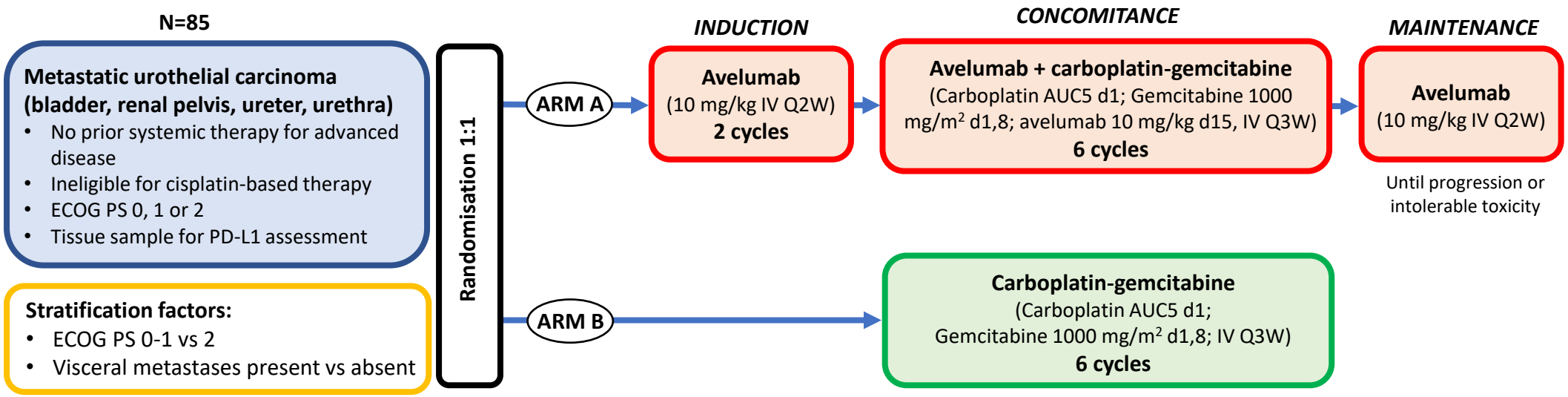
N=85
Metastatic urothelial carcinoma (bladder, renal pelvis, ureter, urethra)
• No prior systemic therapy for advanced disease
• Ineligible for cisplatin-based therapy
• ECOG PS 0, 1 or 2
• Tissue sample for PD-L1 assessment
Stratification factors:
• ECOG PS 0-1 vs 2
• Visceral metastases present vs absent
Randomisation 1:1
ARM A
ARM B
INDUCTION
Avelumab
(10 mg/kg IV Q2W)
2 cycles
CONCOMITANCE
Avelumab + carboplatin-gemcitabine
(Carboplatin AUC5 d1; Gemcitabine 1000 mg/m² d1,8; avelumab 10 mg/kg d15, IV Q3W)
6 cycles
MAINTENANCE
Avelumab
(10 mg/kg IV Q2W)
Until progression or intolerable toxicity
Carboplatin-gemcitabine
(Carboplatin AUC5 d1;
Gemcitabine 1000 mg/m² d1,8; IV Q3W)
6 cycles