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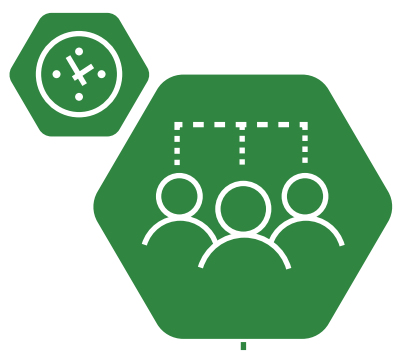
A best practice approach for achieving **EMA policy 0070 compliance**

Based on **21 submissions made by 9 pharmaceutical companies**, this best practice approach will help any Life Sciences company as they implement their own clinical data anonymisation project.

Starting a new project? Here's your step-by-step guide:

1 Define scope, teams, process and timelines

- Start early in the process, as soon as the dossier is submitted to EMA
- Define appropriate and targeted team members
- Familiarise team members with policy requirements
- Design a robust project plan: who-how-when
- Keep an open communication with all stakeholders
- Implement learnings to future projects and teams



2 Evaluate documents

- Make available the final versions of all in-scope documents as PDFs
- Identify all applicable direct, quasi and other variables specific to submission documents
- In case of multiple submission packages of varying sizes, start with the smallest submission package first

3 Perform initial risk assessment

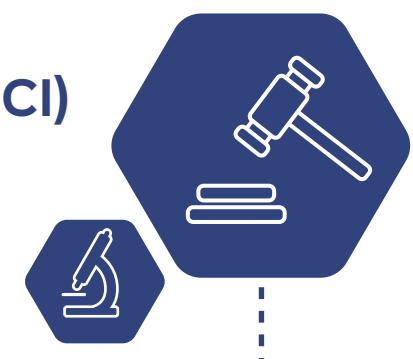
- Evaluate risk based on study characteristics in the documents and datasets
- Consider using different anonymisation strategies
- Perform a quick risk assessment of the defined rules to help avoid rework
- Set objectives to balance 'high' data utility and 'adequate' low risk of re-identification

4 Create anonymisation plan of protected personal data (PPD) based on initial risk assessment

- Define and finalise rules along with their rationale, well-ahead of the document processing to lessen frequent modifications amid processing
- Test rules in a sample document
- For a case narrative, consider both transformation and redaction strategies

5 Review commercially confidential information (CCI)

- Ask medico-legal team to conduct thorough evaluation of CCIs
- Collect publically available evidences on CCIs
- Create a product-specific repository of any potential CCI keywords to aid review

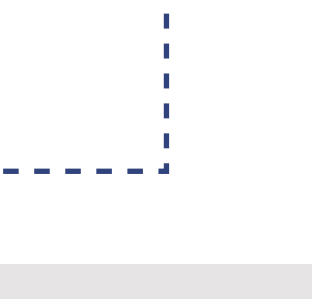


6 Perform quality checks and peer reviews of marked documents (PPD & CCI)

- Create a review checklist based on agreed anonymisation rules
- Ensure extensive communication between stakeholders
- Consider common review platforms for efficient reviews and discussions
- Use secure document exchange and versions tracking

7 Prepare anonymisation report (for PPD) and justification tables (for CCI)

- Make sure justification tables are specific, pertinent, not overstated and appropriate to the relevant section
- Ensure anonymisation report is customised to the product as well as considering the disease, study size population and study setting
- Focus the anonymisation report only on variables and strategies relevant to this submission
- Justify comments received during the redaction proposal phase in the anonymisation report (or in an explanation in the cover letter submitted with the final redacted package)



8 Use automation to support efficient and consistent data anonymisation

An automated data anonymisation platform makes it easier to:

- Manage large volumes, by reducing manual efforts and errors
- Revise anonymisation rules uniformly and efficiently reapply those rules to documents
- Maintain consistency of transformed text across all documents, whilst enhancing overall quality of the redacted package

Get in touch to book your **1:1 assessment with a kinapse expert**

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