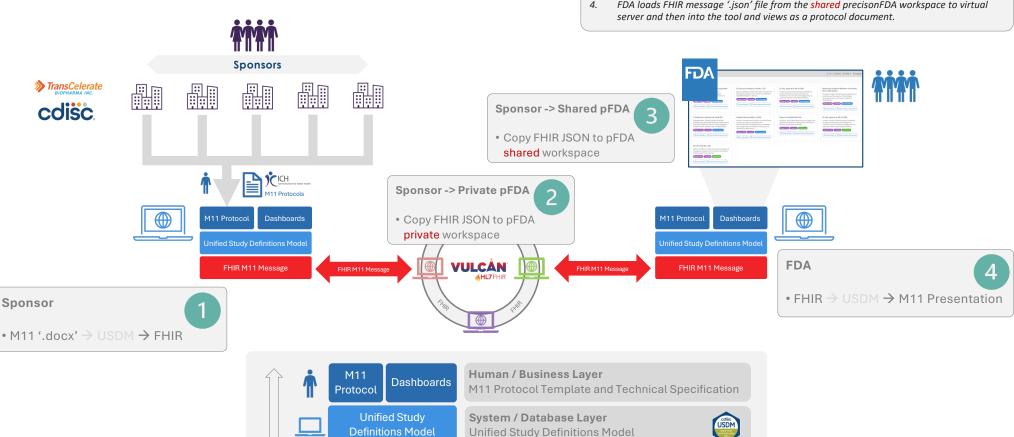
PRISM M11 Use Case

(PrecisionFDA Regulatory Information Service Module)

Overview of Steps

- Sponsor imports M11 '.docx' protocol document into the tool, exports as FHIR message using a '.json' file
- Sponsor loads FHIR message '.json' file into their private precisionFDA workspace
- Sponsor copies FHIR message '.json' file into the shared precisionFDA workspace
- FDA loads FHIR message '.json' file from the shared precisonFDA workspace to virtual



Communication Layer

FHIR M11 message / profile (JSON or XML)

FHIR M11 Message

