June 3rd 2024

CTIS transition – Time is running out!

Do you have trials ongoing in the EU? Are you struggling with the clock as the deadline for adhering to the Clinical Trials Regulation (CTR) is approaching really quickly? Zwiers Regulatory Consultancy can support you with the transition to the Clinal Trials Information System (CTIS). Please allow us to explain in a few minutes why you can trust us to help you; just read below!

Adhering to the timelines and requirements for clinical trials transition

31st January 2025 is a crucial milestone for all Sponsors that are still running clinical trials in the EU countries that were approved under the umbrella of the Clinical Trial Directive (CTD). This date marks the end of a **3 year transition period** for the implementation of the CTR. However there are still several studies that need to be transitioned into the newly implemented system.

The above deadline is approaching and time is really running out considering that it can take **up to 3 months** for Member States (MSs) to complete the authorization procedure, despite an expedited procedure will be applied, if possible. The EMA has prepared several guidelines and training materials to support Sponsors in making the transitions and in discovering a new system to become familiar with.

Do you want to save time? We at Zwiers have the solution, as we already gained experience in working with the CTIS, managing the **submission of new clinical trials** under the CTR for a range of products and trials in various phases of development and submitting **substantial amendments** for already approved trial. So we are already familiar with the newly implemented procedures!

Starting with the definition of the proper timelines and documentation to be prepared, we:

- handle the preparation of the required documents,
- work on the redaction of the commercially confidential information,
- create the application on the system and perform the submission,
- are able to successfully manage the Request For Information (RFI) raised by the involved Authorities within the tight deadlines,
- and have obtained positive outcomes to let our Clients start with the planned clinical trials.

We have also already supported our Clients in **transitioning** multinational clinical trials, previously authorised under the rules of the CTD, to the CTIS. As there will be active sites in the EU as of 30th January 2025, we supported the companies in moving their applications to the new system, checking all the available guidelines to come up with the proper plan to handle the transition as smoothly and quickly as possible. To this end, we carefully checked the pre-requirements as they are crucial to avoid delays and hurdles to be overcame during the procedures.

We put all our efforts in making the difference and reaching the goals for our Clients, so why wait? **Time is now** to transition your clinical trials with Zwiers Regulatory Consultancy!

How can Zwiers and PLG help you?

Zwiers Regulatory Consultancy, a ProductLife Group company, includes a multidisciplinary team of scientists and regulatory experts with extensive expertise in the clinical development of new medicinal products and medical devices and decades of experience in interactions with Regulatory Agencies. Our team is ready to support you with the transitions and submissions of your trials via the CTIS. Therefore, we are a great partner for supporting medicine developers. We will leverage our expertise to help you to move forward with your clinical trials while adhering to the newly implemented Regulation.