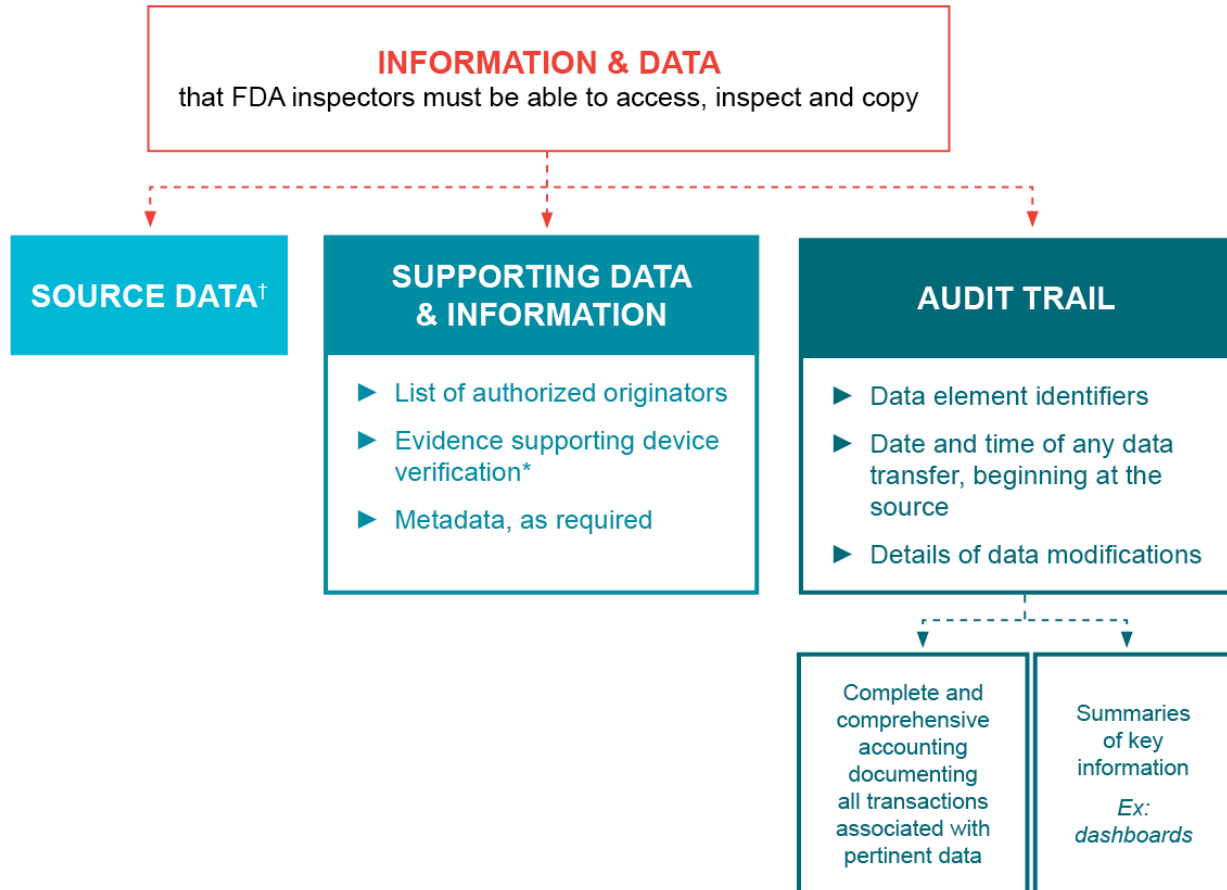


## Figure 1: Data Availability for FDA Inspection

This figure summarizes the data and supportive information CTTI recommends be made available to FDA inspectors. For additional considerations pertaining to data quality, please reference [Section V-2](#) of the recommendations.



Note: FDA regulations, per [21 CFR Part 11](#), do not require data to be maintained in a specific format.

† **Source data** is all information in original records and certified copies of original records detailing clinical findings, observations, or other activities in a clinical investigation used for reconstructing and evaluating the investigation

\* **Verification** is the assessment of accuracy (which may include routine calibration), precision, consistency across time, uniformity across technologies, and possibly also across different environmental conditions. Verification also provides assurance that the relevant firmware /software that generates processed data is accurate, precise, consistent, and uniform. See recommendations on [verification](#).