Regulatory Perspective: Opportunities for Postmarketing CV Safety Outcomes Collection

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Disclosures

- I have no conflict of interest to report
- I will not be discussing off-label use of approved products
FDA Drug Approval

Safety

Efficacy

Overall Benefit: Risk Assessment
When do we collect safety information?
Safety Information

• Before approval:
  – Preclinical studies
  – Monitoring in pivotal studies

• Post approval:
  – Postmarketing safety reporting
  – Non-randomized observational studies
  – Safety Outcome Trials
Postmarketing Safety Reporting

• MedWatch: The FDA Safety Information and Adverse Event Reporting Program
http://www.fda.gov/Safety/MedWatch/

• Medical literature

• Global Database: Summaries of FDA safety analyses on approved products (after 18 months or 10,000 patients) is posted on the new Postmarketing Drug Safety Evaluation website:

• EHR/Claims Data

• Social Media (abuse information)
Non-randomized observational studies

• Pharmacoepidemiologic Studies
  – Protocol, control group and tests prespecified hypotheses
  – Estimation of relative risk

• Registries
  – Organized system for collection of information (medical intervention, risk factor, prior exposure)
  – motHER Registry
Safety Outcome Measures

• Post Marketing Requirement/Commitment (PMR/PMC)
  – Required of or agreed upon by the Applicant
  – Ongoing at the time of approval or conducted after FDA has approved a product for marketing
  – Provides additional information about a product’s safety, efficacy, optimal use, quality, stability or consistency in manufacturing

• Risk Evaluation and Mitigation Strategies (REMS)
  – Can be required by FDA for certain applications to ensure benefits > risks for a drug

*FD&C Act by FDAAA 2007
Conclusions

• Continued CV safety outcomes collection is necessary:
  – To educate patients/survivors and HCP
  – Requires improved CV toxicity data collection
  – Can lead to labeling changes

• Best approach will depend on:
  – Particular signal
  – Question of interest
  – MOA and understanding of CV physiology

• Communication with the FDA essential
Thank You!