Third Party Review Organization Performance Report

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Introduction and Review Timeline Description

The Accredited Persons Program was created by the FDA Modernization Act of 1997 (FDAMA) to improve the efficiency and timeliness of FDA's 510(k) process. Under the program, FDA accredits Third Parties (Accredited Persons) that are authorized to conduct the primary review of 510(k)s for eligible devices. Under MDUFA IV, the FDA committed to publishing the performance of individual accredited Third Parties 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 2018, Q1 through FY 2019, Q3 (October 1, 2017 through June 30, 2019). The number of Third Party Review Organizations with at least 5 completed submissions for each Fiscal Year is shown below:

FY2018	FY2019	FY2020	FY2021	FY2022
3	2	0	0	0

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

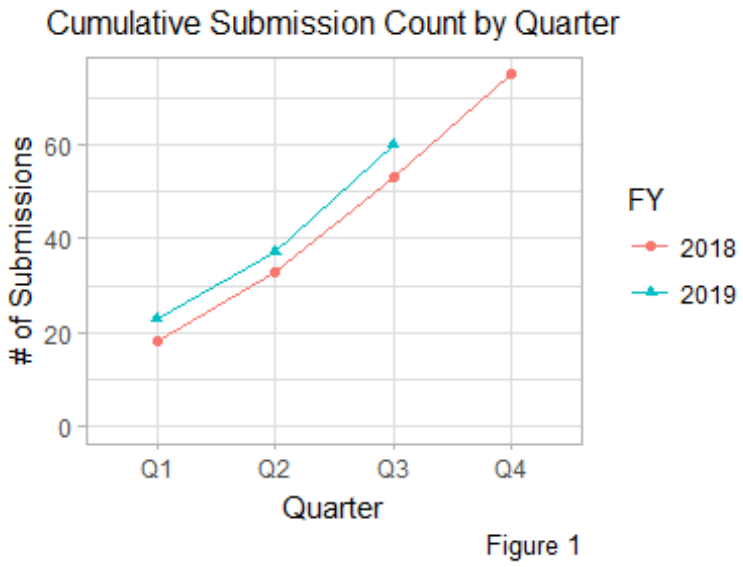
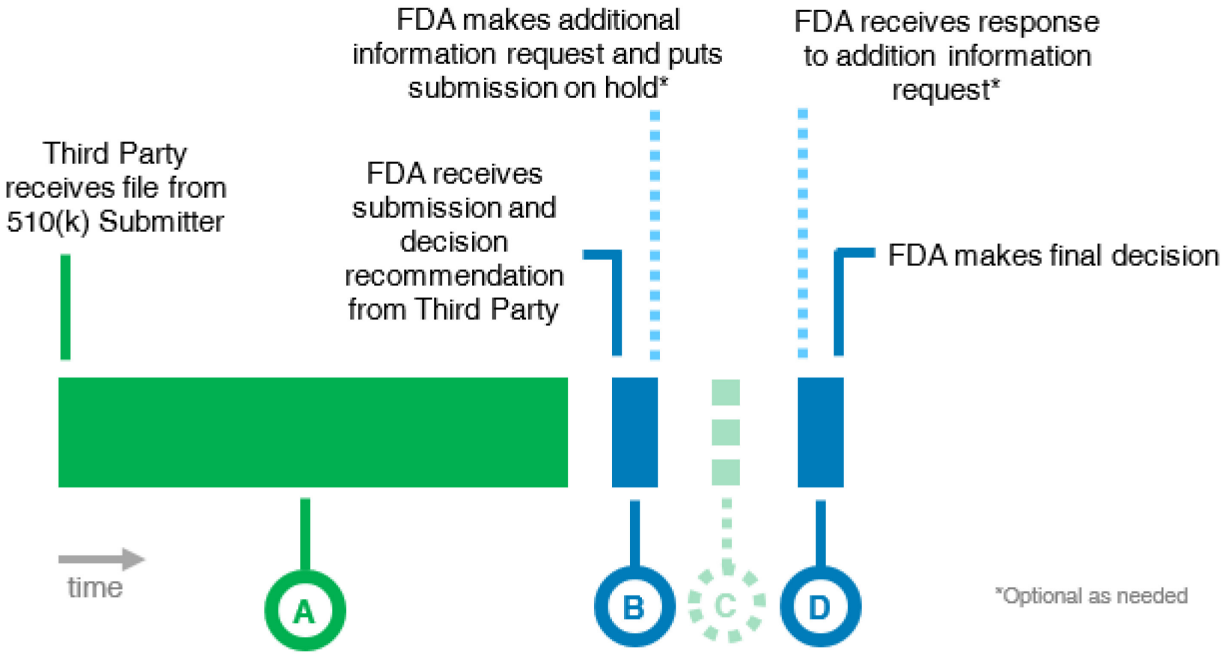


Figure 1

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

- Stage A - The Third Party 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 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, and puts the submission on hold.
- Stage C (Optional) - The Third Party reviews FDA's request for additional information and notifies the 510(k) submitter. The Third Party 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 IV decision (SE or 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 IV 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 IV 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 IV decision (SE or NSE) to a Third Party submission. By statute, FDA must provide a final MDUFA IV 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 IV 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**:

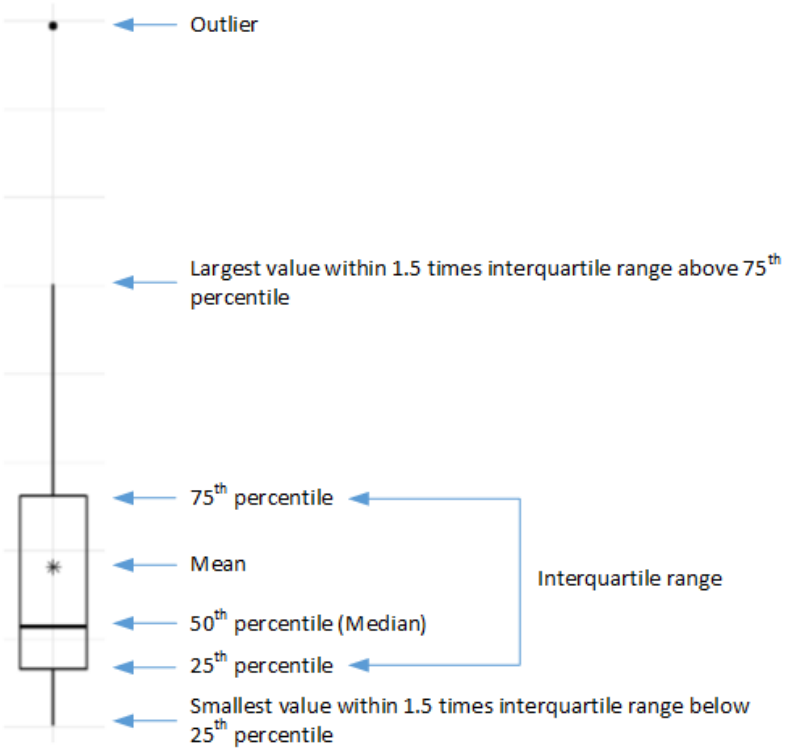
= *Total Third Party Review Time + Total FDA Review Time*

Elapsed time in days for FDA and a Third Party to provide a final MDUFA IV 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	AABB
ADAS	Accelerated Device Approval Services, LLC
BDC	Biomarkers and Diagnostics Consulting, LLC
CMSI	Center for Measurement Standards of Industrial
NYSDOH	New York State Department of Health
NIOM	Nordic Institute of Dental Materials
RTS	Regulatory Technology Services, LLC
TPRG	Third Party Review Group, LLC
TUV	TUV SUD America Inc.

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

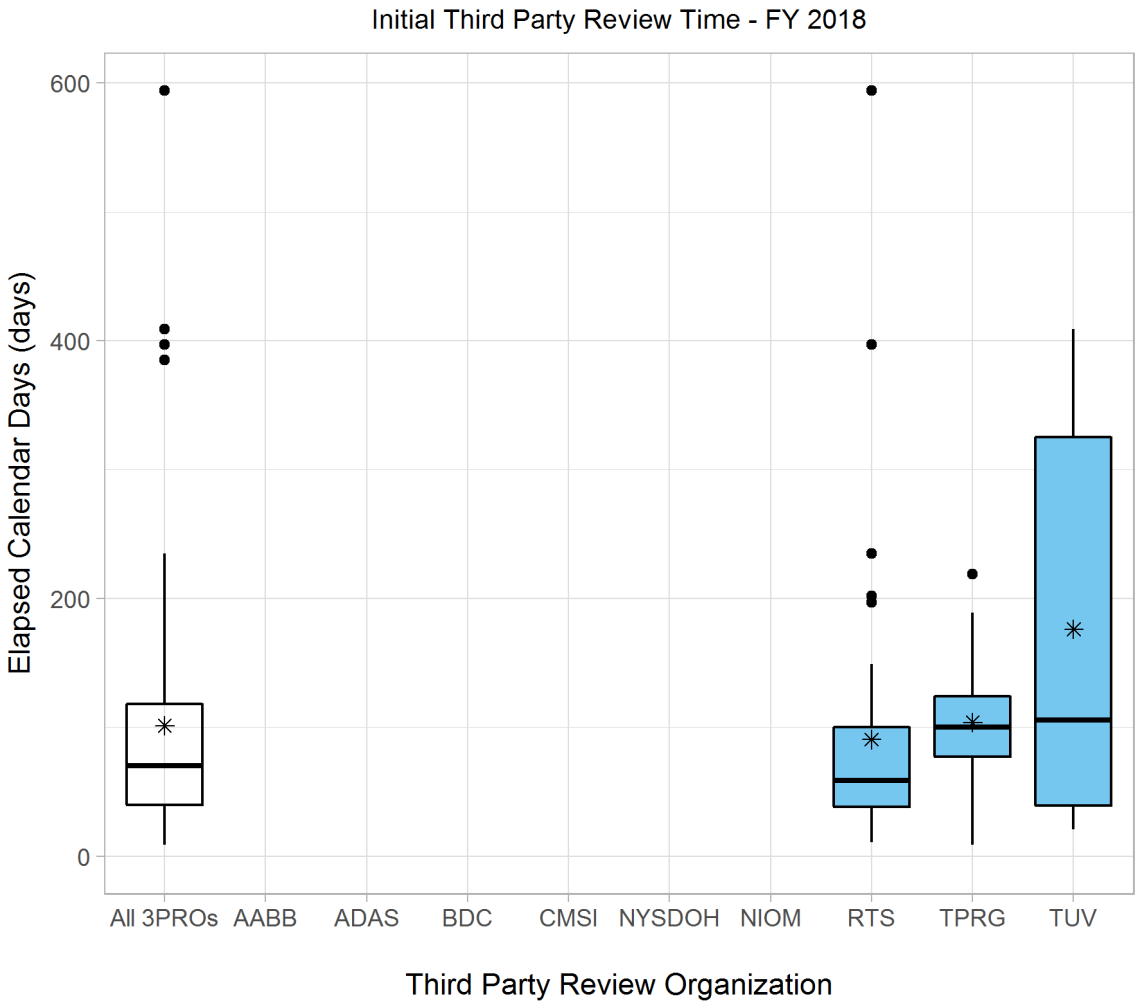


Figure 2

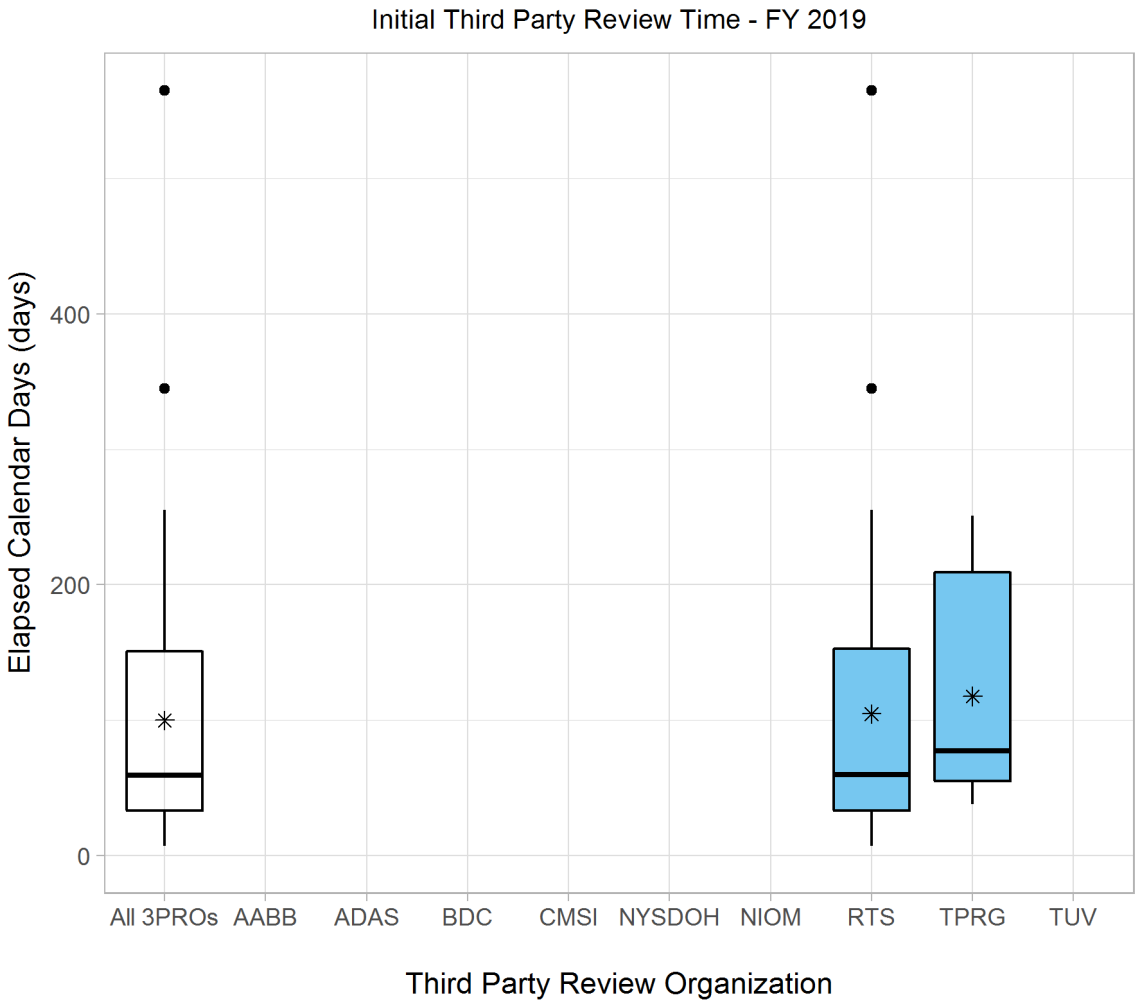

Initial Third Party Review Time - FY 2019
Elapsed Calendar Days (days)
400
200
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 3

Third Party Hold Time

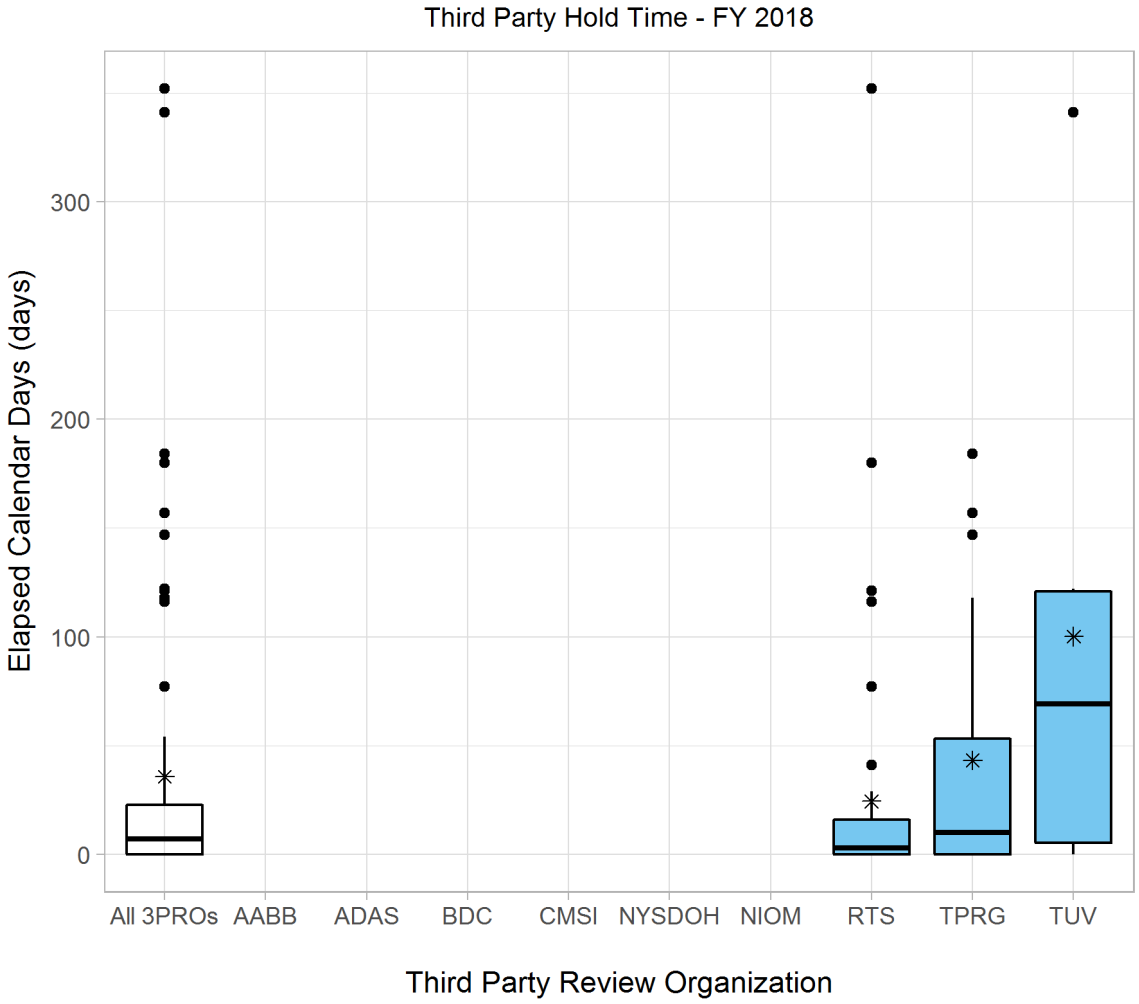


Figure 4

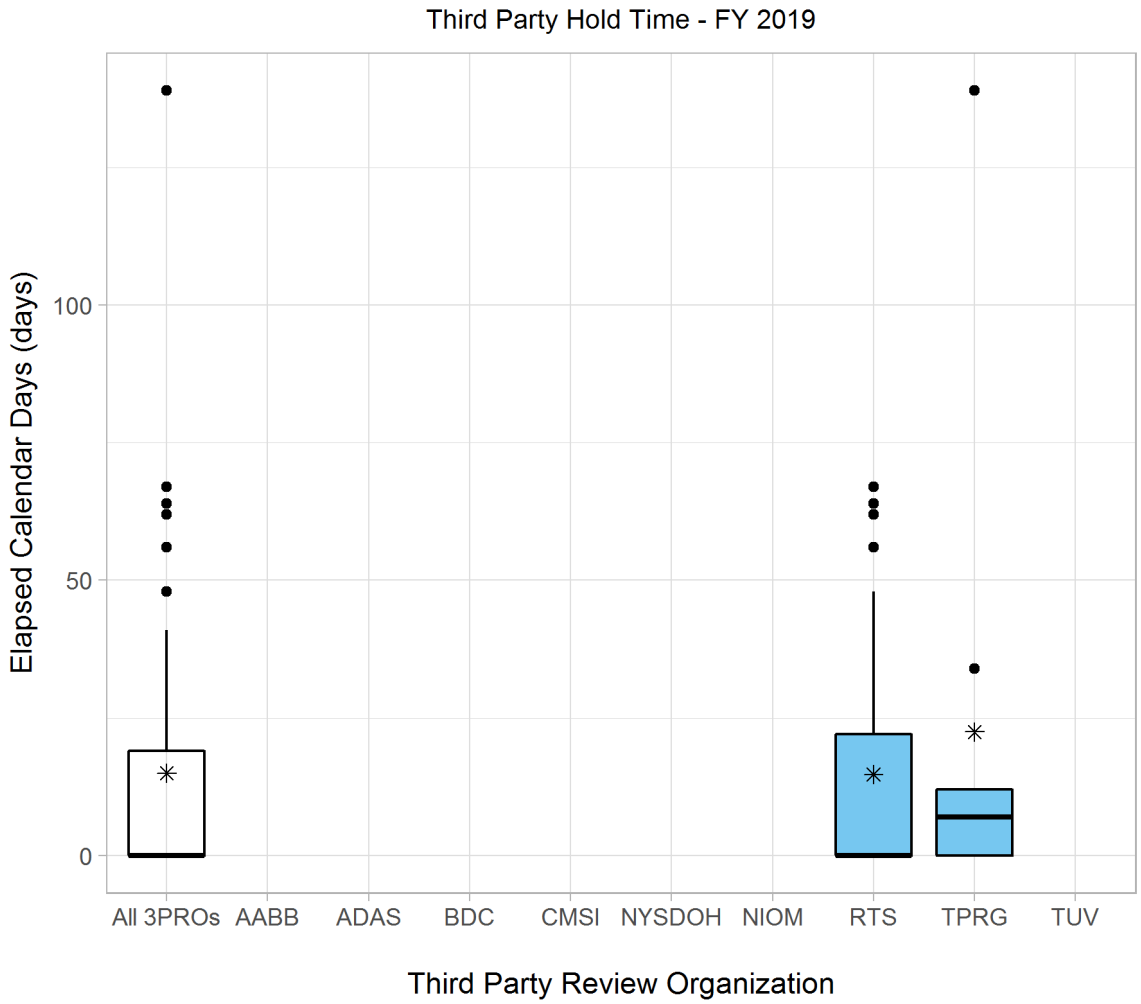

Third Party Hold Time - FY 2019
Elapsed Calendar Days (days)
100
50
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 5

Total Third Party Review Time

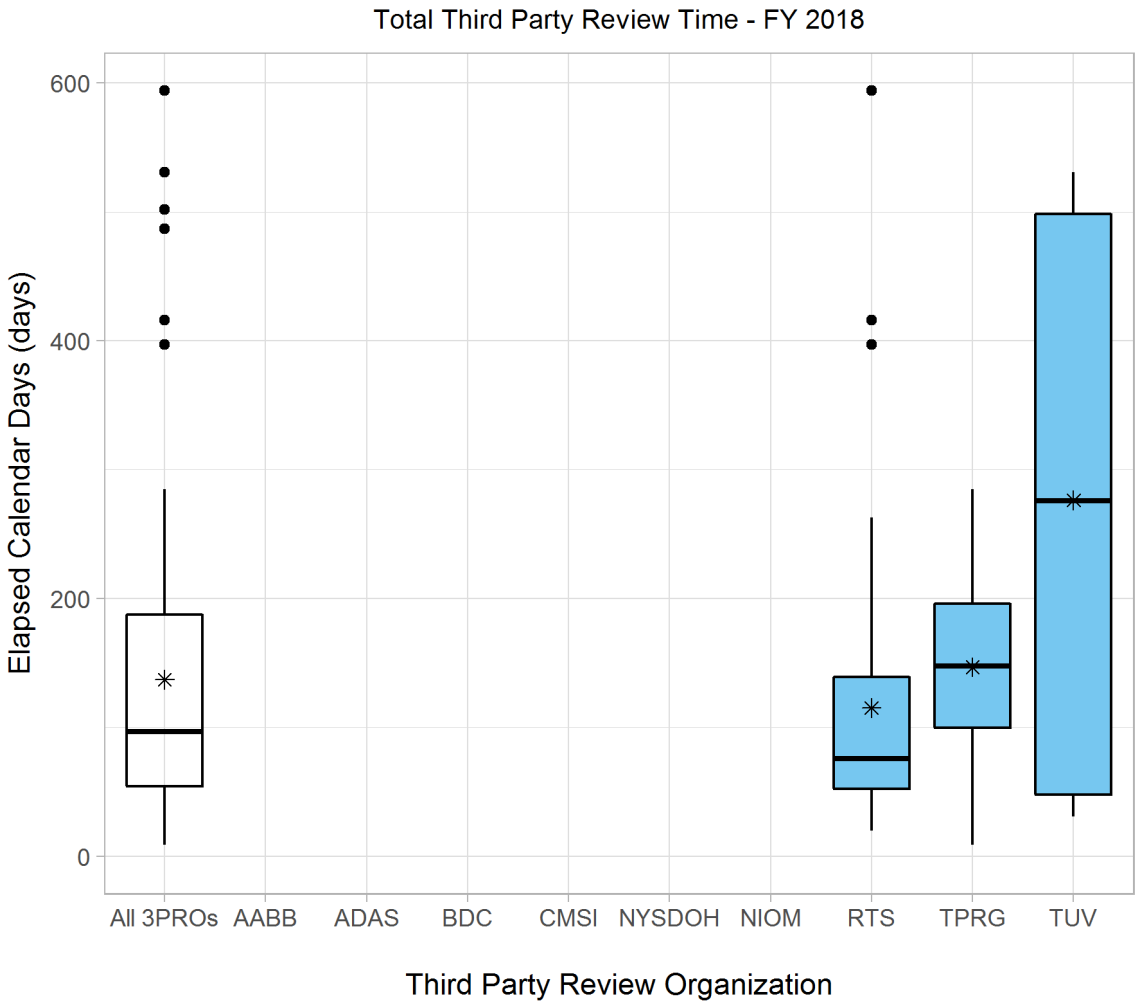


Figure 6


Total Third Party Review Time - FY 2019
Elapsed Calendar Days (days)
400
200
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 7

Total FDA Review Time

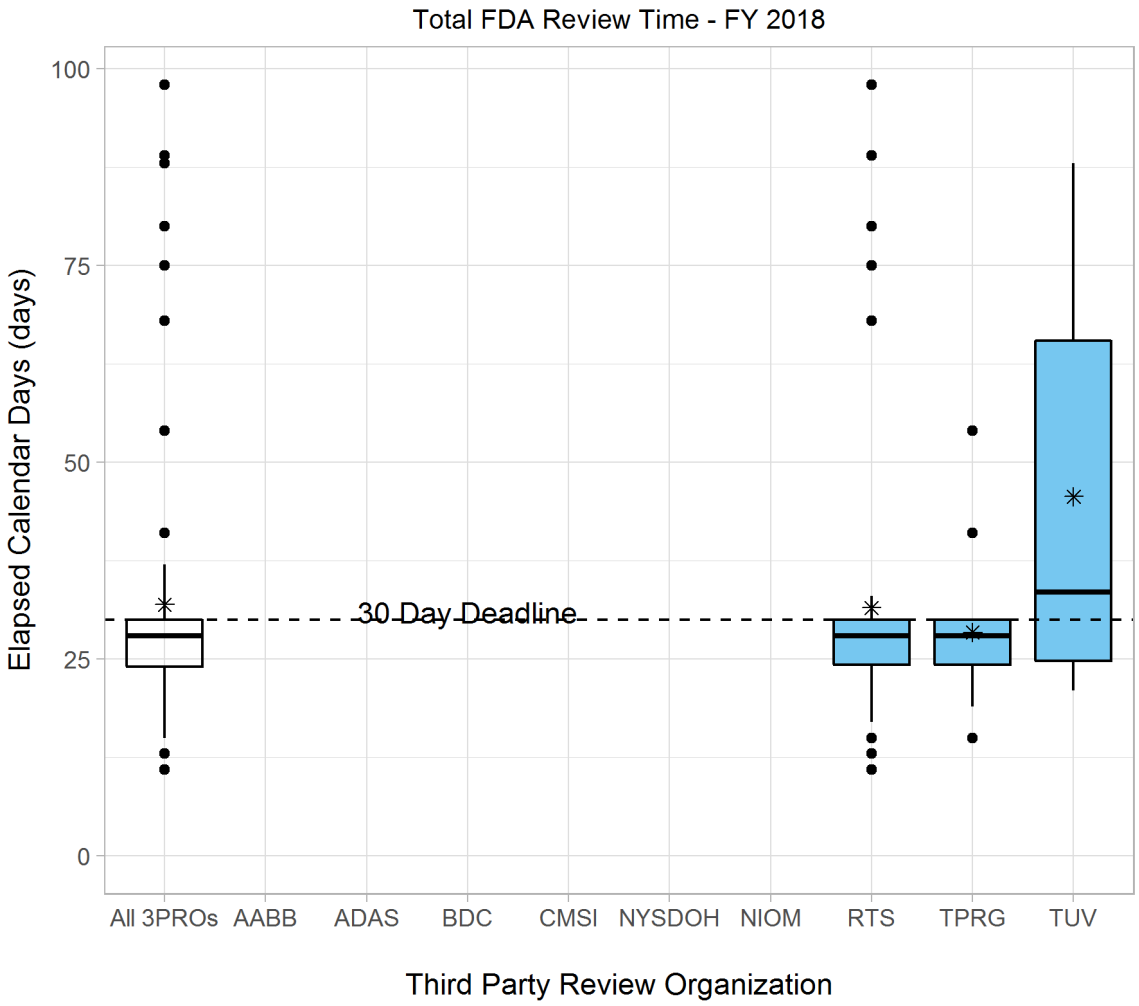


Figure 8

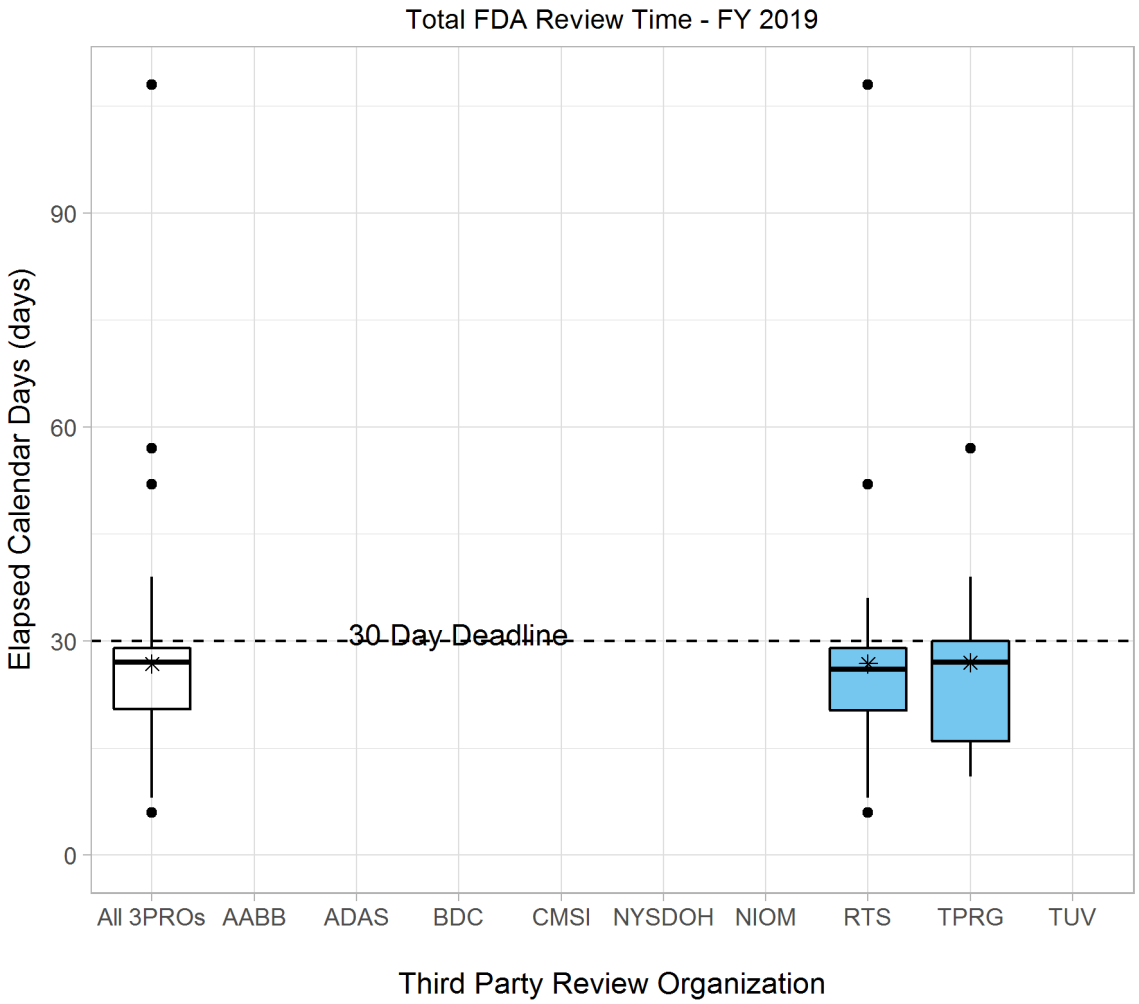

Total FDA Review Time - FY 2019
Elapsed Calendar Days (days)
90
60
30
0
30 Day Deadline
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 9

Total Time to Decision from FDA Receipt

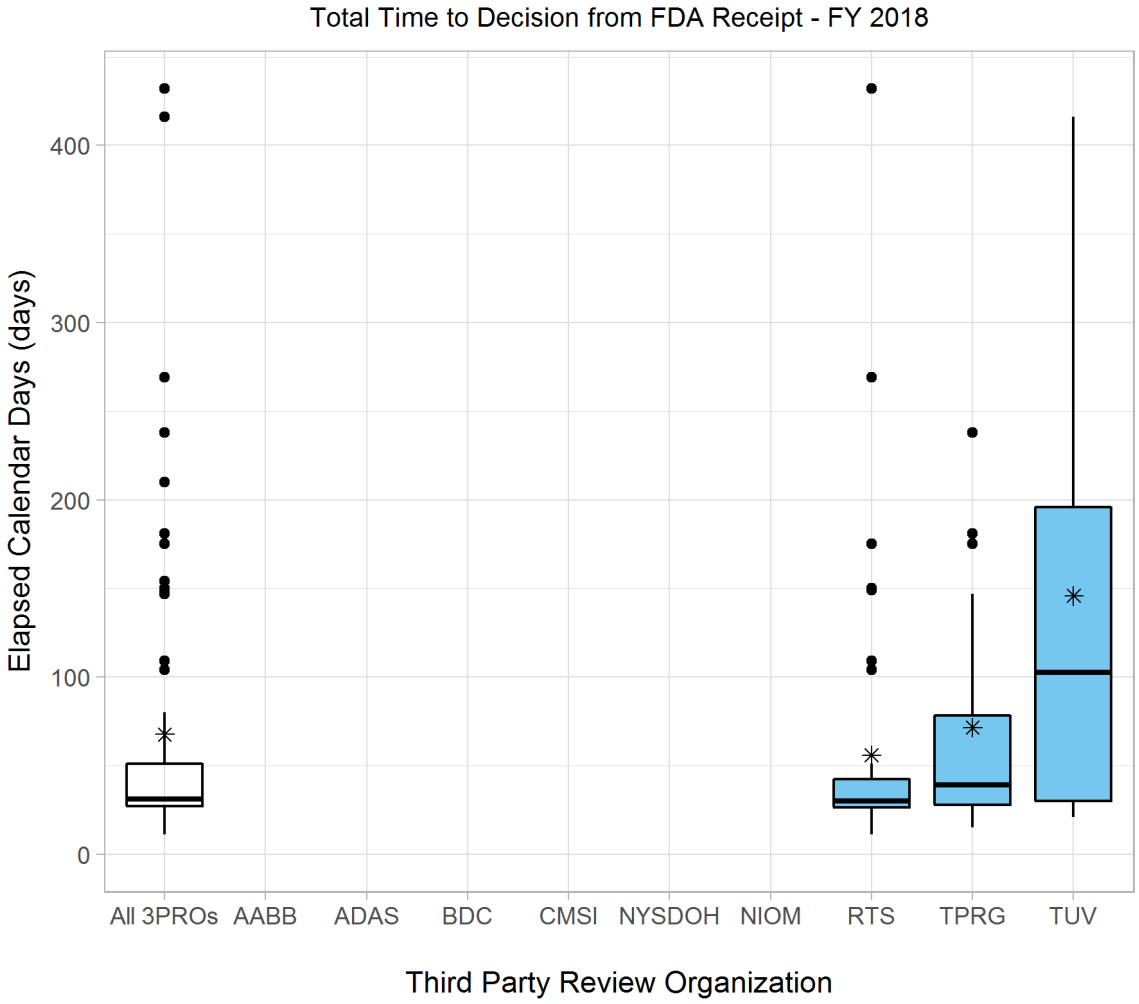


Figure 10

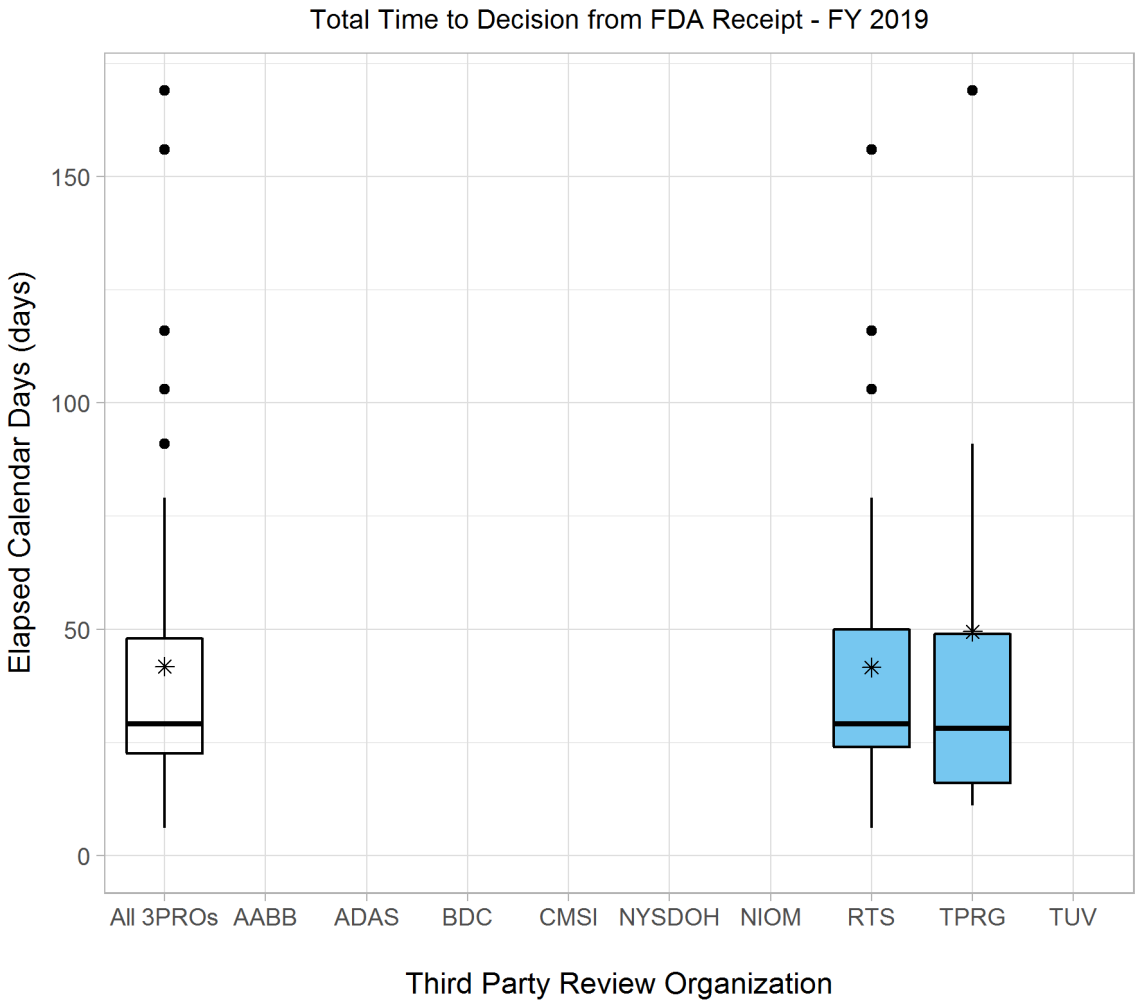

Total Time to Decision from FDA Receipt - FY 2019
Elapsed Calendar Days (days)
150
100
50
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 11

Total Time to Decision from Third Party Receipt

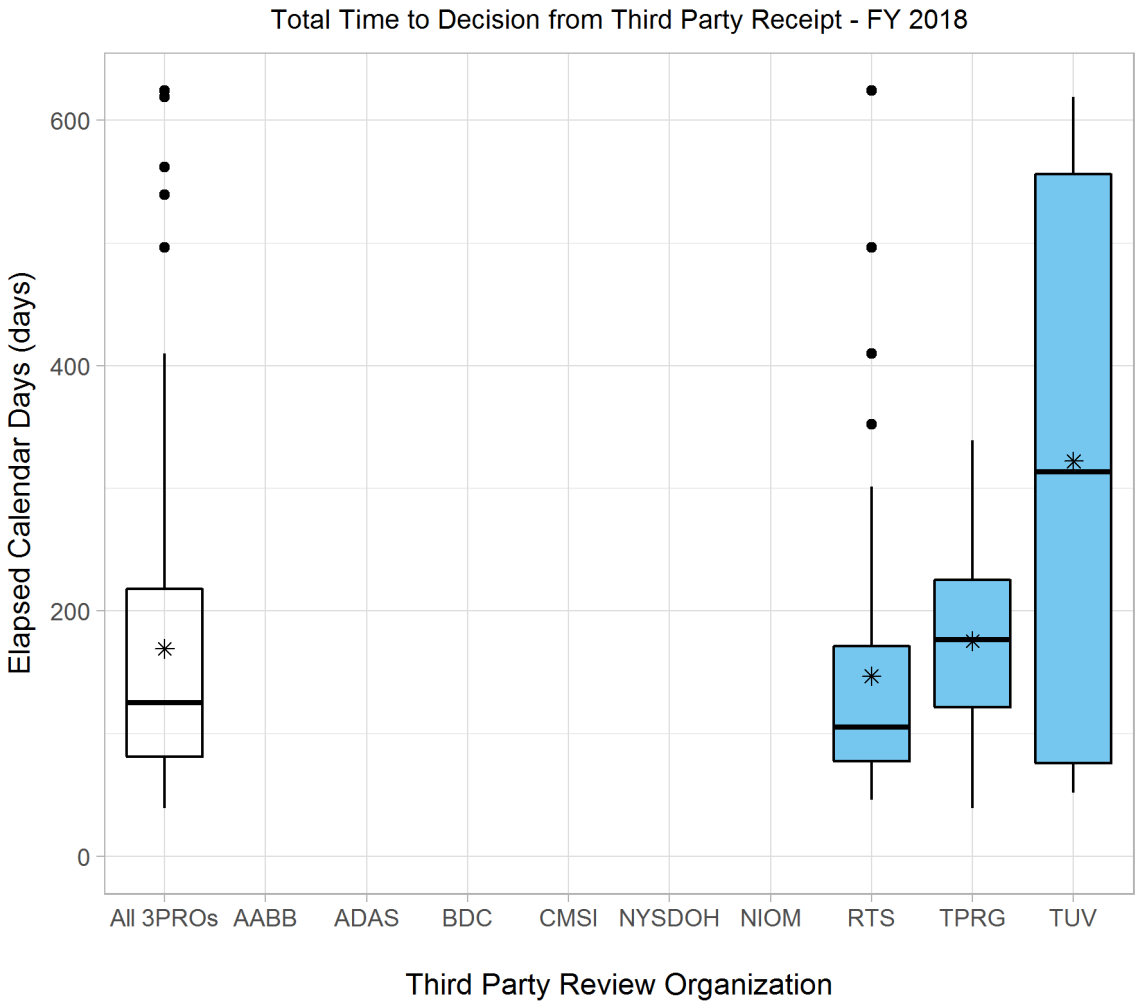


Figure 12

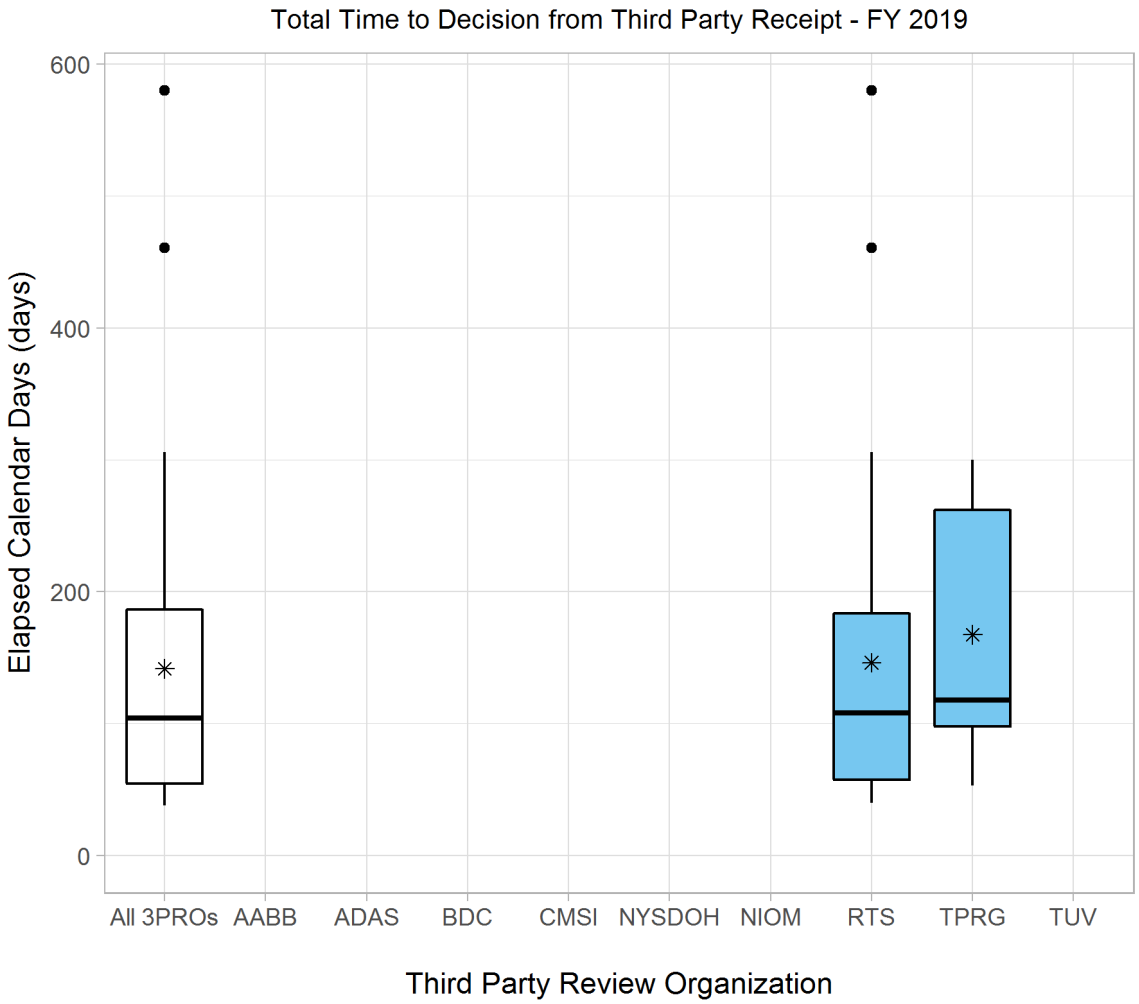

Total Time to Decision from Third Party Receipt - FY 2019
Elapsed Calendar Days (days)
600
400
200
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 13

All Third Party Review Organizations

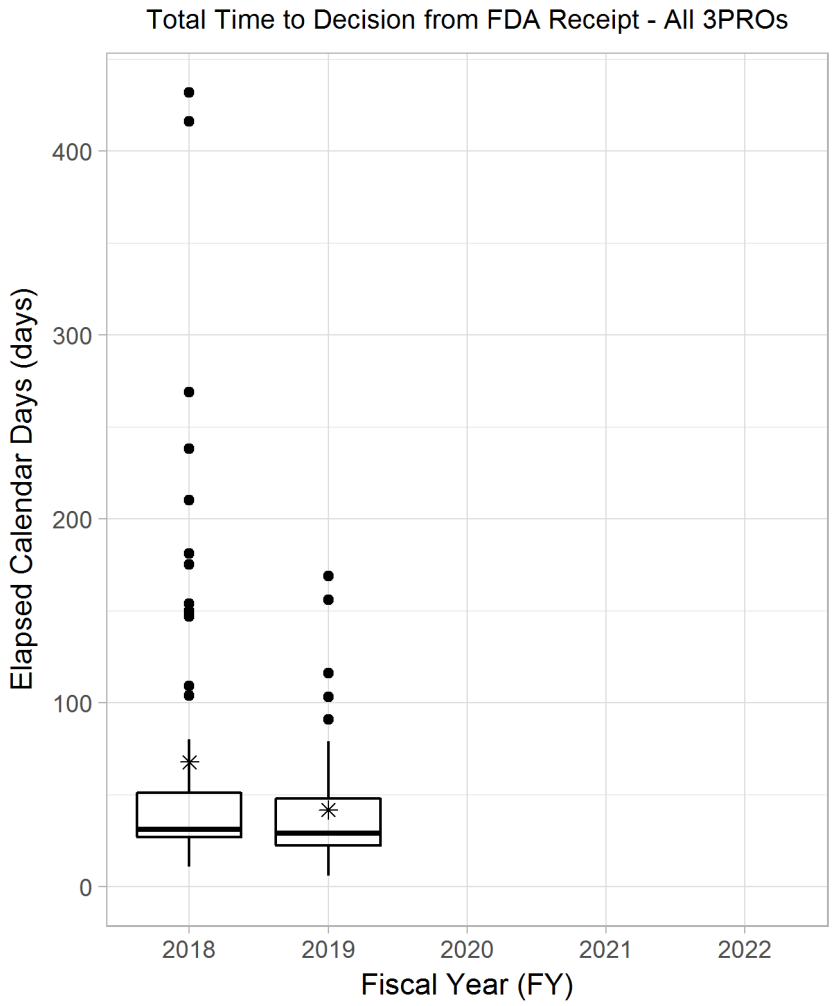


Figure 14

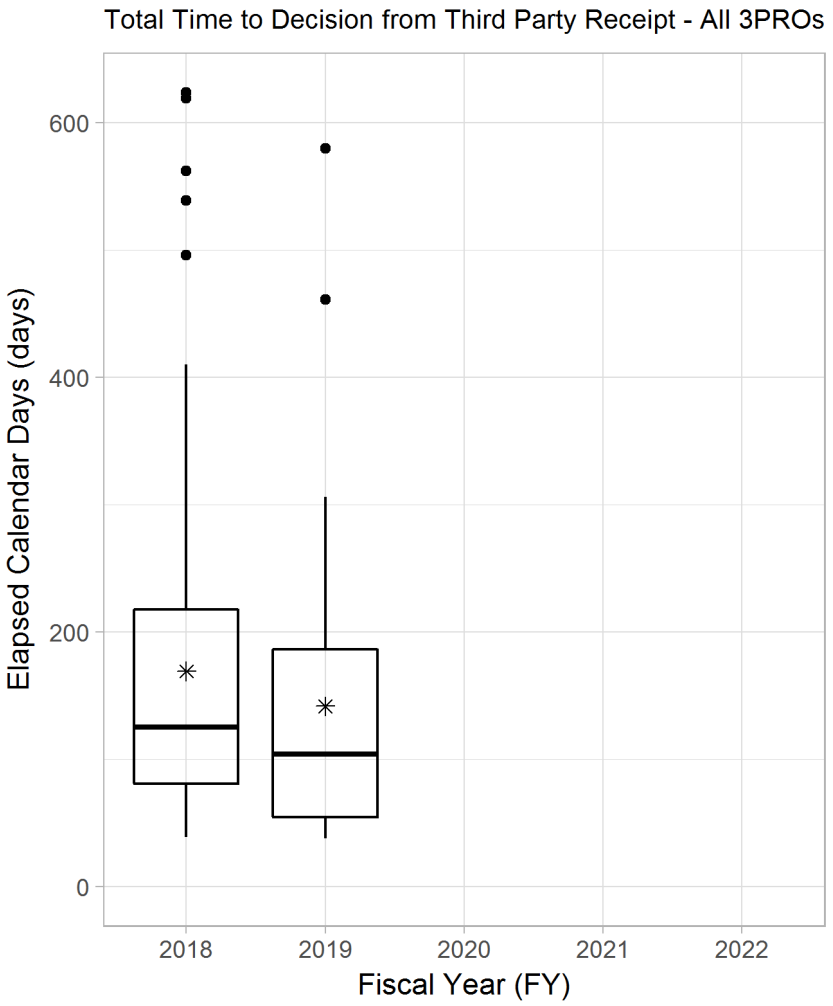


Figure 15

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Total Third Party 510(k) Submissions Accepted	75	60			
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	5 (7%)	2 (3%)			
MDUFA IV Final Decisions: SE or NSE (%)	70 (93%)	47 (78%)			
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	7 (12%)			
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	4 (7%)			
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	83%	90%			
Average Holds					
Third Party Submission with a Final Decision	75	49			
Total # Requests for Additional Information (Holds)	43	20			
Average # Requests for Additional Information per Submission	0.57	0.41			
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	75	49			
Third Party SE Recommendations	75	49			
Third Party NSE Recommendations	0	0			
Third Party SE Recommendations with a Final Decision	75	49			
MDUFA IV Final Decision					
SE	69	45			
NSE	1	2			
Non-MDUFA IV Final Decision					
Withdrawn	3	1			
Deleted	2	1			
Third Party NSE Recommendations with a Final Decision	0	0			
MDUFA IV Final Decision					
SE	0	0			
NSE	0	0			
Non-MDUFA IV Final Decision					
Withdrawn	0	0			
Deleted	0	0			

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Average Initial Third Party Review Time (Calendar Days)	102	100			
25th Percentile Initial Third Party Review Time	39	33			
50th Percentile Initial Third Party Review Time	70	59			
75th Percentile Initial Third Party Review Time	119	151			
Maximum Initial Third Party Review Time	594	565			
Average Third Party Hold Time (Calendar Days)	36	15			
25th Percentile Third Party Hold Time	0	0			
50th Percentile Third Party Hold Time	7	0			
75th Percentile Third Party Hold Time	23	19			
Maximum Third Party Hold Time	352	139			
Average Total Third Party Review Time (Calendar Days)	138	115			
25th Percentile Total Third Party Review Time	54	37			
50th Percentile Total Third Party Review Time	97	74			
75th Percentile Total Third Party Review Time	189	159			
Maximum Total Third Party Review Time	594	565			
Average Total FDA Review Time (Calendar Days)	32	27			
25th Percentile Total FDA Review Time	24	21			
50th Percentile Total FDA Review Time	28	27			
75th Percentile Total FDA Review Time	30	29			
Maximum Total FDA Review Time	98	108			
Average Total Time to Decision from FDA Receipt (Calendar Days)	68	42			
25th Percentile Total TTD from FDA Receipt	27	23			
50th Percentile Total TTD from FDA Receipt	31	29			
75th Percentile Total TTD from FDA Receipt	51	48			
Maximum Total TTD from FDA Receipt	432	169			
Average Total Time to Decision from Third Party Receipt (Calendar Days)	170	142			
25th Percentile Total TTD from Third Party Receipt	81	55			
50th Percentile Total TTD from Third Party Receipt	125	104			
75th Percentile Total TTD from Third Party Receipt	218	187			
Maximum Total TTD from Third Party Receipt	624	580			

AABB (AABB)

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

Accelerated Device Approval Services, LLC (ADAS)

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

Biomarkers and Diagnostics Consulting, LLC (BDC)

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.

New York State Department of Health (NYSDOH)

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

Nordic Institute of Dental Materials (NIOM)

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)

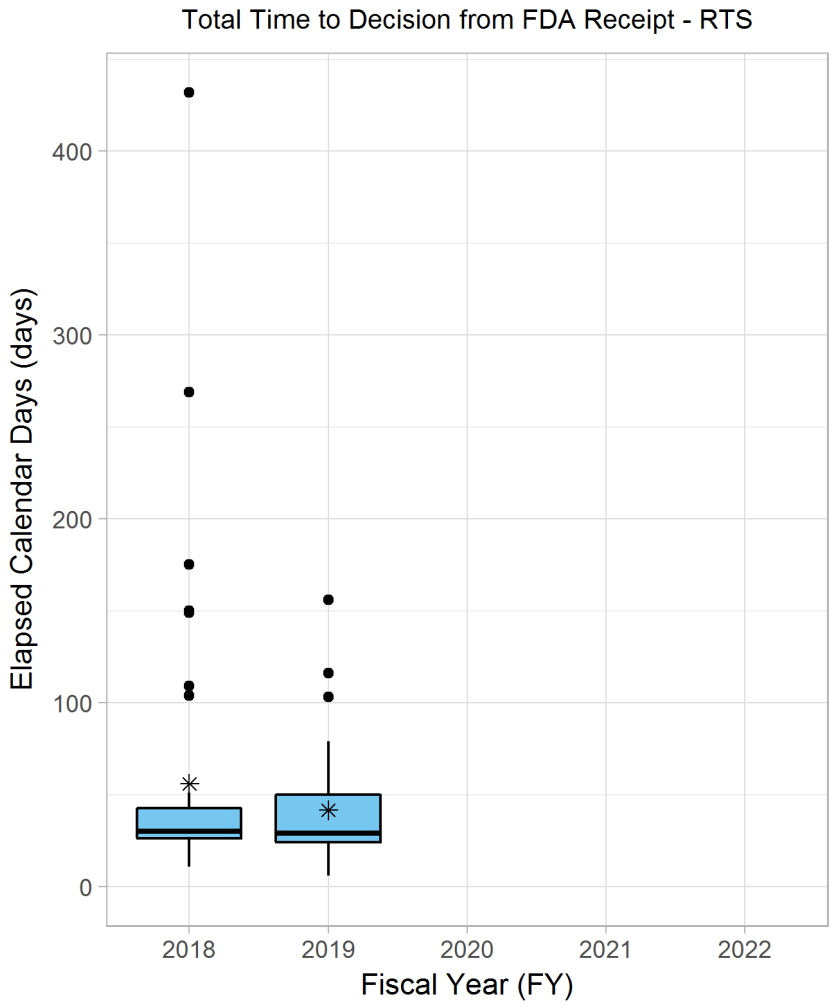


Figure 16

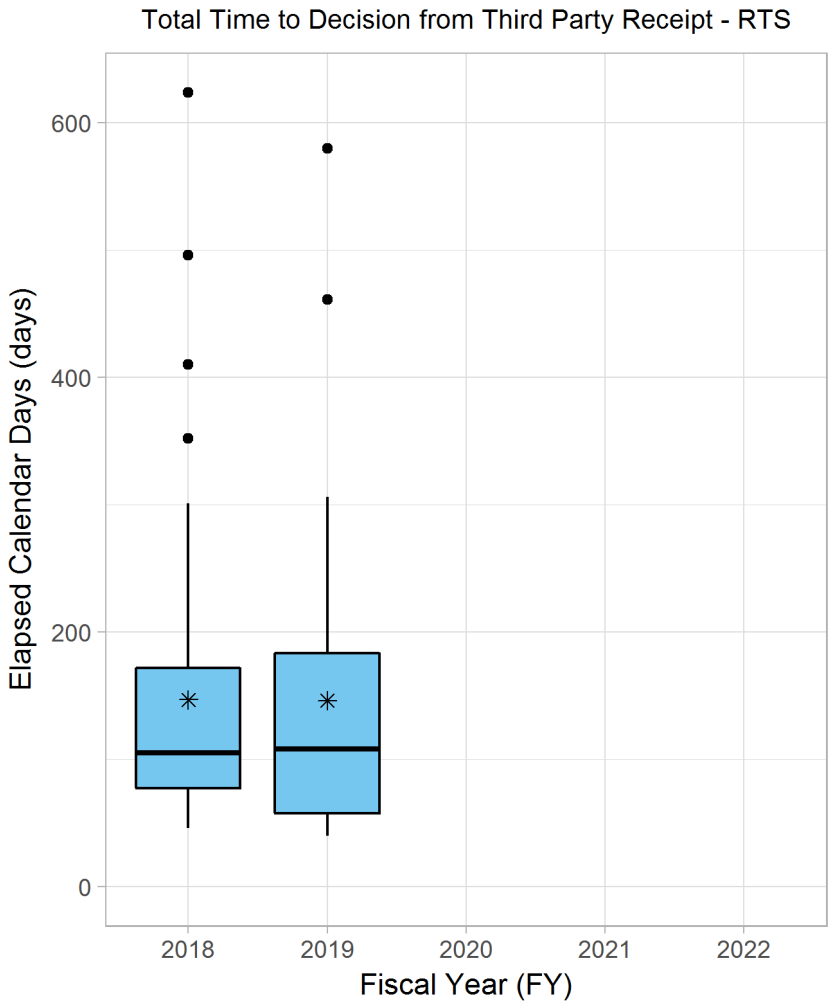


Figure 17

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Total Third Party 510(k) Submissions Accepted	49	39			
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	3 (6%)	2 (5%)			
MDUFA IV Final Decisions: SE or NSE (%)	46 (94%)	34 (87%)			
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	2 (5%)			
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	1 (3%)			
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	85%	92%			
Average Holds					
Third Party Submission with a Final Decision	49	36			
Total # Requests for Additional Information (Holds)	27	15			
Average # Requests for Additional Information per Submission	0.55	0.42			
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	49	36			
Third Party SE Recommendations	49	36			
Third Party NSE Recommendations	0	0			
Third Party SE Recommendations with a Final Decision	49	36			
MDUFA IV Final Decision					
SE	46	33			
NSE	0	1			
Non-MDUFA IV Final Decision					
Withdrawn	3	1			
Deleted	0	1			
Third Party NSE Recommendations with a Final Decision	0	0			
MDUFA IV Final Decision					
SE	0	0			
NSE	0	0			
Non-MDUFA IV Final Decision					
Withdrawn	0	0			
Deleted	0	0			

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Average Initial Third Party Review Time (Calendar Days)	91	105			
25th Percentile Initial Third Party Review Time	38	33			
50th Percentile Initial Third Party Review Time	59	60			
75th Percentile Initial Third Party Review Time	102	154			
Maximum Initial Third Party Review Time	594	565			
Average Third Party Hold Time (Calendar Days)	25	15			
25th Percentile Third Party Hold Time	0	0			
50th Percentile Third Party Hold Time	3	0			
75th Percentile Third Party Hold Time	16	23			
Maximum Third Party Hold Time	352	67			
Average Total Third Party Review Time (Calendar Days)	116	120			
25th Percentile Total Third Party Review Time	52	38			
50th Percentile Total Third Party Review Time	76	82			
75th Percentile Total Third Party Review Time	140	156			
Maximum Total Third Party Review Time	594	565			
Average Total FDA Review Time (Calendar Days)	32	27			
25th Percentile Total FDA Review Time	24	20			
50th Percentile Total FDA Review Time	28	26			
75th Percentile Total FDA Review Time	30	29			
Maximum Total FDA Review Time	98	108			
Average Total Time to Decision from FDA Receipt (Calendar Days)	56	42			
25th Percentile Total TTD from FDA Receipt	26	24			
50th Percentile Total TTD from FDA Receipt	30	29			
75th Percentile Total TTD from FDA Receipt	43	51			
Maximum Total TTD from FDA Receipt	432	156			
Average Total Time to Decision from Third Party Receipt (Calendar Days)	147	147			
25th Percentile Total TTD from Third Party Receipt	77	56			
50th Percentile Total TTD from Third Party Receipt	105	108			
75th Percentile Total TTD from Third Party Receipt	172	184			
Maximum Total TTD from Third Party Receipt	624	580			

Third Party Review Group, LLC (TPRG)

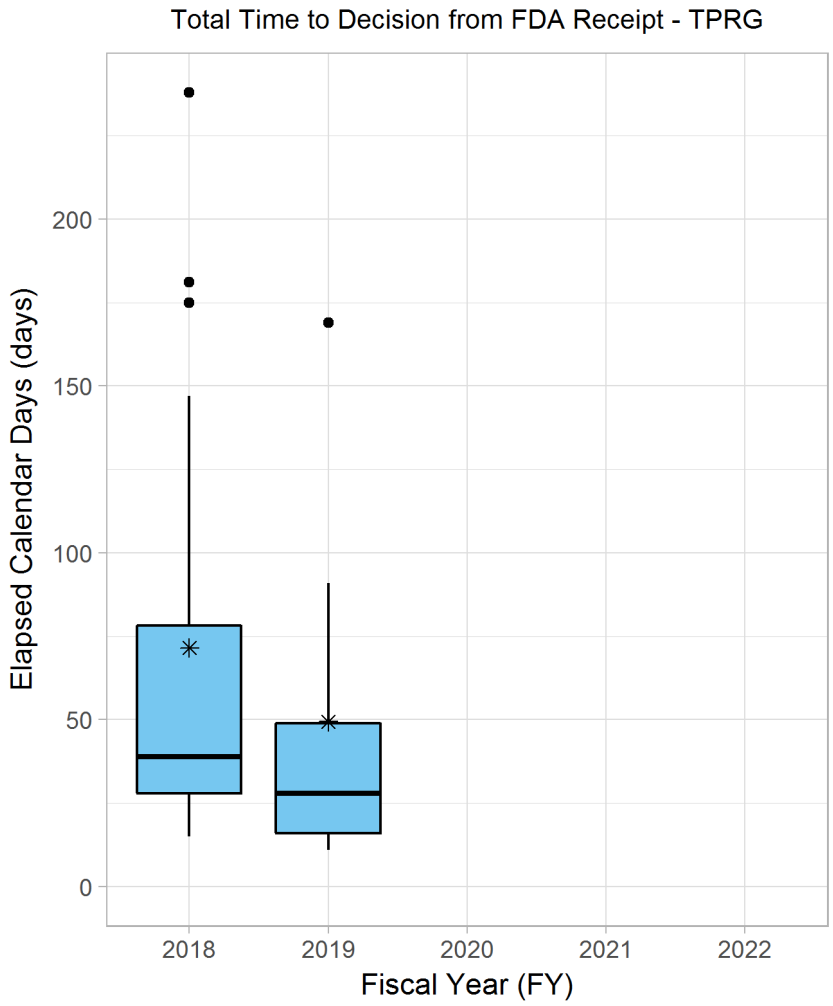


Figure 18

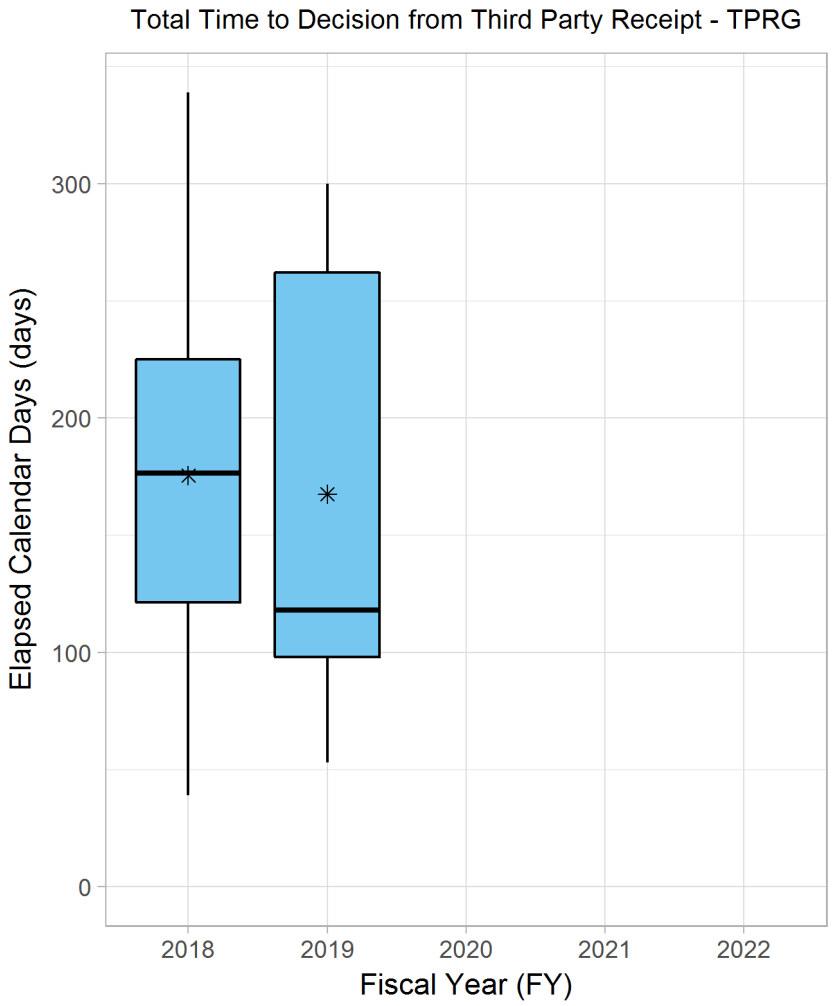


Figure 19

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Total Third Party 510(k) Submissions Accepted	19	13			
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (5%)	0 (0%)			
MDUFA IV Final Decisions: SE or NSE (%)	18 (95%)	9 (69%)			
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	2 (15%)			
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	2 (15%)			
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	89%	78%			
Average Holds					
Third Party Submission with a Final Decision	19	9			
Total # Requests for Additional Information (Holds)	11	5			
Average # Requests for Additional Information per Submission	0.58	0.56			
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	19	9			
Third Party SE Recommendations	19	9			
Third Party NSE Recommendations	0	0			
Third Party SE Recommendations with a Final Decision	19	9			
MDUFA IV Final Decision					
SE	18	8			
NSE	0	1			
Non-MDUFA IV Final Decision					
Withdrawn	0	0			
Deleted	1	0			
Third Party NSE Recommendations with a Final Decision	0	0			
MDUFA IV Final Decision					
SE	0	0			
NSE	0	0			
Non-MDUFA IV Final Decision					
Withdrawn	0	0			
Deleted	0	0			

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

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Average Initial Third Party Review Time (Calendar Days)	104	118			
25th Percentile Initial Third Party Review Time	76	55			
50th Percentile Initial Third Party Review Time	100	77			
75th Percentile Initial Third Party Review Time	126	209			
Maximum Initial Third Party Review Time	219	251			
Average Third Party Hold Time (Calendar Days)	44	23			
25th Percentile Third Party Hold Time	0	0			
50th Percentile Third Party Hold Time	10	7			
75th Percentile Third Party Hold Time	54	12			
Maximum Third Party Hold Time	184	139			
Average Total Third Party Review Time (Calendar Days)	147	140			
25th Percentile Total Third Party Review Time	99	67			
50th Percentile Total Third Party Review Time	148	97			
75th Percentile Total Third Party Review Time	198	230			
Maximum Total Third Party Review Time	285	251			
Average Total FDA Review Time (Calendar Days)	29	27			
25th Percentile Total FDA Review Time	24	16			
50th Percentile Total FDA Review Time	28	27			
75th Percentile Total FDA Review Time	30	30			
Maximum Total FDA Review Time	54	57			
Average Total Time to Decision from FDA Receipt (Calendar Days)	72	50			
25th Percentile Total TTD from FDA Receipt	28	16			
50th Percentile Total TTD from FDA Receipt	39	28			
75th Percentile Total TTD from FDA Receipt	80	49			
Maximum Total TTD from FDA Receipt	238	169			
Average Total Time to Decision from Third Party Receipt (Calendar Days)	176	168			
25th Percentile Total TTD from Third Party Receipt	119	98			
50th Percentile Total TTD from Third Party Receipt	177	118			
75th Percentile Total TTD from Third Party Receipt	227	262			
Maximum Total TTD from Third Party Receipt	339	300			

TUV SUD America Inc. (TUV)

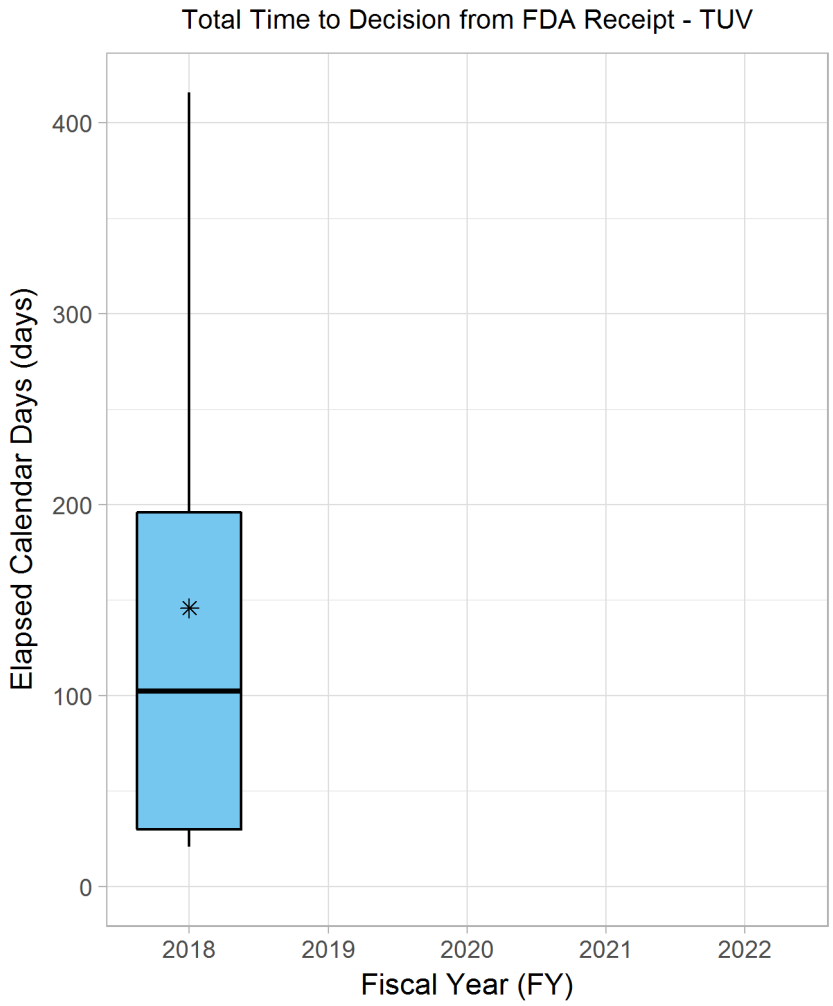


Figure 20

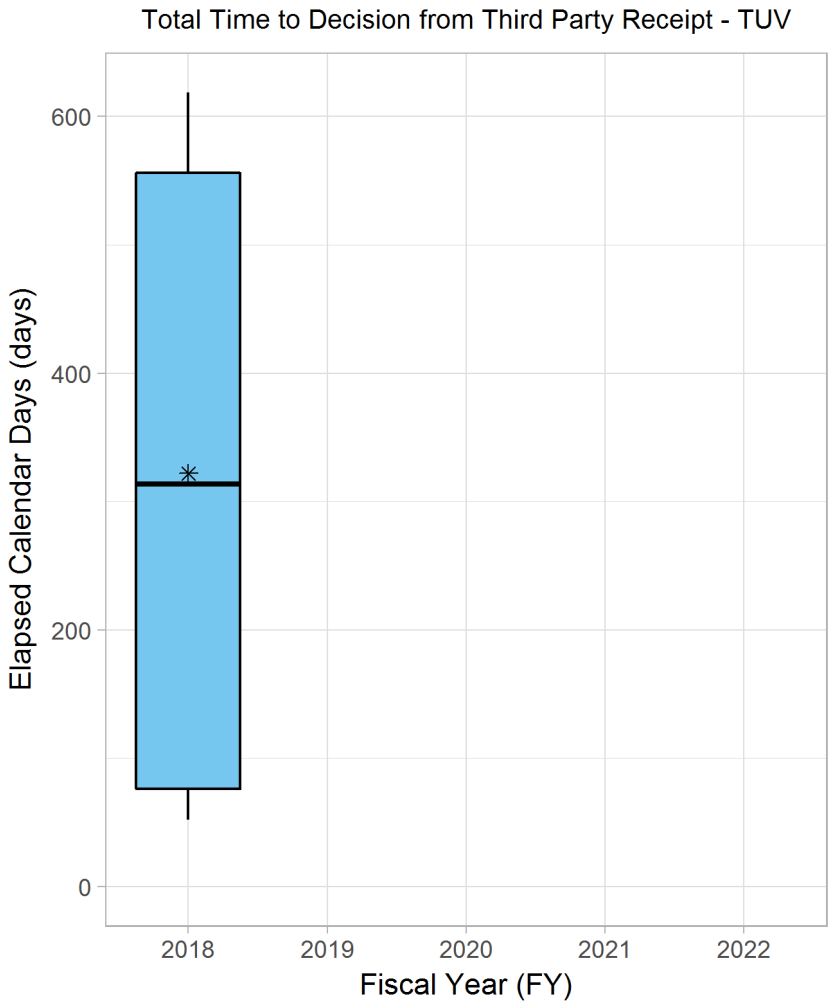


Figure 21

Table 4.1: Third Party 510(k) MDUFA IV Decision Performance Goals - TUV SUD America Inc. (TUV).

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Total Third Party 510(k) Submissions Accepted	7				
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (14%)				
MDUFA IV Final Decisions: SE or NSE (%)	6 (86%)				
Pending Final Decision for less than 30 FDA days (%)	0 (0%)				
Pending Final Decision for more than 30 FDA days (%)	0 (0%)				
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	50%				
Average Holds					
Third Party Submission with a Final Decision	7				
Total # Requests for Additional Information (Holds)	5				
Average # Requests for Additional Information per Submission	0.71				
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	7				
Third Party SE Recommendations	7				
Third Party NSE Recommendations	0				
Third Party SE Recommendations with a Final Decision	7				
MDUFA IV Final Decision					
SE	5				
NSE	1				
Non-MDUFA IV Final Decision					
Withdrawn	0				
Deleted	1				
Third Party NSE Recommendations with a Final Decision	0				
MDUFA IV Final Decision					
SE	0				
NSE	0				
Non-MDUFA IV Final Decision					
Withdrawn	0				
Deleted	0				

Table 4.2: Third Party 510(k) MDUFA IV Decision Performance Goals - TUV SUD America Inc. (TUV).

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Average Initial Third Party Review Time (Calendar Days)	177				
25th Percentile Initial Third Party Review Time	31				
50th Percentile Initial Third Party Review Time	106				
75th Percentile Initial Third Party Review Time	385				
Maximum Initial Third Party Review Time	409				
Average Third Party Hold Time (Calendar Days)	101				
25th Percentile Third Party Hold Time	0				
50th Percentile Third Party Hold Time	69				
75th Percentile Third Party Hold Time	122				
Maximum Third Party Hold Time	341				
Average Total Third Party Review Time (Calendar Days)	277				
25th Percentile Total Third Party Review Time	42				
50th Percentile Total Third Party Review Time	276				
75th Percentile Total Third Party Review Time	502				
Maximum Total Third Party Review Time	531				
Average Total FDA Review Time (Calendar Days)	46				
25th Percentile Total FDA Review Time	23				
50th Percentile Total FDA Review Time	34				
75th Percentile Total FDA Review Time	75				
Maximum Total FDA Review Time	88				
Average Total Time to Decision from FDA Receipt (Calendar Days)	146				
25th Percentile Total TTD from FDA Receipt	23				
50th Percentile Total TTD from FDA Receipt	103				
75th Percentile Total TTD from FDA Receipt	210				
Maximum Total TTD from FDA Receipt	416				
Average Total Time to Decision from Third Party Receipt (Calendar Days)	322				
25th Percentile Total TTD from Third Party Receipt	72				
50th Percentile Total TTD from Third Party Receipt	314				
75th Percentile Total TTD from Third Party Receipt	562				
Maximum Total TTD from Third Party Receipt	619				

Change Log

Date	Description
2018-January	Initial Report
2018-October	Added new 3PRO - ADAS
2018-October	Added boxplot legend
2019-January	Added new 3PRO - BDC
2019-January	Updated timeline graphic
2019-January	Added reporting by Fiscal Year and plots for individual 3PROs
2019-February-14	Process change for new second hold policy requiring concurrence from the 510(k) Third Party FDA staff. This change may affect Average Holds and the rate of NSE decisions.
2019-April	Added cumulative submission count graph
2019-April	Clarified definitions to state reporting is for MDUFA decisions (SE or NSE)