

Case Report Form Design

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Family Health International

GCP Connection

✦ 1.11 Case Report Form

- A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

CRF Design

- ◆ **Standard CRF Modules**
 - performing multiple studies in same research area
- ◆ **Design Standards**
 - standardize the “look and feel”
- ◆ **CRF Connectivity**
 - link data from one CRF to another for analysis

Standard CRF Modules

- ◆ **Reusable CRFs as templates**
 - useful starting point, customize as needed
- ◆ **Design goals**
 - Gather accurate data that answers study questions
 - avoid duplication of data
 - ease of entry on CRF
 - conformance with the study protocol
 - Ease of data entry
 - Ease of analysis

Standard CRF Modules

- ◆ **Forms likely to use standard templates**
 - Inclusion/Exclusion
 - Adverse events
 - Concomitant medications
 - Protocol Violation Forms
 - Final status

Design Standards

◆ Header

- Study number - Preprinted
- Site number
- Participant number
- Form ID – Preprinted
- Form Sequence Number (FSN) – Preprinted
- Contact Date – Can preprint “20”

Header Items

330051

LAB

LAB			
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Center Number	Study Number	Participant Number	Visit Date
0 8 5 3	9860	1 0 1	0 5 / 0 7 / 2 0 0 7 <small>mm dd yyyy</small>

<p>1 = Visit 1 (Screening) 2 = Visit 2 (Enrollment) 3 = Visit 3 (Start of ph. 2) 4 = Visit 4 (One week FU) 5 = Visit 5 (Two week FU) 6 = Visit 6 (Final Visit - Main)</p>	<p>PITTSBURGH ONLY 7 = Substudy Visit 1 8 = Substudy Visit 2 9 = Substudy Visit 3 0 = Unscheduled Visit</p>	<p style="text-align: center;">Visit Type</p> <p style="text-align: center; font-size: 24px;">2</p>
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For any abnormal test results, complete AE form (except for Screening and Enrollment visits)

Wet Mount Results (Required for Visit 1; all other "as indicated")	0 = Negative 1 = Positive 2 = Not done
1. Candida	2
2. Trichomonas	2
3. Bacterial Vaginosis	2

GCP Connection

- ◆ 2.11 The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirements.
- ◆ 5.5.5 The sponsor should use an unambiguous subject identification code that allows identification of all the data reported for each subject.

Data Entry Screens – Design Headers

- ◆ Standardize naming convention for header items.
- ◆ Facilitates query of data
 - Reporting errors
 - Tracking of errors at the sites
- ◆ Facilitates reporting of data
- ◆ Tracking enrollment totals over time

Electronic Form Header

The screenshot shows a software window titled "Clintrial Enter - Erik Jolles - TPK_9860 - STUDY_DATA". The window contains a menu bar (File, Edit, View, Navigate, List, Flags, Notes, Discrepancies, Reports, Custom, Window, Help) and a toolbar. Below the toolbar is a sub-window titled "101.Lab.Lab - LAB.2 (UPDATE)". This sub-window contains the following fields:

- FSN:
- Center Number: Study Number: Participant Number: Visit Date: (with sub-labels mm, dd, yyyy)
- LAB
- Visit Type: Visit 2 (Enrollment)
- 1. Candida:
- 2. Trichomonas:
- 3. Bacterial Vaginosis:
- 4. Other (TEXT):

A blue oval highlights the FSN, Center Number, Study Number, Participant Number, and Visit Date fields.

Standard Reports

Report: 1 - AE Serious

Start Date: 15 JAN 2007

Center: All

End Date: 15 JAN 2008

Apply

PRINT

9845 AE Report:

AE Serious

Center: All

Start Date: 15-JAN-2007

End Date: 15-JAN-2008

CN	PN	FSN	CONDATE	AEDGLO	AEBLFSNO	AEONDATE	AEREL	AERECUR	AESER	AESEV	AEACT	AE
9994	2530	339067	09-FEB-07	APPENDICITIS		20-JAN-07	0		1	2	0	
10168	5754	330965	15-JAN-07	HYPERTENSION		07-DEC-06	0		1	1	0	
9994	2644	334065	22-FEB-07	VIRAL FEVER		01-NOV-06	0		1	1	2	
10168	5140	330873	15-JAN-07	SPONTANEOUS MISCARRIAGE		10-JAN-07	0		1	3	0	
10168	5754	330944	15-JAN-07	CELLULITIS LEFT LEG		07-DEC-06	0		1	1	0	
8997	6971	337098	16-JAN-07	MALARIA		13-JAN-07	0		1	1	0	

Screened Enrolled Report

International		Database Counts Custom Assess Manage Logout																	
Study: CSHP_9845 User: Erik Counts Discrepancy Count Discrepancy Ageing Monthly Entries Panel Records by CN Monthly Entry Intervals Count on Field Summary Report Date: 04-02-2008	Center: All	Start Date: 04 FEB 2006	Apply																
		End Date: 04 FEB 2007	PRINT																
	Summary Report Center: All Start Date: 04-FEB-2006 End Date: 04-FEB-2007																		
	<table border="1"> <tr><td>Total Subjects Screened</td><td>1638</td></tr> <tr><td>Total Screening Failures</td><td>794</td></tr> <tr><td>Total Subjects Enrolled</td><td>894</td></tr> <tr><td>Total Subjects Discontinued Before Month 12 Visit</td><td>23</td></tr> <tr><td>Total Subjects Discontinued Due to Medical Reason (product related)</td><td>0</td></tr> <tr><td>Total Subjects Discontinued Due to Medical Reason (NOT product related)</td><td>3</td></tr> <tr><td>Total Subjects Completing Month 12 Visit</td><td>593</td></tr> <tr><td>Total Subjects With Serious AEs</td><td>62</td></tr> </table>			Total Subjects Screened	1638	Total Screening Failures	794	Total Subjects Enrolled	894	Total Subjects Discontinued Before Month 12 Visit	23	Total Subjects Discontinued Due to Medical Reason (product related)	0	Total Subjects Discontinued Due to Medical Reason (NOT product related)	3	Total Subjects Completing Month 12 Visit	593	Total Subjects With Serious AEs	62
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FEVER																			

Design Standards

◆ Footer

- Study Name
- Date
- Version number
- Page number if necessary

Design Standards - Footer

Si presente clasifique el tipo y ubicación marcando la caja apropiada.

	Base	Apex	Borde Izquierdo para - esternal
Eyección sistólico			
Regurgitación sistólico			
Estenotic diastólico			
Regurgitación diastólico			

Firma de quien completó la forma

Fecha

RHDECHO6 CRF version .4

Página 1 de 2

7/25/2006

Design Standards

- ✦ **Library of precoded answer sets**
 - Yes/no/don't know/not applicable
 - Method of administration of medicine
 - Severity of adverse event/experience
 - Education level

Precoded Answer Sets - Visit

330051

LAB

LAB			
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Center Number	Study Number	Participant Number	Visit Date
0853	9860	101	05 / 07 / 2007 <small>mm dd yyyy</small>

<p>1 = Visit 1 (Screening) 2 = Visit 2 (Enrollment) 3 = Visit 3 (Start of ph. 2) 4 = Visit 4 (One week FU) 5 = Visit 5 (Two week FU) 6 = Visit 6 (Final Visit - Main)</p>	<p>PITTSBURGH ONLY 7 = Substudy Visit 1 8 = Substudy Visit 2 9 = Substudy Visit 3 0 = Unscheduled Visit</p>	<p>Visit Type</p> <p style="font-size: 1.5em;">2</p>
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For any abnormal test results, complete AE form (except for Screening and Enrollment visits)

Wet Mount Results (Required for Visit 1; all other "as indicated")	0 = Negative 1 = Positive 2 = Not done
1. Candida	2
2. Trichomonas	2
3. Bacterial Vaginosis	2

1. Blood Para (LABS).Blood Parameters (LABS).1 (UPDATE)

FSN: 420027
 Study Number: 0101
 Participant Number: 1
 Date of Visit: 09/19/2007

458678

Blood Parameters (LABS) page 1 of 3

Phase I Study of the Safety and Acceptability of UC-781 Topical Vaginal Microbicide in Heterosexual Women and their Male Partners
 HC 101

Subject Code Number: [] [] [] [] [] []
 Completed
 Mon Year

1. Collection Date: [] [] [] [] [] [] [] [] [] []
 DAY MON YEAR
 1a. Not Done

2. VISIT
 Screening Day 7
 Day 0 Day 14
 Unscheduled

CBC Auto Differential

3. Was auto differential done? Yes No
 4. Was manual differential done? Yes No

5. WBC (10 ³ /uL) [] [] . []	6. RBC (10 ⁶ /uL) [] [] . [] []	7. Hemoglobin (g/dL) [] [] . []
8. Hematocrit (%) [] [] . []	9. MCV (fl) [] [] [] []	10. MCH (pg) [] [] . []
11. MCHC (g/dL) [] [] . []	12. Platelet Count (10 ³ /uL) [] [] [] []	13. Polys (%) [] [] . []

BLOOD PARAMETERS

Collection date: 9/19/2007
 day mon year
 1a. Not done
 2. Visit: Screening
 Auto differential done: YES
 Manual differential done: NO
 CBC (10³/uL): 4.9
 RBC (10⁶/uL): 4.77
 Hemoglobin (g/dL): 14.2
 Hematocrit (%): 42.3
 MCV (fl): 88.6
 MCH (pg): 29.9
 MCHC (g/dL): 33.7
 Platelet Count (10³/uL): 252
 Polys (%): 50
 Lymphs (%): 36
 Mono (%): 11
 Eos (%): 2
 Basos (%): 1

Pre-coded Answer Sets

1. Date of LMP: 08 / 25 / 2006
mm dd yyyy

2. Day of cycle: 5

3. Has the participant engaged in any of the following:

a. Vaginal intercourse: 1 YES

b. Vaginal product: (None) NO
Vaginal product Specify 0 NONE

c. Other (recipient of oral se... bation, anal... penetration of vagina by fing... oys, or any c...

4. Does participant have any u... symptoms:

a. Irritation/burning: 1

b. Itching: 0

5. Time of visit 11 :00

6. Does the participant have any of the following symptoms at this visit

a. Discharge: 0 NO

b. Burning: 0 NO

c. Irritation: 0 NO

d. Itching: 0 NO

e. Pain: 0 NO

f. Other: 0 NO

Specify _____

17. Marque con un chulo los siguientes signos o síntomas relacionados con la infección faríngea que el niño tenga actualmente o haya tenido en los últimos siete días:

<input type="checkbox"/> 1) Contacto con personas con faringitis:	<input type="checkbox"/> 12) Náuseas:	<input type="checkbox"/> 23) Ganglios cervicales ant. ag
<input type="checkbox"/> 2) Dolor de garganta:	<input type="checkbox"/> 13) Vómito:	<input type="checkbox"/> 24) Ganglios cervicales ant. do
<input type="checkbox"/> 3) Dolor al deglutir:	<input type="checkbox"/> 14) Dolor abdominal:	<input type="checkbox"/> 25) Estomatitis anterior:
<input checked="" type="checkbox"/> 4) Dificultad al deglutir:	<input checked="" type="checkbox"/> 15) Diarrea:	<input checked="" type="checkbox"/> 26) <u>Úlceras orales pequeñas:</u>
<input type="checkbox"/> 5) Ronquera:	<input type="checkbox"/> 16) Amígdalas con exudado:	<input type="checkbox"/> 27) Rash escarlatiniforme:
<input type="checkbox"/> 6) Secreción nasal:	<input type="checkbox"/> 17) Amígdalas eritematosas:	<input type="checkbox"/> 28) Otro tipo de Rash:
<input checked="" type="checkbox"/> 7) Tos:	<input type="checkbox"/> 18) Faringe eritematosa:	describa: _____
<input type="checkbox"/> 8) Dolor de cabeza:	<input checked="" type="checkbox"/> 19) Amígdalas agrandadas:	29) Temperatura (actual): _____
<input type="checkbox"/> 9) Malestar general:	<input type="checkbox"/> 20) Petequias en el paladar:	
<input type="checkbox"/> 10) Fiebre:	<input type="checkbox"/> 21) Úvula eritematosa:	
<input type="checkbox"/> 11) Escalofrío:	<input type="checkbox"/> 22) Conjuntivitis:	

20. Vaginal swab

2 NO

a. Anterior proximal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
b. Anterior distal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
c. Posterior proximal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
d. Posterior distal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
e. Right lateral proximal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
f. Right lateral distal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
g. left lateral, proximal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75
h. Left lateral distal half:	<input checked="" type="radio"/> Blank	<input type="radio"/> 1 - 25	<input type="radio"/> 26 - 50	<input type="radio"/> 51 - 75	<input type="radio"/> > 75

Design Standards

- ◆ **Guidelines for CRF design**
- ◆ **Boxes to hold answers**
 - boxes provide visual cues
 - limit circling of answers (hard to interpret)
- ◆ **Specified density of questions on page**
- ◆ **Separation of columns with thick lines**

SILCS Diaphragm Study					
History Form – Visit 1: Screening/Enrollment					
Center Number	Study Number	Couple Number	Visit Date		
091021	9911	217	00	25	2008
CFHC ONLY: Sub-site Number			Month	Day	Year
Unless otherwise indicated, answer with either 0= NO or 1= YES. All dates should be in month/day/year format.					
1. Did the participant meet all subject eligibility criteria set forth in the protocol at the time of screening?					1
2. Did the participant use an antibiotic, antiviral or antifungal product within 14 days of screening?					0
3. Were all criteria met at the time of enrollment?*					1
4. Was the participant enrolled in the NICHD BufferGel study?					0
If yes, specify her participant number:					□□□□
5. Was the participant enrolled in the FemCap/diaphragm study?					0
If yes, specify her participant number:					□□□□
6. Date of birth			11/10/1979		
7. Ethnicity			1= Hispanic/Latina 2= Not Hispanic/Latina		
Race			1= Asian 2= Black or African American 3= Native American or Alaskan Native 4= Native Hawaiian or other Pacific Islander 5= Caucasian 6= More than one race 7= Other		
8. Education (school years completed)			112		
9. Partner Status			1= Living with partner 2= Not living with partner		
10. Length of Relationship			0= < 4 months* 1= 4 – 6 months 2= > 6 months		
11. Average number of acts of intercourse per month			60		
Obstetrical/Gynecological History					
13. Was participant ever pregnant? If no, skip to item #16					1
14. Date of last pregnancy outcome					04/22/2004

*= If the question is answered with "0," then the participant should not be enrolled.

Initials of person completing form: mnej

Date: 7/17/08

Version #5.0
11/13/07

Clintrial Enter - Erik Jolles - GSS_9726 - STUDY_DATA

File Edit View Navigate List Flags Notes Discrepancies Reports Custom W

1515-100779. Follow-up Question. 1. Follow-up Questionnaire page 1

Form Sequence Number: 211471 Page 8
 Study Number: 9726 Page Repeat
 Participant Number: 100779 Visit 1 PTID
 Center Number: 1515 Default Visit = 99.9
 Language on form: 07

FOLLOW-UP QUESTIONNAIRE

Visit date 31/08/2007 Clinic record number: 0C/002/99
 dd/mm/yyyy

1. Since your last visit how many times have you been pregnant?: 00 mm yyyy

1a. When was your last pregnancy completed? 01 mm yyyy

1b. Since your last visit did you breastfeed? 2 NO

1c. Are you currently breastfeeding? mm yyyy

1c1. When did you stop breastfeeding: 01 mm yyyy

MEDICAL HISTORY
 1=YES 2=NO 3=DK ongoing?:

2a. tuberculosis: 2 No

2b. blood transfusion: 2 No

3a. heart disease: 2 No

3b. high blood pressure: 2 No

3c. hepatitis: 2 No

3d. diabetes: 2 No

3e. cervical dysplasia or cancer: 2 No

9726 Help File

File Edit Bookmark Options Help

Contents Index Back Print << >>

Follow-up Quest - GFQ Interim Visit - GIV Serious AE - GSAE Comments GCOM Missed Visit - GMV

End of Study - GSEI Termination - GTM Schedule Change - GSC Participant Incident Log - GPIL

There are several new things in this protocol that is a little different from other protocols.

Enroll

The center number for each participant comes from the first four digits of the participant ID. **Do not use the center listed on the batch flow sheet this is only the mailing center not the center the participant was originally enrolled in.** The Participant Number comes from the last six digits of the patient ID. Once the participant is enrolled what you will see on the navigator is the Participant Id, which combines the Center number and the PN. On the Navigator the participant will be order by increasing center number and then by increasing participant number.

Dates

There are two types of dates in this protocol. One format is a 10-digit text format, which should be filled in the format dd/mm/yyyy with the slashes included. The other is a two field, month and year, format in which the day will be not enterable and defaulted to "01". You will see the "01" actually grayed out.

Visit

Visit items are all float items, which means they are set up to have a decimal point. There are two forms that do not have visit items. These are the [Termination](#) form and the [End of Study Inventory](#). On these forms the visit should simply be defaulted to 99.9.

Block repeats

Repeating multiple page forms are set up as repeating blocks so that the blocks rather than the pages are repeated. When a block is repeated all the pages for that block are repeated. It makes it easier that you do not have to search for the different page numbers when a block

Design Standards

- ◆ **Skip pattern information**
 - Bold, italicized instructions
 - Limit skips by placement of questions
 - Tell where to skip TO, not what to skip
 - Skip to “section name” not question number if possible

08713

FAMILY HEALTH INTERNATIONAL
 A Comparative Assessment of a Plastic Condom and A Latex Condom:
 Breakage and Slippage
 CONDOM USE QUESTIONNAIRE

BSCUQ2

Center number: Study number: Couple number:
 Condom type: 1 = Latex 2 = Plastic

Answer the following questions if you were able to put the condom on the penis without it breaking.

17. Was the condom pulled/unrolled down the shaft of the penis? Circle one.
 0 = No 1 = Yes

18. After the condom was put on, did it cover the entire penis? Circle one.
 0 = No 1 = Yes

19. Did you use the provided lubricant after putting on the condom, but before intercourse? Circle all that apply.
 0 = No
 1 = Yes, on the outside of the condom
 2 = Yes, inside the vagina
 3 = Yes, inside the anus

20. Did you use another type of lubricant after putting on the condom, but before intercourse? Circle all that apply.
 0 = No
 1 = Yes, on the outside of the condom
 2 = Yes, inside the vagina
 3 = Yes, inside the anus
 If yes, specify lubricant type _____

21. Did the condom break after putting it on, but before intercourse? Circle one.
 0 = No
 1 = Yes, at the condom tip
 2 = Yes, along the condom shaft
 3 = Yes, at the condom opening
 4 = Yes, other

If you did not have intercourse wearing this condom, skip to Question 33, otherwise answer the following questions.

22. Did you use the provided lubricant during sex? Circle all that apply.
 0 = No
 1 = Yes, on the penis
 2 = Yes, inside the vagina
 3 = Yes, inside the anus

23. Did you use another type of lubricant during sex? Circle all that apply.
 0 = No
 1 = Yes, on the penis
 2 = Yes, inside the vagina
 3 = Yes, inside the anus
 If yes, specify lubricant type _____

24. While wearing this condom, in which of the following did you engage? Circle all that apply.
 1 = front entry vaginal sex
 2 = rear entry vaginal sex
 3 = other vaginal sex
 4 = anal sex
 5 = oral sex on male partner

25. Did the condom break during sex or while removing the condom from the penis? Circle one.
 0 = No
 1 = Yes, during front entry vaginal sex
 2 = Yes, during rear entry vaginal sex
 3 = Yes, during other type of vaginal sex
 4 = Yes, during withdrawal from the vagina
 5 = Yes, during anal sex
 6 = Yes, during withdrawal from the anus
 7 = Yes, during oral sex on the male partner
 8 = Yes, while taking condom off the penis
 9 = Yes, other or don't know when

26. Where did the condom break? Circle one.
 0 = did not break
 1 = at the tip of the condom
 2 = along the shaft of the condom
 3 = at the opening of the condom
 4 = other

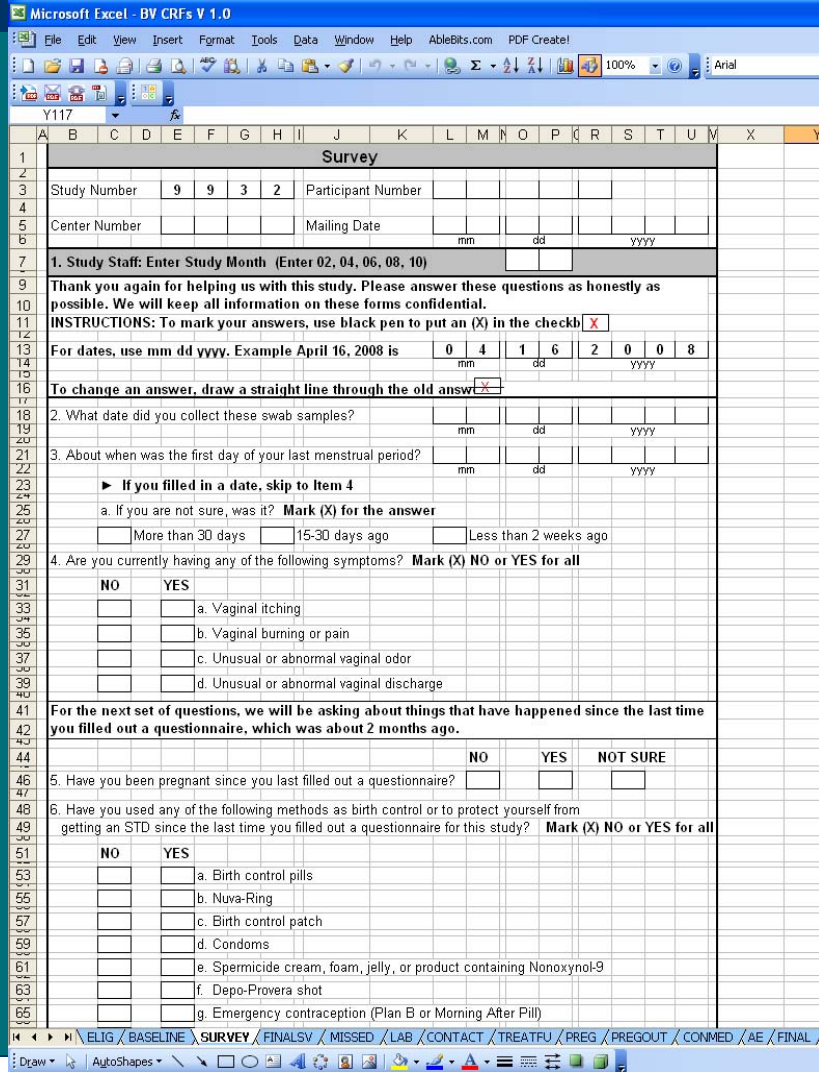
27. How many minutes was the condom worn during vaginal intercourse?

if yes, skip to Question 33

CRF Design tools

- ◆ Word
- ◆ Excel
- ◆ Adobe Page Maker
- ◆ Other

CRFs in Excel



BRAVO Study SURVEY

Survey	
Study Number	9 9 3 2 Participant Number
Center Number	Mailing Date
1. Study Staff: Enter Study Month (Enter 02, 04, 06, 08, 10)	
Thank you again for helping us with this study. Please answer these questions as honestly as possible. We will keep all information on these forms confidential.	
INSTRUCTIONS: To mark your answers, use black pen to put an (X) in the checkbox. <input checked="" type="checkbox"/>	
For dates, use mm dd yyyy. Example April 16, 2008 is	
	0 4 1 6 2 0 0 8
To change an answer, draw a straight line through the old answer. X	
2. What date did you collect these swab samples?	
3. About when was the first day of your last menstrual period?	
▶ If you filled in a date, skip to Item 4	
a. If you are not sure, was it? Mark (X) for the answer	
<input type="checkbox"/> More than 30 days <input type="checkbox"/> 15-30 days ago <input type="checkbox"/> Less than 2 weeks ago	
4. Are you currently having any of the following symptoms? Mark (X) NO or YES for all	
NO	YES
<input type="checkbox"/>	<input type="checkbox"/> a. Vaginal itching
<input type="checkbox"/>	<input type="checkbox"/> b. Vaginal burning or pain
<input type="checkbox"/>	<input type="checkbox"/> c. Unusual or abnormal vaginal odor
<input type="checkbox"/>	<input type="checkbox"/> d. Unusual or abnormal vaginal discharge
For the next set of questions, we will be asking about things that have happened since the last time you filled out a questionnaire, which was about 2 months ago.	
	NO YES NOT SURE
5. Have you been pregnant since you last filled out a questionnaire? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
6. Have you used any of the following methods as birth control or to protect yourself from getting an STD since the last time you filled out a questionnaire for this study? Mark (X) NO or YES for all	
NO	YES
<input type="checkbox"/>	<input type="checkbox"/> a. Birth control pills
<input type="checkbox"/>	<input type="checkbox"/> b. Nuva-Ring
<input type="checkbox"/>	<input type="checkbox"/> c. Birth control patch
<input type="checkbox"/>	<input type="checkbox"/> d. Condoms
<input type="checkbox"/>	<input type="checkbox"/> e. Spermicide cream, foam, jelly, or product containing Nonoxynol-9
<input type="checkbox"/>	<input type="checkbox"/> f. Depo-Provera shot
<input type="checkbox"/>	<input type="checkbox"/> g. Emergency contraception (Plan B or Morning After Pill)
<input type="checkbox"/>	<input type="checkbox"/> h. IUD (intra-uterine device, Mirena, ParaGard)
<input type="checkbox"/>	<input type="checkbox"/> i. Tubal ligation
<input type="checkbox"/>	<input type="checkbox"/> j. Other, please list _____

CRF Connectivity

- ✦ **Standard method of linking CRFs**
 - Boxes that store the Form Sequence Number (FSN) of the related form
 - Open-ended text fields to hold list of FSNs separated by commas

CRF Connectivity - Form Sequence Number (FSN)

- ◆ 6-digit number (no leading 0)
- ◆ Assigned to each CRF
 - Same FSN for each sheet of multipage CRF
- ◆ FSNs are unique within each study

GCP Connection

- ✦ 2.10 All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification.

FAMILY HEALTH INTERNATIONAL
Comparative Assessment of the Contraceptive Effectiveness of Slip-On Plastic Condoms and Latex Condoms
ADVERSE EVENT REPORT FORM

135376

STUDY IDENTIFICATION

1. Center number: 9021
2. Study number: 0747

5. Gender of participant:
0) Female
1) Male

6. Specify FSN of form reporting the adverse event:
113226

7. Adverse event (diagnosis, if known):
Upper Respiratory Infection

8. Date of onset: 09/28/1999
Month Day Year

FAMILY HEALTH INTERNATIONAL
Comparative Assessment of the Contraceptive Effectiveness of Slip-On Plastic Condoms and Latex Condoms
CLINIC VISIT FORM

113226

STUDY IDENTIFICATION

1. Center number: 9021
2. Study number: 0747

CONTACT DATA

5. Type of visit:
1) Week 4
2) Week 10
3) Week 16
4) Week 22
5) Final Week
6) Unschedule

145226 **FAMILY HEALTH INTERNATIONAL** EZCM
Comparative Assessment of the Contraceptive Effectiveness of Slip-On Plastic Condoms and Latex Condoms
CONCOMITANT MEDICATION FORM

STUDY IDENTIFICATION

1. Center number: 9021
2. Study number: 0747
3. Couple number: 11001
4. Date of contact: 10/07/1999
Month Day Year

5. Gender of participant:
0) Female
1) Male

6. Describe medication that was administered: Entex

7. Average daily dose: 1 tablet

8. Route of administration:
1) Topical
2) Other

9. Date medication started: 09/30/1999
Month Day Year

10. Date medication ended: 09/30/1999
Month Day Year

Or, code '1' in this box if medication was still ongoing when participant discontinued from the study.

11. Reason for medication:
a) Adverse event(s)
0) No
1) Yes
Specify FSN(s) from EZAE form(s) 1135376

7. Was the couple still together at the end of their study?
0) No
1) Yes →

CRF Connectivity - Review of CRFs

- ✦ **Map all links between forms**
 - Multiple instances of forms can affect the linkage
 - Are the links bi-directional?
 - Are CRF dates used for linkage?

CRF Design Conclusions

- ◆ Reusable modules enforce data integrity and efficiency of forms
- ◆ Design standards improve quality of data collected and increase efficiency of data analysis
- ◆ CRF connectivity is crucial when planning complex analyses

Recent Medical History

- 1. Study Number: | 8 | 7 | 6 | 5 |
- 2. Screening Number: | | | | | |
- 3. Center Number: | | | | | |
- 4. Date of Visit: | | | / | | | / | | | | | |
day month year
- 5. ID # of person completing form: | | | |

Please respond to items 6-11 with reference to the Past 12 months.

6. Has participant had any allergies?.....| | |
 0=No
 1=Yes → **Specify:** _____

7. Has participant not had any dermatological problems?.....| | |
 0=No
 1=Yes → **Specify:** _____

8. Has participant had any episodes of migraine
 headaches?.....| | |
 0=Yes
 1=No

9. Has participant had any seizures?.....| | |
 0=No
 1=Yes

10. Number of seizures| | |

WILDCAT CS Phase 3 Study

Lab Results form

- 1. Study Number: | 9 | 8 | 4 | 5 |
- 2. Screening Number: | | | | | |
- 3. Center Number: | | | | |
- 4. Date of Visit: | | | / | | | / | | | | | |
day month year
- 5. ID # of person completing form: | | | |

6. Pregnancy tests results?.....| | |
 0 = Negative
 1 = Positive

7. Chlamydia tests results?.....| | |
 0= Negative
 1= Positive
 3 = Not Done → **Specify reason:** _____

8. HIV tests results?.....| | |
 0= Negative
 1= Positive
 2 = Not Done → **Specify reason:** _____

9. Influenza A test results ?.....| | |
 0=Negative
 1=Positive
 2=Not Done → **Specify reason:** _____

10. Number of seizures| | |

