

# Academic investigators and academic Sponsors would benefit from:

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## ➤ Regulatory advice

- Access to informal pre-liminary regulatory advice early on while developing a grant proposal (NCA)
- Paving the way to a well prepared, formal scientific advice meeting - if needed (NCA/EMA)
- Fee waivers for academia essential (non-profit organisation vs for-profit industry)
- Pre-grant regulatory advice as basis for a realistic estimation of necessary budget and timelines

# Academic clinical trial needs:

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## ➤ Academic Sponsor

- Early inclusion in pre-grant preparation essential
- Identification of all mandatory Sponsor requirements
- Necessary resources, knowledge and expertise

## ➤ Funding Bodies

- Sponsor responsibility costs in research grants
- Funding for multi-national trials (across borders!)
- Review of not only the scientific excellence, but also realistic timelines and accurate regulatory considerations