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FIGURE 1: Definition for safety and tolerability adapted from the International Conference for Harmonization (ICH) E9 guideline glossary

- **SAFETY:** The *medical risk* to the subject, usually assessed in a clinical trial by laboratory tests (including clinical chemistry and hematology), vital signs, clinical adverse events (diagnoses, signs and symptoms), and other specific diagnostic tests or evaluations (e.g. ECGs, visual field testing).
- **TOLERABILITY:** The degree to which *overt adverse effects* can be tolerated by the subject.

Adapted from ICH E9 glossary. ⁶