

Clinical trial results:

A Phase 3, Randomized, Double-blind, Controlled Study Evaluating the Efficacy and Safety of VX-445 Combination Therapy in Subjects With Cystic Fibrosis Who Are Heterozygous for the F508del Mutation and a Minimal Function Mutation (F/MF)

Summary	
Results information	
Trial information	
Trial identification	
Additional study identifiers	
Sponsors	
Paediatric regulatory details	

Results analysis stage	
General information about the tr	ial
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Population of trial subjects	
Subjects enrolled per country	

Subjects enrolled per age group	

Subject disposition Recruitment **Pre-assignment** Period 1 Arms Arm title Arm title

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lumber of subjects in period [1]			
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Baseline characteristics Reporting groups Reporting group values



End points reporting groups				
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Primary: Absolute Change in F Second (ppFEV1)	Percent Predicte	ed Forced Exp	iratory Volum	e in 1
End point values				
Statistical analyses				
Statistical analysis title				

End points

Secondary: Absolute Change in P Second (ppFEV1)	ercent Predic	cted Forced E	xpiratory Vol	ume in 1
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End point values				
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Statistical analyses				
Statistical analysis title				

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Secondary: Number of Pulmonar	y Exacerbatio	ns (PEX)	
End point values			
Statistical analyses			
Statistical analysis title			
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Secondary: Absolute Change in S	weat Chloride	e (SwCI)	
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End point values				
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Statistical analyses				
Statistical analysis title				
				
				
Secondary: Absolute Change	in Cystic Fibro	sis Questio	nnaire Revi	sed (CFQ-R)
Respiratory Domain Score				

End point values			
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Statistical analyses			
Statistical analysis title			
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Secondary: Absolute Change in E	Body Mass Inc	lex (BMI)	
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End point values			
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Statistical analyses			
Statistical analysis title			
Secondary: Absolute Change in S	weat Chlorid	е	
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End point values			
Statistical analyses			
Statistical analysis title			

				
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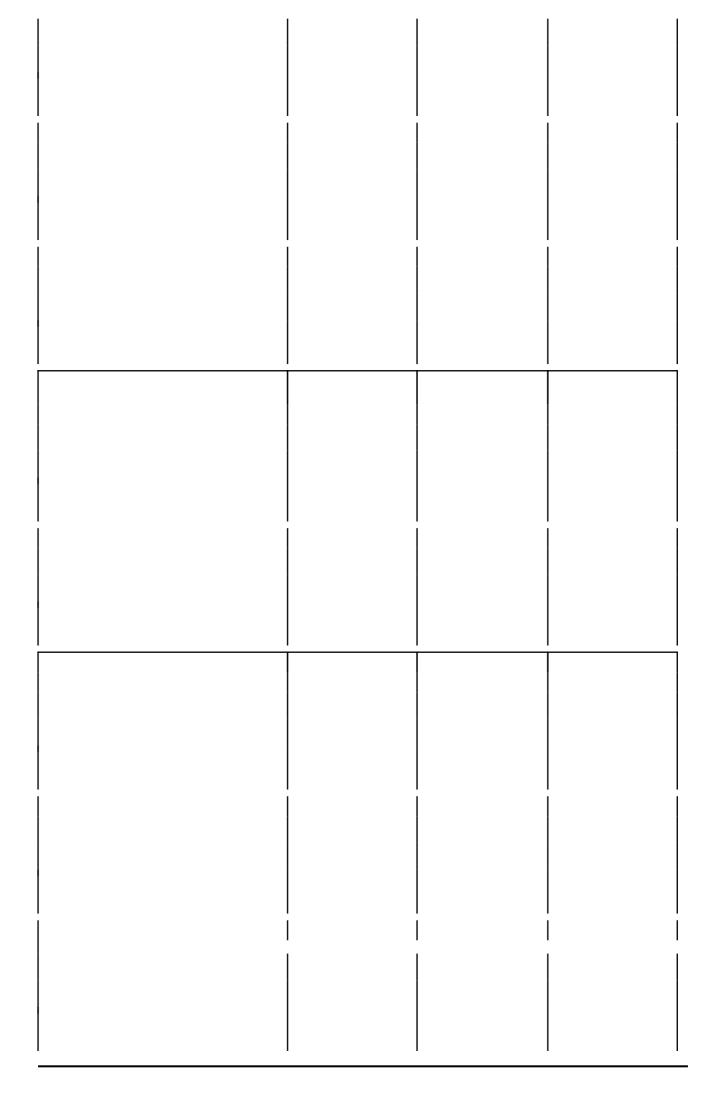
Secondary: Time-to-first Pulmonary Exacerbation (PEx)					
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End point values					
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Secondary: Absolute Chan Baseline	ge in B	MI Z-score fo	or Subjects <	=20 Years of	Age at
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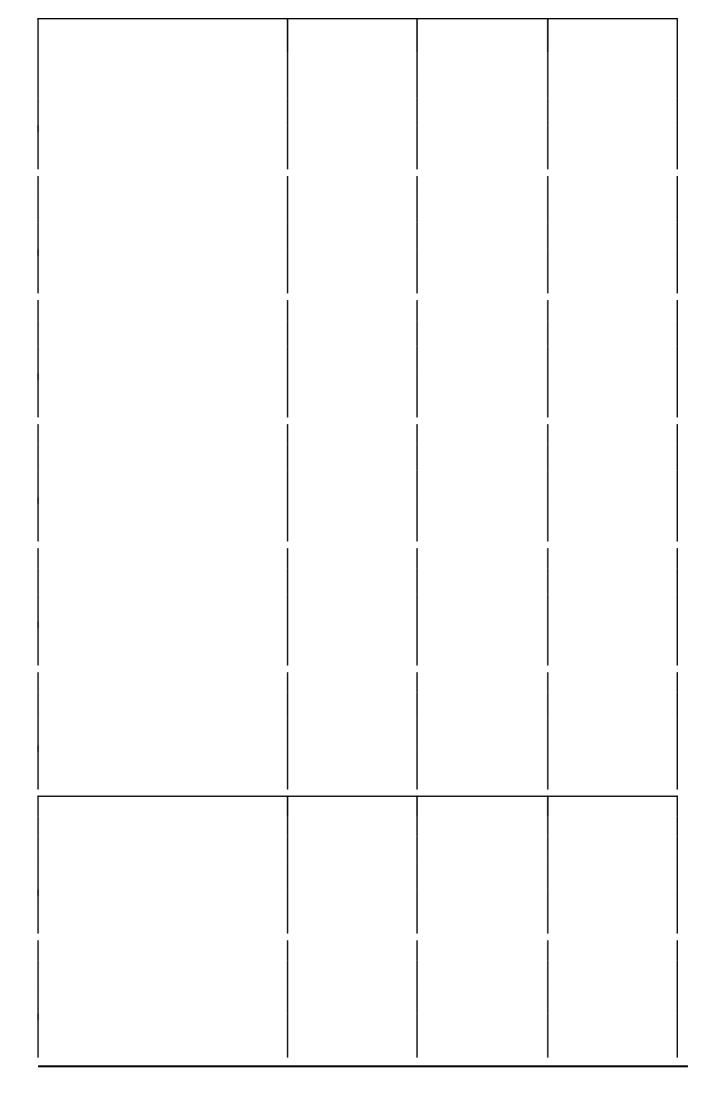
Statistical analyses			
Statistical analysis title			
Secondary: Absolute Change in	Body Weight	 	
End point values			
Statistical analyses			
Statistical analysis title			
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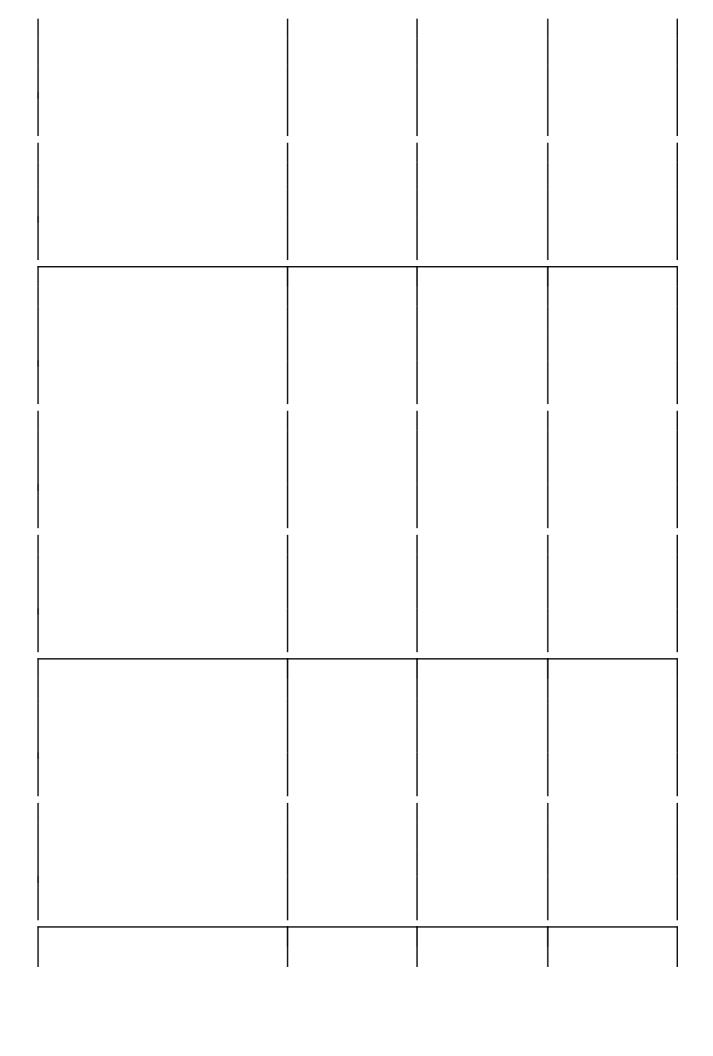
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econdary: Safety and Tol	erability as Asse	essed by Numb	er of Subject	s With
reatment-Emergent Adve	erse Events (AES) and Serious	Adverse Even	its (SAES)
nd point values				
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statistical analyses				
econdary: Observed Pre-	dose Concentrat	ion (Ctrough)	of VY-445 T	F7 M1_TE7
nd IVA	aose concentrat	.ion (Calough)	UI VA-443, II	LE, MIT-1EE,
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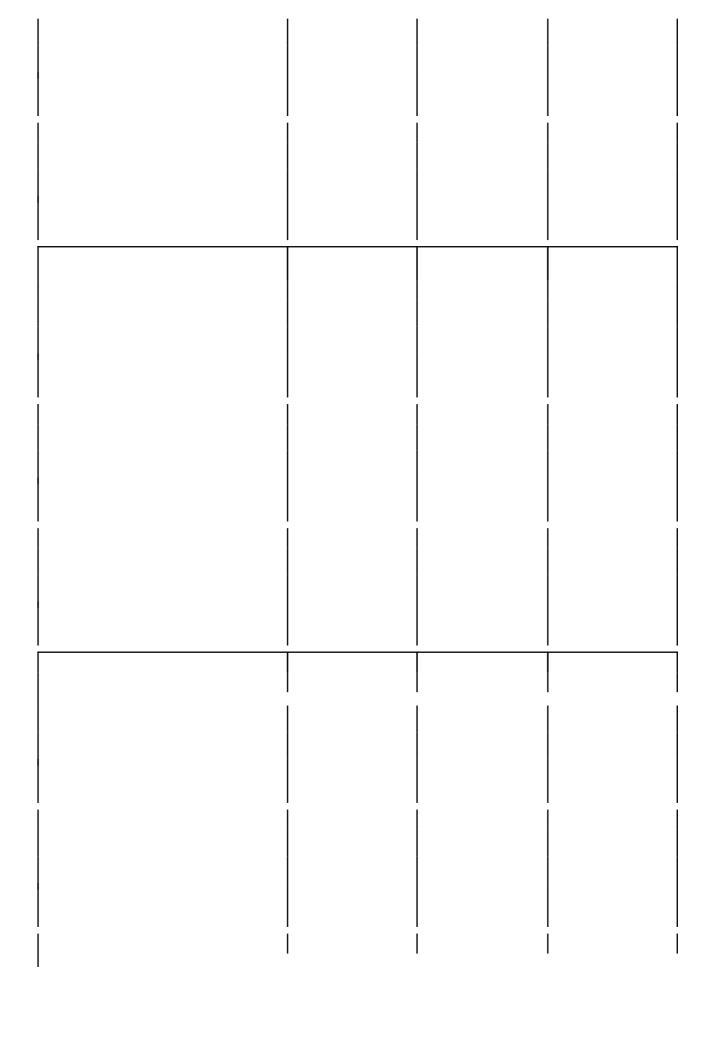
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End point values			
Statistical analyses			

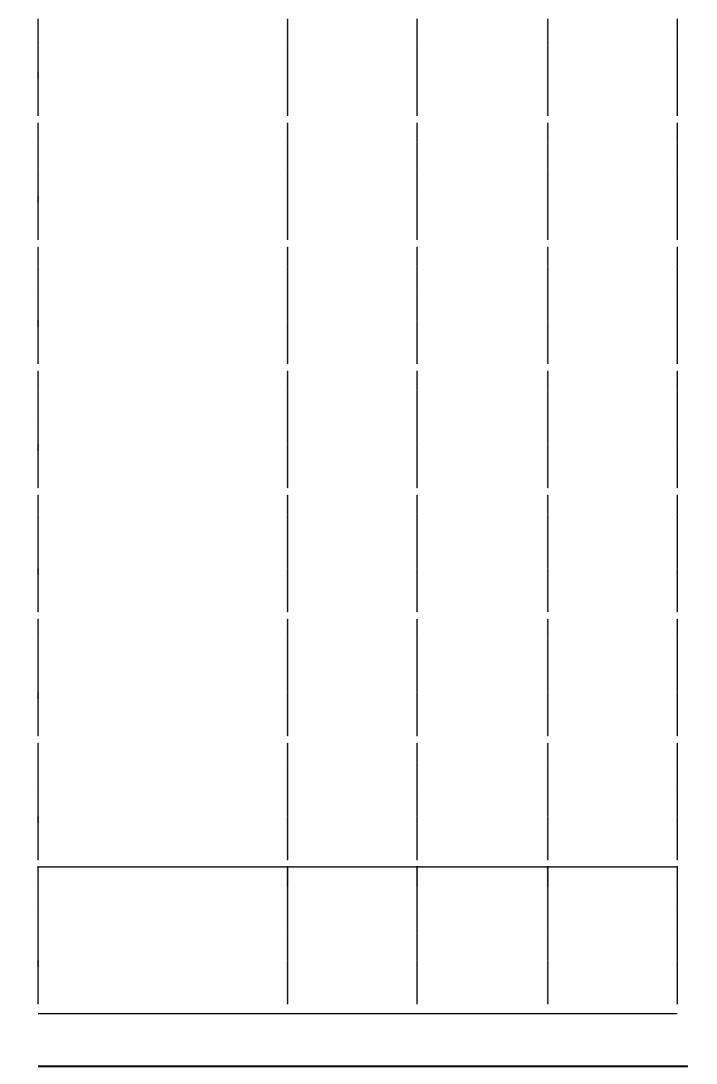
Adverse events Adverse events information Dictionary used Reporting groups Serious adverse events



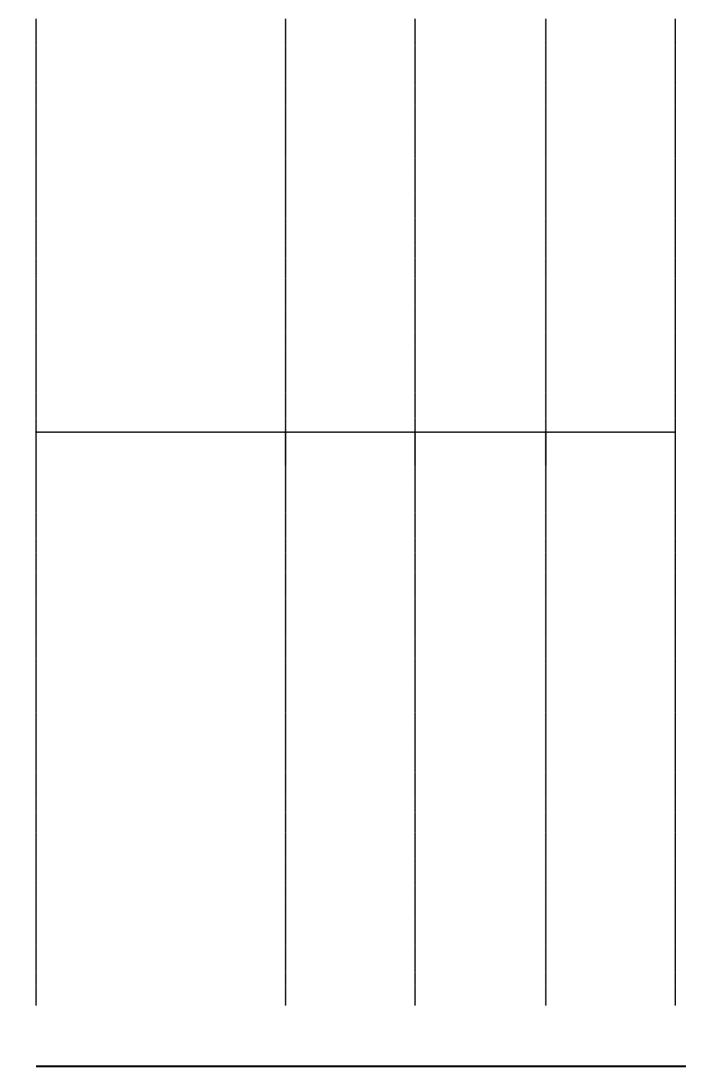








Non-serious adverse events		
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More information

Substantial protocol amendments (globally)

Amendment
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Interruptions (globally)

Limitations and caveats