

**Requests for OMB Review and Approval For  
Office of the Assistant Secretary for Technology Policy/ Office of the  
National Coordinator for Health Information Technology  
National Survey of Digital Health Companies**

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# **Supporting Statement for Office of the Assistant Secretary for Technology Policy/ Office of the National Coordinator for Health Information Technology National Survey of Digital Health Companies**

## **A. Justification**

### **1. Circumstances Making the Collection of Information Necessary**

The Office of the Assistant Secretary for Technology Policy/ Office of the National Coordinator for Health Information Technology (ASTP/ONC) is seeking approval for a new data collection effort to field a National Survey of Digital Health Companies. This survey will help ASTP/ONC better understand companies' adoption of various types of application programming interfaces (APIs) for electronic health record (EHR) integration, use of the HL7 Fast Healthcare Interoperability Resources (FHIR) standard, status of EHR integrations, underlying characteristics of digital health companies, perceived benefits of federal health IT policy, and needed improvements to API standards and relevant federal health IT policies.

The digital health sector has rapidly grown over the past decade, fueled in large part by the implementation of EHRs and the availability of APIs that allow third-party applications to work with EHR data in various ways. It is critical to assess the digital health ecosystem's experiences with federally regulated, standards-based application programming interfaces (APIs) for health data exchange, as mandated under the 21<sup>st</sup> Century Cures Act (42 U.S.C. § 300jj-11 and § 300jj-52). The Cures Act aims to promote secure, standardized access to and exchange of electronic health information (EHI) through certified APIs "without special effort." This supports patient access to their medical information and allows for third-party innovation in the private sector.

In 2022, ASTP/ONC partnered with University of California San Francisco (UCSF) to conduct a national survey of 141 digital health companies that provided the first insights into digital health company experiences with electronic health record (EHR) integration via standards-based APIs. This data collection effort aimed to capture early impacts of the Cures Act and assess the state of API adoption and interoperability among digital health companies. The findings were published in [the Journal of the American Medical Informatics Association](#) and showed widespread API adoption but persistent challenges such as high fees, limited clinical data, and incomplete access to necessary data elements. These challenges can impede innovation and competition, ultimately impacting patient care. Prior to this, the California Health Care Foundation (CHCF) conducted surveys of digital health companies in [2016](#) and [2018](#) focusing on companies' API implementations.

Given the rapidly evolving landscape and policy changes, including the rollout of the United States Core Data for Interoperability (USCDI), the Trusted Exchange Framework

and Common Agreement (TEFCA), and recent updates to the ONC Health IT Certification program, ASTP/ONC must field this survey to assess how these digital health companies' integration experiences and technology use have changed over time. This effort will continue the tracking of essential data to measure the continued adoption and impact of APIs. By evaluating the use of standards-based and proprietary APIs, understanding company experiences with specific EHR vendors, and identifying both barriers and enablers to EHR integration, the survey is essential to inform federal policy and will deliver actionable insights to drive continued innovation and improvement in the digital health ecosystem, ultimately improving patient care delivery.

## **2. Purpose and Use of Information Collection**

The primary goal of this information collection is to generate national statistics on digital health company adoption of and experiences with EHR APIs. The survey will collect data to assess the following:

1. Use of proprietary and standards-based APIs (including FHIR-based APIs) to integrate with EHRs.
2. Barriers to API integration, such as cost, vendor support, and availability of test data.
3. Experiences with specific EHR vendors and numbers of vendors integrated with.
4. Perceptions of policy initiatives such as TEFCA, information blocking regulations, and USCDI.
5. Prioritized clinical data elements for future regulatory focus; and
6. Strategies to improve interoperability and ease of integration.

Findings will help ASTP/ONC evaluate implementation of Cures Act provisions, support data-driven policy development, and identify needed technical assistance or regulatory refinements. Survey results will be published, shared with stakeholders, and inform ASTP/ONC rulemaking and program design.

## **3. Use of Improved Information Technology and Burden Reduction**

This study will rely on data gathered from a self-administered, web-based survey of leaders in digital health companies. The survey will be administered electronically to alleviate burden on the respondents. The web-based survey permits respondents to complete the instrument at their preferred time. Respondents who begin the survey and, if unable to complete it in one session, will be able to save their responses and resume work on the survey later.

We will be using the web-based survey tool Qualtrics©. This tool is commonplace and has strong capabilities to support complex survey design (e.g., branching logic) as well as respondent communication and tracking. The tool will be extensively tested to ensure the accuracy of branching and skip logic, accuracy of piped text, clarity of question display, and adherence to other survey usability guidelines.

## **4. Efforts to Identify Duplication and Use of Similar Information**

There are no current federal efforts that duplicate this data collection. The 2022

ONC/UCSF survey forms the foundation for this project, and the current effort updates and expands upon it, with new content aligned to policy changes and emerging stakeholder needs.

ASTP/ONC considers it critical to support this survey of digital health companies to assess how their use of APIs and integration experiences have evolved considering federal policies. This information is essential to informing policy strategies that facilitate companies' adoption of APIs that promote secure and efficient access to electronic health information (EHI).

#### **5. Impact on Small Businesses or Other Small Entities**

Digital health companies vary in size; some may be considered small businesses. The survey is voluntary and short (estimated 30 minutes) and is designed to minimize burden. The information being requested or required is limited to the absolute minimum necessary for the intended use of the data. Participation will help ensure these companies' perspectives are represented in federal policymaking.

#### **6. Consequences of Not Collecting the Information**

Failure to collect this data will hinder ASTP/ONC's ability to evaluate progress toward implementing key Cures Act policies. The agency will lack timely information on the digital health ecosystem's challenges and needs, limiting its ability to address persistent interoperability gaps, foster competition, and ensure technology is accessible "without special effort." Broader federal efforts, particularly relating to TEFCA, information blocking, and artificial intelligence (AI), also require timely data on the current state of digital health companies.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This data collection request is fully consistent with the guidelines. There are no special circumstances required for the collection of information in this data collection.

#### **8. Comments in Response to the Federal Register Notice/Outside Consultation**

The 60-day FRN soliciting public comment on this survey data collection was published in the Federal Register on May 21, 2025 at 90 FR 21785. No comments were received from the public.

#### **9. Explanation of any Payment/Gift to Respondents**

Incentives to encourage participation in the survey will include listing participating companies on public and peer-reviewed reports, providing copies of reports to respondents, and inviting respondents to partner on panels, presentations, and webinars that will be held to report out on results and insights stemming from the survey findings. Respondents will not receive financial compensation or honoraria for their time.

#### **10. Assurance of Confidentiality Provided to Respondents**

No individually identifiable information will be published or shared. We will not attribute responses to any specific organization. These data will only be presented in aggregate and may be published in a peer-reviewed journal and shared on the ASTP/ONC website.

The information for this study is being collected by the Division of Clinical Informatics & Digital Transformation, Department of Medicine, University of California, San Francisco (UCSF), on behalf of ASTP/ONC, and in partnership with ScaleHealth and Clinovations. Based on the UCSF’s Human Research Protection Program Institutional Review Board (IRB) review, an exempt certification was granted for this study (#21-35074).

**11. Justification for Sensitive Questions**

No questions of a sensitive nature are asked in this data collection.

**12. Estimates of Annualized Hour and Cost Burden**

We will target sending the survey to approximately 282 key senior respondents from digital health companies, such as computer and information systems managers, who will be knowledgeable about the topic areas covered. We assume a 50 percent response rate, 141 respondents. The survey was pre-tested with a total of 7 separate respondents, from which we derived the 30 minute per respondent burden estimate.

**Exhibit 1. Estimated Annualized Burden Hours**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>No. of Respondents</b>	<b>No. of Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Computer and Information Systems Managers	Digital Health Company Survey	282	1	0.5	141
<b>Total</b>					141

**Exhibit 2. Estimated Annualized Burden Costs**

<b>Type of Respondent</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Total Respondent Costs</b>
Computer and Information Systems Managers <sup>1</sup>	141	\$90.38	\$12,743.58
<b>Total</b>			<b>\$12,743.58</b>

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There are no annualized capital/startup or ongoing operation and maintenance costs involved in collecting the information.

#### **14. Annualized Cost to Federal Government**

The estimated cost to the Federal Government for the data collection activities is \$345,365.00 over 24 months, or \$172,682.50 annually. The contractual costs to the UCSF for data collection activities associated with this submission is \$290,269.00 over 24 months, or \$145,134.50 annually. The cost of federal employees providing oversight and some analysis is \$55,096.00 over 24 months, or \$27,548.00 annually.

#### **15. Explanation for Program Changes or Adjustments**

This is a new information collection request.

#### **16. Plans for Tabulation and Publication and Project Timeline**

ASTP/ONC and UCSF will jointly conduct three types of analyses based on the survey results, building on our longstanding tradition of using survey research to assess the national landscape of health data exchange and policy impacts. Insights derived from our analyses of this survey will expand upon knowledge acquired from prior efforts, such as our 2024 JAMIA publication on digital health company experiences integrating with EHR APIs, which explored the implications of API regulation on interoperability, use of FHIR, and market access challenges. Furthermore, this data collection effort will allow for longitudinal comparisons and trend assessments.

First, we will describe response rate and, using characteristics such as company size, application type, and market presence, assess the representativeness of the sample to the target population of digital health companies. Second, we will conduct descriptive analyses that provide national estimates for key measures including use of EHR APIs, the extent to which the FHIR standard is adopted, the integration landscape of EHR vendors that APIs are integrated with, and barriers and enablers of successful integration. Finally, we will conduct more advanced multivariable regression analyses that will examine predictors of key indicators such as successful integration with multiple EHR vendors, extensive use of FHIR, and low reported burden. Through these analyses, we aim to identify structural and policy-relevant factors associated with API integration scalability and sustainability. Results will be stratified by company size, maturity, and application domain, where appropriate.

We will conduct preliminary analyses and solicit input internally within ASTP/ONC, UCSF, ScaleHealth, and Clinovations to ensure that our analytic approach reflects the expertise from these organizations. The results will be published, like the 2022 findings, in peer-reviewed publications or other public documents, and shared via conferences and through blog posts to ensure they are widely disseminated.

The project timeline is 24 months, starting in August of 2024 and ending in July of 2026. Data collection will occur over 6 months and is scheduled to begin immediately upon receiving OMB approval.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

All data collection materials will display the OMB expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.