

Safe Passage Study Update



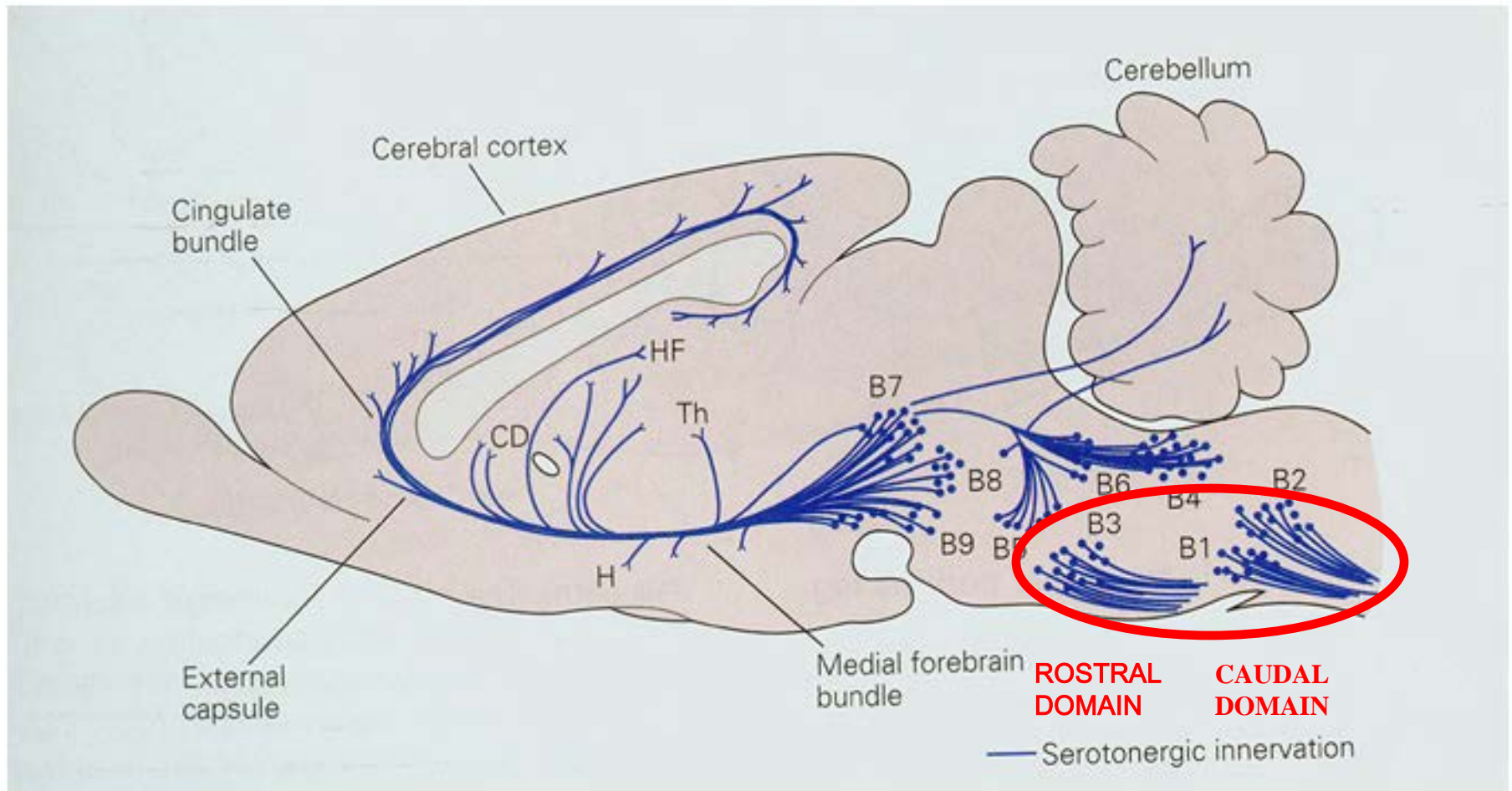
Aberdeen Area Indian Health Service
Perinatal Infant Mortality Review
Board (PIMR)

Aberdeen Area Infant Mortality
Study

Aberdeen Area Infant Mortality Study (1992-1996)

- 9 tribes and 1 urban area in the Northern Plains participated
- Sample Size
 - 72 deaths
 - 38 of 72 (53%) confirmed as SIDS
- Significant risk factors for SIDS
 - Maternal drinking during periconceptional period: ↑ 6x
 - Maternal binge drinking during the 1st trimester: ↑ 8x
 - Two or more layers of clothing at death: ↑ 6x

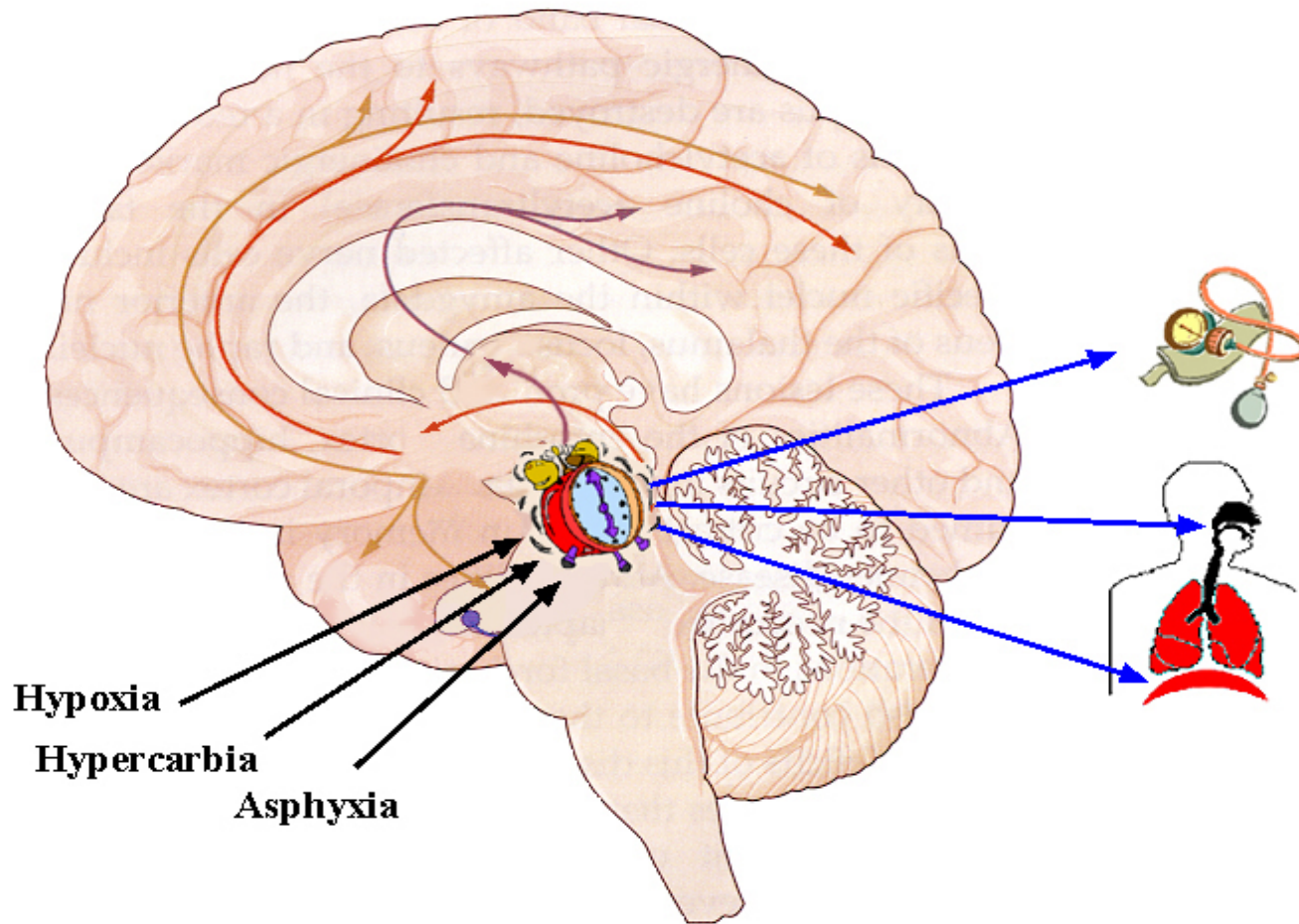
The Rostral and Caudal Domains of the Serotonergic (5-HT) Brainstem System



Rostral Domain (upper brainstem): Cognition and Affective Behavior

Caudal Domain (lower brainstem): Integration & modulation of resp, autonomic control, temp reg, upper airway reflexes

SIDS: Failure of the **Serotonin** Brainstem “Alarm” System
Resulting in an Inability to Wake Up to Dangerously Low Levels of Oxygen and/or
Dangerously High Levels of Carbon Dioxide During Sleep



Step 1

Life-threatening event

Asphyxia and brain hypoperfusion



Head lifting or turning

Step 2

Failure of arousal

Progressive asphyxia



Step 3

Hypoxic coma

Step 4

Bradycardia and gasping

Step 5

Failure of autoresuscitation resulting in death

Prenatal
Alcohol,
SIDS, and
Stillbirth

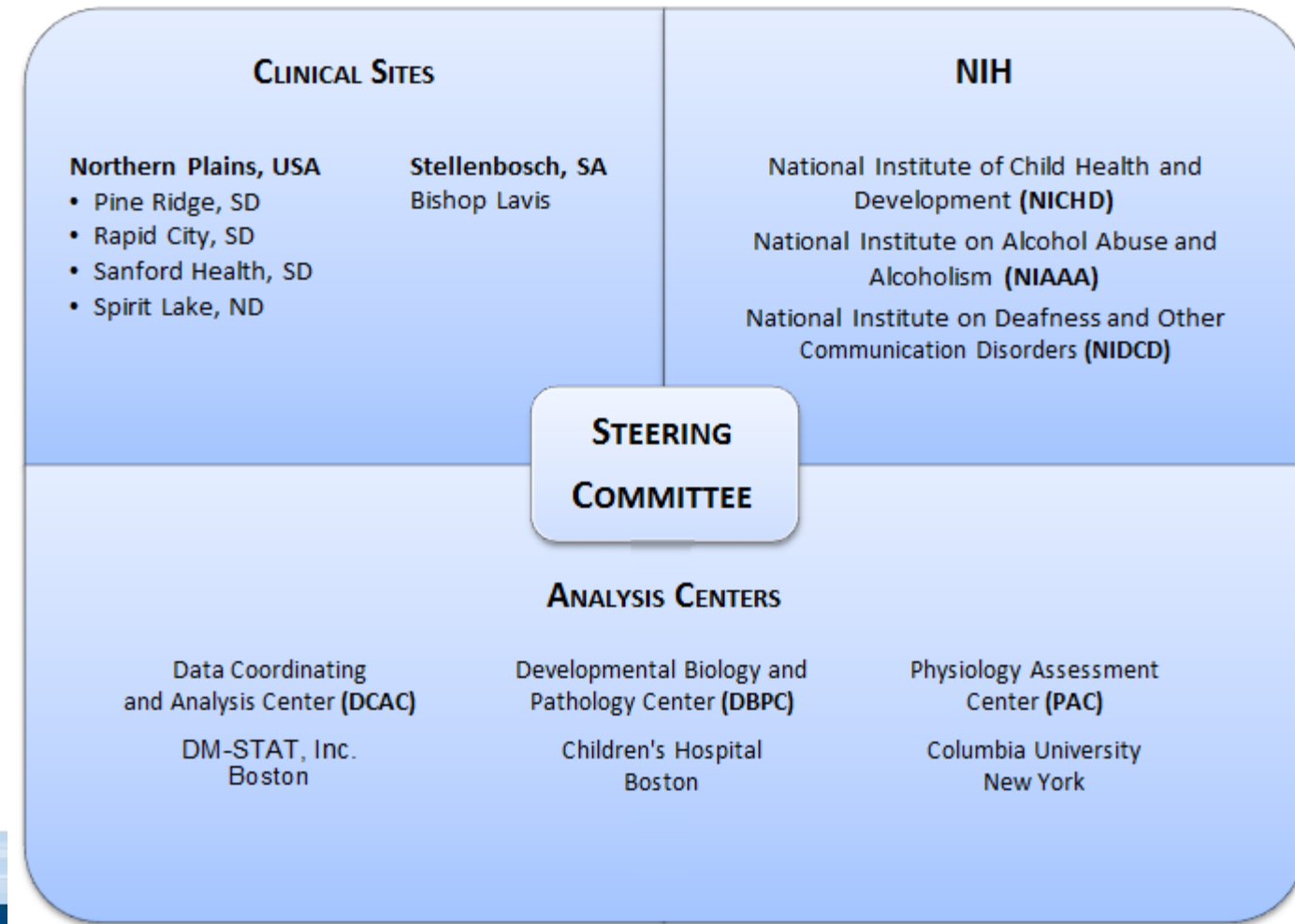


Phase I, 2003-2006: Development of hypotheses and protocols; pilot/feasibility studies

Phase II, 2006-2016: Performance of full-scale, hypotheses-driven studies (prospective and retrospective studies planned)

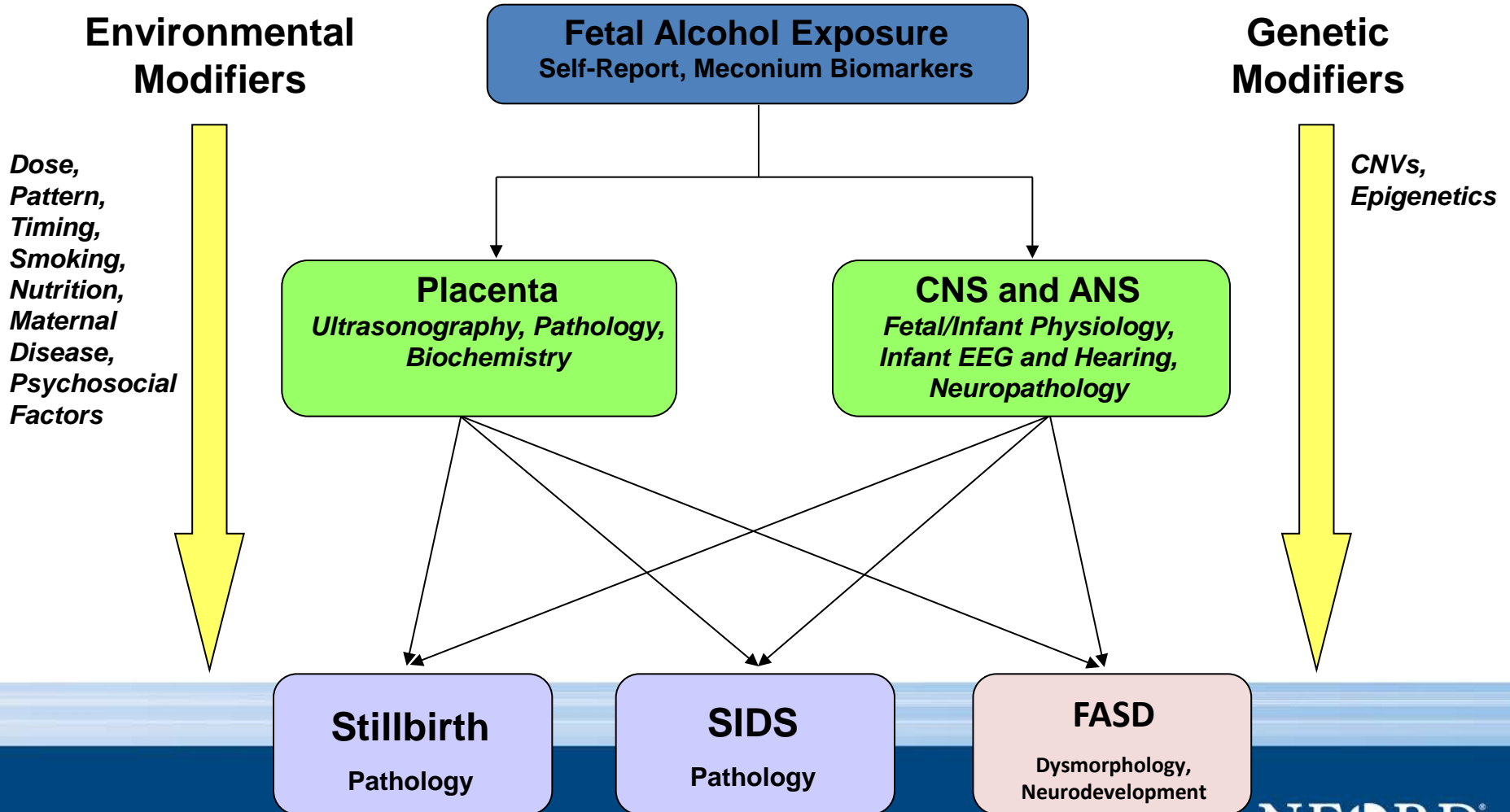
Enrollment complete n= 12,024

PASS Network Organizational Structure



With oversight from the Advisory and Safety Monitoring Board (**ASMB**)

Multidisciplinary Approach



Northern Plains Infrastructure

- Tribal
 - Community involvement from study initiation
 - Tribal Resolutions – Oglala Sioux Tribe & Spirit Lake Nation
 - Multiple time points
- Regulatory
 - IRB's: Sanford; Oglala Sioux Tribe Research Review Board; Aberdeen Area Indian Health Service; UND (agreement); Regional Health (agreement);
- Federal
 - Certificate of Confidentiality
 - Judge Linda Chezem, NIAAA
- State
 - MOA - South Dakota Dept of Social Services
 - MOA – WIC (recruitment)

PASS Partners

Sioux Falls (SD)

- Sanford Health
- Sanford Women's, Sioux Falls
- LCM Pathologists, Sioux Falls

Spirit Lake/Altru (ND)

- Mercy Hospital, Devil's Lake, ND
- Spirit Lake MCH – IHS , Fort Totten, ND
- Altru Clinic, Devil's Lake, ND
- University of North Dakota

Pine Ridge (SD)

- Pine Ridge IHS
- Oglala Lakota College, Dept. of Nursing
- WIC

Rapid City (SD)

- Rapid City Regional Hospital
- Native Women's Health Center
- USD Sanford School of Medicine
- WIC
- Black Hills Ob-Gyn
- Black Hills Peds
- Rapid City Community Health
- Clinical Lab of the Black Hills

Compliance:

- On average, a given woman came in for **82.8%** of all scheduled prenatal, delivery, newborn, and postnatal contacts
- Consent for DNA for research: 98.5%
- Consent for placental tissues for research: 94.3%
- Consent for photographs of infant face: 99.3%
- Withdrawal of overall study consent: 3%
- Pregnancy outcome ascertainment rate: 97.6%

Future Steps

- Last baby anticipated birth Aug. 2015
 - Become unblinded to stillbirth data
 - Primary analysis complete by Jan. 2016
- Last 1 year visit completed Aug. 2016
 - Become unblinded to SIDS data
 - Primary analysis complete by Jan. 2017
- Numerous other secondary findings in process

What it's been like managing the study(s) in Pine Ridge



Cultural Competency; Understanding the Customary beliefs and social norms

Challenges

- Spiritual beliefs, teachings and understanding

- Transportation



Successes

- Transparency
- Respect
- Transportation



Vision for the Future

- The same but different “Culture is one group of people preferred way of meeting their basic human needs” - Carol Iron Rope Herrera (2014)

- **TEAMWORK**



Funding Acknowledgements

- PASS: NICHD/NIAAAA/NIDCD – U01-HD045935
(Elliott)

Pilamaya (thank you)!

