Steps to reduce identification of participants

A. Anonymise the participant’s personal information as soon as practically possible.

B. Store the participant ID code separately from the CRF/database with restricted access.

C. Manage participant-identifiers in the study database.

1. Limit participant-identifying data to what is necessary to address the study aims.
2. Tag fields containing participant-identifying data and restrict access.
3. Manage user access throughout the lifecycle of the trial (e.g., that site-specific access is implemented where appropriate; that expired or suspended user accounts are removed).