BLOG

Key Strategies for Successful Clinical Trial Submissions:

Navigating Regulatory Procedures with EMA's OMS

Across the globe, health authorities are embracing a digital trend that prioritizes centralizing, standardizing, and integrating regulatory data and submissions. These collective efforts seek to simplify and optimize the regulatory process and foster increased cooperation between organizations. Digital transformation in regulatory practices is not just technical—it's a cultural shift towards transparency and cooperation in global health. But the more we centralize and streamline healthcare data, the less room there is for errors. Precision is more than a goal; it's a requirement.

Tigermed, a leading international clinical research organization (CRO), has a proven track record of guiding pharmaceutical sponsors through the complexities of the EU regulatory landscape. Our expertise extends to seamlessly integrating new regulatory systems/platforms and navigating evolving compliance guidelines. With our comprehensive support, sponsors gain a clear understanding of intricate regulatory workflows, sidestepping common pitfalls that could derail project timelines. By leveraging Tigermed's full-service approach, sponsors can confidently advance their EU projects while staying on schedule and fully compliant.

Learn more about how Tigermed can help sponsors successfully navigate the European Medicines Agency (EMA) Organisation Management Service (OMS) and its integration with other EU regulatory systems.

What is Organisation Management Service (OMS)?

In November 2021, the EMA began requiring OMS data for Centrally Authorised Product applications. The agency has steadily introduced OMS for electronic applications since 2017, intending to eventually mandate its use.

The requirement impacted several application components, including:

Electronic Application form procedures

Marketing Authorisation Applications, variations applications, and renewals.

Marketing Authorisation Holder transfer Applications

Procedures for Ancillary Medicinal Substances in Medical Devices

EU-Medicines Applications

Pre-Submission Requests

Eligibility, Rapporteurship or Letter of Intent, notification of change, ATMP certification, accelerated assessment, and meetings.

The OMS requirement was spurred by the EMA's ongoing effort to implement the International Organization for Standardization (ISO) mandated standards for identifying medicinal products (IDMP). ISO IDMP requires standardized definitions in identifying and describing medicinal products for human use to optimize the sharing of product information.

To apply ISO IDMP standards, the EMA created a data management system called the SPOR portal (substances, products, organisations, and referential). By centralizing and standardizing data, the EMA sought to increase regulatory efficiency and facilitate information sharing.

While ISO IDMP did not require organization data, it was recognized as essential for the SPOR portal master dataset and included marketing authorisation holders, sponsors, regulatory authorities, and manufacturers.

OMS manages the organizational data component of the SPOR portal master dataset, called The OMS Dictionary. This system provides a single source of validated organization information referenced for regulatory activities. Organizations are categorized in OMS by type (e.g., educational institution) and organizational size.

OMS Requirements for Regulatory Submissions

Sponsors must ensure that their OMS submissions align exactly with EMA guidelines, as any discrepancies or outdated information can lead to application delays or rejection. Strict adherence to the guidelines can create challenges as sponsors navigate the detailed and complex registration process. OMS requires numerous supporting documents for guideline compliance, requiring significant attention to detail.

The regulatory procedures described above require sponsors and other stakeholders to register their organization data with OMS and keep this information updated. To change existing organization data with OMS, sponsors must submit a “Change Request” before any EMA application submission.

Navigating an OMS Change Request

1

Log into the OMS portal with an EMA account.

To create a new organization or update the OMS database, the user will need an EMA account and will need to complete the appropriate SPOR user registration.

EMA accounts are unaffiliated with any organization until users select their existing organization within OMS or create a new one. Organization affiliation requires that the user obtain access through SPOR National Competent Authority or Industry user roles with EMA Account Management.

Only users with this approved access and affiliation level in OMS can request changes to published records.

2

Search for the organization in OMS.

The user can search for organizations in the OMS portal under the Organisations tab on the OMS homepage.

3

Complete and submit the change request form.

If no results appear in the search field, a new organization registration must be submitted. New organizations can be registered by clicking “Request New Organisation” in the bottom right corner.

The user will then need to populate the registration form and attach appropriate supporting documentation. Once submitted, the request status can be tracked under “View Requests” on the OMS homepage.

Existing organizations will populate the search page, and the user can click the spyglass icon on the right to go to the organization’s information page. Once there, the user can click the “Request change” button, populate the form with the reason for the change request, and attach supporting documentation.

Additional guidance is provided in the “Documents” section of the OMS portal under “E-OMS Change Request.”

Streamlining OMS Change Requests with Tigermed

Sponsors looking to break into the EU market greatly benefit from having a partner with expertise in EMA regulations and procedures, including OMS. Without this expertise, several problems can arise while setting up or changing organizational information in OMS.

Case Study: Resolving OMS Submission Errors to Prevent Delays

The Challenge

Consider a case where a Tigermed client independently initiated their OMS registration, successfully completing the EMA's general information requirements. However, they overlooked the correctness of crucial supporting information—the court registry, complete company name, and official address. This oversight led to a rejected submission during the OMS data review.

Our Solution

Our teams helped the client get back on track with OMS by rectifying supporting documentation and navigating resubmission. The client's subsequent exclusion from the system could have brought additional issues had there been ongoing clinical trial submission. Fortunately, the issue was resolved at an earlier stage.

Discover below how to shield yourself from costly regulatory missteps.

Eliminating Registration and Access Barriers to OMS

Sponsors commonly face challenges in establishing OMS user roles and setting up or maintaining their organization information in OMS.

Geographical and language barriers can arise for sponsors from non-European countries (e.g., Korea, China), such as obtaining login information and navigating OMS without localized support.

Acquisitions and mergers may also complicate the OMS process as these events necessitate strict updates and re-registrations. Any lapses in updating organizational changes and ensuring all changes are accurately reflected in the system may cause the organization to fall out of compliance with regulatory guidelines.

Our Tigermed teams can assist with registration and access to OMS by helping sponsors create and manage their legal entity profiles, set up OMS user roles, and set up login and passwords for EMA portals. This administrative support simplifies OMS setup and assists sponsors in following detailed EMA guidance.

Facilitating Supporting Documentation Submission

Providing the correct supporting documentation for an OMS Change Request is often a primary pain point for sponsors. Some documentation processes are manual (e.g., printing and signing), which can become time-consuming and error-prone. These legal documents and registries must be continuously verified to ensure compliance. New transparency rules and compliance requirements also add a layer of complexity, requiring sponsors to ensure all activities comply with the latest regulations.

Whether the documents provided are insufficient, incorrect, or obsolete, this error can result in the request being rejected and produce processing delays. Tigermed helps sponsors navigate the Change Request process to get it right the first time.

For sponsors who want to streamline the entire OMS process, Tigermed can manage the submission of OMS change requests end-to-end for maximum efficiency and time savings.

Our teams provide initial guidance and preparation, including detailed guidelines and step-by-step instructions, preliminary meetings, and documentation preparation (e.g., business registry extracts, legal entity information, etc). We also facilitate compliance and submission by ensuring all procedures follow the detailed EMA guidance. This service includes assisting with uploading required documents and ensuring correct formatting with necessary electronic signatures.

OMS Integration with Other EU Systems

OMS aims to streamline regulatory processes and set up easier integration with additional regulatory systems.

In 2022, the EMA integrated OMS with:

- Clinical trial applications through the Clinical Trials Information System (CTIS)
- Union Product Database (UPD)
- Variation applications with the digital application dataset integration (DADI) network project and Manufacturing / Importers Authorisations (MIA)
- Good Manufacturing Practice (GMP) inspections
- Wholesale distribution authorisations

Integrating these systems requires careful coordination and management. To remain compliant with guidelines and operationally efficient, sponsors need to ensure seamless data flow between systems.

Synchronizing data between EMA portals like OMS and CTIS can take up to five to seven working days and must be accounted for appropriately in project timelines. Sponsors should manage the delay time for data synchronization and ensure all information is correct and up-to-date.

There are also frequent updates and changes to the EMA guidelines and associated systems requiring continuous monitoring and adaptation to remain compliant.

Tigermed Solutions for Coordinating Regulatory Processes

Significant challenges require multi-faceted tools and strategies to achieve optimal performance. Tigermed offers an array of support services to take the hassle out of data synchronization and EMA compliance.

Data entry and management

Our teams support registering investigational substances and products and ensure correct linking to the investigator's brochure and clinical trial reference. We verify all entered data for accuracy and compliance and make certain that all locations, entities, and subsidiaries are correctly linked within the system with accurate details.

Ongoing support and troubleshooting

Tigermed offers real-time technical support and submission status monitoring. We keep our clients looped in on any new guidelines, transparency rules, or system updates that may affect their registration and compliance.

Training and knowledge transfer

Our teams provide user manuals, frequently asked questions, and other training materials to help sponsors who wish to navigate the system independently. Tigermed also hosts webinars and training sessions to educate sponsors and share insights and lessons learned to avoid common pitfalls and streamline processes.

Follow-up and review

Tigermed clients enjoy world-class customer service, including regular check-ins and feedback collection with sponsors. These steps ensure ongoing compliance and help sponsors address any gaps or challenges.

Summary

As the EMA integrates and optimizes its regulatory processes, sponsors can rely on an experienced partner like Tigermed to maintain compliance and minimize project timeline setbacks. We can help sponsors understand and confidently engage with regulatory systems like OMS to empower efficiency and accuracy in their submissions.

Streamline your EMA regulatory submissions today by scheduling a meeting with our Tigermed team HERE.