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Conflict of Interest Statement

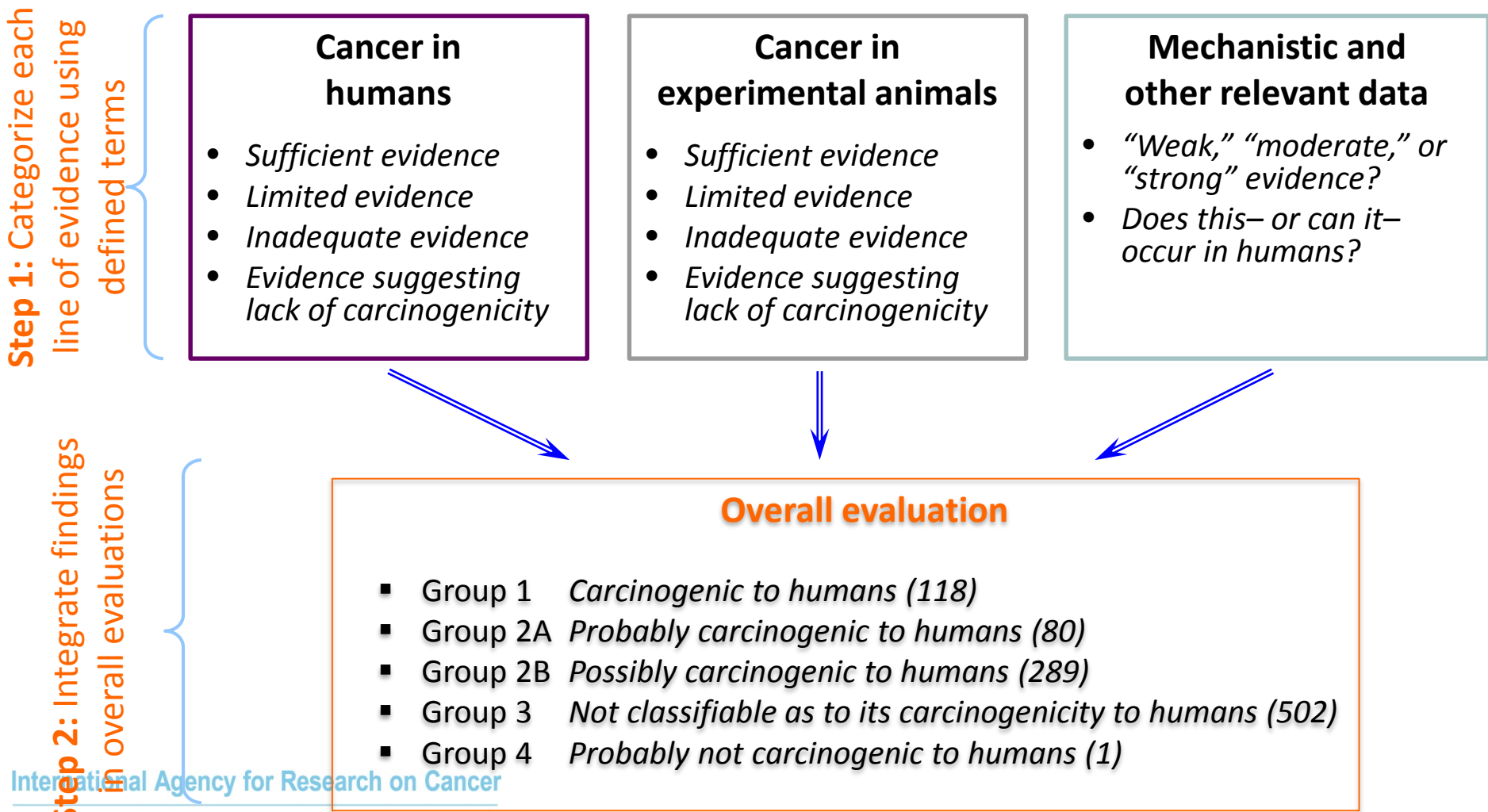
I declare no financial interests related to the subject matter of my presentation.



Session 3 Science Topic:

Use of 2-stage carcinogenicity bioassays

The IARC Monographs Evaluations: *A Two-Step Process*



Cancer in Experimental Animals: *Categories of Evidence*

Cancer in humans

Cancer in experimental animals

— Preamble Part B, Section 6(b)

Mechanistic and other relevant data

Sufficient evidence

Causal relationship has been established through either:

- Multiple positive results (2 species, studies, sexes of GLP)
- Single unusual result (incidence, site/type, age, multi-site)

Limited evidence

Data suggest a carcinogenic effect but: (*e.g.*) single study, design ?s, benign tumours only, promoting activity only

Inadequate evidence

Studies permit no conclusion about a carcinogenic effect

Evidence suggesting lack of carcinogenicity

Adequate studies in at least two species show that the agent is not carcinogenic
Conclusion is limited to the species, tumour sites, age at exposure, and conditions and levels of exposure studied

Cancer in Experimental Animals: *Limited Evidence*

Cancer in
humans

Cancer in
experimental animals

— Preamble Part B, Section 6(b)

Mechanistic and
other relevant data

The data suggest a carcinogenic effect but are limited for making a definitive evaluation because, e.g.:

- (a) the evidence of carcinogenicity is restricted to a single experiment;
- (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies;
- (c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or
- (d) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.