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Submitted via regulations.gov

Mehmet Oz, M.D., Administrator, Centers for Medicare & Medicaid Services
Thomas Keane, M.D., Assistant Secretary for Technology Policy and National Coordinator for Health Information Technology
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0042–NC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Request for Information on Health Technology Ecosystem [CMS-0042-NC]

Dear Dr. Oz and Dr. Keane,

We appreciate the opportunity to respond to the Request for Information (RFI) on the Health Technology Ecosystem (CMS-0042-NC). Datavant commends CMS and ASTP/ONC for initiating this vital dialogue to enhance data interoperability, foster digital health innovation, and ultimately improve outcomes for Medicare beneficiaries and the broader healthcare system.

Datavant is a data platform company for healthcare and the world's leader in secure healthcare data exchange, working with more than 80,000 hospitals and clinics, every health insurance company in the nation, 18 of the top 20 pharmaceutical companies, government agencies, and more than 300 real-world data partners. We are a company of health information interoperability, privacy, and security experts, with a mission to make health data secure, accessible, and actionable.

This RFI represents a pivotal moment to position America as the premier global leader in healthcare technology innovation. Our recommendations directly support the administration's "Make America Healthy Again" agenda by focusing on policy initiatives that will empower patients with deep access to their health information while unleashing market competition and innovation.

Drawing on our experience supporting nationwide health data connectivity, our response offers practical recommendations to help advance a modern, standards-based infrastructure that empowers patients, reduces provider burden, and unlocks data-driven solutions for care delivery, public health, and innovation. Specifically, we recommend that CMS and ONC:

1. Accelerate open API adoption—including Bulk FHIR—for research, quality improvement, and care coordination;
2. Eliminate systemic barriers to data access, including opaque API pricing and misuse of information blocking exceptions;
3. Promote fit-for-purpose networks and privacy-preserving identity solutions as scalable complements to TEFCA;
4. Expand patient and developer access to all forms of health information, including unstructured and non-EHR data, including the approximately 80% of data that is currently trapped in unstructured formats;
5. Strengthen health information technology (IT) certification program requirements and interoperability expectations based on real-world data exchange utility, not just technical compliance;
6. Support secure, federated digital identity approaches that reduce friction while enhancing security; and
7. Leverage privacy-preserving record linkage (PPRL) to connect siloed data in a privacy-aware manner, and unlock the full potential of health data for AI-driven analytics, biosurveillance, chronic disease modeling, and more.

While not the focus of this letter, a foundational prerequisite for a patient-centric ecosystem is the establishment of a comprehensive federal privacy standard that extends robust protections to all personal health information, even outside HIPAA's framework. We recommend CMS and ASTP/ONC consult with Congress to encourage comprehensive privacy legislation that:

- harmonizes with existing HIPAA protections while extending equivalent safeguards to health data that moves beyond traditional covered entities or business associates;
- preempts the current patchwork of state laws that create compliance complexity and impede interstate data exchange;
- leverages proven enforcement mechanisms rather than creating duplicative regulatory structures;
- maintains the strong tenets of HIPAA as the core standard for health information privacy while closing gaps in coverage; and
- enables secure data exchange without compromising privacy protections through privacy-preserving technologies like record linkage.

In the interim, we support expanding FTC authority to provide HIPAA-equivalent protections for entities trading in health information outside the current HIPAA framework, ensuring consistent privacy standards across the evolving digital health ecosystem without creating additional burdens for entities already subject to HIPAA.

To support these recommendations, our feedback is organized by specific proposals, with detailed responses to the RFI questions provided in table form following this letter.

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Datavant Recommendations

Recommendation 1: Accelerate open API adoption—including Bulk FHIR—for research, quality improvement, and care coordination

The administration's commitment to patient empowerment and healthcare choice requires immediate action to make Bulk FHIR APIs a cornerstone of value-based care and health IT policy. Despite technical standards being established, real-world adoption remains limited due to weak incentives and market barriers that favor incumbent monopolies. Disparities in technical resources, uneven readiness across health IT companies, and other persistent barriers disproportionately affect smaller institutions and hinder progress on critical use cases, including population health management, research, and public health surveillance.

To unlock the transformative potential of Bulk FHIR, CMS and ONC should embed its use within value-based care and public health initiatives. This includes establishing enforceable performance benchmarks—such as FHIR endpoint availability, minimum throughput, and uptime—for certified API technology, as well as funding shared infrastructure to ease implementation and onboarding. Aligning the health IT certification program's Electronic Health Information (EHI) export requirements with standardized API protocols would further streamline access and promote consistency across electronic health record systems and other platforms. Strengthening the API certification criteria under 45 CFR §170.315(g)(10) is essential to ensure that certified API technology enables timely, comprehensive, and actionable data exchange.

(For detailed responses, see RFI #s: PR-5, TD-2.d, TD-8, TD-9.e, TD-11.a-c, TD-15.a-b)

Recommendation 2: Eliminate systemic barriers to data access, including opaque API pricing and misuse of information blocking exceptions

Opaque and unpredictable API pricing structures, specifically for "proprietary" or "non-standards-based" APIs (including APIs that transmit non-EHI data), effectively function as tollgates, imposing financial burdens on healthcare organizations seeking to access and use their own data with the partners and vendors they choose. Revenue-share based API pricing models and per transaction fees unrelated to hosting costs serve to

undermine interoperability policy goals. CMS and ASTP/ONC should require transparent, cost-based pricing for APIs that reflect actual technical expenses, while prohibiting fees based on data control, opportunity cost, or data monetization models. Publicly available and standardized pricing schedules must also be required to enable accountability and comparability.

Equally urgent is the need to address the misuse of information blocking exceptions—particularly the "Infeasibility" and "Manner"exceptions—which appear to be used by some regulated actors as pretexts to delay, restrict, or price-out legitimate requests to access, exchange, and importantly use EHI. These exceptions are used opportunistically as loopholes that diminish the efficacy of the 21st Century Cures Act and frustrate innovation. CMS and ONC should narrow the scope of such exceptions, pursue enforcement through the HHS Office of Inspector General (OIG), and align Promoting Interoperability (PI) metrics with interoperability measures that reflect real-world impact and utility. These reforms are essential to ensuring transparency, fostering trust, and advancing meaningful access to data across the healthcare ecosystem (that will ultimately reduce costs for providers and patients).

(See RFI #s: TD-1, TD-2.c, TD-4, TD-10, TD-13.a, TD-18.a-c)

Recommendation 3: Support competitive, fit-for-purpose interoperability networks and privacy-preserving identity solutions as scalable complements to TEFCA.

Datavant supports the goals of the Trusted Exchange Framework and Common Agreement (TEFCA) as a foundational step toward national interoperability. However, its current trajectory risks suppressing innovation and reinforcing dominant intermediaries (and the very real phenomenon of vendor lock-in). Federal policy should support a pluralistic ecosystem that allows fit-for-purpose interoperability solutions to thrive alongside Qualified Health Information Networks (QHINs). In particular, TEFCA's resources and focus should be directed toward high-impact use cases such as Treatment and Individual Access Services which represent the most urgent needs for care coordination, patient health, and consumer empowerment. Markets have demonstrated the ability to support data exchange where data monetization provides commercial incentives; by contrast, Treatment and Individual Access require deliberate policy prioritization and careful execution. Datavant's own proprietary network, connecting more than 80,000 hospitals and clinics and 300 real-world data partners, serves as a proven example of a scalable, efficient, and purpose-built interoperability model that seamlessly complements the QHIN framework.

To enhance alignment and encourage scalable network participation, Datavant recommends the removal of the TEFCA Manner Exception from the information blocking

regulations, which effectively discourages alternatives by favoring TEFCA-compliant exchange pathways. This change would enable different models to compete based on real-world performance, value, and efficiency. We further recommend shifting regulatory focus away from rigid technical requirements and toward measurable outcomes, while embedding pro-competitive oversight into the governance of health information exchange.

In parallel, federated digital identity approaches leveraging Privacy-Preserving Record Linkage (PPRL) should be prioritized. These approaches can reduce login fatigue for patients and lower integration burdens for providers while supporting secure, scalable, and privacy-centric exchange. Strong oversight and accountability for Credential Service Providers (CSPs) are critical to ensuring trust and effectiveness in the digital identity verification process.

(See RFI #s: TD-1, PC-8.c, TD-3.a-b, TD-6.a-b, TD-14.c, TD-16.a-b, TD-17)

Recommendation 4: Expand patient and developer access to all forms of health information, including unstructured and non-EHR data, including the approximately 80% of data that is currently trapped in unstructured formats

Timely access to complete clinical information is vital for improving patient care, powering research, and enabling sound policy decisions. Yet much of this information remains siloed across public and private repositories, and substantial portions—particularly unstructured data—remain inaccessible under current standards.

One key limitation of the United States Core Data for Interoperability (USCDI) is its narrow emphasis on structured EHR data. This focus on structured, standards-based data has the effect of severely constraining AI applications and advanced analytics needed for the administration's chronic disease prevention goals. An estimated 80% of health data, including imaging, genomic sequences, and free-text notes, is unstructured[1] and therefore excluded from many current interoperability efforts. Datavant supports expanding certification criteria to encompass the full scope of Electronic Health Information (EHI) and non-electronic health information data (such as facility, provider, administrative, and other data that does not directly tie back to a patient), including unstructured data, and enabling its exchange via standardized APIs.

This expansion will unlock enormous value for American healthcare innovation: enhancing AI applications, improving clinical decision-making, and streamlining analysis through multi-modal models. Health IT certification program criteria should be updated to require

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC6372467/

that certified API technology support access to all components of a patient's chart and certified health IT developers should be encouraged to actively incorporate AI capabilities to organize, process, and make available unstructured data.

(See RFI #s: PC-8.c, TD-2.a-d, TD-7.a-d, TD-9.c, TD-13.a-b)

Recommendation 5: Strengthen health information technology (IT) certification program requirements and interoperability expectations based on real-world data exchange utility, not just technical compliance

Current certification programs prioritize technical compliance over functional outcomes, enabling "checkbox" approaches that fail to deliver meaningful interoperability. This has created a system where nominal certification can mask ineffective or inaccessible implementations. The administration's results-oriented governance approach requires certification reforms that measure actual impact. Datavant urges CMS and ASTP/ONC to redefine health IT certification around API-enabled, outcome-oriented capabilities—particularly those that demonstrate patient data access, care coordination, and data portability.

We recommend enhancing specific ONC Certification Criteria for Health IT that are proven effective in promoting interoperability and market competition. These include:

- API Certification Requirements (45 CFR §170.315(g)(10))
- Service Base URL Publication Requirement (45 CFR 170.315(g)(10))
- Electronic Health Information (EHI) Export Criterion (45 CFR §170.315(b)(10))
- FHIR Bulk Data Support for Multi-Patient Requests (§170.315(g)(10))

Simultaneously, the health IT certification process should be streamlined to eliminate administrative requirements that do not meaningfully advance interoperability.

To better align provider incentives, CMS should revise Promoting Interoperability (PI) programs to measure actual data exchange volumes, successful care transitions, and patient access rates. Standardizing EHI Export to emphasize API functionality and the use of standards, where available, will reduce vendor variability and enhance readiness. The EHI Export should support exchanging data from all aspects of the patient's chart as well as non-EHI data that may support patient-related initiatives.

Finally, full realization of the "access without special effort" principle of the 21st Century Cures Act depends on directly addressing anti-competitive health IT marketplace

behaviors, mandating cost-based API pricing, information blocking enforcement, and further refining the information blocking exceptions.

(See RFI #s: TD-1, TD-8, TD-9.a-b, TD-9.d-e, TD-10, TD-11.a-c)

Recommendation 6: Support secure, federated digital identity approaches that reduce friction while enhancing security

The lack of a cohesive digital identity framework continues to hamper secure and efficient access to health data. Patients are often forced to juggle multiple logins, while providers bear the cost of proprietary and duplicative authentication systems. High-assurance, federated identity solutions—rooted in a unified federal privacy framework—are essential for modernizing the healthcare ecosystem. Strong, federated identity solutions will enhance both cybersecurity and patient access while reducing administrative burden.

CMS and ONC should require the use of strong digital identity credentials (e.g., NIST 800-63-3 IAL2/AAL2), along with Multi-Factor Authentication (MFA), across all sensitive access points. This will substantially improve cybersecurity, enhance auditability, and support secure access controls for both conventional and AI-driven data environments.

In parallel, CMS can ease adoption by supporting providers in transitioning away from fragmented authentication tools and toward interoperable credentialing systems. Doing so will not only improve security but also reduce friction in patient-provider interactions and data exchange.

(See RFI #s: TD-1, TD-3.a-b)

Recommendation 7: Leverage privacy-preserving record linkage (PPRL) to connect siloed data in a privacy-aware manner, and unlock the full potential of health data for AI-driven analytics, biosurveillance, chronic disease modeling, and more

Privacy-Preserving Record Linkage (PPRL) represents a foundational capability for secure, scalable health data integration that addresses privacy concerns while enabling innovation. By generating de-identified patient tokens through HIPAA-aware cryptographic hashing, PPRL plus deidentification efforts allows diverse datasets to be linked while safeguarding individual privacy.

Datavant's large-scale implementation of PPRL in the NIH All of Us Research Program—supporting over 180 studies and 800,000 patients—demonstrates its technical maturity and value. Through token re-encryption, this infrastructure enables patient-level

linkage across multiple data sources without revealing underlying identifiers, making it well suited for federated environments such as Trusted Research Environments (TREs).

CMS can play a pivotal role in accelerating adoption of PPRL across public health and research use cases. This approach not only enhances data utility for biosurveillance and chronic disease modeling, but also addresses growing privacy concerns—especially re-identification risk in the era of large-scale analytics. Datavant's ongoing research already leverages AI and language models to evaluate unstructured health data types like imaging and genomic data, demonstrating how AI-derived data sources can be securely connected with prospectively collected data. PPRL enables the type of large-scale, multi-source analysis needed for AI-driven chronic disease prevention while maintaining the highest privacy standards.

(See RFI #s: PC-8.c, TD-1, TD-3.b, TD-7.d, TD-13.a-b, TD-15.b)

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Our detailed RFI responses, provided in table form immediately following this letter, elaborate on these critical recommendations. We particularly emphasize the need for meaningful enforcement to address information blocking practices and for clearer, simpler rules alongside incentives to foster a more collaborative and trusted approach between government and all stakeholders.

We recognize that achieving a truly interoperable, patient-centered health data ecosystem requires more than technical standards—it demands investment in infrastructure, a flexible regulatory approach, and a holistic framework for incentives that align with the realities of providers, payers, and patients alike. We urge Federal policymakers to build on what works, invest in its own modernization, and ensure that new requirements are paired with robust support for those most affected by change. Technology must be an enabler of, not a barrier to, person-centered care and coverage.

We welcome continued engagement and encourage you to contact us at alya@datavant.com with any questions or to discuss our recommendations further.

Thank you,

Alya Sulaiman

Alya Sulaiman, JD, CIPP/US
Senior Vice President, Regulatory Affairs
Chief Compliance and Privacy Officer

Detailed RFI Responses

RFP ID	Question	Datavant Response
		2. Patients and Caregivers
PC-8.	In your experience, what health data is readily available and valuable to patients or their caregivers or both?	Claims data is among the most readily available forms of health data, particularly through payer systems. However, it is generally not the most valuable for patients and caregivers, as it lacks the clinical richness needed for direct care decisions. Its primary value lies in secondary use cases such as population health analytics and clinical research, where it serves as a standardized, longitudinal source of information. To improve the utility of available data for patients and caregivers, enhancements to the **ASTP/ONC Certification Criteria for Health IT**[2] (EHR Certification Criteria)—particularly around consistent access to high-quality clinical data—should be prioritized. Clinical data remains the source of truth for understanding an individual's health status and care trajectory. In the absence of more widespread access to such data, efforts to improve the longitudinality, completeness, and usability of claims data sets would offer significant value.
PC-8.c	What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?	The integration of clinical data from disparate sources remains a central challenge to enabling meaningful clinical research and the generation of actionable evidence. Clinical data today remains fragmented across government agencies, industry stakeholders, healthcare providers, and research networks. These silos create operational barriers and inhibit the formation of complete, longitudinal patient datasets necessary for robust research and analytics. There is a significant opportunity for CMS to lead in addressing this fragmentation. Given its unique position, CMS is well-suited to convene stakeholders and drive the adoption of infrastructure and standards that enable linkage and interoperability across complex and diverse datasets. By prioritizing connectivity and accessibility, CMS can help unlock the value of these datasets for research and policy development. To that end, we recommend that CMS leverage privacy-preserving record linkage (PPRL) to connect siloed data, enable AI-driven analytics for biosurveillance and improved modeling of chronic disease risk, and enhance patient

[2] https://www.healthit.gov/topic/certification-ehrs/certification-health-it

RFP ID	Question	Datavant Response
		privacy. By promoting the adoption of PPRL as a foundational capability, CMS can accelerate the creation of a secure, interoperable research infrastructure that supports innovation while safeguarding sensitive health information. Datavant has direct experience addressing these challenges through its work on large-scale data integration programs, including the NIH All of Us Research Program. In this context, Datavant has helped establish data centers capable of linking disparate sources of information. Central to this effort is Datavant's privacy-preserving record linkage (PPRL) technology, which has been used to support over 180 clinical trials and observational research programs, involving more than 800,000 individual patients. The cornerstone of this approach is the generation of unique, de-identified patient tokens. These tokens are created using Datavant software that de-identifies PII and PHI through a HIPAA-compliant cryptographic hashing method that meets the Expert Determination Standard[3]. Each token is unique to the input PII and incorporates an irreversible one-way hash combined with site-specific encryption. This method allows disparate datasets to be linked securely while preserving patient privacy. Datavant's technology supports re-encryption of tokens from different sources into a common encryption scheme—under the appropriate privacy certifications and contractual agreements—thereby enabling de-identified, patient-level linkage across sources. This software can be deployed in both on-premise and cloud environments, offering flexibility across use cases. In practice, this privacy-preserving linkage has been implemented to support Trusted Research Environments (TREs) such as the All of Us Center for Linkage and Acquisition of Data[4] and the N3C Data Enclave. These deployments demonstrate how flexible PPRL infrastructure can underpin federated data architectures while maintaining data security and compliance. Furthermore, Datavant is uniquely positioned to support government agencies through its combined capabilities in medical record retrieval and patient-level tokenization. These offerings represent the integrated value of Datavant and its acquired companies, delivering best-in-class tools for secure, scalable clinical data integration.

[3] https://www.hhs.gov/hipaa/for-professionals/special-topics/de-identification/index.html#guidancedetermination
[4] https://allofus.nih.gov/article/center-for-linkage-and-aquisition-of-data

RFP ID	Question	Datavant Response
PR-5	Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:	The Standardized API for Patient and Population Services and Bulk FHIR (all EHI) certification criteria represent important technical progress in enabling access to non-transactional, longitudinal health data. These standards lay the groundwork for extracting population-level datasets to support a wide range of use cases, including research, public health, analytics, and care coordination. However, despite the technical requirements being in place, real-world implementation remains limited. Key challenges include: ● Lack of incentives or mandates: Many providers view these capabilities as compliance checkboxes rather than operational priorities. ● Resource constraints: Technical and staffing limitations, especially in smaller or safety-net institutions, frequently delay deployment of Bulk FHIR or patient-matching tools. ● Absence of governance models: There is no national framework (e.g., through TEFCA or CMS Innovation initiatives) that compels or facilitates routine exposure of these APIs for population-level exchange. As a result, while API capabilities technically exist, they are underutilized due to the absence of consistent incentives, onboarding infrastructure, and operational support. To fully realize the intent of these certification criteria, CMS and ONC should consider complementary policies, such as: ● Embedding Bulk FHIR usage into value-based payment models or public health preparedness programs; ● Establishing minimum operational performance standards (e.g., uptime, throughput) for certified APIs; ● Supporting regional collaboratives or shared service partnerships to reduce onboarding costs and facilitate scale.

RFP ID	Question	Datavant Response
E. Technology Vendors, Data Providers, and Networks		
TD-1	What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?	To stimulate developer interest in digital health products for Medicare beneficiaries and caregivers, CMS should focus on creating a policy environment that promotes interoperability, reduces regulatory burdens, and encourages the use of advanced technologies like AI and privacy-preserving record linkage (PPRL). Recommendations: ● Modernize regulatory frameworks: Refocus programs like the Medicare Promoting Interoperability (PI) Program and the Health IT Certification Program on actual health outcomes rather than prescriptive technical requirements. This would allow for greater flexibility and enable the adoption of innovative solutions tailored to specific needs. ● Encourage use of open, standards-based APIs: This ensures open, standards-based data access that enables third-party innovation and creates transparency for API discovery. The current patchwork of opaque, non-standardized API pricing practices creates significant barriers to innovation by making it prohibitively expensive for healthcare organizations to access their own data through third-party tools. ● Advance privacy-preserving technologies: Encourage the use of technologies like PPRL to securely connect health data while protecting patient privacy. This can unlock vast amounts of health data for AI development and research, leading to new digital health products. ● Support patient-centric data access: Empower individuals to easily and seamlessly access their own health information and securely share it with third-party applications of their choice. This includes providing education for choosing secure technologies and ensuring patient visibility when data moves from HIPAA-protected to non-protected environments. ● Reduce information blocking: Close loopholes in information blocking regulations that are currently used to delay, deny, or price out legitimate requests for electronic health information (EHI). This behavior undermines interoperability and impedes patient-centered innovation.

RFP ID	Question	Datavant Response
TD-2.a	What additional data would be most valuable if made available through CMS APIs?	Clinical data, comprehensive non-clinical data, non-medical drivers of health, and more complete claims data would be highly valuable for inclusion in CMS APIs. ● Full clinical picture: Access to comprehensive clinical data is crucial because critical decisions around patient care, medical outcomes research, disease prevention, and reimbursement are compromised when timely access to complete clinical information is lacking. ● Comprehensive claims data: Beyond basic Medicare Part A, B, and D claims, more detailed and validated claims data would be valuable. Validating claims data with medical records, particularly for social needs, is recommended to reduce improper payments and gain insights into healthcare needs drivers.
TD-2.b	What data sources are most valuable alongside the data available through the Blue Button 2.0 API?	Data from electronic health record (EHR) systems, other medical documentation systems, and real-world data sources are valuable alongside Blue Button 2.0 API data. Real-world data (RWD) includes EHR data, medical claims, specialty labs and diagnostics, retail pharmacy, specialty pharmacy, and other non-clinical data.
TD-2.c	What obstacles prevent accessing these data sources today?	Several obstacles hinder access to valuable health data: ● Data fragmentation and silos: Health data is collected and stored in disparate public and private silos that do not interact or share information, making optimization of understanding and utilization difficult. ● Proprietary systems and complex integrations: The average health system may have many different EHR systems and other medical documentation systems, many of which contain relevant clinical information, creating complexity and friction. Access often requires considerable follow-up from API users due to inconsistent vendor preparedness for Cures Act implementation. ● Information blocking: Broad and ambiguous exceptions to information blocking regulations are used to delay, deny, or impose cost-prohibitive barriers on data access, exchange, or use. ● Opaque and unjustified API pricing: Unpredictable and unjustified charges for API access act as "tollgates," layering new fees on top of already costly infrastructure, deterring integration with innovative tools. ● Limited functionality of Health Information Exchanges (HIEs): The coverage and depth of information and capabilities across HIEs vary significantly, making it problematic for some entities to meet interoperability measures or engage in bi-directional exchange through other means. ● Manual effort for data sharing: Despite increased digital data, significant manual effort is still required to compliantly, seamlessly, and securely share patient data due to dispersion across different repositories (including physical ones) and privacy protections.

RFP ID	Question	Datavant Response
		• Lack of standardization in data formats: there is a need to bring unstructured data (estimated at ~80% of all health data) into a usable format, as currently, accurately labeled data for AI is manual and inefficient.
TD-2.d	What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?	CMS and ASTP/ONC should prioritize APIs that enable access to the entirety of a patient's electronic health information (EHI), including unstructured data, and support efficient data transfer for various use cases. • APIs supporting all aspects of a patient's chart: Certification criteria should require APIs to consistently support exchanging data from all aspects of the patient's chart, such as faxed records, free text, and discrete data. • Bulk FHIR APIs: Increased use of bulk FHIR would improve use cases and data flow, particularly for population health management innovation and reducing provider burden for quality reporting. • APIs for administrative workflows: Standards and policies are needed for patients' third-party digital products to access administrative workflows, such as auto-populating intake forms, viewing provider information and schedules, and making/modifying appointments.
TD-3.a	Regarding digital identity implementation: a. What are the challenges and benefits?	Challenges • Patient/Caregiver adoption: Challenges exist in getting patients and caregivers to sign up and use digital identity credentials. • Provider hesitation: Providers need help to transition to a single set of trusted digital identity credentials for patients instead of proprietary logins for each provider relationship. • Overlapping review cycles: Current maintenance and documentation requirements for security measures can create an overlapping patchwork of review cycles, ranging from monthly to annual, which can divert resources from direct security activities to compliance paperwork. Benefits • Improved cybersecurity and data exchange: Requiring digital identity credentials (e.g., NIST 800-63-3 IAL2/AAL2 CSPs) can enhance cybersecurity and data exchange by providing a robust patient privacy and security platform. Multi-factor authentication (MFA) is a highly effective defense against credential-based attacks, especially for remote and privileged accounts. • Reduced burden: Digital identity implementation can help reduce provider and patient burden. • Consistent protections: A unified federal privacy framework that maintains HIPAA as the primary standard for health data privacy, while extending equivalent protections to health data that moves beyond HIPAA's jurisdiction, creates regulatory certainty and ensures consistent protection regardless of which entity processes it.

RFP ID	Question	Datavant Response
TD-3.b	How would requiring digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 CSPs) impact cybersecurity and data exchange?	Requiring such credentials would significantly improve cybersecurity by bolstering a robust patient privacy and security platform. It would also improve access to health information. This would include at a minimum access control and use of AI data being continually monitored, ongoing testing of AI platforms with human involvement, de-identification of training data to limit re-identification risk, robust evaluation of model inputs and outputs, and iterative re-evaluation of models and privacy plans if new information is added. MFA should be required across all access points to sensitive data, with priority on remote access and privileged accounts.
TD-4.	How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?	CMS can encourage the use of open, standards-based, publicly available APIs by: • Mandating cost-based pricing for API access: Current opaque and non-standardized pricing practices for proprietary APIs act as "tollgates," creating financial barriers for providers to adopt innovative tools. CMS should mandate cost-based pricing tied to documented technical expenses only, prohibit pricing based on opportunity cost or data monetization, and require transparent, standardized fee schedules. • Strengthening API Certification Requirements: Maintaining and strengthening API Certification Requirements under 45 CFR §170.315(g)(10) ensures open, standards-based data access that enables third-party innovation. The service base URL publication requirement (45 CFR 170.315(g)(10)) also creates transparency for API discovery. • Eliminating information blocking loopholes: The Manner Exception Exhausted sub-exception to the Infeasibility Exception allows regulated actors to steer requestors through predetermined acceptable manners then declare infeasibility, hindering the adoption of cutting-edge technologies like modern FHIR-based APIs.
TD-5	How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?	A nationwide provider directory of FHIR endpoints could significantly improve access to health information for patients, providers, and payers by: • Facilitating seamless data exchange: It would simplify the process of locating and connecting to provider data endpoints, accelerating data flow and improving care coordination. • Enhancing interoperability: It would provide a centralized resource for discovering FHIR-based data access points, promoting broader interoperability across the healthcare ecosystem. • Supporting patient access and choice: Patients could more easily find providers and access their health information through a standardized directory, empowering them to make informed decisions and fostering competition among providers.

RFP ID	Question	Datavant Response
		• Improving value-based care: It would help improve access to patient data and understanding of claims data sources, which is critical for success in value-based care arrangements.
TD-6.a	What unique interoperability functions does TEFCA perform? a. What existing alternatives should be considered?	TEFCA is an important federal initiative to strengthen nationwide interoperability through trusted governance and standardized exchange protocols. It aims to create a universal governance, policy, and technical floor for nationwide interoperability, enable individuals to access their EHI, and simplify connectivity for organizations to securely exchange information. It supports greater health information exchange nationwide in support of patient care. TEFCA's current strengths are best leveraged to address challenges in treatment and individual access exchange. TEFCA's current strengths are best leveraged to address challenges in Treatment and Individual Access exchange—domains where ensuring comprehensive access is paramount for care delivery and patient empowerment. These are also the areas where the market has least incentive to solve on its own, unlike commercial or research-driven data uses. Federal efforts should therefore focus TEFCA on these core use cases, where the societal benefits are highest and the stakes are greatest. • Existing Alternatives and Concerns: While Datavant supports TEFCA's core objectives, we have concerns that TEFCA's current path may create anticompetitive risks and hinder innovation if it becomes a mandated, one-size-fits-all framework. • Purpose-built API and network solutions: Datavant's own network connects to over 80,000 hospitals and clinics, 75% of the largest health systems, and 300 real-world data partners, facilitating data exchange through proprietary technology and value-added services. These purpose-built interoperability platforms can complement the QHIN model by offering scalable, efficient solutions. • Direct API connections and specialized clinical networks: These alternatives allow for fit-for-purpose interoperability tailored to specific clinical, technical, or research needs. Organizations with unique needs, such as life sciences innovators or public sector programs, require flexibility to use specialized exchange networks. • Existing exchanges: Congress intended TEFCA to be voluntary and avoid disrupting existing exchanges between participants of health information networks. • Proprietary APIs and other methods: Datavant connects to EHRs using various integration methods, including FHIR APIs, database connections, HL7v2, and private APIs, demonstrating a diversity in data exchange approaches.
TD-6.b	Are there redundant standards, protocols or	Datavant advocates for preserving and protecting alternative exchange pathways and a diverse ecosystem of purpose-built information exchange channels, rather than consolidating into a single, potentially monopolistic

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	channels or both that should be consolidated?	framework like TEFCA. As such, we call for a refocus federal policy on actual health outcomes rather than prescriptive technical requirements, which will lead to a more streamlined approach to standards based on demonstrated effectiveness. There is also a concern that the TEFCA Manner Exception undermines the principle of fit-for-purpose exchange and imposes redundant infrastructure costs by steering data through TEFCA even when other methods might be more efficient. Removing this exception would allow different interoperability approaches to compete based on performance, cost, and capabilities.
TD-7.a	To what degree has USCDI improved interoperability and exchange and what are its limitations? a. Does it contain the full extent of data elements you need?	USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. We believe that USCDI has improved interoperability and exchange and support the adoption of USCDI v4. However, USCDI does not contain the full extent of data elements needed for comprehensive clinical pictures or advanced uses like AI training and research.
TD-7.b	If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?	Limitations arise from both the definition of the USCDI format and how it is utilized: ● Limited scope of information: The scope of Electronic Health Information (EHI) as defined in the information blocking prohibition, aligned with the USCDI data set, may not be broad enough. ● Lack of comprehensive coverage: Relying solely on EHR-derived, standardized data (like USCDI) can limit the completeness, accuracy, and timeliness of data used for quality measurement. A significant amount of clinical data exists in disparate repositories, including physical ones, requiring manual effort to share. ● Exclusion of unstructured data: A major limitation is that USCDI primarily focuses on structured data, while an industry consensus estimates that around 80% of all health data is unstructured (e.g., images, genomics data, free text notes). The ability to de-identify and extract important elements from unstructured data is crucial for enhanced insight generation.
TD-7.c	If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?	Adding more data elements to USCDI would add value by expanding access to more data via FHIR APIs that meet ONC adopted standards. This would support efforts to increase the amount of health data available digitally and give patients secure, electronic access to their personal health information. Datavant believes that expanding the scope of data available through the information blocking prohibition to all EHI, rather than limiting it to USCDI, would be a more appropriate way to advance interoperability. Addressing scoping challenges would involve: ● Recognizing the value of diverse data sources: Encouraging collection of digital health information across

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		multiple data sources, not just EHRs, to provide more comprehensive and robust data. ● Leveraging AI for unstructured data: AI can help bring unstructured data into a usable realm by analyzing images, genomics data, or parsing free text. AI models can also be trained to label data or fill in missing data, improving data quality.
TD-7.d	Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?	Datavant and other industry leaders are leveraging AI and language models to handle less structured data for improved data coverage and insights. Datavant's research initiatives are already leveraging AI to evaluate unstructured health data types, such as imaging and genomic data, to enhance privacy assessments and data handling. The ability of AI to de-identify and extract relevant elements from unstructured data would provide an enhanced opportunity to connect AI-derived data sources with prospectively collected data.
TD-8	What are the most effective certification criteria and standards under the ONC Health IT Certification Program?	Several certification criteria and standards under the ONC Health IT Certification Program are effective in promoting interoperability and market competition: ● API Certification Requirements (45 CFR §170.315(g)(10)): These ensure open, standards-based data access that enables third-party innovation. ● Service Base URL Publication Requirement (45 CFR 170.315(g)(10)): This creates transparency for API discovery. ● Electronic Health Information (EHI) Export Criterion (45 CFR §170.315(b)(10)): This prevents vendor lock-in by guaranteeing data portability for patients and populations. ● FHIR Bulk Data Support for Multi-Patient Requests (§170.315(g)(10)): This enables population health management innovation. ● Patient-Requested Restrictions Requirement within the View, Download, and Transmit (VDT) certification criterion: This supports privacy considerations and empowers patients with control over their EHI. Datavant strongly advocates for maintaining and strengthening these core requirements that genuinely promote interoperability and market competition, while streamlining the program by removing elements that impose administrative burden without materially advancing interoperability.
TD-9.a	Regarding certification of	Prioritizing API-enabled capabilities over software functionality would:

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	health IT: a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?	• Promote innovation: It would enable healthcare organizations to select and integrate best-in-class tools and solutions tailored to their needs, fostering a dynamic and open health IT ecosystem. • Ensure data portability: APIs provide a mechanism for data to be accessed, exchanged, and used without special effort. • Reduce vendor lock-in: By guaranteeing open, standards-based data access, it prevents healthcare organizations from being locked into using native EHR functionality even when more targeted third-party solutions exist. • Support specialized solutions: It allows for the development and adoption of specialized exchange networks tailored to population-specific needs or particular clinical domains.
TD-9.b	What would be the drawbacks?	Datavant has concerns about regulatory overreach and unnecessary burdens that could hinder innovation or divert resources, which might indirectly occur if the new definitions are too prescriptive or costly to implement. If new requirements are not incorporated into the definition of Base EHR, it could limit the availability of products meeting the revised definition.
TD-9.c	How could ASTP/ONC revise health IT certification criteria to require APIs to consistently support exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data)?	ASTP/ONC could revise criteria by: • Acknowledging diverse data formats: Recognizing that a significant portion of health data (around 80%) is unstructured (images, genomics, free text). • Leveraging AI capabilities: Given improvements in language models, APIs could be required to support less structured formats, even if it requires more processing by the receiver, as AI can help parse and organize such data. • Addressing existing challenges: Current challenges include accessing different data formats, their impact on patient care quality, technical barriers, and cost/privacy implications. Datavant's experience in aggregating data from multiple EHR systems and other record systems, including both structured and unstructured data, highlights the feasibility and value of this.
TD-9.d	What policy changes could CMS make so providers are motivated to respond to API-based data requests with best possible coverage and	CMS could motivate providers by: • Refocusing incentives: Shift the emphasis of programs like the Promoting Interoperability (PI) program to measure real-world data exchange volumes, successful care transitions, and patient access rates, rather than rigid technical specifications that favor incumbent vendors. The PI program measures should credit the use of purpose-built health information exchange technologies, not just participation in formal frameworks like TEFCA.

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	quality of data?	• Addressing cost barriers: Implement reforms to ensure health data API access is governed by true cost-based pricing, and prohibit discriminatory pricing structures that deter data sharing. • Consolidating reporting responsibilities: Consolidate interoperability and quality reporting responsibilities so investments can be dually purposed. • Providing clear guidance: Offer detailed guidance on interpreting and implementing data sharing policies, including concrete examples and objective criteria, to minimize confusion and inconsistent application.
TD-9.e	How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS? What capabilities are needed to show benefit? What concerns are there with this approach?	EHRs capable of bulk data transfer (Bulk FHIR APIs) could significantly reduce provider burden for quality performance data reporting to CMS. Benefits • Streamlined data flow: Improves data flow and use cases. • Reduced administrative burden: Enables CMS to perform quality metrics calculations instead of provider-side technology, streamlining processes. • Population health management: FHIR Bulk Data support for multi-patient requests enables innovation in population health management. Capabilities Needed • Standardized formats: Data should be in standardized formats, accessible, and meaningful. • Data integrity and provenance: High quality data with understood profiles and provenance are essential for high-quality AI performance and reliable outputs. • Automated data labeling/filling: AI can help accurately label data or fill in missing data, improving quality.
TD-10	For EHR and other developers subject to the ONC Health IT Certification Program, what further steps should ASTP/ONC consider to implement the 21st Century Cures Act's API condition of certification (42 U.S.C. 300jj-11(c)(5)(D)(iv)) that requires a developer's	To implement the "access without special effort" condition, ASTP/ONC should: • Address anti-competitive tactics: Implement policies to prevent health IT developers from employing anti-competitive tactics that seek to maintain control over data within proprietary software, which undermines interoperability and limits authorized access to EHI. • Ensure comprehensive data access: Require APIs to consistently support exchanging data from all aspects of the patient's chart, regardless of storage format (e.g., scanned documents, faxed records, free text, discrete data) and for non-EHI data that may support patient-related initiatives. Datavant's experience indicates that the average health system has 16 EHR systems, and significant manual effort is still required to compliantly and securely share patient data due to dispersion in different repositories, including physical ones. • Refine information blocking exceptions: Focus information blocking exceptions to close loopholes and eliminate overly broad interpretations that allow actors to opportunistically delay, deny, or price out

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	APIs to allow health information to be accessed, exchanged, and used without special effort, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws?	legitimate requests. The current tendency of certified health IT developers to implement only the bare minimum required for API Condition of Certification requirements, neglecting the spirit of interoperability, must be addressed. • Mandate cost-based pricing for all health data APIs (including those that transmit non-EHI data): Ensure that health data API access is governed by true cost-based pricing to remove financial barriers that force healthcare organizations to pay exorbitantly for access to their own data
TD-11.a	Now that this capability has been in production for over a year, CMS and ASTP/ONC seek input on the following: a. Should this capability be revised to specify standardized API requirements for EHI export?	Yes, the capability to perform an electronic health information export or "EHI export" for a single patient as well as for patient populations (45 CFR 170.315(b)(10)) should be revised to specify standardized API requirements for EHI export. Leaving EHI export accomplishment entirely to the health IT developer, as currently done, can lead to variability in processes and hinder the seamless flow of information. While some propose re-scoping EHI export to solely focus on USCDI data, Datavant strongly emphasizes that limiting EHI export to USCDI would undermine the goal of comprehensive data access and impede innovation, particularly for advanced AI applications and research that rely heavily on the estimated 80% of health data that is unstructured. Our recommendation is to ensure APIs consistently support exchanging all aspects of a patient's chart, regardless of format, leveraging advancements in AI to parse and organize less structured data, thereby unlocking vast amounts of critical health information.
TD-11.b	Are there specific workflow aspects that could be improved?	• Inconsistent vendor preparedness: Vendor readiness and processes for Cures Act implementation have been highly variable, contributing to a fragmented information exchange landscape. Standardized API requirements would improve this. • Prioritization of technology over process: A disproportionate emphasis on technology implementation without corresponding attention to process development for information sharing has hampered effective data exchange. Workflows for EHI export often require considerable follow-up from API users. • Minimal compliance with certification requirements: Certified health IT developers often implement only

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		the bare minimum, neglecting the full spirit of interoperability.
TD-11.c	Should CMS consider policy changes to support this capability's use?	Yes, CMS should consider policy changes to support this capability's use. These changes should aim to: • Promote transparency: Mandate transparent, standardized API fee schedules to remove cost barriers for accessing EHI export capabilities. • Strengthen enforcement: Bolster enforcement against information blocking practices that delay or deny legitimate EHI export requests. • Encourage use of advanced technologies: Promote the use of technologies like privacy-preserving record linkage (PPRL) to enable secure and compliant data sharing for research and other purposes, leveraging EHI exports for large datasets
TD-12	Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?	Yes, CMS should consider endorsing non-CMS data sources and networks. Datavant recognizes the value of diverse data sources beyond just claims data (e.g., clinical data, real-world data) for comprehensive insights and improved patient outcomes. Criteria/Metrics for endorsement: • Quality and integrity of data: Data should be of high quality, fit-for-purpose, representative of the population, and have a well-understood profile to avoid bias and ensure accurate decision-making. Regular data audits and standardized formats/protocols for data exchange should assure quality and integrity. • Privacy and security protocols: The data must remain secure and patient privacy protected, employing robust data governance frameworks, data protection protocols, strong encryption, and de-identification whenever possible. • Accessibility and usability: The data should be easily accessible by interested parties such as researchers and providers. • Interoperability: The ability to facilitate data linkage across disparate datasets and interconnect with other networks is important. • Ethical considerations: Compliance with evolving privacy laws and the promotion of ethical AI use are paramount. • Demonstrated outcomes: CMS could consider metrics that evaluate the quality and quantity of unique patient records exchanged, diversity of exchange partners, timeliness of data exchange, and breadth and

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		completeness of exchange data
TD-13.a	What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)? a. What are the primary obstacles to this?	Providing access to the entirety of a patient's EHI through APIs would unlock significant opportunities: ● Enhanced AI applications: AI can analyze large volumes of unstructured data, leading to enhanced insight generation and multi-modal models that join disparate data sets at the patient level. This includes applications in clinical trials, drug repurposing, synthetic data development, and smart trial design. ● Improved clinical decision-making: Timely access to the complete clinical picture enables critical decisions around patient care, medical outcomes research, disease prevention, and reimbursement. ● Streamlined analysis and research: AI can classify and prepare data as part of a data pipeline, facilitating streamlined analysis. In clinical use cases with small cohorts, AI can expand the research pool and improve data quality by predicting missing values. ● Reduced friction and costs: AI, when implemented correctly, can provide an additional layer of protection for underlying patient data, reducing costs and easing frictions within the data pipeline, thereby increasing data mobility. ● Better patient engagement: Patients would have greater control and understanding of their health information, enabling better health management and care navigation. That said, primary obstacles include: ● Data fragmentation: EHI is dispersed across different repositories, including physical ones, requiring significant manual effort for compliant sharing. Many health systems have multiple EHR systems that contain relevant clinical information. ● Information blocking: Broad and ambiguous exceptions to information blocking rules are used to delay, deny, or price out legitimate EHI requests. ● Privacy concerns with full EHI access: Making a wide range of patient information available, especially to commercial entities without clear privacy restrictions, could erode existing privacy protections and lead to unintended consequences, including monetization of sensitive patient data. ● Cost barriers: Opaque and non-standardized pricing practices for APIs act as "tollgates," deterring access to EHI.
TD-13.b	What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data	● USCDI: Provides a standardized and defined set of core data elements, improving baseline interoperability and exchange. However, it may limit the completeness, accuracy, and timeliness of data for certain purposes, especially given that much health data is unstructured. The scope of EHI, when limited to USCDI, may not be broad enough for advanced uses.

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	processing capabilities today?	• Full EHI: Offers the potential for more comprehensive insights, enhanced AI applications, and improved clinical decision-making by including all data elements, including unstructured data. However, it raises substantial privacy concerns if not handled with robust privacy safeguards, especially regarding re-identification risk from massive datasets. It also presents challenges in data access due to fragmentation and information blocking. With more flexible data processing capabilities today, particularly with AI, there is a strong argument for moving towards full EHI access, provided robust privacy-preserving technologies and governance frameworks are in place. The tradeoff is between the manageability and established standardization of USCDI versus the comprehensive utility and innovation potential of full EHI, balanced by advanced privacy and security measures.
TD-14.a	Regarding networks' use of FHIR APIs: a. How many endpoints is your network connected to for patient data sharing? What types, categories, geographies of endpoints do you cover? Are they searchable by National Provider Identifier (NPI) or organizational ID?	Datavant's network connects to a vast number of endpoints for patient data sharing: • Organizations: 7,089 total live sites with 3,350 new digital connections to sites overall (YTD 2025) • Hospitals and Clinics: More than 80,000 Hospitals and clinics through the largest health data retrieval network. This includes 75% of the nation's 100 largest health systems. • Real-World Data (RWD) Partners: An ecosystem of more than 300 real-world data partners with 2.2 trillion records processed for linkage annually. • Life Sciences Companies: 18 of the top 20 pharmaceutical companies. • Government Agencies: 17 Federal, State, and Local Government Agencies • Record Requests: 7M+ Charts digitally fulfilled in 2024 with 1.6K+ Terabytes of data annually exchanged. • Datavant has 533,870 NPIs (Datavant Affiliate Network) with 24,113 Tax ID Numbers (TINs).
TD-14.b	How are these connections established (for example, FHIR (g)(10) endpoints, TEFCA/Integrating the Health Enterprise (IHE) XCA, or proprietary APIs)?	Datavant connects to EHRs and other systems using a variety of integration methods, including: • FHIR APIs • Database connections • HL7v2 • Proprietary APIs • Privacy-preserving record linkage (PPRL) technology (tokenization), which creates a universal, de-identified key to link records across datasets
TD-14.c	Do you interconnect with	Datavant works with various stakeholders to enable secure data connectivity. While Datavant supports TEFCA as

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	other networks? Under what frameworks (for example, TEFCA, private agreements)?	a helpful facilitator of national interoperability, specifically for Treatment and Individual Access Purposes (where public oversight is paramount), and is evaluating participation in the network, we recognize the need for alternative exchange pathways (e.g., direct API connections, specialized clinical networks, private agreements). Datavant's PPRL implementation enables token interoperability with other PPRL solutions, ensuring efficient pooling and aggregation of data even on proprietary platforms. This highlights interconnection capabilities beyond formal frameworks like TEFCA.
TD-15.a	Regarding bulk FHIR APIs: a. How would increased use of bulk FHIR improve use cases and data flow?	Increased use of bulk FHIR APIs would significantly improve use cases and data flow by: ● Enabling population health management innovation: Bulk FHIR supports multi-patient requests, which is essential for managing health at a population level. ● Reducing provider burden for quality reporting: EHRs capable of bulk data transfer can be used to reduce the burden on providers for reporting quality performance data to CMS, potentially allowing CMS to perform quality metrics calculations directly. ● Accelerating research and analytics: Bulk data transfer is critical for generating insights from large datasets for research, value-based care, and AI training.
TD-15.b	What are the potential disadvantages of their use?	While not particularly "disadvantages" any large-scale data use, which bulk FHIR facilitates, must address the following: ● Privacy concerns: Development of massive datasets, even with de-identification, brings up substantial privacy concerns if elements cannot be assessed for re-identification risk. Policies that make wide ranges of patient information available to commercial entities could erode privacy protections. Datavant's PPRL solution can solve for this concern over re-identification risk. ● Sparseness: AI modeling used for real-world data analyses needs to be trained on a framework for handling data sparseness often observed in real-world healthcare data.
TD-16	What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?	Point-to-point models offer direct connections but can be inefficient, complex, and difficult to scale across a vast and fragmented healthcare ecosystem (e.g., 16 EHR systems per health system).
TD-16.a	Do current rules	Current rules do not sufficiently encourage scalable network participation and may even hinder it.

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	encourage scalable network participation?	• TEFCA's potential for bottleneck: While TEFCA is an important initiative, Datavant and other industry partners have concerns that its current path may lead to it becoming a bottleneck that impedes broader interoperability goals. • Regulatory preferences for TEFCA: The TEFCA Manner Exception creates a de facto regulatory safe harbor for routing health information exchange through TEFCA, even when other methods may be more efficient or appropriate. This discourages investment in alternative, potentially more scalable, or specialized interoperability solutions. • Anticompetitive effects: Regulatory programs like CMS PI and ONC Health IT Certification have facilitated market concentration and can lock providers into specific technologies, preventing adoption of innovative solutions and potentially discouraging network participation outside of incumbent systems.
TD-16.b	What changes would improve alignment (for example, API unification, reciprocal access)?	To improve alignment and encourage scalable network participation: • Remove the TEFCA Manner Exception. This would eliminate the effective regulatory preference for TEFCA over competitive, fit-for-purpose alternatives, allowing different interoperability approaches to compete based on performance, cost, and capabilities. • Refocus regulatory frameworks on outcomes. Shift emphasis to measuring real-world data exchange volumes and successful care transitions, rather than enforcing rigid technical specifications or specific participation models. • Mandate cost-based API pricing. Eliminate unpredictable and unjustified charges that act as "tollgates" and deter integration with innovative tools. • Preserve alternative exchange pathways. Protect direct API connections, specialized clinical networks, and purpose-built health information technology infrastructure from being disadvantaged by TEFCA-centric policies. • Embed competition principles. Establish a standing interagency task force to assess the competition implications of federal health IT regulations, ensuring pro-competitive principles are embedded proactively.
TD-17	Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing	CMS and ASTP/ONC have a critical role in ensuring the viability of healthcare data sharing networks to drive usage and outcomes. Their role should be to: • Promote a competitive ecosystem: Support a competitive ecosystem of exchange options, rooted in minimum necessary principles and privacy-by-design, rather than creating government-sanctioned monopolies.

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	networks, including enough supply and demand, that results in usage and outcomes?	• Implement cost-based API pricing, widely. This would reduce the financial burden on healthcare organizations and encourage integration with innovative tools, thereby increasing supply and demand for data exchange. • Streamline certification requirements. Refocus health IT certification on actual health outcomes and open standards, allowing innovative developers to compete and encouraging provider flexibility. • Close information blocking loopholes. Strengthen enforcement against practices that delay or deny legitimate data access, exchange and importantly, use, which currently stifle data flow and innovative care/business models. • Ensure voluntary participation. Reinforce that TEFCA is a voluntary network for all participating entities, including Participants and Subparticipants, to avoid disrupting existing exchanges and prevent duplicative costly work. • Embed competition principles through coordinated oversight. Establish interagency task forces to assess competition implications of health IT regulations proactively.
TD-18.a	Information blocking: a. Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?	Datavant, as a technology vendor and facilitator of health data exchange, has observed several practices that constitute information blocking: • Anti-competitive tactics by health IT developers: Certain developers seek to maintain control over data within their proprietary software, which undermines interoperability and limits valid, authorized access to electronic health information (EHI). This behavior is observed when third-party tools compete with native offerings. • Inconsistent vendor preparedness for Cures Act implementation: This has led to a fragmented information exchange landscape, where processes enabling API access to certified API technology are highly variable and often require considerable follow-up from API users. This results in situations of non-responsiveness or unusable responses. • Disproportionate emphasis on technology over process: Focusing solely on technology implementation without developing corresponding processes for information sharing hampers effective data exchange. For example, variability in FHIR API implementations means even health systems using the same EHR can have vast differences in adoption, performance, and throughput, creating bottlenecks and necessitating workarounds. • Minimal compliance with certification requirements: Certified health IT developers may implement only the bare minimum required for API Condition of Certification, neglecting the full spirit of interoperability. • Exploitation of exceptions: Broad and ambiguous exceptions, particularly the "Infeasibility" and "Manner" exceptions, are opportunistically used to delay, deny, or price out legitimate requests. Actors cite

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		exaggerated technical or financial burdens to avoid facilitating valid data access, even when these obstacles could be readily addressed. The "Manner Exception Exhausted" sub-exception allows actors to steer requestors through predetermined "acceptable manners" then declare infeasibility, preventing adoption of cutting-edge technologies. Some of these information blocking exceptions have also been exploited to create substantial financial barriers to “proprietary” non-”alternative manner” interoperability technologies,, with a lack of transparency in how fees are calculated for proprietary APIs and interfaces. The lack of transparency has the effect of discouraging providers from information sharing or integrating with best-in-class solutions.
TD-18.b	What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?	ASTP/ONC and CMS should implement the following policies: ● Close loopholes in exceptions: Focus information blocking exceptions to eliminate overly broad, opportunistic interpretations, particularly for Infeasibility and Manner exceptions. ● Standardize expectations and best practices: Provide clear, consistent information sharing expectations and recommended best practices to reduce vendor discretion. ● Bolster enforcement by HHS OIG: Ensure timely investigation of complaints and meaningful penalties for misuse of exceptions. The current lack of meaningful federal enforcement has already spurred increased litigation at the state level and have not deterred information blocking practices. ● Mandate cost-based API pricing: This would prevent the use of prohibitive fees as a barrier to data access and promote fair competition. ● Refocus Promoting Interoperability (PI) Program: Shift the PI program to measure actual health outcomes and data exchange volumes, rather than rigid technical specifications that could be gamed.
TD-18.c	Are there specific categories of healthcare actors covered under the definition of information blocking in section 3022(a)(1) of the Public Health Service Act (PHSA) that lack information blocking disincentives?	As noted above, in absence of HHS OIG enforcement and through the select opportunistic reliance on existing Information Blocking exceptions, some regulated actors may be able to engage in information blocking without sufficient disincentives. Datavant's growing concern is that the existing information blocking exceptions can be weaponized by certain regulated actors to maintain market control and block healthcare organizations from investing in innovation. Failing to address information blocking through enforcement could undermine the effectiveness of any new health IT or interoperability initiatives.