FDA Tool Captures Real World Data from Patients

The FDA has announced a new app meant to capture real world data from patients. This information will be used for drug development and safety monitoring. It is a voluntary effort and patient privacy is protected, according to the FDA press release.

However, it appears to allow computerized medical records to be reviewed prior to consent to find potential participants. Then these individuals are targeted for recruitment, and then they are asked to sign consent forms for research. So, it appears an intrusion happens before the consent form is signed. Keep that in mind when you’re asked to participate, and ask detailed questions about access to all the data in the app and in your medical record.


Presented daily by Twila Brase, President, Citizens’ Council for Health Freedom.