

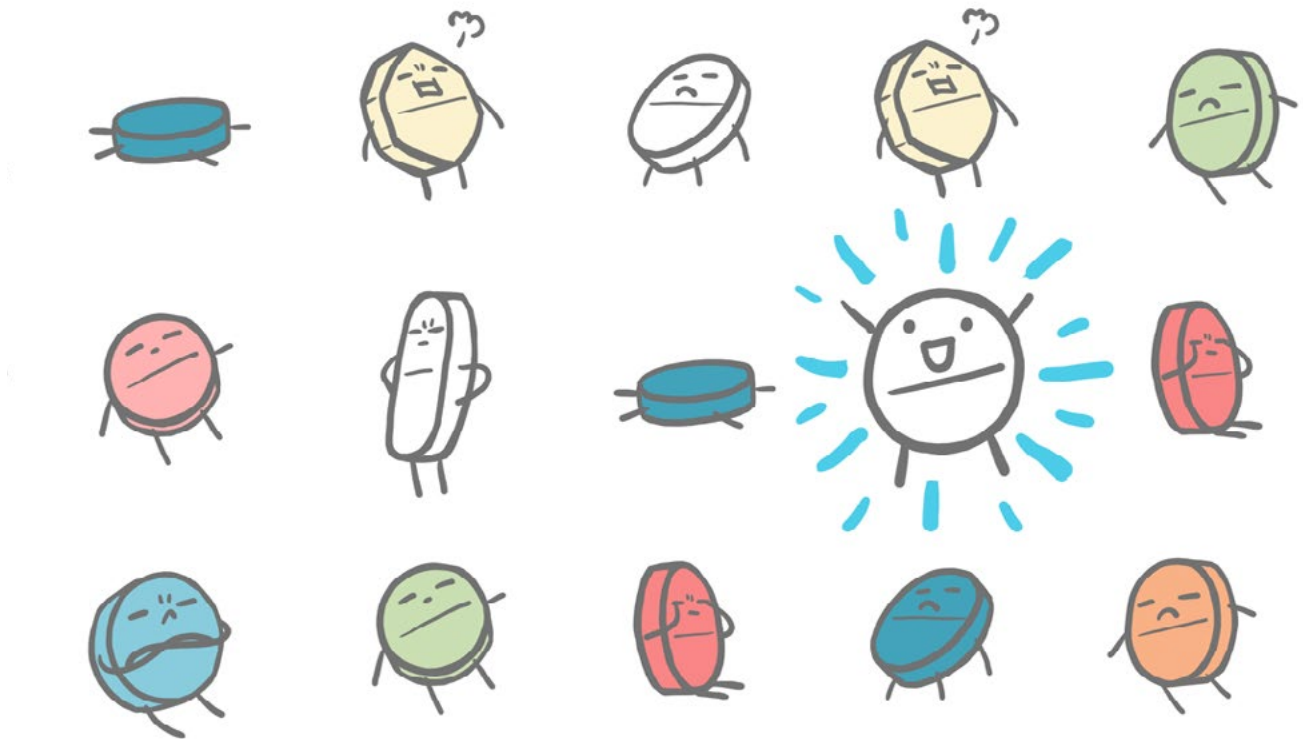
How Merck and Co. used Biorelevant Media During Preclinical Development

- Solubility testing in Biorelevant Media highlighted the difficulty of developing a BCS Class II Preclinical Drug Candidate (GPR-119 agonist for type 2 diabetes)
- Biorelevant dissolution testing aided Merck in their Formulation Selection



Formulation Development Challenges

- In Preclinical Development, Merck identified two polymorphs (solid materials in more than one crystal structure) of GPR-119 agonist
- Although the first polymorph presented better aqueous solubility, it appeared to convert into the second, less soluble polymorph
- The second polymorph was therefore chosen for Formulation Development but a strategy was required to improve its aqueous solubility



Biorelevant Tests

- During Physicochemical Profiling, solubility testing in Biorelevant Media was used to characterize solubility of the second unformulated polymorph of GPR-119 agonist
- During Formulation Development, dissolution testing of different formulations of GPR-119 agonist in Biorelevant Media helped Formulation Selection



Results

- Biorelevant Media from biorelevant.com was used during Preclinical Development by Merck and Co.
- Biorelevant Media helped different Merck departments (Discovery, Biopharmaceutics, Global Product Management, Toxicology, Pharmacokinetics and Drug Metabolism) decide to terminate development of the GPR-119 agonist

