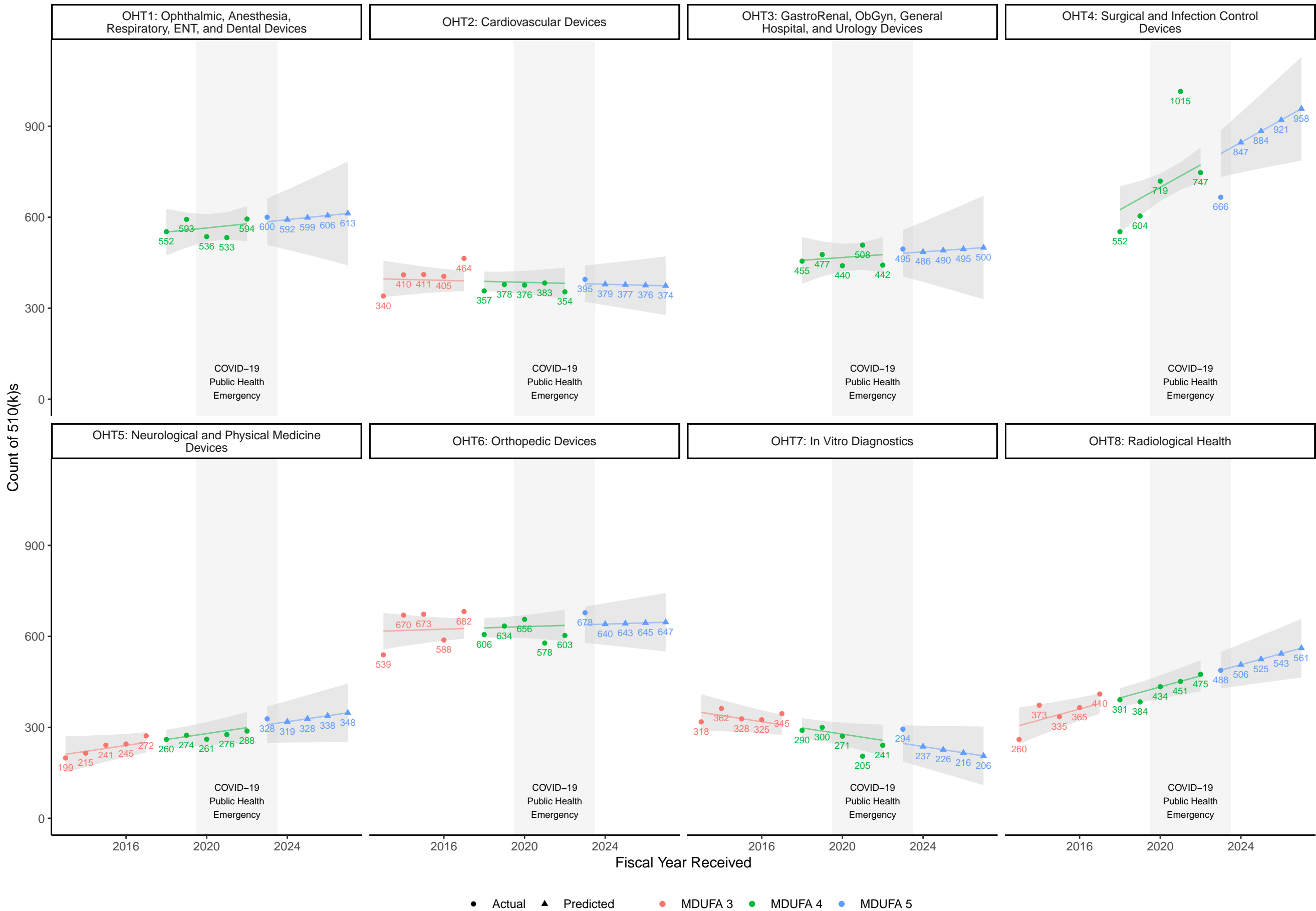


510(k)s received

By review group and fiscal year received

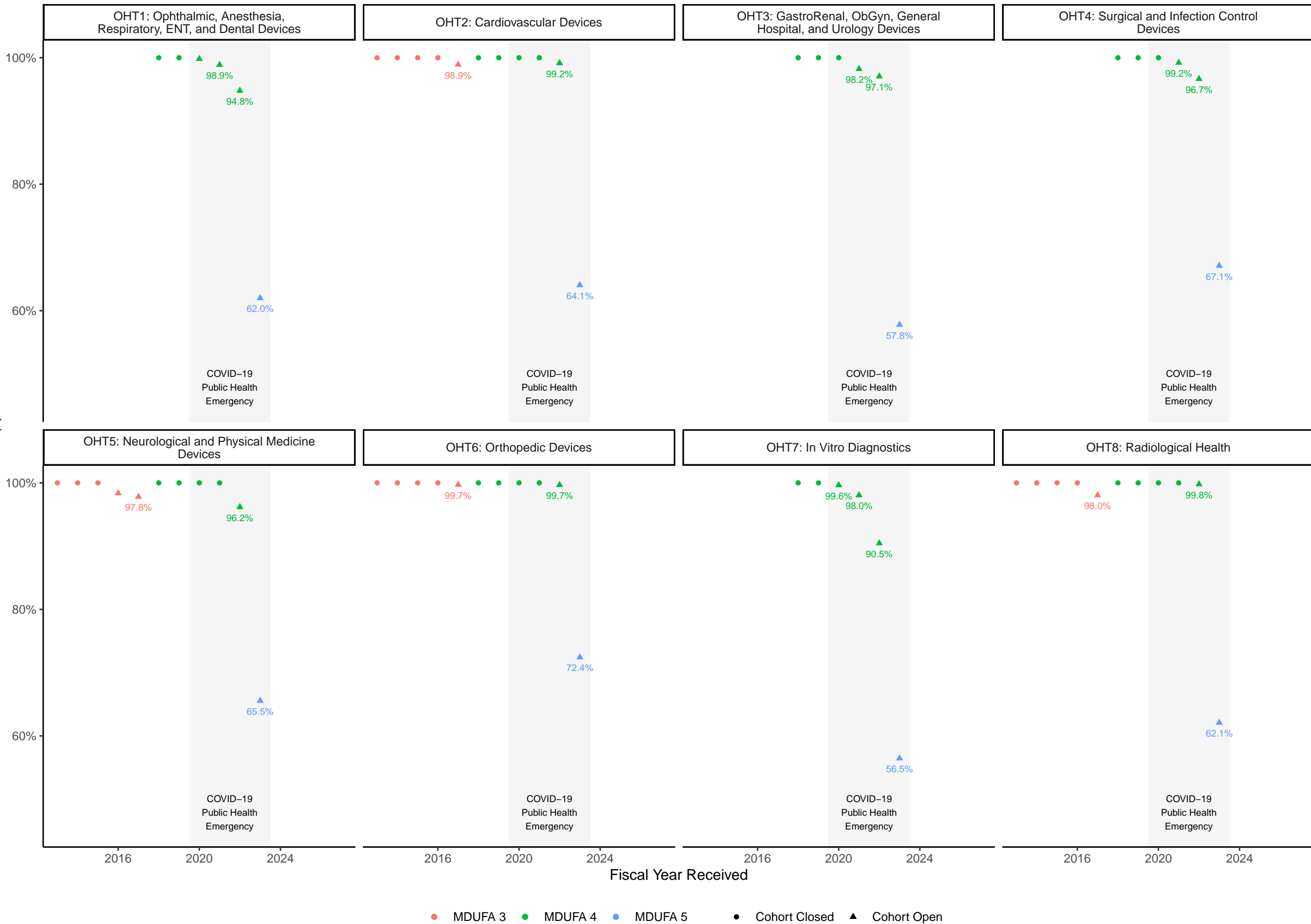


● Actual ▲ Predicted ● MDUFA 3 ● MDUFA 4 ● MDUFA 5

Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

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

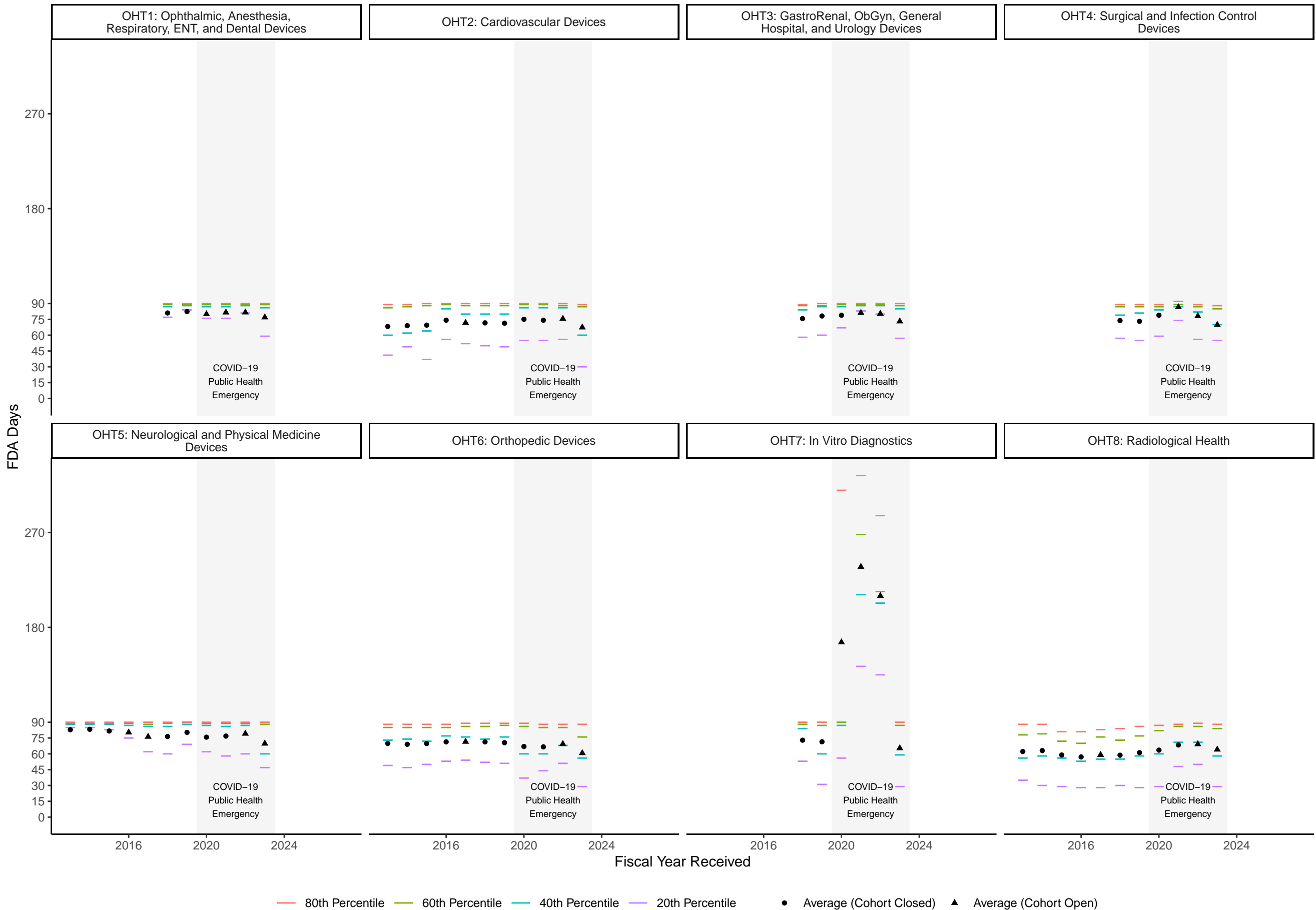
By review group and fiscal year received



Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

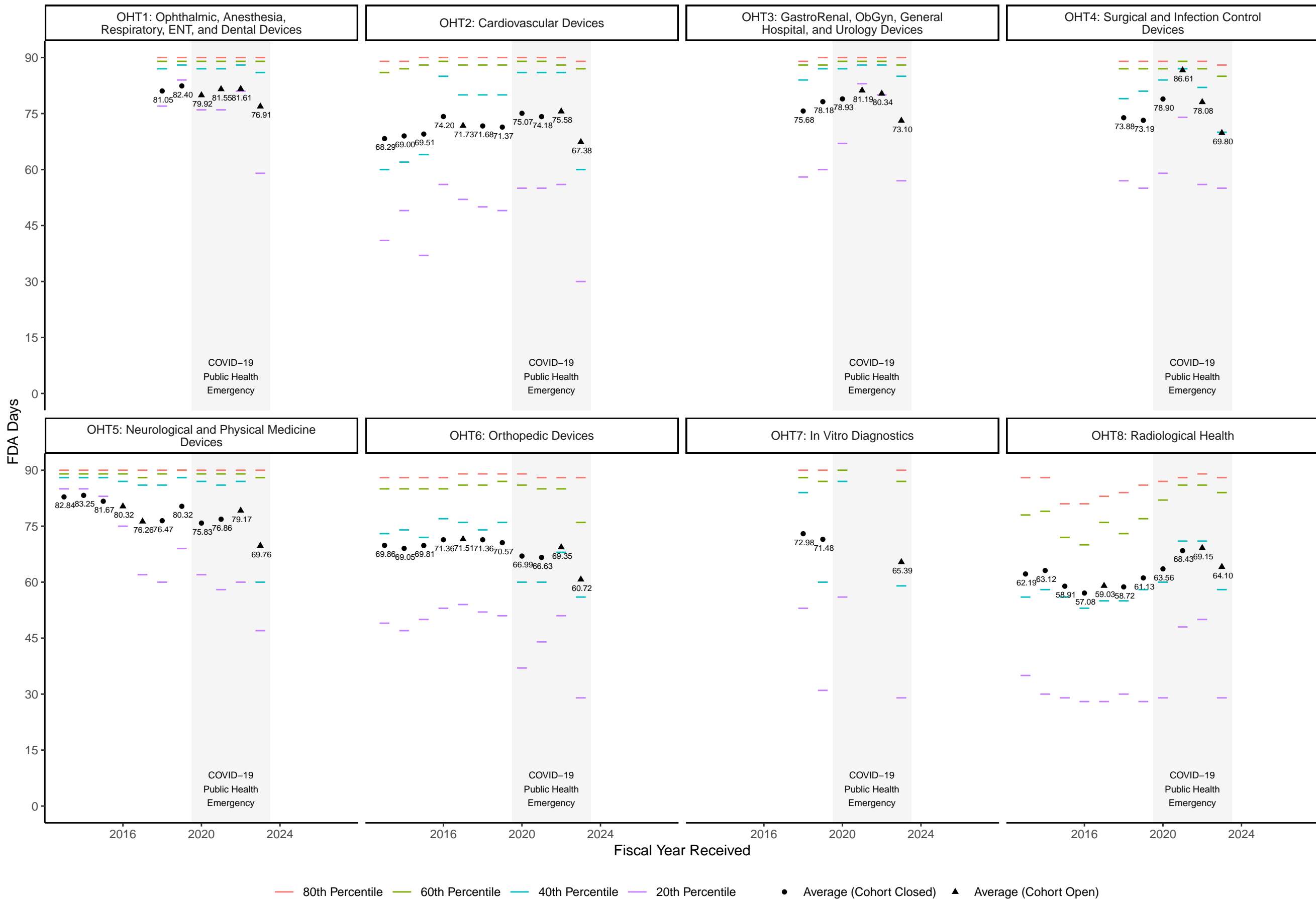
510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

By review group and fiscal year received



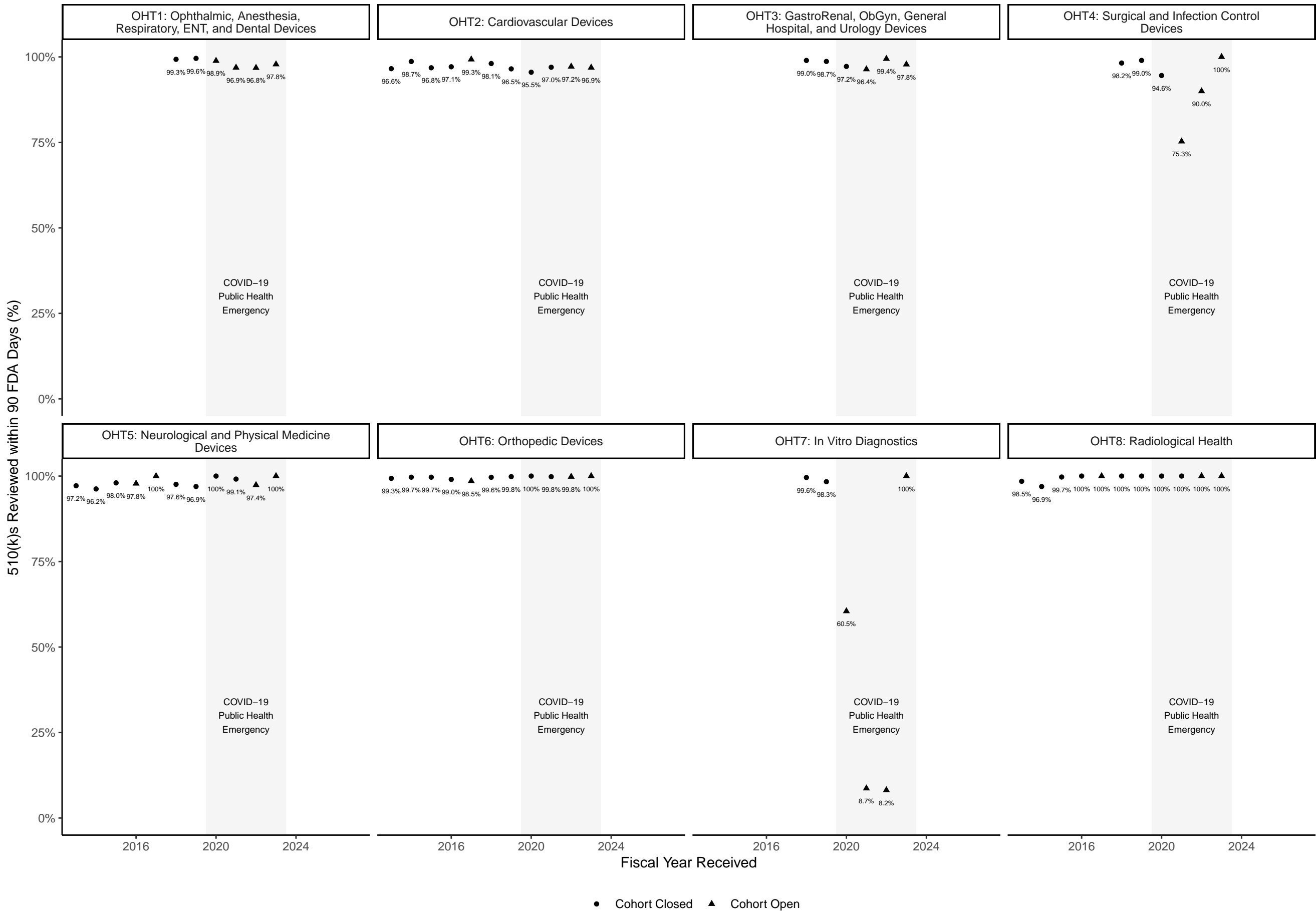
510(k) FDA Days performance metrics as of MDUFA performance report cutoff dates

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



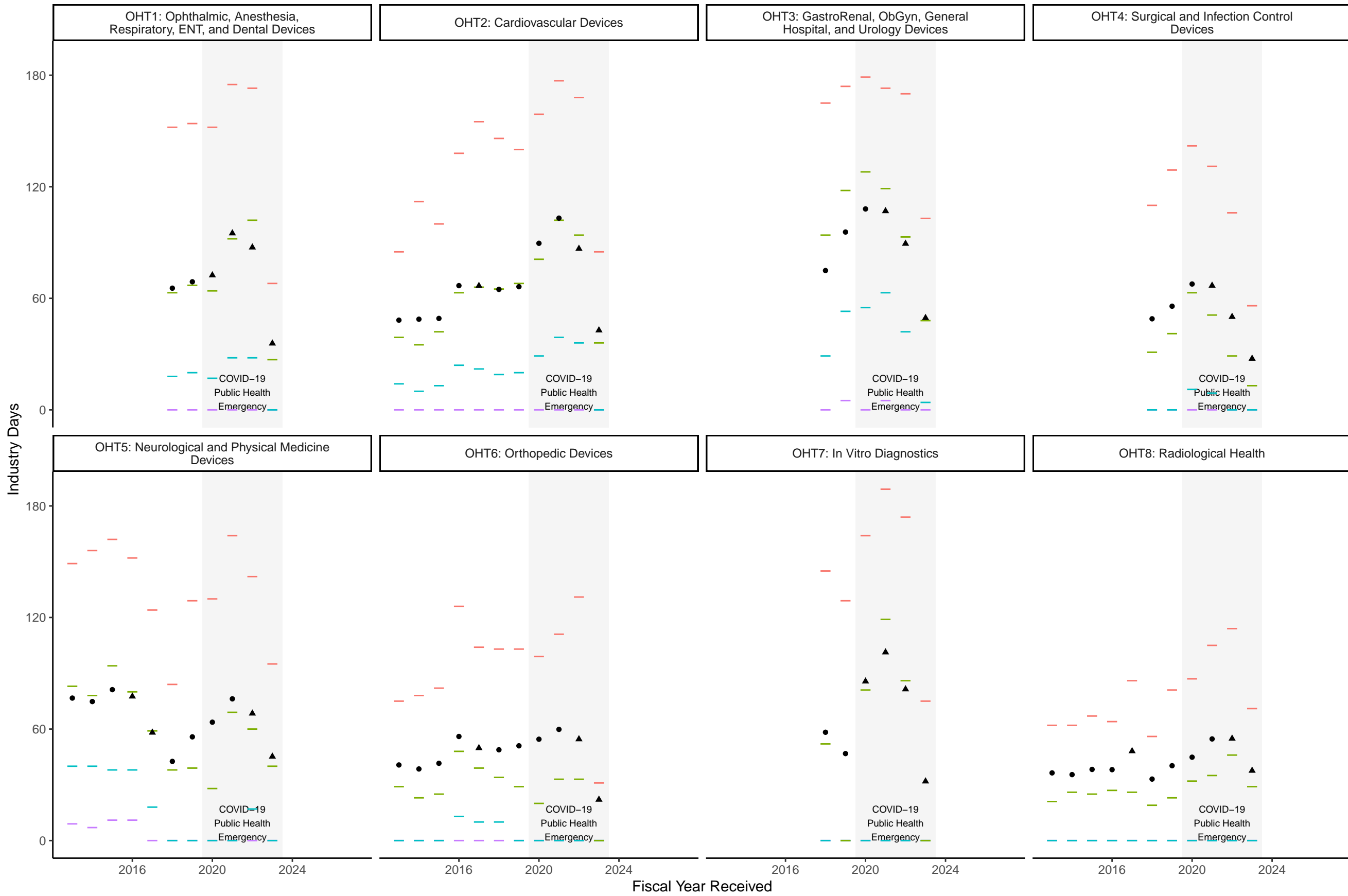
FDA Days on-time performance percentage for 510(k)s as of MDUFA performance report cutoff dates

By review group and fiscal year received



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

By review group and fiscal year received

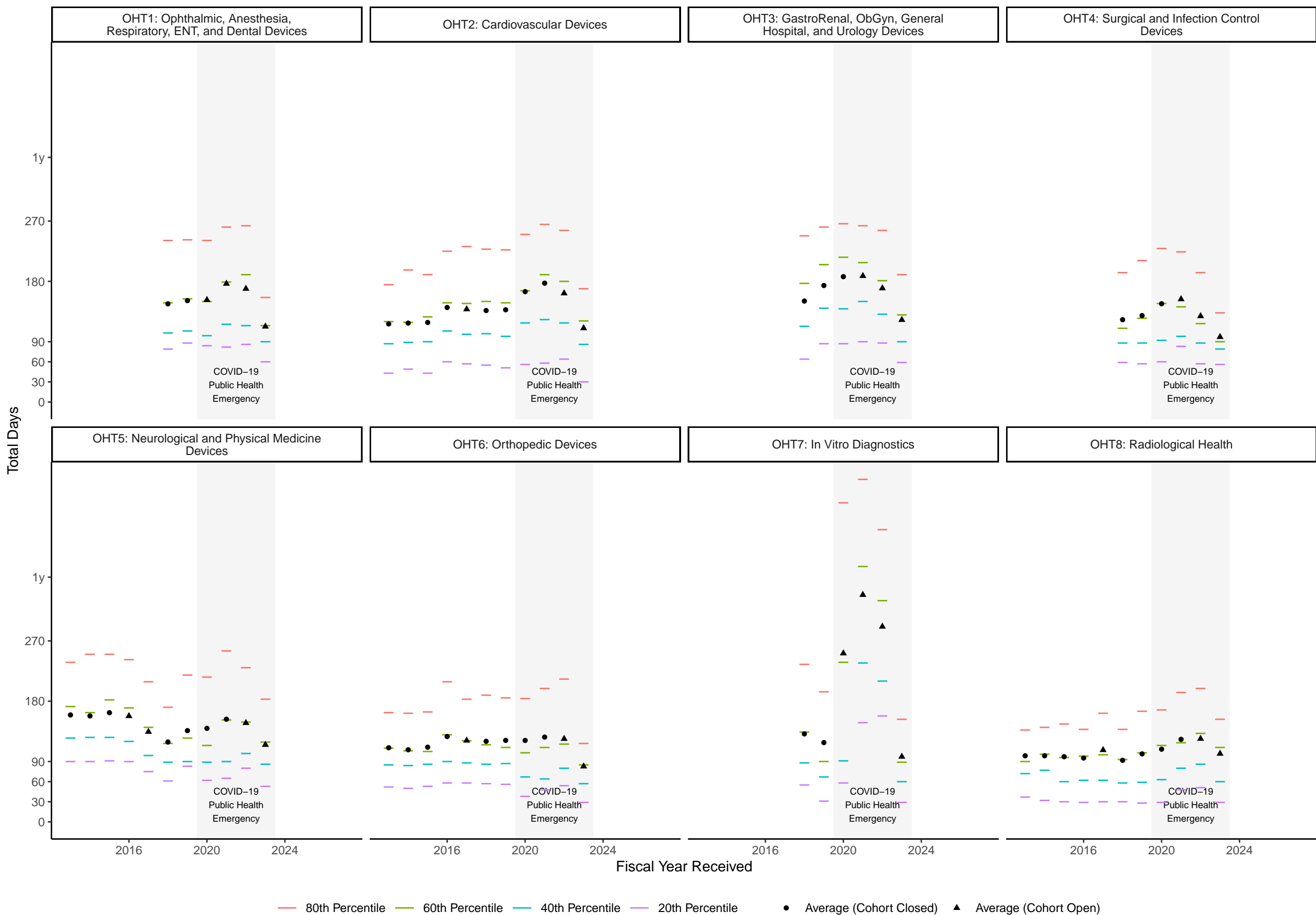


— 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile • Average (Cohort Closed) ▲ Average (Cohort Open)

Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

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

By review group and fiscal year received

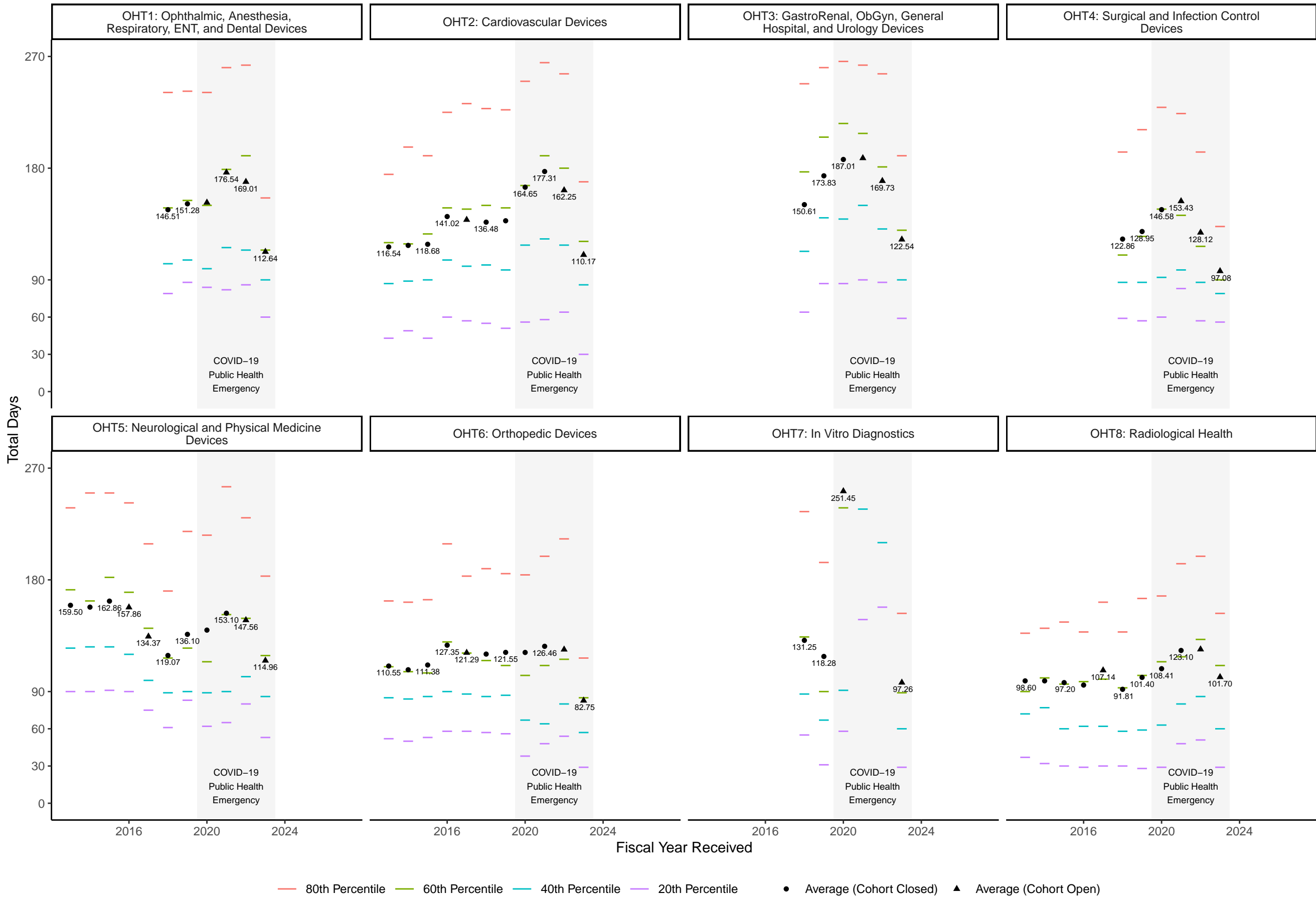


— 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile • Average (Cohort Closed) ▲ Average (Cohort Open)

Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

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

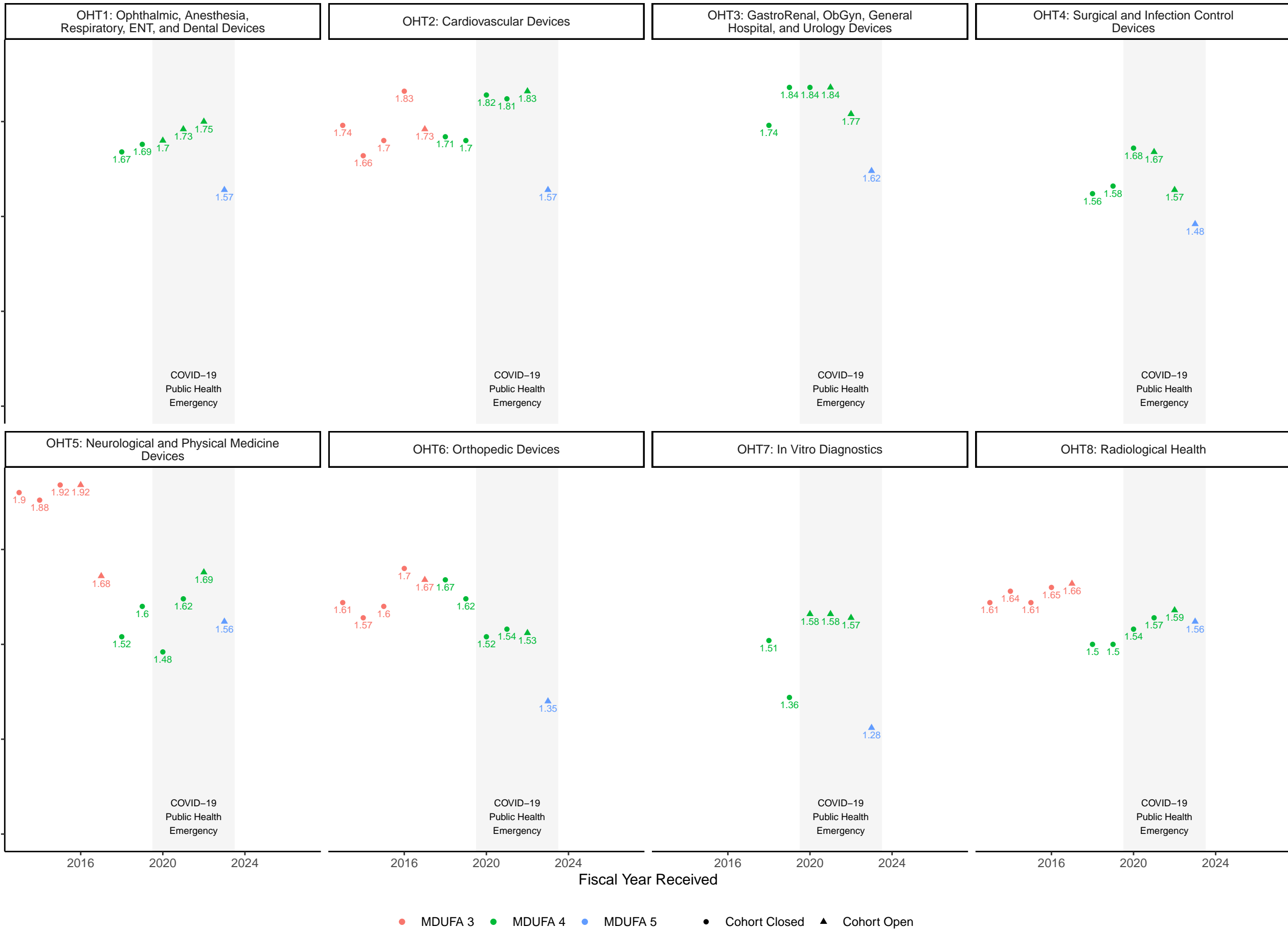


— 80th Percentile — 60th Percentile — 40th Percentile — 20th Percentile • Average (Cohort Closed) ▲ Average (Cohort Open)

Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

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

By review group and fiscal year received



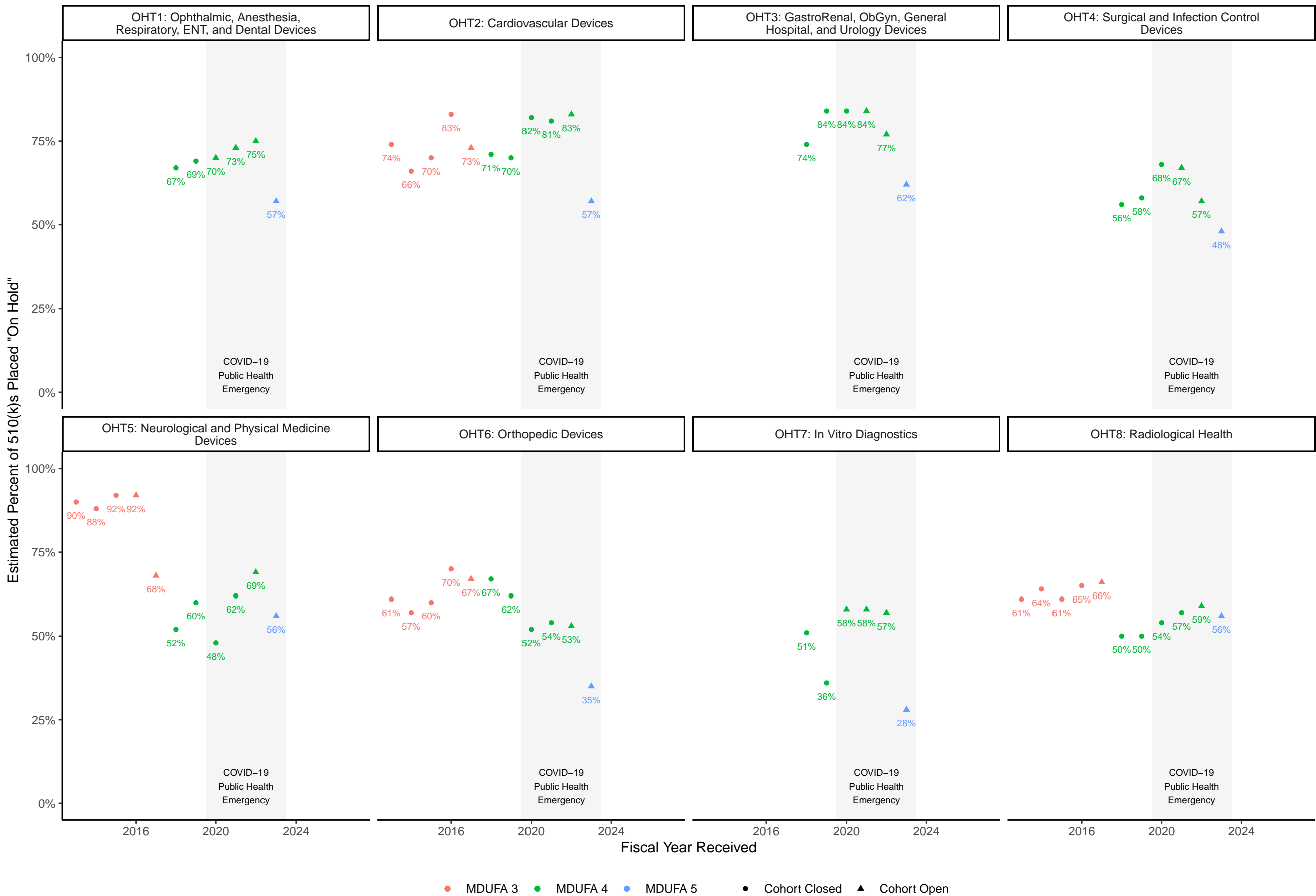
● MDUFA 3 ● MDUFA 4 ● MDUFA 5 ● Cohort Closed ▲ Cohort Open

Sources: December 10, 2018 MDUFA III Performance Report (Archive)
 November 16, 2023 MDUFA IV Performance Report
 November 16, 2023 MDUFA V Performance Report

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

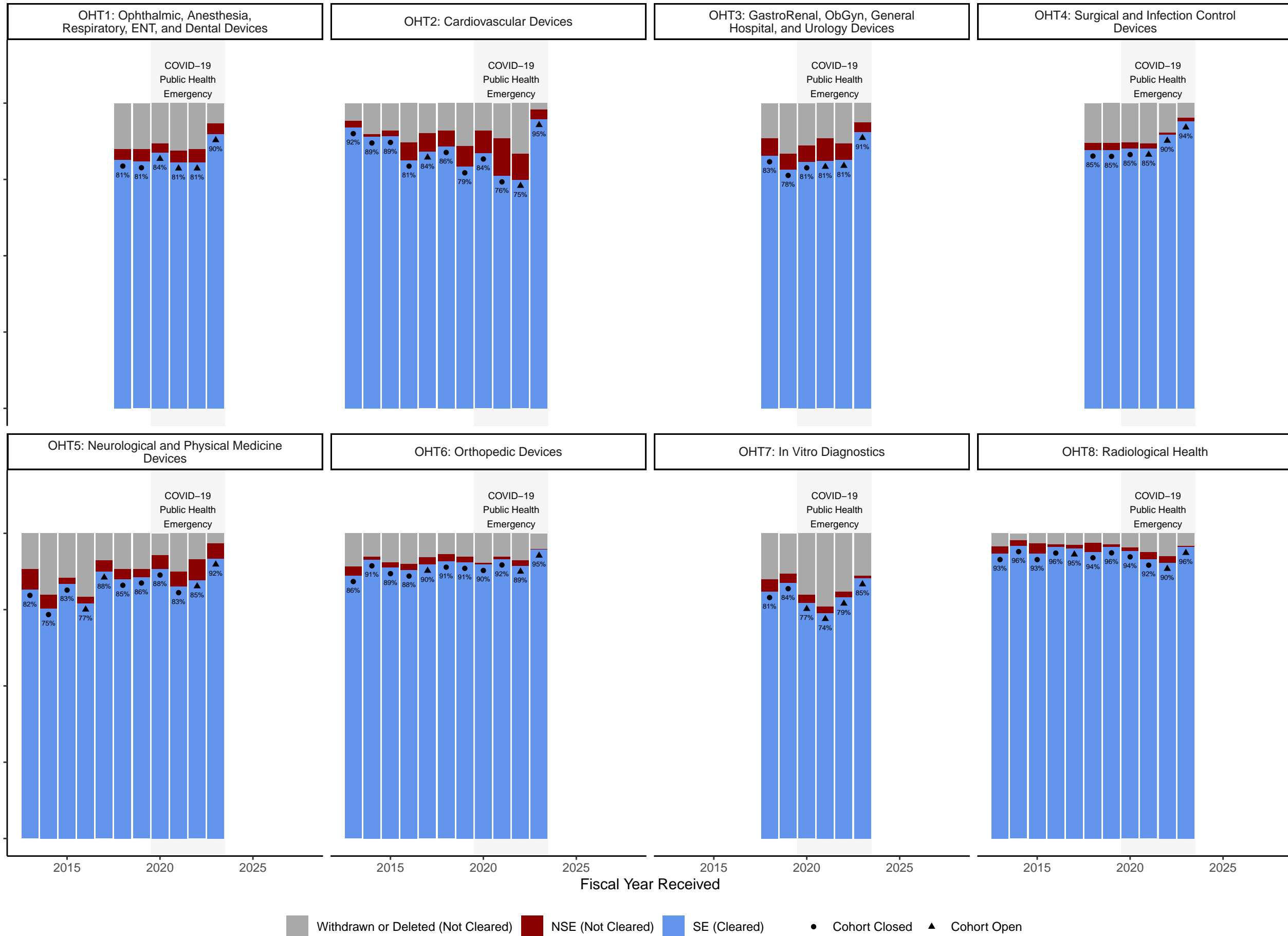
By review group and fiscal year received

Estimates based on the average number of review cycles



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

By review group and fiscal year received



Withdrawn or Deleted (Not Cleared)
 NSE (Not Cleared)
 SE (Cleared)
 ● Cohort Closed
▲ Cohort Open