CRCG-FDA Drug-Device Combination Products: Updates and Challenges in Demonstrating Generic Substitutability

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Determining “Other Design Differences” and Ways to Support Generic Substitutability

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Product Design

Appearance

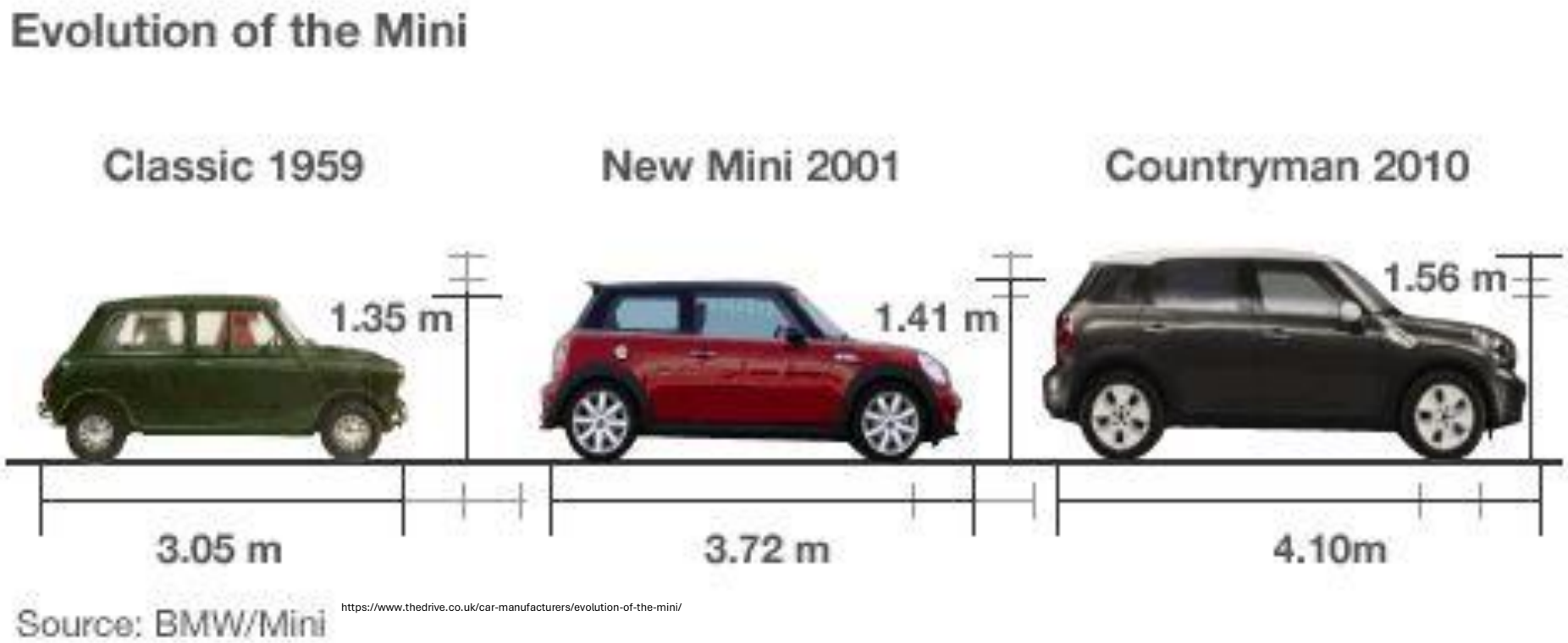
Functionality

Manufacturability

Value

Improves life

Design Changes



Are these the same?

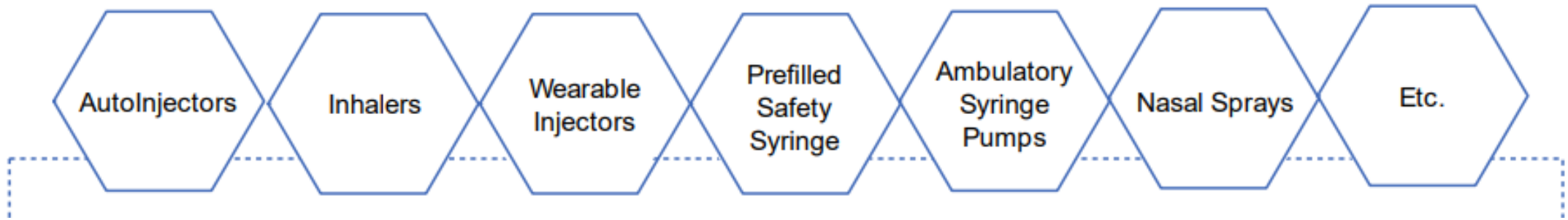
Ketchup

Are these the same?

Are they substitutable?

…..it depends on the task.
…..it depends on the context.

Comparative Analyses for Generics



…..not as easy as ketchup.

How do we describe DESIGN when there’s no common vocabulary?

How do we link DESIGN (attributes) to TASKS?

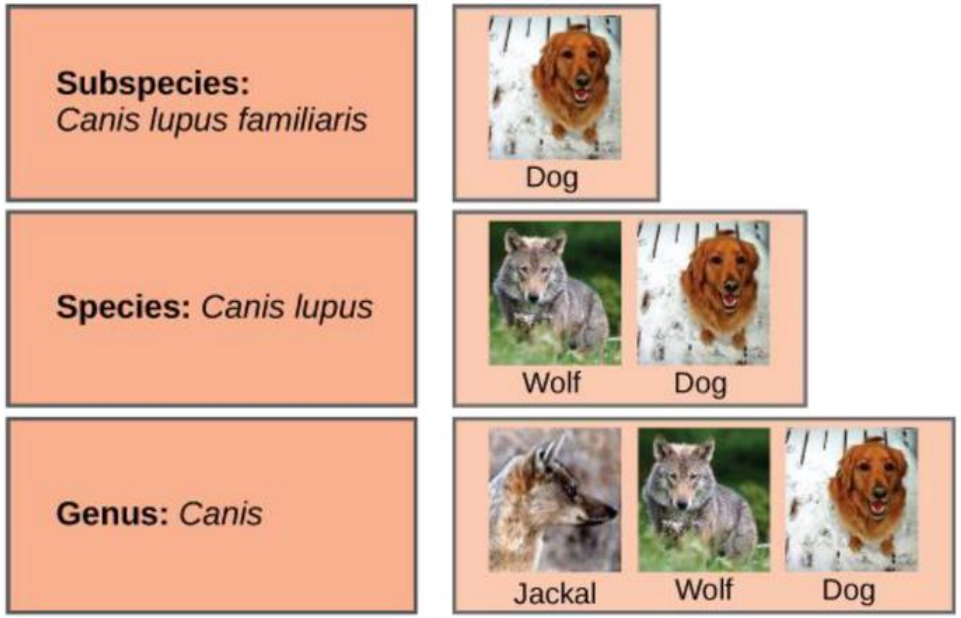
How do others compare differences?

Examples span biological research and education

Recognized in Human Factors

- Use of WHO's International Classification for Patient Safety (ICPS) as a human factors taxonomy to identify contributing factors for medical/surgical complications (Mitchell, 2018)
- Classification of Human Factors Accidents in Aviation Accidents (Weigman, 2005)

Hierarchical Classification of the Common Dog



https://courses.lumenlearning.com/boundless-biology/chapter/organizing-life-on-earth/

…..Build Taxonomies.

Just an IDEA!

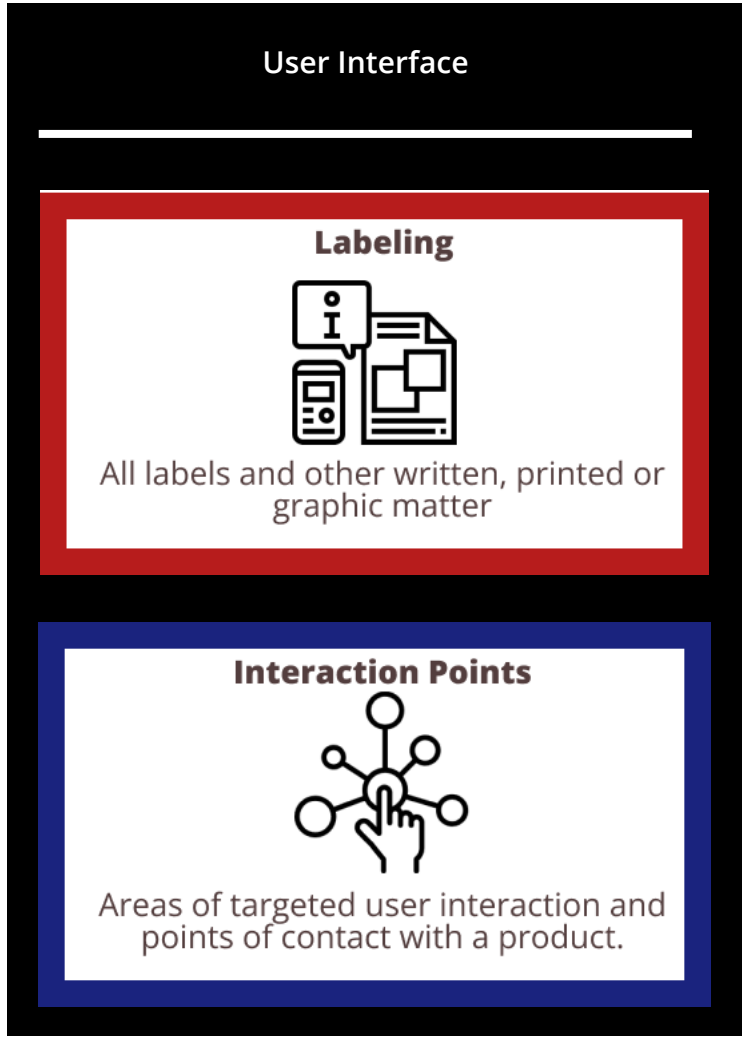
What if …… ?

Repeatable method to **simplify** and **standardize** classification of design attribute differences for DDCP interface design

Guide the process of determining “minor” vs “other” design differences

Just an IDEA!

Taxonomy of design:
A method for organizing subject-specific concepts and creating a vocabulary for those concepts



Just an IDEA!

Link Design Feature to Task

Instructions on using Design Feature Taxonomy

1. Use Taxonomy to identify & classify design

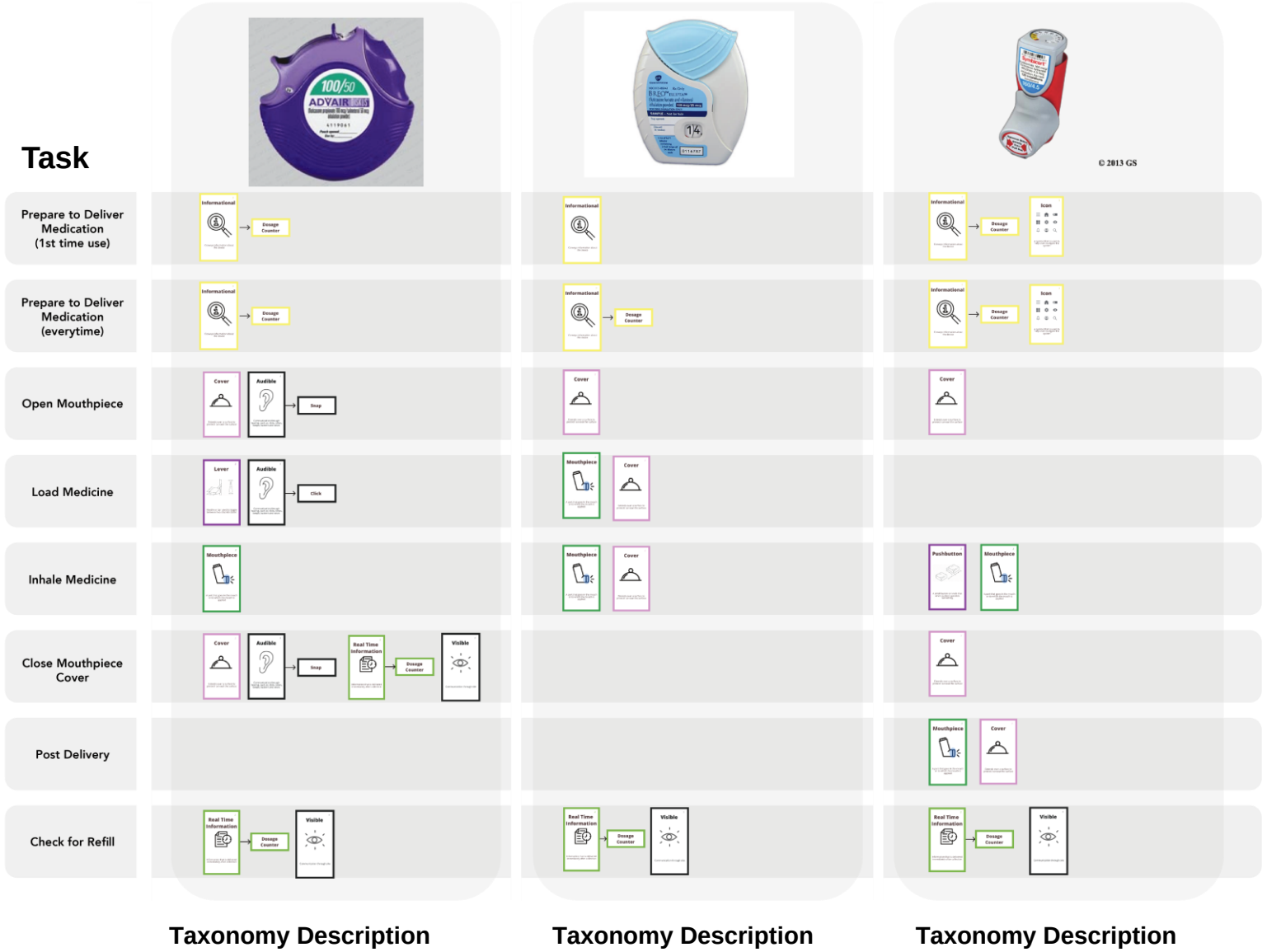
2. Use Task Analysis to relate design features to tasks

3. Conduct Risk Analysis [using TA]

4. Compare RLD to Generic based on taxonomy to determine design differences

   Minor difference = change within a sub-category

   Other difference = change in design feature identification (e.g., IFU is printed on device rather than paper handout)



Thanks!

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