Bio

Where and How

Using Accelerated Approval to Improve Drug Development

Drugs granted accelerated approval must meet the same statutory standards of evidence for safety and effectiveness as those granted traditional approval.

In using the accelerated approval pathway (AAP):

- A sponsor must show that the drug demonstrates substantial evidence of an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict a clinical benefit.

Where does the FDA come in?

- FDA labeling of indications approved under the AAP is **designed to clearly communicate to patients and physicians the meaning of the accelerated approval pathway** and the ongoing trials to verify clinical benefit.
- FDA provides additional oversight of promotion of products approved under the AAP to **ensure effective communication with physicians and patients** and can withdraw the accelerated approval if the sponsor uses false or misleading promotional materials.
- Sponsors are required to conduct with due diligence phase 4 post-marketing trials to verify the clinical benefit of the drug. **FDA may withdraw the accelerated approval if one of the following occurs:**

Evidence demonstrates that the product is not shown to be safe or effective

The post-marketing trials do not verify clinical benefit or are not conducted with due diligence

The sponsor disseminates false or misleading promotional materials