Case Study

Accelerated Risk Management Plan Response Submission

BIOMETRICS

Problem Identification

EMA RMP submission with a very short turnaround based on data collected previously over a period of three decades using multiple data standards and unclear scope of work.

The European Medicines Agency (EMA) mandates that a risk management plan (RMP) be submitted every year for established products in compliance with regulatory requirements to ensure favorable risk-benefits profile. As a part of this regulatory requirement, the EG Life Sciences team was requested to provide clinical reports on an anti-fungal drug used to treat invasive fungal infection among people whose immunity is compromised with an accelerated timeline.

The RMP involved pooling data from 12 clinical studies and the production of 15 adverse events, 35 laboratory and another 50 miscellaneous clinical reports for collation and incorporation into our RMP submission. A timeline of two months was given for both the programming and medical writing parts of this accelerated response submission.

Clinical studies, which were incorporated into this RMP submission, had data collected in three different standards over a period of three decades. In order to pool this data in a sensible way, we had to forward map them to the current data standard used by our client, which included the update of adverse event terms, the up-conversion to the current version of MedDRA, and the update of laboratory data including lab range's to current standards to ensure consistency across various clinical studies.

Once EG Life Sciences performed the initial assessment of scope and the complexity of work required, we recommended to the client the assembly of a joint team of subject matter experts to work on this submission. As a result of multiple in-depth conversations with our client, a joint team consisting of our experienced programmers and their subject matter experts was assembled and, in turn, completed the submission within the prescribed timeframe without any quality issues.

This accelerated RMP response submission demonstrates our expertise and ability to successfully provide programming and statistical support and to work within tight timeframes while still delivering quality results. EG Life Sciences was able to manage expectations of stakeholders and to communicate effectively and collaboratively with them when the initial scope of work was unclear in order to achieve successful results.

Nature and Scope of Challenge

- RMP involved pooling data from 12 clinical studies and production of 15 adverse events, 35 laboratory and another 50 miscellaneous clinical reports to be incorporated as part of RMP submission.
- A timeline of two months was given for both programming and the medical writing part of this accelerated response submission.
- Data collected in clinical trials conducted over a period of three decades in three different, inconsistent standards.
- Adverse events, laboratory terms, and ranges were very different.
- Unclear scope of work and limited experience of client handling this RMP submission.

Problem Resolution

- Negotiated with stakeholders to clarify scope of work.
- Built a team of subject matter experts consisting of both the client's and EG Life Sciences' team members.
- Worked with client as a part of their extended team.

Value Proposition

This accelerated RMP response submission has demonstrated our ability to successfully provide programming and statistical expertise and support. It also showcases EG Life Sciences' ability to effectively manage stakeholder relationships to clarify scope of work and contribute as a part of a joint team.

EG Life Sciences

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