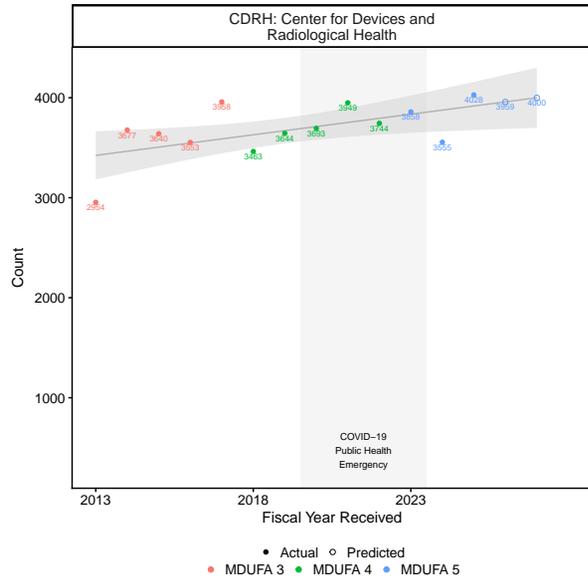


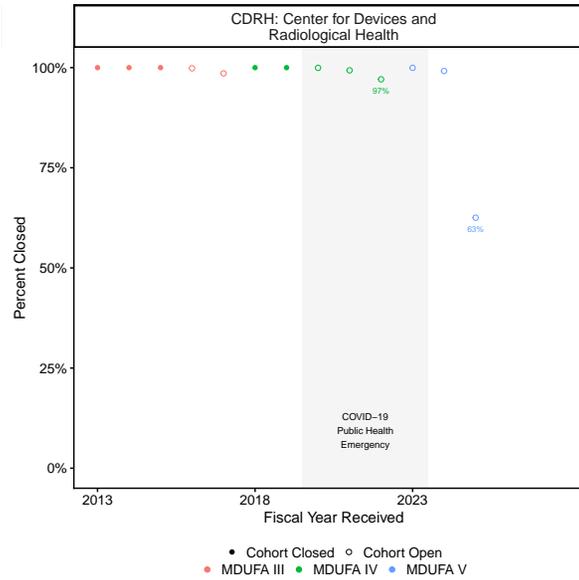
### 510(k)s received



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Percent of 510(k)s closed

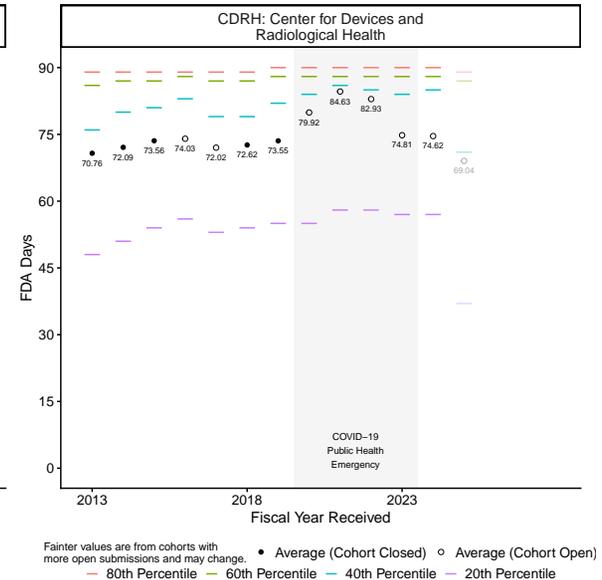
As of MDUFA performance report cutoff dates



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### 510(k) FDA Days performance metrics

As of MDUFA performance report cutoff dates

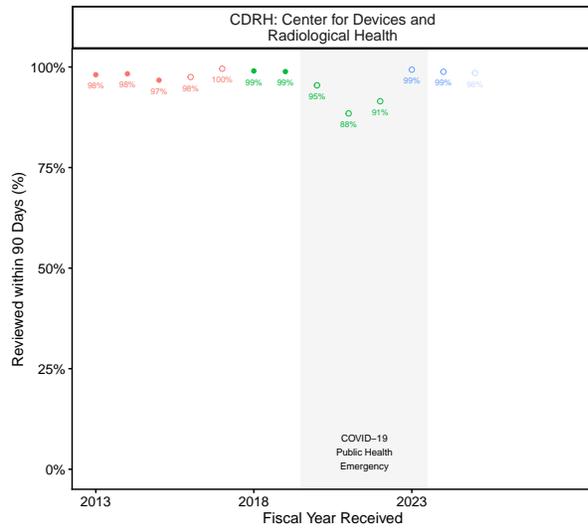


Fainter values are from cohorts with more open submissions and may change.

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### FDA Days on-time performance percentage for 510(k)s

As of MDUFA performance report cutoff dates

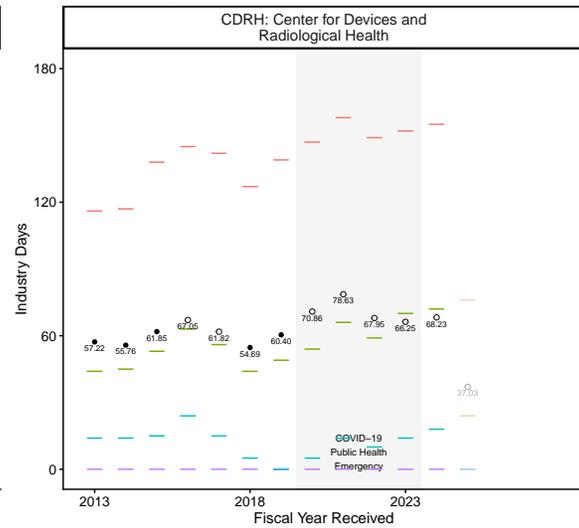


Fainter values are from cohorts with more open submissions and may change.

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### 510(k) Industry Days performance metrics

As of MDUFA performance report cutoff dates

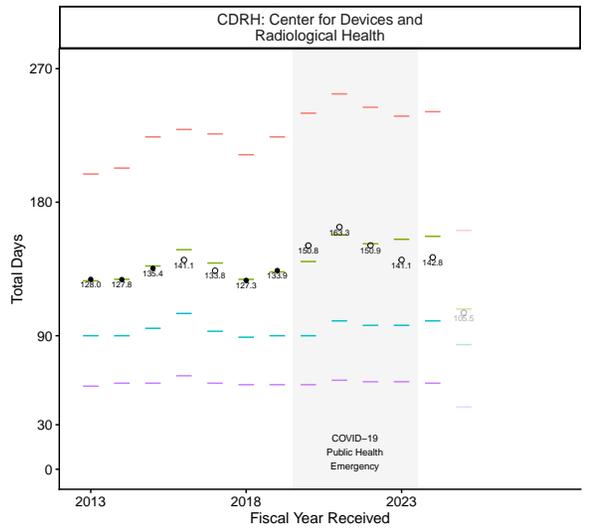


Fainter values are from cohorts with more open submissions and may change.

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### 510(k) Total Days performance metrics

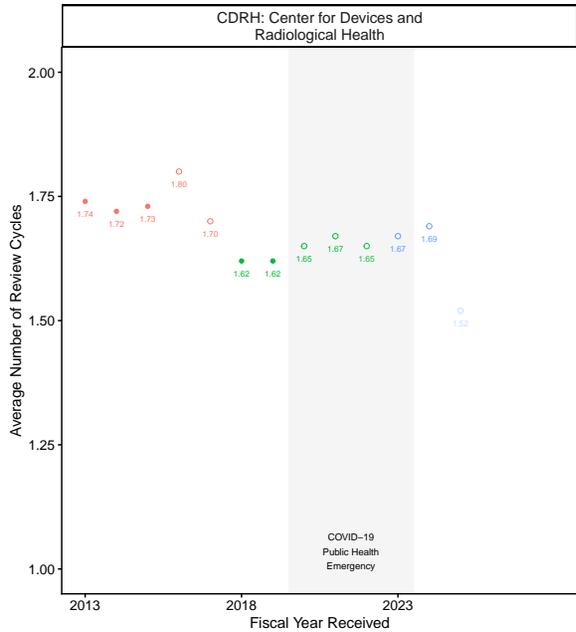
As of MDUFA performance report cutoff dates



Fainter values are from cohorts with more open submissions and may change.

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

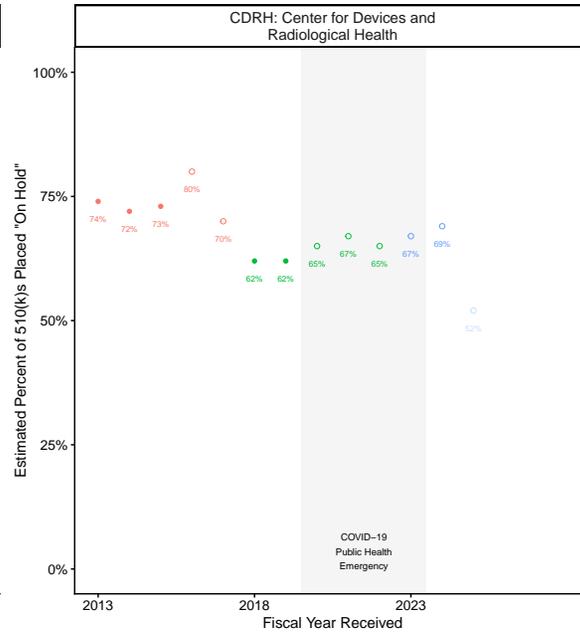
Average number of review cycles for 510(k)s  
As of MDUFA performance report cutoff dates



Fainter values are from cohorts with more open submissions and may change. ● Cohort Closed ○ Cohort Open  
● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

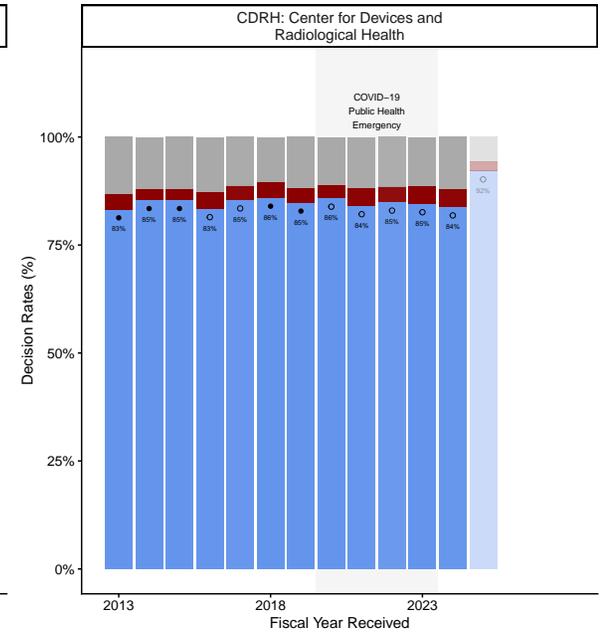
Estimated rate at which 510(k)s are placed "on hold"  
As of MDUFA performance report cutoff dates  
Estimates based on the average number of review cycles



Fainter values are from cohorts with more open submissions and may change. ● Cohort Closed ○ Cohort Open  
● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

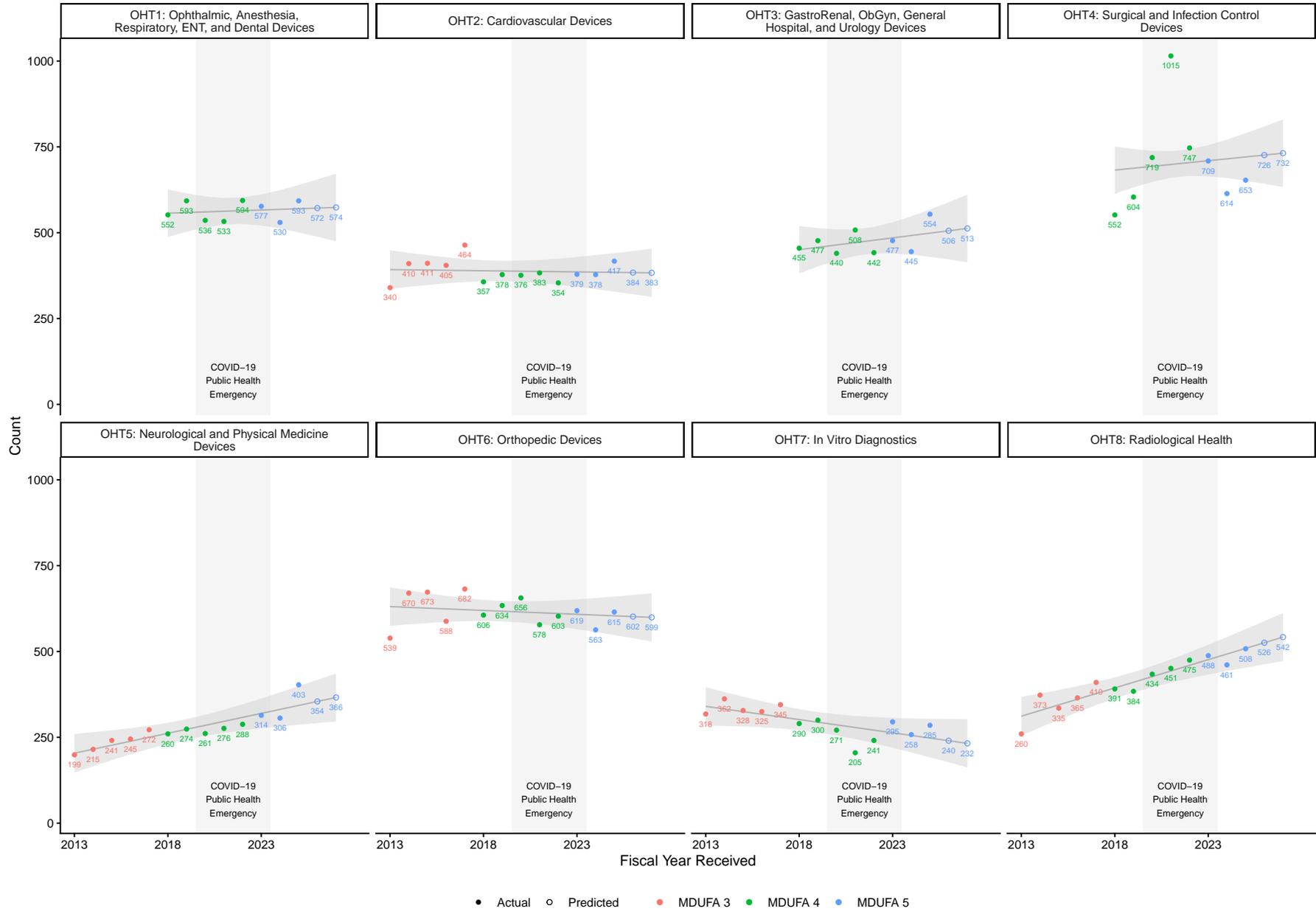
Rate at which 510(k)s are cleared for market  
As of MDUFA performance report cutoff dates



Fainter values are from cohorts with more open submissions and may change. ● Cohort Closed ○ Cohort Open  
■ Withdrawn or Deleted (Not Cleared) ■ NSE (Not Cleared) ■ SE (Cleared)

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

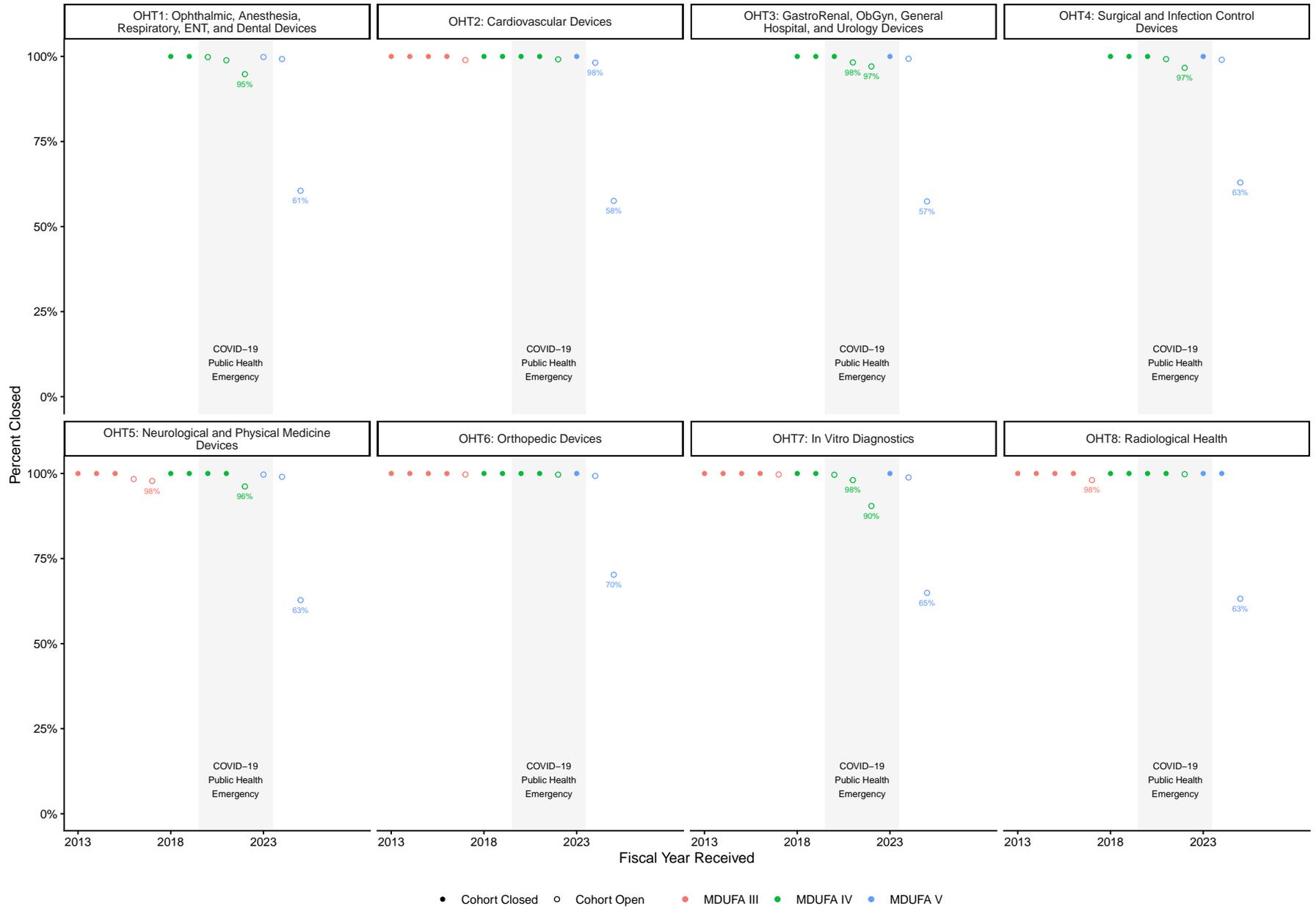
510(k)s received  
By review group and fiscal year received



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# Percent of 510(k)s closed as of MDUFA performance report cutoff dates

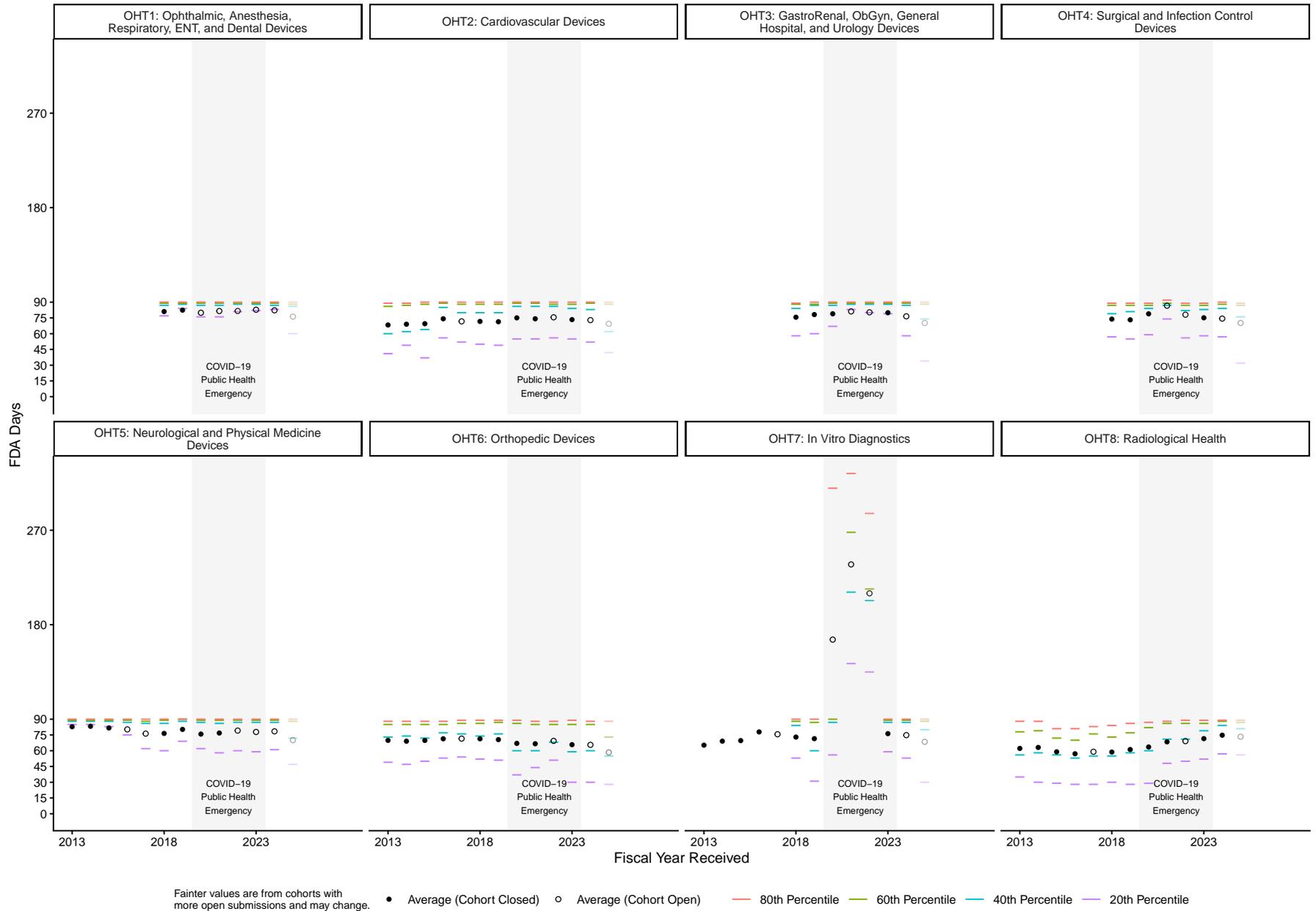
By review group and fiscal year received



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### 510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

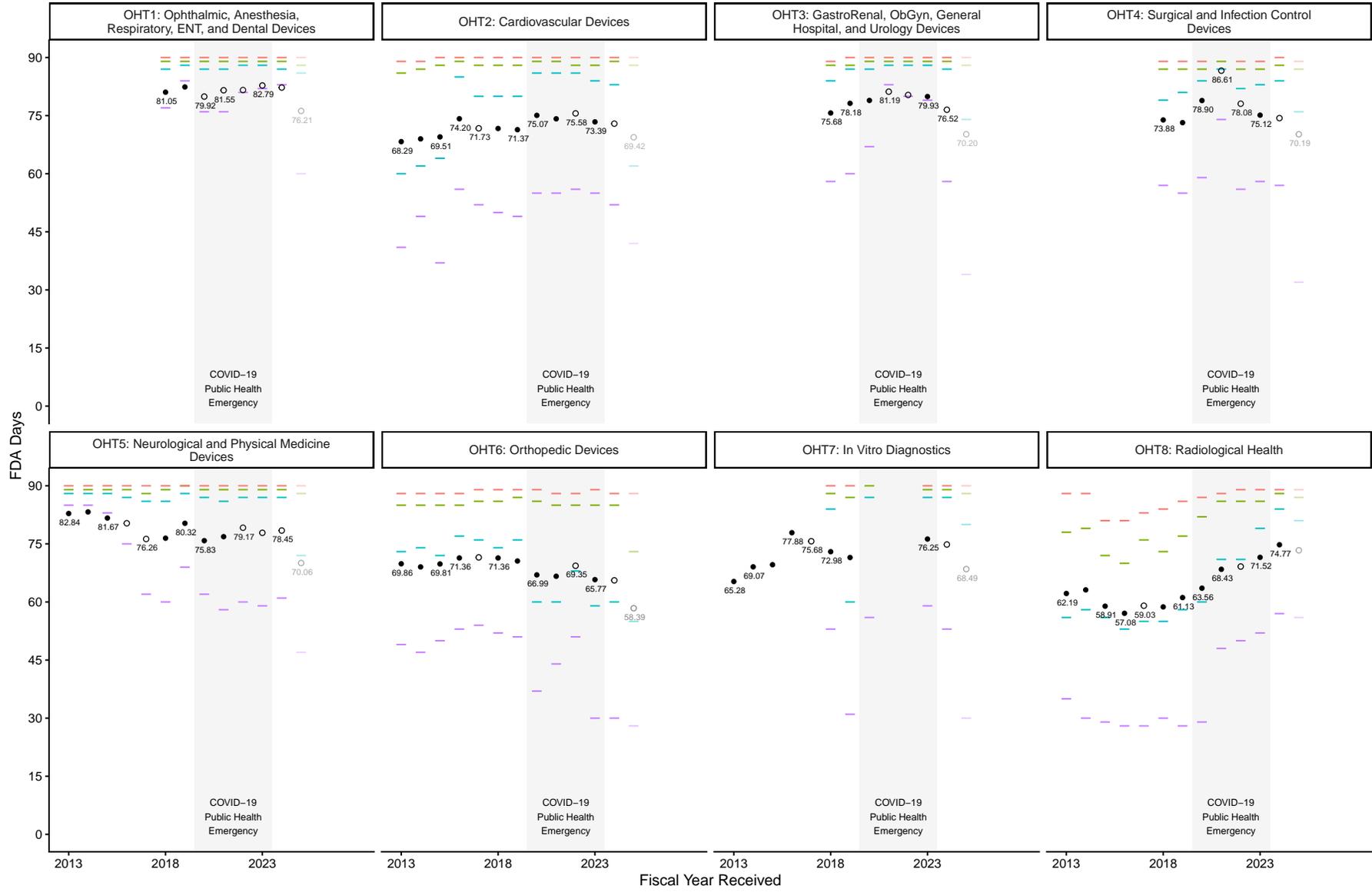
By review group and fiscal year received



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# 510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received  
 Values above 90 FDA Days are not shown

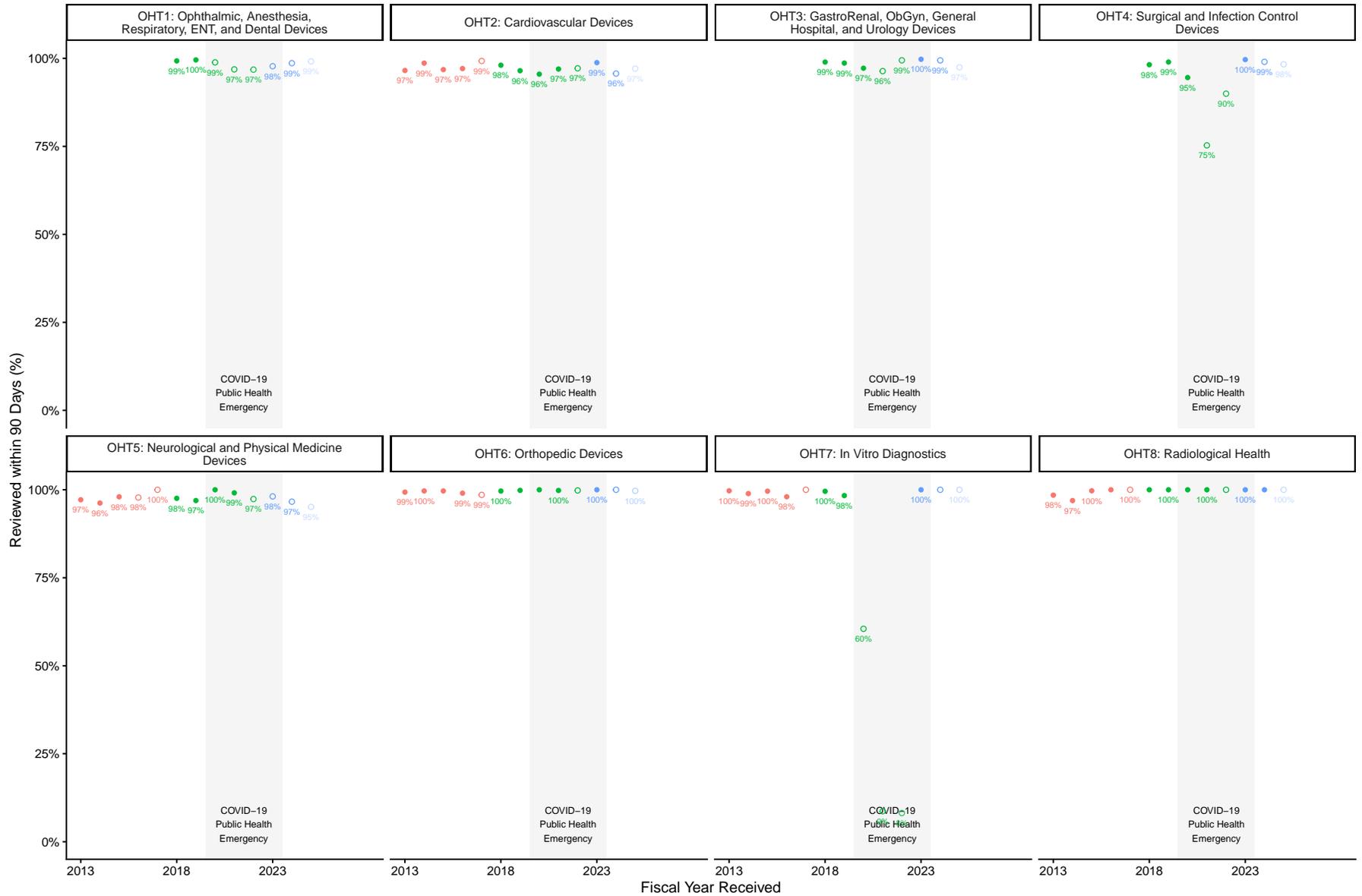


Fainter values are from cohorts with more open submissions and may change. ● Average (Cohort Closed) ○ Average (Cohort Open) — 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# FDA Days on-time performance percentage for 510(k)s as of MDUFA performance report cutoff dates

By review group and fiscal year received



Fainter values are from cohorts with more open submissions and may change.

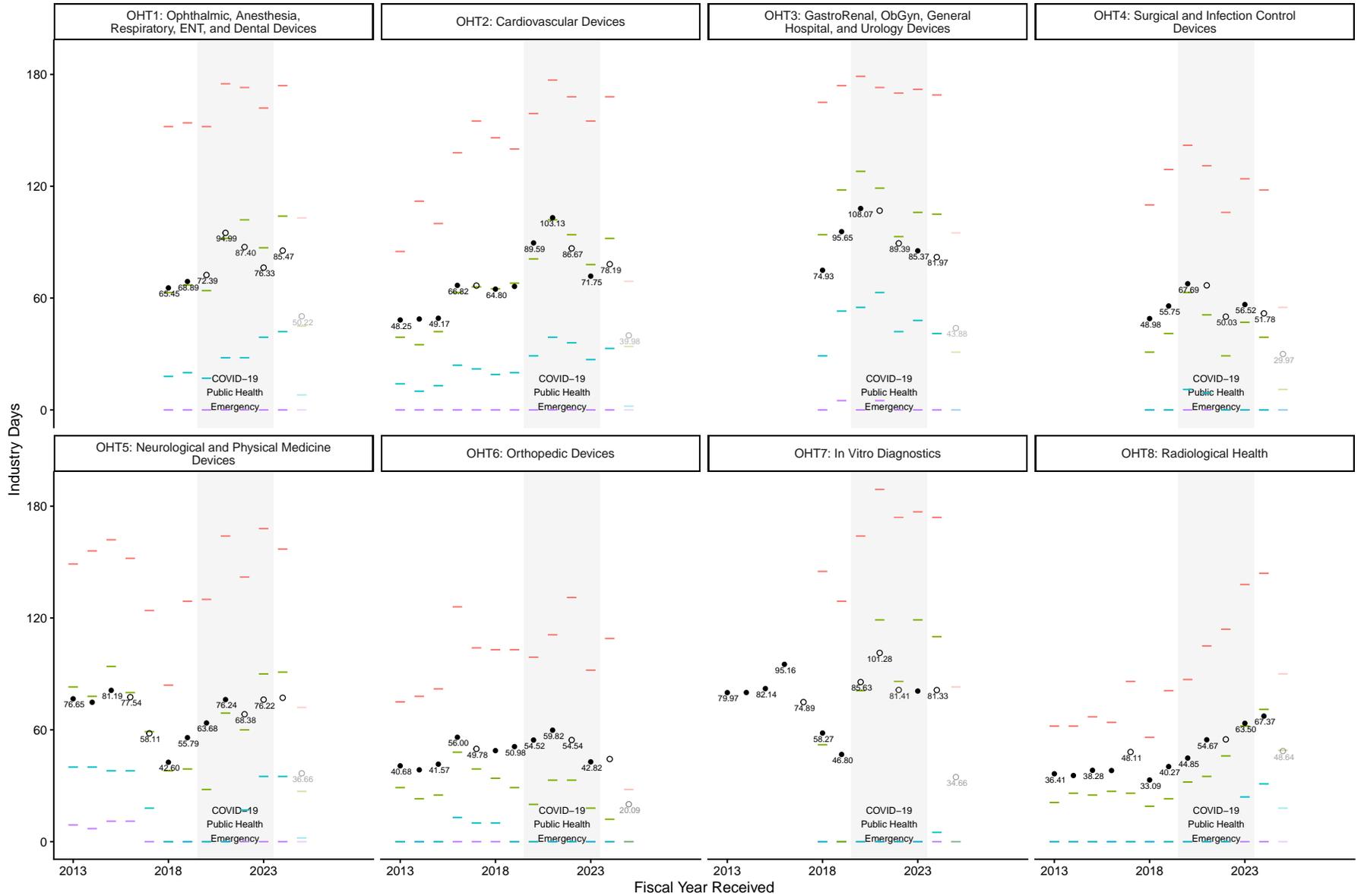
● Cohort Closed ○ Cohort Open

● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# 510(k) Industry Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received

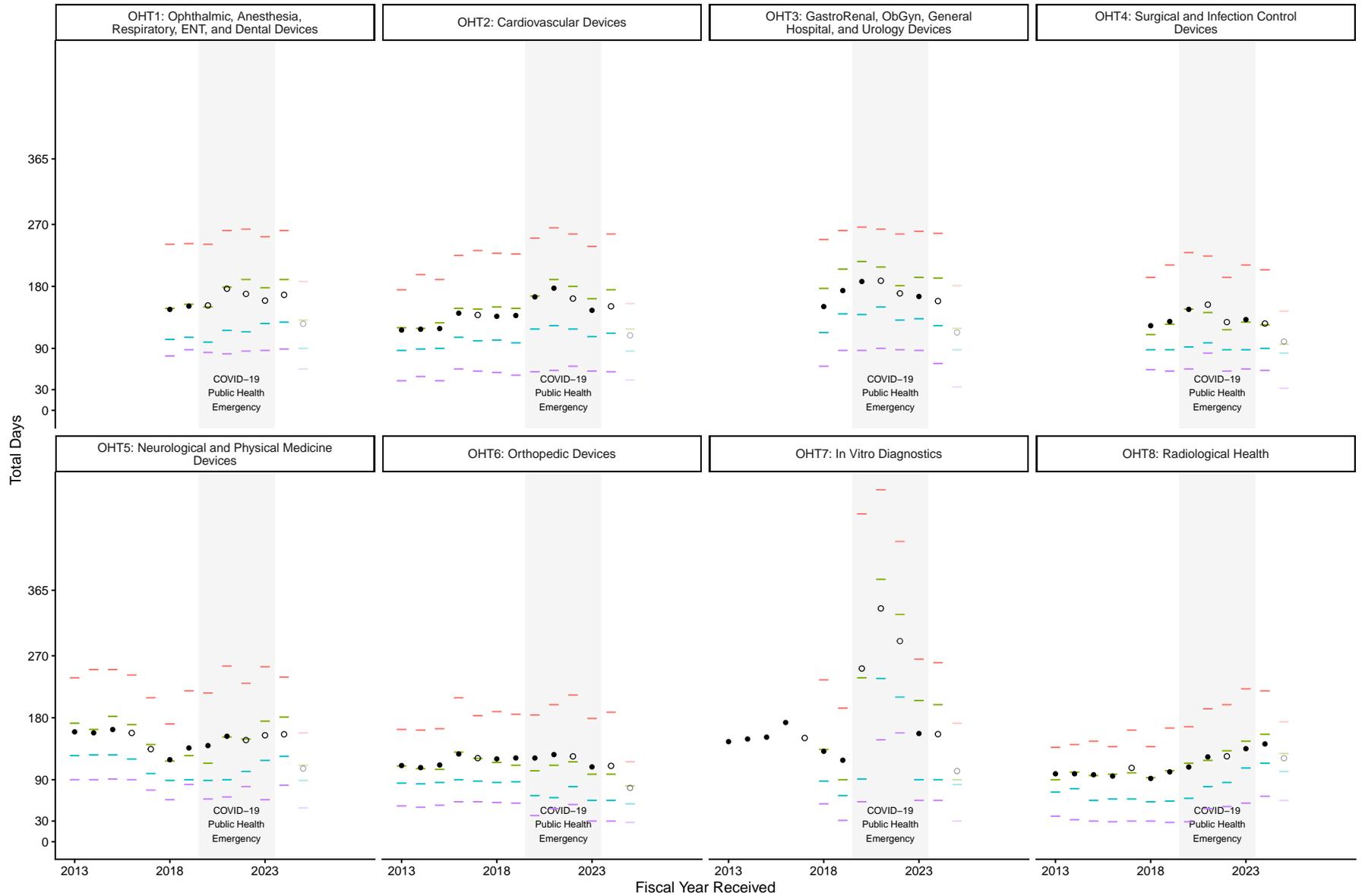


Fainter values are from cohorts with more open submissions and may change. ● Average (Cohort Closed) ○ Average (Cohort Open) — 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

510(k) Total Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received

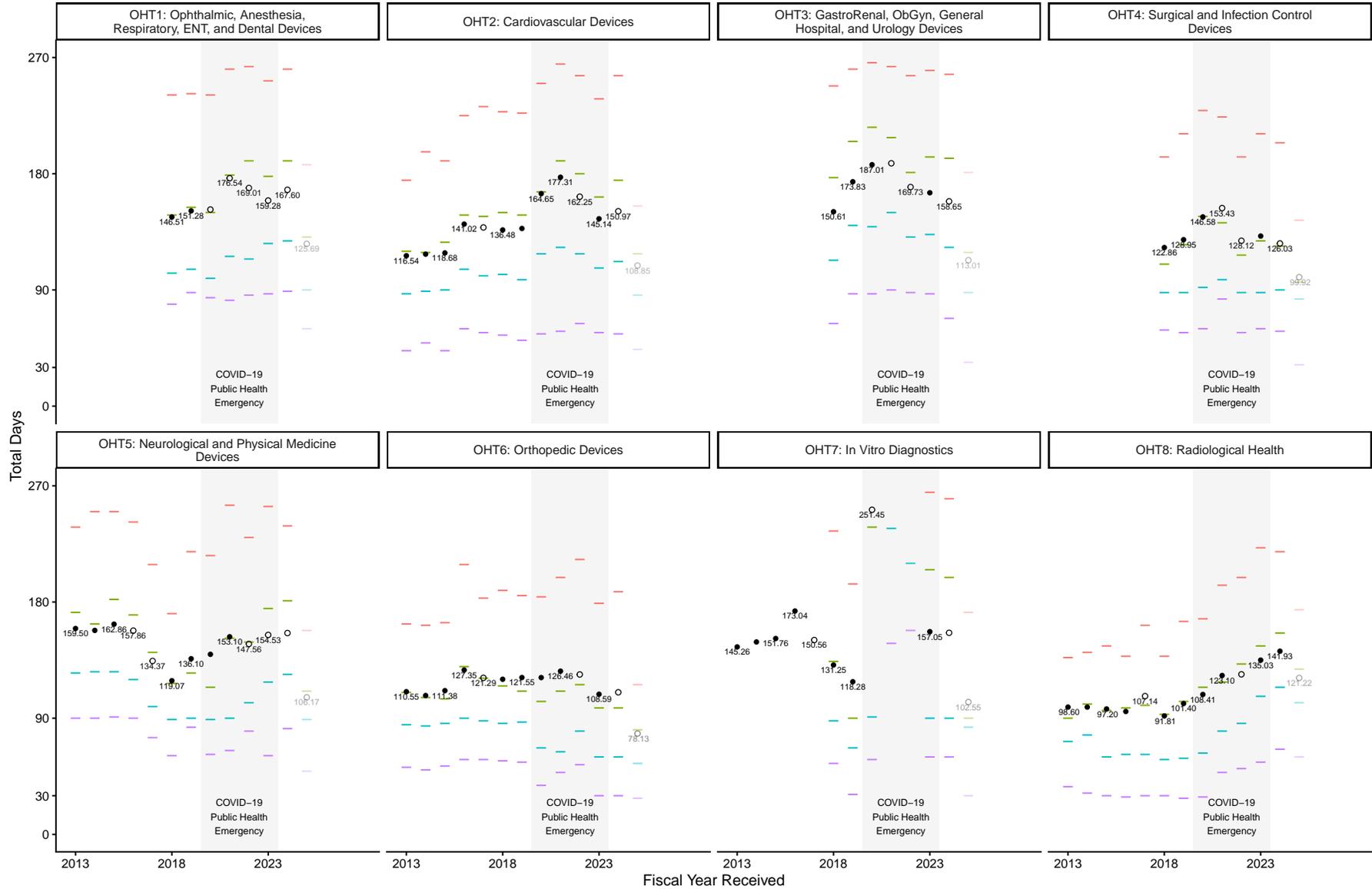


Fainter values are from cohorts with more open submissions and may change. ● Average (Cohort Closed) ○ Average (Cohort Open) — 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### 510(k) Total Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received  
 Values above 270 Total Days are not shown

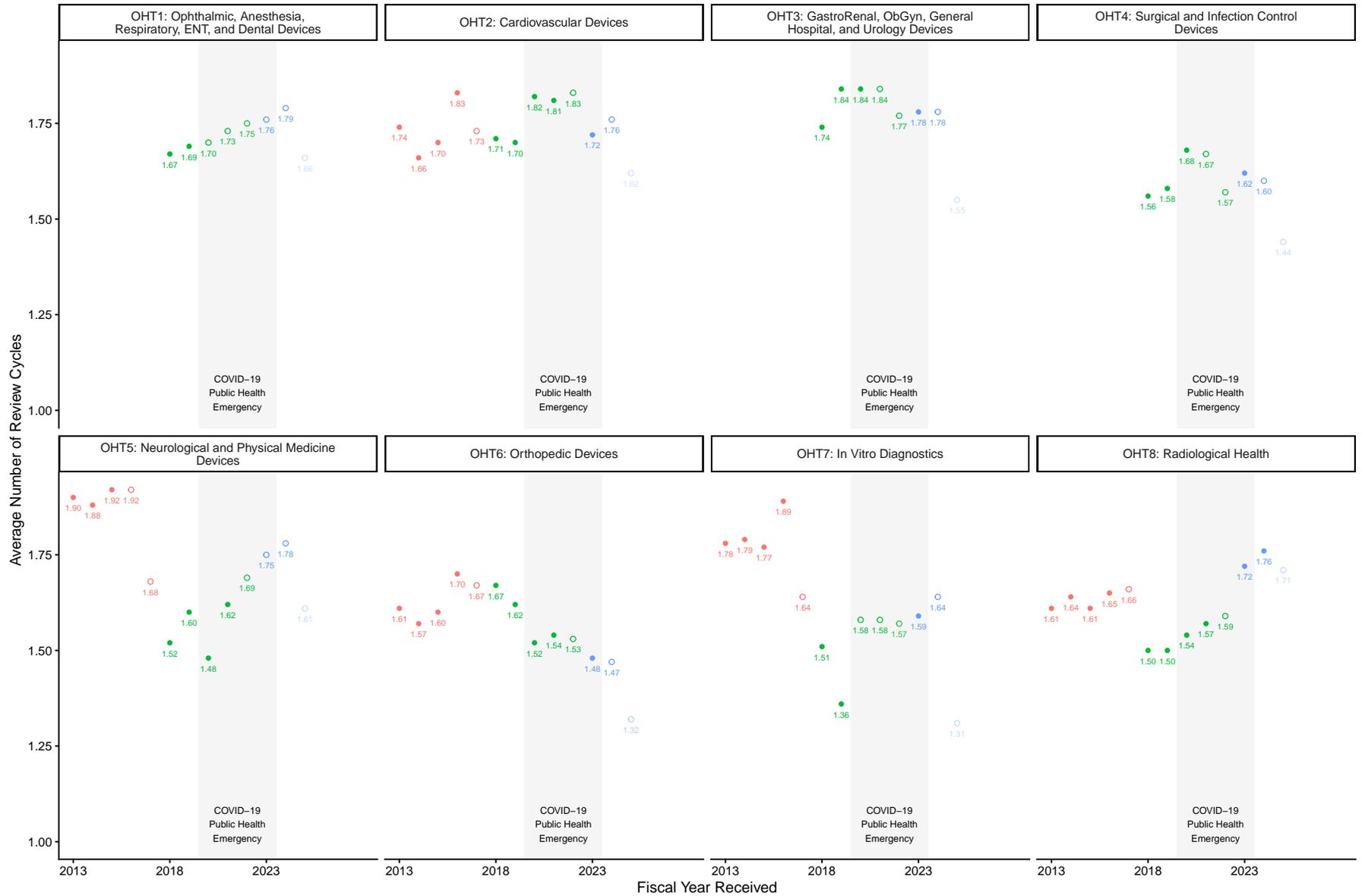


Fainter values are from cohorts with more open submissions and may change. ● Average (Cohort Closed) ○ Average (Cohort Open) — 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# Average number of review cycles for 510(k)s as of MDUFA performance report cutoff dates

By review group and fiscal year received



Fainter values are from cohorts with more open submissions and may change.

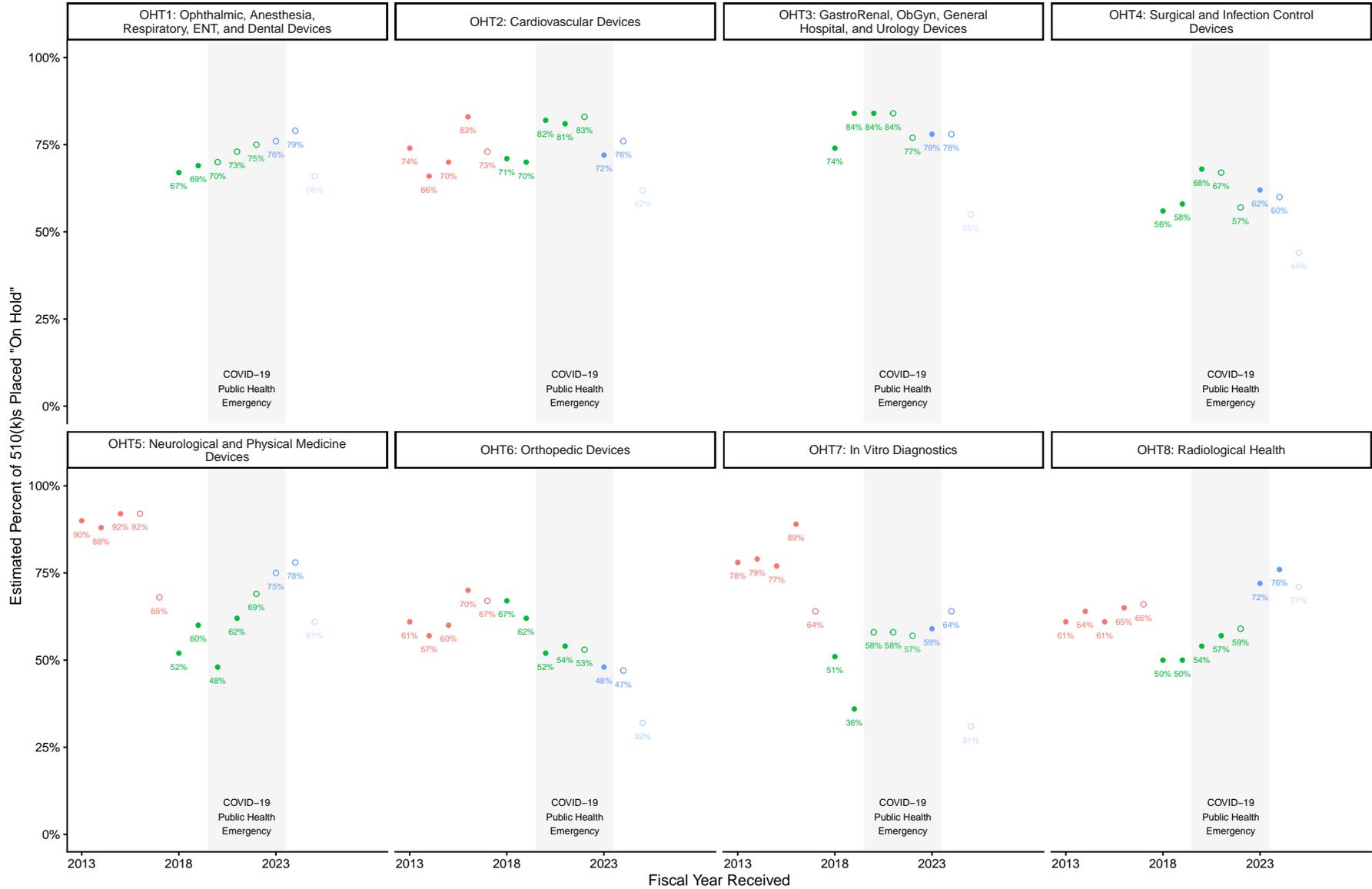
● Cohort Closed ○ Cohort Open ● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

Estimated rate at which 510(k)s are placed "on hold"

By review group and fiscal year received

Estimates based on the average number of review cycles



Fainter values are from cohorts with more open submissions and may change.

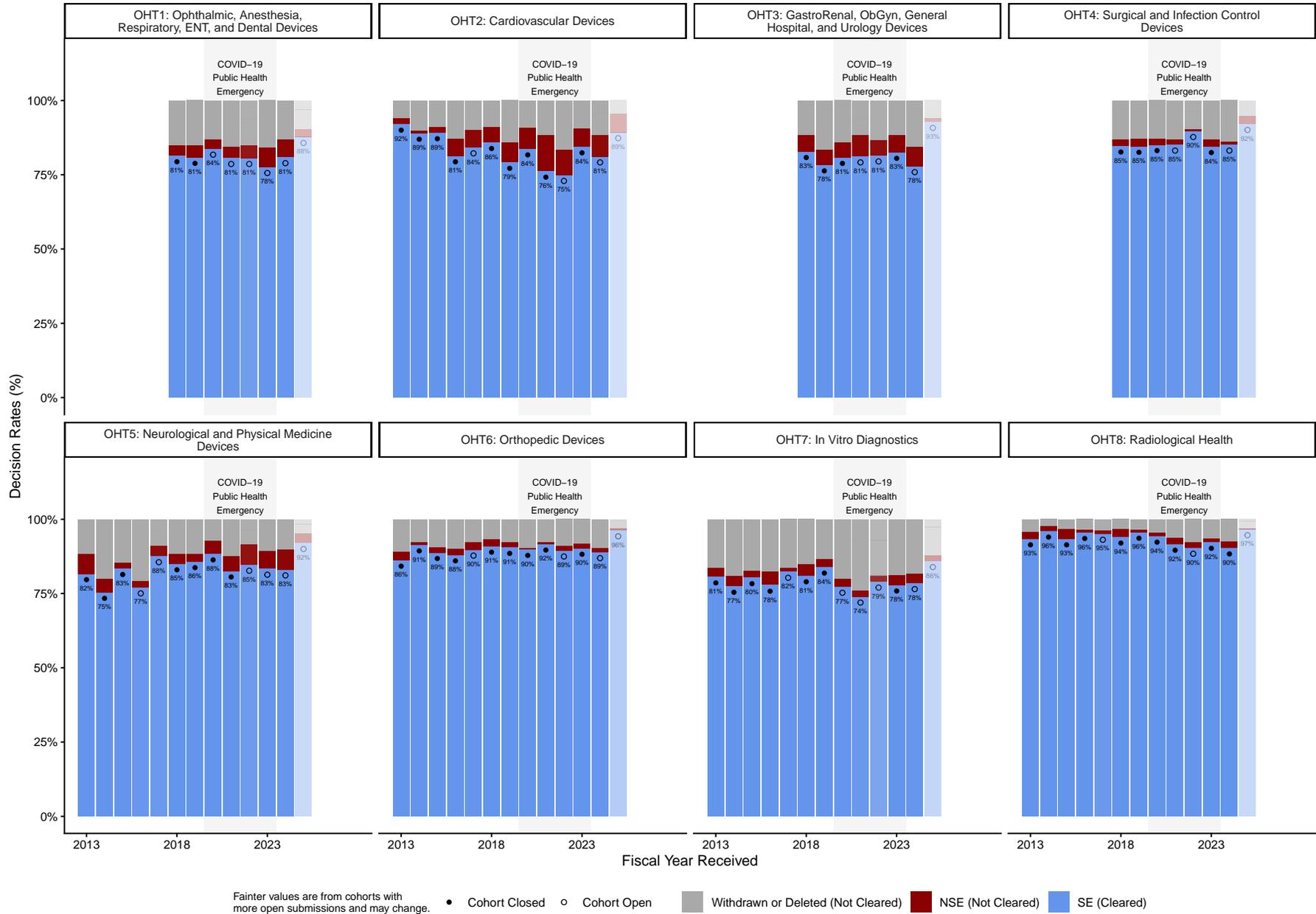
● Cohort Closed ○ Cohort Open

● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

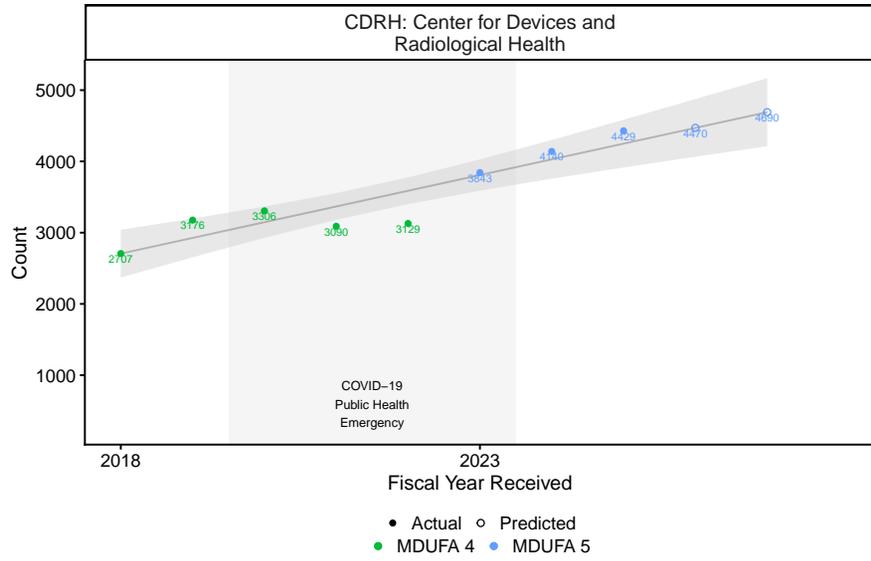
# Rate at which 510(k)s are cleared for market as of MDUFA performance report cutoff dates

By review group and fiscal year received



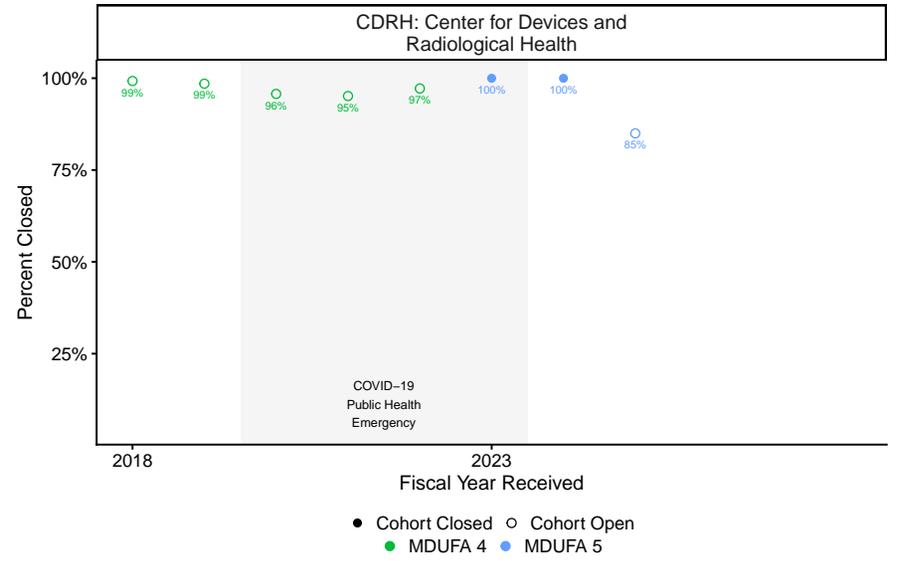
Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Pre-Submissions received



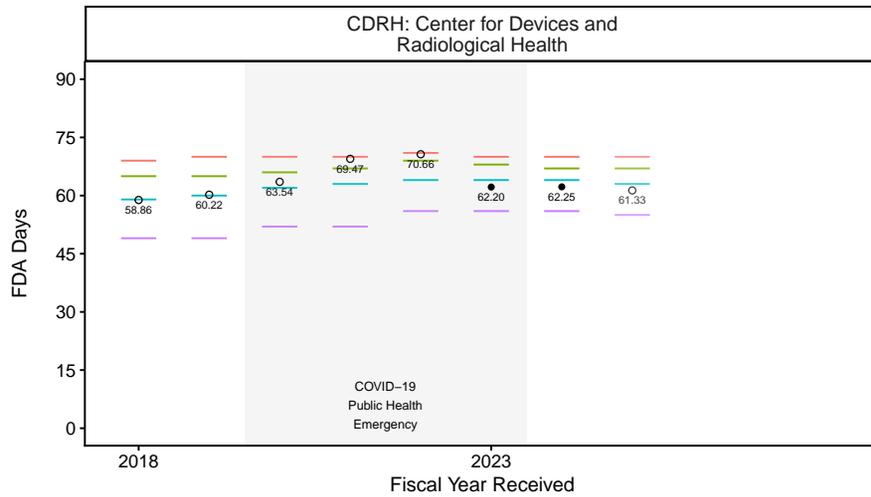
Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Percent of Pre-Submissions closed As of MDUFA performance report cutoff dates



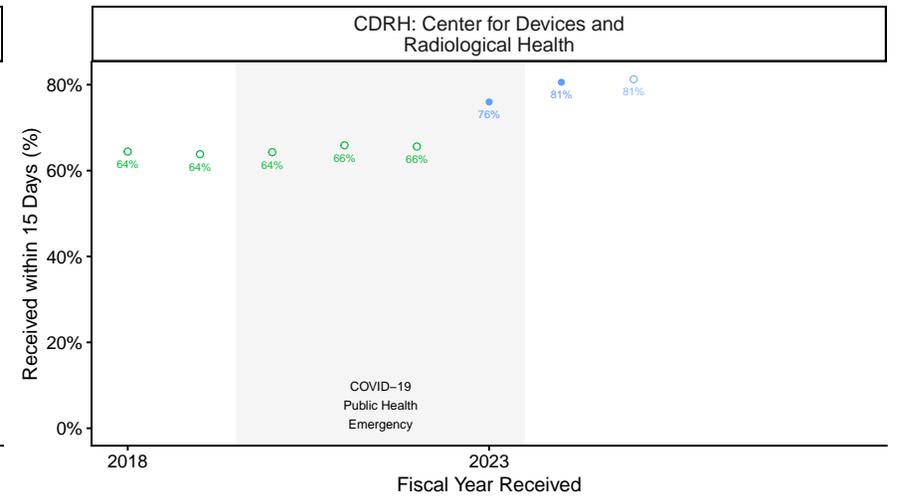
Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Pre-Submission FDA Days performance metrics As of MDUFA performance report cutoff dates



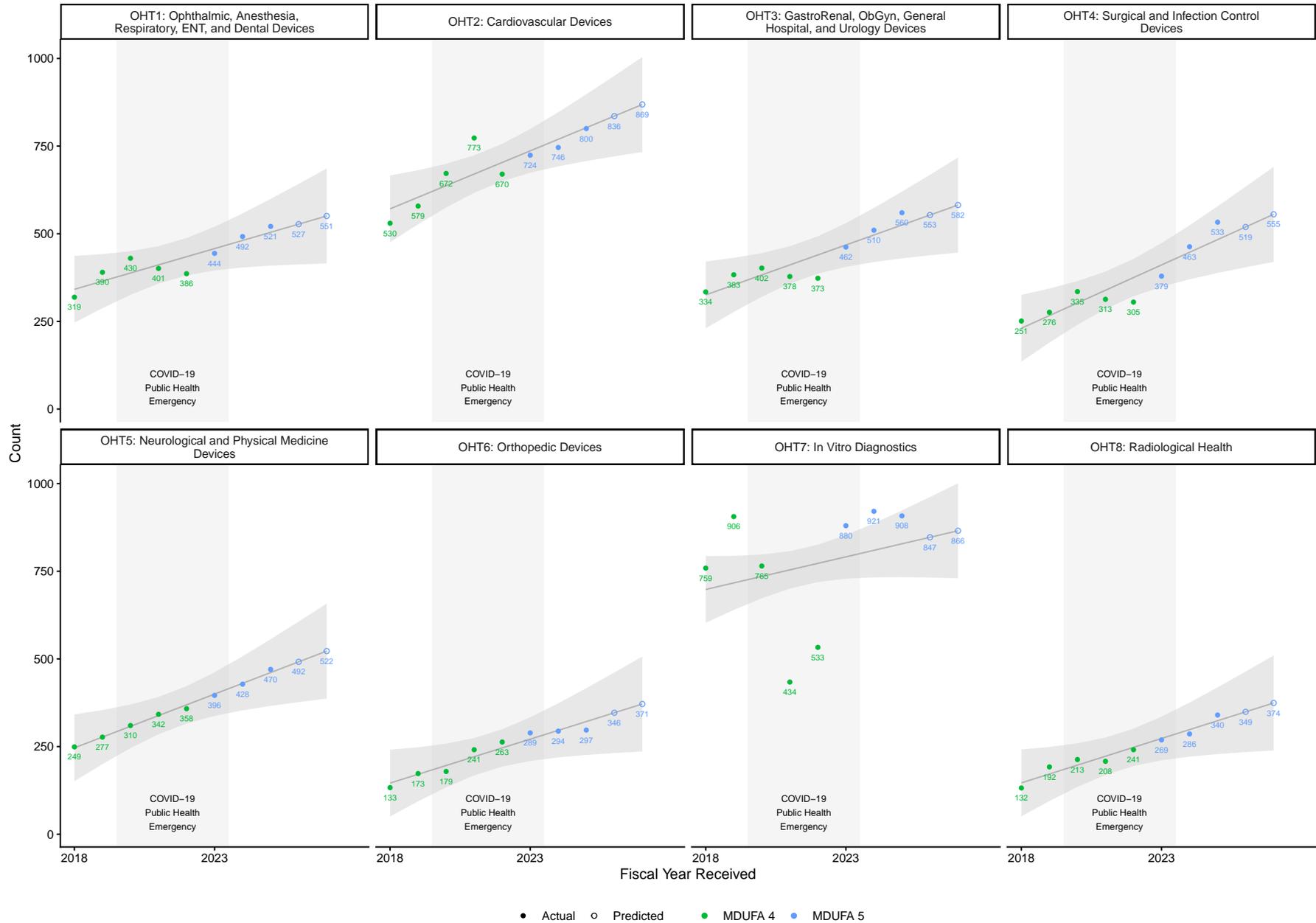
Fainter values are from cohorts with more open submissions and may change.  
 Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Industry Meeting Minutes on-time performance As of MDUFA performance report cutoff dates



Fainter values are from cohorts with more open submissions and may change.  
 Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

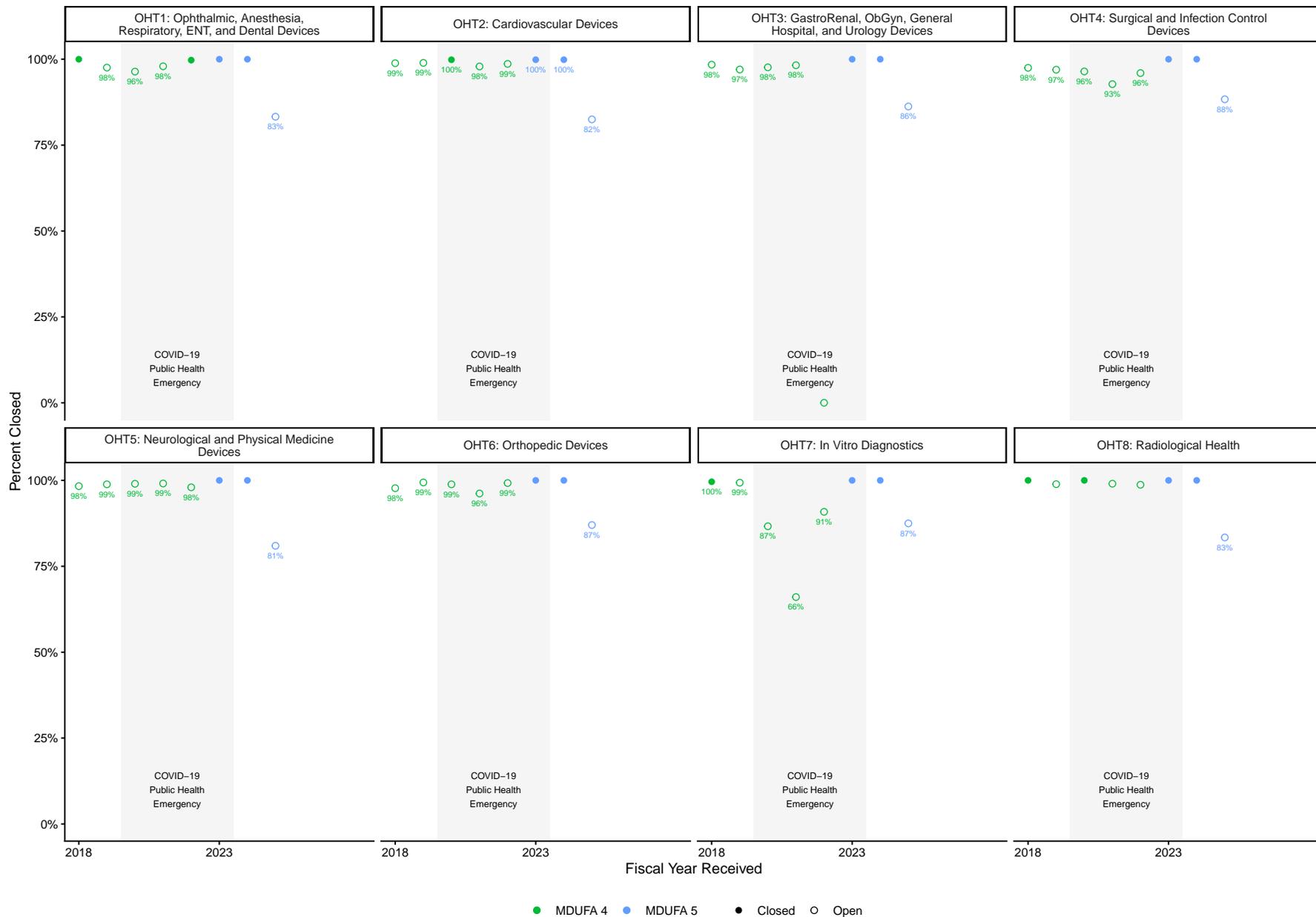
Pre-Submissions received  
By review group and fiscal year received



Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

### Percent of Pre-Submissions closed as of MDUFA performance report cutoff dates

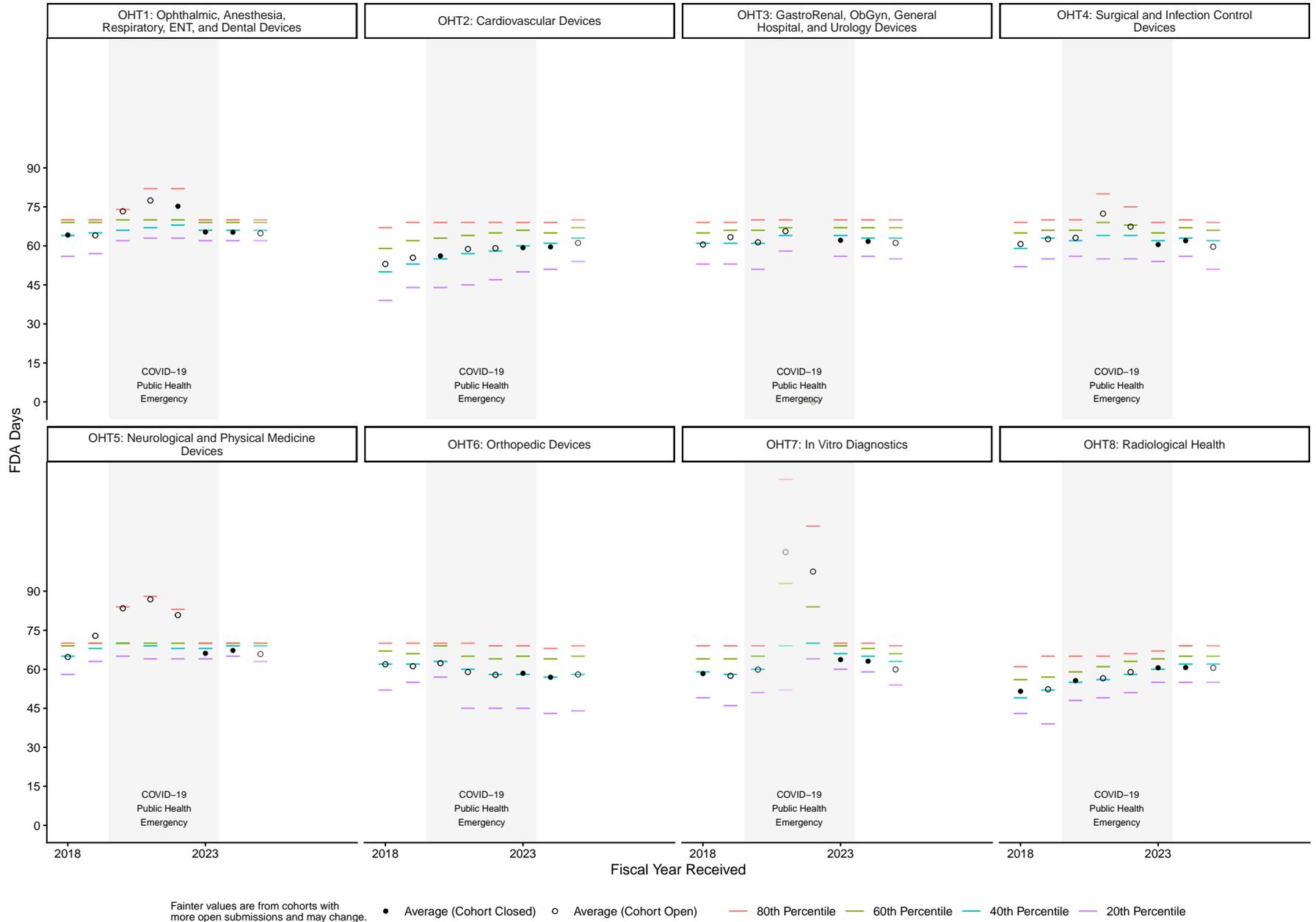
By review group and fiscal year received



Sources: December 10, 2018 MDUFA III Performance Report (data through September 30, 2018)  
 November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

Pre-Submission FDA Days performance metrics as of MDUFA performance report cutoff dates

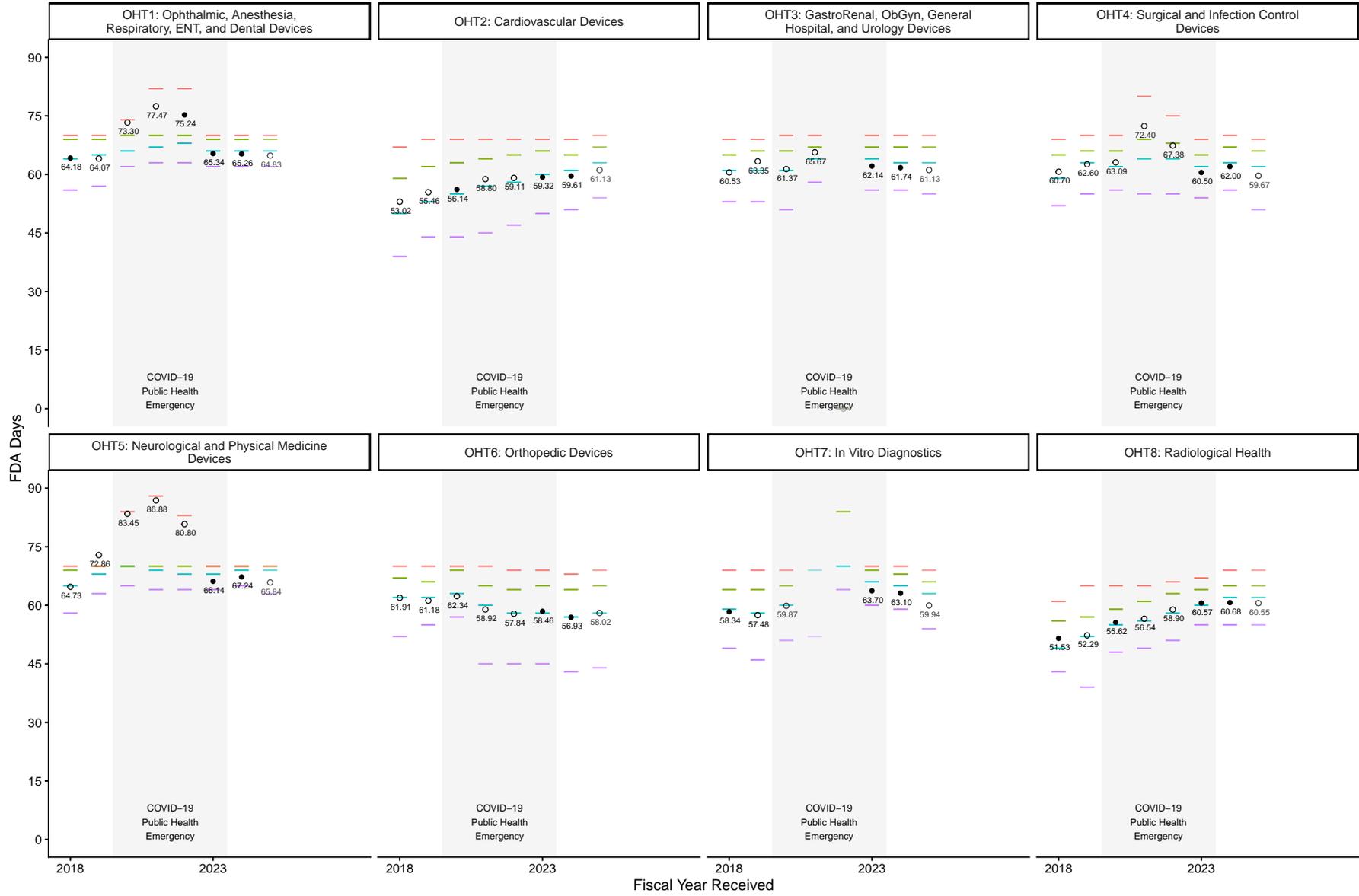
By review group and fiscal year received



Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

Pre-Submission FDA Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received  
 Values above 90 FDA Days are not shown

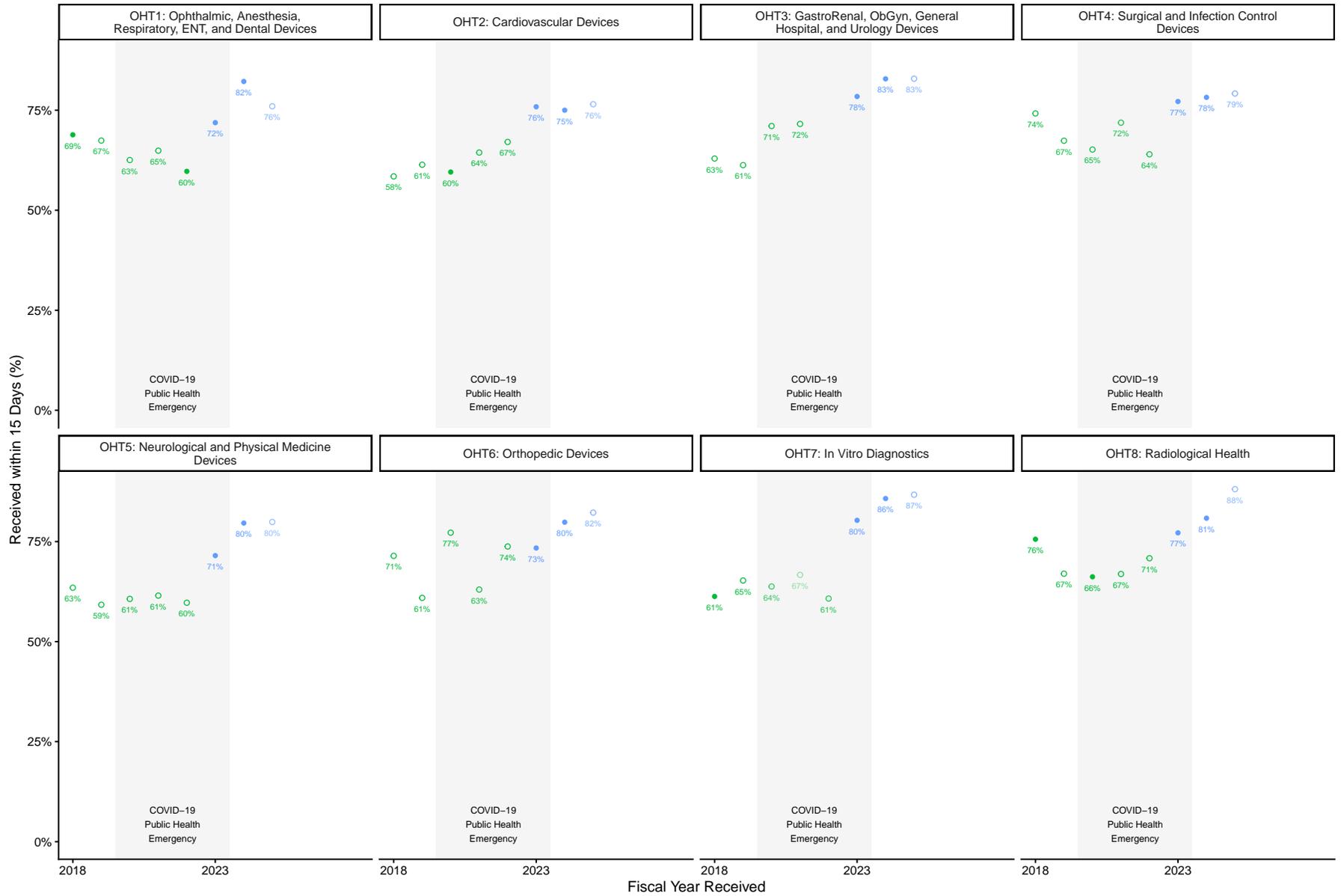


Fainter values are from cohorts with more open submissions and may change. • Average (Cohort Closed) ○ Average (Cohort Open) — 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile

Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
 November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)

# Industry Meeting Minutes on-time performance as of MDUFA performance report cutoff dates

Percent of Pre-Submission meetings for which industry provided draft minutes within 15 days



Fainter values are from cohorts with more open submissions and may change. • Cohort Closed ○ Cohort Open ● MDUFA 4 ● MDUFA 5

Sources: November 16, 2023 MDUFA IV Performance Report (data through September 30, 2023)  
November 20, 2025 MDUFA V Performance Report (data through September 30, 2025)