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# Manual of Standard Operating Procedures and Policies

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## Regulatory - Communication

### Administrative Processing of Documents Received Prior to Submitting Investigational or Marketing Applications (Pre-Application)

SOPP 8114

Version #1

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#### 1. Purpose

The purpose of this document is to describe the policies and procedures for administrative processing and tracking of documents received for regulatory review or comment from sponsors/applicants that are not associated with an investigational or marketing application.

#### 2. Definitions

##### **Pre-application -**

Any document, paper or electronic, which has been submitted to the Center for Biologics Evaluation and Research (CBER) for regulatory review or comment but which is not an application type recognized by the Code of Federal Regulations (CFR) and therefore does not logically fall under an existing regulatory database for tracking.

The submission may or may not be associated with a future regulatory application.

Pre-application materials for a Biologics License Application (BLA) supplement would not be considered a pre-application because the submission falls under the existing BLA number and would be tracked as product correspondence in RMS/BLA.

A submission that does not constitute a full or rolling marketing application and cannot be associated with any existing application would be considered a pre-application.

Pre-application documents relative to the proposed following applications include but are not limited to:

- Investigational and Related Applications (IRA)
  - Investigational New Drug application ( IND)
  - Investigational Device Exemption (IDE)
  - Master Files (MF)
  - Special Protocol Assessment (SPA)
- Marketing Applications
  - Biologics License Application (BLA)
  - 510(k)
  - Pre Marketing Application (PMA)
  - New Drug Application (NDA)

- Abbreviated New Drug Application (ANDA)
- Protocol Development Plan (PDP)
- Other:
  - Draft protocols that cannot be associated with an existing IND or IDE.
  - Pharmacogenomic Data Submissions.

### **DATS Log Number**

The Document and Accountability Tracking System (DATS) generated document tracking number associated with the pre-application. This number will be assigned to the document if the pre-application is received in CBER's Document Control Center (DCC).

### **Pharmacogenomic Data Submission**

A Voluntary Genomic Data Submission (VGDS) is most easily identified if the submitter has used the voluntary submission coversheet (see Guidance for Industry; Pharmacogenomic Data Submissions) designating the submission as voluntary. If the submitter does not use the cover sheet, consider the submission voluntary unless it is clearly labeled as a supplement or amendment to an existing IND or BLA number.

## **3. Background**

Investigational and marketing applications are administratively tracked in CBER regulatory databases (BIRAMS, RMS/BLA, BLT, etc). However, until the development of the Pre-Application Tracking System (PTS), documents received in CBER that precede a formal application have been encouraged but have not been tracked. In order to improve administrative and review efficiency, enable cross-referencing to applications, and enable determining pre-application workload, the PTS was developed.

These procedures will:

- Standardize administrative processing of pre-applications across the Center;
- Provide instructions for entering tracking information into the pre-application tracking system; and
- Support the creation, maintenance and disposition of pre-application tracking records.

## **4. Policy**

It is CBER policy that all pre-applications received after the effective date of this SOPP must be processed in accordance with these procedures and linked to the appropriate investigational or marketing application once it is received by CBER, if applicable.

On occasion, the division/staff associated with the regulatory management of the pre-application may receive the pre-application directly and not through the CBER Document Control Center. The PTS enables data entry of pre-applications that have not been assigned a DATS Log number.

The same pre-application tracking number will be used for all subsequent submissions until a regulatory application number ( IND, IDE, BLA, etc) has been established. Once a regulatory application number is established, the pre-application number will, in most cases, be closed.

If there is no activity on a pre-application for five years, the file will be closed. The office may choose to contact the sponsor to confirm there will be no further activity on the pre-submission prior to closing the pre-application file.

## **5. Responsibilities and Procedures**

### **A. Receipt and Processing of Pre-submission**

#### **i. DCC**

- a. Receives and processes the pre-application, either paper or electronic, in accordance with existing procedures for regulatory submissions, including entry into DATS and barcoding.
- b. Forwards the pre-application to the division/staff associated with its regulatory management.

#### **ii. Division/Office**

- a. Determines if the document(s) are a new pre-application or a new communication related to

an existing pre-application.

- b. Ensures the appropriate information is entered into PTS per the PTS User Guide.
- c. Ensures the pertinent information is also entered into the CBER Regulatory Meeting Tracking System (CRMTS) if the pre-application is or contains a meeting request.
- d. Communicates the pre-application tracking number to the sponsor/applicant through a telecon or inclusion in a written communication.

#### B. Filing the Pre-submission

##### i. Regulatory Project Manager (RPM)

- a. Ensures that a complete set of documents constituting the pre-application is sent to DCC for filing according to DCC Procedure Guide 3.
- b. Ensures that any subsequent communications with the sponsor/applicant will be filed in DCC according to DCC Procedure Guide 3.

#### C. Closing out the Pre-submission

##### i. RPM

- a. Once the investigational or marketing application is received, the RPM/reviewer will ensure the cross-reference information is entered in the PTS and the appropriate regulatory database (BIRAMS, RMS-BLA, BLT etc).
- b. Ensures the pre-submission is closed.
- c. If the information in the pre-application will be associated with additional investigational or marketing applications, the pre-application file stays open until the last application is received.

#### 6. Pharmacogenomic Data submissions

If the submission is a Voluntary Genomic Data Submission (VGDS) that is not associated with an existing IND or BLA, then the submission will be forwarded to the Interdisciplinary Pharmacogenomic Review Group (IPRG) in CDER at HFD-850 (see Guidance for Industry; Pharmacogenomic Data Submissions). There will be no entry into PTS.

#### 7. References

DCC Procedure Guide 3

Pre-application Tracking System (PTS) Data Dictionary

#### 8. Effective Date

April 16, 2007

#### 9. History

| Written/Revised | Approved                 | Approval Date  | Version Number | Comment                     |
|-----------------|--------------------------|----------------|----------------|-----------------------------|
| BPWG/RMCC       | Robert A. Yetter,<br>PhD | April 13, 2007 | 1              | First issuance of this SOPP |

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