Patient Registries as a Prelude to Clinical Trials and Post-Approval Studies

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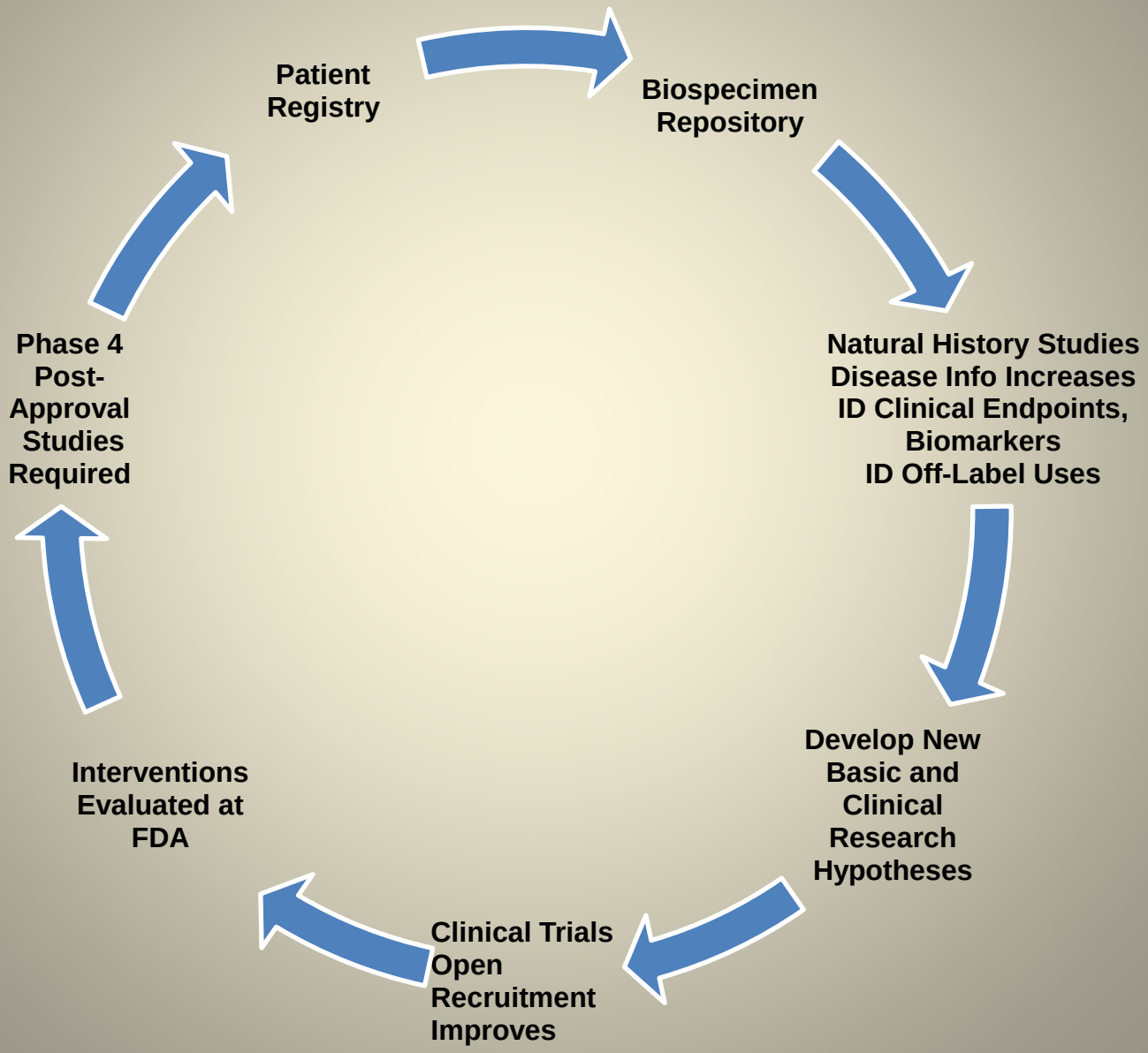
Patient Registries Developing Pathways to Interventions Through Partnerships



Value of Patient Registries

- Improve Recruitment of Patients/Participants
- Identify Possible Patient Cohorts for Studies
- Lead-In to Natural History Studies
- Integrate Patient-reported & Clinical Data From Multiple Sources Into Single Repository
- Stimulate New Research On The Causes, Treatments, and Outcomes Of Disorders
- Accelerate Knowledge Discovery and Gain New Scientific Insights from Patients With Rare Diseases
- Enhance Creative Data Mining Within & Across Disorders

Developing Patient Registries – Before You Start

- Establish Purpose Of The Registry and Control of the Data
- Establish Process Of Data Collection, Storage , and Access to Identified and De-Identified Data
- Develop Procedures for Data Aggregation and Analyses Across Multiple Platforms
- Establish Data Curator Role
- Identify Type Of Informed Consent - Restricted Or Broad Access to Data
- Meet IRB and FISMA Approval Requirements
- Provide Protection of Patient Privacy
- Identify Source(s) Of Data Collected
  - Patient/Family/Caregiver Entered Data
  - Health Care Provider Entered Data
  - Electronic Health Record data

Developing Patient Registries - Before You Start

- Use Common Data Elements (CDEs) and Unique Data Elements (UDEs) - Diseases Specific Questions
- Data Mapping Strategy for Data Elements
- Develop Data Sharing Policies and Collaborators
- Consider Options For Data Updates
- Integrate Patient and Clinical Data with Biospecimen Samples Information with Global Unique Identifier (GUID)
- Seek Feedback From Current Or Past Users
- Determine Sustainability from Funding Source(s)

Common Data Elements

- Current Contact Information
- Socio-demographic Information
- Diagnosis
- Family History
- Birth And Reproductive History
- Anthropometric Information
- Patient-reported Outcome
- Medications, Devices, And Health Services
- Clinical Research Participation And Biospecimen Donation
- Communication Preferences
- Organ Systems And Disease Specific UDEs
- Contact: Yaffa.Rubinstein@nih.gov

NIH Common Data Element (CDE) Resource Portal

Home | Resource Summaries | Glossary

Home

Home

http://cde.nih.gov

NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. This portal provides access to NIH-supported CDE initiatives and other tools and resources that can assist investigators developing protocols for data collection. What is a CDE?

NIH CDE Initiatives

Collections of CDEs that have been identified for use in particular NIH-supported research projects or registries after a formal evaluation and selection processes.

Summary Table

Subject Areas

NIH CDE Tools and Resources

Databases and repositories of data elements and case report forms that may assist investigators in identifying and selecting data elements for use in their projects.

Summary Table

Subject Areas

The CDE Resource Portal also includes Other CDE Resources and Relevant Standards. Descriptions of all four groups can be found in the Glossary.

The CDE Working Group of the Trans-NIH BioMedical Informatics Coordinating Committee (BMIC) developed this Portal to improve the coordination of CDEs. BMIC encourages researchers to use CDEs from the Resources in this Portal where applicable, and to consider existing CDE initiatives before starting additional initiatives.

Are we missing a CDE Resource? Contact us.

Patient Registries – Future Needs

- Develop, Share, and Agree to Use of Common and Unique Data Elements by Developers, National Library of Medicine, Institutes and Centers, Researchers, Industry, and Patient Advocacy Groups
- Establish a Forum For Sharing Experience from Registry Developers Each Time A New Registry Is Developed, It Is Started Using A Different Platform
- Develop Partnerships with Rare Diseases Patient Organizations, Academic Researchers, Biopharmaceutical and Medical Devices Industries
- Consider Global Collaborations and Multiple Language Requirements – IRDiRC and ICORD Resources