



What is Healthcare Data Interoperability and Why Does It Matter for Clinical Research?

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What Is Healthcare Data Interoperability?

Healthcare data interoperability is the ability to efficiently, effectively, and seamlessly communicate, securely store, and securely share electronic health data in a timely manner. This enables relevant parties to access full medical histories within the healthcare ecosystem. Ultimately, the goal is to positively impact health outcomes for patients.

Figure 1: What is Interoperability in Healthcare

What is **Interoperability** in Healthcare?

Interoperability in healthcare is the ability for two or more systems to exchange and make use of healthcare data, with respect to both parties formats, standards, IT infrastructure, and intended use.

Defining Data Interoperability in Healthcare

The **HIMSS** (Healthcare Information and Management Systems Society) describes healthcare data interoperability as:



... the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries to provide timely and seamless portability of information and optimize the health of individuals and populations globally.

Health data exchange architectures, application interfaces, and standards enable data to be accessed and shared appropriately and securely across the complete spectrum of care, within all applicable settings and with relevant stakeholders, including the individual.”

Four levels of healthcare data interoperability need to be in place:

- 1 Foundational**
The ability to share data from one source to another, e.g., emails and PDFs.
- 2 Structural**
The ability for data to be opened and used on different systems, e.g., standardized data formats, syntaxes, and structures such as codes, identifiers, and simple text.
- 3 Semantic**
The use of standardized vocabulary and terminology, establishing a common foundation for data input. Examples include the Medical Dictionary for Medical Regulatory Activities (MedDRA)¹ and International Statistical Classification of Diseases and Related Health Problems (ICD 10) codes.²
- 4 Organizational**
Refers to regulatory and legal governance, oversight, policies, and other organizational considerations.

Why Is Data Interoperability Important in Healthcare?



Understanding how data unlocks paths for different treatments and different opportunities [is the key]... Data is a currency for patient communities. Data is a currency when it comes to treatment options.”

Alicia Staley
Chief Patient Officer
Medidata



Complete visibility of patients’ healthcare and medical records is critically important. This enables relevant parties—patients, care providers, labs, researchers, payers, researchers, and public health administrators—to make informed decisions.

Recognizing this, efforts have been made globally to build electronic health record (EHR) ecosystems.

Speaking about EHRs in the United States at Medidata NEXT New York, November 2024, Micky Tripathi, PhD, MPP, Assistant Secretary for Technology Policy, National Coordinator for Health IT, and Acting Chief AI Officer, US Department of Health and Human Services (HHS), said:



Just ten to twelve years ago we had 10%-20% adoption of electronic health records across the [United States]. A lot of those [were] homegrown systems, mostly hospitals, [with] very little on the ambulatory side. We’ve done a ton of work on the public and the private side to get us to the place we are now, where 97% of hospitals and 80% of physician offices across the country have certified electronic health records.”

Whilst this is a major first step, there are several challenges that the HHS and the industry are working to address. For example, when different versions of patients' healthcare data reside in multiple disparate systems, this results in duplication of data, gaps, or inconsistencies when accessing different electronic healthcare record (EHR) systems, electronic medical record (EMR) systems, and other sources. This creates potential issues, including errors in diagnosis or treatment and delays to patient care while tests are repeated unnecessarily. Delays have a significant impact on patients who are forced to live with life-changing or life-threatening conditions.

Micky Tripathi confirmed that the HHS is continuing its work to reduce operational and data segregation in healthcare and clinical research, and it is also under pressure from the Food and Drugs Administration (FDA) and the National Institute of Health (NIH) to address healthcare data interoperability challenges between the two areas.

Internationally, efforts have gathered momentum to address the issues and needs of country-

specific and cross-border healthcare data access. We highlight these in the “Future of Healthcare Interoperability” section below.

Also, additional data is collected now: demographics, lifestyle choices, behavioral patterns (smoking, diets, etc.), and genetic predispositions. This data enables care providers and public health administrators to carry out detailed analyses of overall healthcare needs and health trends, to make decisions regarding every element of the system—to improve therapies, drive new developments, amend or create policies, identify gaps in medical histories, and improve quality of care.

The healthcare sector, regulatory bodies, and governments recognize that it is critically important that relevant stakeholders have secure, appropriate, and timely access to necessary data to make healthcare decisions—hence the need for healthcare data interoperability.

Surprisingly, true healthcare data interoperability does not exist everywhere... yet.



Key Benefits of Healthcare Data Interoperability

As healthcare is data-driven, healthcare data interoperability can benefit almost every aspect of the ecosystem.

The core benefits are:



Improved Patient Care

Patients receive a higher quality of care when care providers have access to patients' complete electronic medical records. Access to full healthcare data in emergencies is particularly critical, where life and death decisions need to be made instantly by care providers. For example, if an unconscious accident victim is admitted into the emergency assessment unit of a hospital and the emergency team does not have access to complete medical records through their EHR/EMR, and therefore is not aware of an allergy to certain medications, treatment could result in a serious adverse event or worse.



Patient Empowerment

Many countries are working to empower patients with easy and full access to their medical data, helping them to take control of their healthcare, e.g., to seek second opinions, learn more about their health, and make numerous other healthcare-related decisions. Healthcare data interoperability is the key to achieving this.

In the US, the Centers for Medicare & Medicaid Services (CMS) published a ruling to achieve this “by liberating patient data using CMS authority to regulate Medicare Advantage, Medicaid, Children’s Health Insurance Program, and Qualified Health Plan issuers on the Federally-facilitated Exchanges.”³



Cost Savings, Efficiencies, and Reduced Burdens

The financial impact of a lack of healthcare data interoperability within the US healthcare industry has been estimated at \$30 billion, which would be avoidable if a truly interoperable healthcare data ecosystem existed.⁴ Many costs are attributed to inefficiencies and duplication of tasks. Examples include: increases in the length of stays for patients caused by delays in information transfer; adverse events that were avoidable if healthcare data interoperability existed; redundant testing carried out due to inaccessible information; manual entry of information by healthcare professionals; managing duplicated or inconsistent data; and additional provider costs associated with integrating electronic health records and other systems.



Support for Public Health Initiatives

Government initiatives to improve public health need insights across the healthcare spectrum. The gathering of anonymized data to drive improvements, research, and developments, and to monitor progress is complicated by the sheer number of sources and complexity of data.

Healthcare data interoperability enables quick, efficient, streamlined, and accessible routes to monitor health trends, track diseases, identify research and development opportunities, and highlight risks.



Regulatory Compliance

Globally, regulatory bodies and governments have responded to the critical nature of healthcare data interoperability by issuing regulatory requirements and guidance. Examples include: the US Food and Drugs Administration (FDA), whose guidance regarding medical device interoperability spans from 2010 to the present day⁵; the UK Medicines & Healthcare products Regulatory Agency (MHRA)'s new Data Strategy that includes "Harmonised standards and ontologies permitting [healthcare data] interoperability"⁶; and the US Trusted Exchange Framework and Common Agreement (TEFCA), the "universal governance, policy, and technical floor for nationwide [healthcare data] interoperability" of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC).⁷



Why Does It Matter for Clinical Trials?

From the perspective of most patients, their care may be provided by a single, overarching (albeit complex) healthcare system. As touched on above by Micky Tripathi, the reality is that there are distinct lines drawn between healthcare providers and the life sciences sector, including clinical trials.

Healthcare data interoperability between the sectors is almost non-existent. Healthcare providers typically use different systems for clinical research and day-to-day patient care. Sharing data between these systems has been manual or very limited, making accessibility and use of patients' healthcare data for clinical research decisions difficult.

The absence of true healthcare data interoperability has impeded clinical research for decades, and this is why global efforts to break down barriers have been a key focus for so long.

Benefits for Clinical Research and Development

The clinical research and development sector leverages anonymized public health data to assist in multiple areas of clinical studies, including identifying opportunities, risks, and patterns within therapeutic areas. Authorized personnel, such as doctors and monitors, will have access to a patient's EHR.

Standards like TEFCA create a healthcare data interoperability floor that enables innovators like Medidata to empower patients, sites, CROs, and sponsors.

Medidata has developed, or is working on, [several use cases that have been made possible by leveraging TEFCA](#) with [Medidata Health Record Connect](#).

Clinical research and healthcare use cases where TEFCA and other standards can make a difference include:



Bringing clinical research activities closer to patient care workflows

This eliminates the need for switching between healthcare and clinical trial technologies to reduce site burden.



[Data entry automation \(EHR-EDC\)](#)

This technology eliminates manual data duplication of EHR data into the EDC system and enables scalable data access.



Patient recruitment

Allowing research sites to query their patients, create cohorts, and aggregate and visualize local cohorts for pharmaceutical and medical device clinical studies.



Patient registries

Connecting patients' medical records to registries to qualify patients quantitatively.



Real World Evidence (RWE)

Collecting, aggregating, and analyzing data from multiple sources in the healthcare ecosystem, including EHRs, labs, claims data, and more.



Visibility of appropriate studies

Enabling sites to identify candidate clinical research trials for their patients using their electronic health records.

Challenges to Achieving Healthcare Data Interoperability

As mentioned above, true healthcare data interoperability does not exist, even after decades of industry and regulatory collaboration.



The healthcare ecosystem is driven by vast volumes of data from many disparate sources—patient examinations, diagnosis, tests, treatment plans and records, demographic information, prescriptions, doctors’ notes, sensors, wearable devices, and other data generated across the ecosystem. It’s highly complex and multi-layered.

Key challenges include the following:

Sheer volume and velocity of data

Manual processes and legacy systems cannot keep up with the sheer volume of data the healthcare system generates. An average patient’s EHR is approximately 80 Mb per year.⁸ In 2020 the World Economic Forum estimated that 2.3 zettabytes, that’s 2,300,000,000,000,000 megabytes of data, was produced within healthcare, and this increases every year.⁹ Additionally, the velocity of data, the sheer speed at which it can be generated for analysis, is staggering, particularly with the increased adoption of more technologically advanced systems and AI-assisted platforms.

Security and privacy

Patient data is subject to privacy and security regulations and the accessibility needs of authorized stakeholders within the healthcare ecosystem. Globally, guidance, regulations, and resources are in place to secure these. For example, in the US the Health Insurance Portability and Accountability Act (HIPAA) requires that any vendors providing a patient-facing service must abide by HIPAA rules.¹⁰

The [Global Digital Health Partnership \(GDHP\)](#) is an international collaboration of governments, government agencies, and the World Health Organization (WHO), with members from [forty countries](#), committed to improving digital health services for better care across the globe. According to its report in 2020, patient access, along with privacy and security concerns, scored medium-to-high priority in most countries, with others such as Switzerland, Austria, and Estonia prioritizing patient access above other concerns. Providing patient access in the US was a high priority, but a lack of widespread patient engagement was cited as a hindrance.¹¹

Financial and resource limitations

The costs of upgrading legacy systems and implementing interoperable technologies can be off-putting, particularly for hospitals and smaller healthcare organizations with limited budgets and resources. When considering the risks to patients, financial losses from operational inefficiencies, and the inability to make fully informed data-driven decisions, the need for healthcare data interoperability from an ethical, health, safety, and economic perspective is unquestionable.

Disparate systems

Advancements in technology have seen a plethora of disparate systems offering solutions to enhance healthcare processes, usually designed to improve efficiency and speed, reduce costs, improve experiences, etc. While any system that can achieve this is very welcome, the disparate nature of these systems has also led to healthcare data interoperability and integration challenges, which in turn have caused delays, costs, and additional resource requirements for all stakeholders involved in the healthcare and research side.



Putting this into context, David Vulcano, VP, Clinical Research Compliance & Integrity, from [HCA Healthcare](#), one of the leading providers of healthcare services in the world (186 hospitals and 2,400+ sites), shared that HCA receives scores of requests every single day from disparate third-party solution providers to integrate with them.

David shared his insights during Medidata NEXT New York, November 2024. He is also on the leadership council and an honorary President of the Society for Clinical Research Sites and is an advisor for the Society for Clinical Data Management. With cyber-security challenges and with the increase in AI-based solutions, the audit, onboarding, and integration process has become slower and more complex. Of particular note, he also stated that “...if we’re introducing the technology on a per-study basis, [onboarding new systems] gets deprioritized... patient care is always going to be first.”

This touches on one of the reasons why sponsors who choose disparate systems to support trials—as opposed to mature, established, widely used technology platforms such as Medidata’s—will often encounter delays and associated costs when they are introduced on a per-study basis. David suggested that if sponsors were to advocate for sites to choose their vetted technology, such as the Medidata platform, that would go a long way toward addressing these issues.

In the same panel discussion, Henry Wei, Head of Development Innovation, Regeneron, and James Coutcher, Senior Director, Global Head of Emerging Methods and Solutions, Real World Solutions, IQVIA Technologies, agreed that there isn’t a ‘one size fits all’ approach to studies, so adaptability is important.

James also touched on RWE and trial data linkage, a topic covered [here](#). This process would benefit from the EHR data linked to an EDC system to minimize the burden on sites.

These points highlight the industry’s experience that implementing disparate systems to create custom-built solutions on a study-by-study basis causes delays and integration issues and exacerbates healthcare data interoperability challenges for sites, CROs, and sponsors. The answer is to implement a single, highly adaptable platform, like Medidata’s, or use a solution that enables data interoperability between systems from different vendors, such as [IQVIA’s One Home for Sites](#).

A core challenge in achieving healthcare data interoperability has been the lack of unified standards in the industry, which leads us to the following topic:

Figure 2: Healthcare Data Standards

Standardization

Due to healthcare data interoperability challenges between EHRs and other systems, three major standards emerged that are still in use today:

Standard Name	Descriptions	Year Involved
HL7	Point to Point messaging standard	1989
CDA	Architecture to communicate document based clinical summaries	1996
FHIR	Set of resources and APIs to communicate healthcare concept	2012

HL7 (Health Level Seven International) (1989):¹² point-to-point messaging standard.

HL7 CDA (Clinical Document Architecture) (1996): An architecture to communicate document-based clinical summaries.

HL7 FHIR (Fast Healthcare Interoperability Resources) (2012): FHIR (pronounced “fire”) is a set of resources and APIs (application programming interface: a way of communicating with a particular computer program or internet service) to communicate healthcare concepts.¹³

When researching healthcare data interoperability, USCDI (United States Core Data for Interoperability) will frequently be referred to concerning healthcare data exchange. The standards we discuss in this paper focus on how data is shared between systems. The USCDI standard, or CDI as it is sometimes called, refers to the actual healthcare data that is exchanged, such as patient information, notes, lab results, etc. The ONC maintains and develops USCDI for the US healthcare system.

Several other standards exist, with varying levels of adoption. The GDHP 2020 paper “[Advancing Interoperability Together Globally](#)” provides a thorough overview of standards used in twenty-two member countries. A few excerpts from their report are:



The most significant barriers are a lack of EHR capabilities to take action and make effective use of exchanged data, and poor usability: these are the weakest links in the interoperability chain.”

“Economics remains an obstacle, as costs can inhibit organizations from implementing interoperability. Sometimes there may be more incentive to not exchange data because of how healthcare is reimbursed.”

“Countries and territories that have not yet overcome barriers can learn from the experiences of those who have overcome them by using standards, legislation, policies, and best practices. Several respondents offered to share their solutions with other countries.”

Figure 3: GDHP Advancing Interoperability Together Globally report, Table 3: Health data standards crosswalk, page 49¹⁵

Country/ Territory	Standard										
	HL7® v2	HL7® v3	HL7 CDA®	HL7 FHIR®	IHE	OpenEHR	ISO	ICD (9/ 10/11)	SNOMED CT	LOINC	DICOM
Argentina				✓	✓			✓	✓		
Australia	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Austria	✓	✓	✓		✓			✓	✓	✓	✓
Brazil	✓	✓		✓	✓	✓		✓			
Canada	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Estonia		✓	✓		✓			✓	✓	✓	✓
Hong Kong SAR	✓		✓					✓	✓	✓	✓
India	✓		✓	✓		✓	✓	✓	✓	✓	✓
Italy	✓	✓					✓	✓	✓	✓	✓
Japan	✓		✓		✓		✓	✓			✓
Kingdom of Saudi Arabia	✓	✓	✓	✓	✓		✓		✓	✓	✓
The Netherlands	✓	✓	✓	✓	✓			✓	✓	✓	✓
New Zealand	✓		✓	✓				✓	✓	✓	✓
Poland	✓	✓	✓	✓	✓			✓	✓		✓
Portugal	✓	✓	✓	✓	✓		✓	✓	✓	✓	
Republic of Korea	✓	✓	✓	✓	✓		✓	✓		✓	✓
Singapore		✓		✓				✓	✓	✓	✓
Sweden	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
Switzerland	✓	✓	✓	✓	✓			✓	✓	✓	✓
United Kingdom	✓	✓		✓	✓			✓	✓	✓	✓
United States	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓
Uruguay	✓	✓	✓	✓	✓			✓	✓	✓	
Total Countries and Territories	19	17	17	17	17	4	10	21	19	16	18

As mentioned, the US healthcare sector loses billions, which is reflected in all countries' experiences. Efforts for standardization have fallen far short of their goals.

There are three core challenges to address: ambiguity and flexibility in data standards, challenges related to point-to-point connections or multiple networks, and the need for data-sharing agreements and trust frameworks.

The Future of Healthcare Data Interoperability

There are many important initiatives around the world to address the challenges of both national and cross-border healthcare data interoperability.

UNITED STATES

In 2016, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) called for a new framework, the [Trusted Exchange Framework and Common Agreement \(TEFCA\)](#), which was passed under the 21st Century Cures Act to interoperate and share data using gateways and networks. The Trusted Exchange Format (TEF) refers to the technical standards for exchange; the Common Agreement (CA) relates to data-sharing agreements allowing for open data sharing within the network. The ONC TEFCA Recognized Coordinating Entity (RCE) is responsible for developing, implementing, and maintaining the CA part of TEFCA.

Figure 4: What is TEFCA?



TEFCA is not a data repository and does not have a central database. It is a conduit for information exchange—a technical healthcare data interoperability floor that empowers innovators to build scalable systems and solutions with the most complete healthcare data available in a way that has not been possible before.

TEFCA was launched in 2021, and we've seen major developments since then with a growing network that shares health data across the US using data hubs called Qualified Health Information Networks (QHINs) and health information exchanges (HIEs).

The RCE expects that regulations will change over time. Since TEFCA exchanges data with the USCDI, the RCE, in their statement below, has made clear how all data created must conform:



The QHIN Technical Framework (QTF) states that all data created or captured and sent on or after December 31, 2024, should conform to the appropriate data classes, data elements, and vocabulary requirements from the USCDI v1, when such data are maintained. Beginning January 1, 2026, all data created or captured and sent must conform to USCDI v3 data classes, data elements, and vocabulary requirements.”¹⁸

TEFCA is a significant step towards true healthcare data interoperability, empowering system and technology solution providers to participate in a unified data system and enabling the benefits above.

More about TEFCA can be found [here](#).

EUROPE

The European Parliament adopted the [European Health Data Space \(EHDS\)](#) that was put forward by the European Commission in 2022 and agreed upon in spring 2024. Hailed as a groundbreaking initiative, it aims to enable the EU to “fully benefit from the potential offered by a safe and secure exchange, use, and reuse of health data to benefit patients, researchers, innovators, and regulators.”¹⁹

As shown on the EHDS site, it will:



Empower individuals to take control of their health data and facilitate the exchange of data for the delivery of healthcare across the EU (primary use of data)”²⁰

“Foster a genuine single market for electronic health record systems”

“Provide a consistent, trustworthy, and efficient system for reusing health data for research, innovation, policy-making, and regulatory activities (secondary use of data)”²¹

Their goal is to “place citizens at the center of their healthcare, granting them full control over their data, to achieve better healthcare across the EU” and “to allow the use of health data for research and public health purposes, under strict conditions.”

THE UNITED KINGDOM

The UK Medicines & Healthcare products Regulatory Agency (MHRA)’s new Data Strategy includes **“Harmonised standards and ontologies permitting [healthcare data] interoperability.”**²² In October 2024, the UK government announced **a plan to provide digital access to a single patient record** with a full medical history, test results, and letters through a National Health Service (NHS) app, all part of their 10-year plans to overhaul the NHS. Current medical record access is available through local sources such as surgeries, clinics, and hospitals.

THE INTERNATIONAL PATIENT SUMMARY (IPS)

Internationally and across borders, the International Patient Summary (IPS) is a “minimal and non-exhaustive set of basic clinical data of a patient, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) patient care.” For example, if a person falls ill whilst traveling abroad in a country that uses IPS, the local care team can access a summary of the patient’s medical records, such as allergies or prescribed medications, but not their full medical history.

IPS is an HL7 FHIR-based standard that has been developed by the European Committee for Standardization/Technical Committee (CEN/TC 251)²³, HL7, Integrating the Healthcare Enterprise (IHE)²⁴, International and Systematized Nomenclature of Medicine (SNOMED) International²⁵, ONC, and the International Standards Organization (ISO), all led by the Joint Initiative Council (JIC).²⁶



Launched in 2016²⁷, IPS was published by the ISO 215 Committee as ISO 27269:2021. The first IPS global deployment pilot contributed to the Coronavirus disease 2019 (COVID-19) immunization block by issuing the international COVID-19 immunization certificate.

The IPS is currently under active development in many countries, including [Canada](#), Latin America ([Argentina](#) and [Brazil](#)), [England](#), [The Netherlands](#), [Sweden](#), [New Zealand](#), [Indonesia](#), [Malaysia](#), and Vietnam.²⁸

The WHO supports the IPS, including supporting multiple languages for the ICD classifications and recommending international nonproprietary names for drugs.

ADDITIONAL GUIDANCE ON THE WAY FORWARD

“[\[Attempts at\] Solving the Interoperability Conundrum](#)”, a paper written by Samir Jain, Senior Director, EHR Solutions, Medidata’s product lead for Medidata’s EHR and interoperability solutions, recommends a multi-pronged approach to interoperability and evaluating tools leveraged by healthcare institutions. In the paper, Samir quotes [Postel’s Robustness Principle](#) from the original Transmission Control Protocol (TCP) specification published in 1980, “be conservative in what you do, be liberal in what you accept from others”.²⁹ In this case, expect a wide variety of inputs and interpretations of standards, and ensure your stack is robust enough to account for the implementation of specific variations.³⁰



Summary

Patients, quality of care, the healthcare ecosystem, research and development, and government policies are all reliant on the full availability of healthcare data across the disparate systems used throughout. Healthcare data interoperability is a critical requirement that impacts health outcomes, public health, and safety and has a major financial impact on everyone.

As healthcare practices and technology have evolved, the volume and velocity of data generated continue to increase exponentially year-on-year. The only way to realistically reach healthcare data interoperability goals is to build a foundation for the industry by addressing the ambiguity and flexibility in data standards, to reach data-sharing agreements and trust frameworks, and to provide a technological mechanism that allows efficient data communication. In the US, the TEFCA initiative presents the foundation for these.

Healthcare technologies that leverage this new level of healthcare data interoperability will be at the forefront of driving better healthcare outcomes. As Medidata has done, inevitably, technology solution providers will further innovate across the healthcare and clinical trial landscape in areas such as patient-centered care, personalized medicine, AI-driven decision

support, data management, streamlined workflows, reduced burdens on resources, and enabling real-time data sharing between systems and stakeholders.

Financial and resource burdens will be significantly reduced and, most importantly, patients' lives will be improved and even saved.

The UK's National Institute for Health and Care Research (NIHR) states that the relationship of clinical trials with healthcare is "an essential part of the process of evidence-based practice and can help guide treatment decisions for both healthcare professionals and patients."³¹

With the whole industry, regulators, and governments working towards truly global healthcare data interoperability, Medidata is at the forefront of EHR integration and healthcare data interoperability with [Medidata Health Record Connect](#), a solution that securely and compliantly acquires, transforms, and exchanges EHR data, enabling an unprecedented level of collaboration and visibility into patients' healthcare data.

To learn more about the significant benefits that Medidata Health Record Connect brings to your organization, please visit [our page here](#).

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