Clinical trial results:
A Phase II study of immunotherapy with durvalumab and tremelimumab in combination with capecitabine or without capecitabine in adjuvant situation for biliary tract cancer

Summary

EudraCT number	2021-002389-41
Trial protocol	DE
Global end of trial date	20 February 2025

Results information

Result version number	v1 (current)
This version publication date	15 January 2026
First version publication date	15 January 2026
Summary attachment (see zip file)	Non-serious AE Listing (ADJUBIL non-serious AEs.pdf)

Trial information

Trial identification

Sponsor protocol code	ADJUBIL

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05239169
WHO universal trial number (UTN)	-
Other trial identifiers	AIO Study Number: AIO-HEP-0421/ass, EU-CT number: 2024-511847-24-00

Notes:

Sponsors

Sponsor organisation name	Frankfurter Institut für Klinische Krebsforschung IKF GmbH
Sponsor organisation address	Steinbacher Hohl 2-26, Frankfurt am Main, Germany,
Public contact	IKF, Frankfurter Institut für Klinische Krebsforschung IKF GmbH am Krankenhaus Nordwest, 0049 6976014420, adjubil@ikf-khnw.de
Scientific contact	IKF, Frankfurter Institut für Klinische Krebsforschung IKF GmbH am Krankenhaus Nordwest, 0049 6976014420, adjubil@ikf-khnw.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 August 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 February 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the anti-tumor activity of the combination of durvalumab and tremelimumab with or without capecitabine by the recurrence-free survival rate after 12 months (RFS@12).

Protection of trial subjects:

This clinical trial study was designed and shall be implemented and reported in accordance with the protocol, the AMG (Arzneimittelgesetz), the ICH Harmonized Tripartite Guidelines for Good Clinical Practice, with applicable local regulations (including European Directive 2001/20/EC), and with the ethical principles laid down in the Declaration of Helsinki. The trial was authorized/Approved by the competent authority (Paul-Ehrlich-Institut, PEI) and the competent ethics committee responsible for the trial ("federführende Ethikkommission). Before recruitment into the clinical trial, each patient was informed that participation in the study is completely voluntary, and that he or she may withdraw his or her participation in the trial at any time without any declaration of reasons, which will not lead to any disadvantage for the respective patient. The eligibility of a new patient was determined by the local investigator during regular clinical visits. The examinations for the study and the inclusion of the patient were done after detailed written and oral education about aims, methods, anticipated benefits and potential hazards of the study by use of the informed consent forms and after given written consent of the patient. Safety was monitored continuously by careful monitoring of all adverse events (AEs) and serious adverse events (SAEs) reported. An independent safety data monitoring committee (SDMC) was responsible for assessment of reports summarizing safety data or study results and gave recommendations for planned protocol amendments.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 February 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Between June 2022 and January 2024, 46 patients were screened for eligibility and 40 patients from a total of 12 different trial sites were eventually randomized into the trial. Study Arm A consisted of 21 patients, whereas Arm B included 19 patients.

Pre-assignment

Screening details:

Patients with histologically proven und curatively resected biliary tract cancer (intrahepatic, hilar or distal CCA as well gallbladder carcinoma) without metastatic disease.

Period 1

Period 1 title	Overall Period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm A

Arm description:

Patients in Arm A received 8x cycles of capecitabine (1,250 mg/m² p.o. twice a day on days 1 to 14 of a 3-week cycle) in combination with durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients received durvalumab at a fixed dose of 1500 mg as an IV infusion over 1 hour, on day 1 together with the Tremelimumab infusion. Durvalumab only infusion was repeated every 4 weeks for a maximum of 12 months on day 1 of each cycle.
An exception to the fixed dosing listed above for durvalumab is made for patients with low body weight (below 30 kg): Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to 20 mg/kg Q4W, until weight increases to greater than 30 kg.

Investigational medicinal product name	Tremelimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients received tremelimumab at a fixed dose of 300 mg as an IV infusion over 1 hour on day 1 of cycle 1.

Investigational medicinal product name	Capecitabine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patient's received capecitabine at 1250 mg/m² p.o. twice a day on days 1 to 14 of a 3-weekly cycle (eight cycles).

Arm title	Arm B

Arm description:

Patients in Arm B received durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.

Arm type	Experimental
Investigational medicinal product name	Durvalumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients received durvalumab at a fixed dose of 1500 mg as an IV infusion over 1 hour, on day 1 together with the Tremelimumab infusion. Durvalumab only infusion was repeated every 4 weeks for a maximum of 12 months on day 1 of each cycle.
An exception to the fixed dosing listed above for durvalumab is made for patients with low body weight (below 30 kg): Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to 20 mg/kg Q4W, until weight increases to greater than 30 kg.

Investigational medicinal product name	Tremelimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Patients received tremelimumab at a fixed dose of 300 mg as an IV infusion over 1 hour on day 1 of cycle 1.

Number of subjects in period 1	Arm A	Arm B
Started	21	19
Completed	5	6
Not completed	16	13
Unrelated medical illness or complication	1	-
Physician decision	-	1
Toxicity	7	4
Patient's wish	2	1
Death	-	1
Progressive disease	6	6

Baseline characteristics

Reporting groups	
Reporting group title	Arm A
Reporting group description:	
Patients in Arm A received 8x cycles of capecitabine (1,250 mg/m² p.o. twice a day on days 1 to 14 of a 3-week cycle) in combination with durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.	
Reporting group title	Arm B
Reporting group description:	
Patients in Arm B received durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.	

Reporting group values	Arm A	Arm B	Total
Number of subjects	21	19	40
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
median	65	62	
full range (min-max)	43 to 84	48 to 79	-
Gender categorical			
Units: Subjects			
Female	10	9	19
Male	11	10	21
ECOG performance status			
Units: Subjects			
Status 0	17	15	32
Status 1	4	4	8
Tumor site/type BTC			
Units: Subjects			
Extrahepatic CCA	12	11	23
Intrahepatic CCA	6	6	12
Gallbladder	3	2	5
Resection status (microscopic)			
Units: Subjects			
R0	17	12	29
R1	4	7	11
BTC stage			

Units: Subjects			
Stage 0	2	0	2
Stage IA	1	3	4
Stage IB	1	2	3
Stage II	3	1	4
Stage IIA	1	1	2
Stage IIB	5	5	10
Stage IIIA	2	1	3
Stage IIIB	4	4	8
Stage IIIC	1	1	2
Stage IVA	1	0	1
Stage IVB	0	1	1
TNM at first diagnosis T Units: Subjects			
T1(a/b)	4	5	9
T2(a/b)	12	10	22
T3	4	4	8
T4	1	0	1
TNM at first diagnosis N Units: Subjects			
N0	9	6	15
N1	9	8	17
N2	3	3	6
Nx	0	2	2
TNM at first diagnosis M Units: Subjects			
M0	21	19	40
Histopathological grade Units: Subjects			
G1	0	1	1
G2	14	14	28
G3	6	4	10
Gx	1	0	1
Time since resection until randomization Units: months			
median	2	2	
full range (min-max)	0.8 to 3.7	1.0 to 3.8	-

End points

End points reporting groups

Reporting group title	Arm A

Reporting group description:

Patients in Arm A received 8x cycles of capecitabine (1,250 mg/m² p.o. twice a day on days 1 to 14 of a 3-week cycle) in combination with durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.

Reporting group title	Arm B

Reporting group description:

Patients in Arm B received durvalumab (1,500 mg, i.v. on day 1 of each 4-week cycle) and a single dose of tremelimumab (300 mg, i.v. on day 1 of cycle 1; STRIDE regime) for up to 12 months.

Primary: RFS@12

End point title	RFS@12[1]

End point description:

Recurrence-free survival at 12 months (RFS@12) was defined as the proportion of allocated subjects without any recurrence/progression and alive at 12 months after the date of treatment allocation.

End point type	Primary

End point timeframe:

until 12 months after treatment allocation

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: RFS@12 was analyzed to select the more promising arm in the Pick-the-Winner design. As this was a decision-oriented design, no p-value was calculated; the decision was based on the observed RFS@12 and the safety profile of the arms

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	19		
Units: %	52	58		

Statistical analyses

No statistical analyses for this end point

Secondary: recurrence-free survival

End point title	recurrence-free survival

End point description:

Recurrence-free survival (RFS) was determined as time from the date of treatment allocation to the date of any recurrence/progression (local or regional [including invasive ipsilateral tumor and invasive locoregional tumor], or distant) or death due to any cause. Patients without event were censored at the date of their last tumor assessment prior to any subsequent anticancer therapy.

End point type	Secondary

End point timeframe:

from the date of treatment allocation to the date of any recurrence/progression or death due to any cause

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	19		
Units: month				
median (confidence interval 95%)	15.0 (7.3 to 999999)	17.0 (8.0 to 999999)		

Statistical analyses

No statistical analyses for this end point

Secondary: overall survival

End point title	overall survival

End point description:

Overall survival (OS) will be determined as time from the date of treatment allocation to the date of death due to any cause. A subject who has not died will be censored at last known date alive.

Median OS was not reached for Arm B (here displayed as 9999)

End point type	Secondary

End point timeframe:

from the date of treatment allocation to the date of death due to any cause

End point values	Arm A	Arm B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	19		
Units: month				
median (confidence interval 95%)	18.5 (18.3 to 999999)	999999 (999999 to 999999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were assessed continuously during the study, starting with randomization and until 90 days after last dose of study treatment.

Adverse event reporting additional description:

Listed here are all serious adverse events and the most common non-serious adverse events, which occurred in ≥ 20% of the patients in at least one of both arms.
A detailed listing of all non-serious adverse events which occured in ≥ 5% of the patients is attached as pdf file (summary attachment)

Assessment type	Systematic

Dictionary used

Dictionary name	NCI CTCAE
Dictionary version	5.0

Reporting groups

Reporting group title	Safety analysis set Arm A
Reporting group description: -	
Reporting group title	Safety analysis set Arm B

Reporting group description: -

Serious adverse events	Safety analysis set Arm A	Safety analysis set Arm B	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 21 (57.14%)	11 / 19 (57.89%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0		
Vascular disorders			
thromboembolic event			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aneurysm of arteria hepatica dextra			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Encephalopathy			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Stroke			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolysis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Diarrhoea			
subjects affected / exposed	1 / 21 (4.76%)	2 / 19 (10.53%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
fever			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bad general condition			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vigilance reduction			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Umbilical hernia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Autoimmune disorder			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 21 (9.52%)	3 / 19 (15.79%)	
occurrences causally related to treatment / all	1 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatic failure			

subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal hypertension			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Portal vein stenosis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	2 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal deformity			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Herpes simplex			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint infection			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
infection with gram-negative rods			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Safety analysis set Arm A	Safety analysis set Arm B	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 21 (95.24%)	19 / 19 (100.00%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 21 (19.05%)	5 / 19 (26.32%)	
occurrences (all)	5	6	
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 21 (28.57%)	6 / 19 (31.58%)	
occurrences (all)	8	6	
Blood bilirubin increased			
subjects affected / exposed	5 / 21 (23.81%)	2 / 19 (10.53%)	
occurrences (all)	5	2	
Platelet count decreased			
subjects affected / exposed	6 / 21 (28.57%)	1 / 19 (5.26%)	
occurrences (all)	7	1	
Lipase increased			
subjects affected / exposed	2 / 21 (9.52%)	6 / 19 (31.58%)	
occurrences (all)	2	9	

Pruritus subjects affected / exposed occurrences (all) Amylase increased subjects affected / exposed occurrences (all)	3 / 21 (14.29%) 3 0 / 21 (0.00%) 0	4 / 19 (21.05%) 4 4 / 19 (21.05%) 4	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	8 / 21 (38.10%) 13	1 / 19 (5.26%) 3	
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	9 / 21 (42.86%) 11	5 / 19 (26.32%) 5	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all)	11 / 21 (52.38%) 14 10 / 21 (47.62%) 12	5 / 19 (26.32%) 5 4 / 19 (21.05%) 4	
Skin and subcutaneous tissue disorders Palmar-plantar erythrodysaesthesia syndrome subjects affected / exposed occurrences (all)	6 / 21 (28.57%) 9	0 / 19 (0.00%) 0	
Endocrine disorders Hyperthyroidism subjects affected / exposed occurrences (all)	4 / 21 (19.05%) 5	4 / 19 (21.05%) 4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 July 2023	• extension of recruitment period from 12 to 18 months extension of the total study duration from 2 to 2.5 years • formal correction of Inclusion criterion #2 and exclusion criterion #2 & #15 • addition of coagulation and 3-times ECG in screening according to inclusion criterion #7 and exclusion criterion #16 to the Schedule of Assessments • adaptations according to the updated IB of durvalumab and the SmPC of capecitabine • adjustment of the description of the randomization procedure
06 February 2024	• adaption to CTR 536/2014 • name change of sponsor • adaptations according to the updated IB of durvalumab and tremelimumab
12 November 2024	• name change of sponsor • change of fax-number of the sponsor • adaptations according to the updated IB of durvalumab

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported