CARA

The Intelligent Content Services Platform

Driving Innovation in Regulated Industries

www.generiscorp.com

generate 2019
CARA Days

Princeton, New Jersey | July 17th 2019
The Hyatt Regency Princeton
102 Carnegie Center, Princeton, NJ 08540

Cambridge, Massachusetts | 18th July 2019
The Hyatt Regency Cambridge
575 Memorial Drive, Cambridge, MA, 02139

San Francisco, California | 22nd July 2019
Hilton San Francisco Bayfront
600 Airport Boulevard, Burlingame, CA 94010

Lake Forest, Illinois | 23rd July 2019
The Deer Path Inn
255 E Illinois Road, Lake Forest, IL 60045

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Generate Conferences

Next Up:

Generate Europe – March 2020 - Barcelona
Generate US – May 2020 – Sarasota, FL

About Us

Over 400,000 Users Globally

CARA Modern Q2 2019

20 Years

CARA Released

Generis Founded

HQ in Sarasota, FL

Offices in US, UK, Europe

Our Knowledge

Industry Experience

Over 20 years working with many of the top life science companies demonstrates Generis' unparalleled industry experience and enduring presence in the market.

Unique TED Approach

URS → BE → TED → FRS

Project Services

- Project Management & Administration
- Requirements & Configuration
- Data Migration
- Validation
- Integration Management
- Installation & Deployment
- Training

Partners

Working with selected partners, we are able to provide significant business value to customers by combining their industry experience, expertise and complementary products with CARA.

AERO EXPERTS YOU NEED
ADLIB
Alfresco
Armedia
box
Capgemini
DocuSign
DOSSPLORER Viewing matters!
EXTEDO eRegulatory Affairs
INCONSULT
Infosys
kinapse a SYNEOS HEALTH company
Lorenz LIFE SCIENCES GROUP
MAIN 5
OSTHUS
Planet Pharma Solutions
SPOTLINE
tcs 50
Tech Mahindra
USDM Life Sciences
VALIANCE
WAVE TECHNOLOGY SOLUTIONS GROUP

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Pfizer
BAYER
MERCK
VISA
citi
AstraZeneca
Otsuka
GILEAD
Gen Re
MFS
Roche
Bristol-Myers Squibb
FannieMae
Biogen
CHUGAI
Abbott
A Promise for Life
Farm Credit Canada
PACIFIC LIFE
Johnson & Johnson
NOVARTIS
ucb
Mylan
rb
gsk
Ameritas
fulfilling life
3M
FRESENIUS KABI
Kadmon
hannover re
U.S. DEPARTMENT OF HOMELAND SECURITY
THE GREAT SEAL OF THE STATE OF NORTH CAROLINA
THE NOBLEST MOTIVE IS THE PUBLIC GOOD
COUNTY OF SAN DIEGO
MIAMI-DADE COUNTY
City of SACRAMENTO
NSW GOVERNMENT
Transport for NSW
TOTAL
COMMITTED TO BETTER ENERGY
DOW CORNING
Chevron
Canadian Natural
covestro
MEG ENERGY


Walt Disney Studios
QVC
SAG·AFTRA
GE Power & Water
Water & Process technologies
ALTA DEVICES
bhpbilliton
Pratt & Whitney
A United Technologies Company
J. J. Keller
& Associates, Inc.®
Since 1953

Gartner Group Statement – ECM is dead

Michael Woodbridge
Research Director, Gartner
Blog on gartner.com (2017)

https://blogs.gartner.com/michael-woodbridge/the-death-of-ecm-and-birth-of-content-services

Michael Woodbridge, Research Director at Gartner, wrote a blog where he stated that he has had to change a view of Content Management that he spent the majority of his career defining. He states that he now considers that ECM is dead.

By this he explains that he means the push to consolidate to a centralized enterprise-wide platform. In his view, this has proven to be "almost impossible" to achieve. Instead, in order to ensure compliance, business knowledge retention / dissemination, cost efficiency and innovation, companies should switch to a Content Services approach.

This approach is to build a family of applications that communicate together well, and overrules consolidation for its own sake, to ensure maximum functionality for minimum risk, while allowing for a single source of truth.

He states that this approach is the truly strategic rather than technology oriented approach which is not only the reality facing almost all enterprises now, but positions them best to cope with future technologies.

What Gartner is saying

Consolidation to a single Enterprise tool does not work

Where most companies are today

A Family of Apps that communicate is the target

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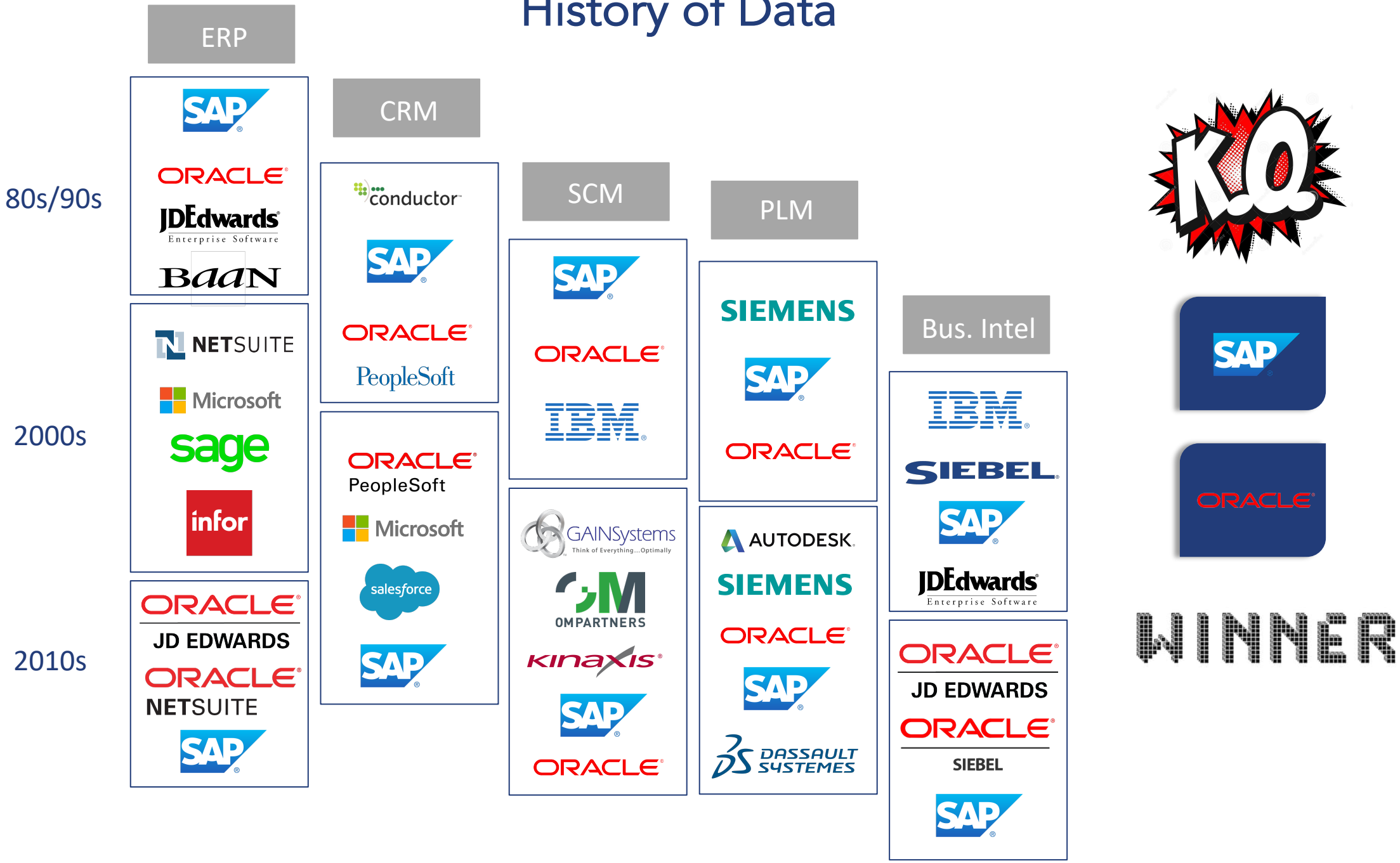
History of Data

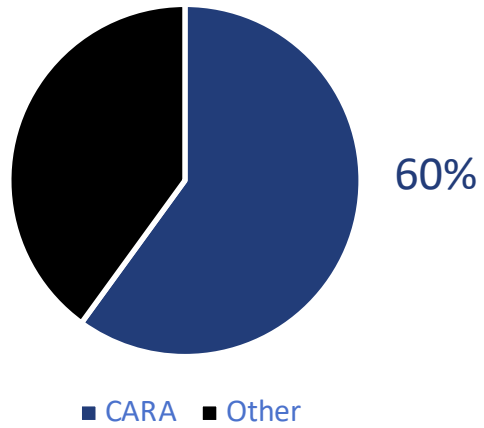


History of Business Process ECM

ECM

80s/90s	2000s	2010s
Webtop	cara, FirstDoc, Webtop, D2	cara, D2, Veeva

Top 15 Global Life Science



History of Storage

	Pure Storage	Storage +	Archive	Cloud
80s/90s	IBM, ORACLE	FileNet, documentum	documentum, IBM, mimecast, Barracuda	
2000s		documentum, FileNet An IBM Company, ORACLE WebCenter, Alfresco, SharePoint, box	box	Google, amazon web services S3, box
2010s				

History of Integration

80s/90s

2000s

2010s

Simple Exchange

Electronic Data Interchange

Sun microsystems

xerox

Common Language

W3C XML

IBM SOAP

Microsoft

REST & JSON

Middleware

IBM

ORACLE

redhat

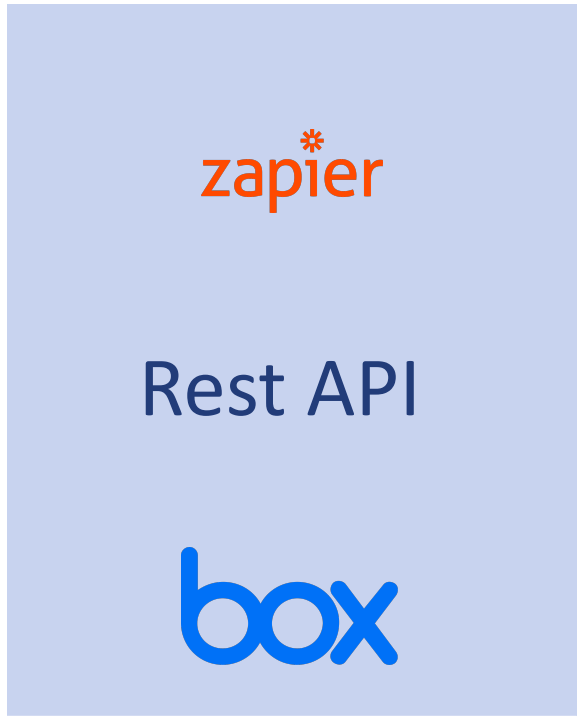
IaS

MuleSoft

tray.io

zapier

Convergence



cara

cara

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cara

Data

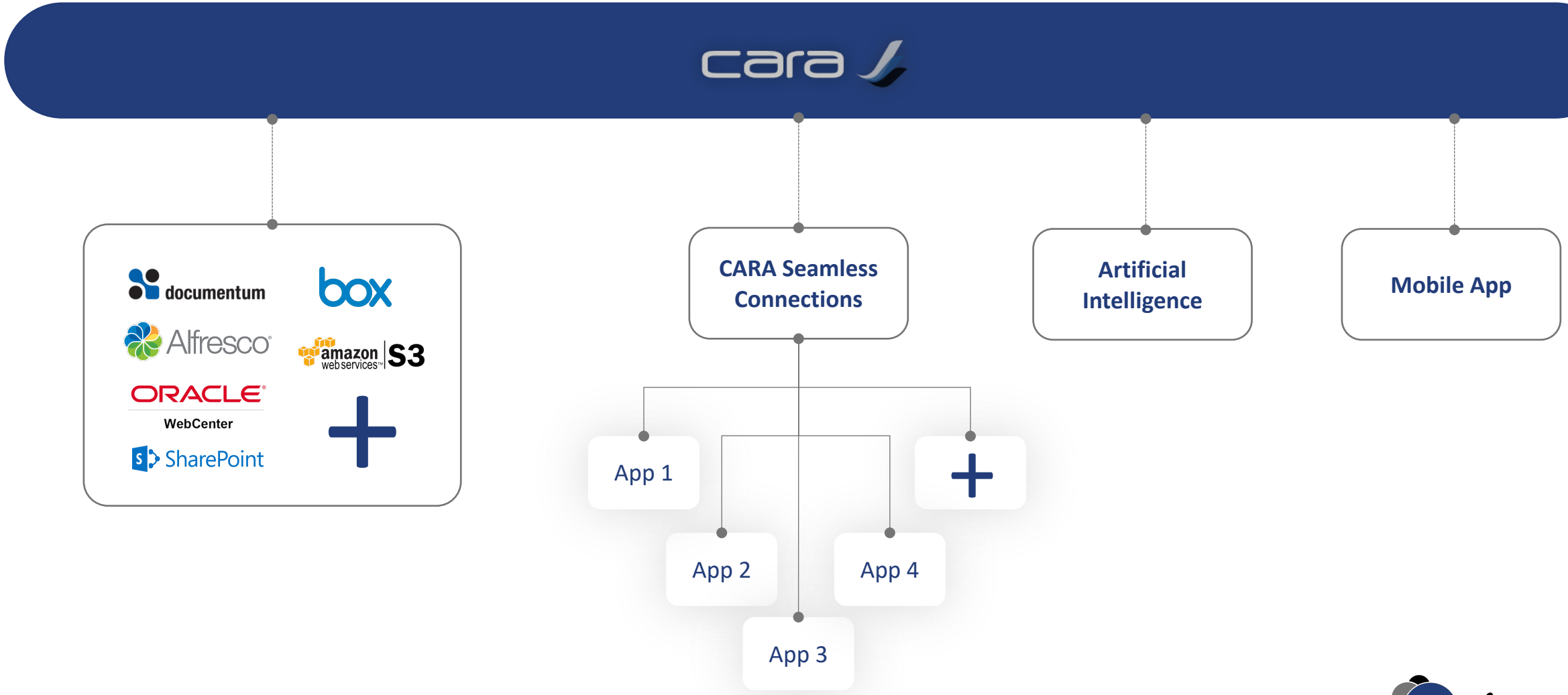
BP ECM

Storage

Integration

Intelligent Content Services Platform

Our Platform



End-to-End Life Sciences

R&D / REGULATORY SUBMISSIONS / ECTD

Standard data structure and metadata based on the DIA Reference Model for handling submission documents of all kinds including publishing and eCTD viewing.

GXP / SOP / QUALITY

Standard data structure and metadata based on the DIA Reference Model for SOPs and other Quality documents including controlled printing, full lifecycle and workflows and a viewing portal.

ETMF

Standard data structure based on the DIA Reference Model for Electronic Trial Master File documents, including new site handling, reporting (missing documents etc.) and integration with multiple CTMS systems and an Investigator Portal.

LABELLING

Full label lifecycle from Core Data Sheet through translations to brancl versioning per country and Health Authority approval management. Structured content authoring and print shop portal.

SAFETY DATA EXCHANGE AGREEMENTS

Store and track Safety Data Exchange Agreements (SDEA) with contract expiration workflows and automatic single button generation of PSMF Annexes for submissions.

MEDICAL INFORMATION

Deal with incoming Medical Information requests via call centers, emails and more. Real time searching for answers, including automatic sending, and full per-country data privacy handling.

LIMS

Document handling optimised for clean-room conditions on mobile devices, including QR code usage and easy form filling to generate dynamic PDFs.

REGULATORY CORRESPONDENCE

Automate capture of incoming correspondence via the CARA Staging area, including email attachment extraction. Link to Dossiers and prepare and relate answers and commitments.

MEDICAL DEVICES

DIA Reference Model-based data structure and management of Design History Files (DHF), Device Master Records (DMR) and Device History Records (DHR).

SALES & MARKETING

Leverage submitted labelling and manage the associated sales and marketing documentation, including videos (with built in preview and annotation) and artwork.

CORPORATE (IT, LEGAL, HR)

Full set of standard templates and data structure for IT project documentation, contract / legal functionality such as document comparison and review / portal sharing, and Human Resources files.

IDMP

Data management through CARA integrated with your content management to provide IDMP functionality integrated with other solutions in the RIM space.

PSURS / EDUCATIONAL MATERIALS

Manage the dissemination of PSURs to affiliates and partners, along with Educational Materials, and track the progress of reporting to local agencies.

PHARMACOVIGILANCE

Integrate seamlessly with ARGUS or ARISg for case management with content securely stored and versioned in CARA.

SUBMISSION PLANNING & TRACKING

Build dossiers from planning sheets, Excel export lists or third party tools, and then track the progress, including metrics from one submission to the next for process improvement.

RIM

Combine one or more of the CARA solutions, and/or integrate with existing tools to make CARA the RIM portal for your enterprise.

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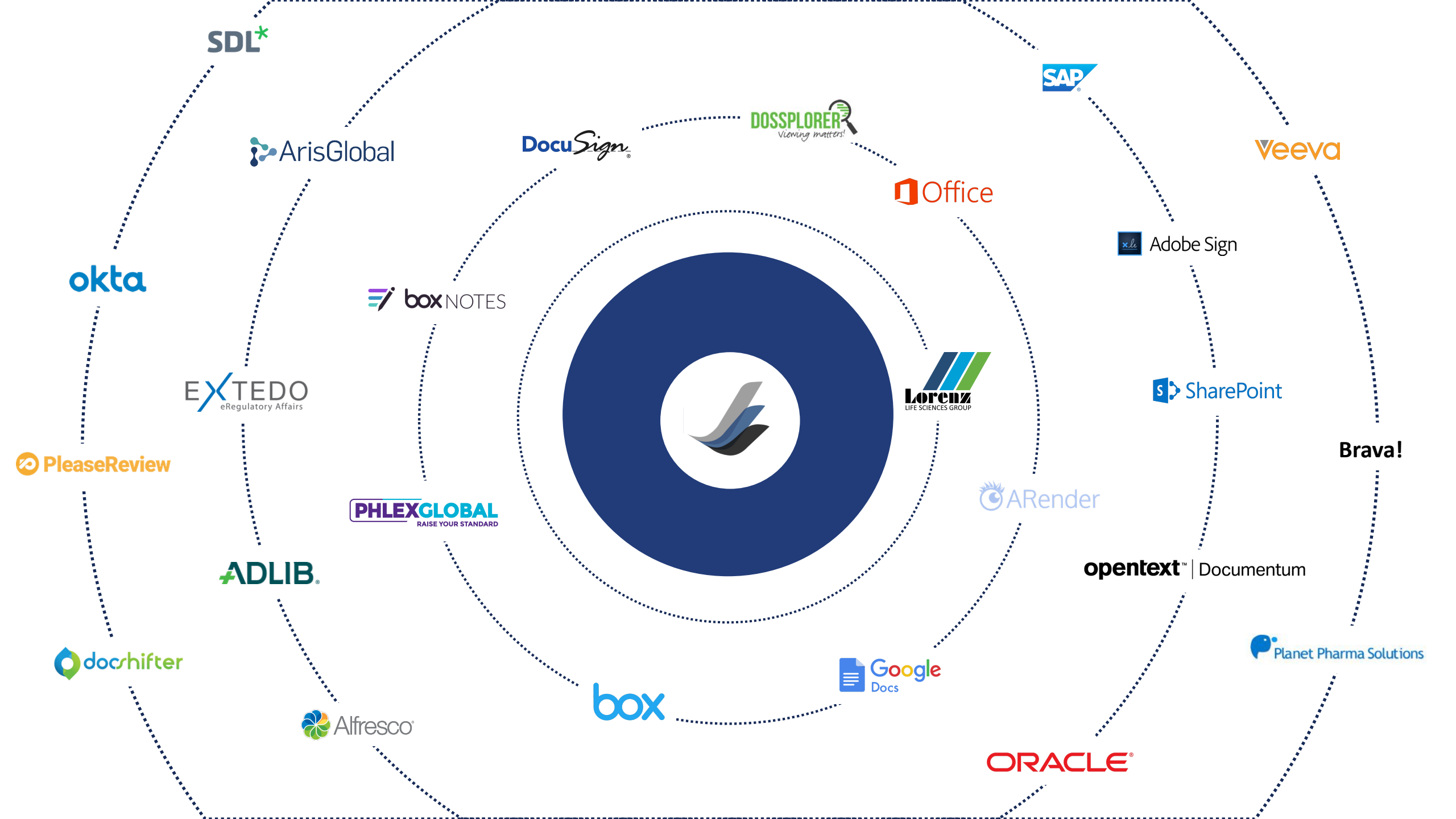
SDL
SAP
ArisGlobal
DocuSign
DOSSPLORER
Viewing matters!
Veeva
Office
Adobe Sign
okta
box NOTES
EXTEDO
eRegulatory Affairs
Lorenz
LIFE SCIENCES GROUP
SharePoint
PleaseReview
Brava!
PHLEXGLOBAL
RAISE YOUR STANDARD
ARender
ADLIB
opentext™ | Documentum
docshifter
Planet Pharma Solutions
Google
Docs
box
Alfresco
ORACLE

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Thank You

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