Trends in EDC

Wednesday 25-JAN-2017
Clinical trials session – Advancements in clinical research
Bart Segers
Disclosure

Speaker name:
Bart Segers

I have the following potential conflicts of interest to report:

Co-founder and stockholder of a CRO:

• GENAE ASSOCIATES NV

Co-founder and stockholder of a Digital Health Data company:

• HILBERT PARADOX NV
Electronic Data Capture (EDC)

- A computerized system that collects clinical data in an electronic format.
- Mainly used for clinical trials.
- Replaces paper-based data collection.
- Widely adopted by pharma and CRO’s.
Trends in EDC

• Despite eCRF dynamics, EDC is mostly conducted in a traditional working environment.
• WiFi and eMobility on the move.
• New devices affect the way online EDC software has to be built.
Future of EDC

Further include efficiencies that previously would have sold as separate software solutions:

• Clinical data management systems (CDMS).
• Clinical trial management systems (CTMS).
• Business Intelligence, Analytics and Reporting.
• Integrate payment execution.
• Electronic Medical Records (EMR) integration.
AI

- Applied & General AI
- Machine Learning (ML), Natural Language Processing (NLP), Image Recognition, Neural Networks
Break down the data silos
General Data Protection Regulation

- Understanding the GDPR is first step to compliance.
- Designed to enable individuals to control their personal data.
- Reduce regulation.

KEEP CALM AND PREPARE FOR THE GDPR
Background and timelines

European Commission publishes the legislative proposal
Separate negotiations within Council and European parliament
EP reaches agreement
Negotiations and approval among the three institutions
Adoption of the Regulation
Two years implementation phase
Regulation starts to apply

2012
Spring 2014
2015
24-May 2016
2016
2017
2018
25-May
1. Harmonization in and beyond the EU. Data Protection Agency (DPA) requirements will be the same for all member states.
2. Collecting data about EU citizens requires compliance with the GDPR. Consider using a global CRO / EDC provider with physical presence in EU and non-EU countries.
GDPR highlights

3. IP addresses and cookies are personal data. There is no distinction between private, public or work roles. The person is the person.
4. New regulation imposes data protection obligation to the data processor (CRO/EDC provider). Only 6% of cloud providers comply with GDPR today. **Source:** Skyhigh Networks survey 2016
Summary

• EDC remains a cautious technology adopter,
• merges efficiencies from other software solutions,
• eMobility and AI are on the move,
• the regulatory framework and our mindsets permitting...

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