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NCI Clinical Trials Assessment of Infrastructure Matrix Tool (CT AIM)

Alliance for Cancer Clinical Trials
Rosemont, IL

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November 7, 2014

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

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Agenda

The CT AIM Tool

- Foundation and Development
- Evolution & Formative Evaluation
- Next Steps

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What is the CT AIM Tool?

- A **self-assessment** and benchmarking tool to facilitate research program improvements
- Consists of 11 attributes
  - 3 progressive levels
    - From less (Level 1) to more (Level 3) exemplary CT infrastructure
  - Community cancer research sites "self-assess" their program
- Moves beyond the minimal standards of Good Clinical Practice (GCPs)

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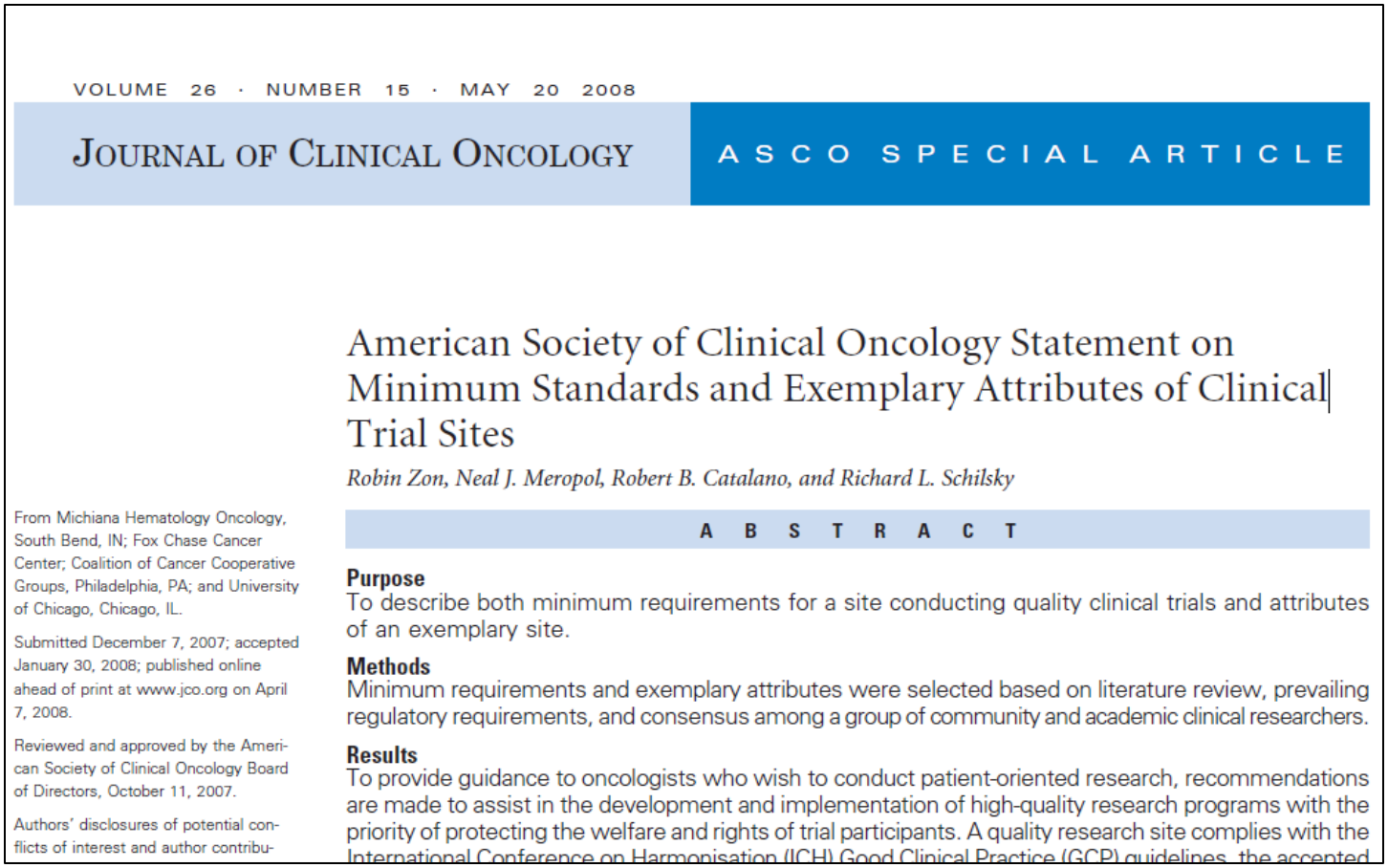
The Tool's Foundation



VOLUME 26 · NUMBER 15 · MAY 20 2008

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites

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From Michiana Hematology Oncology, South Bend, IN; Fox Chase Cancer Center; Coalition of Cancer Cooperative Groups, Philadelphia, PA; and University of Chicago, Chicago, IL.

Submitted December 7, 2007; accepted January 30, 2008; published online ahead of print at www.jco.org on April 7, 2008.

Reviewed and approved by the American Society of Clinical Oncology Board of Directors, October 11, 2007.

Authors' disclosures of potential conflicts of interest and author contribu-

A B S T R A C T

Purpose
To describe both minimum requirements for a site conducting quality clinical trials and attributes of an exemplary site.

Methods
Minimum requirements and exemplary attributes were selected based on literature review, prevailing regulatory requirements, and consensus among a group of community and academic clinical researchers.

Results
To provide guidance to oncologists who wish to conduct patient-oriented research, recommendations are made to assist in the development and implementation of high-quality research programs with the priority of protecting the welfare and rights of trial participants. A quality research site complies with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, the accepted

R. Zon, et al., *JCO,* 2008; *JOP*, 2011; A. Baer et al., *JOP,* 2010

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ASCO Exemplary CT Site Attributes

- Clinical Trial Portfolio Diversification
- High Accrual (> 10%)
- Participation in Clinical Trial Process
- Formal Maintenance of High Education Standards
- Quality Assurance
- Multidisciplinary Care
- Clinical Trials Awareness

(Zon R, et.al., JCO 5/20/08)

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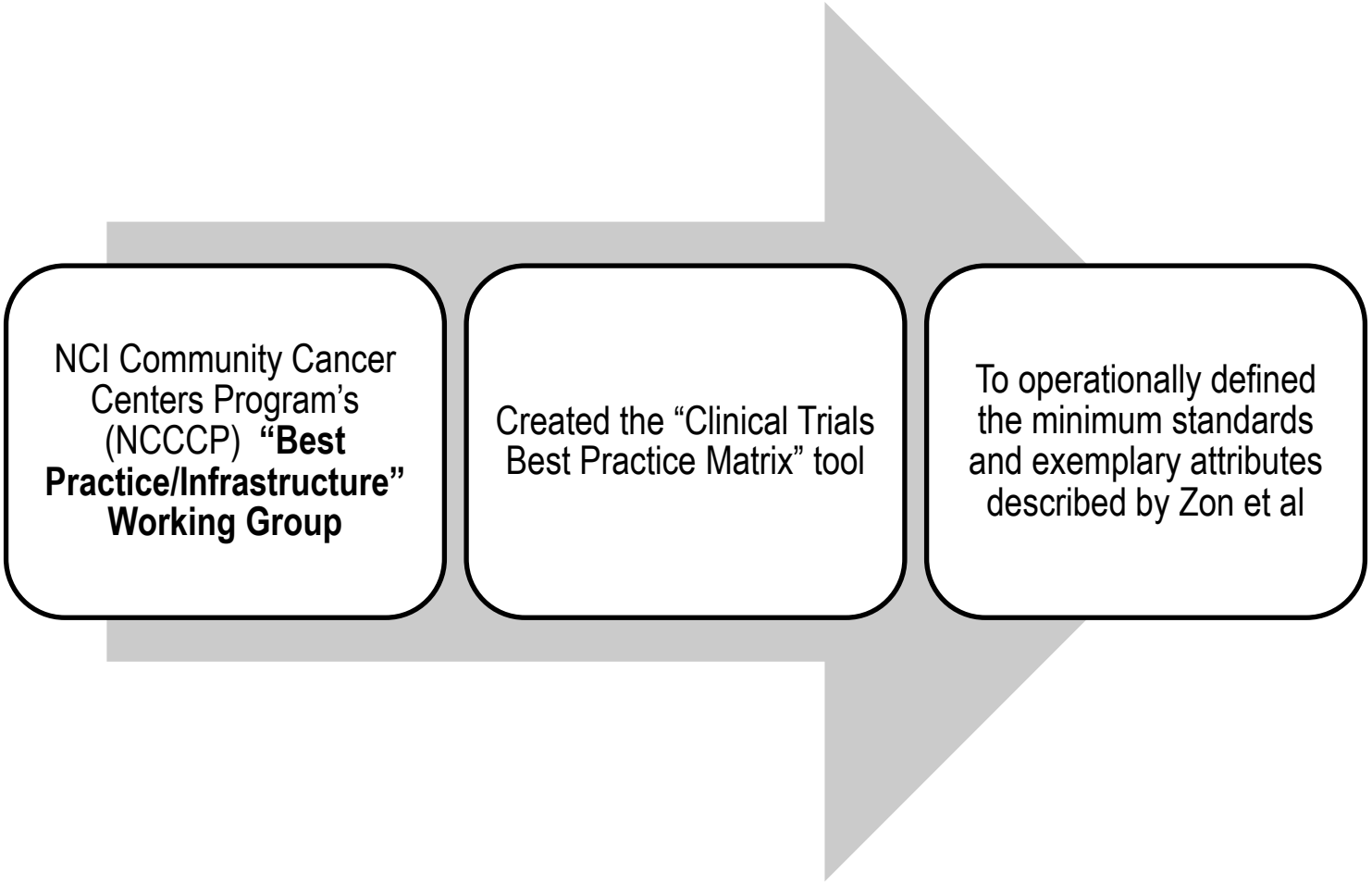
CT AIM Beginnings



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NCCCP Tool Attributes

- Underserved community outreach and accrual
- Quality assurance
- CT portfolio diversity and management
- Physician engagement in CTs
- Participation in the CT process (e.g., attending sponsor meetings, active on national committees)
- Multidisciplinary team involvement
- Education standards
- Accrual
- CT communication and awareness (e.g., within oncology, beyond oncology, in lay community)

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Tool Pilot Data: Process and Method

- 21 NCCCP sites self-assessed their CT programs annually using the tool in 2011, 2012 and 2013
- Self-assessments were reviewed to ascertain program infrastructure change over time
  - indicated by movement toward more complex (exemplary) scoring (More Level IIIs)

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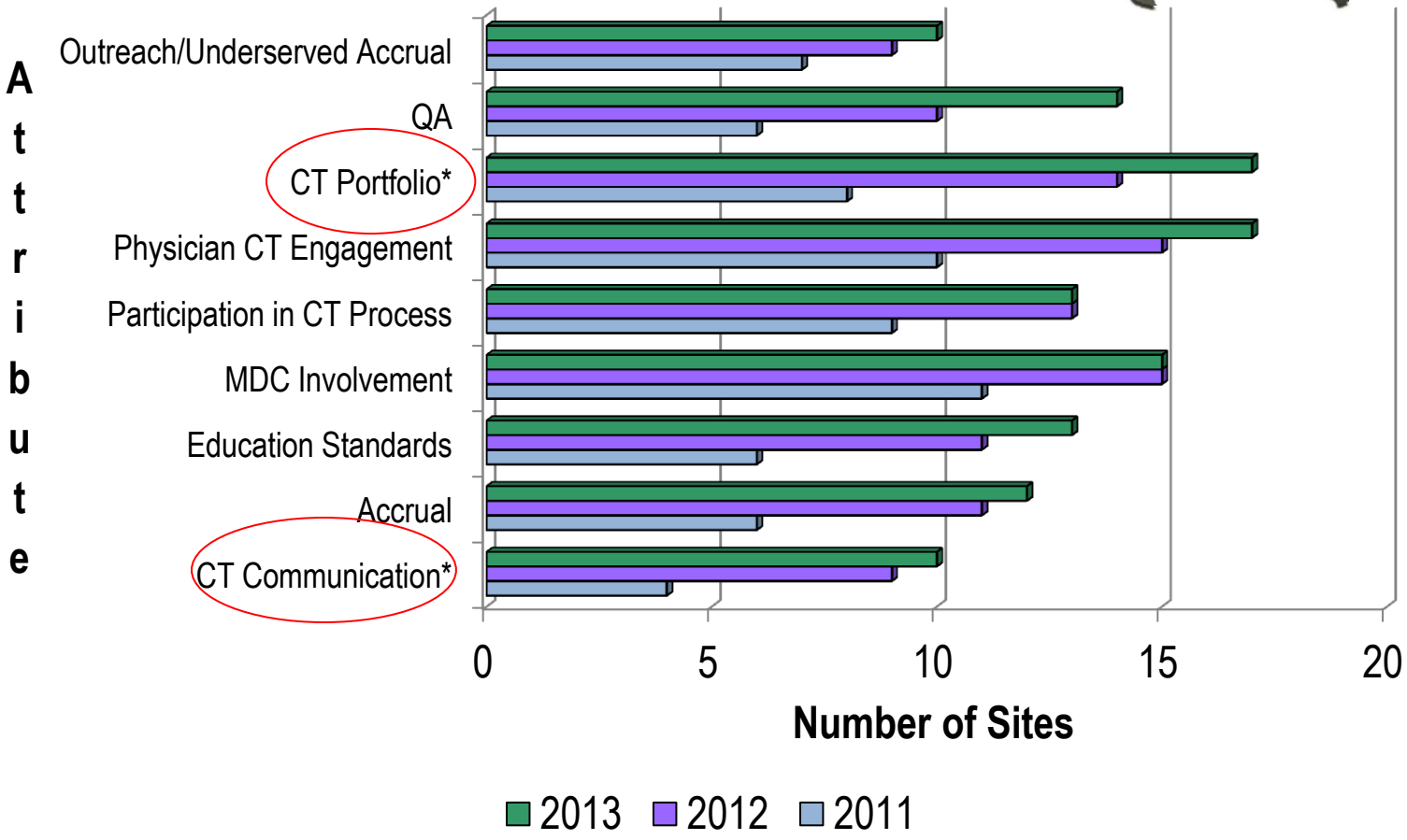
Results

Significant Change in Level III Over Time for *All* Attributes Combined



*Significant p - value for change over time (CT Communication, p 0.0281; CT Portfolio, p 0.0228)

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Formative Evaluation Methods

- Community input
  - National research meetings and via quarterly calls
  - Research expertise beyond NCI funded programs obtained via the ASCO Community Research Forum
- Cognitive interviews
  - 4 Principal Investigator-Program Administrator pairs from NCI-funded community cancer programs

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Formative Evaluation Results

- Expanded infrastructure attributes
  - 9 to11
- Renamed tool
  - “Best practice” designation replaced with “Assessment of Infrastructure”
- Reordered attributes based on perceived importance
- Updated terms to improve clarity
- Reworded text to clarify the cumulative levels of indicators
- Improved metrics to decrease ambiguity

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Formative Evaluation Methods (cont'd)

- **Pilot test**
  - web-based version was conducted with 4 more PI/PA pairs to assess ease of recall and consistency in responses within pairs.
- **Field test**
  - revised web-based version was conducted with 9 more PIs to compare alternative scoring methods and feedback reporting.
- **Delphi panel**
  - conducted with 6 PIs to ascertain attributes ranking based on perceived order of importance

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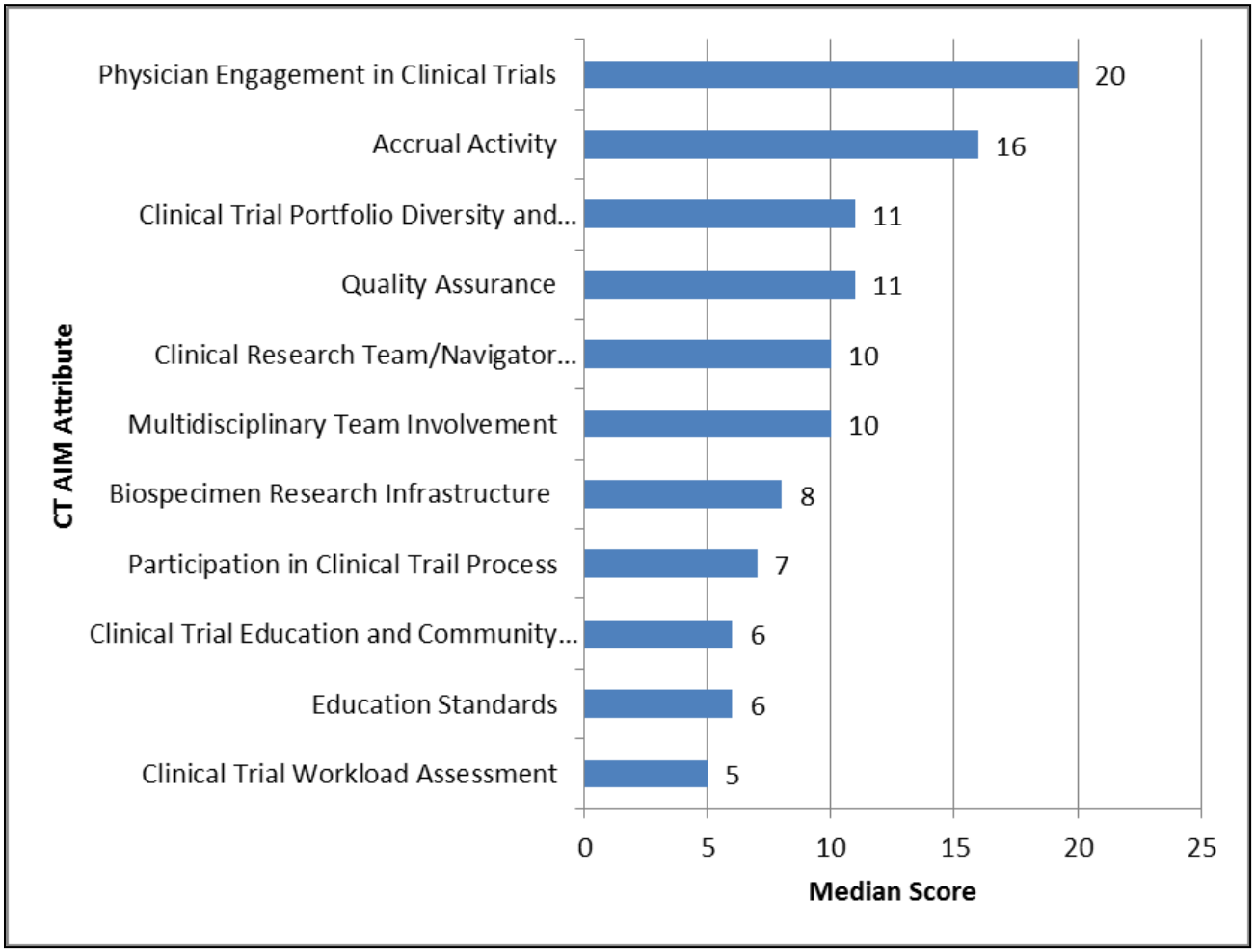
Formative Evaluation Results (cont.)

Delphi Panel: ***Round 2***



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CT AIM Attributes Today

- Quality assurance
- CT portfolio diversity and management
- Physician engagement in CTs
- Participation in the CT process
- Multidisciplinary team involvement
- Education standards
- Accrual activity
- CT education and community outreach
- CT workload assessment
- Clinical research team/Navigator engagement
- Biospecimen research infrastructure

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Attribute "CT Portfolio Diversity" in 2010 (V 1.0)

- Indicator criteria within each Level listed together
- Not all indicators represented at all levels

BEST PRACTICE	LEVEL I	LEVEL II	LEVEL III
4. Clinical Trial Portfolio Diversity and Management	Site/Investigator goals for screening and accrual established; Phase III treatment trials active	Phase II, cancer control, prevention, and QOL trials and at least 4 different disease sites; regular review of trial diversity and status of activated trials occur to monitor perfomance/analyze issues of poor accruing trials	Phase I or Phase I/II, tissue procurement, and more than 4 different disease sites; proactive trial portfolio management; research team routinely addresses poor accruing trials

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Attribute "CT Portfolio Diversity" in 2012 (V 2.0)

- Indicators separated
- More comprehensive descriptions
- Levels 1, 2, and 3 defined for each indicator

Attribute	Level I	Level II	Level III
Clinical Trial Portfolio Diversity and Management	Active **Phase III treatment** trials over the past year	Active Phase III treatment trials **and Phase II trials** over the past year	Active Phase III treatment trials, Phase II trials, **and either Phase I or Phase I/II** trials over the past year
	Trial portfolio includes **cancer control** trials.	Trial portfolio includes **cancer control, prevention, screening and correlative** trials	Trial portfolio includes cancer control, prevention, screening , correlative trials **and Cancer Care Delivery Research** trials
	Trial diversity is reviewed **once/year** or less often	Trial diversity is reviewed **2-3 times/year**	Trial diversity is reviewed **quarterly**
	Active trials in **1-3 disease** sites over the past year	Active trials in at least **4 disease** sites over the past year	Active trials in **5 or more** disease sites over the past year
	Screening log data used to assess accrual barriers and clinical trial portfolio **once a year or less often**	Screening log data used to assess accrual barriers and clinical trial portfolio **twice a year**	Screening log data used to assess accrual barriers and clinical trial portfolio **at least quarterly**

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Attribute "CT Portfolio Diversity" in 2014 (V 3.0)

- Indicator descriptions more metric-sensitive
- Added a "Pre-level" option for sites not yet at Level 1
- Radio buttons allow only one answer per indicator

Attribute	Indicator					Notes
Clinical Trial Portfolio Diversity and Management	Trial portfolio phases	Pre-Level	Level I	Level II	Level III	None
		○	○	○	○	
			In the past year, clinical trial portfolio included active Phase III treatment trials	In the past year, clinical trial portfolio included active Phase III treatment trials and Phase II trials	In the past year, clinical trial portfolio included active Phase III treatment trials, Phase II trials, and either Phase I or Phase I/II trials	
	Trial portfolio purpose types	Pre-Level	Level I	Level II	Level III	
		○	○	○	○	
			In the past year, clinical trial portfolio included cancer treatment and control trials	In the past year, clinical trial portfolio included cancer treatment and control trials, prevention, screening and correlative trials	In the past year, clinical trial portfolio included cancer treatment and control trials, prevention, screening, correlative trials	
	Trial portfolio disease types	Pre-Level	Level I	Level II	Level III	
		○	○	○	○	
			In the past year, clinical trial portfolio included 2-3 disease sites	In the past year, clinical trial portfolio included 4 disease sites	In the past year, clinical trial portfolio included 5 or more disease sites	
	Trial portfolio review	Pre-Level	Level I	Level II	Level III	
		○	○	○	○	
			Clinical trial portfolio diversity was reviewed once in the past year	Clinical trial portfolio diversity was reviewed 2-3 times in the past year	Clinical trial portfolio was reviewed 4 or more times in the past year	
	Screening log data review	Pre-Level	Level I	Level II	Level III	
		○	○	○	○	
			Screening log data was used to assess accrual barriers and the clinical trial portfolio once in the past year	Screening log data was used to assess accrual barriers and the clinical trial portfolio 2-3 times in the past year	Screening log data was usedto assess accrual barriers and the clinical trial portfolio 4 or more times in the past year	

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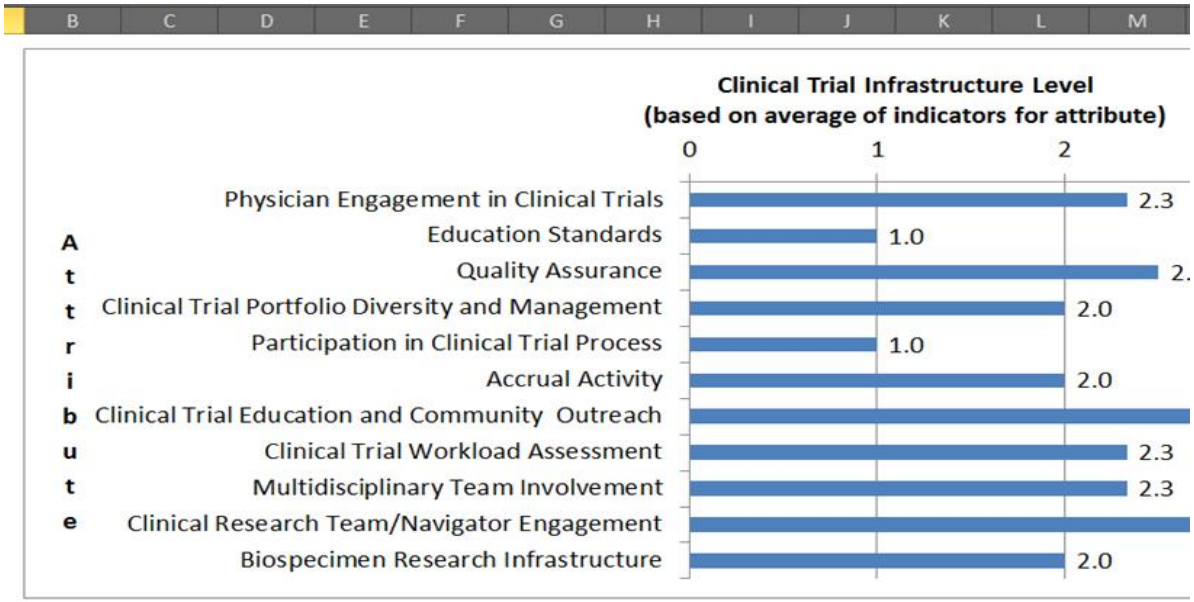
Scoring Tool Feedback



	Number of Indicators at this Level (n=37)	Percentage of indicators at this Level
Pre-Level	0	0%
Level 1	5	14%
Level 2	20	54%
Level 3	12	32%

Overall Score (for all attributes)	2.2

Intro | Form | Data | Results

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Why use CT AIM?

- Provides a roadmap for focus and prioritization in addressing infrastructure development/improvement
- Creates real-time reporting that can be utilized internally to track progress/change
- Facilitates collaborative learning from each other
- Allows site and network benchmarking over time
- Provides aggregate data across sites on the network's strengths and challenges
- Supports tailored education/collaborative learning as need areas are identified through self assessment

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Future work with the Tool

- Collection of objective site data to correlate with site self-scoring as a means to better define/validate “exemplary” research performance metrics
- Further refinement of Attributes and Indicator Levels in varied environments across NCORP
- Potential research/validation efforts

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Next Steps

- Hope for representation from all the NCORP and MU NCORP sites
- Establish baseline assessments around Jan 2015
- Incorporate the tool into CCOPSYS so use is seamless
- Future webinar for interested sites to provide additional detail:
  - Looking closely at the tool
  - Logistics (who will complete it, how to access etc.)
  - Providing clarifications

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Acknowledgements

Stephen Grubbs, Christiana Care, Newark, DE

Robin Zon - Michiana HemOnc PC, South Bend, IN

Lucy Gansauer, James Bearden - Spartanburg Regional Medical Center, Spartanburg, SC

Beth LaVasseur, Phil Stella - St. Joseph Mercy Hospital, Ann Arbor, MI

Kathy Wilkinson - Billings Clinic Cancer Center, Billings, MT

Eileen Dimond, Diane St. Germain, Andrea Denicoff, Marjorie Good, Worta McCaskill-Stevens - NCI

Maria Gonzalez – Providence Hospital, Burbank, CA

Mitchell Z. Berger -

Donna Bryant - Our Lady of the Lake Regional Medical Center and Mary Bird Perkins Cancer Center, Baton Rouge, LA

Maria Bell - Sanford Health, Sioux Falls, SD

Angela Carrigan, Kathleen Igo - Leidos Biomedical Research Inc., Frederick, MD

Octavio Quinones - DMS, Frederick, MD

Bryan Weiner, Randall Teal, UNC

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Albert Einstein Medical Center, Philadelphia, PA
Ascension Health, St. Louis, MO
- *Columbia/St. Mary's – Milwaukee, WI*
- *Seton/Brackenridge – Austin, TX*
- *St. Vincent – Indianapolis, IN*

Billings Clinic Cancer Center, Billings, MT
Catholic Health Initiatives, Denver, CO
- ***Good Samaritan – Kearney, NE***
- ***Penrose – Colorado Springs, CO***
- ***St. Elizabeth – Lincoln, NE***
- ***St. Francis – Grand Island, NE***
- *St. Joseph/Towson – Towson, MD*

Christiana Care, Newark, DE
Geisinger Medical Center, Danville, PA
Gundersen Lutheran Medical Center, La Crosse, WI
Hartford Hospital, Hartford, CT
Lehigh Valley Hospital, Allentown, PA
Maine Medical Center, Portland, ME
Mercy Medical Center, Des Moines, IA
Northside Hospital, Atlanta, GA
Norton Hospital, Louisville, KY
Our Lady of the Lake Regional Medical Center and Mary Bird Perkins Cancer Center, Baton Rouge, LA
Providence Portland Medical Center, Portland, OR
Saint Mary's Health Care, Grand Rapids, MI
Sanford Health, Sioux Falls, SD
Spartanburg Regional Hospital, Spartanburg, SC
St. Joseph/Candler Hospital, Savannah, GA
St. Joseph Hospital, Orange, CA
St. Joseph Mercy Hospital, Ann Arbor, MI
St. Luke's Regional Medical Center, Boise, ID
The Queen's Medical Center, Honolulu, HI
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