



**Design fit for purpose regulatory framework that will enable clarity early in the development**

Establishment of a new legal provision that would result in a dedicated VAM regulatory pathway.



**Recognise VAM as a category of innovation with proportionate incentives**

Recognise innovation in form of granting a non cumulative period of 4 years of data exclusivity.



**Recognise and define value for healthcare systems**

Pricing and reimbursement rules should be shaped to adequately assess continuous innovation.

**EU environment for value added innovation**