

Implementing Vault Submissions and Re-engineering Our Content Planning

Benoit Poupin and Richard Knowles
October 21, 2014

Benoit Poupin

Ipsen Innovation

Director IT Regulatory & CMO

benoit.poupin@ipsen.com

Richard Knowles

Ipsen Biopharm Limited

Manager Global Dossier Management

richard.knowles@ipsen.com

Veeva R&D Summit
21-22 October 2014



Ipsen Group

Global specialty-driven pharmaceutical company with total sales exceeding €1.2 billion in 2013.

Its development strategy is supported by 3 franchises: Neurology, Endocrinology and Uro-oncology

Also present in primary care in the symptomatic treatment of certain forms of cognitive disorders in the elderly as well as in gastroenterology and rheumatology.

Ipsen's R&D is focused on its innovative and differentiated technological platforms, peptides and toxins.

The Group has close to 4,900 employees and operates in 115 countries

For more information on Ipsen, visit www.ipсен.com

Agenda

- **Choosing Vault Submissions**
- **Implementation Approach**
- **Content Planning and Publishing**
- **What's Next?**

Choosing Vault Submissions

Ipsen's Strategic vision

Standardise on a
single, cloud-based
platform across the
entire Enterprise
R&D, Quality, Commercial

Align with business
strategy to in/out-license
products, capabilities and
work more effectively with
strategic Partners

Choosing Vault Submissions

Benefits from selection

- Meets all functional requirements
- Intuitive and easy for users to learn
- Reduced / simplified training plan for on-boarding
- Supports Ipsen's plans for rapid growth
- Enhances capabilities for collaboration both internally and externally
- Part of integrated suite of applications supporting all of R&D
- Software stays current, won't get stuck on seven-year old version

Implementation Approach

Process Harmonisation

'OPERA'

Conducted prior to implementation
Looked at business processes across regions and partners
Assessed what should be done internally vs. by a partner

Processes are not system driven, workflows can be easily updated or modified

Process best practice supported within the systems
Can leverage on process streamlining

Implementing access profiles

... Finding the **right Compromise** between **Confidentiality** and **Open Collaboration**

Moved from in-house to an open collaborative system

Decide on appropriate level of access for CROs and other partners

Flexibility allows for a hybrid model

Advice – Trust Your Users*

*As far as possible...

Implementing Doc types, subtypes and classifications

Key decisions and considerations

Accessibility

No folder structure

Attributes

Mandatory and comprehensive

Continuity

Migration

Integration of publishing solution

Legacy Migration

... the critical path

Strategy

What's IN or OUT of scope
Cleaning Before or After

Cleaning
Mappings &
Picklist Values

Working in
regulated
environment

GxP requires system
maintained in a
validated state
4 month SaaS
release model

Streamline the
Validation effort
by capitalizing on
**Pre-Validated
system**

Implementation Approach

Change Management

Out of the Box!

Not quite...

Cannot build Rome in a day
Introducing new technology
is a big step in itself

Intuitive

but...

New way of working quite
different to Documentum

Submission Content Planning and Publishing

Prior to Vault

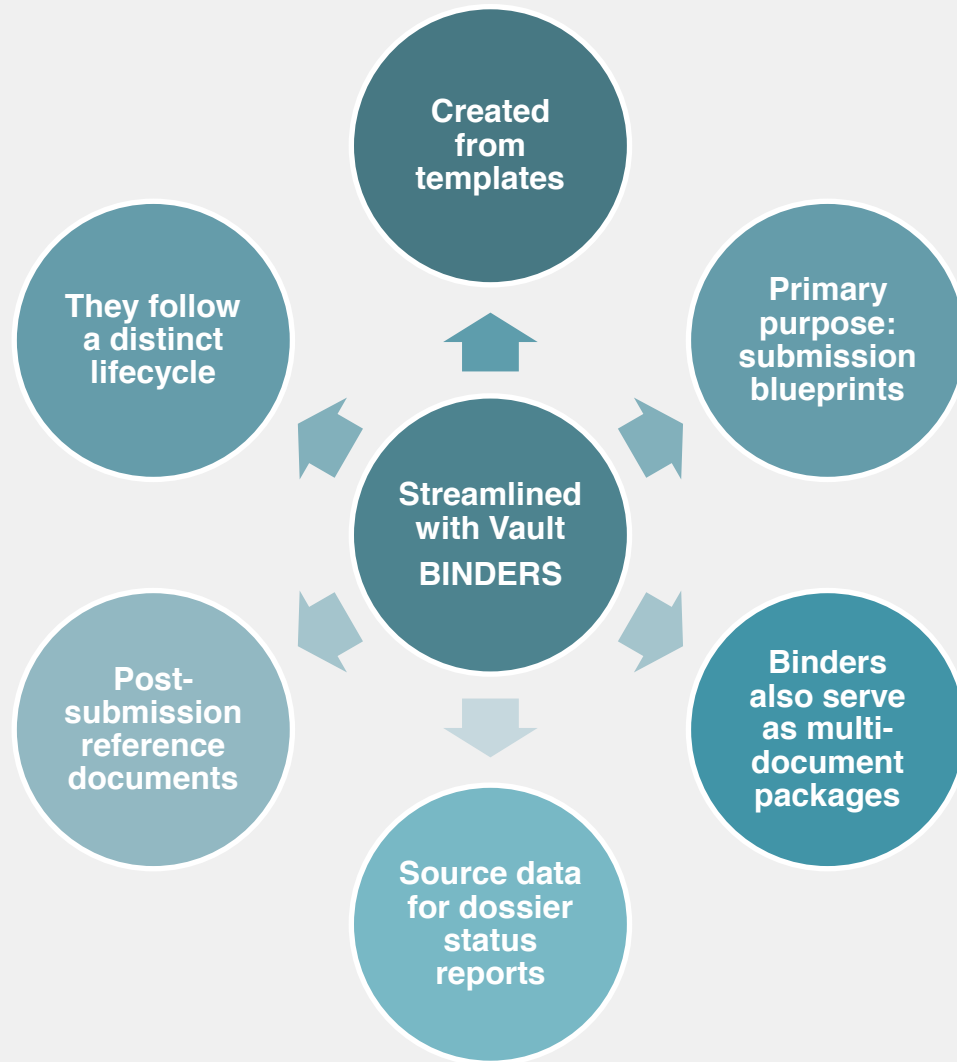
Detailed content plans were maintained in Excel spreadsheets

Efforts to track progress were disjointed

Source document versions were scattered

No consistency of authoring

Submission Content Planning and Publishing



Created From Templates

VAULT Submissions

HOME LIBRARY REPORTS DASHBOARDS [+ Create](#) [Upload](#)

Create Binder (Step 1 of 2)

Choose binder type

Type*:

Subtype*:

Classification*:

- Asean
- CIS Submission TEMPLATE
- CTA
- Full Submission
- IMPD
- IND
- Module 1
- Module 2
- Module 3, 4, or 5
- Other
- PIP

VAULT Submissions

HOME LIBRARY REPORTS DASHBOARDS [+ Create](#) [Upload](#)

Create Binder (Step 1 of 2)

Choose binder type

Type*:

Subtype*:

Classification*:

Choose binder template

- None
- EU CTD (Modules 1 - 5)
- EU CTD (Modules 1 - 5) - Planned
- Substantial Amendment-MHRA
- US CTD (Modules 1 - 5)


Currently around 20 binder templates

Can serve as multi-document packages

- ▼ Synopsis
 - xxxxxxxxxx-synopsis (Planned, v0.1)
- ▼ Report Body
 - xxxxxxxxxx-csr-report-body (Planned, v0.1)
- ▼ Demography and Baseline Characteristics
 - xxxxxxxxxx-csr-report-body-demogtabfiggraph (Planned, v0.1)
- ▼ Efficacy Data
 - xxxxxxxxxx-csr-report-body-effecttabfiggraph (Planned, v0.1)
- ▼ Safety Data
 - xxxxxxxxxx-csr-report-body-safetabfiggraph (Planned, v0.1)
- ▼ Narratives of Deaths, Other Serious and Certain other Significant Advers...
 - xxxxxxxxxx-csr-report-body-narratives (Planned, v0.1)
- ▼ Protocol and Protocol Amendments
 - xxxxxxxxxx-protocol (Planned, v0.1)
 - xxxxxxxxxx-protocol-amendment (Planned, v0.1)
- ▼ Sample Case Report Form
 - xxxxxxxxxx-sample-crf (Planned, v0.1)
 - xxxxxxxxxx-sample-crf-subjectdiary (Planned, v0.1)
- ▼ List of IECs or IRBs
 - xxxxxxxxxx-iec-irb-listofinstitutions (Planned, v0.1)
 - xxxxxxxxxx-iec-irb-consentform (Planned, v0.1)
- ▼ List of Investigators
 - xxxxxxxxxx-investigator-list (Planned, v0.1)
 - xxxxxxxxxx-investigator-cv (Planned, v0.1)
- ▼ Signatures of Principal or Coordinating Investigators
 - xxxxxxxxxx-signatures-investigators (Planned, v0.1)
- ▼ Listing of Subjects Receiving Test Drugs from Different Batches
 - xxxxxxxxxx-list-subjects-batches (Planned, v0.1)
- ▼ Randomisation Scheme and Codes
 - xxxxxxxxxx-randomisation-scheme (Planned, v0.1)

- Binder sections pre-filled with RFS document templates
- Content authored from within binder
- Completed binder added to relevant section of submission binder
- Contributing department owners are responsible for their section(s) of binders

Source data for dossier status reports


Binder Status 

Report Type Document

▼ Filters (optional)

Dossier ID Number equals 10318

Clinical Study Number equals Registry study EU and US

Edit Column to Display 

Search:

Available Columns

- Additional description
- additional viewer
- Agency Name
- Applicant Name
- Application Number
- Application Type
- Author
- Author / Word Reviewer
- Batch Number
- BIRD Number
- blinded document manager
- Blinded Document Managers
- Business Unit
- Classification
- Clinical Study Number
- CMS
- Company Brand Name
- Consumer
- Container Closure
- Controlled Document Number
- Coordinator
- coordinator (start workflow)
- Country
- Created Date
- CRO

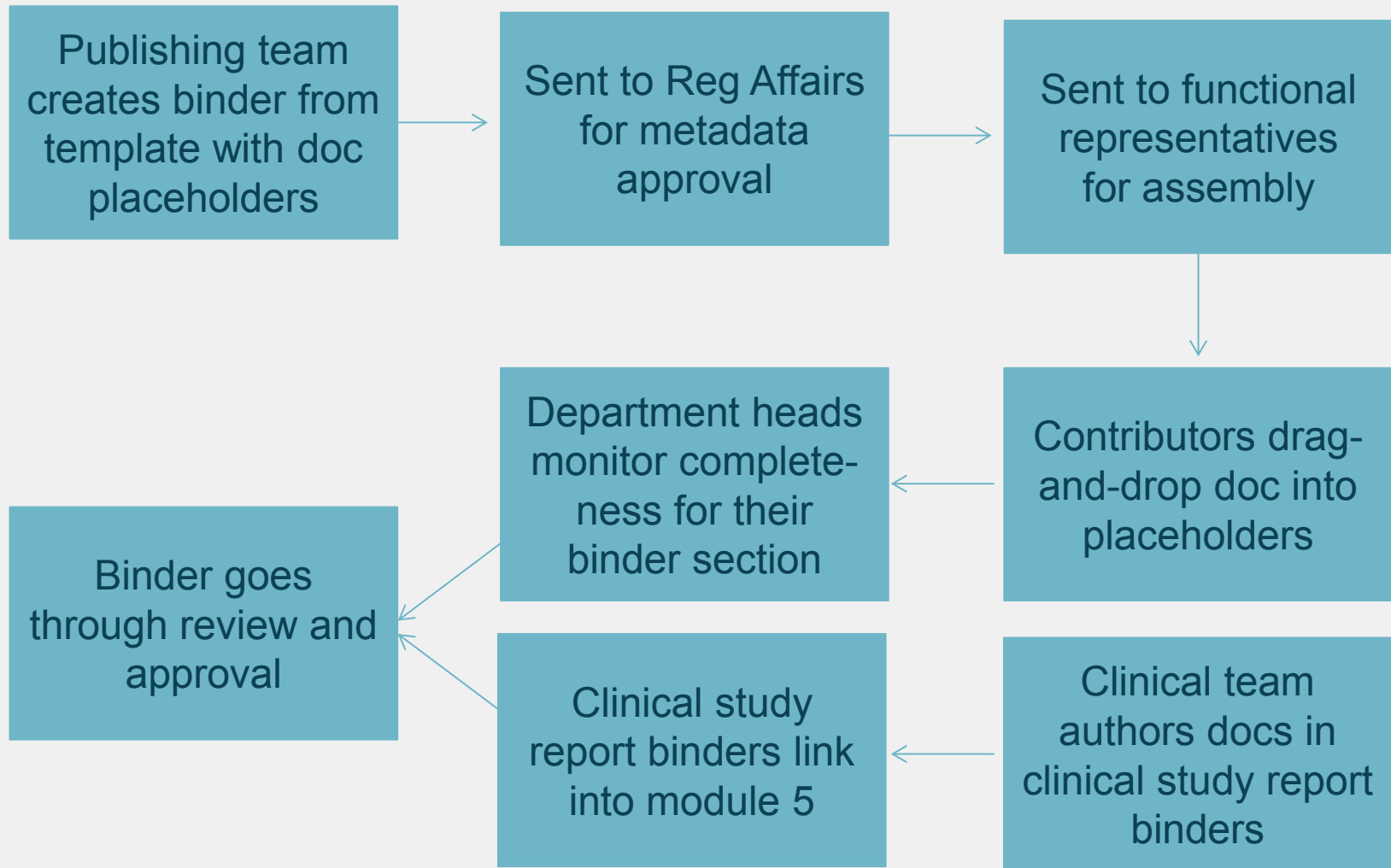
Displayed Columns [Restore](#)

- Document Name
- Document Number
- Created By
- Document Status
- Days In Review
- Reviewer
- Days in Approval
- Approver
- Approved Date
- Expected RFS Date
- Submission Date

OK Cancel

- Centralised authoring promotes better control and visibility into the status of content
- Dashboards and reports enable routine status reporting

Basic binder process



Integration with EXTEDO's eCTDManager

- Primarily utilise navigation to and through binders to pull Vault content and metadata into eCTDManager but single document drag and drop is also possible

The screenshot displays two windows from the eCTDManager interface. The 'Project-Explorer' window on the left shows a hierarchical tree of folders representing different countries and submission types, such as 'DYSPORT', 'Austria', 'Belgium', 'Bulgaria', 'Cyprus', 'Czech Republic', 'Denmark', 'Estonia', 'European Union', 'Finland', 'France', 'Germany', 'Greece', 'Hungary', 'Ireland', and 'Italy'. Under 'Greece', there are sub-folders for 'DYSLINE 300 Units', 'DYSLINE 300 Units EL', '0000 : 10218 - Change to the assay used in the determination of protein cor', '0001 : 10205 RTQ Dysline MAA', and 'DYSPORT 300 Units and 500 Units EL'. The 'Submission-Explorer' window below it shows a 'Country Filter' set to 'All Countries' and a list of submission folders, including '0000: EU-envelope', '0000: Module 1 EU', and various numbered folders (1.0 to 1.10) for '0000: Responses to Questions'. A specific folder '0000: Greece' is highlighted, with a sub-folder '0001: Response to Questions 300U MAA' visible below it.

The 'Open Document from DMSDriver ...' dialog box is open in the foreground, showing the 'Current path' as `https://ipsen-idocs.veevavault.com/api/v8.0/metadata/objects/documents/types/submission_c/subtypes/submission_structure_c/classifications/full_submission_c/binder/167905/section/1412148191027/section/1412148191133`. The dialog contains a table with the following data:

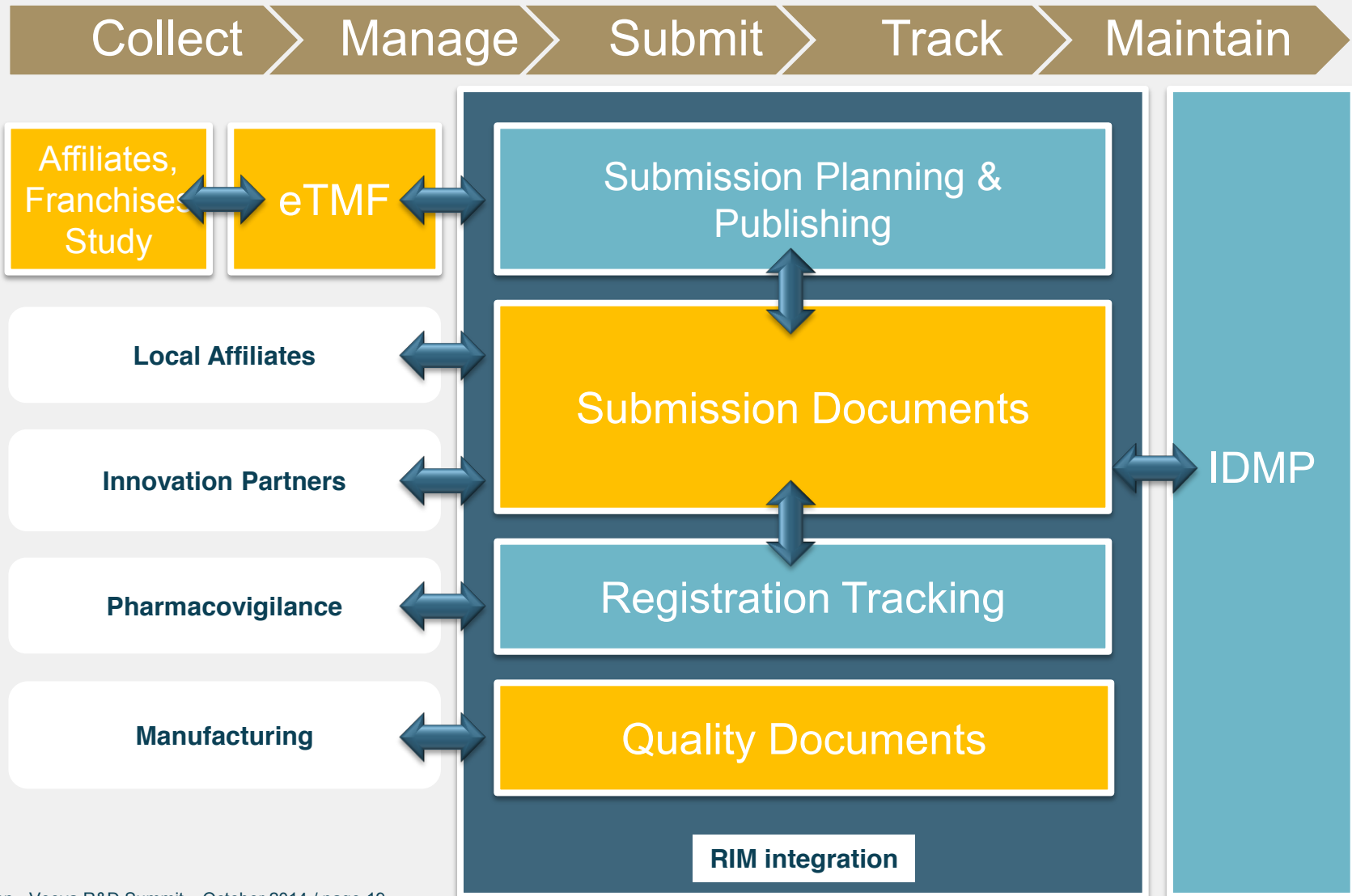
Objects	Document Version	Last Modified Date	File Size	Format	Version
Dysline RtQ Oct 2014 Greece 300U	1.0	03/10/2014 14:16:51	2144 KB	doc	1.0
Dysline RtQ Oct 2014 Greece 300U	0.1	03/10/2014 09:56:39	2144 KB	doc	0.1

The dialog also has checkboxes for 'Show Versions' (checked) and 'Show document assignment' (unchecked), and buttons for 'OK', 'Cancel', and 'Help'.

Production Experience to Date

- ✓ **Very positive end-user experience / feedback**
 - *“From the 1st most unpopular Regulatory System to one of the most popular so far”*
 - *“This new tool is much most appropriate for our work. It meets expectations, is more user friendly, easier than BIRD*!”*
- ✓ **Improved compliance with system usage**
- ✓ **Supportive of Ipsen’s recent process optimization and harmonization efforts – appropriate and answers to our needs**
- ✓ **Simplified submission planning and tracking**
- ✓ **Change management, Training effort reduced by half**
- ✓ **Trend to confirm: reduced overall IT support burden**

What's Next?



Thank you

Questions?

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Richard Knowles

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