Genomics

Genomic Data Submissions – Quick Reference Guide

Submitting data to an:	IND	New (Unapproved) NDA, BLA, or Supplement	Previously Approved NDA or BLA
Known Valid Biomarker	Must be submitted, pursuant to 21 CFR 312.23 (a) (8), (9), (10) (iv) or (11).	Must be submitted, pursuant to 21 CFR 314.50 and 601.2. See section IV.B. of the guidance.	Must be submitted pursuant to 21 CFR 314.81 in annual report and should be submitted pursuant to § 601.12 as synopses or abbreviated reports.
Probable Valid Biomarker	Does not need to be submitted if not used by the sponsor in decision making. *The FDA welcomes voluntary submission of such data in a VGDS.*	The FDA recommends submission, using algorithm in section IV.B. of the guidance.	Must be submitted pursuant to 21 CFR 314.81 in annual report and should be submitted pursuant to § 601.12 as synopses or abbreviated reports.
Exploratory or Research Pharmacogenomic Data	*The FDA welcomes voluntary submission of such data in a VGDS.*	The FDA recommends submission, using algorithm in section IV.B. of the guidance. *The FDA welcomes voluntary submission of such data in a VGDS.*	*The FDA welcomes voluntary submission of such data in a VGDS.*