

EUFEMED Webinar

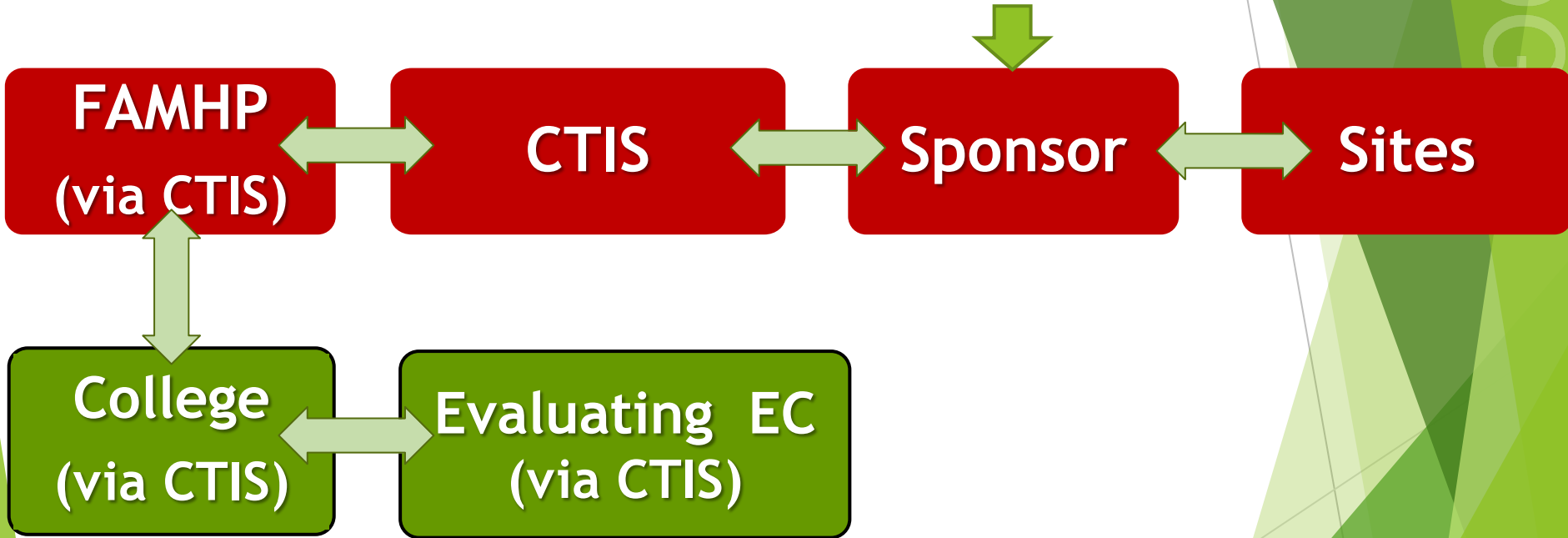
CT College

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Organization of ethical review in Belgium



College

Independent federal body (FPS of Health)

Administrative Staff + BOARD of experts (physicians, lawyers, experts in quality)

Role of the College :

- Single contact point for FAMHP and Ethics Committees (EC)
- Selection of EC in charge of evaluation
 - Objective criteria defined by legislation
 - Cannot be the EC of the study site(s)
- Ensure a consistent application of the legislation by the ECs
- Coordination, harmonisation, support, evaluation and follow-up of the quality control activities carried out by the ECs



College does not take part in the evaluation of dossiers

The assessment of the CTA

AR = assessment report

Part I of the dossier :
Clinical, statistical, quality

Part II of the dossier :
Ethical and national aspects

