

TTFields in combination with radiation therapy

CLINICAL DEVELOPMENT

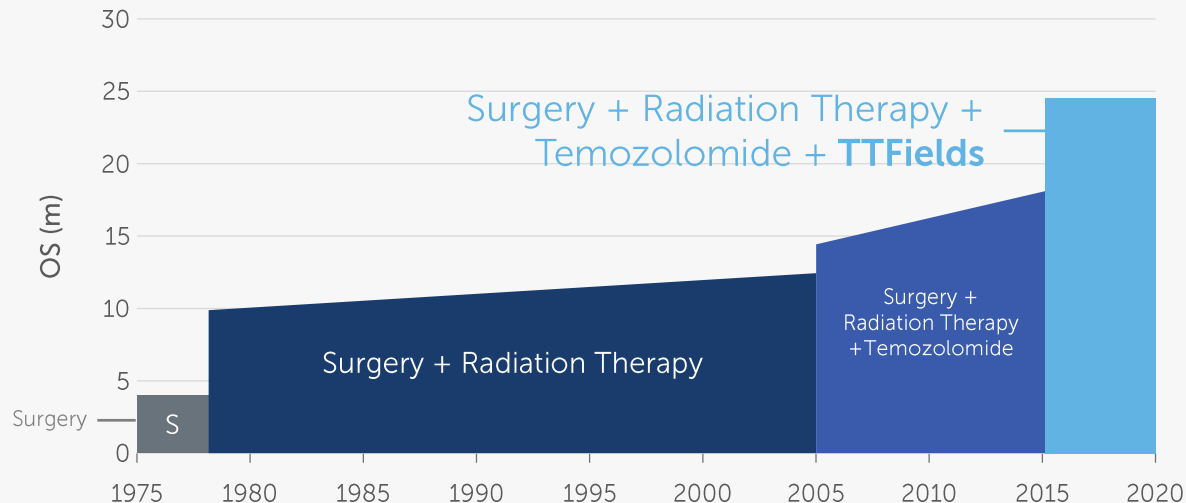
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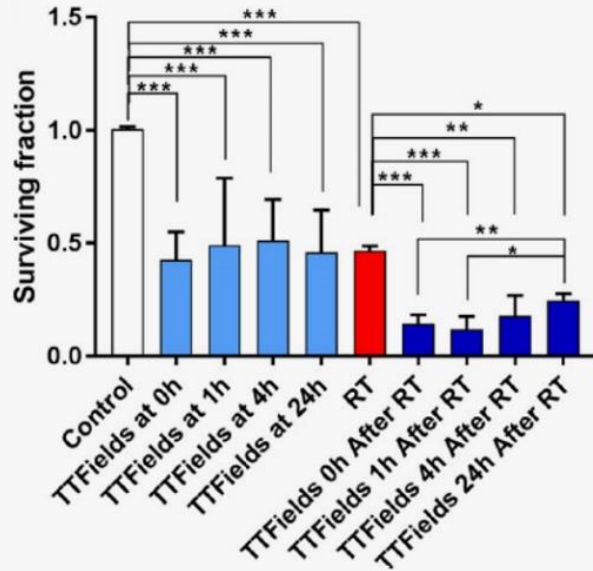
strong scientific
rationale to combine
TTFields with
radiation therapy

combination treatment is most successful anti-cancer strategy

GBM treatment outcomes over time



improved survival benefits observed when applying TTFields earlier and for a longer period



early application of TTFields delayed DNA damage repair following radiation

skin toxicity can be addressed

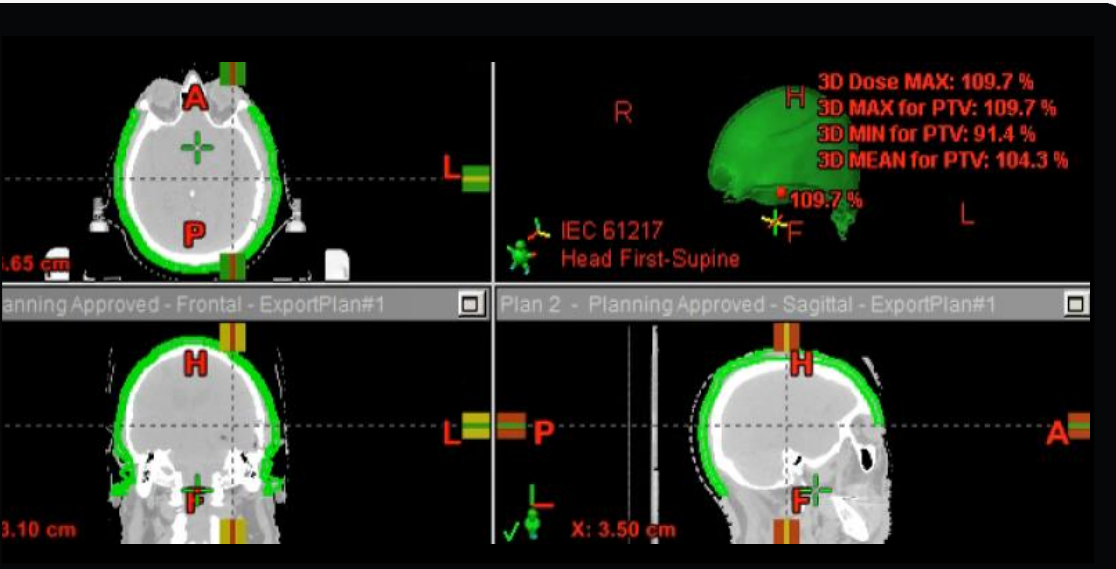


Table 2 Dosimetric parameters for scalp-sparing radiation

Subject No.	Scalp mean dose (Gy)	Scalp max dose (Gy)	Scalp D20cc (Gy)	Scalp D30cc (Gy)
1	8.2	48.0	26.3	23.7
2	5.3	41.3	19.8	16.8
3	6.5	40.7	17.7	14.8
4	4.9	35.9	18.0	14.8
5	7.5	40.2	21.7	19.3
6	8.3	54.2	23.4	20.3
7	10.1	55.8	29.1	26.7
8	7.9	40.1	24.5	22.4
9	13.2	56.5	36.8	33.4
10	7.2	43.7	21.54	18.7
Median	7.7	42.5	22.5	19.8

scalp dose constraints were achieved for all patients

no severe skin toxicity reported

early clinical trials demonstrated feasibility and tolerability of TTFields and radiation therapy

Journal of Neuro-Oncology
https://doi.org/10.1007/s12220-020-02946-z

CLINICAL STUDY

Initial experience with scalp sparing radiation with concurrent temozolomide and tumor treatment fields (SPARE) for patients with newly diagnosed glioblastoma

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Adverse event	Grade 1	Grade 2
Fatigue	7 (70%)	1 (10%) ^a
Cognitive impairment ^b	3 (30%)	
Pruritus	6 (60%)	
Dermatitis ^c	8 (80%)	1 (10%) ^a
Headaches	3 (30%)	
Dizziness	1 (10%)	
Nausea	1 (10%)	

No related adverse events ≥ Grade 3 during either concurrent or maintenance phases

^aGrade 2 events occurred in same patient on maintenance therapy, now resolved

^bCognitive impairment includes: concentration, memory, confusion

^cDermatitis includes scalp irritation, dry skin, folliculitis, erythema, color change, rash

frontiers
in Oncology

ORIGINAL RESEARCH
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Concurrent Tumor Treating Fields (TTFields) and Radiation Therapy for Newly Diagnosed Glioblastoma: A Prospective Safety and Feasibility Study

Felix Bokstein^{1,2}, Deborah Blumenthal^{1,2}, Dror Limon³, Carmit Ben Harosh⁴, Zvi Ram⁵ and Rachel Grossman^{6*}

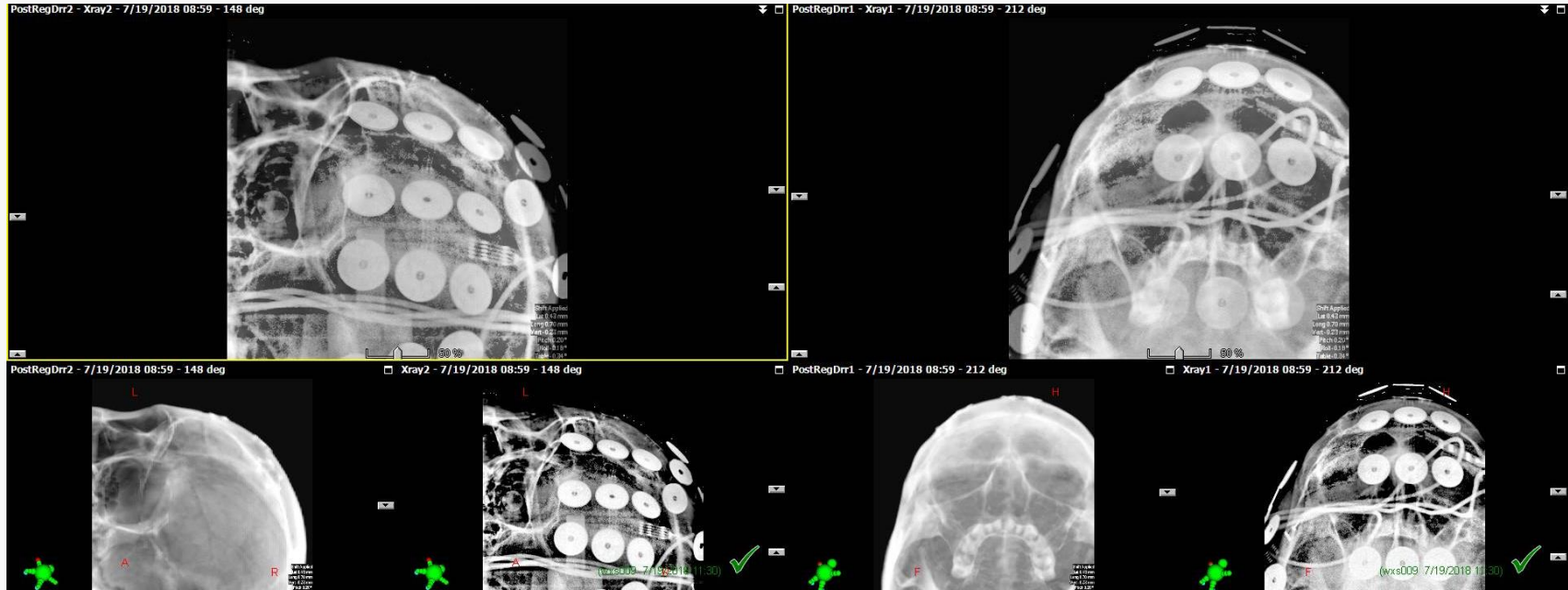
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AEs	RT + TTFields (N = 10)		
	Total	Grade 1–2	Grade 3–4
Patients with ≥ 1 AE, n (%)	10 (100)	6 (60)	4 (40)
Local complications, n (%)	8 (80)	8 (80)	0
Scalp skin complications	8 (80)	8 (80)	0
Application site blisters	1 (10)	1 (10)	0
Application site erosions	3 (30)	3 (30)	0
Application site erythema	4 (40)	4 (40)	0
Contact dermatitis	4 (40)	4 (40)	0
Dermatitis	1 (10)	1 (10)	0
Eczema	1 (10)	1 (10)	0
Pruritus	1 (10)	1 (10)	0
Reluctance to continue	1 (10)	1 (10)	0

early clinical trials demonstrated feasibility and tolerability of TTFields and radiation therapy

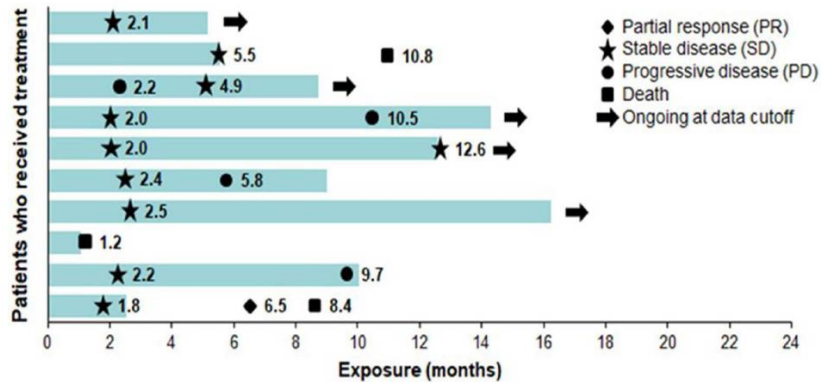


early clinical trials demonstrated feasibility and tolerability of TTFields and radiation therapy

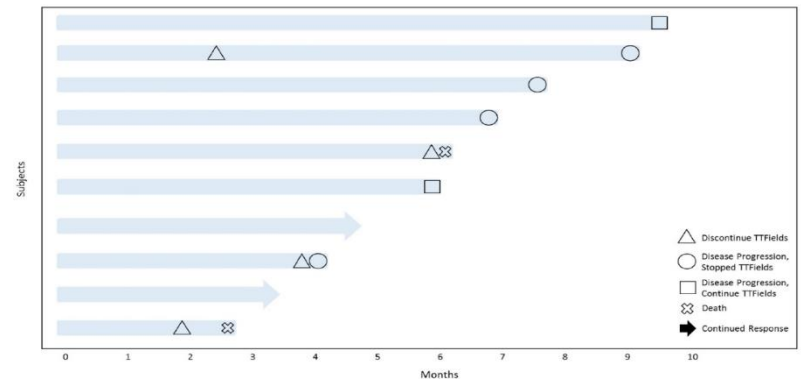


early clinical trials demonstrated feasibility and tolerability of TTFields and radiation therapy

Bokstein et al. Front Rad Onc Apr 2020 PFS: 8.9 m



Song et al. JNO March 2020 PFS: 6.9 m

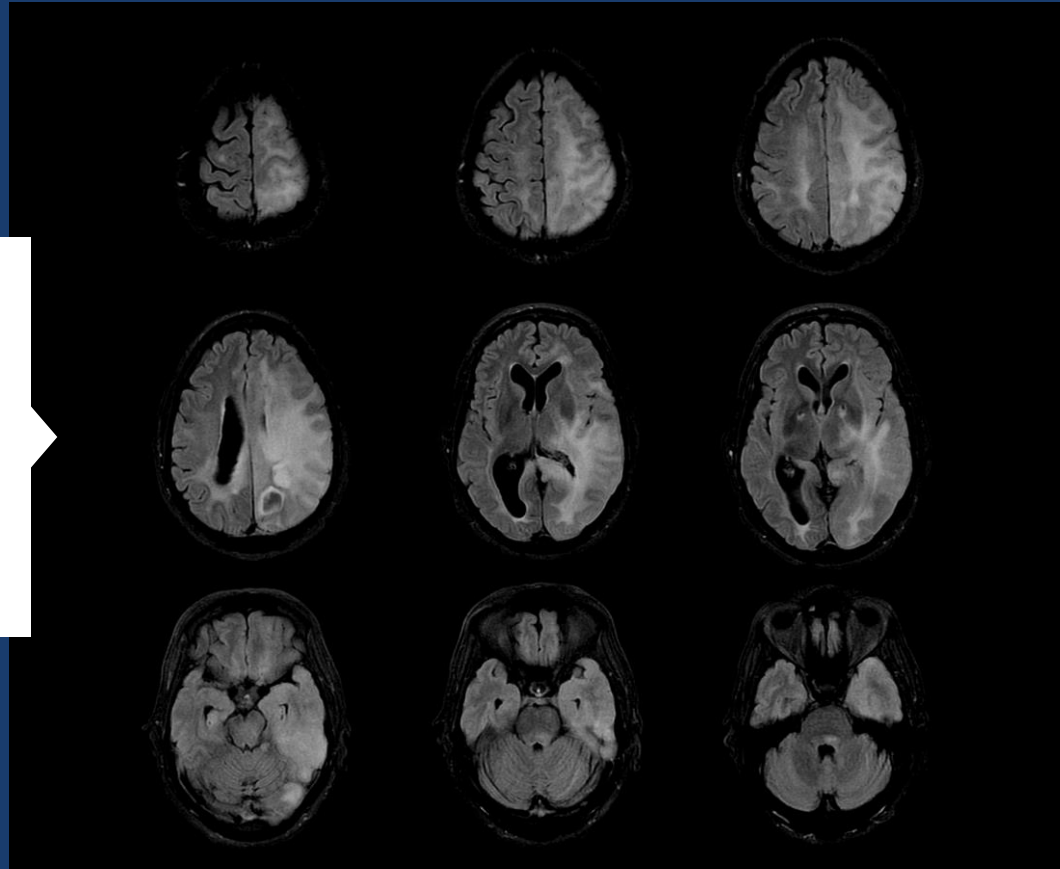


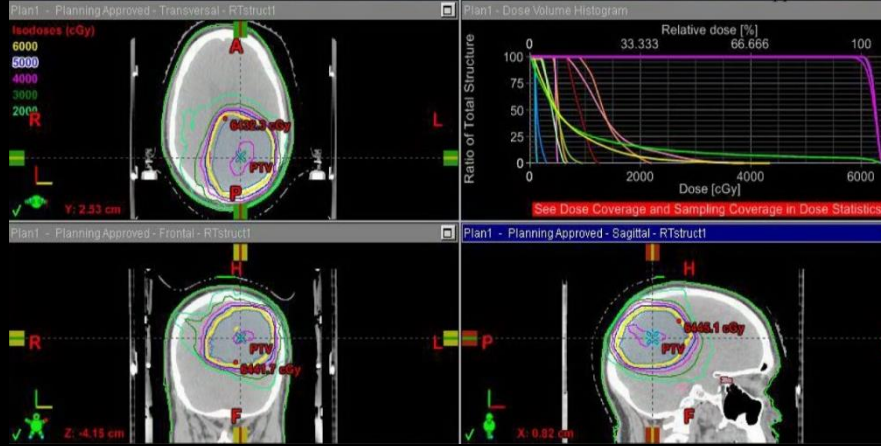
real, positive impact
on our patients

CASE STUDY

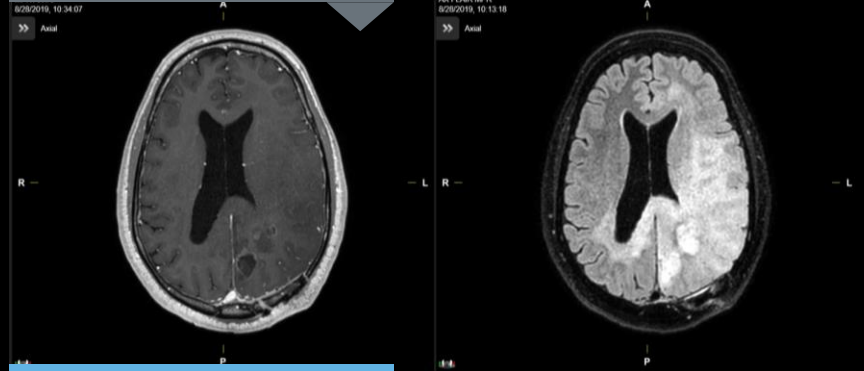
gliomatosis

- 64 yo African American male
- Presented with seizure
- **MRI:** Left parietal enhancing lesions
- **Pathology:**
 - GBM
 - MGMT Promotor Methylated

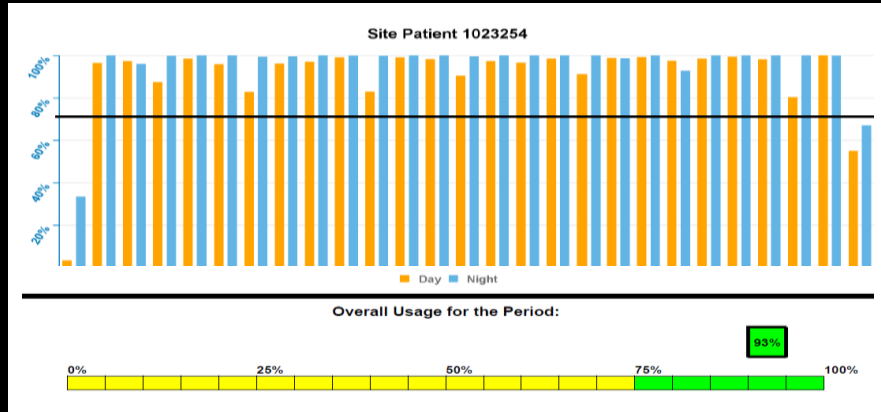
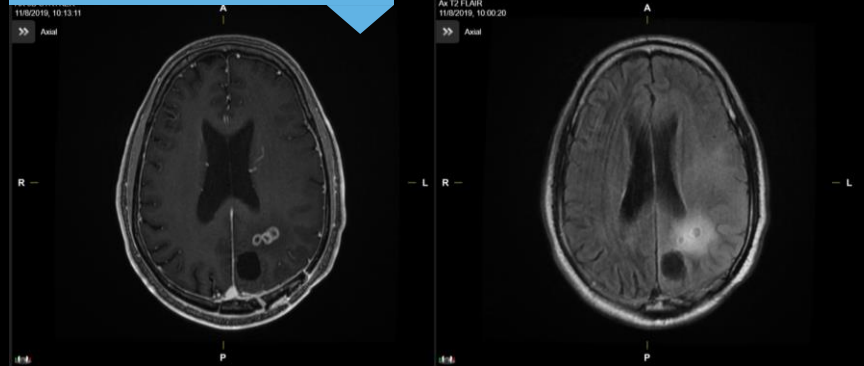




pre-radiation



post-radiation



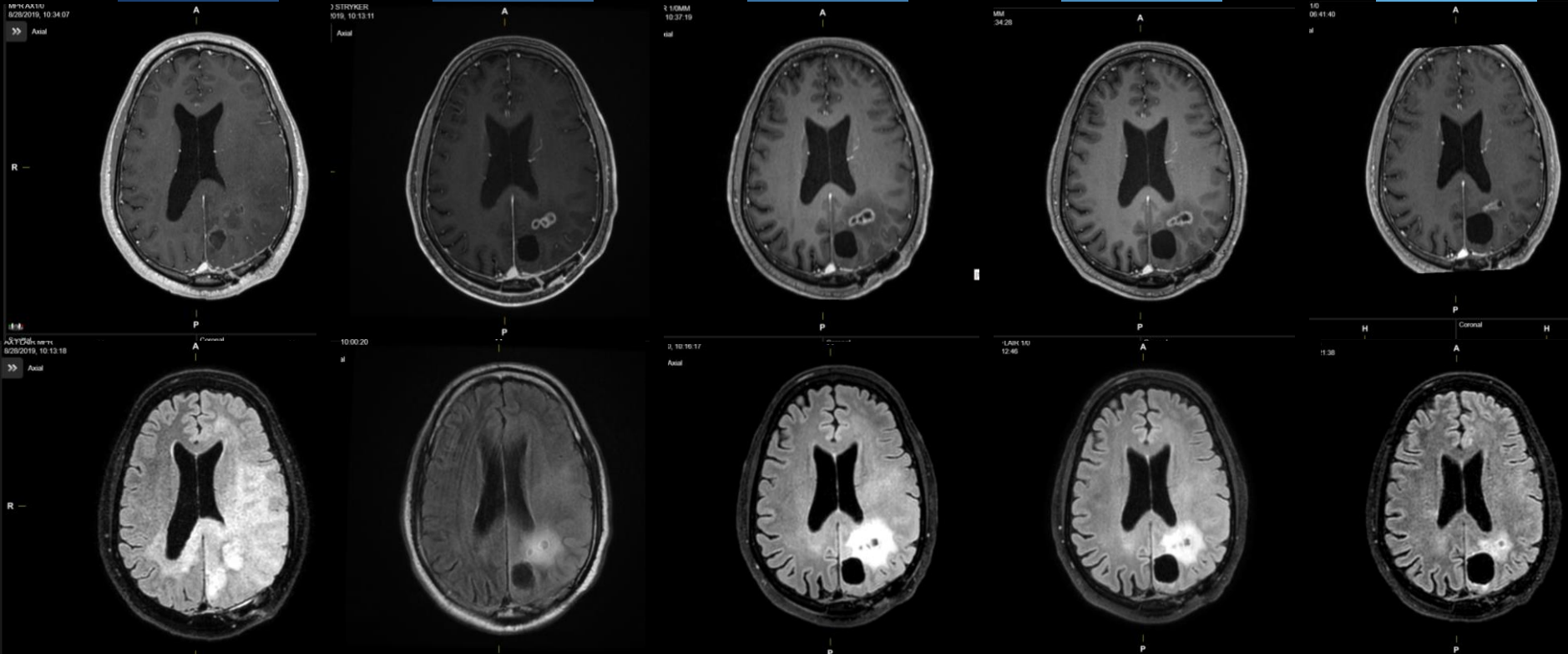
pre-RT

1m

3m

5m

8m



TRIDENT phase 3 pivotal trial

Pivotal, randomized, open-label study of Tumor Treating Fields (200 kHz) concomitant with radiation and temozolomide for the treatment of newly diagnosed GBM.

- Testing the safety and potential survival benefit of initiating Optune® concurrent with radiation therapy
- Expect to enroll 950 patients in multiple European and North American medical centers
- **Primary endpoint:**
 - Overall survival (OS)
- **Secondary endpoints include:**
 - Progression-free survival (PFS)
 - 1- and 2-year survival rates
 - Overall radiological response rate
 - Severity and frequency of adverse events
 - Quality of life
 - Dependence of OS on TTFIELDS dose at the tumor

