EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Instructor's Guide:

How to search, view and download a CT and a CTA (Authority)

CTIS Training Programme – Module 15

Version 1.2 – October 2021

What you will find

- Overall guidelines on how to disseminate the knowledge.
- Overview of the audiences targeted in module 15.
- Overview of the training materials prepared as part of module 15.
- Recommendations on how to prepare and develop the training sessions.

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01

Introduction

Scope and objectives

This instructor guide is designed to help you, as a trainer, to disseminate the knowledge and the training materials prepared as part of the Clinical Trials Information System (CTIS) Training Programme to your target audience.

More specifically, this guide is focused on the **fifteen Module of the CTIS Training Programme** (hereafter referred to as 'CTTM15'). The module provides an overview of how users can search for clinical trials (CTs) and clinical trial applications (CTAs), and how to view and download CT and CTA data and documents. **This guide contains** an overview of the audiences targeted with CTTM15, the training materials available, and a suggested methodology for disseminating the materials.

The training activities proposed in this instructor guide are available in English and have been designed for people with reading and hearing abilities. Please, feel free to enrich the course with your contributions and/or adapt it to your participants' needs, but always taking into account the learning objectives and key ideas presented.

For any questions regarding the materials, please contact the CTIS Training Programme team at CT.training@ema.europa.eu.

02

Course elements

Target audiences

CTTM15 targets **authority users** including Member States' national competent authorities, Member States' ethics committees and the European Commission.

CTTM15 learning objectives

The learning objectives of CTTM15 are:

1. Remember how to search for a clinical trial (CT) and a clinical trial application (CTA).
2. Understand how to view the information displayed in a CT and a CTA.
3. Understand how to download information and associated documents.
4. Understand which user roles can view and download specific CT/CTA information.

Materials available

- **CTTM15 Quick guide:** Practical and simple quick reference guide with images to prepare users on how to search for a CT and a CTA, understand the information displayed in the CT sub-tabs and CTA sections, and the information and file types available for download. This allows users to have useful information always at hand.
- **CTTM15 Step-by-step guide:** Short and practical document that includes the most relevant steps of the processes described in the module.
- **CTTM15 video-clips:** Two video-clips showing a demonstration in the system of how to search for a CT, the information displayed in the clinical trial page sub-tabs and clinical trial application page sections, and the information available for download.
    - Clip 1: How to search for a CT in the authority workspace (5 minutes 55 seconds).
    - Clip 2: How to view and download CTs in the authority workspace (5 minutes 29 seconds).
- **CTTM15 FAQs:** List of Frequently Asked Questions regarding the search functionalities available in CTIS, how to view CTs and CTAs information, and how to download CT and CTAs and available file types.

03

Course preparation

To ensure that the learning objectives of CTTM15 are met and that the training materials are optimally disseminated and consumed, we suggest that you follow a **blended learning approach** combining an activity where participants interact with the content individually and at their own pace and preferred timing (**asynchronous** learning), with an activity bringing together all participants at the same time (**synchronous** learning). For more information on this approach to learning, please refer to our general dissemination guidelines.

- First, we suggest that you **share the CTTM15 Quick guide** with the participants. This will allow them to understand the contents of the module at their own pace and reflect on questions they may have.

- Second, we suggest that you organise **a webinar** around one week after having shared the Quick guide with the participants. This will allow you to verify that participants understood the steps presented in the Quick guide and preferably show them how to perform the described steps in practice during the webinar in order to address any question they may have.

As the instructor, you are the **sole responsible for organising and hosting the webinar** with the materials provided by the CTIS Training Programme team. You may, of course, prefer to arrange a face-to-face session if the resources and the availability allow you to do so.

Please note that this guide only provides recommendations and suggestions on how to convey the knowledge to the participants. Do not hesitate to adapt it to your needs and preferences, including the possibility to combine one or more modules in the same webinar.

Preparation of a webinar

This section summarises some useful tips to help you organise a webinar successfully.

- **Prepare an online quiz** to be launched during the webinar with some questions for the participants as an 'icebreaker' and to check whether the participants have understood the key concepts of the Quick guide. The purpose of this activity is to start the webinar in an interactive manner and see if participants have acquired some basic information beforehand. The feedback gathered in this exercise will help you to better adapt your speech and presentation to the participants' knowledge level.

- **Review other relevant modules of the CTIS Training Catalogue,** such as Module 2, where a first introduction to the search functionality is presented:
    - Module 2: Overview of CTIS workspaces and common system functionalities.
- **Send the Quick guide and the Step-by-step guide** to the training participants one week in advance.
- **Choose the right platform** to host your webinar, and make sure the participants are aware of the connection requirements by sharing with them the instructions.
- **Limit participation** to a maximum of 20 participants and up to a maximum of two hours duration, to maintain optimal interaction and keep the participants focused.

04

Course development

In this section, we describe the proposed timings for each activity, the material to be used, the objective of the activity, and the steps to be followed by you as a trainer:

Activity 1: Reviewing the Quick guide and Step-by-step individually

Time: One week before the webinar.

Material: CTTM15 Quick guide and CTTM15 Step-by-step guide.

Objective:

This activity consists in the review by participants of the CTTM15 Quick guide and Step-by-step guide by themselves, so they can have an overview of the process and identify questions that are not clear to them.

Steps:

1. Send the Quick guide and the Step-by-step guide to the participants and ask them to review them before the webinar day.

2. Send an email reminder one or two days before the webinar, asking them to write down any questions they may have ahead of the webinar.

Activity 2: Webinar

Time: Ca two hours and a half.

Material: CTTM15 quick guide, CTTM15 Step-by-step guide, CTTM15 video-clips, CTTM15 FAQs, and password-protected feedback form built by the CTIS Training Programme team with EU survey tool for participants to provide feedback anonymously.

Objective:

This proposed activity consists in the organisation of a webinar to:

- Assess if participants have gathered the knowledge presented in the CTTM15 Quick guide.
- Present the additional materials for the CTTM15.
- Answer any questions regarding the content of the CTTM15.
- Receive feedback regarding the learning materials and training delivery methodology.

We propose to structure this activity in seven parts, described below:

1. **Part 1:** Introduction to the webinar (*approximately 15 minutes*).
    a. Introduce yourself as a trainer and remind participants of the basic rules of the session.
    b. Explain the aim of the webinar and describe briefly the materials that will be used for the session.
    c. Open a quick roundtable to allow participants to introduce themselves briefly.
2. **Part 2**: Questions on the material reviewed and interactive knowledge check (*approximately 25 minutes*).
    a. Ask if participants have any questions regarding the CTTM15 Quick guide and the Step-by-step guide.
    b. Launch an online quiz to check if participants understood the key concepts from the CTTM15 Quick guide and Step-by-step guide.
3. **Part 3:** Screening of CTTM15 video-clips (*approximately 20 minutes*).
    a. Make a brief introduction to the CTTM15 video-clips, so that participants have an understanding of the content they are about to watch. Explain that the aim of the video-clips is to show them how the functionalities of Module 15 work in practice in the system.
    b. You may want to prepare a short slide deck with key concepts to display on the screen after viewing the video-clips.
    c. After each video-clip, allow five minutes so that participants can ask questions. Be ready to have CTIS open to be able to show how something works on the system in practice. Be also ready to replay a video-clip once more if an aspect was not clear enough or covered too quickly.
4. **Part 4**: How to view, search, and download activity (*approximately 30 minutes*).

a. Share the document with the exercise (*see Annex*) with the participants explaining the activity. Indicate the time they have to read and solve it. There are **six cases** described with **three possible solutions** in each case, only one being correct. Please refer to the exercise document in the Annex of this document to find out the correct answer.

b. We suggest that you give them up to 15 minutes to read the document and complete the solution table on the third page of the document with the solution that best suits each case description.

c. Use the remaining 15 minutes estimated for this activity to discuss the scenarios that participants have selected for each case and address any question or incorrect answer.

d. Key for the instructor: the table below outlines the correct scenarios for each of the cases.

Case ID	Correct solution	Comments/justification for the instructor
1	A **Basic search**	The best search to find the CT, in this case, is the basic search, as the user knows the **EU CT number**.
2	C **Application advanced search**	**The user knows specific criteria only available in the application advanced search**, such as application status and the submission period, making this a better choice.
3	B C **Both are correct**	Either of the advanced searches is suitable for this search given that **the criterion the user knows about the required CTs (the sponsor organisation name) is a parameter common in both advanced searches**.
4	B **Trial advanced search**	The user knows that other MSC is either of the two options he/she has in mind. The user also knows that the recruitment status is either pending or ongoing, **he/she should launch a trial advanced search** because the **recruitment status criterion** is available only in this advanced search, the **MSCs criterion** is available in both and the user can enter two values in a search parameter and will get the results matching either of them.
5	C **Clinical trial page (Full trial information sub-tab)**	Since the user wants to have a **comprehensive look at all the relevant information about a CT** such as protocol information, objectives, the population of trial subjects, or recruitment arrangements, **the best place to view that information is in the full trial information sub-tab**. Other sub-tabs in the clinical trials page show more summarised information.
6	A **Search results list (Download trials)**	The best way for the MSC user to **download all the documentation would be to do it from the search results list**. In there the user would select the trial he/she is interested in, and click on the 'Download' button to download **all the CT information, data and documentation** that the user has permissions to see in a **Zip folder**.
7	C **Clinical trial application page (Evaluation section – Assessment sub-section)**	The best way for the MS user to download the Draft Assessment Report of a CTA would be to go to the **CTA page, click on the evaluation section and open the Draft Assessment Report subsection of the Assessment Part I**. The Draft Assessment Report will be located there. Users can **click on the radio buttons to select the document and then click on the 'Download' button** to download such document.

Break: (10 minutes)

5. **Part 5:** Questions and answers (*approximately 20 minutes*).

    a. Present the CTTM15 FAQs document (*approximately 5 minutes*).

    b. Give some time to the participants to think and ask the questions they have on the material.

    c. Prepare a blank slide as an empty whiteboard where participants can add relevant information, raise questions or pinpoint different logics to use the search and download functionalities not foreseen in the materials.

    d. Note the questions of the participants. Allow them to ask them orally or via the chat. *We suggest gathering all questions at the beginning of this exercise to make sure that all questions are captured without time constraints.*

    e. Answer the questions using the CTTM15 FAQs. *We suggest that you note the questions of the participants that you are not able to answer surely. After the training session, you can send the unanswered questions, to the CTIS Training Programme Team (CT.training@ema.europa.eu), who can support you with preparing the answers. You should disseminate the answers to all the participants of the webinar.*

6. **Part 6:** Gather feedback about the training materials and methodology (*approximately 15 minutes*).

    a. Share the link of the feedback form on EU Survey and the credentials to access it with the participants.

    b. Give them 15 minutes to complete it. *If the time is not enough, you may decide to share the link to the survey with the participants via email and ask them to complete it after the webinar.*

7. **Part 7:** Wrap up the webinar (*approximately 5 minutes*).

    a. Conclude the webinar and reference for future training modules and/or training sessions.

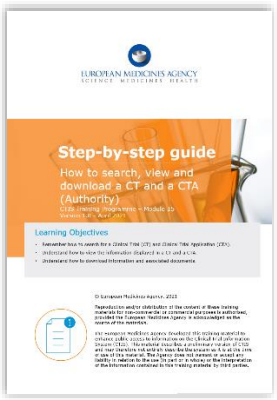
    b. Allow participants to ask final questions.

05

Annex

Quick guide

Step-by-step guide

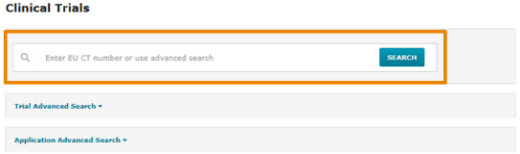


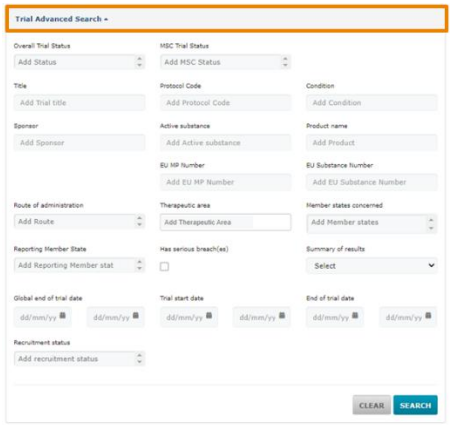
FAQs

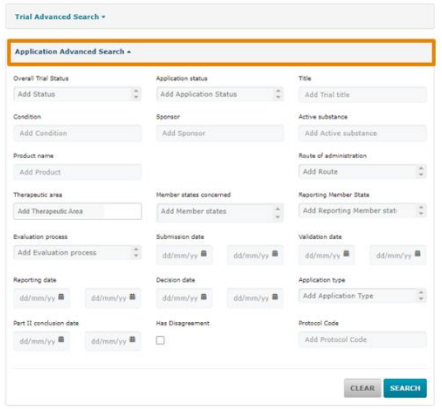
Video-clips

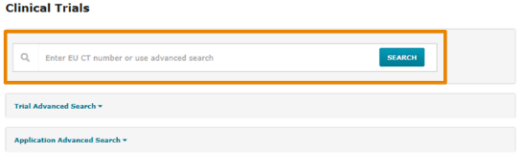
Dissemination guidelines

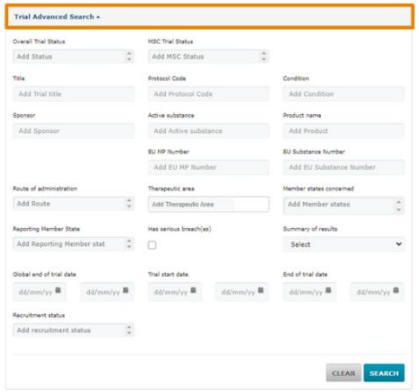
How to view, search and download activity

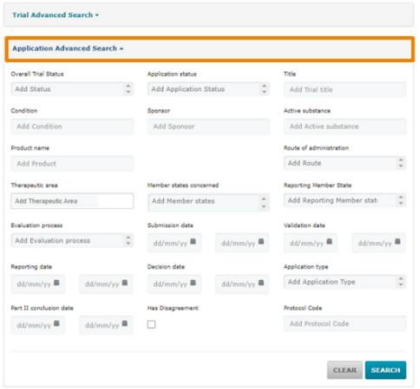
<table>
<tr><td>Use case 1</td><td colspan="3">A user with a scope of all trials is performing supervision activities in Germany. The user needs to open the initial CTA of a CT, the user only knows the EU CT number. What type of search would be best to retrieve the trial?</td></tr>
<tr><td>Possible Solutions</td><td>A
 

Basic search</td><td>B
 

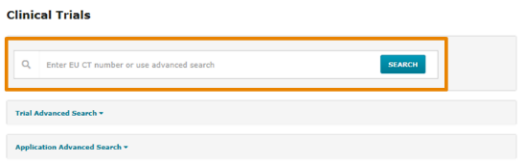
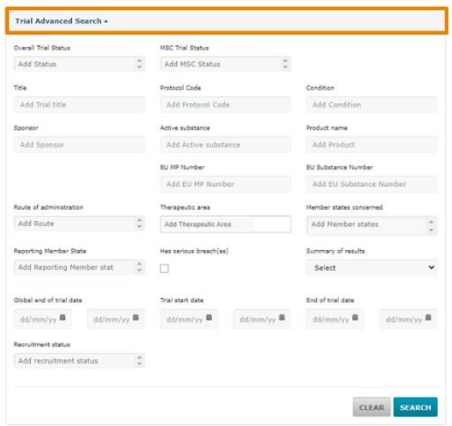
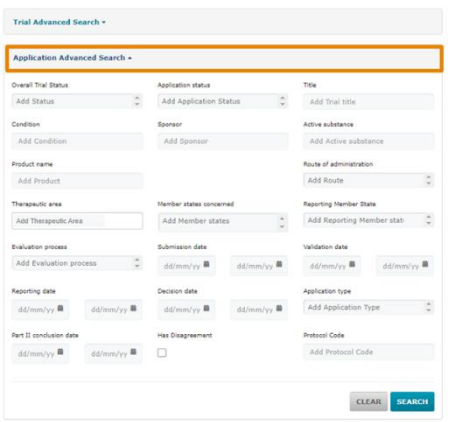
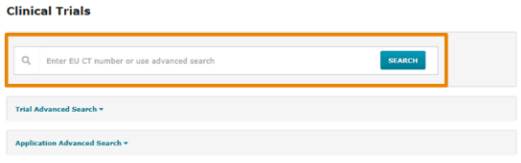
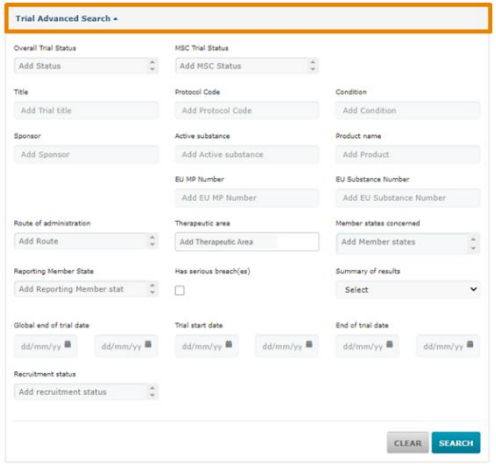
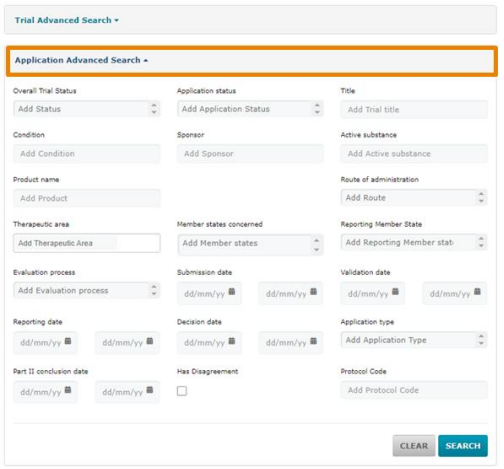
Trial advanced search</td><td>C
 

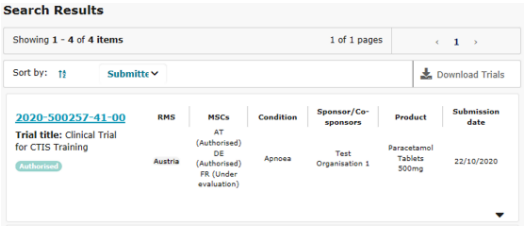
Application advanced search</td></tr>
<tr><td>Use case 2</td><td colspan="3">There are more than 500 trials being conducted in Poland. The user is looking for a trial for which he/she knows the following details: Poland is the only MSC, the initial CTA is authorised, and it was submitted in January 2020. What type of search would be best to retrieve the trial?</td></tr>
<tr><td>Possible Solutions</td><td>A
 

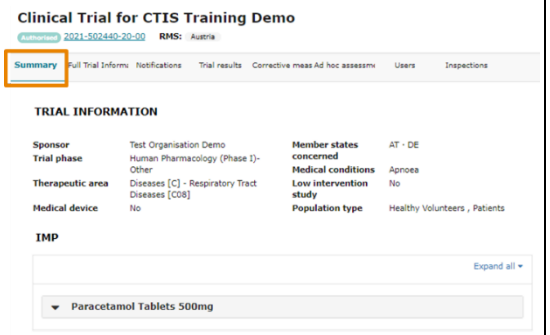
Basic search</td><td>B
 

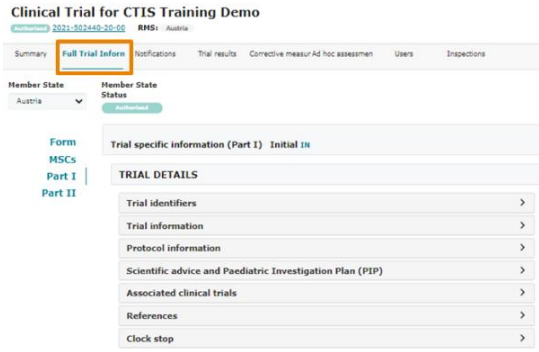
Trial advanced search</td><td>C
 

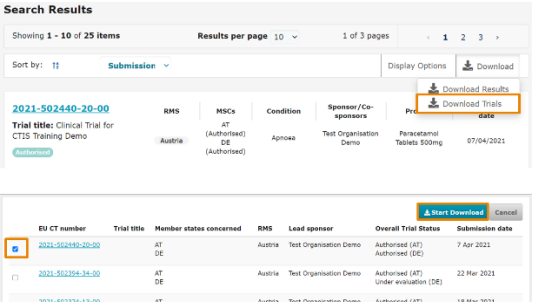
Application advanced search</td></tr>
</table>

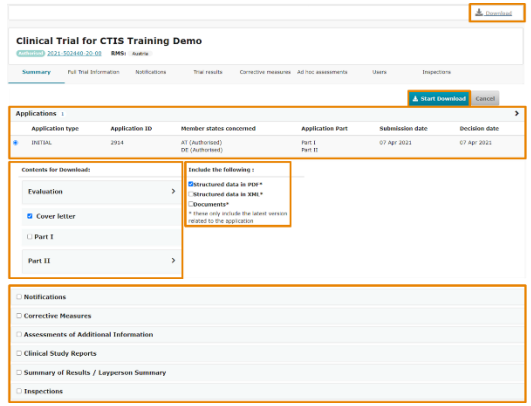
Use case 3	A user who has a supervision role with a scope of all trials wants to find a list of the 10 trials being conducted by the sponsor organisation named Virtualmedics Pharmaceuticals. **What type of search would be best to retrieve the trial?**		
Possible Solutions	A  **Basic search**	B  **Trial advanced search**	C  **Application advanced search**
Use case 4	An MS Admin user is looking for a specific CT but is unsure whether the other MSC is France or Spain. Also, the user is unsure about the recruitment status being either pending or ongoing. **What type of search is best to retrieve a list where this CT can be found?**		
Possible Solutions	A  **Basic search**	B  **Trial advanced search**	C  **Application advanced search**

<table>
<tr><td>Use case 5</td><td colspan="3">An MS admin wants to have a comprehensive look at all the relevant information about one CT (e.g. protocol information, objectives, trial duration, population of trial subjects, recruitment arrangements, etc.). Where can the user view all the CT information?</td></tr>
<tr><td rowspan="2">Possible Solutions</td><td>A
 

Search results list</td><td>B
 

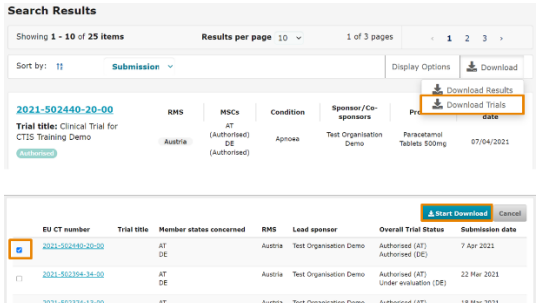
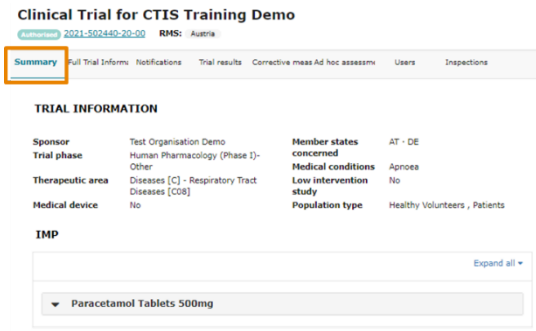
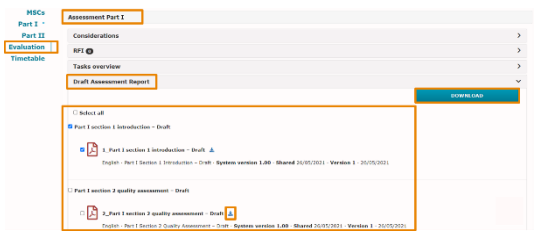
Clinical trial page
(Summary sub-tab)</td><td>C
 

Clinical trial page
(Full trial information sub-tab)</td></tr>
<tr><td>Use case 6</td><td colspan="3">An MS Admin needs to download all the documentation and structured data about one CT. From where should the user download all the CT data and documents in this case?</td></tr>
<tr><td>Possible Solutions</td><td>A
 

Search results list
(Download trials)</td><td>B
 

Clinical trial page
(Download specific CT sections)</td><td>C
 

Clinical trial application page
(Download specific documents of the CTA)</td></tr>
</table>

Use case 7	An MS Admin needs to download the Draft Assessment Report of the Assessment Part I of a CTA to perform supervision activities. **From where should the user download that document?**
Possible Solutions	A  **Search results list (Download trials)** B  **Clinical trial page (Summary sub-tab)** C  **Clinical trial application page (Evaluation section – Assessment sub-section)**

Solutions table

Case ID	Correct solution
1	
2	
3	
4	
5	
6	
7	

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Clinical Trials Information System (CTIS)

Instructor's guide: How to search, view and download a CT and a CTA (Authority).