

REVISION OF THE CLINICAL TRIALS DIRECTIVE: THE BIOSCIENCE INDUSTRY PERSPECTIVE

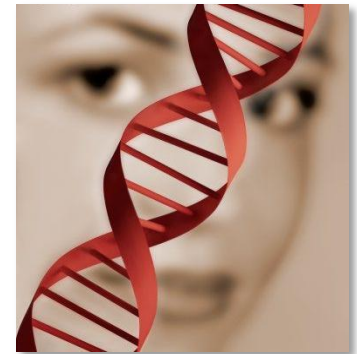
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Simplified and efficient regulatory framework

Why does it matter?

- Making Europe a more attractive place for clinical research and development of new and innovative medicines
- Increasing the benefits for all stakeholders
 - Allowing faster access to innovative treatments for patients
 - Reducing the administrative burden and costs for public and private sector researchers as well as for EU Member States



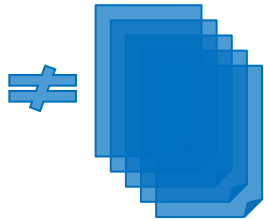
Streamlining clinical trial approval processes

- As a first step

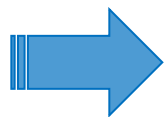


- Common standardised Clinical Trial Application (format and content) for all EU Member States

- Reflecting the requirements in the current European Commission guidelines



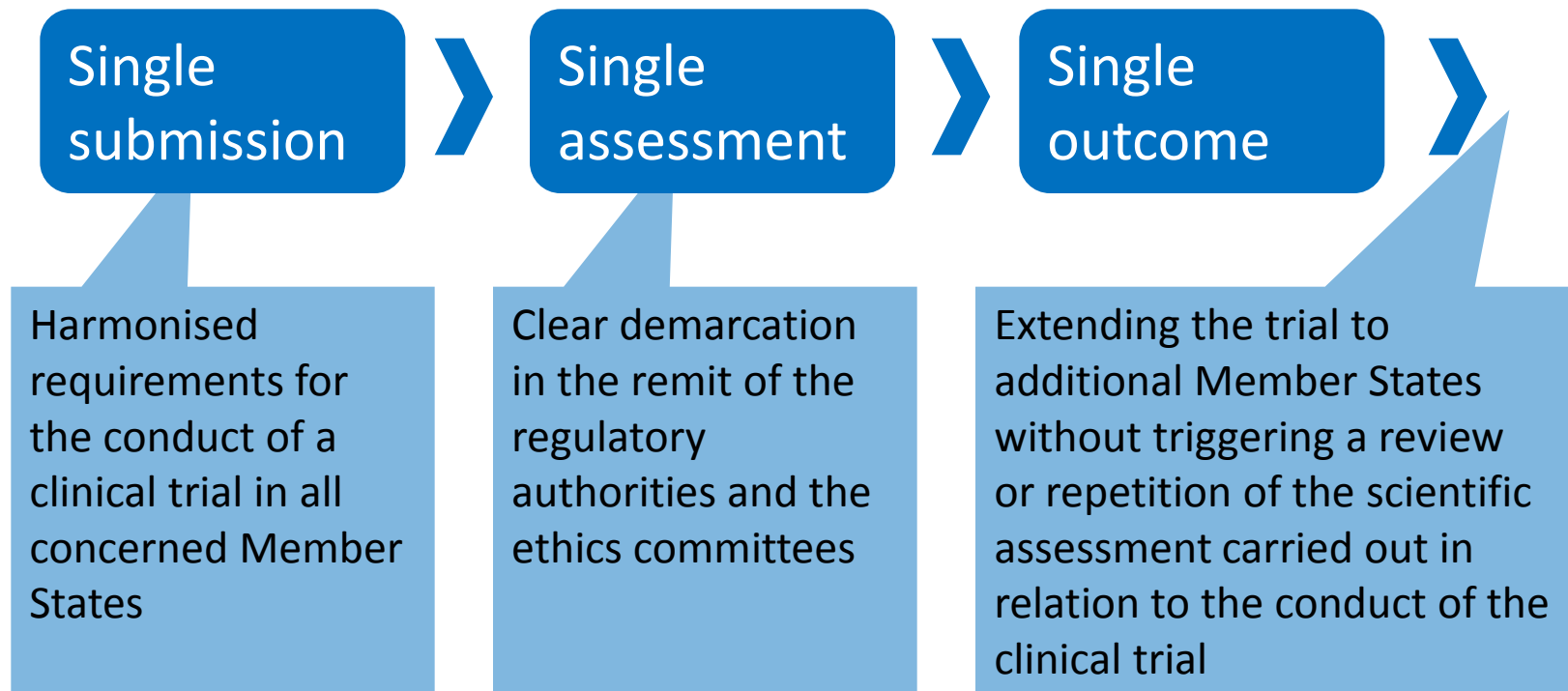
- Not consisting of a cumulative list of all the present national requirements



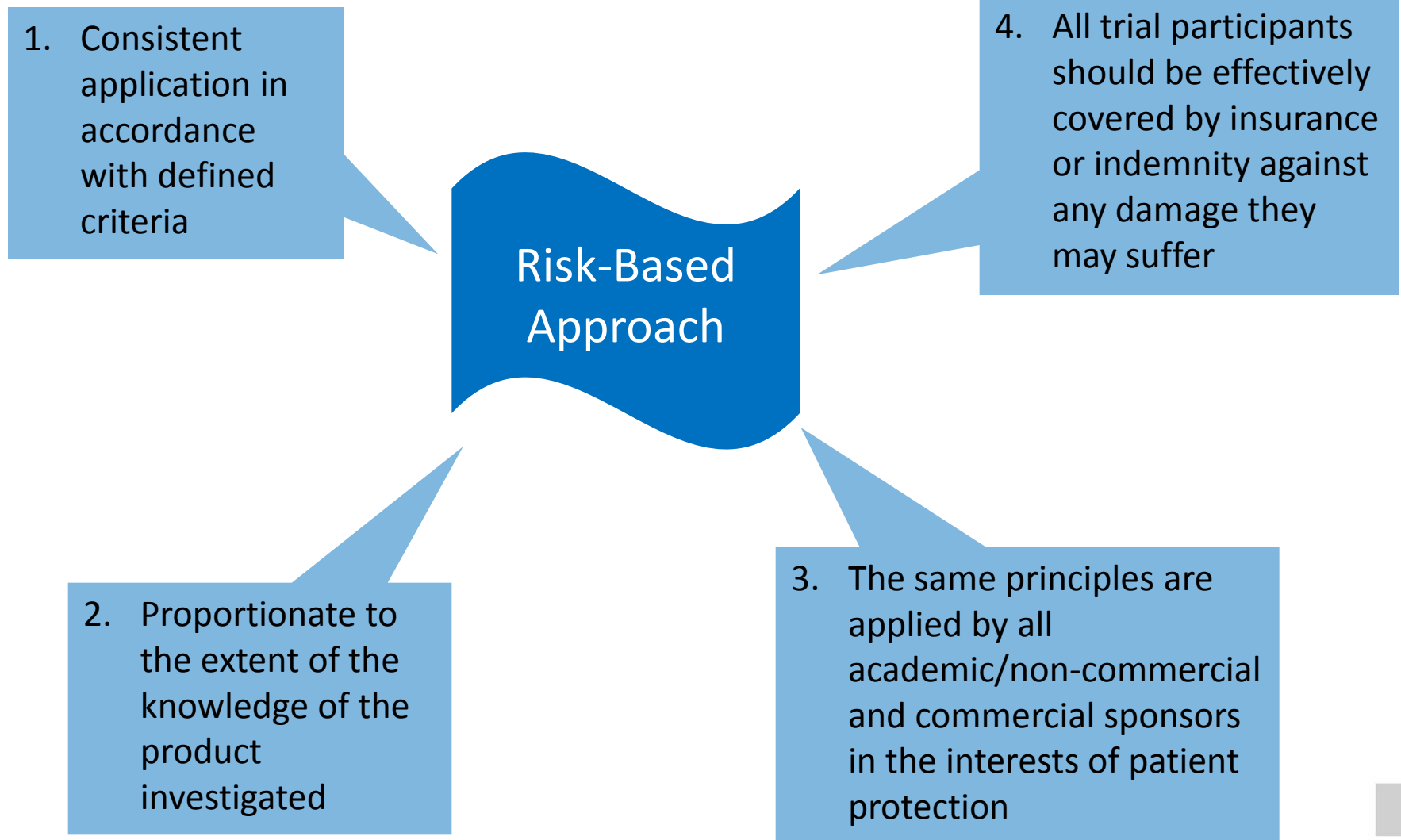
- Ultimately a single dossier submitted through a single point 'the EU portal'

How to improve the approval of multi-state clinical trials?

- A single submission dossier followed by a single scientific assessment resulting in a single pan-European outcome



Introducing a risk-adapted approach to the regulation of clinical trials



In conclusion

- Collaborating with all stakeholders in the clinical eco-system and working with the European Commission and Members of the European Parliament to retain the competitiveness of the EU as a place to conduct clinical research
- Innovation will lead to better outcomes for patients, to the development of the knowledge-based economy, and economic growth