Hype Cycle for Life Science Clinical Development, 2023

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Initiatives: Healthcare and Life Science Digital Optimization and Modernization; Healthcare and Life Science Digital Transformation and Innovation

> Amid highly disruptive advances in artificial intelligence this year, life science companies must continue to navigate the strong current of inflationary market forces. CIOs must make difficult choices, selecting innovations that enable operational excellence and robust returns on investment.

More on This Topic

This is part of an in-depth collection of research. See the collection:

- 2023 Hype Cycles: Deglobalization, AI at the Cusp and Operational Sustainability

Analysis

What You Need to Know

This year brought dramatic changes from the “triple squeeze” — persistent high inflation, tight labor market and global supply disruptions — challenging life science companies’ ability to thrive. High inflation was likely the most impactful of these, impacting life science technology budgets, vendor contracts and the ability of biotech startups and venture-back tech companies to capitalize. Life science organizations continued their investments in cell and gene therapies, biotechnology and precision medicine products focused on cancer treatments — even as overall revenue was reduced in 2023. This, combined with the effects of inflation, has driven life science companies to redouble their efforts to push operational excellence in clinical development using digital technologies (see 2023 CIO and Technology Executive Agenda: A Life Science Perspective). Furthermore, with the advent of Generative AI and the promise of hyperoptimization, we expect continued experimentation and investment to automate clinical development in the coming year, which may accelerate further once the high inflation dissipates.

The Hype Cycle

CIOs in life sciences seek new innovative and differentiating capabilities while driving operational effectiveness at scale. This Hype Cycle explores innovative technologies that are specifically relevant to life science clinical development programs in the pharmaceutical, biotechnology, diagnostics, medical device, research institution and contract research sectors. The ongoing need to support new products and rapidly drive them to commercialization leads to continual disruption and reinvention. As a result, clinical and regulatory IT includes many niche applications serving a broad canvas of needs, with specialized teams supporting the many business processes.

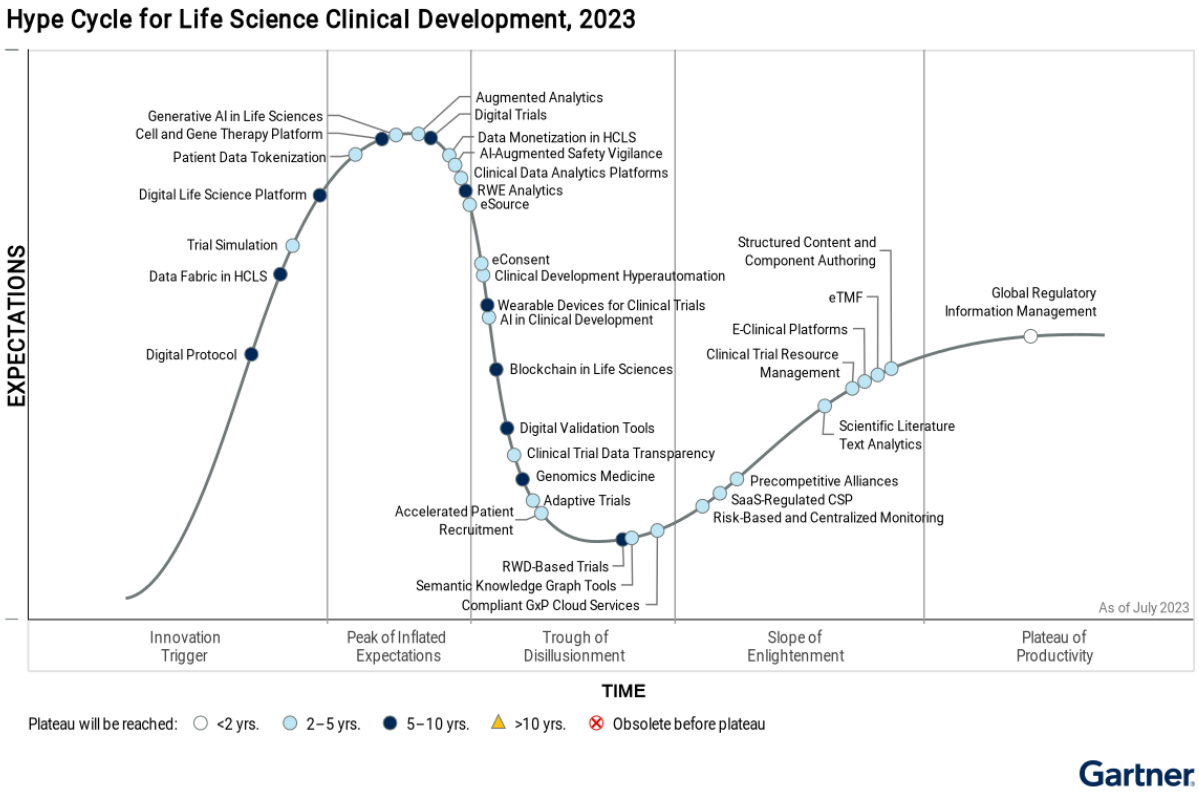
This Hype Cycle is part of a family of four life-science-focused Hype Cycles. The others include the Hype Cycle for Life Science Discovery Research, 2023; Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2023 and the Hype Cycle for Life Science Commercial Operations, 2023. These combined research notes help CIOs apply a comprehensive view on emerging technologies across the entire life science value chain (see Understanding Gartner's Hype Cycles).

With so many innovative new digital technologies that can play a role in aiding clinical development and process optimization initiatives, we see significant opportunities in life science technology investments. However, previously overhyped innovations such as digital trials may take longer to mature, while newly hyped technologies such as patient data tokenization and large language models in HCLS may progress more rapidly due to increased investments in these products. To reflect this high degree of digital innovation, we introduced five technology innovations this year:

- Data Fabric in HCLS
- Generative AI in Life Sciences
- Digital Protocol
- Patient Data Tokenization
- eConsent

This research will help you and your executive peers evaluate and prioritize technologies to align with your organization's future vision and enterprise goals. Use the information in this Hype Cycle to identify technologies that have the potential to deliver the value your organization demands while evaluating the risks associated with those innovations. By selecting the right technologies, timing and approaches, you can better meet the needs of your business teams, support clinical development initiatives and achieve operational excellence across development.

Figure 1: Hype Cycle for Life Science Clinical Development, 2023



The Priority Matrix

This Hype Cycle includes many areas of innovation that will enable your organization to respond to industry challenges. Look at each of the technologies in your portfolio and consider how they support your organization's ambitions to digitalize. Gaining a competitive advantage requires you to not only leverage existing technologies to their maximum potential, but also identify which technologies you should replace, augment or retire.

The Priority Matrix is a summary companion to the Hype Cycle graphic. Using data from the benefit rating and time-to-plateau values for each technology, it plots the answers to two key questions:

- How much value could your organization expect to realize from the effective implementation of a particular technology?
- When will the technology be mature enough to help deliver that value?

Quickly maturing, high-importance transformational technologies are up and to the left of the Priority Matrix, and include innovations like digital trials and digital life science platforms. Below them are technologies that are still important, but with a lesser scope of potential impact. Emerging technologies with great potential that are further away from their full maturity, including blockchain in life sciences and trial simulation, are in the upper-right. Technologies with lower benefit ratings and longer times to value are listed in the Priority Matrix's lower-right sections.

Table 1: Priority Matrix for Life Science Clinical Development, 2023

(Enlarged table in Appendix)

Benefit	Years to Mainstream Adoption			
↓	Less Than 2 Years ↓	2 - 5 Years ↓	5 - 10 Years ↓	More Than 10 Years ↓
Transformational		E-Clinical Platforms Generative AI in Life Sciences	Blockchain in Life Sciences Data Fabric in HCLS Digital Life Science Platform Digital Trials Genomics Medicine	
High		Adaptive Trials AI in Clinical Development Augmented Analytics Clinical Data Analytics Platforms eSource eTMF Patient Data Tokenization Risk-Based and Centralized Monitoring SaaS-Regulated CSP Scientific Literature Text Analytics Semantic Knowledge Graph Tools Trial Simulation	Cell and Gene Therapy Platform Digital Protocol Digital Validation Tools RWD-Based Trials RWE Analytics Wearable Devices for Clinical Trials	
Moderate	Global Regulatory Information Management	Accelerated Patient Recruitment AI-Augmented Safety Vigilance Clinical Development Hyperautomation Clinical Trial Data Transparency Clinical Trial Resource Management Compliant GxP Cloud Services Data Monetization in HCLS eConsent Precompetitive Alliances Structured Content and Component Authoring		
Low				

Source: Gartner (July 2023)

Off the Hype Cycle

On the Rise

Digital Protocol

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Digital protocol is an evolving concept in which a clinical trial protocol — a set of rules defining clinical trial conduct, from the visit schedule to clinical endpoints and expected outcomes — is developed as digital content and reproduced as an electronic document. The trial protocol is first developed as interactive content and trial parameters that begin as structured data elements as defined in a specification.

Why This Is Important

Transitioning from a traditional documented-based clinical trial protocol to a digital protocol is a rational first step into digital data workflow. Digitalizing this protocol results in a single source of truth for the entire study and enables trial leaders to digitally develop the core study design, procedures, schedules, endpoints, timelines and protocols. Then it can be managed in a metadata library and then used to automate trial design in downstream systems and facilitate clinical study report development.

Business Impact

The digital protocol represents the first step for most life science companies in the conversion of serially authored content (i.e., documents) into structured and component-based digital authoring approaches. Establishing a digital clinical trial protocol promises more standardized protocol builds, reusable components and data specifications that transfer directly to downstream solutions to automate trial builds.

Drivers

- Digital protocol solutions can offer many benefits resulting from the use of structured content and component authoring, including content reuse, protocol quality and consistency improvements, searchability, change management, and reduced transcription errors.

- These solutions can promote a more agile and flexible process flow by leveraging APIs for data entry into a standard library or individual protocol, and APIs for information flow out of an individual protocol into various dynamic content publishing solutions.
- Clinical trials often are plagued by protocol revisions resulting from errors missed during authoring. Digital protocol solutions can lead to improved data quality and documentation compliance by ensuring consistency of content definition and development, enabled by content and object libraries that can be managed as controlled components for reuse across multiple protocols.
- Evolution of these digital systems can lead to the development of a scalable framework for data exchange and interoperability between multiple systems. Examples include similar datasets used for the generation of other foundational definition files for study operation and clinical data analysis (such as statistical analysis plans or monitoring plans).
- As digital protocol data standards are developed and deployed by organizations, this will lead to enhanced data sharing and collaboration between technology and research partners, increased transparency and parallel development.
- TransCelerate BioPharma's Digital Data Flow initiative is also driving interest in digital protocol projects, as organizations collaborate to finalize a data model that can promote data sharing and solution standards for development.
- The digital protocol is new on the Hype Cycle this year and placed in the Innovative Trigger phase.

Obstacles

- Poor understanding of the clinical domain rules by technology vendors can result in drawn-out timelines or additional resource requirements.
- Lack of protocol open data standards and compatible solution architecture in upstream and downstream solutions can lead to interoperability challenges, limiting the potential benefits.
- With a lack of marketed digital protocol solutions, and available solutions being of low maturity, vendor and solution selection may be problematic.
- As a nascent technology, there is a dearth of experts with experience in application development, or managing the adoption, of digital protocol solutions.

- Clinical scientists are not yet comfortable building documents from structured components, leading to a high potential for issues with change management and product adoption.

User Recommendations

- Execute a proof of concept (POC) to prove the business case, attaching a longer-term ROI to these initiatives, allowing experimentation and more flexibility for replans and rescoping as needed.
- Judge vendor products by the completeness of vision and the vendors by their capabilities and their ability to execute, expecting that few vendors will have products that meet all requirements. Then, make a build, buy or ally (partner, co-develop) decision.
- Initiate projects with user experience as the first priority, ensuring that a document output will be a needed reference model for most users as they build their protocol using components.
- Explore using TransCelerate BioPharma's Digital Data Flow data model as the core element for your application, which will likely be adopted by many organizations and will shortcut development efforts.

Sample Vendors

Accenture; Dassault Systèmes; Deloitte; Faro Health; Formedix; InteliNotion; intilaris LifeSciences; Nurocor; Virtusa; ZS (Trials.ai)

Gartner Recommended Reading

2023 CIO and Technology Executive Agenda: A Life Science Perspective

Life Science CIOs: Map Your Pathway to Digital Trials

Industry Vision: Life Science CIOs Must Transform Clinical Development With Digital Trials

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Quick Answer: 4 Factors for Build, Buy or Ally Decision Making in Life Science R&D

Data Fabric in HCLS

Analysis By: Gregg Pessin

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

A data fabric is a design framework for attaining flexible, reusable and automated data integration pipelines, services and semantics. It supports a broad spectrum of operational and analytics use cases on various platforms. Data fabric design provides the necessary data access capabilities for the composable healthcare enterprise.

Why This Is Important

Due to uncertainty and constantly changing market conditions, healthcare organizations need to be able to create and recompose business and clinical capabilities more quickly. Composable architecture is the solution to this requirement, and data fabric is the foundation of that architecture. Data fabrics will significantly reduce or eliminate manual data integration tasks and augment (in some cases, completely automate) data integration design and delivery.

Business Impact

Data fabric solves the healthcare industry's data problem. The sector has disparate data sources across care delivery, payer and life science enterprises. These isolated data sources hinder the timely, full-value delivery of enterprise-level information insights. Data fabric improves data access velocity, improving decision making. It offers an opportunity to eliminate manual data integration tasks significantly and automate data integration design and delivery.

Drivers

- The healthcare industry is in the midst of a digital transformation, which at its core requires composable enterprise architectures for success. Data fabric is a crucial enabler of composability. Adoption is low currently, but the hype is creating more interest as the healthcare industry begins to apply composable concepts to their application solution sets.
- Most organizations will find that they already have some of the base components of a data fabric, creating a solid foundation to begin the journey.
- Data science as a practice is maturing in healthcare, motivated by the need to expose more value from data. At the same time, new independent data sources with higher complexity drive the need for better data access solutions.
- Data fabric offers an alternative approach to traditional interoperability requirements. The data integration, interfacing and interoperability issues that plague the industry have another solution option with data fabric.
- New technologies that support the data fabric solution set are becoming generally available, including knowledge graphs, active metadata management and semantics management.

Obstacles

- Healthcare industry organizations lack enough high-quality data to train the machine learning (ML) required to activate metadata and enable a fabric.
- Lack of metadata in the early stages of data management initiatives — especially for on-premises deployments — will put initial pilots at risk of failure.
- Healthcare data returned from data fabric stacks must consider the privacy of the data-owning patient. In gathering the healthcare information, the data fabric technology layers must each comply with local regulations such as Health Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR).
- In addition to privacy, patient/member/consumer/citizen consent for access to their healthcare data is gaining momentum and shifting in complexity as granular consent gains traction. Data fabric capabilities must include honoring individual consent approvals to the data element level.

User Recommendations

- Assemble a fusion team of D&A practitioners, IT engineers and business users completing significant, manual data preparation for their projects. The CIO will find the right automation opportunities and gather the right team by finding personnel that experience the mundane task involved in delivering value from data.
- Task this newly formed team to identify where the data resources do not meet business or clinical requirements. The team should look for key technology solutions where users find accessing and using the associated data difficult.
- Develop KPIs that align with business outcomes, and capture performance before and after the pilot. Examples include correlating patient length of stay, delays due to an EHR availability outage, payer overpayment due to 30+ days, delay in access to paid claims data, or delayed clinical trial progress due to IT system inefficiencies.

Sample Vendors

Cambridge Semantics; Cinchy; CluedIn; Denodo; IBM; Informatica; Semantic Web Company; Stardog; Talend

Gartner Recommended Reading

Quick Answer: What Is Data Fabric Design?

Data and Analytics Essentials: How to Define, Build and Operationalize a Data Fabric

Trial Simulation

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Trial simulation refers to the simulation of aspects of a clinical trial using digital technology, including creating patients in silico, verifying trial feasibility with analytics applied to real-world data (RWD) and providing protocol-optimizing insights. These digital approaches can also simulate organ response to drugs, AI frameworks to optimize dosing and predict disease progression, and other insights to accelerate preclinical activities and optimize trial planning.

Why This Is Important

As digital technology matures and becomes pervasive within clinical development organizations, clinical and IT leaders must move from operational analytics to predictive analytics and simulation approaches to better plan, optimize and execute clinical trials. Trial simulation technology can improve decision intelligence around protocol development, from drug interactions to site and subject locations, thereby avoiding unneeded trial work.

Business Impact

Investments yield high value by making trials feasible, via simulation and synthetic arms, where previously it would not have been possible due to patient enrollment challenges. Simulation approaches can use previous trial data to optimize trial protocols, both reducing trial resources needed and improving the chance of success. Preclinical simulations can include digital twins to predict organ response and drug interactions, dosing regimens, predictions around drug toxicity and other insights.

Drivers

- Life science companies are accelerating strategies to execute more in silico, digital twin and modeling work prior to running clinical trials. As new approaches become available, clinical leaders see the many benefits of simulation technologies used to de-risk clinical trials or accelerate the time to completion.
- Most life science companies are developing treatments for orphan diseases, where finding patients can be an enormous challenge. This dearth of patients is driving clinical leaders to consider the use of simulation and synthetic control arms, which can reduce the number of “real” subjects in a trial, making such trials feasible.
- Trials continue to get more expensive to run, and advanced technology, predictive analytics and simulation approaches can reduce enormous amounts of waste by ensuring the right trial is run. Synthetic arms can also optimize other trials, reducing the cost of starting up sites of low productivity.
- RWD and advanced AI technology are increasingly available, informing and enabling new approaches. These new resources can work together to create a virtuous cycle enriching the value and improving the capability of simulation models over time, by allowing existing in silico and digital twin models to iteratively improve.
- As a recent technology on the Hype Cycle, trial simulation falls in the Innovation Trigger phase, and is expected to reach the Plateau of Productivity within five years.

Obstacles

- The sheer complexity and data requirements of these methodologies can steer away clinical researchers who do not have the deep bench needed to properly support such efforts.
- Although the FDA and other regulators have signaled their interest in investing in these approaches, regulatory concerns prevail. Models must be sufficiently tested against more conventional approaches to demonstrate viability, which takes time and effort.
- Approaches such as synthetic control arms have unique data requirements and often the RWD needed to support such efforts is not available.
- Software solutions are still evolving and can be black boxes to researchers who must clearly understand and validate the inner workings. Most solutions require significant hand-holding from vendors, and technology transfer of capability is still in the early development stages.

User Recommendations

- Champion trial simulation initiatives and POCs, and prioritize them as the high-value opportunities they can be over low-value optimization approaches on the trials themselves. Running the wrong trial quickly is a much lower value than running the right trial slowly.
- Work with business and IT colleagues to build your own technology and scientific bench to support these simulation approaches. You will be able to most effectively use existing solutions as well as partner with available vendors, which will best position your organization for success.
- Evaluate vendors for both technology platform and service capability, as both will be needed to mature simulation models and build an internal bench for future projects.
- Partner with business teams or vendor experts to evaluate RWD data sources carefully when such data is needed to fuel insights or simulate subjects, and ensure project viability before going “all in.”

Sample Vendors

AIBODY; Ariana Pharmaceuticals; Certara; Dassault Systèmes (Medidata); Deloitte; Novadiscovery; Ontada; SAS; Syapse; ZS

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Digital Life Science Platform

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: Less than 1% of target audience

Maturity: Emerging

Definition:

A digital life science platform (DLSP) is an architectural approach that enables companies to nimbly adapt their business and operating model, in response to external disruption and change in business strategy. The DLSP sources and integrates functionality from internal and ecosystem partners to create packaged business capabilities (PBCs). Nontechnical and IT staff can use PBCs to compose new experiences.

Why This Is Important

Life science (LS) organizations realize the limitations of monolithic ERP-centric or heavily customized or niche business application portfolios. The siloed nature of current architectures has stifled innovation and slowed digital transformation. Business users are exhausted by feeble attempts at interoperability by vendors, resulting in an excessive total cost of ownership (TCO) and fragmented user experiences.

Business Impact

The DLSP supports the following capabilities:

- Digital consumer and patient engagement for personalized experiences for drug regimens, device usage and therapies, using plug-and-play capabilities from external ecosystem players.
- Decentralized, digital clinical trials.
- Advanced health analytics, using tools that leverage data sources from R&D, precision medicine and real-world evidence.
- Digital laboratory research connected across multiple scientific and experimental disciplines, like chemistry and biology.

Drivers

- Business users want to transform the business. They want to enable a "composable" life science enterprise that leverages technologies to solve increasingly complex therapeutic issues. The composed experience will be realized through business-user-focused application experiences that are independent of the underlying set of commercial off-the-shelf (COTS) or legacy monolithic applications.
- Clients want a more effective means of bringing together different domains (e.g., clinical and AI subject matter experts [SMEs]) to provide a focus for democratized innovation among a range of stakeholders (see Fusion Teams: A Proven Model for Digital Delivery).
- The DLSP approaches are removing critical technological barriers to digital innovation and transformation (see Best Practices for Reimagining Your Life Science Company as a Digital Business Technology Platform).
- Organizations are starting to deliver business outcomes by delivering PBCs. These are application building blocks that have been purchased or developed internally or with third parties.
- Many clients and vendors are adopting a platform strategy as the primary vehicle for digital business transformation.
- As this is a relatively new concept, it is still in the Innovation Trigger phase of the Hype Cycle.

Obstacles

- This is an architectural approach that ultimately needs to be enabled by the end user. However, many end users want “holistic solutions” provided by vendors, which do not exist yet.
- Vendors often posture as having a platform. However, they think more in terms of software, and not architectural approaches, which creates confusion. End users, working with vendors, will need to provide a means of rapidly producing composable digital products and services from different sources (not just their marketplace or product offerings).
- DLSP requires vision and alignment with the business and IT, and may involve functional leads to help drive requirements. Since this is a big departure from application-centric thinking, we expect delays in design and essential partner selections.
- As the approach reaches peak hype, clients will inevitably be underwhelmed by either the vendor’s capabilities or their aspirations not meeting reality.

User Recommendations

- Align digital and IT strategy with existing business strategy through the power of people from business and IT backgrounds in the form of digital fusion teams (see IT-Business “Fusion” Teams and How They Can Deliver Innovation).
- Evaluate vendor solutions on their compatibility with the composable architecture that is emerging. Take appropriate actions on vendor and key technology sourcing across the current and future enterprise application portfolio (see Healthcare and Life Science Business Driver: Medical Technology Innovation).
- Drive technology and data architecture decisions, and organizational models that redefine the relationship between the business and IT. Plan to modernize legacy applications toward the PBC model.
- Verify the attributes of “composability” when assessing new vendor capabilities or solution offerings, and when renewing contracts with incumbent vendors. Explore strategic relations with hyperscale solution providers and channel partners.

Sample Vendors

Amazon; Google; IBM; Microsoft; Oracle, Salesforce; SAP; Veeva Systems

Gartner Recommended Reading

Innovation Insight for Digital Life Science Platforms

Democratizing Digital Delivery in Healthcare and Life Sciences

Healthcare and Life Science Business Driver: Strategic Technology Change

Quick Answer: What Should Life Science CIOs Know About Data Fabrics?

Quick Answer: What Are Packaged Business Capabilities in Healthcare and Life Sciences?

At the Peak

Patient Data Tokenization

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Patient data tokenization is the process by which clinical trial subjects/patients consent to have their anonymized health information linked to a subject identifier or token. The token can also be linked to existing real-world data (RWD) sources like healthcare claims and laboratory results. This enables life science companies to link patients who have consented to their retrospective RWD, following their activities prospectively for ongoing insights about branded treatments on patient health.

Why This Is Important

Patient data tokenization (PDT) enables patient data to be connected between different data sources, enabling life science companies to formulate a holistic, longitudinal view of the patient journey. RWD made available via tokenization can provide significant insight about patient health history, enabling insights about outcomes after a trial, intervention or treatment has been administered by a life science company.

Business Impact

PDT is enabling new commercial insights, expanding available trial designs, and assisting in long-term follow-ups as well as late-phase observational research. PDT simplifies the execution of pragmatic study types and allows trial protocols to more readily include RWD as a form of evidence. Even though this data may not meet the gold standard of a randomized trial, it still carries significant value. As the availability of RWD increases, PDT of trial data will gradually become standard practice.

Drivers

- Data marketplaces have opened up new opportunities for trial teams to leverage RWD data and continuously follow patient lives after trial. This yields a more comprehensive view of patient outcomes, cancer stage and connected treatments.

- Tokenization approaches, derived from commercial areas and targeted advertising, offer new possibilities for anonymizing patients while still tracking data and events linked to these individuals.
- Tracking patients' lives on and off trials using RWD can inform the viability of current treatment indications, safety profile short- and long-term, and possible new treatment indications. It has the potential to answer regulatory questions and demonstrate outcomes without running a clinical trial.
- Electronic processes have allowed for more seamless and personalized consent management, giving patients the easy ability to "opt in," and support ongoing research initiatives.
- In countries such as the U.K. and the U.S., data markets have matured and developed to allow new infrastructure vendors and data aggregators to help manage data selling, tokenization, analytics as a service (AaaS) solutions, privacy and cybersecurity, providing the needed capabilities.
- Trials involving the treatment of chronic conditions, such as oncology, urgently need complete longitudinal datasets of patient lives. This can include both retrospective and prospective RWD, providing a complete picture to support research and provide real-world evidence (RWE) of treatment outcomes.
- Regulatory bodies, such as the U.S. Food and Drug Administration (FDA), have continued to advance RWE guidance, providing the necessary clarity to facilitate the use of RWD in drug submissions, including the use of RWE to support conclusions partially based on tokenized patient datasets.
- PDT is a new technology on the Hype Cycle this year, introduced high on the Innovation Trigger and close to the Peak of Inflated Expectations.

Obstacles

- RWD is often not universally accessible for all patients on trial, making it unreliable for consistent use by trial teams, thereby complicating tokenization efforts.
- RWD is not always globally available, due to privacy laws and country-specific regulations. This can make it cost-prohibitive or unavailable for third-party use on trials, limiting the range of RWD sources and potential insights.
- Tokenization vendors do not always have enough RWD about a patient to tie into a trial, due to low-match confidence, duplicate patients or other data-quality-related issues.

- Vendors utilize proprietary algorithms to generate tokens for their RWD datasets, restricting their clients' ability to cross-reference and analyze data across RWD sources.
- RWD is not always fit for purpose, as most is collected as metadata related to patient care, and not health data recorded by a physician, which limits the use of this data as tokenized RWE.

User Recommendations

- Explore available vendor options first, prior to developing internal capabilities for the use of tokenized patient data on clinical trials.
- Experiment with proofs of concept (POCs) on applicable trials to ensure viability, fit for business, and regulatory and quality approach, due to the newness of this technology.
- Partner with business areas to ensure all aspects are managed, from data and analytics (D&A) requirements, consent processes, trial recruitment impact, and observational research repercussions to ensure optimal outcomes.
- Ensure trial tokenization approaches are taken into account in the overall data analytics strategy, given the potential for impact on existing D&A architecture, storage requirements and interoperability needs.

Sample Vendors

Dassault Systèmes (Medidata); Datavant; HealthVerity; ICON; IntegriChain; IQVIA; Komodo Health; LexisNexis

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Factors Affecting U.S. Race and Ethnicity Data Quality in Healthcare and Life Sciences

Cell and Gene Therapy Platform

Analysis By: Reuben Harwood, Maria Nieradka, Michael Shanler

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Cell and gene therapy (CGT) platforms are systems designed to help collect, analyze and prepare biological samples as therapies for patients. The American Society of Gene & Cell Therapy defines gene therapy as the use of genetic material to manipulate a patient's cells for the treatment of an inherited or acquired disease. Cell therapy is defined as the infusion or transplantation of whole cells into a patient for the treatment of an inherited or acquired disease.

Why This Is Important

Spurred on by the successful approval of new CGT products, life science companies are investing heavily in new platforms that support R&D. While research organizations have put experimental cellular therapies into practice for decades, solutions managing the end-to-end process did not exist until recently. Most CGT is supported using heavily customized supply chain and logistics software. A handful of vendors have developed configurable solutions that simplify the support and delivery of CGT.

Business Impact

Currently, most CGT operations are fairly manual and have complex and inefficient process steps that threaten the quality of delivery. Business teams are searching for marketed solutions that can meet timing, logistics and quality requirements. CGT solutions can automate many of these steps from a process and delivery perspective. They can also facilitate clinical trials and logistics and patient/subject/physician and manufacturer communications.

Drivers

- CGT is becoming a more centralized strategy at many pharmaceutical companies, augmenting traditional drug portfolios. Personalized medicines, individualized therapeutics and more targeted approaches to therapies are trends that are driving new business models and creating this market.
- There are currently 28 FDA-approved cell and gene therapies. The number of regulatory approvals is likely to rise significantly in the near future as more than 1,500 clinical trials for CGTs are currently registered in ClinicalTrials.gov. These cover a wide range of disease categories, such as oncology, rare diseases, regenerative medicine and others.
- The approval of the first CRISPR gene-editing therapy (from Vertex and CRISPR Therapeutics) may occur in 2023. If commercially successful, it will bring added momentum to the field of gene editing.
- The demand for CGT clinical trials has accelerated, making CGT platforms that match the therapy area essential to streamlining trials and getting commercial products to the market.
- The data associated with CGT increasingly has broader uses across the business throughout the product life cycle, from R&D and commercial areas to specialized manufacturing and supply chain operations. Those requirements are becoming more acute for organizations supporting a “personalized medicine” approach, where markets consist of individuals. Once patient, manufacturing, operations and clinical data policies are updated, CGT systems will be even more scalable for supporting different kinds of CGT research and medicine programs.

Obstacles

- High inflation has slowed the development of cell and gene therapies, with reduced investment in R&D and higher production and transport costs.
- Life science companies and other research institutes can expect adoption challenges due to the complex nature of these therapies. Solutions must support several different types of models: allogeneic (the donor is different than the recipient), autologous (the donor and patient are the same) and variations of stem cell and T-cell therapies.
- In each of these cases, clients have unique needs and wildly different interventions and touchpoints they must orchestrate among R&D staff, healthcare professionals, lab technicians and supply chain personnel. This will cause complexity in vendor selection and system design, delaying adoption.
- Given its early stage of adoption, we position this technology in the Innovation Trigger phase with plateau achieved in five to 10 years.

User Recommendations

- Ascertain from leadership (such as the chief science officer) if CGT platforms will be necessary to support your business strategy. Focus on the touchpoints between CGT and major systems, such as ERP, manufacturing execution systems, electronic batch records, quality management systems and patient and healthcare-facing systems.
- Evaluate whether the newly established vendors can provide the capabilities you need versus building a custom solution.
- Work closely with product leaders to understand the commercial challenges (such as high price per therapeutics), including payer contracts that may affect architecture- and CGT-related information communication.
- Ensure extensive process, clinical and IT system validation is performed by the software provider's organizations and that those vendors properly support CGT processes. Work with quality teams to verify that governance and policies are in place to maintain vigilant compliance and that patient privacy is protected.

Sample Vendors

Autolomous; Be The Match BioTherapies; CellPort Software; Cytiva; FarmaTrust; Hypertrust Patient Data Care; IDBS; L7 Informatics; Tenthpin; TrakCel

Gartner Recommended Reading

How Technology Can Support the Next Phase of Commercial-Scale Cell and Gene Therapies

Life Science CIO's Strategy for Delivering Cell and Gene Therapy Capabilities

Prioritize Patients in Supply Chain Design for Cell and Gene Therapies

Generative AI in Life Sciences

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

Generative AI can generate new derived versions of content, strategies, designs and methods by learning from large repositories of original source content. Generative AI has profound business impacts, including on content discovery, creation, authenticity and regulations, automation of human work, and customer and employee experiences. In the life science industry, generative AI can be applied for a wide range of scientific, medical and commercial purposes.

Why This Is Important

Generative AI exploration is accelerating, thanks to the popularity of Stability AI (Stable Diffusion), Midjourney, ChatGPT and other applications leveraging large language models (LLMs). Today, life science organizations are aggressively experimenting with generative AI to help tune AI for images, videos, audio, molecular- and engineering-based formats. Use cases include identifying new drug targets, improving clinical site selection, monitoring drug reactions and accelerating marketing content development.

Business Impact

Most technology products and services will incorporate some form of generative AI capabilities in the next 12 months, in turn, leading to their democratization. Generative AI will progress rapidly, especially in the area of scientific discovery and technology commercialization. The technology will have broad impacts for the entire organization, including education and training for appropriate use; updates to security and governance; and skills investments.

Drivers

- ChatGPT is a very hyped technology and the number of technology proofs of concept have escalated.
- Life science industry's interest in generative AI is rapidly growing. Engagements with analysts are significantly up to explore capabilities and vendors. Enterprises are examining generative AI as employee-facing tools for assembling information and creating reports that aggregate information from financial, HR, learning management and project management functions.
- In life science commercial operations, the technology is being explored for publication summarization in medical affairs as well as generating market performance insights for sales and marketing business users.
- Generative AI is already speeding up the drug discovery process. This includes creating research article drafts, aggregating research intelligence, identifying novel targets and predicting novel drug-like chemical structures, and generating validation reports,
- Generative pretrained transformer (GPT) enables non-native English speakers to be included in collaborations across the scientific community.
- Clinical and regulatory leaders are exploring the technology to improve site selection, develop enrollment, recruitment and retention reports, aggregate clinical intelligence findings, and create clinical summaries.
- Manufacturing, quality and supply chain staff are using the technology for creating SOPs for recipe and formulation, developing procedures for laboratory workflows, and assembling regulatory information.
- Generative AI will disrupt "low code" and "no code" software programming. Combined with development automation techniques, it can automate 30% to 40% of programmers' work. This is highly attractive across the life science value chain, especially with informatics and analytics applications teams due to prevalence of "high code" technology and heavily customized legacy systems.
- We are introducing this technology at the peak, and expect it to reach a plateau in two to five years.

Obstacles

- A wide range of new regulations on generative AI are emerging globally. For instance, in 2023, a call to pause giant AI experiments (Future of Life Institute) for six months was signed by many AI and technology dignitaries.
- The risk of generative AI creating incorrect scientific assumptions or recommendations that put patients at risk is causing pause at many organizations.
- Corporate policy on use of generative AI, especially those leveraging public models and applications, is driving “fit for purpose” rubrics while updating and educating staff on intellectual property, trust and privacy issues.
- The black-box nature and a lack of experience with a full AI life cycle for proprietary systems might preclude the use of generative AI for critical use cases where there are high barriers to explainability or validation.
- The validation requirements, such as GxP can challenge use of the tool in operations and decision making, as regulatory guidance on AI validation remains unclear.
- Some vendors will use generative AI terminology for trying to sell subpar “generative AI” solutions.

User Recommendations

- Accelerate clear and effective internal communications by ensuring business, clinical and technology leaders have a common set of definitions for key terms in generative AI and a foundational understanding of how LLMs, such as GPT, work.
- Establish a technology leader as the enterprise subject matter expert on generative AI technology by allocating time for this individual to digest industry updates as they unfold, create guidance and communications for leadership, and oversee experimentation and learning across the broader organization.
- Identify initial use cases where you can improve your solutions with generative AI by relying on purchased capabilities or partnering with specialists. Consult vendor roadmaps to avoid developing similar solutions in-house.
- Ensure your vendor partnerships are positioning their products and services to maximize the value and manage the risk by making generative AI a regular point of discussion.

Sample Vendors

Amazon; Atomwise; Google; Huma.AI; insitro; Microsoft; OpenAI; Schrödinger; Stability AI; Tencent

Gartner Recommended Reading

Innovation Insight for Generative AI

Emerging Tech Roundup: ChatGPT Hype Fuels Urgency for Advancing Conversational AI and Generative AI

Emerging Tech: Generative AI Needs Focus on Accuracy and Veracity to Ensure Widespread B2B Adoption

Glossary of Terms for Generative AI and Large Language Models

Augmented Analytics

Analysis By: David Pidsley, Anirudh Ganeshan

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Augmented analytics uses AI to automate analytics workflows in platforms, contextualizing user interfaces with automated insights, generative storytelling explanations and collaborative exploration. Driven by ML and generative AI, it enables natural language queries and personalized analytics catalogs. It democratizes advanced analytics with augmented data ingestion, preparation, analytics content and DSML model development. It also curbs human biases and accelerates insights for diverse users.

Why This Is Important

Many activities associated with data, including preparation, pattern identification, transformation, model development and insight sharing, remain highly manual. This friction limits the user adoption and business impact of analytics. Enhancing these capabilities with generative AI democratizes analytics and reduces barriers to entry by allowing users to perform complex analytics tasks with low/no code.

Business Impact

Augmented analytics is transforming how users interact with analytics content. Features like conversational interfaces are making analytics more accessible, explainable and expedient. Generative AI is changing how people interact with augmented analytics, enabling access to deeper insights from data. Once confined to experts only, insights from advanced analytics are now in the hands of business analysts, decision makers and operational workers across the enterprise. These augmented consumers are driving new sources of business value.

Drivers

- Organizations increasingly want to analyze more complex datasets combining diverse data from both internal and external sources. With an increasing number of variables to explore in such harmonized data, it is practically impossible for users to explore every pattern combination. It is even more difficult for users to determine whether their findings are the most relevant, significant and actionable. Expanding the use of augmented analytics will reduce the time users spend on exploring data, while giving them more time to act on the most relevant insights.
- Generative AI has accelerated market interest in dynamic data stories and other combinations of augmented analytics features that automate insights. Generative AI combines augmented analytics with natural language query, natural language generation, and anomaly detection to dynamically generate data stories for users in their contexts. This type of multiexperience UI will reduce the use of predefined dashboards for monitoring and analysis, and increase the use of augmented analytics.
- Vendor technology innovation is pushing augmented analytics forward. With the explosion of generative AI, augmented analytics is receiving heightened attention. ABI platforms are now integrating large language models like GPT-4, allowing users to generate, debug and convert code, create data stories, and aid in data preparation. This integration has also enabled newer users to emerge, fueling analytics adoption. In a next wave of generative analytics experiences, users may see the entire workflow become AI-driven.
- Most organizations leverage multiple ABI platforms, causing exponential proliferation of analytics content. Coupled with a lack of governance, this proliferation often leads to inconsistencies in metrics and insights, duplication of reports and dashboards, and an overall decline of trust in data. Hence, analytics catalogs, powered by augmented analytics capabilities with generative AI, are becoming key in allowing users to find and recommend analytics content.
- By integrating with digital workplace applications (e.g., Microsoft Teams and Slack), augmented analytics features allow users to share and collaborate on insights.

Obstacles

- **Lack of trust in autogenerated models and insights:** Organizations must ensure that the augmented approach is transparent and auditable for accuracy and bias. They must establish a process to review and certify analyses created. These guardrails are especially important with generative AI being included within ABI platforms.
- **Training and rapidly evolving skills needs:** Obtaining desired skill sets and data literacy standards is a never-ending challenge, and leaders need broad and diverse training for multiple personas.
- **Ecosystem requirements:** It will be critical to build an ecosystem that includes not only tools, but also data assets, people and processes to support the use of augmented analytics.
- **Cultural barriers:** Analytics developers writing analytics-as-code and business analysts accustomed to visual self-service analytics may regard augmented analytics as a “nice to have” feature. However, they neither utilize nor rely on it in their analytics content production workflows.

User Recommendations

- Identify the personas and use cases that will benefit most from augmented analytics capabilities.
- Ensure that users can get value from new augmented analytics features by providing targeted and context-specific training. Invest in data literacy to ensure responsible adoption.
- Focus on explainability as a key feature to build trust in autogenerated models. Create learning opportunities for those who wish to know more about the theory and inner workings of augmented analytics solutions.
- Assess the augmented analytics capabilities and roadmaps of ABI platforms, data science platforms, data preparation platforms and startups as they mature. Look into the upfront setup and data preparation required, the range of data types and algorithms supported, the integration with existing tools, the explainability of the models, and the accuracy of the findings.
- Provide incentives for citizen data scientists to collaborate with, and be coached by, specialist data scientists who still need to validate models, findings and applications.

Sample Vendors

AnswerRocket; iGenius; Microsoft; Oracle; Pyramid Analytics; Qlik; Sisense; Tableau; Tellius; ThoughtSpot

Gartner Recommended Reading

Market Guide for Augmented Analytics

Magic Quadrant for Analytics and Business Intelligence Platforms

Critical Capabilities for Analytics and Business Intelligence Platforms

Is Your Business Intelligence Enabling Intelligent Business?

Top Trends in Data and Analytics, 2023

Digital Trials

Analysis By: Jeff Smith

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Digital trials are combined technologies enabling the digitalization of clinical trials, where data is an asset and paper processes are reduced. Digital trials include decentralized trial processes in which priority is given to trial participants, rather than clinical sites and trial sponsors. “Digital trial” supporting technologies include remote data capture via wearable devices, eSource, eConsent and mobile engagement apps with video, visit schedulers and medication management.

Why This Is Important

Digital trials will transform the trial process, leading to improved quality, reduced cost and reduced trial cycle time. Initial gains include improvement in patient experience, completion rate, medication adherence and trial participation. Many innovative life science companies and CROs are now experimenting with digital trial proofs of concept (POCs). A growing number of clinical leaders are maturing to the next level by scaling digital trials into their long-term technology roadmaps.

Business Impact

Digital trials will have a significant business impact on clinical trials by automating the complicated data logistics needed to conduct trials. We anticipate digital trials to move faster, with greater ease in finding and attracting subjects and optimizing existing data-cleaning processes. Digital trials will put harder-to-measure disease conditions within reach and make plain to researchers more subtle indicators of health with digital wearables, dramatically impacting well-being.

Drivers

- Patient-centric approaches are driving experiments in remote, home-based and siteless trials, with clinical teams eager to expand the scope of available trial subjects by catering to their needs. This is a factor in cases of subjects with limited mobility in oncology trials and is even more important when trial subjects are geographically dispersed in rare disease trials.
- The promise of remote patient monitoring exists where continuous data streams from devices can provide new biomarkers, adding a more continuous trial context into the subject's disease state and the outcomes of the therapy.
- Regulators are very involved in discussing new trial modalities with the industry, as evidenced by the U.S. Food and Drug Administration's (FDA's) Decentralized Clinical Trials (DCT) Draft Guidance, released in Spring 2023.
- Trials focused on precision medicine treatments with limited patient populations are notoriously difficult to recruit trial participants for inclusion using conventional means. Decentralized trial approaches are expected to have a positive impact, making participation easier, decreasing patient burden and consequently facilitating trial recruitment.
- Experimentation with digital trials continues to accelerate dramatically, pushing it past the Peak of Inflated Expectations very quickly. Many organizations are experimenting with digital and decentralized trial approaches this year, examining the benefits of decentralization while pursuing the advantages of new digital technologies such as eConsent, eSource, patient engagement apps and clinical wearables.

Obstacles

- Life science companies and their vendors have made many advances in electronic processes for trial optimization. However, these have not reduced the escalating costs of trials or cut their cycle time. Trial operations continue to be an area fraught with paper processes. Many of them are focused on the management of more antiquated site-based processes, which have barely changed for decades.
- Life science companies are often slow in their conversion to digital approaches. This is due to deeply ingrained expectations about trial process, overly complex procedures and quality practice and organizational risk aversion that slow process change.
- Digitalization and decentralization of trials require capital investment and a multiyear strategy, which will challenge adoption as trial leaders look for immediate ROI. The investigation will be needed by clinical operations experts to better understand where digital technology and decentralized approaches can really make a difference in outcomes on trials.

User Recommendations

- Connect the technology elements of wearables with eSource, providing a seamless flow of data from the patient to the clinical team. Services that enable remote testing must be in place. This includes home and/or virtual visits by research nurses, Internet of Medical Things (IoMT) hubs to secure data flow from the patient and data analytics that allow clinical teams to review the data for signals, building the evidence to support the trial endpoints.
- Build an incremental strategy toward the long-term goal of digital trials, and make investments based on specific trial needs that can help reach short-term objectives.
- Evaluate where investments may pay off, when to partner and when to go at it alone when developing these use cases. Eventually, this innovation will fundamentally transform how trials are executed and will provide new innovative therapies entering the market.

Sample Vendors

Castor; Curebase; Dassault Systèmes (Medidata); Datacubed Health; IQVIA; Medable; Medocity; ObvioHealth; Science 37; THREAD

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Industry Vision: Life Science CIOs Must Transform Clinical Development With Digital Trials

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Data Monetization in HCLS

Analysis By: Jeff Cribbs, Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Data monetization is a practice adopted by a healthcare and life science (HCLS) organization by which they make their proprietary data available to sell to external parties. The most mature examples are payers selling deidentified medical claims data to life science companies. This profile tracks monetization of new data types, utilizing new sharing mechanisms and vendors, targeted at new use cases, which are driving a new cycle of data monetization initiatives.

Why This Is Important

HCLS data and analytics (D&A) leaders have a mandate to derive more value from enterprise data assets and, in some cases, to identify opportunities for new revenue generation. The direct monetization of proprietary health data is one avenue that has received increased attention in recent years. This practice raises important ethical, strategic and technology considerations. D&A leaders are best positioned to act as SMEs for the organization, and ensure a cohesive and defensible strategy.

Business Impact

The direct business impact is quite straightforward. Large healthcare organizations, mainly providers and payers, can generate significant net new revenue. However, there are more complicated potential impacts, both positive and negative, in other areas, such as mission (i.e., contributing data for research and policy analysis), brand, security posture, vendor relationships and competitive positioning.

Drivers

- There is growing demand for new sources of revenue and funding, especially among health systems that have struggled financially during the pandemic. This is often accompanied by a fear of missing out on the revenue opportunity as competitors in the market participate in data monetization efforts.
- The absolutist stigma that has prevented many healthcare organizations from pursuing monetization initiatives have eased. This is a result of widely publicized data-selling practices across industries, demonstrable benefit of shared data to medical science and policy research, and the time data monetization practices have been a part of the healthcare market.
- Data marketplaces have matured, such as those hosted by data and analytics platforms (like Snowflake Marketplace) and industry cloud vendors (like AWS Data Exchange).
- Privacy-enhancing computing techniques, especially synthetic data and federated learning, allow for new use cases, and easier matching of data buyers and sellers by lowering the administrative overhead of accessing and profiling datasets.
- Emerging value propositions for data sharing more broadly, including publishing synthetic datasets for training of algorithms for digital health companies, public health monitoring, policy analysis and operational benchmarking.
- New ecosystem opportunities for data monetization are available, with tokenization vendors enabling enhanced value from connected health datasets, as well as more sophisticated analytics, providing improved visibility and insights from aggregated health data.

Obstacles

- Many global health systems effectively prohibit direct health data monetization, thereby reducing the total addressable market.
- Global regulation of data sharing, especially in the context of emerging technologies, are undeveloped areas of the law, creating uncertainty around the legal obligations of participants.
- Tightening the healthcare venture funding environment may lead to vendor consolidation.
- Concerns over negative press coverage raising alarm among consumers and regulators.
- Fear of losing visibility into the security of the data, the handling of the data by the broker and the payments made by data buyers.
- Lack of rational healthcare data pricing and lack of transparency of the public benefit make it difficult for healthcare organizations to assess the value in pursuing monetization initiatives.
- Limited technical and strategic resources to evaluate and design a data monetization initiative, which requires specialized data and technology competencies.

Analyst Notes: After a flurry of hype from 2020-2022, we position data monetization as just past peak in 2023. We expect some vendor consolidation and some lull in large new data selling partnerships, as early adopters await financial benefits of their upfront investments.

User Recommendations

- Assert yourself (or delegate a technology peer) as the subject matter expert (SME) for the organization on data monetization. Technology leadership is best positioned to understand the opportunities, costs and risks to the organization, while aligning interests and concerns across the organization.
- Organize a new data monetization initiative as a product line and ask for the technical and strategic resources you will need to make good recommendations to the organizations.
- Take a methodical and reasoned approach. Talk directly with vendors, especially if you know they are approaching senior leaders in your organization directly and creating an urgency to engage for “fear of missing out.”
- Adopt a partnering strategy for these initiatives, knowing that the developing health data ecosystem consists of many players working together (including, at times, competitors) for monetizing data to specific clients and use cases.

Sample Vendors

Dandelion Health; Datavant; Devron, HealthVerity; LexisNexis; Medicom; Segmed; Sitra; TripleBlind; Truveta

Gartner Recommended Reading

Quick Answer: Why Is There So Much Hype About Data Monetization in Healthcare?

Case Study: Data Ethics Decision-Making System (Highmark Health)

Quick Answer: How Do I Get Started With Data Monetization?

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

AI-Augmented Safety Vigilance

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Augmented safety vigilance entails the use of new technologies, such as artificial intelligence (AI) and robotic process automation (RPA) to augment and optimize solutions specialized in adverse event (AE) detection and processing. Life science companies and vendors use augmented safety vigilance to cope with the increase in AEs, as well as to optimize AE detection by leveraging new data sources, such as real-world data (RWD), augmented by advanced analytics.

Why This Is Important

Safety cases are increasing due to the rising complexity of products and therapies, such as biologics, cell and gene therapies, within increasingly crowded markets, and accompanied by trends like aging global populations. This increases pressure on life science organizations to develop and deploy solutions that can cope with these challenges. New technologies such as AI and hyperautomation are optimizing safety intake and processing, implemented within increasingly integrated safety platforms.

Business Impact

With the steady rise in safety cases, current processes will become difficult to sustain, with costs continuing to run beyond projections. Integrated safety platforms combined with AI models have the potential to transform safety vigilance solutions. These include the ability to identify AEs in large amounts of healthcare data, detect subtle patterns and signals of new drug interactions and streamline and automate data intake, triage, routing, processing and reporting.

Drivers

- The demand to enhance and optimize safety processes will drive the need to build integrated, cloud-based safety vigilance platforms and use these augmented capabilities to manage the complete end-to-end process.
- Regulators consider the standard industry approach of voluntary reporting of AEs by healthcare professionals to be insufficient. They are requesting life science companies turn to other data sources to ensure they are supplied with the most updated information on a product's benefits and risks. New approaches will be required to manage the increase of case volume from RWD.
- With the influx of AEs reporting due to RWD, AI tools are now required, available and able to further enhance and automate signal detection, AE medical coding, case triage, routing and form autocompletion.
- The introduction of therapies with companion applications is resulting in complex issues for safety teams, and the emergence of new sources of information, such as wearables and social media, is providing real-time data that may require additional safety obligations.
- Due to the rise in safety cases and rapid adoption of advanced capabilities in safety, including the use of AI, especially advanced semantics and large language models, AI-augmented safety vigilance is just beyond the Peak of Inflated Expectations for 2023.

Obstacles

- The priority given to safety vigilance by regulators is underscored by the number of inspections, warning letters and fines, and has a cooling effect on innovation in technology solutions supporting this highly regulated niche of R&D. As a result, the augmentation of safety vigilance solutions will proceed slowly.
- Some life science leaders are hesitant to adopt solutions using AI, questioning whether these technologies can be made GxP compliant.
- The complex nature of these solutions indicates that platforms may be slow to mature and business teams slow to adopt new approaches.
- Managing AI solutions requires resources with specialized expertise in data analytics, machine learning (ML), and natural language processing. Organizations struggle to find and retain skilled professionals with the necessary expertise, leading to slower adoption of AI tech.

User Recommendations

- Select SaaS cloud deployments of adverse event intake, triage and reporting solutions. Vendors have overcome many of the initial compliance concerns about cloud solutions in the safety vigilance space. Also, solutions using ML and rationalizing the lessons from multiple companies should prove to be vastly more efficient than isolated solutions.
- Accelerate the process to capture RWD from healthcare players, or if feasible, leverage vendor solutions that already have those partnerships and access to that data. Prioritize APIs and direct data connections from call centers over form-based data.
- Search for signal detection solutions that can detect patterns, offer visualization to enable nonstatistical contributors and enable safety analysts to interact with the data to look for patterns and problems. More data means more noise and the need for better tools to identify real safety events or challenges. Solutions should be flexible and adaptable to new sources of data, which are in constant flux.

Sample Vendors

ArisGlobal; Data Foundry; Ennov; IQVIA; Oracle; PVAI; RxLogix; TATA Consultancy Services (TCS); TriNetX (Advera Health Analytics); Veeva Systems

Gartner Recommended Reading

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Market Guide for Life Science Regulatory Information Management Solutions

Quick Answer: How Can Life Science CIOs Accelerate Remote Audit Adoption?

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Clinical Data Analytics Platforms

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Clinical data analytics platforms bring modern data and analytics approaches to clinical trial data processes, expanding on existing clinical data repository solutions and data science laboratories by integrating them under a modern logical data warehouse architecture. They expand the capabilities of existing solutions involved in intake, processing, and management of clinical and operational data from source systems and enable end-user analytics point solutions supporting trial operations.

Why This Is Important

The current lack of data and analytics technology and process maturity makes clinical data analytics platforms important. These solutions can harmonize the intake of data from the myriad of clinical trial sources and present data from separate systems as a single source. With the upward trend of more complex trial types, these solutions assist in eliminating data silos, supporting trial builds, normalizing metadata and enabling integrated insight generation during trial conduct.

Business Impact

Clinical data analytics platforms benefits include:

- Risk-based and centralized monitoring, enabling risk identification for study, site and subject
- Subject safety surveillance and impact on clinical endpoints
- Data workbench capability, including data cleansing and study data tabulation model (SDTM) mapping
- Clinical data library management and study setup optimization
- Data science features for statistical analysis and early looks at trial data

Drivers

- Modern, cloud-based data and analytics solutions are now available that have been prepackaged for clinical development, offering new data visibility and optimization options for IT leaders. These modern solutions combine the traditional relational data model approach with nonrelational data lakes into “lake houses” and include data governance and advanced visualization tools.
- Clinical data analytics platforms present an opportunity for clinical and IT leaders to supplement legacy data warehouses with data lake technology. This facilitates seamless and transparent links among operations, data management and biostatistics groups.
- Many clinical data analytics platforms integrate more advanced visualization technology, custom reports and dashboards — putting more control in the hands of the end user. Vendors also extend platform capabilities with novel technologies like AI and semantic knowledge graphing, enabling data insights and optimization that are still being explored by clinical teams.
- Successful implementation of clinical data analytics platforms blurs boundaries among departments, breaks up data silos, democratizes data analytics and accelerates clinical trial operations. These platforms streamline business processes and simplify workflows, as well as provide advanced analytics tools, reports and visualizations deployed on an integrated data model.
- As the life science industry pursues and deploys more strategic digital solutions, we place this profile as just beyond the Peak of Inflated Expectations and moving toward the Trough of Disillusionment.

Obstacles

- Although life science companies are digitalizing, many paper processes still remain, particularly within clinical operations. Moving beyond these legacy processes requires a vision and push from IT leaders to overcome the prevailing operations culture.
- Many companies have data warehouses for reporting purposes, and have not yet adopted the newer data analytics and data operations “lake house” solutions. IT leaders can be hesitant to replace legacy systems due to cost of replacement and integration with source systems. These factors lead to an undervaluing of investments in these platforms.
- Trial processes are often still managed by content-workflow-driven approaches. Moreover, data sources are not yet available to be leveraged by these new data and analytics platform solutions for insights.
- Many in core IT consider digital data flow solutions to be foundational to core IT and are hesitant to adopt vendor solutions that provide business-facing analytics in core capability areas.

User Recommendations

- Work with clinical leaders to select an approach — either build, buy or ally. You can: (1) Build out the existing technology stack to expand organization capabilities beyond an existing data warehouse, and layer in new visualization technology, APIs and data science capability; (2) You can acquire a vertical or horizontal vendor solution that includes the requisite logical data warehouse (LDW) elements that can be contextualized for data management and operations; or (3) License an existing SaaS vendor clinical data analytics platform that can provide these capabilities to supplement the existing IT architecture.
- Include in your IT strategy an awareness that clinical data analytics platforms will expand in capability, enabling new optimizations in clinical data management and trial operations. Investing in these tools will require similar investments in core IT skills. As more capability is given over to business teams, more data science familiarity, data quality and data literacy will also be required.

Sample Vendors

Algorics; eClinical Solutions; EDETEK; Entimo; IQVIA; PointCross; Remarque Systems; Saama; Sycamore Informatics; ThoughtSphere

Gartner Recommended Reading

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

eSource

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

eSource technology collects clinical trial data directly in electronic case report forms (eCRFs) or into a clinical database without first being recorded on paper. eSource systems include eConsent, electronic patient-reported outcome (ePRO), electronic clinical outcome assessment (eCOA), electronic health records, direct data capture (DDC) devices or clinical wearables.

Why This Is Important

eSource is the next technology step forward in realizing the goal of maintaining all trial data, both source and results datasets, in digital format, instead of maintaining paper records. This, in turn, paves the way for further efficiencies, allowing much of trial monitoring to be performed remotely, and allowing easier and faster access to trial results with fewer queries. The end result will be operational gains, faster decisions and responses on trial results and improved data quality.

Business Impact

eSource deployments and adoption into clinical trial systems continue to accelerate, boosted by other technologies like digital trials, eConsent, and the increasing use of mobile technology in trials. Capturing clinical data electronically directly from the source dispenses the need to review, update, maintain and archive paper records at a study site. It also can prevent transcription errors, unnecessary data queries and data cleaning inefficiencies that can plague EDC data collection approaches.

Drivers

- Adoption of eSource represents the full digitalization of clinical trials, which offers significant benefits in trial optimization, data quality, data depth, records management, communication and coordination of trial activities. Adoption of eSource begins at the record level and ends with all trial content represented in a digital system.
- eSource avoids the unnecessary duplication of data in different media. Not needing to transcribe data from paper documents into electronic data capture (EDC) systems changes the focus of site monitoring and moves it toward more value-added activities during site performance visits, which can be performed remotely. These benefits help drive the adoption of eSource solutions.
- The adoption of eSource solutions leads trial sponsors to broader considerations of trial data, collection approaches and technologies used, beyond the limitations of the eCRF format.
- Recent advances have made eSource tools even easier through the proliferation of bring-your-own-device (BYOD) apps that support direct patient data collection, improving both patient experience and patient centricity.
- Digital technology use in clinical trials continues to accelerate, and the eSource profile is now past peak hype and moving toward the Trough of Disillusionment.

Obstacles

- The clinical data quality benefits of eSource are often misunderstood or underestimated, and are not factored into IT leaders' ROI calculations. For example, the multiple data queries and the resulting back and forth between the site and sponsor are often a result of poor transcription or trial programming faults, which can be resolved by the use of eSource.
- The multitude of data collection devices and the myriad data formats, standards and metadata, with varying levels of data exchange and interoperability with the trial eCRF system is a challenge. Often the transfer of eSource data is a manual or semiautomated process that includes similar challenges to the management of paper source data.
- Operational challenges, such as site-level equipment provisioning and management logistics, as well as the culture and process change required, slow the transition away from paper processes and the adoption of the technology.

User Recommendations

- Accelerate POCs for solutions that capture trial data directly in sponsor systems, enabling eCRF data to be the data source of record. This extends beyond eCOA, ePRO and e-patient diaries to include the capture of the clinical data itself into a DDC device (smartphone or tablet device linked to the eCRF system) or into a medical health record collection system.
- Keep 21 CFR Part 11 and good clinical practice (GCP) validation principles in mind when considering eSource systems. Regulatory authorities will place greater scrutiny on these systems due to the absence of a site paper record, and clinical teams will need to rely on the system's availability, accessibility and data integrity.
- Elevate eSource solutions that ensure integration with existing technology architecture, data interfaces and communication protocols. Partner with quality and regulatory personnel to ensure that the appropriate procedures are in place to support the use of eSource data in a trial.

Sample Vendors

Aparito; Clinical ink; Clario; CliniOps; Dassault Systèmes (Medidata); EvidentIQ; IQVIA; Medrio; Signant Health; YPrime

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Market Guide for Life Science E-Clinical Platforms

Industry Vision: Life Science CIOs Must Transform Clinical Development With Digital Trials

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Quick Answer: 4 Factors for Build, Buy or Ally Decision Making in Life Science R&D

RWE Analytics

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Real-world evidence (RWE) studies derive insights from real-world data (RWD) to help interventional and noninterventional studies develop evidence that supports product safety or effectiveness claims. RWE conclusions are drawn from the aggregation and analysis of tokenized and deidentified data. This data is collected from RWD domains that include multiple data sources, predominantly consisting of insurance claims data, electronic health records, biobanks, and patient and disease registries.

Why This Is Important

RWE is expanding deeper into clinical development with increasing promise in new use cases, prompting vendors to create packaged analytics solutions for clinical research. RWE generation is particularly important with the rise of precision medicine and is increasingly beneficial in rare disease and oncology use cases. Regulatory acceptance of RWE both decreases development costs for new products, while opening up new areas of R&D.

Business Impact

RWE supports conclusions about therapeutic products, their treatment effectiveness and safety profile. LS companies can improve clinical study design for both postmarket and new studies by using RWE to refine study endpoints and patient subpopulations. It provides real-world perspectives on patients with comorbidities and can support health economics and outcomes claim to healthcare payers. Increasingly, RWE is being used to support market authorization from regulators.

Drivers

- The hype surrounding RWE continues to grow, with more vendors and solutions available to support both evidence and outcome measurement using RWE. With increased competition for market share and proliferation of me-too compounds, RWE is critical to demonstrate treatment valuation and earn fair reimbursement from payer organizations.
- FDA continues to refine recommendations around RWE, with at least 10 guidance documents released to support the industry in 2023, with some of these in draft state. This serves to accelerate RWE by signaling to companies that RWE can be used in regulatory approvals. Leveraging RWE conclusions can assist with preregulatory approval by supporting the economic case for a new product, or demonstrating status as an orphan drug.
- As precision medicine fills clinical development pipelines, RWE is used to refine study endpoints and patient subpopulations. Targeting drugs to specific patient populations allows for improved treatments and reduced side effects, which is critical to the case life science (LS) companies must make to regulators when demonstrating the need for a new treatment.
- Technologies that support the deidentification of patient data and tokenization of this data are driving the availability of RWE. The RWD ecosystem continues to evolve, with new vendors offering high-quality tokenization services and data brokers providing a marketplace for acquiring and licensing access to this RWD from healthcare providers and payers.
- RWE Analytics is currently just past the peak of hype this year, slowly moving down the slope into the Trough of Disillusionment. Although the RWD marketplace continues to evolve, LS companies still struggle with data quality challenges and a lack of data depth and breadth from available RWE providers.

Obstacles

- Expect progress to move slowly as LS companies must overcome many issues before RWE will have a bigger impact. These barriers include patient deidentification, the process of informed consent, the availability of quality longitudinal patient datasets and the maturation of RWE standards and practice for supporting regulatory approvals.
- Data quality remains a concern. RWE is based on RWD which often originates from electronic health records, where the data can be unstructured, of poor quality, and/or in inconsistent format. Robust data is essential to formulate a longitudinal view of the patient journey that can meaningfully assist researchers in comparing interventions and outcomes.
- Staffing issues remain a challenge, with data scientists experienced in analyzing RWD and building RWE conclusions in great demand. Business teams struggle with building an RWE competency, while IT leaders often find existing data and analytics capability insufficient to meet the demands of RWE leaders.

User Recommendations

- Partner with cross-organizational business teams to outline RWE strategy. Health economics and outcomes research (HEOR) has long relied on RWE to assist with demonstrating treatment outcomes to payer organizations. Observational research is relying more on RWE to support postlaunch conclusions.
- Explore licensed or purchased data sources for applicability to therapeutic area needs and ability to support RWE conclusions. The quality of EHR and claims datasets are key to generating findings of statistical relevance.
- Evaluate vendor solutions based on alignment with established use cases, and data vendors based on quality and scope of available datasets. Datasets available for licensing vary greatly in quality and depth.
- Make strategic investments in data brokers and analytics-as-a-service (AaaS) vendors that are building partnerships with provider organizations, biobanks and other prime data sources.

Sample Vendors

Aetion; Flatiron Health; Foundation Medicine; Health Catalyst; IQVIA; Optum; Prognos Health; Tempus; TriNetX

Gartner Recommended Reading

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Innovation Insight for the Healthcare Industry Data Fabric

Hype Cycle for Healthcare Data, Analytics and AI, 2022

Sliding into the Trough

Clinical Development Hyperautomation

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Clinical development hyperautomation uses off-the-shelf process design and automation tools such as robotic process automation (RPA), business process automation (BPA), process mining and intelligent document processing (IDP) to optimize processes in clinical development. These tools are often enabled by low- or no-code platforms, but may exist as independent solutions as well.

Why This Is Important

Automation technology in clinical development — including BPA, RPA, process mining, IDP and other hyperautomation tools — enables business and IT teams to optimize older technologies, inefficient processes and labor-intensive workflows. BPA and process mining can enable business teams, facilitated by IT, to develop process workflow and middleware solutions. RPA and IDP provide a means to automate low-value tasks, allowing teams to focus more on task planning and strategy.

Business Impact

Business teams benefit by being empowered to build their own solutions, with more control and flexibility during implementation. Hyperautomation tools have been used across many areas within clinical and regulatory operations. Such areas include clinical site documentation workflow and electronic trial master file (eTMF), data management for automating query workflow, adverse event intake, automated testing, clinical research organization (CRO) communications, and regulatory submissions.

Drivers

- Business teams have been empowered for several years now with BPA solutions, formerly known as iBPMS, with RPA along with enabling AI engines. More recently, these solutions have been combined with IDP tools for content intake and process mining tools for optimizing content and data flow, and made available on low-code/no-code platforms. These combined toolsets have opened enticing new hyperautomation options for both business and IT leaders, adding to the existing hype.
- As business operational excellence and optimization initiatives continue to draw investments within clinical development, hyperautomation technologies come into sharper focus with their potential to integrate with existing processes and automate information workflow. This is particularly true when they are used alongside hard-to-replace legacy solutions.
- Existing low-code application platforms (LCAPs) have added even more to the hype — for example, with vendors based on Salesforce competing with legacy vendors for market share in content workflow-heavy business solution areas.
- With hyperautomation and low- or no-code platforms maturing rapidly, this technology has moved quickly over the hype curve as IT leaders discover the benefits — and the resulting limitations — of these tools. Gartner expects hyperautomation tools to move rapidly along the hype curve, reaching maturity in two to five years.

Obstacles

- Most life science companies struggle with scaling the technology once proofs of concept (POCs) have concluded, encountering issues with poorly documented processes, organizational politics and IT governance.
- Scaling hyperautomation technologies successfully across heterogeneous, changing environments often proves a challenge for business teams. Support from IT teams can make the difference, coordinating with the business to define areas of low change that are ripe for automation and ensuring that time is spent wisely when assessing these opportunities.
- Many of these tools are new, and business teams lack subject matter expertise to execute projects independently. IT organizations that do not empower business teams run the risk of delaying benefit as they struggle to find areas that are a good fit for these technologies.

- Hyperautomation relies heavily on accurate and standardized data, but data quality can be a challenge in clinical development, where data sources are heterogeneous, fragmented and distributed.

User Recommendations

- Run POCs with hyperautomation tools that include simple process design and repetitive workflow tasks, and ensure that the tool works. These projects should start with the selection of a common platform, or combined toolset, and move into POC and implementation when project assessment determines a good fit.
- Apply process mining solutions to stack and sequence activities that can be automated by the RPA bot, with a preparation step added before and a quality check after.
- Evaluate integrated low-code/no-code platforms that include combined toolsets first, ensuring the selection of a foundational hyperautomation platform rather than multiple technologies that are poorly integrated.
- Work alongside business teams as a subject matter expert (SME) to ensure project execution and tool selection. Building a hyperautomation capability as an innovation team or center of excellence is a means of ensuring good use of resources and creating organizational hyperautomation expertise over time.

Sample Vendors

AODocs; Appian; Automation Anywhere; Blue Prism; Mendix; MSB Docs; Pegasystems; Salesforce; ServiceNow; UiPath

Gartner Recommended Reading

Creating the Composable Healthcare Organization for Healthcare and Life Science CIOs

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

eConsent

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Electronic informed consent (eConsent) allows trial sponsors to manage the consent process more effectively by providing digital means of consenting to a trial protocol. eConsent allows a trial participant or legal representative to consent to a trial protocol via electronic signature, digital signature, voice, video and other means — improving quality and efficiency of the consent process.

Why This Is Important

Informed consent processes can be complex, with a high cost of failure, if not managed well on a clinical trial. eConsent simplifies the consent management process, while also expanding the available modes for a patient's consent to be recorded, allowing voice, video, electronic and digital signature to indicate consent.

Business Impact

Initiatives such as eConsent hold promise as the vanguard of trial digitalization efforts, providing direct benefits for digitalizing the consent process. Sponsors benefit by having a digitally managed consent process, with reduced legal and quality risks, and expanded consent capabilities and modes. eConsent can enable decentralized trial approaches, eliminate paper processes and reduce quality and legal exposure.

Drivers

- Clinical and IT leaders continue to be informed by the U.S. Food and Drug Administration guidance, " Use of Electronic Informed Consent in Clinical Investigations — Questions and Answers" in which recommendations around electronic consent of trial subjects were outlined. This began the drive toward eConsent several years ago, and life science companies continue to look to regulators for guidance and approach.
- eConsent enables improved records management, compliance, quality and protection from legal challenges.
- eConsent technologies expand available modes of consent capture, as well as enabling improvements in training content, documents, video and supporting consent.
- eConsent supports digitalization initiatives, such as elimination of paper processes, decentralization and more virtual experiences.
- Previously, eConsent was considered as part of the eSource technology, and as a result is similar in position on the Hype Cycle to eConsent. eConsent is maturing more rapidly, however, we place it descending the slope to the Trough of Disillusionment.

Obstacles

- Sites are digitalizing at different rates, and some are very mature with a selection of electronic solutions, while others are still locked into paper-based processes.
- Implementing eConsent comes with upfront costs in setup time and software, as consent requirements and regulations can differ between different trials and geographic areas. Some countries, like the USA, accept electronic signatures for consent explicitly. Countries like Finland have no regulation specifying the type of signature permitted. Others, such as Switzerland, will only accept wet ink signatures.
- Trials can be as unique in their consent requirements as the conditions afflicting those involved. Some subjects may be unable to sign, requiring that consent be captured using other means, such as voice. In other situations, parents must consent for their children, or a patient consent through the help of a designee. Consent solutions must therefore be flexible and multimodal to meet all scenarios, adding complexity.

User Recommendations

- Spread awareness of the different signature types provided by eConsent solutions, ensuring organizational awareness when scaling eConsent across trials. This is required to ensure success of global deployments as no single approach is accepted by regulators across all countries and regions.
- Practice a multimodal approach toward eConsent, selecting vendors that can support these multiple modalities stretching from paper and e-forms, digital signatures, e-signatures, voice and video consent approaches.
- Manage expectations about upfront setup and configuration to ensure eConsent setup is built into the trial setup process, and that the organization is set up for success.

Sample Vendors

Clinical ink; CliniOps; Florence Healthcare; IQVIA; Kayentis; Medable; Medidata; Medrio; Signant Health; YPrime

Gartner Recommended Reading

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Creating the Composable Healthcare Organization for Healthcare and Life Science CIOs

Life Science CIOs: Map Your Pathway to Digital Trials

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

AI in Clinical Development

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Artificial intelligence (AI) in clinical development represents the use of the multiple AI disciplines to optimize aspects of trial activities. These include machine learning (ML), deep learning (DL), natural language processing (NLP), generative AI and AI-enabled advanced analytics. As AI use and expertise become more prevalent, Gartner expects AI to be ingrained in software development and part of a standard set of capabilities built into application development.

Why This Is Important

AI in clinical development combines ML, DL, NLP, generative AI and AI-enabled advanced analytics as core capabilities now being used in specific use cases in clinical development, such as medical imaging, safety signal detection and data management. Among other use cases, AI has the capacity for driving high performance from automated processes involving large data throughput, aiding insight discovery over large datasets and applying machine intelligence to user interactions.

Business Impact

These tools have many possible areas of application across clinical and regulatory operations, including AI medical imaging, medical coding, protocol feasibility and design, recruitment, retention, risk and quality signals monitoring, and safety signal detection. AI in these areas can reduce trial timelines and full-time equivalents (FTEs) and, most importantly, increase visibility into trial activities, improving risk assessment and overall trial quality.

Drivers

- Recent news about Open AI's ChatGPT has greatly increased the hype around AI, and specifically around generative AI capabilities, which offers many new use cases supporting business needs for text summarization, classification, generation, and query and response.
- The use of AI models and analytics tools accelerates the understanding of diseases along with identifying suitable trial subjects and clinical study investigators. In contrast, legacy processes involved in clinical development are lengthy and have low success rates.
- Clinical development involves many diverse datasets required to support clinical processes. AI, such as ML and DL, can enable better predictive clinical capabilities based on patterns in static data supplemented by ongoing learning from evolving datasets. This learning can validate assumed relationships between trial endpoints and protocols, or enable the discovery of potential risks to quality or the discovery of important clinical relationships.
- Clinical development involves intake of many data sources. AI such as NLP enables the structuring of large, unstructured clinical and biostatistic datasets, making sense and order from physicians' notes and consumers' conversations, enabling the automated discovery of previously hidden insights. Applying ML in operations automates, streamlines and enhances the quality of clinical business processes that were previously manual, time-intensive and prone to error.
- The advent of real-world data (RWD) sources has the potential to provide many new insights, accelerating trial startup, recruitment and protocol creation, or informing safety vigilance. AI has the capability to analyze RWD at scale and accelerate throughput and insights from the many use cases.

Obstacles

- While AI techniques are just becoming proven in the field, clients are finding that AI also requires sophisticated governance, processes, culture and data science teams to execute. Often, technology teams successfully conduct proofs of concept (POCs) that do not easily scale to provide broader organizational value.
- IT leaders wrestle with difficulties in building up core competence and quality, and business leaders only gradually have been able to answer questions and overcome challenges around good x practice (GxP) validation of AI processes.
- While AI carries enormous potential, finding the appropriate use cases that generate value is often problematic. IT teams who build an AI hammer in search of a use-case nail are not always successful in finding the right application of the technology. For this reason, we see AI in clinical development midway down the slope to the Trough of Disillusionment this year.

User Recommendations

- Start by aligning specific technologies and datasets to the business activity and the value created. Defining this alignment is key to successful selection, implementation and sustained investment value. This requires CIOs and IT leaders to evaluate potential applications of AI in specific disciplines, and make build or buy decisions.
- When making the decision to develop and scale AI capabilities, examine major elements such as resourcing, technical abilities, management focus and investment, maturity, and culture. Data science and engineering capabilities must run in parallel with AI technology acumen, so leverage hosted AI services and build capability through both internal and contract resources.
- Evaluate new vendors in part by their ability to incorporate more advanced AI approaches into existing solutions.

Sample Vendors

Aizon; BioGPT; Cortical.io; DataArt; EPAM; Huma.AI; Innoplexus; Mendel; Merative; SciBite

Gartner Recommended Reading

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Quick Answer: What Healthcare Provider CIOs Need to Know About LLM Applications Such as ChatGPT

Emerging Tech Roundup: ChatGPT Hype Fuels Urgency for Advancing Conversational AI and Generative AI

Wearable Devices for Clinical Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

Wearable devices for clinical trials transform trial data collection by using biometric and environmental monitoring wearables and sensors that trial sponsor's use to collect data directly from the patient. This includes health and wellness devices that monitor the subject's health across a continuous time series, collecting trial-grade clinical data while the patient is in a real-world environment, like at their home. It then transmits this data into a sponsor's electronic data capture system.

Why This Is Important

Wearable devices enable continuous monitoring that provides greater insight into a patient's health over time, rather than only during periodic visits to the clinic. Wearables can also enable patient-centric approaches that improve trial retention and completion and allow more accurate measurement of treatment outcomes. In the near future, use of wearable devices may more effectively demonstrate trial outcomes and endpoints, leading to new medicinal or digital products.

Business Impact

Wearable devices provide transformative benefits to trial leaders, allowing them to better engage patients, collect data leading to improved treatment outcomes and clinical data quality. Trial leaders can continuously monitor the subject's health to improve insights, inform sensitive outcomes measurements and respond to health issues. With continued improvements in usability, data connectivity and solution availability, the use of wearables in trials is becoming easier to manage and deploy.

Drivers

- Although investment has recently slowed due to inflationary pressures, there remains significant venture capital (VC) investment in digital device startups over the past several years. These startups have been driving hype by achieving notable successes, connecting wearables with data analytics and AI to create new 510(k)-approved digital biomarkers that would accelerate trial insight generation, potentially leading to new discoveries.
- Larger life science organizations increasingly recognize the value of novel insights from clinical wearables as driving new product value, and look to invest in connected health capabilities for use in product development areas.
- Increasing use of and experimentation with commercial-grade wearables partly drives the success of these devices in the clinical space. The proliferation of commercial devices has driven standardization and maturation of vendor capabilities that clinical leaders have leveraged with success on trials.
- Available research platforms, such as the Apple ResearchKit and the Android ResearchStack, have made the use of mobile-connected sensor data even more accessible for use on trials. Specialty vendors continue to build capabilities that integrate multiple clinical wearables with more-scalable data platforms, enabling data review and analysis.
- With the continued progress and increase in proofs of concept (POCs) with the use of wearables on trials, we see wearable devices for clinical trials moving further into the Trough of Disillusionment this year.

Obstacles

- The U.S. Food and Drug Administration's (FDA's) digital health software precertification program concluded in 2022, with the final report published. The program was not able to validate a working precertification approach under current regulations, and called for new regulation, which may slow digital health product innovation.
- The complex chain of data flow that must be validated for trial use remains a challenge for leaders. Each device contains its own specific attributes that must be tested and validated individually, along with large volumes of time-series data that must be captured and analyzed for insights.
- There remain many obstacles to scaling clinical wearables that could slow adoption, including cost barriers, provisioning challenges and lack of vendor plug-and-play services.
- Other challenges include GxP validation, data integration, battery life and patient adherence over long treatment durations.

User Recommendations

- Partner with trial operations, marketing, regulatory, security, privacy and legal teams to outline the solutions required to enable wearables and related technologies for handling and processing data.
- Elevate these device deployments as part of the overall digital strategy because new skills, resources, policies and controls will be necessary.
- Evaluate and build an organizational capacity for the management of clinical wearables on trials. Wearables deployed by study teams for electronic clinical outcome assessment purposes on an individual trial basis, without IT involvement, can often lead to one-off deployments that cannot be scaled more broadly.
- Develop technology or platform partnerships with device integration vendors that can provide expertise and experienced approaches. Focus on supporting an ecosystem, or a platform supporting multiple wearables and patient health metrics, allowing sustainable use of plug-and-play wearables for an expanding set of trials in multiple therapeutic areas.

Sample Vendors

ActiGraph; AliveCor; Biofourmis; Current Health; Koneksa; physIQ; Verisense Health; VitalConnect; Vivalink; Vivify Health

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Business Moment: Digitalized, Remote Clinical Trials for Pharma

Creating the Composable Healthcare Organization for Healthcare and Life Science CIOs

Emerging Tech: Venture Capital Growth Insights for Biosensor Technology

Blockchain in Life Sciences

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Blockchain platforms provide the foundation to create and run blockchain solutions and decentralized networks. This includes support for distributed ledgers, decentralized consensus, tokenization and smart contracts. They enable the creation of blockchain solutions that provide immutability, transparency, decentralized contract execution, and tokenization of physical or digital assets. In life science (LS), blockchain can facilitate the secure exchange of health and LS manufacturer information.

Why This Is Important

Primary applications of blockchain technologies in the LS industry include anti-counterfeiting (serialization), genomic and/or clinical data sharing, revenue management and materials transfer. It is a popular strategy topic with Gartner clients, especially as blockchain-based topics run rampant in the mainstream media and organizations attempt to transform operations. Although blockchain is still hyped across many industries, the LS industry continues to be slower than others to develop use cases into production.

Business Impact

The impacts of blockchain in LS are:

- Blockchain and distributed-ledger concepts hold the promise of transforming LS industry operating models. Transformations are just beginning with projects such as PharmaLedger, Zuellig Pharma Holdings and MSD, and are largely unproven at scale.
- LS organizations want to reach new customers, extend relationships with supply chain partners, improve quality and create more complete links between events.
- Executives want to move the boundaries of traditional LS businesses including enabling direct-to-consumer models.

Drivers

- The number of active blockchain projects within the LS industry grew from 2020 to 2023. For example, Merck & Co. and Novartis are running very public supply-chain POCs. Gartner clients report a rise in blockchain to support platform-centric ecosystems including projects such as PharmaLedger. See Supply Chain Executive Report: Realizing the True Potential of Ecosystem Partnerships.
- Industry consortia have been active as well with 12 pharmaceutical companies joining PharmaLedger, an EU blockchain consortium.
- Some clients are exploring concepts where blockchain would streamline clinical trials and extended regulatory filings, exchange genomic information, manage intellectual property generation, handle payments to drug distributors, and conduct health record and exchange transactions.
- Blockchains are supporting technology architectures and digital interoperability for transitioning toward more tailored medicines, patient-centricity and virtuous cycles of data centered in and around cradle-to-grave product life cycle management.

Obstacles

- LS industry stakeholders are learning that blockchain-based models are difficult to scale due to disagreements on the degree of centralization and channels.
- Most industry professionals have still not settled on the right type of governance to drive the necessary innovation, collaboration and cultural shifts.
- Digital maturity, legacy infrastructure and siloed work practices could limit value realization for blockchain discovery or readiness to deploy.
- Today, there are few vendors, IT consultant firms and sponsor organizations that have a deep LScapability and that understand blockchain models and underlying technologies.
- There are only a few successes with scaling blockchain pilots for track and trace, verification services and wholesalers, much of which is driven by regulations such as the Drug Supply Chain Security Act (DSCSA) via stakeholder-led models.
- Blockchain was extremely hyped a few years ago, but many clients now realize the limitations and challenges. For this reason, this technology is positioned on the trough.

User Recommendations

- Assess the impact of change across the LS sector. The terminology surrounding blockchain is also in flux. This uncertainty masks the potential ability to meet business use cases.
- Identify how the term “blockchain” is being applied, both internally and by providers, to better understand the return on capital employed, especially compared to (or augmented with) existing, proven technologies.
- Proactively learn the differences between the four implementation options as part of your organization’s strategic planning efforts, especially as they relate to specific business use cases and operational risk assessments.
- Assign resources to track the evolution of blockchain across industries, such as consensus mechanism development, sidechains and distributed ledger.
- Develop knowledge around vendor solutions’ evolution, especially through formal stakeholder-led models addressing critical requirements, compliance mandates and the success of resulting proofs of concept (POCs).

Sample Vendors

Bloqcube; Chronicled; EncrypGen; EY; Genecoin; Nebula Genomics; Schrocken; ServBlock; Tech Mahindra; Wipro

Gartner Recommended Reading

Guidance for Blockchain Solution Adoption

Power of the Profession Supply Chain Awards 2023: Global, Social and E2E Innovation Rise

The Future of the Supply Chain for Life Sciences — 2023 Report

Supply Chain Executive Report: Fostering a Digital Supply Chain Ecosystem

Gartner's Top Strategic Predictions for 2023 and Beyond — Seizing Uncertainty

Digital Validation Tools

Analysis By: Jeff Smith, Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Adolescent

Definition:

Digital validation tools deliver life sciences manufacturers tools, services, expertise and applications to assure that documents, software, operations infrastructure and processes remain optimized and comply with the requirements set out for specified purposes of their intended use. Tools and services may support specific regulations or requirements, such as the U.S. FDA's Title 21 Code of Federal Regulations (21 CFR) Part 11 and observed industry best practices (e.g., GxP, cGMP or GAMP).

Why This Is Important

Services and tools supporting GxP validation are on the rise. They enable global life science companies to ensure process methods, protocols, equipment and operations infrastructure and technologies continually comply with the requirements for their intended use. Gartner has observed renewed interest from manufacturers on how digital and virtual validation approaches will transform existing best practices as companies seek to transition to paperless and more automated operations in the cloud.

Business Impact

Validation is a globally adopted and expansive range of systematic principles to embed the delivery of continuous quality over the entire production process. This spans active pharmaceutical ingredients (APIs) through to finished goods manufacturing to postmanufacturing phases. Validation requirements can include an entire manufacturing site (or partner site), system audits or specific analytical methods, computer software and processing steps.

Drivers

- With more movement toward cloud and SaaS applications, validation tools and services are in higher demand. These help reinforce compliance across a very diverse set of process and workflow metrics, as well as robustly monitor on a frequent basis to check and ratify compliance and adherence.
- Key areas creating demand for these tools include: (a) wholesale adoption of equipment and software tools, such as laboratory information management systems; (b) cleaning and sterilization cycles pre- and postmanufacturing; (c) computer system validation, including paperless validation and automated testing for software and hardware; (d) vendor risk assessment and auditing; (e) process validation of packaging processes and equipment use; (f) mobile technology supporting manufacturing and logistics operations; (g) use of manufacturing systems for batch processing, such as manufacturing execution systems, serialization and quality management; (h) adoption of electronic and digital signatures for batch processing and release; (i) site validation for outsourcing partners, such as CMOs; (j) systems managing standard operating procedures and training materials for manufacturing associates; (k) regulatory validation and compliance.
- The increased adoption of cloud-based applications throughout the industry has enabled service providers to deliver enhanced ranges of digitized prevalidated documentation, templates and scripts.
- Use of broader service platforms that continually enable automated monitoring and continuous validation, without the need for resource-intensive customizations or retrospective upgrades.
- Compliant GxP cloud service variations include the hosting of validated applications, client infrastructure, the provisioning of managed compliance services and compliant cloud computing.
- The U.S. Food and Drug Administration's draft guidance of Computer Software Assurance is the latest in an industry push toward modernization of processes, this time focused on computer systems validation. This guidance provides clearer direction toward risk assessment of systems as part of a validation approach, further driving adoption of new technologies and methodologies.

Obstacles

- Increased product sophistication (such as a transition to biologics and personalized medicines) will require a more intensified and open approach to continuous monitoring and embedded levels of product excellence. Yet, companies remain overly reliant on legacy monitoring and 100% verification checks, slowing adoption of new continuous validation approaches.
- Historic validation processes have overrelied on paper-based systems of records (especially operating procedure, work instructions and process methods relating to manufacturing). Quality practices are highly ingrained and aligned to paper-based methodologies, with organizations slow to change.
- Despite regulators' new positioning on GxP Validation, deeply ingrained legacy approaches to validation slow adoption, with many companies slow to invest in an area where change may introduce additional risks to compliance. As a result, this technology is positioned in the trough.

User Recommendations

- Establish targeted teams assigned to specific validation assignments, ensuring a multidisciplinary level of representation from affected experts and stakeholders.
- Ensure services provider evaluation concentrates on supplementing internal resources around exceptions, critical path and process risk gaps.
- Assess vendors and integrators who can demonstrate expertise for delivering across life sciences phases of product development, processing and distribution.
- Determine solutions' readiness for robust "qualification" steps in areas including people, technology systems, physical machines and batch processing.
- Use providers that can offer a complement of services and tools for validation alongside cloud-based configurations for phased migration to standardized and digital validation scripts and templates.

Sample Vendors

GXP Manager; IKCON PHARMA; Kneat; Onshore Technologies; OpenText; Performance Lab; SL Controls; Sware; Tricentis; ValGenesis

Gartner Recommended Reading

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Innovation Insight for Bias Detection/Mitigation, Explainable AI and Interpretable AI

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Clinical Trial Data Transparency

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Clinical trial data transparency (CTDT) and clinical trial disclosure are the practices of exposing deidentified or anonymized clinical data back to researchers or patients upon request. The approach for anonymizing and masking sensitive commercial information can include the use of software and manual anonymization processes with internal or outsourced staff. Trial data is typically accessed and analyzed in secure cloud environments and cannot be downloaded.

Why This Is Important

CTDT is maturing quickly, with regulatory agencies continuing to develop new programs to encourage increased transparency of trial results. Although the European Medicines Agency (EMA) CTDT policy is several years old, the U.S. Food and Drug Administration (FDA) recently completed their CTDT pilot program and is deliberating new guidance. Companies continue to engage by crafting policies committing to greater CTDT, including registration and disclosure of trial results in external registries and peer-reviewed journal publications.

Business Impact

CTDT enables compliance with European laws and U.S. guidance, and affects brand image and reputation. A life science company receiving a poor “scorecard” or one that is perceived as a poor citizen, may face backlash from media, doctors, consumers and patients, especially when clinical side effects or safety issues are involved. With the release of the General Data Protection Regulation (GDPR) and the call for personal data protection, IT leaders must ensure proper patient data anonymization and that patient personal data is secure.

Drivers

- The launch of the Clinical Trials Information System (CTIS) by the EMA. It requires all information stored in the CTIS database to be publicly available except personal data, commercially confidential information, communication between EU member states and supervision of clinical trials by the EU member states.
- Multiple vendors have entered the market in recent years with tools and solutions for trial data redaction, anonymization, web portals and data storage and hosting, and trial registration with authorities, among other CTDT requirements.
- Many CTDT tools have been implemented within life sciences, and because transparency is now mandated, these types of projects have been prioritized. To meet research demand, some life science companies have developed their own request portals, and are making select study raw data available on request from researchers.
- New regulations and continued public pressure motivate life science companies to stay in line with the regulations and monitor public sentiment toward transparency.
- The development of SaaS vendor solutions that help manage compliance with CTDT regulations is driving CTDT quickly through the Trough of Disillusionment and toward the Slope of Enlightenment.

Obstacles

- Granting public access to clinical trial data means that consent will become even more important — and more complex. Even where data is aggressively deidentified, sponsors are worried about the potential leaks, legal challenges and reidentification of participants.
- Informed consent policies and procedures require updates. Managing the anonymization process requires new technology, skills and process knowledge. Patient data privacy concerns, questions around regulations, such as GDPR, and concerns about subject reidentification have dampened the CTDT hype.
- Technical challenges in the run-up to CTIS implementation, as well as rollout delays, have contributed to sponsor delays in the use of the system, and some fragmentation among European member states around required documents. Issues aside, the EMA has been steadfast in its commitment to implementation.

User Recommendations

- Address organizational requirements with regulatory leaders to disclose clinical data by making foolproof anonymization and governance, risk and compliance (GRC) activities core to any trial process and system.
- Keep the degree of transparency and scope of information central in determining the anonymization approach (i.e., software, outsourced professional services and internal manual processes). For example, a small Phase 1 study may be more amenable to leveraging internal resources, while a large Phase 3 study for a blockbuster candidate may require new software or support from service vendors.
- Develop a balanced strategy with business teams that meets disclosure, cybersecurity and anonymization requirements for clinical reports and patient data. Data privacy concerns on one side and ethical questions on the other should be balanced carefully to avoid exposure from disclosure of too much data to not enough data, ensuring processes and solutions are in line with guidance and regulations.

Sample Vendors

Anju Software; ArisGlobal; Certara; Citeline (TrialScope); Instem (d-wise); SAS; TrialAssure; Xogene

Gartner Recommended Reading

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Market Guide for Life Science Regulatory Information Management Solutions

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Genomics Medicine

Analysis By: Reuben Harwood

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Genomics medicine enables the use of genetic information for medical research and treatment (for example, diagnosis, therapy, risk management). It is a component of precision medicine and focuses on leveraging a patient's genomic data and clinical insights derived from it. Technologies include gene sequencing, variance calling, high-performance computing, AI-informed risk assessment and clinical decision support.

Why This Is Important

Genomics medicine is already saving lives, and its promise to improve health outcomes is driving adoption in healthcare. Upstream technologies supporting research and gene sequencing data collection are well-developed and yield increasing amounts of efficiency in genomics. Technologies that use genetic information in clinical care delivery are progressing toward delivering quick, reliable and actionable patient-specific insights.

Business Impact

Genomics medicine's business and population health impact is substantial and an essential component of precision medicine. The value of genomics medicine is demonstrated across multiple areas, including:

- Targeted therapies for cancer and rare diseases
- Accurate and patient-specific clinical diagnosis and treatment decisions
- Patient-genetics-based diagnostic tests to eliminate or reduce extra costs during treatment
- Precision care for prenatal and genetics-directed therapies

Drivers

- Next-generation sequencing (NGS) and third-generation sequencing (such as nanopore sequencing, single-molecule real-time [SMRT] sequencing) have enabled vendors to bring new capabilities at the end-user level, broadening the utilization of genetic information across multiple clinical specialties (such as chronic disease management) and beyond oncology.
- Achievement of key milestones has brought additional momentum to genomics medicine, such as the Broad Institute's launch of a $1,000 sample-to-report clinical whole-genome sequencing service and the new Guinness World Record awarded to a team at Stanford University in California, U.S. for the fastest DNA sequencing at five hours and two minutes.
- Technology and services related to genomics are progressing as the cost of genomic sequencing decreases. Research has identified more practical uses in diagnosing and treating patients, for example, companion diagnostics that indicate an individual's likely receptivity to a specific medicine by measuring a specific genetic biomarker. Other uses of genomics range from genetic testing for rare and undiagnosed diseases, next-generation therapeutics including gene therapy and RNA therapy, testing for treatment receptivity, to precision cancer treatment.
- Adoption will continue to grow as researchers identify more correlations between genetic biomarkers and health, disease prevention and treatments. The adoption of electronic health records (EHRs) globally creates rich sources of health data ripe for epigenomic exploration.
- EHR vendors have begun incorporating discrete genomic data into the patient record, enabling genomics medicine via point-of-care pharmacogenomic clinical decision support (CDS).
- Data analytics, including AI and machine learning, now have great potential to aid in discoveries leveraging that data. For these reasons, we move this innovation further along on the Hype Cycle with five to 10 years to the mainstream.

Obstacles

- Translating genomic data into actionable clinical insights has required decades of research. However, the maturation of AI and machine learning approaches will accelerate the pace of scientific discovery and translation into clinical action.
- It is equally challenging to make this knowledge actionable by physicians. Many are not well-trained to incorporate actionable insight from genomics within their workflows.
- Although new genetic markers are constantly being discovered, they require frequent reanalysis of patients' sequencing data. This comes with high costs that hinder the development of new tests, drugs and therapies.
- Researchers, life science and healthcare providers demand more genomics information integrated into the EHR, including raw sequencing data, analysis and clinical recommendations. Interoperability remains a barrier to information exchange among scientists, providers, patients and families for collaboration and counseling.

User Recommendations

- Establish a surveillance process to stay updated with the practical use of genomics in diagnosis and treatment and the implications for IT. Initiate discussions with peers as to whether it is worth pursuing an in-house genomics center of excellence or outsourcing this function.
- Outline business process, compliance, laboratory, regulatory and IT implications when including genomics medicine disciplines for decisions about research, therapies and business opportunities, while ensuring patient privacy.
- Architect an IT infrastructure, inclusive of outside services, that supports the acquisition, storage, collaboration and analytics requirements demanded by genomic datasets and therapy delivery.
- Evaluate your EHR vendor for their plans to support genomics medicine needs. Determine if the EHR can record, store, secure and access genetic marker data from patients, and their ancestors and family members at the point of care.

Sample Vendors

DNAnexus; Genedata; Helix; Igenbio; Illumina; L7 Informatics; NantHealth; Velsera

Gartner Recommended Reading

Healthcare and Life Science Business Driver: Medical Technology Innovation

Healthcare and Life Science CIO's Genomics Series: Part 1 — Understanding the Business Value of Omics Data

Healthcare and Life Science CIO's Genomics Series: Part 2 — Formulating an Omics Vision

Healthcare and Life Science CIO's Genomics Series: Part 3 — Prioritizing Omics Investments

Accelerated Patient Recruitment

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Accelerated patient recruitment solutions apply novel recruitment technologies, including AI, to real-world data (RWD) sources, like patient networks, to expedite the search for suitable trial candidates. Patient networks can include sponsored communities and advocacy groups through which participants are recruited for clinical trials. RWD sources can include trial, health claims, electronic health records (EHRs), labs data, social media listening, and available patient and disease registries.

Why This Is Important

With their increasing focus on rare disease and oncology trials, life science companies have started utilizing new approaches to identify patients for trial recruitment. RWD datasets augmented by AI and advanced analytics can accelerate locating potential trial subjects compared to traditional sources. Other approaches, such as leveraging online communities and patient networks, social media listening and digital marketing, have also accelerated recruitment and simplified this problem.

Business Impact

Clinical trials are often delayed due to poor enrollment. Some trials fail due to poor engagement, even after patients are enrolled. By leveraging new approaches to provide more efficient and targeted recruitment, researchers are able to improve trial outcomes and performance. Improving recruitment performance indicators by even just a few percentage points can translate into reduced trial timelines, which in turn translates into cost savings and cost avoidance.

Drivers

- Advocacy groups, medical forums, patient-powered research networks (PPRNs) and patient communities have added significant online presence, including capabilities for educating patients about available trials. Examples include PatientsLikeMe, the Michael J. Fox Foundation for Parkinson's Research and the National Patient-Centered Clinical Research Network (PCORnet).
- RWD is increasingly available (in the form of claims, point of sale and EHR data) in varying degrees of depth and breadth to support recruitment use cases. This data can be licensed directly by life science companies, or accessed via analytics as a service (AaaS) vendors that provide insights into patient cohorts, potential clinical sites or potential trial subjects.
- New solutions vendors offer capabilities such as using AI to curate large RWD datasets and predict where potential subjects are located.
- Long-standing recruitment service vendors continue to expand on existing recruiting methods to include the use of patient networks, RWD sources, AI technologies and multichannel marketing via social media, digital banner ads and print publications.

Obstacles

- Questions about patient data protection and regulations, such as the U.S. Health Insurance Portability and Accountability Act (HIPAA) and the EU General Data Protection Regulation (GDPR), continue to raise concerns about the use of customer data to target ads on social media, particularly within Europe.
- Challenges in localizing patients and cohorts due to restrictions from data protection laws, insufficient global data sources and lack of depth in available patient data significantly limit the utility of vendor solutions.
- Data quality and completeness of RWD remains an issue, as recruitment datasets often leverage medical claims and point-of-sale data, which may not provide the completeness needed to determine the viability of a trial candidate.
- Solutions continue to mature, but lack of in-depth RWD continues to challenge the search for trial participants. For this reason, these solutions continue into the Trough of Disillusionment this year and will reach maturity in two to five years.

User Recommendations

- Use novel recruitment vendor solutions for untapped resources and trial optimization opportunities. Vendors' approaches are diverse: curation of site networks, patient community partnerships and agreements with providers, payers and patient data exchange vendors to obtain RWD.
- Evaluate investments and partnerships, as recruitment networks are frequently measured by disease prevalence, geographic reach and number of patients. Engage with patient communities because they are more likely to be a potential source of participants with diseases that are rare or chronic.
- Deploy a combination of approaches in a layered fashion, since each applies to specific trial scenarios or to different stages along the intake funnel. When disease indicators are prevalent in claims data, adopt vendor solutions using RWD patient curation. For chronic conditions, a PPRN or patient community may be best. More advanced predictive analytics may apply when specific biomarkers are unclear.

Sample Vendors

Aspen Insights; AutoCruitment; Circuit Clinical; Deep 6 AI; Elligo Health Research; Inato; Inspirata; IPM.ai; Komodo Health; Trialbee

Gartner Recommended Reading

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Adaptive Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

An adaptive trial is a clinical trial that leverages treatment outcomes and trial indicators to evaluate and change aspects of trial conduct. Based on periodic evaluation of these indicators, trial variables (i.e., dosage, subject selection criteria and timelines) are adaptively modified according to predefined protocol parameters. The trial protocol is set before the trial begins, with the protocol specifying the adaptation schedule and processes.

Why This Is Important

As life science products shift toward precision medicine and treat more complex disease states, more flexible trial approaches are needed to demonstrate efficacy of new treatments. Adaptive trials include more variable scenarios, flexible timelines, varied dosing and nonlinear approaches. With the disruption of standard trial operations during the pandemic, adaptive trials have grown in importance and experiments during the pandemic have stimulated further adoption of adaptive trial designs.

Business Impact

With adaptive trials, organizations can save clinical trial costs, prevent failures and reduce timelines. Adjusting trial parameters within predetermined ranges in the middle of conducting them can allow adaptive trials to save lives and improve outcomes. Adaptive trials can be used to combine trials in some situations, avoiding the need to run multiple trials. Also, they can rescue promising drug candidates showing suboptimal efficacy with a specific patient cohort or use.

Drivers

- Standardized guidance published by the FDA entitled “Adaptive Designs for Clinical Trials of Drugs and Biologics,” which discusses principles for designing, conducting and reporting adaptive trial results, has facilitated the adoption of adaptive trial approaches. Since publication, FDA has continued to promote advanced trial designs under their complex innovative trial design meeting program.
- With major vendors such as Oracle, Medidata and Merative accepting adaptive trial approaches by having built-in capabilities on top of their platforms, use of adaptive trials will accelerate.
- With CROs and solution vendors experimenting with digital twin approaches to trials — and regulators signaling their openness to new approaches — we see adaptive trials continuing more rapidly down the slope this year.

Obstacles

- A few large life science companies have embraced the idea of adaptive trial design. However, most are slower to adopt as trial leaders implement the approach in select situations, when warranted by the disease state, patient populations and treatment requirements.
- Running adaptive trials requires better resolution with real-time data, new protocols to support the adaptive trial approach, sponsor and investigator training — all of which will prove difficult and slow down adoption.
- Due to continued obstacles from existing electronic data capture (EDC) tools, and resistance to change to more adaptive methodologies, we see this profile continuing down the slope into the Trough of Disillusionment.

User Recommendations

- Ensure that in an adaptive trials approach, EDC systems support multiple simultaneous treatment arms and that the business and technology partners have experience conducting these trials.
- Explore how well your current partners can support adaptive trials. If your organization is new to adaptive trials, leverage an experienced CRO for your first few attempts. Implementing process workarounds within clinical organizations and activities to ensure business needs are met can be more expensive than investing in toolsets with built-in modeling capability for adaptive trials.
- Discuss how adaptive trials will likely stress current e-clinical systems, and whether they can support the more complex trial design and multiple arms required, with clinical groups. Review the way e-clinical systems and the processes they support will need to be modified to support the adaptive trial approach. Decide with partners which add-on modules or capabilities you will need to implement to support adaptive trials.

Sample Vendors

Berry Consultants; Clario; Cytel; Dotmatics (Statsols); IQVIA; Medidata; Merative; Unlearn; Vial

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

Quick Answer: What Must Life Science CIOs Do to Jump-Start IDMP Compliance?

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

RWD-Based Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Real-world data (RWD)-based trials use RWD to optimize trial activities with applications that deliver improvements to patient recruitment and retention, protocol optimization, trial feasibility, and safety signal detection. As RWD becomes more available, life science companies and vendors are leveraging it to support effective protocol design, precision methods of finding subjects to successfully complete the trial, and improved data capture that leverages patient health records.

Why This Is Important

Improved accessibility of RWD data (such as electronic health records [EHRs], pharmacy and payer claims data) is enabling application vendors to optimize trial operations with RWD-analytics-driven solutions. Examples of high-value use cases include study feasibility, patient recruitment, safety surveillance and clinical research, where RWD analytics help to provide insights for improved planning, operations, safety profiling and research insights into existing treatments.

Business Impact

RWD has many broad-reaching use cases that are demonstrating value in many areas of clinical development. This includes use in trial feasibility and design, accelerating patient recruitment, supporting health economics and outcome research, aiding treatment outcome measurements, optimizing safety and complaint management, and underlying the continuous product improvement initiatives for medical device manufacturers.

Drivers

- Initial uses of RWD-based trial solutions demonstrate that they can increase recruitment rates and physician participation in clinical trials, and optimize trial operations. They can also increase retention and reduce overall screen failures. These benefits alone justify RWD investment. However, further uses for RWD continue to emerge, including improved protocol design, study feasibility assessment, synthetic control arms, publication review and patient monitoring.
- Analytics-as-a-service vendors continue to innovate and engineer new solutions that resolve obstacles, such as consent management, patient anonymization and General Data Protection Regulation (GDPR) compliance, finding new approaches to both comply with regulators and monetize enormous value from these data insights.
- Data owners are beginning to recognize the value of RWD, in particular healthcare claims, point of sale and EHRs, and have expressed more willingness to collaborate to create solutions, licensing opportunities or new services.
- Increasingly, deidentified and tokenized RWD is available from data brokers for trial leaders, who need retrospective RWD to inform trial endpoints. These are available as prospective data once the trial concludes, allowing a longitudinal look at the patient journey pretreatment, on-treatment and post-treatment follow-up.
- As RWD becomes increasingly available for recruitment and trial evidence purposes, we place RWD-based trials as moving slowly out of the trough and on path to mature within five to 10 years.

Obstacles

- Patient data used for research must be deidentified, and obtaining patient authorization and consent can be limiting factors in the use of RWD.
- Bringing together comprehensive, contemporaneous and high-quality datasets of RWD continues to challenge clinical trial leaders, as it requires the merging of multiple RWD domains from source data to achieve actionable insights.
- Along with the increase in active exploration of RWD on trials, many clients are frustrated by the lack of quality data and data sources, and various bias including selection bias, measurement bias, and confounding variables.
- Regulations such as the GDPR and concerns about patient data protection have had a dampening effect on RWD availability.
- Life science organizations often struggle finding the talent needed to support RWD initiatives, from the data scientists needed to create insights from the data, to the data engineers required to normalize the clinical data.

User Recommendations

- Explore how RWD can add value by collaborating with business peers and prioritizing use cases that improve the randomized clinical trial design.
- Evaluate how RWD could also be used to improve patient recruitment into trials, either by leveraging existing patient networks, or by using RWD to determine geographic locations of probable sites or subjects. For executives exploring how to improve patient engagement and medical adherence, explore how RWD can augment current trial designs.
- Seek out new uses of RWD to develop synthetic control arms on trials, reducing the number of patients recruited for placebo and optimizing trial costs. Although significant data challenges remain, overcome these obstacles by focusing on vendor solutions with proven results.
- Evaluate the RWD marketplace for vendors that can tokenize and license RWD pretrial, particularly for precision medicine therapies where participant selection and disease progression visibility are continual challenges for researchers.

Sample Vendors

Clarify Health Solutions; ConcertAI; Dassault Systèmes (Medidata); HealthVerity; IQVIA; Komodo Health; Oracle; Panalgo; Prognos Health; TriNetX

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Semantic Knowledge Graph Tools

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Semantic knowledge graph tools comprise software and technology that enable staff to search, mine and draw relationships on information. This includes exposing relationships in journal texts, chemical structures, biomolecular content, clinical and scientific relationships, genomics data, real-world data, disease pathways and other complex scientific research.

Why This Is Important

Knowledge graphs arrived in many different forms a decade ago and quickly reached peak hype. However, only over the past three years have the applications and infrastructures been injected with semantic search capabilities, cloud data processing and graphical relationship models necessary to handle scientific big data. They have also been instilled with massive cloud computing power needed to improve performance.

Business Impact

The use of these systems can:

- Help accelerate innovation activities, such as the discovery of new pathways, disease indications and therapeutic targets.

- Expose complex relationships and correlations to scientific stakeholders.
- Support collaboration and innovation strategies as they relate to drug discovery, translational medicine, competitive intelligence and clinical research.
- Interpret relationships among very complicated processes.

Drivers

- Life science organizations need better tools for mapping an array of available data sources (such as data warehouses, data marts, application silos, subscription databases or data from the public domain) to more efficiently derive insights. New scientific data is being exposed by systems on a continuous basis. It is impossible for individual humans to interpret and draw relationships on concepts without tools when the information is so complex and presented at such high volumes.
- Precursor systems were never designed for performance when handling large datasets, and they suffered from severe performance limitations due to a lack of computing power and poor orchestration. New SaaS tools have alleviated many of these early defects and enabled life science organizations to pilot these projects without significant risk.
- As companies continue to expand the use of generative AI and other natural language processing (NLP) techniques and share scientific knowledge sets, these systems have become easier to use and have higher performance, leading to increased client adoption. These enhancements drive adoption, which accelerates improvements. In the next two years, the infrastructure for handling big scientific datasets will evolve and enable a better ROI.

Obstacles

- Due to both scientific data challenges and R&D IT complexities (e.g., variable governance and lack of data standards within labs), the learning curve for using this software is steep, which is slowing the adoption rate. Few users within organizations will know the holistic R&D and IT requirements.
- Processes, cultures and skills gaps in data cataloging and enrichment have created challenges for larger enterprise adoption of semantic knowledge graphing. We expect these challenges to continue for two to three more years before the major issues are sorted out. For this reason, we position the technology on the hype curve sliding deeper into the Trough of Disillusionment.

User Recommendations

- Explore these systems with the goal of improving knowledge mapping and collaboration by developing insights from complicated scientific big data. The conversation about ROI will involve strategic R&D heads in addition to IT.
- Partner with scientific leads, data scientists and informaticians to develop internal best practices for their use since there is a high level of complexity associated with learning these systems. Cross-functional teams should address data quality, data standards and common ontologies.
- Work with department subject matter experts to understand which datasets need to be connected and which catalogs to update before building out new systems to connect internal and external data that is relevant to R&D.
- Educate end users on the different aspects of big data, because the volume, velocity and complexity will dictate which systems deserve investments.

Sample Vendors

Cambridge Semantics; Clarivate; Cytoscape; Elsevier (SciBite); IO Informatics; LabVantage-Biomax; LeapAnalysis; ONTOFORCE; Sinequa; Stardog Union

Gartner Recommended Reading

Graph Technology Applications and Use Cases

How to Build Knowledge Graphs That Enable AI-Driven Enterprise Applications

Quick Answer: 4 Factors for Build, Buy or Ally Decision Making in Life Science R&D

Quick Answer: How Is AI Being Used in Preclinical Drug Development?

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Compliant GxP Cloud Services

Analysis By: Michael Shanler, Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Compliant GxP cloud services include compliant hosting, managed services and platform, application, and quality support, including services for validation. The associated infrastructure, platform or software as a service (SaaS) systems need to comply with the U.S. Food and Drug Administration's (FDA's) 21 Code of Federal Regulations (CFR) Part 11 and International Organization for Standardization (ISO) requirements for medical device quality management systems.

Why This Is Important

As life science organizations adopt a "cloud-first" strategy, they'll need help qualifying infrastructure and managing compliant cloud applications and platforms. Compliant GxP cloud services enable life science business areas like research, labs, clinical, manufacturing and supply chains to more easily leverage the benefits of the cloud for hosting a variety of applications and data. This is while relegating the work of maintaining a multiapplication environment in a validated state to a service provider.

Business Impact

The business impacts of compliant GxP cloud services are:

- The self-service nature empowers business teams to accelerate business operations as it improves scalability, adds more expansive data capabilities and is a less restrictive use of resources.
- Adopting GxP cloud services provides for more efficient use of IT resources and enables a governance-centric operational model.
- Compliant GxP cloud services provide flexibility and economies of scale, as well as access to on-demand expertise and resources to maintain these environments.

Drivers

- Life science organizations are continually focusing on reducing costs, resource use and complexity, increasing the need for GxP support on cloud platforms. Service providers bring their expertise and managed service capabilities to support cloud platforms for smaller biotechs that lack these capabilities and the range of related expertise.
- Life science organizations prefer to partner with companies that are transparent, open to audits, and committed to compliance and security. Compliant cloud services provide assurance of expertise from a specialized service provider managing compliant clouds for many clients.
- IT and validation teams are actively choosing partners with expertise in previous deployments (like managing Health Insurance Portability and Accountability Act [HIPAA] compliance or protected health information [PHI] data), or integration across the life science industry in heavily regulated environments.
- IT teams are looking to build credibility with internal stakeholders in support of cloud-first digital strategies and agile methodologies for development.
- As vendors evolve services to manage GxP cloud environments more effectively, IT teams increasingly see the advantage of leveraging market platforms, rather than maintaining these in-house, sourcing risk and cost of compliance externally.

Obstacles

- Adoption of cloud resources for batch-oriented, computing-intensive workloads may be temporarily hindered by industry-specific requirements, such as GxP compliance for pharmaceutical development.
- Life science organizations continue to deal with unrealistic expectations with changing cost models and overall complexity and cultural hurdles, given the highly regulated nature of the industry.
- Before cloud computing for general workloads can achieve mainstream adoption, GxP quality and security policies must be revised and embraced by organizations that have traditionally been resistant to change from on-premises approaches. As a result, we see this profile beginning to progress up the slope.

User Recommendations

- Factor in the total cost of ownership for a system delivered via GxP cloud services versus internal approaches. Take into consideration the fully loaded costs required for ongoing upgrades and maintenance.
- Research vendors that can expand with your needs, extending into different functional domains (like quality, clinical, regulatory and manufacturing).
- Favor service providers with add-on compliance services, dashboards, and other quality and compliance real-time reporting capabilities.

Sample Vendors

Ambit Software; Arbour Group; ByteGrid; ClearDATA; Epista Life Science; Iperion (GxP Cloud); MUSA; NNIT; Odyssey VC; Validated Cloud

Gartner Recommended Reading

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Quick Answer: Meet Healthcare and Life Science Buyers' Regulatory Compliance Needs

Survey Analysis: Industry Cloud Platforms — A Life Science Perspective

Healthcare and Life Science Business Driver: Strategic Technology Change

Quick Answer: 4 Factors for Build, Buy or Ally Decision Making in Life Science R&D

Climbing the Slope

Risk-Based and Centralized Monitoring

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

Risk-based and centralized monitoring (RBM) applies a quality risk management approach to clinical trials and allows trial operations teams to monitor trials, investigator sites and patient data based on evaluated risk to patient safety and trial outcomes. By centralizing trial data and using RBM techniques, monitoring activities performed during on-site visits, such as source data verification (SDV), can be optimized. These activities are also known as risk-based quality management (RBQM).

Why This Is Important

RBM improves site monitoring over the legacy practice where quality checks are performed on 100% of the data during trials. RBM and RBQM assess study processes and protocols for risk at the trial, site and patient levels — determining quality verification activities. Sites are evaluated for risk and performance, with the amount of SDV and other low-value, on-site activities reduced for low-risk sites. This leads to cost and time savings with focused monitoring of high-risk areas.

Business Impact

Successful RBM can significantly optimize site monitoring processes, thereby reducing costs. Centralized monitoring can enhance trial visibility, with insights leveraged to improve the trial design or site selection. Well-executed RBM practices reduce the likelihood of errors created during clinical trials, improve the overall safety of trial subjects and give greater visibility into clinical trial operations, which can accelerate timelines and improve overall quality.

Drivers

- The ongoing mandate for clinical IT leaders to constantly improve the quality and efficiency of clinical research across all phases drives the basic need for risk-based and centralized monitoring. RBM helps enhance quality control and provides better data accuracy.
- Regulatory agencies continue to evolve RBM approaches, with the Food and Drug Administration releasing a draft guidance in March 2019, now final in April 2023, that included further clarifications and answers to common RBM-related questions. Over the years, there have been many guidance and approach documents released regarding RBM from regulatory agencies, and from industry consortia such as TransCelerate BioPharma, helping to drive implementation.
- ICH E6 Revision 2 (R2) continues to drive trial leaders to implement RBQM, with its expanded risk assessment approaches. With RBQM, monitoring activities also include patient data monitoring and identifying critical data related to the trial endpoints or patient safety.
- The ongoing push for life science organizations to digitalize processes often includes the implementation of RBM and centralized monitoring practices, which are increasingly seen as primary for developing data-driven trial operational approaches.
- Remote and virtual monitoring approaches were accelerated by the COVID-19 pandemic, driving many organizations to recalibrate initiatives and push RBM practices to the forefront, or improve existing practices to expand the use of remote monitoring approaches. Thus, risk-based and centralized monitoring continues to advance up the Slope of Enlightenment and is expected to reach the Plateau of Productivity within five years.

Obstacles

- Legacy clinical trial processes have an increased dependence on traditional approaches for data management and site monitoring, which is often a barrier to RBM adoption.
- Siloed applications and processes result in the inability of clinical IT leaders to see the bigger picture from a data, subject or operational control perspective. Paper-based and spreadsheet approaches to operations tracking make the task of centralizing data even more daunting.

- RBM implementation challenges are typically due to the complex large-scale and cross-departmental process changes that must be undertaken to effectively implement RBM technology and processes. These often include substantial changes in work culture mindset and legacy approaches.
- Although the value of reduced SDV and remote monitoring visits is clear, many organizations are challenged to adopt reduced and targeted monitoring and lean toward 100% on-site visits.

User Recommendations

- Evaluate RBM tools that focus on identifying and mitigating risks, optimizing trial operations and study, site and data quality. RBM tools can displace some of the labor required to perform on-site data verifications and give greater visibility into risks with site performance and critical study data.
- Start with RBM tools your e-clinical platform vendor provides, as they may have capabilities that smooth risk identification and SDV management. Using a platform strategy for managing clinical trials can centralize and simplify data sources used in RBM processes.
- Evaluate analytics-based "bolt-on" RBM tools that can provide analytics across multiple data sources when using clinical research organizations (CROs) or multiple e-clinical point solutions for trial operations.
- Because newer trial analytics tools can often provide benefits beyond the original RBM focus of on-site risk and performance, allow deeper analysis of trial critical data and patient safety risk.

Sample Vendors

CluePoints; Cyntegrity; Dassault Systèmes (Medidata); eClinical Solutions; MaxisIT; PerkinElmer; Remarque Systems; Saama Technologies; ThoughtSphere; Triumph Research Intelligence (TRI)

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs: Adopt Latest Data and Analytics Platforms to Manage Clinical Data Challenges

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

SaaS-Regulated CSP

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

SaaS-regulated content services platforms (CSPs) are life-science-specific, cloud-based systems for managing documents and unstructured data in compliant, regulated environments. Previously known as electronic document management systems, CSPs support areas such as clinical, quality, pharmacovigilance, manufacturing, regulatory and marketing. Features include collaborative authoring, metadata management, search, regulatory tracking and publishing.

Why This Is Important

SaaS-regulated CSPs have been gaining traction among CIOs in the life science industry, largely due to their increased robustness, security and cost advantages over traditional on-premises systems. Although this transition has been uneven across various life science domains, SaaS-regulated CSPs are rapidly maturing and now offer some of the most mature cloud offerings.

Business Impact

Adopting SaaS-regulated CSPs can simplify deployments and reduce support resources, especially when content services platform as a service (CSPaaS) capabilities are used. Furthermore, SaaS-regulated CSPs enable and facilitate both global deployment and centralized control and governance, providing a cloud-native CSP, including built-in content workflow, automation, governance and content processing tools. This, in turn, provides more content flexibility and control to supported business areas.

Drivers

- At many larger companies, older systems are now at the end of their service lives and are unsustainable. As a result, there is new interest by life science companies in exploring simpler cloud-based solutions, rather than upgrading older on-premises IT systems with significant maintenance burdens.
- Life science companies are increasingly shifting from legacy CSPs to cloud-native CSPs, particularly in clinical development and regulatory, as well as quality areas. These are taking advantage of more powerful CSPaaS capabilities and robust global implementations supported by multitenant cloud deployments.
- Companies have started moving away from single-tenant-hosted cloud CSP due to more acceptance of multitenancy.
- The regulatory environment for life sciences is becoming increasingly complex, with multiple agencies and regulations governing different aspects of drug and device development and approval. SaaS-regulated CSP can help life science companies manage this complexity by providing a centralized platform for storing, managing, and sharing regulatory content.
- With continuous change in the regulatory environment, SaaS-regulated CSPs can be scaled up or down as needed, depending on the size and complexity of a life science organization's regulatory requirements. They can also be customized to meet the specific needs of different stakeholders, including regulatory agencies, internal teams and external partners.
- As many of the initial obstacles to acceptance of SaaS-regulated CSPs have evaporated and GxP validated cloud technology matures, this profile proceeds quickly past the trough and starts up the slope with two to five years' time to plateau.

Obstacles

- Some larger life science companies are challenged in adopting SaaS-based solutions in niche areas, due to overly complex processes that have resulted in legacy customizations on overengineered, monolithic systems.
- Many clients report the movement from on-premises CSP to cloud as challenging, especially when dynamic and historical data and documents are stored within the same system. Upgrading a CSP from a legacy system with lots of historical data to a new system often turns into two projects — a migration project and a software upgrade. In most cases, these are intensive projects with considerable professional services expenses.
- Many vendors use the terms “cloud” and “SaaS” interchangeably and are less clear about tenancy in the cloud. This adds confusion and slows adoption of more advanced CSP approaches.

User Recommendations

- “Think digital” and emphasize the need for search, analytics and dashboarding capabilities that will be more self-service-oriented. When going to a SaaS model, consider that adopting SaaS may also require different service and support models.
- Evaluate the differences between cloud-hosted and single-tenant versus multitenant SaaS architecture during vendor assessment. Be aware of vendors’ hype and creative license around these terms, and ensure they support the correct type of cloud for business needs.
- Work with quality assurance and regulatory teams early in the process, to bring them along into cloud deployments from internally hosted architectures. Set expectations about SaaS license costs and ensure that cost projections reflect application growth under new licensing models.
- Review solutions that address all overlapping components of development — including clinical trials, quality and regulatory, and contract management — when considering pure CSP deployments.

Sample Vendors

Aurea; Box; DXC Technology; Egnyte; Generis Group; IQVIA; M-Files; OpenText; TransPerfect; Veeva Systems

Gartner Recommended Reading

Electronic Trial Master File Strategy Alignment

Market Guide for Life Science E-Clinical Platforms

Life Science Manufacturer CIO Top Actions for 2023

2023 CIO and Technology Executive Agenda: A Life Science Perspective

Market Guide for Content Services Platforms

Precompetitive Alliances

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Precompetitive alliances are nonprofit industry groups that work to solve common technical problems that affect participating members. They can develop shared technology platforms and/or processes, scientific, informatics and data standards. Participating members are expected to pool resources to achieve a common goal.

Why This Is Important

Precompetitive alliance participation is now part of the general life science industry vision for accelerating R&D, and there is a much higher degree of openness within the scientific community to conquer shared IT and data challenges. Along with industry consortia, they play a critical role in accelerating scientific and technology initiatives, developing common standards, and laying the groundwork for future innovative products and approaches.

Business Impact

The business impacts of precompetitive alliances are broad:

- Engaging in precompetitive discussions will yield positive implications for collaboratively solving IT challenges, networking and knowledge building.

- Successful engagements with precompetitive alliances will reduce IT complexity, integration challenges and the overall burden on internal staff for validation efforts for “shared industry” problems.

Drivers

- The Pistoia Alliance, which originally focused on solving data aggregation, sharing and analytics for pharma research, has nearly 200 contributing organizations including technology and scientific startups, not-for-profit, government, academic and small, medium and large pharmaceutical companies.
- The R&D IT community is looking to solve common technical issues and is increasing participation with other organizations including the Allotrope Foundation, BioCelerate, Digital Therapeutics Alliance, and the Pharmaceutical R&D Information Systems Management Executive (PRISME) Forum.
- Many other foundations, organizations and institutes allow for community involvement with a focus on standards development, transparency, collaborative projects and scientific and medical knowledge sharing. Examples include: The U.S. National Institutes of Health (NIH), Accelerating Medicines Partnership (AMP), Biomarkers Consortium, European Molecular Biology Laboratory-European Bioinformatics Institute (EMBL-EBI), Innovative Medicines Initiative (IMI), The IMI’s European Lead Factory, i2b2 tranSMART Foundation, Open Targets (formerly the Center for Therapeutic Target Validation), Clinical Trials Transformation Initiative (CTTI), Transcelerate Biopharma, Clinical Data Interchange Standards Consortium (CDISC), and Accumulus Synergy.
- Technology vendors are also investing, e.g., Accenture with mostly Oracle customers created a consortium to drive common technologies onto its own platform INTIENT. Veeva Systems launched Align Biopharma to develop technology standards with HCPs and has since integrated components into their product offering. Finally, laboratory informatics providers such as Thermo Fisher Scientific and PerkinElmer Informatics created a cloud-based platform for collaborative academic research.
- Most large and midsize companies are now involved and yielding benefits with precompetitive alliances, and thus this is positioned on the Slope of Enlightenment.

Obstacles

- Challenges with culture, shared investment and active participation still plague precompetitive alliances. Sometimes individual contributors at organizations participate, such as scientists, so they can solve issues related to their projects, but do so without sanctioned involvement by leaders at the enterprise level.
- Because many organizations have a variety of issues, engaging in open forums and discussions can quickly become a distraction.
- With the growth in participation, we anticipate that most organizations doing life science R&D will participate, but not all of them will see benefits from these activities within the next five years.
- Many clients report a high level of frustration in dealing with the shared objectives and project prioritization of these alliances, and are unsure about what is the right level of participation and investment.

User Recommendations

- Encourage R&D stakeholders to explore industry community activities for programs that have common elements at competitor companies. When engaging precompetitive alliances, evaluate the business benefit (such as reducing IT complexity, developing interoperability standards, determining shared clinical site quality standards and so on) versus the likelihood of solving an issue on your own.
- Determine which alliances and at what level of participation your enterprise will support. Standards don't always add equal benefits to all industry participants. Only invest time and effort into alliances if it will lead to long-term innovation, improvements to quality, improvements to efficiency or improved profitability.
- Invest in industry consortia if the key partners provide a long-term strategic advantage and if the working group has a strong chance of success. Many industry consortia have only short-term impacts and little value beyond a handful of modest initiatives.

Sample Vendors

Allotrope Foundation; CDISC; Digital Therapeutics Alliance; Pistoia Alliance; TransCelerate BioPharma; Veeva Systems (Align Biopharma)

Gartner Recommended Reading

Life Science CIOs Need to Improve Their Organization's Digital Partnerability

Build Industry Ecosystem Culture, Connections and Capability to Solve Issues Beyond Your Enterprise

3 Steps for Effective Supplier Engagement in Sustainability

Quick Answer: How Do You Know That You're Building a Truly Digital Life Science Lab of the Future?

Scientific Literature Text Analytics

Analysis By: Reuben Harwood, Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Scientific literature text analytics extracts data from unstructured internal and external text sources that contain scientific information. These applications and services aggregate information and competitive intelligence for use in R&D programs. Text and data are mined and used for content search, summarization, sentiment analysis, and investigation and classification of data types.

Why This Is Important

- Scientific information and the number of journal articles have exploded, representing a wealth of information for mining and graphing. This is a difficult, manual exercise without computer systems.
- Recent attention and advances in natural language processing (NLP) and generative AI (including large language models [LLMs]) have given rise to a myriad of tools for searching, analyzing, summarizing and generating scientific content.

Business Impact

Scientific literature text analytics can have the following business impacts:

- Combining extracted, unstructured data with traditional, structured data to provide a more complete view of the issue or topic.

- Use of sorted data downstream with traditional data mining or business intelligence and intellectual property (IP) tools.
- Knowledge graph, NLP and other tools can simplify insight discovery and classification approaches, enabling rapid analysis of new research and cross-indexing with research topics.

Drivers

- R&D programs engaged in product development seek more ways to leverage insights from scientific text analytics and annotators. This approach creates new opportunities, as scientific journals are published, competitive products are launched and ideas are filed at patent offices.
- The price point for such software and supporting services is moderating, and software is consolidating into larger products via company mergers and acquisitions. This environment makes the technology more attractive to small and midsize engineering companies, academic institutions, contract research organizations, biotechnology companies and medical device manufacturers.
- The recent explosion in tools leveraging NLP and generative AI, such as those built on OpenAI's ChatGPT, continues to increase the availability of specialized text analysis tools across life sciences R&D disciplines. Advancements in context enrichment, search and translation capabilities are expanding the global footprints of these systems, especially for drug discovery, clinical development and competitive intelligence.
- New cloud-based systems have removed some of the heavily customized legacy systems and allow for more agile end-user configuration.
- Based on our assessment of adoption trends and the diverse use cases being driven by life sciences organizations, we position this technology just entering the Plateau of Productivity.

Obstacles

- Many services offer similar outputs for text analytics, and increasingly NLP and text analytics are being included in content platforms. CIOs have to make decisions about where this capability becomes “core.” Options include search engines, content curators, content platforms or text analytics platforms.
- NLP-based mining often produces too much information. Vendors are combining NLP with ML to filter noise/false positives, which is a complex process requiring domain discipline that many organizations lack.
- Some organizations desire a centralized platform, whereas others want the capability built into specific applications, such as discovery, development or regulatory applications. This tension is delaying some decision making on how much development should be done in the individual domains.
- Vendors often offer competing and overlapping capability, but the technology and delivery mechanisms are not clearly communicated, clouding the vision.

User Recommendations

- Design a text analytics strategy with direct support to R&D and patent mining, and select spaces such as mechanism of action and pathway analysis for competitive advantages.
- Work with R&D groups to develop subject matter experts in text analytics to directly support R&D product development, IP submission teams and technical marketing groups.
- Examine the life cycle stage and costs of your difficult-to-support, customized legacy system.
- Evaluate new vendor packages that reduce the complexity of supporting R&D innovation. Uncover overhyped AI-enabled vendor offerings by understanding how AI affects analysis quality, efficiency and scalability.
- Prioritize cloud-based systems that will support mission-critical R&D innovation and competitive intelligence activities over technology-based systems that do not have workflows and plug-ins (e.g., bioinformatics, sequencing, chemical reaction symbology) designed for scientific literature mining.

Sample Vendors

Cambridge Semantics; Clarivate; DeepDyve; IQVIA; LabVantage; Lexalytics; Ontotext; ONTOFORCE; PharmGKB; SciBite

Gartner Recommended Reading

Market Guide for Intelligent Document Processing Solutions

Quick Answer: How Is AI Being Used in Preclinical Drug Development?

Infographic: Artificial Intelligence Use-Case Prism for Life Science Manufacturers

2023 Planning Guide for Analytics and Artificial Intelligence

Clinical Trial Resource Management

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Clinical trial resource management systems are the technology capabilities used to manage the resources of a clinical trial, such as investigative sites, contract research organizations (CROs), clinical study staff, supplies, relationships and patients. Included are the capabilities to plan, manage and execute clinical study activities using tools that manage resource utilization and effectiveness, provide operational analytics, track study milestones and facilitate issue management.

Why This Is Important

Life science companies are investing in resource management tools to improve operational excellence in trial operations by adopting capabilities that provide a more holistic view of trial processes. Companies continue to integrate multiple solutions, including clinical site payments, sample and logistics management, interactive response technology (IRT) and clinical trial management systems (CTMS), to properly manage trial operations.

Business Impact

Clinical studies have high stakes that require substantial resources to plan and execute. They need lockstep coordination of multiple groups from trial operations to monitoring, data management, biostatistics and clinical and IT resources to reach a positive conclusion. Sophisticated clinical trial resource management is essential to ensuring the efficient use of resources, management of relationships and closure of financial compensation to participating CROs, investigative sites and patients.

Drivers

- The evolution of capabilities from the use of ad hoc spreadsheets and common business intelligence (BI) tools for reporting to the use of robust, more specialized applications that manage the complex elements of a clinical trial drives adoption of CTMS.
- Resource management tools that help with clinical supply management, such as interactive response technology and randomization and trial supply management (RTSM), are of high interest among life science companies because they can help with reducing product waste. This is even more important as treatments such as biologics get more expensive to produce. These tools are more frequently integrated with depot-level trial supply logistics tools and provide insight into patient enrollment pace and location, replenishment needs, simulation and optimization.
- Linking planning and execution activities for clinical and operational support areas enables a higher degree of performance from clinical resources, which can drive faster trials at lower costs.
- Integration of multiple clinical operations systems — notably electronic trial master file (eTMF), site payments and RTSM — into connected platforms is helping to drive innovation, promoting multiexperience UX and integrated analytics.
- Recently, there has been increasing interest in CTMS as risk-based monitoring approaches have mainstreamed and are driving a more data-centric approach to operations. This has led to new vendor offerings and continues to drive this technology up toward the plateau.

Obstacles

- CTMS have yet to consolidate into more unified forecasting, planning and management platforms, which inhibits their optimization and user experience potential on trials.
- Siloed applications in clinical operations inhibit the development of these solutions toward interoperability, with life science companies only slowly taking a holistic view of end-to-end trial operations.
- The stalled development of interoperability standards for data exchange between CROs and pharma companies also delays more comprehensive views of data, milestones and metrics by operations personnel.
- Existing site paper processes and low levels of digitalization complicate the optimization of trial resource management tools, maintaining paper workflows and reducing process normalization across sites.

User Recommendations

- Opt for solutions that can be linked to allow more integrated operations. Seek solutions that are the most advanced and amenable to integration — typically available in e-clinical platforms — and that compress the time from plan to execution.
- Prioritize the use of CTMS for core clinical planning activities at tactical and operational levels. Note that their capabilities are expanding and increasingly taking a role in integrating the activities of multiple CRO partners at sponsor companies.
- Seek solution providers that offer open exchanges of operational information — including performance metrics and dashboards — and have links to applications that create visibility across clinical trials to support resource management.
- Deploy specialty point solutions to fill gaps in this base, and use “overlay” BI or business process management (BPM) tools as needed to satisfy the remaining analytic needs, automate workflows and enable quality checks.

Sample Vendors

ArisGlobal; BSI Life Sciences; Clario; Dassault Systèmes (Medidata); eClinical Solutions; Oracle; Signant Health; Slope; TransPerfect; Veeva Systems

Gartner Recommended Reading

Master Trial Efficiency With Clinical Trial Resource Management

Market Guide for Life Science E-Clinical Platforms

Navigate a Path to Digital With the Life Science Clinical Development Landscape and Definition of Terms

Life Science CIOs, Accelerate Clinical Development With New Applications of Artificial Intelligence

E-Clinical Platforms

Analysis By: Jeff Smith

Benefit Rating: Transformational

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

E-clinical platforms support the end-to-end needs of clinical trial planning and execution. They are composed of integrated solution suites used for protocol development, electronic data capture (EDC), clinical trial management systems (CTMS), randomization and trial supply management systems (RTSM), electronic trial master files (eTMF), trial analytics and reports, and related capabilities that support clinical trial operations.

Why This Is Important

E-clinical platforms represent an opportunity to simplify the clinical IT environment, optimize operations and improve data quality. Trial sponsors, historically, purchased clinical trial applications as point solutions and loosely integrated them, relying on informal, manual processes and middleware solutions to manage trial activities. New e-clinical platforms feature multiple point solutions built on a common codebase, or tightly integrated on a separate codebase or over a data fabric.

Business Impact

E-clinical platforms provide a view of key clinical trial performance indicators, such as actual patient enrollment versus target, length of time for query resolution, investigator payment status and other critical performance indicators. They also enable risk-based and centralized monitoring of trial data, which uses performance data from multiple point solutions, and allow trial staff to view trial, site and subject risk more lucidly, optimizing responses to trial events.

Drivers

- While many life science organizations still purchase point solution components, they are increasingly seeing value in more integrated platforms that are managed as a service from a single vendor. The integration is improving over time, with platform vendors and sponsors taking advantage of business process management (BPM) and robotic process automation (RPA), middleware and other low-code hyperautomation capabilities.
- Vendors continue to enhance their capabilities by strengthening their architectures around a core of end-to-end process management activities, including protocol design, data management, clinical trial management and budgeting, monitoring, and clinical supply, allowing for cross-study perspectives. They are progressively integrating disparate systems supporting trials into their platforms, which simplifies vendor management, user experience (UX), analytics and interoperability issues.
- E-clinical platforms are helping IT leaders move away from legacy custom-made systems and are creating opportunities to optimize, automate and speed trial processes. Interoperability enables process optimizations through seamless communications among component solutions.
- E-clinical platforms continue to evolve into business areas facing multiexperience platforms, providing a seamless UX where relevant information is available to make business decisions within a single application environment.
- As e-clinical platforms continue to evolve into more composable architectures, we see these platforms continuing up the Slope of Enablement to the Plateau of Productivity.

Obstacles

- Transitioning to platforms from legacy point solutions can be a challenge for business teams, slowing adoption. Individual point solutions can have residual staying power due to user preference and key features.
- Reluctance to shift from legacy sourcing approaches can slow the uptake. Organizations often focus on individual solution features, with selection processes limited to specific departments and predefined solution categories, making the shift to a platform more complex.
- E-clinical platforms often have areas of strength and differentiation, and other solutions that are less refined and lacking key features, making platform selection more complex. IT can be placed at odds with business teams when platforms offer key security and performance advantages but lack key business capabilities.
- Some e-clinical platforms may be too rigid in their design to accommodate the unique needs of a trial, limiting choices for life science companies who have gone “all in” on a specific platform.

User Recommendations

- Establish an IT architecture strategy for clinical trials that reflects an integrated vision of trial planning and execution. Use a layering and building-block approach for evolving toward that architecture, as opportunity presents, to replace a component system with a new system that is more in alignment with the integrated end goal.
- Select a vendor partner carefully when choosing new systems and component solutions — one that shares the vision of process workflow and optimization that is aligned with your goals.
- Review the degree of integration, as well as vendors’ product roadmaps and time frames, before committing. Trial sponsors can better ensure the achievement of their e-clinical visions by selecting an e-clinical platform that strategically integrates point solutions for maximum value to the business.

Sample Vendors

Advarra; Anju; ArisGlobal; Clario; Datatrack; Ennov; Medidata; Merative; Oracle; Veeva Systems

Gartner Recommended Reading

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs: Map Your Pathway to Digital Trials

Navigate a Path to Digital With the Life Science Clinical Development Landscape and Definition of Terms

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

eTMF

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

An electronic trial master file (eTMF) is a formalized means of planning, organizing, managing and storing documents, metadata, images and other digital content for clinical trials in a fashion compliant with government regulatory agencies. Regulatory agencies have issued required elements of eTMF systems that address the content and data models of clinical trials and require capabilities for digital content archiving, access and security, change control processes, audits and validation.

Why This Is Important

After the Food and Drug Administration (FDA) issued guidance that outlined eTMF requirements, sponsors accelerated implementations of eTMF systems. More recently, eTMF has been accepted by global regulators in the EU and Japan, and eTMF cloud solutions have proliferated, with enhancements exposing new insights and supporting more efficient processes. Insights on these solutions have improved by connecting directly to site systems, automating document workflows and facilitating collaborations.

Business Impact

Life science manufacturers have shifted to cloud eTMF across the board due to a clear reduction in costs versus managing paper-based or legacy systems. Business teams have benefited from this shift with increased flexibility, access and solution integrations that reduce overall operational costs. Other benefits include increased time savings via improved turnaround time on document review during study conduct and analytics that provide site-level visibility into task completion.

Drivers

- Multiple regulatory agencies encouraged manufacturers running clinical trials to streamline their processes and reduce the mountains of paper that can be a significant problem during technical scale-up. This is leading to the wide-scale adoption of eTMF solutions over time, as paper-based archiving as submission is costly, inefficient and prone to errors.
- eTMF mobile apps are simplifying tasks for the site monitor in making site documents visible to the sponsor. Site systems for managing the investigator site file are going digital and being integrated or made interoperable with eTMF applications.
- eTMF systems drastically improve the ability to respond to agency inspections, sponsor audits and internal audits. There has been an industrywide push to develop shared and open standards to improve the interoperability of eTMF data among clinical sponsors, contract research organizations, vendors, investigator sites, academic research centers and regulatory bodies.
- The drive to connect eTMFs with electronic Investigator Site Files (eISFs) to facilitate document exchange and review has opened up the space for new vendors, value propositions, selling approaches and interoperability.
- New capabilities around text extraction and automated intake — and interoperability with clinical trial management systems and other eClinical solutions — are expected to continue to drive value as eTMF becomes a fully digital solution.
- As new efficiencies are realized from AI, digitalization of site processes and ecosystem connections, we expect eTMF to continue to move up the slope, reaching the plateau within five years.

Obstacles

- Life science manufacturers with legacy paper and quality processes, and existing on-premises infrastructure, may hesitate to drive cloud initiatives such as eTMF as a result of sunk costs into existing processes, operational support and infrastructure investments.
- Due to the slow adoption of standards to improve the interoperability of eTMF, integration between competing platforms and eISFs or data exchange between eTMFs will remain a challenge. This will prevent seamless content sharing between organizations, leading to staggered, transactional operations.
- A confusing array of eTMF platform solutions with widely varying technology maturity can make the RFP process a challenge. Competition on price point can lead companies to choose older solutions and miss the opportunity to leverage newer, digital eTMF that can help accelerate operations.

User Recommendations

- Pursue a SaaS-based approach and, ideally, multitenancy. Because eTMF is often the first step in management of content in SaaS cloud, ensure the eTMF selected fits within the overall cloud strategy before proceeding.
- Examine eTMF interoperability with CRO partners and clinical sites. Do not invest in a solution that claims to reduce IT complexity without first evaluating the customization required for interoperability.
- Investigate how eTMF systems with planning tools and analytics can improve regulatory compliance and reduce the effort to present information to regulatory bodies and partners. Although the Drug Information Association (DIA) reference model is often listed as foundational to system design, ensure there is enough flexibility to accommodate changes as the reference model evolves.
- Rate eTMF vendors based on how they best implement features like AI-augmented document workflow and cross-platform analytics to help facilitate remote operations and optimized document workflow.

Sample Vendors

ArisGlobal; Egnyte; Ennov; Florence; IQVIA; Montrium; PharmaLex (Phlexglobal); SureClinical; TransPerfect; Veeva Systems

Gartner Recommended Reading

Electronic Trial Master File Strategy Alignment

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Life Science CIOs: Map Your Pathway to Digital Trials

Predicts 2023: Digital Transformation of Healthcare Beckons New Era for Life Sciences

Structured Content and Component Authoring

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: More than 50% of target audience

Maturity: Early mainstream

Definition:

Structured content authoring (SCA) and component-based authoring (CBA) consist of technologies and processes for managing data and content captured in manufacturing, regulatory, quality, clinical and other activities used in life science regulatory filings. They include the management information required to meet regulatory requirements, such as product labeling, standard operating procedures, study protocols, clinical study reports and marketing information.

Why This Is Important

SCA supersedes traditional document-based approaches, where content is often inaccessible over time or redundantly captured. It decomposes documents, data and other content into discrete components that can be flexibly reused, assembled into different end requirements and versioned. This results in greater productivity and control for life science companies operating in complex, global regulatory environments.

Business Impact

SCA and CBA improve regulatory compliance, speed up cycle times in protocol development, make regulatory filings smooth, increase productivity in content management, and improve collaboration across global clinical and regulatory groups. They also enable distributed authoring in parallel, improving timelines, and allowing report components to be reused and overall report development to become less of an individual chore.

Drivers

- SCA and CBA complement CIOs' urgency to increase the digitalization of internal processes in life science organizations. This will be indicated by the treatment of regulatory deliverables as structured content, representing the decomposition of documents into data, reassembly and retasking for many purposes within an organization and in various submissions across regulatory agencies.
- SCA and CBA reduce effort and time to create clinical operations, quality and submission content. They also help in improving overall quality and compliance, which drives their adoption.
- Newer regulatory requirements, such as identification of medicinal products (IDMP), are influencing life science companies' adoption of standardized descriptions for regulatory content, including labels and associated product collateral. Efforts will increasingly focus on process optimization and compliance.
- The use of AI to automate certain types of content creation, metadata completion and quality checks indicates CIOs' and business leaders' continued interest in optimizing content creation. Recent advances in generative AI are expected to further spur investment in the use of these tools to generate regulatory content components.
- Solution vendors continue to invest in tools to enable managing content on this basis, and their use will expand. Progress of this innovation profile accelerates as more life science organizations digitalize regulatory processes, and this profile continues steady progress up the Plateau of Productivity and is expected to reach the plateau within two years.

Obstacles

- Although these tools have matured and have been available for some time, some companies have been slow to adopt them due to the extensive process changes that must be implemented.
- Long traditions in the use of MS Word and desktop-based word processing have delayed the transition to more advanced online tools that are better adapted to SCA architectures.
- Progress in adopting SCA solutions has been delayed for years due to the challenge of building atomic structured content, with many organizations maintaining content as PDFs in document repositories rather than maintaining this information in a database. Attempts have been sporadic and limited to localized departments as a result.
- Lack of centralization of regulatory content and the need to manage content from sources mired in document-driven content approaches are leading to hybrid content creation and stymied attempts at CBA and SCA.

User Recommendations

- Work with clinical and regulatory leaders to include CBA and SCA capabilities in their process and technology architecture to evolve with global regulatory requirements, improve interoperability with external applications, expedite content creation and management and progress toward fully digitalized systems.
- Adopt technologies that facilitate content decomposition and management to simplify content creation. Solutions should support the concept of an information life cycle, mapping the source to each transformation at a component level, moving toward the final submission content.
- Work with regulatory leaders to take an integrated view of all regulatory content and its associated metadata, and align this with SCA and CBA solutions to optimize the content creation process.

Sample Vendors

Anju; Author-it Software Corporation (ASC); Dassault Systèmes; Generis; Glemser; Infrastructures for Information (i4i); InteliNotion; Nurocor; RWS; Yseop

Gartner Recommended Reading

Innovation Insight: Digital Protocol for Clinical Trials

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Market Guide for Life Science Regulatory Information Management Solutions

Life Science CIOs: Use Computer Software Assurance to Modernize Your GxP Validation Practice

Market Guide for Quality Management System Software

Entering the Plateau

Global Regulatory Information Management

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Global regulatory information management (RIM) provides capabilities that a life science company needs, in order to manage the regulatory approval and maintenance of a life science product for commercial use. These capabilities include product registrations, submission content management, and dossier tracking and publishing. RIM solutions increasingly include subcomponents such as clinical trial disclosure, e-submission gateway, IDMP compliance information and structured product labeling tools.

Why This Is Important

RIM enables pharma companies to comply with regulatory requirements, improve efficiency and make better decisions. It helps companies streamline regulatory processes, reduce duplication of effort, and manage risks associated with noncompliance, product recalls, or adverse events. It also helps to allocate resources more effectively, respond quickly to issues, and bring safe and effective drugs to market more efficiently.

Business Impact

By improving compliance with regulatory requirements, RIM helps companies to avoid penalties and fines. RIM systems can help regulatory affairs teams improve their responsiveness to regulatory changes, better manage correspondence and planning with regulators, and normalize product market approvals. This further helps companies to bring new drugs to market more efficiently, reducing the time and resources required to gain regulatory approval.

Drivers

- There are constant changes in new regulatory requirements for launching products approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA) and National Medical Products Administration (NMPA). These include regulations, such as electronic Common Technical Document (eCTD) publishing standards, EU's Identification of Medicinal Products (IDMP), updated EU medical device regulations and new requirements to manage more complex products, such as biologics. This drives regulatory leaders to adopt RIM systems to improve responsiveness to changes, better manage correspondence and planning with regulators, and normalize product market approvals.
- Most global companies are attempting to efficiently manage regulatory information at a global level and have been advocating for global RIM deployments, which allows them to scale central regulatory teams to support multiple regional affiliates more effectively.
- The push to new regulated markets, such as China and the Southeast Asia region, increases the overall complexity of the management of regulatory information and exposes the deficiencies in existing nonscalable Microsoft Excel-based processes.
- Companies are optimizing regulatory processes integrating RIM systems with ancillary and upstream systems, such as electronic trial master file (eTMF), drug safety systems and quality management systems.

Obstacles

- Many clients report that centralization and regulatory uncertainty cause delays in global decision making and lessen local agility. Due to this, there are still a great deal of RIM customizations and resulting complexities.
- RIM providers do not always have equal capability on all RIM solutions, which slows platform deployment and leads to fragmented, best-in-breed approaches to RIM.
- Many companies do not yet see RIM as a strategic initiative, with underinvestment leading to nonscalable and spreadsheet-driven approaches.
- Although solutions continue to mature, RIM platform adoption progress remains slow due to deeply ingrained, best-in-breed approaches and lack of consistent quality in vendor RIM offerings. For these reasons, global RIM continues to move slowly up the Slope of Enlightenment toward the Plateau of Productivity.

User Recommendations

- Ensure RIM solutions incorporate improved global capabilities, especially when operating across multiple regulatory regions, that enable regulatory affiliates to hub communications, allowing regulatory capability to scale as the organization grows.
- Move forward with robust RIM tools that lightly interface with other solutions such as electronic data capture (EDC), adverse events reporting systems (AERS), eTMF, ERP, product life cycle management (PLM) and master data management (MDM) systems.
- Go cloud-first and focus primarily on SaaS-based offerings, which are ubiquitous in this area, and offer robust RIM platform capabilities.
- Partner with regulatory peers to make the case for connected and integrated RIM solutions. Focus on moving to a holistic RIM, with an emphasis on a single source of entry and a single source of truth.

Sample Vendors

ArisGlobal; Calyx; Ennov; Freyr Solutions; Generis; IQVIA; LORENZ; RegDesk; Rimsys; Veeva Systems

Gartner Recommended Reading

Market Guide for Life Science Regulatory Information Management Solutions

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Market Guide for Quality Management System Software

Quick Answer: What Must Life Science CIOs Do to Jump-Start IDMP Compliance?

Appendixes

See the previous Hype Cycle: Hype Cycle for Life Science Clinical Development, 2022

Hype Cycle Phases, Benefit Ratings and Maturity Levels

Table 2: Hype Cycle Phases

(Enlarged table in Appendix)

Phase	Definition
Innovation Trigger	A breakthrough, public demonstration, product launch or other event generates significant media and industry interest.
Peak of Inflated Expectations	During this phase of overenthusiasm and unrealistic projections, a flurry of well-publicized activity by technology leaders results in some successes, but more failures, as the innovation is pushed to its limits. The only enterprises making money are conference organizers and content publishers.
Trough of Disillusionment	Because the innovation does not live up to its overinflated expectations, it rapidly becomes unfashionable. Media interest wanes, except for a few cautionary tales.
Slope of Enlightenment	Focused experimentation and solid hard work by an increasingly diverse range of organizations lead to a true understanding of the innovation's applicability, risks and benefits. Commercial off-the-shelf methodologies and tools ease the development process.
Plateau of Productivity	The real-world benefits of the innovation are demonstrated and accepted. Tools and methodologies are increasingly stable as they enter their second and third generations. Growing numbers of organizations feel comfortable with the reduced level of risk; the rapid growth phase of adoption begins. Approximately 20% of the technology's target audience has adopted or is adopting the technology as it enters this phase.
Years to Mainstream Adoption	The time required for the innovation to reach the Plateau of Productivity.

Source: Gartner (July 2023)

Table 3: Benefit Ratings

Benefit Rating ↓	*Definition* ↓
Transformational	Enables new ways of doing business across industries that will result in major shifts in industry dynamics
High	Enables new ways of performing horizontal or vertical processes that will result in significantly increased revenue or cost savings for an enterprise
Moderate	Provides incremental improvements to established processes that will result in increased revenue or cost savings for an enterprise
Low	Slightly improves processes (for example, improved user experience) that will be difficult to translate into increased revenue or cost savings

Source: Gartner (July 2023)

Table 4: Maturity Levels

(Enlarged table in Appendix)

Maturity Levels	Status	Products/Vendors
Embryonic	In labs	None
Emerging	Commercialization by vendors Pilots and deployments by industry leaders	First generation High price Much customization
Adolescent	Maturing technology capabilities and process understanding Uptake beyond early adopters	Second generation Less customization
Early mainstream	Proven technology Vendors, technology and adoption rapidly evolving	Third generation More out-of-box methodologies
Mature mainstream	Robust technology Not much evolution in vendors or technology	Several dominant vendors
Legacy	Not appropriate for new developments Cost of migration constrains replacement	Maintenance revenue focus
Obsolete	Rarely used	Used/resale market only

Source: Gartner (July 2023)

Document Revision History

Hype Cycle for Life Science Clinical Development, 2022 - 26 July 2022

Hype Cycle for Life Science Research and Development, 2021 - 19 July 2021

Hype Cycle for Life Science Research and Development, 2020 - 13 August 2020

Hype Cycle for Life Science Research and Development, 2019 - 2 August 2019

Hype Cycle for Life Science Research and Development, 2018 - 27 July 2018

Hype Cycle for Life Science Research and Development, 2017 - 17 July 2017

Hype Cycle for Life Science Research and Development, 2016 - 19 July 2016

Recommended by the Author

Some documents may not be available as part of your current Gartner subscription.

Understanding Gartner's Hype Cycles

Tool: Create Your Own Hype Cycle With Gartner's Hype Cycle Builder

Life Science CIOs: Map Your Pathway to Digital Trials

Tool: Life Science CIO's Executive Presentation for Building the Composable "Digital Therapeutech"

Creating the Composable Healthcare Organization for Healthcare and Life Science CIOs

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Table 1: Priority Matrix for Life Science Clinical Development, 2023

Benefit	*Years to Mainstream Adoption*			
↓	***Less Than 2 Years*** ↓	***2 - 5 Years*** ↓	***5 - 10 Years*** ↓	***More Than 10 Years*** ↓
Transformational		E-Clinical Platforms Generative AI in Life Sciences	Blockchain in Life Sciences Data Fabric in HCLS Digital Life Science Platform Digital Trials Genomics Medicine	

Benefit ↓	*Years to Mainstream Adoption*			
	Less Than 2 Years ↓	*2 - 5 Years* ↓	*5 - 10 Years* ↓	*More Than 10 Years* ↓
High		Adaptive Trials AI in Clinical Development Augmented Analytics Clinical Data Analytics Platforms eSource eTMF Patient Data Tokenization Risk-Based and Centralized Monitoring SaaS-Regulated CSP Scientific Literature Text Analytics Semantic Knowledge Graph Tools Trial Simulation	Cell and Gene Therapy Platform Digital Protocol Digital Validation Tools RWD-Based Trials RWE Analytics Wearable Devices for Clinical Trials	

Benefit	*Years to Mainstream Adoption*			
↓	*Less Than 2 Years* ↓	*2 - 5 Years* ↓	*5 - 10 Years* ↓	*More Than 10 Years* ↓
Moderate	Global Regulatory Information Management	Accelerated Patient Recruitment AI-Augmented Safety Vigilance Clinical Development Hyperautomation Clinical Trial Data Transparency Clinical Trial Resource Management Compliant GxP Cloud Services Data Monetization in HCLS eConsent Precompetitive Alliances Structured Content and Component Authoring		
Low				

Source: Gartner (July 2023)

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Source: Gartner (July 2023)