Regulatory Perspective: Opportunities for Postmarketing CV Safety Outcomes Collection

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September 22, 2016

Disclosures

- I have no conflict of interest to report

- I will not be discussing off-label use of approved products

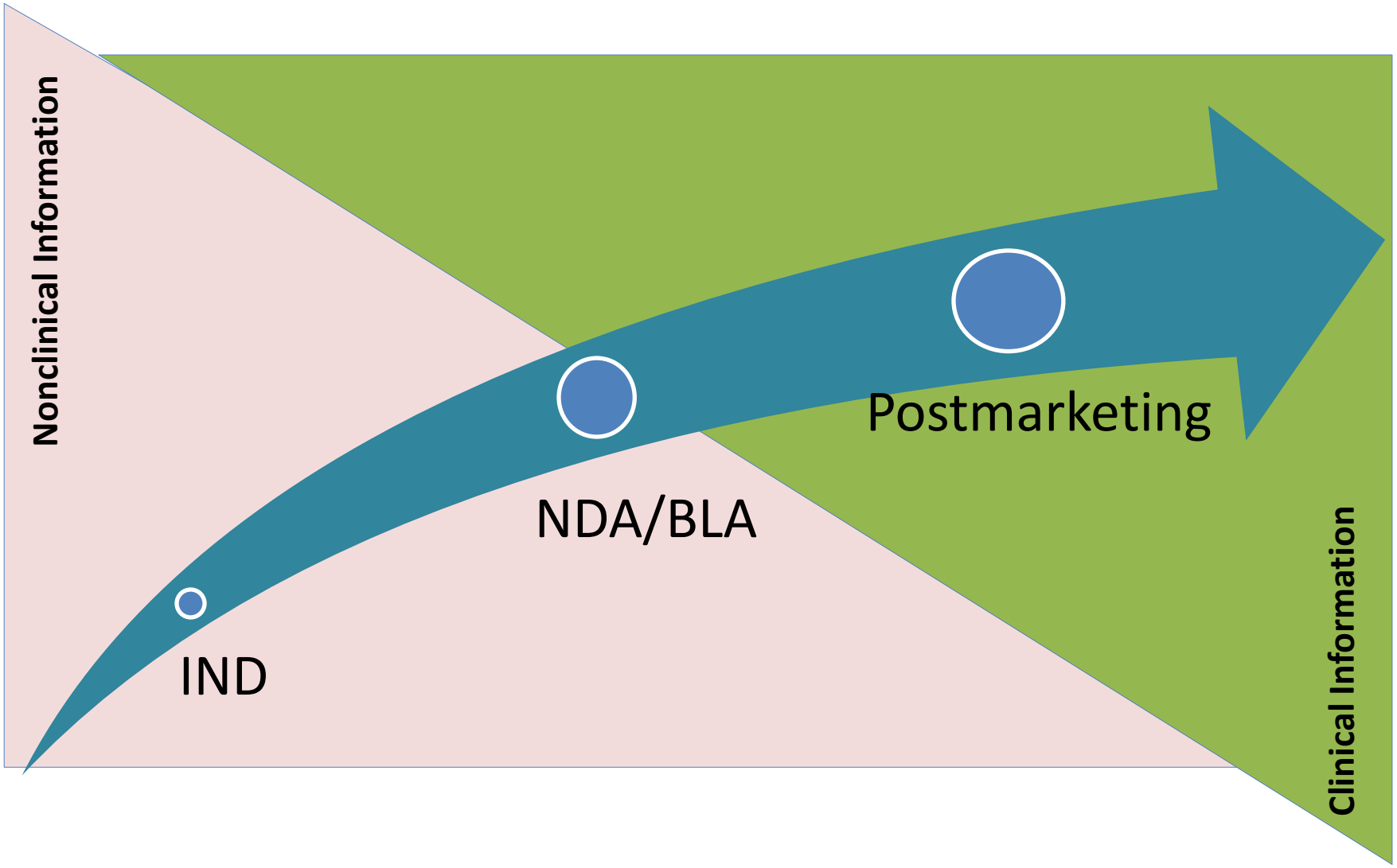
FDA Drug Approval

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:
  http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm
- 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

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Thank You!

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