



Guidance on anonymization of protected personal data in RMPs

TRENDING TOPICS

Hints and tips on:

Anonymisation of Protected Personal Data and assessment of Commercially Confidential Information during the preparation of RMPs (main body and annexes 4 and 6).

Patient-level information 'is neither required nor expected' in RMPs, the agency notes. If such information is part of case narratives or individual patient entries, companies should evaluate what to remove on a case-by-case basis, taking factors such as the type of medicinal product, indication and the size of the study into account (e.g., studies assessing rare diseases or information on genetic characteristics for small studies could lead to the identification of participants).

EMA advises companies to delete or reword the subject ID or screening randomisation number. The guidance also recommends generalizing or deleting the i. dates of birth and ii. death of study's participant, iii. participants age and iv. sensitive and/or newsworthy information at participant's level (e.g., drug abuse, genetics, elective abortion), if generalization is not possible.

Most information about company personnel constitutes Protected Personal Data (PPD) and should be deleted, with the exception of QPPV's name. EMA expects applicants to propose deletions of commercially confidential information (CCI) where applicable. The agency also may request the removal of information that is not essential and may be considered CCI e.g., detailed information on studies which are part of an ongoing paediatric development plan (PIP) to the extent that piece of information is not already in the public domain incl. the published PIP decision.

