



Case Study

Big Pharma Company Achieves Compliance with EMA 0070 Policy

www.geninvo.com

North America | UK | Europe | India



The Challenge

A global pharmaceutical company learned of our anonymization service and the successful product launch of Shadow™. They came to us with these challenges:

- ▶ To achieve complete anonymization along with generation of anonymization report for two studies.
- ▶ Each study consisted of 12 and 14 analysis data-sets, with a total of 5000 pages to anonymize.
- ▶ Two-week timeline for completion.
- ▶ Due to Brexit, EMA was accepting submission of redaction proposal only until the end of July 2018 and final package until the end of August 2018.



www.geninvo.com
North America | UK | Europe | India

The Solution

Our team implemented Shadow™ into the client's processes enabling the ability to perform data and document anonymization.

The GENINVO Difference

- ▶ De-identified dataset initially as per PhUSE rules, then adjusted de-identification to achieve residual risk threshold.
- ▶ Few of the methods used were:
 - ▷ Pseudonymize
 - ▷ Date Offset
 - ▷ Generalization for Age, Country, Race, Ethnicity
 - ▷ Variable suppression for free text variables
- ▶ De-identified values from dataset to document.
- ▶ Link between data maintained between analysis datasets and CSR documents



www.geninvo.com
North America | UK | Europe | India

The Result

- ▶ Complete anonymization of the two studies with generation of anonymization report and finalized redaction package before due date.
- ▶ Anonymized documents published on EMA website in September 2018.
- ▶ Risk of (attempt from adversary) = 1 in lieu of public release.
- ▶ Risk of re-identification calculated for different combinations of quasi-identifiers as suggested in policy 0070, Kniola (2016), IOM guidelines.
- ▶ Risk Threshold = 0.09
- ▶ Risk metric used = Maximum
- ▶ Risk of re-identification in de-identified data = 0.0286



Apart from the Plug and Play offerings of our premium product **SHADOW™**, we also provide **Anonymization as a Service** for CROs and Pharmaceutical Companies to avail Data and Document Anonymization services.

Contact us today to feel
the GENINVO Difference!



www.geninvo.com
North America | UK | Europe | India



Ideas
Delivered
Intuitively

Thank You!

www.geninvo.com | Reach out to us info@geninvo.com

