Compound	Protocol	Study Site	IIN	Visit	Baseline Number	Allocation Number
V501	016-00					

A Study to Demonstrate Immunogenicity and Tolerability of the Quadrivalent HPV (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine in Preadolescents and Adolescents, and to Determine End-Expiry Specifications for the Vaccine

Vaccination Report Card

(10 - 15 Years of Age)

Only the PARENT or GUARDIAN of the subject should complete this vaccination report card. Corrections to the vaccination report card by the parent or guardian should be dated and initialed by the parent or guardian.

The STUDY NURSE will enter the dates where needed.

Complete this card for **15 days after vaccination** (until _____ month/day/year) and return the card to the study site when it is complete.

Study Personnel Telephone Number: _ _ _ _ _ _ _ _ _ _

Parent or Guardian's Comments:

Study Site Personnel Comments:

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

TEMPERATURE MEASUREMENT

It is important that you take your child's temperature every day starting with the day of vaccination through Day 5.

Take your child's temperature orally and record this temperature in the appropriate box below.

Take your child's temperature in the evening whenever possible. If you need to take your child's temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	**DATE** (month/day/year)	**ORAL TEMPERATURE**
1		
2		
3		
4		
5		

Investigator's name:	**I have reviewed this information.** Staff's initials: Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at it's largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 **(Example A)**
2 if the greatest width is anywhere in the area marked 2
3 if the greatest width is anywhere in the area marked 3 **(Example B)**
Over 3 if the greatest width is in any area marked with a number over 3. *Write* in the number. **(Example C)**
If the reaction is wider than the area marked 7, write in 8.

On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

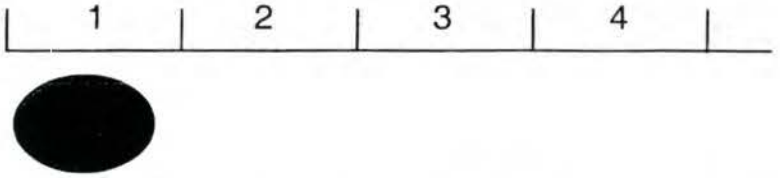
mild is awareness of symptom, but easily tolerated
moderate is definitely acting like something is wrong
severe is extremely distressed or unable to do usual activities

Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

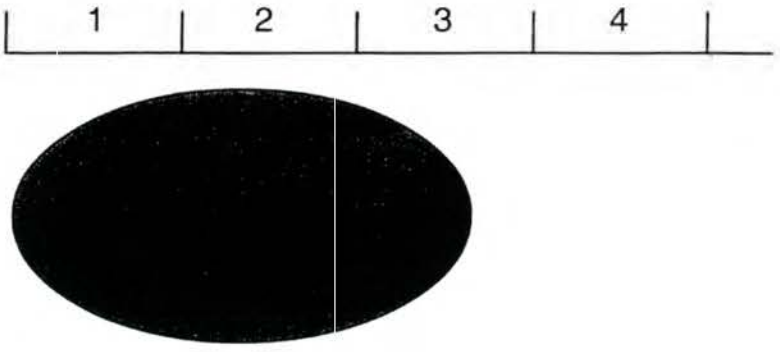
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

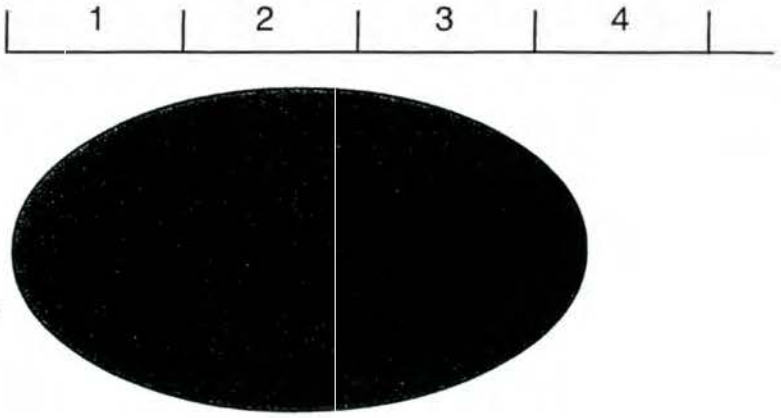
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site *(check one per page)*: ☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____

	DAY 1 Vaccination Day _____ month/day/year	DAY 2 _____ month/day/year	DAY 3 _____ month/day/year	DAY 4 _____ month/day/year	DAY 5 _____ month/day/year	LAST DATE REACTION PRESENT _____ month/day/year
SWELLING	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
REDNESS	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	

If an injection site reaction **began** 6 or more days after your child's vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it **started** and the **last date it was present.**

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is definitely acting like something is wrong

severe is extremely distressed or unable to do usual activities

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination your child did not have any other complaints or illnesses check the box here: ☐ ***None***

OTHER COMPLAINTS OR ILLNESSES	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

MEDICATIONS

Please list any prescription or over the counter medications your child takes starting from Day 1 _____ (month/day/year) through Day 15 _____ (month/day/year) after your child's injection.

LIST THE NAME OF THE MEDICATION	DATE MEDICATION STARTED (month/day/year)	DATE MEDICATION LAST TAKEN (month/day/year)	REASON FOR TAKING THE MEDICATION

NON-STUDY VACCINATIONS

Record any vaccines administered during the 15 days after your child received the study vaccine and report card.

LIST VACCINATION	SITE OF VACCINATION	DATE RECEIVED (month/day/year)
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	

I confirm that the information on this card is accurate

_____ (Parent's Initials) _____ (Date when follow-up is completed)

Compound	Protocol	Study Site	IIN	Visit	Baseline Number	Allocation Number
V501	016-00					

A Study to Demonstrate Immunogenicity and Tolerability of the Quadrivalent HPV (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine in Preadolescents and Adolescents, and to Determine End-Expiry Specifications for the Vaccine

Vaccination Report Card

(10 - 15 Years of Age)

Only the PARENT or GUARDIAN of the subject should complete this vaccination report card. Corrections to the vaccination report card by the parent or guardian should be dated and initialed by the parent or guardian.

The STUDY NURSE will enter the dates where needed.

Complete this card for **15 days after vaccination** (until _____ day/month/year)
and return the card to the study site when it is complete.

Study Personnel Telephone Number: _ _ _ _ _ _ _ _ _ _

Parent or Guardian's Comments:

Study Site Personnel Comments:

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

TEMPERATURE MEASUREMENT

It is important that you take your child's temperature every day starting with the day of vaccination through Day 5.

Take your child's temperature orally and record this temperature in the appropriate box below.

Take your child's temperature in the evening whenever possible. If you need to take your child's temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	**DATE** (day/month/year)	**ORAL TEMPERATURE**
1		
2		
3		
4		
5		

	I have reviewed this information.
Investigator's name:	Staff's initials: Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at it's largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 **(Example A)**
2 if the greatest width is anywhere in the area marked 2
3 if the greatest width is anywhere in the area marked 3 **(Example B)**
Over 3 if the greatest width is in any area marked with a number over 3. *Write* in the number. **(Example C)**
If the reaction is wider than the area marked 7, write in 8.

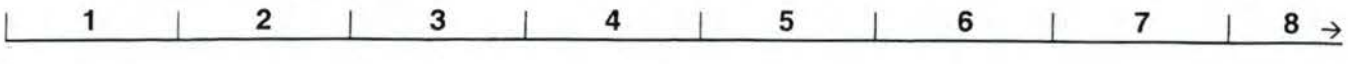
On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

mild is awareness of symptom, but easily tolerated
moderate is definitely acting like something is wrong
severe is extremely distressed or unable to do usual activities

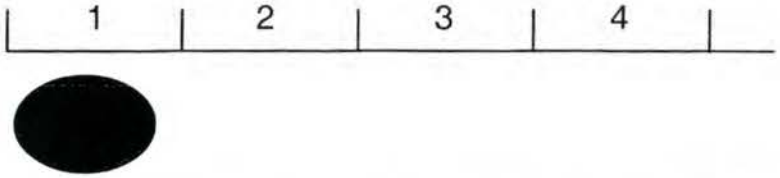
Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

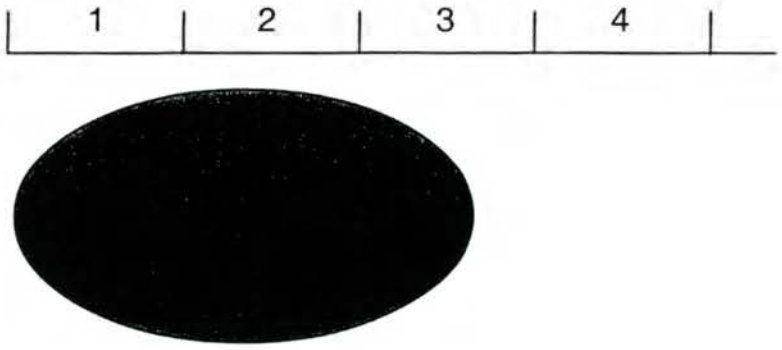


EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

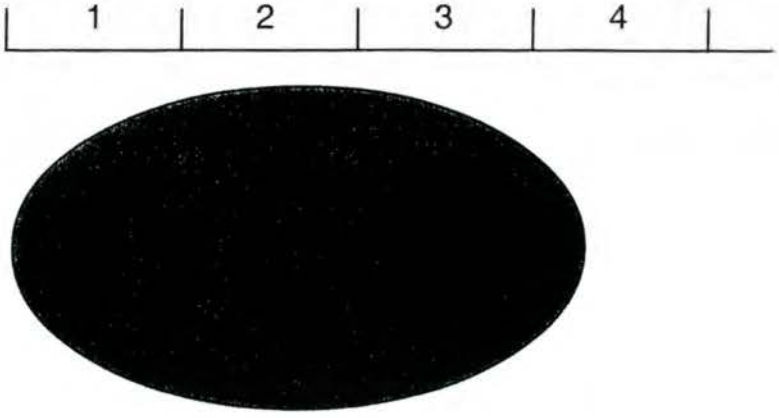
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site *(check one per page)*: ☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____

	DAY 1 Vaccination Day _____ day/month/year	DAY 2 _____ day/month/year	DAY 3 _____ day/month/year	DAY 4 _____ day/month/year	DAY 5 _____ day/month/year	LAST DATE REACTION PRESENT _____ day/month/year
SWELLING	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
REDNESS	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	

If an injection site reaction **began** 6 or more days after your child's vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (day/month/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it **started** and the **last date it was present.**

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is definitely acting like something is wrong

severe is extremely distressed or unable to do usual activities

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination your child did not have any other complaints or illnesses check the box here: ☐ ***None***

OTHER COMPLAINTS OR ILLNESSES	DATE (day/month/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

MEDICATIONS

Please list any prescription or over the counter medications your child takes starting from Day 1 _____ (day/month/year) through Day 15 _____ (day/month/year) after your child's injection.

LIST THE NAME OF THE MEDICATION	DATE MEDICATION STARTED (day/month/year)	DATE MEDICATION LAST TAKEN (day/month/year)	REASON FOR TAKING THE MEDICATION

NON-STUDY VACCINATIONS

Record any vaccines administered during the 15 days after your child received the study vaccine and report card.

LIST VACCINATION	SITE OF VACCINATION	DATE RECEIVED (day/month/year)
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	

I confirm that the information on this card is accurate

_____ (Parent's Initials) _____ (Date when follow-up is completed)

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

A Study to Demonstrate Immunogenicity and Tolerability of the Quadrivalent HPV (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine in Preadolescents and Adolescents, and to Determine End-Expiry Specifications for the Vaccine

Vaccination Report Card

(16 – 23 Years of Age)

Only the SUBJECT should complete this vaccination report card. Corrections to the vaccination report card by the subject should be dated and initialed by the subject.

The STUDY NURSE will enter the dates where needed.

Complete this card for **15 days after vaccination** (until _____ month/day/year) and return the card to the study site when it is complete.

Study Personnel Telephone Number: _ _ _ _ _ _ _ _ _ _

Subject's Comments:

Study Site Personnel Comments:

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

TEMPERATURE MEASUREMENT

It is important that you take your temperature every day starting with the day of vaccination through Day 5.

Take your temperature orally and record this temperature in the appropriate box below.

Take your temperature in the evening whenever possible. If you need to take your temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	**DATE** (month/day/year)	**ORAL TEMPERATURE**
1		
2		
3		
4		
5		

	I have reviewed this information.
Investigator's name:	Staff's initials: Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at it's largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 **(Example A)**
2 if the greatest width is anywhere in the area marked 2
3 if the greatest width is anywhere in the area marked 3 **(Example B)**
Over 3 if the greatest width is in any area marked with a number over 3.
Write in the number. **(Example C)**
If the reaction is wider than the area marked 7, write in 8.

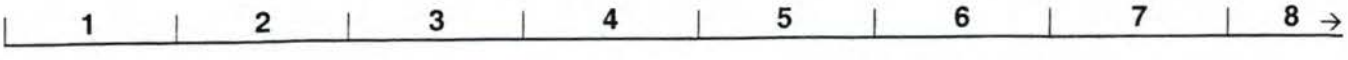
On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

mild is awareness of symptom, but easily tolerated
moderate is discomfort enough to cause interference with usual activities
severe is incapacitating with inability to work or do usual activity

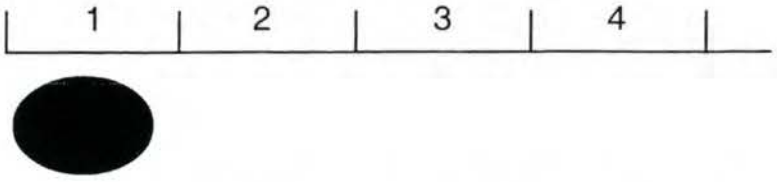
Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reaction".

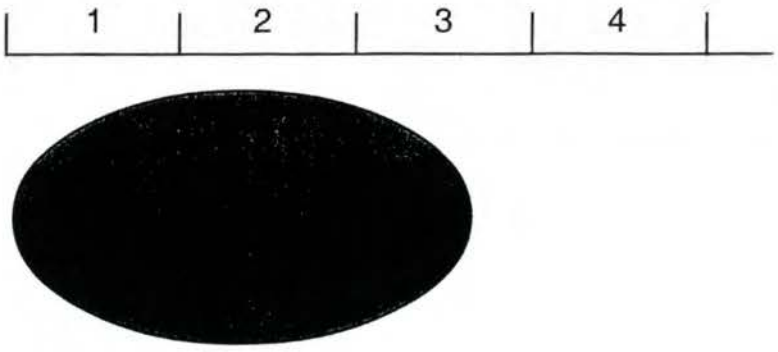


EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

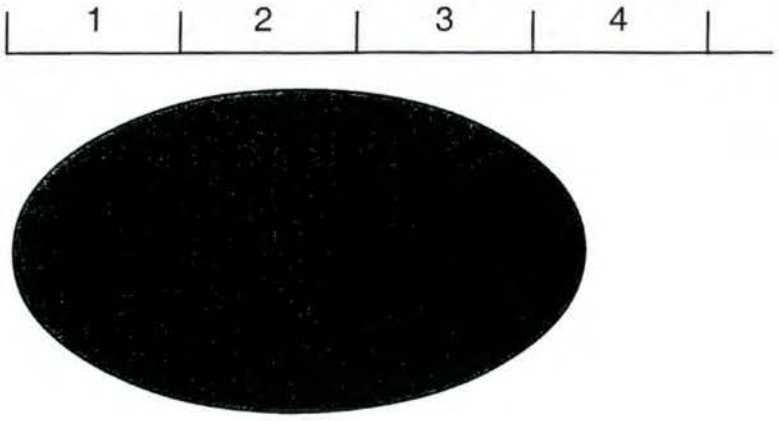
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site *(check one per page)*: ☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____

	DAY 1 Vaccination Day _____ month/day/year	DAY 2 _____ month/day/year	DAY 3 _____ month/day/year	DAY 4 _____ month/day/year	DAY 5 _____ month/day/year	LAST DATE REACTION PRESENT _____ month/day/year
SWELLING	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
REDNESS	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	

If an injection site reaction **began** 6 or more days after your vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it **started** and the **last date it was present.**

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is discomfort enough to cause interference with usual activities

severe is incapacitating with inability to work or do usual activity

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination you did not have any other complaints or illnesses check the box here: ☐ ***None***

OTHER COMPLAINTS OR ILLNESSES	DATE (month/day/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
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			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

MEDICATIONS

Please list any prescription or over the counter medications you take starting from Day 1 _____ (month/day/year) through Day 15 _____ (month/day/year) after your injection.

LIST THE NAME OF THE MEDICATION	DATE MEDICATION STARTED (month/day/year)	DATE MEDICATION LAST TAKEN (month/day/year)	REASON FOR TAKING THE MEDICATION

NON-STUDY VACCINATIONS

Record any vaccines administered during the 15 days after you received the study vaccine and report card.

LIST VACCINATION	SITE OF VACCINATION	DATE RECEIVED (month/day/year)
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	

I confirm that the information on this card is accurate

_____ (Subject's Initials) _____ (Date when follow-up is completed)

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
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A Study to Demonstrate Immunogenicity and Tolerability of the Quadrivalent HPV (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine in Preadolescents and Adolescents, and to Determine End-Expiry Specifications for the Vaccine

Vaccination Report Card

(16 – 23 Years of Age)

Only the SUBJECT should complete this vaccination report card. Corrections to the vaccination report card by the subject should be dated and initialed by the subject.

The STUDY NURSE will enter the dates where needed.

Complete this card for **15 days after vaccination** (until _____) and return the card to the study site when it is complete.
day/month/year

Study Personnel Telephone Number: _ _ _ _ _ _ _ _ _ _

Subject's Comments:

Study Site Personnel Comments:

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
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TEMPERATURE MEASUREMENT

It is important that you take your temperature every day starting with the day of vaccination through Day 5.

Take your temperature orally and record this temperature in the appropriate box below.

Take your temperature in the evening whenever possible. If you need to take your temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY		
DAY	**DATE** (day/month/year)	**ORAL TEMPERATURE**
1		
2		
3		
4		
5		

Investigator's name:	**I have reviewed this information.** Staff's initials: Date:

INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following pages entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at it's largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

1 if the greatest width is anywhere in the area marked 1 **(Example A)**
2 if the greatest width is anywhere in the area marked 2
3 if the greatest width is anywhere in the area marked 3 **(Example B)**
Over 3 if the greatest width is in any area marked with a number over 3.
Write in the number. **(Example C)**
If the reaction is wider than the area marked 7, write in 8.

On the following pages entitled "Injection Site Reactions", please estimate the severity of any **pain or tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

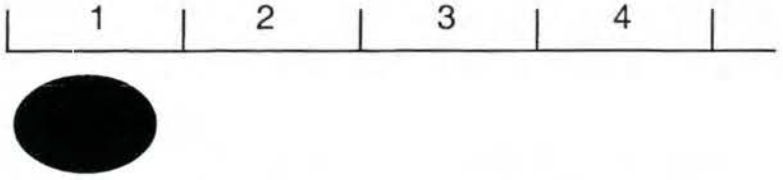
mild is awareness of symptom, but easily tolerated
moderate is discomfort enough to cause interference with usual activities
severe is incapacitating with inability to work or do usual activity

Complete one column each day, starting with Day 1 (the day of vaccination - 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

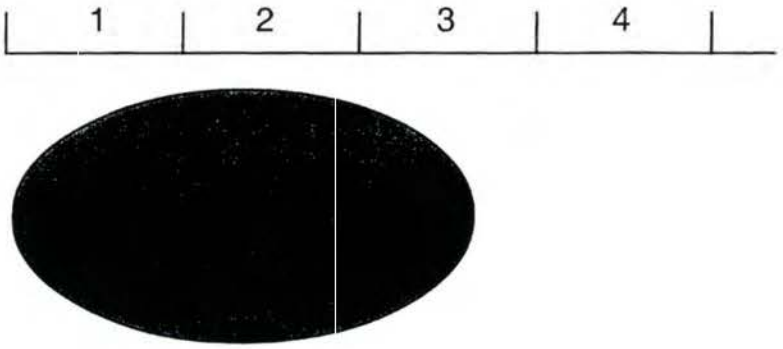
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reaction".

EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

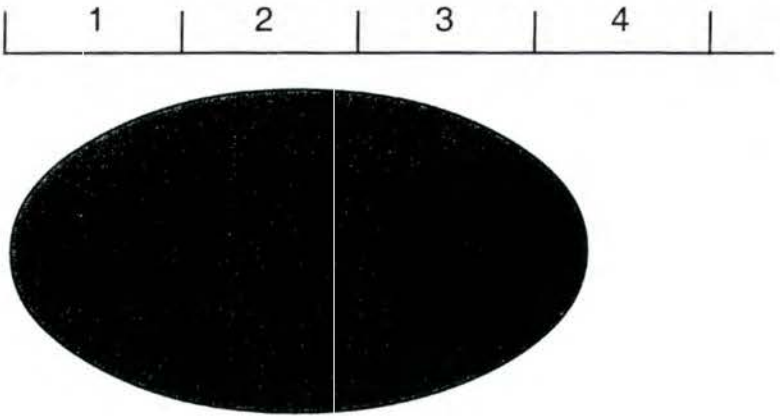
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site for this page by checking one box below.

Injection Site *(check one per page)*: ☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____

	DAY 1 Vaccination Day _____ day/month/year	DAY 2 _____ day/month/year	DAY 3 _____ day/month/year	DAY 4 _____ day/month/year	DAY 5 _____ day/month/year	LAST DATE REACTION PRESENT
SWELLING	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	_____ day/month/year
REDNESS	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3: ___	_____ day/month/year
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	_____ day/month/year
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	_____ day/month/year
OTHER INJECTION SITE REACTION *(specify):*	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	_____ day/month/year

If an injection site reaction **began** 6 or more days after your vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (day/month/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	VISIT	Baseline Number	Allocation Number
V501	016-00					

OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it **started** and the **last date it was present.**

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate is discomfort enough to cause interference with usual activities

severe is incapacitating with inability to work or do usual activity

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination you did not have any other complaints or illnesses check the box here: ☐ ***None***

OTHER COMPLAINTS OR ILLNESSES	DATE (day/month/year)		SEVERITY
	Started	Last Present	
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe
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			☐ mild ☐ moderate ☐ severe
			☐ mild ☐ moderate ☐ severe

Compound	Protocol	Study Site	IIN	Visit	Baseline Number	Allocation Number
V501	016-00					

MEDICATIONS

Please list any prescription or over the counter medications you take starting from Day 1 _____ (day/month/year) through Day 15 _____ (day/month/year) after your injection.

LIST THE NAME OF THE MEDICATION	DATE MEDICATION STARTED (day/month/year)	DATE MEDICATION LAST TAKEN (day/month/year)	REASON FOR TAKING THE MEDICATION

NON-STUDY VACCINATIONS

Record any vaccines administered during the 15 days after you received the study vaccine and report card.

LIST VACCINATION	SITE OF VACCINATION	DATE RECEIVED (day/month/year)
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other _____	

I confirm that the information on this card is accurate

_____ (Subject's Initials) _____ (Date when follow-up is completed)