FDA Program Alignment
Bioresearch Monitoring Program
FY2016 Action Plan

Introduction

Following completion of the commitments in the FY 2015 Action Plan, the Bioresearch Monitoring (BIMO) Program Alignment Implementation Team has developed an Action Plan to guide continued implementation and transition in FY 2016. Much of the work performed in FY 2015 was analytical and reflective upon historical accomplishments in the BIMO Program in order to envision a stand-alone BIMO Program. Defining specialization for the BIMO Program was a major focus in FY 2015, as was determining a training and development foundation for the program, identifying best practices across the BIMO Program, identifying gaps in processes and identifying where revised or new guidance/regulation was necessary to support the program.

With the decision of the BIMO Program specialization model, the focus of the BIMO Program Alignment Implementation Team is on establishing the infrastructure needed to support and guide the program, defining and beginning to monitor success metrics, developing common practices and communications across the program and redefining work planning activities for the most efficient utilization of resources. In FY 2016, the BIMO Program Alignment Implementation Team will be working on transition and establishment of the programmatically aligned BIMO Program.

Included in the plan are the agreed upon areas the BIMO Program Alignment Implementation Team believes we need to accomplish in order to move the program forward to stand up in FY 2017. The BIMO Program Alignment Implementation Team recommends establishing a BIMO Governance Board, which requires senior agency leadership support and approval.

Other highlights of the Action Plan include:

Formally establishing the BIMO Harmonization Workgroup, which will work on implementing best practices, common procedures across the program and common templates for assignments.

Establish a Curriculum Committee to oversee execution of a consolidated training and development program across the program.

Define and project the inspectional resource needs for the BIMO Program along with developing a risk-informed process for ensuring resources are allocated to shared strategic priorities and work plan goals.

Develop a transition plan for the ORA BIMO Program.

I. The FY 2016 BIMO Program Action Plan

A. Program Implementation and Resource Allocation Metrics

1. ORA will refine and implement the overarching transition plan covering the transition from geographic management to program based management developed in FY2015 and provide regular progress updates.

2. Analyze current and historical data to establish resource and staffing needs. Data should include numbers of applications received and filed for review, inspectional assignments issued (all inspection assignments – application-based, surveillance, etc.) and inspectional accomplishments, complaints received, assignments issued and inspection/investigation accomplishments. Data to be analyzed will include any additional programs being moved under the BIMO program such as Postmarketing Adverse Drug Experience (PADE) and Risk Evaluation and Mitigation Strategies (REMS).

3. After identification of dedicated ORA BIMO investigators, evaluate inspectional accomplishment data (average number of hours reported per inspection type - IRB, CI, GLP, Sponsor/CRO, BE, RDRC) for these dedicated BIMO investigators for FY 2013-2015. Determine if there are any differences between current operation module hours per inspection type versus current data using all ORA investigators who perform BIMO inspections.

4. Project inspectional resource needs by Center for FY 2017. Include number of planned inspections and resource costs.

5. Conduct GIS mapping of the offices containing assigned ORA BIMO staff and identify ORA BIMO Program Specialists.

6. Review and evaluate proposed program success metrics to determine where current data sources exist or need to be developed, establish relevant baseline data where applicable and initiate proactive monitoring.

B. Training and Development

1. Establish a BIMO Curriculum Committee to oversee the development and execution of a consolidated training and development program. The BIMO Curriculum Committee will include representation from all Centers, ORA and OGCP and will work cooperatively with ORA/ORM/DHRD.

   The Committee will prioritize and select for initiation the following in FY16:

   - Develop further training and guidance for inspection types such as:

     a. Analytical Facility bioequivalence
     b. Foods that bear a nutrient content claim or a health claim, infant formulas, dietary supplements, food and color additives, etc.
     c. Radioactive Drug Research Committees (RDRC)
     d. Postmarketing Adverse Drug Experience (PADE) reporting
     e. Risk Evaluation and Mitigation Strategy (REMS)
     f. Accredited Third Party Review Program for 510(k) devices
     g. Device post-approval studies
     h. Electronic Data Capture (EDC) Systems and audit trails
     i. Tobacco product studies

   - Add the following new topics to the BR201 for FY2016:

     a. Preparing for Inspections
     b. Vulnerable Populations
     c. Developing an Audit Plan
     d. For Cause Assignments and Special Investigations

     Note: *The above topics were recently incorporated and offered at the last FY2015 Advanced Good Clinical Practices course (BR301).*

   - Expand the following topics beginning in the FY2016 course presentations:

a. CI inspections – collection of routine documents requested in the assignment and the identification and cross-referencing of exhibits in the final report
b. IRB inspections – scope of the board's review, selection of projects for review, evaluation of risk assessments for pediatric and medical device studies, and continuing review activities
c. Sponsor inspections – data management, investigator site file reviews, test article stability, and expiration data extensions
d. Clinical bioequivalence inspections – observation of standard practices, review of employee qualifications, and the collection of reserve samples

- Using the FY2016 DHRD BR201 and BR301 course agendas as a reference, develop an updated pilot FY2016 center BIMO training course for new center BIMO staff.

2. Working with DHRD, conduct a Job Task Analysis (JTA) for Nonclinical Laboratory (Good Laboratory Practice) and Bioequivalence investigator positions during FY2016.

3. Request resources for opportunities through European Medicines Agency (EMA)-sponsored training to be shared among BIMO Program staff.

4. Explore opportunities for hiring and retention incentives.

C. BIMO Program Processes and Resource Allocation

1. Develop a prioritization scheme and plan for revising/updating CPGM within the BIMO program. Establish a regular schedule for review and the process for updates. Existing agency clearance processes will continue to be observed.

2. Begin to update program processes and procedures based on needs identified in the gaps analysis performed in FY15 with priority given to those processes needed for successful transition of the BIMO Program in FY 2017.

3. Formally establish the BIMO Harmonization workgroup and begin to implement the best practices identified in FY15, including the development of a standard assignment memo template for all BIMO program areas. The BIMO Harmonization workgroup will continue to be overseen by the BIMO Leads group.

4. Establish and develop the charter for a BIMO Governance Board. This board will be empowered to make decisions regarding BIMO Program

processes and priorities. A charter will be developed outlining the scope of the board so as to not conflict with existing policy oversight. The charter will also define matters within the purview of the board and those matters requiring elevation to agency senior leadership, i.e., Center Director/Associate Commissioner for Regulatory Affairs level. This board will monitor, but not direct, the use of the Centers' allocated inspection resources to ensure that each Center's expectations are being met.

5. Establish regularly scheduled meetings for BIMO program information sharing among leadership of ORA and Center BIMO offices. Determine meeting frequencies, purpose, process and attendees.

6. Begin to develop an Intelligent Questionnaire for one BIMO inspection type to support the implementation of eNSpect.

Summary

The BIMO Program Alignment Implementation Team will oversee completion of all of the above commitments during FY 2016 to ensure a successful launch of the stand-alone BIMO Program in FY 2017. In October 2015, each commitment will be reviewed by the BIMO Leads group to prioritize, define critical elements to be completed and included in the final deliverable product, set due dates for milestones of the commitment and final deliverable, as well as define what format will be used to present the final deliverable product. For example:

- Lead Organization(s):
- Critical elements:
- Due Date:
- Milestones:
- Deliverable Format/template (e.g. SOP, Process Map, White Paper)