Hype Cycle for Life Science Research and Development, 2021

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Initiatives: Healthcare and Life Science Digital Transformation and Innovation

As life science companies continue to build out digital capabilities, the constantly shifting technology landscape requires diligent recalibration. CIOs can use this Hype Cycle to better identify innovative technologies that are maturing more rapidly, enabling smarter investments.

Analysis

What You Need to Know

Digitalization across life science organizations moved at an accelerated pace during the COVID-19 pandemic, with the industry scaling and refining ever more digital initiatives in 2021. The overwhelming success of vaccine ventures has improved perceptions of the industry and provided a tangible glimpse into the potential of new medical innovations, shifting investments from big tech into biotech. Life science CIOs must remain attuned to these business drivers, underlying the demand for new digital tools (see 2021 Business Drivers for Life Science CIOs) in order to better anticipate the needs of the business areas they support.

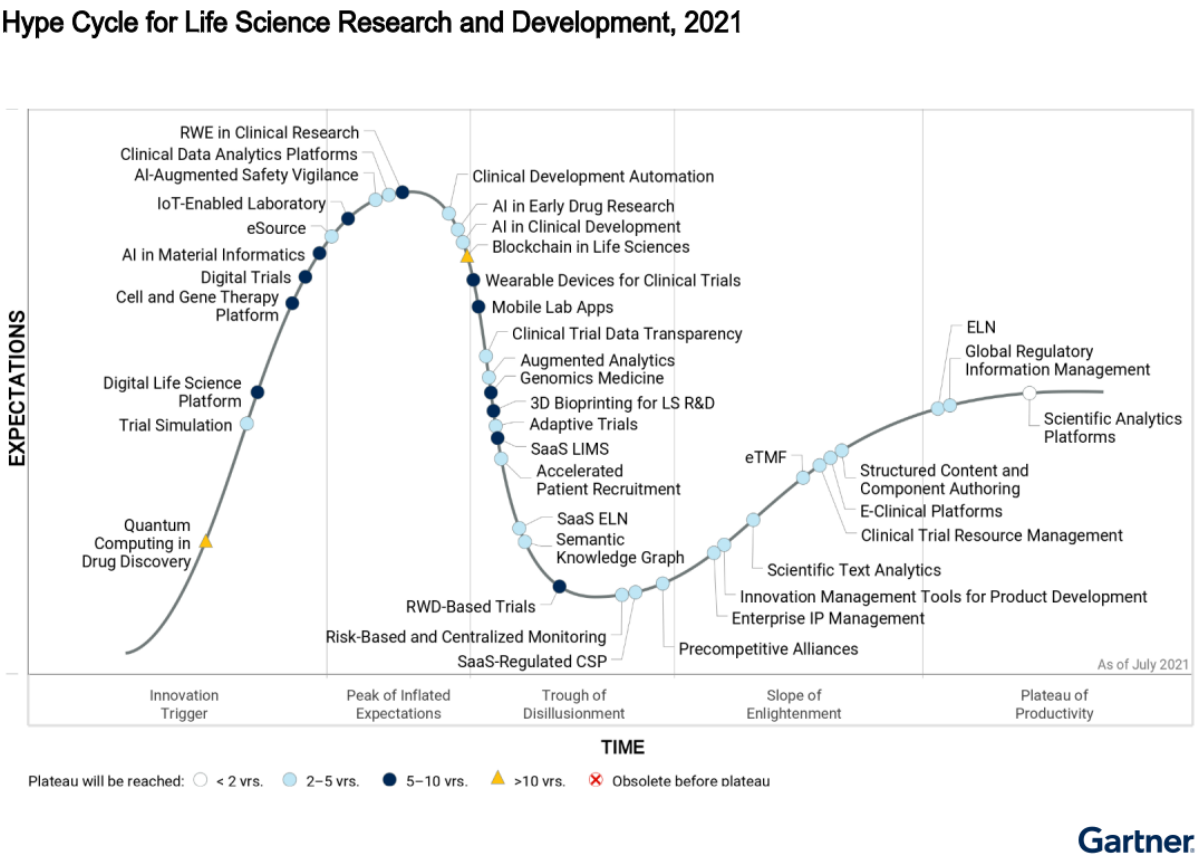
This Hype Cycle explores innovative technologies relevant to life science R&D product development programs in the pharmaceutical, biotechnology, diagnostics, medical device, research institution and contract research sectors. Where applicable, a select subset of technologies is also represented in Hype Cycle for Life Science Commercial Operations, 2021, which focuses on topics related to product commercialization and sales. Additional technologies representing innovations in the life science manufacturing and supply chain areas can be found in Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2021.

The Hype Cycle

The ongoing search for new products and medicines leads to continual disruption and reinvention, resulting in a variety of niche supporting vendors, custom-made applications, consultancies and service providers. As a result, R&D IT includes many niche applications serving a wide variety of functions, with specialized teams supporting the many business processes that make up the landscape of R&D operations. Use this research to help assess the risk and reward of each maturing innovation. Then, create a technology roadmap by defining initial investments in your strategy, and then evaluating innovations holistically and aligning them to your organization's digital ambition, maturity and growth profile.

With so many innovative digital technologies playing a role in aiding new discovery and process optimization initiatives, we see significant opportunities in life science R&D technology investments. This year, we have moved several technologies faster along the curve due to acceleration caused by the pandemic, with digital trials and clinical development automation advancing forward the most rapidly. Approximately 25% of the innovations are moving up the curve to the peak of hype, and even more have been spurred along by investments during the pandemic. However, remember that overhyped and more complex innovations such as blockchain in life sciences may take longer to mature, while other technologies such as adaptive trials may progress more rapidly (see Understanding Gartner's Hype Cycles). Use the information in this Hype Cycle to identify technologies that have the potential to deliver the value your business colleagues demand while evaluating the risks associated with those innovations.

Figure 1: Hype Cycle for Life Science Research and Development, 2021



Source: Gartner (July 2021)

Downloadable graphic: Hype Cycle for Life Science Research and Development, 2021

The Priority Matrix

This Hype Cycle includes many areas of innovation that will enable you and your organization to respond to industry challenges. You must 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, genomics medicine and augmented analytics. Below them are technologies that are still important, but with a lesser scope of potential impact. Look to the right, and you will find emerging technologies with great potential that are further away from their full maturity, including blockchain for life sciences and quantum computing in drug discovery. 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 Research and Development, 2021

(Enlarged table in Appendix)

Benefit	*Years to Mainstream Adoption*			
↓	*Less Than 2 Years* ↓	*2 - 5 Years* ↓	*5 - 10 Years* ↓	*More Than 10 Years* ↓
Transformational		Augmented Analytics E-Clinical Platforms	Digital Life Science Platform Digital Trials Genomics Medicine	Blockchain in Life Sciences
High	Scientific Analytics Platforms	Adaptive Trials AI in Clinical Development AI in Early Drug Research Clinical Data Analytics Platforms ELN eSource eTMF Innovation Management Tools for Product Development Risk-Based and Centralized Monitoring SaaS ELN SaaS-Regulated CSP Scientific Text Analytics Semantic Knowledge Graph Trial Simulation	3D Bioprinting for LS R&D Cell and Gene Therapy Platform IoT-Enabled Laboratory RWD-Based Trials RWE in Clinical Research Wearable Devices for Clinical Trials	Quantum Computing in Drug Discovery
Moderate		Accelerated Patient Recruitment AI-Augmented Safety Vigilance Clinical Development Automation Clinical Trial Data Transparency Clinical Trial Resource Management Enterprise IP Management Global Regulatory Information Management Precompetitive Alliances Structured Content and Component Authoring	AI in Material Informatics Mobile Lab Apps SaaS LIMS	
Low				

Source: Gartner (July 2021)

Off the Hype Cycle

This year, to clarify alignment of technology types to manufacturing and supply chain processes, we have moved the following technologies from this Hype Cycle to the Hype Cycle for Life Science Manufacturing, Quality and Supply Chain, 2021:

- 3D Printed Drugs
- Quality by Design
- Pharma PLM
- Enterprise Laboratory Informatics
- Compliant GxP Cloud Services

On the Rise

Quantum Computing in Drug Discovery

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: Less than 1% of target audience

Maturity: Embryonic

Definition:

Quantum computing (QC) in drug discovery is the application of QC hardware, software, algorithm development and applications for early drug research within the life science industry and is delivered using an as-a-service model (QCaaS). QC has been applied in many areas, including molecular generation, molecular comparison and other high-compute areas that are not feasible using traditional silicon-based computation within a reasonable time frame.

Why This Is Important

QC is a type of nonclassical computing that operates on the quantum state of subatomic particles. The particles represent information as elements denoted as quantum bits (qubits). A qubit can represent all possible values of its two dimensions (superposition) until read. Quantum algorithms manipulate linked qubits in their entangled state, and address vast combinatorial complexity. QC can be superior for problems with enormous combinatorial complexity — especially in the drug discovery space.

Business Impact

QCaaS will have an impact on biomolecular optimization, genomics analysis, machine learning for pathway analysis, drug discovery, and organic chemistry and synthesis. QCaaS has the potential to accelerate in silico activities and reduce timelines in drug discovery. R&D leaders will be able to augment and potentially replace screening efforts and work at the lab bench, especially as more QCaaS hits the market. This impacts key drug research partnerships and helps augment drug pipelines.

Drivers

- R&D teams are under immense pressure to deliver new molecular leads and refine offerings in their portfolios. Only recently has QCaaS for drug discovery become available through new software vendors, consultants and biotechnology companies. Once the technology has evolved and stabilized, Gartner expects QC to provide a high-value tool, handling the more complex computational challenges in drug discovery.
- Scientists' expectations of QC capabilities will rapidly increase as new vendors get involved in drug discovery.
- We see an increase in QC staff training. Initial QC-knowledgeable personnel are already becoming managers attempting to drive competitive differentiation through the application of this technology.

As this is still an extremely new area with service companies only a few years old, we position it in the Innovation Trigger phase. Gartner expects it to rapidly approach peak hype, as these as-a-service companies engage sponsor clients running discovery programs.

Obstacles

- While QC itself is near peak hype, it is poorly understood and supported in the market. While we see advancements in quantum algorithmic development on the horizon, adoption will take time. For these reasons, it is still in the trigger phase. We do not expect either QC or QCaaS in life science to reach mainstream for at least 10 years.
- Due to the immense cost of QC equipment and resources, and limited regionally based expertise, QC is often a collaborative initiative with researchers, limiting its availability. For the foreseeable future, QC will be delivered to end users as QCaaS.
- While a handful of large pharmaceutical companies are sponsoring quantum projects (e.g., Biogen worked with Qbit and Accenture for quantum-enabled molecular comparisons in 2017), results will remain unproven.
- If partnering with these companies, expect extensive consultancy fees, as organizations do not have dedicated scientific informatics disciplines or prepackaged workflows.

User Recommendations

- Start limited pilots today for QC in drug discovery to develop the skills and refine strategy required for a longer term program.

- Evaluate if QCaaS is a good fit for these application areas: binding site prediction, high-content imaging, antibody design and research, catalyst research, molecular generation, affinity calculations, QSAR, screening, docking programs, predictive spectra, quantum mechanics, molecular dynamics, protein structure design and predictions, molecular-molecule interactions, large molecule dynamics, and material and formulation design.

- Evaluate the benefits of using a general QC provider that will require extra consulting and services to implement (such as those provided by IBM, IonQ, D-Wave Systems, Rigetti Computing, Honeywell, QCI and Microsoft, etc.) versus the more focused QCaaS companies that have life science domain expertise and applications.

Sample Vendors

ApexQubit; ChemAlive; Cloud Pharmaceuticals; PharmCADD; POLARISqb; ProteinQure; Riverlane; Silicon Therapeutics; Xanadu; XtalPi

Gartner Recommended Reading

Predicts 2021: Disruptive Potential During the Next Decade of Quantum Computing

Emerging Technologies and Trends Impact Radar: 2021

Trial Simulation

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Trial simulation refers to 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 study” 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. As a new technology on the Hype Cycle, trial simulation falls in the Innovation Trigger phase.
- 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 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.

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 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 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

Certara; Deloitte; HumMod; Medidata; Novadiscovery; Ontada; Syapse; Virtusa

Gartner Recommended Reading

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

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

Market Guide for Life Science E-Clinical Platforms

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Digital Life Science Platform

Analysis By: Michael Shanler

Benefit Rating: Transformational

Market Penetration: Less than 1% of target audience

Maturity: Embryonic

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 and heavily customized or niche business applications portfolios. The siloed nature of current architectures (as seen in research informatics packages, clinical development tools, sales CRMs and manufacturing suites) has stifled innovation and slowed digital transformation. Customers are exhausted by feeble attempts at interoperability by vendors resulting in a bloated total cost of ownership (TCO).

Business Impact

- 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 leveraging data sources from R&D, precision medicine, and real world evidence
- Digital laboratory research
- Digital prescriber engagement for personalized communications and information sharing

Drivers

- Clients want to enable a composable life science enterprise (or perhaps a “digital therapeutech”) that is realized through business-user focused application experiences that are independent of the underlying set of COTS or legacy monolithic applications.
- Clients want a more effective means of bringing together different domains (e.g., clinical and AI SMEs) to provide a focus for democratized innovation among a range of stakeholders (see Fusion Teams: Cross-Functional Collaboration for the Digital Era).
- 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 packaged business capabilities (PBCs). PBCs are application building blocks that have been purchased or developed internally or with third parties.
- Many clients and vendors are including platform strategies as the main vehicle for ushering in a new era for digital business, where individualized experiences that mash up both application data, as well as analytics, created by underlying PBCs and supported via broader data fabrics, are underpinning this IT transformation.

Obstacles

- Leading vendors in this space will be those that can provide a means of rapidly producing composable digital products and services from different sources (not just their own marketplace or product offerings).
- Clients are already reporting being overwhelmed by vendor messaging regarding platforms. This is creating some paralysis for decision making.
- DLSP requires vision and alignment with both 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 on design and key partner selections.
- We expect this innovation profile to reach the Peak of Inflated Expectations in three years as new visionary platform entrants and large sponsors force incumbent vendors to open up their architectures. As this happens, clients will inevitably be let down by either the vendor capabilities or their own 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 Fusion Teams: Cross-Functional Collaboration for the Digital Era).
- Take appropriate actions on vendor and key technology sourcing across the current and future enterprise application portfolio (see A CIO's Hype Cycle Reference Guide for the Healthcare and Life Science Industries).
- 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.
- Use the attribute of "composability" as a high priority in making and renewing vendor relationships.
- Explore strategic relations with hyperscale solution providers and channel partners.

Sample Vendors

Amazon; Google; IBM; Microsoft; Salesforce; SAP

Gartner Recommended Reading

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

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

Best Practices for Reimagining Your Life Science Company as a Digital Business Technology Platform

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

Future of Applications: Delivering the Composable Enterprise

Cell and Gene Therapy Platform

Analysis By: 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 central 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.
- Two key autologous chimeric antigen receptor (CAR) T-cell therapies were launched over the past several years, driving up hype and interest in these therapies. Novartis launched KYMRIAH and Kite Pharma launched Yescarta for B-cell lymphoma. In 2021, there are over 250 CAR-T drugs in trials, and numerous other types of CGTs (see Cell Therapy Manufacturing: The Supply Chain Challenge).
- The demand for CGT clinical trials has accelerated, making CGT platforms matching 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

- Life science organizations 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 patients 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.
- We position this technology in the Innovation Trigger phase, given its early stage of maturity and adoption.

User Recommendations

- Find out 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; L7 Informatics; Skyland Analytics; TrakCel; Vineti

Gartner Recommended Reading

Healthcare and Life Science Business Driver: Medical Technology Innovation

2021 Business Drivers for Life Science CIOs

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Critical Capabilities for Manufacturing Execution Systems

Digital Trials

Analysis By: Jeff Smith

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Digital trials is the combination of technologies representing the full digitalization of clinical trials, including remote data capture via devices, use of eSource and the shifting of trial processes away from clinical sites and toward the trial subjects themselves. Digital trials includes the confluence of several underlying technology advances applied to clinical trials, including IoT, cloud computing, advanced analytics, wearables and mobile.

Why This Is Important

Many innovative life science companies and solution vendors are piloting supportive technologies for digital trials. While many organizations have designed trial types that are home-based, patient-centric, direct to patient, remote, virtual, and decentralized over the past five years, today only a handful of clients are taking these to the next level. They are pursuing fully digital trials in their long-term technology roadmaps.

Business Impact

Digital trials are expected to 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 finding and attracting subjects, and optimize 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

- Recent challenges due to the COVID-19 pandemic, such as social distancing and quarantines, dominate many discussions among clinical leaders about possible solutions that will allow trial operations to proceed with minimal disruptions. These solutions include reviewing decentralized trial approaches, experimenting with telehealth solutions and remote monitoring.
- 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 done particularly in cases of subjects with limited mobility in rare disease and oncology 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.

Obstacles

- Life science companies and their vendors have made many advances in electronic processes for trial optimization, but these have not reduced the escalating costs of trial operations or cut their cycle time. Trial operations continue to be an area fraught with paper workflow systems. Many of them are focused on management of more antiquated site-based processes, which have remained relatively unchanged for decades.
- Life science companies are often slow in their conversion to digital approaches. This is due to deeply ingrained expectations about trial approaches, overly complex procedures, and approaches to quality and organizational risk aversion that slow process change.

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, 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

Clinical Ink; Datacubed Health; IQVIA Technologies; Medable; Medidata; Medocity; ObvioHealth; Science 37; THREAD Research

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

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

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

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

AI in Material Informatics

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

AI-enabled material informatics solutions are software and services that apply advanced learning techniques to materials-related big data for better predicting results by the characteristics of each material. Typically, life sciences organizations apply the resulting insights to the use, selection, discovery and development of materials in downstream engineering, and product development and manufacturing.

Why This Is Important

- This technology enables organizations to move beyond loosely packaged materials databases with light search functionality.
- Clients are looking to simplify either customized, proprietary in-house systems; outsourced work with CROs that perform material science; or modify their own drug-discovery-oriented cheminformatics applications or electronic laboratory notebooks (ELNs). Machine learning and advanced analytics for these approaches are on the rise.

Business Impact

- Making investments in advanced materials informatics reduces the amount of time it takes to drive materials through in silico design processes.
- The technology can drive candidates for new materials that were previously undiscoverable using existing methodologies.
- The technology can be applied to streamline recipe formulation as well as modeling reductions for toxicity and carcinogenicity.

Drivers

- As investments in materials engineering and science increase, and software engineers begin to embrace data science and machine learning capabilities, the footprint of AI-enabled material informatics solutions will expand and become more prominent.
- The desired capability is now part of strategic plans at many small and large enterprises including medical devices, diagnostics equipment manufacturers, food and beverage, oil and gas, materials, chemicals, crop science, battery, electronics manufacturers, automotive, and aerospace and defense.
- Many organizations are looking to replace their current “standard” approach and move to newer and more advanced solutions. They want to better leverage the output and data streams from these solutions for downstream engineering software, such as CAD, CAE and PLM.
- Process integration will further fuel innovations and inspire new startups to bring more capabilities to market. We also expect established engineering software companies to look toward these smaller materials and informatics companies as potential acquisition targets, or areas where they build their own capabilities. This trend will continue because the synergies between materials informatics and R&D engineering enable a broader perspective on the overall product life cycle.
- This technology is rapidly climbing the Innovation Trigger phase on the Hype Cycle because today, most manufacturers with R&D programs are starting to explore these and other AI-related solutions in the domain of materials development.

Obstacles

- Many clients report that building out an AI strategy requires data that is configured to be machine-learning-readable, yet many organizations have not performed the data refinement needed.
- Clients often report that their own internal R&D datasets lack standards, governance and data principles.
- Most clients are still operating without a platform strategy to manage and govern scientific, laboratory, and formulation data, which is required to power and train the algorithms with proper datasets.
- CIOs report that they have multiple competing internal AI-platforms, analytics software packages and custom-made software that is difficult to keep validated.
- Developing an AI-enabled materials strategy means addressing data and infrastructure fundamentals (such as data management, platform requirements, data resolution) while engaging shadow IT in the lab, which is often challenging to influence.

User Recommendations

- Collaborate with R&D and manufacturing business leads for understanding which capabilities need to be augmented in the life cycle roadmap. While advanced analytics applications represent a new space, the R&D staff required to operate these systems must be more scientifically oriented.
- Assess targeted pilots as it will take five to 10 years before these systems are fully simplified to mesh seamlessly into broad product development processes.
- Map the value of these systems to arrange data, especially if the system will “learn” based on existing datasets. Ensure stakeholders understand the fidelity and resolution of vendor-provided or public datasets.
- Align the materials informatics strategy to the product life cycle strategy before extending the application to the rest of the R&D enterprise. Most new instances of AI-enabled materials informatics will be targeted toward specific R&D functional areas and disciplines.

Sample Vendors

Ansatz AI; Citrine Informatics; DataRobot (Nutonian); Enterra Solutions; Exabyte.io; MatSci AI; Tilde Materials Informatics; Turing; Uncountable

Gartner Recommended Reading

A Framework for Applying AI in the Enterprise

Innovation Insight for AI-Augmented Development

Magic Quadrant for Data Science and Machine Learning Platforms

Successfully Implementing AI in Department of Defense and Military Supply Chains

At the Peak

eSource

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

eSource technology enables the collection of 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 (EHRs), direct data capture (DDC) devices or clinical wearables.

Why This Is Important

eSource continues to be adopted into clinical trial systems. FDA guidance has clarified that in situations where the eCRF is the medium used to first record patient results, the eCRF can be considered the source data. This dispenses the need to review, update, maintain and archive paper records at a study site. In situations where the data has been captured from other remote systems into eCRFs, the system that captures the data at the point of care is the eSource.

Business Impact

eSource is the next technology step forward in realizing the goal of maintaining all trial data, both source and results datasets, in electronic format. This, in turn, paves the way for further efficiencies, allowing much of trial monitoring to be performed remotely, 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.

Drivers

- The COVID-19 pandemic has accelerated all digital technology use in clinical trials, and so the eSource profile moves even closer to the peak of hype.

- 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 by the proliferation of bring your own device (BYOD) apps that support direct patient data collection, improving both patient experience and patient centricity.
- Clinical and IT leaders continue to be informed by the FDA guidance, "Use of Electronic Informed Consent in Clinical Investigations — Questions and Answers" in which recommendations around electronic consent of trial subjects were outlined. This continues to drive the conversation, and leads to more vendor solutions built to manage the consent process, often with completely electronic solutions with electronic signatures.

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.
- Logistical challenges around equipment provisioning and management at the site level, as well as the change in process and work culture required, with many sites slow to transition away from paper processes. These operational challenges slow down the adoption of the technology.

User Recommendations

- Examine available 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 are likely to 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 availability, accessibility and data integrity.
- Evaluate eSource solutions to 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; CliniOps; ERT; Medable; Medidata; Medrio; Signant Health

Gartner Recommended Reading

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

Life Science CIOs: Map Your Pathway to Digital Trials

Business Moment: Digitalized, Remote Clinical Trials for Pharma

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

Market Guide for Life Science E-Clinical Platforms

IoT-Enabled Laboratory

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Emerging

Definition:

Internet of Things (IoT)-enabled laboratories leverage sensors, beacons and systems for communicating information between lab entities such as instruments, informatics systems and smart consumables. By leveraging analytics across the portfolio of IoT-enabled capabilities and connecting previously disconnected data elements generated from the existing instrumentation, users can monitor performance and generate new insights. IoT enablement is foundational for the Laboratory of the Future (LotF).

Why This Is Important

IoT is nascent in the lab space but is delivering initial value in the consumer and industrial world. Organizations are exploring how to connect entities such as lab equipment (e.g., pH meters and balances), laboratory informatics (e.g., electronic laboratory notebook [ELN] and laboratory information management system [LIMS]), and smart consumables (e.g., buffers and reagents) with enterprise assets (e.g., RFID badges, ERP and environmental, health and safety [EH&S]).

Business Impact

IoT-enabled laboratories and connecting labs help IT leaders:

- Enable “smart lab” and LotF strategies and drive autonomous processes based on algorithms and machine learning that leverage IoT data.
- Enable organizations to converge their virtual and physical work and create digital twins for lab processes, improving innovation, efficiency, quality and compliance.

Drivers

- Both PRISME and Pistoia Alliance included LotF as a topic at annual meetings over the last four years.
- Nascent strategies related to LotF, such as “Digital Lab,” “Laboratorie 4.0” and “Internet of Lab Things-Io(L)T” will take root through 2021.
- The impacts of COVID-19 on the ability of laboratory personnel to access laboratory operational data will accelerate this technology.
- Several instrument vendors are offering cloud-based IoT platforms; however, these are initially designed for remote field service, and asset tracking and monitoring.
- A variety of vendors now enable data-lake-based instrument data management, which divorces lab connectivity components from traditional lab informatics packages such as electronic laboratory notebook (ELN) and Laboratory Information Management System (LIMS) software.
- Given the nascent nature of IoT in the lab space, we position this technology as approaching the Peak of Inflated Expectations.

Obstacles

- Life science institutions with laboratories already have high capital spending, hence incremental spending with clear ROI will be hard to justify. We expect smaller proofs of concept for IoT before typical users undertake any “big bang” approaches to modernize laboratory environments.
- Incremental technology investments in tools and staff will be required in order to make sense of the data and leverage the analytics for insights.

User Recommendations

- Outline the business benefits your organization can achieve by “going digital” in its laboratories. Focus on how people, systems and things on equal footing will create new possibilities to improve quality, accelerate innovation and improve operational effectiveness.
- Identify opportunities for LoTF efforts by focusing on where IoT analytics can lead to innovation, quality, operational efficiencies and improved safety/risk monitoring.
- Define “digital business moments” and model examples for laboratories that will have direct impacts on creating new value by identifying outcomes such as faster time to data lock, improvements in instrument operations, and higher compliance.

Sample Vendors

Apprentice; Bosch.IO; Connected Labs; Elemental Machines; Labforward; SAP; Scitara, Simplifier; TetraScience; WattIQ

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science CIOs’ Plans for the Lab of the Future Must Enable Digital Business

Envision the IoT-Enabled R&D Digital Laboratory of the Future

Chart a New Course With Io(L)T-Enabled Life Science Laboratory Business Moments

AI-Augmented Safety Vigilance

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

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 optimize detection, AE intake from new data sources such as real-world data (RWD), triage and reporting to regulatory authorities.

Why This Is Important

Safety cases will increase in the long term due to the availability of RWD, complexity of products and therapies with biologics, cell and gene therapies (CGT), competing product launches, and aging populations in Europe and North America. This increase will continue to apply tremendous pressure on IT teams to look for optimization solutions. New technologies such as AI can optimize safety intake and processing in more integrated safety platforms.

Business Impact

With the steady rise in safety cases, there has been a collective realization that the current process will become difficult to sustain; and change is needed. Cloud-based AE processing solutions can generally cope with the new volume of cases, but costs continue to run beyond yearly projections. New technology solutions can provide expanded case throughput capability and more efficient digital approaches to better position life science companies to handle the subsequent increase in case load.

Drivers

- Constant 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 as insufficient. They are requesting life science companies to 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 potential influx of AEs due to RWD, AI tools are now both required, available and able to further enhance and automate signal detection, AE medical coding, case triage, routing and form autocompletion.
- Due to factors like the COVID-19 pandemic influencing both a rise in safety cases and increased scrutiny in safety vigilance by life science leadership, we place this innovation profile at the peak of hype this year.

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.

User Recommendations

- Select SaaS cloud deployments of AERs and case intake and triage solutions, as 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.
- Look 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

Advera Health Analytics; ArisGlobal; Ennov; Genpact; Oracle; RxLogix; TCS; Veeva Systems

Gartner Recommended Reading

2021 Business Drivers for Life Science CIOs

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Market Guide for Life Science Regulatory Information Management Solutions

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

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

Clinical Data Analytics Platforms

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Emerging

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 manage separate systems as a single solution. With the upward trend of more-complex trial types, these solutions can eliminate data silos and make data more transparent, supporting trial builds, normalizing metadata and providing data-driven insights during trial conduct.

Business Impact

Clinical data analytics platforms provide a foundation for more-advanced technologies and capabilities. Business areas benefited include:

- Risk-based and centralized monitoring enabling risk identification for study, site and subject
- Subject safety surveillance and impact on clinical endpoints
- Clinical data workbench capability, including data cleansing and SDTM conversion
- Clinical data library management and study setup optimization
- Data science features for statistical analysis of trial data

Drivers

- Life science companies can accelerate trials through the use of modern, cloud-based data and analytics solutions that have been prepackaged and verticalized for clinical development. These modern solutions combine the traditional relational data model approach with nonrelational data lakes 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. Clients seek new data and analytics toolsets to enable more seamless and transparent links between 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. Platforms also extend capabilities with novel technologies like AI and semantic knowledge graphing, enabling data insights and optimization that are still being explored by clinical teams.
- The implementation of clinical data analytics platforms is expected to blur the boundaries between departments, break up data silos, democratize data analytics and accelerate 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 at the peak of hype this year.

Obstacles

- Although life science companies are digitalizing, many paper processes remain, particularly within clinical operations. Moving toward clinical data analytics platforms in this area requires a vision and push from IT leaders to overcome the prevailing operations culture and legacy approaches.
- Many companies have data warehouses for reporting purposes, and are not yet familiar with the rapid advances in data analytics and data operations solutions, leading to an undervaluing of investments in these platforms.
- Trial processes are often still driven by paper or content-workflow-driven approaches. Moreover, data sources are not yet available to be leveraged by these new data and analytics platform solutions for insights.

User Recommendations

- Work with clinical leaders to select an approach. You can acquire a vertical or horizontal vendor solution that includes the requisite LDW elements that can be contextualized for data management and operations; build out the existing technology stack to expand organization capabilities beyond an existing data warehouse, and layer in new visualization technology, APIs, data laboratory capability and other desired business features; and 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 IT core 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

eClinical Solutions; EDETEK; Entimo; IQVIA Technologies; Remarque Systems; Saama; Snowflake for Life Science; Sycamore Informatics; ThoughtSphere

Gartner Recommended Reading

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

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

Market Guide for Life Science E-Clinical Platforms

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

RWE in Clinical Research

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

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 RWD domains collected from multiple data sources, which predominantly consist of insurance claims data, electronic health records, biobanks, and patient and disease registries.

Why This Is Important

RWE potential continues to expand in clinical development. In past years, life science (LS) companies used RWE more commonly for commercial purposes. More recently the data has shown increasing promise in new use cases, prompting vendors to create packaged solutions for clinical research. RWE generation is primarily important in a time when precision medicine is becoming increasingly relevant to LS where the focus has shifted to rare-disease and oncology drugs.

Business Impact

Using RWD to develop RWE can support conclusions about products, treatment effectiveness and safety. Furthermore, LS companies can improve clinical study design for postmarket studies and new studies by using RWD treatment data to refine study endpoints and patient subpopulations. RWE can also provide real-world perspectives on patients with comorbidities who may have been excluded from the clinical trial. Increasingly, RWE is being used to support market authorization from regulators.

Drivers

- As precision medicine is gaining a lot of traction, RWD treatment data 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 companies must make to regulators when demonstrating the need for a new treatment.
- Leveraging RWE conclusions can assist with preregulatory approval by supporting the economic case for a new product, or demonstrating status as an orphan drug.
- 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.
- The hype surrounding RWE continues, with more players and solutions available to support both evidence and outcome measurement using RWE. In December 2018, the FDA released the "Framework for FDA's Real-World Evidence Program," and then released a draft guidance in May 2019, entitled "Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics." This serves to accelerate RWE by signaling to companies that RWE can be used in regulatory approvals, and by providing a framework to do so.

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 regulatory authorities' acceptance and adoption of evidence drawn from RWD.
- Data quality remains a constant concern. RWE is based on RWD that 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.
- Although currently at the peak of hype, Gartner positions RWE in Clinical Research as moving down the slope into the Trough of Disillusionment, as more life science companies begin to experience challenges due to data quality, and a lack of data depth and breadth from available RWE providers.

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. LS companies can have measurable impact when they can draw clear conclusions, or RWE, from high-quality RWD sources.
- 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 as a service” 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; Practice Fusion; Tempus; TriNetX;

Gartner Recommended Reading

2021 Business Drivers for Life Science CIOs

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: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Clinical Development Automation

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

Definition:

Clinical development automation uses off-the-shelf process design and automation tools, such as robotic process automation (RPA) or business process modeling (BPM), to optimize processes in clinical development. BPM tools provide graphical UI for building application middleware. RPA tools automate manual tasks or processes for non-IT personnel, link to external systems and add automation to legacy systems. Gartner now collectively refers to these solutions as low-code platforms.

Why This Is Important

Automation technology in clinical development, including BPM and RPA, enables business and IT teams to optimize older technologies, inefficient processes and labor-intensive workflows. BPM puts process design into a low-code/no-code environment, enabling business teams, facilitated by IT, to build the processes they need to operationalize. RPA provides a means to automate non-value-adding tasks, allowing teams to focus less on task execution and more on task planning and strategy.

Business Impact

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

Drivers

- As business operational excellence and efficiency increasingly become top priorities within clinical development, both technologies come into focus with their potential to integrate with existing processes and automate information workflow. Gartner predicts that by the end of 2022, 50% of the top 100 life science companies will have deployed some form of RPA. RPA bots can run continuously, are easy to scale, significantly reduce processing cycle time and deliver associated cost savings.
- BPM and RPA technologies offer opportunities for business process automation, with BPM tools often morphing into process automation and low-code solutions over time. However, IT and business leaders should not use these solution types for the same problems, as RPA is intended for process automation while BPM is meant for process orchestration.
- The advent of intelligent BPM (iBPM) that can utilize an AI hub has raised the stakes for many clients. iBPMs and low-code/no-code platforms with enabling AI engines continue to drive innovation and expand capabilities, opening up new and more flexible automation options for both business and IT leaders in clinical development, and adding to existing hype.
- With RPA, BPM, iBPMs and low-code/no-code platforms maturing rapidly, this innovation profile has moved quickly over the hype curve as IT leaders discover the limitations of these tools and now begins moving down the slope into the Trough of Disillusionment.

Obstacles

- Most RPA and BPM end users struggle with scaling the technology once POCs have concluded, because they encounter issues with poorly documented processes, organizational politics and IT governance.
- Scaling RPA 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 time is spent wisely when assessing these opportunities.
- 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.

User Recommendations

- Run POCs with RPA and BPM 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, and move into POC and implementation when project assessment determines a good fit.
- Apply process reengineering to stack and sequence activities that can be automated by the bot, with an activity preparation step added before and a quality check added afterward.
- Evaluate the ease of scripting or the level of coding needed to complete working scripts and applications. RPA and BPM purchasing occurs either directly from the software provider or through consulting partners and system integration specialists. RPA contract alternatives include annual or perpetual license per bot or sometimes a consumption-based pricing model, whereas BPM tools are generally sold by seat user licenses for the platform.

Sample Vendors

AODocs; Appian; Automation Anywhere; Conduent; DXC Technology; Genpact; MSB Docs; UiPath

Gartner Recommended Reading

2021 CIO Agenda: A Life Science Perspective

Market Guide for Life Science Regulatory Information Management Solutions

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Life Science CIOs Reduce Runaway Costs With Innovative Safety Vigilance Technology

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

AI in Clinical Development

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Emerging

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) and deep learning (DL), natural language processing (NLP) and natural language generation (NLG), 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, NLG and AI-enabled advanced analytics as core capabilities now being used in specific use cases in clinical and regulatory, such as medical coding, medical imaging, safety signal detection and protocol optimization. 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

- 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 often requires sophisticated governance, processes, culture and data science teams to execute. Often, technology teams successfully conduct 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, and 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.

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 capability must run in parallel with AI technology acumen, so leverage hosted AI services, and build capability through both internal and contract resources. Use internal resources to build on a data science or ML platform, and purchase or rent software solutions from “niche” or industry-specific vendors.

Sample Vendors

DataArt; EPAM; IBM Watson Health; Innoplexus; IQVIA Technologies; Mendel.ai; SciBite

Gartner Recommended Reading

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

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

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

AI in Early Drug Research

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Artificial intelligence (AI) in early drug research represents the use of AI disciplines to optimize aspects of early R&D and scientific research activities. This umbrella profile covers machine learning (ML) and deep learning (DL), natural language processing (NLP) and generation (NLG), and AI-enabled advanced analytics to evolve drug discovery and related scientific, molecular and biologic leads before next-stage clinical phases of R&D.

Why This Is Important

AI in early drug discovery is a fast moving area. It combines ML, DL, NLP, NLG and AI-enabled advanced analytics as core AI capabilities that are being used in a variety of scientific, research and informatics areas. Different kinds of AI are being bundled by both vendors and life sciences organizations to deliver enhancements in drug discovery and early research. AI is exploding within this space, and the number of application areas that have moved from POCs into production is accelerating.

Business Impact

R&D application areas with impacts on speed, quality and costs include:

- NLP for publication search
- Causal ML for preclinical toxicity testing
- Semantic knowledge graphs for biomarker research
- Advanced text analytics for experimental protocol optimization
- Deep learning for molecular structure modeling
- Knowledge graph creation for key opinion leaders
- Advanced search and curation for research metadata
- ML and NLP for target identification and discovery
- Using neural networks and ML for repurposing compounds

Drivers

- AI in pharma research, although still extremely hyped, is establishing a track record for accelerating drug discovery activities and reducing the time to preclinical phases. In some organizations, use cases, like scientific searches, lead selection and toxicity predictions, have reduced precious time for processes that previously took years down to weeks or months.
- R&D IT leaders understand there is truth behind the hype. AI in these areas can increase efficiencies and, thus, reduce both costs and the timeline to achieve R&D milestones and improve confidence in the R&D portfolio. AI tools will enable R&D organizations to be more insightful and achieve faster decision making.
- Adoption continues to accelerate. Most large life science organizations have already built out ML and data science capabilities, including platforms and low- and no-code developers' tools for researchers. In contrast, smaller life science firms often bring in AI capabilities via partnerships with academic research organizations, biotechnology companies, or IT and vendor partners that offer as-a-service models.
- High-value use cases continue to evolve and mature. Aspects of AI, such as ML and DL, can enable better predictive capabilities based on patterns in static data supplemented by ongoing learning from evolving datasets including real-world data. This learning typically validates or invalidates assumed relationships or enables the discovery of new ones. Other types of AI, such as NLP, enable the structuring of large unstructured datasets, making sense and order from scientific research observations, enabling the automated discovery of previously hidden insights.

Obstacles

- Quality and business leaders will struggle to overcome challenges with the validation of AI processes as new data formats and scientific datasets become ML-ready. Therefore, we position this profile sliding down into the Trough of Disillusionment as IT and business partners wrestle with the difficulties of AI.
- Many organizations remain challenged in building up a bench of AI experts to support initiatives. R&D, informatics and IT teams must continue to develop governance, skills and the technology platforms to drive business success in AI.
- With so much AI being driven into individual groups of scientists by vendors, there is a high probability of competing platforms, vendor management issues, validation challenges and governance issues that will require orchestration and ongoing mediation.
- Many R&D groups apply AI in isolation and will see difficulty in expanding AI capabilities across research platforms. Many clients continue to report that their initial POCs are not scaling easily.

User Recommendations

- Align specific technologies and datasets with the associated research and drug discovery business activities to succeed with AI. R&D IT leaders must evaluate potential applications in specific disciplines and specify the leading technologies and vendors with associated competencies.
- Develop data science and engineering capabilities in parallel with AI technology acumen. Resourcing, technical abilities, management focus and investment, maturity and culture are major elements to consider when making the decision to develop AI capabilities.
- Leverage hosted AI services, and build this out with a blend of internal and contract resources.
- Build AI capabilities on a data science or ML platform.
- Purchase or rent software solutions from “niche,” industry-specific vendors.
- Use consultants to build what you want.

Sample Vendors

Dassault Systèmes (BIOVIA); Databricks; Google; IBM; KNIME; Microsoft; Palantir; RapidMiner; Vyasa Analytics

Gartner Recommended Reading

Life Science CIOs, Accelerate Early-Stage Discovery Research With New Applications of Artificial Intelligence

A Framework for Applying AI in the Enterprise

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

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

Blockchain in Life Sciences

Analysis By: Andrew Stevens, Michael Shanler

Benefit Rating: Transformational

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

Definition:

A blockchain is an expanding list of cryptographically signed, irrevocable transactional records shared by participants in a network. Each record contains a time stamp and reference links to previous transactions. A blockchain is one architectural design of the broader concept of distributed ledgers. Blockchain in life sciences is contextualized for the biotechnology, pharmaceutical and medical device sectors for use cases where value exchange transactions are sequentially grouped into blocks.

Why This Is Important

Primary applications of blockchain technologies in the life science industry include anticounterfeiting (serialization), genomic and/or clinical data sharing, and materials transfer. It is a popular strategy topic with Gartner clients.

While blockchain is still hyped across many industries, the life science industry continues to be slower than others to develop use cases into production.

Business Impact

- Blockchain and distributed-ledger concepts hold the promise of transforming life science industry operating models; however, these transformations are still widely unproven at scale.
- Blockchain will enable efficiencies for reaching new customers, extending relationships with supply chain partners, better quality and more complete links between events, and it should expand the boundaries of traditional life science businesses.

Drivers

- Across 2020, there were a growing number of active blockchain projects within the life science industry.
- 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, among others.
- Blockchains could have the potential to support 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

- Life science industry stakeholders are learning that blockchain-based models are difficult to scale.
- Most industry professionals have still not settled on the right type of governance to drive innovation, collaboration and the cultural shifts needed.
- 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 life science capability, and 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.

User Recommendations

- Assess the impact of change across the life sciences 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 understand 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

Blockpharma; Bloqcube; Chronicled; EncrypGen; EY; Genecoin; Nebula Genomics; Tech Mahindra; Wipro

Gartner Recommended Reading

Four Compelling Blockchain Initiative Types for Healthcare and Life Science

Predicts 2020: Life Science CIOs Must Digitalize for Business Growth

Sliding into the Trough

Wearable Devices for Clinical Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: Less than 1% of target audience

Maturity: Emerging

Definition:

Wearable devices for clinical trials are biometric and environmental monitoring systems that trial sponsors integrate into a clinical environment to support data capture. Generally these are health and wellness devices that measure subject health across a continuous time series, collecting patient data that is sent via IoT or Bluetooth connectivity to electronic data capture (EDC) systems or electronic health record (EHR) data repositories.

Why This Is Important

The pandemic has increased investment into virtual technologies, and wearable devices for clinical trials is no exception. With recent improvements to usability and data connectivity, along with the availability of vendor offerings, use of wearables on trials becomes easier to manage and deploy. Wearables enable continuous monitoring that provides greater insight into patient health, as well as enabling patient-centric approaches that lead to improved trial recruitment, retention and completion.

Business Impact

Wearable devices in clinical trials are an opportunity to better inform and engage patients, collect treatment insights and outcomes, and improve the data quality going into e-clinical systems. Wearables allow trial leaders to continuously monitor subject health, which enables new insights, more sensitive measurements of treatment outcomes, and more responsiveness to health issues. Smartphones can facilitate data collection, enabling easier consent, education, and engagement in the trial.

Drivers

- Advancements in this space, such as the FDA's digital health software precertification program, has helped to drive adoption, most notably with devices from Apple, Fitbit and Samsung during the agency's pilot. In September 2020, the FDA issued revised guidance and updates about their product life science approach, and more than nine firms are participating in 2021.
- There have been many startups and smaller companies driving hype by achieving notable successes, connecting wearables with data analytics and AI to build 510(k)-approved digital biomarkers that would accelerate the speed from sensor to insights on trials.
- 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 (ARK) and the Android ResearchStack have made the use of mobile-connected sensor data even more accessible for use on trials.
- With the continued progress and increase in POCs with use of wearables on trials, we see this innovation profile moving past the Peak of Inflated Expectations this year and heading toward the Trough of Disillusionment.

Obstacles

- The complex chain of data flow that must be validated for trial use remains a challenge for IT leaders. Each device contains their own specific attributes that must be tested and validated individually, not to mention the large volume of monitoring data that must be captured and analyzed for insights to inform the trial endpoint.
- There is continuing negative sentiment around clinical wearables that could slow adoption, with clients discussing the cost barriers, provisioning challenges and lack of vendor plug-and-play services that could simplify incorporation of wearables into trials.
- Other challenges include GxP validation, data integration, battery life and development of clinical insights from large quantities of biosensor data.

User Recommendations

- Work with clinical development, marketing, regulatory, security, privacy and legal teams to outline the new business opportunities that enable wearables and the wearable ecosystem for handling and processing data. It is important to 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 management of clinical wearables on trials. Wearables deployed by study teams for eCOA 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 preintegrated wearables for an expanding set of trials in multiple therapeutic areas.

Sample Vendors

ActiGraph; AliveCor; Apple; Current Health; Fitbit; Garmin; Koneksa Health; PhysIQ; Shimmer; VitalConnect

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World DataUse the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Business Moment: Digitalized, Remote Clinical Trials for Pharma

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Mobile Lab Apps

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Mobile lab apps enable scientists and researchers to create and consume electronic laboratory data via mobile applications and grant access via smartphones, tablets, and other connected devices. These purpose-built applications address laboratory science, process, experimentation, quality control and informatics.

Why This Is Important

Many laboratory automation, electronic lab notebook (ELN) and laboratory information management system (LIMS) providers support web enablement that allows user access to existing systems via mobile devices such as smartphones and tablets. While true mobility has been hampered by ill-conceived layouts, devices incompatible with sterile or highly regulated environments, and difficult screen sizes, mobile-enabled lab apps represent a chance to improve user experience and productivity.

Business Impact

There are multiple opportunities for mobility to have an impact in the laboratory on lab and quality efficiencies, research innovations, and lab logistics. It can lead to strategic initiatives for improved operational efficiencies, quality and innovation. Use of mobility can enable employees unfettered access to systems, around the clock, supporting productivity. It can enable collaboration beyond the firewall, particularly when conveniently deployed onto personal devices.

Drivers

- Vendors have started to release a plethora of lab capabilities for smartphones and tablets such as data review, instrument control, and operational analytics. More laboratory and scientific informatics providers have released specific cloud-native or progressive web apps with purpose-built mobile interfaces.
- The majority of enterprise informatics vendors are now marketing mobile applications. Many vendors have started to use HTML5 to facilitate adoption in the mobile laboratory space. Gartner expects this space to evolve quickly as the remaining ELN and LIMS providers deploy solutions.
- The number of science-based apps that are relevant to the industrial laboratory has exploded. As these apps become more powerful and sophisticated, and have better integration with existing laboratory automation and informatics systems, the adoption rate will increase.

Obstacles

- Most companies are reviewing mobile security, as it relates to potentially patentable information and sensitive data being stored on personal mobile devices.
- Many clients report that these applications are often driven at the laboratory level with little oversight from corporate IT, raising the potential of noncompliance and other challenges from a lack of IT involvement.
- From a vendor perspective, the possibilities are endless, but clients report difficulty in meeting the initial promise of these solutions. For these reasons we position lab app mobility in the Trough of Disillusionment.

User Recommendations

- Explore with laboratory staff how both personal and company-issued mobile devices are used today in the laboratory, in the office and beyond the firewall.
- Perform a preinstallation assessment with business teams to determine if mobile apps and software access via mobile devices for the laboratory are compatible with work processes, security, compliance, and culture.
- Work with business leaders to prioritize investments for mission-critical apps that have clear alignment toward innovation, collaboration, quality, compliance, effectiveness and traceability, as well as alignment with inventory visibility initiatives.
- Engage supplier R&D groups actively for their input into the next iteration of mobile apps. Many vendors actively seek customer participation to help guide the design of such systems and inform their app roadmap.

Sample Vendors

BioData (Labguru); Dassault Systèmes; LabArchives; METTLER TOLEDO; PerkinElmer; Sartorius; Tecan; Thermo Fisher Scientific

Gartner Recommended Reading

Key Considerations When Building Web, Native or Hybrid Mobile Apps

3 Reasons Mobile Apps Fail

JavaScript: A Single Language for Web, Mobile and Microservices Apps

Clinical Trial Data Transparency

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

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 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 CTDT policy is several years old, the FDA completed their CTDT pilot program last year 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 GDPR and the call for personal data protections, IT leaders must ensure proper patient data anonymization and that patient personal data is secure.

Drivers

- 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 motivates 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 this profile quickly through the trough 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 General Data Protection Regulation (GDPR), and concerns about subject reidentification has dampened the CTDT hype.

User Recommendations

- With regulatory leaders, address organizational requirements to disclose clinical data by making foolproof anonymization and governance, risk and compliance (GRC) activities core to any trial process and system; and keeping the degree of transparency and scope of information central in determining the anonymization approach (e.g., software, outsourced professional services, 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 that meets disclosure, cybersecurity and anonymization requirements for clinical reports and patient data. With data privacy concerns on one side and ethical questions on the other, you should balance carefully to avoid exposure from disclosure of too much data to not enough data, and ensure processes and solutions are in line with guidance and regulations.

Sample Vendors

Anju Software; ArisGlobal; Certara; d-wise; SAS; TrialAssure; TrialScope; Xogene

Gartner Recommended Reading

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Navigate a Path to D-Clinical With the Digital Clinical Trial Landscape and Definition of Terms

2021 CIO Agenda: A Life Science Perspective

Market Guide for Life Science Regulatory Information Management Solutions

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Augmented Analytics

Analysis By: Rita Sallam

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

Augmented analytics uses AI and ML techniques to automate data preparation, insight discovery, data science, and machine learning model development and insight sharing for a broad range of business users, operational workers and citizen data scientists.

Why This Is Important

Many of the activities associated with preparing data, finding patterns in data, building models on complex combinations of data, and sharing insights with others, remain highly manual. This limits user adoption and potential business impact.

Business Impact

- Augmented analytics is transforming how and where users interact with analytics content as it has become a core component of most analytics and BI and data science platforms.
- Insights from advanced analytics — once available only to skilled analysts, citizen data scientists and data science specialists — are now in the hands of business analysts and a broad range of decision makers and operational workers across the enterprise — the augmented consumer — driving new sources of business value.

Drivers

- Organizations increasingly want to analyze more complex datasets combining diverse data from across the enterprise as well as from external sources. With an increasing number of variables to explore in data harmonized from many diverse datasets, it is practically impossible for users to explore every possible pattern combination, and even more difficult to determine whether their findings are the most relevant, significant and actionable. Expanding 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.
- Augmented analytics capabilities are increasingly mainstream features of data preparation, analytics and BI platforms and data science and machine learning tools. They are also being embedded in enterprise applications and domain and industry specific solutions. This is delivering insights most relevant to a broad set of application users to improve decision-making and actions.
- Dynamic data stories are an example of a combination of augmented analytics features used to automate insights. This combines augmented analytics with natural language query (NLQ), natural language generation (NLG) and anomaly detection into dynamically generated data stories delivered to users in their context. This type of user experience will reduce the use of predefined dashboards for monitoring and analysis and increase the use of augmented analytics.

Obstacles

- Trust in autogenerated models. Organizations must ensure that the augmented approach is transparent and auditable for accuracy and bias, and that there is a process to review and certify analyses created.
- Training. With more automation comes greater user responsibility and the need for more, but different user training.
- Collaboration. Establishing a collaborative environment, pairing expert data scientists with nonexperts across the analytic life cycle will be essential to capitalize on the skills of all parties.
- User outreach. Using augmented analytics not only to support new and less expert analytic users, but also to shorten time to insight for more expert users.
- Ecosystem. It will be critical to build an ecosystem that includes not only tools but also data, people and processes to support the use of augmented analytics.

User Recommendations

Data and analytics leaders looking to make analytics more pervasive should:

- Identify the personas that will benefit most from augmented analytics capabilities.
- Ensure 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.
- Assess the augmented analytics capabilities and roadmaps of analytics and BI, data science, data preparation platforms, and startups as they mature. Look for upfront setup and data preparation required, the types of data and range of algorithms supported, integration with existing tools, explainability of models and the accuracy of the findings. Also evaluate emerging dynamic data storytelling capabilities.
- 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

Microsoft (Power BI); Oracle (Analytics Cloud); Qlik; SAP Analytics Cloud; SAS; Tableau; Tellius; ThoughtSpot; AnswerRocket; Igenius; Conversight.ai; TIBCO Spotfire

Gartner Recommended Reading

Magic Quadrant for Analytics and Business Intelligence Platforms

Critical Capabilities for Analytics and Business Intelligence Platforms

Tool: Visual Guide to Analytics and Business Intelligence Platform Capabilities

Top Trends in Data and Analytics for 2021

How Augmented Analytics Will Transform Your Organization: A Gartner Trend Insight Report

Genomics Medicine

Analysis By: Sachin Dev, Michael Shanler

Benefit Rating: Transformational

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

Genomics medicine technology enables the use of genetic information for medical research and treatment (e.g., diagnosis, therapy, risk management). It is a component of precision medicine and focuses on leveraging genomic data and insights derived to treat patients. Technologies include gene sequencing, variance calling, high-performance computing, artificial intelligence (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

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 decision.
- Specific and targeted diagnostic tests based on a patient's genetic profiles eliminates or reduces extra cost.
- Precision care for prenatal and genetics-directed chemotherapy.
- The business and population health impact of genomics medicine are substantial and a key component of precision medicine.

Drivers

- Healthcare and life science organizations with notable success in genomics medicine demonstrate many genomic programs and studies to utilize the molecular-level insights, from genes to personalize treatments, and improve healthcare outcomes. The emergence of a new class of next-generation sequencers (NGS) is enabling vendors to bring new capabilities at end-user level, broadening the utilization of genetic information across multiple clinical specialties (such as chronic disease management) and beyond oncology.
- Technology and services related to genomics are steadily progressing as the cost of genomic sequencing continues to go down and as research has identified more practical uses in diagnosing and treating patients. For example, companion diagnostics is rapidly expanding in biopharma whereby an individual's receptivity for a specific medicine is measured by matching a specific genetic biomarker. Research in the field is investigating many other uses of genomics, ranging from genetic testing for rare and undiagnosed diseases, gene therapy, testing for treatment receptivity, precision cancer treatment and gene editing to "correct" for abnormalities, among others.
- Adoption will continue to grow as researchers identify more correlations between genetic biomarkers and health, disease prevention and treatments. Advances in gene discovery and specific drugs that target them (PGx) will have the most direct impact. The accelerated adoption rate of electronic health records (EHRs) now pervasively deployed throughout the world creates rich sources of health data ripe for epigenomic exploration. Data analytics, including AI techniques such as machine learning, now have great potential to aid in new discoveries leveraging that data. For these reasons, we move this profile further along on the Hype Cycle with five to 10 years to the mainstream.

Obstacles

- Progress in genomic medicine proceeds at the pace of scientific discovery. It requires decades of extensive research to translate genomic data into actionable clinical practices.
- It is equally challenging to make this knowledge actionable by physicians, as many are not well-trained to incorporate an actionable insight from genomics within their workflows.
- Although new genetic markers are constantly being discovered, they require frequent reanalysis of patients' sequencing data that hinders the development and regulatory approval of new tests, drugs and therapies.
- Researchers, life science and healthcare providers demand genomics raw sequencing data, analysis and recommendations from sequencing data are integrated in their EHR system. 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. This includes the ability to record, store, secure and access genetic marker data from patients, and their ancestors and family members, within the individual patient's record.

Sample Vendors

DNAnexus; Genedata; Helix; IBM Watson; Igenbio; Illumina (GenoLogics); L7 Informatics; NantHealth; Sema4; Seven Bridges

Gartner Recommended Reading

Healthcare Provider CIOs' COVID-19 Cost Optimization Action Plan

Cool Vendors in Life Sciences

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

3D Bioprinting for LS R&D

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Early mainstream

Definition:

3D bioprinting for life science R&D is the use of 3D printing technologies to understand disease and drug responses in lifelike 3D environments. It's use cases span printed cells, impregnated hydrogels, DNA, proteins, chemicals and biologics. It is primarily used in drug discovery, metabolism, cell-cell interaction and cell cultures; target identification assays; autologous and allogeneic cell therapies; and testing new techniques for generating vasculatures, tissues and organs.

Why This Is Important

- 3D printing of cells on scaffolds for assays will increase rapidly over the next three to five years. However, delivering quality 3D printing biomaterials, services and equipment today still requires as much art as it does science. Hence, variable quality and irregular supply issues will temper the “hype.”
- Bioprinting will not necessarily replace existing assays. In most cases, it complements existing ones.

Business Impact

- 3D bioprinting leads to new scientific insights. R&D groups need lifelike assays to improve leads going into human trials.
- The 3D assays are often reported as more lifelike than traditional 2D, cell-adherent models.
- This technology helps researchers find new discoveries and develop innovations for drugs and therapies. This includes advancing the science of complex organ development and tissue regeneration (such as skin, cartilage, bones and blood vessels).

Drivers

- In 2020, a significant amount of research was generated by the academic and industrial communities using both scaffold-based and scaffold-free printing. That progress validated the long-term potential of this technology.
- The mainstream media has mostly covered bioprinting for studying complex organ development and tissue regeneration (such as skin, cartilage, bones and blood vessels). However, the bulk of the activities within the life science industry are instead targeted at improving assays for drug toxicity in vitro organ models, organ-on-chip studies and cosmetics assays. As more science is developed and proven, the 3D bioprinting market is expanding, and the number of bioprinting use cases and customers is increasing.
- There are now nearly 50 different vendors and service providers selling automation, consumables or contract services for 3D bioprinting, and over a dozen platform vendors. Thirty of these vendors have incorporated in the last 10 years. Many of these companies may have a strong foundation in science.
- R&D teams have already started to leverage information generated from assays run in these environments from early-stage drug discovery through later-stage pharmacokinetic analysis.

Obstacles

- High-quality and reliable value chains for emerging technologies are not established overnight. While more small and inexpensive benchtop 3D printing instruments have become available to researchers, the support models for end users are inadequate, which inhibits end-user progress.
- Experimental information from bioprinting will confirm some existing hypotheses, but will also conflict with other findings. We expect a long trial-and-error process with bioprinting as the informatics components improve.
- While 3D bioprinting accelerates, life science organizations continue to be frustrated with the lack of support between the instrument and informatics interfaces. Many Gartner clients report vendors positioning future capabilities for products and services, while currently being saddled with quality and delivery issues. Even though adoption has increased, for these reasons, bioprinting is now early mainstream, and is positioned as slipping further into the Trough of Disillusionment.

User Recommendations

- Close the loop between the physical testing and informatics-based simulations to improve the outcomes from 3D bioprinting by building workflow automation and data management tools that confirm building of 3DP material and endpoints or analytical findings.
- Work with R&D IT or informatics teams to define the data repositories and platforms that will be used to perform confirmation testing prior to acceptance for any new 3D bioprinting technology.
- Develop a plan to harmonize and/or scale 3DP bioprinting methodologies with a focus on analytics to compare 3D bioprinted methodologies versus previous legacy assay approaches.

Sample Vendors

Allevi; Aspect Biosystems; CELLINK; EnvisionTEC; Hangzhou Regenovo Biotechnology; nScrypt; Organovo; Poietis; REGENHU

Adaptive Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 1% to 5% of target audience

Maturity: Adolescent

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 and conditions, more complex and flexible trial approaches are needed to demonstrate efficacy of new treatments. Adaptive trials continue to make headlines with their ability to enable trials with more variable scenarios, flexible timelines, varied dosing and nonlinear approaches. With the disruption of standard trial operations during the pandemic, adaptive trials have only grown in importance.

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.
- The COVID-19 pandemic is accelerating adaptive trial adoption as trial leaders experiment with more “pandemic-proof” decentralized trial designs.
- With major vendors such as Oracle and Medidata accepting adaptive trial approaches by having built-in capabilities on top of their platforms, adaptive trials will accelerate.

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 the business and technology partners have some 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 capability for adaptive trial types.
- Discuss adaptive trials with clinical groups to learn how adaptive trials will likely stress current e-clinical systems. Review the way these 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

Bioclinica; Cytel; ICON; IQVIA Technologies; Medidata; Statsols; Parexel

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

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

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

SaaS LIMS

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: Moderate

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

A SaaS laboratory information management system (LIMS) is a vendor-managed laboratory informatics solution that focuses on sample- and process-centric laboratory testing, spanning results log-in to certificate of analysis issuance. Laboratory test data is used to support key processes, including R&D, manufacturing and clinical research. SaaS LIMS is purchased via a monthly subscription model.

Why This Is Important

Many life sciences organizations have only recently become more comfortable with having their critical laboratory data in the cloud. Newer organizations are gravitating toward pure-cloud or cloud-enhanced solutions whenever possible, which is closer to true SaaS offerings. Gartner expects the percentage of on-premises systems to continue to fall, as the cloud-based LIMS solutions improve, while cost pressures continue to drive operational effectiveness in the laboratory.

Business Impact

Many IT groups are driving “cloud first” IT strategies to better globalize lab capabilities. True SaaS-based LIMSs significantly reduce capital costs and fit with trends toward rationalizing legacy systems and reducing overall IT complexity, support and maintenance. Depending on the life cycle of existing applications, the ROI for hosted services is favorable, especially when legacy systems are at the end of life and implementation and are in smaller or midsize organizations.

Drivers

- With organizations intent on “going paperless,” improving quality, creating knowledge platforms and drive collaboration, SaaS LIMSs will continue to see wider adoption and drive “digital lab of the future” strategies.
- Customers that do not have a legacy system, as well as smaller and midsize businesses and institutions, have a hunger for SaaS models as a means to lower cost and maintain a smaller IT profile.
- The trade-off of pursuing SaaS LIMS is some reduced flexibility within the laboratory as LIMS vendors, integrators and delivery firms further refine their services.

Obstacles

- Larger organizations have been slow to adopt SaaS LIMSs due to high system complexity and historical customization required for their business processes.
- Most SaaS LIMS are more amenable to nonregulated industries or lab processes that are at the lower end of the spectrum for complexity.
- While many vendors market cloud-hosted LIMS as SaaS LIMS, they typically are not fully transparent in the marketing of their cloud architecture or their subscription pricing, impeding adoption.
- SaaS technologies are becoming more popular as products get refined; however, systems that have extreme quality and integration requirements are limiting adoption.
- While cloud and SaaS are becoming more central to CIOs’ strategies for lab processes, many organizations encounter difficulties satisfying good x practice (GxP) validation, regulatory, intellectual property performance, and risk-related requirements. We place the technology near the middle of the Trough of Disillusionment on the Hype Cycle.

User Recommendations

- Pursue SaaS LIMS only if you have a strategy for cloud validation. GxP environments for labs, manufacturing and clinical will require extra care, upfront discussions, revised quality policy and planning to support risk-based validation, security, compliance and controls. These systems are not yet widely implementation-ready for manufacturing environments without a revised GxP validation process and support infrastructure.
- Explore SaaS-based LIMS opportunities if the application does not require customization, the instrument integration needs are light, and the system does not need to support a complex environment (e.g., R&D).
- Investigate the degree of elasticity and multitenancy before investing. Solution vendors often use the terms “SaaS” and “cloud” interchangeably. This creates a lot of confusion within the marketplace, as most LIMS vendors sell single-tenant, managed hosted environments via partnerships, and not multitenant, shared environments.

Sample Vendors

Abbott Informatics; AgileBio; AgiLab; Blaze Systems; CloudLIMS; EuSoft; LabVantage Solutions; LabWare; LIMSABC; Thermo Fisher Scientific

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science CIOs’ Plans for the Lab of the Future Must Enable Digital Business

Life Science’s Lab Informatics Digital Criteria to Separate Vendor Leaders From Laggards

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 involves applying novel artificial intelligence (AI) and analytics technologies 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 connect with recruiters for clinical trials. RWD sources can include electronic health record and trial 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 (LSCs) 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, monitoring social media, and multichannel marketing, have also accelerated recruitment and simplified this problem.

Business Impact

- Up to 70% of clinical trials are delayed due to poor enrollment. Other 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 who 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 on social media, Google ads and traditional 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 have significantly limited 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.

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. Your strategy should also include AI optimizations.
- Evaluate investments and partnerships, as recruitment networks are frequently measured by disease prevalence, geographic reach and number of patients. Patient networks provide potential subjects, as they are more likely to have participants for diseases that are rare, chronic or debilitating.
- Use one or a combination of approaches, as each methodology applies to specific trial scenarios as defined by the protocol. When disease indicators are prevalent in claims data, consider 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

Accelerated Enrollment Solutions (AES); Antidote; AutoCruitment; Deep 6 AI; IQVIA; Komodo Health; Trialbee

Gartner Recommended Reading

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

2021 CIO Agenda: A Life Science Perspective

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges Life Science CIOs Must Deliver High-Value Analytics Solutions Using Real-World Data

SaaS ELN

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

SaaS-based electronic laboratory notebooks (ELN) are cloud subscription-based laboratory informatics solutions. They are used by laboratory staff to securely collect intellectual property, store laboratory data, exchange findings and disseminate experimental data in the R&D process. They are also used as a collaborative platform for connecting with external scientific partners.

Why This Is Important

Many life science companies have recently invested in more sophisticated, SaaS-based ELNs to support globalization and externalization strategies. These solutions enable more collaborative approaches, making data visible, and available at a more optimized cost with simplified management. As companies become more comfortable with storing intellectual property using SaaS providers, accelerated use is expected.

Business Impact

Adopting a SaaS-based ELN can reduce capital costs, increase the speed of deployment, and reduce IT complexity, especially as it relates to management, revisions and upgrades. In many cases, using SaaS-based software ultimately reduces the validation challenges, system interfaces or APIs (if available from the vendor), and has positive impacts on IT staffing and operations.

Drivers

- SaaS-based ELNs are gaining popularity due to the ease of deployment and low startup costs when compared with on-premises or hosted ELNs.
- We expect SaaS adoption to increase more rapidly as ELN technologies improve and vendors begin to either acquire (for example, Thermo Fisher Scientific acquired Core Informatics in 2017), or evolve and offer reengineered or new solutions (for example, IDBS).
- Today, Gartner estimates nearly 40% of ELNs are SaaS-based.

Obstacles

- Many users are adjusting to SaaS models and are confronted with some restrictions — namely reduced capabilities due to the configuration-only approach supported by SaaS models.
- Many older generation ELNs (deployed on-premises) were heavily customized, making transitions difficult.
- The vast majority of ELNs in use in life science manufacturing still have not migrated to cloud, due to good x practice (GxP) compliance and validation challenges. Vendors are struggling with support models for GxP.
- While the platforms are evolving, many users are struggling with promised functionalities and inflated expectations set by vendors. For these reasons, we are accelerating this innovation profile through the Hype Cycle toward the Trough of Disillusionment.

User Recommendations

- Evaluate your laboratory's needs, the depth of the vendor's domain expertise and your own internal capabilities in managing a SaaS-based ELN vendor.
- Ensure solution features are clearly aligned with business expectations to ensure successful adoption. While many vendors claim to have the same features in cloud-based products as those that are deployed on-premises, there are often differences between the packages.
- Identify cloud-based ELNs to facilitate scientific collaboration and reduce cost, particularly the smaller companies that do not have legacy systems or deep instrument integration requirements.
- Identify SaaS-based ELNs, primarily for driving collaboration with external parties or to bridge scientific groups that operate in multiple facilities.
- Investigate security, maintenance costs and update schedule before committing to a solution.
- Outline the procedures for retrieving your data and have a clear "exit strategy" when engaging a SaaS vendor.

Sample Vendors

Benchling; Bruker (Arxspan); Dassault Systèmes; Dotmatics; IDBS; LABTRACK; PerkinElmer; RSpace; Scilligence; Thermo Fisher Scientific

Gartner Recommended Reading

Market Guide for Laboratory Informatics

Life Science's Lab Informatics Digital Criteria to Separate Vendor Leaders From Laggards

Life Science CIOs' Plans for the Lab of the Future Must Enable Digital Business

Semantic Knowledge Graph

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Semantic knowledge graph for R&D comprises software and technology that enable staff to search, mine (e.g., chemical structures, text and system biology models), aggregate, and share complex life science data relationships. This includes journal texts, chemical structures, biomolecular content, clinical and scientific relationships, disease pathways, and other 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 six years the applications and infrastructures have been injected with semantic search capabilities and graphical relationship models necessary to handle scientific big data. They have also been instilled with massive cloud computing power that is needed to improve performance.

Business Impact

The use of these systems can:

- Help accelerate innovation activities.

- Expose complex relationships with 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).
- 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.
- As companies continue to expand 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 the 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; Dassault Systèmes; Exaptive; IO Informatics; LeapAnalysis; ONTOFORCE; Sinequa; Stardog

Gartner Recommended Reading

Magic Quadrant for Metadata Management SolutionsAssessing Semantic Layers to Achieve Successful Self-Service Analytics

Critical Capabilities for Metadata Management Solutions

Emerging Technologies: Data Fabric Is the Future of Data Management

How to Activate Metadata to Enable a Composable Data Fabric

RWD-Based Trials

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

Definition:

RWD-based trials use real-world data (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

RWD is becoming increasingly available for purchase or license. It is often packaged in vendor solutions and used for a variety of high-value use cases within trial operations, feasibility assessment, patient recruitment, safety vigilance and clinical research. Among the many deidentified RWD sources, electronic health records (EHRs), point of sale pharmacy data and payer claims data have demonstrated high potential as data sources useful to clinical development in RWD analytics solutions.

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, as well as increase retention and reduce overall screen failures. These benefits justify RWD investment alone, but further uses for RWD continue to emerge, including improved protocol design, study feasibility assessment, synthetic control arms, publication review and patient monitoring.
- Data-as-a-service vendors continue to innovate and engineer new solutions that resolve obstacles, such as consent management, patient anonymization and 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.

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. Also, regulations such as GDPR and concerns about patient data protection have had a dampening effect on innovation in some areas.
- 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 and structure the information within clinical databases.
- As a result of these obstacles, we place RWD-based trials as moving slowly out of the trough.

User Recommendations

- Explore how RWD can add value to the overall “digital clinical trial” by collaborating with business peers and prioritizing pilot 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 use of 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.

Sample Vendors

ConcertAI; IQVIA Technologies; Medidata; Oracle; Protocol First; SAS; Verantos, Virtusa

Gartner Recommended Reading

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

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

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

2021 Business Drivers for Life Science CIOs

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Risk-Based and Centralized Monitoring

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Adolescent

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.

Why This Is Important

RBM is the improved approach to legacy on-site monitoring practice and 100% data quality checks during trials. Using RBM, study processes and protocols are assessed for risk at the trials, site and patient levels, thus 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, in turn, leads to cost and time savings, and enables focused monitoring on 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 trial design or site selection. Well-executed RBM practices reduce the likelihood of errors created during clinical trials, improve overall safety of trial subjects and give greater visibility into clinical trial operations, which can accelerate timelines and improve overall quality.

Drivers

- 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 practice to expand the use of remote monitoring approaches. This has advanced the profile along the Hype Cycle toward the Slope of Enlightenment.
- 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 in enhancing quality control and provides better data accuracy.
- Regulatory agencies continue to evolve RBM approaches, with the FDA releasing a draft guidance in March 2019 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, such as the FDA, and from precompetitive alliances, such as TransCelerate BioPharma, helping to drive implementation.
- ICH E6 Revision 2 (R2) continues to lead trial leaders to expand risk assessment approaches. With the new revision, monitoring activities frequently include patient data monitoring as well, 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 operation approaches.

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 makes the task of centralizing data even more daunting.
- Challenges while implementing RBM 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.

User Recommendations

- Evaluate RBM tools with a focus on identifying and mitigating risks, and 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 risk identifiers for site performance and critical study data.
- Start with RBM tools provided by your e-clinical platform vendor, 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.
- Consider 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.
- Recognize that newer trial analytics tools can often provide benefits beyond the original RBM focus of on-site risk and performance, and allow deeper analysis of trial critical data and patient safety risk.

Sample Vendors

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

Gartner Recommended Reading

Life Science CIOs: Map Your Pathway to Digital Trials

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

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Market Guide for Life Science E-Clinical Platforms

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

SaaS-Regulated CSP

Analysis By: Jeff Smith, Michael Shanler

Benefit Rating: High

Market Penetration: 5% to 20% of target audience

Maturity: Adolescent

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

CIOs have increasingly adopted newer SaaS and cloud vendors over on-premises systems, to benefit from the increased robustness, security and cost advantages. This transition has been uneven across life science domains, with commercial areas leading the way, followed by clinical, regulatory, manufacturing and labs. However, SaaS-regulated CSPs are maturing quickly and include some of the most mature cloud offerings, providing a robust and flexible browser-based environment for content storage.

Business Impact

Adopting SaaS-regulated CSPs can help simplify deployments and reduce support resources, especially when content services platform as a service (csPaaS) capabilities are used. 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

- The COVID-19 pandemic has accelerated life science companies' push to SaaS-regulated CSPs, thus moving this profile further along toward the Slope of Enlightenment.
- 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 to explore 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 permeating regulatory and quality areas, taking advantage of more powerful csPaaS capabilities and robust global implementations supported by multitenant cloud deployments.
- As many of the initial obstacles to acceptance of SaaS-regulated CSPs have evaporated, and real gains begin to be realized, we place this profile moving up the Slope of Enlightenment toward the plateau.

Obstacles

- Some larger life science companies are challenged in adopting SaaS-based solutions in niche areas due to over complex processes resulting 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 then the 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 QA 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 cost projections reflect application growth under new licensing models.
- Review solutions that address all overlapping components of development, including clinical trials, quality, regulatory and contract management, when considering pure CSP deployments.

Sample Vendors

ArisGlobal; Box; DXC Technology; Ennov; Generis; M-Files; OpenText; Veeva

Gartner Recommended Reading

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Accelerate Digital Capabilities by Migrating Validated Life Sciences Applications to the Cloud

Electronic Trial Master File Strategy Alignment

Market Guide for Life Science E-Clinical Platforms

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Precompetitive Alliances

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: Moderate

Market Penetration: 5% to 20% 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 process, 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.

Business Impact

The business impacts of precompetitive alliances are broad:

- Engaging in precompetitive discussions should have positive implications for collaboratively solving IT challenges, networking and knowledge building.
- Successful engagements with precompetitive alliances should yield a reduction in IT complexity, integration challenges and burden on internal staff for validation efforts.

Drivers

- The Pistoia Alliance, which originally focused on solving data aggregation, sharing and analytics for pharma research, now has nearly 200 contributing organizations including technology and scientific startups, not-for-profit, government, academic, and small, medium and large pharmaceutical companies. Active projects in 2021 include: “Hierarchical Editing Language for Macromolecules (HELM),” “Centre of Excellence in Artificial Intelligence and Machine Learning (AI/ML),” “Controlled Substance Expert Community (CSCS),” “FAIR Implementation,” “Ontologies Mapping,” “Chemical Safety Library,” and “Map of Alliances.”
- Other examples of similar precompetitive organizations include the Allotrope Foundation, BioCelerate, Digital Therapeutics Alliance, and the Pharmaceutical R&D Information Systems Management Executives (PRISME) Forum.
- Many other foundations, organizations and institutes allow for community involvement with a focus on standards development, transparency, collaborative projects and knowledge sharing. Examples of these 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); and Clinical Trials Transformation Initiative (CTTI).
- Technology vendors are in on the action, too. Accenture, with mostly Oracle customers, has created a consortium for driving some common technologies onto its own platform called INTIENT. Veeva Systems launched Align Biopharma for developing technology standards with HCPs. Finally, laboratory informatics providers such as Thermo Fisher Scientific and PerkinElmer have created a cloud-based platform for collaborative academic research.

Obstacles

- Challenges with culture, shared investment and active participation still plague the precompetitive alliances. Sometimes participation is driven more by individuals at organizations attempting to solve issues on their own rather than coordinating sanctioned enterprise involvement.
- 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 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. For these reasons, we position the use of standards organizations, consortia and precompetitive alliances in the Trough of Disillusionment.

User Recommendations

- Encourage R&D stakeholders to explore industry community activities, especially 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; Digital Therapeutics Alliance; Pistoia Alliance; TransCelerate BioPharma (BioCelerate); Veeva Systems (Align Biopharma)

Gartner Recommended Reading

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

Product Innovation Strategies That Enable Supply Chain Purpose

COVID-19: Take Action Now on Fakes and Counterfeits

Climbing the Slope

Enterprise IP Management

Analysis By: Michael Shanler

Benefit Rating: Moderate

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Enterprise intellectual property (IP) management spans the systems that manage all aspects of IP assets, including invention disclosures, patent portfolios, trade secrets, trademarks and copyrights, as well as the operational activities associated with partnerships, agreements and licensing.

Why This Is Important

- Until recently, IP management was a manual process involving many disparate systems.
- Updating portfolios often was a spreadsheet-based exercise. However, for large companies with complex IP landscapes, this has proved to be incredibly inefficient.
- As life science companies increasingly globalize and leverage external partnerships to drive innovation, the ability to maintain favorable IP positions is causing enterprise-level IP software to become a priority for legal, R&D and financial groups.

Business Impact

- Enterprise IP solutions lead to better visibility into the maintenance costs of carrying all types of IP.
- By improving the analytics across the IP systems, financial, legal and R&D groups will have more success in streamlining activities for managing IP capital and assets.
- Having a more effective invention disclosure records (IDR) submission process and method for vetting IP positioning leads to better decisions. Submission portals expose more employees to the innovation process.

Drivers

- Many legal groups report to Gartner that organizations lack visibility into their native IP and into the costs and strategic and financial benefits of supporting IP positions. Also, continuing to maintain poor IP positions on a global basis is a costly endeavor.
- Organizations need better visibility into retiring IP in a timely manner so that they don't spend money needlessly on protections that are no longer relevant. Not all IP should be blindly protected. Rather, it should be frequently reassessed with strong visibility into future spend (for example, retired products, products that are no longer central to the business strategy and low-performing product lines).
- IP asset management companies have begun harmonizing and developing templates for end-to-end workflows involving IP. Many software providers now offer portals for IDRs to help scientists, engineers and other innovators submit new ideas into the legal process. For the most part, these systems are not yet tightly integrated with ideation software, innovation management, content management, collaboration platforms (such as Microsoft SharePoint), project (or program) and portfolio management (PPM), project management offices (PMOs) or ERP systems. However, vendors are developing APIs, which signifies growing maturity and a desire for process integration.
- These types of solutions have been used in practice for over a decade and have seen fairly wide adoption. The drivers are further accelerating use. For these reasons, we position this technology in the Slope of Enlightenment phase of this Hype Cycle.

Obstacles

- The biggest obstacle for adoption of these systems is culture. Many R&D organizations or companies that have innovation processes often have a loosely defined, manual process for capturing ideas, performing ideation and managing content associated with IP.
- In many cases, the IP is managed in file share systems, email and spreadsheets. Many groups are reluctant to change the process if they are more focused on "development" versus "research."
- There are a variety of software vendors that provide different aspects of innovation for manufacturers. Disparate systems often capture only a narrow slice of the overall process, but they market the solutions as "innovations" with confusing messaging about what the solutions actually do. This confusion in the marketplace inhibits decision making.

User Recommendations

- Evaluate enterprise IP management as an upgrade to existing patchworks of systems. IP management can be a strategic, enabling system that drives protective and financial benefits. Work with legal, financial and R&D stakeholders to understand the business impacts and process workflows for IP and outline the gaps and opportunities.
- Factor in the costs of doing nothing, and for allowing inefficient processes (for example, paying for baseless IP protection for products that have been retired).
- Explore the fit of SaaS offerings, but understand that not all organizations are ready to put IP into the cloud, and that there may be significant risk management and cultural barriers.
- Map IP processes and determine how much bidirectional visibility or integration is required with adjacent PPM, PMO, ERP, content management and collaboration systems that are associated with new product development.

Sample Vendors

Anaqua; Clarivate; CPA Global (IPfolio); GQ Life Sciences; Innovation Asset Group; Patrix; SAP

Gartner Recommended Reading

Executing on Innovation: Design the Process From Idea to Value

Your Context and Principles Are Key When Starting an Innovation Journey

Product Planning Must Move From Technology Innovation to Product Innovation

Leading Digital Product Innovation

Organizing for Innovation: Maturing From Accidental to Intentional Innovation

Innovation Management Tools for Product Development

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Innovation management tools for product development shepherds in new product and process ideas for the business. The software helps users collect, rank, store and facilitate collaboration on ideas. It supports open innovation and crowdsourced platforms where product development teams harvest valuable information from both internal groups and from external collaborative development partners and customers. It harmonizes the collection, refinement and development of new intellectual property.

Why This Is Important

- Innovation management tool vendors have broad functionality to serve a wide range of users. Hence, the adoption has increased.
- Until recently, these tools were only capable of storing and ranking ideas; however, now they can be integrated with CRM, product information management (PIM), product development, portfolio management and product life cycle management (PLM) solutions.
- As CEOs have made innovation a higher priority, these tools are moving to the center of the innovation process.

Business Impact

- This technology enables leaders responsible for the innovation process to execute with greater effectiveness and speed for commercialization.
- R&D, strategic marketing and innovation teams can use these tools to drive an automated and collaborative process.
- Innovation leaders can share information and collaborate while facilitating more transparency among functions.
- Companies that adopt these technologies see healthier pipelines, as well as an increase in downstream patent applications.

Drivers

- Vendors are adding key capabilities, such as ideation and patent drafting, which is attractive to next-generation research operations leaders.
- Technology advances allow for more efficient and faster ideation, rapid evaluation and smarter selection to support the overall innovation portfolio. Most R&D teams have increased their spending on SaaS innovation platforms.
- Within the last five years, the emergence of idea management technologies with enhanced collaboration capabilities has begun to enable and expedite the refinement of ideas. Analytics and reporting for innovation management tools are much improved, with enhanced graphics, analytics and trending capabilities. Also, the new social software features that support different functional disciplines, dispersed facilities and extended partners allow users to tag a running commentary to ideas and create opportunities for enhanced collaboration across the enterprise and beyond.
- In the next two years, Gartner believes that at least 50% of consumer goods and life science companies with innovation strategies will have elements of innovation systems in place. Additionally, easy user access to “open innovation” technologies and marketplaces is putting more pressure on user organizations to have a solid outside-in innovation process backed by the right enabling technology.
- Gartner positions this technology entering the Slope of Enlightenment, and it should reach the plateau by 2022.

Obstacles

- Simply adopting the tools is not enough. Firms need to adjust product development processes to capitalize on the opportunities these technologies enable. The original wave of innovation management technologies had overpromised capabilities that are now being offered.
- Many adjacent groups and business units struggle with building process connections with these tools, especially when innovation cultures are lagging.
- Several other software categories including CRM, PPM and PLM have elements of these tools, which can create conflicts with organizations’ architecture and competing platforms.

User Recommendations

- Examine investing in these tools when you need to accelerate innovation, particularly where you have complicated organizational structures and diverse portfolios and customers.
- Identify the tools that will fit into your R&D-oriented systems and the specific vertical you occupy within life sciences. Although other systems (CRM, PIM, idea management and PLM) can be tailored to handle elements of innovation management, they may be too complicated to adjust to dynamic workflows.
- Include key functional stakeholders (marketing, quality and operations) when outlining the deployment strategy.
- Focus on where tools can enhance synchronous and asynchronous collaboration.
- Evaluate how to use the tools with innovation boards, scientific advisory team meetings, NPD team meetings, brainstorming sessions, focus groups, patent explorations, social media monitoring sessions and social network analyses.
- Maintain a digital thread among ideas, product data and audit logs when making design changes.

Sample Vendors

Anaqua; Corel; IdealScale; InnoCentive; Inova; Jive Software; MindMatters Solutions; Planbox; Planview (Spigit); Sopheon

Gartner Recommended Reading

Executive Leadership: Innovation Management Primer for 2021

Use 3 Design Thinking Principles in Everyday Product Management to Drive Innovation

Product Portfolio Management: Aligning Strategies, Ideation and Innovation

Market Guide for Innovation Management Tools

Scientific Text Analytics

Analysis By: Michael Shanler

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Text analytics for scientific research 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 summarization, sentiment analysis, and investigation and classification of data types.

Why This Is Important

- Sorting through vast amounts of scientific information is essential for driving innovation, but is difficult without computer-assisted systems.
- Scientific information and the number of journal articles have exploded, representing a treasure trove of information for mining and graphing.
- Many large organizations have already invested in expensive and heavily customized legacy systems and services, but new systems have removed some of the complexity and allow for more agile end-user configuration.

Business Impact

- The largest impact of scientific text analytics will come from life sciences (LS) organizations, deploying them to combine extracted, unstructured data with traditional, structured data to provide a more complete view of the issue or topic.
- Data sorted by these systems can be efficiently analyzed using downstream traditional data mining or business intelligence and IP tools, unveiling new insights and opportunities.

Drivers

- R&D programs engaged in product development seek more ways to leverage insights from scientific text analytics and annotators. This is creating 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, making the technology more attractive to small and midsize engineering companies, academic institutions, contract research organizations, biotechnology companies and medical device manufacturers. Over the past few years, plug-ins that expand the utility of text analytics have been developed for a variety of scientific software applications. New natural language processing (NLP), context enrichment, search and translation capabilities are expanding the global footprints of these systems, especially for drug discovery, clinical development and competitive intelligence.
- 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

- There are many services that offer similar outputs for text analytics, and increasingly NLP and text analytics are being included in content platforms. CIOs are now having to make decisions about where this capability becomes “core.” Options now include in search engines, content curators, content platforms or text analytics platforms.
- 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

CIOs and R&D leaders should:

- 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, intellectual property (IP) submission teams and technical marketing groups.
- Assume that text analytics will not capture every detail in searches, and work with teams to continually evolve dictionaries, sources and search methods.
- Consider 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, especially when storing lots of unstructured information that is IP-relevant.
- Evaluate cloud-based systems that will support mission-critical R&D innovation and competitive intelligence activities.

Sample Vendors

Cambridge Semantics; Clarivate; Exaptive; IQVIA; Lexalytics; Ontotext; ONTOFORCE; SAS; SciBite; Vyasa Analytics

Gartner Recommended Reading

Market Guide for Text Analytics

Emerging Technologies: Emergence Cycle for NLP Intelligent Applications and Text Analytics

eTMF

Analysis By: Jeff Smith

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early 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 U.S. Food and Drug Administration (FDA) issued guidance that outlined eTMF requirements, sponsor companies accelerated implementations of eTMF systems. More recently, business and IT leaders have pushed these systems into the cloud, enhancing them to expose insights and support more efficient processes. Insights on these solutions have improved by connecting directly to site systems, automating workflows of document images, 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. Often, fully loaded costs remain similar, but they benefit from increased flexibility, access and solution integrations that reduce overall operations cost. Business teams see increasing 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 companies running clinical trials to streamline their processes and reduce the mountains of paper that can be a significant problem during technical scale-up. This would eventually lead to the adoption of eTMF solutions as paper-based archiving as submission are 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. As a result of these factors and a high rate of user adoption, eTMF continues its slow move up the Slope of Enlightenment this year.
- 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 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.
- As new efficiencies are realized from AI, digitalization of site processes and ecosystem connections, we expect eTMF to continue to move up the slope toward the plateau.

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 slow adoption of standards to improve 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.

User Recommendations

- Pursue a SaaS-based approach, and ideally multitenancy in the cloud. As 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 reduces IT complexity without first evaluating the customization required to connect internally and with partners.
- Investigate how eTMF systems with planning tools and analytics can improve regulatory compliance and reduce effort to present information to regulatory bodies and partners. Although the Drug Information Association (DIA) reference model is often listed as a foundation for which a system is designed, ensure there is enough flexibility to accommodate changes as the reference model evolves.
- Rate eTMFs vendors based on features like AI-augmented document workflow and cross-platform analytics, that best facilitate remote operations and optimized document workflow.

Sample Vendors

Ennov; Florence; IQVIA Technologies; MasterControl; Montrium; Phlexglobal; SureClinical; TransPerfect; Veeva

Gartner Recommended Reading

Electronic Trial Master File Strategy Alignment

Navigate a Path to D-Clinical With the Digital Clinical Trial Landscape and Definition of Terms

Market Guide for Life Science E-Clinical Platforms

Use the Digital Value Framework to Optimize Clinical Trials and Clarify Your Investments

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

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 (CTMS) 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 simulate trial protocol implications, estimate resource consumption, respond to change and manage resource utilization and effectiveness.

Why This Is Important

Life science companies are investing in resource management tools to improve operational excellence in trial operations generally by adopting capabilities that provide a more holistic view of trial processes. Many large companies continue to integrate multiple solutions, including enterprise PPM and spreadsheets, to perform capacity and resource planning. As SaaS solutions become more capable, some are evaluating larger footprint applications to replace multiple legacy systems and processes.

Business Impact

Clinical studies require substantial resources to plan and execute, with high stakes on outcomes. They need lockstep coordination of multiple groups from trial operations to monitoring, data management, biostatistics, clinical and IT resources to reach a positive conclusion. Sophisticated clinical resource management is essential to ensure the efficient use of resources, management of relationships and closure on 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, 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.
- 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 few life science companies taking a holistic view of end-to-end trial operations.
- The slow 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.

User Recommendations

- Opt for solutions that can be linked to allow more integrated operational planning. 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 a tactical and an operational level. 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 workflow and enable quality checks.

Sample Vendors

Bioclinica; BSI; Calyx; DSG; eClinical Solutions; Enrich; Medidata; Oracle; Veeva

Gartner Recommended Reading

Master Trial Efficiency With Clinical Trial Resource Management

Navigate a Path to D-Clinical With the Digital Clinical Trial Landscape and Definition of Terms

Market Guide for Life Science E-Clinical Platforms

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

E-Clinical Platforms

Analysis By: Jeff Smith

Benefit Rating: Transformational

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

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

Why This Is Important

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. Increasingly, e-clinical platforms feature multiple point solutions built on a common codebase, or tightly integrated on a separate codebase or over a data fabric. Interoperability enables process optimizations through seamless communications between component solutions.

Business Impact

E-clinical tools 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 performance indicators critical to trial operations. They also enable risk-based and centralized monitoring of trial data, which uses performance data from multiple point solutions, and allows 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 simproving over time with platform vendors and sponsors taking advantage of business process management (BPM) and robotic process automation (RPA) middleware, cloud microservices and other improvements.
- 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.
- As e-clinical platforms continue to evolve into more composable architectures, we see this profile continuing up the slope to the Plateau of Productivity.

Obstacles

- Multiple challenges in transitioning to platforms from legacy point solutions slow the adoption of unified solutions. Sponsors often support many legacy trials in progress and manage external partners, such as contract research organizations (CROs), to support the execution of trial activities. R&D, clinical and regulatory IT leaders should expect the transition to e-clinical platforms to be gradual, beginning with field-facing applications, such as EDC, CTMS, RTSM or eTMF, and moving from these to encompass other capabilities supporting trial operations.
- Reluctance to shift from legacy contracting processes of purchasing clinical trial applications as point solution components and loosely integrating them can slow the uptake. Organizations often focus on individual solution features, with selection processes limited to specific departments and predefined solution categories. This creates complicated multivendor environments and costs associated with validation when making changes.

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

Anju Software; ArisGlobal; Ennov; IQVIA; Medidata; Oracle; Veeva

Gartner Recommended Reading

Market Guide for Life Science E-Clinical Platforms

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

Navigate a Path to D-Clinical With the Digital Clinical Trial Landscape and Definition of Terms2021 CIO Agenda: A Life Science Perspective

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

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) are the technologies and processes of 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 goes beyond 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 and assembled into different end requirements and change managed, resulting in greater productivity and control for life science companies operating in complex, global regulatory frameworks.

Business Impact

In addition to improving compliance, SCA and CBA 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. The technologies also enable distributed authoring in parallel, improving timelines, and allow report components to be reused and overall report development to become less of an individual chore.

Drivers

- SCA and CBA use will increase in parallel with the increase in digitalization of internal processes in life cycle 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 are reducing effort and time to create clinical operations, quality and submission content, and can improve overall quality and compliance.
- 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, and 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. Solution vendors will continue to develop tools to enable managing content on this basis, and their use will expand.
- Progress of this innovation profile begins to pick up this year as more organizations digitalize regulatory processes, and this profile continues steady progress up the Plateau of Productivity.

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.
- Progress adopting SCA solutions has been delayed for years due to the challenge of representing content as data, which is linked to the organization's digital maturity. Attempts have been sporadic and limited to localized departments as a result.
- SCA and CBA adoption is also hindered due to lack of centralization of regulatory content and the need to manage content from sources mired in document-driven content approaches, 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.
- Take an integrated view of all regulatory content and its associated metadata, and align this with SCM and CBA solutions to optimize the content creation process, when working with regulatory leaders.

Sample Vendors

Anju Software; Author-it Software Corporation (ASC); Cognizant; Fonto; Generis; IntelliNotion; i4i; Yseop

Gartner Recommended Reading

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Life Science Top Actions for 2021: Prioritize Composability in Digital Trial Operations

2021 Business Drivers for Life Science CIOs

Market Guide for Life Science Regulatory Information Management Solutions

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

Entering the Plateau

ELN

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

Market Penetration: More than 50% of target audience

Maturity: Mature mainstream

Definition:

Electronic laboratory notebooks (ELNs) are informatics solutions to help research and production analysts in R&D, manufacturing and quality organizations capture and manage scientific laboratory data. Additionally, ELNs are used to record potential intellectual property, perform calculations, port information from instruments to repositories, leverage operational technologies, initiate lab-instrumentation instructions and execute processes within the laboratory.

Why This Is Important

With “lab of the future” initiatives and efforts to “go paperless,” especially in light of COVID-19, improving quality, creating knowledge platforms and driving collaboration, ELN adoption continues to expand. As ELNs become easier to maintain and deploy, they are becoming more integral in enabling evolving scientific and experimental data capture.

Business Impact

ELNs have a high impact on laboratory productivity in R&D and QA/QC groups and support innovation and automation strategies. They improve collaboration efforts between dispersed lab personnel and provide a system of record in lab test environments. ELNs offer an opportunity to replace paper-bound notebooks and disparate electronic systems. Some ELNs can be augmented with scientific plug-ins (e.g., chemical formulations), as well as sophisticated workflow automation and instrument integration.

Drivers

- Business leaders demand capabilities from ELNs to increase productivity, improve quality and reduce the amount of paper used in laboratories. The technology is now widely available, and ELNs fit with modernization strategies for capturing, analyzing and reporting laboratory and scientific findings.

- Initially, ELNs were used as “electronic sticker books” to replace paper-bound laboratory notebooks. They now have technology embedded in the software that expands capabilities well beyond capturing electronic data for experiments and ideas, and replacing paper-bound notebooks. In fact, ELNs have much deeper functionality spanning biology, chemistry and quality assurance (QA)/quality control (QC).
- As scientific laboratories have become more virtualized and electronic, ELN providers have created application-specific templates, and solutions have been optimized for different disciplines, including materials, polymers, biology, chemistry, proteomics, genomics, bioanalytical contract services and QA/QC manufacturing.
- ELNs are being used as scientific knowledge management system portals, and have been augmented with semantic search capabilities to leverage both internal and external data. Some laboratory information management system (LIMS) vendors are now offering ELNs, as well.
- The new versions of ELNs enable organizations to increase productivity, improve quality and reduce the amount of paper used in laboratories. As organizations push to reduce transcription and writing errors, improve collaboration, and reduce the time it takes to recover necessary files during internal and external audits, ELNs will become a more standard tool and replace traditional paper notebooks.
- Therefore, we advanced the ELN profile to the Plateau of Productivity stage in the Hype Cycle, and expect mainstream adoption in two years.

Obstacles

- Many organizations support multiple ELN environments (e.g., biology, chemistry, QA/QC, formulation, analytical), with competing capabilities, which makes scaling those solutions difficult.
- The predominantly LIMS-vendors have “bolt on” ELN capabilities, which have been marketed for extending into other non-LIMS groups, but most lack deep functionality.
- Clients report being overwhelmed and confused by the number of overlapping vendor messages. This hampers harmonization, rationalization and vendor selection processes.
- Most of the ELN companies are small, early-stage businesses and lack the professional services required to sustain midsize and large organizations.

- Many legacy vendors also have overengineered customized environments, which has damaged some of their credibility with clients.
- Some ELN companies overreached with the messaging on their capabilities.
- Many scientists are in the habit of using paper notebooks and are reluctant to adopt new electronic recording systems.

User Recommendations

- Collaborate with decision makers who are familiar with laboratory processes when selecting a system. Different disciplines and research labs have divergent needs.
- Know that an R&D-centric ELN will not function well in a quality/operations environment, and a QM-oriented solution may not operate well in an R&D area.
- Consider ELNs with enhanced bioinformatics, analytical and reporting capabilities in organizations that conduct drug discovery or therapeutic research.
- Look for future features that enhance collaboration by securely connecting scientists and analysts (such as tablet compatibility and handwriting recognition). Also, consider hybrid models that can be deployed as client/server and web-based models to support decentralized research activities.
- Assess laboratory execution system (LES)-centric ELNs for use in good x practice (GxP) environments or environments that have stringent quality, regulatory and compliance requirements.

Sample Vendors

Agilent; Benchling; Dassault Systèmes; Dotmatics; IDBS; Labguru; LabVantage Solutions; LabWare; PerkinElmer; Thermo Fisher Scientific

Global Regulatory Information Management

Analysis By: Jeff Smith

Benefit Rating: Moderate

Market Penetration: 20% to 50% of target audience

Maturity: Mature mainstream

Definition:

Global regulatory information management (RIM) represents a set of key capabilities that a life science company needs to manage the regulatory approval and maintenance of a life science product for commercial use. These 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 capabilities enable a global perspective of obligations and their fulfillment. Companies that are not in compliance with worldwide regulations for marketing and selling their products will face penalties and fines, as well as the potential market withdrawal of those noncompliant products. Each RIM solution capability addresses a specific need in the development path to gain and maintain regulatory authorization to sell in each country in which a life science company operates.

Business Impact

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. Companies using RIM gain control over the market authorization processes, resulting in lower audit risks, a heightened ability to meet regulatory requirements and fewer issues during regulatory submission. RIM solutions can enable effort reductions along the entire end-to-end regulatory process.

Drivers

- Frequently changing, complex and diverse regulatory requirements drive regulatory leaders to adopt RIM systems to improve responsiveness to changes, better manage correspondence and planning with regulators, and normalize product market approvals.
- European Medicines Agency's Identification of Medicinal Products (IDMP) compliance requirements is also causing a push for a more global view, with European Medicines Agency (EMA) timelines now requiring compliance with the regulation by fall of 2022.
- 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.
- 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, this Innovation Profile continues to move slowly up the Slope of Enlightenment to the Plateau of Productivity.

User Recommendations

- Re-envision, along with regulatory leaders, RIM as a strategic element for enabling growth into new markets. When operating across multiple regulatory regions, ensure RIM solutions incorporate improved global capabilities 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 software-as-a-service-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; EXTEDO; Generis; IQVIA Technologies; LORENZ; Phlexglobal; Veeva

Gartner Recommended Reading

Market Guide for Life Science Regulatory Information Management Solutions

Strategic Life Science Regulatory Information Management: From Fragmented to Holistic

Accelerate Digital Capabilities by Migrating Validated Life Sciences Applications to the Cloud

Market Guide for Quality Management System Software

Delayed and Confusing IDMP Compliance Requirements Demand Life Science CIOs Pursue a Two-Part Strategy

Scientific Analytics Platforms

Analysis By: Michael Shanler, Rohan Sinha

Benefit Rating: High

Market Penetration: 20% to 50% of target audience

Maturity: Early mainstream

Definition:

Scientific analytics platforms encompass analytics and aggregation software used for processing large amounts of scientific, clinical, engineering and experimental data in R&D environments. Typically, these solutions are used to evaluate big data, test hypotheses, define trends and predict outcomes. These tools allow rapid analysis of a large R&D data mine, emphasize the scientific relevance of the resulting insights and often contain an aggregation layer that is optimized for R&D content.

Why This Is Important

R&D disciplines typically handle the complicated queries and analyses using a scientific subject matter expert as a guide. In recent years, business and laboratory users have found that the enterprise tools that lack scientific plug-ins (such as molecular files) are not suitable for doing scientific research. Scientific analytics platforms include dedicated tools with the core functions that are required to facilitate the scientific method.

Business Impact

These scientific-oriented solutions deliver high value to researchers, primarily through broader end-user access to analytics capabilities (empowering users to perform analyses, rather than relying on data scientists and engineers). Also, these analytics platforms provide better maintenance of existing models by increasing their reuse and performance, and improving product design by enabling the detection of patterns in large volumes of scientific data, with data mining and predictive analytics.

Drivers

- The life science industry, an early leader in applying R&D analytics by giving the tools directly to scientists, hungers for more analytics plug-ins in native applications, such as open-source R statistical programming language. R&D organizations are increasingly elevating templates, workflows and automation for science, raising the profile of capable analytics platforms to support the scientific method.
- Scientific staff members and engineers are increasingly requesting the ability to ask questions that impact design and they want the ability to make inquiries with a few variables for a large dataset — without having to engage a data scientist. This has increased interest in platforms that can natively provide these capabilities.
- Now that vendors have simplified these tools for addressing big data in R&D, the tools are being extended to a broader group of biologists, chemists and engineers who do not have deep informatics backgrounds, thus increasing both the interest and hype.
- These solutions are known entities and have been in use for well over a decade at a wide variety of R&D organizations. Therefore, we position this technology on the Plateau of Productivity and will reach mainstream adoption in two years.

Obstacles

- There are a wide variety of tools designed for specific domains, and R&D business users are increasingly purchasing them without IT's involvement. Fragmented analytics approaches can result from issues arising at some organizations in the form of competing platforms, challenges with customization or configuration support, and licensing agreements.
- A variety of IT consultant vendors are pushing nonscientific enterprise tools into the space. While this may simplify support and create an enterprise-level of familiarity, scientists often push back on these tools and elevate poor experiences back to IT and management. This can create divisions and lower trust between IT and R&D business areas.

User Recommendations

As the data deluge increases, R&D organizations are increasingly swamped with extremely complicated design, scientific, clinical and regulatory information. Organizations with legacy systems must decide on one of two strategies:

- Use general tools and adapt them into scientific environments that may involve customization.
- Use specific tools designed for science, which may have limitations for configuring the tools for other enterprise purposes.

No matter the decision, having access to tools to visualize data and develop insights will only grow in importance for scientific staff. Organizations should plan to invest in these tools for R&D and manufacturing as datasets get larger, and develop a core skill set supported by IT. Pay particular attention to vendor capabilities for pivot table analysis, visualization tools, and predictive modeling and analytics.

Sample Vendors

IBM; MaxisIT; Palantir; PerkinElmer; Saama; SAS; Stardog; Talend; Tamr; TIBCO Software

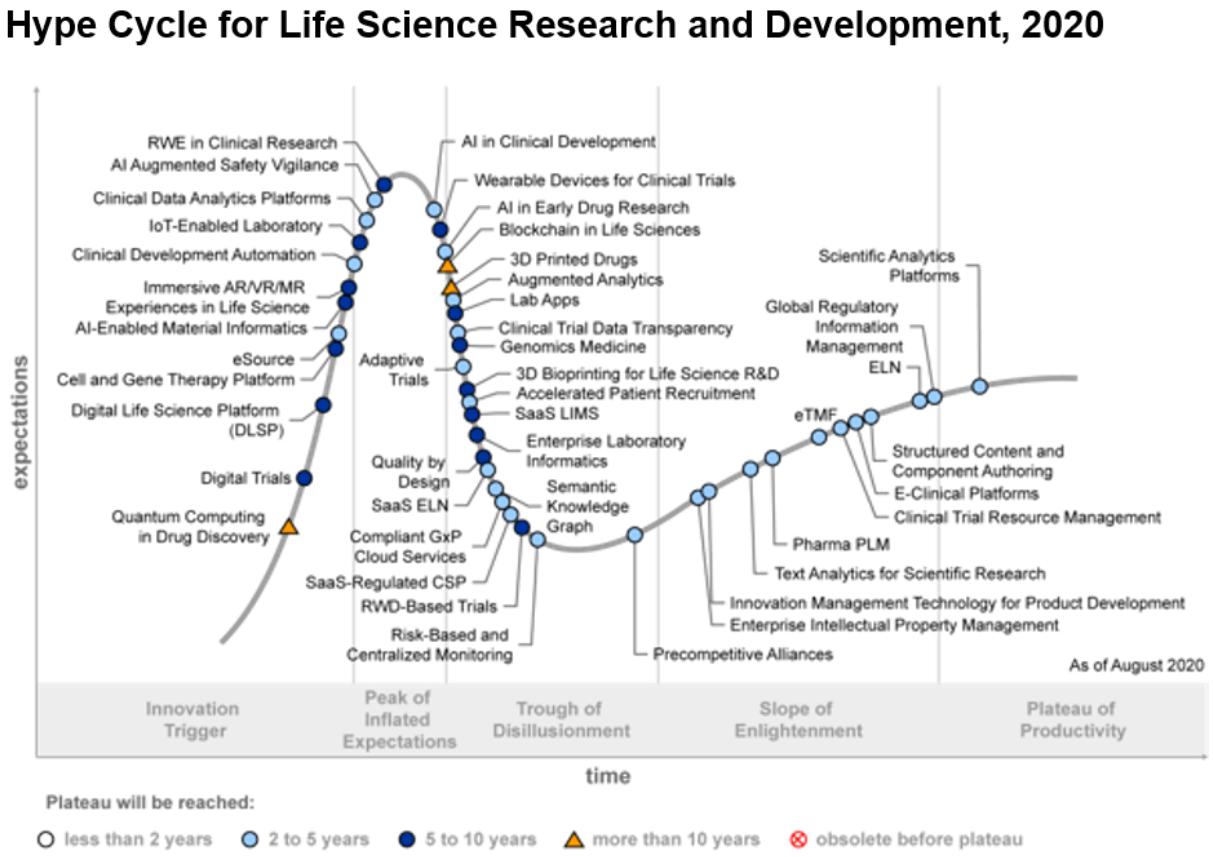
Gartner Recommended Reading

Life Science CIOs: Embrace Next-Generation Data and Analytics Platforms to Manage Clinical Data Challenges

Demystifying the Data Science Lab and AI Hub for Business Analytics

Appendixes

Figure 2: Hype Cycle for Life Science Research and Development, 2020



Source: Gartner
ID: 450338

Gartner

Source: Gartner (August 2020)

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 2021)

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 2021)

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 2021)

Document Revision History

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 Authors

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

Understanding Gartner's Hype Cycles

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

2021 Business Drivers for Life Science CIOs

Use Gartner Reset Scenarios to Move From Survival to Renewal for Life Science Companies

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

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

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

Predicts 2021: Life Science Companies Must Quickly Adapt as Digital Expectations Change

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Table 1: Priority Matrix for Life Science Research and Development, 2021

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

Benefit	*Years to Mainstream Adoption*			
↓	***Less Than 2 Years*** ↓	***2 - 5 Years*** ↓	***5 - 10 Years*** ↓	***More Than 10 Years*** ↓
High	Scientific Analytics Platforms	Adaptive Trials AI in Clinical Development AI in Early Drug Research Clinical Data Analytics Platforms ELN eSource eTMF Innovation Management Tools for Product Development Risk-Based and Centralized Monitoring SaaS ELN SaaS-Regulated CSP Scientific Text Analytics Semantic Knowledge Graph Trial Simulation	3D Bioprinting for LS R&D Cell and Gene Therapy Platform IoT-Enabled Laboratory RWD-Based Trials RWE in Clinical Research Wearable Devices for Clinical Trials	Quantum Computing in Drug Discovery

Benefit ↓	*Years to Mainstream Adoption*			
	Less Than 2 Years ↓	***2 - 5 Years*** ↓	***5 - 10 Years*** ↓	***More Than 10 Years*** ↓
Moderate		Accelerated Patient Recruitment AI-Augmented Safety Vigilance Clinical Development Automation Clinical Trial Data Transparency Clinical Trial Resource Management Enterprise IP Management Global Regulatory Information Management Precompetitive Alliances Structured Content and Component Authoring	AI in Material Informatics Mobile Lab Apps SaaS LIMS	
Low				

Source: Gartner (July 2021)

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