



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: April 3, 2009

To: NCCTG Primary Clinical Research Associates

From: Lynn Flickinger
Protocol Development Coordinator

Re: N0735, Phase II Trial of Albumin-Bound Paclitaxel in Combination with Gemcitabine and Bevacizumab in Patients with Metastatic Breast Cancer

The purpose of this memorandum is to provide investigators with a recent industry report of an adverse event that has occurred in association with Bevacizumab at a non-NCCTG institution. You may have also received this communication directly from the drug manufacturer.

263914_F5_03Apr2009

Please note that all risks currently cited in the NCCTG consent form cannot be omitted; it is at the discretion of your local IRB as to whether they wish to add risks based on the enclosed information. If a determination has been made by the NCCTG Research Base that a protocol amendment is necessary, you will receive the NCI-approved protocol addendum at a later date; for purposes of cross-reference, this communication will cite the adverse event noted above.

Please submit this adverse event to your Institutional Review Board.

If you have any questions concerning this communication, please contact Lynn Flickinger at Flickinger.lynn@mayo.edu or 507-538-7034.

LF/kjm
enclosure

Genentech

IN BUSINESS FOR LIFE

Date: 28 October 2008

Axel Grothey, MD
Mayo Clinic
200 First Street S.W.
Rochester, MN 55905

→ APLB

RE: IND Safety Report/Expedited Case Safety Report

Investigational Product(s): **Bevacizumab**

NC AL

GNE MCN: **263914 Follow** Other Reference Number(s):

Up# 5

Dear Dr. Grothey

Attached is a case summary of a serious and unexpected adverse drug reaction that occurred in a subject exposed to Bevacizumab. Good Clinical Practice regulations require that you promptly submit a copy of this IND safety report/expedited case safety report to your Institutional Review Board or Independent Ethics Committee. File a copy of this IND safety report/expedited case safety report in your protocol file so that it is available for review during a Sponsor monitoring visit and/or regulatory audit.

In the European Economic Area (EEA) Genentech, Inc. or its designee will directly inform the Institutional Review Boards/Ethics Committees, as appropriate.

This IND safety report/expedited case safety report must be filed with your Investigator Brochure (IB) for information only. This IND safety report/expedited case safety report is not considered an addendum to your safety reference document.

Although this adverse event has been documented and reported to the appropriate Regulatory agencies, the report does not necessarily reflect a conclusion by Genentech or the Regulatory agencies that bevacizumab contributed to the adverse event.

If questions arise, please contact the undersigned.

Sincerely,



Eric Hedrick
Medical Monitor
AVF3918s AVF3870s

For use by user-facilities,
importers, distributors and manufacturers
for MANDATORY reporting

MEDWATCH
3500A Facsimile

Mfr Report #	263914
UF/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at Time of Event: 52 Years or Date of Birth:	3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male	4. Weight 112.5 lbs or 51.0 kgs
In confidence			
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g., defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (Check all that apply)			
<input type="checkbox"/> Death: (mm/dd/yyyy)		<input type="checkbox"/> Disability or Permanent Damage	
<input type="checkbox"/> Life-threatening		<input type="checkbox"/> Congenital Anomaly/Birth Defect	
<input checked="" type="checkbox"/> Hospitalization - initial or prolonged		<input type="checkbox"/> Other Serious (Important Medical Events)	
<input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage (Devices)			
3. Date of Event (mm/dd/yyyy) 05/23/2008		4. Date of This Report (mm/dd/yyyy) 10/24/2008	
5. Describe Event or Problem Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) necrotizing fasciitis [NECROTISING FASCIITIS]			
Case Description: IND SAFETY REPORT			
This case, manufacturer control number 263914, is a report from Malaysia referring to a 52 year-old female subject (ID#). An Investigator reported this case from study AVF3693G, A phase III, multicenter, randomized, placebo-controlled trial evaluating the efficacy and safety of bevacizumab in combination with chemotherapy regimens in subjects with previously treated metastatic breast cancer.			
On 26-MAR-2008, the subject received bevacizumab or placebo, (780 mg, Q3W, Intravenous) and gemcitabine hydrochloride (1875 continued in additional info section...			
6. Relevant Tests/Laboratory Data, Including Dates #1 05/27/2008 CULTURE (Continued)			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) Race: Asian #1 06/26/2008, Procedure, DEBRIDEMENT (Continued) #2 09/12/2007 to UNK Historical Condition, (Continued) #3 09/05/2007, Procedure, COLOSTOMY (Continued) continued in additional info section...			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1. BEVACIZUMAB OR PLACEBO (Bevacizumab) (Continued)			
#2. GEMCITABINE (GEMCITABINE HYDROCHLORIDE)			
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration) from/to (or best estimate)	
#1. 780 mg, Q3W, Intravenous		#1. 03/26/2008 to UNK	
#2. 1875 mg, Q3W, Intravenous		#2. 03/26/2008 to UNK	
4. Diagnosis for Use (Indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1. metastatic breast (Continued)		#1. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2. METASTATIC (Continued)		#2. <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?	
#1. 913303	#1.	#1. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
#2.	#2.	#2. <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't Apply	
9. NDC# or Unique ID			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
G. ALL MANUFACTURERS			
1. Contact Office - Name/Address (and Manufacturing Site for Devices) Genentech, Inc. James Nickas Pharm.D. 1 DNA Way South San Francisco, CA 94080 UNITED STATES		2. Phone Number 6502255591	
4. Date Received by Manufacturer (mm/dd/yyyy) 10/17/2008		5. (A)NDA # IND # BB 7023 STN # PMA/ 510(k) # Combination Product <input type="checkbox"/> Yes Pre-1938 <input type="checkbox"/> Yes OTC Product <input type="checkbox"/> Yes	
6. If IND, Give Protocol # AVF3693G		3. Report Source (Check all that apply) <input checked="" type="checkbox"/> Foreign MYS <input checked="" type="checkbox"/> Study <input type="checkbox"/> Literature <input type="checkbox"/> Consumer <input checked="" type="checkbox"/> Health Professional <input type="checkbox"/> User Facility <input type="checkbox"/> Company Representative <input type="checkbox"/> Distributor <input type="checkbox"/> Other:	
7. Type of Report (Check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 30-day <input type="checkbox"/> 7-day <input type="checkbox"/> Periodic <input type="checkbox"/> 10-day <input type="checkbox"/> Initial <input checked="" type="checkbox"/> 15-day <input checked="" type="checkbox"/> Follow-up #5			
9. Manufacturer Report Number 263914		8. Adverse Event Term(s) NECROTISING FASCIITIS	
E. INITIAL REPORTER			
1. Name and Address		Phone #	
2. Health Professional?		3. Occupation	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
4. Initial Reporter Also Sent Report to FDA			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unk			

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MEDWATCH

3500A Facsimile (Back) (Continued)

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ADDITIONAL INFORMATION**B5. EVENT DESCRIPTION (Continued)**

mg, frequency and route not reported). The lot number for bevacizumab or placebo was 913303. The last dose of bevacizumab or placebo and gemcitabine prior to the event onset was administered on 16-APR-2008.

On 23-MAY-2008, the subject was hospitalized with grade 3, life-threatening, necrotizing fasciitis (NECROTIZING FASCIITIS). Relevant laboratory tests included culture showing proteus mirabilis. Treatment included unspecified medications, wound debridement and colostomy closure with T-colostomy and wound closure. Treatment with bevacizumab or placebo and gemcitabine was discontinued.

At the time of the report, the event remained ongoing.

On 07-JUL-2008, the subject was unblinded and found to be on bevacizumab.

The Physician assessed the event necrotizing fasciitis as related to bevacizumab. The physician did not provide a causality assessment for gemcitabine in relation to the event. In the reporter's opinion, other possible etiological factors included unspecified concurrent illness.

This report contains case details known at the time of the submission.

Additional information has been requested. If received, the case will be updated accordingly.

ADDITIONAL INFORMATION RECEIVED 09-JUL-2008

On an unreported date, the event resulted in death. No autopsy was performed.

Additional information has been requested, if received the case will be updated accordingly.

This report contains case details known at the time of the submission.

ADDITIONAL INFORMATION RECEIVED ON 15-AUG-2008:

The subject's necrotizing fasciitis was reported to have been a recurring problem.

The subject was reported to have presented with bleeding from the colostomy site.

On 07-APR-2008, the subject died. The cause of death was reported as aspiration pneumonia. It was not reported if an autopsy was performed.

The outcome of the event necrotizing fasciitis was amended to not resolved. Treatment for the event included Amoxicillin and Clavulanate Potassium.

This report contains case details known at the time of the submission.

No further information was available.

27-AUG-2008: AFTER REVIEW OF THIS CASE, FURTHER CLARIFICATION IS REQUIRED.

The statement "On 07-APR-2008, the subject died." should be "On 04-JUL-2008, the subject died."

No further information was available.

ADDITIONAL INFORMATION RECEIVED ON 11-SEP-2008

The subject's past medical history included necrotizing fasciitis of the peri-anal region for which treatment included incision and drainage on 04-SEP-2007 and post-operative sigmoid colostomy and wound debridement on 05-SEP-2007. Per report, the subject had pre-existing fasciitis around the colostomy upon entering the study. Conflicting information was provided regarding onset date of necrotizing fasciitis, both 28-SEP-2007 and 04-SEP-2007 were reported. Additional relevant history included subcutaneous abscess (refer to MCN 261133) and concurrent conditions present at the time of the event included hypercholesterolemia, diabetes mellitus

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and hypertension. Per report, the subject was not treated for diabetes, but was on dietary control.

On 26-MAR-2008, the subject initiated treatment with gemcitabine (intravenous, day 1 and day 8, every 3 weeks).

On 04-MAY-2008, the subject was hospitalized for subcutaneous peristomal abscess (refer to MCN 261133) on the anterior wall, close to the colostomy site. On 07-MAY-2008, the abscess was drained and on 10-MAY-2008, the subject was discharged.

On 23-MAY-2008, the subject was reported to have been re-hospitalized for necrotizing fasciitis (NECROTIZING FASCIITIS) that affected the anterior abdomen/abdominal wall. Treatment included ampicillin, sulbactam sodium, cefuroxime, metoclopramide hydrochloride, erythromycin, dopamine hydrochloride, and acetaminophen.

Per report, the remained hospitalized and the event of necrotizing fasciitis remained unresolved, which subsequently led to sepsis.

On 04-JUL-2008, the subject developed aspiration pneumonia (refer to MCN 264309) and died. Per report, the subject had been admitted to the surgery department and died in that care.

This report contains case details known at the time of the submission.

Additional information has been requested, if received the case will be updated accordingly.

ADDITIONAL INFORMATION RECEIVED ON 17-OCT-2008:

On 26-JUN-2008, the subject underwent wound debridement and a Hartman procedure.

On an unspecified date, the subject was reported to have developed sepsis (Ref MCN 270329) in the background of the necrotizing fasciitis, which was reported to have contributed to the subject's death.

This report contains case details known at the time of the submission.

No further information was available.

PREVIOUSLY FILED IND SAFETY REPORTS OF SIMILAR EVENTS

Genentech has not filed previous IND safety reports of necrotizing fasciitis or IND safety reports of similar events for subjects receiving bevacizumab.

Based on review of available data, the Sponsors cannot establish or exclude the possibility of a cause and effect relationship between administration of bevacizumab and the occurrence of necrotizing fasciitis.

At this time, the Sponsors does not believe changes to the conduct of this clinical trial are warranted.

B6. LABORATORY DATA

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	05/27/2008	CULTURE		
		PROTEUS MIRABILIS		

B7. OTHER RELEVANT HISTORY

#	Start/Stop Date	Condition Type / Condition	Notes
1	06/26/2008 UNK	Procedure DEBRIDEMENT	With Hartman procedure
2	09--/2007 UNK	Historical Condition NECROTISING FASCIITIS	peri-anal region

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3	09/05/2007 UNK	Procedure COLOSTOMY	sigmoid
4	09/05/2007 UNK	Procedure DEBRIDEMENT	
5	05/04/2008 UNK	Other SUBCUTANEOUS ABSCESS	refer to MCN 261133
6	09/--/2007 UNK	Current Condition HYPERCHOLESTEROLAEM IA	
7	09/--/2007 UNK	Current Condition DIABETES MELLITUS	
8		Current Condition HYPERTENSION	

C1. NAME (Continued)

Suspect Medication #1: BEVACIZUMAB OR PLACEBO(Bevacizumab) Powder and solvent for solution for infusion, 100mg

C4. DIAGNOSIS FOR USE (Continued)

#1:metastatic breast cancer (METASTATIC BREAST CANCER)

#2:METASTATIC BREAST CANCER (METASTATIC BREAST CANCER)

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY MALAYSIA	2. DATE OF BIRTH			2a. AGE 52 Years	3. SEX Female	3a. WEIGHT 51.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
								23	MAY	2008	<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) necrotizing fasciitis [NECROTISING FASCIITIS] Case Description: IND SAFETY REPORT This case, manufacturer control number 263914, is a report from Malaysia referring to a 52 year-old female subject (ID#). An Investigator reported this case from study AVF3693G, A phase III, multicenter, randomized, placebo-controlled trial evaluating the efficacy and safety of bevacizumab in combination with chemotherapy regimens in subjects with previously treated metastatic breast cancer. (Continued on Additional Information Page)											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?
#1) BEVACIZUMAB OR PLACEBO (Bevacizumab) Powder and solvent for solution for infusion, 100 mg {Lot # #2) GEMCITABINE (GEMCITABINE HYDROCHLORIDE) (Continued on Additional Information Page)		
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NA
#1) 780 mg, Q3W #2) 1875 mg, Q3W	#1) Intravenous #2) Intravenous	
17. INDICATION(S) FOR USE		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1) metastatic breast cancer (METASTATI #2) METASTATIC BREAST CANCER (M (Continued on Additional Information Page)		
18. THERAPY DATES(from/to)	19. THERAPY DURATION	<input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
#1) 26-MAR-2008 / Unknown #2) 26-MAR-2008 / Unknown	#1) Unknown #2) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)		
From/To Dates	Type of History / Notes	Description
26-JUN-2008 to Unknown	Procedure With Hartman procedure	WOUND DEBRIDEMENT (DEBRIDEMENT)
SEP-2007 to Unknown	Historical Condition peri-anal region	NECROTIZING FASCIITIS (NECROTISING FASCIITIS)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26. REMARKS
Genentech, Inc. James Nickas 1 DNA Way South San Francisco, CA 94080 UNITED STATES Phone: 6502255591		
24b. MFR CONTROL NO.	25b. NAME AND ADDRESS OF REPORTER	
263914		
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE	
17-OCT-2008	<input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT	25a. REPORT TYPE	
24-OCT-2008	<input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 5	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

On 26-MAR-2008, the subject received bevacizumab or placebo, (780 mg, Q3W, Intravenous) and gemcitabine hydrochloride (1875 mg, frequency and route not reported). The lot number for bevacizumab or placebo was 913303. The last dose of bevacizumab or placebo and gemcitabine prior to the event onset was administered on 16-APR-2008.

On 23-MAY-2008, the subject was hospitalized with grade 3, life-threatening, necrotizing fasciitis (NECROTIZING FASCIITIS). Relevant laboratory tests included culture showing proteus mirabilis. Treatment included unspecified medications, wound debridement and colostomy closure with T-colostomy and wound closure. Treatment with bevacizumab or placebo and gemcitabine was discontinued.

At the time of the report, the event remained ongoing.

On 07-JUL-2008, the subject was unblinded and found to be on bevacizumab.

The Physician assessed the event necrotizing fasciitis as related to bevacizumab. The physician did not provide a causality assessment for gemcitabine in relation to the event. In the reporter's opinion, other possible etiological factors included unspecified concurrent illness.

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Additional information has been requested. If received, the case will be updated accordingly.

ADDITIONAL INFORMATION RECEIVED 09-JUL-2008

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ADDITIONAL INFORMATION RECEIVED ON 15-AUG-2008:

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No further information was available.

27-AUG-2008: AFTER REVIEW OF THIS CASE, FURTHER CLARIFICATION IS REQUIRED.

The statement "On 07-APR-2008, the subject died." should be "On 04-JUL-2008, the subject died."

No further information was available.

ADDITIONAL INFORMATION RECEIVED ON 11-SEP-2008

The subject's past medical history included necrotizing fasciitis of the peri-anal region for which treatment included incision and drainage on 04-SEP-2007 and post-operative sigmoid colostomy and wound debridement on 05-SEP-2007. Per report, the subject had pre-existing fasciitis around the colostomy upon entering the study. Conflicting information was provided regarding onset date of necrotizing fasciitis, both 28-SEP-2007 and 04-SEP-2007 were reported. Additional relevant history included subcutaneous abscess (refer to MCN 261133) and concurrent conditions present at the time of the event included hypercholesterolemia, diabetes mellitus and hypertension. Per report, the subject was not treated for diabetes, but was on dietary control.

On 26-MAR-2008, the subject initiated treatment with gemcitabine (intravenous, day 1 and day 8, every 3 weeks).

On 04-MAY-2008, the subject was hospitalized for subcutaneous peristomal abscess (refer to MCN 261133) on the anterior wall,

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

close to the colostomy site. On 07-MAY-2008, the abscess was drained and on 10-MAY-2008, the subject was discharged.

On 23-MAY-2008, the subject was reported to have been re-hospitalized for necrotizing fasciitis (NECROTIZING FASCIITIS) that affected the anterior abdomen/abdominal wall. Treatment included ampicillin, sulbactam sodium, cefuroxime, metoclopramide hydrochloride, erythromycin, dopamine hydrochloride, and acetaminophen.

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On 04-JUL-2008, the subject developed aspiration pneumonia (refer to MCN 264309) and died. Per report, the subject had been admitted to the surgery department and died in that care.

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Based on review of available data, the Sponsors cannot establish or exclude the possibility of a cause and effect relationship between administration of bevacizumab and the occurrence of necrotizing fasciitis.

At this time, the Sponsors does not believe changes to the conduct of this clinical trial are warranted.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	27-MAY-2008	CULTURE		
PROTEUS MIRABILIS				

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) BEVACIZUMAB OR PLACEBO (Bevacizumab) Powder and solvent for solution for infusion, 100 mg {Lot # 913303}; Regimen #1	780 mg, Q3W; Intravenous	metastatic breast cancer (METASTATIC BREAST CANCER)	26-MAR-2008 / Unknown; Unknown
#2) GEMCITABINE (GEMCITABINE HYDROCHLORIDE) ; Regimen #1	1875 mg, Q3W; Intravenous	METASTATIC BREAST CANCER (METASTATIC BREAST CANCER)	26-MAR-2008 / Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
05-SEP-2007 to Unknown	Procedure sigmoid	COLOSTOMY (COLOSTOMY);
05-SEP-2007 to Unknown	Procedure	WOUND DEBRIDEMENT (DEBRIDEMENT);
04-MAY-2008 to Unknown 24-Oct-2008 14:45	Other refer to MCN 261133	SUBCUTANEOUS ABSCESS (SUBCUTANEOUS ABSCESS);

ADDITIONAL INFORMATION

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
SEP-2007 to Unknown	Current Condition	HYPERCHOLESTEREMIA (HYPERCHOLESTEROLAEMIA);
SEP-2007 to Unknown	Current Condition	DIABETES (DIABETES MELLITUS);
Unknown	Current Condition	HYPERTENSION (HYPERTENSION);