Background, Significance & Approach

The pediatric clinical research domain contains unique concepts that are not prevalent in clinical research focused on adults. The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) has an ongoing effort to establish a core library of harmonized pediatric terms through stakeholder consensus. Consistent terminology will provide clinical researchers with the infrastructure necessary to compare and aggregate data and information across NICHD’s and other NIH Institutes/Centers’ clinical research portfolios, as well as across the broader research community. In the first phase of developing a harmonized pediatric terminology, the NICHD has undertaken an effort to generate harmonized neonatal and infant examination terms. These terms are part of a broader terminology framework that is under development that follows a child’s development from pre-birth through 21 years of age. The pediatric terminology initiative identifies specific concepts and terms within pediatric research and uses existing resources to harmonize the various fields to develop a consistent terminology. The NICHD will facilitate stakeholder review for the proposed terminology within the pediatric community. Once the key concepts are identified, the terminology is incorporated into the NCI Thesaurus, and a model is developed to depict the concepts, attributes, and relationships between concepts. This model is then used to generate content specific data acquisition tools (for example, clinical research forms) based on the terminology. The Terminology Development Process is depicted in Exhibit 1.

Partnership Approach

In an effort to ensure the harmonized terminology generated is truly a collaborative effort, the Institute is working closely with organizations with the appropriate subject matter expertise in pediatric research and clinical care and with experience using the tools, processes, and resources required for this effort.

- National Cancer Institute (NCI): The NICHD is leveraging the NCI’s semantic infrastructure, including the NCI Thesaurus, and open source clinical research tools to generate harmonized pediatric terminology and associated clinical research tools for use by the pediatric community.

- The National Children’s Study (NCS): The objective of the NCS is to assess the impact, biological and environmental exposures on child development while appropriately accounting for behavioral and environmental influences. This ambitious agenda requires a longitudinal cohort study of at least 100,000 mother-child pairs, with a time horizon of more than 20 years, and the ability to document specific life histories and related data. Semantics developed and standards deployed for NCS will be incorporated into the evolving Pediatric Developmental Stage Framework.

- International Organizations and Pediatric Research Organizations and Societies: The NICHD Pediatric Terminology Harmonization effort seeks to engage organizations related to international health standards and pediatric research in order to provide input into the terminology and to validate the structure and content.

Pediatric Terminology Metastructure

The NICHD Pediatric Terminology structure will be based on the stages in a child’s life, as depicted in Exhibit 2. The timeline for a child’s life cycle is from pre-birth to 21 years of age. Child Life Stage classifications are used by other standards like the International Conference on Harmonisation (ICH), Clinical Data Interchange Standards Consortium (CDISC), American Academy of Pediatrics (AAP), Centers for Disease Control and Prevention (CDC), and Systematized Nomenclature of Medicine (SNOMED) and have a range of variability. As part of the NICHD Pediatric Terminology effort, child life stage classifications based on standards used by such organizations were mapped and harmonized across the timeline of child life. These child life stages were then mapped to the proposed terminology metastructure among the highest level ontological categories of: Observable Entity, Process, Regimen/Procedure/ Intervention, Disease/Disorder/Condition, and Diet/Nutrition. This list of high level categories is not intended to be exhaustive and will continue to grow as the terminology evolves and further expert input is received. The Terminology is developed in a modular fashion based on established child health use cases, including the first module of neonatal and infant examination terms. Additional child health use cases will scope subsequent modules of terms for harmonization and validation.

Anticipated Results

As a result of this pediatric terminology initiative, the NICHD anticipates the following results which will have significant impact on the pediatric research community:

- Development of a set of harmonized concepts that can be used by researchers to aggregate data in the same format to determine key outcomes as well as the ability to easily access information
- Development of a framework or life cycle for further expansion and maintenance of the pediatric terminology
- Enhancement to the existing NCI Thesaurus through addition of pediatric terminology; currently NCI Thesaurus contains terminology with an adult focus

For more information, please visit the “NICHD Efforts to Harmonize Pediatric Terminology” webpage at http://www.nichd.nih.gov/health/clinicalresearchterminology/