



Food and Drug Administration
Center for Tobacco Products
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**2021 FDA CTP Email Survey Audience Analysis Study
Version 10/5/2021**

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Abstract

The FDA Center for Tobacco Products (CTP) uses email marketing as one of its primary tactics for conveying important tobacco education and regulatory information to stakeholders and the public. On average, CTP sends email communications (also referred to as “emails”) six times per month to approximately 44,300 subscribers. This study aims to continue deepening our understanding of CTP’s email subscribers’ preferences and their evolving information needs. Investigators will administer a short, anonymous, and voluntary online survey with a sample of approximately 1,329 CTP email subscribers. This survey includes self-reported items assessing demographic information, opinions about CTP email communications, and aspects of CTP communications that can be improved. Study aims are: (1) to determine the current information gaps that exist for subscribers; (2) to assess opportunities to provide subscribers CTP content on digital channels where they prefer to receive information; (3) to identify the reach and impact of CTP email communications; and (4) to obtain demographic information about the email subscriber base. The findings from this study will continue to guide CTP in developing updated and fresh content, sustaining current and engaging new stakeholders, and tailoring effective public affairs activities.

I. SUMMARY OF PROJECT

The FDA Center for Tobacco Products (CTP) uses email marketing as one of its primary tactics for conveying important tobacco education and regulatory information to stakeholders and the general public. On average, CTP sends email communications (also referred to as “emails”) six times per month to approximately 44,300 subscribers.

The goal of the 2021 FDA Center for Tobacco Products (CTP) Email Survey Audience Analysis Study (“2021 FDA CTP Email Survey”), a Customer Satisfaction Survey presented in this protocol, is to expand and refine our knowledge of the CTP email subscriber base across its three email communications (i.e., *CTP Connect*, *CTP News*, and *Spotlight on Science*). The 2021 administration of this survey represents the fifth wave of inquiry; this survey has been administered annually since 2017. The results from the 2021 CTP Email Survey Audience Analysis Study will continue to guide the Center in three areas:

- Content development. What are the current information gaps, and what content does CTP need to develop to address those gaps?
- Digital strategy. On which digital platforms do subscribers prefer to receive tobacco-related news?
- Public affairs activities. What is the reach and impact of CTP messaging, news, and research?

The research team will email its approximately 44,300 email subscribers inviting them to complete the 2021 FDA CTP Email Survey online. Programmed via Qualtrics, the 2021 FDA CTP Email Survey will be in the field for four weeks. The research team will send three reminders to complete the survey during these four weeks. Respondents may complete the survey on a desktop computer, tablet, or mobile phone. The research team will program the survey to limit one survey per device to reduce the potential for multiple survey completions by one individual. The survey information collected is in no way connected to responses of previous years’ surveys (for those respondents who may have completed the FDA CTP Email Survey in 2020, 2019, 2018, and/or 2017).

In this year’s (2021) administration, the research team will be conducting a 50/50 A/B test to understand the difference in response rate between a short 8-question survey and a longer 17-question survey. The short version of the survey takes approximately 5 minutes to complete, and the long version takes approximately 8 minutes to complete. Our experience with the 2020 administration of this survey yielded a sample size of 437 (response rate: 1.0 percent). While the research team hopes many invitation recipients will complete the survey, we anticipate that between one percent and three percent of the 44,300 subscribers will complete the survey—for a maximum sample size of 1,329 completed surveys.

This study will provide CTP with an audience analysis that will further deepen the Center’s understanding of the information needs and preferences of its current and intended target audiences. With this understanding, CTP will develop resources of greatest value to its target audiences and increase engagement with CTP among target audience members.

II. INTRODUCTION / BACKGROUND

FDA’s Center for Tobacco Products oversees the implementation of the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act, signed into law on June 22, 2009. Also, section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public’s health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to the FDA for

the enforcement of the FD&C Act. Further, the FD&C Act also authorizes the FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D)). In addition to regulating the manufacture, distribution, and promotion of tobacco products, CTP conducts studies to inform regulatory actions and communications.

FDA sends email communications to its approximately 44,300 subscribers featuring easy-to-understand information that reaches key target audiences and meets subscribers' needs. These members have opted in, voluntarily, to be included in the database by registering through the CTP website page, "Sign Up for Email Updates from CTP" (<https://www.fda.gov/tobacco-products/ctp-newsroom/sign-email-updates-ctp>). Once registered, members receive complimentary copies of CTP newsletters and announcements via email. CTP's Office of Health Education and Communication plans to assess these communications. The study proposed in this document will improve the following CTP email communications:

1. *CTP Connect*
 - Regular updates on the health effects of tobacco, public health educational resources, and highlights on current tobacco issues and regulations.
2. *CTP News*
 - Tobacco product news as it happens, including information about regulations, guidances, enforcement actions, and other announcements.
3. *Spotlight on Science*
 - Tobacco regulatory science and research, tobacco scientific publications and study findings, CTP grants, and more in this newsletter.

III. STUDY GOAL AND OBJECTIVES

An analysis of CTP's audiences will further deepen the Center's understanding of the information needs and preferences of its current and intended target audiences. The results of this study will allow CTP to more effectively communicate with stakeholders who need to be aware of the changing regulatory environment and other breaking news and updates related to tobacco products.

The objectives of the 2021 FDA CTP Email Survey Audience Analysis Study are to determine the following:

- What are the current informational needs of CTP's subscribers?
- How has satisfaction changed over time among CTP's intended audiences with CTP's emails?
- How can CTP continue to improve its email communications to better serve subscribers?
- How have CTP's email subscribers changed over time?
 - o Who is currently engaging with CTP?
- Are the CTP emails reaching the *types* of subscribers CTP intends to reach and the *number* of subscribers CTP intends to reach?
- On which device(s) do subscribers view CTP emails?

Armed with a clearer image of its current subscribers, CTP will have the needed insights to:

- Refine current email practices based on subscriber feedback and develop evergreen email campaigns based on subscribers' information needs.
- Refine the key performance indicators for email marketing to determine the success of CTP's emails.
- Continue making across-time (across-year) assessments for measuring trends and progress and addressing needs as they change.

IV. METHODS AND STUDY POPULATION

CTP is requesting approval of this study protocol for collecting information using a brief, self-administered online survey. CTP maintains an email subscriber list of approximately 44,300 members. The approximately 44,300 subscribers have voluntarily subscribed to at least one of the following email communications:

- *CTP Connect*
- *CTP News*
- *Spotlight on Science*

To meet the goal of the 2021 CTP Email Survey Audience Analysis Study, the research team will use GovDelivery to create an A/B test campaign to send the initial invitation to subscribers to complete the survey. Email A will be sent to 50 percent of CTP's subscribers and will contain a link to the short version of the email. Email B will be sent to the remaining 50 percent of CTP's email subscribers and will contain a link to the longer version of the survey (see **Appendix A, 2021 CTP Email Survey Email Invitation**). Since no personally identifiable information (PII) is collected (e.g., IP address or email address), the survey is entirely anonymous. Survey respondents must be able to read and write in English. Not all subscribers are from the United States; respondents from any country will have the opportunity to participate in the survey.

During Week 1 and Week 2 (after approval from Ethical & Independent Review Services (E&I), which will serve as the IRB of record, and the Office of Management and Budget [OMB] for the 2021 CTP Email Survey Audience Analysis Study), the research team will program the online survey instrument in Qualtrics, pretest the online survey for technological issues, and modify the online survey based on the pretest findings. If any survey item changes are required, an amendment will be submitted to CTP RIHSC and E&I.

During Week 3, the research team will send an email to the entire database of approximately 44,300 CTP email subscribers, inviting them to participate in the online survey.

When administering the FDA CTP Email Survey in 2017, 2018, 2019, and 2020, we received 322, 359, 372, and 437 completed surveys, respectively (0.83, 0.88, 0.90, and 1.0 percent response rate, respectively). The successful average delivery rate of the CTP emails is 97 percent, the average CTP email open rate is 14.6 percent, and the average CTP email click-through rate is 4.8 percent. The research team thus expects to receive a maximum of 1,329 completed surveys—that is, between one percent and three percent of the approximately 44,300 current CTP email subscribers.

To avoid the potential of one individual completing the survey more than one time, the research team will program the survey to limit one survey per device.

The research team will field the survey for four weeks. The research team will send three reminders during this period—the first reminder during Week 5, the second reminder during Week 6, and the final reminder during Week 7. (**See Appendix C for the 2021 CTP Email Survey Timeline.**)

Everly Macario, Sc.D., M.S., Ed.M. (IQ Solutions) is the Principal Investigator, and Debra Mekos, Ph.D., is the FDA Project Lead for the research. Dr. Mekos will be involved both with survey design and analysis.

The research team also consists of the following IQ Solutions staff:

- Sarah Byrnes, M.A. – Strategist

- Malini Runnells, M.A. – Project Manager
- Yvette Frias, M.P.H – Research Analyst

IQ Solutions staff will be working with the Qualtrics software and have an objective, independent role in developing the survey instrument and accompanying materials (e.g., email invitation announcements), conducting the data analyses, and reporting the findings. They will be responsible for providing CTP with the final executive summary report and delivering the presentation. CTP staff will never have direct contact with the raw data from Qualtrics.

CVs and certificates of completion of Human Subjects Protection training from all project team members listed here are included with this application.

V. STUDY RECRUITMENT AND PARTICIPANT SCREENING

To be eligible to participate in the online 2021 CTP Email Survey, each respondent must:

- Subscribe to at least one of the following: *CTP Connect*, *CTP News*, and/or *Spotlight on Science*.
- Be 18 years of age or older.
- Have access to the Internet.

Note: The online survey will be mobile-friendly.

The short version of the survey contains 8 questions and takes approximately 5 minutes to complete, and the long version of the survey contains 17 questions and takes approximately 8 minutes to complete. The estimated average time to complete each survey was determined by an internal survey review in its online format. The survey begins by providing potential respondents with informed consent information about the study, including the purpose, benefits and risks, and anonymous nature of the survey. After the informed consent information, respondents are asked to click either "Start survey now" or "Exit survey" to ensure that those who complete the survey are doing so voluntarily. See **Appendix B, 2021 CTP Email Survey Instrument**

The short survey version asks respondents about:

- Their professional backgrounds (i.e., professional roles).
- Which email option(s) they receive (*CTP Connect*, *CTP News*, and/or *Spotlight on Science*).
- Why they are interested in receiving CTP emails.
- A ranking of CTP topics of interest.
- How informative they find CTP's emails.
- Their level of satisfaction with CTP email communications.
- Through which FDA digital channels do they get their tobacco-related news.
- Additional suggestions for how email communications can be improved.

The long survey version asks respondents about:

- Their professional backgrounds (i.e., professional roles).
- Whether or not they are a government employee and at what level of government do they work.
- Which email option(s) they receive (*CTP Connect*, *CTP News*, and/or *Spotlight on Science*).
- Why they are interested in receiving CTP emails.
- A ranking of CTP topics of interest.

- How informative they find CTP's emails.
- Their level of satisfaction with CTP email communications.
- Through which FDA digital channels do subscribers get their tobacco-related news.
- To which trusted sources do they turn for health and regulatory information on tobacco.
- If they took the survey in any previous year.
- On what kind of device they view CTP's emails (i.e., desktop, mobile, or tablet).
- Whether they are current nicotine product users, which nicotine products they use, and how their tobacco use has changed over the last 12 months.
- General demographic items (e.g., gender identity, race/ethnicity, country of residence).
- Additional suggestions for how email communications can be improved.

Only individuals 18 years of age or older will be eligible for this study. If the respondent indicates that they are 17 years of age or younger, the program will terminate this respondent's participation at the screener.

The survey is anonymous. Names and email addresses are disassociated from the survey responses. The survey link URLs that are given in the invitation do not automatically capture the respondents' email. As such, there is no automatic connection between respondents' surveys and their email addresses. Although Qualtrics will limit the survey to one time per device, the researchers will not obtain Internet Protocol (IP) information. In addition, previous years' survey responses cannot be connected to the current year's survey responses. Respondents are asked if they participated in previous years' surveys, but there is no way to link previous years' survey responses with current survey responses.

Once the survey is initiated, the survey will detect what type of device respondents are on (i.e., desktop, mobile, or tablet). In line with the anonymous nature of this survey, no IP addresses or other forms of PII will be recorded. Although the survey does prevent respondents from taking the survey more than once based on the participant's IP address and internet cookies, Qualtrics' propriety methods mask the IP address and cookies from researchers and thus, they are never recorded in the dataset.

VI. PROCEDURE

Potential survey respondents will receive either an invitation to the short version of the survey or an invitation to complete the long version of the survey. Individual email subscribers will be randomly assigned to one of the two email invitations in GovDelivery, FDA CTP's email marketing platform. This random assignment will be a 50/50 split between the two possible survey options. If a recipient of the invitation is interested in taking the survey, they will click on a link URL provided to them in the electronic invitation.

The first page of the online survey, after the screener questions, will include informed consent information as well as the contact information of the study's Principal Investigator should a respondent wish to contact a study team member for any reason (see **Appendix D for the 2021 CTP Email Survey Informed Consent**).

VII. JUSTIFICATION FOR SENSITIVE QUESTIONS

This study asks respondents their birth year, gender, race/ethnicity, country of residence, and state of employment (if in the United States). The purpose of these questions is to describe the survey respondent sample, compare selected demographic groups, and tailor services and resources to CTP audience segments. These potentially sensitive questions are asked at the end of the survey, by which point respondents are more comfortable with the survey instrument, process, and sponsor. Some of the survey's questions may induce negative thoughts, and respondents may feel uncomfortable sharing reservations or criticisms they might have with CTP email communications.

Again, respondents will be assured that the information is voluntary and will be treated as private and anonymous, and they do not have to respond to any question that makes them uncomfortable. If participants do not want to answer a question, there is a “prefer not to answer” option for each question. One survey question, in the long survey but not in the short survey, asks respondents if they have used a nicotine product in the last 30 days and if so, which nicotine product(s) they have used. This question can be skipped and offers a “prefer not to answer” option. Subsequently, there is a question, in the long survey but not in the short survey, regarding how an individual’s tobacco use has changed over the last 12 months and why an individual selected that response. This question can be skipped and offers a “prefer not to answer” option.

CTP will not retain the raw data from this data collection effort once the data have been extracted and compiled. The information will never become part of a system of records containing permanent identifiers that can be used for retrieval. There are no personal identifiers, only the raw data will ever be contained and maintained by IQ Solutions (not CTP), using Qualtrics. The survey data in Qualtrics will be deleted three years after data collection. As previously mentioned, email addresses will not be linked to responses.

VIII. PROCEDURES FOR OBTAINING INFORMED CONSENT

Before the informed consent page, respondents will be given a brief description of the survey with two screener questions assessing study eligibility. These two questions are asked before the informed consent to ensure respondents meet the study criteria for completing the survey.

Before the beginning of the survey, the online 2021 CTP Email Survey will include the informed consent information that will invite prospective respondents to actively choose to participate in the survey voluntarily and noting there will be no negative repercussions for participating or choosing not to participate. After reading the informed consent information, respondents are asked to select “Start survey now” or “Exit survey” to assure that those who complete the survey are doing so voluntarily. The statement that will provide respondents’ informed consent is worded as follows:

If you click on “Start survey now,” you voluntarily agree to take part in this survey. Click one of the options below.

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

Start survey now / I voluntarily agree to participate in this study.
[\[BEGIN SURVEY\]](#)

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

Exit survey / I do not want to participate in this study. [\[TERMINATE SURVEY; GO TO TERMINATION TEXT 3\]](#)

[\[TERMINATION TEXT 3:\]](#) You have indicated that you do not want to participate in the 2021 CTP Email Survey and will now exit the survey. If you decide later that you would like to participate, you can use the same email invitation to access the survey. Thank you for your time!

IX. ASSURANCE OF PRIVACY PROVIDED TO PARTICIPANTS

A. Potential Risks and Benefits

The methodology for the 2021 CTP Email Survey Audience Analysis Study involves two versions (short and long) of one online survey. The risk level for survey respondents is less than minimal risk (i.e., the probability of harm or discomfort anticipated in the research is not greater in and of

itself than what would ordinarily be encountered in daily life or during the performance of routine physical or psychological examinations or tests). Moreover, identification of the survey respondents or their responses reasonably would not place them at risk of criminal or civil liability; would not be damaging to their financial standing, employability, insurability, and reputation; and would not be stigmatizing. The project team is committed to abiding by strict anonymity best practices in research investigations.

Respondents will have the option of not answering any questions they do not want to answer.

Respondents of the online survey will receive no direct benefits by participating in this study. CTP communications will improve based on the information collected.

B. Privacy, Data Handling, and Recordkeeping

Qualtrics will be the software used for data collection and storage. All Qualtrics data are stored in a cloud and are encrypted at rest and in transit, under password protection in both instances. For raw data collected during this research, all servers are hosted using industry-standard firewalls. Industry-standard firewalls include the ability to allow or block traffic based on multiple forms of connection (e.g., state, port, protocol), rather than only one connection, meaning that access is limited to those who are allowed entry. IQ Solutions will also follow the Standard of Good Practice (SoGP, <https://www.securityforum.org/tool/the-isf-standard-good-practice-information-security-2018/>) security practices, which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and safety of the end-user environment. Following these guidelines, data and sensitive information monitoring will occur following the SoGP security practices such as limiting access to information and data encryption. Only designated members of the research team will have access to the information through a secure log-in using a password on an HTTPS site, which ensures that data will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

The research team will keep all aggregated, anonymous electronic data downloaded from Qualtrics for the study in a password-protected computer. Only study team members who are directly involved with the research study will access the aggregated data. The principal investigator will be responsible for overseeing that these data protection measures are put in place and sustained responsibly over time.

IQ Solutions will produce an executive summary report of the aggregated data (which will contain no PII).

D. DATA PRIVACY AND SECURITY

Information provided by respondents will be kept private and anonymous to the extent allowable by law. This will be communicated to respondents in the informed consent information placed first in the survey instrument (i.e., the informed consent information is what a prospective respondent will see first after clicking the survey URL).

Respondents also will be advised of the following: the nature of the data collection activity; the purpose and use of the data collected; the FDA sponsorship; and the fact that participation is always voluntary. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the study as a whole or to any particular question. There is also a “prefer not to answer” response option to allow participants to opt-out of any question for any reason.

All research team staff will commit to measures to ensure the privacy and anonymity of data. All electronic and hard copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers, and hard copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be in aggregate form, with no links to individuals. Reports will be used only for research purposes and for the development of resources.

Dr. Everly Macario, Sarah Byrnes, Malini Runnells, and Yvette Frias of IQ Solutions will have access to the raw data. They have completed their CITI Human Subjects Protection training (see **Appendices E and F for CITI Certificates and CVs**). Dr. Debra Mekos of CTP will have access to view-only (non-editable) organized, “clean,” and unidentified datasets containing no PII.

IQ Solutions will store all data records safely for a minimum of three years after completion of this study, as is standard practice, and IQ Solutions will destroy the study data after this storage period.

X. INCENTIVES

Since engagement in the study is minimal, respondents will not be paid an incentive to participate in the online survey. All participation in this study is voluntary.

XI. DATA ANALYSIS PLAN

The IQ Solutions team will program the online survey of the 2021 CTP Email Survey Audience Analysis Study using Qualtrics software. The short version of the survey includes 8 questions, and the long version of the survey contains 17 questions. Except for one open-ended question, the survey questions include closed-ended response categories where the respondent must select one of various options or select all that apply when indicated.

To analyze the quantitative data collected from the online survey’s closed-ended questions, IQ Solutions will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs to assess how demographic and other variables and survey items may be associated.

XII. ASSESSMENT AND REPORTING OF PROTOCOL DEVIATIONS AND ADVERSE EVENTS

The principal investigator (PI) will ensure that appropriate oversight systems are in place to monitor all research activities and identify any adverse events or deviations from the study protocol. Upon discovering an adverse event, the PI is responsible for reporting protocol deviations to Ethical & Independent Review Services (E&I) using the standard reporting form.

The PI will review all protocol deviations to assess whether respondent safety or study integrity has been affected by the deviation and how the deviation has affected the project. If the deviation is a protocol violation, appropriate measures will be taken to address the occurrence, which may include the development of a corrective action plan. All protocol violations and corrective action plans will be reported to E&I. Corrective actions that lead to a change in the protocol shall be submitted to the FDA Project Lead before implementation.

Subject privacy and data confidentiality breaches are serious risks and will be reported within one hour of discovery to the FDA Project Lead and Ethical & Independent Review Services (E&I) (info@eandireview.com).

The following will be communicated as at least an initial notification to the FDA Project Lead and Ethical & Independent Review Services (E&I) (info@eandireview.com) as soon as possible

(generally within 24 hours) with a full report submitted within 10 days. In the case of any adverse events, IQ Solutions will remove the respondent's survey from the analysis and provide support to the respondent as needed.

- **Serious Adverse Event:** An adverse health event that is life-threatening or results in death, initial or prolonged hospitalization, disability or permanent damage, congenital anomaly or congenital disability, or requires medical or surgical intervention to prevent one of the other outcomes.
- **Unexpected Adverse Event:** Adverse health events that were not identified in nature, severity, or frequency in the research protocol / informed consent documents.
- **Unanticipated Problem:** Any incident, experience, or outcome that meets all of the following criteria:
 - 1) Unexpected (in terms of nature, severity, or frequency) given: a) the research procedures that are described in the protocol-related documents, such as the research protocol and informed consent document; and b) the characteristics of the subject population being studied.
 - 2) Related or possibly related to the subject's participation in the research; and
 - 3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
- **Protocol Violation:** Any change, divergence, or departure from the study design or procedures of a research protocol that affects the subject's rights, safety, or well-being and/or the completeness, accuracy, and reliability of the study data.

The following will be communicated on a routine non-urgent basis but no less than annually:

- **Expected adverse events:** Those health effects and other risks that are listed in the protocol and informed consent forms as being likely to occur or as a result of participation in the study.
- **Protocol deviation:** Any change, divergence, or departure from the study design or procedures of a research protocol under the investigator's control and has not been reviewed by E&I.
- **Minor Protocol Deviation:** Any change, divergence, or departure from the study design or procedures of a research protocol that has not been reviewed by E&I and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy, and reliability of the study data.

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Study Materials:

Appendix A. 2021 CTP Email Survey: Email Invitation

Appendix B. 2021 CTP Email Survey: Instrument

Appendix C. 2021 CTP Email Survey: Timeline

Appendix D. 2021 CTP Email Survey: Informed Consent

Appendix E. 2021 CITI Certificates

Appendix F: CVs