CMTP

Green Park Collaborative

A partnership for innovation and effectiveness

GREEN PARK-USA ANNUAL PROGRESS REPORT

2013-2014

Funders

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The Green Park Collaborative (GPC-USA) is a unique and timely forum that brings together the many stakeholders who want to improve the quality, relevance, and efficiency of clinical research in the U.S.

Collaborative Progress

The Center for Medical Technology Policy (CMTP) is pleased to present our inaugural Green Park Collaborative-USA Progress Report.

The Green Park Collaborative (GPC-USA) is a unique and timely forum that brings together the many stakeholders who want to improve the quality, relevance, and efficiency of clinical research in the United States. Payers, life sciences companies, patients, clinicians, researchers, and regulators are collaborating on the development of condition- and technology-specific study design recommendations to guide the generation of evidence needed to inform both clinical and reimbursement decisions. Together, we can increase the quality and relevance of future studies on treatments, devices, and diagnostics. And through this challenging work, we can speed up the adoption of useful and needed innovations that improve our individual and collective health.

During the past year, GPC-USA has made rapid and exciting progress. We have created two disease-specific consortia: one focuses on developing methodological standards to support oncology and the other on diabetes research. We are nearing the completion of an Effectiveness Guidance Document (EGD) on patient-centered outcomes in diabetes, and an EGD on sequencing and prioritization in cancer treatment. In addition, we recently began development of an EGD on next generation sequencing (NGS) tests for cancer treatment. All three EGDs will provide needed methodological standards for the research required to make important clinical, reimbursement, and other policy decisions.

This report offers a broad overview of these accomplishments, as well as brief reviews of two seminal meetings, where GPC-USA's diverse stakeholders had an opportunity to share perspectives and ideas, as well as roll up their sleeves and help the Collaborative take some important first steps.

We thank our current members and collaborators for their contributions so far, welcome new members, and invite prospective members to join us in this very essential work.

Convening, Collaborating

In the past year, GPC-USA has twice gathered its key stakeholders together to exchange ideas, set direction, and catalyze the work of the Collaborative. Both events proved extremely productive and will serve as models for future meetings.

INAUGURAL MEETING

CMTP kicked off the initiative with the inaugural meeting of GPC-USA on May 1, 2013, in Baltimore, Maryland. This gathering convened leaders from throughout the health care enterprise. Through formal presentations, small group conversations, and informal networking, participants offered a range of perspectives on the important role GPC-USA could play as a neutral forum that would allow payers, patients, clinicians, life sciences companies, researchers, regulators, and others to engage in dialogue regarding methodological standards that will help studies demonstrate effectiveness and value.

Presenters described the development of two Effectiveness Guidance Documents (EGDs), one titled *Recommendations for Incorporating Patient-Reported Outcomes (PROs) into Clinical Comparative Effectiveness Research (CER) in Adult Oncology* , and the other, *Evaluation of Clinical Validity and Utility of Actionable Molecular Diagnostic Tests in Adult Oncology*, which was officially released at the meeting. EGDs are analogous and complementary to regulatory guidance documents but are focused on the evidence expectations of payers, patients, and providers. Participants also discussed the initial work priorities for the Collaborative, including goals and criteria for setting research priorities.

Presentations from this meeting can be found at: www.cmtpnet.org

FIRST ANNUAL MEETING

Six months later, CMTP hosted the first Annual Meeting of GPC-USA on November 12, 2013. Nearly 60 health care leaders representing payers, industry, patients, regulators, and academia participated in a series of presentations and roundtable discussions.

Presenters described the Collaborative's progress in establishing two new disease-specific Consortia that will develop and publish new EGDs within 12 months. The priority areas for these consortia are **Endocrine and Metabolic Diseases** and **Oncology**.

Presentations and materials from this meeting can be found at: www.cmtpnet.org.

NEW LEADERSHIP FOR GPC-USA

In January 2014, CMTP proudly announced the selection of Elisabeth (Els) Houtsmuller, PhD, as Senior Program Director, GPC-USA. Since then, Dr. Houtsmuller has taken a central role in the Collaborative's operations—leading, planning, and coordinating the project's diverse meetings, processes, and activities.

By way of brief background, prior to her role at GPC-USA, Dr. Houtsmuller served as managing editor at Hayes, Inc., a health technology assessment and consulting firm. At Hayes, she oversaw the production of evaluations of the efficacy and safety of medical and mental health treatments, diagnostics, and technologies. Earlier, Dr. Houtsmuller was an associate professor in the Department of Psychiatry, Johns Hopkins School of Medicine, where she led a clinical research lab. Her work focused primarily on drug and alcohol abuse and dependence.

At the first Annual Meeting of Green Park Collaborative-USA, held on November 12, 2013, in Baltimore, MD, nearly 60 health care leaders representing payers, industry, patients, regulators, and academia participated in a series of presentations and roundtable discussions.

The Consortia: Key Working Structures for GPC-USA

The GPC-USA's Consortia are the bodies through which much of the Collaborative's work is accomplished. These groups include a range of expertise and perspectives from key thought leaders in research, clinical and patient decision-making, reimbursement, and regulation. They conduct their work through in-person workshops, video/web-supported conference calls, and electronic communication. The launch and subsequent development of two Consortia represent exciting and substantive milestones in the development of GPC-USA.

ENDOCRINE-METABOLIC DISEASES CONSORTIUM

The Endocrine-Metabolic Diseases Consortium is led by C. Daniel Mullins, PhD, Professor, Pharmaceutical Health Services Research Department (PHSR) at the University of Maryland School of Pharmacy. Its current Technical Working Group, which takes more direct responsibility for the Consortium's EGDs, is chaired by Nisa Maruthur, MD, MHS, Assistant Professor of Medicine and Epidemiology at the Johns Hopkins University School of Medicine.

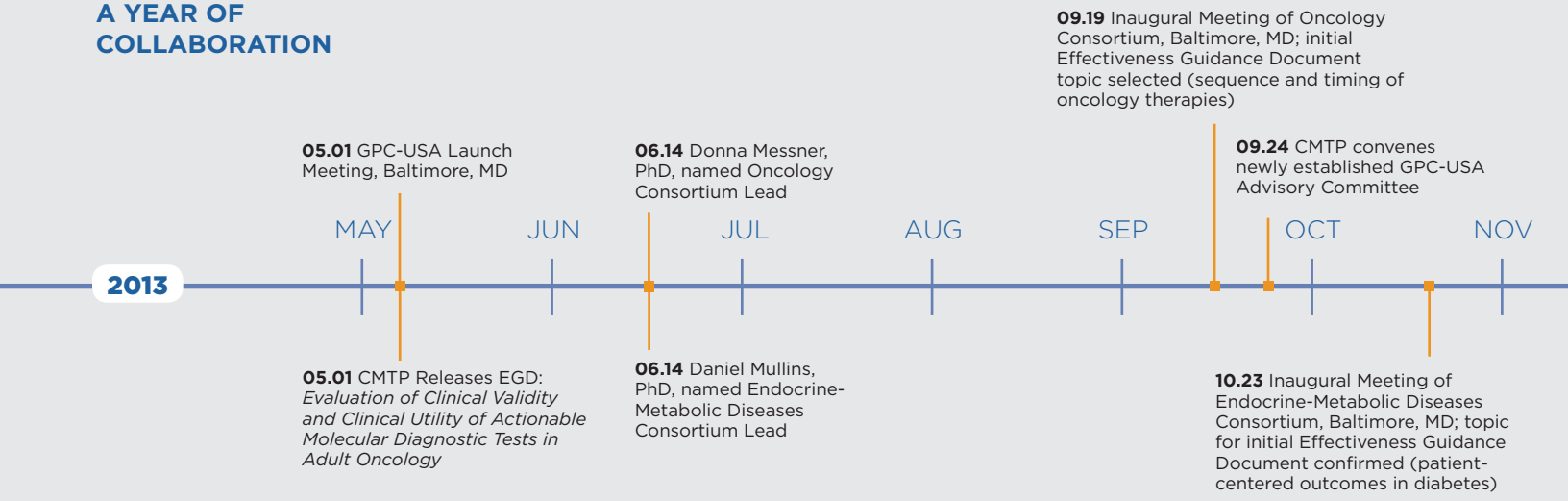
Prior to establishing this Consortium, CMTP conducted background research and hosted a Diabetes Comparative Effectiveness Research Workshop on October 16th, 2012. Patient-centered outcomes in diabetes emerged as an important EGD topic during the meeting. Subsequently, GPC-USA sponsored a series of 19 key informant interviews to inform the development of a preliminary set of EGD recommendations.

The inaugural meeting of the Endocrine and Metabolic Diseases Consortium took place in Baltimore, Maryland, on October 23rd, 2013. Members provided feedback on the preliminary recommendations for diabetes studies, and the Consortium decided to focus its initial EGD more specifically on guidance for designing trials that provide better information about real-world effectiveness and outcomes that are most meaningful to diabetes patients. Publication is scheduled for early summer.

ONCOLOGY CONSORTIUM

Donna Messner, PhD, Research Director at CMTP, leads the Oncology Consortium. Over the past year, it has focused on developing methodological recommendations and data strategies to help shape research on the best ways to sequence cancer care treatments. Anne Schott, MD, who specializes in medical oncology at the University of Michigan, chairs the Technical Working Group, which developed initial recommendations for the Consortium's first EGD.

A YEAR OF COLLABORATION



In developing those recommendations, the Oncology Consortium built on CMTP's prior work in this area, which included four previously published EGDs: (1) *Recommendations for Incorporating Patient-reported Outcomes into Clinical Comparative Effectiveness Research in Adult Oncology*, (2) *Evaluation of Clinical Validity and Clinical Utility of Actionable Molecular Diagnostic Tests in Adult Oncology*, (3) *Recommendations for Designing Clinical Trials for New Indications of Approved Oncology Drugs for Treatment of Late Stage Disease*, and (4) *Gene Expression Profile Tests for Early Stage Breast Cancer*.

Much of the Consortium's work on its first EGD is focused on identifying methods and best practices needed to determine the sequence and timing of multiple "lines" (or combinations) of oncology therapy to yield optimal net benefits to patients. This topic is of significance for several types of cancer, including renal cell carcinoma, castration-resistant prostate cancer, and relapse of ovarian cancer. Publication of this EGD is scheduled for fall 2014.

EXPANDING ACTIVITIES

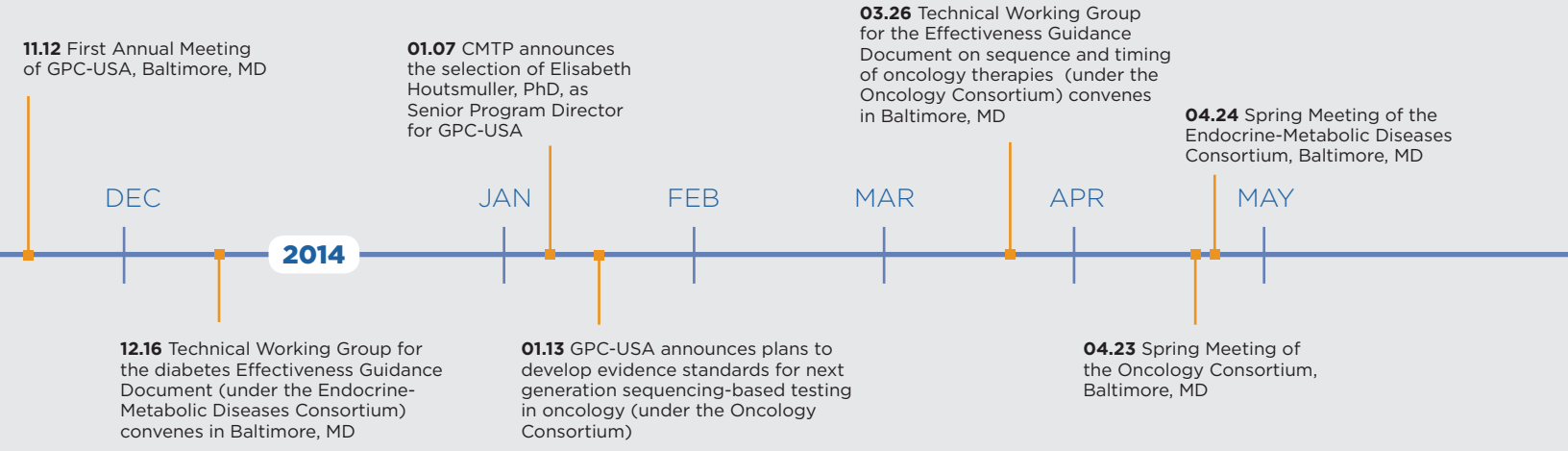
In addition to meetings and Consortia activities, GPC is looking forward to supporting various new initiatives, including web conferences and workshops.

NGS: A SECOND ONCOLOGY EGD

Recently, the Oncology Consortium launched a new effort to develop methodological guidance on the kinds of evidence needed to evaluate promising tests in the rapidly developing field of next generation sequencing (NGS) for cancer diagnosis and treatment.

NGS streamlines the technical aspects of molecular testing for a whole variety of diseases and produces higher volumes and breadth of genomic information, at increasingly competitive costs. When applied in oncology, NGS promises to accelerate our growing understanding of cancer, helping to define tumors' biological pathways and genetic characteristics. NGS has the potential to yield a much more accurate picture of these diseases and spur a new generation of targeted therapies. Assessing the clinical utility of these innovations, however, remains challenging.

The project's EGD will focus in particular on NGS-based tests used to manage patients with a known diagnosis of cancer (as opposed to risk prediction testing). Its recommendations will be aligned with existing and emerging regulatory guidance where relevant. This effort will be informed by CMTP's recent work on evidentiary standards for studies of the clinical validity and clinical utility of molecular diagnostics in oncology.



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CENTER FOR MEDICAL TECHNOLOGY POLICY (CMTP)

The Center for Medical Technology Policy (CMTP) is an independent, non-profit 501(c)(3) organization that aims to make health care more effective and affordable by improving the quality, relevance, and efficiency of health care research. We focus on the design and implementation of comparative effectiveness research to produce information that helps patients, clinicians, and payers make informed treatment and policy decisions. CMTP provides a trusted forum in which a broad range of stakeholders can collaborate to identify important research questions, design appropriate studies, and develop innovative partnerships to implement these studies.

GPC-USA AND GREEN PARK COLLABORATIVE INTERNATIONAL (GPC-I)

The work of the GPC-USA is informed by CMTP's experience managing GPC-International, a partnership between Health Technology Assessment International (HTAi) and CMTP. A GPC-I pilot project on Alzheimer's Disease assessed the feasibility of developing global guidance for the life sciences industry on the design of clinical studies to meet the needs of Health Technology Assessment (HTA) and coverage bodies. This project was completed in the Spring of 2013. For additional information on GPC-I, visit www.cmtpnet.org.

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