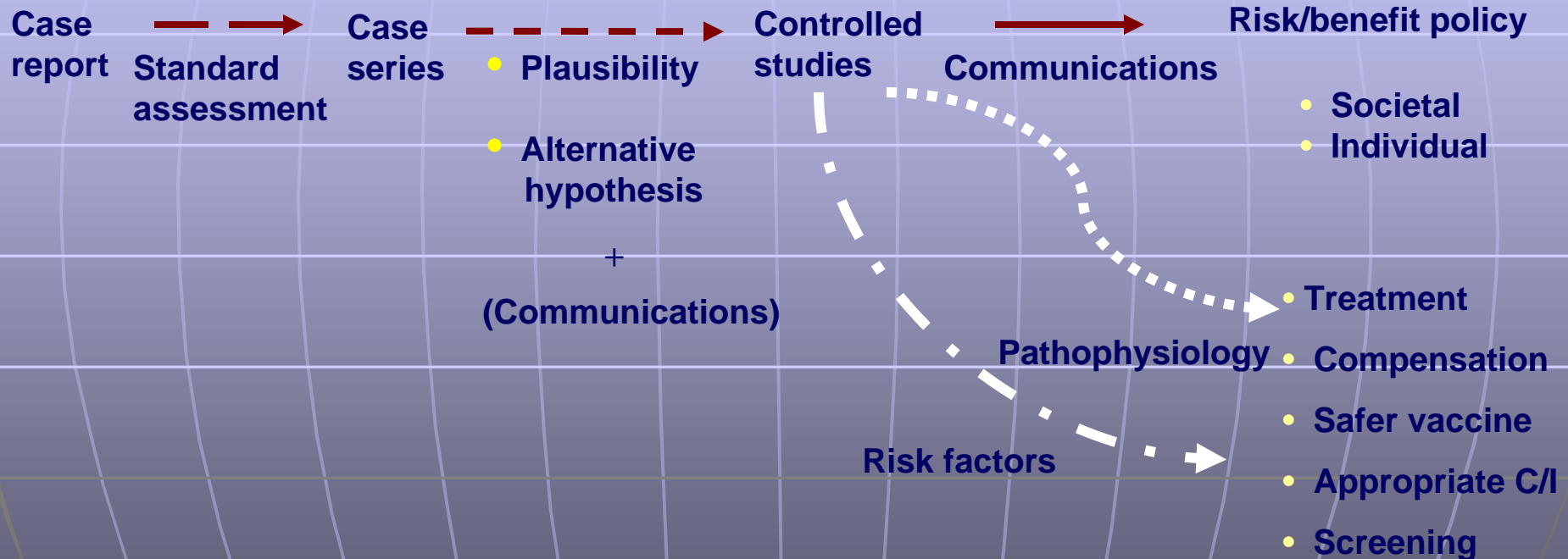


Clinical Immunization Safety Assessment Centers

Life Cycle of a Vaccine Safety Concern



Clinical Immunization Safety Assessment (CISA) Centers: The Need

- Limits of pre-licensure trials => reliance on post-licensure for safety surveillance.
- Most common post-licensure surveillance: passive “spontaneous” reporting system.
- AE’s occur rarely => each reporter likely doing so 1st time => non-standardized data
 - unlike clinical trial
 - data heterogeneity => interpretation difficult

Clinical Immunization Safety Assessment (CISA) Centers

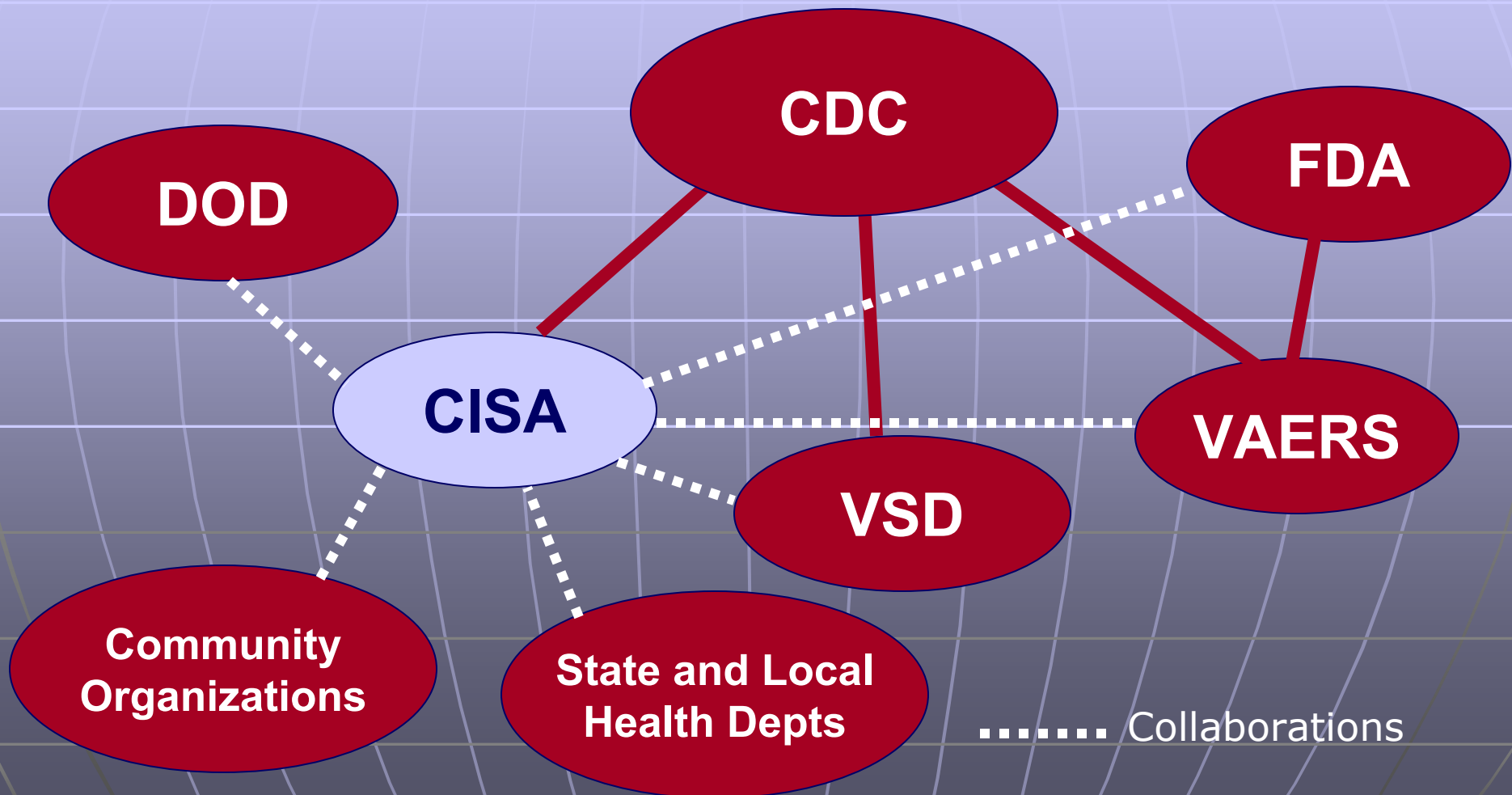
■ Tasks:

- Intensive study: person with true reactions.
- Standard assessment => => new "syndrome X"?
- Monitoring next dose in patients with severe AE.
- Consultation for clinical safety questions + follow-up to track compliance & outcome.

■ Goal:

- Increase scientific knowledge of "outliers."
- Maximize utility of VAERS as "disease registry".
- Eventual regional distribution.
- Disseminate protocols and findings via web.

Investigation of Vaccine Safety



CISA Network

**Kaiser Permanente
Oakland**

**Boston Medical
Center / Boston
University**

Columbia Univ

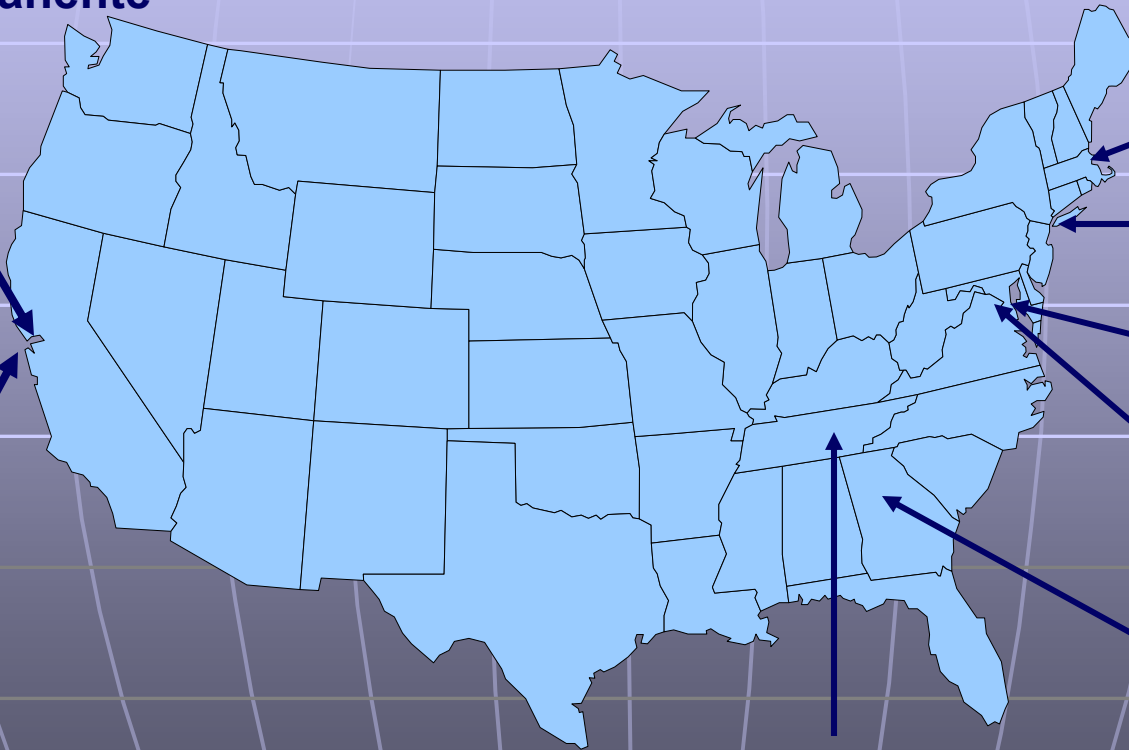
Univ. Maryland

**John Hopkins
University**

CDC

**Stanford
University**

**Vanderbilt
University**



CISA Centers

- **Kaiser Permanente Oakland CA**
Steven Black MD
Henry Shinefield MD
- **Stanford University**
Corry Dekker MD
- **Vanderbilt University**
Kathryn Edwards MD
- **University of Maryland**
Margaret Rennels MD
- **Johns Hopkins Univ**
Neal Halsey MD
- **Boston Medical Center/Boston Univ**
Colin Marchant MD
William Adams MD
Elizabeth Barnett MD
Catherine Fleming MD
Jerome Klein MD
- **Columbia University**
Phillip LaRussa MD
Ann Gershon MD
Matilda Irigoyen MD

Some Examples of CISA Projects

- Vaccinia protocols and algorithms
- Limb swelling after the 5th dose of DTaP
- Lymphoma and SV-40 virus
- Genetics of adverse reactions to smallpox vaccine
- Neurologic reactions after immunization

Clinical Immunization Safety Assessment Centers