



07Dec2017

Mr Tim Stoddard
Flatiron Health
200 Fifth Ave 8th Fl
New York, NY 10010

Re: Protocol #: F1:01.01
IRB Tracking #: FLI1-17-070

"The Flatiron Health Analytic Database"

Dear Mr Stoddard,

This letter is to inform you that the following document(s) received IRB approval on 06Dec2017:

- Amendment 42 version 2.0 dated 05 Dec 2017

Please note: If any of the above approved items require translation, please submit via MyConnexus using the Translation Request Form. This form can be found at www.cgirb.com/forms.

If you have any questions, please do not hesitate to contact us.

Sincerely,

Dana Moeller
Lead, Study Management

cc: Dr. Amy Abernethy, Flatiron Health (Web Portal)
Mr. Tim Stoddard, Flatiron Health (Web Portal)



Investigator List

07Dec2017

IRB Tracking Number: FLI1-17-070

Protocol ID: F1:01.01

Sites: 1

Investigator	Approved	City State	Translation	Site IC
Abernethy, Amy	08Mar2017	New York NY		

Copernicus Group IRB
5000 CentreGreen Way, Suite 200
Cary, NC 27513

Experience and Innovation in Ethical Review ®

Telephone: 919-465-4310
Toll-Free: 888-303-2224
Fax: 919-465-4311
E-Mail: irb@cgirb.com
Web: www.cgirb.com

*Confidentiality Notice: This document is for the sole use of the intended recipient(s) and may contain confidential and privileged information.
Any unauthorized review, use, disclosure or distribution is prohibited.
If you are not the intended recipient, please contact the sender and destroy all copies of the original message.*

Institutional Review Board (IRB) #: 15-159v3.0

Sub-Study Title: Effectiveness of Cetuximab in Left-sided vs. Right-sided Metastatic Colorectal Cancer in the Real World

Sub-Study Date: 05 Dec 2017

Sub-Study #: 42 version 2.0 which is in reference to parent protocol # 15-159. Reference the parent protocol for full information regarding the Flatiron Health Analytic Database as it applies to this sub-study.

Principal Investigator (PI): Rebecca Miksad

1. Purpose and Objectives

Primary

Compare the effectiveness of cetuximab and bevacizumab as a first-line treatment of KRAS wild-type metastatic colorectal cancer (mCRC) by tumor sidedness (left-sided and right-sided) in the real world.

2. Background and Significance

A study comparing frontline therapy with bevacizumab (avastin) or cetuximab (Erbix) combined with Folfex or Folfiri resulting in a comparable survival benefit in patients with KRAS wild-type mCRC. (Broderik, 2014) A retrospective analysis from a clinical trial found that the location of the primary tumor within the color can predict survival and may help inform optimal treatment selection. (The ASCO Post, 2016)

3. Design and Procedures

Study Design:

This is a retrospective outcomes study with secondary use of data derived from the Flatiron Health Analytic Database. The primary objective focuses on comparing the effectiveness of cetuximab and bevacizumab as a first-line treatment of KRAS wild-type mCRC by tumor sidedness (left-sided and right-sided) in the real world.