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| 4.2.3.3.1 | *In vitro* |  |
| 4.2.3.3.2 | *In vivo (*including supportive toxicokinetics evaluations) |  |
| 4.2.3.4 | Carcinogenicity (including supportive toxicokinetics evaluations) |  |
| 4.2.3.4.1 | Long-term studies (in order by species, including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics) |  |
| 4.2.3.4.2 | Short or medium term studies (including range finding studies that cannot be appropriately included under repeat-dose) |  |
| 4.2.3.4.3 | Other studies |  |
| 4.2.3.5 | Reproductive and developmental toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following subheadings should be modified accordingly) |  |
| 4.2.3.5.1 | Fertility and early embryonic development |  |
| 4.2.3.5.2 | Embryo-foetal development |  |
| 4.2.3.5.3 | Prenatal and postnatal development, including maternal function |  |
| 4.2.3.5.4 | Studies in which the offspring (juvenile animals) are dosed and/or further evaluated |  |
| 4.2.3.6 | Local tolerance |  |
| 4.2.3.7 | Other toxicity studies (if available) |  |
| 4.2.3.7.1 | Antigenicity |  |
| 4.2.3.7.2 | Immunotoxicity |  |
| 4.2.3.7.3 | Mechanistic studies (if not included elsewhere) |  |
| 4.2.3.7.4 | Dependence |  |
| 4.2.3.7.5 | Metabolites |  |
| 4.2.3.7.6 | Impurities |  |
| 4.2.3.7.7 | Other |  |
| 4.3 | Literature references |  |
| Module 5 - Clinical Study Reports | | |
| 5.1 | Table of contents of Module 5 |  |
| 5.2 | Tabular listing of all clinical studies |  |
| 5.3 | Clinical study reports |  |
| 5.3.1 | Reports of biopharmaceutic studies |  |
| 5.3.1.1 | Bioavailability (BA) Study Reports |  |
| 5.3.1.2 | Comparative BA and Bioequivalence (BE) Study Reports |  |
| 5.3.1.3 | *In vitro-in vivo* correlation study reports |  |
| 5.3.1.4 | Reports of bioanalytical and analytical methods for human studies |  |
| 5.3.2 | Reports of studies pertinent to pharmacokinetics using human biomaterials |  |
| 5.3.2.1 | Plasma Protein Binding Study Reports |  |
| 5.3.2.2 | Reports of Hepatic Metabolism and Medicine Interaction Studies |  |
| 5.3.2.3 | Reports of Studies Using Other Human Biomaterials |  |
| 5.3.3 | Reports of human pharmacokinetic (PK) Studies |  |
| 5.3.3.1 | Healthy Subject PK and Initial Tolerability Study Reports |  |
| 5.3.3.2 | Patient PK and Initial Tolerability Study Reports |  |
| 5.3.3.3 | Intrinsic Factor PK Study Reports |  |
| 5.3.3.4 | Extrinsic Factor PK Study Reports |  |
| 5.3.3.5 | Population PK Study Reports |  |
| 5.3.4 | Reports of human pharmacodynamic (PD) studies |  |
| 5.3.4.1 | Healthy Subject PD and PK/PD Study Reports |  |
| 5.3.4.2 | Patient PD and PK/PD Study Reports |  |
| 5.3.5 | Reports of efficacy and safety studies |  |
| 5.3.5.1 | Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication |  |
| 5.3.5.2 | Study Reports of Uncontrolled Clinical Studies |  |
| 5.3.5.3 | Reports of Analyses of Data from More than One Study |  |
| 5.3.5.4 | Other Study Reports |  |
| 5.3.6 | Reports of Post-marketing experience |  |
| 5.3.7 | Case report forms and individual patient listings |  |
| 5.4 | Literature references |  |

1. Amendments guideline [↑](#footnote-ref-2)
2. Amendments guideline [↑](#footnote-ref-3)
3. Amendments guideline [↑](#footnote-ref-4)
4. [↑](#footnote-ref-5)
5. [↑](#footnote-ref-6)