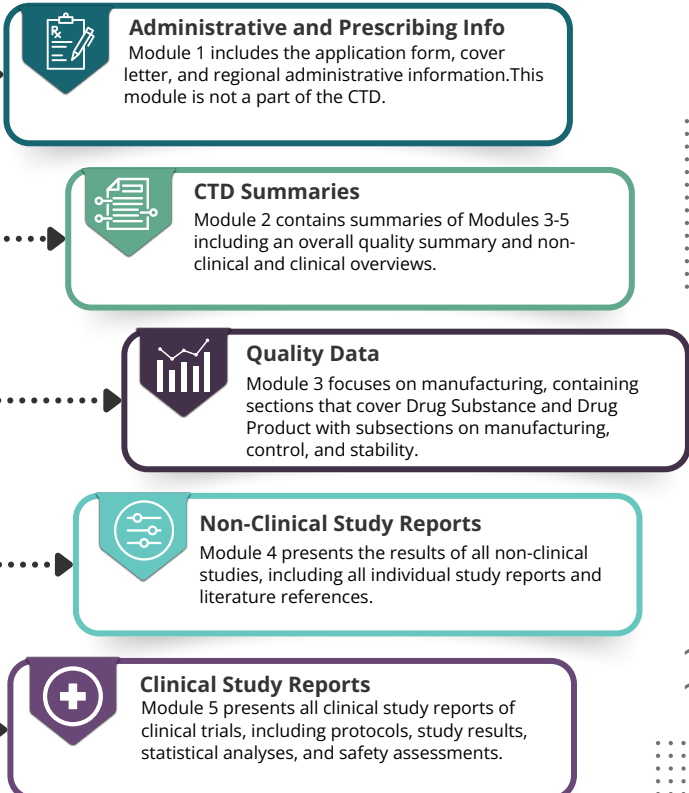


### The Structure of eCTD

The Electronic Common Technical Document (eCTD) allows the FDA and other regulatory agencies to streamline regulatory processes, improve data quality and integrity, facilitate global submissions, and enhance communication between stakeholders



## SUBMISSION: THE ELECTRONIC SUBMISSIONS GATEWAY

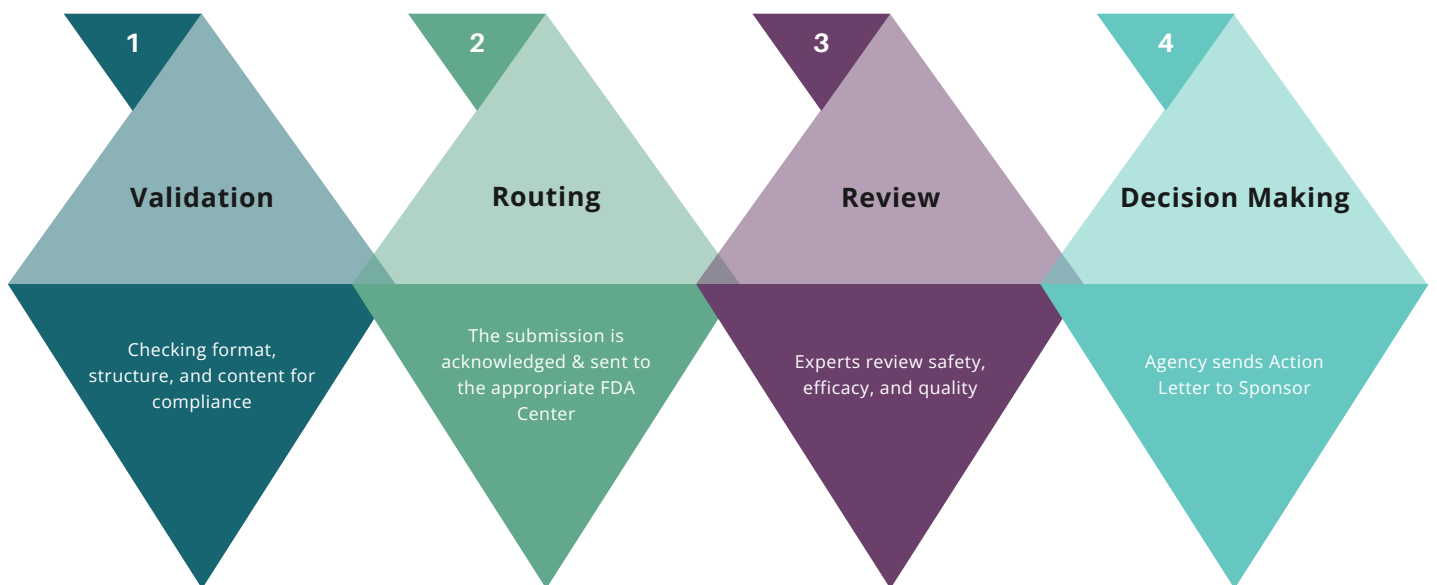
The FDA's Electronic Submissions Gateway (ESG) is an agency-wide solution for accepting eCTDs. The ESG serves as a 'highway' for submissions, accepting them and routing them to the appropriate FDA center. The ESG is the central transmission point for sending information electronically to the FDA.

### USING THE ESG: CURRENT METHODS FOR SUBMISSION (Initial testing of the ESG NextGen is just starting.)



## What Happens After Submission?

FDA's Submission Process



## BENEFITS OF THE FDA VALIDATOR RULES

FDA Validator Rules are a set of technical criteria and guidelines used during the receipt and processing of regulatory submissions by the agency.

