

How the Integration-Platform-as-a-Service Model is Rapidly Growing and Disrupting the Traditional Clinical Trial Operation Model

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This white paper explores the advent of integration-platform-as-a-service systems (iPaaS), what's spurred their popularity in recent years, and how they've revolutionized what's possible for clinical trial operations today.

ABSTRACT:

Everyone is already familiar with the growth in popularity and usage of cloud applications to help business operations run smoother, more efficiently – and last, but not least, save significant money in infrastructure costs. This white paper explores a new vertical in the cloud computing space that has proven to help clinical trial organizations of all sizes better serve their customers. This new solutions approach is called integration-platform-as-a-service or iPaaS, and it's an extension of the booming software-as-a-service industry.

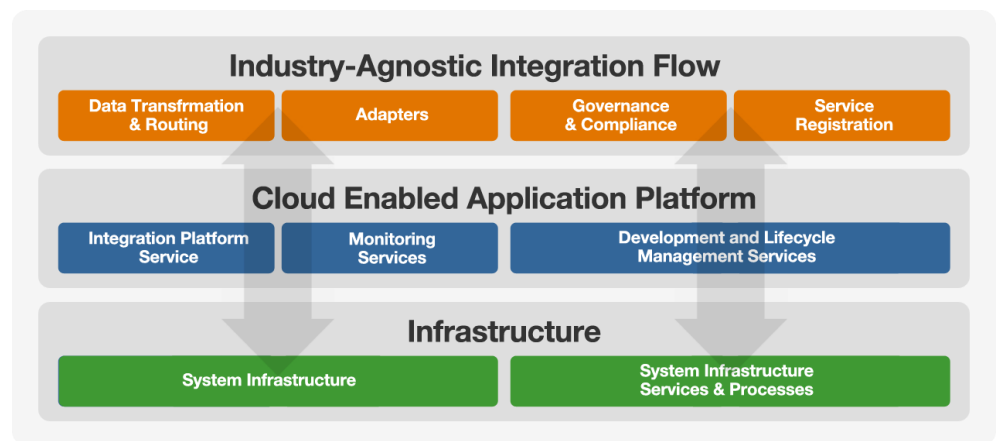
We set out to first describe the anatomy of iPaaS and then explain in what ways such technology can help streamline the complex technology ecosystems that are employed in the conduct of Clinical Trials. Furthermore, we illustrate how well constructed and validated iPaaS platforms can allow clinical operations data management to move from simple “Integration” to true “Interoperability”, where true interoperability will be the catalyst for improved patient care and safety through real-time clinical data workflow.

What is an Integration-Platform-as-a-Service?

By many measures integration-platform-as-a-service (iPaaS)-based systems have been a huge success for healthcare and life science operations. If you're unfamiliar with the term, iPaaS systems are a suite of cloud services enabling development, execution and governance of integration flows connecting any combination of on premise and cloud-based processes, services, applications

and data within individual or across multiple organizations¹. In essence, it takes the cloud-based software-as-a-service (SaaS) model, and applies it to the up-and-coming systems integration application market.

The unique setup of these platforms have helped both large and small organizations stay leaner and be more efficient, while expending less waste in the form of IT equipment and procedural overlap than ever before. Furthermore, and of far greater importance, iPaaS systems have been a key element in expediting the setup and break down times of research studies.



In fact, when tallying the combined Worldwide installments of iPaaS systems, Gartner estimates that these markets grew by 55% in 2015 alone. "The PaaS segment showed the most impressive growth [when compared to Application platform as a service (aPaaS), not just in the AIM (application infrastructure and middleware) market but across the entire enterprise software market," said Fabrizio Biscotti, research director at Gartner. "Integration PaaS (iPaaS) grew 55 percent in U.S dollars, while application PaaS (aPaaS) grew 40 percent, despite headwinds from the appreciating U.S. dollar.

In other words, it's fair to say that iPaaS has become a vital component of any IT strategy.

The Growth of iPaaS

Many technological trends and developments of recent years have driven the need and want for iPaaS solutions. A few of these technological trends include:



Growth in Cloud Applications

With companies like Salesforce leading the way, software and services that once brought reasonable hardware and servers to their knees can now be accessed anywhere at a fraction of the cost of antiquated systems.



Advent of the Personal Cloud

Experts at Gartner predict that the personal cloud will gradually replace the PC as the location where individuals keep their personal content, access their services and personal preferences and center their digital lives.



Improved Security in the Cloud

In years past, software administrators had real concerns around the security of cloud-based iPaaS systems. These concerns focused on the potential vulnerability to hacking and theft, privacy and ownership of information in an environment that resides outside of agency firewalls, lack of portability standards, weak records management capability, and potential inside threats due to insufficient standards and protocol. Today, enterprise powerhouses like IBM Security, Sungard Availability, Oracle, Rackspace and others have advanced the security of cloud computing that was historically only available through location-based servers and services.



The Rise of Big Data and Solutions around Dark Data

Big Data is moving from a focus on individual projects to an influence on enterprises' strategic information architecture. This realization is leading organizations to abandon the concept of a single enterprise data warehouse containing all information needed for decisions. Instead they are moving towards multiple systems, including content management, data warehouses, data marts and specialized file systems tied together with data services and metadata, which will become the "logical" enterprise data warehouse.

Open APIs, Data Streams, web and mobile apps, cloud platforms, and other advances in technology are causing enormous amounts of data to be generated, shared and stored in data-silos across many different types of applications and organizations. Data is becoming increasingly disconnected between web and cloud-based apps.

How do iPaaS systems impact clinical trials?

When it comes to clinical trials, the need for comprehensive iPaaS solutions is heightened, due to the intrinsic complexities of handling disparate data sources and private patient data. The complexities are further compounded by regulatory agencies like the FDA which demand adherence to principles of good clinical practices (GCPs) and third-party audits that require advanced procedural protocols that affect time and money. In other words, the old model simply could not last.

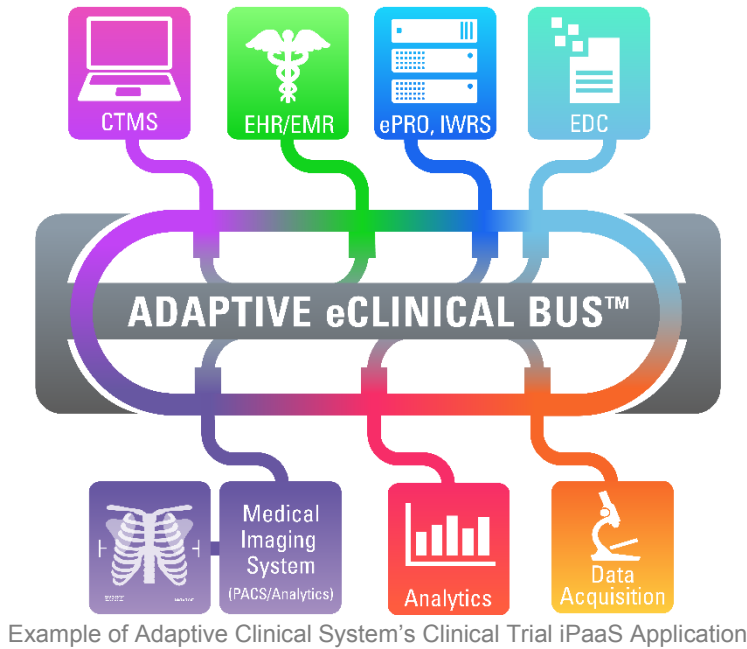
For example, traditional point-to-point and ad hoc integration have a very short life span in the rapidly changing world of cloud-speed releases and system changes. This can lead to problems with data integrity and could cause one to run afoul of validation and compliance – something that will require costly and ongoing manual steps to share data. Applications often involved include Electronic Data Capture (EDC), Clinical Data Management Systems (CDMS), Clinical Trial Management Systems (CTMS), Clinical Data Repositories (CDR) and Statistical Analysis Systems. While many large pharmaceutical firms and indeed most any sponsor use a standardized EDC system and can transform data in the right format before sending it to their partner CROs, many smaller firms don't have that capability. In turn, CROs may or may not have systems in place that can effectively accept and translate that data in a way that the sponsors need during the trial or when it's time to submit data to the FDA.

iPaaS systems however are designed to automate the process of integrating and aggregating clinical trial information to support the smooth transition of data from one system to the next. This flexibility reduces the time necessary to setup and conduct clinical trials by:

- Reducing the amount of time to gather data for analysis
- Increasing the speed of data flow once changes are made during trial activity
- Decreasing the time necessary to clean up data overlap or faulty information from manual procedures
- Improved capacity to manage and administer multiple clinical trials at once

Data integration vs. interoperability, and why it matters

Especially in today's pursuit for the next big thing in technology, terms like "integration" and "interoperability" are often used interchangeably when discussing the optimization of clinical trial data flow. However, while clinical trial data has traditionally been sought to be integrated into an electronic record, true interoperability is not the same thing.



The integration of clinical trial data is a process of getting disparate technology, such as medical imaging information and data from the MR system, to send and receive intelligible data by the simplest means possible. The focus here is passing the data by maximizing the way it is streamlined between systems. Interoperability, on the other hand, is far more complex. It is a means of connecting patient data, a variety of medical devices and IT systems, and changes in clinical trial analysis in a way that brings about new meaning, context and clinical insights through the combination of diverse sources of data. True interoperability will be the catalyst for improved patient care and safety, and real-time clinical data workflow by providing an entire suite of functions and meaning from each device, not just a limited set of data fields.

In other words, true interoperability in clinical trials requires an intelligent and validated platform that's structured to take data from various systems and comprehensively convert it into a standardized communication format for it to be shared in real-time with all connections in the clinical trial work flow. This focus here is not simply passing on "data", but the simultaneous sharing of it through meaningful transactions. Only true interoperability can do this. For example, codifying routine derivations that often require input from multiple data sources and involvement of clinical staff goes well beyond any data transfer as per prevailing data format standards. That is where we achieve the true benefits of integration or better described we go from integration to interoperability. Many clinical trial operations get this misconstrued when selecting data integrators and find that the problems of manual entry and disparate systems is only half-way addressed. The iPaaS systems approach

helps make interoperability possible in clinical trials because, synonymous with the structure of cloud systems, these integration platforms are designed to easily transform data, regardless of time, location, and source.

In short, an interoperable clinical trial operation empowered by an iPaaS platform allows the trial provider to spend less time focusing on resources, and more time on the results of the testing and the patients they serve.

A Look Around the Corner:

The future of clinical trials in conjunction with iPaaS systems

As discussed earlier, experts consider iPaaS as the fastest growing integration middleware approach. Savvy clinical trial operations staff understand that iPaaS systems offers huge gains in efficiency and accuracy of clinical trial operations using different EDC, CTMS, EHR/EMR, and Medical Imaging Systems. Furthermore, it prepares them for new-to-market software and solutions that may not be natively configured to pass data seamlessly to pre-established systems, but could plug into an iPaaS system that makes the sharing of this information readily available - and at a relatively low-cost.

Thinking less industry-specific, Gartner identifies three categories of iPaaS vendors, each of which emphasizes a different area of integration:

1. E-commerce and B2B integration
2. Cloud integration, and Enterprise Service Bus (ESB)
3. Service Oriented Architecture (SOA) infrastructure

If this is applied to where the clinical trial industry is going, we see a plethora of opportunities on the horizon, including:

- Self-administered studies
- Location agnostic clinical trials
- Increased capacity to cross-reference clinical trials
- Improved Real-time data analysis
- Inter-study adjustments for improved outcomes

Conclusion

At the heart of idealistic goals, clinical trial operators and patients want the same thing: Successful clinical trials that accelerate the research and findings of effective medicine for the benefit of human health. To best achieve this, clinical trials must continually coordinate the data flow of various systems and software to efficiently share information that is vital to measuring outcomes from the trial. With this foundation, we can now consider that:

- Technological advancements have not only been the catalyst for the iPaaS growth, but have made this approach possible for the benefit of clinical trials organizations.
- The iPaaS model benefits clinical trial operations utilizing various data systems regardless of size or location. This becomes exceedingly beneficial for clinical trial organizations with the dual goals of becoming leaner and more efficient while also expending less waste in the form of IT equipment and procedural overlap.
- The future of iPaaS makes it a practical approach to preparing a clinical trial operation for incorporation of future technologies and solutions. The reality of silo's among disparate clinical trial systems, has given way to a more stable and permanent ecosystem where free flow of data "bi-directionally" from source to destination is the norm rather than the exception.

Consideration for implementing an eSource strategy centered on an iPaaS approach is a big step for any organization, especially those operating in the highly regulated clinical trial industry. However, if market trends are an indication to the future of iPaaS, and personal experiences in difficulty managing disparate systems or inaccuracies in data disbursement or are fresh in the minds of those taking consideration, we may find that the leap is easier than imagined.

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