

## Immuno-Oncology: Personalized Medicine of the Future

The field of immuno-oncology seems to be the hottest topic in biotech. Following the approval of Rituximab, the first antibody to treat cancer in 1997, the field has been growing in momentum. The first cellular cancer vaccine, Sipuleucel-T, was recently approved (2010), and more novel and innovative ideas are being explored every day, including how to reprogram an immune system to target cancer. The field is dynamic and changing, exploring therapeutic vaccines and modified t-cell therapies, as well as learning to target HLA ligands and t-cell epitopes specific to the patient and the tumor. CTI has had the unique opportunity to be part of this exciting and dynamic evolution over the past two decades.

Several immono-oncology therapies have recently been approved or will be approved in the very near future by regulatory authorities around the world. These include agents against melanoma, lung, colorectal, renal and prostate cancers. Each of these programs have unique challenges, including defining pre-clinical models, negotiating regulatory pathways into the clinic and to approval, managing complex patient populations in clinical trials, organizing a comprehensive manufacturing and supply depot approach to the investigational product, and assessing a pricing and reimbursement strategy that can be defended to payers, healthcare providers and patients. CTI can assist in all of the above assessments. From our global regulatory affairs department, who interacts frequently with authorities, to our experienced clinical operations team, who can expedite enrollment and ensure quality data to support approval, to our health economics outcomes research group, who performs analysis to develop optimal pricing and reimbursement strategies - CTI has played an integral role in many of the leading programs currently in development today.

Immuno-oncology is the frontier of personalize medicine, and it is an area CTI excells in. Approximately 30% of CTI's most recent programs are in oncology and cell therapy, and over half of our recent projects are deeply rooted in immunological indications. Our approach has stayed true to our therapeutic focus and clinical trial expertise. We focus in complex and critically ill patient populations, bringing a huge reservoir of immunology and cellular therapy expertise to these programs.

> For more information: Ryan Gifford - Assistant Director, Business Development - rgifford@ctifacts.com

> > www.ctifacts.com 513.598.9290

Cincinnati Children's

Cincinnati Children's Hospital Cancer Survivorship Center

Cincinnati Children's Cancer Survivorship Center provides specialized medical care and psychosocial support to childhood cancer survivors — continuously and without interruption through adulthood. Cincinnati Children's established the program 25 years ago as one of the first of its kind in the country.

Greatly expanded in the past five years, the Cancer Survivorship Center today cares for more than 1,800 children and adult survivors, who range in age from 5 to 65+ years old.

The Cancer Survivorship Center is designed for people who were diagnosed with a pediatric cancer at least five years ago and completed treatment for their cancer at least two years ago.

Nominated by: Kathy Wekselman -Senior Director, Regulatory & Scientific Affairs

Click here for more information and to donate!

## Successful Immuno-Oncology Programs

Experienced regulatory strategy negotiations	Expert clinical operations dealing with complex patients
Efficient trial supply management	Therapeutic expertise
Strong site and	Pricing/

investigator relationships Pricing/ Reimbursement optimization

### **Recruiting Spotlight**

Join us and work on some of the most groundbreaking clinical research, including trials in regenerative medicine, rare disease, first-in-man, transplantation, and other complex disease areas.

Clinical Research Associate (US, Germany, France, Spain, Brazil, Australia)

-Experience in monitoring complex indication, inpatient, rare disease and oncology trials

-Our CRAs monitor Phase I through Phase IV clinical research studies with their knowledge of the drug development process, ICH/ GCP and applicable local regulations

#### Director/Manager Health Outcomes Research (United States)

-Interact with clients and multidisciplinary team to determine health outcomes / economic needs

-Design and conduct analysis of large scale databases, retrospective data analyses, clinical analyses

-Develop publications including abstracts, manuscripts, white papers, briefing documents based on analyses

Manager, Proposal Development

#### (Cincinnati, OH)

-Develops budgets, proposals, work order attachments, and CTI intercompany work orders

-Performs financial and analytical functions as needed and coordinates with partners and 3rd party subcontractors as required

> For more information and to apply: www.ctifacts.com/careers 513.598.9290

#### Upcoming Meetings We Will Be Attending

Stem Cell Meeting on the Mesa La Jolla, CA - October 7 - 9

To schedule a meeting with us at one of these, please <u>click here</u>

# New Additions & Promotions at CTI

Elizabeth Gabbard joins as Study Coordinator

Bonnie Grzegorzewski promoted to Senior Project and Account Manager

Michaela Heekin joins as Research Associate

Sibylle Lawson promoted to Assistant Director, Clinical Trials

Bret Marshall joins as Research Associate

Ashley Martz joins as Study Coordinator

Elizabeth Newell joins as Assistant Study Manager

Els Roggeman promoted to Senior Clinical Project Manager

Günter Stetter promoted to Senior Director, Clinical Operations Europe

Michael Wyble promoted to Study Coordinator

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

Administrative Assistant, Business Development (Cincinnati, OH)

Clinical Data Manager (Cincinnati, OH)

Clinical Research Associate (US, Germany, France, Spain, Australia, Brazil)

Corporate Counsel (Cincinnati, OH)

CRA Manager (Cincinnati, OH)

Director/Manager Health Outcomes Research (United States)

Manager, Proposal Development (Cincinnati, OH)

Study Manager (Cincinnati, OH; Raleigh, NC; Philadelphia, PA; San Francisco, CA)

<u>Click here for more information and</u> to apply!