Technology Transfer for Local Data Collection

Simion Pruna, PhD

Institute of Diabetes "N. Paulescu" Bucharest

Introduction

- Medicine is a rapidly advancing science and clinical research plays a pivotal role in establishing evidence

- There is an increasing interest for multi-centric clinical trials across the EU particularly in new EU countries

- Data Collection and validation are critical components in every research project

Introduction (2)

- Collecting, collating and validating data across multiple geographically distant locations in multi-centric clinical trial is an ongoing challenge

- Information technology offers several solutions to over come these challenges

- In BIRO we design a system, SEDIS that is build with free and open source components for web based clinical research management

Web based solution

- In a multi centric clinical trial data from different geographic location need to be centrally pooled and available for data analysis as well as data mining

- A web based clinical research system allows an online continuous data flow multi directionally

- However using an internet platform for data collection has some drawbacks, **patient privacy and security** is a prime concern

# Open Privacy Management Framework (OPMFH)

- This is a framework for providing robust access control and authentication functions to ensure the privacy of patient and healthcare worker information

Open Privacy Management Framework for BIRO TT

- We see this framework as being based on four major modules:
  1. Authentication
  2. Authorization
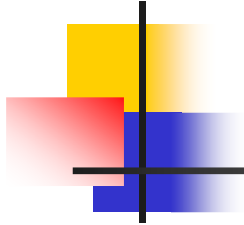 3. Transport
  4. Logging

Authentication
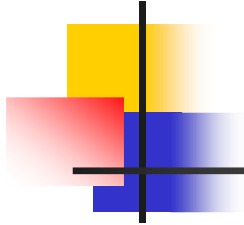
- Deals with a user logging in to the web interface that would allow him / her to interact with the system
  - could be *implemented classically*, by using **a username and password,** in which case, the system is responsible for providing a secure password policy
  - *next generation type of implementation* could be optionally adopted, by using **biometrics** and by having users, instead of using their login credentials, place their thumb on a finger print reader and entering the system based on their thumb print.

Authorization

- The authorization module deals with restricting the user, while in the system, only to the actions that are allowed for that certain user profile
  - the system will have the capability of adding user group permissions
  - each screen in the system could limit it's functions based on the permissions of the certain user accessing it
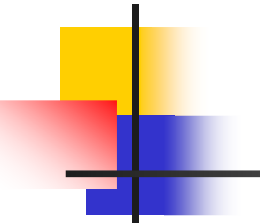
Transport

- The transport module will deal with moving data back and fourth in between the client machine and the server machine

  - highly sensitive data must be protected at all times, including and especially during the transport procedure, where it tends to move through various networks, and could be exposed to anybody listening
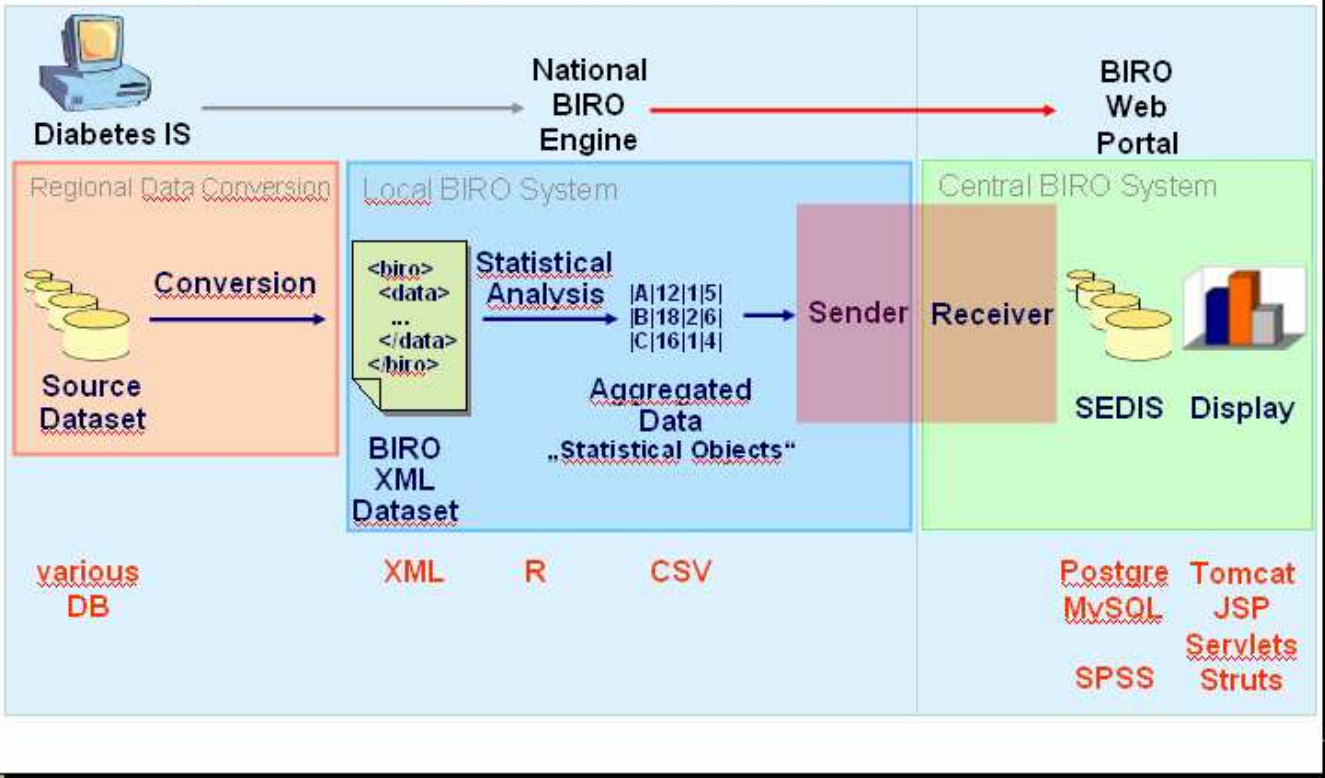
Transport (2)

- The Java Cryptography Extension and Java Secure Socket Extension will be employed here, in order to encrypt the data before sending it through the networks.

- This would ensure that anybody listening, won't be able to make anything of the encrypted data.
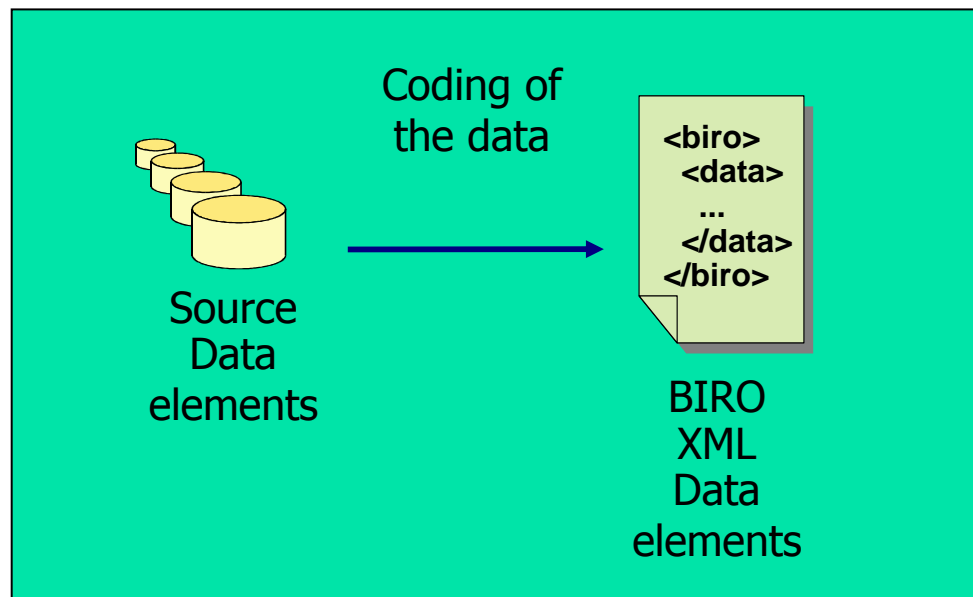
Logging

- Although the logging module doesn't deal with privacy directly, it ensures that anything done in the system is properly tracked, in order to be able to investigate should any breaches to the system might occur.

- A second aspect of the logging module is that of keeping historical records of modified data.

- Ensures that the data can never be maliciously modified without being able to revert to a previous correct version

Coding / encoding procedures for the fields

Coding of the data

Source Data elements

```
<biro>
  <data>
  ...
  </data>
</biro>
```
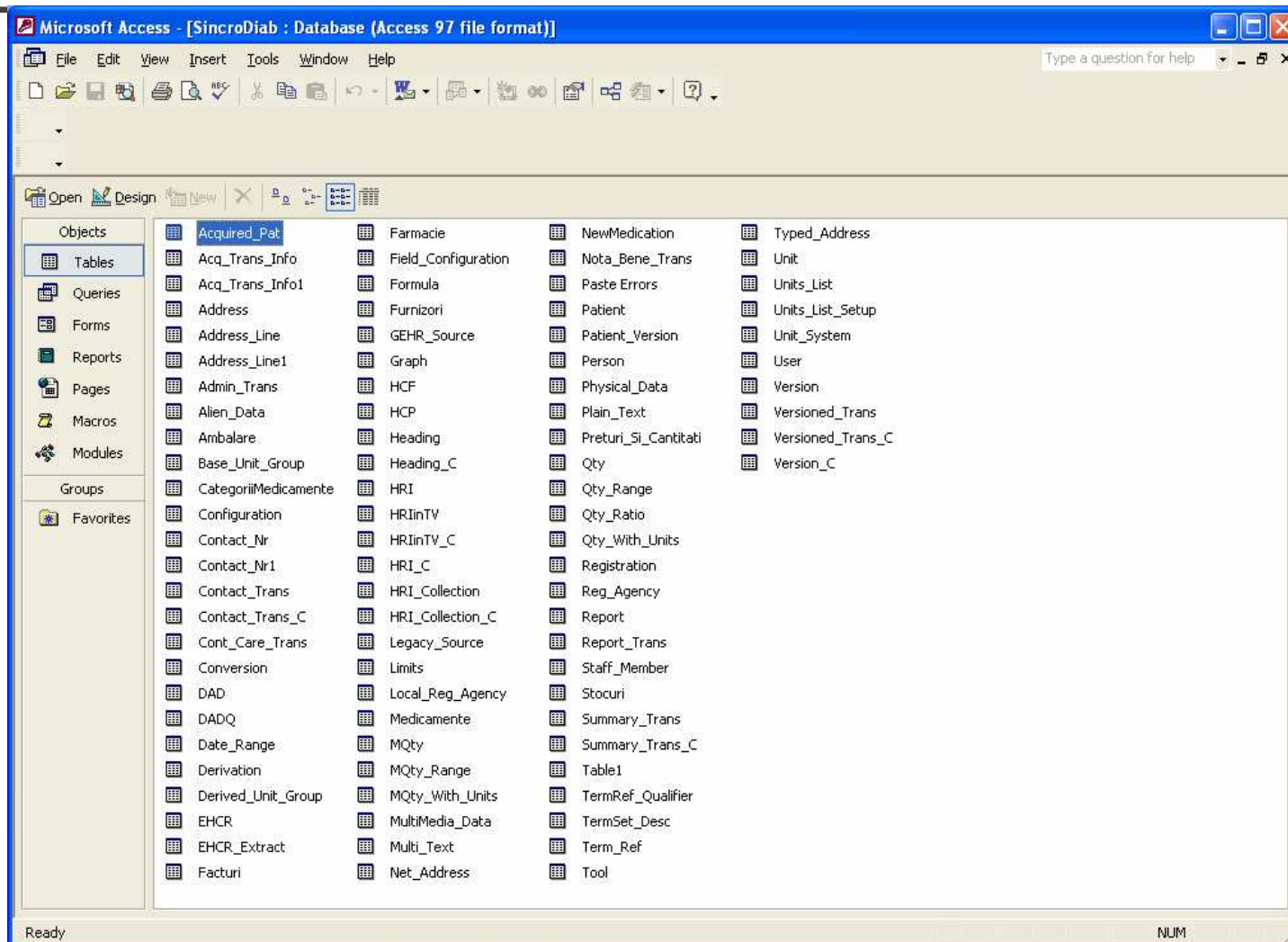
BIRO XML Data elements

Keeping historical records

- It is required by GEHR for an EHCR application never to delete any information

- This ensures that the data can never be maliciously modified without being able to revert to a previous correct version

SincroDiab – 88 tables

Local Data export

SincroDiab XML dataset

Microsoft Excel - Cons.xml

A1 = Id

#	L (Health insu)	M (recipe num)	N (duration of)	O (Height cm)	P (Weight kg)	Q (Glycemia)	R (HbA1C(%))	S (Cholestero)	T (ASAT)	U (Uree)	V (Urycemia)	W (Triglyceride)	X (ALAT)	Y (Serum cre)	Z (right dz ret)
1	Health insu	recipe num	duration of	Height cm	Weight kg	Glycemia	HbA1C(%)	Cholestero	ASAT	Uree	Urycemia	Triglyceride	ALAT	Serum cre	right dz ret
2	Bucuresti		60	171	72	178									
3	Bucuresti		60	158	70	151			64	37			96	88.4	
4	Bucuresti		60	155	75	230									
5	Ilfov		60	165	81	298									
6	Bucuresti		60	162	84	129			16	23			18	88.4	
7	Bucuresti		60			239		1.78	40	65	8	2.18	48	88.4	
8	Bucuresti		60	173	84	154		0.87	41	20		1.1	44	88.4	
9	Bucuresti		60	163	87	152									
10	Dambovita		60	174	77	165									
11	Bucuresti		60	163	83	131			21	20			22	88.4	
12	Bucuresti		60	168	90	199									
13	Bucuresti		60	155	105	190		1.05	31	70		1.32	24	88.4	
14	Giurgiu		60	176	137	164									
15	Bucuresti		60	158	87	188									
16	Giurgiu		60	151	62	212									
17			60	137	83					44					
18			60	165	70										
19			60												
20			60												
21			60	152	79									88.4	
22	Bucuresti		60	143	80	120									
23	Bucuresti		60	159	81	100		1.42	24	42		1.75	16	88.4	
24	Bucuresti		60	155	86	148		1.24	69		6	1.53	48	88.4	
25	Bucuresti		60	158	60	147	602		16	39			20	88.4	
26	Bucuresti		60	158	94	165			36				47		
27	Bucuresti		60	166	74										
28	Bucuresti		60	160	59	203									
29	Bucuresti		60	160	77	217			35	35			30	88.4	
30	Bucuresti		60	160	81	208				31	6			88.4	
31	Buzau		60	184	115	140	7	0.77		32	5	9.8		88.4	
32	Bucuresti		60	159	84	126									
33	Bucuresti		60	182	114	148			48	36			32	88.4	
34	Ilfov		60	160	120	167			17	60			24	88.4	
35	Bucuresti		60	162	75	300			12	36			16	88.4	

Cons

Ready NUM
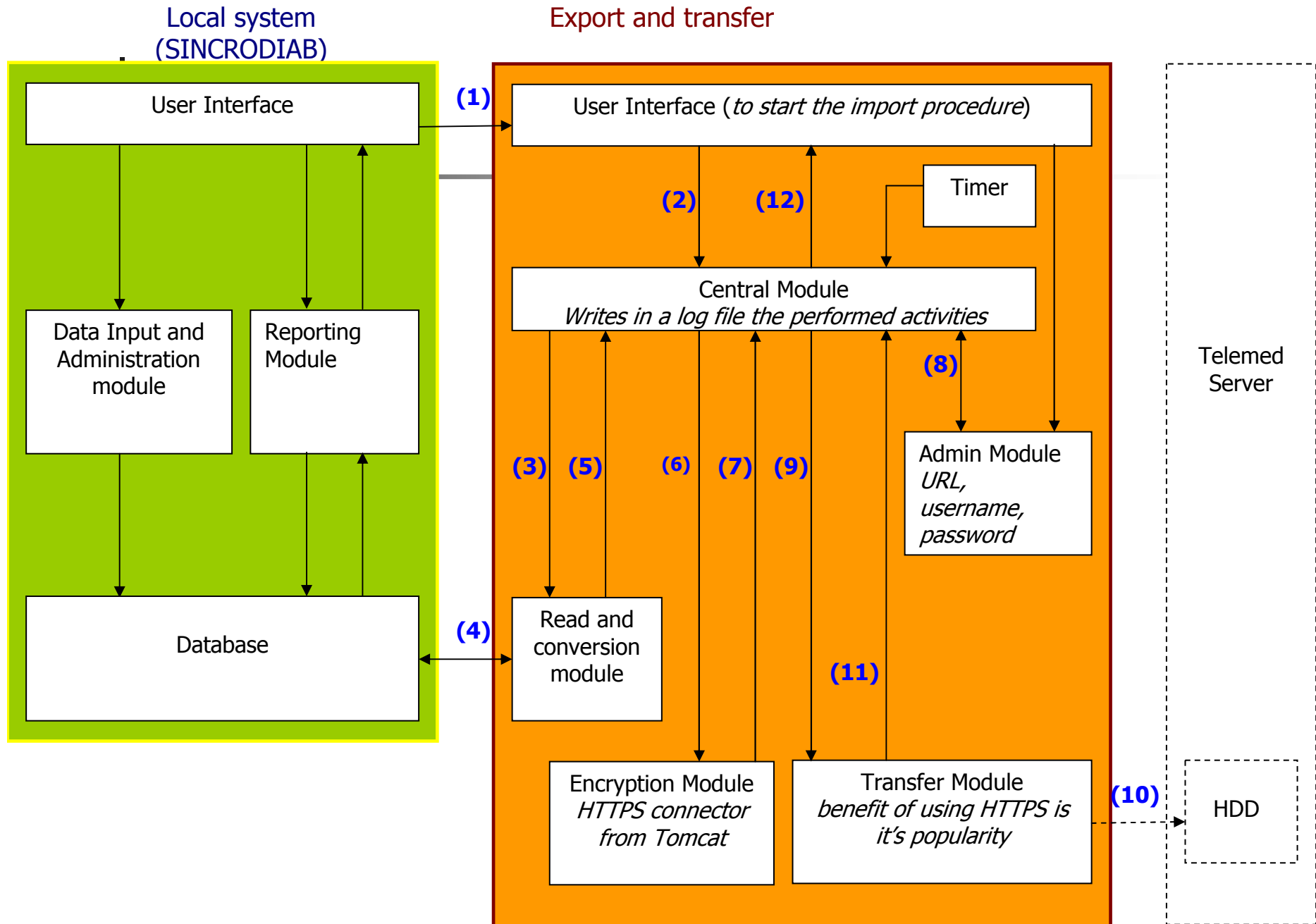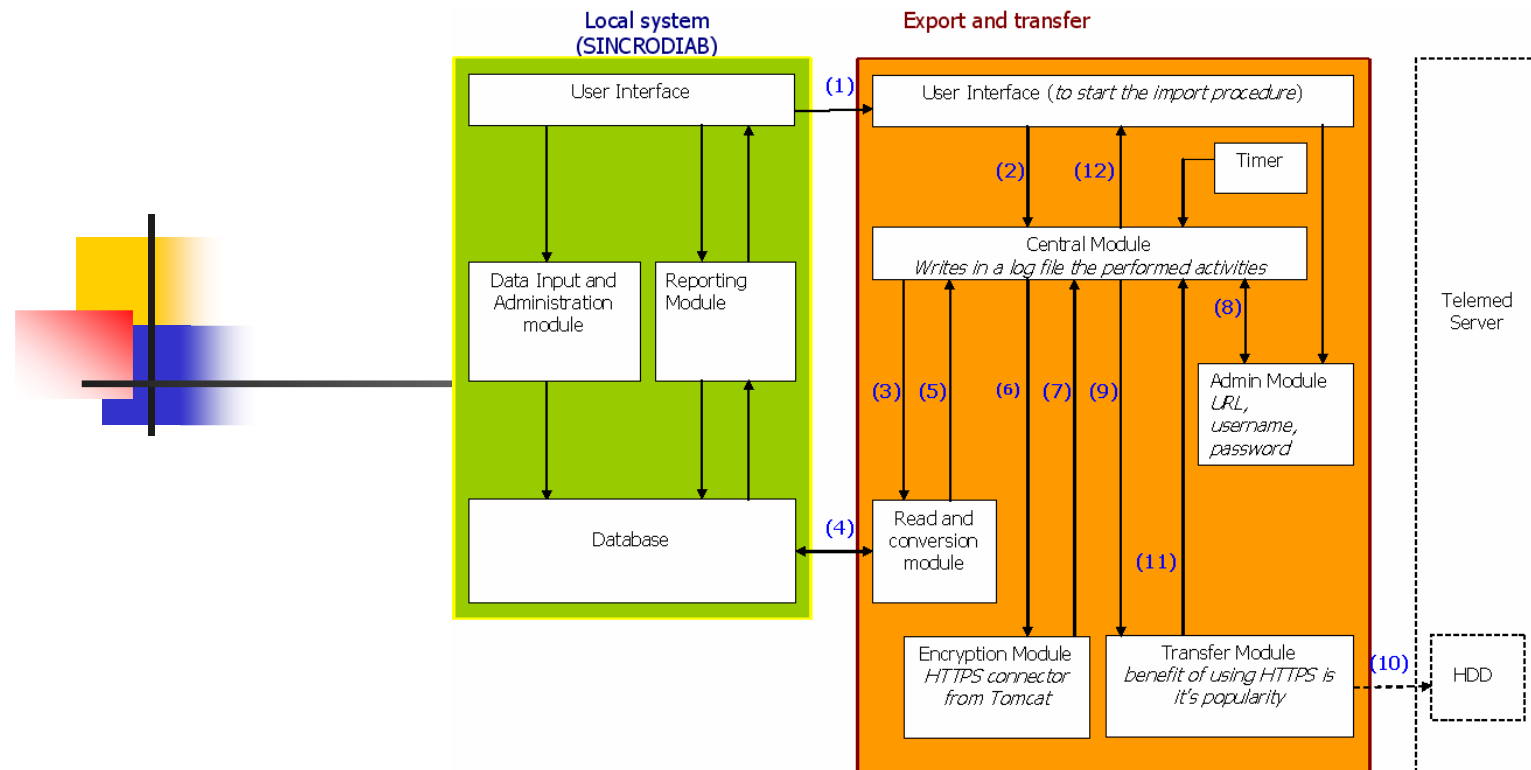
Information Flow:

- The user from within the medical unit accesses the "export and transfer application" from the SINCRODIAB interface or running an executable file (1)
- The query is ran from the interface of the export and transfer application (2)
- The central module calls upon the read and conversion module (3)
- The read and conversion module connects to the SINCODIAB database, takes the information to be transferred out and converts it to a XML Web Service (4)
- The read and conversion module initializes transfer with the remote Paulescu Institute (BIRO) server (5)
- The import server decodes the XML (6) and creates new Hibernate POJO's with the data for insert into the remote database (7)
- The central module reads the parameters for the data transfer, available in the administration module, such as URL, username and password (8)
- The transfer module signals to the central module when the transfer has been finished, if the procedure has been started by a user (9)
- The central module notifies the user through the interface that the transfer has finished (10).

Export & Transfer application

- The application could be built in Java, and should employ the portable capabilities of the JDBC layer plus the Hibernate Database Dialect

- This will ensure that **the application will be able to connect to any type of database** software and use the same SQL code (HQL which is translated by the Hibernate Database Dialect into the actual SQL dialect to be used)

Export & Transfer application (2)

- The export itself should be done using XML Web Services through a HTTP-S (Secure / Encrypted) port

- Due to the portable nature of Java, there are no concerns about system compatibility of any of the two servers with the Java Import / Export tool, because the Java application is guaranteed to run on any platform

Open Healthcare Reports

- The reports framework, should be a higher level framework based on already existing open source frameworks meant to present data to the user either in *spreadsheet format, written format or graphical format.*

- Open source such as Jasper, JFreeChart, JFreeReport, iText and Jakarta POI should be used to ensure the ability of the system to present data to the users in any format.

BSEC new project

- ## Study of the Capabilities and Requirements of Operational Client-Server Health Information System for Diabetes *TeleDiab*

  - Telemedica Consulting SRL, Buch. (coordinator)
  - Institute of Diabetes, Nutrition and Metabolic Diseases "Prof. N Paulescu", Bucharest
  - Greece: Centre for Research and Technology Hellas (CERTH), Thessaloniki
  - Turkey: Middle East Technical University (METU), Ankara

TeleDiab Impact

- The Black Sea Economic Cooperation (BSEC) Project Development Fund (Istanbul, 21 March 2007) examined our project application and took a final decision to approve and fund it.

- BSEC represents a region of some 350 million people

- The Black Sea littoral States, the Balkans and the Caucasus with an area of nearly 20 million square kilometers.

Adviser or EUBIROD partner

- <u>Anders Green</u>

Thank you for your attention!