AI Powered Automation Proven in Life Sciences

Real Results In Action Today

WEBINAR

COMPLIANCE THROUGH DIGITAL AUTOMATION

cunesoft
compliance delivered

PHLEXGLOBAL
RAISE YOUR STANDARD

Jim Nichols
March 18, 2020

PHLEXGLOBAL

Phlexglobal, the leading technology and services organization for clinical and regulatory matters with a focus on helping clients to master their digital agenda via proven AI solutions.

About us

Established in 1997
Life Sciences Industry Focus
Software Solutions & Expert Services
500 FTE's worldwide
Global Offices: UK, US, POL, GER, IND
Privately Held

Track Record

10.000 users
500 studies executed
4000 submissions published
7M documents, 30M pages processed
> 17.000 products managed

> 200 clients worldwide

Pharmaceuticals
CRO's
Biotech's
Generics and API
Medical Devices

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COVID-19 Response Support

Resources to Fast Track Trials and Ensure Business Continuity

Phlexglobal can balance the need for speed with the importance of quality control in a time of crisis.

A SPECIAL PHLEXGLOBAL WEBINAR

Solutions to COVID-19 Business Continuity and Fast Track Trial Challenges – Clinical and Regulatory Aspects

Wednesday, April 1, 2020
11am Eastern / 4pm GMT / 5pm Central Europe

Karen Roy
Chief Strategy Officer

Jim Nichols
Vice President
Product Management

- Status on COVID-19 guidelines from major health authorities (FDA, EMA, MHRA etc.)
- Fast track implications for IND and CTA filings to start trials without delay
- Impact for clinical trials – rapid deployment of teams, accelerated document processing, maintaining required quality
- Chances and potential of automation tools to reduce trial time
- Planning ahead for NDA and MMA filings to ensure quality submissions and a speedy start to the review process

Phlexglobal.com/webinars

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Today's Speaker

Jim Nichols

Vice President of Product Management, Business Applications

- Over 30 years' experience with compliant software solutions for regulated processes.
- Senior management positions at Liquent, Thomson Reuters and DitaExchange & Cunesoft.
- Bachelor of Science in Mathematics from The Pennsylvania State University.

Content Overview

- Welcome to the Digital Age
- The Reality of AI
- Real Results from Real Clients
  - IDMP Readiness
  - eTMF Quality
  - Submission Automation
  - Health Authority Communications
- Real Intelligence Delivered
- Q&A

We Are In The Digital Age

Becoming data-centric and mastering digital transformation is the most important topic for life sciences organizations of all sizes.

How will you act on YOUR digital agenda?

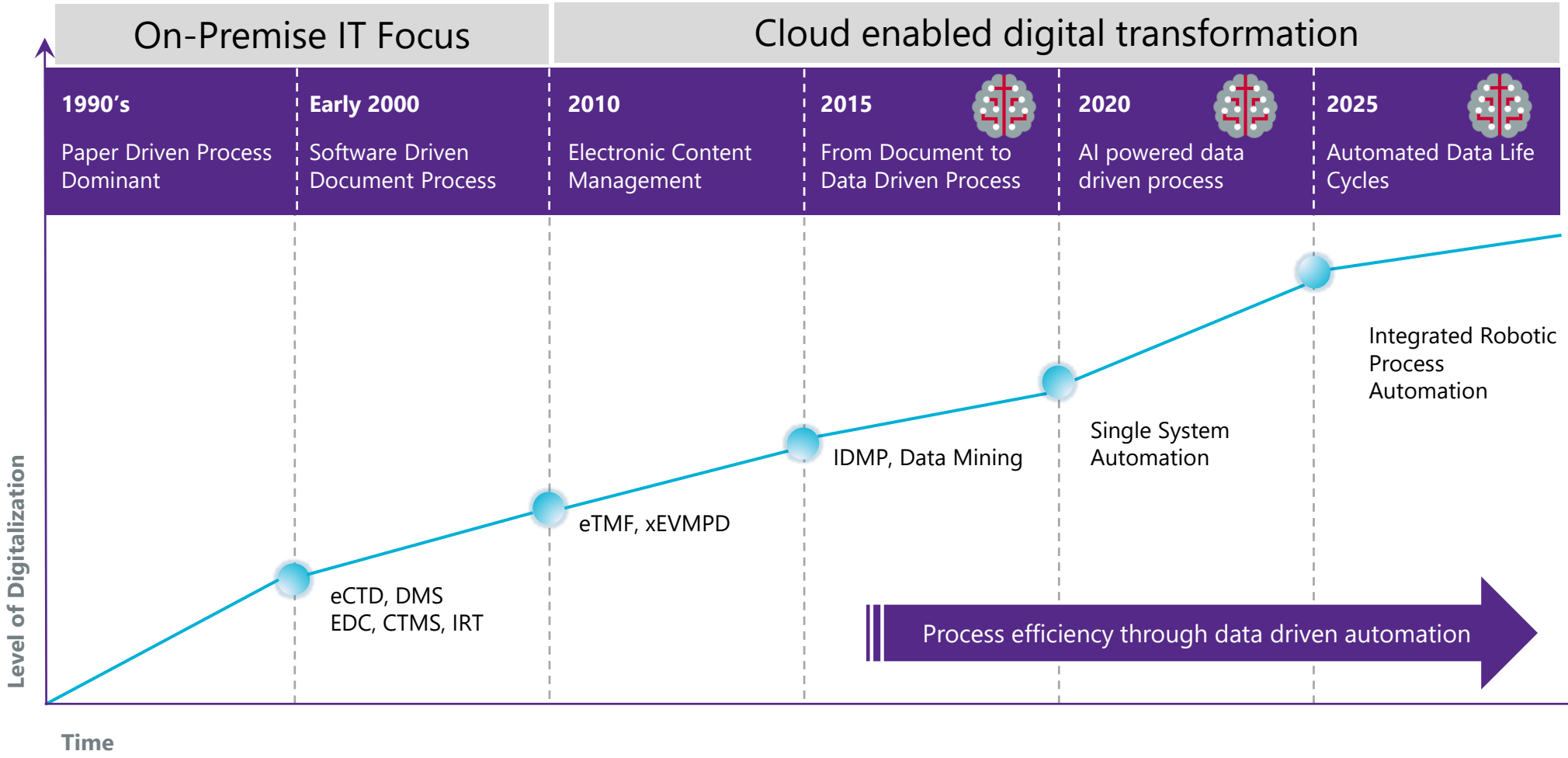
You May Be Considering…

- What are the specific steps we need to take?
- How can we leverage existing IT systems/investments?
- How can we solve increased compliance burdens?
- How can we manage the increased need to gather data?
- What parts of our business strategy need to change?
- What does it mean for our jobs?
- Is it really worth it?

Digital Health Evolution

- *Compliance through Digital Automation* -

"Data becomes the new gold. Enable your Digital Agenda. Become data centric. Where do you stand?"



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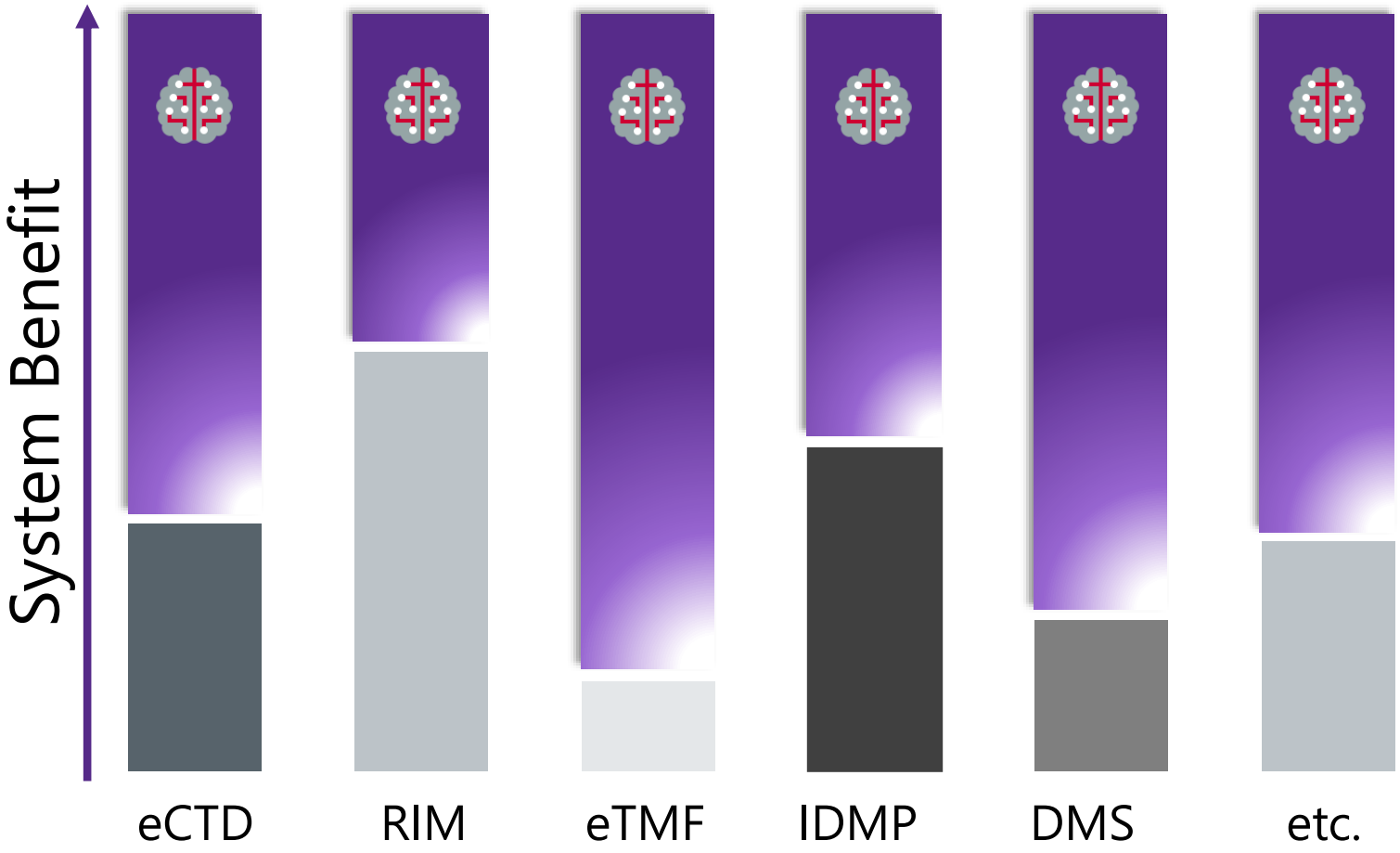
Give your systems a brain

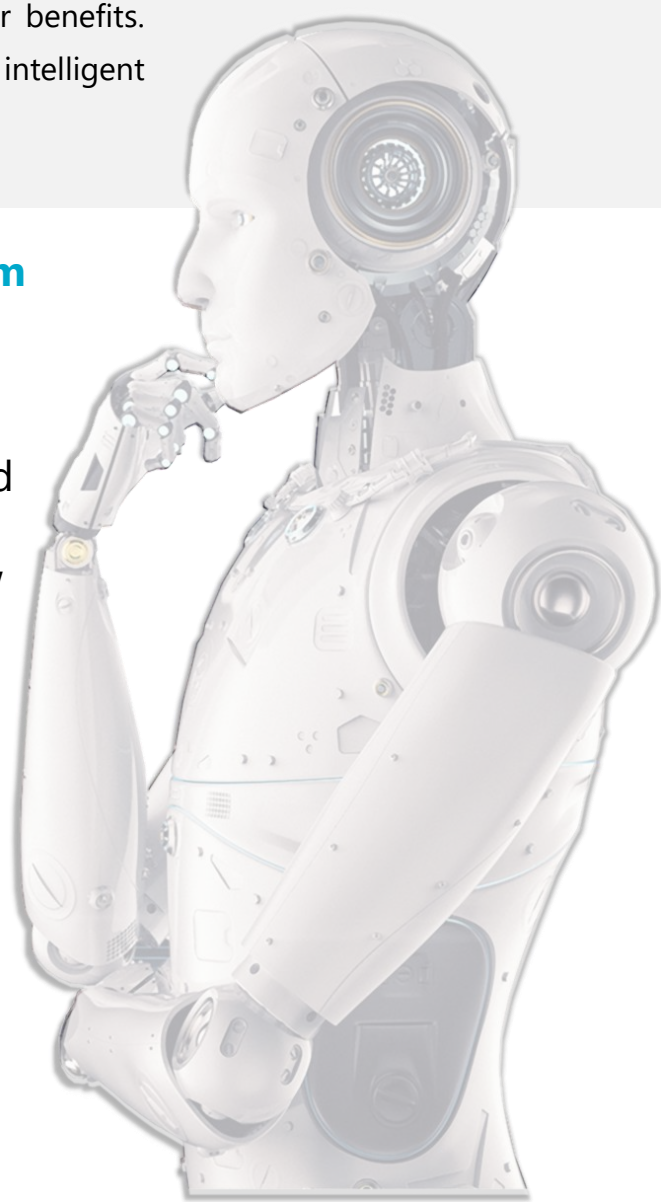
- Unlock Hidden Potential with Automation -

Most systems have not yet delivered on their promise of improved results and greater benefits. Now you can unlock new value using intelligent process automation.



Depth of System Capabilities

Automated in-process content classification and data mining do enable workflow automation and broaden system usability.



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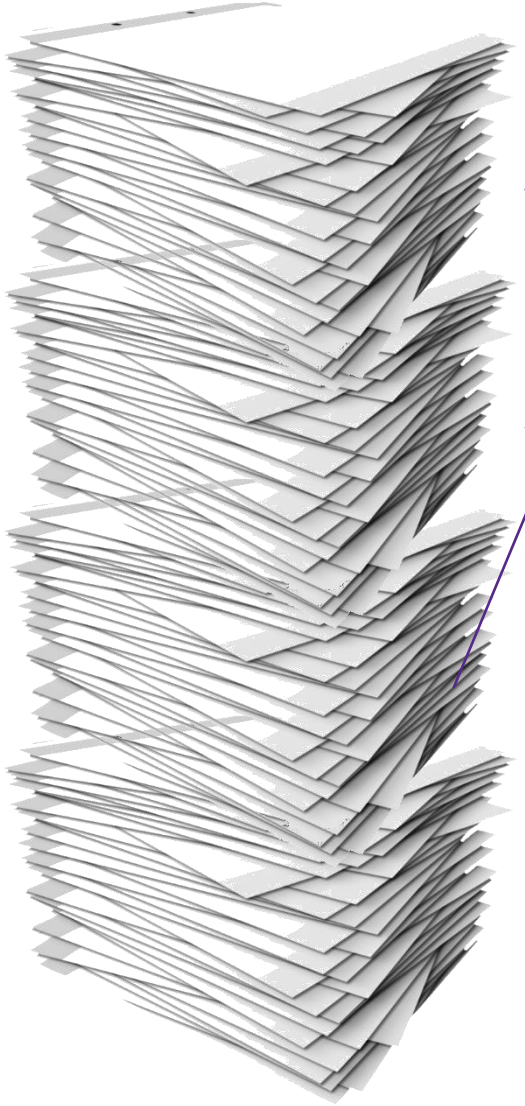
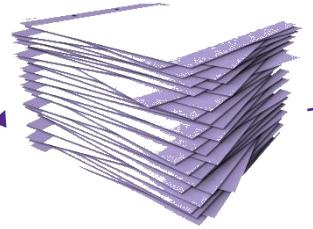
The Reality of AI

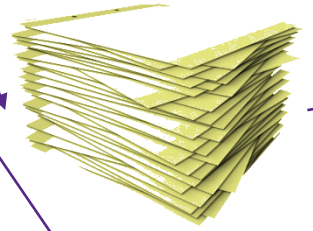
- **Artificial Intelligence is already here**
  - Smart Homes
  - Smart Cars
  - Biopharmaceutical Research
- **How are your industry peers already benefitting from AI?**
  - Classifying, extracting and encoding structured data from unstructured sources

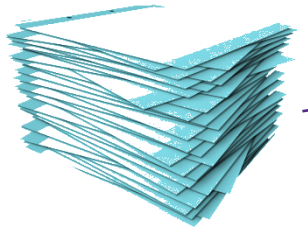
The Problem: Terabytes of unstructured content that contains rich data



Classify: Analyze content and determine each type of content







Extract: Find desired data points within each class of document content

Field 1	Field 2	Field 3
John	Smith	United States
Barb	Jones	Canada

Field 1	Field 2	Field 3
Pain	Fever	Ibuprofen
Swelling	Tiredness	Aspirin

Field 1	Field 2	Field 3
Johnson	123 Main Street	Philadelphia
Franklin	456 Front Ave	Chicago

Encode: Map results to controlled vocabularies and codes

Field 1	Field 2	Field 3
John	Smith	USA
Barb	Jones	CA

Field 1	Field 2	Field 3
Pain	Fever	392493
Swelling	Tiredness	689020

Field 1	Field 2	Field 3
Johnson	123 Main Street	Philadelphia
Franklin	456 Front Ave	Chicago

ACTIONABLE DATA: can drive processes and provide actionable information

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IDMP Readiness

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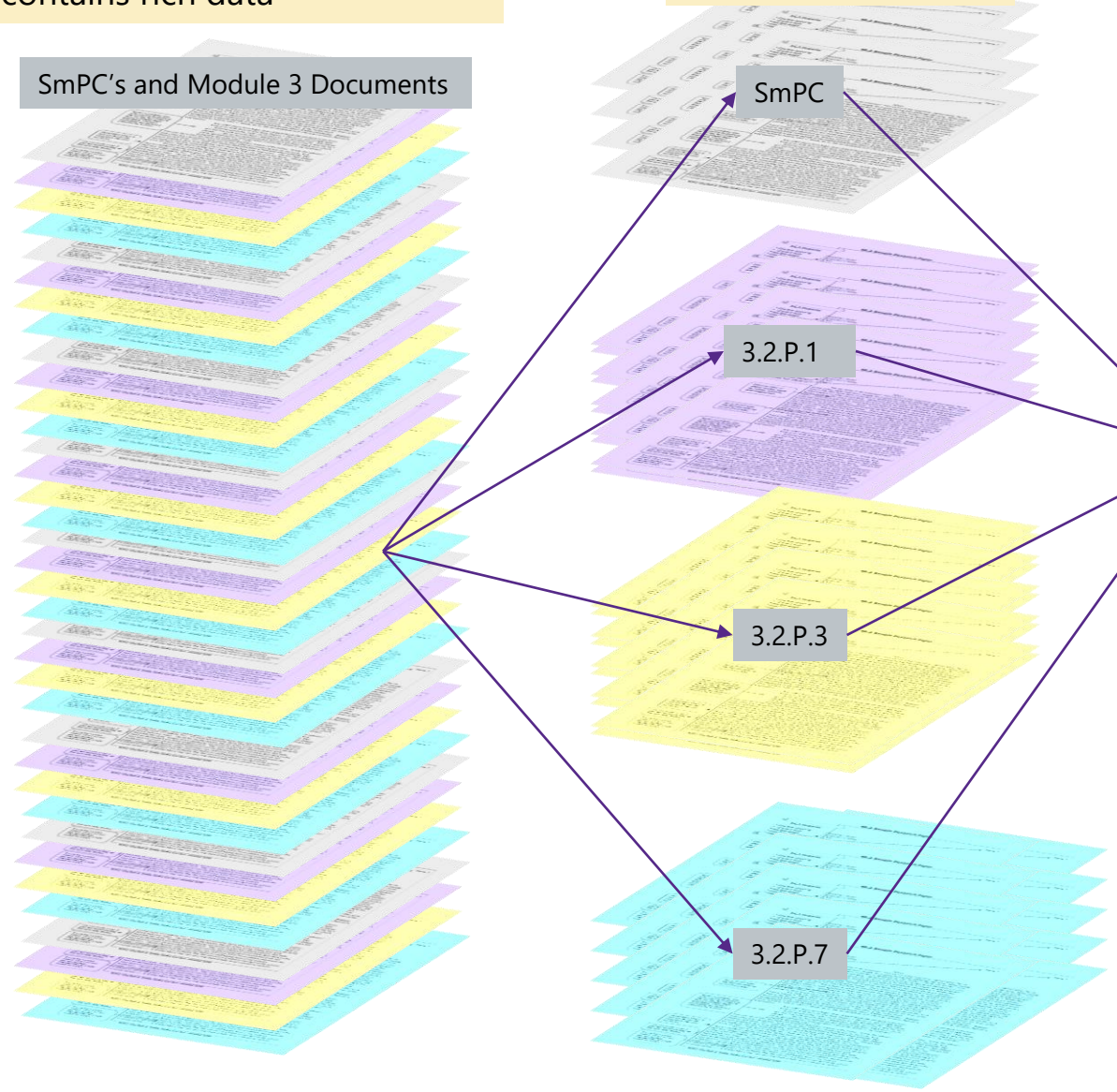

Entity	Value	Code
Full Name	Alacunesoft 30mg tablets	
Country	EMA	EMA
Marketing Authorization Number	UK 18024/0009	
Marketing Authorization Holder	PhlexPharma LTD	
Indication	Leg pain	10033446
Administrable Dose Form	Tablet	C38288
Route of Administration	Oral	PRO00333PHL
Package Description	Box containing 2 15-tablet blisters	
Unit of Presentation	Tablet	TBLT
Manufactured Dose Form	30mg tablet	
Strength	30mg	
Full Indication Text	Pain and swelling of legs	
ATC Code	N02BG10	
Contraindications	Pregnancy, high blood pressure	021.9; T70.4XXA
Ingredient	Cornstarch	42669-231-04
Ingredient Role	Excipient	
Substance	Acetominophen	
Authorization Type	Centralized Procedure	CP

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Case Study

Get Ready for IDMP

AstraZeneca

Business problem

- Preparation for IDMP iteration I deadline
- Increase compliance overall
- Data Extraction from SmPC & eCTD M3 documents

Project preparation

- Phlex-Distiller System Setup and Configuration
- Training of Customers specific Extraction Algorithms
- Implementation of Customer URS “Must-Criteria”
- Data extraction from 1591 Customers SmPC’s in 26 languages (ca. 35 data entities per SMPC)
- Data extraction from 272 3.2.P.1 eCTD M3 documents (substance data extraction)
- MedDRA coding of extracted indications
- Data curation of extracted data by Cunesoft data extraction team

Project feedback

- Validation of data-sets to ~90% accuracy

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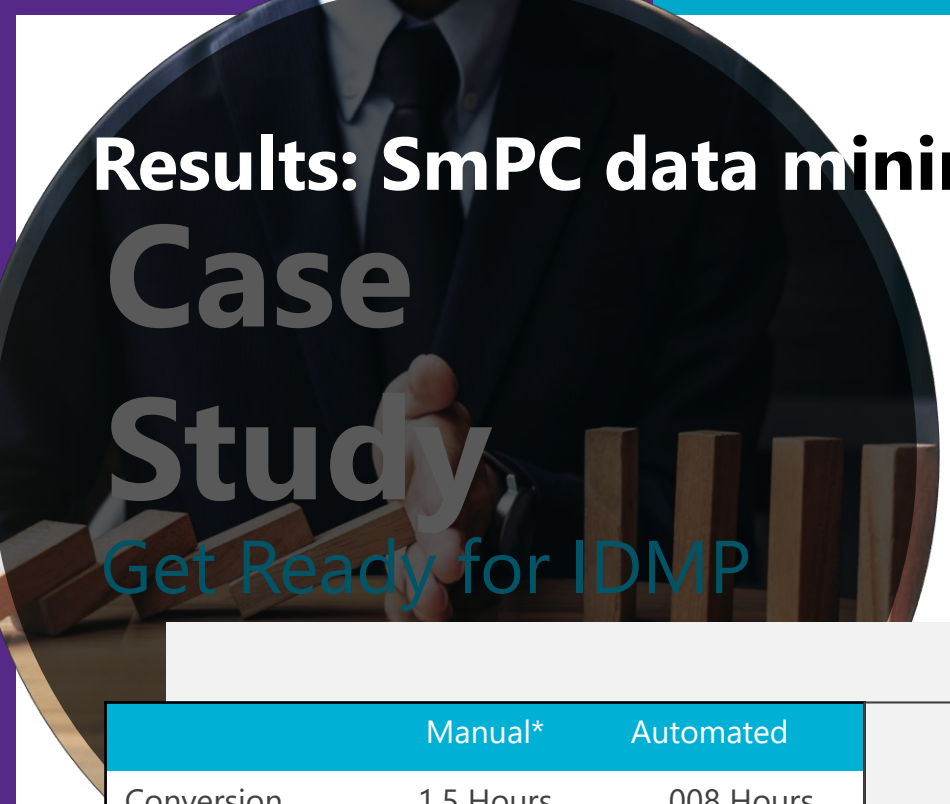
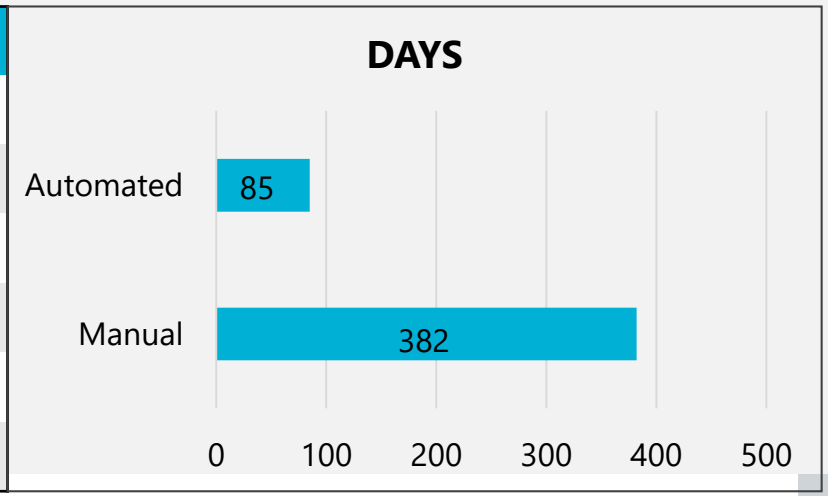
Results: SmPC data mining Statistics & Savings



	Manual*	Automated
Conversion	1.5 Hours	.008 Hours
1591 SmPCs	2387 Hours	13 Hours
	299 Days	1.7 Days
QA of Results	663 Hours	663 Hours
	83 Days	83 Days



Case Study Results:

- 1591 SmPC's in 26 languages
- 100 eCTD M3 documents in English
- Reduced Processing Time by factor 4-5
- Included QC times results in higher quality

*Manual data extraction assumption: 60 minutes data mining & 30 minutes data mapping (EV-Codes, G-SRS, MedDRA)

eTMF Quality

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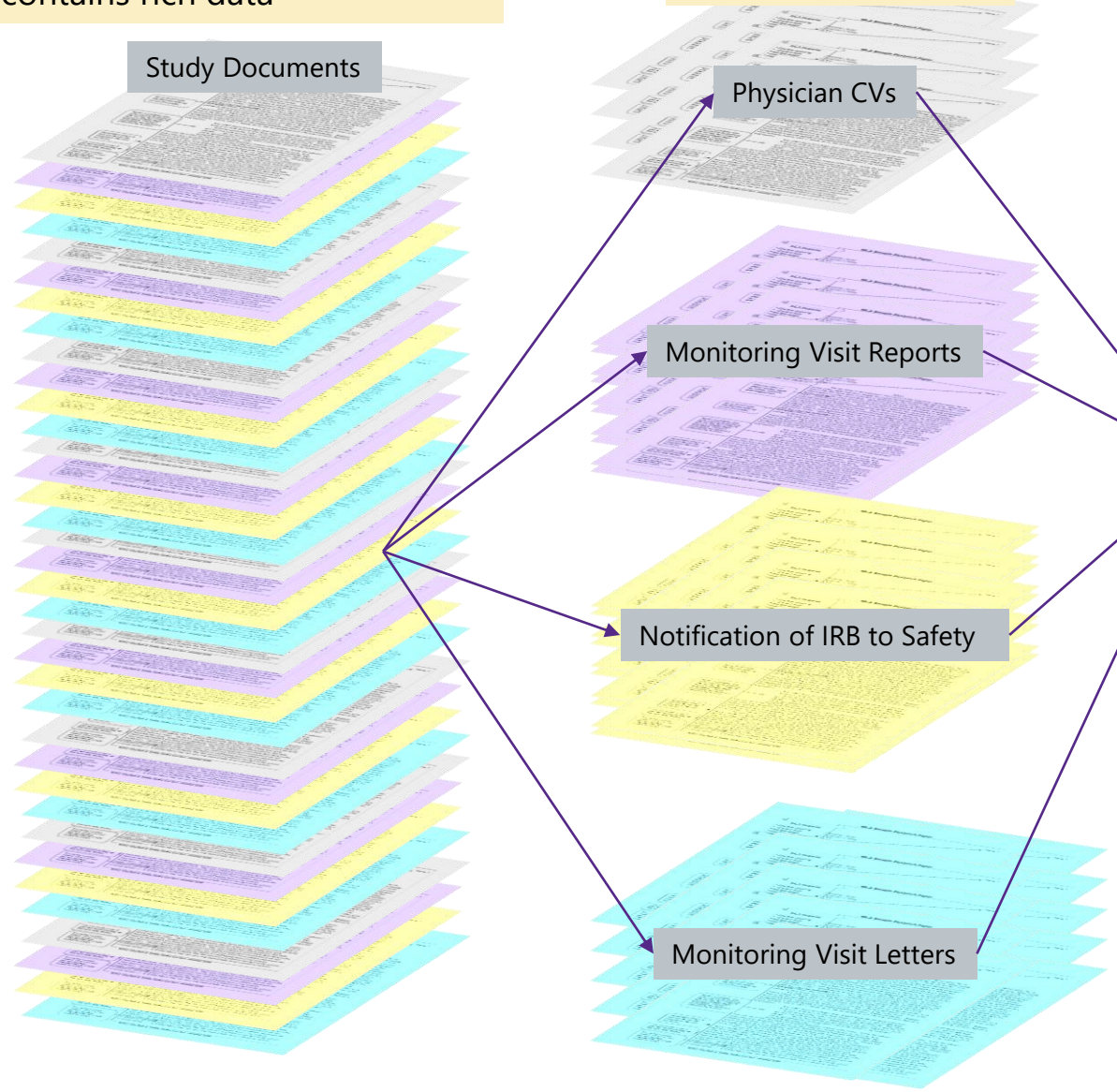

Entity	Value	Code
Protocol	Longitudinal Study of Adverse Effects	PRO28983
File Type		
Country	United States	USA
Site	University Hospital, 123 Main St, Anytown	SIT39933
Artifact	Monitoring Visit Report	05.04.03
Sub-artifact	Routine Monitoring Visit Reports	RMV
Signature Date	04-January-2020	
Record Date	08-January-2020	
Event Date	02-January-2020	
Expiry Date	31-January-2020	
Language	English	en
Vendor	ABC Vendor	VEN39932
Version	1.0	
Support Documentation		
Unblinding	General	GEN
Subject Number	SUBJ28839	
Case Number	CAS049399	

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Case Study

The Smarter TMF

Business Problem

- Constantly increasing trial content – nearly 700 different types of documents in a TMF
- Non-scalable manual processes reach limits of efficiency
- Inconsistent eTMF data extraction quality increases risk when TMF review occurs

Project preparation

- Automated TMF document type detection
- Automated TMF attribute extraction
- Integrate cune-Distiller into PhlexEview for TMF document indexing

Project Feedback

- Facilitate a seamless user experience enhanced with indexing suggestions
- Increase eTMF creation speed by factor 5 – 1% of typical TMF documents represents nearly 40% of the typical and most frequent documents
- Manage cost levels while increasing eTMF output
- Nearly immediate ROI achieved

Submission Automation

The Problem: Terabytes of unstructured content that contains rich data

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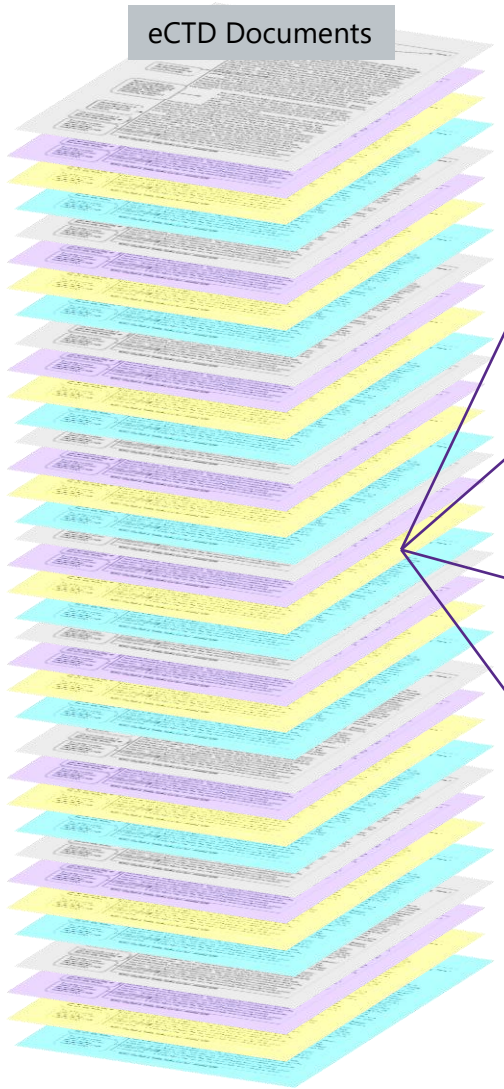

Manufacturing Process Development

Entity	Value
Substance	isophlexatol
Substance Mfr	Phlexglobal
Folder	3.2.S.2.6 Manufacturing Process Development

Code
SUB00013MIG
OMS00293ABC
3.2.S.6

Validation of Analytical Procedures

Entity	Value
Product	Phlexafine
Product Mfr	Phlexglobal
Folder	3.2.P.5.3 Validation of Analytical Procedures

Code
PRO00333PHL
OMS00293ABC
3.2.P.5.3

Letter of authorization

Entity	Value
Folder	1.4.1 Letter of Authorization

Code
1.4.1

Quality overall summary

Entity	Value
Folder	2.3 Quality Overall Summary

Code
2.3

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Case Study

Let My Documents Speak

Top 10 Pharma

Business Problem

- Regulatory submissions in eCTD have potentially 100's of possible folders in which documents can be placed
- Increasing submission volume is leading to needs for smarter ways of organizing documents into submissions globally
- Document authors/owners don't necessarily know relationship of their documents to the eCTD structure

Project preparation

- Analyze archive of submissions and the associated documents to train classification and extraction models
- Map classifications and extracted attributes to eCTD folder model including 'metadata nodes'
- Enable submission editor to leverage document attributes created by this process to automatically place documents in correct folder locations

Project Feedback

- Over 95% time savings when compared to individual document drag & drop process
- Gets smarter and smarter over time
- Now more people can help with creating submissions

Health Authority Communications

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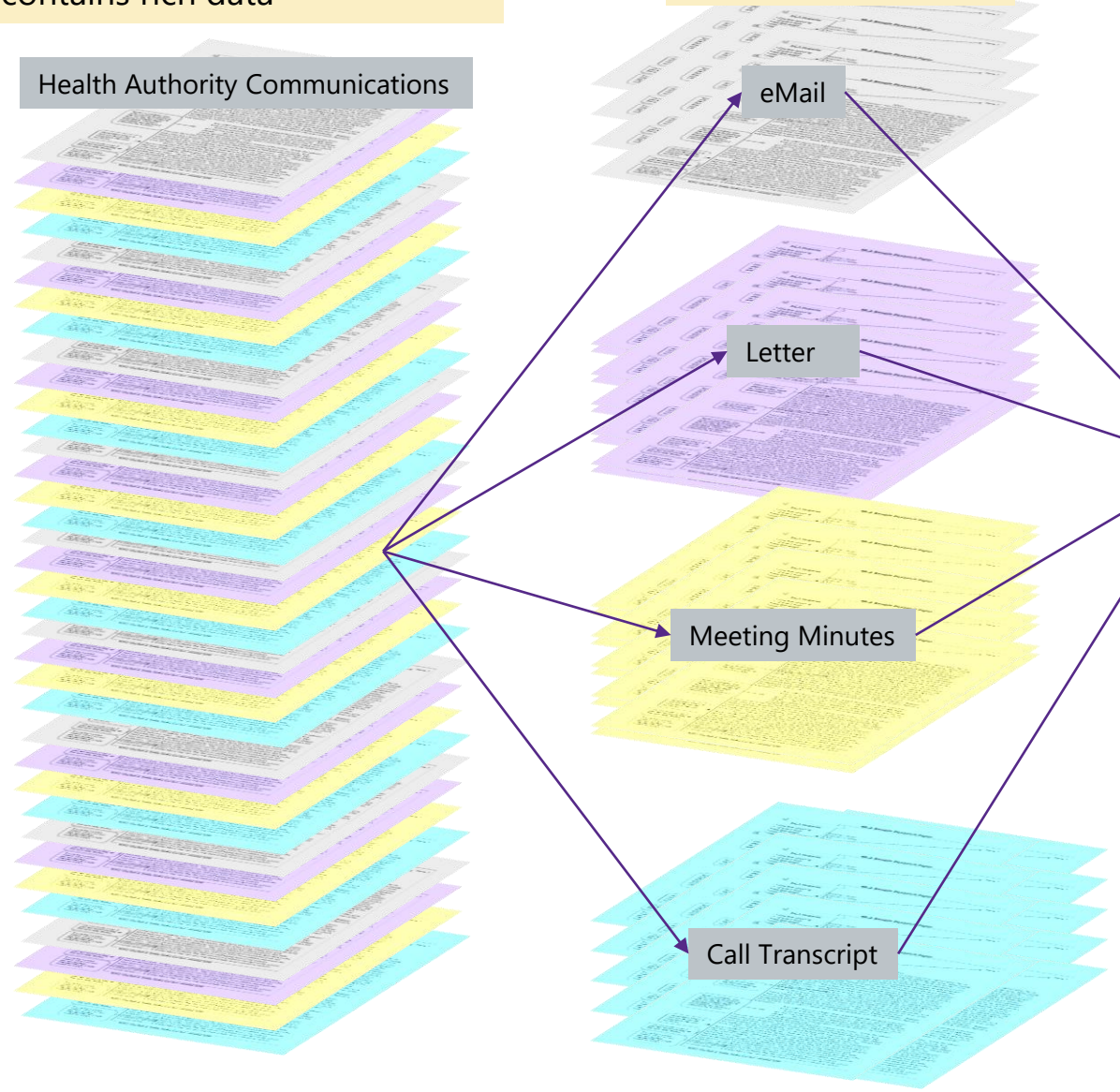

Entity	Value	Code
Name	Letter from FDA	
Type	Request for information	RFI
SubType	Reviewer comment	COMM
Language	English	EN
ProductName	Phlexafine 50mg Tablets	PRO00333PHL50
Active Substance	isophlexatol	SUB00013MIG
DrugProduct	Phlexafine	PRO00333PHL
Applications	323232, 532211	
Submissions	NDA Sequence 0001	323232-0001
HealthAuthority	FDA	
Received End Date	02-Jan-2020	
Issued Start Date	03-Jan-2020	
Topic	Study results	
SubTopic	More info needed	
Description	Automatically generated description of communication	
Communication Format	Letter	
Regulatory Objective	New drug approval	NDA
Country	United States	USA

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Case Study

A Flood of HA Comms

SANOFI

Business problem

- Constant flow of Health Authorities Communication documents - over 15 000 documents a year.
- Manually processing each communication takes 10-12 minutes
- Users capture minimal attributes to save time
- Delays in capturing can result in prolonged response times

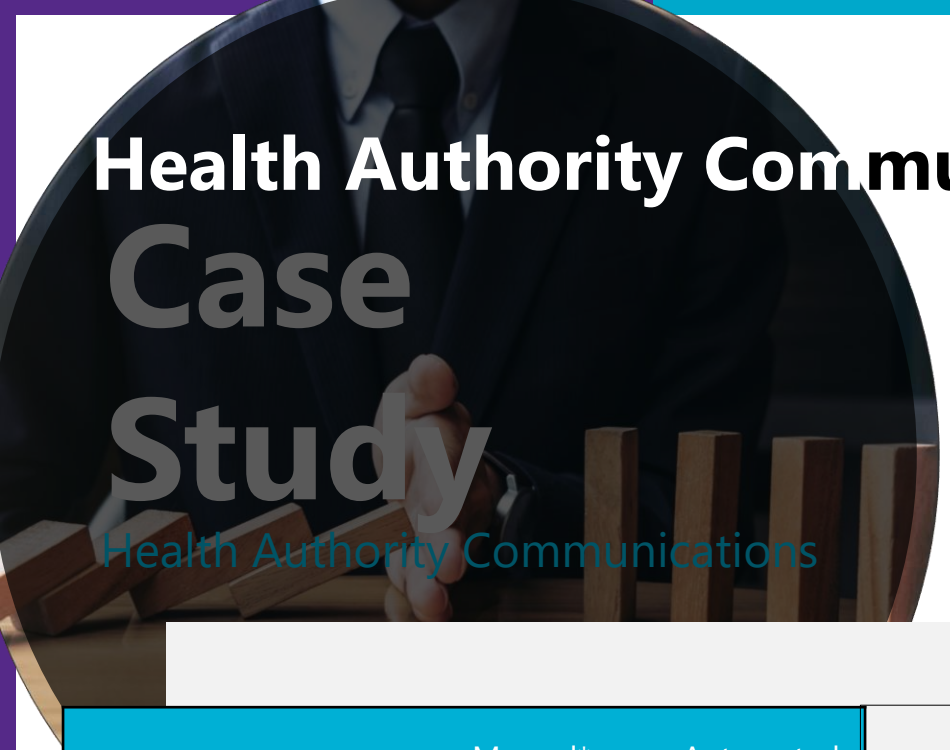
Project preparation & implementation

- Trained AI models on various types of HA Communications to classify and extract information such as related product, submission, agency and many more
- Connected to multiple internal repositories for data curation and validation
- Connected to Veeva Vault and its taxonomies for document attribution
- Push classified content directly into Veeva Vault

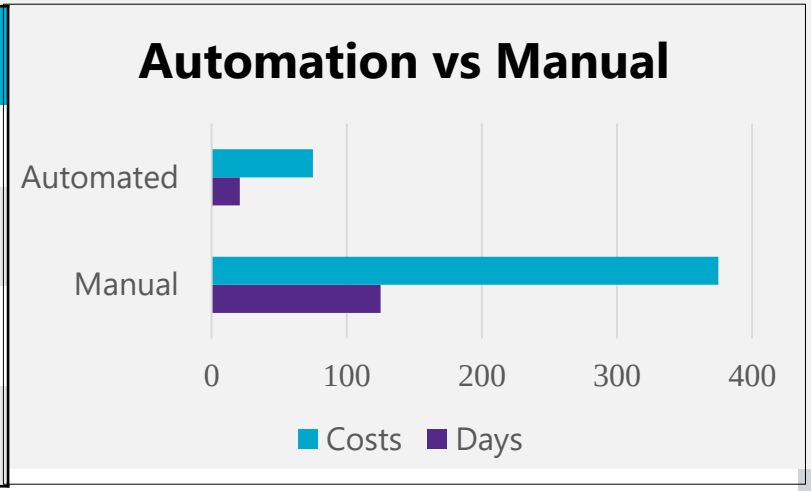
Benefit

- "What used to take me 2 days now only takes me 2 hours"
- Achieved accuracies during process of over 90%
- Faster document processing time results in a speed increased by a factor of 10
  - 1 – 2min (automated) vs 10-12 min (manual)
- Increase in savings estimated to be at least $3MM annually
- Improved internal compliance with centralized repository (Veeva Vault)

Health Authority Communications



	Manual*	Automated
1 HAC document	10 -12 Min	1 - 2 Min
15 000 HAC documents	125 Days	20.8 Days
Cost	3.75M USD	750 000 USD
Data quality	Average	Higher than average



Case Study Results:

- Ca. 15.000 Health Authority documents received per year
- Manual data extraction and data entering into the RIM systems takes ca. 10 minutes per document
- Automated data tagging 1-2 minutes per documents.
- Process savings factor 10
- Monetary savings at ca. 3M USD at average rates per hour

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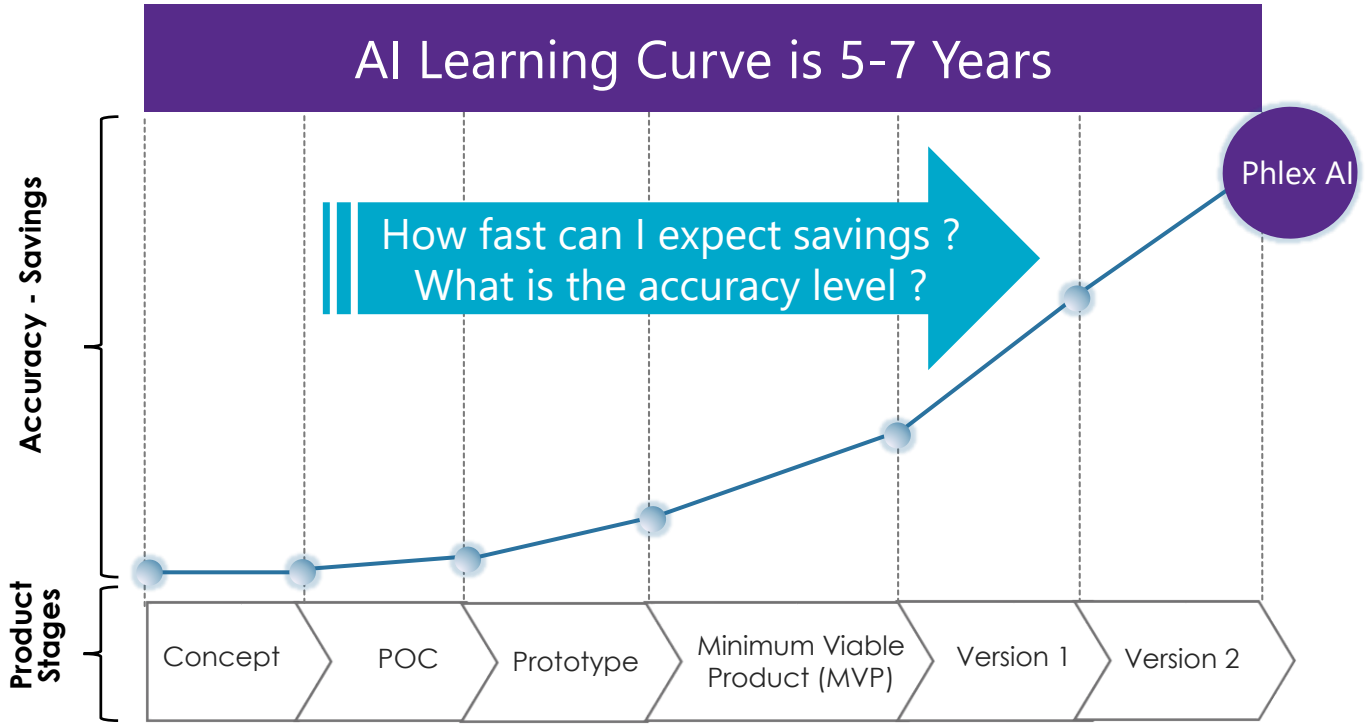
Real Intelligence & Value Delivered

Value Driver – Data Centric Foundation

- ✓ Efficiency – More Output
- ✓ Speed – Faster Results
- ✓ Quality – Higher Accuracy



REAL LIVE PROJECT

- Document Classification
- Data Extraction
- Data Curation

The Benefit of Having Data

- ✓ Start driving advanced analytics
- ✓ Become really intelligent
- ✓ Automate your compliance & audit management
- ✓ Set yourself up for the next wave of benefits
- ✓ Advance from your competition

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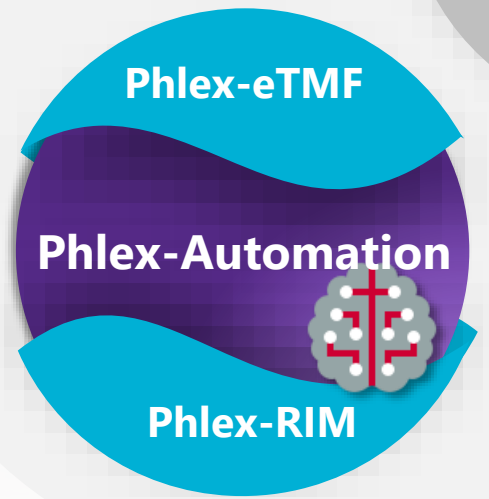
Built-In or Plugged-In ?

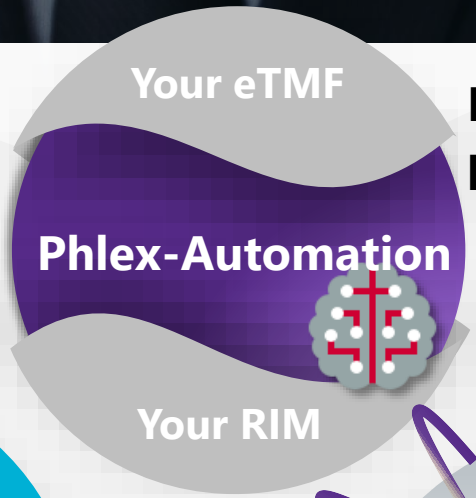
- The choice is yours -

Many companies have reached a plateau of digitalization. While compliance is a key driver for technology investments, the ROI objectives, user adoption and process automation in many companies still have room for improvement.

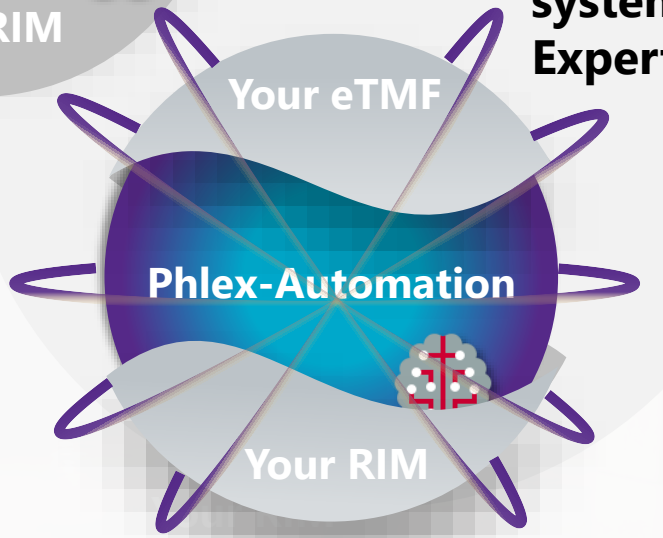
End to End Smart System from Phlexglobal

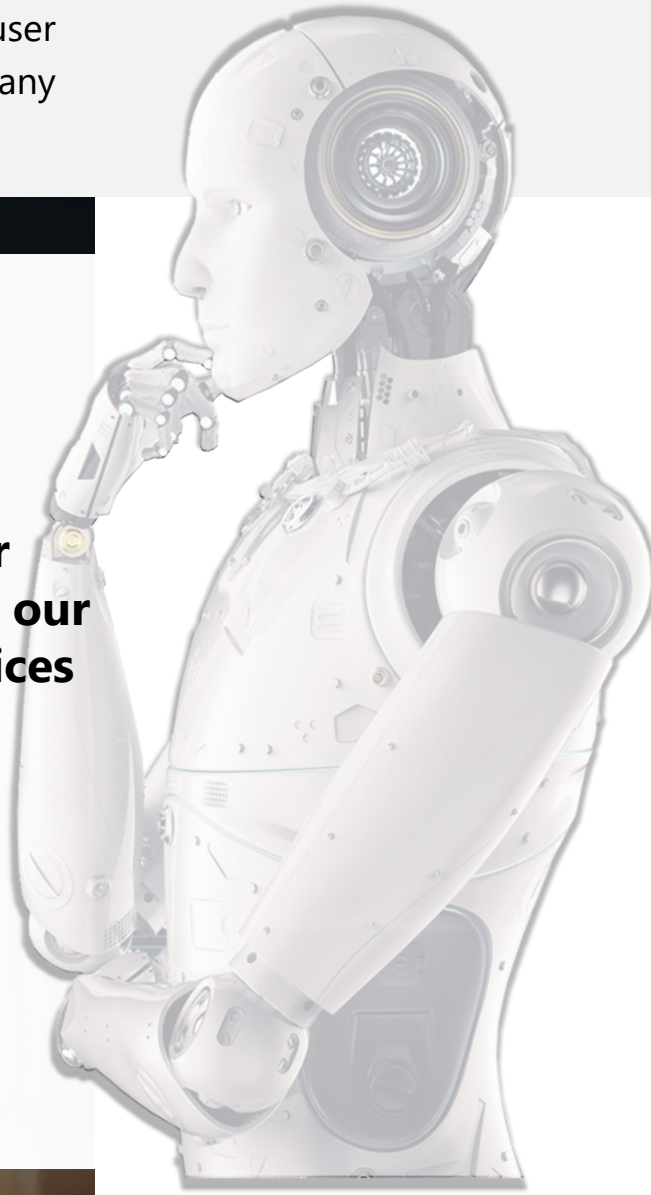


Keep your system but make it smart



We run your system with our Expert Services





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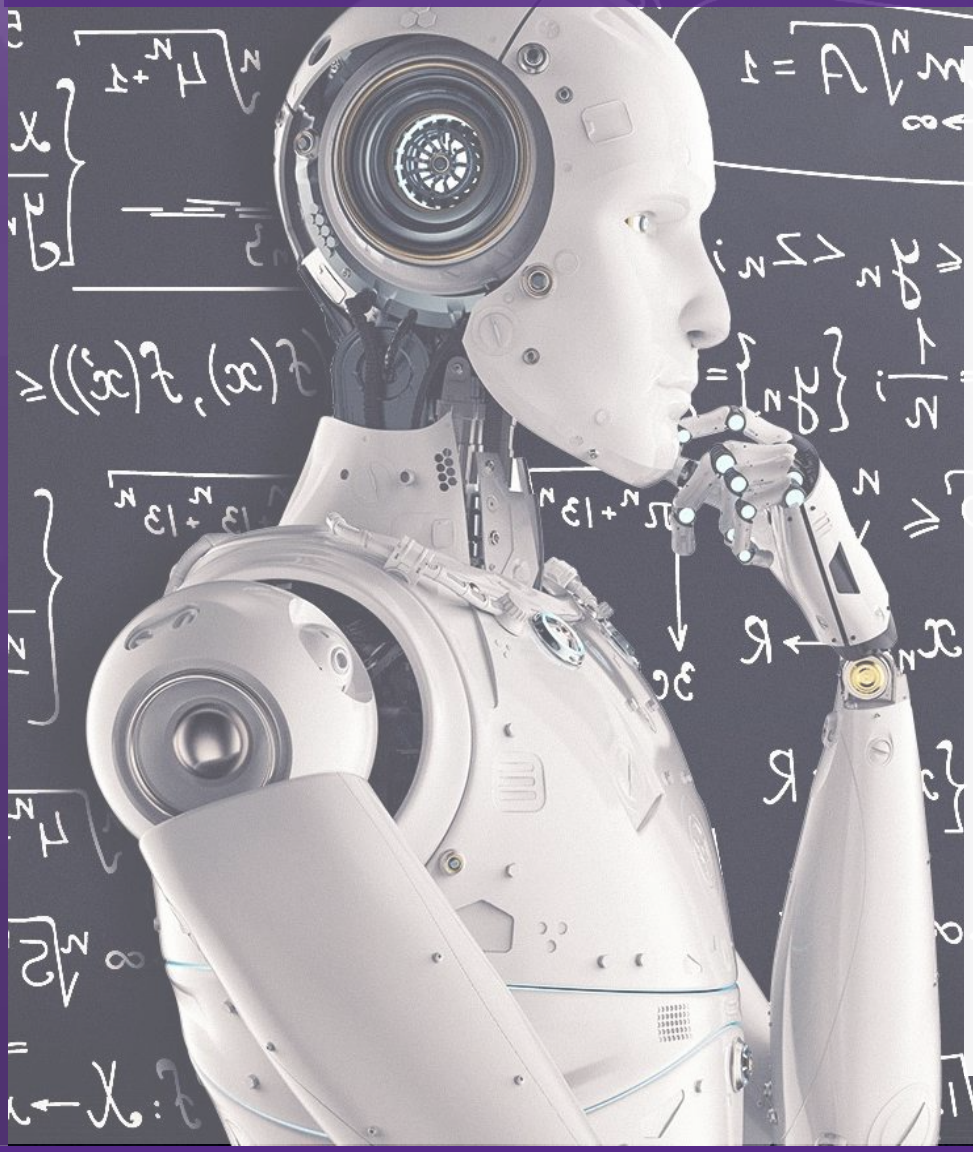
Digital Transformation Enablement – 5 Reasons to Choose Phlexglobal



1 Clinical and Regulatory Expertise

Over 500 TMF projects 4000 submissions

2 Efficiency through Enterprise Design

More than 17,000 products managed in our software

3 Speed through automation and machine learning

Focus on project ROI and gaining immediate savings

4 Consistency through integration and standards

Modern and proven system integration options

5 Simplicity through modern UI concept

Usability-driven software design

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More on Digitalization and Automation

Now available
A New Phlexglobal Infographic