Third Party Review Organization Performance Report

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*As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews

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 2022, Q3 (October 1, 2017 through June 30, 2022). 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	3	3	3	2

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

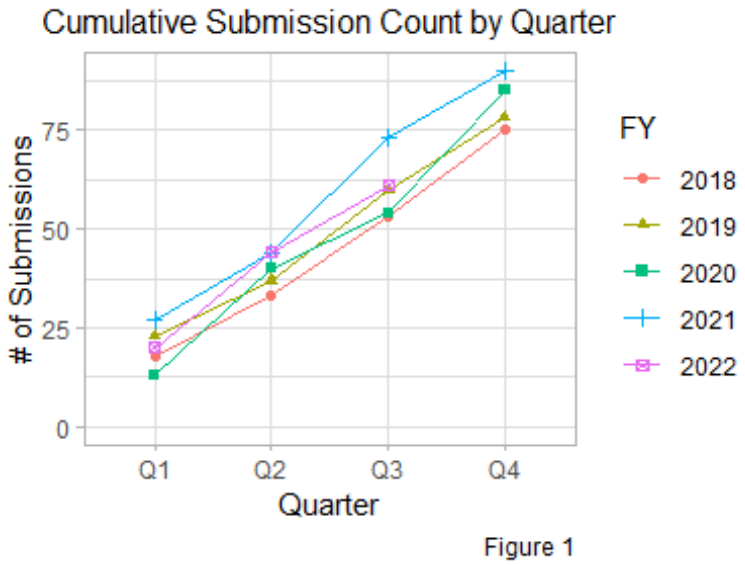
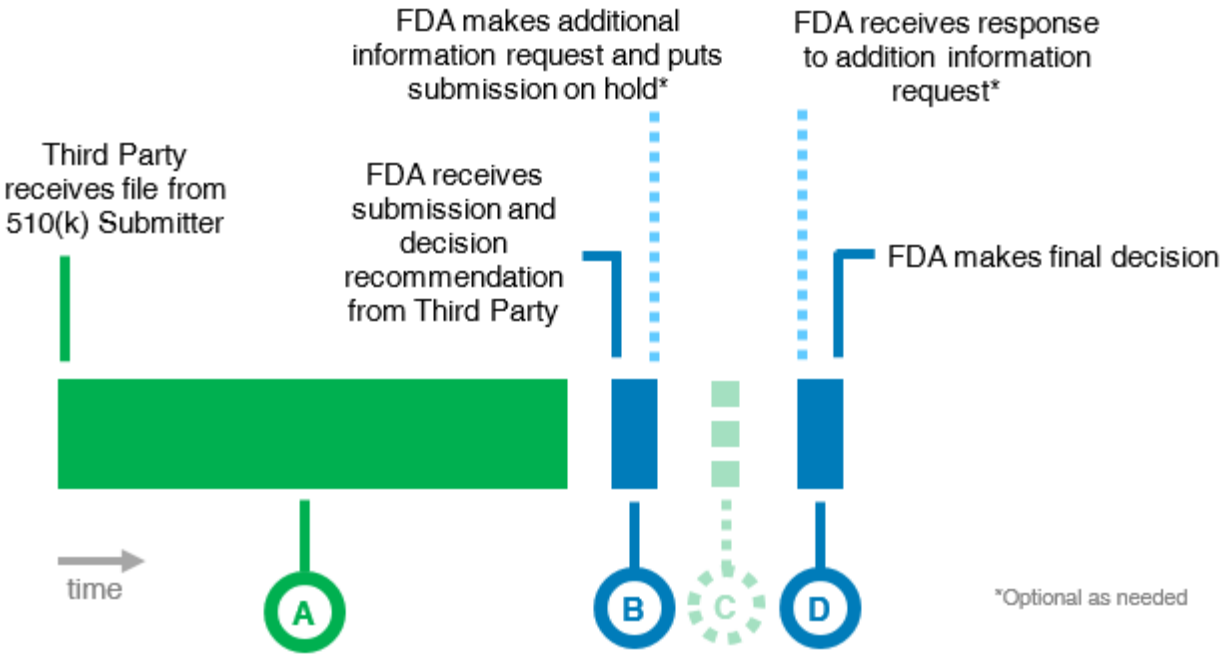


Figure 1

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**:

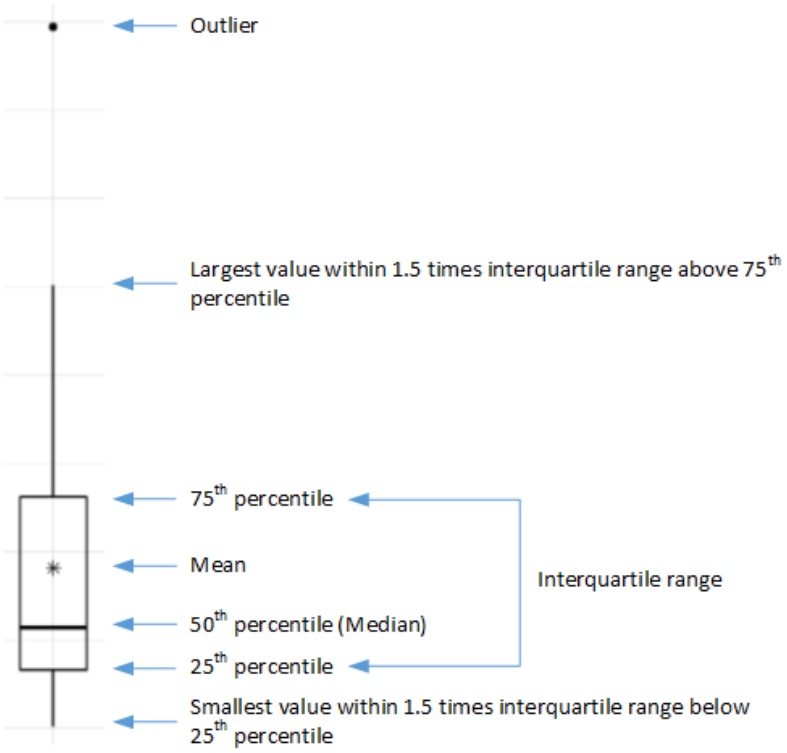
= *Total Third Party Review Time + Total FDA Review Time*

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
BSV	BeanStock Ventures
CMSI	Center for Measurement Standards of Industrial
COLA	COLA, Inc.
GQRS	Global Quality and Regulatory Services
NYSDOH	New York State Department of Health
NIOM	Nordic Institute of Dental Materials
RTS	Regulatory Technology Services, LLC
SGS	SGS North America
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.

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Third Party Performance Data

Initial Third Party Review Time

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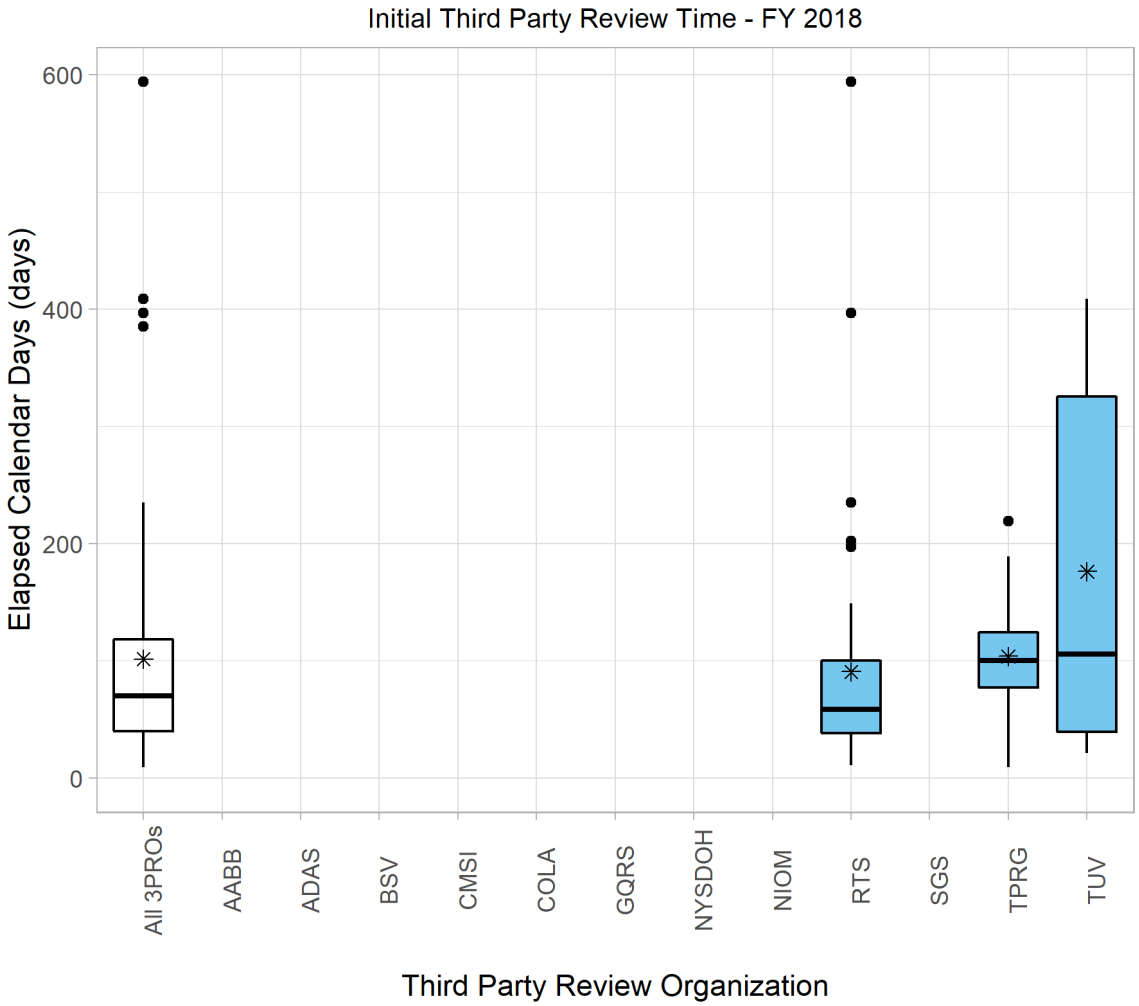

Figure 2

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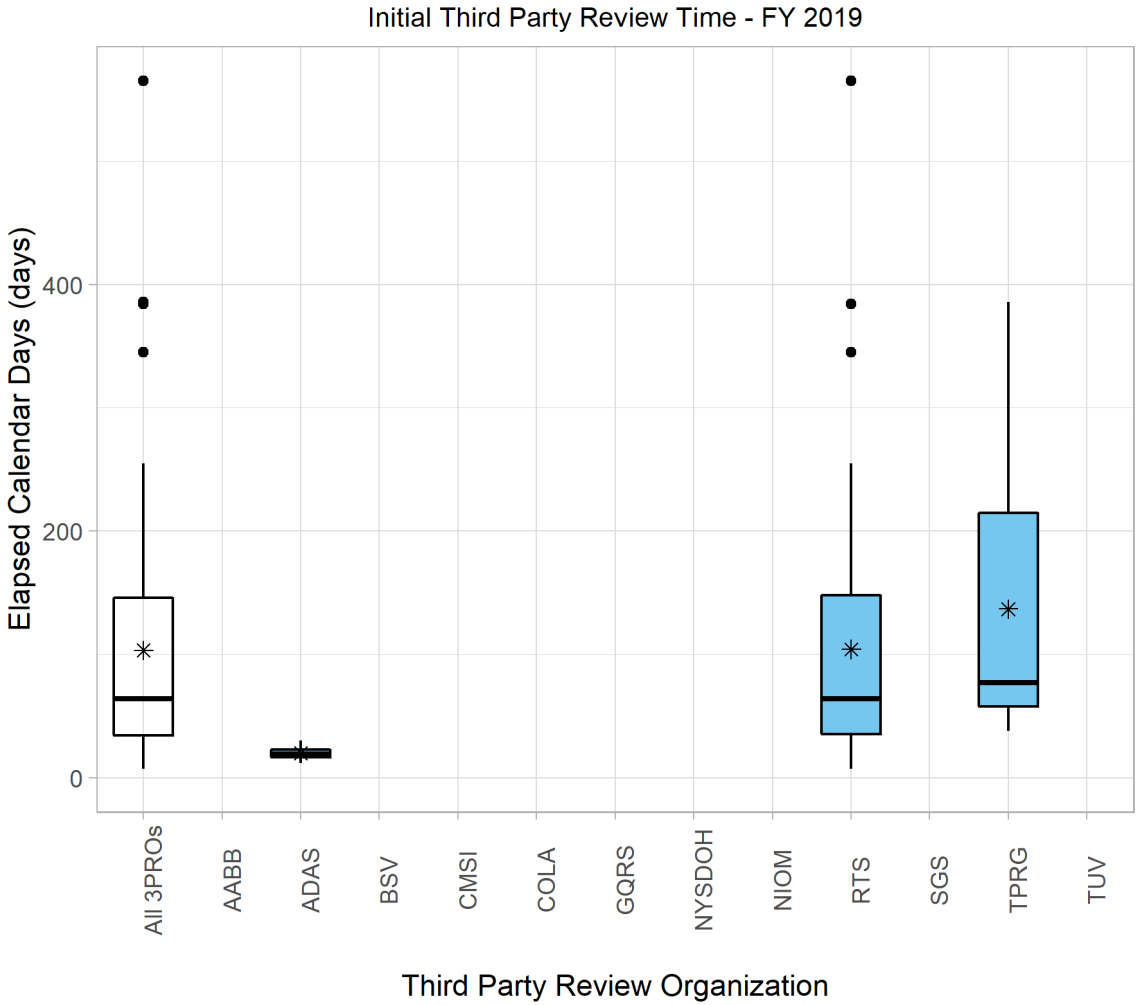

Figure 3

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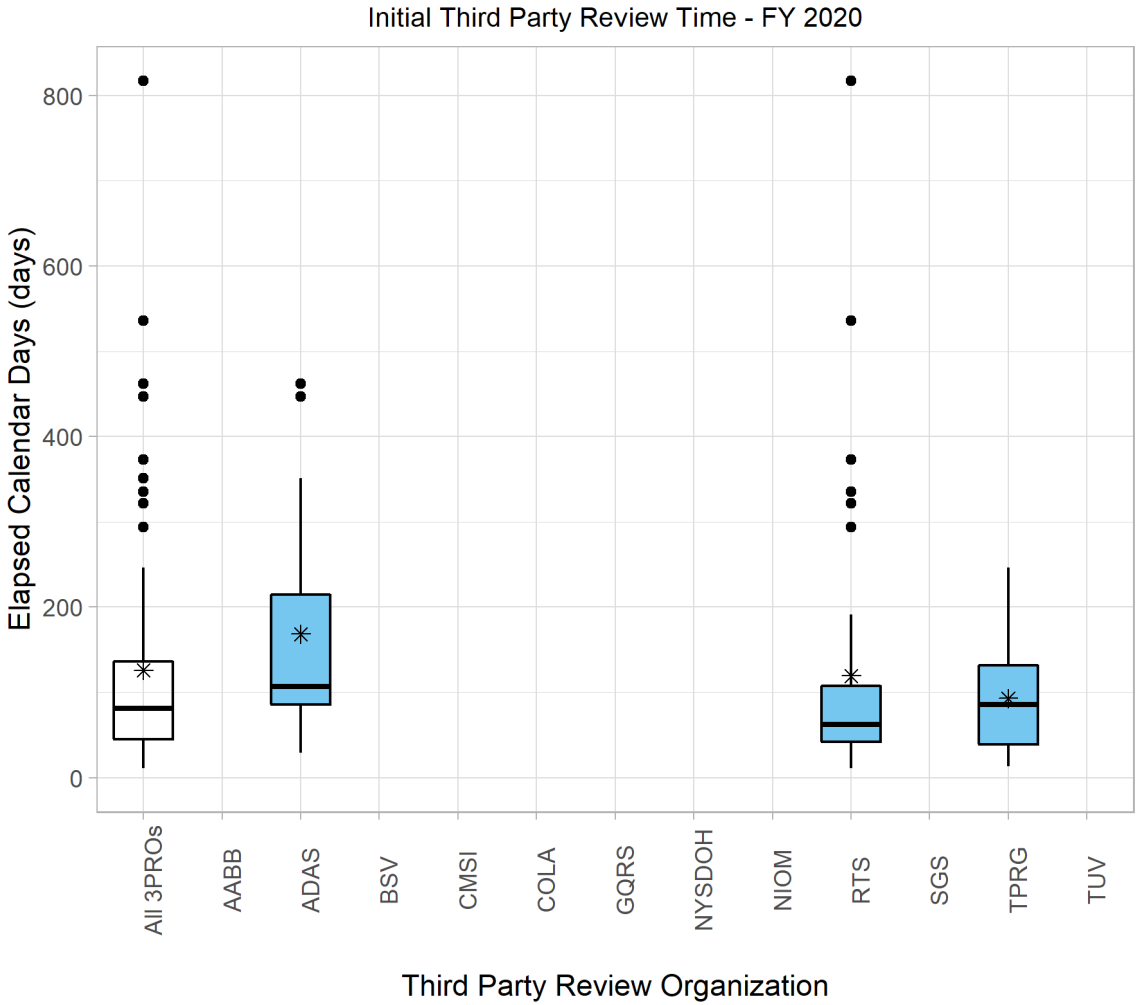

Figure 4

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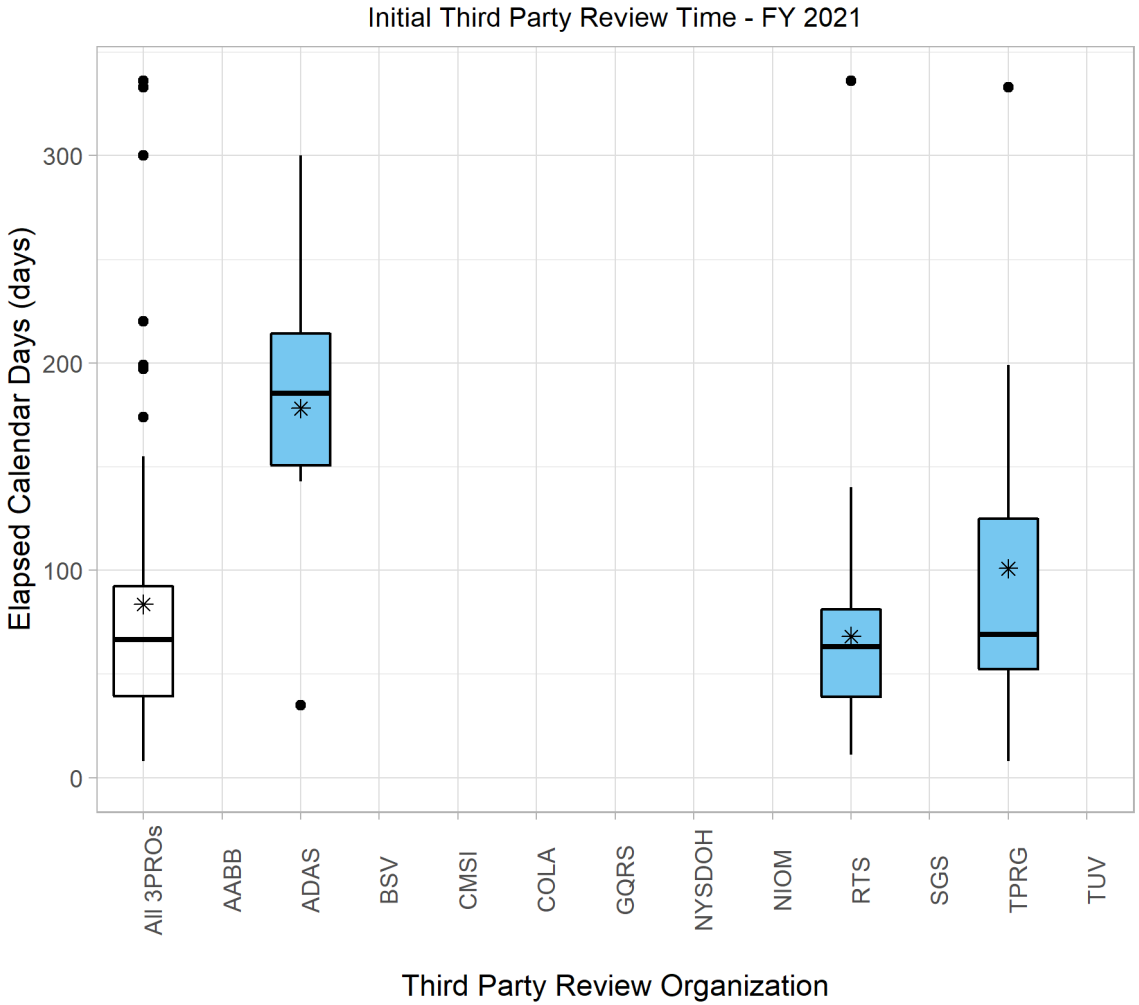

Figure 5

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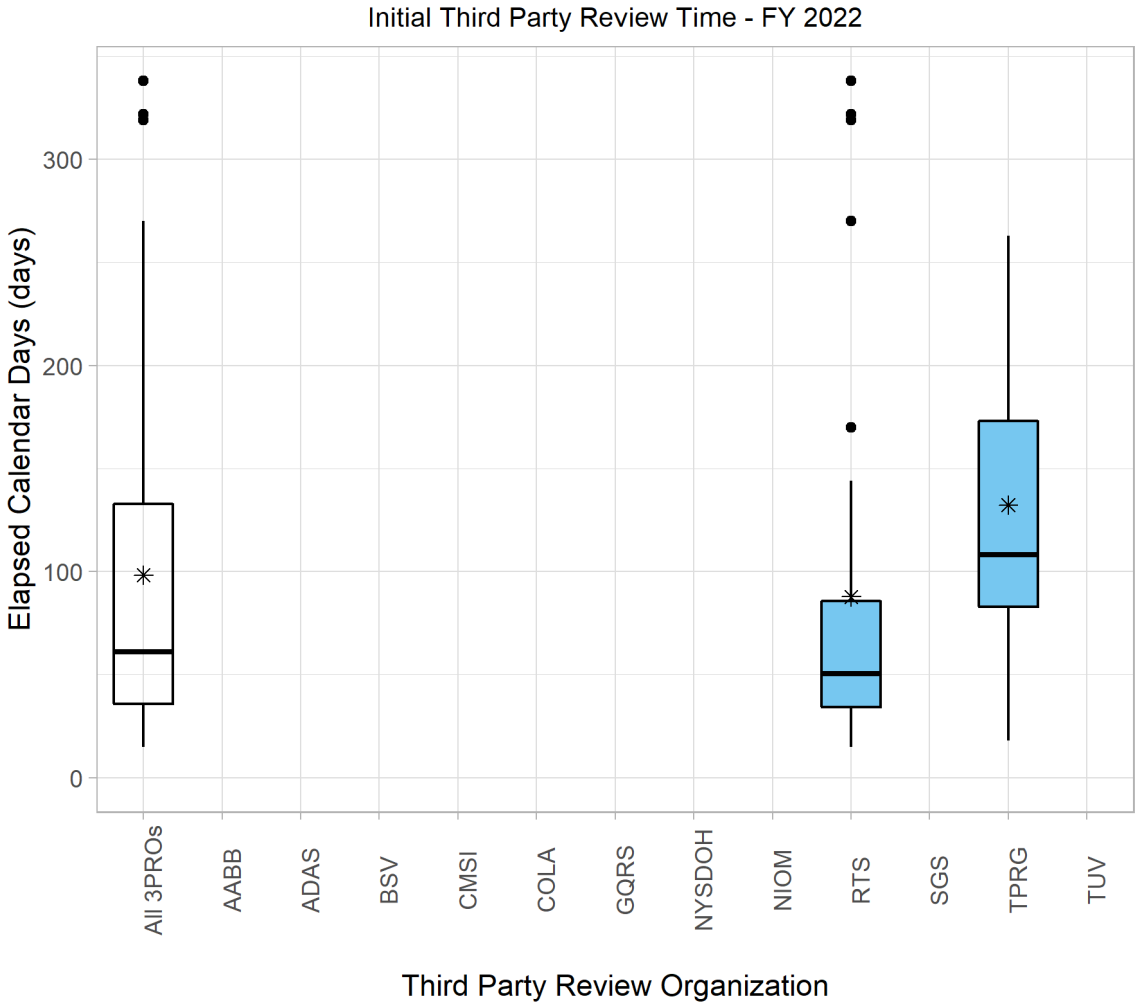

Figure 6

Third Party Hold Time

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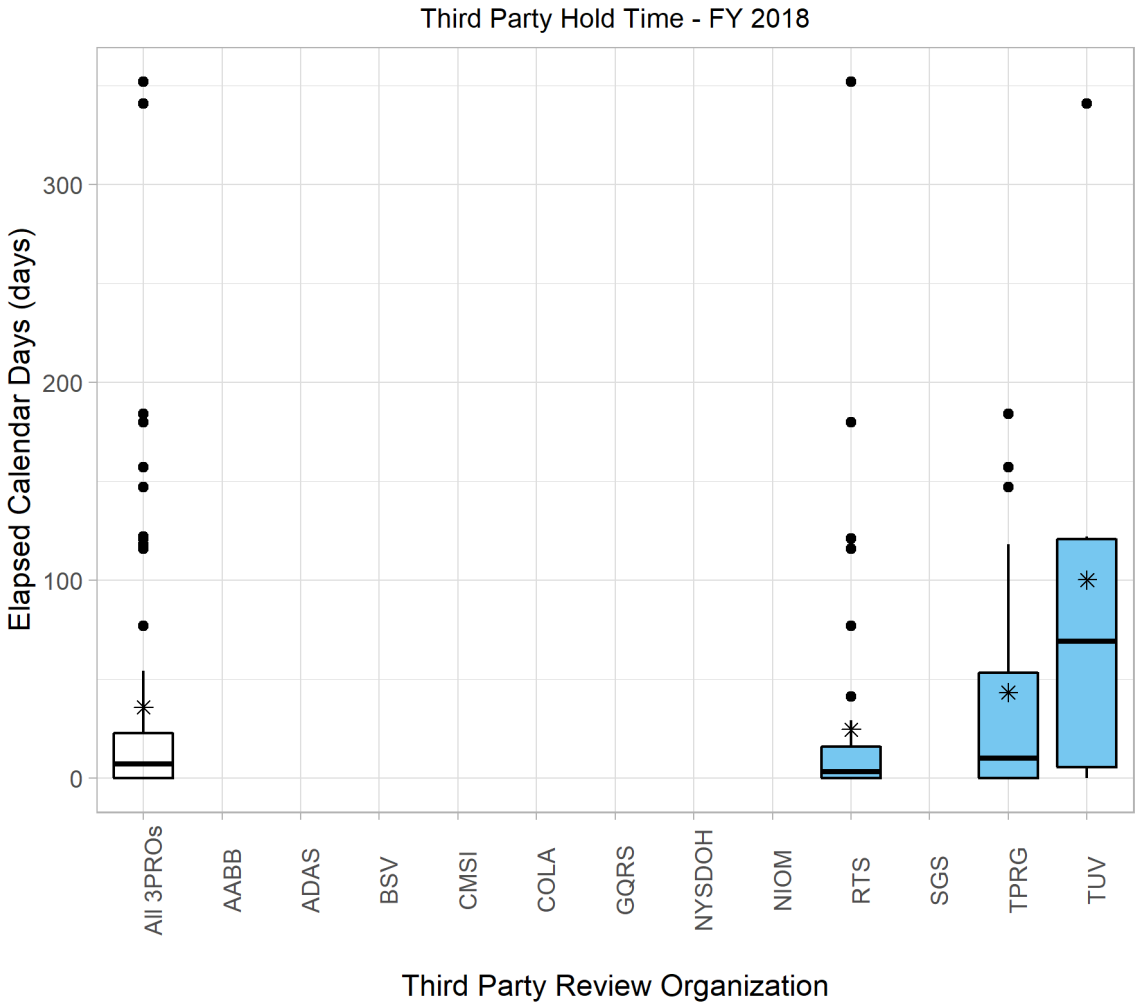

Figure 7

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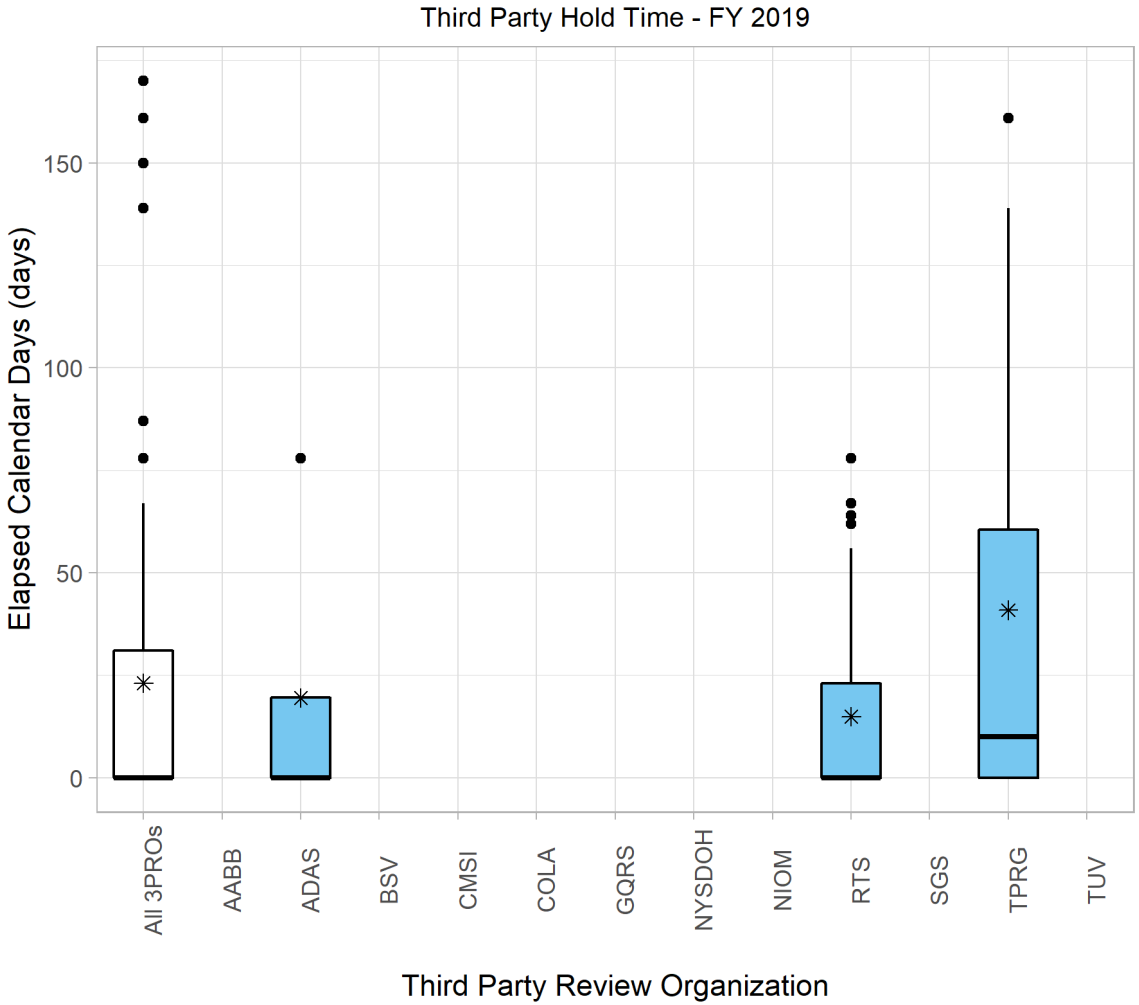

Figure 8

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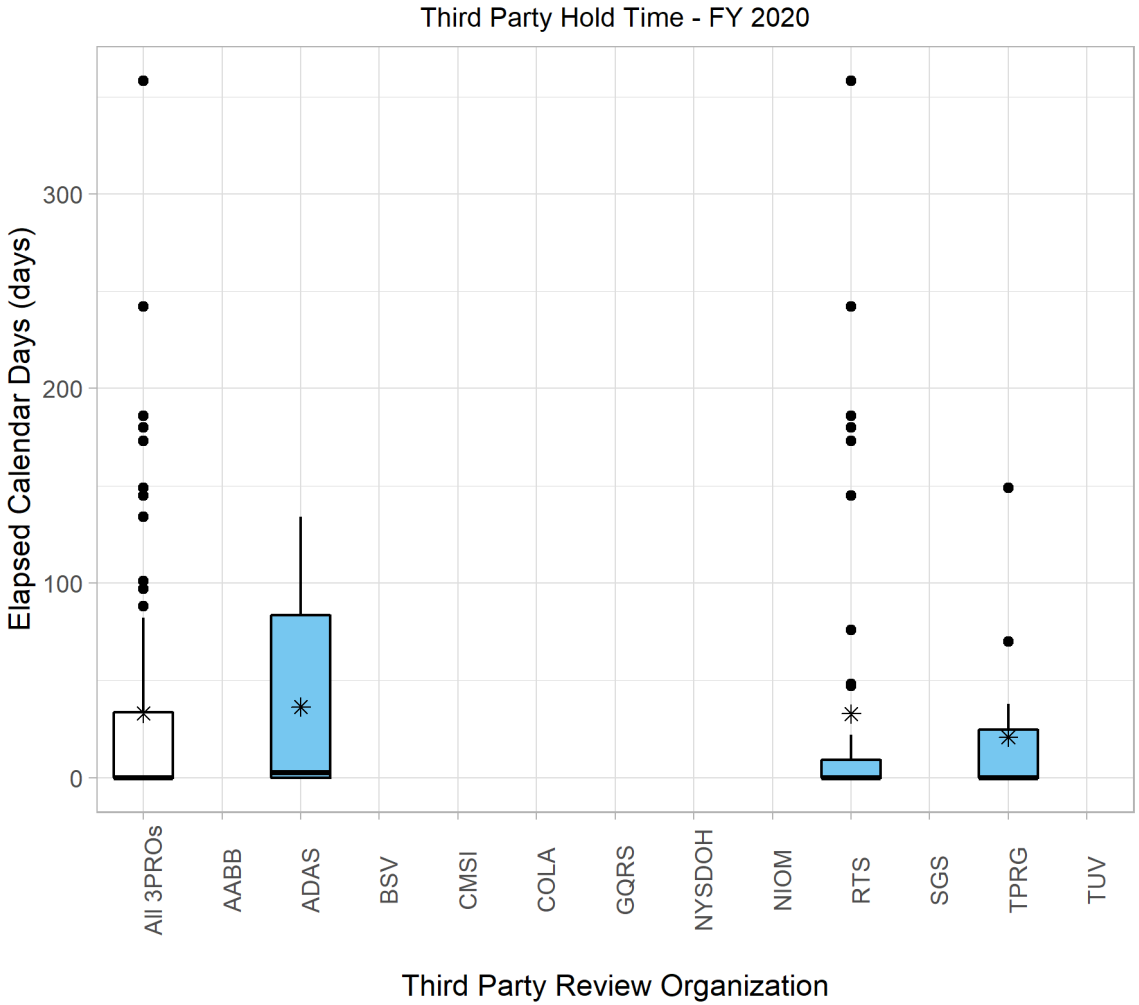

Figure 9

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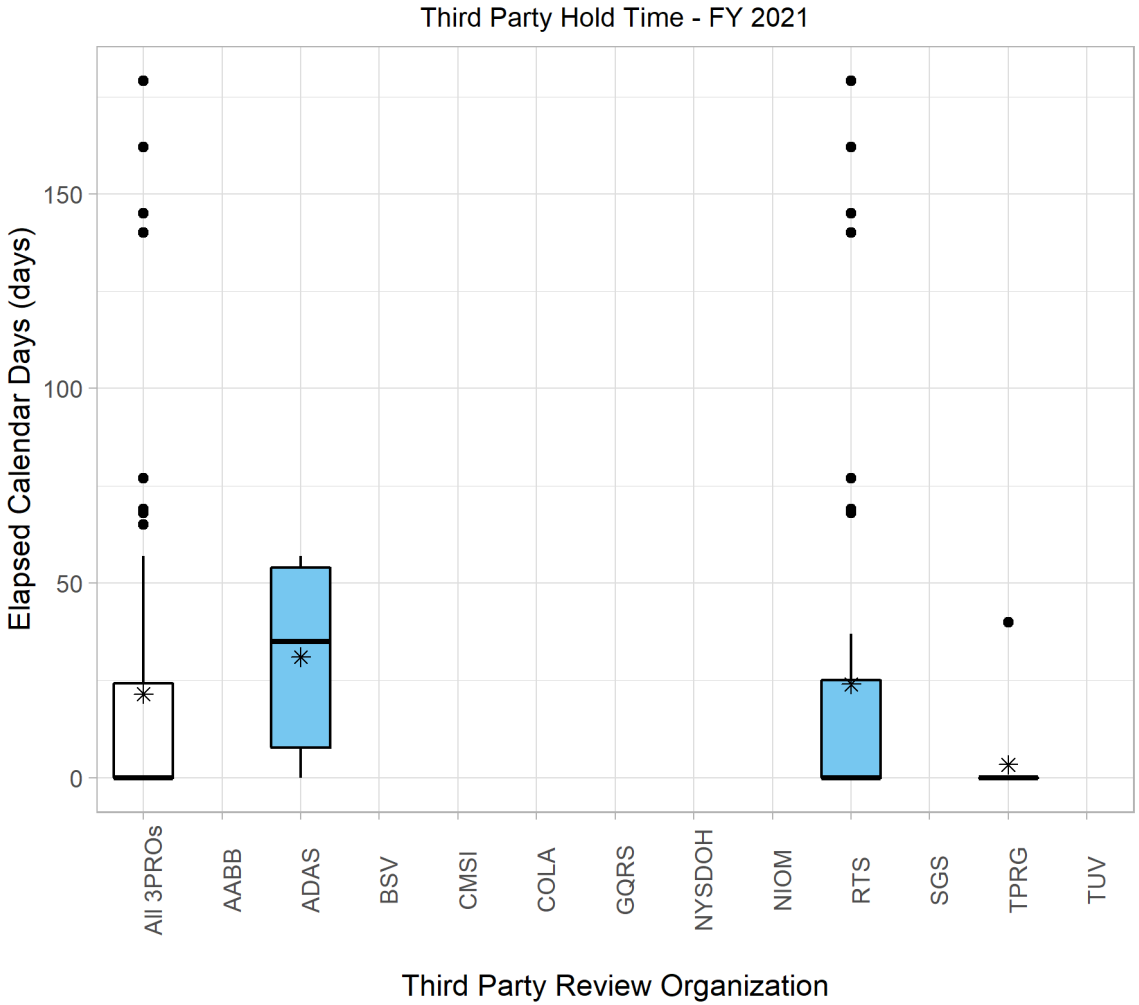

Figure 10

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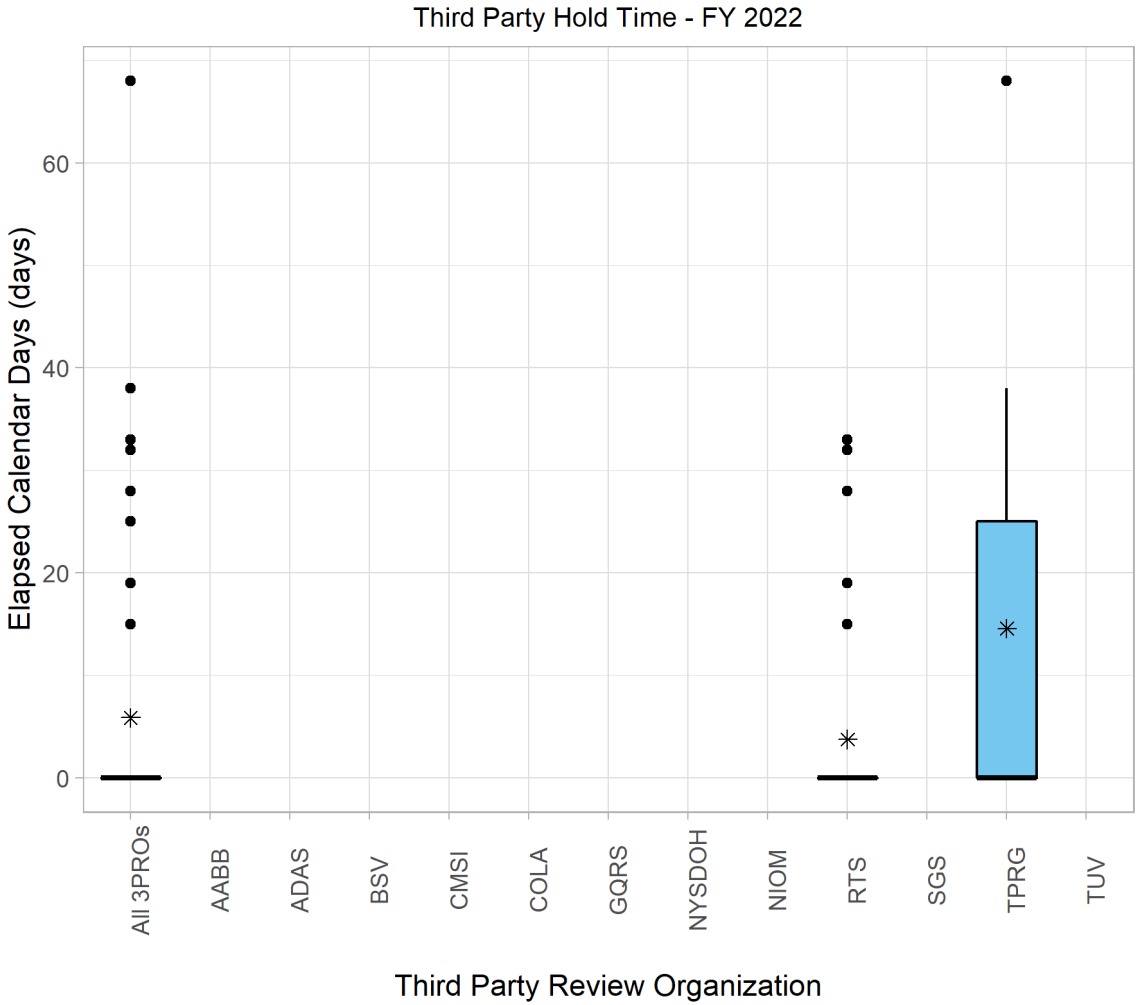

Figure 11

Total Third Party Review Time

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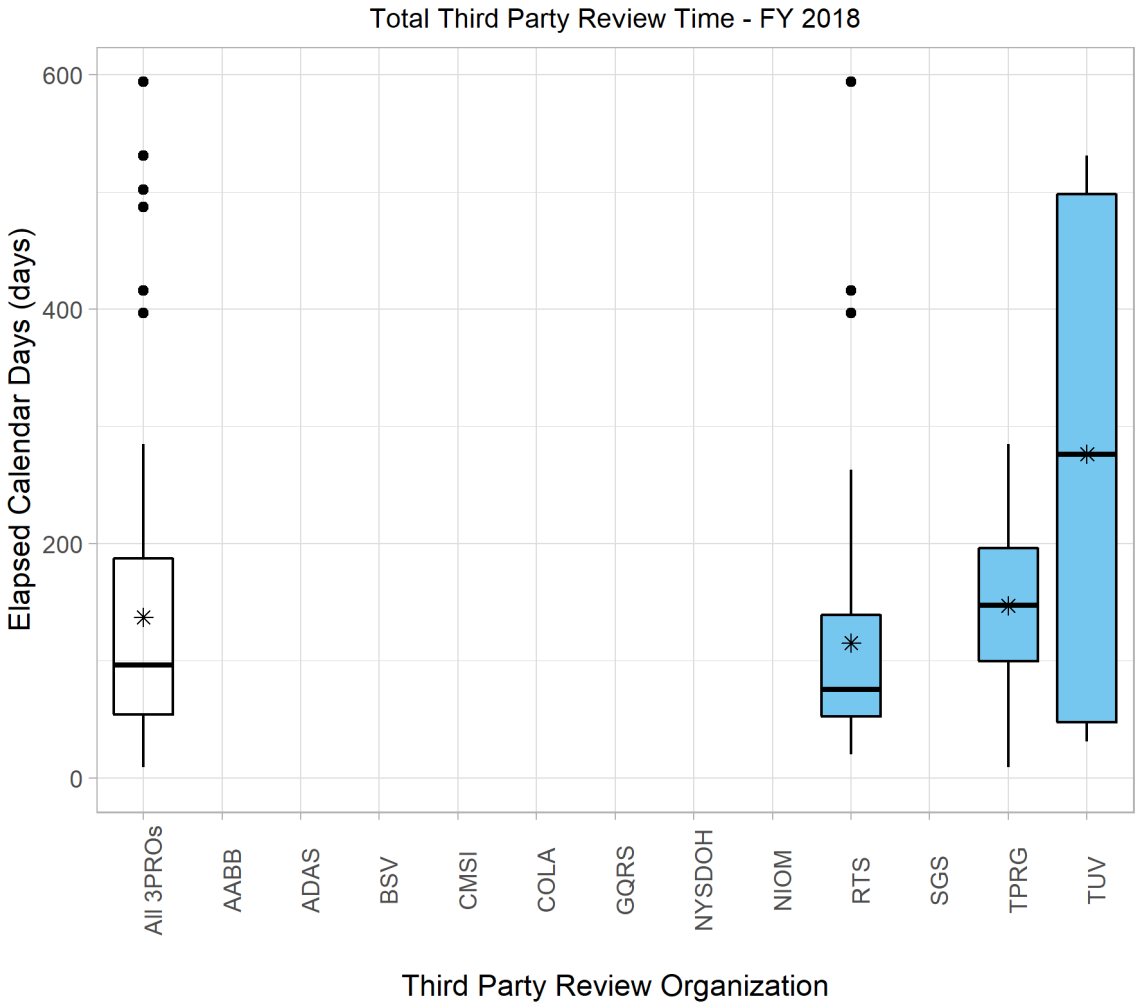

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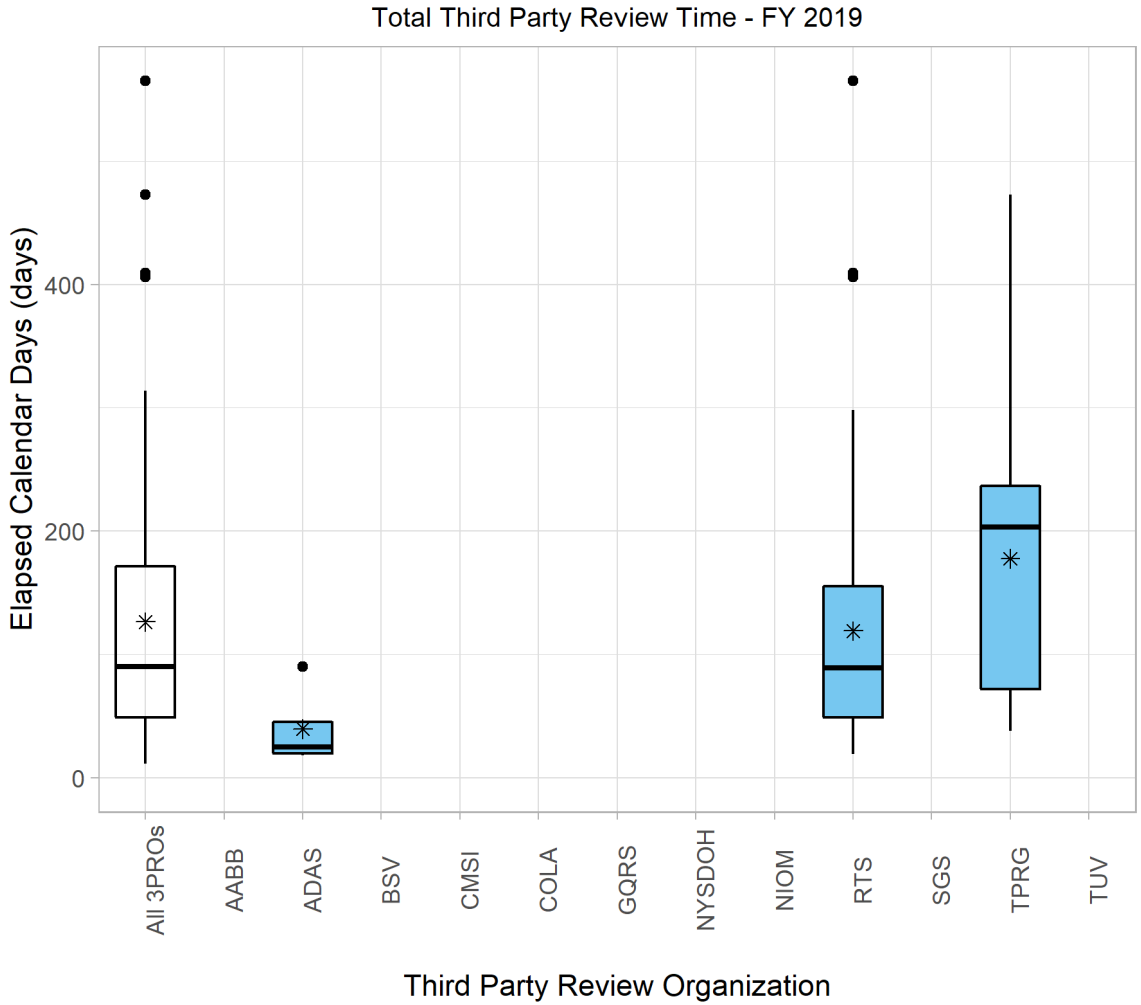

Figure 13

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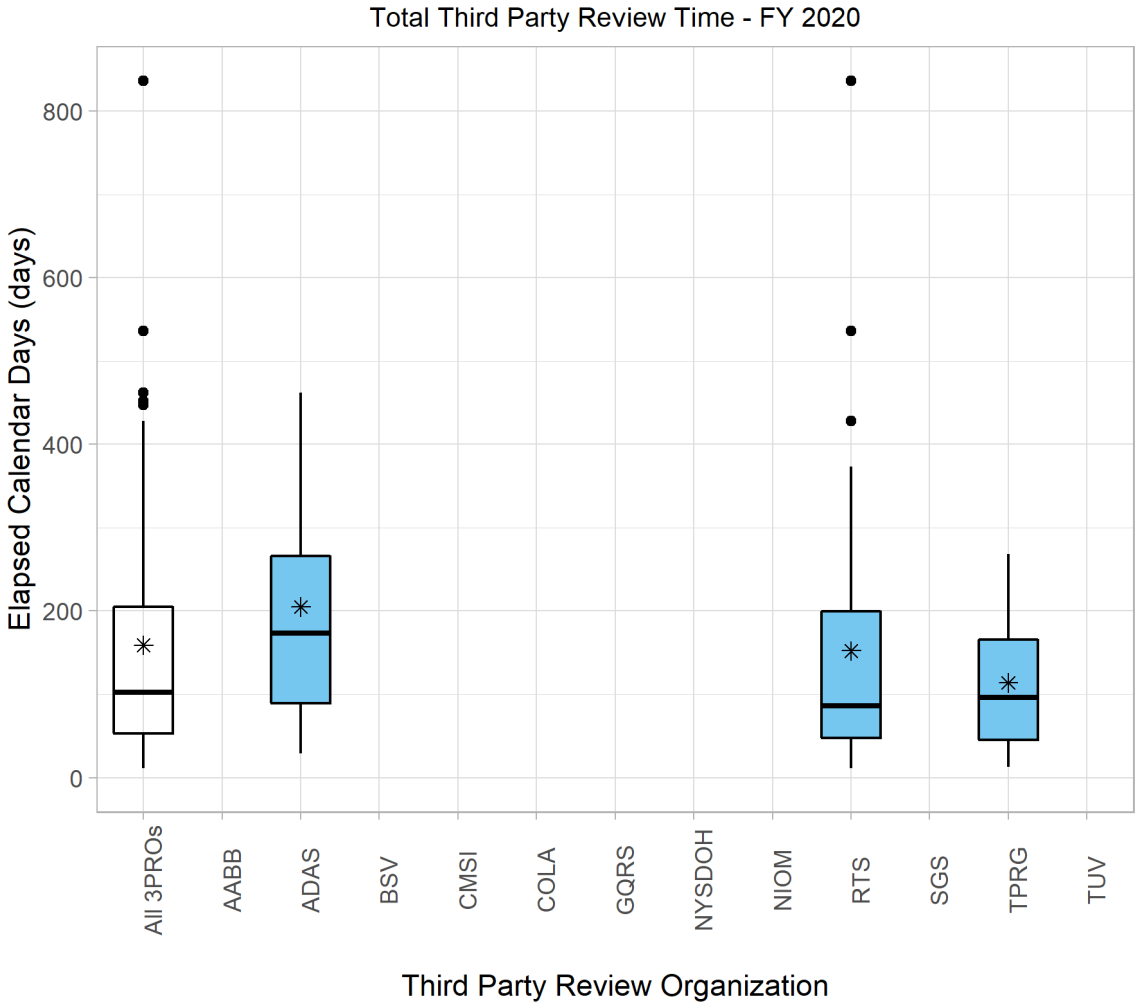

Figure 14

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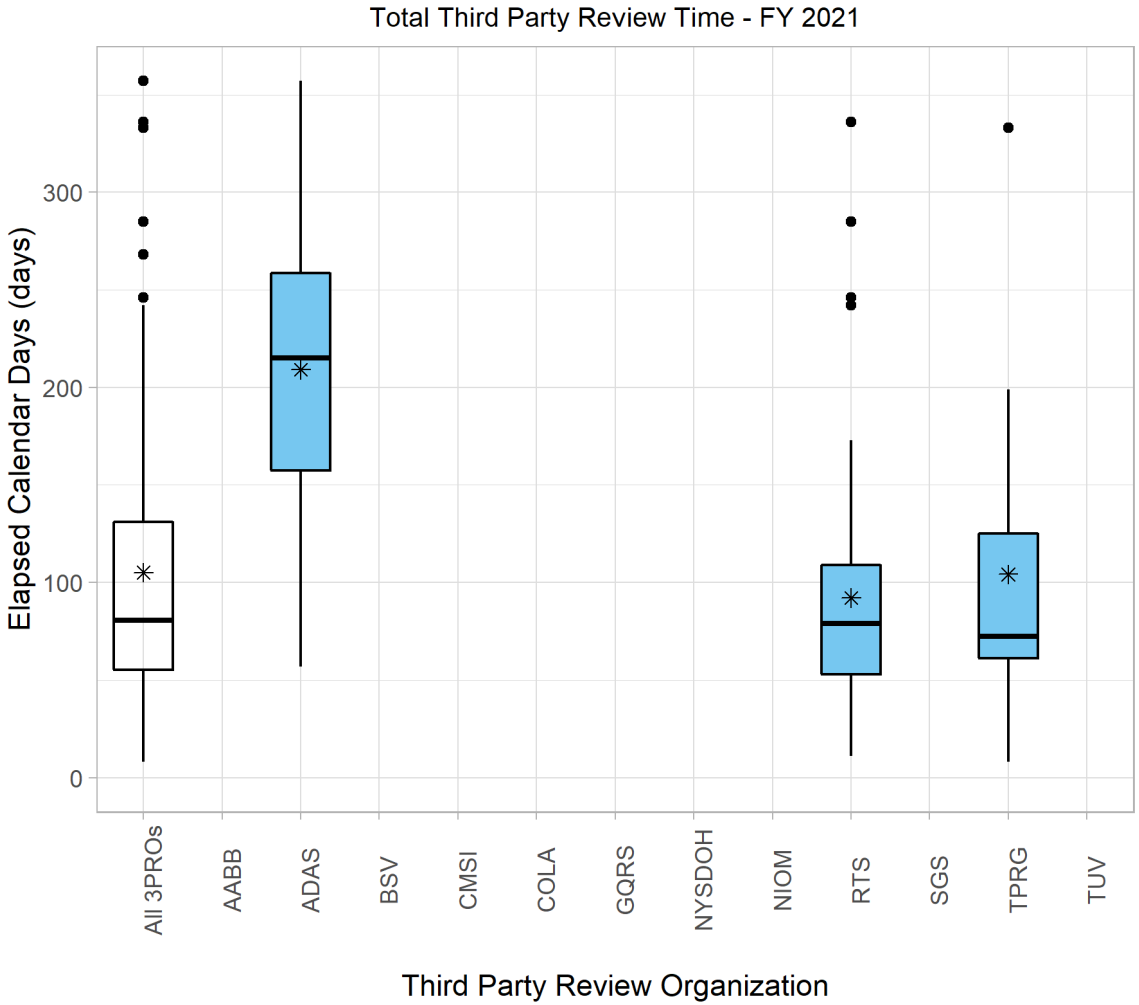

Figure 15

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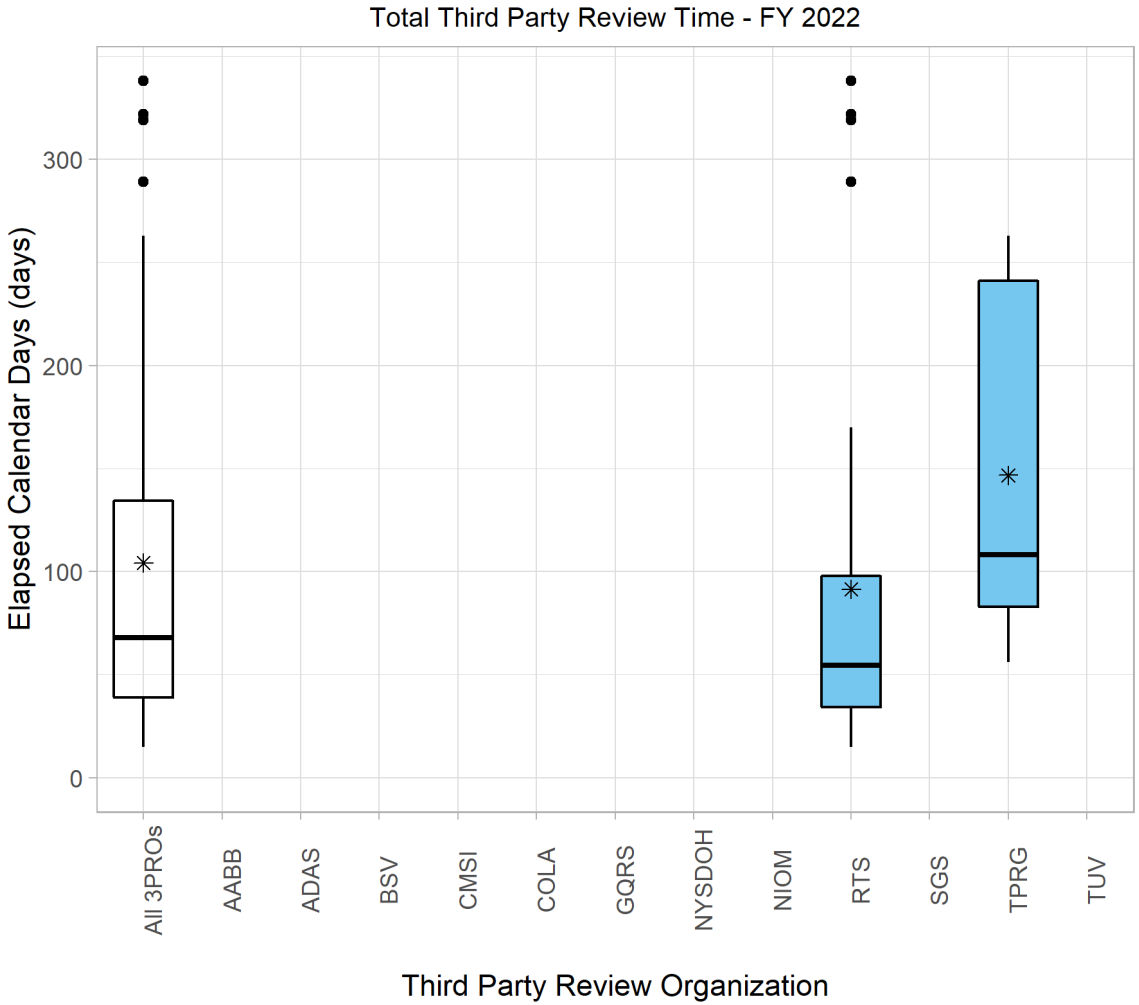

Figure 16

Total FDA Review Time

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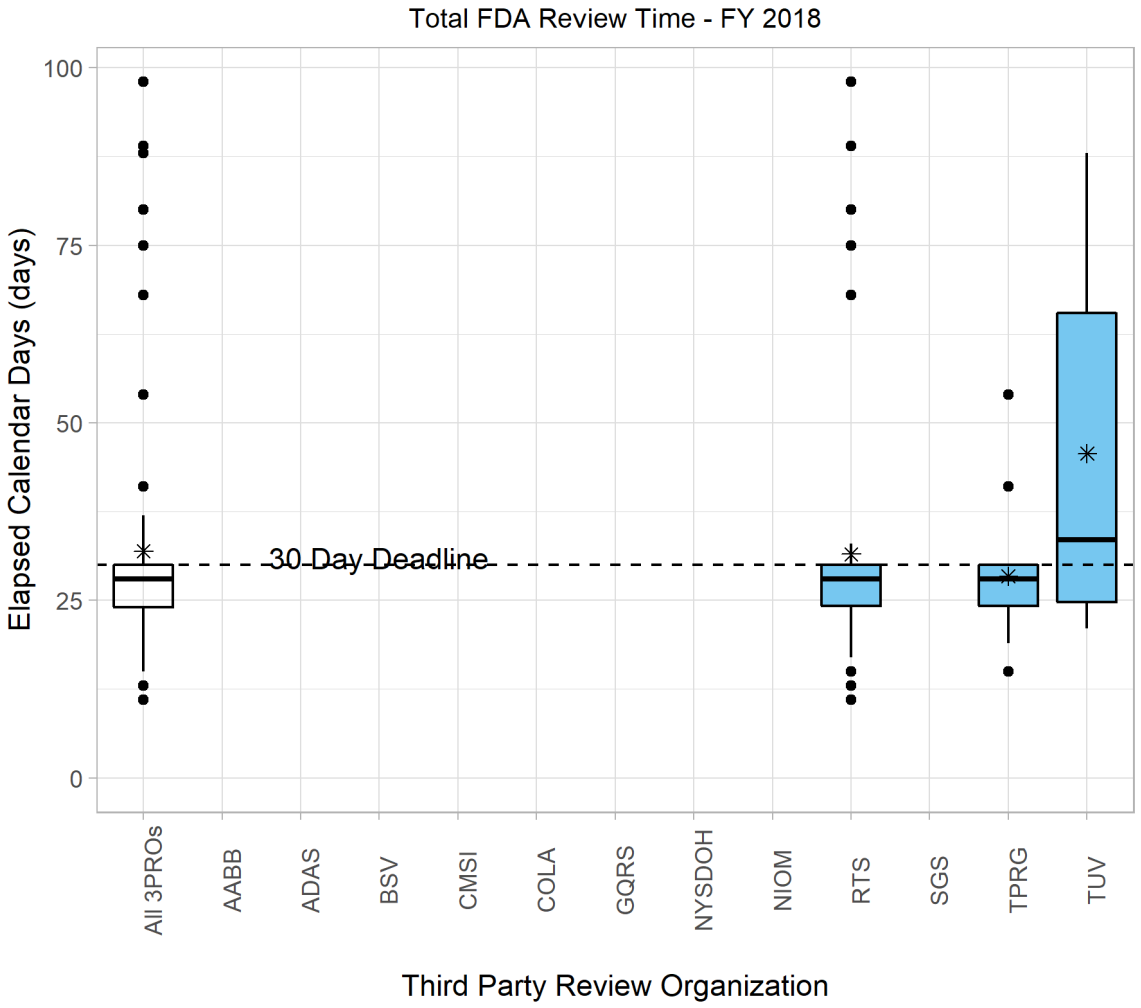

Figure 17

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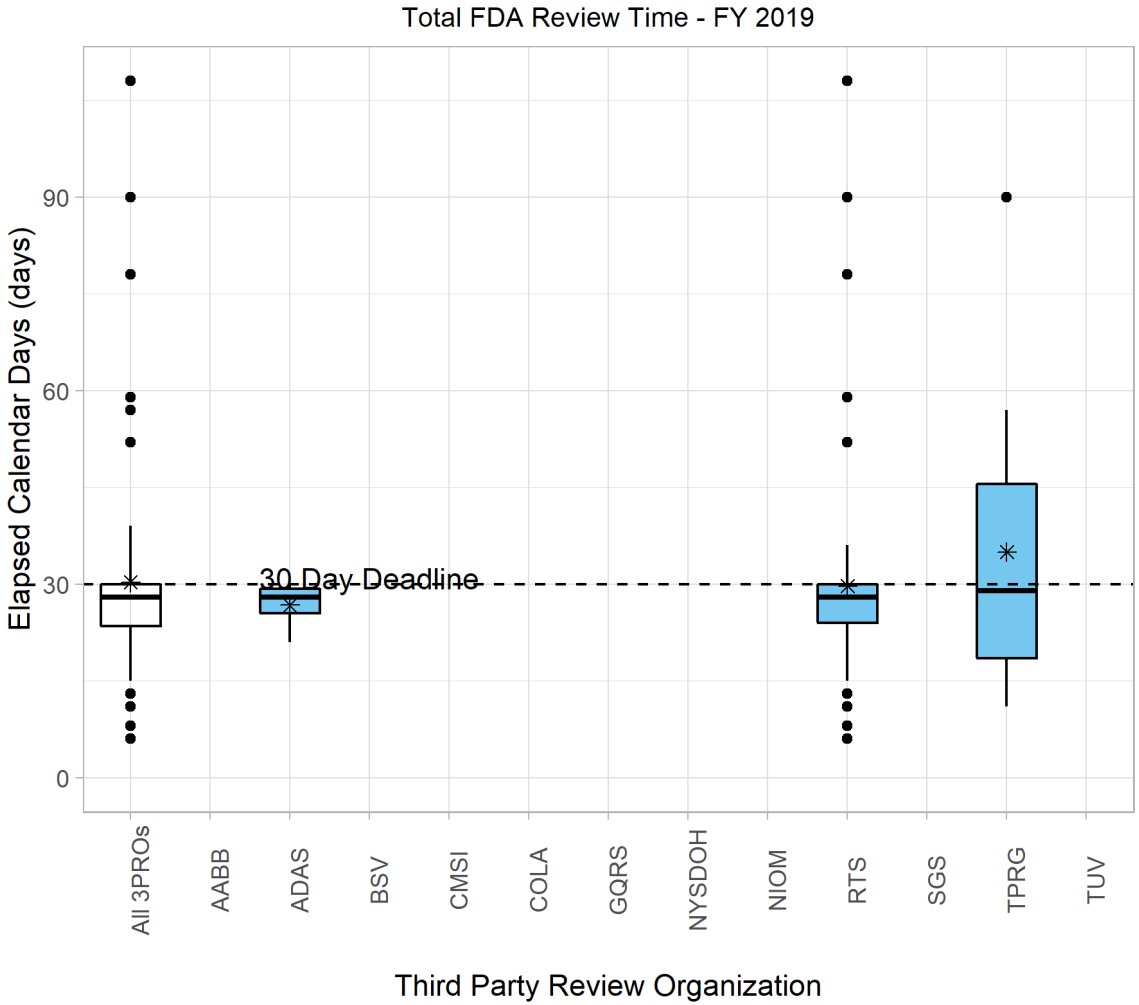

Figure 18

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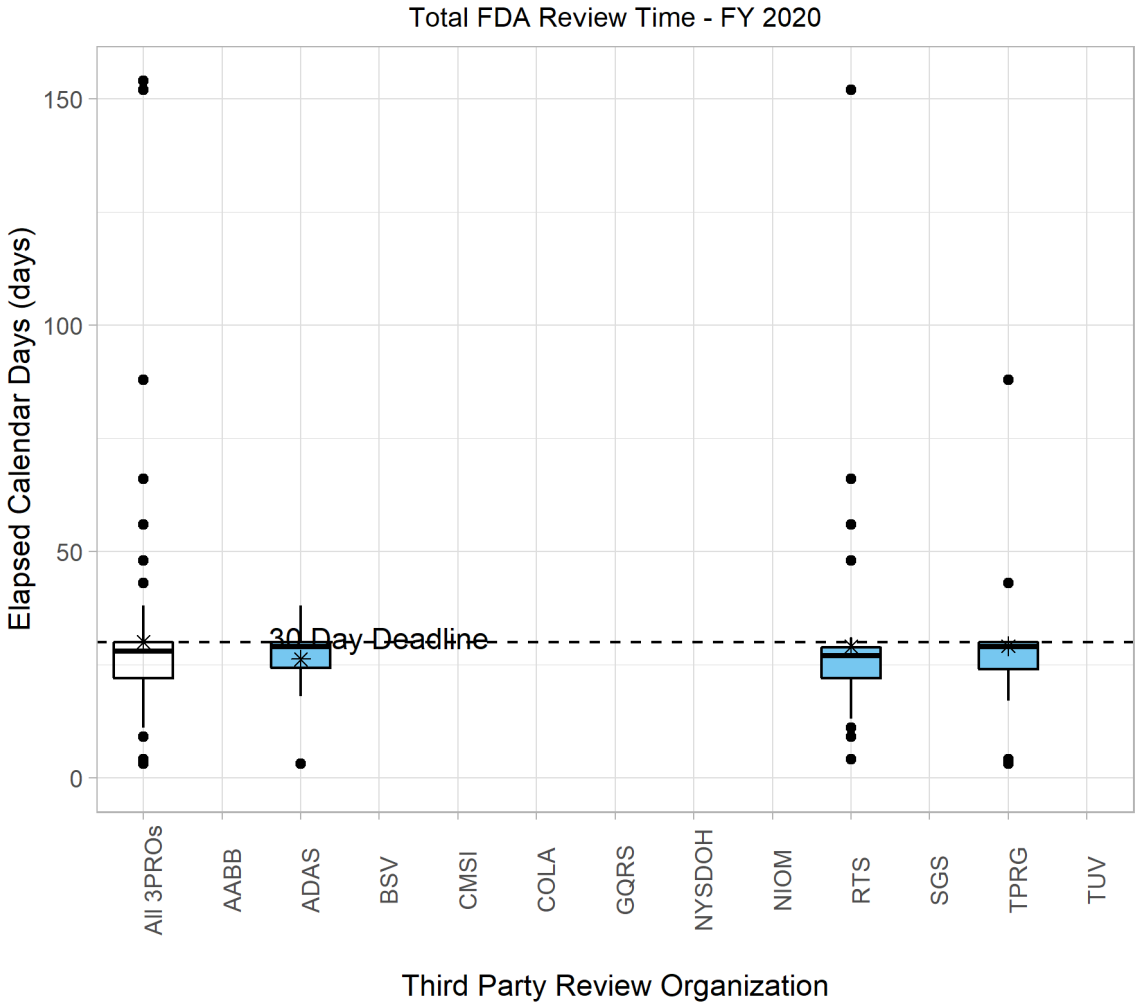

Figure 19

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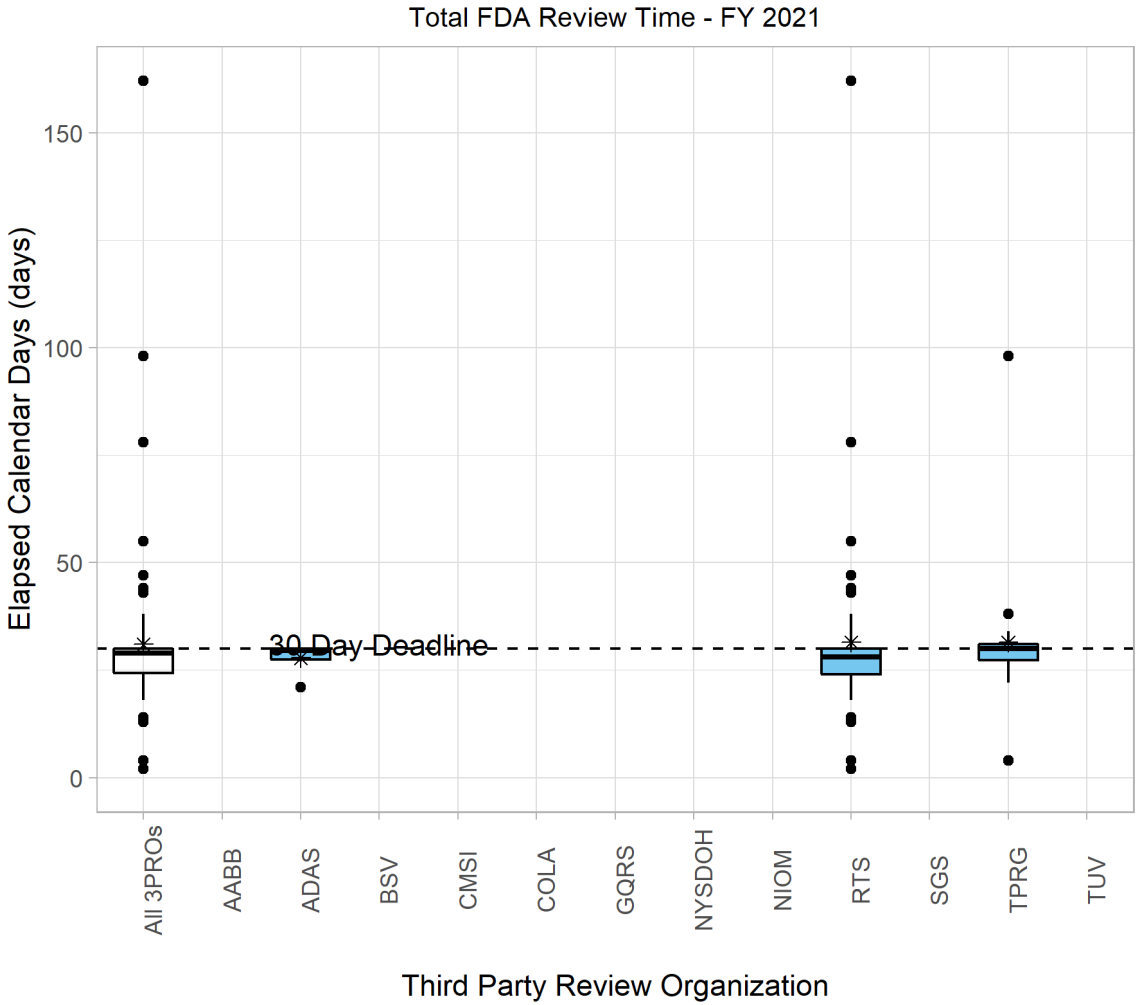

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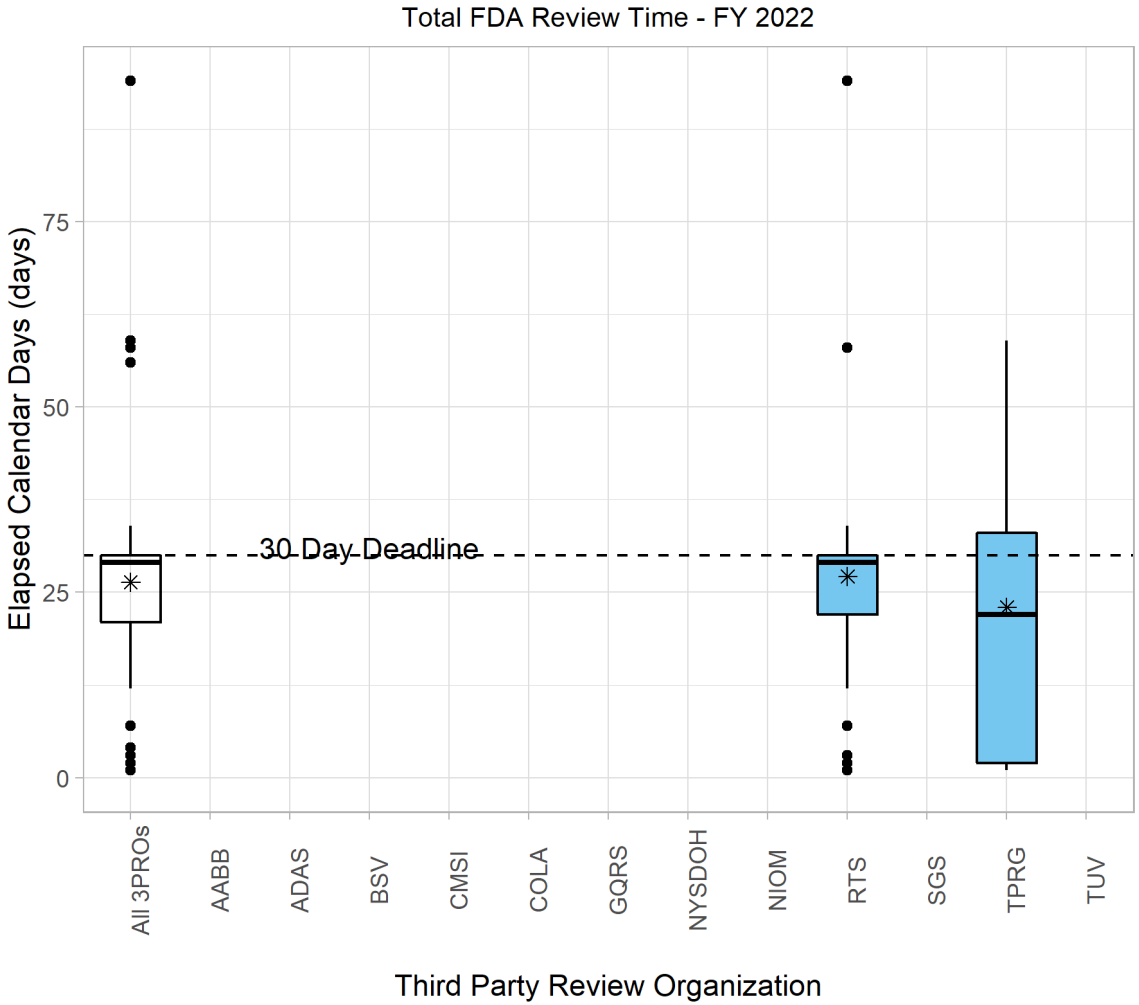

Figure 21

Total Time to Decision from FDA Receipt

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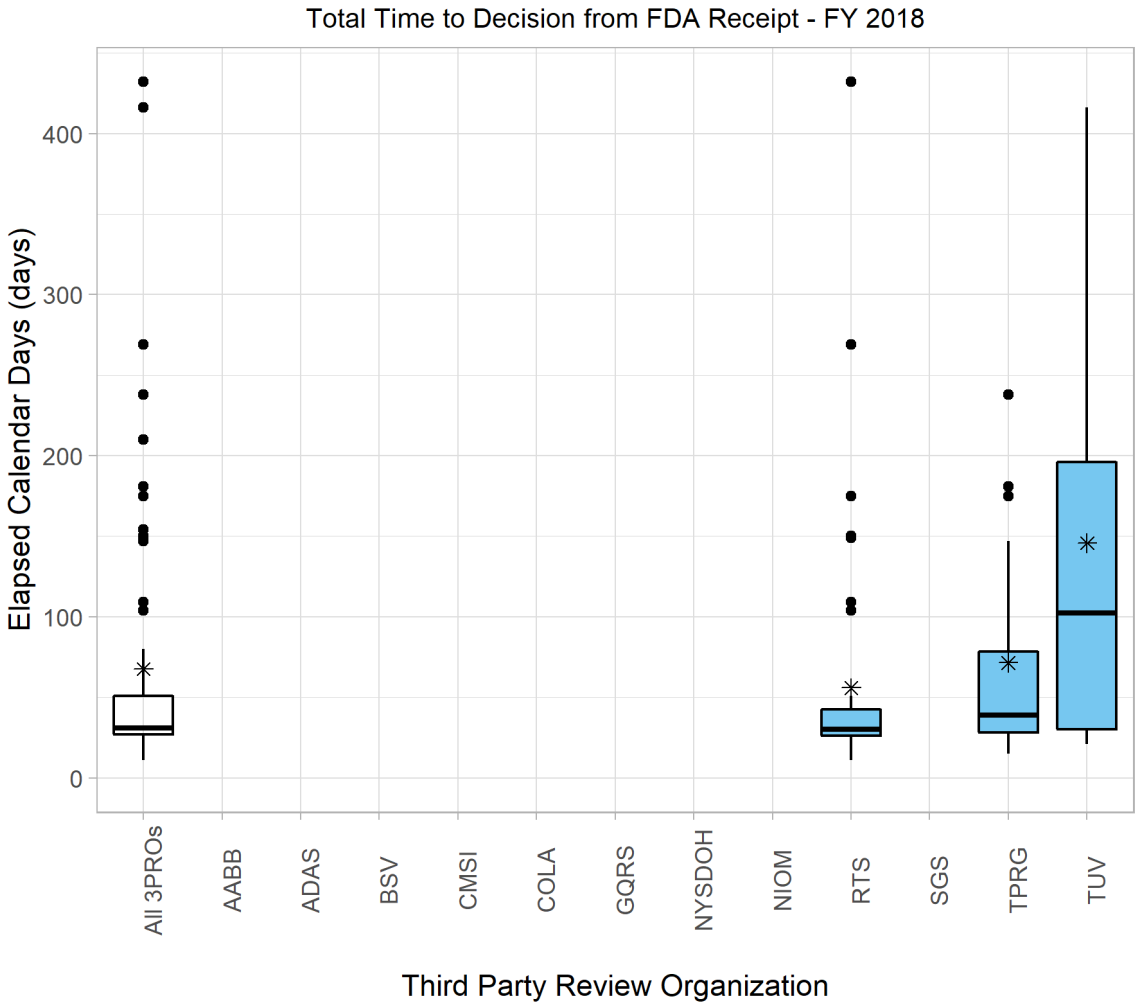

Figure 22

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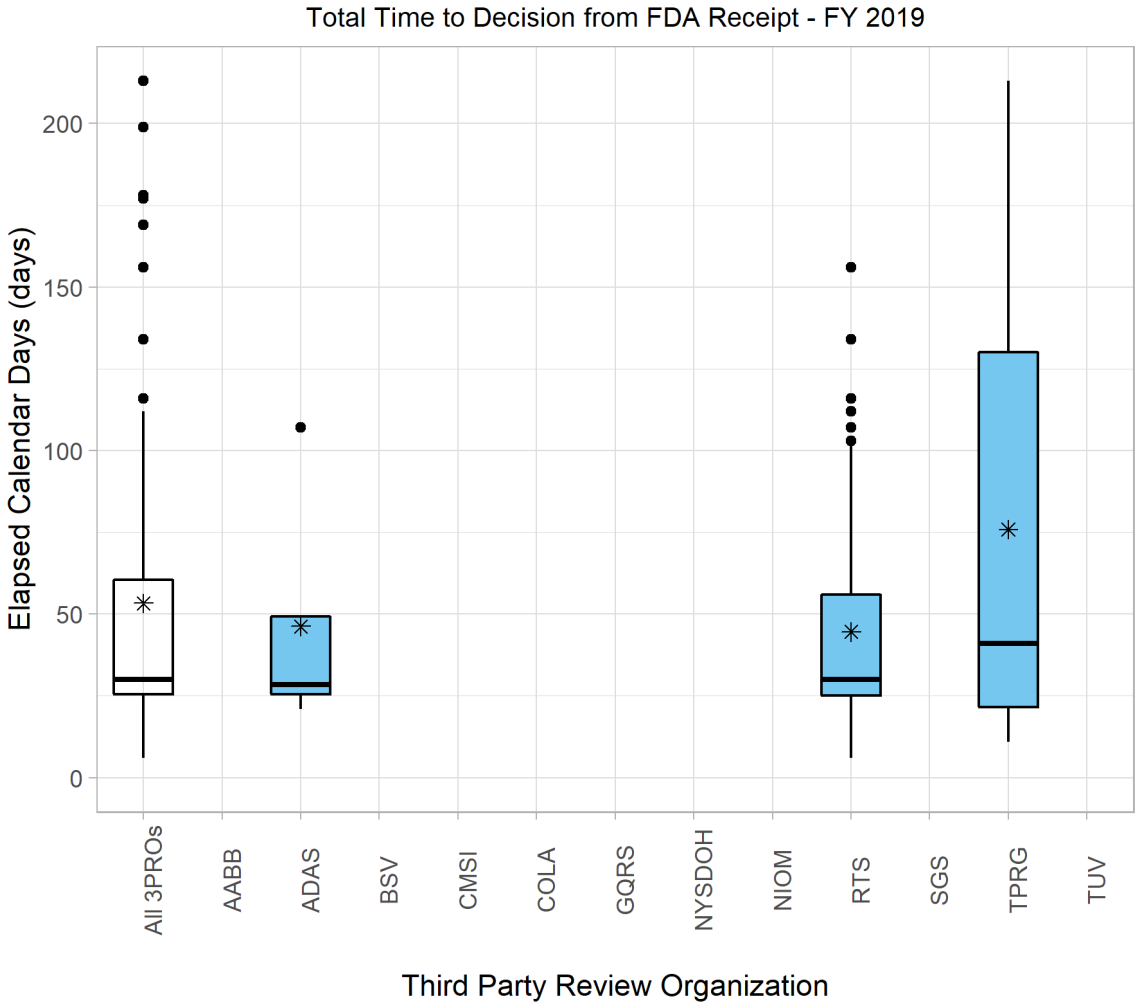

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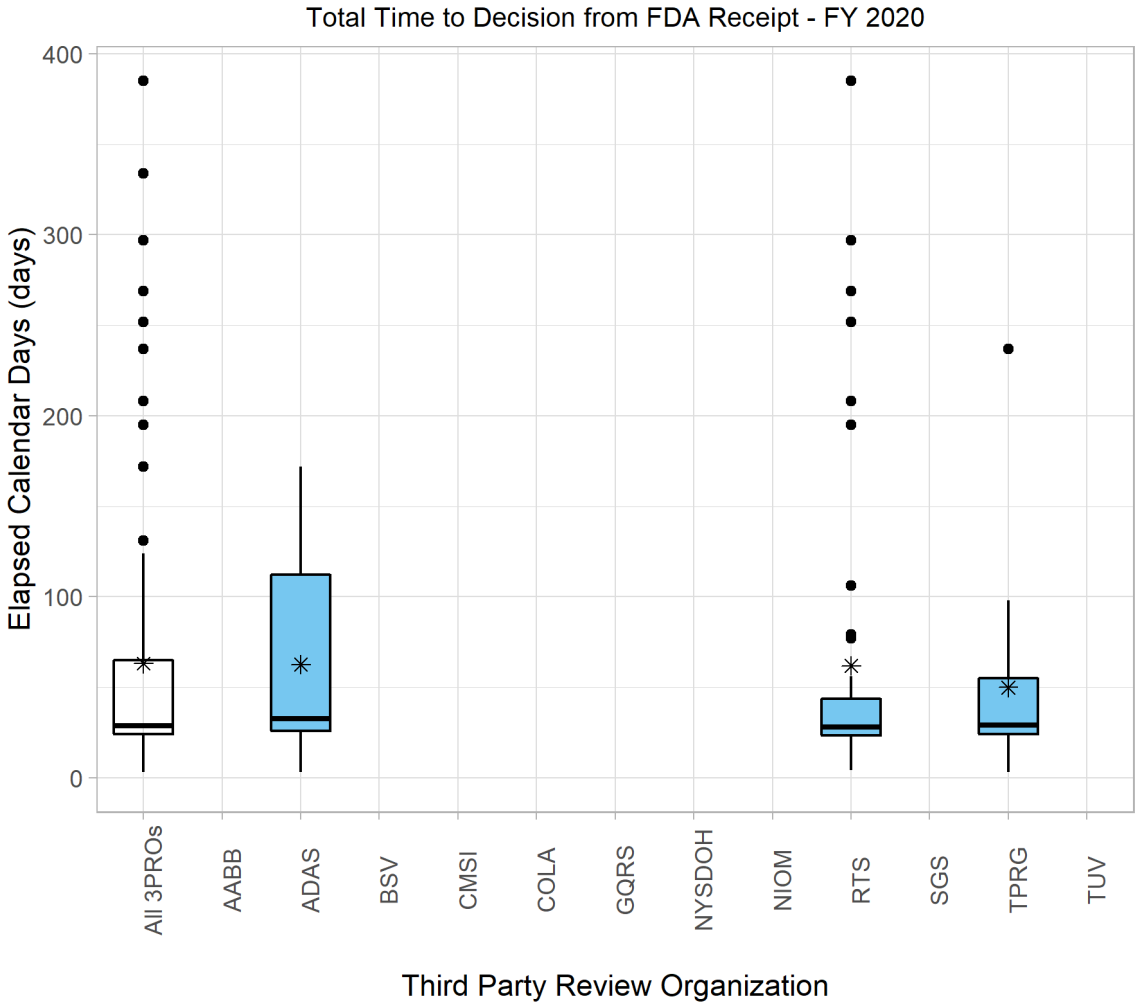

Figure 24

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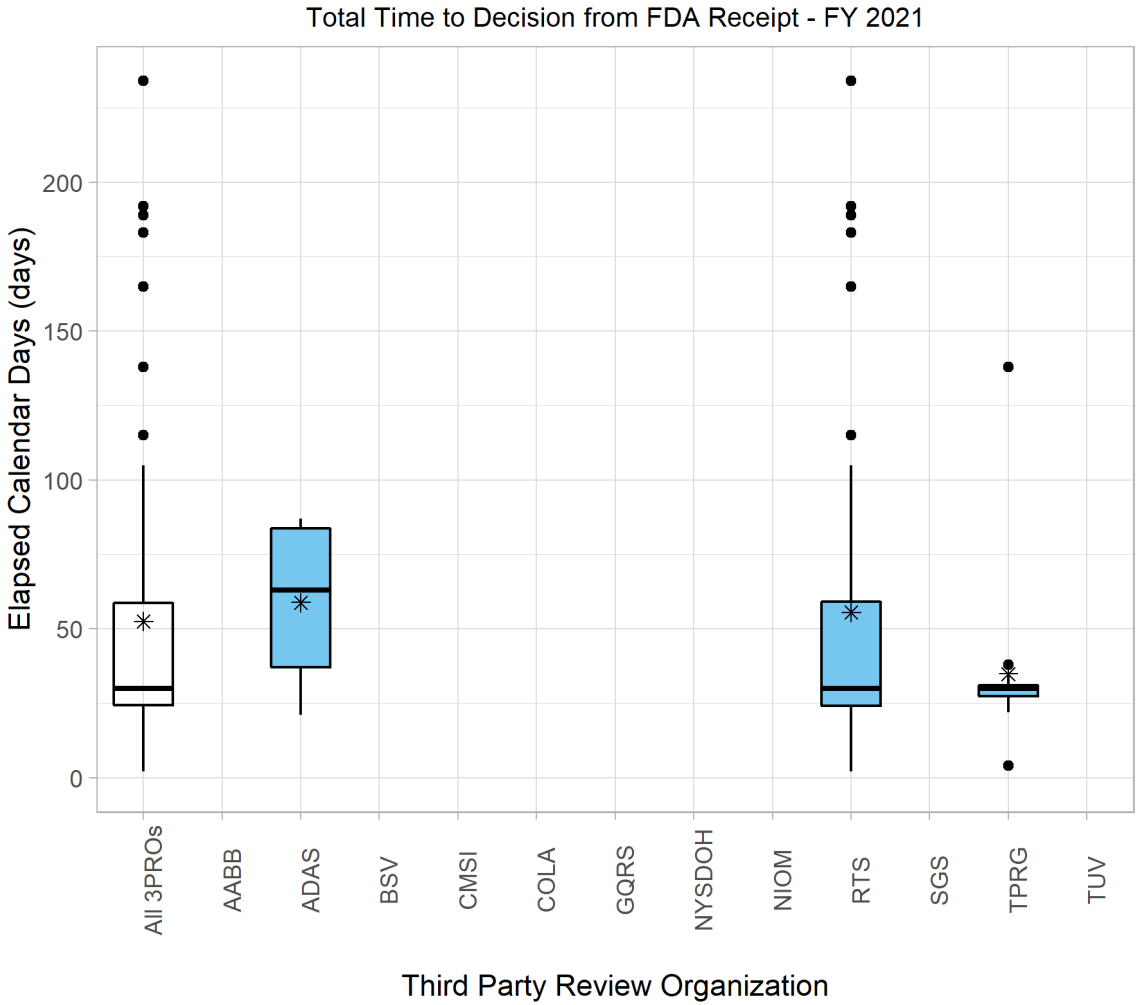

Figure 25

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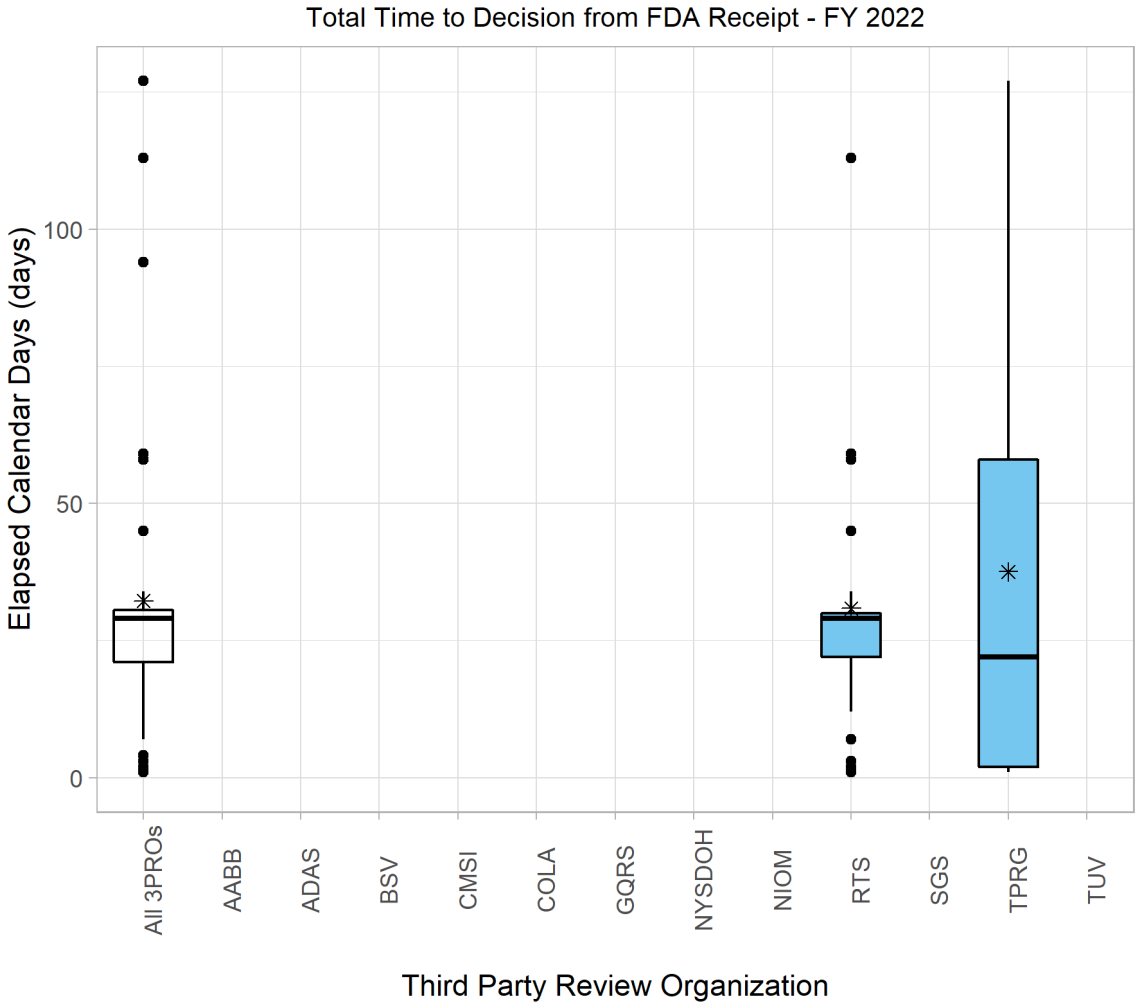

Figure 26

Total Time to Decision from Third Party Receipt

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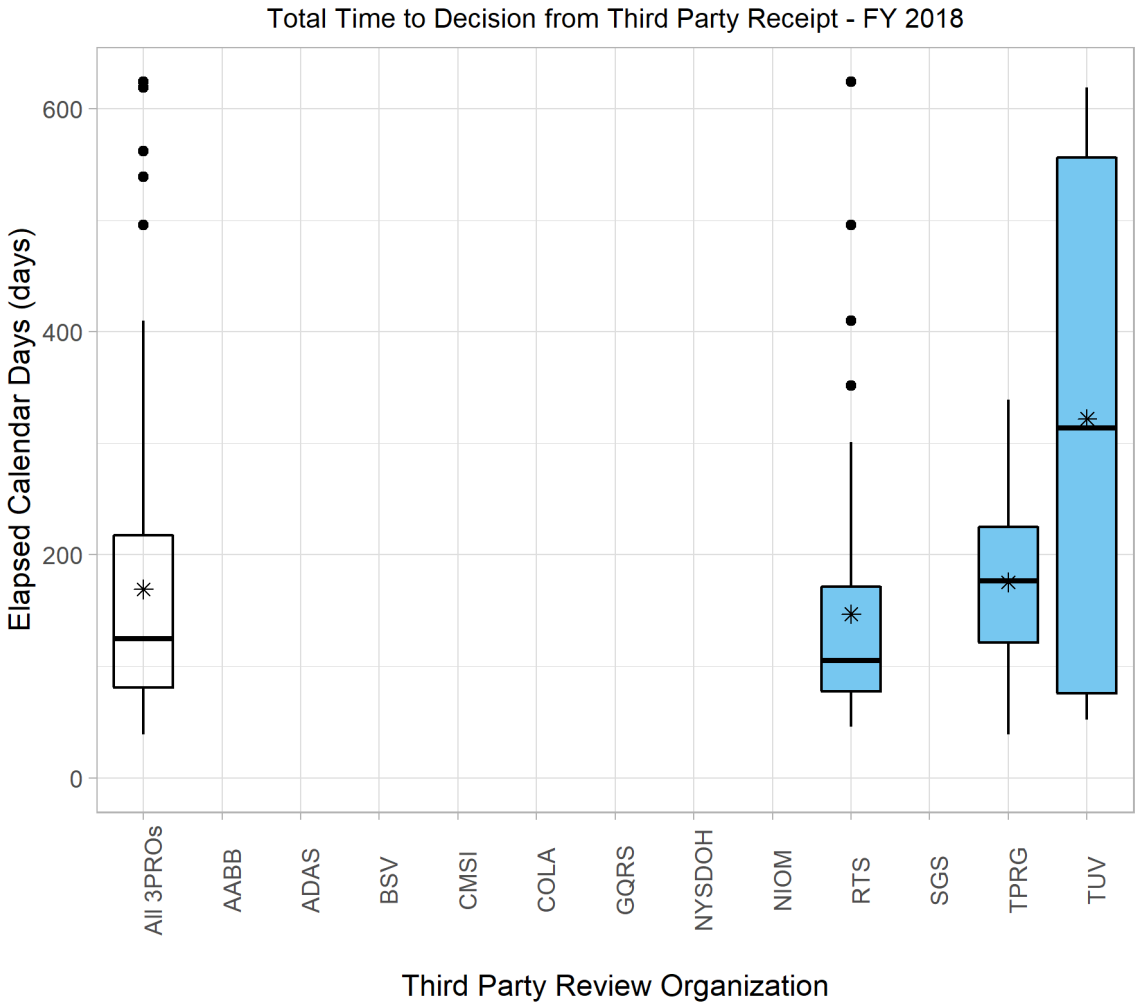

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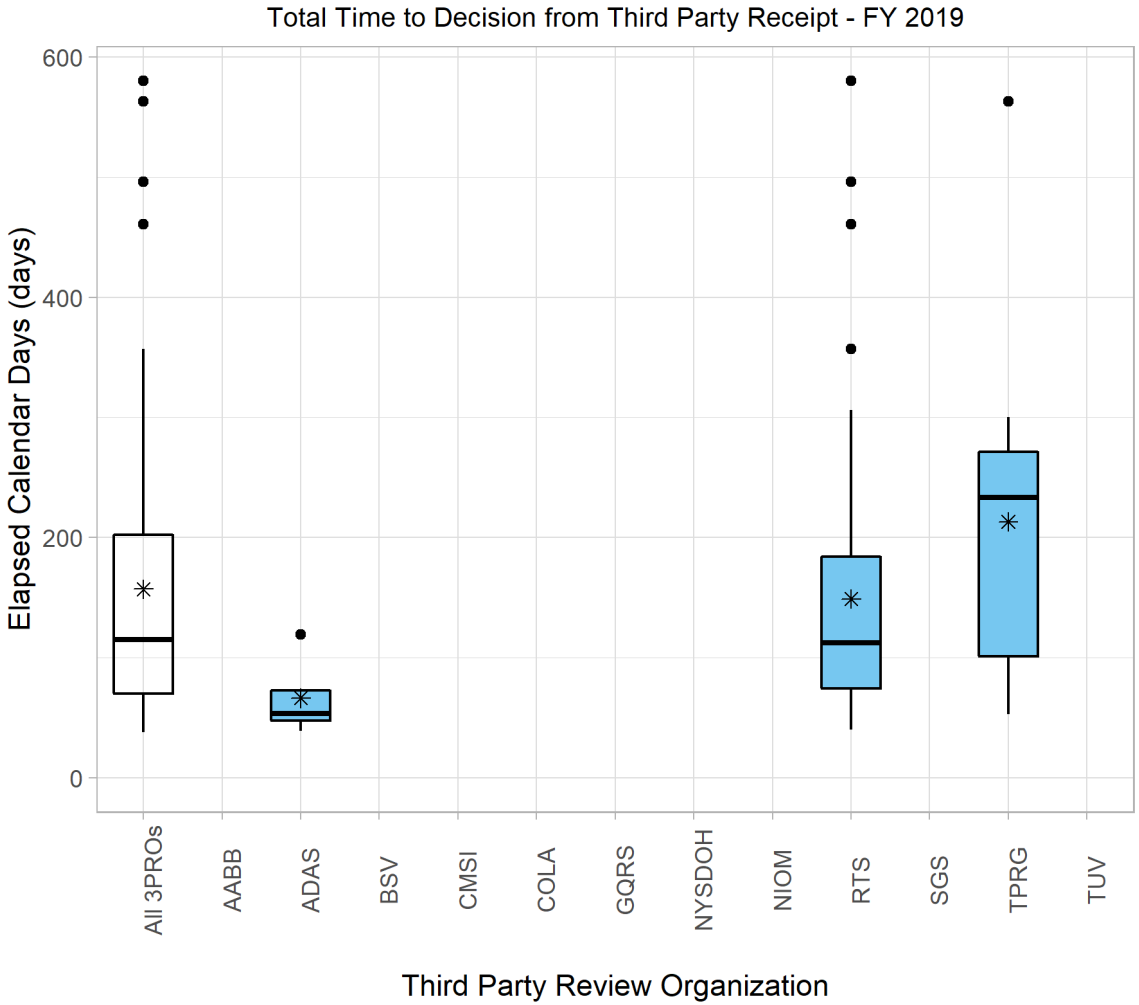

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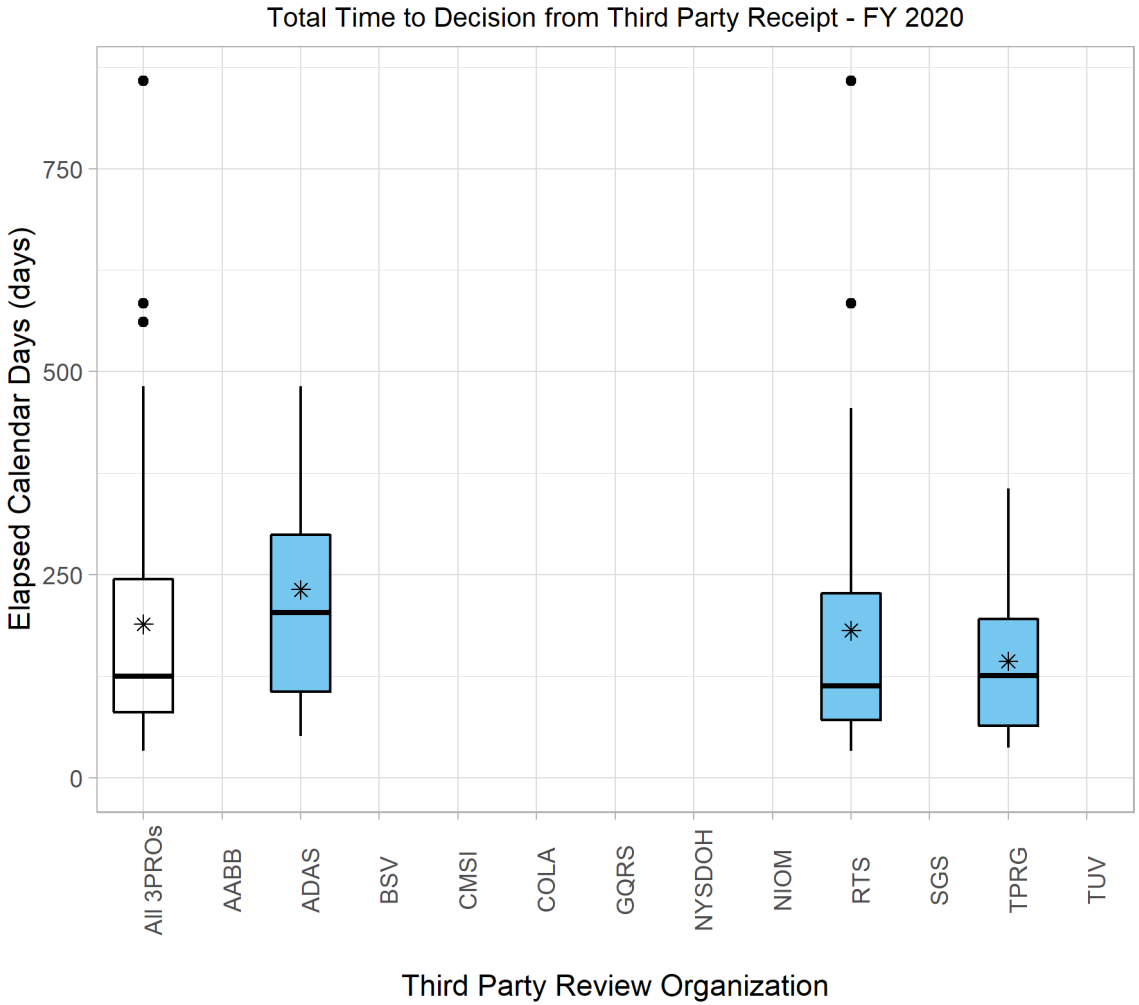

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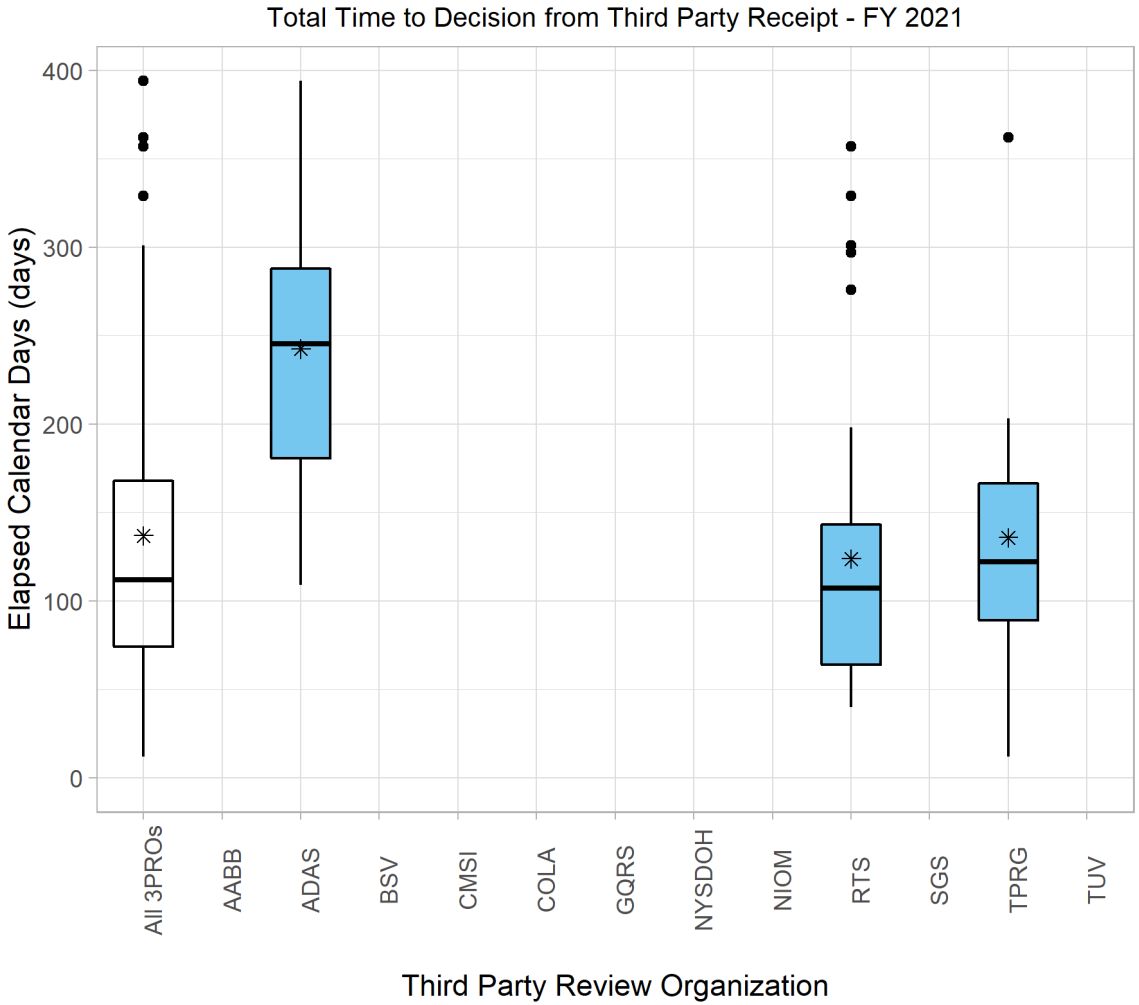

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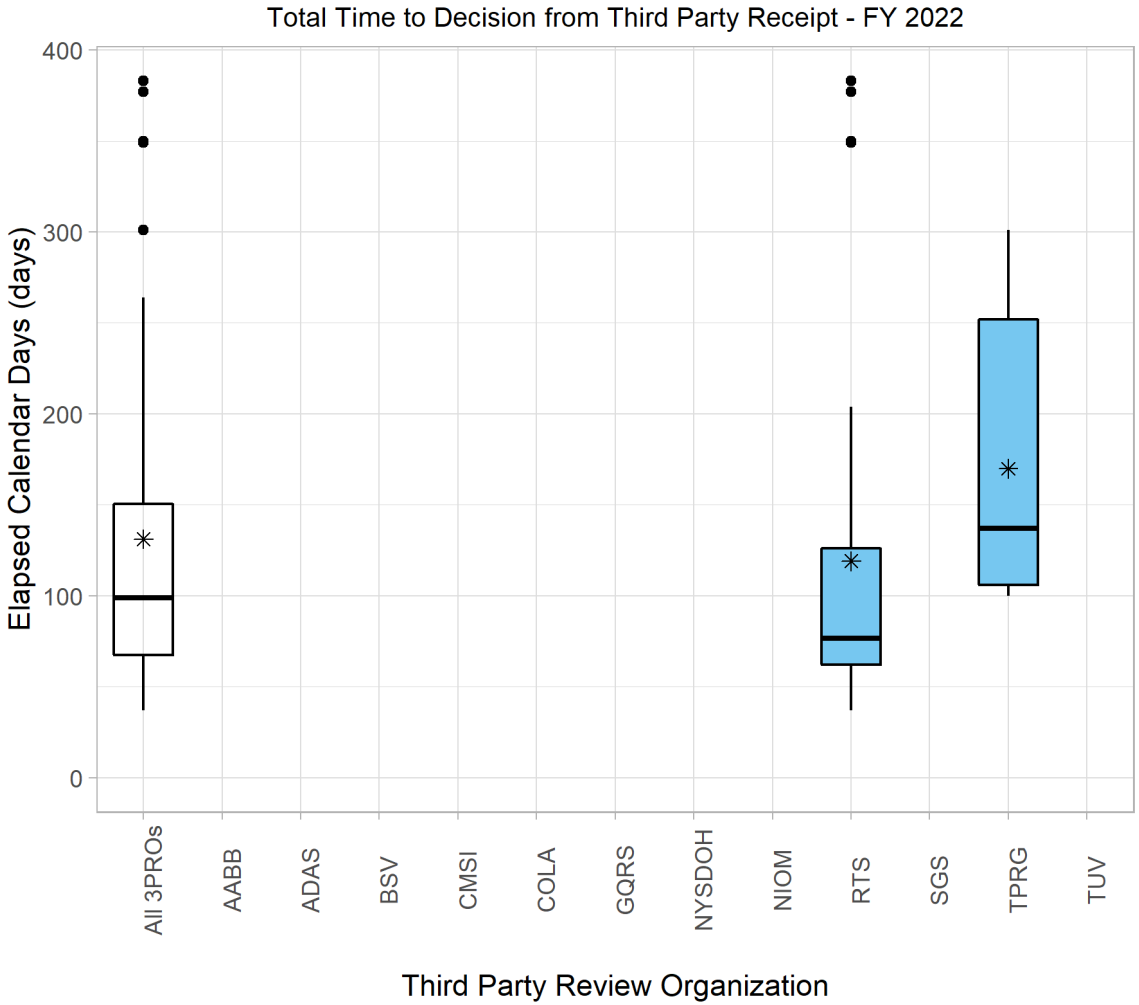

Figure 31

All Third Party Review Organizations

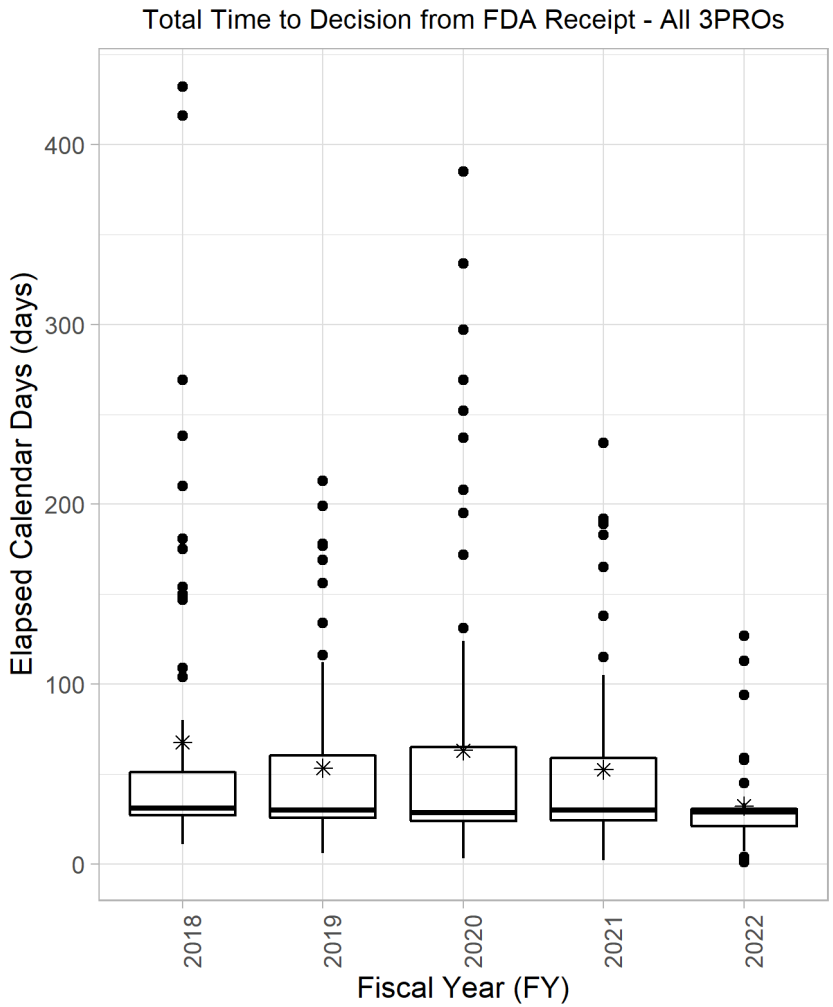

Figure 32

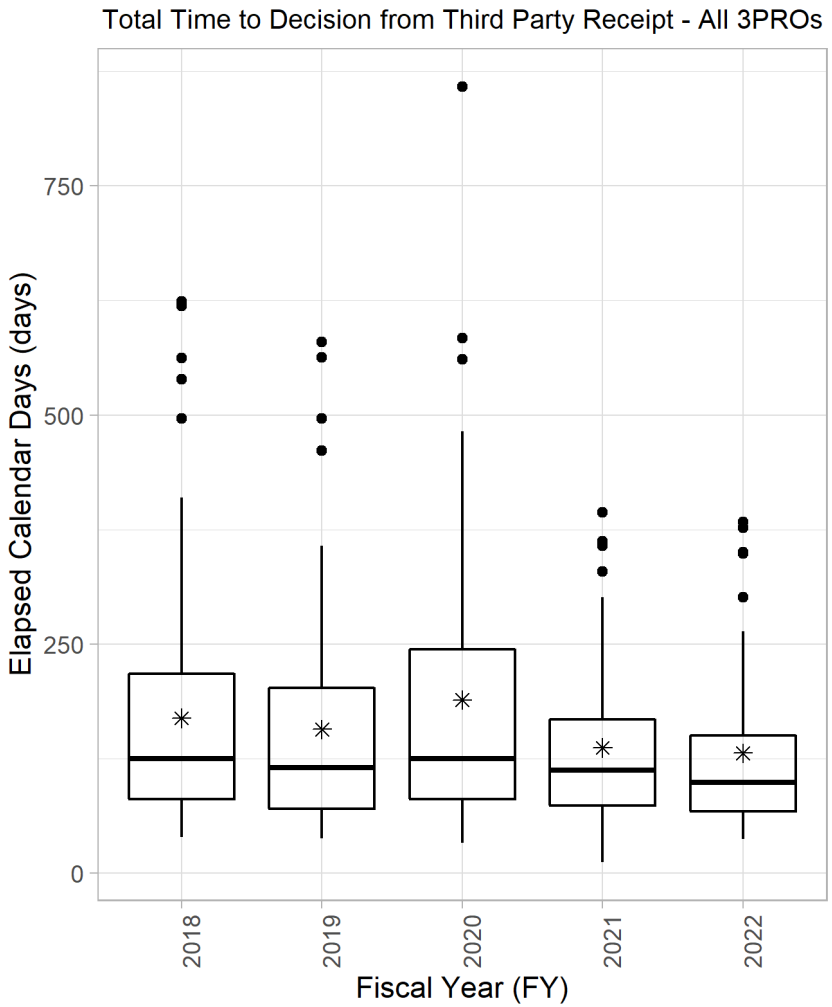

Figure 33

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	78	85	90	61
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	5 (7%)	7 (9%)	7 (8%)	16 (18%)	3 (5%)
MDUFA IV Final Decisions: SE or NSE (%)	70 (93%)	71 (91%)	78 (92%)	70 (78%)	44 (72%)
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	11 (18%)
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	2 (2%)	3 (5%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	83%	86%	89%	82%	82%
Average Holds					
Third Party Submission with a Final Decision	75	78	85	86	47
Total # Requests for Additional Information (Holds)	43	34	30	40	9
Average # Requests for Additional Information per Submission	0.57	0.44	0.35	0.47	0.19
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	75	78	85	86	47
Third Party SE Recommendations	75	78	85	86	47
Third Party NSE Recommendations	0	0	0	0	0
Third Party SE Recommendations with a Final Decision	75	78	85	86	47
MDUFA IV Final Decision					
SE	69	69	74	69	43
NSE	1	2	4	1	1
Non-MDUFA IV Final Decision					
Withdrawn	3	5	6	14	3
Deleted	2	2	1	2	0
Third Party NSE Recommendations with a Final Decision	0	0	0	0	0
MDUFA IV Final Decision					
SE	0	0	0	0	0
NSE	0	0	0	0	0
Non-MDUFA IV Final Decision					
Withdrawn	0	0	0	0	0
Deleted	0	0	0	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	104	126	84	99
25th Percentile Initial Third Party Review Time	39	34	45	39	36
50th Percentile Initial Third Party Review Time	70	64	82	67	61
75th Percentile Initial Third Party Review Time	119	146	137	93	137
Maximum Initial Third Party Review Time	594	565	817	336	338
Average Third Party Hold Time (Calendar Days)	36	24	34	22	6
25th Percentile Third Party Hold Time	0	0	0	0	0
50th Percentile Third Party Hold Time	7	0	0	0	0
75th Percentile Third Party Hold Time	23	31	36	25	0
Maximum Third Party Hold Time	352	170	358	179	68
Average Total Third Party Review Time (Calendar Days)	138	127	159	106	105
25th Percentile Total Third Party Review Time	54	49	52	55	38
50th Percentile Total Third Party Review Time	97	90	103	81	68
75th Percentile Total Third Party Review Time	189	172	206	134	140
Maximum Total Third Party Review Time	594	565	836	357	338
Average Total FDA Review Time (Calendar Days)	32	31	31	32	27
25th Percentile Total FDA Review Time	24	24	22	24	21
50th Percentile Total FDA Review Time	28	28	28	29	29
75th Percentile Total FDA Review Time	30	30	30	30	30
Maximum Total FDA Review Time	98	108	154	162	94
Average Total Time to Decision from FDA Receipt (Calendar Days)	68	54	64	53	33
25th Percentile Total TTD from FDA Receipt	27	26	24	24	21
50th Percentile Total TTD from FDA Receipt	31	30	29	30	29
75th Percentile Total TTD from FDA Receipt	51	61	68	59	31
Maximum Total TTD from FDA Receipt	432	213	385	234	127
Average Total Time to Decision from Third Party Receipt (Calendar Days)	170	158	190	137	132
25th Percentile Total TTD from Third Party Receipt	81	70	80	74	67
50th Percentile Total TTD from Third Party Receipt	125	115	125	112	99
75th Percentile Total TTD from Third Party Receipt	218	202	249	169	151
Maximum Total TTD from Third Party Receipt	624	580	858	394	383

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 (ADAS)

*As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews

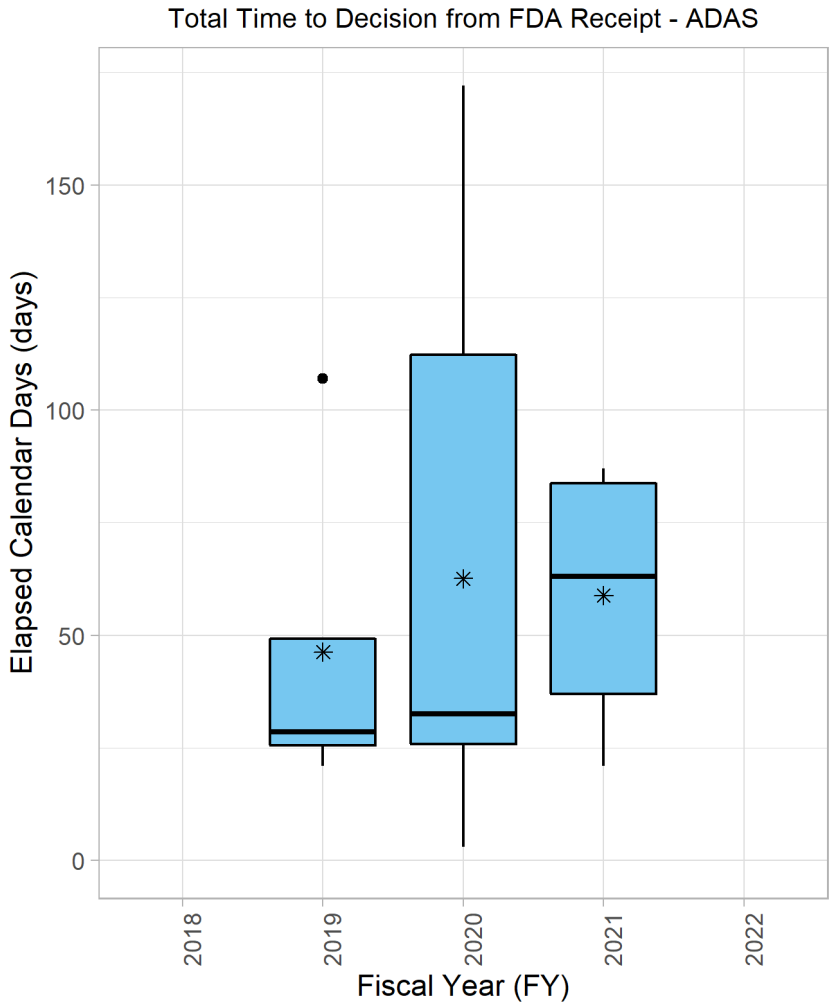

Figure 34

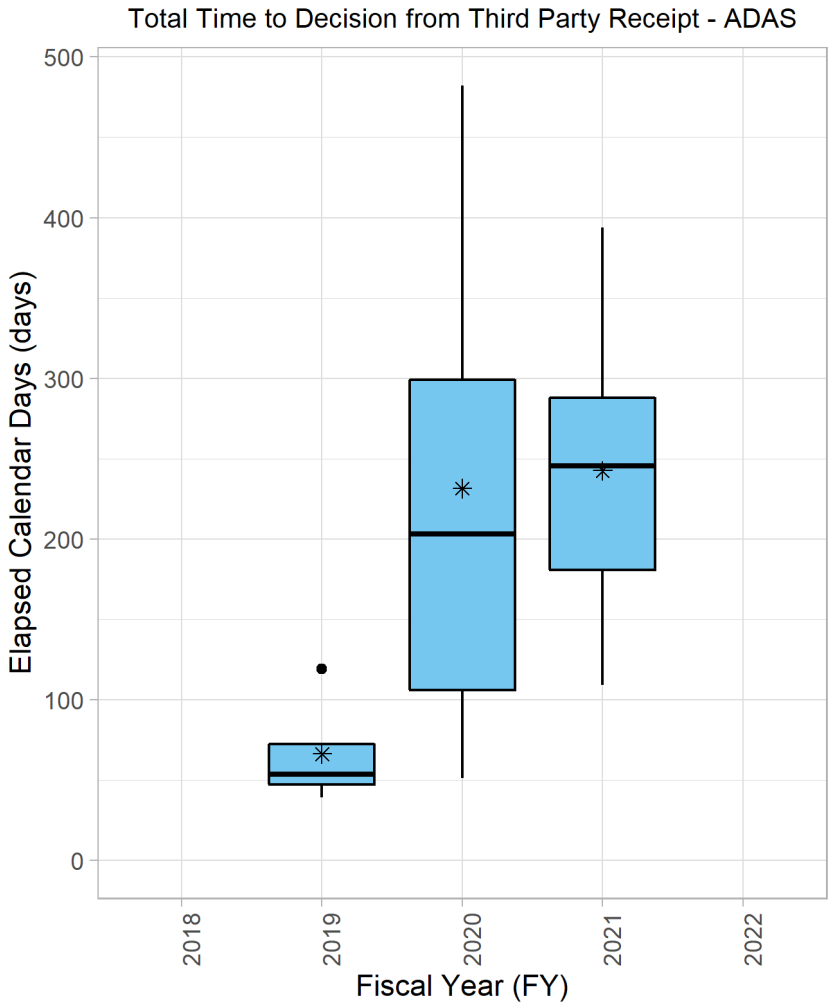

Figure 35

Table 2.1: Third Party 510(k) MDUFA IV Decision Performance Goals - Accelerated Device Approval Services (ADAS).

*As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Total Third Party 510(k) Submissions Accepted		6	19	16	
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)		2 (33%)	3 (16%)	10 (62%)	
MDUFA IV Final Decisions: SE or NSE (%)		4 (67%)	16 (84%)	6 (38%)	
Pending Final Decision for less than 30 FDA days (%)		0 (0%)	0 (0%)	0 (0%)	
Pending Final Decision for more than 30 FDA days (%)		0 (0%)	0 (0%)	0 (0%)	
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)		100%	94%	100%	
Average Holds					
Third Party Submission with a Final Decision		6	19	16	
Total # Requests for Additional Information (Holds)		2	10	11	
Average # Requests for Additional Information per Submission		0.33	0.53	0.69	
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision		6	19	16	
Third Party SE Recommendations		6	19	16	
Third Party NSE Recommendations		0	0	0	
Third Party SE Recommendations with a Final Decision		6	19	16	
MDUFA IV Final Decision					
SE		4	14	6	
NSE		0	2	0	
Non-MDUFA IV Final Decision					
Withdrawn		2	3	9	
Deleted		0	0	1	
Third Party NSE Recommendations with a Final Decision		0	0	0	
MDUFA IV Final Decision					
SE		0	0	0	
NSE		0	0	0	
Non-MDUFA IV Final Decision					
Withdrawn		0	0	0	
Deleted		0	0	0	

Table 2.2: Third Party 510(k) MDUFA IV Decision Performance Goals - Accelerated Device Approval Services (ADAS).
*As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews

Performance Metric	FY2018	FY2019	FY2020	FY2021	FY2022
Average Initial Third Party Review Time (Calendar Days)		20	169	179	
25th Percentile Initial Third Party Review Time		15	78	143	
50th Percentile Initial Third Party Review Time		19	107	186	
75th Percentile Initial Third Party Review Time		25	222	220	
Maximum Initial Third Party Review Time		30	462	300	
Average Third Party Hold Time (Calendar Days)		20	37	31	
25th Percentile Third Party Hold Time		0	0	3	
50th Percentile Third Party Hold Time		0	3	35	
75th Percentile Third Party Hold Time		39	85	56	
Maximum Third Party Hold Time		78	134	57	
Average Total Third Party Review Time (Calendar Days)		40	205	210	
25th Percentile Total Third Party Review Time		19	86	143	
50th Percentile Total Third Party Review Time		25	173	215	
75th Percentile Total Third Party Review Time		60	292	268	
Maximum Total Third Party Review Time		90	462	357	
Average Total FDA Review Time (Calendar Days)		27	27	28	
25th Percentile Total FDA Review Time		24	24	27	
50th Percentile Total FDA Review Time		28	29	30	
75th Percentile Total FDA Review Time		30	30	30	
Maximum Total FDA Review Time		30	38	30	
Average Total Time to Decision from FDA Receipt (Calendar Days)		47	63	59	
25th Percentile Total TTD from FDA Receipt		24	25	33	
50th Percentile Total TTD from FDA Receipt		29	33	63	
75th Percentile Total TTD from FDA Receipt		69	113	86	
Maximum Total TTD from FDA Receipt		107	172	87	
Average Total Time to Decision from Third Party Receipt (Calendar Days)		67	232	243	
25th Percentile Total TTD from Third Party Receipt		45	103	164	
50th Percentile Total TTD from Third Party Receipt		54	203	246	
75th Percentile Total TTD from Third Party Receipt		88	327	297	
Maximum Total TTD from Third Party Receipt		119	482	394	

BeanStock Ventures (BSV)

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. (COLA)

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.

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)

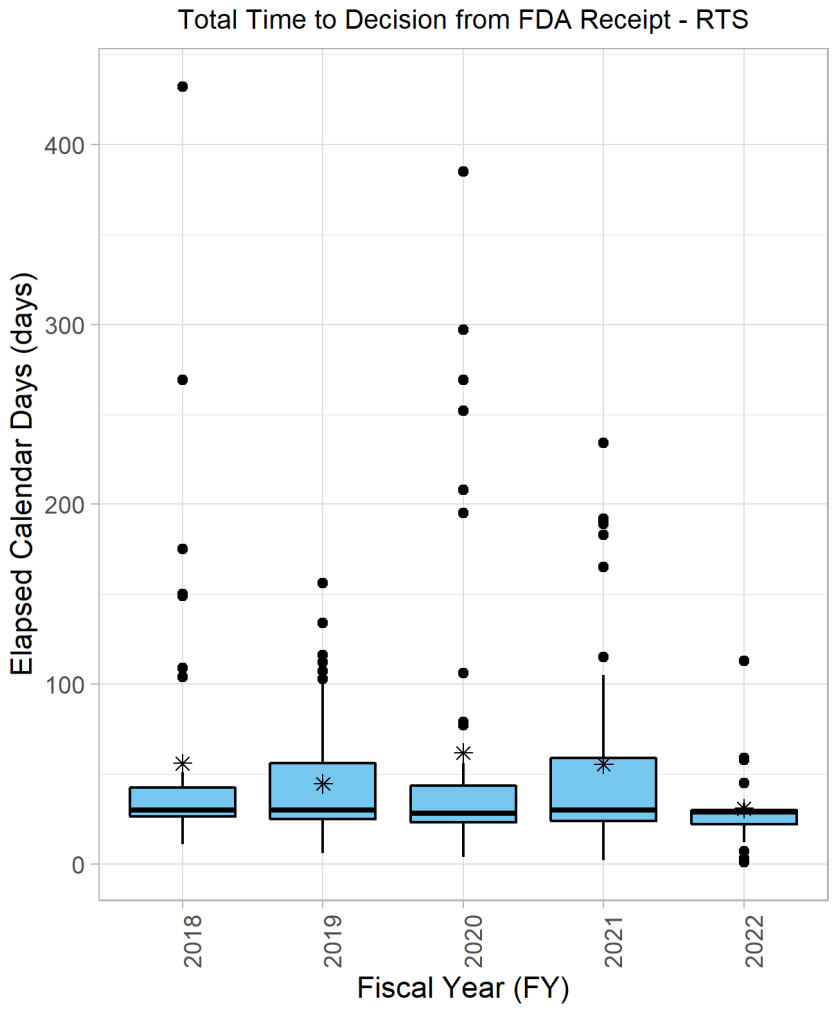

Figure 36

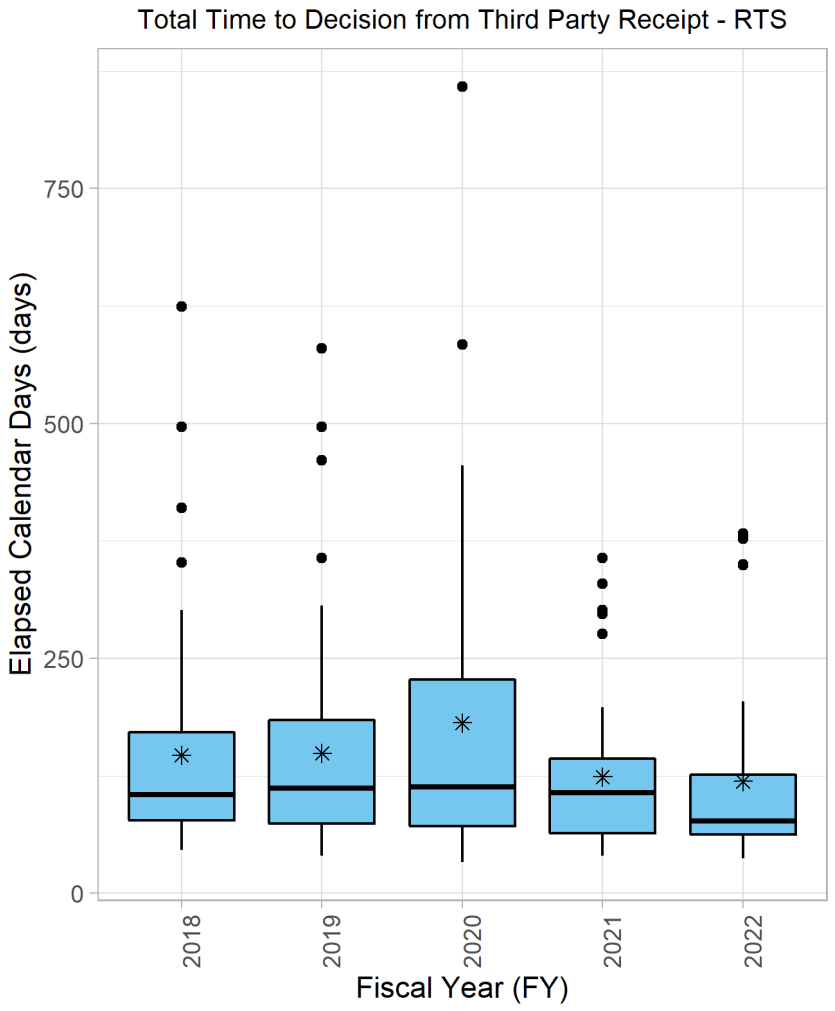

Figure 37

Table 3.1: 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	56	49	57	45
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	3 (6%)	3 (5%)	3 (6%)	4 (7%)	3 (7%)
MDUFA IV Final Decisions: SE or NSE (%)	46 (94%)	53 (95%)	46 (94%)	49 (86%)	34 (76%)
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	2 (4%)	6 (13%)
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	2 (4%)	2 (4%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	85%	89%	90%	80%	86%
Average Holds					
Third Party Submission with a Final Decision	49	56	49	53	37
Total # Requests for Additional Information (Holds)	27	23	13	25	6
Average # Requests for Additional Information per Submission	0.55	0.41	0.27	0.47	0.16
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	49	56	49	53	37
Third Party SE Recommendations	49	56	49	53	37
Third Party NSE Recommendations	0	0	0	0	0
Third Party SE Recommendations with a Final Decision	49	56	49	53	37
MDUFA IV Final Decision					
SE	46	52	45	48	33
NSE	0	1	1	1	1
Non-MDUFA IV Final Decision					
Withdrawn	3	2	2	3	3
Deleted	0	1	1	1	0
Third Party NSE Recommendations with a Final Decision	0	0	0	0	0
MDUFA IV Final Decision					
SE	0	0	0	0	0
NSE	0	0	0	0	0
Non-MDUFA IV Final Decision					
Withdrawn	0	0	0	0	0
Deleted	0	0	0	0	0

Table 3.2: 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	120	69	88
25th Percentile Initial Third Party Review Time	38	35	42	39	34
50th Percentile Initial Third Party Review Time	59	64	62	63	51
75th Percentile Initial Third Party Review Time	102	148	108	81	86
Maximum Initial Third Party Review Time	594	565	817	336	338
Average Third Party Hold Time (Calendar Days)	25	15	33	25	4
25th Percentile Third Party Hold Time	0	0	0	0	0
50th Percentile Third Party Hold Time	3	0	0	0	0
75th Percentile Third Party Hold Time	16	23	12	25	0
Maximum Third Party Hold Time	352	78	358	179	33
Average Total Third Party Review Time (Calendar Days)	116	120	153	93	92
25th Percentile Total Third Party Review Time	52	49	46	53	34
50th Percentile Total Third Party Review Time	76	89	86	79	55
75th Percentile Total Third Party Review Time	140	155	202	109	102
Maximum Total Third Party Review Time	594	565	836	336	338
Average Total FDA Review Time (Calendar Days)	32	30	29	32	28
25th Percentile Total FDA Review Time	24	24	22	24	22
50th Percentile Total FDA Review Time	28	28	27	28	29
75th Percentile Total FDA Review Time	30	30	29	30	30
Maximum Total FDA Review Time	98	108	152	162	94
Average Total Time to Decision from FDA Receipt (Calendar Days)	56	45	62	56	31
25th Percentile Total TTD from FDA Receipt	26	25	23	24	22
50th Percentile Total TTD from FDA Receipt	30	30	28	30	29
75th Percentile Total TTD from FDA Receipt	43	56	44	59	30
Maximum Total TTD from FDA Receipt	432	156	385	234	113
Average Total Time to Decision from Third Party Receipt (Calendar Days)	147	149	182	124	120
25th Percentile Total TTD from Third Party Receipt	77	74	70	64	62
50th Percentile Total TTD from Third Party Receipt	105	112	113	107	77
75th Percentile Total TTD from Third Party Receipt	172	184	230	143	130
Maximum Total TTD from Third Party Receipt	624	580	858	357	383

SGS North America (SGS)

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

Third Party Review Group, LLC (TPRG)

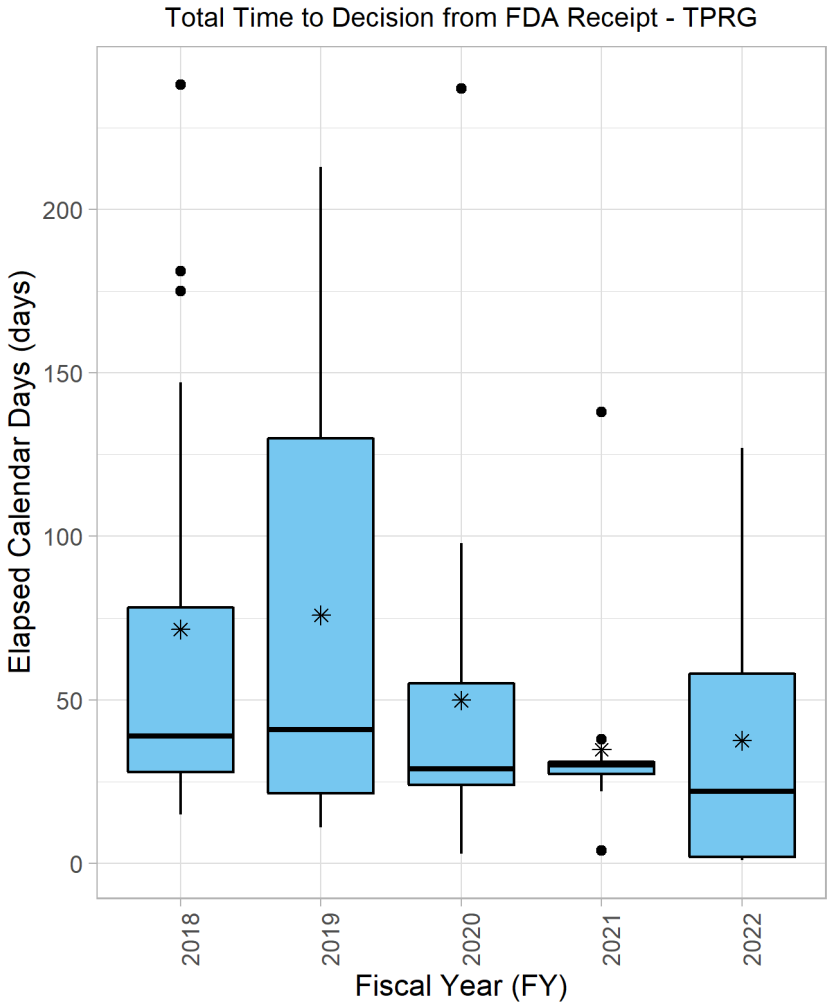

Figure 38

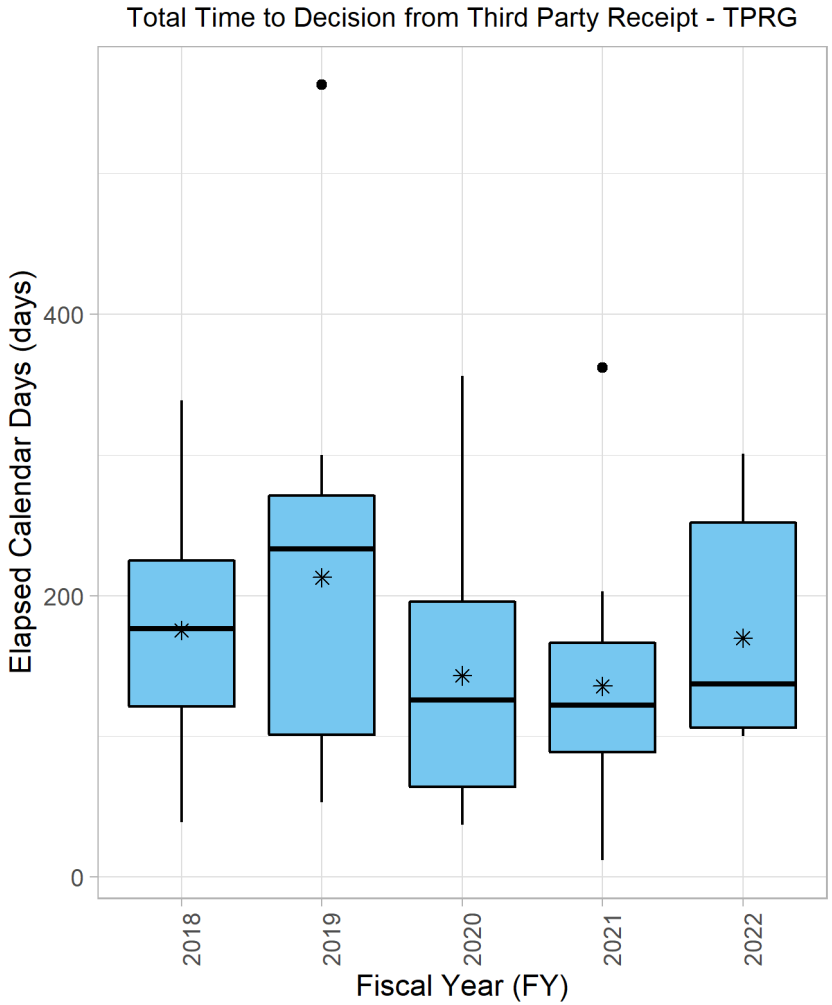

Figure 39

Table 4.1: 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	16	14	15
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (5%)	2 (15%)	1 (6%)	2 (14%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	18 (95%)	11 (85%)	15 (94%)	12 (86%)	9 (60%)
Pending Final Decision for less than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (33%)
Pending Final Decision for more than 30 FDA days (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	89%	64%	87%	75%	67%
Average Holds					
Third Party Submission with a Final Decision	19	13	16	14	9
Total # Requests for Additional Information (Holds)	11	7	6	1	3
Average # Requests for Additional Information per Submission	0.58	0.54	0.38	0.07	0.33
Third Party Recommendation and Final Decision Agreement					
Third Party Submissions with a Final Decision	19	13	16	14	9
Third Party SE Recommendations	19	13	16	14	9
Third Party NSE Recommendations	0	0	0	0	0
Third Party SE Recommendations with a Final Decision	19	13	16	14	9
MDUFA IV Final Decision					
SE	18	10	14	12	9
NSE	0	1	1	0	0
Non-MDUFA IV Final Decision					
Withdrawn	0	1	1	2	0
Deleted	1	1	0	0	0
Third Party NSE Recommendations with a Final Decision	0	0	0	0	0
MDUFA IV Final Decision					
SE	0	0	0	0	0
NSE	0	0	0	0	0
Non-MDUFA IV Final Decision					
Withdrawn	0	0	0	0	0
Deleted	0	0	0	0	0

Table 4.2: 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	137	94	101	133
25th Percentile Initial Third Party Review Time	76	58	39	47	83
50th Percentile Initial Third Party Review Time	100	77	86	69	108
75th Percentile Initial Third Party Review Time	126	215	132	128	173
Maximum Initial Third Party Review Time	219	386	246	333	263
Average Third Party Hold Time (Calendar Days)	44	41	21	4	15
25th Percentile Third Party Hold Time	0	0	0	0	0
50th Percentile Third Party Hold Time	10	10	0	0	0
75th Percentile Third Party Hold Time	54	61	25	0	25
Maximum Third Party Hold Time	184	161	149	40	68
Average Total Third Party Review Time (Calendar Days)	147	178	114	105	147
25th Percentile Total Third Party Review Time	99	72	45	60	83
50th Percentile Total Third Party Review Time	148	203	96	73	108
75th Percentile Total Third Party Review Time	198	237	166	128	241
Maximum Total Third Party Review Time	285	473	268	333	263
Average Total FDA Review Time (Calendar Days)	29	35	30	32	23
25th Percentile Total FDA Review Time	24	19	24	26	2
50th Percentile Total FDA Review Time	28	29	29	30	22
75th Percentile Total FDA Review Time	30	46	30	32	33
Maximum Total FDA Review Time	54	90	88	98	59
Average Total Time to Decision from FDA Receipt (Calendar Days)	72	76	50	35	38
25th Percentile Total TTD from FDA Receipt	28	22	24	26	2
50th Percentile Total TTD from FDA Receipt	39	41	29	30	22
75th Percentile Total TTD from FDA Receipt	80	130	55	32	58
Maximum Total TTD from FDA Receipt	238	213	237	138	127
Average Total Time to Decision from Third Party Receipt (Calendar Days)	176	213	144	136	170
25th Percentile Total TTD from Third Party Receipt	119	101	64	86	106
50th Percentile Total TTD from Third Party Receipt	177	233	126	122	137
75th Percentile Total TTD from Third Party Receipt	227	271	196	169	252
Maximum Total TTD from Third Party Receipt	339	563	356	362	301

TUV SUD America Inc. (TUV)

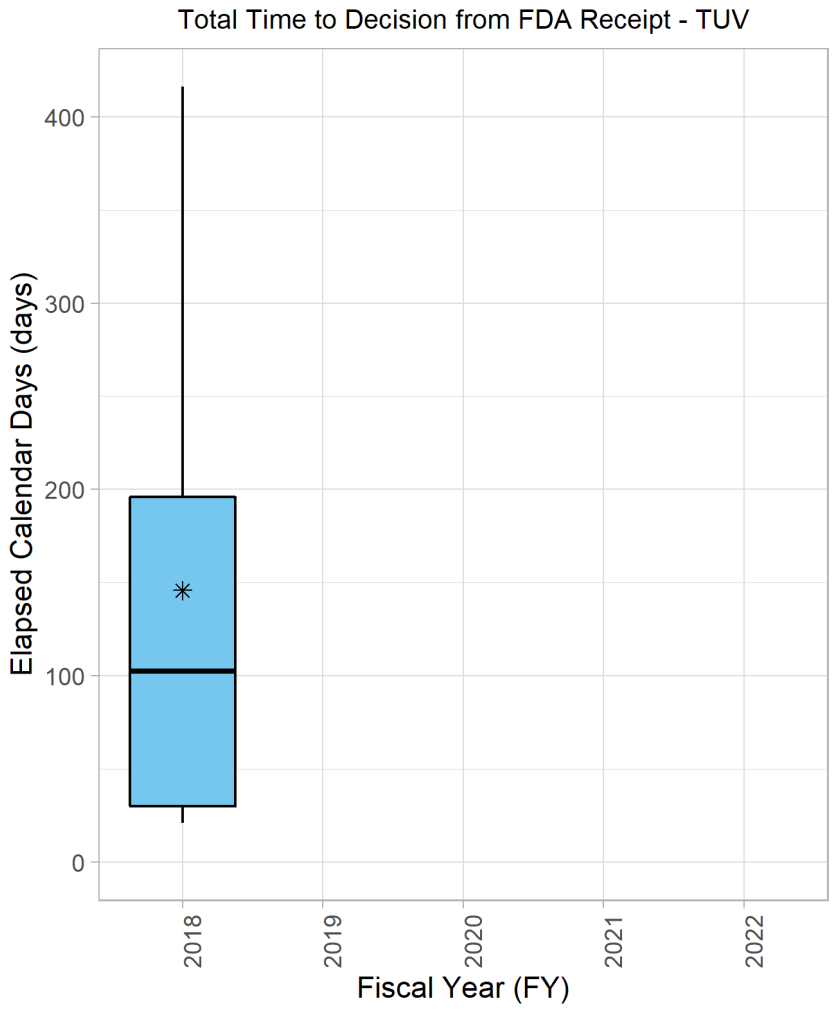

Figure 40

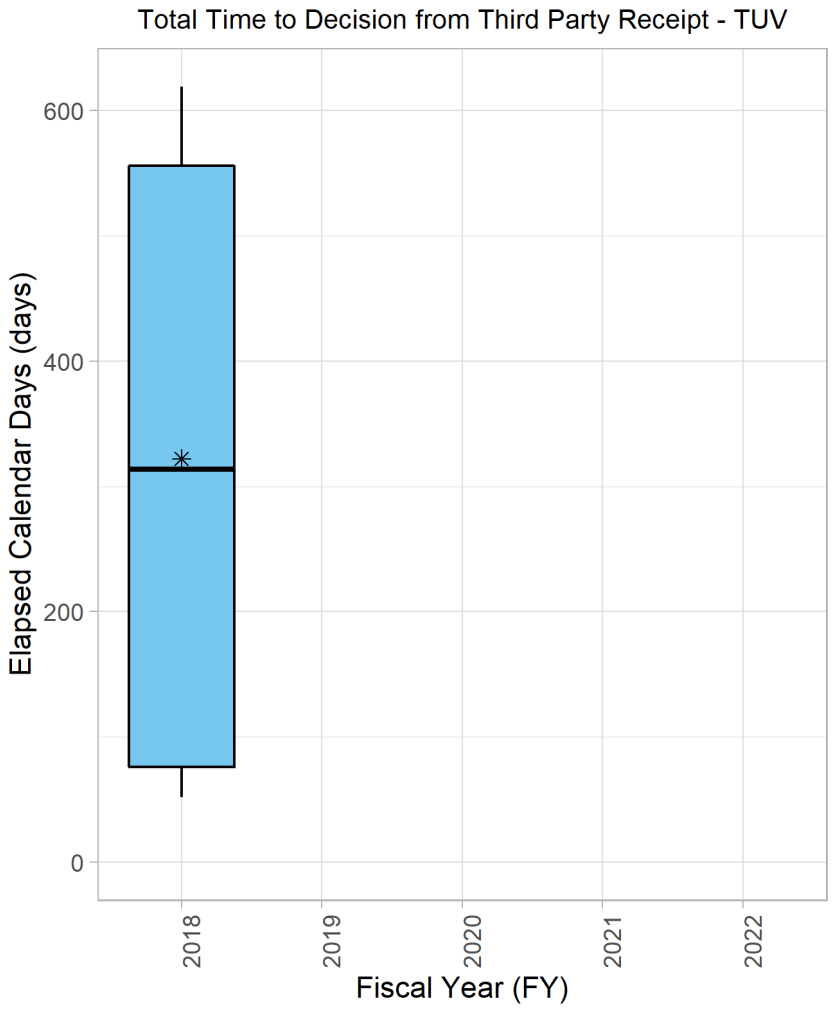

Figure 41

Table 5.1: 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 5.2: 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)
2020-July	Added new 3PRO - COLA
2021-January	Added new 3PROs - BSV and SGS
2021-April	Name change for BDC to GQRS
2021-August	As of August 13, 2021, Accelerated Device Approval Services, LLC (ADAS) is no longer recognized to conduct 510(k) Third Party Reviews
2022-January	FY 2022 reporting information and graphics are incorporated