CTIS: FIRST OPTIMAPHARM EXPERIENCES

AN INTERVIEW WITH SARA WEYTJENS

In recent years, CTIS has become a major topic of discussion in the field of EU clinical research. The implementation of this system has completely transformed traditional practices and had a significant impact on the way trials are conducted.

CTIS has presented new opportunities for making trials run more efficiently, bringing transparency to clinical studies, improving collaboration between stakeholders, and enhancing regulatory compliance.

However, the introduction of CTIS has also presented a number of challenges for industry professionals. In order to effectively utilize the system, they must have a deep understanding of its functionality, effectively integrate it with existing processes, provide training to staff members, ensure high-quality data, meet regulatory requirements, manage change, and effectively collaborate with vendors.

To gain insight into the first-hand experiences of implementing CTIS, we spoke with Sara Weytjens, Vice President of Regulatory and Site Activation at Optimapharm. Sara played a key role in the transformation of the Regulatory Affairs department into a Global Site Activation Unit, which encompasses regulatory affairs, start-up management, site contract and budget management, and green light package approval processes. Since January 2022, Sara has been working on preparing for the new Clinical Trials Regulation (CTR) while also obtaining the first approvals in CTIS.

Sara, could you please give us a brief overview of Clinical Trial Information System (CTIS) and explain its importance in clinical research?

On 31 January 2022, the EU Clinical Trials Regulation (Regulation (EU) No 536/2014) came into application harmonising the submission, assessment, and supervision processes for clinical trials in the European Union (EU).

The backbone of the changes brought about by the EU CTR is the new Clinical Trials Information System

(CTIS). CTIS is a single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data which includes a public searchable database for healthcare professionals, patients and the general public.
With CTIS, sponsors can now apply for authorisations in up to 30 EU/EEA countries at the same time and with the same documentation. Publication of the trial information is built in the system.

What are the critical steps involved in implementing CTIS within a clinical research organization, and what challenges can arise during the process?

The critical steps are having a good strategy in place with realistic timelines. The site selection process plays a crucial role in the preparation of the submission. Especially in case the strategy is to submit part I at the same time as part II documentation for all participating Member States. This is due to the fact that there is only one submit button in the CTIS system Obviously with the new way of submitting, we also had to adapt internally which roles were involved in which step of the process.
There are also new documents that need to be collected from the sites and not all stakeholders are used to these new templates yet.

The advantage of the CTIS portal that there is only one application done through the portal to all the Member States Concerned that are involved in the trial and that you get one decision per Member State based on the part I core scientific data dossier and part II the country-specific documentation.

Finally, there is more administrative work involved as certain documents that will become available to the general public need to be redacted, although this effort is reduced with the revised transparency rules that EMA published on 5th October 2023.

Can you explain how CTIS can enhance patient engagement in clinical trials?

CTIS can enhance patient engagement as patients have now direct access to the clinical trials being conducted within the EU by going onto the public part of the portal. All information that could be useful for them is available there.

What are the key benefits that sponsors can expect when implementing CTIS?

1. **Digitalisation and improved efficiency:** CTIS is a single portal with a single application dossier covering all involved EEA countries. The entire study lifecycle is covered by the platform: from initial application over yearly safety reporting, potential modifications until end of trial. All information is exchange electronically.
2. **Increased transparency:** patients, health care professionals and the general public can search for clinical trials information in the portal.
3. **Clear timelines:** once an initial application is submitted, there is a timetable available in the portal that shows all the different steps and timepoints during the review process.

Tell us more about first Optimapharm experiences with CTIS.

When I'm counting the submissions where we were responsible for part I, part II as well as submitting the trial, we have done more than 10 initial applications, submitted 2 substantial modifications and 1 transition trial. We are flexible in our services and have supported much more part II preparation work whereby we uploaded only those packages and the sponsor preferred to handle part I and to perform the submission itself within the portal.

What are the common challenges faced by CROs, sponsors and investigators in utilizing CTIS, and what strategies can help address these challenges?

The common challenges faced by all stakeholders is that this process is still fairly new, we just had the one-year anniversary. This means that not all sponsors, site staff and even agencies across the EEA countries are fully versed in using the new system. EMA, as well as the countries, are still updating guidelines, templates, and country requirements. As also the portal is still new, there are still bugs in the system. I can imagine that it will still take a few years for this to become the new standard and everyone is used to working with it.

How does Optimapharm approach training and support for staff members to use CTIS effectively in their daily practice?

We have written dedicated detailed SOPs & Working Instructions. Besides that, we have organised general training sessions as well as training sessions tailored to the audience so that each of our internal stakeholders have the right information as well as practical information on how to work within the CTIS portal where appropriate.

What advice or best practices can you offer to companies looking to leverage CTIS effectively in their clinical research operations?

Discussions in the best submission strategy for their project is key and should took place as soon as possible after the project is started, considering the overall impact, risks & timelines.