Patient Registries

Customized solutions and specialized tools for rare diseases

PC PAL's solutions for Patient Registries are successful because they are customized to match the exact needs of both clinics and sponsors, based upon true experience in the field.

Over the last 25 years PC PAL has built two major registry platforms for pediatric and adult endocrinology (growth hormone), managing more than 75 000 patients.

In parallel, other successful disease registries have been deployed (acromegaly, ophthalmics, diabetes). More recently, rare disease registries have been a perfect match, needing multiple medical aspects coverage for complex patient contexts and long term follow up.

PC PAL's Application Framework is a common framework of reusable code, especially developed for registries. It allows intelligent reuse of basic functionality, allowing custom development when needed.

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Easy, intuitive use

PC PAL's registry systems are easy to use. All functions are readily available where and when you need them through links and buttons. The vertical Tree View menu gives a good overview of the application architecture and users can navigate freely among the screens while performing data entry. Data can be entered and updated at any time, even after submission, which helps data quality.

Instant Feed Back

- Numerical variables can have charts associated with them to show their evolution over time. Instant Feed Back Charts™ give enhanced data quality in the registry as users can act upon incorrectly entered data and correct it.

- Lab data and anthropometric parameters can use multiple units, and when data is presented in charts or tables, the values are automatically converted into a default unit for each parameter.

- Calculations are executed automatically as soon as a dependent variable is entered or modified.

- Data validations, when triggered, immediately show up next to entered data. Validations can be simple range checks, more complex age and gender related or custom built. Such checks can take into account other values, entered or calculated, as well as go across visits or forms, taking into account the entire patient data set.
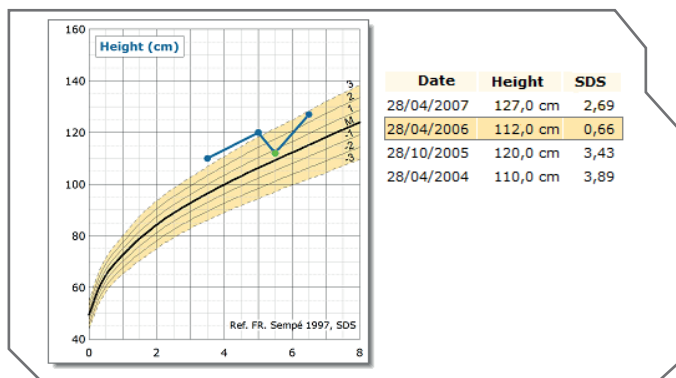
Instant Feedback Charts™ show how individual parameters evolve over time and allow users to act upon incorrectly entered data immediately.

Patient Management

A PC PAL's registry solution can be equipped with a variety of patient management forms, actions and reports. The forms focus on medical investigation areas. The patient file actions such as move or delete simplify the follow up process. Patient Reports can be predefined or user configurable and Data Tables allow data to be extracted, printed and exported.

Proven performance

The system architecture is well suited to handle both small registries with hundreds or thousands patients, as well as large ones with more than 100 000 patients.

Triggers and notifiers

Triggers can be set up to automatically act upon user activity such as data entry, or be linked to scheduled services. A trigger can generate an email to be sent in case of an adverse event, or to remind users that data entry is due for a specific patient.

Data quality and completeness

Our systems encourage data quality through ease of use and instant feedback to the users. Data can be entered in any order, and even saved halfway through. The user can complete the data later. Users are also further encouraged to enter data as they can make use of it within the system through the patient management features. Data completeness reports can be generated to review and encourage data completeness of core data.

Regulatory compliant

PC PAL's solutions are compliant with ICH GCP, 21 CRF part 11 and EU directive (2002/58/EC) and contain all the standard features required for registries and medical data bases, such as electronic signatures, user access management, audit trails, activity logs and encryption. Our experience in the field has also led us to standardize routines and a quality system, for consistent validation of every release of a specific registry software.

Web technology

The application is reachable through a web link and installs with Microsoft Click Once technology as well as PC PAL Click Twice™ technology. Just click and run! The client application connects to the server using standard web protocols (http/ https) providing encryption based upon standard SSL technology.

Native code on the clinic side allows the application to react instantly and provide a very pleasant user experience. Native code is to Windows what Apps are to iPhones – a small application that allows code to execute on the client as well as the server side. Applications also update themselves automatically when new versions are made available to sites.

Data entry - three way entry

PC PAL's systems are typically designed to allow data entry in a variety of ways, and allow the clinician to use the most appropriate one to a specific situation. Data entered on any form is automatically replicated on other forms. For example, general examination data such as Height and Weight automatically display on a study form if those parameters are part of the study form.

Patient database

Medical investigation form

User defines form

Study specific form
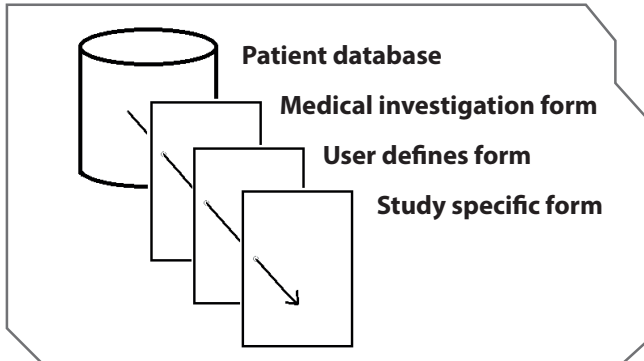
Users can choose whichever is the most suitable form for editing and reviewing data. Data entered on one form will automatically be shown on other forms avoiding double data entry. Validation checks automatically apply regardless of the actual form used.

#1 Medical investigation forms

Regular data entry screens are organized in a logical way for the disease or disease area and screens are subdivided into different tabs to allow users to quickly locate the appropriate section and enter data narrowly focused. The same structure is also used in configuration modules for reports, tables and when setting up user defined forms.

#2 User defined forms

User defined forms, sometimes called Quick Forms, allow the user and clinic to define forms that suit their needs. These forms can have fields from one or many different sections. The selection of fields as well as display order is completely customizable.

#3 Study specific forms

Study forms are set up in relation to a specific study and contain selected fields grouped in a way that suits the study. Specific forms can be devel- oped for studies such as product registries, national registries or for a substudy for a group of patients within the registry.

Multi-study solution

PC PAL's registry platform was created to be the best possible tool for the individual clinics and at the same time to satisfy the needs of the study, or multiple studies, for which it was designed.

Data can reside in the clinic database without the intention of study participation, just to make use of the patient management features within the application. If study participation is decided upon and study forms are created, available data automatically populate the forms. When a form is electronically signed, a copy is physically sent over to the central registry for that study.

PC PAL's registry platform was built to handle electronic submission, updates and deletions of registry data to an off-site server across the internet.
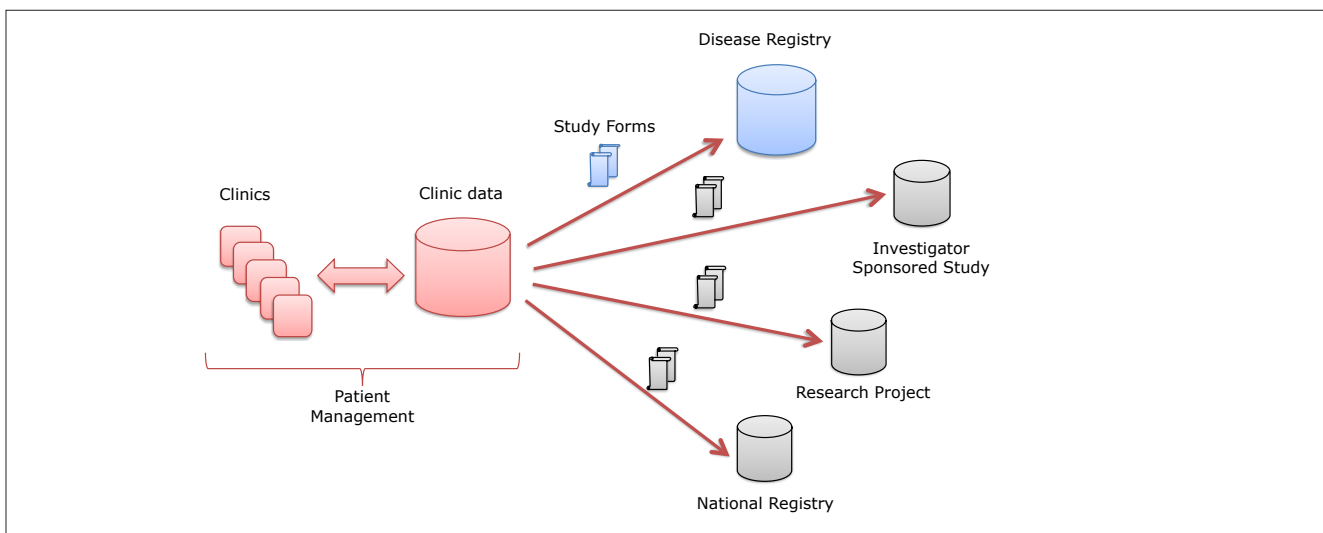
#1 The patient does not participate in a study

Patients can reside in the system without being part of any study at all. The patient data reside solely in the clinic database and cannot be accessed by any other than the staff of that clinic.

#2 The patient participates in one study, or another

The data base can handle groups of patients that participate in different studies, so that the clinic can have one unique database for all of their patients within one disease category.

#3 The patient participates in several studies

Multiple study participation for one patient could occur when patient data is reported to a national registry in addition to a product registry.
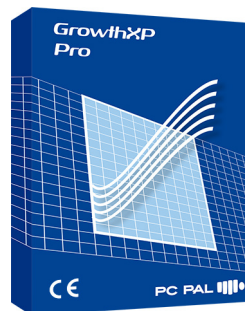
Disease Registry

Study Forms

Clinics

Clinic data

Investigator Sponsored Study

Research Project

Patient Management

National Registry

*This is a simplified scenario of a complex architecture that may need collaboration of several parties.

PC PAL – Software applications for medical institutions

GrowthXP

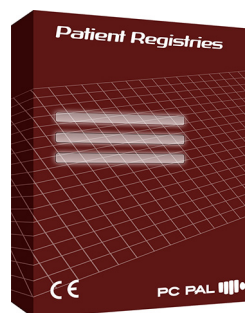World's leading growth chart software
www.growthxp.com

PedigreeXP

Genetic family tree drawing tool
www.pedigreexp.com

Patient Registries

Rare disease follow up
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How can we assist you?

Our areas of expertise are applications for outcome surveys and clinical trials and other applications for the health care sector such as electronic health records (EHR), electronic patient records (EPR), growth charts, laboratory data and pedigrees. We've worked extensively in the area of pediatric and adult endocrinology, ophthalmology as with genetic syndromes and rare disorders.

The secret of PC PAL's systems is that we offer a combination of great visual output together with advanced data validation handling. This has made our applications widely appreciated by both customers and end-users since the beginning of the 1990's. Products developed by PC PAL are used in more than 40 countries by thousands of users.

PC PAL

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