CBER's Mini-Sentinel Protocol Based Evaluations

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Role of Protocol Based Evaluations

- Best evidence to assess the safety of medical products
  - Assess safety on a population level
  - Sophisticated analytic methods
  - Exposures and outcomes validated by medical records
- Enables FDA to conduct independent safety studies
  - Large, nationwide, multi-site surveillance population
  - Prospectively monitor safety of new products after licensure
  - Evaluate populations not studied clinical trials (e.g. pregnancy)
- Pandemic response
- Complements existing systems (AERS and VAERS)

PRISM Protocol Based Studies

	Surveillance Study	Anticipated Protocol Posting Date	Anticipated Final Study Report Posting Date
1	Rotavirus vaccines and intussusception	Posted 10/24/11	Fall 2013
2	Gardasil and venous thromboembolism	Posted 3/30/12	Winter 2013/14
3	Influenza vaccines and febrile seizures	Posted 1/25/13	Spring 2014
4			
5			
6			
7			

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4	**Influenza vaccines and miscarriages**	**Summer 2013**	**TBA**
5	**Influenza vaccines and cleft lip and palate**	**Summer 2013**	**TBA**
6	**Influenza real-time safety surveillance**	**Summer 2013**	**TBA**
7	**Prevnar 13 and Kawasaki Disease**	**Spring 2014**	**TBA**

BloodSCAN Protocol Based Studies

	Surveillance Study	Anticipated Protocol Posting Date	Anticipated Final Study Report Posting Date
1	Intravenous immunoglobulins and thromboembolic events	Winter 2013/14	TBA

Frequently Asked Questions

- **How does CBER select what to study?**
  - Questions emerging from FDA licensure process (i.e. pharmacovigilance planning)
  - Address questions from other sources and surveillance systems
  - Better define risk using Mini-Sentinel's large population
- **Does CBER plan to conduct chart review?**
  - Yes, currently planned for all CBER protocol based studies

Frequently Asked Questions, cont.

- **How does CBER coordinate with other Federal Partners?**
  - Routinely interface with Centers for Disease Control and Prevention, Department of Defense, Centers for Medicaid and Medicare, etc.
  - Coordinate through Immunization Safety Task Force and National Vaccine Program Office
  - Share resources and work collaboratively (e.g. CDC Vaccine Safety Datalink)

Plans for Transparency

- Post all study protocols online
  - Public comment period
  - Notify manufacturers of protocol postings
- Post final study reports online
- Present at public federal advisory committees
- Publish findings in medical literature

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