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## The use of saliva instead of plasma as a surrogate in drug bioavailability and bioequivalence studies in humans

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**Introduction:** Salivary excretion of some drugs has been reported previously as a good indicator for drug bioavailability, therapeutic drug monitoring, pharmacokinetics and drug abuse because saliva sampling offers simple, non-invasive and cheap method as compared with plasma sampling with no contamination risk. The rules of drug protein binding and membrane permeability on salivary excretion were previously investigated for several drugs, where a salivary excretion classification system (SECS) was proposed.

**Aim:** The research purpose is to study and compare the pharmacokinetics of selected drugs in plasma and saliva matrixes in healthy human volunteers, and to suggest using non-invasive saliva sampling instead of plasma as a surrogate in bioavailability and bioequivalence (BA/BE) studies.

**Materials & Methods:** Four different pilot BA/BE studies were done in 12-18 healthy humans. Saliva and plasma samples were collected for 3-5 half life values of metformin, tolterodine, rosuvastatin, and paracetamol after oral dosing. Saliva and plasma samples were assayed using LC-MSMS, then pharmacokinetic parameters were calculated by non-compartmental analysis using Kinetica program. Effective intestinal permeability ($P_{eff}$) values were also optimized to predict the actual average plasma profile of each drug by Nelder-Mead algorithm of the Parameter Estimation module using SimCYP program.

**Results & Discussion:** All studied drugs showed salivary excretion with strong correlation coefficients between saliva and plasma concentrations. The optimized $P_{eff}$ ranged 1.44–68.3 x $10^{-4}$ cm/sec for the drugs under investigation. Saliva/plasma concentrations ratios ranged 0.17–1.5. Inter and intra individual variability of primary pharmacokinetic parameters in saliva matrix were either close to or higher than plasma matrix. This requires larger sample size in saliva studies for some drugs. Our results suggested that there is a potential in BA/BE studies for saliva to be considered as a surrogate for plasma concentration, which goes along with drug regulations. The use of saliva instead of plasma in such studies makes them non-invasive, easy and with a lower clinical burden.

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## Accelerating growth

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Accelerating growth requires a new way of thinking about overcoming obstacles and acting on new opportunities. All too often, change comes from the outside in, forcing us to react by slipping into a crisis management mode, and putting out fires. This presentation is about opportunity management, identifying the driving forces of predictable change, driving growth strategies from the inside out, and taking control of our future. Daniel Burrus is a highly successful entrepreneur who has founded and managed six businesses, three of which were national leaders in the first year. For over 30 years, he has established a worldwide reputation for his exceptional record of accurately predicting how technological, social, and business forces are converging to create enormous, untapped opportunities. In this eye-opening and motivating presentation, the author of six books, including *The New York Times* and *Wall Street Journal*, best selling book *Flash Foresight: How to See the Invisible and Do the Impossible* and the international best seller *Technotrends*, takes you to the next level by sharing valuable insights into the opportunities yet to come, preparing you to capitalize on the next wave of technological change.

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