
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

REVIEW OF BIORESEARCH MONITORING (BIMO) ESTABLISHMENT
INSPECTION REPORTS (EIRS)

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I. Purpose

This document describes our current procedures and responsibilities for reviewing a Bioresearch Monitoring (BIMO) Establishment Inspection Report (EIR).

II. What is a BIMO Establishment Inspection Report (EIR)?

An Establishment Inspection Report (EIR) documents the findings and observations made by the FDA district office after they conduct a Bioresearch Monitoring (BIMO) inspection. The BIMO inspection is usually conducted at the request of one of ONADE'S reviewers.¹

In addition to the EIR, inspection documentation generally includes an endorsement to the EIR describing the reason for the inspection, a brief history of previous findings, a summary of current findings, and if applicable (or if issued to those being inspected), an FDA Form 483 (Notice of Observations).

The district office includes an inspection classification in the EIR, and recommends a classification of No Action Indicated (NAI), Voluntary Action Indicated (VAI), or Official Action Indicated (OAI).

III. RECEIVING A request for a CONSULTING EIR review

The Pre-Market Compliance and Administrative Team in the Office of Surveillance and Compliance's Division of Compliance (i.e., the "BIMO team") will electronically request a consult from the appropriate ONADE personnel (generally the ONADE reviewer who requested the BIMO inspection or their team leader). Once the consulting review is assigned, the ONADE reviewer can view the

¹ See P&P 1243.8220.

materials through CDP web. The presumptive classification of the inspection should be included in the consulting review request. However, if it was not included in the consulting review request, the ONADE reviewer should email the individual who requested the consulting review to request the presumptive classification. The ONADE reviewer may include the email with the presumptive classification as an attachment in the consulting review.

IV. ONADE review of the EIR

The ONADE reviewer assigned the EIR consulting review evaluates the EIR and recommends whether the inspection classification assigned by the district office is appropriate. The ONADE reviewer also uses the EIR to help determine whether the inspected study or studies may be used in support of an (A)NADA.

The ONADE reviewer should prepare the EIR using the ONADE review template. In the review, include the following minimum information:

1. A brief description of the EIR, for example:
 - a. The type of inspection (GLP, clinical investigator, or sponsor/contract research organization/monitor);
 - b. The name of the inspected facility, investigator, or sponsor/contract research organization/monitor;
 - c. Date(s) of inspection;
 - d. The relationship of the inspected facility, investigator, or sponsor/contract research organization/monitor to the investigational drug project (e.g., Dr. Smith conducted a field study to demonstrate the effectiveness of drug X for the treatment of respiratory disease in sheep);
 - e. Whether a Form FDA 483 was issued;
 - f. The district office's presumptive classification of the EIR.
2. The administrative history/background relevant to the BIMO inspection should be included in the review. Relevant information could include:
 - a. The drug's proposed indication;
 - b. Whether the inspection was directed or routine;
 - c. Whether CVM accompanied the district office on the inspection;
 - d. Whether the data for the study been submitted/reviewed.

3. If a Form FDA 483 was issued, list the issues and discuss the impact, if any, on the integrity and acceptability of the data.
4. Describe other pertinent findings from the EIR and the impact, if any, on the integrity and acceptability of the data.
5. If the presumptive classification is "Official Action Indicated", describe what action CVM should take (e.g., whether the study will be considered acceptable or if a follow-up inspection is needed, etc.). ONADE's classification may differ from the presumptive classification issued by the BIMO team.
6. Communicate with the BIMO Team as needed before and/or after the consult is returned to determine the appropriate actions.

The Conclusions section of the review includes a statement indicating whether the ONADE reviewer agrees with the presumptive classification of the EIR. If the ONADE reviewer does not agree with the presumptive classification, a brief discussion of the reason for disagreement should be provided along with a recommendation for a new classification.

In the Recommendations section of the review, indicate that the EIR (including copies of all exhibits) should be filed in the administrative file for the (J)INAD.

V. Returning the consulting review to the BIMO Team

Follow team or division procedures for clearance of consulting reviews. Return the consulting review package through Appian.

VI. Filing and retention

The BIMO Team includes the original, electronically signed copy of the ONADE consulting review for the EIR on paper in the BIMO Team's records. The BIMO Team assigns the final classification for the inspection and issues a "close-out" memo to the district office. The BIMO Team develops any regulatory action documents (e.g. warning letters or disqualification proceedings) as warranted by the results of the inspection. The BIMO Team forwards a copy of all BIMO documents to the Records and Information Management (RIM) team to file in the (J)INAD administrative record after the BIMO inspection and all associated reviews are completed. The completed final action package will not be located in CDMS. Therefore, if an ONADE reviewer needs to reference a completed review, either a STARS Document Scanning Request must be submitted to the RIM team or the document can be checked out from DCU.

VII. References

FDA Compliance Program Guidance (CPG) Manual

CP 7348.808 – Good Laboratory Practice

CP 7348.810 – Sponsor, Contract Research Organizations, and Monitors

CP 7348.811 – Clinical Investigators

CVM Program Policy and Procedure Manual

1243.3009 – Format and Style Conventions for Reviews and Submission Summaries

1243.3029 – Closing Out Consulting Reviews for STARS Submissions

1243.3200 – Routing a request to obtain a review for an INAD, JINAD, ANADA, NADA or VMF submission

1243.8220 – BIMO inspection and status check request process

VIII. Version history

November 16, 2001 – original version

March 1, 2010– The document was reviewed by ONADE and Office of Surveillance and Compliance BIMO Team to determine if any changes needed to be made. Edits were made to include more specific information about the review process, information for generic animal drug applications and investigational files, and reformat the document and make it conform to ONADE document principles.

May 19, 2015 – Updated to reflect the electronic processing of submissions and electronic consulting requests.