1. Candidate PGx Drug

2. Identify Key PGx Gene(s):
   - Critical review of published and public data
   - Inclusion of gene(s) with at least 1 genetic variant associated with clinically relevant drug response (e.g. altered efficacy or adverse reaction); consistently observed in published studies.

   For each Gene

3. Identify Drug-Specific Key Genetic Variants:
   Review Published/Public data and summarize key gene variant features:
   a) Minimum set of DNA variation(s) defining the functional gene variant
   b) dbSNP ID, nucleotide position, mutation effect on protein function and activity, population frequency, key publications

4. Drug-Specific Gene Variant Evidence Scoring (As described in Table 1)
   - For each variant categorization of Key Publications
   - Score strength of evidence supporting association of each variant with effect on drug response.

5. Partition Variants Based on Evidence
   Drug-specific Clinically Relevant Variants
   - Included variants
   - Variants Lacking Sufficient Evidence
   - Excluded variants

6. Drug-specific Genotype-Phenotype Interpretation
   Evidence code \( \leq 7 \)
   Evidence code \( \geq 8 \)


8. Develop Risk Report
   If Approved
   INCLUDED variants
   EXCLUDED variants

   Possible gap in knowledge – need for further research

Figure 1