Oracle IDMP Enterprise Foundation Suite

The fastest and most efficient way to create a cross-functional product domain and achieve IDMP compliance as a byproduct

Soon to be mandated by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) as a product safety and anti-counterfeiting initiative, the Identification of Medicinal Products (IDMP) standards call for a new level of transparency from life sciences companies, requiring them to clearly describe the relationship between product attributes across Regulatory Affairs, Pharmacovigilance, R&D, and CMC. IDMP is not just another extension of the EudraVigilance Medicinal Product Dictionary (EVMPD), nor is it a replacement of the existing regulatory submission process.
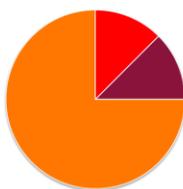
Why Should IDMP Become a Management Priority?

Oracle has been conducting an online IDMP survey since May 2015 and more than 50 life sciences companies have responded globally. The most important finding of this survey is the management awareness gap. While the vast majority of survey participants agree that IDMP means a major shift in regulatory requirements which requires new ways of working, management does not always fully understand its business impact on the organization.

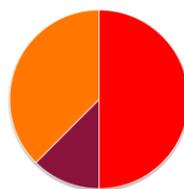### A Call for New Ways of Working...

From a business perspective, would you say that IDMP?

- Is a regulatory requirement which needs to be met to stay compliant
- Is a compelling reason to change ways of working in pharma
- Both of the above

Management Awareness...

In general, would you say that your management

- Does not fully understand the business impact of IDMP
- Fully understands the impact but does not commit the right level of resources
- Fully understands the impact and is investing for the long term

Source: Oracle IDMP Survey, 50+ unique responses from pharma companies – Sept 2015

Figure 1 – Oracle IDMP Survey Results: Perceived Business Impact of IDMP

Multiple delays in both the publication of technical guidelines and the implementation by health authorities have bought the industry some additional time to become compliant. But how much longer can life sciences companies afford to ignore IDMP?
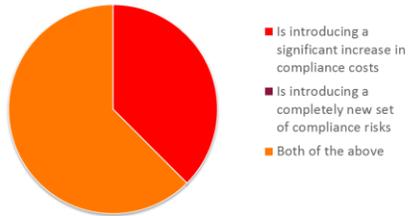

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Oracle IDMP Enterprise Foundation Suite is a comprehensive, best-of-breed IDMP compliance solution that helps life sciences companies to break down the barriers between siloed business units.

- **Oracle Product Lifecycle Management** manages relationships between the various department-specific views of a product defining an IDMP record.
- **Oracle Thesaurus Management System** manages terminologies and dictionaries, and enables coding of verbatim terms.
- **Oracle Argus** manages adverse event reports from intake through coding, assessment, and reporting.
- **Oracle Life Sciences Experts** help you to design the best approach and integrate Oracle's solution into your landscape

Whether the solution is deployed in the cloud or on premise, Oracle's consulting organization and partners provide focused services to implement fast-track IDMP compliance projects.

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What's Hiding Behind IDMP Compliance?

IDMP compliance should not be seen as an isolated milestone, but rather as a reflection of the need to create and maintain meaningful and reliable relationships between different views of the same product at the enterprise level. These views are discipline-specific: R&D, Regulatory, CMC, and Safety.

Additional Costs & Risks...

From a compliance perspective, would you say that IDMP?

■ Is introducing a significant increase in compliance costs
■ Is introducing a completely new set of compliance risks
■ Both of the above

Source: Oracle IDMP Survey, 50+ unique responses from pharma companies – Sept 2015

Figure 2 – Oracle IDMP Survey Results: Costs & Risks Linked to IDMP Compliance

Among the top priorities of the survey participants, identifying and solving discrepancies in IDMP source data rank as the most important. Why is this so challenging?

In today's life sciences landscape, development and approval speed and cost have become ever more important. Especially when considering compliance costs, the nature of the IDMP requirements should be considered a game changer.

What are your major challenges?
Please rate by importance (1=most important, 10 least important)

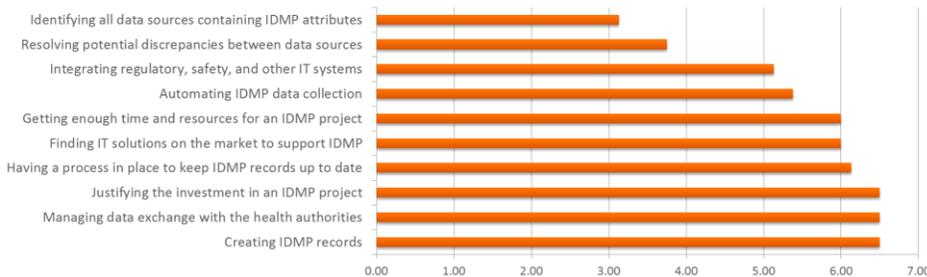| Challenge	Value
Identifying all data sources containing IDMP attributes	~3.2
Resolving potential discrepancies between data sources	~3.8
Integrating regulatory, safety, and other IT systems	~5.1
Automating IDMP data collection	~5.4
Getting enough time and resources for an IDMP project	~6.0
Finding IT solutions on the market to support IDMP	~6.0
Having a process in place to keep IDMP records up to date	~6.2
Justifying the investment in an IDMP project	~6.5
Managing data exchange with the health authorities	~6.5
Creating IDMP records	~6.5

Figure 3 – Oracle IDMP Survey Results: Top Challenges

Behind the IDMP requirements is the need to break down the silos within life sciences organizations – a challenge but also an opportunity to redesign the structure of compliance costs. This must become a business imperative in order to comply with the increasing set of regulations surrounding clinical trials and market authorization.

The time has come to rethink some of the key processes at the heart of developing and approving medicinal products. The Oracle IDMP Enterprise Foundation Suite enables life sciences organizations to achieve this goal and create a cross-functional product domain that overcomes the traditional barriers between siloed departments.
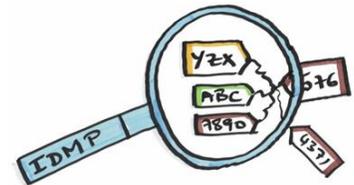
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What Makes the Oracle IDMP Solution Unique?

Oracle is the only vendor that provides a holistic end-to-end solution to IDMP implementation, in the cloud or on premise, including collation of the IDMP data from multiple sources into a central repository, management of changes to the product data including approval workflows, submission of product information, and coding and submission of adverse event reports. Unlike other solutions, the Oracle IDMP Enterprise Foundation Suite offers industry-proven, market-leading applications and integration technologies for life sciences organizations.
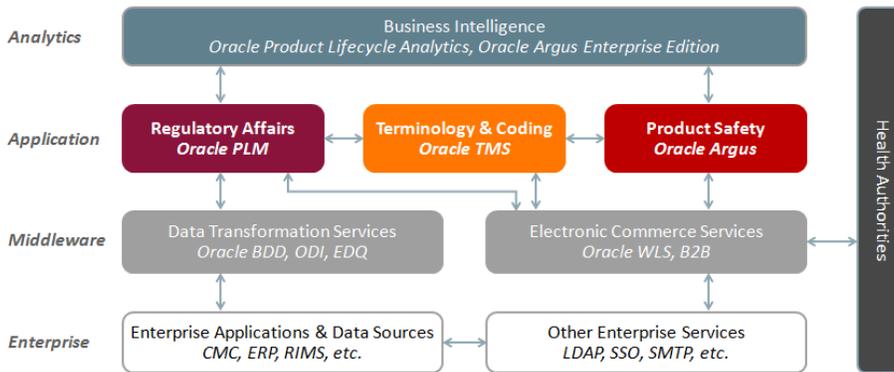
IDMP Record Dashboard

IDMP Medicinal Product

IDMP Packaged Medicinal Product

IDMP Record Change Process

Figure 4 – Oracle IDMP Enterprise Foundation Suite

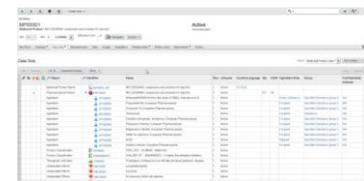At the heart of the suite, three core applications provide the essential functionality:

✓ **Oracle Product Lifecycle Management (PLM)** manages all product attributes including CMC information and regulatory records. Oracle PLM provides strong change control capabilities, as well as a ready-to-use, role-based user interface for managing product information in a compliant fashion. Oracle PLM is already in production globally at large and small pharmaceutical and medical device manufacturers since more than 10 years.

✓ **Oracle Thesaurus Management System (TMS)** manages all terminologies, dictionaries, and thesauri including WHO-DDE, MedDRA, and SNOMED CT. Oracle TMS provides dictionary linking, dictionary merging, multiaxial coding, synonym management, and custom list management capabilities. Oracle TMS is already in production globally at large and small pharmaceutical and medical device manufacturers since more than 10 years.

✓ **Oracle Argus** manages all adverse events that require regulatory reporting including clinical SAEs and spontaneous reactions. Oracle Argus provides a configurable workflow for managing AE cases including intake, coding, assessment, expedited reporting, and aggregate reporting. Oracle Argus is already in production globally at large and small pharmaceutical and medical device manufacturers since more than 10 years.

Although the primary goal is to achieve compliance with the regulations, the Oracle IDMP Enterprise Foundation Suite provides the optimal infrastructure for life sciences companies to gain additional benefits that go beyond compliance. An optional analytics layer – already integrated out of the box with the rest of the suite – provides critical insight into the aggregate data managed by the applications. The architecture is also designed to allow additional applications to consume the IDMP data, effectively ensuring unique product identification across the organization. And since all of the Oracle applications can handle multiple data models, not just IDMP, the Oracle IDMP Enterprise Foundation Suite can also be used for more than just IDMP. This means more options for life sciences companies, a greater opportunity to benefit, and a strategic solution that is future-proof.
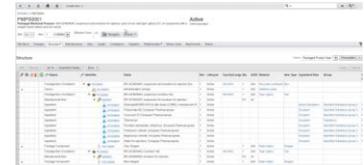
A Journey to IDMP Compliance

Some may choose not to actively engage on the journey to IDMP compliance because the guidelines are not finalized. In fact, there are still many questions about what will be required, by when and in which format. However much is known already. Oracle stays in close contact with the health authorities, standards organizations, and working groups to influence and track progress and decisions. Despite delays, details will be finalized soon and companies that procrastinate will struggle to meet the deadline. The time to begin the journey is now.
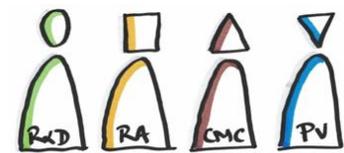

Business Landscape

Figure 5 – A Journey to IDMP Compliance

Cross-Functional Teams

Need for Transparency

How do you get there and who should you partner with? Details will surely change as you navigate towards IDMP compliance, but in general the journey can be viewed from two different perspectives:

- **Change Management:** What should be implemented from a business process perspective, and what should be changed? This is an opportunity to redesign the interactions between departments to be more efficient.
- **IT Solution:** Oracle IDMP Enterprise Foundation Suite provides important advantages over a custom MDM solution or an IDMP-specific application. It's the only solution that offers a true end-to-end approach to IDMP and enables benefits beyond compliance.

Contact Oracle today at iso_idmp_ww_grp@oracle.com and find out how we can help you to quickly and efficiently reach the goal of IDMP compliance.

Industry-Proven Solutions