FDA DOCUMENTATION FOR THE GENERIC CLEARANCE ON DATA TO SUPPORT DRUG PRODUCT COMMUNICATIONS (0910-0695)

TITLE OF INFORMATION COLLECTION: Educating Groups Influencing Generic Drug Use (interviews)

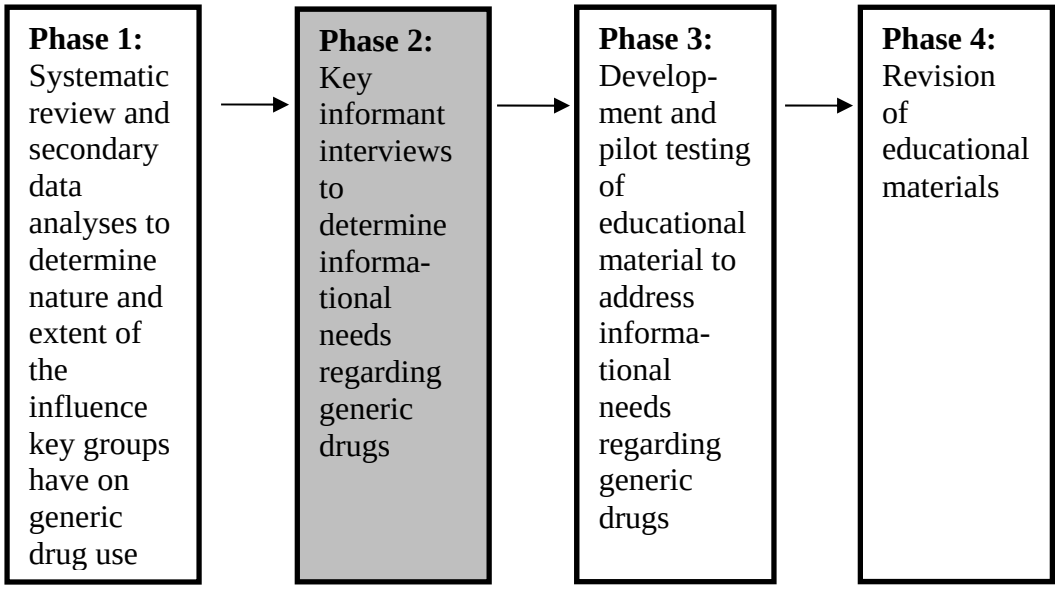
DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of Need:

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is seeking OMB approval under the generic clearance 0910-0695 to conduct key informant interviews (KII) for the project "Educating Groups Influencing Generic Drug Use."

Based on the supporting statement for generic clearance 0910-0695,[1] the purpose of information collection under this generic clearance is "to provide tools to assess the need for communications on specific topics and to assist in the development and modification of communication messages to promote public health and compliance with regulations." The specific collection described in this memo aims to determine the informational needs of a variety of groups influencing generic drug use in order to develop communications addressing gaps in knowledge regarding generic drugs and promoting generic drug use. Exhibit 1 illustrates the full set of research phases for this project; please note that this information collection request concerns only Phase 2.

Exhibit 1. Overview of Research Phases



[1] http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201509-0910-002

Congress passed the Generic Drug User Fee Amendments (GDUFA, Title III of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144)) in July 2012. Under GDUFA, FDA obtains industry and public input to create regulatory science initiatives regarding research on generic drugs that advance public health.[2] Once marketed, certain generic drugs are often not preferred over brand drugs[3] even though generic drugs generally cost less than brand drugs.[4] Research to characterize the key influencers of generic drug use (particularly for drug classes with low generic drug use), including their knowledge base and perceptions toward generic drugs, is needed to effectively design and deliver communications about generic drugs to the key groups influencing consumer acceptance and use of generic drugs. To address this regulatory science need regarding generic drugs, the FDA entered into a cooperative agreement with investigators at Auburn University (Auburn) and IMPAQ International (IMPAQ) (Grant Number 1U01FD005486-01).

In addition to prescribers, other groups such as pharmacists, patients and their caregivers, formulary managers / pharmacy and therapeutics (P&T) committees, federal and state policy makers, and larger purchasers of drugs (group purchasing organizations, pharmacy chains, etc.) also influence the nature and extent of generic drug use.[5,6]

Through a cooperative agreement with Auburn and IMPAQ, the informational needs of these key groups regarding generic drugs will be explored by key informant interviews.

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[2] http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm370952.htm

[3] Scher, S. (2013) The Branded Advantage. *Ophthamol Mgmt*. July: p18 http://www.ophthalmologymanagement.com/printarticle.aspx?articleID=108618

Alloway, RR, Isaacs R, Lake K, Hoyer P, First R, Helderman H, Bunnapradist S, Leichtman A, Bennett MW, Tejani A, Takemoto SK. (2003) Report of the American Society of Transplantation Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants. *A J Transpl* 3: 1211.

Liow K, Barkley GL, Pollard JR, Harden CL, Bazil CW. (2007) Position statement on the coverage of anticonvulsant drugs for the treatment of epilepsy. *Neurology* 68: 1249.

American Thyroid Association, The Endocrine Society, and American Association of Clinical Endocrinologists. (2004) Joint Statement on the U.S. Food and Drug Administration's Decision Regarding Bioequivalence of Levothyroxine Sodium. *Thyroid* 14: 486.

[4] IMS Institute for Healthcare Informatics. (2013) Avoidable Costs in U.S. Healthcare: The $200 Billion Opportunity from Using Medicines More Responsibly. http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS Institute/RUOM-2013/IHII_Responsible_Use_Medicines_2013.pdf

[5] Tang Y, Gellad WF, Men A, Donohue JM. (2014) Impact of Medicare part D plan features on use of generic drugs. *Medical care*. 52(6):541-548.

[6] Berg MJ, Gross RA, Haskins LS, Zingaro WM, Tomaszewski KJ. (2008) Generic substitution in the treatment of epilepsy: patient and physician perceptions. *Epilepsy & behavior* 13(4):693-699.

2. Intended use of Information:

Data collected from these key informant interviews will be used to inform the development of educational materials to address the key groups' knowledge gaps regarding generic drugs (Phase 3).

3. Description of Respondents:

Key informants in each of the following 6 groups will be interviewed:

- Patients / caregivers
- Prescribers
- Pharmacists
- Formulary managers
- Policymakers (federal and state)
- Large purchasers of drugs (group purchasing organizations, pharmacy chains, etc.)

4. Date(s) to be Conducted:

- September 15, 2016 – March 14, 2017

5. How the Information is Being Collected:

Recruitment

A marketing research firm, Baltimore Research, will assist with recruitment and scheduling. Baltimore Research will utilize private lists to recruit physicians, pharmacists, patients, and/or caregivers. Participant screeners differ by group (see Table 1 below and attachments). Participants will receive a reminder from Baltimore Research of their scheduled interview two days prior to the scheduled interview. The Auburn University/IMPAQ research team will develop a list of formulary managers, policymakers, and large purchasers of drugs for recruitment. Participants for these three groups will be identified in collaboration with the FDA and GPhA and no formal screeners will be utilized in identifying members for these three groups. More targeted, informal recruitment will be conducted with these three groups in order to allow the research team to better identify participants from various stages of generic drug utilization (e.g. large purchasers) or across different levels of policy (e.g. state or federal levels of policymaking) rather than general eligibility as with the patient, pharmacist and physician groups.

Table 1. Eligibility for Respondent Groups

Group	Eligibility
Physicians	Prescribed a drug in a community/institution setting in the past month
Pharmacists	Practicing and dispensing/managing at a pharmacy in any setting (chain, independent, or hospital)
Patient/Caregiver	Is 19 years or older, and has taken a generic drug/or serves as a proxy to a patient who has taken a generic drug in the past 6 months
Formulary Managers	Current member of a P&T committee at the hospital or health plan level
Policymakers	Current federal or state government employee with jurisdiction over generic drug policy
Large Purchasers of Drugs	Bulk purchaser of drugs for large retail chains (e.g., with more than 10 pharmacies) or group purchasing organization

Key Informant Interviews

Skilled interviewers from Auburn and IMPAQ will conduct up to sixty (60) phone interviews with no less than nine participants from the patient/caregiver, physician and pharmacist groups and no less than four participants from the formulary managers, policymakers and large drug purchasers of drugs groups. Each sixty (60) minute interview will be based on a list of questions (interview guides attached), with additional probing and discussion. Interviews will be audio recorded and transcribed (see below).

Participation is voluntary. Before the interview begins, the facilitator will obtain verbal consent from the participant to record the session. The informational letter (attached) also mentions the audiotaping. The interviewer will review the informational letter and request permission to audio record the interview prior to the start of the interview.

Transcription of the audio recordings will be used to analyze participant responses.

6. Confidentiality of Respondents:

Auburn, IMPAQ, Baltimore Research, and FDA will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The interviewees will be informed about how the recordings are used in the analyses, and assured that the recorded data are kept strictly confidential. Recordings will be saved on a secure webserver prior to being stored on a secure server at the IMPAQ headquarters. Once recordings are downloaded to the IMPAQ server, they will be deleted from the webserver. Audio recordings will be transcribed, and transcriptions will be saved and stored in a de-identified format on the IMPAQ server. Verbatim quotes included in the final report will not be attributed to any individual.

Data from this study may be used in publications and/or presentations. Participant names and other identifying information will be removed before the data is used. Identifying information will not be used in publications unless written consent from participants is obtained.

7. Amount and Justification for any Proposed Incentive:

The proposed compensation for each group may be found in Table 2. The proposed compensation or "incentive" is not a reward or salary. Rather, it is a stimulus to participate in the interview. Proposed incentive rates are in accordance with standard practice and based on several factors including education and training, level of expertise, access to participants, and willingness to participate. More specifically, incentives for subspecialties of physicians and pharmacists are based on these factors as well as the necessity to include representation from these subspecialties for their unique role in generic drug utilization. It is well documented in the research that money spent on the promotion of prescription drugs varies significantly between primary care providers and specialists, ultimately influencing their prescribing patterns[7] and oncologists are likely to prescribe very high cost drugs.[8] Likewise, differences in setting may uniquely influence retail-based pharmacists and hospital-based pharmacists.[9] Therefore, to ensure that we capture a complete picture of the beliefs, informational needs, etc., of generic drugs among primary care providers as well as specialists and high cost drug prescribers such as oncologists and surgeons, it is imperative that the research team be able to recruit participants from each of these subspecialties.

[7] Kornfield, R., Donohue, J., Berndt, E., & Alexander, C. (2013). Promotion of Prescription Drugs to Consumers and Providers, 2001–2010. PLOS One, 8(3), 1-7.

[8] Experts in Chronic Myeloid Leukemia. (2013). The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: From the perspective of a large group of CML experts. Blood, 121(22), 4439-4442.

[9] Chiarello, E. (2012). How organizational context affects bioethical decision-making: Pharmacists' management of gatekeeping processes in retail and hospital settings. Social Science and Medicine, 98, 319-329.

Incentives are based on Baltimore Research's experience. Offering an incentive below these rates may result in increased costs exceeding the amount saved with a lower incentive. Consequences of insufficient incentives include increased time and cost of recruitment, increased "no-show" rates, and increased probability of cancelled or postponed interviews.

Table 2. Respondent Compensation

Group	**Incentive Amount**
Physicians[10]	
• Primary Care Providers	$175
• Specialist	$250
• Oncologists and Surgeons	$375
Pharmacists[11]	
• Retail	$150
• Hospital	$200
Patient/Caregiver	$50
Formulary Managers	$150
Policymakers	Not Applicable
Large Purchasers of Drugs	$150

Incentives will be distributed upon completion of the interviews. For those participants receiving $50 incentives (i.e., patients and caregivers), the incentive will be distributed as two $25 gift cards. No taxes will be withheld. The name and address of the recipient and date mailed will be the only information noted. Participants receiving an incentive over $50 will be required to complete an information form as well as a W-9 form. These will allow IMPAQ International accountants to properly withhold taxes on the recipient's behalf. Incentive amounts calculated after tax withholdings will be distributed in checks. All financial records will be kept confidential and stored on a secure server. Information will not be shared with anyone outside of the IMPAQ financial staff. Upon completion of this project, all confidential participant information not pertinent to financial record keeping will be destroyed.

8. Questions of a Sensitive Nature:

There will be no questions of a sensitive nature asked of participants.

[10] Incentives are based on physician specialty, level of expertise, years in school and average salaries. The more schooling and training, the higher the incentive. Incentives are also based on willingness to participate. For example, dermatologists are very difficult to recruit because their rate is high enough that it is more beneficial to see patients than to participate in research.

[11] The $150 incentive is for retail pharmacists. The incentive for hospital pharmacists is $200. These incentives are based on the pharmacist, availability, specialty and willingness to participate. More specifically, retail pharmacists are more prevalent than hospital-based pharmacists, making hospital pharmacists more difficult to recruit.

9. Description of Statistical Methods:

This is a qualitative study using a convenience sample. As such, the analyses do not entail the use of statistics.

Using NVivo 10 software, initial themes from the transcripts will be identified and then discussed until all team members agree on major themes and a final code book. Team members' coded data will be compared for variations and periodically discussed as needed until consensus is reached.

BURDEN HOUR COMPUTATION (Number of responses (X), estimated response or participation time in minutes (/60) = annual burden hours): Approximately 60 hours in total based on 1 hour interviews for a maximum of 60 participants across 6 groups. It should be noted that the anticipated total number of interviews is only 54, but we have included the maximum number of respondents and burden in order to allow the researchers the possibility to conduct additional interviews to reach saturation.

Table 3. Estimated Reporting Burden

Type/Category of Respondent	**No. of Respondents**	**Participation Time** (minutes)	**Burden** (hours)
Patients / caregivers	14	60	14
Prescribers	14 (at least 1 oncologist or surgeon and 2 specialists)	60	14
Pharmacists	14 (at least 2 hospital-based pharmacists)	60	14
Formulary managers	6	60	6
Policy makers (federal and state)	6	60	6
Large purchasers of drugs (group purchasing organizations, pharmacy chains, etc.)	6	60	6
Total			60

REQUESTED APPROVAL DATE: July 1, 2016. Approval later than the beginning of July 2016 would likely hinder recruitment for the proposed interview dates.

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