

AMPLEXOR
LIFE SCIENCES

2023
Be The Expert

EMPOWERING EFFICIENCY



BE THE EXPERT

Gary Wilson

SPORIFY, an ArisGlobal company

ArisGlobal completes acquisition of SPORIFY



Accelerating Data Governance and IDMP Compliance

Presented by: Gary Wilson

Presentation Agenda

01

SPORIFY's origin story

Why our design resonated and next steps with ArisGlobal

02

The data governance problem

A persistent challenge for life sciences and how we can fix it together

03

Accelerating and maintaining IDMP compliance

Regulatory update and how SPORIFY can add value to your organization

01

SPORIFY's Origin Story



An elegant solution to a complex problem

- Regulators and industry shared the challenge of EMA IDMP/SPOR implementation
- Stakeholders already had systems in place and were hesitant to change
- Mechanism in the middle to act as a broker and translate data



Who's using SPORIFY today?



Regulators



Industry



EU Project
Teams



Vendor
Integrations



Consultancies

Providing key capabilities to a wider market

- ✓ Creating system interoperability for life sciences
- ✓ Facilitating the transfer of structured data submissions
- ✓ Growing use of IDMP and product data standards globally



02

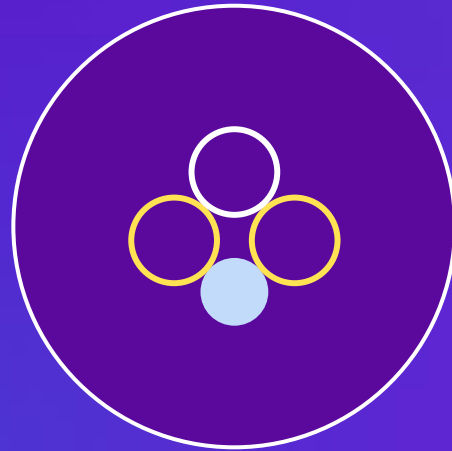
Solving the Data Governance Problem



The persistent data governance problem



**Organizational
Culture**



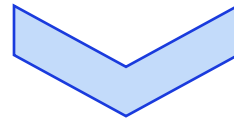
**Process
and Ownership**



**Systems and
Sustainability**

Why does data governance matter?

Good data governance creates high-quality, reliable data



High-quality data creates confidence for:



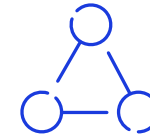
Ingestion



Harmonization



Accessibility



Interconnectivity



Enables Strategic Decision Making

80%

Data preparation
and initial mapping
Efficiency Gains



Top 5 multinational pharma



Challenge: Mapping internal
Referentials, Organisations &
Substances to RMS, OMS & SMS



User friendly, quick to implement

“I consider  **SPORIFY** my
fourth colleague”

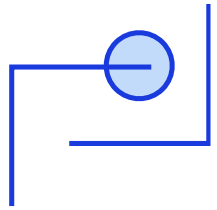
Master Data Manager
Bayer AG

03

Accelerating and Maintaining IDMP Compliance

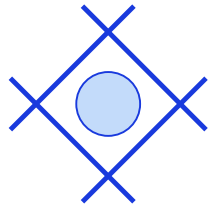


Solution Overview



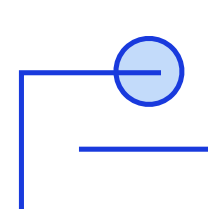
Mapping

A single solution that enables mapping between your systems and SPOR master data



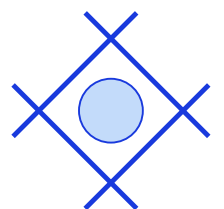
Integration

Link mapped data to your source systems



Syncing

Data sync to latest EMA SPOR changes and instant access to live information



Notification

Delivers real-time notifications as SPOR updates are available

Data Review & Approval

The screenshot displays the SPORIFY application interface. A modal window titled "Stage: Reviewed" is open, showing the review and approval process for a "Capsule" term (ID: 2000000000004). The workflow consists of three stages: Pending Review, Reviewed, and Approved. The "Reviewed" stage is currently active, showing a "Passed" status by Isabel (Data Steward). The "Approved" stage is also shown, indicating the term is "Accepted (Passed)" by Tom (Data Owner). The "Approval Options" section shows a dropdown menu with "Accept (Publish: No)" selected and a "Save" button.

SPORIFY << 23 CorriT\Admingw

← dose form Pharmaceutical Dose

Search keyword

67% Matched <1% Multiple Choice

Actions Source Term

Actions	Source Term	Target Tags
⋮	Cachet Unique ID: 37	
⋮	Capsule Unique ID: 325	
⋮	Capsule, hard Unique ID: 14	Capsule, hard Term id: 100000073375 (CURRENT)

Stage: Reviewed [Close]

Capsule | ID: 2000000000004

Pending Review | **Reviewed** | **Approved**

Review
SPORIFY
(EMA Data Updated)
09-Jun-2023 13:40:21

Passed
Isabel
(Data Steward)

Accepted (Passed)
Tom
(Data Owner)

Approval Options: Accept (Publish: No) [Save]



- Dashboard
- Substances >
- Organisations >
- Referentials >
- Source Lists
- SPOR >
- Health Canada >
- FDA >
- Administration >
- User Guides >
- Policies >

Referentials Source Lists

Manage Referentials Source Lists

Q Search keyword

✔ 38% Matched
💡 25% Suggested
⚙️ 36% Not Set



Actions	Source List	Target List	System	Progress	Created By
⋮	Units - RIM		LSRIM	<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
	SPOR: Referentials	Units of Measurement		<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
⋮	Units - Safety		LSMV	<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
	SPOR: Referentials	Units of Measurement		<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
	FDA: PQCMC	PQ/CMC Units of Measure Terminology		<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
⋮	Units- Clinical		CTMS	<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
	SPOR: Referentials	Units of Measurement		<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw
	FDA: PQCMC	PQ/CMC Units of Measure Terminology		<div style="width: 38%; background-color: green;"></div> <div style="width: 25%; background-color: orange;"></div> <div style="width: 36%; background-color: grey;"></div>	Admingw

EU Regulatory Update



- SPOR and IDMP implementation updates
- SPOR KUG to establish parallel work streams for RMS, OMS and SMS topics.
- Global approach to IDMP with FDA implementation guide published earlier this year

Meeting you wherever you are on the journey

Minimal data points to get started



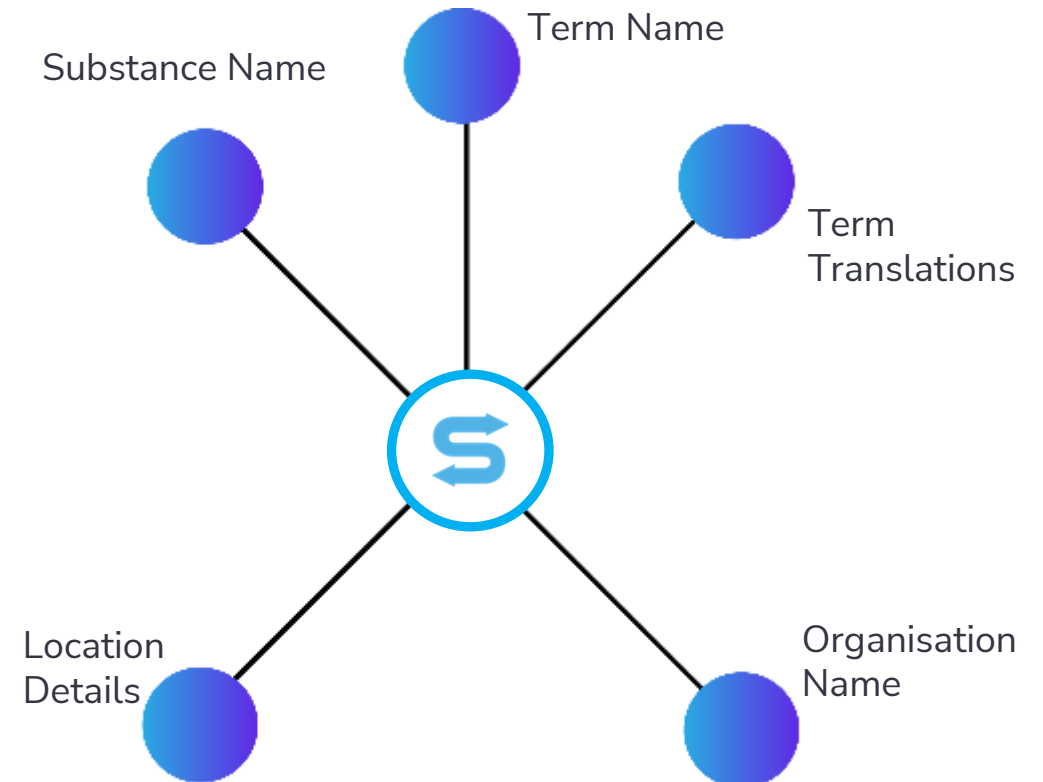
Excel spreadsheets to full RIM system implementations



1 product to a large portfolio of globally marketed products



Any size organization – 2 people to review and approve data up to a team of 150+



Give you back the entire associated SPOR data model



Be The Expert

2023

THANK YOU!