# Accelerating Clinical Trials Through Shared Access to Patient Records

**Improved Access to Clinical Data Across Hospitals and Systems Helps Pharmaceutical Companies Reduce Delays and the Costs Associated With Bringing New Treatments to Market**

InterSystems®

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## Executive Summary

The pharmaceutical and life sciences industry has a strategic imperative to accelerate clinical research in order to reduce overall R&D costs while delivering innovative treatments.[1] Yet virtually all pharmaceutical manufacturers and contract research organizations (CROs) recognize that the limited quantity and quality of available patient data are fundamental problems that have led to escalating costs and delays in clinical trials for new drugs and treatments.

**The underlying problem is accessing and sharing connected, comprehensive, and credible patient records across hospitals, healthcare organizations, communities, and countries.**

The answer is to provide the clinical trials ecosystem with a foundational health informatics platform and complementary solutions that enable researchers to access and use clinical data from hospitals and other healthcare providers. With such a solution in place, clinical researchers can more quickly evaluate protocol feasibility, identify and recruit viable patient candidates for trials, track patients enrolled in clinical trials, and conduct efficient, accurate health surveillance and observational studies once a drug or treatment is on the market.

## Delays Due to Poor Access to Patient Information

One of the biggest challenges for pharma and life sciences to overcome is reducing the time it takes to bring a drug or treatment to market. Every day of delay can cost the sponsors of a clinical trial up to $8 million (U.S.) in lost revenue opportunity.[2]

Almost half of all clinical trial delays are caused by patient recruitment problems[3], and 50% of today's clinical trials fail to reach the target recruitment rate[4]. Researchers' poor access to comprehensive information on the patient population of interest is a major source of these challenges. The lack of patient information is dragging down the entire clinical research process, across all phases of clinical trials:

- **Protocol feasibility**—Is there clinical data available to support the study design? Simply determining whether the appropriate data exists requires the ability to query, normalize, and aggregate clinical records in different formats and from disparate sources.
- **Trial site selection**—Which hospitals and health systems can assemble the critical mass of patients needed for the study?
- **Patient identification and recruitment**—Can the right patients for the study be identified and contacted?
- **Observational studies**—After a drug is released, how can populations of patients and widely dispersed clinical data be accessed and studied?

The questions may be simple, but arriving at the answers is complex, and significant obstacles stand in the way.

## The Challenges in Clinical Trials Today

- Patient records are currently stored in disparate systems (care, pharmacy, lab) in different clinical settings (hospital, primary care, community services), and in different formats (data models, structured vs. unstructured data). The data may also be in multiple languages, use a variety of clinical terminologies, and be governed by different regulatory and privacy policies.
- The current lack of comprehensive and searchable patient data to support clinical research is perhaps the biggest cause of patient recruitment delays in clinical trials. A given hospital may have a searchable health records system, but no such system exists for entire populations across different health systems, markets, and/or countries—which is often necessary, especially in Europe, in order to identify and recruit the required number of patients who fit the defined profile.
- Once a drug or treatment is on the market, researchers are no longer working with a defined, enrolled group of patients. Still, they must be able to find instances of drug/therapy utilization and associated outcomes, adverse reactions, and allergies in order to conduct accurate observational studies. In addition, researchers must now contend with a greater number of caregivers, data sources, and patients. In these instances, a project such as the European Medical Information Framework (EMIF), which convenes organizations as part of an information network, plays an important role in mining clinical data from many sources.

Any solution addressing the use of clinical patient data for research requires a connected, interoperable information ecosystem that links pharmaceutical companies, CROs, and healthcare organizations.

Some pilot initiatives are already under way to enable the use of clinical data for clinical research. These projects have helped clarify the need for a commercial solution. For example, in the U.K., a new National Health Service (NHS) system will allow anonymized patient information to be stored centrally and shared to help improve care and research. In Europe, the Innovative Medicines Initiative (IMI) is facilitating collaboration between the key players involved in healthcare research, including universities, the pharmaceutical industry, small and medium-size enterprises, patient organizations, and medicines regulators. The consortium project Electronic Health Records for Clinical Research (EHR4CR) is implementing a proof-of-concept project integrating 11 hospitals and 10 pharmaceutical companies across seven European countries, to demonstrate interoperability and achieve the goal of using patient data for clinical research.

These initiatives have helped stakeholders identify the four requirements that a commercial solution must satisfy in order to make patient records readily available for research, create the required comprehensive patient data set, and accelerate the process of clinical trials.

## The Four Solution Requirements

While no vendor or technology can single-handedly address all aspects of the use and sharing of patient data for clinical research, a health informatics platform is the essential foundational element of the four solution requirements. A health informatics platform provides the advanced technology needed for interoperability among systems and for creating connected, comprehensive, credible, and current patient records that aggregate all of a patient's clinical data from disparate systems and locations while integrating with data security, privacy, and access controls.

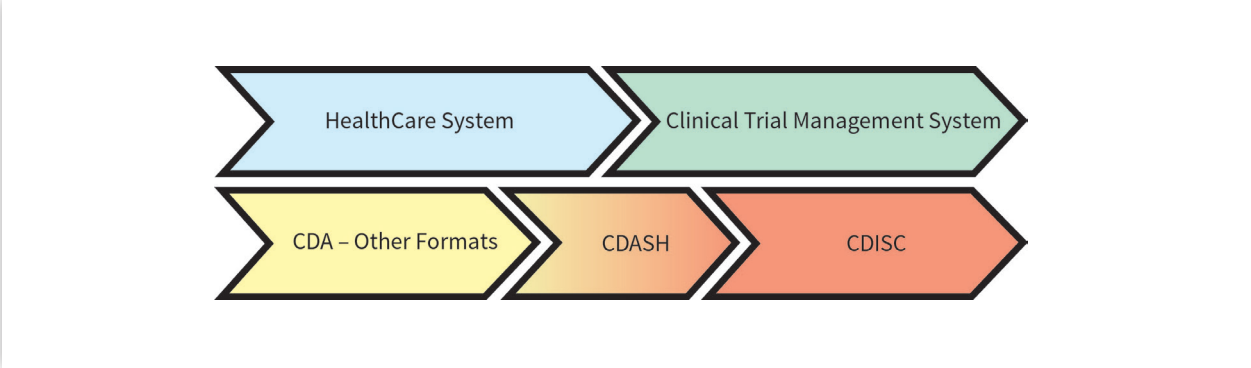
## 1. Interoperability

**Imperative:** Overcome semantic interoperability challenges arising from the use of different languages, data models, and systems.

Patient records are generated by single institutions—that is, a doctor has a set of information for each patient; if the patient goes to a different doctor, another set of information is created. How can the records be combined? Through interoperability. Interoperable health information systems "make the right information available to the right people at the right time across applications and organizations in a way that can be relied upon and meaningfully used by recipients."[5]

Interoperability among clinical, administrative, and other third-party systems is the core functionality required to aggregate and use comprehensive patient records from disparate sources. Interoperability eliminates the bottlenecks presented by separate systems, different data models, different coding and content standards, different usage of structured (e.g. laboratory result) and unstructured (e.g. clinical narrative) data, and different languages.

In its source system, the clinical data may adhere to a specific data standard, such as HL7 Clinical Document Architecture (CDA). As it moves from its source healthcare system into the clinical trials management system, the data may need to be translated into other standards that can address the full life cycle of a clinical trial, such as Clinical Data Acquisition Standards Harmonization (CDASH) or the Clinical Data Interchange Standards Consortium (CDISC).




*In addition to the technology needed to support structural and semantic interoperability, mapping, and terminology services for data that use different languages and coding models, a human element is also required to develop and maintain the mapping tables for new codes and sources of data.*

## 2. Data security, privacy, and regulatory compliance

**Imperative:** Protect the security of the data, and comply with privacy and reporting regulations, which vary worldwide.

Ethical, legal, and privacy requirements differ from country to country. Patient consent must be gathered, and patient data must be anonymized and/or de-identified at various phases in order to protect patient privacy. These functions are typically performed by trusted third parties that partner with platform providers and that specialize in ensuring data security, enforcing access policy, protecting patient privacy, and meeting compliance regulations as patient data is shared among systems. Again, these capabilities must cross systems, regions, and countries.

## 3. Comprehensive data

**Imperative:** Ensure the quality and completeness of data, and be able to evaluate both structured and unstructured data.

All clinical data must be connected, comprehensive, and credible to ensure fitness for its intended purpose and engender confidence in the results. Additionally, for patient recruitment and observation studies, the data must be current.

Interoperability addresses the issue of connected, standardized data. The issue of comprehensive data is addressed by an interoperability platform that can aggregate heterogeneous health information. Clinical records comprise images, structured diagnoses, adverse reactions, medication administrations, orders, results, nursing and physician notes, survey responses—in short, anything and everything. It is therefore essential that the platform be able to find meaning in comprehensive records that include both structured and unstructured data. For example, a patient with a condition of interest may have a relevant structured diagnosis code, a descriptive pathology result, or a comment in a clinical note.

For the connected, comprehensive data to be credible, it must also be free from errors that may be introduced during transmission and aggregation. Ideally, healthcare information is captured as close to the time and place of care delivery as possible, since a single error in capturing data presents risks that can be magnified as the data is transmitted downstream through the clinical trials process.

## 4. Sustainable and scalable

**Imperative:** Leverage the platform to support a spectrum of business cases that deliver benefits across the entire clinical trials ecosystem—to pharma/life sciences companies, CROs, payers, providers, and patients.

The informatics platform and other solution components used across the phases of clinical trials must be adaptable, reusable, standards-based, and governed within a sustainable ecosystem. The selected solution must be built for the long term and support other pharma business cases beyond the use of clinical data to support research. Additional business cases include:

- Pre-clinical trial analytics to identify patient groups most suited for a drug or treatment.
- Electronic data entry that eliminates error-prone and time-consuming manual re-entry of data from the hospital system to the system used to conduct the clinical trials.
- Safety monitoring, such as accessing updated patient records to detect adverse events.

## Where InterSystems Provides Value

For registries, researchers, hospitals, and healthcare organizations in many countries, InterSystems' HealthShare informatics platform successfully integrates, delivers, and enhances data. These capabilities provide comprehensive patient information that helps improve care coordination, manage population health, support observational research, and control healthcare costs. The pharmaceutical industry has a similar, urgent need for comprehensive patient information—and HealthShare is a natural and strategic fit in the clinical trials ecosystem. The querying systems used by clinical researchers connect to hospital systems containing patient information, with InterSystems HealthShare providing data integration and interoperability among systems.

One of HealthShare's unique strategic advantages is its ability to evaluate and integrate unstructured data, such as clinical notes, as well as structured data. Unstructured data constitutes 80% of clinical data, and its availability for querying and analysis is integral to the success of the clinical trials process.

InterSystems has the presence, expertise, and relationships with trusted third parties in the global healthcare community to provide all the capabilities required for the sharing of clinical data for research purposes, including system and semantic interoperability services, terminology services, language translations, unstructured data management, consent management, auditing services, patient privacy protections, security services, anonymization and de-identification of patient records, and user authentication.

InterSystems has been widely recognized as a healthcare industry leader by experts and analysts. Gartner positioned InterSystems as a Leader in the "Magic Quadrant for Operational Database Management Systems."[6] In addition, in its study *"HIE 2014: Revisiting Great Expectations,"* research firm KLAS reported that InterSystems HealthShare was the only product that 100% of customers surveyed described as a "part of their long-term plans" and said that they "would buy this again."[7]

**Bottom line: HealthShare reduces costs and accelerates the pace of clinical trials** because it can more quickly deliver the clinical data to researchers in a format that helps them validate protocols, identify a panel of patient candidates, and track patients throughout the clinical trials process.

## InterSystems' Success in Supporting Clinical Research

- **University Hospital Brussels**—Conducted analysis of predominantly unstructured data (notes) along with structured data to identify patients for clinical trials.
- **Belgium**—Teamed with a pharmaceutical company to identify patients at risk of developing Hepatitis C by analyzing unstructured clinical notes for the prevalence of tattoos, acupuncture, piercings, prison stays, and other high-risk factors rarely reported in structured data.
- **Hixny**—Provided platform and services for the leading health information exchange in the state of New York that connects disparate data sources and types, and accommodates different governance organizations and varying policies to create comprehensive patient records for use at the point of care or for research purposes.

**InterSystems technology sets the gold standard for healthcare:**

- Nearly all U.S. academic medical centers are InterSystems customers.
- All 17 of the U.S. News & World Report 2014-2015 Honor Roll of Best Hospitals are InterSystems customers.[8]
- InterSystems is the leading supplier of state- and country-wide solutions in Scotland, Sweden, Denmark, Brazil, Chile, the U.S., and elsewhere.
- Two-thirds of Americans receive care where InterSystems technology plays a key role.
- Two of the three major EHR solutions that Gartner calls "Global Solutions" run on InterSystems technology.[9]

[1] "Integrating New Approaches for Clinical Development: Translational Research and Relative Effectiveness," by Jean-Pierre Lehner, Robert S. Epstein, and Tehseen Salimi. Journal of Comparative Effectiveness Research, Vol. 1, Issue 1s, 2012.

[2] "Recruiting Special Patient Populations," by Donna Beasley, Applied Clinical Trials, June 1, 2006.

[3] "Study Participant Recruitment and Retention in Clinical Trials," by Business Insights, May 31, 2007.

[4] "Fixing the Protocol Feasibility Process," by Beth Harper and Nikki Christison. Journal of Clinical Research Best Practices, Vol. 8, No. 1, 2012.

[5] "Connecting Health and Care for the Nation: A 10-Year Vision to Achieve Interoperable Health IT Infrastructure," from The Office of the National Coordinator for Health Information Technology, June 5, 2014.

[6] "InterSystems Recognized as a Leader in Gartner Magic Quadrant for Operational Database Management Systems," Oct. 21, 2014.

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[9] "Magic Quadrant for Global Enterprise EHR Systems," by Thomas J. Handler, Gartner, Sept. 9, 2013.

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