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NAPOLI 3 Trial Deep Dive: ASCO 2025 Updated OS Analysis

Author(s) [Paul E. Oberstein, MD](#), [Priyadarshini Pathak, MBBS](#), [Tara E. Seery, MD](#)

Panelists discuss how the PRODIGE-4 and NAPOLI-3 trials differed in patient populations, age limits, and comparator arms, leading to similar regimens with dosage modifications that have become standard practice.



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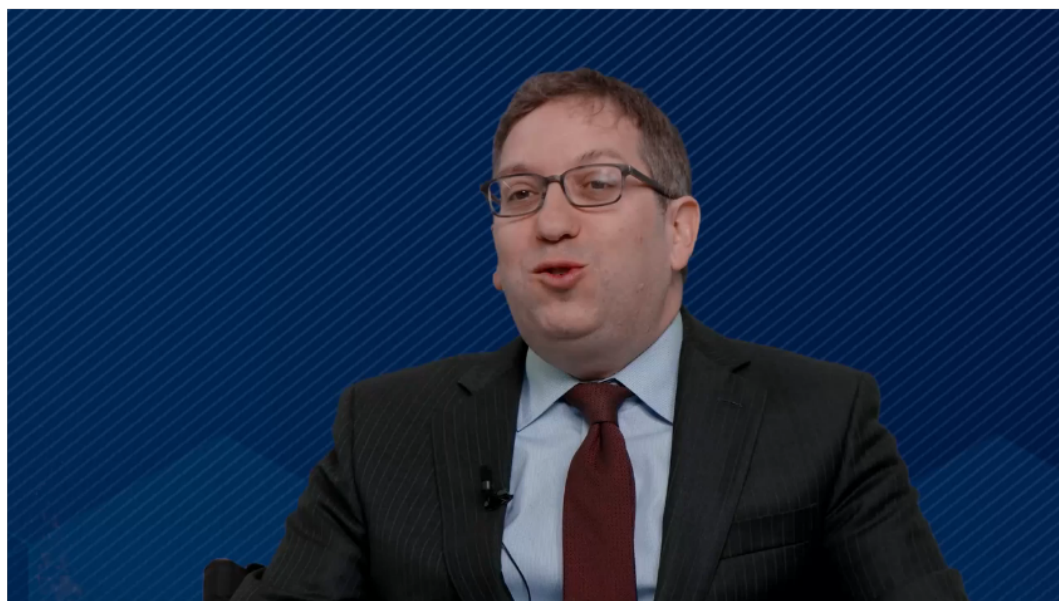
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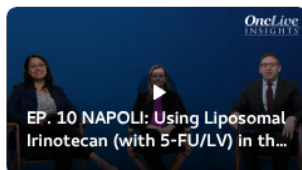
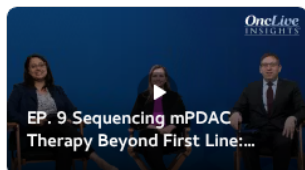
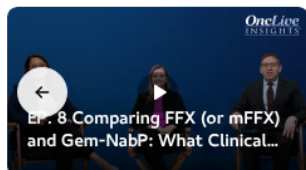
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NAPOLI-3 and PRODIGE-4 trials, conducted approximately 15 years apart, represent pivotal studies in metastatic pancreatic cancer treatment but differ significantly in design and patient populations. PRODIGE-4

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The NAPOLI-3 and PRODIGE-4 trials, conducted approximately 15 years apart, represent pivotal studies in metastatic pancreatic cancer treatment but differ significantly in design and patient populations. PRODIGE-4 was a more selective, single-country study excluding patients over 75 years, comparing FOLFIRINOX with gemcitabine monotherapy in a younger, more homogeneous population. In contrast, NAPOLI-3 included patients up to 85 years old, representing a more diverse, global population comparing NALIRIFOX with gemcitabine plus nab-paclitaxel standard of care.

The trial design differences reflect evolving standards of care, with NAPOLI-3 using the more contemporary gemcitabine/nab-paclitaxel comparator rather than single-agent gemcitabine. Both studies involved metastatic pancreatic adenocarcinoma patients, but NAPOLI-3's broader inclusion criteria and larger, more heterogeneous patient population potentially provide more generalizable real-world applicability. The oxaliplatin dosing modifications in NALIRIFOX compared with original FOLFIRINOX reflect lessons learned about tolerability optimization.

Modern clinical practice has universally adopted modified FOLFIRINOX dosing rather than the original full-dose regimen due to tolerability concerns, making direct trial comparisons challenging. The evolution from PRODIGE-4 to NAPOLI-3 demonstrates the field's progress in developing more tolerable yet effective treatment combinations. These trials collectively established triplet chemotherapy as the standard of care for fit patients with metastatic pancreatic cancer, though direct head-to-head comparisons remain absent.



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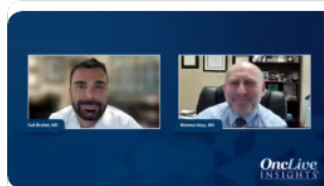
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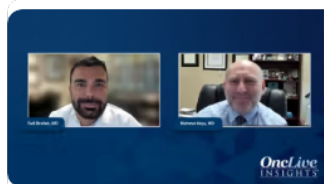
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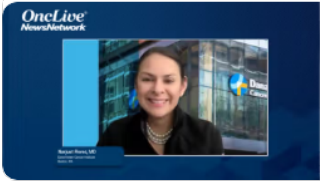
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