EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Personal data protection principles governing CTIS

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Protection of personal data and CCI for documents uploaded and published via CTIS: Workshop on draft guidance

CTR and personal data

- GDPR / EUDPR applies to processing of personal data within CTIS
- CTIS is to enable cooperation between the competent authorities of the MSs concerned to the extent that it is necessary for the application of the CTR and to search for specific clinical trials – Article 81(2)
- CTIS shall be publicly accessible except where justified to protect the confidentiality of personal data - Article 81(4)
- CTIS shall contain personal data only insofar as this is necessary for enabling cooperation and communication between the different users - Article 81(6)
- No personal data of subjects shall be publicly accessible - Article 81(7)

Roles and responsibilities

- Protection of personal data in CTIS is a joint responsibility (see JCA)
- Each party should ensure that personal data are processed according to the principles of the GDPR (MS, sponsors, MAAs, MAHs) and EUDPR (EMA and EC)
- Sponsors/applicants responsible for the content of uploaded CTA documentation
- MAAs/MAHs responsible for the content of the uploaded CSR
- MSs responsible for the content of the uploaded Assessment Reports
- EC responsible for the content of the Union Controls plans/programmes & reports
- EMA responsible for the users management within CTIS

Types of personal data in CTIS

- Data variables
  - Direct identifier - permits direct recognition or communication with an individual
  - Indirect identifier - doesn't point to an individual on its own but in combination with other indirect identifiers
- Personal data of clinical trial participants (pseudonymised format)
  - Data variables – subject ID number & indirect identifiers (e.g. demographics, lab results, medical history…)
- Personal data of individuals other than clinical trial participants such as staff of the sponsor, marketing authorisation applicant/holder, qualified person for GMP documentation, principal investigators, MS employees
  - Data variables – direct identifiers (name, handwritten signature, direct contact details) & indirect identifiers (position, study role, affiliation)

Management of personal data in CTIS

- CTIS allows to upload a document version '**for publication**' and '**not for publication**'
- **Personal data**, if needed during the scientific and regulatory review carried out by the Member States concerned, should be provided in the document version '***not for publication' (e.g. pseudonymised for trial participants)***
- **Personal data** in the document version '**for publication' must be anonymised**, *with exception* of personal data of *principal investigators at the clinical site, head of the facilities signing the state of compliance of the facility and sponsor legal representative in the EU when applicable*

Annex I – documents submitted to CTIS and the types of personal data contained

Anonymisation of personal data - **documents 'for publication'**

- **Anonymous data** - information which does not relate to an identified or identifiable natural person (Recital 26 of GDPR and Recital 16 of EUDPR)
- ***Individuals other than clinical trial participants***
  - Personal data must be anonymised in the version of documents 'for publication'
  - Exceptions
    - Personal data of principal investigators, legal representative of the sponsors, head of the clinic/institution,
    - The full name (not signatures) of the sponsor and coordinating investigator signatories of the clinical study report and the identities of the investigator(s) who conducted the trial
- ***Clinical trial participants***
  - Must be anonymised in the version of documents 'for publication'
  - No exceptions

Anonymisation techniques

- Several techniques can be employed on a data set

➢ **Masking**

- Original variable removed, typically used for direct identifiers (e.g. names)

➢ **Generalisation**

- Replace the original variable with a less granular variable (age – age range)
- Allows to retain data utility

➢ **Randomisation**

- Replace the original value with a similar value (health data calendar dates – shift/offset them with a number of days)
- Allows to retain data utility

Pseudonymisation of personal data of trial participants - **documents 'not for publication'**

- Pseudonymisation consists of **replacing one variable** (typically a unique attribute) in a record **by a variable no longer attributed to the individual** (i.e. patient name replaced with study participant ID)
- Pseudonymisation **reduces the ability to link a dataset with the original identity** of a data subject, therefore data protection rules still apply
- **Personal data of trial participants** may be contained in pseudonymised format in the CTIS secure domain in the **document version 'not for publication'**
- **Principles of data minimisation and proportionality** should be applied when preparing the documents '**not for publication**'