Request for Approval under the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB#: 0925-0648 Exp., date: 06/2024)

TITLE OF INFORMATION COLLECTION: Feedback survey questions associated with the Optimizing Clinical Trials workshop

PURPOSE: To gain useful insight for framing content and topics for the workshop such as: identify areas of improvement in planning better clinical trials and considering the key factors that are critical to a successful trial, including patient and stakeholder engagement, pre-trial analysis of the study population and landscape, and better planning around clinical trial recruitment.

DESCRIPTION OF RESPONDENTS: Clinical Trial investigators, patients, research coordinators, advocates, Federal and non-federal, who registered for the Optimizing Clinical Trials workshop.

TYPE OF COLLECTION: (Check one)

[ ] Customer Comment Card/Complaint Form
[ ] Usability Testing (e.g., Website or Software
[ ] Focus Group
[ ] Customer Satisfaction Survey
[ ] Small Discussion Group
[X] Other: Feedback Survey

FREQUENCY OF REPORTING: (Check one)

[X] Once
[ ] Monthly
[ ] Annually
[ ] Quarterly
[ ] On Occasion
[ ] Other _____

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.
3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

Name: Dr. Kevin Abbott

To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [ ] Yes [X] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [ ] Yes [ ] No
3. If Applicable, has a System or Records Notice been published? [ ] Yes [ ] No
4. Privacy Act Systems of Records Title: _____ FR Citation ____FR___

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [ ] Yes [X] No

ESTIMATED BURDEN HOURS and COSTS

Category of Respondent	**No. of Respondents**	**No. of Responses per Respondent**	**Time per Response (in hours)**	**Total Burden Hours**
Individuals or Households	113	1	20/60	38
Totals		113		**38**

Category of Respondent	**Total Burden Hours**	**Hourly Wage Rate***	**Total Burden Cost**
Individuals or Households	38	$29.76	$1,130.88
Totals	**38**		$1,130.88

*Source: U.S. Bureau of Labor Statistics May 2022 National Occupational Employment and Wage Estimates, United States all occupations median salary

FEDERAL COST: The estimated annual cost to the Federal government is **$5688.90**

Staff	**Grade/Step**	**Salary***	**% of Effort**	**Fringe (if applicable)**	**Total Cost to Gov't**
Federal Oversight					
Senior Scientific Officer	RF-0	$233,445	2%		$4,668.90
Contractor Cost		$1,020.00	2%		$1,020.00
Travel					
Other Cost					
Total					$5688.90

*the Salary in table above is cited from **https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB.pdf**

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

   [] Yes [X] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The respondent list is curated from registrants to the Optimize Clinical Trial Workshop. There are about 225 registrants, but we estimate 50% or less response rate to this survey. Respondents will receive an email with the survey link.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
   - [X] Web-based or other forms of Social Media
   - [ ] Telephone
   - [ ] In-person
   - [ ] Mail
   - [ ] Other, Explain
2. Will interviewers or facilitators be used? [ ] Yes [ ] No