KWF

Problem case: Limited scientific advice for academic developers

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Problem statement

Limited scientific advice (SA) for academic developers

- Limited regulatory knowledge and capacity of academic developers
- High fees for SA as academic developer (EMA)
- National SA is suboptimal for multinational EU trials; differences among national agencies, and EMA
- Not enough (early) interaction between academics and regulators undermines regulatory feasibility of academic clinical trials to support marketing authorization dossiers
- Legal issue (fees, set up scientific advice) and operational issue (limited knowledge and interaction)

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Possible solutions

Limited scientific advice (SA) for academic developers

- Enhance academic-regulator interaction through early national SA: increase knowledge and stress early SA for academic clinical trials
- Enhance access to SA with EMA for non-orphan indications: lower SA fees for academics (in particular for multinational clinical trials)
- Enhance regulatory feasibility of funded grants: pre-grant advice

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Pre-grant advice

Limited scientific advice for academic developers

STARS: pre-grant advice as recommendation to funders

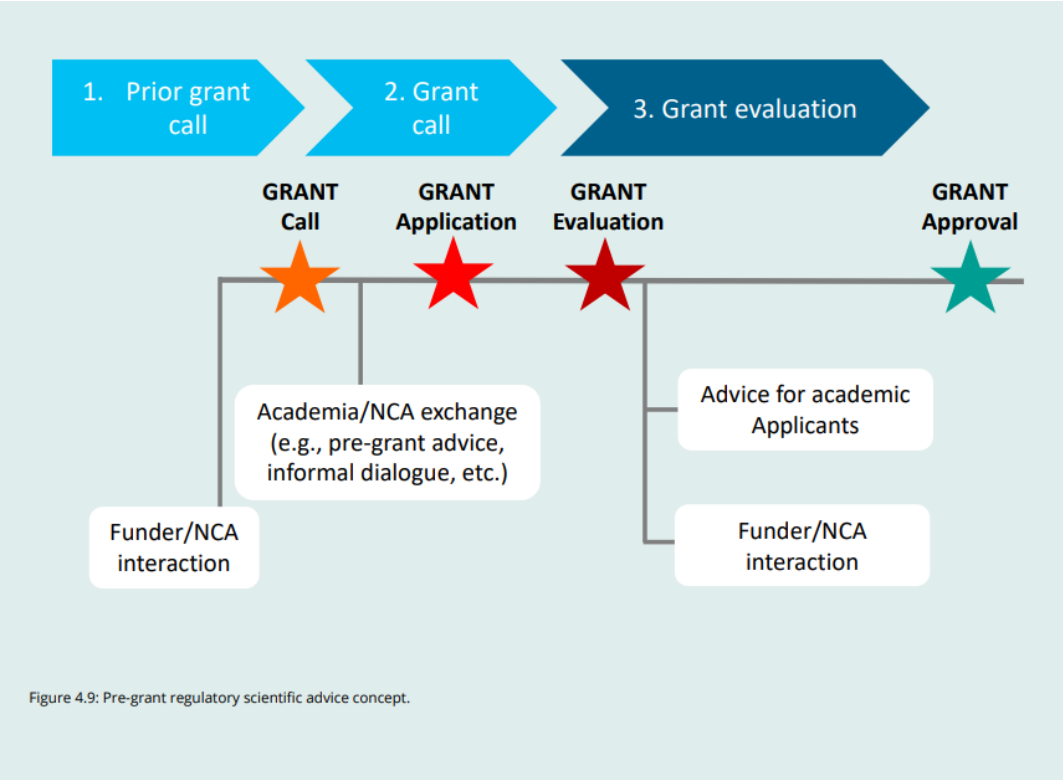

Figure 4.9: Pre-grant regulatory scientific advice concept.

https://www.csa-stars.eu/files/STARS_Common_Strategy.pdf

- Pilot with CBG-MEB ongoing in PIPELINE call
- Efforts are made to implement it in the ATTRACT call with 3 national agencies
- Issue: there is no formal procedure, it is difficult to align national agencies on format. Engage EMA?

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