CRO Insights and Experiences: How to solve challenges on the implementation of DCT elements in clinical research

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Joint session between ACRO and EUCROF

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Points for consideration

CYBERSECURITY - GDPR

- Patient Safety
- Data Protection
- Quality of data

HYBRID STUDIES – DATA HETEROGENEÏTY

Topic 1

- Regulatory harmonization

DCT elements that are implementable in some countries and regulatory jurisdictions but not in others:

- Electronic Informed Consent & Electronic Signature
- Telehealth visits
- Home Health (Nursing) Services
- Direct to Patient Shipment of the Investigational Medical Product …

Can some hybrid DCT elements be deployed in some countries and not in others under the same protocol? And for those countries in which DCT elements are not deployable, can we deploy traditional/in-person approaches under the same protocol?

Will this point be addressed in the recommendations in preparation ? Is it possible to implement some harmonization process & how ?

Topic 2

- Site readiness

DCT is having multiple impacts on how clinical research is carried out in Clinical Sites:

- Multiple sponsors with multiple technologies to be implemented …
- Some technologies may be highly site dependent : EMR, telehealth visits systems …
- Sites may not accept some of the suggested options ?
- They may require upgrades both from technical and organizational standpoint : e.g. for rSDV giving access to the EMR system of the hospital and only to the "need to know" patient records …
- Interoperability between CR systems and HIS software ?
- How to handle DPIA in certain situations ?

We witness the development of "proof-of-concept" approaches with sponsor / sites / CROs partnerships…

What would be EMA's recommendations on such issues ? How shall sponsors (academic and private) handle such heterogeneous situations ? Is this point addressed ? Shall we envisage some specific action plan ?

Topic 3

- Data Protection

The EU GDPR regulation is often perceived as an "inhibitor" for the adoption of innovation as it introduces new concepts for which there are different perceptions and obligations to sponsors and sites (DPIA, processes registries …)

To our view, it is an **innovative regulation** that shall facilitate the adoption of technological and organizational innovations for DCTS :

- Articles 40 & 41 of the General Regulation foresee the implementation of **codes of conducts** in domains with specificity, as well as other mechanisms (certifications …)
- The regulator provides to the stakeholders a unique opportunity to **co-build the regulation**
- A **cooperation mechanism** to create the conditions of a **harmonized landscape** throughout the 27 EU Member States
- Through the Process / Controller / Processor new concepts, contribute to better define responsibilities & mitigate cybersecurity risks and foster transparency and trust

Should Data Protection issues be left outside of the domain, and the opportunities offered by GDPR codes of conduct (or other approaches) could at least be mentioned and related initiatives supported…

Other topics for further discussions

- ## Protocol flexibilization / Hybrid situations

  Is there a way from the regulatory viewpoint to allow patients to change in-person versus remote visits during a DCT randomly and at their convenience? Or must patients commit to one way of participating in a DCT either remote or in person as dictated by the protocol?

  Can differences in the adoption of DCT tools & methods among sites be allowed in a the same trial ? Etc …

- ## Responsibility / role of local HC providers versus DCT personnel

  When is a local healthcare provider considered part of the DCT personnel? When is a local healthcare provider just that and not part of DCT personnel? How are responsibilities split between investigator and home nurses" ?

  Shall we reassess the scope of responsibility of the hospital investigator: keep the supervision of the study to the investigator, but limit the responsibility for homecare to the homecare healthcare professionals

EUCROF relevant activities

https://www.eucrof.eu/news-eucrof/publications
https://cro.eucrof.eu/eucrof-code-public-registry

- Electronic Informed Consent Implementation Guide – March 21
- Propositions Paper on Remote SDV/SDR (endorsed by EFPIA - 2 June 22)
- EUCROF GDPR Code of Conduct for Service Providers in the 27 EU Member states

➔ *Create the conditions of trust & confidence to foster innovation for better care with appropriate patient involvement*

- Implementing Decentralised Clinical Trials in Italy (June 2022)
- Recommendations on DCTs by FR Working Group …

Thank you for your attention!

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