



# **EXPERIENCES FROM THE CTR PILOT PROCEDURE**

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# INTRODUCTION



# Advantages



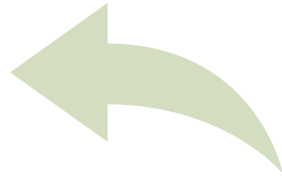
Clear guidance and  
templates



Combined CA/EC  
application



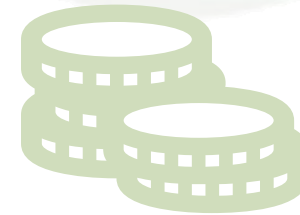
Easy and fast  
submission via CESP



Simultaneous feedback  
by CA and EC



Clear timelines for each  
step in the process



No regulatory fee



# Advantages



## Clear guidance and templates

- Structure of the submission dossier
- Templates to use

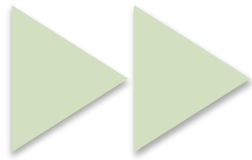


## Combined CA/EC application

- Reduction of effort & time



# Advantages



Easy and fast  
submission via CESP

- Portal



Simultaneous feedback  
by CA and EC

- Feedback from both sides  
can be combined into one  
answer

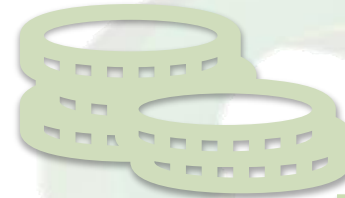


# Advantages



Clear timelines for  
each step in the  
process

- Theoretically easy to plan



No regulatory fee

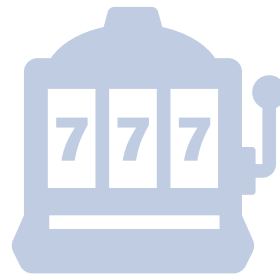
- Pilot phase is free of costs



# Challenges



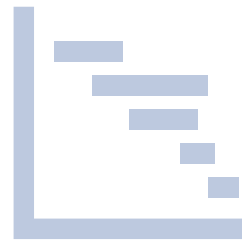
More documents  
requested



Time slots



Short timelines to  
respond



Timeline compliance &  
planning



Additional procedures  
outside CTR



Budget/timelines for  
business development



# Challenges



## More documents requested

- ICF procedure
- Suitability sites document



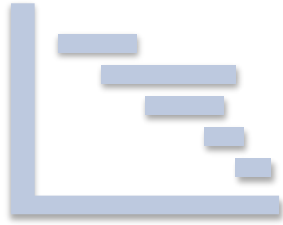
## Time slots

- Requiring planning far ahead
- Requires site list to be known
- Available slots quickly taken





# Challenges



Timeline  
compliance &  
planning

- Delays in T0



Short timelines to  
respond

- Response within 12  
calendar days required



# Challenges



## Additional procedures outside CTR

- Local procedures pre or post CTR at site level



## Budget/timelines for business development

- Budget and timeline agreement at contracting phase



# Wishlist for CTIS implementation

- Harmonization local procedures (if any)
- Possibility to submit when ready
- More time to respond to comments
- Timeline compliance