

Protection of personal data and CCI for documents uploaded to CTIS

EMA Workshop 14-July-2022

Session 2

Ruediger Pankow, Parexel (ACRO)

Names of natural persons in dossier

Expectation of actual individuals to be named in the dossier and whether or not they would fall under holding a “legal role”?

- Which natural persons names fall under “legal roles”, e.g. sponsor, legal representative, principal investigator, issuer of facility suitability statement, other...
- Consolidated EU/EEA approach for part I documentation independent of MSC(s) composition in particular trial
 - Names of DSMB members in DSMB charter
 - Names of individuals other than principal investigator (sub-investigator, names of site personnel)
 - Names of issuers on certificates (e.g. QP declaration, GCP training, insurance)
 - Other...?

Personal data in RFI text field

Consideration number	Application section parts	Part II	Application section and document	Financial and other arrangements
Consideration	Could contain Personal identifiable information (name), where required for RFI context			
Sponsor response				
Documents related to the response				

- RFI data fields cannot be redacted and will be subject to publication
- RFI consideration may contain name of an individual required for RFI context reasons, but inappropriate to be published
- Even if dossier is updated in RFI response and first individual replaced by another one, that first individual's name will still get disclosed with the RFI consideration, while they never hold the legal role (e.g. "principal investigator") they were foreseen at time of decision