U.S. Food and Drug Administration

European Commission

European Medicines Agency

Guiding principles
Processing Joint FDA EMEA Voluntary Genomic Data Submissions (VGDSs)
within the framework of the Confidentiality Arrangement

CONTENTS

PURPOSE
BACKGROUND
REFERENCES
DEFINITIONS
GENERAL POLICY
PROCEDURES
RESPONSIBILITIES
TIMELINES
EFFECTIVE DATE

PURPOSE

This document explains how the U.S. FDA and the EMEA will process requests for Joint FDA-EMEA voluntary genomic data submission (VGDS) briefing meetings.

BACKGROUND

The FDA and the EMEA issued *Guidance for Industry:* Pharmacogenomic Data Submissions and Guideline on Pharmacogenetics Briefing Meetings, respectively. Both documents encourage the voluntary submission of genomic data by the sponsors to the Agencies.

The guiding principles describe how the Agencies process voluntary submissions (i.e., submissions that are not required as part of a regulatory submission) and the associated briefing meetings. Both documents also emphasize that voluntary submissions are used to help the Agencies gain an understanding of genomic data, and are not part of the regulatory decision making processes.

Recently, FDA and the EMEA have agreed to expand the VGDS process to include the option for sponsors to have joint FDA-EMEA VGDS Briefing meetings. This document explains how such requests are received, processed and reviewed by the Agencies.

DEFINITIONS (alphabetical order)

Associated VGDS: A voluntary genomic data submission that is submitted to an existing application (e.g., investigational new drug application (IND), 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.

Briefing Meeting: An optional informal meeting between a sponsor and regulators at the EMEA for the purpose of sharing scientific and technical information.

CHMP: The Committee for Medicinal Products for Human Use

EMEA: European Medicines Agency

FDA: Food and Drug Administration, United States of America

GDS: A Genomic Data Submission

IPRG: Designation for the FDA's Interdisciplinary Pharmacogenomic Review Group. The IPRG will reviews all VGDSs submitted to the FDA (see FDA/CDER MAPP 4180.2, describing the formation and responsibilities of the IPRG) and consult, upon request, on the required GDSs

PG: Pharmacogenomics and/or Pharmacogenetics, terms often used interchangeably

PG Working Party (PGWP): The EMEA Pharmacogenetics Working Party is a permanent working party of the EMEA CHMP, and provides recommendations on all matters relating directly or indirectly to Pharmacogenetics

Stand-alone VGDS: A voluntary GDS that is not associated with an existing application.

VGDS: A Voluntary Genomic Data Submission.

GENERAL POLICY

- Submissions encompassing data used for regulatory decision making are not part of this voluntary process.
- VGDS briefing packages will be sent to and reviewed by the IPRG and PGWP; they will not be sent to or reviewed by the FDA review divisions (as detailed in the FDA Pharmacogenomics Guidance) or CHMP formal evaluation teams.
- Both the FDA and EMEA will hold all submissions confidential to the extent permitted by law. A draft summary of the meeting will be created by the sponsor and sent to both agencies.

- A final summary of the meeting will be issued jointly by the FDA and EMEA and will be sent to the sponsor. Final summaries will be drafted on a rotating basis by FDA and EMEA. FDA and EMEA will keep the final summaries confidential to the extent permitted by law.
- The IPRG and the PGWP may send a copy of the final summary of the meeting to the corresponding review division and to the CHMP for information as appropriate.
- FDA and EMEA have the right to accept or decline to participate in any specific Joint VGDS Briefing meeting based on current practices, resources, and logistics in the Regions.

PROCEDURES

Contact Information

Sponsors requesting joint VGDS Briefing meetings should send requests to both FDA and EMEA for the agencies' consideration. The contact points are:
FDA: Executive Secretary of the IPRG (fdagenomics@fda.hhs.gov); with a copy to Michelle Limoli, Office of International Programs (Michelle.Limoli@fda.hhs.gov)
EMEA: PGWP Secretary, Sector Clinical Safety and Efficacy, Pre-Authorization Unit European Medicines Agency (BriefingMeetings@emea.eu.int); with a copy to Arielle North, Executive Support Sector (Arielle.North@emea.eu.int).

Request for Joint VGDS Meeting

The formal request by a sponsor for a Joint VGDS Briefing meeting should include the scope of the meeting, the meeting date requested, a list of sponsor attendees, an executive summary, and a list of issues to be addressed.

Decision and Scheduling for the Joint VGDS Meetings

Since Joint VGDS Meetings are voluntary and resource-intensive, decisions to hold Joint VGDS Meetings will be made on a case-by-case basis. This decision will be made jointly by the FDA IPRG and the EMEA PGWP, based on current practices in the Regions, within two weeks from the receipt of a formal request.

Once it is determined that a request has been approved for a meeting, a meeting can be scheduled according to the EMEA PGWP meeting schedule.

Meeting Documentation

The sponsor is responsible for providing a draft summary of the meeting to both agencies one week after the joint VGDS meeting.

Venue for holding the Joint VGDS Briefing meetings

Due to the locations, time differences and logistics of the parties, the Joint VGDS briefing meetings will normally be held by videoconference with conference sites located at both FDA and EMEA. In order to maximize scientific interactions at these meetings, it is anticipated that the sponsor requesting the meeting will be present at one or both these sites. Additional videoconference sites may also be requested and will be accommodated as is feasible.

RESPONSIBILITES AND TIMELINES

Responsibilities for Organizing the Joint VGDS Meetings

The responsibility for organizing the Joint VGDS Briefing meetings will alternate between FDA IPRG and EMEA PGWP.

The sponsor requesting the meeting will be responsible for submitting the meeting request; providing the briefing package and background information; preparing questions to be addressed; providing copies of presentations and other materials as necessary; and submitting a draft summary of the Joint VGDS Briefing meeting to the agencies after the meeting. All the above submissions relating to the meeting should be made to both FDA and EMEA concurrently.

Timelines

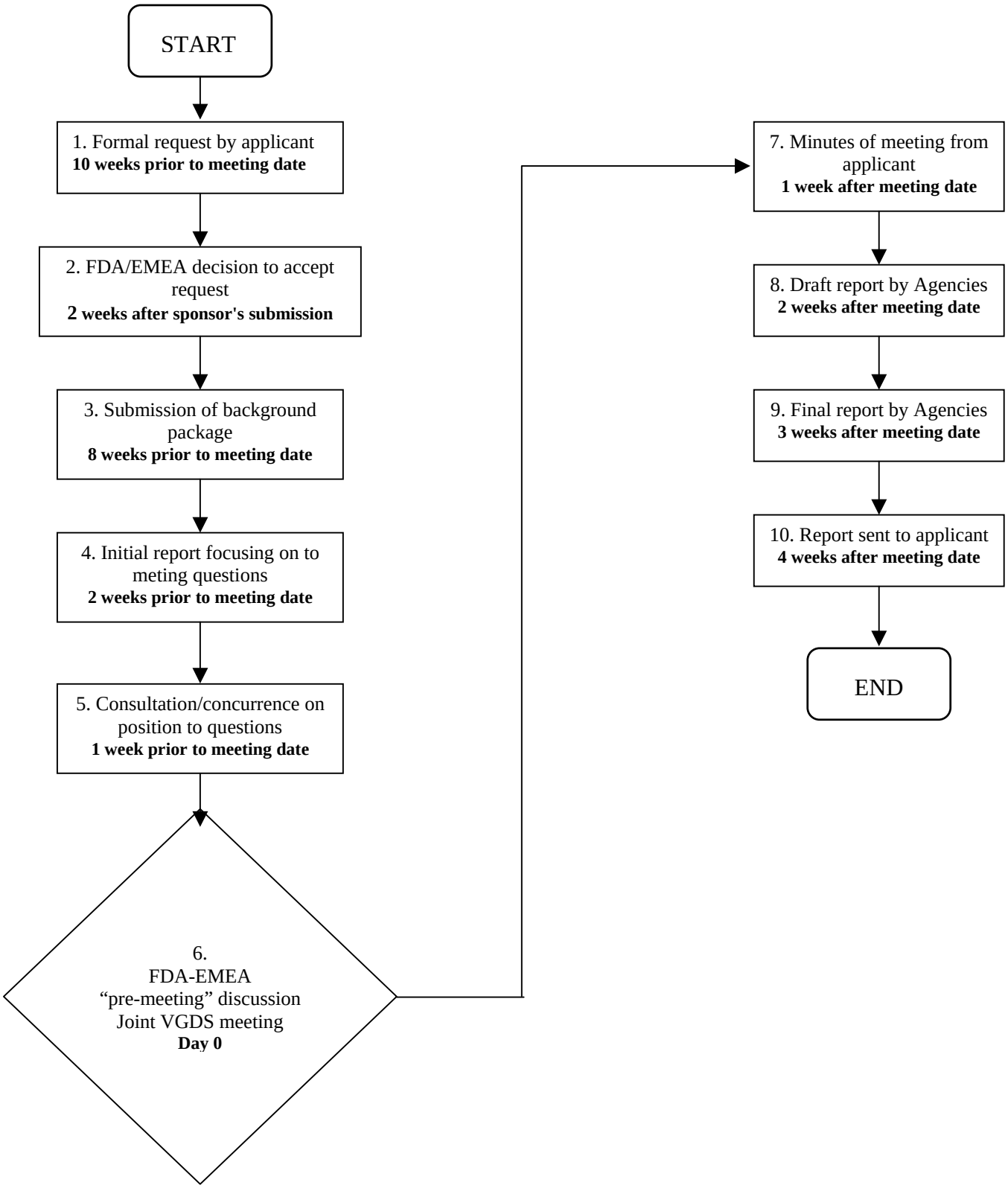
Informal request by sponsor (including proposal for a meeting date)	
Formal request by applicant	10 weeks prior to meeting date
Submission of background package (to both agencies)	8 weeks prior to meeting date
Draft Agency responses to sponsor's questions[1]	2 weeks prior to meeting date
Agencies develop a consolidated response to sponsor's questions	1 week prior to meeting date
FDA-EMEA "pre-meeting" discussion[2]	
Joint VGDS Briefing meeting with the Sponsor	Day 0
Draft summary of meeting from sponsor	1 week after meeting date
Draft summary by Agencies[3]	2 weeks after meeting date
Final summary by Agencies[4]	3 weeks after meeting date
Summary sent to Sponsor	4 weeks after meeting date

[1] This initial draft will be prepared by the Rapporteur identified either within the PGWP or the IPRG
[2] Pre-meeting discussion is mainly focused on areas of divergent views
[3] The lead Rapporteur will propose the updated version to be supplemented by the other Agency
[4] If there are divergent views at this point discussion will be organized among PGWP/IPRG Chairs and Rapporteurs to finalize the joint report.

REFERENCES

- EMEA Draft Guideline on Briefing Meetings EMEA/81167/2006
- EMEA Mandate of Pharmacogenetics Working Party EMEA/81167/2006
- EMEA application procedures (http://www.emea.eu.int/index/indexh1.htm)
- FDA Guidance for Industry*: Pharmacogenomic Data Submissions*
- FDA/CDER MAPP 4180.2, Establishment of the Interdisciplinary Pharmacogenomic Review Group (IPRG)
- FDA/CDER MaPP 4180.3, Processing and Reviewing Voluntary Genomic Data Submissions (VGDSs)
- FDA/CBER SOPP 8204, Processing of Voluntary Genomic Data Submissions
- FDA/CBER SOPP 8114, Administrative Processing of Documents Received Prior to Submitting
- Investigational or Marketable Submissions (Pre-Submissions)
- www.fda.gov/cder/genomics

Effective Date: May 19, 2006


START
1. Formal request by applicant
10 weeks prior to meeting date
2. FDA/EMEA decision to accept request
2 weeks after sponsor's submission
3. Submission of background package
8 weeks prior to meeting date
4. Initial report focusing on to meting questions
2 weeks prior to meeting date
5. Consultation/concurrence on position to questions
1 week prior to meeting date
6.
FDA-EMEA
"pre-meeting" discussion
Joint VGDS meeting
Day 0
7. Minutes of meeting from applicant
1 week after meeting date
8. Draft report by Agencies
2 weeks after meeting date
9. Final report by Agencies
3 weeks after meeting date
10. Report sent to applicant
4 weeks after meeting date
END