者集団，TC1の被験者集団，TC0の被験者集団の順に，0.40（95%CI：0.22～0.74），1.02（95%CI：0.63～1.65），0.93（95%CI：0.53～1.63），0.73（95%CI：0.60～0.89）であった。

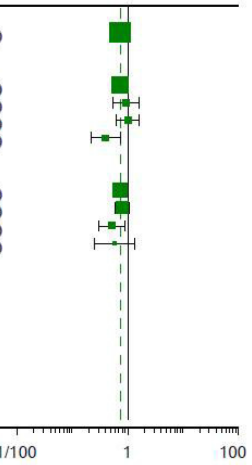
2) IC スコア別の部分集団の OS の解析

ドセタキセル群と比較した本剤群の OS の Unstratified HR は，IC3の被験者集団，IC2の被験者集団，IC1の被験者集団，IC0の被験者集団の順に，0.58（95%CI：0.25～1.36），0.52（95%CI：0.30～0.92），0.81（95%CI：0.61～1.08），0.74（95%CI：0.59～0.94）であった。

図 2.7.3.3.3.3-4 OS の TC スコア別部分集団解析及び IC スコア別部分集団解析（OAK 試験）

Forest plot - Subgroup Analysis of Duration, Overall Survival
First 850 Randomized Intent-to-Treat Patients
Protocol: GO28915 (Data Cut: 7JUL2016)

Baseline Risk Factors	Total n	Docetaxel (N=425) n	Events	Median (Months)	Atezolizumab (N=425) n	Events	Median (Months)	Hazard Ratio	95% Wald CI
All Patients	850	425	298	9.6	425	271	13.8	0.73	(0.62, 0.86)
TC Score (0 to 3) per TC1IC1 Reread									
0	590	296	212	9.1	294	188	13.3	0.73	(0.60, 0.89)
1	79	38	22	9.4	41	28	12.3	0.93	(0.53, 1.63)
2	94	48	34	10.9	46	33	10.7	1.02	(0.63, 1.65)
3	79	39	27	9.7	40	18	23.3	0.40	(0.22, 0.74)
IC Score (0 to 3) per TC1IC1 Reread									
0	429	219	160	9.2	210	134	12.7	0.74	(0.59, 0.94)
1	300	142	90	10.1	158	104	14.1	0.81	(0.61, 1.08)
2	79	44	33	8.7	35	19	16.6	0.52	(0.30, 0.92)
3	34	16	12	12.2	18	10	22.2	0.58	(0.25, 1.36)



NE= Not estimable; Median survival was estimated from Kaplan-Meier method. Unstratified hazard ratio relative to Docetaxel and 95% CI for the hazard ratio were estimated using Cox regression. The vertical dashed line indicates the hazard ratio for all patients. The diameter of a square is proportional to the square root of the total number of events. Randomized treatments are displayed.
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.
Program: /opt/BIOSTAT/prod/cdt7692h/s28915g/g_fstg02.sas Output: /opt/BIOSTAT/prod/cdt7692h/s28915g/reports/g_fstg02_IT850_pg4_os.pdf 24SEP2016 17:58

［5.3.5.1-1 Figure 18を再掲］

2.7.3.3.3.4 その他の部分集団解析

OAK 試験及び POPLAR 試験の人口統計学的特性及びベースライン時の特性について，OS の部分集団解析を行った結果を以下に示す。

(1) OAK 試験

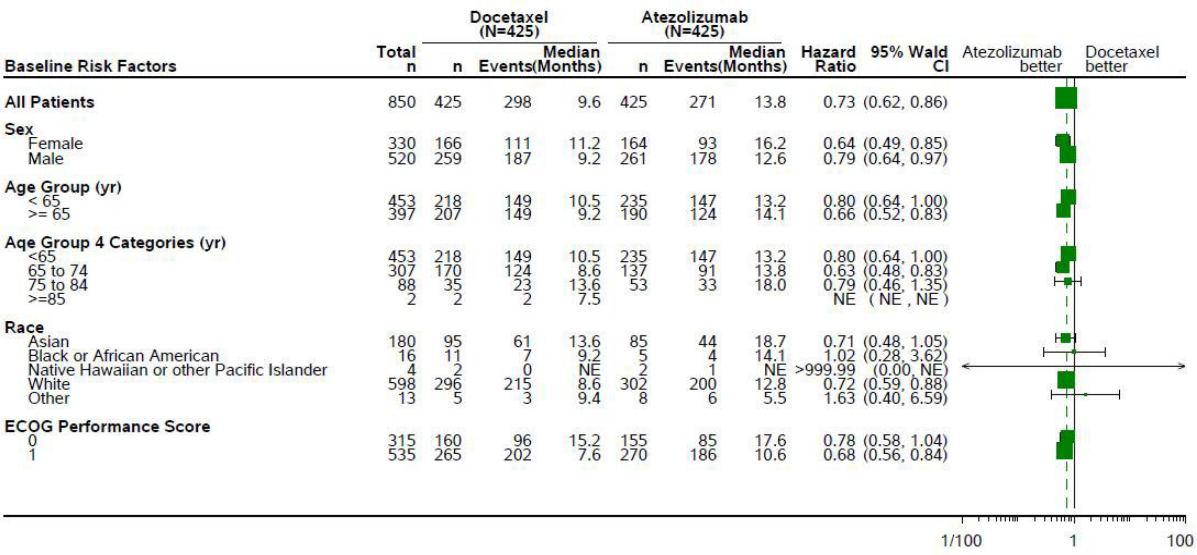
OAK 試験の OS の部分集団解析を要約した Forest Plot を図 2.7.3.3.3.4-1に示す。

EGFR 遺伝子変異陽性の部分集団など一部の部分集団で被験者数が限られていたが，大部分の部分集団で本剤の一貫した治療効果が示された。

図 2.7.3.3.3.4-1 OS の部分集団解析（OAK 試験）

Forest plot - Subgroup Analysis of Duration, Overall Survival
First 850 Randomized Intent-to-Treat Patients
Protocol: GO28915 (Data Cut: 7JUL2016)

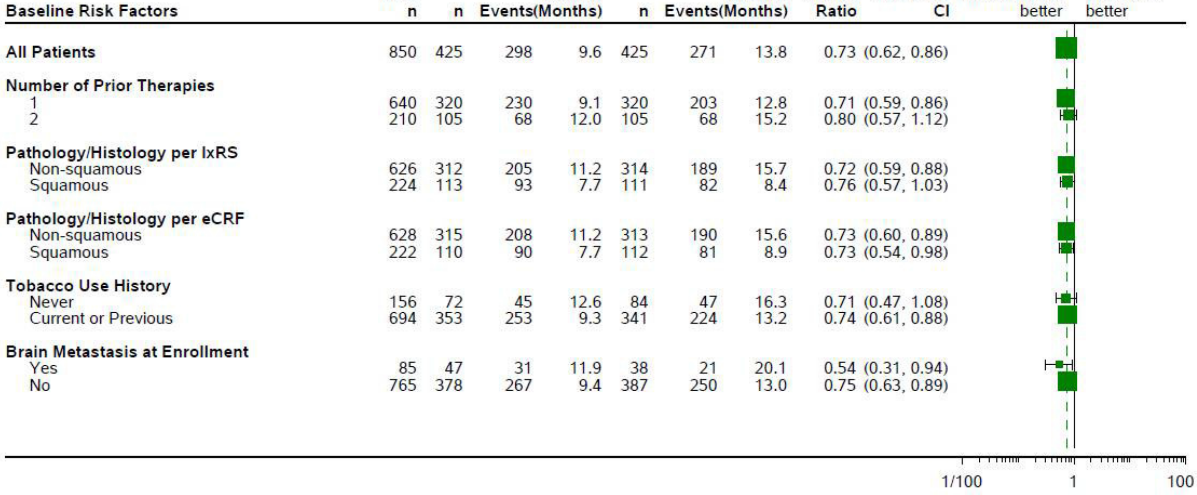
Baseline Risk Factors	Total n	Docetaxel (N=425) n	Docetaxel (N=425) Events	Docetaxel (N=425) Median(Months)	Atezolizumab (N=425) n	Atezolizumab (N=425) Events	Atezolizumab (N=425) Median(Months)	Hazard Ratio	95% Wald CI
All Patients	850	425	298	9.6	425	271	13.8	0.73	(0.62, 0.86)
Sex									
Female	330	166	111	11.2	164	93	16.2	0.64	(0.49, 0.85)
Male	520	259	187	9.2	261	178	12.6	0.79	(0.64, 0.97)
Age Group (yr)									
< 65	453	218	149	10.5	235	147	13.2	0.80	(0.64, 1.00)
>= 65	397	207	149	9.2	190	124	14.1	0.66	(0.52, 0.83)
Age Group 4 Categories (yr)									
<65	453	218	149	10.5	235	147	13.2	0.80	(0.64, 1.00)
65 to 74	307	170	124	8.6	137	91	13.8	0.63	(0.48, 0.83)
75 to 84	88	35	23	13.6	53	33	18.0	0.79	(0.46, 1.35)
>=85	2	2	2	7.5				NE	(NE , NE)
Race									
Asian	180	95	61	13.6	85	44	18.7	0.71	(0.48, 1.05)
Black or African American	16	11	7	9.2	5	4	14.1	1.02	(0.28, 3.62)
Native Hawaiian or other Pacific Islander	4	2	0	NE	2	1	NE	>999.99	(0.00, NE)
White	598	296	215	8.6	302	200	12.8	0.72	(0.59, 0.88)
Other	13	5	3	9.4	8	6	5.5	1.63	(0.40, 6.59)
ECOG Performance Score									
0	315	160	96	15.2	155	85	17.6	0.78	(0.58, 1.04)
1	535	265	202	7.6	270	186	10.6	0.68	(0.56, 0.84)



NE= Not estimable; Median survival was estimated from Kaplan-Meier method. Unstratified hazard ratio relative to Docetaxel and 95% CI for the hazard ratio were estimated using Cox regression. The vertical dashed line indicates the hazard ratio for all patients. The diameter of a square is proportional to the square root of the total number of events. Randomized treatments are displayed.
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.
Program: /opt/BIOSTAT/prod/cdt7692h/s28915g/g_fstg02.sas Output: /opt/BIOSTAT/prod/cdt7692h/s28915g/reports/g_fstg02_IT850_pg1_os.pdf 24SEP2016 17:51

Forest plot - Subgroup Analysis of Duration, Overall Survival
First 850 Randomized Intent-to-Treat Patients
Protocol: GO28915 (Data Cut: 7JUL2016)

Baseline Risk Factors	Total n	Docetaxel (N=425) n	Docetaxel (N=425) Events	Docetaxel (N=425) Median(Months)	Atezolizumab (N=425) n	Atezolizumab (N=425) Events	Atezolizumab (N=425) Median(Months)	Hazard Ratio	95% Wald CI
All Patients	850	425	298	9.6	425	271	13.8	0.73	(0.62, 0.86)
Number of Prior Therapies									
1	640	320	230	9.1	320	203	12.8	0.71	(0.59, 0.86)
2	210	105	68	12.0	105	68	15.2	0.80	(0.57, 1.12)
Pathology/Histology per IxRS									
Non-squamous	626	312	205	11.2	314	189	15.7	0.72	(0.59, 0.88)
Squamous	224	113	93	7.7	111	82	8.4	0.76	(0.57, 1.03)
Pathology/Histology per eCRF									
Non-squamous	628	315	208	11.2	313	190	15.6	0.73	(0.60, 0.89)
Squamous	222	110	90	7.7	112	81	8.9	0.73	(0.54, 0.98)
Tobacco Use History									
Never	156	72	45	12.6	84	47	16.3	0.71	(0.47, 1.08)
Current or Previous	694	353	253	9.3	341	224	13.2	0.74	(0.61, 0.88)
Brain Metastasis at Enrollment									
Yes	85	47	31	11.9	38	21	20.1	0.54	(0.31, 0.94)
No	765	378	267	9.4	387	250	13.0	0.75	(0.63, 0.89)



NE= Not estimable; Median survival was estimated from Kaplan-Meier method. Unstratified hazard ratio relative to Docetaxel and 95% CI for the hazard ratio were estimated using Cox regression. The vertical dashed line indicates the hazard ratio for all patients. The diameter of a square is proportional to the square root of the total number of events. Randomized treatments are displayed.
Data Cut-off: 7 Jul 2016; RAVE Data Extracted: 19 Aug 2016.
Program: /opt/BIOSTAT/prod/cdt7692h/s28915g/g_fstg02.sas Output: /opt/BIOSTAT/prod/cdt7692h/s28915g/reports/g_fstg02_IT850_pg2_os.pdf 12OCT2016 23:46