

## 6 Appendix 1

### Study Types and their Critical Phases

#### **General Toxicology**

- Body weight
- Clinical Observation
- Dosing
- ECG
- Biological Fluids Sampling
- Necropsy
- Food consumption
- Water consumption
- Ophthalmology
- Impactor/filter sampling (inhalation studies)

#### **Reproductive Toxicology**

- Body weight
- Clinical Observations
- Dosing
- Biological Fluids Sampling
- Necropsy
- Food consumption
- Water consumption
- Foetal examination
- Skeletal examination
- Vaginal smears

#### **Genetic Toxicology**

##### **In vivo studies**

- Dosing
- Cell harvesting
- Scoring/assessment

##### **In vitro studies**

- Formulation preparation/Dosing
- Cell harvesting
- Scoring/assessment

#### **Safety Pharmacology**

##### **In vivo studies**

- Body weight
- Dosing
- Biological Fluids Sampling
- Clinical Observation or Study specific observations, as applicable
- Necropsy – gastric emptying and intestinal motility studies (UK only)