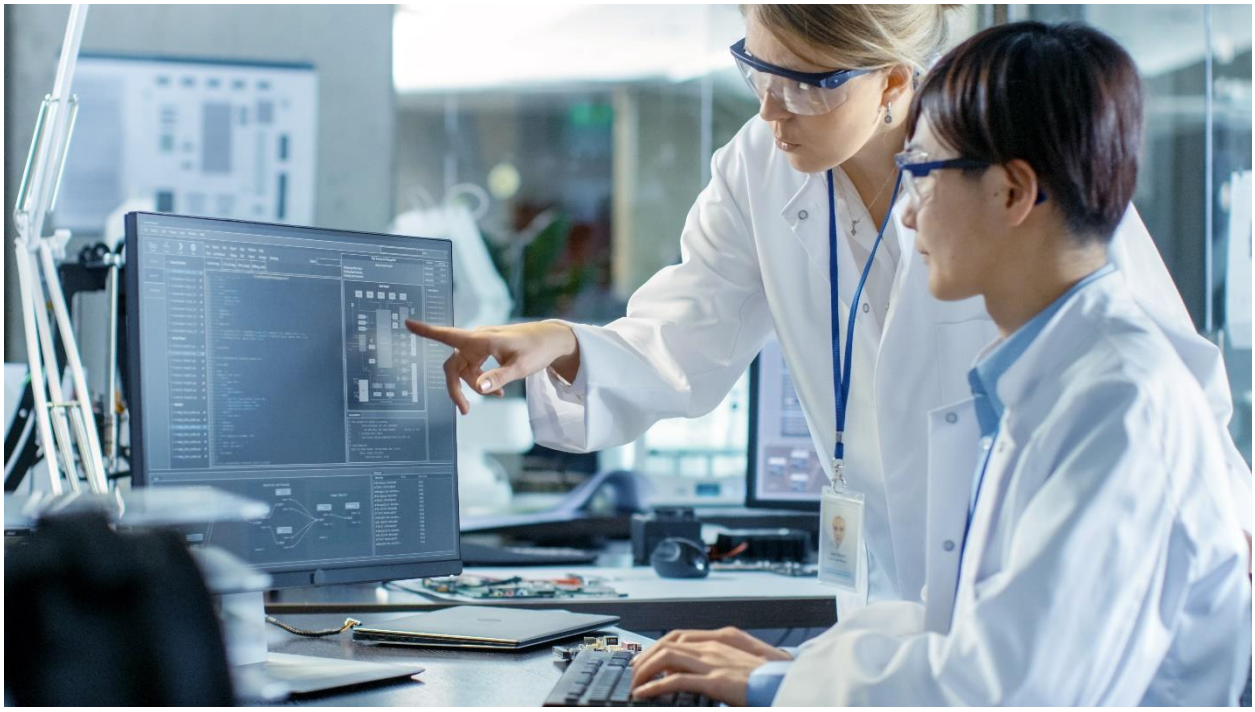

Training programme and procedures CleanWeb solution

Reference	*SUP-108-COM-EN*
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1 - Object

Telemedicine Technologies (TTSA) has an obligation to provide its customers with training in its software in accordance with the following principles: to enable them to adapt to their workstation and to ensure that their ability to hold a job is maintained, particularly with regard to changes in jobs, technologies and organisations. The training courses must be uniform and adapted to the trainees, including, within the limits of reasonable accommodation, people with disabilities or health problems. Trainees must be able to provide proof of the training they have received.

This document summarises the training programmes and in particular the various modules of the CleanWeb solution, as well as the terms and conditions under which TTSA provides these services.

Telemedicine Technologies' activity as a training organisation is registered under number 11 92 19676 92. This registration does not constitute 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 French Labour Code, internal regulations applicable to participants have been drawn up.

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

3 - Rates

By way of indication, the price is €1,800.00 excluding VAT per day of in-company face-to-face or distance learning training.

Pricing for the WEBINAR or the e-Learning platform is based on:

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

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

4 - Training access times

A minimum of one week is required to organise the training.
The scheduling of training courses depends on the number of days to be scheduled, the agendas of each participant and therefore their number, and in the case of face-to-face training, the availability of the training room. This lead time can therefore extend to 1 or even 2 months.

5 - Types and duration of sessions

Two types of session are available:

- individual session
- group session: minimum 4 to 5 people; limited to a maximum of 12 people for face-to-face sessions; no maximum number of people for remote sessions except for CleanWeb Designer training (maximum 12 people)

Note: some user modules, for example, can accept more than 12 people (although this excludes any manipulation of the software).

Session duration:
varies according to the course: from 1 hour to 4 hours, and/or 1, 2 or even 4 days.

6 - Group session formats

Two formats for group sessions:

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

In the case of inter-company training, courses can be organised remotely or via a WEBINAR platform including a self-registration system and, where applicable, an online payment system (see § WEBINAR platform).

7 - Training venue

Face-to-face training:

The training courses take place face-to-face at the customer's designated premises or at Telemedicine Technologies' premises.

In the event that training courses take place on premises unknown to Telemedicine Technologies, the Trainer ensures that the premises are accessible and suitable for everyone and that the necessary training resources are made available (video projector, PC, installed software, etc.).

The venue for in-company training courses is decided in agreement with the customer.

The venue for inter-company training courses is decided by TTSA.

In the case of group training, if the number of people enrolled is less than 4. Telemedicine Technologies reserves the right to cancel the course.

Distance learning or WEBINAR:

Training courses can also be conducted remotely, particularly if they last less than half a day. The contact details for the meeting are sent in advance of the course, 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, etc.) depending on the accessibility of the software for the participants.

If the number of people registered is less than 5. Telemedicine Technologies reserves the right to cancel the WEBINAR.

E-learning training:

The courses can be taken autonomously by participants using the RiseUp e-learning platform offered by TTSA. Self-registration following receipt of an e-mail proposing the various possible training courses and containing the links inherent in registration, followed by validation, are necessary before participants receive their access codes for the e-learning platform.

The training venues depend in part on the type, format and duration of the session.

8 - WEBINAR platform

This platform makes it possible to plan and carry out inter-company distance learning courses.

This platform uses a number of linked software packages to enable participants to self-register and pay online.

Pricing is based on:

- or a cost-per-token system (1 token = 1 hour/participant) in the case of a contract for the purchase of a batch of tokens. A token count is carried out 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 involves the following process:

1. The dates and topics of training courses are set by TTSA.

2. Sending of several mailings informing customers of the themes of the training courses on offer and the corresponding scheduled dates (a reminder of the URL https://tentelemed.com/trainings/ where the information (SUP-108-COM-EN Training programme and procedures) and contacts can be found is included). Two separate types of email may be sent: one to employees of companies that have purchased a batch of tokens, and 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. Invitation e-mail containing webinar contact details, enabling potential participants to self-register and pay online (needs analysis questionnaires and training programmes or fact sheets are attached).
4. Registered persons may be validated
5. E-mail reminders of webinar contact details are programmed 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 specific features of this platform will be highlighted by a visual reminder: "WEBINAR:".

9 - e-Learning platform

This platform offers self-study distance learning courses.

This platform uses a number of linked software packages to enable participants to self-register and pay online.

Pricing is based on:

- or a cost-per-token system (1 token per training session; or even 2 depending on the length of the training session) in the case of a contract for the purchase of a batch of tokens. A token count is carried out for each participant.
- or a fixed cost per course. In this case, payment is made directly online. The invoice is available in the order confirmation email.

Setting up and running an e-learning course involves the following process:

1. A mailing informing the customers concerned by the solution of the training modules available on the e-Learning platform for this solution (a reminder of the URL https://tentelemed.com/trainings/ where the information can be found (SUP-108-COM-EN Training programme and procedures) and the contacts is included). Two distinct types of email are potentially sent out: one to referees designated by companies that have purchased a batch of tokens, and another to employees of companies that have not purchased a batch of tokens. In the latter case, the price of the training module is indicated. This mailing contains the registration links for each training module offered, enabling potential participants to self-register and, where applicable, pay online.
2. Once the registrations have been validated, an e-mail containing the access codes for the training module will be sent to the person who has registered.

> Customers who have ordered a batch of tokens may reserve the right to validate their employees' registrations. This validation takes the place of a needs assessment.

3. The participant logs on to the e-Learning platform and independently follows the course for which they have registered at a time of their choosing. The course can be completed in one or more sessions. The e-Learning platform can be used to track whether the course has been completed by the participant, replacing the attendance sheet.
4. A training module can be made up of several stages, each culminating in a quiz (which constitutes the learning assessment questionnaire) with a required percentage of correct answers. At the end of the session, a link is provided to the support documents (guides).
5. Hot and cold satisfaction questionnaires are sent automatically by e-mail.
6. A training certificate is automatically generated by the platform when learners complete the course, including all the stages. Learners receive the document by e-mail or download it at the end of the course .

In the following paragraphs, the specific features of this platform will be highlighted by a visual reminder: "e-Learning:".

10 -Training objectives

The objective of the training courses differs according to the modules to which they relate.

- In the case of modules requiring configuration (e.g. CleanWeb Designer), the aim of the training is to transfer knowledge so that the learner can independently build an eCRF and/or the inherent management environment.
- In the case of modules accessible to end users (CleanWeb WEB, Connector) such as investigators, CRAs or Study Nurses, the aim is to enable them to use the software's functions independently.

> This training can be given to intermediaries. The latter can introduce investigators or Study Nurses to the software when the study is set up 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 programme description sheets (Cf. § Programmes and description sheets).

11 -Teaching approach

The teaching 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 start of the course, in addition to the needs assessment questionnaire prior to the course, in order to check prerequisites, refine needs and, if necessary, adapt the training strategy/materials and put in place any adaptations for people with disabilities.
- 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 start of the course. New skills or knowledge are gradually built up, particularly for the more traditional or complex points, by moving from theory to practice on concrete cases where the learner is asked to look for solutions.
- The training is evaluated by means of a questionnaire to assess what has been learnt, which is also offered at the end of the course. In addition, in the case of knowledge transfer, assessment is carried out through practical application (creation of eCRF or other parameterisation). This assessment is made possible by the existence of a post-training parameter-setting aid available to the learner, who

can contact the hotline for parameter-setting assistance. The trainer can thus assess not only the acquisition of knowledge and skills, but also their development.

12 -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 formation-cleanweb@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.

The participant's surname, first name, e-mail address, company name and the name of the course they wish to follow are the minimum information required to be provided to TTSA.

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

WEBINAR: For inter-company training courses, the dates are planned by TTSA. Participants register directly via the link provided in the invitation e-mail and complete the needs analysis questionnaire. If there is no contract with the participant's company, the participant pays for the course via the online payment system (an invoice is generated and added as an attachment to the order confirmation email in this case).

e-Learning: In the case of e-learning courses, the participant self-registers directly from the link corresponding to the desired course provided in the information email sent regularly by TTSA. If there is no contract with the participant's company, the participant pays for the course via online payment (an invoice is generated and added as an attachment to the order confirmation email in this case).

The training course is subject to online payment (in the case of inter-company training via the WEBINAR platform or e-Learning training), the drawing up of a contract (in terms of the number of training days or batches of tokens), or a training agreement (article L 6353-2 of the French Labour Code) between the training provider and the purchaser of the training - a company, for example.

However, the purchase order may be used for one-off purchases of short or repetitive training courses as part of a flexible procedure for purchasing training courses. 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 has been provided.

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

If the number of participants is not too large, the Trainer or Digital Training Manager will create the participants' user accounts on the Hotline site (https://hotline.tentelemed.com) if they do not already have access to it, so that they can access the user guides corresponding to the training course.

PLEASE NOTE: All registrations for face-to-face or WEBINAR training courses are counted as attendance, unless cancelled at least 24 hours before the course date by sending an e-mail to formation-cleanweb@tentelemed.com.

13 -Needs analysis

The needs analysis is based on the requirements of the customer requesting training for its staff whose job requires the use of the software supplied by TTSA.

A needs assessment questionnaire is sent to participants prior to the course to determine whether the course is suitable. This questionnaire is used to assess the presence of prerequisites (relevant job, level of experience in clinical research or software), needs and expectations, and to identify any disabled persons requiring special arrangements.

If the number of participants allows, the needs analysis can be supplemented at the start of the course by a preliminary interview between the Trainer and each trainee to define the objectives and the points to be

covered or worked on in particular. During this interview, the Trainer also looks at the level of knowledge and experience acquired, in order to adapt the pace and support provided.

e-Learning: it is assumed that the needs analysis for these training methods has been carried out by the participant (or their employer validating their enrolment) as a result of their self-enrolment. The needs analysis questionnaire is not used in this case.

14 -Convocation

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

- The terms and conditions of the training course (date, times and venue, programme, objectives, terms and conditions, support documents, internal regulations and any technical prerequisites) and/or a reminder of the URL of the TTSA website where most of this information can be found.
- In the case of face-to-face training, the access map and, where applicable, the arrangements for people with disabilities or people with reduced mobility are added if these people were identified during the needs analysis (Cf. § Needs analysis).
- In the case of distance learning (including inter-company training via the WEBINAR platform), the invitation also contains the connection details.
- e-Learning: An e-mail, generated manually by the Digital Training Manager once the participant's registration has been validated, containing the access codes for the course available on the e-learning platform, is sent out as an invitation.

A map of the Telemedicine Technologies premises is available at the following URL:
https://tentelemed.com/offices/

The terms and conditions and internal rules are also available at the following URL:
https://tentelemed.com/trainings/

15 -Teaching and technical resources

Depending on the training venue, the teaching resources may vary in terms of equipment.

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

16 -Teaching methods

Our face-to-face and distance learning courses are predominantly participative and practical. The transfer of knowledge includes theoretical contributions (affirmative method) and is based on teaching situations close to the learner's own experience and practical case studies (demonstrative method). The concrete approach to the concepts studied enables the learner to transpose the concepts covered to their current or future real-life situation. The teaching 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 learners and employers, defined in the personalisation phase of access to training. As far as possible, examples and exercises are chosen from situations in the learner's own life.

TTSA has comprehensive guides to all the software's functions, which make up the majority of support documents. The guides corresponding to the training course 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 session. These support documents support the trainer's presentation and thus contribute to the rapid memorization of the key elements of the programme.

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 progressively more difficult.

The trainer alternates lectures with sequences of reflection (interrogative method) and guided exercises (active method) enabling participants to put their new knowledge into practice.

WEBINAR: Most of the training is demonstrative. Some time may be set aside for questions and answers.

e-Learning: The training is mainly demonstrative. However, learners can ask questions from the platform. The trainer will answer them.

17 -Assessment of learning by the trainer

At the end of the course, the trainer will give participants a questionnaire to assess what they have learnt.

This questionnaire sets out the objectives of the course and includes questions specific to the course attended, which the participant must answer so that the trainer can classify the acquisition of knowledge and/or skills in 3 categories: Not acquired, In the process of being acquired, Acquired.

e-Learning: Each training module is broken down into stages which are largely completed by quizzes based on the learning assessment questionnaire inherent in the training module. A percentage of correct answers of between 75 and 80% must be achieved by the learner before he or she can move on to the next stage or complete the course.

18 -Satisfaction questionnaires

A training satisfaction questionnaire is handed out (face-to-face training) or sent by e-mail at the end of the session to collect participants' comments anonymously.

An email containing a training satisfaction questionnaire or a link to it is sent out after a few months to gather anonymous feedback from participants.

WEBINAR: The satisfaction questionnaires (hot and cold) can be accessed via a link in the e-mail sent by the trainer.

e-Learning: Satisfaction questionnaires (hot and cold) can be accessed via a link in the e-mail sent automatically by the platform, according to deadlines set by the Digital Training Manager.

Questions relating to organisation and equipment (Q11, Q12 and Q13) have been removed from the on-the-spot satisfaction questionnaire so that it can be adapted to e-Learning training.

A score from 1 to 10 for overall satisfaction has been added to the hot and cold satisfaction questionnaires. These questionnaires are automatically sent to learners by e-mail.

A customer satisfaction questionnaire is submitted annually by the Training Centre Manager or Trainer to the employers of the people who have been trained during the year.

The Training Centre Manager analyses these questionnaires, draws up an annual report for management and implements measures to improve any areas requiring improvement.

The results for the year are updated once a year, at the beginning of the year, and can be accessed on the TTSA website (managed by the Marketing and Communications Manager) at the following URL: https://tentelemed.com/trainings/. These results concern the following items:

- Number of training certificates issued
- Number of training days completed

- Overall satisfaction rate of trainees

19 -Attendance sheet

An attendance sheet must be signed at the end of the course by each participant and by the trainer.

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

e-Learning: The list of registered participants who have taken a course is automatically managed by the e-learning platform, replacing the attendance sheet.

20 -Certificate of attendance

A certificate of attendance is provided to each participant at the end of the course by the Trainer or the Digital Training Manager if the participant has signed the attendance sheet and completed the post-training questionnaires.

This certificate identifies the participant(s), the trainer or the person in charge of the training centre, the title of the course and the dates, duration and location of the course.

e-Learning: A certificate of attendance, issued by the Digital Training Manager, is automatically e-mailed to the participant on completion of the course or can be downloaded by the participant at the end of the course.

21 -Accessibility and Disability Officer

The courses are accessible, within the limits of reasonable accommodation, to people with disabilities or health problems.

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

Mr Patrick BLANDIN

Email: pbl@tentelemed.com

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

22 -Claims

In the event of difficulties encountered by the participant or customer at any stage of the process: registration, during the course, after the course (practical application, etc.).

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

- By telephone or e-mail directly to the trainer and/or sales representative.
- Via a dedicated e-mail formation-cleanweb@tentelemed.com posted on the TTSA website (https://tentelemed.com/trainings/).
- By creating a ticket on the hotline site (https://hotline.tentelemed.com) dedicated to the software supplied by TTSA and choosing as the type of request "Training-related complaint" or any other type of request in the event of difficulty in putting the training course into practice.

Each request generates a ticket which is then processed until it is resolved (solution accepted by the person making the complaint). Communication can also take place at the same time as the complaint is being processed, by other means (e-mail, telephone contact, meeting).

23 -List of modules in the CleanWeb solution

The CleanWeb solution modules are as follows (non-exhaustive list):

- Designer
- WEB (eCRF online)
- CTMS (Administrative)
- CTMS (Monitoring)
- ePRO
- eTMF
- IWRS and IP management
- Data Management
- Double entry
- Medical coding
- Vigilance Module
- Imaging Module
- eConsent
- Expert appraisal or tender
- Early access
- Shared diary

This list may be updated as new versions are released.

24 -Programmes and fact sheets

24.1 CleanWeb Designer

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

Course title	**CleanWeb Designer: Basic functions**
Aim of the course	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 classic operators and the creation of constraints - Use of standard functions (libraries, copy-paste, etc.)
Target audience	Anyone wishing to acquire or consolidate practical knowledge of eCRF design using CleanWeb software: CRAs, Data Managers, Project Managers, etc.
Course content	- Overview of the CleanWeb solution - Installing the software - Global editing/configuration of a study - Online / history - Modules / Forms - Variables - Referencing - Page layout / tabs - Tables - How constraints work - Operators - Constraints - Inclusion constraint - Patient reference - Audit documents - Using libraries - Checker and Preview mode - Copy and paste - Methods, examples and tips
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 days depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory
Supporting documents	CW-054-USM-EN Designer and Connector installation CW-067-USM-EN DESIGNER 1 - Basic Functions CW-168-USM-EN DESIGNER 4 - Operators

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

Course title	**CleanWeb Designer: Advanced functions**
Aim of the course	Acquire the basics of parameterisation to enable advanced eCRF functions to be parameterised
Knowledge / skills	- Using advanced functions - Setting access by profile - Thesaurus management - Basic planning settings - Language settings - Template creation - E-mail and fax settings
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the CleanWeb Designer functions: CRAs, Data Managers, Project Managers, etc.
Course content	- CDISC mode - Multilingual management - Patient status - Access rights & profiles - Export/import - Managing an amendment - MCQ and Thesaurus filter - Planning and alerts - Sending faxes and e-mails - Merger documents - CRF cover page and print mask - Duplicate management - Editing services - Patient transfer CleanWeb Connector specific - Page mode - Statistics and progress reports - Dashboards - Planning - Duplicate management
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 or 2 days depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory Installation of LibreOffice/OpenOffice software recommended Knowledge of the basic functions of CleanWeb Designer

Supporting documents	CW-097-USM-EN DESIGNER 2 - Advanced functions CW-050-USM-EN Information service edition CW-052-USM-EN Duplicate Detection CW-122-USM-EN Planning and alerts Design CW-049-USM-EN Patients Transfer and Sharing

Course title	**CleanWeb Designer: Variable settings (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions

Course title	**CleanWeb Designer: Layout**
Aim of the course	Acquire the basics of eCRF form layout
Knowledge / skills	- Standard layout - Mastery of different page layout methods - Controlling layout parameters - Use of containers - Setting up tabs and sub-forms - Streamlining page layout
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the CleanWeb Designer functions: CRAs, Data Managers, Project Managers, etc.

Course content	- Layout of variables in a form - Order of variables - Layout parameters - Indentation - Alignment - Weight and anchor - Adding a variable - Changing the position of a variable - Multi-column page layout - Drag&drop method - Use of containers - Tabs and sub-forms - Copy and paste - Examples and tips
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	½ to 1 day depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions

Course title	**CleanWeb Designer: Operators and constraints**
Aim of the course	Acquire the basics of setting the constraints of an eCRF
Knowledge / skills	- How constraints work - Operator knowledge - Creating constraints - Standard constraints (display, calculation, consistency checks, etc.) - Constraints linked to an amendment - Invalid constraints - Using the preview functions - Use of standard functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the CleanWeb Designer functions: CRAs, Data Managers, Project Managers, etc.

Course content	- How constraints work - Operators - Constraints - Dynamic behaviour or display constraints - Calculation constraints (BMI, score, etc.) - Consistency check constraints - Inclusion constraint - Constraints linked to an amendment - Wrong constraints - Using the console - Patient test - Copy and paste - Examples and tips
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 to 2 days depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions CW-168-USM-EN DESIGNER 4 - Operators

Course title	**CleanWeb Designer: Libraries**
Aim of the course	Learn the basics of using libraries
Knowledge / skills	- Creating a library - Exporting and importing entities from a library - Library management - Library sharing
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the CleanWeb Designer functionalities: CRAs, Data Managers, Project Managers, etc.
Course content	- Creating a library - Exporting entities to a library - Importing entities from a library - Managing libraries on the workstation - Sharing and updating libraries - Language management - Examples and tips
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-learning, distance learning or WEBINAR 1H

Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions

24.2 CleanWeb IWRS and IP management

Course title	**CleanWeb IWRS and IP management: design**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer and CTMS to set the parameters for randomisation, IP management and IP resupply.
Knowledge / skills	- Principles of randomisation and IP management - Setting randomisation according to different options - Specific operators and creation of the constraints required for randomisation and allocation of IPs - Creation and implementation of randomisation and IP lists - Different statuses of an IP - Manual modification of IPs and their properties - IP stock management for automatic IP resupply - Setting up automatic resupply
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of how to use CleanWeb in the context of randomisation and IP management: Data manager, CRA, Project manager, etc.
Course content	- Principles associated with randomisation - Associated rights - Randomisation settings - Randomisation and IP lists - Algorithm for allocating an IP - Unblinding - Constraints (Rando + IP) - General monitoring of IPs - IP statutes - Expiry date - Manual changes to IPs - Resupply of IPs - Resupply fax settings - Pharmacy data management - Delivery time - IP stock management <u>Advanced functions:</u> - Randomisation by minimisation - Selection of IPs after randomisation - List of IPs independent of randomisation - Multiple randomisations - Multiple lists of IPs - Early drawdown of IP - Adding an IP / randomisation list - Emergency IP stock (Connector)
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 day
Training mode	Face-to-face or distance learning (preferable)

Prerequisites	Designer installation CTMS installation (fat client) PDF Creator
Supporting documents	CW-127-USM-EN DESIGNER 3 - Randomisation CW-056-USM-EN CTMS Installation CW-061-USM-EN IP Management CW-162-USM-EN General parameters and administration

Course title	**CleanWeb IWRS**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to set randomisation parameters
Knowledge / skills	- Principles of randomisation and IP management - Setting randomisation according to different options - Specific operators and creation of the constraints required for randomisation and allocation of IPs - Creation and implementation of randomisation and IP lists
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of how to use CleanWeb in the context of randomisation: Data manager, CRA, Project manager, etc.
Course content	- Principles associated with randomisation - Associated rights - Randomisation settings - Randomisation and IP lists - Algorithm for allocating an IP - Unblinding - Constraints (Rando + IP) <u>Advanced functions:</u> - Randomisation by minimisation - Selection of IPs after randomisation - List of IPs independent of randomisation - Multiple randomisations - Multiple lists of IPs - Early drawdown of IP - Addition of an IP / randomisation list - Emergency IP stock (Connector)
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 to 5 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Designer installation PDF Creator

Supporting documents	CW-127-USM-EN DESIGNER 3 - Randomisation CW-162-USM-EN General parameters and administration

Course title	**CleanWeb IP management**
Aim of the course	To provide the basis for using IP management and IP resupply
Knowledge / skills	- How the IP Management and Resupply Module works - Different statuses of an IP - Manual modification of IPs and their properties - Expiry management - IP stock management for automatic IP resupply - Setting up automatic resupply
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the use of CleanWeb CTMS in the context of IP management: pharmacists, CRAs, Project managers, etc.
Course content	- Principles associated with randomisation - Associated rights - IP lists - Algorithm for allocating an IP - General monitoring of IPs - IP statutes - Expiry date - Manual changes to IPs - Resupply of IPs - Resupply fax settings - Pharmacy data management - Delivery time - IP stock management <u>Advanced functions:</u> - Selection of IPs after randomisation - IP list independent of randomisation - Multiple lists of IPs - Early drawdown of IP - Addition of an IP list supplement - Emergency IP stock (Connector)
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	½ to 1 day depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	CTMS installation (fat client) PDF Creator
Supporting documents	CW-056-USM-EN CTMS Installation CW-061-USM-EN IP Management CW-162-USM-EN General parameters and administration

Course title	**CleanWeb Unblinding (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

24.3 CleanWeb CTMS: Administrative

Course title	**CleanWeb CTMS: Administration**
Aim of the course	Provide the basics of using CleanWeb CTMS to set up a study and its users
Knowledge / skills	- Overall knowledge of the platform - Knowledge of a director's duties - Setting study options - Creating centres and users - Management of general directories (establishment and participants) - Creation and configuration of functions and user profiles - Managing a study directory - Sending access codes
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb CTMS: CRA, Project Manager, Administrator, etc.
Course content	Overview of the CleanWeb solution Authentication Access rights <u>Study management:</u> - Creating or cloning a study - Study parameters and configuration - Generation of monitoring curves - Language management - Authorisation to start production - Study status management - Archiving a study <u>General directory:</u> - Organisations directory - Create an organisation or service - Participants directory - Create a participant <u>Rights, functions and profiles:</u> - Managing functions and profiles - Administrator profiles <u>Study directory:</u> - Centre management - Management of service providers - Participants management - Habilitations - Import/export of centres and/or service providers - Import/export of participants - Sending access codes - Sending emails
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	½ to or 1 day depending on level and number of participants

Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR
Prerequisites	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Study Management CW-060-USM-EN Access rights CW-228-USM-EN CTMS User Profiles and Functions CW-130-USM-EN CTMS Administration

Course title	**CleanWeb CTMS: Study management**
Aim of the course	To provide a basic understanding of how to use CleanWeb CTMS to set up and manage studies
Knowledge / skills	- General knowledge of study management - How to create or clone a study - Managing parameters - Managing add-on modules - Knowing how to manage the status of a study
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb CTMS for research management: Project Managers, Data Managers, Administrators, etc.
Course content	- Access rights - Creating a study - Study parameters - Generation of monitoring curves - Module configuration - Language management - Metadata - Cloning a study - Authorisation to start production - Study status management - Archiving a study
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Study Management CW-130-USM-EN CTMS Administration CW-162-USM-EN General parameters and administration

Course title	**CleanWeb CTMS: General directory (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

Course title	**CleanWeb CTMS: Rights, functions and user profiles (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-228-USM-EN CTMS User Profiles and Functions

Course title	**CleanWeb CTMS: Study directory**
Aim of the course	To provide the basis for using CleanWeb CTMS to manage study centres and users
Knowledge / skills	- General knowledge of a study directory - Adding or creating centres and service providers - Managing centres - Managing service providers - How to add a speaker - Knowing how to manage participants and authorisations - Know how to send emails to speakers
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb CTMS: CRAs, Project Managers, Data Managers, Administrators, etc.
Course content	- Directory services presentation - Access rights <u>Centre management</u> - Add/delete a centre - Add a service - Managing a centre's status - Export/Import of centres <u>Management of service providers</u> - Add/delete a service provider - Concept of roles and services - Service management - Export/import of service providers <u>Participants management</u> - Participants properties - Adding or attaching a participant - Export/Import of players - Modifications to a participant - Habilitations - Sending emails and access codes
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	E-Learning, distance learning or WEBINAR 2H
Prerequisites	Access to a web browser
Supporting documents	CW-130-USM-EN CTMS Administration

Course title	**CleanWeb CTMS: General parameters and administration**
Aim of the course	Providing the basics of using CleanWeb CTMS General parameters and administration
Knowledge / skills	- Overall knowledge of the platform - Knowledge of the ancillary functions of a director - Knowledge and use of general parameters and administration
Target audience	Anyone with knowledge or experience of CleanWeb wishing to acquire or consolidate practical knowledge of how to use CleanWeb general parameters and administration of studies: Project manager, Administrator, etc.

Course content	- Overview of the CleanWeb solution
	- Access rights and authentication
	- Complementary management of randomisation
	  ○ Importing an additional randomisation list
	  ○ Generating a randomisation list
	- Complementary IP management
	  ○ Importing an IP list complement
	  ○ Cancel an IP draw
	  ○ Allocate an IP
	  ○ Moving an IP
	- Patient number management
	  ○ Changing the patient number
	  ○ Changing the sequence counter
	- Locks
	  ○ Patient lock on Connector
	  ○ Designer study lock
	  ○ Locking a user account
	- Deleted patients
	- Audit trail
	- Type of service
	
	<u>Advanced functions:</u>
	
	- Metadata
	- Group management
	- Customisation
	- Users Notifications

Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 to 2 hours
Training mode	Face-to-face or distance learning (preferable) or 1H WEBINAR, (e-learning coming soon)
Prerequisites	Access to a web browser
Supporting documents	CW-162-USM-EN General parameters and administration CW-227-USM-EN CTMS Study Management

24.4 CleanWeb CTMS: eTMF

Course title	**CleanWeb CTMS: eTMF**
Aim of the course	Provide the basics of using CleanWeb CTMS to set up and use an eTMF
Knowledge / skills	- Overall knowledge of the platform - Logging in and managing access codes - Activation of the eTMF Module - Implementation of an eTMF repository - Study-specific settings - Knowledge of document properties - Document management - Use of eTMF functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb eTMF: CRAs, Project Managers, Administrators, etc.
Course content	- Authentication <u>Setting up:</u> - Activation of eTMF - Access rights - TMF Reference Model - References management: TMF, Global - Metadata - Study-specific list configuration - Workflow - Parameters <u>Document management:</u> - Access rights - Study directory - Calculating the documents to be collected - Tabs: Documents and Types - Using filters - Downloading a document - Document properties - Validating and/or signing a document - Version management - Adding/deleting a document - Follow-up of study documents - Access by user profile - Links - Audit trail - Export - Transversal documents
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	Distance learning or WEBINAR 2H
Prerequisites	Access to a web browser

Supporting documents	CW-227-USM-EN CTMS Study Management CW-162-USM-EN General parameters and administration CW-229-USM-EN eTMF

Course title	**CleanWeb CTMS: eTMF: Configuration**
Aim of the course	Provide the basics of using CleanWeb CTMS to set up an eTMF
Knowledge / skills	- Overall knowledge of the platform - Logging in and managing access codes - Activation of the eTMF Module - Implementation of an eTMF repository - Study-specific settings
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the implementation of CleanWeb eTMF: Project managers, Administrators, etc.
Course content	- Authentication - Activation of eTMF - Access rights - TMF Reference Model - References management: TMF, Global - Metadata - Study-specific list configuration - Workflow - Parameters
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Study Management CW-162-USM-EN General parameters and administration CW-229-USM-EN eTMF

Course title	**CleanWeb CTMS: eTMF: Document management**
Aim of the course	To provide the basics of using CleanWeb CTMS to run an eTMF
Knowledge / skills	- Logging in and managing access codes - Knowledge of document properties - Document management - Use of eTMF functions

Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb eTMF: CRAs, Project Managers, Administrators, etc.
Course content	- Authentication - Access rights - Study directory - Calculating the documents to be collected - Tabs: Documents and Types - Workflow - Using filters - Downloading a document - Document properties - Validating and/or signing a document - Version management - Adding/deleting a document - Follow-up of study documents - Access by user profile - Links - Audit trail - Export - Transversal documents
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-229-USM-EN eTMF

24.5 CleanWeb CTMS: Financial monitoring

Course title	**CleanWeb CTMS: Financial monitoring (coming soon)**
Aim of the course	Provide the basis for using CleanWeb CTMS to monitor fees and/or additional hospital costs
Knowledge / skills	- Overall knowledge of the platform - Setting costs - Fee management - Managing additional costs - Use of the various monitoring tables
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb CTMS for financial monitoring: CRAs, Project managers, administrators, etc.
Course content	- Overview of the CleanWeb solution - Access rights and authentication - Setting costs - Fee tracking tables - Document tracking - Monitoring fees - Setting additional costs - Table for monitoring additional costs - Document tracking
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	Face-to-face or distance learning (preferable) or 2H WEBINAR
Prerequisites	Access to a web browser
Supporting documents	CW-233-USM-EN Financial Management CW-227-USM-EN CTMS Study Management

24.6 CleanWeb WEB: Users

Several CleanWeb WEB software training courses are available, depending on the audience concerned.

Course title	**CleanWeb WEB: Users (Investigator and CRA)**
Aim of the course	To provide the basis for using CleanWeb WEB (eCRF online) to enter data, validate and monitor entries
Knowledge / skills	- Logging in and managing access codes - Familiarity with the interface and use of the various menus - Patient creation, inclusion and randomisation - Entering and recording all types of data - Data signature - Query management - Knowledge of Investigator functions - Using advanced functions - Data validation
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use a CleanWeb WEB eCRF: Investigator, Study nurse, CRA, Project Manager, etc.
Course content	Investigator: - Authentication - Preferences - Main menu functions - Creating a patient - Navigating the eCRF - Data entry (various types, including tables) - Data recording - Data verification - Context menu and help - Reports - Include/Randomise - Signature - Responding to Queries or DCFs Advanced functions: - Instantiated modules or forms - IP draw - Merger documents - Audit trail - Post-it - Printing eCRFs - Planning - Accessible services (Information, contacts, FAQ...) - Dashboards and queries - Unblinding - Duplicates - Patient transfer - Using locks - Deleting an eCRF CRA: - Validation (CRA) - Adding Queries or DCF

Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 hours
Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR
Prerequisites	Access to a web browser
Supporting documents	CW-063-USM-EN Investigator Manual CW-065-USM-EN CRA Monitor Manual CW-059-USM-EN Concurrent access management CW-051-USM-EN Data Signature CW-074-USM-EN Using access codes CW-098-USM-EN eCRF suppression CW-099-USM-EN Planning and alerts User CW-050-USM-EN Information service edition CW-052-USM-EN Duplicate Detection CW-049-USM-EN Patients Transfer and Sharing

Course title	**CleanWeb WEB: Investigator or Study nurse**
Aim of the course	Provide the basis for using CleanWeb WEB (eCRF online) to enter data
Knowledge / skills	- Logging in and managing access codes - Familiarity with the interface and use of the various menus - Patient creation, inclusion and randomisation - Entering and recording all types of data - Data signature - Query management - Knowledge of Investigator functions - Using advanced functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use a CleanWeb WEB eCRF: Investigator, Study nurse, CRA, Project Manager, etc.

Course content	- Authentication - Preferences - Main menu functions - Creating a patient - Navigating the eCRF - Data entry (various types including tables) - Data recording - Data verification - Context menu and help - Reports - Include/Randomise - Signature - Responding to Queries or DCFs Advanced functions: - Instantiated modules or forms - IP draw - Merger documents - Audit trail - Post-it - Printing eCRFs - Planning - Accessible services (Information, contacts, FAQ...) - Dashboards and queries - Unblinding - Duplicates - Patient transfer - Using locks - Deleting an eCRF
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 hours
Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR
Prerequisites	Access to a web browser
Supporting documents	CW-063-USM-EN Investigator Manual CW-059-USM-EN Concurrent access management CW-051-USM-EN Data Signature CW-074-USM-EN Using access codes CW-098-USM-EN eCRF suppression CW-099-USM-EN Planning and alerts User

Course title	**CleanWeb WEB: CRA or Project Manager**
Aim of the course	Provide the basis for using CleanWeb WEB (eCRF online) to validate and monitor data entry
Knowledge / skills	- Logging in and managing access codes - Familiarity with the interface and use of the various menus - Knowledge of Investigator functions - Data validation - Query management - Using advanced functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use eCRF CleanWeb WEB: CRAs, Project Managers, etc.
Course content	- Authentication - Preferences - Main menu functions - Navigating the eCRF - Data recording - Data verification - Context menu and help - Reports - Validation - Adding Queries or DCF - Investigator functions (creation, registration, signature, etc.) <u>Advanced functions:</u> - Instantiated modules or forms - Merger documents - Audit trail - Post-it - Printing eCRFs - Planning - Accessible services (Information, contacts, FAQ...) - Dashboards and queries - Duplicates - Patient transfer - Using locks - Deleting an eCRF
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 hours
Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR
Prerequisites	Access to a web browser

Supporting documents	CW-065-USM-EN CRA Monitor Manual CW-059-USM-EN Concurrent access management CW-074-USM-EN Using access codes CW-099-USM-EN Planning and alerts User CW-050-USM-EN Information service edition CW-049-USM-EN Patients Transfer and Sharing

Course title	**CleanWeb WEB: Dashboards and queries**
Aim of the course	Provide the basis for using CleanWeb WEB's customised dashboards and queries to validate and monitor data entry
Knowledge / skills	- Understanding how dashboards and queries work in general - Creating and modifying a dashboard - Creating and modifying a query - Using a dashboard or a query - Creating a graph - Managing dashboard options - Setting a default dashboard or query
Target audience	Anyone wishing to acquire or consolidate practical knowledge of CleanWeb WEB's customised dashboards and queries: Investigator, Study nurse, CRA, Project Manager, Data Manager, Vigilant, etc.
Course content	- Principle of a customised dashboard - Access rights - System items and eCRF items - Creating a dashboard - Using a dashboard - Selection by module - Modifying a dashboard - Calculating and updating dashboards - Variable not visible, not exportable, personal data - Creating and viewing a graph - Creating and applying a query - Access profile management - Default dashboard - Default query - Format 1 line or several lines - Satellite application - Superset dashboard - Export and export options
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour depending on level and number of participants
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser

Supporting documents	CW-063-USM-EN Investigator Manual CW-065-USM-EN CRA Monitor Manual CW-319-USM-EN Dashboards and requests (coming soon)

24.7 CleanWeb WEB: Planning and alerts

Course title	**CleanWeb WEB: Planning and alerts**
Aim of the course	To provide a basic understanding of how to use CleanWeb WEB to set up and use patient schedules and alerts
Knowledge / skills	- Knowledge of planning principles - Setting up the schedule - Theoretical visit settings - Understanding and using the properties of visits - Alert management - Access to the schedule - Knowledge of the different statuses - Theoretical and actual dates - Using the planning functions
Target audience	Anyone with knowledge or experience of CleanWeb Designer and WEB and wishing to acquire or consolidate practical knowledge of CleanWeb in order to design and use a patient schedule: Data manager, CRA, Project manager
Course content	- Planning principles <u>Design</u> - Schedule activation - 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 - Planning alert options and tags - How alerts work - Stop condition - Recalculating the calendar <u>User</u> - Access to the schedule - Filters and sorting - Theoretical dates and deviations - Visit status - Details of visits and alerts - Comments - Alert management - Export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable) or 3H WEBINAR
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 Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-097-USM-EN DESIGNER 2 - Advanced functions CW-122-USM-EN Planning and alerts Design CW-099-USM-EN Planning and alerts User CW-063-USM-EN Investigator Manual CW-065-USM-EN CRA Monitor Manual

Course title	**CleanWeb WEB: Planning and alerts: Design**
Aim of the course	To provide a basic understanding of how to use CleanWeb WEB to set up patient schedules and alerts
Knowledge / skills	- Knowledge of planning principles - Setting up the schedule - Theoretical visit settings - Understanding and using the properties of visits - Alert management
Target audience	Anyone with knowledge or experience of CleanWeb Designer and WEB and wishing to acquire or consolidate practical knowledge of CleanWeb in order to design a patient schedule: Data manager, CRA, Project manager
Course content	- Planning principles - Schedule activation - 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 - Planning alert options and tags - How alerts work - Stop condition - Recalculating the calendar
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours depending on level and number of participants
Training mode	E-Learning, distance learning 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 Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-097-USM-EN DESIGNER 2 - Advanced functions CW-122-USM-EN Planning and alerts Design

Course title	**CleanWeb WEB: Planning and alerts: User**
Aim of the course	To provide a basic understanding of the use of CleanWeb WEB for patient planning and alerts
Knowledge / skills	- Knowledge of planning principles - Access to the schedule - Knowledge of the different statuses - Theoretical and actual dates - Alert management - Using the planning functions
Target audience	Anyone with knowledge or experience of CleanWeb WEB and wishing to acquire or consolidate practical knowledge of patient planning: Data manager, CRA, Project manager
Course content	- Planning principles - Access to the schedule - Filters and sorting - Theoretical dates and deviations - Visit status - Details of visits and alerts - Comments - Alert management - Export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-099-USM-EN Planning and alerts User CW-063-USM-EN Investigator Manual CW-065-USM-EN CRA Monitor Manual

24.8 CleanWeb CTMS: Monitoring and rSDV

Course title	**CleanWeb CTMS: Monitoring**
Aim of the course	Provide a basic understanding of how to use CleanWeb CTMS to set up monitoring tools
Knowledge / skills	- Activation and general settings - Schedule settings - Setting up the monitoring control repository - Setting up monitoring visit reports - Adapting the reference system to a study - Using CRA-specific functions - Using dashboards - Managing a monitoring visit
Target audience	Anyone wishing to acquire or consolidate practical knowledge of setting up and using the CleanWeb monitoring module: Administrators, Project Managers, CRAs, etc.

Course content	<u>Settings</u>
	- Activation of planning and monitoring
	- Access rights
	- Monitoring tables and curves
	- Patient status
	- Patient visits schedule
	- Repository of monitoring controls and deviations
	- Monitoring controls by type of visit
	- Standard reports
	- Monitoring plan
	<u>Monitoring on the eCRF (on site or remote monitoring)</u>
	- Verifier / Validation / Queries / alerts / global report
	- Progress curves
	- Planning
	- Dashboards
	- Monitoring visit
	- Preparing for the visit:
	  ○ Patient follow-up
	  ○ Monitoring plan/Advancement
	- Telephone contacts
	- Scheduling a monitoring visit
	- Drafting of a monitoring visit report (active PDF)
	- Tracking deviations/Actions
	<u>Advanced functions:</u>
	- rSDV and CWMeet
	- Monitoring of a study not linked to an eCRF CleanWeb

Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 to 5 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR

Prerequisites	CleanWeb Designer installed Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-227-USM-EN CTMS Study Management CW-162-USM-EN General parameters and administration CW-130-USM-EN CTMS Administration CW-169-USM-EN CTMS Monitoring CW-122-USM-EN Planning and alerts Design CW-097-USM-EN DESIGNER 2 - Advanced functions CW-065-USM-EN CRA Monitor Manual CW-099-USM-EN Planning and alerts User

Course title	**CleanWeb CTMS: Monitoring: Settings**
Aim of the course	Provide a basic understanding of how to use CleanWeb CTMS to set up monitoring tools
Knowledge / skills	- Activation and general settings - Schedule settings - Setting up the monitoring control repository - Setting up monitoring visit reports - Adapting the reference system to a study
Target audience	Anyone wishing to acquire or consolidate practical knowledge of setting up the CleanWeb Monitoring Module: Administrators, Project Managers, etc.
Course content	- Activation of planning and monitoring - Access rights - Monitoring charts and curves - Patient status - Patient visits schedule - Repository of monitoring controls and deviations - Monitoring controls by type of visit - Standard reports - Monitoring plan <u>Advanced functions:</u> - Monitoring of a study not linked to an eCRF CleanWeb
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours depending on level and number of participants
Training mode	Distance learning or WEBINAR 2H, (e-learning coming soon)
Prerequisites	CleanWeb Designer installed Access to a web browser

Supporting documents	CW-227-USM-EN CTMS Study Management CW-162-USM-EN General parameters and administration CW-130-USM-EN CTMS Administration CW-169-USM-EN CTMS Monitoring CW-122-USM-EN Planning and alerts Design CW-097-USM-EN DESIGNER 2 - Advanced functions

Course title	**CleanWeb CTMS: Monitoring: User**
Aim of the course	Provide the basis for using CleanWeb CTMS for patient follow-up and monitoring
Knowledge / skills	- Using CRA-specific functions - Using dashboards - Managing a monitoring visit
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use the CleanWeb monitoring module: CRAs, Project managers, etc.

Course content	<u>Monitoring on the eCRF (on site or remote monitoring)</u>
	- Verifier / Validation / Queries / Reports / Global report
	- Progress curves
	- Planning
	- Dashboards
	<u>Monitoring visit</u>
	- Preparing for the visit:
	  ○ Patient follow-up
	  ○ Monitoring plan/Advancement
	- Telephone contacts
	- Scheduling a monitoring visit
	- Drafting of a monitoring visit report (active PDF)
	- Tracking deviations/Actions
	<u>Advanced functions</u>
	- rSDV and CWMeet
	- Monitoring of a study not linked to an eCRF CleanWeb

Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours depending on level and number of participants
Training mode	Distance learning or WEBINAR 3H, (e-learning coming soon)
Prerequisites	Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-065-USM-EN CRA Monitor Manual CW-169-USM-EN CTMS Monitoring CW-099-USM-EN Planning and alerts User

24.9 CleanWeb CDMS

Course title	**CleanWeb CDMS: Data Management**
Aim of the course	To provide the basis for using CleanWeb WEB for Data Management
Knowledge / skills	- Using CDISC mode - Using the Medical Coding Module - Use of functions linked to data management queries - Using dashboards and the general report
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the use of CleanWeb WEB in a Data Management context: Data managers, statisticians
Course content	Use of CDISC standards (CDASH, ODM) - Associated rights - CDASH naming - Export ODM - ODM imports 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 - Generating alerts and messages - Setting up automatic queries - Presentation of the interface - Configuring and managing a validation - Status and filters - PDF printing Dashboards and Global Report
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	4 to 5 hours depending on the level and number of participants and the Module chosen
Training mode	Face-to-face or distance learning (preferable) or 4H WEBINAR
Prerequisites	Access to a web browser Acrobat Reader V10 or higher

Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions CW-097-USM-EN DESIGNER 2 - Advanced functions CW-124-USM-EN Medical Coding CW-123-USM-EN Automatic queries and Data Management

Course title	**CleanWeb CDMS: Automatic queries**
Aim of the course	Provide the basics for using CleanWeb WEB to manage automatic queries
Knowledge / skills	- Knowing the rights associated with automatic queries - Differentiating between manual and automatic queries - Setting controls at designer level - Generation of automatic batch queries - Knowledge of the different statuses of a query - Setting up the queries template - Using queries functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the use of CleanWeb CDMS in the context of automatic queries: Data managers, statisticians, etc.
Course content	- Generating alerts and messages - Missing data - Notion of data confirmation - Setting up automatic queries - Rights associated with queries - Presentation of the interface - Configuring and managing a validation - Status and filters - Changing the status of a query - Using the queries table - Revision of queries - Creating a template - PDF printing - Audit trail
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	distance learning or WEBINAR 2H, (e-learning coming soon)
Prerequisites	Access to a web browser Acrobat Reader V10 or higher
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions CW-123-USM-EN Automatic queries and Data Management

Course title	**CleanWeb CDMS: Medical coding**
Aim of the course	To provide a basic understanding of how to use the CleanWeb WEB medical coding module
Knowledge / skills	- Knowledge of how the medical coding module works - Creation of a dictionary in CSV format - Use of different coding modes - Validation and export of coding
Target audience	Anyone wishing to acquire or consolidate practical knowledge of the use of CleanWeb WEB in the context of medical coding: Data managers, medical coders, etc.
Course content	Medical coding (MedDRA, ICD10, WHODrug, ATCCode) Setting - Associated rights - Dictionary format - Loading dictionaries - Setting the variables to be coded Medical coding - Automatic/manual coding - Coding validation - Export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	distance or WEBINAR 1H, (e-learning coming soon)
Prerequisites	Access to a web browser Dictionary available in CSV format
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions CW-124-USM-EN Medical Coding

Course title	**CleanWeb CDMS: Data extraction**
Aim of the course	Provide the basis for using CleanWeb WEB (eCRF online) to extract data
Knowledge / skills	- Logging in and managing access codes - Knowledge of extraction access conditions - Knowledge of the options available - Setting up export tables - How to extract data - Understanding the format of the data and files generated - Archiving eCRFs

Target audience	Anyone wishing to acquire or consolidate practical knowledge of using an eCRF CleanWeb WEB: Data Manager, Statistician, Project Manager, etc.
Course content	- Authentication (optional) - Preferences (optional) - Associated rights and access conditions - Extraction models - Scope of extraction - Data format - Table configuration - Options (audit trail, coding, etc.) - Test archive - Running an extraction model - Extraction history - Files generated - ODM extraction - PDF archives - Custom extraction
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 to 2 hours depending on level and number of participants
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser Software for decompressing files in .zip format Acrobat Reader V10 or higher
Supporting documents	CW-057-USM-EN Data Extraction CW-190-USM-EN CDISC ODM Import-Export

Course title	**CleanWeb CDMS: Import module**
Aim of the course	Provide the basis for using CleanWeb WEB to import data
Knowledge / skills	- Knowledge of how the Import Module works - Associated rights - Knowledge of expected formats - Creating the import file - Understanding import options - Understanding import errors - ODM import concept
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use CleanWeb's Import Module: Data Managers, Project Managers, etc.

Course content	- General principle of patient import - Access rights - Extraction models and export options to be respected - Expected files and data format - Data mapping - Creation of the import file - Importing the data file - Setting import options - Case of an import on an investigator - Import from a list of investigators - Data verification - Error report - Launching the import - ODM imports
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable) or 3H WEBINAR
Prerequisites	Access to a web browser Software for compressing/decompressing files in zip format Installation of LibreOffice/OpenOffice software recommended
Supporting documents	CW-057-USM-EN Data Extraction CW-092-USM-EN Data import CW-190-USM-EN CDISC ODM Import-Export

Course title	**CleanWeb CDMS: Double Data Entry: Designer**
Aim of the course	To provide the basics of using the CleanWeb Double Data Entry Module Designer
Knowledge / skills	- Installing the CTMS fat client - Logging in and managing access codes - Knowledge of the principles of double entry - Setting up the Double Data Entry study - Input mask design options - Understanding the functions of the double-entry designer
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use the CleanWeb Double Data Entry Module designer: Data Managers, Project Managers, etc.

Course content	- Installing the CleanWeb software Double entry - Authentication - General principle - Creating a study - Access rights - Fictitious investigator or not - Patient reference - How to enter MCQs - Category of CRF - Design of input screens with or without templates - Variables - Page layout - Using models - Designer functions
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning or WEBINAR 3H
Prerequisites	Installing CleanWeb CTMS software (fat client)
Supporting documents	CW-227-USM-EN CTMS Study Management CW-130-USM-EN CTMS Administration CW-228-USM-EN CTMS User Profiles and Functions CW-060-USM-EN Access rights CW-056-USM-EN CTMS Installation CW-094-USM-EN Double entry Design

Course title	**CleanWeb CDMS: Double Data Entry: Database acquisition**
Aim of the course	To provide the basics of using the CleanWeb Double Entry Module
Knowledge / skills	- Installing the CTMS fat client - Logging in and managing access codes - Knowledge of the principles of double entry - CRF tracking management - Data entry - Confrontation of seizures - Understanding the functions of the double entry module - Extracting the database
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use the CleanWeb Double Data Entry Module: Data Manager, Data Entry Operator, etc.

Course content	- Installing the CleanWeb software Double entry - Authentication - General principle - Access rights - Tracking table - Enrolling an eCRF - Input 1 - Input 2 - Flags review - Review of differences - Reopening data entry - Extraction - Audit trail
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning or WEBINAR 3H
Prerequisites	Installing CleanWeb CTMS software (fat client)
Supporting documents	CW-056-USM-EN CTMS Installation CW-093-USM-EN Double Data Entry User

24.10 CleanWeb ePRO Module

Course title	**CleanWeb ePRO Module**
Aim of the course	Provide a basic understanding of how to use CleanWeb ePRO to set up and monitor patient self-questionnaires
Knowledge / skills	- Knowledge of how ePRO works - Setting up self-questionnaires - Setting up schedules and alerts - Knowledge of ancillary settings - Using the Planning tab functions - Contact data management - Data entry - Monitoring the status of a self-administered questionnaire - Pin code and alert management - Entering data for the patient
Target audience	Anyone with knowledge or experience of CleanWeb and wishing to acquire or consolidate practical knowledge of CleanWeb in order to design and monitor ePROs: Data manager, CRA, Project manager, etc.
Course content	- ePRO principles - Personal data <u>Design:</u> - Study settings - Setting up self-questionnaires - Constraints - Access to questionnaires - Language management - Planning rights - Setting the patient schedule - Alert settings - Stop condition - Activation mail - Recalculating the calendar - Customisation <u>User:</u> - Planning board functions (status, details, etc.) - Contact information (import) - Patient account activation and validation - Web-based data entry - Data input from a smartphone - Filling monitoring - Pin code forwarding - Stop sending alerts - Refusal to seize - Filling by other users (associated rights)
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable) or 3H WEBINAR

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 Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-122-USM-EN Planning and alerts Design CW-183-USM-EN ePRO Design CW-099-USM-EN Planning and alerts User CW-107-USM-EN ePRO User CW-162-USM-EN General parameters and administration

Course title	**CleanWeb ePRO Module: Design**
Aim of the course	To provide a basic understanding of how to use CleanWeb ePRO to set up patient self-questionnaires
Knowledge / skills	- Knowledge of how ePRO works - Setting up self-questionnaires - Setting up schedules and alerts - Knowledge of ancillary settings
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb Designer in order to design ePROs: Data manager, CRA, Project manager, etc.
Course content	- ePRO principles - Personal data - Study settings - Setting up self-questionnaires - Constraints - Access to questionnaires - Language management - Planning rights - Setting the patient schedule - Alert settings - Stop condition - Activation mail - Recalculating the calendar - Customisation
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours depending on level and number of participants
Training mode	E-Learning, distance learning 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 Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-122-USM-EN Planning and alerts Design CW-183-USM-EN ePRO Design CW-162-USM-EN General parameters and administration

Course title	**CleanWeb ePRO Module: User**
Aim of the course	To provide the basis for using CleanWeb ePRO to monitor the completion of patient self-questionnaires
Knowledge / skills	- Knowledge of how ePRO works - Using the Planning tab functions - Contact data management - Data entry - Monitoring the status of a self-administered questionnaire - Pin code and alert management - Entering data for the patient
Target audience	Anyone wishing to acquire practical knowledge of CleanWeb ePRO: Investigators, Study nurses, CRAs, Project Managers, etc.
Course content	- ePRO principles - Planning board functions (status, details, etc.) - Contact information (import) - Patient account activation and validation - Patient's language - Web-based data entry - Data input from a smartphone - Filling monitoring - Pin code forwarding - Stop sending alerts - Refusal to seize - Filling by other users (associated rights)
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-099-USM-EN Planning and alerts User CW-107-USM-EN ePRO User

24.11 CleanWeb Adjudication Module

Course title	**CleanWeb Adjudication Module**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to set up the Adjudication Module and monitor expert assessments
Knowledge / skills	- Knowledge of the operating principles of the Adjudication Module - Activating the adjudication service - Setting up the appraisal form - Knowledge of the different roles and associated rights - Batch generation - Seizure by an expert - Treatment of a consensus by the moderator Use of data
Target audience	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 Adjudication Module: Data manager, CRA, Project manager, etc.
Course content	- Principles relating to the Adjudication Module <u>Design:</u> - Activating the adjudication service - Adjudication module functions - Setting up the adjudication form - Variables subject to expert assessment - Patient adjudication - Event adjudication <u>User:</u> - Definition of roles: Moderator and Expert - Access rights - Interface description - Batch generation - Referring a case to an expert - Modifying an expert assessment - Dealing with a consensus - Statistics - Data export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	Face-to-face or distance learning (preferable) or 2H WEBINAR
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory Access to a web browser

Supporting documents	CW-060-USM-EN Access rights CW-067-USM-EN DESIGNER 1 - Basic Functions CW-172-USM-EN Adjudication Design CW-176-USM-EN Adjudication User

Course title	**CleanWeb Adjudication Module: Design**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to set up the Adjudication Module
Knowledge / skills	- Knowledge of the operating principles of the Adjudication Module - Activating the adjudication service - Setting up the appraisal form
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb Designer in order to design an Adjudication Module: Data manager, CRA, Project manager, etc.
Course content	- Principles relating to the Adjudication Module - Activating the adjudication service - Adjudication module functions - Setting up the adjudication form - Variables subject to expert assessment - Patient adjudication - Event adjudication
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory
Supporting documents	CW-060-USM-EN Access rights CW-067-USM-EN DESIGNER 1 - Basic Functions CW-172-USM-EN Adjudication Design

Course title	**CleanWeb Adjudication Module: User**
Aim of the course	Provide a basic understanding of how to use CleanWeb's Adjudication Module to monitor expert assessments
Knowledge / skills	- Knowledge of the operating principles of the Adjudication Module - Knowledge of the different roles and associated rights - Batch generation - Seizure by an expert - Treatment of a consensus by the moderator - Use of data
Target audience	Anyone wishing to acquire practical knowledge of CleanWeb Adjudication Module: Expert, Investigator, Study nurse, CRA, Project Manager, etc.
Course content	- Principles relating to the Expertise Module - Definition of roles: Moderator and Expert - Access rights - Interface description - Batch generation - Referring a case to an expert - Modifying an expert assessment - Dealing with a consensus - Statistics - Data export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-060-USM-EN Access rights CW-176-USM-EN Adjudication User

24.12 CleanWeb Vigilance Module

Course title	**CleanWeb Vigilance Module**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to configure the Vigilance Module and monitor undesirable events
Knowledge / skills	- Knowledge of the operating principles of the Vigilance Module - Activating the Vigilance Module - Setting up the AE form - Creation of an AE - Notification of an AE - AE follow-up - Using the AE Monitoring Table - Managing an AE
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb in order to design and use the Vigilance Module: Data manager, CRA, Project manager, etc.
Course content	- Principles of the Vigilance Module <u>Design</u> - Activation of the vigilance service - Access rights - Principles of the Vigilance Module - Activation of the vigilance service - Access rights - Setting up the AE form and reserved variables - Setting the notification constraint - Setting up the print template with tags - Setting recipient email addresses - Notification options - Special case of integration with an external platform <u>Use</u> - Access rights - Notification - Creating an AE - Notifying an AE - Create a follow-up - AE monitoring table - AE details, alerts and history - Printing the notification form - Access to the eCRF form - Vigilance registration number - Export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours
Training mode	Face-to-face or distance learning (preferable) or 2H WEBINAR

Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory Access to a web browser
Supporting documents	CW-060-USM-EN Access rights CW-227-USM-EN CTMS Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-348-USM-EN Vigilance Design CW-349-USM-EN Vigilance User

Course title	**CleanWeb Vigilance Module: Design**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to configure the Vigilance Module
Knowledge / skills	- Knowledge of the operating principles of the Vigilance Module - Activating the Vigilance Module - Setting up the AE form
Target audience	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, etc.
Course content	- Principles of the Vigilance Module - Activation of the vigilance service - Access rights - Setting up the AE form and reserved variables - Setting the notification constraint - Setting up the print template with tags - Setting recipient email addresses - Notification options - Special case of integration with an external platform
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 to 2 hours
Training mode	E-Learning, distance learning 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-EN Access rights CW-227-USM-EN CTMS Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-348-USM-EN Vigilance Design

Course title	**CleanWeb Vigilance Module: User**
Aim of the course	To provide a basic understanding of how to use CleanWeb's Vigilance Module to monitor undesirable events
Knowledge / skills	- Knowledge of the operating principles of the Vigilance Module - Creation of an AE - Notification of an AE - AE follow-up - Using the AE Monitoring Table - Managing an AE
Target audience	Anyone wishing to acquire practical knowledge of the CleanWeb Vigilance Module: Investigators, CTAs, CRAs, Project Managers, etc.
Course content	- Principles of the Vigilance Module - Access rights - Notification - Creating an AE - Notifying an AE - Create a follow-up - AE monitoring table - AE details, alerts and history - Printing the notification form - Access to the eCRF form - Export
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 to 2 hours
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-060-USM-EN Access rights CW-349-USM-EN Vigilance User

24.13 CleanWeb Imaging Module

Course title	**CleanWeb Imaging Module**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to set up and use the Imaging Module
Knowledge / skills	- Knowledge of the operating principles of the Imaging Module - Activating the Imaging Module - Setting imaging variables - Imaging variable options - Understanding anonymisation - Mastering image uploading - Playing back images
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb in order to design and use the Imaging Module: Data manager, CRA, Project manager, etc.
Course content	- Principles of the Imaging Module <u>Design</u> - Activating the File Storage service - Setting a variable File - File category options: standard, DICOM and video - Naming strategy - Using the SetFileName operator <u>User</u> - Anonymisation of files - Downloading 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) - Playing back images
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 hours
Training mode	Face-to-face or distance learning (preferable) or 2H WEBINAR
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory DICOM viewer installation Access to a web browser
Supporting documents	CW-227-USM-EN CTMS Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-340-USM-EN Medical Imaging

Course title	**CleanWeb Imaging Module: Design**
Aim of the course	To provide a basic understanding of how to use CleanWeb Designer to set the parameters of the Imaging Module
Knowledge / skills	- Knowledge of the operating principles of the Imaging Module - Activating the Imaging Module - Setting imaging variables - Imaging variable options
Target audience	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, CRA, Project manager, etc.
Course content	- Principles of 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
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning 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 Study Management CW-067-USM-EN DESIGNER 1 - Basic Functions CW-340-USM-EN Medical Imaging

Course title	**CleanWeb Imaging Module: User**
Aim of the course	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 image uploading - Playing back images
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb in order to use the Imaging Module: Investigator, CRA, Project Manager, etc.

Course content	- Principles of the Imaging Module - Anonymisation of files - Downloading 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) - Playing back images
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Installation of the CleanWeb Designer software with administrator rights on the directory DICOM viewer installation Access to a web browser Activation of the Imaging service on the server and the study
Supporting documents	CW-340-USM-EN Medical Imaging

24.14 CleanWeb WEB miscellaneous

Course title	**CleanWeb Duplicate management (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-052-USM-EN Duplicate Detection

Course title	**CleanWeb Service edition (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-050-USM-EN Information service edition

Course title	**CleanWeb MFA (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	

Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-371-USM-EN Multi-Factor Authentication (MFA)

24.15 CleanWeb E-Consent

Course title	**CleanWeb e-Consent (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-370-USM-EN eConsent User

Course title	**CleanWeb e-Consent: Design (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

Course title	**CleanWeb e-Consent: User (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	

Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	CW-370-USM-EN eConsent User

24.16 CleanWeb Online thesaurus

Course title	**CleanWeb Online Thesaurus**
Aim of the course	To provide the basis for using the online thesaurus in conjunction with CleanWeb Designer to set up and use a regularly modifiable thesaurus
Knowledge / skills	- Understanding the principle and advantages of an online thesaurus - How to handle a file encoded in UTF-8 - Knowledge of the various stages involved in configuring an online thesaurus - Knowledge of the functions of the online thesaurus application - How to edit and publish a thesaurus online
Target audience	Anyone with knowledge or experience of CleanWeb Designer and wishing to acquire or consolidate practical knowledge of CleanWeb in order to use the online Thesaurus module or anyone responsible for managing and/or updating thesauri: Data Manager, Project Manager, Coordinator, Administrator, etc.

Course content	- Principles and benefits of the Online Thesaurus
	<u>Configuration</u>
	- Activating the online Thesaurus for a study
	- Creation of a thesaurus in UTF-8 format
	- Presentation of the administrative section of the online Thesaurus
	  ○ Account management
	  ○ Management of servers and studies
	- Adding a thesaurus to the online thesaurus application
	- Association of a thesaurus with one or more studies
	- Associating a user with a thesaurus
	- Publication of the thesaurus
	- Linking a study to the online thesaurus from Designer
	<u>Use</u>
	- Authentication to access the application
	- User interface
	- Thesaurus metadata
	- Modifications to a thesaurus
	- Publication: changes made available

Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	1 hour
Training mode	E-Learning, distance learning or WEBINAR 1H
Prerequisites	Access to a web browser
Supporting documents	CW-067-USM-EN DESIGNER 1 - Basic Functions CW-328-USM-EN Online Thesaurus

24.17 CleanWeb Early Access (MAP)

Course title	**CleanWeb Early Access (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

Course title	**CleanWeb Early Access: Designer (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

Course title	**CleanWeb Early Access: User (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	

Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

24.18 CleanWeb API

Course title	**CleanWeb API and Webservices**
Aim of the course	To provide a basic understanding of how to use the CleanWeb API to set up and use webservices
Knowledge / skills	- Knowledge of the operating principles of web services - Knowledge of REST API formalism - Knowledge of the CleanWeb web services panorama - Using a web service with PostMan - Using a web service with a Python client - Retrieving data from a CleanWeb eCRF - Updating eCRF CleanWeb data
Target audience	Anyone (Data manager, Data engineer, CRA, Project manager, etc.) wishing to acquire or consolidate practical knowledge of REST APIs in general, and CleanWeb web services in particular. Previous knowledge or experience of web services is not necessary.

Course content	How REST web services work - What is a web service / API? - Practical example 1 - What is a REST API? - Practical example 2 - What are the different HTTP methods for REST APIs? - What are the different responses and their status - Authentication and access management - Practical example 3 CleanWeb Web services - Authentication services - Retrieving data from an eCRF - Patient lists, dashboards - Updating eCRF data - Retrieving metadata from eCRFs - Expert module - Management of facilities and services - User management - Managing study centres - Managing participation in a study - Profile management - Study management - The Thesaurus module - Managing study files - Extraction management - Managing monitoring visits - Retrieving study statistics - Retrieving server statistics - Retrieving server options/parameters - Investigational products Management (IPM) - AE management - DataViz moduleExample of use: POSTMAN - Installing Postman / Accessing the Web version - Configuring authentication (OAuth2) - Retrieving eCRF metadata from a CleanWeb study Example of use: Python client - Installing the VScode editor / Accessing an online editor - Installation of the necessary modules - Implementing OAuth2 authentication - Retrieving the metadata of an eCRF from a CleanWeb study
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	2 to 3 hours depending on level and number of participants
Training mode	E-Learning, distance learning or WEBINAR 2H
Prerequisites	Access to a web browser Recovery of access tokens (client ID and client secret) from a CleanWeb test server Installation of Postman and/or Python 3 + text editor
Supporting documents	CW-287-USM-EN API REST Technical Guide

24.19 CleanWeb Shared diary

Course title	**CleanWeb Shared diary (coming soon)**
Aim of the course	
Knowledge / skills	
Target audience	
Course content	
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	
Training mode	
Prerequisites	
Supporting documents	

24.20 CleanWeb Connector (eCRF offline)

Several CleanWeb Connector software training courses are available, depending on the audience concerned.

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

Course title	**CleanWeb Connector: Investigator or Study nurse**
Aim of the course	Acquire 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 access codes - Familiarity with the interface and use of the various menus - Patient creation, inclusion and randomisation - Entering and recording all types of data - Responding to queries - Signing data - Using advanced functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use an eCRF CleanWeb Connector: Investigator, Study nurse, CRA, Project Manager, etc.
Course content	- Installing the CleanWeb Connector software - Authentication - Preferences - Main menu functions - Creating a patient - Navigating the eCRF - Data entry (various types including tables) - Data verification - Data recording - Context menu and help - Include/Randomise - Synchronising and quitting the software - Using locks - Queries or DCF - Signature <u>Advanced functions:</u> - Email alerts - Sending emails - Instantiated modules or forms - Printing an eCRF - Deletion of a eCRF - Planning - Duplicates - Pulling IPs and emergency IPs - Patient profiles - Merger documents - Generation of eCRF archives - Audit trail - Using Offline mode
Category of training action	Training actions (article L.6313-1 of the French Labour Code)

Course duration	½ to 1 day depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installing CleanWeb Connector
Supporting documents	CW-054-USM-EN Designer and Connector installation CW-070-USM-EN Investigator Manual - Connector CW-071-USM-EN Planning management - Connector CW-068-USM-EN Note Quit by synchronising

Course title	**CleanWeb Connector: CRA and Project Manager**
Aim of the course	Provide the basis for using CleanWeb Connector (eCRF offline) to validate and monitor data entry
Knowledge / skills	- Installing the Connector and understanding how it works - Logging in and managing access codes - Familiarity with the interface and use of the various menus - Knowledge of Investigator functions - Data validation - Creating queries - Using advanced functions
Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use an eCRF CleanWeb Connector: CRAs, Project Managers, etc.

Course content	- Installing the CleanWeb Connector software - Authentication - Preferences - Main menu functions - Navigating the eCRF - Data verification - Context menu and help - Synchronising and quitting the software - Using locks - Queries or DCF - Validation Advanced functions: - Email alerts - Sending emails - Instantiated modules or forms - Printing an eCRF - Deleting an eCRF - Multilingual management - Patient transfer - Planning - Duplicates - Patient profiles - Generation of eCRF archives - Audit trail - Using Offline mode
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 to 4 hours depending on level and number of participants
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installing CleanWeb Connector
Supporting documents	CW-054-USM-EN Designer and Connector installation CW-072-USM-EN CRA Manual - Connector CW-071-USM-EN Planning management - Connector CW-068-USM-EN Note Quit by synchronising

Course title	**CleanWeb Connector: Data extraction**
Aim of the course	Acquire the basics of using CleanWeb Connector (eCRF offline) to extract data
Knowledge / skills	- Installing the Connector and understanding how it works - Logging in and managing access codes - Knowledge of the options available - Setting up export tables - Understanding the format of the data and files generated

Target audience	Anyone wishing to acquire or consolidate practical knowledge of how to use an eCRF CleanWeb Connector: Data managers, Statisticians, Project managers, etc.
Course content	- Installing the CleanWeb Connector software - Authentication - Preferences - Main menu functions - Synchronising and quitting the software - Audit trail - Export templates - Configuration options - Standard table configurations - Customised table configurations - Extraction and generated files - Data format
Category of training action	Training actions (article L.6313-1 of the French Labour Code)
Course duration	3 hours
Training mode	Face-to-face or distance learning (preferable)
Prerequisites	Installing CleanWeb Connector
Supporting documents	CW-054-USM-EN Designer and Connector installation CW-058-USM-EN Data Extraction - Connector

25 -Glossary

API	Application Programming Interface
CRA	Clinical research assistant
CDISC	Clinical Data Interchange Standards Consortium
CTMS	Clinical Trial Management System
CDMS	Clinical Data Management System
eCRF	electronic Case Report Form (observation booklet)
ePRO	electronic Patient Report Outcome
FAQ	Frequently Asked Questions
IWRS	Interactive Web Randomization System
rSDV	Remote Source data Validation
IP	Investigational product
TMF	Trial Master File

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