Third Party Review Organization Performance Report

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Introduction and Review Timeline Description

The Third Party (3P) Program, formally known as the Accredited Persons Program, was created by the FDA Modernization Act (FDAMA) of 1997 to improve the efficiency and timeliness of FDA's 510(k) process. Under the program, FDA accredits Third Party Review Organizations (ROs) that are authorized to conduct the primary review of 510(k)s for eligible devices.

Under MDUFA IV and MDUFA V, FDA committed to publishing the performance of accredited Third Party Review Organizations with at least five completed submissions on the Web (e.g., average number of holds, average time to final decision).

A summary of Third Party Performance Metrics will be posted on a quarterly basis. This report contains data from FY 2023, Q1 through FY 2025, Q1 (October 1, 2022, through December 31, 2024). The number of Third Party Review Organizations with at least 5 completed submissions for each Fiscal Year is shown below:

FY2023	FY2024	FY2025	FY2026	FY2027
2	2	2	0	0

The cumulative number of Third Party 510(k) submissions accepted by Quarter for each Fiscal Year is shown below:

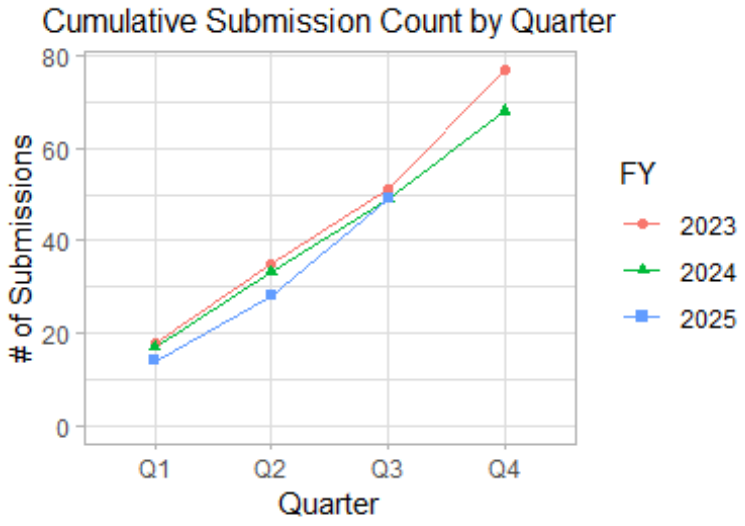
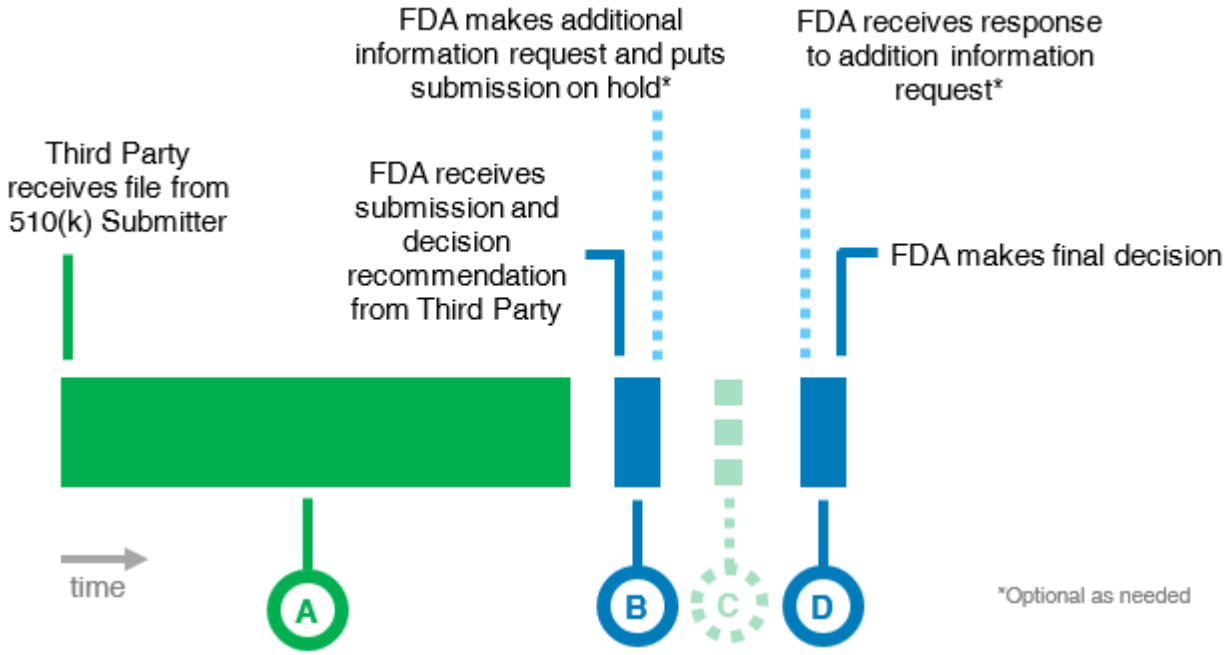


Figure 1

A Third Party 510(k) submission goes through up to four different stages before a final decision is made by FDA.

- Stage A - The Third Party Review Organization receives the file from the 510(k) Submitter, reviews the file, and sends the file and its decision recommendation to FDA.
- Stage B - FDA reviews the submission to ensure that the Third Party Review Organization has submitted all the information needed to make a final decision. If more information is needed, FDA makes a request of additional information, notifies the Third Party Review Organization, and puts the submission on hold.
- Stage C – If FDA makes a request of additional information, the Third Party Review Organization reviews FDA's request and notifies the 510(k) Submitter. The Third Party Review Organization responds to FDA's deficiencies, updating the review memo and submission as necessary. The submission is considered on hold until FDA receives a complete response to its request for additional information.
- Stage D - FDA reviews the additional information and makes a final decision.



Definitions

1) **Initial Third Party Review Time**:

= Date FDA receives Third Party submission
- Date Third Party receives the file from the 510(k) Submitter

Elapsed time in days for the Third Party to review the 510(k) Submitter's file and determine its decision recommendation for a final MDUFA V decision (Substantially Equivalent (SE) or Not Substantially Equivalent (NSE)). The elapsed time includes the time needed for the 510(k) Submitter to resolve deficiencies. The Third Party provides the Submitter's file, its associated Third Party review documentation and its decision recommendation to FDA.

2) **Third Party Hold Time**:

= Date FDA receives response to request for additional information
- Date FDA makes decision to put submission on hold

Elapsed time in days for the Third Party to respond to a request for additional information from FDA for a final MDUFA V decision (SE or NSE). If the Third Party does not receive a request for additional information, *Third Party Hold Time* is set to 0 days. If the file is placed on hold more than once, this is the total number of days the file has been on hold.

3) **Total Third Party Review Time**:

= *Initial Third Party Review Time* + *Third Party Hold Time*

Elapsed time in days for a Third Party to review a file from a 510(k) Submitter, including the time it is on hold for a final MDUFA V decision (SE or NSE).

4) **Total FDA Review Time**:

= Date FDA makes Final Decision - Date FDA receives Third Party Submission
- *Third Party Hold Time*

Elapsed time in days for FDA to provide a final MDUFA V decision (SE or NSE) to a Third Party submission. By statute, FDA must provide a final MDUFA V decision in 30 days. *Total FDA Review Time* does not include the number of days that a submission is on hold waiting for additional information from the Third Party.

5) **Total Time to Decision from FDA Receipt**:

= *Total FDA Review Time* + *Third Party Hold Time*

Elapsed time in days between FDA's receipt of a Third Party submission and FDA's final MDUFA V decision (SE or NSE). *Total Time to Decision from FDA Receipt* includes *Third Party Hold Time*, while *Total FDA Review Time* does not. For non-Third Party files, *Total Time to Decision from FDA Receipt* is called Total Time to Decision (TTD).

6) **Total Time to Decision from Third Party Receipt**:

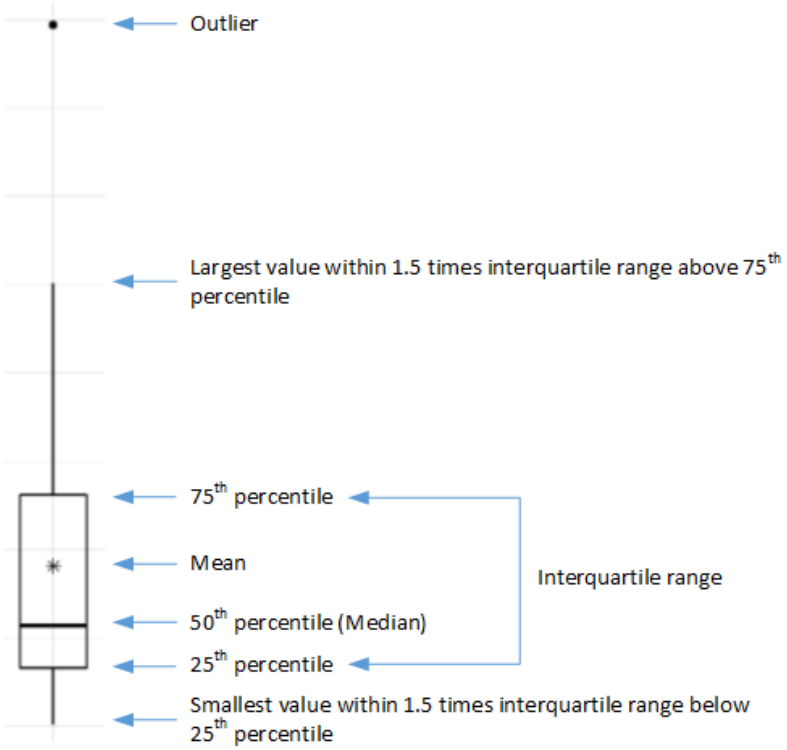
= *Total Third Party Review Time + Total FDA Review Time*

Elapsed time in days for FDA and a Third Party to provide a final MDUFA V decision (SE or NSE) to a submitter. *Total Time to Decision from Third Party Receipt* spans the entire lifecycle of a TP submission.

Names of Third Party Review Organizations

All 3PROs	All Third Party Review Organizations
AABB	Association for the Advancement of Blood & Biotherapies
BSC	BeanStock Consulting
CMSI	Center for Measurement Standards of Industrial
COLA	COLA, Inc.
GQRS	Global Quality and Regulatory Services
RTS	Regulatory Technology Services, LLC
TPRG	Third Party Review Group, LLC

Box Plot Legend:



Box Plot Sources:
Tukey (John W. Tukey (1977). Exploratory Data Analysis. Addison-Wesley.)
H. Wickham. ggplot2: Elegant Graphics for Data Analysis. Springer-Verlag New York, 2016.

Third Party Performance Data

Initial Third Party Review Time

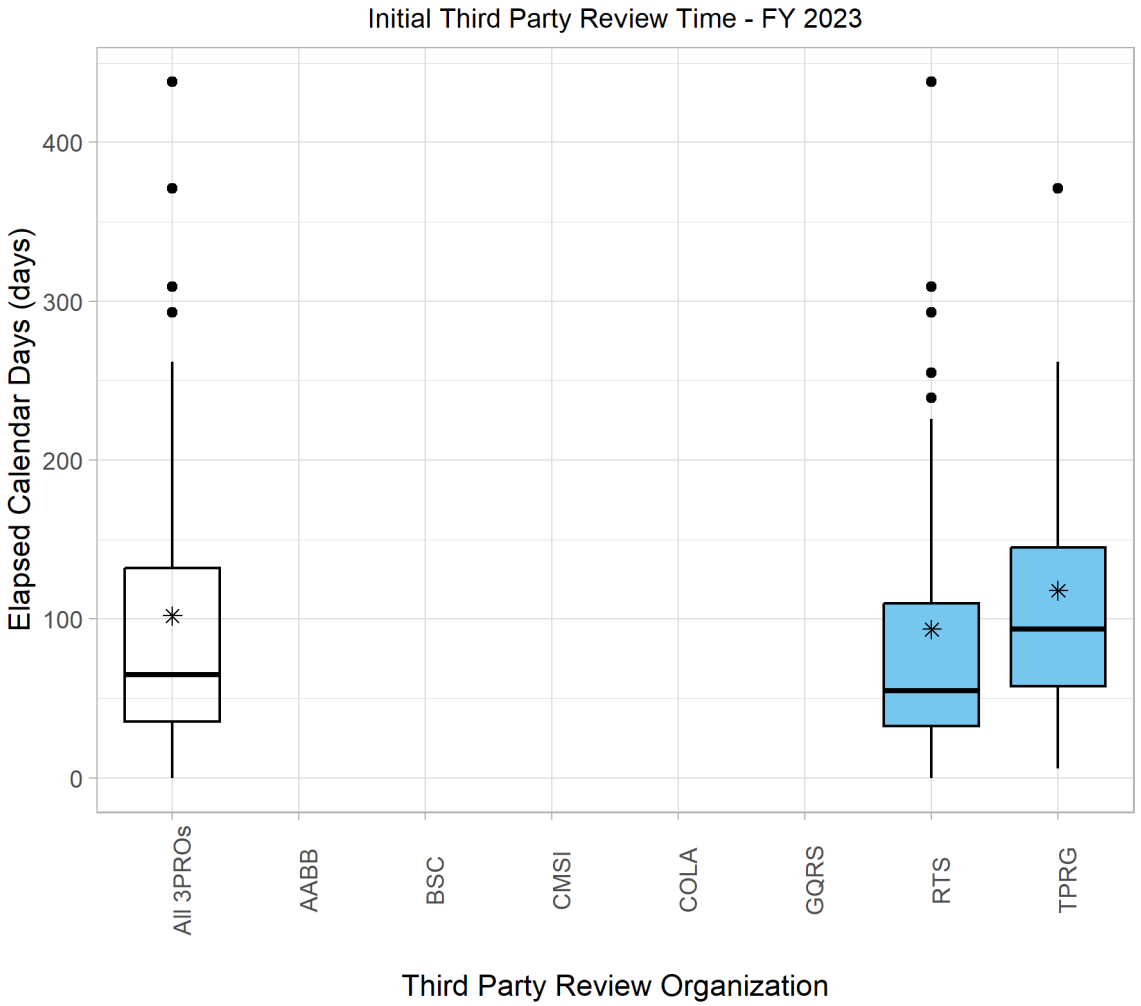


Figure 2

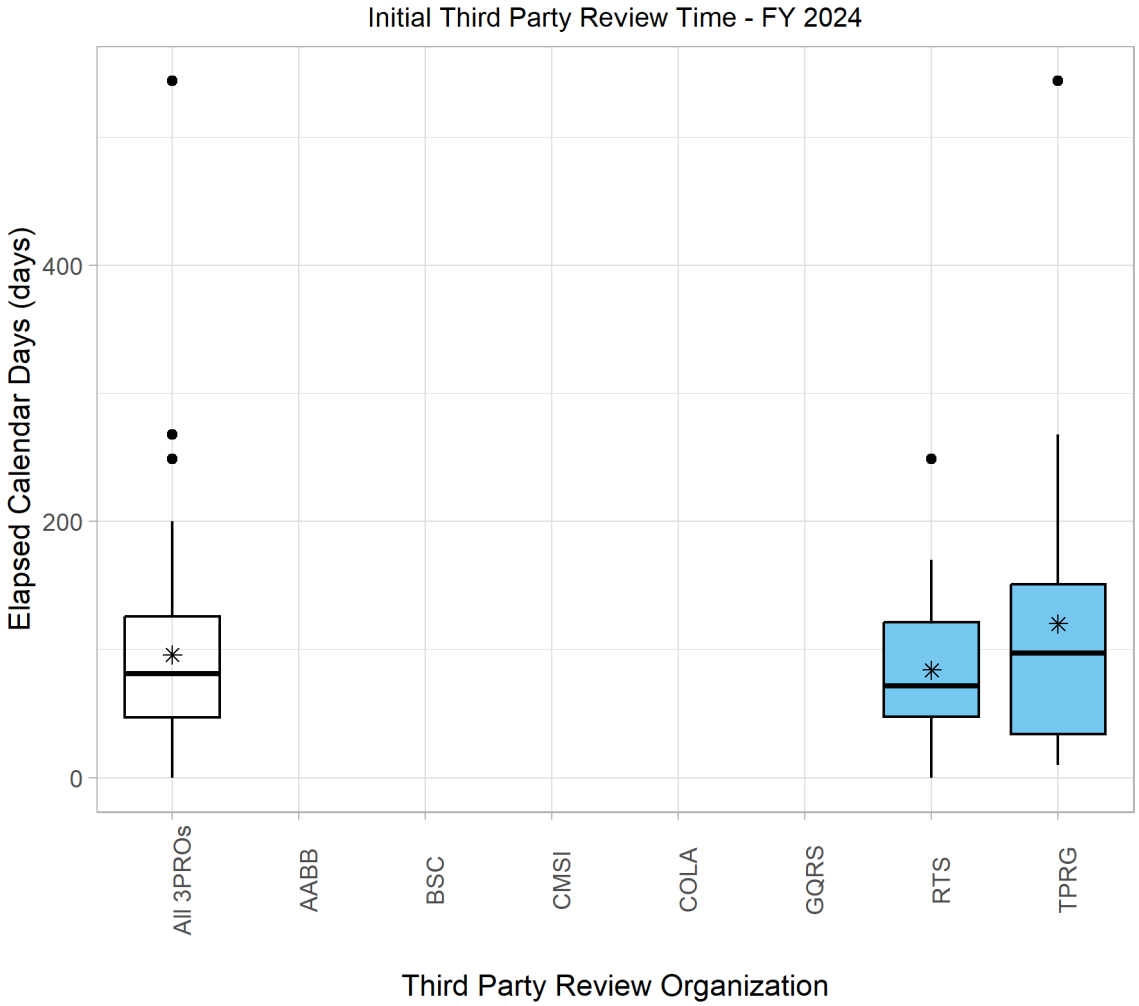

Initial Third Party Review Time - FY 2024
Elapsed Calendar Days (days)
400
200
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 3

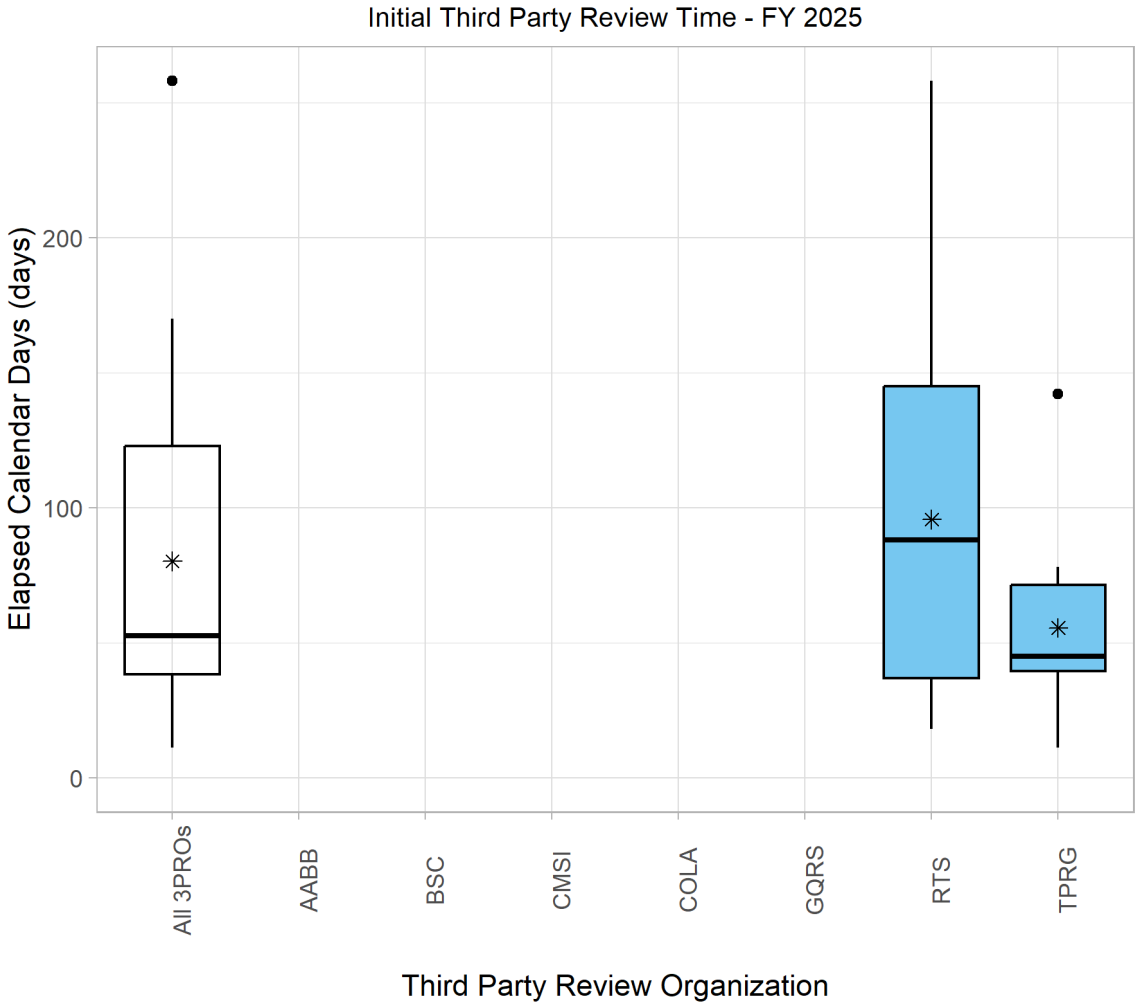

Initial Third Party Review Time - FY 2025
Elapsed Calendar Days (days)
200
100
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 4

Third Party Hold Time

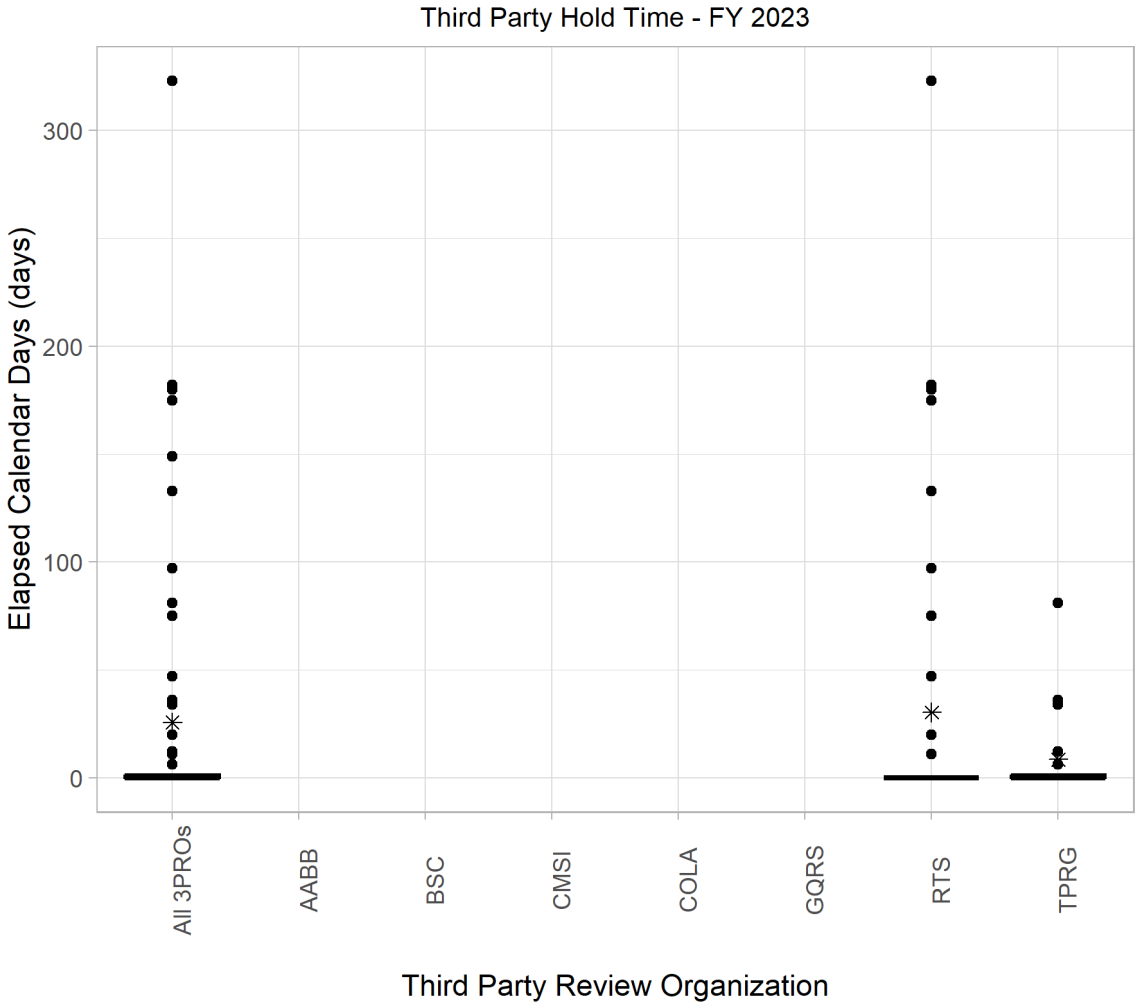


Figure 5

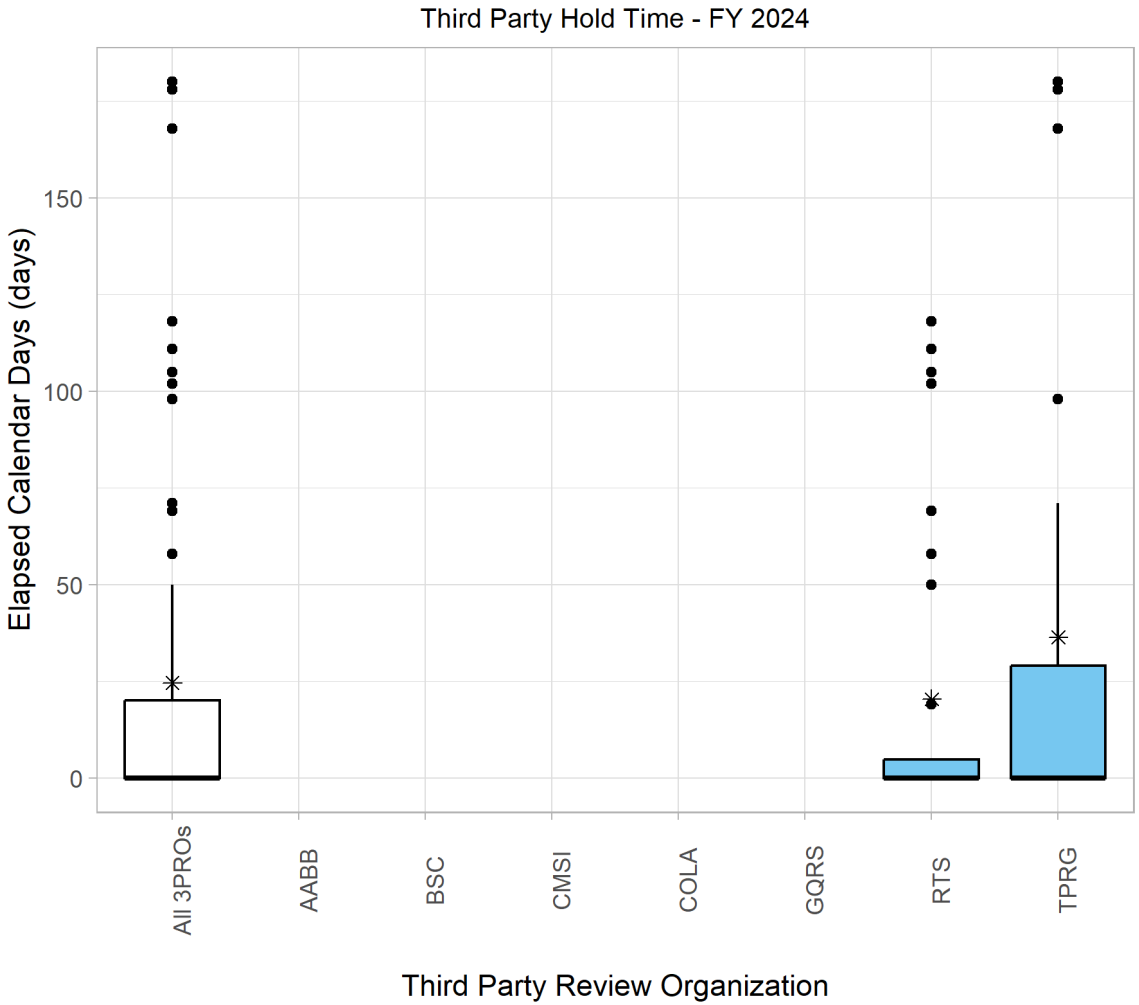

Third Party Hold Time - FY 2024
Elapsed Calendar Days (days)
150
100
50
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 6

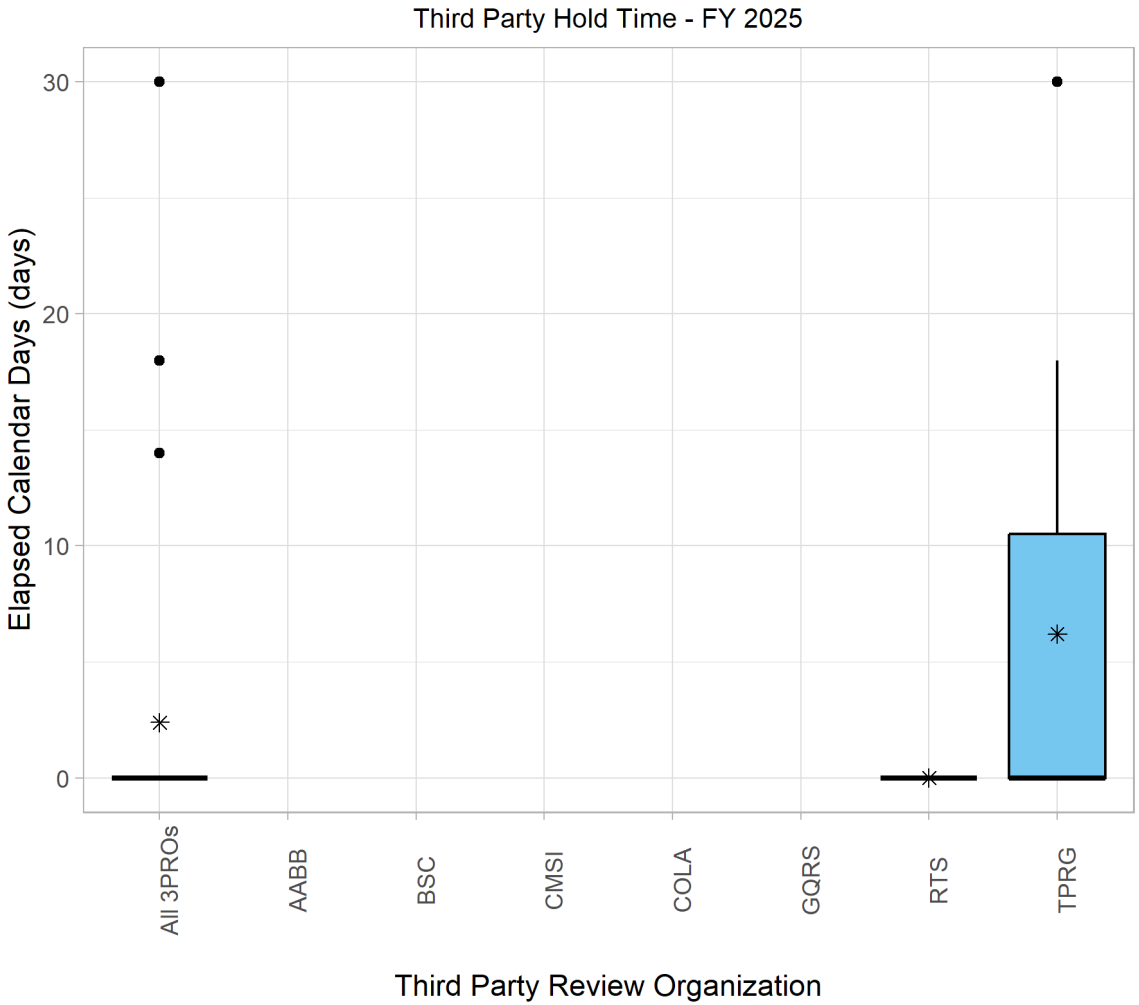

Third Party Hold Time - FY 2025
Elapsed Calendar Days (days)
30
20
10
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 7

Total Third Party Review Time

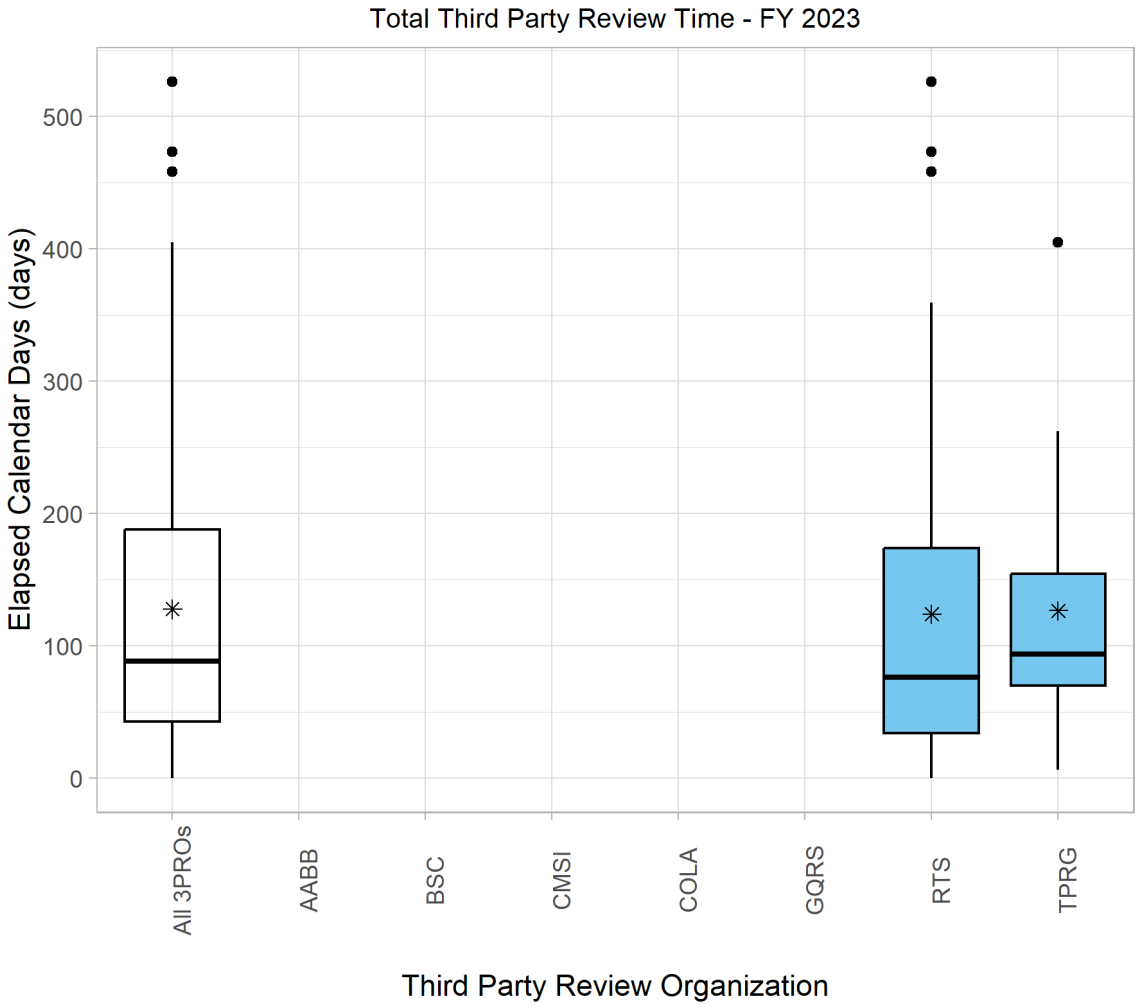


Figure 8

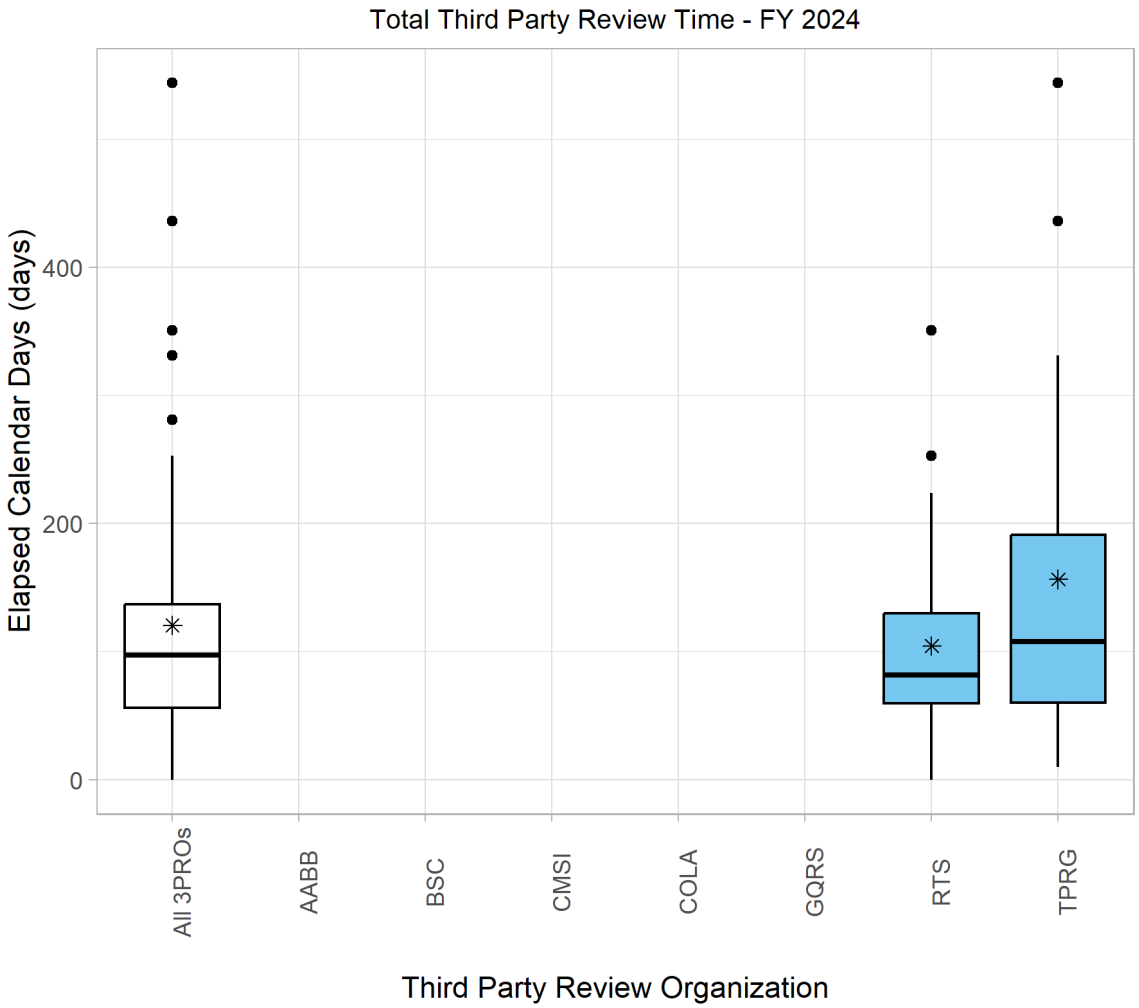

Total Third Party Review Time - FY 2024
Elapsed Calendar Days (days)
400
200
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 9

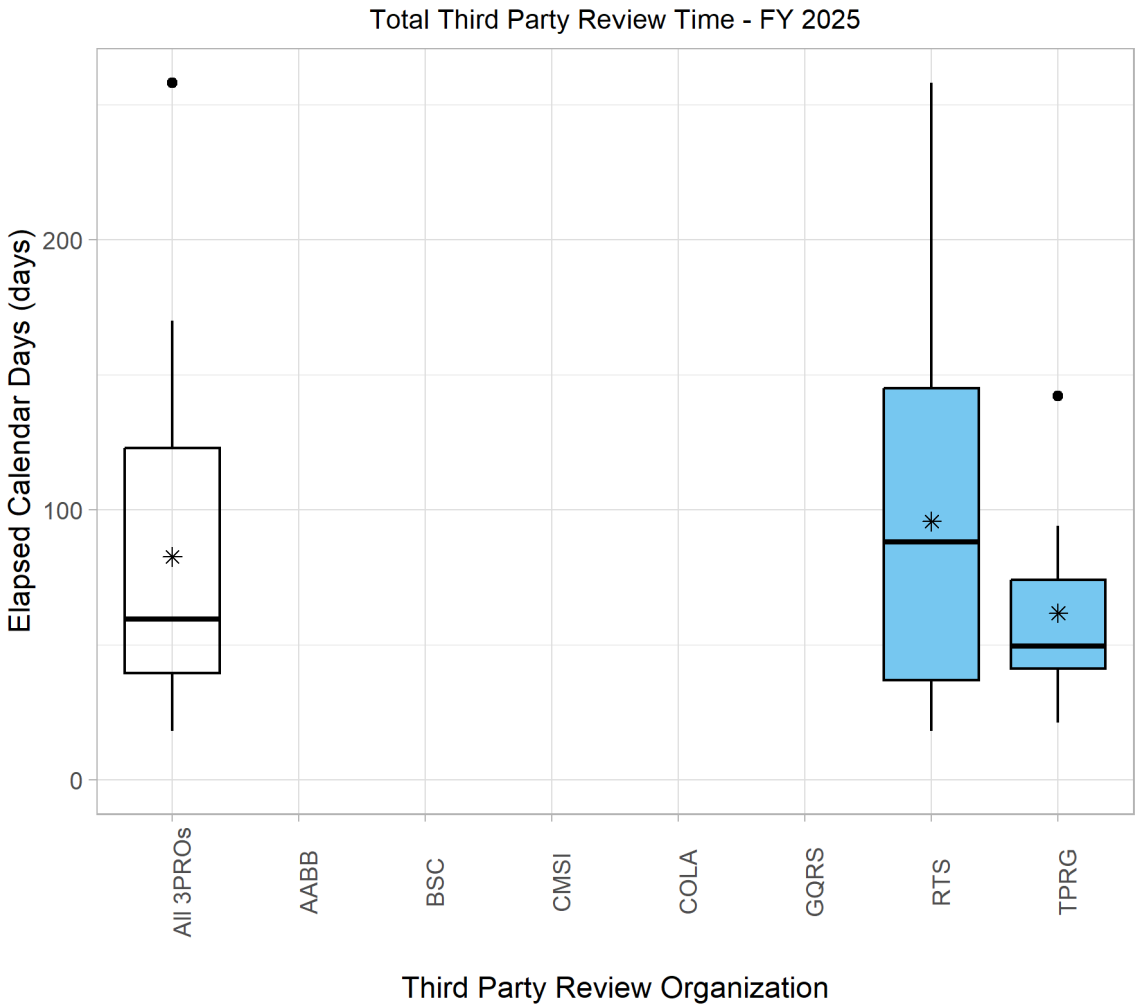

Total Third Party Review Time - FY 2025
Elapsed Calendar Days (days)
200
100
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 10

Total FDA Review Time

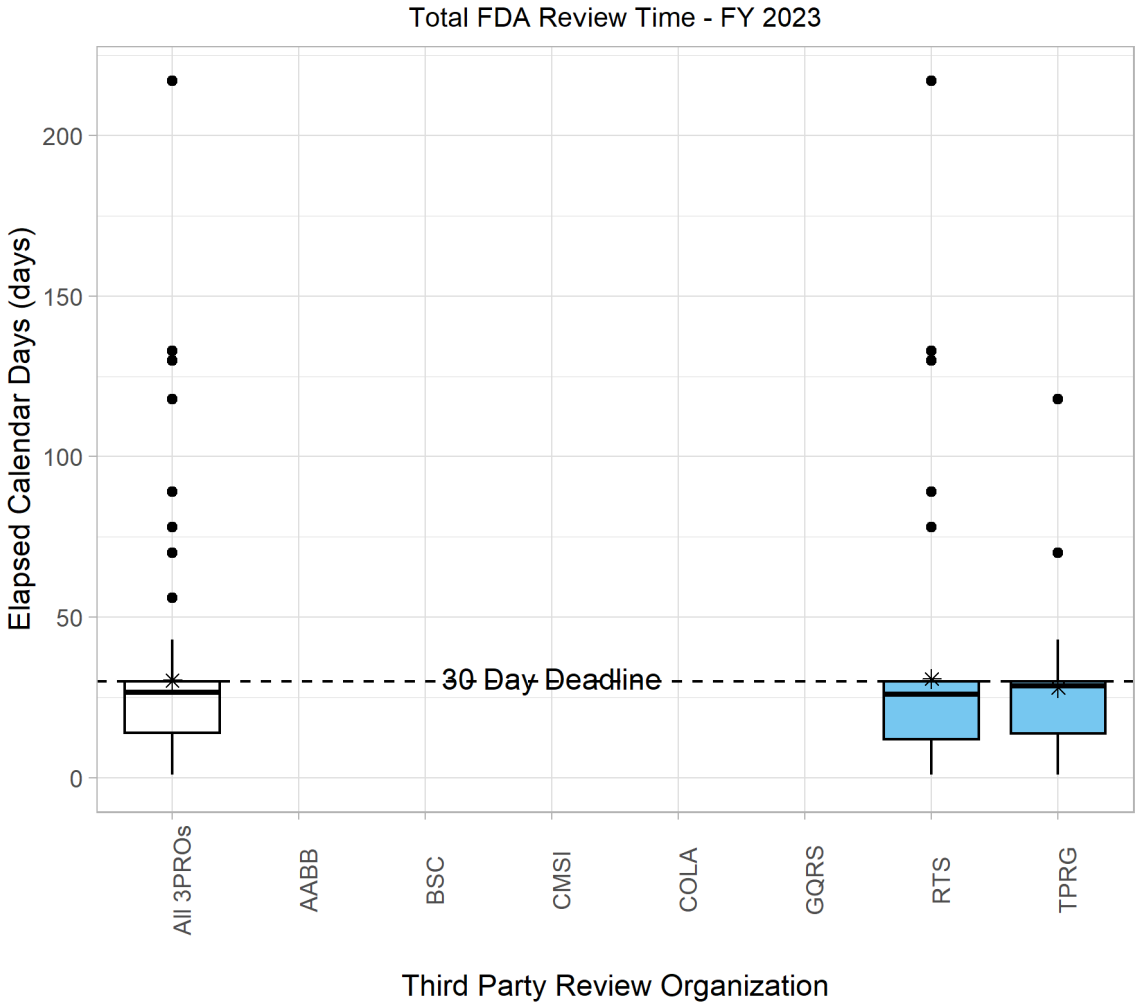


Figure 11

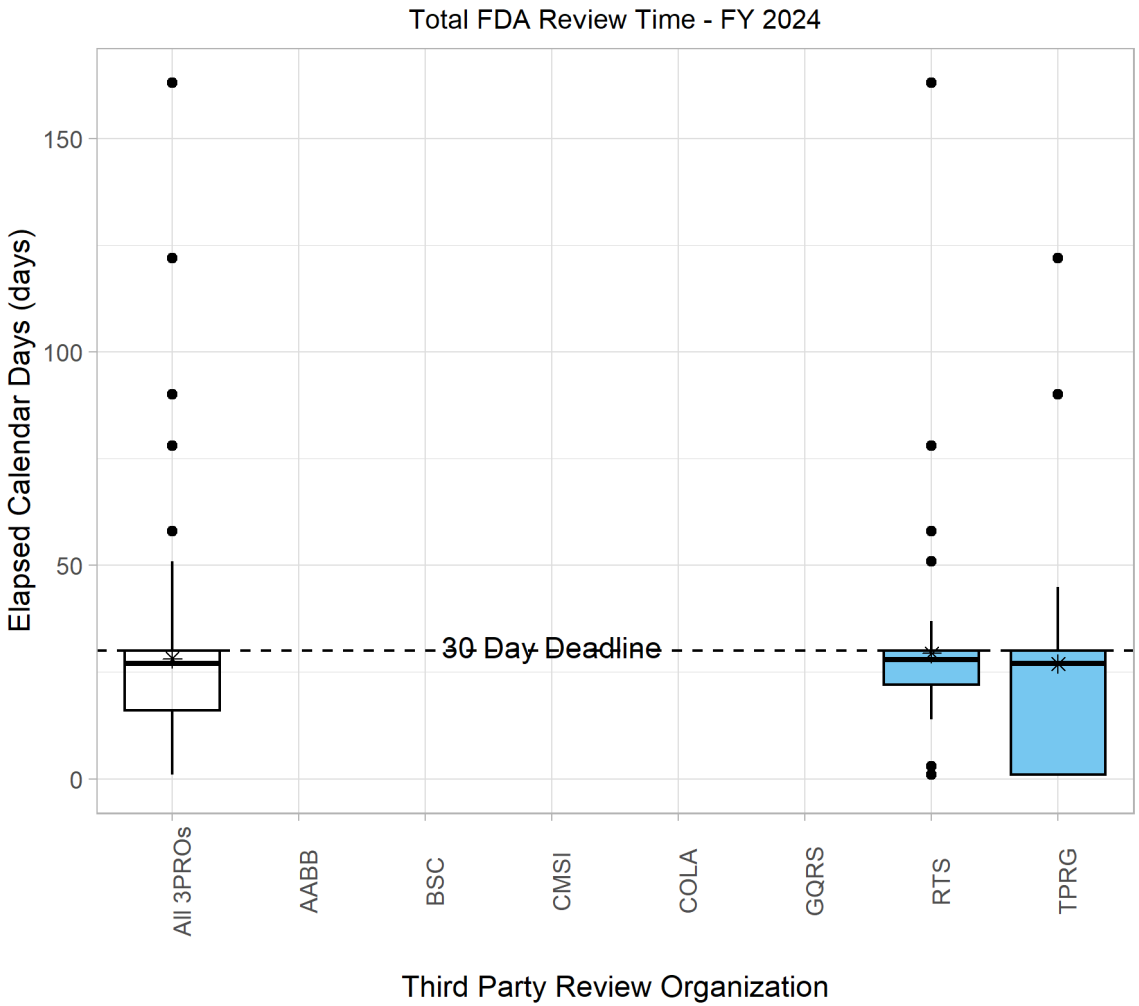

Total FDA Review Time - FY 2024
Elapsed Calendar Days (days)
150
100
50
0
30 Day Deadline
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 12

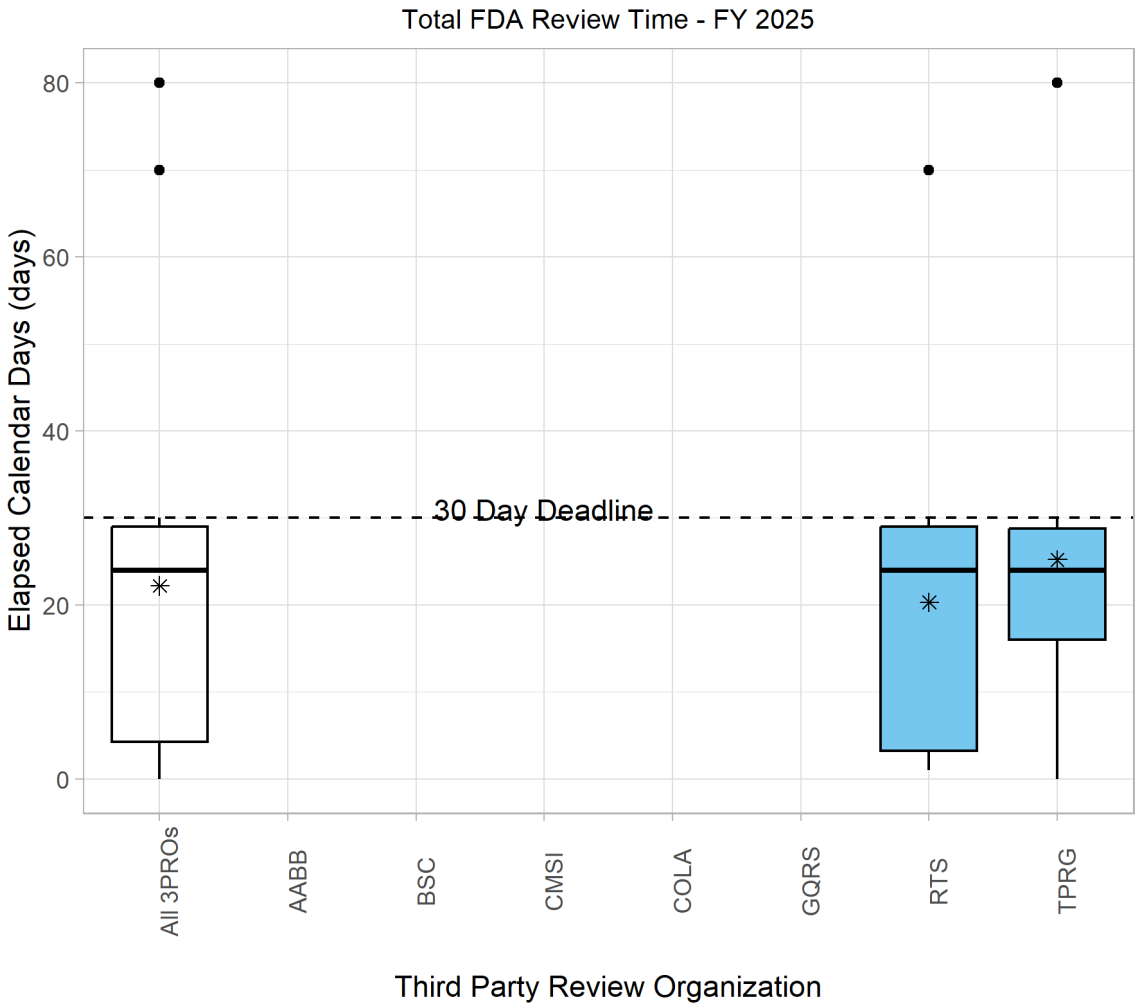

Total FDA Review Time - FY 2025
Elapsed Calendar Days (days)
80
60
40
20
0
30 Day Deadline
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 13

Total Time to Decision from FDA Receipt

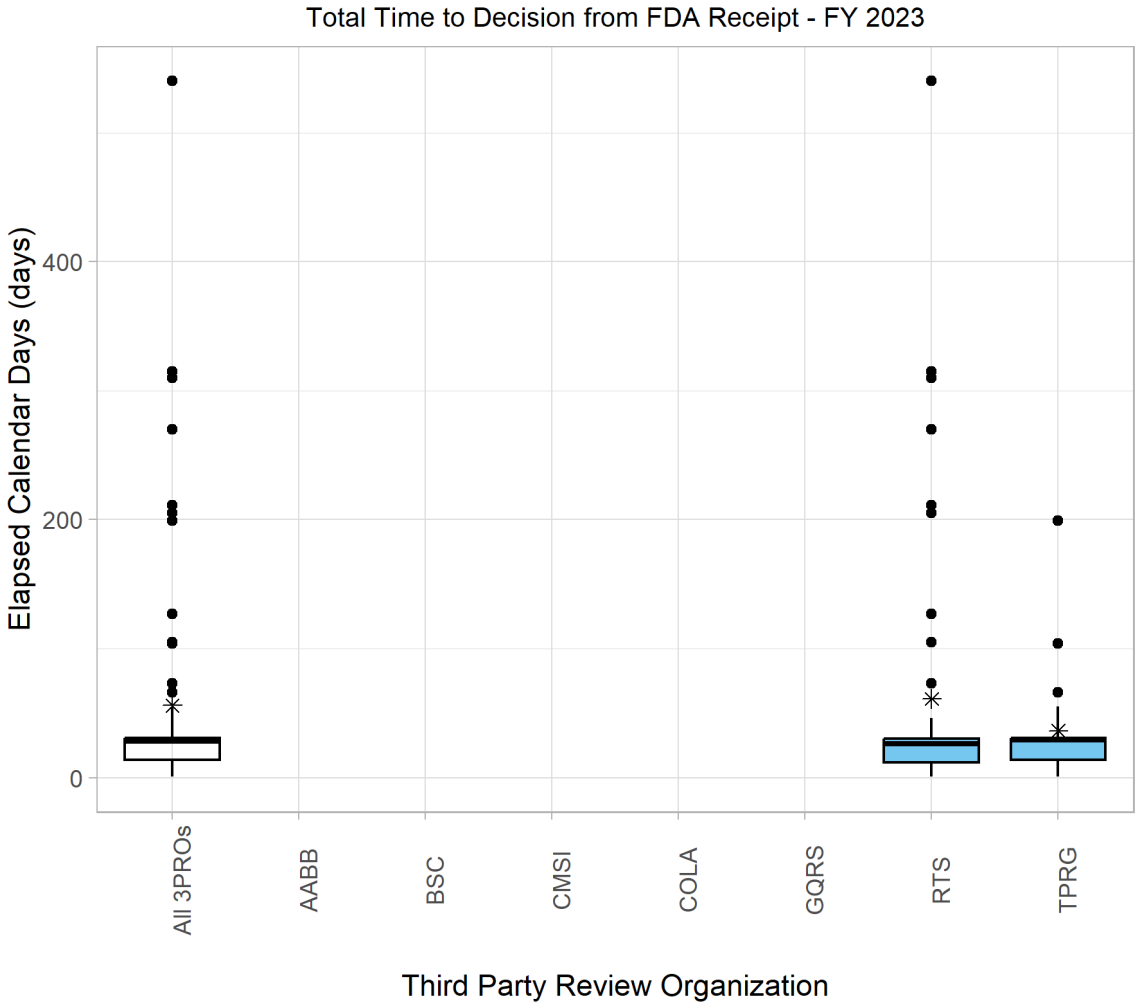


Figure 14

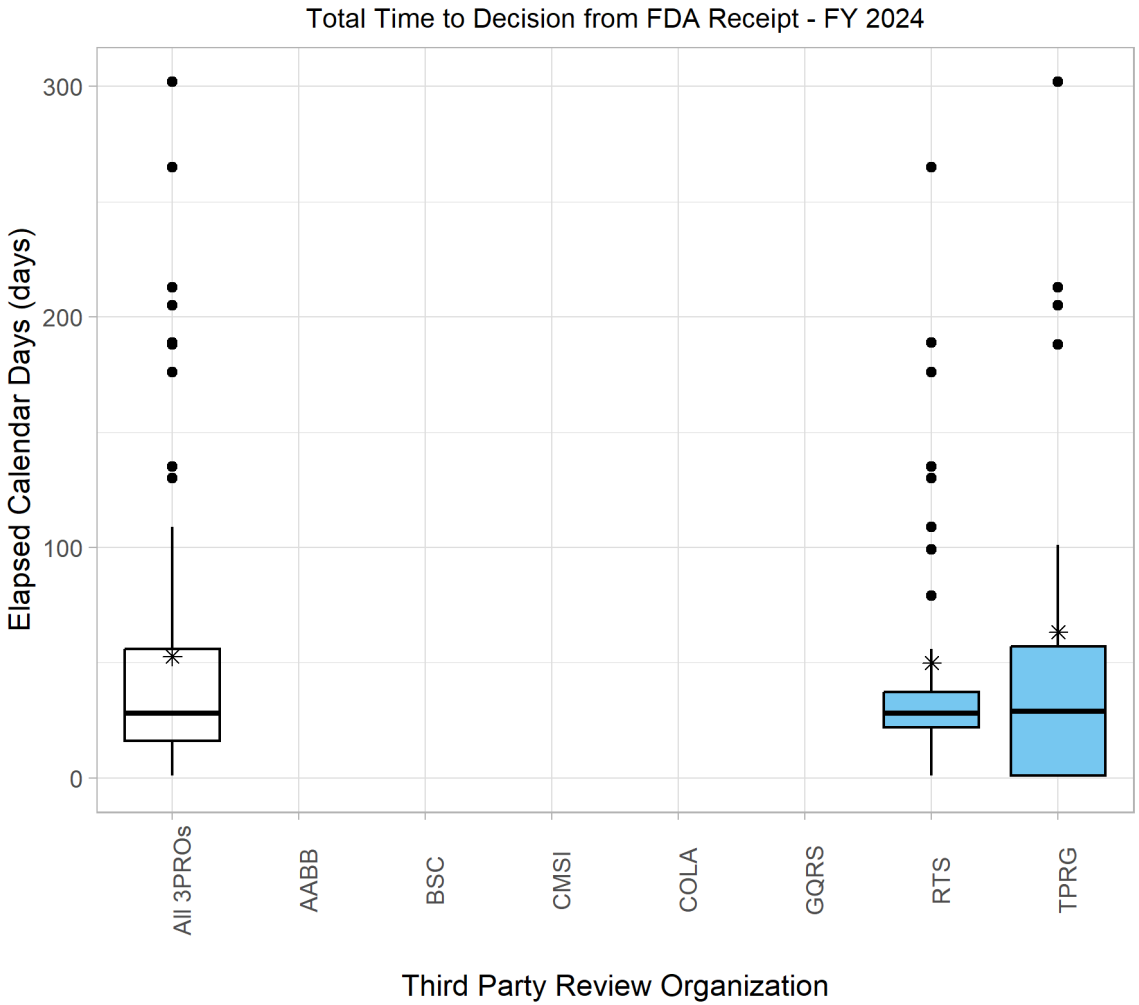

Total Time to Decision from FDA Receipt - FY 2024
Elapsed Calendar Days (days)
300
200
100
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 15

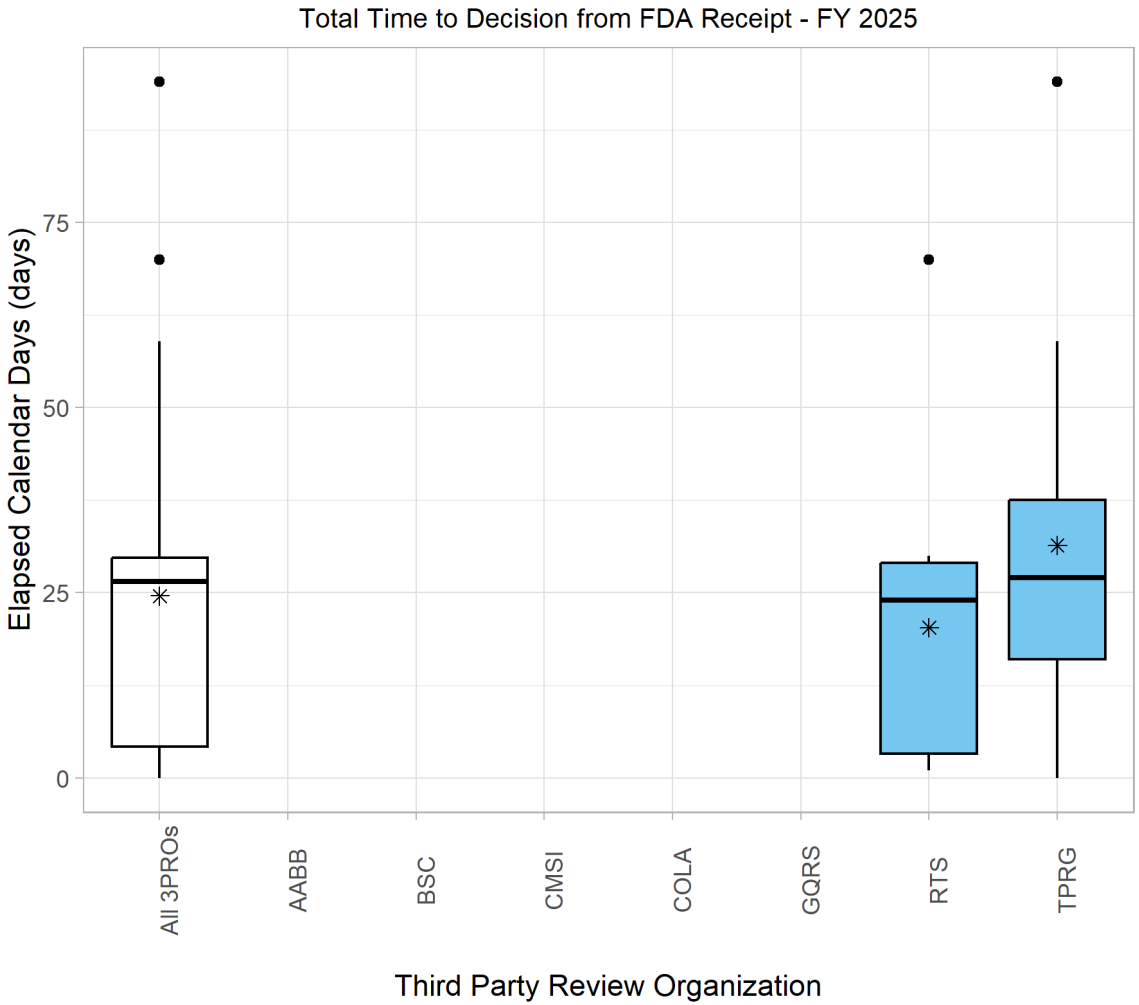

Total Time to Decision from FDA Receipt - FY 2025
Elapsed Calendar Days (days)
0
25
50
75
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 16

Total Time to Decision from Third Party Receipt

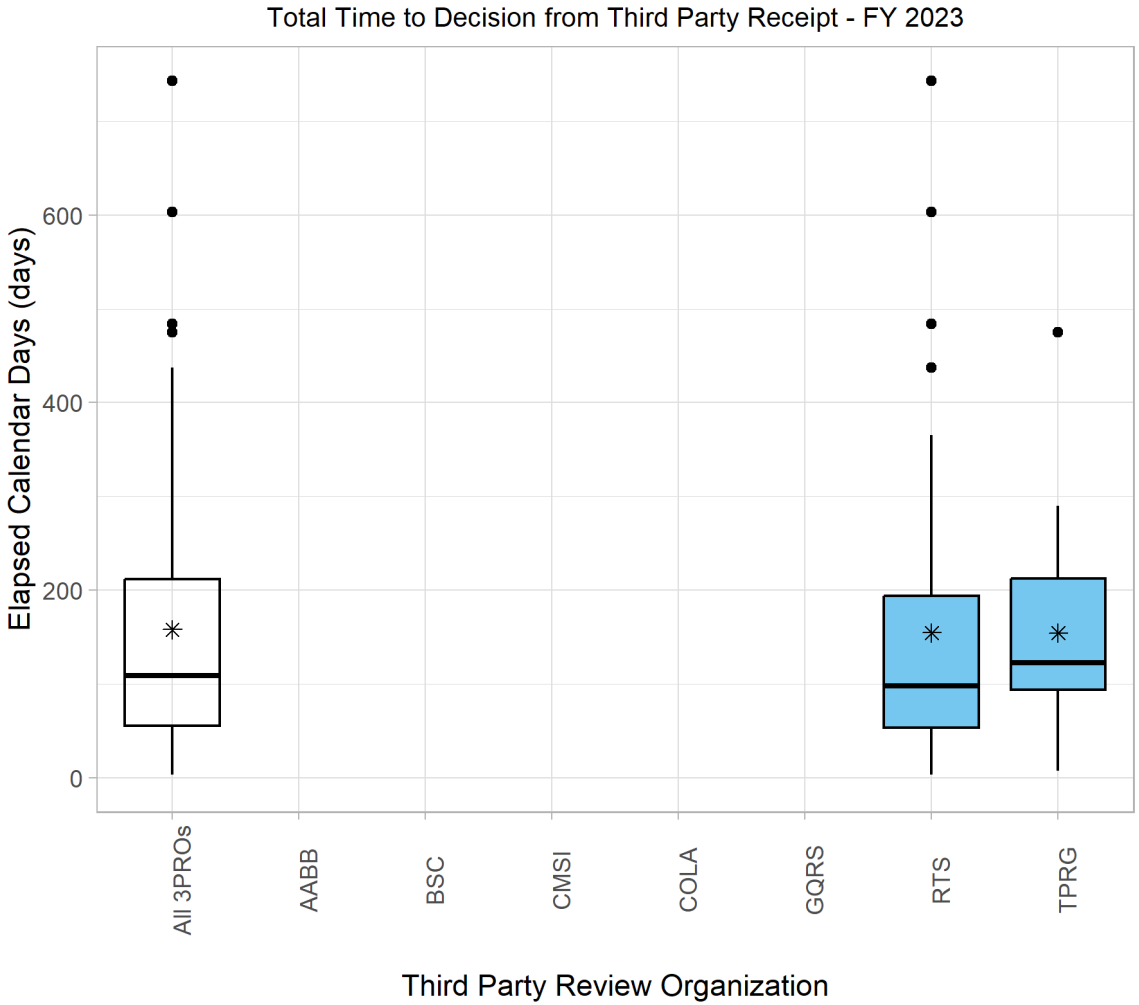


Figure 17

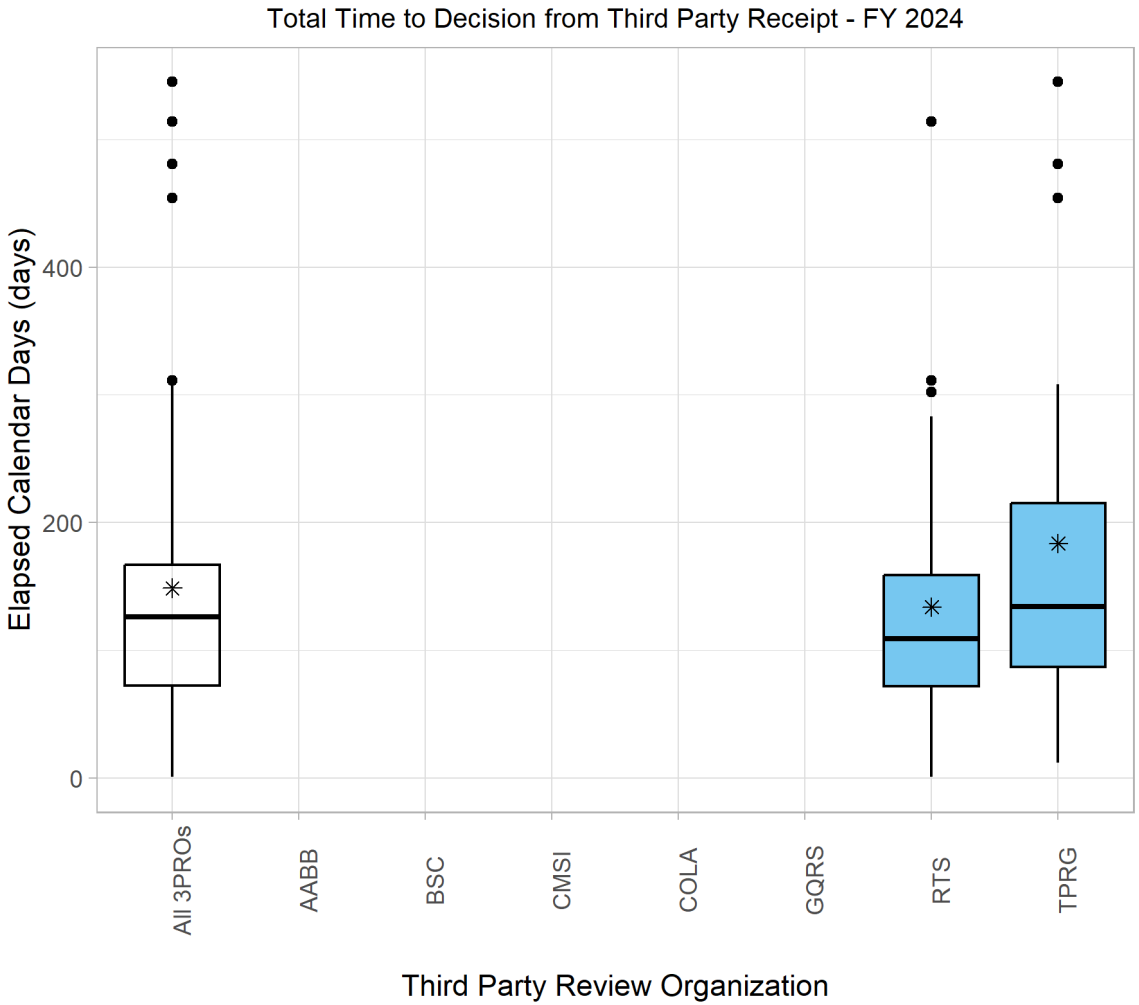

Total Time to Decision from Third Party Receipt - FY 2024
Elapsed Calendar Days (days)
400
200
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 18

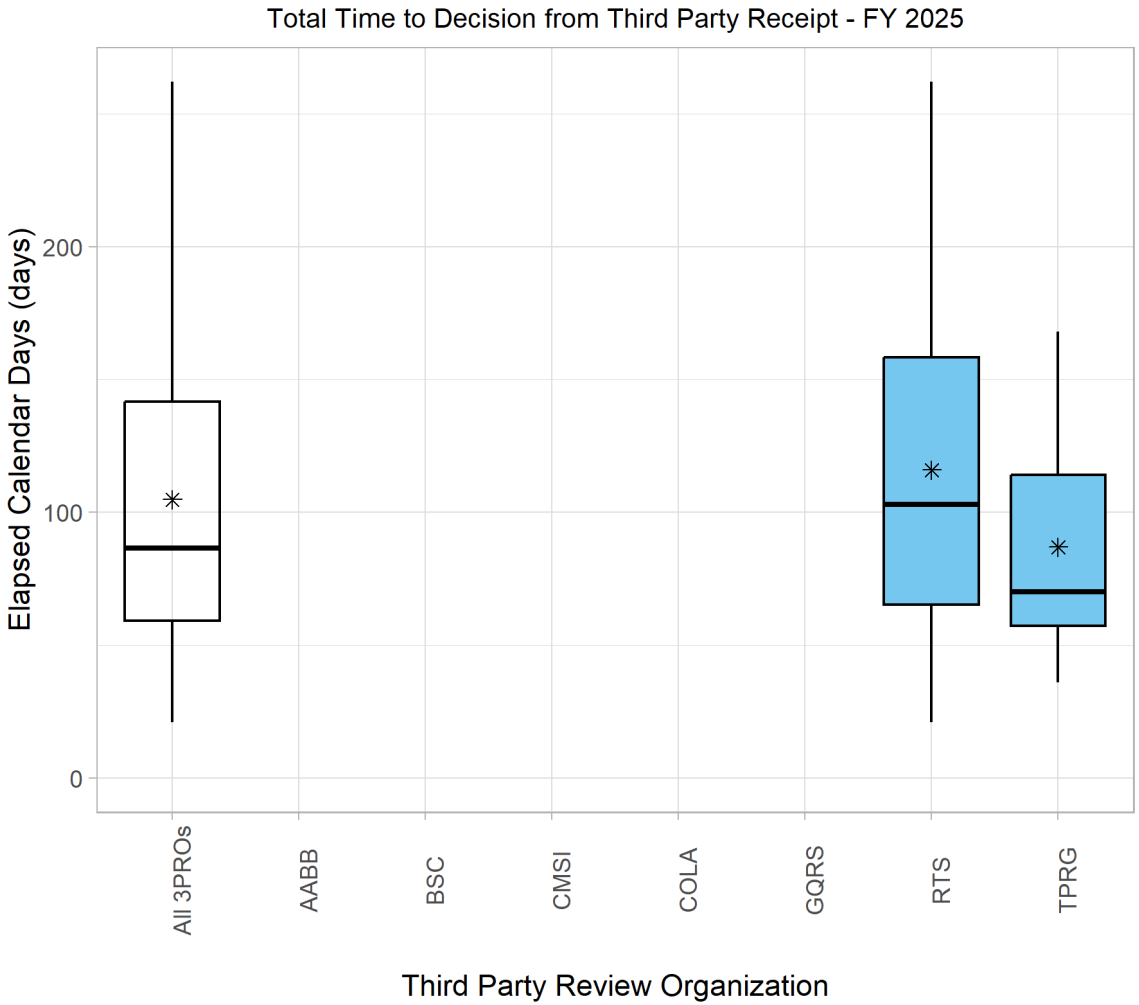

Total Time to Decision from Third Party Receipt - FY 2025
Elapsed Calendar Days (days)
200
100
0
All 3PROs
AABB
BSC
CMSI
COLA
GQRS
RTS
TPRG
Third Party Review Organization

Figure 19

All Third Party Review Organizations

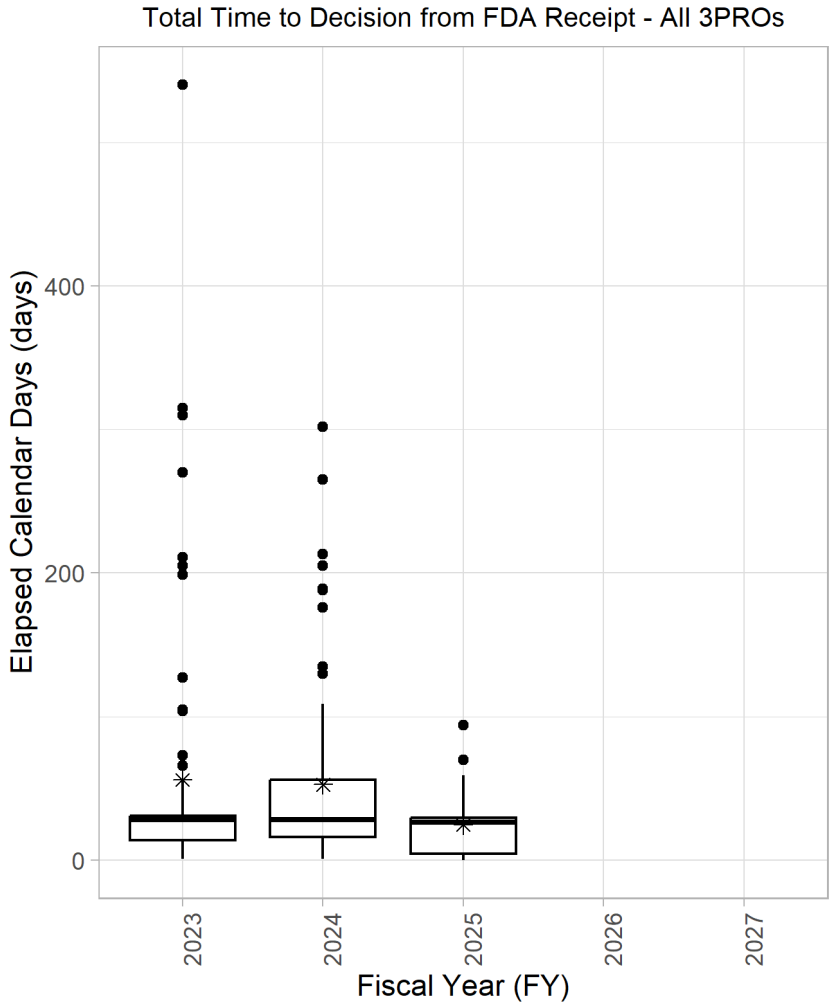


Figure 20

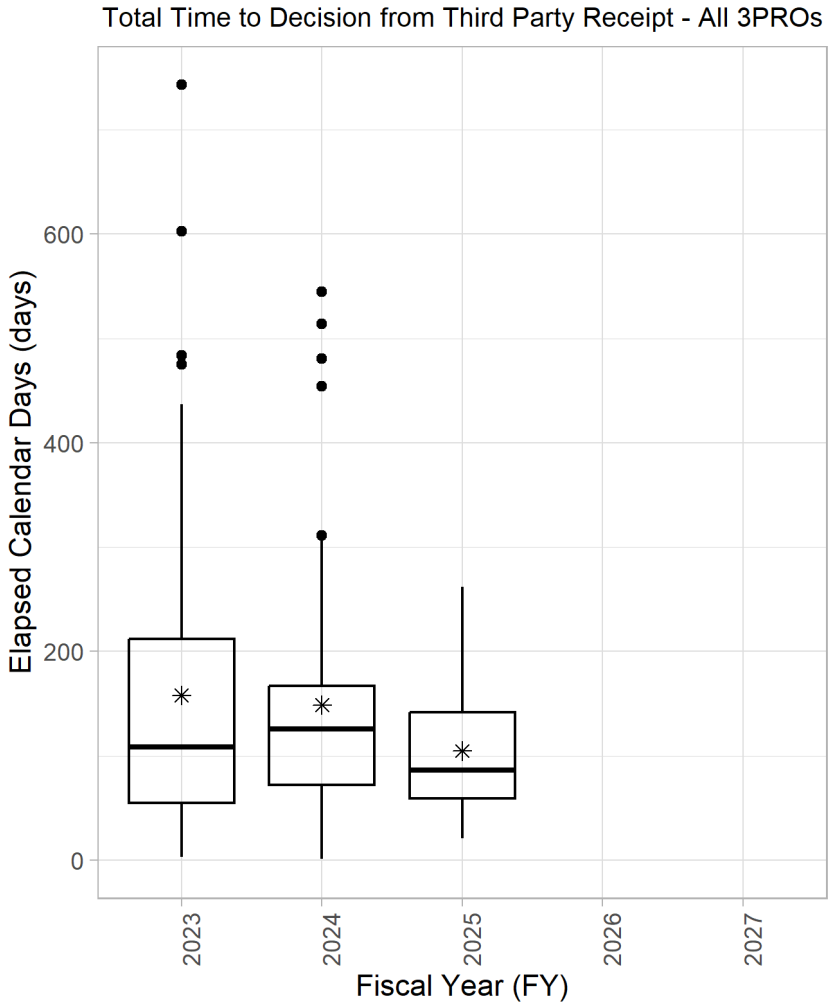


Figure 21

Table 1.1: Third Party 510(k) MDUFA V Decision Performance Goals - All Third Party Review Organizations.

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	77	68	49		
Non-MDUFA V Final Decisions: Withdrawn, Deleted, or Other (%)	9 (12%)	6 (9%)	4 (8%)		
MDUFA V Final Decisions: SE or NSE (%)	68 (88%)	61 (90%)	26 (53%)		
Pending Final Decision for less than 30 days (%)	0 (0%)	0 (0%)	12 (24%)		
Pending Final Decision for more than 30 days (%)	0 (0%)	1 (1%)	7 (14%)		
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 Days (%)	87%	84%	93%		
Average Holds					
Third Party Submission with a Final Decision	77	67	30		
Total # Requests for Additional Information (Holds)	19	19	3		
Average # Requests for Additional Information per Submission	0.25	0.28	0.1		
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	77	67	30		
Third Party SE Recommendations	77	67	30		
Third Party NSE Recommendations	0	0	0		
Third Party SE Recommendations with a Final Decision	77	67	30		
MDUFA V Final Decision					
SE	64	60	26		
NSE	4	1	0		
Non-MDUFA V Final Decision					
Withdrawn	5	6	4		
Deleted	3	0	0		
Other	1	0	0		
Third Party NSE Recommendations with a Final Decision	0	0	0		
MDUFA V Final Decision					
SE	0	0	0		
NSE	0	0	0		
Non-MDUFA V Final Decision					
Withdrawn	0	0	0		
Deleted	0	0	0		

Table 1.2: Third Party 510(k) MDUFA V Decision Performance Goals - All Third Party Review Organizations.

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Days)	102	96	81		
25th Percentile Initial Third Party Review Time	35	47	38		
50th Percentile Initial Third Party Review Time	65	81	53		
75th Percentile Initial Third Party Review Time	136	126	126		
Maximum Initial Third Party Review Time	438	544	258		
Average Third Party Hold Time (Days)	26	25	3		
25th Percentile Third Party Hold Time	0	0	0		
50th Percentile Third Party Hold Time	0	0	0		
75th Percentile Third Party Hold Time	3	20	0		
Maximum Third Party Hold Time	323	180	30		
Average Total Third Party Review Time (Days)	128	121	83		
25th Percentile Total Third Party Review Time	42	56	39		
50th Percentile Total Third Party Review Time	88	97	60		
75th Percentile Total Third Party Review Time	189	137	126		
Maximum Total Third Party Review Time	526	544	258		
Average Total FDA Review Time (Days)	31	29	23		
25th Percentile Total FDA Review Time	12	16	4		
50th Percentile Total FDA Review Time	27	27	24		
75th Percentile Total FDA Review Time	30	30	29		
Maximum Total FDA Review Time	217	163	80		
Average Total Time to Decision from FDA Receipt (Days)	56	53	25		
25th Percentile Total TTD from FDA Receipt	12	16	4		
50th Percentile Total TTD from FDA Receipt	28	28	27		
75th Percentile Total TTD from FDA Receipt	32	56	30		
Maximum Total TTD from FDA Receipt	540	302	94		
Average Total Time to Decision from Third Party Receipt (Days)	158	149	105		
25th Percentile Total TTD from Third Party Receipt	55	72	58		
50th Percentile Total TTD from Third Party Receipt	109	126	87		
75th Percentile Total TTD from Third Party Receipt	214	167	142		
Maximum Total TTD from Third Party Receipt	743	545	262		

Association for the Advancement of Blood & Biotherapies (AABB)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

BeanStock Consulting (BSC)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Center for Measurement Standards of Industrial (CMSI)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

COLA, Inc.

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Global Quality and Regulatory Services (GQRS)

This Third Party Review Organization had fewer than 5 completed submissions for each Fiscal Year in the current reporting period.

Regulatory Technology Services, LLC (RTS)

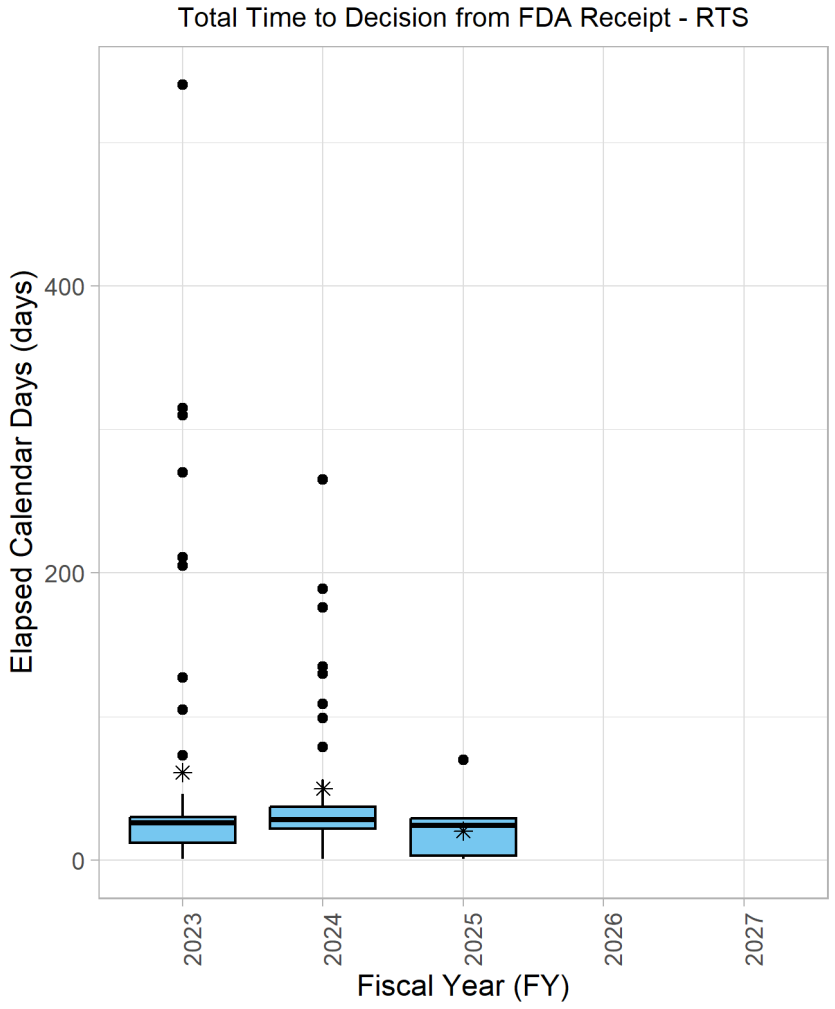


Figure 22

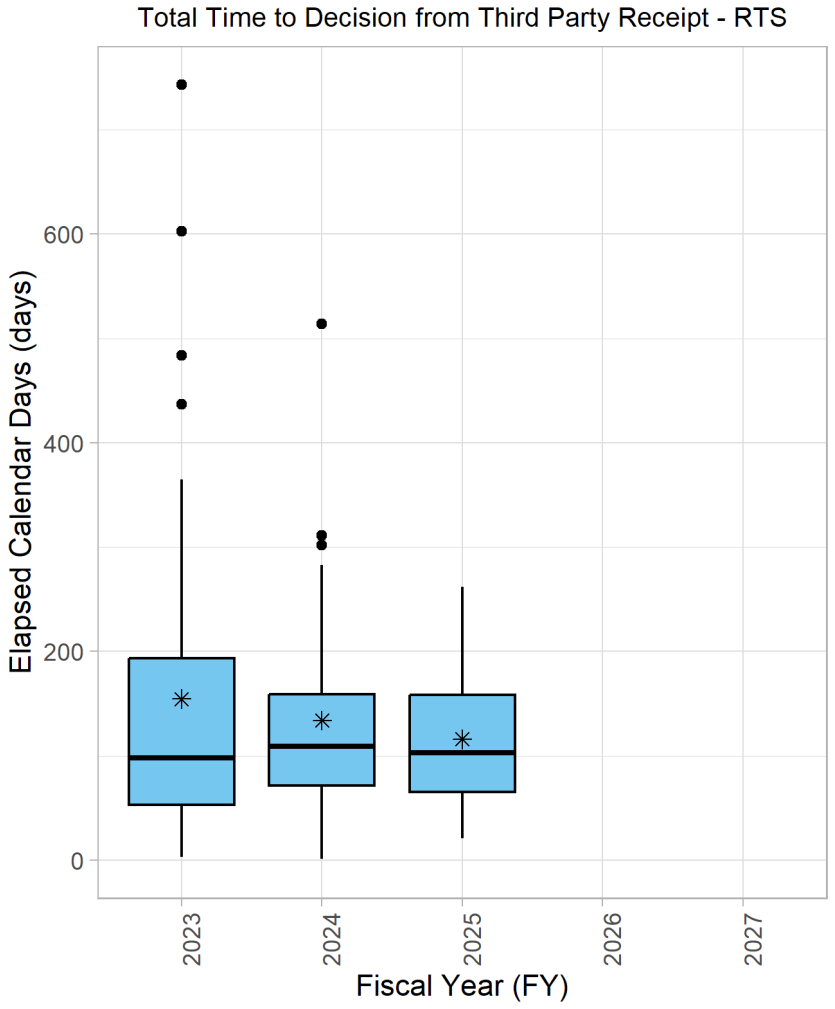


Figure 23

Table 2.1: Third Party 510(k) MDUFA V Decision Performance Goals - Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	54	40	30		
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	7 (13%)	3 (8%)	2 (7%)		
MDUFA V Final Decisions: SE or NSE (%)	47 (87%)	36 (90%)	16 (53%)		
Pending Final Decision for less than 30 days (%)	0 (0%)	0 (0%)	7 (23%)		
Pending Final Decision for more than 30 days (%)	0 (0%)	1 (2%)	5 (17%)		
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 Days (%)	90%	84%	94%		
Average Holds					
Third Party Submission with a Final Decision	54	39	18		
Total # Requests for Additional Information (Holds)	12	10	0		
Average # Requests for Additional Information per Submission	0.22	0.26	0		
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	54	39	18		
Third Party SE Recommendations	54	39	18		
Third Party NSE Recommendations	0	0	0		
Third Party SE Recommendations with a Final Decision	54	39	18		
MDUFA V Final Decision					
SE	44	36	16		
NSE	3	0	0		
Non-MDUFA V Final Decision					
Withdrawn	4	3	2		
Deleted	3	0	0		
Third Party NSE Recommendations with a Final Decision	0	0	0		
MDUFA V Final Decision					
SE	0	0	0		
NSE	0	0	0		
Non-MDUFA V Final Decision					
Withdrawn	0	0	0		
Deleted	0	0	0		

Table 2.2: Third Party 510(k) MDUFA V Decision Performance Goals - Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Days)	94	84	96		
25th Percentile Initial Third Party Review Time	33	48	36		
50th Percentile Initial Third Party Review Time	55	72	88		
75th Percentile Initial Third Party Review Time	110	123	150		
Maximum Initial Third Party Review Time	438	249	258		
Average Third Party Hold Time (Days)	31	21	0		
25th Percentile Third Party Hold Time	0	0	0		
50th Percentile Third Party Hold Time	0	0	0		
75th Percentile Third Party Hold Time	0	10	0		
Maximum Third Party Hold Time	323	118	0		
Average Total Third Party Review Time (Days)	124	105	96		
25th Percentile Total Third Party Review Time	34	59	36		
50th Percentile Total Third Party Review Time	76	82	88		
75th Percentile Total Third Party Review Time	174	131	150		
Maximum Total Third Party Review Time	526	351	258		
Average Total FDA Review Time (Days)	31	30	21		
25th Percentile Total FDA Review Time	12	22	3		
50th Percentile Total FDA Review Time	26	28	24		
75th Percentile Total FDA Review Time	30	30	29		
Maximum Total FDA Review Time	217	163	70		
Average Total Time to Decision from FDA Receipt (Days)	62	50	21		
25th Percentile Total TTD from FDA Receipt	12	22	3		
50th Percentile Total TTD from FDA Receipt	26	28	24		
75th Percentile Total TTD from FDA Receipt	30	44	29		
Maximum Total TTD from FDA Receipt	540	265	70		
Average Total Time to Decision from Third Party Receipt (Days)	155	134	116		
25th Percentile Total TTD from Third Party Receipt	53	72	65		
50th Percentile Total TTD from Third Party Receipt	98	109	103		
75th Percentile Total TTD from Third Party Receipt	194	160	161		
Maximum Total TTD from Third Party Receipt	743	514	262		

Third Party Review Group, LLC (TPRG)

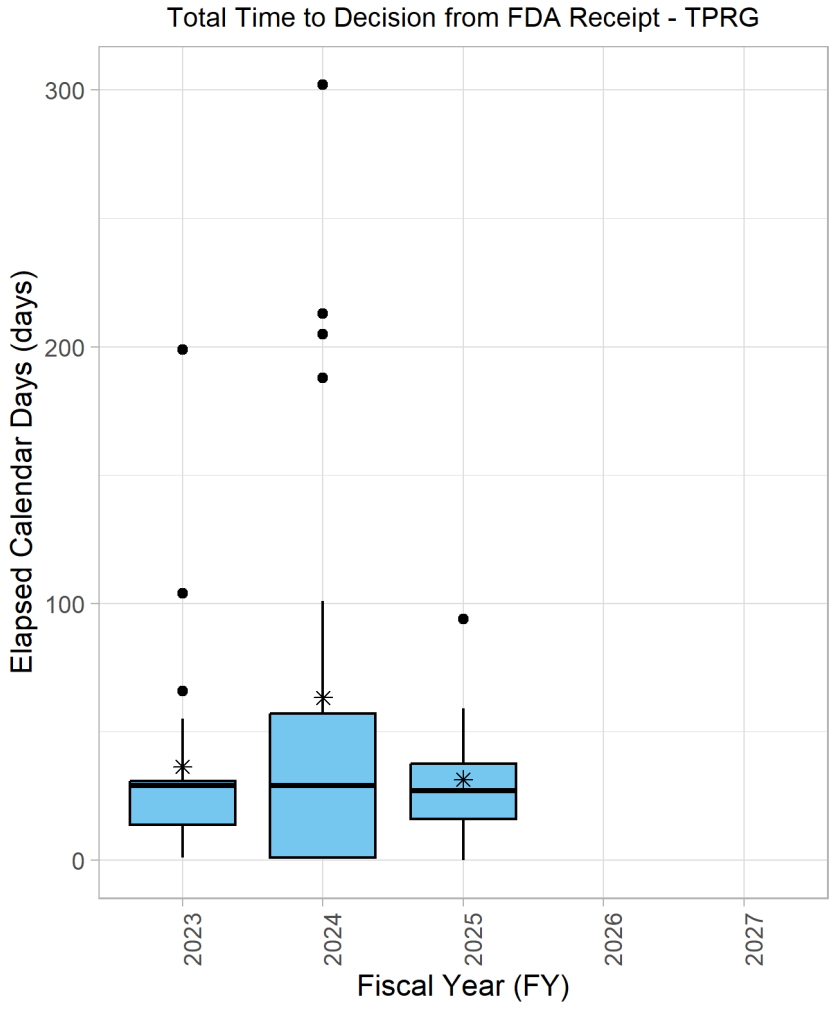


Figure 24

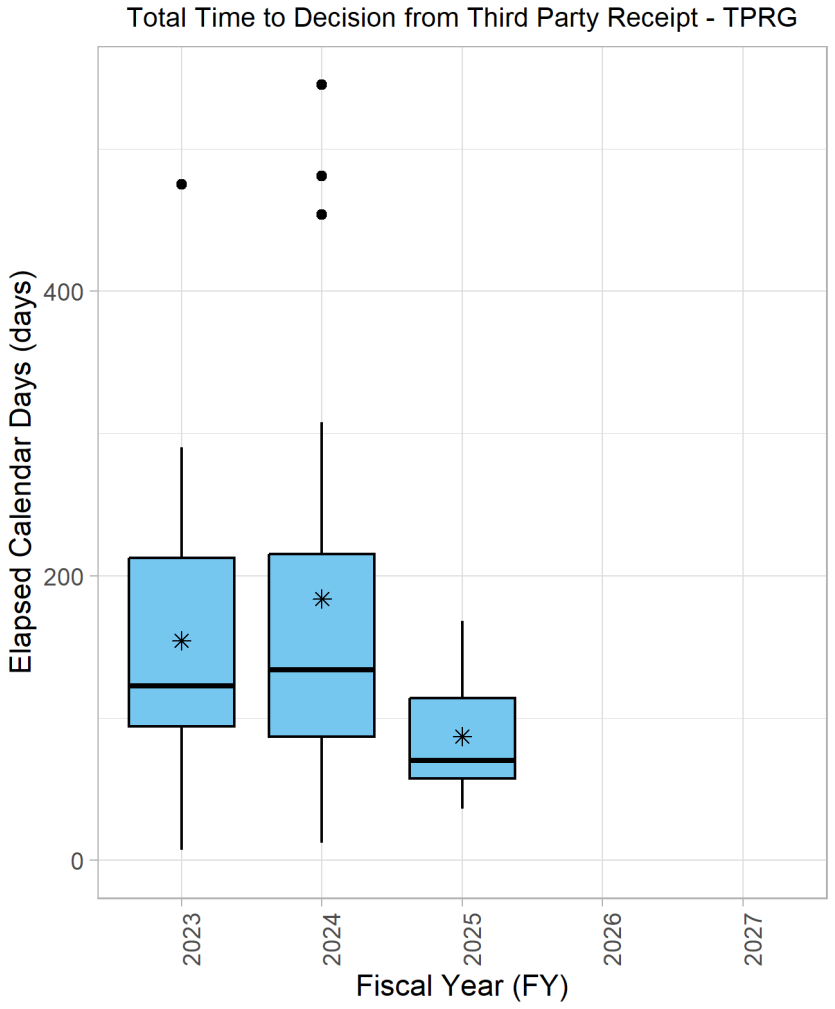


Figure 25

Table 3.1: Third Party 510(k) MDUFA V Decision Performance Goals - Third Party Review Group, LLC (TPRG).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Total Third Party 510(k) Submissions Accepted	21	24	17		
Non-MDUFA V Final Decisions: Withdrawn or Deleted (%)	1 (5%)	3 (12%)	2 (12%)		
MDUFA V Final Decisions: SE or NSE (%)	20 (95%)	21 (88%)	10 (59%)		
Pending Final Decision for less than 30 days (%)	0 (0%)	0 (0%)	3 (18%)		
Pending Final Decision for more than 30 days (%)	0 (0%)	0 (0%)	2 (12%)		
Current Performance: Third Party Submissions that received MDUFA V Final Decisions (SE or NSE) within 30 Days (%)	85%	81%	90%		
Average Holds					
Third Party Submission with a Final Decision	21	24	12		
Total # Requests for Additional Information (Holds)	6	9	3		
Average # Requests for Additional Information per Submission	0.29	0.38	0.25		
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	21	24	12		
Third Party SE Recommendations	21	24	12		
Third Party NSE Recommendations	0	0	0		
Third Party SE Recommendations with a Final Decision	21	24	12		
MDUFA V Final Decision					
SE	19	20	10		
NSE	1	1	0		
Non-MDUFA V Final Decision					
Withdrawn	1	3	2		
Deleted	0	0	0		
Third Party NSE Recommendations with a Final Decision	0	0	0		
MDUFA V Final Decision					
SE	0	0	0		
NSE	0	0	0		
Non-MDUFA V Final Decision					
Withdrawn	0	0	0		
Deleted	0	0	0		

Table 3.2: Third Party 510(k) MDUFA V Decision Performance Goals - Third Party Review Group, LLC (TPRG).

Performance Metric	FY2023	FY2024	FY2025	FY2026	FY2027
Average Initial Third Party Review Time (Days)	118	121	56		
25th Percentile Initial Third Party Review Time	58	34	39		
50th Percentile Initial Third Party Review Time	94	97	45		
75th Percentile Initial Third Party Review Time	148	151	76		
Maximum Initial Third Party Review Time	371	544	142		
Average Third Party Hold Time (Days)	9	37	7		
25th Percentile Third Party Hold Time	0	0	0		
50th Percentile Third Party Hold Time	0	0	0		
75th Percentile Third Party Hold Time	3	29	14		
Maximum Third Party Hold Time	81	180	30		
Average Total Third Party Review Time (Days)	127	157	62		
25th Percentile Total Third Party Review Time	69	60	41		
50th Percentile Total Third Party Review Time	94	108	50		
75th Percentile Total Third Party Review Time	166	191	78		
Maximum Total Third Party Review Time	405	544	142		
Average Total FDA Review Time (Days)	28	27	26		
25th Percentile Total FDA Review Time	10	1	15		
50th Percentile Total FDA Review Time	29	27	24		
75th Percentile Total FDA Review Time	30	30	29		
Maximum Total FDA Review Time	118	122	80		
Average Total Time to Decision from FDA Receipt (Days)	37	64	32		
25th Percentile Total TTD from FDA Receipt	10	1	15		
50th Percentile Total TTD from FDA Receipt	29	29	27		
75th Percentile Total TTD from FDA Receipt	32	57	40		
Maximum Total TTD from FDA Receipt	199	302	94		
Average Total Time to Decision from Third Party Receipt (Days)	155	184	87		
25th Percentile Total TTD from Third Party Receipt	91	87	57		
50th Percentile Total TTD from Third Party Receipt	123	134	70		
75th Percentile Total TTD from Third Party Receipt	215	215	116		
Maximum Total TTD from Third Party Receipt	475	545	168		