



29 November 2023
EMA/781194/2021 Rev. 1
Stakeholders and Communication Division

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

General guidance

This document aims at giving general guidance to companies on the retention/removal of Protected Personal Data (PPD) and identification of Commercially Confidential Information (CCI). All the changes suggested in this guidance are of editorial nature and should be implemented in the Risk Management Plan (RMP) during the scientific review process prior to the Opinion and adoption of the final RMP version.

1. Protected Personal Data (PPD)

Identifiers related to study personnel/company employees	Anonymisation rules
QPPV's name	Retain
QPPV's contact details (email address, phone address, office number, etc.)	Delete
Names of company's employees (including contact person and/or authors of RMP) and their direct contact details (e.g. e-mail, phone number)	Delete
Handwritten signatures, names, dates or other handwritten text ⁽¹⁾	Delete

(1) Handwritten and electronic signatures should be avoided since they will require to be redacted before publication. The MAHs are encouraged to use the statement on the RMP template informing that the signature is kept on file.

Individual study participant/patient level information **is neither required nor expected in RMPs**. If this kind of information had been included as part of case narratives and/or individual patient entries, the decision on retaining or removing/rewording PPD may be conditioned by the type of medicinal product and its indication(s) (e.g. orphan indication for a small population), the size of the study (e.g. in the case of a small study, information on diagnostic values or genetic characteristics could lead to the identification of the patients) and a case-by-case analysis should always be performed.



Identifiers related to individual study participants in narratives or individual participant entries	Anonymisation rules
Study participant/subject ID or screening randomisation number	<ul style="list-style-type: none"> Delete and reword (e.g. 'one/a study participant')
Serious Adverse Event number/code	<ul style="list-style-type: none"> Delete and reword if applicable (e.g. 'one case')
Study participant's date of birth	<ul style="list-style-type: none"> Delete OR Generalize (age band¹)
Study participant's place of birth/nationality	<ul style="list-style-type: none"> Delete
Study participant's date of death	<ul style="list-style-type: none"> Generalize to relative study day (e.g. 'Day 30' or '30 days after the first dose') OR Delete (if generalization is not possible)
Reporting country for Adverse Event/Adverse Drug Reaction	<ul style="list-style-type: none"> Delete
Sensitive and/or newsworthy information at participant's level (e.g. <i>drug abuse, genetics, elective abortion, means of attempting to commit suicide, means of death, specifics on accidents, country-specific concomitant medication, participant's profession, other</i>)	<ul style="list-style-type: none"> Delete OR Generalize (only if possible)
Participant's sex/gender and personal/possessive pronouns	<ul style="list-style-type: none"> Retain OR Delete (e.g. if small-sized gender group)
Participant's age	<ul style="list-style-type: none"> Generalize (age band¹) OR Delete (if generalization is not possible, e.g. if age-specific study or if small study population size)
Participant's health data / study calendar dates	<ul style="list-style-type: none"> Generalize to relative study day
Participant's study relative dates	<ul style="list-style-type: none"> Retain
Participant's race	<ul style="list-style-type: none"> Delete OR Retain (if relevant for data utility and interpretation)
Participant's ethnicity	<ul style="list-style-type: none"> Delete OR Retain (if relevant for data utility and interpretation)

(1) As an alternative to deletion, age can be generalised by using an age-range. Age ranges may start with 10-year age increments. Wider age ranges (e.g. <30, over 60 or child) can be employed as considered clinically relevant for the context/pathology/medicine safety profile. Predefined age ranges (e.g. 0-2 year or infant, 2-12 year or child)

can also be used and adapt to the study clinical setting. Nouns defining larger age groups can also be employed: child, young adult, adult, elderly.

2. Editorial / administrative notes

- “Confidential” or confidentiality statements to be deleted from Headers/footers of document prior to its adoption/publication.
- Check that all document properties (e.g. author’s name) and metadata have been removed from the final RMP PDF document.

3. Commercially Confidential Information (CCI)

The MAH should propose CCI deletions where applicable. Prior to the RMP adoption EMA can also request to remove certain pieces of information which are not necessary and may be considered by the company as commercially confidential.

There is the expectation that no CCI is present in RMPs. Nevertheless, the information below (non-exhaustive list) **may** constitute CCI, unless it can be found in the public domain.

Examples:

- Exposure data (patient exposure and sales volume) by country¹;
- Detailed information on ongoing clinical studies such as evaluation of *new* formulation or exploring the effect of the medicinal product in *new* indications or populations to the extent it is not available in the public domain (such as in company web-pages – pipeline, clinical trial registers EudraCT, CTIS, Clinicaltrials.gov), unless such studies are proposed as part of *Part III: Pharmacovigilance Plan* to address safety concerns, or imposed for efficacy reasons and included in *Part IV: Plans for post-authorisation efficacy studies*;
- Information on future development plans or regulatory strategy such as line extension/variation;
- 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 (such as in company web-pages – pipeline, clinical trial registers EudraCT, CTIS, Clinicaltrials.gov) including the published EMA PIP decision;
- Specifics on manufacturing and QC of active substance and final product (e.g. batch size, quantitative information on excipients, acceptance criteria, other);
- Names /Contractual agreements of/with service providers/material suppliers (except for CROs for non-clinical and clinical studies).

The following information will **not** be deemed to be CCI:

- Cumulative exposure data in part II, module SIII (including cumulative data per indication, treatment duration, patient population, formulation), when presented in an aggregated form;

¹ Including but not limited to individual EEA countries, USA, Japan, Canada, China.

- The standard method to calculate exposure based on the posology of the product and/or treatment cycles and sales and global exposure data presented in an aggregated form. The deletion would be accepted for data pertaining to national exposure data, if included.