U.S. Approval Pathways for Drugs and Biologics

- ***Traditional approval***
  - Denotes the longstanding route of drug approval based on the demonstration of clinical benefit or an effect on a surrogate endpoint known to predict clinical benefit
- ***Accelerated Approval***
  - Designed to facilitate delivery of products **appearing to provide a benefit** for a *serious* or *life-threatening illness* **lacking satisfactory treatment**
    - Supported by clinical data which shows an effect on a **surrogate endpoint** that is "reasonably likely to predict clinical benefit"
  - Promulgated in 1992
  - This requires a PMR or "post marketing requirement" to verify and describe the actual clinical benefit