

**CONCEPT CLEARANCE RECORD
FY 2017 RESEARCH INITIATIVE – NCATS**

TITLE: The NIH/NCATS Registry Program

OBJECTIVE(S): The objective of this initiative is to provide a coordinated and comprehensive approach for NCATS to promote standardized patient registries that are feasible and sustainable and that result in high-quality data to advance clinical research and therapy development. Activities are wide-ranging and may include research operations support, information management, data management, informatics, project management and administrative support.

DESCRIPTION: The awardee(s) will provide centralized operational, informatics, and data and project management support to ensure a sound and efficient approach to supporting high-quality and high-impact patient registries for NCATS. Patient registries, collections of standardized information, are an indispensable resource in rare diseases research, since they contribute to multiple phases of the research lifecycle, including participant recruitment for research studies (contact registries); development of datasets to better understand disease progression, biomarkers and clinical outcomes (natural history registries); and collection of safety and efficacy data after regulatory approval (post-marketing registry). To maximize their value, registries should incorporate data content, validity and quality standards, and they should be readily usable in Food and Drug Administration submission standards. They should be able to integrate data from multiple sources, including electronic health records and patient-reported data. Tasks will include overall operational, informatics and data management. The awardee(s) will assist NCATS staff in the coordination with patient groups, NIH and other federal partners and will help in the development, demonstration and dissemination of standards, tools and templates.

IMPORTANCE: This initiative will provide research, operational and informatics support for the Office of Rare Diseases Research registry program to promote frameworks and standards that result in the collection of high-quality, research-ready data that can help accelerate progress along the path from discovery to health benefit for rare diseases.

HISTORY: This new phase of the NIH/NCATS Registry Program builds on the previous accomplishments of the [NIH/NCATS Global Rare Diseases Registry \(GRDR®\) program](#), which has developed [common data elements for rare diseases registries](#). In its most recent phase, the GRDR program has partnered with researchers at Harvard University to map data from several rare diseases registries into an i2b2/tranSMART platform. The proposed new phase builds on these experiences and integrates them into one framework and set of standards for further dissemination.

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