

Dear Educational Coordinator:

Thank you for registering your facility to participate in our highly anticipated broadcast entitled "*Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention*," to be held on **Tuesday, June 14, 2011**. This activity will broadcast LIVE at 12:00 PM ET, and will re-air at 1:00 PM, 2:00 PM, and 3:00 PM ET.

This activity will be available via Satellite, Webcast, and Teleconference. We intend to reach healthcare providers in multiple facilities throughout the United States. The 12:00 PM ET broadcast will include faculty presentations, directly followed by a LIVE question-and-answer session, which will be replayed at all other times.

Program Schedule

If you are unable to schedule a noon meeting, the broadcast will also be available at other times throughout the day (depending on your time zone). You can reference the chart below for a complete listing of times the program will be made available via Satellite, Webcast, and Teleconference.

Time Zone			
Eastern	Central	Mountain	Pacific
12:00 PM	11:00 AM	10:00 AM	9:00 AM
1:00 PM	12:00 PM	11:00 AM	10:00 AM
2:00 PM	1:00 PM	12:00 PM	11:00 AM
3:00 PM	2:00 PM	1:00 PM	12:00 PM

We realize that your role as an Educational Coordinator is vital. Please carefully review the enclosed Participant Kit, which contains the following information you will need to conduct this event:

- Instructions on handling logistics for your site
- Attendance Sheet
- Post-broadcast Evaluation Forms
- Program Guide (includes faculty information and slide presentation)

If you have not done so already, you'll want to reserve room within your facility now for this broadcast on **Tuesday, June 14, 2011**.

If you have any questions, please feel free to contact one of our ConneXion360 specialists at **877-238-8500**, and they will be happy to assist you.

Best regards,



Joan Lingenfelter
Broadcast Network Manager
ConneXion360

EDUCATIONAL COORDINATOR YOUR CRITICAL ROLE

1 to 2 Days Prior to Activity

1. Confirm meeting space
2. Instruct attendees to arrive 10 to 15 minutes prior to the activity
3. Confirm that you have enough meeting materials for your group
4. The Participant Kit can be downloaded online at www.thebce.com/onlinesyllabus/lungtrials

Day of Activity

1. Test equipment (see instruction in the Participant Kit)
2. Obtain names of all participants
 - All participants must fill out and sign the Attendance Sheet prior to receiving their Participant Kits
 - Distribute Participant Kits to signed-in attendees
3. Facilitate broadcast at your site
4. Collect Post-broadcast Evaluation Forms
5. At the conclusion of the activity, return all documentation to the CBCE

Post-broadcast

The Evaluation Forms and Attendance Sheet must be completed and returned to the CBCE following this activity.

Please fax or mail the Evaluation Forms and Attendance Sheet to:

The CBCE
1707 Market Place Blvd.
Suite 370
Irving, TX 75063
Fax: 214-260-0509

INSTRUCTIONS FOR PARTICIPATION

Satellite

Participants affiliated with a ConneXion360 site should contact their in-house Educational Coordinator for viewing instructions for this activity.

Individual participants and Educational Coordinators can obtain the Satellite coordinates to tune their receivers for this activity, below.

11:00 AM ET, CT, MT, and PT— EQUIPMENT TEST

- A pre-show will start 1 hour before each broadcast. Please utilize this time to test your Satellite equipment to ensure it is working properly and that you are receiving the program

12:00 PM ET, CT, MT, and PT — BROADCAST

Ku-Band - DIGITAL

Satellite Broadcast Coordinates

Satellite	Galaxy 19
Transponder	27
Virtual Channel	BTB
Orbital Slot	97° West
Downlink Frequency	12177
Audio	L and R
FEC	3/4
Symbol Rate	23000

C-Band - ANALOG

Satellite Broadcast Coordinates

Satellite	Galaxy 3C
Transponder	23C
Orbital Slot	95° West
Downlink Frequency	4160 Horizontal
Audio	L and R

If you experience technical difficulties with your Satellite receiver, please call 877-698-6008. All other general calls should be directed to ConneXion360 at 877-238-8500.

Webcast

11:30 AM ET— EQUIPMENT TEST

- A pre-show will start 30 minutes before the 12:00 PM ET broadcast. Please utilize this time to test your equipment to ensure it is working properly and that you are receiving the Webcast
- To join the Webcast, please visit
<http://video.webcasts.com/events/conn001/38376>
- If you are experiencing technical difficulty during the Webcast, please dial 866-709-8255 for assistance
- If you are having difficulty hearing the audio, please feel free to dial in to the Teleconference. However, please note that the Teleconference audio will not sync with the video on the Webcast

12:00 PM ET, CT, MT, and PT — LIVE BROADCAST

- To participate in the interactive question-and-answer session at the end of the live broadcast, when prompted by the moderator:
 - Submit questions using the Instant Message text box located at the bottom of the screen
 - Or call **877-X360Now (877-936-0669)**
 - If you dialed in to the audio Teleconference number, please e-mail your questions directly to questions@connexion360.com

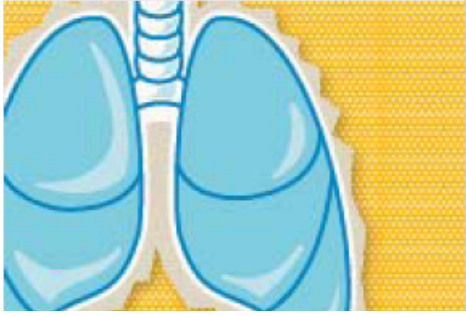
Teleconference

11:45 AM ET, CT, MT, and PT — DIAL IN TO THE TELECONFERENCE

- The dial-in number for all broadcast times is **1-800-760-6794**
 - 12:00 PM ET Live Participant Passcode is **63895904**
 - 1:00 PM ET Re-air Participant Passcode is **63901040**
 - 2:00 PM ET Re-air Participant Passcode is **63901656**
 - 3:00 PM ET Re-air Participant Passcode is **63902076**

12:00 PM ET — LIVE BROADCAST

- To participate in the interactive question-and-answer session at the end of this live broadcast, when prompted by the moderator:
 - Press *1 (star 1) and an operator will assist you
 - OR please e-mail your questions directly to questions@connexion360.com



Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention

A Live Satellite Broadcast, Webcast, and Teleconference

Tuesday, June 14, 2011

12:00 PM-1:00 PM ET

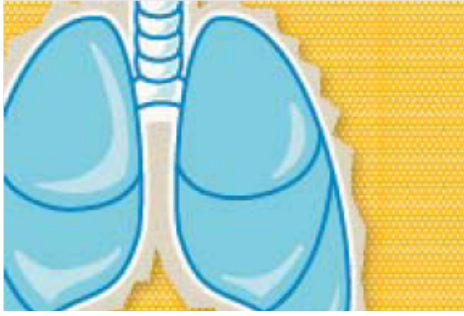
Broadcast to Re-Air 1:00 PM, 2:00 PM, and 3:00 PM ET
(Please adjust for your time zone.)

Hospital/Institution Attendee Sign-in Sheet

Educational Coordinator Name:		Educational Coordinator E-mail:			
Educational Coordinator Telephone:		Educational Coordinator Fax:			
Facility/Institution Name and Address:		City:	ST:	Zip:	
Method of Participation (circle one):		Satellite	Wecast	Teleconference	Number of Participants:
Participation Time:	Time Zone (circle one):	Eastern	Central	Mountain	Pacific

Full Name, Mailing Address, and E-mail (please print)				Signature
1.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
2.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
3.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
4.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
5.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:

Please return to: The CBCE, 1707 Market Place Blvd., Suite 370, Irving, TX 75063, Fax: 214-260-0509



Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention

A Live Satellite Broadcast, Webcast, and Teleconference

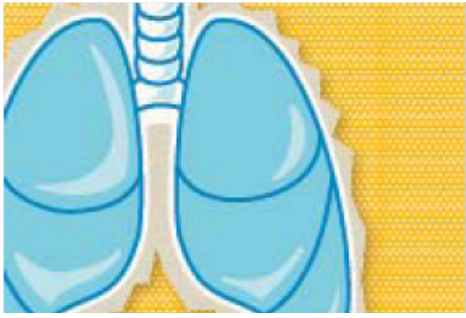
Tuesday, June 14, 2011

12:00 PM-1:00 PM ET

Broadcast to Re-Air 1:00 PM, 2:00 PM, and 3:00 PM ET
(Please adjust for your time zone.)

Full Name, Mailing Address, and E-mail (please print)				Signature
6.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
7.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
8.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
9.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
10.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
11.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
12.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
13.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:

Please return to: The CBCE, 1707 Market Place Blvd., Suite 370, Irving, TX 75063, Fax: 214-260-0509



Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention

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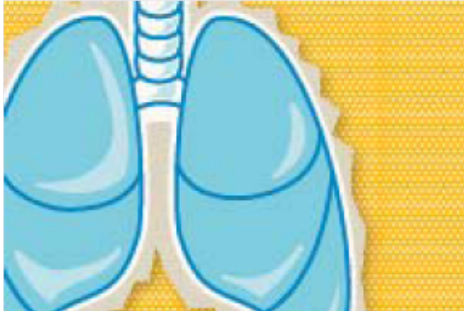
Tuesday, June 14, 2011

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Broadcast to Re-Air 1:00 PM, 2:00 PM, and 3:00 PM ET
(Please adjust for your time zone.)

Full Name, Mailing Address, and E-mail (please print)				Signature
14.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
15.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
16.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
17.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
18.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
19.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
20.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
21.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:

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Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention

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Tuesday, June 14, 2011

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(Please adjust for your time zone.)

Full Name, Mailing Address, and E-mail (please print)				Signature
22.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
23.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
24.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
25.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
26.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
27.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
28.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:
29.	Name:			
	Address:			
	Specialty:	Degree:	Medical License:	E-mail:

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***Overcoming Key Challenges to
Lung Cancer Clinical Trial
Recruitment and Retention***

***A Live Satellite Broadcast and
Webcast***

**Tuesday, June 14, 2011
12:00-1:00 PM ET**

Chair

Joan Schiller, MD

Professor

Chief, Division of Hematology/Oncology

Deputy Director, Simmons Comprehensive Cancer Center

University of Texas Southwestern Medical Center

Dallas, TX

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Accreditation Information

Statement of Need

Survival rates of patients with lung cancer have not significantly improved in the past 5 years, and lung cancer remains the leading cause of cancer-related death in the United States, despite the introduction of several novel anticancer therapies. Clinical trials are key to the development of new treatment regimens that have made an impact in the management of patients with this devastating malignancy. However, only 14% of patients with lung cancer are aware of clinical trials as a treatment option, and fewer than 10% of patients with lung cancer are enrolled in clinical trials. As a result, it has been projected that the current rate of patient enrollment in lung cancer clinical trials is inadequate to sustain the growth of novel therapies. Commitment to collaborate is needed from clinical researchers, patient advocates, government agencies, and private industries to improve clinical trial enrollment and retention through building relationships, strengthening communication, educating patients and caregivers, streamlining protocols, and developing clinical trials that address the most compelling needs in patients with lung cancer. Timely activation, accrual, and completion of clinical trials will ensure that treatment arms in the trial do not lag behind the standard of care and that subsequent results are relevant to current clinical practice. At the end of this activity, participants will be able to explain the importance of clinical trial enrollment and retention in advancing patient care, identify potential barriers that impact enrollment in clinical trials, and discuss strategies that can be used to overcome challenges in recruiting and retaining participants in lung cancer clinical trials.

Purpose

Although it is recognized that clinical trials are critical to the development of new treatment regimens that are needed to improve the treatment of patients with lung cancer, only 14% of patients with lung cancer are aware of clinical trials as a treatment option, and fewer than 10% of patients with lung cancer are enrolled in clinical trials. Commitment from clinical researchers, patient advocates, government agencies, and private industries is needed to improve clinical trial enrollment and retention through building relationships, strengthening communication, educating patients and caregivers, streamlining protocols, and developing clinical trials that address paramount needs in patients with lung cancer. This satellite broadcast will illustrate the importance of clinical trial enrollment and retention in advancing patient care, explain potential barriers that impact enrollment in clinical trials, and discuss strategies that can be used to overcome challenges in recruiting and retaining participants in lung cancer clinical trials.

Target Audience

This activity is intended for clinical researchers, medical oncologists, thoracic surgeons, radiation oncologists, advanced practice nurses, patient advocates, physician assistants, and other healthcare professionals involved in the management of patients with lung cancer.

Educational Objectives

Upon completion of this activity, learners will be able to

1. Discuss the importance of clinical trial enrollment and retention in advancing the treatment of patients with lung cancer.
2. Summarize patient-, physician-, and protocol-related barriers that impact enrollment in lung cancer clinical trials.
3. Evaluate strategies that can be used to overcome challenges in recruiting and retaining patients with lung cancer in clinical trials, especially those who belong to minority or elderly patient subgroups.

Method of Participation

This 1-hour live satellite broadcast will utilize multiple methods of participation to engage attendees and enhance the learning process, including an interactive question-and-answer session and a series of case studies. Each portion of the case studies will be followed by a related didactic presentation that will address case study discussion points. Participants can ask questions via phone, e-mail, or fax during the live broadcast. To participate in the interactive question-and-answer session at the end of this live satellite broadcast, when prompted by the moderator:

- Submit questions using the Instant Message text box located at the bottom of the screen, or
- Call (888) NOW-U-ASK ([888]-669-8275), or
- If you dialed into the audio teleconference, press *1 (star 1), and an operator will assist you in speaking directly to the faculty

Accreditation

The CBCE™ (The Center for Biomedical Continuing Education) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The CBCE designates this live activity for a maximum of 1.0 *AMA PRA Category 1 Credit*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

AAPA accepts certificates of participation for educational activities certified for Category 1 credit from AOACCME, Prescribed credit from AAFP, and *AMA PRA Category 1 Credit*™ from organizations accredited by ACCME or a recognized state medical society. Physician assistants may receive a maximum of 1.0 hour of Category 1 credit for completing this program.

The CBCE™ (The Center for Biomedical Continuing Education) is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's COA.

The CBCE designates this educational activity for 1.0 contact hour.

Accreditation by the American Nurses Credentialing Center's COA refers to recognition of educational activities and does not imply approval or endorsement of any product.

Credit Instructions

Live Satellite Broadcast

The Evaluation and Request for Credit Form must be completed and returned to the CBCE following this activity to obtain credit. Participants will receive their certificate 4-6 weeks after the CBCE receives their form.

Live Webcast

Successful completion of this activity includes the following:

- Complete the online posttest and score 70% or above.
- Complete the online Evaluation and Request for Credit Form.

Print your online certificate by selecting the "Print Certificate" button.

Acknowledgement of Commercial Support

The CBCE gratefully acknowledges the educational grant provided by Lilly USA, LLC.

Educational Inquiries

For further information, please contact the CBCE, 1707 Market Place Blvd., Suite 370, Irving, TX 75063; Phone: (214) 260-9024; Fax: (214) 260-0509; E-mail: info@thebce.com.

Disclaimer

The content and views presented in this educational activity are those of the faculty and do not necessarily reflect the opinions or recommendations of the CBCE or Lilly USA, LLC. This material has been prepared based on a review of multiple sources of information but is not comprehensive. Participants are advised to critically appraise the information presented, and they are encouraged to consult the available literature on any product or device mentioned in this activity.

Disclosure of Unlabeled Uses

This educational activity may contain discussion of published and/or investigational uses of agents that are not approved by the US Food and Drug Administration. For additional information about approved uses, including approved indications, contraindications, and warnings, please refer to the prescribing information for each product or consult the latest edition of the *Physicians' Desk Reference*.

Faculty will inform learners when unlabeled uses will be discussed.

Disclosure of Financial Relationships With Any Commercial Interest

Faculty who refuse to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author, and cannot have control of or responsibility for the development, management, presentation, or evaluation of the

educational activity. For an individual with no relevant financial relationship, participants must be informed that no relevant financial relationship exists.

Disclosure of Potential Conflicts of Interest

The CBCE assesses conflicts of interest with its faculty, planners, and managers of CBCE activities. Identified conflicts of interest are thoroughly evaluated for fair balance, scientific objectivity relative to studies utilized in this activity, and patient-care recommendations. The CBCE is committed to providing participants with high-quality, unbiased, and state-of-the-art education.

The following faculty reported real or apparent conflicts of interest, and these conflicts have been resolved through a peer-review process:

Walter J. Curran Jr, MD

Honoraria

Amgen Inc.

Bayer HealthCare Pharmaceuticals

Lilly USA, LLC

Alan Sandler, MD

Advisory Board Member

Abraxis BioScience, LLC

Agennix AG

Allos Therapeutics, Inc.

Boehringer Ingelheim

Biodesix, Inc.

Celgene Corporation

F. Hoffmann-La Roche Ltd.

Genentech, Inc.

GlaxoSmithKline

Lilly USA, LLC

NewLink Genetics Corporation

Novartis Pharmaceuticals Corporation

OXIGENE, Inc.

Pfizer Inc.

Roche Diagnostics

Consultant

Abraxis BioScience, LLC

Agennix AG

Allos Therapeutics, Inc.

Boehringer Ingelheim

Biodesix, Inc.

Celgene Corporation

F. Hoffmann-La Roche Ltd.

Genentech, Inc.

GlaxoSmithKline

Lilly USA, LLC

Alan Sandler, MD (Cont)

NewLink Genetics Corporation
Novartis Pharmaceuticals Corporation
OXiGENE, Inc.
Pfizer Inc.
Roche Diagnostics
Grant/Research Support
Bristol-Myers Squibb Company
Genentech, Inc.
Lilly USA, LLC
Pfizer Inc.
Honoraria
Agennix AG
Boehringer Ingelheim
Bristol-Myers Squibb Company
Celgene Corporation
Chugai Pharmaceutical Co., Ltd.
Daiichi-Sankyo, Inc.
Genentech, Inc.
GlaxoSmithKline
Lilly USA, LLC
OXiGENE, Inc.
Roche Diagnostics
Quintiles
Legal Consultant
Genentech, Inc.
Pfizer Inc.
OSI Pharmaceuticals, Inc.
Roche Diagnostics
Speaker's Bureau
Genentech, Inc.
Lilly USA, LLC
Quintiles

Joan Schiller, MD

Advisory Board
Agennix AG
Amgen Inc.
AVEO Pharmaceuticals, Inc.
Bayer HealthCare Pharmaceuticals
Biodesix, Inc.
Bristol-Myers Squibb Company
Celgene Corporation
Daiichi-Sankyo, Inc.
Genentech, Inc.
Lilly USA, LLC
Merck & Co., Inc.

Joan Schiller, MD (Cont)

Novartis Pharmaceuticals Corporation

Oncothyreon Inc.

Onyx Pharmaceuticals, Inc.

Pfizer Inc.

Syndax Pharmaceuticals, Inc.

Telik, Inc.

Clinical Studies

Geron Corporation

Synta Pharmaceuticals Corp.

Consultant

Agennix AG

Amgen Inc.

AVEO Pharmaceuticals, Inc.

Bayer HealthCare Pharmaceuticals

Biodesix, Inc.

Bristol-Myers Squibb Company

Celgene Corporation

Daiichi-Sankyo, Inc.

Genentech, Inc.

Lilly USA, LLC

Merck & Co., Inc.

Novartis Pharmaceuticals Corporation

Oncothyreon Inc.

Onyx Pharmaceuticals, Inc.

Pfizer Inc.

Syndax Pharmaceuticals, Inc.

Telik, Inc.

Independent Peer Reviewer Disclosure

The peer reviewer had no real or apparent conflicts of interest to report related to this activity.

Institutional Disclosure

The CBCE receives educational grants from the pharmaceutical industry and other commercial sources. Companies providing grants to the CBCE include the commercial supporter of this activity as well as the manufacturers of certain drugs and/or devices discussed in this activity.

Staff Disclosure

The CBCE staff have declared they have no financial relationships that require disclosure.

Agenda

12:00-12:05 PM

Introduction: Assessing the Current Challenges of Lung Cancer Clinical Trial Accrual and Retention

Joan Schiller

12:05-12:20 PM

Barriers to Lung Cancer Clinical Trial Enrollment and Retention

Walter J. Curran Jr

12:20-12:40 PM

Strategies to Overcome Barriers to Clinical Trial Enrollment and Retention

Alan Sandler

12:40-1:00 PM

Panel Discussion and Question-and-Answer Session



Evaluation and Request for Credit Form
Overcoming Key Challenges to Lung Cancer Clinical Trial Recruitment and Retention
June 14, 2011

Participant Demographics

Years in practice or field: <input type="checkbox"/> 1-5 <input type="checkbox"/> 6-10 <input type="checkbox"/> 11-20 <input type="checkbox"/> More than 20		Is your practice principally patient care? <input type="checkbox"/> Yes <input type="checkbox"/> No	
What is your degree? <input type="checkbox"/> MD/DO <input type="checkbox"/> PhD <input type="checkbox"/> PA <input type="checkbox"/> Pharmacy <input type="checkbox"/> RN <input type="checkbox"/> RPH <input type="checkbox"/> NP <input type="checkbox"/> Medical Student <input type="checkbox"/> Other _____			
Approximate percentage of patients you manage for the disease(s) addressed by this activity: <input type="checkbox"/> 0%-20% <input type="checkbox"/> 21%-40% <input type="checkbox"/> 41%-60% <input type="checkbox"/> 61%-80% <input type="checkbox"/> 81%-100%			
Specialty: <input type="checkbox"/> Hematology <input type="checkbox"/> Hematology/Oncology <input type="checkbox"/> Medical Oncology <input type="checkbox"/> Primary Care <input type="checkbox"/> Radiation Oncology <input type="checkbox"/> Surgical Oncology <input type="checkbox"/> Other _____			
Area of focus: <input type="checkbox"/> Breast Cancer <input type="checkbox"/> Gastrointestinal Cancer <input type="checkbox"/> Genitourinary Cancer <input type="checkbox"/> Head & Neck Cancer <input type="checkbox"/> Hematology <input type="checkbox"/> Lung Cancer <input type="checkbox"/> Melanoma <input type="checkbox"/> Multitumor <input type="checkbox"/> Ovarian Cancer <input type="checkbox"/> Other _____			
Type of practice: <input type="checkbox"/> Academic/Research <input type="checkbox"/> Cancer Center <input type="checkbox"/> Hospital <input type="checkbox"/> Private/Group <input type="checkbox"/> Other _____			

Participant History

My preferred educational format is: <input type="checkbox"/> Symposium/Conference/Workshop <input type="checkbox"/> Satellite Broadcast <input type="checkbox"/> Podcast <input type="checkbox"/> Monograph/Journal Supplement <input type="checkbox"/> Online Activity <input type="checkbox"/> Mobile CME

Educational Objectives

Indicate on a scale from 1 to 5 the extent to which you agree that the activity met the following educational objectives. Please use the following codes to evaluate: 1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

Discuss the importance of clinical trial enrollment and retention in advancing the treatment of patients with lung cancer.	① ② ③ ④ ⑤
Summarize patient-, physician-, and protocol-related barriers that impact enrollment in lung cancer clinical trials.	① ② ③ ④ ⑤
Evaluate strategies that can be used to overcome challenges in recruiting and retaining patients with lung cancer in clinical trials, especially those who belong to minority or elderly patient subgroups.	① ② ③ ④ ⑤

Activity Expectations

Indicate on a scale from 1 to 5 the extent to which this activity met your expectations. Please use the following codes to evaluate: 1=Strongly Disagree 2=Disagree 3=Neutral 4=Agree 5=Strongly Agree

Addressed competencies identified by my specialty.	① ② ③ ④ ⑤
Addressed barriers to optimal patient management.	① ② ③ ④ ⑤
Provided clear evidence to support content.	① ② ③ ④ ⑤

Commercial Support and Disclosure

	Yes	No	Comments
Disclosures of faculty relationships or affiliations with commercial organizations were made available.	<input type="radio"/>	<input type="radio"/>	
The commercial supporter was acknowledged.	<input type="radio"/>	<input type="radio"/>	

If you answered "No" to any of the above, please provide details: _____

Teaching Effectiveness

Please use the following codes to evaluate: 1=Poor 2=Fair 3=Good 4=Very Good 5=Excellent

Faculty	Knowledge of Subject Matter	Appropriateness of Teaching Strategies	Fair and Balanced
Walter J. Curran Jr, MD	① ② ③ ④ ⑤	① ② ③ ④ ⑤	<input type="checkbox"/> Yes <input type="checkbox"/> No
Alan Sandler, MD	① ② ③ ④ ⑤	① ② ③ ④ ⑤	<input type="checkbox"/> Yes <input type="checkbox"/> No
Joan Schiller, MD	① ② ③ ④ ⑤	① ② ③ ④ ⑤	<input type="checkbox"/> Yes <input type="checkbox"/> No

Additional comments about the faculty: _____

Activity Effectiveness

Please use the following codes to evaluate: 1=Needs Improvement 2=Below Average 3=Average 4=Above Average 5=Excellent

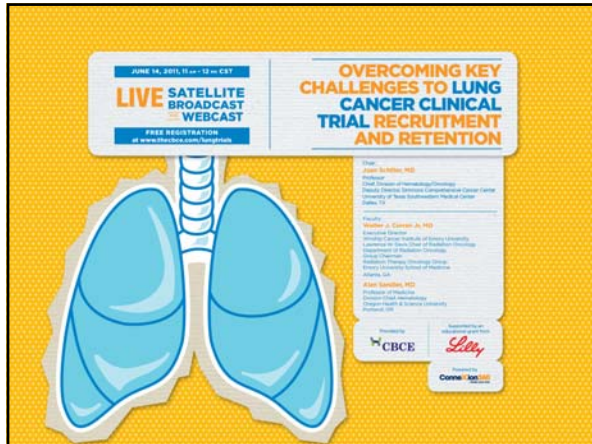
Compared with all other activities that I have reviewed over the past year, I would rate this activity as:	① ② ③ ④ ⑤
My competence level was increased as a result of this activity.	① ② ③ ④ ⑤
Content was current and up-to-date.	① ② ③ ④ ⑤
What percentage of the content of this activity was new to you? <input type="checkbox"/> 0%-20% <input type="checkbox"/> 21%-40% <input type="checkbox"/> 41%-60% <input type="checkbox"/> 61%-80% <input type="checkbox"/> 81%-100%	
Major strengths of the activity:	
Major weaknesses of the activity:	

Future Educational Needs

Please list any other topics or delivery formats you would like to see in future educational activities: _____

Additional Comments

Are there any other comments to share regarding this activity or faculty? _____



Accreditation

The CBCE™ (The Center for Biomedical Continuing Education) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

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Accreditation (cont.)

Credit Instructions
 The Evaluation and Request for Credit Form must be completed and returned to the CBCE following this activity to obtain credit. Participants will receive their certificate 4-6 weeks after the CBCE receives their form.

Educational Objectives

Upon completion of this activity, learners will be able to

1. Discuss the importance of clinical trial enrollment and retention in advancing the treatment of patients with lung cancer.
2. Summarize patient-, physician-, and protocol-related barriers that impact enrollment in lung cancer clinical trials.
3. Evaluate strategies that can be used to overcome challenges in recruiting and retaining patients with lung cancer in clinical trials, especially those who belong to minority or elderly patient subgroups.

Disclosure of Financial Relationships

As an accredited provider, it is the policy of the CBCE

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For additional information about approved uses, including approved indications, contraindications, and warnings, please refer to the prescribing information for each product or consult the latest edition of the *Physicians' Desk Reference*.

The CBCE™ (The Center for Biomedical Continuing Education) gratefully acknowledges the educational grant provided by

Lilly USA, LLC

Introduction: Assessing the Current Challenges of Lung Cancer Clinical Trial Accrual and Retention

Joan Schiller, MD

Professor

Chief, Division of Hematology/Oncology
Deputy Director, Simmons Comprehensive Cancer Center
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Joan Schiller, MD

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Joan Schiller, MD (cont.)

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Syndax Pharmaceuticals, Inc.
Telik, Inc.

Patients With Cancer Who Were Aware of Trials But Did Not Participate

Harris Interactive Healthcare News 2001

- 5972 patients with cancer
- Phone interviews
- 85% of patients were either unaware of trials or did not know cancer clinical trials were an option
 - 75% of these patients indicated they would have been willing to enroll had they known it was possible
- 16% were aware of clinical trials refused participation

Patients With Cancer Who Were Aware of Trials But Did Not Participate (cont.)

Major Reason	%
Belief that they would be better off taking "the standard treatment"	37
Fear that they might get a placebo rather than actual treatment	31
Belief that "the standard treatment" would be more effective	30
Fear of being treated "like a guinea pig"	22
Distance they would have to travel to obtain treatment	21
Belief that the cost of treatment would not be covered by insurance	20
Amount they would have to pay out-of-pocket	18
Fear that their doctor would not be able to choose best treatment	18
The effort involved in the informed consent process	6

It's Not Just the Patients...

It's the doctors as well

Population-Based Assessment of MD Involvement in Clinical Cancer Trials

Klabundo JNCI 2011

- Cancer Care Outcomes Research and Surveillance Consortium
- 1533 specialty physicians who care for patients with colorectal cancer and lung cancer
 - 496 medical oncology
 - 228 radiation oncology
 - 909 surgeons
- 61% return rate

Characteristics of Medical and Radiation Oncologists Enrolling More Patients: Multivariate Analysis

Klabundo JNCI 2011

Characteristic	Adjusted OR (95% CI)	P Value
Practice type		
Office-based, solo	0.3 (0.1 to 0.6)	0.018
Office-based, group	0.8 (0.4 to 1.4)	
Hospital-based	1.00	
Practice affiliated with a CCOP		
Yes	2.1 (1.2 to 3.7)	0.016
Practice affiliated with an NCI-designated cancer center		
Yes	2.8 (1.2 to 6.4)	0.023
Teaches medical students and/or residents		
Yes	2.7 (1.5 to 5.0)	0.003

Factors NOT associated with patient enrollment: physician age, gender, practice size, and percentage of patients in managed care

Barriers to Lung Cancer Clinical Trial Enrollment and Retention

Walter J. Curran Jr, MD

Executive Director

Winship Cancer Institute of Emory University
Lawrence W. Davis Chair of Radiation Oncology

Group Chairman

Radiation Therapy Oncology Group
Atlanta, GA

Walter J. Curran Jr, MD

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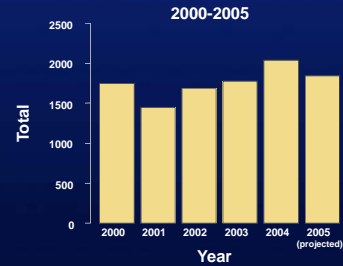
Cooperative Group Lung Cancer Research: Recent Selected Accomplishments

- First positive trial for targeted therapy for lung cancer
- Defined optimized chemo-RT regimens
- Landmark use of stereotactic RT for lung cancer
- Defined role of lung cancer surgical staging
- Defined value of lung cancer screening

RT=radiotherapy.

How about enrollment?

Lung Cancer Trial Enrollments by Year US Cooperative Groups

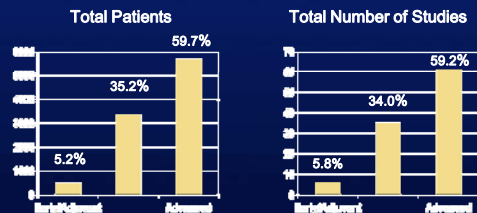


Methodology

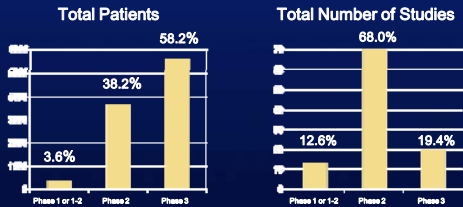
Joseph Unger, John Crowley, Coalition et al
CDUS 2000-June 2005

- 9602 patients enrolled in lung cancer trials in 5.5 years
- 103 clinical trials phases 1-3 for lung cancer
- Average of 1746 patients/year or 145/month
- Assuming 175,000 lung cancer cases diagnosed/year
- Ratio of registered/diagnosed=962,500/5.5 years
- 1.00% ratio of enrolled to diagnosed

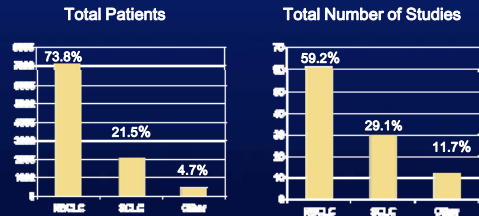
Accrual and Number of Studies by Study Type Cooperative Groups, 2000-June 2005



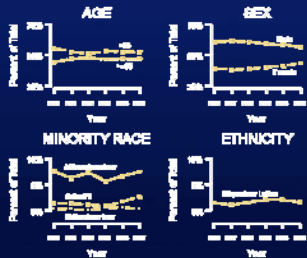
Accrual and Number of Studies by Study Phase Cooperative Groups, 2000-June 2005



Accrual and Number of Studies by Histology Cooperative Groups, 2000-June 2005



Enrollment by Demographics: Cooperative Group Lung Trials



Accrual by Group: 2000-2005

- Southwest Oncology Group (SWOG): 30%
- Cancer and Leukemia Group B (CALGB): 24%
- Eastern Cooperative Oncology Group (ECOG): 20%
- Radiation Therapy Oncology Group (RTOG): 9%
- North Central Cancer Treatment Group (NCCTG): 9%
- National Cancer Institute of Canada (NCIC): 6%

Lung Cancer Accrual: Summary

- Accrual stable over half decade
- Ratio of accrued to diagnosed: 1%
- Majority of patients accrued: stage IV

Issues Raised

- What should our ratio goal be?
 - Currently 1%
 - 2% is 300 patients/month
 - Unrepresented are the low PS?
 - Early-stage trials still rare
 - Will second-line trials add numbers?
 - Reasonable number of patients >65

Obstacles to Enrollment: Cooperative Group Lung Cancer Enrollment

- Financial disincentive: cost > revenue
- Too few trials open: approval process
- Cross-group participation?
- High institutional regulatory burden?
- Increasing complexity of lung cancer?
- Technical accreditation
 - Biomarkers
 - Radiation oncology
 - PET scanning

Obstacles to Enrollment: Cooperative Group Lung Cancer Enrollment

- More interesting trials outside the groups?
- Short window of opportunity for patients with lung cancer?
- Stringent eligibility criteria?
 - Comorbid conditions
 - Pulmonary function
 - Prior therapies
 - Availability of all subspecialty expertise?

Despite This...

- Complex, low reimbursing trials can accrue well
 - RTOG 0617
 - Standard-dose vs high-dose RT
 - Concurrent chemo
 - Cetuximab vs no cetuximab
 - Tough eligibility; radiation oncology accreditation
- Will complete accrual 1 year in advance in 2011!

Issues for Discussion

- Decline in phase 3 trial accrual
- Low number of phase 1/2 trials
- Can the groups handle a greater patient load?
- What has happened since 2005?
- What about the future?

Current Cooperative Group Trials

- Adjuvant role of targeted therapy?
- Role of concurrent targeted therapy with concurrent chemo-RT?
- Better understanding of maintenance therapy?
- Stereotactic RT vs surgery for impaired patients?
- Testing of new agents?

Cooperative Group Consolidation: Implications for Lung Cancer Review

- 7 groups currently conduct lung cancer trials
 - American College of Radiology Imaging Network (ACRIN)
 - American College of Surgeons Oncology Group (ACOSOG)
 - CALGB
 - ECOG
 - NCCTG
 - RTOG
 - SWOG
- 4 groups will conduct lung cancer trials after 2014
 - CALGB/NCCTG/ACOSOG
 - ECOG/ACRIN
 - RTOG/ (National Surgical Adjuvant Breast and Bowel Project [NSABP]/Gynecologic Oncology Group [GOG])
 - SWOG

Future State

- Fewer trials?
- More rapid accrual?
- Greater use of biomarkers?
- Greater use of advanced imaging?
- Continued testing of surgical questions?
- Continued testing of RT innovations?

Strategies to Overcome Barriers to Clinical Trial Enrollment and Retention

Alan Sandler, MD
Oregon Health & Science University

Alan Sandler, MD

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Alan Sandler, MD (cont.)

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Problems

- Accrual to cancer clinical trials in the United States is poor
- Clinical trial process is complex and cumbersome
- Increasing competition – clinical trial research is being outsourced
 - How applicable are these data to the US?
- Conducting clinical research is fiscally challenging

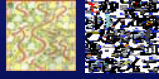


ASCO & JCO 2009, 2010

- Of 248 phase 3 therapeutic trials opened by 5 national cooperative groups between 1993-2002, 35% did not achieve sufficient accruals
 - Schroen AT, Petroni GR, et al. *J Clin Oncol.* 2009; 27:15s (suppl); abstr 6562
- Of all ECOG phase 2 and 3 trials from 1977 to 2006, "over a quarter of the trials failed to achieve accrual goals and to complete"
 - Go RS, Meyer CM, et al. *J Clin Oncol.* 2010; 28:15s (suppl); abstr 6069
- Of 191 CTEP sponsored phase 3 trials from 2000 to 2007, 42 (22.0%) failed due to accrual issues
 - Korn EL, et al. *J Clin Oncol.* 2010;28(35):5197-5201



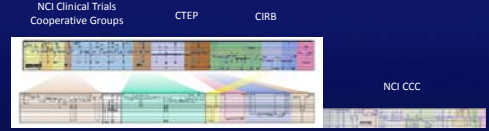
Steps for Opening a Phase 3 Cooperative Group Trial¹



	NCI Cooperative Group	CTEP / CIRB	NCI Cancer Center	Total
Process Steps	>458	>216	>95	>769
Working Steps	>399	>179	>73	>651
Decision Points (chairs or ladders)	59	37	22	148
Potential Loops ² (all chairs)	26	15	8	49
No. of Groups Involved	11	14	11	36

1. Representative Cooperative Oncology Group and Comprehensive Cancer Center
2. Process steps reported only show one loop in the process. Actual development frequently includes multiple loops

Time for Opening a Phase 3 Cooperative Group Trial



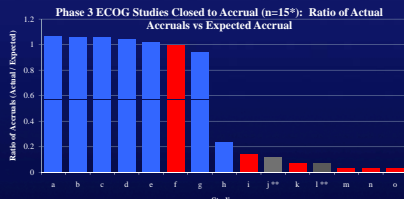
Median: 784 to 808 days*
Range: 435-1604 days

Median: 116 to 252 days*
Range: 21-836 days

Total Median Time from idea to opening ~920 days (2.5 years)
Range: 456 - 2440 days (1.25 - 6.7 yrs)

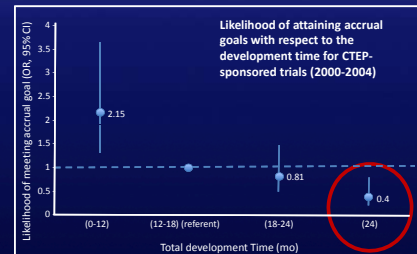
*Depending upon site, based on the phase 3 trials studied

Does Time Matter? At 1 Cooperative Group



*All phase 3 studies activated and closed to accrual between January 2000 and July 2006
Legend:
■ Studies taking greater than the median time to open
■ Studies taking less than the median time to open
■ Studies closed due to reasons other than poor accrual

Does Time Matter? CTEP



Cheng SK, et al. Clin Cancer Res. 2010;16(22):5557-5563.

Foreign Subjects in FDA Trials

DHHS Office of Inspector General Report, June 2010
OIG-01-08-00519

Table 2: Number and Percentage of Foreign Subjects and Sites From Clinical Trials Supporting Drug- and Biologic-Marketing Applications Approved in FY 2008

	Drugs	Biologics	Drugs and Biologics
Number of Foreign and Domestic Subjects	92,859	206,842	299,701
Number of Foreign Subjects	52,820	179,712	232,532
Percentage of Foreign Subjects	56.9%	86.9%	77.6%
Number of Foreign and Domestic Trial Sites	11,227	717	11,944
Number of Foreign Trial Sites	6,129	356	6,485
Percentage of Foreign Trial Sites	54.6%	49.7%	54.3%

Note: These numbers are based on data from 193 clinical trials with complete subject and site information.
Source: OIG analysis of FDA marketing applications approved in FY 2008.

FDA was unable to provide detailed clinical trial data for 29 of the 129 (22.5%) applications within our review. FDA was unable to find any portion of 8 of 29 (6.3%) applications.

Globalization of Clinical Research

Ethical and Scientific Implications of the Globalization of Clinical Research

- Approximately one third of the trials (157 of 509) are being conducted solely outside the United States and that a majority of study sites (13,521 of 24,206) are outside the United States. Many of these trials are being conducted in developing countries, including the rapidly evolving countries of Eastern Europe and the Russian Federation
- The number of countries serving as trial sites outside the United States more than doubled in 10 years

Adapted from Glickman SW, et al. N Engl J Med. 2009;360(8):816-823.

Outsourcing of Drug Trials Is Faulted

- Ethical quagmire: drugs intended for wealthy nations are tested on people in developing countries
- Human volunteers in foreign countries may be unduly influenced with the promise of financial compensation or free medical care to participate in clinical trials

Singer N. *New York Times*. February 19, 2009.

How Do We Improve?

A National Cancer Clinical Trials System for the 21st Century Reinvigorating the NCI Cooperative Group Program

- Report of the Operational Efficiency Working Group of the Clinical Trials and Translational Research Advisory Committee
- Compressing the Timeline for Cancer Clinical Trial Activation

March 2010. National Institutes of Health, National Cancer Institute, and US Department of Health and Human Services

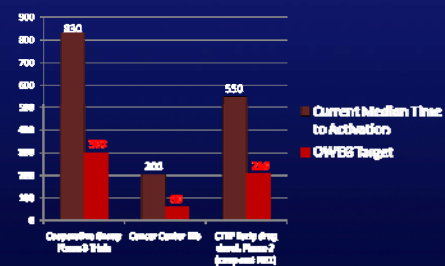
Summary of Committee Recommendations

- **Goal 1. Improve the speed and efficiency of the design, launch, and conduct of clinical trials**
 - Review and consolidate some front office operations of the Cooperative Groups on the basis of peer review
 - Consolidate back office operations and improve processes
 - Streamline and harmonize government oversight
 - Improve collaboration among stakeholders
- **Goal 2. Incorporate innovative science and trial design into cancer clinical trials**
 - Support and use biorepositories
 - Develop and evaluate novel trial designs
 - Develop standards for new technologies

Summary of Committee Recommendations (cont.)

- **Goal 3. Improve the means of prioritization, selection, support, and completion of cancer clinical trials**
 - Reevaluate the role of NCI in the clinical trials system
 - Increase the accrual volume, diversity, and speed of clinical trials
 - Increase funding for the Cooperative Group Program
- **Goal 4. Incentivize the participation of patients and physicians in clinical trials**
 - Support clinical investigators
 - Cover the cost of patient care in clinical trials

Operational Efficiency Working Group (OEWG) Recommendations



Focusing on Setups:

- Do not assume that the set-up time is fixed
- Specifically study what *is* done (not what *is thought* to be done) and *why* each action is done

Morison EE. *Men, Machines, and Modern Times*. Cambridge, MA: The MIT Press; 1966.

Solutions

- Know why a step is done
- Eliminate non-value added steps and waste (muda)

Muda	Non-Value Added Activities
Overproduction	-Number of trial tracking identifiers -Number of overlapping reviews
Inventory	Batching of work
Waiting	Stacks of paper
Unnecessary transport	Moving paper back and forth
Unnecessary processing	Corrections/Competing stipulations
Defects	Repeated steps

Sample Listing of Participants Involved in the Opening of an Oncology Clinical Trial

Primary

- Principal investigators
- Sponsor
- Clinical trials office
- Regulatory staff
- Institutional review board
- Scientific review committee
- Contracts and grants office
- Division chair
- Department head
- Core medical team

Secondary

- Clinical research center
- Compliance office
- Director, medical affairs/oncology administration
- US Food and Drug Administration
- Finance department
- General hospital review board
- Human subjects radiation committee
- Institutional biosafety committee
- Legal department
- Medical ethics board
- Office of sponsored research
- Pharmacy
- Radioactive drug research committee
- Site coordinator

Adapted from Dilts DM, Sandler AB. Inevitable barriers to clinical trials: the impact of structural, infrastructural, and procedural barriers to opening clinical trials. *J Clin Oncol*. 2006;24(28):4545-4552.

Create Standard Clinical Trial Building Blocks

- Standard Case Report Forms, Contracts, Informed Consents, Protocol Components, etc
- NCI START contract clauses
- *"We already do that, so what's the issue?"*



Standard Building Blocks

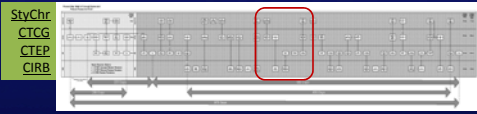
- *"We already do that, so what's the issue?"*
- Problem:
 - Nearly every institution or organization creates their own "standard templates"
 - Little or no sharing of templates
 - No universal "set of blocks"
- Example: Case Report Forms



Solutions

- Know what horses you are holding
- Eliminate non-value added steps
- Harmonize work and use global standards

Example Flow: Tinkering and Looping



Looping

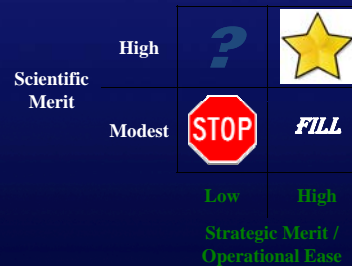
- Why Loop?
 - “Inspect in quality”
 - Implying an unreliable process
 - Tweaking
 - Scope Creep
 - When one group or organization expands the scope of its authority or power
- *Implicit Theory*: more reviews = better study
- *Practice*: more reviews = slower opening trials, with no evidence of improvement

Solutions

- Know why a step is taken
- Eliminate non-value added steps
- Harmonize work and use global standards
- Stop tweaking
 - “Le mieux est l'ennemi du bien”
 - Or “The best is the enemy of the good”
 - François-Marie Arouet (aka, *Voltaire*), La Bégueule (1772)
- ♦ *But if a trial does not accrue, all steps are non-value added*

Triaging Concepts:

A Technique for Determining Entrance



Solutions (cont.)

- Know why a step is taken
- Eliminate non-value added steps
- Harmonize work and use global standards
- Stop tweaking
- **Triage trials**
- **Increase resources**

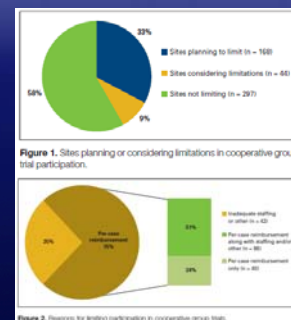
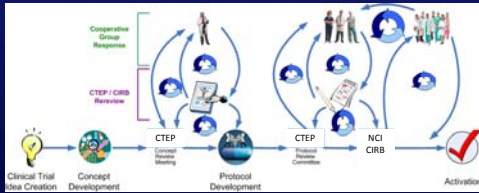


Figure 1. Sites planning or considering limitations in cooperative group trial participation.

Figure 2. Reasons for limited participation in cooperative group trials.

Baer AR, et al. *J Oncol Pract.* 2010; 6(3):114-117.

High Level Process Flow for Phase 3 Studies



Solutions (cont.)

- Know why a step is done
- Eliminate non-value added steps
- Harmonize work and use global standards
- Stop tweaking
- Triage trials
- **Throw money at the problem**
- **Fund appropriately for results, not activities**

Conclusion

- Nationally – restructure the entire system
- Locally, clean up the clutter in:
 - Processes
 - Number of slow opening trials
 - Number of non-accruing trials
 - Barriers to working together
- Speed up the process
 - Harmonize and Standardize, but not on scientific questions
- Reward outcomes, not activities
- Focus on the goal