



Recruitment Project Expert Meeting

Agenda of the Expert Meeting held November 9-10, 2015

DoubleTree by Hilton Hotel Washington DC – Silver Spring
8727 Colesville Road, Silver Spring, MD

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- ▶ Present findings from the CTTI Recruitment Project's evidence gathering
- ▶ Obtain stakeholder perspectives and critical feedback on draft considerations for more effective recruitment planning
- ▶ Develop consensus across multiple stakeholder perspectives on the mechanisms for moving recruitment planning upstream and achieving culture change
- ▶ Identify implementation barriers to achieving change
- ▶ Develop consensus across multiple stakeholder perspectives on the mechanisms for overcoming barriers to achieving change

Monday, November 9, 2015

7:30-8:00 Breakfast (*Provided*)

8:00-8:25 Welcoming Remarks

Jamie Roberts, Clinical Trials Transformation Initiative, CTTI
Pamela Tenaerts, CTTI

Session I

The Landscape

Objectives:

- ▶ Learn about the landscape of clinical trial recruitment
- ▶ Learn about the patients' perceptions of clinical research

8:25-9:00 An Imperative for Action: Patients Are Waiting

Mary Woolley, Research!America

Session II

Background, Findings, and Current Status of Project

Objectives:

- ▶ Learn about the background of the project and our evidence gathering process
- ▶ Review key findings from the project

9:00-9:45 Key Findings from the CTTI Recruitment Planning Project

Jonca Bull, Food and Drug Administration

9:45-10:15 Panel Discussion with Recruitment Project Team Leaders and Audience

Facilitator: Jamie Roberts

Panelists: Patricia Furlong, Parent Project Muscular Dystrophy (PPMD); Beth Mahon, Janssen; Jonca Bull, FDA

10:15-10:30 Break

Session III

Presentation of Draft Considerations and Discussion

Objectives:

- ▶ Review draft points of consideration for improving recruitment planning
- ▶ Obtain critical feedback on points of consideration through interactive discussion

10:30-10:45 Trial Design and Protocol Development

Beth Mahon, Janssen

10:45-11:45 Open Discussion with Panel and Audience

Facilitator: Grant Huang, Department of Veterans Affairs

Panelists: Beth Mahon, Janssen; Jonca Bull, FDA; Patricia Furlong, PPMD; Anuja Rastogi, FDA; Barbara LeStage, Patient Representative

11:45-12:15 Lunch (*Provided*)

Monday, November 9, 2015 (Continued)

Session III (Continued)

12:15-12:30 Trial Feasibility Analyses and Site Selection

Beth Harper, Clinical Performance Partners

12:30 - 1:30 Open Discussion with Panel and Audience

Facilitator: Kelly McKee, Merck

Panelists: Ashish Oza, St. Jude Medical; Beth Harper, Clinical Performance Partners; Claire Meunier, The Michael J Fox Foundation (MJFF)

1:30 - 1:45 Recruitment Communication Planning

Jim Kremidas, Association of Clinical Research Professionals (ACRP)

1:45 - 2:45 Open Discussion with Panel and Audience

Facilitator: Claire Meunier, MJFF

Panelists: Holly Massett, National Institutes of Health (NCI); Leslie Kelly, Duke University; David Ciavarella, CR Bard; Jim Kremidas, ACRP

2:45 - 3:00 Break

Session IV

Anticipated Implementation Challenges, Root Cause Analyses & Prioritization

Objectives:

- ▶ Rank which considerations will be the most difficult to implement
- ▶ Review the Implementation Root Cause Analysis Process and Prioritization
- ▶ Expectations for the Discussion Session

3:00 - 3:30 What Can We Do Tomorrow? What Can't Be Done Until We Colonize Mars and Why? An Interactive Presentation

Beth Harper & Jim Kremidas

3:30-4:30 Open Discussion with Audience

Facilitators: Beth Harper & Jim Kremidas

4:30-5:00 A New Framework for Innovation: Trial Recruitment as a Mechanism of Action

Joseph Kim, Eli Lilly and Company

5:00 Day One Highlights and Wrap-Up

Kelly McKee, Merck

5:15-7:30 Dinner Reception (Connection I, second level)

Tuesday, November 10, 2015

7:30-8:00 **Breakfast** (*Provided in Connection I, Second Level*)

8:00-8:15 **Welcome, Overview of Day One, Game Plan for Day Two**

Jamie Roberts, CTTI

Objectives:

- ▶ Identify implementation challenges, brainstorm solutions
- ▶ Begin to build consensus on solutions to implementation challenges

Session V:

Why It's Time for a National Public Education Campaign

Objective:

- ▶ Discuss the need for, and critical success factors associated with, establishing an effective national engagement campaign

8:15 - 8:45 **Establishing Engagement through Coordinated National Outreach**

Ken Getz, Tufts University School of Medicine

8:45-10:45 **Breakout Sessions: Interactive Problem Solving**

▶ **Trial Design and Development**

Facilitators: Grant Huang, VA & Jonca Bull, FDA

▶ **Site Selection and Feasibility**

Facilitators: Beth Harper, Clinical Performance Partners & Claire Meunier, MJFF

▶ **Recruitment Communication Planning**

Facilitators: Jim Kremidas, ACRP & Kelly McKee, Merck

10:45-11:00 **Break**

Session VI

Interactive Problem Solving Report Outs

11:00-11:40 **RCA: Trial Design and Development Group**

Report Out & Open Discussion: Recommendations & Needed Tools

Grant Huang, VA

11:40-12:20 **RCA: Group Site Selection and Feasibility**

Report Out & Open Discussion: Recommendations & Needed Tools

Beth Harper, Clinical Performance Partners

12:20 - 1:00 **RCA: Group Recruitment Communication Planning**

Report Out & Open Discussion: Recommendations & Needed Tools

Jim Kremidas, ACRP

Working Lunch (*Provided*)

Tuesday, November 10, 2015 (Continued)

Session VII
Getting the Word Out

1:30 - 2:00 A Dissemination Plan Discussion

Facilitator: Matthew Harker, CTTI

Objectives:

- ▶ Identify who needs to learn of the recommendations
- ▶ Identify the best channels and champions for dissemination

**2:00-2:30 Taking Recruitment Planning to the Next Level: Where Do We Go From Here?
Panel and Audience Discussion**

Facilitator: Jamie Roberts, CTTI

Panelists: Grant Huang, VA; Beth Harper, Clinical Performance Partners;
Jim Kremidas, ACRP

2:30pm Adjourn

For more information, contact the Recruitment Project Manager Jamie Roberts at Jamie.Roberts@duke.edu or visit <http://www.ctti-clinicaltrials.org>.

Appendix A. Meeting/Workshop Background

Background

Clinical trial sponsors are facing an increasingly difficult task of meeting recruitment goals. According to the Tufts Center for the Study of Drug Development (CSDD),¹ only 39% of sites achieve their enrollment targets, 37% fail to meet their targets and 11% fail to enroll a single subject into trials in which they agree to participate and study timelines are typically doubled beyond their planned enrollment periods. 32% of sites do not receive any sort of centralized recruitment and retention support, most of which are traditional recruitment tactics such as physician referrals and mass media (newspaper ads and flyers). Fewer than 15% of recruitment strategies focus on new technologies (e.g., electronic medical records, data mining) and web 2.0 (social media and networking, and online advertising). Sub-optimal trial recruitment directly translates into missed opportunities for patients who can benefit from clinical trials, the chance to advance the science and understanding of disease and find new therapies, as well as wasting time, funds, and other resources.

Issue

Clinical trials that fail to meet their recruitment goals may be terminated early or be unable to answer their primary research questions as well as exposing potential to risk with limited to no meaningful benefit to advancing therapies or scientific understanding. Many explanations have been offered to elucidate the failure to recruit adequate numbers of patients including poor study design, lack of patient engagement, insufficient staff time, inadequate attention to determine and identify available patients who meet eligibility criteria, and inadequate centralized site support. Actionable solutions are needed.

The Clinical Trials Transformation Initiative's Recruitment Project was initiated to identify barriers (both real and perceived) and optimal approaches to improving recruitment to clinical trials.

¹ Tufts Center for the Study of Drug Development Impact Report. Vol. 15. No. 1, 2013.

MULTI-STAKEHOLDER EXPERT MEETING ATTENDEES

CTTI Multi-Stakeholder Expert Meeting participants include representatives from a broad cross-section of the clinical trial enterprise including regulators, government sponsors of clinical research, academia, industry, patient advocates, clinical investigators, and other interested parties. Participants are expected to be actively engaged in dialogue both days. A comprehensive meeting participant list will be provided onsite along with printed meeting materials.

CTTI RECRUITMENT PROJECT TEAM MEMBERS

Jonca Bull*	Food and Drug Administration, CDER
David Ciavarella	CR Bard
Pat Furlong*	Parent Project Muscular Dystrophy (PPMD)
Beth Harper	Clinical Performance Partners
Grant Huang	Department of Veterans Affairs
Adwoa Hughes-Morley	Systematic Techniques for Assisting Recruitment to Trials (START)
Leslie Kelly	Duke University
James Kremidas	Association of Clinical Research Professionals (ACRP)
Barbara LeStage	Patient Representative
Elizabeth Mahon*	Janssen
Holly Massett	National Institutes of Health, NCI
Claire Meunier	The Michael J Fox Foundation (MJFF)
Kelly McKee	Merck
Ashish Oza	St. Jude Medical
Anuja Rastogi	Food and Drug Administration, CBER

**CTTI Recruitment Project Team Leads*

CTTI STAFF

Matthew Harker, CTTI Associate Director of Projects
 Jamie Roberts, CTTI Recruitment Project Manager
 Pamela Tenaerts, CTTI Executive Director
 Kelly Killibarda, Whitsell Innovations