

Form 81 - Pelvic Exam

Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

Participant ID

Variable # 1

Usage Notes: none

Sas Name: ID

Sas Label: Participant ID

Categories: Study: Administration

F81 Days since randomization

Days between randomization and the date the form was initiated

Variable # 2

Sas Name: F81DAYS

rume. Totaltie

Sas Label: F81 Days since randomization

Usage Notes: none

Categories: Study: Administration

N	Min	Max	Mean	Std Dev
76598	7	3055	1161.0332	615.52647

F81 Visit type

Variable # 3

Sas Name: F81VTYP

Sas Label: Visit type

Usage Notes: none

Categories: Study: Administration

Valu	ies	N	%
1	Screening Visit	0	0.0%
2	Semi-annual Visit	512	0.7%
3	Annual Visit	75,426	98.5%
4	Non Routine Visit	660	0.9%

76,598

F81 Visit number

Number of the visit for which this form was collected.

Variable # 4

Sas Name: F81VNUM

Sas Label: Visit number

Usage Notes: none

Categories: Study: Administration

N	Min	Max	Mean	Std Dev
75938	1	8	3.17082	1.68347

F81 Days from randomization to pelvic exam date

Variable # 5

Usage Notes: none

Sas Name: PELVICDY

Categories:

Clinical Tests: Pelvic Exam

Reproductive

Sas Label: Days from rand to pelvic exam

N Min Max Mean S

 N
 Min
 Max
 Mean
 Std Dev

 76074
 -139
 3185
 1152.5515
 616.62504

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Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Pelvic exam performed by

Variable # 6

Other

Missing

Sas Name: PELVICBY

Sas Label: Pelvic exam performed by

 Values
 N

 1
 CC staff
 67,490

240 76,598

8,868

%

88.1%

11.6%

0.3%

Usage Notes: none

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Doctor found anything wrong

Were there any abnormal findings found during the pelvic exam?

Variable # 7

Sas Name: PLVABNRM

Sas Label: Doctor found anything wrong

 Values
 N
 %

 0
 No
 8,211
 10.7%

 1
 Yes
 320
 0.4%

 .
 Missing
 68,067
 88.9%

 76,598

Usage Notes: Sub-question of F81 V6 Q6 "Pelvic exam performed by".

Not collected on all versions of Form 81.

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Loss of adipose tissue

External genitalia (vulva): loss of adipose tissue

Variable # 8

Sas Name: ADIPOSE

Sas Label: Loss of adipose tissue

Values % Ν No 27.789 36.3% Yes, probably benign 39.978 52.2% Yes, possibly malignant 2 0.0% 8,829 11.5% Missing 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Thinning of hair

External genitalia (vulva): thinning of hair

Variable # 9

Sas Name: PLVHAIR

Sas Label: Thinning of hair

Values % Ν 19,184 25.0% 63.4% Yes, probably benign 48,595 2 3 0.0% Yes, possibly malignant Missing 8,816 11.5% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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Form 81 - Pelvic Exam

Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Genitalia - Abnormal discoloration

External genitalia (vulva): abnormal discoloration

Variable # 10

Sas Name: DISCVLVA

Sas Label: Genitalia - Abnormal discoloration

 Values
 N
 %

 0
 No
 64,686
 84.4%

 1
 Yes, probably benign
 3,087
 4.0%

 2
 Yes, possibly malignant
 24
 0.0%

 Missing
 8,801
 11.5%

76,598

76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Genitalia - Ulceration

External genitalia (vulva): ulceration

Variable # 11

Sas Name: ULCERVLV

Sas Label: Genitalia - Ulceration

 Values
 N
 %

 0
 No
 67,474
 88.1%

 1
 Yes, probably benign
 302
 0.4%

 2
 Yes, possibly malignant
 5
 0.0%

 .
 Missing
 8,817
 11.5%

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Genitalia - Growth

External genitalia (vulva): growth

Variable # 12

Sas Name: GROWVLVA
Sas Label: Genitalia - Growth

Valu	ies	N	%
0	No	66,509	86.8%
1	Yes, probably benign	1,059	1.4%
2	Yes, possibly malignant	3	0.0%
	Missing	9,027	11.8%
		76,598	

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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Form 81 - Pelvic Exam

Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Vagina - Atrophy

Variable # 13

Sas Name: ATROPHY

Sas Label: Atrophy

Values Ν % No 27,256 35.6% Yes, probably benign 52.9% 40,516 0.0% Yes, possibly malignant 2 11.5% Missing 8,824 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Smooth

Variable # 14

Sas Name: PLVSMTH

Sas Label: Smooth

Values Ν % No 24,855 32.4% 55.9% Yes, probably benign 42.855 Yes, possibly malignant 4 0.0% 8.884 11.6% Missing 76,598

Usage Notes: Not collected on all versions of Form 81

Not required if "Pelvic exam performed by" is "Other"...

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Pale

Variable # 15

Sas Name: PLVPALE

Sas Label: Pale

Values % Ν 39,121 51.1% No Yes, probably benign 28,562 37.3% Yes, possibly malignant 0.0% 1 Missing 8,914 11.6% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Friable with contact

Variable # 16

Sas Name: FRIABVAG

Sas Label: Vagina - Friable with contact

Values % Ν No 66,543 86.9% Yes, probably benign 1,125 1.5% Yes, possibly malignant 3 0.0% 11.7% Missing 8,927 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

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Reproductive

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Form 81 - Pelvic Exam

Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Vagina - Blood present

Variable # 17

Sas Name: BLOODVAG

Sas Label: Blood present

Values Ν % No 66,958 87.4% Yes, probably benign 0.9% 716 0.0% Yes, possibly malignant 6 Missing 8,918 11.6% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Abnormal discoloration

Variable # 18

Sas Name: DISCVAG

Sas Label: Vagina - Abnormal discoloration

 Values
 N
 %

 0
 No
 66,764
 87.2%

 1
 Yes, probably benign
 919
 1.2%

 2
 Yes, possibly malignant
 4
 0.0%

 Missing
 8,911
 11.6%

 76,598
 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Ulceration

Variable # 19

Sas Name: ULCERVAG

Sas Label: Vagina - Ulceration

Values Ν % 67,613 88.3% No Yes, probably benign 77 0.1% Yes, possibly malignant 0.0% 1 Missing 8,907 11.6% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Vagina - Growth

Variable # 20

Sas Name: GROWVAG

Sas Label: Vagina - Growth

Values % Ν No 67,266 87.8% Yes, probably benign 341 0.4% Yes, possibly malignant 8 0.0% Missing 8,983 11.7% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

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Reproductive

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Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Vagina - Cystocele

Variable # 21

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Sas Name: CYSTOCEL

Sas Label: Cystocele

Categories: Clinical Tests: Pelvic Exam

Reproductive

Valu	ies	N	%
0	None	42,826	55.9%
1	Grade 1 (in vagina)	21,031	27.5%
2	Grade 2 (to introitus)	3,771	4.9%
3	Grade 3 (outside vagina)	232	0.3%
	Missing	8,738	11.4%

76,598

F81 Vagina - Rectocele

Variable # 22

Sas Name: RECTOCEL

.

Sas Label: Rectocele

Value	es	N	%
0	None	54,434	71.1%
1	Grade 1 (in vagina)	10,772	14.1%
2	Grade 2 (to introitus)	2,358	3.1%
3	Grade 3 (outside vagina)	163	0.2%
	Missing	8,871	11.6%

76,598

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Cervix (absent/present)

Variable # 23

Sas Name: PLVCERVX

-

Sas Label: Cervix

Values		N	%
0	Absent	341	0.4%
1	Present	67,601	88.3%
	Missing	8,656	11.3%
		76,598	

Usage Notes: Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Cervix - Flush with vaginal vault

Variable # 24

Sas Name: CRVFLUSH

Sas Hame. ONVI LOOM

Sas Label: Flush with vaginal vault

Valu	ies	N	%
0	No	60,312	78.7%
1	Yes, probably benign	6,409	8.4%
2	Yes, possibly malignant	1	0.0%
	Missing	9,876	12.9%
		76,598	

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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F81 Cervix - Friable with contact

Variable # 25

Sas Name: FRIABCRV

Sas Label: Cervix - Friable with contact

 Values
 N
 %

 0
 No
 61,078
 79.7%

 1
 Yes, probably benign
 5,588
 7.3%

 2
 Yes, possibly malignant
 13
 0.0%

 .
 Missing
 9,919
 12.9%

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Cervix - Surface lesion/growth

Cervix: surface lesion/growth (other than ectopy, Nabothian cyst)

Variable # 26

Sas Name: LESION

Sas Label: Surface lesion/growth

 Values
 N
 %

 0
 No
 65,659
 85.7%

 1
 Yes, probably benign
 973
 1.3%

 2
 Yes, possibly malignant
 25
 0.0%

 .
 Missing
 9,941
 13.0%

76,598

76,598

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Cervix - Polyp

Variable # 27

Sas Name: POLYP

Sas Label: Polyp

Valu	ies	N	%
0	No	64,416	84.1%
1	Yes, probably benign	2,197	2.9%
2	Yes, possibly malignant	6	0.0%
	Missing	9,979	13.0%
		76,598	

Usage Notes: Sub-question of F81 V6 Q9 "Cervix".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Uterus

Uterus (absent/present/unable to palpate)

Variable # 28

Sas Name: PLVUTER

Sas Label: Uterus

Values Ν % 0 Absent 419 0.5% 75.8% 58,071 Present Unable to palpate 9,358 12.2% 8,750 11.4% Missing 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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File Date: 04/12/2005 Data File: f81_ep_fu_pub **Structure:** Multiple rows per participant Population: E+P participants

Categories:

F81 Uterus - Prolapse

Variable # 29

Sas Name: PROLAPSE

Sas Label: Prolapse

Values Ν % None 49,957 65.2% Grade 1 (in vagina) 6,646 8.7% 456 0.6% Grade 2 (to introitus) 0.2% Grade 3 (outside vagina) 158 19,381 25.3% Missing 76,598

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Clinical Tests: Pelvic Exam

Reproductive

F81 Uterus - size (weeks)

Variable # 30

Sas Name: UTERSIZE

Sas Label: Uterine size (weeks)

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

N	Min	Max	Mean	Std Dev
55914	0	80	4.209	1.62206

F81 Uterus - Enlarged since last exam

Variable # 31

Sas Name: UTERENLR

Sas Label: Enlarged since last exam

Values		N	%
0	No	48,602	63.5%
1	Yes	740	1.0%
	Missing	27,256	35.6%
		76,598	

Usage Notes: Sub-question of F81 V6 Q10 "Uterus".

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Adnexae

Adnexae (normal/mass present/unable to palpate)

Variable # 32

Sas Name: ADNEXAE

Sas Label: Adnexae

Values % N 26,084 34.1% Normal Mass present 298 0.4% Unable to palpate/absent 41,386 54.0% Missing 8,830 11.5% 76,598

Usage Notes: Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

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Form 81 - Pelvic Exam

Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Mass present

Adnexae: location of mass

Variable # 33

Sas Name: MASSLOC

Sas Label: Mass present

 Values
 N
 %

 1
 Right
 122
 0.2%

 2
 Left
 109
 0.1%

 3
 Both
 39
 0.1%

 .
 Missing
 76,328
 99.6%

Usage Notes: Sub-question of F81 V6 Q11 "Adnexae".

Not collected on all versions of Form 81.

Not required if "Pelvic exam performed by" is "Other".

Categories: Clinical Tests: Pelvic Exam

Reproductive

F81 Pap smear obtained

Variable # 34 Usage Notes: Not collected on all versions of Form 81.

Sas Name: PAPSMEAR

Categories: Clinical Tests: Pelvic Exam

Sas Label: Pap smear obtained Reproductive

76,598

Valu	ies	N	%
0	No, not done	21,793	28.5%
1	No, send for outside report	1,411	1.8%
2	Yes, vaginal smear	323	0.4%
3	Yes, Pap smear	49,135	64.1%
	Missing	3,936	5.1%
		76,598	

F81 Referral made for follow-up

Sas Name: PLVREFER

Sas Name: PLVREFDY

Was a referral made for follow-up care (pelvic exam)?

Variable # 35 Usage Notes: none

Sas Label: Referral made for follow-up

Categories: Clinical Tests: Pelvic Exam

Values N %

 0
 No
 69,067
 90.2%

 1
 Yes
 1,923
 2.5%

 .
 Missing
 5,608
 7.3%

 76,598

F81 Days from randomization to PE referral

Variable # 36 Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Sas Label: Days from rand to PE referral

Categories: Clinical Tests: Pelvic Exam

s Label: Days from rand to PE referral Reproductive

 N
 Min
 Max
 Mean
 Std Dev

 1718
 35
 2979
 1095.6234
 587.02223

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Data File: f81_ep_fu_pub File Date: 04/12/2005 Structure: Multiple rows per participant Population: E+P participants

F81 Pelvic follow-up results

Variable # 37

Sas Name: PLVFURES

Sas Label: Pelvic follow-up results

 Values
 N
 %

 0
 Normal
 370
 0.5%

 1
 Benign changes
 580
 0.8%

 2
 Possibly malignant
 22
 0.0%

 .
 Missing
 75,626
 98.7%

76,598

Usage Notes: Sub-question of F81 V6 Q13 "Referral made for follow-up".

Not collected on all versions of Form 81.

Categories: Clinical Tests: Pelvic Exam

Reproductive

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