DOCUMENTATION FOR THE GENERIC CLEARANCE FOR THE COLLECTION OF QUALITATIVE RESEARCH & ASSESSMENT

TITLE OF INFORMATION COLLECTION:

Improving the Efficiency of Clinical Trials for Drug and Medical Device Development—Expert Questionnaire

[ ] INTERVIEWS
[ ] SMALL DISCUSSION GROUPS
[ ] FOCUS GROUPS
[X] QUESTIONNAIRES
[ ] OTHER (EXPLAIN:)

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Intended purpose

The U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (HHS/ASPE) has an ongoing interest in encouraging drug, device, and vaccine development while containing costs. HHS/ASPE has awarded a contract to Eastern Research Group, Inc. (ERG) identify possible interventions that would reduce the time and cost of conducting clinical trials, and to model the clinical trial decision-making process. As part of this contract ERG is updating an existing expected net present value (ENPV) model of the drug development decision process[1]. This model estimates the impacts of uncertainty, clinical trial characteristics, and time on the cost of innovative drug and device development and estimates likely market sizes for innovative drugs and devices. The model allows users to explore the impact of policy interventions on the ENPV by entering likely values for changes in model parameters. This study will elicit opinions from key experts, including academic researchers and industry representatives, using an online questionnaire to provide insight into likely impacts of various policy interventions to guide the model.
The ENPV model draws information from multiple sources. This study is intended to be used with the results of a literature review to inform estimates of the impact of policy interventions.

2. Need for the collection

To our knowledge, there is no information that has been or is currently being collected similar to these questions that will be asked. This is an exploratory study to answer questions that we currently do not have the data to answer. This study has been developed in consultation with

[1] A description on that model is publicly available in Appendix C of the document at: https://aspe.hhs.gov/report/examination-clinical-trial-costs-and-barriers-drug-development

experts from the Food and Drug Administration, National Institutes of Health, and Office of the Assistant Secretary for Health.

3. Planned use of the data

The data collected through this questionnaire will inform the range of estimates for the impacts of potential interventions on in the operational ENPV model of clinical trial decision-making. The model examines the decision-making process for a drug/device sponsor as a stylized decision tree that looks at the process for formulating a clinical trial from the point of view of an expected-revenue-maximizing sponsor in the face of uncertainty (or risk). The data collected through this questionnaire will be used in the model to estimate the impacts of several interventions on clinical trial costs, duration, and probability of success. The model is currently used only internally by ASPE, NIH, and FDA economists to examine potential implications of different types of initiatives on clinical trial costs as well as the returns to drug developers.

4. Date(s) and location(s)

Data collection will begin after obtaining OMB approval, provisionally estimated to be in January 2017 and continue for approximately one month.

5. Collection procedures

We will develop an online questionnaire to be administered to experts in the clinical trial field, including academics, physicians, industry representatives, and venture capitalists. The questionnaire will elicit estimates of the impact of different types of interventions on the clinical trial process. We will ask experts to explain their reasoning behind the estimates they provide and will conduct follow-up interviews if answers are ambiguous. The interventions to be included are:

- Wider use of mobile technologies, including electronic data capture (EDC).
- Simplified clinical trial protocols and reduced amendments.
- Reduced source data verification (SDV).
- Improvements in the FDA review process.
- Staged approval process.
- Biomarkers as surrogate endpoints.
- Predictive/prognostic biomarkers.
- Use of electronic health records (EHR).
- Use of registry data.
- Use of adaptive design.
- Use of standardized contracts.
- Use of central IRBs (for medical devices only).
- CDC/NIH developing epidemiological data on disease incidence (for vaccines only).
- Federally supported cGMP-compliant manufacturing facilities (for vaccines only).

The questionnaire will be designed to minimize respondent burden, we anticipate that it will take 60 minutes or less to complete. Respondents will be able to complete the questionnaire at their own pace depending on their own schedules using their computers, tablets, or smartphones. We will not be asking for any personally identifiable information.

6. Number of collections (e.g., focus groups, surveys, sessions)

We anticipate a sample of approximately 30-40 experts to be contacted for the study.

7. Description of respondents/participants

Respondents will be experts in the clinical trial field, including academic researchers, physicians, industry representatives, and venture capitalists.

8. Description of how results will be used

The results will be used in conjunction with other data as part of a decision-making model, to estimate the impact of the interventions listed in item 5. on the clinical trial cost, duration, and probability of success, which in turn affect the expected net present value (eNPV) to a trial sponsor.

9. Description of how results will or will not be disseminated and why or why not

The results of this model will be compiled in a final report that may be posted on ASPE's website. The responses to the questionnaire will be kept confidential; only aggregate results will be used in the clinical trial decision-making model.

AMOUNT OF ANY PROPOSED STIPEND OR INCENTIVE

No stipend will be provided, although we are concerned that this will have a negative impact on participation.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clinical trial experts	40	1	1	40	$78.40	$3,136.00
TOTALS	40	40		40		$3,136.00

Sources: Bureau of Labor Statistics (BLS). 2017. Employer Costs for Employee Compensation Supplementary Tables Historical Data December 2006 – December 2016. Available at https://www.bls.gov/ncs/ect/sp/ecsuphst.pdf (Accessed March 24, 2017).

Rice, C. 2002. Wage Rates for Economic Analysis of the Toxics Release Inventory Program. June 10, 2002
Environmental Protection Agency (EPA). 2002. Revised Economic Analysis for the Amended Inventory Update Rule: Final report. August, 2002. Docket ID: EPA-HQ-OPPT-2002-0054-0260. Available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2002-0054-0260 (Accessed January 28, 2015).
Note: Wage used is the loaded hourly wage for professional/technical personnel, with a 17 percent overhead rate applied.

BURDEN COST COMPUTATION

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Social Science Analyst, GS 11	30	$57.79	$1,733.70
Social Science Analyst, GS 15	20	$114.50	$2,290.00
Estimated Total Cost of Information Collection			$3,253.70

Source: US Office of Personnel Management (OPM). 2017. Salary Table 201-DCB (LEO) (Hourly Rate) - Effective January 2017. Available at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/17Tables/html/DCB_h.aspx (Accessed March 24, 2017).
Note: A 60 percent fringe and overhead factor is applied to base wages.

OTHER SUPPORTING INFORMATION

REQUESTED APPROVAL DATE: December 5, 2017

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DEPARTMENT/OFFICE/BUREAU: U.S. Department of Health and Human Services (HHS), Assistant Secretary of Planning and Evaluation (ASPE), Science and Data Policy (SDP)