What is special about regulating nanomedicines?

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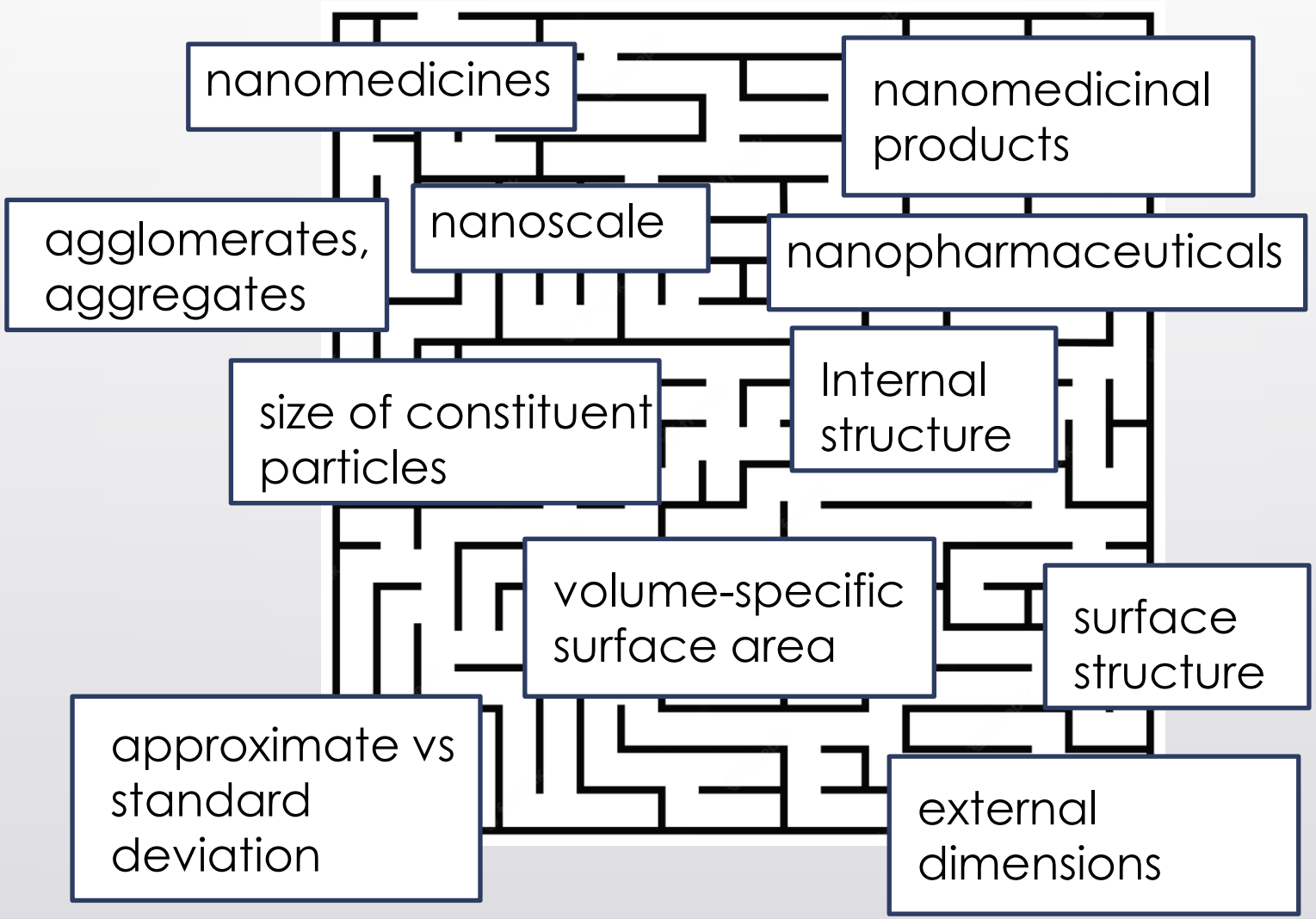
Objective

Navigating through the maze of nanomedicines: Avoiding pitfalls

A maze of terms

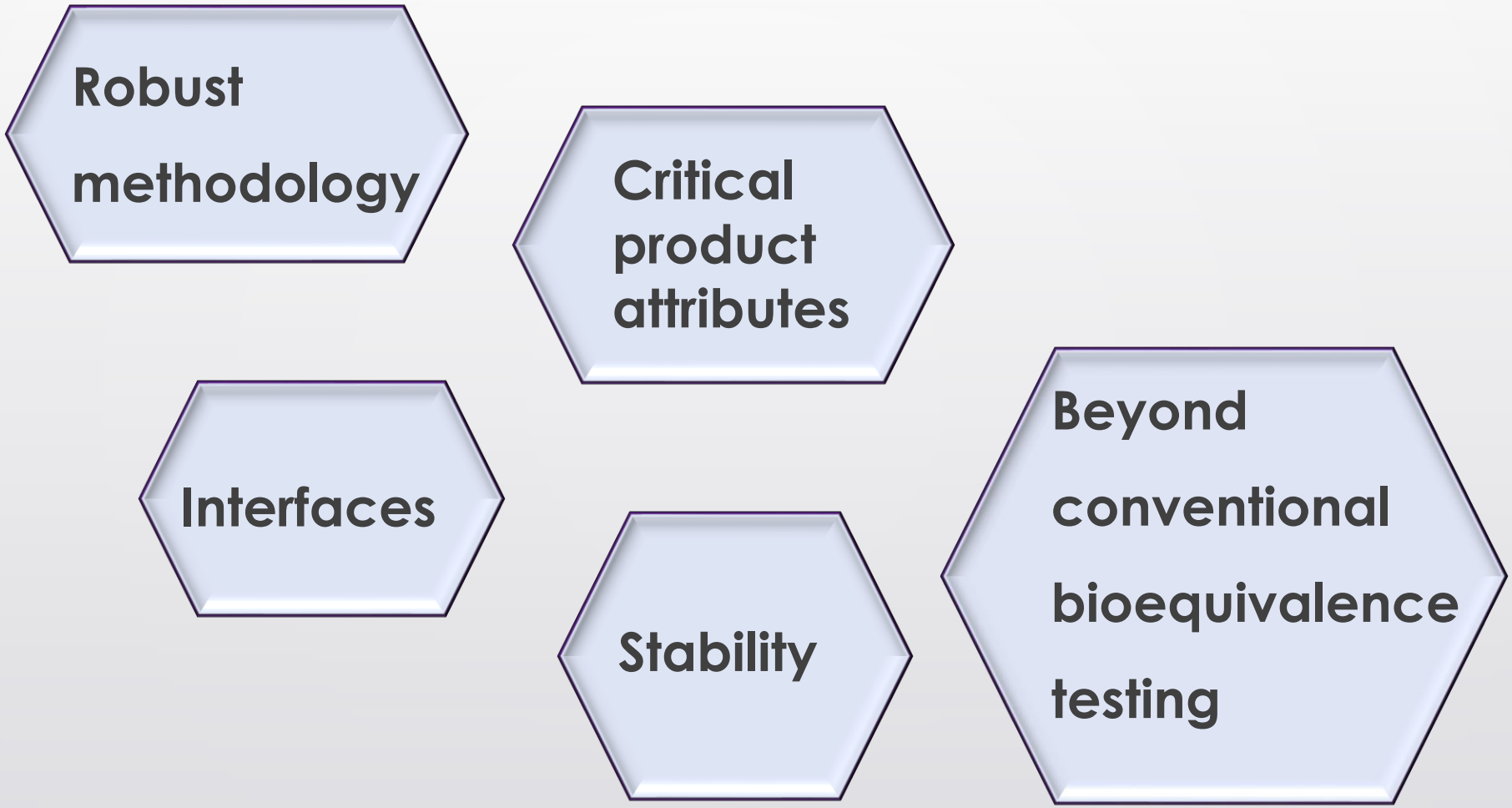


Meeting patients needs for nanomedicines

- Transparency
- Clarity on safety/risk
- Variability between nanosimilars

- Information on special characteristics of nanomedicines
- Addressing unmet needs

Technical challenges



Strategy

Corporate responsibility

Transition from research to clinical use

Professionalisation: resources and support

Political and strategic leap forward

Role of the Regulator

Regulation specific to nanomedicines

- Impact on relationship between healthcare professionals and patients
- Relating towards personalised medicine
- Special requirements for pharmacovigilance
- Nanomaterials-nanomedicines-medical devices
- Consensus living document

Key messages

1. A nano-medicinal product is a medicine which satisfies quality, safety and efficacy norms and takes into consideration also environmental and accessibility aspects.

2. A nanosimilar and its reference originator are expected to have a similar safety and efficacy. Nanosimilars need to be authorised for all or selected indications of the reference medicinal product.

Key messages

3. The **definition** for nano-medicinal products includes a factor of dimension, approximately 1 nanometer -100 nanometers.

In order to establish a comprehensive and harmonised regulatory process, the definition must be refined without becoming too exclusive.

Key messages

4. Standards of EU Good Manufacturing Process (GMP) must apply to nanomedicines with special reference to the possible effect of the GMP process on **toxicity**.

5. Nanomedicines present an opportunity to make available **innovative** medicines of significant benefits to patients.

Key messages

6. Attempts should be made to ensure that the process of making nanomedicines produced and/or available in the European market is **competitive**.

Nanomedicines bring to medical sciences new treatment options which should be financially **sustainable** in the EU healthcare systems.

Key messages

7. A decision needs to be made whether all nanomedicines should be centrally authorised in the EU in order to gain a marketing authorisation.

8. The controversies met with interchangeability, substitution or switching between biosimilars should be avoided through regulation in the case of nanosimilars.

Thank You

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