Join your local peers from the pharmaceutical and biotech industry for breakfast along with an educational and practical exploration of electronic Clinical Outcomes Assessments in clinical research in Copenhagen, Denmark in October 2018. ERT and a panel of sponsor experts will cover the current and future impact of “Bring-Your-Own-Device” trials, lessons learned and future implications from successful eDiary trials. They’ll also engage in a debate over the trade-offs between paper and electronic Patient Reported Outcomes (PRO) data collection.

EVENT DETAILS & REGISTRATION

Date: October 23, 2018

Time: 9:00am–12pm

Location:
Crowne Plaza Copenhagen Towers
Ørestads Boulevard 114-118
DK-2300 Copenhagen S
Denmark
www.cpcopenhagen.dk

Register now at ert.com/ecoa-seminars

AGENDA

8:30 – 9:15 AM — BREAKFAST

9:15 – 10:00 AM — PRESENTATION

LESSONS LEARNED FROM eDIARIES & THE IMPACT ON FUTURE eCLINICAL TECHNOLOGY ADOPTION

Valdo Arnera
MD, Scientific Advisor, ERT

Overview: In clinical research, more so than in other industries, the past helps us to better predict the future. Which future technologies will completely change the way we perform clinical trials? The adoption of eCOA technology 20 years ago, which allowed clinical trial patients to record assessments and symptoms electronically along with objective measures generated from medical devices and wearables, allows us in many ways to
predict which future technologies will be adopted and why.
Participants will:

- Learn how eCOA — a once-upon-a-time “new technology” — was started, adopted, and where it stands today, including success stories and lessons learned
- Understand the criteria for new technologies to be successfully adopted, including better quality data, convenience for the patient (“patient-centricity”), regulatory authorities buy-in and more
- Delve into the dynamics of patient and site education and training that influence the acceptance and understanding of the benefits of new technologies
- Explore several examples about new initiatives aimed at defining which new technology endpoints should be considered in future clinical trials and why

10:00 – 10:45 AM — PRESENTATION

BYOD – THE CURRENT STATE OF PLAY & FUTURE POTENTIAL

Chris Watson
PHD, Director of Product Strategy – Digital Patient, ERT

Overview: Electronic clinical outcomes assessments (eCOA) are no longer just about patient diaries. With recent technological advancements, eCOA has become a valuable tool that helps sponsors gain greater insight into patient experiences during clinical development — especially in site-less trials. Chris will share Bring-Your-Own-Device (BYOD) and flexible provisioning success stories, and demonstrate why sponsors need to incorporate this approach into study protocols and post-marketing evidence programs. Learn how a BYOD approach to eCOA, coupled with wireless integration with mobile medical devices, open up a whole new world of data collection options for trial sponsors, sites and patients. Participants will:

- Learn what’s really meant by “eCOA”, “BYOD” and “flexible provisioning”
- Discover how FDA, EMA and regional regulators view BYOD data
- Review considerations for BYOD — technical, operational and regulatory dimensions
- Understand how to select a study for BYOD — what should you do to be comfortable with when introducing BYOD to your studies?
- Explore the future of BYOD and what to expect

10:45 – 11:00 AM — BREAK

11:00 – 11:45 AM — PANEL DISCUSSION

CHOOSING TO IMPLEMENT PAPER VERSUS ELECTRONIC IN COA STUDIES

Speaker Panel:

Ane H. Jensen
Senior e-Source Data Manager, Novo Nordisk A/S

Vesna Malmberg
Clinical ePRO Manager, Ferring Pharmaceuticals

Anders Mortin
Consultant, Co-founder at TriTicon

Valdo Arnera
MD, Scientific Advisor, ERT (Moderator)

Overview: In this panel discussion, we will explore the fundamentals of paper and eCOA trials and discuss how sponsors and CROs of all sizes can cost-effectively reduce risk while generating higher-quality data in their next study. Participants will:

- Discuss the trade-offs of paper vs. eCOA in data quality, patient safety and visibility into study trajectory
- Share the impact on study timelines and costs, patient engagement and on integration with other data sources
- Explore the myths and truths behind the statement: “Implementing eCOA is expensive and cumbersome”

11:45 AM – 12:00 PM — CLOSING REMARKS

For questions or help with registration contact Jillian Tygh jillian.tygh@ert.com

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