CDRH 2014-2015 Strategic Priorities

STRENGTHEN THE CLINICAL TRIAL ENTERPRISE

GOAL	TARGET	DATE	RESULTS[1,2]
IMPROVE THE EFFICIENCY, CONSISTENCY, AND PREDICTABILITY OF THE IDE PROCESS TO REDUCE THE TIME AND NUMBER OF CYCLES NEEDED TO REACH APPROPRIATE IDE FULL APPROVAL FOR MEDICAL DEVICES, IN GENERAL, AND FOR DEVICES OF PUBLIC HEALTH IMPORTANCE, IN PARTICULAR.	**IDE CYCLES**		
	Reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25 percent compared to FY 2013 performance.	September 30, 2014	✓ 34 Percent Reduction
	For disapproved IDEs, offer all sponsors a teleconference or in-person meeting to occur within 10 business days of the IDE decision.	September 30, 2014	All but one in 2014 ✓ 100 Percent in 2015
	Reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 50 percent compared to FY 2013 performance.	June 30, 2015	✓ 53 Percent Reduction
	TIME TO IDE APPROVAL		
	Reduce the overall median time to appropriate full IDE approval by 25 percent compared to FY 2013 performance.	September 30, 2014	✓ 53 Percent Reduction
	Reduce the overall median time to full appropriate IDE approval to 30 days.	June 30, 2015	✓ 30 Days Overall Median
INCREASE THE NUMBER OF EARLY FEASIBILITY/FIRST-IN-HUMAN IDE STUDIES SUBMITTED TO FDA AND CONDUCTED IN THE U.S.	**EARLY FEASIBILITY/FIRST-IN-HUMAN IDE STUDIES**		
	Increase the number of early feasibility/first-in-human IDE studies submitted to each premarket Division compared to FY 2013 performance.	June 30, 2015	✓ 50 Percent Increase

[1] "Strengthening the Clinical Trial Enterprise for Medical Devices: An FDA/CDRH Strategic Priority Update," http://blogs.fda.gov/fdavoice/index.php/2015/09/strengthening-the-clinical-trial-enterprise-for-medical-devices-an-fdacdrh-strategic-priority-update/

[2] "A CDRH Priority: Clinical Trials in the U.S.," http://blogs.fda.gov/fdavoice/index.php/2015/01/a-cdrh-priority-clinical-trials-in-the-u-s/

CDRH 2014-2015 Strategic Priorities

STRIKE THE RIGHT BALANCE BETWEEN PREMARKET AND POSTMARKET DATA COLLECTION

GOAL	TARGET	DATE	RESULTS[3,4]
ASSURE THE APPROPRIATE BALANCE BETWEEN PREMARKET AND POSTMARKET DATA REQUIREMENTS TO FACILITATE AND EXPEDITE THE DEVELOPMENT OF PUBLIC HEALTH IMPORTANCE. AND REVIEW OF MEDICAL DEVICES, IN PARTICULAR HIGH-RISK DEVICES.	**DEVICE TYPES SUBJECT TO PMA**		
	Review 50 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.	December 31, 2014	✓ 69% Reviewed
	Review 75 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.	June 30, 2015	✓ 85% Percent Reviewed
	Review 100 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.	December 31, 2015	✓ 100% Percent Reviewed

[3] CDRH FDA Track Dashboard, http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cdrh&id=CDRH-Cumulative-Percentage-of-Device-Types-Evaluated

[4] "Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection," https://www.federalregister.gov/articles/2015/04/29/2015-09884/retrospective-review-of-premarket-approval-application-devices-striking-the-balance-between

CDRH 2014-2015 Strategic Priorities

PROVIDE EXCELLENT CUSTOMER SERVICE

GOAL	TARGET		DATE[5,6]
PROVIDE EXCELLENT CUSTOMER SERVICE.	**CUSTOMER SATISFACTION**		
	Achieve at least 70 percent customer satisfaction.	December 31, 2014	85 Percent Customer Satisfaction, included: ✓ 86 Percent External Customer Satisfaction ✓ 83 Percent Internal Customer Satisfaction
	Achieve at least 80 percent customer satisfaction.	June 30, 2015	88 Percent Customer Satisfaction, included: ✓ 91 Percent External Customer Satisfaction ✓ 84 Percent Internal Customer Satisfaction
	Achieve at least 90 percent customer satisfaction.	December 31, 2015	87 Percent Customer Satisfaction, included: ✓ 91 Percent External Customer Satisfaction ▪ 85 Percent Internal Customer Satisfaction

[5] CDRH Customer Service, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/ucm384176.htm
[6] CDRH FDA Track Dashboard, http://www.accessdata.fda.gov/scripts/fdatrack/view/track.cfm?program=cdrh&id=CDRH-Cumulative-Percent-Satisfied-Customers-End-Of-Month