This is the landing page for the UG-Pediatrics. What would you like to do?

- **Read the UG-Pediatrics**
  
  There are two options, depending on your reading preference:
  
  - **TAUG-Pediatrics compiled** — This lets you view the entire document as a single web page, but is more prone to errors with the JIRA Connector. Please allow time for the whole document to load in your browser.
  
  - **UG-Pediatrics sections** — This displays each section on its own page, and comprises the source of the content displayed on the compiled view.

1 **INTRODUCTION**
   
   1.1 How to Read this Document
   1.2 Organization of this Document
   1.3 CDASH Metadata and Annotated CRFs
   1.4 Known Issues

2 **INFORMATION ABOUT THE SUBJECT**
   
   2.1 Demography
      
      2.1.1 Date of Birth and Age
      2.1.2 Sex
      2.1.3 Ethnicity and Race
      2.1.4 Date of Death
   2.2 Vital Signs
      
      2.2.1 Body Function Tests
      2.2.2 Body Measurements
      2.2.3 Result Summarization
   2.3 Medical Conditions
      
      2.3.1 Physical Examination
      2.3.2 Prespecified Conditions
   2.4 Treatment
      
      2.4.1 Exposure to Study Products
      2.4.1.1 Outcome of Study Treatment
      2.4.2 Concomitant and Prior Medications
      2.4.3 Non-drug Therapies
   2.5 Healthcare Utilization
   2.6 Reproductive Development
   2.7 Diet and Nutrition
      
      2.7.1 Food and Fluid Consumption
      2.7.1.1 Diet
      2.7.1.2 Types of Food
      2.7.1.3 Meals
      2.7.1.4 Individual Food/Fluid Items
      2.7.2 Breast-fed Indicator
   2.8 Substance Use
   2.9 Laboratory Assessments
   2.10 Body System Assessments
      
      2.10.1 Cardiovascular Assessments
      2.10.2 Musculoskeletal Assessments
      2.10.3 Neurological Assessments
      2.10.4 Ophthalmic Assessments
      2.10.5 Auricular Assessments

3 **INFORMATION ABOUT THE SUBJECT’S FAMILY**
   
   3.1 Family Background
   3.2 Family Medical Conditions
   3.3 Family Procedures
   3.4 Family Medications
   3.5 Family Substance Use

4 **PREGNANCY AND BIRTH**
   
   4.1 Pregnancy and Birth Events
      
      4.1.1 Pregnancy-related Events
      4.1.2 Pregnancy Conditions
      4.1.3 Perinatal Events and Birth Complications
   4.2 Multiple Births

5 **STUDY CONDUCT**
   
   5.1 Identifiers
   5.2 Elements and Arms
   5.3 Protocol Milestones and Subject Disposition
      
      5.3.1 Informed Consent and Informed Assent
   5.4 Visits
   5.5 Eligibility Criteria
   5.6 Product Accountability

6 **QUESTIONNAIRES, RATINGS, AND SCALES (QRS)**
APPENDICES
Appendix A: Pediatrics Team
Appendix B: Glossary and Abbreviations
Appendix C: Non-Standard Variables (NSVs)
Appendix D: References
Appendix E: Representations and Warranties, Limitations of Liability, and Disclaimers

- Draft Standards of Interest to UG-Pediatrics — These are CDISC standards-in-development that have influenced the development of the UG-Pediatrics, and are used in examples and/or modeling advice.

- Look at examples
  - UG-Pediatrics examples — This is where all examples used in the UG-Pediatrics live.

  Note: Readers are recommended to use this directory only after reading the UG-Pediatrics in its entirety at least once.

- Provide feedback
  - Instructions for Reviewers — Detailed instructions for how to use JIRA to provide feedback on the UG-Pediatrics are given here.

Other resources you may find helpful:

- Introduction to Therapeutic Area Standards — This provides an overview of what to expect, and what not to expect, from a therapeutic area user guide such as the TAUG-
- TA001 - Overview of Therapeutic Area User Guides — This is a free introductory course on therapeutic area standards on the CDISC training campus.
- Reading on the Wiki — This page touches on some of the ways the Wiki edition of the UG-Pediatrics has been optimized for web use, with which a reader new to the CDISC Wiki may be unfamiliar.
- TA Specification — This is a spreadsheet that provides information, for newer and proposed domains and variables, on their relationships with versions of SDTM and the SDTMIG.

TA Specifications were developed to assist FDA in their testing processes, but can also provide implementers with advice on how to adapt the representation of data shown in the TAUG to different versions of the standards. TA Specifications are provided as a resource to reviewers; we are not seeking comment on the TA Specification. However, we would appreciate being informed of inconsistencies in the content of the TA Specification and the TA User Guide.

Comments on the UG-Pediatrics should be entered into JIRA at: https://jira.cdisc.org/projects/PEDIAC. For more detail, see the Instructions for Reviewers.