PARTNERS HEALTHCARE

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

IRB Work Activity

Q2 FY2014

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

Executive Summary

Completed/Approved Submissions

- Approval volumes (Q2 vs. Q1 FY14)
  - Increased 4% in Q2 FY14, mainly from an increase in expedited continuing reviews
  - 357 full board approvals in Q2 FY14 (5% of all IRB approvals), compared to 387 in Q1 FY14 (6% of all approvals)

- Full Board Approvals in Q2 FY14 consisted of:
  - 98% on intervention/interaction protocols
  - 94% had one or more required modifications and/or deferrals, which increases turn around times
    - The majority of full board continuing reviews had 1 modification (67%) while the majority of full board initial reviews had 2 or more modifications (80%)
    - Full board amendments were fairly evenly split between submissions with 1 modification and those with 2 or more modifications
  - The IRB is currently reviewing protocols with more than one review to determine the causes and develop solutions to reduce the number of required modifications and/or deferrals

- Expedited Approvals in Q2 FY14 consisted of:
  - 69% on intervention/interaction protocols, 16% on health/medical records, 8% on secondary use protocols, with the remaining 7% encompassing excess human material, data repository, coordinating center/core labs, tissue repository, and emergency single patient protocols
  - 79% were approved with zero modifications (72% if study staff amendments are excluded)
    - By type of expedited process: 90% of study staff amendments had zero modifications, 88% of continuing reviews, 69% of other events, 67% of amendments, and 42% of initial reviews had zero modifications
  - Lower turnaround times on expedited reviews (vs. Full Board) include the following reasons:
    - Types of protocols reviewed , e.g., research limited to health/medical records, excess human material, etc., which present lower overall complexity for review
    - Less modifications
    - No wait time for IRB meeting as only one reviewer is involved in an expedited review (can take a few days to get on the IRB Full Board meeting schedule and IRB Full Board reviewers receive submission information one week prior to the meeting for review)

Executive Summary

Pending Submissions (Q2 vs. Q1 FY14)

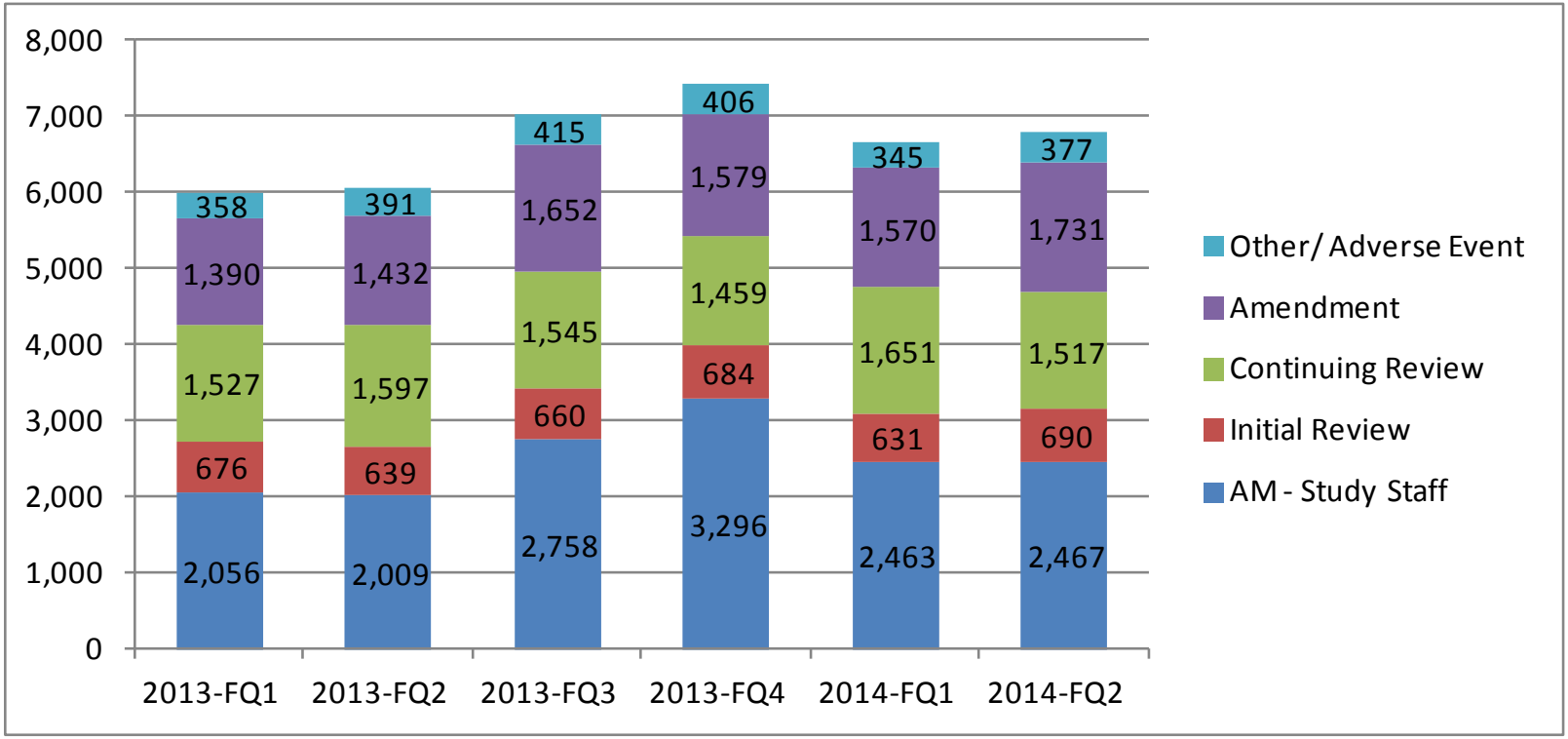
- 13% decrease, mainly due to a large decrease in pending continuing reviews (CRs)
- 76% of the pending submissions at 4/18/14 were awaiting action from a PI/Submitter, 22% were awaiting action from the IRB, and 2% were awaiting action from an Ancillary Department
- The majority of pending submissions awaiting IRB action relate to continuing reviews (44%), while initial reviews accounted for the majority of submissions awaiting PI/Submitter action (43%). CRs are not always reviewed on a first-come-first-serve basis by the IRB because CRs are prioritized based on expiration date in addition to date received. 95% of the CRs awaiting IRB review were outstanding 0-30 days.
- 5% increase in submissions pending more than 120 days. The IRB will review submissions pending more than 120 days to withdraw submissions no longer needed or no longer pursued by an investigator.
- There are currently 55 pending submissions over one year old. These include 31 initial reviews, 11 continuing reviews, 9 amendments, 3 study staff amendments, and 1 adverse event. 52 of these pending items are awaiting PI action and 3 are awaiting IRB action. The IRB is in the process of reviewing these items.
- Currently, any submissions which are awaiting a submitter review for more than a year (without any action being taken by the submitter) will automatically be closed out in Insight

Notes: 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 quarter - Q1 FY13 to Q2 FY14

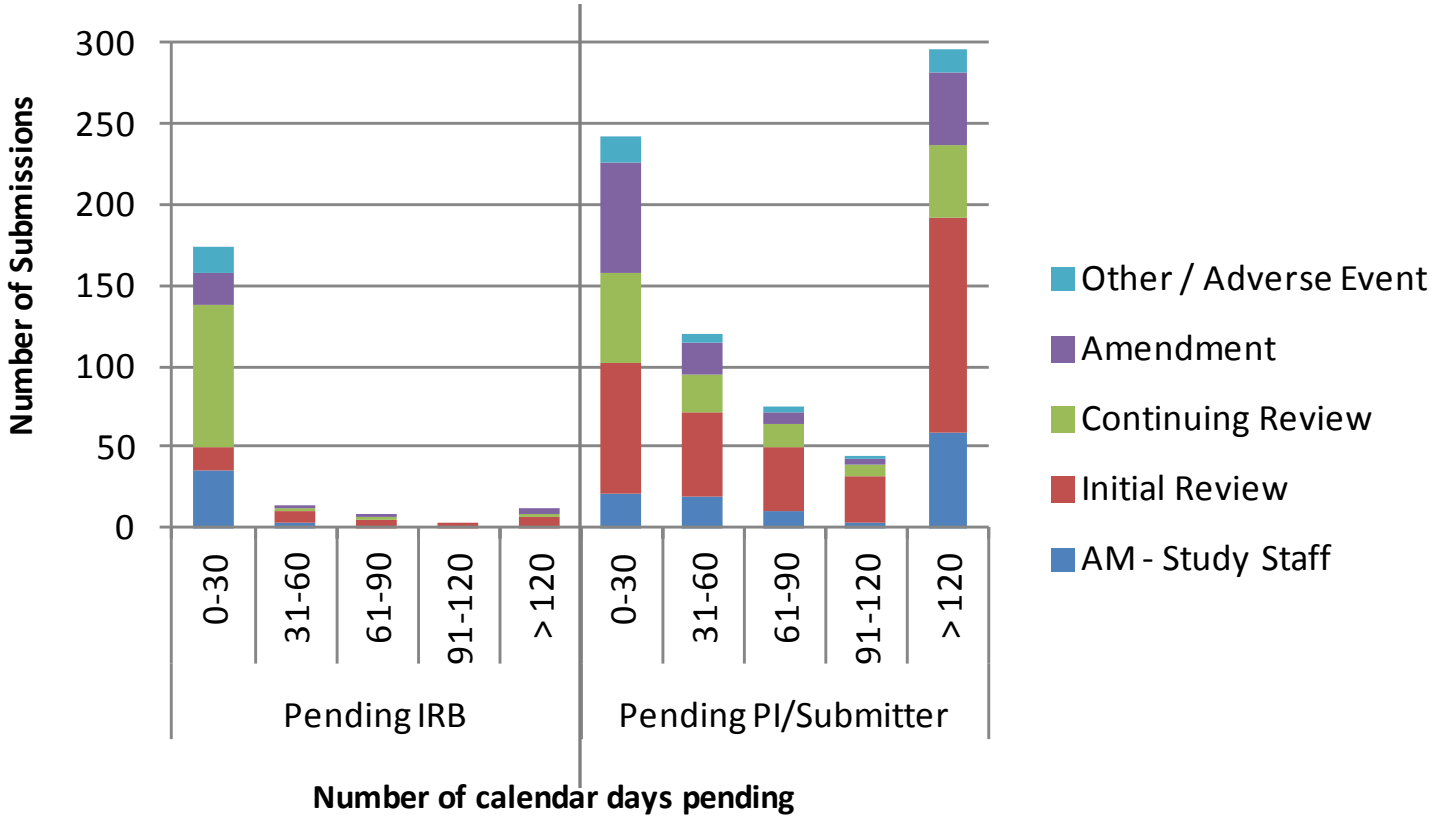


▪ In comparison to Q1 FY14, both amendments and initial reviews increased 10% in Q2 FY14, other/adverse events were up 9%, while continuing reviews were down 8% and study staff amendments were flat. Historically, submissions received by the IRB were higher in Q3 and Q4 FY13 mainly due to the seasonality of study staff amendments.

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

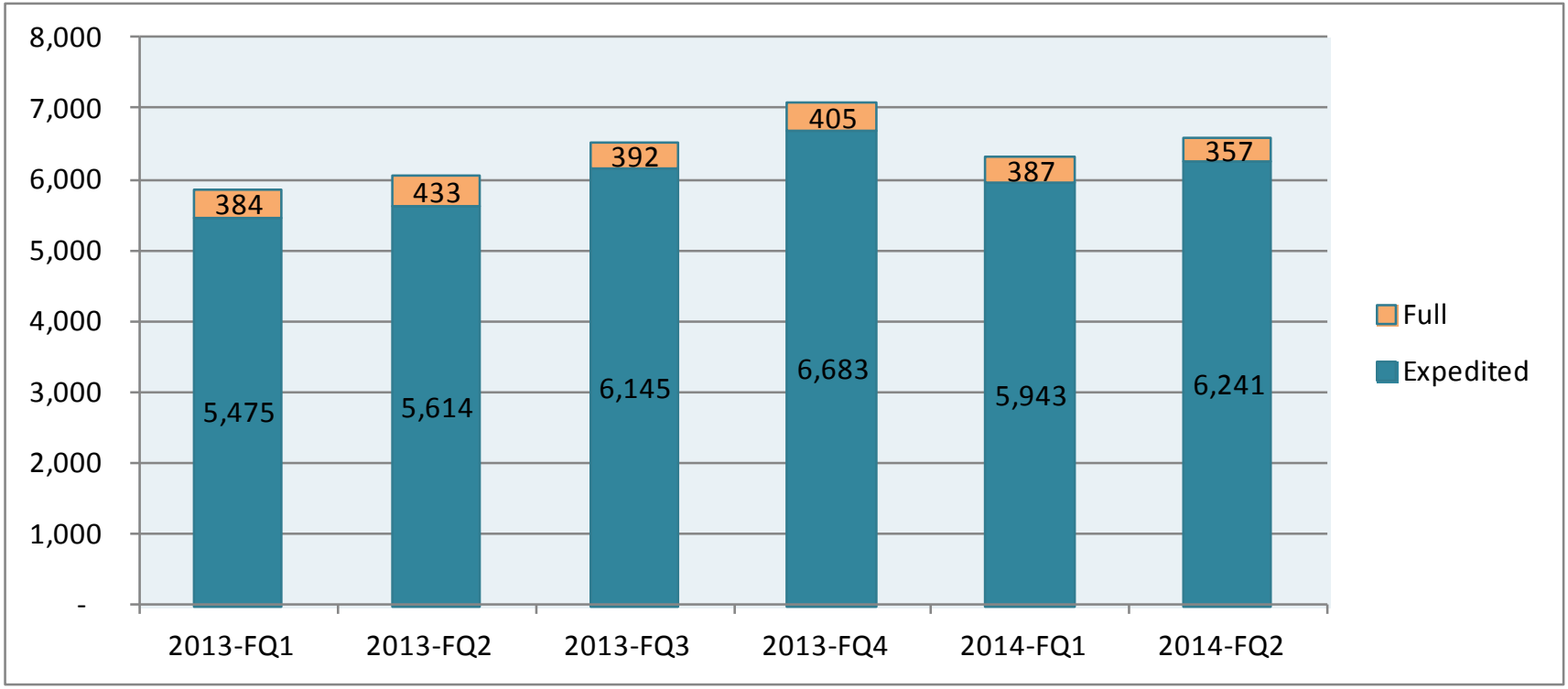
As of April 18, 2014



- The majority of submissions awaiting IRB action relate to continuing reviews (44%), while initial reviews accounted for the majority of submissions awaiting PI/Submitter action (43%). 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 in addition to date received. There was a 13% decrease in pending submissions in Q2 (compared to Q1), mainly due to a large decrease in pending CRs attributed in part due to increased capacity for completing CRs due to the return of an expedited CR reviewer from leave in January FY14. However, there was a 5% increase in submissions pending more than 120 days. The IRB will review submissions pending more than 120 days and withdraw submissions no longer needed or no longer pursued by an investigator.

Volume of IRB Approvals by Quarter - Summary*

Number of Full and Expedited Reviews – Q1 FY13 to Q2 FY14

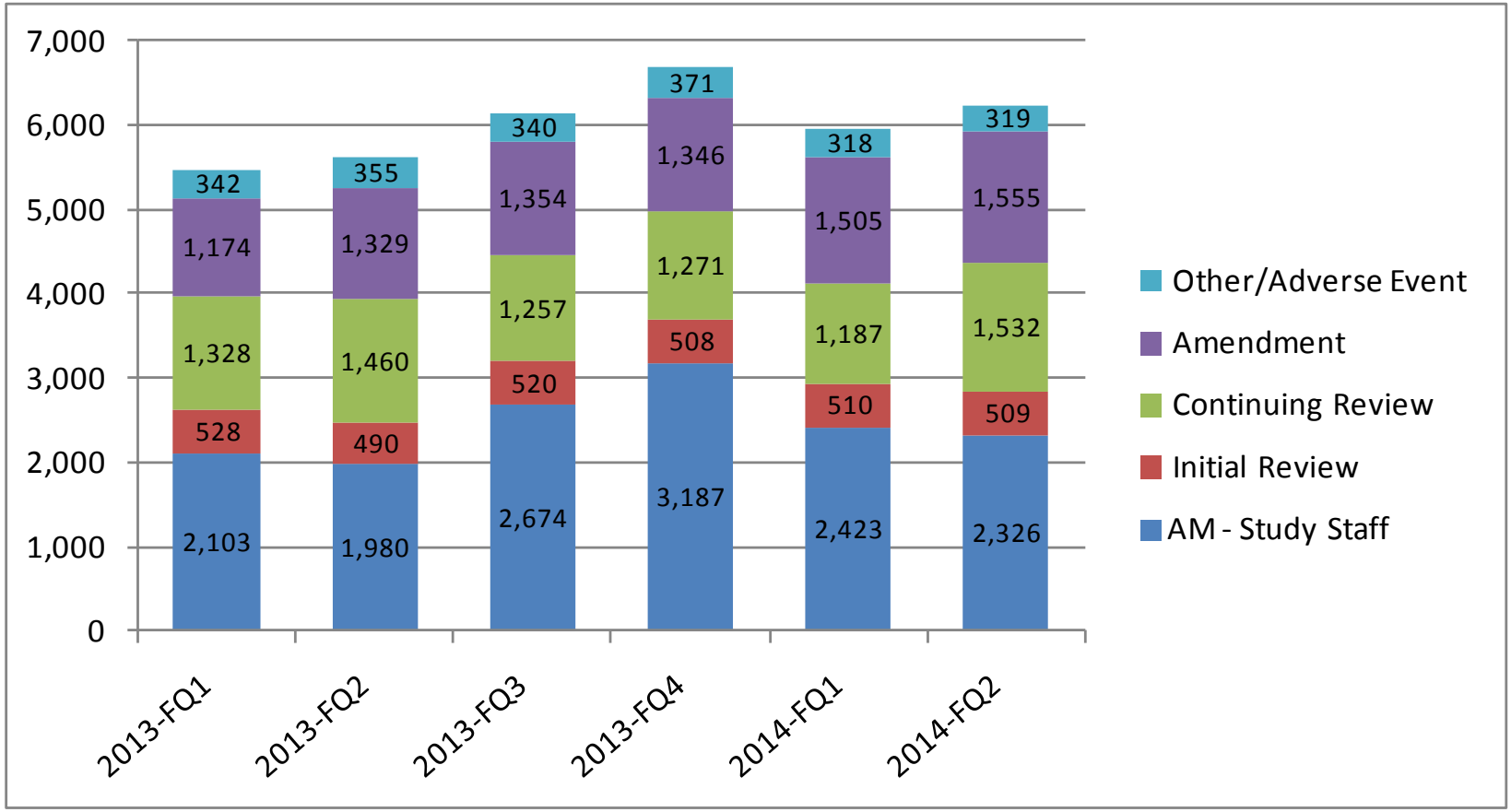


- Approved submissions with full board reviews accounted for 5% of all IRB approvals in Q2 FY14. Approval volumes increased in Q2 FY14, from the previous quarter, due to an increase in expedited continuing reviews (CRs). Increase attributed in part due to increased capacity for completing CRs due to return of expedited CR reviewer from leave in January FY14.

*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 Q2 FY14

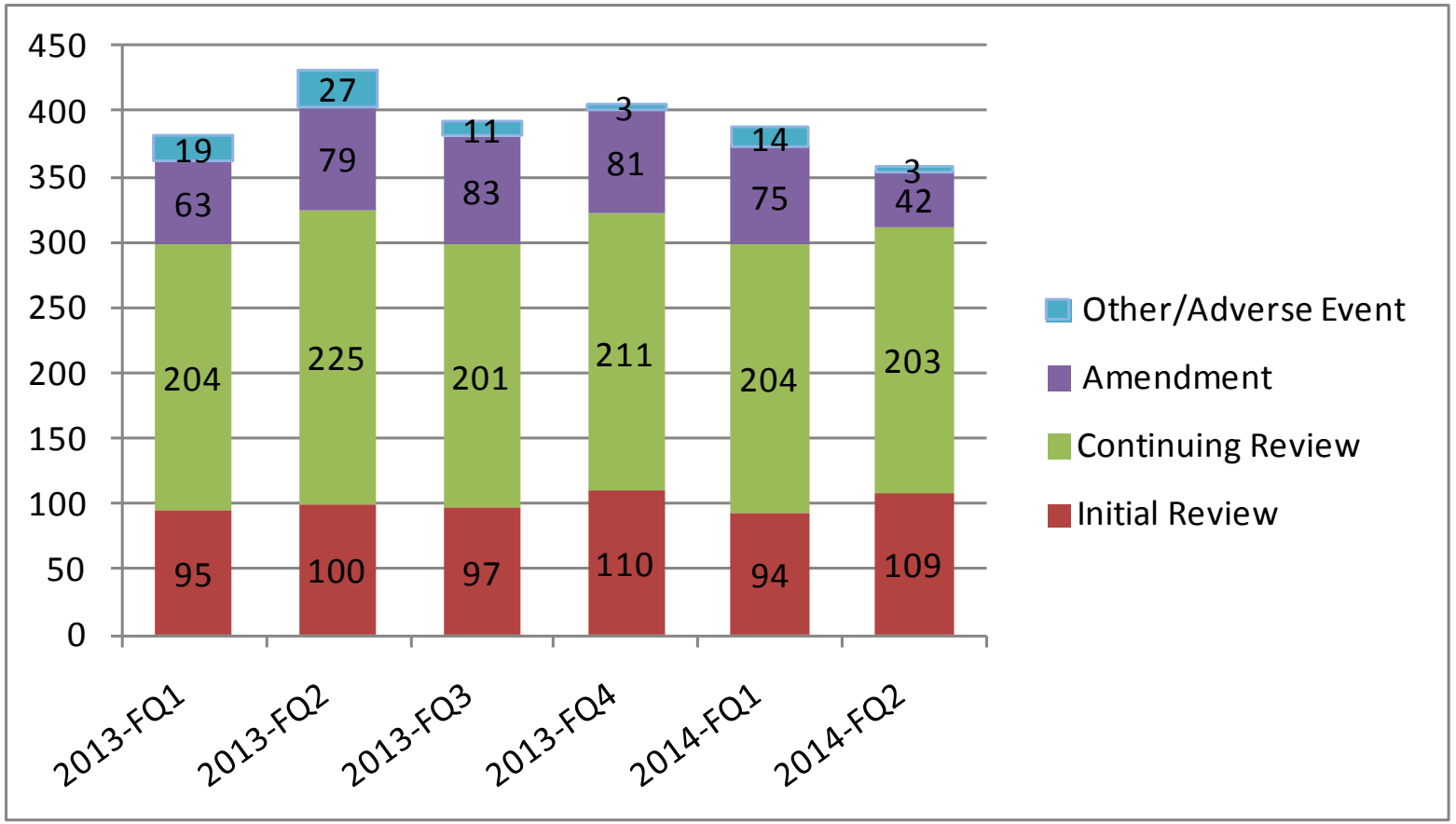


- In comparison to Q1 FY14, the number of expedited reviews increased 5% to 6,241. Continuing reviews (CRs) increased 29%, due in part due to increased capacity for completing CRs due to return of expedited CR reviewer from leave in January FY14. Amendments increased 3%, and study staff amendments decreased 4% in Q2 FY14. Initial reviews and other/adverse events 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 Q2 FY14

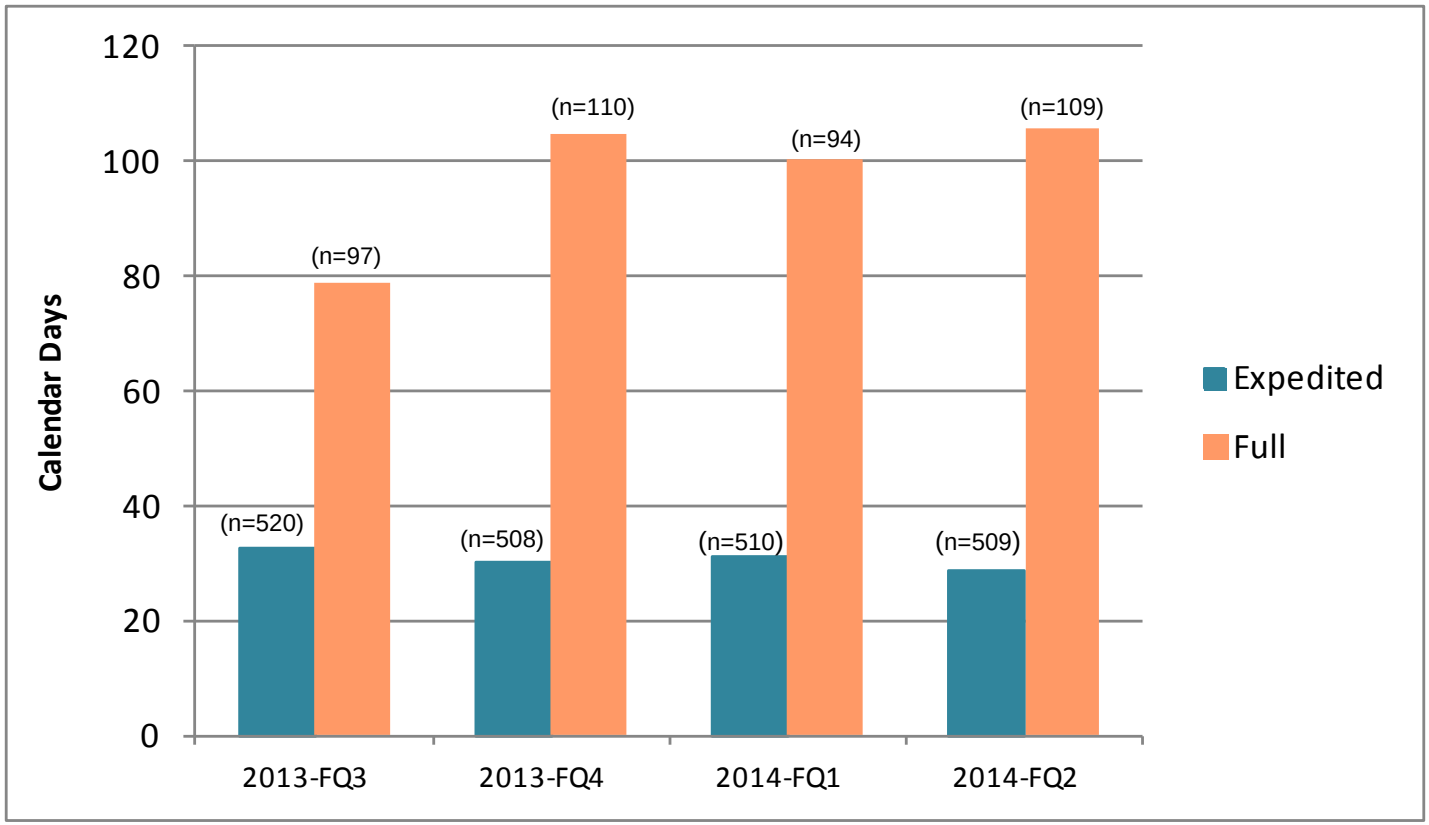


▪ The volume of full board review approvals remains fairly consistent throughout the year. There was an 8% decrease in Q2 in full board reviews (from Q1 FY14), mainly due to a 44% decrease in amendments as a higher proportion of amendments were reviewed by expedited review due to meeting the criteria for minimal risk research or the amendment included only a minor change in more than minimal risk research.

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

Initial Review Applications (IR)

Turnaround Time by Quarter

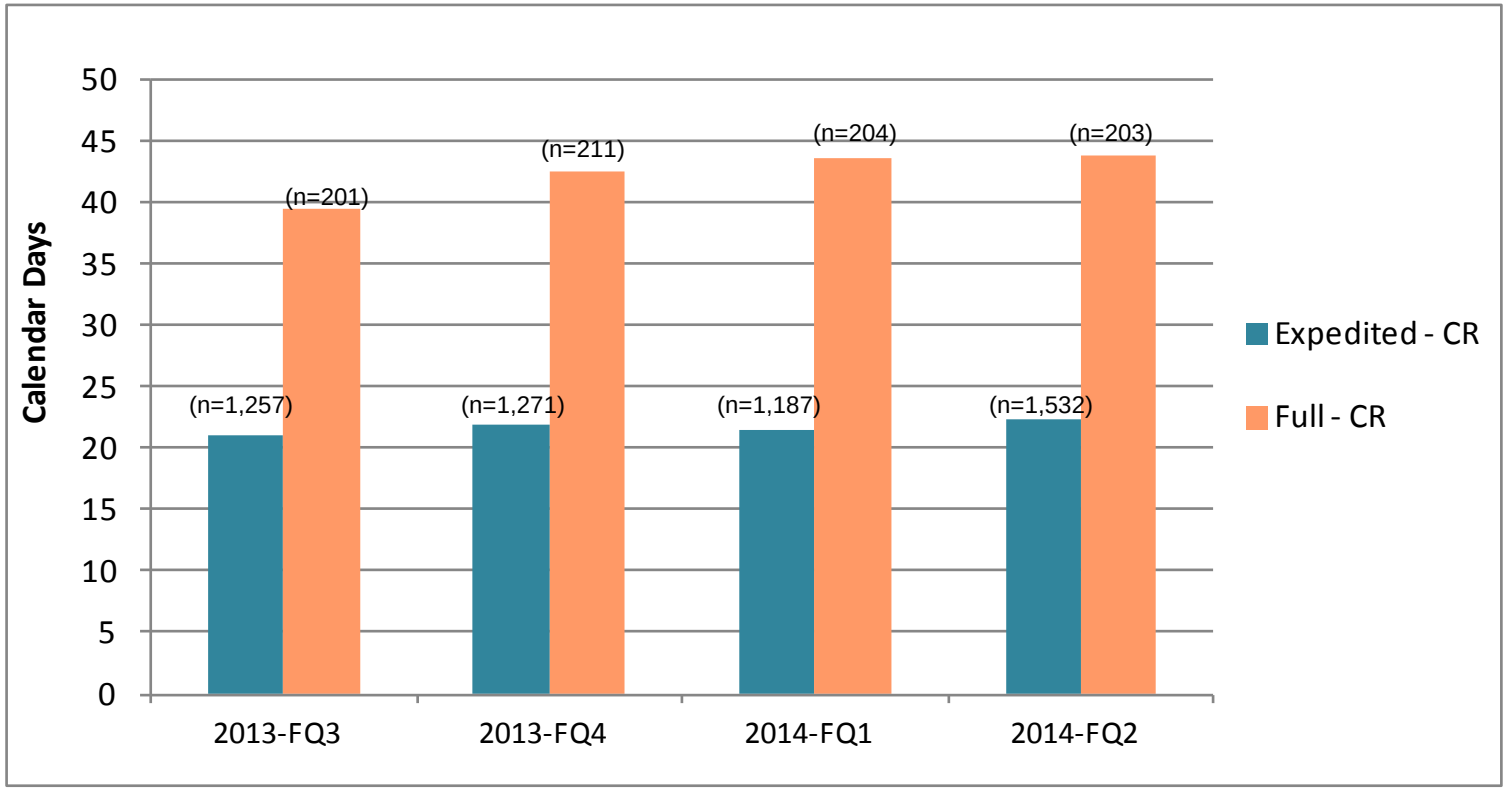


▪ In the last 3 quarters, turnaround times have remained fairly consistent, with expedited reviews averaging 30 day TATs and full board reviews averaging 104 day TATs.

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

Continuing Reviews (CR)

Turnaround Time by Quarter

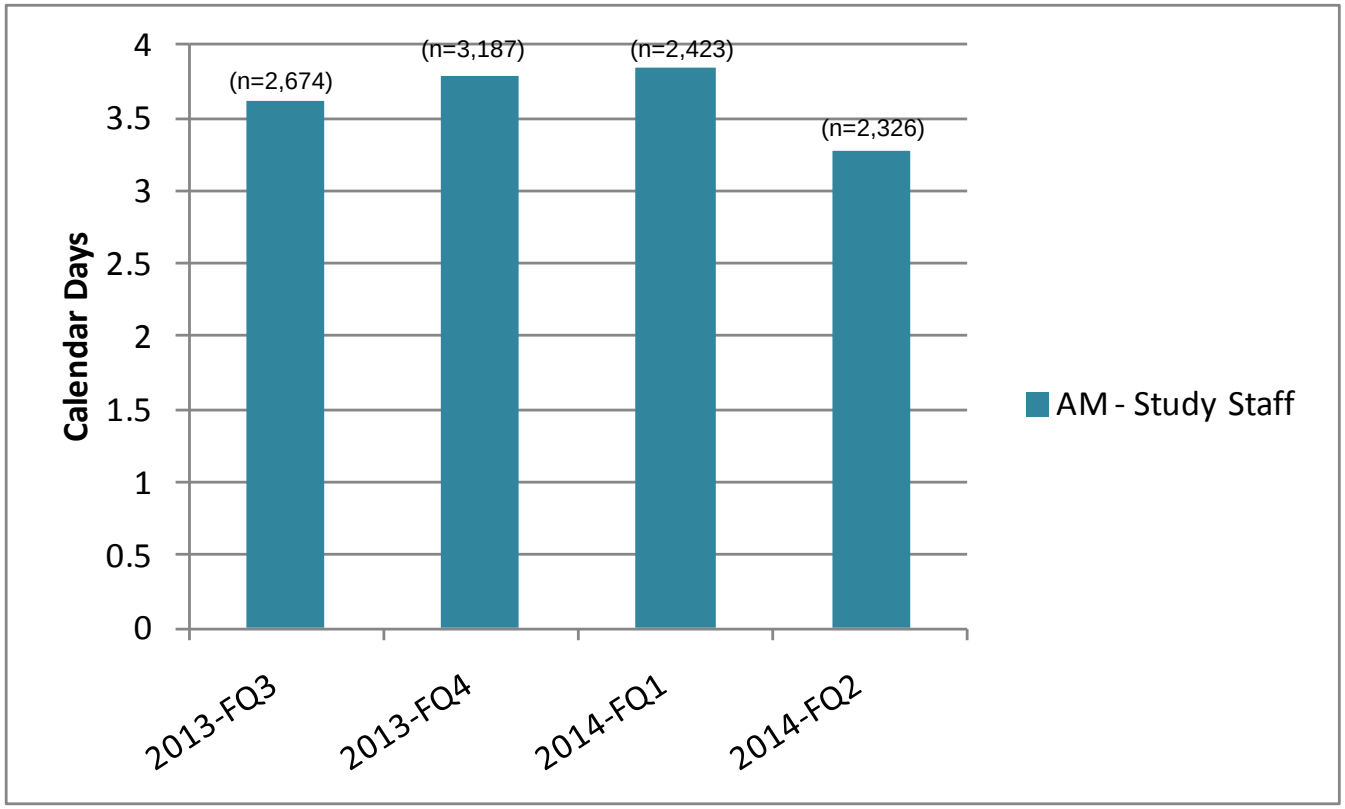


- In the last 3 quarters, turnaround times have remained consistent, with expedited reviews averaging 22 day TATs and full board reviews averaging 43 day TATs.

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

Study Staff Amendments (SSAME)

Turnaround Time by Quarter

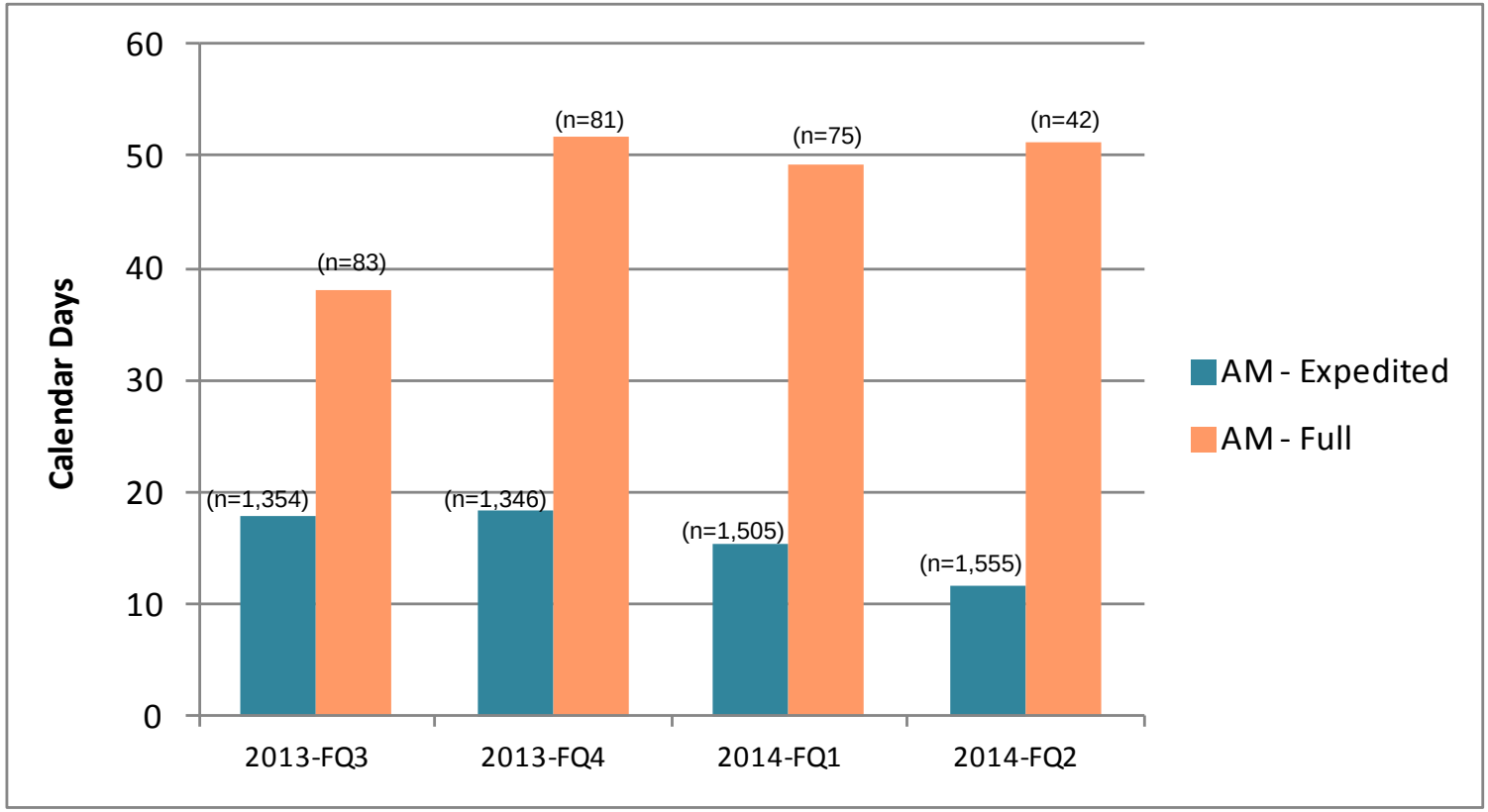


- The average turnaround time (TAT) for study staff amendments decreased from 3.8 days in Q1 to 3.3 days in Q2 FY14 due to a decline in submissions requiring modifications. Although only 10% of study staff amendments required modifications in Q2 (versus 11% in Q1 FY14), modifications dramatically increased the TATs for study staffs. In Q2, a study staff amendment with zero modifications had a 1.1 day average TAT, while study staff amendments with one modification averaged 21 days and those with 2 or more modifications averaged TATs of 34 days (usually related to external study staff or conflicts of interest disclosures).

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

Amendments (AME)

Turnaround Time by Quarter



▪ Turnaround times have decreased for expedited reviews of amendments by 3 days in the last 2 quarters (from 18 days in Q4 FY13 to 15 days in Q1 and 12 days in Q2), as an expedited reviewer was added in October FY13. Full board reviews averaged 51 day turnaround times in the last 3 quarters.

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

PARTNERS HEALTHCARE

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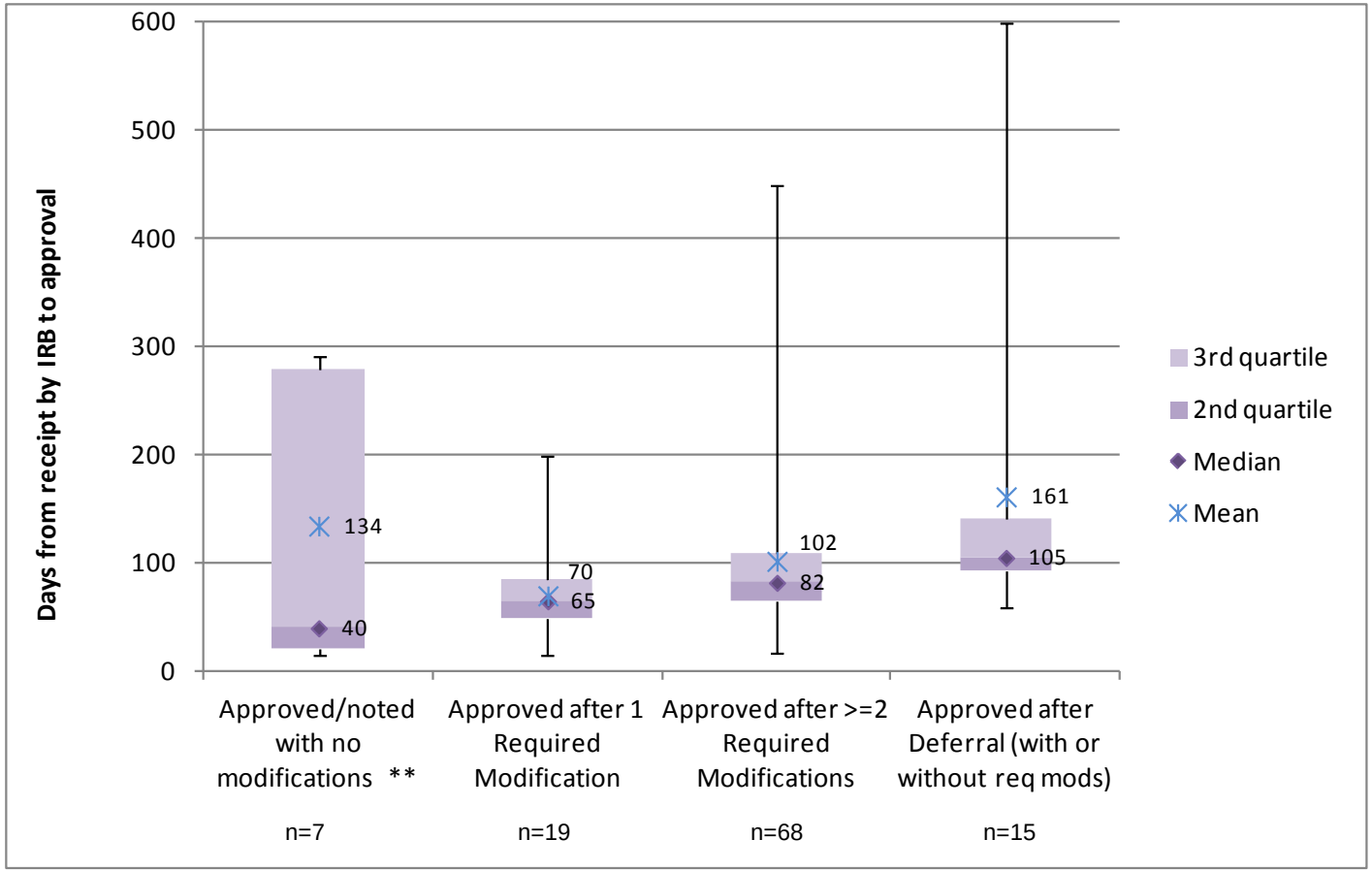
Appendix

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

Full Board – Initial Review Applications Turnaround Time

by Type of Modification for Approvals in Q2 FY14



The purpose of this slide is to show the distribution of turn around times by number/type of modifications for full board initial reviews completed in Q2 FY14. Half of the submissions are included in the boxed areas, while the whiskers show the range which includes the minimum and maximum turn around times for individual submissions.

** 3 emergency single patient reviews (with no modifications) were reviewed and noted by a full board in June and July of FY13; however, the protocols were not officially closed out in the system until February FY14.

Turnaround Time (TAT) by Protocol Type and Number of Modifications

for Full Board Reviews – Q2 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	2	31.5	22.5
			1 Total Mods	21	44.8	17.1
			>= 2 Total Mods	18	58.3	18.3
		Secondary Use	>= 2 Total Mods	1	96.0	7.0
Full	Continuing Review	Intervention/Interaction	0 Total Mods	12	28.0	20.9
			1 Total Mods	137	42.3	22.7
			>= 2 Total Mods	54	50.8	25.8
Full	Initial Review	Emergency Sgl Pt	0 Total Mods	6	135.2	20.3
		Intervention/Interaction	0 Total Mods	1	25.0	20.0
			1 Total Mods	19	72.6	15.1
			>= 2 Total Mods	82	112.7	18.7
		Tissue Repository	1 Total Mods	1	54.0	7.0
Full	Other Event	Intervention/Interaction	0 Total Mods	2	19.0	16.5
			>= 2 Total Mods	1	139.0	2.0
Total				**357**	**63.6**	**21.0**

- 98% of full board approvals in Q2 were on intervention/interaction protocols. Protocols with zero modifications typically had dramatically lower turnaround times than protocols with modifications, however, only 6% of protocols were approved with zero modifications. The majority of full board continuing reviews had 1 modification (67%) while the majority of full board initial reviews had 2 or more modifications (80%). Full board amendments were fairly evenly split between submissions with 1 modification and those with 2 or more modifications.

*Note 1: 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).

Note 2: Modifications include both required modifications and deferrals.

Turnaround Time (TAT) by Protocol Type and Number of Modifications

for Expedited Reviews – Q2 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	4	5.8	3.3
			1 Total Mods	1	12.0	11.0
		Data Repository	0 Total Mods	22	9.2	6.7
			1 Total Mods	7	22.4	3.6
			>= 2 Total Mods	2	16.0	7.0
		Excess Human Material	0 Total Mods	25	4.7	3.7
			1 Total Mods	10	31.5	7.3
			>= 2 Total Mods	2	16.5	1.0
		Health / Medical Records	0 Total Mods	81	7.1	5.0
			1 Total Mods	19	14.9	3.7
			>= 2 Total Mods	4	42.3	7.5
		Intervention/Interaction	0 Total Mods	838	7.0	3.6
			1 Total Mods	382	16.6	3.8
			>= 2 Total Mods	69	43.8	4.7
		Secondary Use	0 Total Mods	63	6.3	4.9
			1 Total Mods	18	20.6	5.9
			>= 2 Total Mods	3	64.0	4.7
		Tissue Repository	0 Total Mods	4	10.5	9.0
			>= 2 Total Mods	1	59.0	18.0
Expedited	AM - Study Staff **	Coordinating Center / Core Labs	0 Total Mods	11	0.5	
			1 Total Mods	4	3.0	
			>= 2 Total Mods	1	95.0	
		Data Repository	0 Total Mods	65	1.2	
			1 Total Mods	2	12.5	
		Excess Human Material	0 Total Mods	99	0.8	
			1 Total Mods	8	64.4	
			>= 2 Total Mods	1	72.0	
		Health / Medical Records	0 Total Mods	350	1.1	
			1 Total Mods	22	17.0	
			>= 2 Total Mods	5	39.0	
		Intervention/Interaction	0 Total Mods	1,432	1.2	
			1 Total Mods	163	16.7	
			>= 2 Total Mods	21	29.6	
		Secondary Use	0 Total Mods	134	1.1	
			1 Total Mods	5	123.6	
			>= 2 Total Mods	1	4.0	
		Tissue Repository	0 Total Mods	2	0.5	

- In Q2, 69% of expedited review approvals are on intervention/interaction protocols, while 16% are on health/medical records and 8% on secondary use protocols, with the remaining 7% encompassing excess human material, data repository, coordinating center/core labs, tissue repository, and emergency single patient protocols.
- In contrast to full board reviews, 79% of expedited reviews were approved with zero modifications (72% 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 – Q2 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	18.0	14.0
		Data Repository	0 Total Mods	31	23.1	1.0
			1 Total Mods	3	45.3	0.3
		Excess Human Material	0 Total Mods	100	20.3	0.8
			1 Total Mods	1	62.0	0.0
		Health / Medical Records	0 Total Mods	283	24.9	0.6
			1 Total Mods	2	11.0	0.5
		Intervention/Interaction	0 Total Mods	731	18.7	13.2
			1 Total Mods	151	38.5	14.1
			>= 2 Total Mods	30	40.8	9.3
		Secondary Use	0 Total Mods	196	17.8	0.2
			1 Total Mods	2	25.0	0.0
		Tissue Repository	0 Total Mods	1	10.0	3.0
Expedited	Initial Review	Coordinating Center / Core Labs	0 Total Mods	2	5.5	5.0
			1 Total Mods	13	51.5	7.5
		Data Repository	0 Total Mods	1	8.0	7.0
			1 Total Mods	2	38.0	7.0
			>= 2 Total Mods	3	34.7	16.0
		Excess Human Material	0 Total Mods	17	9.6	6.1
			1 Total Mods	13	35.9	6.4
			>= 2 Total Mods	1	23.0	8.0
		Health / Medical Records	0 Total Mods	129	9.4	6.0
			1 Total Mods	62	28.5	6.3
			>= 2 Total Mods	20	56.1	7.2
		Intervention/Interaction	0 Total Mods	29	10.6	7.8
			1 Total Mods	78	37.0	7.5
			>= 2 Total Mods	62	74.5	7.3
		Secondary Use	0 Total Mods	35	7.7	6.8
			1 Total Mods	26	18.4	6.4
			>= 2 Total Mods	11	30.5	7.2
		Tissue Repository	0 Total Mods	2	11.0	7.5
			1 Total Mods	2	26.5	15.0
			>= 2 Total Mods	1	106.0	14.0
Expedited	Other Event	Data Repository	0 Total Mods	1	2.0	2.0
		Emergency Sgl Pt	0 Total Mods	1	0.0	0.0
		Intervention/Interaction	0 Total Mods	219	4.1	1.9
			1 Total Mods	79	13.2	2.1
			>= 2 Total Mods	18	62.3	1.9
		Secondary Use	1 Total Mods	1	8.0	5.0
Total				**6,241**	**12.5**	**5.8**

* Note 1: 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).

Note 2: Modifications include both required modifications and deferrals .

Aging of Pending Submissions

As of April 18, 2014

Current Pending Status	Latest Board Review Type	Submission Type	Calendar days pending 0-30	31-60	61-90	91-120	> 120	Total Submissions
Pending PI/Submitter	Expedited	AM - Study Staff	20	19	10	3	45	97
		Amendment	38	13	4	4	21	80
		Continuing Review	6	11	7	1	10	35
		Initial Review	52	24	23	15	80	194
		Other / Adverse Event	13	5	3		8	29
		Total	**129**	**72**	**47**	**23**	**164**	**435**
	Full	Amendment	4	1	1		1	7
		Continuing Review	14	7	3	1	8	33
		Initial Review	25	23	17	12	30	107
		Other / Adverse Event	1		1	1		3
		Total	**44**	**31**	**22**	**14**	**39**	**150**
	UNASSIGNED	AM - Study Staff					14	14
		Amendment	27	5	2	1	23	58
		Continuing Review	36	5	4	5	27	77
		Initial Review	4	6		1	23	34
		Other / Adverse Event	2				6	8
		Total	**69**	**16**	**6**	**7**	**93**	**191**
	Total		**242**	**119**	**75**	**44**	**296**	**776**
Pending IRB	Expedited	AM - Study Staff	4	2				6
		Amendment	20		2		2	24
		Continuing Review	7	1				8
		Initial Review	3	5	4	1		13
		Other / Adverse Event	9					9
		Total	**43**	**8**	**6**	**1**	**2**	**60**
	Full	Amendment		1				1
		Continuing Review	3	1	1			5
		Initial Review		3	1	1	5	10
		Other / Adverse Event					1	1
		Total	**3**	**5**	**2**	**1**	**6**	**17**
	UNASSIGNED	AM - Study Staff	31					31
		Amendment	11	1			2	14
		Continuing Review	78				2	80
		Initial Review	11				1	12
		Other / Adverse Event	7					7
		Total	**138**	**1**			**5**	**144**
	Total		**184**	**14**	**8**	**2**	**13**	**221**
Pending Ancillary	Expedited	Amendment	5					5
		Initial Review	3	1				4
		Other / Adverse Event	1					1
		Total	**9**	**1**				**10**
	Full	Amendment	1					1
		Initial Review	3	1	6	1	2	13
		Total	**4**	**1**	**6**	**1**	**2**	**14**
	Total		**13**	**2**	**6**	**1**	**2**	**24**
Total			**439**	**135**	**89**	**47**	**311**	**1,021**

- 76% of the pending submissions at 4/18/14 were awaiting action from a PI/Submitter, 22% were awaiting action from the IRB, and 2% were awaiting action from an Ancillary Department.

- 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 closed and then subsequently reactivated).