



**Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding**

**Data File:** f10\_50\_ep\_fu\_pub **File Date:** 07/18/2005 **Structure:** Multiple rows per participant **Population:** E+P participants

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**Participant ID**

**Variable #** 1 **Usage Notes:** none  
**Sas Name:** ID **Categories:** Study: Administration  
**Sas Label:** Participant ID  
**Type:** Continuous

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**F10/50 Days since randomization**

Days between randomization and initiation of form  
**Variable #** 2 **Usage Notes:** none  
**Sas Name:** F1050DYS **Categories:** Study: Administration  
**Sas Label:** F10/50 Days since randomization  
**Type:** Continuous

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**F10/50 Visit Type**

**Variable #** 3 **Usage Notes:** none  
**Sas Name:** F1050VTYP **Categories:** Study: Administration  
**Sas Label:** Visit Type  
**Type:** Categorical

**Values**

1	Screening Visit
2	Semi-Annual Visit
3	Annual Visit
4	Non-Routine Visit
5	6-Week HRT Phone Call

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**F10/50 Visit number**

Number of the visit for which this form was collected.  
**Variable #** 4 **Usage Notes:** none  
**Sas Name:** F1050VNUM **Categories:** Study: Administration  
**Sas Label:** Visit Number  
**Type:** Continuous

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**Had a hysterectomy**

Has the participant had a hysterectomy?  
**Variable #** 5 **Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.  
**Sas Name:** HYST **Categories:** Medical History: Reproductive  
**Sas Label:** Had a hysterectomy  
**Type:** Categorical

**Values**

0	No
1	Yes

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**Had vaginal bleeding**

Variable # 6

Usage Notes: none

Sas Name: VAGBLEED

Categories: Reproductive: Menstrual

Sas Label: Had vaginal bleeding

Type: Categorical

Values

0	No
1	Yes

**How heavy was vaginal bleeding**

Variable # 7

Usage Notes: Not collected on all versions of Form 10.

Sas Name: HEAVYBLD

Categories: Reproductive: Menstrual

Sas Label: How heavy was vaginal bleeding

Type: Categorical

Values

1	Spotting - approx 1 pad/day
2	Light - 2 or 3 pads/day
3	Moderate - 4 to 7 pads/day
4	Severe - 8 or more pads/day

**Days from randomization to vaginal bleeding start**

Variable # 8

Usage Notes: Not collected on all versions of Form 10.

Sas Name: STARTDY

Categories: Reproductive: Menstrual

Sas Label: Days from randomization to vaginal bleeding start

Type: Continuous

**Did vaginal bleeding start and stop again**

Variable # 9

Usage Notes: Not collected on all versions of Form 10.  
Not collected on all versions of Form 50.

Sas Name: INTERMIT

Categories: Reproductive: Menstrual

Sas Label: Did vaginal bleeding start and stop again

Type: Categorical

Values

0	No
1	Yes

**Are you bleeding from the vagina now**

Variable # 10

Usage Notes: Not collected on all versions of Form 10.

Sas Name: BLEEDNOW

Categories: Reproductive: Menstrual

Sas Label: Are you bleeding from the vagina now

Type: Categorical

Values

0	No
1	Yes



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**Days from randomization to vaginal bleeding stop**

**Variable #** 11

**Sas Name:** STOPDY

**Sas Label:** Days from randomization to vaginal bleeding stop

**Type:** Continuous

**Usage Notes:** Not collected on all versions of Form 10.  
Sub-question of "Are you bleeding from the vagina now".

**Categories:** Reproductive: Menstrual

**Had any breast tenderness**

Since your last contact, have you had any breast tenderness?

**Variable #** 12

**Sas Name:** BRSTTEND

**Sas Label:** Had any breast tenderness

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Breast

**Values**

0	No
1	Yes

**Breast tenderness severity**

Was your breast tenderness mild, moderate, or severe?

**Variable #** 13

**Sas Name:** SEVTEND

**Sas Label:** Breast tenderness severity

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q7 "Had any breast tenderness"

**Categories:** Medical History: Breast

**Values**

1	Mild
2	Moderate
3	Severe

**Any changes in your breasts**

Have you noticed any changes in your breasts (new lumps, nipple discharge, or skin changes)?

**Variable #** 14

**Sas Name:** BRSTCHNG

**Sas Label:** Any changes in your breasts

**Type:** Categorical

**Usage Notes:** Not collected on Form 50.

**Categories:** Medical History: Breast

**Values**

0	No
1	Yes



**Taking or prescribed Corticosteroids**

Are you now taking, or has a doctor prescribed, any Corticosteroids (such as Prednisone, Decadron, Medrol in pill form)?

Variable # 15

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: CORTICOS

Categories: Medical History: Medications

Sas Label: Taking or prescribed Corticosteroids

Type: Categorical

**Values**

0	No
1	Yes

**Taking or prescribed blood thinning medications**

Are you now taking, or has a doctor prescribed any blood thinning medications (such as Coumadin or Warfarin)?

Variable # 16

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: ANTICOAG

Categories: Medical History: Medications

Sas Label: Taking or prescribed blood thinning medications

Type: Categorical

**Values**

0	No
1	Yes

**Taking or prescribed Estrogen**

Are you now taking, or has a doctor prescribed Estrogen?

Variable # 17

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: ESTROGEN

Categories: Medical History: Medications  
Reproductive: Hormones

Sas Label: Taking or prescribed Estrogen

Type: Categorical

**Values**

0	No
1	Yes

**Taking or prescribed Progesterone**

Are you now taking, or has a doctor prescribed Progesterone?

Variable # 18

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: PROGEST

Categories: Medical History: Medications  
Reproductive: Hormones

Sas Label: Taking or prescribed Progesterone

Type: Categorical

**Values**

0	No
1	Yes



### Taking or prescribed Testosterone

Are you now taking, or has a doctor prescribed Testosterone?

Variable # 19

Sas Name: TESTOST

Sas Label: Taking or prescribed Testosterone

Type: Categorical

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Medications  
Reproductive: Hormones

#### Values

0	No
1	Yes

### Taking or prescribed Tamoxifen

Are you now taking, or has a doctor prescribed Tamoxifen, Raloxifene (Evista) or other medications know as SERMS?

Variable # 20

Sas Name: TAMOXIF

Sas Label: Taking or prescribed Tamoxifen

Type: Categorical

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Medications  
Reproductive: Hormones

#### Values

0	No
1	Yes

### Endometrial hyperplasia

Since your last contact has a doctor told you that you had Endometrial hyperplasia?

Variable # 21

Sas Name: ENDOHYP

Sas Label: Endometrial hyperplasia

Type: Categorical

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Reproductive

#### Values

0	No
1	Yes

### High triglycerides in blood

Since your last contact has a doctor told you that you had high triglycerides in your blood (triglycerides are not the same as cholesterol)?

Variable # 22

Sas Name: HIGHTRIG

Sas Label: High triglycerides in blood

Type: Categorical

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Other Disease/Condition

#### Values

0	No
1	Yes



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**Were your triglycerides over 1000 (mg/dl)**

**Variable #** 23

**Sas Name:** TRIG1000

**Sas Label:** Were your triglycerides over 1000 (mg/dl)

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q11.2 "High triglycerides in blood".

**Categories:** Medical History: Other Disease/Condition

**Values**

0	No
1	Yes

**Blood clot to your leg or lung**

Since your last contact has a doctor told you that you had a blood clot to your leg or lung?

**Variable #** 24

**Sas Name:** BLDCLLOT

**Sas Label:** Blood clot to your leg or lung

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Cardiovascular

**Values**

0	No
1	Yes

**Melanoma of skin**

Since your last contact has a doctor told you that you had melanoma of skin?

**Variable #** 25

**Sas Name:** MELANOMA

**Sas Label:** Melanoma of skin

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Cancer

**Values**

0	No
1	Yes

**Heart attack or stroke**

Since your last contact has a doctor told you that you had a heart attack or stroke?

**Variable #** 26

**Sas Name:** HEARTSTK

**Sas Label:** Heart attack or stroke

**Type:** Categorical

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Cardiovascular

**Values**

0	No
1	Yes



**Meningioma, or tumors in the brain**

Since your last contact has a doctor told you that you had meningioma, or tumors in the brain?

Variable # 27

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: MENINGIO

Categories: Medical History: Cancer

Sas Label: Meningioma, or tumors in the brain

Type: Categorical

**Values**

0	No
1	Yes

**Breast cancer**

Since your last contact has a doctor told you that you had breast cancer?

Variable # 28

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: BRSTCANC

Categories: Medical History: Cancer

Sas Label: Breast cancer

Type: Categorical

**Values**

0	No
1	Yes

**Gall bladder disease**

Since your last contact has a doctor told you that you had gall bladder disease?

Variable # 29

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: GALLBLAD

Categories: Medical History: Other Disease/Condition

Sas Label: Gall bladder disease

Type: Categorical

**Values**

0	No
1	Yes

**Problems with your pancreas**

Since your last contact has a doctor told you that you had problems with your pancreas?

Variable # 30

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: PANCREAS

Categories: Medical History: Other Disease/Condition

Sas Label: Problems with your pancreas

Type: Categorical

**Values**

0	No
1	Yes



**Participant advised to continue study medications**

Resulting action from participant reports of symptoms or concerns: Participant reassured and advised to continue with current study medications.

**Variable #** 31 **Usage Notes:** Not collected on all versions of Form 10.  
**Sas Name:** CONTMEDS **Categories:** Study Interventions: HRT Intervention/Management  
**Sas Label:** Participant advised to continue study medications  
**Type:** Categorical

**Values**

0	No
1	Yes

**Participant advised to return for evaluation**

Resulting action from participant reports of symptoms or concerns: Participant advised to return to clinic for evaluation.

**Variable #** 32 **Usage Notes:** Not collected on all versions of Form 10.  
**Sas Name:** RTRNEVAL **Categories:** Study Interventions: HRT Intervention/Management  
**Sas Label:** Participant advised to return for evaluation  
**Type:** Categorical

**Values**

0	No
1	Yes

**Consulting gynecologist notified**

Resulting action from participant reports of symptoms or concerns: Consulting gynecologist notified.

**Variable #** 33 **Usage Notes:** Not collected on all versions of Form 10.  
**Sas Name:** GYNNOTE **Categories:** Study Interventions: HRT Intervention/Management  
**Sas Label:** Consulting gynecologist notified  
**Type:** Categorical

**Values**

0	No
1	Yes

**Participant referred to primary physician**

Resulting action from participant reports of symptoms or concerns: Participant referred to primary physician.

**Variable #** 34 **Usage Notes:** Not collected on all versions of Form 10.  
**Sas Name:** PHYSNOTE **Categories:** Study Interventions: HRT Intervention/Management  
**Sas Label:** Participant referred to primary physician  
**Type:** Categorical

**Values**

0	No
1	Yes



### Medications changed or stopped

Resulting action from participant reports of symptoms or concerns: Medications changed or stopped.

Variable # 35

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: MEDCHNG

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Medications changed or stopped

Type: Categorical

#### Values

0	No
1	Yes

### Other action taken

Resulting action from participant reports of symptoms or concerns: Other.

Variable # 36

Usage Notes: Not collected on all versions of Form 10.

Sas Name: OTHERACT

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Other action taken

Type: Categorical

#### Values

0	No
1	Yes

### How often did you take the study pills

Since your last contact, how often did you take the study pills?

Variable # 37

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: PILLFREQ

Categories: Study Interventions: HRT Intervention/Management

Sas Label: How often did you take the study pills

Type: Categorical

#### Values

0	Not at all
1	Less than once per week
2	1 - 2 days per week
3	3 - 4 days per week
4	5 - 6 days per week
5	Every day of the week

### How many days missed taking pills in last month

About how many days have you missed taking your pills in the last month?

Variable # 38

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: DAYSMISS

Categories: Study Interventions: HRT Intervention/Management

Sas Label: How many days missed taking pills in last month

Type: Continuous



**Took all pills every day**

If there were days you did not take the pills, what were the reasons you didn't: Took all pills every day

Variable # 39

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: ALLPILLS

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Took all pills every day

Type: Categorical

**Values**

0	No
1	Yes

**Experienced symptoms**

If there were days you did not take the pills, what were the reasons you didn't: Experienced symptoms

Variable # 40

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: EXPSYMP

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Experienced symptoms

Type: Categorical

**Values**

0	No
1	Yes

**Forgot pill(s)**

If there were days you did not take the pills, what were the reasons you didn't: Forgot pill(s)

Variable # 41

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: FRGTPILL

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Forgot pill(s)

Type: Categorical

**Values**

0	No
1	Yes

**Forgot bottle**

If there were days you did not take the pills, what were the reasons you didn't: Forgot bottle

Variable # 42

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: FRGTBOTL

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Forgot bottle

Type: Categorical

**Values**

0	No
1	Yes



**Needed/Took a break**

If there were days you did not take the pills, what were the reasons you didn't: Needed/Took a break

Variable # 43

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: TOOKBRK

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Needed/Took a break

Type: Categorical

**Values**

0	No
1	Yes

**Afraid of health problems**

If there were days you did not take the pills, what were the reasons you didn't: Afraid of health problems

Variable # 44

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: AFRAID

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Afraid of health problems

Type: Categorical

**Values**

0	No
1	Yes

**Family/Friend recommendation**

If there were days you did not take the pills, what were the reasons you didn't: Family/Friend recommendation

Variable # 45

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: FAMRCMND

Categories: Study Interventions: HRT Intervention/Management

Sas Label: Family/Friend recommendation

Type: Categorical

**Values**

0	No
1	Yes

**MD recommendation**

If there were days you did not take the pills, what were the reasons you didn't: MD recommendation

Variable # 46

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Sas Name: MDRCMND

Categories: Study Interventions: HRT Intervention/Management

Sas Label: MD recommendation

Type: Categorical

**Values**

0	No
1	Yes



**Didn't have any pills**

If there were days you did not take the pills, what were the reasons you didn't: Didn't have any pills

**Variable #** 47

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Sas Name:** NOPILLS

**Categories:** Study Interventions: HRT Intervention/Management

**Sas Label:** Didn't have any pills

**Type:** Categorical

**Values**

0	No
1	Yes

**Other reason for missing pills**

If there were days you did not take the pills, what were the reasons you didn't: Other

**Variable #** 48

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Sas Name:** OTHRMISS

**Categories:** Study Interventions: HRT Intervention/Management

**Sas Label:** Other reason for missing pills

**Type:** Categorical

**Values**

0	No
1	Yes

**Should be put on Intensive Adherence Program**

Should participant be put on Intensive Adherence Program (IAP)?

**Variable #** 49

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Sas Name:** IAP

**Categories:** Study Interventions: HRT Intervention/Management

**Sas Label:** Should be put on Intensive Adherence Program

**Type:** Categorical

**Values**

0	No
1	Yes

**Should participant be recontacted in one month**

Should participant be recontacted in one month by phone for clinical follow-up

**Variable #** 50

**Usage Notes:** Not collected on all versions of Form 10.

**Sas Name:** RECONTAC

**Categories:** Study Interventions: HRT Intervention/Management

**Sas Label:** Should participant be recontacted in one month

**Type:** Categorical

**Values**

0	No
1	Yes