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Project Name		PROsIT: A Total Patient-Reported Outcomes Solution (SBIR Phase I)			
Project ID	1 R43 MH069169				
Sponsor	National Institute of Mental Health				
Project Period	9/15/2003 - 3/31/2004				
Funding Level	\$107,000				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Chih-Hung Chang, PhD	Northwestern U.	Assist. Professor	
	Investigator	Joshua M. Hauser, MD	Northwestern U.	Instructor	
Clinical Site	AIDS Clinical Trial Unit, Northwestern University				
# Subjects	30				
Abstract	<p>The PROsIT Project seeks to promote the use of Patient-Reported Outcomes (PROs) in both clinical and research practices for AIDS by developing and commercializing a comprehensive, practical and integrated system for PROs management with cross-discipline efforts. It offers innovative solutions to user accessibility and item bank management issues.</p>				
	<p>The specific Phase 1 aims are to: 1) develop the prototype of an Item Response Theory (IRT)-based adaptive PROs assessment engine supporting access from both web and phones; 2) elicit system requirements from both patients' and physicians' perspectives; and 3) identify potential system usage barriers in clinical settings.</p>				
	<p>This study extends from our earlier work on computerized outcomes solutions for AIDS and cancers. The FAHI questionnaire will be used. Focus group discussions with physicians and patients and face-to-face interviews with pilot-testing participants will be conducted to evaluate system usability and usefulness, refine requirements, and identify potential barriers.</p>				
<p>PROsIT is a generic outcomes collection, analysis and reporting solution applicable to AIDS and other diseases. It enables researchers to further understand the strengths and limitations of PROs in helping clinical decisions by reaching to a broader patient base. It also has wide-ranging applications for pharmaceutical companies, hospitals, insurers, and government agencies and accreditation organizations.</p>					

Project Name		PROsIT: A Total Patient-Reported Outcomes Solution (SBIR Phase II)			
Project ID	2 R44 MH069169				
Sponsor	National Institute of Mental Health				
Project Period	7/19/2005 - 7/18/2008				
Funding Level	\$736,813				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Perry Nicassio, PhD	UCLA	Clinical Professor	
	Co-PI	John Flaherty, MD	Northwestern U.	Professor	
	Investigator	Robert Murphy, MD	Northwestern U.	Professor	
	Investigator	Sarah Sutton, MD	Northwestern U.	Assist. Professor	
	Investigator	Richard Novak, MD	U. Illinois at Chicago	Professor	
	Investigator	Jonathan Uy, MD	U. Illinois at Chicago	Assist. Professor	
	Consultant	Lawrence Lin, PhD	Baxter Healthcare Corp.	Baxter Res. Scientist	
	Consultant	Michael Kallen, PhD	Baylor College Medicine	Assist. Professor	
Clinical Site	AIDS Clinical Trial Unit, Northwestern University Department of Infectious Diseases, University of Illinois at Chicago				
# Subjects	450				
Abstract	<p>The PROsIT Project seeks to promote the use of patient-reported outcomes (PROs) for HIV-infected patients in clinical settings by developing and commercializing a comprehensive, practical and integrated system for PROs management with cross-discipline efforts.</p> <p>In Phase I, we successfully implemented and pilot-tested an IRT-based adaptive PROs assessment engine supporting secure access from both web and phones. Patient and physician surveys showed strong support for our system usability and usefulness, providing early evidence of the commercial viability of our product.</p> <p>Based on our original long-term goals and the lessons learned from the Phase I effort, our specific Phase II aims are to: 1) allow the PROsIT System be accessible from Tablet PCs and PDAs; 2) build an HIV-focused item bank; 3) add multi-lingual support to the PROsIT System; 4) assess the value and the practicality of using the PROsIT System in clinical practice; and 5) publish our study results in peer-reviewed journals.</p> <p>The end result of this project will be a generic multi-platform, multi-lingual adaptive survey system and an HIV-focused item bank that could help promote the use of PROs in routine clinical setting. The study results will also further the understanding of the value of PROs in improving patient care.</p>				

Project Name	Comprehensive PRO Management for Oncology Practice (SBIR Phase I)			
Project ID	HHSN261200544014C			
Sponsor	National Cancer Institute			
Project Period	9/01/2005 - 3/02/2006			
Funding Level	\$100,132			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Chih-Hung Chang, PhD	Northwestern U.	Assist. Professor
	Investigator	Charles Bennett, MD	Northwestern U.	Professor
	Investigator	Madelyn Iris, PhD	Northwestern U.	Assoc. Professor
Clinical Site	Lynn Sage Breast Cancer Center, Northwestern Memorial Hospital Comprehensive Breast Cancer Center, Rush University Medical Center			
# Subjects	26			
Abstract	<p>Despite the abundant research in patient-reported outcomes (PRO) for cancer, PRO data are not routinely collected and utilized at oncology clinics due to technological and logistical constraints and lack of knowledge in interpreting, monitoring and responding to such data. Our long-term goal is to integrate patient-reported outcomes information, clinically relevant information, evidence-based medicine, and technology and methodology to provide on-demand and individualized clinical guidelines and treatment decision trees to improve cancer patients' care.</p>			
	<p>Our Phase I project aims are to (1) conduct focus groups, interviews and site visits to collect system functional and operational requirements; (2) perform literature reviews to assess scientific and technical feasibility; (3) create system design specifications; (4) develop and pilot test a prototype system; and (5) construct the initial PRO item bank focusing on breast cancer.</p>			
	<p>The proposed PRO management system is designed for both oncology clinicians and patients. The novelties are in the integration of well-developed psychometrics and advanced information technologies for daily practice and research application in clinical settings. With existing and increasing numbers of cancer patients in the U.S., the need for such an integrated system that we propose to develop is substantial.</p>			

Project Name		Comprehensive PRO Management for Oncology Practice (SBIR Phase II)			
Project ID	HHSN261200700046C				
Sponsor	National Cancer Institute				
Project Period	9/30/2007 – 9/29/2010				
Funding Level	\$749,917				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Ana Maria López, MD	Univ. Arizona	Assoc. Professor	
	Co-PI	Hannah Linden, MD	Univ. Washington	Assoc. Professor	
	Investigator	Linda Larkey, PhD	Univ. Arizona	Assoc. Professor	
	Investigator	Karon Cook, PhD	Univ. Washington	Sr. Res. Scientist	
	Investigator	Kendon Conrad, PhD	Univ. Illinois Chicago	Professor	
	Investigator	Michael Kallen, PhD	Univ. Texas	Assist. Professor	
	Investigator	Perry Nicassio, PhD	UCLA	Clinical Professor	
	Clinical Site	Arizona Cancer Center, University of Arizona Seattle Cancer Care Alliance, University of Washington (Y-Me National Breast Cancer Organization)			
# Subjects	650				
Abstract	<p>The long-term goal of this project is to build a breast cancer-specific patient-reported outcomes (PRO) system that can be integrated into clinical practice and provides clinically relevant analyses and recommendations to clinicians and patients. During our Phase I project, we have produced functional and operational requirements, a working prototype, design and planning documentations, and a pool of breast cancer-specific PRO items.</p>				
	<p>Our Phase II project aims are to 1) complete system implementation and further refine the system based on user feedback; 2) deploy and test the system in real clinical settings; 3) incorporate PROMIS adaptive PRO instruments into our system with a standardized approach; 4) implement standards-based integration solutions to exchange PRO assessment results with other EMR systems; 5) evaluate benefits of using this system in clinical practice; 6) create user manuals and tutorials; and 7) publish study results in peer-reviewed journals.</p>				
	<p>This is a novel cancer-specific PRO application addressing issues hindering the utilization of PRO in clinical practice using well-developed methodology and advanced technology. With existing and increasing numbers of cancer patients in the U.S., the need for such an integrated system that we propose to develop is substantial. This project could also further our understanding and knowledge of the value of PRO for cancer patient care, so that better treatment decisions can be made and resources be better allocated.</p>				

Project Name		Home-Centered Teleoncology Care Model (SBIR Phase I)			
Project ID	HHSN261200700055C				
Sponsor	National Cancer Institute				
Project Period	9/30/2007 – 6/30/2008				
Funding Level	\$150,000				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Ana Maria López, MD	Univ. Arizona	Assoc. Professor	
	Investigator	Linda Larkey, PhD	Univ. Arizona	Res. Assoc. Professor	
Clinical Site	Arizona Cancer Center of the University of Arizona				
# Subjects	50				
Abstract	<p>The long-term objective of this study is to increase access to care, empower patient self-management and ultimately deliver better patient outcomes by uniting telemedicine technologies, patient-reported outcomes research and dialogue-based patient-provider communication. The technical objectives for this Phase I proposal are 1) develop a home-centered coordinated cancer care (HC4) model and 2) develop and evaluate a working prototype of a tracking system to monitor and facilitate the delivery of care as specified in the HC4 model.</p>				
	<p>The HC4 model will be defined from various perspectives including organization, procedure, assessment, clinical and technology. Our approach includes systematic literature review and iterative refinement of the model through discussions and interviews with physicians, nurses, patients and caregivers. The prototype system will be developed following standard object-oriented analysis and design process. Focus groups will be convened to discuss model and system design options. Several controlled pilot test runs will be conducted to gain preliminary evaluation of system design in terms of interface usability and clinical usefulness.</p>				
	<p>It is expected that Phase I results will validate the feasibility of the proposed system from the perspectives of both practicality and technology for the purpose of Phase II execution and ultimate commercialization.</p>				

Project Name	Telenursing Model for Management of Chemotherapy Side Effects (SBIR Phase I)			
Project ID	R43NR010441			
Sponsor	National Institute of Nursing Research			
Project Period	7/16/2008 – 1/15/2009			
Funding Level	\$93,382			
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President
	Co-PI	Ana Maria López, MD	Univ. Arizona	Professor
	Investigator	Elizabeth Krupinski, PhD	Univ. Arizona	Res. Professor
Clinical Site	Arizona Cancer Center of the University of Arizona			
# Subjects	50			
Abstract	<p>The goal of this specific project is to develop a cost-effective proactive telenursing system for the management of chemotherapy side effects. Patients will use this system to report health status on a daily basis during treatment, either on the Web or via interactive voice response system over the phone. Depending on the reported severity, the system may deliver just-in-time, evidence-based, context-sensitive patient education materials tailored to the patient’s disease status and treatment regimen, and/or alert the oncology clinical care team to provide timely remote monitoring and consultation.</p>			
	<p>Our Phase I aims are to (1) design a telenursing model with the special focus on tailored patient instructions via systematic literature review, web resource review, focus group discussions, and personal interviews; and (2) develop a working prototype based on the resultant telenursing model and conduct controlled pilot study in realistic settings to evaluate technical feasibility, the acceptance level by providers and patients, and the effects on clinical outcomes and perceived intervention effectiveness. The initial focus of the Phase I feasibility study is on neutropenia, fatigue and nausea, three of the common chemotherapy side effects, for lymphoma patients and will be extended to other side effects and cancer sites in Phase II.</p>			
	<p>This project is consistent with our long-term strategic direction to improve access to care, promote patient self-management, facilitate provider-patient communication, and ultimately improve clinical outcomes and reduce healthcare costs with multidisciplinary approaches integrating telehealth and e-health technologies, evidence-based medicine, patient-reported outcomes methodologies, and patient education research.</p>			

Project Name		Coordinated Cancer Screening and Diagnosis Model (SBIR Phase I)			
Project ID	HHSN261200800032C				
Sponsor	National Cancer Institute				
Project Period	9/30/2008 – 12/31/2009				
Funding Level	\$149,973				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Ana Maria López, MD	Univ. Arizona	Professor	
	Investigator	Linda Larkey, PhD	Arizona State U.	Professor	
Clinical Site	Arizona Cancer Center of the University of Arizona				
# Subjects	54				
Abstract	<p>The long-term goal of this study is to facilitate early colorectal cancer (CRC) detection by developing a care coordination system that will facilitate both screening and diagnostic processes via e-health, telemedicine, clinical decision support, patient-reported risk information, patient education, and coordinated care models and technologies. Specifically, we seek to 1) provide alerts to health care providers (HCP) to help them track CRC screening/diagnosis referrals for persons at normal risk and due for screening, and for those at greater risk due to family history or specific signs/symptoms; 2) present just-in-time, individually tailored education instructions to patients based on PRO data; 3) coordinate care team tasks with EMR/telemedicine integration; and 4) coordinate assistance from all support resources, including community health advisors.</p>				
	<p>This approach is especially important for the Latino population along the US-Mexico border in Arizona, who are often seen in Federally Qualified Healthcare Clinics (FQHCs). The technical objectives for this Phase I proposal are to 1) develop the CRC-specific screening and diagnostic care coordination model via literature review, focus groups, interviews, and a retrospective medical record review of CRC patients; 2) develop a web-based prototype system to facilitate the execution of the CRC screening and diagnosis model; and 3) evaluate the prototype in terms of usability and usefulness.</p>				

Project Name		Collaborative Palliative and hospice Care Using PRO (SBIR Phase I)			
Project ID	HHSN261200800050C				
Sponsor	National Cancer Institute				
Project Period	9/30/2008 – 12/31/2009				
Funding Level	\$149,956				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Michael Kallen, PhD	Univ. Texas	Assistant Professor	
	Investigator	Eduardo Bruera, MD	Univ. Texas	Professor	
	Consultant	Chih-Hung Chang, PhD	Northwestern U.	Assoc. Professor	
Clinical Site	M.D. Anderson Cancer Center of the University of Texas				
# Subjects	45				
Abstract	<p>Our long-term objective is to develop a computer system facilitating the use of patient-reported outcomes (PRO) information to monitor patient status and assist clinical decision-making for cancer patients under palliative and hospice care. This system will integrate PRO and other clinical data with evidence-based treatment guidelines and pathways to care and interface with and foster collaborative decision-making between the patient, the caregivers, and the medical care team.</p>				
	<p>This project will leverage the BrightOutcome architecture for PRO management developed in our other SBIR efforts, already implementing CAT/IRT capability, multiple delivery platforms, graphical reports highlighting clinically meaningful PRO score changes, and alert/reminder mechanism.</p>				
	<p>Considering the project goals and our past and current R&D efforts, we define the specific Phase I technical objectives as follows: 1) Define a palliative/hospice care model to integrate PRO assessment results with evidence-based pathways to care to provide clinical decision support for clinicians and education opportunities for patients and caregiver via literature review, focus groups, and interviews; 2) Design a system architecture facilitating the sharing and transfer of PRO-related medical data between cancer clinics, hospices, and patients' homes; 3) Develop a working prototype following object-oriented and knowledge-based software development methodologies; and 4) Evaluate the usability and usefulness of the prototype solution via controlled pilot tests.</p> <p>It is expected that Phase I results will validate the feasibility of the proposed solution from the perspectives of both practicality and technology for the purpose of Phase II execution and ultimate commercialization.</p>				

Project Name		Defining Interoperability Standards for PRO Assessments (ARRA)			
Project ID	RC1CA146181				
Sponsor	National Cancer Institute				
Project Period	9/30/2009 – 8/31/2011				
Funding Level	\$999,413				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Richard Gershon, PhD	Northwestern U.	Director	
	Consultant	David Cella, PhD	Northwestern U.	Professor	
	Consultant	Seung Choi, PhD	Northwestern U.	Director	
Abstract	<p>There is a growing recognition of the importance of subjective patient-reported outcomes (PRO) in patient care. Several recent studies have observed positive impacts of routine use of PRO assessments in clinical practice, reporting improved physical, functional and emotional well-being, reduced hospitalization, better detections of less observable and subjective PRO concerns, and better patient-provider communication. Recognizing the value and potential of PRO assessments, the NIH is completing a 5-year \$25MM Roadmap Initiative, called the Patient-Reported Outcomes Management Information System (PROMIS), and in the process of funding the second round of PROMIS research activities. The goal of the PROMIS Initiative is to develop and validate a new set of standardized PRO instruments based on modern computerized adaptive testing (CAT) and item response theory (IRT). A primary benefit, amongst many others, of CAT/IRT-based instruments is that they are dynamically administered, tailored to each individual's past responses, and hence much shorter (i.e., fewer items) but without sacrificing measurement precision.</p>				
	<p>Parallel to the PROMIS endeavor, enormous interests exist within both the government and the private industry in developing interoperability standards to facilitate data exchange between heterogeneous healthcare information systems; in particular the government's Health Information Technology (HIT) Initiative that heavily leverages existing industry standards. Standardization efforts for the clinical research community are also in progress; most notably by the Clinical Data Interchange Standards Consortium (CDISC). The promotion of electronic medical records (EMR) system by the Administration as part of the healthcare reform effort furthers the cause of data standardization.</p>				
	<p>Ideally, the vast investment on EMR and data standardization and on PRO-related research such as the PROMIS project should bring the goal of wide adoption of PRO in clinical research and practice closer to fruition. Unfortunately a major gap still exists to prevent this goal from being achieved, namely the lack of data standardization for PRO instruments and assessment results. There has been no concerted effort to bring the PRO community into any data standardization endeavors. This project thus intends to bridge this gap between the PROMIS Initiative and various standardization initiatives so that the benefits of the PROMIS project and the field of outcomes research in general can be fully realized.</p>				
	<p>Specifically, this project seeks to a) establish interoperability data standards for patient-reported outcomes (PRO) instruments and assessment results, including both the conventional static PRO questionnaires and the new adaptive item banks from the NIH PROMIS project; and b) develop interoperability reference implementations of these standards demonstrating integration scenarios with open-sourced electronic medical record (EMR) and clinical trial management (CTM) systems.</p>				

Project Name		Patient-Centered Communication for Post-Diagnosis Care (SBIR Phase I)			
Project ID	HHSN261200900044C				
Sponsor	National Cancer Institute				
Project Period	9/30/2009 – 6/30/2010				
Funding Level	\$149,992				
Investigators	PI	DerShung Yang, PhD	BrightOutcome	President	
	Co-PI	Ana Maria López, MD	Univ. Arizona	Professor	
	Investigator	Linda Larkey, PhD	Arizona State U.	Professor	
Clinical Site	Arizona Cancer Center of the University of Arizona				
# Subjects	63				
Abstract	<p>Building on top of our success in developing coordinated cancer care systems for patients either during active treatment or during screening/diagnosis processes, we are proposing in this project to focus on helping post-diagnosis patients, with a special focus on the period between the diagnosis of ovarian cancer and the start of the treatment. Although this period is relatively short, it is one of the most agonizing, terrifying, and confusing period for cancer patients and their families to deal with. Communication at all levels is needed to help patients understand the disease and the treatment options and understand when and how to ask for help. Clinicians also need communication help to understand the patient’s health-related priorities, beliefs, and emotional states to aid clinical decision-making.</p>				
	<p>From a patient-centered communication perspective, this project will address the topics of fostering healing relationships, exchanging information, responding to emotions, managing uncertainty, making decisions, and enabling patient self-management to various degrees. One novelty of this project is the use of video clips as a major communication media. Videos produced in the local clinic setting showing the providers that patients will interface with can put a more personal touch on the information to be conveyed to patients and could be more effective.</p> <p>The technical objectives for this Phase I proposal are to 1) develop an ovarian cancer-specific care model (including video scripts) for the period between diagnosis and treatment via literature review, focus groups, and interviews; 2) develop a prototype system (including video production) to deliver this care model and 3) evaluate the prototype in terms of usability and usefulness via pilot test.</p>				