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:

- 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

REGISTER NOW AT ert.com/ecoa-seminars