

0910-0847

Data to Support Social and Behavioral Research as Used by FDA

Project Summary: Health Care Providers' Understanding of Opioid Analgesic Abuse-Deterrent Formulations

FDA/CDER/OCOMM used Generic IC 0910-0847, Data to Support Social and Behavioral Research as Used by FDA, to conduct qualitative focus group research to inform our understanding of healthcare professionals' knowledge, attitudes, experiences, and behaviors related to abuse deterrent formulation opioids and the terminology used to describe them. The project received OMB approval on 3/1/2019 under ICR# 201709-0910-002.

Problem being investigated:

Recognizing their potential to help combat the opioid epidemic, the Food and Drug Administration's (FDA's) (2017) Opioids Action Plan calls for expanding access to abuse-deterrent formulations, or ADFs. Although ADF prescribing presents opportunities for healthcare providers (HCPs) to prevent opioid abuse and addiction, little is known about their attitudes, perceptions, and behaviors related to these medications, and evidence suggests considerable variability in their knowledge about them. Given the magnitude and scope of the opioid crisis, and FDA and Congressional concerns about HCP misunderstanding about ADF products and terminology, this objective of this initial focus group phase of this project is to explore HCPs' knowledge, attitudes, perceptions, and behaviors related to ADF opioid analgesics. This will include their perceptions of the terminology and information used to describe these drugs and to solicit input on other language that may better describe ADF products that hold potential for decreasing the nation's serious opioid epidemic. This qualitative evidence will be used to inform subsequent quantitative phases of the project, which will be submitted separately for OMB review and approval.

Methodology used to collect the data:

Online qualitative focus groups were conducted using a video-based platform with four types of HCPs who prescribe or dispense opioids: physicians, nurse practitioners, physician assistants and pharmacists. Two trained moderators conducted the groups, which lasted 90 minutes or less, using a semi-structured discussion guide approved by OMB. HCPs were recruited by professional market research firms using a structured screener developed to identify HCPs who met certain eligibility criteria. The screener was also approved by OMB. The groups were audio- and video-recorded with participants' consent, and FDA researchers were allowed to listen in silently without interacting with the participants. Participants were required to provide consent prior to participation.

Burden Imposed:

40 burden hours were approved to conduct the recruitment screening to ensure that selected participants met the eligibility criteria included in the pre-approved screening questionnaire. This was based on an estimated time of 10 minutes to screen 240 respondents. An additional 216 burden hours were approved for the focus groups (based on 144 participants and 90-minute focus groups) which amounts to 256 hours total.