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 and link to evaluation report
Statistical analysis plan	Include location and link to statistical analysis plan for evaluation report
Investigator's brochure	Include location and link to Investigator's brochure
Highlights of Clinical Pharmacology and Cardiac Safety	Include location and link to completed Highlights of Clinical Pharmacology and Cardiac Safety Table (https://www.fda.gov/media/129685/download)
Datasets	Include location and link 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) For submissions including scanned/digitized paper ECGs (e.g. PDF): analysis datasets should include the automatic ECG measurements (i.e., as automatically generated by the ECG device in the clinical site without any adjustment). If the subject identifiers in the SDTM and ADaM datasets differ from the subject identifiers in the ECG waveform files, then please provide a separate dataset with the mapping between the subject identifiers.
Analysis programs	Include location and link to analysis programs used in the evaluation report
Adverse Event analysis	Include location and link 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 and link to an integrated categorical analysis based on all studies included in the QT evaluation report.
Narratives summaries and case report forms	Include location and link 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	Arms	ECG waveform files	ECG collection and analysis methods for QT characterization
Study ID: Population: e.g., healthy volunteers or patients Design: e.g., cross-over, parallel, or parallel with nested cross-over Protocol: Location and link Report: Location and link	Sample size: Exposure (Cmax) for Highest Dose Group: Placebo: Yes / No Positive control (e.g., moxifloxacin): Yes / No	For all ECGs uploaded through the FDA Electronic Submission Gateway (ESG), we recommend the following location: m5 -> datasets -> [study-id] -> misc -> aecg. (Include location and link) **Digital ECGs:** Digital ECGs with annotations should be submitted in electronic format (XML) following the HL7 annotated ECG (aECG) standard. Provide either the location in the eCTD folder if submitted through the ESG or the Application ID, Study ID and upload ID if submitted through the FDA ECG Warehouse. **Paper ECGs:** Scan paper ECGs into PDF and submit to FDA only if digital ones are not available, preferably organized by site, subject or similar to reduce individual file size.	ECG collection method: e.g., continuous Holter or standard 12-lead. Digital ECG acquisition: Yes/No Name of ECG central laboratory (if applicable): Analysis method: e.g., manual, semi-automatic or fully-automatic. Blinding (if applicable): What were ECG readers were blinded to Replicates: Yes/No Baseline: e.g., pre-dose or time-matched baseline Timing of ECG/PK collection: **Digital ECGs:** - Total number of ECGs (across all subjects) - Number of subjects with ECGs - Planned number of ECGs per subject (per protocol) - Annotation method (i.e., rhythm strip or derived beat); - Primary annotation lead (e.g., II, V5, GLOBAL); - Number of annotated beats per aECG
Non-clinical studies supporting QT evaluation *Please add additional rows as needed*			

Study	Overview file	Raw data
Study ID: Report: Location and link	If applicable, include location and 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 location and 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.