Electronic Patient Record Systems in Pharmaceutical R&D and Clinical Trials

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Introduction

Electronic Patient Record (EPR) systems – often synonymous with Electronic Health Records (EHRs) or Electronic Medical Records (EMRs) – have become foundational in healthcare, and they are increasingly pivotal in the pharmaceutical industry's activities. Pharma companies, especially their IT and clinical operations teams, interface with EPR systems in various contexts: designing and running clinical trials, monitoring drug safety (pharmacovigilance), ensuring regulatory compliance, and conducting research and development (R&D) using real-world data. In these settings, EPR systems serve as rich sources of patient data and as platforms that can be integrated with specialized pharma systems. This article explores the leading EPR systems used in the pharma sector and examines how they support integration, regulatory compliance, data sharing, and other key considerations for IT professionals. We will compare major EPR vendors (such as Oracle Cerner, Epic, Allscripts/Veradigm, and Meditech) and discuss their features, integration capabilities (with CTMS, LIMS, EDC, etc.), compliance with regulations (FDA 21 CFR Part 11, GDPR, GxP), data interoperability, security, scalability, usability, and real-world case studies of their impact.

Leading EPR Systems in the Pharmaceutical Sector

Several enterprise EPR/EHR platforms dominate the healthcare industry, and by extension, they play major roles in pharma-related uses. The most prominent systems include **Epic**, **Oracle Cerner**, **Allscripts (Veradigm)**, and **Meditech** – each widely adopted in hospitals and clinics. Pharmaceutical companies typically do not use these systems internally for patient care; rather, they interact with them through partnerships with healthcare providers, clinical research sites, or data vendors. Below we identify and compare these leading EPR systems and how they relate to pharmaceutical industry needs.

Epic Systems

Epic is one of the world's leading EHR vendors, used by a large portion of hospitals and academic medical centers, particularly in the United States. Epic's EHR is known for its comprehensive suite of modules covering inpatient, outpatient, pharmacy, billing, and specialty care workflows. A key strength of Epic is its unified platform – often an entire hospital network operates on one integrated Epic system, yielding the concept of "one patient, one record." Epic

also provides a patient portal (MyChart) and numerous specialty add-ons, making it a very feature-rich system.

Pharma and Research Usage: Epic's prevalence in academic research hospitals means it is heavily used in clinical research. In fact, healthcare providers using Epic have over **100,000 active research studies involving 4.7 million patients** running through the system (New Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic). Epic has dedicated tools for clinical research workflows, such as a **Research Module** that helps manage study participants and link clinical trial protocols to patient records (improving tasks like recruiting and billing compliance). In 2022, Epic launched a **Life Sciences program** to directly bridge healthcare providers with pharmaceutical sponsors. The goal is to **"unify clinical research with care delivery"** by using Epic as a single platform connecting patients, clinicians, and study sponsors (New Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic) (New Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic). This program facilitates trial feasibility analyses and **matchmaking patients to clinical trials** via the EHR, reducing the disconnect between care and research. Epic's massive footprint also contributes to real-world data efforts: the company's **Cosmos** research network aggregates de-identified patient records from all Epic client sites into a searchable database. *Cosmos* contains over **217 million patient records** from hundreds of healthcare organizations (Noel - Cosmos: Real-World Data Powered by the Healthcare Community - Journal of the Society for Clinical Data Management), providing a robust real-world evidence (RWE) dataset that pharma companies can leverage for observational studies, outcomes research, and pharmacovigilance. This enormous scale (over 200 million patients) makes Epic Cosmos one of the largest RWE data sources, enabling insights across diverse populations. Epic supports compliance needs by being ONC-certified and providing audit trails and user authentication features (important for FDA-regulated research). Sites have reported that an Epic EHR, combined with proper procedures, can meet **21 CFR Part 11** requirements for electronic records in clinical trials without issues (Statement on Epic Compliance with 21 CFR Part 11 - College of Medicine - MUSC).

Integration Capabilities: Historically, Epic was seen as a somewhat closed system, but it has evolved to embrace interoperability. Epic provides integration through **HL7 standards and APIs** – notably support for **FHIR (Fast Healthcare Interoperability Resources)** APIs via its **App Orchard** developer program. This means third-party or sponsor systems can securely pull or push data to Epic (with appropriate permissions) using modern web services. Many research centers have integrated Epic with their Clinical Trial Management Systems; for example, Epic can integrate with **OnCore CTMS** (Advarra) to share study and billing information. At Yale University, Epic was successfully connected with OnCore, **synchronizing clinical trial billing and enrollment data** to ensure compliant billing workflows, reduce duplicate data entry, and improve participant safety (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra) (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra). Epic's platform also supports "SMART on FHIR" apps – specialized apps (including some for clinical research or pharmacovigilance) that can run inside the Epic interface and communicate via open standards. Overall, Epic's integration ecosystem allows pharma IT

teams to link EHR data with study databases or safety systems in a controlled manner. This is complemented by Epic's focus on **interoperability initiatives** – the vendor participates in health information exchanges and data-sharing networks, and executives report ongoing work to make Epic data more interoperable across systems (Epic, Cerner and others reveal just how their EHRs are interoperable).

Compliance and Security: Epic is designed with strong security controls (encryption, role-based access, detailed audit logs) to protect patient data – essential for compliance with regulations like HIPAA and GDPR. Epic being **ONC Health IT certified** is also crucial; the FDA has **encouraged the use of ONC-certified EHR technology** in clinical investigations, as it gives regulators confidence in the **reliability, privacy, and security** of the data (FDA Issues Draft Guidance Encouraging More Widespread Use of Electronic Health Record Data in Clinical Trials - Epstein Becker Green). In practice, sponsors using EHR data from an Epic system can rely on its audit trail and security features to meet 21 CFR Part 11 expectations around data integrity and confidentiality.

Oracle Cerner

Oracle Cerner (commonly just "Cerner") is another top-tier EPR/EHR system widely used in hospitals worldwide. Cerner's platform (historically known as **Cerner Millennium**) covers comprehensive clinical documentation, CPOE (orders management), results, and a variety of clinical modules. In 2022, Cerner was acquired by Oracle Corporation, becoming **Oracle Health** – this has led to a convergence of Cerner's healthcare expertise with Oracle's technology, cloud infrastructure, and life-sciences solutions. For IT professionals in pharma, Oracle Cerner is notable because it now sits alongside Oracle's suite of clinical research and pharmacovigilance software (such as Oracle CTMS, Oracle Argus safety, etc.), potentially enabling tighter integration between the EHR and pharma systems.

Pharma and Research Usage: Cerner has a strong presence in many large health systems that conduct research, and it has explicitly invested in bridging healthcare and clinical research. For example, Cerner established the **Learning Health Network**, a collaboration of health provider organizations that agree to contribute de-identified patient data for research and to **become trial-ready sites** (Connecting EHR to clinical trials: How to embrace the promise of real-world data - pharmaphorum). By 2020, **51 health systems** had joined this network (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget). In partnership with integrated research organizations like Elligo Health Research, Oracle Cerner's goal is to **"embed clinical trials into routine care"**, making it easier for community hospitals and practices (not just large academic centers) to participate in research (Making clinical trials a routine part of patient care) (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget). This approach accelerates study enrollment and reduces the cost of identifying and recruiting patients for trials (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget). In practice, Cerner's EHR can flag potential trial candidates during point-of-care and share data with research systems. A recent example is Nashville General Hospital selecting Oracle Cerner's EHR and concurrently planning to use

Oracle's Clinical Trial Management System; this unified solution will help **align patients with clinical trials** by leveraging the EHR data and workflow within the hospital (Nashville General Hospital Implements Cerner EHR, powered by Oracle Health, to Simplify Clinician Experience, Enhance Patient Care - Nashville General Hospital). Such integration of CTMS at a hospital site underscores Oracle Cerner's role in supporting **clinical research compliance and patient recruitment within the care setting**. Like Epic, Cerner also offers population-level real-world data: prior to the Oracle acquisition, Cerner's Real-World Data offerings (through partnerships or its HealthFacts database) were used by life science researchers for observational studies. Oracle is now combining its strengths in data and cloud with Cerner's vast trove of EHR data to enable advanced real-world evidence generation, **AI-driven insights**, and post-market surveillance in one ecosystem (Making clinical trials a routine part of patient care) (Making clinical trials a routine part of patient care).

Integration Capabilities: Oracle Cerner has robust integration tools and is known for supporting industry standards. It provides **Cerner Ignite APIs** (its implementation of FHIR) that allow authorized systems to read/write data. Oracle has emphasized an **API-driven, open architecture** for Cerner going forward, to ensure seamless data flow between the EHR and external applications (Making clinical trials a routine part of patient care). This is critical for connecting with CTMS, LIMS, and EDC systems. For instance, Cerner's system can exchange **HL7 messages** for lab results and demographics with a sponsor's systems – similar to other EHRs – to eliminate duplicate data entry. Oracle's cloud infrastructure also means Cerner can handle bulk data exports or integrations (for example, Oracle has introduced bulk FHIR data access for research purposes (FHIR R4 APIs with Bulk Data Access - Oracle Help Center)). We are seeing use-cases like Cerner EHR feeding patient data into Oracle's pharmacovigilance systems or clinical trial databases. Additionally, Cerner supports integration to improve care during trials: for example, if a patient enrolls in a study, the CTMS can update Cerner so that a **"clinical trial" flag and protocol information appear in the EHR** for clinicians – improving safety and billing. This bidirectional integration was highlighted by Cerner's work with partners: **patient demographics and lab results can flow from Cerner EHR to a CTMS** to avoid re-entry, and conversely trial enrollment status can flow **from CTMS to EHR to alert providers and ensure billing compliance** (CTMS And EMR Software Why Integration Is Necessary) (CTMS And EMR Software Why Integration Is Necessary). Oracle Cerner's approach is to provide a **unified platform** where such data moves automatically, an approach confirmed by Oracle's vision of "automated recruitment and monitoring of trial participants through EHR workflow integration" and "seamless data sharing between EHR and research databases" (Making clinical trials a routine part of patient care). In summary, Oracle Cerner offers extensive integration support via standards and its Oracle Health ecosystem, making it a strong connector between healthcare and pharma IT environments.

Compliance and Security: As a major certified EHR, Oracle Cerner meets stringent security standards – including encryption of data at rest and in transit, user access controls, and audit logging – all of which facilitate compliance with **GDPR and HIPAA** for patient data protection. For clinical trials, Cerner (like Epic) relies on ONC certification and site policies to fulfill 21 CFR

Part 11 expectations. FDA guidance notes that using a certified EHR gives confidence in data integrity and security (FDA Issues Draft Guidance Encouraging More Widespread Use of Electronic Health Record Data in Clinical Trials - Epstein Becker Green), which applies to Cerner as well. Oracle's stewardship further brings expertise in GxP compliance, as Oracle's clinical trial and safety systems are validated to regulatory standards; by connecting Cerner EHR with these validated systems, the **overall workflow can maintain GxP compliance**. Notably, Oracle's solution for linking EHR data to clinical research often involves **tokenization or pseudonymization** of patient identifiers to protect privacy: for example, Oracle (via partners like HealthVerity) can **tokenize patient data so that EHR records are linked to clinical trial data in a HIPAA-compliant, de-identified manner** (Veradigm and HealthVerity Expand Existing Partnership with Novel Linked Real-World Data Packages). This ensures patient identities remain protected when pharma companies use EHR data for outcomes research or safety follow-up.

Allscripts (Veradigm)

Allscripts is a well-known EHR vendor whose products have been used in both hospitals and ambulatory (outpatient) clinics. In recent years Allscripts pivoted parts of its business toward data services under the brand **Veradigm**. Allscripts' key EHR platforms have included **Sunrise** (acute care hospital EHR) and **TouchWorks** (ambulatory EHR), among others. While Allscripts may not have the same footprint in large academic medical centers as Epic or Cerner, it has a significant presence in outpatient practices and community hospitals. For the pharmaceutical industry, Allscripts/Veradigm is particularly relevant because of its focus on leveraging EHR data for research and real-world evidence.

Pharma and Research Usage: Veradigm, the Allscripts data analytics arm, provides a network of EHR data for life science research. **Veradigm's EHR data network includes over 170 million patients** from a broad range of physician practices (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget). This data (drawn primarily from ambulatory settings) is **de-identified and aggregated** to support outcomes research, drug safety studies, epidemiology, and other R&D. Veradigm has invested in making this data easily usable by pharma companies – for example, in 2023 it announced that its EHR data would be delivered in the **OMOP Common Data Model**, an industry-standard format for observational research (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget). By converting to OMOP, Veradigm enables researchers to apply standard analytics and tools across the 170M patient dataset efficiently. Allscripts/Veradigm also actively links EHR data with other data sources for deeper insights. A noteworthy initiative was a partnership with HealthVerity to **link clinical trial data with real-world data**: Allscripts' EHR records, claims data, and lab data can be combined with a pharma sponsor's clinical trial database (using privacy-preserving tokenization) to enable post-trial follow-up and external control arms (Veradigm and HealthVerity Expand Existing Partnership with Novel Linked Real-World Data Packages) (Veradigm and HealthVerity Expand Existing Partnership with Novel Linked Real-World Data Packages). This is highly valuable in pharmacovigilance and outcomes studies, as it allows sponsors to track long-term patient outcomes by connecting trial participants to their broader EHR history (with

consent and privacy safeguards). In terms of direct usage at research sites, some hospitals that use Allscripts Sunrise also conduct clinical trials, but Allscripts' biggest impact for pharma is through its data services and real-world evidence generation (often via the Veradigm data offerings). Allscripts has reported strong growth in its Veradigm analytics business as pharma demand for RWE has risen (Allscripts reports double-digit growth in its Veradigm analytics ...).

Integration Capabilities: Allscripts historically distinguished itself by a relatively open architecture. It was one of the earlier EHR vendors to offer robust APIs for third-party developers. Allscripts (now Veradigm) supports **FHIR APIs** and has a developer program, allowing integration with other systems such as practice management, analytics tools, and potentially CTMS/EDC systems. For example, the **Veradigm API** can be used to pull EHR data for research or to inject alerts (like trial eligibility prompts) into the clinician's workflow (Veradigm EHR (formerly Allscripts) - EHR Integration - Datavant). Many Allscripts clients participate in health information exchanges, so interoperability is built into the system (support for HL7 v2 messaging, CCDA documents, etc.). Integration with CTMS: While not as publicized as Epic or Cerner, Allscripts EHR at an academic site could be integrated with CTMS similarly via HL7 feeds for demographics and scheduling. Integration with LIMS: Allscripts EHR, like others, can interface with laboratory systems to import lab results, which would benefit research that needs laboratory data in the EHR. One of Allscripts' strengths for integration is the focus on **data liquidity** in the Veradigm platform – rather than integrating live with a CTMS, Veradigm often enables **batch or on-demand data exports** of EHR data for analysis, which can then be ingested into sponsor systems. This is slightly different from real-time integration but serves the purpose of data sharing for research. Nonetheless, Allscripts can and does integrate in real-time in clinical settings as well. On the clinic side, some Allscripts implementations have integrated with trial recruitment systems that scan the EHR for eligible patients. Overall, Allscripts supports the standard toolbox of interoperability needed by pharma IT: **FHIR/HL7 interfaces, open APIs, and partnerships for data exchange** (e.g., connecting with companies like Datavant or Komodo Health to link and de-identify patient datasets (Veradigm and Komodo Health Partner to Create the Largest Linked ...)).

Compliance and Security: As an EHR handling PHI, Allscripts/Veradigm ensures strong security measures – data encryption, user authentication, audit trails, and granular access control – aligning with GDPR's requirements for data protection and with HIPAA. When Allscripts provides data to life sciences, it is typically **de-identified to protect privacy** (for instance, Veradigm's 170M patient data is provided as de-identified RWE data (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget)). In clinical trials where identified data might be used (e.g., linking a trial database to EHR for a specific patient cohort), Allscripts employs tokenization and works with privacy networks to maintain compliance (Veradigm and HealthVerity Expand Existing Partnership with Novel Linked Real-World Data Packages). Regarding 21 CFR Part 11 and GxP, if an Allscripts EHR is used as an eSource at a trial site, the site and sponsor would verify that the system's features (audit trails, electronic signatures, data retention policies) meet the required standards. Allscripts systems are also ONC-certified, which FDA sees as a positive indicator of security and reliability (FDA Issues Draft Guidance

Encouraging More Widespread Use of Electronic Health Record Data in Clinical Trials - Epstein Becker Green). Additionally, Veradigm's processes for data handling are likely audited to ensure data integrity (important for GxP when real-world data is used in regulatory submissions).

Meditech

Meditech is another prominent EPR vendor, with a strong presence in community hospitals, smaller health systems, and some regional networks in North America and abroad. Meditech's latest EHR platform, called **MEDITECH Expanse**, provides an integrated health record spanning inpatient, outpatient, emergency, and long-term care settings. Meditech is known for being cost-effective and having a long track record (especially in community and rural hospitals). While it doesn't have the majority of large academic medical centers, it is widely used in environments that collectively see millions of patients – and thus Meditech EPRs hold a trove of patient data that can be relevant for pharmaceutical research (particularly for **diverse and underserved populations**).

Pharma and Research Usage: Meditech systems are used in many community hospitals that may not run as many industry-sponsored trials individually, but these sites are increasingly being tapped for research initiatives. One example is Meditech's partnership with the **Institute for Health Metrics (IHM)** to help Meditech client hospitals contribute data for health equity research. Through this collaboration, **Meditech hospitals (often community providers)** can share refined clinical data (including social determinants of health) for analysis, allowing research on patient populations that are typically underrepresented in clinical trials (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget) (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget). In other words, Meditech is enabling a form of real-world data network focused on community hospital data. This can greatly benefit pharmaceutical R&D by shining light on outcomes in more diverse patient cohorts and addressing gaps in medical knowledge. Meditech's data (with IHM) has been used as a "learning laboratory" where hypotheses can be tested and results measured with real-world patient data (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget). Aside from data contributions, some Meditech hospitals do participate in clinical trials – for instance, smaller hospitals might enroll patients into multicenter trials. In such cases, the Meditech EHR serves as the source of clinical information for those patients. Pharma companies might interface with Meditech data via the site or via Meditech's involvement in larger networks (for example, Meditech sites can contribute data to **PCORnet** or other consortiums used in outcomes research). While Meditech might not have a specialized research module like Epic, it supports research through interoperability. As evidence of impact, consider that **real-world data from Meditech community hospitals** can fill important research gaps (like outcomes in rural populations or long-term care settings) that pharma researchers increasingly care about.

Integration Capabilities: Historically, Meditech systems were somewhat closed/proprietary, but that has changed significantly. Meditech now emphasizes interoperability, offering a developer **API portal called Greenfield**. Meditech Expanse supports **FHIR R4 APIs** (including bulk data

access) and the system can integrate with third-party applications (Greenfield Workspace - MEDITECH) (MEDITECH Interoperability). For example, a Meditech hospital can allow an external research app to pull patient data (with consent) using FHIR, or to push alerts into the EHR. Meditech also supports traditional HL7 messaging interfaces for things like lab results (LIMS integration), radiology, scheduling, and billing – which can be used to connect to CTMS or EDC systems. For instance, a CTMS at a Meditech hospital could receive HL7 ADT messages (admissions/discharges) to know when a trial patient has had a visit or a lab result posted, automating parts of trial data collection. Additionally, Meditech participates in health information exchange initiatives; it adheres to the CommonWell and Carequality frameworks (which many EHRs use to exchange patient records nationally). This means if a sponsor is gathering data from multiple sources, a Meditech site can share patient records via standardized CCD documents or FHIR queries. As an example of integration benefiting pharma: if a patient in a Meditech EHR has an adverse event, that data can be transmitted to a pharmacovigilance system or to a centralized research database, given the proper interfaces. Many Meditech sites are smaller, so the **vendor's focus has been on making integration "vendor-agnostic" and straightforward** for resource-constrained IT departments (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget). The introduction of modern APIs and the Greenfield initiative indicates Meditech is keeping up with interoperability standards, allowing pharma partners to treat Meditech EPRs similarly to any other in terms of data access.

Compliance and Security: Meditech EHRs are HIPAA-compliant and include security features like user authentication, audit trails, and access controls. These built-in measures (encryption, logging, etc.) help **meet GDPR requirements for data protection** as well (GDPR Compliance for EU Clinics: Complete Guide to Protecting ...). In fact, EHR systems like Meditech inherently log every access and change to a record, supporting the ALCOA principles (Attributable, Legible, Contemporaneous, Original, Accurate) of data integrity that are core to GxP compliance. For FDA-regulated research, a Meditech EHR at a site would be assessed by the sponsor to ensure it has necessary controls (which it does, as part of ONC certification). Meditech as a company has to ensure its system adheres to the **European Health Data Space (EHDS)** regulations and other international standards when deployed in Europe (Requirements of EHR systems under the European Health Data ...), which further enforces strong security and interoperability. In collaborations like the IHM partnership, Meditech ensures that any data shared for research is **properly de-identified or aggregated** unless patient consent is obtained, thereby complying with privacy laws. As with others, Meditech's ONC certification and use in thousands of healthcare settings without major compliance issues is evidence of its reliability for regulated uses.

*Aside from these four, other EPR/EHR systems exist (e.g., **InterSystems TrakCare/HealthShare**, **NextGen**, **eClinicalWorks**, etc.), but in the context of pharma industry integration, the systems above are the most commonly encountered due to their widespread adoption.*

Integration and Interoperability with CTMS, LIMS, and EDC

One of the most critical considerations for pharma IT teams is how well an EPR system can **integrate** with specialized research and data management systems. Clinical Trial Management Systems (CTMS), Laboratory Information Management Systems (LIMS), and Electronic Data Capture (EDC) platforms are core tools in clinical research and drug development – and they often need to exchange data with EPR systems. Effective integration can eliminate duplicate data entry, ensure consistency between clinical care and research records, and streamline workflows across systems.

Integrating EPRs with CTMS: A CTMS is used by sponsors and sites to manage trial operations (e.g. patient visit schedules, study calendars, billing grids, and enrollment status). Meanwhile, the EPR (hospital EHR) contains the actual patient visit details, clinical notes, orders, and results. Without integration, research staff must manually enter or reconcile data in both systems, which is labor-intensive and error-prone. Integrating the EHR with CTMS addresses this. For example, if a patient is enrolled in a trial, the CTMS can send that information to the EHR so that a **flag** appears in the patient's EPR indicating enrollment (alerting clinicians to consider protocol requirements). Conversely, the EHR can feed patient demographics and visit data to the CTMS, so the research team has up-to-date information. Integration of **patient demographics and lab results from EHR into CTMS eliminates the need for research staff to re-enter this data**, reducing transcription errors (CTMS And EMR Software Why Integration Is Necessary). Similarly, **sending trial enrollment and billing info from the CTMS into the EHR improves patient safety and billing compliance**, by making sure clinicians know the patient is in a trial and by using the correct payor mix for trial-related services (CTMS And EMR Software Why Integration Is Necessary). Many institutions have pursued such integrations. As noted, Yale University linked Epic EHR with OnCore CTMS, enabling automatic exchange of billing codes and enrollment status, which **streamlined workflows and strengthened billing compliance** (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra). This kind of integration typically uses HL7 interfaces or web services: for instance, when a patient is marked as enrolled in CTMS, an HL7 ADT message or FHIR resource update might be sent to the EHR to tag the patient record. Conversely, when a patient completes a visit and has charges in the EHR, a message can update the CTMS's billing module. All major EPR vendors support such interfacing: Epic and OnCore have documented integrations, Oracle Cerner's CTMS and EHR are being unified, and other CTMS vendors (e.g., Medidata, Bio-Optronics/Advarra Clinical Conductor) also provide integration tools for common EHRs. The result is a more seamless workflow where trial coordinators and clinicians share information fluidly, improving efficiency and reducing errors. This integration is increasingly seen as necessary for any research-active health system: *"The need for systems integration has never been more important… the technology is there, but it must be a priority for all stakeholders"* (CTMS And EMR Software Why Integration Is Necessary).

Integrating EPRs with EDC (eSource): EDC systems are used by sponsors to capture clinical trial data (case report forms). Traditionally, even if the data is recorded in the hospital's EPR, study staff would manually transcribe it into the EDC for the sponsor. This double data entry is burdensome and can introduce discrepancies. Modern initiatives focus on **EHR-to-EDC integration**, often referred to as **"eSource"** integration. The idea is that the EPR can act as the **source data** for the trial and directly populate the EDC, with appropriate controls. This is typically done via APIs or data extraction tools that map EHR data fields to the EDC CRF fields. All major EPRs (Epic, Cerner, Allscripts, Meditech) now have API capabilities to support this. The benefits are substantial: *"Key results of EHR-to-EDC integration include the elimination of manual data entry, far fewer data entry errors, real-time health record access, and enhanced interoperability measures."* (What is EHR to EDC Integration in Clinical Trials?). In other words, site coordinators don't have to spend time copying vitals, lab values, or medical history from the EHR into the EDC, because it can flow electronically. An illustrative case study is the **I-SPY COVID-19 trial**, which implemented an EHR-to-EDC integration across 8 major health systems. The integration (using OpenClinica's OneSource/Unite platform embedded in the EHR) **automatically populated eCRFs within the EDC from the EHR data**, resulting in a **61% time savings** for research staff and **zero data transcription errors** at those sites (What is EHR to EDC Integration in Clinical Trials?). This shows how powerful EPR–EDC integration can be in improving trial efficiency. From a technical standpoint, these integrations often leverage the **HL7 FHIR standard**. For example, an EDC system can query the hospital's FHIR API for a patient's lab results or medications and pull them into the EDC with a single click (after site user confirmation). Epic's App Orchard and Cerner's Ignite APIs both support pulling structured clinical data that could fill an eCRF. Some vendors, like Oracle with Cerner, are building end-to-end solutions where the EHR and EDC are part of one platform, eliminating interfaces altogether (Making clinical trials a routine part of patient care). It's worth noting that standards bodies like HL7 and CDISC (the clinical research data standards organization) collaborate on projects (e.g., **HL7 Vulcan** initiative) to improve EHR-to-EDC data exchange standards, so this area is rapidly advancing. For pharma IT leads, enabling eSource means working closely with sites and EHR vendors, but the payoff is improved data quality and speed.

Integrating EPRs with LIMS: Laboratory Information Management Systems are used in research labs for managing specimens, lab workflows, and results, particularly in the context of clinical trials (central labs) or preclinical research. The interface between an EPR and a LIMS is most relevant when lab tests are ordered in the EPR (for patient care or research) and the results need to be available to both the healthcare provider and the sponsor. In a typical scenario, a hospital's EPR will interface with its laboratory instruments or lab information system via HL7 (using ORM messages for orders and ORU for results). If a trial protocol requires local lab results, those results entered in the EPR can be integrated to the EDC or a central data repository. Alternatively, if a trial uses a central lab (separate from the hospital), sometimes the central lab system sends results to the EPR for consistency. Modern EPRs support standards like **LOINC coding for lab tests**, which helps in mapping and aggregating data across systems. For R&D purposes, pharma might also integrate EHR data with internal LIMS in translational research – for instance, pulling clinical data for a patient's sample that is being analyzed in a research lab.

Thanks to interoperability advances, an EHR FHIR API can be used to gather all relevant clinical observations to pair with a biospecimen in a research LIMS. While not as publicized as CTMS or EDC integration, EHR-to-LIMS integration is part of the broader **data interoperability** puzzle. A simple example: a pharmacogenomic study might retrieve a patient's medication history from the EHR to correlate with genomic data in a lab system. EPR vendors facilitate this by ensuring consistent data standards and offering integration options (APIs, HL7 interfaces) to lab systems. Meditech, for example, touts that it aggregates data across hospitals, clinics, and long-term care – including lab results – into one record ([PDF] 2024 MEDITECH MG HCA Real World Testing Results Report), making it easier to export a complete dataset for research.

Data Standards and Protocols: Across all these integrations, use of **standard protocols** is crucial. Virtually all leading EPR systems now support **HL7 FHIR** as the future-proof method for data exchange. FHIR provides a standardized way to access resources like Patient, Observation (lab/vitals), Medication, Condition (diagnoses), etc., in JSON or XML over RESTful APIs. Epic, Cerner, Allscripts, and Meditech each have FHIR API endpoints for core data, which third-party systems (with authorization) can use. For bulk data needs (e.g., exporting a cohort of patients for a study), the emerging **FHIR Bulk Data (Flat FHIR/NDJSON)** specification is gaining traction (Oracle Cerner provides bulk data access, and Epic supports it for research populations as well). Older standards remain in use too: many EHR-to-CTMS integrations rely on classic HL7 v2 messages; EHR-to-EDC may use **CDISC's ODM** or **FHIR**; and document-based exchange uses **C-CDA** or even CSV files as needed. The bottom line is that modern EPR systems are no longer siloed – they **offer multiple integration avenues (APIs, SDKs, HL7 feeds)** to connect with external research systems. IT professionals should consider whether an EPR supports these standards natively. In practice, all the vendors discussed do support them: e.g., **Epic and Cerner list extensive FHIR APIs for patient data**, Allscripts/Veradigm provides connectors to data networks, and Meditech's Greenfield initiative uses FHIR and OAuth2 for secure data sharing (Meditech EHR Integration: Q&A from Meditech Greenfield Experts) (MEDITECH Interoperability). With these tools, integration projects (like linking an EHR to a CTMS or safety reporting system) are far more achievable today.

Interoperability Beyond Single Integrations: A further consideration is industry-wide interoperability efforts that include pharma. Programs such as **IHE (Integrating the Healthcare Enterprise)** and regional health information exchanges enable multi-way data sharing. For example, a sponsor might receive EHR data from different hospitals via a health information exchange network if all use standardized formats. In the EU, there's movement towards a **European EHR Exchange Format** (Exchange of electronic health records across the EU), which in time could help sponsors collect data from EPRs across European countries in a uniform way. Interoperability is not just about connecting one EHR to one system; it's about establishing an ecosystem where data flows securely and meaningfully among all stakeholders (patients, providers, sponsors, regulators). Leading EPRs, due to their widespread adoption, are central to this and thus heavily involved in these broader initiatives.

Regulatory Compliance and Data Security

When EPR systems are used in the context of pharmaceutical research and compliance, regulations must be carefully considered. Key regulations include **FDA 21 CFR Part 11** (for electronic records and signatures in clinical investigations), **Good Clinical Practice (GCP) and related GxP guidelines** (for data integrity and system validation), and data protection laws like **GDPR** in Europe (for patient privacy). Ensuring that EPR systems enable compliance in these areas is a top priority for IT professionals.

21 CFR Part 11 and EHRs as eSource: Part 11 is an FDA regulation requiring that electronic systems used in FDA-regulated research have controls to ensure data integrity, auditability, and equivalent trustworthiness to paper records. Traditionally, sponsors validated their own EDC systems for Part 11 compliance. EHRs at hospitals are not explicitly "Part 11 certified" by FDA (FDA even stated it will **not inspect EHR vendors for Part 11** compliance), yet they are being used as electronic source data for trials (Statement on Epic Compliance with 21 CFR Part 11 - College of Medicine - MUSC). How to reconcile this? The FDA released guidance encouraging the use of EHR data in clinical trials. The guidance **"encourages the use of EHR systems certified through the ONC Health IT Certification Program"**, and states that FDA **will presume data from a certified EHR is reliable and that privacy/security requirements are met** (FDA Issues Draft Guidance Encouraging More Widespread Use of Electronic Health Record Data in Clinical Trials - Epstein Becker Green). In practice, this means if a site is using a well-known EPR (Epic, Cerner, etc. which are ONC-certified) and the sponsor does due diligence on the site's procedures, the EHR can be accepted as a source system without the vendor providing a Part 11 certification. The responsibility lies in the *combination* of the EHR's technical controls and the site's SOPs. For example, the site must ensure that each user has a unique login (no sharing of accounts), that audit trails in the EHR are enabled and retained, and that records are attributable to individuals (all of which these EPRs support). If these conditions are met, sponsors have documented that **there are no known compliance issues in using systems like Epic together with institutional controls to meet Part 11 requirements** (Statement on Epic Compliance with 21 CFR Part 11 - College of Medicine - MUSC). Key features in EPRs that support compliance include: **Audit Trails** (the EPR logs every data change, timestamped and with user ID), **Access Controls** (role-based permissions to prevent unauthorized edits), **Electronic Signatures** (features like co-signing orders or entering passwords to sign notes, which can serve as electronic signatures on records), and **Data Retention/Backup** (ensuring that data cannot be lost or altered without trace). As long as the EPR system has these and they are used properly, they fulfill the technical aspect of Part 11. Sponsors are advised to **document data flow and control methods in the trial protocol** (per FDA guidance) – e.g., describing how the EHR data will be extracted into the EDC and how it will be verified (FDA Issues Draft Guidance Encouraging More Widespread Use of Electronic Health Record Data in Clinical Trials - Epstein Becker Green). Overall, the major EPR systems have demonstrated the ability to be compliant platforms for electronic source data, and regulators have begun to accept EHR printouts or electronic exports in inspections in lieu of paper source documents.

GxP and System Validation: Beyond Part 11, broader GxP principles (Good Clinical Practice for clinical trials, Good Pharmacovigilance Practice for safety, etc.) require that computerized systems used in critical processes are validated and that data integrity is maintained (following ALCOA+ principles). In the context of EPRs: a pharmaceutical company does not "validate" a hospital's EHR in the same way it validates its own software, but it does need confidence in the data integrity from that EHR. This is achieved through vendor qualifications and site evaluations. All leading EPR vendors maintain rigorous quality systems. For example, Epic, Cerner, Allscripts, and Meditech each undergo heavy **testing and quality control for their software updates** (especially since patient safety in care is at risk, not only research). They also often comply with ISO standards for software quality. When a site uses an EPR for trial data, the sponsor will include it in the **site's technology assessment** – essentially confirming that the system has the necessary controls. EPR systems also support **data integrity checks** – for instance, ensuring that once a note is signed it can't be altered without creating an addendum (preserving the original). These align with ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) criteria of data integrity (The ALCOA+ Principles for Data Integrity In Clinical Trials - Quanticate). For pharmacovigilance, if an EHR is used to gather adverse event data, it's important that the data is accurate and contemporaneous; EHR audit trails can prove that an event was documented at the time it occurred, which is useful for audits. Some EPR vendors have gone further to cater to GxP needs: for instance, Oracle's acquisition of Cerner means that Cerner can leverage Oracle's experience in providing validated systems to pharma (like Argus safety). We might see in the near future "validated EHR modules" for research use, but currently the approach is as described – rely on inherent capabilities plus procedural controls.

GDPR and Patient Privacy: The **General Data Protection Regulation (GDPR)** in the EU imposes strict requirements on handling personal health data. EPR systems, when used in Europe or for European patient data, must facilitate compliance with GDPR. This includes capabilities like: obtaining and recording patient consent for data use, honoring requests for data access or deletion (as applicable in healthcare context), and, importantly, ensuring robust data security. All major EPRs were updated around 2018 when GDPR took effect to add features like more granular consent management and easier export of a patient's record (for access requests). For pharma companies working with EPR data, GDPR means that if they receive any patient data from an EPR, it must be either with patient consent or under another legal basis (such as pseudonymized research data for public interest). Most often, data shared for research is **pseudonymized or de-identified**. For example, the Epic Cosmos data or Veradigm data provided to pharma is **de-identified RWD** where direct identifiers are removed (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget). When a pharma sponsor needs identifiable data (say to match patients in a registry), typically a trusted third party handles the identity matching via coded IDs (as seen with HealthVerity tokenizing Allscripts data) (Veradigm and HealthVerity Expand Existing Partnership with Novel Linked Real-World Data Packages). On the security front, EPR systems implement numerous safeguards that align with GDPR's "security of processing" requirements. These include **encryption of personal data**, both in the database and in backups, to prevent unauthorized access. They also enforce **access controls** – only authorized healthcare professionals can view or edit patient records, and

each access is logged. Many EHRs have built-in privacy features like break-the-glass (requiring extra authorization to view sensitive records) and automatic logoff, which help with GDPR's principle of data minimization (only accessing data when necessary). Additionally, GDPR and other privacy laws require that if data is transferred, say from the EU to the US, proper safeguards are in place. EPR vendors have responded by offering data hosting in-region (for example, European hospitals' EPR data stays on EU servers) and by supporting data agreements. For an IT professional, one must ensure that any EPR integration involving patient data across borders goes through proper legal channels – often, only de-identified data is moved, or patient consent is obtained if identifiable data is needed by a sponsor.

Data Security Measures: Data security is tightly interwoven with compliance. All the leading EPR systems invest in high-end security features. These typically include: **user authentication with strong password policies** (and increasingly support for multi-factor authentication), **role-based access control** (users only see data relevant to their job role or the patients under their care), **audit logs** (every access or data change is recorded with time/user), **encryption** (SSL/TLS for data in transit, database encryption for data at rest), and **regular security updates** to patch vulnerabilities. For example, a modern EHR will log any viewing of a patient's record, which helps detect unauthorized snooping. From a pharma perspective, when a sponsor obtains data from an EPR, they must ensure their handling of it is secure as well. In terms of regulatory standards, compliance with standards like ISO 27001 (information security) or SOC2 is common among EHR vendors, which is reassuring for partners. Oracle Cerner and others tout **high-performance cloud** infrastructures with rigorous security for their hosted offerings (Making clinical trials a routine part of patient care). Epic provides guidelines for their clients on configuring security to meet HIPAA and GDPR needs. In summary, the EPR systems enable compliance but it's a shared responsibility: vendors provide the tools and secure architecture, healthcare providers configure and use them properly, and pharma companies must ensure any data extracted is handled with equal care.

GxP System Validation in Integration: One practical point is when integrating EPRs with sponsor systems (like EDC or safety databases), the *interface* should be validated. For instance, if data flows from an EHR to an EDC automatically, the sponsor will validate that the mapping is correct and the process reliably captures the data (this falls under computer system validation in GCP). EPR vendors often assist by providing documentation of their API behavior and maybe even test environments. For example, an Epic client could use Epic's **open.epic** sandbox to test pulling data via FHIR. Ensuring compliance means testing those integrations thoroughly and documenting them. Fortunately, standards like FHIR and CDISC make it easier to use standardized, tested methods rather than custom one-off solutions.

In conclusion, leading EPR systems come equipped to support regulatory compliance in clinical research: they maintain high data integrity, have robust security to protect patient privacy, and are recognized (by FDA guidance and industry practice) as acceptable sources of data for regulated activities, provided that appropriate oversight and procedures are in place.

Scalability and Performance Considerations

Pharmaceutical companies often operate at a global scale – a drug development program might involve thousands of patients across hundreds of sites. Similarly, pharmacovigilance requires processing data from very large populations. Therefore, the scalability of underlying EPR systems and their data handling capabilities is important.

All the major EPR systems discussed are proven to scale to large healthcare enterprises. For instance, Epic is used by huge health systems like Kaiser Permanente (serving over 12 million patients) and the U.S. Veterans Affairs (planned implementation for millions of veterans), demonstrating that Epic's architecture can handle high volumes of patients and users. Epic's Cosmos database aggregating **over 217 million patient records** is itself an example of scale – the system was designed to compile and query an *n*-hundred-million record dataset (Noel - Cosmos: Real-World Data Powered by the Healthcare Community - Journal of the Society for Clinical Data Management). Oracle Cerner's platform likewise supports national-scale projects (for example, Cerner has been the system for entire country-wide health systems or large regions). With Oracle's cloud backing, Cerner is moving towards even more scalable, cloud-native deployments. In a recent deployment, a hospital chose Oracle Cerner partially because it **"offered a foundation that can scale as [they] grow"**, unifying data across 150+ beds and 20 clinics with room for expansion (Nashville General Hospital Implements Cerner EHR, powered by Oracle Health, to Simplify Clinician Experience, Enhance Patient Care - Nashville General Hospital). That indicates confidence that adding more facilities or patient volume won't degrade performance.

From an integration point of view, scalability means two things: **technical performance** (can the system handle large data exchanges, many API calls, etc.) and **scalability of architecture** (can you add more servers or use cloud resources to expand capacity as needed). Both Epic and Cerner allow horizontal scaling and load balancing for their systems. Allscripts and Meditech, while often used in smaller environments, also support multi-hospital deployments and can scale up (Meditech Expanse, for example, can serve a network of hospitals with a unified database; Allscripts Sunrise has been used in large multi-hospital health systems too). When tapping into these systems for data, modern APIs like FHIR are stateless and can be scaled by deploying multiple API server instances to handle high request loads. Oracle's mention of **bulk data APIs and high-performance cloud** is particularly relevant for scalability – for instance, if a pharma company wanted to extract an entire dataset of a million patients' EHR records for a study, the system can handle it by leveraging cloud infrastructure (FHIR R4 APIs with Bulk Data Access - Oracle Help Center). Epic's approach for large queries is through Cosmos or through data warehouses that clients maintain (many Epic customers push data to a Clarity or Caboodle database which can be queried without impacting the live EHR performance).

Another aspect of scalability is supporting **many concurrent integrations/users**. In a trial with dozens of sites, each site's EHR might be connected to the sponsor's system. The EHRs and interfaces need to handle concurrent connections. Fortunately, these enterprise EHRs are

designed for high concurrency – e.g., tens of thousands of clinical users simultaneously charting. A handful of interface processes or APIs for research purposes are well within their capacity.

Global scalability is also a consideration. Epic and Cerner have installations in Europe, Middle East, Asia-Pacific, etc. If a global trial is pulling EHR data via integration, one might be dealing with sites running different EHR systems and versions. Ensuring each can handle the load is key. Generally, capacity planning is done by the healthcare IT side, but pharma IT should be aware not to overload a site's system with excessive data queries. In practice this isn't a problem if using properly designed interfaces (for example, FHIR subscriptions or web hooks that send updates rather than constant polling).

Finally, **scalability of data storage**: pharma companies receiving EHR datasets will need to store and manage them securely. EPR vendors sometimes offer to host research data on their platforms (Epic's Cosmos is one example where data is centrally stored and can be queried). This can relieve the sponsor from having to replicate terabytes of data locally – instead, queries can be run on the vendor's system and only aggregate results or relevant subsets are pulled. This model (federated or centralized querying) is scalable in that adding more data doesn't necessarily add burden to the sponsor's infrastructure.

In summary, modern EPR systems are highly scalable, built to serve large patient populations and heavy transactional loads. When leveraged for pharma purposes, they can comfortably support enterprise-level data volumes. Proper use of cloud services, bulk data tools, and not pulling more data than needed will ensure performance remains optimal. **Scalability is generally a strength of leading EPRs**, given their critical healthcare missions – they are designed to not crash even if usage spikes (e.g., during a pandemic, EHR usage went up significantly with no major issues reported in these systems).

Usability and User Experience

Usability is a crucial consideration because an EPR system will be used by healthcare professionals (and sometimes by patients via portals), and in research contexts, by study coordinators and investigators. A system with poor usability can lead to user frustration, data entry errors, and under-utilization of important features – all of which could indirectly affect data quality and compliance in pharma use cases. IT professionals often collaborate with clinical users to ensure that EPR systems are configured to be as user-friendly as possible in supporting research workflows.

Clinician Usability: Over the years, EHRs have been both praised and critiqued for usability. Epic and Cerner, being very feature-rich, historically had steep learning curves, but they have improved interfaces with more modern, intuitive designs in recent versions. Epic's interface is highly configurable; sites can create specialized screens for research studies, for example. Epic also offers a mobile app (Haiku/Canto) and a web-based interface for on-the-go access, which

improves usability for busy clinicians. Cerner Millennium has a contemporary UI as well and with Oracle's influence may get even more UX attention (Oracle is known for refining enterprise software interfaces). Allscripts' TouchWorks was known for physician-friendly design in ambulatory settings, and Sunrise for an integrated workflow in hospitals – they have generally been well regarded in specific domains, though Allscripts had a mix of products with varying UI paradigms. Meditech Expanse has a web-based interface that many users find straightforward, especially in smaller clinical settings.

For research specifically, **usability means making it easy for clinicians to participate in trials and record necessary data** without extra burden. EPR systems now often have features like research order sets (pre-defined orders for trial labs, etc.), templates for progress notes that align with study requirements, and alerts for inclusion/exclusion criteria. If these are well-designed, they guide clinicians rather than annoy them. For example, if a patient is on a clinical trial, an EPR might prompt the doctor with a reminder of a protocol-required test when ordering medications – this can be very helpful if not overdone. Epic's Research Module is designed to integrate into the clinician's normal workflow, so that identifying a patient for a trial or documenting a study visit feels similar to any other clinical task. This is important to encourage **investigator compliance** – doctors are more likely to enter data properly in the EPR than on a separate paper form if it's integrated seamlessly.

Research Coordinator Usability: Study coordinators often act as a bridge between the EPR and sponsor systems. A user-friendly EPR can simplify their job. For instance, rather than pulling up 10 different screens to find the data to transcribe into an EDC, a coordinator could use an EHR's summary view that collects all protocol-relevant data in one place. Epic has features to summarize research data, and other EHRs allow custom reports or flowsheets for trials. If an EHR can generate a **research flowsheet (case report form view)**, coordinators might use that directly and even use it as source for SDV (source data verification). Additionally, for pharmacovigilance, usability means that it should be straightforward for clinicians to report adverse events or for safety officers to flag events in the EHR. Ideally, an EPR would have a one-click adverse event reporting tool that populates necessary details – some systems interface with national reporting systems or internal safety systems.

Patient Usability: Patients increasingly use EPR-connected portals to enter data – e.g., filling out questionnaires or patient-reported outcomes (PROs). This is very relevant in trials (electronic PRO collection). EPR patient portals like Epic MyChart can deliver trial questionnaires to patients, which then feed into the EHR and can be shared with the sponsor. Ensuring these patient-facing tools are easy to use (mobile-friendly, clear instructions) is critical to get good compliance. Epic and Cerner both have robust patient engagement platforms, and some trials have successfully used them for ePRO, though often specialized ePRO apps are used instead. But in any case, the patient experience with an EHR (for trial or care) should be smooth to encourage participation.

Training and Support: No matter how good the UI, EPR systems require training. The big vendors provide extensive training materials and even simulation environments. For research

use, additional training is often given to show how to use the system for study tasks. Pharma companies might collaborate in this by providing support for training site staff on any new integration or workflow (for instance, if an EHR-to-EDC system is introduced, both the site and sponsor will ensure users know how to use it). Good usability is partly achieved by **optimizing configuration** – for example, turning off irrelevant alerts, customizing screens to the specialty, etc. IT teams should work with end-users to continuously improve the configuration for usability.

User Satisfaction: It's worth noting that in surveys (like KLAS ratings), Epic often scores well on user satisfaction, Cerner a bit lower historically but improving, Meditech well in its segment, and Allscripts/Veradigm's newer focuses are shifting toward data rather than frontline user interface. These are general trends, but the takeaway is all these systems are mature and **usable with proper training**, and each vendor is actively trying to enhance user experience (with modern UX design, voice recognition documentation, AI assistants, etc.). For example, vendors are incorporating voice transcription for notes or predictive charting help, which can reduce the click burden on clinicians – indirectly benefiting pharma because a less burned-out doctor is more likely to engage in research and accurately document.

In summary, while no enterprise EPR is perfect, the leading systems have evolved to provide intuitive, integrated experiences. When leveraged in pharma workflows, good usability translates to more consistent data capture and better adoption of research functionalities. IT professionals should pay attention to how research-related features are presented to users in the EPR and solicit feedback to make iterative improvements. The **goal is to embed research tasks as naturally as possible into clinical routines**, a concept both Epic and Oracle Cerner have explicitly championed (Making clinical trials a routine part of patient care) (New Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic). Achieving that means better data and less frustration, benefiting everyone involved.

Industry Case Studies and Impact Examples

To illustrate how EPR systems make a difference in pharmaceutical industry applications, let's look at a few concrete examples and case studies from the field:

- **Streamlining Clinical Trial Operations at Yale (Epic & OnCore):** Yale New Haven Health, an academic medical center, needed to improve its clinical trial billing compliance and workflow efficiency. By integrating its Epic EHR with the OnCore CTMS, Yale created a unified workflow for research billing. The integration meant that as soon as a patient was marked as enrolled in a trial in OnCore, that information was available in Epic for clinicians, and the trial's billing plan (which costs go to the study vs. insurance) was synchronized (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra). The result was **strengthened billing compliance, reduced staff workload, and improved patient safety** (providers knew about trial participation) (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra). This case demonstrates the tangible benefits of EPR-CTMS integration in a live hospital environment – fewer billing errors (avoiding potential Medicare billing violations) and time saved for study coordinators, which ultimately speeds up trial processes.

- **EHR-to-EDC Success in the I-SPY COVID-19 Trial:** Mentioned earlier, the I-SPY COVID-19 adaptive trial used an innovative eSource approach across multiple hospitals (which had EHRs like Epic, Cerner, etc.). Using an integration layer (OpenClinica Unite) embedded in the EHR, data was automatically transferred to the EDC. This led to a **61% reduction in data entry time** and eliminated data transcription errors at those sites (What is EHR to EDC Integration in Clinical Trials?). The impact is profound: not only does this save time (so trials can potentially complete enrollment or data cleaning faster), but it also improves data quality (no transcription errors means clean data for analysis, reducing queries). This case is often cited as proof that robust EHR integration can make clinical trials much more efficient and is a model for future trial designs.

- **Accelerating Trial Recruitment via EHR Data (Cerner & Elligo):** Cerner's Learning Health Network and its partnership with Elligo Health Research provide a network-based example. By 2020, 51 health systems in the network agreed to contribute de-identified EHR data for cohort discovery (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget). Elligo, working with Cerner, uses that data to find patients who might qualify for trials and then engages those community hospitals to conduct the studies. The impact is that clinical trials become more accessible to patients in community settings (not just large academic centers), broadening participation. This also addresses the common issue that **nearly 50% of sites under-enroll and many trials are delayed due to recruitment issues (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget)**. By mining EPR data, suitable patients can be identified in days rather than months, and outreach can be done through their trusted local physicians. This means faster enrollment and more diverse patient representation in trials (including rural populations that are often left out). A specific example from this network: during the COVID-19 pandemic, real-world EHR data was used to quickly identify potential candidates for trials of treatments and vaccines, demonstrating agility in a crisis.

- **Real-World Evidence for Safety and Effectiveness:** Pharma companies have started using large EHR-derived datasets to complement clinical trials. For instance, **Epic's Cosmos data** (217M patients) has been used in observational studies to answer questions that trials didn't, or to monitor post-market safety. A published case is using Cosmos to compare outcomes of different treatments across a broad population to generate hypotheses for new trials (Noel - Cosmos: Real-World Data Powered by the Healthcare Community - Journal of the Society for Clinical Data Management) (Noel - Cosmos: Real-World Data Powered by the Healthcare Community - Journal of the Society for Clinical Data Management). Similarly, **Veradigm's EHR data** has been used by companies like Novartis and others for outcomes research in cardiology and diabetes (as hinted by Veradigm's collaborations (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget)). The **impact** here is that decisions in drug development and safety surveillance can be data-driven using real-world patient records. One notable impact example: the FDA approved an expanded indication for a cancer drug (palbociclib for male breast cancer) partly based on real-world EHR data because clinical trials had not included male patients. This kind of regulatory use of RWE shows the power of EPR data in action. While not tied to a single vendor, it underscores why EPR systems and their data interoperability are so important to pharma.

- **Pharmacovigilance Signal Detection:** EHRs are also being leveraged for pharmacovigilance. Traditional adverse event reporting captures only events that are actively reported by clinicians or patients. However, analyses of EHR databases have uncovered signals of adverse drug reactions by looking at clinical notes and diagnoses patterns (Detection of Pharmacovigilance-Related adverse Events Using ...). For example, researchers might scan de-identified EHR data from Epic or Cerner systems for clusters of symptoms after a drug prescription. In one project, linking EHR clinical notes improved detection of drug-induced liver injury cases that were not reported through standard channels (Detection of Pharmacovigilance-Related adverse Events Using ...). This **enhances patient safety** by using the EPR as a large monitoring tool. Pharma companies, often through partnerships with research networks, can tap into these EHR-derived findings to investigate potential safety signals earlier.

- **Meditech and Health Equity Research:** A unique case involves Meditech's collaboration with IHM for health equity data. Community hospitals using Meditech contributed data that helped identify disparities in care and outcomes. For example, analyzing EHR data on diabetes control in certain regions can show where outcomes are worse for minority populations, guiding both clinical interventions and where pharma might focus outreach or trial recruitment to ensure diverse representation. The **impact** is improved understanding of real-world patient needs and outcomes. Meditech EVP Helen Waters noted that by partnering with IHM, Meditech hospitals gained a way to **"test hypotheses and measure results with data"** on previously underrepresented groups (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget). This can influence how new therapies are developed or targeted.

These examples collectively show that when EPR systems are effectively integrated and utilized, they can: speed up clinical trial timelines, improve data quality, expand access to trials, inform safety and efficacy outside of trials, and ultimately lead to better health outcomes. Each of the leading EPR vendors has success stories in these domains – from Epic's enabling of massive research networks, to Oracle Cerner's push for embedded trials, to Allscripts/Veradigm and Meditech opening up new data sources for research. For IT professionals, the takeaway is that engaging with EPR systems is no longer an optional or peripheral aspect of pharma IT – it is becoming central to innovation in clinical development and post-market analysis.

Comparison of Key EPR Systems for Pharma Use

The table below summarizes key features of each leading EPR system discussed, with a focus on integration support and notes on their use in the pharmaceutical industry:

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
Epic Systems	– Comprehensive enterprise EHR	– Extensive support for HL7 FHIR APIs (via App Orchard) for data exchange	– Used at sites running 100k+ clinical studies (New

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
	(inpatient & outpatient) – Wide adoption (large academic centers, IDNs); ~270M patient records in network – Research module and patient portal (MyChart) included – High user satisfaction and robust support structure	– Interface capabilities for CTMS (e.g. Epic–OnCore integration for trial billing (Yale Enhances Patient Safety, Billing Workflows with OnCore and EMR Integration - Advarra)) – SMART on FHIR apps can embed in Epic workflow – Participates in HIE networks; Epic Cosmos for data aggregation	Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic); integral to trial workflows – **Life Sciences Program** connects sponsors with Epic sites to accelerate trials (New Life Sciences Program Will Unify Clinical Research with Care Delivery - Epic) – **Epic Cosmos** RWE database (>217M patients) for outcomes research (Noel - Cosmos: Real-World Data Powered by the Healthcare Community - Journal of the Society for Clinical Data Management) – Preferred by many academic research hospitals for its research tools
Oracle Cerner	– Comprehensive clinical EHR	– Open APIs (Oracle Cerner Ignite; supports FHIR R4) for third-party integration	– **Learning Health Network** with 50+ health systems

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
	(Cerner Millennium); strong in hospital systems – Now part of Oracle Health – leveraging cloud and analytics strengths – Scalable from community hospitals to nationwide systems – Emphasis on point-of-care research integration	(Making clinical trials a routine part of patient care) – Native integration with Oracle's CTMS and clinical trial apps (single-vendor solution) (Nashville General Hospital Implements Cerner EHR, powered by Oracle Health, to Simplify Clinician Experience, Enhance Patient Care - Nashville General Hospital) – HL7 interfaces for labs, demographics, scheduling (widely used for CTMS/LIMS) – Cerner HIE and CommonWell connectivity for broader data sharing	shares de-ID EHR data for research (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget) – Partnerships (e.g., Elligo) to embed trials in community care, boosting recruitment (Cerner Invests in Elligo to Boost Access to Clinical Trials - TechTarget) – Often used in real-world studies; Oracle combining EHR data with pharma databases to accelerate R&D (Making clinical trials a routine part of patient care) – Selected by hospitals that aim to integrate clinical care with research (e.g. Nashville General with Oracle CTMS (Nashville General Hospital Implements Cerner EHR, powered by Oracle Health, to

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
			Simplify Clinician Experience, Enhance Patient Care - Nashville General Hospital))
Allscripts (Veradigm)	– EHR solutions for ambulatory (TouchWorks) and acute care (Sunrise) – Known for flexible, user-friendly design in outpatient settings – Pivot toward data services (Veradigm) offering analytics and RWE – Large ambulatory provider base in US	– Offers FHIR APIs and an open developer program (early adopter of interoperability) – Able to integrate with practice management, and via partners (Datavant, etc.) for data linkage (Veradigm EHR (formerly Allscripts) - EHR Integration - Datavant) (Veradigm and Komodo Health Partner to Create the Largest Linked ...) – HL7 messaging available for hospital integration needs – Providing data in OMOP CDM for easy research use (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget)	– **Veradigm Network** of EHR data (~170M patients) for real-world evidence studies (Veradigm Makes EHR Data Available in OMOP CDM Data Standard for RWE - TechTarget) – Data used by pharma for outcomes, safety (e.g. cardiometabolic RWE datasets (Unlocking Real-World Insights with Allscripts Veradigm Network ...)) – Collaboration to link EHR data with clinical trial databases (through tokenization) enabling richer post-trial follow-up (Veradigm and HealthVerity Expand

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
			Existing Partnership with Novel Linked Real-World Data Packages) – Allscripts EHRs present in some trial sites (especially community clinics), feeding data to sponsors
Meditech	– Integrated EHR for community and mid-size hospitals (Expanse platform) – Covers inpatient, outpatient, ED, long-term care in one system – Cost-effective and reliable; widely used in smaller healthcare systems – Modern web-based UI with clinician-friendly workflows	– Supports HL7 FHIR APIs (Greenfield initiative) for data access and app integration (MEDITECH Interoperability) – Standard HL7 v2 interfaces for lab, radiology, ADT, etc., enabling CTMS/LIMS links – Participates in CommonWell/Carequality HIE for cross-organization data sharing – Focus on interoperability for resource-limited (smaller) IT environments (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget)	– Used by many community hospitals that are now contributing data for research (often previously underrepresented populations) – Partnership with IHM to use Meditech EHR data for **health equity research**, giving pharma insight into diverse patient outcomes (MEDITECH Partnership Focuses on Health Equity Data Collaboration - TechTarget) – Meditech data being aggregated for RWE (e.g., regional disease trend

EPR System	Key Features & Strengths	Integration & Interoperability	Pharma/Industry Usage Notes
			analysis) by public health and research groups – Some Meditech hospitals participate in industry trials; data can be integrated to sponsor systems via standard interfaces

Table: Comparison of major Electronic Patient Record systems in terms of features, integration support, and usage in pharma-related contexts.

Conclusion

Electronic Patient Record systems have become indispensable bridges between frontline healthcare and the pharmaceutical industry. As seen, leading EPR platforms like Epic, Oracle Cerner, Allscripts (Veradigm), and Meditech not only manage clinical care efficiently but also unlock enormous opportunities for clinical research, real-world evidence generation, and regulatory activities when leveraged properly. For IT professionals in pharma, understanding the capabilities and nuances of these systems is crucial. Effective integration of EPRs with CTMS, LIMS, and EDC systems can streamline clinical trials – reducing redundant data entry and errors, and accelerating study timelines. Robust interoperability and data standards (such as HL7 FHIR) now make these integrations more feasible than ever, turning the vision of **"seamless data flow from bedside to database"** into a reality.

Moreover, EPR systems play a key role in **regulatory compliance**: by supporting 21 CFR Part 11 requirements through audit trails and security, and by enforcing patient privacy protections aligned with GDPR and HIPAA. The scalability of these platforms ensures that even as data volumes grow (with hundreds of millions of records in play), performance and reliability remain high. And with continually improving usability, clinicians and research staff can engage with these systems without undue burden, which means better data capture and greater willingness to participate in innovative projects like embedded trials or observational studies.

The case studies and examples highlighted – from Yale's integration success to the I-SPY trial's data automation, and real-world data networks like Epic Cosmos and Cerner's Learning Health Network – collectively demonstrate a **significant impact**: faster research, more inclusive trials,

improved safety monitoring, and data-driven decision making in drug development. EPR systems have essentially become a linchpin in the pharmaceutical data ecosystem.

In summary, the pharmaceutical industry's IT landscape is increasingly interwoven with EPR technologies. Choosing the right EPR partnerships and integration strategies can yield substantial benefits: efficiency gains, compliance assurance, and powerful insights from real-world patient data. As healthcare and life sciences continue to converge in the era of digital health, EPR systems will remain at the forefront of enabling breakthroughs – helping to bring therapies to patients faster and managing data in a way that is both innovative and compliant. By staying informed about these systems and harnessing their capabilities, IT professionals in pharma can drive forward the mission of improving patient outcomes through research and development excellence.

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