

## **Clinical trial results:**

A Phase 4, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Pharmacokinetics and Safety of Obeticholic Acid in Patients with Primary Biliary Cholangitis and Moderate to Severe Hepatic Impairment Summary

Results information	
Trial information	
Trial identification	
Additional study identifiers	
Sponsors	
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Paediatric regulatory details	
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Population of trial subjects				
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Subjects enrolled per age group				
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Number of subjects in period 2	

## **Baseline characteristics** Reporting groups Reporting group values

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## End points reporting groups

**End points** 

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Secondary: Change From Baseline in MELD-Sodium (Na) Score at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15					
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Secondary: Change From Bas 30, 36, and 48; and Extensio	seline in Chilo n Months 3, (	d-Pugh Score 6, 9, 12, and	e at Day 1, W 15	eeks 6, 12, 18, 2
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Secondary: Number of Par Categories)	ticipants by Chil	d-Pugh Score Co	mponent (As	cites
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Statistical analyses				
Secondary: Number of Participan Time Categories)	nts by Child-P	ugh Score Co	mponent (Pro	othrombin
End point values				

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Statistical analyses				
<b>Secondary: Number of Participar</b>	nts by Child-P	ugh Score Co	mponent (Se	rum Albumin
Categories)				
	<u>                                       </u>			
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End point values		

Secondary: Number of Par Categories)	ticipants by Ch	nild-Pugh Sco	re Component	: (Total Bilirubi
	1		ı	<u> </u>
nd point values				

End point values		

Statistical analyses					
Secondary: Change From Baseline in Total Bilirubin at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15					
30, 42, aliu 40, aliu Extelision Pix		12, and 15			
	T				
	<u> </u>				
End point values	1				
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Statistical analyses				
Secondary: Change From Baselin	e in Direct Bi	lirubin at We	eks 3, 6, 12, :	18, 24, 30,
36, 42, and 48; and Extension Mo	onths 3, 6, 9,	12, and 15		
	Г			
End point values				

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Statistical analyses				
Casandawy Changa From Basalin	a in Alkalina	Dhaanhataaa	at Weeks 2	5 12 10 24
Secondary: Change From Baselin 30, 36, 42, and 48; and Extension	n Months 3, 6	, 9, 12, and 1	5	0, 12, 10, 24,
End point values				
End point values				

Statistical analyses				
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Secondary: Change From Baselin 18, 24, 30, 36, 42, and 48; and E	ne in Alanine <i>I</i> Extension Mon	Aminotransfe ths 3, 6, 9, 1	rase at Week 2, and 15	s 3, 6, 12,
End point values				

Statistical analyses				
Secondary: Change From Baselin	e in Aspartat	e Aminotrans	ferase at We	eks 3, 6, 12,
18, 24, 30, 36, 42, and 48; and E	xtension Mon	tns 3, 6, 9, 1	2, and 15	
	I			
End point values				

Statistical analyses				
Secondary: Change From Baselin	e in Gamma (	Glutamyl Trar	sferase at W	eeks 3, 6,
12, 18, 24, 30, 36, 42, and 48; ar	nd Extension	Months 3, 6, 9	9, 12, and 15	
End point values				

Statistical analyses				
Secondary: Change From Baselin	e in Prothron	nbin INR at W	eeks 3, 6, 12	, 18, 24, 30,
36, 42, and 48; and Extension Mo	ontns 3, 6, 9,	12, and 15		
End point values				

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Statistical analyses					
Secondary: Change From B	aseline in Cre	atinine at W	aeks 3 6 12	18 24 30 36 42	
and 48; and Extension Mon	ths 3, 6, 9, 12	2, and 15	eeks 5, 0, 12,	10, 24, 30, 30, 42	
	<u> </u>				
End point values					

Statistical analyses					
Secondary: Change From and 48; and Extension N	m Baseline in Albı Months 3, 6, 9, 12	umin at Week , and 15	s 3, 6, 12, 18	3, 24, 30, 36, 42	2,
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Statistical analyses					
Secondary: Change From Bas	seline in Plate	elets at Weeks	. 3. 6. 12. 18.	. 24. 30. 36. 42.	
and 48; and Extension Month	s 3, 6, 9, 12,	and 15			
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nd point values					

 condary: Change From Baselin		Statistical analyses				
Secondary: Change From Baseline in Total Bile Acids Concentration at Weeks 6, 12						
Secondary: Change From Baseline in Total Bile Acids Concentration at Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Month 3						
d point values						

Statistical analyses

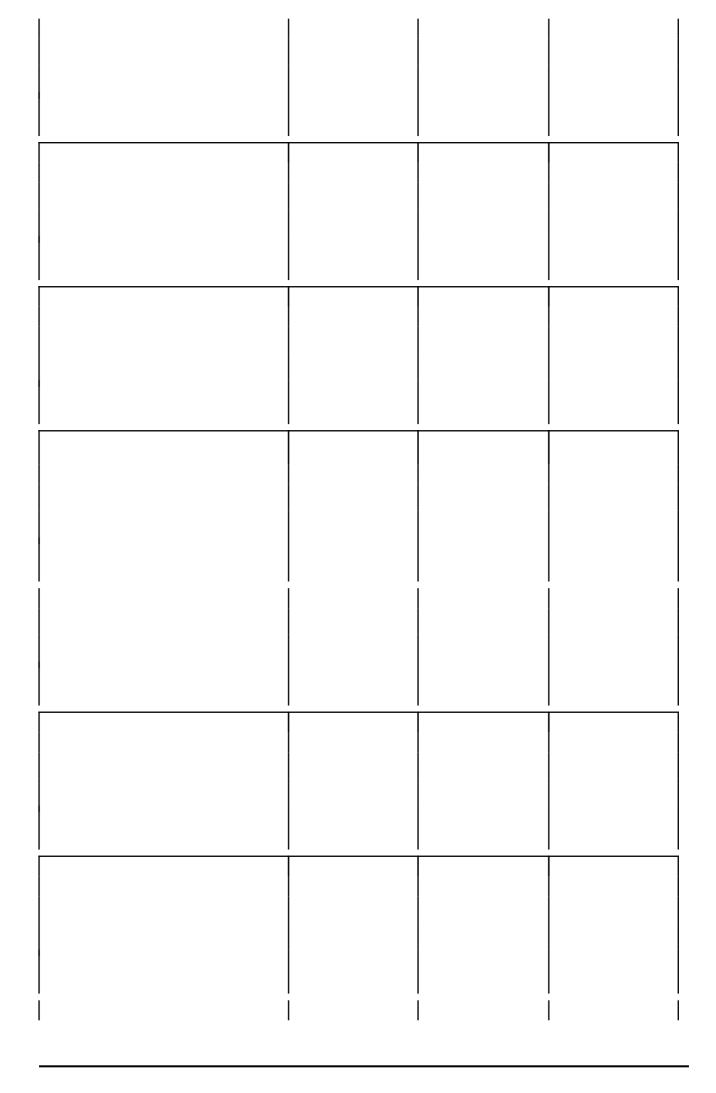
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atistical analyses				
aandamu Okasa	!:! <b>-</b>	.	shalasts 2	no (64) -+ 144 - 1
condary: Change From E 12, 18, 24, 30, 36, and <sup>2</sup>	saseline in 70 18; and Exter	n-nydroxy-4-d nsion Month 3	cnolesten-3-ol	ne (C4) at Week

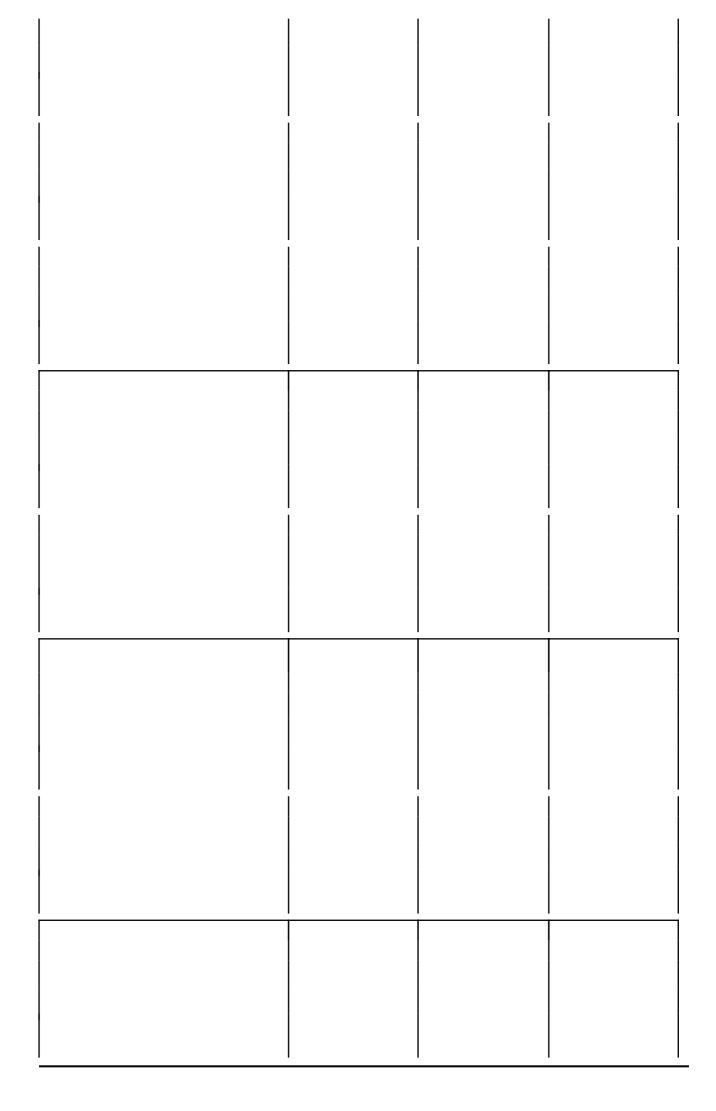
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	l				
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Secondary: Change From Baselin	e in Fibroblas	st Growth Fac	tor-19 (FGF-	19)	
Concentrations at Weeks 6, 12, 1	8, 24, 30, 36	, and 48; and	Extension M	onth 3	
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End point values		

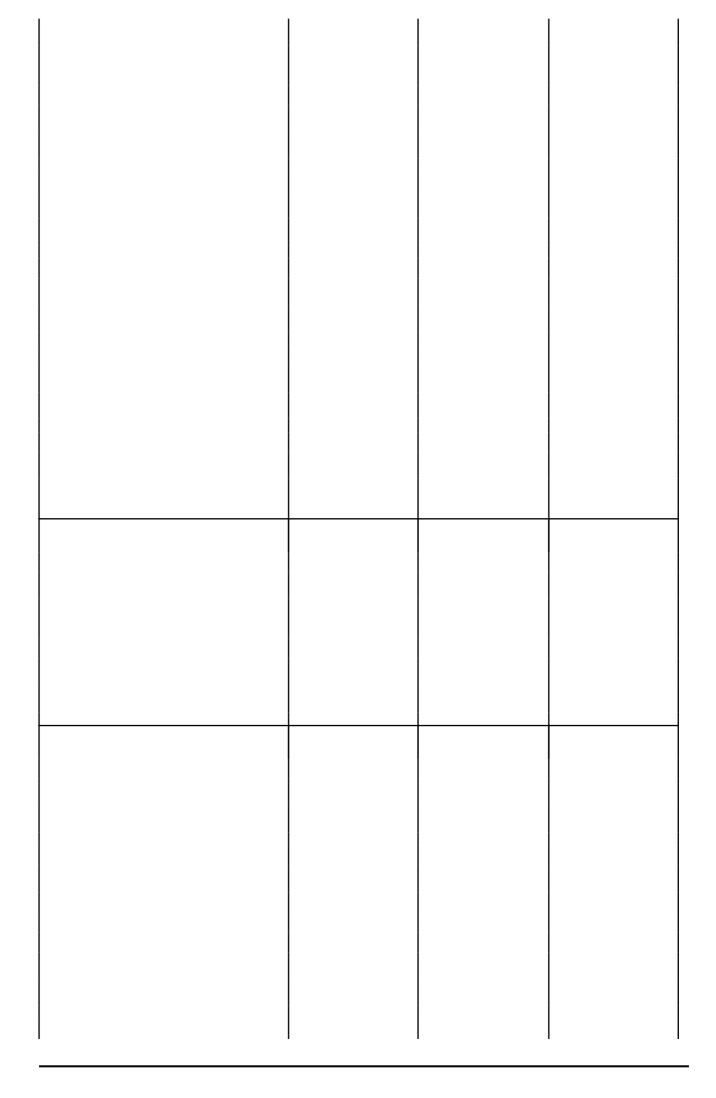
Statistical analyses	Sta	tisti	cal a	nal	/ses
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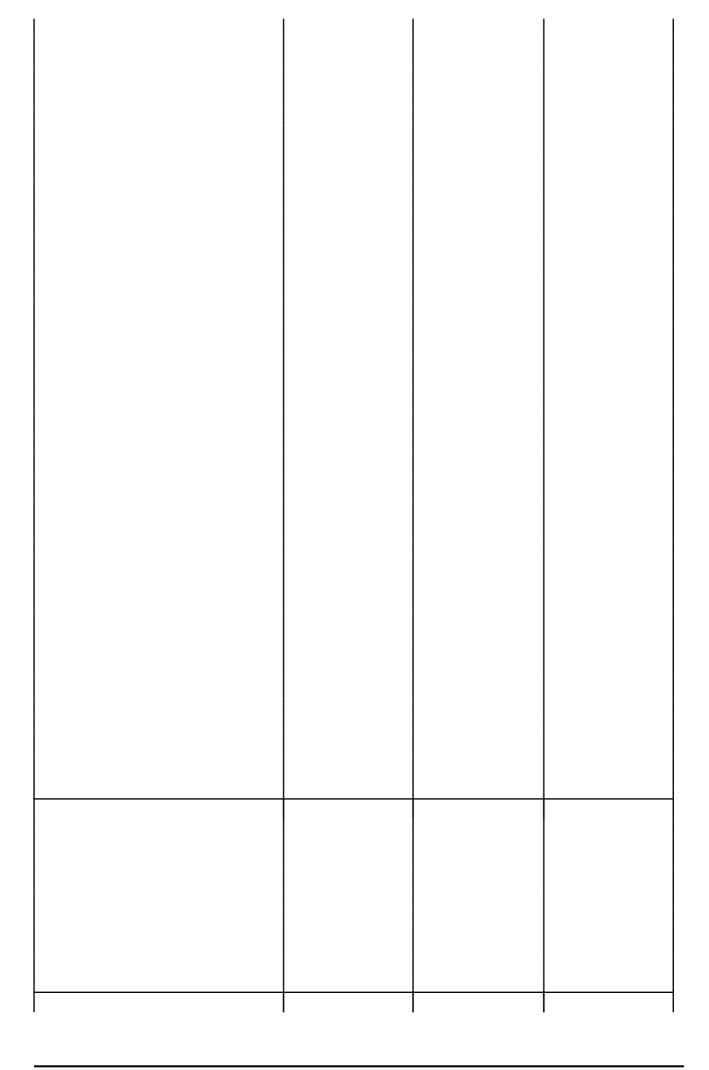
## **Adverse events Adverse events information Dictionary used Reporting groups** Serious adverse events

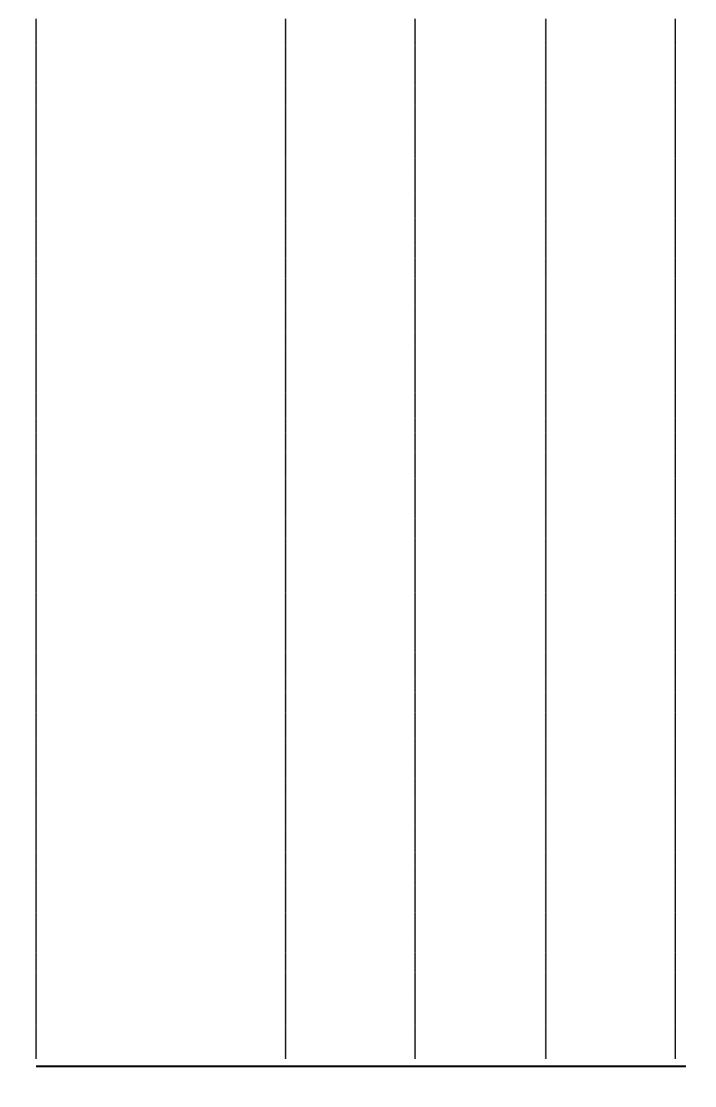


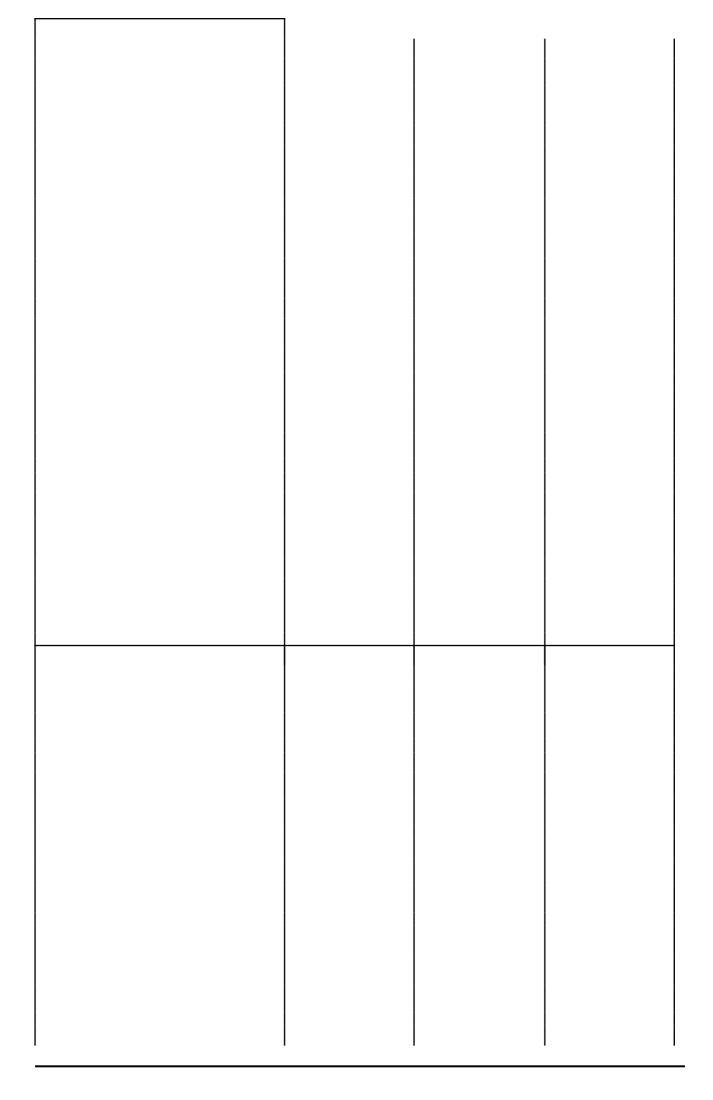


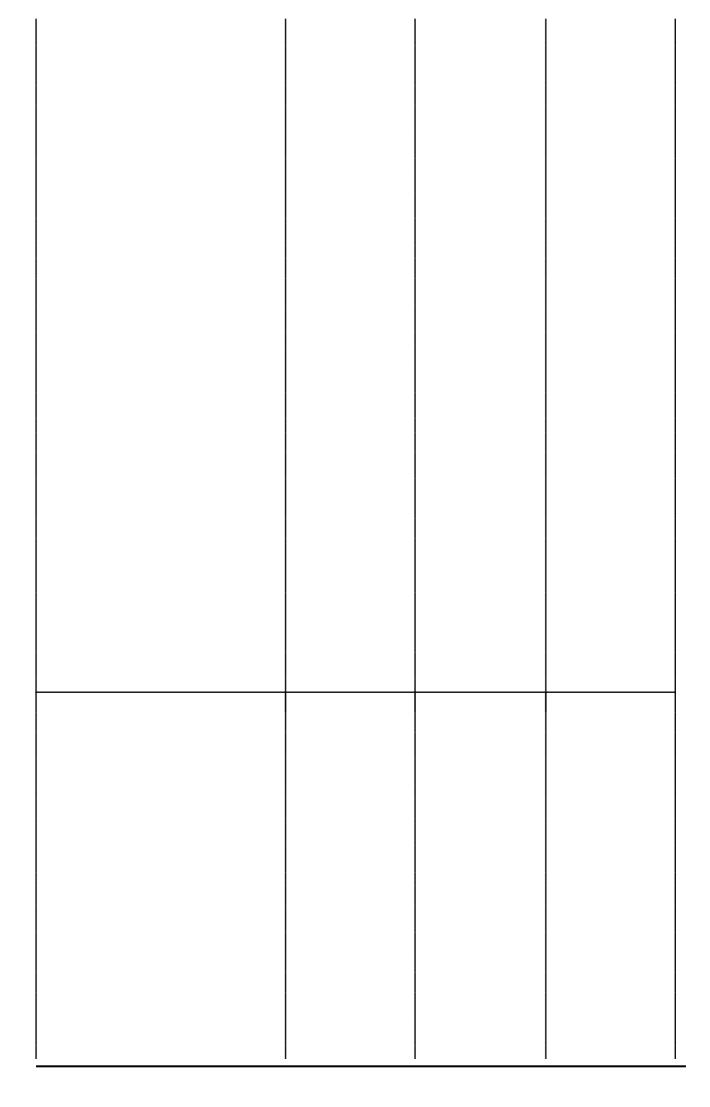
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Non-serious adverse events		











## **More information**

## Substantial protocol amendments (globally)

Date	Amendment

Interruptions (g	Jlobally)		
Limitations and	caveats		