

BUSINESS CASE

Case Study Analysis: Transparency Policy 0070



CHALLENGE

A leading global pharmaceutical company, interested in full regulatory support for the management of Policy 0070 for a new active substance on the centralized procedure registration

The Client faced the following challenges:

- **Lack of experience** and technical know-how (first time dealing with Policy 0070).
- **Not having in-house resources.**
- **Large documentation package** (more than 60,000 pages).
- **Tight timeframe.**



SOLUTION

The activities performed by Asphalion included:

- **Specialised regulatory support.**
- **List of Expected Documents revision** and determination of out of scope pages.
- Establishment of **Risk Assessment approach.**
- **Pre-submission meeting** preparation and attendance to define the anonymisation strategy.
- Definition of detailed **anonymisation rules** and **anonymisation report** preparation.
- Compilation of **justification tables** for **commercially confidential Information**, including guidance in formulating strong and substantiated explanations.
- **Execution of anonymisation** and redaction processes, including Quality Check.
- **Publishing and submission** activities.
- **Liaison with the EMA Clinical Data Publication team.**



OUTCOME

Successful Policy 0070 implementation:

- **Successful pre-submission meeting**, agreeing with the EMA on the anonymisation strategy and achieving an **extension of timelines.**
- First time **validation** of Redaction Proposal Document Package.
- **Acceptance of written responses** to the Agency's observations without additional comments.
- Adaptation to the change of the Anonymisation Report Form template.
- Delivery of **Final Redacted Document Package with minor comments.**
- Completion of the project within the **agreed timelines and competitive budget .**



CLIENT TESTIMONIAL

“Many thanks for your **expertise** and patience to walk us through the EMA policy exercise and for the **successful approach** to comply with the EMA's CCI and PPD rules”.