

Assigning Causality

- Key element in decision to file to FDA
 - Note: Investigator reports causality but sponsor retains final decision on causality when filing to the FDA
- Key element in defining a Suspected Adverse Reaction
 - “Reasonable possibility” is specifically defined in Final Rule: it means there is evidence to suggest a causal relationship between the drug and AE
 - Reasonable possibility = possibly, probably, or definitely related

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**Conrad G. Brunk, Lawrence
Haworth, Brenda Lee**



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