Harmonization issues for trials in rare gynecological cancers

GCIG Rare Tumors working group

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STATEMENT

- Small number of patients affected means small number of patients available for clinical research
- Need for international clinical trials, international cooperation and Intergroup studies

➔ Many methodological, regulatory , organisational and harmonization challenges

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Organisational and Harmonization issues

- What are these issues ?
- Are there possible solutions to get around these issues?

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Identification of issues

- Multicenters, multicountries, multicontinents trials
- Many countries ➔ many legislations : EU legislation versus US legislation versus Asian
- Small number of patients BUT large number of centers
- Long period of recruitment
- And…

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NO (or very limited) BUDGET !!!

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Need to be creative :

- Simplify the protocol and CRF
- Adapt the monitoring
- Adapt the SOPs (use +++ the existing GCIG harmonization documents)
- Reduce the administrative tasks
- Build efficient processes for patient referral
- Share some tasks between groups

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Simple protocol, simple CRF

- Simple study design
- Clear inclusion and exclusion criteria
- Simple flow chart = should stick to standard of care (no extra cost, no extra exam)
- Simple CRF : agreement on common data elements for rare tumours, minimal amount of data
- E-CRF with a flexible structure (easy to amend if necessary)

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Adapted monitoring

- Centralized rather than on site
- Data quality checks through the e-CRF
- Initiation visits by phone or webex
- Communication with the site by phone or email
- « audit » on site if suspected quality issues

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Adapted SOPs

- Use the existing GCIG harmonization documents
  - Importance of the Intergroup Agreement
    - Ex 1 : Clear cell carcinoma study (JGOG) : participation of France GINECO + SGCTG
    - Ex 2 : mEOC study (MRC)
  - Country specific Appendix to protocol
  - Template for translational informed consent form
- Each country responsible for insuring its sites according to national laws

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Find efficient processes for patient referral

- Option : to build a network of reference centres for rare gynecological cancers
- Example of France could be extended to other countries and continents

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3 national reference centres and 22 regional centres (clinicians + pathologists as experts)

Centres experts cliniques & pathologiques

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Reducing admistrative tasks

- To open the sites only when a patient is in screening
- To minimize the number of documents to be signed with sites
  - Protocol
  - Contract

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Sharing some tasks between groups

- The leading group can share some tasks in order to share the costs :
  - Pharmacovigilance
  - Stat
  - E-CRF
  - Others…

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Conclusion

- To lighten as often as possible the operational processes in order to decrease the budget
- To be based on the Intergroup Agreement
- To facilitate the constitution of a national network of reference centres
- To share some tasks between groups

➢ And we will be able to succeed !

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