



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

Data File: f10\_50\_ct\_pub

File Date: 07/19/2007

Structure: Multiple rows per participant

Population: HT participants

#### Participant ID

**Variable #** 1 **Usage Notes:** none

**Sas Name:** ID **Categories:** Study: Administration

**Sas Label:** Participant ID

**Type:** Continuous

#### 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

#### F10/50 Visit type

**Variable #** 3 **Usage Notes:** none

**Sas Name:** F1050VTYP **Categories:** Study: Administration

**Sas Label:** Visit type

**Type:** Categorical

**Values**

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

#### F10/50 Visit year

Visit year for which this form was collected.

**Variable #** 4 **Usage Notes:** none

**Sas Name:** F1050VY **Categories:** Study: Administration

**Sas Label:** Visit year

**Type:** Continuous

#### 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



**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