

POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

**Good Review Practice:
Clinical Review of Investigational New Drug Applications**

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PURPOSE

- This MAPP provides policies and procedures for the clinical review of investigational new drug applications (INDs) using good review practices (GRPs) within the Center for Drug Evaluation and Research. These GRPs can be found in the document titled “Good Review Practice: Clinical Review of Investigational New Drug Applications.”¹
- This MAPP was prepared to assist FDA clinical review staff in reviewing INDs during drug development. This MAPP does not address the format and content of an IND clinical review document or the time frame in which it should be completed.
- This MAPP is one in a series of MAPPs designed to document GRPs for review staff in accordance with MAPP 6025.1 *Good Review Practices*. General policies, responsibilities, and procedures regarding all GRPs are contained in MAPP 6025.1 and apply to this MAPP.

BACKGROUND

- This MAPP addresses the clinical review of an IND from the pre-IND phase through the time of the pre-new drug application/biologics license application

¹ This document can be found on the Good Review Practices (GRPs) web page (<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm118777.htm>).

meeting. Although the primary focus is on the clinical review of INDs for new molecular entities, many of the principles can be applied to all INDs and to the review of new drug applications/biologics license applications.

- The GRPs described within this MAPP do not address how submissions will be prioritized for review, the time frames for reviewing submissions, nor the extent to which each submission type should be reviewed. Rather, they describe a systematic and standardized approach to clinical review.

POLICY

- General policies regarding all GRPs are contained in MAPP 6025.1 *Good Review Practices* and apply to this MAPP.

RESPONSIBILITIES AND PROCEDURES

- General responsibilities and procedures regarding all GRPs are contained in MAPP 6025.1 *Good Review Practices* and apply to this MAPP.

EFFECTIVE DATE

This MAPP is effective upon date of publication.