

# Experiences from the CTR pilots and VHP Plus procedures

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# CTR Pilot – UZ Leuven acts as sponsor

- Single submission
  - Single point of contact
  - Informing participating sites
- Initial submission vs. amendments
  - Initial/Substantial modifications: clear communication
  - Notifications/Annual reports/End of Trial: no confirmation
- CESP: learning curve

# CTR Pilot – UZ Leuven participating center

- Sponsors/CRO to inform sites
- Less involvement in the submission process
  - Single point of contact receives approval  
(no direct written approval for the participating site)
  - Not possible to consult status - difficulties to prepare site for first patients
  - Safety events
  - Amendments can be submitted without involvement of the site

# VHP Plus

- Goal: Harmonisation and uniformity
  - Process unclear
  - No information about timelines
  - No involvement of the site
- Lack of knowledge and experience in academic setting

# Conclusion

- More involvement in submission process
  - Consulting status?
  - Notification initial submission and amendments?
  - Access CTIS?
- Need for training
  - Academic sponsors
  - Participating sites