APPENDIX 3 – TABLES OF CIN 2 AND CIN 3 CASES ASSOCIATED WITH NON-VACCINE HPV TYPES 31, 33, 35, 39, 45, 51, 52, 56, 58, AND 59 IN SUBJECTS NAÏVE (PCR NEGATIVE) FOR THE SPECIFIC NON-VACCINE HPV TYPE AT BASELINE.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 31 and P- at baseline for relevant HPV types (Close-out of Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *31*	15	32 (8 also naïve for Vax HPV)	HPV *31* Total	8	21 (5 also naïve for Vax HPV)
31 alone	7	14	*31* alone	7	7
31, 6	0	1	*31, 6, 16, 39*	0	1
31, 6, *33, 35*	0	1	*31, 16*	0	1
31, 16	1	2 (2 naïve 16)	*31, 16, 18, 56, 58*	0	1
31, 16, 18	0	1	*31, 16, 33, 45, 58*	0	1
31, 16, 33, 58	0	1	*31, 18, 51*	0	1
31, 16, 39, 51	0	1	*31, 35*	0	1
31, 16, 51, 52	0	2 (1 naïve 16)	*31, 45, 51*	0	1
31, 16, 56, 58, 59	0	1	*31, 51, 58*	1	0
31, 18, 45	0	1	*31, 51, 59*	0	1
31, 18, *51, 58*	0	1	*31, 52*	0	3
31, 33	2	0	*31;52*	0	1
31, 35	0	1	*31, 56*	0	1
31, 39	0	1	*31, 59*	0	1
31, 51	0	1			
31, 51, 52	0	1			
31, 51, 58	1	0			
31, 52	1	1			
31, 52, 56	1	0			
31, 52, 58	0	1			
31, 52, 59	1	0			
31, 56, 58	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 33 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *33* Total	18	19 (8 also naïve for Vax HPV)	HPV *33* Total	15	14 (2 also naïve for Vax HPV)
33 alone	8	5	*33* alone	6	6
33, 6	0	1	*33, 16*	0	1
33, 6, 16	0	1	*33, 16, 31, 45, 58*	0	1
33, 6, 31, 35	0	1	*33*, 16, *39, 51, 52*	0	1
33, 16	0	2	*33, 18, 56*	0	1
33, 16, *18*	0	2	*33, 35*	0	1
33, 16, *39*	1	0	*33, 39*	1	1
33, 16, 31, 58	0	1	*33, 39, 45, 52*	0	1
33, 16, 51, 56	0	1	*33, 51, 52*	1	0
33, 16, 52	0	1	*33, [52] ,56*	1	0
33, 18	0	1	*33*, 56	5	1
33, 31	2	0	*33, 58*	1	0
33, 31, 51, 56	1	0			
33, 35	1	0			
33, 39	0	1			
33, 39, 59	0	1			
33, 51, 56	1	0			
33, 52	1	0			
33, 56	2	0			
33, 56, 58	0	1			
33, 59	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 35 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *35* Total	10	5 (1 also naïve for Vax HPV)	HPV *35* Total	4	11 (3 also naïve for Vax HPV)
35 alone	4	2	*35* alone	2	6
35, 6, *18*, 45, *51*, 52, *56*	0	1	*35, 16*	0	1
35, 6, *31, 33*	0	1	*35, 16, 39*	0	1
35, 16	1	0	*35, 16, 51*	0	1
35, 31	0	1	*35, 31*	0	1
35, 33	1	0	35, 31, 39, *52*	1	0
35, 45	1	0	*35, 33*	0	1
35, 51	2 (1 naïve 51)	0	*35, 39, 56*	1	0
35, 52	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

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CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 39 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *39* Total	5	12 (1 also naïve for Vax HPV)	HPV *39* Total	9	14 (5 also naïve for Vax HPV)
39 alone	1	0	*39* alone	4	3
39, 6, 16, 58	0	1	*39, 6*	0	1
39, 16	0	3	*39, 6, 16, 31*	0	1
39, 16, 31, 51	0	1	*39, 16*	0	1
39, 16, 33	1	0	*39*, 16, *33, 51, 52*	0	1
39, 16, *52*, 58	1	0			
39, 31	0	1	*39, 16, 35*	0	1
39, 31, 52	0	1	*39, 18, 52*	0	1
39, 33	0	1	*39, 33*	1	1
39, 33, 45, 52	0	1	*39, 33, 45, 52*	0	1
39, 33, 59	0	1	*39, 35, 56*	1	0
39, 45	1	0	*39, 51, 52*	1	0
39, 45, 52	0	1	*39, 52*	0	1
39, 52	0	1	*39, 52, 56*	0	1
39, 56	1	0	*39, 56*	1	0
			39, 58	1	1

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 45 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *45* Total	10	8 (4 also naïve for Vax HPV)	HPV *45* Total	2	5 (2 also naïve for Vax HPV)
45 alone	3	1	*45* alone	1	0
45, 16	2	1 (naïve for 16)	*45, 16*	0	1
45, 16, *18*, 31	0	1	*45, 16, 18, 51, 52*	0	1
45, 16, 52	1	1 (naïve for 16 and 52)			
			45, 16, 31, 33, 58	0	1
45, 16, 58	1	0			
45, 18, 31	0	1	*45, 31, 51*	0	1
45, 33, *39*, 52	0	1	*45, 33, 39, 52*	0	1
45, 35	1	0	*45, 52*, 56, 58	1	0
45, 39	1	0			
45, 51,*52*	0	1			
45, 51, 56	0	1			
45, 56	1	0			

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 51 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *51* Total	11	13 (3 also naïve for Vax HPV)	HPV *51* Total	18	25 (11 also naïve for Vax HPV)
51 alone	4	2	*51* alone	6	5
51, 6, 16	0	1	*51, 6*	0	1
51, 6, *18*, 35, 45, 52, *56*	0	1	*51*, 6, 56	1	0
51, 16	1 (naïve for 16)	1	*51, 11*	0	1
51, 16, 31	0	1	*51, 16*	0	3
51, 16, *31*, 52	0	2 (1 naïve for 16, 1 naïve for 52)	*51*, 16	0	1
51, 16, *33, 56*	0	1	*51, 16, 18, 45, 52*	0	1
51, 16, *56*	0	1	*51, 16, 33, 39, 52*	0	1
51, 18, *31*, 58	0	1	*51*, 16, 35	0	1
51, *31*, 52	0	1	*51*, 16, 52, 58	0	1
51, 31, 58	1	0	*51*, 18, *31*	0	1
51, 33	1	0	*51*, 18, 52	0	1
51, 33, 56	1	0	*51*, 18, 52, 58	0	1
51, 35	1	0	*51*, 31	0	1
51, 39, 56	1	0	*51*, 31, 45	0	1
51, 45, 56	0	1	*51*, 31, 52, 58	1	0
51, 58	1	0	*51, 31, 59*	0	1
			51, 33, 52	1	0
			51, 39, 52	1	0
			51, 52	2	0
			51, 52, 56, 58	1	0
			51, 52, 58	0	2
			51, [52], 59	1	0
			51, 56	3	1
			51, 56, 58	0	1
			51, 59	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 52 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *52* Total	18	26 (8 also naïve for Vax HPV)	HPV *52* Total	24	25 (6 also naïve for Vax HPV)
52 alone	7	6	*52* alone	13	6
52, 16	1	5 (4 naïve for 16)	*52, 6*	0	1
52, 16, 18	0	1	*52, 6*, 31	0	1
52, 16, 31, 51	0	2	*52, 16*	0	1
52, 16, 33	0	1	*52, 16, 18, 45, 51*	0	1
52, 16, 39, 58	1	0	*52,* 16, *33, 39, 51*	0	1
52, 16, 45	0	1	*52, 16, 51, 58*	0	1
52, 16, 56	0	3 (2 naïve for 16 and 2 naïve for 56)	*52, 18, 51*	0	1
52, 16, 58	0	1	*52, 18, 51, 58*	0	1
52, 31	1	1	*52, 18, 56, 59*	0	1
52, 31, 51	0	1	*52, 31*	0	3
52, 31, 56	1	0	*52; 31*	0	1
52, 31, 58	0	1	*52,* 31, *35*, 39	1	0
52, 31, 59	1	0	*52, 31, 51, 58*	1	0
52, 33	1 (naïve for 33)	1	*52, 33, 39, 45*	0	1
52, 39	1	0	*52, 33, 51*	1	0
52, 45	0	1	*[52], 33, 56*	1	0
52, 51	1	1	*52, 39*	0	1
52, 51, 56	1	0	*52, 39, 51*	1	0
52, 58	1	0	*52, 39, 56*	0	1
52, 59	1	0	*52, 45,* 56*, 58*	1	0
			52, 51	2	0
			52, 51, 58	0	2
			[52], 51, 59	1	0
			52, 56	0	1
			52, 58	1	0
			52, 58, 59	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 56 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *56* Total	9	16 (7 also naïve for Vax HPV)	HPV *56* Total	21	16 (6 also naïve for Vax HPV)
56 alone	1	1	*56* alone	8	1
56, 6, *18*, *35*, 45, *51*	0	1	*56, 16*	0	2
56, *11*, 16	0	1	*56, 16, 31, 58*	0	1
56, *11*, 16, <u>*18*</u>, 51, *58*	0	1	*56, 18*	0	2
56, 16	2	1 (naïve for 16)	*56, 18, 33*	0	1
56, 16, 18	0	1	*56, 18, 52, 59*	0	1
56, 16, 31, 58, 59	0	1	*56, 31*	0	1
56, 16, 33, 51	0	1	*56, 33*	5	1
56, 16, 35	0	1	*56, 33, [52]*	1	0
56, 16, *51*	0	1	*56, 35, 39*	1	0
56, 16, 52	0	2	*56, 39*	1	0
56, 31, 33, 51	1	0	*56, 39, 52*	0	1
56, 31, 58	1	0	*56, 51*	3	1
56, 33	1	0	*56, 51, 52, 58*	1	0
56, 33, 58	0	1	*56, 51, 58*	0	1
56, 45	1	0	*56, 52*	0	1
56, 45, 51	0	1	*56, 58*	1	1
56, 51, 33	1	0	*56, 59*	0	1
56, 51, 39	1	0			
56, 58	0	2			

<u>18</u> above indicates serology below cutoff but not undetectable
HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 and CIN 2 Cases associated with Non-Vaccine HPV type 58 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *58* Total	8	16 (5 also naïve for Vax HPV)	HPV *58* Total	12	17 (6 also naïve for Vax HPV)
58 alone	4	4	*58* alone	6	6
58, 6	0	1	*58, 6*	0	1
58, 11, 16, <u>18</u>, 51, *56*	0	1	*58, 16, 31, 33, 45*	0	1
58, 16	0	1	*58, 16, 18, 31, 56*	0	1
58, 16, 31, 33	0	1			
58, 16, 31, 56, 59	0	1	*58, 16, 51, 52*	0	1
58, 16, *56*	0	1	*58, 18, 51, 52*	0	1
58, 18, *31, 51*	0	1	*58, 31*	0	1
58, 31, 51	1	0	*58, 33*	1	0
58, 31, 52	0	1	*58, 39*	1	1
58, 31, *56*	1	0	*58, 51, 52*	0	2
58, 33, 56	0	1	*58, 51, 52, 56*	1	0
58, 51	1	0	*58, 51, 56*	0	1
58, 52	1	0	*58, 52*	1	0
58, 56	0	2	*58, 52, 59*	1	0
58, 59	0	1	*58, 56*	1	1

<u>18</u> above indicates serology below cutoff but not undetectable
HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.

CIN 3 Cases and CIN 2 Cases associated with Non-Vaccine HPV type 59 and P- at baseline for relevant HPV types (Close-out Data for Studies HPV-013 and HPV-015)

CIN 3	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800	CIN 2	Gardasil N=2717 (013) N=6082 (015) Total = 8799	Control N=2725 (013) N=6075 (015) Total = 8800
HPV *59* Total	6	6 (3 also naïve for Vax HPV)	HPV *59* Total	3	7 (3 also naïve for Vax HPV)
59 alone	2	0	*59* alone	0	1
59, 16	0	3 (2 naïve for 16)	*59, 16*	0	1
59, 16, 31, 56, 58	0	1	*59, 18*	0	1
59, 31	1	0	*59, 18, 52, 56*	0	1
59, 31, 52	1	0	*59, 31*	1	1
59, 33	1	0	*59, 31, 51*	0	1
59, 33, 39	0	1	*59, 51*	1	0
59, 52	1	0	*59, 51, [52]*	1	0
59, 58	0	1	*59, 56*	0	1
			59, 52, 58	1	0

HPV types in italics represent P- for the relevant non-vaccine HPV type and other HPV types
Case may appear in more than one table for both CIN 2 and CIN 3 cases.