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":
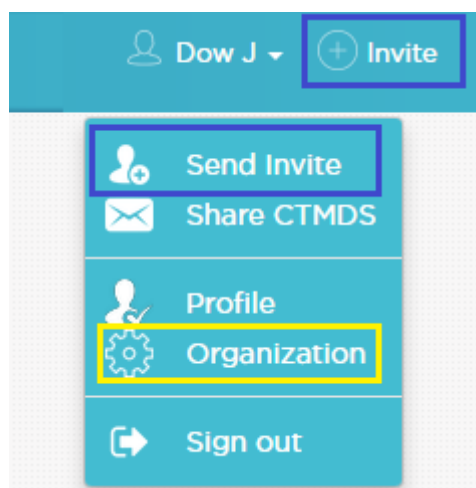
Using the menu section "Invite", you send invitations <u>for registration of members of your research team on the study site.</u> For this, it's necessary to fill in the field of electronic mail address, on which there will be delivered an invitation with the registration link and role of the invited 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):

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**):

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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(+) Add Person

(+) Send recovery email

Profile ‹ 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 CTDMS 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

Profile

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:

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:

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:

First, fill in the section "Schedule":

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):

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:

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:

Person	Role	Delete
Dow John	Principal Investigator	✕
Williams David	Study Coordinator	✕
Harry Thomas	Sub-Investigator	✕
Wing Charlie	Study Nurse	✕

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:

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):

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:

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":

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:

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:

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:

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:

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:

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:

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:

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:

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:

There's a possibility to add unscheduled visits into the schedule (button "+" Visit):

Visits					Procedures		
№ / 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:

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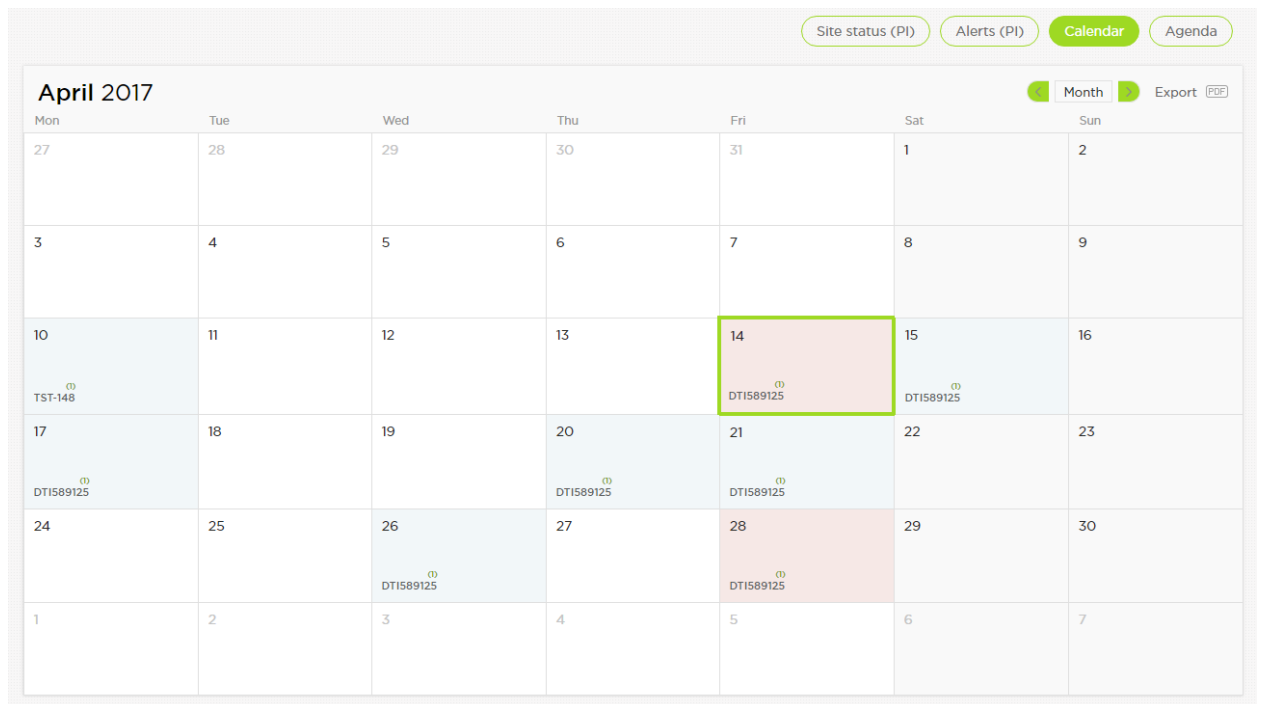
Additionally, the coordinating investigator and the principal investigator have possibility to review alerts to allowed deviations (in the schedule; missed visits) and in the general status of enrolling in the site:

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)	📅	👤	📄	⌛

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:

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

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:

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

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:

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:

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

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