

# Institute of Neuro Immune Medicine

# INIIM



# What are the goals of the CDE Project?

- Develop **common definitions** and **standardize** case report forms (CRF) and other instruments
- Help investigators conduct clinical research through the development of these uniform formats by which clinical data can be **systematically collected, analyzed** and **shared** across the research community









## What is a CDE?

- Standardized question and potential answers
- Allows for consistent collection and sharing of data
- Semantic value (the CDE name) with clear definitions and permissible values

### Example:

- CDE name: “Birth head circumference value”
- Definition: “Circumferential measurement of the head at the ...”
- Data Type: “Numeric Values”
- Input Restrictions: “Free-form Entry”

### Case Report Form:

Prenatal and Perinatal History	
[Study Name/ID pre-filled]	Site Name: _____
	Subject ID: _____

- 1) Birth weight: \_\_\_ pounds and \_\_\_ ounces OR \_\_\_\_\_ grams
- 2) Birth length: \_\_\_\_\_  centimeters  inches  meters  feet
- 3) Birth head circumference:   centimeters  inches
- 4) Gestational age value: \_\_\_\_\_ weeks \_\_\_\_\_ days

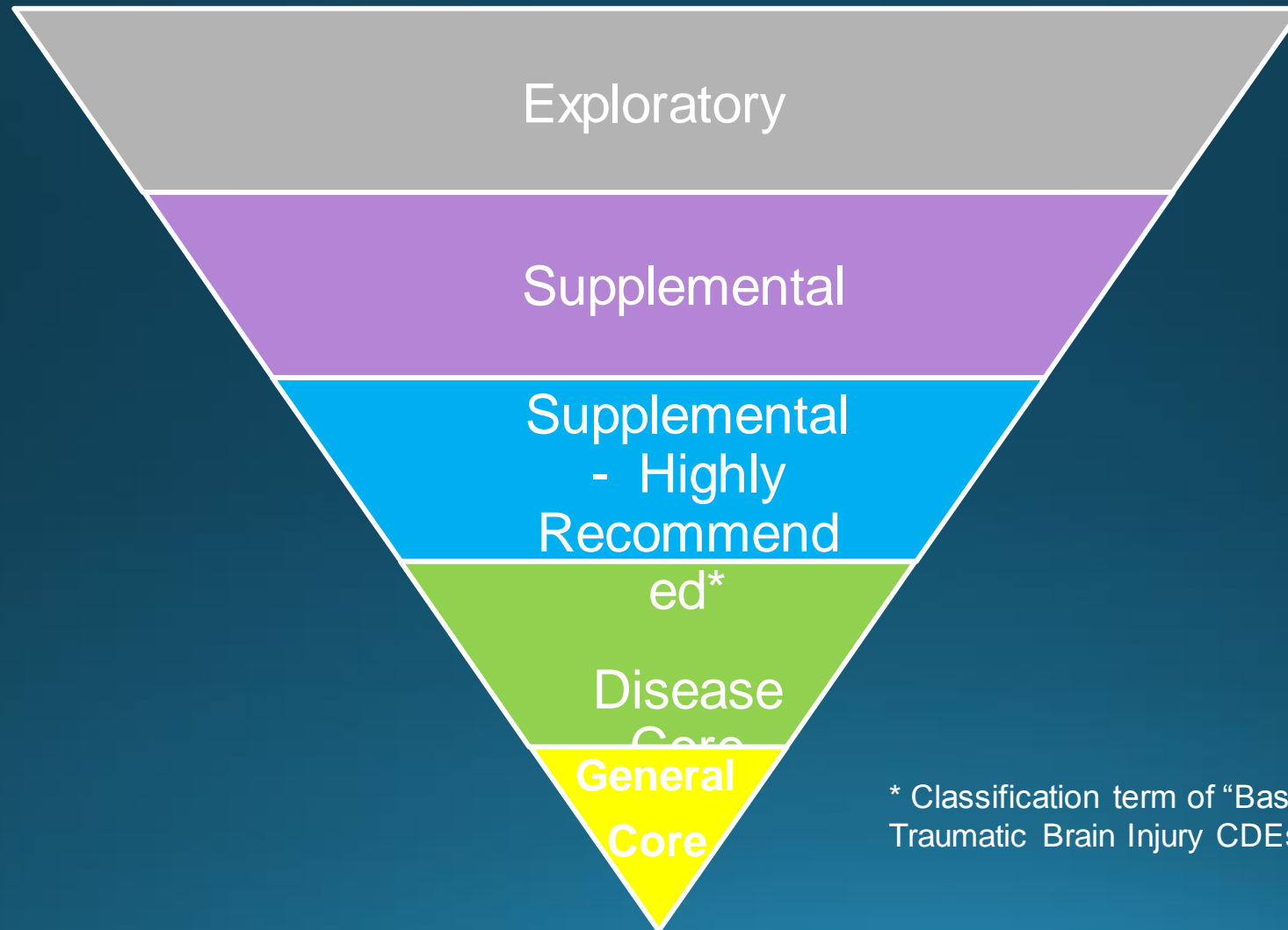
### CDE Details:

CDE ID	CDE Name	Variable Name	Definition / Description	Question Text	Data Type	Instructions	References	Population	Classification (e.g., Core)	Version #	Version Date	Aliases for Variable Name	CRF Module / Guideline	Sub-Domain	Domain	Previous Title	Input Restrictions
C12940	Birth head circumference value	BthHeadCircumVal	Circumferential measurement of the head at the widest point taken at birth - the distance from above the eyebrows and ears and around the back of the head	Birth head circumference	Numeric Values	Record the head circumference of the participant/subject in centimeters. If another unit of measure is preferred, it can be used, however the final data should be converted to centimeters. This is a pediatric-specific element.	Pryor H and Thelander H. (1968). Abnormally small head size and intellect in children J Pediatr. 73:593-598.	Pediatric	Supplemental	3.0	7/24/2013	Aliases for variable name not defined	Prenatal and Perinatal History	General Health History	Participant/Subject History and Family History	Birth head circumference value	Free-Form Entry

# What are the objectives of the CDE Project?

- Identify CDEs used in clinical research
  - (age, gender, race, etc.)
- Present data elements in a standard format available to all
- Identify common definitions
  - (including permissible values, range checks, etc.)
- Standardize CRFs and other instruments
- Provide information to researchers for clinical data collection and sharing

# CDE Terminology – Classifications



\* Classification term of “Basic” used for Traumatic Brain Injury CDEs



# NINDS Common Data Elements

Harmonizing Information. Streamlining Research.

▼ CDEs

▼ Tools

▼ Learn

**Streamline Your Neuroscience Clinical Research** using content standards that enable clinical investigators to systematically collect, analyze, and share data across the research community.

The NINDS strongly encourages researchers who receive funding from the Institute to ensure their data collection is compatible with these common data elements (CDEs). Learn more about the CDE Project.



### Launch Your Own Studies Faster

- ▶ Case report form modules
- ▶ Standardized data element definitions
- ▶ Instrument recommendations



### Incorporate CDEs Into Systems

- ▶ Search for current CDEs
- ▶ Download CDE metadata
- ▶ Download Case Report Forms



### Learn About the CDE Project

- ▶ Project overview and background
- ▶ Meetings and Presentations
- ▶ Collaboration with developers around the world

CDEs Now Available	CDEs Under Review	CDEs in Development
General (CDEs that cross diseases)		
Amyotrophic Lateral Sclerosis		
Cerebral Palsy		
Chiari I Malformation		
Epilepsy		
Friedreich's Ataxia		
Headache		
Huntington's Disease		
Mitochondrial Disease		
Multiple Sclerosis		





# GWJ Common Data Elements meeting

Day 1 :

## The Utility of the ME/CFS platform

12:00 pm - 12:30 pm	Welcome and Introductions	Nancy Klimas
12:30 pm - 1:00 pm	GWJ Common Data Elements Overview and Review of Tasks	Nancy Klimas and Vic Kalasinsky
1:00 pm - 2:00 pm	ME/CFS Common Data Elements (CDE) Process and Recommendations	Beth Unger
2:00 pm - 2:15 pm	BREAK	
2:15 pm - 4:00 pm	Breakout: Working Groups	Team
4:00 pm - 5:00 pm	Working Group Reports and Discussion of Future Process	

## **Working Group 1: Symptom Assessment**

### ➤ Symptom Assessment Modules:

Baseline/Covariate Information, Fatigue, Post-Exertional Malaise (PEM), Sleep, Pain, Quality of Life (QoL)/Functional Status/CPET/Activity

## **Working Group 2: Systems Assessment**

### ➤ Systems Assessment Modules:

Neurologic/Cognitive/CNS Imaging, Autonomic, Neuroendocrine, Immune, Biomarkers

# Common Data Elements Project: Implementation Issues

9:00 am – 10:00 am Integration of Assessment into Platform

VA and non-VA Collaborative Platforms

REDCap Database

Becky McNeil

Behind the VA Firewall

Bonnie Paris

10:00 am – 11:30 am Implementation Panel Discussion: Nancy Klimas, Moderator

Victor Kalasinsky, VA, Kristy Lidie, CDRMP, Becky McNeil, RTI, Beth Unger, CDC, Kim Sullivan, PhD, BU, Dane Cook, PhD, VA

11:30 am – 11:45 am BREAK

11:45 am – 1:00 pm Future GWI CDE Topics Team

Working Lunch (Catered available)



- Potential Future Consensus Issues and Topics
  - GWI Research Case Definition
  - Entry, Inclusion/exclusion Criteria
  - Recruitment and veteran engagement
  
- Where to go from here
  - Timelines and Tasks
  - Public Comment Posting

1:00 pm – 1:30 pm

GWI Common Minimal Data Elements

Nancy Klimas, Next Steps

# NSU Institute for Neuro-Immune Medicine

## Research Team Leaders:

Nancy Klimas, MD Institute Director

Mary Ann Fletcher, PhD Immunology/Biomarker Discovery

Travis Craddock, PhD, Computational Biology

NSU Gordon Broderick, PhD RIT Computational Biology

Mariana Morris, PhD Neurotoxic Injury, C/V, Autonomics

Lubov Nathanson, PhD Genomics

Paula Waziry, PhD Virology/Cell Biology

Richard Deth, PhD Mitochondria/Oxidative Stress

Stephen Grant, PhD toxicology/biomarkers

Alison Bested, MD, Integrative Medicine

Irma Rey, MD Environmental Medicine

Maria Vera Nunez MD, Clinical Research



# The INIM Team

## **INIM Administration**

Nancy Klimas– Director  
Ana Del Alamo– Administrative Director  
Nilda Hernandez  
Kerline Geffrard – clinics manager  
Anabel Cabrera  
Tramiel Dillard  
David Freeman  
Melanie Pere  
Beth Gilbert

## **Cardiovascular Research**

Mariana Morris – Director  
Luis Salgueiro, PhD  
Aman Cheema, PhD  
Jaqueline Machi, PhD  
Rodrigo Schmidt

## **Immunology Lab**

Mary Ann Fletcher – Director  
Kristina Aenlle, PhD co-director  
Maria Abreu, PhD co-director  
Lubov Nathanson , PhD  
Paula Waziry , PhD  
Xiao Rong Zeng, PhD  
Zach Barnes,  
Lissette Pierlus  
Howard Lin  
Claudia Vizcarra  
Gilbert Eugene  
Sandra Yudice  
Zachary Barnes  
Bisha Chen  
Jared Urban  
Armando Perez  
Bernny Saladin

## **Clinical Systems Biology**

Travis Craddock – Director  
Patrick Gourdet  
Tory Toole  
Leonor Sarria  
Mary Jeffrey  
Rajeev Jaundoo  
Lindsey Russell  
Trevor Barker  
Gaytri Patel  
Gordon Broderick – Director, RIT  
Mark Rice  
Saurabh Vashishtha

## **Oxidative Stress**

Richard Deth, PhD, Director  
Malav Trivedi





# The INIM Team

## **Clinic/ Clinical Research**

Alison Bested, MD, Medical Director

Irma Rey, MD

Maria Vera, MD

Nancy Klimas, MD

Violetta Renesca, ARNP

Irina Rozenfeld, ARNP

Jeff Cournoyer, Exercise Physiologist

Annette Green

Kerline Geffrard - manager

Coveannda Sumpter

Renam Fernandez

Elizabeth Balbin – Projects Manager

Devra Cohen

Precious Leaks-Gutierrez

Fanny Collado, RN

James Blount

Melanie Perez

Chris Larrimore

Melyssa Suarez

Monica

Kelly Hilton

Becky Martinez , RN

Katherine Llosa

Jose Chen

