Supplementary Table. Comparison of 2 statistical models (Cox regression model and Poisson regression model) for analyzing Vaccine Efficacy, when Adjusting for Region & Protocol

Description	Poisson Regression Model¶		Cox Model¶	
	Efficacy %	95% CI	Efficacy %	95% CI
HPV 6/11/16/18-related CIN1, PP	95.9	91.2, 98.1	95.9	91.2, 98.1
HPV 6/11-related CIN1, PP	100.0	<0, 100	100.0	<0, 100
HPV 16-related CIN1, PP	94.0	86.3, 97.4	93.9	86.2, 97.3
HPV 18-related CIN1, PP	97.9	84.8, 99.7	97.9	84.8, 99.7
HPV 6/11/16/18-related VIN1, PP	100.0	100, 100	100.0	<0, 100
HPV 6/11-related VIN1, PP	100.0	100, 100	100.0	<0, 100
HPV 16-related VIN1, PP	N/A*	N/A*	N/A	N/A
HPV 18-related VIN1, PP	N/A*	N/A*	N/A	N/A
HPV 6/11/16/18-related VaIN1, PP	N/A*	N/A*	100.0	<0, 100
HPV 6/11-related VaIN1, PP	N/A*	N/A*	100.0	<0, 100
HPV 16-related VaIN1, PP	N/A*	N/A*	100.0	<0, 100
HPV 18-related VaIN1, PP	N/A*	N/A*	100.0	<0, 100
HPV 6/11/16/18-related Condyloma, PP	99.0	95.8, 99.7	99.0	95.8, 99.7
HPV 6/11-related Condyloma, PP	98.9	95.8, 99.7	98.9	95.7, 99.7
HPV 16-related Condyloma, PP	N/A*	N/A*	100.0	<0, 100
HPV 18-related Condyloma, PP	N/A*	N/A*	100.0	<0, 100
HPV 6/11/16/18-related CIN1, MITT2, True Day 1	94.9	90.9, 97.1	94.9	90.8, 97.1
HPV 6/11-related CIN1, MITT2, True Day 1	96.7	86.4, 99.2	96.6	86.2, 99.2
HPV 16-related CIN1, MITT2, True Day 1	95.6	90.1, 98.1	95.6	90.1, 98.1
HPV 18-related CIN1, MITT2, True Day 1	93.9	83.3, 97.8	93.9	83.4, 97.8
HPV 6/11/16/18-related VIN1, MITT2, True Day 1	89.9	57, 97.6	89.9	57, 97.6
HPV 6/11-related VIN1, MITT2, True Day 1	88.8	51.7, 97.4	88.8	51.7, 97.4
HPV 16-related VIN1, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 18-related VIN1, MITT2, True Day 1	N/A*	N/A*	N/A	N/A
HPV 6/11/16/18-related VaIN1, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 6/11-related VaIN1, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 16-related VaIN1, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 18-related VaIN1, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 6/11/16/18-related Condyloma,	96.0	92.5, 97.9	96.0	92.5, 97.9

MITT2, True Day 1				
HPV 6/11-related Condyloma, MITT2, True Day 1	96.3	92.8, 98.1	96.3	92.8, 98.1
HPV 16-related Condyloma, MITT2, True Day 1	96.3	72.7, 99.5	96.2	72.3, 99.5
HPV 18-related Condyloma, MITT2, True Day 1	N/A*	N/A*	100.0	<0, 100
HPV 6/11/16/18-related CIN1, ITT	69.0	61.8, 74.9	68.8	61.5, 74.7
HPV 6/11-related CIN1, ITT	78.2	64.2, 86.7	78.0	63.9, 86.6
HPV 16-related CIN1, ITT	66.3	56.7, 73.8	66.0	56.3, 73.6
HPV 18-related CIN1, ITT	78.1	64.4, 86.5	78.1	64.4, 86.5
HPV 6/11/16/18-related VIN1, ITT	69.1	31.8, 86	69.1	31.8, 86
HPV 6/11-related VIN1, ITT	65.1	22, 84.4	65.1	22, 84.4
HPV 16-related VIN1, ITT	N/A*	N/A*	100.0	<0, 100
HPV 18-related VIN1, ITT	N/A*	N/A*	N/A	N/A
HPV 6/11/16/18-related VaIN1, ITT	83.3	51.9, 94.2	83.3	52, 94.2
HPV 6/11-related VaIN1, ITT	74.9	<0, 94.7	75.0	<0, 94.7
HPV 16-related VaIN1, ITT	85.7	37, 96.7	85.7	37.1, 96.8
HPV 18-related VaIN1, ITT	83.3	<0, 98	83.3	<0, 98
HPV 6/11/16/18-related Condyloma, ITT	79.5	73.1, 84.3	79.4	73.0, 84.3
HPV 6/11-related Condyloma, ITT	79.3	72.8, 84.3	79.2	72.7, 84.2
HPV 16-related Condyloma, ITT	90.6	69.3, 97.1	90.4	68.6, 97.1
HPV 18-related Condyloma, ITT	95.5	66.3, 99.4	95.3	65.1, 99.4
Any HPV type related CIN1, RMITT2, True Day 1	30.0	17.5, 40.6	29.9	17.3, 40.5
Any HPV type related VIN1, RMITT2, True Day 1	74.6	24.1, 91.5	74.6	23.9, 91.5
Any HPV type related VaIN1, RMITT2, True Day 1	49.3	14.2, 70	49.2	14, 70
Any HPV type related Condyloma, RMITT2, True Day 1	82.8	74.5, 88.4	82.8	74.5, 88.4
Any HPV type related CIN1, ITT	20.5	12.7, 27.6	20.0	12.1, 27.2
Any HPV type related VIN1, ITT	32.2	<0, 58.4	32.1	<0, 58.4
Any HPV type related VaIN1, ITT	31.1	4.8, 50.2	31.2	4.9, 50.2
Any HPV type related Condyloma, ITT	62.0	53.6, 68.9	61.9	53.5, 68.8

¶ Both Poisson regression model and Cox model included the following independent variables: treatment (vaccine or placebo), region (Asia-Pacific, Europe, Latin America & North America) and study (Protocol 15: Yes/No).

N/A* Efficacy couldn't be calculated because there was no event in either or both treatment groups.