

Form title **Supplemental Data Definitions**

Document reference **Study** [REDACTED]

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| Domain AE | <ul style="list-style-type: none">• Documentations on both forms and data sets, adverse events (AE) and serious adverse events (SAE), were combined into the domain AE and supplementary information in SUPPAE.• On the adverse events form no field was planned for start and end year of an AE. This could be concluded without doubt from the domain DM and SV. |
| Domains AE, PE, CM, etc. | <ul style="list-style-type: none">• Original verbatim terms of the investigator were not available in the original data base, only coded by a dictionary or free coding list or a mix of both. These coded texts were used as 'verbatim' and were re-coded with the latest dictionary version if applicable. |
| Several Domains | <ul style="list-style-type: none">• Year was missing in several cases, but could be concluded from without doubt as year=2000. This procedure was only used for critical dates such as exposure or laboratory dates. |
| Domain LB | <ul style="list-style-type: none">• Laboratory dates/times documented in the CRF could not be clearly be combined with corresponding results data sets. Because in the results data sets dates/times were available, these were used in the domain LB• For Patient no. 51 a year of 200 was set to 2000 which could be clearly concluded. |