



You submit electronic, standardized data to CDER

Study Data

Electronic Submission Gateway



OCS Services and Tools:

- JumpStart 
- Data Quality Assessments
- FDA Validator

What's Rules Got to Do With It?

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PhUSE CSS 2018

Will Use

Technical Rejection Criteria ¹

CDISC Conformance Rules ²

FDA Business Rules ³

FDA Validator Rules ⁴

Uses

*Reviewers **



¹

<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM523539.pdf>

² <https://www.cdisc.org/standards/foundational/study-data-tabulation-model-implementation-guide-sdtmig/sdtmig-v32>

^{3, 4} <https://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm2005545.htm>

** Reviewers have access to many tools and services, not just those in OCS*