

### **Clinical trial results:**

## Efficacy and Safety of a Novel Tetravalent Dengue Vaccine in Healthy Children Aged 2 to 14 Years in Asia

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

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

Subject disposition			
Recruitment			
Pre-assignment			
Period 1	T		
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Arm title			
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Number of subjects in period 1		
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Period 2		
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Number of subjects in period 2	

End points				
End points reporting groups	<b>5</b>			
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Primary: Number of Sympto to Any Serotype During the Elither CYD Dengue Vaccine	Active Phase	Post-Dose	irmed Dengue 3 Following I	(VCD) Cases Due njection (Inj.) Wit
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End point values				

Statistical analyses	
Statistical analysis title	
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Parental Dengue Virus Strain Ber Tetravalent Vaccine or a Placebo	rs of Antibodies Against Each Serotype With the fore and Following Inj. With Either CYD Dengue
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End point values				
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Statistical analyses				
Secondary: Percentage of Subject Dengue Virus Serotype Strain Be Placebo	ts With Antib fore and Follo	ody Titers >= owing Inj. Wi	= 10 1/Dil Ag th CYD Dengi	ainst Each ue Vaccine or

End point values		

Statistical analyses				
Secondary: Number of Subjects V Any and Each Inj. With Either CY	With Solicited 'D Dengue Va	Injection Sit	e Reactions Facebo	
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End point values				

Chatistical analyses				
Statistical analyses				
Secondary: Number of Symptoma Days Post-Dose 1 Following Inj.	atic VCD Case With Either C	s Due to Any YD Dengue V	Serotype Occard	curring 28 acebo
End point values				
Statistical analyses				
Statistical analyses Statistical analysis title				

Secondary: Number of Symptoma Organization (WHO) Criteria Dur Serotype Following Inj. With Eith	ing the Surve	illance Expar	sion Period D	alth Oue to Any
End point values				
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tatistical analyses				
econdary: Number of Cli xpansion Period Due to accine or a Placebo	inically Severe Any Serotype	VCD Cases Du Following Inj.	ring the Surv With Either C	eillance YD Dengue
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nd point values				
tatistical analyses				
anaryses				
	mntomatic VC	D Cases Due to	o Any Serotyp	e 28 Days Post
econdary: Number of Sy ose 2 Following Inj. Wit	h Either CYD I	Dengue Vaccino	e or a Placebo	

End point values				
Statistical analyses				
Statistical analysis title				
Statistical allarysis title				
Secondary: Number of Symptoma	atic VCD Case	s Due to Any	Serotype Du	ring the
Active Phase in Either CYD Dengu	le vaccine or	Placebo Grou	1b	
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1XPEHU RI VXEMHFWV DQD	) \ V H G			
8QLWV &DVHV				
QXPEHU QRW DSSOLFDEOH				

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&RPSDULVRQ JURXSV	&<' 'HQJXH 9DFFLQH *URXS Y 30DFHER *URXS
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3DUDPHWHU HVWLPDWH	9DFFLQH (IILFDF\
3RLQW HVWLPDWH	
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VLGHV	VLGHG
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	'XH WR \$Q\ 6HURW\SH )ROORZLQJ ,QM :LWK (LWKHU &
	9DFFLQH RU D 3ODFHER

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End point values				
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Statistical analyses				
Secondary: Number of Subje	cts With S	vstemic Peacti	ions Following	π Any and Fach
Inj. With Either CYD Dengue	Vaccine or	a Placebo	ions i onowing	g Ally alla Lacii
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End point values				
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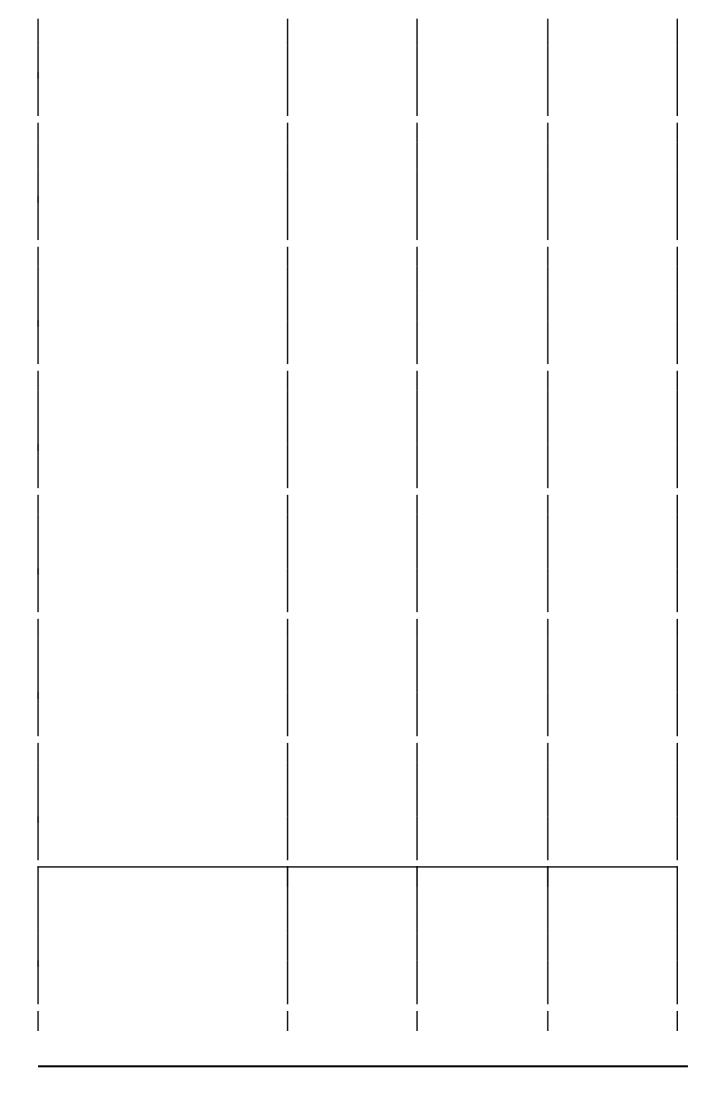
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Statistical analyses				
Secondary: Number of Hospitalia	zed VCD Cases	S During the S	Surveillance E Dengue Vaco	expansion oine or a
Period Due to Any Serotype Follo Placebo	owing Inj. Wit			
Period Due to Any Serotype Follo	owing Inj. Wit			
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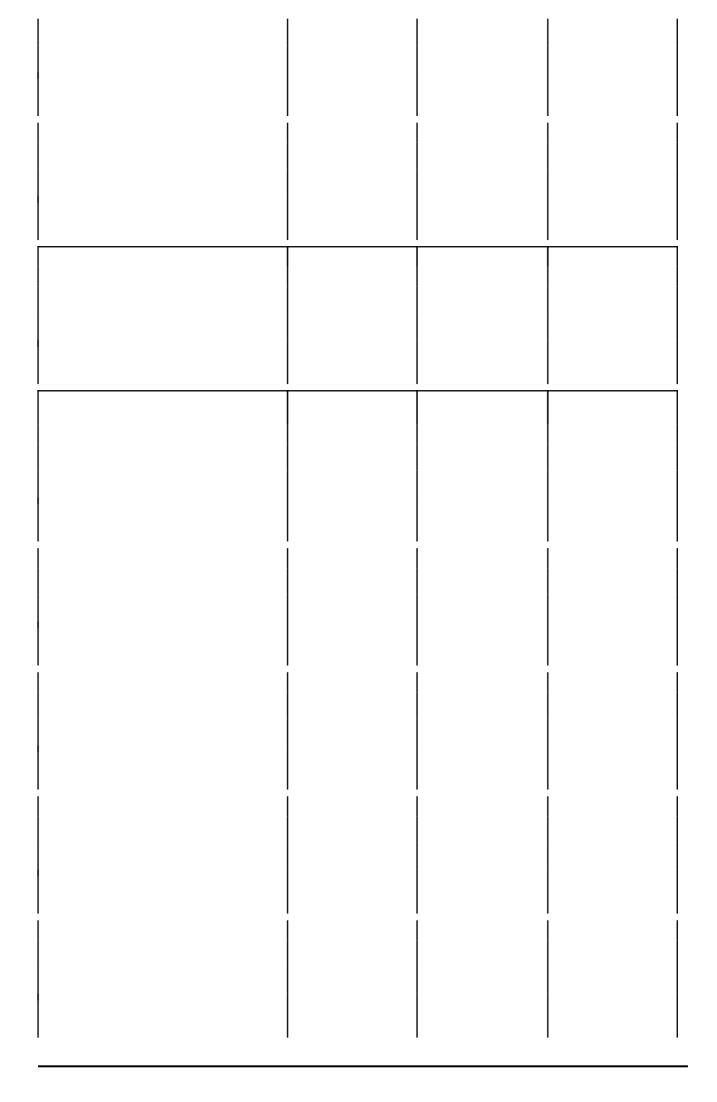
End point values				
Statistical analyses				
Secondary: Number of Hospitaliz Serotype Following Inj. With Eitl	ed VCD Cases ner CYD Deng	Throughout ue Vaccine o	the Trial Due a Placebo	to Any
End point values				
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End point values  Statistical analyses				

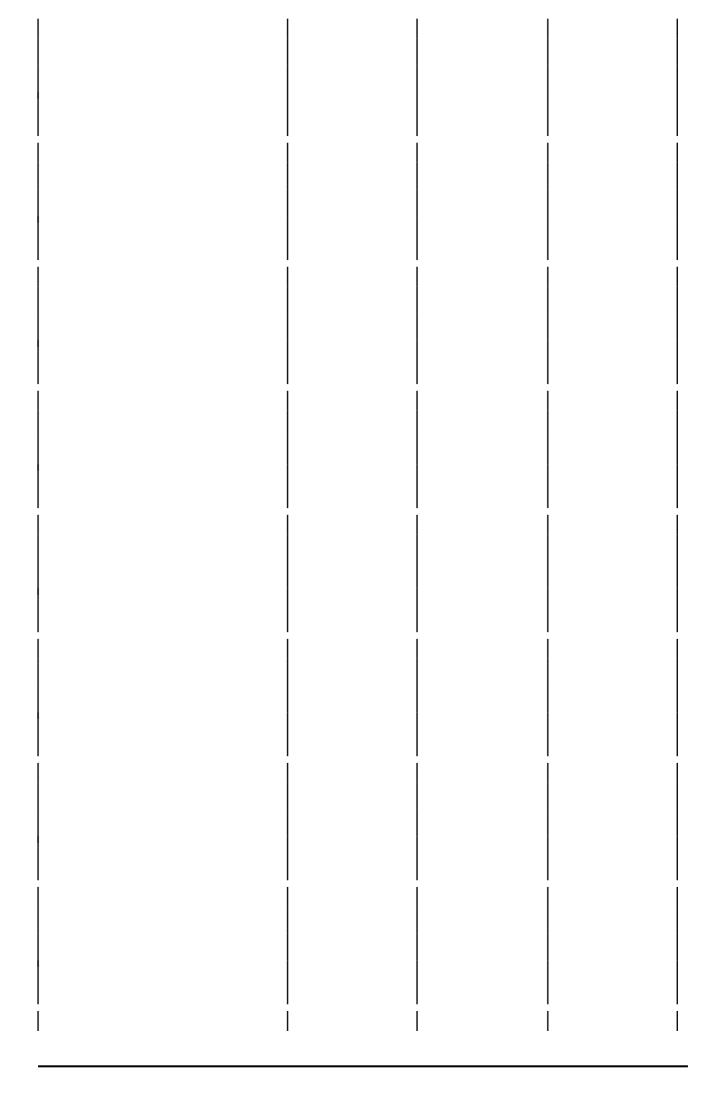
Secondary: Number of Symptoma Throughout the Trial Due to Any Vaccine or a Placebo	atic VCD Case Serotype Foll	s Meeting 19 owing Inj. W	97 WHO Crite	eria O Dengue
End point values				
Statistical analyses				

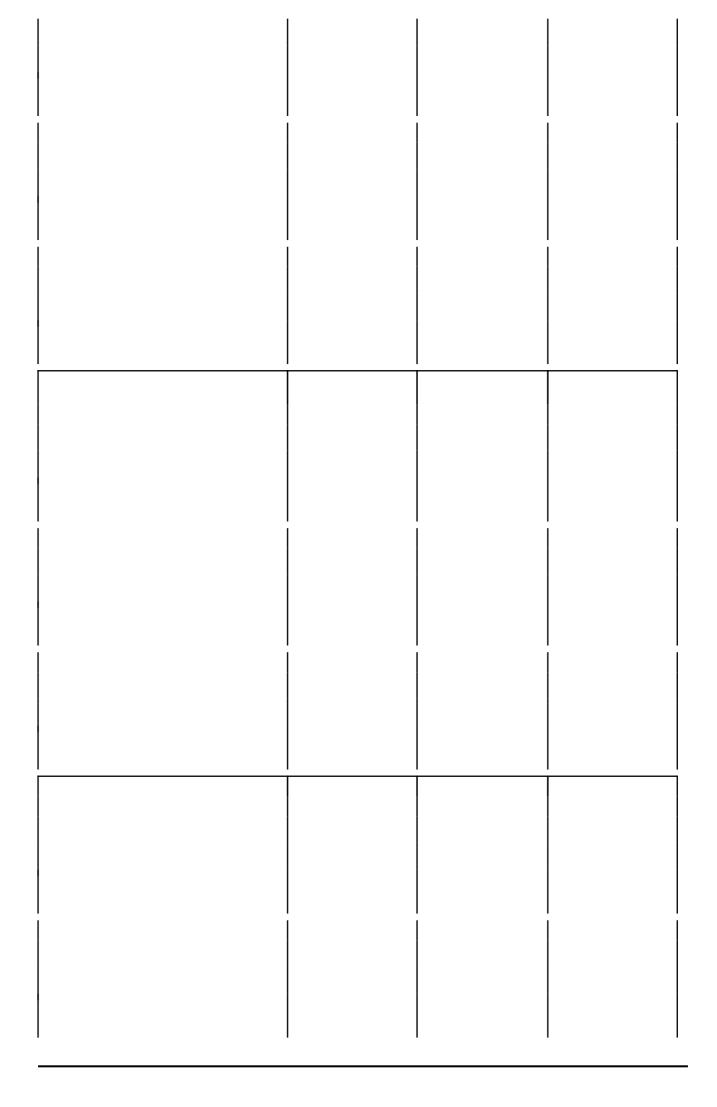
# **Adverse events Adverse events information Dictionary used** Reporting groups Serious adverse events

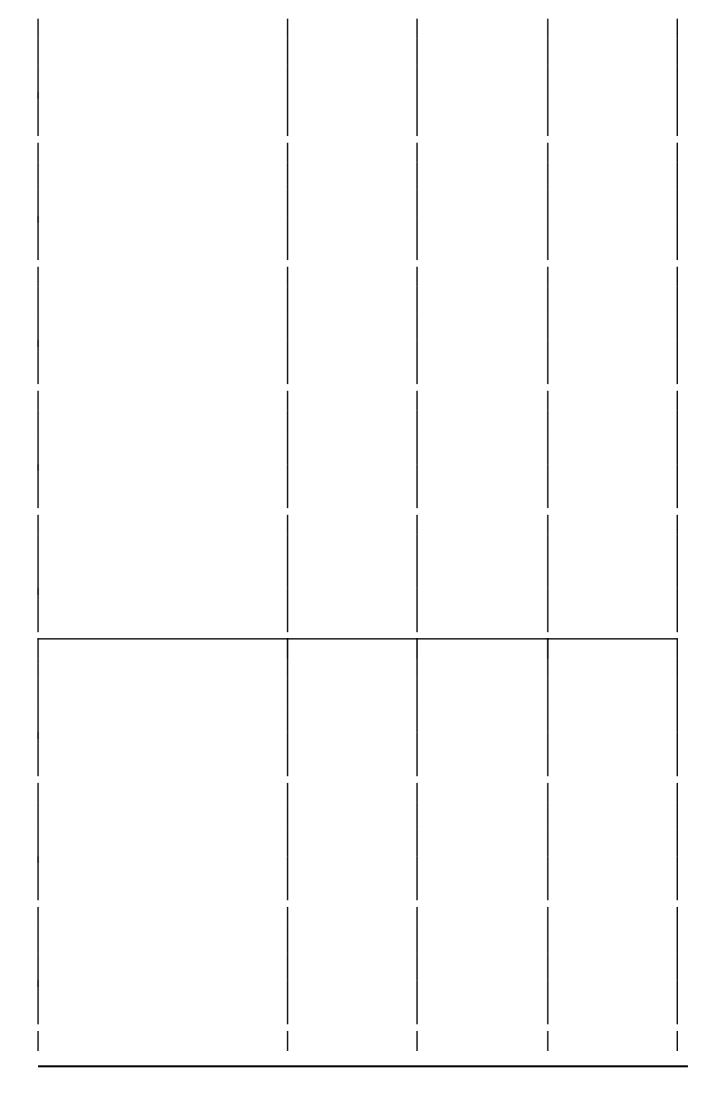


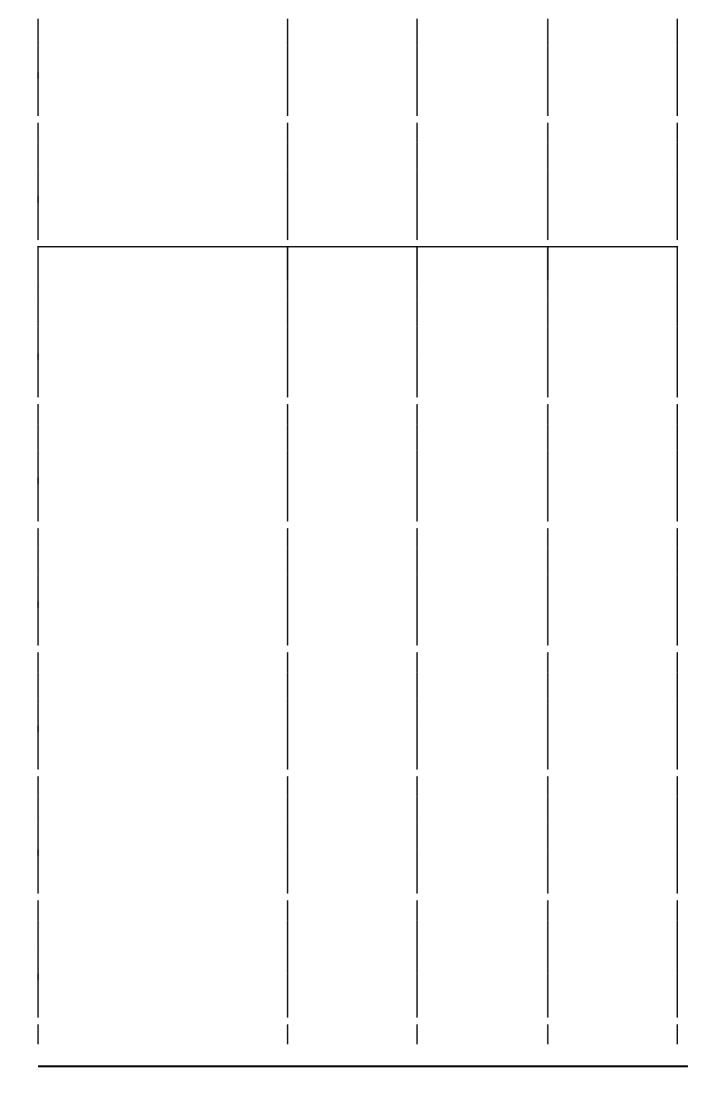


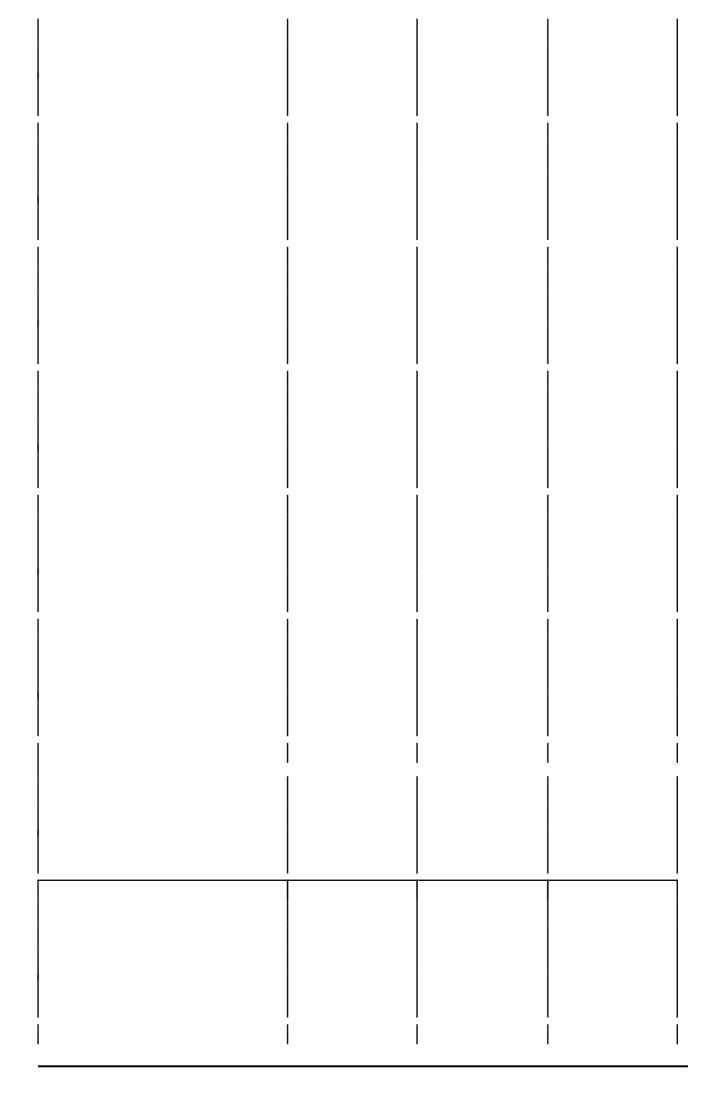




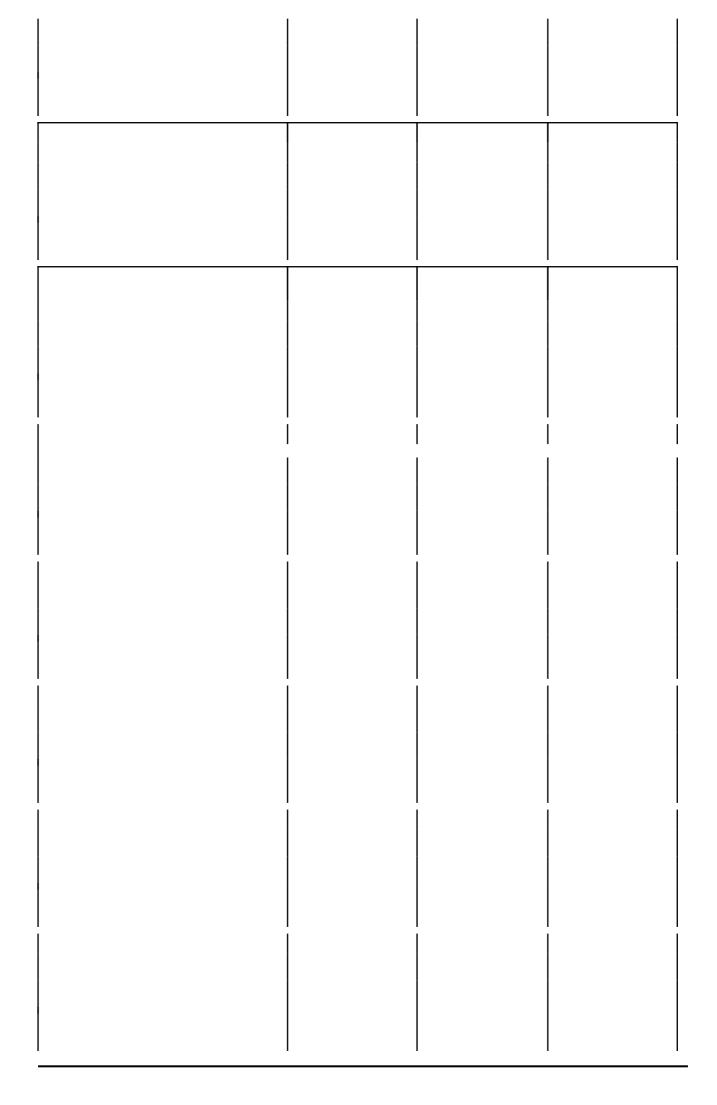


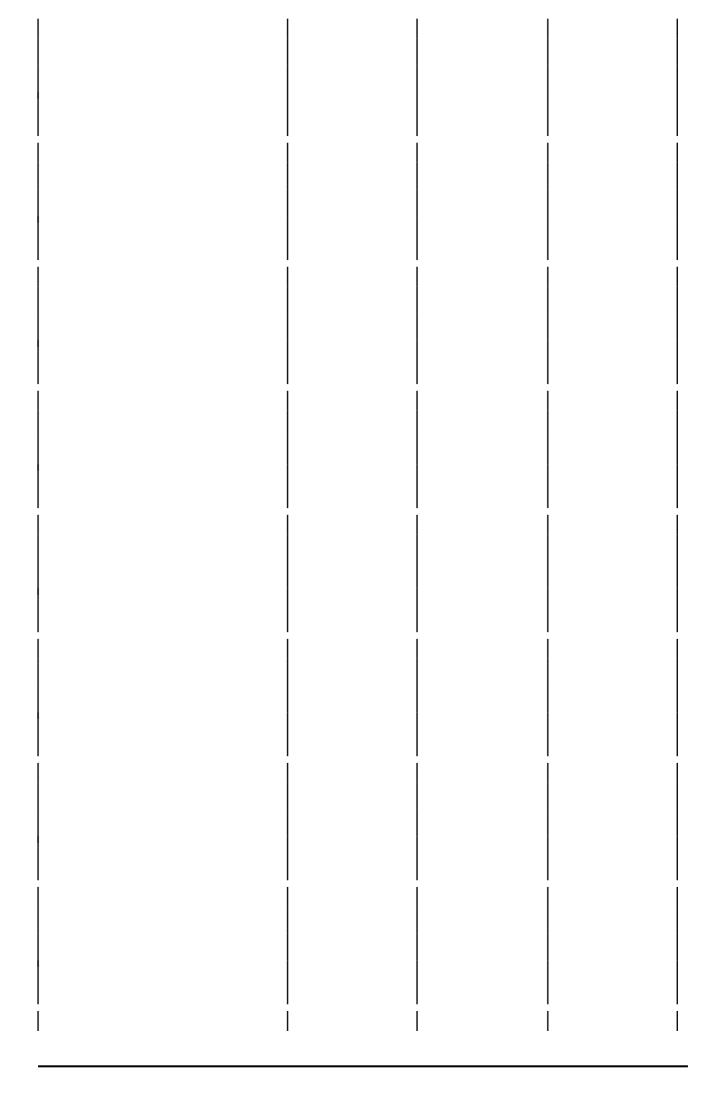












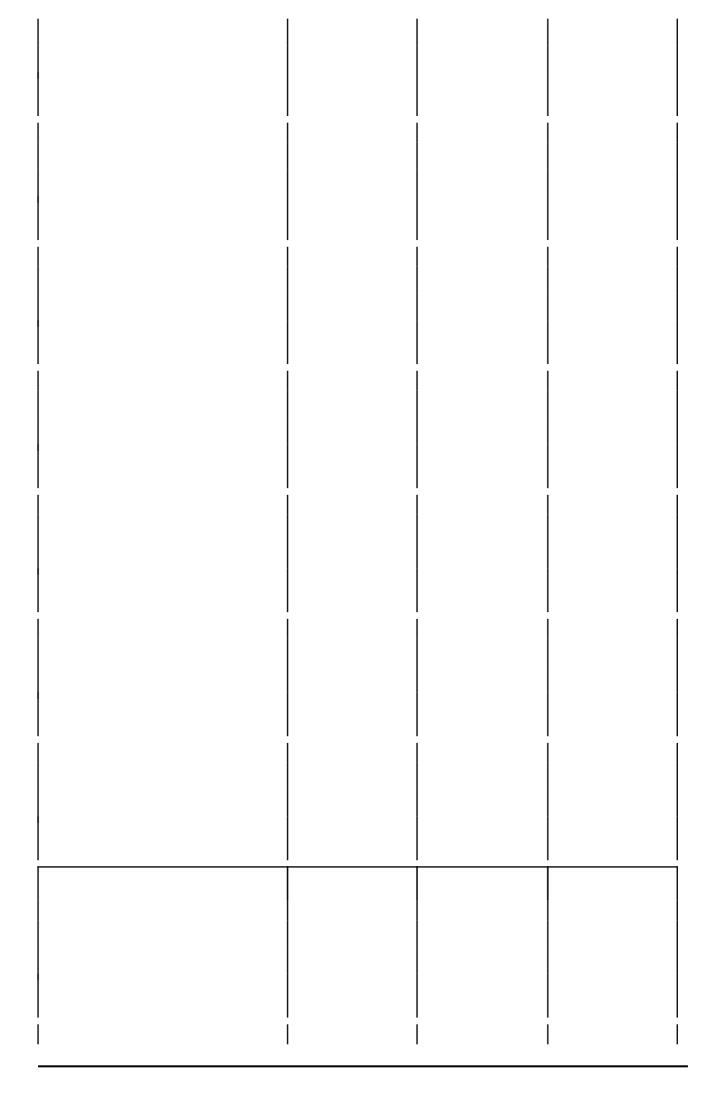


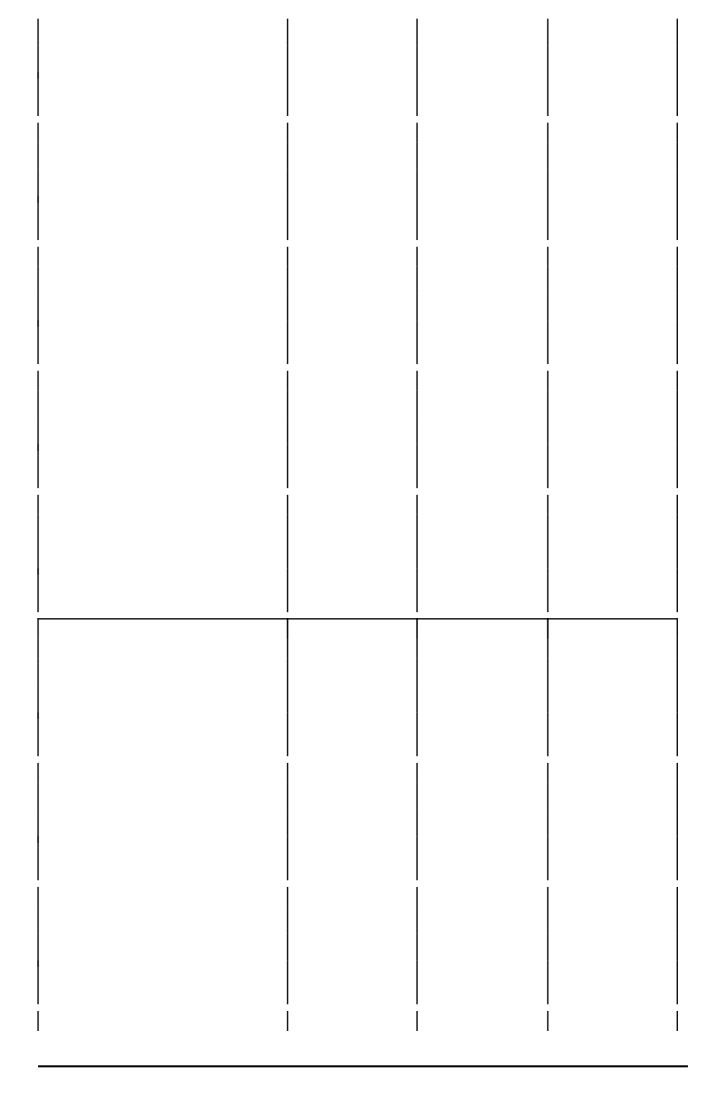


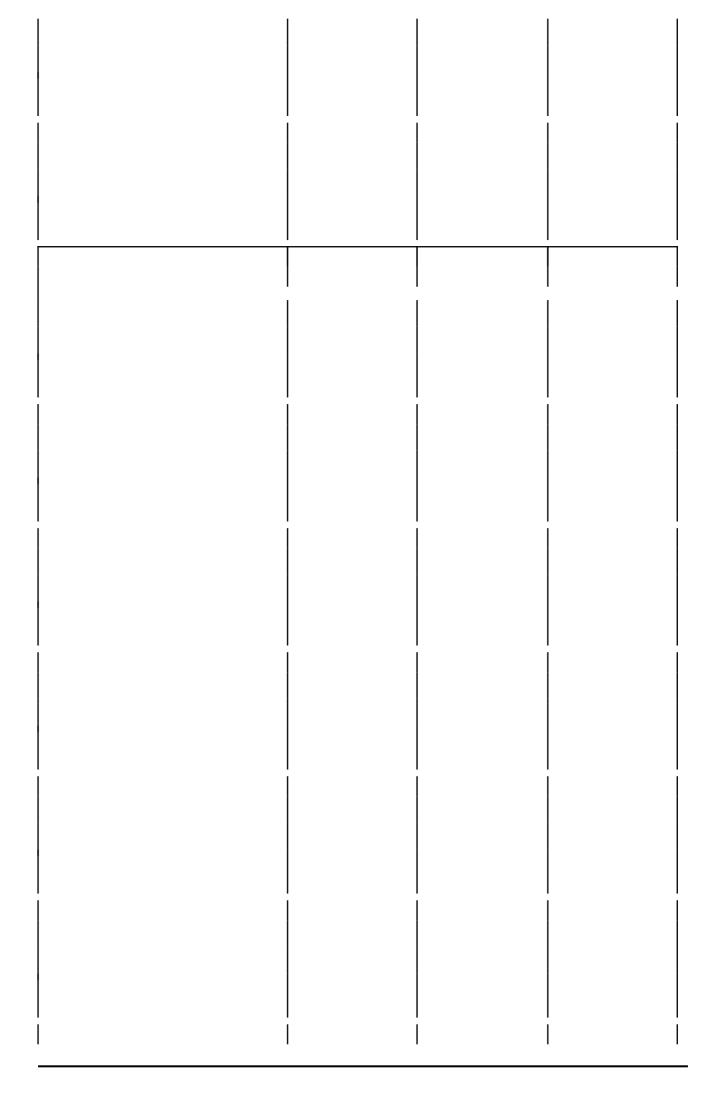




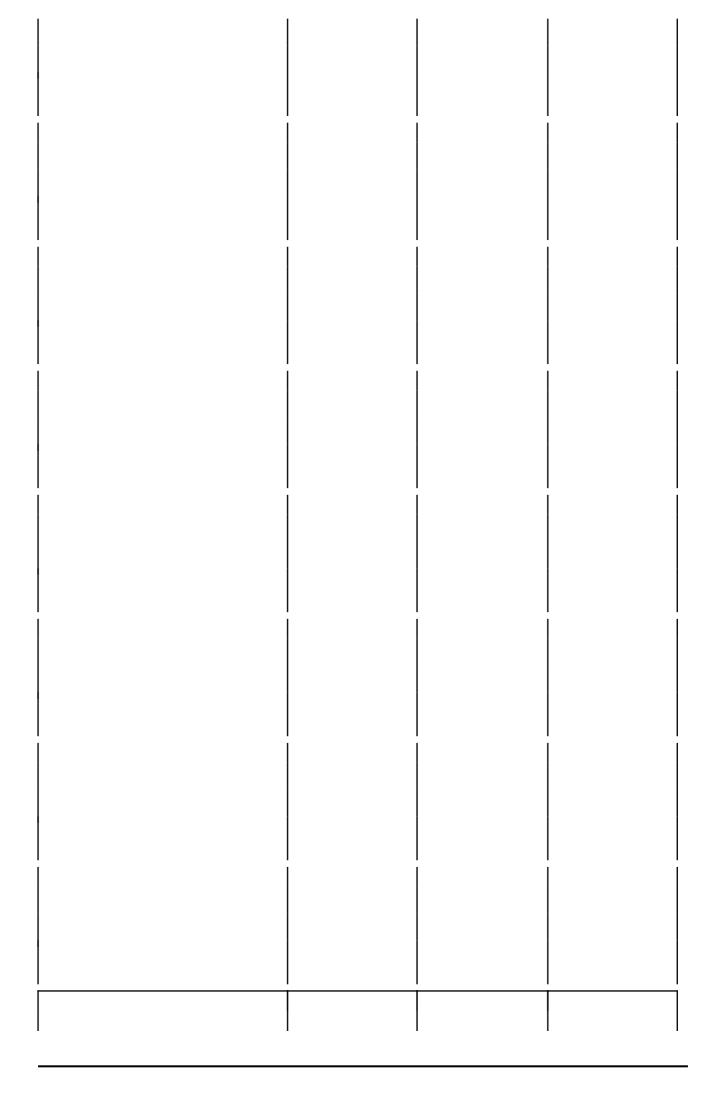


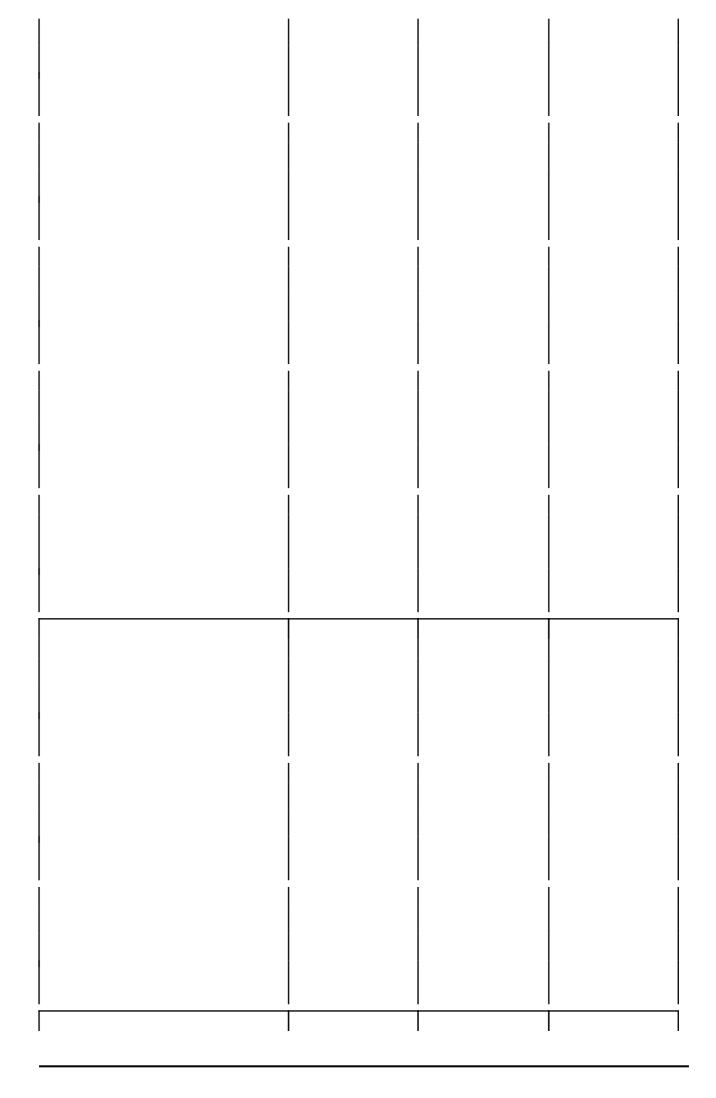


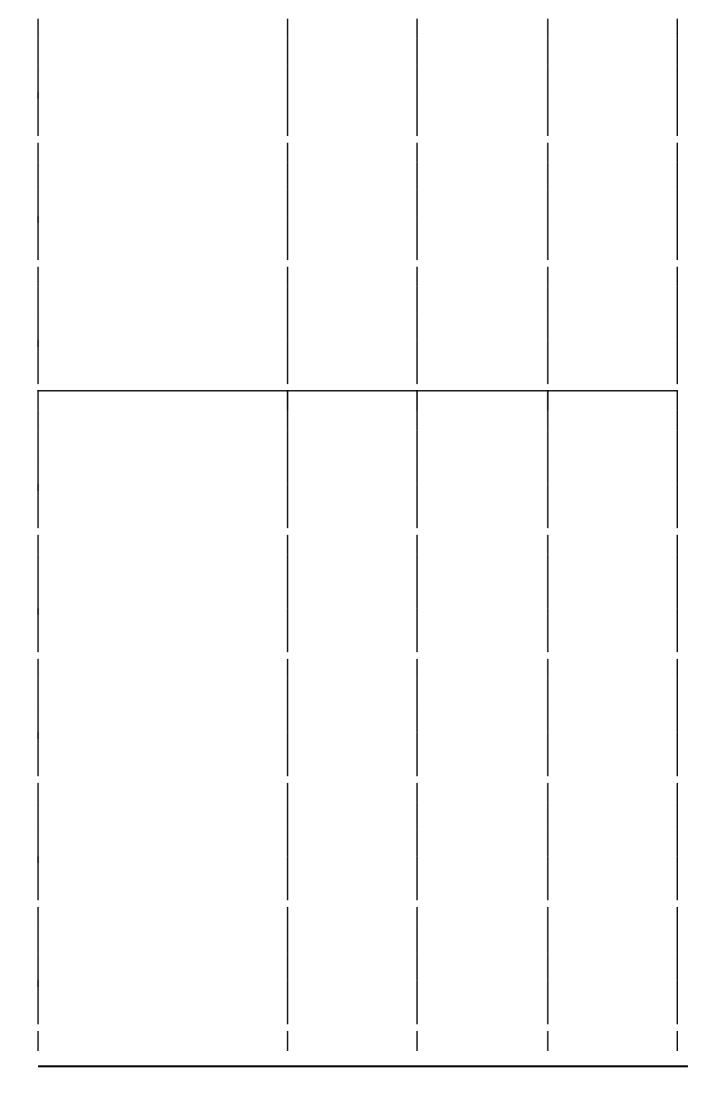








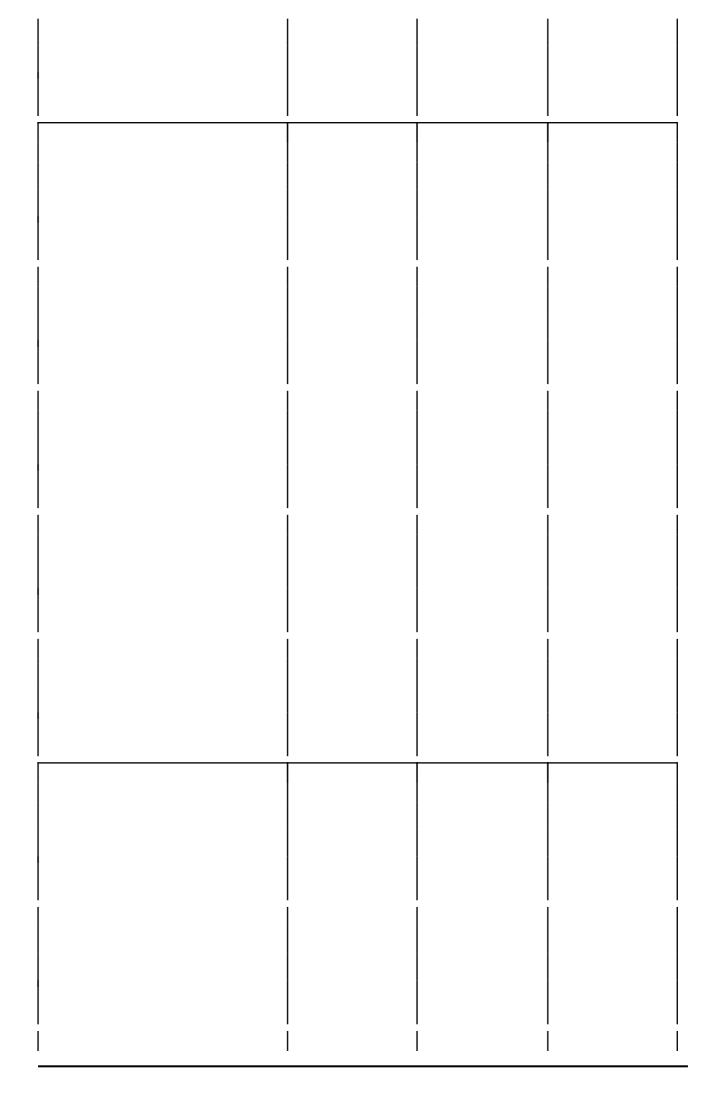


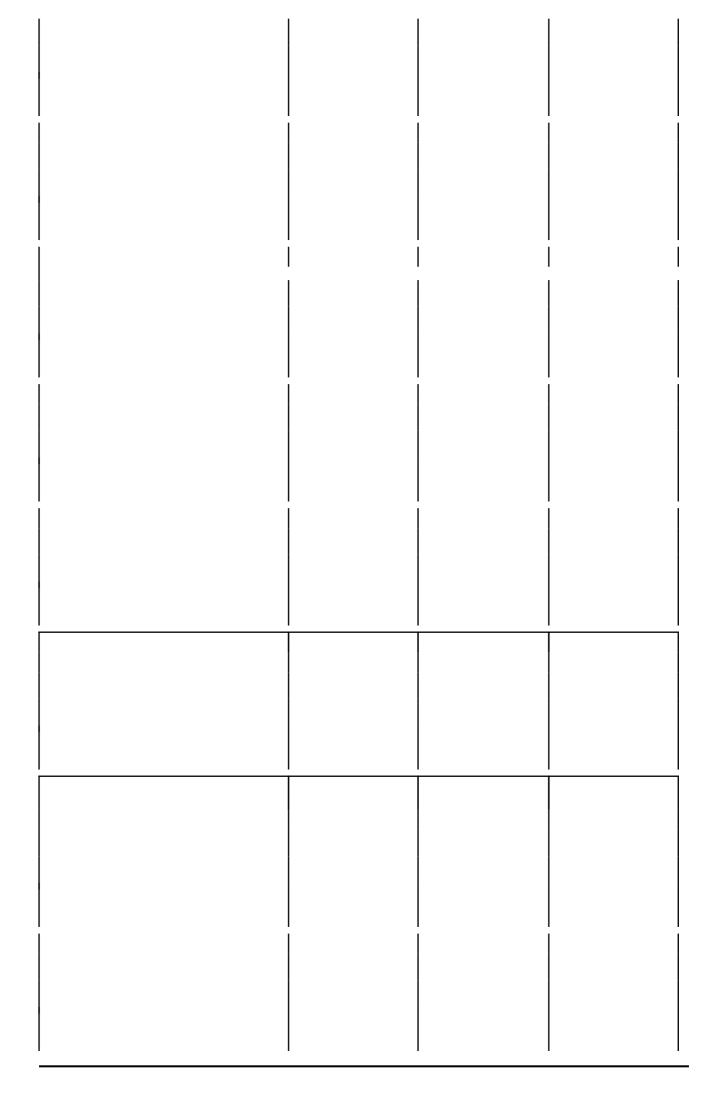


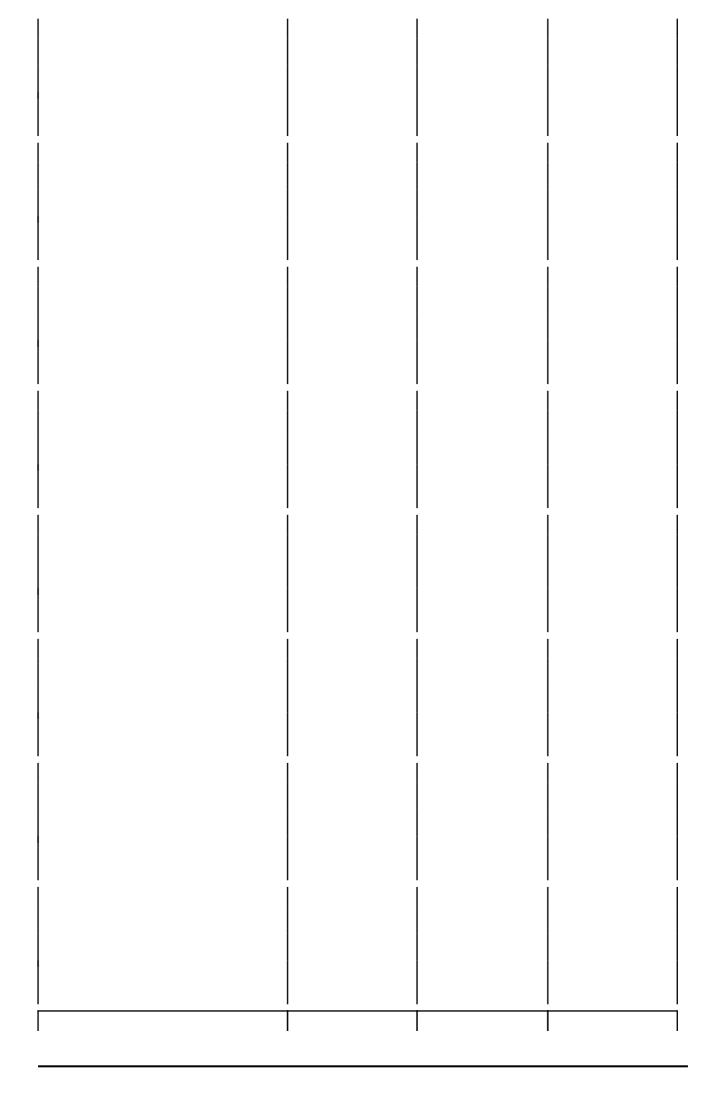


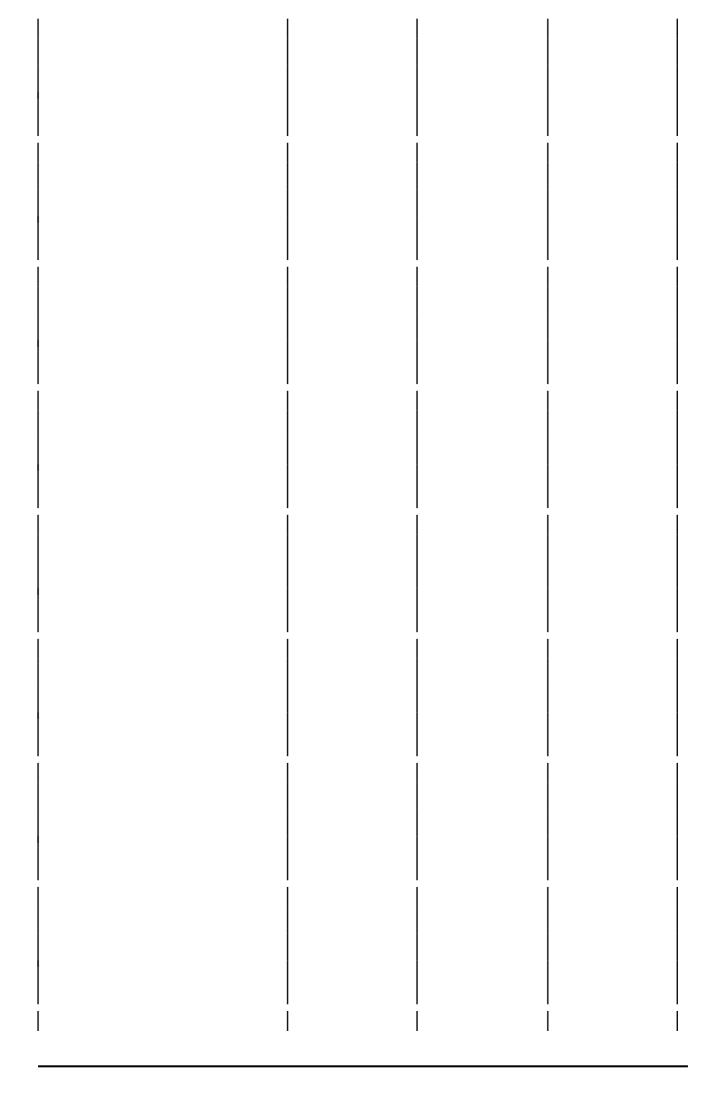










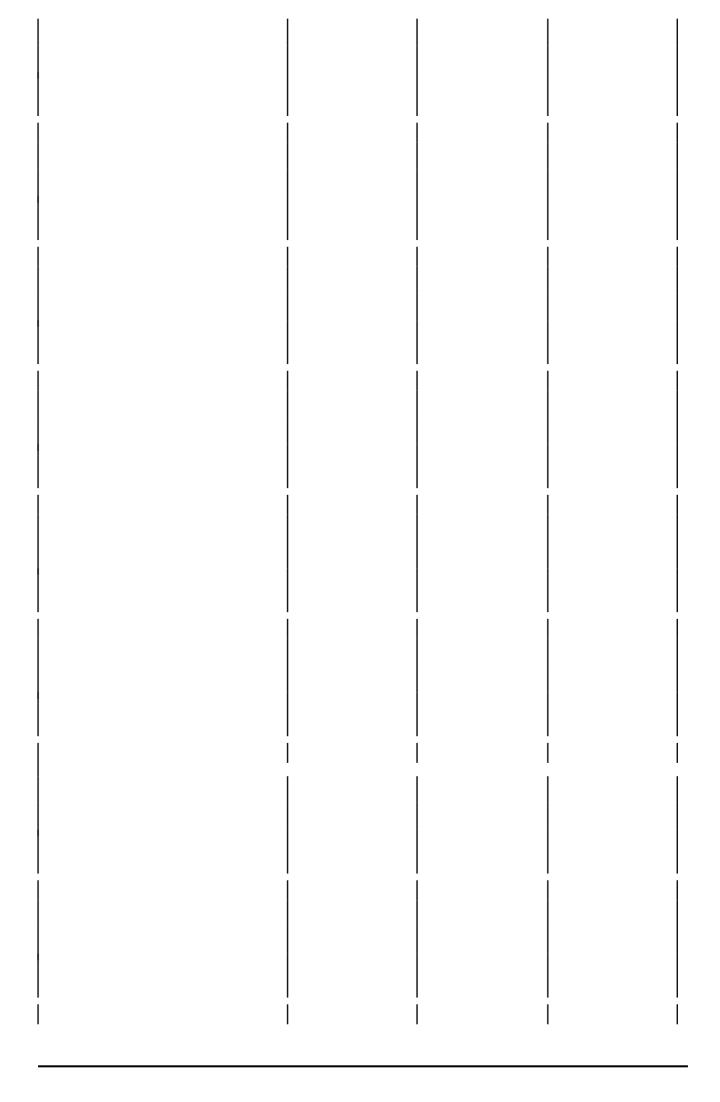












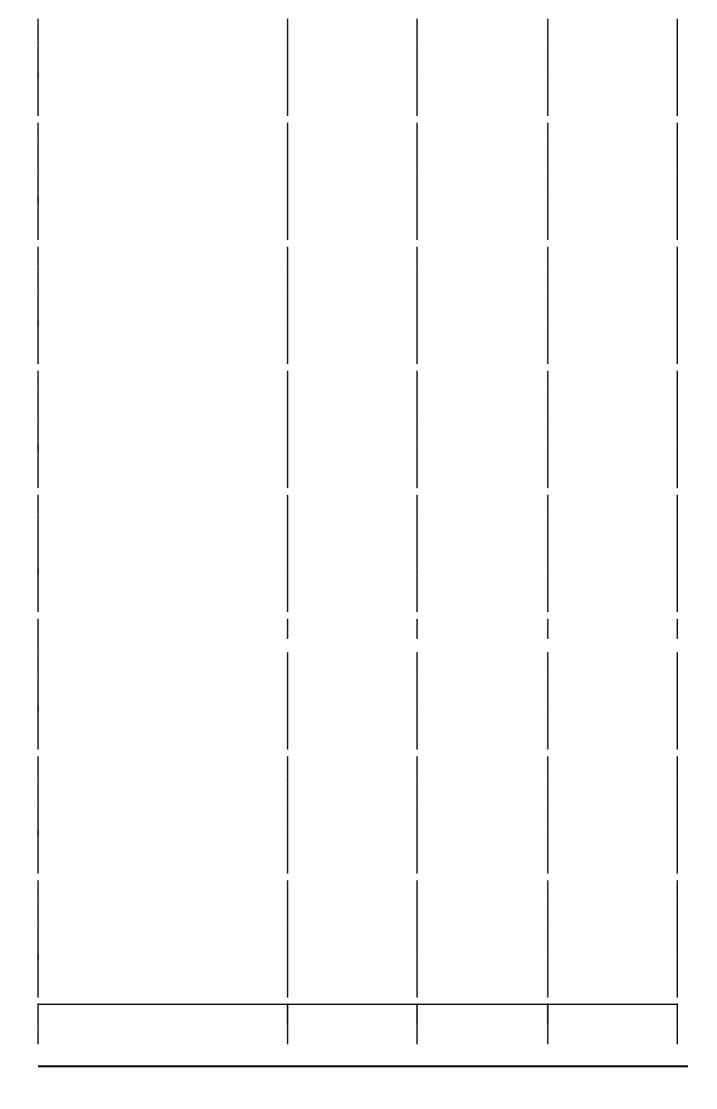




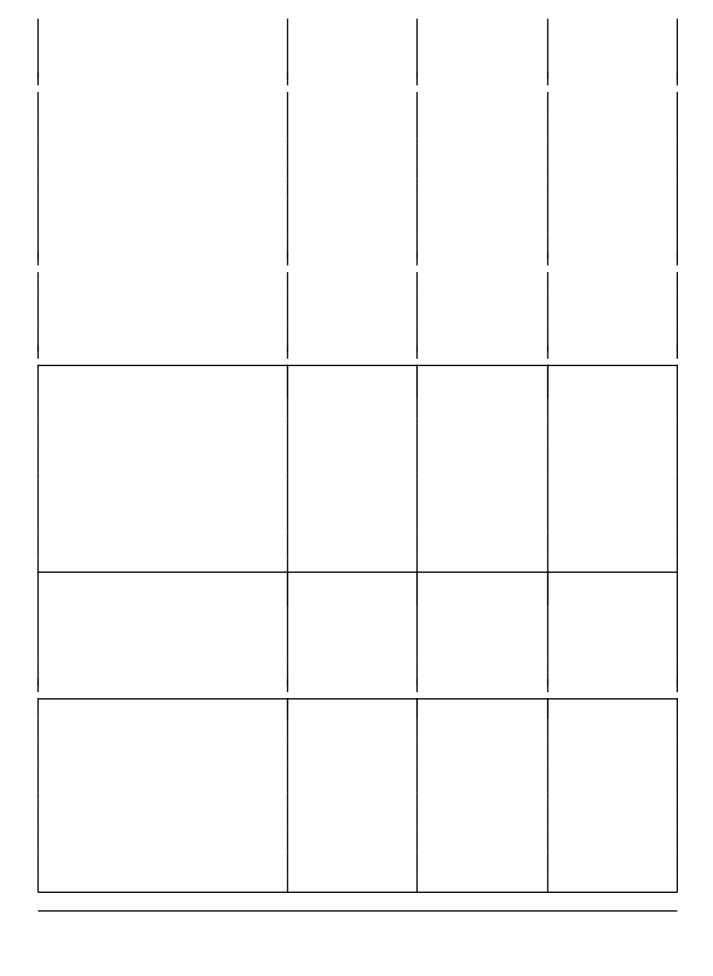








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## **More information**

## Substantial protocol amendments (globally)

Date	Amendment
Interruptions (	(globally)
interruptions (	(globally)
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Limitations and	i caveats
Online reference	ces