

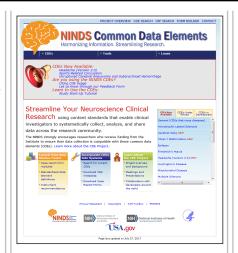
# The National Institute of Neurological Disorders and Stroke (NINDS) Chiari I Malformation Common Data Elements (CDE) Recommendations Version 1.0

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### Introduction

The National Institute of
Neurological Disorders and Stroke
(NINDS) is the leading source of
funding in the United States for
clinical research of neurological
conditions. To harmonize data
collection and use, the NINDS
Office of Clinical Research has led
an effort to develop Common
Data Elements (CDEs) for use in
all clinical studies in
neuroscience.

Through a partnership with the Chiari & Syringomyelia Foundation, the NINDS is promoting Chiari I malformation (CMI) CDEs as part of the NINDS project to develop standards for all funded clinical research in neuroscience. CMI CDEs strive to significantly reduce start-up time by providing standard definitions for commonly used outcome variables so that they may be used in a uniform fashion across research studies. Using CDEs ensures standard data collection, improved data sharing and metaanalyses, and education of new clinical investigators.



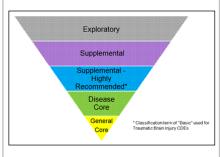
#### **Methods**

- 1. CMI CDE Working Groups (WG) consisting of 40+ worldwide experts developed recommendations for CMI CDEs.
- 2. The WGs developed CMIspecific CDES and associated case report forms, selecting among, refining, and adding to existing, field-tested data elements from national registries and studies.
- 3. The NINDS CDE Team compiled the WG recommendations into data definition tables and case report forms and posted the preliminary CDEs for public review in **July 2016**.

#### Results

The NINDS CMI version 1.0 CDEs were released to the NINDS CDE website in October 2016 and span the following domains: Core Demographics Database, Epidemiology; Presentation, Natural History, Signs Symptoms, Co-morbidities, Risk Factors, Genetics, Spinal Anomaly, Stability/Imaging, Treatment, and Outcome. The NINDS CDE website provides uniform names and structures for each data element, data dictionaries, template case report forms, guidance documents, and disease -specific recommendations.

# **Classifications of CDEs**



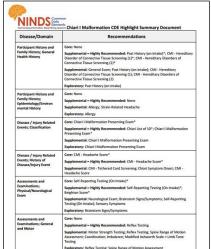
Presentation on behalf of the Chiari I Malformation CDE Working Groups

## **Implementation and Feedback**

NINDS encourages use of the CMI-specific CDEs by the CMI clinical research community and in collaboration with researchers beyond this community to standardize the collection of research data across studies. The CMI CDEs are an evolving resource that will be updated as research progresses and recommended measures become better established.

# Data Standards Page and Example Documents







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