A STRATEGIC APPROACH TO IDMP

PAREXEL's Global Network Offers

- A Proven Strategic Partner, Driven by Innovation
- 625 Regulatory Professionals
- An Integrated Approach to Deliver an End-to-End IDMP Solution
- Delivery of Consulting and Technology Services that Increase Productivity and Reduce Costs
- Breadth of Expertise Across Regulatory, Pharmacovigilence, Clinical, Manufacturing, & Change Management
- A Single Shared Technology Platform
- Cost Effectiveness, Technology-Enabled & Metrics-Driven Solutions

With EMA submission deadlines looming for IDMP (Identification of Medicinal Products), companies are taking a proactive approach to implement the regulations. The goal of the IDMP initiative is to improve patient safety signal detection by creating shared standards and codes. This will facilitate unambiguous identification of both registered and investigational medicinal products.

To date, companies have found that the required data is not all readily available and will, therefore, need to be mined or developed, codified, formatted, stored and updated. Internal processes will also need to be assessed and enhanced to ensure the data remains of high quality for the lifetime of the product. Although the IDMP requirement starts in Europe, the FDA as well as other global regulatory agencies are not far behind in their plans to accept and require IDMP data.

PAREXEL's operational expertise, global and local regulatory intelligence and enabling technology, provide a scalable and flexible model for clients to reduce IDMP-related complexities, workloads and budgets.

OVERCOMING THE CHALLENGES INHERENT IN MEETING IDMP REQUIREMENTS

- **Successful preparation for compliance** with IDMP requires strategic, long-term thinking, a solid approach to governance and change management, and a creative, comprehensive solution.
- **Advanced and thoughtful planning** will enable companies to quickly adapt to complying with the EMA iterative approach, as well as to future regulations globally.
- **A centralized database** using the five ISO standards as a base, and a process for continually updating and maintaining high quality data, thus providing businesses with a valuable asset beyond IDMP compliance.

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BENEFITS OF AN END-TO-END INTEGRATED SOLUTION

PAREXEL's team of regulatory professionals provides practical, best practice-based expertise and regulatory consulting which enables clients to implement a comprehensive long term IDMP solution. Our methodology includes planning for the targeted EMA iterations which, when combined with the proper data and process governance, will ensure a high level of quality for your IDMP program.

Additionally, our technology assets can facilitate critical IDMP requirements by:

- Generating IDMP messages through automated event triggers
- Processing the returned acknowledgements and providing intuitive actionable reporting of the results
- Providing a seamless user interface between LIQUENT InSight® for Registrations and LIQUENT InSight® for IDMP, enabling users to perform the right tasks at the right time
- Providing an agile solution that can be quickly updated to meet agency changes and new submission requirements
- Providing extensive integration capabilities, enabling Sponsors to leverage multiple datasets from a single source

With more than 30 years of experience in research, development and regulatory approval of medicinal products, PAREXEL can offer a robust and scalable model to support IDMP submissions for health authorities globally.

MORE INFORMATION

To discuss your company's readiness for IDMP compliance, please contact one of our regional business development representatives.

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Five Phases of Achieving Global Data Harmonization

1. **Analyze**
   - Project Initiation
   - As-is Process Assessment
   - Data Pilot
   - Readiness-Assessment
2. **Plan**
   - Gap Resolution Approach
   - Iteration Alignment
   - Governance & Change Management Framework
3. **Execute**
   - Process Enhancement Roll-out
   - Integration Development
   - Collection Processes
4. **Deploy**
   - InSight for IDMP
   - Agency Submissions
   - Acknowledgement Processing
   - Realignment
5. **Monitor and Maintain**
   - Maintain Submissions/ Acknowledgements
   - Monitor for Quality
   - Monitor for Agency Updates

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