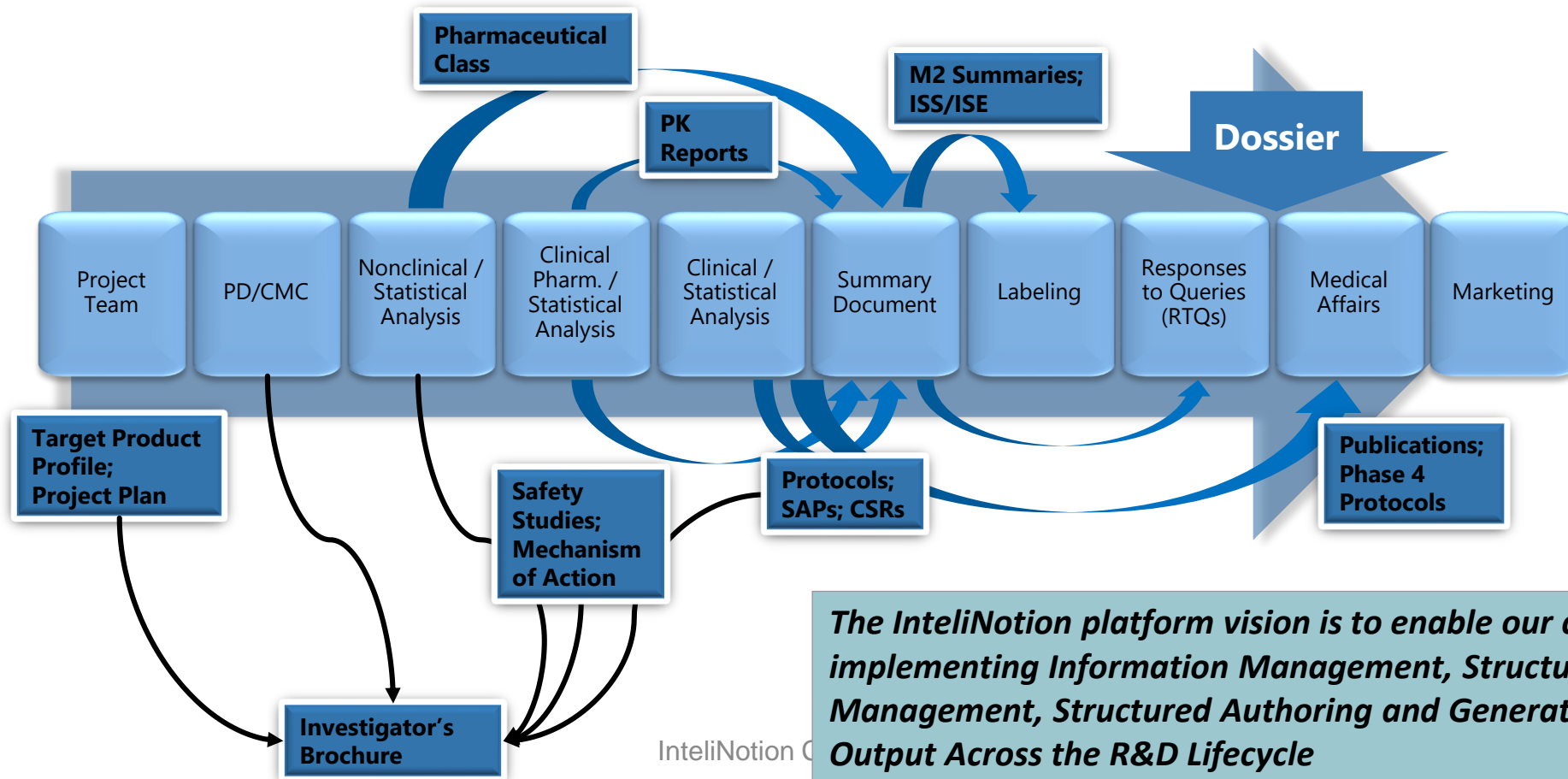# InteliNotion
Business Challenges and Value Proposition

Business Value

Information Flow Across the R&D Lifecycle

Across Lifecycle of a Drug, Content is Reused Repeatedly.

Traditional document-centric processes limit content reuse and traceability, result in authoring and review inefficiencies, add QC burden, and increase risk of introducing content errors.

Pharmaceutical Class

PK Reports

M2 Summaries; ISS/ISE

Dossier

| Project Team | PD/CMC | Nonclinical / Statistical Analysis | Clinical Pharm. / Statistical Analysis | Clinical / Statistical Analysis | Summary Document | Labeling | Responses to Queries (RTQs) | Medical Affairs | Marketing |

Target Product Profile; Project Plan

Safety Studies; Mechanism of Action

Protocols; SAPs; CSRs

Publications; Phase 4 Protocols

Investigator's Brochure

The InteliNotion platform vision is to enable our clients in implementing Information Management, Structured Content Management, Structured Authoring and Generate Required Output Across the R&D Lifecycle

InteliNotion C...

Business Opportunity

- Organizations create many unstructured documents throughout the product development lifecycle to gain approval of our products and get to market.

- An approach to improve quality and consistency of information represented and shared within these documents throughout the product development period is critical *to accelerate approval and time to market.*

  - Structuring the information within documents into meaningful components and reusing information within and across documents with full traceability provides a mechanism to streamline and substantially improve our efficiencies.

  - Structuring, tracking and tracing a collection of related documents (Dossier) submitted for product approval

  - Organizations have an opportunity to improve by implementing a Structured Content Management and Authoring capability across the organization for regulated or any business content management.

Why is this useful?

Quality:

- Create content once and reuse – improved consistency
- Controlled content editing – lock content that should not be edited
- Govern and use standardized content

Efficiencies:

- Document generation – auto-populate relevant content and variables/ data into the document when creating
- Reuse – content while authoring with traceability
- Notify author of content changes while opening document when content within document has been reused
- Minimize copy/ paste, rewriting, editing of approved content
- Avoid review and QC of preapproved content

Generate output from single Information Model

- Documents, PDF
- XML
- Generate variants from core document, applying localized reuse rules
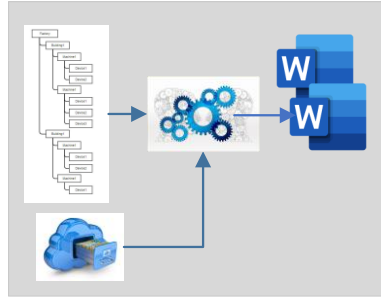
Improve Change Management

- Understand and manage impacts of content change effectively with visibility to everywhere content is reused
- Have complete visibility to the variants of the content that have been created and where it is used
- Authors notified of change to reused content to allow them to compare differences and take action

InteliNotion Document Production Process

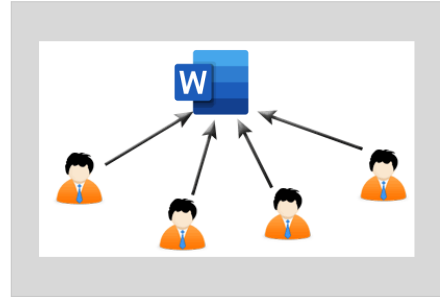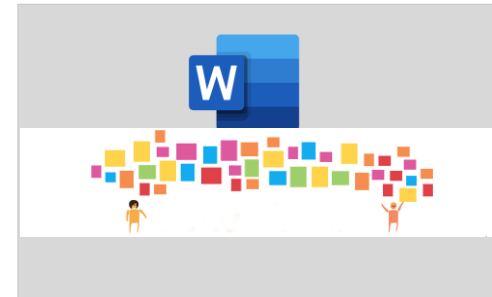| Document Generation	Document Authoring	Document Review	Document Output

Features

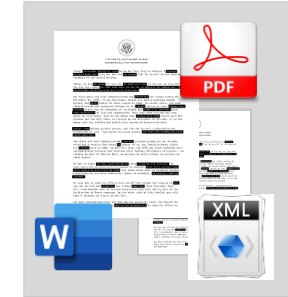|			
✓ Auto-generate ✓ Reuse ✓ Auto-populate	✓ Structured Content Authoring ✓ Co-authoring ✓ Versioning – document & components	✓ Collaborative Review ✓ Review in native MS Word or Browser	✓ Output PDF, Word, XML, Excel ✓ Redaction ✓ Anonymization

Benefits

✓ Auto-inserted content ✓ Auto-inserted metadata ✓ Rules-based reuse from Libraries & upstream documents ✓ Full Traceability	✓ Full structured authoring & co-authoring features ✓ Native MS Word User Experience	✓ Parallel Review ✓ Respond to Comments ✓ Offline Review ✓ Track Changes ✓ Original text visibility	✓ Original text maintained for Redacted text ✓ Policy 70 Compliant

Single Platform, Reduced Costs, Easier Implementation

Let us show you..

InteliNotion

How can we help?