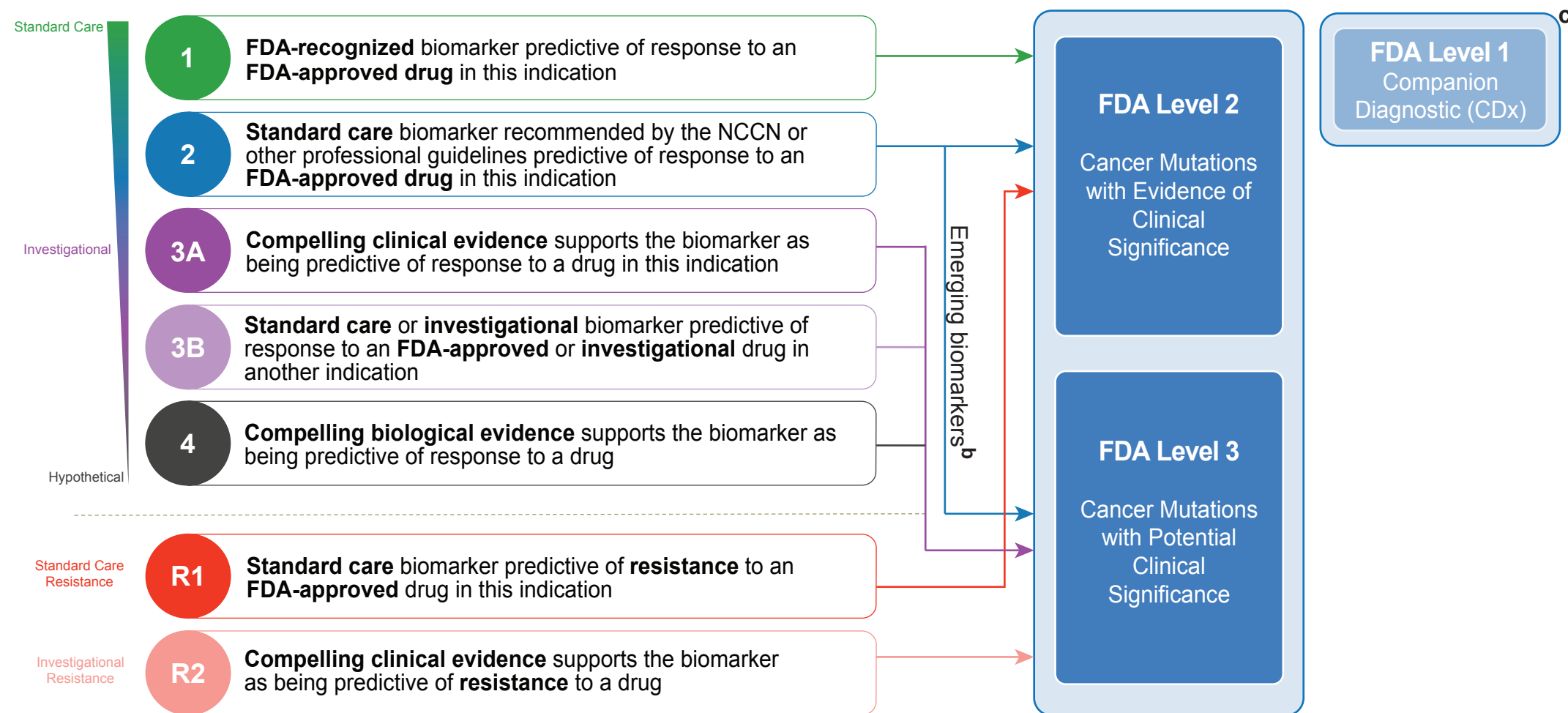


Mapping between the OncoKB Levels of Evidence and the FDA Levels of Evidence

OncoKB Levels of Evidence

FDA Levels of Evidence^a



Footnotes

^a The FDA levels of evidence presented here are modified from the FDA white paper titled “CDRH’s approach to tumor profiling next-generation sequencing tests”.

^b **Emerging biomarkers** are defined as those alterations listed as a NCCN guideline category 2A biomarker based on limited clinical data, for example early Phase I and Phase II clinical studies with limited patient data/responses. They qualify as OncoKB Level 2, but map to FDA Level 3. For example, ERBB2 exon 20 insertions and mutations in NSCLC based on a basket study of Ado-Trastuzumab Emtansine.

^c Since OncoKB does not include any companion diagnostic claims prescriptive for a specific therapeutic product, by definition, no variants in OncoKB are considered FDA Level 1.