When submitting your QT evaluation report, we recommend that you include the following completed table to facilitate review of your submission.

QT evaluation report	
Evaluation report	Include location to evaluation report
Statistical analysis plan	Include location to statistical analysis plan for evaluation report
Investigator's brochure	Include location to Investigator's brochure
Highlights of Clinical Pharmacology and Cardiac Safety	Include location to completed Highlights of Clinical Pharmacology and Cardiac Safety Table (https://www.fda.gov/media/129685/download)
Datasets	Include location to SDTM and ADaM datasets used in the evaluation report. The ADaM datasets should be formatted using the Technical Specification for QT datasets (https://www.fda.gov/media/128187/download)
Analysis programs	Include location to analysis programs used in the evaluation report
Adverse Event analysis	Include location to an Adverse Event analysis using the MedDRA SMQ "Torsade de pointes/QT Prolongation" and include the preferred term "Seizure" by treatment and dose level.
Integrated categorical analysis	Include location to an integrated categorical analysis based on all studies included in the QT evaluation report.
Narratives summaries and case report forms	Include location to narratives and case report forms for any of the following: - Deaths - Serious adverse events - Episodes of ventricular tachycardia or fibrillation - Episodes of syncope - Adverse events resulting in the subject discontinuing from the study

Studies included in QT evaluation

Please add additional rows as needed

Study ID	Protocol	CSR	ECG Warehouse ID	ECG collection and analysis methods
Study ID 1	Include link	Include link	Application ID and Study ID used in warehouse upload	Short description of ECG collection (e.g., holter) and analysis methods (e.g., fully-manual or semi-automatic)

Non-clinical studies supporting QT evaluation

Please add additional rows as needed

Study ID	Report	Overview file	Raw data
Nonclinical study 1	Include link	If applicable, include link to an overview file, describing the experimental conditions for each of the raw electrophysiology records. The description should include at a minimum the name of the file, temperature of the recording, when drugs and at what concentrations were added, and other information relevant to interpret the results.	If applicable, include link to Raw and unaltered electrophysiology records (e.g. no baseline subtraction or zero'ing of baseline). The file format for the raw electrophysiology records should be in xls, xlsx or xpt format, and contain at a minimum information about time, voltage and current signals (note specific units for these signals). For current clamp experiments, time and voltage as well as stimulus characteristics.