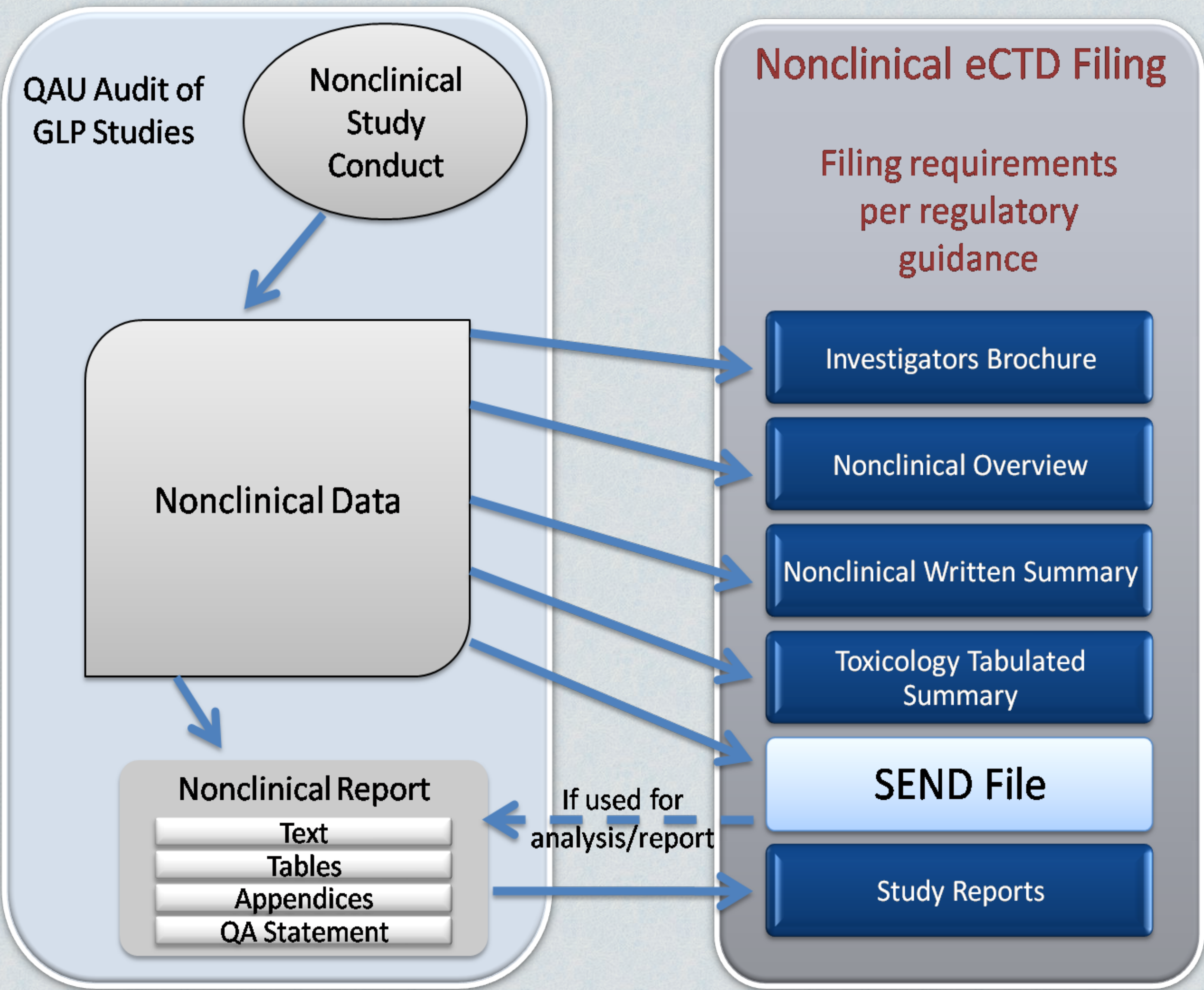


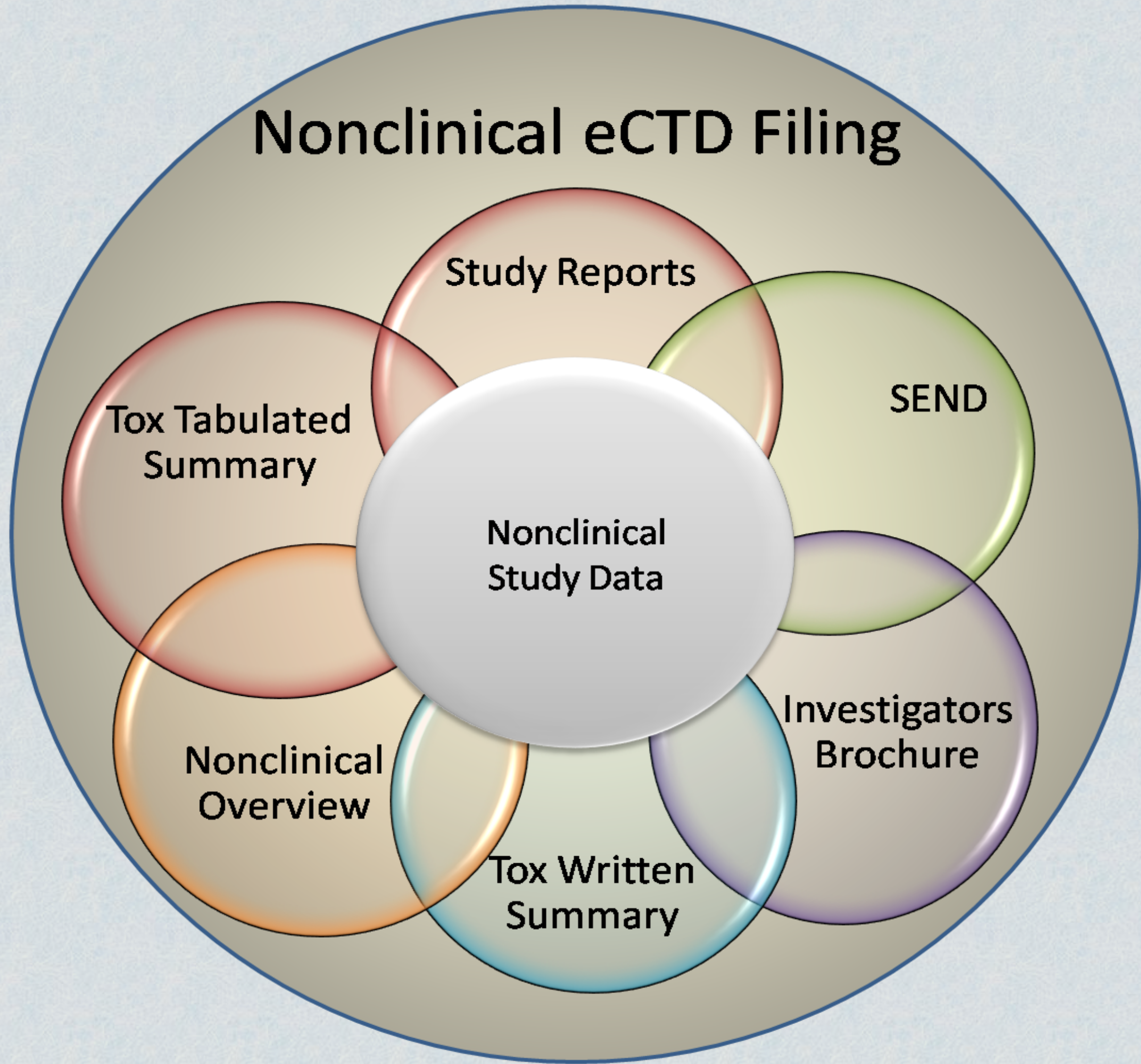
Quality System for the Generation and Submission of SEND Files

Interorganizational SEND

GLP Audited Study Data Utilized in Other Components of the eCTD Submission



The issuance of initial draft guidance by the FDA regarding SEND (Standard for the Exchange of Nonclinical Data) has prompted discussion about the structure of quality systems to support implementation of the standard. This evaluation generated a new perspective on the regulatory and quality system implications.



Regulatory Basis – SEND Quality System

- ❖ GLP nonclinical study conduct, data and reporting require GLP audit per 21 CFR 58.35
- ❖ **Tabulated data is a submission requirement per 21 CFR 312.23(a)(8)(ii)(b) and SEND will standardize the submission of electronic nonclinical data per Food and Drug Administration Safety and Innovation Act (FDASIA)**
- ❖ If SEND is utilized for report table generation or analyses presented in the report, an output from SEND may become a report element requiring GLP audit
 - Similar to statistical analyses reported based on tumor.xpt

Factors Influencing SEND Quality System

- ❖ SEND does not support reporting of an audit trail
- ❖ SEND files may also be submitted for non-GLP studies which would be outside GLP requirements
- ❖ Flexibility to comply with Guidance if SEND quality system outside of GLP requirements
 - e.g. addition of CAS number after study finalization

Quality System Proposal

- ❖ Existing GLP controls required for GLP source data and reporting
- ❖ Quality System elements for SEND similar to those for other submission components
 - Procedures, review/QC check, training, system qualification
- ❖ Additional SEND-specific quality checks
 - Management of translations, SEND conformance checker

Quality System Elements	Non-GLP Data & Report	GLP Data & Report	SEND Files	Other Submission Components
GLP QAU Auditing		✓		
Study Director Oversight/Review	✓	✓	?	
Training	✓	✓	✓	✓
Procedures/Standard Processes	✓	✓	✓	✓
Review/QC Check	✓	✓	✓	✓
System Qualification/Validation	✓	✓	✓	✓
Management of Standard Translations			✓	
SEND Conformance Checker			✓	

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Note: The opinions expressed in this poster are those of the authors and do not necessarily represent the opinions of their respective companies.