Third Party Review Organization Performance Report

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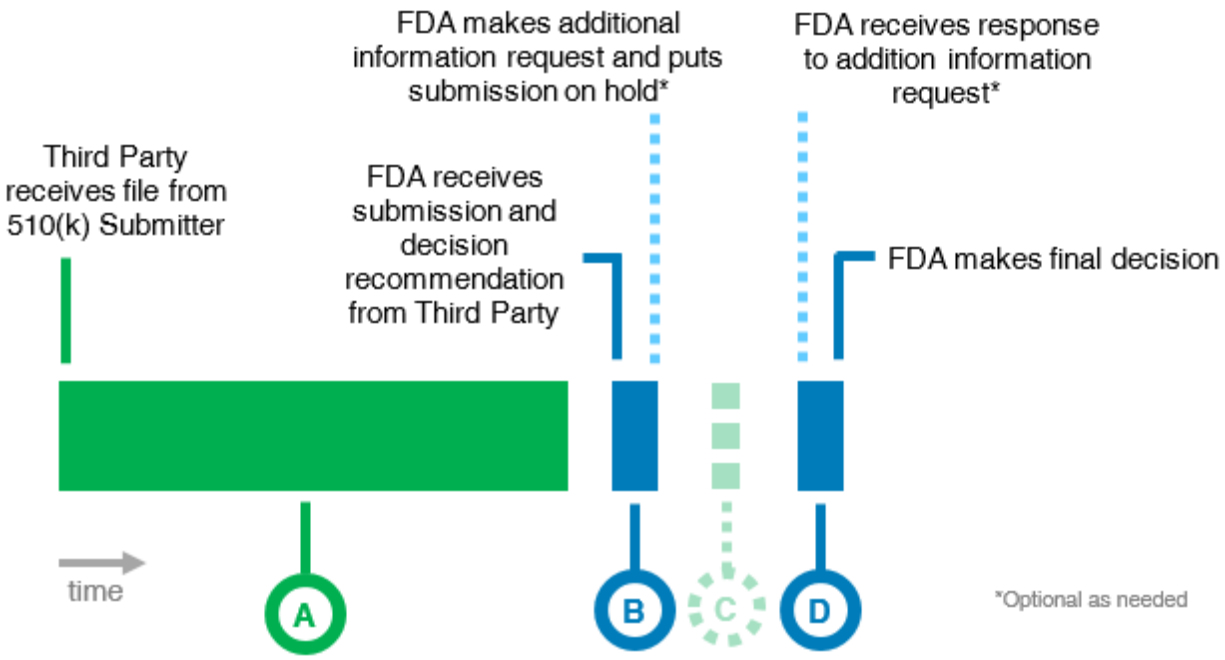
Introduction and Review Timeline Description

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, Q1 (October 1, 2017 through December 31, 2018). 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
2	1	0	0	0

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.


FDA makes additional information request and puts submission on hold*
FDA receives response to addition information request*
Third Party receives file from 510(k) Submitter
FDA receives submission and decision recommendation from Third Party
FDA makes final decision
time
A
B
C
D
*Optional as needed

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. 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. 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.

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. *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**:

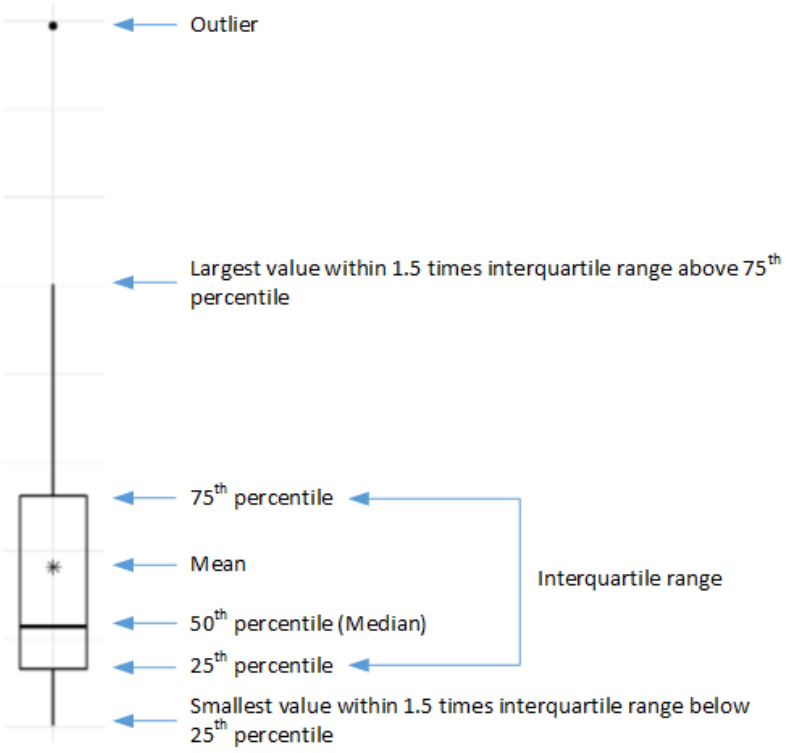
= *Total Third Party Review Time + Total FDA Review Time*

Elapsed time in days for FDA and a Third Party to provide a final MDUFA IV decision 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
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

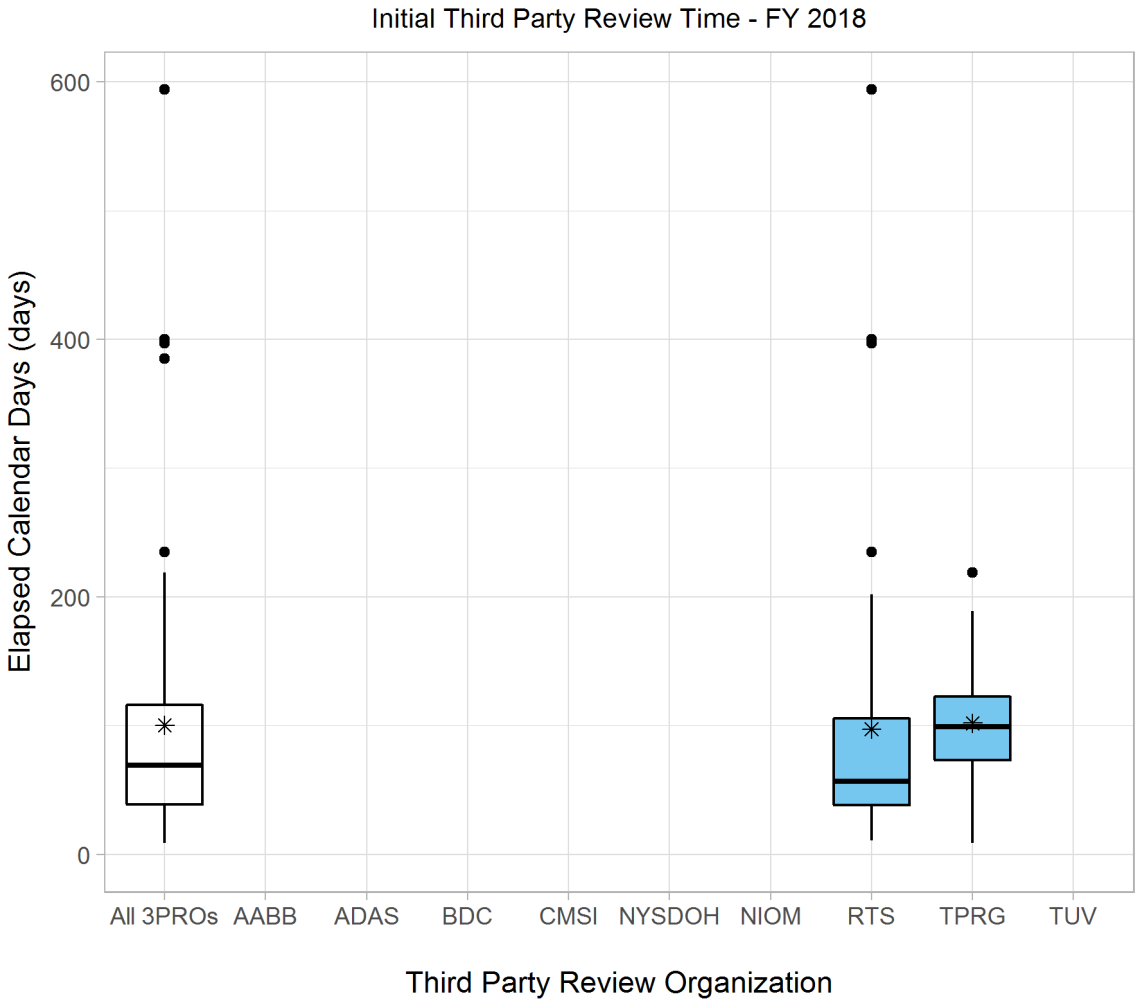


Figure 1

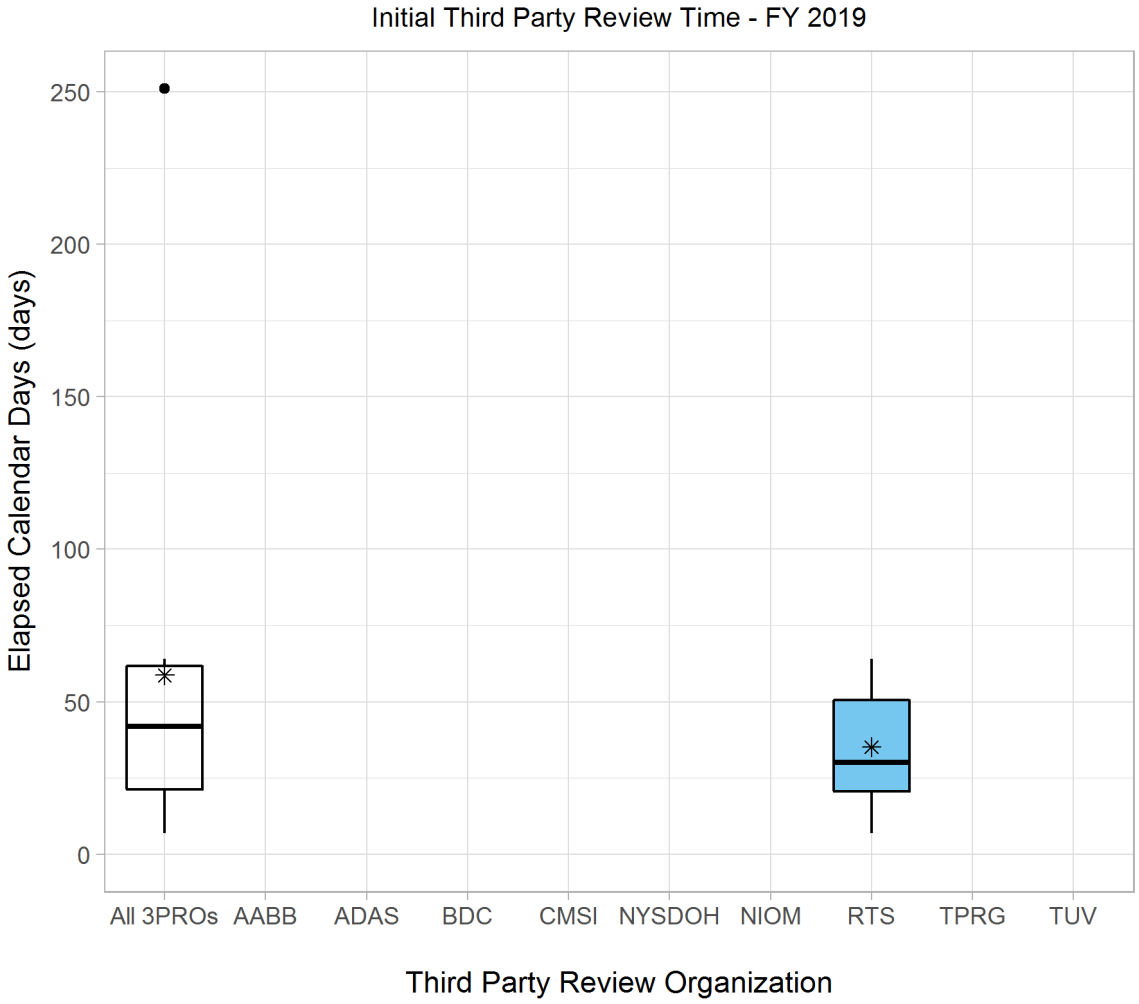
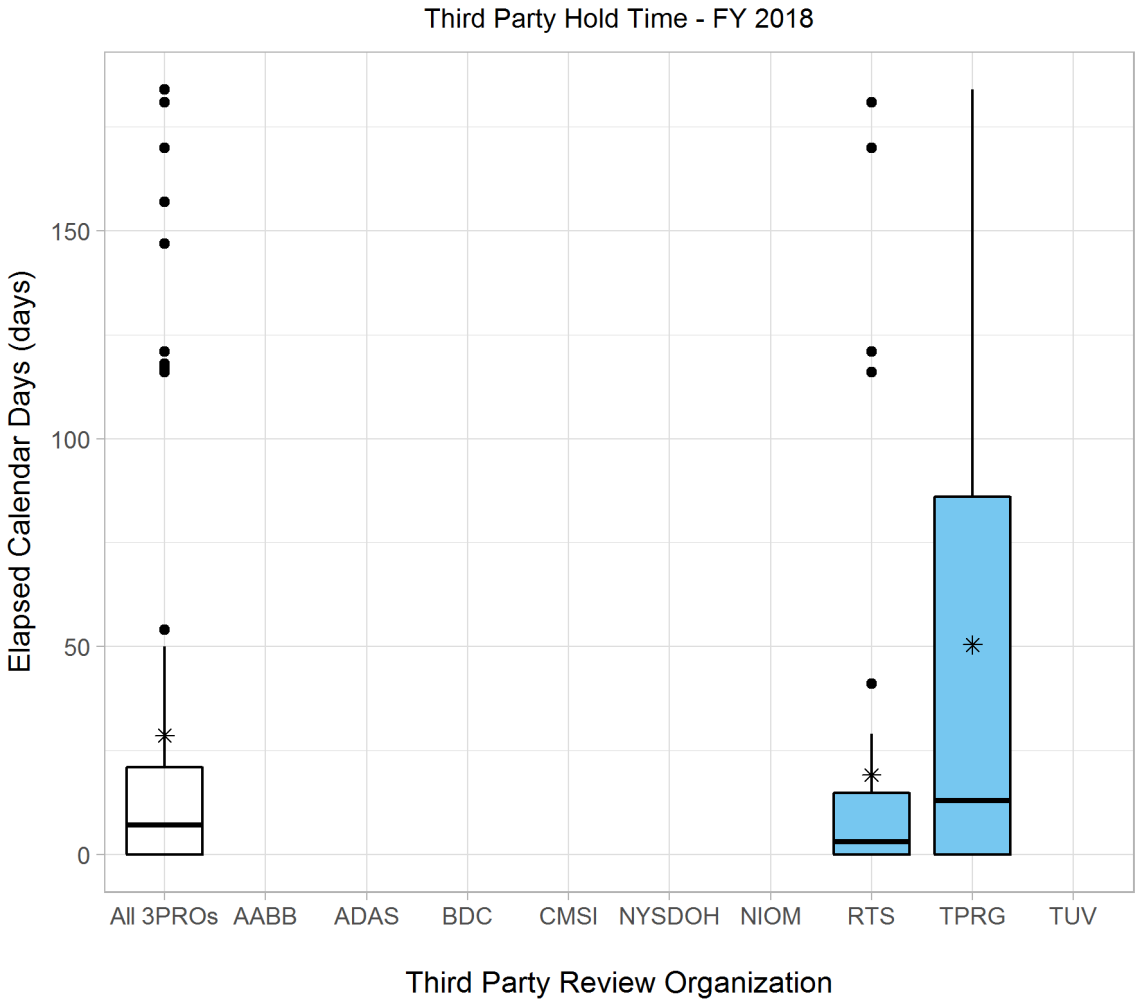

Initial Third Party Review Time - FY 2019
Elapsed Calendar Days (days)
250
200
150
100
50
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 2

Third Party Hold Time



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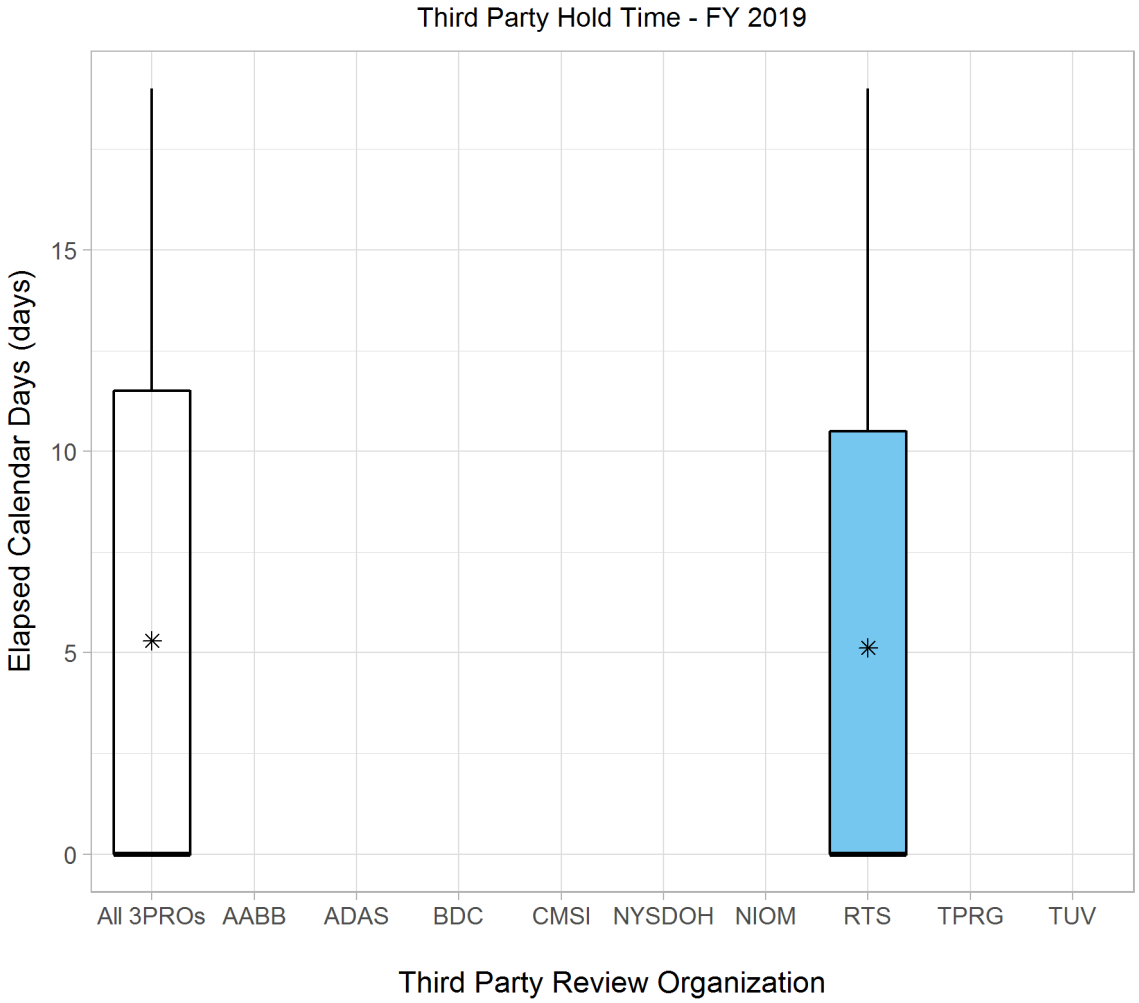

Third Party Hold Time - FY 2019
Elapsed Calendar Days (days)
15
10
5
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 4

Total Third Party Review Time

Figure 5

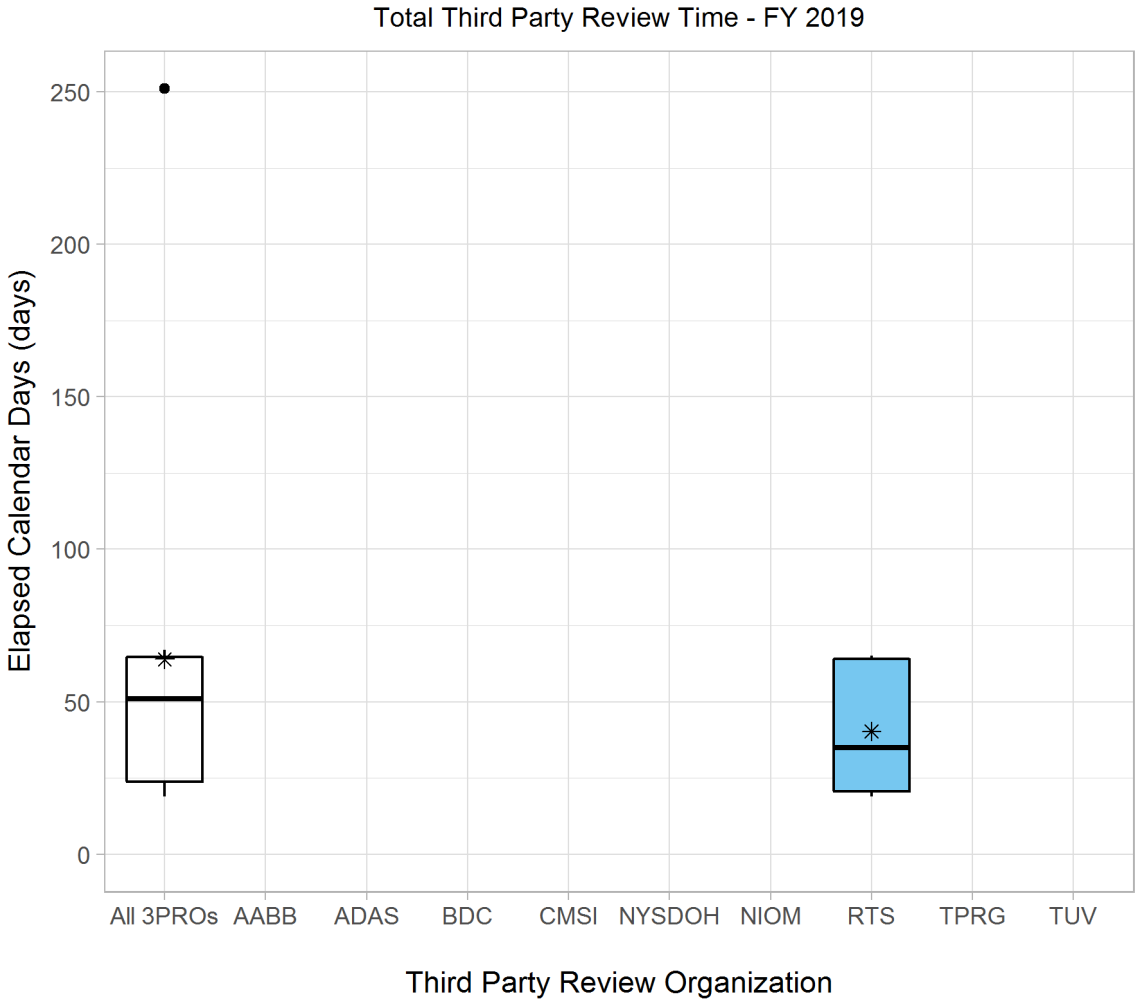

Total Third Party Review Time - FY 2019
Elapsed Calendar Days (days)
250
200
150
100
50
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 6

Total FDA Review Time

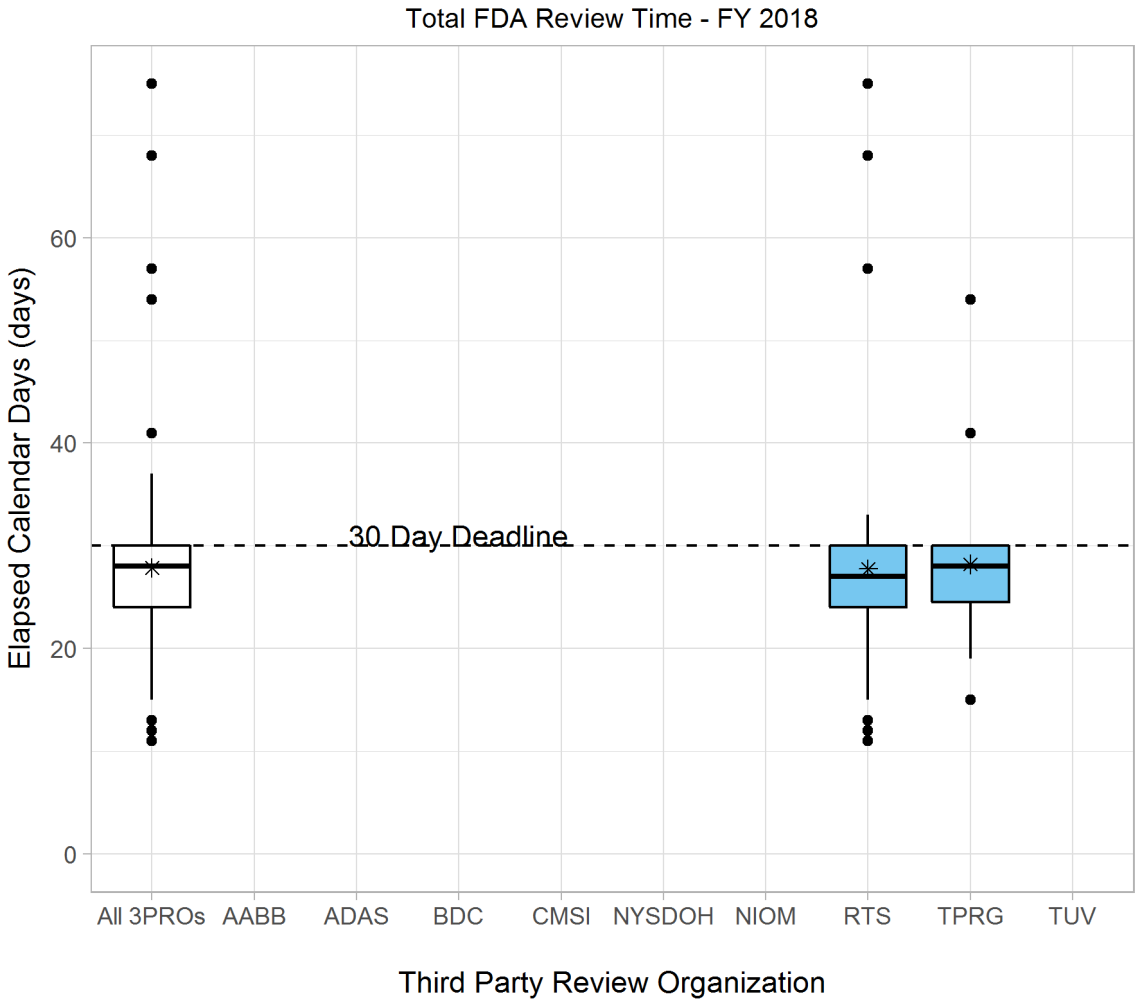


Figure 7

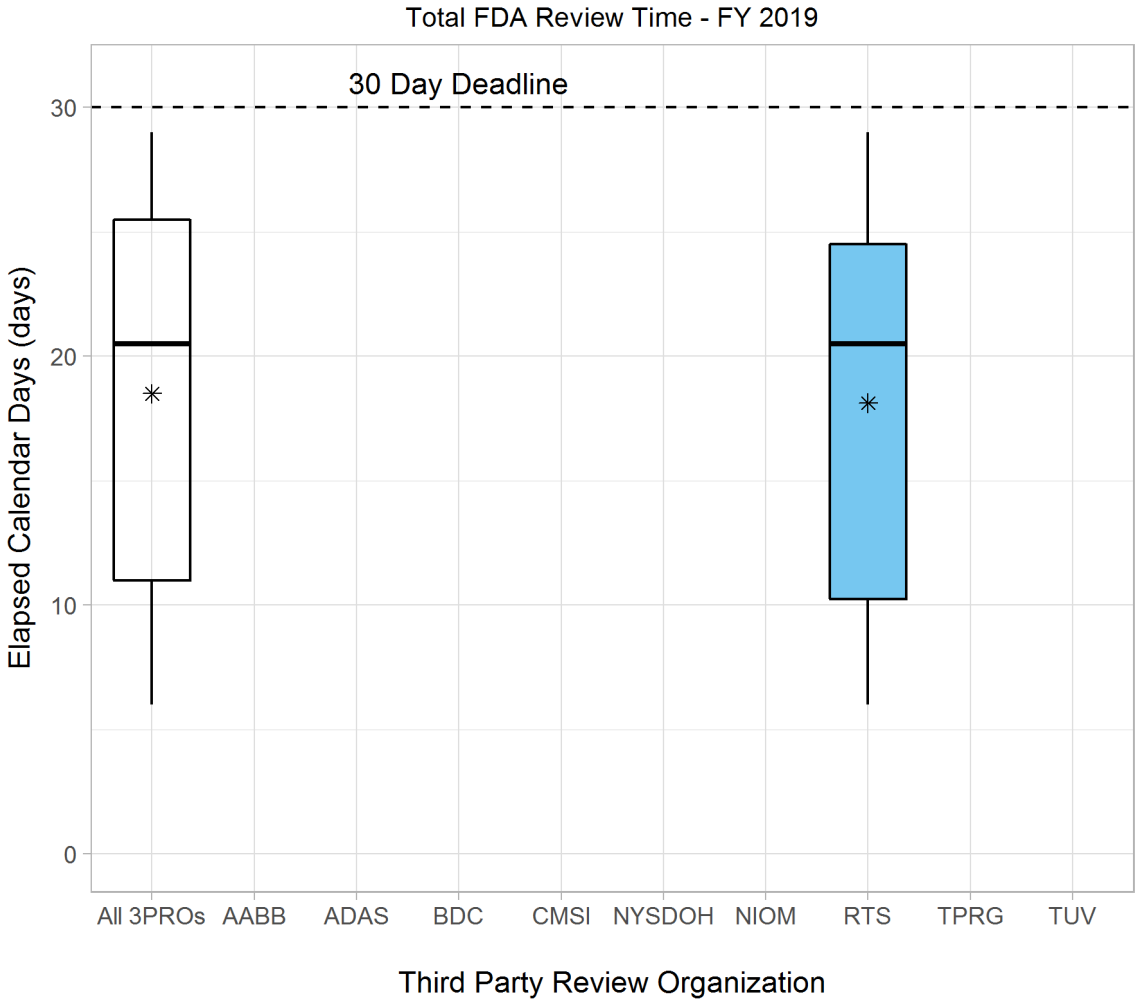

Total FDA Review Time - FY 2019
30 Day Deadline
30
20
10
0
Elapsed Calendar Days (days)
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 8

Total Time to Decision from FDA Receipt

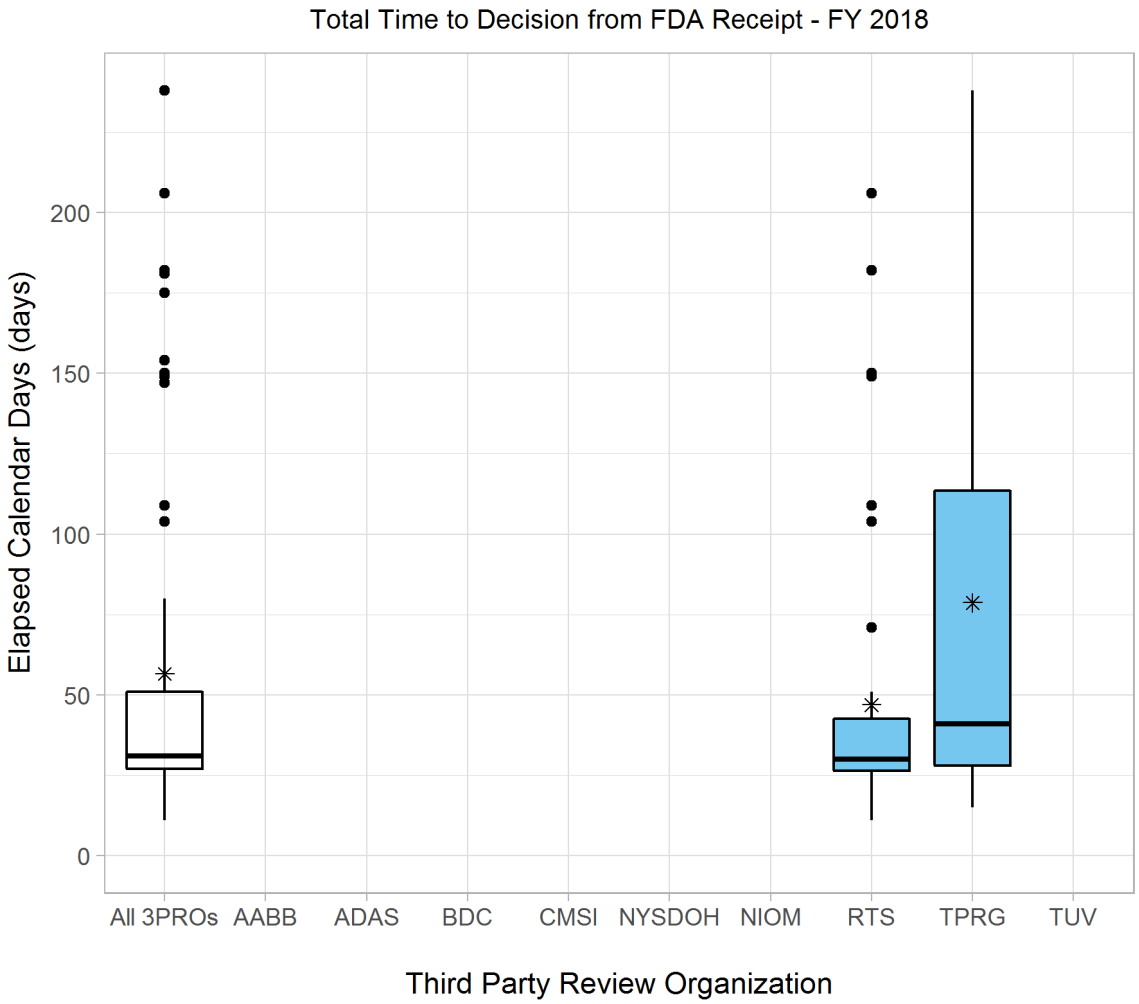


Figure 9

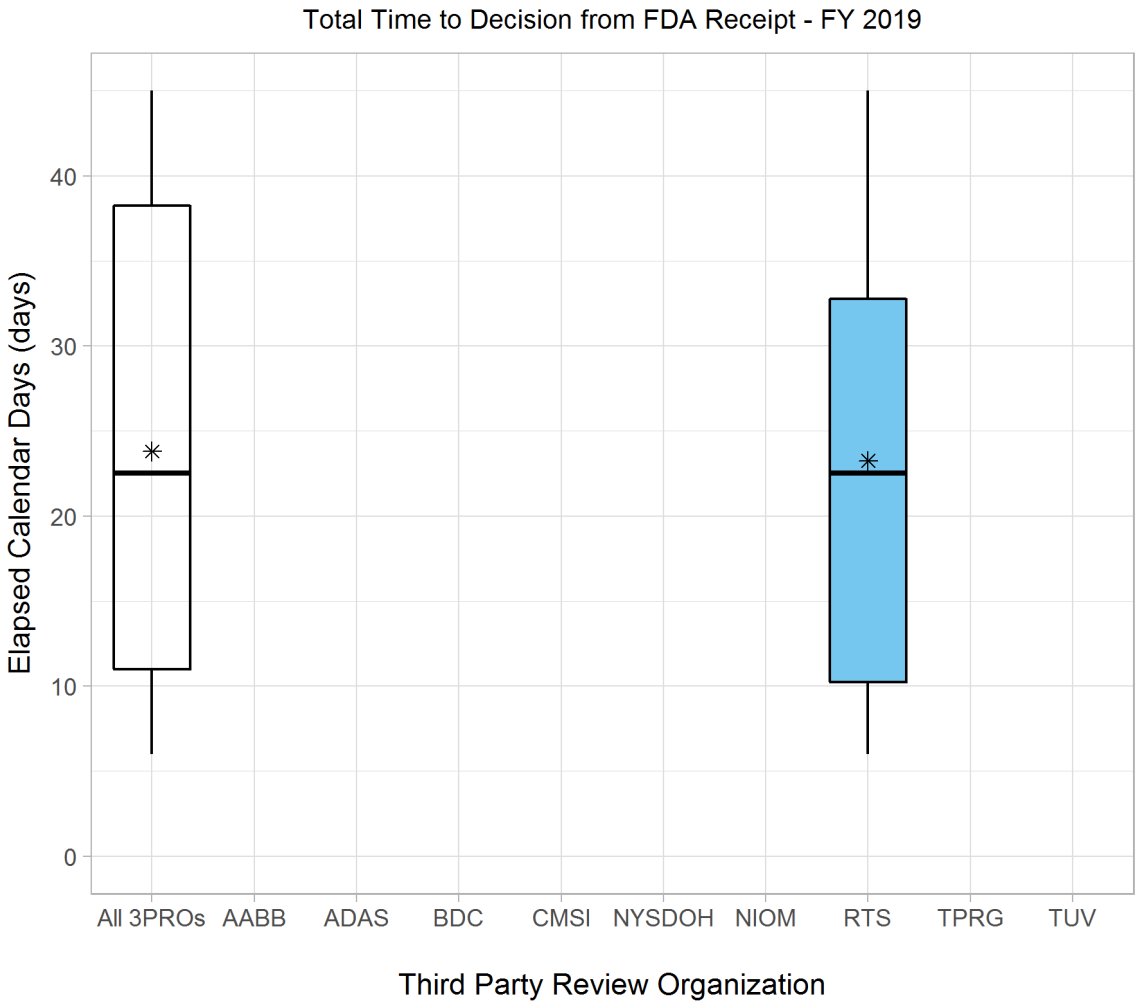
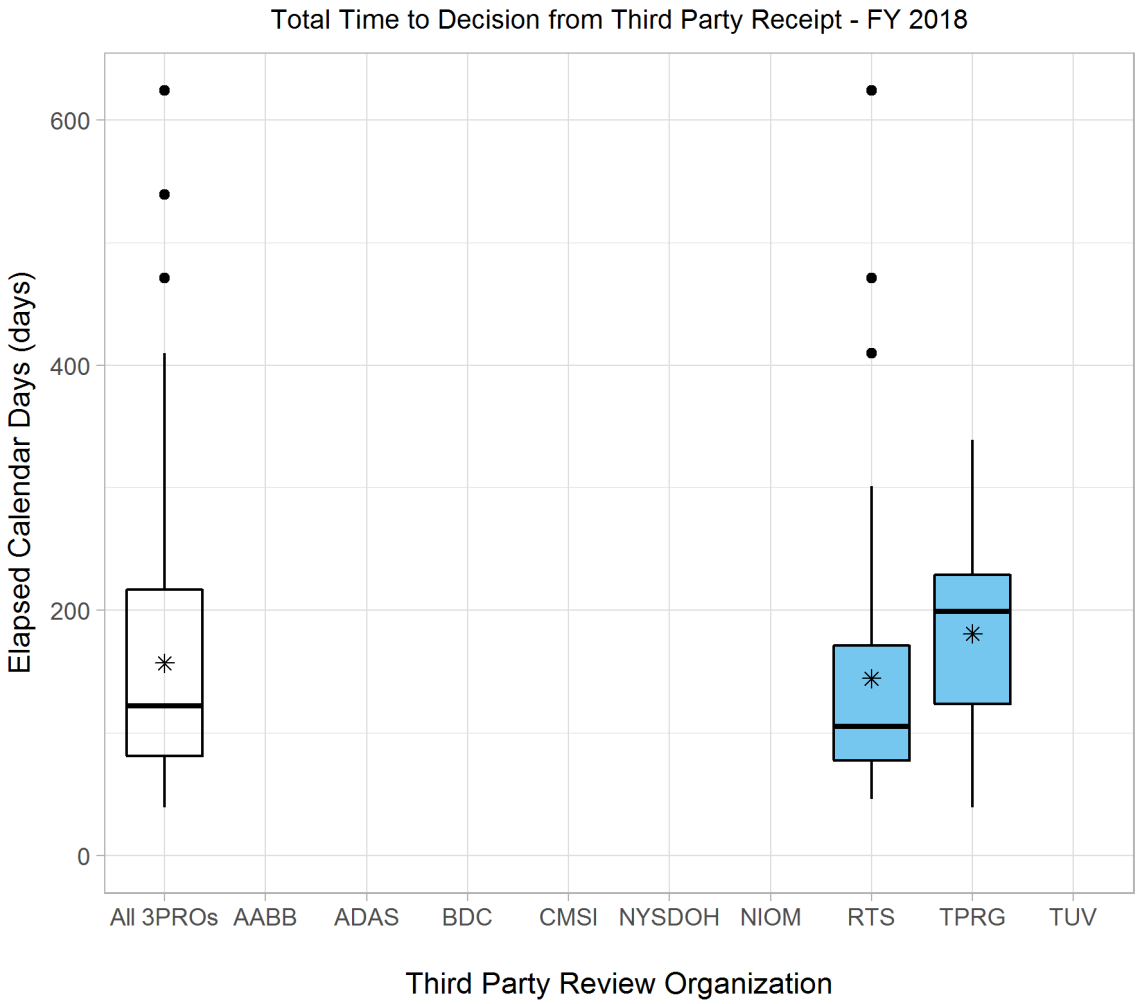

Total Time to Decision from FDA Receipt - FY 2019
Elapsed Calendar Days (days)
0
10
20
30
40
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 10

Total Time to Decision from Third Party Receipt



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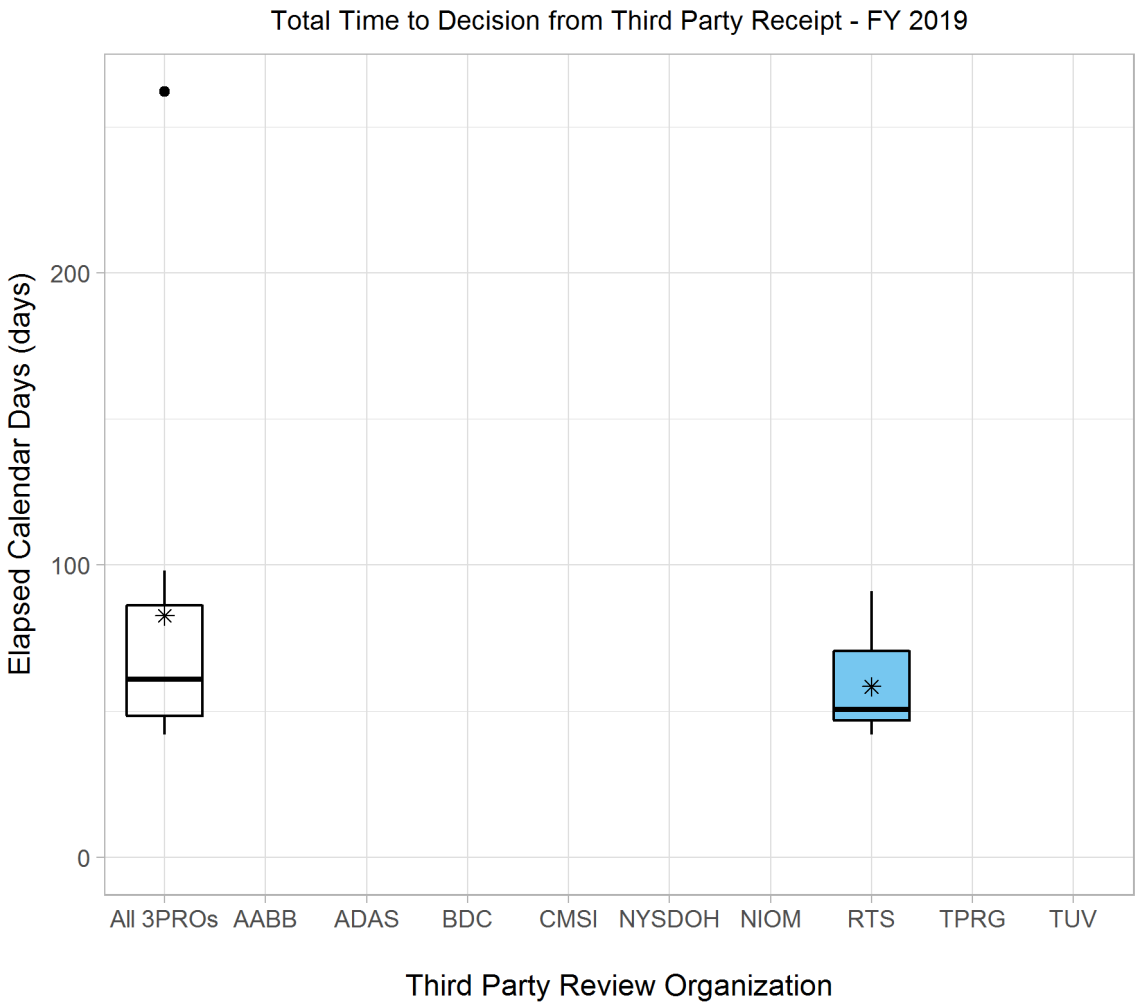
Total Time to Decision from Third Party Receipt - FY 2019
Elapsed Calendar Days (days)
200
100
0
All 3PROs
AABB
ADAS
BDC
CMSI
NYSDOH
NIOM
RTS
TPRG
TUV
Third Party Review Organization

Figure 12

All Third Party Review Organizations

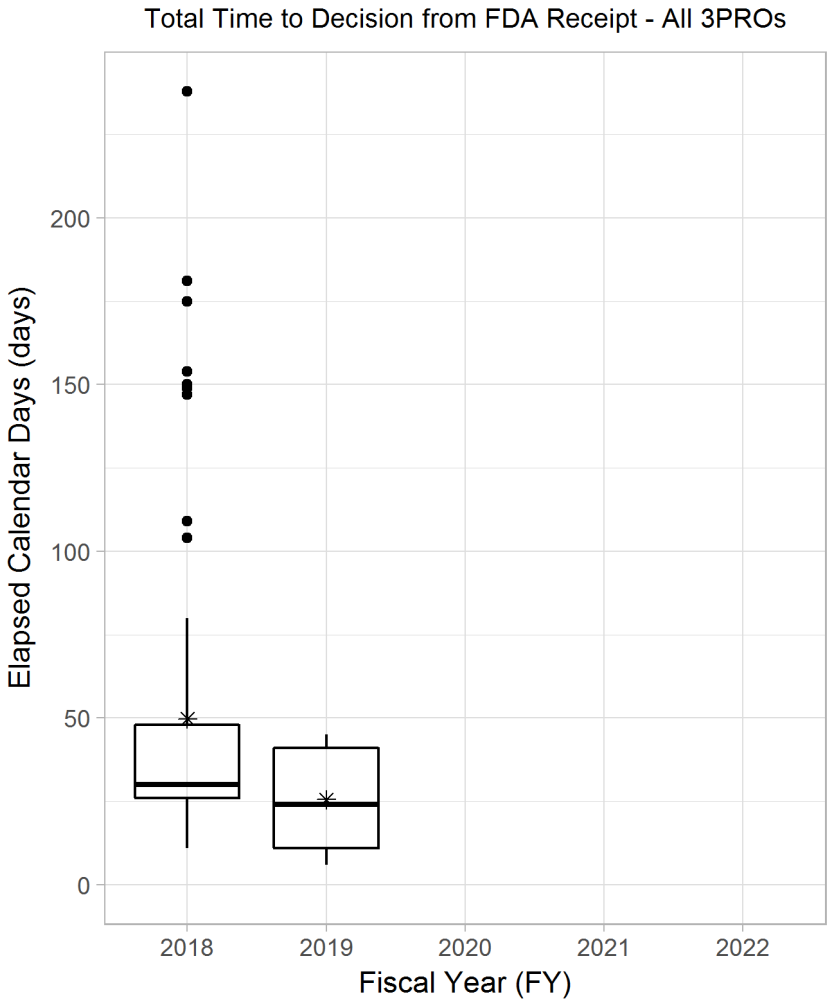

Figure 13

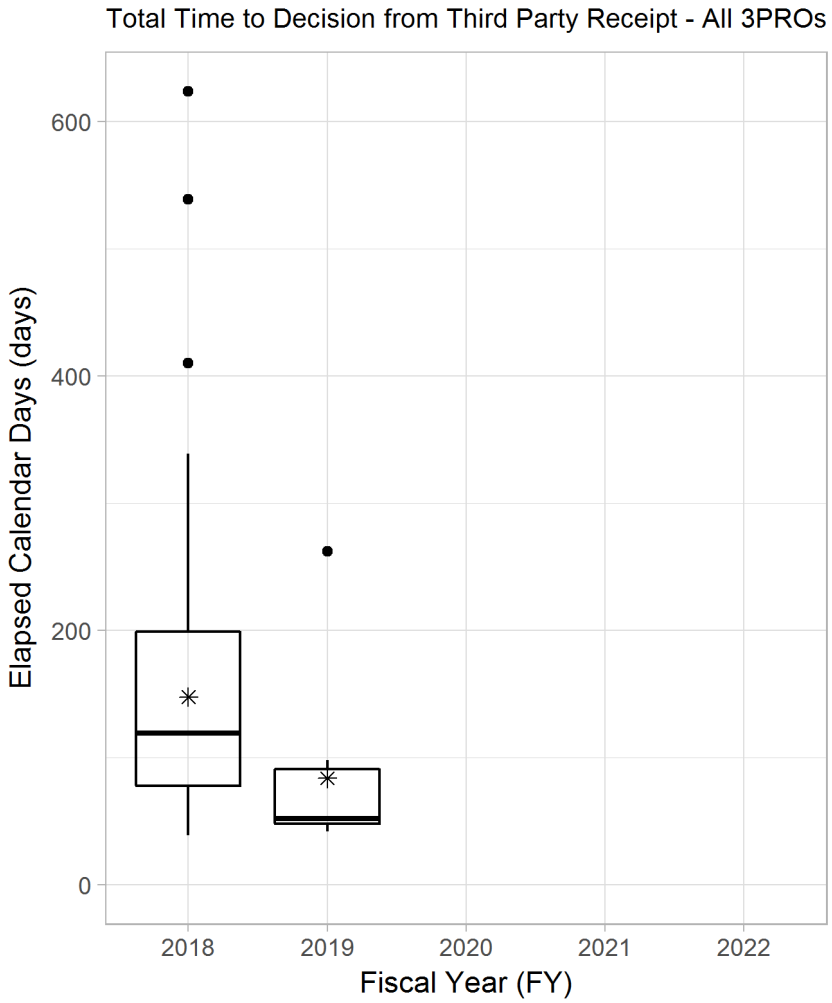

Figure 14

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	23			
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	4 (5%)	1 (4%)			
MDUFA IV Final Decisions: SE or NSE (%)	65 (87%)	9 (39%)			
Pending Final Decision for less than 30 FDA days (%)	4 (5%)	12 (52%)			
Pending Final Decision for more than 30 FDA days (%)	2 (3%)	1 (4%)			
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	90%	100%			
Average Holds					
Third Party Submission with a Final Decision	69	10			
Total # Requests for Additional Information (Holds)	35	4			
Average # Requests for Additional Information per Submission	0.51	0.4			
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	69	10			
Third Party SE Recommendations	69	10			
Third Party NSE Recommendations	0	0			
Third Party SE Recommendations with a Final Decision	69	10			
MDUFA IV Final Decision					
SE	65	8			
NSE	0	1			
Non-MDUFA IV Final Decision					
Withdrawn	3	1			
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 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)	98	59			
25th Percentile Initial Third Party Review Time	39	21			
50th Percentile Initial Third Party Review Time	69	38			
75th Percentile Initial Third Party Review Time	116	55			
Maximum Initial Third Party Review Time	594	251			
Average Third Party Hold Time (Calendar Days)	22	6			
25th Percentile Third Party Hold Time	0	0			
50th Percentile Third Party Hold Time	0	0			
75th Percentile Third Party Hold Time	20	12			
Maximum Third Party Hold Time	184	19			
Average Total Third Party Review Time (Calendar Days)	120	64			
25th Percentile Total Third Party Review Time	53	21			
50th Percentile Total Third Party Review Time	90	38			
75th Percentile Total Third Party Review Time	169	65			
Maximum Total Third Party Review Time	594	251			
Average Total FDA Review Time (Calendar Days)	28	20			
25th Percentile Total FDA Review Time	24	11			
50th Percentile Total FDA Review Time	28	21			
75th Percentile Total FDA Review Time	30	26			
Maximum Total FDA Review Time	75	29			
Average Total Time to Decision from FDA Receipt (Calendar Days)	50	26			
25th Percentile Total TTD from FDA Receipt	26	11			
50th Percentile Total TTD from FDA Receipt	30	24			
75th Percentile Total TTD from FDA Receipt	48	41			
Maximum Total TTD from FDA Receipt	238	45			
Average Total Time to Decision from Third Party Receipt (Calendar Days)	148	84			
25th Percentile Total TTD from Third Party Receipt	78	48			
50th Percentile Total TTD from Third Party Receipt	119	52			
75th Percentile Total TTD from Third Party Receipt	199	91			
Maximum Total TTD from Third Party Receipt	624	262			

AABB (AABB)

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

Accelerated Device Approval Services (ADAS)

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

Regulatory Technology Services, LLC (RTS)

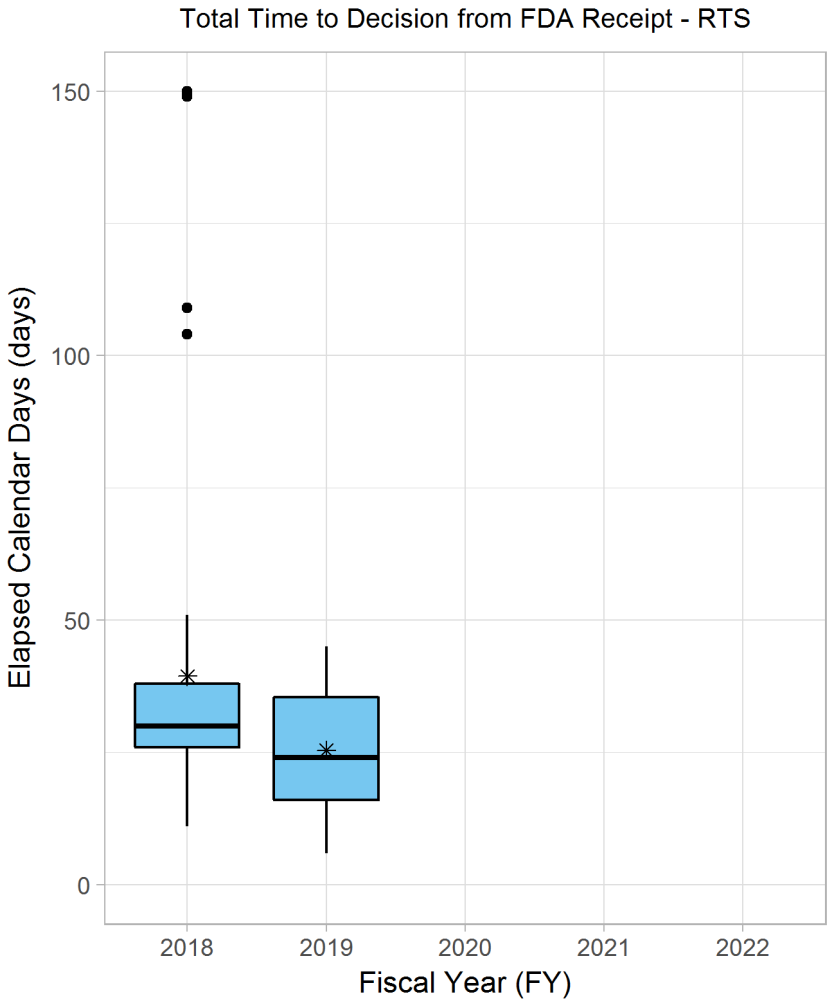

Figure 15

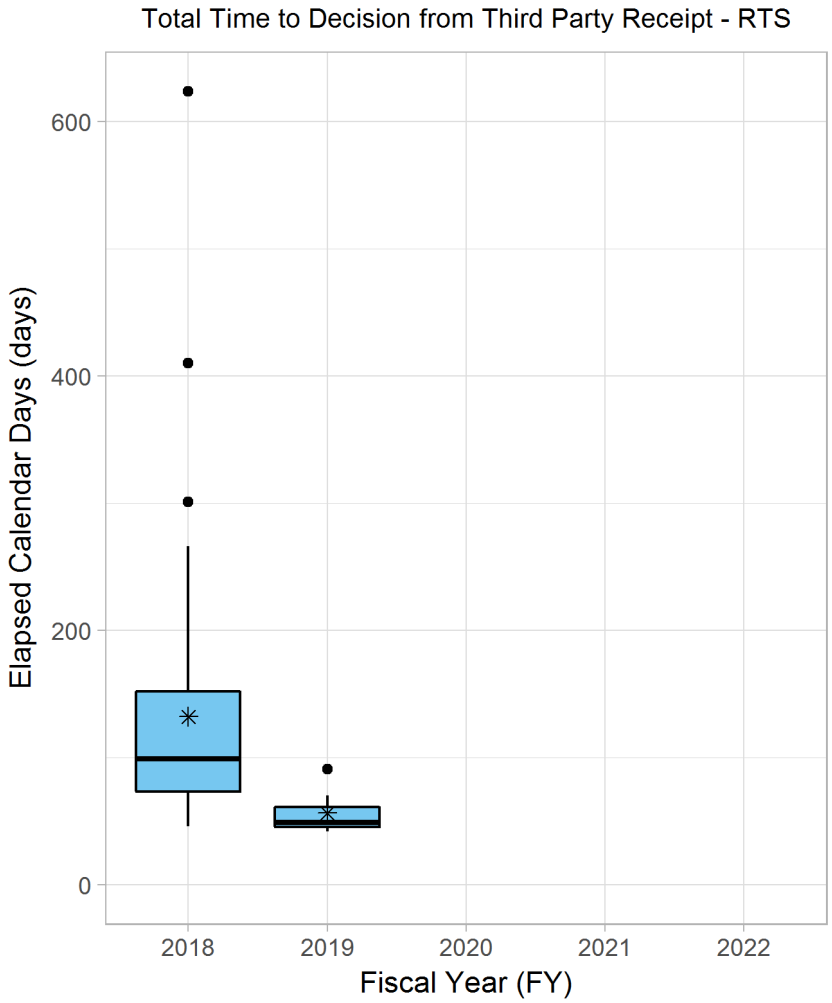

Figure 16

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	20			
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	3 (6%)	1 (5%)			
MDUFA IV Final Decisions: SE or NSE (%)	43 (88%)	7 (35%)			
Pending Final Decision for less than 30 FDA days (%)	2 (4%)	11 (55%)			
Pending Final Decision for more than 30 FDA days (%)	1 (2%)	1 (5%)			
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	91%	100%			
Average Holds					
Third Party Submission with a Final Decision	46	8			
Total # Requests for Additional Information (Holds)	22	3			
Average # Requests for Additional Information per Submission	0.48	0.38			
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	46	8			
Third Party SE Recommendations	46	8			
Third Party NSE Recommendations	0	0			
Third Party SE Recommendations with a Final Decision	46	8			
MDUFA IV Final Decision					
SE	43	7			
NSE	0	0			
Non-MDUFA IV Final Decision					
Withdrawn	3	1			
Deleted	0	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 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)	93	31			
25th Percentile Initial Third Party Review Time	36	20			
50th Percentile Initial Third Party Review Time	57	22			
75th Percentile Initial Third Party Review Time	105	42			
Maximum Initial Third Party Review Time	594	64			
Average Third Party Hold Time (Calendar Days)	12	6			
25th Percentile Third Party Hold Time	0	0			
50th Percentile Third Party Hold Time	0	0			
75th Percentile Third Party Hold Time	13	11			
Maximum Third Party Hold Time	121	19			
Average Total Third Party Review Time (Calendar Days)	105	37			
25th Percentile Total Third Party Review Time	47	20			
50th Percentile Total Third Party Review Time	70	32			
75th Percentile Total Third Party Review Time	126	51			
Maximum Total Third Party Review Time	594	65			
Average Total FDA Review Time (Calendar Days)	28	20			
25th Percentile Total FDA Review Time	24	16			
50th Percentile Total FDA Review Time	27	21			
75th Percentile Total FDA Review Time	30	25			
Maximum Total FDA Review Time	75	29			
Average Total Time to Decision from FDA Receipt (Calendar Days)	40	26			
25th Percentile Total TTD from FDA Receipt	26	16			
50th Percentile Total TTD from FDA Receipt	30	24			
75th Percentile Total TTD from FDA Receipt	38	36			
Maximum Total TTD from FDA Receipt	150	45			
Average Total Time to Decision from Third Party Receipt (Calendar Days)	133	57			
25th Percentile Total TTD from Third Party Receipt	73	46			
50th Percentile Total TTD from Third Party Receipt	99	49			
75th Percentile Total TTD from Third Party Receipt	152	61			
Maximum Total TTD from Third Party Receipt	624	91			

Third Party Review Group, LLC (TPRG)

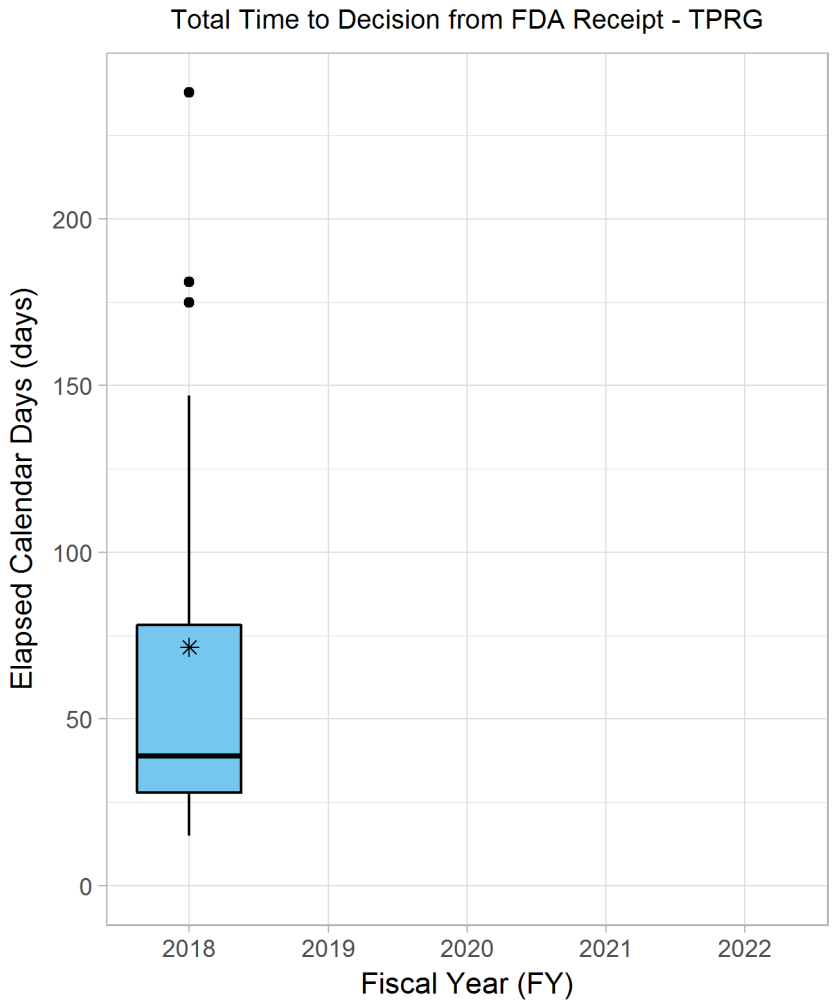

Figure 17

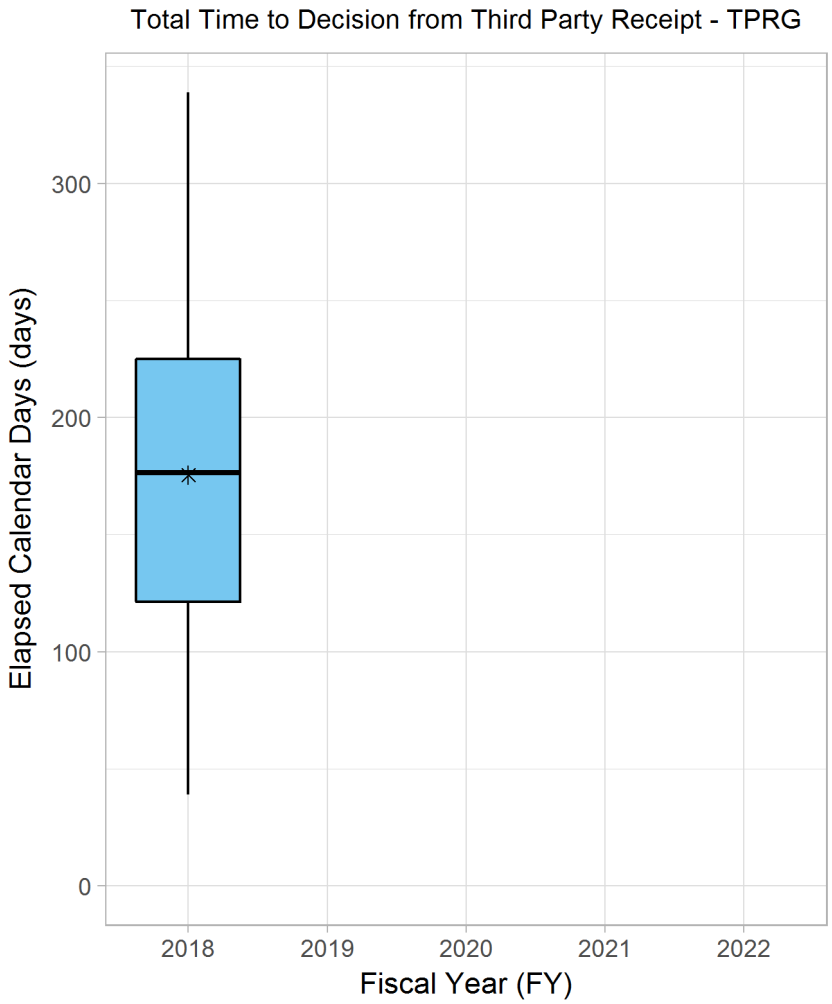

Figure 18

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				
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (5%)				
MDUFA IV Final Decisions: SE or NSE (%)	18 (95%)				
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 (%)	89%				
Average Holds					
Third Party Submission with a Final Decision	19				
Total # Requests for Additional Information (Holds)	11				
Average # Requests for Additional Information per Submission	0.58				
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	19				
Third Party SE Recommendations	19				
Third Party NSE Recommendations	0				
Third Party SE Recommendations with a Final Decision	19				
MDUFA IV Final Decision					
SE	18				
NSE	0				
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 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				
25th Percentile Initial Third Party Review Time	76				
50th Percentile Initial Third Party Review Time	100				
75th Percentile Initial Third Party Review Time	126				
Maximum Initial Third Party Review Time	219				
Average Third Party Hold Time (Calendar Days)	44				
25th Percentile Third Party Hold Time	0				
50th Percentile Third Party Hold Time	10				
75th Percentile Third Party Hold Time	54				
Maximum Third Party Hold Time	184				
Average Total Third Party Review Time (Calendar Days)	147				
25th Percentile Total Third Party Review Time	99				
50th Percentile Total Third Party Review Time	148				
75th Percentile Total Third Party Review Time	198				
Maximum Total Third Party Review Time	285				
Average Total FDA Review Time (Calendar Days)	29				
25th Percentile Total FDA Review Time	24				
50th Percentile Total FDA Review Time	28				
75th Percentile Total FDA Review Time	30				
Maximum Total FDA Review Time	54				
Average Total Time to Decision from FDA Receipt (Calendar Days)	72				
25th Percentile Total TTD from FDA Receipt	28				
50th Percentile Total TTD from FDA Receipt	39				
75th Percentile Total TTD from FDA Receipt	80				
Maximum Total TTD from FDA Receipt	238				
Average Total Time to Decision from Third Party Receipt (Calendar Days)	176				
25th Percentile Total TTD from Third Party Receipt	119				
50th Percentile Total TTD from Third Party Receipt	177				
75th Percentile Total TTD from Third Party Receipt	227				
Maximum Total TTD from Third Party Receipt	339				

TUV SUD America Inc. (TUV)

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