From: OC GCP Questions
To: [redacted]
[redacted]
Subject: Real World Evidence
Date: Monday, July 30, 2018 2:00:00 PM
Attachments: [redacted]

Good morning –

Please see FDA's Real World Evidence website. Real World Evidence There is an email address at the end of the page. Or email Center for Devices (CDER) Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov if the study you mentioned is a drugs study.

If the study is a device study, please also see the Center for Devices (CDRH) webpage on Real World Evidence
Workshops & Conferences (Medical Devices) > Webinar - Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices - October 10, 2017 There is an email on the front page of the guidance inserted in the webpage. You may contact CDRH using this email.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, July 30, 2018 10:02 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Real World Evidence

Good morning,

Given the recent attention on Real World Data and Real World Evidence, I am seeking clarification on whether research conducted by an investigator using such data in a non-interventional study design (e.g., records review or observational) with no industry support and no intention to submit the data to the FDA is subject to the FDA regulations at 21 CFR 50 and 56?

Many thanks,

[redacted]