# **EUFEMED Webinar**

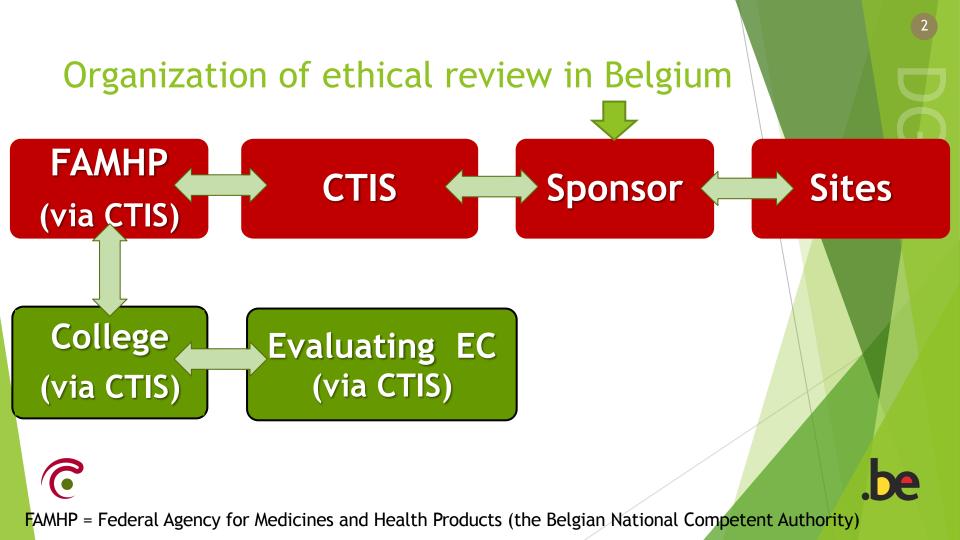
**CT College** 

ir. Sébastien Vanhiesbecq









## 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 followup of the quality control activities carried out by the ECs





### **Ethics Committees**

#### **Ethics committees with 2017 recognition**

15 ECs recognized under the law of 7 May 2017

list available at website of the CT-College: <a href="www.ct-college.be">www.ct-college.be</a> > sheet Legislation

#### **Communication with the Ethics Committees**

In order to guarantee an independent evaluation of the CTAs, the Sponsors are not allowed to communicate with the evaluating Ethics Committees or the College.

FAMHP (NCP) is the only contact point for the Sponsors!





### 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

