EORTC
European Organisation for Research and Treatment of Cancer
The future of cancer therapy

Supporting non commercial trials

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Non-commercial trials

Selected observations

- Non commercial trials are central for changing practice
- They may address a specific clinical situation, not necessarily a specific drug.
- They may or may not support a regulatory decision, whether drug specific or not
- They can address class of agents in place of specific drug
- They can be multidisciplinary, combination of drugs
- They tend to be more pragmatic by trial design and data collection
- Regulations and related solutions tend to marginalise them, often by a misunderstanding of the full landscape of clinical trials

Contextualisation

- They address a different but complementary agenda to that of the commercial sector
- They can provide solid information to be up taken in the regulatory decision process
- EU solutions should facilitate and accommodate all types of clinical trials for greater attractiveness of the EU and patient centricity
- GDPR, CTR, MDR, IVDR.. may not accelerate clinical trials in the EU. The pace is set by the most stringent framework.
- Impact of regulations on the costs of trials / budgets of academic sponsors must not be under – estimated.