OFFICE OF THE CENTER DIRECTOR

Processing and Reviewing Voluntary Genomic Data Submissions (VGDSs)

CONTENTS

PURPOSE

This MAPP explains how the Center for Drug Evaluation and Research (CDER) will process and review voluntary genomic data submissions (VGDSs) to the Food and Drug Administration (FDA).

BACKGROUND

The Agency has issued its final guidance on *Pharmacogenomic Data Submissions*, which encourages the voluntary submission of genomic data to the Agency. The guidance describes how the Agency will handle voluntary submissions (i.e., submissions that are not required as part of a regulatory submission). The guidance emphasizes that data submitted voluntarily will be used to help the Agency gain an understanding of genomic data while not being used as part of the regulatory decision making process. This MAPP explains how VGDSs will be received, reviewed, and maintained by the Agency.

The concept of voluntary data submission has been created with the goal of gaining access to drug development data that are vital for future reviews of drug applications containing genomic information. Therefore, CDER's goal in reviewing VGDSs is not only to understand them, but also to ensure that the *lessons learned* are communicated to all interested parties, in particular the review divisions, within the FDA.

REFERENCES

- Guidance for industry*, Pharmacogenomic Data Submissions*
- CDER MAPP 4180.2, Establishment of the Interdisciplinary Pharmacogenomic Review Group (IPRG)
- CBER SOPP 8204, Processing of Voluntary Genomic Data Submissions
- CBER SOPP 8114, Administrative Processing of Documents Received Prior to Submitting Investigational or Marketable Submissions (Pre-Submissions)

DEFINITIONS

GDS: A Genomic Data Submission

Voluntary GDS (VGDS): Designation for Voluntary Genomic Data Submission

Stand-alone VGDS: A voluntary GDS that is not associated with an existing application. Such voluntary submissions will be handled as submissions to a new pre-IND application.

Associated VGDS: A voluntary GDS that is submitted to an existing application (e.g., investigational new drug application (IND) (also pre-INDs), new drug application (NDA), biologics licensing application (BLA), or supplement). Such VGDSs will be submitted to the existing application, but will not be used by FDA in the process of regulatory decision making regarding the existing application.

Required GDS: A GDS that is required to be submitted to, or as part of, an existing application (e.g., IND, NDA, BLA, or supplement) and that will be used during the regulatory decision making process. This MAPP does not address required GDS submissions, which will be processed according to the usual standards for routine application submissions.

IPRG: Designation for Interdisciplinary Pharmacogenomic Review Group. The IPRG will review all VGDSs submitted to the Agency (see MAPP 4180.2, describing the formation and responsibilities of the IPRG) and consult, on request, on the required GDSs.

GENERAL POLICY

- VGDSs will be sent to and reviewed by the IPRG; they will not be sent to or reviewed by the review divisions.
- The IPRG will send a summary of its report to the sponsor.
- The IPRG will send a copy of its report to the appropriate review division.
- The FDA will not use information submitted through the voluntary process for regulatory decision making.
- The IPRG will be available, as needed, to respond to consults from the reviewing divisions on required GDSs submitted with an application.

PROCEDURES FOR RECEIPT AND PROCESSING VGDSs

Receipt

- All VGDSs must be accompanied by the *Voluntary Genomic Data Submission* cover sheet to ensure processing according to this MAPP. If not identified appropriately, the submission may be processed according to standard processing for routine application submissions.
- All VGDSs will be received and processed by the Central Document Room staff. Voluntary submissions will be identifiable by the *Voluntary Genomic Data Submission* cover sheet (see Attachment B).
- If a VGDS is submitted to a Division Document Room, it will be identifiable by the *Voluntary Genomic Data Submission* cover sheet (see Attachment B), and forwarded to the Central Document Room for processing.

Submission Processing

1. Stand-alone VGDSs (not submitted to an existing application):

- Upon receipt of any submission accompanied by the VGDS cover sheet, the Central Document Room Staff will:
  - – Stamp the submission with the receipt date.
  - – Establish a pre-IND number for the submission.
  - – Perform data entry in the corporate database for document tracking.
  - – Identify the submission by putting it in the IPRG jacket.
  - – Deliver the submission, using a courier, to the IPRG for review.

2. Associated VGDSs (submitted to a previously established application):

Note: Voluntary submissions to existing applications can be received, processed, archived, and reviewed regardless of the status of the application. For example, a sponsor can submit a voluntary submission to a withdrawn application. Such submissions will not change the status of the application.

- Upon receipt of any submission accompanied by the VGDS cover sheet, the Central Document Room staff will:
  - – Stamp the submission with the receipt date.
  - – Perform data entry in the corporate database for document tracking.
  - – Identify the VGDS by putting it in the IPRG jacket.
  - – Deliver the VGDS, using a courier, for review to the IPRG.

  The IPRG will maintain a log of VGDS sent to the IPRG for review.

PROCEDURES FOR REVIEWING VGDSs

Procedures

- The IPRG is responsible for reviewing all VGDSs and is the primary point of contact for the sponsor during and after the review process on matters relating to voluntary submission of pharmacogenomic data.

- The IPRG meets monthly to discuss VGDS-related issues.
- Reviewers from CDER, CBER, and CDRH are appointed by the respective Center Delegates to ensure adept review of the submission.
- To facilitate the review process, the IPRG can meet with the sponsor (refer to the section on meetings).
- The IPRG will write a VGDS report. The Chair of the IPRG and the Director of the Office of Clinical Pharmacology and Biopharmaceutics (OCPB) or his/her designee are responsible for documenting concurrence or any differences of opinion regarding the report and the interpretation of the data and how such differences were resolved.
- The IPRG is responsible for entering the report into DFS with copies to all IPRG members and the Chief of the Project Management Staff in the appropriate review division.
- A summary report of the VGDS review will be sent to the sponsor.
- The IPRG intends to review a VGDS as soon as possible, with a target timeline of no longer than 6 months from receipt of the VGDS to the sponsor's receipt of the IPRG's summary.
- If the IPRG determines that the VGDS data are applicable to the regulatory review of a drug that is the subject of an investigational or marketing application, the IPRG will notify the sponsor and ask that the information be submitted to the relevant application as a required submission.
- If it is unclear whether a submission is voluntary or required, the IPRG can convene a meeting (or telecon) with the sponsor and representative(s) from the relevant review division to help determine the status of the submission in question.
- The IPRG will organize educational seminars and workshops (internal and public) and advisory committee meetings to discuss findings based on VGDSs. The IPRG will ensure that data presented at such public meetings are appropriately redacted or that permission to present the data is obtained from the sponsor.
- The IPRG will store all VGDS documents (electronic and paper).

Meetings Relating To VGDSs

- **Presubmission Meeting with IPRG**

A pre-VGDS meeting can be requested by a sponsor wishing to discuss aspects of a VGDS. See the guidance for industry on *Formal Meetings with Sponsors and Applicants for PDUFA Products* for procedures on requesting and granting meetings.

Note: Although PDUFA regulations do not apply to pre-VGDS meetings, the goal is to follow the procedures laid out in the guidance, using type B meeting timelines.

- **VGDS Meeting with IPRG**

During the review process, one or more meetings between the IPRG and the sponsor may be held. Meetings can be requested by a sponsor or the FDA.

- **Postreport Meeting**

A meeting with the IPRG can be requested by the sponsor to discuss the findings in the report.

RESPONSIBILITIES

Central Document Room Staff

- Receive and process voluntary submissions
- Establish a pre-IND application if a submission is a stand-alone VGDS
- Enter data into the corporate database for tracking
- Distribute all submissions (paper and electronic) to the IPRG

Division Document Room

- Forward submissions accompanied by the VGDS cover sheet to the CDR for processing

IPRG

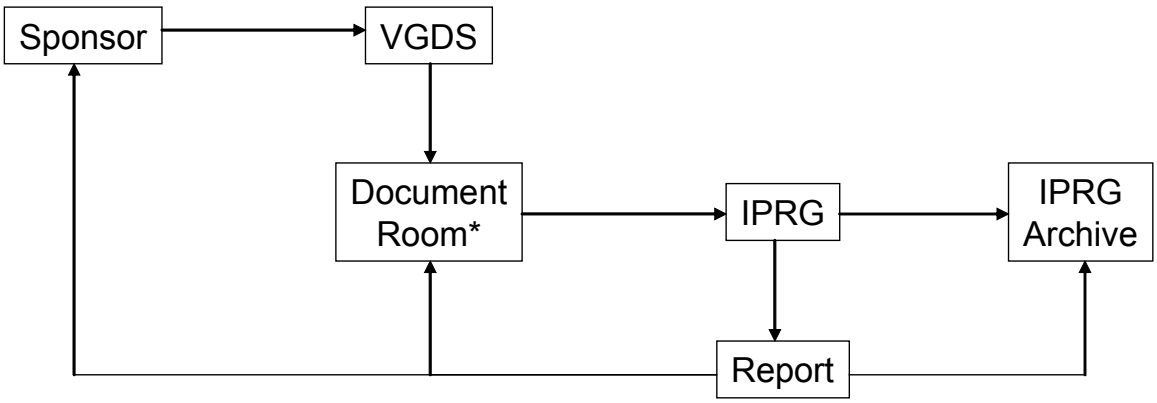
- Maintain a log of VGDSs reviewed by the IPRG
- Review all written VGDS reports
- Send a summary report to the review divisions and the sponsor and file reports in DFS
- Meet with the sponsor and applicable review division as needed
- Store all VGDS documents (paper and electronic)
- Coordinate communications with sponsors and interested parties on issues related to VGDSs

For more detail on the constitution and functions of the IPRG, see MAPP 4180.2

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT A: Procedure for Receipt and Processing of VGDS



ATTACHMENT B: Voluntary Genomic Data Submission Cover Sheet

Send all CDER voluntary genomic data submissions to the following address accompanied by this coversheet:
FDA/CDER
Central Document Room (CDR)
5901-B Ammendale Road
Beltswille, MD 20705-1266

Attention!

This is a

Voluntary
Genomic Data Submission

Application number _____ (leave blank if this is the first submission for a stand-alone VGDS)

_____Initial Submission

_____Subsequent Submission

Please route directly to the IPRG (HFD-850) After processing in the CDR!