

Gilbert Inhaler: Prototypes

Pre-prototype

- Technology 'Proof of Concept'

Demonstrators and prototype

- **Compounds / therapies:**
 - Proprietary and generic / biosimilar
 - Locally acting / systemically acting
- **Regulatory test and approval:**
 - Lung deposition assessments
 - Therapeutic equivalence (non-inferiority) / bio-equivalence
 - Phase I, Phase II and Phase III
 - Dossier filing



EUROPEAN MEDICINES AGENCY
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