



Integrated solution for electronic clinical trial management From the design of the electronic observation book to the freezing of the database

Training program and procedures CLEANWEB SOLUTION

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1 - Object

Telemedicine Technologies has an obligation to ensure the training of its customers to its software within the framework of the following principles: to allow them to adapt to their workstation and to ensure the maintenance of their capacity to occupy a job, in particular with regard to the evolution of jobs, technologies and organizations. The training courses must be homogeneous and adapted to the trainees, including, within the limits of reasonable accommodation, to people with disabilities or health problems. Trainees must be able to justify the training they have received

This document summarises the training programs and in particular the different modules of the CleanWEB solution, as well as the terms and conditions for the provision of these services by TTSA.

The activity of Telemedicine Technologies as a training organisation is registered under the number 11 92 19676 92. This registration does not imply state approval.

2 - Rules of Procedure

In accordance with the provisions of Articles L.6352-3, L.6352-4 and L.6352-5 and R.6352-1 to R.6352-15 of the Labour Code, internal regulations applicable to participants shall be drawn up (see Annex A3).

These rules are available to customers and/or participants on the TTSA website (https://tentelemed.com/fr/formations/).

3 - Pricing

As an indication, the rate is €1800.00 excluding VAT per day of in-company training, either face-to-face or distance learning.

In the context of the WEBINAR platform, pricing is based on :

- Either a cost per token system (1 token = 1 hour/participant=110.00 € excl. tax): this rate is degressive according to the number of hours of the webinar and the number of tokens purchased by the client.
- or a fixed cost per webinar based on the equivalent unit cost of the tokens.

For more information on the contractual and financial aspects of the training courses, please contact TTSA by e-mail (<u>formation-cleanweb@tentelemed.com</u> or contact@tentelemed.com) or complete the contact form at the following URL: https://tentelemed.com/contact/.

4 - Time limits for access to training

A minimum of one week is needed to organise the implementation of a training course. Knowing that the programming of training depends on the number of days of training to be programmed, the agendas of each protagonist and therefore their number, and in the case of a face-to-face training, the availability of the training room. This period can therefore extend to 1 or even 2 months.

5 - Place of training

The trainings take place in person at the customer's designated premises or at Telemedicine Technologies' premises.

In the case of training courses taking place in premises unknown to Telemedicine Technologies, the Trainer ensures that the premises are accessible and suitable for everyone and that the necessary means for the training are made available (video projector, PC, installed software, etc.).

Training can also be conducted remotely, especially if the duration is less than half a day. The contact details of the meeting are transmitted prior to the training after ensuring that the tool used for distance learning is accessible to all participants.

The choice of software used for distance learning is left to the discretion of the Trainer (TEAMS, GoToMeeting, GoToWebinar, Skype, Zoom, WebEx...) depending on the accessibility of the software for the participants.



The locations of the training courses are partly dependent on the type, format and duration of the session.

6 - Types and duration of sessions s

Two types of sessions are offered:

- individual session
- group session: limited to a maximum of 12 people in face-to-face sessions; no limit on the number of people in distance learning
- Note: some modules concerning users, for example, can accept more than 12 people (this excludes any manipulation of the software).

Duration of sessions :

- variable according to the training: from 1 hour to 4 hours, and/or 1, 2 or even 4 days.

7 - Session formats

Two formats for group sessions:

- Intra-company: involves people from the same company
- Inter-company: involves people from different companies

Within the framework of inter-company training, training courses can be organised via a WEBINAR platform including a self-registration system and, if necessary, an online payment system (see § WEBINAR platform).

8 - WEBINAR platform

This platform allows you to plan and carry out inter-company distance learning courses.

This platform uses several coupled software packages to allow self-registration of participants and eventual online payment.

Pricing is based on :

- Either on a system of cost per token (1 token = 1 hour/participant) in the case of a contract to purchase a batch of tokens. A count of the tokens is made for each participation.
- or a fixed cost per webinar. In this case, payment is made directly online. The invoice is available in the order confirmation email.

Setting up and running an inter-company webinar follows the following process:

- 1. The dates and topics of the courses are set by TTSA
- 2. Sending of several mailings informing customers of the topics of the proposed training courses and the corresponding planned dates (a reminder of the URL where the information (CW-108-COM EN Training program and modalities) and the contacts can be found is included). Two different types of emails are potentially sent: one to employees of companies that have purchased a batch of tokens, another to employees of companies that have not purchased a batch of tokens. In the latter case, the price of the webinar is indicated.
- 3. Sending of the invitation email containing the webinar contact details allowing potential participants to self-register and possibly pay online (the needs analysis questionnaires and the training programs or descriptive sheets are attached).
- 4. A validation of the registrants is eventually carried out
- 5. E-mail reminders of the webinar details are scheduled on the WEBINAR platform to be sent to registered participants



- 6. The training is carried out by the trainer.
- 7. The satisfaction and learning assessment questionnaires are sent manually by the trainer or automatically by the WEBINAR platform
- 8. Training certificates are sent to participants

In the following paragraphs, the specificities of this platform will be highlighted by a visual reminder:

"WEBINAR:".

9 - Registration

The customer contacts Telemedicine Technologies by the means of communication of his choice (for example by contacting the sales department or by sending an e-mail to formationcleanweb@tentelemed.com), in order to formulate his request for training according to his needs from the list of training courses provided on request or from this commercial document available on the TTSA website.

Unless the training is included in a more general contract, a suitable quotation is sent to the client for acceptance by TTSA.

On request, the training center manager will provide the information needed for the client to put together a file requesting that his or her training be paid for by an OPCO (e.g. within the framework of the use of the CPF), and at least :

- the training program
- the place, date and duration of the training
- WEBINAR: In the case of inter-company training, the dates are planned by TTSA. The participant selfregisters directly from the link provided in the invitation email and completes the needs analysis questionnaire. In the absence of a contract with the participant's company, the participant pays the cost of the training via online payment.
 - Note: All registrations for a webinar are counted as participation in the webinar, unless cancelled at least 24 hours before the webinar by sending an email to formation-cleanweb@tentelemed.com.

The training action is subject to online payment (in the case of inter-company training via the WEBINAR platform), to the drawing up of a contract or a training agreement (Article L 6353-2 of the French Labor Code) concluded between the training provider and the purchaser of the training - a company for example.

However, the purchase order may be used in the case of one-off purchases of short or repetitive training courses as part of a flexible procedure for purchasing training activities. The purchase order or invoice is produced in the absence of a contract, bearing in mind that the essential elements concerning the training service provided or to be provided must be clearly identified. An invoice is issued as soon as the training service is provided.

In the context of a request for financing by the OPCO (Operators of skills), the training action is necessarily subject to the acceptance of the financing of the training by the OPCO or, if necessary, if the answer of the OPCO is not yet received, to the reception by Telemedicine Technologies of the certificate of commitment of payment previously provided to the customer. The relations with the OPCO are taken care of by the client.

Special case: in the case of a natural person who undertakes training on an individual basis and at his or her own expense (Art. L6353-3 to L 6353-7 of the Labor Code), a training contract is concluded directly with this person.

10 - Training objectives

The objective of the training courses is different depending on the modules to which the courses relate.

• In the case of modules requiring parameterisation (e.g. CleanWEB Designer), the objective of the training is to transfer knowledge so that the learner can independently build an eCRF and/or the inherent management environment.



- Within the framework of modules accessible to end-users (CleanWEB WEB, Connector) such as investigators, CRAs or CTEs, the objective is to enable them to use the software's functionalities in an autonomous way.
 - These training sessions can be given to intermediary persons. The latter can introduce the investigators or TECs to the software during the implementation of the study in the investigating centres.

The objectives that participants must achieve correspond to a list of knowledge and/or skills that they must acquire and which are listed in each of the training program descriptions (see § Programs and descriptions).

11 - Pedagogical approach

The pedagogical approach is divided into three parts:

- Needs analysis: needs are often implicit in the content of the training modules, but an interview is always carried out at the beginning of the training in addition to the needs assessment questionnaire prior to the training in order to check the prerequisites, to refine the needs and possibly to adapt the training strategy/materials and to put in place possible accommodations for DSPs.
- The training itself, which uses the teaching methods listed below and is adapted to the participant's level of knowledge and the objectives set out at the beginning of the training. The progressive construction of new skills or knowledge is carried out, particularly for the most classic or complex points, by a passage from theory to practice on concrete cases where the learner is asked to seek solutions.
- The evaluation of the training is carried out by means of a questionnaire for the evaluation of the acquired knowledge is also proposed at the end of the training. In addition, in the case of knowledge transfer, evaluation is carried out through practical application (implementation of eCRF or other parameterisation). This evaluation is possible because of the existence of a post-training parameterisation aid available to the learner who can contact the hotline service for parameterisation assistance. The Trainer can thus evaluate not only the acquisition of knowledge and skills, but also their evolution.

12 -Needs analysis

The needs analysis is based on the customer's requirements for training of their staff whose function requires the use of the software provided by TTSA.

A needs assessment questionnaire is sent to the participants before the training to determine whether the training is suitable. This questionnaire allows us to assess the presence of prerequisites (relevant job, level of experience in clinical research or software), their needs and expectations and possibly to identify a person with a disability requiring accommodation.

If the number of participants allows it, the needs analysis can be completed at the beginning of the training course by a preliminary interview between the trainer and each trainee in order to define the objectives and the points to be addressed or worked on in particular. During this interview, the level of knowledge and experience acquired is also sought by the trainer in order to adapt the pace and support.

13 - Convocation

The invitation to a training course is sent by e-mail by the trainer. This mail contains :

- The terms and conditions of the training (date, time and place, program, objectives, modalities, support documents, rules of procedure and possibly technical prerequisites) and/or a reminder of the URL of the TTSA website where most of its information can be found.
- In the case of face-to-face training, the access map and, if applicable, the arrangements for receiving people with disabilities or people with reduced mobility are added if they were identified during the needs analysis (see § Needs analysis)
- In the case of distance learning (including inter-company training via the WEBINAR platform), the invitation also contains the connection details.



The access map to the Telemedicine Technologies premises is available from the URL: https://tentelemed.com/fr/bureaux/.

14 -Pedagogical and technical means

Depending on the location of the training courses, the teaching resources may vary in terms of material.

- Presentation of the software from a video projector or via the distance learning software
- Whiteboard; can be replaced remotely by drawing software
- Manipulations and exercises applied on the participant's own computer or on a computer connected to the Internet made available to the participant
- Solving practical cases proposed by the participants
- Exchange of experience
- Questions and answers
- Videos
- Training materials and/or user guides

15 -Teaching methods and procedures

The training courses are mainly participative and practical. The transfer of knowledge includes theoretical contributions (affirmative method) and is based on teaching situations close to the learner's experience and practical case studies (demonstrative method). The concrete approach to the concepts studied enables the learner to transpose the notions covered to his or her current or future real-life situation. The pedagogical methods are described in a pedagogical path.

The scenario of our training courses and the vocabulary used both verbally and in the training materials are adapted to the learners' professions in order to make direct reference to the expectations of the learners and employers, defined in the personalisation phase of access to the training. The examples and exercises are, as far as possible, chosen from situations arising from the learner's own experience.

TTSA has comprehensive guides to all the software's features which form the majority of the support documents. The guides corresponding to the training are available on the hotline site (https://hotline.tentelemed.com). The links to access the guides are sent to the learner in electronic form

before the training. These support documents support the trainer's presentation and thus contribute to the rapid memorization of the key elements of the program.

The many practical case studies are designed to bring the learner closer to his or her own world in order to sustain interest.

Particular care is taken to ensure that the exercises are progressive in difficulty.

Our trainers alternate lectures with reflection sequences (questioning method) and directed exercises (active method) allowing the participant to put his new knowledge into practice.

WEBINAR: The training is mainly demonstrative. A time is reserved for questions and answers.

16 - Assessment of achievements

An evaluation questionnaire is given to the participant at the end of the course.

This questionnaire contains the objectives of the training and includes questions specific to the training course followed, which the participant must answer so that the trainer can classify the acquisition of his or her knowledge and/or skills in three categories: Not acquired, In the process of being acquired, Acquired.

17 - Satisfaction questionnaires

A training satisfaction questionnaire is handed out at the end of the session in order to anonymously collect the participants' observations.



A training satisfaction questionnaire is sent out after a few months in order to collect anonymous feedback from the participants.

A customer satisfaction questionnaire is submitted annually to the employers of those who have been trained during the year.

A satisfaction questionnaire is submitted annually to the OPCOs that the trainees have used.

The Training Centre Manager analyses these questionnaires, writes an annual report for the management and implements measures to improve the necessary points.

The results for the year are updated once a year, at the beginning of the year, and are available on the TTSA website at the URL: https://tentelemed.com/fr/formations/. These results concern the following items:

- Number of training certificates issued
- Number of training days completed
- Overall satisfaction rate of trainees

18 -Certificate of participation in the training

An attendance sheet is to be signed by each participant and the trainer during the course.

WEBINAR: The list of participants generated automatically by the WEBINAR platform replaces the attendance sheet.

A certificate of participation in the training is provided to each participant at the end of the training if the participant has signed the attendance sheet and completed the post-training questionnaires.

This certificate identifies the participant(s), the trainer, the title of the training and the dates, duration and location of the training.

19 - Accessibility and Disability Officer

The courses are accessible, within the limits of reasonable accommodation, to people with disabilities (PSH) or health difficulties.

Contact details of the Disability Referent in the training organisation for Telemedicine Technologies:

Mr Patrick BLANDIN

Email : pbl@tentelemed.com

The disability referent identifies DSPs and encourages them to make their situation known. He/she can be contacted (directly or via the needs assessment questionnaire) prior to the training course by any participant to explain his/her disability situation. The disability advisor will use his or her knowledge and/or network of disability resources to make the necessary adjustments to ensure that the training runs smoothly (tools, pace, or special procedures adapted to the disability expressed).

20 -Claims

In case of difficulties encountered by the participant or the client which may arise at any time during the process: registration, during the training, after the training (practical application, etc.)

Stakeholders can make a complaint by contacting TTSA through various means:

- By telephone or by e-mail directly to the trainer and/or sales representative.
- Via a dedicated email <u>formation-cleanweb@tentelemed.com</u> distributed on the TTSA website (https://tentelemed.com/fr/formations/).
- By creating a ticket on the hotline site (https://hotline.tentelemed.com) dedicated to the software provided by TTSA and choosing as type of request "Complaint related to a training course" or any other type of request in case of difficulty in putting into practice the training course followed.



Each request generates a ticket which is then processed until it is resolved (solution accepted by the person making the complaint). Communication in parallel with this processing can also be done by other means (e-mail, telephone contact, meeting).

21 -List of the different modules of the CleanWEB solution

The modules of the CleanWEB solution are the following (non-exhaustive list):

- Designer
- WEB (eCRF online)
- CTMS (Administrative)
- CTMS (Monitoring)
- Double entry
- ePRO
- eTMF
- IWRS and TU management
- Data Management
- Vigilance Module
- Imaging Module

This list may be subject to change as new versions are developed.



22 -Programs and fact sheets

22.1 CleanWEB Designer

Depending on the level of knowledge acquired on this Module, several training courses are provided.

Title of the course	CleanWEB Designer : Basic Functions
Objective of the training	Acquire the basics of parameterisation to enable the design of an eCRF
Knowledge / skills	 Overall knowledge of the platform Installing the designer and understanding how it works Knowledge of basic study settings Creation and layout of forms Knowledge and setting of options for all types of variables Knowledge of classical operators and creation of constraints Use of standard functions (libraries, copy and paste, etc.)
Public concerned	Anyone wishing to acquire or consolidate practical knowledge of eCRF design via CleanWEB software: ARC, Data Manager, Project Manager
Content of the course	 Overview of the CleanWEB solution Installation of the software Editing / global setting of a study On-line / history Modules / Forms Variables Referencing Layout / Tabs Tables How constraints work Operators Constraints Inclusion constraint Patient reference Audit documents Use of libraries Checker and Overview mode Copy and paste Methods, examples and tips
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 to 4 days depending on the level and number of participants
Mode of training	Face-to-face (preferred) or remote
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-054-USM - Installation_Guide_Designer CW-067-USM- DESIGNER 1 basic functions CW-168-USM - DESIGNER 4 Operators



The following training requires the participant to have acquired the knowledge and practical experience corresponding to the training "CleanWEB Designer: Basic functions".

Title of the course	CleanWEB Designer : Advanced Features
Objective of the training	Acquire the basics of parameterisation to enable the parameterisation of advanced functions of an eCRF
Knowledge / skills	 Use of advanced functions Setting up access by profile Thesaurus management Basic planning settings Language settings Template creation E-mail and fax settings
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the CleanWEB Designer functionalities: ARC, Data Manager, Project Manager
Content of the course	 CDISC mode Access rights & profiles Multilingual management Patient status Export/Import Managing an amendment MCQ and Thesaurus filter Planning and alerts Sending faxes and emails Merger documents CRF cover sheet and print mask Duplicate management Editing services Patient transfer CleanWEB Connector specific Page mode Statistics and progress reports Scorecards Planning Duplicate management
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 or 2 days depending on the level and number of participants
Mode of training	Face-to-face (preferred) or remote
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Open office or Libre Office
Supporting documents	CW-097-USM- DESIGNER 2 advanced functions CW-050-USM- Information Service Edition



CW-052-USM- Duplicate Detection Guide
CW-122-USM- Planning Designer Guide
CW-049-USM-Guide Patient Transfer and Sharing



22.2 IWRS and IMP management

Title of the course	CleanWEB IWRS and IMP Management: Design
Objective of the training	Provide the basics of using CleanWEB Designer and CTMS for setting up randomisation, IMP management and IMP replenishment
Knowledge / skills	 Principles related to randomisation and IMP management Setting up the randomisation according to different options Specific operators and creation of constraints for randomisation and allocation of IMP s Creation and implementation of randomisation and IMP lists Different statutes of a IMP Manual modification of IMP s and their properties Management of IMP stocks for automatic IMP replenishment Setting up an automatic replenishment
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and wishing to acquire or consolidate practical knowledge of the use of CleanWEB in the context of randomisation and IMP management: Data manager, ARC, Project manager
Content of the course	 Principles associated with randomisation Associated rights Setting up the randomisation Randomisation and IMP lists Algorithm for allocating a IMP Lifting of blindness Constraints (Rando + IMP) General monitoring of IMP s Statutes of the IMP s Statutes of the IMP s Expiry date Manual changes to IMP s Replenishment of IMP s Replenishment fax settings Pharmacy data management Delivery time IMP stock management Drawing of IMP s after randomisation List of TUs independent of randomisation Multiple randomisations Multiple lists of IMP s Advance drawing of IMP s Advance drawing of IMP s
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 day
Mode of training	Face-to-face (preferred) or remote



Prerequisites	Installing the Designer CTMS installation (fat client) PDF Creator
Supporting documents	CW-127-USM - DESIGNER 3 - Randomisation CW-056-USM- CTMS Installation Guide CW-061-USM- IMP Management Guide CW-162-USM - General Administration

Title of the course	CleanWEB IWRS
Objective of the training	To provide the basics of using CleanWEB Designer to set up randomisation
Knowledge / skills	 Principles related to randomisation and IMP management Setting up the randomisation according to different options Specific operators and creation of constraints for randomisation and allocation of IMPs Creation and implementation of randomisation and IMP lists
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and wishing to acquire or consolidate practical knowledge of the use of CleanWEB in the context of randomisation: Data manager, CRA, Project manager
Content of the course	 Principles associated with randomisation Associated rights Setting up the randomisation Randomisation and IMP lists Algorithm for allocating a IMP Lifting of blindness Constraints (Rando + IMP) Advanced functions : Randomisation by minimisation Drawing of IMPs after randomisation
	 List of IMPs independent of randomisation Multiple randomisations Multiple lists of IMPs Advance drawing of IMPs Adding a list of IMPs / randomisation Emergency IMP stock (Connector)
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 to 5 hours depending on the level and number of participants
Mode of training	Face-to-face (preferred) or remote
Prerequisites	Installing the Designer PDF Creator



Supporting documents	CW-127-USM - DESIGNER 3 - Randomisation
	CW-162-USM - General Administration

Title of the course	CleanWEB IMP Management
Objective of the training	To provide the basis for the use of IMP management and IMP replenishment
Knowledge / skills	 How the IMP Management and Replenishment Module works Different status of a IMP Manual modification of IMPs and their properties Expiry management IMP stock management for automatic IMP replenishment Setting up an automatic replenishment
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of CleanWEB CTMS in the context of IMP management: Pharmacist, CRA, Project Manager
Content of the course	 Principles associated with randomisation Associated rights IMP lists Algorithm for allocating a IMP General monitoring of IMPs Statues of the IMPs Expiry date Manual changes to IMPs Replenishment of IMPs Replenishment fax settings Pharmacy data management Delivery time IMP stock management Drawing of IMPs after randomisation List of IMPs independent of randomisation Multiple lists of IMPs Advance drawing of IMPs Advince drawing of IMPs Addition of a IMP list complement Backup IMP stock (Connector)
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1/2 to 1 day depending on the level and number of participants
Mode of training	Face-to-face or distance learning (preferred)
Prerequisites	CTMS installation (fat client) PDF Creator
Supporting documents	CW-056-USM- CTMS Installation Guide CW-061-USM- IMP Management Guide



CW-162-USM - General Administration



22.3 CTMS (Administrative)

Title of the course	CleanWEB CTMS: Administration
Objective of the training	To provide the basics of using CleanWEB CTMS to set up a study and its users
Knowledge / skills	 Overall knowledge of the platform Setting the options for a study Creation of centres and users Management of general directories (institutions and stakeholders) Creation and setting of functions and user profiles Management of the directory of a study Sending access codes
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of CleanWEB CTMS: ARC, Project Manager, Administrator
Content of the course	 Overview of the CleanWEB solution Authentication Study management : Creation or cloning of a study Parameters of a study Generation of monitoring curves Language management Authorisation to start production Study status management Archiving a study General directory : Directory of institutions Setting up an establishment, a service Directory of stakeholders Create a stakeholder Management of functions and profiles Administrator profiles Study directory : Centre management Stakeholder management Entitlements Import/export of centres and/or providers Import/export of stakeholders Sending access codes Sending emails
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	¹ / ₂ to or 1 day depending on the level and number of participants
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser



Supporting documents	CW-227-USM - CTMS Guide Education Management
	CW-060-USM- Summary of Rights Guide
	CW-228-USM-EN CTMS Guide User Profiles and Functions
	CW-130-USM - CTMS Administration Guide



Title of the course	CleanWEB CTMS : General administration
Objective of the training	To provide the basics of using CleanWEB General administration
Knowledge / skills	 Overall knowledge of the platform Knowledge of the ancillary functions of an administrator Knowledge and use of general administration functions
Public concerned	Any person with knowledge or experience of CleanWEB who wishes to acquire or consolidate practical knowledge of the use of CleanWEB General administration of studies: Project manager, administrator
Content of the course	 Overview of the CleanWEB solution Access rights and authentication Additional management on randomisation Import of a randomisation list complement Generation of a randomisation list Complementary management of IMPs Import of a IMP list complement Cancelling a IMP draw Assigning a IMP Moving a IMP Patient number management Changing the patient number Changing the sequence counter Locks Patient lock on Connector Locking a study on Designer Lock on a user account Audit trail Type of service Advanced functions : Group management Customisation
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 to 2 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-162-USM - General Administration CW-227-USM - CTMS Guide Education Management



Title of the course	CleanWEB CTMS : eTMF
Objective of the training	Provide the basics of using CleanWEB CTMS to set up and use an eTMF
Knowledge / skills	 Overall knowledge of the platform Login and access code management Activation of the eTMF Module Implementation of an eTMF repository Study-specific settings Knowledge of document properties Document management Uses of the eTMF functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of CleanWEB eTMF: ARC, Project Manager, Administrator
Content of the course	 Overview of the CleanWEB solution Authentication Setting up : Activation of eTMF Access rights TMF Reference Model and repository management Cross-cutting documents Creation of a list specific to the trial Study directory Document management : Tabs: Documents and Types Calculation of the documents to be collected Dovnloading a document Validation of a document Version management Use of filters Follow-up of the study documents
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Remote or WEBINAR 2H
Prerequisites	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-162-USM-EN General Administration CW-229-USM-EN eTMF Guide



Title of the course	CleanWEB CTMS : Financial follow-up (to come)
Objective of the training	Provide the basics of using CleanWEB CTMS to set up the monitoring of fees and/or hospital surcharges
Knowledge / skills	 Overall knowledge of the platform Setting up costs Fee management Management of additional costs Uses of the different monitoring tables
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of CleanWEB CTMS in the context of financial monitoring: CRAs, project managers, administrators
Content of the course	 Overview of the CleanWEB solution Access rights and authentication Setting up costs Fee tracking tables Document tracking Monitoring of fees Setting of additional costs Monitoring table for additional costs Document tracking
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 2H
Prerequisites	Access to a web browser
Supporting documents	CW-233-USM-EN Financial Management Guide



22.4 CleanWEB WEB Users

Several CleanWEB WEB software courses are available depending on the audience.

Title of the course	CleanWEB WEB : Users (Investigator and ARC)
Objective of the training	Provide the basis for using CleanWEB WEB (eCRF online) for data entry, validation and monitoring
Knowledge / skills	 Login and access code management Knowledge of the interface and use of the different menus Patient creation, inclusion and randomisation Data capture and recording of all types of data Signature of data Query management Knowledge of the functions Investigator Use of advanced functions Data validation
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of an eCRF CleanWEB WEB: Investigator, CTA, CRA, Project Manager
Content of the course	Investigator : - Authentication - Preferences - Main menu functions - Creating a patient - Navigating the eCRF - Data entry (different types including tables) - Data recording - Checking the data - Contextual menu and help - Reports - Include/Randomise
	 Signature Responding to Queries or DRCs Advanced functions :
	 Instantiated modules or forms Drawing of IMP Merger documents Audit trail Post-it Printing of eCRFs Planning Accessible services (Information, contacts, FAQ) Dashboards and queries Lifting of blindness Duplicates Transfer of patients Use of locks Deleting an eCRF
	ARC : - Validation (ARC) - Adding Queries or DRC



Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser
Supporting documents	CW-063-USM- WEB Investigator Guide
	CW-065-USM- eCRF WEB Monitor Guide
	CW-059-USM- Competitor Access Guide
	CW-051-USM- Investigator Signature Guide
	CW-074-USM- Use of Access Codes
	CW-098-USM- Patient Removal Notice
	CW-099-USM - User Planning Guide
	CW-050-USM- Information Service Edition
	CW-052-USM- Duplicate Detection Guide
	CW-049-USM-Guide Patient Transfer and Sharing

Title of the course	CleanWEB WEB : Investigator or TEC
Objective of the training	Provide the basis for using CleanWEB WEB (eCRF online) for data entry
Knowledge / skills	 Login and access code management Knowledge of the interface and use of the different menus Patient creation, inclusion and randomisation Data capture and recording of all types of data Signature of data Query management Knowledge of the functions Investigator Use of advanced functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of an eCRF CleanWEB WEB: Investigator, CTA, CRA, Project Manager
Content of the course	 Authentication Preferences Main menu functions Creating a patient Navigating the eCRF Data entry (different types including tables) Data recording Checking the data Contextual menu and help Reports Include/Randomise Signature Responding to Queries or DRCs
	Advanced functions :



	 Instantiated modules or forms Drawing of IMP Merger documents Audit trail Post-it Printing of eCRFs Planning Accessible services (Information, contacts, FAQ) Dashboards and queries Lifting of blindness Duplicates Transfer of patients Use of locks Deleting an eCRF
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser
Supporting documents	CW-063-USM- WEB Investigator Guide CW-059-USM- Competitor Access Guide CW-051-USM- Investigator Signature Guide CW-074-USM- Use of Access Codes CW-098-USM- Patient Removal Notice CW-099-USM - User Planning Guide

Title of the course	CleanWEB WEB : ARC or Project Manager
Objective of the training	Provide the basis for using CleanWEB WEB (eCRF online) for validation and monitoring of data entry
Knowledge / skills	 Login and access code management Knowledge of the interface and use of the different menus Knowledge of the functions Investigator Data validation Query management Use of advanced functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of an eCRF CleanWEB WEB: ARC, Project Manager



Content of the course	 Authentication Preferences Main menu functions Navigating the eCRF Data recording Checking the data Contextual menu and help Reports Validation Adding Queries or DRC Investigator functions (creation, registration, signature)
	Advanced functions : - Instantiated modules or forms - Merger documents - Audit trail - Post-it - Printing of eCRFs - Planning - Accessible services (Information, contacts, FAQ) - Dashboards and queries - Duplicates - Transfer of patients - Use of locks - Deleting an eCRF
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser
Supporting documents	CW-065-USM- eCRF WEB Monitor Guide CW-059-USM- Competitor Access Guide CW-074-USM- Use of Access Codes CW-099-USM - User Planning Guide CW-050-USM- Information Service Edition CW-049-USM-Guide Patient Transfer and Sharing



22.5 CTMS (Monitoring and rSDV)

Title of the course	CleanWEB CTMS : Monitoring
Objective of the training	To provide the basics of using CleanWEB CTMS in order to set up the monitoring tools
Knowledge / skills	 Activation and general settings Setting up the schedule Setting up the monitoring control repository Setting up monitoring visit reports Adaptation of the benchmark to a study Use of ARC-specific functions Use of dashboards Management of a monitoring visit
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the implementation and use of the CleanWEB Monitoring Module: Administrator, Project Manager, ARC
Content of the course	Settings - Activation of planning and monitoring - Access rights - Monitoring tables and curves - Patient status - Patient visit schedule - Monitoring and deviation repository - Monitoring controls according to type of visit - Standard reports - Monitoring on the eCRF (on site or remote monitoring) - Verifier / Validation / Queries / Alerts / Global Report - Progress curves - Planning - Scorecards - Monitoring visit - Preparation of the visit : - Preparation of the visit : - Preparation of the visit : - Patient follow-up - Monitoring Visit - Telephone contacts - Scheduling a monitoring visit report (active PDF) - Follow-up of deviations/actions Advanced functions : - - rSDV and CWMeet - Monitoring of a study not coupled to a CleanWEB eCRF
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 to 5 hours depending on the level and number of participants
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H



Prerequisites	Cleanweb Designer installed Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-227-USM - CTMS Guide Education Management CW-162-USM - General Administration CW-130-USM - CTMS Administration Guide CW-169-USM - CTMS Monitoring Guide CW-122-USM-EN Planning Designer Guide CW-097-USM- DESIGNER 2 advanced functions CW-065-USM- eCRF WEB Monitor Guide CW-099-USM - User Planning Guide

Title of the course	CleanWEB CTMS : Monitoring : Settings
Objective of the training	To provide the basics of using CleanWEB CTMS in order to set up the monitoring tools
Knowledge / skills	 Activation and general settings Setting up the schedule Setting up the monitoring control repository Setting up monitoring visit reports Adaptation of the benchmark to a study
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the implementation of the CleanWEB Monitoring Module: Administrator, Project Manager
Content of the course	 Activation of planning and monitoring Access rights Monitoring tables and curves Patient status Patient visit schedule Monitoring and deviation repository Monitoring checks according to type of visit Standard reports Monitoring plan Advanced functions : Monitoring of a study not coupled to a CleanWEB eCRF
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 to 3 hours depending on the level and number of participants
Mode of training	Remote or WEBINAR 2H
Prerequisites	Cleanweb Designer installed Access to a web browser



Supporting documents	CW-227-USM - CTMS Guide Education Management
	CW-162-USM - General Administration
	CW-130-USM - CTMS Administration Guide
	CW-169-USM - CTMS Monitoring Guide
	CW-122-USM-EN Planning Designer Guide
	CW-097-USM- DESIGNER 2 advanced functions

Title of the course	CleanWEB CTMS : Monitoring : User
Objective of the training	To provide the basis for the use of CleanWEB CTMS for patient follow-up and monitoring
Knowledge / skills	 Use of ARC-specific functions Use of dashboards Management of a monitoring visit
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of the CleanWEB monitoring module: ARC, Project Manager
Content of the course	Monitoring on the eCRF (on site or remote monitoring) - Verifier / Validation / Queries / Reports / Global Report - Progress curves - Planning - Scorecards
	Monitoring visit - Preparation of the visit : o Patient follow-up o Monitoring Plan/Advancement - Telephone contacts - Scheduling a monitoring visit - Drafting of a monitoring visit report (active PDF) - Monitoring of deviations/actions
	Advanced functions rSDV and CWMeet Monitoring of a study not coupled to a CleanWEB eCRF
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 to 3 hours depending on the level and number of participants
Mode of training	Remote or WEBINAR 3H
Prerequisites	Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-065-USM- eCRF WEB Monitor Guide CW-169-USM - CTMS Monitoring Guide CW-099-USM - User Planning Guide



22.6 CDMS (Data Management)

Title of the course	CleanWEB WEB : Data Management
Objective of the training	Provide the basics of using CleanWEB WEB for Data Management
Knowledge / skills	 Using the CDISC mode Using the Medical Coding Module Use of functions related to data management queries Use of the dashboards and the general report
Public concerned	Anyone wishing to acquire or consolidate practical knowledge of the use of CleanWEB WEB in a Data Management context: Data manager, statistician
Content of the course	Use of CDISC standards (CDASH, ODM) - Associated rights - Naming CDASH - Export ODM - Import ODM Medical coding (MedDRA, ICD10, WHODrug, ATCCode) - Associated rights - Dictionary format - Loading dictionaries - Setting the variables to be coded - Automatic/manual coding - Coding validation - Export Automatic queries - Associated rights - Generation of alerts and messages - Setting up automatic queries - Validation - Status and filters - PDF printing Scorecards and Global Report
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	4 to 5 hours depending on the level and number of participants and the Module chosen
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-067-USM- DESIGNER 1 basic functions CW-097-USM- DESIGNER 2 advanced functions



CW-124-USM- Medical Coding User Guide
CW-123-USM- Automatic Queries and Data Management Guide

Title of the course	CleanWEB WEB : Data extraction
Objective of the training	Provide the basis for using CleanWEB WEB (eCRF online) for data extraction
Knowledge / skills	 Login and access code management Knowledge of the options available Setting up export tables Understanding the format of the data and the files generated Archiving of eCRFs
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of an eCRF CleanWEB WEB: Data Manager, Statistician, Project Manager
Content of the course	 Authentication Preferences Associated rights and access conditions Extraction models Scope of extraction Data format Table configuration Options (audit trail, coding) Test archive Extraction history Generated files Extraction ODM PDF Archive Customised extraction
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 to 3 hours depending on the level and number of participants
Mode of training	Remote or WEBINAR 2H
Prerequisites	Access to a web browser Software to decompress .zip files Acrobat Reader V10 or higher
Supporting documents	CW-057-USM- Extraction Guide (WEB)



Title of the course	CleanWEB WEB : Import module
Objective of the training	Provide the basis for using CleanWEB WEB (eCRF online) to import data
Knowledge / skills	 Knowledge of the operating principle of the Import Module Associated rights Knowledge of expected formats Creating the import file Understanding the import options Understanding import errors Concept of ODM import
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of the CleanWEB Import Module: Data Manager, Project Manager
Content of the course	 General principle of patient import Access rights Extraction templates and export options to be respected Expected files and data format Data Mapping Constitution of the import file Importing the data file Setting import options Case of an import on an investigator Case of an import on a list of investigators Checking the data Error report Launching the import
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 to 4 hours depending on the level and number of participants
Mode of training	Face-to-face or remote (preferred) or WEBINAR 3H
Prerequisites	Access to a web browser Software for compressing/decompressing files in zip format Installation of LibreOffice software recommended
Supporting documents	CW-057-USM- Extraction Guide (WEB) CW-092-USM-EN Data import CW-190-USM-EN CDISC-ODM Import Export Module



Title of the course	CleanWEB Double Data Entry : Designer
Objective of the training	To provide the basics of using the CleanWEB Double Entry Module Designer
Knowledge / skills	 Installation of the CTMS thick client Login and access code management Knowledge of the principles of double entry Setting up the study in Double entry Design options for the input mask Understanding the functions of the double entry designer
Public concerned	Anyone wishing to acquire or consolidate practical knowledge of the use of the CleanWEB Double Data Entry Module designer: Data Manager, Project Manager
Content of the course	 Installation of the CleanWEB software Double entry Authentication General principle Creation of a study Access rights Fictitious or nonfictitious investigator Patient reference How to enter MCQs Category of CRF Design of input screens with or without templates Variables Layout Use of the models Designer functions
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 to 4 hours depending on the level and number of participants
Mode of training	Face-to-face or remote or WEBINAR 3H
Prerequisites	Installation of CleanWEB CTMS software (fat client)
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-130-USM-EN CTMS Administration Guide CW-228-USM-EN CTMS Guide User Profiles and Functions CW-060-USM-EN Summary of Rights Guide CW-056-USM-EN CTMS Installation Guide CW-094-USM-EN Designer Double entry



Title of the course	CleanWEB Double Data Entry: Database Acquisition
Objective of the training	To provide the basics of using the CleanWEB Double Entry Module
Knowledge / skills	 Installation of the CTMS thick client Login and access code management Knowledge of the principles of double entry CRF tracking management Data entry Confrontation of seizures Understanding the functions of the Double Entry Module Extraction of the database
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of the CleanWEB Double Data Entry Module: Data Manager, Data Entry Operator
Content of the course	 Installation of the CleanWEB software Double entry Authentication General principle Access rights Tracking table Enrolling an eCRF Entry 1 Input 2 Review of flags Review of differences Reopening of the entry Extraction Audit trail
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 to 4 hours depending on the level and number of participants
Mode of training	Face-to-face or remote or WEBINAR 3H
Prerequisites	Installation of CleanWEB CTMS software (fat client)
Supporting documents	CW-056-USM-EN CTMS Installation Guide CW-093-USM-EN Double entry



22.7 CleanWEB ePRO

Title of the course	CleanWEB ePRO
Objective of the training	To provide the basics of using CleanWEB ePRO for setting up and monitoring patient self-assessments
Knowledge / skills	 Knowledge of the ePRO operating principle Setting up the self-questionnaires Setting up the schedule and alerts Knowledge of ancillary settings Using the functions of the Planning tab Contact data management Data entry Monitoring the status of a self-questionnaire Pin code and alert management Data entry on behalf of the patient
Public concerned	Anyone with knowledge or experience of CleanWEB who wants to acquire or consolidate practical knowledge of CleanWEB in order to design and monitor ePROs: Data manager, ARC, Project manager
Content of the course	 ePRO principles Personal data Design: Study settings Setting up the self-questionnaires Constraints Access to the questionnaires Language management Planning law Setting up the patient schedule Setting up alerts Stopping condition Activation mail Recalculation of the calendar Customisation User: Planning board functions (status, details) Contact information (import) Patient account activation and validation Data entry from the web Data entry from a smartphone Filling monitoring Stop sending alerts Refusal of entry Filling by other users (associated rights)
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 to 4 hours depending on the level and number of participants
Mode of training	Face-to-face or remote (preferred) or WEBINAR 3H



Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-067-USM- DESIGNER 1 basic functions CW-122-USM-EN Planning Designer Guide CW-183-USM - ePRO Designer Guide CW-099-USM - User Planning Guide CW-107-USM - ePRO User Guide CW-162-USM - General Administration

Title of the course	CleanWEB ePRO : Design
Objective of the training	To provide the basics of using CleanWEB ePRO for setting up patient self- questionnaires
Knowledge / skills	 Knowledge of the ePRO operating principle Setting up the self-questionnaires Setting up the schedule and alerts Knowledge of ancillary settings
Public concerned	Anyone with knowledge or experience of CleanWEB Designer who wishes to acquire or consolidate practical knowledge of CleanWEB Designer in order to design ePROs: Data manager, ARC, Project manager
Content of the course	 ePRO principles Personal data Study settings Setting up the self-questionnaires Constraints Access to the questionnaires Language management Planning law Setting up the patient schedule Setting up alerts Stopping condition Activation mail Recalculation of the calendar Customisation
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 to 3 hours depending on the level and number of participants
Mode of training	Remote or WEBINAR 2H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory


	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Guide Study Management
	CW-067-USM- DESIGNER 1 basic functions
	CW-122-USM-EN Planning Designer Guide
	CW-183-USM - ePRO Designer Guide
	CW-162-USM - General Administration

Title of the course	CleanWEB ePRO : User
Objective of the training	To provide the basis for using CleanWEB ePRO to monitor the completion of patient self-assessments
Knowledge / skills	 Knowledge of the ePRO operating principle Using the functions of the Planning tab Contact data management Data entry Monitoring the status of a self-questionnaire Pin code and alert management Data entry on behalf of the patient
Public concerned	Any person wishing to acquire practical knowledge of CleanWEB ePRO: Investigator, CTA, CRA, Project Manager
Content of the course	 ePRO principles Planning board functions (status, details) Contact information (import) Patient account activation and validation Patient's language Data entry from the web Data entry from a smartphone Filling monitoring Pin code forwarding Stop sending alerts Refusal of entry Filling by other users (associated rights)
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 hour
Mode of training	Remote or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-099-USM - User Planning Guide CW-107-USM - ePRO User Guide



22.8 Expert Module

Title of the course	CleanWEB Expert Module
Objective of the training	To provide the basics of using CleanWEB Designer to set up the Expertise Module and monitor the expertise
Knowledge / skills	 Knowledge of the operating principles of the Expertise Module Activation of the expertise service Setting up the expertise form Knowledge of the different roles and associated rights Generation of a batch Seizure by an expert Treatment of a consensus by the moderator Use of the data
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and wishing to acquire or consolidate practical knowledge of CleanWEB in order to design and use an Expertise Module: Data manager, ARC, Project manager
Content of the course	 Principles related to the Expertise Module Access rights
	Design : - Activation of the expertise service - Functions of the expert module - Setting up the expertise form - Variables subject to expertise - Patient expertise - Event expertise
	User :-Definition of roles: Moderator and Expert-Batch generation-Referring to an expert-Modifying an expertise-Dealing with a consensus-Statistics-Data export
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 2H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Access to a web browser
Supporting documents	CW-060-USM- Summary of Rights Guide CW-067-USM- DESIGNER 1 basic functions CW-172-USM - Expert Designer Module Guide



CW-176-USM - Expert User Module Guide

Title of the course	CleanWEB Expert Module : Design
Objective of the training	To provide the basics of using CleanWEB Designer to set up the Expertise Module
Knowledge / skills	 Knowledge of the operating principles of the Expertise Module Activation of the expertise service Setting up the expertise form
Public concerned	Anyone with knowledge or experience of CleanWEB Designer who wishes to acquire or consolidate practical knowledge of CleanWEB Designer in order to design an Expertise Module: Data manager, ARC, Project manager
Content of the course	 Principles related to the Expertise Module Access rights Activation of the expertise service Functions of the Expert Module Setting up the expertise form Variables subject to expertise Patient expertise Event expertise
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 hour
Mode of training	Remote or WEBINAR 1H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-060-USM- Summary of Rights Guide CW-067-USM- DESIGNER 1 basic functions CW-172-USM - Expert Designer Module Guide



Title of the course	CleanWEB Expert Module : User
Objective of the training	To provide the basics of using the CleanWEB Expert Module for the follow- up of expert reports
Knowledge / skills	 Knowledge of the operating principles of the Expertise Module Knowledge of the different roles and associated rights Generation of a batch Seizure by an expert Treatment of a consensus by the moderator Use of the data
Public concerned	Any person wishing to acquire practical knowledge of CleanWEB Expert Module: Expert, Investigator, TEC, ARC, Project Manager
Content of the course	 Principles related to the Expertise Module Access rights Definition of roles: Moderator and Expert Batch generation Referring to an expert Modifying an expertise Dealing with a consensus Statistics Data export
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 hour
Mode of training	Remote or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-060-USM- Summary of Rights Guide CW-176-USM - Expert User Module Guide



22.9 Vigilance Module

Title of the course	CleanWEB Vigilance Module
Objective of the training	To provide the basics of using CleanWEB Designer to set up the Vigilance Module and monitor adverse events
Knowledge / skills	 Knowledge of the operating principles of the Vigilance Module Activation of the Vigilance Module Setting up the AR form Creation of an IE Notification of an AR Follow-up of an AR Using the AR Tracking Chart Managing an IA
Public concerned	Anyone with knowledge or experience of CleanWEB Designer who wishes to acquire or consolidate practical knowledge of CleanWEB in order to design and use the Vigilance Module: Data manager, ARC, Project manager
Content of the course	 Principles related to the Vigilance Module <u>Design</u>
	 Activation of the vigilance service Access rights Principles related to the Vigilance Module Activation of the vigilance service Access rights Setting up the AR form and reserved variables Setting up the print template with the tags Setting up the recipients' email addresses Notification options Use Access rights Concept of notification Creating an IA Notifying an AR Create a follow-up AR monitoring table AR details, alerts and history Printing the notification form Access to the eCRF form Vigilance registration number Export
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 to 3 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 2H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory



	Access to a web browser
Supporting documents	CW-060-USM- Summary of Rights Guide
	CW-227-USM - CTMS Guide Education Management
	CW-067-USM- DESIGNER 1 basic functions
	CW-348-USM - Vigilance Module Guide

Title of the course	CleanWEB Vigilance Module : Design
Objective of the training	To provide the basics of using CleanWEB Designer to set up the Vigilance Module
Knowledge / skills	 Knowledge of the operating principles of the Vigilance Module Activation of the Vigilance Module Setting up the AR form
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and wishing to acquire or consolidate practical knowledge of CleanWEB Designer in order to design a Vigilance Module: Data manager, CRA, Project manager
Content of the course	 Principles related to the Vigilance Module Activation of the vigilance service Access rights Setting up the AR form and reserved variables Setting the notification constraint Setting up the print template with the tags Setting up the recipients' email addresses Notification options
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 to 2 hours
Mode of training	Remote or WEBINAR 1H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Access to a web browser
Supporting documents	CW-060-USM- Summary of Rights Guide CW-227-USM - CTMS Guide Education Management CW-067-USM- DESIGNER 1 basic functions CW-348-USM - Vigilance Module Guide



Title of the course	CleanWEB Vigilance Module : User
Objective of the training	To provide the basics of using the CleanWEB Vigilance Module to monitor adverse events
Knowledge / skills	 Knowledge of the operating principles of the Vigilance Module Creation of an IE Notification of an AR Follow-up of an AR Using the AR Tracking Chart Managing an IA
Public concerned	Any person wishing to acquire practical knowledge of CleanWEB Vigilance Module: Investigator, CTA, CRA, Project Manager
Content of the course	 Principles related to the Vigilance Module Access rights Concept of notification Creating an IA Notifying an AR Create a follow-up AR monitoring table AR details, alerts and history Printing the notification form Access to the eCRF form Export
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 to 2 hours
Mode of training	Remote or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-348-USM - Vigilance Module Guide



22.10 Imaging Module

Title of the course	CleanWEB Imaging Module
Objective of the training	To provide the basics of using CleanWEB Designer to set up and use the Imaging Module
Knowledge / skills	 Knowledge of the operating principles of the Imaging Module Activation of the Imaging Module Setting up imaging variables Imaging variable options Understanding anonymisation Mastering the uploading of images Playback of images
Public concerned	Anyone with knowledge or experience of CleanWEB Designer who wishes to acquire or consolidate practical knowledge of CleanWEB in order to design and use the Imaging Module: Data manager, ARC, Project manager
Content of the course	- Principles related to the Imaging Module
	Design
	 Activating the File Storage service Setting a variable File
	 File category options; standard, DICOM and video
	 Naming strategy Using the SetFileName operator
	User
	- Notion of anonymisation of files
	- Uploading standard images
	 Actions on images Uploading a DICOM image
	- Actions on DICOM images
	 Uploading a video Actions on video images
	- DICOM viewers (Artiview, Weasis, PACS)
	- Playback of images
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Face-to-face or remote (preferred) or WEBINAR 2H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Guide Study Management
	CW-067-USM-EN DESIGNER 1 basic functions
	CW-340-USM-EN Medical imaging guide



Title of the course	CleanWEB Imaging Module : Design
Objective of the training	To provide the basics of using CleanWEB Designer to set up the Imaging Module
Knowledge / skills	 Knowledge of the operating principles of the Imaging Module Activation of the Imaging Module Setting up imaging variables Imaging variable options
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and wishing to acquire or consolidate practical knowledge of CleanWEB Designer in order to design an Imaging Module: Data manager, ARC, Project manager
Content of the course	 Principles related to the Imaging Module Activating the File Storage service Setting a variable File File category options; standard, DICOM and video Naming strategy Using the SetFileName operator
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 hour
Mode of training	Remote or WEBINAR 1H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-067-USM-EN DESIGNER 1 basic functions CW-340-USM-EN Medical imaging guide



Title of the course	CleanWEB Imaging Module : User
Objective of the training	To provide the basics of using CleanWEB to use the Imaging Module
Knowledge / skills	 Knowledge of the operating principles of the Imaging Module Understanding anonymisation Mastering the uploading of images Playback of images
Public concerned	Anyone with knowledge or experience of CleanWEB Designer who wishes to acquire or consolidate practical knowledge of CleanWEB in order to use the Imaging Module: Investigator, CRA, Project Manager
Content of the course	 Principles related to the Imaging Module Notion of anonymisation of files Uploading standard images Actions on images Uploading a DICOM image Actions on DICOM images Uploading a video Actions on video images DICOM viewers (Artiview, Weasis, PACS) Playback of images
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 hour
Mode of training	Remote or WEBINAR 1H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory Access to a web browser Activation of the imaging service on the server and the study
Supporting documents	CW-340-USM-EN Medical imaging guide



22.11 E-Consent

Title of the course	CleanWEB e-Consent (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	

Title of the course	CleanWEB e-Consent : Design (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge



Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	

Title of the course	CleanWEB e-Consent : User (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	



22.12 Online Thesaurus

Title of the course	CleanWEB Online Thesaurus (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	



22.13 Early access

Title of the course	CleanWEB Early Access (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	

Title of the course	CleanWEB Early Access : Designer (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge



Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	

Title of the course	CleanWEB Early Access: User (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Face-to-face or distance learning
Prerequisites	
Supporting documents	



22.14 API

Title of the course	CleanWEB API (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	



22.15 Shared agenda

Title of the course	CleanWEB Shared Agenda (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	



22.16 Sub-training modules

Title of the course	CleanWEB Designer : Layout
Objective of the training	Acquire the basics of form layout in an eCRF
Knowledge / skills	 Standard layout Mastery of the different layout methods Control of layout parameters Use of containers Setting up tabs and subforms Streamline the layout
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the CleanWEB Designer functionalities: ARC, Data Manager, Project Manager
Content of the course	 Layout of variables in a form Order of variables Layout parameters Indentation Alignment Weights and anchors Adding a variable Changing the position of a variable Multi-column layout Drag&drop method Use of containers Tabs and subforms Copy and paste Examples and tips
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1/2 to 1 day depending on the level and number of participants
Mode of training	Face-to-face or distance learning or WEBINAR 4H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM- DESIGNER 1 basic functions

Title of the course	CleanWEB Designer : Operators and constraints
Objective of the training	Acquire the basics of setting the constraints of an eCRF
Knowledge / skills	 How constraints work Operator knowledge Creating constraints Classic constraints (display, calculation, consistency check) Constraints related to an amendment Invalid constraints Using the preview functions



	- Use of standard functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the CleanWEB Designer functionalities: ARC, Data Manager, Project Manager
Content of the course	 How constraints work Operators Constraints Dynamic behaviour or display constraints Calculation constraints (BMI, score) Consistency check constraints Inclusion constraint Constraints related to an amendment Wrong constraints Using the console Patient test Copy and paste Examples and tips
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	1 to 2 days depending on the level and number of participants
Mode of training	Face-to-face or distance learning
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM- DESIGNER 1 basic functions CW-168-USM - DESIGNER 4 Operators

Title of the course	CleanWEB Designer : Libraries
Objective of the training	Acquire the basics of using libraries
Knowledge / skills	 Creation of a library Export and import of entities from a library Library management Library sharing
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the CleanWEB Designer functionalities: ARC, Data Manager, Project Manager
Content of the course	 Creation of a library Exporting entities to a library Importing entities from a library Management of libraries on the workstation Sharing and updating libraries Language management Examples and tips
Type of training action	Acquisition, maintenance or improvement of knowledge



Duration of the course	1 hour
Mode of training	WEBINAR 1H
Prerequisites	Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM- DESIGNER 1 basic functions

Title of the course	CleanWEB WEB : Planning
Objective of the training	Provide the basics of using CleanWEB WEB for setting up and using patient schedules and alerts
Knowledge / skills	 Knowledge of the principles of planning Setting up the planning Setting up theoretical visits Understanding and using the properties of visits Alert management Access to the schedule Knowledge of the different statutes Theoretical and actual dates Uses of the planning functions
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and WEB who wishes to acquire or consolidate practical knowledge of CleanWEB in order to design and use a patient schedule: Data manager, CRA, Project manager
Content of the course	Design - Planning principles - Activating the schedule - Access rights - Setting up a theoretical visit - Properties and types of visits - Classic configurations - Classic configurations - Configurations using the SetCalendarEvent operator - Setting up alerts linked or not to the schedule - Planning alert options and tags - How alerts work - Stopping condition - Recalculation of the calendar User - - Access to the schedule - Filters and sorting - Theoretical dates and deviations - Visit status - Visit details and alerts - Comments - Alert management - Export
Type of training action	Acquisition, maintenance or improvement of knowledge



Duration of the course	4 to 5 hours depending on the level and number of participants
Mode of training	Face-to-face or remote (preferred) or WEBINAR 4H
Prerequisites	Access to a web browser Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-067-USM-EN DESIGNER 1 basic functions CW-097-USM-EN DESIGNER 2 advanced functions CW-122-USM-EN Planning Designer Guide CW-099-USM-EN User Planning Guide CW-063-USM-EN WEB Investigator Guide CW-065-USM-EN eCRF WEB Monitor Guide

Title of the course	CleanWEB WEB : Planning and alerts : Design
Objective of the training	To provide the basics of using CleanWEB WEB to set up patient schedules and alerts
Knowledge / skills	 Knowledge of the principles of planning Setting up the planning Setting up theoretical visits Understanding and using the properties of visits Alert management
Public concerned	Anyone with knowledge or experience of CleanWEB Designer and WEB who wishes to acquire or consolidate practical knowledge of CleanWEB in order to design a patient schedule: Data manager, CRA, Project manager
Content of the course	 Planning principles Activating the schedule Access rights Setting up a theoretical visit Properties and types of visits Classic configurations Configurations using the SetCalendarEvent operator Setting up alerts linked or not to the schedule Options and tags for planning alerts How alerts work Stopping condition Recalculation of the calendar
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 hours
Mode of training	Face-to-face or remote or WEBINAR 3H



Prerequisites	Access to a web browser Installation of the Cleanweb Designer software with administrator rights on the directory
Supporting documents	CW-227-USM-EN CTMS Guide Study Management CW-067-USM-EN DESIGNER 1 basic functions CW-097-USM-EN DESIGNER 2 advanced functions CW-122-USM-EN Planning Designer Guide

Title of the course	CleanWEB WEB : Planning : User
Objective of the training	Provide the basics of using CleanWEB WEB for patient scheduling and alerts
Knowledge / skills	 Knowledge of the principles of planning Access to the schedule Knowledge of the different statutes Theoretical and actual dates Alert management Uses of the planning functions
Public concerned	Anyone with knowledge or experience of CleanWEB WEB who wishes to acquire or consolidate practical knowledge of patient planning: Data manager, CRA, Project manager
Content of the course	 Planning principles Access to the schedule Filters and sorting Theoretical dates and deviations Visit status Visit details and alerts Comments Alert management Export
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	2 hours
Mode of training	Remote or WEBINAR 2H
Prerequisites	Access to a web browser
Supporting documents	CW-099-USM-EN User Planning Guide CW-063-USM-EN WEB Investigator Guide CW-065-USM-EN eCRF WEB Monitor Guide



Title of the course	CleanWEB WEB : Dashboards and queries (under construction)
Objective of the training	
Knowledge / skills	
Public concerned	
Content of the course	
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	
Mode of training	
Prerequisites	
Supporting documents	



22.17 CleanWEB Connector (eCRF offline)

Several training courses for the CleanWEB Connector software are available depending on the audience.

The offline version (Connector) of CleanWEB is no longer supported

Title of the course	CleanWEB Connector : Investigator or TEC
Objective of the training	Learn the basics of using CleanWEB Connector (eCRF offline) for data entry
Knowledge / skills	 Installing the Connector and understanding how it works Logging in and managing your access codes Knowledge of the interface and use of the different menus Patient creation, inclusion and randomisation Data capture and recording of all types of data Signing data and responding to queries Use of advanced functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of a CleanWEB Connector eCRF: Investigator, CTA, CRA, Project Manager
Content of the course	 Installing the CleanWEB Connector software Authentication Preferences Main menu functions Creating a patient Navigating the eCRF Data entry (different types including tables) Checking the data Data recording Contextual menu and help Include/Randomise Synchronising and quitting the software Use of locks Queries or DRC Signature
	Advanced functions : - Email alerts - Sending emails - Instantiated modules or forms - Printing an eCRF - Deletion of a eCRF - Planning - Duplicates - Drawing of UTs and emergency UTs - Patient profiles - Merger documents - Generation of eCRF archives - Audit trail Using Offline Mode
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	¹ / ₂ to 1 day depending on the level and number of participants
Mode of training	Face-to-face or distance learning (preferred)



Prerequisites	Installing Cleanweb Connector
Supporting documents	CW-054-USM-EN Installation Guide Connector and Designer
	CW-070-USM-EN Investigator Guide Connector
	CW-071-USM-EN Managing the Planning Connector
	CW-068-USM-EN Note to exit by synchronising

Title of the course	CleanWEB Connector : ARC and Project Manager
Objective of the training	Provide the basis for using CleanWEB Connector (eCRF offline) for validation and monitoring of data entry
Knowledge / skills	 Installing the Connector and understanding how it works Logging in and managing your access codes Knowledge of the interface and use of the different menus Knowledge of the functions Investigator Data validation Creating queries Use of advanced functions
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of a CleanWEB Connector eCRF: ARC, Project Manager
Content of the course	 Installing the CleanWEB Connector software Authentication Preferences Main menu functions Navigating the eCRF Checking the data Contextual menu and help Synchronising and quitting the software Use of locks Queries or DRC Validation
	Advanced functions : - Email alerts - Sending emails - Instantiated modules or forms - Printing an eCRF - Deleting an eCRF - Multilingual management - Transfer of patients - Planning - Duplicates - Ratient profiles - Generation of eCRF archives - Audit trail - Using Offline Mode
Type of training action	Acquisition, maintenance or improvement of knowledge



Duration of the course	3 to 4 hours depending on the level and number of participants
Mode of training	Face-to-face or distance learning (preferred)
Prerequisites	Installing Cleanweb Connector
Supporting documents	CW-054-USM-EN Installation Guide Connector and Designer CW-072-USM-EN Guide ARC Connector CW-071-USM-EN Managing the Planning Connector CW-068-USM-EN Note to exit by synchronising

Title of the course	CleanWEB Connector : Data Extraction
Objective of the training	Acquire the basics of using CleanWEB Connector (eCRF offline) for data extraction
Knowledge / skills	 Installing the Connector and understanding how it works Logging in and managing your access codes Knowledge of the options available Setting up export tables Understanding the format of the data and the files generated
Public concerned	Any person wishing to acquire or consolidate practical knowledge of the use of an eCRF CleanWEB Connector: Data Manager, Statistician, Project Manager
Content of the course	 Installing the CleanWEB Connector software Authentication Preferences Main menu functions Synchronising and quitting the software Audit trail Export templates Configuration options Standard table configurations Custom table configurations Extraction and generated files Data format
Type of training action	Acquisition, maintenance or improvement of knowledge
Duration of the course	3 hours
Mode of training	Face-to-face or distance learning (preferred)
Prerequisites	Installing Cleanweb Connector
Supporting documents	CW-054-USM-EN Installation Guide Connector and Designer CW-058-USM - Guide Extraction Connector



23 - Glossary

ARC	Clinical Research Assistant
eCRF	electronic Case Report Form
ePRO	electronic Patient Report Outcome
FAQ	Frequently Asked Questions
IWRS	Interactive Web Randomization System
TEC	Clinical Study Technician
UT	Therapeutic Unit (investigational drug)
TMF	Trial Master File