

Feedback on the CTR pilot project

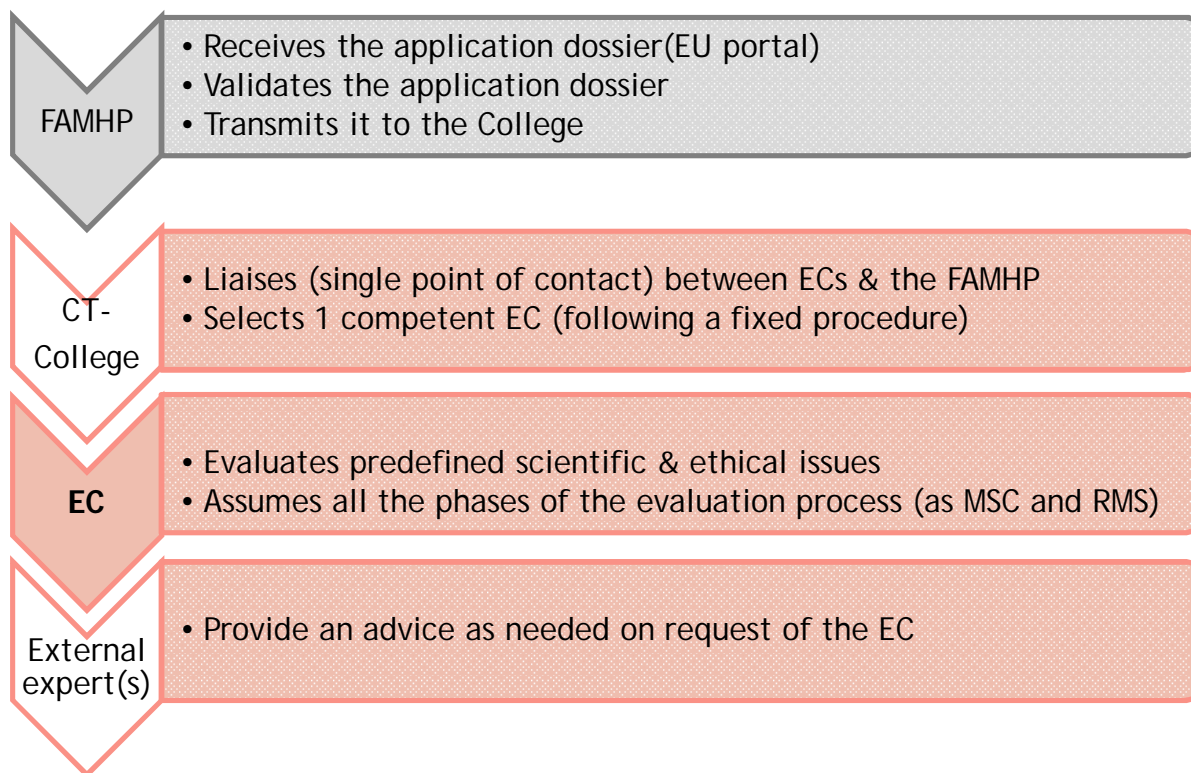
CT-College point of view

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The ethics assessment (new procedure)



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Some major changes for the Ethics Committee (EC)

- Independent federal College created within the FPS Health, Food Chain Safety and Environment. => single point of contact
- EC is indepent from the participating trial sites
- No direct contact with the Sponsor anymore
- Only 1 EC involved in the assessment (versus current system with central and local ECs)
- The use of an assessment report template (part I + II)
- Only 1 round of questions

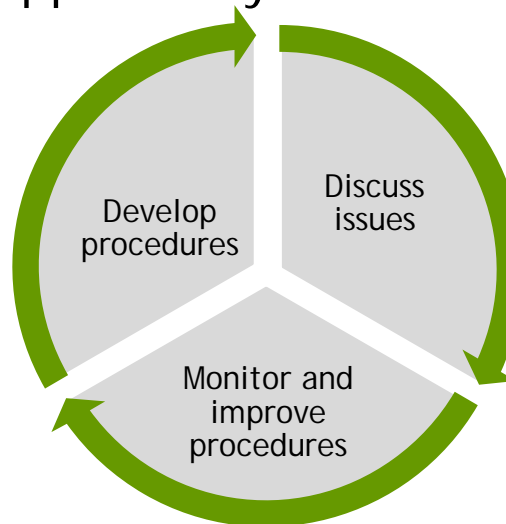


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Change is a process, not an event

- Pilot projects: unique opportunity for learning by doing

- Working group:
 - FAMHP
 - CT-College
 - EC



- CT-college organises frequent information sessions for all ECs (19) involved in the pilot project



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Challenges pilot project (1) (point of view CT-College)

Preparation of the application dossier:

- Involvement trial sites: written statement on their suitability
 - *Important for the evaluating EC*
 - *Template provided*
- Change of planning necessary?



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Challenges pilot project (2) (point of view CT-College)

- Major changes in ethical review process => process of change
- Communication with FAMHP and ECs is very intensive (resources and time) as the portal is not yet available and everyone is still learning
- ECs & sponsors are not familiar with 1 round of questions + only 12 days to answer them

keep in mind there is only "1 shot" when preparing & answering the questions



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Feedback received: procedure local ECs not always clear

- In new procedure only 1 EC evaluates the application file
- Local ECs informed:
 - In general:
 - ✓ *information sessions (BAREC,)*
 - ✓ *Website expected soon*
 - For every pilot dossier the CT-College keeps all local ECs informed:
 - ✓ *Upfront*
 - ✓ *Application dossier*
 - ✓ *Decision*

Sponsor does not have to submit to the local EC



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Results of the surveys completed by ECs

- Too much administration, cumbersome procedure => should be better after implementation of the portal
- Learning curve: optimisation of the procedures/templates
- Very good way to gain experience
- Positive feedback on communication (CT-College-EC)



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Conclusion pilot project (point of view CT-College)

- Some challenges, but overall a positive impression
- Very efficient way to gain experience by all stakeholders

CT-College would like to thank:

- Sponsors
- ECs and BAREC
- FAMHP colleagues

for their participation to the pilot project and for the intensive and constructive collaboration

