

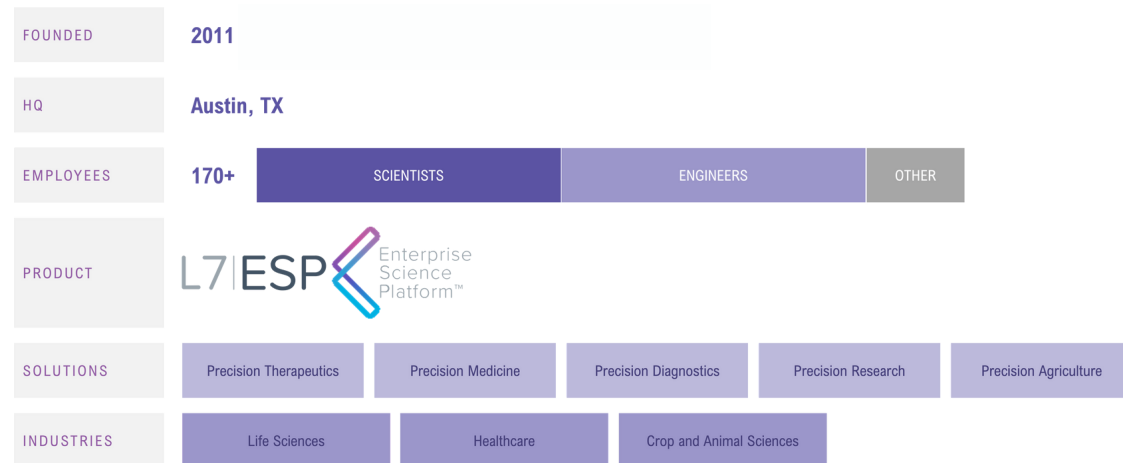
EBOOK

# L7 | PRECISION MEDICINE

streamline and automate the patient workflow by  
digitalizing diagnosis-to-treatment

# About L7

L7 Informatics, Inc. is a leading provider of integrated scientific data and analytics solutions. The company offers a comprehensive platform that enables seamless data integration, advanced analytics, and collaborative workflows, empowering scientists and researchers to accelerate discoveries, improve operational efficiencies, and drive innovation. L7's mission is to revolutionize how scientific data is managed, analyzed, and utilized, facilitating breakthroughs in research, drug discovery, development, and manufacturing.



## Gartner 'Cool Vendor' 2020

In 2020, L7 was one of only five companies recognized in the Gartner Cool Vendors in Life Sciences report that technology leaders should watch to help accelerate life science business results.

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## Deloitte Technology 'FAST 500' 2021

With a 3-year growth of 8,288%, L7 Informatics is ranked #26 and #1 Life Sciences Software.



## Deloitte Technology 'FAST 500' 2022

Honored that L7 Informatics made the list again with another impressive 3-year growth of 1,543%.

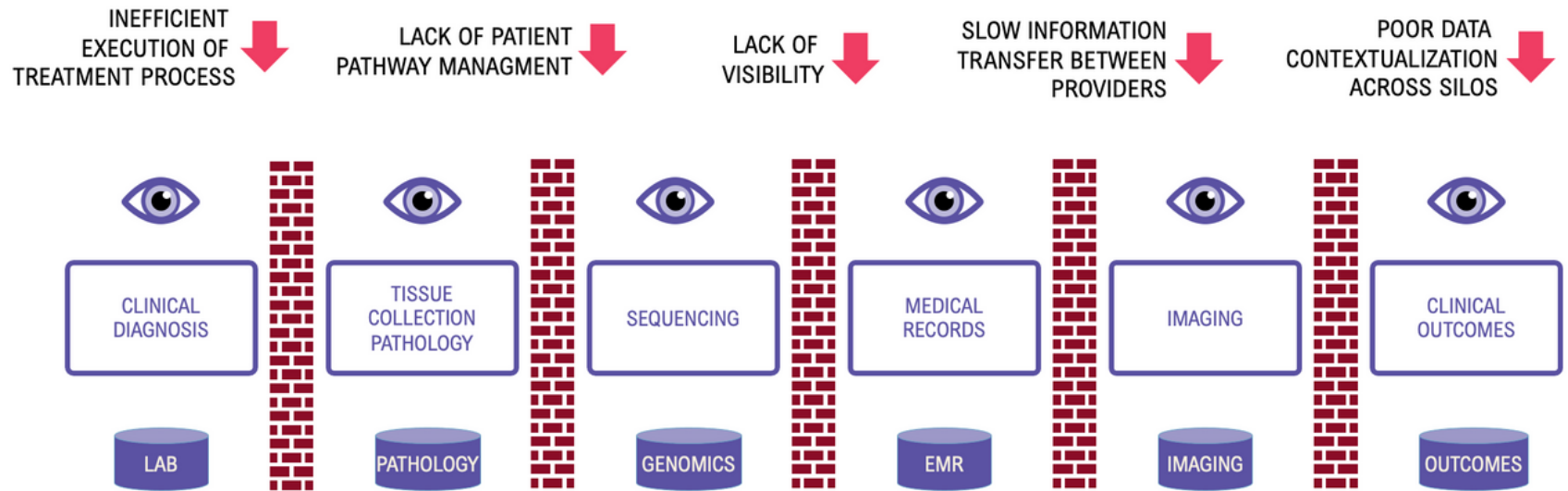


## Deloitte Technology 'FAST 500' 2023

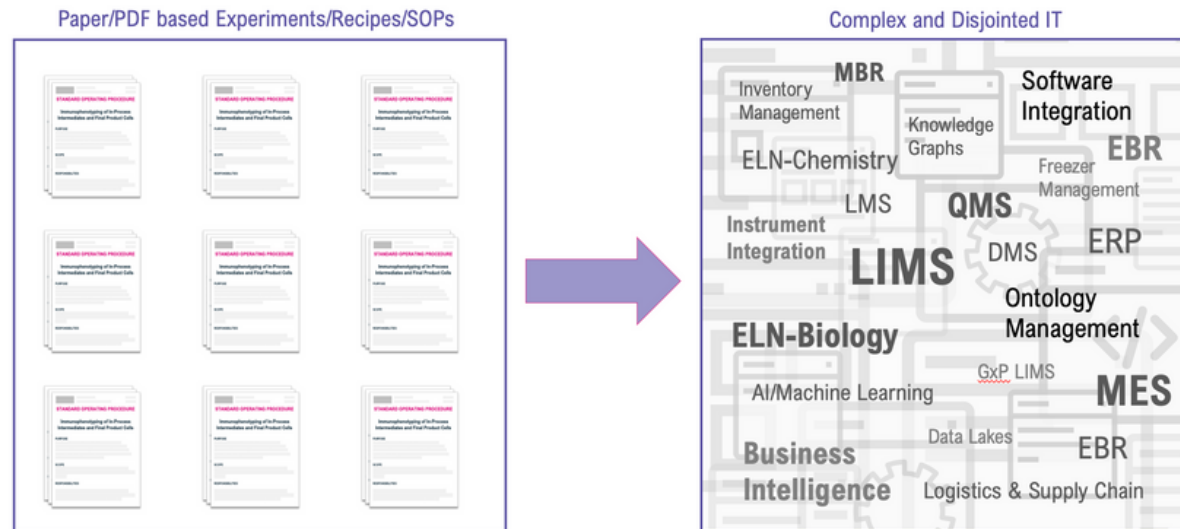
For a third consecutive year, we made the list again, and celebrate a significant 3-year revenue growth of 2047%.

# The Problem

Legacy data silos and processes hinder Precision Medicine pathways, increasing the risk for business and patients.

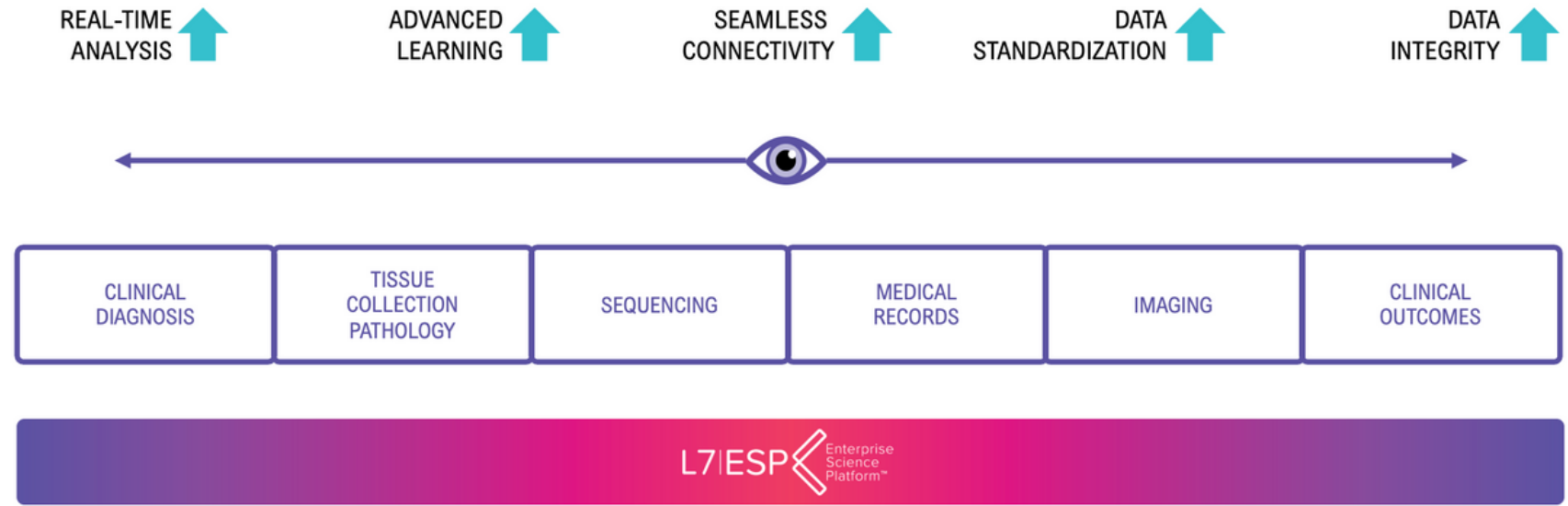


Paper-based “Standard Operating Procedures” implemented across siloed IT systems make digitalization and validation of systems difficult and reduce the velocity of the business and create data integrity problems

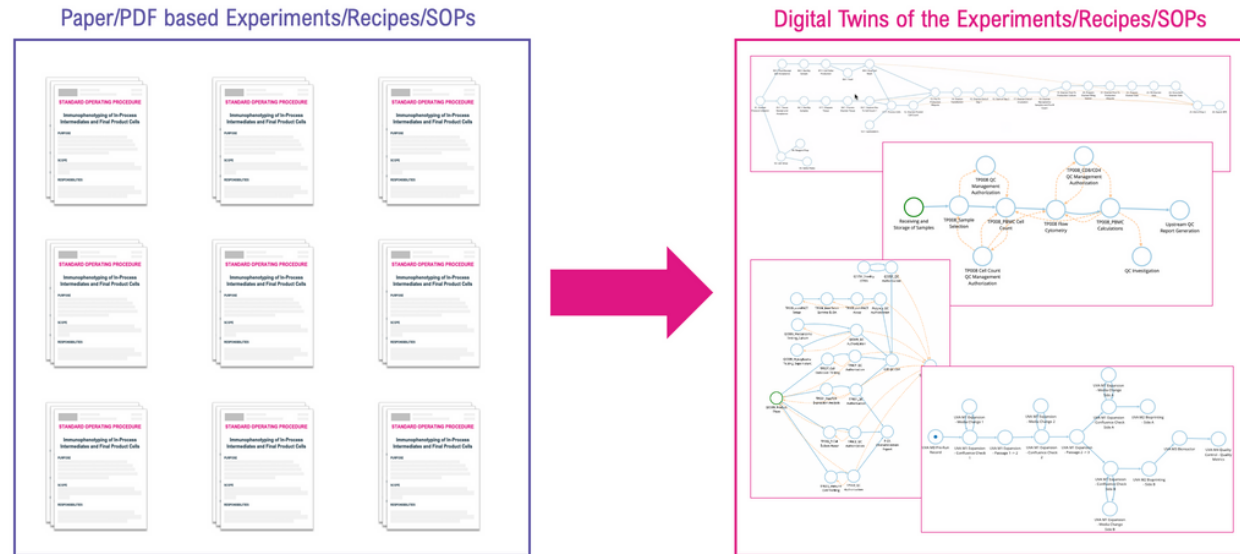


# The Solution

L7|ESP accelerates Precision Medicine requirements for integrated data + intelligence, improving efficiency, velocity, and science, and reducing risk for business and patients



L7|ESP creates digitalized twins of Experiments, Recipes and SOPs, making the validation of systems easier, increasing the velocity of the business, and reducing data integrity problems.



# Unified Platforms for Precision Medicine Pathway Management

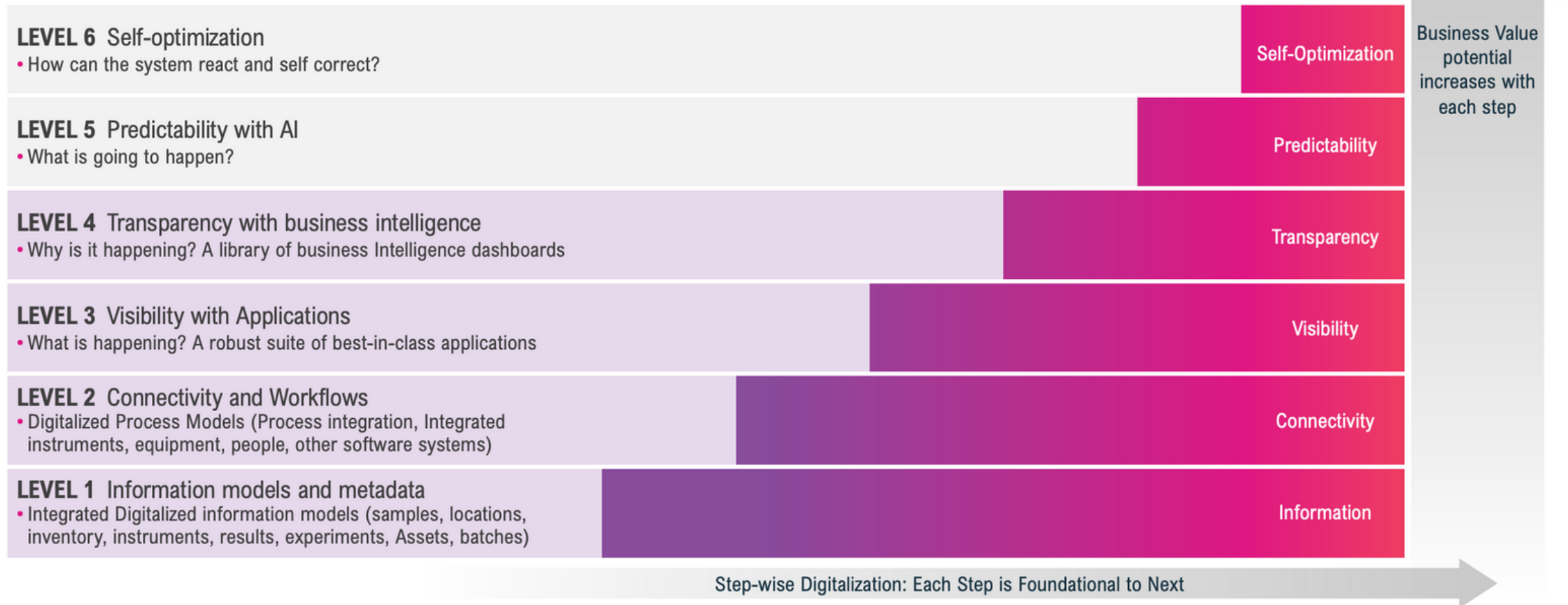
## [Scales to Other Disease States]





# L7|ESP - A Unified Platform Built on Industry 4.0 Principles

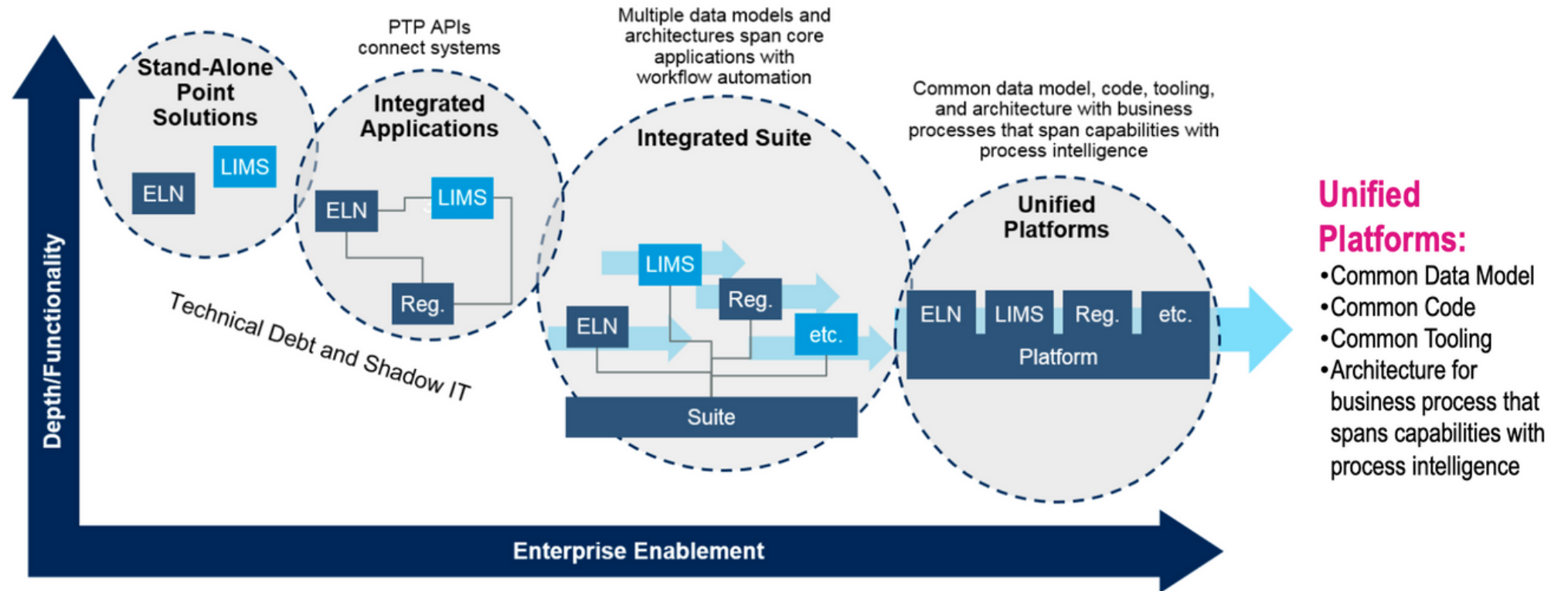
## Industry 4.0 Principles



# L7|ESP - A Unified Platform for Life Sciences



"Life Science Lab Informatics Digital Criteria"  
Published 20 December 2018  
- Source: © Gartner, Inc 2018



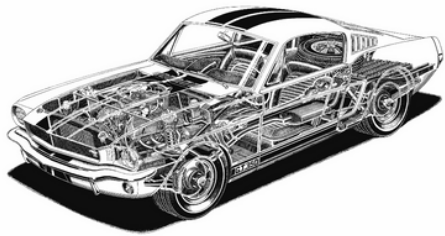
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© 2018 Gartner, Inc.

# Composable Platforms Built of 'Primitives'

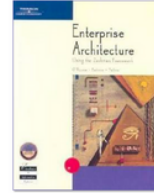
## COMPOSITE MODELS vs PRIMITIVE MODELS

Composite models are fixed functionality and difficult to modify



Reference: Enterprise Architecture - using the Zachman Framework, ©Riska, Fishman, Lubow

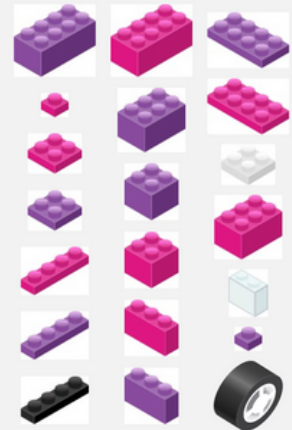
Primitive models provide quick assembly, modification, and reusability



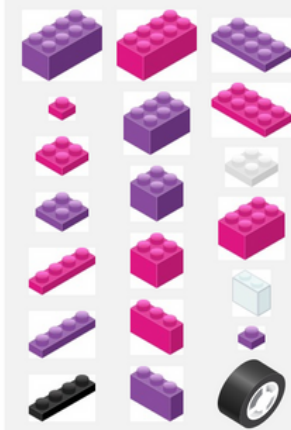
Enterprise Architecture using the Zachman Framework

PRIMITIVE MODELS PROVIDE QUICK ASSEMBLY, MODIFICATION, CUSTOMIZATION, AND REUSABILITY

L7 HUB "STORE"



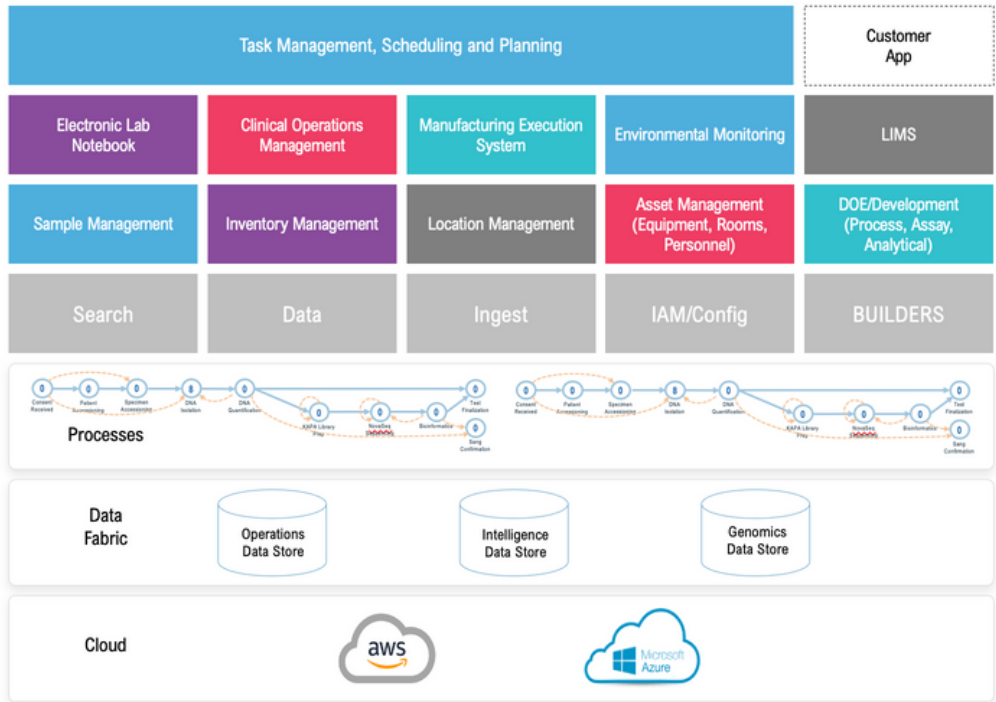
L7 HUB "STORE"





# Unified Platforms

Meet all of your data and process needs with a single solution, L7's unified platform, L7|ESP, equipping your business with a comprehensive operating environment and software stack that adapts to your unique requirements while preserving data provenance and integrity.



## Business Apps

- Clinical Operations
- Electronic Batch Records
- Electronic Lab Notebook
- Environmental Monitoring
- Inventory
- LIMS
- Locations
- Manufacturing Scheduling
- Stability Testing
- See roadmap

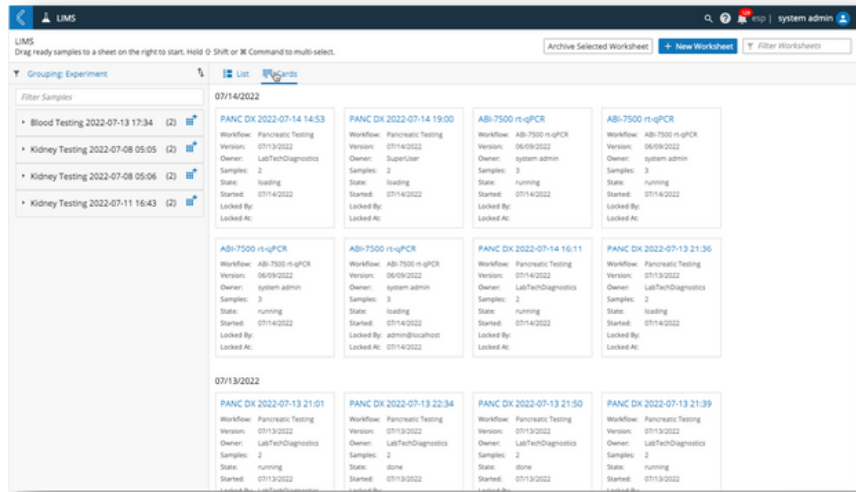
## Standard Apps

- Assets
- Dashboards
- Reports
- Data
- Entities
- Ingest
- Projects
- Samples
- Search

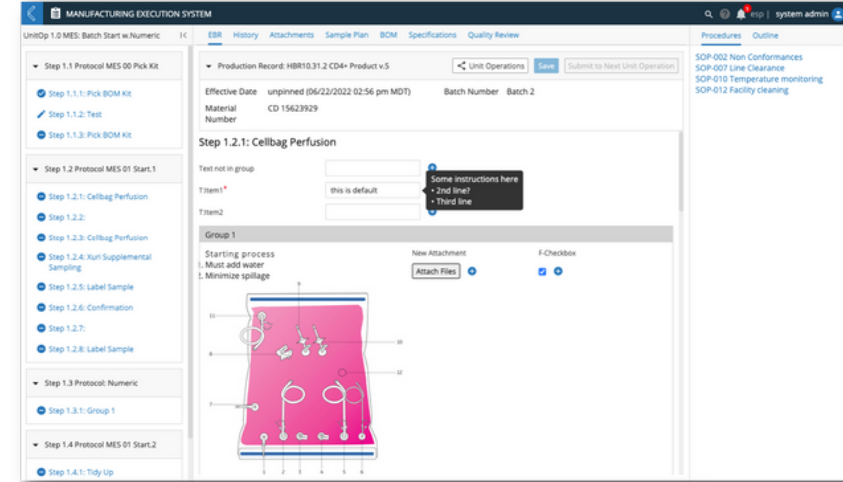
## Configuration Apps

- Applets
- Master (Builders)
- IAM

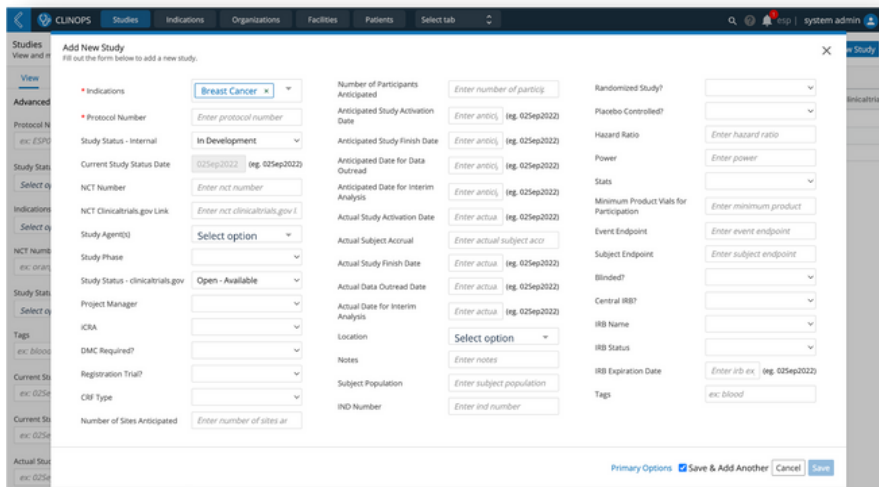
# L7 Business Apps - Every Application Needed for the Scientific Enterprise



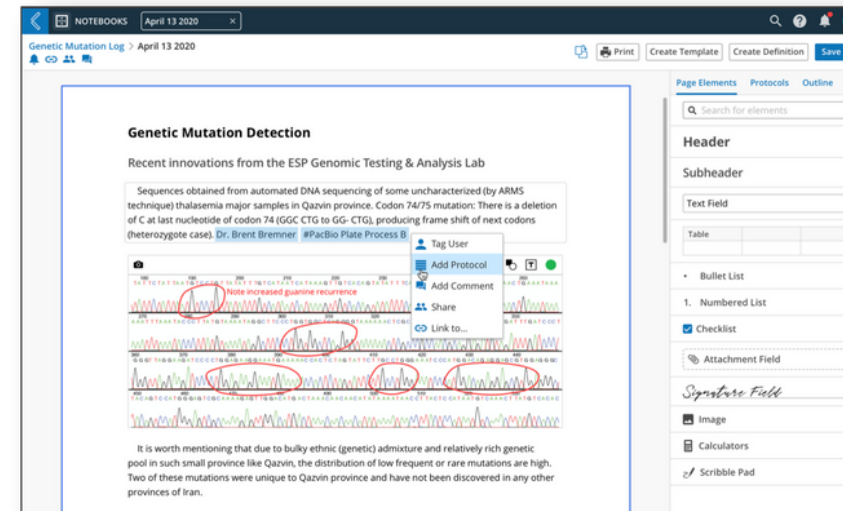
Integrated LIMS + LES (GMP/GLP/GCP compliant)



Manufacturing Execution System



Clinical Operations



Electronic Lab Notebook

# L7 Business Apps (continued)

The screenshot displays the 'Environment Monitor' interface for 'Room A'. It features a sidebar with details for the room, including name, description, grade, and tags. The main area shows a table of tasks with columns for Task, Entity ID, Days of the week, Repeating, Start Date, End Date, Grace Days, and Actions. A dropdown menu is open over the 'Actions' column, showing options like 'Execute', 'Initiate', and 'Delete'.

Task	Entity ID	Days of the week	Repeating	Start Date	End Date	Grace Days	Actions
Microbial Monitoring	Task0001	Mon, Wed, Fri	Every week	03/01/2018	-	5	Execute
Cleaning	Task0002	Tue, Thu	Every 2 weeks	06/01/2020	06/14/2020	2	Initiate
Room Quality	Task0003	Mon, Fri	Every 3 months	01/01/2019	-	0	Delete
Cleaning	Task0004	Mon, Tues, Wed, Thu, Fri	Every 4 weeks	06/01/2020	05/31/2021	5	Execute
Microbial Monitoring	Task0005	Mon, Wed, Fri	Every year	01/01/2020	-	3	Initiate
Microbial Monitoring	Task0006	All	Every 6 weeks	06/01/2020	06/30/2020	5	Delete
Cleaning	Task0007	Mon, Tue, Wed	Every 8 weeks	02/01/2020	-	10	Execute
Microbial Monitoring	Task0008	Task0008	Every 2 weeks	03/01/2018	-	0	Initiate
Microbial Monitoring	Task0009	Task0009	Every 3 months	06/01/2020	-	3	Delete
Cleaning	Task0010	Task0010	Every 4 weeks	01/01/2019	-	2	Execute
Cleaning	Task0011	Task0011	Every year	06/01/2020	07/31/2020	1	Delete

Environmental Monitoring

The screenshot shows the 'Manufacturing Scheduling' dashboard. It includes a top navigation bar with 'Requests', 'Events', 'Open Slots', 'Event Status', and 'Clients'. The main area features a Gantt chart for 'Room B2 191' with a color-coded timeline. To the right, there is a list of events with columns for Client, Subject ID, Type, Date Received, Event Name, Room, Client, Lot #, and Day.

Client #	Subject ID	Type	Date Received	Event Name	Room	Client	Lot #	Day
191	ABC0000881	Clinical Run	1 day ago	Isolation	B2	191	713	3 of 3
980	ABC0005560	HD Split Run	1 day ago	Media Change	B9	191	456	1 of 1
121	ABC0006670	Media Change	2 days ago	Clinical Run	B5.2	001	783	7 of 7
331	ABC0009000	Clinical Run	2 days ago	Expansion	B13.2	331	213	10 of 10
001	ABC0009990	Run D4	3 days ago	Isolation	B16	980	445	1 of 1

Scheduling

The screenshot displays the 'Inventory' interface with a table of items. The table has columns for Group, Name, sum(Current Qty), sum(Units), Lot Number, Status, and Expiration Date. The items are categorized into groups like EtOH, Extraction Buffer, and Gloves.

Group	Name	sum(Current Qty)	sum(Units)	Lot Number	Status	Expiration Date
EtOH (1)	70% Ethanol	100	L	58926	Pending Verification	06/30/2023
Extraction Buffer (5)	HEPES-NaOH	20	L	365897	Verified	10/13/2022
	Ligation Buffer	25	L	8631945	Verified	12/30/2022
	NP-40	10	L	2409571	Pending Verification	06/30/2022
	RIPA	3	L	45319-110	Pending Verification	07/09/2022
Gloves (3)	Tris-HCl	8	L	8365-0	Quarantined	09/22/2022
	Nitrile - Large	5	box	A53456	Verified	
	Nitrile - Medium	5	box	A53778	Verified	
	Nitrile - Small	5	box	A53792	Verified	

Inventory

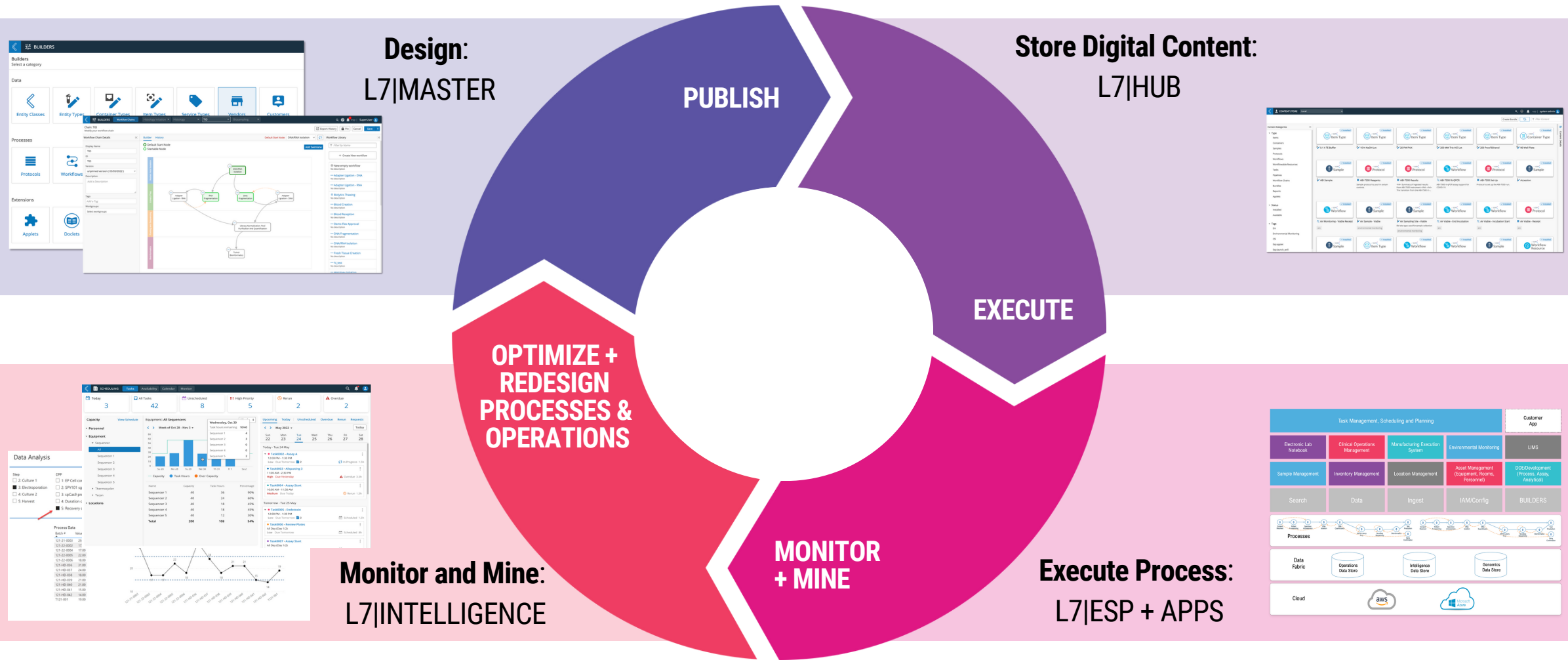
The screenshot shows the 'Location' interface for a '-84C Freezer'. It includes a 'Container View' section with a table of item pools and their locations. The table has columns for Item Pool, Location, and Quantity.

Item Pool	Location	Quantity
ESPO00001	1A	(3)
ESPO00002	1B	(0)
ESPO00003	1C	(0)
ESPO00004	1D	(0)
ESPO00004	2A	(3)
ESPO00005	2B	(0)
ESPO00006	2C	(0)
ESPO00007	3A	(3)
ESPO00008	3B	(0)
ESPO00009	3C	(0)
ESPO00010	4A	(3)
ESPO00011	4B	(0)
ESPO00012	4C	(0)
ESPO00012	4D	(0)

Location

# Digitalization Lifecycle

Design > Publish > Execute > Monitor + Mine > Optimize



# L7 Informatics Customers





# CASE STUDIES





# QC of Early Phase Cell Therapy Trials



A regulatory-compliant platform to digitalize all manufacturing and QC operations

## SITUATION

Cell Manipulation Core Facility (CMCF) at DFCI seeks to implement quality control of their Cellular Therapy Products to Ensure Quality, and Purity using L7|ESP pre-built workflows and integrations. CMCF also wanted eliminate all paper batch records.

## SOLUTION

Implementing L7|ESP a single unified “validated” platform to digitalize all operations starting with QC for early phase cell therapies. Digitalizing and Automating 31 QC Processes (Workflow Chains) with over 90 unit-lab-operations

## WORKFLOW CHAINS

### WORKFLOW CHAINS

#### FLOW CYTOMETRY PANELS

- |                              |                                 |
|------------------------------|---------------------------------|
| 01. 6Color Lymphocyte Panel  | 13. INKT ENRICHMENT Flow Panel  |
| 02. ARC-T Panel              | 14. INKT EXPANSION Flow Panel   |
| 03. BCMA Panel               | 15. INKT TETRAMER Flow Panel    |
| 04. Sponsor BCMA Panel       | 16. iPSC Characterization Panel |
| 05. CAR TEAM-E Flow Panel    | 17. iPSC Differentiation Panel  |
| 06. CAR79B19 Flow Panel      | 18. LITTMUS Treg Flow Panel     |
| 07. CD34 Enumeration Panel   | 19. ROR1 Panel                  |
| 08. CD34 Dual Platform Panel | 20. Sponsor TREG Flow Panel     |
| 09. Duraclone Panel          | 21. Sponsor TREG Flow Panel     |
| 10. EGFR CAR Flow Panel      | 22. TCRαβ Flow Panel            |
| 11. EVE LYMPH Panel          | 23. TREG Panel                  |
| 12. EVE TREG Panel           | 24. TriPRIL Flow Panel          |

#### AUTOMATED AND MANUAL ASSAYS

01. ABO/Rh Typing
02. Appearance Test
03. Automated Cell Counts
04. BacT 14-day Sterility
05. CFU
06. CFU Gene Therapy
07. ELISA
08. Endotoxin Testing
09. Manual Gram Stain
10. Manual Sterility
11. Mycoplasma
12. Trypan Blue Viability

#### OTHER WORKFLOW CHAINS

01. Client Receipt
02. Product Pooling
03. Product Receipt
04. Product Issue/Disposition
05. Product Splitting
06. Sampling Process
07. Sampling Receipt
08. Subject Association

## VALUE COMPARISON OF THE L7|ESP UNIFIED PLATFORM VS INTEGRATED POINT SOLUTIONS → TCO

INVESTMENT	L7 ESP	INTEGRATED POINT SOLUTIONS
<b>Licenses</b>	Annual License Model: Core License + Additional Packages (Lab Operations, Research, etc...). Updates to the latest release are included.	Multiple licenses for multiple solutions (ELN, LIMS, Inventory Management, Freezer Management, Instrument Integration, Data Management, Reporting, etc...). Upgrades to the latest release may incur additional license fees.
<b>Maintenance Fees</b>	Maintenance is included in the annual license.	Typically 20% - 22% of the license fee for each solution.
<b>Integration</b>	Because L7 ESP is a unified platform and leverages a single data fabric, no integration is required to enable an end-to-end process other than, for example, an ordering portal or ERP system (as required).	Multiple point solutions require multiple integration points, leading to higher costs and preventing full contextualization of the overall data model, making it extremely difficult or even impossible to obtain meaningful insights.
<b>IT Resources</b>	Only a single set of common skills (Python, HTML, and JavaScript) are required to maintain and extend all aspects of research, development, and lab operations. Fewer IT resources are required to maintain such a unified platform.	Multiple solutions require multiple technical skillsets to maintain the solutions, thus requiring additional IT resources and cost.

# VALUE COMPARISON OF THE L7|ESP UNIFIED PLATFORM VS INTEGRATED POINT SOLUTIONS → CAPABILITIES

INVESTMENT	L7 ESP	INTEGRATED POINT SOLUTIONS
<b>Data Model</b>	L7 ESP offers a flexible late binding data model tailored to customer needs with the Builders no-code configuration tool. Ontology Services like SciBite ensure adherence to ontology rules across the organization. With a single data fabric, L7 ESP can collect and execute data for any end-to-end process, leading to comprehensive insights into scientific and operational data.	Some solutions require customers to adjust their data models to fit an existing structure. This can result in changes to customer processes to accommodate inflexible data models, leading to time-consuming and costly analysis of data from multiple integrated systems. This can also result in a loss of contextualization and value of the data collected.
<b>Process Model</b>	L7 ESP's low code/no code configuration tool allows for easy configuration of any process using both predefined and new content without requiring the customer to change any part of their current processes.	Some solutions force customers to adapt their processes to fit a predetermined structure and may not support all protocols and workflows within an end-to-end process.
<b>Predefined and Reusable Content</b>	L7 Informatics continually creates reusable content to enhance implementation efficiency and speed. This content includes data entity definitions, workflow components, instrument connectors, and more, which can be shared easily between departments to improve collaboration and speed to value.	Without the use of a composable architecture and unified platform, implementations tend to be more custom and deployed in silos across different departments.
<b>Business Analytics Enablement</b>	L7 ESP uses a single data fabric including an intelligence data store that can be used by any business intelligence tool such as Microsoft PowerBI, Tableau, etc. to enable scientific and operational insights into all processes and data within L7 ESP. With L7 ESP's single data fabric, all data is contextualized to enable deeper and more meaningful insights.	Data sourced from multiple systems typically is exported to a data lake system for analysis. However, data stored in a data lake will lose context as the different data sources are joined, which restricts the value that can be obtained from the analysis.
<b>Communication and Visibility</b>	Users across all groups (Biospecimen Management, Sample Management, Lab Operations, Pathologists, Bioinformatics, etc.) all work seamlessly in the same platform. All requests, status, results, reconciliations, and more are easily available.	Communication via email, internal messaging services, etc. is required to communicate requests, status, results, issues, etc. when using multiple solutions. Visibility to critical information regarding requests, status, results, reconciliations is much more difficult when using multiple solutions.
<b>Sample Lineage and Provenance Tracking</b>	L7 ESP tracks each sample from storage in the BSSR to use in each lab and includes tracking via couriers and external partners, as applicable. L7 ESP automatically manages and tracks all sample parent-child relationships as well as all sample movement to provide full Chain of Identity and Chain of Custody for all samples.	Using multiple systems to enable any end-to-end process increases the difficulty to not only track but also to maintain sample lineage and provenance when sample related data must be exchanged between systems, sometimes multiple times within a single process.
<b>End-to-End Audit Trail</b>	L7 ESP includes a complete and immutable audit trail of each change in the database including all implemented end-to-end processes.	Multiple solutions not only requires multiple audit trail exports but also mapping and assemblage of different audit trail formats to produce a single audit trail of an end-to-end process.



# VALUE COMPARISON OF THE L7|ESP UNIFIED PLATFORM VS INTEGRATED POINT SOLUTIONS → IMPLEMENTATION + MAINTENANCE

INVESTMENT	L7 ESP	INTEGRATED POINT SOLUTIONS
<b>IT Resources</b>	Only a single set of common skills (Python, HTML, and JavaScript) are required to maintain and extend all aspects of research, development, and lab operations. Fewer IT resources are required to maintain such a unified platform.	Multiple solutions require multiple technical skillsets to maintain the solutions, thus requiring additional IT resources and cost.
<b>Ease of Configuration</b>	Because most of the process and data modeling changes can be performed by anyone trained in the L7 Master low code / no code configuration tool, changes can be made much more rapidly since IT resource typically do not need to be involved.	Many point solutions required IT resources to make basic changes such as extending the data model or modifying a protocol step, thus increasing costs and delays while decreasing flexibility and speed to market.
<b>Implementation Approach and Skillsets</b>	Uses Low Code / No Code configuration tool for Data and Process Modeling, Reporting, Data Processing, and Automation leverages commonly used technical skills, including Python, HTML, and JavaScript.	Multiple solutions typically require multiple technical skillsets across all the solutions from database management to configuration to coding and more with each solution potentially requiring a different set of technical skills.
<b>Implementation SDLC</b>	L7 Informatics' well defined customer content SDLC provide a single roadmap for a successful implementation of any end-to-end process in L7 ESP. Each customer implementation is fully documented.	Implementing multiple systems requires multiple implementation approaches and models increasing costs and time to value.
<b>Verification and Validation</b>	Each major release of L7 ESP is verified and validated. In addition, each customer implementation is verified by L7 Informatics' QA resources. Verification and validation documentation including test matrices, trace matrices, Verification Summary Report, Release Notes, and more are provided to each customer to support their own verification and validation efforts.	Verification and Validation is required for each system, leading to higher overall validation costs. Some vendors may provide verification and validation documentation while others may not.
<b>Updates</b>	L7 Informatics is a PaaS solution which means that L7 ESP updates are provided to each customer who can then implement those updates on their own schedule. Any required verification and validation related to L7 ESP updates or additional implementation phases need only be performed in one system.	Verification and validation will be required (as applicable) to each system update as well as each system impacted by additional implementation phases.



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### **About L7 Informatics**

L7 Informatics, Inc. is a leading provider of integrated scientific data and analytics solutions. The company offers a comprehensive platform that enables seamless data integration, advanced analytics, and collaborative workflows, empowering scientists and researchers to accelerate discoveries, improve operational efficiencies, and drive innovation. L7's mission is to revolutionize how scientific data is managed, analyzed, and utilized, facilitating breakthroughs in research, drug discovery, development, and manufacturing. To learn more, visit [www.l7informatics.com](http://www.l7informatics.com).

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