

Quintiles Phase I Female Medical History

DEMOGRAPHIC DATA

Name: _____ **Age:** _____ **Date of Birth:** ____/____/____

Street Address: _____

City: _____ **State:** _____ **Zip code:** _____

Telephone: Day _____ Evening _____

Cell phone: _____ **May we text you?** Yes No

Best Number to reach you: Day Evening Cell

May we leave a message if not answered? Yes No

Occupation: _____ **E-mail** _____

Emergency Contact: _____ **Relationship:** _____

Daytime phone: _____ **Evening phone:** _____

Street Address: _____

City: _____ **State:** _____ **Zip code:** _____

Physician: _____ **Phone:** _____

Street Address: _____

City: _____ **State:** _____ **Zip code:** _____

Hospital: _____

Would you like Quintiles to notify your physician of your potential participation in this trial? Yes No

To ensure that your physician gets notified of your participation you must complete name, address, city, and state where they are located.

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2. List ALL past hospitalizations and surgeries:

PLEASE USE MM/DD/YY FORMAT FOR ANY DATES GIVEN

List REASON/ILLNESS or <input type="checkbox"/> NONE <small>Example: (cesarean section)</small>	Where <small>(hospital or city)</small>	Date <small>(01/15/09)</small>	COMMENTS <small>(planned - no complications)</small>

3. List ALL Drug Allergies:

PLEASE USE MM/DD/YY FORMAT FOR ANY DATES GIVEN

List DRUG ALLERGIES or <input type="checkbox"/> NONE <small>Example: (Aspirin)</small>	Onset Date <small>(01/15/09)</small>	Date of Last Occurrence <small>(03/01/09)</small>	Ongoing <input checked="" type="checkbox"/>	What happened to you <small>(hives)</small>

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Medical History: Please check yes to all that apply, either **previous or current** or check None. Explain each yes in the space provided at the end of the selections (on page 4).

SKIN		DENTAL/THROAT		GASTROINTESTINAL	
Yes	or <input type="checkbox"/> None	Yes	or <input type="checkbox"/> None	Yes	or <input type="checkbox"/> None
	Skin problems, rash, itching		Poor teeth/gums		Vomited blood
	Cuts that won't heal		Wear dentures		Passed blood in stool
	Change in skin color or moles		Unexplained hoarseness		Black stools
	Skin lumps or tumors		Bleeding gums		Recurrent nausea
	Skin biopsies		Swollen glands or lumps in neck		Recurrent vomiting
	Other _____		Other _____		Hemorrhoids
EYES		CHEST/LUNGS			Change in Bowels
Yes	or <input type="checkbox"/> None	Yes	or <input type="checkbox"/> None		Change in appetite
	glasses/contacts (circle which) Distance (myopia) Reading (hyperopia/presbyopia) Astigmatism		Asthma (circle which) Childhood With exercise Adult onset		Weight loss
	Light sensitivity		Shortness of breath		Gallbladder trouble/removal
	Excess tearing		Chronic cough		Abnormal liver function tests
	Cataracts		Coughed up blood		Heartburn or reflux
	Glaucoma		Positive TB skin test		Hepatitis
	Chronic eye problems		Pneumonia		Special diet
	Other _____		Chronic bronchitis or emphysema		Difficulty swallowing
EARS			Abnormal chest x-ray		Difficulty swallowing pills
Yes	or <input type="checkbox"/> None		Other lung disease		Other _____
	Hearing loss (Right, left, or both)		Other _____	URINARY SYSTEM	
	Frequent earaches	HEART		Yes	or <input type="checkbox"/> None
	Ringing in ears	Yes	or <input type="checkbox"/> None		Bladder infection
	Frequent ear discharge		Chest pain		Kidney failure
	Other _____		Heart attack		Kidney infection
NOSE			Heart murmur		Kidney stones
Yes	or <input type="checkbox"/> None		High blood pressure		Involuntary loss of urine
	Sinus problems		Irregular heart beats		Urinate at night
	Allergic congestion		Ankle swelling		Pain on urination
	Non-allergic congestion		Leg cramps with exercise		Blood in urine
	Recurrent sneezing		Varicose veins		Difficulty urinating
	Nasal discharge		Elevated cholesterol (list past or present treatment in comments)		Other _____
	Nosebleeds		Elevated triglycerides (list past or present treatment in comments)	ENDOCRINE	
	Nasal polyps		Prior electrocardiogram	Yes	or <input type="checkbox"/> None
	Other _____		Prior Holter monitor		Recurrent fatigue
			Prior stress test		Thyroid trouble
			Prior echocardiogram		Heat intolerance
			Other _____		Cold intolerance
					Diabetes
					Elevated blood sugar
					Other _____

Do not write below tables or on back. If more space is needed please request an extra form.

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Medical History continued. Please check yes to all that apply, either **previous or current** or check None. Explain each yes in the space provided at the end of the selections (on page 4).

MUSCULOSKELETAL		NEUROLOGIC		PSYCHIATRIC	
Yes	or <input type="checkbox"/> None	Yes	or <input type="checkbox"/> None	Yes	or <input type="checkbox"/> None
	Recurrent muscle pain		Headaches(More than once a week)		Inpatient treatment for emotional problems
	Muscle wasting		Migraines		Outpatient treatment for emotional problems
	Muscle weakness		Head injury		Treatment for alcohol abuse
	Joint stiffness/pain		Fainting spells		Treatment for substance abuse
	Arthritis		Memory problems		Treated for depression
	Gout		Dizzy spells		Suicidal thoughts
	Recurrent backaches		Seizures		Suicide attempt(s)
	Broken bones (list below)		Stroke or TIA		Hallucinations
	Joint trauma		Weakness in arms or legs		Memory change
	Osteoporosis		Paralysis		Change in sleeping habits
	Other _____		Uncontrolled movements (trembling/shakiness)		Recurrent nightmares
FEMALE GU/BREASTS			Tingling, numbness		Anxiety
Yes	or <input type="checkbox"/> None		Unsteady gait		Panic Attacks
	Pap Smear		Spinal cord problems		Other _____
	Endometriosis		Other _____	VACCINATIONS	
	Fibroids	HEMATOLOGY		Yes	or <input type="checkbox"/> None
	Pain/discomfort with sexual intercourse	Yes	or <input type="checkbox"/> None		Hepatitis B
	Vaginal discharge/itching		Anemia		Hepatitis A
	Pregnancy		Low iron		Influenza
	Miscarriage/Abortion		Sickle cell disease		BCG (TB vaccine)
	Complications from pregnancy		Sickle cell trait		Pneumonia
	Difficult becoming pregnant		Hemophilia		Other _____
	Breast non-cancerous lumps		Leukemia or lymphoma	ALLERGIES	
	Breast cancer		Bruise easily	Yes	or <input type="checkbox"/> None
	Breast cysts		Bleed easily		Allergies to medications
	Breast discomfort		Blood transfusion		Reaction to medications
	Discharge from nipples		Tested positive for HIV/AIDS		Allergy to latex
	Nipple retraction		Blood Clots		Allergy to dust/pollen
	Mammogram		Thalassemia		Food allergy
	Gonorrhhea		Other _____		Allergy to animals
	Syphilis				Other _____
	Genital Herpes				
	Genital Warts				
	Chlamydia				
	Other STD _____				
	Other _____				

Do not write below tables or on back. If more space is needed please request an extra form.

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1. If you answered yes to any of the selections listed above, please explain below. (If more space is needed please request an extra form.)

PLEASE USE MM/DD/YY FORMAT FOR ANY DATES GIVEN (For Vaccine History only YY is required)

List PROBLEM/SYMPTOM or <input type="checkbox"/> NONE	Onset Date	Date of Last Occurrence	Ongoing	COMMENTS
Example: (Broken right ankle)	(01/15/09)	(03/01/09)	<input checked="" type="checkbox"/>	(Broke ankle from fall - wore cast)

2. List ALL past hospitalizations and surgeries: (If more space is needed please request an extra form.)

PLEASE USE MM/DD/YY FORMAT FOR ANY DATES GIVEN

List REASON/ILLNESS or <input type="checkbox"/> NONE	Where	Date	COMMENTS
Example: (cesarean section)	(hospital or city)	(01/15/09)	(planned - no complications)

3. List ALL Drug Allergies: (If more space is needed please request an extra form.)

PLEASE USE MM/DD/YY FORMAT FOR ANY DATES GIVEN

List DRUG ALLERGIES or <input type="checkbox"/> NONE	Onset Date	Date of Last Occurrence	Ongoing	What happened to you
Example: (Aspirin)	(01/15/00)	(03/01/09)	<input checked="" type="checkbox"/>	(hives)

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4. Have you ever used recreational drugs, marijuana, cocaine, IV drugs or any other drugs? Yes No

What drug(s): _____ Date of last use: ___/___/___ (MM/DD/YY)

What drug(s): _____ Date of last use: ___/___/___ (MM/DD/YY)

5. **MENSTRUAL AND BIRTH CONTROL HISTORY- PLEASE USE MM/DD/YY FORMAT FOR ALL DATES**

a. Do you currently take hormonal replacement therapy (HRT) or hormonal birth control (birth control pills, Norplant, Depo-Provera, Mirena IUD, OrthoEvra patch, or Nuva Ring)? Yes No

If yes, list _____ Start Date ___/___/___ (MM/DD/YY)

End Date ___/___/___ (MM/DD/YY) or ongoing?

b. Do you still have menstrual cycles? YES, complete below. NO, Skip to C.

- Indicate the date of the 1st day of your last menstrual cycle here: ___/___/___ (MM/DD/YY)
- Are your periods? Regular Irregular
- How frequent are your periods (e.g., how many days separate the first day of each cycle)? _____ days
- What is the duration of your period (e.g., how many days does your cycle last)? _____ days
- On the average, is your flow: Heavy Moderate Light
- At what age did your menses begin? _____ years old
- Do you experience any of the following pre-menstrual symptoms (please check all that apply):

NONE Bloating Breast tenderness Mood changes Cramps Headache Other: _____

c. If you no longer have menstrual cycles, complete below. (If "YES" on 5b, SKIP TO 6)

- Indicate month & year of your last menstrual period here: ___/___ (MM/YY)
- Are you currently going through menopause? Yes No
- Do you experience any of the following symptoms (please check all that apply):

NONE Night Sweats Hot flashes Mood changes Cramps Other: _____

6. Do you have tattoos? Yes No If YES, list location(s) below:

If yes, Date of last tattoo ___/___/___ (MM/DD/YY)

7. Do you have body piercing? Yes No If Yes, list location(s) below:

If yes, Date of last piercing: ___/___/___ (MM/DD/YY)

8. Do you have any significant birthmarks, scars, or burns? Yes No If Yes, list location(s) below:

Birthmarks: _____ Scars: _____ Burns: _____

9. Do you do any form of exercising? Yes No If Yes, list below:

Type: _____ How often: _____ Week Month, Date last exercised: ___/___/___ (MM/DD/YY)

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FAMILY HISTORY

10. Mother's Age _____ Alive Deceased Unknown Father's Age _____ Alive Deceased Unknown

Does your family have a history of? (For this section, all questions must be answered as either Yes Or No. Any 'Yes' answers must also include information of the family member.)

YES	NO	DISEASE/CONDITION	FAMILY MEMBER Example: (mother, father, sister)
		Alcohol or drug abuse	
		Asthma or allergies	
		Blood diseases (hemophilia, sickle cell disease, thalassemia)	
		Cancer	
		Diabetes	
		Heart attack or heart disease	
		High blood pressure	
		Kidney disease	
		Mental illness	
		Stroke or TIA	
		Other	

Comments:

I declare that my answers and statements are correctly recorded, complete, and true to the best of my knowledge and belief.

Volunteer Signature and Date _____

_____/_____/_____
(MM/DD/YY)

For Physician Only:

Investigator Signature and Date _____

_____/_____/_____
(MM/DD/YY)

Investigator:

Any clinically significant history relevant to the applicant's participation in the study Yes No

If yes, please comment:
