MasterClass in Bladder Cancer 2026

Neoadjuvant/perioperative therapy is the best option

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HENDERE HEALTHCARE
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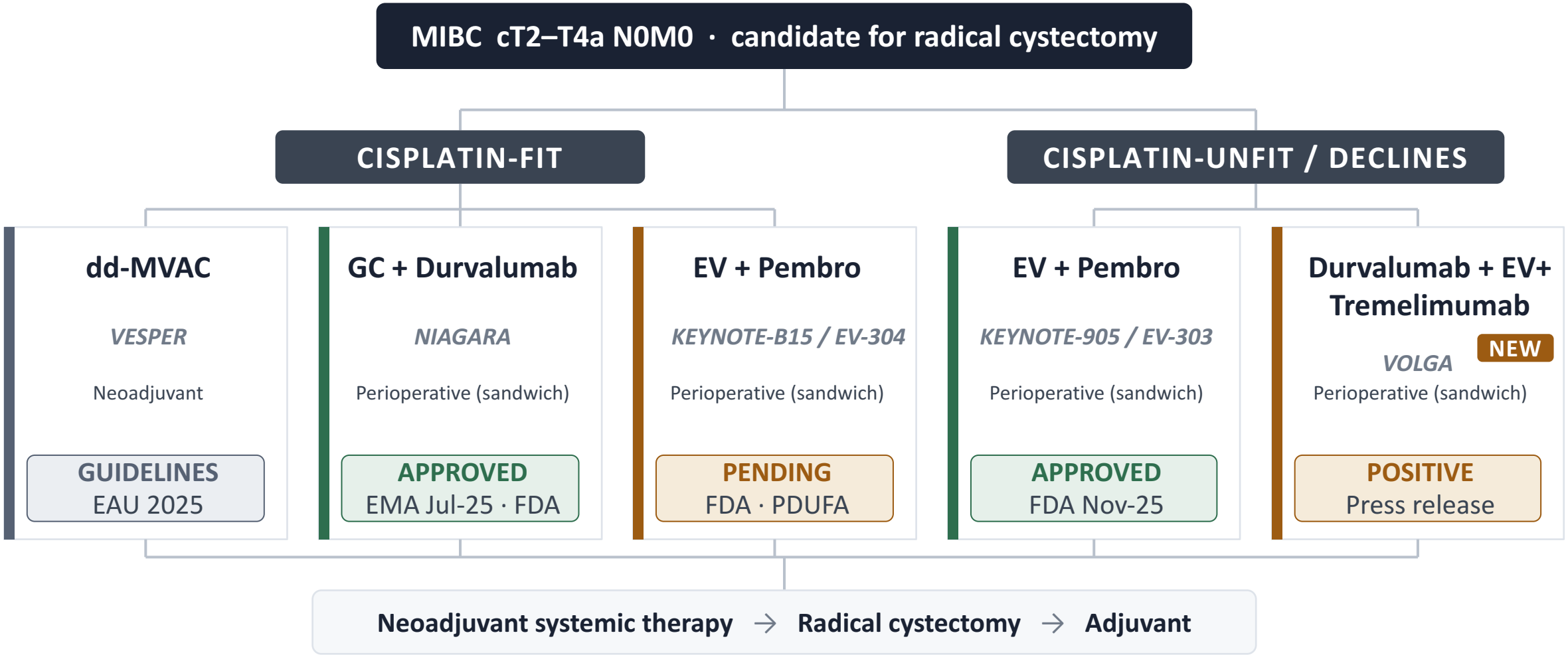
Perioperative Treatment Algorithm — MIBC 2026

Regimen selection by cisplatin eligibility · regulatory status as of May 2026



dd-MVAC: neoadjuvant chemotherapy only (no adjuvant immunotherapy). EV = enfortumab vedotin · GC = gemcitabine–cisplatin · ICI = immune checkpoint inhibitor · PDUFA = FDA target action date · CHMP = EMA committee positive opinion.

The Expanding Cisplatin-Eligible Population

From Galsky criteria to the cisplatin-independent era

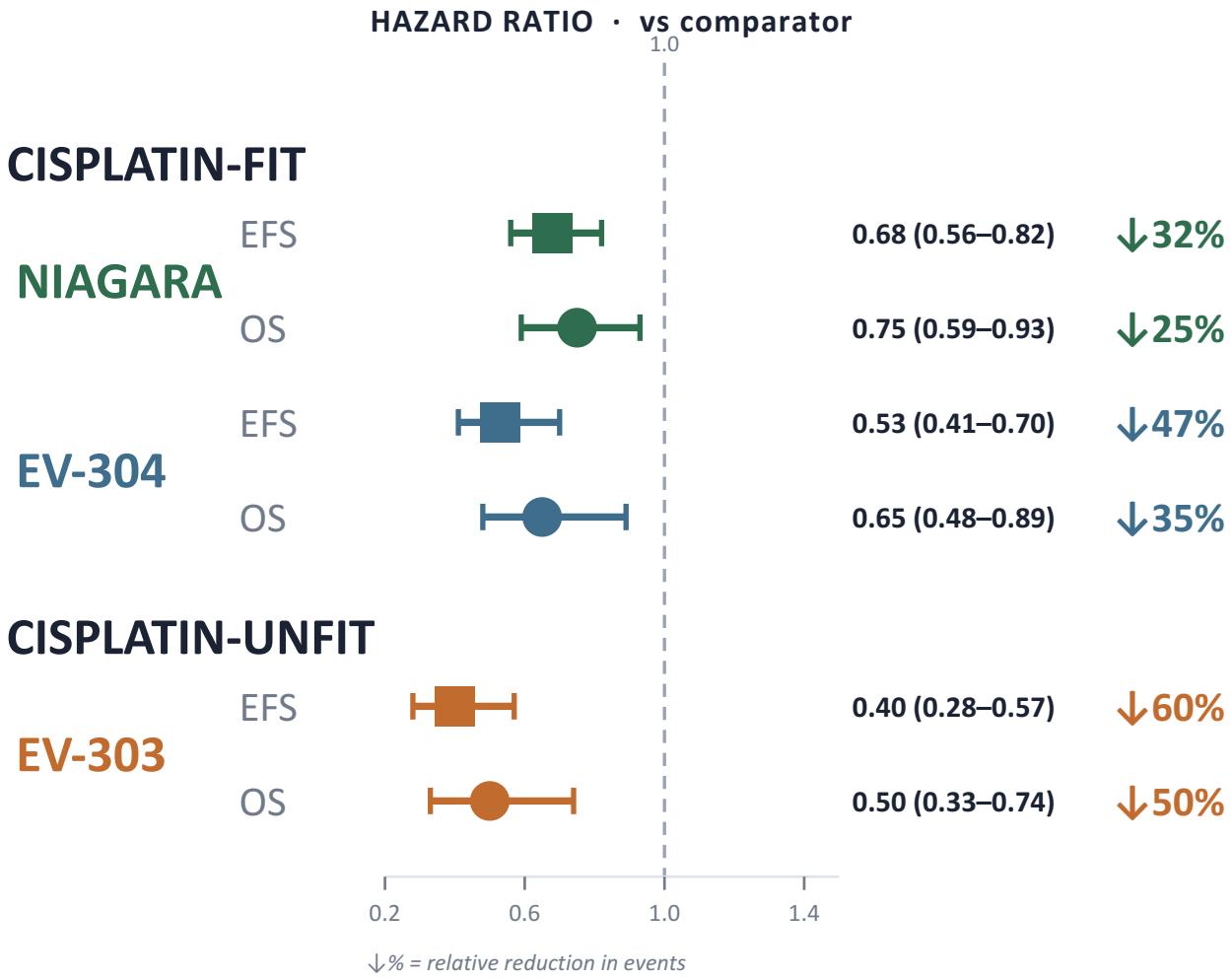
≈ 50% → **85–90%**

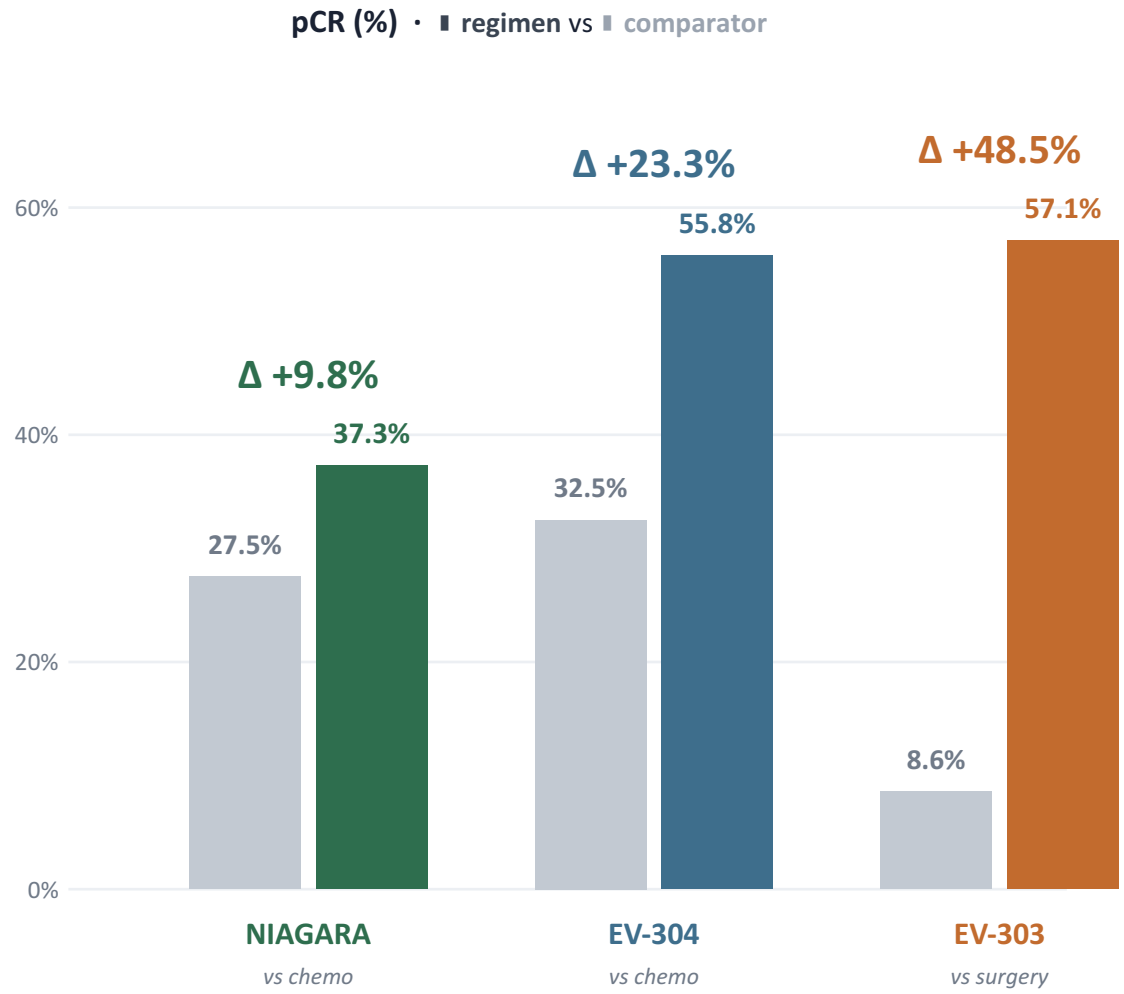
of patients now cisplatin-eligible → split-dose cisplatin and cisplatin-free regimens widen the gate

10–15% REMAIN INELIGIBLE — *it is not "everyone"*

- Frailty
- IO contraindication (autoimmune, transplant)
- Pure non-urothelial subtypes
- Severe organ dysfunction
- Refuses all systemic therapy / inoperable

Efficacy Across Endpoints — Every Regimen Beats Its Comparator

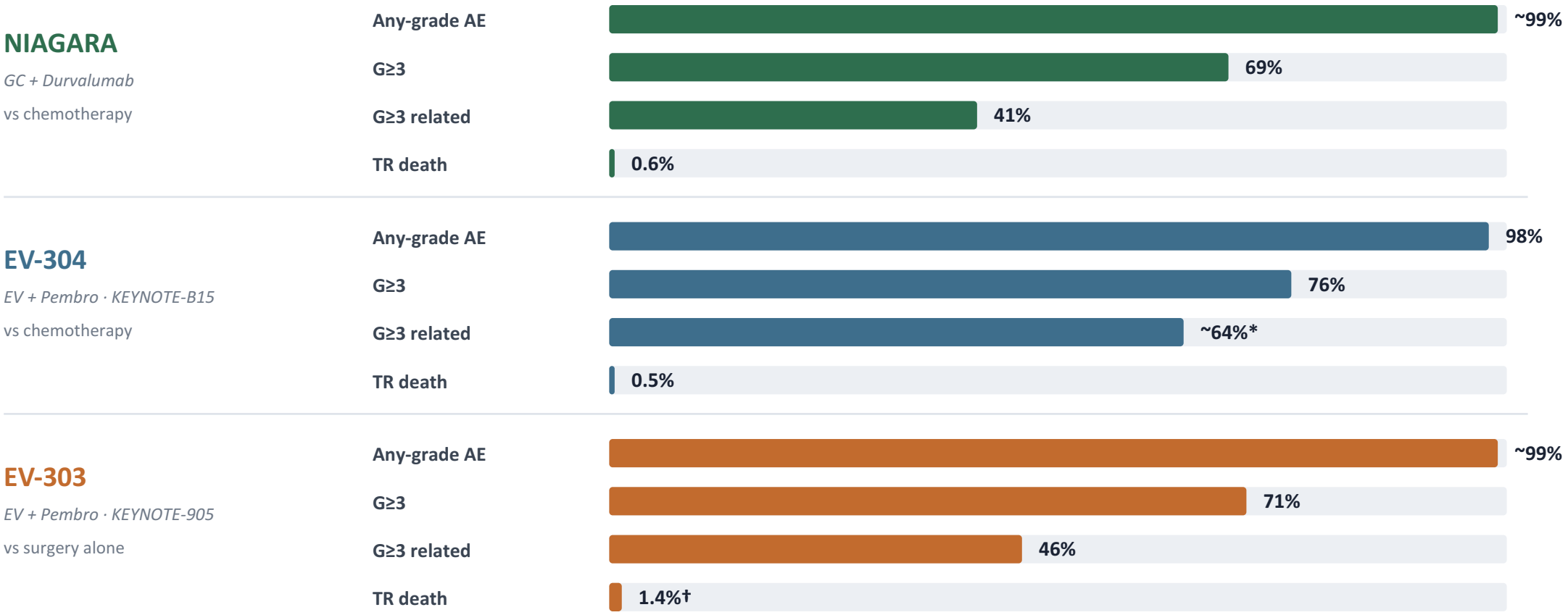




Not a head-to-head — comparators, populations and endpoints differ; EV-303 is vs surgery alone (control pCR 8.6%). Read each row against its own comparator.

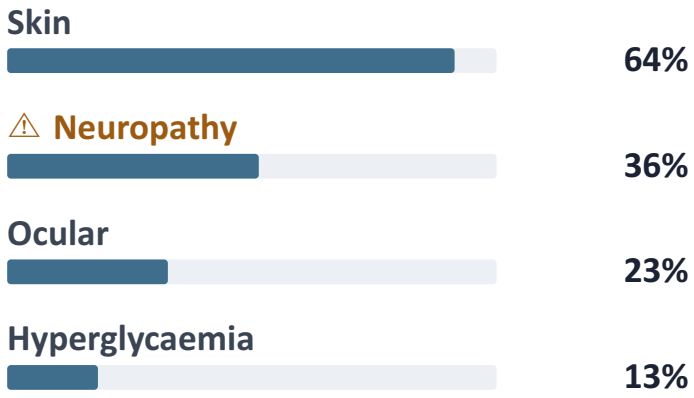
Toxic, Not Lethal

Almost every patient has some toxicity and high-grade events are common — but treatment-related death is rare



Different Drugs, Different Signatures — Shared Immune Backbone

EV-SPECIFIC
antibody-drug conjugate



→ *drives de-intensification (drop EV, keep the IO)*

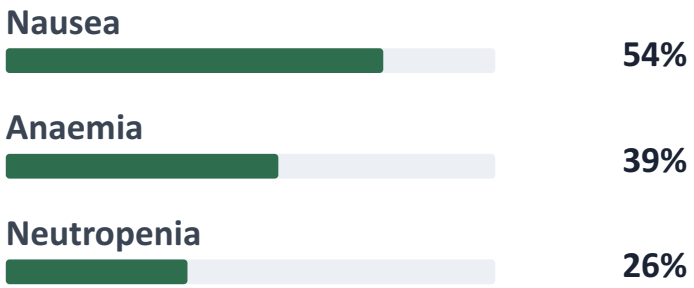
SHARED — IMMUNE BACKBONE
occur with both regimens

- Hypothyroidism
- Pneumonitis
- Colitis
- Hepatitis

e.g. hypothyroidism ~10–12%
similar in both regimens

→ *same IO engine in both*

CHEMO-SPECIFIC
cisplatin / gemcitabine



→ *front-loaded, largely reversible*

Principles of the Existing Evidence: The Trials Tested the Whole Sequence

✓ WITHIN THE EVIDENCE

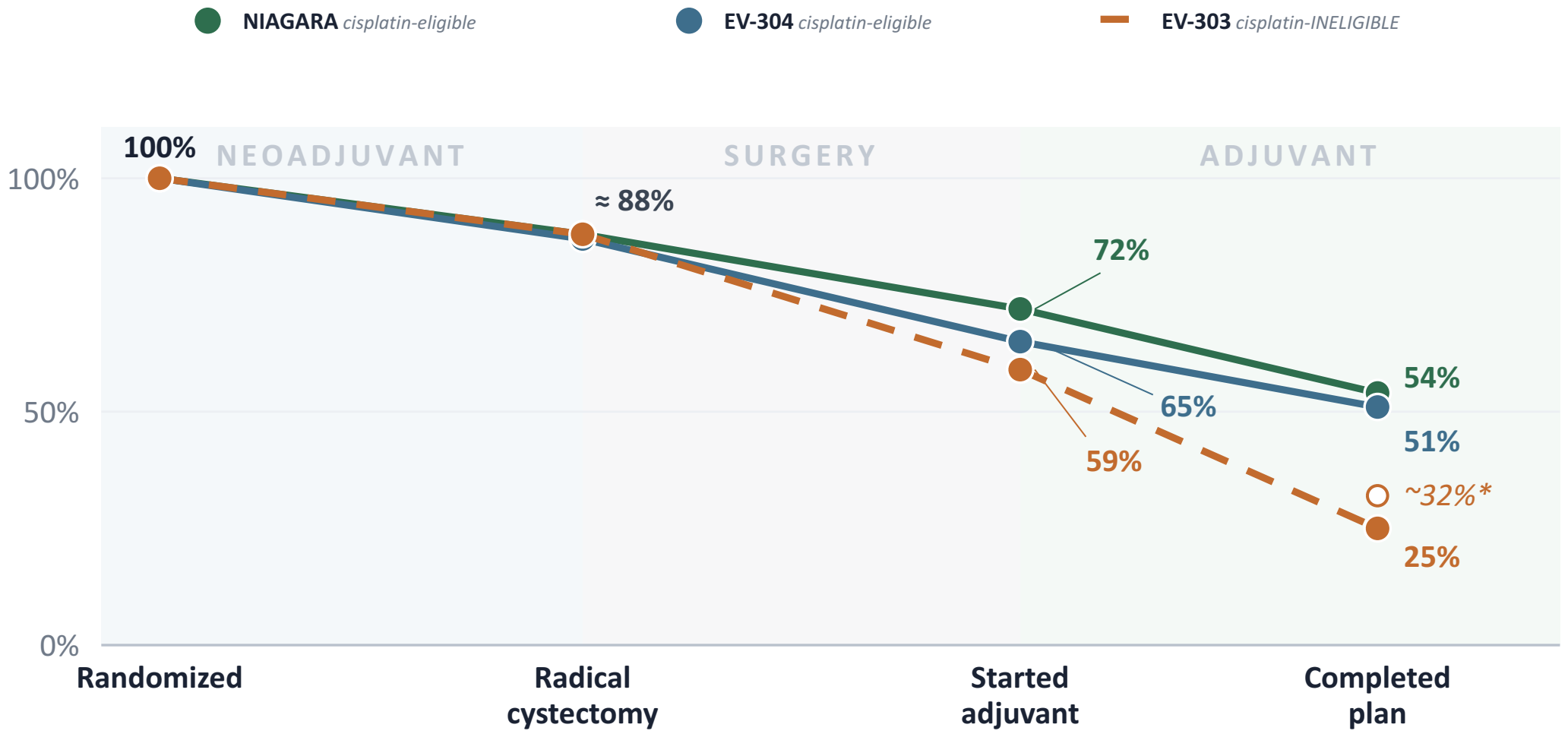
- ✓ **Radical cystectomy + PLND** — in every trial
- ✓ **De-intensify *within* a phase** — lower dose, or drop one drug and continue the other

✗ OUTSIDE THE EVIDENCE

- ✗ **Declining cystectomy / bladder-sparing** with these regimens
- ✗ **Omitting an entire phase** — e.g. skipping adjuvant altogether

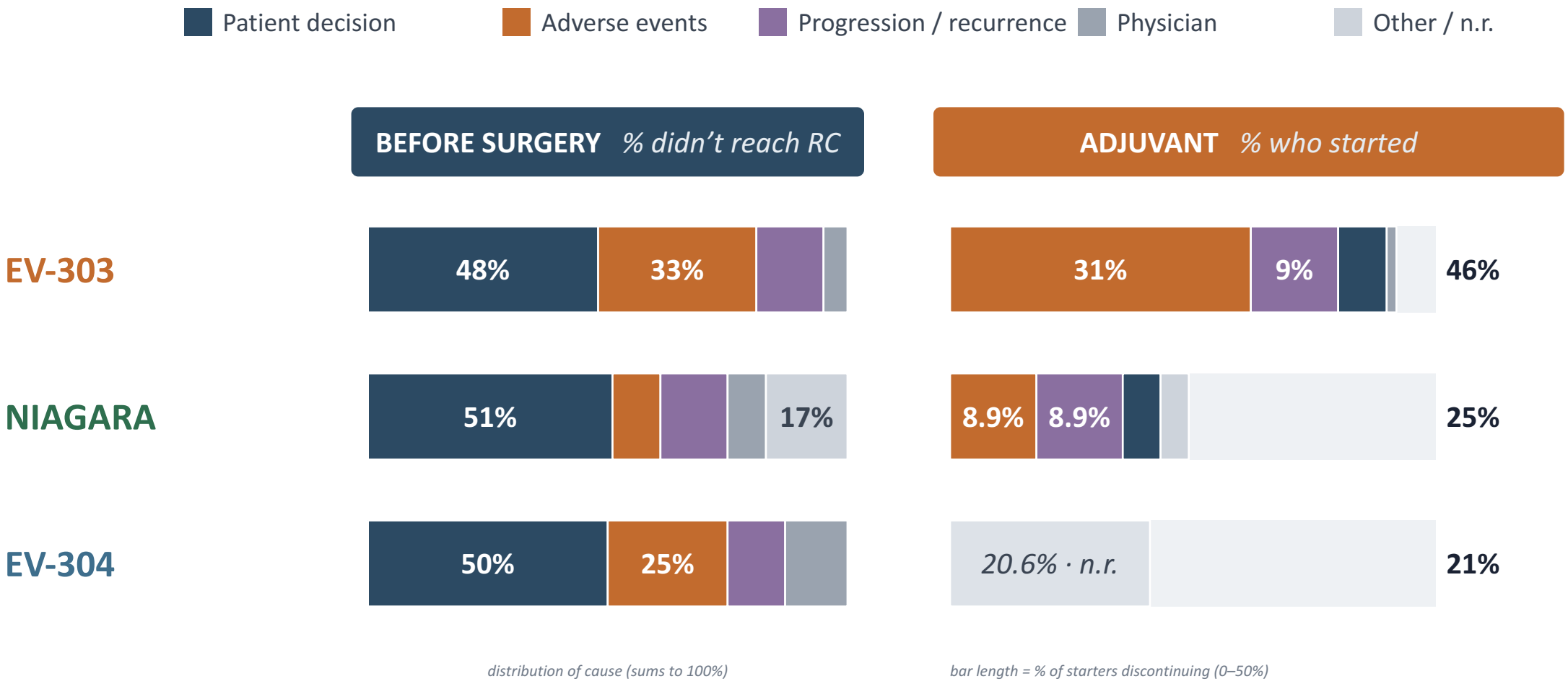
The validated unit is the **full perioperative regimen with radical surgery**. De-intensify ***within*** a phase — never by ***omitting*** one.

Most Reach Surgery — *Few Finish the Whole Plan*



88% still reach radical surgery; the adjuvant phase is what often goes unfinished.

What Drives Attrition — *by Trial, and It Shifts*



Before surgery the bottleneck is the patient's choice; in the adjuvant it becomes adverse events

Take-Home

1. **Perioperative is the standard — fit and unfit.** *The eligibility bottleneck is broken.*

2. **The validated unit is the full regimen with radical surgery —** *flex the systemic, not the surgery.*

3. **The next question isn’t more treatment —** *it’s how much less, and for whom.*