

Aligning Good Transparency Practice with the ISO/IEC 27559 De-identification Framework



Authors: Abby McDonell et al. amcdonell@privacy-analytics.com

Current trends emphasise the importance of public disclosure and sharing of clinical trial documents and data. Sponsors may be required to make anonymised clinical documents publicly available to comply with health authority transparency regulations or may choose to participate in voluntary data sharing to facilitate secondary research. The **PHUSE Good Transparency Practice** white paper outlines how the Data Controller, Data Anonymiser, and Data Recipient each play distinct and important roles in the safe handling of clinical trial data. The aim for this poster is to review the responsibilities of each party, while providing guidance on best practices that align with international standard **ISO/IEC 27559 De-identification Framework**. With this context, organizations can effectively share and reuse data while meeting regulatory expectations by adhering to international best practices.

Principles of GTP

1. Clinical trial data sharing should be conducted in accordance with the applicable regulatory requirement(s) and local legislature.
2. Anonymisation should adequately protect the privacy of patients and prevent a serious possibility of identifying individuals in the data
3. Prioritise retaining maximum amount of analytically-valuable information during the anonymisation process while maintaining patient privacy.
4. The chosen anonymisation strategy should be documented in an anonymisation report made available to the Data Recipient

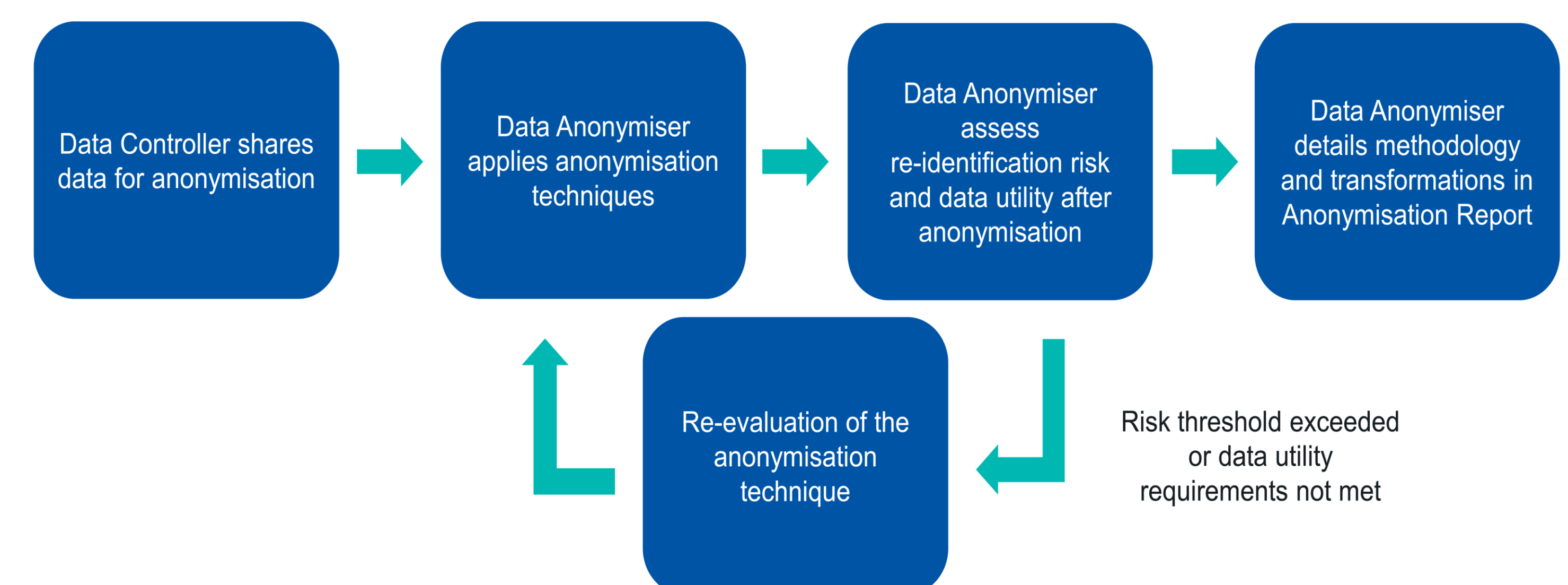


Figure 1: Application of anonymisation strategy following the assessment of re-identification risk. The anonymisation strategy is selected by the Data Controller and applied by the Data Anonymiser. Both quantitative and qualitative risk assessment strategies may be used but should demonstrate how the chosen methodology results in a re-identification risk lower than the default threshold of 0.09

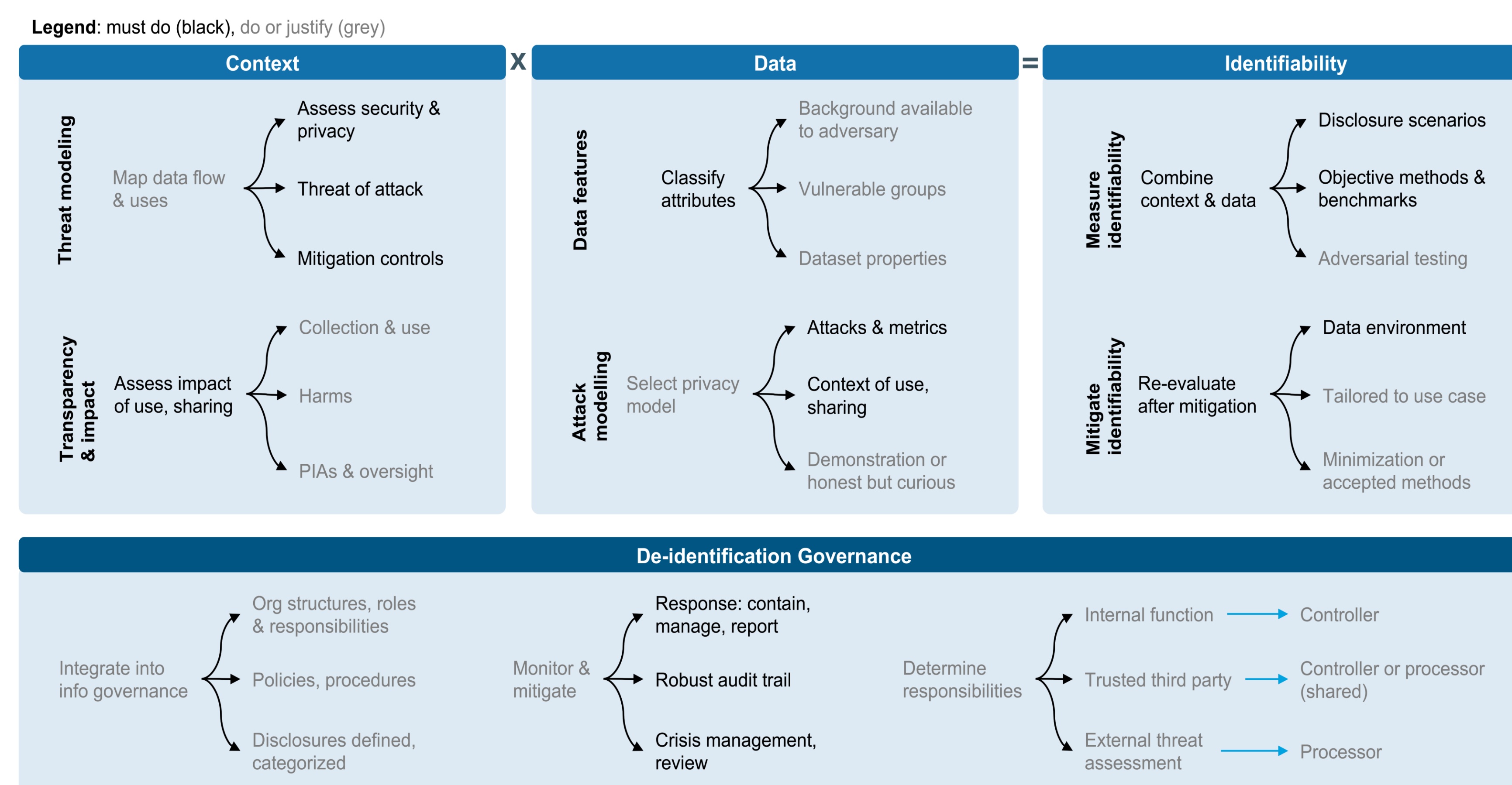


Figure 2: Activities and evidence of practices needed to satisfy ISO/IEC 27559. Depending on their role and responsibilities within a given data flow, these activities may be applicable to the Data Controller, Anonymiser, or Recipient. Each party's responsibilities can vary based on the data sharing scenario.

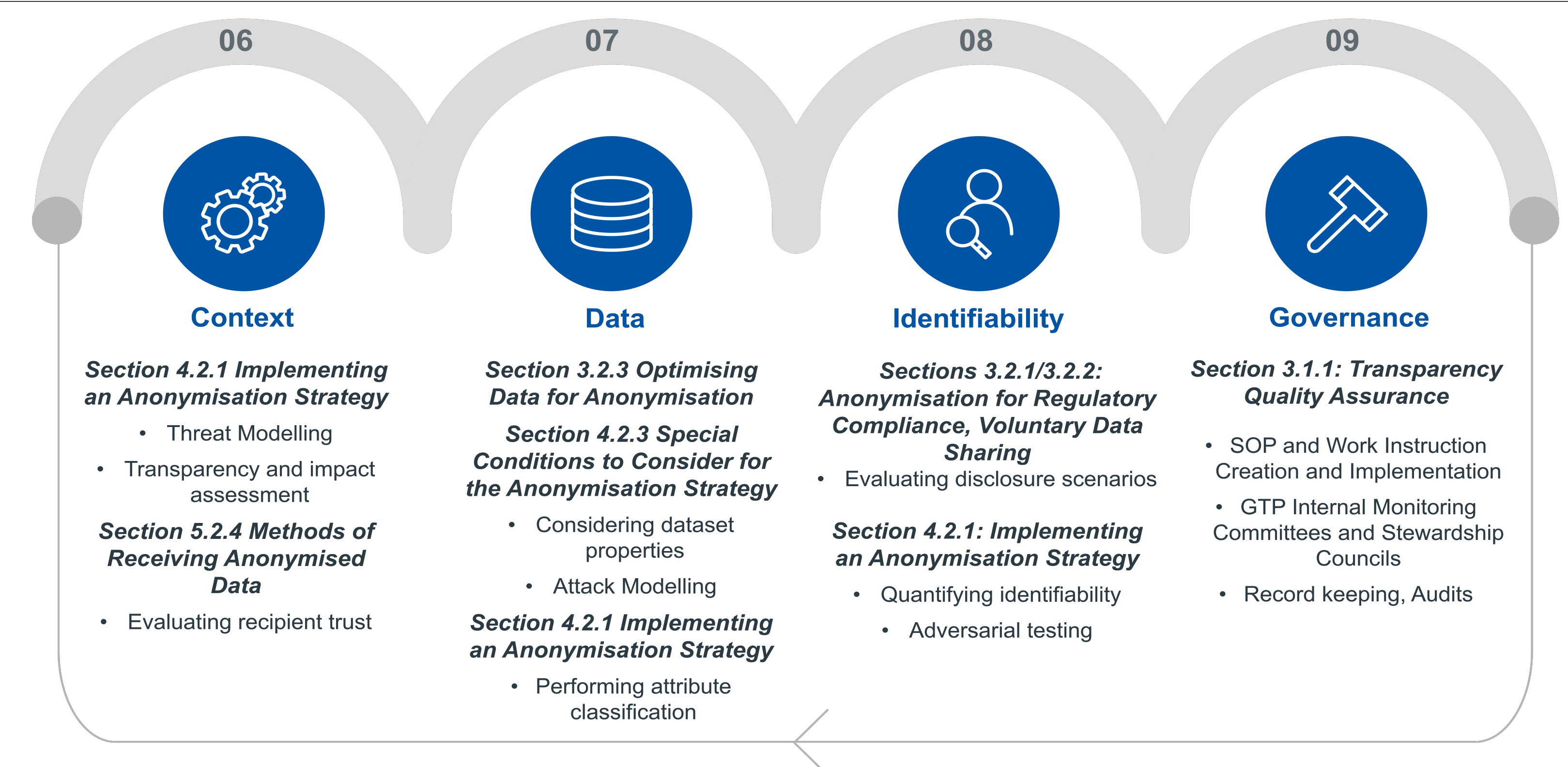


Figure 3: GTP components address requirements (clauses) of ISO/IEC 27559 and provide guidance on satisfying activities which may applicable to the Data Controller, Anonymiser, or Recipient.