

COMET INITIATIVE NORTH AMERICA NETWORK MEETING

(AND A BIT ABOUT PAYERS AND COS)

19 November 2014

Sean R. Tunis, MD, MSc.



Green Park Collaborative | USA

A partnership for innovation and effectiveness



CENTER FOR MEDICAL TECHNOLOGY POLICY

COMET-NA MEETING OBJECTIVES

- Enable COS developers to share experience, insights, best practices, challenges with each other
- Learn about work of federal agencies and other major organizations that intersect with work on COS
- Explore opportunities for collaboration
- Promote more and better work on COS in North America
- Identify mechanisms to increase impact

INVITATION PROCESS

- COS paper published since 2008
- Lead author from USA or Canada
- Included face to face discussions
- Involved clinicians and patients in some way
- Range of health conditions sought
 - 13 projects identified; 6 attended
- All above except patient involvement
 - 17 projects, 4 attended (reached max of 10)

Core Outcome Set Development in Childhood Cerebral Palsy

Jilda Vargus-Adams MD MSc

Division of Pediatric Rehabilitation

Departments of Pediatrics and
Neurology & Rehabilitation Medicine

OUTCOME MEASURES: NEUROENDOCRINE TUMORS

James C. Yao, MD

Professor and Deputy Chair, Gastrointestinal Medical Oncology
University of Texas M. D. Anderson Cancer Center

Irritable Bowel Syndrome (IBS):



Clinical Outcomes- The example of a disaster

Mark Pimentel, MD
Director, GI Motility Program
Cedars-Sinai Medical Center

Outcome Assessments and Endpoints:

Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia

John H. Powers, MD FACP FIDSA

Senior Medical Scientist

Leidos Biomedical Research in support of Division of Clinical Research

National Institute of Allergy and Infectious Diseases

Associate Clinical Professor of Medicine

George Washington University School of Medicine

ABNORMAL UTERINE
BLEEDING:
DIVERSE DISEASE, DIVERSE OUTCOMES

David D. Rahn, MD

Gynecology, University of Texas Southwestern Medical Center

Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) Core Outcome Measures

Shannon M. Smith, Ph.D.

Assistant Professor, Anesthesiology
University of Rochester School of Medicine and Dentistry
Assistant Director of ACTION

COMET Initiative Network Meeting

April 28, 2014

PARTICIPANTS – FEDERAL AGENCIES, OTHER ORGS

Amy Abernethy, MD, PhD	Duke Clinical Research Institute (DCRI)
Ethan Basch, MD, MSc	University of North Carolina (UNC)
Kay Dickersin, PhD	US Cochrane Center
David Flum, MD, MPH	Director, Surgical Outcomes Research Center (SOURCE) University of Washington, Department of Surgery
Jason Gerson, PhD	Patient-centered Outcomes Research Institute (PCORI)
William Lawrence, MD, MS	Agency for Healthcare Research & Quality (AHRQ)
Bryan Luce, PhD, MD	Patient-centered Outcomes Research Institute (PCORI)
Elektra Papadopoulous, MD	FDA/CDER – Study Endpoints and Labelling Development
Bill Riley, PhD	National Institutes of Health/National Cancer Institute (NIH/NCI); Patient Reported Outcomes Measurement Information System (PROMIS)
Jerry Sheehan, MS	National Institutes of Health/National Library of Medicine (NIH/NLM)
Marc Walton, MD, PhD	FDA /CDER – Office of Translational Science
Becky Williams, PhD	ClinicalTrials.gov/ National Institutes of Health (NIH)

SELECTED INSIGHTS FROM DISCUSSION

- Networking meeting – check!!
 - “Nice to know there are others like me”
 - Many federal agency folks unfamiliar with COS
- Many noted need for COS quality standards
- Methods for stakeholder engagement not well defined
 - Particularly patient/public engagement
 - Which stakeholders, when, doing what
- Need for effective mechanisms to promote uptake
- Not easy to find funding to support COS development

QUOTE OF THE DAY

“Standards are like toothbrushes: everybody wants one, but nobody wants to use anybody else’s.”

Jerry Sheehan, NIH/NLM
(citing Doug Fridsma, AMIA)

NA COMET NETWORK MTG - THANKS!

- Paula Williamson, Liz Gargon
- Peter Tugwell, Maarten Boers
- Sandra Hwang, Janelle King
- European Union
- PCORI

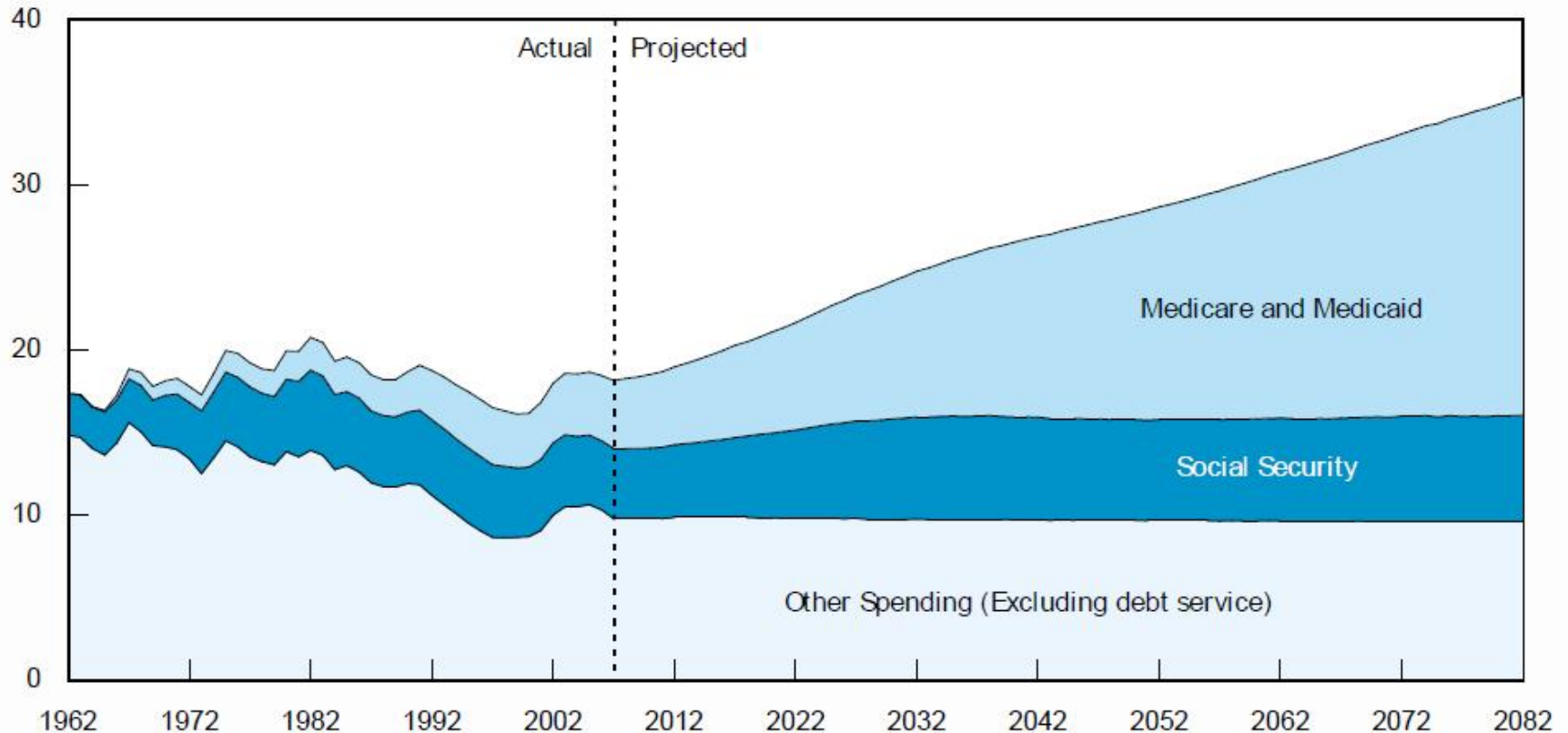
WHY SHOULD COS DEVELOPERS CARE ABOUT PAYERS AND HTA GROUPS?





Long-Term Fiscal Gap and Health Care Costs

Percentage Share of GDP



Source: CBO (2007)

THE NEW EVIDENCE CHALLENGE

- Development of more and better evidence of effectiveness, safety and value for payers, patients, clinicians, and policymakers
- In an environment of increasing downward pressure on spending
- Without doing major damage to ecosystem for development of new health technologies

PAYERS/HTA GROUPS ARE GIVING ADVICE

- NICE scientific advice
- EMA/payer parallel advice process
- EUnetHTA early dialogue with multiple HTA/payers
- Green Park Collaborative

GREEN PARK COLLABORATIVE - USA

- A multi-stakeholder forum to clarify the evidence expectations of public and private payers
 - Informed by input from patients, clinicians, regulators, methods experts, life sciences, others
- Produce “effectiveness guidance documents”
 - Analogous to regulatory guidance
 - Condition and technology-specific study design recommendations for researchers

PAYERS INVOLVED IN GPC

- AHIP
- Humana
- Aetna
- CMS central office
- MACs (Palmetto, Noridian, Novitas, others)
- United
- Kaiser
- Wellpoint
- BCBSA
- Johns Hopkins Health Plan
- Many smaller regional payers



Green Park Collaborative

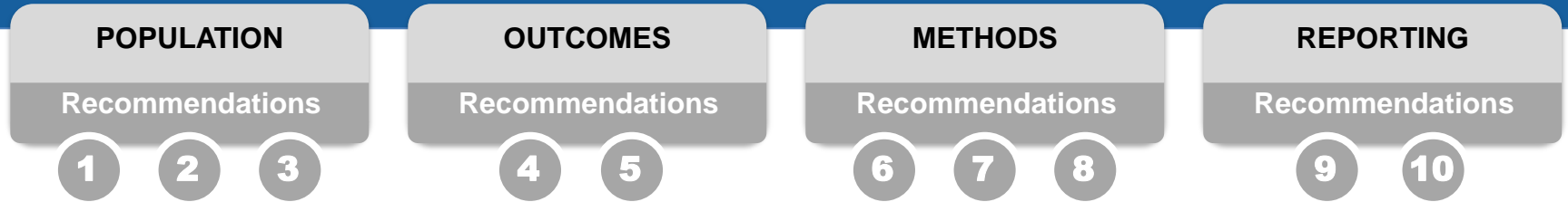
A partnership for innovation and effectiveness

RECOMMENDATIONS FOR LATE PHASE DRUG STUDIES IN TYPE 2 DIABETES



The Green Park Collaborative is a major initiative of the
Center for Medical Technology Policy

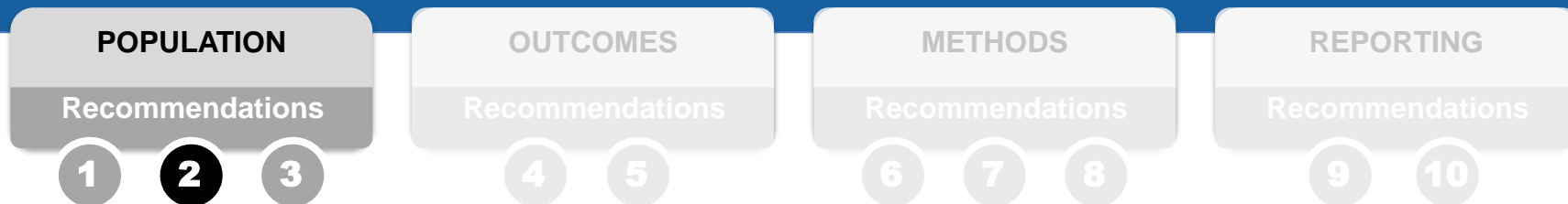
RECOMMENDATIONS: OVERVIEW



- The recommendations provided in this EGD focus on study design, data collection, and reporting
- This EGD presents 10 recommendations organized in four categories: Population, Outcomes, Methods, Reporting for Patient Stakeholders



RECOMMENDATION 2: DON'T EXCLUDE PATIENTS WITH OTHER CONDITIONS

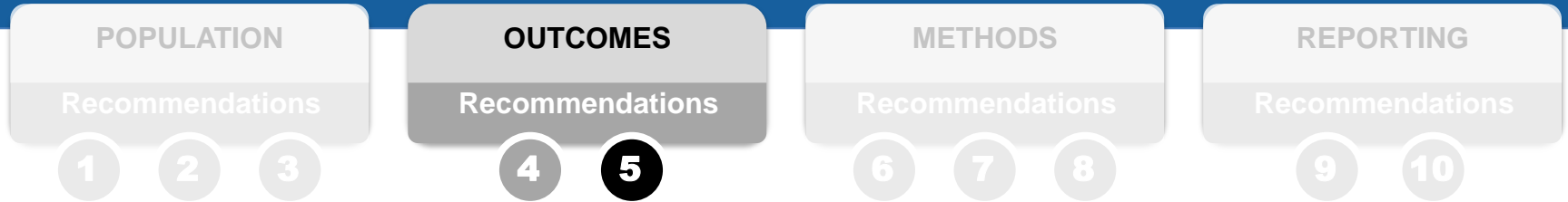


Diabetes patients with other medical conditions are often excluded from studies, which makes it difficult to know how treatments will affect these patients.

Patients should not be excluded just because they have cardiovascular disease, depression, a history of cancer, mild cognitive impairment, or diabetes complications



RECOMMENDATION 5: MONITOR EFFECTS OF WEIGHT GAIN OR LOSS

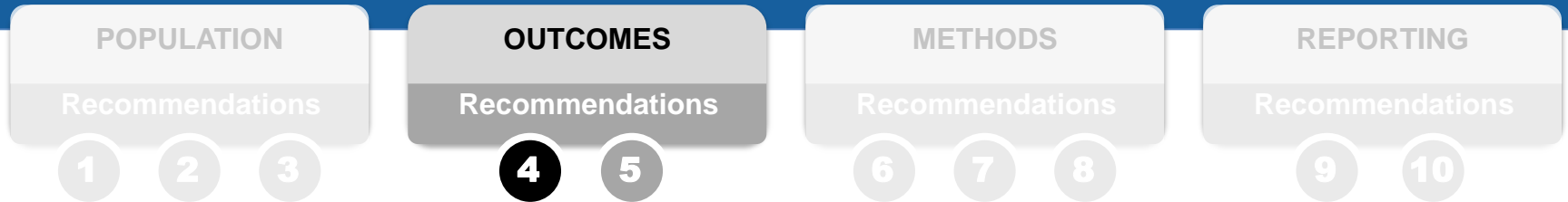


Patients report they find treatment effects on weight extremely important

➔ **Studies should report more information about treatment effects on weight, including how many patients lost or gained 5%, 5-10% and more than 10%**



RECOMMENDATION 4: REPORT QUALITY OF LIFE MEASURES



Quality of life is an important factor for patients evaluating treatments

Studies should include quality of life measures, specifically the Audit of Diabetes-Dependent Quality of Life (ADDQoL-19) and the Diabetes Treatment Satisfaction Questionnaire before treatment and after 1 year of treatment



GPC AND COMET – INCREASING UPTAKE OF COS

- GPC may provide a mechanism to leverage increasing influence of payers to promote uptake of COS
- In any case, payers/HTA groups are influencing choice of outcomes, so would be wise to explore how to engage
- It will require careful consideration of precisely when and how to work with payers and HTA groups

CONTACT INFO

- sean.tunis@cmltpnet.org
- www.cmltpnet.org
- 410-547-2687 x120 (D)
- 410-963-8876 (M)



Green Park Collaborative | USA

A partnership for innovation and effectiveness

EXTRA SLIDES

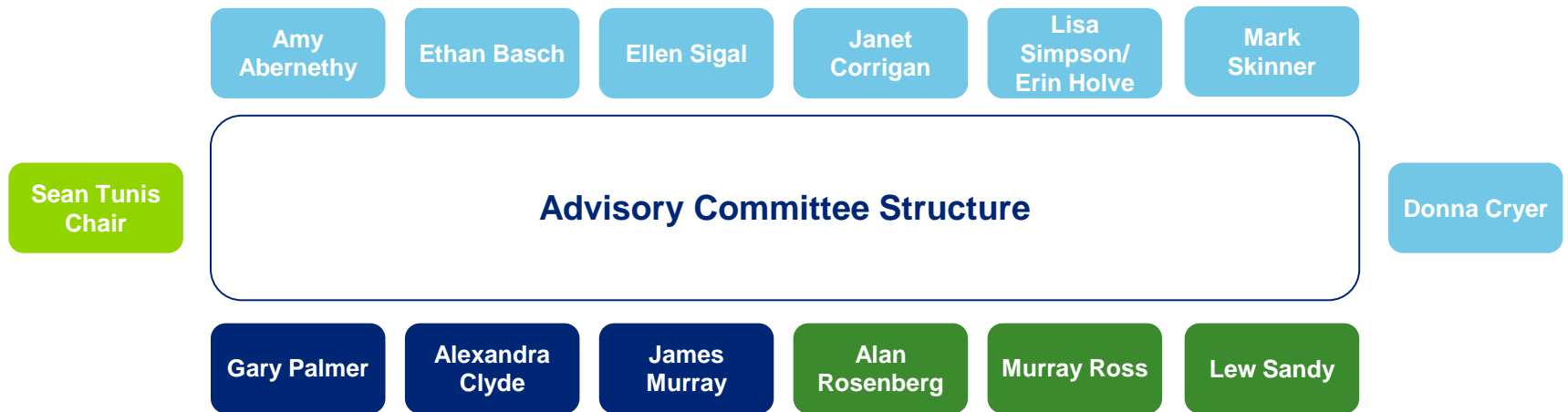


KEY STAKEHOLDERS

Stakeholder Categories



GPC – USA ADVISORY COMMITTEE



Ex Officio

FDA	CMS	PCORI	NIH	AHRQ	VA	Avalere
Bob Temple	Patrick Conway	Rachael Fleurence	Michael Lauer	Jean Slutsky	David Atkins	Tanisha Carino
Murray Sheldon	Louis Jacques	Jason Gerson				
Peter Marks						

Board Composition Key

