

*Public Workshop: New Insights for Product Development and
Bioequivalence Assessments of Generic Orally Inhaled and Nasal
Drug Products (OINDPs)*

January 09, 2018

Session 2: Novel Analytical Tools for Characterization of Nasal Suspensions

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Opinions expressed in this presentation are those of the speaker and do not necessarily reflect the views or policies of the FDA.

Nasal Drug-Device Combination Products (NDPs)



Metered Nasal Solution



Metered Nasal Suspension



Nasal Spray (Unit Dose)

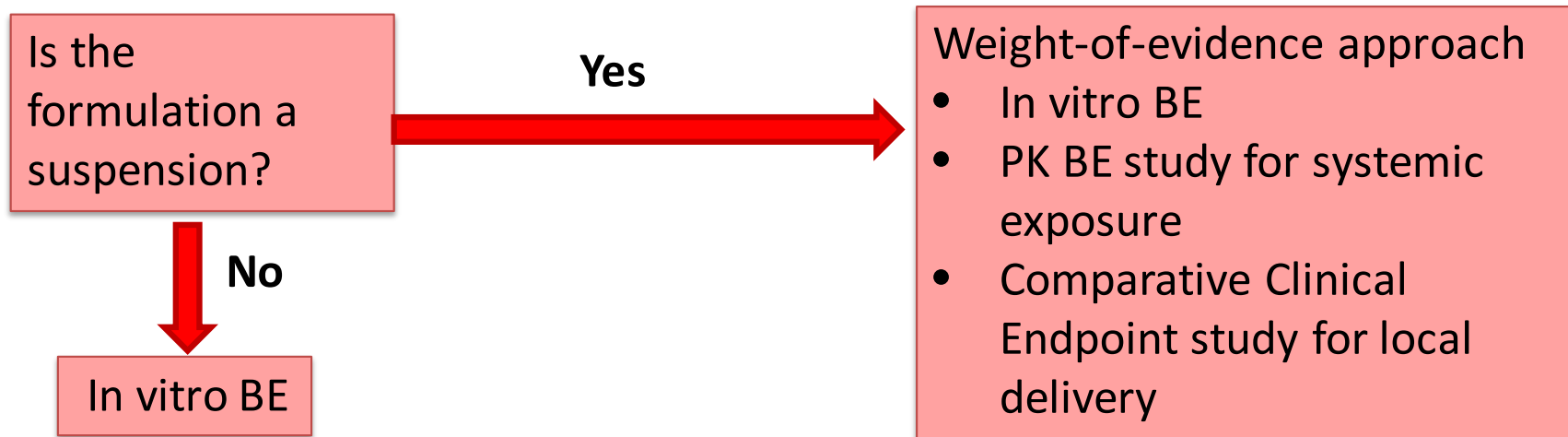


Metered Nasal Aerosol



Nasal Powder (Unit Dose)

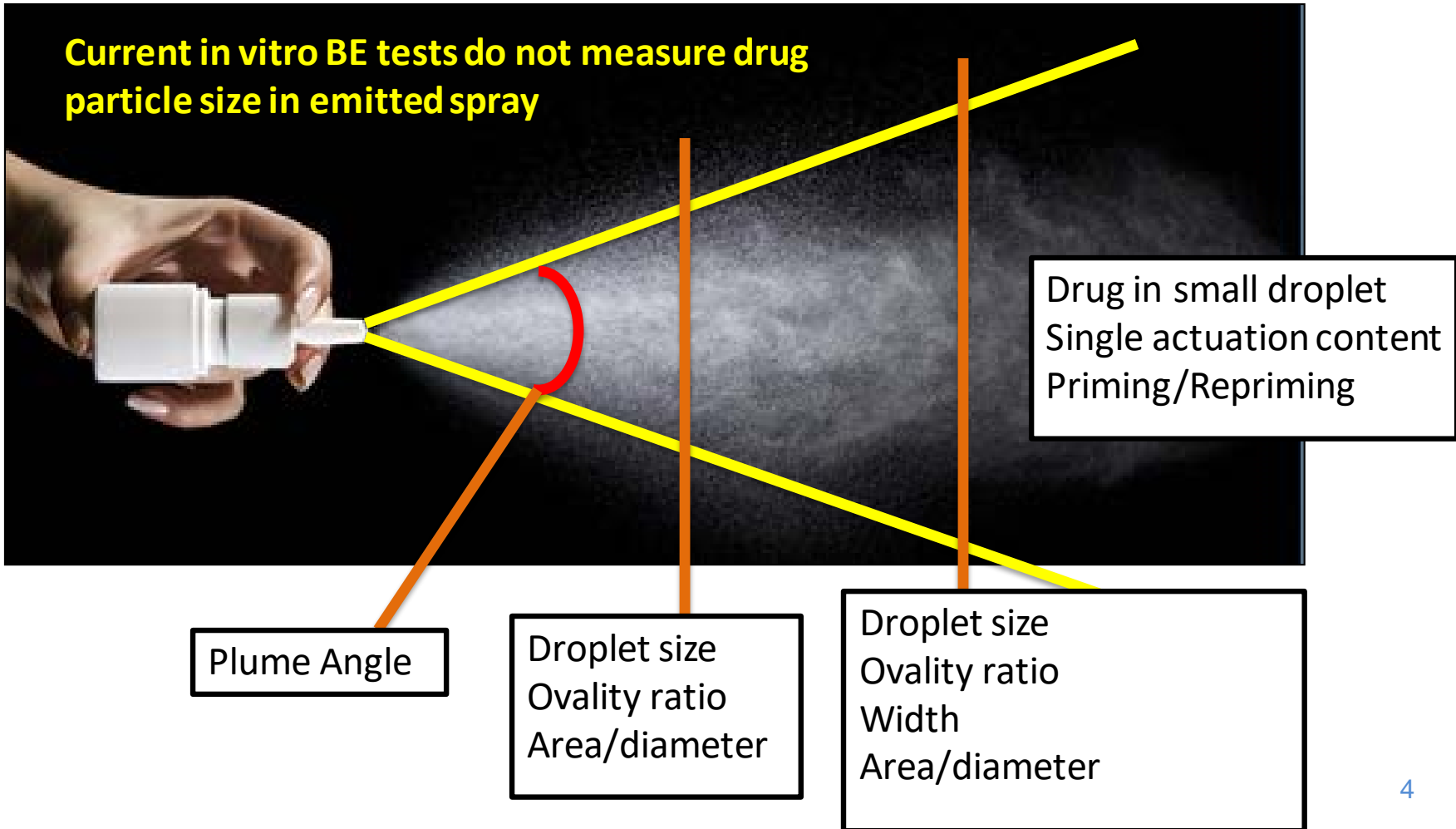
Current BE Recommendations for Q1/Q2 the Same Locally Acting Nasal Spray Products



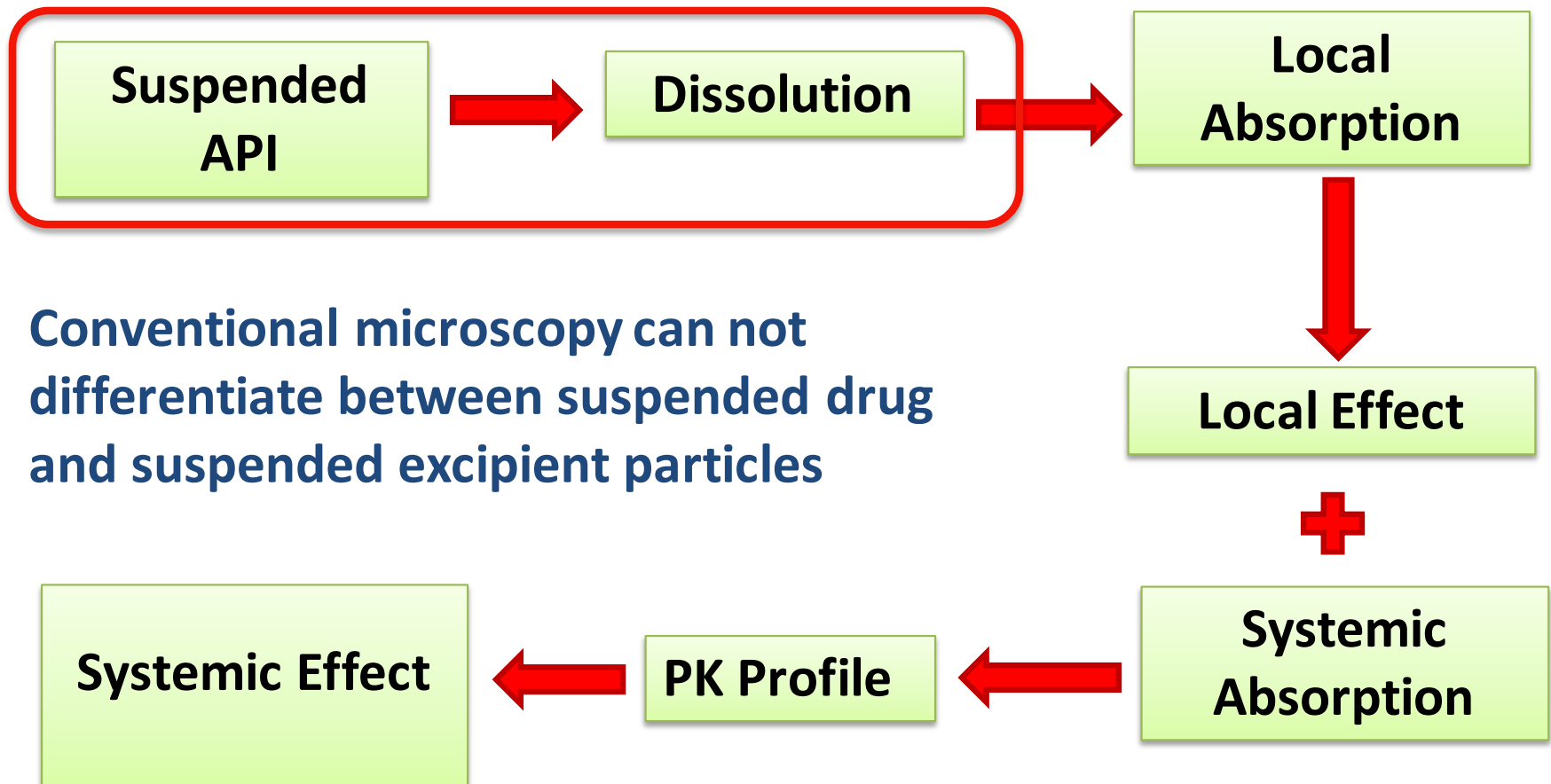
A clinical endpoint BE study is currently recommended for nasal suspension product because of an inability to adequately characterize drug particle size distribution (PSD) in sprays using commonly used analytical methods.

Current In vitro BE tests

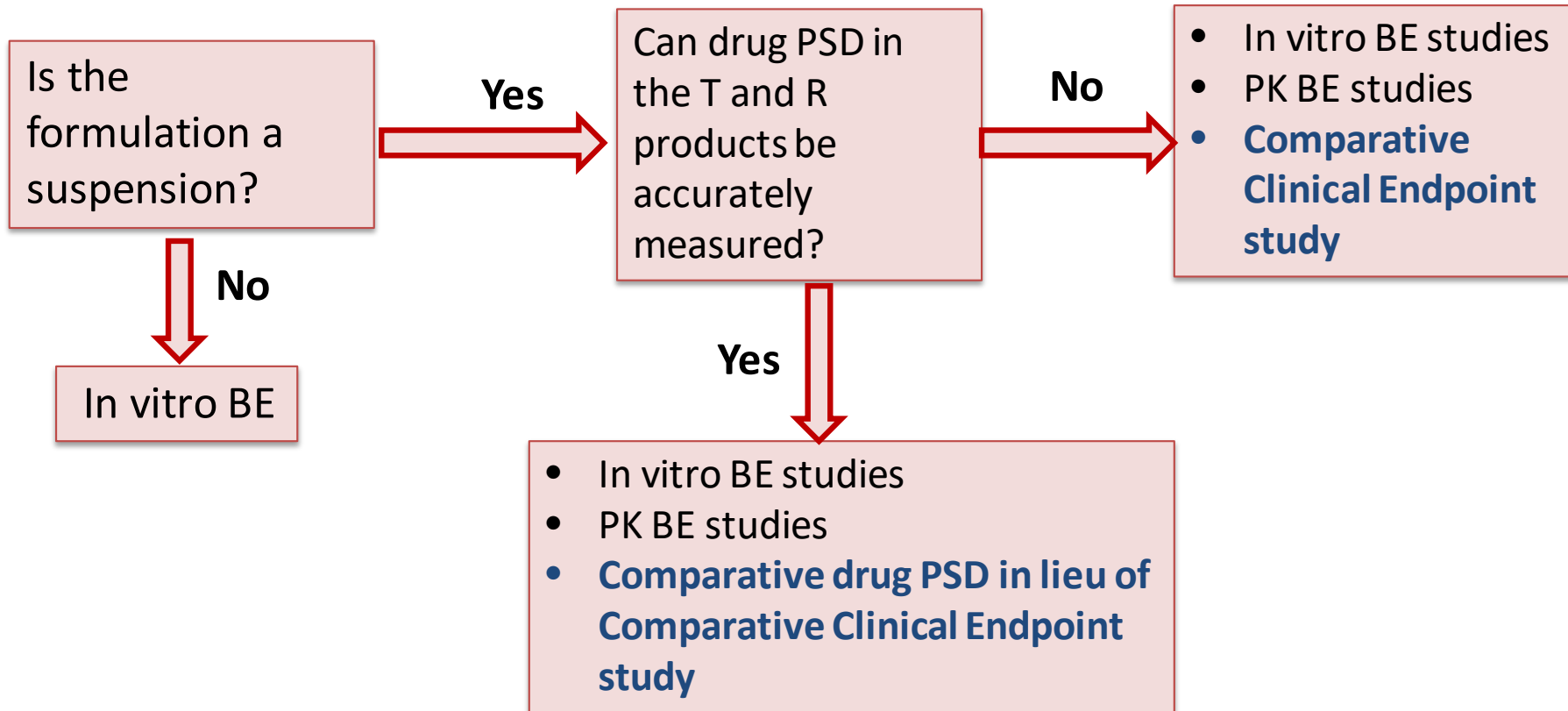
Current in vitro BE tests do not measure drug particle size in emitted spray



Current Challenges



Exploration of Alternative BE Pathway



Focus of the Session

- Characterization of drug PSD in nasal suspension products
 - Feasibility
 - Method development
 - Validation
 - Limitations
- Orthogonal methods if the selected drug PSD characterization method is not sensitive to measure particles of a certain size range
 - Dissolution
 - Rheological properties
 - Other Q3 characterization

Presentation 1: Analytical Method Development for Ingredient-Specific Particle Sizing of Nasal Spray Suspensions - Changning Guo, PhD (FDA)

Presentation 2- Advanced Characterization Approaches to Demonstrate Bioequivalence of Nasal Suspension Drug Products – Jag Shur, PhD (University of Bath)