CDRH Clinical Trial Enterprise Targets and Performance

IDE Cycles

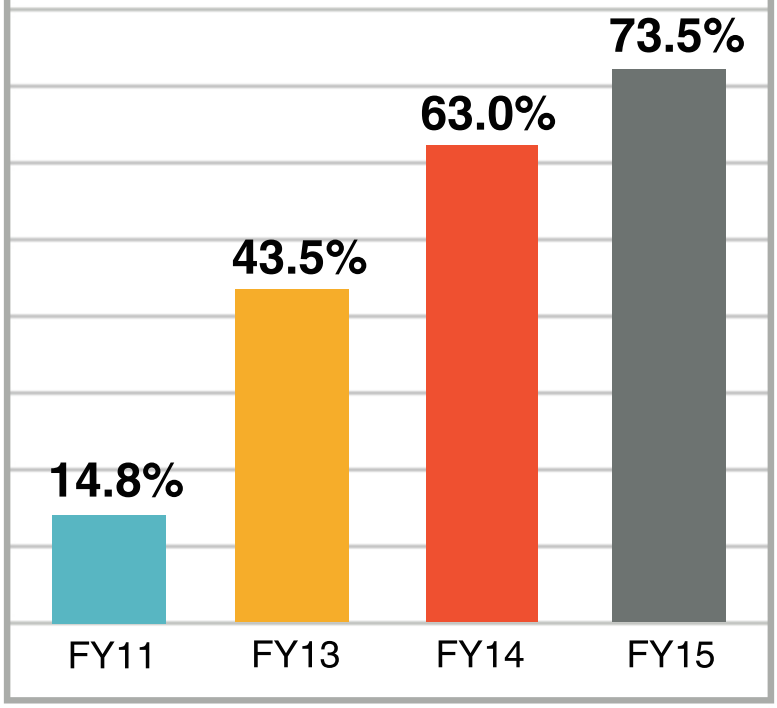
Goal: By September 30, 2014, reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25% compared to FY 2013 performance.

Results: 34% reduction, Goal Met

Goal: By June 30, 2015, reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 50% compared to FY 2013 performance.

Results: 53% reduction, Goal Met

Percent of IDE Studies Fully Approved within Two Cycles



Time to IDE Approval

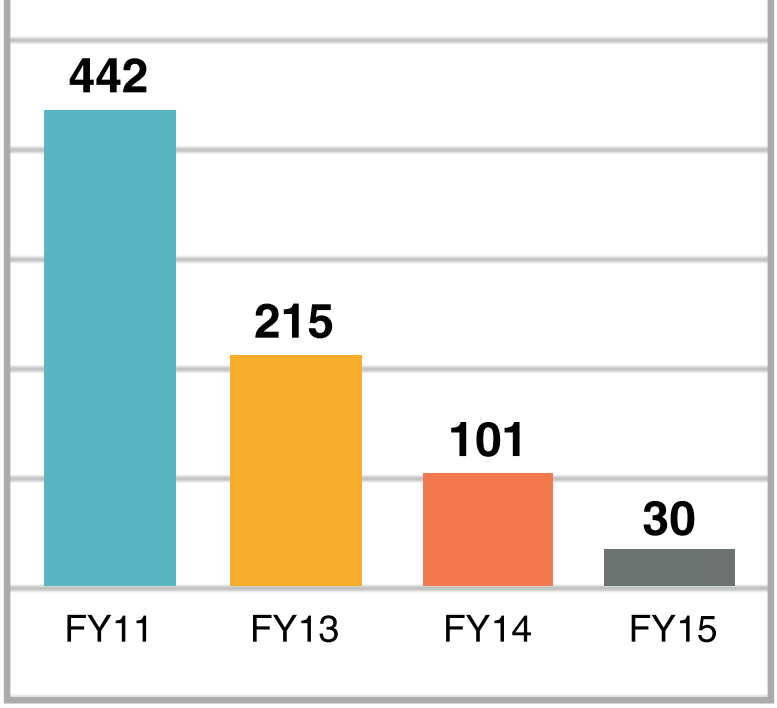
Goal: By September 30, 2014, reduce the overall median time to appropriate full IDE approval by 25% compared to FY 2013 performance.

Results: 53% reduction, Goal Met

Goal: By June 30, 2015, reduce the overall median time to full appropriate IDE approval to 30 days.

Results: Goal Met

Median Days to Full IDE Study Approval

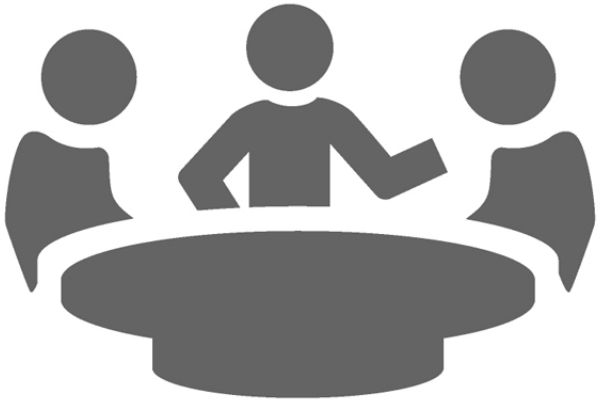


CDRH Clinical Trial Enterprise Targets and Performance

Post-Decision Interaction

Goal: By September 30, 2014, for disapproved IDEs, offer all sponsors a teleconference or in-person meeting to occur within 10 business days of the IDE decision.

Results: Teleconferences or in-person meetings were offered for all disapproved IDEs in Office of Device Evaluation (ODE) since September 30, 2014.



Early Feasibility Studies

Goal: By June 30, 2015, increase the number of early feasibility/first-in-human IDE studies submitted to each premarket Division compared to FY 2013 performance.

Results: Overall there was a 50% increase in the number of Early Feasibility Study (EFS) submissions for the first 9 months of FY 2015 compared with FY 2013.

Results: Over the same time period there was over 100% increase in the number of EFS approvals.

Results: There was an increase in the number of EFS submissions in 6 of the 7 ODE review divisions for FY 2015 compared with FY 2013.