SMG 3210.10

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

INFORMATION RESOURCES MANAGEMENT

INFORMATION TECHNOLOGY MANAGEMENT

FDA AUTOMATIC TECHSTAT POLICY

Effective Date: October 4, 2018

1. PURPOSE

This Staff Manual Guide (SMG) establishes the FDA Automatic TechStat policy. The purpose of this policy is to establish and maintain a partnership, common understanding, and decision-making structure between the FDA Chief Information Officer (CIO), the Office of Enterprise Portfolio Management (OEPM), and the Enterprise and Business Information Technology (EIT and BIT) communities when a TechStat review is triggered.

2. BACKGROUND

Office of Management and Budget (OMB) guidance specifies that “a TechStat is a face-to-face, evidence-based accountability review of an IT investment. A TechStat results in concrete actions to address weaknesses and reduce wasteful spending by turning around troubled programs/investments and terminating failed programs sooner.”

TechStats were established as a requirement for Federal agencies as part of the “25 Point Implementation Plan to Reform Federal Information Technology Management” to strengthen IT governance and improve accountability. The TechStat Toolkit issued by the OMB and required by the Federal Information Technology Acquisition Reform Act (FITARA), serves as the basis for the FDA’s TechStat policy and processes. Per OMB, Memorandum M-15-14, FITARA mandates that “if an investment has a high-risk rating (red CIO evaluation in the IT Dashboard (ITDB) for three consecutive months

(starting back on July 1, 2015), agencies must hold a TechStat session on that investment. The session must be held within 30 business days of the completion of the third month. If this investment remains categorized with a red CIO evaluation one year following the TechStat session, then OMB may take appropriate performance and/or budgetary actions until the agency has addressed the root cause and ensured the investment's ability to complete the remaining activities within planned cost and schedule."

3. POLICY

This policy applies to all FDA Major IT investments/programs and the following requirements shall be followed.[1]

A. Investment Selection for a TechStat and Scheduling TechStat

FDA TechStats must be conducted on all Major IT investments based on the defined criteria as follows:

- Major IT Investments with high risk or moderate high-risk ratings from the PMT HHS CIO Evaluation for **two** consecutive months.

- Major IT Investments with **three or more** Baseline Change Events (BCEs) for rebaselines submitted over a **six-month** period. The investment's baseline includes all planned costs and planned schedules for all project activities and/or operational performance metrics for the investment. A rebaseline BCE includes changes to an investment's Funding Strategy, Change in Scope, Adding New Iteration, Contract Related, etc. For specific information contact the FDA CPIC Team.

- Major IT Investments that are requested for a TechStat review by the FDA CIO, Office of Information Management and Technology (OIMT) Leadership Council, or the Center/Office Associate Deputy CIO (ADCIO), due to concerns over cost, schedule, performance, risk, or mission alignment.

- Major IT Investments with an overall weighted score during Control Review of less than (<) 2.5 (red) for **three** consecutive quarters and there are no indications that the score will improve.

B. Scheduling and Conducting the TechStat

When a FDA IT investment is selected for a TechStat, both the Investment Functional/Business Sponsor and the Investment Manager will be notified and a

[1] Non-Major IT investments are removed from this policy and will follow the FDA IT Investment Accountability Review (ITIAR) process. Contact the FDA CPIC Team or your Center-specific CPIC Manager for further information.

TechStat meeting will be held within 30 business days of that notification. For specific information on how a FDA TechStat is conducted, please refer to the FDA Automatic TechStat Process Standard Operating Procedure or the FDA TechStat Guide which can be obtained from the FDA CPIC Team.

C. Adherence to the TechStat Process and Corrective Action Plan (CAP) Development

FDA Leadership (CIO, Executive Officers, ADCIOs) serve as the primary governing body to enforce the decisions resulting from a TechStat session.

1. The TechStat process must be followed to ensure appropriate steps are taken to identify a troubled investment, analyze an investment's data and artifacts, and provide FDA Leadership with an in-depth understanding of the investment so recommendations for improvement can be made.

2. The decision(s) taken by FDA Leadership can result in the following: halting investment activities, terminating an investment, applying additional resources to an investment or a recommendation of corrective actions for an investment. TechStat corrective actions will be documented within the CAP Report after the TechStat. The CAP Report will detail investment findings and corrective actions with the assignment of owners.

D. TechStat Corrective Action Plan Concurrence

The following signatures are required for concurrence with the planned corrective actions on the finalized CAP Report:

EIT Investments:

- FDA CIO (or Designee)
- OIMT Leadership Council
- Investment Functional/Business Sponsor
- Investment Manager
- TechStat Lead

BIT Investments:

- FDA CIO (or Designee)
- Center/Office ADCIO
- Investment Functional/Business Sponsor
- Investment Manager
- TechStat Lead

4. PROCEDURES

All standard operating procedures related to the Automatic TechStat process are available upon request via the FDA CPIC Team.

5. RESPONSIBILITIES

A. FDA CIO

The FDA CIO is responsible for the monitoring and oversight of IT as delegated by the Department of Health and Human Services (HHS) CIO. The FDA CIO will provide sign-off on the CAP Report and facilitate TechStat Sessions as necessary. The FDA CIO can designate an alternate senior staff member to conduct/be briefed on the FDA TechStat.

B. OIMT Leadership Council– EIT Investments Only

The OIMT Leadership Council having been apprised of all TechStat activities and correspondence by the TechStat Lead, will provide input to the TechStat process as necessary, attend the TechStat meeting and provide signoff on the CAP Report after the TechStat.

C. Center/Office ADCIO – BIT Investments Only

The Center/Office Associate Deputy CIO, having been apprised of all TechStat activities and correspondence by the TechStat Lead, will provide input to the TechStat process as necessary, attend the TechStat meeting, and provide signoff on the CAP Report after the TechStat.

D. Functional/Business Sponsor

The Functional/Business Sponsor is the organization executive who advocates for the IT investment and is the primary point of contact to the FDA CIO and the FDA IT Governance board. The Functional/Business Sponsor is responsible for reviewing and implementing, as necessary, IT governance board recommendations. Take appropriate action to address IT investment performance issues, including decisions made collaboratively with FDA's CIO, IT Governance Board, and Contracting Officer.

E. Investment Manager

The Investment Manager is responsible for the investment's performance, risk, and integration of supporting projects as well as providing TechStat supporting artifacts to the TechStat Lead and executing the corrective actions identified in the CAP Report.

F. TechStat Lead

The TechStat Lead is responsible for initiating, facilitating, and managing the TechStat process. The TechStat Lead is responsible for communication of TechStat results and status reports to senior leadership at the close of the TechStat and via the FDA Control Process.

6. REFERENCES

OMB Circular No. A-11 “Preparation, Submission, and Execution of the Budget”, Current Fiscal Budget Year

OMB Memorandum M-15-14 “Management and Oversight of Federal Information Technology”, June10, 2015

25 Point Implementation Plan to Reform Federal Information Technology Management, December 9, 2010

OMB FY2020 IT Budget Capital Planning Guidance, July 2018

Federal IT Acquisition Reform Act (FITARA), December 2014

Department of Health and Human Services (HHS) FITARA Implementation Plan

Department of Health and Human Services (HHS) Policy for Information Technology (IT) - Capital Planning and Investment Control (CPIC), September 2016

7. EFFECTIVE DATE

The effective date of this guide is October 4, 2018.

8. Document History - SMG 3210.10, “FDA Automatic TechStat Policy”

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	11/29/2016	N/a	Director, Office of Enterprise Portfolio Management (OEPM)	FDA Chief Information Officer
Revision	03/29/2017	N/a	Director, Office of Enterprise Portfolio Management (OEPM)	FDA Chief Information Officer
Revision	09/07/2018	N/a	Director, Office of Enterprise Portfolio Management (OEPM)	FDA Chief Information Officer

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