

Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods. Statistical Considerations and Definitions of Endpoints

Overall survival (OS) was the primary endpoint of this study, defined as the time from the date of randomization to the death date for the intention-to-treat population. In the absence of death confirmation or for patients alive as of the OS cut-off date, the survival time was censored at the date of last study follow-up or the cut-off date, whichever was earlier. The cut-off date for OS was defined by the date of the 384th death.

Progression-free survival was defined as the time from the date of randomization until the date of the investigator-assessed radiological disease progression or death due to any cause. Patients who were alive with no disease progression as of the analysis cut-off date were censored at the date of the last tumor assessment. Patients who received non-study cancer treatment before disease progression, or with clinical but not radiologic evidence of progression, were censored at the date of the last evaluable tumor assessment before the non-study cancer treatment was initiated.

The time to deterioration of Eastern Cooperative Oncology Group (ECOG) performance status was defined as the time from randomization to the first date on which an ECOG performance status score of ≥ 2 was observed. Patients not reaching an ECOG performance status score of ≥ 2 were censored at the last recorded performance status assessment during the study.

Adverse events (AEs) were defined as events that started on or after treatment or started before treatment and worsened after the start of treatment through 30 days after the last dose of study treatment. Verbatim AE terms were coded and classified by system organ class and preferred term according to the Medical Dictionary for Regulatory Activities (MedDRA) version 20.1 terminology, and the severity of the toxicities were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 4.03, if applicable. AE incidence was calculated using the worst CTCAE grade at every level of summarization.

eTable 1. List of Ethics Committees/Institutional Review Boards in the Phase 3 TAGS trial

IRB Name	Institution Name	City	State / Province	Country
Western Institutional Review Board	California Pacific Medical Center	San Francisco	CA	United States
Quorum Review, Inc.	St. Jude Heritage Healthcare	Fullerton	CA	United States
Quorum Review, Inc.	Illinois CancerCare, P.C.	Peoria	IL	United States
Mount Sinai Hospital Institutional Review Board, F404	Mount Sinai Hospital Medical Center	Chicago	IL	United States
USC IRB	USC/Norris Comprehensive Cancer Center	Los Angeles	CA	United States
USC IRB	USC/Norris Comprehensive Cancer Center	Los Angeles	CA	United States
Quorum Review, Inc.	Banner MD Anderson	Gilbert	AZ	United States
Memorial Sloan Kettering IRB	Memorial Sloan Kettering Cancer Center	New York	NY	United States
Quorum Review, Inc.	21st Century Oncology	Jacksonville	FL	United States
Institutional Review Board, University of Chicago	University of Chicago	Chicago	IL	United States
Medical College of Wisconsin/FH IRB	Medical College of Wisconsin	Milwaukee	WI	United States
Quorum Review, Inc.	University of Pittsburgh Medical Cancer Center	Pittsburgh	PA	United States
Western Institutional Review Board	University of Rochester Medical Center	Rochester	NY	United States
Wake Forest University Health Sciences Institutional Review Board	Wake Forest Baptist Health	Winston-Salem	NC	United States

IRB Name	Institution Name	City	State / Province	Country
Human Research Review Committee	Roger Williams Medical Center	Providence	RI	United States
The NYU Institutional Review Board	Laura & Isaac Perlmutter Cancer Center	New York	NY	United States
The NYU Institutional Review Board	Laura & Isaac Perlmutter Cancer Center	New York	NY	United States
University of Kentucky Office of Research Integrity	University of Kentucky	Lexington	KY	United States
Western Institutional Review Board	University of Wisconsin	Madison	WI	United States
Alta Bates Summit IRB	Alta Bates Summit Comprehensive Cancer	Berkeley	CA	United States
Quorum Review, Inc.	Dartmouth-Hitchcock Medical Center (DHMC)	Lebanon	NH	United States
USC IRB	USC/Norris Comprehensive Cancer Center	Los Angeles	CA	United States
Quorum Review, Inc.	Southern California Oncology Research Alliance (SCORA) Network	Torrance	CA	United States
Iwate Medical University IRB	Iwate Medical University	Morioka-shi	Iwate	Japan
Tochigi Cancer Center IRB	Tochigi Cancer Center	Utsunomiya-shi	Tochigi	Japan
Gunma Prefectural Cancer Center	Gunma Prefectural Cancer Center	Ota-shi	Gunma	Japan
National Cancer Center IRB	National Cancer Center	Kashiwa-shi	Chiba	Japan

IRB Name	Institution Name	City	State / Province	Country
Clinical Research Ethical Review Committee	Ibaraki Prefectural Central Hospital	Kasama-shi	Ibaraki	Japan
Toyama University Hospital IRB	Toyama University Hospital	Toyama-shi	Toyama	Japan
Osaka General Medical Center IRB	Osaka General Medical Center	Osaka-shi	Osaka	Japan
Sakai City Medical Center IRB	Sakai City Medical Center	Sakai-shi	Osaka	Japan
Osaka National Hospital IRB	Osaka National Hospital	Osaka-shi	Osaka	Japan
Ethisch Comité UZA	University Hospital Antwerpen	Edegem		Belgium
UZ Leuven	UZ Leuven	Leuven		Belgium
GHdC	Grand Hopital de Charleroi	Charleroi		Belgium
UCL St.-Luc	Clinique universitaire Saint Luc	Brussels		Belgium
Eticka komise VFN v Praze	VFN Praha	Praha		Czech Republic
Eticka komise FNHK	Faculty Hospital Hradec Kralove	Hradec Králové		Czech Republic
Eticka komise FN Olomouc	FN Olomouc	Olomouc		Czech Republic
Eticka komise FN u sv. Anny	Fakultni Nemocniceu sv. Anny v Brne	Brno		Czech Republic
Eticka komise nemocnice Na Homolce	Nemocnice Na Homolce	Praha 5		Czech Republic
CPP OUEST-II	Centre Eugène Marquis	RENNES CEDEX		France
CPP OUEST-II	Centre Leon Berard	Lyon		France

IRB Name	Institution Name	City	State / Province	Country
CPP OUEST-II	Centre René Gauducheau	Saint Herblain		France
CPP OUEST-II	Centre René Gauducheau	Saint Herblain		France
CPP OUEST-II	Hopital Europeen Georges Pompidou	Paris		France
CPP OUEST-II	Hopital de La	Marseille		France
CPP OUEST-II	Centre Val D' Aurelle	Montpellier		France
CPP OUEST-II	Hôpital Saint-Jean	Perpignan		France
CPP OUEST-II	Groupe Hospitalier Pitié Salpêtrière	Paris Cedex 13		France
CPP OUEST-II	Hôpital Haut-	PESSAC		France
CPP OUEST-II	Hôpital Saint Joseph	Marseille		France
Ethik-Kommission der Bayrischen Landesärztekammer	Städtisches Krankenhaus Muenchen Neuperlach	Muenchen		Germany
Ethikkommission des Landesamts fuer Gesundheit und Soziales	Charite Universitaetsmedizin Berlin	Berlin		Germany
Ethikkommission der Universitaet Ulm	Universitaetsklinikum Ulm	Ulm	Baden-Wuerttemberg	Germany
Ethik-Kommission der MHH	Medizinische Hochschule Hannover	Hannover		Germany
Ethik-Kommission der Bayrischen Landesärztekammer	Leopoldina-Krankenhaus	Schweinfurt	Bayern	Germany
Ethikkommission der Fakultät für Medizin der Technischen Universität München	Technische Universität München	Muenchen	Bayern	Germany
Clinical Research Ethics Committee of the Cork Teaching Hospital	The Adelaide and Meath Hospital, Dublin, Incorporating The National Children's Hospital	Dublin 24		Ireland

IRB Name	Institution Name	City	State / Province	Country
Clinical Research Ethics Committee of the Cork Teaching Hospital	Waterford Regional Hospital	Waterford		Ireland
Clinical Research Ethics Committee of the Cork Teaching Hospital	St James Hospital	Dublin		Ireland
COMITATO ETICO REGIONE TOSCANA - AREA VASTA NORD OVEST	Azienda Ospedaliero Universitaria Pisana (AOUP)	Pisa		Italy
COMITATO ETICO REGIONALE DELLA LIGURIA (SEZIONE N. 2)	Azienda Ospedaliera San Martino	Genova		Italy
COMITATO ETICO DEGLI IRCCS ISTITUTO EUROPEO DI ONCOLOGIA E CENTRO CARDIOLOGICO MONZINO	Istituto Europeo di Oncologia (IEO)	Milan	Milano	Italy
COMITATO ETICO INDIPENDENTE ISTITUTO CLINICO HUMANITAS	Istituto Clinico Humanitas	Rozzano (MI)		Italy
COMITATO ETICO MILANO AREA C	A.O. Ospedale 'Niguarda Ca Granda'	Milano		Italy
COMITATO ETICO SECONDA UNIVERSITÀ DEGLI STUDI DI NAPOLI, AOU SUN - AORN OSPEDALI DEI COLLI	A.O.U. Seconda Università degli Studi di Napoli	Napoli		Italy
COMITATO ETICO INDIPENDENTE CRO AVIANO IRCCS	IRCCS Centro di Riferimento Oncologico – Aviano	Aviano (PN)		Italy

IRB Name	Institution Name	City	State / Province	Country
COMITATO ETICO INTERAZIENDALE PER LE PROVINCE DI LECCO COMO E SONDRIO	A.O. della Valtellina e della Valchiavenna Ospedale di Sondrio	Sondrio		Italy
COMITATO ETICO AREA CREMONA MANTOVA LODI	Struttura Complessa di Oncologia	Cremona		Italy
COMITATO ETICO INDIPENDENTE ISTITUTO CLINICO HUMANITAS	Humanitas Gavazzeni	Bergamo		Italy
COMITATO ETICO UNICO REGIONALE PER LA BASILICATA	A.O.R. San Carlo	Potenza		Italy
COMITATO ETICO IRST IRCCS E AVR	IRCCS - Istituto Scientifico Romagnolo Per lo Studio e la Cura Dei Tumori (I.R.S.T.)	Meldola (FC)		Italy
COMITATO ETICO DELL'AZIENDA OSPEDALIERO UNIVERSITARIA SAN LUIGI GONZAGA	A.O.U. San Luigi Gonzaga	Orbassano (TO)		Italy
COMITATO ETICO DELLA PROVINCIA DI BRESCIA	Fondazione Poliambulanza Istituto Ospedaliero	Brescia		Italy
Komisja Bioetyczna przy Centrum Onkologii - Instytucie im. Marii Skłodowskiej-Curie	Maria Skłodowska-Curie Memorial Cancer Center, Institute of Oncology	Warszawa		Poland
Komisja Bioetyczna przy Centrum Onkologii - Instytucie im. Marii Skłodowskiej-Curie	Szpital MSWiA i Warmińsko – Mazurskie Centrum Onkologii w Olsztynie	Olsztyn		Poland

IRB Name	Institution Name	City	State / Province	Country
Komisja Bioetyczna przy Centrum Onkologii - Instytucie im. Marii Skłodowskiej-Curie	Szpital Uniwersytecki w Krakowie	Kraków		Poland
Komisja Bioetyczna przy Centrum Onkologii - Instytucie im. Marii Skłodowskiej-Curie	Opolskie centrum Onkologii	Opole		Poland
Comissão de Ética para a Investigação Clínica (CEIC)	Centro Hospitalar de Tras-os-Montes e Alto Douro, EPE	Vila Real		Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Centro Hospitalar do Porto, E.P.E	Porto	Porto	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Hospital Garcia de Orta, E.P.E.	Almada	Setubal	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Fundação Champalimaud	Lisboa	Lisboa	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Unidade Local de Saúde de Matosinhos E.P.E.- H.	Matosinhos	Porto	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Centro Hospitalar de São João, EPE	Porto	Porto	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Hospital da Luz, S.A.	Lisboa	Lisboa	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Instituto Português de Oncologia do Porto	Porto	Porto	Portugal
Comissão de Ética para a Investigação Clínica (CEIC)	Hospital de Braga	Braga		Portugal
National Bioethics Commission of Medicine and Medical Devices	Spitalul Judetean "Sf Ioan Cel Nou	Suceava	Suceava	Romania

IRB Name	Institution Name	City	State / Province	Country
CEIC Hospital Universitario La Paz	Hospital Universitario La Paz	Madrid	Madrid	Spain
Comité de Etica dela Investigación del Principado de Asturias	Hospital Universitario Central de Asturias	Oviedo	Asturias	Spain
CEIC IRICYS-Fundación para la Investigación Biomédica del Hospital Ramón y Cajal	Hospital Universitario Ramon y Cajal	Madrid	Madrid	Spain
CEIC del Hospital Universitario Vall d'Hebron	Hospital Universitario Vall d'Hebron	Barcelona	Cataluña	Spain
CEIC Hospital General Universitario "Morales Meseguer"	Hospital Universitario Morales Meseguer	Murcia	Murcia	Spain
Fundació Parc Taulí	Corporacio Parc	Sabadell	Cataluña	Spain
NRES Committee London-Hampstead	Sarah Cannon Research Institute	London		United Kingdom
NRES Committee London-Hampstead	Leicester Royal Infirmary	Leicester		United Kingdom
NRES Committee London-Hampstead	Belfast Health and Social Care Trust - Belfast City Hospital	Belfast		United Kingdom
NRES Committee London-Hampstead	The Christie NHS Foundation Trust	Manchester		United Kingdom
NRES Committee London-Hampstead	Guy's Hospital NHS Foundation Trust			United Kingdom
NRES Committee London-Hampstead	The Royal Marsen NHS Foundation			United Kingdom
NRES Committee London-Hampstead	NHS Grampian			United Kingdom
NRES Committee London-Hampstead	The Royal Marsen NHS Foundation			United Kingdom

IRB Name	Institution Name	City	State / Province	Country
Local Ethics Committee at Republican center for oncology and medical radiology n.a. Alexandrov	Republican center for oncology and medical radiology n.a. Alexandrov	Minsk region		Belarus
Local Ethics Committee at Minsk City Clinical Oncology Dispensary	Minsk City Clinical Oncology Dispensary	Minsk		Belarus
Local Ethics Committee at State Institution the Republican Research Center for Radiation Medicine	Gomel Regional Clinical Oncology Dispensary	Gomel		Belarus
Hadassah EC	Hadassah Ein Karem	Jerusalem	-	Israel
Rambam EC	Rambam healthcare campus	Haifa	Haifa	Israel
Sheba EC	Sheba Medical Center	Ramat Gan		Israel
Rabin Medical Centre EC	Rabin MC Belinson Hospital	Petah Tikva		Israel
Tel Aviv Sourasky Medical Center EC	Tel-Aviv Sourasky MC	Tel Aviv		Israel
Soroka MC EC	Soroka MC	Beer-Sheva		Israel
Local Ethics Committee at Budget Institution of Healthcare Omsk Region - Clinical Oncology Dispensary	Budget Institution of Healthcare Omsk Region - Clinical Oncology Dispensary	Omsk		Russian Federation

IRB Name	Institution Name	City	State / Province	Country
Local Ethics Committee at FSBSI "N.N. Blokhin Russian Cancer Research Center"	FSBSI "N.N. Blokhin Russian Cancer Research Center"	Moscow		Russian Federation
Local Ethics Committee at North-Western State Medical University named after I.I. Mechnikov	North-Western State Medical University named after I.I. Mechnikov Hospital	Saint Petersburg		Russian Federation
Local Ethics Committee at FSBSI "N.N. Blokhin Russian Cancer Research Center"	Cancer Research Center n.a. Blokhin	Moscow		Russian Federation
Local Ethics Committee at Republican Oncology Center	Republican Oncology Center	Ufa		Russian Federation
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Bezmi Alem University	Istanbul		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Baskent University Adana Practice and Research Centre Kista Oncology Centre	Adana		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Marmara Uni. Pendik Training and Research Hospital	Istanbul		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Dokuz Eylul University Medical Faculty Oncology Institute Dept of Medical Oncology	Izmir		Turkey

IRB Name	Institution Name	City	State / Province	Country
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Istanbul University, Cerrahpasa Medical Faculty	Istanbul		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Hacettepe University Cancer Institute	Ankara		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Dr.Abdurrahman Yurtaslan Ankara Oncology Training and Research Hospital	Ankara		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Diskapi (Yildirim Beyazit) Egitim ve Arastirma Hastanesi	Ankara		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Trakya University Medical Faculty Hospital	Edirne		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Uludag University Medical Faculty	Bursa		Turkey
Hacettepe Universitesi Tip Fakultesi Klinik Arastirmalar Etik Kurulu	Ankara University Cebeci Training and Research Hospital Medical	Ankara		Turkey

eTable 2. Baseline Demographics and Disease Characteristics of Patients Who Had or Had Not Undergone Gastrectomy^a

Characteristic	Patients With Gastrectomy		Patients Without Gastrectomy	
	Trifluridine/tipiracil (n = 147)	Placebo (n = 74)	Trifluridine/tipiracil (n = 190)	Placebo (n = 96)
Age, y				
Mean (SD)	63.1 (10.6)	61.6 (9.9)	62.6 (11.0)	62.4 (10.2)
Median (range)	64.0 (38–89)	62.0 (32–80)	63.0 (24–83)	63.0 (32–82)
Sex, No. (%)				
Male	107 (72.8)	49 (66.2)	145 (76.3)	68 (70.8)
Body surface area, m²				
Mean (SD)	1.7 (0.2)	1.7 (0.2)	1.8 (0.2)	1.8 (0.2)
Geographic region, No. (%)				
Europe	118 (80.3)	57 (77.0)	152 (80.0)	81 (84.4)
Japan	22 (15.0)	15 (20.3)	24 (12.6)	12 (12.5)
USA	7 (4.8)	2 (2.7)	14 (7.4)	3 (3.1)
ECOG PS, No. (%)				
0	59 (40.1)	30 (40.5)	64 (33.7)	38 (39.6)
1	88 (59.9)	44 (59.5)	126 (66.3)	58 (60.4)
HER2 status, No. (%)				
Positive	33 (22.4)	16 (21.6)	34 (17.9)	11 (11.5)
Negative	88 (59.9)	40 (54.1)	119 (62.6)	66 (68.8)
Not available	26 (17.7)	18 (24.3)	36 (18.9)	19 (19.8)
Number of metastatic sites, No. (%)				
1–2	88 (59.9)	39 (52.7)	67 (35.3)	33 (34.4)
≥3	59 (40.1)	35 (47.3)	123 (64.7)	63 (65.6)
Number of prior regimens, No. (%)				
2	37 (25.2)	18 (24.3)	89 (46.8)	46 (47.9)
3	65 (44.2)	22 (29.7)	69 (36.3)	38 (39.6)
≥4	45 (30.6)	34 (45.9)	32 (16.8)	12 (12.5)
Prior radiotherapy,^b No. (%)				
Curative intent	44 (29.9)	13 (17.6)	27 (14.2)	13 (13.5)
Palliative	28 (19.0)	8 (10.8)	12 (6.3)	1 (1.0)
Palliative	18 (12.2)	7 (9.5)	18 (9.5)	12 (12.5)
Gastric resection status, No. (%)				
Total resection	95 (64.6)	58 (78.4)	--	--

Partial resection	42 (28.6)	14 (18.9)	--	--
Unknown	10 (6.8)	2 (2.7)	--	--

Abbreviations: ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; SD, standard deviation.

^aIntent-to-treat population.

^bSome patients received both palliative and curative-intent radiotherapy.

eTable 3. Supportive Treatment for Hematologic Toxicities in Patients Who Had or Had Not Undergone Gastrectomy^a

	Patients With Gastrectomy No. (%)		Patients Without Gastrectomy No. (%)	
	Trifluridine/tipiracil (n = 145)	Placebo (n = 73)	Trifluridine/tipiracil (n = 190)	Placebo (n = 95)
Supportive treatment for any hematologic toxicities	51 (35.2)	4 (5.5)	52 (27.4)	8 (8.4)
Supportive treatment for neutropenia	33 (22.8)	1 (1.4)	25 (13.2)	2 (2.1)
G-CSF	30 (20.7)	1 (1.4)	24 (12.6)	2 (2.1)
Sodium nucleate	3 (2.1)	0	2 (1.1)	0
Supportive treatment for anemia	26 (17.9)	3 (4.1)	35 (18.4)	6 (6.3)
Blood cells/transfusion	25 (17.2)	2 (2.7)	32 (16.8)	6 (6.3)
Erythropoietin products	1 (0.7)	2 (2.7)	5 (2.6)	0
Supportive treatment for thrombocytopenia	2 (1)	0	1 (0.5)	0
Platelets	2 (1.4)	0	1 (0.5)	0

Abbreviations: G-CSF, granulocyte colony stimulating factor.

^aAs-treated population.

eTable 4. Treatment Exposure in Patients Who Had or Had Not Undergone Gastrectomy^a

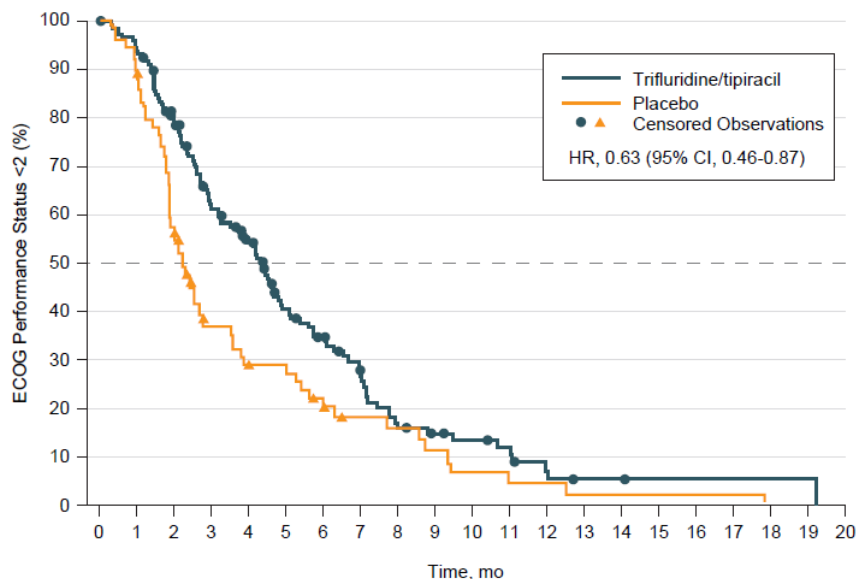
	Patients With Gastrectomy		Patients Without Gastrectomy	
	Trifluridine/tipiracil (n = 145)	Placebo (n = 73)	Trifluridine/tipiracil (n = 190)	Placebo (n = 95)
Mean (SD) total dose administered, mg/m ²	2160.5 (1665.2)	1323.2 (712.4)	2101.9 (1645.3)	1657.2 (1638.0)
Mean (SD) dose intensity, mg/m ² /week	145 (28)	159 (23)	151 (25)	152 (31)
Mean (SD) relative dose intensity	0.83 (0.16)	0.91 (0.13)	0.86 (0.15)	0.87 (0.18)
Median (range) cycles initiated per patient	2 (1–14)	2 (1–6)	2 (1–12)	2 (1–16)
Mean (SD) treatment duration, weeks	12.7 (11.8)	5.8 (4.4)	11.6 (11.2)	8.1 (9.6)

Abbreviations: SD, standard deviation.

^aAs-treated population.

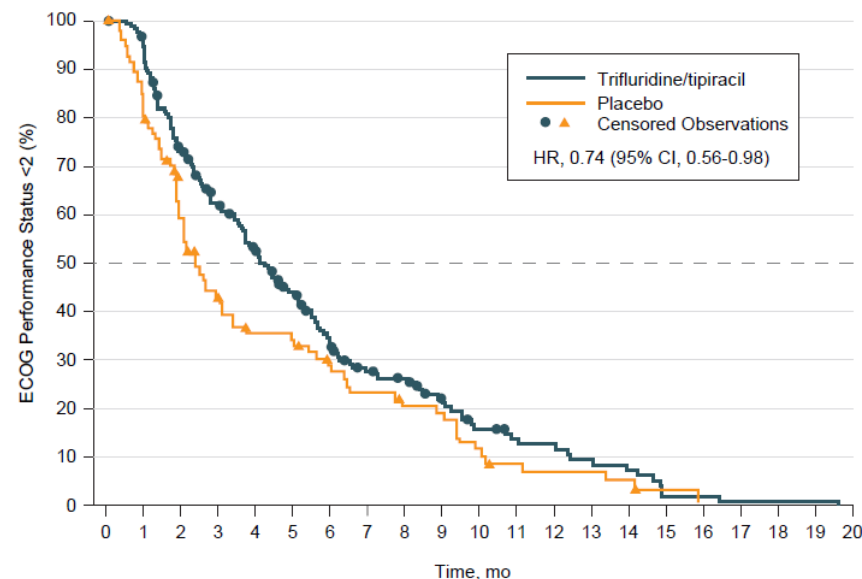
eFigure 1. Time to Deterioration of ECOG Performance Status Score to 2 or Higher in (A) Patients Who Had Undergone Gastrectomy and (B) Patients Who Had Not Undergone Gastrectomy

A Time to deterioration of ECOG performance status score to 2 or higher in patients with gastrectomy



No. at risk	
Trifluridine/tipiracil	147 137 111 80 66 44 36 25 15 12 10 8 4 2 2 1 1 1 1 1 0
Placebo	74 66 41 23 17 16 11 8 7 5 3 2 2 1 1 1 1 1 1 0

B Time to deterioration of ECOG performance status score to 2 or higher in patients without gastrectomy



No. at risk	
Trifluridine/tipiracil	190 171 134 107 87 68 49 38 34 24 17 13 12 8 7 2 2 1 1 1 0
Placebo	96 76 53 35 28 26 21 17 14 13 7 5 4 4 3 1 0

Median times to deterioration of ECOG performance status scores were assessed using the Kaplan–Meier method. In patients with gastrectomy (A), the median time to deterioration was 4.4 months (95% CI, 3.3–4.8) in the trifluridine/tipiracil group and 2.2 months (95% CI, 1.9–2.8) in the placebo group. In patients without gastrectomy (B), the median time to deterioration was 4.2 months (95% CI, 3.6–5.1) in the trifluridine/tipiracil group and 2.4 months (95% CI, 1.9–3.1) in the placebo group. CI indicates confidence interval; ECOG, Eastern Cooperative Oncology Group; HR, hazard ratio.

eResults. Hematologic AEs in FTD/TPI-treated Patients Who Had or Had Not Received Prior Irradiation

In the gastrectomy subgroup, incidences of neutropenia and anemia were 54.4% (24 of 44 patients) and 40.9% (18 of 44 patients), respectively, among patients who had undergone prior radiotherapy and 62.4% (63 of 101 patients) and 58.4% (59 of 101 patients) among those who had not undergone radiotherapy. In the no-gastrectomy subgroup, incidences of neutropenia and anemia were 33.3% (9 of 27 patients) and 25.9% (7 of 27 patients), respectively, among patients who had undergone prior radiotherapy and 49.1% (80 of 163 patients) and 40.5% (66 of 163 patients) among those who had not undergone radiotherapy.

