

Congratulation on your successful registration in the service CTDMS!

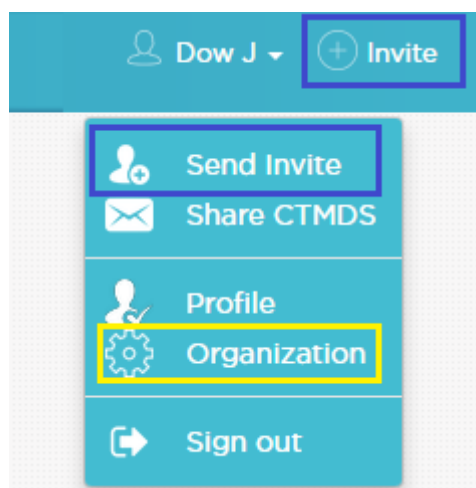
Below you will find the description of available features of the service and recommendations on its use for organization of work of your study site.

To start the work:

1. Create a new research study
2. Register a patient (patients)
3. Enroll the patient
4. Invite members of your research team to register on the site

1. Information about the study site and management of users and members of the study site

Immediately after registration in the service, you receive an Administrator permission for the study site. We recommend you to fill in the information about your study site in the user menu – section “Organization”:



Study site
Audit

CTDMS

Name	DEMO Clinic
Phone	4420654321
Address	
Email	
Language	English

Save

Using the menu section “Invite”, you send invitations for registration of members of your research team on the study site. For this, it’s necessary to fill in the field of electronic mail address, on which there will be delivered an invitation with the registration link and role of the invited member in the system: “Administrator” (will have full access permission), “User” or “Principal Investigator” (in addition to general member permissions, he or she will be able to create new study protocols):

×

✉

Invite to study site

@

Email (required)

Select Role...

Select Role...

Administrator

Principal Investigator

User

As the Administrator of the Organization, in the **menu section “Personnel”**, you will be able to manage the members of your study site **(as well as to add a member without invitation and then send to him or her a password recovery e-mail)**:

[+ Add Person](#)

Site personnel							
Name	Department	Email	Speciality	Phone	Limit patients	View	Edit
Dow John	Clinical Trials	jd@ctdms.net	General practitioner	4420123456	3		
Williams David	Clinical Trials	dw@ctdms.net	General practitioner	4420741852	5		
Harry Thomas	Internal Diseases	th@ctdms.net	Pulmonologist	4420987456	4		
Wing Charlie	Internal Diseases	cw@ctdms.net	Nurse	4420159753	10		

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[+ Send recovery email](#)

[< Back](#)

Name	John	Email	jd@ctdms.net
Surname	Dow	Phone	4420123456
Speciality	General practitioner	Max patients per day	3
Department	Clinical Trials	Time zone	(GMT+03:00) Europe/Moscow
Status	Active	Role	Admin

[Save](#)

The following possibilities are also available:

- editing of personal data of members
- changing of the status of members
- setting the limitation to the number of patients who can visit a member per day (upon overlimit, there will be displayed a message informing that the member is overcharged)
- changing of the role of the member in the service (User, Principal Investigator, Administrator)
- sending of a password recovery e-mail

The **menu section “Share CTMDS”** is designed for sending an information message about the service CTMDS on your behalf.

By selecting the **menu section “Profile”**, you can edit information about yourself, change your password, e-mail address, and **enable two-factor authentication**.

[General](#)
[User](#)

[Enable 2-Step Verification](#)

[< Back](#)

Name	John	Phone	4420123456
Surname	Dow	Number of Agenda days	30
Speciality	General practitioner	Limit patients per day	3
Department	Clinical Trials		

There are available detailed instructions on setting the two-factor authentication:

Enable Google Authenticator

Generate QR-code

1. Install Google Authenticator on your phone
2. Open the Google Authenticator app.
3. Press "Generate QR-code", on this page
4. Tap menu, then tap "Set up account", then tap "Scan a barcode"
5. Your phone will now be in a "scanning" mode. When you are in this mode, scan the barcode below
6. Once you have scanned the barcode, enter the 6-digit code below

Enable GA

Cancel

2. Creating of a new study protocol

In the menu section “Studies”, the members with Administrator and Principal Investigator permissions, have possibility to create new studies. “Users” have permission to overview the studies they are taking part:

filter	<input checked="" type="checkbox"/> Active only <div>New study</div>				
Study code	Study name	Principal Investigator	Status	Mode	Print
DTI589125	New drug clinical trial	Dow John	Active		
SKR-032	New drug clinical trial 2	Dow John	Active		
TRI001	New drug clinical trial 3	Dow John	Active		
TST-123	New study	Dow John	Active		
TST-148	New clinical trial	Dow John	Active		

Upon creating a new study protocol, you specify general information and the Principal Investigator for the specified study (any member registered in the site may be the Principal Investigator). The member appointed as the Principal Investigator receive permission to edit the study completely:

General
Schedule
Personnel
Procedures
Local Limitation
Forms & Docs
Finance

Study: DTI589125 New drug clinical trial < Back

Study code	DTI589125
Study name	New drug clinical trial
Start date	2017-01-01
End date	
Status	Active
Remarks	

First, fill in the section “Schedule”:

General
Schedule
Personnel
Procedures
Local Limitation
Forms & Docs
Finance

☒ Autoarrange
Export PDF

	Visit -2 Prescreening Day -2w, +5 -5 days	Visit -1 Screening Day -1w, +4 -4 days	Visit 1 Randomization Day 1d, + - days	Visit 2 Week 2 Day 2w, +3 -3 days	Visit 3 Week 4 Day 4w, +3 -3 days	V D
	Randomization day					
Visit on site	✓	✓	✓	✓	✓	
Phone contact						
Blood sample	✓		✓		✓	
Urine sample	✓		✓			
ECG	✓					
Chest X-Ray	✓					

Save

For comfortable filling in, there is available a pop-up menu for editing / doubling / deleting / moving the visits and study procedures.

Horizontally, you add study visits (name, number, day/week/month and an allowable window of the visit in days +/-, as well as the note if the day is a randomization day):

Add visit

Nº visit

Day

Type

+d

-d

6

Day

☐ Randomization day

Ok

Vertically, you add study procedures (it's allowed to include into the schedule only those procedures, which are important for you in planning visits of patients, for example, taking history as part of the whole visit may be missed out). Adding of procedures is made from the reference-book with possibility to edit them according to your needs:

Add procedure(s)

filter

Visits

☒ Visit on site

☐ Phone contact

Laboratory

☐ Blood sample

☒ Urine sample

Diagnostic procedures

+ Add new

Ok

At the intersection of the columns and rows of the schedule table, it is noted if the specified procedure should be made during the specified visit.

In the **menu section “Personnel”**, you should enter the members of the site who take part in the study as well as their roles in the study:

GeneralSchedulePersonnelProceduresLocal LimitationForms & DocsFinance

+ Add new Role

Study: DTI589125 New drug clinical trial

< Back

Person	Role	Delete
Dow John	Principal Investigator	<div>×</div>
Williams David	Study Coordinator	<div>×</div>
Harry Thomas	Sub-Investigator	<div>×</div>
Wing Charlie	Study Nurse	<div>×</div>

In the **menu section “Procedures”**, when applicable, you appoint the members of your team who are responsible for performing of specified procedures. One of the members can be responsible for performing several procedures and one procedure may be performed by one of the several members:

General	Schedule	Personnel	Procedures	Local Limitation	Forms & Docs	Finance
Study: DTI589125 New drug clinical trial < Back						
Procedure			Personnel			
Visit on site	+ Add person		Williams David	✗		
Phone contact	+ Add person		Harry Thomas	✗		
			Williams David	✗		
Blood sample	+ Add person		Wing Charlie	✗		
Urine sample	+ Add person		Wing Charlie	✗		
ECG	+ Add person		Wing Charlie	✗		
Chest X-Ray	+ Add person		Harry Thomas	✗		

In the **menu section “Limitation”**, you set the limits for the study upon planning the visits of patients (for example: a procedure may be made for not more than 1/2 patients per day or only on specified week days):

General	Schedule	Personnel	Procedures	Local Limitation	Forms & Docs	Finance
Study: DTI589125 New drug clinical trial < Back						
Procedure			Limit			
Visit on site	+ Add limit		Subjects per day: 1	✗		
Phone contact	+ Add limit					
Blood sample	+ Add limit		Day of week: Mon Tue Wed Thu	✗		
Urine sample	+ Add limit		Day of week: Mon Tue Wed Thu	✗		
ECG	+ Add limit					
Chest X-Ray	+ Add limit		Subjects per day: 2	✗		

The **menu section “Forms and documents”** allows you to save all files relating to this study for the study team in one storage (for example: the template forms for the source documentation and commentaries).

The **menu section “Finance”**, upon its activation, allows to keep records of allowances for the members for their visits. In the section, the payment currency is specified (for instance: multicurrency approach on the site) and for each visit, for each procedure and for each member responsible for the procedure there is specified the sum of allowance upon completion of the visit. Beside this, it is possible to create and account additional expenses both connected and not connected with the member of the site:

General
Schedule
Personnel
Procedures
Local Limitation
Forms & Docs
Finance
Enable accounting

Study: DTI589125 New drug clinical trial

EUR

Visit / Procedure	Personnel	Cost, [EUR]
Visit: -2 / Prescreening		
Visit on site	Williams D.	150.00
Blood sample	Wing C.	25.00
Urine sample	Wing C.	
ECG	Wing C.	25.00
Chest X-Ray	Harry T.	45.00
Total:	Additional expense	Visit cost (min-max) 245 - 245 [EUR]
Visit / Procedure	Personnel	Cost, [EUR]
Visit: -1 / Screening		

3. Creating a patient and database of patients

In the menu section “Patients”, there is kept the database of the patients who are practically or potentially taking part in the clinical studies. Any member can create a new patient by clicking the button “New Patient”:

filter

Search

Refresh

New Patient

ExportPDF

ID	Surname (Initials)	Name	DOB	Status	Edit	Schedule
50063	LVL		1982 Jan 01 (35)	DTI589125		
78101	PLO		1936 Jan 01 (81)	DTI589125		
52389	IAF		1974 May 03 (42)	DTI589125		
789548	TIL		1956 Jan 01 (61)	SKR-032		
998777	WSQ		1967 Sep 07 (49)	TRI001		
3854714	IVS		1984 Jan 03 (33)	SKR-032		
854723	KKL		1965 Mar 25 (52)	TRI001		
74125	LVB		1938 May 05 (78)	DTI589125		
4512	PTT		1974 Apr 07 (43)	SKR-032		
347851	LLV		1978 Dec 03 (38)	TRI001		

After filling in the personal information about the patient (if needed, it’s allowed to use anonymized data of the patient – for example, only initials and birth date or individual number), additional sections appear:

General
Health
Studies
Comments
Export PDF PDF

ID 50063 LVL < Back

ID	50063	Address	
Surname (Initials)	LVL	Phones	
Name		E-mail	
Mid. name		Relatives	
Date of birth	1982-01-01	Remarks	
Sex	Male		

In the **menu section “Health”**, health history of the patient is recorded. Upon adding a new record and entering a part of the diagnosis, there is performed the search of matches in ICD-10 and output of suggestions according to the matches. At that, it is allowed to fill in the field of the diagnosis with your own text without the use of the guide ICD-10. The use of the codes of ICD-10 will allow to specify diagnosis consistently, and consequently, to make easier the search for the patients with specified diagnosis or condition:

General
Health
Studies
Comments
Add Health

ID 50063 LVL < Back

Diagnosis / Condition	Start diagnosis date	Details	Edit	Delete
I11 - Hypertensive heart disease	2007-09-01	II-III		
E11 - Non-insulin-dependent diabetes mellitus	2001-01-01			

Additional Information

Save

Diagnosis / Condition	Anaem
Start diagnosis date	D46.0 - Refractory anaemia without ringed sideroblasts, so stated
Diagnosis details	D46.1 - Refractory anaemia with ringed sideroblasts D46.2 - Refractory anaemia with excess of blasts

In the **menu section “Studies”**, there is specified the whole history of the patient’s assistance in clinical studies with possibility to go to the schedule of his or her visits:

General
Health
Studies
Comments

ID 50063 LVL < Back

Study	Subject ID	Status
DTI589125	101201	Enrolled on 2017-01-30

The **menu section “Comments”** is designed for storing of random notes about the patient with subsequent possibility to search for the notes.

In the patients list, an advanced search is available for selection of participants of the clinical studies:

Search

Refresh

New Patient

Export PDF

Advanced Search

Clear Search

Age from

Age to

Sex

Comment

Select sex...

Diagnosis

Diagnosis Details

Days from last trial

Study

Remarks

Search

ID	Surname (Initials)	Name	DOB	Status	Edit	Schedule
875412	FDL		1956 May 09 (60)	DTI589125		
458957	KLT		1983 Jan 01 (34)	Available		

4. Enrolling of a patient into the study and visits schedule

After registration of a new patient, his or her enrolling into the study is possible to perform from the patients list or from the patient card:

ID	Surname (Initials)	Name	DOB	Status	Edit	Schedule
875412	FDL		1956 May 09 (60)	DTI589125		
458957	KLT		1983 Jan 01 (34)	Available		

General

Health

Studies

Comments

Remove Patient

Enroll

Export PDF PDF

ID 458957 KLT

< Back

ID	458957	Address	
Surname (Initials)	KLT	Phones	
Name		E-mail	

In the dialogue window of enrolling into the study, it is needed to select the study, the investigator, the date of the visit and signing of the ICF. Preview of the schedule of visits of the patient is available:

Enroll patient

ID:

Name:

Date of birth:

Study

TRI001

Investigator

Dow John

ICF Date

2017-04-14

Preview schedule

Enroll

After enrolling the patient, there will be created a schedule of his or her visits in accordance with requirements of the study with account of allowed windows of visits, in the beginning – before the moment of randomization, and after the randomization – until completion of assistance in the study:

KLT 1983 Jan 01 (Age: 34)

Preview

+ Add visit

Randomize

Screen Fail

Export PDF PDF

Study: DTI589125

Patient ID in Study:

Comments:

Save

Visits					Procedures	
N° / Name	Day / Window	Planned date / Window	Actual day	Status	Procedure	Person
-2 / Prescreening	-2 w (+5 -5)	<div>2017-04-14</div>	-14		Visit on site	Williams David
					Blood sample	Wing Charlie
					Urine sample	Wing Charlie
					ECG	Wing Charlie
					Chest X-Ray	Harry Thomas
-1 / Screening	-1 w (+4 -4)	<div>2017-04-21</div> <div>(17 Apr - 25 Apr)</div>	-7		Visit on site	Williams David
1 / Randomization	1 d (+0 -0)	<div>2017-04-28</div>	1		Visit on site	Williams David
					Blood sample	Wing Charlie
					Urine sample	Wing Charlie

In the schedule, it's possible to specify an ID-number assigned to the patient in this study and notes. The procedures with the dates for whatever reason breaking the limitations specified in the study or in the

employee card (overcharge, not valid day) are highlighted in red. The dates of the visits may be changed within the frame of allowed windows:

Status	Procedure	Person
	Visit on site	Williams David
	Day of week not valid	
	Blood sample	Wing Charlie
	Urine sample	Wing Charlie
	ECG	Wing Charlie

2017-04-21

-7

1

April 2017

Mo	Tu	We	Th	Fr	Sa	Su
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

Also, it is possible to change the member responsible for performing of a procedure both in a specified visit and in all successive visits at once.

Upon clicking the column “Status”, the visit is marked as performed:

					Visit on site	Williams David	▼
					Blood sample	Wing Charlie	▼
					Urine sample	Wing Charlie	▼
					ECG	Wing Charlie	▼
					Chest X-Ray	Harry Thomas	▼
-2 / Prescreening	-2 w (+5 -5)	2017-04-14	-14	✓			

There’s a possibility to add unscheduled visits into the schedule (button “+” Visit):

Add unscheduled visit

Visit name

Retest

Personnel

Dow John

2017-04-14

Add

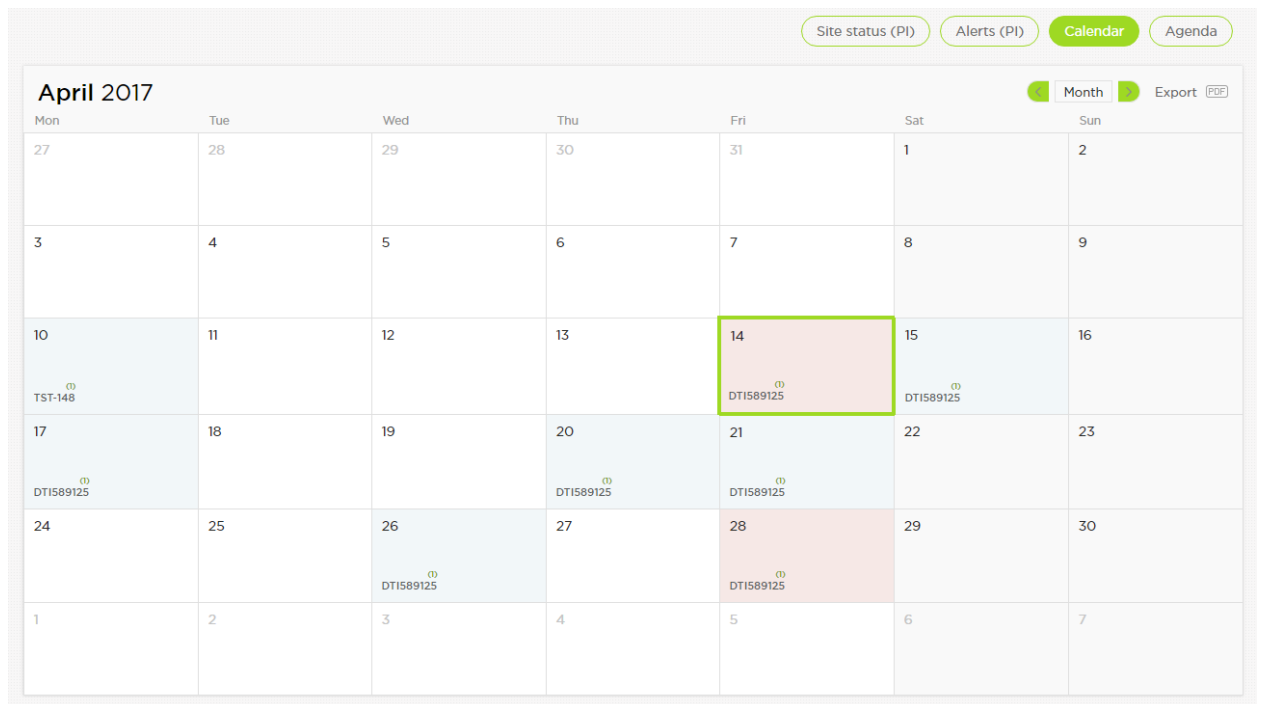
Visits					Procedures	
N° / Name	Day / Window	Planned date / Window	Actual day	Status	Procedure	Person
-2 / Prescreening	-2 w (+5 -5)	2017-04-14	-14	✓	Visit on site	Williams David ▾
					Blood sample	Wing Charlie ▾
					Urine sample	Wing Charlie ▾
					ECG	Wing Charlie ▾
					Chest X-Ray	Harry Thomas ▾
Retest	-	2017-04-15	-13	✓	Dow John	▾ ✗

5. Schedule of the site/member, calendar, alerts

In the menu section “Panel”, there is specified a working visits schedule for the patients of the studies. Co-investigator sees planned visits of the patients, and the coordinating investigator and the principal investigator see the visits of all patients of the studies, where they are appointed as the coordinating investigator and the principal investigator:

Active studies		Show active patients		2017-04-14	2017-05-14	Site status (PI)	Alerts (PI)	Calendar	Agenda	PDF
<div>All studies</div> <div>DTI589125</div> <div>SKR-032</div> <div>TRI001</div> <div>TST-123</div> <div>TST-148</div>		Date	Study	Subject		Visit	Status			
		14 Friday April 2017 1 LIMIT	DTI589125	KLT		-2	✓			
		15 Saturday April 2017 1	DTI589125	KLT		0	✓			
		17 Monday April 2017 1	DTI589125	IAF		4				
		20 Thursday April 2017 1	DTI589125	LVB		4				

Calendar view is available:



Additionally, the coordinating investigator and the principal investigator have possibility to review alerts to allowed deviations (in the schedule; missed visits) and in the general status of enrolling in the site:

from to ☐ Show closed Site status (PI) **Alerts (PI)** Calendar Agenda

Date	Personnel	Alert	Calendar	Subject	Study	Closed
2017-04-10	Dow John	Missed visit for patient: ARL (TST-148)				
2017-03-23	Dow John	Missed visit for patient: LVB (DTI589125)				
2017-03-20	Dow John	Visit out of window: FDL (DTI589125)				
2017-03-20	Dow John	Missed visit for patient: IAF (DTI589125)				
2017-03-20	Dow John	Missed visit for patient: ARL (TST-148)				
2017-03-20	Dow John	Missed visit for patient: FDL (DTI589125)				
2017-03-20	Dow John	Visit out of window: ARL (TST-148)				
2017-03-15	Dow John	Missed visit for patient: FDL (DTI589125)				
2017-03-09	Dow John	Missed visit for patient: LVB (DTI589125)				
2017-03-07	Dow John	Missed visit for patient: LLV (TRI001)				

Active studies (Total / Screen Failed / Finished)			Active personnel (Studies / Subjects)		
Study code	Study	Subjects	Personnel	Agenda	Subjects
DTI589125 (6 / 0 / 0)			Dow John (7 / 11)		
SKR-032 (3 / 0 / 0)			Williams David (3 / 0)		
TRI001 (3 / 0 / 0)			Harry Thomas (3 / 2)		
Tect 1 (0 / 0 / 0)			Wing Charlie (4 / 0)		
RUK-156 (0 / 0 / 0)					
TST-123 (2 / 0 / 2)					
TST-148 (1 / 0 / 0)					

In the schedule, there are hyperlinks to the patient card, his or her visits agenda and to the study.

6. Finance module

If the study includes financial accounting, then, upon marking the patient's visit as performed, the performers of the visit will receive payments according to amended tariffs. In the menu section "Finance" for co-investigators, there is specified the bulletin with payments for the studies, in which they assisted:

2017-04-01		2017-04-30		My finance	Accounting	Payments	Extra accruals	Export PDF
Study	Debt on [2017-04-01]	Accrued	Paid	Debt on [2017-04-30]				
DTI589125	0 EUR	160.00 EUR	110.00 EUR	50 EUR				
Total	0 EUR	160.00 EUR	110.00 EUR	50 EUR				

Upon a mouse click, there will be available an itemization of billings and payments:

Study: DTI589125 Currency: EUR		Export PDF			×
Date	Action	Sum, [EUR]	Correction	Comment	
2017-04-14	Patient: KLT Visit: -1 / Visit on site	160.00	0.00		
2017-04-14	Payment	(110.00)			
Balance for the period		50 EUR			

The principal investigator and the coordinating investigator have access to the calculations of all members of the site assisting in the studies as well as the sections for making payments to the members and for registration of additional billings and making corrections:

2017-04-01

2017-04-30

By study

By personnel

My finance

Accounting

Payments

Extra accruals

Export PDF

Study	Debt on [2017-04-01]	Accrued	Paid	Debt on [2017-04-30]
DTI589125	0 EUR	405.00 EUR	110.00 EUR	295 EUR
Dow J.	0 EUR	160.00 EUR	110.00 EUR	50 EUR
Williams D.	0 EUR	150.00 EUR	0 EUR	150 EUR
Wing C.	0 EUR	50.00 EUR	0 EUR	50 EUR
Harry T.	0 EUR	45.00 EUR	0 EUR	45 EUR
Total	0 EUR	405.00 EUR	110.00 EUR	295 EUR

Here, upon a mouse click, there is available an itemization of billings and payments with possibility of making necessary corrections:

Personnel: Williams David

Export PDF

Date	Study	Action	Sum	Correction	Comment
2017-04-14	DTI589125	Patient: KLT Visit: -2 / Visit on site	150.00 EUR	-150.00	Visit missed
Balance for the period			0 EUR		

The menu section **“Payments”** contains information about the payments made to the members who assisted in the studies:

My finance

Accounting

Payments

Extra accruals

Export PDF

2017-04-01




2017-04-30

Select study... ▼

Select personnel... ▼

Select additional... ▼

+ New payment

Study	Personnel / Expense	Date	Sum	Currency	Comment	Actions
DTI589125	Dow J.	2017-04-14	110.00	EUR		  
Total			110	EUR		

In the menu section **“Extra accruals”**, it is possible to account random extra accruals (bonuses etc.) in the context of the studies:

My finance

Accounting

Payments

Extra accruals

Export PDF




2017-04-01

2017-04-30

Select study...

Select personnel...

+ Add accrual

Study	Personnel / Expense	Date	Sum	Currency	Comment	Actions
DTI589125	Harry T.	2017-04-14	50.00	EUR	Bonus	  
Total			50	EUR		

- All sections of the service have an option **“Export PDF”**, which allows to create and, if needed, to print out the report forms.