

Franco-Vietnamese Hospital Hepatitis Data Collection

GFMER Internet Database
Web-application

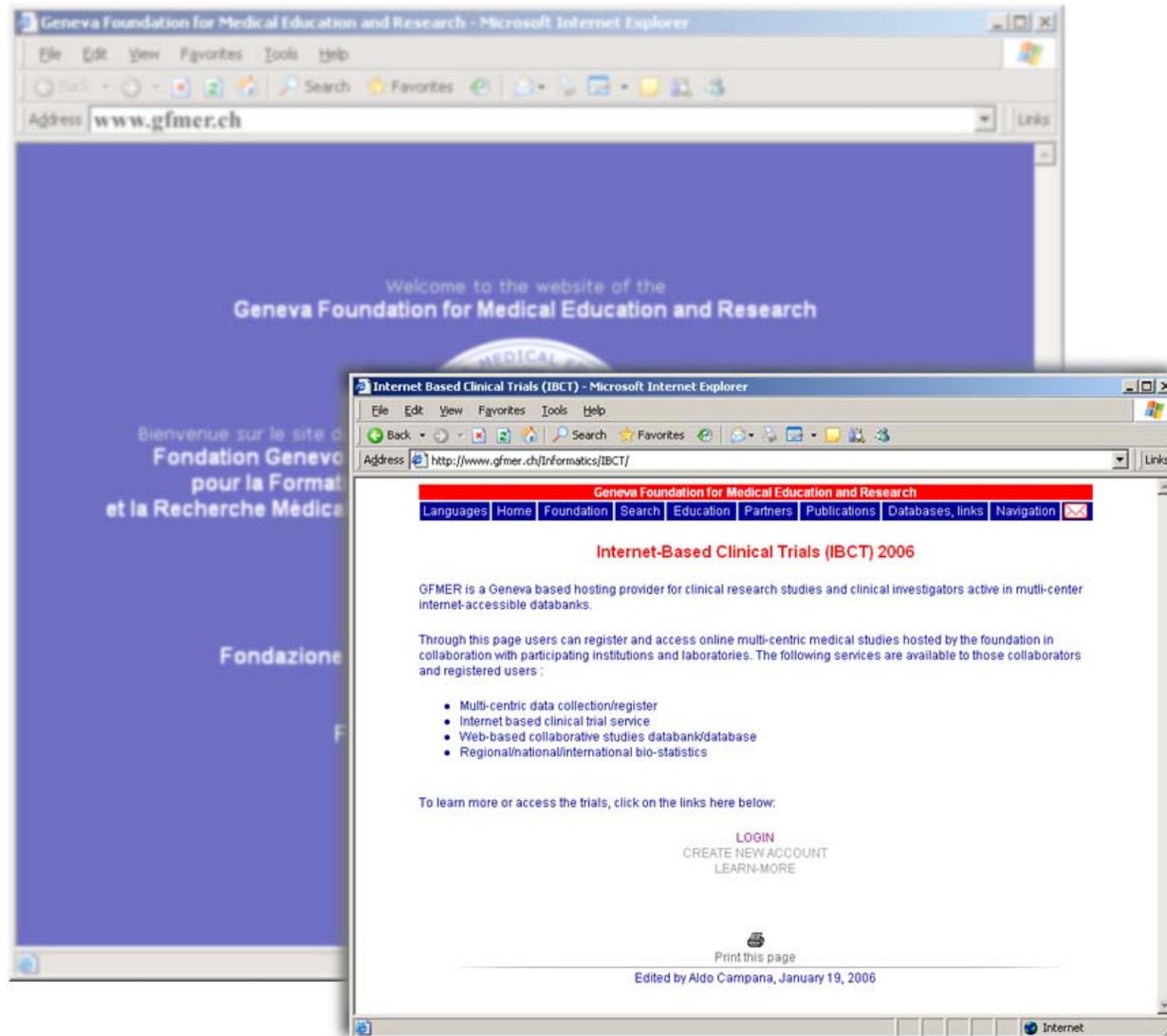
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FValse

Franco Vietnamese Association for Liver Studies and Education

GFMER

Geneva Foundation for Medical Education and Research
WHO Collaborating Centre

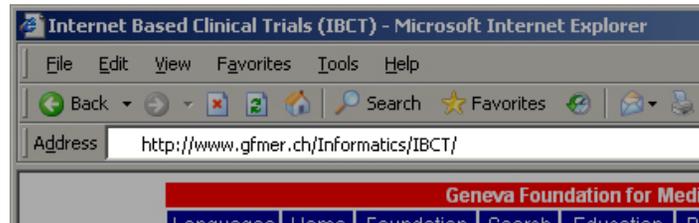


The secure login page can be accessed at the following internet address:

<http://www.gfmer.ch/Informatics/IBCT/>

STEP 1 – access

- Get a user name and password
 - Email shawn.koppenhoefer@gfmer.ch requesting a username and password for accessing the FV Hepatitis database
- Use INTERNET EXPLORER to go to the secure login page and click on 'login'



- Fill the login form with your username and password, and then click on the 'submit' button.

Security Access Login	
User ID	<input type="text" value="johndoe"/>
Password	<input type="password" value="•••••"/>
<input type="button" value="Submit"/>	

Step 2 – fill in the data

New Patient

Enrollment | Liver biopsy | Laboratory tests | Liver Scores

The following data-form is a draft proposition and may not yet be submitted.

FORM 1 : Enrollment

1. Number :

2. FVH number:

3. Study staff initials :

4. Form date :

Day

Month

Year

5. Protocol

FVH-VHC

FVH-VHB

FVH-HCC

-There are 4 data collection forms

- Enrollment, Liver Biopsy, Laboratory tests, and Liver Scores

- Click on the tabs to switch between the different forms

- Inside each form are fields for collecting data

- BOXES hold text or numbers

- CHECK-CIRCLES can be clicked to make choices between multiple values

Example (step 2)

Tabs to select which form is being displayed

New Patient

Enrollment | Liver biopsy | Laboratory tests | **Liver Scores**

The following data-form is a draft proposition and may not yet be submitted.

FORM 4 : Liver Scores

1. Number :

2. FVH number:

3. Study staff initials :

4. Form date :

Day

Month

Year

A : Child-Pugh score

5. Encephalopathy no confusion coma

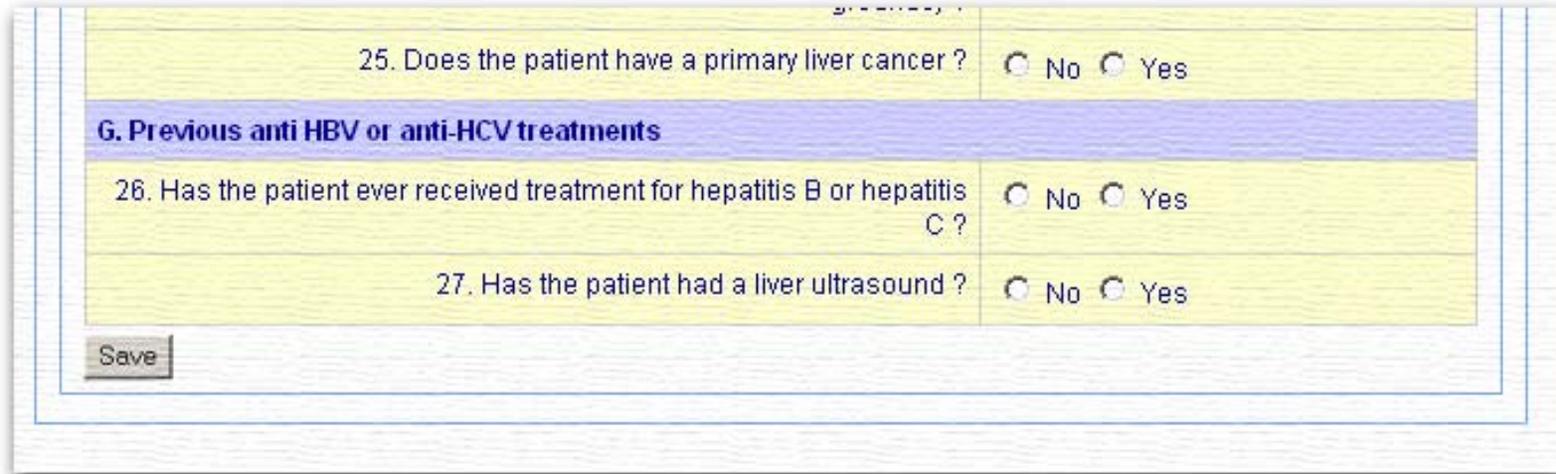
6. Ascites no moderate tense

7. Bilirubin $\mu\text{mol/l}$ < 35 35-50

Text boxes to collect numeric or alpha-numeric data

Radio choices to collect data based on choices

Step 3 – save your data



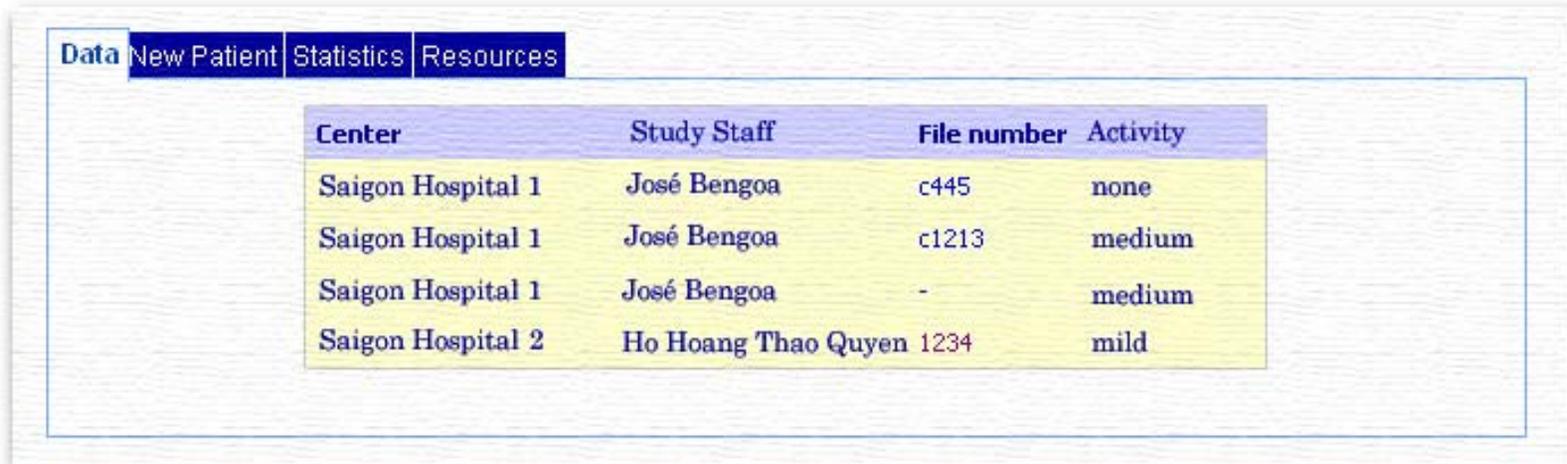
The screenshot shows a web-based data entry form with a light yellow background. It contains three questions, each with radio button options for 'No' and 'Yes'. A blue header bar is positioned between the first and second questions. At the bottom left of the form is a 'Save' button.

25. Does the patient have a primary liver cancer ?	<input type="radio"/> No <input type="radio"/> Yes
G. Previous anti HBV or anti-HCV treatments	
26. Has the patient ever received treatment for hepatitis B or hepatitis C ?	<input type="radio"/> No <input type="radio"/> Yes
27. Has the patient had a liver ultrasound ?	<input type="radio"/> No <input type="radio"/> Yes

Save

- Once the 'SAVE' button is clicked, the data on that form is saved in a secure electronic place on our server
 - All the data is backed up once a week and stored at GFMER
 - The data may be exported by authorized users into an EXCEL readable format (or SPSS or other similar software package)
 - Conform to FDA guidelines, typical standard operating procedures (SOPs) are respected by the system including auditing, backup, authentication, security, and activity logging.

Step 4 – looking at your data

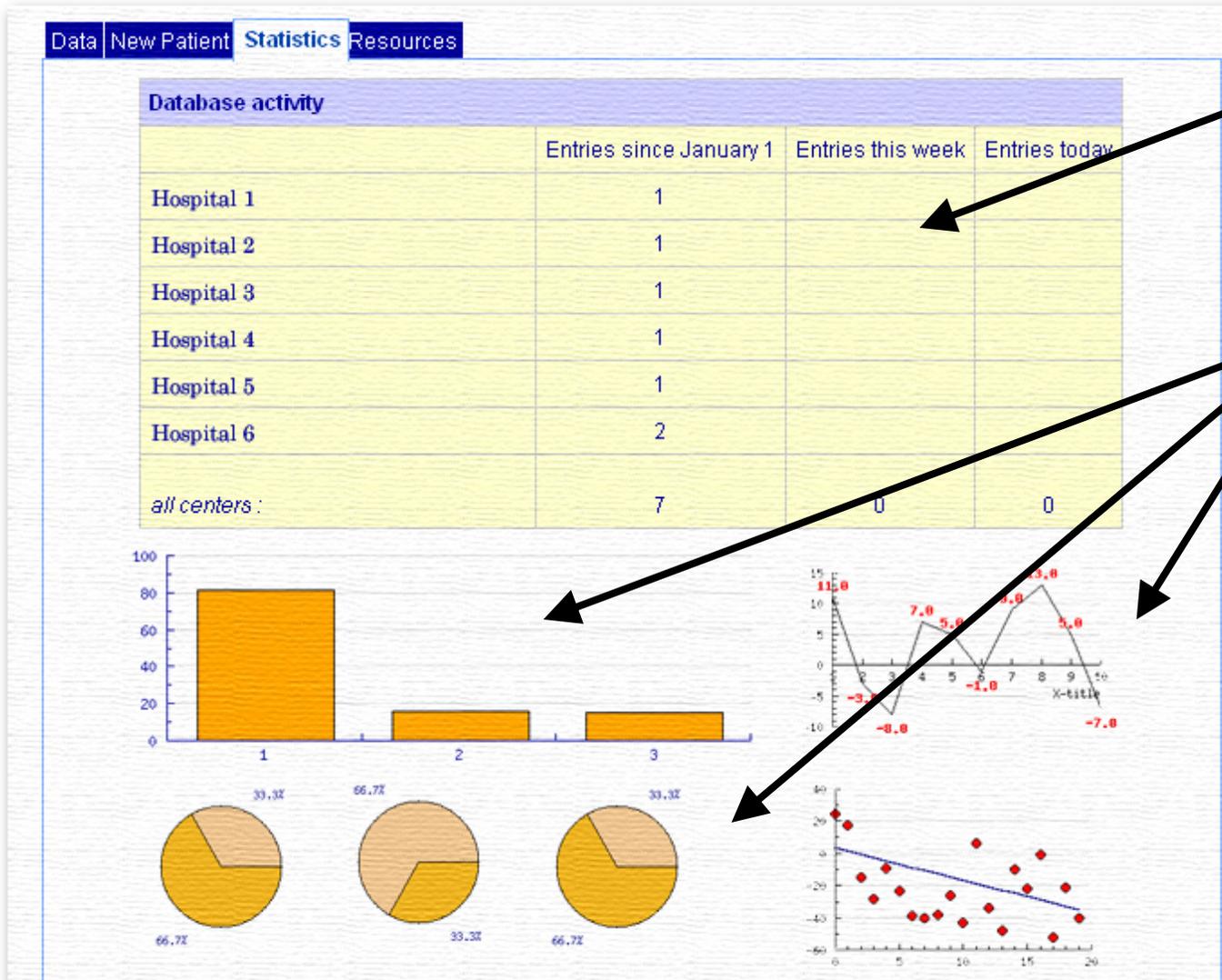


The screenshot shows a web application interface with a navigation menu at the top containing 'Data', 'New Patient', 'Statistics', and 'Resources'. Below the menu is a table with four columns: 'Center', 'Study Staff', 'File number', and 'Activity'. The table contains four rows of data.

Center	Study Staff	File number	Activity
Saigon Hospital 1	José Bengoa	c445	none
Saigon Hospital 1	José Bengoa	c1213	medium
Saigon Hospital 1	José Bengoa	-	medium
Saigon Hospital 2	Ho Hoang Thao Quyen	1234	mild

- Clicking on the File number will call up all of the forms for that patient with the data fields as they were saved
- The forms may be modified and re-saved by authorized users
- Three levels of authorization can be defined in order to limit the visibility of data to the relevant users

Step 5 – looking at your statistics



Tabular statistics show the activity of the data coming into the database

Statistical calculations are determined using the most recent version of the data stored in the database.

Summary

- The GFMER web-application for collection, managing, and analyzing data is currently being used or developed in several studies.
 - In one ongoing study over 20'000 forms have been filled out and are being managed.
- The system is easy to use, and takes into consideration key elements of FDA requirements for online data collection

More information can had by visiting the GFMER website

<http://www.gfmer.ch/>