

	Objectives	Activities	Main Guidance Material	Outputs
Establish Context	<p>Key stakeholders and necessary approvers are identified</p> <p>Interfaces are defined and controlled</p> <p>The Data Safety assessment is planned</p> <p>Data Artefacts are identified</p>	<p>Describe the organisational context</p> <p>Describe the system context</p> <p>Plan the assessment</p> <p>Identify Data Artefacts</p>	<p>Organisational Data Risk (ODR) assessment</p> <p>Data Safety Culture questionnaire</p> <p>System lifecycle, producers and consumers</p> <p>Supplier data maturity questionnaire</p> <p>Data Types</p>	<p>A list of key stakeholders and necessary approvers for data safety activities</p> <p>An interface control plan or list of control measures</p> <p>An estimate of the level of data-related risk (e.g., an ODR rating)</p> <p>A plan for the remaining parts of the data safety assessment</p> <p>A collection of Data Artefacts</p>
Identify Risks	<p>Generic and historic examples of data-related issues are reviewed</p> <p>Risks are identified and linked to Data Artefacts and Data Properties</p>	<p>Review the general, historical perspective</p> <p>Conduct a top-down approach</p> <p>Conduct a bottom-up approach</p> <p>Update planning documents</p>	<p>Historical accidents and incidents</p> <p>Generic ways data can cause problems</p> <p>Data Properties</p> <p>Hazard and Operability Study Guidewords</p>	<p>A description of the process used for risk identification</p> <p>List of risks linked to Data Artefacts and associated Data Properties</p> <p>Plans updated to account for quantity and complexity analysis</p>
Analyse Risks	<p>The required Data Safety Assurance Levels are established and justified</p> <p>The required Data Safety Assurance Levels are analysed as part of system safety activities</p>	<p>Establish Data Safety Assurance Levels</p> <p>Analyse DSALs as part of system safety activities</p>	<p>Data Safety Assurance Levels (DSALs)</p> <p>Relationship between DSALs and other Integrity Levels</p>	<p>A DSAL (and supporting justification) for each identified risk</p>
Evaluate and Treat Risks	<p>Data Safety requirements are identified, documented and reviewed</p> <p>Methods used to provide Data Safety assurance are defined and implemented</p> <p>Evidence of compliance with the Data Safety requirements is documented, reviewed and approved</p>	<p>Review each risk and either: Avoid, Accept, Transfer, or Treat</p> <p>Establish treatment methods for relevant risks</p> <p>Implement and verify treatment methods</p>	<p>Methods and Approaches tables</p>	<p>A record of the agreed responses to each of the identified risks</p> <p>Data Safety requirements that follow from these responses</p> <p>A record of the treatment adopted for each of the identified risks</p> <p>An assessment as to whether the risk has been suitably mitigated</p>