



## **PARC-ITP on-line database – <https://www.parc-itp.net>**

Pediatric and Adult Intercontinental Registry on Chronic Idiopathic Thrombocytopenic Purpura (ITP)

A worldwide, prospective, multicenter registry on chronic ITP, conducted by The Intercontinental Childhood ITP Study Group (ICIS)

### **GUIDE**

On-line data submission by the participating investigator

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## General information

The PARC-ITP database has been designed for the participating investigator to conveniently submit patient data. By using the PARC-ITP on-line database (via internet) you are helping to ensure data quality of the PARC-ITP registry.

A special feature allows the participating investigators not only to submit patient data of the forms, but also to enter confidential patient data such as name and comments in order to easily keep track of your patients. This **personal patient data** is saved in a separate database and – by contract with the developer of the PARC-ITP database application, Kalleysoft AG, Allschwil BL, Switzerland – is not accessible to the PARC-ITP administration at any time. This data may be viewed and downloaded by the responsible investigator only.

If you prefer, you may send the completed paper forms instead, preferably by FAX to +41 61 685 6566 or by e-mail to [info@parc-itp.net](mailto:info@parc-itp.net).

## Data collection

Data will be collected at different time points:



After completing data of your patients with ITP online, you will receive an automated email confirming data submission.

Data submission of referral patients is possible (back to 18 months).

The PARC-ITP study protocol can be downloaded at [www.unibas.ch/itpbasel](http://www.unibas.ch/itpbasel).

## 1 First steps (Signing up, login)

### 1.1 How to apply for participation in the PARC-ITP study

Please go to <https://www.parc-itp.net> and click on 'Investigator's Participation Form'. Fill in the form on your screen and print it. Click the 'continue' button to register online. You will receive your username and password by email. Please sign and stamp your print-out and send it **by postal mail** to

PARC-ITP, ICIS Central Data Office  
University Children's Hospital Basel  
Hematology/Oncology  
P.O. Box, CH-4005 Basel, Switzerland

Thank you.

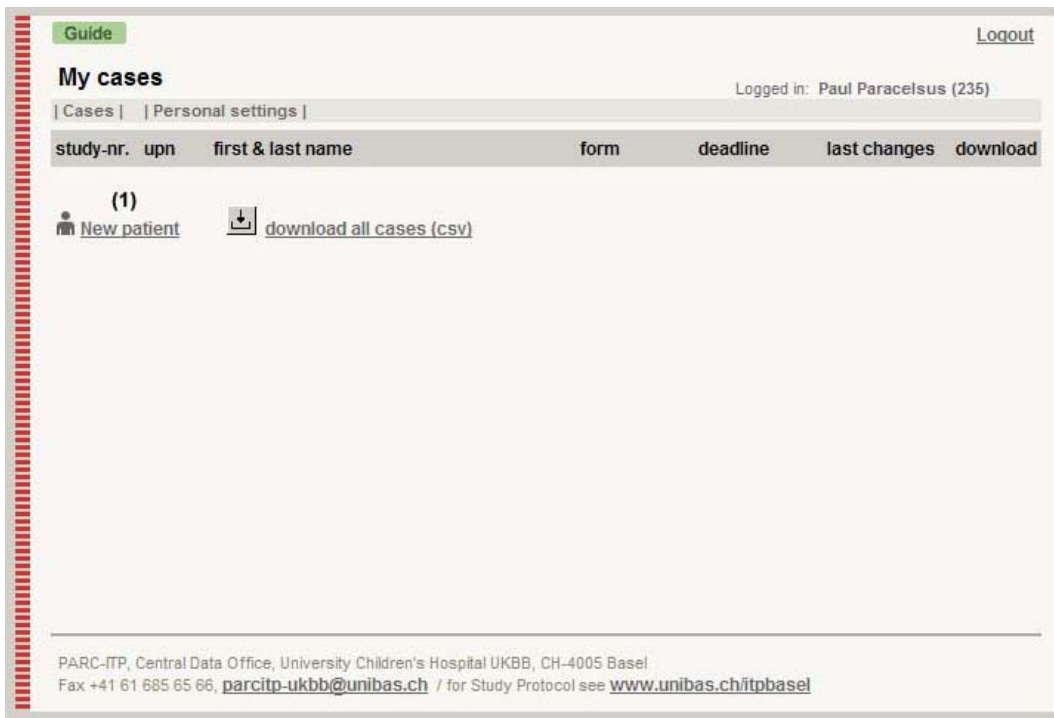
## 1.2 Login

Go to [www.parc-itp.net](http://www.parc-itp.net) and enter your username and password. Click 'login'.

When logging in for the first time, you will be prompted to change your password for security reasons. Enter a new password and confirm. Please remember both username and password for future data submission.

## 2 Patient registration and data submission (Initial form)

### 2.1 How to register a new patient



Click on [New Patient](#) (1).

The colour of the vertical bar on the left indicates the form you are currently completing.

red	List of your cases, personal settings of investigator
green	Initial form
blue	6-Month or Yearly Follow-up forms

## 2.2 Completing the Initial form

To complete a form you will be guided from one window to the next and through the questions on the forms. The boxes in the lower left hand corner (2) represent the windows of this form. For example, on the Initial form five boxes indicate that there are five windows in which to enter data. The box with the **red frame** indicates the window that is currently displayed on your screen. It will move from left to right as you move to the next window by clicking on '>>' (3). You may also move back to the previous window by clicking '<<' (4) or jump to any window by clicking on the boxes (2).

The screenshot shows a web interface for an 'Initial form'. At the top, there is a 'Guide' link and a 'Logout' link. The user is logged in as 'Paul Paracelsus (233)'. The form is titled 'Initial form' and shows the following fields:

- 1. Investigator: First Name Paul, Last Name Paracelsus
- 2. Institution Name: Paracelsus Center
- 3. Inst. ID (assigned by Central Data Office): to be assigned
- 4. Patient: Ca9876 (Personal patient datas, only visible for investigators)
- 4.1 Patient Identification (e.g. UPN): Ca9876
- 4.2 Has informed consent been obtained?  yes  no

At the bottom, there is a navigation bar with five window indicators. The first indicator is highlighted in red. A pop-up message (5) says 'incomplete, 4 answers missing'. Navigation buttons '<<' (4) and '>>' (3) are visible, along with a 'register completed form' button.

When holding the cursor over the box (without clicking), a pop-up message will also be displayed, telling you if the data of this window is complete or incomplete (5).


If all the necessary information of a window has been entered, the respective box will turn **gray** when moving to the next window.

If you have not fully completed the data of the form, the entered data will nonetheless be saved and may be completed later on, during the current or another login session. On the list of your cases this form will not yet be listed under completed forms.

Once you have completed all data of a form please submit the form by clicking '**register completed form**' to save permanently. The data of this patient may be viewed during another login session in the future, but changes will no longer be excepted.

## 2.3 Viewing your cases

Patient data that you have submitted may be viewed on a list by clicking 'cases' (6) in the upper left menu.

Please note: Only one patient is activated at a time. Click on the study number (7) next to the symbol  to activate the case and see an overview of the complete and incomplete forms.

Edit the personal patient data of each patient by clicking the UPN number (8). A pop-up window will open.

View data of the respective forms by clicking e.g. 'Initial'(9), etc. If the form has been completed and registered, you will be able to view the entered data, but changes can no longer be made.

The screenshot shows a web interface titled "My cases" with a "Logout" link in the top right. Below the title, it says "Logged in: Doctor Paracelsus (11542)". There are two tabs: "(6) Cases" and "Personal settings". The main content is a table with the following columns: study-nr., upn, first & last name, form, deadline, last changes, and download. The table contains three rows of data. The first row has study number 216 (with a mouse cursor pointing to it), UPN1, and "1 Testpatient". The form is "12-month" and the deadline is "28.11.2004". The second row has study number 217, UPN2, and "2 Testpatient". The form is "6-month" and the deadline is "15.04.2004". Below the table, there is a section for "Completed forms:" with a link "Initial (9)" and a date "15.10.2003". The third row has study number 218, UPN3, and "3 Testpatient". The form is "6-month" and the deadline is "30.12.2003". At the bottom of the interface, there are links for "New patient" and "download all cases (csv)".

study-nr.	upn	first & last name	form	deadline	last changes	download
▶ 216	UPN1	1 Testpatient	12-month	28.11.2004	---	↓
▼ 217	UPN2	2 Testpatient	6-month	15.04.2004	---	↓
Completed forms:				Initial (9)	15.10.2003	30.11.2004
▶ 218	UPN3	3 Testpatient	6-month	30.12.2003	---	↓

PARC-ITP, Central Data Office, University Children's Hospital UKBB, CH-4005 Basel  
 Fax +41 61 685 65 66, [info@parc-itp.net](mailto:info@parc-itp.net) / for Study Protocol see [www.unibas.ch/itpbase](http://www.unibas.ch/itpbase)

## 2.4 Reminder for follow-up

After submitting data of the Initial form you will receive an automated email with a status report of your ITP patients, listing completed forms and next due dates. You will also be reminded by email approximately 3 weeks before the appointed date of the next follow-up.

## 3 Submitting follow-up data

### 3.1 Login

Login at [www.parc-itp.net](http://www.parc-itp.net) with your username and password.

After you are logged in, the list of your cases will appear. Click on the study number (7) to activate the case and to see the forms you have completed. Follow-up forms are automatically generated and if yet incomplete, listed with a green background.

### 3.2 Lost to follow-up

If a patient is lost to follow-up, you may mark this case. This patient will be listed at the bottom and you will not be prompted to submit follow-up data. If at a later time point you have new data of this patient, the case can be re-activated by un-checking the box.

Guide Logout

**Initial form** Logged in: Dr. Specimen (11521)

| Cases | | Personal settings |

Please note: If you mark a patient as "lost to follow-up" in the edit view, the following sign **X** will appear and the patient will move to the bottom of the list. Please download your Status report (bottom right) after you have entered your data!

study-nr.	upn	first & last name	form	deadline	last changes	download
▼ 196	ITP1	Pat P	6-month	01.09.2005	---	↓
<input type="checkbox"/> Lost to Follow-up		Completed forms: <u>Initial</u> 01.03.2005 18.04.2006				
▶ 198	ITP3	Cate C	6-month	15.07.2005	---	↓
▶ 199	ITP4	Dhana D	6-month	02.08.2005	---	↓
▶ 197	ITP2	<b>X</b> Ben B	6-month	01.10.2005	---	↓

New patient
 download all cases (csv)
 download status report ()

### 3.3 Download a list of your ITP patients (Status report)

To download a list of your ITP patients with an overview of forms completed and next due dates, click on 'download status report' in the lower right hand corner. In the dialog window, click 'open'. The list will appear in Excel format. Save to your local files and print.

Your list should look like this:

2		<b>Status Report</b>			
3					
4	<b>Username</b>	Your username			
5					
6	<b>Name of Investigator</b>	Your Name			
7	<b>Tel</b>				
8	<b>First name</b>	Your First Name			
9	<b>email</b>	Your email			
10	<b>Institution</b>	Your Institution			
11	<b>Research nurse</b>				
12	<b>City</b>				
13	<b>Research nurse Tel</b>				
14	<b>Country</b>				
15	<b>Nr. of patients registered</b>	4			
16					
17	Status report of patient data submission to the online PARC-ITP database at <a href="http://www.parc-itp.net">www.parc-itp.net</a>				
18	<b>Patient UPN</b>	<b>Name</b>	<b>Last form completed on: Appointed date of next follow-up:</b>		
19	ITP1	P Pat	initial-form	18.04.2006	01.09.2005
20	ITP3	C Cate	initial-form	18.04.2006	15.07.2005
21	ITP4	D Dhana	initial-form	18.04.2006	02.08.2005
22					
23	<b>Patients lost to follow-up</b>				
24	ITP2	B Ben	initial-form	18.04.2006	Lost to Followup
25					
26	Please note: forms that should be completed now or as soon as possible are marked in red.				

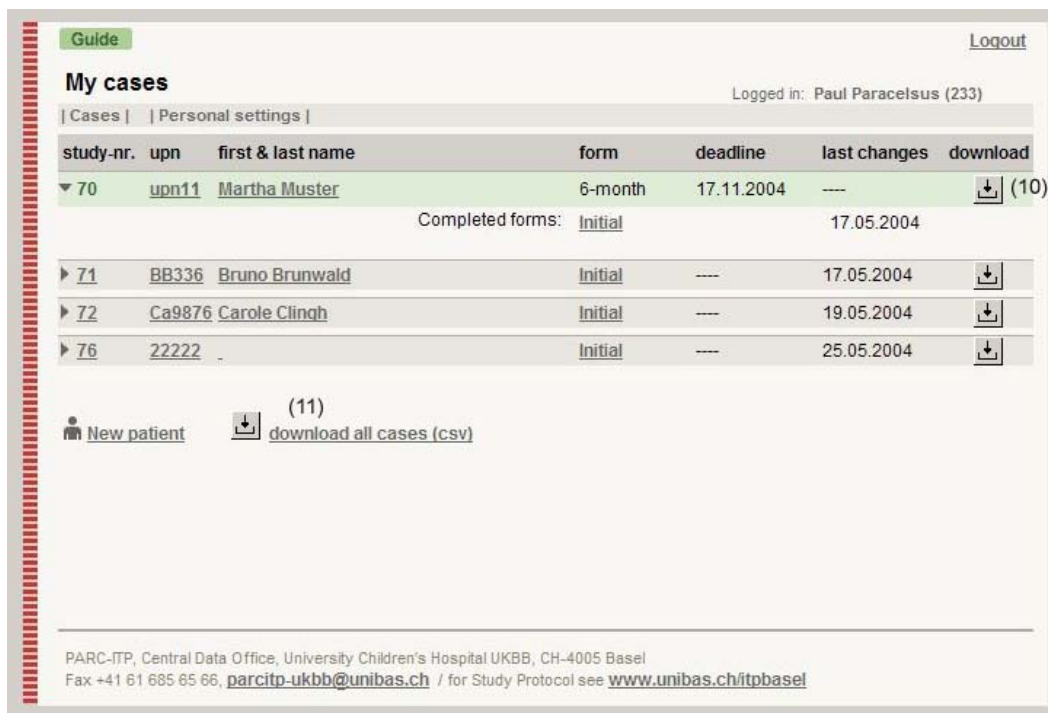
Note: If you have entered patient names to the database, they will be displayed on the list. Patient names are not accessible by ICIS, which is why investigators must generate their list during a login session at <https://www.parc-itp.net/>.

### 3.4 Reminder for next follow-up of your patient

You will be reminded by email to submit follow-up data at regular time points. You will not be prompted for cases that are marked as 'lost to follow-up'.

## 4 Downloading your patient data

### 4.1 Download your patient files to Excel



The screenshot shows a web interface for 'My cases'. At the top right, there is a 'Logout' link. Below it, the user is logged in as 'Paul Paracelsus (233)'. The interface includes a navigation bar with 'Cases' and 'Personal settings'. A table lists patient cases with columns for 'study-nr.', 'upn', 'first & last name', 'form', 'deadline', 'last changes', and 'download'. The first case is expanded to show 'Completed forms: Initial' and a date '17.05.2004'. Below the table, there is a 'New patient' button and a 'download all cases (csv)' button with a download icon and the number '(11)'. At the bottom, contact information for PARC-ITP, Central Data Office, University Children's Hospital UKBB, CH-4005 Basel is provided, including a fax number and email address.

study-nr.	upn	first & last name	form	deadline	last changes	download
70	upn11	Martha Muster	6-month	17.11.2004	---	(10)
Completed forms: Initial						17.05.2004
71	BB336	Bruno Brunwald	Initial	---	17.05.2004	(10)
72	Ca9876	Carole Clinqh	Initial	---	19.05.2004	(10)
76	22222	.	Initial	---	25.05.2004	(10)

To download data of a single case please click the symbol at the right (10).

To download all cases please click on the symbol at the bottom of the window (11).

Data of your patients will be displayed in a list in CSV format. To save this document as an Excel file click 'file' and 'save as'. Choose the excel format.

(If headings appear in only one column please try the following: Activate the column by clicking in the top bar A. From the menu choose 'Data' and 'Text in columns'. Check 'delimited' margins and click the next button. For delimiters click 'other' and enter ';', click 'next' and 'finish'.)

If not all data is displayed correctly, adjust the column width by double clicking the right margin (12).

Microsoft Excel - PatiententabelleParacelsus

File Edit View Insert Format Extras Data Window Acrobat

100%

	A	B	C	D	E	F	G	H	I	J	K	L
	Study No.	UPN	Name	Firstname	Comment 1	Comment 2	Comment 3	Form status	Date of Data Submission	Informed consent	Birth date	Gender
1	70	upn11	Muster	Martha					***** y	*****	m	
2	71	BB336	Brunwald	Bruno					***** n	*****	f	
3	72	Ca9876	Clingh	Carole					***** y	*****	f	
4	76	DD22222	Dubois	Dirk					***** y	*****	m	
5												
6												

## 5 Mutations

### 5.1 Forgot password?

If you have forgotten your password you may apply for a new one at [www.parc-itp.net](http://www.parc-itp.net).

### 5.2 Change of responsible investigator

If you or a previous investigator are no longer practising at the same institution, please let us know. A successor may take over the patients that have already been registered and also submit data of new patients in the future. If you would like to participate as a succeeding investigator please contact the Central Data Office at [info@parc-itp.net](mailto:info@parc-itp.net).

### 5.3 Change of address, phone number, email, username

Changes of address, phone number, fax and email may be entered by clicking 'personal settings' (13) in the upper left menu. Thank you for being as accurate as possible and keeping your current contact information **up to date**.

Guide Logout

**My cases** (13) Logged in: Paul Paracelsus (233)

| Cases | | Personal settings |

study-nr.	upn	first & last name	form	deadline	last changes	download
▼ 70	upn11	Martha Muster	6-month	17.11.2004	---	↓
					Completed forms: Initial	17.05.2004
▶ 71	BB336	Bruno Brunwald	Initial	---	17.05.2004	↓
▶ 72	Ca9876	Carole Clingh	Initial	---	19.05.2004	↓
▶ 76	22222	.	Initial	---	25.05.2004	↓

[New patient](#)
[download all cases \(csv\)](#)

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PARC-ITP, Central Data Office, University Children's Hospital UKBB, CH-4005 Basel  
 Fax +41 61 685 65 66, [parc-itp-ukbb@unibas.ch](mailto:parc-itp-ukbb@unibas.ch) / for Study Protocol see [www.unibas.ch/itpbase/](http://www.unibas.ch/itpbase/)



## **6 Logout**

Please click the 'logout' button in the upper right hand corner to leave the PARC-ITP database.

## **7 Your comments**

Your comments and suggestions are important to us. Please contact us at [info@parc-itp.net](mailto:info@parc-itp.net). Thank you for participating in the PARC-ITP study.

## Annex

### A Information on the Initial form (Form A)

**Note:** All information completed in this form concerns the condition **at the time of initial presentation/diagnosis**, if not stated otherwise.

3	Institution ID	An institution ID No. will be assigned to each participating institution by the Central Data Office of PARC-ITP.
4.1	Patient Identification	Please make sure to identify your patient for future follow-up. Note that you may enter personal patient data such as name, comments by clicking Personal Patient Data. At the end of your login session please download a list of your cases for easy tracking, see 3.3.
4.2	Informed Consent	Only patients of whom there is Informed consent may be registered in the PARC-ITP database.
5	Today's Date	Today's Date (Date of data entry) is automatically generated. No changes can be made.
6	Sex	Please mark the relevant box.
7	Ethnic status	The categories have been chosen in respect to later evaluation. Please mark all the relevant boxes. It is best to ask your patient which category is most suitable for him or her.
8.1	Family history	Mark the relevant box.
8.2	Family history	If you have marked 'yes' in 8.1, mark one of the boxes. Siblings are sister and brother with the same parents. Second degree relatives are grandmother, grandfather, uncle and aunt.
9.1	Co-morbidity	If you mark 'none', no other boxes can be marked. If co-morbidity was present at first presentation of your patient, mark the relevant box/boxes.
9.2	Drug therapy	If you mark 'none', no other boxes can be marked. If drug therapy occurred during first presentation, mark the relevant box/boxes.
10	Blood counts	Please enter date the blood count was taken. This date is a reference for next follow-ups.
10.1- 10.3	Platelet count Hemoglobin count  Leukocyte count	Please use the format ___x 10 <sup>9</sup> /L for the platelet count. Please use the format ___x g/dL for hemoglobin. (100 g/L = 10 g/dL) Please use the format ___x 10 <sup>9</sup> /L for the leucocyte count.
11.1	Platelet transfusion	Before or at diagnosis
11.2	Anemia	If anemia is present, please note if hereditary or acquired and continue to fill in. If no anemia is present, leave blank.
14	Laboratory tests	Please mark all tests that were performed at the time of initial diagnosis of ITP. Mark all tests that were not performed accordingly.
15	Bleeding and management	Please mark all the relevant boxes to indicate a bleeding episode and the corresponding management. Note that for the Initial form this applies to the time of initial diagnosis.

The initial form may only be registered if all fields of the questionnaire are complete.

B. Information on 6-Month form and Yearly follow-up form (Forms B and C)

**Note:** All information completed on the follow-up forms (6-Month form and yearly follow-up forms), collect information of **the past time period (=interval) since the last data collection**, if not otherwise stated.

1 to 4		Will be filled in automatically
5	Appointed date of follow-up Today's date	Will be automatically generated (no changes possible) Reference date for all follow-ups is the blood count date at initial diagnosis. Please enter data of the patient record that are as close to the appointed date as possible. (+/- 3months of the appointed date are allowed.)
6	Patient Identification	Will be automatically filled according to the Initial form of this patient. Click <a href="#">Personal Patient Data</a> to display the name of this patient.
7.1-7.2	Patient alive/deceased	Even if your patient has died, please continue to fill in as much information as possible. After completing the respective follow-up form, you will no longer be prompted to submit follow-up data for this patient.
8	Blood count	Please enter the most recent counts (the closest to the appointed date of follow-up). Please use the format ___x 10 <sup>9</sup> /L for the platelet count. Please use the format ___x g/dL for hemoglobin. Please use the format ___x 10 <sup>9</sup> /L for the leucocyte count.
9	Drug therapy	If you mark 'none', no other boxes can be marked. If drug therapy occurred during first presentation, mark the relevant box/boxes.
10.1	Primary ITP	
10.2	Secondary ITP	Mark all boxes that apply. If your patient has secondary ITP, we appreciate if you could continue to submit data for as long as possible.
11.1 11.2	Pregnancy and Delivery	This question will not be active if your patient is male. If pregnancy occurred within the time interval since last data submission please mark yes, else no. If delivery occurred within the time interval since last data submission please mark yes, else no.
11.3	Treatment of mother during pregnancy	If you mark 'none', no other boxes can be marked. If treatment occurred during pregnancy, mark the relevant box/boxes.
11.4	Prenatal platelet count	Mark the relevant box.
12	Laboratory Tests	Please mark all tests that were performed within the time interval since the last data submission. Mark all tests that were not performed accordingly.
13.1	Bleeding	Mark the relevant box according to bleeding within the time interval since last data submission.
13.2	Bleeding episodes	Mark the relevant box/boxes according to bleeding episodes within the time interval since last data submission.
14.2	Drug treatment	Mark the relevant box/boxes according to drug treatment within the time interval since last data submission.