



Turn Data into Actionable Wisdom

BIOPHICS
Center of Excellence for Biomedical
and Public Health Informatics

Introduction to Data Management for Clinical Research

Jaranit Kaewkungwal

Biomedical Research Cycle



Multidisciplinary Team in Clinical Research Process

1. Clinical Investigator
2. Site coordinator (CRC)
3. Pharmacologist
4. Trialist/Methodologist
5. Biostatistician
6. Lab Coordinator
7. Reference lab
8. Project manager
9. Clinical Research Manager/Associate
10. Monitor
11. Safety Surveillance Associate (SSA)
12. Regulatory affairs
13. Clinical Data Management
14. Clinical IT
15. IT/IS personnel
16. Trial pharmacist
17. Clinical supply
18. Auditor/Compliance

Data Management Definition

What is Data Management?

A process that begins with conception and design of a research project, continues through data capture and analysis to publication, data archiving and data sharing with the broader scientific community.

Project
Initiation

Data Design

Data Acquisition
and
Quality Control

Data Manipulation
and
Quality Assurance

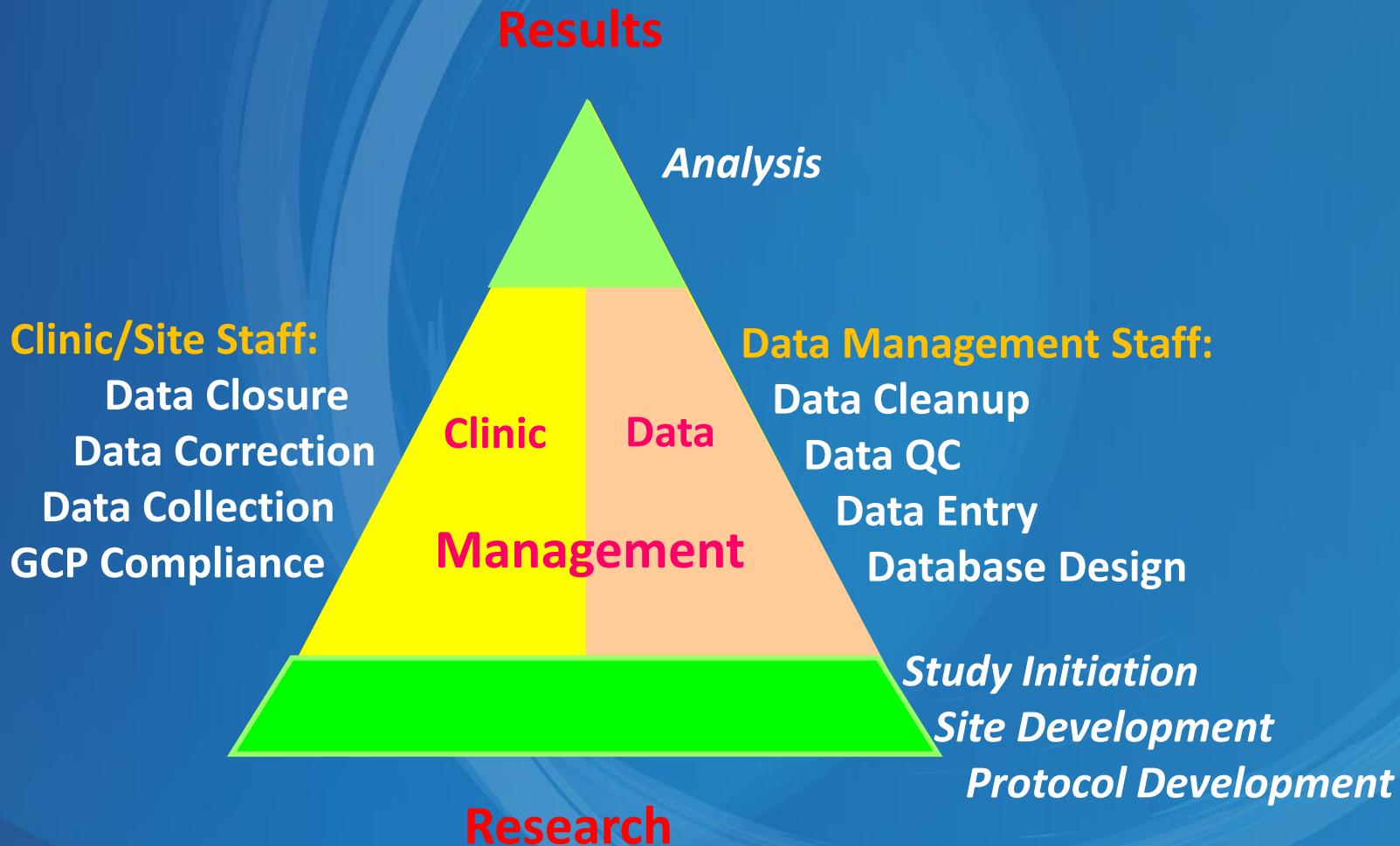
Data Analysis
and
Interpretation

Data Access
and
Archiving

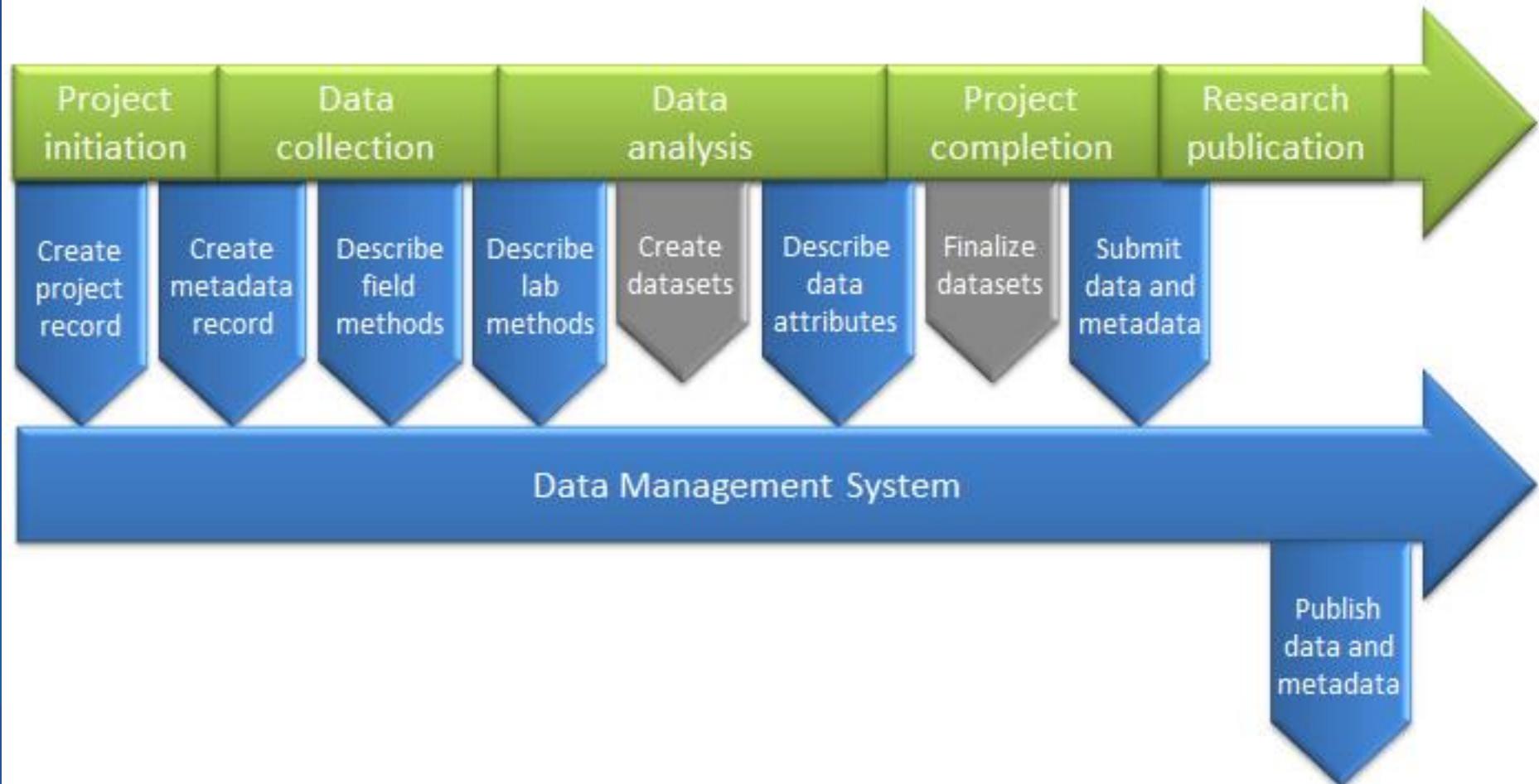
Publication

Primary Functions of Clinical Data Management (CDM)

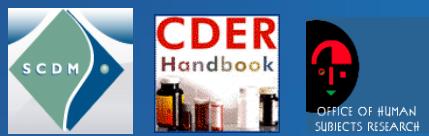
Time



Data Management Workflow



Source: <https://researchadmin.asu.edu/dmp>



Regulatory & Guidelines



Regulatory & Guidelines

GCP & Computer / Database Management Systems

- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- The European Agency for the Evaluation of Medicinal Products (EMEA)
- FDA Center for Drug Evaluation and Research (CDER)
- Human Subject Protections- Office of Human Subjects Research, NIH (OHSR)
- WORLD MEDICAL ASSOCIATION
- Standard operating procedures for clinical investigators (WHO GCP SOP)

Regulatory & Guidelines

GCP & Computer / Database Management Systems

TABLE 2.—LIST OF RELEVANT ICH GUIDANCES AND TOPICS

Code	Topic
E1	The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions
E2A	Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
E2B	Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
E2C	Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
E3	Structure and Content of Clinical Study Reports
E4	Dose-Response Information to Support Drug Registration
E5	Ethnic Factors in the Acceptability of Foreign Clinical Data
E6	Good Clinical Practice: Consolidated Guideline
E7	Studies in Support of Special Populations: Geriatrics
E8	General Considerations for Clinical Trials
E9	Statistical Considerations in the Design of Clinical Trials
E10	Choice of Control Group in Clinical Trials
M3	Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals
S6	Safety Studies for Biotechnology-Derived Products

Regulatory - Environment & Systems

GCP – E6

Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance

Additional copies are available from:
the Drug Information Branch (HFD-210),
Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
<http://www.fda.gov/cder/guidance/index.htm>
or
Office of Communication,
Training, and Manufacturers Assistance (HFM-40)
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike, Rockville, MD 20852-1448,
<http://www.fda.gov/cber/guidelines.htm>
(Fax) 888-CBERFAX or 301-827-3844
(Voice Information) 800-835-4709 or 301-827-1800

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
April 1996
ICH

GCP – E2A (Data Management & Reporting)

Guideline for Industry

Clinical Safety Data Management: Definitions and Standards for Expedited Reporting

ICH-E2A
March 1995

GCP – E2B(R3) (Data Elements & Transmission)

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL
REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN
USE

DRAFT CONSENSUS GUIDELINE

REVISION OF THE ICH GUIDELINE ON
CLINICAL SAFETY DATA MANAGEMENT
DATA ELEMENTS FOR TRANSMISSION OF
INDIVIDUAL CASE SAFETY REPORTS
E2B(R3)

Current Step 2 version
dated 12 May 2005

At Step 2 of the ICH Process, a consensus draft text or guideline, agreed by the appropriate ICH Expert Working Group, is transmitted by the ICH Steering Committee to the regulatory authorities of the three ICH regions (the European Union, Japan and the USA) for internal and external consultation, according to national or regional procedures.

Regulatory - Environment & Systems

Computer Systems

DBMS

(21 CFR Part 11 – May 2007)

Guidance for Industry Computerized Systems Used in Clinical Investigations

Additional copies are available from:

Office of Training and Communication
Division of Drug Information
Center for Drug Evaluation and Research (CDER)
(Tel) 301-827-4573
<http://www.fda.gov/cder/guidance/index.htm>

or

Office of Communication, Training and
Manufacturers Assistance
Center for Biologics Evaluation and Research
<http://www.fda.gov/cber/guidelines.htm>
(Tel) 800-835-4709 or 301-827-1800

or

Office of Communication, Education, and Radiation Programs
Division of Small Manufacturers, International, and Consumer Assistance
Center for Devices and Radiological Health
<http://www.fda.gov/cdER/gppman.htm>
Email: dsma@fda.hhs.gov
Fax: 240-776-3151

(Tel) Manufacturers and International Assistance: 800-638-2041 or 240-276-3150

or

Office of Food Additive Safety
Center for Food, Safety and Applied Nutrition
(Tel) 301-435-1200
<http://www.cfsan.fda.gov/guidance.html>

or

Communications Staff, HFF-12
Center for Veterinary Medicine
(Tel) 240-276-9300
<http://www.fda.gov/cvm/guidance/published>

or

Good Clinical Practice Programs
Office of the Commissioner

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner (OC)
May 2007

GCP – E9 (Data Analysis)

GCDMP



Good Clinical Data Management Practices

Published April 2009

The need for Good Clinical Data Management Practices is not new. In the early 1970s, the Public Health Service recognized this need through a contract to a major research university for training of research data managers. However, the need continues, the need changes over time, and the need for good clinical data management practices has become even more important as biopharmaceutical and medical device industry and regulatory bodies rely more and more heavily on the evaluation of electronically transmitted clinical trials data for critical data-based decision making.⁷

Thus, the Society for Clinical Data Management provides the *Good Clinical Data Management Practices* to the SCDM membership.

This document constitutes neither consensus nor endorsement by regulatory agencies, pharmaceutical or biotech companies, contract research organizations or the academic community, but rather reflects the current views of SCDM membership. Additionally, none of the recommendations contained herein supersede regulations or regulatory guidelines, which should always be consulted prospectively to assure compliance. The document should not be considered an exhaustive list of topics.

SCDM
Society for Clinical Data Management

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Guidance for Industry E9 Statistical Principles for Clinical Trials

Additional copies are available from:

Office of Training and Communications
Division of Drug Information (HFD-240),
Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
<http://www.fda.gov/cder/guidance/index.htm>

or

Office of Communication, Training, and Manufacturers Assistance (HFM-40)
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike, Rockville, MD 20852-1448
<http://www.fda.gov/cber/guidelines.htm>; (Fax) 888-CBERFAX or 301-827-3844
(Voice Information) 800-835-4709 or 301-827-1800

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
September 1998
ICH

Society for Clinical Data Management

<http://www.scdm.org>

Society For Clinical Data Management - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites Home Print Mail Links

Address http://www.scdm.org/ Go

Society For Clinical Data Management

MEMBER LOGIN | Username: Password: GO

Conferences

2007 Fall Conference
SEPTEMBER 16-19, 2007
HYATT REGENCY CHICAGO
ON THE RIVERWALK
CHICAGO, ILLINOIS

2007 Fall Conference registration

2007 Fall Conference Sponsor and Exhibitor Online Application

EDC Project Life Cycle
Startup, Conduct, Closeout
Webinar Series 2
July 25, August 22 and September 26

Register today

Publications

Good Clinical Data Management Practices (GCDMP)
AVAILABLE NOW

Download the GCDMP by Chapter!

Lifetime Maintenance Plan
[GCDMP Comment Form](#)
Your input will be used by the Comments Review subcommittee to guide future revisions of the GCDMP.

DATA BASICS

Members may [click here](#) to view the latest Data Basics.

Professional Development

Elections for 2008 Board of Trustees

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RENEW MEMBERSHIP NOW

Certification
Certification exam now available.
CERTIFIED CLINICAL CDM DATA MANAGER
New members have joined the group of CCDMs »

CDM Employment

Unable to connect to preferred wireless network

Windows could not connect to any of your preferred wireless networks. Windows will keep trying to connect. To see a list of all networks, including others you can connect to, click this message

start guideline Society For Clinical D... guidelines EN 2:11 PM

Regulatory & Guidelines

GCDMP

Good Clinical Data Management Practices



October 2013 Edition



Recipient, 2007 Clinical Research Excellence Award
"Most Successful Company or Programme of the Year in
Raising GCP Standards" category

Society for Clinical Data Management

Contents

Executive Summary	2 pages	
Acknowledgements.....	2 pages	
Introduction	2 pages	
Data Privacy.....	Revised April 2009	14 pages
Data Management Plan.....	Added Dec 2008.....	16 pages
Project Management for the Clinical Data Manager	Added June 2010.....	24 pages
Vendor Selection and Management	Revised March 2010.....	24 pages
Data Management Standards in Clinical Research.....	Added July 2009.....	20 pages
Design and Development of Data Collection Instruments	Revised Oct 2010.....	18 pages
Edit Check Design Principles	Added Dec 2009.....	18 pages
Electronic Data Capture—Concepts and Study Start-up.....	Added Sep 2008.....	54 pages
Electronic Data Capture—Study Conduct.....	Added Sep 2008.....	24 pages
Electronic Data Capture—Study Closeout	Added Sep 2008.....	14 pages
CRF Completion Guidelines.....	Revised June 2008.....	8 pages
CRF Printing and Vendor Selection	Revised May 2007	8 pages
Database Validation, Programming, and Standards.....	Revised March 2009.....	20 pages
Laboratory Data Handling	Added Oct 2009	22 pages
External Data Transfers	Revised May 2007	14 pages
Patient-Reported Outcomes	Added July 2009.....	14 pages
CDM Presentation at Investigator Meetings.....	Revised July 2008.....	6 pages
Training.....	Revised May 2007	14 pages
Metrics in Clinical Data Management.....	Revised April 2011	20 pages
Assuring Data Quality.....	Revised Oct 2013	20 pages
Measuring Data Quality	Revised Sep 2008	12 pages
Data Storage.....	Revised May 2007	6 pages
Data Entry Processes.....	Revised Oct 2009	20 pages
Medical Coding Dictionary Management and Maintenance	Revised May 2009	16 pages
Safety Data Management and Reporting	Revised May 2007	22 pages
Serious Adverse Event Data Reconciliation	Revised Jan 2008	8 pages
Database Closure	Revised Oct 2013	12 pages
Clinical Data Archiving	Revised June 2008	10 pages
Glossary.....	Revised October 2013	32 pages

GCDMP

- Data Collection
- Data Acquisition
- Data Management Plan & Database Setup
- Data Entry
- Data Quality
- Data Security
- Data Storage, Archival & Transfer
- Training
- Project Management for DM

Good Clinical Data Management Practices



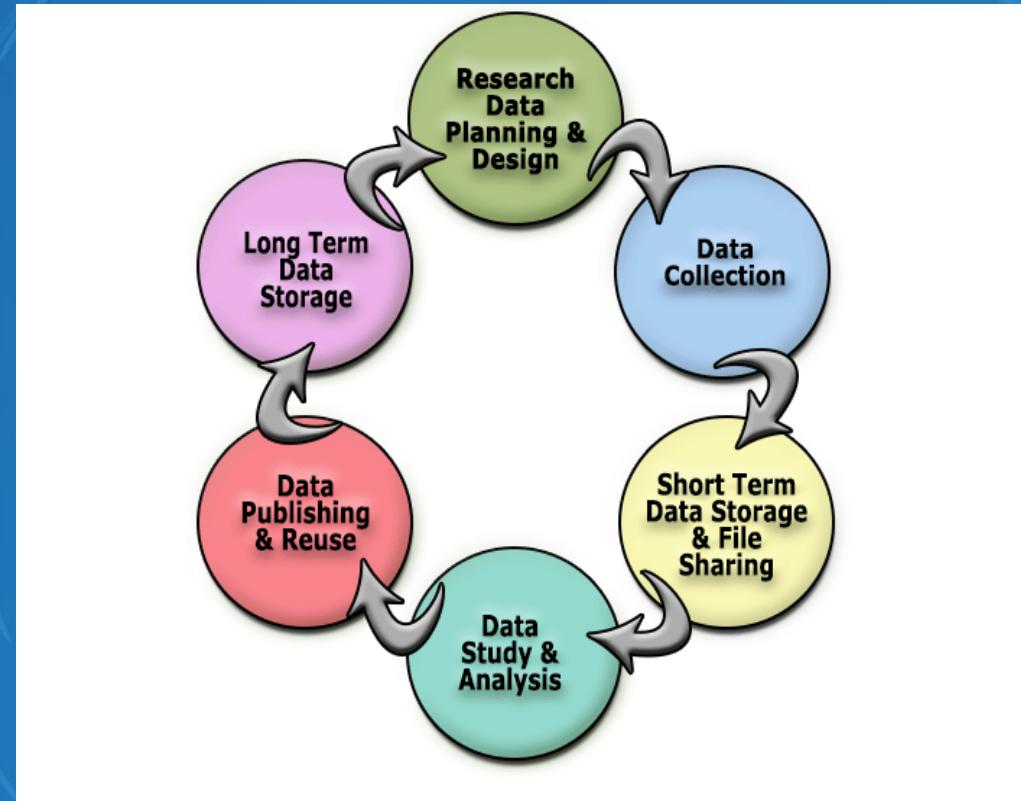
October 2013 Edition



Recipient, 2007 Clinical Research Excellence Award
"Most Successful Company or Programme of the Year in
Raising GCP Standards" category



Data Collection



Source Document & CRF

Hospital data collection form

Medical records

Laboratory results

CRF(s)

<p>QUEEN SIRIKIT NATIONAL INSTITUTE OF HEMATOLOGY - HEMOSTASIS LABO</p> <p>Clinical indication : HEMATOLOGY <input type="checkbox"/> Hemoglobin Typing</p> <p>QUEEN SIRIKIT NATIONAL INS CLINICAL MICROSCO</p> <p>Clinical indication : MS5 <input checked="" type="checkbox"/> Urinalysis Routine Urinanaly Color TAT Blood TAT</p> <p>QUEEN SIRIKIT NATIONAL INSTITUTE CLINICAL MICROSCOPY LAB</p> <p>Clinical indication IS1 <input type="checkbox"/> COMPLETE BLOOD COUNT HEMATOLOGY PROFILE <input checked="" type="checkbox"/> Hemoglobin <input checked="" type="checkbox"/> Hematocrit <input checked="" type="checkbox"/> White Blood Cell... corrected WBC <input checked="" type="checkbox"/> Platelet number <input checked="" type="checkbox"/> Red Blood Cell Differential count (%) Neutrophils Band Eosinophils Basophil</p>	FOLLOWUP FORM SURVEILLANCE OF HIV-POSITIVE PATIENTS AT BAMRASNARADURA HOSPITAL	
	I. IDENTIFYING INFORMATION	
	F100. Identification number assigned to patient:	UU - UUUU
	F101. Given name(s) of patient:	_____
	F102. Family name(s):	_____
	F103. Hospital number (H.N.):	_____
	F104. Date of visit: day <input type="checkbox"/> month <input type="checkbox"/> year <input type="checkbox"/> [2][5] <input type="checkbox"/> <input type="checkbox"/>	UUUUUU
	F105. Current ADDRESS:	UUUU
	II. DIAGNOSES	
	F200. AIDS Clinical status at this visit {1} Known to have AIDS before this visit {2} Known to have illness due to HIV - not diagnosed as AIDS {3} Known HIV-seropositive, not sick before this visit {4} No known HIV-related illness	U
F201. Presenting diagnoses: _____	UUUU.UU	
F202: _____	UUU.UU	
F203: _____	UUU.UU	
F204: _____	UUU.UU	
F205. New diagnoses this visit: _____	UUUU.UU	
F206: _____	UUU.UU	
F207: _____	UUU.UU	
F208. Status: {1} Admit {2} Home Alive {3} Dead	U	
III. TREATMENT THIS VISIT		
(202) INH (104) Itraconazole Other _____ F300 <input type="checkbox"/> <input type="checkbox"/> F306 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
(205) RF (102) Fluconazole Other _____ F301 <input type="checkbox"/> <input type="checkbox"/> F307 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
(204) PZA (105) Ketoconazole Other _____ F302 <input type="checkbox"/> <input type="checkbox"/> F308 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
(201) EMB (533) Clotrimazole troche Other _____ F303 <input type="checkbox"/> <input type="checkbox"/> F309 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
(301) ZDU (046) Cotrimoxazole Other _____ F304 <input type="checkbox"/> <input type="checkbox"/> F310 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
(302) DDI Other _____ F305 <input type="checkbox"/> <input type="checkbox"/> F311 <input type="checkbox"/> <input type="checkbox"/>	UUU.UU	
Drug adverse reaction: _____	F312 <input type="checkbox"/> <input type="checkbox"/> F314 <input type="checkbox"/> <input type="checkbox"/> F313 <input type="checkbox"/> <input type="checkbox"/> F315 <input type="checkbox"/> <input type="checkbox"/>	
IV. LABORATORY DATA AT THIS VISIT		
F400. Date of FACSCAN test	day <input type="checkbox"/> month <input type="checkbox"/> year <input type="checkbox"/> [2][5] <input type="checkbox"/>	
F401. Total White blood cells	UUU.UU/cc	
F402. Percent Lymphocytes	<input type="checkbox"/>	
F403. Total CD4+ Cells	UUU.UU cells/cc	
F404. Percent CD4+ cells	<input type="checkbox"/>	
F405. Total CD8+ Cells	UUU.UU cells/cc	
F406. Percent CD8+ cells	<input type="checkbox"/>	
F407. CD4+/CD8+ ratio	UUU.UU	

Source Document & CRF

QUEEN SIRIKIT NATIONAL INSTITUTE OF CHILD HEALTH

Form TPR & BI for DHF (ສິນການດໍາເລີນປາກ 9 ທະກິດໄສເມືອງ)

Date	Time	B.P.	T.	P.	R.	Hct	Treatment	Symptom	Remark	
18/11/23	10:50	93/60	39.5	126	32		9ipara			
	13:15							Hct 99%		
	14:00	108/63	38.6	136	30	371		Stool 3		
	16:50	150/90	40.5	128	30		oedema: Pandal (52) 126G U1			
	18:00	106/56	40	112	26		pmn ໂພນທຸກຄົນ	93		
	20:00			120		18%				
	21:15	120/80	39.8	120	28		ຝົນຕີ ສັບຜົນດີ 100c			
	22:30	115/57	38	122	28		ສັບຜົນ 50 c	64 64		
18/11/23	01:00	106/62	40.1	118	28		ຫຼັກ 80 cc + 100 cc	Melena		
	04:00		38.2	114	28		ຫຼັກ 50 cc			
	06:00	120/96	39	114	26			93		
	10:00	112/70	38.5	112	26	40/				
	14:00	115/70	36.5	98	26					
	18:00	109/77	36.5	102	24			55		
	22:00	100/70		108						
19/11/23	02:00	102/67	125							
	6:00	99/69	36.2	122	28			52		
	10:00	97/61	37	112	28	40/	ມູນຄາໂນ ລວມຄາ.			
	14:00	102/65		108						
	18:00	105/10	37	98	28			52		
	22:00	112/61	37	108	28					
20/11/23	02:00	104/60	36.5	104	24					
	6:00	100/67	32	107	26	40/		57		
	10:00	102/62		102						
CBC and LOFD							Maintenance Fluid			
Hct = 96 WBC = 3400							BW = 39.5 kgs. High = 133 cm. IBW =	Date of		
PR = 120/min Lym = St							M = 7000 ± 8000/mm ³ 19cc/kg	Day of		
ATL = 3							SI + 5%D = 3900 ± 1000/mm ³ 4cc/kg	T.T =		
							Bleeding			
Name: A.D. H.H. H.P. M.M. D.D.		Age: Yr. 6 Mo. D.	HN: 006691							
Department: Med		Ward: N 9 V	Attending Ph:							
Pulse: F=Full, M=Moderate, R=Rapid Pulse, N=No Palpable										

Date	Time	B.P.	T.	P.	R.	Hct
18/11/23	10:50	93/60	39.5	126	32	
	13:15					
	14:00	108/63	38.6	136	30	371
	16:50	150/90	40.5	128	30	
	18:00	106/56	40	112	26	
	20:00			120		18%
	21:15	120/80	39.8	120	28	
19/11/23	02:30	115/57	38	122	28	

Source Document & CRF

CRFs

- Patient demographic details → OPD
- Patient medical history → OPD, Form 108, Form 00, Form 01
- Patient physical exam & vital signs → PE, Form TPR, Form 02
- Concurrent medication & treatment details → Doctor Order, Form 54, LV Form
- Laboratory data / X-ray / serological data → Clinic Lab, Form 12, AFRIMS
- Diagnosis & Adverse Events → Form 42, Form 32
- Discharge / death status → Form 00/1, Death Form

Source Document (Patient/Hospital Records)

Source Document & CRF

Urine Pregnancy Log

URINE PREGNANCY TEST	
Site Code _____	
<input type="checkbox"/> Visit 1	Pregnancy Assay Kit _____
Date _____	Internal Control Valid _____
Time _____	Urine Pregnancy Test _____
Initial _____	LMP : _____
<input type="checkbox"/> Visit 3	Pregnancy Assay Kit _____
Date _____	Internal Control Valid _____
Time _____	Urine Pregnancy Test _____
Initial _____	Remark: _____
<input type="checkbox"/> Visit 5	Pregnancy Assay Kit _____
Date _____	Internal Control Valid _____
Time _____	Urine Pregnancy Test _____
Initial _____	LMP : _____
<input type="checkbox"/> Visit 7	Pregnancy Assay Kit _____
Date _____	Internal Control Valid _____
Time _____	Urine Pregnancy Test _____
Initial _____	Remark: _____
<input type="checkbox"/> Visit _____	Pregnancy Assay Kit _____
Date _____	Internal Control Valid _____
Time _____	Urine Pregnancy Test _____
Initial _____	LMP : _____
	Remark: _____

Vaccine Administration

VACCINE ADMINISTRATION FORM

Site Code _____ Date _____ PIN Number _____ Subject Initial _____ V3

STUDY AGENT ADMINISTRATION

Not Done (specify) _____

ALVAC	Time of Injection	Injection Site
ALVAC	24 hour clock hh:mm	<input type="checkbox"/> Left Deltoid <input type="checkbox"/> Other _____

ACUTE REACTOGENICITY ASSESSMENT

Observed for ≥ 30 minutes after injection? yes no (specify in Medical Record)

Local Reaction	ALVAC No local reactions <input type="checkbox"/>	Remarks
Pain/Tenderness	<input type="checkbox"/>	0 = None 1 = Mild 2 = Moderate 3 = Severe
Swelling	<input type="checkbox"/>	
Limitation of injected arm movement	<input type="checkbox"/>	
Induration	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Enter in millimeters
Erythema	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	

Systemic Reaction	No systemic reactions <input type="checkbox"/>	Remarks
Headache	<input type="checkbox"/>	0 = None 1 = Mild 2 = Moderate 3 = Severe
Fatigue	<input type="checkbox"/>	
Nausea and/or Vomiting	<input type="checkbox"/>	
Myalgia	<input type="checkbox"/>	
Arthralgia	<input type="checkbox"/>	
Rash	<input type="checkbox"/>	

Oral Temperature _____ °C

Analgesic/Antipyretic used? No Yes, (specify) _____

Completed by _____

Protocol RV 144 Version 4 Feb 03

Vaccination CRF - VADM

MoPH - TAVEG USAMRMC Second Vaccine Administration (VADM-2)

RV144 VADM 012

Site Code _____ Study Number _____ PIN _____ Date of Visit 3 dd mm yyyy Missed Visit

Completed by: _____ Signature/Date: _____ Urine Pregnancy Test: negative positive N/A(male subject) not done

STUDY AGENT ADMIN (ALVAC/LEFT) Not Done

24 hour clock	Injection site:
Reconstruction: <input type="checkbox"/> hh:mm	<input type="checkbox"/> Left Deltoid
Time of Injection: <input type="checkbox"/> hh:mm	<input type="checkbox"/> Other, specify: _____

ACUTE REACTOGENICITY ASSESSMENT: Observed for at least 30 minutes after injection? yes no

ALVAC—LOCAL (INJECTION SITE) LEFT

No local reactions <input type="checkbox"/>
Pain/Tenderness <input type="checkbox"/> <input type="checkbox"/>
Swelling <input type="checkbox"/> <input type="checkbox"/>
Limitation of injected arm movement <input type="checkbox"/> <input type="checkbox"/>
Induration <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> mm
Erythema <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> mm

SYSTEMIC REACTIONS Oral temperature: . °C No systemic reactions

Headache <input type="checkbox"/>	Nausea/ Vomiting <input type="checkbox"/>	Arthralgia <input type="checkbox"/>
Fatigue <input type="checkbox"/>	Myalgia <input type="checkbox"/>	Rash* <input type="checkbox"/>

Analgesic/Antipyretic used? no yes *Any rash must be described on AE CRF

CONFIDENTIAL: This material is the property of MoPH-TAVEG/USAMRMC, and may not be disclosed or used except as authorized in writing by said organization.

Page 4 Version #9.94 (draft), 12-Mar-03

Design and Development of Data Collection Instruments

Minimum Standards

- Design CRFs to collect the data specified by the protocol.
- Document the process for CRF design, development, approval, and version control.
- Document training of clinical site personnel on the protocol, CRF completion instructions and data submittal procedures prior to subject enrollment.
- Ensure CRFs are available at the clinical site prior to enrollment of subjects.

Design and Development of Data Collection Instruments

Best Practices

- Establish and maintain a library of standard forms and associated edit checks (CRFs, CRF completion guidelines, subject diaries, etc.).
- Use a multidisciplinary team to provide input into the CRF design and review processes.
- Consult the protocol, study biostatistician(s) or review the statistical analysis plan (SAP) (if available) to ensure all key endpoints are collected.
- Keep the CRF's questions, prompts, and instructions clear, concise and conformant to CDISC CDASH standards, where possible.
- Design the CRF to follow the data flow, taking into account the flow of study procedures.

CRF Design Process

- Content
- Logistic
- Format

LABCRATORY FORM			
1. Subject's ID _____			
2. Date of examination			
3. Sniff test (KOH 10% test)	(1) positive	(2) negative	
4. Candida sp.	(1) positive	(2) negative	
5. Trichomonas vaginalis	(1) positive	(2) negative	
6. Lactobacillus sp.	(1) decrease	(2) normal	
7. Clue cells	(1) positive	(2) negative	
8. Culture for Neisseria gonorrhoea	(1) positive	(2) negative	
9. CPR test for chlamydia trachomatis	(1) positive	(2) negative	
10. Sperm	(1) positive	(2) negative	
11. Conclusion of lab. Examination			
(1) normal			
(2) infection other than BV			
RPR / (3) BV positive			
12. (TPHA) positive (2) negative			
Lab. Technician ID number []			
<p>Tests 3,6 and 7 are done in the Clinic</p>			
<p>What significance will be attached to this observation?</p>			

CRF Design Process

Successfully treated : The sum of cases who were cured and who completed treatment (expressed as a percentage of the number registered in the cohort).

(Remark: According to the opinions of three chest physicians at Khon Kaen Medical School “successfully treated” in a clinical point of view should be used instead of cured. It may compose of the following characters:

- Completed treatment according to the given regimen and
- Absent of respiratory symptoms, e.g. cough, hemoptysis and
- Absent of constitutional symptoms, e.g. fever, weight loss, loss of appetite and
- Absent of active pulmonary lesion in chest x-ray. e.g. cavitary lesion.

B. The ultimate indicator at the end of treatment

43. Was the patient completed treatment as prescribed by the treating physician?

1. No (Go to question 50)

2. Yes, please specify duration of TB treatmentmonth.....week

44. Was there any report for the following symptoms/signs of the patient at the completion of tuberculosis treatment?

Respiratory symptoms

44.1 Cough 1. Yes 2. No

44.2 Hemoptysis 1. Yes 2. No

Constitutional symptoms

44.3 Fever 1. Yes 2. No

44.4 Loss of appetite 1. Yes 2. No

44.5 Weight loss 1. Yes 2. No

44.6 Weight gain 1. Yes 2. No

Operational definition

Items in CRF

CRF Design Process

Site Number	Subject Number	Chk	Initials
-------------	----------------	-----	----------

Pretest &
Version 1

15. ในช่วง 6 เดือนที่ผ่านมา ทำนิมเพศสัมพันธ์กับคุณนอนที่หานอยด้วยน้อยแค่ ไหน

(In the last six months, how often have you had sexual intercourse with your live-in partner? Would you say:)

- น้อยกว่าเดือนละครั้ง (Less than once a month)
- ทุกเดือนแต่ไม่ทุกสัปดาห์ (Every month, but not every week)
- ทุกสัปดาห์แต่ไม่ทุกวัน (Every week, but not every day)
- เกือบทุกวัน
- ไม่ทราบ
- ไม่ตอบ

Site Number	Subject Number	Chk	Initials
-------------	----------------	-----	----------

15. ในช่วง 6 เดือนที่ผ่านมา ทำนิมเพศสัมพันธ์กับคุณนอนที่หานอยด้วยน้อยแค่ ไหน

(In the last six months, how often have you had sexual intercourse with your live-in partner? Would you say:)

- ไม่มีเลข (None)
- น้อยกว่าเดือนละครั้ง (Less than once a month)
- ทุกเดือนแต่ไม่ทุกสัปดาห์ (Every month, but not every week)
- ทุกสัปดาห์แต่ไม่ทุกวัน (Every week, but not every day)
- เกือบทุกวัน (About every day)
- ไม่ทราบ (Don't Know)
- ไม่ตอบ (Non-response)

Revised &
Version 2

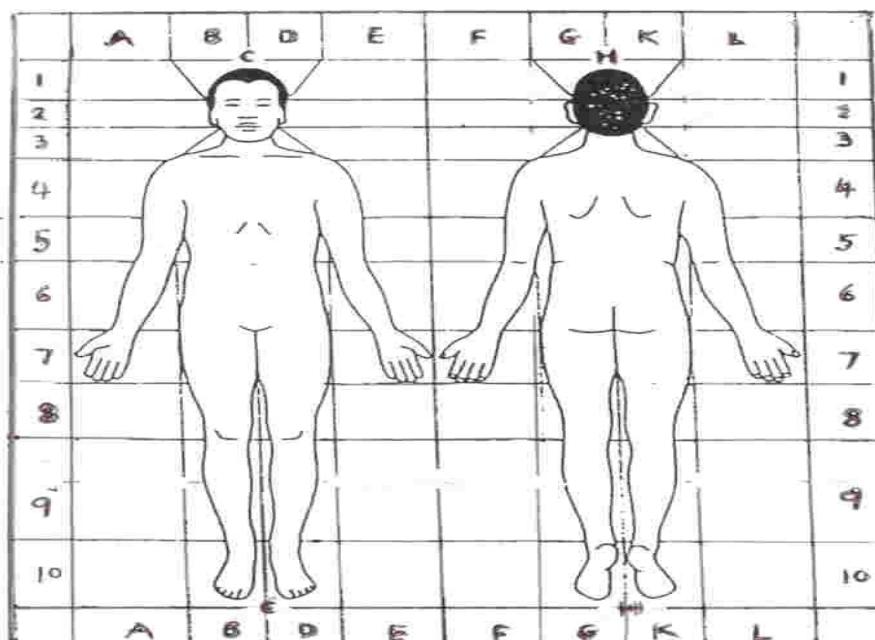
Form Design: Art & Science

Describe 1st detected lesion by the patient

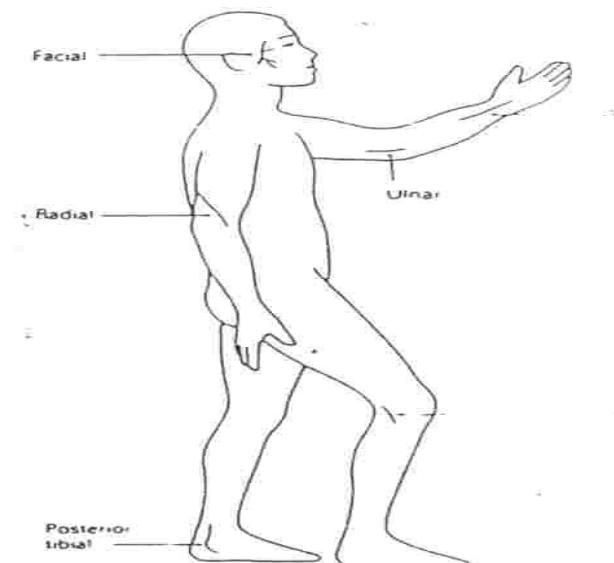
site _____ size _____ symptom _____

Mapping present lesions in to the diagram

- hypopigmented lesion
- erythematous raised shiny lesion



WEIGHT IN ADULTS



Happy Face Scale

Likert Type Scale

Visual Analogue Scale

Form Design: Art & Science

Please circle the face that best describes how well you feel today.



เข่าข้างที่ท่านปวดมากที่สุดในครั้งนี้		<input type="checkbox"/> 1 ข้างขวา	<input type="checkbox"/> 2 ข้างซ้าย	<input type="checkbox"/> 3 ทั้งสองข้าง									
อาการปวดข้อเข่า	ไม่ปวด เลย	ระดับอาการปวดข้อเข่า									ไม่สามารถ ทนไม่ได้	N/A	
		0	1	2	3	4	5	6	7	8	9		
1. ปวดข้อเข่าเฉื่อยๆ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2. ปวดข้อเข่าเฉื่อยๆ จนลงบันได	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Can you mark on the line the position which best represents the pain?

no pain
at all

worst pain you
can imagine

Item Design Technique

*Close-ended
Question
(Fixed choice)*

Long Term Influenza Prophylaxis with Inhaled Zanamivir or Oral Oseltamivir												HADS				
SEA004 (Study 082)						Hospital Anxiety & Depression Scale (HADS-pt21)						<input type="checkbox"/> V1	<input type="checkbox"/> V3	<input type="checkbox"/> V4	<input type="checkbox"/> V6	
Site No.			Participant No.			Date of Visit			<input type="checkbox"/> V8	<input type="checkbox"/> V10	<input type="checkbox"/> WD					
						<input type="checkbox"/> Day	<input type="checkbox"/> Month	2 0	Year							
HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS)																
1. คุณรู้สึกตึงเครียด				<input type="checkbox"/> 3 เป็นส่วนใหญ่	<input type="checkbox"/> 2 น้อยครั้ง											
				<input type="checkbox"/> 1 เป็นบางครั้ง	<input type="checkbox"/> 0 ไม่เป็นเลย											
2. คุณรู้สึกเพลิดเพลินใจกับสิ่งต่างๆที่มีความชอบอยู่ได้				<input type="checkbox"/> 0 เห็นใจเดิน	<input type="checkbox"/> 1 ไม่เห็นใจเดินต่อ											
				<input type="checkbox"/> 2 มีเพียงเล็กน้อย	<input type="checkbox"/> 3 เก็บไว้มีโดย											
3. คุณมีความรู้สึกล้าบ้านว่าตัวเองจะมีเรื่องไม่ดีเกิดขึ้น				<input type="checkbox"/> 3 มีและค่อนข้างรุนแรงตัวอย	<input type="checkbox"/> 2 มีแต่ไม่มากนัก											
				<input type="checkbox"/> 1 มีเพียงเล็กน้อยและไม่ทำให้กังวลใจ	<input type="checkbox"/> 0 ไม่มีเลย											
4. คุณสามารถหัวเราะและมีอารมณ์ขันในการเรื่องต่างๆได้				<input type="checkbox"/> 0 เห็นใจเดิน	<input type="checkbox"/> 1 ไม่เห็นใจเดิน											
				<input type="checkbox"/> 2 มีรือ	<input type="checkbox"/> 3 ไม่มีเลย											
5. คุณมีความกังวลติดกันจัด				<input type="checkbox"/> 3 เป็นส่วนใหญ่	<input type="checkbox"/> 2 น้อยครั้ง											
				<input type="checkbox"/> 1 เป็นบางครั้ง แต่ไม่รือ	<input type="checkbox"/> 0 นานๆครั้ง											
6. คุณรู้สึกเมื่อไถบินนาน				<input type="checkbox"/> 3 ไม่มีเลย	<input type="checkbox"/> 2 ไม่รือบ้าน											
				<input type="checkbox"/> 1 เป็นบางครั้ง	<input type="checkbox"/> 0 เป็นส่วนใหญ่											
7. คุณสามารถทำให้ตัวตามตามสายและรู้สึกผ่อนคลาย				<input type="checkbox"/> 0 ได้ดีมาก	<input type="checkbox"/> 1 ได้ดีอยู่ทั่วไป											
				<input type="checkbox"/> 2 ไม่รือบ้าน	<input type="checkbox"/> 3 ไม่ได้ดีเลย											
8. คุณรู้สึกว่าตัวเองคิดอะไร ทำอะไร เชื่องช้ำลงกว่าเดิม				<input type="checkbox"/> 3 เก็บใจตลอดเวลา	<input type="checkbox"/> 2 น้อยมาก											
				<input type="checkbox"/> 1 เป็นบางครั้ง	<input type="checkbox"/> 0 ไม่รีบเลย											
9. คุณรู้สึกไม่สามารถทำให้ปั่นป่วนในห้อง				<input type="checkbox"/> 0 ไม่มีเลย	<input type="checkbox"/> 1 เป็นบางครั้ง											
				<input type="checkbox"/> 2 ค่อนข้างรือ	<input type="checkbox"/> 3 น้อยมาก											
10. คุณเปลี่ยนเนื้อร่องร่องตัวไม่สามารถใช้ติดต่อ				<input type="checkbox"/> 3 ใช่	<input type="checkbox"/> 2 ไม่ค่อยใช้เท่าที่ควร											
				<input type="checkbox"/> 1 ใช้ใจน้อยกว่าเดิม	<input type="checkbox"/> 0 บ้างใจเดนอย่างหรือเดิน											
11. คุณรู้สึกกระซิบกระซิบต่างหากว่าตนจะขอซู่นี่ๆไปได้				<input type="checkbox"/> 3 เป็นมากที่เดียว	<input type="checkbox"/> 2 ค่อนข้างมาก											
				<input type="checkbox"/> 1 ไม่รือบ้าน	<input type="checkbox"/> 0 ไม่รีบเลย											
12. คุณมองสิ่งต่างๆในอนาคตด้วยความเบิกบานใจ				<input type="checkbox"/> 0 มากกว่าที่เคยเป็น	<input type="checkbox"/> 1 ค่อนข้างรือยกว่าที่เคยเป็น											
				<input type="checkbox"/> 2 น้อยกว่าที่เคยเป็น	<input type="checkbox"/> 3 เก็บใจไม่รีบ											
13. คุณรู้สึกพอใจตอกใจขึ้นมาอย่างกระพันหัน				<input type="checkbox"/> 3 น้อยมาก	<input type="checkbox"/> 2 ค่อนข้างรือ											
				<input type="checkbox"/> 1 ไม่รือบ้าน	<input type="checkbox"/> 0 ไม่มีเลย											
14. คุณรู้สึกเพลิดเพลินไปกับการต่อานหนังสือ ฟังวิทยุหรือ ดูโทรทัศน์ หรือกิจกรรมอื่นๆที่เคยเพลิดเพลินได้				<input type="checkbox"/> 0 เป็นส่วนใหญ่	<input type="checkbox"/> 1 เป็นบางครั้ง											
				<input type="checkbox"/> 2 ไม่รือบ้าน	<input type="checkbox"/> 3 น้อยมาก											
คะแนนรวมจากการวัดกังวล (ข้อ 1, 3, 5, 7, 9, 11, 13) <input type="checkbox"/>													คะแนนรวมจากการชี้มีครัว (ข้อ 2, 4, 6, 8, 10, 12, 14) <input type="checkbox"/>			
Signature: _____													Date: <input type="checkbox"/> 2 0 <input type="checkbox"/>			
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													Draft, 03-Jan-08			

Item Design Technique

Close-ended Question (Check all that apply)

เอกสารโครงการวิจัย Measurement of Anogenital Wart Burden and Cost of Illness in Bangkok																																									
Site	Subject No.	Initials																																							
<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>																																							
<input type="checkbox"/> Check if SRS																																									
<input type="checkbox"/> D0 <input type="checkbox"/> D7 <input type="checkbox"/> M1 <input type="checkbox"/> M3 <input type="checkbox"/> M6 <input type="checkbox"/> Missed Visit																																									
Date of Assessment <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> 2 5 <input type="checkbox"/> <small>กม ๒๕ กม</small>																																									
การตรวจร่างกาย การวินิจฉัยโรคและแผนการรักษา (เพศหญิง)																																									
1. กุญแจระบุตำแหน่งที่เกิดหูด <table border="1" style="float: left; margin-right: 20px;"> <tr><td></td></tr> <tr><td>1 2 3</td></tr> <tr><td>4 5</td></tr> <tr><td>6 7</td></tr> <tr><td>8 9</td></tr> <tr><td>10 11</td></tr> <tr><td>12 13</td></tr> <tr><td>14 15</td></tr> <tr><td>16 17</td></tr> <tr><td>18 19</td></tr> <tr><td>20 21</td></tr> <tr><td>22</td></tr> </table> <table border="1" style="float: left; margin-right: 20px;"> <tr><td>Female Pelvic</td></tr> <tr><td><input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</td></tr> <tr><td><input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6</td></tr> <tr><td><input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9</td></tr> <tr><td><input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12</td></tr> <tr><td><input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15</td></tr> <tr><td><input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18</td></tr> <tr><td><input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21</td></tr> <tr><td><input type="checkbox"/> 22</td></tr> </table> <table border="1" style="float: left; margin-right: 20px;"> <tr><td></td></tr> <tr><td>1 2 3</td></tr> <tr><td>4 5 6</td></tr> <tr><td>7 8 9</td></tr> <tr><td>10 11 12</td></tr> <tr><td>13 14 15</td></tr> <tr><td>16 17 18</td></tr> <tr><td>19 20 21</td></tr> <tr><td>22</td></tr> </table> <table border="1" style="float: left;"> <tr><td>Cervix</td></tr> <tr><td><input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3</td></tr> <tr><td><input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6</td></tr> <tr><td><input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9</td></tr> <tr><td><input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12</td></tr> <tr><td><input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15</td></tr> <tr><td><input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18</td></tr> <tr><td><input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21</td></tr> <tr><td><input type="checkbox"/> 22</td></tr> </table>				1 2 3	4 5	6 7	8 9	10 11	12 13	14 15	16 17	18 19	20 21	22	Female Pelvic	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6	<input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9	<input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	<input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15	<input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18	<input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21	<input type="checkbox"/> 22		1 2 3	4 5 6	7 8 9	10 11 12	13 14 15	16 17 18	19 20 21	22	Cervix	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6	<input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9	<input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	<input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15	<input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18	<input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21	<input type="checkbox"/> 22
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16 17 18																																									
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<input type="checkbox"/> 22																																									
2. คุณเคยตั้งครรภ์หรือไม่ <input type="checkbox"/> ₁ เคย ตั้งครรภ์.....ครั้ง <input type="checkbox"/> ₀ ไม่เคย <input type="checkbox"/> ₁ บุตรมีชีวิต.....คน <input type="checkbox"/> ₂ แท้งอ่อน.....ครั้ง <input type="checkbox"/> ₃ ทำแท้ง.....ครั้ง																																									
Abdomen <input type="checkbox"/> ₀ Normal <input type="checkbox"/> ₁ Abnormal, specify <input type="checkbox"/> ₁ RUQ <input type="checkbox"/> ₂ LUQ <input type="checkbox"/> ₃ RLQ <input type="checkbox"/> ₄ LLQ																																									

Item Design Technique

*Open-ended
question*

Serious Adverse Event Report **SAE2** **AE**

Long Term Influenza Prophylaxis with Inhaled Zanamivir or Oral Oseltamivir

SEA004 (Study 082) **Adverse Events (AE-plt61)**

Site No. Participant No.

Page of

Check if None:

Check if last page in series

ADVERSE EVENTS

AE# Adverse Event _____

Start Date **End Date** **If less than 24 hrs, list duration** :
 Day Month Year Day Month Year hh mm

Severity
 1=Mild
 2=Moderate
 3=Severe
 4=Life-threatening

Relationship to Study Drug
 1=Unrelated
 2=Partially recovered
 3=Possible
 4=Probable
 5=Definitely

Outcome
 1=Recover completely
 2=Partially recovered
 3=Deteriorated
 4=Permanently damaged
 5=Ongoing
 6=Death*

SAE?
 No
 Yes**

AE# Adverse Event _____

Start Date **End Date** **If less than 24 hrs, list duration** :
 Day Month Year Day Month Year hh mm

Severity
 1=Mild
 2=Moderate
 3=Severe
 4=Life-threatening

Relationship to Study Drug
 1=Unrelated
 2=Partially recovered
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 4=Probable
 5=Definitely

Outcome
 1=Recover completely
 2=Partially recovered
 3=Deteriorated
 4=Permanently damaged
 5=Ongoing
 6=Death*

SAE?
 No
 Yes**

AE# Adverse Event _____

Start Date **End Date** **If less than 24 hrs, list duration** :
 Day Month Year Day Month Year hh mm

Severity
 1=Mild
 2=Moderate
 3=Severe
 4=Life-threatening

Relationship to Study Drug
 1=Unrelated
 2=Partially recovered
 3=Possible
 4=Probable
 5=Definitely

Outcome
 1=Recover completely
 2=Partially recovered
 3=Deteriorated
 4=Permanently damaged
 5=Ongoing
 6=Death*

SAE?
 No
 Yes**

* Complete FINAL-CRF, ** Complete SAE-CRF
 Signature: _____
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 Date: **2 0**

Draft, 03-Jan-08

Item Design Technique

Fixed vs. Open Lab Units

Long Term Influenza Prophylaxis with Inhaled Zanamivir or Oral Oseltamivir										BCHEM						
 SEA004 (Study 082)					 Biochemistry (BCHEM-plt32)					<input type="checkbox"/> V1 <input type="checkbox"/> V4 <input type="checkbox"/> V6 <input type="checkbox"/> V8 <input type="checkbox"/> V11 <input type="checkbox"/> WD <input type="checkbox"/> ILI						
Site No.		Participant No.		Date of Sample Collection			Date of Visit									
<input type="text"/>		<input type="text"/>		<input type="text"/>	<input type="text"/>	2	0	<input type="text"/>	<input type="text"/>	2	0					
				Day	Month	Year	Day	Month	Year							
BIOCHEMISTRY																
Test	Result						Units									
a. Glucose	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
b. Urea nitrogen (BUN)	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
c. Creatinine	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
d. Direct bilirubin	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
e. Total bilirubin	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
f. Total protein	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	g/dL				
g. Albumin	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	g/dL				
h. Alkaline phosphatase (ALP)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	IU/L				
i. Aspartate aminotransferase (AST)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	IU/L				
j. Alanine aminotransferase (ALT)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	IU/L				
k. Total cholesterol	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
l. Triglyceride	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmol/L				
m. Sodium (Na)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmol/L				
n. Potassium (K)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmol/L				
o. Chloride (Cl)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmol/L				
p. Total CO ₂ (bicarbonate)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmol/L				
q. Calcium total (Ca)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
r. Magnesium	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
s. Creatine phosphokinase (CPK)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	IU/L				
t. Lipase	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg/dL				
Any results clinically significant?	<input type="checkbox"/> Yes, please complete AE-CRF						<input type="checkbox"/> No									
Signature: _____										Date:	<input type="text"/>	<input type="text"/>	<input type="text"/>	2	0	<input type="text"/>
This document is the property of University of Oxford, UK. Its content is confidential. Any reproduction, transfer or use of information contained herein is strictly prohibited.																
Draft, 03-Jan-08																

Schedule for Data Collection

DATA COLLECTION FORMS SCHEDULE

02-01-00
10-20-99

STUDY 366 - YEAR 1

X = Required form
V = May be required

	WEEKS →	ON STUDY DRUG										OFF STUDY DRUG			
		4	8	12	16	20	24	32	40	48	52	Premature Discontinuation	Toxicity Endpoint	Virologic/Clinical Endpoint	Follow Up
• NE4141(366)	Trail Making A and B		V		V		V			V			V	V	
• NE4142(366)	CES Depression Scale Scoring		V		V		V			V			V	V	
• NE4143(366)	Profile of Mood States Scoring		V		V		V			V			V	V	
• NE4144(366)	Auditory Verbal Learning Test - Revised		V		V		V			V			V	V	
• NE4145(366)	Play Performance Scales		V		V		V			V			V	V	
• NE4146(366)	Woodcock Johnson Tests of Cognitive Ability		V		V		V			V			V	V	
• NE4147(366)	Preschool Cancellation Test		V		V		V			V			V	V	
• NE4148(366)	Seidel Continuous Attention Test (SCAT)		V		V		V			V			V	V	
PKW0126(366)	PACTG 366 Pharmacokinetics II	X		X							X				
SPW0079(366)	Clinic Immunology Specimen Tracking ⁴			X ⁴		X ⁴			X ⁴	X ⁴					
SPW0123(366)	CMV Specimen and Results Tracking														
SSW0005(366)	Cutaneous Toxicity Evaluation	X	X	X	X	X	X	X	X	X	X				
TXW0065(366)	PACTG 366 Treatment Record ⁵	X	X	X	X	X	X	X	X	X	X				
FF1600R(366)	Off Study ^{5,6}														
FF3002	Virology Specimen Tracking Form		X	X	X	X	X	X	X	X	X				
FF3102(366)	Plasma HIV-1 RNA Tracking		X	X	X	X	X	X	X	X	X				
FF3103(366)	Plasma HIV-1 RNA Results II		X	X	X	X	X	X	X	X	X				
PE0009(366)	CBC HIV Clinical Classification for Children < 13 Years of Age ⁷	X	X	X	X	X	X	X	X	X	X				
PE0031(366)	Pediatric Measurements II			X	X	X	X	X	X	X	X				
PE0410(366)	Concomitant Medications	X	X	X	X	X	X	X	X	X	X				
PE4005(366)	Permanent Discontinuation of Study Drugs II ⁵														

⁴ Send with immunology samples for subjects in immunology subset only.

⁵ Must be keyed within 48 hours - Yellow Forms.

⁶ Located in section labeled "Off Study."

⁷ Complete either the PE0009 or the PE5809, depending on subject's age.

CRF Completion

SEA_0001 CRF COMPLETION INSTRUCTIONS

SEA_0001 CRF COMPLETION INSTRUCTIONS

General

Please

Serology Laboratory Form (LABSEROL)

TEXT

1. C

This form is used to record influenza serology results from hemagglutination inhibition (HI) and neutralization assays (NA). One form is used for a single participant only.

2. A
site

First row: please fill in study site number, participant number, the date the form is completed and the identification number of the lab where serology is performed (see page 1). These data can be found in the Catalyzer database.

3. W

4. A
C Hemagglutination inhibition(HI): the HI results are recorded under items 1 through 5.

Item 1: record here the date HI is performed. In case HI is not performed for a specific participant for whatever reason, please tick not done. If Not Done, leave 2-5 blank.

C

5. E
b
W Item 2: tick here which type of red blood cells is used for HI: guinea pig, goose, horse, human O cells. In case other red blood cells are used, specify these in writing in CAPITALS on the designated line.

Items 3-5: here the titers are recorded for up to three different study days of the same participant. First state the date of collection and the aliquot number used (data retrieved from Catalyzer database). In the next column record the HI titer for the four antigens listed. In case the titer is <10, fill in 0000. In case the titer is >5120, fill in 9999. In case one or more antigens are not tested, tick 'not done' behind the corresponding antigen(s).



Data Acquisition



Simple Work /Data Flow Between DMU and Clinical Sites

3 Clinical Sites

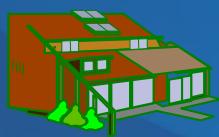
Complete CRFs



Verification Source CRFs



Verification & Correction into both CRFs & QCs



3 Sites copy all completed CRFs & Fill out CRF Binder Log Monthly

Mail the whole CRF package to DMU via Postal Parcel.



Fax only Corrected QCs to DMU by dial long distance call



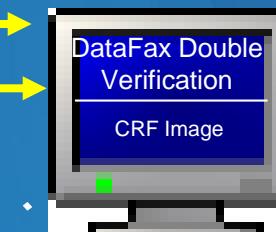
DMU faxes long distance QCs to each provincial clinical sites within 7 days



DMU

- Summary Report
- DataSets for Sub-study Analysis (Per Request)

Study Reports



Edit Check

Primary Data Base

Error

Data Clarification Report

No Error

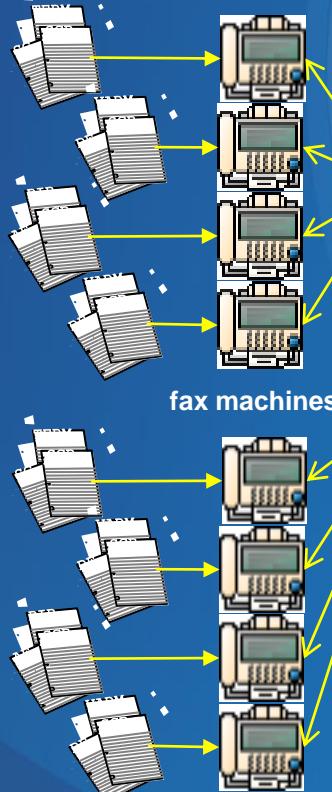
Clean Data Sets/ Transport Files

Work /Data Flow Using Leased Line Connecting with DMU

Specimen Processing Centre & Central Laboratory



Provincial Centers

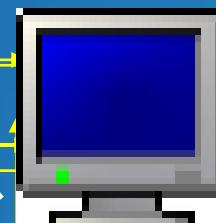


DMU - Data Management Unit

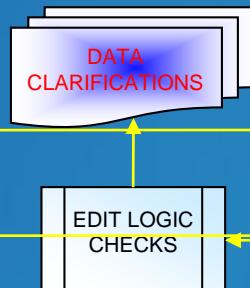


Ministry of Public Health
Study Center &
Study Collaborators

RAYONG



Primary Data Base

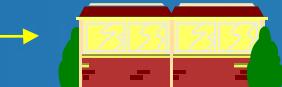


SAS Data Sets/
Transport Files

BANGKOK
THAILAND

DMU Study
Monitoring
Reports

Independent Statistician Team



Data Coordinating And Analysis Center



MedDRA Coding Team



MARYLAND,
U.S.A

Work /Data Flow for Electronic Data Capture (EDC)

Clinical Sites complete their own Source Documents.



Each Site is doing his/her own Data Entry to the Electronic CRFs using iDataFax



Each Site is resolving his/her own queries through iDataFax



Encrypted Data transferred through an INTERNET to DMU

Database is backup on a daily basis

Data Clarification will be flagged to any problem fields



DMU validates the data.

No Error

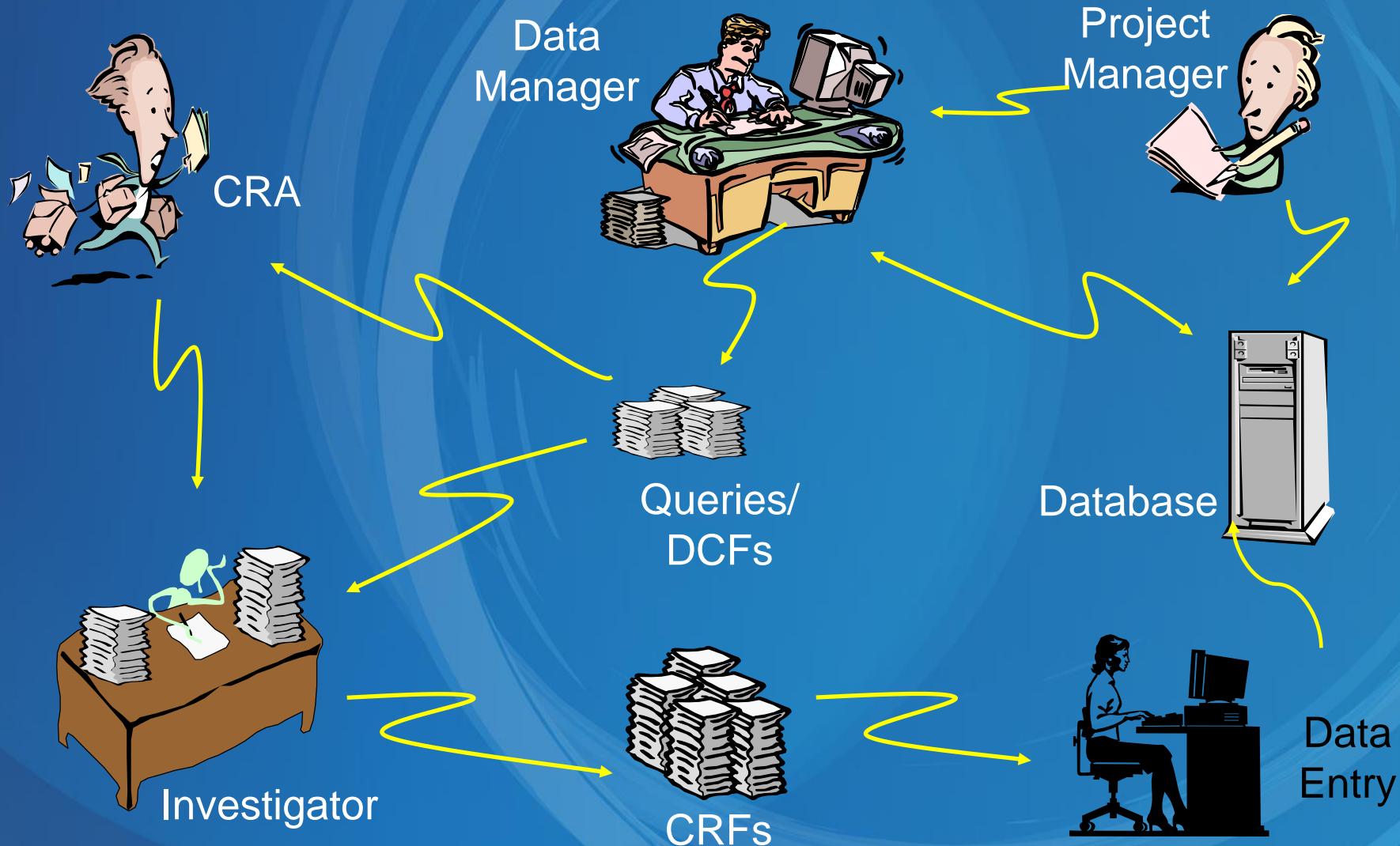
Clean Data Set

Error

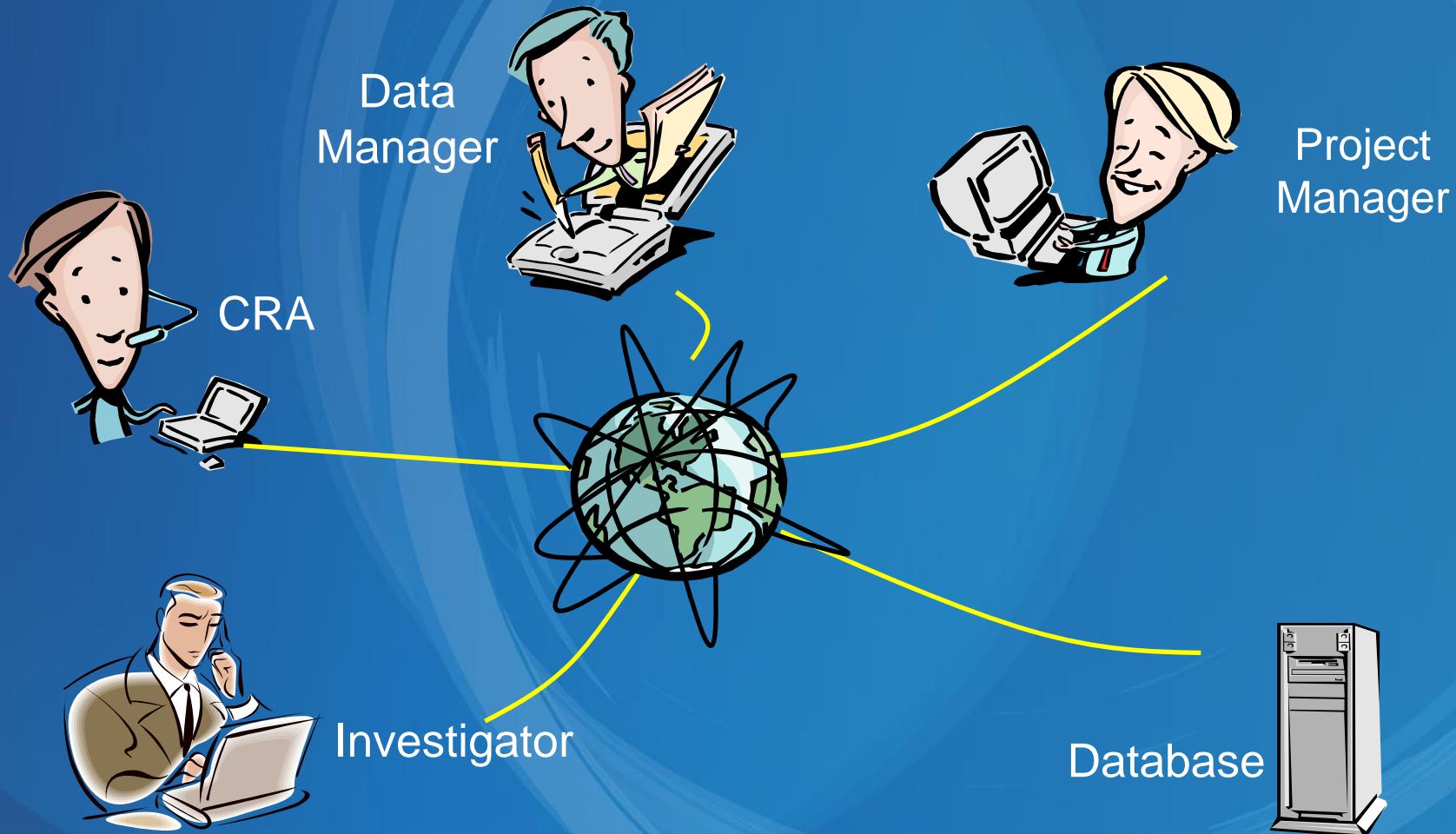
- Summary Report
- DataSets for Sub-study Analysis (Per Request)

Exported Data Per requested Format. (i.e. SPSS, Microsoft Excel)

Comparing Paper-based vs. EDC

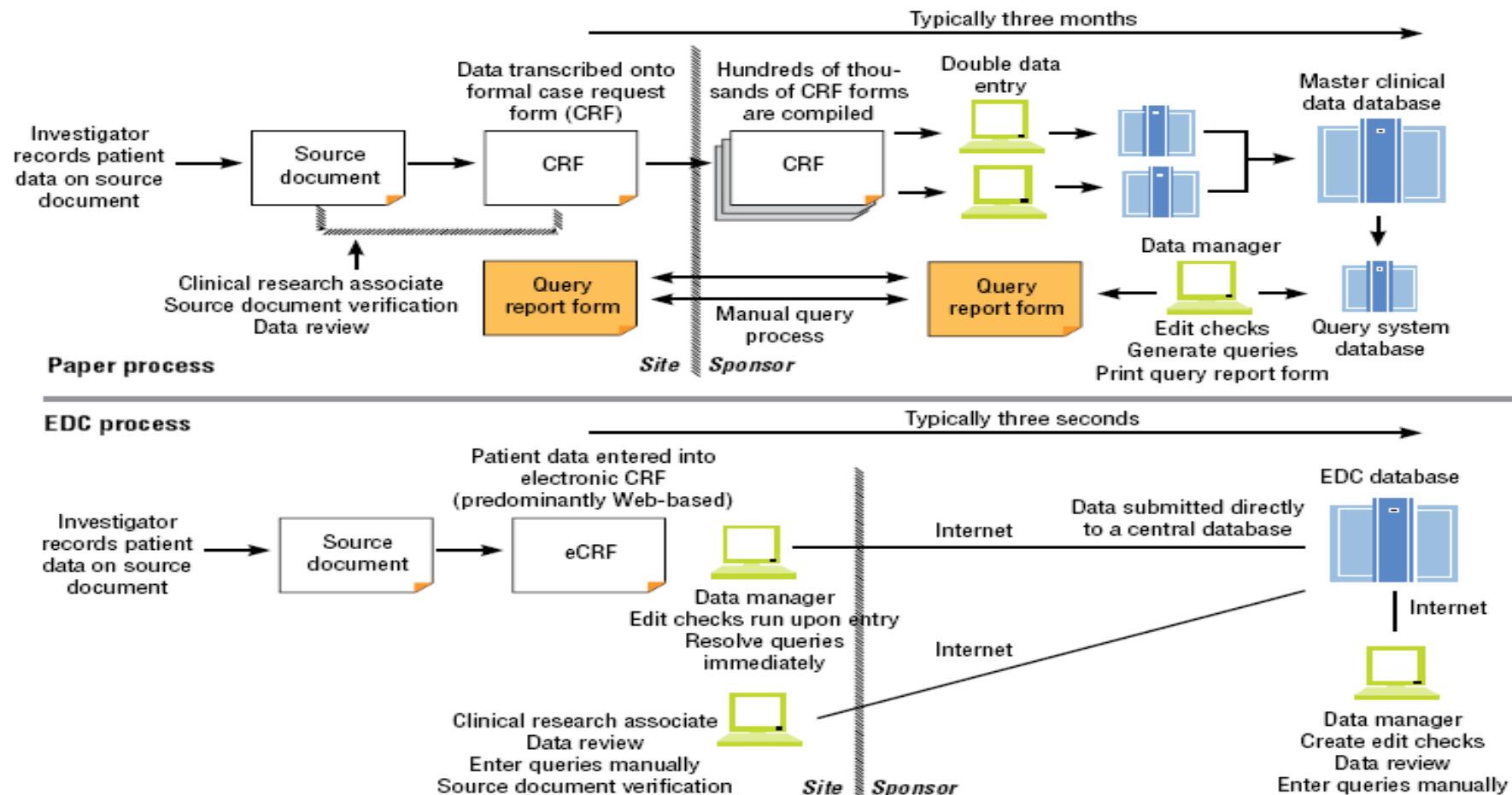


Comparing Paper-based vs. EDC



pCRF vs. eCRF

Figure 3. Using EDC is more accurate and faster than using paper-based methods to collect clinical trial data.



Source: IBM Global Business Services, 2005.

pCRF vs. eCRF

Paper-based CRF

DFValidate [datafax] TSRR101

Site: Screening No.: Initials: วันที่เข้าสู่ระบบ: 18/01/2549 ชั่วโมง: 08:00 ผู้ดูแล: 30/01/8491

เพศ: Male Female อายุ (ปี): 54 วันเดือนปี: 30/01/8491

คุณสมบัติที่ผู้เข้าร่วมต้องมีเพื่อเข้าร่วมในการทดลอง (INCLUSION CRITERIA)

หากตอบ “ใช่” จึงให้ประเมิน ซึ่งว่าทุกประวัติพัฒนาทางการแพทย์ ให้ตรวจสอบอย่างเข้มข้นที่สุด

- อายุมากกว่า 18 ปี
- ผู้เข้าร่วมต้องไม่มีประวัติแพ้ยาที่รักษา
- มีลักษณะไข้ต่ำๆ 48 ชั่วโมง
- สามารถท่องหนังสือได้ด้วยตนเอง
- ไม่ทราบว่ามีไข้หรือไม่
- สามารถอ่านภาษาไทยได้ดีกว่า 30 นาที โดยไม่เสียการบันทึกหรือรีบเริง
- ผู้เข้าร่วมต้องเข้ารับการศึกษา

คุณสมบัติที่ผู้เข้าร่วมไม่ต้องมีเพื่อเข้าร่วมในการทดลอง (EXCLUSION CRITERIA)

หากตอบ “ใช่” จึงให้ประเมินที่ก้าบที่ไม่ใช่ว่าทุกประวัติพัฒนาทางการแพทย์ ให้ตรวจสอบอย่างเข้มข้นที่สุด

- มีอาการทางการแพทย์ที่ไม่สามารถตัดสินใจได้ เช่น ผู้ป่วยมีผลเสื่อม ภาวะไว้ใจฟ้าฟ้าหัวใจ หัวใจเต้นเร็ว
- โรคติดต่อร้ายแรง
- มีภาวะทางจิต เช่น ใจหลอน
- มีภาวะทางการแพทย์อื่นๆ ที่อาจก่อให้เกิดความเสี่ยง

7. หมายเหตุทั่วไป

ผู้เข้าร่วมต้องระบุ Study Number 0003
ไม่ผ่านการคัดกรอง

รายชื่อผู้รักษา/รับยา: _____

เอกสารนี้เป็นแบบฟอร์มที่ต้องการให้ผู้เข้าร่วมต้องอ่านและทำความเข้าใจอย่างดี ก่อนที่จะลงนามในแบบฟอร์มนี้

TSRR101 SCR (page 1) Week 0

Site: Screening No.: Initials: วันที่เข้าสู่ระบบ: 18/01/2549 ชั่วโมง: 08:00 ผู้ดูแล: 30/01/8491

เพศ: Male Female อายุ (ปี): 54 วันเดือนปี: 30/01/8491

คุณสมบัติที่ผู้เข้าร่วมต้องมีเพื่อเข้าร่วมในการทดลอง (INCLUSION CRITERIA)

หากตอบ “ใช่” จึงให้ประเมิน ซึ่งว่าทุกประวัติพัฒนาทางการแพทย์ ให้ตรวจสอบอย่างเข้มข้นที่สุด

- อายุมากกว่า 18 ปี
- ผู้เข้าร่วมต้องไม่มีประวัติแพ้ยาที่รักษา
- มีลักษณะไข้ต่ำๆ 48 ชั่วโมง
- สามารถท่องหนังสือได้ด้วยตนเอง
- มีลักษณะไข้ต่ำๆ 48 ชั่วโมง
- สามารถท่องหนังสือได้ดีกว่า 30 นาที
- ผู้เข้าร่วมต้องเข้ารับการศึกษา

คุณสมบัติที่ผู้เข้าร่วมไม่ต้องมีเพื่อเข้าร่วมในการทดลอง (EXCLUSION CRITERIA)

หากตอบ “ใช่” จึงให้ประเมินที่ก้าบที่ไม่ใช่ว่าทุกประวัติพัฒนาทางการแพทย์ ให้ตรวจสอบอย่างเข้มข้นที่สุด

- มีอาการทางการแพทย์ที่ไม่สามารถตัดสินใจได้ เช่น ผู้ป่วยมีผลเสื่อม ภาวะไว้ใจฟ้าฟ้าหัวใจ หัวใจเต้นเร็ว
- โรคติดต่อร้ายแรง
- มีภาวะทางจิต เช่น ใจหลอน
- มีภาวะทางการแพทย์อื่นๆ ที่อาจก่อให้เกิดความเสี่ยง

7. หมายเหตุทั่วไป

ผู้เข้าร่วมต้องระบุ Study Number 0003
ไม่ผ่านการคัดกรอง

Reason for Data Value

Missing Value

eCRF (EDC)

DAILY1 (pt 81) 1003 D1 D2 D3 D4 D5 D6 D7 Study Day Missed Visit Not Done

Site No. Participant No. Assessment Date 505001 / / year

DAILY ASSESSMENT FORM 1

Day 1 is the day after first dose of study drug.
Study day is the actual day of the assessment for hospital days and follow-up visits.

- Time of assessment: _____
- Presence of symptoms within the last 24 hours: Check if all not assessed

2a. Diarrhea	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2b. Nausea	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2c. Vomiting	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2d. Myalgia	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2e. Cough	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2f. Rash	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2g. Short of breath	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2h. Chest pain	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2i. Confusion	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2j. Convulsions / seizures	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2k. Coma	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
2l. Other symptoms	<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Not Assessed
- If Yes, specify: _____
- Hospitalization:

3a. Is participant currently hospitalized?	<input type="radio"/> Yes → Skip to question 3c	<input type="radio"/> No
3b. Is this the first assessment since discharge?	<input type="radio"/> Yes, Date of discharge: / / year	→ Skip to question 4
3c. Is participant in ICU?	<input type="radio"/> Yes	<input type="radio"/> No
3d. Mechanical Ventilation/Intubation	<input type="radio"/> Yes	<input type="radio"/> No
3e. Supplemental Oxygen	<input type="radio"/> Yes, Percent of oxygen (FiO ₂): _____ %	<input type="radio"/> No
3f. Transcutaneous arterial saturation	<input type="radio"/> Room air	<input type="radio"/> Supplemental O ₂
1. Performed: _____

Save Final Incomplete Pending view only permission

Electronic Data Capture – Minimum Standards

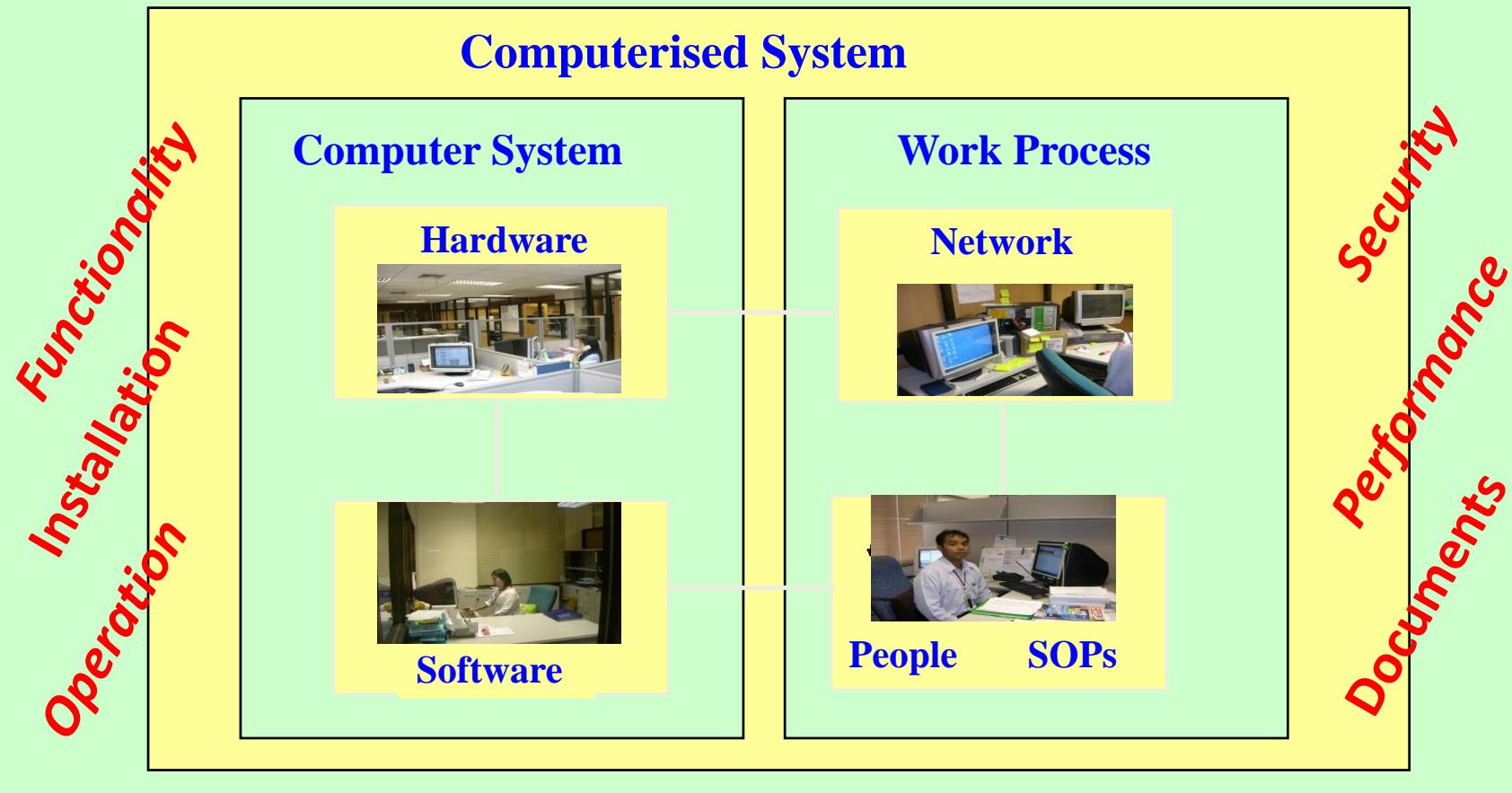
- Ensure compliance with 21 CFR 11
- Stated quality standards should support the utilization of automated data capture, management and archiving.
- Ensure requirements are defined for data transfers and integration with other systems.
- Software systems validation should be scheduled and completed prior to EDC study implementation.
- Verify training is provided for all users of the EDC systems
- Verify access to data is limited to authorized individuals.
- Ensure sites have access and control of data up to database lock.

Electronic Data Capture – Best Practices

- Ensure systems are user-friendly and flexible for data entry.
- Ensure EDC systems do not restrict answers site staff can provide in a way that introduces bias into the study.
- Ensure adequate edit check procedures and query management tools are built into EDC software.
- Ensure data can be traced from the time of original input through the reporting and analysis files via easily accessible audit trails.
- Ensure your EDC system integrates as needed with other databases
- Ensure change control procedures include complete documentation.
- Provide an instruction manual for study workflow processes.
- Provide training customized to each user's role.

21CFR Part 11 – IT System

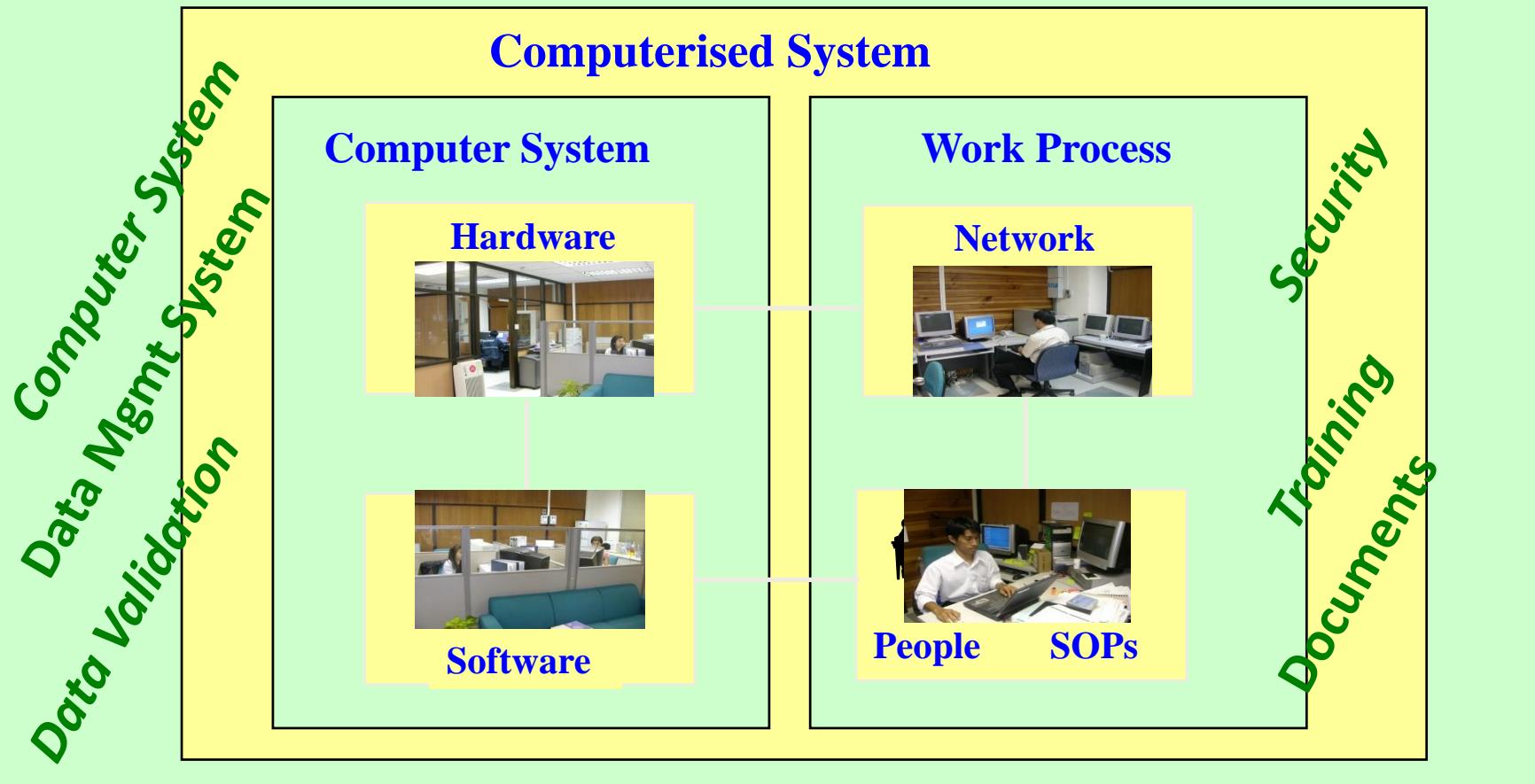
GxP System Environment



Source: Validation Principles for GxP Regulated Computerized Systems, <http://www.gcp.suite.dk/slides.ppt>

21CFR Part 11 – CDMS

GxP System Environment



Source: Validation Principles for GxP Regulated Computerized Systems, <http://www.gcp.suite.dk/slides.ppt>

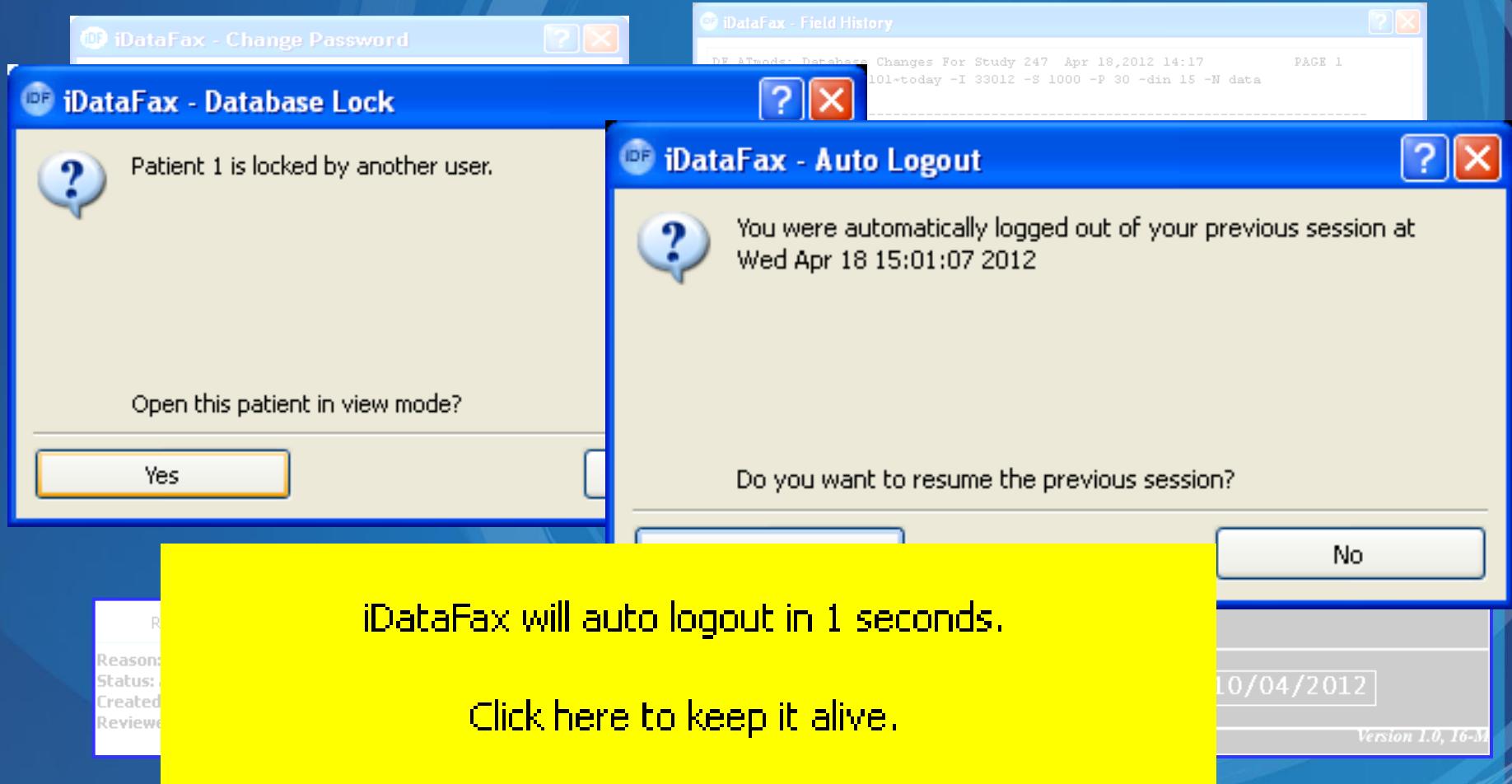
Password Policy

- US-FDA 21 CFR Part 11 Compliance including e-signatures, audit trails, and rules for password complexity, aging and notification



System Authentication

- US-FDA 21 CFR Part 11 Compliance including e-signatures, audit trails, and rules for password complexity, aging and notification



Record Repository & Time Stamps

RV144_SAS_export - Notepad

File Edit Format View Help

```
RECORD 11
1 DFSTATUS DataFax Record Status
2 DFVALIDID DataFax Validation Level
3 DFERASTER DataFax Raster Name
4 DFSTUDY DataFax Study Number
5 DFPLATE DataFax Plate Number
6 vadm1_visit1 Visit Number
```

RV144_SAS_export.d02 - Notepad

File Edit Format View Help

20001		2		1		0340/0002001		144		11		0100		WARA		210002		01/09/2003		1 10 05 10 20 1 1 1 1 1 1 1 1 1 1 37.0 1 2 03/10/10 11:03:05 03/10/10 11:03:05
20005		2		2		0340/0003055		144		11		0100		SKSK		210105		29/08/2003		0 09 00 15 00 1 1 1 1 1 1 1 1 1 1 38.0 2 2 03/10/09 17:52:01 03/10/09 17:52:01
20006		1		2		0341/0002002		144		11		0100		RUNT		201073		29/09/2003		1 10 05 10 30 1 1 1 1 1 1 1 1 1 1 37.3 0 1 03/10/10 14:31:50 03/10/10 14:31:50

30 vadm1_vac1s8 VADM1-nausea/vomiting
31 vadm1_vac1s9 VADM1-myalgia
32 vadm1_vac1s10 VADM1-arthralgia
33 vadm1_vac1s11 VADM1-rash
34 vadm1_vac1s12 VADM1-analgesic
35 DFSCREEN DataFax Screen Status
36 DFCREATE DataFax Create Stamp
37 DFMODIFY DataFax Modify Stamp

RECORD 12
1 DFSTATUS DataFax Record Status

Electronic Signatures

DFstatus [rawee] RV148

File Actions Help

Server Status
DataFax Master is running on PB
Study Server is running on PB
Number of records awaiting validation 0
Number of records being validated 0

User Status

User	Display	Tool	? On Since	In Use
waraporn	192.168.1.40:	Validation Tool	A Thu Jan 22 14:31:23 2004	0
rawee	192.168.1.43:	QC Tool	A Thu Jan 22 14:29:47 2004	0
rawee	192.168.1.43:	Status Tool	A Thu Jan 22 14:39:22 2004	0

Database Status

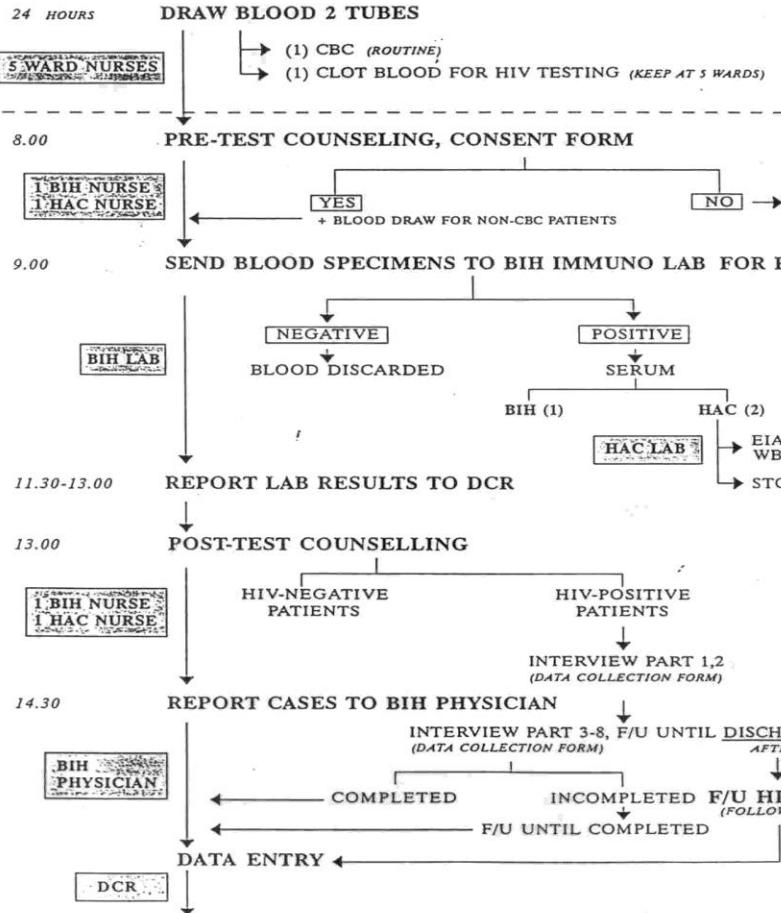
Centers ...
Patient Ids ...
Visits ...
Plates ...

Level	Clean	Dirty	Error	CLEAN	DIRTY	ERROR	Lost	Total	In Use
1	6	0	0	0	0	0	0	6	0
2	0	0	0	0	0	0	0	0	0
3	692	0	0	20	1	0	0	713	0
4	1655	6	0	55	308	5	0	2029	0
5	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0
Total	2353	6	0	75	309	5	0	2748	0
P Total	2359	2359	S Total	384	389				

Last update: Thu Jan 22 14:39:26 2004

Standard Operating Procedure (SOP)

**TENTATIVE FLOW CHART
SURVEILLANCE OF HIV-POSITIVE PATIENTS AT BIH
(HIV/AIDS COLLABORATION : BIHCART.CH3, 17 NOV. 1993)**



**Thai Stroke
Rehabilitation
Registry SOP**

การปฏิบัติงานของแต่ละ Clinical site

Doc. No.: TSR-001-00

Rev. No.: 00

Date: มีนาคม 2549

Page 2 of 5

1.0 วัตถุประสงค์

เพื่อขอรับใบอนุญาตและรายละเอียดการปฏิบัติงาน สำหรับใช้ในการบันทึกข้อมูลใน CRF ให้ตรงกันในแต่ละ Clinical Site

2.0 ขอบเขตการปฏิบัติงาน

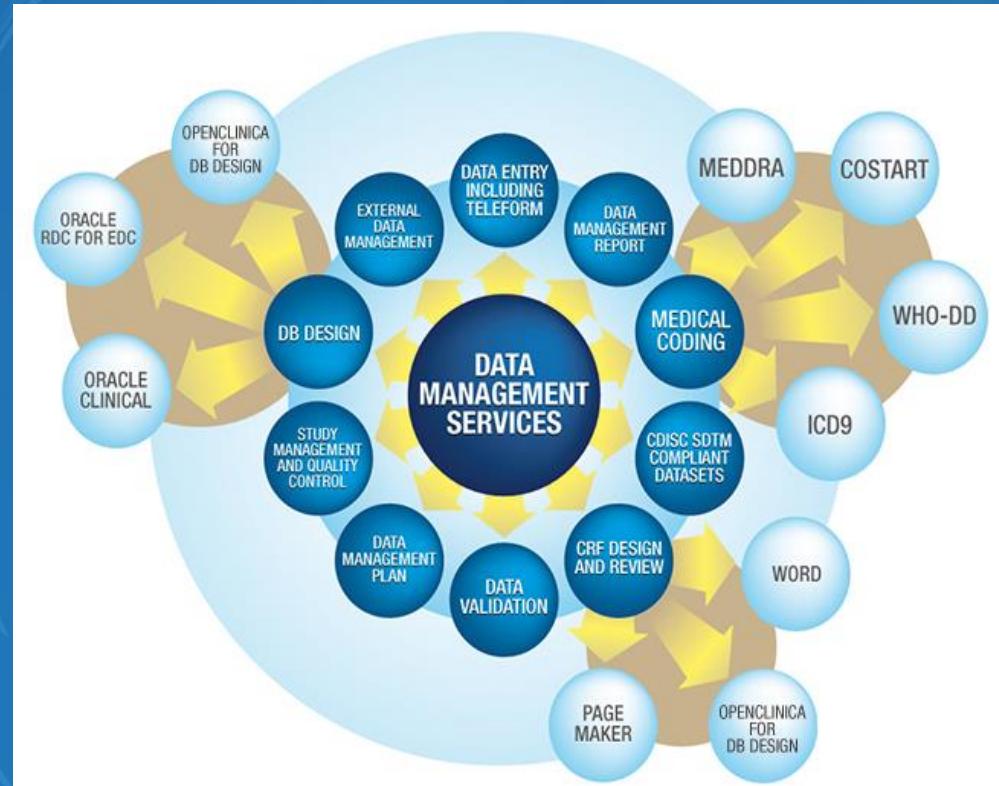
ขอบเขตการปฏิบัติงานจะครอบคลุม เอกพากเจ้าหน้าที่ หรือ หน่วยงาน ที่มีส่วนเกี่ยวข้องในการปฏิบัติงานในโครงการศึกษาวิจัย TSRR เท่านั้น โดย SOP จะบันทึกไว้รวมถึงการปฏิบัติงานตามอื่นที่ไม่เกี่ยวข้องกับโครงการ

3.0 หน้าที่รับผิดชอบ

TSRR PI	ผู้อำนวยการโครงการมีหน้าที่บริหารจัดการโครงการวิจัยให้เป็นไปตามมาตรฐาน GCP
PI	มีหน้าที่บริหารการจัดเก็บข้อมูลในแต่ละ site ให้เป็นไปอย่างถูกต้องตามมาตรฐาน GCP
Research assistant	มีหน้าที่เก็บข้อมูลตามที่ PI แต่ละ site กำหนด
ราชวิทยาลัยแพทย์ เวชศาสตร์ทันตแพทย์ ประภะเภสัช	สถาบันฯ ลงทุนที่ปรึกษาที่ประสานงานระหว่างโรงพยาบาลที่เข้าร่วมทำวิจัยทั้งหมด

4.0 เอกสารแนบ

4.1 ตารางกาหนดเวลา site (เอกสารแนบท้าย)



Data Management Plan

Database Setup

Data Management Plan - Minimum Standards

- Complete a draft of the DMP prior to enrollment of the first subject.
- Ensure the DMP supports compliance with applicable regulations and oversight agencies.
- Identify and define the personnel and roles involved with decision making, data collection, data handling and data quality control.
- Ensure data management processes are described and defined from study initiation until database closeout.

Data Management Plan - Best Practices

- Develop the DMP in collaboration with all stakeholders to ensure that all responsible parties understand and will follow the processes and guidelines
- Develop and maintain a DMP template for the organization that ensures consistency and standardization across all projects.
- Ensure the DMP for each study is kept current, including proper versioning, and that all responsible parties are aware of and agree to the current content.
- Ensure that an approved, signed version of the DMP is completed prior to starting on the work it describes.

Data Management Plan (DMP)

DMU

แผนการบริหารจัดการข้อมูล



สารบัญ

หน้า	
1.0 คำจำกัดความ	3
2.0 ผู้ดำเนินงานวิจัย	4
3.0 เจ้าหน้าที่หน่วยบริหารฐานข้อมูล	5
4.0 องค์การเพื่อการวิจัยโดยวิธีสัญญาชั้งงาน	5
5.0 วัตถุประสงค์ของโครงการ	6
6.0 โปรแกรมสำหรับบริหารจัดการข้อมูล	6
7.0 แผนกวิชา	6
8.0 วิธีดำเนินการวิจัย	7
9.0 แบบสอบถาม/เอกสารที่ใช้ในงานวิจัย	8
10.0 การรับ-ส่ง CRF ระหว่าง DMU และ Clinical Site	10
11.0 โครงการสร้างระบบฐานข้อมูล	10
12.0 การนับทีกและการตรวจสอบข้อมูล	12
13.0 การเก็บไขข้อมูล	13
14.0 การ Lock ข้อมูล	13
15.0 การแก้ไขข้อมูลที่ Lock แล้ว	13
16.0 การรักษาความปลอดภัยของข้อมูล	13
17.0 การเก็บสำรองข้อมูล	14
18.0 การจัดเก็บข้อมูล	14
19.0 การจัดเก็บเอกสารของโครงการ	14
20.0 การจัดส่งข้อมูล	14
21.0 แผนผังการทำงาน เอกสารแนบ	15
	15

Statistical Analysis Plan

CONFIDENTIAL-RV144
DRAFT Data Analytic Plan
Exhibit Listing
December 2, 2003

CLINICAL STUDY PROTOCOL
A PHASE III TRIAL OF AVENTIS PASTEUR LIVE RECOMBINANT
ALVAC-HIV (vCP1521) WITH VAXGEN gp120 B/E (AIDSVAX B/E)
BOOSTING IN HIV-UNINFECTED THAI ADULTS

DRAFT

DATA ANALYSIS PLAN
EXHIBIT LISTING

SAP Table of Content

1. Introduction
2. Study Design And Plan
 - 2.A. Study Design
 - 2.B. Selection Of Study Population
 - 2.C. Study Vaccines/Drugs and Placebos and Their Administration
3. Objectives, Hypotheses, and Study Endpoints
 - 3.A. Objectives
 - 3.A.1. Primary Objective
 - 3.A.2. Secondary Objectives
 - 3.B. Hypotheses
 - 3.B.1. Primary Hypotheses
 - 3.B.2. Secondary Hypotheses
 - 3.C. Study Endpoints
 - 3.C.1. Primary Efficacy Endpoint
 - 3.C.2. Secondary Endpoints

4. Analysis Populations
5. Protocol Implementation
 - 5.A. Randomization and Blinding
 - 5.A.1. Method of Assigning Subjects to Study Groups
 - 5.A.2. Blinding Procedures
6. Interim Data Monitoring
7. Analysis
 - 7.A. Enrollment and Baseline Characteristics
 - 7.B. Safety
 - 7.C. Risk Behaviors
 - 7.D. Efficacy Analysis
 - 7.D.1. Methods
 - 7.D.2. Primary Efficacy Results
 - 7.E. Additional Analyses

Data Management Standards in Clinical Research

Minimum Standards

- Use the most current version of any standard, if appropriate.
- Use standards required by regulatory agencies in the country where the study is conducted.
- Do not modify published standards.

Data Management Standards in Clinical Research

Best Practices

- Use accepted standards whenever possible, and strive for interoperability.
- Use all standards recommended by regulatory agencies in the locale of the study.
- Review implementation guidelines for any standard having associated guidelines documents.

- Clinical Data Acquisition Standards Harmonization (CDASH)
- Laboratory Model (LAB)
- Operational Data Model (ODM)
- Study Data Tabulation Model (SDTM)
- Analysis Dataset Model (ADaM)

CDISC

For more information about CDISC, visit <http://www.cdisc.org/>.

CDISC *MedDRA*
HL 7 *SNOMED*
ICD 9 /10 *WHO DD*

Clinical Data Interchange Standards Consortium

<http://www.cdisc.org>

Standard Domains Study Data Tabulation Model (SDTM)

The SDTM contains the following domains and respective codes, which fall into six general categories.

- Special Purpose Domains

- Demographics (DM)
- Comments (CO)
- Subject Elements (SE)
- Subject Visits (SV)

- Interventions

- Concomitant Medications (CM)
- Exposure (EX)
- Substance Use (SU)

- Events

- Adverse Events (AE)
- Disposition (DS)
- Medical History (MH)
- Protocol Deviations (DV)

- Trial Design Domains

- Trial Arms (TA)
- Trial Elements (TE)
- Trial Visits (TV)
- Trial Inclusion/Exclusion Criteria (TI)
- Trial Summary (TS)

- Special Purpose Relationship Datasets

- Supplemental Qualifiers (SUPPQUAL)
- Related Records (RELREC)

- Findings

- ECG Test Results (EG)
- Inclusion/Exclusion Criterion Not Met (IE)
- Laboratory Test Results (LB)
- Physical Examinations (PE)
- Questionnaires (QS)
- Subject Characteristics (SC)
- Vital Signs (VS)
- Drug Accountability (DA)
- Microbiology Specimen (MB)
- Microbiology Susceptibility Test (MS)
- Pharmacokinetic Concentrations (PC)
- Pharmacokinetic Parameters (PP)
- Findings About (FA)

REGISTRATION NOW OPEN FOR THE CDISC D

Italy - Register by 24 September

New SENDIG v3.1 Draft B Now Available

Review - Comments due 10 September

BECOME A MEMBER MEMBER | USER LOGIN

Medical Dictionary for Regulatory Activities (MedDRA)

TABLE 4: Frequency of Serious Adverse Events by MedDRA System Organ Class

System Organ Class (SOC)	Frequency	Percent
Injury, poisoning and procedural complications	758	39.21
Infections and infestations	464	24.00
Pregnancy, puerperium and perinatal conditions	197	10.19
Gastrointestinal disorders	140	7.24
Psychiatric disorders	47	2.43
Nervous system disorders	44	2.28
General disorders and administration site conditions	26	1.35
Reproductive system and breast disorders	16	0.83
Respiratory, thoracic and mediastinal disorders	16	0.83
Renal and urinary disorders	16	0.83
Cardiac disorders	14	0.72

Database Structure

Features of Database Management System:

- Ease of data entry
- Automatic data validation
- Automatic error checking
- Alternative is a stack of paper forms

Multi-Table Relational Database:

- Eliminates redundancy
- Ensures data integrity

Source Docs (CRFs) & Data Files Design

one

1. ENROLLMENT FORM		No. [] [] --- [] []
I. PERSONAL INFORMATION		
H.N.	[] [] [] [] [] []	
Name of patient.....	[] [] [] [] [] []	
Sex 1. Male 2. Female	[]	
Address Province.....	[] [] [] - [] [] [] []	
Date of Birth (d-m-y)	[] [] [] - [] [] [] []	
Date of enrollment (d-m-y)	[] [] [] - [] [] [] []	

many

2. FOLLOW UP FORM		No. [] [] --- [] []
I. PERSONAL INFORMATION		
H.N.	[] [] [] [] [] []	
Name of Patient.....	[] [] [] [] [] []	
Province.....	[] [] [] [] [] []	
Date of visit (d-m-y)	[] [] [] - [] [] [] []	
Current Status 1. Inpatient 2. Outpatient	[]	

many

4. CARE TAKERS		No. [] [] --- [] []
I. PATIENT (CHILD) INFORMATION		
H.N	[] [] [] [] [] [] []	
Name of patient.....	[] [] [] [] [] [] []	
Date of visit (d/m/y)	[] [] - [] [] [] []	

one

3. PATIENT'S DEATH		No. [] [] --- [] []
H.N.	[] [] [] [] [] [] []	
Name of patient.....	[] [] - [] [] [] []	
Date of death (d/m/y)	[] [] - [] [] - [] []	

Database Validation, Programming and Standards - Minimum Standards

- Ensure the CDMS meets user/functional and regulatory requirements
- Implement the CDMS carefully, testing according to specifications, documenting all testing and issues
- Ensure documentation remains complete and current.
- Ensure that only qualified staff develop, maintain and use the system.

Database Validation, Programming and Standards - Best Practices

- Confirm that study-specific programming applications perform as intended based on the user requirements (data management plan requirements, CRF requirements, database specifications, edit check specifications, validation plan, etc.).
- Confirm accuracy, reliability, performance, consistency of processing and the ability to identify invalid or altered records. Confirm through testing and document.
- Confirm that the study-specific application has been configured properly.

Related Documents about Validation

*Data Spec
Data Entry
Edit Check*

คู่มือรหัส, คุณสมบัติ และค่าของตัวแปร
โครงการประสิทธิภาพของการพื้นฟูสมรรถภาพ
สำหรับผู้ป่วยโรคหลอดเลือดสมองระยะกึ่งเฉียบพลัน

DMU

ลักษณะการแก้ไขปรับปรุงเอกสาร: 0
วันที่แก้ไขปรับปรุงเอกสาร: 4 พฤษภาคม 2549

DMU

คู่มือตรวจสอบและป้อนข้อมูล

โครงการประสิทธิภาพของการพื้นฟูสมรรถภาพ
สำหรับผู้ป่วยโรคหลอดเลือดสมองระยะกึ่งเฉียบพลัน

คู่มือตรวจสอบความผิดพลาดของข้อมูล

โครงการประสิทธิภาพของการพื้นฟูสมรรถภาพ
สำหรับผู้ป่วยโรคหลอดเลือดสมองระยะกึ่งเฉียบพลัน

ออกสาร: 01
ราช: 4 พฤษภาคม 2549

ลักษณะการปรับปรุงเอกสาร: 01
วันที่ปรับปรุงเอกสาร: 22 มีนาคม 2549

Related Documents about CDMS



LIST OF STANDARD OPE

DMS

- Data Management Plan
- Study Set up
- Database Access Control
- Database Design & Testing
- Data Validation & Programming
- Data Entry & Verification
- Data Discrepancy & Resolution Management
- Database Quality assessment
- Database Lock
- SAS Programming Practice
- SAS Program Validation

QAS

- Document Control
- Document Access
- Quality Assurance Procedure
- Internal Audit of IT & DM Sections
- Training & Qualification
- General Change Control

G-010 Ethics Committee Review

ITS

- System Change Control
- Software Version Control
- Physical & Logical Security
- Backup & Archive
- Disaster Recovery

Edit Check Design – Minimum Standards

- Finalize protocol and complete initial database specifications prior to designing edit checks.
- Specify edit checks based on parameters of case report form (CRF)
- Specify edit checks for all primary study endpoints data.
- If applicable, specify edit checks with external data (e.g., laboratory data) for reconciliation purposes.
- Ensure all edit checks are programmed, validated, and documented
- Ensure all edit checks specification documents are appropriately version controlled.
- Provide training to relevant personnel on the impact of edit checks on their individual roles in entering and managing clinical data.

Edit Check Design – Best Practices

- Review edit checks with appropriate clinical and statistical personnel to ensure edit checks meet study needs and help identify inconsistencies in study endpoints.
- Develop a library of standard CRFs and edit checks based on standards used, such as CDASH
- Perform a quality control review of edit check design and specifications prior to performing user acceptance testing (UAT) of edit checks.
- Evaluate the effectiveness of edit checks once in active use, and modify, delete or create new edit checks accordingly.

Type of Data Checks

Type of check	Front-end check	Back-end check
Missing values	X	
Missing CRF pages	X	X
Range checks	X	
Checks for duplicates	X	X
Logical inconsistencies across single CRF	X	
Inconsistencies across CRF pages or modules		X
Checks of external data		X
Protocol violations	X	X

Example of Edit Check

CRF	Field Name (Number)	Check Name	Edit Check	Edit Check Message
ENROLL	Subject ID (2)	DUP_REC	Duplicate subject ID number	This subject ID number has already been assigned for this site. Please confirm correct ID number.
DEMOG	Subject ID (2)	NO_SUBJ_ID	Missing subject ID number	A subject ID number has not been entered for this record.
DEMOG	Subject DoB (6)	INVLD_AGE	Subject age is out of range	The date of birth value entered may be invalid. Please confirm correct date of birth.

Edit Check Requirements

Form	Form	Section	Item	Check with			Specification/ Detail	Type of question		
				Form	Section	Item		Inconsistent (recheck)	Confirm	Additional information
DEM-plt1	Patient Dem	IEC-plt2	4.2) Empirical therapy: nosocomial infection with failure of previous treatment	PANTI-plt15	Previous AB therapy	previous AB therapy	If 4.2 or 4.3 or 4.4 are selected, previous anti AB page much be "yes" and provide previous AB treatment and if 4.4 is selected, check with initial culture at study entry must has an organism ESBL-producing strain in the table	x	x	
IEC-plt2	Elig Crite		4.3) Modified therapy: known pathogens with resistance to cephalosporin, aminoglycoside, fluoroquinolone or beta-lactam / betalactamase inhibitor and susceptible to carbapenem	PANTI-plt15	Previous AB therapy	previous AB therapy				
	Elig Crite		4.4) Modified therapy: known infection caused by ESBL-producing gram negative bacteria	PANTI-plt15, MBIOS-plt30	Previous AB therapy, Culture at study entry	previous AB therapy, oraganism at initial culture				

From Edit Check Requirements to Validation Plan

Validation Plan : Edit_Checking Document

Version 4.0 : 17 Mar 2011

Influenza Vaccine in Healthy Thais Part B

DAILYB

GPO Flu Vaccine-1 Part B(SE029)			At Day7 and Day 28: Must have page PIRLB1, PIRLB2, PIRSB1 and PIRSB2 (Day 7 must mark as 1st immunization, Day 28 must mark as 2nd immunization on these pages)				<input type="checkbox"/> 1 st Immunization	<input type="checkbox"/> 2 nd Immunization			
Site	Part	Study No.	<input type="checkbox"/>	day	month	2 0 <input type="checkbox"/> year	<input type="checkbox"/> Day 7	<input type="checkbox"/> Day 28			
study No: - check against with all pages - check no duplicate number with others subject			<input type="checkbox"/>			<input type="checkbox"/> Day 42	<input type="checkbox"/> Day 60	<input type="checkbox"/> Missed Visit	<input type="checkbox"/> Not Done		
DAILY ASSESSMENT											
1. Vital Signs											
1a. Temperature		<input type="checkbox"/> . <input type="checkbox"/>		°C		<p>-If missed visit is marked, Date of visit on header and all data must leave blank (N/A). -If Not done is marked, Date of visit on header should be provided and leave blank all data. These are applies for all pages.</p>					
1b. Pulse		1b. Query if outside 056-110		ts per minute							
1c. Blood Pressure		Systolic	1c. systolic -Query if outside 80-160		Diastolic					1c. Diastolic -Query if outside 50-120	
1d. Respiratory rate		1d. Query if outside 14-28		s per minute							

Manual Queries

1. Medication Name

GLIBENCLAMIDE

2. Formulation



capsule

gel

iDataFax - Edit Query

Site: 3, Patient: 300002, Assessment: No. 02, Page: 3201 MED #02

Field: 9. Reason-other,specify

Reported Value: HYPERTENSION

Problem: Inconsistent

Status:

Details: P

Note:

Reply: [REDACTED] 08-Feb-2012 11:45:02

9. Reason for therapy = Other specify : Type 2 Diabetes Mellitus

Status: Resolved corrected

Created: [REDACTED] 27-Jan-2012 13:41:11

Modified: [REDACTED] 10-May-2012 14:42:46

Resolved: [REDACTED] 08-Feb-2012 14:10:16

Created: [REDACTED]

Modified: [REDACTED]

Resolved: [REDACTED]

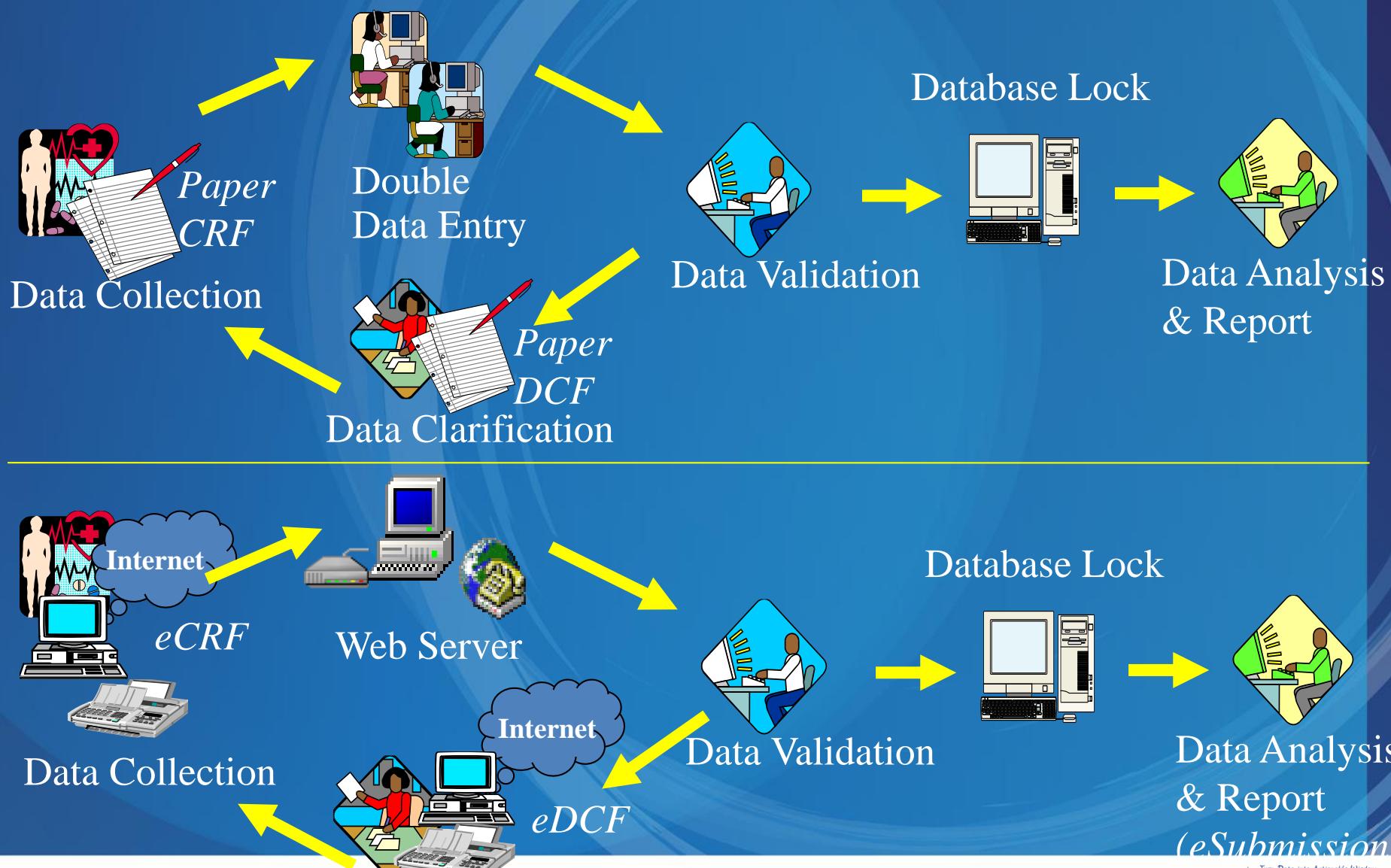
OK



Data Entry



Standard Data Management Flow



Guidelines for all CRFs EDC and Paper CRF Studies

- Ensure that all required fields on each CRF are completed.
- Provide contact information if questions arise while completing the CRF.
- Ensure that all free text entries are spelled correctly and are clinically appropriate.
- Provide a list of acceptable abbreviations, which may vary between studies or indications

Guidelines for Paper CRF Studies

- Ensure the use of permanent media (blue or black ink).
- Ensure that all items captured in the CRF are legible.
- Specify procedures for making corrections to data.
- Provide instructions for the process flow of completed documents, including shipping address, which copies of the CRF to ship, etc.

Guidelines for EDC Studies

- Do not share user IDs or passwords with anyone.
- Do not record and/or store user IDs and/or passwords in non-secure locations.

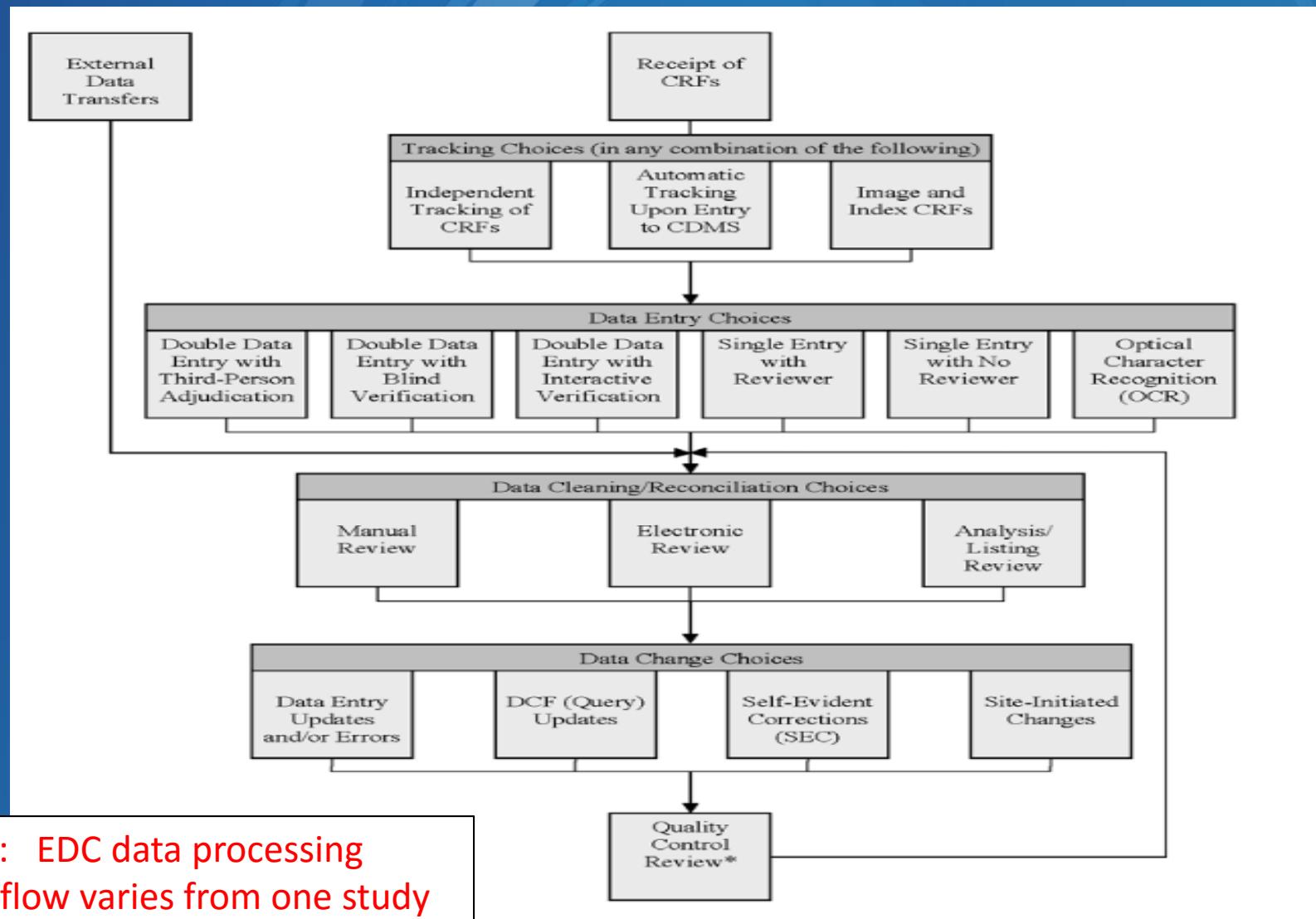
Data Entry Options

	Traditional Data Capture via Manual Forms		Electronic Data Capture	
	Use current system for manually entering forms	Implement scanable forms	Store and Forward using in home, hand held data entry tools	On line data capture using internet based data entry tools
Time for site staff to enter data and send CRF	⌚⌚	⌚⌚	⌚	⌚⌚
Time for data center to receive CRF, enter & verify data	⌚⌚⌚	⌚⌚	⌚	⌚
Ease of Data Entry - Study site - Data center	👍👍 👍	👍👍 👍👍	👍👍👍 👍👍👍	👍👍 👍👍👍
Cycle time from Data Entry through Data Validation and Availability	⌚⌚⌚	⌚⌚	⌚	⌚

Data Entry Options

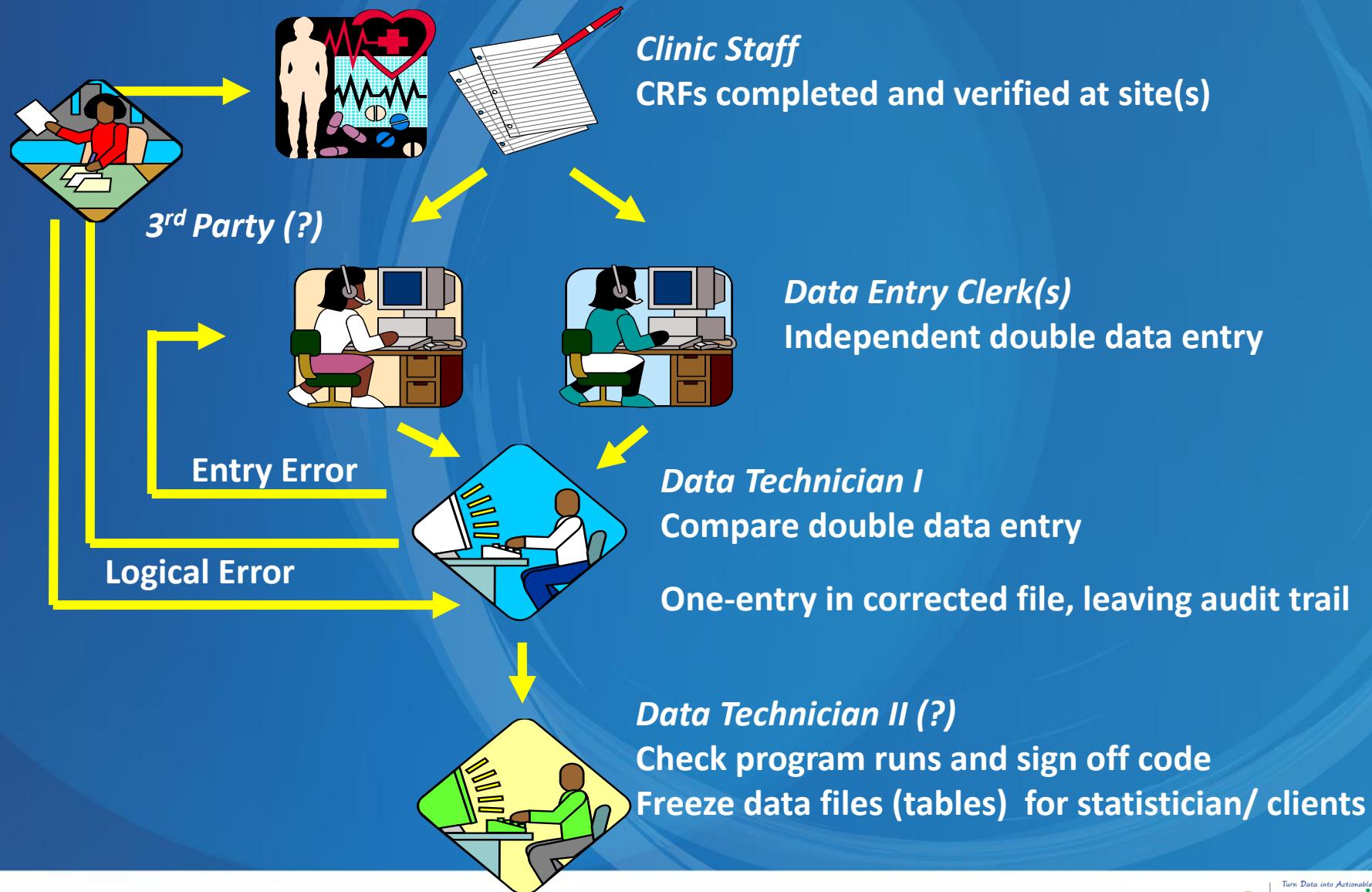
	Traditional Data Capture via Manual Forms		Electronic Data Capture	
	Use current system for manually entering forms	Implement scanable forms	Store and Forward using in home, hand held data entry tools	On line data capture using internet based data entry tools
Staff Needed	 <i>Study site</i> <i>Data center</i>			
Development Cost	\$	\$\$	\$\$\$	\$\$\$
Hardware and Software cost - <i>Study site</i> <i>Data center</i>	\$ \$\$	\$ \$\$	\$\$\$ \$	\$\$ \$
IS Support Needs - User Support - System Support	 	 	 	 
Technology and Training Requirements			 	 

Standards of Paper CRF Data Processing Workflow



Note: EDC data processing workflow varies from one study to another depends of SW used

Standard Data Entry Flow



Data Entry @ Site

	Event Description	Severity	Vaccination Schedule	Relationship to Vaccine	Onset Date
					Resolution Date
8	ABRASION WOUND RT. CALF FROM MOTORCYCLE ACCIDENT	1	1	1	17 / 01 / 02 23 / 01 / 02
9	SUPERFICIAL BURN RIGHT CALF	2	1	1	23 / 01 / 02

1	Name of Drug	Indication	Dose, Unit	Start Date (dd/mm/yy)
			Route, Frequency	Stop Date (dd/mm/yy)
1	Tetanus Toxoid	abrasion wound at left arm	0.5 ml	02 / 05 / 00
		and left leg due to motorcycle accident	IM , 1 dose	02 / 05 / 00
2	Tetanus Toxoid	abrasion wound at left arm and	0.5 ml	16 / 06 / 00
		left leg due to motorcycle accident	IM , 1 dose	16 / 06 / 00

Data Problem: Data Entry @ Site

Event Description		Subject Number	Chk	Initials
		71098	4	LPT, GLL
1	Right lower arm injury	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	24 / 09 / 99	
2	chest pain related to hurt by the police related to hurt by the police	SP14 Aug 02 <input checked="" type="checkbox"/> 3 <input type="checkbox"/>	08 / 12 / 99 11 / 12 / 99	
3	laceration wound (was hurted)			
4	Insomnia			

29a. ອີ່ລາຍະນະໃຫຍ່ທີ່ໄດ້ຮັບ (If Yes: Please describe the benefits you have experienced.)

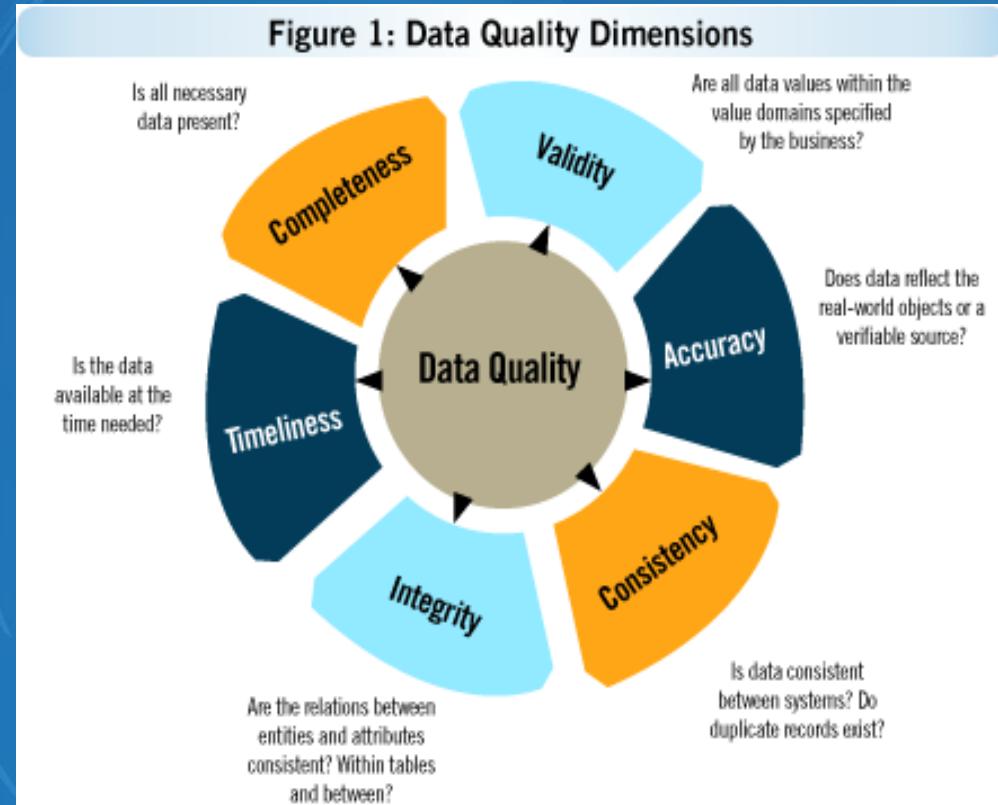
ໃຫຍ່ທີ່ໄດ້ຮັບ (Money for transportation, AIDS information and AIDS Vax & Vaccine information)

Data Problem: Data Entry @ Site

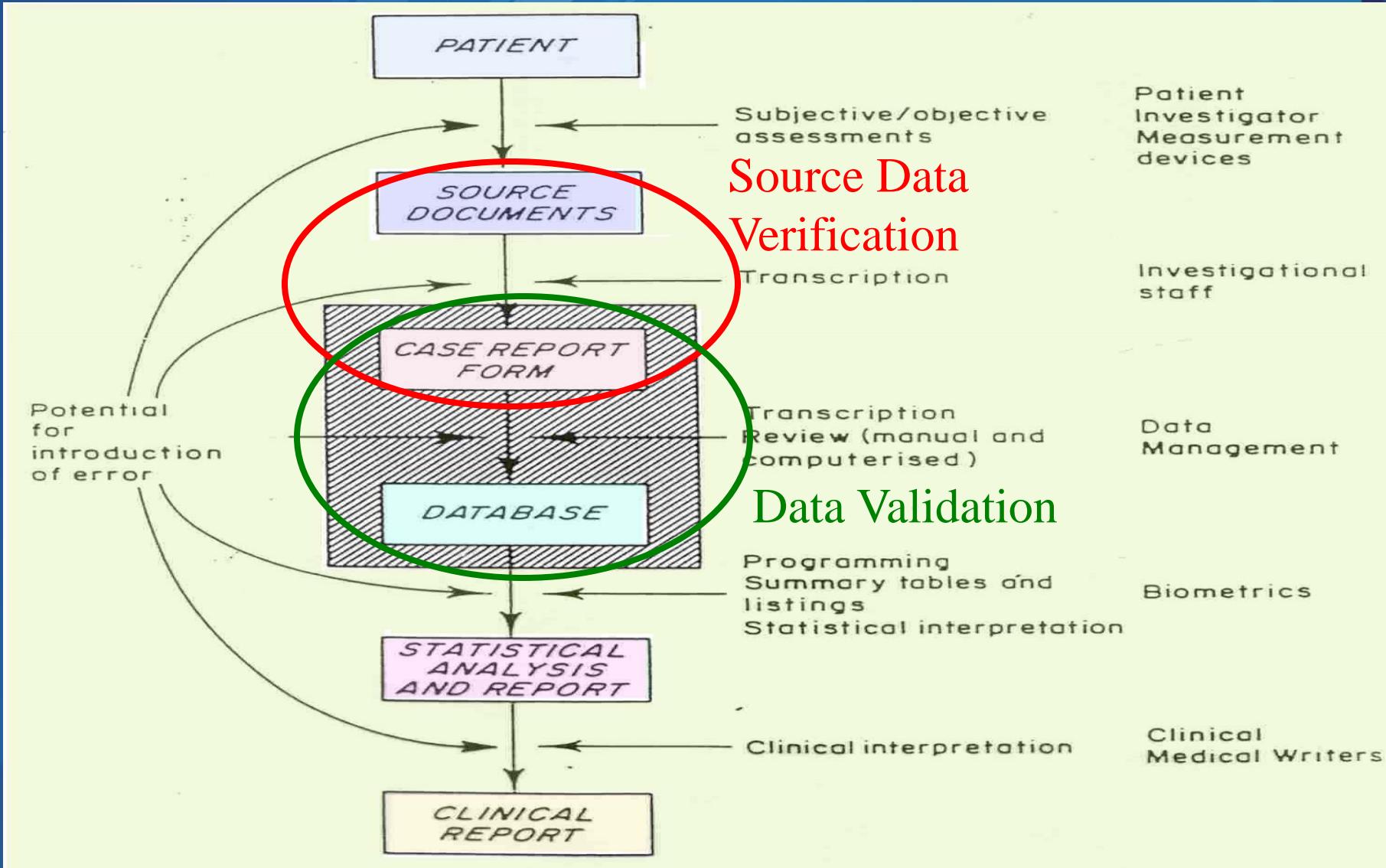
OBS	CODE	TYPE	BAGNUM
1	n673-5661	τ	n32928
2	₩620-5411	M	n25623
3	₩620-7174	+	₩09057
4	₩664-4664	II	n42615
21	₩646-6444	°1	n36277
22	₩646-6444	°1	n45662



Data Quality



Sources of Error



Data Problem:

Data Coding

CHECK MIS-CODED DATA

OBS	CODE	SEX	BAGNUM
1	q460-1464	G	02750-33
2	q460-1464	G	07196-33
3	q460-1464	G	15932-33
4	q460-1464	G	11839-33
5	q460-1464	G	n12379

Data Problem: *Inconsistency*

VAX103	Screening (001)	C H A 109-0044	VAX003	Demographics (003)	Month 00.0 (000)	
1. รหัสคลินิก - หมายเลขผู้เข้าร่วมการคัดกรอง (Clinic Number) (Screening Number)	24 06 (Screening Date) dd mm	109-7036-4 KALI	Site Number	Subject Number	Chk	Initials
2. วันที่เข้าร่วมการคัดกรอง						
3. หมายเลขอุปกรณ์ประจำนวน ของผู้เข้าร่วมการคัดกรอง						
4a. ชื่อในนี้ ขอให้ใช้หนาเด่นบัตรหจกราชการ (number)	_____					
5. ที่อยู่ของผู้เข้าร่วมการคัดกรอง (Current Address)	5a. แขวง/ตำบล (Sub-district) CHOI	5b. เขต/อำเภอ (District) CHOI	5c. จังหวัด (Province) BANGKOK			
6. วัน-เดือน-ปีเกิด ของผู้เข้าร่วมการคัดกรอง (Subject Date of Birth)	21 06 66	dd mm yy				
7. เพศของผู้เข้าร่วมการคัดกรอง (Sex)	<input checked="" type="checkbox"/> ชาย (Male at birth)	<input type="checkbox"/> หญิง (Female at birth)				

Data Problem: Illegibility

Name of Drug	Indication	Dose, Unit	Start Date (dd/mm/yy)
		Route, Frequency	Stop Date (dd/mm/yy)
1 Amoxycillin	Pharyngitis	500 mg 2x500mg qid oral qid	05 /06 /00 11 /06 /00
2 Cloxacillin	abscess at posterior triangle of neck at left side abscess at posterior triangle of neck left side BP 142mm Hg	500 mg oral qid	19 /09 /00 23.09.2000 25 /09 /00
3 Amoxycillin	RHINITIS	500 mg oral, qid	03 /01 /01 10 /01 /01

Instructions: Physical exam directed by history, systems review and symptoms only. 25 28MAY01

Body System	Normal	Abnormal	Not Done	Comment on all abnormalities	discharge
6. HEENT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	interted pharynx with mucopurulent discharge	
7. Lymph Nodes	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	at post pharynx at post pharynx	
8. Cardiovascular	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		28MAY01

Data Problem: Illegal Values (?)

	Event Description	Severity	Vaccination Relationship Schedule to Vaccine		Onset Date
					Resolution Date
1	MOTORCYCLE ACCIDENT RIGHT AT 1/6/10 LACERATED WOUNDS → 5 th RP. FINGER, AT 28/4/99 LEFT IN ST/99 AND SS LT. KHEE. AT 28/4/99	1			12 / 4 / 99 16 / 4 / 99
2	AT 1/6/11				/ /
	Event Description	Severity	Vaccination Relationship Schedule to Vaccine		Onset Date
					Resolution Date
1	Toothache	1	1	1	17 / 05 / 00 20 / 05 / 00
2	vaccinated area itching at left deltoid around	1	1	4	08 / 11 / 00 11 / 11 / 00
3	cat bite at right leg from Aberration wound	1	1	1	14 / 04 / 01 17 / 04 / 01

Data Problem: Unclear Data

Event Description	Severity	Vaccination Relationship		Onset Date
		Schedule	To Vaccine	
1 Right lower arm injury	1	1	1	24 / 09 / 99
2 chest pain related to hurt by the police related to hurt by the police	3	1	1	08 / 12 / 99 11 / 12 / 99
3 laceration wound at posterior neck (was hurted by other prisoner)	2	1	1	09 / 01 / 00 16 / 01 / 00
4 Insomnia	1	1	1	10 / 09 / 00 11 / 09 / 00

Heart or Hurt?

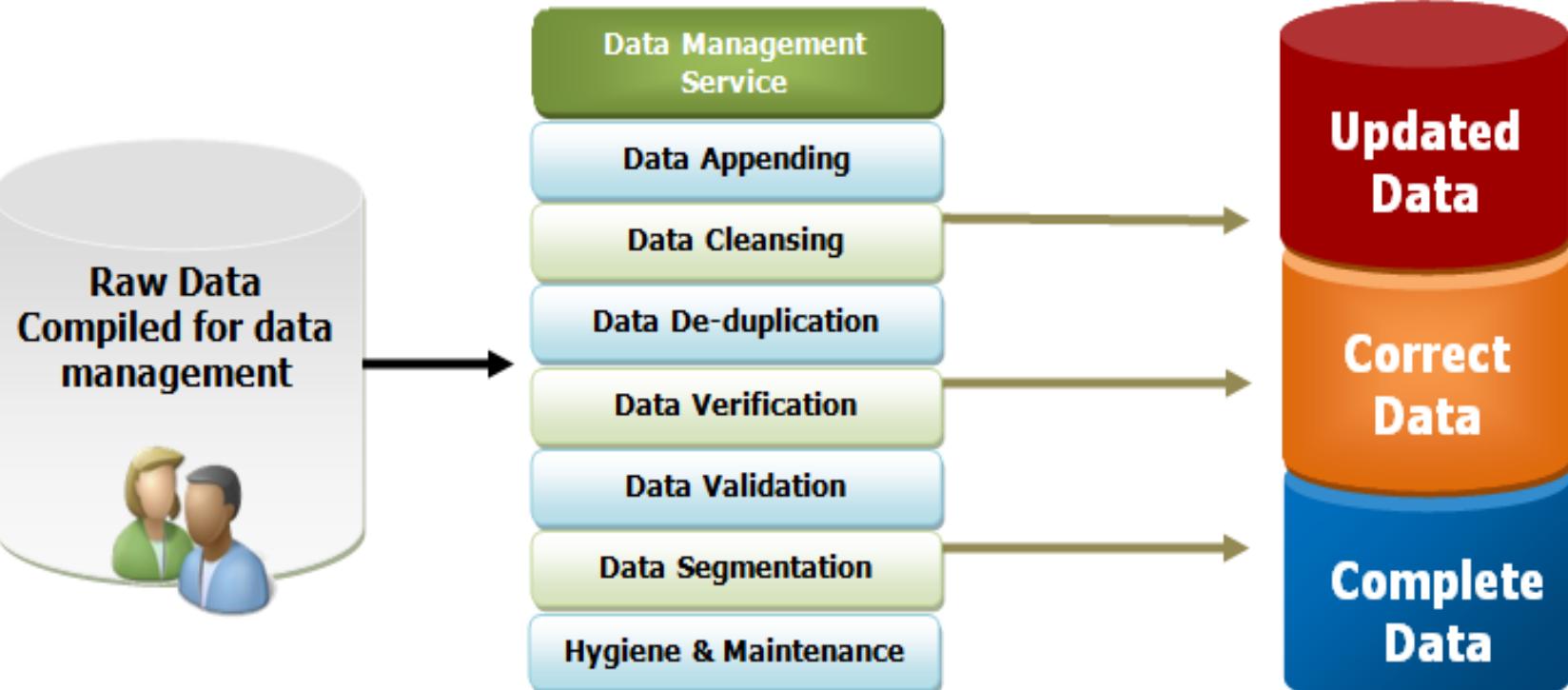
1 Right lower arm injury

2 chest pain related to hurt by the police
related to hurt by the police

3 laceration wound at posterior neck
(was hurted by other prisoner)

4 Insomnia

Data Quality Check



Assuring Data Quality - Minimum Standards

- Provide sufficient information in data-processing documentation to reproduce final analyses from source data.
- Assure data quality for all studies, whether submitted for regulatory review or not (e.g., marketing studies, observational studies or for publication-only studies).
- Ensure data quality is appropriate for study analyses according to parameters laid out in a statistical analysis plan, if one exists.

Assuring Data Quality - Best Practices

- Create and maintain documentation of all roles and responsibilities involved in managing a clinical study.
- Use well-documented processes for data collection and handling.
- Minimize the number of data-processing steps in order to minimize potential sources of error.
- Ensure data quality audits assess compliance of procedures to regulations, compliance of practices to written documentation, conformance of data to source documentation, and conformance of data to written procedures.
- Ensure all data management personnel are trained on and knowledgeable

General clinical data checks

- Endpoint checks
- Safety checks
- Protocol compliance
- Programmed checks
- Manual checks
- Listings checks
- External checks

Quality Assurance

Standard Quality Assurance Aspects:

- Study/Trial Conduct
- Study/Trial Monitoring
- Study/Trial Progress

Key questions:

- Violation / deviation from protocol or assumptions?
- Meet the study target /goal as planned?
- Chance to answer the study objectives/questions?

Data Assurance: Trial Conduct/Monitoring

คุณสมบัติของอาสาสมัครที่สามารถเข้าร่วมโครงการฯ (INCLUSION CRITERIA)

หากตอบ “ไม่ใช่” ข้อใดข้อหนึ่ง ถือว่าขาดคุณสมบัติการเป็นอาสาสมัคร กรอกแบบฟอร์มทุกชื่อ ยกเว้นข้อ 11 แล้วหยุดท่านออกจากโครงการฯ

	ใช่	ไม่ใช่
1. อายุ 20-30 ปี (หมายถึง อั้งไม่ครบ 31 ปี บริบูรณ์ และถ้าอายุ 18-19 ปี ต้องแต่งงานอย่างถูกต้องตามกฎหมายแล้ว)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
วันเกิด: วัน/เดือน/ปี พ.ศ. 1 9 0 4 2 5 2 6 21		
2. มีบัตรประจำตัวที่มีหมายเลขบัตรประชาชน 13 หลัก.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. สามารถเข้าร่วมโครงการได้ตลอด 3 ปี ครึ่ง และเต็มใจเข้าร่วมโครงการฯ.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. สามารถอ่านและเข้าใจหนังสืออินซีดและอินข้อมูลเข้าร่วมโครงการฯ.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>

ผู้ตอบ “ใช่” ทั้งหมด 4 ข้อ จึงสามารถเข้าร่วมโครงการฯ ได้

หากตอบ “ไม่ใช่” ข้อใดข้อหนึ่ง ถือว่าขาดคุณสมบัติการเป็นอาสาสมัคร กรอกแบบฟอร์มทุกชื่อ ยกเว้นข้อ 11 แล้วหยุดท่านออกจากโครงการฯ

	ใช่	ไม่ใช่
1. อายุ 20-30 ปี (หมายถึง อั้งไม่ครบ 31 ปี บริบูรณ์ และถ้าอายุ 18-19 ปี ต้องแต่งงานอย่างถูกต้องตามกฎหมายแล้ว)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
วันเกิด: วัน/เดือน/ปี พ.ศ. 4 9 0 4 2 5 2 6 05 12 2532 14		วันเกิดที่ 31/12/05
2. มีบัตรประจำตัวที่มีหมายเลขบัตรประชาชน 13 หลัก.....	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. สามารถเข้าร่วมโครงการได้ตลอด 3 ปี ครึ่ง และเต็มใจเข้าร่วมโครงการฯ.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. สามารถอ่านและเข้าใจหนังสืออินซีดและอินข้อมูลเข้าร่วมโครงการฯ.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Data Assurance: Trial Conduct/Monitoring

Duplicate Patient Listing Report by Thai ID

As of Nov 12, 1999

Thai ID / Other ID	Screen ID	Screen Date	Initial	Date of Birth	Clinic Name	Enroll
[REDACTED]993	1140063	4/11/99	JAKU	23/05/79	Khlong Toey	
[REDACTED]993	1060080	9/7/99	JAGO	22/05/79	Wat That Thong	No
[REDACTED]450	1070187	5/11/99	JICH	12/10/74	Boonmi Phuru Ratcharungsan	
[REDACTED]450	1070054	4/6/99	JICH	12/10/74	Boonmi Phuru Ratcharungsan	No

Data Assurance: Trial Conduct/Monitoring

DEVIATIONS LOG

DMU Monthly Report : DMR 207-00

Summary of Deviation Reports (1 - 31 March 2007)

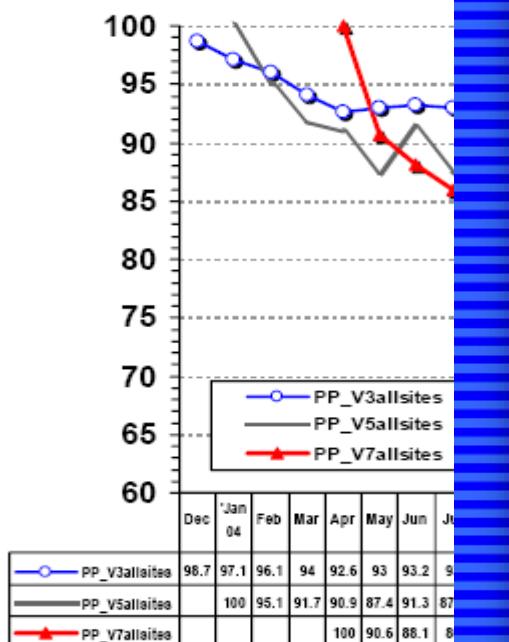
Deviation Code	Description	Deviation Number	%	Cumulative Number	%
RV144	Deviation Reports received	22		2155	
Data Deviation Report					
01	Errors in treatment assignment	0	0%	2	0%
02	Incorrect administration of product	0	0%	8	0%
04	Volunteer met vaccine-withholding criteria	0	0%	2	0%
05	Volunteer received excluded concomitant treatment	0	0%	401	19%
08	Vaccine outside visit window	0	0%	686	32%
09	Other Data Deviation	2	9%	236	11%
21	Other SOP/Administrative deviation	1	5%	3	0%
Safety Deviation Report					
06	Pregnancy during vaccination phase	5	23%	295	14%
09	Pregnancy after vaccine phase	2	9%	154	7%
SOP/ADMIN Deviation Report					
10	Consent process not completed	2	9%	66	3%
13	Failure to report SAEs/Deaths	0	0%	2	0%
14	Incomplete data collection	6	27%	152	7%
16	Vaccine administration	0	0%	31	1%
18	Required data collected out of sequence	0	0%	7	0%
20	Enrollment without satisfying criteria	1	5%	7	0%
21	Other SOP/Administrative deviation	3	14%	103	5%
RV148	Deviation Reports received	0		558	
SOP/ADMIN Deviation Report					
10	Consent process not completed	0	0%	27	5%
12	Incorrect lab reporting of HIV results	0	0%	2	0%
14	Incomplete data collection	0	0%	50	9%
18	Required data collected out of sequence	0	0%	1	0%
19	Duplicate enrollment	0	0%	148	27%
20	Enrollment without satisfying criteria	0	0%	196	35%
21	Other SOP/Administrative deviation	0	0%	134	24%

Record No.2721-2742 as of March, 2007

Data Assurance:

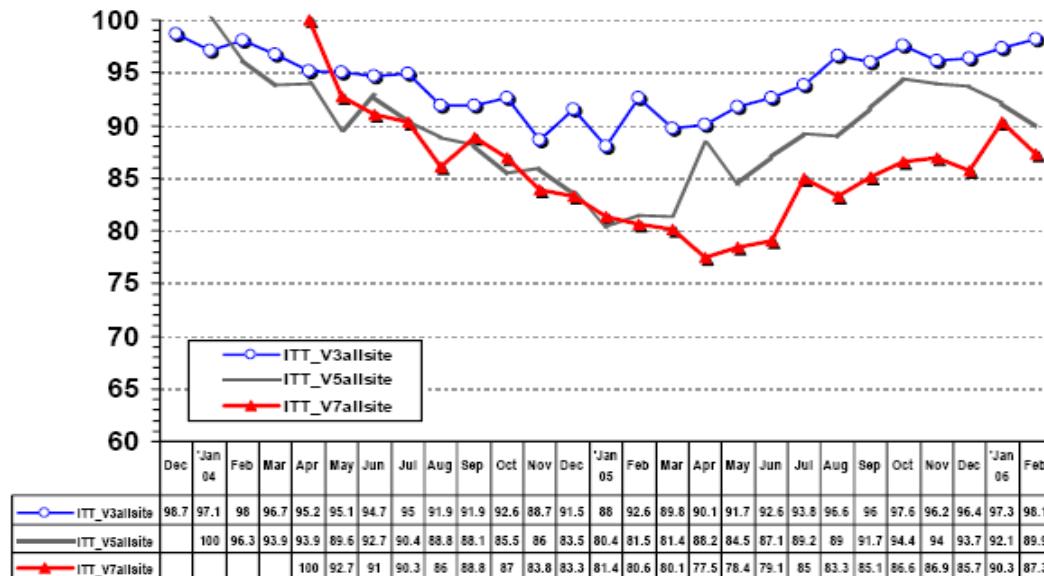
Trial Progress (Central Collaboration)

Per-protocol retention: All sites, as of 4 March 2006



Source: DMU – retention report, Table 10.4, Ta

ITT retention: All sites, as of 4 March 2006



Source: DMU – retention report, Table 10.4, Table 10.5, and Table 10.6 as of 4 March 2006



Quality Control

Data Management Perspective

Data Quality	Characteristics Description	Example Metric
Accuracy	A quality of that which is free of error. A qualitative assessment of freedom from error, with a high assessment corresponding to a small error.	<i>Percent of values correct that are when compared to the actual value. For example, M=Male when the subject is</i>
Completeness	Completeness is the degree to which values are present in the attributes that require them.	<i>Percent of data fields having values entered into them.</i>
Consistency	Consistency is a measure of the degree to which a set of data satisfies a set of constraints.	<i>Percent of matching values across tables/files/records.</i>

Quality Control

Data Management Perspective

Data Quality	Characteristics Description	Example Metric
Timeliness	As a synonym for currency, timeliness represents the degree to which specified data values are up to date.	<i>Percent of data available within a specified threshold time frame (e.g., days, hours, minutes).</i>
Uniqueness	The state of being the only one of its kind. Being without an equal or equivalent.	<i>Percent of records having a unique primary key.</i>
Validity	The quality of data that is founded on an adequate system of Classification and is rigorous Enough to compel acceptance.	<i>Percent of data having values that fall within their respective domain of allowable values.</i>

Data Validation

Standards in data validation:

- Making sure that the raw data were accurately entered into a computer-readable file.
- Checking that character variables contain only valid values.
- Checking that numeric values are within predetermined ranges.
- Checking for and eliminating duplicate data entries.
- Checking if there are missing values for variables where complete data are necessary.
- Checking for uniqueness of certain values, such as subject ID's.
- Checking for invalid date values and invalid date sequences.
- Verifying that complex multi- file [or cross panel] rules have been followed. For example, if an adverse event of type X occurs, other data such as concomitant medications or procedures might be expected.

Accuracy/Completeness Logical Check: Unmatched Cases (Case – Specimen Tracking)

PT_LAB1st_2apr04 - SPSS Data Editor

The diagram illustrates the logical check for unmatched cases between two datasets: the Lab Results Data File and the Patient Registry Data File. The Lab Results Data File is shown on the left, and the Patient Registry Data File is shown on the right, both overlapping the central data view.

Lab Results Data File:

case	thalasse	lab_id	relation	diagno_1	sex_1	birthdat	age	agegrp
116	pcu46-0030	447.00	father	Hb E trait	male	18-MAY-2002	1.76	.
117	pcu46-0031	3	patient	Hb H disease	male	13-JUN-1994	0.5	0-5
118	pcu46-0032		father	Hb E trait	male	03-MAR-2003	3.4	0-5
119	pcu46-0033		patient	Hb H disease	female	01-FEB-1997	11-15	
120	pcu46-0034		patient	Hb H disease	male	09-AUG-1994	2.18	0-5
121	pcu46-0035		patient	Hb H disease	male	19-MAY-1994	4.47	0-5
122	pcu46-0036		patient	Hb H disease	female	10-JUL-1994	9.73	6-10
123	pcu46-0037	0	patient	Beta-thal/Beta-th	female	0	4.34	0-5
124	pcu46-0038	.00	patient	Hb H disease	female	2	2.95	0-5
125	pcu47-0001	9.00	patient	Beta-thal/HbE	female	10-NOV-1993	5.66	.
126	pcu47-0002	451.00	mother	Beta-thal trait	female	14-FEB-2003	-.59	.
127	pku46-0001	17.00	patient	Hb A-E Bart's - C
128	pku46-0003	400.00	patient	Other	male	23-OCT-1990	12.57	11-15
129	pku46-0004	403.00	patient	Hb H with Hb CS	male	06-FEB-1997	6.15	6-10
130	pku46-0005	401.00	patient	Beta-thal/HbE	female	12-AUG-2002	1.00	0-5
131	pku46-0006	402.00	patient	Hb A-E Bart's	female	20-NOV-2001	1.61	0-5
132	pku46-0008	404.00	patient	Beta-thal/HbE	male	27-JUN-2000	3.03	0-5
133	pku46-0009	405.00	patient	Hb H with Hb CS	female	17-AUG-2000	2.95	0-5
134	pku46-0010	406.00	patient	Hb H disease	female	19-JUN-2001	2.11	0-5
135	pku46-0011	407.00	patient	Hb H with Hb CS	female	04-MAY-1997	6.24	6-10
136	pku46-0012	408.00	patient	Hb H with Hb CS	male	31-AUG-2000	3.07	0-5

Patient Registry Data File:

case	thalasse	lab_id	relation	diagno_1	sex_1	birthdat	age	agegrp
116	pcu46-0030	447.00	father	Hb E trait	male	18-MAY-2002	1.76	.
117	pcu46-0031	3	patient	Hb H disease	male	13-JUN-1994	0.5	0-5
118	pcu46-0032		father	Hb E trait	male	03-MAR-2003	3.4	0-5
119	pcu46-0033		patient	Hb H disease	female	01-FEB-1997	11-15	
120	pcu46-0034		patient	Hb H disease	male	09-AUG-1994	2.18	0-5
121	pcu46-0035		patient	Hb H disease	male	19-MAY-1994	4.47	0-5
122	pcu46-0036		patient	Hb H disease	female	10-JUL-1994	9.73	6-10
123	pcu46-0037	0	patient	Beta-thal/Beta-th	female	0	4.34	0-5
124	pcu46-0038	.00	patient	Hb H disease	female	2	2.95	0-5
125	pcu47-0001	9.00	patient	Beta-thal/HbE	female	10-NOV-1993	5.66	.
126	pcu47-0002	451.00	mother	Beta-thal trait	female	14-FEB-2003	-.59	.
127	pku46-0001	17.00	patient	Hb A-E Bart's - C
128	pku46-0003	400.00	patient	Other	male	23-OCT-1990	12.57	11-15
129	pku46-0004	403.00	patient	Hb H with Hb CS	male	06-FEB-1997	6.15	6-10
130	pku46-0005	401.00	patient	Beta-thal/HbE	female	12-AUG-2002	1.00	0-5
131	pku46-0006	402.00	patient	Hb A-E Bart's	female	20-NOV-2001	1.61	0-5
132	pku46-0008	404.00	patient	Beta-thal/HbE	male	27-JUN-2000	3.03	0-5
133	pku46-0009	405.00	patient	Hb H with Hb CS	female	17-AUG-2000	2.95	0-5
134	pku46-0010	406.00	patient	Hb H disease	female	19-JUN-2001	2.11	0-5
135	pku46-0011	407.00	patient	Hb H with Hb CS	female	04-MAY-1997	6.24	6-10
136	pku46-0012	408.00	patient	Hb H with Hb CS	male	31-AUG-2000	3.07	0-5

Time Logical Check : *Error or Illogical Dates*

PT_Lab_Birth - SPSS Data Editor

File Edit View Data Transform Analyze Graphs Utilities Window Help

17 : thalasse prm46-0007

	thalasse	relation	lab_date	birthdat	age	va
1	mcu46-0009	patient	08/19/2003	10/30/1966	36.80	
2	mcu46-0010	patient	06/19/2003	07/13/1962	40.93	
3	mcu46-0011	patient	10/28/2003	06/11/1979	24.38	
4	mku46-0004	patient	08/28/2003	01/01/1931	72.65	
5	mku46-0008	patient	10/20/2003	07/12/1952	51.27	
6	mmk46-0002	patient	06/13/2003	.	.	
7	mmk46-0003	patient	06/13/2003	01/01/1942	61.45	
8	mmk47-0002	patient	11/17/2003	12/18/1986	16.91	
9	mrm46-0003	patient	05/06/2003	03/27/1996	7.11	
10	mrm46-0005	patient	05/06/2003	03/01/1991	12.18	
11	pcm46-0006	patient	05/12/2003	08/19/2002	.73	
12	pcm46-0007	patient	05/26/2003	04/20/2003	.10	
13	pku46-0001	patient	04/29/2003	.		
14	pku46-0009	patient	07/30/2003	08/17/1900	102.95	
15	pku46-0012	patient	09/25/2003	08/31/2000	3.07	
16	pku46-0013	patient	09/11/2003	.		
17	prm46-0007	patient	08/27/2003	11/08/2003	-.20	
18	prm46-0008	patient	08/06/2003	09/13/2003	-.10	
19	prm46-0011	patient	08/16/2003	04/06/2003	.36	

Data View / Variable View / SPSS Processor is ready

Validity Logical Check: Illogical Data

LOGICAL DATA CHECK

```

* PURPOSE: Determine difference values between 2 demographic
vars between 2 of CSW
*-----;
libname in 'C:\Users\Asus\OneDrive\';
options ls=150 ps=56;

data label;
set in.crs_04;
if chansero >= 0 and chansero < 0.2 then echan02=2;
else if chansero >=0.2 then echan02=1;
ecswyr=e010age-e018csw;
ersexyr=e010age-e017rsex;
efsexyr=e010age-e016fsex;
run;

```

Sexual Behavior Information					
ECSWYR	Frequency	Percent	Frequency	Percent	
-3	1	0.2	1	0.2	
-2	1	0.2	2	0.4	
-1	4	0.9	6	1.3	
0	110	23.7	116	25.0	
1	65	14.0	181	39.0	
2	56	12.1	237	51.1	
3	56	12.1	293	63.1	
4	22	4.7	315	67.9	
5	39	8.4	354	76.3	
6	15	3.2	369	79.5	
7	12	2.6	381	82.1	
16	5	1.1	447	96.3	
17	5	1.1	452	97.4	
18	4	0.9	456	98.3	
19	1	0.2	457	98.5	
20	2	0.4	459	98.9	
22	2	0.4	461	99.4	
23	1	0.2	462	99.6	
25	1	0.2	463	99.8	
33	1	0.2	464	100.0	

Validity Logical Check: *Illogical Data*

BLOOD DRAW DATE (dd/mm/yyyy)		RESULT		FINAL COUNSELING DATE (dd/mm/yyyy)	
Visit 07 00 (Specimen 0700)	<input type="checkbox"/> Missed Visit	<input checked="" type="checkbox"/> Not Infected <input checked="" type="checkbox"/> Confirmed Infected <input type="checkbox"/> Not Done		Visit 08 00 SP 27/01/06	<input checked="" type="checkbox"/> Missed Visit SP 16/11/06 SP 27/01/06
0 6 1 2 2 0 0 5				2 0 1 2 2 0 0 5	1 5 1 1 6
Visit 09 00 (Specimen 0900)	<input checked="" type="checkbox"/> Missed Visit SP 15/11/06	<input type="checkbox"/> Not Infected <input checked="" type="checkbox"/> Confirmed Infected <input type="checkbox"/> Not Done		Visit 10 00 SP 19/11/06	<input checked="" type="checkbox"/> Missed Visit
1 5 1 1 2 0 0 6				0 6 1 2 2 0 0 6	
Visit 11 00 (Specimen 1100)	<input type="checkbox"/> Missed Visit	<input type="checkbox"/> Not Infected <input checked="" type="checkbox"/> Confirmed Infected <input type="checkbox"/> Not Done		Visit 12 00 SP 20/06/07	<input checked="" type="checkbox"/> Missed Visit
1 8 0 1 2 0 0 7				1 4 0 3 2 0 0 7	
Visit 13 00 (Specimen 1300)	<input type="checkbox"/> Missed Visit	<input checked="" type="checkbox"/> Not Infected <input type="checkbox"/> Confirmed Infected <input type="checkbox"/> Not done		Visit 14 00	<input type="checkbox"/> Missed Visit
1 4 0 6 2 0 0 7				1 8 0 7 2 0 0 7	

Validity Logical Check: *Out of Range Data*

Neutrophil count

			day 0	day 7
6	1		7.78	2.56
2			4.63	12.40
3			8.35	2.07
4			6.06	1790.00
5			5.54	.
Total	N		5	4

Out of Range Value?

Consistency Logical Check:

Data Consistency

ITCHING		Freq	Percent	Cum.	
1.0		242	24.2%	24.2%	Yes
2.0		756	75.6%	99.8%	No
9.0		2	0.2%	100.0%	Missing
Total	1000	100.0%			

cross check if they are consistent with reported symptoms

SYMPTOMS		Yes	1.0	2.0	9.0		Total
Yes			211	29	2		506
No			31	463	0		494
Total			242	756	2		1000

Check why those stated as having no symptoms say yes to itching
 Current selection: SYMPTOMS=2 and ITCHING=1

Audit Trails

Definition

AUDIT is the procedure to compare source data with data on case record forms (CRF) and interim and final reports. This would include validation of data both pre- and post-computer entry

The aim of audit is to confirm that:

- *the data reported are the data analyzed.*
- *the data analyzed are the data recorded on CRF.*
- *the data on the CRF are the data generated.*
- *the data generated are in compliance with the protocol.*
- *the protocol and all aspects of the trial/experimental preparation conduct and analysis are in compliance with the standard operating procedures (SOPs).*



(Definition: Richard K. Rondel, UK)

Audit Trail of Edit Changes: Initial & Date

Month 0~~1~~6.0

x Page 14 of 14

Month ~~2~~0.0

3 Page 6 of 14

JL.

Risk Assessment Page 5 (0)

6908-1 P_A_R_U

Subject Number Chk Initials

Risk Assessment Page 5 (0)

2
6908-1 P_A_R_U

Subject Number Chk Initials

SP 6/1/00

Data Correction Form (DCF)

Standard Audit Trail: *Data Clarification Form (DCF)*

GENENTECH CORRECTIONS FORM ADDENDUM TO THE REPORT				47083
Date Generated: 01-Aug-95		Patient Number: 2100-0007		
Protocol Number: VOL 33g		Patient Initials: JA WI		
Investigator:				
CRF Page/Visit	Item to be Corrected	Original Entry	Corrected Entry	Change Generated By/ Study Site Contact
11	Relatively	Possibly	Not Related	By: _____ Date: _____
12	Vaccine	Possibly	Not Related	Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
13	HG	Possibly	Not Related	By: _____ Date: _____
20		Not Related	(no change)	Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
21		Not Related	(no change)	By: _____ Date: _____
22		(b)mt	Not Related	Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
23		Possibly	Not Relatd	By: _____ Date: _____
23	Onset date	28-3-95	28-3-95	Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
23	Event Resolved?	IV/No	✓ Yes	By: _____ Date: _____
27	Mrd Ind. Route Dose Freq. Act Started Continued? Data Slipped	(blank)	Methadone IV injection PO 40 mg gamt 28-11-94 100 Yes 16 P	Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
14	Visit date	28-2-95	21-2-95	By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____ By: _____ Date: _____ Site Contacted <input type="checkbox"/> Yes <input type="checkbox"/> No Contact Person _____
Principal Investigator's Signature				Date 6-10-95
Genentech Clinical Research Associate				Date 02-Dec-95
Genentech Clinical Research Department 460 Pt. San Bruno Blvd. South San Francisco CA 94080				
GCF 05/24/91				

Audit trails

- US-FDA 21 CFR Part 11 Compliance including e-signatures, audit trails, and rules for password complexity, aging and notification

iDataFax - Field History

DF_ATmods: Database Changes For Study 247 Apr 18,2012 14:17 PAGE 1
-t 20120101~today -I 33012 -S 1000 -P 30 -din 15 -N data

ID=33012 SEQ=1000 PLT=30
2012/03/27 13:06:47 vsil DATA: NEW RECORD at level 2, final
15. Signature = [REDACTED]
REASON new at level 2: Set by edit check ChkUserName

2012/04/03 08:12:14 [REDACTED] DATA: DELETED record at level 2
15. Signature:
REASON deleted from level 2: Set by edit check ChkUserName

2012/04/03 13:02:51 [REDACTED] DATA: NEW RECORD at level 2, final
15. Signature = [REDACTED]
REASON new at level 2: Set by edit check ChkUserName

2012/04/04 09:46:58 [REDACTED] DATA: DELETED record at level 2
15. Signature:
REASON deleted from level 2: Set by edit check ChkUserName

2012/04/10 11:12:31 [REDACTED] DATA: NEW RECORD at level 2, final
15. Signature = [REDACTED]
REASON new at level 2: Set by edit check ChkUserName

OK Print

Threats to Data Quality

- Literature has suggested that
 - up to 1% of data is in error, which could impact findings
 - Not all error is random
- Systematic error can often be attributed to:
 - lack of resources
 - lack of skills or knowledge
 - lack of attention to details
 - lack of clearly defined data elements

Derived from: Rita E. Adkins, Matthew G. Hile, Keith Eldridge, Missouri Institute of Mental Health,
Tools for Evidence: Building a Quality Dataset

Deviation Log & Exemption Report

Deviation & Violation

ATTACHMENT B: SAMPLE EXEMPTION/DEVIATION REPORT FORM

- RV144: send to VTC (02 354-9174)
- RV144 Pharmacy: send to VQAO (02-644 4824)
- RV148: send to BCO (benensonmw@afrims.org)

- Exemption request (for vaccination or enrollment)
- Data/Safety deviation report
- SOP/Admin deviation report

Site Code:

Visit:

Study Number:

PIN:

DEVIATIONS LOG

NOTE: DEVIATIONS that are reported by the DMU (such as missed visits, missing data points, or visits occurring outside of window) do NOT need to be recorded on this form.

MAJOR DEVIATIONS: Errors which affect volunteer safety or trial data (also report separately as per SOP):

- 01 Errors in treatment assignment or pharmacy preparation that has an effect on product given to volunteer.
- 02 Incorrect administration of product (wrong dose/wrong route/wrong volunteer)
- 03 Volunteer immunized without satisfying entry criteria
- 04 Volunteer met withdrawal criteria but was not withdrawn
- 05 Volunteer met immunization-withholding criteria, but immunization was given.
- 06 Volunteer received excluded concomitant treatment that would affect volunteer safety or trial data.
- 07 Consent process not completed properly (consent signed after enrollment, wrong form used, form not signed,etc)
- 08 Incorrect diagnosis of primary endpoint (not notifying HIV+, or wrongly notifying HIV-).
- 09 Break in cold chain resulting in significant trial delay
- 10 Pregnancy within first 9 months (also record on Pregnancy CRFs), vaccine withheld
- 11 Vaccine administered to pregnant woman
- 12 Duplicate enrollment leading to duplicate vaccination
- 13 Failure to report SAEs/Deaths on study appropriately
- 14 Other Major deviations (specify in DESCRIPTION)

MINOR DEVIATIONS

- 15 Incomplete data collection or volunteer leaving the site without completing all study procedures.
- 16 Break in vaccine cold chain with minor effects on trial
- 17 Volunteer received excluded concomitant medication that would have a minimal effect on volunteer safety or trial data.
- 18 Error in vaccine administration
- 19 Error in vaccine preparation
- 20 Vaccine Visit outside of visit window
- 21 Non-vaccine Visit outside of visit window
- 22 Required data obtained outside time window
- 23 Duplicate enrollment that does not result in duplicate vaccination.
- 24 Minor errors in consent (eg, wrong date or no date).
- 25 Inappropriate enrollment (no injections given)
- 26 Missing time point on refrigerator temperature log.
- 27 Other Minor deviations (specify in DESCRIPTION)

DEVIATION NUMBER	DATE DEVIATION OCCURRED	DATE DEVIATION RECORDED	SUBJECT STUDY NUMBER	DEVIATION CODE	CHECK IF MAJOR	DESCRIPTION

Completed by _____ Date _____

DATE SUBMITTED TO DATA BASE: _____ PAGE _____



Data Security

EXPLAIN IT

- contextualise your material and data
Describe the circumstances prevailing at the time of your research and the parameters within which you were working.
- describe your research process
Help people understand your material and data in the future by explaining why you used a particular methodology, or how you analysed your data.
- explain acronyms and jargon
Don't assume the reader will understand specialist terms - remember they may be reading your material in several years' time.
- provide information (sometimes called metadata) about each file
This will help a preservation service to index your material and people to find it. Some of this might be generated automatically by the digital equipment you use.

STORE IT SAFELY

- make multiple copies
Use different types of storage media and store copies in different locations.
- use open file formats where possible
Choosing non-proprietary formats means that files are more likely to be readable in the future. Your library or preservation service should be able to advise you on suitable formats.
- control who can access your files
Take particular care about how you handle and store sensitive information.
- decide when to delete digital material and data
Be selective about what you keep so that it is easier to find relevant and useful information.

SHARE IT

- to gain more impact
Other researchers - in your field or in different disciplines - may want to make use of your material, now and in the future.
- to enhance your reputation
Making research available allows you to demonstrate research excellence, increases your citations and can lead to collaborations.
- to increase the chance of funding
Most funding agencies respond positively to you making your material and data available to others.
- use repositories and data centres for archiving your material
Consider making your research openly available. Choose a repository with controlled access if this is more appropriate for your research.
- redact or embargo when necessary
Your material can still have value when personal or confidential information is removed, and most preservation services will embargo your material while you wait for publications or patents.

Data Privacy – Minimum Standards

- Ensure all personnel (including vendors) who directly or indirectly handle identifiable personal data are properly trained on data privacy issues.
- Design data-collection instruments with the minimum subject identifiers needed, including the design of case report forms (CRFs), clinical and laboratory databases, data transfer specifications, and any other area of data collection that may contain personal information.
- Ensure personal data is not identifiable, other than subject identifiers used to link documentation to a database record, from documentation
- Review and update data management processes regularly to ensure consistency with current company privacy policies and government regulations.

Data Privacy – Best Practices

- Develop and maintain an environment that respects the privacy of research subjects. Applying strict criteria when handling personal information, and verification that procedures are in compliance with regulations.
- Implement procedures prior to data transfer between sites, departments, subsidiaries, and countries to ensure all privacy considerations have been considered, addressed, and documented.
- Implement procedures for using data for an alternate or new purpose other than what was originally intended by the informed consent.
- Put stringent procedures in place to securely transfer, store, access, and report on extremely sensitive data (e.g., genetic information).
- Maintain proper physical and electronic security measures. Data should be stored in protective environments relevant to the type of media being stored.

Security

Physical Security

-Access control
(Access Card)



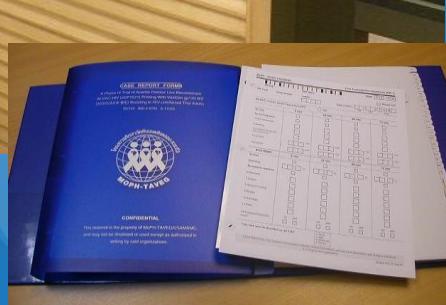
Logical Security
– Authorization
(Password Policy)



Database Security
– Protection of Records
(Tape backup & Safe Box)
(disaster recovery)

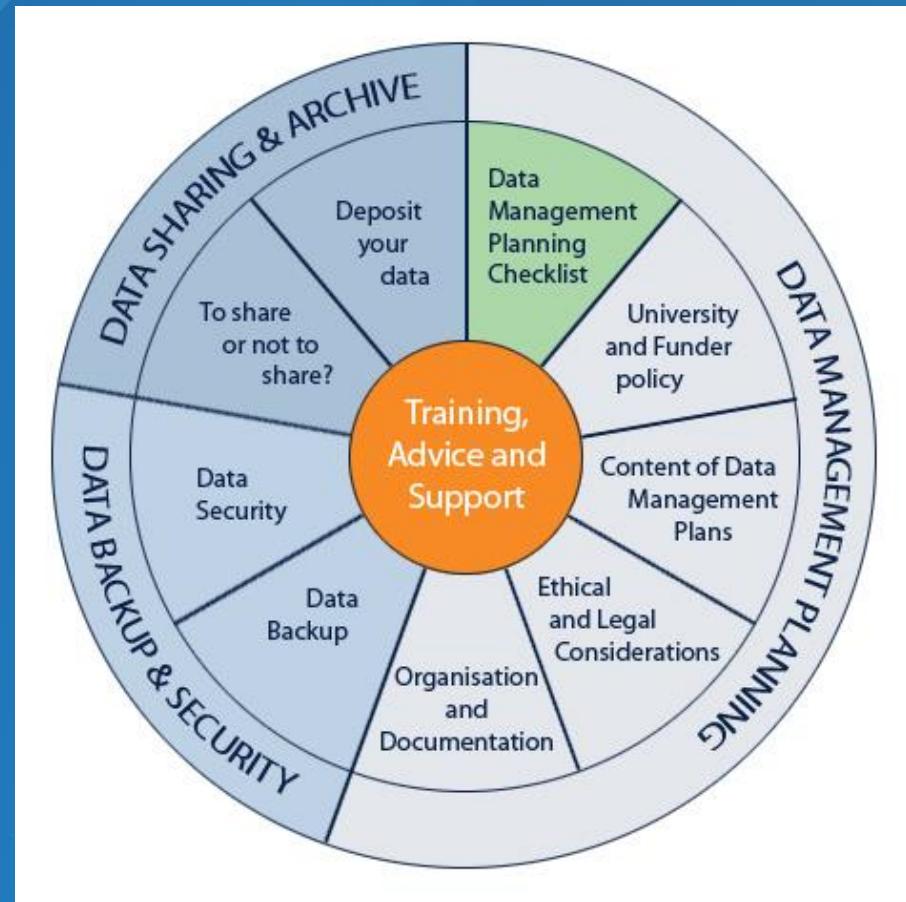


Documentation - QA & Access/Change Control





Data Storage, Archival, & Transfer



Data Storage - Minimum Standards

- During the conduct of a clinical trial, store all original data collected (e.g., case report forms and electronic laboratory data) in secured areas such as rooms or file cabinets with controlled access (e.g., locks).
- Document the procedures for granting access to database servers, establishing system controls, and assigning passwords.

Data Storage - Best Practices

- Store clinical data in such a way that backup copies can be easily and frequently made. For example, paper documents should be scanned and archived electronically.
- Use open formats for archival, storage, and transport of data (e.g., ASCIISAS Transport, Portable Document Format (PDF), and the CDISC ODM Model) whenever possible.

Data Archival

- Database design specifications
- Raw data
- Audit trail
- Final data: Preserved in a standard file format (e.g., ASCII, SAS transport)
- Original study documents
- Procedural variation documentation: Memos and relevant information about any variations from standard operating procedures or working practices
- Database closure
- Site copies of data (may be required for audit purposes)

External Data Transfers – Minimum Standards

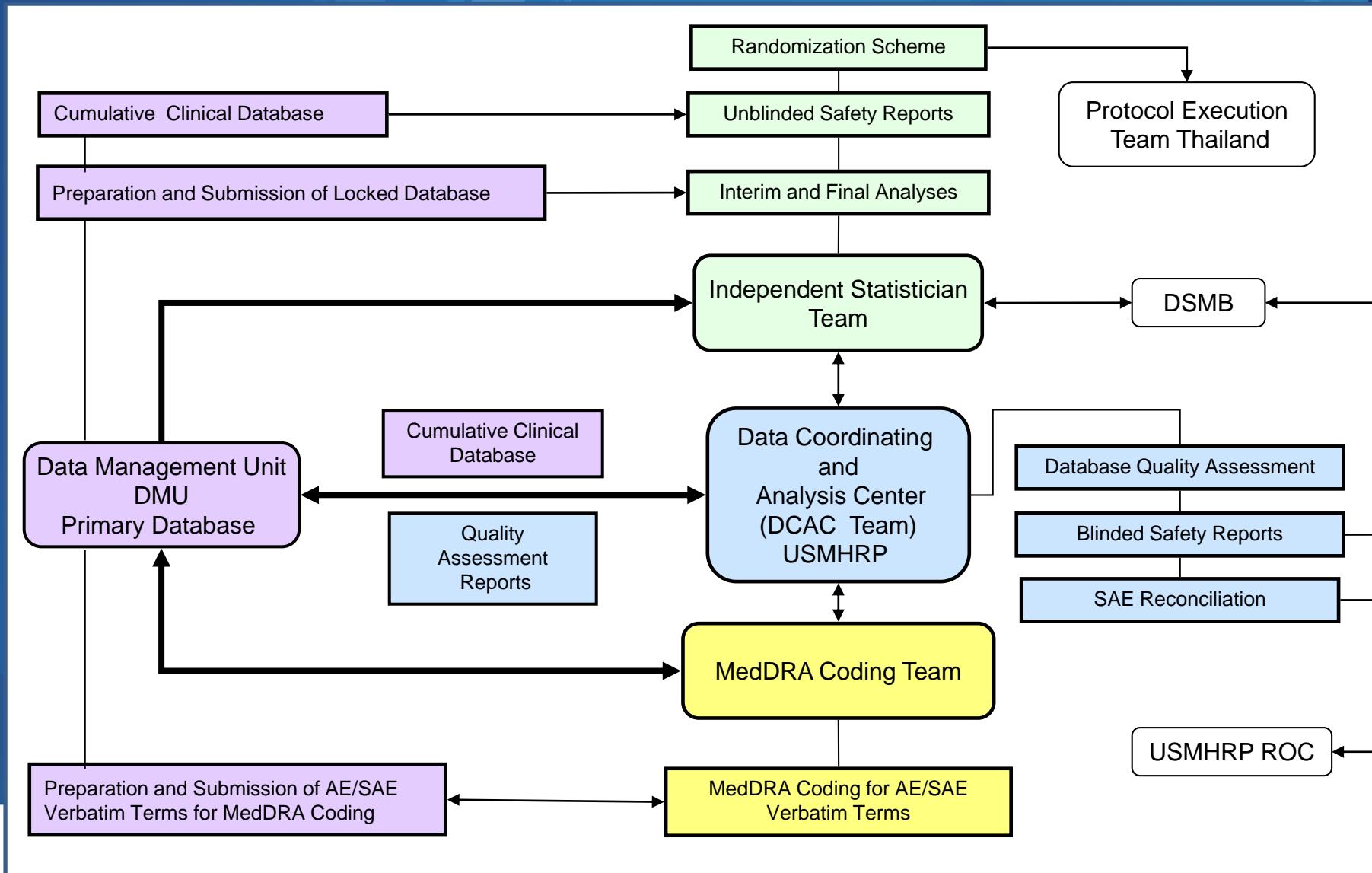
- Establish the procedures for collecting, transferring, loading, validating, and editing external data through sponsor and vendor collaboration.
- Identify key individuals for communication and follow through.
- Maintain a documentation trail.
- Apply quality control procedures to each stage of data handling to ensure that all data are reliable and have been processed correctly.

External Data Transfers – Best Practices

- Validate all programs and systems used for processing clinical trial data in a clinical research environment

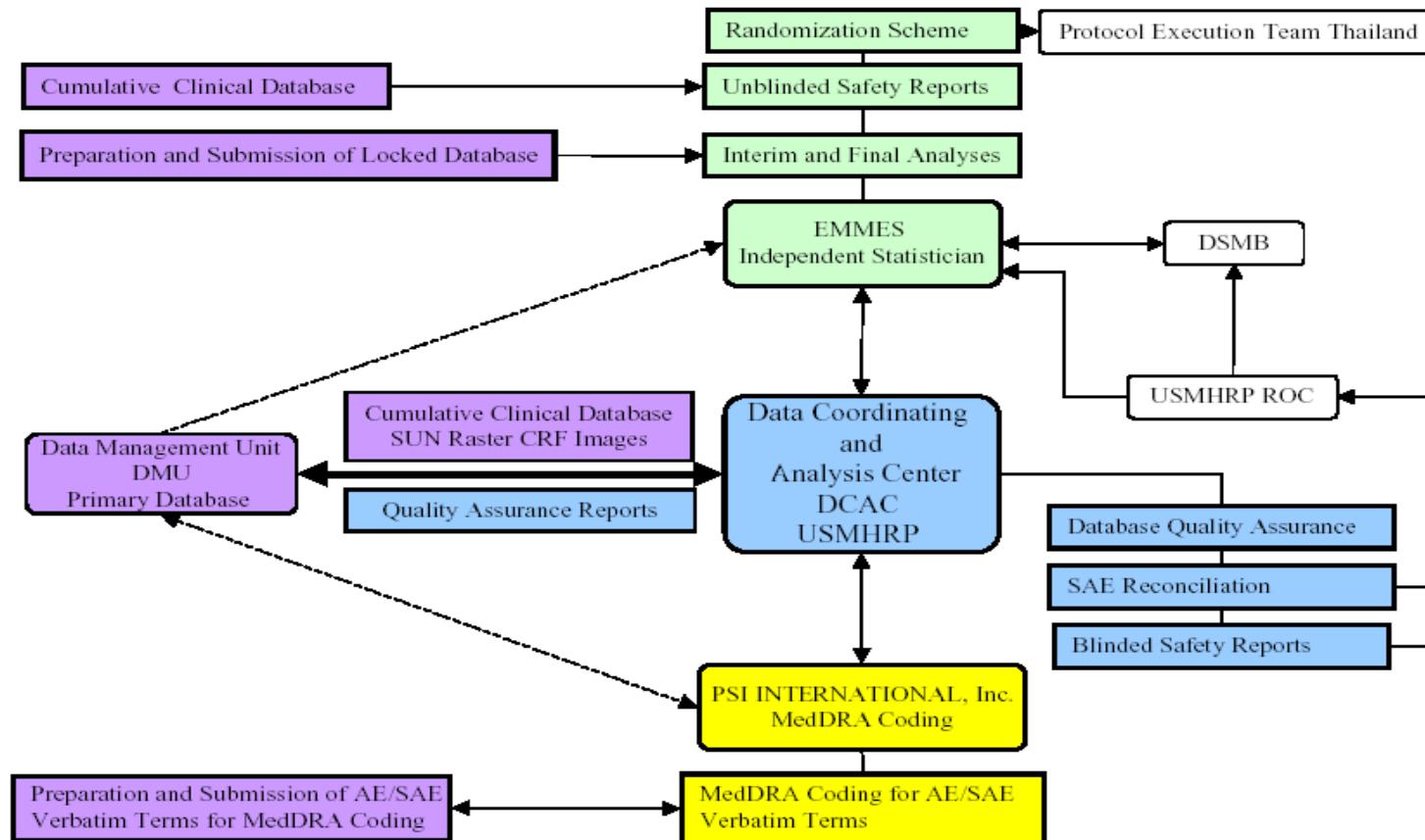
Data Management - Collaborating Teams

Example: Phase III Efficacy Trial of Prime-Boost HIV Vaccine



System & Data Flow Set-up - (Open System)

1. HIVV P3 Study Data Management Interactions



RV144 Flow Diagrams 11/20/2003

System & Data Flow Set-up - (Open System)

Attachment

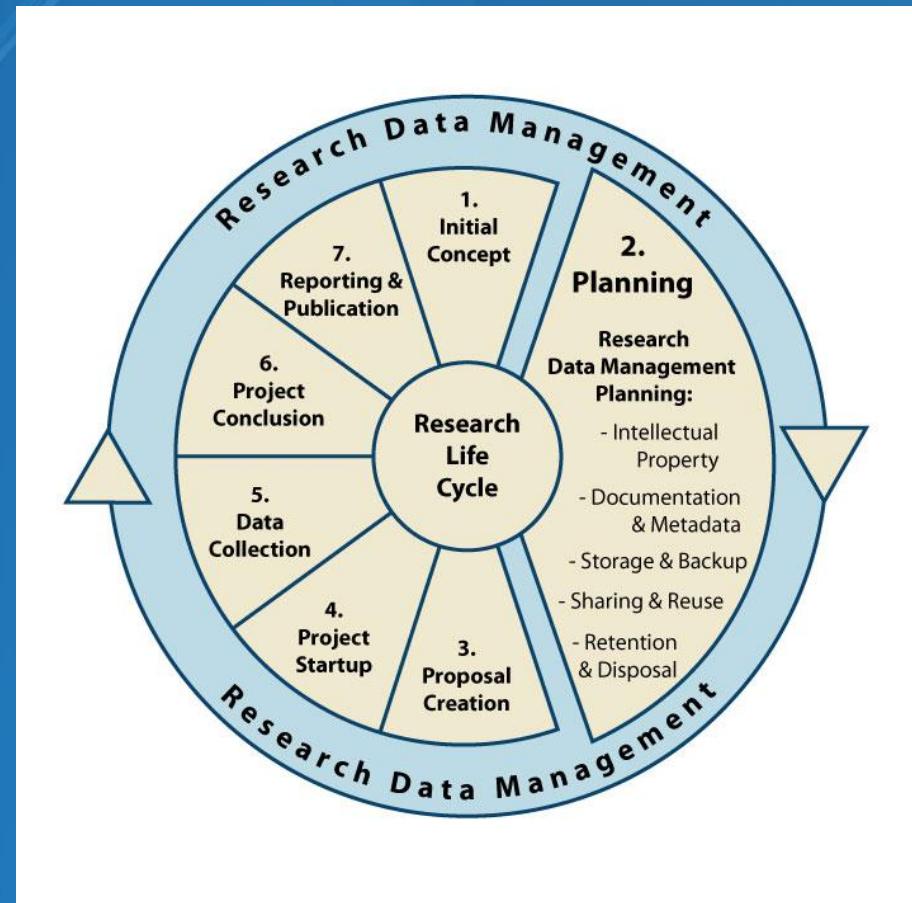
Submitting Organization Name and Address

Page _____ of _____

DCAC ELECTRONIC DATA TRANSMISSION FORM



Training



Training – Minimum Requirements

- Review and update curriculum and individual course offerings regularly, including applicable SOPs, to ensure that content remains current and relevant.
- Train all CDM staff members to perform the job functions that are currently required for their assigned roles.
- Ensure that training documentation is maintained a



Training – Best Practices

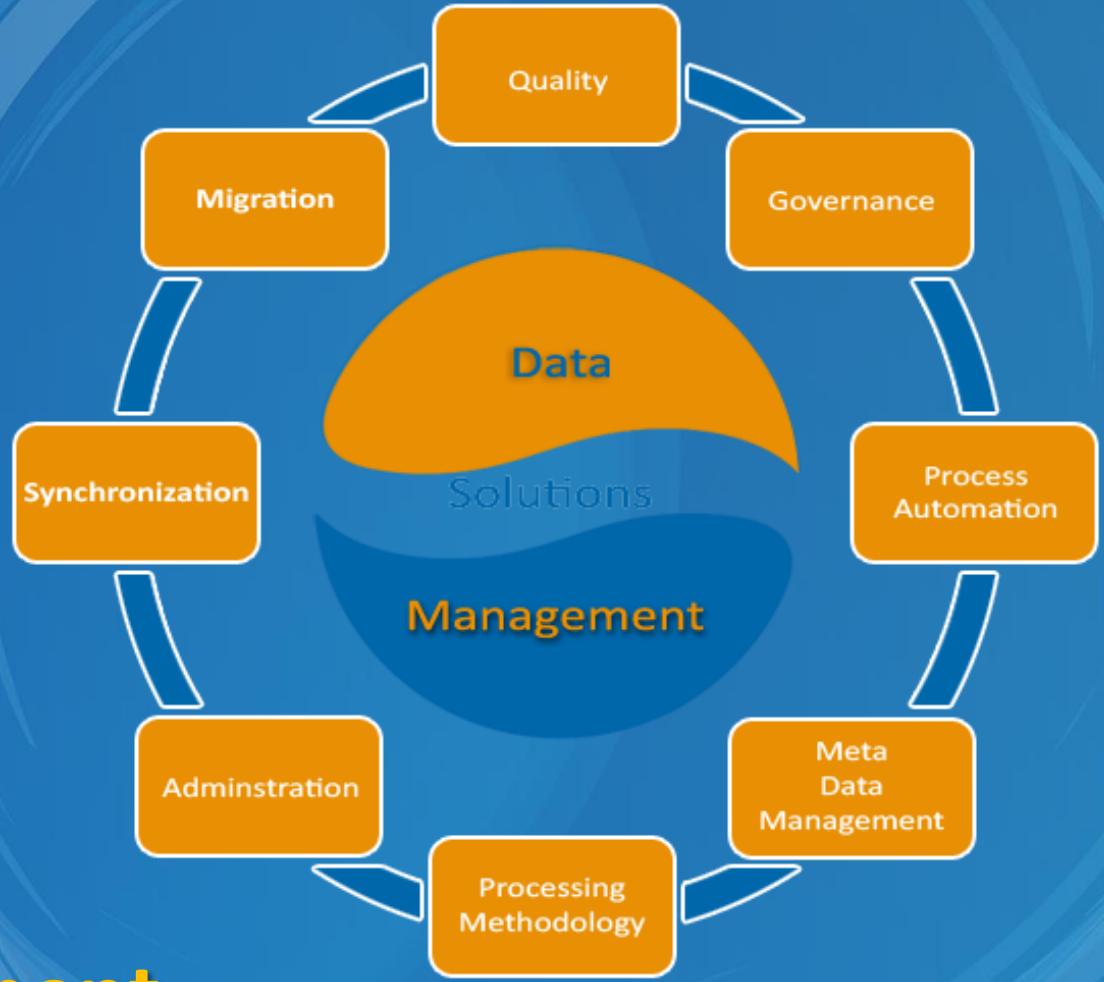
- Document a role-specific training curriculum for each position within the CDM organization.
- Ensure that a master training plan, which is regularly reviewed and revised, documents and prioritizes training needs of the CDM function.
- Perform job-needs analyses and audience analyses to guide development
- of the training plan.



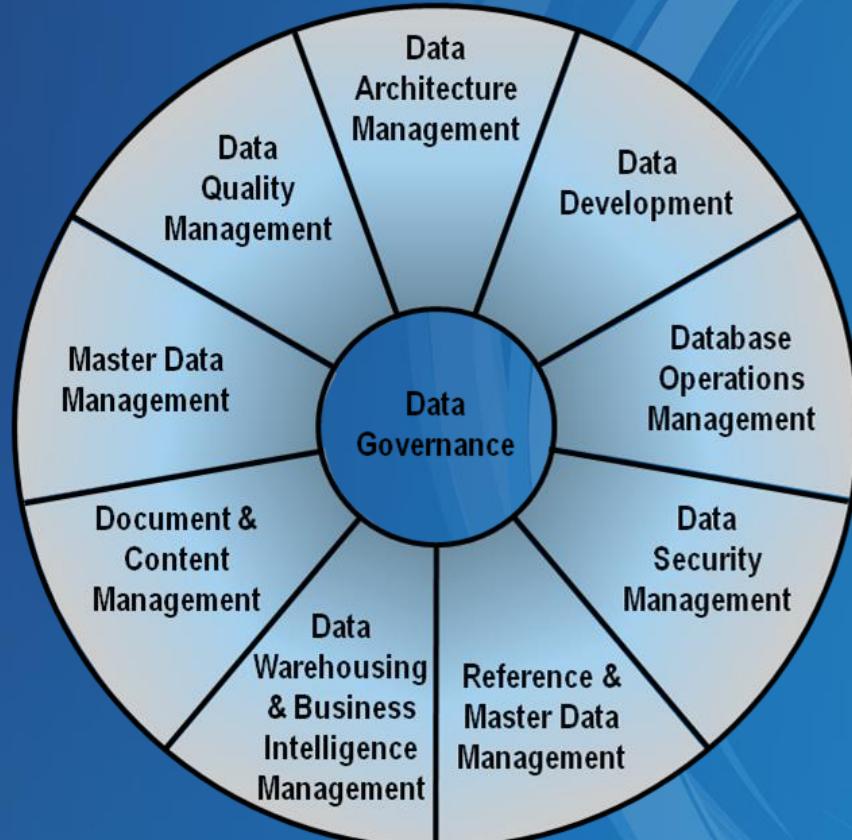
DMU Training Log for Amnat					
No.	Date	Training Course	Organize	Place	Reference
1	7-11/06/00	Solaris 2.X System Administration Essentials SA135	Logic Co.Ltd.	Logic Co.Ltd.	Certificate
2	6-9/20/00	DataFax DFUG 2000 Whistler, British Columbia	Clinical DataFax Systems Inc.	Whistler, British Columbia, CANADA	Document No.1
3	7-10/11/00	macosx@sun.com ด้าน route วิธีการตั้งค่าใน Mac OS X	TROPINED	Lecture Room, 7/F, Tower, Chongqing, China	Document No.2
4	3-4/03/02	DataFax DFUG 2002 Montréal	Clinical DataFax Systems Inc.	Montréal, Québec, CANADA	Document No.3
5	6-10/02/02	Unix for User	Logic Co.Ltd.	Logic Co.Ltd.	Certificate
6	15-16/07/02	training@sun.com ด้าน route วิธีการตั้งค่าใน Mac OS X	TROPINED	Reference Room, 9/F, Champsquare Building	Document No.4
7	25-26/11/02	DataFax Setup	BOAHP, Darby	DMU2	- Certificate - Agenda



Project Management for DM



Summary: Data Management Functions & Elements



10 Data Management Functions



7 Elements

Source: http://tsort.info/iabok/data_management.htm

Project Management for the Clinical Data Manager

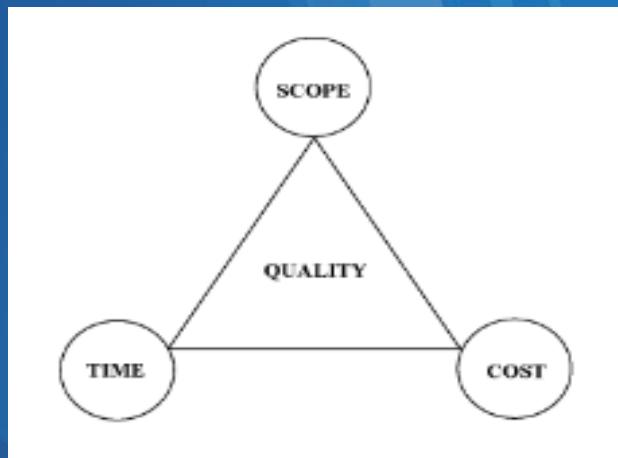
Minimum Standards

- Identify all data management study team members, stakeholders, and respective alternates wherever possible and as early in study setup as possible.
- Identify, define, and document all study-specific processes.
- Ensure clear, comprehensive, and technically feasible timelines of scheduled tasks
- Assure a thorough assessment has been made of CDM team members' familiarity with clinical study processes, disciplines, or functional lines.
- Ensure appropriate project- or study-specific training is delivered, maintained and documented for all study personnel performing CDM tasks.

Project Management for the Clinical Data Manager

Best Practices

- Create a responsibility matrix that describes activities to be conducted during the course of the study.
- Continually assess project processes and modify processes as needed to function more efficiently.
- Ensure all process changes are communicated, documented, and version controlled.



Data Management Metrics

Criterion	Study Startup	Study Conduct	Study Closeout
Quantity	<p>Number of expected subjects</p> <p>Total number of data fields (may be quantified differently by different organizations)</p>	<p>Amount of data entered</p> <p>Amount of data cleaned</p> <p>Expected amount of entered data compared to data in database</p>	<p>Final number of subjects</p> <p>Number of outstanding queries</p> <p>Missing pages report</p>
Cost	Total estimated resources (such as people, licenses, infrastructure, printing, etc.) needed for a study	Number of monitoring visits	<p>Total study costs</p> <p>Average cost per subject enrolled</p>
Time	<p>Projected overall study timeline</p> <p>Time needed for protocol/CRF review and finalization</p> <p>Final approved protocol to database activation</p>	<p>Time from subject visit to data available to CDM</p> <p>Time from subject visit to data cleaned and locked</p>	<p>Time from first subject enrolled to last subject visit</p> <p>Time from last subject visit to final database lock</p> <p>Time from final database lock to clinical study report</p>
Quality	Systems validation results	<p>Number of queries and re-queries</p> <p>Number of data transfer errors</p> <p>Metrics generated from audit trail</p>	<p>Number of data errors per number of total data fields (error rate) (used in paper studies)</p> <p>Number of protocol deviations</p>
Performance	Number of programmed procedures that validate correctly	<p>Comparison of data entry rates across sites</p> <p>Time from subject visit to data entered</p> <p>Average time for query resolution</p>	<p>Number of database unlocks to correct data errors</p> <p>Number of protocol amendments</p>

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SERVICES

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- HEALTH-RELATED GEOGRAPHICAL INFORMATION SYSTEM (GIS)
- DATA ANALYSIS
- SURVEILLANCE TRACKING SYSTEM DEVELOPMENT
- CONSULTATION AND TRAINING SERVICES

CDMS & USER INTERFACE SYSTEMS

EXPERIENCES

SUPPORTS

NEWS AND EVENTS

BIOPHICS



Background :

BIOPHICS is the center of excellence for biomedical and public health informatics located at the Faculty of Tropical Medicine (FTM), Mahidol University, Ratchavithi Campus, Bangkok, Thailand. The goal of the center within the FTM environment is to be the resources for both "teaching and reaching" the public with integrity and quality health informatics. The center has set its mission not only to serve Thailand needs but also to reach other countries, especially those in the same tropical environment. It is also planned to bridge and network with other existing centers for knowledge-based and health informatics for global health outcomes at large.

BIOPHICS also provide a wide range of development, management and consulting services to pharmaceutical industries, biotechnology, academic institutes and public health organizations. BIOPHICS has experiences in managing clinical databases for several large clinical trials as well as other observational studies and disease registry. The clinical trials ranged from PK study, Phase I to Phase III studies, and Phase IV monitoring adverse drug reaction (ADR). BIOPHICS offers other service of computerized system development



Remember Mr Pooter is not just a 'patient', he's an important source of valuable and readily marketable data!

The End of Introduction to Data Management for Clinical Research