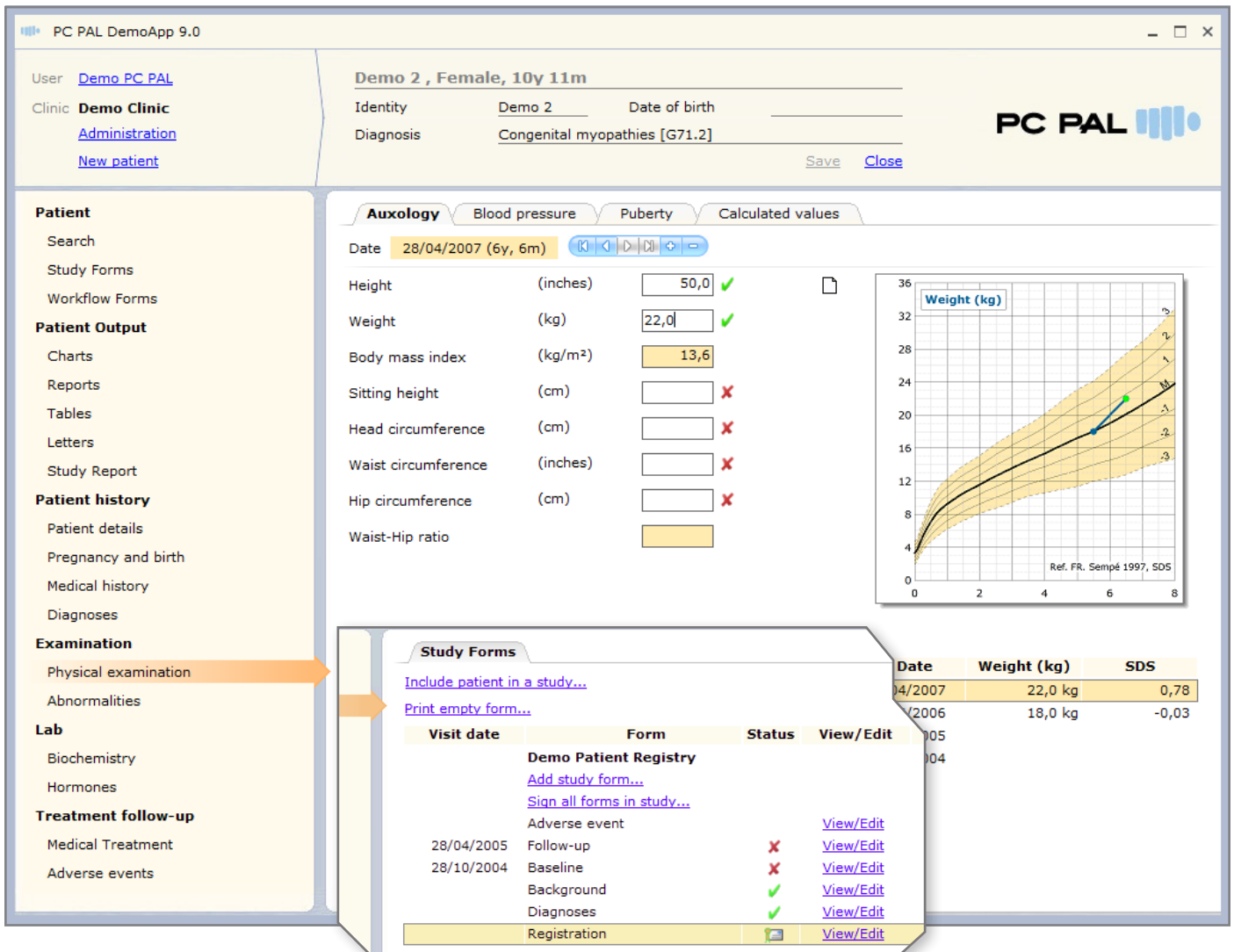


*PC PAL presents a platform for patient registries built upon 20 years of experience in registries and rare disorders.*

# >>> Customized solutions for Patient Registries



The screenshot displays the PC PAL DemoApp 9.0 interface. At the top, it shows the user 'Demo PC PAL' and clinic 'Demo Clinic'. The patient information is 'Demo 2, Female, 10y 11m' with a diagnosis of 'Congenital myopathies [G71.2]'. The main area is divided into tabs: 'Auxology', 'Blood pressure', 'Puberty', and 'Calculated values'. Under 'Auxology', various measurements are listed with input fields and status indicators (green checkmarks for Height, Weight, and Body mass index; red X's for Sitting height, Head circumference, Waist circumference, and Hip circumference). A 'Weight (kg)' growth chart is shown on the right, plotting weight against age with a shaded normal range. Below the chart is a table of weight measurements:

Date	Weight (kg)	SDS
04/2007	22,0 kg	0,78
02/2006	18,0 kg	-0,03
05/2005		
04/2004		

An inset window titled 'Study Forms' is open, showing options to 'Include patient in a study...' and 'Print empty form...'. It contains a table of study forms:

Visit date	Form	Status	View/Edit
	<b>Demo Patient Registry</b>		
	<a href="#">Add study form...</a>		
	<a href="#">Sign all forms in study...</a>		
	Adverse event		<a href="#">View/Edit</a>
28/04/2005	Follow-up	X	<a href="#">View/Edit</a>
28/10/2004	Baseline	X	<a href="#">View/Edit</a>
	Background	✓	<a href="#">View/Edit</a>
	Diagnoses	✓	<a href="#">View/Edit</a>
	Registration		<a href="#">View/Edit</a>

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

In the early 1990's PC PAL built one of the first ever patient registries for pediatric endocrinology (growth hormone) and later extended it to adult endocrinology and ophthalmics. With the launch of the first orphan drug in Europe, PC PAL moved into the rare disease area with a registry for Fabry's disease (FOS). This registry has since been followed by several others.

The PC PAL Application Framework is a common framework of reusable code especially developed for registries. It allows intelligent reuse of basic functionality, yet doesn't prevent custom development where needed. We never say "it can't be done" and when we do custom coding it integrates seamlessly into the application just giving your registry the extra touch you need.

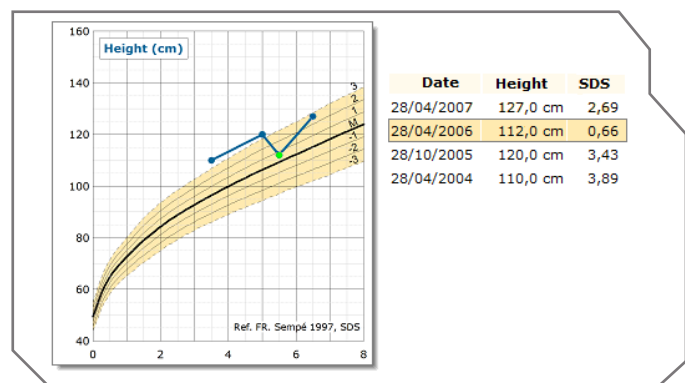
## Easy, intuitive use

PC PAL registry systems are easy to use. So easy in fact we took away the Windows menus or toolbars. All functions are readily available where and when you need them through links and buttons. The vertical Tree View gives a good overview of the application architecture and users can navigate freely among the screens also saving time while performing data entry. Data can be entered and updated at any time, even after submission which helps data quality.

Field	Value	Status
Gestational age (weeks)	34	
Birth weight (g)	2050	✓
Birth weight SDS	-0,23	
Birth length (cm)	39,0	✗
Birth length SDS	-5,78	
Birth head circumference (cm)		✗

## 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 react 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 standard unit for each parameter.
- » Calculations are executed automatically as soon as a dependent variable is entered or modified.
- » Data validations, when triggered, immediately shows up next to entered data. Validations can be simple range checks, or more complex age and sex related, or be 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 react upon incorrectly entered data immediately.

## Patient Management

A PC PAL 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, 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 a thousand patients as well as larger ones with 75.000 patients or more.

## Triggers and notifiers

Triggers can be set up to automatically react 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 its ease of use and instant feedback to the users. Data can be entered in any order, and even saved half way through. The user can return later to complete the data. 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 solutions are compliant with ICH GCP, 21 CFR 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 standardized routines and a quality system for consistent validation of every release of a specific registry software.

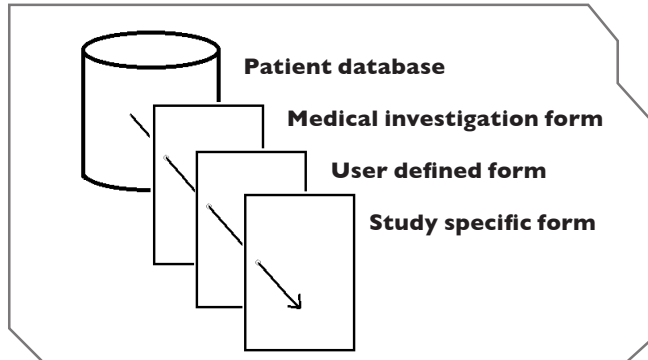
## Web technology

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 the iPhone – 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 systems typically are designed to allow data entry in a variety of ways, and allow the clinician to use the most appropriate one in 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.



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 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 developed for studies such as product registries, national registries or for a substudy for a group of patients within the registry.

## Multi-study solution

The PC PAL registry platform was created to be the best possible tool for the individual clinics and at the same time 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.

The PC PAL registry platform was built to handle electronic submission, updates and deletions of registry data to an off-site server across the internet.

### - The patient does not participate in a study

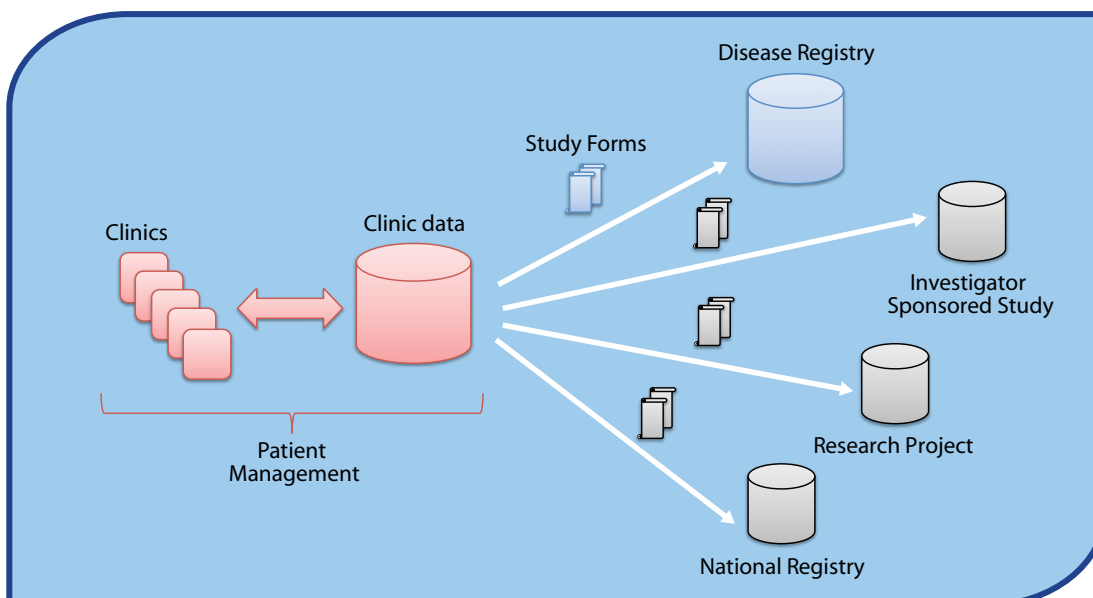
Patients can reside in the system without being part of any study at all. The patient data reside solely in the clinic database and cannot be accessed by any other than the staff of that clinic.

### - The patient participates in one study, or another

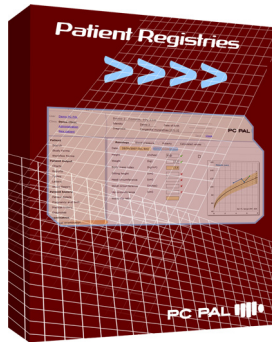
The data base can handle groups of patients that participate in different studies, so that the clinic can have one unique database for all of their patients within one disease category.

### - 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.



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



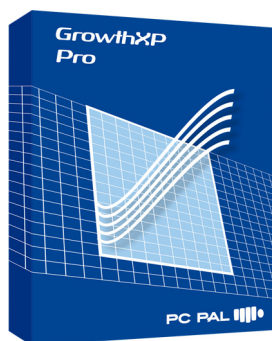
## Patient Registries

The PC PAL solution for Patient Registries and Outcomes (PRO) is a customized multi-study form based data entry system, integrating Instant Feedback Charts™ and advanced validations for high quality data outcome as well as Patient Reports and Data Tables for data analysis. Electronic signatures, audit trails, activity logs and validation routines assure that regulatory requirements are met.

The PC PAL PRO Framework has evolved over 20 years of work with registry design and we have a proven track record of creating, maintaining and supporting long term patient registries, in particular within the field of rare disorders. We also have a proven track record of successful completion of data migrations from other registries with minimal downtime per clinic.

*Contact us to discuss how we can help you with your registry!*

[www.pcpal.eu](http://www.pcpal.eu)

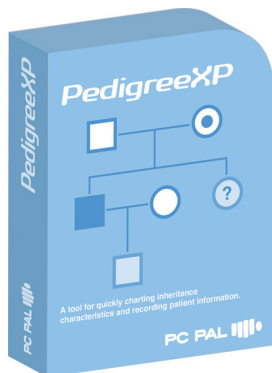


## GrowthXP

PC PAL is the world leader in advanced, high quality, electronic growth charts for integration into registries and medical records. National as well as disease specific charts are designed to suit local needs and data sets from our huge reference library can be used to implement new charts for any population. The drawing module is available as a component that can be built into registry products, or medical record systems from other vendors. PC PAL growth charts have been made available to more than 100.000 users world wide.

[www.GrowthXP.com](http://www.GrowthXP.com)

[www.GrowthCharts.info](http://www.GrowthCharts.info)



## PedigreeXP

Building on its success in the growth chart component area and its experience in the rare disease area, PC PAL also offers Pedigree drawing tools that allow users to visually build up a family pedigree, and assign data properties to individuals in the pedigree. For X-linked diseases PedigreeXP can automatically detect affected persons and carriers within a family once a proband has been identified.

[www.PedigreeXP.com](http://www.PedigreeXP.com)

**PC PAL**

[www.pcpal.eu](http://www.pcpal.eu)

■ SWEDEN  
+46 8 724 44 00

■ FRANCE  
+33 1 69 53 46 20

■ USA/CANADA  
Toll-free: +1 877 469 7272

SWEDEN: Kaplansbacken 3, SE-112 24 Stockholm, Sweden, Phone: +46 8 724 44 00, Fax: +46 8 724 45 01  
FRANCE: 3 Avenue Jeanne Garnerin, FR-91320 Wissous, France, Phone: +33 1 69 53 46 20, Fax: +33 1 69 53 69 81