

Kick-Start Your Clinical Trial Document Anonymization

A fast and affordable way to discover the full value of Privacy Analytics' statistical method

If you're a clinical trial sponsor, you already know that a single clinical trial document submission can include tens, even hundreds of thousands of pages of documentation packed with sensitive patient data – data that exists in a free-text, unstructured format.

Redaction is not enough

Redacting patient information is increasingly unacceptable to regulators¹. That's because redaction destroys the utility of clinical information needed for vital health research.

At the same time, regulators encourage quantitative, not qualitative, methods for assessing the identifiability of trial participants in clinical study reports. Under tight timelines, you must meet these ever more stringent requirements when submitting clinical trial documents for regulatory approval.

How well equipped is your team to adapt to this shift in the regulatory landscape?

Clinical Trial Document Anonymization Program – a fast and affordable “kick-start”

Privacy Analytics specializes in statistical anonymization which strikes the ideal balance between data utility and patient privacy – while meeting the most stringent regulatory requirements for clinical document submissions.

For a small investment, our team will *kick-start* your experience with statistical anonymization.

Once an agreement is approved, we will deliver our results within 60 days.

We begin with a project initiation meeting including a methodology session for you and your team to ensure alignment on all aspects of the program. We work with a subset of your actual clinical trial documents to demonstrate the reliability and effectiveness of our approach.

¹ The European Medicines Agency (EMA) Policy 0070 and Health Canada Public Release of Clinical Information (PRCI) are leading examples.

How your organization benefits from this special offer?

- **Demonstrated Reliability:** A practical proof-of-concept for the most up-to-date, internationally recognized approach to data anonymization.
- **Rich Data:** The highest possible data utility and transparency. Clinical information transformed only where necessary.
- **Defensible Results:** A numeric result which can be easily demonstrated to fall below regulatory thresholds and protect your company's reputation.

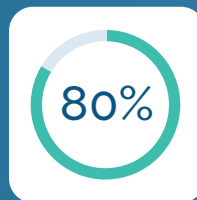
Kick-start your statistical anonymization program in three phases:

1. **Proposal Package:** Similar to what would be provided in a regulatory submission for approval:
 - PDFs in which patient identifiers have been flagged, with suggested transformations to mitigate patient identifiability/re-identification risk.
 - Detailed Anonymization Report outlining the methodology, the quantitative re-identification risk measurement values, and the mitigation strategies applied to ensure patient identifiability meets the regulator-mandated threshold.
2. **Final Package:**
 - PDFs in which the suggested replacement values have been fully incorporated, reflecting regulator feedback (if applicable). This is analogous to fully anonymized documents that would be shared on a public portal in a regulatory submission.
 - Shortened Anonymization Report tailored for sharing on a public portal in a regulatory submission.
3. **Program Evaluation Report:**
 - Summary report of the process and outcomes of the engagement, including any recommendations for future consideration.

Why Trust Privacy Analytics?



9 of the top 10 global pharma companies listed on PharmExec's Top 50 have trusted Privacy Analytics



80%* of the dossiers published by EMA that used a statistical method were anonymized by Privacy Analytics.
*as of June 2020



Hundreds of clinical documents anonymized every year, helping sponsors achieve transparency

If you're interested in finding out more about our *Kick-Start* offer, contact us today to discuss your needs.

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