

LIST OF TABLES

TABLE	TITLE	PAGE NUMBER
1	Efficacy of Gardasil to Prevent HPV 16- or 18 Related CIN 2/3, AIS, or Worse (PPE and MITT-3 Populations)	8
2	Efficacy of Gardasil to Prevent HPV 6-, 11-, 16- or 18 Related CIN 2/3, AIS, or Worse (PPE and MITT-3 Populations)	8
3	Efficacy of Gardasil to Prevent HPV 6-, 11-, 16- or 18 Related Condyloma Acuminata (PPE and MITT-3 Populations)	9
4	Efficacy of Gardasil to Prevent HPV 6-, 11-, 16- or 18 Related Vulvar Intraepithelial Neoplasia (VIN) Grades 2/3 and Vaginal Intraepithelial Neoplasia (VaIN) Grades 2/3 (PPE and MITT-3 Populations)	10
5	Efficacy of Gardasil to Prevent HPV 6-, 11-, 16- or 18 Related Cervical Intraepithelial Neoplasia (CIN) Grade 1 (PPE and MITT-3 Populations)	10
6	Efficacy of Gardasil to Prevent HPV 6-, 11-, 16- and/or 18 Related Vulvar Intraepithelial Neoplasia (VIN) Grade 1 and Vaginal Intraepithelial Neoplasia (VaIN) Grade 1 (PPE and MITT-3 Populations)	11
7	Subjects Administered at least one dose of monovalent HPV vaccine, Gardasil, or placebo in clinical studies in the BLA	12
8	Protocol 001: Treatment Plan	20
9	Protocol 001: Procedures	21
10	Protocol 001: Proportions of Subjects with anti-HPV 11 \geq 200 mMU/mL and GMTs at Week 4 Postdose 3 (Per Protocol Population)	23
11	Protocol 001: Results of Statistical Analysis Comparing the Percentage of Subjects with HPV 11 Neutralization to 30% at 4 Weeks postdose 3 (Per Protocol population)	23
12	Protocol 002: Treatment Plan	25
13	Protocol 002: Schedule of Clinical Observations and Laboratory Measurements	27
14	Protocol 002: Immunogenicity Summary of Percentage of Subjects Achieving Anti-HPV 16 RIA \geq 20 mMU/mL and GMTs with 95% CIs (Per Protocol Population)	28
15	Protocol 002: Results of Statistical Analysis of Acceptability Immune Response (Percentage of Subjects with HPV 16 Serum RIA Levels \geq 20 mMU/mL at Month 7 (4 weeks postdose 3) (Per Protocol Population)	29
16	Protocol 004: Treatment Plan	31

TBLE	TITLE	PAGE NUMBER
17	Protocol 004: Schedule of Clinical Observations and Laboratory Measurements	32
18	Protocol 004: Immunogenicity Summary of Anti-HPV 16 Serum cRIA Levels ≥ 20 mMU/mL and GMTs Following Administration of Placebo or HPV 16 L1 VLP Vaccine (Per Protocol population – initially HPV 16 seronegative)	33
19	Protocol 006: Treatment Plan and Vaccination Schedule	39
20	Protocol 006: Schedule of Clinical Observations and Laboratory Measurements	40
21	Protocol 006: Immunogenicity Summary of Anti-HPV 18 Serum cRIA Responses to HPV 18 L1 VLP Vaccine in Initially Seronegative Subjects (Per Protocol Population)	41
22	Regulatory Background Information	44
23	Phase I-II studies with Monovalent HPV VLP Vaccines	44
24	Quadrivalent HPV 6, 11, 16, 18 L1 VLP Vaccine Summary of Pivotal Phase IIb-III Trials	45
25	Protocol 015: Schedule of Clinical Observations and Laboratory Measurements	49
26	Protocol 015: Clinical Products Used	50
27	Definitions of Efficacy Populations	55
28	Protocol 015: Subject Disposition	58
29	Protocol 015: Accounting for Substudy Participants	59
30	Protocol 015: Number of Subjects in Each Efficacy Population	59
31	Protocol 015: Subject Characteristics by Vaccination Group	60
32	Protocol 015: Summary of Sexual History at Enrollment by Vaccination Group	61
33	Protocol 015: Gynecologic History at Enrollment by Vaccination Group ($\geq 1\%$)	62
34	Protocol 015: Prevalence of Non-HPV CV Infections and STDs at Day 1 by Vaccination Group	62
35	Protocol 015: Summary of Pap Test Results at Day 1 by Vaccination Group	63
36	Protocol 015: Primary Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse by HPV Type and Severity (PPE Population)	66
37	Protocol 015: Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse by HPV Type and Severity (MITT-2 Population)	68
38	Protocol 015: Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse by HPV Type and Severity (MITT-3 Population)	69

TABLE	TITLE	PAGE NUMBER
39	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN by HPV Type and Severity (PPE Population)	72
40	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN by HPV Type and Severity (MITT-3 Population)	73
41	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 Related EGL by HPV Type and Severity (PPE Population)	74
42	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 Related EGL by HPV Type and Severity (MITT-3 Population)	76
43	Protocol 015: Analysis of Efficacy Against CIN Irrespective of HPV Type (Restricted MITT-2 population)	77
44	Protocol 015: Analysis of Efficacy Against CIN Irrespective of HPV Type (MITT-3 population)	78
45	Protocol 015: Analysis of Efficacy Against EGL by Severity Irrespective of HPV Type (Restricted MITT-2 population)	81
46	Protocol 015: Analysis of Efficacy Against EGL by Severity Irrespective of HPV Type Including Biopsies Outside the context of the study (MITT-3 population)	81
47	Protocol 015: Analysis of Efficacy Against Cervicovaginal and External Genital Disease Irrespective of HPV Type	82
48	Protocol 015: Analysis of Vaccine and Non-Vaccine HPV types in EGL, CIN, and EGL+CIN (RMITT-2 population)	83
49	Protocol 015: Impact of Vaccination on Pap Test Abnormalities (RMITT-2 and MITT-3 Populations)	83
50	Protocol 015: Impact of Vaccination on Gynecologic Procedures (RMITT-2 and MITT-3 Populations)	84
51	Protocol 015: Analysis of Efficacy Against Vaccine HPV Type Related CIN at Day 1 Among Subjects who were PCR Positive <u>and/or</u> Seropositive for the Relevant HPV Type at Day 1	85
52	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 related CIN or Worse Among Subjects who were PCR Negative and Seropositive for the Relevant HPV type(s) at baseline	86
53	Protocol 015: Analysis of Efficacy Against HPV 16/18 related CIN 2/3 or Worse Among Subjects who were Seronegative and PCR Positive for the Relevant HPV type at Day 1 – (Cases counted starting at 30 days postdose 1)	86
54	Protocol 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN or AIS Among Subjects who were Seropositive <u>and</u> PCR Positive for the Relevant HPV Type at Day 1	87

TABLE	TITLE	PAGE NUMBER
55	Protocol 015: Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse Among Subjects who were Seropositive <u>and</u> PCR Positive for the Relevant HPV Type at Day 1-(Cases Counted Starting at 30 Days Postdose 1)	88
56	Protocol 015: Analysis of Efficacy Against Vaccine HPV Type Related EGLs Among Subjects who were PCR Negative and Seropositive for the Relevant Vaccine HPV Type(s) at Day 1	89
57	Protocol 015: Analysis of Efficacy Against Vaccine HPV Type Related EGLs Among Subjects who were PCR Positive and Seronegative for the Relevant Vaccine HPV Type(s) at Day 1	90
58	Protocol 015: Analysis of Efficacy Against Vaccine HPV Type Related EGLs Among Subjects who were PCR Positive and Seropositive for the Relevant Vaccine HPV Type(s) at Day 1	91
59	Protocol 015: Clinical Adverse Experience Summary (Days 1-15 Following Any Vaccination Visit) – All Vaccinated Subjects	92
60	Protocol 015: Clinical Adverse Experience Summary: Days 1-15 Following Any Vaccination Visit -Detailed Safety Cohort (US)	92
61	Protocol 015: Clinical Adverse Event Experience after Dose 1, Dose 2, and Dose 3 Days 1-15 after vaccination (Detailed Safety Cohort, US)	93
62	Protocol 015: Clinical Adverse Events in those who were Seronegative and PCR Negative at Baseline, and in those who were Seropositive or PCR Positive at baseline (after any Vaccination, and after doses 1, 2, and 3, Days 1-15) (Detailed Safety Cohort, US)	93
63	Protocol 015: Number (%) of Subjects with Injection Site AEs (\geq 1%) and Risk Differences Days 1-5 after any Vaccination Visit – Detailed Safety Cohort US)	94
64	Protocol 015: Number (%) of subjects with Injection site AEs (Incidences \geq 1%) Days 1-5 after any vaccination with Gardasil: Seronegative and PCR Negative, and Seropositive or PCR Positive (Detailed Safety Cohort, U.S)	95
65	Protocol 015: Number (%) of Subjects with Most Common Systemic AEs (Days 1-15 after any vaccination visit) (Detailed Safety Cohort) with Risk Differences	96
66	Protocol 015: Number (%) of Subjects with Elevated Temperatures by Vaccination Visit (Day 1-5 after any Vaccination Visit) (Detailed Safety Cohort US)	97
67	Protocol 015: Deaths in Gardasil and Placebo recipients	97
68	Protocol 015: SAEs in Vaccinees in Protocol 015 (Excluding Deaths and Ob-GYN Conditions)	99

TABLE	TITLE	PAGE NUMBER
69	Protocol 015: Serious Ob-GYN Adverse Events (Excludes Deaths)	100-101
70	Protocol 015: Comparison of Vaccination Groups with Respect to the Number (%) of Subjects who Reported SAEs Days 1-15 Days After any Vaccination or Vaccine Related SAEs at Any Time During the Study	102
71	Protocol 015: Comparison of Vaccination Groups with Respect to the Number (%) of Subjects who Reported Severe Injection Site AEs Days 1-5 Days After Any Vaccination –Detailed Safety Cohort (US)	103
72	Protocol 015: Pregnancy Outcome Summary (Entire Study Period, All Vaccinated Subjects)	104
73	Protocol 015: Percentages of subjects with spontaneous abortions (including all subjects with known outcomes, with or without subjects from Latin America)	105
74	Protocol 015: Infants (live births) with SAE Born to Mothers who Received Gardasil or Placebo	108
75	Protocol 015 Month 24 (Consistency Lot Substudy): Anti-HPV cLIA GMTs by Day 1 Serostatus and PCR Status	114
76	Protocol 015: Summary of Anti-HPV Serum cLIA GMTs by Consistency Lot and Seroconversion Rates (Per Protocol Population)	117
77	Protocol 015: Statistical Analysis of Equivalence of GMTs at Month 7 Comparing Vaccine Lots 1, 2, and 3 (PPI)	118
78	Protocol 011: Concomitant Hepatitis B Vaccine Administration Substudy	126
79	Protocol 012: Monovalent HPV 16 Bridging Substudy	126
80	Protocol 011: Vaccine Products Used	127
81	Protocol 012: Vaccine Products Used	127
82	Protocol 013: Schedule of Clinical Observations and Laboratory Measurements – (includes Protocols 011 and 012)	130
83	Definitions of MITT-4 Population	133
84	Protocol 013: Definitions of Immunogenicity Populations for Protocols 011 and 012	135
85	Protocol 013: Subject Disposition	136
86	Protocol 011: Subject Disposition	137
87	Protocol 012: Subject Disposition	138
88	Protocol 013: Subjects Enrolled by Region	138
89	Protocol 013: Number of Subjects with Efficacy Phase Follow-up in the Per Protocol Efficacy Population by Vaccination Group	139
90	Protocol 013: Primary Efficacy Analysis Against HPV 6/11/16/18 Related CIN and External Genital Lesions (Per Protocol Efficacy Analysis)	144

TABLE	TITLE	PAGE NUMBER
91	Protocol 013: Efficacy Analysis Against HPV 6/11/16/18 Related CIN by HPV Type and Severity (PPE Population)	145
92	Protocol 013: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN by HPV Type and Severity (MITT-3 Population)	146
93	Protocol 013: Incidence of Non-Vaccine HPV Type Related CIN by Severity (MITT-3)	149
94	Protocol 013: Analysis of Efficacy Against HPV 16/18 Related CIN by HPV Type and Severity (PPE Population)	150
95	Protocol 013: Analysis of Efficacy Against HPV 6/11/16/18 Related EGLs by HPV Type and Severity (PPE Population)	151
96	Protocol 013: Analysis of Efficacy Against HPV 6, 11, 16, 18 related EGLs by HPV Type and Severity (MITT-3 Population)	153
97	Protocol 013: Analysis of Efficacy Against HPV 6/11/16/18 related CV and EGL Disease by HPV Type (Per Protocol Efficacy Population)	155
98	Protocol 013: Analysis of Efficacy Against HPV 6/11/16/18 Related CV and EGL Disease by HPV Type (MITT-3 Population)	156
99	Protocol 013: Analysis of Efficacy Against All CIN Irrespective of HPV Type by Severity (RMITT-2 Population)	157
100	Protocol 013: Analysis of Efficacy Against CIN Irrespective of HPV Type by Severity (MITT-3 Population)	158
101	Protocol 013: Analysis of Efficacy Against EGL Irrespective of HPV Type by Severity (RMITT-2 Population)	159
102	Protocol 013: Analysis of Efficacy Against EGL Irrespective of HPV Type by Severity (MITT-3 Population)	160
103	Protocol 013: Secondary Analysis of Efficacy Against EGL Irrespective of HPV Type (Per Protocol Approach)	163
104	Protocol 013: Exploratory Analysis of Potential Replacement of Vaccine HPV Types in CIN (RMITT-2 Population)	164
105	Protocol 013: Exploratory Analysis of Potential Replacement of Vaccine HPV Types in EGL (RMITT-2 Population)	164
106	Protocol 013: Analysis of Efficacy Against Vaccine HPV Type Related CIN Among Subjects who were PCR Positive <u>and/or</u> Seropositive for the Relevant HPV Type at Day 1	166
107	Protocol 013: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN or Worse Among Subjects who were PCR Negative and Seropositive for the Relevant Vaccine HPV Type(s) at Day 1	166
108	Protocol 013: Analysis of Efficacy Against Vaccine HPV Type Related CIN Among Subjects who were PCR Positive and Seronegative for the Relevant HPV Type at Day 1	167

TABLE	TITLE	PAGE NUMBER
109	Protocol 013: Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse Among Subjects who were PCR Positive and Seronegative for the Relevant Vaccine HPV Type	168
110	Protocol 013: Analysis of Efficacy Against Vaccine HPV Type Related CIN Among Subjects who were PCR Positive and Seropositive for the Relevant Vaccine HPV Type at Day 1	168
111	Protocol 013: Analysis of Efficacy Against Vaccine HPV Type Related EGLs Among Subjects who were PCR Positive and Seronegative for the Relevant Vaccine HPV Type at Day 1	169
112	Protocol 013: Protocol 013: Analysis of Efficacy Against Vaccine HPV Type Related EGLs Among Subjects who were PCR Positive and Seropositive for the Relevant Vaccine HPV Type at Day 1	170
113	Protocol 011: Summary of Anti-HPV GMTs and Seroconversion Rates at Month 7 in the Subjects who Received Active HPV Vaccine With and Without Hepatitis B Vaccine (HPV PPI)	171
114	Protocol 011: Statistical Analysis of Non-Inferiority Comparing Month 7 Anti-HPV cLIA GMTs Between Subjects who Received HPV Vaccine With and Without Hepatitis B Vaccine (HPV PPI)	172
115	Protocol 011: Statistical Analysis of Non-Inferiority Comparing Month 7 Seroconversion Rates Between Subjects who Received HPV Vaccine With and Without Hepatitis B Vaccine (HPV PPI)	173
116	Protocol 011: Summary of Hepatitis B RIA GMTs by Vaccination Group (Hep B PPI)	173
117	Protocol 011: Number (%) of Subjects with Hepatitis B RIA Titers ≥ 10 mIU/mL by Vaccination Group (Hep B PPI)	174
118	Protocol 011: Statistical Comparison of Non-Inferiority Comparing Month 7 Anti-HBs Seroprotection Rates Between Subjects who Received Hepatitis B Vaccine With or Without HPV Vaccine (Hep B PPI)	176
119	Protocol 012: Summary of anti-HPV 16 GMTs and Seroconversion Rates at Month 7 in the Subjects who Received Final Manufactured Product Quadrivalent HPV Vaccine Pilot Manufacturing Material Monovalent HPV 16 Vaccine (HPV PPI)	177
120	Protocol 012: Statistical Analysis of Non-Inferiority Comparing Month 7 Anti-HPV 16 cLIA GMTs between Subjects who Received Final Manufactured Product Quadrivalent Vaccine and Pilot Manufacturing Material Monovalent HPV 16 Vaccine (PPI Population)	178
121	Protocol 012: Statistical Analysis of Non-Inferiority Comparing Month 7 anti-HPV 16 cLIA Seroconversion Rates Between Subjects who Received Final Manufactured Product Quadrivalent HPV VLP Vaccine and Subjects who received Pilot Manufacturing Material Monovalent HPV 16 Vaccine (PPI)	178

TABLE	TITLE	PAGE NUMBER
122	Protocol 013: Summary of anti-HPV cLIA GMTs and Seropositivity Rates in Quadrivalent HPV Vaccines in Protocol 013	179
123	Protocol 013 Frozen File: Clinical Adverse Experience Summary (Over Entire Study Period)	185
124	Protocol 011: Number (Percentage) of Subjects with Injection Site AEs (Incidence \geq 1%) Days 1-5 after any Vaccination Visit	186
125	Protocol 012: Number (Percentage) of Subjects with Injection Site AEs (Incidence \geq 1%) Days 1-5 after any Vaccination Visit	186
126	Protocol 011: Number (%) of subjects with systemic AEs in Days 1-15 after any Vaccination Visit	187
127	Protocol 012: Number (%) of subjects with systemic AEs in Days 1-15 after any Vaccination Visit	188
128	Protocol 013: Number (%) with Systemic AEs Days 1-9999 after any vaccination visit (Frozen File-8/11/05)	189
129	Protocol 013: Number (%) of subjects with elevated Ts Days 1-5 after any Vaccination Visit	190
130	Protocol 013: SAEs in Vaccines	191-192
131	Protocol 013: Comparison of Vaccination Groups with Respect to Number (%) of Subjects who Reported SAEs Days 1-15 After Any Vaccination Visit	193
132	Protocol 013: Pregnancy Outcome Summary	195
133	Protocol 013: SAEs in Infants Born to Vaccines	197
134	Protocol 007: Vaccination Regimen – Part A	204
135	Protocol 007: Vaccination Regimen – Part B	204
136	Protocol 007: Clinical Supplies: Formulation Numbers, Control Numbers, Dosage and Package Information (Part A)	205
137	Protocol 007: Clinical Supplies: Formulation Numbers, Dosage, and Package Information (Part B)	205
138	Protocol 007: Case Definitions of Persistent Infection for Subjects who had Biopsies Showing Pathologic Evidence of HPV Disease (as Defined by the Consensus Diagnosis of the Pathology Panel) and Who Had Not Had Definitive Therapy Performed	206
139	Protocol 007: Case Definitions of Persistent Infection for Subjects who had Biopsies Showing Pathologic Evidence of HPV Disease (as Defined by the Consensus Diagnosis of the Pathology Panel) and Who Had Not Had Definitive Therapy Performed	207
140	Protocol 007: Schedule of Clinical Observations and Laboratory Measurements	208
141	Protocol 007: Definitions of Immunogenicity Populations	211

TABLE	TITLE	PAGE NUMBER
142	Protocol 007: Subject Disposition (Part B, Dose Ranging Phase)	213
143	Protocol 007: Subject Accounting for the PPE Efficacy and Immunogenicity Populations (Part B)	214
144	Protocol 007: Analysis of Efficacy Against HPV 6, 11, 16, or 18 Related Persistent Infection or Disease (Per Protocol Efficacy Population)	218
145	Protocol 007: Secondary Analysis of Efficacy Against HPV 6, 11, 16, 18 Related Persistent Infection or Disease (Per Protocol and Modified Intent to Treat Populations)	219
146	Protocol 007: Analysis of Efficacy Against Cervical and External Genital Disease Irrespective of HPV type (PPE, MITT-2, and MITT-3 Populations)	223
147	Protocol 007: Month 36 Pap Test Diagnoses	223
148	Protocol 007: Month 36 Cervical Biopsy Diagnoses	224
149	Protocol 007: Clinical AE Summary (Days 1-15 following any vaccination visit) Dose Ranging Study	230
150	Protocol 007: Pregnancy Outcomes by Vaccination Group	233
151	Protocol 005: Treatment Plan	234
152	Protocol 005: Vaccine Products Used	234
153	Protocol 005: Schedule of Clinical Observations and Laboratory Measurements	236
154	Protocol 005: Case Definitions of Subjects who have Biopsies showing pathologic evidence of HPV disease and who have not had a LEEP performed	238
155	Protocol 005: Case Definitions of subjects who have biopsies showing pathologic evidence of HPV disease and who have had a LEEP	238
156	Protocol 005: Subject Accounting	241
157	Protocol 005: Subject Accounting for the Efficacy and Immunogenicity Analysis Populations by Vaccination Group	242
158	Protocol 005: Analysis of Efficacy Against Persistent HPV 16 Infection (Per Protocol Efficacy Population, Fixed Case Analysis)	245
159	Protocol 005: Analysis of Efficacy Against Persistent HPV 16 Infection (Per Protocol Efficacy Population, End of Study)	246
160	Protocol 005: Analysis of Efficacy Against Persistent HPV 16 Infection (MITT Populations, Fixed Case Analysis)	247
161	Protocol 005: Analysis of Efficacy Against Persistent HPV 16 Infection (MITT Populations, End of Study)	247

TABLE	TITLE	PAGE NUMBER
162	Protocol 005: Analysis of Efficacy Against Persistent HPV 16 Infection (MITT-3 Population, End of Study)	248
163	Protocol 005: Analysis of Efficacy Against “Super-Persistent” HPV 16 Infection (Per Protocol Efficacy Population, End of Study)	249
164	Protocol 005: Analysis of Efficacy Against HPV 16 Related CIN (Per Protocol Population, End of Study)	250
165	Protocol 005: Efficacy Against HPV 16 Related CIN (MITT-3 Population, End of Study)	251
166	Protocol 005: Efficacy Against CIN Irrespective of HPV Type (Per Protocol Efficacy Population with Normal Pap Test Results at Day 1 through Month 7, End of Study)	252
167	Protocol 005: Incidence of HPV 6, 11, or 18 Related External Genital Lesions (Per Protocol Population within the Relevant HPV Type)	253
168	Protocol 005: Month 48 Pap Diagnoses	255
169	Protocol 005: Month 48 Cervical Biopsy Diagnoses	255
170	Protocol 005: Summary of Anti-HPV 16 GMTs by cRIA (PPI)	256
171	Protocol 005: Clinical Adverse Events Summary (Days 1 – 15 Following Any Vaccination Visit)	259
172	Protocol 005: Injection Site Adverse Events within 5 days of injection	260
173	Protocol 005: Outcomes of Pregnancies that Occurred from Day 1 through Month 7 by Vaccination group	263
174	Protocol 016: Dose Arms	265
175	Protocol 016: Vaccine Products Used, Adolescent Immunogenicity Substudy	265
176	Protocol 016: Vaccine Products Used, End Expiry Substudy	265
177	Protocol 016: Study Flow Chart, 10-15 Year Old Males and Females	267
178	Protocol 016: Study Flow Chart, 16-23 Year Old Females	268
179	Protocol 016:-Adolescent Immunogenicity Substudy: Populations Enrolled/Analyzed and Subject Disposition	270
180	Protocol 016-End Expiry Substudy: Subject Disposition	271
181	Protocol 016: Summary of Subjects Excluded from the PPI Populations by Group	272
182	Protocol 016-End Expiry Substudy: Summary of Subjects Excluded from the PPI Population	273
183	Protocol 016-Adolescent Immunogenicity Substudy: Subjects Enrolled by Region	274
184	Protocol 016-Adolescent Immunogenicity Substudy: Summary of Subject Characteristics by Demographic Cohort	274
185	Protocol 016-End Expiry Substudy: Subjects Enrolled by Region	275

TABLE	TITLE	PAGE NUMBER
186	Protocol 016-End Expiry Substudy: Summary of Subject Characteristics by Demographic Cohort	275
187	Protocol 016: Summary of HPV Serostatus at Day 1 by Demographic Cohort	276
188	Protocol 016- Adolescent Immunogenicity Substudy: Summary of Anti-HPV cLIA GMTs by Group (PPI Population) at Month 7	277
189	Protocol 016 - Adolescent Immunogenicity Substudy: Summary of the Proportions of Subjects who Became Seropositive to Vaccine HPV Type by Group (PPI Population) at Month 3 and Month 7	278
190	Protocol 016: Statistical Analysis of Non-Inferiority of Month 7 HPV cLIA GMTs Comparing 10-15 Year Old Females to 16-23 Year Old Females (PPI Population)	280
191	Protocol 016: Statistical Analysis of Non-Inferiority with Comparing Month 7 Seroconversion Rates in 10-15 Year Old Females with 16-23 Year Old Females (PPI Population)	281
192	Protocol 016-End Expiry Substudy: Summary of HPV cLIA GMTs by Vaccination Group (PPI Population)	282
193	Protocol 016-End Expiry Substudy: Summary of the Proportions of Subjects who Became Seropositive to Vaccine HPV Type by Group (PPI Population) at Month 3 and Month 7	283
194	Protocol 016: Statistical Analysis of Non-Inferiority Comparing Month 7 HPV cLAI GMTs Between Subjects who <u>Received Partial Dose Formulations</u> and those who Received Full Dose Formulations (PPI Population)	284
195	Protocol 016: Statistical Analysis of Non-Inferiority Comparing Proportions of Subjects who Seroconverted at Month 7 Between Subjects who <u>Received Partial Dose Formulations</u> and those who Received Full Dose Formulations (PPI Population)	285
196	Protocol 016 - Adolescent Immunogenicity Substudy: Clinical Adverse Experience Summary	286
197	Protocol 016: Number (%) of Subjects With Injection Site AEs (Days 1-5 Following Any Vaccination Visit)	287
198	Protocol 016: Comparison of 10-15 Year Old females and 16-23 Year old females with Respect to the Number (%) of Subjects who Reported Systemic Clinical AEs After Gardasil by System Organ Class (Days 1-15 Following Any Vaccination Visit)	289
199	Protocol 016: Number (%) of Subjects with Elevated Temperatures (Days 1-5 Following Any Vaccination Visit)	290
200	Protocol 016: Risk Differences for Fever in 10-15 year old Females Compared to 16-23 year old Females	291

TABLE	TITLE	PAGE NUMBER
201	Protocol 016- Adolescent Immunogenicity Substudy: SAEs in Vaccinees	292
202	Protocol 016 - -End Expiry Substudy: Clinical Adverse Experience Summary – Days 1-15 after any vaccination	293
203	Protocol 016: End-Expiry Substudy: Number (%) of Subjects with Elevated Temperatures (Days 1-5 Following Any Vaccination Visit)	294
204	Protocol 016 – End Expiry Substudy: Number (%) of Subjects with Elevated Temperatures (Days 1-5 Following Any Vaccination Visit) – 16-23 year old age group	295
205	Protocol 016- End Expiry Substudy: Number (%) of Subjects with Elevated Temperatures (Days 1-5 Following Any Vaccination Visit) – 10-15 year old female age group	295
206	Protocol 016 –End Expiry Substudy: SAEs in Vaccinees	296
207	Protocol 016 – End Expiry Substudy: Pregnancy Outcome Summary	297
208	Protocol 016: SAEs in Infants Born to Vaccinees	298
209	Protocol 018: Treatment Plan	300
210	Protocol 018: Vaccine Products Used	301
211	Protocol 018: Study Flow Chart	302
212	Protocol 018: Subject Disposition by Vaccination Group	304
213	Protocol 018: Subject Disposition for Females (aged 9-15 years of age) by Vaccination Group	305
214	Protocol 018: Subject Disposition for Males (aged 9-15 years of age) by Vaccination Group	306
215	Protocol 018: Summary of Exclusions from Per-Protocol Population by Gender in the Quadrivalent Vaccine Group only	307
216	Protocol 018: Summary of Exclusions from PPI Population By Gender in the Placebo Group Only	308
217	Protocol 018: Summary of Subject Characteristics by Demographic Cohort	309
218	Protocol 018: Subjects Enrolled by Region	309
219	Protocol 018: Summary of Subject Characteristics by Gender Within Vaccination Group	310
220	Protocol 018: Summary of Subject Characteristics by Age Group Within Vaccination Group	311
221	Protocol 018: Summary of HPV GMTs by Gender Among Subjects who received the Quadrivalent HPV Vaccine (Per Protocol Immunogenicity Population)	312

TABLE	TITLE	PAGE NUMBER
222	Protocol 018: Summary of Month 7 Seroconversion Rates by Gender among Subjects who Received the Quadrivalent Vaccine (Per Protocol Immunogenicity Population)	312
223	Protocol 018: Statistical Analysis of Non-Inferiority of Month 7 HPV cLIA GMTs Comparing 9-15 year old Males to 9-15 year old Females (PPI Population)	313
224	Protocol 018: Statistical Analysis of Non-Inferiority of Month 7 Anti-HPV Seroconversion Rates Comparing Boys with Girls Among Subjects who Received Quadrivalent HPV Vaccine (PPI Population)	313
225	Protocol 018: Summary of HPV GMTs by Treatment Group (Per Protocol Immunogenicity Population)	314
226	Protocol 018: Summary of Month 7 Seroconversion Rates by Treatment Groups (Per Protocol Immunogenicity Population)	314
227	Protocol 018: Summary of HPV GMTs by Age Group Among Subjects who Received the Quadrivalent HPV Vaccine (Per Protocol Immunogenicity Population)	315
228	Protocol 018: Summary of Month 7 Seroconversion Rates by Age Group Among Subjects who Received the Quadrivalent Vaccine (Per Protocol Immunogenicity Population)	315
229	Protocol 018: Clinical Adverse Experience Summary Days 1-15 Postvaccination – Protocol 018 (Overall)	316
230	Protocol 018: Comparison of Overall Rate of AEs (Days 1 – 15 after any vaccination)	317
231	Protocol 018- Clinical Adverse Experience Summary Days 1-15 Postvaccination by Gender	317
232	Protocol 018 - Clinical Adverse Experience Summary Days 1-15 Postvaccination by Age	318
233	Protocol 018: Number (%) of subjects with Injection Site AEs Days 1-5 after any Vaccination Visit	319
234	Protocol 018: Comparison of Vaccination Groups with Respect to the Number (%) of Subjects who Reported Specific Injection Site AEs Days 1-5 after any Vaccination	319
235	Protocol 018: Number (%) of Subjects with Injection Site AEs by Gender Within Each Vaccination Group (Days 1-5 After any Vaccination Visit)	320
236	Protocol 018: Number (%) of Subjects with Injection Site AEs by Age Group Within Each Vaccination Group (Days 1-5 After any Vaccination Visit)	320
237	Protocol 018: Number (%) of Subjects with Systemic AEs Days 1-15 After Any Vaccination Visit	322
238	Protocol 018: Number (%) of Subjects with Systemic AEs by Gender Within Each Vaccination Group (Days 1 -15 After Any Vaccination Visit)	323

TABLE	TITLE	PAGE NUMBER
239	Protocol 018: Number (%) of Subjects With Musculoskeletal Adverse Events By Treatment Group (Days 1-15 After Any Vaccination) (Reviewer constructed)	323
240	Protocol 018: Number (%) of Subjects with Elevated Ts Days 1-5 After Any Vaccination Visit	325
241	Protocol 018: Comparison of Vaccination Groups with Respect to the Number of Subjects with Maximum oral $T \geq 37.8$ deg C Days 1-5 After Any Vaccination Visit	325
242	Protocol 018: Number (%) of Subjects with Elevated T by Gender Within Each Vaccination Group Days 1-5 After Any Vaccination Visit	326
243	Protocol 018: Number (%) of Subjects with Elevated T by Age Group Within Each Vaccination Group Days 1-5 After Any Vaccination Visit	326
244	Protocol 018: SAEs (Vaccine Recipients)	327
245	Protocol 018: New Medical Conditions <u>Day 1 through Month 12</u>	329
246	Protocol 018: New Medical Conditions <u>Day 7 through Month 12</u>	330
247	Number of Subjects Enrolled: Distribution by Region	335
248	Protocols 005, 007, 013, and 015: Summary of Enrolled Subject Characteristics by Vaccination Group	335
249	Protocols 005, 007, 013, 015: Number of Subjects Entered by Age Category: All Randomized Subjects	336
250	Protocols 005, 007, 013 and 015: Summary of Pap Test Results at Day 1 by Vaccination Group – Efficacy Population	336
251	Protocols 007, 013, and 015: Composite HPV 6, 11, 16, and 18 Status by PCR and/or Serology at Day 1 by Vaccination Group	337
252	Protocols 005, 007, 013, and 015: Number of HPV Types Detected by PCR at Day 1 by Vaccination Groups – Randomized Subjects	337
253	Protocols 005, 007, 013, 015: Subject Accounting for the Efficacy Analysis Populations by Vaccination Group	338
254	Protocols 005, 007, 013, 015: Number of Subjects, Median Age, and Duration of Follow-up in Efficacy Population (Original BLA submission)	339
255	Protocols 005, 007, 013, 015: Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse	340

TABLE	TITLE	PAGE NUMBER
256	Protocols 005, 007, 013, 015 (Combined and Separately): Analysis of Efficacy Against HPV 16/18 Related CIN 2/3 or Worse –MITT-3 Population	341
257	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN 2/3 – PPE, MITT-2 and MITT-3 Populations	341
258	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN 1 – PPE, MITT-2 and MITT-3 Populations	343
259	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/ 11/16/18 related CIN – PPE, MITT-2 and MITT 3 Population	344
260	Protocols 005, 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18 related CIN by HPV Type – PPE, MITT-2, MITT-3	345
261	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6, 11, 16, 18 related CIN by Severity– PPE and MITT-3 Populations	346
262	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6, 11, 16, 18 Related Condyloma by HPV type – PPE and MITT-3 Populations	347
263	Protocols 007, 013, and 015: Efficacy Against HPV 6, 11, 16, or 18 Related VIN 2/3 or VaIN 2/3 – PPE, MITT-2 and MITT- 3 Populations	348
264	Protocols 007, 013, 015: Efficacy Against HPV 16/18 Related VIN 2/3 or VaIN 2/3 – PPE, MITT-2 and MITT-3 Populations	349
265	Protocols 007, 013, and 015: Efficacy Against HPV 6, 11, 16, or 18 Related VIN 2/3 – PPE and MITT-3 Populations	349
266	Protocols 007, 013, and 015: Efficacy Against HPV 6, 11, 16, or 18 Related VaIN 2/3 – PPE and MITT-3 Populations	350
267	Protocols 007, 013, and 015: Efficacy Against HPV 6, 11, 16, or 18 Related VIN 1 – PPE and MITT-3 Populations	350
268	Protocols 007, 013, and 015: Efficacy Against HPV 6, 11, 16, or 18 Related VaIN 1 – PPE and MITT-3 Populations	351
269	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18 Related EGLs	351
270	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6, 11, 16, 18 related EGL by HPV Type	353
271	Protocols 007, 013, and 015 Combined: Analysis of Efficacy Against HPV 6, 11, 16, 18 Related EGL by Severity of Disease	354

TABLE	TITLE	PAGE NUMBER
272	Protocols 007, 013, and 015 Combined: Impact of GARDASIL on the Incidence of CIN Irrespective of HPV Type by Severity of Disease	355
273	Protocols 007, 013 and 015: Impact of Gardasil on the Incidence of EGLs Irrespective of HPV Type by Severity of Disease-RMITT-2 and MITT-3 Populations	357
274	Protocols 007, 013, and 015: Analysis of Efficacy Against VIN 2/3 and VaIN2/3 Irrespective of HPV Type – MITT-3 Population	359
275	Protocols 005, 007, 013, 015: Efficacy Against HPV 16/18 related CIN 2/3, AIS or Worse – MITT-3 Population, by Initially Baseline HPV Status	360
276	Protocols 007, 013 and 015: Analysis of Efficacy Against Vaccine HPV Type Related CIN Among Subjects who were PCR Positive <u>and/or</u> Seropositive for the Relevant HPV Type at Day 1	361
277	Protocols 007, 013, 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN Among Subjects who were PCR Positive and Seronegative for the Relevant HPV Type(s) at Day 1	361
278	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18 Related CIN Among Subjects who were PCR Negative and Seropositive for the Relevant HPV Type(s) at Day 1	362
279	Protocols 007, 013, and 015: Analysis of Efficacy Against HPV 6/11/16/18-Related CIN or AIS Among Subjects Who Were Seropositive <u>and</u> PCR Positive for the Relevant HPV Type at Day 1	362
280	Size of Seropositive and PCR Positive Population Compared with the General Population of Protocol 013, Protocol 015, and the Database for Protocol 013 and 015 Combined	363
281	Protocols 013 and 015: Percentage of subjects with HSIL at Day 1 in subjects who were Seropositive and PCR Positive at Day 1	364
282	Protocols 007, 013, 015: Endpoint Counts and Efficacy in the Integrated Phase II/III Efficacy Database for Gardasil	365
283	Protocols 007, 013, 015 Combined: Analysis of Efficacy Against HPV 6, 11, 16, 18 Related EGLs in Seropositive and/or PCR positive subjects (Subsets of MITT-3 population)	366
284	Protocols 007, 013, and 015: Impact of Gardasil on Pap Test Abnormalities (RMITT-2 and MITT-3 Populations)	367

TABLE	TITLE	PAGE NUMBER
285	Protocol 007, 013 and 015: Impact of Gardasil on Selected Invasive Procedures	368
286	Protocols 001, 002, 004, 005, 006, 012: Overall Extent of Exposure to <u>Monovalent</u> HPV L1 VLP Vaccines	371
287	Protocols 007, 013, 015, 016, and 018: Number of Subjects Entered by Age Category and Gender – Safety Populations	372
288	Number of subjects 9-17 years of age <u>enrolled</u> by Treatment Group (Males and Females)	372
289	Protocols 007, 013, 015, 016, 018: Overall Extent of Exposure to <u>Gardasil</u>	373
290	Protocols 007, 013, 015, 016, 018: Subject Disposition – Safety Population	374
291	Protocols 007, 013, 015, 016, 018: Subjects in Follow-up Period (after Month 7)	374
292	Protocol 007, 013, 015, 016, and 018: Summary of Subject Characteristics by Vaccination Group –Safety Population (Application Data)	375
293	Protocols 007, 013, 015, and 016: Summary of Composite HPV 6, 11, 16, and 18 Status by PCR and/or Serology at Day 1 by Vaccination Group — Female Subjects 16 to 26 Years of Age at Enrollment in the Safety Population	376
294	Protocols 007, 013, 015, 016, 018: Subjects included in Clinical Adverse Event Summary (Days 1-15 after any Vaccination)	376
295	Protocols 007, 013, 015, 016, and 018: Clinical Adverse Experience Summary (Days 1 to 15 after any Vaccination Visit) - Safety Population (Cumulative Data)	377
296	Protocols 007, 013, 015, 016, and 018: Clinical Adverse Experience Summary (Days 1 to 15 after any Vaccination Visit) - Detailed Safety Population (Cumulative Data)	377
297	Protocols 007, 013, 015, 016, 018: Deaths	379
298	Protocols 007, 013, 015, 016, 018: SAEs by Organ Systems (All Subjects, Cumulative Data, 3/8/06)	381-385
299	Protocols 007, 013, 015, 016, and 018: Subjects who Received Gardasil and Discontinued from their Studies (Excluding Deaths)	386
300	Protocols 007, 013 015, 016, and 018: Subjects Who Received Placebo and Discontinued from their Studies	387
301	Protocols 005, 007, 013, 015, 016, 018: Summary of Subjects Who Reported an Incident Condition Potentially Indicative of Systemic Autoimmune Disorder after Enrollment in clinical trials of Gardasil (<u>At Any Time During Trial</u>)	391
302	Protocols 007, 013, 015, 016 and 018: New Medical Conditions <u>Day 1 through Month 7</u> in the Safety Population	393-394
303	Protocols 007, 013, 015, 016 and 018: New Medical Conditions after Month 7 in the Safety Population	395-396

304	Protocols 007, 013, 015, 016, 018: New Medical Conditions (Number and Percent) During Vaccination Period through Month 7 and after Month 7 for Selected Organ Systems	397
305	Adverse Events in Those who Became Pregnant During the Vaccination Period (Compared to Detailed Safety Population and Safety Population), Days 1-15 Following Any Vaccination Visit	398
306	Protocols 013, 015, 016, 018: Pregnancy Outcomes in the Phase III studies	399
307	Protocols 005, 007, 013, 015, 016*: Gardasil Recipients vs. Placebo Recipients Whose Infants had Congenital Anomalies (Through 11/05)	400
308	Distribution of Congenital Anomaly Cases in the Phase III Clinical Database by EDCn Timing in Relation to Study Vaccination by Time When Diagnosis was Made by Vaccination Group (Protocols 013, 015, 016, and 018) (Cumulative Data)	402
309	Protocols 013, 015, 016: Listing of SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Test Product – Entire Study Period*** (Systemic-Neonatal [Neonatal Period]) – Safety Population (Cumulative Data) [Excludes Congenital Anomalies]	404-408
310	Protocols 013, 015, 016: Listing of SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Test Product – Entire Study Period*** (Systemic-Other [Outside Neonatal Period]) – Safety Population (Cumulative Data)	409-412
311	Protocols 007, 013, 015, 016: Deaths in Infants Potentially Exposed* to Study Material During Follow-up of Phase III studies	412-413
312	SAEs of Subjects During Breast Feeding/Lactation with Gardasil	413
313	Protocols 013, 015, 016: SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Test Product (Entire Study Period-Lactation) Safety Population	414
314	Protocols 013, 015, and 016: SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Placebo (Entire Study Period-Lactation) Safety Population	415
315	Protocols 013, 015, and 016: SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Test Product (Entire Study Period-Lactation) Safety Population	415
316	Protocols 013, 015, and 016: SAEs Reported in Infants of Vaccinated Subjects who were Potentially Exposed to Test Product (Entire Study Period-Systemic Neonatal and Systemic Other) Safety Population	416

TABLE	TITLE	PAGE NUMBER
317	Protocols 007, 013, 015, 016, and 018: Number (%) of Subjects with Injection Site AEs \geq 1% in Days 1-5 after any Vaccination Visit in Detailed Safety Population	418
318	Protocols 007, 013, 015, 016, and 018: Number (%) of Subjects with Injection Site AEs \geq 1% in Days 1-5 after Dose 1, Dose 2, and Dose 3 in Detailed Safety Population	419
319	Number (%) of Subjects Who Developed Injection Site AEs by Maximum Intensity Rating (Days 1-5 Following Any Vaccination Visit) in Detailed Safety Population (Protocols 007, 013, 015, 016, 018)	420
320	Comparison of Vaccination Groups with Respect to Number (%) of Subjects who Reported Severe Injection Site AEs (Days 1-5 Following Any Vaccination Visit) in Detailed Safety Population (Protocols 007, 013, 015, 016, 018)	421
321	Protocols 007, 013, 015, 016, and 018: Number (%) of Subjects with Systemic AEs \geq 1% in Days 1-15 after any Vaccination Visit in Detailed Safety Population	422
322	Number (%) of Subjects with Systemic AEs in Days 1 -15 After Any Vaccination Visit: Gardasil Recipients in Detailed Safety Cohort Overall (Protocols 007, 013, 015, 016, 018) Compared to Non-Alum Placebo Recipients in Protocol 018	422
323	Number (%) of Subjects With Elevated Temperatures (Days 1-5 Following Any Vaccination Visit) in Detailed Safety Population (Protocols 007, 013, 015, 016, 018)	423
324	Protocols 007, 013, 015, 016: Clinical AE Summary (Days 1-15 after any Vaccination) Detailed Safety Population – Female Subjects 18-26 years of age at Study Enrollment	424
325	Protocols 007, 013, 015, 016: Number (%) of subjects with Injection Site AEs (Incidence \geq 1% in One or More Vaccination Groups Days 1-5 after any Vaccination Visit) – Subjects 18-26 years of age at study enrollment	424
326	Protocols 007, 013, 015, 016: Number (%) of Subjects with Elevated T (Days 1-5) after any Vaccination Visit (Detailed Safety Population) – Female Subjects 18-26 years of age at Study Enrollment	425
327	Protocols 007, 013, 015, 016 and 018: Clinical AE Summary (Days 1-15 after any Vaccination Visit) Detailed Safety Population	426

TABLE	TITLE	PAGE NUMBER
328	Protocols 007, 013, 015, 016, 018: Number (%) of subjects with Injection Site AEs (Incidence \geq 1% in One or More Vaccination Groups (Days 1-5 after any Vaccination Visit) – <u>Detailed Safety Population</u> : Female Subjects 9-17 years of age at study enrollment	427
329	Protocols 007, 013, 015, 016, and 018: Number (%) of Subjects With Systemic Clinical Adverse Experiences (Incidence \geq 1% in One or More Vaccination Groups) by System Organ Class (Days 1 to 15 Following Any Vaccination Visit) <u>Detailed Safety Population</u> — Female Subjects 9 to 17 Years of Age at Study Enrollment	428
330	Frequency of Intensity Ratings of All Systemic AEs (Days 1-5 after any Vaccination Visit) Detailed Safety Population – Female Subjects 9-17 Years of Age at Study Enrollment (Protocols 007, 013, 015, 016 and 018)	429
331	Number (%) of Subjects Who Developed Systemic AEs by Maximum Intensity Rating (Days 1-15 Following Any Vaccination Visit) Detailed Safety Population - Female Subjects 9 to 17 Years of Age at Study Enrollment (Protocols 007, 013, 015, 016, 018)	429
332	Number (%) of Subjects With Elevated Temperatures (Days 1-5 Following Any Vaccination Visit) in Detailed Safety Population- Female Subjects 9 to 17 Years of Age at Study Enrollment (Protocols 007, 013, 015, 016, 018)	430
333	Protocols 005, 007, 013, 015, 016, 018: Summary of AEs Across Ethnic Groups	431
334	Protocols 005, 007, 013, 015, 016, 018: Summary of AEs by Baseline HPV Status	432-433
335	Protocols 007 and 016: Clinical Adverse Experience Summary Day 1-15 after any vaccination visit in subjects who received higher dose formulations and partial dose formulations of Quadrivalent HPV 6, 11, 16, 18 vaccine	433
336	Protocol 011: Number (%) of Subjects with Systemic AEs (Incidence \geq 1% in One or More Vaccination Group) by System Organ Class (Day 1 to 15 Following Any Vaccination Visit)	435
337	Protocols 007, 013, 015, 016: Month 7 HPV cLIA GMTs and Seroconversion Rates – 18 to 26 year old females [PPI Population]	437
338	Protocols 007, 013, 015, 016: Month 7 HPV cLIA GMTs and Seroconversion Rates –9-17 year old Females [PPI Population]	437

TABLE	TITLE	PAGE NUMBER
339	Protocols 007, 013, 015, 016: Month 7 HPV cLIA GMTs and Seroconversion Rates –16-17 year old Females [PPI Population]	438
340	Month 7 HPV cLIA GMTs by Baseline Subject Characteristics 9-26 year old females who received Gardasil (PPI Population)	439
341	Month 7 cLIA GMTs by Day 1 Serostatus and PCR Status – 18 to 26 year old females who Completed the Vaccination Regimen with Gardasil (N=4666) and Received Correct Clinical Material	444
342	Protocols 007, 011, 012: HPV cLIA GMTs at Day 1, Month 7, Month 12, and Month 24 in 18-26 year old Female Subjects who Received Gardasil in the PPI population who had Serology Data at All Time Points	445
343	HPV cLIA GMTs at Day 1, Month 7, Month 12, and Month 24 in 16-17 year old Female Subjects who Received Gardasil in the PPI Population who had Serology Data at All Time Points	446
344	HPV cLIA GMTs at Day 1, Month 7, Month 12, and Month 24 in 18-26 year old Female Subjects who Received Gardasil in the PPI Population who had Serology Data at the Corresponding Time Point	447
345	Impact of Time Between Vaccinations 1 and 2 on Month 7 cLIA GMTs – 18 to 26 year old Female Recipients of Gardasil (PPI Approach for Analysis of Dosing Deviation)	452
346	Impact of Time Between Vaccinations 2 and 3 on Month 7 cLIA GMTs – 18 to 26 year old Female Recipients of Gardasil (PPI Approach for Analysis of Dosing Deviation)	453
347	Summary of Month 7 HPV cLIA GMTs – 18-26 year old Female Recipients of Gardasil by Status of Hormonal Contrcaptive Use From Day 1 through Month 7 (PPI population)	453
348	Immunogenicity Bridging Between 9-15 year old Females in the Immunogenicity studies in 16-26 year old Female Recipients of Gardasil in Efficacy Studies (PPI population)	454