CTI CLINICAL TRIAL & CONSULTING

Newsletter

Where Life-changing Therapies Turn First™

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Volume 13, Issue 4

CTI Experts Can Help With The Latest Regulatory Pathway - PRIME

At CTI, we understand that a regulatory strategy should consider critical regulatory and therapeutic information, as well as evaluate the unique characteristics of each product to devise a realistic and effective strategy. We have the ability to bridge the gap between strategy and execution. Our team of multidisciplinary drug and device development professionals, including international regulatory and medical experts, rely on past drug development experience, previous interactions with regulatory authorities, tenure serving on regulatory committees as reviewers, and current data in the public domain to support our sponsors' programs. We have a history of more than 100 drug and device approvals, and countless regulatory designations. Choosing CTI as a partner for strategic regulatory needs adds value to programs by developing realistic plans and strategies that efficiently move programs forward.

The European Medicines Authority (EMA) announced last month their new PRIME program, designed to speed review and approval of investigational drug therapies that demonstrate exceptional promise in early clinical trials. The PRIME program will cover many of the same investigational drug products as the FDA's Breakthrough Designation program, which has been in place in the US since late 2012.

Like US Breakthrough Designation, PRIME is designed to strengthen regulatory support for medicines that address an unmet medical need and show early evidence of a major therapeutic advantage over existing treatments or target conditions for which no approved treatments exist.

PRIME is expected to:

- lead to better informed development plans
- provide frequent advice and consultation to sponsors
- improve the quality of marketing authorization applications
- promote regulatory awareness, thus shortening review times.

The EMA guidance document notes that the appropriateness of accepting an investigational drug into the PRIME scheme will be judged by both the magnitude of the clinical effect and the relevance of the observed clinical outcomes on morbidity, mortality, or progression of the underlying disease.

Unlike the US FDA Breakthrough program, which requires clinical data from all applicants, data requirements for the PRIME program depend on the kind of sponsor who is applying. Specifically, applicants from the academic sector and applicants who have been designated Small or Medium Enterprises (SMEs) in Europe may be accepted into the PRIME program based on demonstration of proof-of-principle with only nonclinical data or perhaps some very early clinical data. Biotech and drug companies without SME designation will need a larger amount of clinical data to support their eligibility for the PRIME program - but can still apply at a fairly early stage in clinical development if efficacy and safety data are strong enough to support eligibility.

For those applicants accepted into the PRIME program, the assistance from EMA will include:

- assignment of a dedicated EMA contact point
- early appointment of a Rapporteur, who will lead the EMA

CTI Cares Spotlight

National Alopecia Areata Foundation

National Alopecia Areata Foundation

The National Alopecia Areata Foundation (NAAF) serves the community of people affected by an autoimmune skin disease called alopecia areata that results in hair loss and emotional pain. NAAF supports research to find a cure or acceptable treatment for alopecia areata, supports those with the disease, and educates the public about alopecia areata.

Nominated by: Megan Ratley, In-house Clinical Research Associate

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assessment team and coordinate scientific and regulatory advice to the sponsor throughout the development program and into assessment of the marketing authorization application (MAA).
• advice on next milestones and key points in the drug development process when scientific advice should be requested
• a kick-off meeting to discuss development plans and regulatory pathways, involving the Scientific Advice Working Party (SAWP) and a multidisciplinary group of experts from relevant committees, such as the Paedeatric Committee (PDCO), Committee for Orphan Medicinal Products (COMP), and Committee for Advanced Therapeutics (CAT)
• confirmation of eligibility for accelerated assessment of the MAA.

Many of the drug development programs supported by CTI will be potential candidates for the PRIME program, since many are cutting-edge therapies with potential to address unmet medical needs in serious conditions - often for orphan populations. The ability of this program to coordinate advice among the SAWP, PDCO, COMP, CAT and Health Technology Assessment (HTA) bodies is likely to be extremely helpful in allowing these development programs to move forward and reach the market as quickly as possible.

For more information:
www.ctifacts.com
513.598.9290

Upcoming Meeting Spotlight

International Society for Pharmacoeconomics and Outcomes Research
21st Annual Meeting
Washington DC
May 21-25 2016

Stop by and visit us at
Booth #42/43 throughout the meeting!

Click here to schedule a meeting with us while we're at ISPOR!

Upcoming Poster/Presentation Spotlight

Heart Rhythm 2016 - 37th Annual Scientific Sessions

May 4-7 2016
San Francisco, CA

Cost Comparison of Radiofrequency Catheter Ablation versus Cryoablation for Atrial Fibrillation in Hospitals Using Both Technologies
Wednesday May 4 PO01-58

International Society for Pharmacoeconomics and Outcomes Research
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An Incremental Cost Analysis of Orbital Atherectomy Plus Angioplasty compared to Angioplasty
Monday May 23 Session I, PCV34

Impact of a Limb Salvage Program on the Economic Burden of Amputation in the United States
Monday May 23 Session I, PCV33

Racial Disparities in Amputation Rates among Native Americans with Peripheral Artery Disease (PAD): Analysis of the Healthcare Cost and Utilization Project (HCUP) Database
Monday May 23 Session I, PCV89

Racial Disparities in Amputation Rates for Patients with Peripheral Artery Disease: Long-term Trends and Projections to 2020
Monday May 23 Session I, PCV90

Racial Disparities in Amputation Rates for the Treatment of Peripheral Artery Disease (PAD) using the Healthcare Cost and Utilization Project (HCUP) Database
Monday May 23 Session I, PCV91

Operating Room Variable Cost of Transcatheter Aortic Valve Replacement (TAVR)
Monday May 23 Session I, PCV44

Acute Myeloid Leukemia (AML): A Retrospective Claims Analysis of Resource Utilization and Expenditures for De Novo Patients from First Line Induction to Remission and Relapse
Tuesday May 24 Session III, PNC181

Differences in Clinical Outcomes and Costs Associated with the Use of Staple Line Buttress in Bariatric Surgery
Tuesday May 24 Session IV, PSY30

New Additions & Promotions at CTI

Jeff Barbian promoted to Study Coordinator

Adam Brown joins as Research Associate

Brianna Earle joins as Safety Scientist II

Kristen Harding promoted to Study Coordinator

Chris Kaas promoted to Assistant Director, Information Technology

Bret Marshall promoted to Study Coordinator

Upcoming Meetings We Will Be Attending

American Society of Gene and Cell Therapy (ASGCT)
Washington DC
May 4-7

Outsourcing in Clinical Trials Europe 2016
Paris, France
May 17-18

International Society for Pharmacoeconomics and Outcomes Research 21st Annual International Meeting (ISPOR)
Washington DC
May 21-25

Join our Team!! We're looking for individuals to fill these positions:

Associate Director, Health Outcomes Research (Cincinnati, OH; Philadelphia, PA; Raleigh, NC)

Clinical Research Assistant (Cincinnati, OH)

Clinical Research Associate (US, Germany, France, Spain, Australia, Brazil, Korea, Taiwan, Japan, Argentina)

Medical Director (Cincinnati, OH)

Molly McKean promoted to Project Manager

Dan Minham joins as IT Validation Analyst

Jeff Osterhaus promoted to Senior Manager, Business Development Operations

Afua Premoh joins as IT Support Specialist

Katherine Thompson joins as Clinical Research Coordinator I

Jeni White promoted to Clinical Operations Coordinator

European Conference on Rare Disease & Orphan Products (ECRD)
Edinburgh, UK
May 26-28

American Society Clinical Oncology 2016 Annual Meeting (ASCO)
Chicago, IL
June 3-7

BIO International
San Francisco, CA
June 6-9

American Transplant Congress 2016
Boston, MA
June 11-15

American Society of Health Economists Biannual Conference (ASHEcon)
Philadelphia, PA
June 12-15

DIA 2016
Philadelphia, PA
June 26-30

To schedule a meeting with us at one of these, please click here

Study Coordinator (Cincinnati, OH)

Study Manager (Cincinnati, OH; Raleigh, NC; Philadelphia, PA; San Francisco, CA; Ulm, Germany; Paris, France; Madrid, Spain)

Vice President, Clinical Monitoring (Cincinnati, OH)

Click here for more information and to apply!