To:
EUCROF Members
(National CRO Associations,
Associate Members and Partners)

15 January 2021

Invitation to become a member of the EUCROF Working Group (WG)
"Clinical Trials Legislation (CTL)"

Dear colleagues,

EUCROF, the European CRO Federation, was founded in 2005 and represents the voice of European CROs. One of its goals is to communicate with European and other regulatory bodies, such as EMA, EU Commission, the FDA or ICH. Following this mission, the CTL WG was founded in 2010 and has commented on a number of documents which were issued for public consultation. Some examples are:

- Guideline for good clinical practice ICH E6 (R2) (2016)
- Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol (2017)
- Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) (2017/2018)
- Guideline on the responsibilities of the sponsor with regard to handling and shipping of investigational medicinal products for human use in accordance with Good Clinical Practice and Good Manufacturing Practice (2018)
- eSource Direct Data Capture (DDC) qualification opinion (2019)
- ICH E8 (R1): General Considerations for Clinical Studies (2019)
- ICH-E19: Optimisation of Safety Data Collection (2019)
- Guidance on the management of clinical trials during the COVID-19 (Coronavirus) Pandemic (2020)
- Guideline on registry-based studies (2020)

I would like to encourage you to join the WG as there are challenging times ahead of us, for example, regarding the EU Clinical Trials Regulation 536/2014 which will finally become effective at the end of 2021. Supporting Guidelines will be on their way which will need input from the stakeholders.

The benefit to be a member of the CTL WG is certainly to have the international exchange of thoughts, to be on the ball and to receive the opportunity to attend meetings in case stakeholders are invited by the regulatory bodies to discuss. There are no cost implications – EUCROF is able to finance trips to internal WG meetings, to the EMA and EU Commission or wherever the meetings might be held. As we all know, meetings will be held online for the foreseeable future.

We realize that being a member of the CTL WG is a demanding task at times, but it gives us the opportunity to contribute to future clinical trial legislation and that is an opportunity we must not miss.

If you are interested in reading, discussing and contributing to future clinical trial legislation, please contact me directly via my email address: (dagmar.chase@clinrex.com). Please understand that we are only interested in active WG participants, meaning that we count on your valuable contribution.

If you have any questions, please feel free to contact me at any time.

I am sending my best regards,

Dagmar Chase
Chair of the EUCROF Clinical Trial Legislation Working Group (CTL WG)

More information on EUCROF: www.EUCROF.eu

Clinrex Munich
Dr Dagmar Chase

Post box 1223
D-85572 Neubiberg, Germany
Phone + 49 (0)89 930 54 48
Mobile + 49 (0)172 853 63 38
Email dagmar.chase@clinrex.com
Internet www.clinrex.com