

- We review data in >9,000 patients included in 21 phase 2b/3 dapagliflozin clinical trials of up to 208 weeks' duration, to illustrate the challenges in assessing the effects of glucose-lowering drugs on bladder cancer.
- Overall, 9/5,936 dapagliflozin-treated patients and 1/3,403 comparator-treated patients reported bladder cancer (incidence rate ratio 5.168, 95% confidence interval: 0.677, 233.55); all within 2 years of starting the study.
- Of the nine dapagliflozin-treated patients with bladder cancer, eight had microscopic hematuria prior to or within 6 months of study start.
- Evidence to date does not suggest a causal relationship between dapagliflozin and bladder cancer; our manuscript illustrates how diagnostic latency and inconsistency in adherence to guidelines for bladder cancer detection, even in a higher risk population, can lead to potential detection biases.
- Any firm conclusion cannot be made without additional clinical data, and as such, bladder cancer events are being carefully investigated in ongoing trials of dapagliflozin.

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