ARE YOU READY FOR EU CTR AND THE USE OF CTIS?

The EU CTR will come into effect on January 31, 2022 and will have a major impact on the organizations involved in the design and implementation of research with medicinal products in Europe. **Where is your organization in preparing for the implementation of the EU CTR?**

Check your status via the readiness checklist below. Mark your answer in the "YES" or "NO" column with a ✓ or x. Count the amount of answers answered with "YES" to get your total points.

Check your score...

Are you ready for EU CTR and the use of CTIS?

Yes	No	
☐	☐	Analysis of impact EU CTR on your processes / SOPs completed?
☐	☐	Analysis of impact EU CTR on your organization structure (roles + collaboration) completed?
☐	☐	Analysis of impact EU CTR on your systems (CTMS/ERMS) completed?
☐	☐	Analysis of impact EU CTR on Document management and Transparency completed?
☐	☐	Disclosure rules of CTR incorporated in company policies/SOPs?
☐	☐	Overview of # current trials created for CTD – CTR transition plan?
☐	☐	SOPs and working documents updated with EU CTR changes
☐	☐	3rd Party processes and operational model checked?
☐	☐	Templates of documents updated with EU CTR requirements?
☐	☐	Business process in place for the differentiation between documents for publication and not for publication?
☐	☐	Processes compliant with the EU CTR IMP Labelling requirements?
☐	☐	Deferral strategy / request procedure in place for public publication of trial related documents?
☐	☐	Process/agreements in place for the monitoring and answering of RFIs within 12 calendar days in CTIS?

More information or questions?
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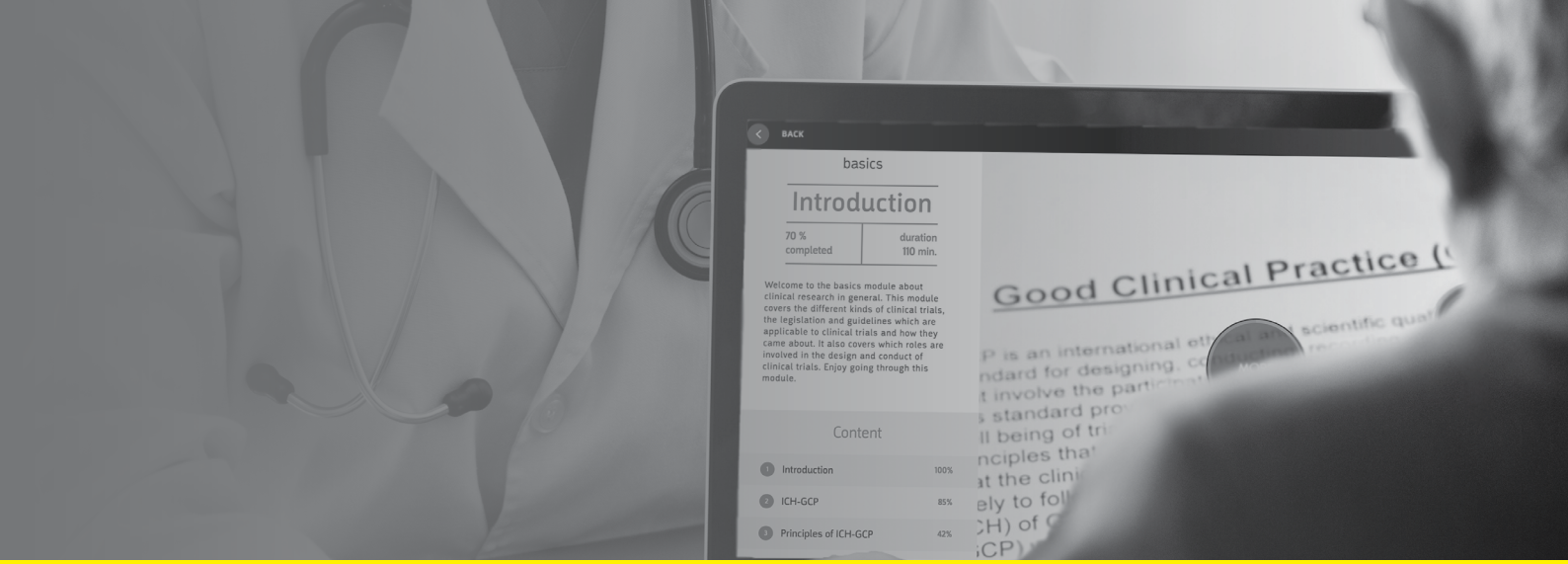

Are you ready for EU CTR and the use of CTIS?

Yes	No	
☐	☐	Operational model (organization centric vs trial centric) and support for end-users CTIS established?
☐	☐	Organisation registered in Organisation Management System (OMS)?
☐	☐	All products used in the trial(s) registered in EMA Product Database (XEVMPD)?
☐	☐	Are the required end-users of CTIS registered in EMA Account Management?
☐	☐	EU CTR and CTIS Implementation plan in place?
☐	☐	Plan for transition of current trials to EU CTR in place?
☐	☐	Strategy in place for submission of new trials during the transition period?
☐	☐	Date of first trial submission via CTIS decided?
☐	☐	Roles assigned to users in CTIS to manage CTAs, notifications, ASRs, Summary of results and CSR?
☐	☐	Have employees with CTIS roles completed the CTIS Training modules?
☐	☐	Are employees trained in their new / adjusted responsibilities and SOPs?
☐	☐	Simulation / pilot study done (in CTIS Sandbox or similar) to see submission flow in action?

Count the amount of answers answered with "YES" to get your total points.
Check your score...

Your score: .....

0	6	14	20	26
I just started (I might need help)	*I'm getting up to speed*	*I'm getting there*	*Almost there*	*I'm ready!*

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