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

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	)
	Study Personnel Telephone Number:	
Parent	t or Guardian's Comments:	
Study S	Site Personnel Comments:	

Compound	Protocol	Study Site	IIN	Baseline Number	Aflocation Number
V501	016-00			Baseline Number	

## 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	Y.						
3							
4							
5							

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

#### 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 <u>largest</u> from edge to edge. Use the <u>ruler marks</u> 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:

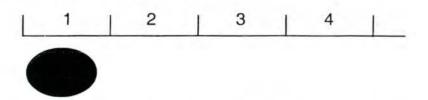
mild is awareness of symptom, but easily tolerated moderate is definitely acting like something is wrong severe is extremely distressed or unable to do usual activities

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.

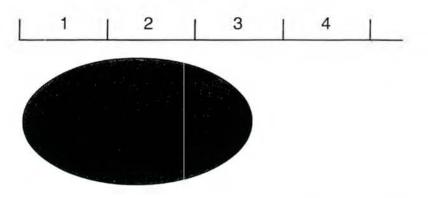
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

# EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

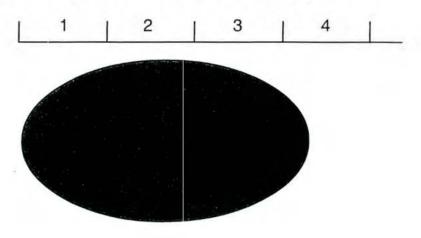
**Example A:** This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



**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.



V501	Protocol 016-00	Study Site	IIN	Baseline Number	Allocation Number
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## INJECTION SITE REACTIONS

		☐ Other				
	DAY 1 Vaccination Day	DAY 2	DAY 3	DAY 4	DAY 5	LAST DATE REACTION PRESENT
	morith/day/year	month/day/year	month/day/year	month/day/year	month/day/year	
SWELLING	□ None □ 1 □ 2	☐ None ☐ 1 ☐ 2	☐ None ☐ 1 ☐ 2	□ None □ 1 □ 2	□ None □ 1 □ 2	
	□ 3 □ over 3:	☐ 3 ☐ over 3:	□ 3 □ over 3:	□ 3 □ over 3:	□ 3 □ over 3:	month/day/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:	month/day/year
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/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	month/day/year
OTHER INJECTION SITE REACTION (specify):	☐ None ☐ Mild ☐ Moderate	☐ None ☐ Mild ☐ Moderate	☐ None ☐ Mild ☐ Moderate	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
SITE REACTION (specify):	□ None □ Mild □ Moderate □ Severe  te reaction beganed and the last of	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate □ Severe	□ None □ Mild □ Moderate	pelow. Recor
INJECTIO	N SITE REACTION	ONS	DATE (month	/day/year)		
	NING 6 OR MOR TER VACCINAT	FINAL TOTAL CONTROL	Started	Last Present	SEVE	RITY
					☐ mild ☐ mode	erate 🗆 severe
					☐ mild ☐ mode	erate 🗆 severe

Commercial	Destroat	I control I	****	V//////////	T. Control of the Con
Compound	Protocol	Study Site	IIN	Baseline Number	Allocation Number
V501	016-00			Baseline Number	

### 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:  $\square$  *None* 

OTHER COMPLAINTS	DATE (mo	onth/day/year)		
OR ILLNESSES	Started	Last Present	SEVERITY	
	0,		☐ 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	

and the state of t	Protocol Si 116-00	tudy Site IIN	Baseline Number	Allocation Number			
		MED	ICATIONS				
Day 1		n or over the cour through Day 15	The state of the s	our child takes starting from fter 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-STUD	Y VACCINATIONS	3			
Record any va study vaccine			ng the 15 days at	fter your child received the			
LIST VACCINATION		SITE OF VACCINATION DA					
	☐ Right Arm	☐ Left Arm ☐ Right	Thigh 🗆 Left Thigh 🗆	Other			
	☐ Right Am	☐ Left Am ☐ Right	Thigh  Left Thigh	Other			
	☐ Right Arm	☐ Left Arm ☐ Right 7	Other				

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

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) and return the card to the study site when it is complete.	
	Study Personnel Telephone Number:	
Parent	t or Guardian's Comments:	
Study	Site Personnel Comments:	

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

### 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 <u>largest</u> from edge to edge. Use the <u>ruler marks</u> 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:

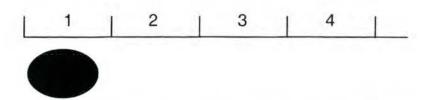
mild is awareness of symptom, but easily tolerated moderate is definitely acting like something is wrong severe is extremely distressed or unable to do usual activities

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.

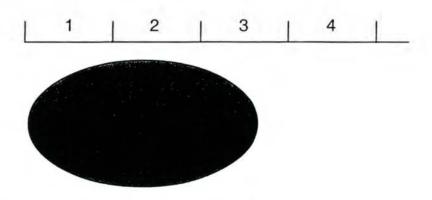
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

# EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

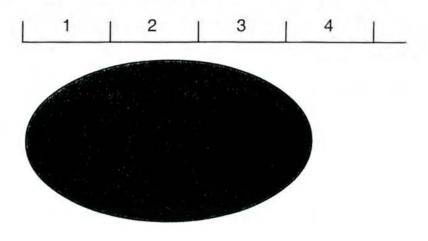
**Example A:** This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



**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.



Comp V5		Study Site III	N (3450	Baseline Number	Allocation Num	ber
		INJEC	TION SITE RE	ACTIONS		
STATISTICS OF STATISTICS OF	opy of this page p		Arm 🗆 Le		page by checking Right Thigh	one box below. ☐ Left Thigh
	DAY 1 Vaccination Day	DAY 2	DAY 3	DAY 4	DAY 5	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
	ed and the last d				please record it b scribes the sever	
BEGINN	N SITE REACTION SITE REACTION OF THE PROPERTY	E	DATE (day/m	Last Present	SEVE	RITY
					☐ mild ☐ mode	

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

#### 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 toleratedmoderate is definitely acting like something is wrongsevere 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:  $\square$  *None* 

OTHER COMPLAINTS	DATE (da	y/month/year)	8 6 6 6	OFVEDITY		
OR ILLNESSES	Started	Last Present	SEVERITY	infant.		
			☐ 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	

			MEDICA	TIONS		
Please list any Day 1		n or over the through Day	15	medications	your child take after your chi	
LIST THE NAMI MEDICAT		DATE MEDICATI STARTE (day/month/)	D   1	DATE MEDICATION LAST TAKEN lay/month/year	THE	N FOR TAKING MEDICATION
		NON-S	TUDY V	ACCINATIO	DNS	
Record any va study vaccine			during	the 15 days	s after your c	hild received th
LIST VACCINATION		S	TE OF V	ACCINATION	rane II	DATE RECEIVE (day/month/year
	☐ Right Arm	☐ Left Am ☐	Right Thigh	n ☐ Left Thigh	Other	
	☐ Right Arm	☐ Left Am ☐	Right Thigh	Left Thigh	Other	
	☐ Right Arm	☐ Left Am ☐	Right Thigh	Left Thigh	Other	

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

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## **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 <b>15 days after vaccination</b> (until and return the card to the study site when it is complete.	)
	Study Personnel Telephone Number:	
Subje	ct's Comments:	
Study	Site Personnel Comments:	

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

## **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	s 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 <u>largest</u> from edge to edge. Use the <u>ruler marks</u> 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:

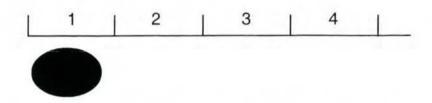
mild is awareness of symptom, but easily tolerated moderate is discomfort enough to cause interference with usual activities severe is incapacitating with inability to work or do usual activity

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.

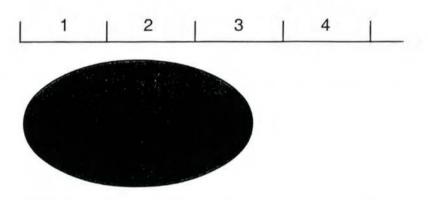
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reaction".

# EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

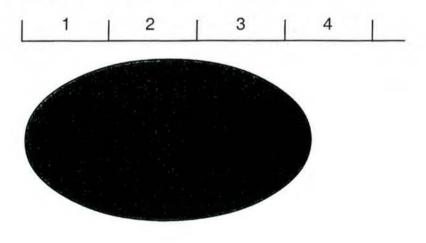
**Example A:** This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



**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.



Compo V50	mpound Protocol Study Site IIN Baseline Number 501 016-00		aseline Number	Allocation Numb		
		INJECT	TION SITE REA	ACTIONS		
and the same of th	opy of this page p	-	Arm □ Le		age by checking o	one box below ☐ Left Thigh
	DAY 1 Vaccination Day	DAY 2	DAY 3	DAY 4	DAY 5	LAST DATE REACTION PRESENT
SWELLING	month/day/year  ☐ None ☐ 1 ☐ 2 ☐ 3 ☐ over 3:	None	None	None	□ None □ 1 □ 2 □ 3 □ over 3:	month/day/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:	month/day/year
PAIN or TENDERNESS	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
OTHER INJECTION HE REACTION Specify):	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
OTHER INJECTION ITE REACTION Specify):	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	month/day/year
If an injection sidate it started a site reaction.	te reaction bega and the last date	n 6 or more day	ys after your vac t. Mark the box	cination, please that best describ	record it below. bes the severity of	Record the of the injection
	N SITE REACTION		DATE (month/o	day/year)	SEVE	RITY

Started

DAYS AFTER VACCINATION

**Last Present** 

5

☐ mild ☐ moderate ☐ severe

severe

☐ mild ☐ moderate

Allocation Number

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

### 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	DATE (mo	TO SEE THE THE TANK				
OR ILLNESSES	Started	d Last Present		SEVERITY		
			☐ 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	

V501	Protocol 016-00	Study Site	IIN	W557///	Baseline Number	Al	llocation Number		
			MED	ICATI	ONS				
Please list a Day 1	ny prescri		over the cough Day 15		medications		starting from ur injection.		
LIST THE NAME OF THE MEDICATION		ME	DATE MEDICATION STARTED (month/day/year)  DATE MEDICATION LAST TAKEN (month/day/year)		T TAKEN	REASON FOR TAKING THE MEDICATION			
			-9						
		NC	N-STUDY	VAC	CINATIONS				
lecord any va nd report car		minister	ed during t	he 15	days after yo	u received	I the study vaccin		
LIST ACCINATION	SITE OF VACCINATION REC					DATE RECEIVED (month/day/year)			
	☐ Rìght Arm	Left Ar	m 🗆 Right Th	nigh 🗆	Left Thigh D Oth	ner	_		
					Left Thigh  Oth		-		
	☐ Right Arm ☐ Left Arm ☐ Right Thigh ☐ Left Thigh ☐ Other								

(Date when follow-up is completed)

(Subject's Initials)

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

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## **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.
	Study Personnel Telephone Number:
Subjec	ct's Comments:
Study S	Site Personnel Comments:

Compound	Protocol	Study Site	IIN	Baseline Number	Allocation Number
V501	016-00			NVS/V Baseline Number	

## 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						

	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 <u>largest</u> from edge to edge. Use the <u>ruler marks</u> 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:

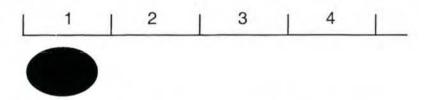
mild is awareness of symptom, but easily tolerated moderate is discomfort enough to cause interference with usual activities severe is incapacitating with inability to work or do usual activity

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.

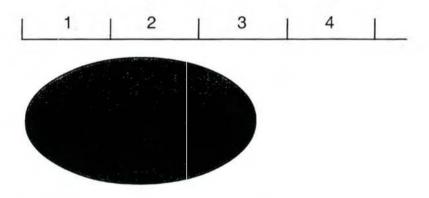
If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reaction".

# EXAMPLES FOR MEASURING THE SIZE OF REACTIONS:

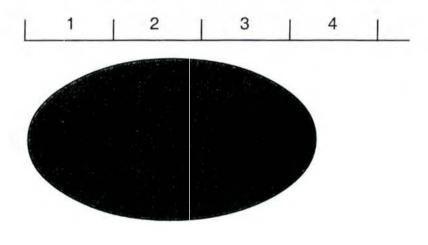
**Example A:** This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



**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.



of this page p		ION SITE REA	ACTIONS		
of this page p	(-11)				
eck one per pa	age): 🗆 Right	Arm □ Le		age by checking o	one box below. □ Left Thigh
DAY 1 accination Day	DAY 2	DAY 3	DAY 4	DAY 5	LAST DATE REACTION PRESENT
day/month/year	day/month/year	day/month/year	day/month/year	day/month/year	
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
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
None Mild Moderate Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	□ None □ Mild □ Moderate □ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	day/month/year
☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	☐ None ☐ Mild ☐ Moderate ☐ Severe	day/month/year
None Mild Moderate	□ None □ Mild □ Moderate	□ None □ Mild □ Moderate	□ None □ Mild □ Moderate	□ None □ Mild □ Moderate	day/month/year
	None 1 2 3 over 3: None 1 2 3 over 3: None 1 2 3 over 3: None Mild Moderate Severe None Mild Moderate Severe None Mild Moderate	DAY 1 accination Day    day/month/year		DAY 1	DAY 1

DATE (day/month/year)

**Last Present** 

5

Started

SEVERITY

☐ mild ☐ moderate ☐ severe

☐ moderate ☐ severe

**8** →

☐ mild

6

INJECTION SITE REACTIONS

BEGINNING 6 OR MORE DAYS AFTER VACCINATION

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

### 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)				
	Started	Last Present	SEVERITY		
			□ 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

V501	016-00					
		MED	ICATIONS			
Day 1	ny prescript	ion or over the co through Day 15		you take starting from after your injection.		
LIST THE NAME OF THE MEDICATION		DATE MEDICATION MEDICATION LAST TAKEN (day/month/year) (day/month/year)		REASON FOR TAKING THE MEDICATION		
Record any va			VACCINATIONS he 15 days after yo	ou received the study vaccin		
LIST ACCINATION	SITE OF VACCINATION			DATE RECEIVED (day/month/year		
	☐ Right Arm ☐	Left Arm Right Th	igh ☐ Left Thigh ☐ Otl	her		
	☐ Right Arm ☐	Left Arm Right Th	igh ☐ Left Thigh ☐ Oth	ner		
	☐ Right Arm ☐	Left Arm Right Th	igh ☐ Left Thigh ☐ Oth	ner		
	Leonfirm	that the information	on on this card is acc	urate		