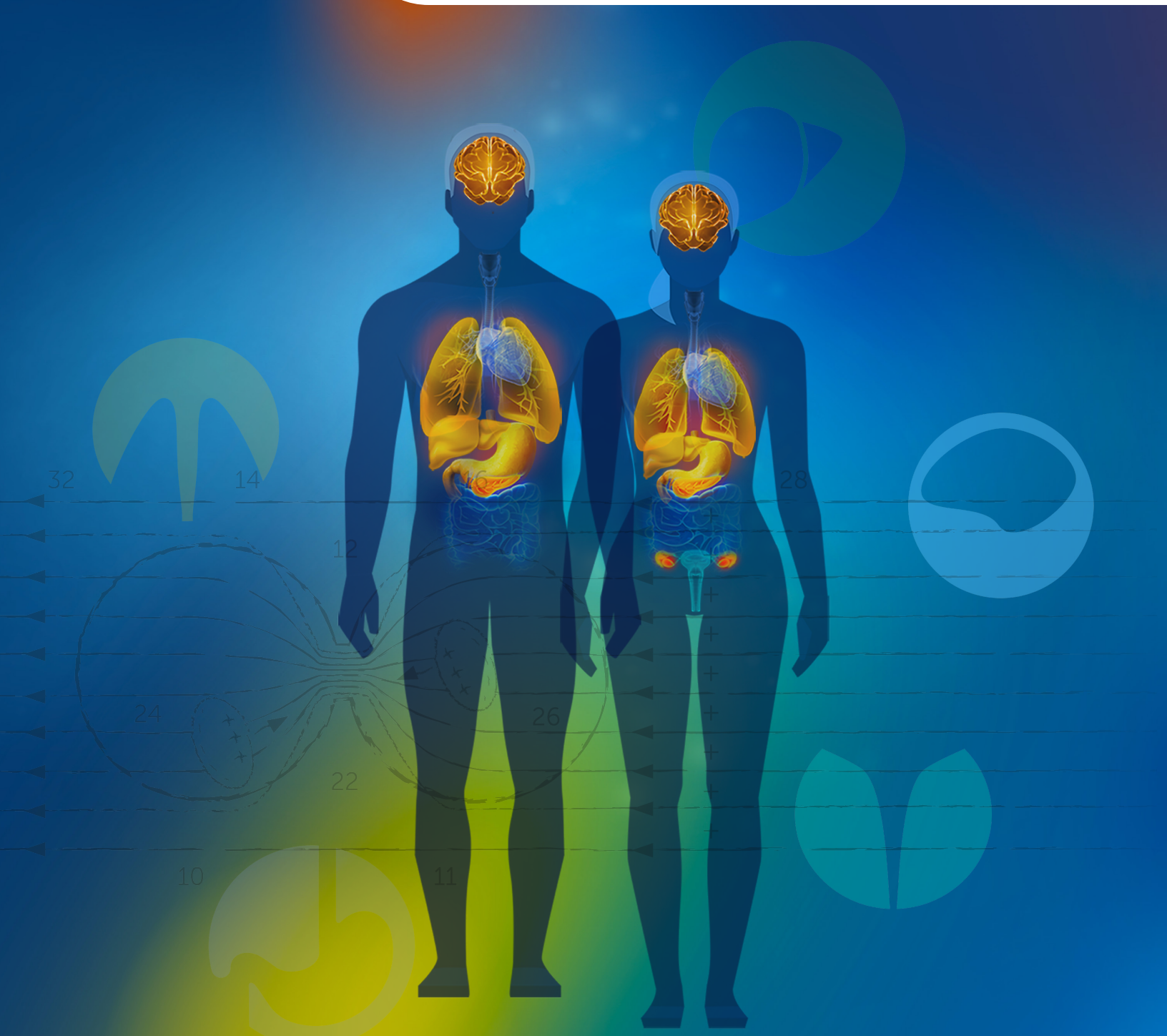
novocure® | clinicaltrials



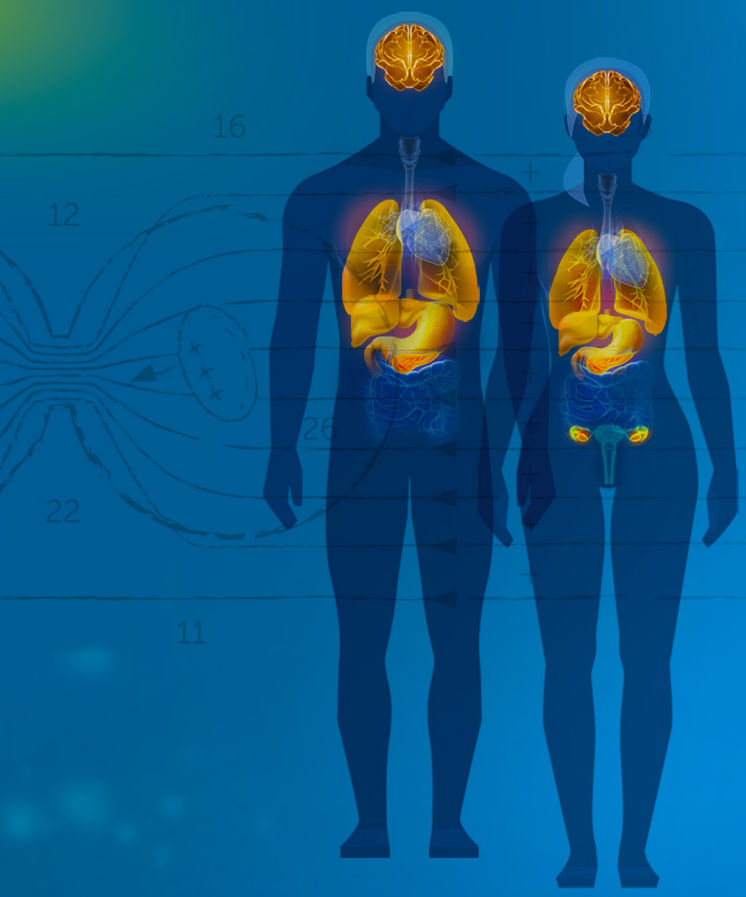
FOCUS on solid tumors

www.novocuretrial.com

novocure®

Novocure was founded in 2000 to provide patients with a cancer treatment based on the hypothesis that alternating electric fields, or Tumor Treating Fields (TTFields), when applied at specific frequencies, can disrupt cancer cell division and potentially cause cancer cell death.

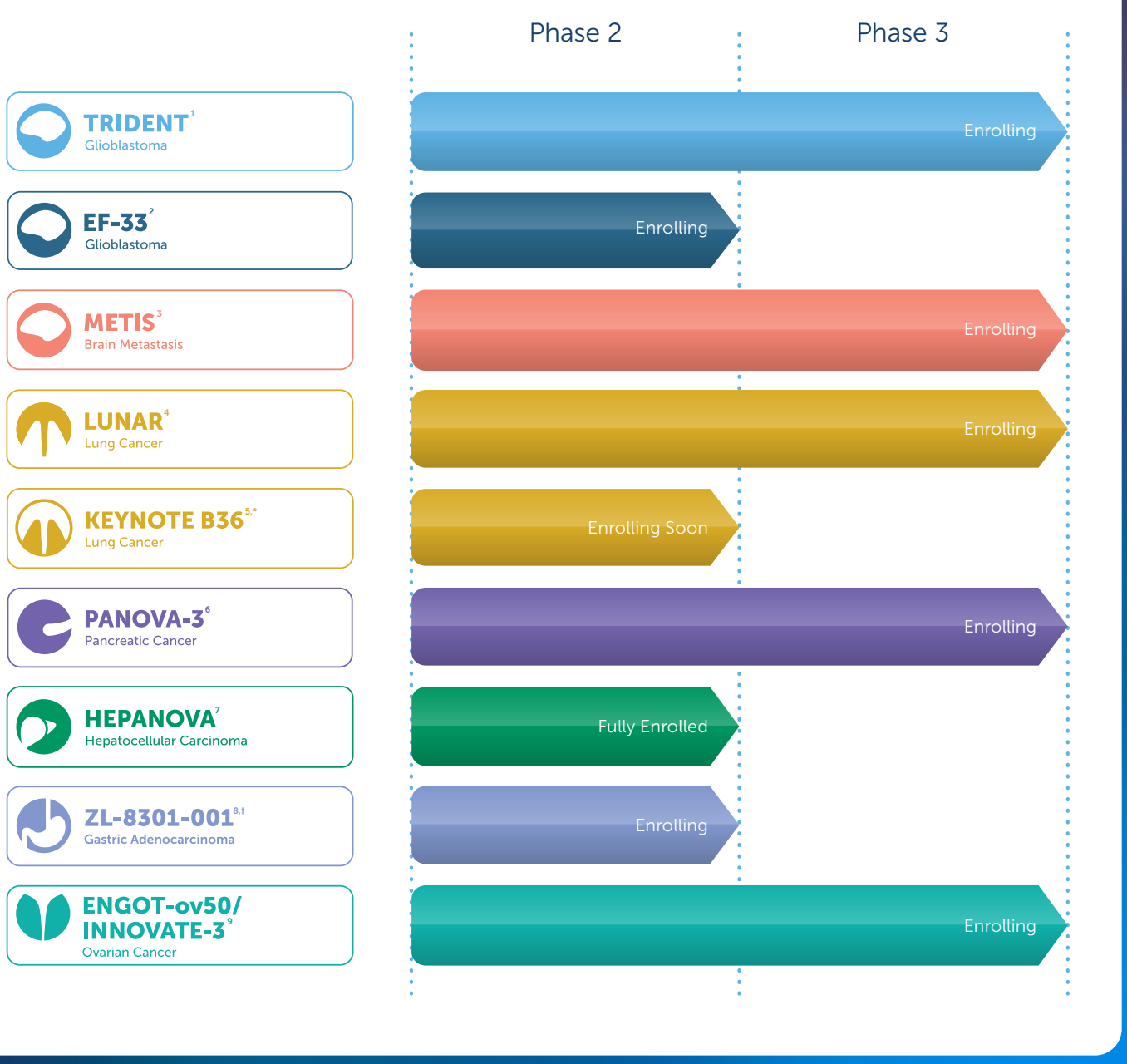
TTFields therapy is approved by the United States Food and Drug Administration for the treatment of glioblastoma and malignant pleural mesothelioma, and is being investigated in a broad range of other solid tumor types. Together with our patients, we strive to extend survival in some of the most aggressive forms of cancer by developing and commercializing our innovative therapy.



Patient-forward Mission

Novocure began with a patient-forward approach that continues to drive our mission today. Patients remain at the heart of the work we do. They are what matters most to us, guiding us forward in our goal to deliver an innovative cancer therapy that could lengthen patient lives while maintaining their quality of life.

Pipeline of Active Clinical Studies



*In collaboration with MSD; †In collaboration with Zai Lab.
Tumor Treating Fields (TTFields) are not approved in the United States or CE marked in Europe for the treatment of brain metastasis, pancreatic cancer, hepatocellular carcinoma, gastric adenocarcinoma, or ovarian cancer. The safety and effectiveness of TTFields for these uses has not been established. TTFields (200 kHz) are approved in the United States for the treatment of adult patients (22 years of age or older) with histologically confirmed supratentorial glioblastoma multiforme (GBM) by the United States Food and Drug Administration (FDA) through the Premarket Approval (PMA) pathway. TTFields have received a CE mark for marketing authorization in Europe for the treatment of GBM. TTFields are not approved in the United States for the treatment of lung cancer. TTFields (150 kHz) are CE marked in Europe for the treatment of advanced non-small cell lung cancer and malignant pleural mesothelioma. TTFields (150 kHz) have been approved in the United States by the FDA under the Humanitarian Device Exemption pathway for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma to be used concurrently with pemetrexed and platinum-based chemotherapy.

References: 1. ClinicalTrials.gov. [NCT04471844]. 2. ClinicalTrials.gov. [NCT04492163]. 3. ClinicalTrials.gov. [NCT02831959]. 4. ClinicalTrials.gov. [NCT02973789]. 5. Novocure. https://www.novocure.com/novocure-announces-clinical-trial-collaboration-with-msd-to-evaluate-tumor-treating-fields-together-with-keytruda-pembrolizumab-in-non-small-cell-lung-cancer/. Published July 15, 2020. Accessed September 30, 2020. 6. ClinicalTrials.gov. [NCT03377491]. 7. ClinicalTrials.gov. [NCT03606590]. 8. ClinicalTrials.gov. [NCT04281576]. 9. ClinicalTrials.gov. [NCT03940196].
Note: Information from ClinicalTrials.gov accessed March 1, 2021.

 This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

TRIDENT
Glioblastoma

Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 200 kHz) Concomitant With Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma (GBM)[1]

Enrolling

Select Inclusion Criteria

- Pathologic evidence of GBM (WHO criteria)
- Recovered from maximal debulking surgery
- ≥ 18 years of age in ex-US and ≥ 22 years of age in US
- ≥ 3-month life expectancy
- KPS ≥ 70
- Stable or decreasing dose of corticosteroids for the last 7 days prior to randomization, if applicable
- Planned treatment with RT/TMZ starting ≤ 8 weeks from surgery followed by TTFields with maintenance TMZ

Select Exclusion Criteria

- Progressive disease
- Infratentorial or leptomeningeal disease
- Prior cytotoxic or biologic anti-tumor therapy
- Significant comorbidities that would preclude RT or TMZ
- Evidence of increased intracranial pressure
- Implanted electronic medical device
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

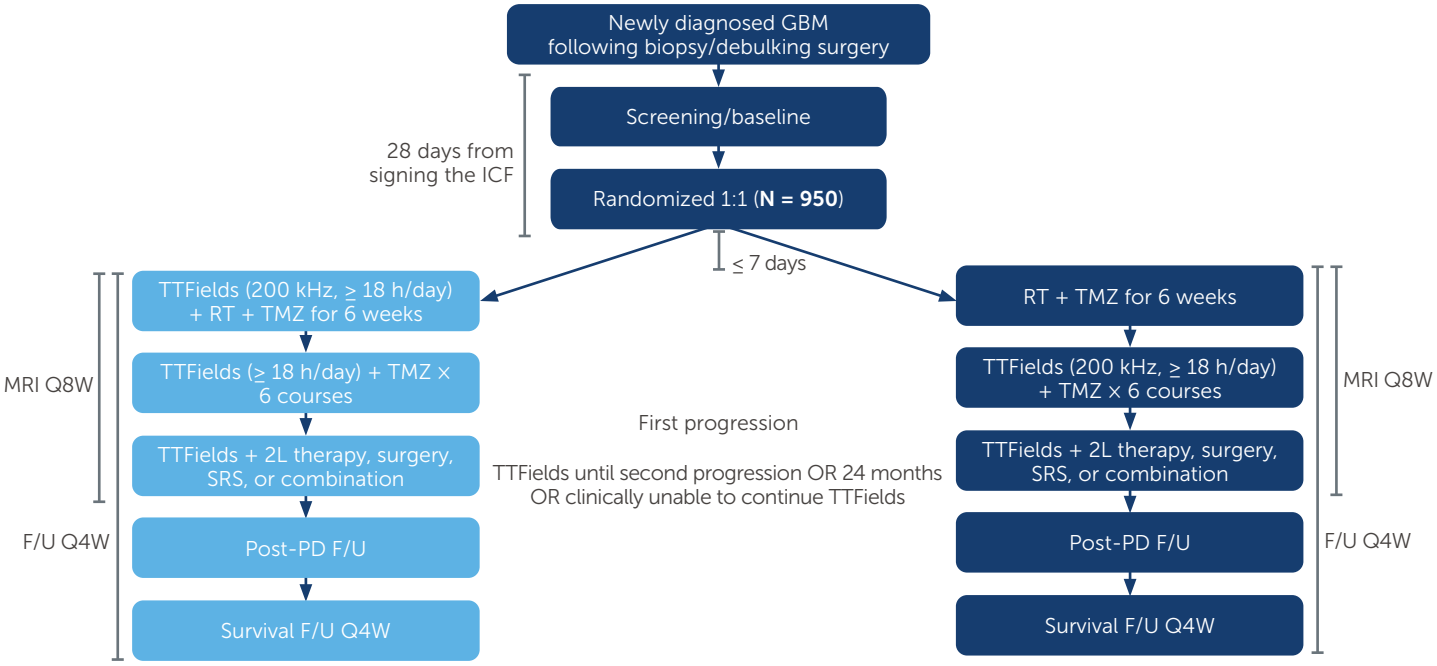
Primary Endpoint

- OS

Key Secondary Endpoints

- PFS
- 1- and 2-year survival rates
- ORR (RANO)
- Next PFS (PFS2)
- PFS6
- PFS12
- Severity and frequency of AEs
- Pathological changes in resected GBM tumors following study treatments
- QoL
- Dependence of OS on TTFields dose at the tumor site

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT04471844.



2L, second-line; AE, adverse event; F/U, follow-up; GBM, glioblastoma; ICF, informed consent form; kHz, kilohertz; KPS, Karnofsky Performance Status; MRI, magnetic resonance imaging; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS6, progression-free survival at 6 months; PFS12, progression-free survival at 12 months; Q4W, every 4 weeks; Q8W, every 8 weeks; QoL, quality of life; RANO, Response Assessment in Neuro-Oncology criteria; RT, radiation therapy; SRS, stereotactic radiosurgery; TMZ, temozolomide; TTFields, Tumor Treating Fields; WHO, World Health Organization.

Reference: 1. ClinicalTrials.gov. [NCT04471844]. Accessed March 1, 2021.

 This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

EF-33
Glioblastoma

An Open-Label Pilot Study of Tumor Treating Fields (TTFields, 200 kHz) With High Density Transducer Arrays for the Treatment of Recurrent Glioblastoma[1]

Enrolling

Select Inclusion Criteria

- Pathologic evidence of GBM (WHO criteria)
- Not a candidate for further radiotherapy or additional resection of residual tumor
- First or second radiological disease progression per RANO criteria documented by MRI ≤ 4 weeks prior to starting therapy
- ≥ 18 years of age
- ≥ 3-month life expectancy
- KPS ≥ 70
- Treatment start ≥ 4 weeks from surgery, chemotherapy, or RT

Select Exclusion Criteria

- Active participation in another clinical trial
- Infratentorial or leptomeningeal disease
- Treatment with TTFields (for newly diagnosed or recurrent disease) prior to enrollment
- Significant comorbidities
- Evidence of increased intracranial pressure
- Implanted electronic medical device
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

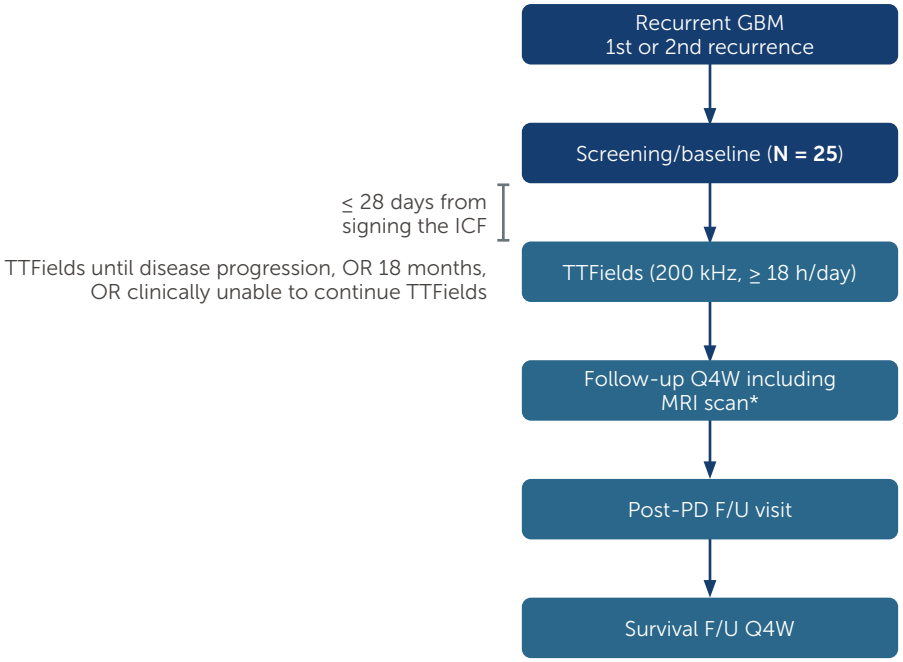
Primary Endpoint

- PFS

Key Secondary Endpoints

- OS
- PFS6
- 1- and 2-year survival rates
- ORR
- Severity and frequency of AEs
- Pathological changes in resected GBM tumors following study treatment
- Dependence of PFS and OS on TTFields dose delivered to the tumor bed

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT04492163.



*Visit schedule changes after 12 visits, MRI schedule changes after 6 visits.
AE, adverse event; F/U, follow-up; GBM, glioblastoma; ICF, informed consent form; kHz, kilohertz; KPS, Karnofsky Performance Status; MRI, magnetic resonance imaging; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS6, progression-free survival at 6 months; Q4W, every 4 weeks; RANO, Response Assessment in Neuro-Oncology criteria; RT, radiation therapy; TTFields, Tumor Treating Fields; WHO, World Health Organization.

Reference: 1. ClinicalTrials.gov. [NCT04492163]. Accessed March 1, 2021.

This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

METIS
Brain Metastasis

Pivotal, Open-Label, Randomized Study of Radiosurgery With or Without Tumor Treating Fields (TTFields, 150 kHz) for 1–10 Brain Metastases From Non-Small Cell Lung Cancer (NSCLC)[1]

Enrolling

Select Inclusion Criteria

- New diagnosis of 1–10 BM from histologically or cytologically confirmed NSCLC
- One inoperable BM or 2–10 brain lesions amenable to SRS
- ≥ 1 measurable lesion per RANO-BM criteria
- ≥ 18 years of age
- ≥ 3-month life expectancy
- KPS ≥ 70
- Must receive optimal systemic therapy for extracranial disease

Select Exclusion Criteria

- Disease amenable to available targeted agents
- Leptomeningeal metastases
- Concurrent brain directed therapy
- Prior WBRT for newly diagnosed brain metastasis
- Significant comorbidities
- Implanted electronic medical device in brain
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

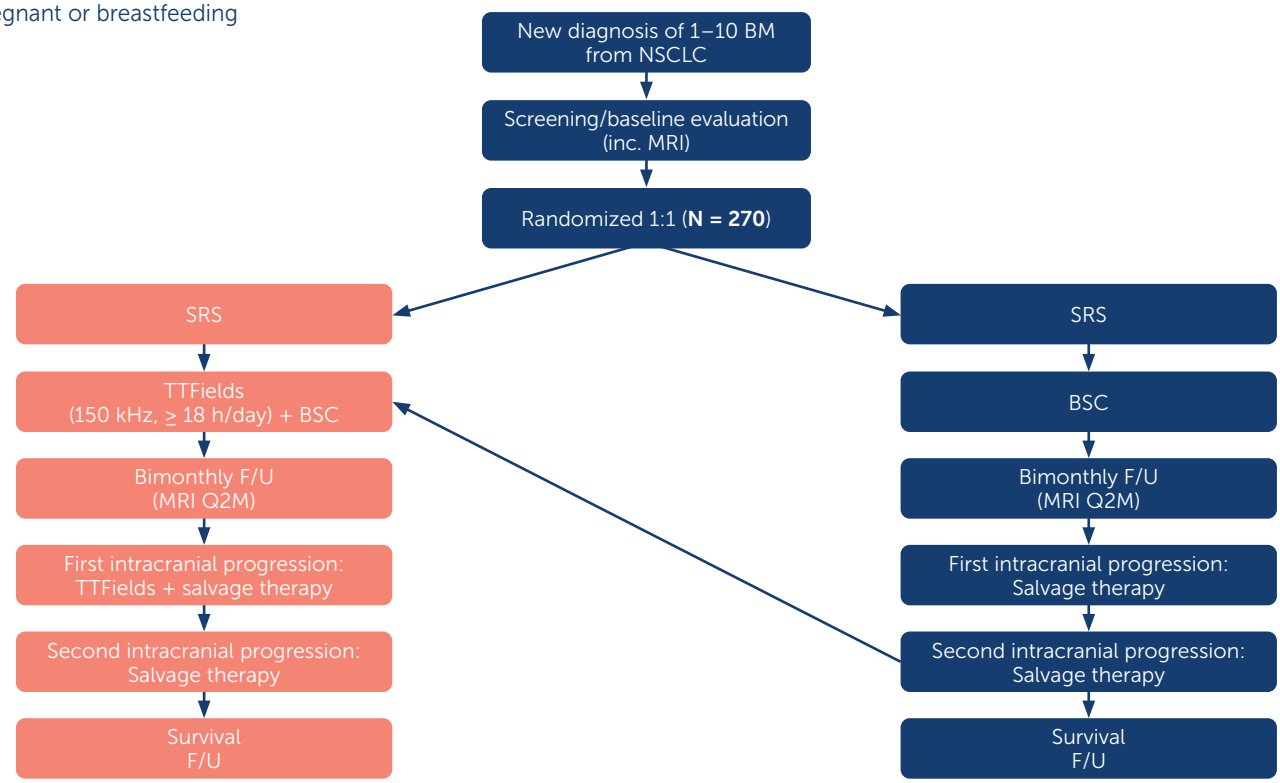
Primary Endpoint

- Time to intracranial progression

Key Secondary Endpoints

- Time to neurocognitive failure
- OS
- Radiological response in the brain
- Time to first and second intracranial progression in 2 cohorts: 1–4 BM and 5–10 BM
- 2-, 4-, 6-, 8-, 10-, 12-month intracranial progression rates
- Severity and frequency of AEs

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT02831959.



AE, adverse event; BM, brain metastases; BSC, best standard of care; F/U, follow-up; kHz, kilohertz; KPS, Karnofsky Performance Status; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; OS, overall survival; Q2M, every 2 months; RANO, Response Assessment in Neuro-Oncology criteria; SRS, stereotactic radiosurgery; TTFields, Tumor Treating Fields; WBRT, whole brain radiotherapy.

Reference: 1. ClinicalTrials.gov. [NCT02831959]. Accessed March 1, 2021.

LUNAR
Lung Cancer

Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 150 kHz) Concurrent With Standard of Care Therapies* for Treatment of Stage IV Non-Small Cell Lung Cancer (NSCLC) Following Platinum Failure[1]

Enrolling

Select Inclusion Criteria

- Histologically confirmed squamous or non-squamous, unresectable, stage IV NSCLC
- Diagnosis of radiological progression while on or after first platinum-based systemic therapy
- ≥ 22 years of age
- ≥ 3-month life expectancy
- ECOG PS ≤ 2
- Randomization within 28 days of diagnosis of last progression

Select Exclusion Criteria

- Brain metastasis or leptomeningeal spread of the disease
- Contraindications to the assigned SOC (docetaxel/immune checkpoint inhibitor)
- Severe comorbidities
- Concurrent treatment with other experimental therapies for NSCLC
- Implanted electronic medical device in the upper torso
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

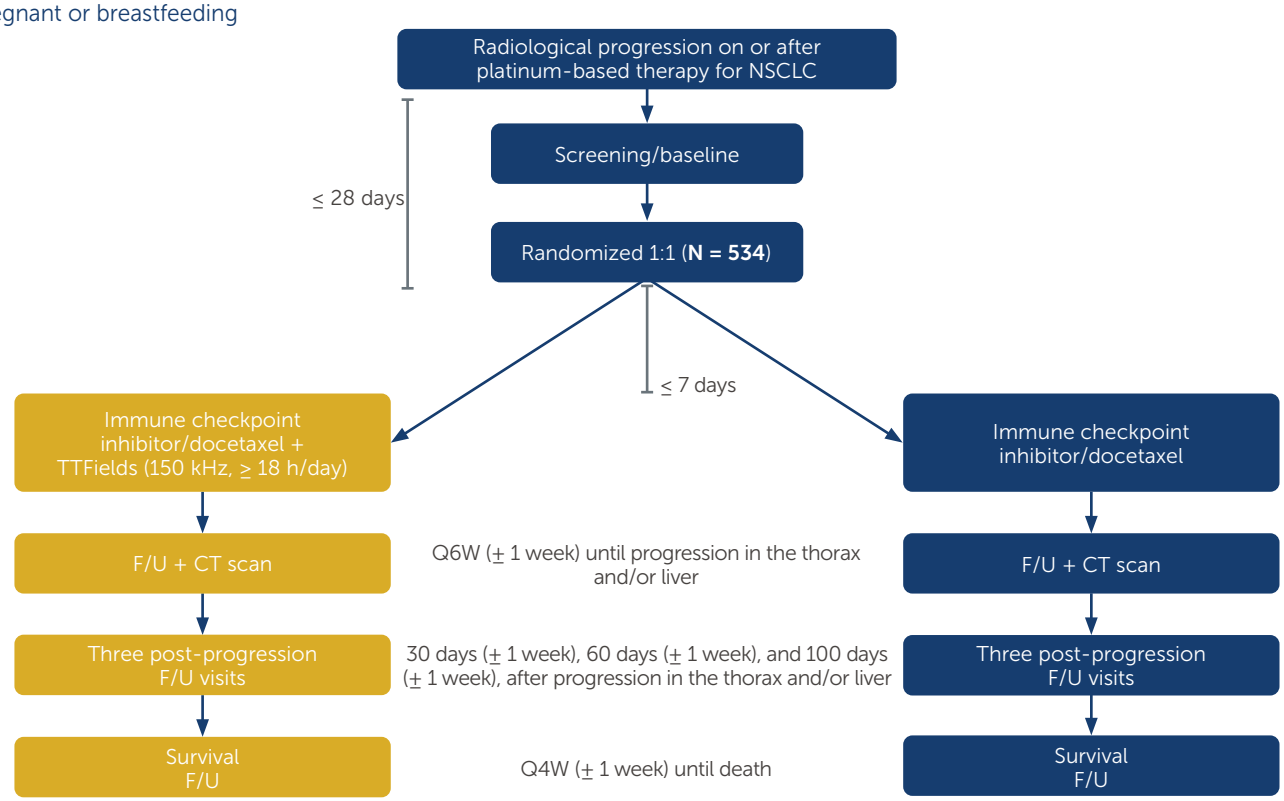
Primary Endpoint

- OS of patients treated with TTFields plus docetaxel or immune checkpoint inhibitors vs docetaxel or immune checkpoint inhibitors alone

Key Secondary Endpoints

- OS of patients treated with docetaxel plus TTFields vs docetaxel alone
- OS of patients treated with immune checkpoint inhibitors plus TTFields vs immune checkpoint inhibitors alone
- PFS (RECIST)
- ORR (RECIST)
- QoL
- TTFields usage
- Severity and frequency of AEs

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT02973789.



*Immune checkpoint inhibitors or docetaxel are included in the LUNAR trial as standard of care therapies.
AE, adverse event; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group Performance Status; F/U, follow-up; kHz, kilohertz; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q4W, every 4 weeks; Q6W, every 6 weeks; QoL, quality of life; RECIST, Response Evaluation Criteria In Solid Tumors; SOC, standard of care; TTFields, Tumor Treating Fields.

Reference: 1. ClinicalTrials.gov. [NCT02973789]. Accessed March 1, 2021.

This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

PANOVA-3
Pancreatic Cancer

Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 150 kHz) Concomitant With Gemcitabine and Nab-Paclitaxel for Front-Line Treatment of Locally Advanced Pancreatic Adenocarcinoma[1]

Enrolling

Select Inclusion Criteria

- Histologically or cytologically confirmed, unresectable, locally advanced, *de novo* pancreatic adenocarcinoma
- ≥ 18 years of age
- ≥ 3-month life expectancy
- ECOG PS ≤ 2

Select Exclusion Criteria

- Prior palliative treatment (eg, surgery, radiation) to the tumor
- Cancer requiring anti-tumor treatment within the 5 years before inclusion
- Significant comorbidities
- Concurrent anti-tumor therapy beyond gemcitabine and nab-paclitaxel
- Implanted electronic medical device in the torso
- Known allergies to medical adhesives or hydrogel, or prescribed chemotherapies
- Pregnant or breastfeeding

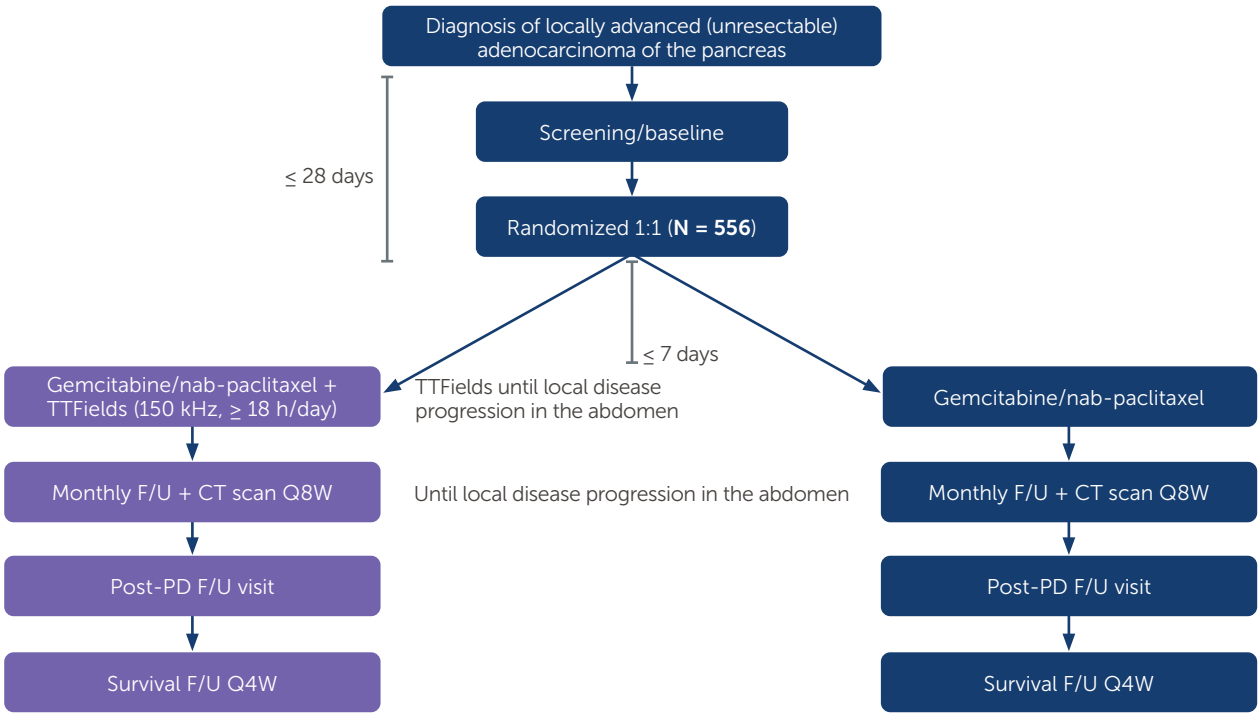
Primary Endpoint

- OS

Key Secondary Endpoints

- PFS
- Local PFS
- ORR
- QoL
- Pain-free survival
- Puncture-free survival
- Rate of resectability
- Toxicity

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT03377491.



CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group Performance Status; F/U, follow-up; kHz, kilohertz; nab, nanoparticle albumin-bound; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; Q4W, every 4 weeks; Q8W, every 8 weeks; QoL, quality of life; TTFields, Tumor Treating Fields.

Reference: 1. ClinicalTrials.gov. [NCT03377491]. Accessed March 1, 2021.

This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

HEPANOVA
Hepatocellular Carcinoma

A Phase 2 Trial of Tumor Treating Fields (TTFields, 150 kHz) Concomitant With Sorafenib for Advanced Hepatocellular Carcinoma (HCC)[1]

Fully Enrolled

Select Inclusion Criteria

- HCC diagnosed by biopsy, or by imaging criteria (CT/MRI) and AFP
- ≥ 18 years of age
- ≥ 3-month life expectancy
- BCLC stages 0–C
- CTP score between 5–8 points
- ECOG PS ≤ 2
- ≥ 4 weeks since major surgery

Select Exclusion Criteria

- Patient candidate for surgical resection or local treatment
- Prior malignancy requiring anti-tumor treatment or concurrent malignancy
- High levels of serum HBV DNA without antiviral therapy
- Significant comorbidities
- Implanted electronic medical device in the torso
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

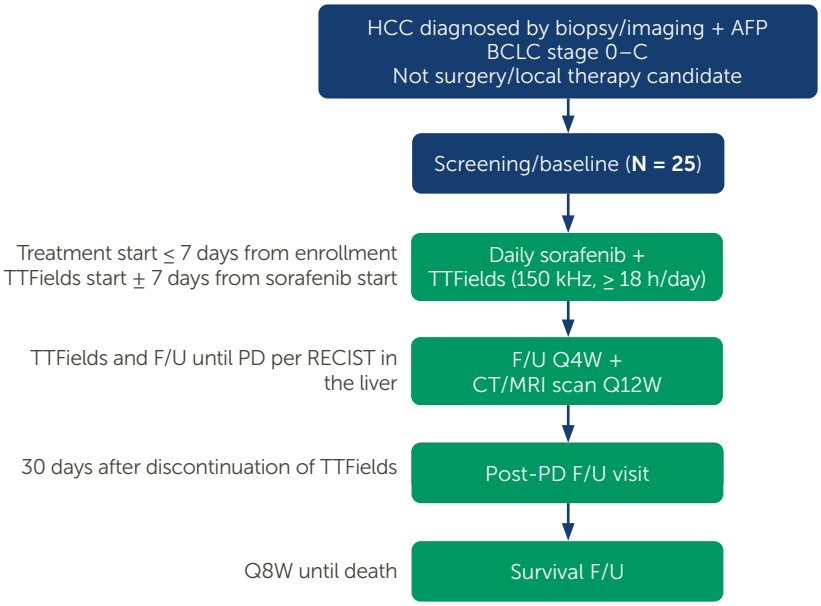
Primary Endpoint

- ORR

Key Secondary Endpoints

- In-field control rate at 1 year
- OS
- PFS
- PFS6 and PFS12
- Distant metastases-free survival at 1 year
- OS rate at 1 year
- Severity and frequency of AEs

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT03606590.



AE, adverse event; AFP, alpha-fetoprotein; BCLC, Barcelona Clinic Liver Cancer; CT, computed tomography; CTP, Child-Turcotte-Pugh; ECOG PS, Eastern Cooperative Oncology Group Performance Status; F/U, follow-up; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; kHz, kilohertz; MRI, magnetic resonance imaging; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS6, progression-free survival at 6 months; PFS12, progression-free survival at 12 months; Q4W, every 4 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; RECIST, Response Evaluation Criteria In Solid Tumors; TTFields, Tumor Treating Fields.

Reference: 1. ClinicalTrials.gov. [NCT03606590]. Accessed March 1, 2021.

This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

ZL-8301-001
Gastric Adenocarcinoma

Enrolling

A Phase 2, Single-Arm, Multi-Center, Open-Label Trial to Evaluate the Safety and Efficacy of Treatment With Tumor Treating Fields (TTFields, 150 kHz) and Chemotherapy as First-Line Treatment for Subjects With Unresectable Gastroesophageal Junction (GEJ) Adenocarcinoma or Gastric Adenocarcinoma[1,*]

Select Inclusion Criteria

- Histologically confirmed unresectable, locally advanced or metastatic GEJ or gastric adenocarcinoma
- Previously untreated with systemic treatment and without resection of primary gastric focus
- Measurable disease per RECIST 1.1
- ≥ 18 years of age
- ≥ 3-month life expectancy
- ECOG PS ≤ 1

Select Exclusion Criteria

- Other malignant tumors have occurred over the past 5 years[†]
- Metastases to central nervous system with clinical symptoms
- Significant comorbidities
- Non-healing wound or ulcer within 3 months prior to study enrollment, or history of bone fracture
- Previous allogeneic organ transplantation or allogeneic bone marrow transplantation
- Implanted electronic medical device in the torso
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

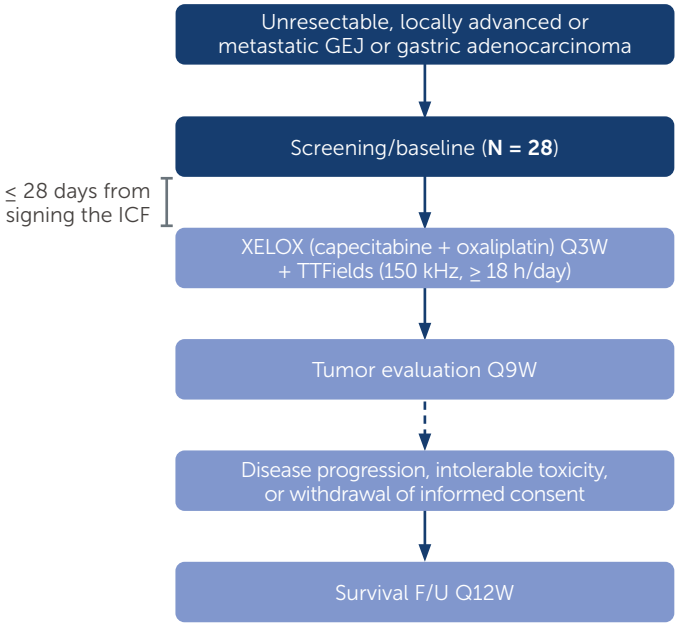
Primary Endpoint

- ORR

Key Secondary Endpoints

- PFS
- OS
- DCR
- Time to progression
- Duration of response
- 1-year survival rate
- Severity and frequency of AEs

For more information, please visit ClinicalTrials.gov. NCT04281576.



*In collaboration with Zai Lab. [†]With the exception of locally curable cancers treated with radical therapy, such as basal or squamous cell skin cancer, superficial bladder cancer, or in situ carcinoma of the cervix, prostate, or breast.
AE, adverse event; DCR, disease control rate; ECOG PS, Eastern Cooperative Oncology Group Performance Status; F/U, follow-up; GEJ, gastroesophageal junction; ICF, informed consent form; kHz, kilohertz; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; Q9W, every 9 weeks; Q12W, every 12 weeks; RECIST, Response Evaluation Criteria In Solid Tumors; TTFields, Tumor Treating Fields.
Reference: 1. ClinicalTrials.gov. [NCT04281576]. Accessed March 1, 2021.

ENGOT-ov50/ INNOVATE-3

Ovarian Cancer

Pivotal, Randomized, Open-Label Study of Tumor Treating Fields (TTFields, 200 kHz) Concomitant With Weekly Paclitaxel for the Treatment of Platinum-Resistant Ovarian Cancer (PROC)[1]

Enrolling

Select Inclusion Criteria

- Epithelial histology of ovarian/primary peritoneal or fallopian tube carcinoma
- ≥ 18 years of age
- ≥ 3-month life expectancy
- ECOG PS ≤ 1
- Maximum 2 prior lines of systemic therapy following diagnosis of platinum resistance
- Maximum total of 5 prior lines of systemic therapy

Select Exclusion Criteria

- Primary platinum-refractory disease
- Prior disease progression on QW paclitaxel for recurrent disease
- Brain metastasis or leptomeningeal spread of disease
- Prior malignancy treated primarily or for recurrence within 2 years
- Significant comorbidities
- Implanted electronic medical device in the torso
- Known allergies to medical adhesives or hydrogel
- Pregnant or breastfeeding

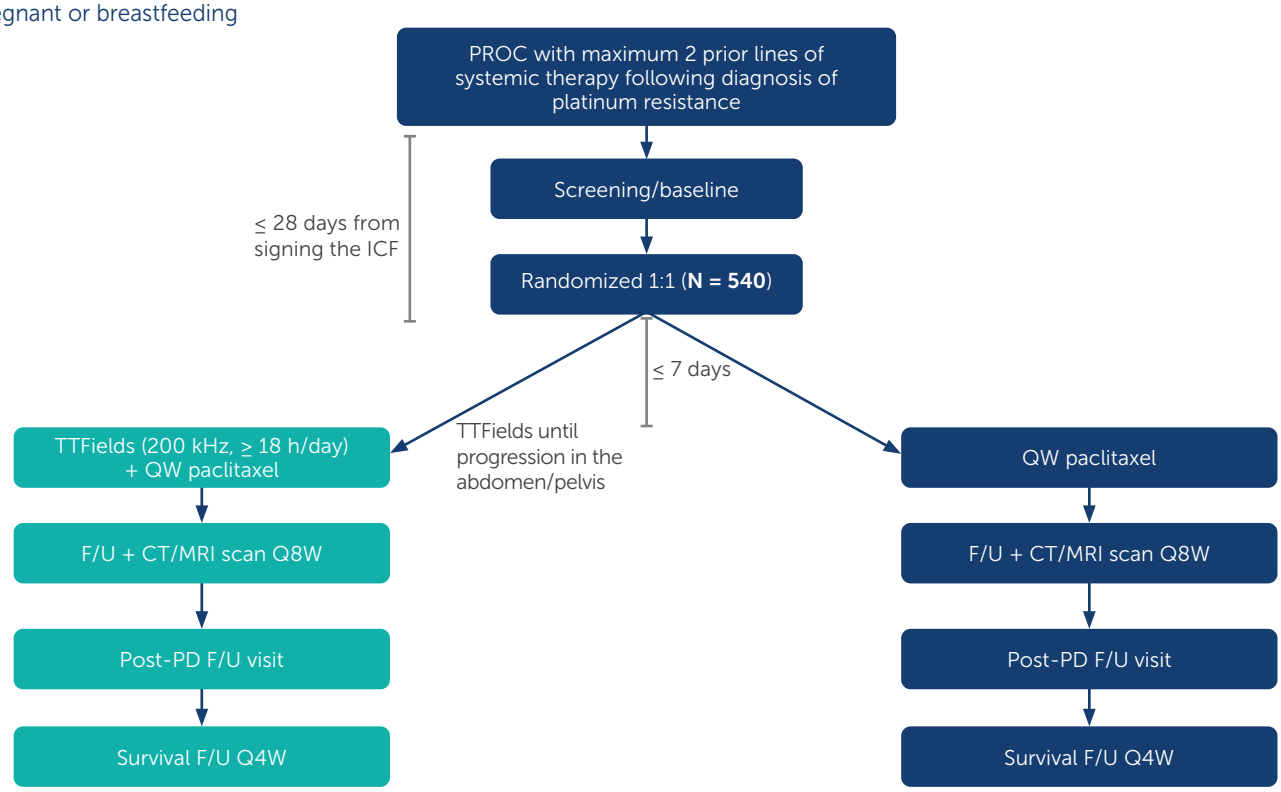
Primary Endpoint

- OS

Key Secondary Endpoints

- PFS
- ORR
- Severity and frequency of AEs

For more information, please visit novocuretrial.com or ClinicalTrials.gov. NCT03940196.



AE, adverse event; CT, computed tomography; ECOG PS, Eastern Cooperative Oncology Group Performance Status; F/U, follow-up; ICF, informed consent form; kHz, kilohertz; MRI, magnetic resonance imaging; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PROC, platinum-resistant ovarian cancer; QW, weekly; Q4W, every 4 weeks; Q8W, every 8 weeks; TTFields, Tumor Treating Fields.

Reference: 1. ClinicalTrials.gov. [NCT03940196]. Accessed March 1, 2021.

 This information is for medical and scientific/educational purposes only. Trial status was updated as of March 2021.

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