Third Party Review Organization Performance Report

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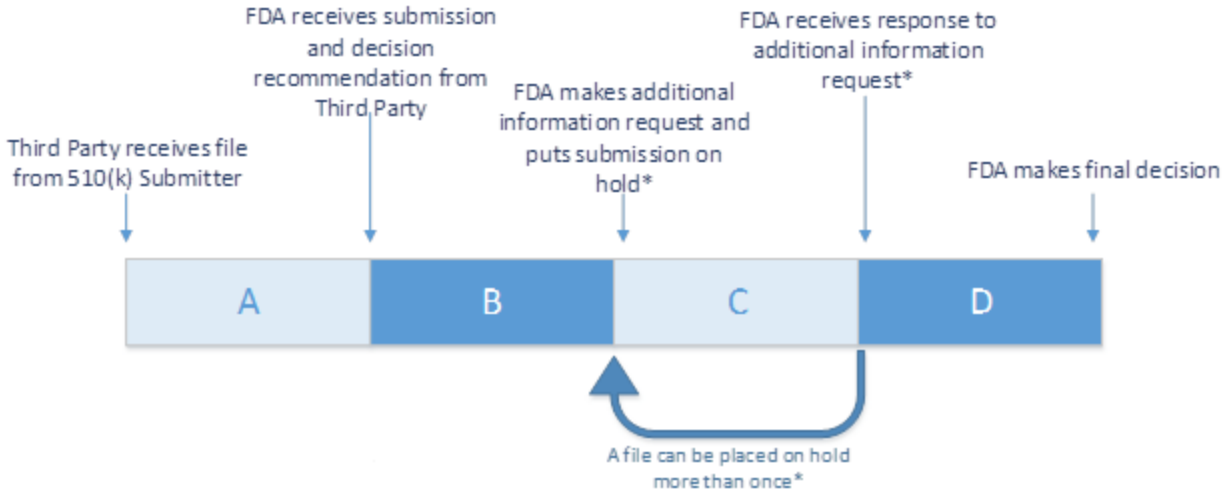
Introduction and Review Timeline Description

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 Q3 (October 1, 2017 through June 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
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.

Third Party Performance Data

Initial Third Party Review Time – FY 2018

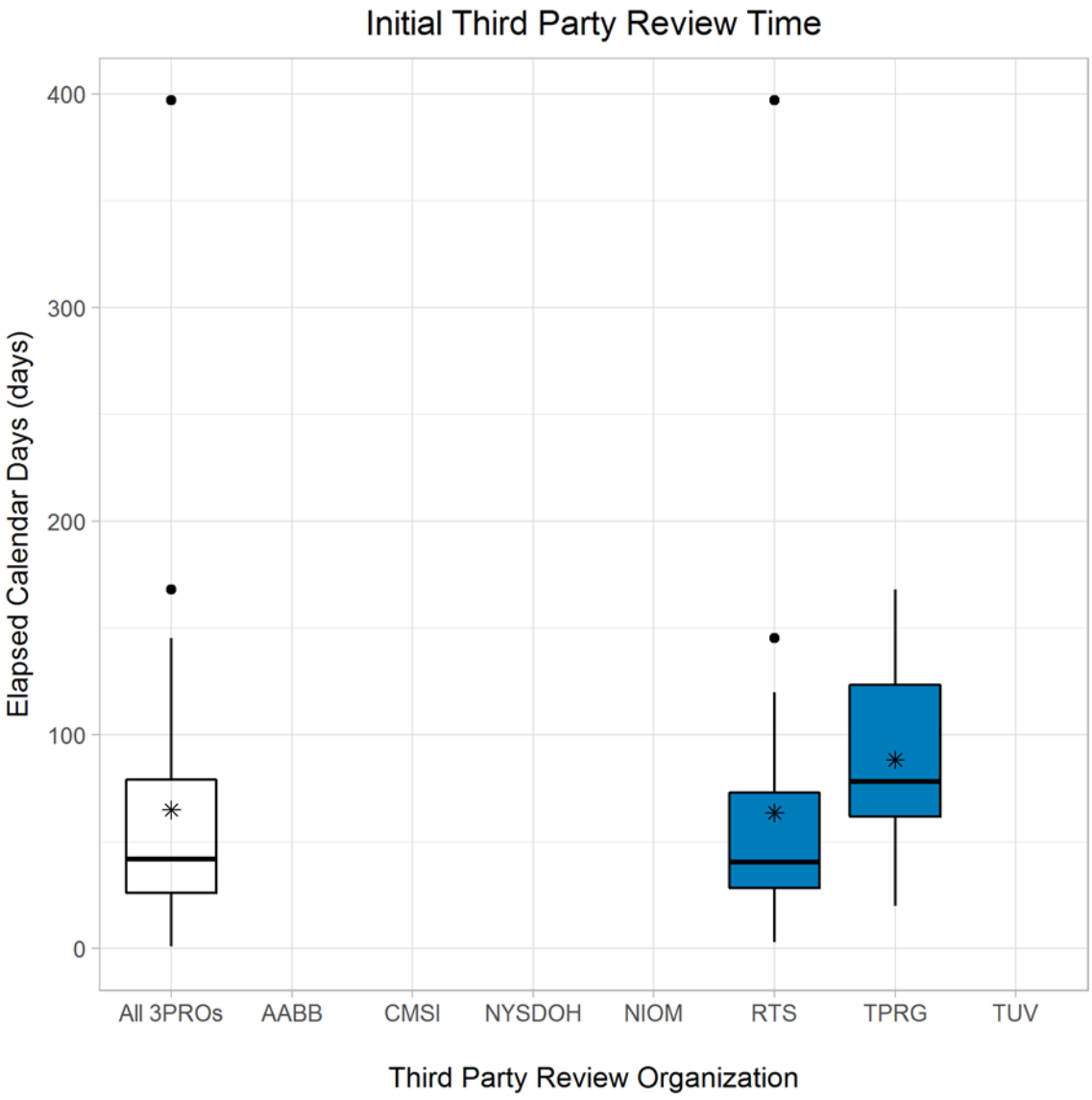


Figure 1. Initial Third Party Review Time.

Third Party Hold Time – FY 2018

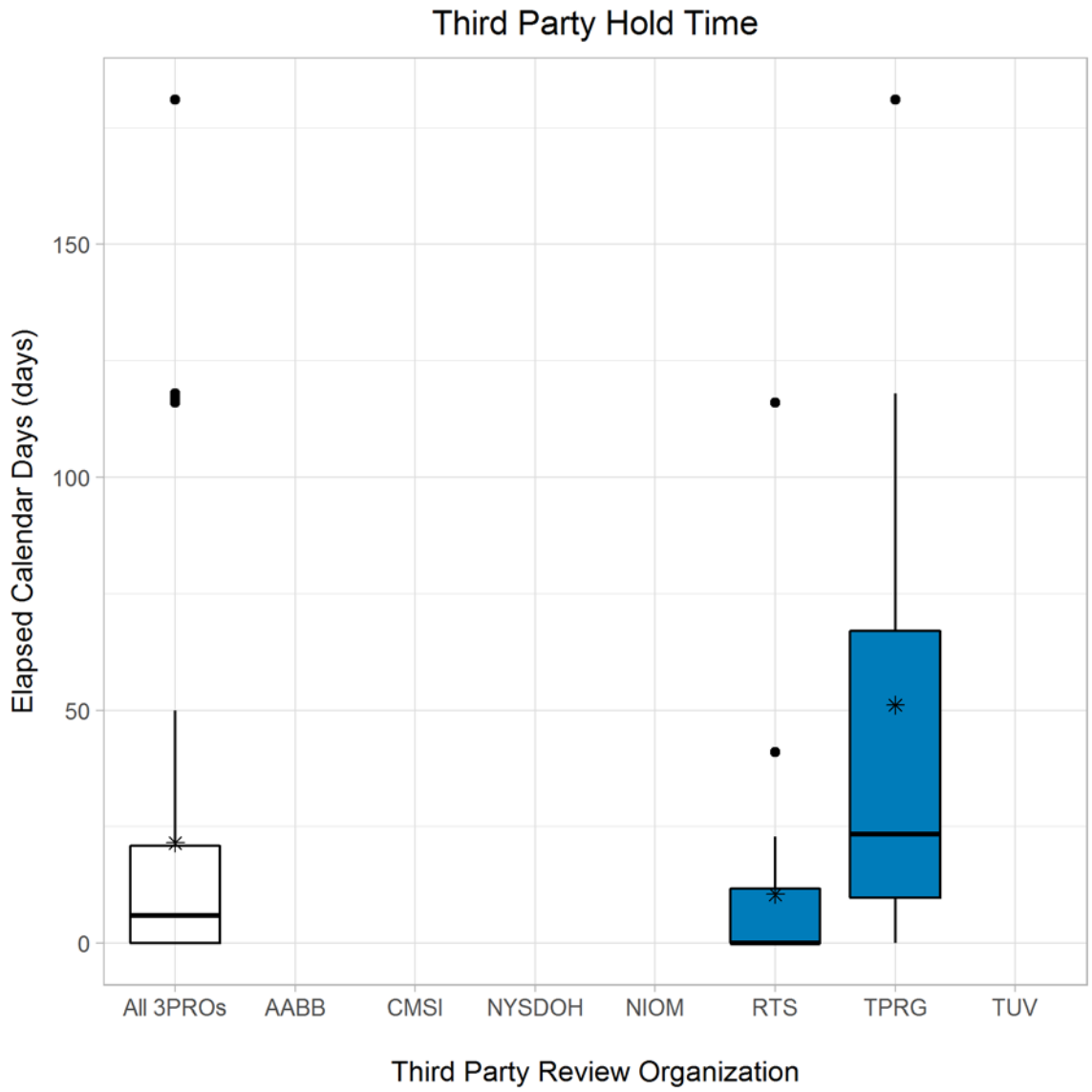


Figure 2. Third Party Hold Time.

Total Third Party Review Time – FY 2018

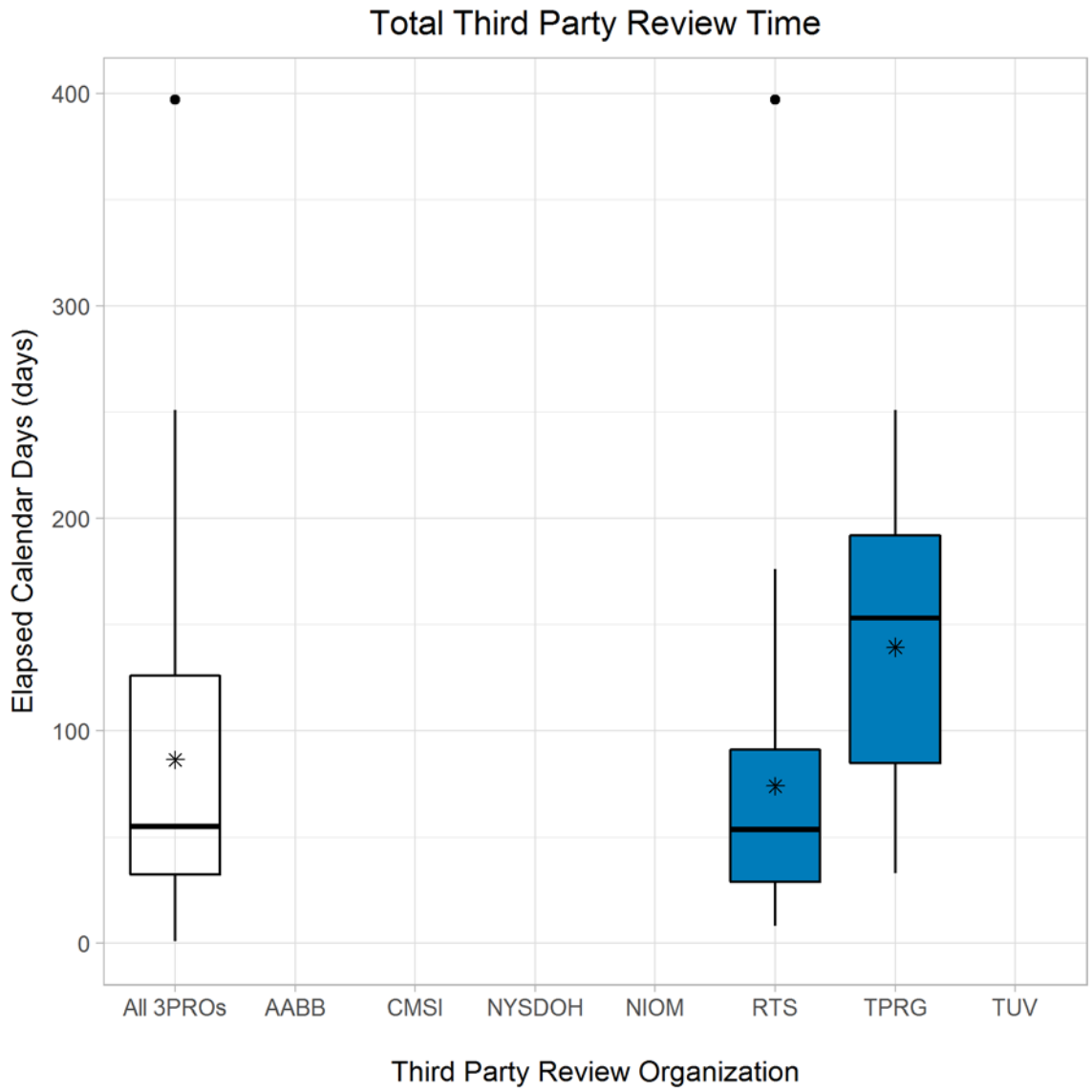


Figure 3. Total Third Party Review Time.

Total FDA Review Time – FY 2018

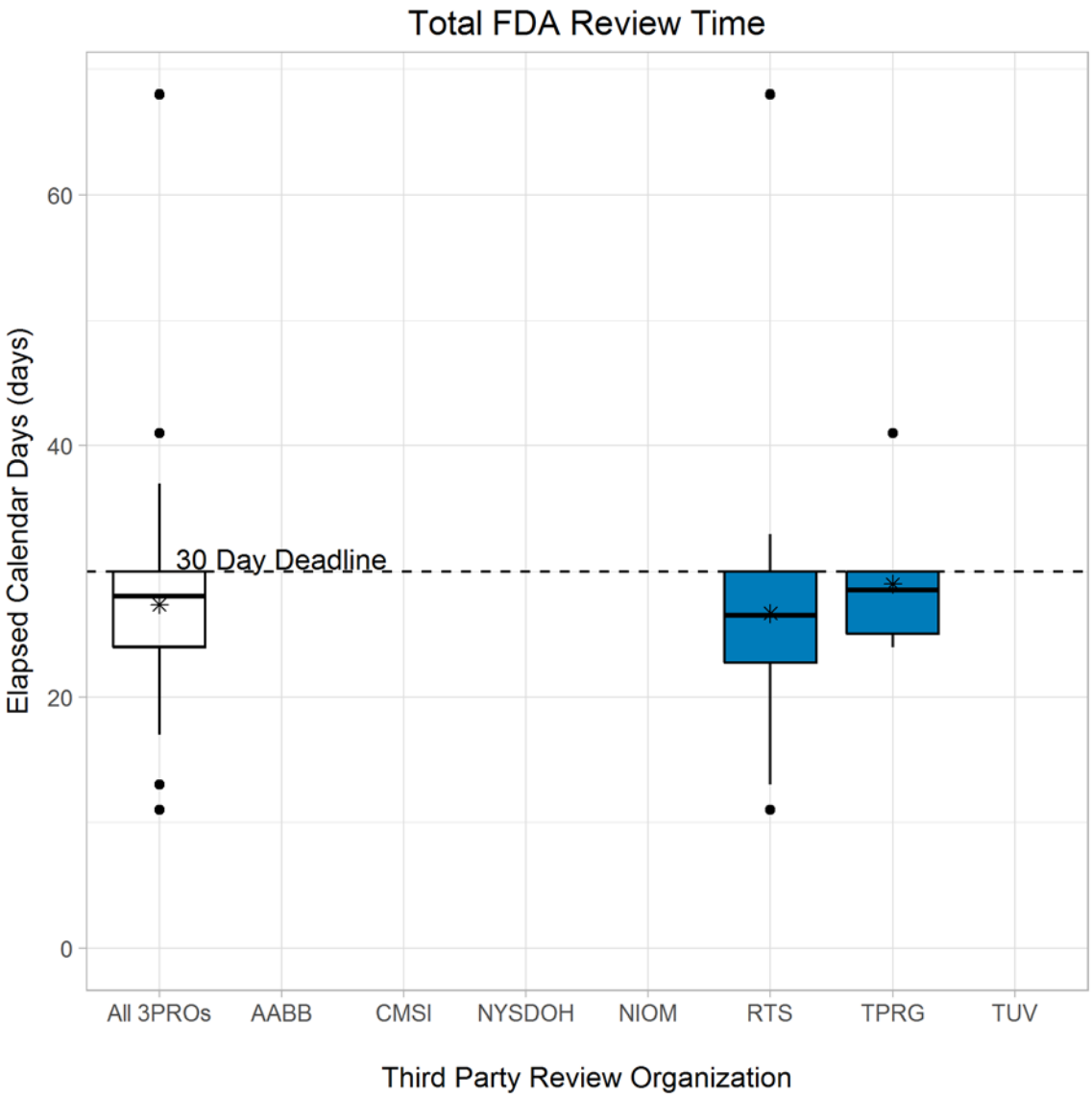


Figure 4. Total FDA Review Time.

Total Time to Decision from FDA Receipt – FY 2018

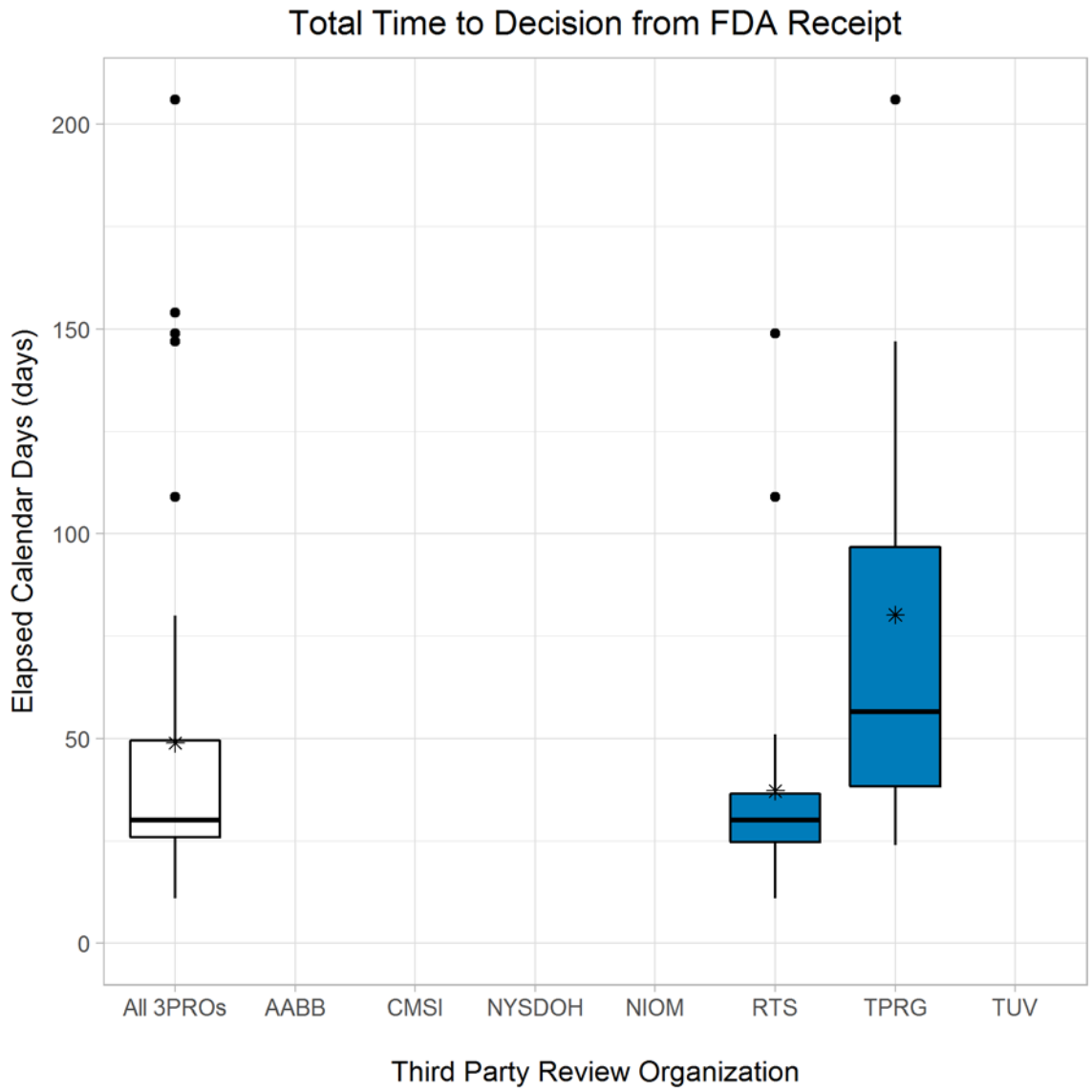


Figure 5. Total Time to Decision from FDA Receipt.

Total Time to Decision from Third Party Receipt – FY 2018

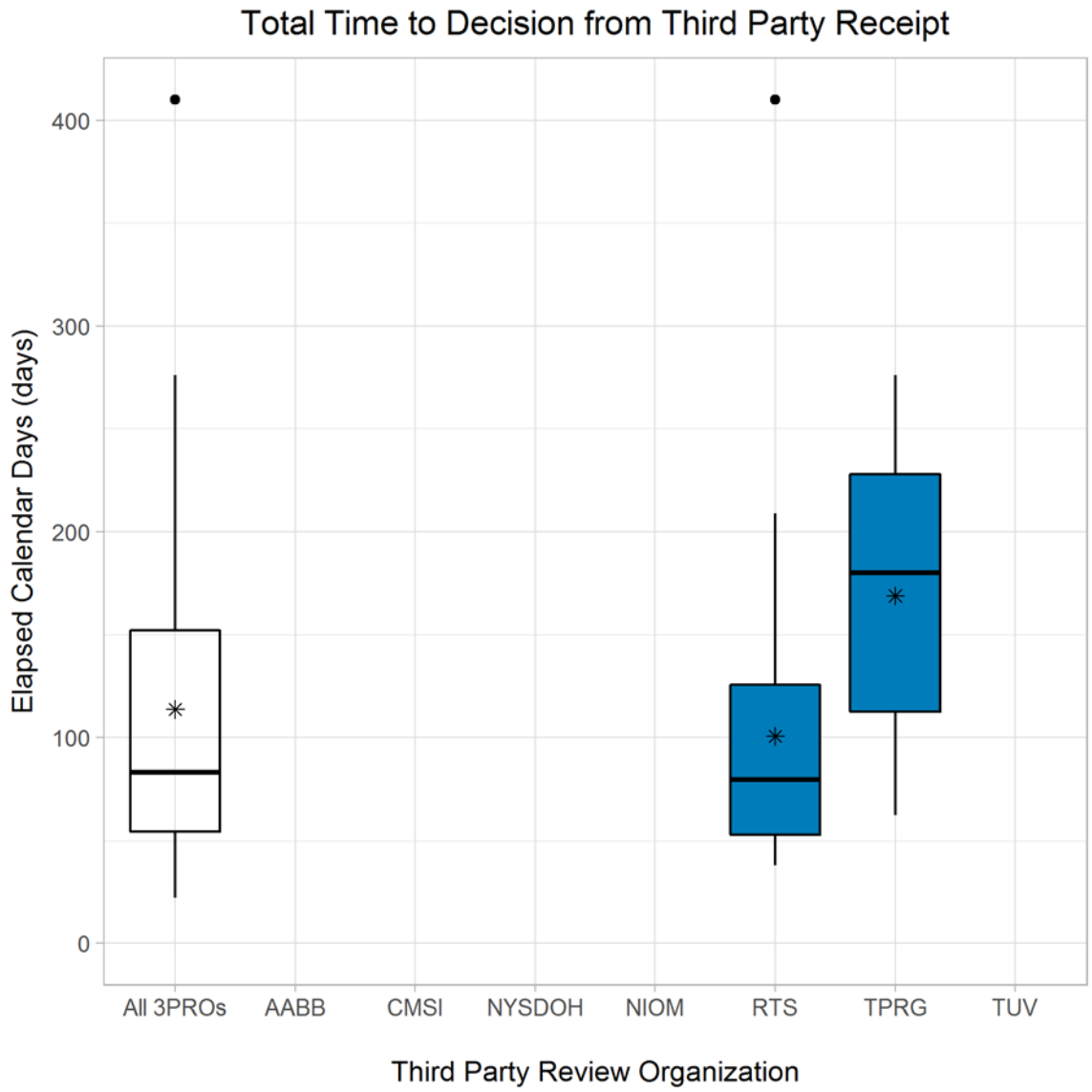


Figure 6. Total Time to Decision from Third Party Receipt.

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	53
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (2%)
MDUFA IV Final Decisions: SE or NSE (%)	38 (72%)
Pending Final Decision for less than 30 FDA days (%)	14 (26%)
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 (%)	90%
Average Holds	
Third Party Submission with a Final Decision	39
Total # Requests for Additional Information (Holds)	20
Average # Requests for Additional Information per Submission	0.51
Third Party Recommendation and Final Decision Agreement	
Third Party Submissions with a Final Decision	39
Third Party SE Recommendations	39 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	39
MDUFA IV Final Decision	
SE	38 (97%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	1 (3%)
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)	65
25th Percentile Initial Third Party Review Time	26
50th Percentile Initial Third Party Review Time	41
75th Percentile Initial Third Party Review Time	80
Maximum Initial Third Party Review Time	397
Average Third Party Hold Time (Calendar Days)	18
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	3
75th Percentile Third Party Hold Time	21
Maximum Third Party Hold Time	118
Average Total Third Party Review Time (Calendar Days)	82
25th Percentile Total Third Party Review Time	33
50th Percentile Total Third Party Review Time	55
75th Percentile Total Third Party Review Time	115
Maximum Total Third Party Review Time	397
Average Total FDA Review Time (Calendar Days)	28
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)	45
25th Percentile Total TTD from FDA Receipt	26
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	49
Maximum Cumulative TTD from FDA Receipt Date	154
Average Total Time to Decision from Third Party Receipt (Calendar Days)	110
25th Percentile Total TTD from Third Party Receipt	54
50th Percentile Total TTD from Third Party Receipt	82
75th Percentile Total TTD from Third Party Receipt	142
Maximum Total TTD from Third Party Receipt	410

AABB

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	36
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	28 (78%)
Pending Final Decision for less than 30 FDA days (%)	8 (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 (%)	93%
Average Holds	
Third Party Submission with a Final Decision	28
Total # Requests for Additional Information (Holds)	13
Average # Requests for Additional Information per Submission	0.46
Third Party Recommendation and Final Decision Agreement	
Third Party Submissions with a Final Decision	28
Third Party SE Recommendations	28 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	28
MDUFA IV Final Decision	
SE	28 (100%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
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)	64
25th Percentile Initial Third Party Review Time	29
50th Percentile Initial Third Party Review Time	41
75th Percentile Initial Third Party Review Time	73
Maximum Initial Third Party Review Time	397
Average Third Party Hold Time (Calendar Days)	11
25th Percentile Third Party Hold Time	0
50th Percentile Third Party Hold Time	0
75th Percentile Third Party Hold Time	12
Maximum Third Party Hold Time	116
Average Total Third Party Review Time (Calendar Days)	74
25th Percentile Total Third Party Review Time	29
50th Percentile Total Third Party Review Time	54
75th Percentile Total Third Party Review Time	91
Maximum Total Third Party Review Time	397
Average Total FDA Review Time (Calendar Days)	27
25th Percentile Total FDA Review Time	23
50th Percentile Total FDA Review Time	27
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	68
Average Total Time to Decision from FDA Receipt (Calendar Days)	38
25th Percentile Total TTD from FDA Receipt	25
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	37
Maximum Cumulative TTD from FDA Receipt Date	149
Average Total Time to Decision from Third Party Receipt (Calendar Days)	101
25th Percentile Total TTD from Third Party Receipt	53
50th Percentile Total TTD from Third Party Receipt	80
75th Percentile Total TTD from Third Party Receipt	126
Maximum Total TTD from Third Party Receipt	410

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	13
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	1 (8%)
MDUFA IV Final Decisions: SE or NSE (%)	7 (54%)
Pending Final Decision for less than 30 FDA days (%)	5 (38%)
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 (%)	86%
Average Holds	
Third Party Submission with a Final Decision	8
Total # Requests for Additional Information (Holds)	5
Average # Requests for Additional Information per Submission	0.62
Third Party Recommendation and Final Decision Agreement	
Third Party Submissions with a Final Decision	8
Third Party SE Recommendations	8 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	8
MDUFA IV Final Decision	
SE	7 (88%)
NSE	0 (0%)
Non-MDUFA IV Final Decision	
Withdrawn	0 (0%)
Deleted	1 (12%)
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)	91
25th Percentile Initial Third Party Review Time	56
50th Percentile Initial Third Party Review Time	80
75th Percentile Initial Third Party Review Time	128
Maximum Initial Third Party Review Time	168
Average Third Party Hold Time (Calendar Days)	33
25th Percentile Third Party Hold Time	7
50th Percentile Third Party Hold Time	22
75th Percentile Third Party Hold Time	38
Maximum Third Party Hold Time	118
Average Total Third Party Review Time (Calendar Days)	124
25th Percentile Total Third Party Review Time	69
50th Percentile Total Third Party Review Time	137
75th Percentile Total Third Party Review Time	180
Maximum Total Third Party Review Time	198
Average Total FDA Review Time (Calendar Days)	30
25th Percentile Total FDA Review Time	27
50th Percentile Total FDA Review Time	29
75th Percentile Total FDA Review Time	30
Maximum Total FDA Review Time	41
Average Total Time to Decision from FDA Receipt (Calendar Days)	63
25th Percentile Total TTD from FDA Receipt	36
50th Percentile Total TTD from FDA Receipt	50
75th Percentile Total TTD from FDA Receipt	72
Maximum Cumulative TTD from FDA Receipt Date	147
Average Total Time to Decision from Third Party Receipt (Calendar Days)	154
25th Percentile Total TTD from Third Party Receipt	97
50th Percentile Total TTD from Third Party Receipt	161
75th Percentile Total TTD from Third Party Receipt	213
Maximum Total TTD from Third Party Receipt	231

TUV SUD America Inc. (TUV)

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