Abstract Template

Project title: The cost implications of conducting a risk assessment prior to developing a monitoring plan for a multicentre clinical trial: The TRUST Thyroid Trial experience

Institution: University College Cork

Project details (max 250 words)

Background: Traditional trial monitoring approaches rely on extensive on-site visits and source data verification. These activities are associated with high cost and limited contribution to data quality. Risk-based monitoring (RBM) has the potential to reduce cost and improve data quality. Risk assessment is central to the development of a RBM plan but the effectiveness and efficiency of conducting a risk assessment prior to developing a clinical trial monitoring plan is unclear. Therefore the aim of this project is to cost and evaluate the process of conducting a risk assessment prior to developing a monitoring plan for the TRUST trial. TRUST is an EUFP7 funded clinical trial in Ireland, UK, Netherlands and Switzerland that recently completed recruitment.

Methods: Cost effectiveness analysis (CEA) will be performed using standard methods.

- Intervention: Countries (UK, Netherlands) with risk assessment prior to developing monitoring plan
- Comparison: Countries (Ireland, Switzerland) without risk assessment prior to developing monitoring plan
- Outcome: Data queries
    1. Costing: Cost of performing risk assessment vs. not performing risk assessment
    2. Micro-costing of staff time to complete tool
    3. Cost of risk assessment tool
    4. Monitoring costs = number and cost of on-site visits
    5.

Conclusion: This project will be registered on the SWAT/SWAR Repository and has the potential to impact on the design and conduct of clinical trial monitoring in Ireland and internationally by providing evidence on cost-effectiveness of RBM.

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