods	1
	1 Total Mods			6	32.2	11.4
	>= 2 Total Mods			4	52.8	5.8
Data Repository	0 Total Mods			2	15.0	13.5
	1 Total Mods			3	18.7	5.3
	>= 2 Total Mods			3	51.0	13.3
Excess Human Material	0 Total Mods			18	6.4	5.8
	1 Total Mods			17	22.6	8.5
	>= 2 Total Mods			4	51.0	11.0
Health / Medical Records	0 Total Mods			125	7.6	6.2
	1 Total Mods			77	31.6	7.0
	>= 2 Total Mods			18	51.4	6.2
Intervention/Interaction	0 Total Mods			19	19.9	6.8
	1 Total Mods			74	45.2	9.8
	>= 2 Total Mods			69	74.4	12.2
Secondary Use	0 Total Mods			35	8.0	6.9
	1 Total Mods	28	25.7	7.9		
	>= 2 Total Mods	6	43.0	6.8		
Tissue Repository	1 Total Mods	1	90.0	7.0		
Expedited	Other Event	Coordinating Center / Core Labs	0 Total Mods	2	8.5	6.0
			1 Total Mods	212	5.9	3.3
		Intervention/Interaction	1 Total Mods	92	13.3	1.5
			>= 2 Total Mods	11	22.3	1.6
	Secondary Use	0 Total Mods	1	8.0	7.0	
Total				5,943	12.9	6.6

* The average turnaround time for the 1st IRB Review includes only the days to review the submission by the Expedited Reviewer during his/her first review of the submission (turnaround time starts when the submission is assigned to the expedited reviewer and ends when his/her first review is complete).

Aging of Pending Submissions

As of January 22, 2014

Current Pending Status	Latest Board Review Type	Submission Type	Calendar days pending					Total Submissions
			0-30	31-60	61-90	91-120	> 120	
Pending PI/Submitter	Expedited	Adverse Event					1	1
		Amendment	28	17	4	7	22	78
		AM - Study Staff	35	12	13	11	44	115
		Continuing Review	7	13	5	1	12	38
		Initial Review	32	41	13	7	67	160
		Other Event	4	1	4	4	3	16
	Full	Amendment		6	2	1	1	10
		Continuing Review	3	11	3	3	6	26
		Initial Review	25	31	10	5	30	101
	UNASSIGNED	Adverse Event					1	1
		Amendment	18	4	6	1	25	54
		AM - Study Staff	1				15	16
		Continuing Review	27	11	1	4	20	63
		Initial Review	7	7	2	1	21	38
		Other Event		1	1		4	6
	Total		187	155	64	45	272	723
	Pending IRB	Expedited	Amendment	18	7	1		2
AM - Study Staff			8	1	1	1	2	13
Continuing Review			18	25	1		1	45
Initial Review			14	6	2	2	1	25
Other Event			6					6
Full		Amendment		1	1			2
		Continuing Review	1	8				9
		Initial Review		4	4	3	10	21
UNASSIGNED		Amendment	25	2			2	29
		AM - Study Staff	56					56
		Continuing Review	122	53	5		2	182
		Initial Review	14				1	15
		Other Event	1					1
Total		283	107	15	6	21	432	
Pending Ancillary	Expedited	Amendment	1		2			3
		Initial Review	2	1				3
		Other Event	2					2
	Full	Initial Review	4	2	4	1	2	13
		Other Event				1		1
	Total		9	3	6	2	2	22
Total		479	265	85	53	295	1,177	

61% of the pending submissions at 1/22/14 were awaiting action from a PI/Submitter, 37% were awaiting action from the IRB, and 2% were awaiting action from an Ancillary Department. 90% of the submissions pending IRB action were originally submitted 0 to 60 days ago, while 47% of the submissions pending PI/Submitter action were submitted 0 to 60 days ago. Currently, there is a guideline that unapproved submissions should be closed out after a year; however, this is not strictly enforced. Tightening procedures and further limiting the amount of time that a submission can be outstanding would reduce pending items; however, this would need to be balanced with the amount of time required to re-work any closed items that are submitted again at a later date (i.e. there can be a significant amount of time invested in a protocol submission, this review time would be lost if a submission is subsequently reactivated).