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WHAT TO CONSIDER WHEN DECIDING TO PARTICIPATE IN A TRIAL AS AN INVESTIGATOR

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Key Points

- Before, during, and after the trial
- Scientific interest
- Commitment
- Accrual
- An adequate team
- Quality

DISCLOSURES

- Jean-Yves Blay reported to have received research support from Roche, Novartis, GSK, Lilly and MSD
- Emiliano Calvo reported no conflict of interest

BEFORE THE TRIAL: SCIENTIFIC VALUE FOR THE INVESTIGATOR

- An important scientific question
  - Limited time for non crucial questions
  - Practice changing
- Inserted in a global professional project
- A team project with other investigators of the trial in other centres
- When relevant, inserted in a long term commitment as contribution to an academic network
  - e.g. EORTC, organ tumour network,…

BEFORE THE TRIAL : SCIENTIFIC VALUE FOR THE CENTRE

- Commitment of the centre to the scientific topic
- Identify the team project on the research site
  - other co-investigators
  - CRAs
  - Contracting Department
  - IRB
- Consider accrual and how to manage it
  - Local
  - Referral
  - Other

BEFORE THE TRIAL: BUDGET

- Needs to be analysed carefully and very early
- Financial feasibility of the trial on site?
- What are the costs to conduct the trial on site?
- If not fully covered, which are:
  - The sources of co-financing?
    - Dependent Country and Centre
    - Is the trial a scientific priority for the site?

BEFORE AND ALONG THE TRIAL : COMMITMENT OF THE INVESTIGATOR

- Time dedicated to the trial
  - Administrative activities to be piloted by the local PI
  - Establishing contract with relevant timelines
  - IRB
- Consider other competitive trials
- When activated
  - Accrual
  - Time to dedicate to follow up, meetings, monitoring
  - Connecting the trial procedures to the SOP of the centre
- After completion
  - Audits
  - Publication

ASK YOURSELF

- Feasibility with other commitments?
- Adequate time to deliver good quality research on site?
- Commitment for the long term?
- Is the trial important enough to be worth the effort?
- Be selective: say no to low-priority trials

BEFORE, DURING AND AFTER THE TRIAL: GOOD CLINICAL PRACTICES

- Regularly updates for you and your team
- Monitor the training of your co-investigators and CRAs
- Ensure the documentation of the trial training for all participants
- Entry/exit dates of investigators, CRAs,…

DURING THE TRIAL: ACCRUAL

- Must be significant
- Strategy established before
  - Local, networks…
- Accrual carefully monitored during the trial
- Adapt the team if slow accrual, or too rapid accrual

CURRENT TRENDS IN CLINICAL RESEARCH

- More administrative work
- More time pressure
- Document all actions
- Fragmentation of nosologies
  - More small trails
  - Each small trial requires a similar amount of work
- Basket trials the next models

CONCLUSIONS: WHAT TO CONSIDER WHEN DECIDING TO PARTICIPATE IN A TRIAL AS AN INVESTIGATOR

- A long term commitment
- For your institution, yourself and your team
- Ensure on time delivery
- Quality at all steps
- Reactivity and adaptation in case of unexpected events
- Communication with the team, the group, the CRO (Clinical research organisation), the pharma

THANK YOU!

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