# Accelerating Clinical Trials Through Access to Real-World Patient Data

Solution Guide

InterSystems®
Creative data technology

## Leveraging Normalized Real-World Patient Data to Streamline Clinical Trials, Reduce Delays, and Costs

The pharmaceutical and life sciences industry needs to accelerate clinical research to reduce overall R&D costs while delivering innovative treatments.[1] However, virtually all pharmaceutical manufacturers and contract research organizations (CROs) recognize that accessing the needed quantity and quality of real-world patient data is a fundamental barrier to reaching this goal. Escalating costs and delays in clinical trials for new drugs and treatments remains the norm.

Easier access to and sharing of real-world data across healthcare organizations, communities, and countries is the solution. But how do you move an industry conditioned to working with highly structured, consolidated data repositories into the unstructured, decentralized, and often chaotic realm of real-world clinical data?

### Number of Registered Studies

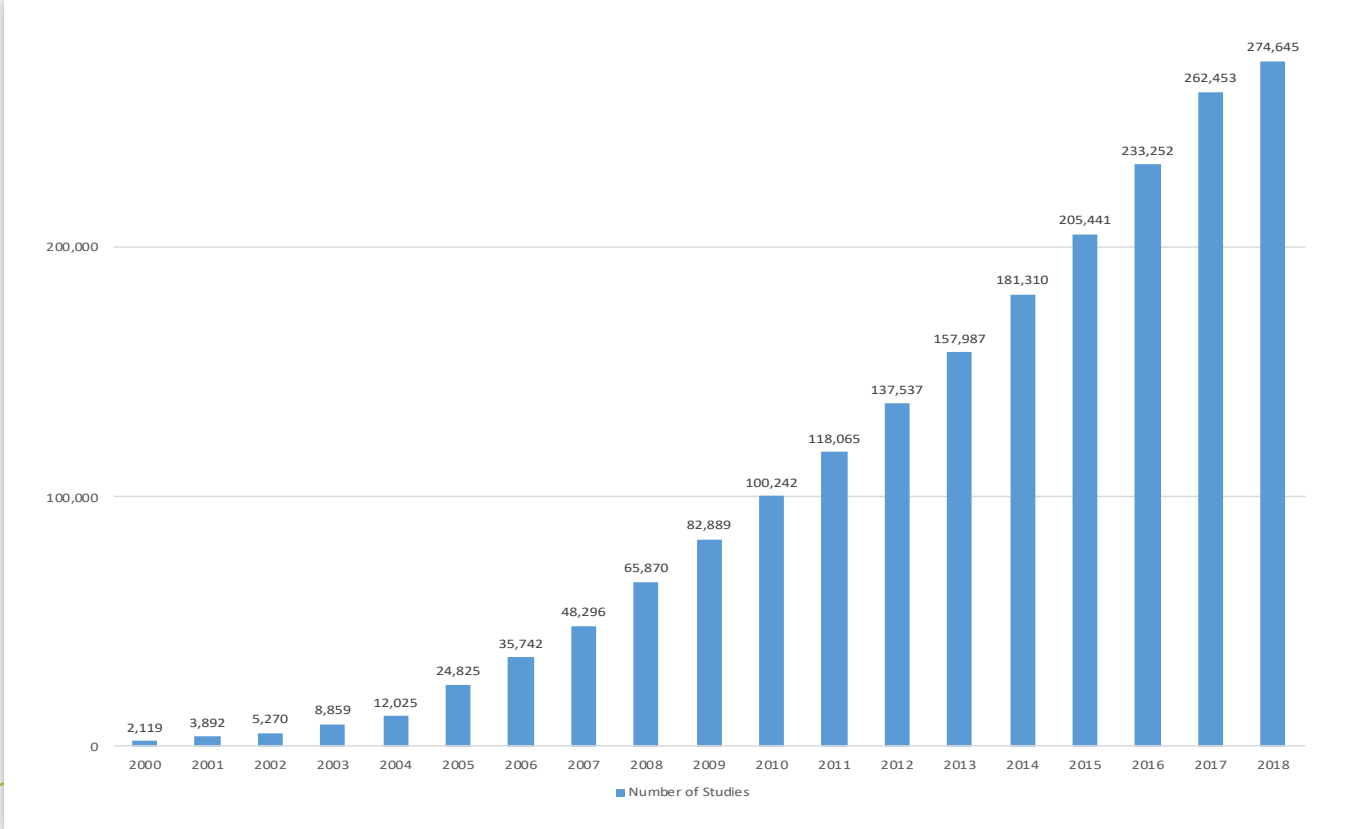


**Figure 1. As of May 2018, lots of trials, lots of time, energy, and money spent. Chart data source: clinicaltrials.gov**

## Number of Registered Studies with Posted Results

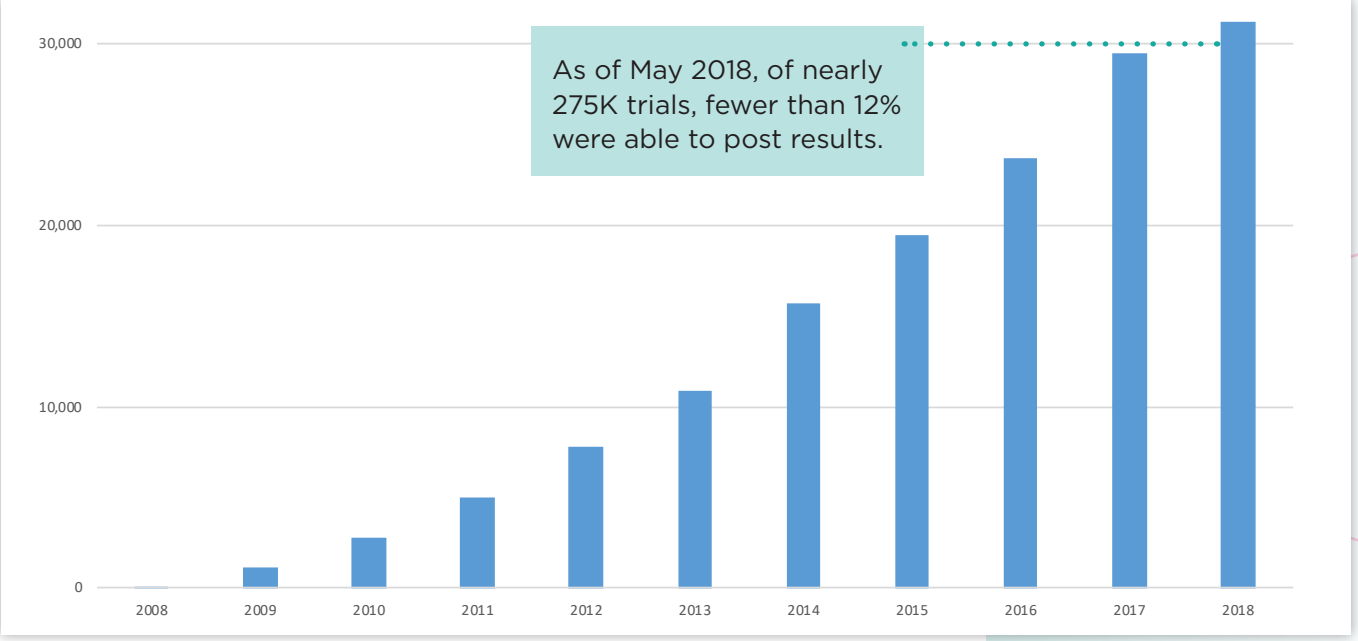


**Figure 2. As of May 2018, a little less than 12% of trials actually posted results. Failure to recruit and retain a sufficient patient population is part of the cause. Industry-wide, 80% of clinical trials fail to reach enrollment timelines[2], and nearly 50% enroll one or no patients[3]. Chart data source: clinicaltrials.gov**

The answer is to provide the clinical trials ecosystem with a foundational health informatics platform that enables researchers to access and use real-world data from hospitals and other healthcare providers. Such a platform and complementary solutions are needed to navigate and normalize the various federated networks being put in place. With a health informatics platform, clinical researchers can more quickly evaluate protocol feasibility, identify and recruit viable patient candidates for trials, and track patients enrolled in clinical trials. Once a drug or treatment is on the market, the platform enables efficient and accurate health surveillance and observational studies using real-world data originating from many different sources.

## Delays Due to Lack of Real-World Patient Data

One of the biggest challenges for pharma and life sciences 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.[4]

Almost half of all clinical trial delays are caused by patient recruitment problems[5], and 50% of today's clinical trials fail to reach the target recruitment rate[6]. Researchers' poor access to comprehensive information on the patient population of interest is a major source of these challenges. The lack of this real-world data is dragging down the entire clinical research process, even as the number of registered clinical trials has grown at a 26% rate since 2000 (clinicaltrials.gov) across all phases of trials.

To reverse this trend, the clinical research process must become far more agile in its use of real-world data to answer the following questions:

- **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.
- **Site Selection** — Which hospitals and health systems can assemble the critical mass of patients needed for the study?
- **Patient Recruitment** — Can the right patients for the study be identified and contacted? Can we help hospitals and clinicians recruit patients?
- **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, with significant obstacles standing 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 real-world 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, 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.

## The Solution Requirements for Real-World Data

These initiatives have helped identify five requirements that a commercial solution must satisfy to make real-world data readily available for research and to accelerate the process of clinical trials. They are:

- Interoperability
- Comprehensive data
- Data security, privacy, and regulatory compliance
- Sustainability and scalability
- Clinician workflow integration

A health informatics platform is central to satisfying all five requirements. It provides the advanced technology needed for interoperability among systems and for creating connected, comprehensive, credible, and current real-world health records that aggregate all of a patient's clinical data from disparate systems and locations. InterSystems technology performs this data aggregation and curation 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 individual electronic medical record (EMR) applications. Even when a primary EMR is in use across a consolidated provider entity, there are still many systems that produce relevant real-world data. How can records from a multitude of clinical systems and multiple clinical organizations be combined?

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.

Real-world data from EMRs and other clinical systems can be shared using a wide range of interoperability languages — from HL7 ®, IHE, DICOM, and ASTM to FHIR®, CDA, and more. Clinical research systems must be able to connect to these applications in their native interoperability languages to effectively ingest all of the desired data.

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). The data will ultimately be converted to the OMOP (Observational Medical Outcomes Partnership) Common Data Model.

## 2. Comprehensive data

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

All real-world data must be connected, comprehensive, and credible to ensure fitness for its intended purpose and 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 a health informatics 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 informatics platform be able to ingest, normalize and rationalize patient data from multiple sources to create detailed views of patients. In addition to normalizing real-world data from providers and across federated data networks, the system must be able to analyze discrete data across the unified records. Clinical data is also a collection of structured and unstructured data — from diagnoses to progress notes. To maximize the utility of real-world data, the solution must be able to derive meaning from both of these data types. 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.

## 3. 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 deidentified at various phases in order to protect patient privacy. These functions are typically performed in partnership with platform providers by trusted third parties that specialize in ensuring data security, enforcing access policy, protecting patient privacy, and meeting compliance regulations as patient data is shared among systems. These capabilities must cross systems, regions, and countries.

## 4. Sustainability and Scalability

**Imperative:** Leverage the health informatics 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 diverse events

## 5. Clinician Workflow Integration

**Imperative:** Engage clinicians and their patients at the moment of encounter to increase patient recruitment success rate.

Finding patients isn't always the challenge in trial enrollment. Instead it's often the difficulty of engaging physicians to recruit their patients into the trial. An advanced health informatics platform can parse the medical record to find patients matching trial inclusion criteria. And it also should notify clinicians within their everyday workflows, such as inside their electronic medical record systems, when they are face-to-face with patients who might benefit from enrollment in a trial.

## InterSystems Brings Together the Information that Matters

Right now, the health records of over 500 million people worldwide rely on InterSystems healthcare solutions. InterSystems HealthShare is our solution for connecting providers, patients, and payers with comprehensive patient records and analytics that span the care continuum. These capabilities help improve care coordination, manage population health, support observational research, and control healthcare costs.

As a health informatics platform, HealthShare is a natural and strategic fit in the clinical trials ecosystem. Having proven itself for over a decade working with data aggregation across health systems, regions, and states and countries, HealthShare can open a treasure trove of real-world data for clinical research in a way few systems can. HealthShare provides a unique means of data integration, data normalization, and real-world data curation capabilities across systems.

### Leveraging Unstructured Data

One of HealthShare's unique 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.

## Global Healthcare Presence, Global Data for Research

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. These capabilities include:

- System and semantic interoperability services
- Terminology services
- Language translations
- Management of unstructured data
- Consent management
- Auditing services
- Patient privacy protections
- Security services
- Anonymization and de-identification of patient records
- User authentication

**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 Supports Clinical Research

- **Northwell Health,** based on Long Island, New York, is one of the largest private health systems in the United States. Northwell uses InterSystems HealthShare to aggregate, integrate, store, and use information from the disparate EMRs and other clinical systems across its 23 hospitals and over 450 ambulatory and physician practices. Using HealthShare's unified health record, Northwell now has at its disposal a healthcare database holding over 1 billion data points. Northwell uses this data to match inclusion criteria for specific trials, with HealthShare's natural language processing technology mining radiology reports, pathology reports, and clinical notes to assess if the patient is suitable. If the patient meets the inclusion criteria, notifications are placed in the EMR to obtain and manage patient consent.

- **Biogen** supports its R&D efforts for Multiple Sclerosis using InterSystems HealthShare. The firm's global "learning health system" network has multiple sites in the U.S. using HealthShare to aggregate clinical information from Epic EMRs. The network's sites in Europe have used the same technology to add information from several German hospitals.
- **Cambridge University Hospital (U.K.)** deployed a national ovarian cancer registry using InterSystems technology. The registry aggregates data not only from the Epic system at the hospital but also data from 4 other cancer centers in the U.K. Information including patient data, treatment, and outcome have been used to support research, policy review, and quality measurement.
- **A Belgian pharmaceutical company** teamed with InterSystems 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.

## InterSystems is the Power Behind What Matters

- Over 500,000,000 patient records worldwide are supported by InterSystems healthcare solutions
- A growing list of CRO, pharma and life sciences customers, including Biogen, GSK, IQVIA, Covance, and Q2 Solutions, partner with InterSystems
- Nearly all U.S. academic medical centers are InterSystems customers
- All 20 of the U.S. News & World Report 2017-2018 Honor Roll of Best Hospitals are InterSystems customers
- The health data of 37% of Americans is held in InterSystems-powered health information exchanges
- Two of the three major EHR solutions that Gartner calls "Global Solutions" run on InterSystems technology

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

[2] Jon Hess, "Web-based Patient Recruitment," (White Paper) Cutting Edge Information, http://www.cuttingedgeinfo.com/process/?ref=122.

[3] CISCRP, "Recruitment and Retention," http://02e37a0.netsolhost.com/professional/facts_pat.html

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

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

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

The power behind what matters.

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