

Name and brief description of initiative and goals:

Patient Reported Outcomes Measurement Information System (PROMIS) is an NIH Roadmap project to improve the assessment of symptoms and other patient reported outcomes in clinical research. The goal of the cooperative network, begun in August of 2004, is to develop highly reliable and valid item banks assessing patient-reported symptoms and other health related domains across a wide range of chronic diseases that can be widely adopted in clinical research. The objectives of this initiative are to: 1) develop and test item banks for a number of health domains with broad applicability in clinical research, 2) utilize Item Response Theory (IRT) and Computer Adaptive Testing (CAT) to accurately and efficiently assess patient reported outcomes across a range of chronic diseases, and 3) create a publicly available, adaptable, and sustainable system for use in clinical research. The initial domains being developed include physical functioning, pain, fatigue, emotional distress, and social role participation. Additional health domains are planned for future development. The resulting system will provide clinical researchers with easy access to tested item banks measuring a variety of health domains and will allow for efficient and automated item administration, data monitoring, and reporting of patient reported outcomes. Equipped with these tools, scientists in industry, academia and government will be better able to assess how patients subjectively perceive changes in their health status resulting from new treatments, thereby directing research to therapies that would be most highly valued by patients.

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Brief description of biomedical informatics and computational biology components and their goals:

PROMIS utilizes Item Response Theory (IRT) and Computer Adaptive Testing (CAT) to select items from the item bank based on prior responses, thereby substantially reducing patient response burden while potentially improving measurement precision. Initial development of PROMIS will provide administration of these item banks to patients via web application, but a variety of administration modalities including PC/MAC, IVR, PDAs, and scannable short forms are also planned. Clinical researchers will have immediate access to item responses and summary reports as well as the capability for data monitoring and downloads. Consistent data standards will allow for potential integration of PROMIS data with other biomedical informatics systems and datasets.

Brief description of resources and tools available for sharing:

PROMIS will be a publicly accessible system. Currently untested item pools and item documentation are available upon request for limited use. After these item pools have been tested and refined, and reliable item banks have been produced, the item bank questions and properties, including the system and support to administer and score both short form instruments and computerized-adaptive tests will be available via Internet access. Paper-based short forms also will be available.

Brief description of integrative efforts:

With expertise in health outcomes research and measurement, psychometrics, qualitative research, information technologies, and health survey methods, the PROMIS network, in the process of developing its item banks and CAT platform, will develop and adopt a conceptual framework and standards for assessing patient health status. These include standard protocols for questionnaire development, questionnaire evaluation, and guidance for use of such questionnaires in clinical research. The PROMIS software will be state-of-the-art for delivering patient-reported outcome assessments via Internet and collecting patient responses for research, monitoring, and decision-making. The PROMIS item banks available in the public domain will have undergone thorough evaluation using the best methods from qualitative and survey methods and psychometrics and will provide a valuable resource for capturing a patient's perceived health status. Further, the PROMIS project is linking with other NIH-funded projects developing similar systems that are disease-specific (e.g., sickle cell disease, cancer). This will enhance the comprehensiveness and depth of the PROMIS measurement system.

Possible opportunities for collaboration or synergy with the NCBCs:

The NIH Project Team includes a representative from each of the institutes and centers to provide a forum for interactions between PROMIS and the measurement and clinical research initiatives of the various NIH institutes. NIH PROMIS also is interacting with other Federal agencies about the potential applications of PROMIS to their clinical or health research efforts. The PROMIS network is open to collaboration and has a number of ongoing and planned collaborations with research groups developing other IRT measurement domains and with clinical research groups and networks. Collaboration with the NCBCs is welcomed.