

Third Party Review Organization Performance Report

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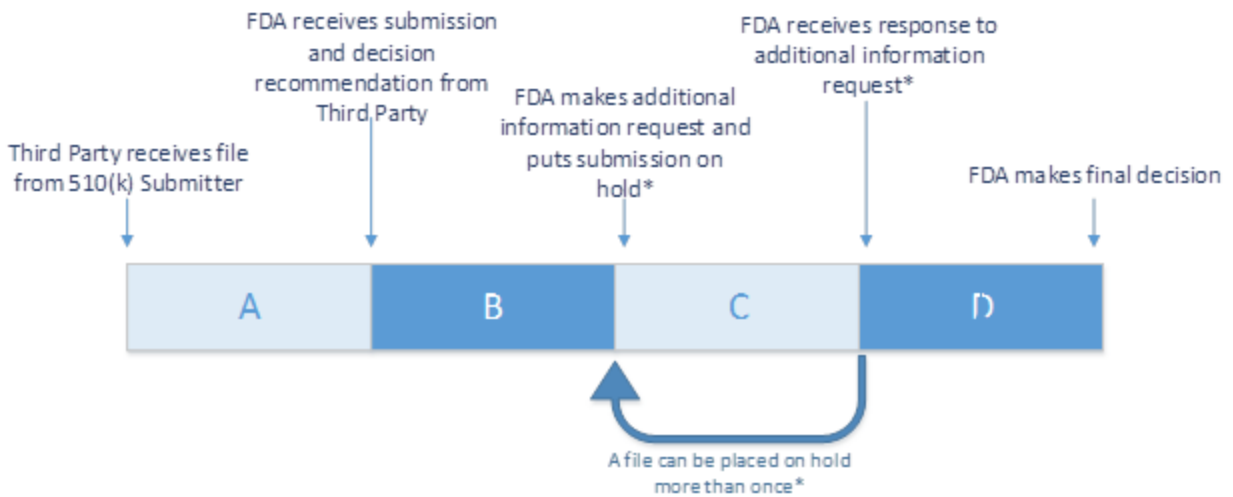
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Introduction and Review Timeline Description

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 Q2 (October 1, 2017 through March 31, 2018). At this time, there is one Third Party Review Organization 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) Third Party Initial Review Time = A
- 2) Third Party Total Review Time = A + C
- 3) Total FDA Days = B + D
- 4) Third Party Hold Time = C*
- 5) Cumulative Time to Decision from FDA Receipt Date = B + C + D
- 6) Cumulative Time to Decision from TP Receipt Date = 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 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:**

- = *Third Party Initial 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

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

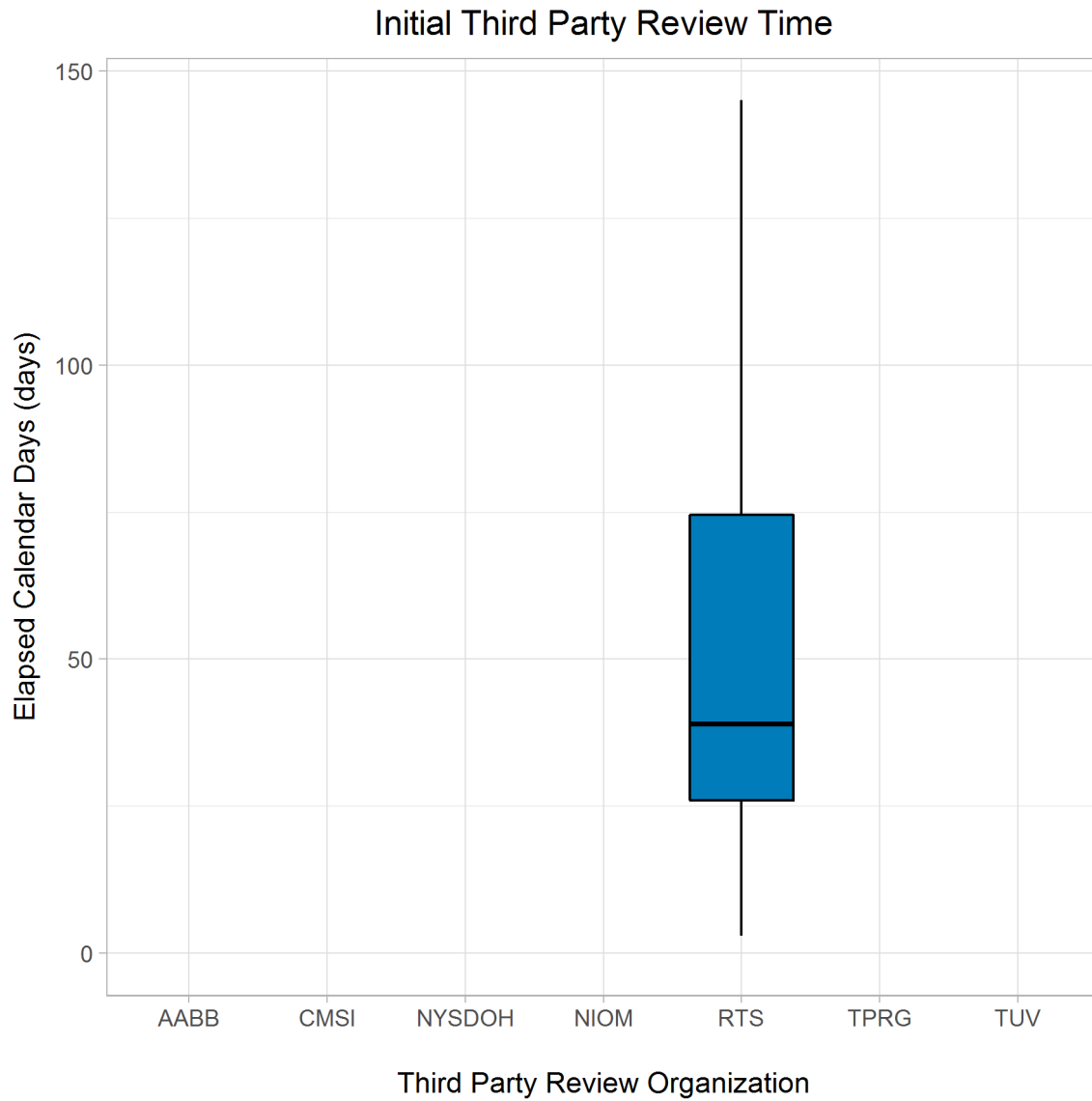


Figure 1. Initial Third Party Review Time.

Third Party Hold Time – FY 2018

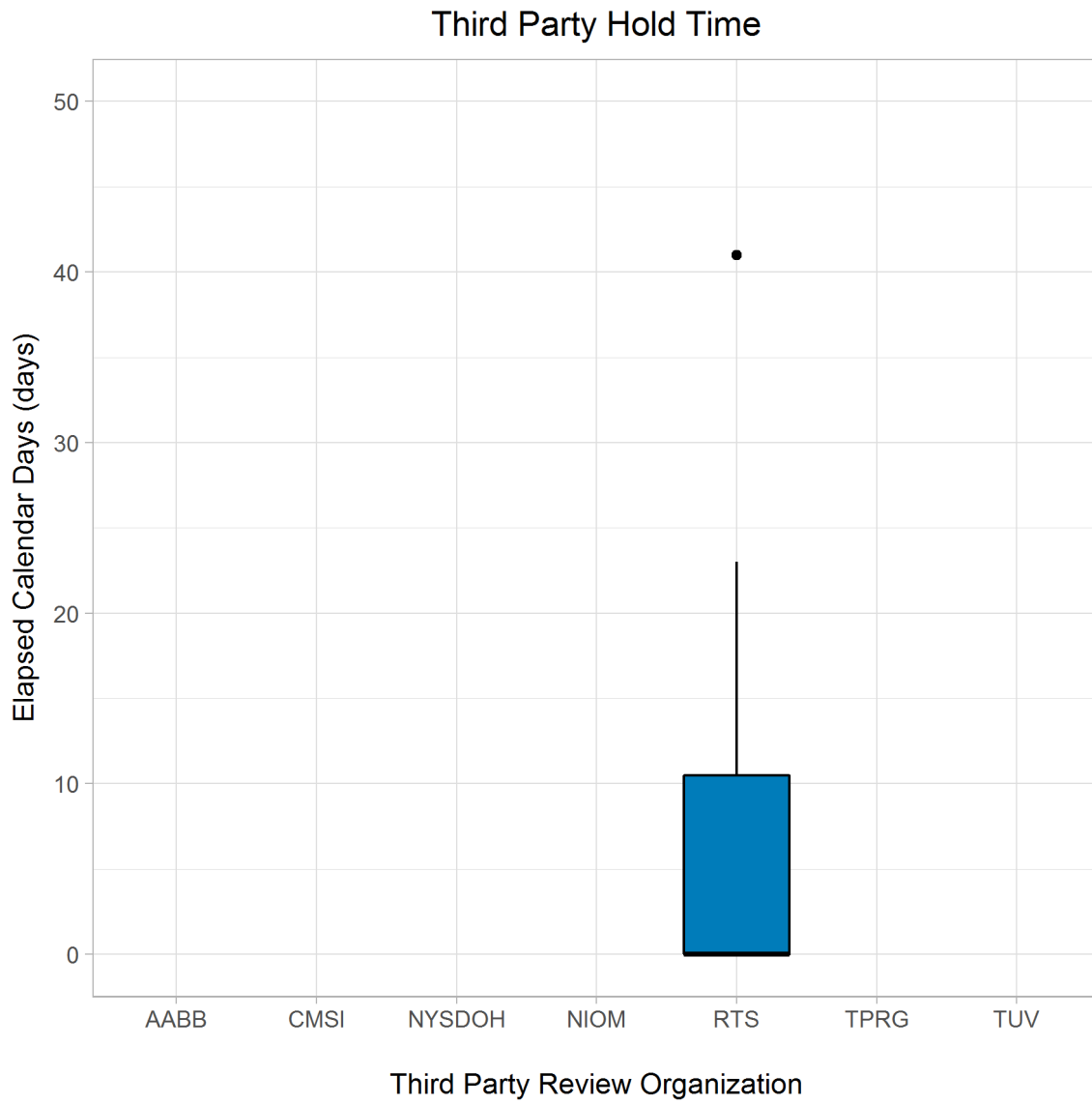


Figure 2. Third Party Hold Time.

Total Third Party Review Time – FY 2018

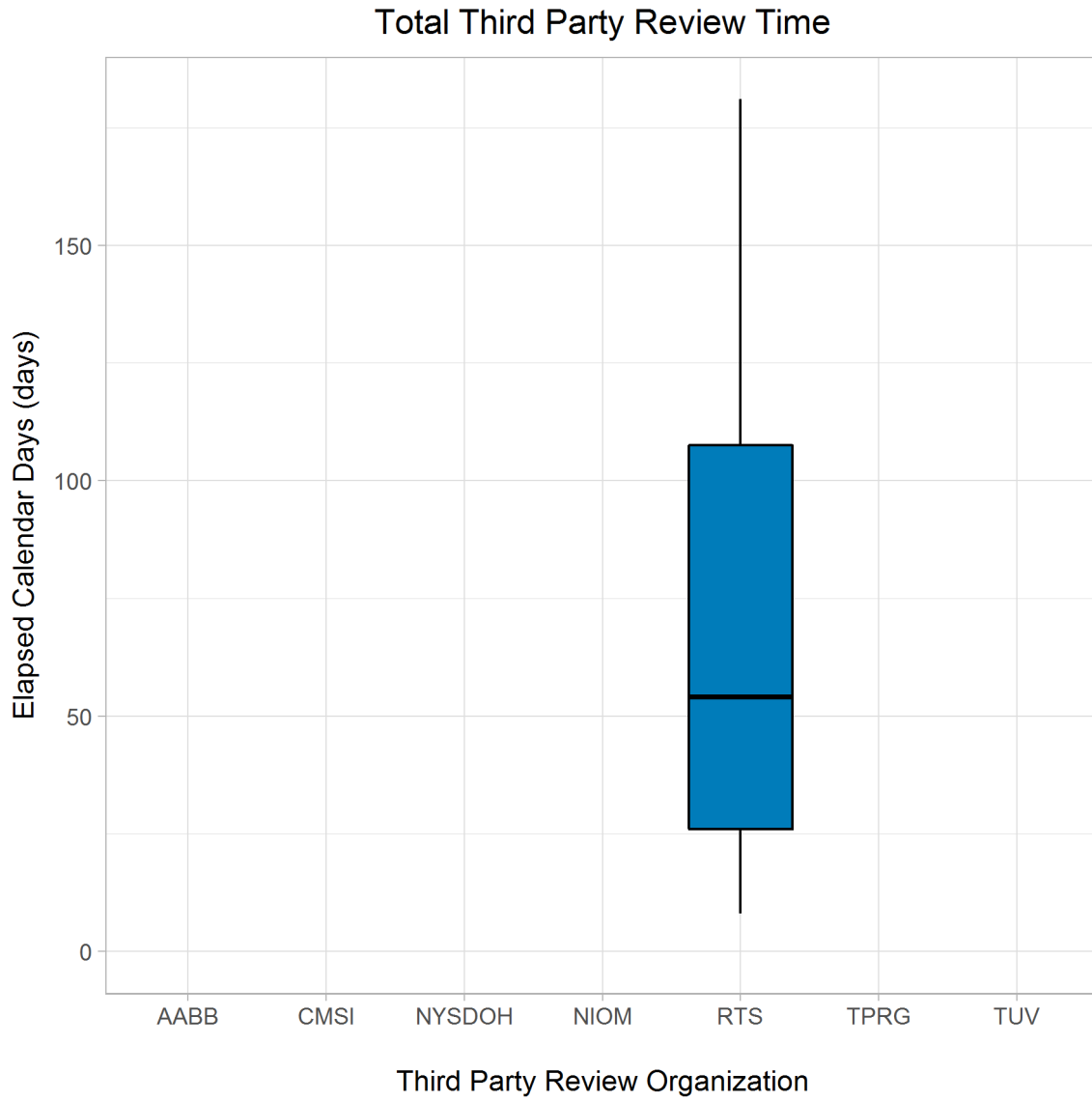


Figure 3. Total Third Party Review Time.

Total FDA Review Time – FY 2018

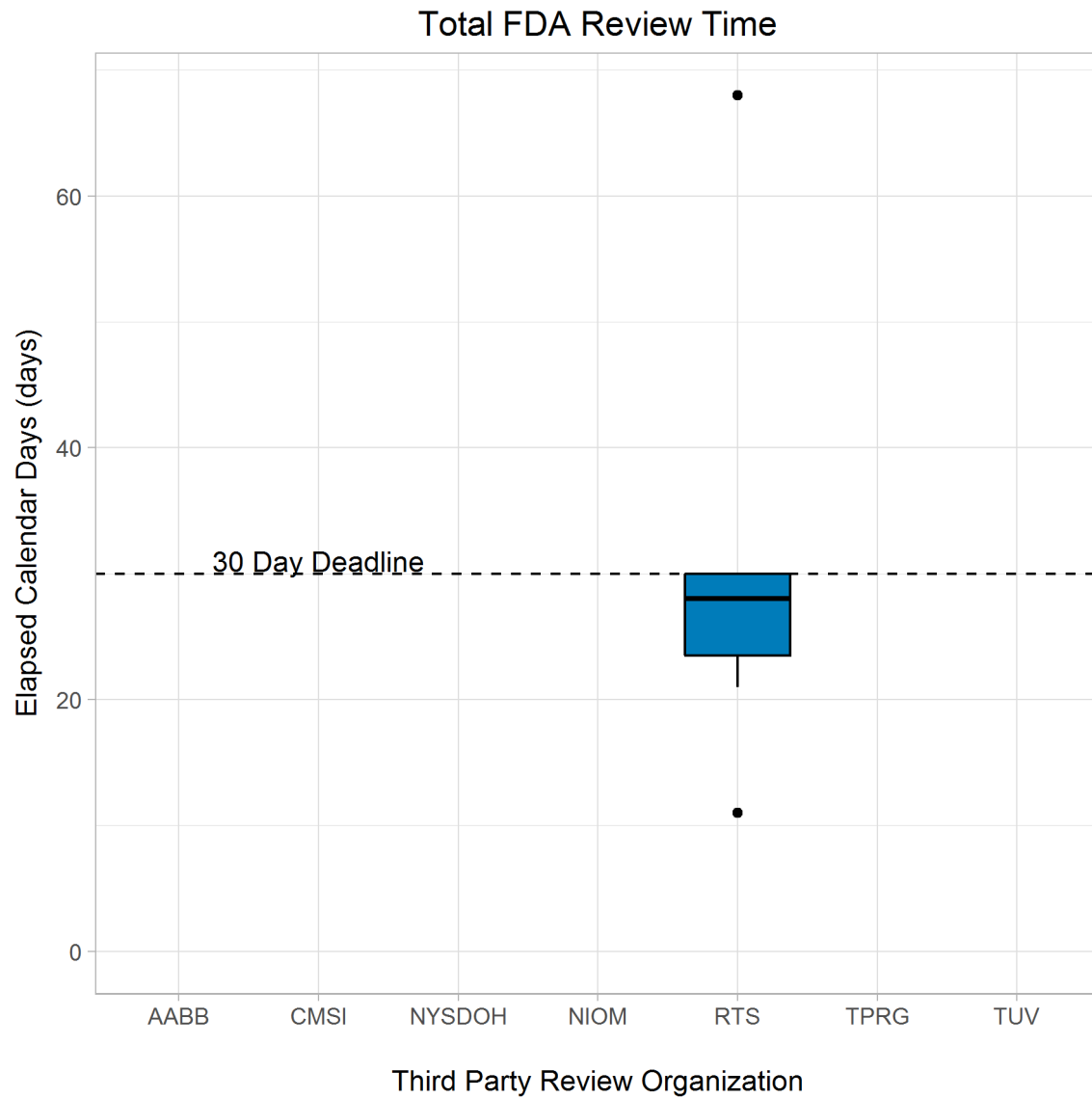


Figure 4. Total FDA Review Time.

Total Time to Decision from FDA Receipt – FY 2018

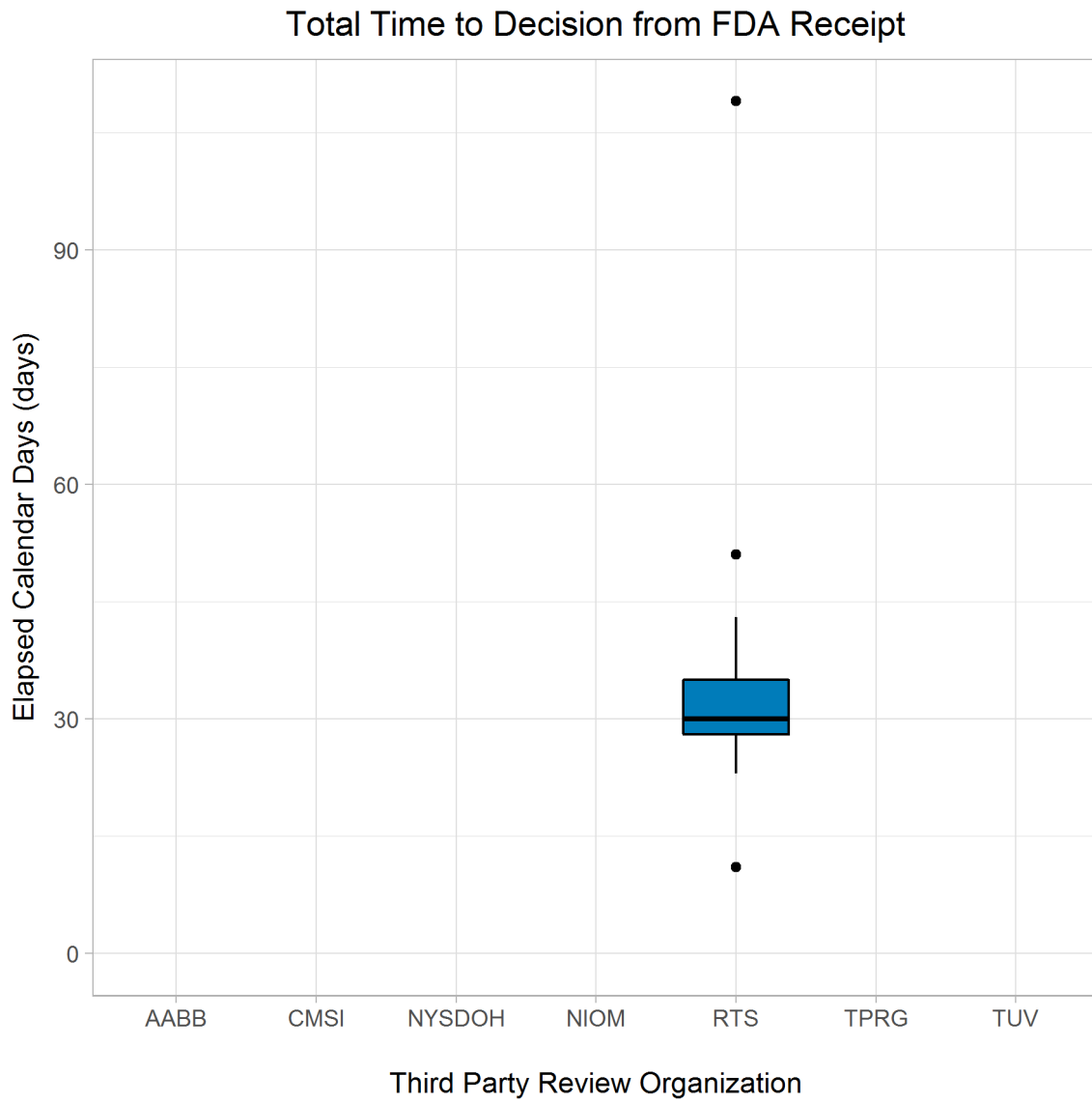


Figure 5. Total Time to Decision from FDA Receipt.

Total Time to Decision from Third Party Receipt – FY 2018

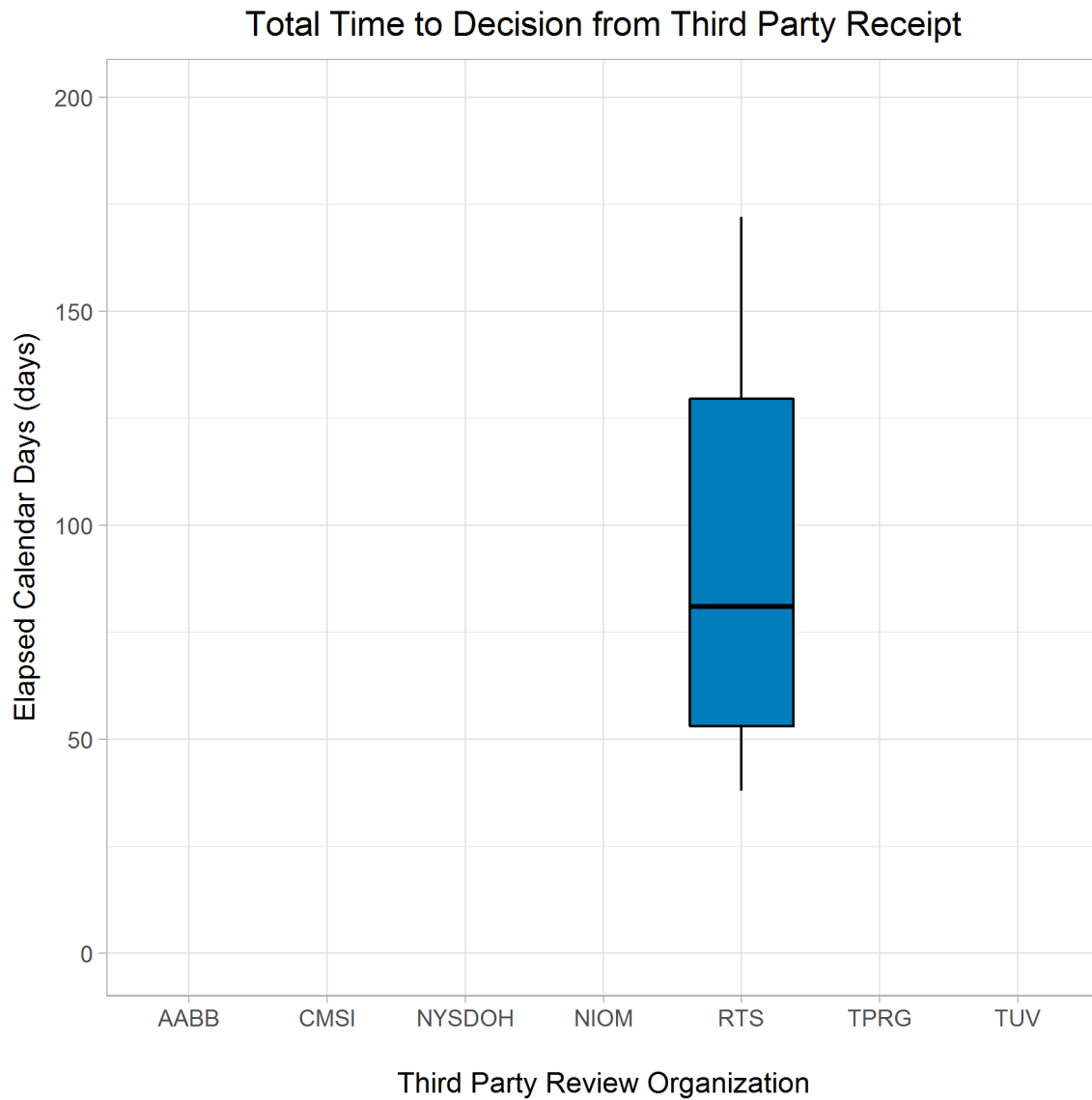


Figure 6. Total Time to Decision from Third Party Receipt.

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	33
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	20 (61%)
Pending Final Decision for less than 30 FDA days (%)	13 (39%)
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 (%)	95%
<i>Average Holds</i>	
Third Party Submission with a Final Decision	20
Total # Requests for Additional Information (Holds)	10
Average # Requests for Additional Information per Submission	0.5
<i>Third Party Recommendation and Final Decision Agreement</i>	
Third Party Submissions with a Final Decision	20
Third Party SE Recommendations	20 (100%)
Third Party NSE Recommendations	0 (0%)
Third Party SE Recommendations with a Final Decision	20
MDUFA IV Final Decision	
SE	20 (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 1.2. All: Third Party 510(k) Review Time Performance Metrics.

Performance Metric	FY2018
Average Initial Third Party Review Time (Calendar Days)	56
25th Percentile Initial Third Party Review Time	26
50th Percentile Initial Third Party Review Time	39
75th Percentile Initial Third Party Review Time	84
Maximum Initial Third Party Review Time	145
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	12
Maximum Third Party Hold Time	50
Average Total Third Party Review Time (Calendar Days)	72
25th Percentile Total Third Party Review Time	26
50th Percentile Total Third Party Review Time	58
75th Percentile Total Third Party Review Time	115
Maximum Total Third Party Review Time	181
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)	37
25th Percentile Total TTD from FDA Receipt	27
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	37
Maximum Cumulative TTD from FDA Receipt Date	109
Average Total Time to Decision from Third Party Receipt (Calendar Days)	93
25th Percentile Total TTD from Third Party Receipt	53
50th Percentile Total TTD from Third Party Receipt	75
75th Percentile Total TTD from Third Party Receipt	138
Maximum Total TTD from Third Party Receipt	199

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	21
Non-MDUFA IV Final Decisions: Withdrawn or Deleted (%)	0 (0%)
MDUFA IV Final Decisions: SE or NSE (%)	15 (71%)
Pending Final Decision for less than 30 FDA days (%)	6 (29%)
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 (%)	94%
<i>Average Holds</i>	
Third Party Submission with a Final Decision	15
Total # Requests for Additional Information (Holds)	8
Average # Requests for Additional Information per Submission	0.53
<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	15 (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)	54
25th Percentile Initial Third Party Review Time	26
50th Percentile Initial Third Party Review Time	39
75th Percentile Initial Third Party Review Time	75
Maximum Initial Third Party Review Time	145
Average Third Party Hold Time (Calendar Days)	8
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	41
Average Total Third Party Review Time (Calendar Days)	71
25th Percentile Total Third Party Review Time	26
50th Percentile Total Third Party Review Time	54
75th Percentile Total Third Party Review Time	108
Maximum Total Third Party Review Time	181
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	68
Average Total Time to Decision from FDA Receipt (Calendar Days)	36
25th Percentile Total TTD from FDA Receipt	28
50th Percentile Total TTD from FDA Receipt	30
75th Percentile Total TTD from FDA Receipt	35
Maximum Cumulative TTD from FDA Receipt Date	109
Average Total Time to Decision from Third Party Receipt (Calendar Days)	90
25th Percentile Total TTD from Third Party Receipt	53
50th Percentile Total TTD from Third Party Receipt	81
75th Percentile Total TTD from Third Party Receipt	130
Maximum Total TTD from Third Party Receipt	172

Third Party Review Group, LLC (TPRG)

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

TUV SUD America Inc. (TUV)

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