Case Study

Bespoke data management for clinical trials

Introduction

Clinical trials around the world involve often hundreds of patients as well as numerous medical practitioners, statisticians, research and administrative staff. Managing the data generated in a way that allows easy & secure capture and storage as well as later analysis requires dedicated solutions. We worked together with Integerafrica Research & Development on two key projects detailed below, in which we implemented state-of-the-art data management solutions for trials in South Africa and South America. Developed in 2013-2014.

The clinical trials

PredART
Investigating TB-IRIS Prevention

The PredART Trial is taking place in the Khayelitsha township in Cape Town, South Africa, and is being conducted by the University of Cape Town. The aim of the trial is to investigate the use of prednisone to prevent immune reconstitution inflammatory syndrome (IRIS) in tuberculosis patients.

Integerafrica R&D designed the trial flow and parameter groupings. The system contains several security and data validation mechanisms.

https://www.predart.org

relahp
Registro Latinoamericano de Hipertensión Pulmonar

RELAHP, the Latin American Registry of Pulmonary Hypertension, is a study being conducted across several Central and South American countries.

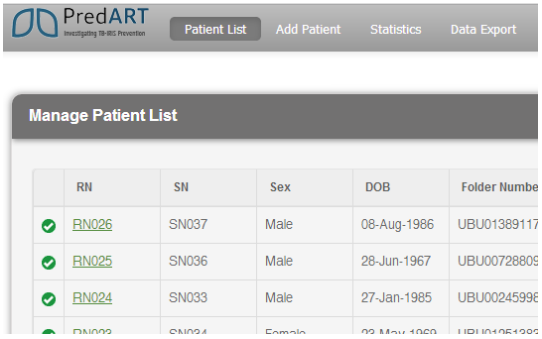
The system has a tri-lingual frontend as well as a backend that includes a support centre and patient data screens designed for ease of use.

Integerafrica R&D designed the trial flow and parameter groupings to be used within the registry.

https://www.relahp.org

The Challenge

The trials involve hundreds or even thousands of patients over an extended period of time (two years for PredART, five years for RELAHP). While data is being captured on physical case report forms (CRFs), analysing this data after the completion of the study would involve extensive overheads with potential for data loss or data contamination through lost, damaged or illegible CRFs.

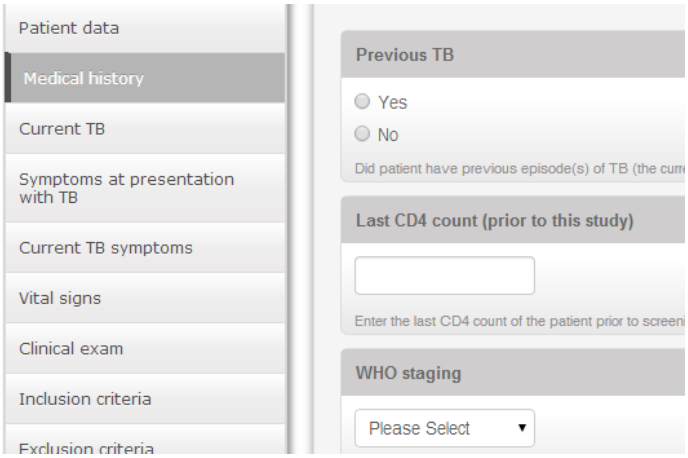


The trials require a system which emulates the physical CRF and recreates the trial flow, while allowing easy capture of the data. Once the trial is completed the data needs to be exportable for analysis into the trial outcome.

System Environment (both systems)

Hosting	Dedicated Server located in South Africa
Encryption	Force SSL connection for secure data transfer
Technology	PHP & MySQL using Yii PHP Framework & Bootstrap front-end

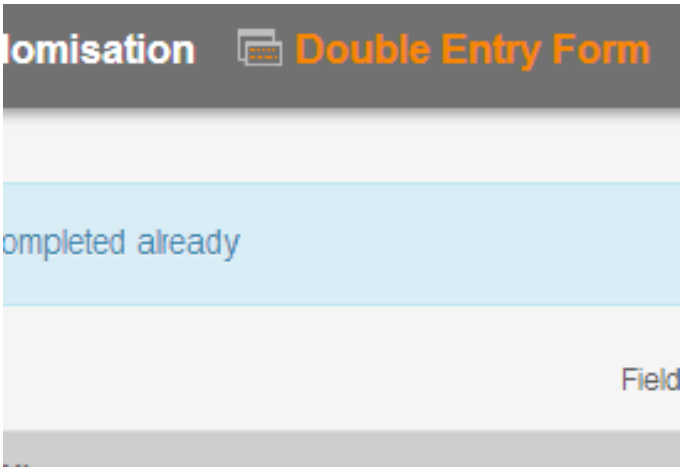
Data Capture & Trial Flow



We implemented the trial flow and parameters designed by Integerafrica R&D in a user-friendly interface that includes instant verification and range checks as well as conditional field display.

The interface guides the user through the parameter groups (seen on the left) and automatically takes the user to the next patient visit in chronological order, while still allowing the user to skip parameter groups or entire visits where data is not yet available for entry.

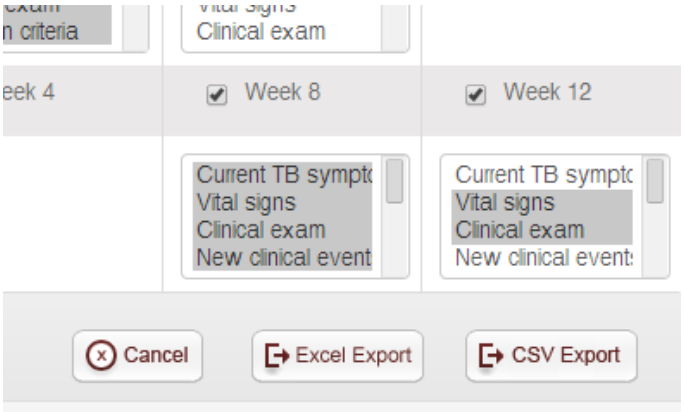
Two-pass verification (double data entry)



A key data integrity feature implemented in the PredART system is double data entry. This feature requires data entry clerks to submit every data point twice.

The system performs an automatic check on all data points and generates a Quality Control Report for the Trial Administrator showing discrepancies within the data. These can then be corrected by the trial administrator within the individual patient records.

Data export



Allowing easy export and analysis of data is by far the most important feature of any clinical data management system. Without being able to analyse and understand the data being captured the entire trial would be futile.

We developed a detailed export tool which allows the user to select up to parameter group level for individual patient visits. Data can be exported as Excel or CSV files for later use in other statistical programmes as well.

Other general system features

- varying levels of data allocations to patients
- individual patient data export to PDF
- patient search.
- user audit trail
- user management & permissions
- statistics