Clinical Trials by Phase

**Phase 1: Is it Safe?**
- First in human; small numbers of patients
- Focus is safety
- Determine what the drug does to the body and what the body does with the drug
- Determine the maximum tolerated dose (MTD)
- No placebo

**Phase 2: Does It Work?**
- Further tests MTD frequently in specific cancers
- Average of 25 to 100 patients
- Ongoing monitoring for safety
- No placebo
- Trend is small “proof of principle” trials; 25 to 35 patients

**Phase 3: Is it Better Than What Is Already Available?**
- Larger number of patients (100s)
- Randomized
- Compared with standard approved therapies
- May be blinded or double-blinded
- May use a placebo
- Often available in community oncology practices

**Phase 4: Testing Factors After Approval**
- Study of approved drug
- Ongoing safety, other indications, etc

Clinical trials can be an important therapeutic tool for the treatment of pancreatic cancer. Let’s Win offers information for patients on therapies being tested in clinical trials: [letswinpc.org/clinical-trials](letswinpc.org/clinical-trials). Others include Pancreatic Cancer Action Network ([clinicaltrials.pancan.org](clinicaltrials.pancan.org)) and [clinicaltrials.gov](clinicaltrials.gov).

## Ongoing Trials of Immunotherapy in Metastatic Pancreatic Cancer

<table>
<thead>
<tr>
<th>Phase</th>
<th>Trial</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Frontline</strong></td>
<td>NCT04377048</td>
<td>Nivolumab Adding on Gemcitabine/S-1</td>
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<tr>
<td>Phase 2</td>
<td>TEDOPAM (NCT03806309)</td>
<td>Maintenance Therapy With OSE2101 Vaccine ± Nivolumab, or FOLFIRI, After Induction Therapy With FOLFIRINOX</td>
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<tr>
<td>Phase 2</td>
<td>COMBAT/KEYNOTE-202 (NCT02826486)</td>
<td>BL-8040 + Pembrolizumab ± Irinotecan + Leucovorin + 5-FU</td>
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<td>Phase 2</td>
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<td>Azacitidine + Pembrolizumab</td>
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<tr>
<td>Phase 2</td>
<td>NCT0310443</td>
<td>Nivolumab + Ipilimumab (MSS or MSI-High Disease)</td>
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<td></td>
<td>DOME (NCT04262388)</td>
<td>Durvalumab + Oleclumab</td>
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<tr>
<td>Phase 1/2</td>
<td>NCT03816358</td>
<td>Anetumab Ravtansine + Nivolumab ± Ipilimumab or Gemcitabine</td>
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<tr>
<td>Phase 1</td>
<td>NCT02757391</td>
<td>CD8+ T Cell Therapy and Pembrolizumab</td>
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<td>NCT02754726</td>
<td>Nivolumab + cisplatin + paricalcitol</td>
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<td>NCT0306302</td>
<td>Epacadostat + Pembrolizumab + CRS-207 ± GVAX Pancreas Vaccine</td>
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<td>NCT0319025</td>
<td>CRS-207 + Nivolumab + Ipilimumab + GVAX/Cy</td>
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<td>NCT04361162</td>
<td>Nivolumab + Ipilimumab + Radiation (MSS Disease)</td>
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<td>NCT01174121</td>
<td>Tumor Infiltrating Lymphocytes + Pembrolizumab</td>
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<td>NCT03250273</td>
<td>Entinostat + Nivolumab</td>
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<td></td>
<td>CheckPAC (NCT02866383)</td>
<td>Nivolumab ± Ipilimumab With Radiotherapy</td>
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<td>NCT03193190</td>
<td>Atezolizumab-Based Combinations</td>
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<td>Epacadostat + Pembrolizumab + CRS-207 ± GVAX Pancreas Vaccine</td>
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<td>NCT04007744</td>
<td>Sonidegib and Pembrolizumab</td>
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<td></td>
<td>NCT04050085</td>
<td>SD-101, Nivolumab, and Radiation Therapy</td>
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</table>

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## Other Ongoing Trials in Metastatic Pancreatic Cancer

<table>
<thead>
<tr>
<th>Category</th>
<th>Status</th>
<th>Phase</th>
<th>Study Identifier</th>
<th>Description</th>
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<tr>
<td>PARP Inhibitors in First-Line Maintenance</td>
<td>Recruiting</td>
<td>Phase 2</td>
<td>NCT03140670</td>
<td>First-Line Maintenance Rucaparib (BRCA1-, BRCA2-, or PALB2-Mutated Patients)</td>
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<td>Recruiting</td>
<td>Phase 1/2</td>
<td>NCT01954992</td>
<td>Glufosfamide vs 5-FU</td>
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<td>Phase 1/2</td>
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<td>Olaratumab + Nab-paclitaxel + Gemcitabine</td>
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<tr>
<td>First-Line: Other Emerging Agents</td>
<td>Active, Not Recruiting</td>
<td>Phase 2</td>
<td>NCT02890355</td>
<td>FOLFIRI or mFOLFIRI and Veliparib</td>
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<tr>
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<td>Recruiting</td>
<td>Phase 2</td>
<td>NCT02498613</td>
<td>Olaparib + Cediranib</td>
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<tr>
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<td>Recruiting</td>
<td>Phase 2</td>
<td>NCT03126435</td>
<td>EndoTAG-1 + Gemcitabine</td>
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<td>Recruiting</td>
<td>Phase 2</td>
<td>DESTINY-PanTumor02 (NCT04482309)</td>
<td>Trastuzumab Deruxtecan in HER2-Expressing Tumors</td>
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<td>Recruiting</td>
<td>Phase 1/2</td>
<td>NCT03368963</td>
<td>Nal-IRI + TAS-102</td>
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<tr>
<td>Previously Treated: PARP Inhibitors</td>
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<td>Phase 2</td>
<td>NCT02677038</td>
<td>Olaparib (BRCA-ness Phenotype)</td>
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<td>NCT02890355</td>
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<td>NIRA-PANC (NCT03553004)</td>
<td>Niraparib After Previous Chemotherapy</td>
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<td>Phase 3</td>
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<td>EndoTAG-1 + Gemcitabine</td>
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<tr>
<td>Previously Treated: Other Emerging Agents</td>
<td>Recruiting</td>
<td>Phase 2</td>
<td>NAPAN (NCT03986294)</td>
<td>Nal-IRI + S1</td>
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<td>NIRA-PANC (NCT03553004)</td>
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<td>FOLFIRI or mFOLFIRI and Veliparib</td>
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### Ongoing Trials of Immunotherapy in Resectable and Locally Advanced Pancreatic Cancer

<table>
<thead>
<tr>
<th>Trial ID</th>
<th>Study Details</th>
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<tbody>
<tr>
<td>NCT03727880</td>
<td>Pembrolizumab + Defactinib (Neoadjuvant/Adjuvant)</td>
<td>Phase 2</td>
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<tr>
<td>NCT03572400</td>
<td>Neoadjuvant CCRT With Gemcitabine + Durvalumab Adjuvant Gemcitabine/ Durvalumab</td>
<td>Phase 1/2</td>
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<tr>
<td>UVA-PC-PD101 (NCT02305186)</td>
<td>Neoadjuvant Pembrolizumab ± Chemoradiotherapy</td>
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<tr>
<td>NCT02648282</td>
<td>CY + Pembrolizumab + GVAX + SBRT</td>
<td>Phase 2</td>
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<tr>
<td>NCT03161379</td>
<td>GVAX + CY + Nivolumab + SBRT in Borderline-Resectable Pancreatic Cancer</td>
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<tr>
<td>MIMIPAC (NCT04156087)</td>
<td>Durvalumab + Tremelimumab + Microwave Ablation for Unresectable Locally Advanced Pancreatic Cancer</td>
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### Other Ongoing Trials in Resectable and Locally Advanced Pancreatic Cancer

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<tr>
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<tbody>
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<td>Phase 2</td>
<td>NCT02562716</td>
<td>Neoadjuvant Nab-paclitaxel + Gemcitabine or FOLFIRINOX</td>
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<td>Phase 2</td>
<td>NCT02125136</td>
<td>Neoadjuvant Nab-paclitaxel + Gemcitabine vs Nab-paclitaxel + Gemcitabine + FOLFIRINOX</td>
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<tr>
<td>Phase 3</td>
<td>NCT02481635</td>
<td>Neoadjuvant Gemcitabine + Nab-paclitaxel + Radiation</td>
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<td>Phase 3</td>
<td>NCT02723331</td>
<td>Perioperative Nab-paclitaxel + Gemcitabine</td>
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<td>Phase 2</td>
<td>NCT02047513</td>
<td>Neoadjuvant Plus Adjuvant or Only Adjuvant Nab-paclitaxel + Gemcitabine</td>
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<td>FOLFIRINOX ± SBRT</td>
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<tr>
<td>Phase 2</td>
<td>NCT01792855</td>
<td>TTFields + Nab-paclitaxel + Gemcitabine</td>
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<td>Phase 2</td>
<td>NCT03377491</td>
<td>Neoadjuvant Nab-paclitaxel + Gemcitabine or FOLFIRINOX</td>
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<td>Phase 2</td>
<td>NCT03861702</td>
<td>Nal-IRI + oxaliplatin + LV + 5-FU (NALIRIFOX)</td>
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<td>Intra-arterial Gemcitabine</td>
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<td>Intratumoral Sterile Nanoparticulate Paclitaxel</td>
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<td>FOLFIRINOX ± SBRT</td>
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<td>NanoKnife System</td>
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Types of Pancreatic Cancer

- Ductal adenocarcinoma (most common)
- Acinar cell carcinoma
- Intraductal papillary mucinous carcinoma
- Pancreatoblastoma
- Neuroendocrine

Normal Function of the Pancreas

- Produces digestive enzymes (exocrine cells)
- Helps to regulate blood sugar (endocrine cells)

Disease Symptoms

- Jaundice
- Pain in the back or abdomen
- Fatigue
- Loss of appetite/unintended weight loss
- Nausea and vomiting
- Acute pancreatitis attacks
- New onset diabetes
- Diarrhea

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Your patient with pancreatic cancer may have questions about clinical trials. This guide provides advice for answering some of the questions patients commonly ask about clinical trials. Additional resources for patients can be found in the references.

**What is a clinical trial?**
A clinical trial is a research study involving human volunteers to help determine if new treatments are safe, effective, or better in some way than standard treatments.

**What are the benefits?**
You may have access to new treatments which are not available outside of a clinical trial. If the treatment is effective, you may be one of the first to benefit. During the trial you will be closely monitored. Patients who participate in clinical trials help advance cancer treatments.

**What are the risks?**
All clinical trials have some risk. The new treatment may not be better than the current standard of care or may help only some of the patients. Side effects of the new treatment might be worse than expected or than the standard treatment. Because patients in clinical trials are closely monitored they may have more doctor visits and more tests to determine the effects of treatment.

**Will I get the placebo?**
Not all clinical trials have a placebo group. You should ask if a trial you are considering has a placebo group and what the chances are that you may be in the placebo group. Placebos are given with the best available treatment for your cancer. If there is no treatment for your cancer, you will receive the best supportive care plus placebo.

**What is informed consent?**
Every patient in a clinical trial is given an informed consent form that they review with a member of the clinical team. After reading the document and obtaining answers to any questions you may have, you will be asked to sign the document.

**Can I leave a clinical trial?**
Yes. You may leave at any time, for any reason.

**Should I enroll in a clinical trial?**
Only the patient can make this decision. Clinicians can provide information and resources to the patient and caregivers and answer questions. Clinical professionals may also search for and help determine eligibility of a patient for a clinical trial.
COVID-19: GUIDANCE ON HOW TO COMMUNICATE TO PATIENTS WITH CANCER

What You Might Say

“If it’s OK, I’d like to try to explain why we are doing things this way.”
- We expect/have a surge in people with COVID-19 here
- The number of people needing care will soon be/is greater than resources (hospital beds, doctors, and medical supplies)
- This has impacted how we are treating our patients with cancer during this difficult time
- As more patients with COVID-19 come into the health system, we need to think carefully about how to:
  - Take the best care of you and optimize your cancer treatment
  - Protect you and others from getting the virus

“I have talked with leaders in the cancer center and my colleagues and thought hard about your case. I/we think the best plan would be [your recommendation].”

“It sounds like you’re scared about delaying your treatment. I want you to know that I want what’s best for you. I wish we could have continued our original plan/schedule.”
- I believe this new plan is a safe/the best way to manage your care over the next few months
- I believe this new plan will reduce your risk of being exposed to the virus
- I believe this new plan will help keep your immune system strong while the virus is spreading in the community

“Part of the difficulty is the uncertainty of how long this will last. Through all of this, I will be your doctor, and we will work together to get you the best possible care.”
- The best way for us to stay in touch would be [method]
- The best things you can do to stay safe are [link to patient resources]
- The cancer center also has more resources [link to patient resources]
Algorithm of Systemic Treatment Selection for Metastatic Pancreatic Cancer

**Patients With Good PS**

**First Line Options**
- Preferred Regimens
  - Nab-paclitaxel + gemcitabine
  - FOLFIRINOX or mFOLFIRINOX
- BRCA1/2 or PALB2 Mutations
  - FOLFIRINOX or mFOLFIRINOX
  - Gemcitabine + cisplatin

**If stable disease**

**Maintenance Options**
- Nab-paclitaxel + gemcitabine (modified schedule)
- Gemcitabine
- Preferred: FOLFIRI
- Other Recommended Regimens:
  - FOLFOX
  - Capecitabine
- Previous Platinum-Based CTX and Germline BRCA1/2 mutations
  - Olaparib

**If disease progression**

**Second Line Options**
Selection is based on prior fluoropyrimidine-based or gemcitabine-based therapy
- Nal-IRI + 5-FU/LV
- FOLFIRI, (m)FOLFIRINOX, FOLFOX, OFF, capecitabine ± oxaliplatin, continuous 5-FU
- Gemcitabine
- Gemcitabine + nab-paclitaxel
- Gemcitabine + cisplatin (only for known BRCA1/2 mutations)

**Maintenance Therapy**
Maintenance therapy is used to extend the time that a patient’s cancer will remain stable, or without tumor progression, after initial treatment. Clinical trials have shown that maintenance therapy in patients with pancreatic cancer is feasible, safe, and can significantly prolong the time to disease progression. The NCCN guidelines recommends that patients with metastatic disease who have response or stable disease after 4-6 months of chemotherapy may undergo maintenance therapy.

**Targeted Therapy Options**
- MSI-H/dMMR Tumors:
  - Pembrolizumab
- TMB-High Tumors:
  - Pembrolizumab
- NTRK Fusion-Positive Tumors:
  - Larotrectinib
  - Entrectinib
- BRCA1/2-mutant Tumors:
  - Olaparib in frontline maintenance setting

**Germline Testing**
The NCCN recommends germline testing for any patient with confirmed pancreatic cancer and tumor/somatic gene profiling for patients with locally advanced/metastatic disease who are candidates for anti-cancer therapy, to identify actionable mutations that could provide a personalized treatment recommendation for the patient.

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Algorithm of Systemic Treatment Selection for Metastatic Pancreatic Cancer

First Line Options

- Gemcitabine: 1,000 mg/m² over 30 minutes, weekly for 3 weeks every 28 days
- Gemcitabine: fixed-dose-rate (10 mg/m²/min) may substitute for gemcitabine over 30 minutes
- Capecitabine
- Continuous infusion 5-FU
- Molecular-Based Treatment Options
  - MSI-H/dMMR Tumors:
    - Pembrolizumab
  - NTRK Fusion-Positive Tumors
    - Larotrectinib
    - Entrectinib

Second Line Options

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- Continuous infusion 5-FU
- Molecular-Based Treatment Options
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    - Pembrolizumab
  - TMB-High Tumors
    - Pembrolizumab
  - NTRK Fusion-Positive Tumors
    - Larotrectinib
    - Entrectinib

Patients With Poor PS

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Emerging Modalities and New Targeted Therapies in Metastatic Pancreatic Cancer

Molecular Mechanism of PARP Inhibition

Platinum chemotherapy inflicts DNA damage via adducts and DNA crosslinking. PARP upregulation enables base-excision repair of DNA damage. Inhibition of PARP disables DNA base-excision repair, leading to replication fork collapse and double-strand DNA break, resulting in cell death. PARP inhibitor blocks PARP, preventing DNA repair and cell survival.

DNA damage affects PARP, triggering PARP upregulation and PARP inhibitor usage. PARP inhibition leads to cell death.

Repair enzymes, NAD+ (Nicotinamide + PAR), and BRCA1 and BRCA2 proteins play roles in DNA repair mechanisms.

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Emerging Modalities and New Targeted Therapies in Metastatic Pancreatic Cancer

Adverse Events Reported in the Phase 3 POLO Trial of Olaparib

Common Adverse Effects
- Nausea, fatigue, vomiting, abdominal pain, anemia, diarrhea, dizziness, neutropenia, leukopenia, influenza, respiratory tract infection, arthralgia/myalgia, dysgeusia, headache, dyspepsia, decreased appetite, constipation, stomatitis, dyspnea, and thrombocytopenia

Serious Adverse Effects
- Risk of hematologic toxicity, including myelodysplastic syndrome or acute myeloid leukemia; pneumonitis; and embryo–fetal toxicity.

Treatment-Related Issues
- Olaparib is metabolized via the cytochrome P-450 (CYP) 3A pathway
- Moderate renal impairment

Nurses Should...
- Monitor and consider interruption or dose reduction (Recommended dose reduction is 250 mg orally twice daily)
- Determine if the patient is also taking medications that are strong or moderate CYP3A inhibitors, as these can increase the circulating levels of olaparib: Either co-administration should be avoided, or the olaparib dose should be decreased
- Reduce olaparib dosage to 200 mg orally twice daily

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Emerging Modalities and New Targeted Therapies in Metastatic Pancreatic Cancer

Tumor Treating Fields (TTFields): A New Modality for Treating Cancer

TTFields are alternating electric fields that are tuned to specific frequencies to disrupt cell division, inhibiting tumor growth and causing affected cancer cells to die.

Effects on Cells Are Frequency Specific and Inversely Related to Cell Size\(^5-8\)

<table>
<thead>
<tr>
<th>Disease</th>
<th>Frequency</th>
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<tbody>
<tr>
<td>Normal intestine</td>
<td>~50 kHz</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>120 kHz</td>
</tr>
<tr>
<td>Mesothelioma</td>
<td>150 kHz</td>
</tr>
<tr>
<td>Pancreatic cancer</td>
<td>150 kHz</td>
</tr>
<tr>
<td>NSCLC</td>
<td>150 kHz</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>200 kHz</td>
</tr>
<tr>
<td>GBM</td>
<td>200 kHz</td>
</tr>
<tr>
<td>SCLC</td>
<td>240 kHz</td>
</tr>
</tbody>
</table>

Integrating TTFields Therapy Into Clinical Practice: Factors to Consider

**Training on TTFields Device**
- Device support specialists/nurses provide training in the patients’ homes
- Comprehensive initial visit: discussion of array placement, equipment use, and skin care
- Monthly visits thereafter: downloading of compliance reports that show patients how many hours of therapy they received each day
- Phone or in-person support as needed

**Patient Factors**
- Positioning of transducer arrays is individualized for every patient
- Patient education and compliance with wearing the device are critical
- Continuous monitoring is necessary

Access the activity, “Making Headway Toward Better Outcomes in Pancreatic Cancer: The Oncology Nurse as a Leader and Advocate for Patients in an Era of Advances in Care and Research,” at PeerView.com/USV40
Management of Common Adverse Events Associated With Chemotherapy Platforms

FOLFIRINOX¹

**Neutropenia/Febrile Neutropenia/Thrombocytopenia**

- Decrease dose of 5-FU or oxaliplatin; omit irinotecan for febrile neutropenia
- Delay treatment until neutrophils ≥1.5 × 10⁹/L after grade 4 neutropenia²

**Diarrhea**

- Decrease dose of ≥1 component
- Diarrhea occurring >24 h after injection may be prolonged and life threatening³
  - Treat promptly with loperamide, fluids, and electrolytes

**Infusion Reactions**

- Slow infusion time, provide atropine and/or proton pump
- Desensitization protocols

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Nab-Paclitaxel + Gemcitabine

**Neutropenia/Febrile Neutropenia/Thrombocytopenia**
- Dose reduction or delays at days 8 and/or 15 based upon severity of neutropenia and prior dose reductions

**Gastrointestinal Toxicity**
- For grade 3 or 4: withhold until grade ≤1
- Resume at next lower dose level

**Cutaneous Toxicity**
- For grade 2 or 3: reduce to next lower level
- Discontinue if toxicity persists

**Peripheral Neuropathy**
- Withhold therapy for grade 3 or 4 peripheral neuropathy
- Resume therapy at next lower dose level when neuropathy improves to ≤ grade 1

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### Nal-Irinotecan (Nal-IRI): Dose Modification

<table>
<thead>
<tr>
<th>Toxicity NCI CTCAE v4.0a</th>
<th>Directions</th>
<th>Nal-IRI adjustment in patients receiving 70mg/m²</th>
<th>Patients homozygous for UGT1A1*28 (who are currently receiving 50 mg/m²)</th>
</tr>
</thead>
</table>
| Grade 2 Diarrhea         | • Withhold Nal-IRI.  
  • Administer loperamide for late diarrhea of any severity.  
  • Administer atropine, if not contraindicated, for early diarrhea of any severity. | N/A | N/A |
| Grade 3 or 4 Diarrhea    | • Withhold Nal-IRI.  
  • Administer loperamide for late diarrhea of any severity.  
  • Administer intravenous or subcutaneous atropine 0.25 mg to 1 mg (unless contraindicated) for early diarrhea of any severity.  
  • Upon recovery to ≤grade 1, resume Nal-IRI at a modified dose. | First Occurrence  
  50 mg/m²  
  Second Occurrence  
  43 mg/m²  
  Third Occurrence  
  Discontinue Nal-IRI | First Occurrence  
  50 mg/m²  
  Second Occurrence  
  43 mg/m²  
  Third Occurrence  
  Discontinue Nal-IRI |
| Grade 3 or 4 Adverse Reactions | • Withhold Nal-IRI. Upon recovery to ≤grade 1, resume Nal-IRI at a modified dose. | First Occurrence  
  50 mg/m²  
  Second Occurrence  
  43 mg/m²  
  Third Occurrence  
  Discontinue Nal-IRI | First Occurrence  
  50 mg/m²  
  Second Occurrence  
  43 mg/m²  
  Third Occurrence  
  Discontinue Nal-IRI |
| Interstitial Lung Disease or Anaphylactic Reaction | First Occurrence: Discontinue Nal-IRI | | |

*a National Cancer Institute Common Terminology Criteria for Adverse Events version 4.0 used for grading.


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