

Third Party Review Organization Performance Report

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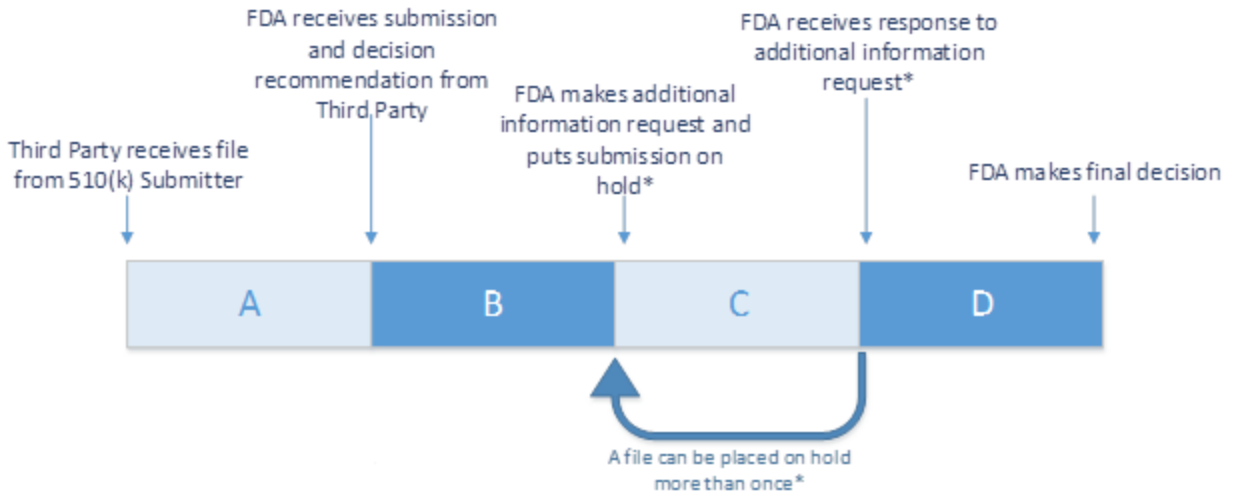
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Introduction and Review Timeline Description

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 2018, Q4 (October 1, 2017 through September 30, 2018). At this time, there are two Third Party Review Organizations with at least 5 completed submissions.

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.



- 1) Initial Third Party Review Time = A
- 2) Third Party Hold Time = C*
- 3) Total Third Party Review Time = A + C
- 4) Total FDA Review Time = B + D
- 5) Total Time to Decision from FDA Receipt = B + C + D
- 6) Total Time to Decision from Third Party Receipt = A + B + C + D

*This data may not be present for all third party submissions.

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:**

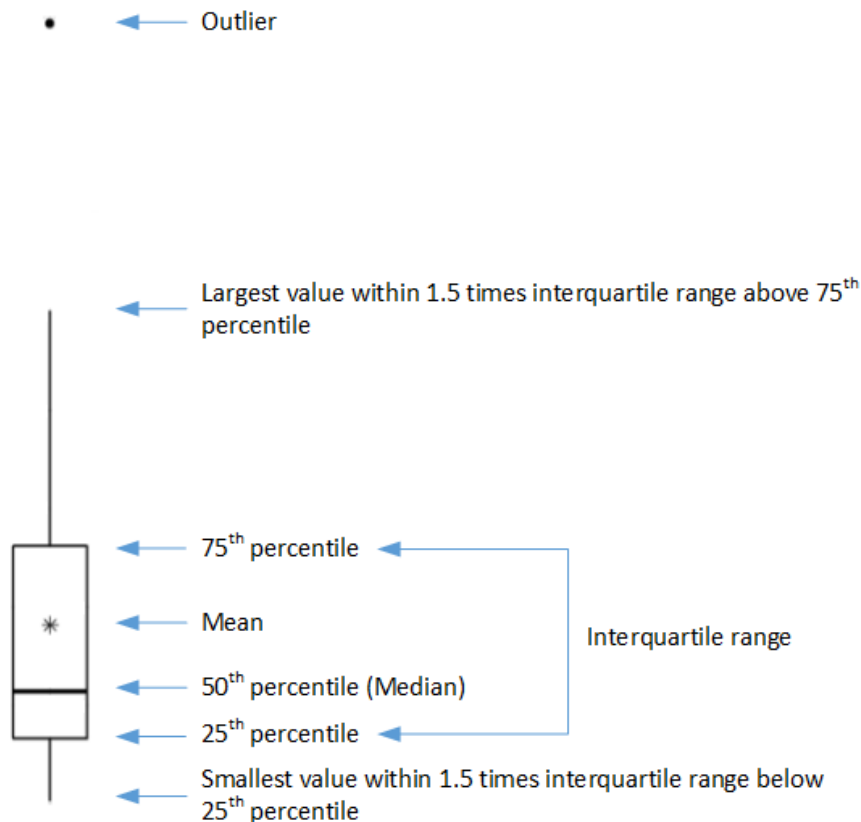
= *Total Third Party Review Time + Total FDA Review Time*

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
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 – FY 2018

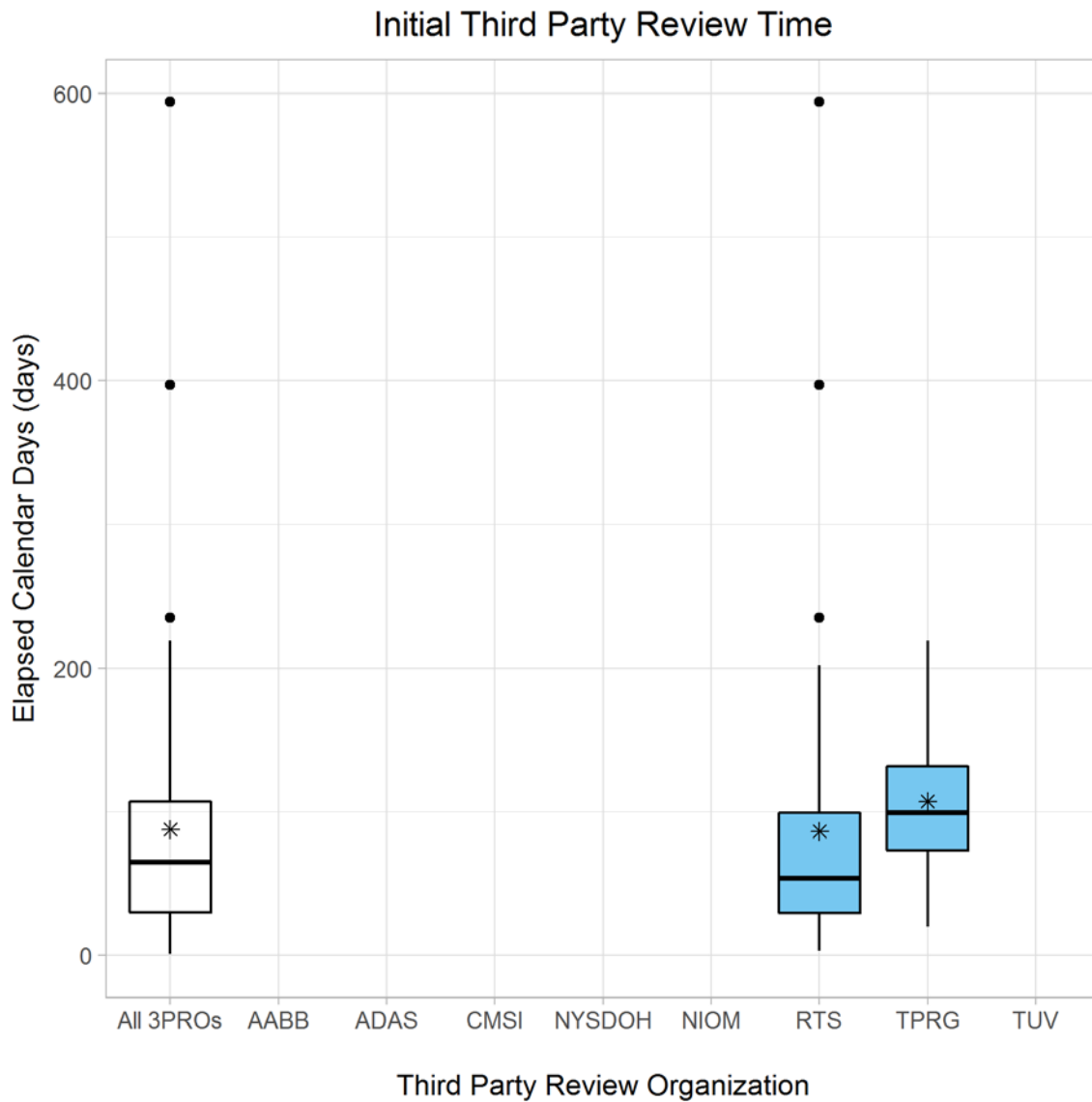


Figure 1. Initial Third Party Review Time.

Third Party Hold Time – FY 2018

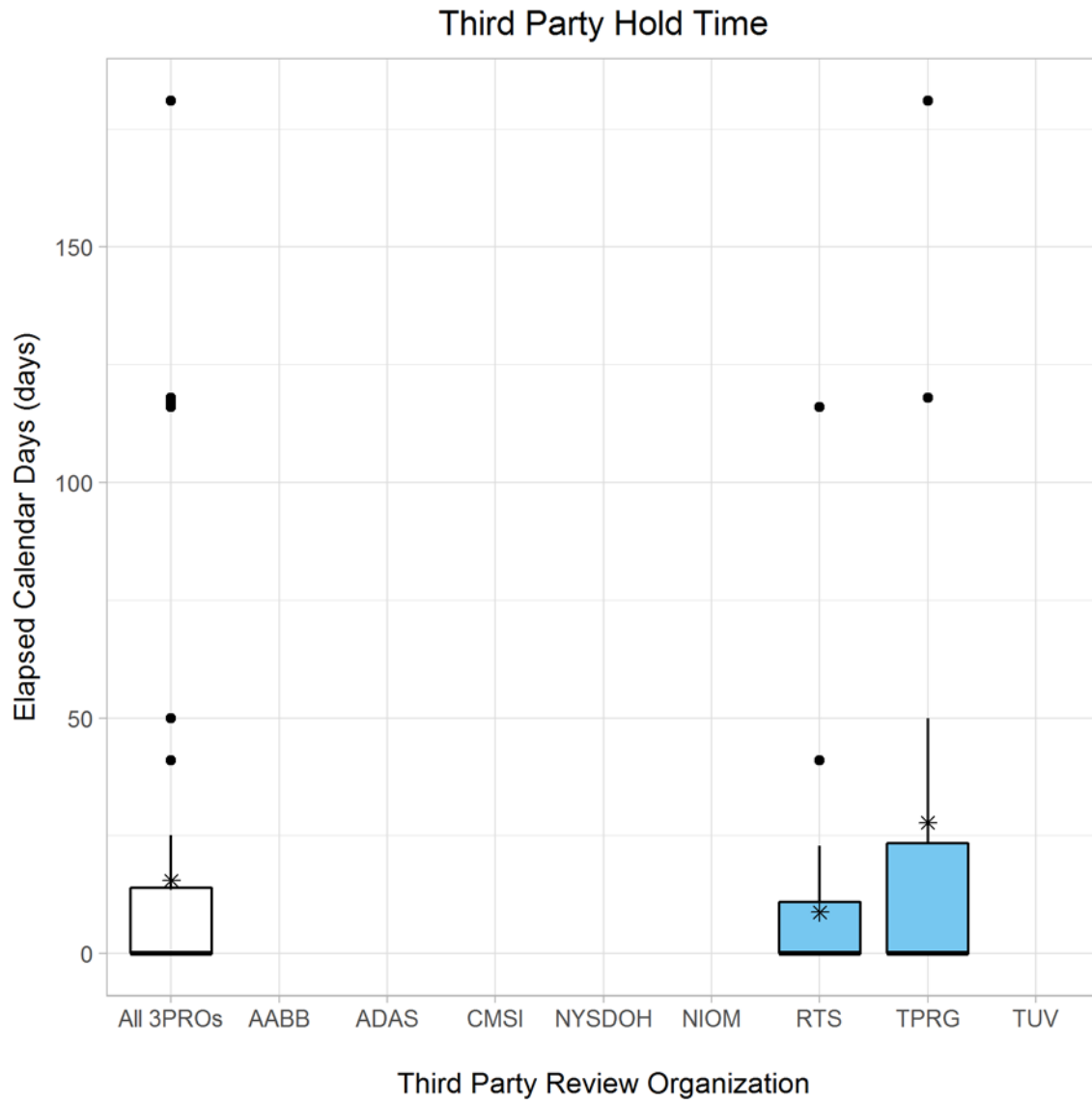


Figure 2. Third Party Hold Time.

Total Third Party Review Time – FY 2018

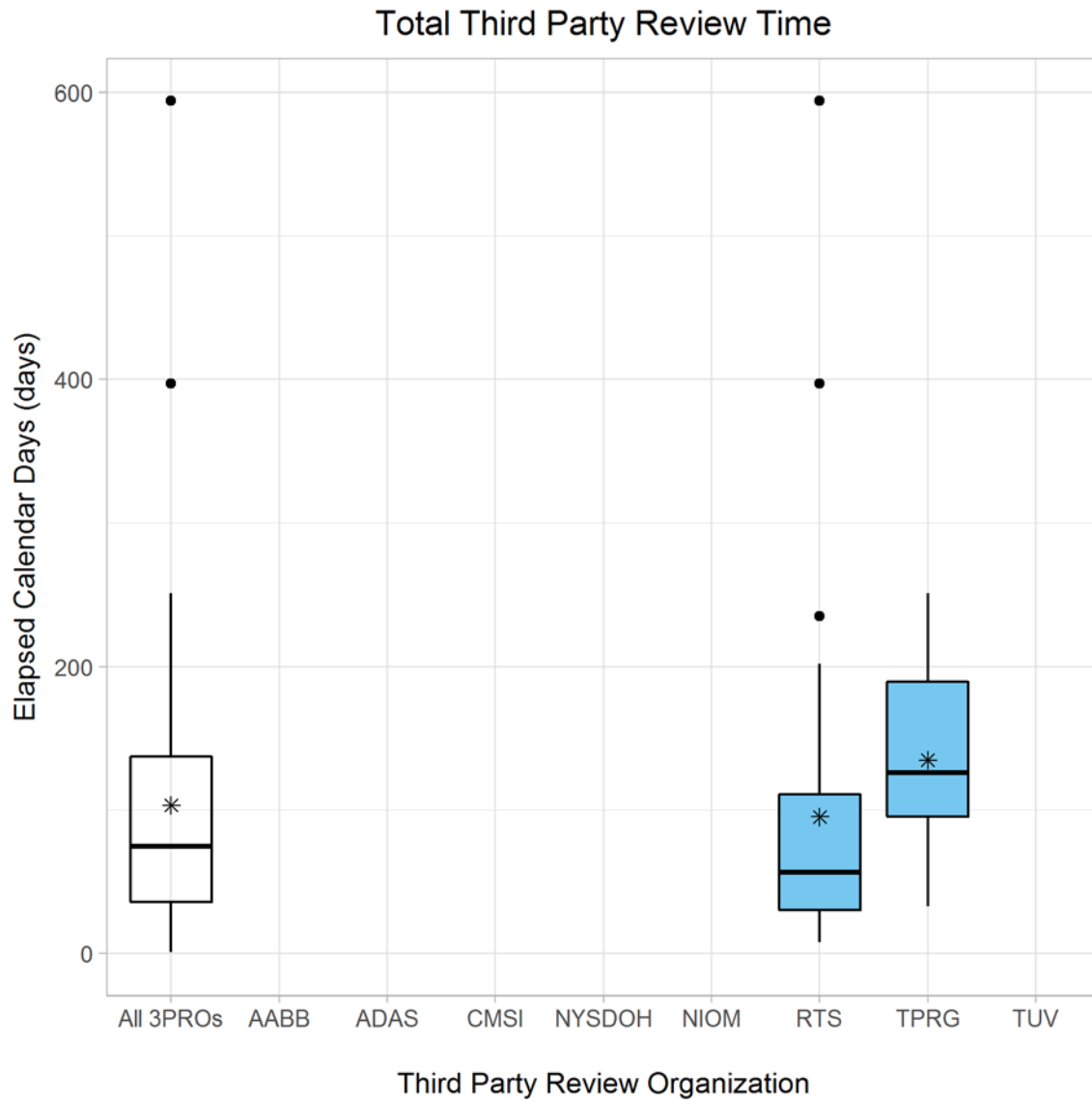


Figure 3. Total Third Party Review Time.

Total FDA Review Time – FY 2018

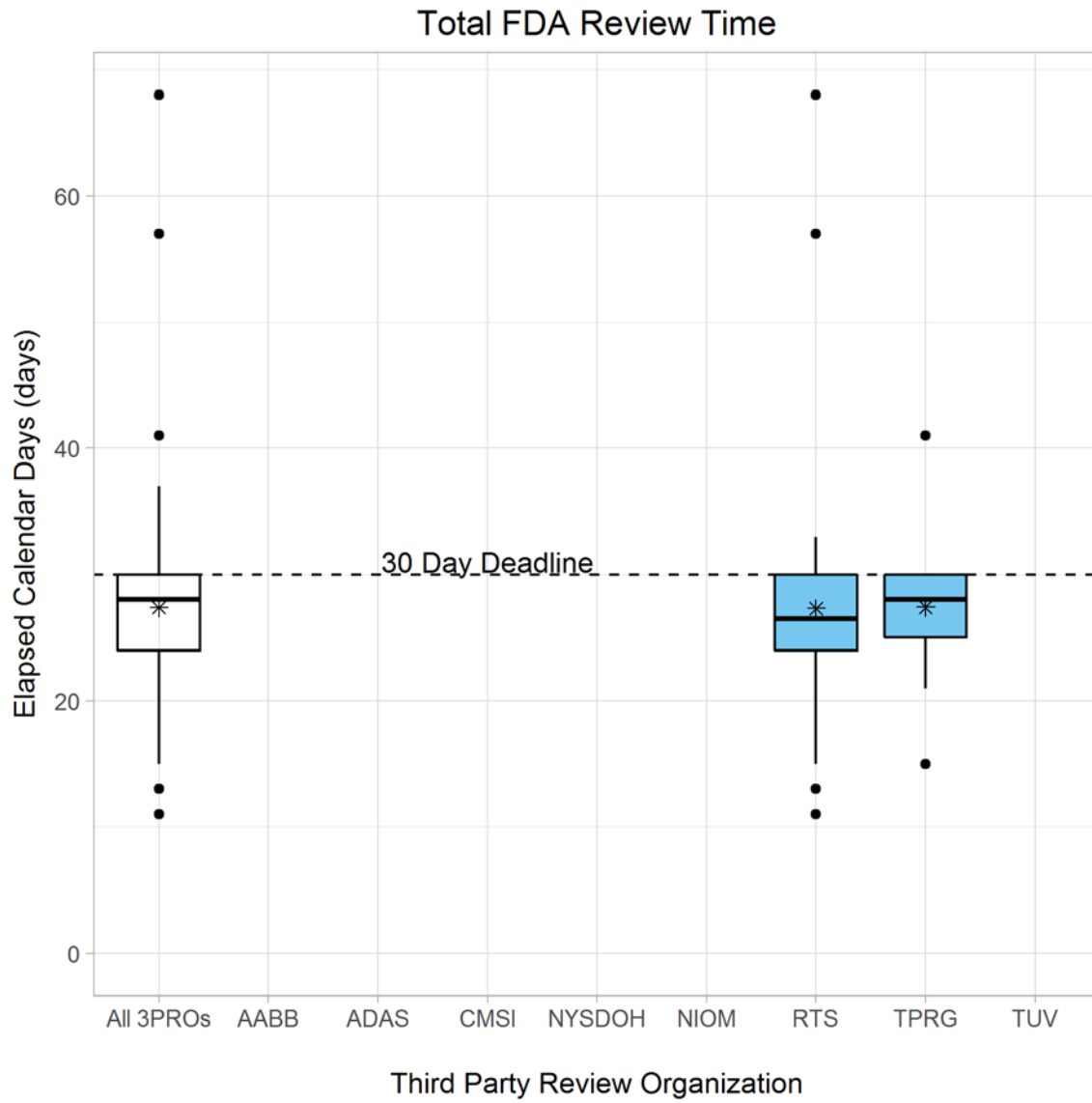


Figure 4. Total FDA Review Time.

Total Time to Decision from FDA Receipt – FY 2018

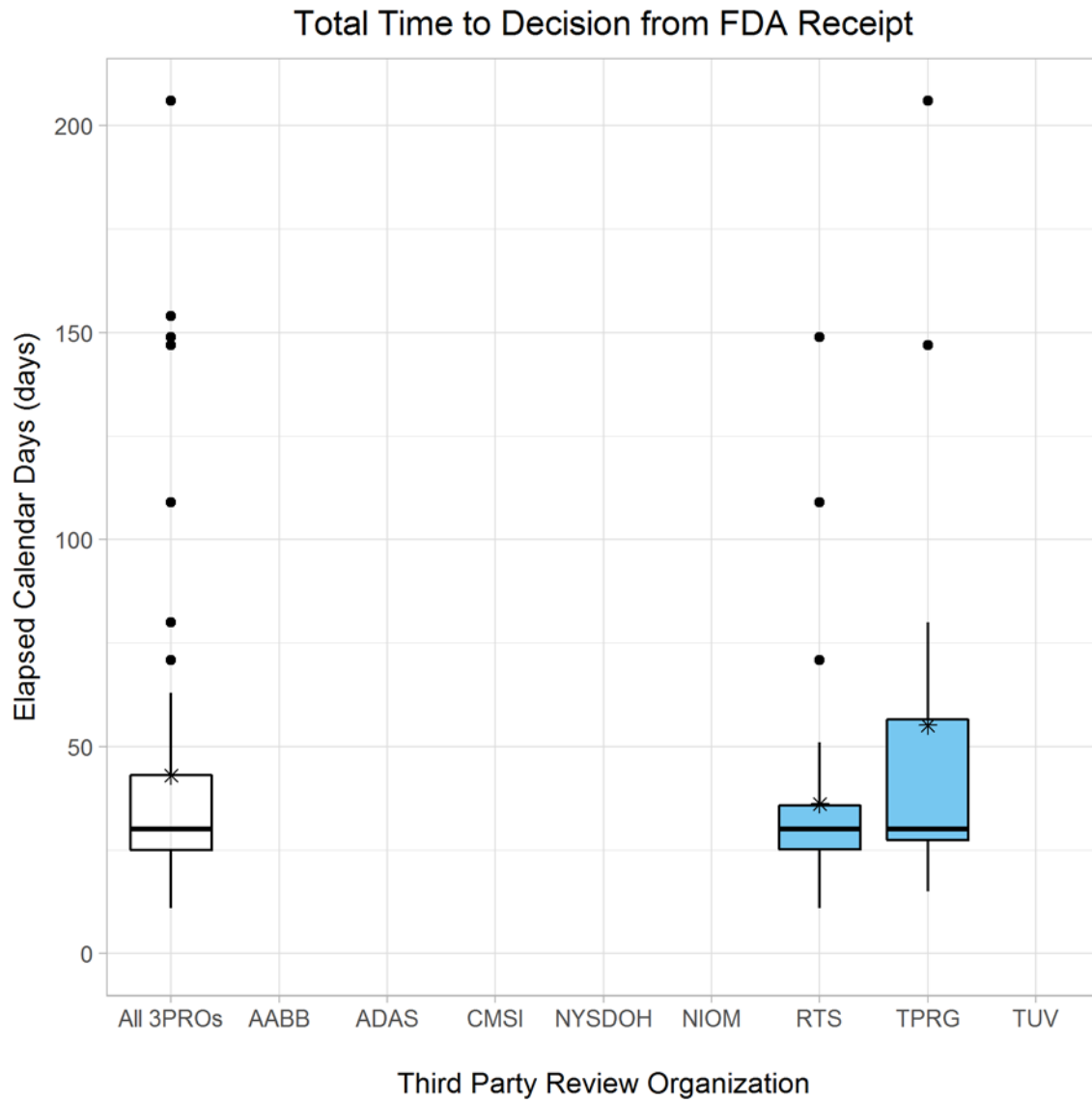


Figure 5. Total Time to Decision from FDA Receipt.

Total Time to Decision from Third Party Receipt – FY 2018

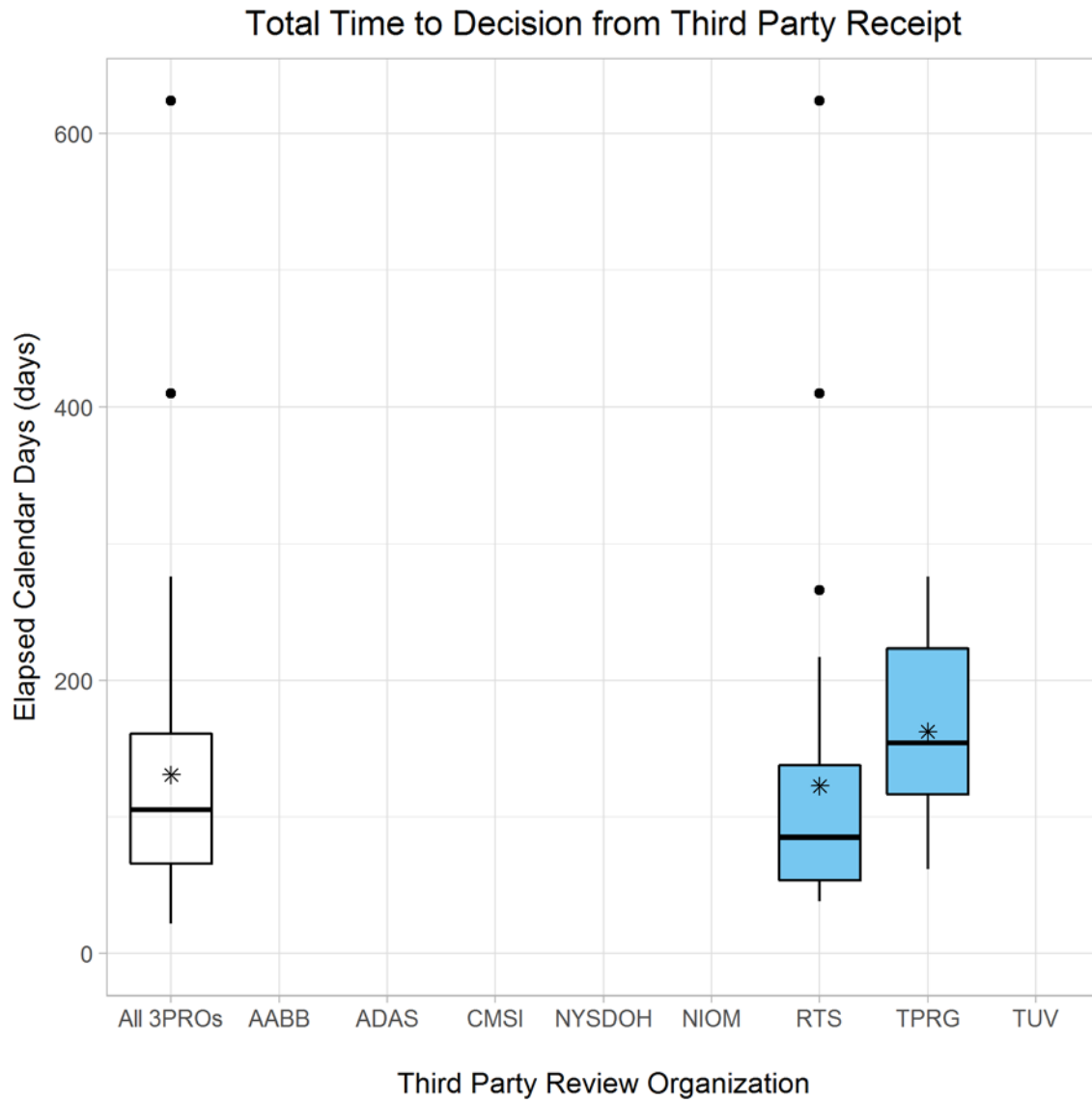


Figure 6. Total Time to Decision from Third Party Receipt.

All Third Party Review Organizations

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

Performance Metric	FY2018
Total Third Party 510(k) Submissions Accepted	75
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	2 (3%)
MDUFA IV Final Decisions: SE or NSE (%)	55 (73%)
Pending Final Decision for less than 30 FDA days (%)	17 (23%)
Pending Final Decision for more than 30 FDA days (%)	1 (1%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	91%
<i>Average Holds</i>	
Third Party Submission with a Final Decision	57
Total # Requests for Additional Information (Holds)	24
Average # Requests for Additional Information per Submission	0.42
<i>Third Party Recommendation and Final Decision Agreement</i>	
Third Party Submissions with a Final Decision	57
Third Party SE Recommendations	57 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	57
MDUFA IV Final Decision	
SE	55 (96%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	1 (2%)
Deleted	1 (2%)
Third Party NSE Recommendations with a Final Decision	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. All: Third Party 510(k) Review Time Performance Metrics.

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	90
25th Percentile Initial Third Party Review Time	31
50th Percentile Initial Third Party Review Time	65
75th Percentile Initial Third Party Review Time	112
Maximum Initial Third Party Review Time	594
Average Third Party Hold Time (Calendar Days)	13
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	14
Maximum Third Party Hold Time	118
Average Total Third Party Review Time (Calendar Days)	102
25th Percentile Total Third Party Review Time	38
50th Percentile Total Third Party Review Time	75
75th Percentile Total Third Party Review Time	137
Maximum Total Third Party Review Time	594
Average Total FDA Review Time (Calendar Days)	27
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	68
Average Total Time to Decision from FDA Receipt (Calendar Days)	40
25th Percentile Total TTD from FDA Receipt	25
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	41
Maximum Cumulative TTD from FDA Receipt Date	154
Average Total Time to Decision from Third Party Receipt (Calendar Days)	130
25th Percentile Total TTD from Third Party Receipt	64
50th Percentile Total TTD from Third Party Receipt	105
75th Percentile Total TTD from Third Party Receipt	161
Maximum Total TTD from Third Party Receipt	624

AABB

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

Accelerated Device Approval Services (ADAS)

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

Center for Measurement Standards of Industrial (CMSI)

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

New York State Department of Health (NYSDOH)

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

Nordic Institute of Dental Materials (NIOM)

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

Regulatory Technology Services, LLC (RTS)

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

Performance Metric	FY2018
Total Third Party 510(k) Submissions Accepted	49
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (2%)
MDUFA IV Final Decisions: SE or NSE (%)	37 (76%)
Pending Final Decision for less than 30 FDA days (%)	11 (22%)
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 (%)	92%
<i>Average Holds</i>	
Third Party Submission with a Final Decision	38
Total # Requests for Additional Information (Holds)	16
Average # Requests for Additional Information per Submission	0.42
<i>Third Party Recommendation and Final Decision Agreement</i>	
Third Party Submissions with a Final Decision	38
Third Party SE Recommendations	38 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	38
MDUFA IV Final Decision	
SE	37 (97%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	1 (3%)
Deleted	0 (0%)
Third Party NSE Recommendations with a Final Decision	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. RTS: Third Party 510(k) Review Time Performance Metrics. Regulatory Technology Services, LLC (RTS).

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	89
25th Percentile Initial Third Party Review Time	30
50th Percentile Initial Third Party Review Time	54
75th Percentile Initial Third Party Review Time	102
Maximum Initial Third Party Review Time	594
Average Third Party Hold Time (Calendar Days)	9
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	11
Maximum Third Party Hold Time	116
Average Total Third Party Review Time (Calendar Days)	98
25th Percentile Total Third Party Review Time	32
50th Percentile Total Third Party Review Time	57
75th Percentile Total Third Party Review Time	112
Maximum Total Third Party Review Time	594
Average Total FDA Review Time (Calendar Days)	27
25th Percentile Total FDA Review Time	24
50th Percentile Total FDA Review Time	26
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	68
Average Total Time to Decision from FDA Receipt (Calendar Days)	36
25th Percentile Total TTD from FDA Receipt	25
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	35
Maximum Cumulative TTD from FDA Receipt Date	149
Average Total Time to Decision from Third Party Receipt (Calendar Days)	124
25th Percentile Total TTD from Third Party Receipt	53
50th Percentile Total TTD from Third Party Receipt	86
75th Percentile Total TTD from Third Party Receipt	138
Maximum Total TTD from Third Party Receipt	624

Third Party Review Group, LLC (TPRG)

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

Performance Metric	FY2018
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 (%)	14 (74%)
Pending Final Decision for less than 30 FDA days (%)	3 (16%)
Pending Final Decision for more than 30 FDA days (%)	1 (5%)
Current Performance: Third Party Submissions that received MDUFA IV Final Decisions (SE or NSE) within 30 FDA Days (%)	93%
<i>Average Holds</i>	
Third Party Submission with a Final Decision	15
Total # Requests for Additional Information (Holds)	6
Average # Requests for Additional Information per Submission	0.4
<i>Third Party Recommendation and Final Decision Agreement</i>	
Third Party Submissions with a Final Decision	15
Third Party SE Recommendations	15 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	15
MDUFA IV Final Decision	
SE	14 (93%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	1 (7%)
Third Party NSE Recommendations with a Final Decision	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. TPRG: Third Party 510(k) Review Time Performance Metrics.
Third Party Review Group, LLC (TPRG).

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	110
25th Percentile Initial Third Party Review Time	77
50th Percentile Initial Third Party Review Time	103
75th Percentile Initial Third Party Review Time	135
Maximum Initial Third Party Review Time	219
Average Third Party Hold Time (Calendar Days)	17
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	20
Maximum Third Party Hold Time	118
Average Total Third Party Review Time (Calendar Days)	127
25th Percentile Total Third Party Review Time	93
50th Percentile Total Third Party Review Time	117
75th Percentile Total Third Party Review Time	184
Maximum Total Third Party Review Time	219
Average Total FDA Review Time (Calendar Days)	28
25th Percentile Total FDA Review Time	26
50th Percentile Total FDA Review Time	28
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	41
Average Total Time to Decision from FDA Receipt (Calendar Days)	45
25th Percentile Total TTD from FDA Receipt	28
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	48
Maximum Cumulative TTD from FDA Receipt Date	147
Average Total Time to Decision from Third Party Receipt (Calendar Days)	155
25th Percentile Total TTD from Third Party Receipt	116
50th Percentile Total TTD from Third Party Receipt	144
75th Percentile Total TTD from Third Party Receipt	214
Maximum Total TTD from Third Party Receipt	240

TUV SUD America Inc. (TUV)

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