



UZ
LEUVEN



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