	(For National Authority Use only)

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cpf"cfqnguegpvu"*×9	
Efficacy during Part III-V:	
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		(For National Authority Use only)
	 *×47 ' ="@ 72 ' "vq">47 ' ="× 97 '	"vq"Ö
•	1	1
×47'+"rgt"vk o g"kpvgtxcn"eq		
•		
•		
Ugk wtg"fwtcvkqp"*cu"encuukhkgf"kp	0 "v jg " fkct $\{+<">52uge."×52"uge"vq"$	$>$ 3" o kp." \times 3" o kp"vq" $>$ 7" o kp." \times 7"
•		
pgf"cu"ug	rk wtg"gzcegtdcvkqp"×322 ' "eqo	rctgf"vq"vjg"dcugnkpg"rgtkqf"
•		
Safety during Part III-V:		
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Baseline definitions:		
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		(For National Authority Use only)
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K0"Vjg"qxgtcm"rtqrqtvkqp"qh"	rcvkgpvu" y kv j "gzcegtdcvkqp"*kpetgcug	$g''qh''\times47'+"eqorctgf"vq"$
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	(For National Authority Use only)
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