

Data Management Operations at HPTN 039 Peruvian sites

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IMPACTA-CTU

Data Management strategies Implemented for HPTN 039

■ QC/QA strategies

- Pre Data management – Fast QC/QA
- Extensive use of tools
- Double QC
- Continuous data management training

■ Error Management strategies

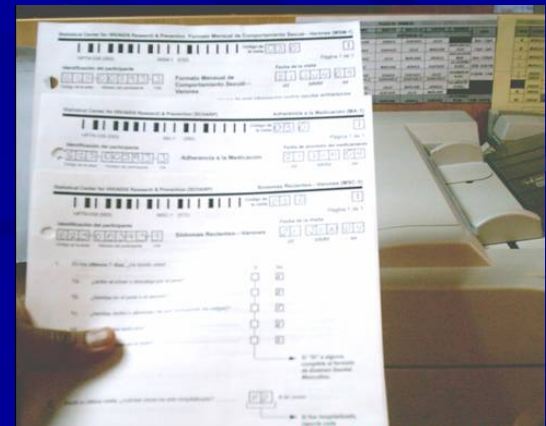
- Error capture / Classification
- Error entry
- Error analysis and dissemination

■ CLIS – Data Management

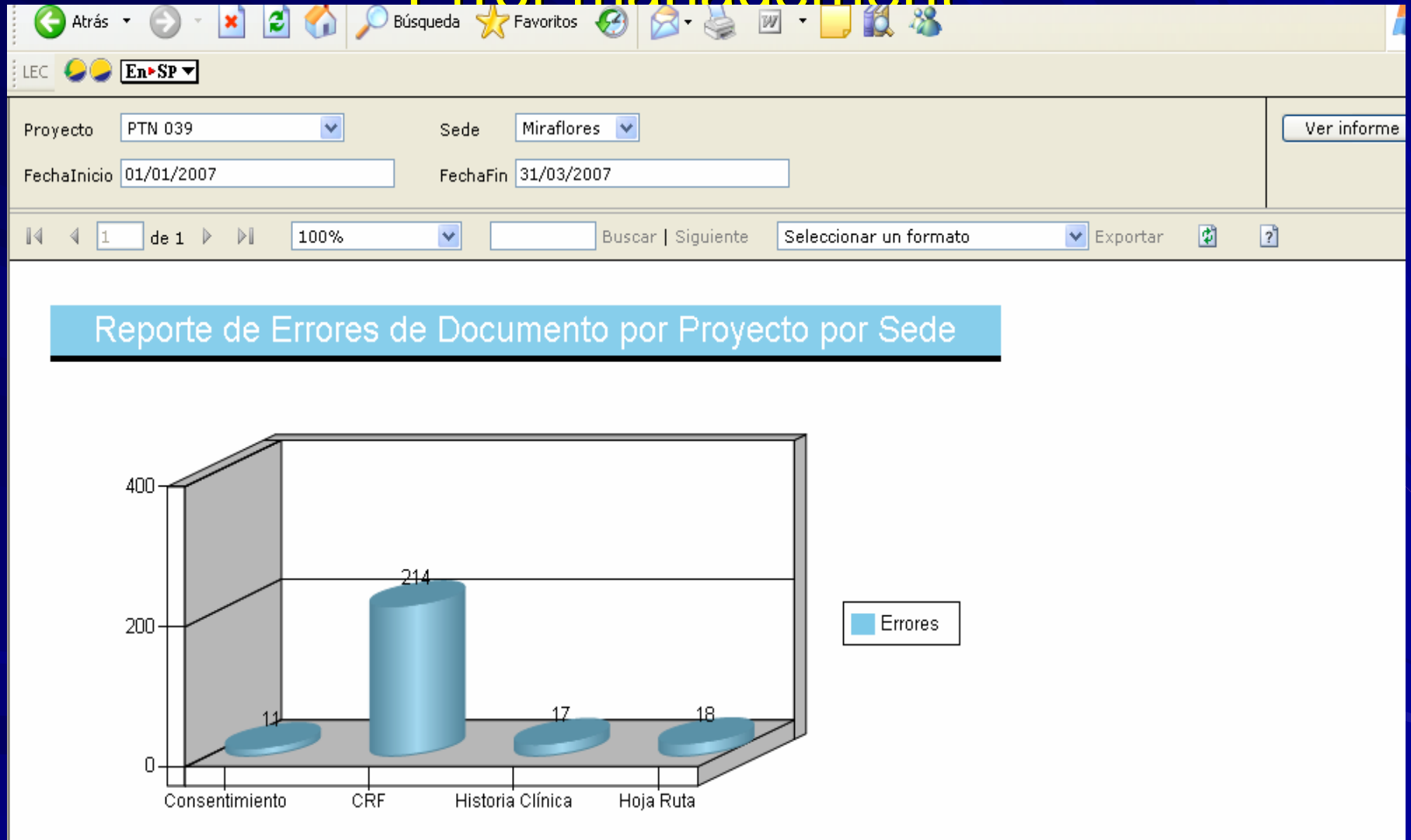
- Alert to prepare and distribute documents
- Document inventory and document transferring

Quality control and Quality Assurance

- Pre quality management
- 2 QC by different data managers and 1 QA to 100% of the documents
- Standardized tools for each CRF, medical chart, lab result
- Continuous QC/QA training

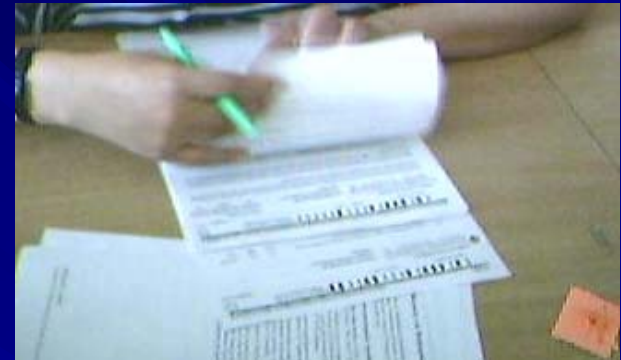


Error management



Document archiving

- CLIS - Tracking Health record
- Alert to prepare documents in advance
- CLIS – Document transferring



Data collection / Reports

- Data entry of data not transmitted: reason of not enrollment
- Screening log on line
- Accrual data on line
- Protocol status on line

Microsoft Internet Explorer
http://intranet.impactaperu.org - ParticipanteNuevosRespuestas

PT ID: 0920-0021-1
Nro de visita: 4
Fecha de Visita: 25/05/2007

Diagnostico

DIAGNOSTICO

1.- Número de diagnóstico:
2

2.- Diagnóstico:
CANDIDIASIS

3.- Número de episodios:
1

4.- ¿Es un Evento Adverso?
 Si
 No
 No aplicable

5.- Método de Diagnóstico:
 Clínico
 Laboratorio

6.- Fecha de inicio
05/05/2007 JDDMMYYYY

Clinic Information System – CLIS

Web based clinic management program

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IMPACTA-CTU

CLIS Overview

- Clinic information program tailored for the management of patient visits, implemented in Peru.
- Developed under NIH regulations (CFR 24 part 11), National Health Ministry Policies and good clinical practices
- Results: High retention rates, world class data management, integrated clinic info

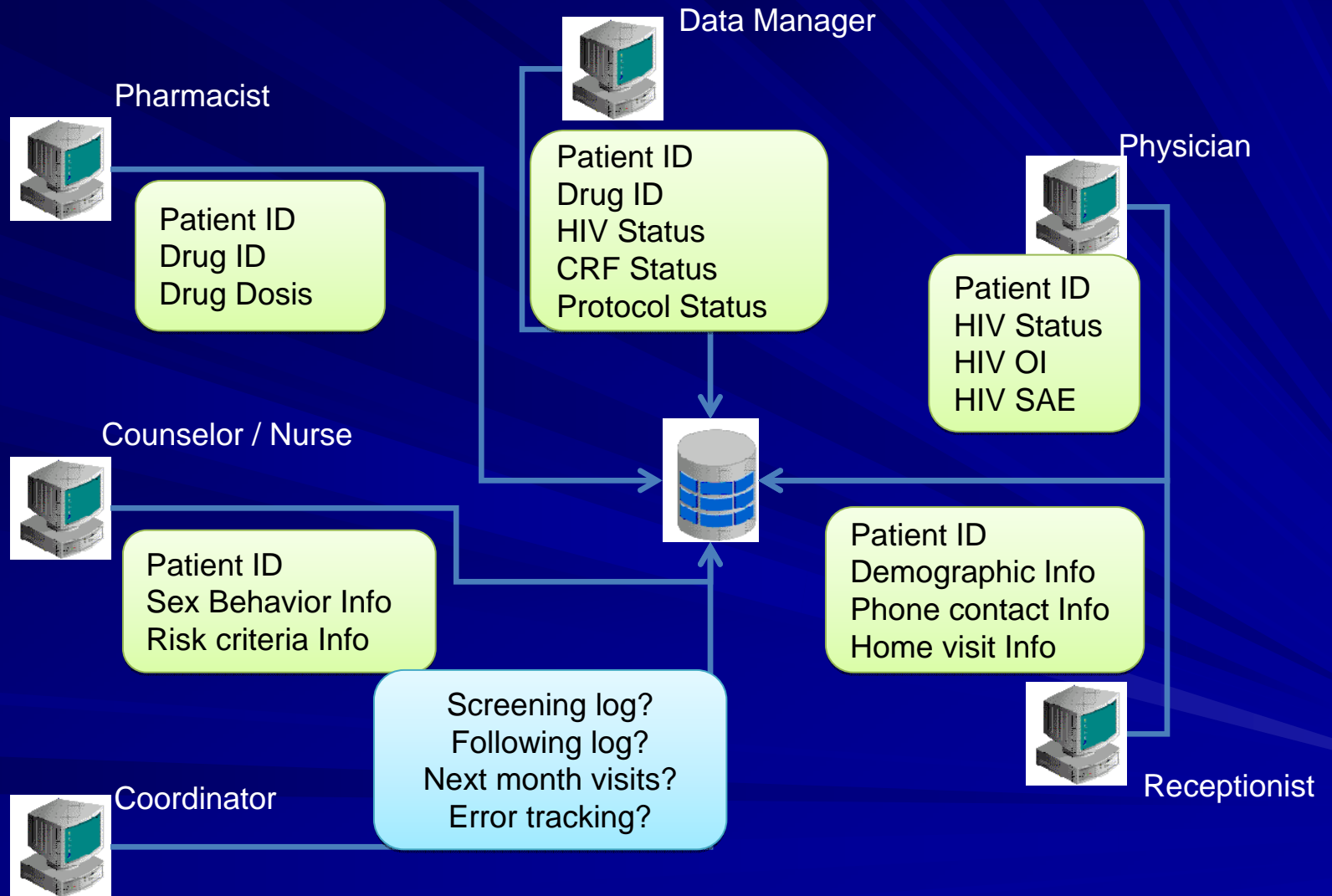
CLIS Goals

- Delivery of quality HIV information
 - Help providers document protocol visit quickly
 - Easy access to visits and treatment history
 - Share critical information within clinical team
- Facilitate protocol monitoring and reporting
 - Automatically generate standard program reports
- Enable analysis of clinic research management and basic HIV outcomes

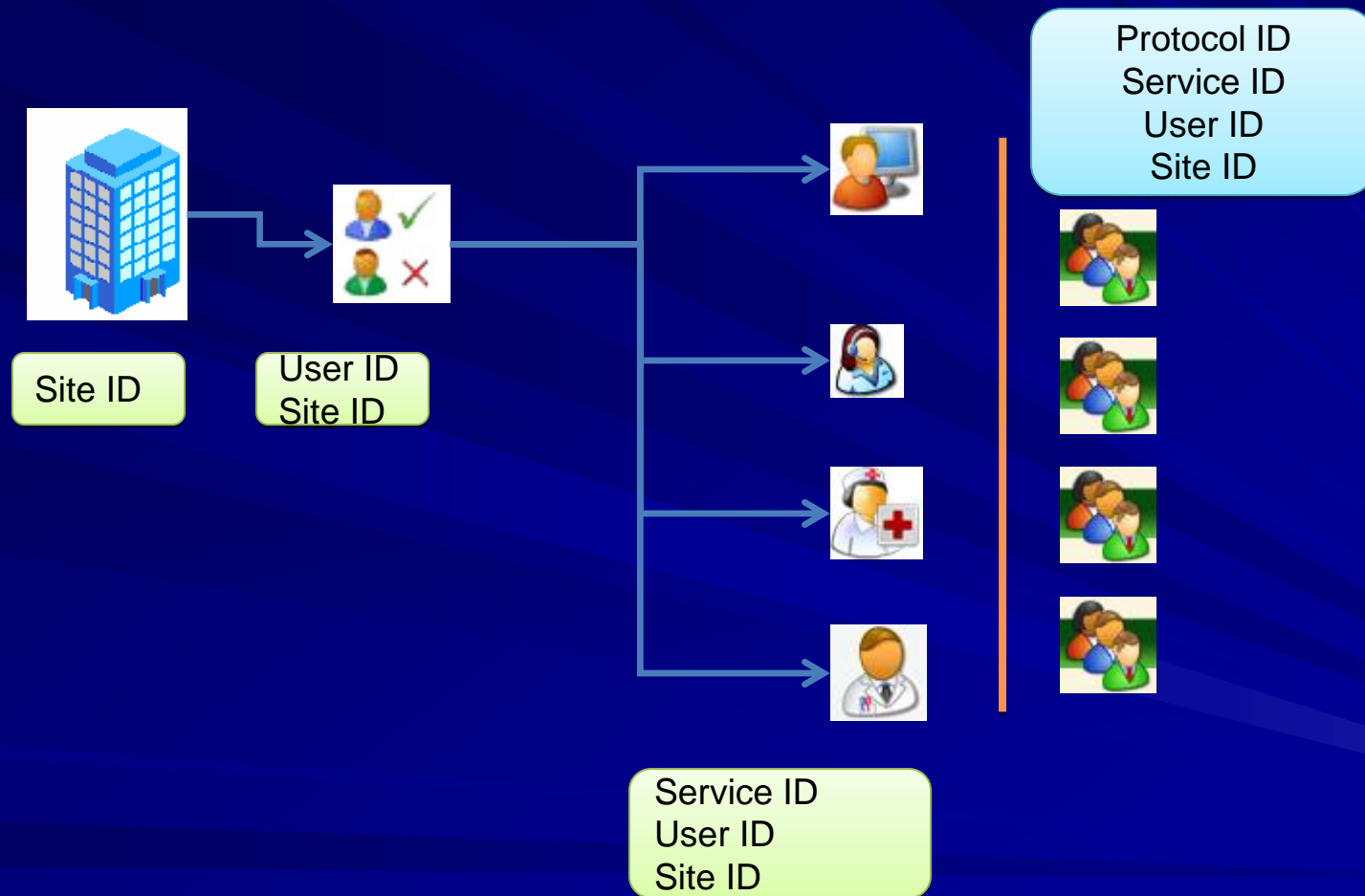
CLIS Design Principles

- Changes in the protocol are possible any time
- Information changes are recorded with username, time and IP address
- None health provider has the complete patient information
- Restricted permissions by site, protocol, and user type

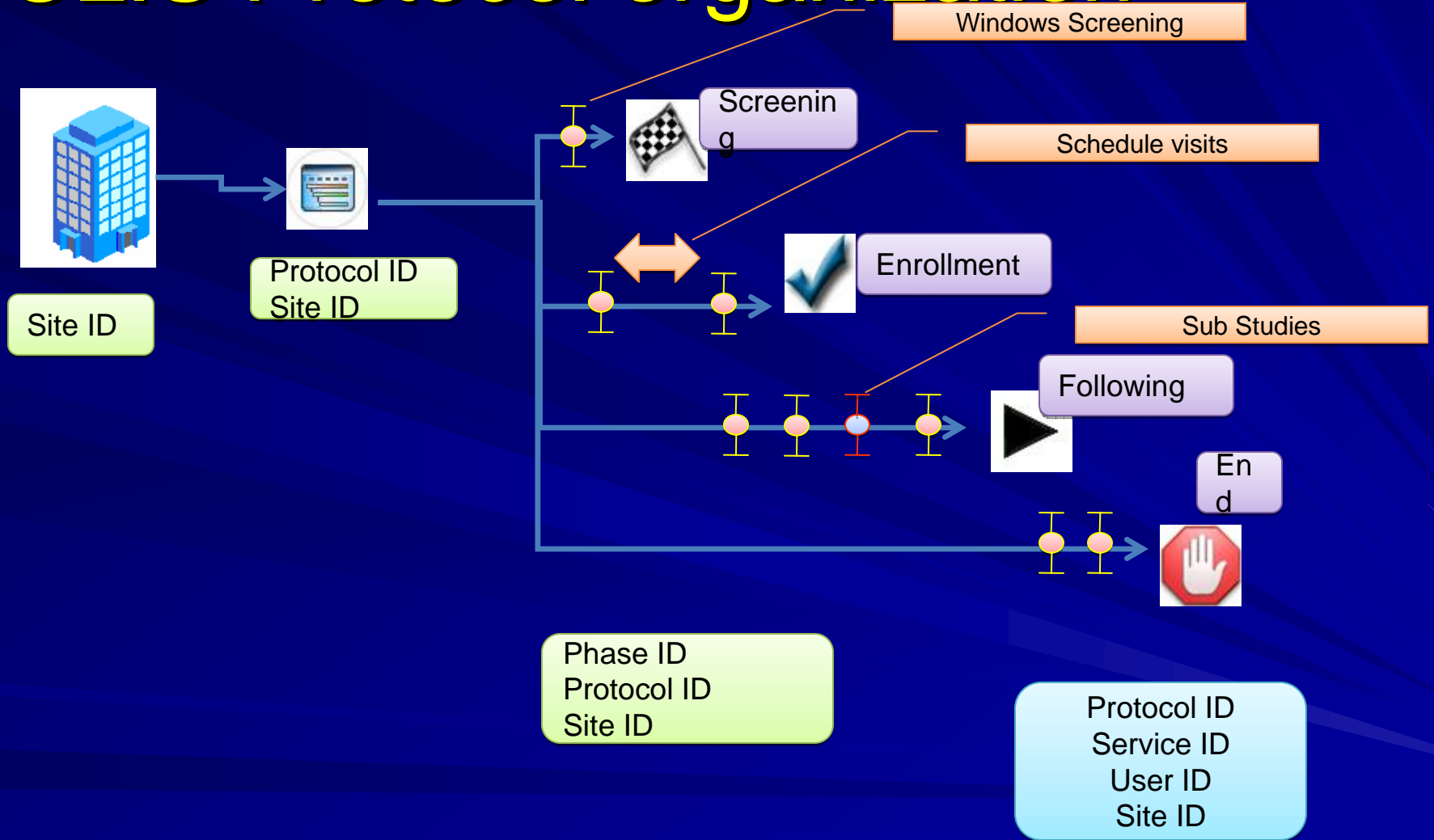
CLIS Modules



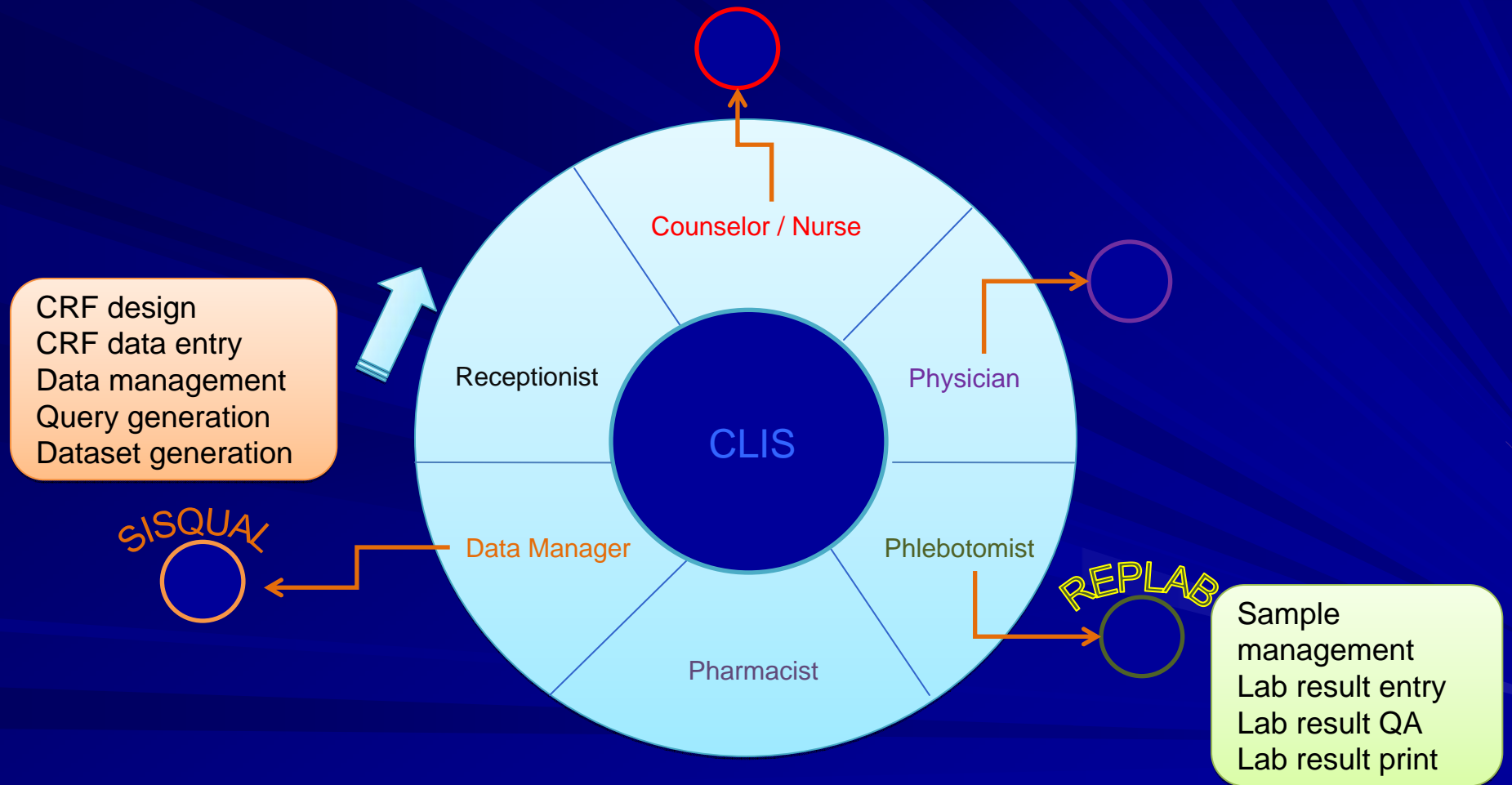
CLIS Users organization



CLIS Protocol organization



CLIS cycle and integration



Calendar tool

SITE

DATE

DAY

PROTOCOL

Fecha Cita:

Sede:

Proyecto:

	Lunes 14	Martes 15	Miercoles 16	Jueves 17	Viernes 18	Sa	
CONSEJERIA 3 Jimenez	PTN 039 - M10- V16 09:00-10:30 PTN 039 - M9 - V15 14:00-15:30 PTN 039 - M11- V18 14:30-16:00 PTN 039 - INT 16:30-18:20	PTN 039 - M9 - V15 16:30-18:00	PTN 039 - TR4- V14 09:30-11:30 PTN 039 - M9 - V15 12:00-13:30 PTN 039 - M9 - V15 14:00-15:30 PTN 039 - TR4- V14 16:30-18:30		PTN 039 - INT 16:00-17:50		
CONSEJERIA 6 gdiaz	PTN 039 - M11- V18 09:00-10:30 PTN 039 - M12- V19 10:30-12:00 PTN 039 - INT 11:00-12:50 PTN 039 - TR4- V14 12:30-14:30 PTN 039 - M9 - V15 16:00-17:30 PTN 039 - TR4- V14	PTN 039 - TR4- V14 09:30-11:30 PTN 039 - TER- V20 10:30-12:30 PTN 039 - M12- V19 15:30-17:00 PTN 039 - M9 - V15 17:00-18:30	PTN 039 - M12- V19 09:00-10:30 PTN 039 - TR4- V14 09:30-11:30 PTN 039 - M12- V19 10:00-11:30 PTN 039 - M9 - V15 10:30-12:00 PTN 039 - INT 10:30-12:20 PTN 039 - INT	PTN 039 - TR4- V14 09:30-11:30 PTN 039 - M12- V19 10:00-11:30 PTN 039 - TR4- V14 10:30-12:30 PTN 039 - M12- V19 15:30-17:00 PTN 039 - M9 - V15 16:00-17:30	PTN 039 - TER- V20 09:00-11:00 PTN 039 - M10- V16 10:30-12:00 PTN 039 - TR5- V17 11:30-13:30 PTN 039 - M9 - V15 12:00-13:30 PTN 039 - INT 14:30-16:20 PTN 039 - TR4- V14		

PROVIDER

PARTICIPANT - VISIT
- HOUR / MINUTES

MISSED
ATTENDED
POSPONED

Visits tool

The screenshot shows a web-based interface for managing visits. At the top, there are dropdown menus for 'Proyecto' and 'Sede', and a 'Crear Cita' button. Below this is a 'Historia Clínica' section. The main part of the interface is a table with columns: 'Eli.', 'Sede', 'Proyecto', 'Etapa', 'Fecha', 'Hora', 'Edi.', 'Log.', 'Estado', 'Ruta', and 'Reprog.'. Two rows of visit data are visible. The first row shows a visit on 'Jun 05/05/2005' with status 'Falta'. The second row shows a visit on 'Jun 14/04/2005' with status 'Atendido'. To the right of the table are icons for phone, home, and a list. Callout boxes point to various elements: 'PROTOCOL' points to the 'Proyecto' dropdown; 'SITE' points to the 'Sede' dropdown; 'GENERATE VISITS' points to the 'Crear Cita' button; 'VISIT STATUS' points to the 'Estado' column; 'REPROGRAM VISITS' points to the 'Reprog.' button; 'PHONE AND HOME CONTACT' points to the phone and home icons; 'RECRUITER DATA' points to the list icon; 'PROVIDER' points to the 'Eli.' column; and 'VISIT AND WINDOWS' points to the 'Fecha' and 'Hora' columns.

Proyecto : ----- Sede: ----- Crear Cita

Historia Clínica

Eli.	Sede	Proyecto	Etapa	Fecha	Hora	Edi.	Log.	Estado	Ruta	Reprog.
	Miraflores	PTN 039	T2	Jue 05/05/2005	11:00-12:30			Falta	Ruta	Reprog.
	Miraflores	PTN 039	T1	Jue 14/04/2005	11:50-14:12			Atendido	Ruta	

GENERATE VISITS

PROTOCOL

SITE

VISIT STATUS

REPROGRAM VISITS

PHONE AND HOME CONTACT

RECRUITER DATA

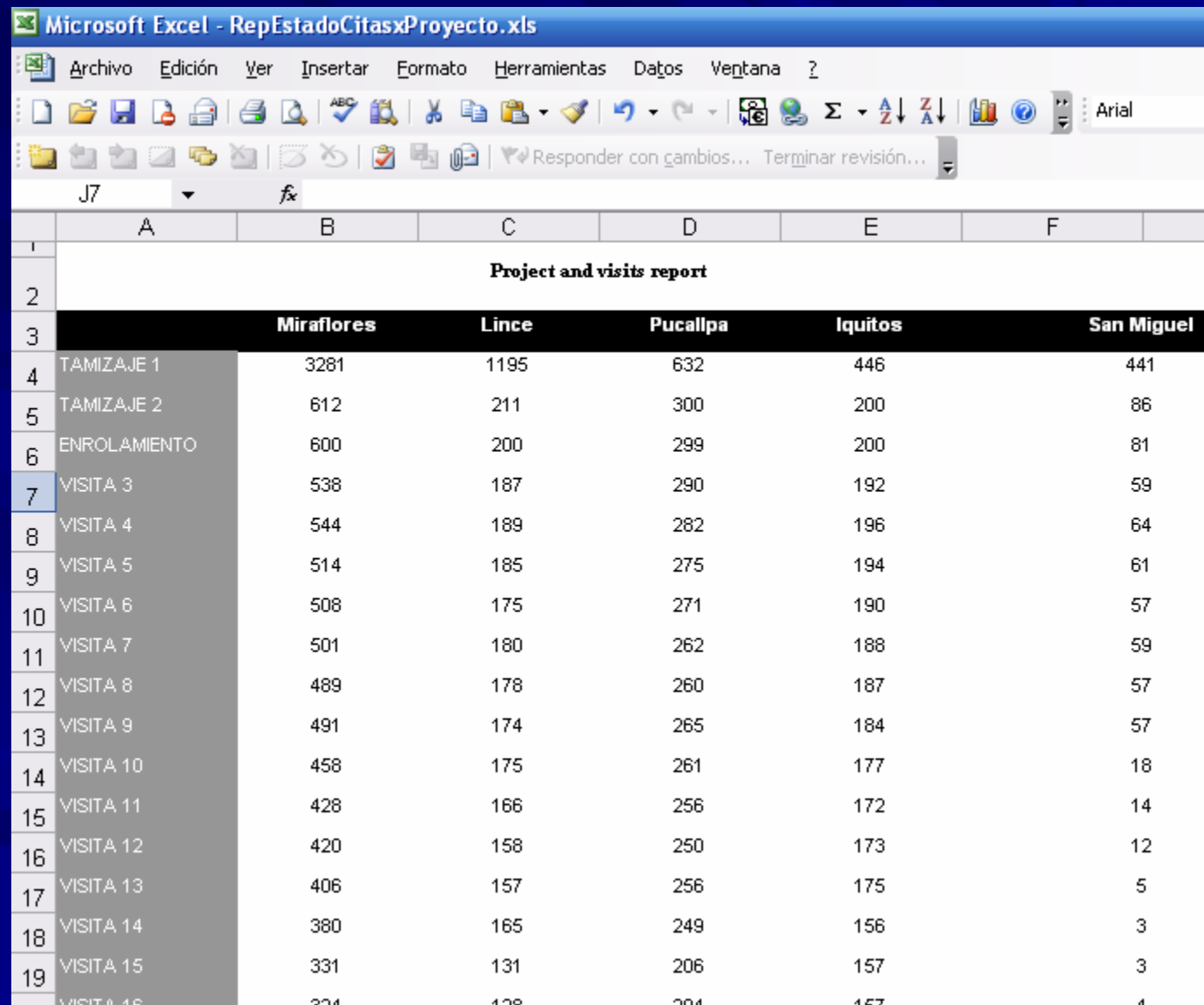
PROVIDER

VISIT AND WINDOWS

Screening log

Sede	Miraflores	Proyecto	PTN 039
Fecha Inicio (DD/MM/AAAA)	16/12/2003	Fecha Fin (DD/MM/AAAA)	19/05/2007 03:44:53 a.m.
1 de 72 100% Buscar Siguiente			
Seleccionar un formato Exportar ?			
<u>Lista de PTID</u>			
<u>PTID</u>	<u>Fecha Tam</u>	<u>Fecha Enrol</u>	
625-00152-8	19/02/2004	11/03/2004	
625-00304-9	02/04/2004		
625-00470-5	04/01/2006		
625-00627-1	07/07/2004		
625-00792-6	11/01/2005		
625-00966-0	08/09/2004		
625-01142-5	17/01/2005		
625-01321-4	26/11/2004		

Protocol status exported to excel



Microsoft Excel - RepEstadoCitasxProyecto.xls

Archivo Edición Ver Insertar Formato Herramientas Datos Ventana ?

J7 fx

	A	B	C	D	E	F
1	Project and visits report					
2						
3		Miraflores	Lince	Pucallpa	Iquitos	San Miguel
4	TAMIZAJE 1	3281	1195	632	446	441
5	TAMIZAJE 2	612	211	300	200	86
6	ENROLAMIENTO	600	200	299	200	81
7	VISITA 3	538	187	290	192	59
8	VISITA 4	544	189	282	196	64
9	VISITA 5	514	185	275	194	61
10	VISITA 6	508	175	271	190	57
11	VISITA 7	501	180	262	188	59
12	VISITA 8	489	178	260	187	57
13	VISITA 9	491	174	265	184	57
14	VISITA 10	458	175	261	177	18
15	VISITA 11	428	166	256	172	14
16	VISITA 12	420	158	250	173	12
17	VISITA 13	406	157	256	175	5
18	VISITA 14	380	165	249	156	3
19	VISITA 15	331	131	206	157	3
20	VISITA 16	324	128	204	157	4

CLIS cycle and integration

- Technology: SQL / ASP
- Database: Data-DB / Structure-DB
- Configured to 300 users, 10 sites in Peru, 1 in Ecuador
- Patients (~10,000)
- Protocols: 24 – active 14 (including sub-studies)
- Cost implementation without backup & firewall
 - SQL license \$300 (educative version)
 - Server \$1000