

Automating Content Preparation with DocShifter

Paul Ireland

DocShifter, VP Life Sciences & Product Owner

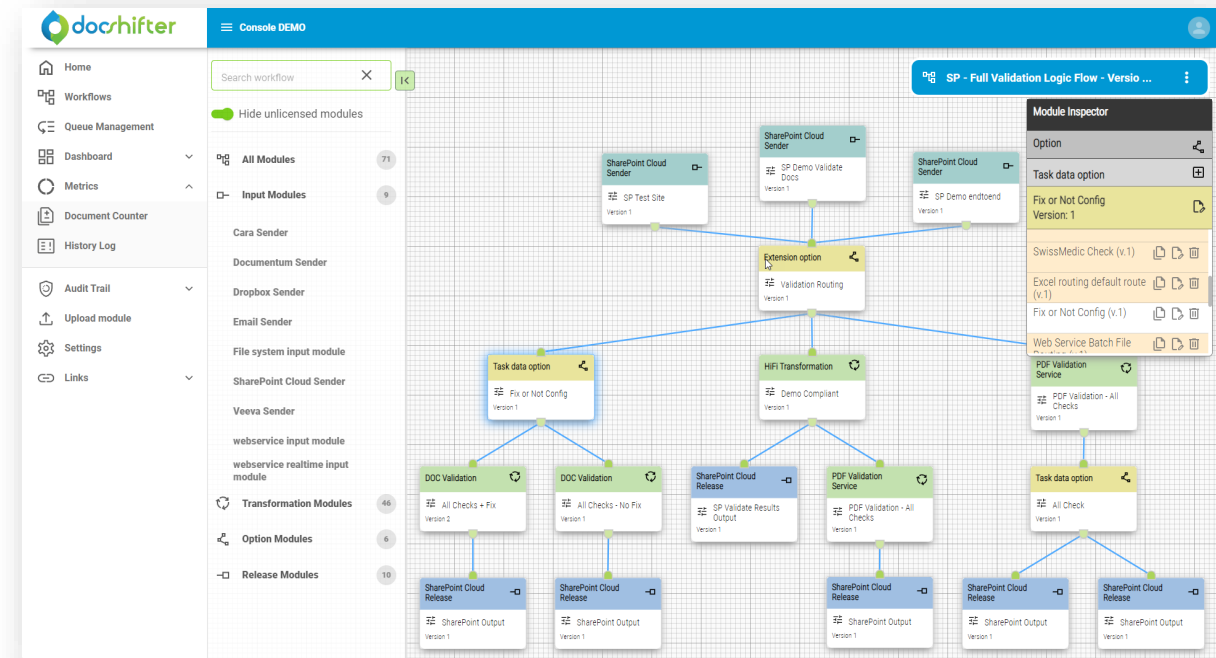
October 16th 2025

3:00pm - 3:30pm	Afternoon Break		
	Ennov Regulatory (📍 Panama Room)	Ennov Quality (📍 Bogota Room)	DocShifter (📍 Amazone Room)
3:30pm - 5:00pm	Part 1: The IDMP Preparation Playbook: Hard-won Insights from Experts Part 2: EMA Updates and Product Demo Alice Merrill, Vanessa Espurz & Pierre Stanislawski	AI Roadmap for Quality & Demo of New AI Features Grégory Desgrandchamps & François Guely	Automated Content Prep with DocShifter Paul Ireland
	Cheese and Wine Tasting Reception All Attendees Invited		



Agenda

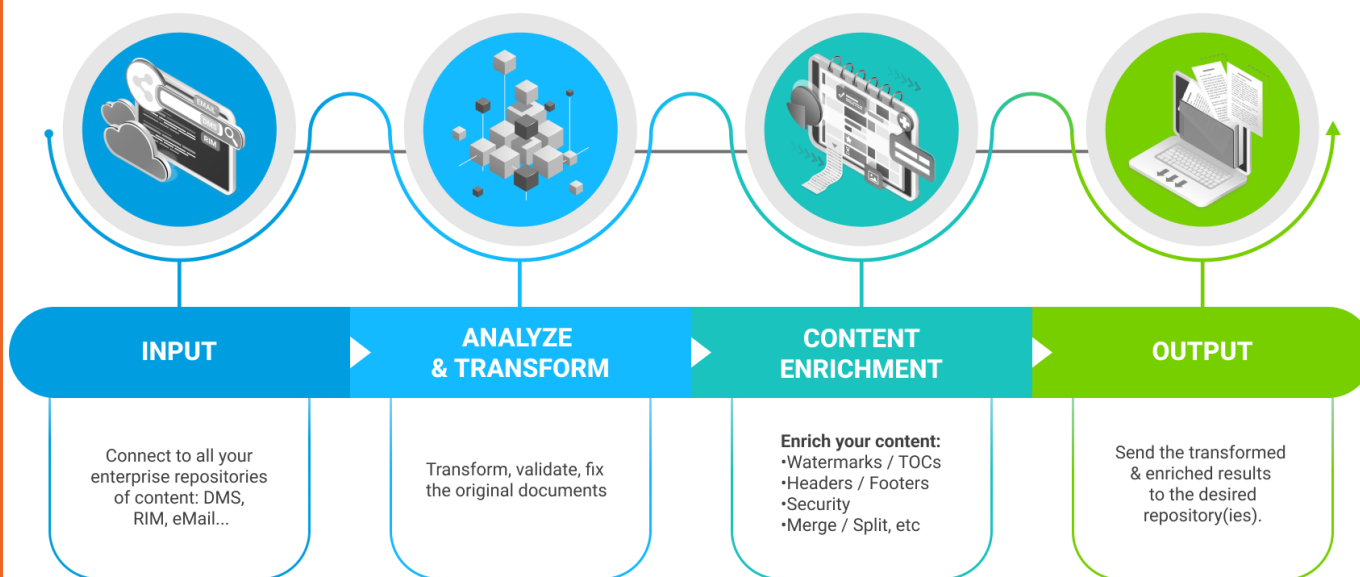
- › Introduction
- › Automating content preparation
 - › Simultaneous global PDF rendition creation
 - › Automated fully compliant PDF report generation
 - › Enriching PDFs with Bookmarks, Hyperlinks, Cleanups & OCR
- › Auto QC and Fixes for Word Docs
- › Auto QC and Fixes for PDF Docs
- › Document comparisons
- › AI-Powered Translation
- › AI-Powered Redaction
- › Wrap-up



Introduction

Automating High Volume Content Preparation

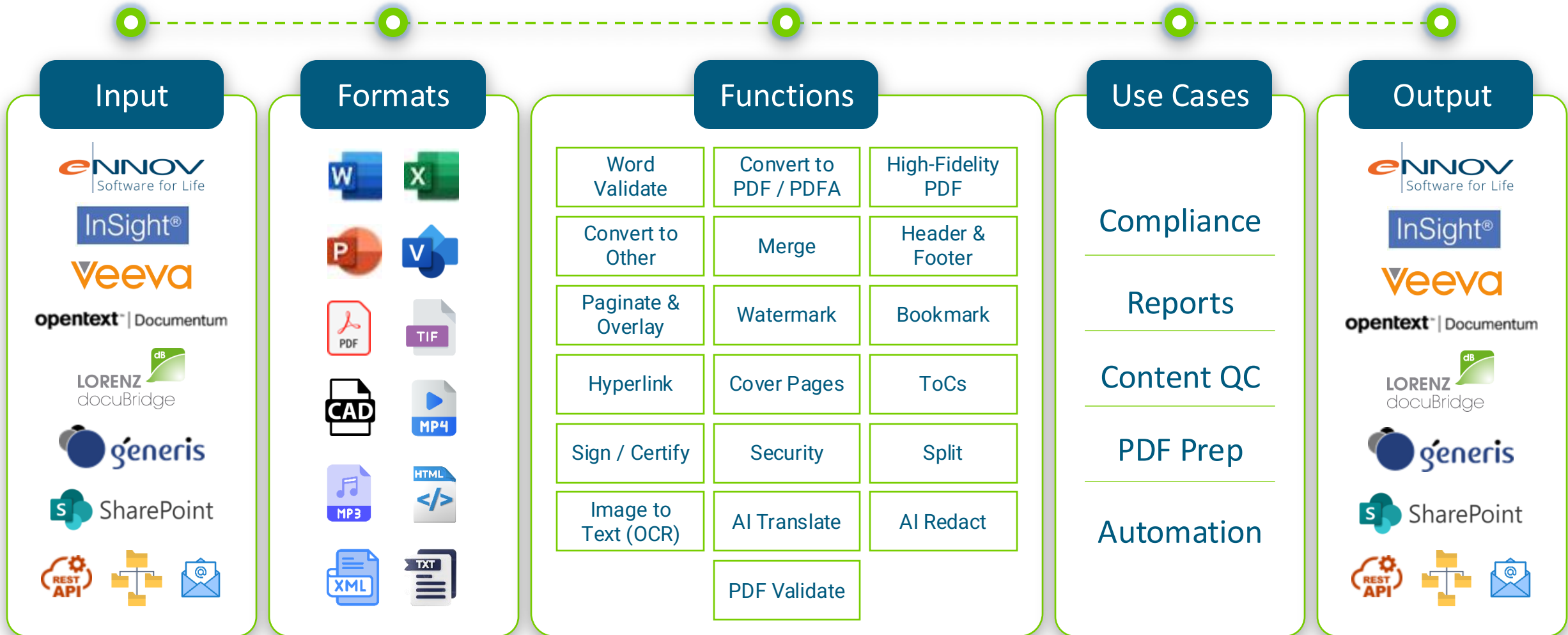
a modular software platform for any-to-any format conversion, analysis & enrichment



On premise or private/public cloud. Administered centrally. 'Set up and run'.

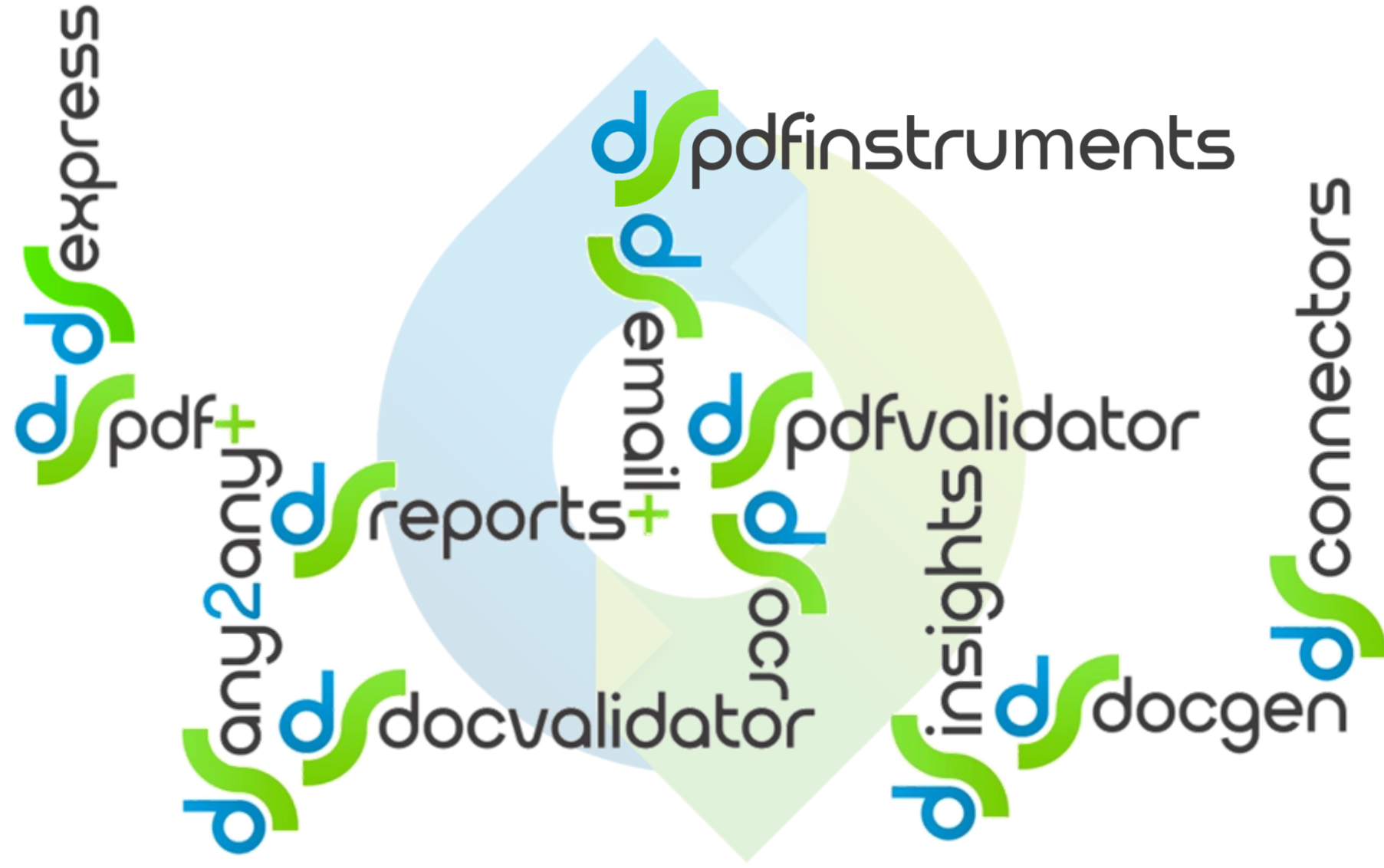


What is DocShifter? *(not a publishing system, more than rendering)*



...automated compliant content preparation...

DocShifter Solutions



DocShifter Solutions



DocShifter Advanced Rendering

- › **Available today**, alongside existing Rendering
- › Can replace any rendition service of a CMS or publishing system:
 - › Proven record of replacing existing solutions



- › Proven record as a replacement of InSight Rendering at Novartis, Gilead, Biogen, Otsuka, etc.

Ennov/InSight Advanced Publishing

Powered by DocShifter



- › Engine for Ennov Publishing tasks move to DocShifter almost complete (included in end of October DocShifter release)
- › On roadmap for InSight
- › All publishing tasks performed by DocShifter instead of existing technology
- › Leverage speed & technology benefits of DocShifter
- › Zero process or user changes for publishers

DocShifter Advanced Rendering

DocShifter Console

demo.docshifter.com/dsexpress

DocShifter

Console Demonstration

0

DSEExpress

1

Select a Template or a Save

Templates

Shared Saves

Personal Saves

Enter the template/Save name to filter

2

Set parameters values

3

Select file(s) to be processed

4

Processing files

Name ↑	Description	Latest Version	Last Modified
1 - DSEExpress - Simple PDF	Create PDF via alltopdf	13	28-04-2025 21:59
DSEExpress - AI Redaction	Select redaction method on next screen	22	14-01-2025 12:13
DSEExpress - AI Translator	Translate input into language selected	28	14-01-2025 12:08
DSEExpress - Bookmark PDF	Add bookmarks to PDF & remove guidance text from source PDF files	29	23-01-2025 16:16
DSEExpress - Compliant Report Generation	Select a ZIP file and receive single merged, paginated PDF with TOC, cover page, etc.	33	31-01-2025 16:53
DSEExpress - DOCX Validator (fix)	Select .docx file(s) and receive fixed .docx files	4	31-10-2024 18:04
DSEExpress - DOCX Validator (full report)	Select .docx file and receive a full validation report	12	14-02-2025 09:09
DSEExpress - DocShifter DOCX documentation to PDF	Documentation workflow (use to convert DS documentation to PDF for customers)	3	31-10-2024 18:04
DSEExpress - EU Translate + Render	Translate to EU languages and render to compliant EU PDF	10	14-01-2025 12:10
DSEExpress - FDA Compliant PDF	Workflow to create FDA compliant rendition	78	24-01-2025 14:41

Items per page: 10

1 - 10 of 24

< >

Next

Also

Acroba

1. Ser

U

S

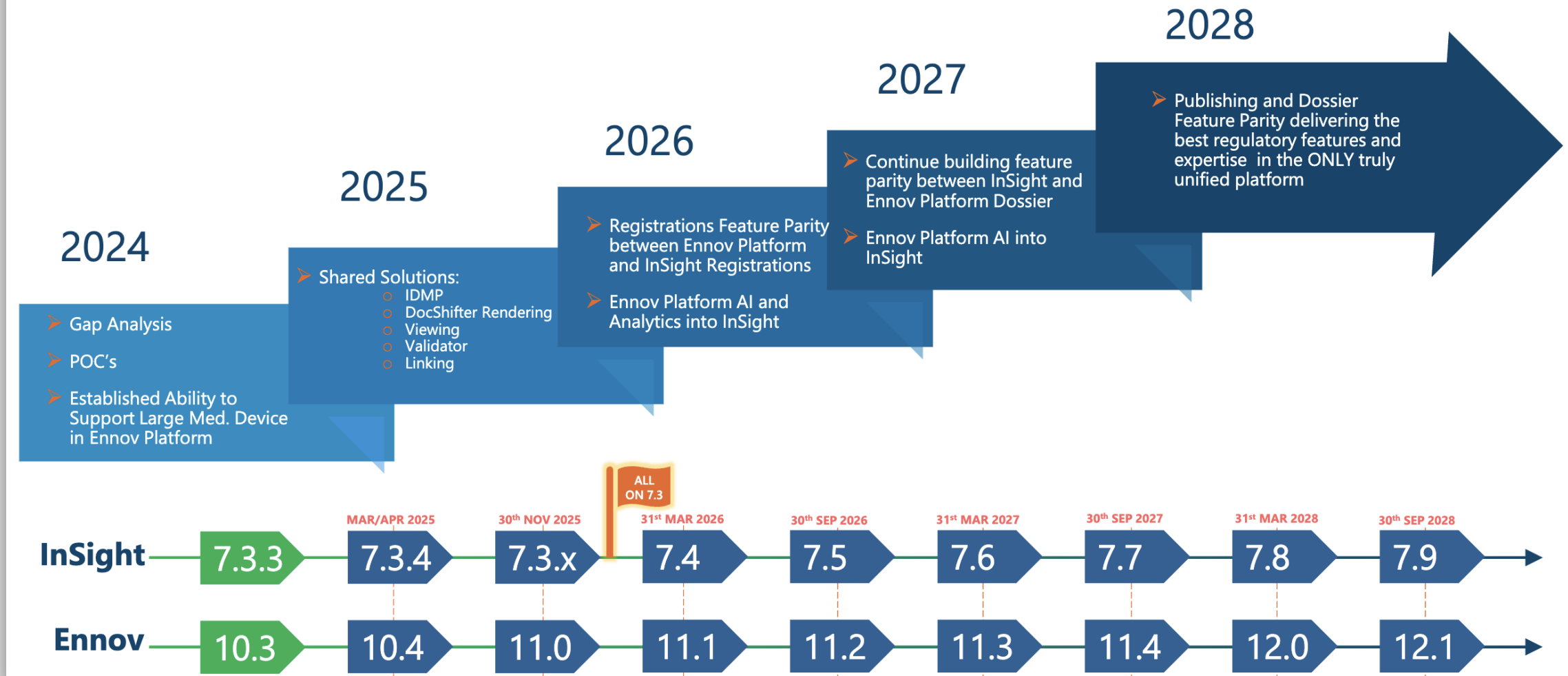
C

D

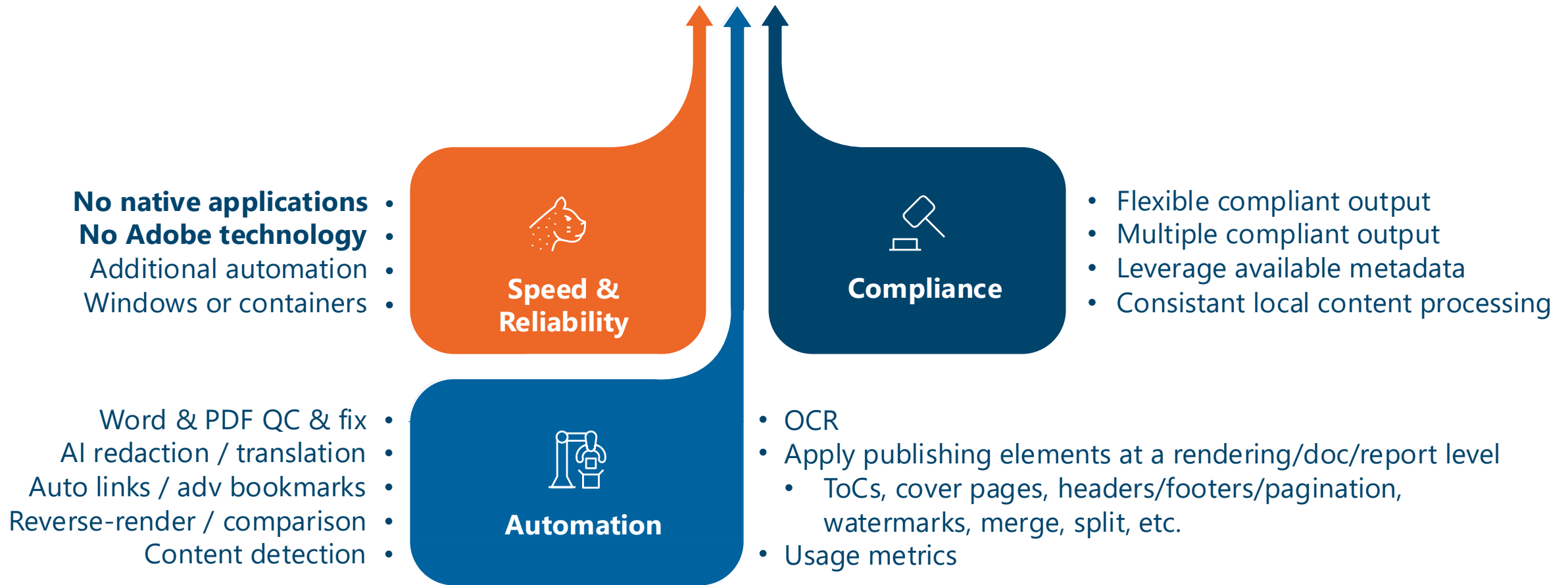
tion tools

ennov Technology Convergence Journey

Trusted Solutions Accelerated through Unification



Benefits of Advanced Rendering with DocShifter



Time-saving through automation

Console DEMO

- Home
- Workflows
- Queue Management
- Dashboard
- Metrics
- Document Counter
- History Log
- Audit Trail
- Upload module
- Settings
- Links

Search workflow

Hide unlicensed modules

All Modules

Input Modules

- Cara Sender
- Documentum Sender
- Dropbox Sender
- Email Sender
- File system input module
- SharePoint Cloud Sender
- Veeva Sender
- webservice input module
- webservice realtime input module

Transformation Modules

Option Modules

Release Modules

DocShifter Workbench

- Configurable workflows
- Automating repetitive processes

SP - Full Validation Logic Flow - Versio ...

```

graph TD
    subgraph InputModules [Input Modules]
        SCS1[SharePoint Cloud Sender]
        SCS2[SharePoint Cloud Sender]
        SCS3[SharePoint Cloud Sender]
    end
    subgraph OptionModules [Option Modules]
        ExtOpt[Extension option]
        TaskData1[Task data option]
        TaskData2[Task data option]
    end
    subgraph TransformationModules [Transformation Modules]
        DocVal1[DOC Validation]
        DocVal2[DOC Validation]
        HiFi[HiFi Transformation]
        SPVal[SharePoint Cloud Release]
        PDFVal[PDF Validation Service]
    end
    subgraph ReleaseModules [Release Modules]
        SPOut1[SharePoint Cloud Release]
        SPOut2[SharePoint Cloud Release]
        SPOut3[SharePoint Cloud Release]
        SPOut4[SharePoint Cloud Release]
        SPOut5[SharePoint Cloud Release]
        SPOut6[SharePoint Cloud Release]
    end

    SCS1 --> ExtOpt
    SCS2 --> ExtOpt
    SCS3 --> ExtOpt
    ExtOpt --> TaskData1
    ExtOpt --> HiFi
    ExtOpt --> TaskData2
    TaskData1 --> DocVal1
    TaskData1 --> DocVal2
    HiFi --> SPVal
    HiFi --> PDFVal
    DocVal1 --> SPOut1
    DocVal1 --> SPOut2
    DocVal2 --> SPOut3
    DocVal2 --> SPOut4
    SPVal --> SPOut5
    PDFVal --> SPOut6
    
```

Module Inspector

Option
Task data option
Fix or Not Config Version: 1
SwissMedic Check (v.1)
Excel routing default route (v.1)
Fix or Not Config (v.1)
Web Service Batch File
PDF Validation Service
PDF Validation - All Checks
Task data option
All Check

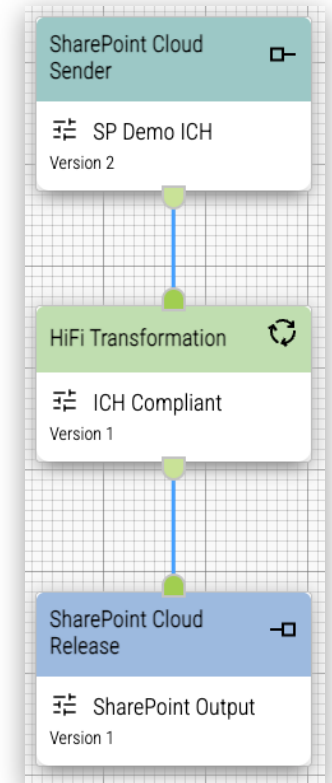
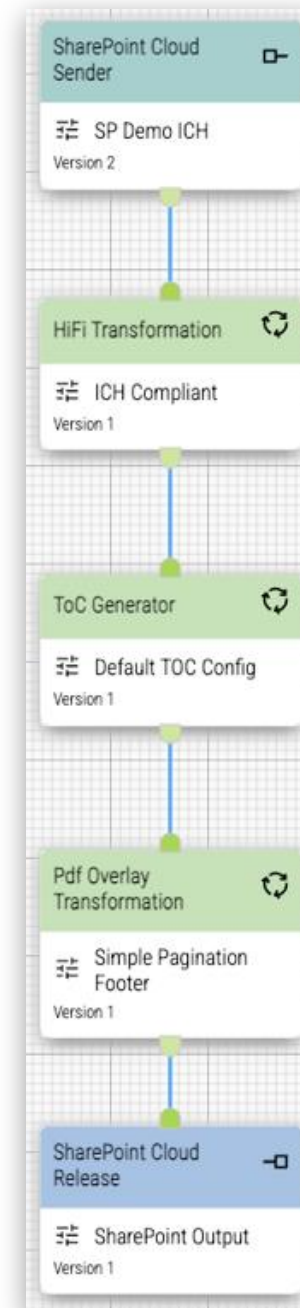
Drag & drop building blocks for your workflows:

- Input – where from?
- Transformation – what to do?
- Logical steps – if/then/else
- Output – where to?

Configure.
Let it run !

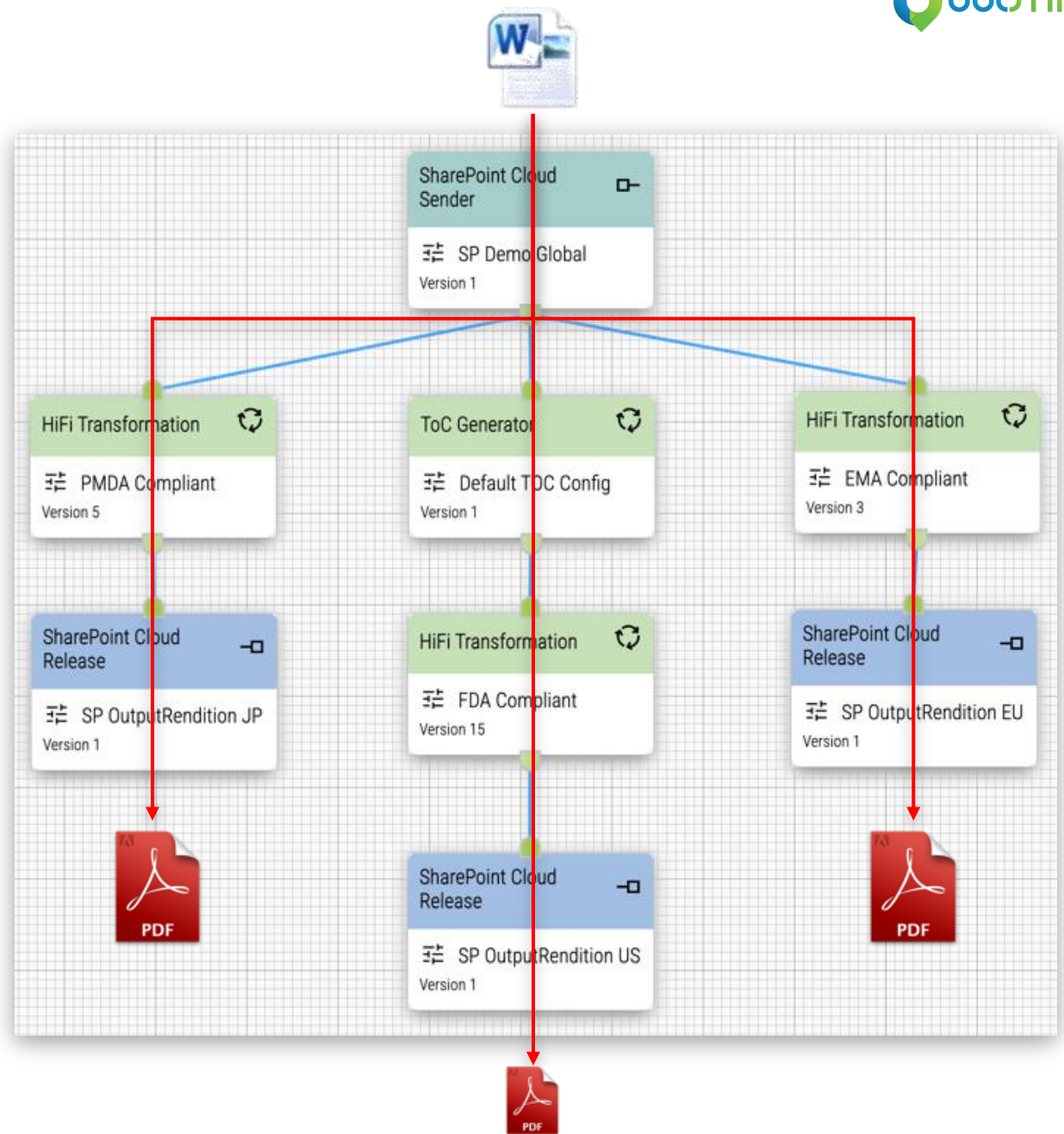
Simple automation

- Linear workflow
- No logic / branching included
- One single route
- Can include multiple transformation steps (modules)



Multi-output automation

- Workflow without Option Modules
 - Document goes through all branches of the workflow
 - One input = multiple output



Automation with logic

- Workflow with Option Modules
 - Document only follows the single route defined in the Option module
 - One input = one output

Demo Filetype Routing Configuration (Version: 0) [Save] [Discard]

Name* Demo Filetype Routing

Description Specific routing for CAD and PDF files to be OCR'd, rest through HiFi only

☐ Show required fields first

☐ Hide irrelevant parameters

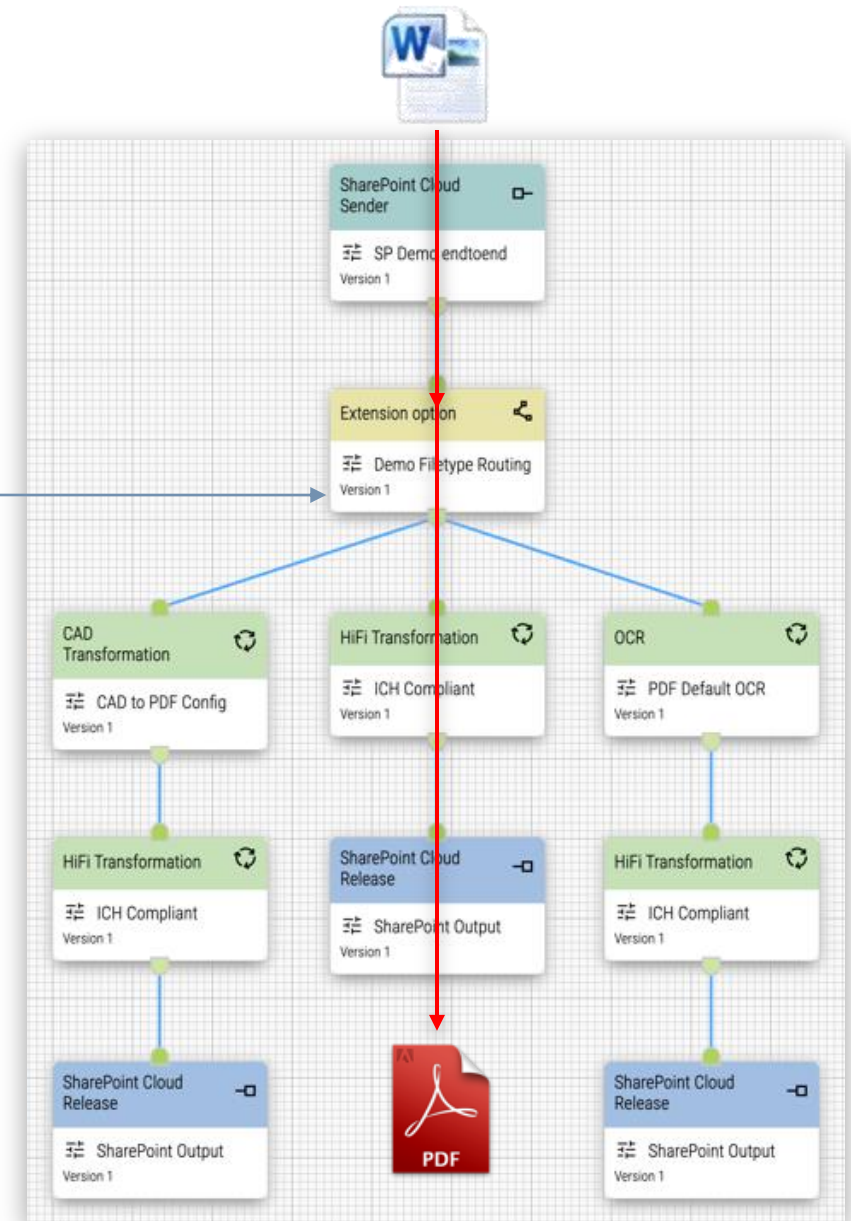
☐ Lock Version

CONFIGURATION PARAMETERS [Filter param by name]

Group	Name	Value
Default	useOriginalFile	false

Uses the original file when performing a transform operation. Default: false

Operator	Field Value	Configuration
default		ICH Compliant
	pdf	PDF Default OCR
	dwg dxf	CAD to PDF Config



Automation with logic

- Workflow with Option Modules
 - Document only follows the single route defined in the Option module
 - One input = one output

Demo Filetype Routing Configuration (Version: 0) Save Discard

Name* Description

☐ Show required fields first

☐ Hide irrelevant parameters

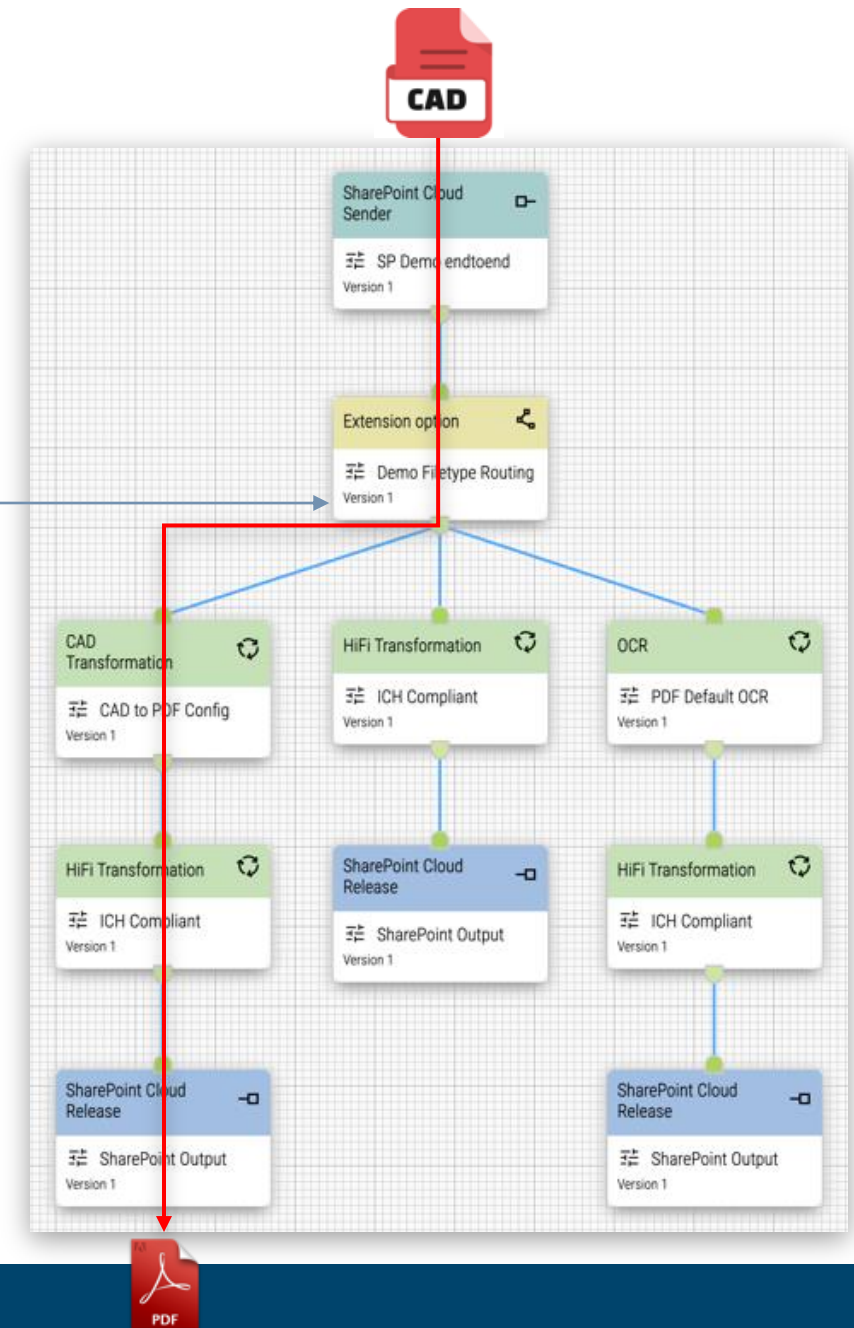
☐ Lock Version

CONFIGURATION PARAMETERS Filter param by name

Group	Name	Value
Default	useOriginalFile	<input type="checkbox" value="false"/>

Uses the original file when performing a transform operation. Default: false

Operator	Field Value	Configuration
default		ICH Compliant
pdf	pdf	PDF Default OCR
dwg dxf	dwg dxf	CAD to PDF Config



Automation with logic

- Workflow with Option Modules
 - Document only follows the single route defined in the Option module
 - One input = one output

Demo Filetype Routing Configuration (Version: 0) Save Discard

Name* Description

☐ Show required fields first

☐ Hide irrelevant parameters

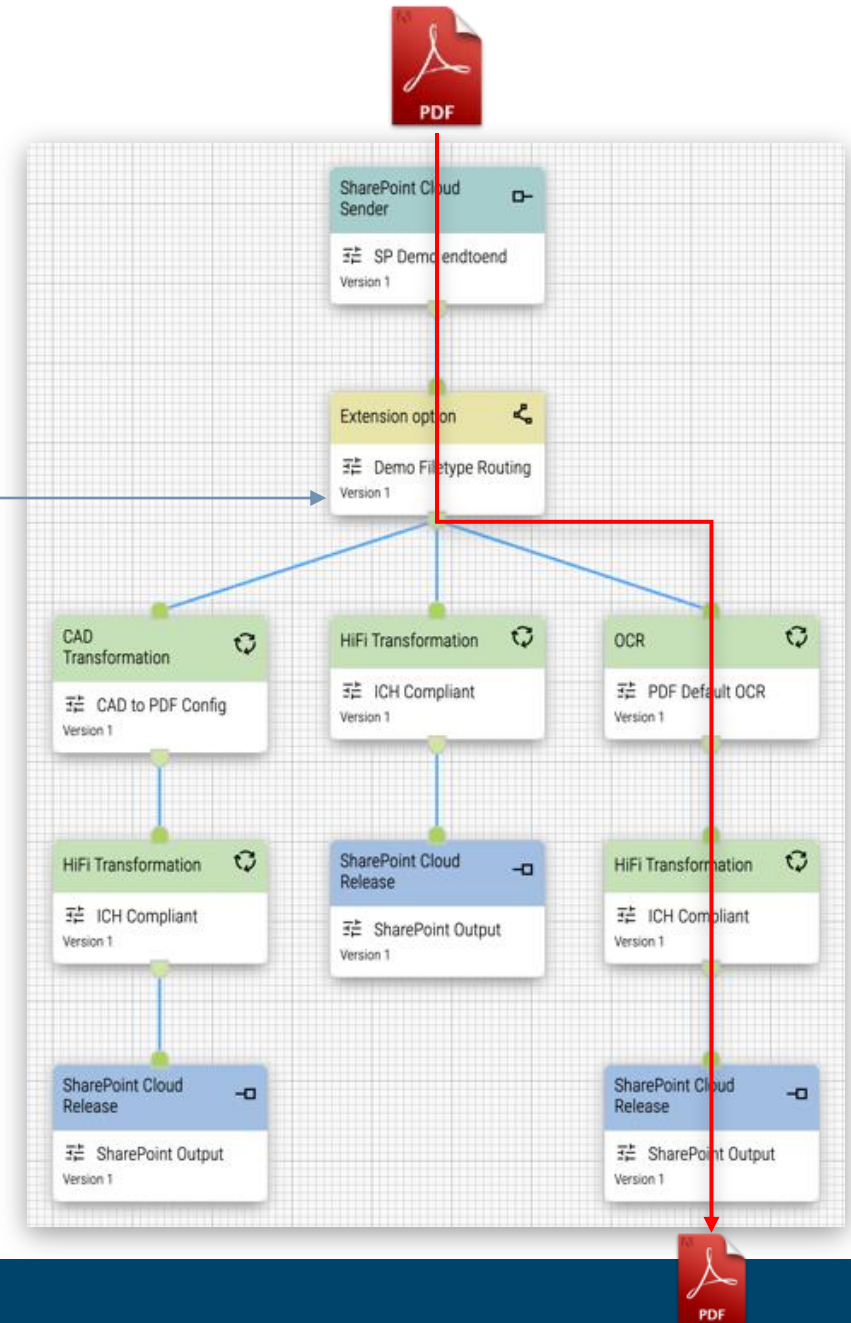
☐ Lock Version

CONFIGURATION PARAMETERS Filter param by name

Group	Name	Value
Default	useOriginalFile	<input type="checkbox" value="false"/>

Uses the original file when performing a transform operation. Default: false

Operator	Field Value	Configuration
default		ICH Compliant
pdf	pdf	PDF Default OCR
dwg dxf	dwg dxf	CAD to PDF Config



Multiple Global Renditions

Simultaneous Global Renditions (leverage CMS metadata)



Configurable for Global Use

ICH Compliant Configuration

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Save

Discard

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

Attribute Handling

Bookmark Handling

Configuration Files

Container Format Handling

Email Handling

Excel Specific

Field Code Hand

Group	Name	Value
Bookmark Handling	addBoundaryTitle	true
Bookmark Handling	addSummaryTables	false
Bookmark Handling	bookmarkGroupingAddEmptyTitles	false
Bookmark Handling	bookmarkOpenLevel	1
Level of bookmarks that should be shown when document opened. Minimum value is 1, only show level 1 bookmarks, i.e. no bookmarks are expanded. If not set, no specific expansion nor collapse is applied.		
Bookmark Handling	createOutlinesForHeadingsInTables	true
Bookmark Handling	documentBoundaryText	
Bookmark Handling	ignoreOutlineLevelsOnText	false

ICH Compliant Configuration

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Save

Discard

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

Attribute Handling

Bookmark Handling

Configuration Files

Container Format Handling

Email Handling

Excel Specific

Field Code Hand

Group	Name	Value
Container Format Handling	embeddedFileFilterDefault	Default
Container Format Handling	embeddedFileFilterWhenZIP	false
Container Format Handling	embeddedFileHandling	Transform and transpose
What to do with embedded files in container formats (Word, PowerPoint, Excel, PDF, Email, ZIP). This parameter recursively applies to the embedded files. Default: Auto (determine behavior based on file type, but never merge)		
Container Format Handling	embeddedFileOrderingXMLFileName	
Container Format Handling	embeddedTransformFailureAction	Retain original (non-transform)
Container Format Handling	retainZipFolderStructure	false
Container Format Handling	saveEmbeddeds	false

Configurable for Global Use

ICH Compliant Configuration

Save Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

rmat Handling

Email Handling

Excel Specific

Field Code Handling

Font Handling

Hyperlink Handling

Image Handling

PDF Specific

Group	Name	Value
Font Handling	enableOpenTypeFeatures	false
Font Handling	fontEmbedding	ALL
Options to enable full or subset font embedding of fonts.		
Font Handling	fontEmbeddingPDF	None
Font Handling	fontSubstitutionAutomated	All (full)
Font Handling	fontSubstitutionDefault	All (Nonstandard + subset)
Font Handling	fontSubstitutionUseFontConfig	All (Nonstandard + full)

ICH Compliant Configuration

Save Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

rmat Handling

Email Handling

Excel Specific

Field Code Handling

Font Handling

Hyperlink Handling

Image Handling

PDF Specific

Hyperlink Handling	addBlueboxLinks	false
Hyperlink Handling	customLinkTextColour	Blue
Hyperlink Handling	customLinkTextColourWhenPDF	false
Hyperlink Handling	customLinkTextColourWhenTrackChanges	false
Hyperlink Handling	customLinkUnderline	false
Hyperlink Handling	disableExternalLinks	false
Hyperlink Handling	disableExternalLinksHandling	Remove Destination
Hyperlink Handling	disableExternalLinksWithTooltip	false
Hyperlink Handling	externalLinkIdentifiers	http:https:mailto
Hyperlink Handling	forceDestinationZoom	Inherit zoom

Configurable for Global Use

ICH Compliant Configuration

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Save

Discard

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

Image Handling

Email Handling

Excel Specific

Field Code Handling

Font Handling

Hyperlink Handling

Image Handling

PDF Specific

Image Handling	imageBitDepth	Leave as-is	⋮
Image Handling	imageBitonalEncoding	Same as original encoding	⋮
Image Handling	imageColorPalette	Leave as-is	⋮
Image Handling	imageDPI		⋮
Image Handling	imageGrayscaleEncoding	Same as original encoding	⋮
Image Handling	imageQuality	100	⋮
Image Handling	imageRGBEncoding		⋮
Image Handling	setCompressImages	false	⋮

Set compress Images, also use imageQuality if true. Default: false

ICH Compliant Configuration

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Save

Discard

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

Image Handling

Email Handling

Excel Specific

Field Code Handling

Font Handling

Hyperlink Handling

Image Handling

PDF Specific

PDF Specific	allowXrefGaps	true	⋮
PDF Specific	embedInputFileInResult	false	⋮
PDF Specific	flattenPDF	No flattening, leave it alone	⋮
PDF Specific	keepOriginalPdfVersion	false	⋮
PDF Specific	pageRange		⋮
PDF Specific	pdfAComplianceLevel	PDF/A-3b	⋮
PDF Specific	performValidation	false	⋮
PDF Specific	performValidationAfterConversion	false	⋮
PDF Specific	postPdfOutput	1.7	⋮

Specify the pdf output as 1.4/1.5/1.6/1.7/2.0/PDFA. Default: 1.7

Configurable for Global Use

ICH Compliant Configuration

Save

Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:	ling	PDF Specific	PowerPoint Specific	Rejection Handling	Revisions Handling	Sizing	System	Text Specific	Viewer Preferences
Rejection Handling			failJobForValidationErrors		false				
Rejection Handling			onlyIfEmbeddedAsicon		false				
Rejection Handling			rejectIfCommentsPresent		false				
Rejection Handling			rejectIfEmbeddedPresent		false				
Rejection Handling			rejectIfEmbeddedPresentPDF		false				
Rejection Handling			rejectIfExternalLinksPresent		true				
Reject i.e. FAIL the Transformation if there are external links (e.g. to http://www.example.com). See also <code>disableExternalLinks</code> . Default: <code>false</code>									
Rejection Handling			rejectIfFontSubstituted		false				
Rejection Handling			rejectIfSigned		false				
Rejection Handling			rejectIfTrackChangesOn		false				

ICH Compliant Configuration

Save

Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:	ling	PDF Specific	PowerPoint Specific	Rejection Handling	Revisions Handling	Sizing	System	Text Specific	Viewer Preferences
Revisions Handling					commitReviews	false			
Revisions Handling					removeComments	true			
Remove comments made in word documents? In the <code>rev_</code> options you can use <code>rev_CommentDisplayMode = HIDE</code> as an alternative to setting this param true. Default: <code>false</code>									
Revisions Handling					removeHiddenContent	false			
Revisions Handling					rev_CommentColor	DEFAULT			
Revisions Handling					rev_CommentDisplayMode	Hide			
Revisions Handling					rev_DeletedTextColor	DEFAULT			
Revisions Handling					rev_DeletedTextEffect	NONE			

Configurable for Global Use

ICH Compliant Configuration

Save

Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

ling

PDF Specific

PowerPoint Specific

Rejection Handling

Revisions Handling

Sizing

System

Text Specific

Viewer Preferences

Group	Name	Value
Sizing	adjustSizeForWideEmails	☐ true
Sizing	keepAspectRatio	☐ true
Sizing	orientation	None - as per original
Sizing	pageSize	A4 (595x842=210x297mm)
For Slides (PowerPoint), Images, Emails, HTML, set a specific Page Size (like A4, Letter etc.). Default: None		
Sizing	upScale	☐ true

ICH Compliant Configuration

Save

Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

ling

PDF Specific

PowerPoint Specific

Rejection Handling

Revisions Handling

Sizing

System

Text Specific

Viewer Preferences

Group	Name	Value
System	alwaysContinueIfPdfOptimizationFail	☐ false
System	continueIfPdfOptimizationFail	☐ false
System	continueIfPdfOptimizationFailWhen	
System	forceAllToPDF	☐ true
System	language	en
System	optimize	☐ true
Optimize PDF and prepare for fast web preview. NOTE: If true, to get EXACTLY the same behaviour as before, set setCompressImages to true and imageQuality to 50. Default: false		
System	optimizeOutput	☐ true

Configurable for Global Use

ICH Compliant Configuration

Save

Discard

Name *

ICH Compliant

Description

Compliant transformation based on ICH guidelines

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Groups:

ling

PDF Specific

PowerPoint Specific

Rejection Handling

Revisions Handling

Sizing

System

Text Specific

Viewer Preferences

Viewer Preferences	view_duplex	Leave it alone	⋮
Viewer Preferences	view_fitWindow	false	⋮
Viewer Preferences	view_hideMenubar	false	⋮
Viewer Preferences	view_hideToolBar	false	⋮
Viewer Preferences	view_hideWindowUI	false	⋮
Viewer Preferences	view_nonFullScreenPageMode	Leave it alone	⋮
Viewer Preferences	view_pageLayout	Default	⋮
The Page Layout to use			
Viewer Preferences	view_pageMode	Leave it alone	⋮

Example Rendering Scenarios

- Document in
- EMA compliant PDF out

Simple EMA compliant workflow



- Document in
- EMA, FDA & PMDA compliant PDFs out

Multiple compliant renditions (EMA, FDA & PMDA) from one workflow



- Document in
- Only EMA compliant PDF out or
- Only FDA compliant PDF out or
- Only PMDA compliant PDF out or
- EMA, FDA & PMDA compliant PDFs out

Compliant renditions for only specific country or all countries



Example DocShifter Workflow

Search workflow

Hide unlicensed modules

All Modules

Input Modules

Transformation Modules

Option Modules

Document Hash Check Option

Extension option

Task data option

Europe Check

ToC Generator

EMA TOC Config

NOP

No processing documents

HIFI Transformation

EMA Compliant

Europe Check Configuration

Name *

Europe Check

Description

Check if EMA rendition is required

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

Group	Name	Value
Default	taskDataParam *	EMA

The task data parameter name to check

Save

Discard

Conditions

Task data option

Canada Check

Extension option

HC - PDF OCR Routing

HIFI Transformation

OCR

OCR default

HC Compliant

HIFI Transformation

HC Compliant

Veeva Export

Veeva New Object Output

Office 365

Demo

Private group

Search

Edit in grid view

Open

Share

Copy link

Download

Delete

Pin to top

Rename

Automate

Move to

Copy to

Home

Conversations

Shared Documents

Shared with us

Notebook

Pages

OutputRendition

Demo

Site contents

Demo > eCTD Test Documents > Module 2 > 26 Nonclinical Summary

Name	Modified	Modified By	FDA	EMA	PMDA	CH	HC	ProcessedByDS
26 Nonclinical Summary.zip	November 22, 2020	SharePoint App						
261-introduction.docx	A few seconds ago	Paul Ireland	✓	✓	✓	✓	✓	✓
261-introduction.pdf	A few seconds ago	Paul Ireland						✓
262-pharmacol-written-summary.docx	A few seconds ago	Paul Ireland	✓	✓	✓	✓	✓	✓
263-pharmacol-tabulated-summary.docx	A few seconds ago	Paul Ireland	✓	✓	✓	✓	✓	✓
264-pharmkin-written-summary.docx	A few seconds ago	Paul Ireland	✓	✓	✓	✓	✓	✓

261-introduction.docx

DocShifter

2.6 Nonclinical Writing

2.6.1 Introduction

GUIDANCE INFORMATION - DE

Has access

Manage access

Leverage repository metadata to help automate

Attribute from Repository to check...

Value(s) of attributes and route to take...

Example DocShifter Workflow

Console DEMO

Search workflow

✕

I<

Hide unlicensed modules

All Modules

72

Input Modules

9

Transformation Modules

47

Option Modules

6

Document Hash Check Option

Extension option

PDF Signature option

PDF/A Validation option

Task data option

Template option

Release Modules

10

EMA Compliant Configuration

Save Discard

Name *

EMA Compliant

Description

EMA Compliant transformation for demo

Show required fields first

CONFIGURATION PARAMETERS

Filter param by name

✕

Groups:

Attribute Handling

Bookmark Handling

Configuration Files

Container Format Handling

Email Handling

Excel Specific

Field Code Handl

Group	Name	Value
Bookmark Handling	addBoundaryTitle	false
Bookmark Handling	addSummaryTables	false
Group Table and Figure bookmarks at end of bookmark list. Default: false		
Bookmark Handling	bookmarkGroupingAddEmptyTitles	false
Bookmark Handling	bookmarkOpenLevel	1
Bookmark Handling	createOutlinesForHeadingsInTables	true
Bookmark Handling	documentBoundaryText	
Bookmark Handling	ignoreOutlineLevelsOnText	false

Grouped bookmarking disabled for EU...

Task data option

Canada Check

Version 1

NOP

No processing documents

Version 1

Extension option

HC - PDF OCR Routing

Version 1

HiFi Transformation

HC Compliant

Version 1

OCR

OCR default

Version 15

HiFi Transformation

HC Compliant

Version 1

Veeva Export

Veeva New Object Output

Version 9

ToC Generator

EMA TOC Config

Version 2

HiFi Transformation

EMA Compliant

Version 1

Veeva New Rendition

Veeva Test New Rendition

Version 1

Save Discard

☒ Show required fields first

Filter param by name

Grouped bookmarking enabled for JP...



Multiple Simultaneous Renditions

266-toxicology-written-summary_with_link1621962035975.pdf

File Edit View Sign Window Help

Home Tools 266-toxicology-writ...

Bookmarks

- 2.6.6 Toxicology Written Summary
 - 2.6.6.1 Brief Summary
 - Table 1
 - 2.6.6.2 Single-Dose Toxicity
 - 2.6.6.3 Repeat-Dose Toxicity
 - Table 2
 - 2.6.6.4 Genotoxicity
 - 2.6.6.5 Carcinogenicity
 - 2.6.6.6 Reproductive and Developmental Toxicity
 - Table 3
 - 2.6.6.6.1 Fertility and Early Embryonic Development
 - 2.6.6.6.2 Embryofetal Development
 - Table 4
 - 2.6.6.6.3 Prenatal and Postnatal Development
 - 2.6.6.6.4 Studies in Offspring
 - 2.6.6.7 Local Tolerance
 - 2.6.6.8 Other Toxicity Studies
 - 2.6.6.9 Discussion and Conclusions
 - 2.6.6.10 Tables and Figures

266-toxicology-written-summary_with_links_+_tables.pdf

File Edit View Sign Window Help

Home Tools 266-toxicology-writ...

Bookmarks

- 2.6.6 Toxicology Written Summary
 - 2.6.6.1 Brief Summary
 - 2.6.6.2 Single-Dose Toxicity
 - 2.6.6.3 Repeat-Dose Toxicity
 - 2.6.6.4 Genotoxicity
 - 2.6.6.4.1 In Vitro Nonmammalian Cell System
 - 2.6.6.4.2 In Vitro Mammalian Cell System
 - 2.6.6.4.3 In Vivo Mammalian System
 - 2.6.6.4.4 Other Systems
 - 2.6.6.5 Carcinogenicity
 - 2.6.6.6 Reproductive and Developmental Toxicity
 - 2.6.6.7 Local Tolerance
 - 2.6.6.8 Other Toxicity Studies
 - 2.6.6.9 Discussion and Conclusions
 - 2.6.6.10 Tables and Figures
 - List of Tables
 - Table 1
 - Table 2
 - Table 3

2.6.6.3 Repeat-Dose Toxicity

GUIDANCE INFORMATION – DELETE WHEN COMPLETED:

Studies should be summarized in order by species, by route, and by duration, giving brief details of the methodology and highlighting important findings (e.g., nature and severity of target organ toxicity, dose (exposure) and/or response relationships, no observed adverse effect levels). Nonpivotal studies can be summarized in less detail (pivotal studies are the definitive GLP studies specified by ICH guidance M3).

Table 2

2.6.6.4 Genotoxicity

GUIDANCE INFORMATION – DELETE WHEN COMPLETED:

Studies should be briefly summarized in the following order:

In vitro nonmammalian cell system

In vitro mammalian cell system

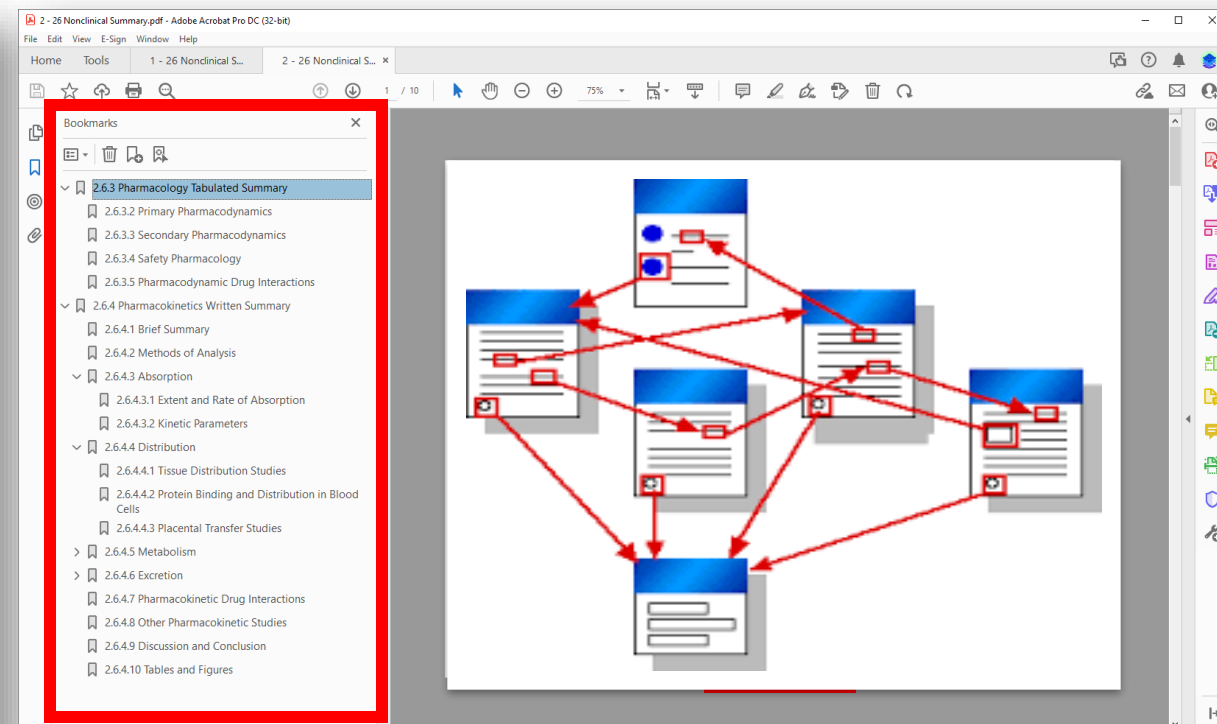
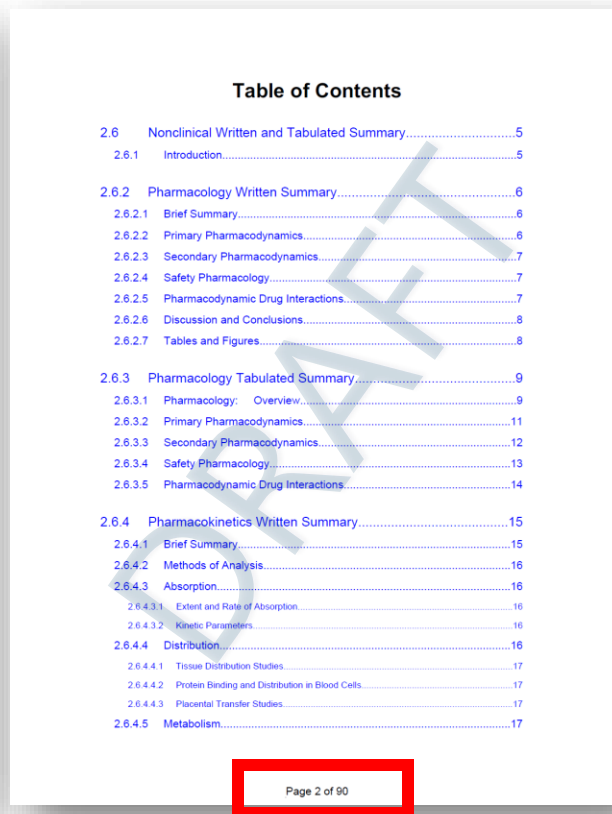
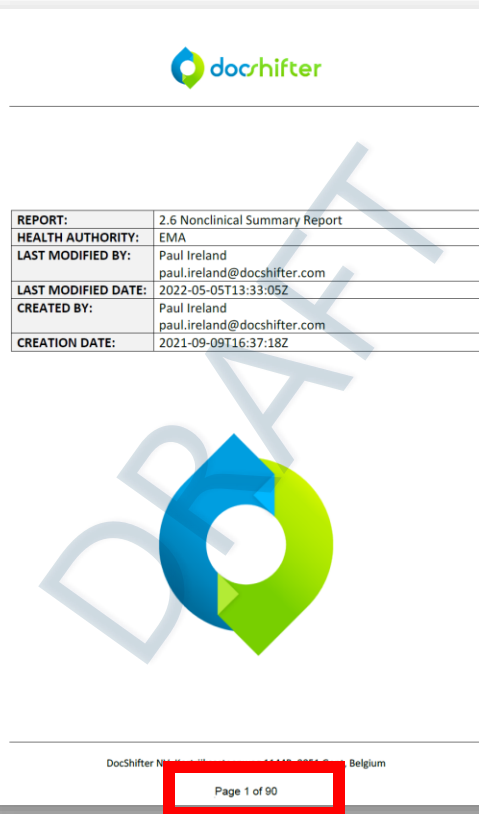
In vivo mammalian system (including supportive toxicokinetics evaluation)

Other systems

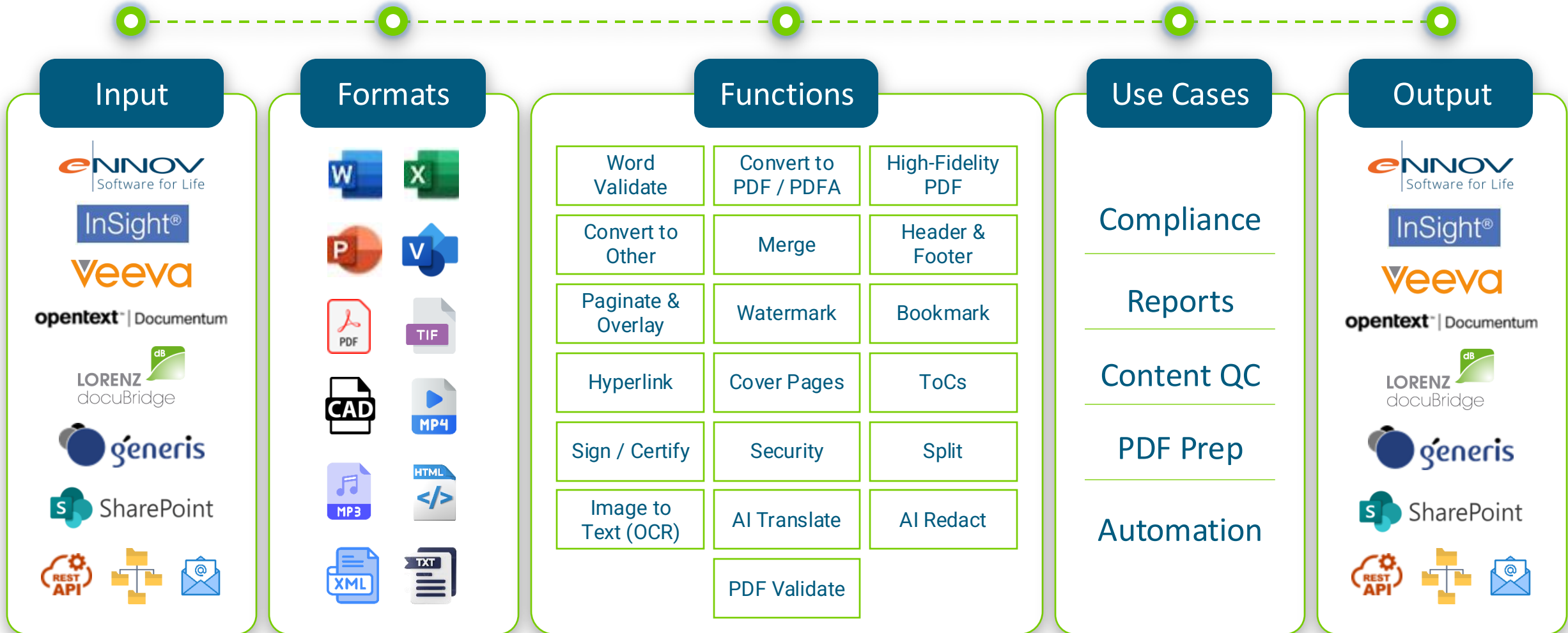
Automated Report Generation

What is a Report?

- One or more files merged into one or multiple enriched PDFs:

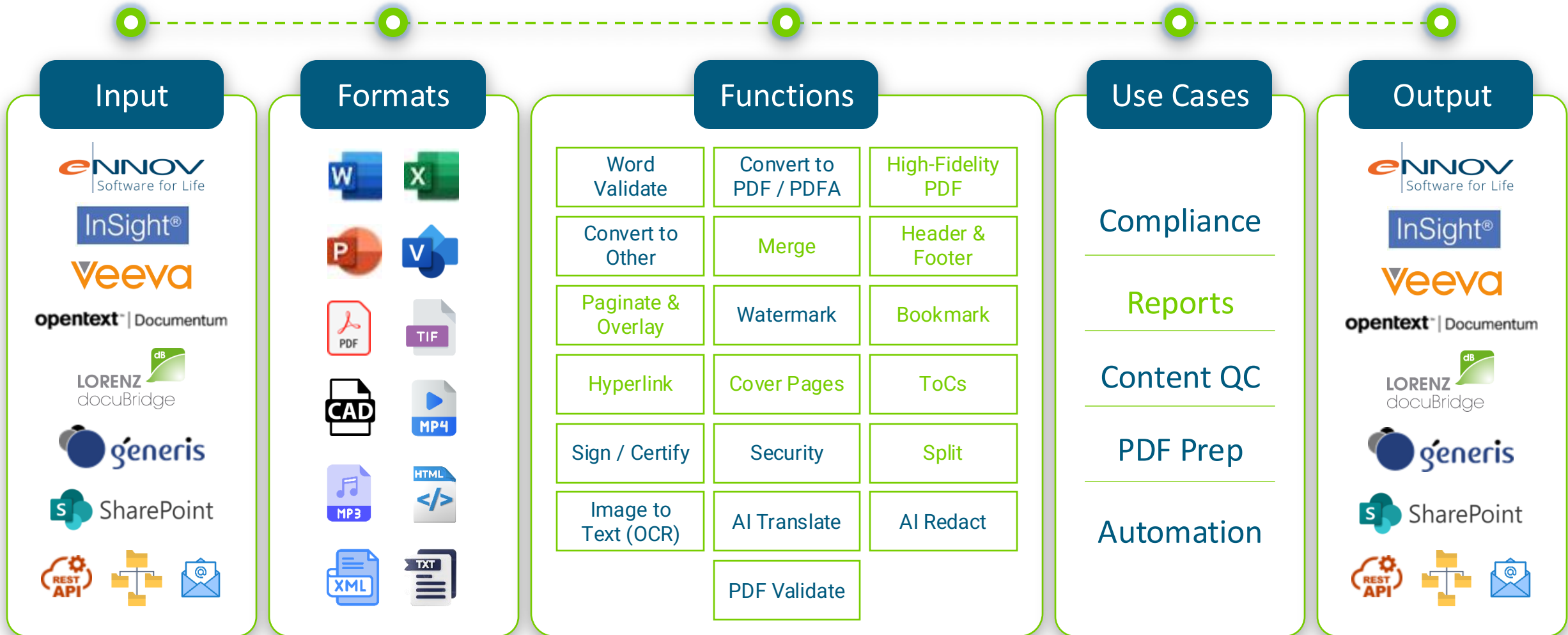


What is DocShifter? *(not a publishing system, more than rendering)*



...automated compliant content preparation...

What is DocShifter? *(not a publishing system, more than rendering)*



...automated compliant content preparation...

Automated Report Generation



Automated Report Generation

- › Monitor for binder/VD/zip status or queue
- › Route based on report type

Report DocType Check Configuration

Name * Save Discard

Description

☐ Show required fields first

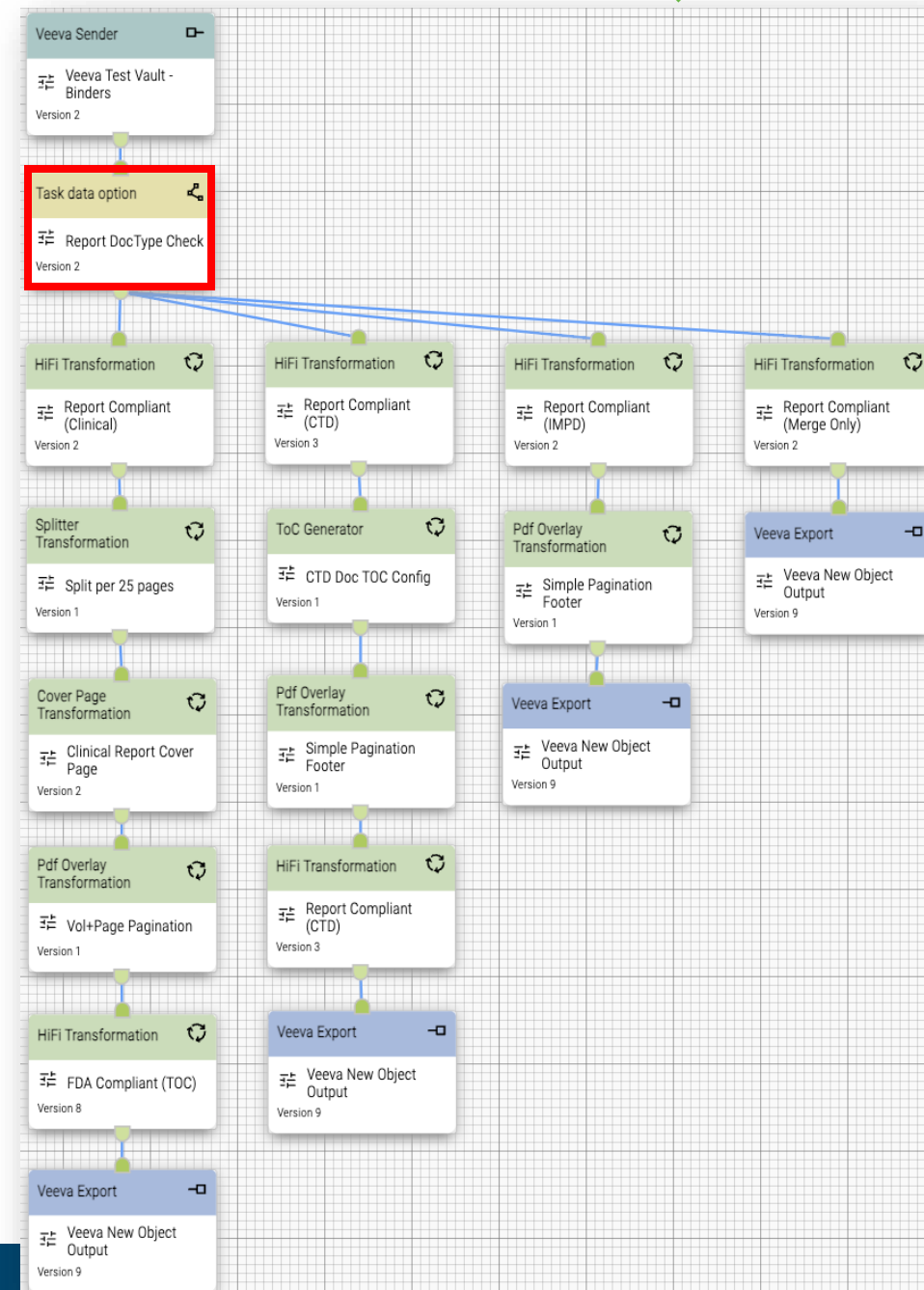
CONFIGURATION PARAMETERS

Filter param by name

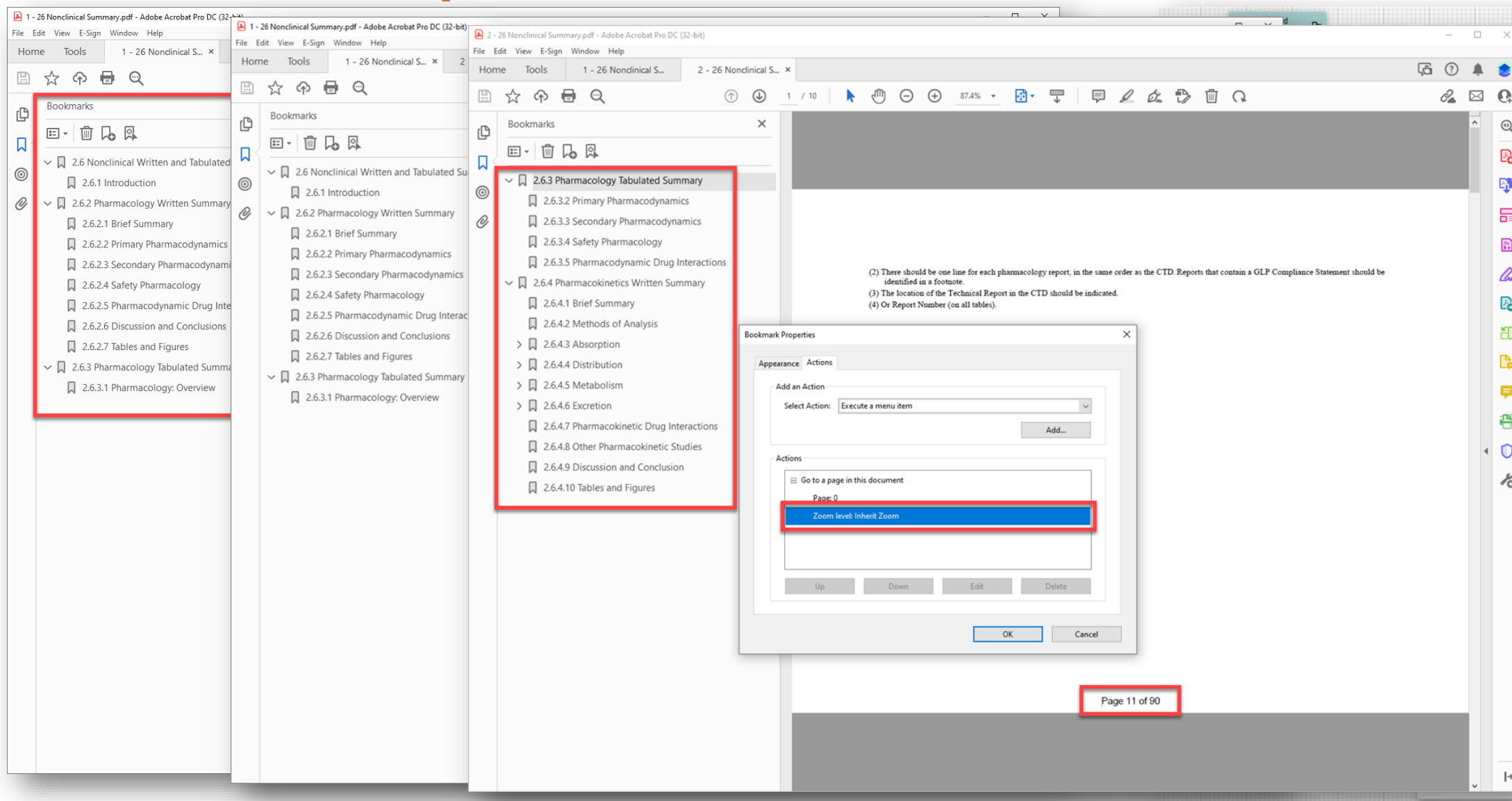
Group	Name	Value
Default	taskDataParam *	Type

The task data parameter name to check

Operator	Field Value	Configuration
==	CTD	Report Compliant (CTD)
==	Clinical	Report Compliant (Clinical)
==	IMPD	Report Compliant (IMPD)
default		Report Compliant (Merge Oni



Automated Report Generation



1 - 26 Nonclinical Summary.pdf - Adobe Acrobat Pro DC (32-bit)

File Edit View E-Sign Window Help

Home Tools 1 - 26 Nonclinical S...

Bookmarks

- 2.6 Nonclinical Written and Tabulated Summary
- 2.6.1 Introduction
- 2.6.2 Pharmacology Written Summary
 - 2.6.2.1 Brief Summary
 - 2.6.2.2 Primary Pharmacodynamics
 - 2.6.2.3 Secondary Pharmacodynamics
 - 2.6.2.4 Safety Pharmacology
 - 2.6.2.5 Pharmacodynamic Drug Interactions
 - 2.6.2.6 Discussion and Conclusions
 - 2.6.2.7 Tables and Figures
- 2.6.3 Pharmacology Tabulated Summary
 - 2.6.3.1 Pharmacology: Overview

1 - 26 Nonclinical Summary.pdf - Adobe Acrobat Pro DC (32-bit)

File Edit View E-Sign Window Help

Home Tools 1 - 26 Nonclinical S...

Bookmarks

- 2.6 Nonclinical Written and Tabulated Summary
- 2.6.1 Introduction
- 2.6.2 Pharmacology Written Summary
 - 2.6.2.1 Brief Summary
 - 2.6.2.2 Primary Pharmacodynamics
 - 2.6.2.3 Secondary Pharmacodynamics
 - 2.6.2.4 Safety Pharmacology
 - 2.6.2.5 Pharmacodynamic Drug Interactions
 - 2.6.2.6 Discussion and Conclusions
 - 2.6.2.7 Tables and Figures
- 2.6.3 Pharmacology Tabulated Summary
 - 2.6.3.1 Pharmacology: Overview

2 - 26 Nonclinical Summary.pdf - Adobe Acrobat Pro DC (32-bit)

File Edit View E-Sign Window Help

Home Tools 1 - 26 Nonclinical S...

Bookmarks

- 2.6.3 Pharmacology Tabulated Summary
 - 2.6.3.2 Primary Pharmacodynamics
 - 2.6.3.3 Secondary Pharmacodynamics
 - 2.6.3.4 Safety Pharmacology
 - 2.6.3.5 Pharmacodynamic Drug Interactions
 - 2.6.4 Pharmacokinetics Written Summary
 - 2.6.4.1 Brief Summary
 - 2.6.4.2 Methods of Analysis
 - 2.6.4.3 Absorption
 - 2.6.4.4 Distribution
 - 2.6.4.5 Metabolism
 - 2.6.4.6 Excretion
 - 2.6.4.7 Pharmacokinetic Drug Interactions
 - 2.6.4.8 Other Pharmacokinetic Studies
 - 2.6.4.9 Discussion and Conclusion
 - 2.6.4.10 Tables and Figures

(2) There should be one line for each pharmacology report, in the same order as the CTD. Reports that contain a GLP Compliance Statement should be identified in a footnote.

(3) The location of the Technical Report in the CTD should be indicated.

(4) Or Report Number (on all tables).

Bookmark Properties

Appearance Actions

Add an Action

Select Action: Execute a menu item

Add...

Actions

- Go to a page in this document
 - Page: 0
 - Zoom level: Inherit Zoom

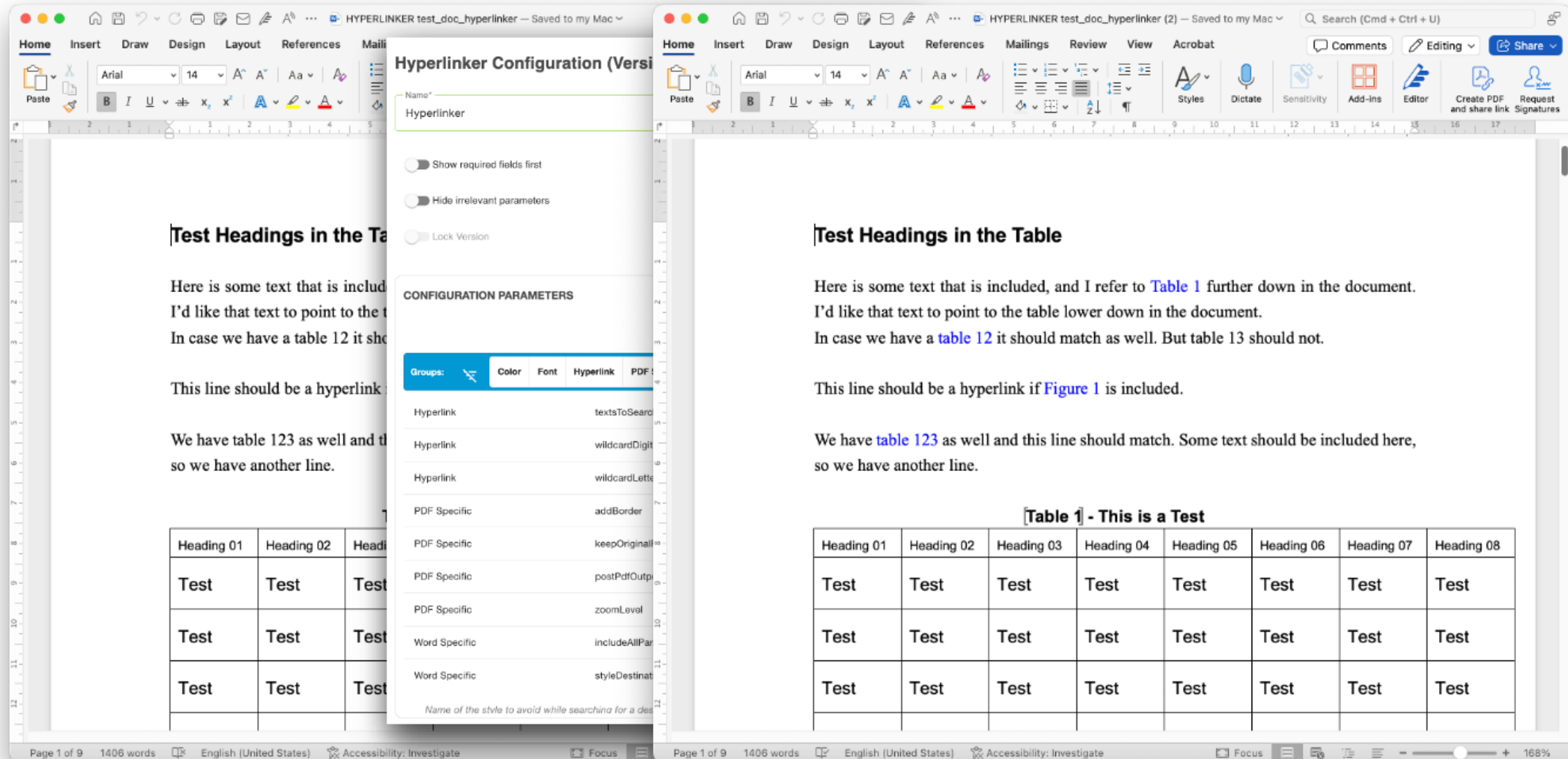
Up Down Edit Delete

OK Cancel

Page 11 of 90

Enriching PDFs with Bookmarks, Hyperlinks, Cleanups & OCR

Automated Hyperlinking



The image displays two side-by-side screenshots of a Microsoft Word document titled "HYPERLINKER test_doc_hyperlinker". The left screenshot shows the "Hyperlink Configuration (Version 1.0)" dialog box open, with the "Hyperlink" tab selected. The dialog includes options to "Show required fields first", "Hide irrelevant parameters", and "Lock Version". Below these are "CONFIGURATION PARAMETERS" for "Groups" (Hyperlink, Color, Font, Hyperlink, PDF), "Texts to Search" (Hyperlink, Hyperlink, Hyperlink), "PDF Specific" (addBorder, keepOriginal, postPdfOut, zoomLevel), and "Word Specific" (includeAllPar, styleDestinat). The right screenshot shows the document content with automated hyperlinks applied to "Table 1", "Figure 1", and "table 123".

Test Headings in the Table

Here is some text that is included, and I refer to [Table 1](#) further down in the document. I'd like that text to point to the table lower down in the document. In case we have a [table 12](#) it should match as well. But table 13 should not.

This line should be a hyperlink if [Figure 1](#) is included.

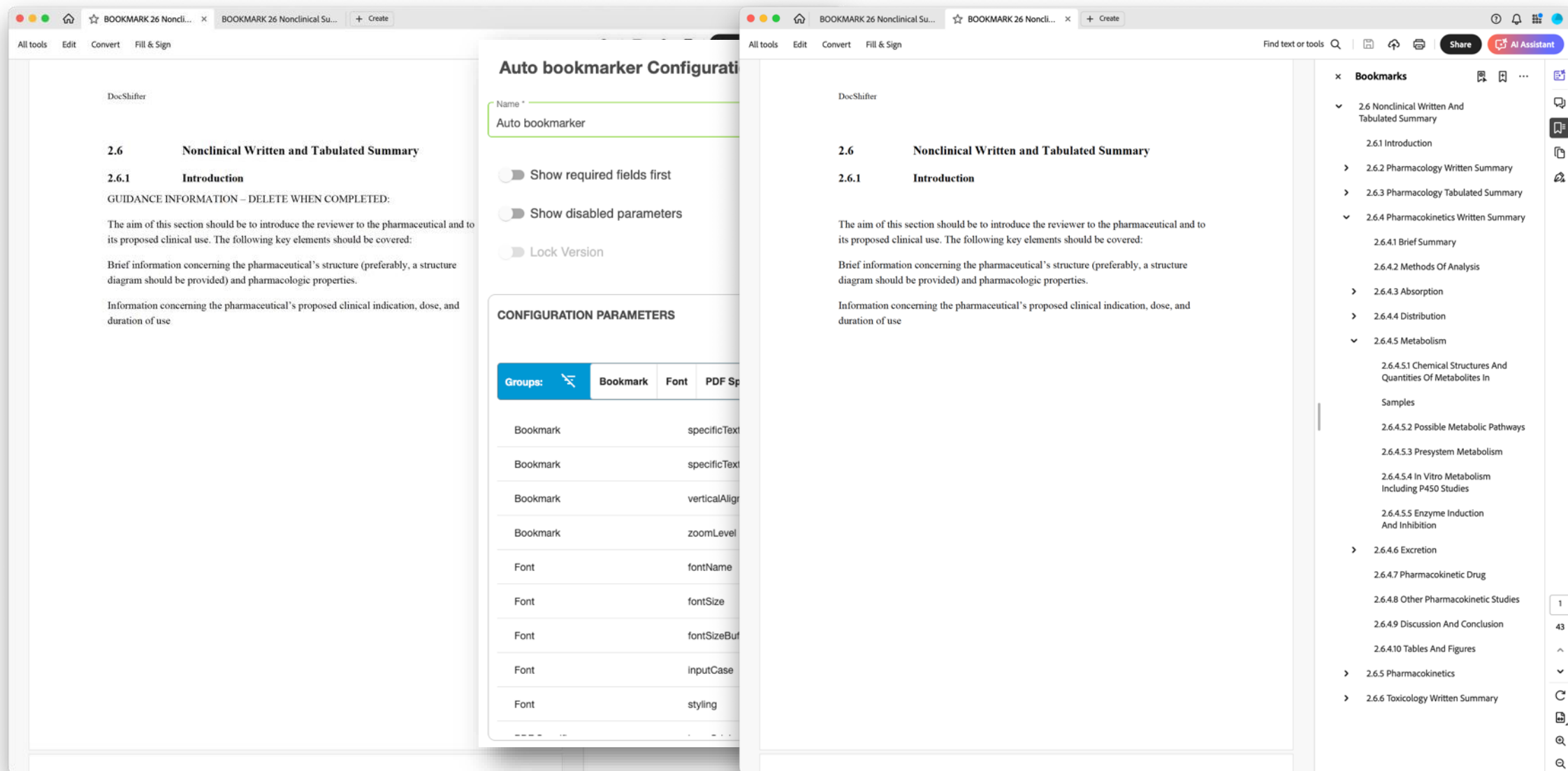
We have [table 123](#) as well and this line should match. Some text should be included here, so we have another line.

Heading 01	Heading 02	Heading 03	Heading 04	Heading 05	Heading 06	Heading 07	Heading 08
Test	Test	Test	Test	Test	Test	Test	Test
Test	Test	Test	Test	Test	Test	Test	Test
Test	Test	Test	Test	Test	Test	Test	Test

Table 1 - This is a Test

Heading 01	Heading 02	Heading 03	Heading 04	Heading 05	Heading 06	Heading 07	Heading 08
Test	Test	Test	Test	Test	Test	Test	Test
Test	Test	Test	Test	Test	Test	Test	Test
Test	Test	Test	Test	Test	Test	Test	Test

Automated Bookmarking & Content Detection



The screenshot displays the DocShifter web application interface. The main document area on the left shows a document titled 'DocShifter' with the following structure:

- 2.6 Nonclinical Written and Tabulated Summary**
 - 2.6.1 Introduction**

GUIDANCE INFORMATION – DELETE WHEN COMPLETED:

The aim of this section should be to introduce the reviewer to the pharmaceutical and to its proposed clinical use. The following key elements should be covered:

Brief information concerning the pharmaceutical's structure (preferably, a structure diagram should be provided) and pharmacologic properties.

Information concerning the pharmaceutical's proposed clinical indication, dose, and duration of use.

An 'Auto bookmarker Configuration' panel is overlaid on the document. It includes a 'Name' field set to 'Auto bookmarker' and three toggle options: 'Show required fields first' (checked), 'Show disabled parameters' (checked), and 'Lock Version' (unchecked). Below this is a 'CONFIGURATION PARAMETERS' table:

Groups:	Bookmark	Font	PDF Sp
Bookmark		specificText	
Bookmark		specificText	
Bookmark		verticalAlign	
Bookmark		zoomLevel	
Font		fontName	
Font		fontSize	
Font		fontSizeBut	
Font		inputCase	
Font		styling	

The right sidebar shows a 'Bookmarks' panel with a hierarchical tree structure:

- 2.6 Nonclinical Written And Tabulated Summary
 - 2.6.1 Introduction
 - 2.6.2 Pharmacology Written Summary
 - 2.6.3 Pharmacology Tabulated Summary
 - 2.6.4 Pharmacokinetics Written Summary
 - 2.6.4.1 Brief Summary
 - 2.6.4.2 Methods Of Analysis
 - 2.6.4.3 Absorption
 - 2.6.4.4 Distribution
 - 2.6.4.5 Metabolism
 - 2.6.4.5.1 Chemical Structures And Quantities Of Metabolites In Samples
 - 2.6.4.5.2 Possible Metabolic Pathways
 - 2.6.4.5.3 Presystem Metabolism
 - 2.6.4.5.4 In Vitro Metabolism Including P450 Studies
 - 2.6.4.5.5 Enzyme Induction And Inhibition
 - 2.6.4.6 Excretion
 - 2.6.4.7 Pharmacokinetic Drug
 - 2.6.4.8 Other Pharmacokinetic Studies
 - 2.6.4.9 Discussion And Conclusion
 - 2.6.4.10 Tables And Figures
- 2.6.5 Pharmacokinetics
- 2.6.6 Toxicology Written Summary

Bookmark from ToC

The image displays two side-by-side screenshots of the DocShifter 9.0 installation and upgrade guide. Both screenshots show the 'Table of Contents' page, which lists sections such as '1 WARM WELCOME & INTRODUCTION', '2 INSTALLATION AND UPGRADING', '3 INSTALLATION', and '4 POST INSTALL STEPS'. The left screenshot includes a sidebar on the right with a 'CONFIGURATION PARAMETERS' section and a 'TOC Testing Configuration' section. The right screenshot includes a sidebar on the right with a 'Bookmarks' section. Both screenshots show the DocShifter logo and the title 'Table of Contents'.

Auto-QC & Fix Word Docs

Identify & Fix MS Word Content Issues

- › From any repository
- › Integrate with existing lifecycles
- › Identify, report & fix issues with:



- › Report / fixed document output

Module Configuration

Name *

All Checks - Some Fixes

Description

Report on all issues.
Fix dept xyz issues

☐ Show required fields first

Save

Discard

CONFIGURATION PARAMETERS

Filter param by name

X

Default	check_1102	Check only
Default	check_1103	Fix with Remove Hyperlink
Check - Internal Hyperlink with No Target		
Default	check_1104	Fix with Remove Hyperlink
Default	check_1105	Fix with Remove Hyperlink
Default	check_1106	Check only
Default	check_1107	Check only
Default	check_1199	Check only
Default	check_1201	Fix with Remove comment
Default	check_1202	Fix with Remove Text
Default	check_1203	Check only

Word QC Report

File Edit Home

Book Book Book Book Book Book Book Book Book Bookmarks

DOC Validation Report

Document

Validation Result

Validation Summary

Validation Details

External Link Formatting	Place	Status
External link formatting found. The patient population and the selection criteria used to enter the patients into the study should be described, and the suitability of the population for the purposes of the study discussed. Specific diagnostic criteria used, as well as specific disease requirements (e.g., disease of a particular severity or duration, results of a particular test or rating scale(s) or physical examination, particular features of clinical history, such as failure or success on prior therapy, or other potential prognostic factors and any age, sex or ethnic factors) should be presented.	Chapter 10.2.1	Correction needed Correction module application not requested
External link formatting found. adverse	Chapter 14.3.1	Correction needed Correction module application not requested

#29 Image with Incorrect Format

Problem: It is recommended to use only standard image formats in the documents, otherwise it can cause issues during the rendition generation.

Module Description: This module finds all images which have a format different from the standard formats (set in the parameters), e.g. JPEG.

How to Fix Manually: Convert the image to a standard format and replace it in the document manually.

Available Correction Function: Not available

Image with Incorrect Format	Place	Status
Image with incorrect format found. Image 1	Chapter 10.3.1.0	Correction needed Correction module application not requested
Image with incorrect format found. Image 2	Chapter 10.3.5	Correction needed Correction module application not requested
Image with incorrect format found. Image 3	Chapter 10.7	Correction needed Correction module application not requested
Image with incorrect format found. Image 4	Chapter 15.0	Correction needed Correction module application not requested

#30 Image in Low Resolution

Problem: It is not allowed in the submission documents to include images with low resolution.

Module Description: This module finds all images in the document which have lower resolution as the minimum (set in the parameters), e.g. 220 dpi.

How to Fix Manually: Change the image (e.g. re-scan) or select the image and choose the required resolution manually in Picture Format > Compress Pictures.

Available Correction Function: Not available

Image in Low Resolution	Place	Status
Image in low resolution found. Image 1 has no compression	Chapter 10.3.1.0	Correction needed Correction module application not requested
Image in low resolution found. Image 2 has no compression	Chapter 10.3.5	Correction needed Correction module application not requested
Image in low resolution found. Image 3 has no compression	Chapter 10.7	Correction needed Correction module application not requested
Image in low resolution found. Image 4 has no compression	Chapter 15.0	Correction needed Correction module application not requested

#31 Internal Reference Document

Problem: The document can contain internal references to other documents which have a document name with predefined format. These references have to be linked to reference section.

Module Description: This module lists all places in the document where an internal document is mentioned with the defined document name, but it is not linked to the reference section.

How to Fix Manually: Format the internal document reference as required.

Available Correction Function: Not available

Internal Reference Document	Place	Status
Internal document is mentioned, but it is not linked to the reference section. RD-2018-20168	Chapter 14	Correction needed Correction module application not requested
Internal document is mentioned, but it is not linked to the reference section. RD-2018-20168	Chapter 14	Correction needed Correction module application not requested
Internal document is mentioned, but it is not linked to the reference section. RD-2018-20168	Chapter 14	Correction needed Correction module application not requested

Word QC Fix

The screenshot shows a Microsoft Word document titled 'VALIDATE Sample - More Issues Document'. The document is split into two pages. The left page (Page 1 of 2) contains four headings and a table. The right page (Page 2 of 2) contains two headings, a comment, and an image. Various callouts point to specific issues in the document.

Callouts and Issues:

- Heading padding spaces:** Points to the first heading on page 1.
- Styling not matching template:** Points to the first paragraph on page 1.
- Heading numbers out of sequence:** Points to the first heading on page 1.
- External hyperlinks:** Points to a link in the first paragraph on page 1.
- Watermarks:** Points to a large 'DRAFT' watermark across the center of the document.
- Table sizing issues:** Points to a table at the bottom of page 1.
- Empty paragraphs:** Points to a paragraph on page 2.
- Comments remaining:** Points to a comment box on page 2.
- Image issues:** Points to an image on page 2.

Table Data (Page 1):

Column 1	Column 2	Column 3	Column 4	Column 5
43	7645	43243	543	432
6546	34	5434	54345	436

Word QC Fix

The screenshot shows a Microsoft Word document titled "VALIDATE Sample - More Issues Document-output - Saved to my Mac". The document is displayed in two pages. The left page (Page 1 of 2) contains the following content:

- 1. First Heading**: The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... Link the quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... DocShifter Website
- 2. Second Heading**: The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog...
- 3. Third Heading**: The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog...
- Table**:

Column 2	Column 3	Column 4	Column 5
7645	43243	543	432
34	5434	54345	436

The right page (Page 2 of 2) contains the following content:

- 4. Fourth Heading**: The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... Link to External Document The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog...
- 5. Fifth Heading**: The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog... The quick brown fox jumps over the lazy dog...
- Image**: A close-up of a hand holding a syringe. Below the image, the text "Image not in-line-in-line" is visible.

Callouts highlighting QC fixes include:

- No padding spaces**: Points to the first heading.
- Styles set to match template**: Points to the first heading.
- Heading numbers in sequence**: Points to the first heading.
- No external hyperlinks**: Points to the first heading.
- Tables adjusted**: Points to the table.
- Watermarks removed**: Points to the bottom of the first page.
- No empty paragraphs**: Points to the fifth heading.
- Comments removed**: Points to the right margin.
- No image issues**: Points to the image.

The status bar at the bottom shows: Page 1 of 2, 343 words, English (United States), Accessibility: Investigate, Focus, 87%.

Auto-QC & Fix PDF Docs

Identify & Fix PDF Content Issues

- › From any repository
- › Integrate with existing lifecycles
- › Identify, report & fix issues with:



- › Report / fixed PDF output

PDF Validation - All Checks Configuration

Name *
PDF Validation - All Checks

Description
All PDF Validation checks enabled

☐ Show required fields first

Save

Discard

CONFIGURATION PARAMETERS

Filter param by name

×

Groups:	Annotations	Bookmarks	Common	Default	Document Properties	Hyperlinks	Initial View	Pages
Group	Name	Value						
Annotations	PDF.ANNO.1 *	☐ true						
Annotations	PDF.ANNO.2 *	☐ true						
Annotations	PDF.ANNO.2.allowed_annotations *	Link						
Annotations	PDF.ANNO.3 *	☐ true						
Annotations	PDF.ANNO.4 *	☐ true						
Bookmarks	PDF.BMRK.1 *	☐ true						
Bookmarks	PDF.BMRK.1.bookmark_expansion_level *	0						

Bookmarks are expanded until the defined level, which is generally a positive integer value of the expected expansion level. Depth level 0 means all bookmarks fully collapsed, while -1 means fully expanded. Default is 1.

PDF QC Report

PDF Validation

Document

File Name	266-toxicology-written-summary.pdf
File Size	57,744 B
File Last Modified	February 10, 2022
PDF Producer	Aspose PDF
PDF Version	1.4

Validation Result

Validation Result	Non-Compliant
Number of Failed Checks	8
Identified Issues	15

Validation Parameters

Engine	OnTrack
Execution Date	January 20, 2022
Configuration Name	full validation
Active / All Checks	38 / 38

Document Properties

Number of Pages	6
Number of Bookmarks	22
Number of Hyperlinks	4
Number of Comments	0

Generated by OnTrack PDF Validator

Validation Summary

Name	Description
Prerequisite	
PDF.PROP.1	PDF file size doesn't exceed configured limit
PDF.TEXT.1	Text is searchable
PDF.SEC.2	PDF is not protected by open password
PDF.PROP.2	PDF contents can be processed successfully
PDF.SEC.3	No certificate protection
PDF Properties	
PDF.PROP.5	PDF version is correct
PDF.PROP.6	Fast Web View option is activated
Security	
PDF.SEC.1	No security (document access) restriction
Font Embedding	
PDF.FONT.1	All used fonts have been embedded
Initial View	
PDF.VIEW.1	Navigation tab setting
PDF.VIEW.2	Page layout is set to Default
PDF.VIEW.3	Magnification is set to Default
PDF.VIEW.4	Document opens to page 1 or TOC
Pages	
PDF.PAGE.1	PDF contains only pages with the configured page range
PDF.PAGE.2	First page orientation is portrait
PDF.PAGE.3	No blank page
PDF.PAGE.4	Sequential page numbering
PDF.PAGE.5	First page and headers do not indicate 'draft'
Bookmarks	
PDF.BMRK.1	Bookmarks are expanded until the defined level
PDF.BMRK.2	Number of bookmark levels doesn't exceed configured limit
PDF.BMRK.3	Bookmark nesting is correct
PDF.BMRK.7	No corrupted bookmarks
PDF.BMRK.8	Magnification of the bookmarks is set to inherit
PDF.BMRK.9	No multiple action bookmark

Generated by OnTrack PDF Validator

2

Name	Description
PDF.BMRK.10	There are bookmarks
PDF.BMRK.11	Provide bookmarks for each item listed in TOC
PDF.BMRK.12	First bookmark leads to first page
Hyperlinks	
PDF.HLNK.2	Internal hyperlinks blued
PDF.HLNK.3	No broken links
PDF.HLNK.4	Relative paths are used in hyperlinks
PDF.HLNK.5	No external hyperlinks to websites
PDF.HLNK.6	Magnification of the hyperlinks is set to inherit
PDF.HLNK.7	No multiple action hyperlink
PDF.HLNK.8	No blue texts without hyperlinks
PDF.HLNK.9	Hypertext linked TOC is included
Annotations	
PDF.ANNO.1	No comments
PDF.ANNO.2	No annotations
PDF.ANNO.3	No digital signatures

Generated by OnTrack PDF Validator

3

Validation Details

PDF Properties

PDF.PROP.5 - PDF version is not appropriate:

Issue
Current version is: 1.4

PDF.PROP.6 - PDF has been created without 'Fast Web Access' active

Font Embedding

PDF.FONT.1 - Font is not embedded:

Font
TimesNewRomanPSMT
TimesNewRomanPS-BoldMT
SegoeUI
Tahoma-Bold

Bookmarks

PDF.BMRK.1 - Bookmarks are over expanded on level 0 (all closed)

PDF.BMRK.1 - Bookmark expanded, but should be collapsed:

Bookmark Title
2.6.6 Toxicology Written Summary

Hyperlinks

PDF.HLNK.2 - Color of link text with no box around it should be Blue:

Hyperlink
Single-dose toxicity
Repeat-dose toxicity

Generated by OnTrack PDF Validator

4

PDF.HLNK.5 - External hyperlink:

Hyperlink
Link 'EMA Website'

PDF.HLNK.8 - Texts are blued but not linked:

Blue Text	Pages
GUIDANCE INFORMATION – DELETE WHEN COMPLETED:	1, 4-6
GUIDANCE INFORMATION – DELETE GRAPHIC WHEN COMPLETED:	2
GUIDANCE INFORMATION – DELETE WHEN COMPLETED	2-3

PDF.HLNK.9 - No hyperlinked Table of Contents found in PDF

Generated by OnTrack PDF Validator

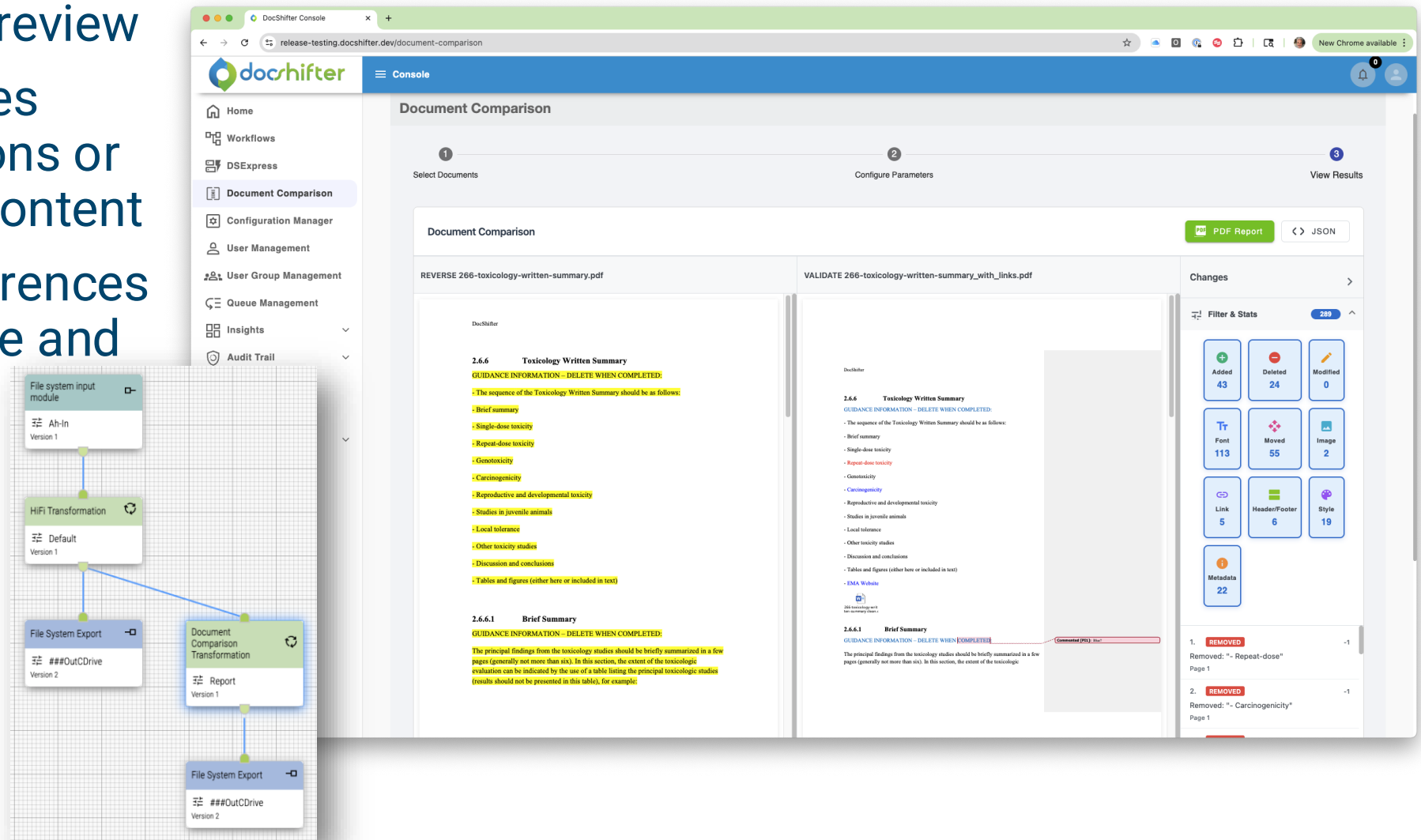
5

January 20, 2022

Document Comparisons

Compare docx and pdf Content

- Aid document review
- Identify changes between versions or duplicates of content
- Check for differences between source and rendition
- Interactive or Automated



The screenshot displays the DocShifter Console interface, which is used for document comparison. The left sidebar shows the navigation menu with options like Home, Workflows, DSEExpress, Document Comparison, Configuration Manager, User Management, User Group Management, Queue Management, Insights, and Audit Trail.

The main area shows the 'Document Comparison' workflow. It includes a 'Select Documents' step where two documents are chosen: 'REVERSE 266-toxicology-written-summary.pdf' and 'VALIDATE 266-toxicology-written-summary_with_links.pdf'. The 'Configure Parameters' step is also visible.

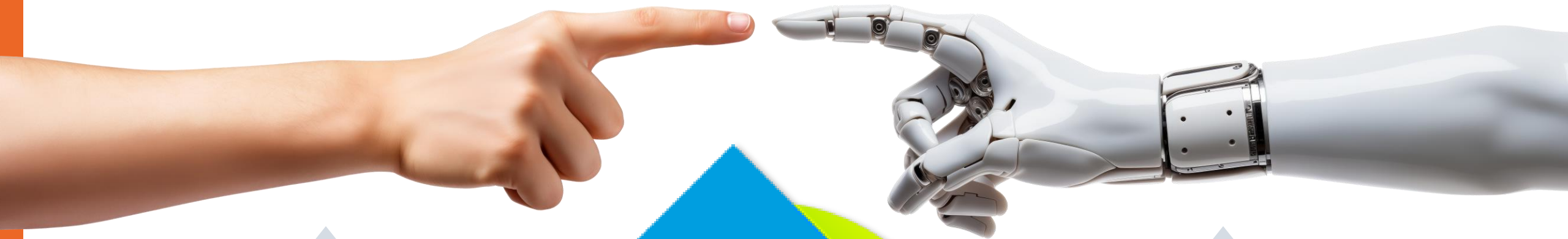
The 'View Results' step shows the comparison results. The left pane displays the 'Document Comparison' results for the selected documents. The right pane shows the 'Changes' section, which includes a 'Filter & Stats' table with the following data:

Filter & Stats	Count
Added	43
Deleted	24
Modified	0
Font	113
Moved	55
Image	2
Link	5
Header/Footer	6
Style	19
Metadata	22

Below the 'Filter & Stats' table, there is a list of changes with details on what was removed and where. The first change is 'Removed: "- Repeat-dose" Page 1' and the second is 'Removed: "- Carcinogenicity" Page 1'.

AI-Powered Translations

Configured AI automation



Automation = where, when, what, how

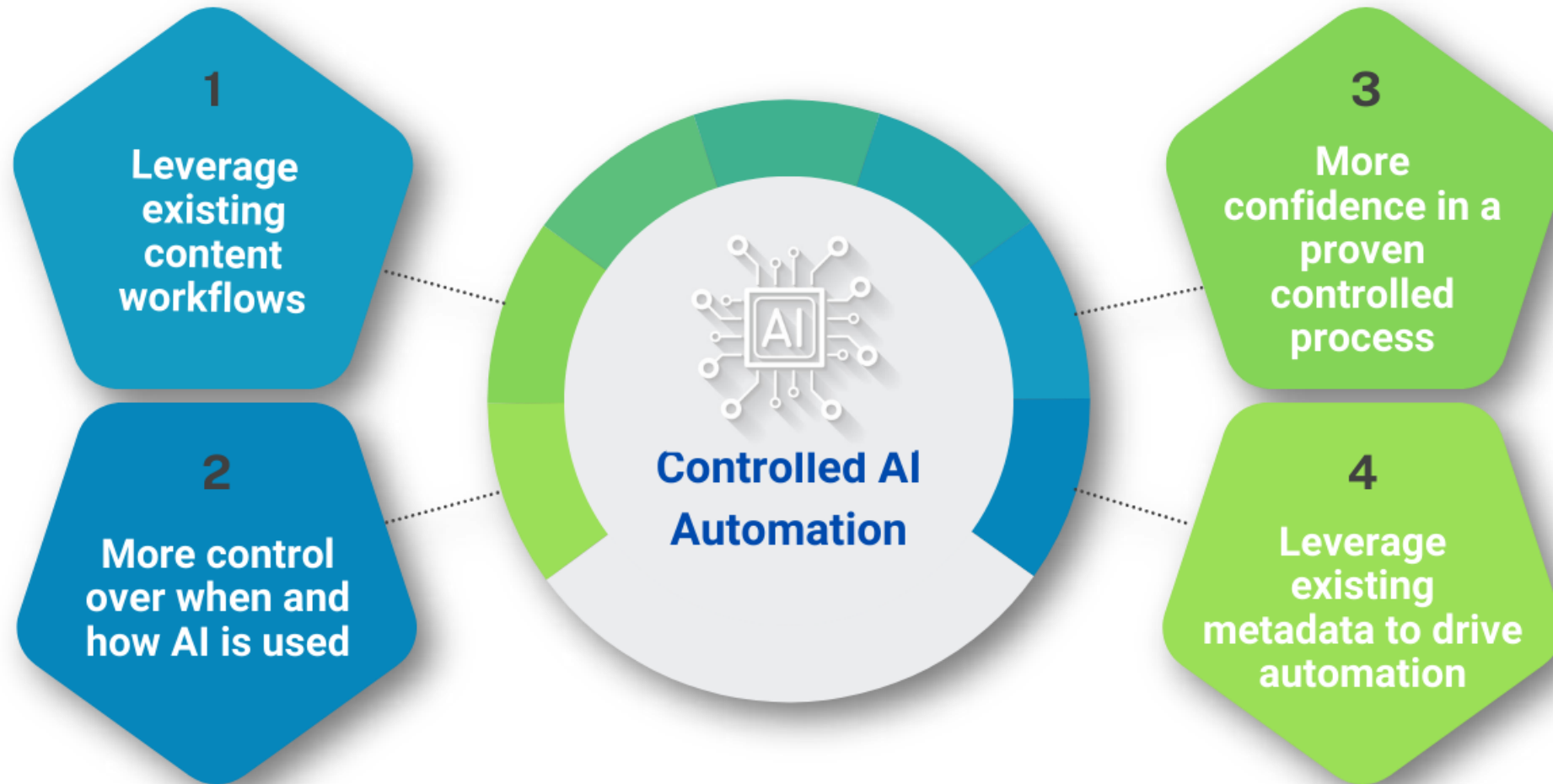
Configured Automation

Where?
When?

What?

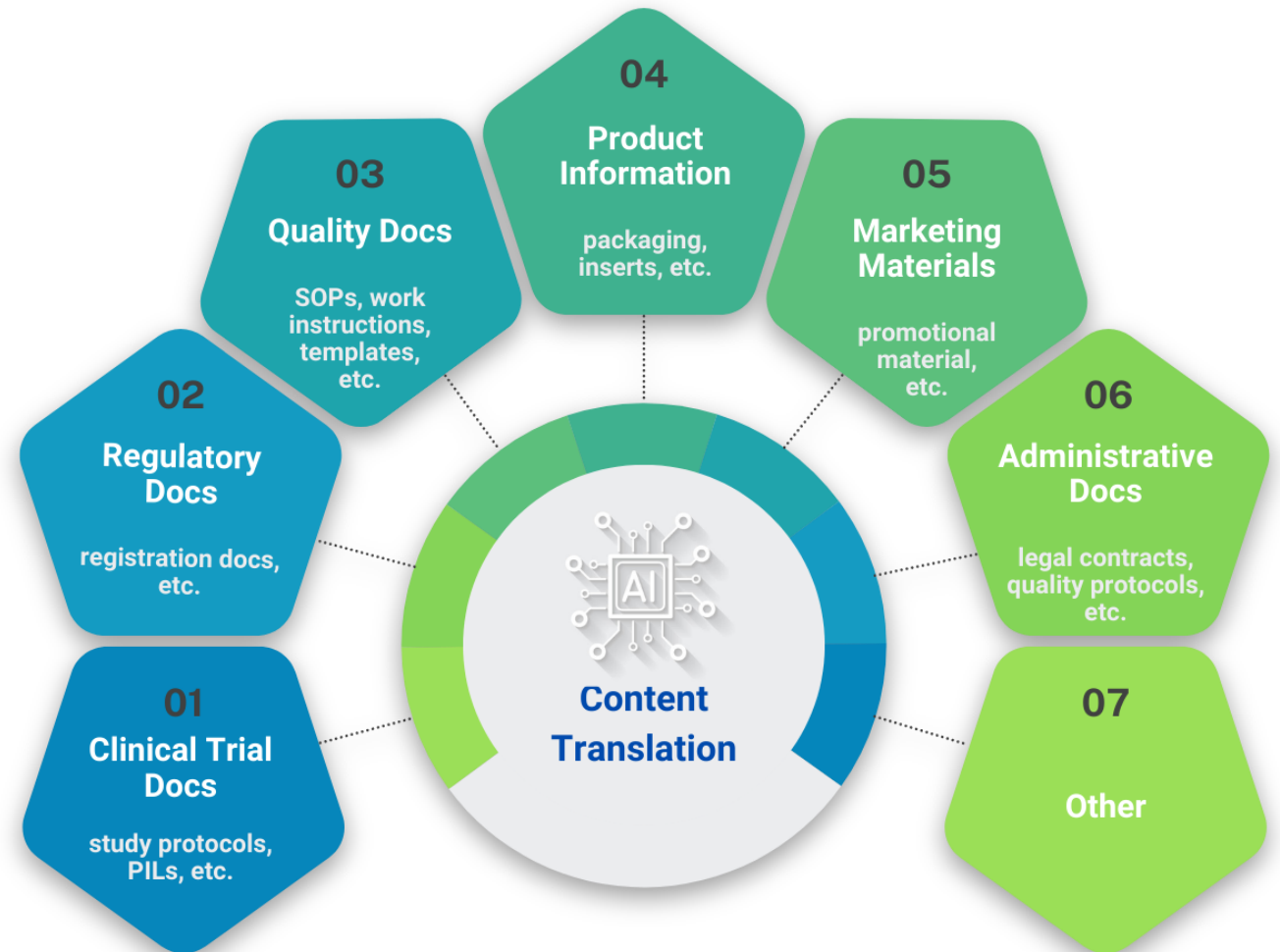
How?
AI

Controlled AI automation

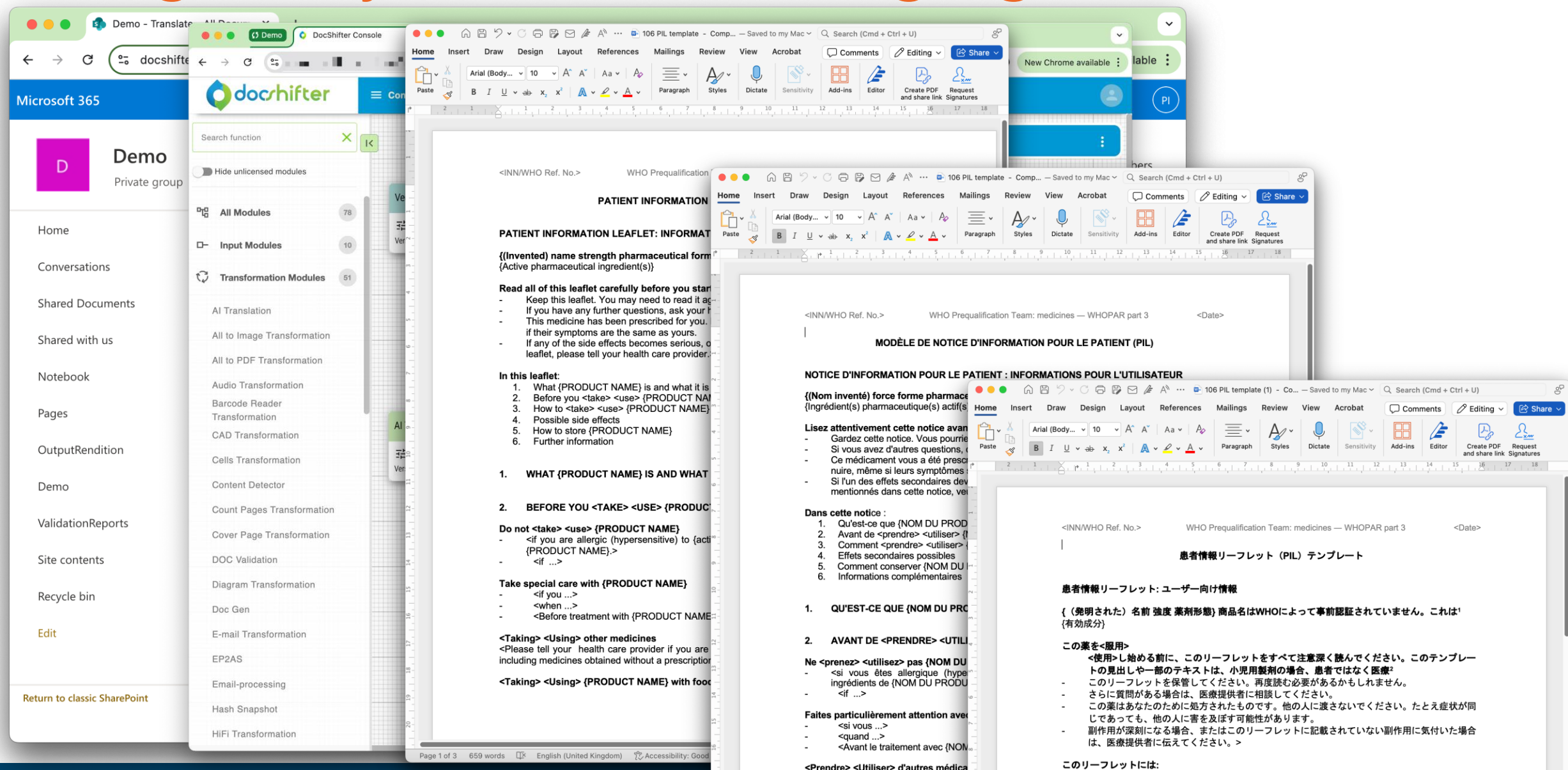


Automated AI content translation

- › Many documents require translation to ensure clear communication and compliance with global regulations.
- › Accurate translation of these documents is crucial to ensure patient safety & compliance.
- › Content requiring translation includes:



Regulatory content multi-language results



The screenshot displays the DocShifter web application interface, which is used for translating regulatory documents. The interface is divided into several sections:

- Left Sidebar (Microsoft 365):** Contains navigation links for Home, Conversations, Shared Documents, Shared with us, Notebook, Pages, OutputRendition, Demo, ValidationReports, Site contents, Recycle bin, and Edit. At the bottom, there is a link to "Return to classic SharePoint".
- DocShifter Console:** A central panel showing a search function and a list of modules. The "Transformation Modules" section is expanded, listing various translation and processing options: AI Translation, All to Image Transformation, All to PDF Transformation, Audio Transformation, Barcode Reader Transformation, CAD Transformation, Cells Transformation, Content Detector, Count Pages Transformation, Cover Page Transformation, DOC Validation, Diagram Transformation, Doc Gen, E-mail Transformation, EP2AS, Email-processing, Hash Snapshot, and HiFi Transformation.
- Document Preview:** The main area shows three overlapping document pages. The top page is a "PATIENT INFORMATION LEAFLET: INFORMATION" in English, detailing instructions for use and side effects. The middle page is a "MODÈLE DE NOTICE D'INFORMATION POUR LE PATIENT (PIL)" in French, providing a template for patient information. The bottom page is a "患者情報リーフレット (PIL) テンプレート" in Japanese, also providing a template for patient information. Each page includes a header with "<INN/WHO Ref. No.>" and a footer with "Page 1 of 3" and "659 words".

AI content translation

> “AI Translation” transformation module

- Intelligent translation into one or multiple languages simultaneously
- Automatically detects input language
- Include as part of any automated content workflow
- Leverage multiple models
- Exclude glossaries, headers, footers, pages, tables

Selectable Configuration (Version: 2)

Save

Discard

Name*

Selectable

Description

For use by DSEExpress

Show required fields first

Hide irrelevant parameters

Lock Version

CONFIGURATION PARAMETERS

Filter param by name

Group	Name	Value
Default	apiKey *	
	The API key required for authentication and authorization of the translation service.	
Default	language *	English Spanish French German Chinese
Default	model *	

AI content translation

- “AI Translation” transformation module
 - Intelligent translation into one or multiple languages simultaneously
 - Automatically detects input language
 - Include as part of any automated content workflow
 - Leverage multiple models
 - Exclude glossaries, headers, footers, pages, tables

Save
Discard

SP Selectable Configuration (Version: 1)

Name*

Description

☐ Show required fields first

☐ Hide irrelevant parameters

☐ Lock Version

CONFIGURATION PARAMETERS

Filter param by name ✕

Groups: ✕

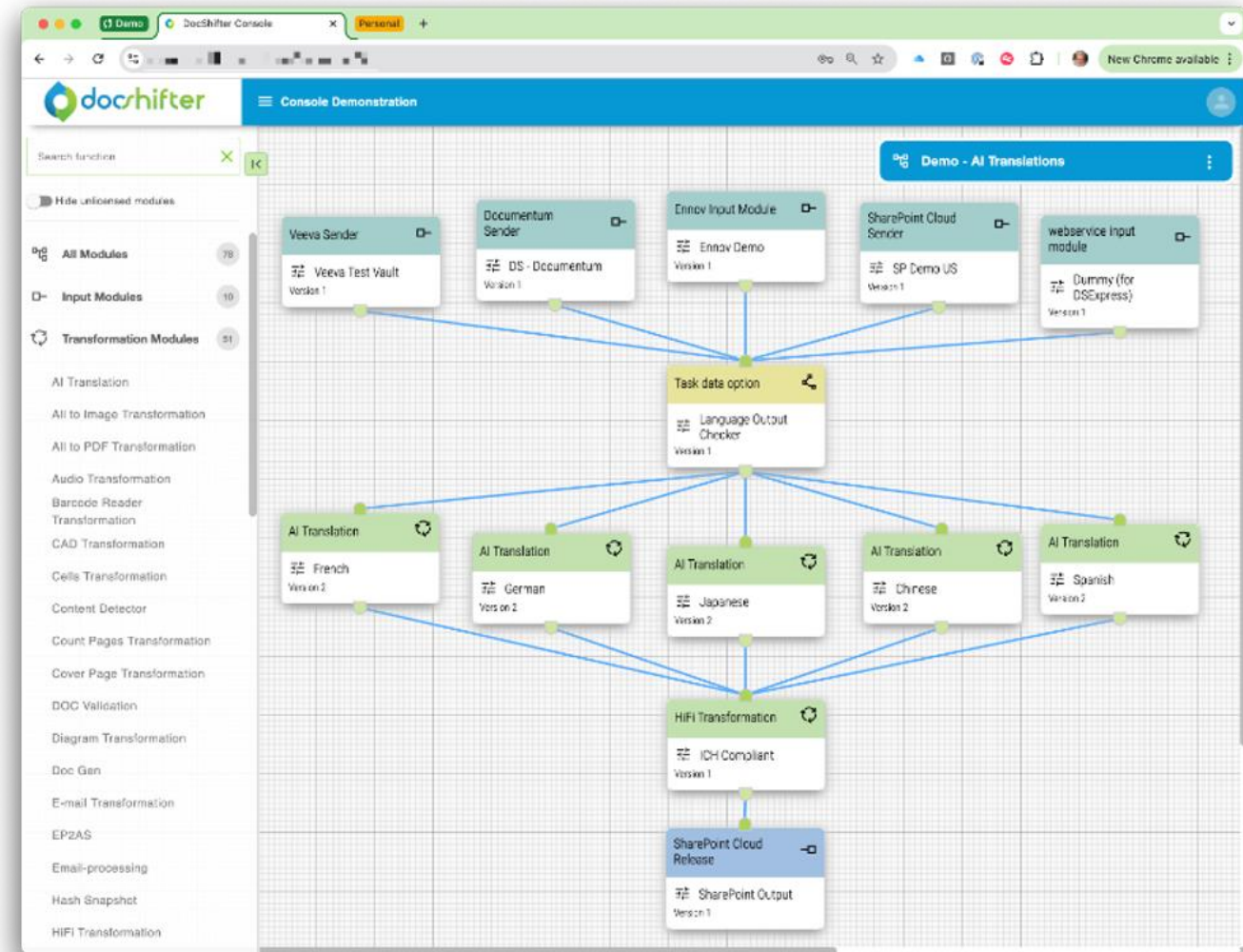
Configuration

Filters

Group	Name	Value
Configuration	apiKey *	
Configuration	language *	\${TranslateLanguage} ⋮
Configuration	model *	GPT-4o ⋮
Filters	footer	false ⋮
Filters	glossaries	
Filters	header	false ⋮
Filters	pageRange	
Filters	tables	false ⋮

AI content translation

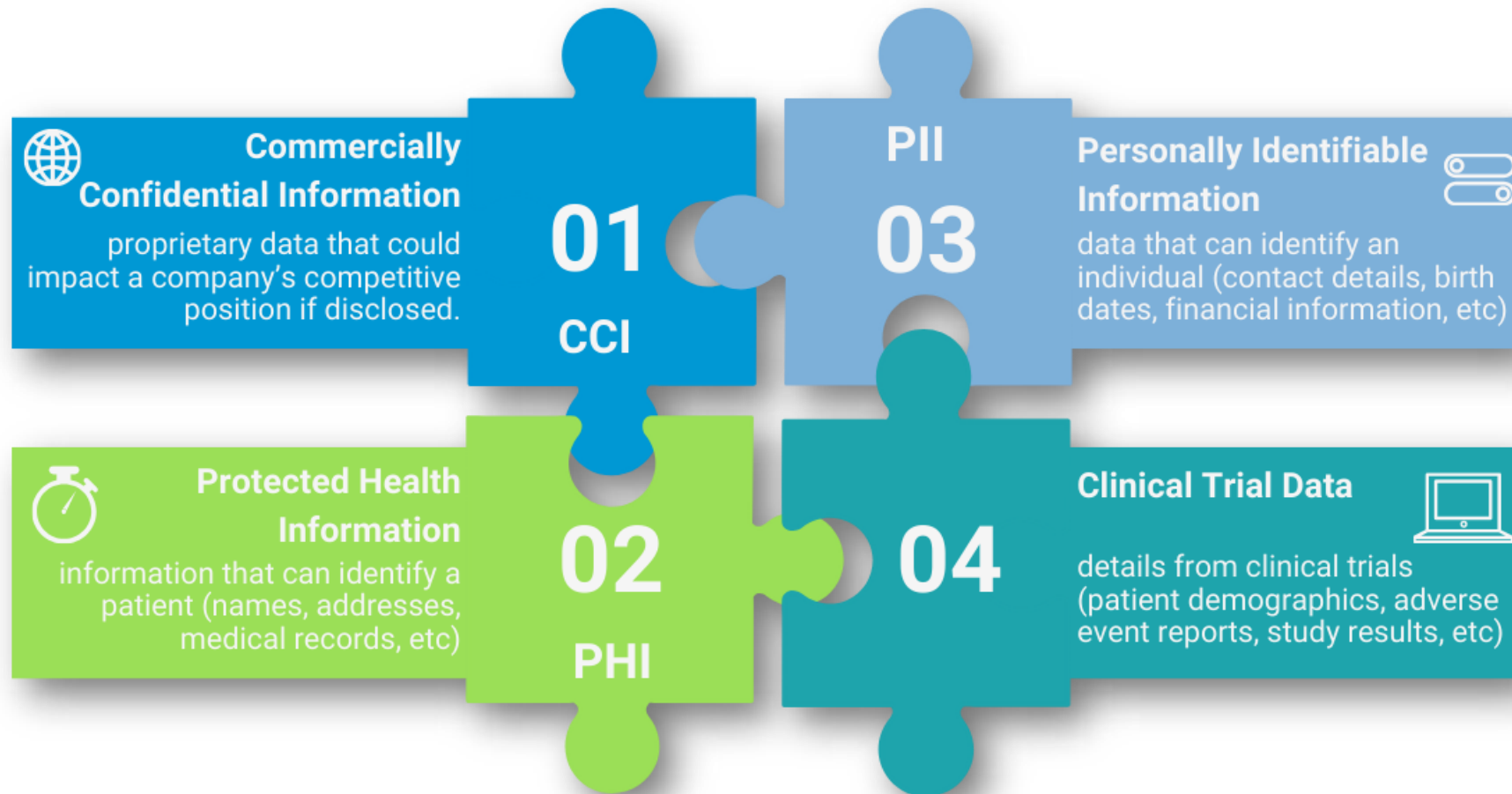
- “AI Translation” transformation module
 - Intelligent translation into one or multiple languages simultaneously
 - Automatically detects input language
 - Include as part of any automated content workflow
 - Leverage multiple GPT models (3.5, 4.0, 4.0-mini)
 - Exclude glossaries, headers, footers, pages, tables



AI-Powered Redaction

Automated AI content redaction

- Many types of content need to be redacted to protect sensitive information and comply with industry regulations.



Automated AI redaction

- > “AI Redaction” transformation module
 - Preview or apply redactions
 - Categories of content to redact
 - AI model to use
 - Method of redaction
 - Redaction text to use
 - Sanitize document
 - Exclude glossaries, headers, footers, pages, tables

Selectable redaction type Configuration (Version: 1)

Save
Discard

Name *
 Selectable redaction type

Description
 Config for use in DSEExpress with user selectable options.

☐ Show required fields first

☐ Hide irrelevant parameters

☐ Lock Version

CONFIGURATION PARAMETERS

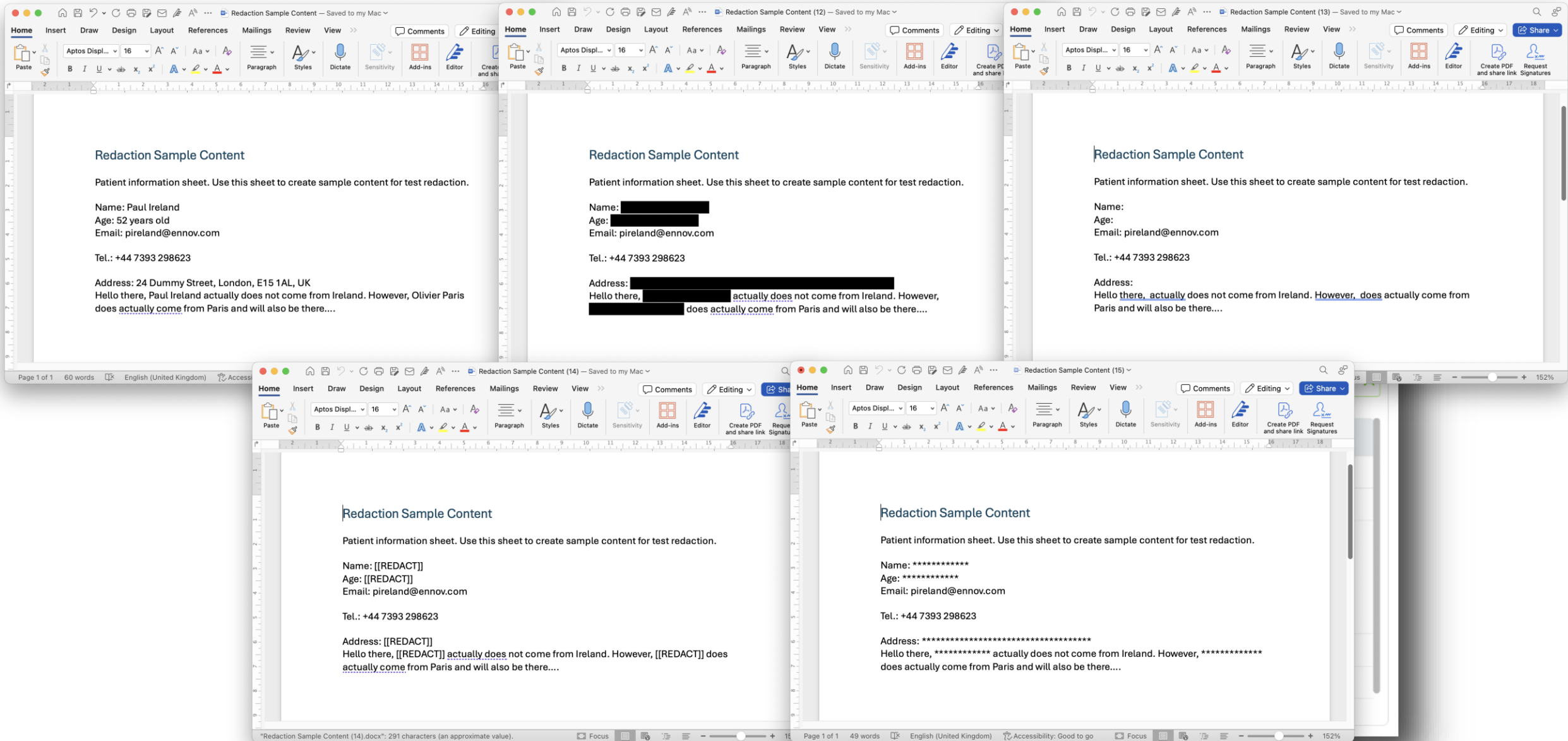
Filter param by name ✕

Groups:

Configuration
Default
Filters

Group	Name	Value
Configuration	action *	{action} ⋮
Choose the action to perform with the redaction tool.		
Configuration	categories *	{categories} ⋮
Configuration	model *	{model} ⋮
Configuration	redactionMethod	{redactionMethod} ⋮
Configuration	redactionText	
Configuration	sanitizeDocument	{sanitizeDocument} ⋮
Default	apiKey *	

Automated AI redaction results



Redaction Sample Content

Patient information sheet. Use this sheet to create sample content for test redaction.

Name: Paul Ireland
Age: 52 years old
Email: pireland@ennov.com
Tel.: +44 7393 298623
Address: 24 Dummy Street, London, E15 1AL, UK
Hello there, Paul Ireland actually does not come from Ireland. However, Olivier Paris does actually come from Paris and will also be there....

Redaction Sample Content

Patient information sheet. Use this sheet to create sample content for test redaction.

Name: [REDACTED]
Age: [REDACTED]
Email: pireland@ennov.com
Tel.: +44 7393 298623
Address: [REDACTED]
Hello there, [REDACTED] actually does not come from Ireland. However, [REDACTED] does actually come from Paris and will also be there....

Redaction Sample Content

Patient information sheet. Use this sheet to create sample content for test redaction.

Name: [REDACTED]
Age: [REDACTED]
Email: pireland@ennov.com
Tel.: +44 7393 298623
Address: [REDACTED]
Hello there, [REDACTED] actually does not come from Ireland. However, [REDACTED] does actually come from Paris and will also be there....

Redaction Sample Content

Patient information sheet. Use this sheet to create sample content for test redaction.

Name: [REDACTED]
Age: [REDACTED]
Email: pireland@ennov.com
Tel.: +44 7393 298623
Address: [REDACTED]
Hello there, [REDACTED] actually does not come from Ireland. However, [REDACTED] does actually come from Paris and will also be there....

Redaction Sample Content

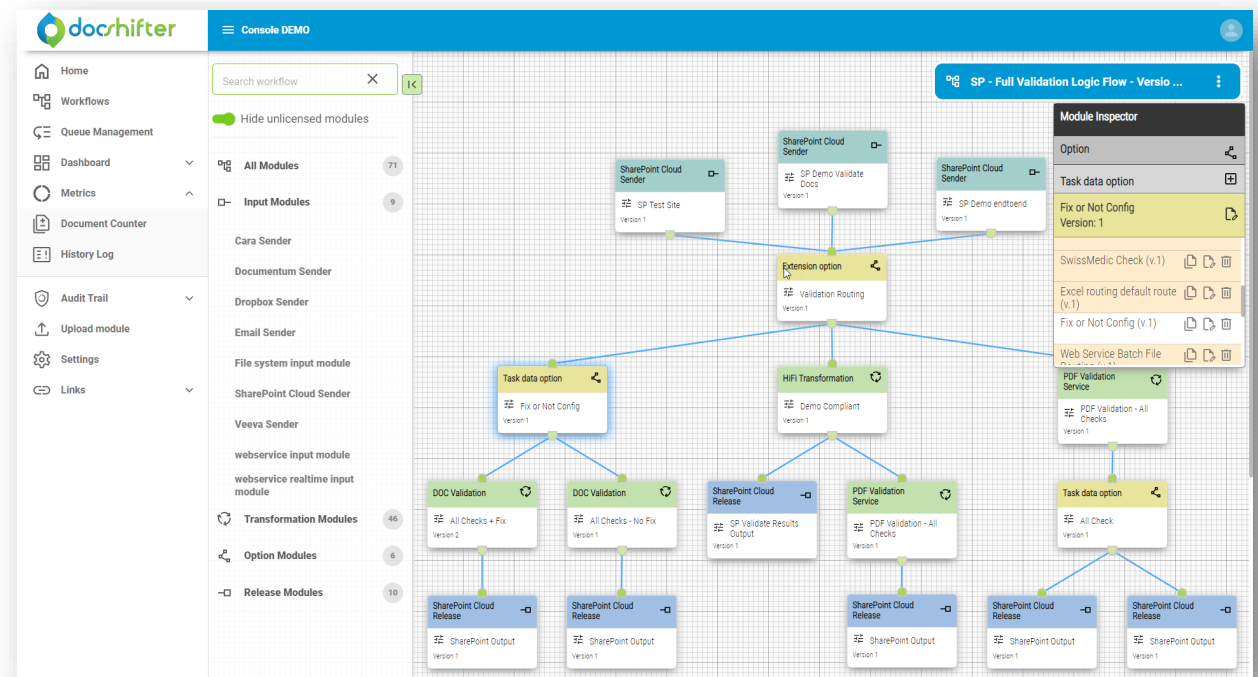
Patient information sheet. Use this sheet to create sample content for test redaction.

Name: [REDACTED]
Age: [REDACTED]
Email: pireland@ennov.com
Tel.: +44 7393 298623
Address: [REDACTED]
Hello there, [REDACTED] actually does not come from Ireland. However, [REDACTED] does actually come from Paris and will also be there....

Wrap-Up

Wrap-Up

- › Reduce manual effort in content preparation
- › Automation does not require AI
- › Automate more today
- › Reduce risk





Paul Ireland

VP Life Sciences & Product Owner

pireland@ennov.com

www.docshifter.com

THANK YOU!

