

## Swallowability- Industry perspective

David **TAN**  
Scientist, Registered Pharmacist  
Pediatric Center of Emphasis  
Abbvie

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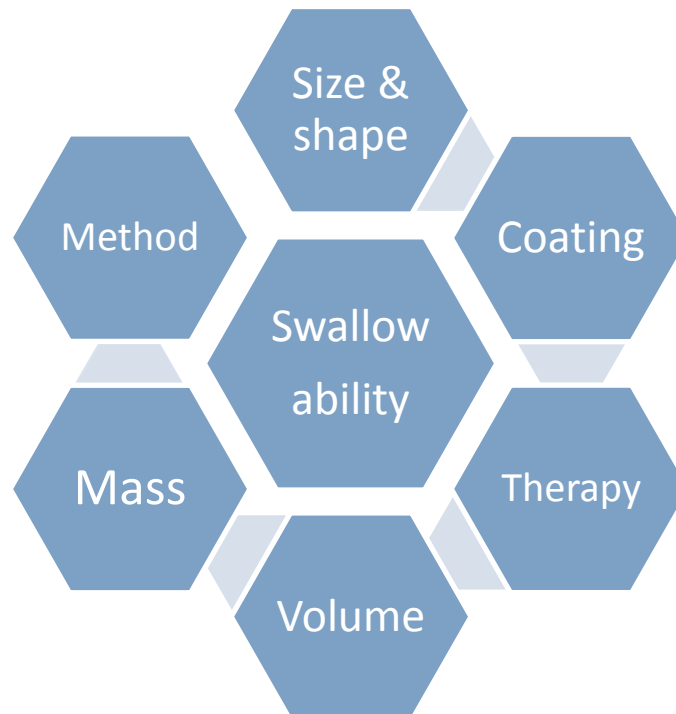
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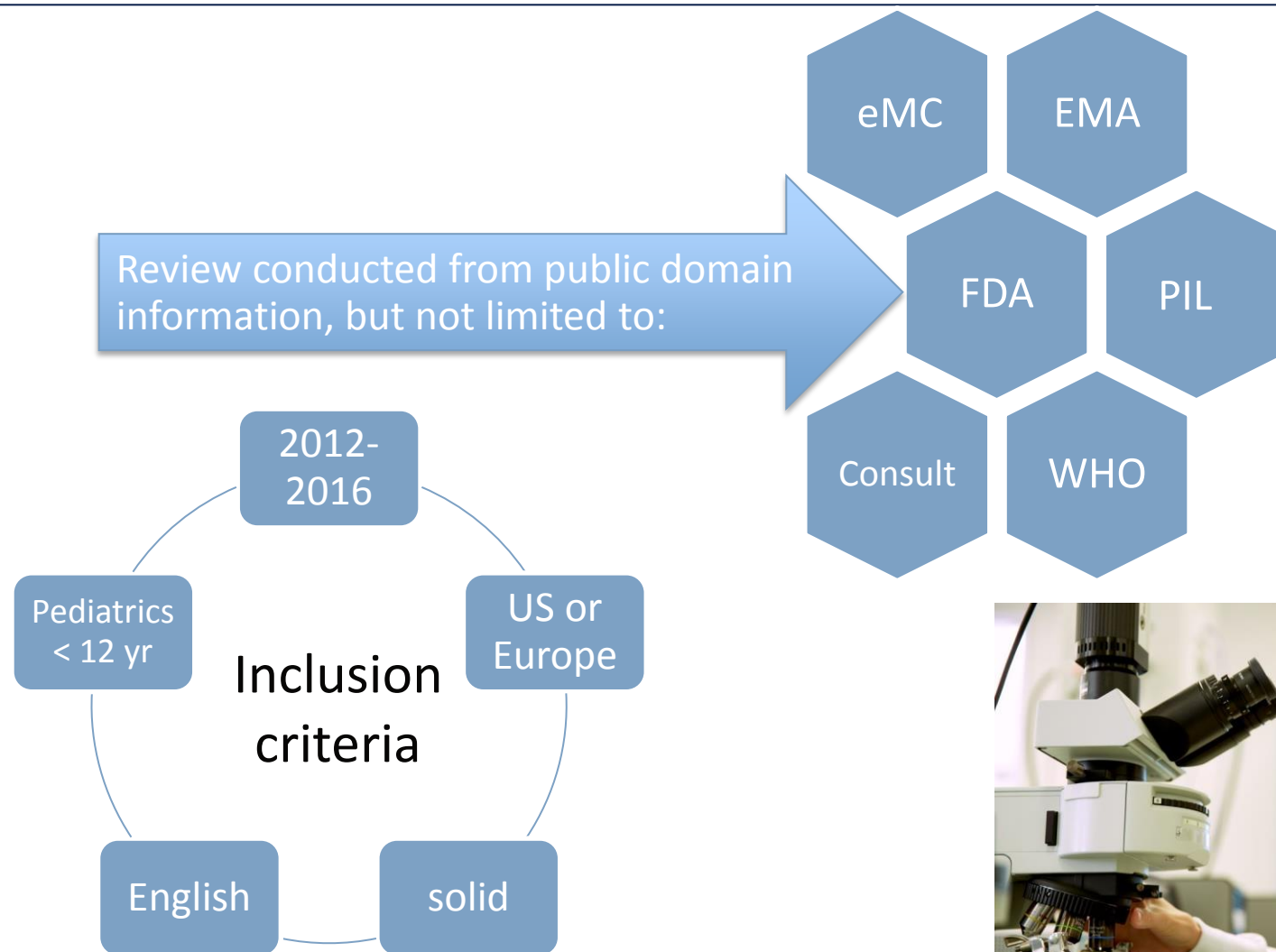
# Introduction

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- The establishment of pediatric regulation in 2007 catalyzed a paradigm shift in pediatric formulation development.
- The understanding of solid dosage form swallowability is important to ensure the development of suitable pediatric formulation.
- **Objective:** To review marketed pediatric drug products focusing on swallowability attributes.



# Methodology



Acronyms: eMC= electronic Medicine Compendium, EMA= European Medicine Agency, FDA= Food Drug Administration, WHO= World Health Organization, PIL= Product information Leaflet

## Results: Age > 6 years old, weight ~ 20kg/44lbs

Name	Company	Indication	Dosage form	Dimension & shape	Administration or manipulation
Kalydeco®	Vertex	Cystic fibrosis	IR coated tablets	16.5 X 8.4mm, modified caplet	Swallow whole without crushing, chewing or dissolving
Intuniv®	Shire	ADHD	ER coated tablets	7.14mm round, 12.34 X 6.10mm oblong, 7.94mm round, 12.34 X 6.10mm oblong	Swallow whole, without crushing, chewing or breaking
Dutrebis™	MSD	HIV	IR coated tablet	N.A.	Swallowed whole, without crushing or chewing
Trokendi XR®	Supernus Pharmaceuticals	Seizure	ER capsules contains spheres	size2 (~18 mm), size0 (~21mm), size00 (~23mm)	Swallow capsule whole and intact. <b><u>Do not</u></b> sprinkle on food, chew or crush.

Results: Age > 2 to 5 years old, weight ~ 12.5kg/27lbs

Name	Company	Indication	Dosage form	Dimension & shape	Administration or manipulation
Kalydeco®	Vertex	Cystic fibrosis	Granules in sachet	2 mm	Mix with 5 ml of soft food or liquid
Translarna™	PTC Therapeutics International	Duchenne muscular dystrophy	Granules in sachet	-	Mix with 30 ml beverage or 3 tablespoons (45 ml) semi-solid food
Qudexy® XR	Upsher-Smith Laboratories	Seizure	Coated beads in capsule	Beads + coating	Option to sprinkle capsule contents on food. Swallow food mixture immediately and not chewed/crushed.

## Results: Age < 2 years old, weight ~ 12kg/26lbs

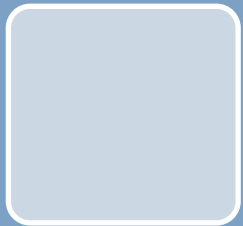
Name	Company	Indication	Dosage form	Dimension& shape	Administration or manipulation
Reyataz®	BMS	HIV	Powder in packet	Within 2.5mm range	Food: 15ml + 15ml Milk/water: 30ml + 15ml Formula liquid: 10ml + 10ml
Lopinavir+ Ritonavir pellets	Cipla	HIV	Pellets in capsules	0.8 mm	Do not crush, chew or stir. Take with soft food or liquid. Limit to 1 teaspoon (5 ml)
Isentress®	MSD	HIV	Coated granules	200-300 µm	Administer with 5ml water
Granupas®	Lucane Pharma	TB	Granules in sachet	1.5 mm	Cannot be crushed or chewed. Granules will not dissolve (gastro-resistant granules ). Graduated spoon provided.
Orphacol®	Laboratoire CTRS	Inborn errors in bile synthesis	Granules in capsule	Lactose monohydrate equivalent	Added to infant formula, or infant-adapted apple/orange or apple/apricot juice
Pheburane®	Lucane Pharma	Urea cycle disorders	Granules in bottle	sugar spheres + coating	Swallowed with beverages or sprinkled on solid food. Graduated spoon provided.



# Conclusion

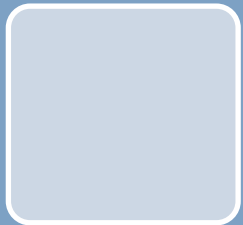
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Different dosage forms/strengths were developed for various age groups. E.g. Kalydeco<sup>®</sup>, Isentress<sup>®</sup>, Reyataz<sup>®</sup>



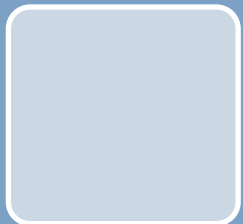
> 6 years old

- Dimension: 7 mm to 23 mm
- Volume: N.A., Shape: Round, caplet, oblong



>2 to 5 years old

- Dimension: Beads to 2 mm
- Volume: 5 ml to 45 ml



< 2 years old

- Dimension: lactose monohydrate to 1.5 mm
- Volume: 1-30 ml. Rinsing 10-15 ml.





# Acknowledgement

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- Organizing committee
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Contact: David Tan ([cheng.tan@abbvie.com](mailto:cheng.tan@abbvie.com))

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