



# National Children's Study Metadata Conference

January 23, 2012  
Bethesda, MD

Steven Hirschfeld, MD PhD  
Captain, U.S. Public Health Service  
*Eunice Kennedy Shriver*  
National Institute of Child Health  
and Human Development

# National Children's Study

- Congressionally mandated by Children's Health Act of 2000
- An integrated system of activities to examine the relationships between environmental exposures and genetics on growth, development and health
- Environment is broadly defined to include factors such as air, water, soil, dust, noise, diet, social and cultural setting, access to health care, socio-economic status and learning.

# What the Law Says

- “(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development;*
- (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.”*

The Study is required to:

- “(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children’s well-being;*
- (2) Gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and*
- (3) Consider health disparities among children, which may include the consideration of prenatal exposures.”*

# NCS Principles

- Data driven
- Evidence based
- Community and participant informed

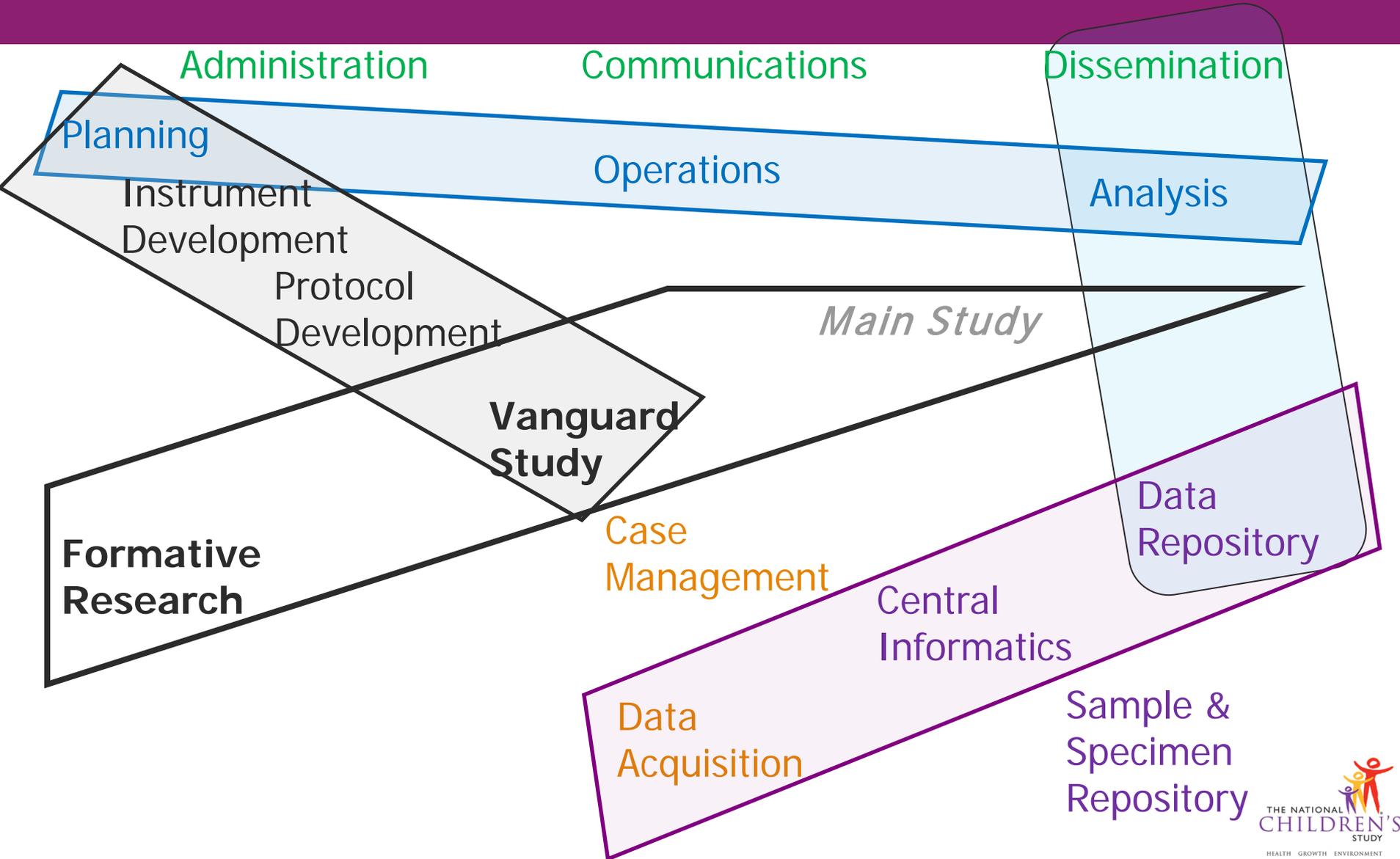
# NCS Structure

- The NCS is an integrated system of activities
- All components and phases together form the NCS
- Current major components are the
  - NCS Vanguard Study- pilot phase for methods-runs for 21 years-started in 2009 with 7 centers- expanded in 2010 with 30 additional centers
  - NCS Main Study-exposure response phase- runs for 21 years about 3 years time shifted from Vanguard Study-planned start in 2012
  - NCS Substudies- studies within studies
  - Formative Research-short term limited studies, often methods development, to support and inform the Vanguard and Main Studies

# NCS as a system

- Multiple interacting components
- Interdependencies and connections
- Flexibility to allocate resources and activities

# NCS Activities



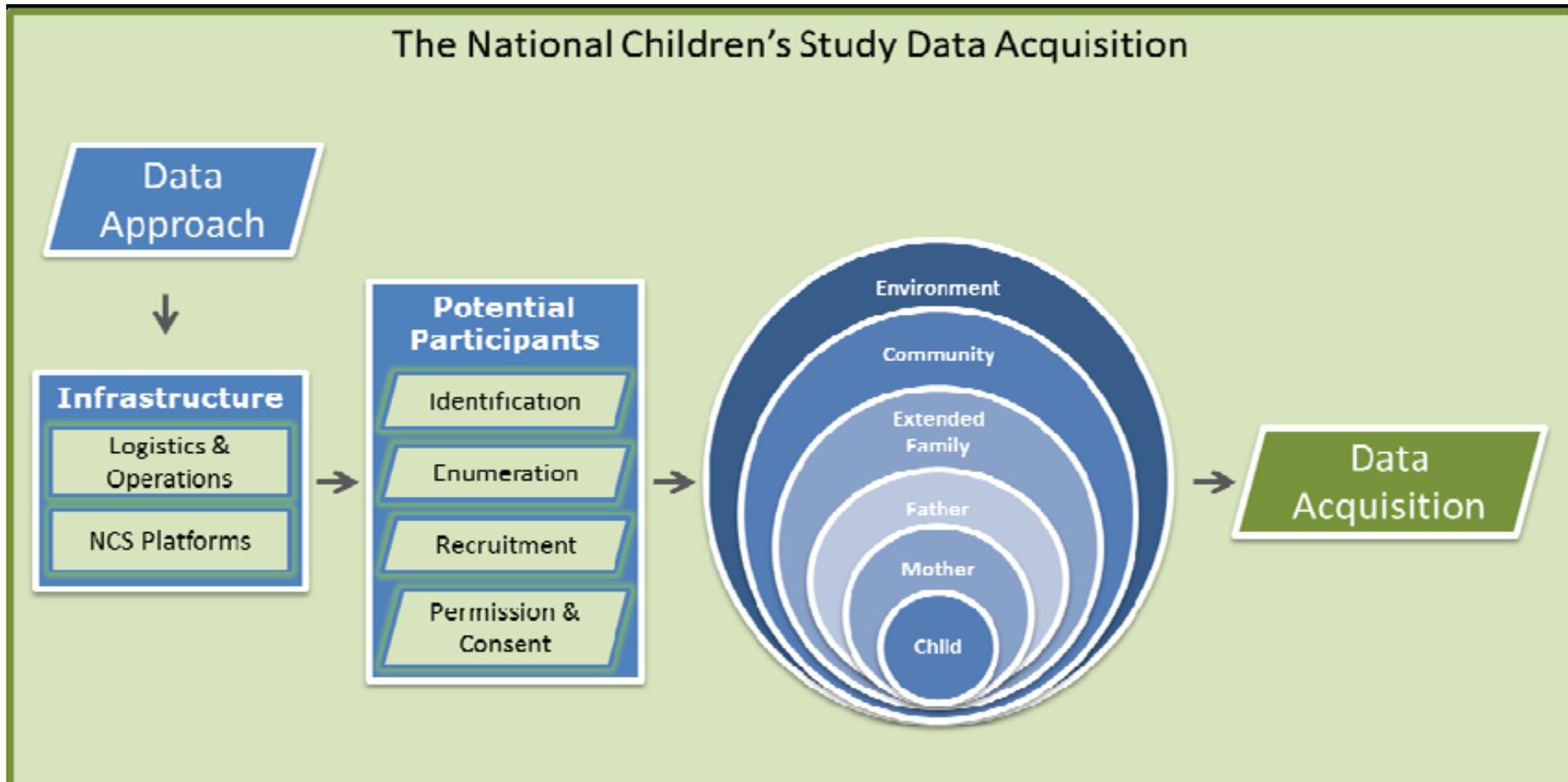
# NCS Study Data Approach

## The National Children's Study Data Approach



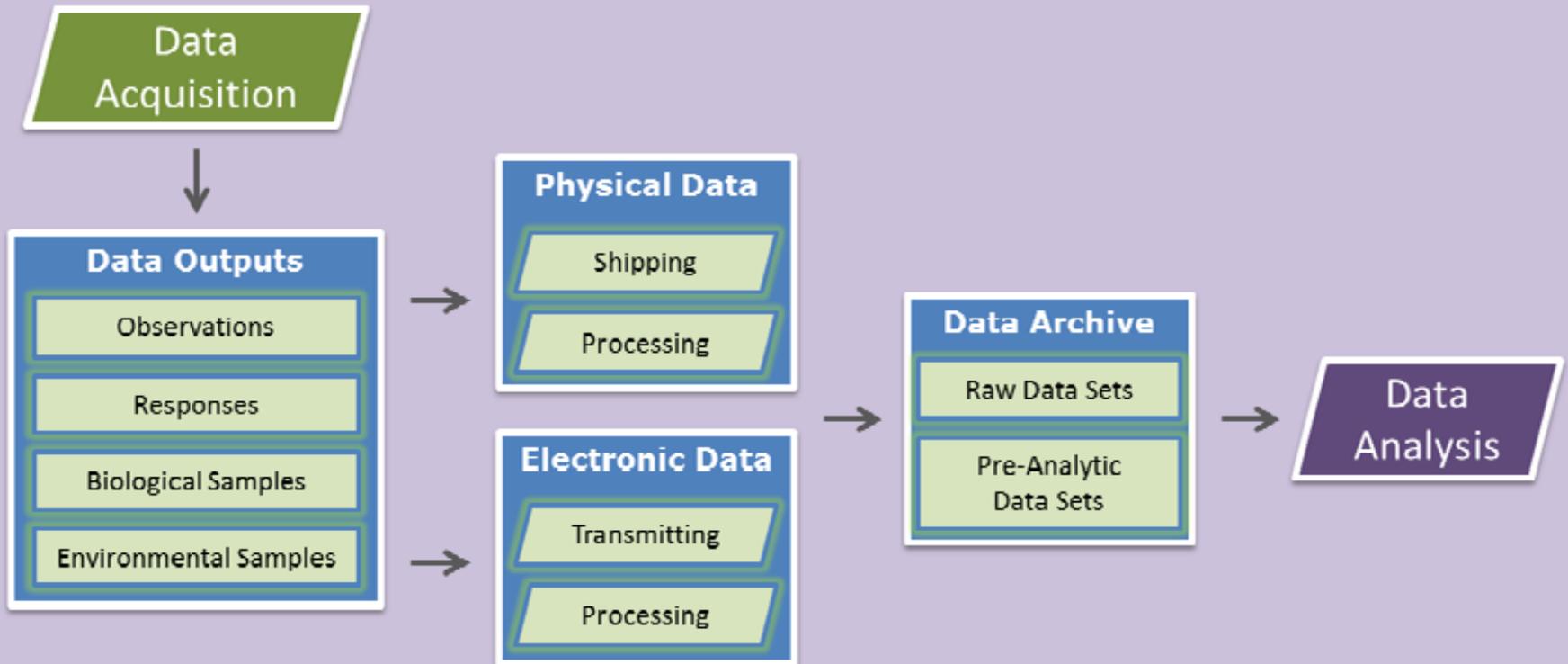
# NCS Study Data Acquisition Model

## The National Children's Study Data Acquisition

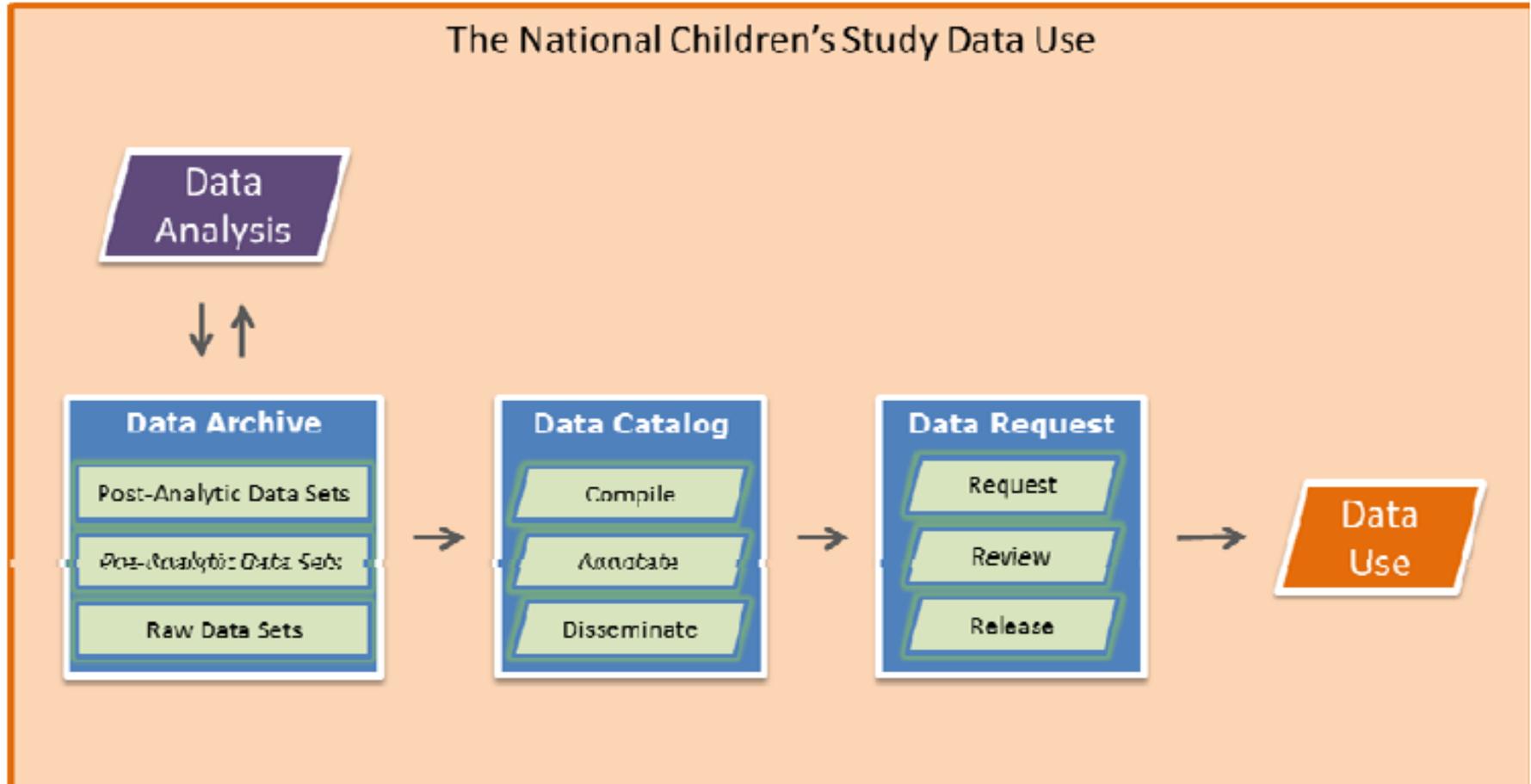


# NCS Study Data Analysis Model

The National Children's Study Data Analysis



# NCS Study Data Use Model



# NCS Vanguard Study Methods Development

- Systematic testing of all study components prior to scale up
- Distributed operations to leverage local and collaborative expertise within a framework of centrally developed specifications
- Vanguard Study focus on Operational Data Elements to quantitatively describe study operations and costs
- Integrating data standards into an “end to end” process across the data life cycle (design, planning, implementation, analysis, archiving, dissemination)
- Harmonizing terminology across subspecialties and developmental stages

# Evaluating Study Visit Assessments for inclusion into Main Study

- Feasible, reliable, reproducible
- Informative
- Value
- Lack of redundancy
- Able to address a question that
  - has potentially important public health impact
  - requires a study of NCS size and robustness to answer
  - unlikely to be answered in another context

# Terminology

- General absence of consistent child health oriented terminology
- NICHD in collaboration with NCI began initiative in 2008
- Linkage of concepts through developmental stages
- Neonatal Terminology as Formative Research Project to refine method and develop proof of concept in 2011

# Trends in Informatics

- Modular architecture
- Terminology with curation
- Semantically aware
- Scalable
- Transmission standards
- Robust security
- Open source platforms with development communities
- Vertical and horizontal integration of process
- Interoperability
- Service aware

# NCS Concept of Meta Data

- The data about the data that provides context, organization and consistency
- Meta data require framework, concepts and definitions
- NCS meta data framework, concepts, definitions and repository should be interoperable and harmonized with national and international standards to become a resource and leverage other resources