Regulatory Considerations for Developing NOAC Reversal Agents

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CSRC Thinktank Meeting
Silver Spring, MD
April 22, 2014

Canada

Disclaimer

- **This presentation reflects my personal opinion only.**

Requirements for a New Drug Submission

- **Two phase III pivotal trials for a new drug**
- **For potentially life-saving drugs, a Notice of Compliance with Conditions (NOC/c) may be granted**
- **Additional studies to confirm the clinical benefit**

Requirements for NOAC Reversal Agents -1

- Clear mechanism of action
- Clear dose-response effect
- Clinical PK/PD
- Maximum dose
- Assessment of immunogenicity if of animal origin
- Reduced toxicity studies (e.g. reproductive tox, carcinogenicity not required)
- It should not cause thrombosis or clots

Requirements for NOAC Reversal Agents -2

- **Targeted patient populations: drug-induced active bleeding, emergency procedures or overdose**
- **Special populations: elderly, renal impairment**
- **Patients concomitant antiplatelet**

Requirements for NOAC Reversal Agents -3

Pivotal Trial:

- **Number of Patients: (about 100)**
- **Control group: standard of care**
- **Trial duration: 7 days or 30 days (?)**
- **Efficacy endpoints: clinical outcomes and coagulation assays**
- **Safety endpoints: (?)**