ADVANCEMENTS IN CLINICAL RESEARCH OPERATIONS FOR ONCOLOGY PRODUCTS

Examining the Complex Clinical Research Environment within Oncology by Providing Insight Surrounding the use of Companion Diagnostics & Biomarkers within a Trial, Defining Strategies used in Managing Multiple Endpoints, as well as Approaches in Demonstrating Overall Survival to Secure Regulatory Approval

PROGRAM OVERVIEW:

With over 200 types of cancer that have been discovered to date, clinical research within the oncology space is becoming increasingly important among pharmaceutical and biotech companies. According to the American Cancer Society, the 5-year relative survival rate for all cancers diagnosed between 2001 and 2007 is 67%, up from 49% in 1975-1977, which has occurred not only because of earlier detection and diagnosis, but also improvements in treatments provided by cutting edge pharmaceutical and biotech manufacturers.

Central to this program will be a vast knowledge share surrounding managing multiple endpoints to assist in overall patient survival, supporting personalized medicine through incorporating companion diagnostics and receiving regulatory guidance on their use as well working with international patient populations to ensure regulatory approval within the US. There will also be opportunities to share best practices in safety and risk management within a trial, strategies used in receiving regulatory approval through accelerated pathways as well as adjusting study design in order to keep up with expedited trial approaches and inspection readiness within oncology.

Designed for pharmaceutical and biotech companies focusing on oncology products, this two-day executive level program will provide participants with extensive networking as well as in-depth learning through interactive sessions, panels and case studies, complemented by multiple networking opportunities with industry peers, speakers and service providers. Attendees will have the opportunity to learn strategies for overcoming key challenges within the oncology space of clinical research while capitalizing on important opportunities. Through fostering a sense of collaboration, this unique conference program will inspire innovation and help bring clarity to professionals that wish to maximize their impact within the oncology community.

DISTINGUISHED PRESENTERS INCLUDE:

Omar Perez Ph.D.
Diagnostics Lead, Associate Director, Worldwide R&D
Clinical Research and Precision Medicine
Pfizer

Roland Regino
Senior Clinical Trial Manager
Genentech

Andrew Koustenis
Principal Clinical Research Scientist
Elililly

Sarper Toker M.D.
Safety Risk Lead
Pfizer

Jonathan Cheng, M.D.
Director, Oncology Clinical Development
Merck

David C. Mitchell
Director / Global Regulatory Lead
Oncology and Early Immunology
ABBVIE

Ryan M. Franke
Senior Pharmacokinetics Scientist
Pfizer

Louise Rochon Ph.D.
Director of Clinical Research
Mallinckrodt, The Pharmaceuticals Business of Covidien

Iman El-Hariry
VP Clinical Research
Synta Pharmaceuticals

Kyle D. Holen, M.D.
Senior Medical Director, Oncology Development
ABBVIE

Premal Shah, Ph.D.
Director, Business Development
Genomic Health, Inc.

Anne Borgman Hagey M.D.
Vice President, Clinical Research & Development
Exelixis

David Conway
Senior Director Clinical Operations
Halozyme Therapeutics

Vadim Paluy, M.D.
Medical Director
Covance

Matthew Wagener
Dir., Research Business Development & Alliances
US Oncology Research
ADVANCEMENTS IN CLINICAL RESEARCH OPERATIONS FOR ONCOLOGY PRODUCTS

DAY ONE / THURSDAY, JUNE 20

7:30 REGISTRATION & CONTINENTAL BREAKFAST

8:20 CONFERENCE WELCOME & CHAIRPERSON OPENING REMARKS

8:30 CREATING PARTNERSHIPS TO ENHANCE CDX DEVELOPMENT SUCCESS

With exponential rising costs within clinical trials of oncology products, pharmaceutical and biotech companies have begun to explore companion tests in order to develop safer, more targeted treatments. Identifying and creating partnerships with diagnostics companies that are in line with the needs of a particular treatment will assist in developing successful and effective companion diagnostic implementation. This session will outline the benefits of a diagnostic partnership while also examining the potential side effects on a trial, such as slowing down drug development due to the diagnostics timeline.

- Strategies to identify a diagnostic company in line with trial needs
- A showcase of the benefits and risks of a diagnostic partnership
- Choosing a business model: partnership, one merged entity or acquisition

7:30 REGISTRATION & CONTINENTAL BREAKFAST

1:30 BEST PRACTICES IN UTILIZING BIOMARKERS TO PREDICT PATIENT COMPATIBILITY OF CANCER TREATMENTS

The effort to discover new biomarkers in order to predict whether a treatment is effective or adverse among patient groups is especially critical and time sensitive among cancer research. Biomarkers must be considered for regulatory approval in design and early phase research, even if the diagnostic itself is not concurrently approved for the market. Early and late phase clinical teams must coordinate efforts for the integration of biomarkers into oncology studies along with additional considerations such as incorporating pre-clinical data into a trial, using surrogate endpoints as well as the possibility of implementing a companion diagnostic with the biomarker.

- Tools to manage biomarker samples
- Approaches to ensure ample data collection
- Using biomarker data to identify patients that will benefit from treatments

Jonathan Cheng, Ph.D., M.D., Director, Oncology Clinical Development

MERCK

2:20 IMAGING MODALITIES WITHIN ONCOLOGY CLINICAL RESEARCH

According to the National Center for Biotechnology Information, imaging will play an increasingly important role in the design of oncology trials addressing molecularly targeted and personalized therapies while also reducing the cost of trials. In many cases, the use of imaging can prove that you are having an effect on the target of interest, or provide a non-invasive predictive test for outcome. Imaging can therefore be used an “early kill” for a program, reducing costs and improving timelines. It is essential, however, for clinical research professionals to understand the limitations of imaging and contain costs while still providing useful data to satisfy FDA requests.

- Using imaging to understand the effects of a novel agent in clinical evaluation
- Adjustments to the trial design in order to include imaging technologies
- The path to approval of an imaging tool as a companion diagnostic

Kyle D. Holen, M.D., Senior Medical Director, Oncology Development

ABBVIE

3:30 INSIGHT ON GAINING ACCESS TO ACCELERATED APPROVAL FOR ONCOLOGY PRODUCTS

In a 2011 FDA study of 37 oncology products, only 14.3% received accelerated approval (AA) over a span of two years and 10.2% failed to confirm a clinical benefit and resulting in withdrawal from the trial. Among oncology clinical research where the discovery of treatments for serious and life threatening diseases is the most time sensitive of its kind; gaining a better understanding of strategies in order to receive regulatory approval through accelerated pathways is a top concern of any clinical research professional.

- A case study on receiving AA
- Strategies in proving substantial benefit over an existing therapy
- Accounting for AA early on in a trial design

*FDA Speaker invited

1:30 BEST PRACTICES IN UTILIZING BIOMARKERS TO PREDICT PATIENT COMPATIBILITY OF CANCER TREATMENTS

The effort to discover new biomarkers in order to predict whether a treatment is effective or adverse among patient groups is especially critical and time sensitive among cancer research. Biomarkers must be considered for regulatory approval in design and early phase research, even if the diagnostic itself is not concurrently approved for the market. Early and late phase clinical teams must coordinate efforts for the integration of biomarkers into oncology studies along with additional considerations such as incorporating pre-clinical data into a trial, using surrogate endpoints as well as the possibility of implementing a companion diagnostic with the biomarker.

- Tools to manage biomarker samples
- Approaches to ensure ample data collection
- Using biomarker data to identify patients that will benefit from treatments

Jonathan Cheng, Ph.D., M.D., Director, Oncology Clinical Development

MERCK

2:20 IMAGING MODALITIES WITHIN ONCOLOGY CLINICAL RESEARCH

According to the National Center for Biotechnology Information, imaging will play an increasingly important role in the design of oncology trials addressing molecularly targeted and personalized therapies while also reducing the cost of trials. In many cases, the use of imaging can prove that you are having an effect on the target of interest, or provide a non-invasive predictive test for outcome. Imaging can therefore be used an “early kill” for a program, reducing costs and improving timelines. It is essential, however, for clinical research professionals to understand the limitations of imaging and contain costs while still providing useful data to satisfy FDA requests.

- Using imaging to understand the effects of a novel agent in clinical evaluation
- Adjustments to the trial design in order to include imaging technologies
- The path to approval of an imaging tool as a companion diagnostic

Kyle D. Holen, M.D., Senior Medical Director, Oncology Development

ABBVIE

3:30 INSIGHT ON GAINING ACCESS TO ACCELERATED APPROVAL FOR ONCOLOGY PRODUCTS

In a 2011 FDA study of 37 oncology products, only 14.3% received accelerated approval (AA) over a span of two years and 10.2% failed to confirm a clinical benefit and resulting in withdrawal from the trial. Among oncology clinical research where the discovery of treatments for serious and life threatening diseases is the most time sensitive of its kind; gaining a better understanding of strategies in order to receive regulatory approval through accelerated pathways is a top concern of any clinical research professional.

- A case study on receiving AA
- Strategies in proving substantial benefit over an existing therapy
- Accounting for AA early on in a trial design

*FDA Speaker invited

4:20 DEMONSTRATING OVERALL SURVIVAL ADVANTAGE DURING AN ONCOLOGY CLINICAL TRIAL

In order to fast track regulatory approval for a cancer treatment, clinical research professionals are held to the gold standard of being able to prove overall survival (OS) advantage to the FDA. Unfortunate factors such as patient drop off and mortality as well as accounting for cross over therapies can often make this task quite difficult. For approval within an oncology clinical trial, patient survival improvements such as positive developments in the patient’s quality of life (QOL) and proof of progression-free survival (PFS), must be proven to be considered an appropriate measure of clinical benefit for a cancer treatment.

- Hearing success stories in establishing OS
- Overcoming financial challenges by prolonged trials
- Ways to decrease toxicity within a trial

Andrew Koustenis, Principal Clinical Research Scientist

ELI LILLY

5:10 DAY ONE CONFERENCE CONCLUSION
DAY TWO / FRIDAY, JUNE 21
ADVANCEMENTS IN CLINICAL RESEARCH OPERATIONS FOR ONCOLOGY PRODUCTS

7:30 REGISTRATION & CONTINENTAL BREAKFAST
7:50 CHAIRPERSON OPENING REMARKS
8:00 GENENTECH CASE STUDY: PRACTICAL ASPECTS OF EARLY ACCESS TO INNOVATIVE DRUGS
While Expanded Access Programs (EAPs) can provide patients the means to treat a serious disease or condition, these programs should be approached differently than the traditional clinical trial. As the primary objective of the EAP is solely to provide access to treatment and not to collect data, the operational approach at both the sponsor and site-level should be tailored to meet this goal. A practical perspective on the strategy, resources, and conduct of the trial is needed to ensure that access is provided quickly, while maintaining patient safety and adhering to GCP guidelines.
• Developing a realistic operation strategy and timelines
• Ensure adequate resources at the site and sponsor levels
• Managing enrollment from FPI through LPI and transition to commercial supply
Roland Regino, Senior Clinical Trial Manager
GENENTECH
8:50 IMPLEMENTATION OF SAFETY & RISK MANAGEMENT STRATEGIES WITHIN AN ONCOLOGY CLINICAL TRIAL
The FDA recently released new guidance on Industry Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring which aims to ‘enhance human subject protection and the quality of clinical trial data’ and is now holding clinical teams to a heightened standard when it comes to patient safety. Assessing patient risks prior to enrollment, as well as continuing to monitor changes in the patient and properly reporting adverse events are key elements in continued patient protection. Ensuring that a proper risk management system is in place prior to the start of a trial will assist in upholding patient safety, continued study accountability and avoiding regulatory violations.
• Development of risk management strategies
• Best practices for enhancing safety measures
• Accounting for humor error factors in documentation
Serper Toker, M.D., MBA, Safety Risk Lead
Pfizer
9:40 COFFEE & NETWORKING BREAK
10:00 APPROACHES FOR MANAGING MULTIPLE ENDPOINTS THROUGHOUT AN ONCOLOGY CLINICAL TRIAL
One of the most pertinent challenges faced by clinical research professionals within the oncology space is how to successfully manage multiple endpoints within a clinical trial. Whether it be proving the safety and efficacy of a treatment during phase I and II of the trial or maintaining progression free survival (PFS) during phase III and IV, effectively managing a trial through numerous endpoints can be a daunting task. Each presenter will discuss endpoints related to specified phases, followed by Q&A:
EARLY PHASE 1&2 CONSIDERATIONS - ENSURING SAFETY AND EFFICACY OF TREATMENTS
Ryan M. Franke, Senior Pharmacokinetics Scientist
Mallinckrodt, The Pharmaceuticals Business of Covidien
LATE PHASE 3&4 CONSIDERATIONS - MAINTAINING OVERALL PATIENT SURVIVAL
Louise Rochon Ph.D., Director of Clinical Research
Mallinckrodt, The Pharmaceuticals Business of Covidien
11:00 IMPROVING PHASE II TRIAL DESIGN TO BETTER PREDICT PHASE III RESULTS
A recent analysis completed by the Centre for Medicines Research showed 108 Phase II clinical trial failures between 2010 and 2012, 20% of which were for cancer treatments. Factors such as trial delay due to inadequate trial design and site selection, as well as failure to prove safety and efficacy during phase II, can cause a barrier to successfully move potential life safe treatments into phase III. This failure rate is concerning to clinical research professionals within oncology and needs to be assessed in order to ensure completion of successful trials for vital cancer treatments.
• Case study failures between Phase II and III: What went wrong?
• Design options for Phase II and III: Beyond randomization
• Considering site selection as a factor in variances between Phase II & III
Anne Borgman Hagey, M.D., VP, Clinical Research & Development
Exelixis
11:50 LUNCHEON FOR ALL ATTENDEES, SPEAKERS & SPONSORS
1:00 ESTABLISHING RELATIONSHIPS WITH PATIENT ADVOCACY GROUPS TO ASSIST IN TRIAL RECRUITMENT
Through the eyes of the patient, understanding and selecting a fitting oncology clinical trial can be a confusing and intimidating process. For the pharmaceutical company, realizing what motivates the patient to enroll in a trial can be as equaling puzzling and cause significant delay in getting a new therapy approved. Utilizing advocacy groups to work with patients to disentangle some of the clinical and legal language can prove to be very beneficial. Advocacy groups can be a tool in helping trial sponsors bring patients simple choices with clear explanations, which will in turn, add to the overall success of the trial.
• Guidelines for interacting with patient advocacy groups
• Best practices in approaching organizations and communicating goals
• Providing patient groups with adequate and tailored information
Kathy Gram, Associate Director Patient Advocacy
Millennium
1:50 CASE STUDY: SUCCESSFULLY LAUNCHING CLINICAL SITES IN EASTERN EUROPE FOR AN ONCOLOGY STUDY
• Overcoming concerns going into the trial
• Strategies for initiating trial set up
• Lessons learned on working with a global CRO
• Ensuring trial maintenance on an international level
David Conway, Senior Director Clinical Operations
Halozyme Therapeutics
2:40 COFFEE & NETWORKING BREAK
3:00 CASE STUDY: AN ANALYSIS OF A REMOTE DATA MONITORING PILOT PROJECTS
• Outlining the cost and time benefits of remote data monitoring
• Monitoring and data analysis design and techniques
• Outlining the reduction of power system operation and maintenance (O&M) costs
Matthew Wagener, Director, Research Business Development & Alliances
US Oncology Research
3:50 OPTIMIZE STUDY RESULTS THROUGH STRONG SITE SELECTION & CONTRACTING PROCESSES
A solid foundation for any clinical trial begins with the selection of the appropriate sites that will meet the needs of the trial from beginning to end. Considering the competitive nature of the industry and the steady increase of clinical trials being conducted, it is becoming more and more difficult to find suitable sites for studies. Once a site has been selected, key protocols must be upheld in order to ensure a trial is carried out properly and with minimal disruptions. Many prospective trials require a site with a specific specialization and often encounter more difficulties that can cause projected timelines to fall behind.
• Implementation of site surveys before signing contracts to ensure efficiency
• Avoiding sites conducting trials of similar products
• Weighing the benefits of smaller site versus larger sites
Vadim Paluy, M.D., Medical Director
Covance
4:40 CONFERENCE CONCLUSION
Executives that will find this program of greatest relevance are those currently working within the clinical research oncology space of pharmaceutical and biotech companies. Job titles of those executives that will find this program to be most applicable to their job functions include VPs, Directors and managers of:

- Clinical Research Operations, Oncology
- Clinical Research Development, Oncology
- Medical Directors of Oncology
- Regulatory Affairs, Oncology

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Clinical Research Organizations (CROs)
- Imaging Lab Services
- Electronic Data Capture (EDC)
- Data Management Software
- Clinical Manufacturing
- Data Analytics

WHO SHOULD ATTEND:

Contact Q1 Productions:

CHICAGO
500 N. Dearborn, Suite 500
Chicago, IL 60654
Phone: 312.822.8100
Fax: 312.602.3834

Q1 Productions designs and develops webinars, training courses, conference programs and forums aimed at specifically targeted audiences in order to provide strategic and timely information. Through a rigid production process focused on end-user research and design, our team is able to understand the immediate business concerns of today’s leading executives. Whether focusing on new or pending legislative issues, enhanced business processes or technologies that will drive efficiency and customer service, our programs provide solutions to the urgent needs of our attendees.

PREVIOUS PARTICIPANTS IN Q1 CONFERENCES INCLUDE:

Abbott  
Abraxis Biosciences  
Astellas Pharmaceuticals  
AstraZeneca  
ATS Medical  
B.Braun  
Bausch & Lomb  
Baxano  
Baxter  
Bayer Healthcare  
Becton Dickinson  
Biogen Idec  
BioMarin  
Boehringer-Ingelheim  
Boston Scientific  
Brahms USA  
Bristol-Myers Squibb  
Celgene  
Cordis  
Covidien  
CR Bard  
Cubist Pharmaceuticals  
Dalichi Sankyo  
Dentsply  
Eli Lilly  
EMD Serono  
EV3  
Ferring Pharmaceuticals  
Forest Laboratories  
FDA  
GE Healthcare  
Genentech  
Genzyme  
Gilead Sciences  
GlaxoSmithKline  
Hologic  
Imclone Systems  
Impax Labs  
InSound Medical  
Intermune  
Merck  
Millennium  
Myriad Genetics  
NDI Medical  
Novartis  
NuVasive  
Onyx Pharmaceuticals  
Ortho-McNeil  
OSI Pharmaceuticals  
Otsuka America  
Pacific Biosciences  
Par Pharmaceuticals  
Pfizer  
Philips Medical  
Purdue Pharmaceuticals  
Qiagen  
Regeneron  
Rox Medical  
Saladax Medical  
Salix Pharmaceuticals  
Sanofi-Aventis  
Seattle Genetics  
Sepracor  
Shire  
Siemens Healthcare  
Sigma Tau Pharmaceuticals  
Smith & Nephew  
Spinal Modulation  
St. Jude’s Medical  
Stryker  
Synta Pharmaceutical  
Takeda  
Talecris BioTherapeutics  
Targacept  
Teva Pharmaceuticals  
Theravance  
Thoratec  
Vertex Pharmaceuticals  
Watson Pharmaceuticals  
Zimmer  
And Many More!