From: OC GCP Questions
To: [redacted]
Subject: Patient Registries - GCP question
Date: Wednesday, October 17, 2018 8:04:05 AM

Good morning –

It is best to contact FDA's Center for Drugs (CDER), Office of Medical Policy (OMP) at CDEROMP@fda.hhs.gov

Kind regards,

The OGCP Group

From: [redacted]
Sent: Sunday, October 14, 2018 8:35 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: RE: Patient Registries - GCP question

Dear Office of Good Clinical Practice,

The [redacted] is currently working with [redacted] and FDA-Catalyst/Office of Medical Policy to leverage FDA's My Study App for our registry, [redacted] The Foundation is optimistic about ongoing 21CC activities to leverage real world data for real world evidence applications. We understand that validation framework is still in development to operationalize RWD collection, however, we were wondering, from the Agency's perspective, if there are best practices established to get registries GCP validated? And if so, if you could point me to those resources.

Best,

[redacted]