

Learning points Ethical comite Pilot study

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Timing Fase 1 is short for EC

We received the pilot study in the summer holidays and had to consult within 10 days :

- A statistician
- An hematologist
- A doctor of nuclear medicine
- Organise a meeting with the EC
- Having two seperate meetings with the secretary
- Holidays are difficult to contact all experts needed

Be accurate in cover letter :

version – date – main study -expansion

- ICF : dose escalation, dose escalation imaging, pharmacokinetic evaluation research project
 - ICF :expansion, expansion imaging, expansion pharmacokinetic evaluation research project,
 - ICF : data collection on pregnancy and birth, declaration of objection after withdrawel of consent
 - Hygiene guidelines
 - Info for family and friends
- The EC reads one language of the ICF, the translation dates were different

Check the quality of the ICF translation before submitting

- The EC reviews the ICF in its native language. It remains the sponsor's responsibility to transfer proposed changes also in the other languages.



Answer unambiguous to the RFI

- Provide a very clear, complete and unambiguous answer to the RFI as there is only one round of questions



Limit the number of modifications

- Only submit when complete
- The EC is independant of the clinical trial sites so a good communication of all modifications from the sponsor to the sites will become even more important.



Collaboration EC's

- Within our hospital network there will be a collaboration between the 3 EC's to have more clinical experts available.

