July 30, 2020

Stephen M. Hahn, MD
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Modernizing the Food and Drug Administration’s Data Strategy

Dear Commissioner Hahn:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Food and Drug Administration’s (FDA) Modernizing the Food and Drug Administration’s Data Strategy public workshop and topics for discussion published in the Federal Register on April 29, 2020.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. The ACS supports the FDA’s efforts to modernize the Agency’s data strategy, and we appreciate the opportunity to comment. Healthcare continues to grow in complexity, in part due to the greater availability of data. Increased development of health information technology and digital tools can allow greater access to these data by both the physician and the patient. Many new opportunities exist to leverage the knowledge ecosystem derived from data through in-workflow clinical solutions, creation of longitudinal data through combined data sets, patient management through real world data collected via biosensors, and more. As the FDA examines such opportunities and develops policies, we stress the importance of common data standards to support shared interoperability. We also urge the FDA to keep the patient or consumer at the forefront and to consider the careful balance between technology solutions that assure patient data remain secure while simultaneously meeting the challenge of leveraging those data to improve clinical care.
Questions

1. **Standards and policy, including:**

   - **How can FDA best use policy and common data standards to help ensure the effective and efficient use of data assets?**

   Common data standards are critical to not only ensure effective and efficient use of data assets, but also to advance interoperability of digital health technology across users and platforms. While the use of common data standards within the FDA is important, coordination of standards should exist across the Federal government as well. As various agencies, offices, and centers within the Federal government work to advance interoperability within a digital information system, standardization in data exchange “languages” across all digital health technologies is imperative. The current use of different data format standards and different versions of such standards continues to make the exchange of data challenging and expensive. For example, many digital health tools are based on the Fast Healthcare Interoperability Resources (FHIR) standard, but all technologies do not use the same version of the FHIR standard, thereby impeding fluid exchange of data.

   Instead, the FDA should consider a policy that supports the voluntary use of a multi-vendor-based implementation of a Federal FHIR server as a turn-key scalable, secure, multi-tenant Software as a Service (SaaS) solution for those seeking FHIR-based interoperability. EHRs, health plans, hospitals, providers, Healthcare Information Exchanges (HIEs) and so forth can provide data through these servers that conform to USCDI v1 FHIR R4 API. This would reduce the burden for each data model to update and maintain their FHIR server to the latest release. It would also allow all Federal agencies to use the same data exchange standard and version in all programs, API development, and certifications. The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have taken a major step in this direction in the recently finalized interoperability rules with the adoption of the HL7 FHIR Release 4.0.1 as the foundational standard to support data exchange via certified Application Programming Interfaces (APIs). The FDA should coordinate with these and other agencies in this goal.

   A Federal government-owned FHIR server could also encourage widespread voluntary conformance to the same data format standard and version, would remove some of the obstacles that currently stand in the way of interoperability and would enable bi-directional data exchange across platforms. Such standards would ensure compatibility by providing API technology suppliers...
with a clear set of rules when fulfilling API requirements. This could also eventually promote uniformity for users of digital tools when attempting to integrate applications. A single nationwide data exchange standard and version would create a more cohesive data environment, and eventually lead to a more comprehensive picture of patient health data.

b. **What are the consequences/issues as we move from “static point-in-time data sets” to updating digital data streams for analyses?**

Both “static point-in-time data sets” and digital streams of data are useful and serve different purposes. For example, digital data streams can be used for continuous management of a patient or disease, whereas “static point-in-time data sets” can be effective as a lookback for reporting and quality improvement. The analytics, data aggregation, and relevancy to the end user are different in each case. An example “static point-in-time data set” is the ACS NSQIP registry, which analyzes 30 days’ worth of surgical data from hospitals and presents the information to the end user on a dashboard. This type of information is most suited for a static data collection and presentation format. As such, we do not believe that digital data streams are preferable in all circumstances.

As the FDA contemplates moving to more digital data streams, many of the issues for consideration are similar to the issues surrounding “static point-in-time data sets” such as the importance of standards, data quality, accuracy, relevance, privacy, and transparency. Additional concerns specific to digital data streams include the requirement for constantly cleaning the data, appropriate data storage, and enabling the end-user to have real-time access to the data in a usable format (i.e. getting the data to the right person at the right time) in order to truly leverage the potential of a digital data stream.

The FDA should also consider the ability of current EHRs to handle real-time data and digital data streams as well as real time streams of data from patient wearables and sensors. Also, with respect to privacy, we urge the FDA to examine privacy concerns surrounding collection of non-protected health information data that are being captured and how these data could be inappropriately used by an API or data aggregator given that this information is not protected by privacy laws.
c. As we move into increased sharing and integrated data sets, how might FDA manage data in a way that avoids unnecessary duplication?

Duplication of data is a problem that complicates the ability to extract meaningful knowledge from the collected data. A clinical example of the confusion that arises from duplication is if data are collected from patient lab test results from multiple providers. A cancer marker from different tests could be slightly different, and the interpretation could lead to dramatically different results. There is no clear pathway for addressing this type of reconciliation challenge. One approach that the FDA might take is to record data in a structured format when possible and store the data in a data warehouse to enable queries of the data to help identify areas of duplication.

On the clinical side, structured data capture incorporated into the clinician’s workflow or into a patient’s biosensor in ways that add the least possible increased burden could be another way to not only expand and improve data but also reduce duplication if the data are sent to a common data model. EHR vendors must become enablers of structured data capture once the structure has met industry standards for implementation and has reliable and valid implementation guides. The structured data as open standards would then ideally become available to the instance of an EHR in addition to becoming a clinical tool for clinical decision support or use in registries.

2. Data security, privacy, and management including:

   a. How can FDA modernize its data strategy to continue ensuring privacy and security of data?

As we continue to expand mechanisms and standards for the collection and exchange of patients’ health data, maintaining the privacy and security of these data are critical. The ACS strongly believes that to ensure the safe management and exchange of patient data, the development of a unique patient identifier (UPI) or a mechanism that allows for accurate and reliable patient matching is necessary. For example, in today’s patient care environment, we know that an individual patient is treated across a care continuum by several clinicians over a variable amount of time, and data sharing is essential to coordinate and optimize care and reduce costs. The development of a patient identity solution, such as a UPI, would allow patient information to move between clinicians, patients, and payers in a secure and private manner, while also guaranteeing that the correct data are being exchanged for the correct patient. The ACS understands that current law does not allow for the creation of a UPI, but we believe this is the best solution to prevent inaccurate patient matching, and
many associated adverse events such as compromised safety and privacy; inappropriate, unnecessary, and even harmful care; unnecessary burden on both patients and physicians to correct misidentifications; time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges; increased health care costs; and poor oversight of fraud and abuse. Therefore, the ACS is extremely supportive of legislative efforts that would allow HHS to explore and adopt a UPI.

As previously stated, the ACS is aware that there are certain barriers that prevent the creation of a UPI, so in the interim, we suggest that the FDA collaborate with other relevant Federal agencies, such as the ONC, to develop a solution that achieves reliable patient matching and allows for the longitudinal management of patient information. Accurate patient matching is essential to achieve data-driven, optimal patient care, while also keeping patient data protected. Therefore, the ACS urges the FDA to explore a solution such as a self-sovereign identity—a blockchain-like solution that allows patients to own and control their own identity. With a self-sovereign identity, a patient would be in control of IDs, that may differ for each domain of their identity, such as a mental health ID for their mental health records, a dental ID for their dental records, an ID for chronic illnesses or other health issues, etc. They would then have to consent to giving certain parties (i.e. healthcare providers, insurers, etc.) access to their data, while also being able to specify data they do or do not want the verified party to access. For example, if a patient were diagnosed with an infectious disease with long-term chronic effects, such as HIV, the patient could choose to only share this information on a need to know basis, whereas they could choose to share all the data within their mental health ID with their psychiatrist. A decentralized identity management solution such as this can keep patient data safe from fraud and hacks, while also giving patients full control of how their data are being used.

In addition to the creation of a patient identity/matching solution, we urge the FDA to work with Congress and other Federal agencies, such as the ONC, Office for Civil Rights (OCR), and the Office of the Inspector General (OIG) to more broadly re-evaluate current policies and enforcement mechanisms that oversee today’s privacy and security standards. Current regulations need to be updated to ensure patient data are not shared unless the patient explicitly authorizes it and limits the extent to which direct-to-consumer and other non-HIPAA covered entities can use and share patient data.
b. What should FDA do to promote the management and organization of data assets across the Agency, as the amount and complexity of data (e.g., in regulatory submissions to FDA) is rapidly increasing?

Use of common data standards is the most direct way to promote the management and organization of data assets across the Agency as the amount and complexity of data coming into the Agency increases. Data that are collected using common data standards and incorporated into common data models can be organized, managed, and analyzed without the added effort of translating data submitted using different “languages.” The integrity and accuracy of the data are also preserved because the risk of information being compromised in translation is eliminated.

Our comments above in response to question (1)(a) stress the need for the availability of a voluntary Federal FHIR server in its latest release for all healthcare entities who seek to use common data standards for shared interoperability. If all Federal agencies were to use the same data format standard and version for all Federal programs, this would go a long way toward encouraging all digital health technologies to use a common data format standard and version to then ensure uniformity for hospitals, physicians, and patients as they use EHRs, wearables, biosensors, registries, third-party applications, and other digital tools.

In addition, as the FDA considers methods of storing data, two options include data warehouses and data lakes. Data warehouses store structured data, while data lakes can store either structured or unstructured data. Data lakes are not based on a common data model, rather, they could include a vast number of data models. This limits the usefulness of data lakes with respect to the types of analyses that can be performed. To analyze data, it would need to be extracted from a data lake into a data warehouse first. Data warehouses, on the other hand use a common data model to store structured data that can more reliably be queried for specific information. For this reason, the FDA should carefully consider which type of date storage option is most suited for the data that are being collected.

3. Data strategies and data sharing, including

   a. How can FDA’s data strategy facilitate broader goals of integration and interoperability of health care data and scientific data/virtual patient data generated using scientific models?

Many of the questions that the FDA poses in these topics for discussion highlight the need for common data standards. The FDA’s data strategy should
include requirements to allow for structured data capture that can be integrated into common data models. Data included in a data model with the right architecture allows for analytics to discover and expose relevant information to the end user in a way that is useful. This might not be possible for all data that the FDA gathers, and in some cases requiring structured data could be overly restrictive; but collection of structured data when possible will advance interoperability and minimize work needed to clean and aggregate data.

Other areas of focus that the FDA should include as it develops its data strategy are data quality, the importance of data that are fit for purpose and can be improved at the point of capture, data relevancy and allowing for access to the right data at the right time for the right user, support of development of longitudinal data to provide a more clear picture of patient and population health for both clinical and research purposes, as well as correct harmonization of data from disparate data sets with the goal of generating more useful data than the single data set alone.

b. How can FDA design its data strategy to reflect a global marketplace and promote clarity to data providers like regulated industry and other stakeholders?

One component of a data strategy that reflects the global marketplace is the use of consistent international data standards. Different countries use different metrics and of course different languages. International standards would reduce the risk of information getting lost in translation and would encourage greater interoperability.

The increase of digital health technologies using artificial intelligence (AI) and machine learning (ML)-based software as well as the development of virtual reality, augmented reality, neural networks, and more amplify the need for a common definitions of terms. The lack of consistent and shared terms and definitions across Federal and state health care regulatory bodies and internationally invites confusion and difficulty in developing policies surrounding these emerging technologies in the digital health space. One example of international coordination is the FDA’s collaboration with the International Medical Device Regulators Forum (IMDRF) to create a risk-based categorization framework for determining the relative risk presented by certain technologies for purposes of determining the level of regulation. We believe this framework, which was created in 2014, is now outdated and is no longer a useful tool for examining the risk of new technology such as technology using AI and ML-based software. But this is one strong example of FDA’s partnership with international bodies to come to a shared understanding on an aspect of regulation.
c. How can FDA design its data strategy and policy development to facilitate appropriate data access, data sharing within the Agency and via data sharing agreements, as well as the appropriate reuse and repurposing of data to advance Agency regulatory science priorities?

No comment at this time.

d. For stakeholders, including regulated industry that submit data to FDA, how can FDA enhance the efficiency of the preparation and submission of data to FDA?

Like our previous comments, an FDA data model that is based on common data standards, perhaps recent FHIR standards, would allow for structured data capture. This would increase efficiency of data analyses and reduce errors in the data once it is received.

The ACS appreciates the opportunity to provide feedback on these topics for discussion and looks forward to continuing dialogue with the FDA on these important issues. If you have any questions about our comments, please contact Vinita Mujumdar, Regulatory Affairs Manager, at vmujumdar@facs.org.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director