CTI CLINICAL TRIAL & CONSULTING
Where Life-Changing Therapies Turn First™

July Newsletter

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Will Right-to-Try Legislation Impact Patient Care?

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The importance of bringing life-changing therapies to patients in need is ingrained in CTI's culture, from our mission statement to the work we do every day. Over the 15 years we have been in business, CTI has managed numerous Expanded Access Programs (EAP), Named Patient Programs, Treatment INDs, Emergency INDs (eINDs), and other pathways to get life-saving treatments to patients in need of them. According to articles from Regulatory Affairs Professional Society and ABC News about 1,000 patients in the United States are treated through these types of programs annually. In the past few years, CTI has been a part of bringing life-saving therapies to more than 300 patients using these types of named patient or emergency use pathways.

Expanded Access Requests Accepted by FDA

	2013	2012	2011	2010
Expanded Access IND				
Single Patient Emergency IND	313	287	442	500
Single Patient IND	550	496	652	484
Intermediate Size IND	27	14	0	2
Treatment IND	0	0	1	0
Subtotal	*890*	*797*	*1094*	*986*
Expanded Access Protocol				
Single Patient Emergency Protocol	2	0	3	0
Single Patient Protocol	62	121	89	16
Intermediate Size Protocol	8	8	1	5
Treatment Protocol	12	10	11	7
Subtotal	*84*	*139*	*104*	*28*
Total	**974**	**936**	**1198**	**1014**

According to "Regulatory Explainer: FDA's Expanded Access (Compassionate Use) Program" by Alexander Gaffney http://www.raps.org/regulatoryDetail.aspx?id=18343

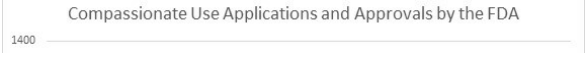
Recently, we have received a number of inquiries on the Right-To-Try legislation that has been signed into law in a handful of states in the United States, and is in progress in several others. The objective of the legislation is to give patients suffering from terminal illnesses, who have no other approved treatment options, the "Right-to-Try" experimental medications that are not yet approved. This is the same basic purpose that EAPs, eINDs and Named Patient Programs serve, but with one fundamental difference - the Right-to-Try legislation removes FDA oversight. This legislation is championed by the Goldwater Institute and includes the key language:

"*The use of available investigational drugs, biological products and devices is a decision that should be made by the patient with a terminal disease in consultation with his or her physician not a decision to be made by the government.*"

The real question here - Will removing government oversight give terminal patients better access to potentially lifesaving therapies that are currently in development?

Maybe.

Under the current process, if a patient would like to try an experimental medicine - the treating physician first needs to contact the manufacturer of that medicine (the pharmaceutical or biotechnology company) to explain the circumstances and request the drug. A request is sent to the FDA only after the manufacturer of the medicine grants approval. Historically, the FDA has approved 99% of these types of requests, some within hours based on a phone call approval, according to multiple sources.



CTI Cares Spotlight

Fisher House

Fisher House Foundation is best known for a network of comfort homes where military and veterans' families can stay at no cost while a loved one is receiving treatment. These homes are located at major military and VA medical centers nationwide, close to the medical center or hospital they serve.

Joseph House - Located in Cincinnati, OH

The Joseph House is certified by the Ohio Department of Mental Health and Addiction Services and offers housing and In-patient chemical dependency treatment at our Marx Recovery Center and housing, Out-patient treatment and Reintegration support in our Ready & Forward program.

Nominated by:
Sharon Blackaby - Executive Administrative Assistant

Click here to learn more and donate!

According to "Push to Get Experiment Drugs With Social Media Pressure on the Rise" by Sydney Lupkin via World News and ABC News http://abcn.ws/1r8QGpy

Expanded Access Requests Rejected by FDA

	2013	2012	2011	2010
Expanded Access IND				
Single Patient Emergency IND	2	2	1	16
Single Patient IND		2		
Intermediate Size IND	1			
Treatment IND				
Subtotal	*3*	*4*	*1*	*16*
Expanded Access Protocol				
Single Patient Emergency Protocol				
Single Patient Protocol				
Intermediate Size Protocol				
Treatment Protocol				
Subtotal	*0*	*0*	*0*	*0*
Total	**3**	**4**	**1**	**16**

According to "Regulatory Explainer: FDA's Expanded Access (Compassionate Use) Program" by Alexander Gaffney http://www.raps.org/regulatoryDetail.aspx?id=18343

Under Right-to-Try legislation - the first and most limiting step is the same; the manufacture or the medicine must give their approval first. Removing the FDA's approval will change less than 1% of the expanded access request.

Currently - to treat a patient under an EAP or eIND type of program, the investigational product must have an IND application filed in the United States. Unfortunately, many promising investigational products are being tested outside the USA and do not have an IND filled with the FDA. It is still unclear if Right-to-Try legislation will give American patients access to investigational medicines being developed outside the US.

CTI will continue to be at the forefront of this legislation and advise our clients on the interpretation and use of Right-to-Try legislation.

For more information:

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513.598.9290

CTI Upcoming Meeting Spotlight

World Transplant Congress 2014

Stop by and visit us at Booth #310 throughout the week!

To schedule a meeting with us while we're here, please click here.

Upcoming Meetings We'll be Attending

2014 World Transplant Congress
San Francisco - July 26 - 31

New Additions & Promotions at CTI

Tommie Grotjan joins as Senior Study Coordinator

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

Tableau Customer Conference
Seattle, WA - September 8 - 12

American College of Clinical Pharmacology
Atlanta, GA - September 14 - 16

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

Jasmin Oeztekin joins as Corporate Counsel, Europe

Donna Poole joins as Patient Recruiter

Elena Rodriguez joins as Senior Auditor, Quality Assurance

Silke Rottman, PhD joins as Auditor, Quality Assurance, Europe

Judith Straub joins as Information Technology Support Specialist, Europe

Christie Crosby transitions to Human Resource Generalist

Elizabeth Valentine transitions to Regulatory Specialist II

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

Clinical Research Associate Manager (Cincinnati, OH)

Medical Director (Cincinnati, OH)

Senior Regulatory Specialist (Cincinnati, OH)

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

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