

Experience from a site perspective with clinical trials

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Disclosures

- Investigator in several multicentre/singlecentre studies
 - AdaptResponse; Medtronic, *Minneapolis, USA*
 - CARAT, Respond, Syncro; LivaNova, *London, UK*
 - NOAH – AFNET, Daichii Sankyō; *Tokyo, Japan*
 - Upgrade, Boston Scientific; *Malborough, USA*

Agenda

- Personal experience
- Inhospital situation
- Reasearch studies
- Why to use EDC?
- Possibilites for improvement

Working with EDC Systems

- Already several years – engaged in several studies and registries
 - Many different systems
 - Omnicomm TrialMaster
 - Marvin
 - Oracle RDC
 - iMedidata
 - Responsible for data acquisition and entry into eCRFs

The inhospital situation

- Work at the hospital is stressful
 - Many patients – little time
 - Madness of bureaucracy
 - In universities additional workload – science
- Data entry into eCRFs when off duty

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Concerning EDC it is **THAT MOMENT** where the wheat separates from the chaff!

Just a little impression...



Research studies

- After the guidelines is before the guidelines
 - New studies conducted to gain knowledge about diseases/diagnostic options/therapeutical decision-making
 - Multicenter studies the heart of guidelines
 - Best level of evidence
 - Less possibilities of bias
 - Progress of medical care

Level of evidence

Level of evidence A

Data derived from multiple randomized clinical trials or meta-analyses

Level of evidence B

Data derived from a single randomized clinical trial or large non-randomized studies

Level of evidence C

Consensus of opinion of the experts and/or small studies, retrospective studies, registries

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Nothing new – why to use EDC?

- Number of studies using EDC continuously increasing
- Classic CRF systems are getting obsolete
 - Velocity
 - Less paperwork
 - More structural order

Nothing new – why to use EDC

- Studies becoming more complex (3 M's)
 - More patients
 - More sites
 - More investigators
- Expenditure of time is increasing
- Classic CRF methods remain as option for smaller/singlecenter studies

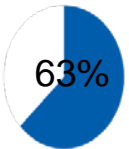
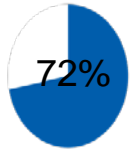
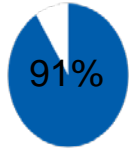


Improvement still possible?

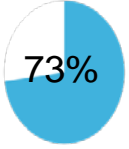
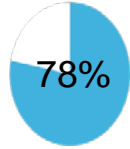
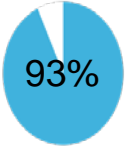
1. Efficiency
2. User friendliness
3. Data security
4. Interdisciplinary approach



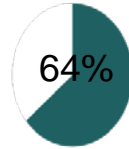
All EDC Systems



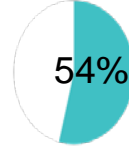
OmniComm TrialMaster



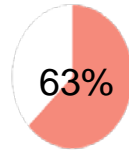
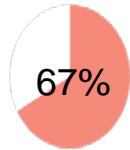
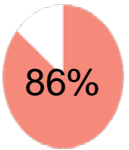
Medidata Rave



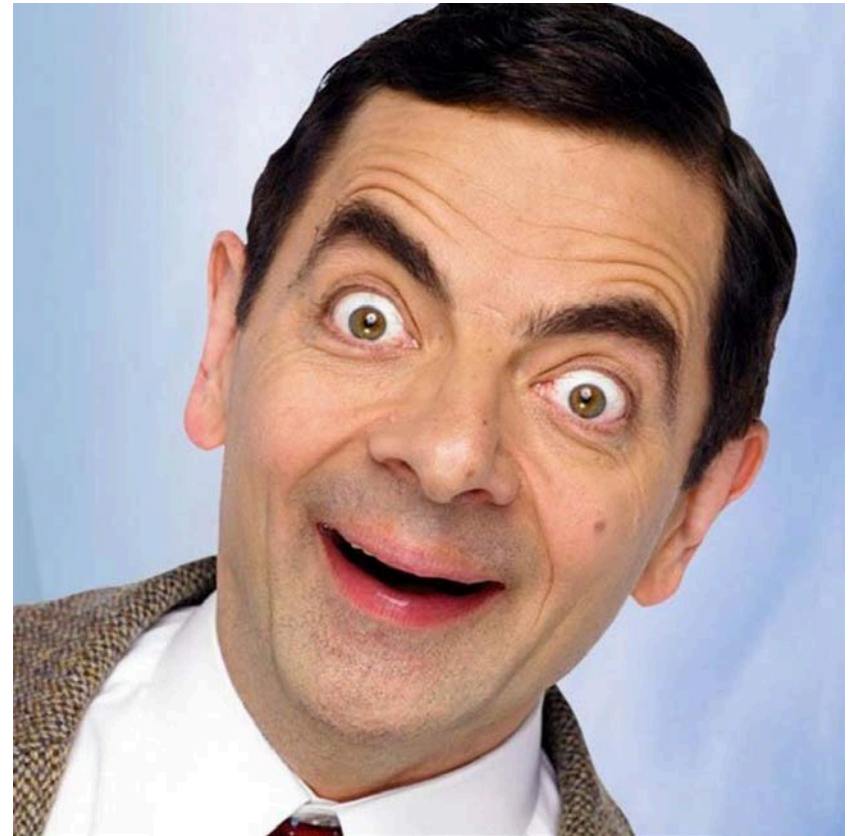
Oracle Inform



All Other EDC Systems



Who is actually the user?



User friendliness

- Stay simple – Ease of use
- Self-explaining – Intuitivity
- Fast communication with corresponding research personal
 - To solve queries more quickly
 - For correct data entry

User friendliness

- Provide demos prior study initiation visit
 - eLearning videos draw less attention
 - Learning by doing approach
- Especially for larger studies
 - Q & A section (FAQ) additionally to customer service might help

Efficiency

- Fast data entry should be possible
 - Leads to higher productivity
 - Less delay in data entries
 - Studies more likely to remain on schedule
- No waiting time – no loading delays
- Dependable

Data security

- Keep up standards for data security
- Data security means respect for privacy of patients participating in trials

Interdisciplinary approach

- It is not only up to you!
- Seek interactivity with users
- Physicians/investigators also have room for improvement
- Together it is easier to find solutions than alone

Conclusion

- Reasons why investigators like to work with EDC systems
- The inhospitable situation
- Why do we conduct studies?
- What does the user look alike?
- EDC systems already reached a high standard
- Small improvements still possible
 - To find these look for an interdisciplinary approach



Thank you!