



Case Study

**Big Pharma Company Achieves Compliance** with **EMA 0070 Policy** 

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## 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 datasets, 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.





## The **Solution**

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

## The GENINVO Difference

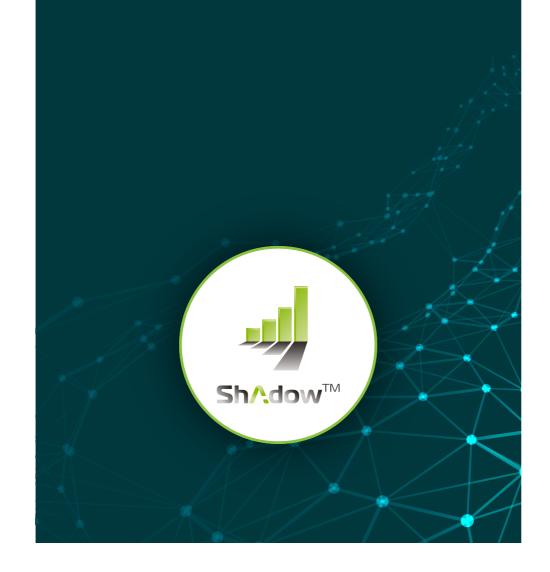
- ▶ De-identified dataset initially as per PhUSE rules, then adjusted de-identification to achieve residual risk threshold.
- ► Few of the methods used were:
  - Pseudonymize
  - ▷ Date Offset
  - ▷ Generalization for Age, Country, Race, Ethnicity
- ▶ De-identified values from dataset to document.
-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



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## 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!** 



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Ideas Delivered Intuitively

Thank You!

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