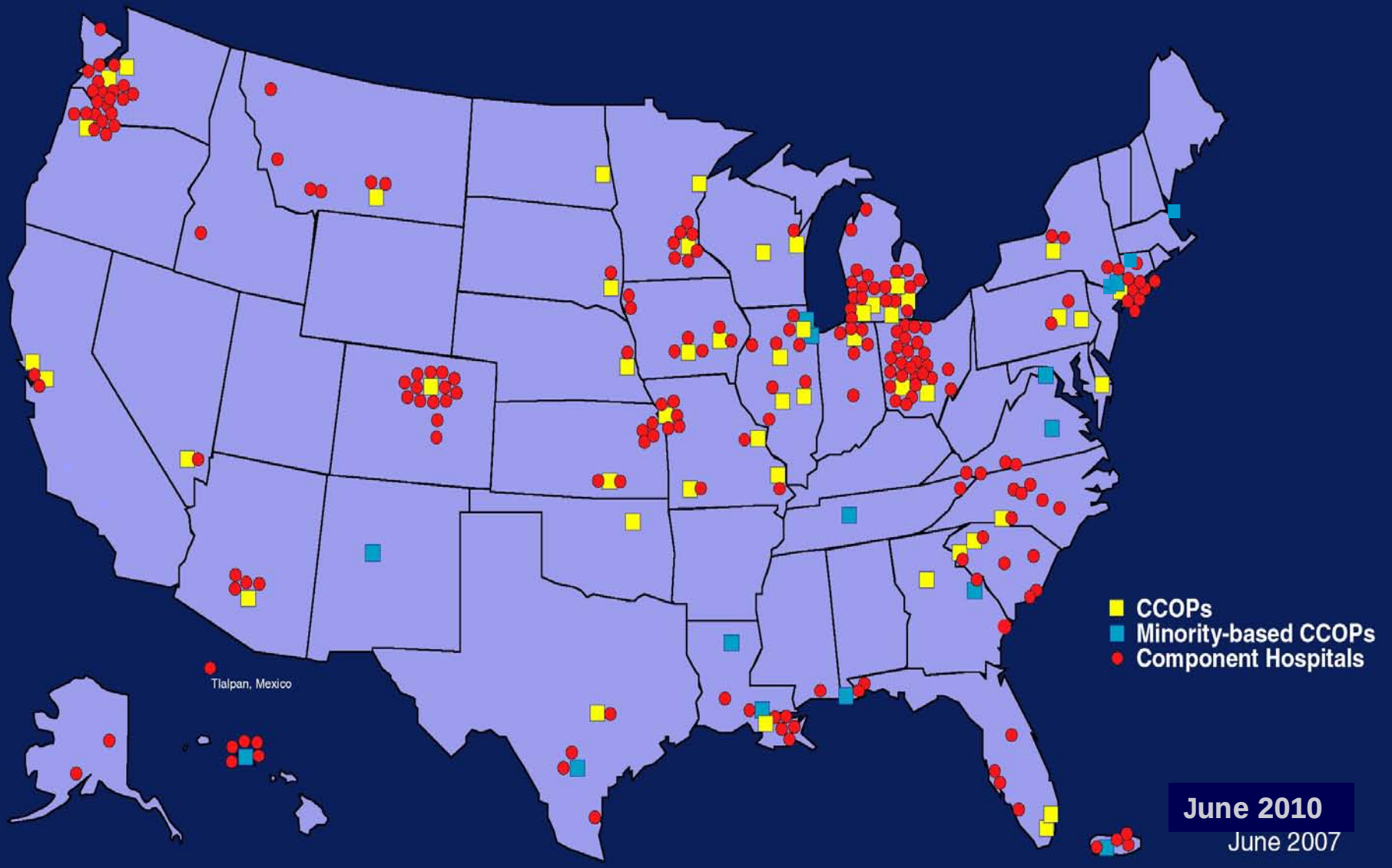
THE IOM REPORT AND A COMMUNITY CLINICAL ONCOLOGY PROGRAM (CCOP) PERSPECTIVE

STEPHEN S. GRUBBS, M.D.
DELAWARE CHRISTIANA CARE CCOP
HELEN F. GRAHAM CANCER CENTER
NEWARK, DELAWARE

CCOPs and Minority CCOPs 63



2010 CCOP STRATEGIC PLANNING

- CCOP Principle Investigators, Administrators, and NCI Leadership
- Leaders:
- James Wade, M.D.
- Anne-Marie Langevin, M.D.
- Christine Ambrosone, PhD.
- Lori Minasian, M.D.
- Worta McCaskill-Stevens, M.D., M.S.
- Joanna Brell, B.D.
- Presented to NCI Leadership and Board of Scientific Advisors 11/2010

CCOP STRATEGIC GOAL #1

Incorporate Emerging Science and Novel Trial Designs into Cancer Prevention and Control (CPC) Research

- Develop Survivorship Research
- Focused on symptom / toxicity research
- Foster Research on Risk Assessment and Risk Modeling for Cancer Prevention and Early Detection
- Explore Funding Mechanisms for Correlative Studies in Association with CPC studies
- Foster Relationships with Basic Science Researchers
- Foster Training for investigators in CPC
- Facilitate Drug Distribution in Cancer Control Trials

CCOP STRATEGIC GOAL #2

Maximize Community Resources to Conduct Complex Clinical Trials (Treatment & CPC)

- Develop mechanism for Bio-specimen Collection
- Develop a Flexible Funding Model
- Encourage Standardization Across the Network
- Monitor the Changing Business Model
- Foster Mentoring Community Investigators
- Enhance Communication Efforts to Educate the Public on Clinical Trials and Provide Tools
- Address Overlap with other programs

CCOP STRATEGIC GOAL #3

Use Epidemiological and Biological Data from Underserved Pop to Address Disparate Health Outcomes

- Identify Relevant Research Questions in Underserved Populations for study by Research Bases
- Develop trans-disciplinary working group to design pilot studies nested within (or stand alone) to evaluate the effect of relaxing eligibility for some studies
- Promote Cancer Risk Assessment in Underserved Populations

CCOP STRATEGIC GOAL #4

Improve Clinical Trials Access and Participation among Populations Underrepresented in Clinical Research

- **Consider broadening eligibility of MB-CCOP**
- **Facilitate Translations of Informed Consents and Patient Information for studies**
- **Develop Plan for assigning credit for screening patients and at risk people for trials**
- **Develop guidelines for publications**
- **Review accrual requirements (in conjunction with flexible funding model) for MB-CCOPs**
- **Incorporate Patient Navigation**
- **Foster development of mentorship**

CCOP STRATEGIC GOAL #5

Build on CCOP/MB-CCOP Success to Improve Ability of Community Groups to Accrue Patients

- Develop Best Practices
- Collect Data on Screening Patients for Trials
- Develop Process to rapidly Identify Clinical Trials with Accrual Issues
- Encourage studies that address accrual specifically

IOM PHYSICIAN AND PATIENT PARTICIPATION INCENTIVES

Patient Recruitment Enhancement

- Broad patient education regarding availability, payment coverage, and value of clinical trials
- Expanded trial eligibility criteria
- Greater patient advocate participation in trial design and recruitment
- Electronic tools to cue clinician of individual patient trial availability
- Site portfolio options from all Cooperative Group trials

IOM PHYSICIAN AND PATIENT PARTICIPATION INCENTIVES

Clinical Trial Care Payment Coverage

- Health care payment policies should value clinical trial participation and adequately compensate for trial care
- CMS federal and state benefits programs, and private insurers should cover all patient care costs of NCI approved trials
- Congress should amend ERISA to prohibit heath plan trial coverage denials (Health Legislation 2010)

INSURER TRIAL POLICY POSTED 1/2011

PHYSICIAN CERTIFICATE OF ATTESTATION

CERTIFICATION OF ROUTINE COSTS
ASSOCIATED WITH PARTICIPATION IN A QUALIFYING CLINICAL TRIAL

Instructions for use:

This Physician Certificate of Attestation must be completed only by the physician requesting approval of routine costs associated with a qualifying clinical trial. Failure to complete this form in its entirety may result in its return to the physician for appropriate documentation and signatures and a delay in the evaluation of the attestation and attachments. All field-completions (eg, checked boxes, initials) and signatures requested in this form must be completed. Completion, signature, and submission of this form is a certification that the services being requested meet all requirements for coverage of routine costs associated with qualifying clinical trials.

Submission Instructions:

Complete and sign the form and include additional documents as indicated.
Fax the completed form and required attachments to the Care Management and Coordination Department at (215) 761-0257. Hours are 8:00 a.m. to 5:00 p.m., Monday through Friday.

Physician's Name (Please Print):
Physician's NPI #:
Physician's Office Contact Name (if different from physician):
Office/Contact Phone #:
Trial Sponsor:
Trial Name:
ClinicalTrials.gov Identifier # (NCT Number):
Patient's Name (please print):
Patient's Member ID #:
Patient's Date of Birth:

☐	Number of services requested
☐	Approximate dates of requested services
☐	Name and address of any facility(ies) where services will be performed
☐	The expected duration of participation in the trial, etc.
☐	Any relevant clinical information
☐	The Trial Protocol (including eligibility criteria for participation in trial)
Please Initial Here: ____	I certify that the participant in this qualifying clinical trial meets the eligibility criteria defined in the attached protocol to participate.
Please Initial Here: ____	A copy of the signed informed patient consent form for participation in the qualifying clinical trial from the trial sponsor is attached.

Please complete the following fields:	
Physician's Name (please print)	
Physician's Signature:	**Date:**

For more information on Routine Costs Associated with Qualifying Clinical Trials, please see medical policy 07.00.20d on this topic.

Please Initial Here: ____	**By completing and signing below, I certify that the services being requested meet the requirements listed in this document:** **Please initial or check (☑) the space or box associated with each section to certify that the requirements for that section are met.**
Please Initial Here: ____ **Please Read and Check All Boxes** ☐ **A**	**Services are being requested for a qualifying clinical trial that meets all of the following requirements:** The qualifying clinical trial has a therapeutic intent for enrolled patients with a diagnosed disease. The qualifying clinical trial has a principal purpose to discern whether the service improves health outcomes for enrolled patients with a diagnosed disease. Services are not approvable for the following because they do not meet this requirement: ○ Participants without disease (eg, normal volunteers or controls) ○ Participants ineligible for the trial ○ Participants treated "off-protocol"
☐ **B.**	The qualifying clinical trial is intended to clarify or establish health outcomes of interventions already in common clinical use as defined by the available evidence.
☐ **C.**	The qualifying clinical trial does not duplicate existing studies.
☐ **D.**	The qualifying clinical trial is designed to collect and disseminate reliable evidence, as defined in the Company policy on Routine Costs Associated with Qualifying Clinical Trials, and answer specific research questions being asked in the trial.
☐ **E.**	The qualifying clinical trial is designed and conducted according to appropriate standards of scientific integrity (such as, but not limited to: there is a beginning and an endpoint to the study; there is a specific number of potential enrollees; the patient accrual period is clearly defined; informed consent is provided to all enrollees; appropriate approvals; patient selection, and exclusion criteria are well-defined; a written protocol outlining all these points exists).
☐ **F.**	The trial complies with federal regulations relating to the protection of human subjects.
Please Initial Here: ____	For members of all other Commercial products that include benefits for routine costs associated with a qualifying clinical trial, one of the following applies:
Please Initial Here: ____	1. The trial is conducted under an investigational new drug application reviewed by the FDA, or an investigational new drug exemption as defined by the FDA.
Please Initial Here: ____	2. The trial is funded by, or supported by centers or cooperative groups that are funded by any one of the following:
Please Check 1:	
☐	The National Institutes of Health (NIH)
☐	Centers for Disease Control and Prevention (CDC)
☐	Agency for Healthcare Research and Quality (AHRQ)
☐	Centers for Medicare and Medicaid Services (CMS)
☐	A research arm of the Department of Defense (DOD)
☐	Department of Veterans Affairs (VA)
ALL OF THE FOLLOWING FIELDS APPLY TO ALL ELIGIBLE PRODUCTS	
Please Initial Here: ____	**Services and supplies requested are routine costs, which include the following:**
A.	Covered services under the individual's product that would typically be provided absent a qualifying clinical trial.
B.	Services and supplies required solely for the provision of the biological product, device, drug, medical treatment, procedure, or therapy under investigation in the clinical trial.
C.	The clinically appropriate monitoring of the effects of the biological product, device, drug, medical treatment, procedure, or therapy under investigation in the clinical trial that is required for the prevention of complications.
D.	The services and supplies required for the diagnosis or treatment of complications.
Please Initial Here: ____	**The routine costs (services and supplies) requested do not include:**
A.	The biological product, device, drug, medical treatment, procedure, or therapy under investigation in the qualifying clinical trial (ie, the experimental/investigational service itself) Experimental/investigational is defined by the individual's product or plan
B.	Services and supplies provided for data collection and analysis or submission.
C.	Services and supplies customarily provided by the research sponsors free of charge to any enrollees.
D.	Any services that the member's plan does not routinely cover such as, but not limited to services that: The plan deems to be experimental/investigational Have met or exceeded applicable benefit limitations described in the member contract Are a benefit contract exclusion Are deemed not medically necessary
Please Initial Here: ____	**ALL OF THE FOLLOWING DOCUMENTS MUST BE INCLUDED:**
Please Initial Here: ____	A Letter of Medical Necessity outlining the specific services requested. At a minimum, this document must include:
Please Check Each:	
☐	Narrative name of requested services
☐	Applicable CPT/HCPCS codes for requested services

IOM PHYSICIAN AND PATIENT PARTICIPATION INCENTIVES

Investigator Recognition

- Academic centers should recognize and reward clinical trial team research in promotion and tenure decisions
- NCI clinical investigator certification program and registry
- Centralized credentialing and audit system

IOM PHYSICIAN AND PATIENT PARTICIPATION INCENTIVES

Financial

- Increase per case reimbursement
- NCI should fund trial and site PI's
- AMA should establish new CPT-4 codes and be reimbursed by health care payers at enhanced levels for offering, enrolling, managing, and following clinical trial patients

PUBLIC SPONSOR CLINICAL TRIAL COST

LEWIN GROUP SURVEY FOR C-CHANGE (6/05)

Cost per Patient	Phase II Trial	Phase III Trial
25th Percentile	$3618	$1996
Median	$6226	$3427
75th Percentile	$9001	$6950

COMMUNITY VOLUNTEERISM IN THE NEW WORLD

- The Cooperative Group Home and TEAM
  - Infrastructure support
  - Mentoring
  - Best Practice
  - Collegiality
- Interaction and connection with academic scientists and clinicians
- Participate in the “process”
- Publication Opportunities
- A distinguishing credential (NCI/Cooperative Group Trialist)
- Time and expense versus best patient care options
- Multidisciplinary and multi Disease Oriented
- Need optimal size Groups but not too large and amorphous

Helen F. Graham Cancer Center
Delaware Christiana Care CCOP
RESEARCH CURES CANCER
Thank You

NCI COMMUNITY CANCER CENTERS PROGRAM

Newark, Delaware