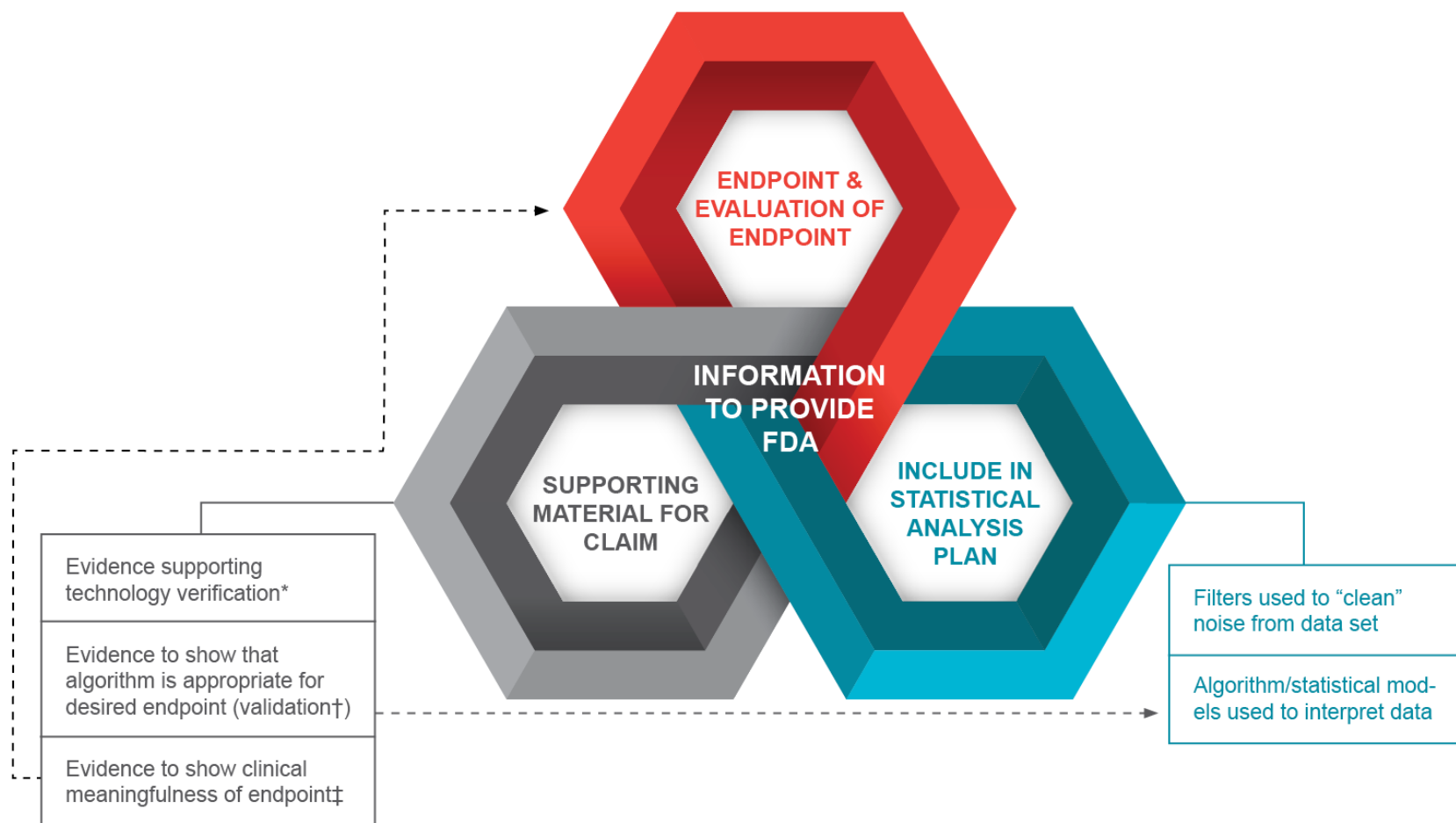


## Figure 2: Data Processes and Information to Provide to FDA

This figure summarizes the supportive documentation CTTI recommends that sponsors include in their submissions to FDA. For additional considerations pertaining to sharing data with FDA, please reference [CTTI Recommendations for Interacting with Regulators](#).



\* 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 considerations on [verification](#).

† Validation the process of ensuring that the digital technology is meeting its intended use by generating objective data that accurately represents the outcome assessment it purports to be measuring. See also considerations on [validation](#).

‡ See [CTTI Recommendations on Developing Novel Endpoints](#)