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# David William Boulton

Editor PPT

# Biography

- David Boulton received his Bachelor of Pharmacy from the University of Otago (Dunedin, New Zealand) in 1991. Following his internship he earned a PhD from the University of Otago in Clinical Pharmacokinetics in 1996. He then completed two postdoctoral fellowships at the Medical University of South Carolina (Charleston, SC) before joining Bristol-Myers Squibb (BMS) in Princeton, NJ as a Clinical Pharmacologist in 2001. At BMS, David has worked in numerous therapeutic areas and he was on the teams that developed medicines such as Abilify, Onglyza/Kombiglyze and Farxiga/Xigduo. David is currently a Group Director in the Clinical Pharmacology and Pharmacometics department and he is the Virology Portfolio Lead where he works on medicines for HIV, HCV and HBV.

# Research Interests

- Clinical Pharmacology & Pharmacometrics
- Development of medicines in:
  - Virology
  - Neuroscience
  - Metabolic & Cardiovascular Diseases

# Recent Publications

- S Kasichayanula, **DW Boulton**, W-L Luo, AD Rodrigues, Z Yang, A Goodenough, M Lee, M Jemal, FP LaCreta. Validation of 4β-Hydroxycholesterol and Evaluation of Other Endogenous Biomarkers for the Assessment of CYP3A Activity in Healthy Subjects. *British Journal of Clinical Pharmacology* 2014; 78: 1122–1134.
- T Leil, S Kasichayanula, **DW Boulton** , FP LaCreta. Evaluation of 4β-Hydroxycholesterol as a Clinical Biomarker of CYP3A4 Drug Interactions using a Bayesian Mechanism-Based Pharmacometric Model. *Clinical Pharmacology and Therapeutics: Pharmacometrics and Systems Pharmacology* 2014 Jun 25;3:e120. doi: 10.1038/psp.2014.18.
- S Kasichayanula, X Liu, F Lacreta, SC Griffen, **DW Boulton**. Clinical Pharmacokinetics and Pharmacodynamics of Dapagliflozin, a Selective Inhibitor of Sodium-Glucose Co-transporter Type 2. *Clinical Pharmacokinetics* 2014, 53: 17-27.
- J-S van der Walt, Y Hong, L Zhang, M Pfister, **DW Boulton**, MO Karlsson. A Semi-Mechanistic Non-Linear Mixed Effects Model to Assess the Effects of Renal or Hepatic Impairment on the Population Pharmacokinetics of Dapagliflozin and Dapagliflozin 3-O-Glucuronide. *Clinical Pharmacology and Therapeutics: Pharmacometrics and Systems Pharmacology* 2013; 2: e42 doi: 10.1038/psp.2013.20
- Gould JC, Kasichayanula S, Shepperly DC, **Boulton DW**. Use of Low-Dose Clinical Pharmacodynamic and Pharmacokinetic Data to Establish an Occupational Exposure Limit for Dapagliflozin, a Potent Inhibitor of the Renal Sodium Glucose Co-Transporter 2. *Regulatory Toxicology and Pharmacology* 2013; 67:89-97.
- RA Defronzo, M Hompesch, S Kasichayanula, X Liu, Y Hong, M Pfister, LA Morrow, BR Leslie, **DW Boulton**, A Ching, FP Lacreta, SC Griffen. Characterization of Renal Glucose Reabsorption in Response to Dapagliflozin in Healthy Subjects and Subjects with Type 2 Diabetes. *Diabetes Care*. 2013; 36: 3169-3176.

# Pharmacokinetics

Pharmacokinetics, sometimes described as what the body does to a drug, refers to the movement of drug into, through, and out of the body—the time course of its absorption, disposition, metabolism and excretion

# PHARMACOKINETICS

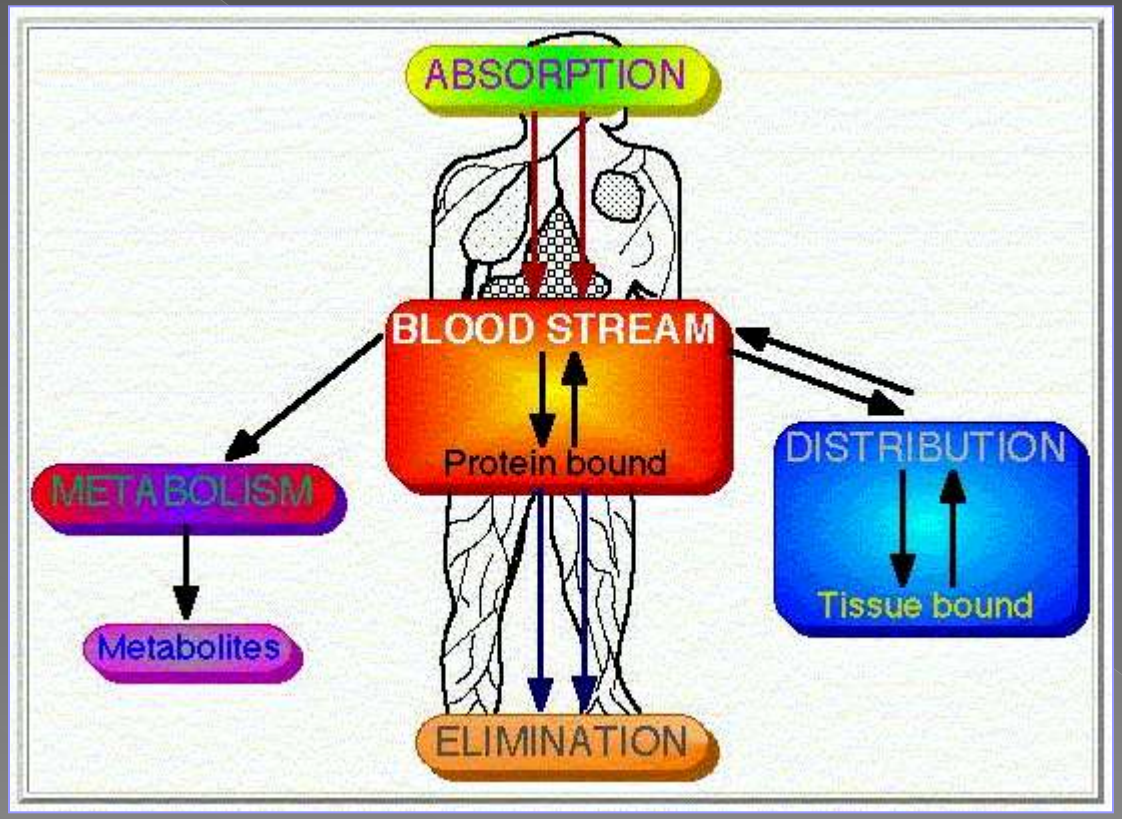
## “What the body does to the drug”

# *Pharmacokinetics (PK)*

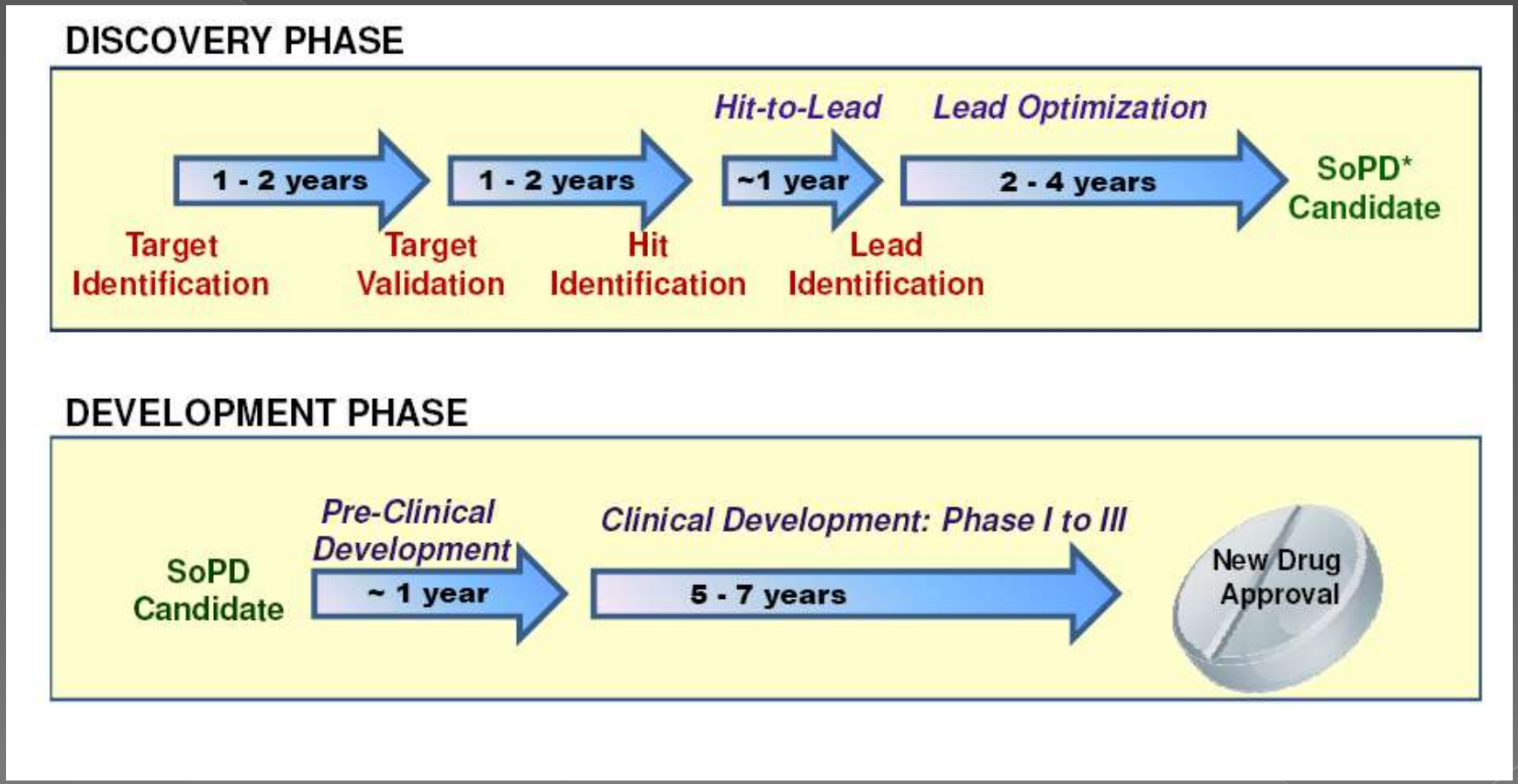
- The study of the ***disposition*** of a drug
- The disposition of a drug includes the processes of ***ADME***
  - **A**bsorption
  - **D**istribution
  - **M**etabolism
  - **E**xcretion

  } Elimination
  - **T**oxicity

# ADMET


ABSORPTION
BLOOD STREAM
Protein bound
METABOLISM
Metabolites
DISTRIBUTION
Tissue bound
ELIMINATION

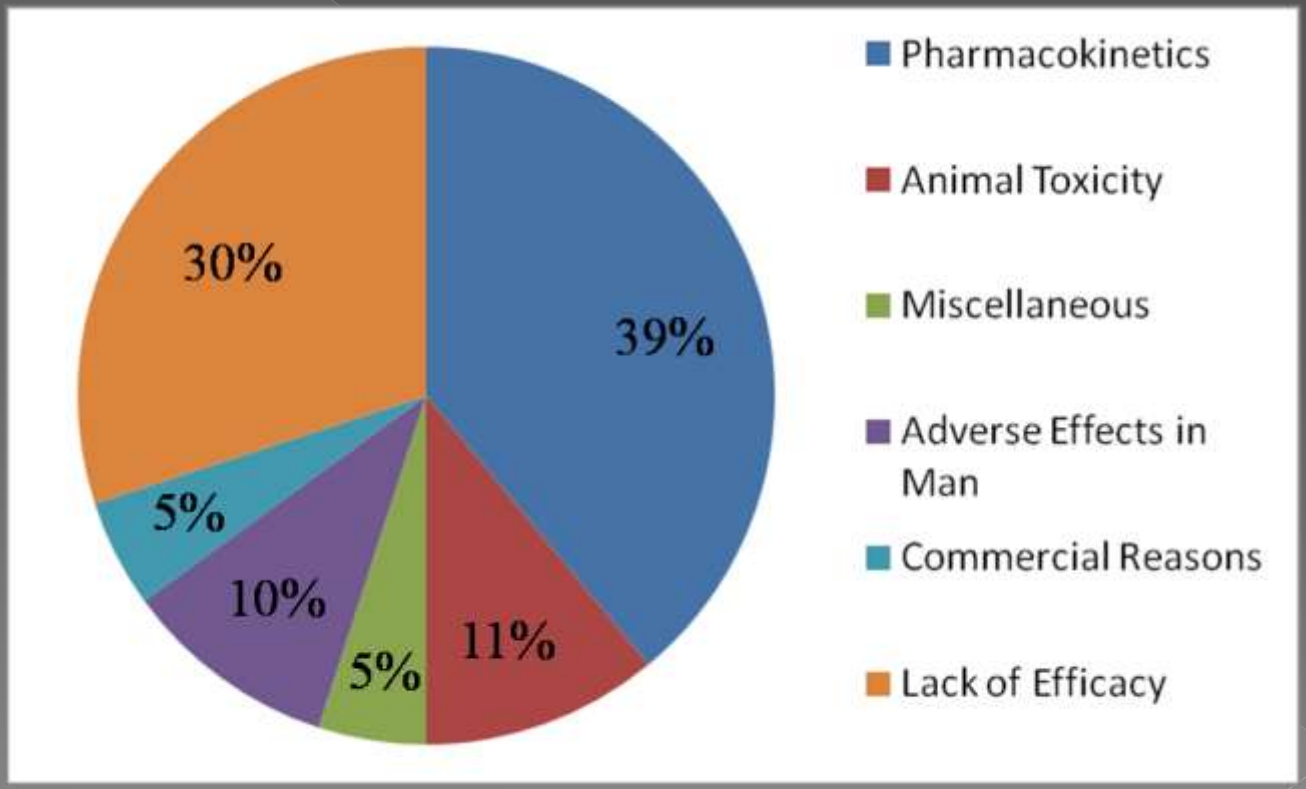
# DRUG R&D




**Drug discovery and development**

- **10-15 years to develop a new medicine**
- **Likelihood of success: 10%**
- **Cost $800 million – 1 billion dollars (US)**

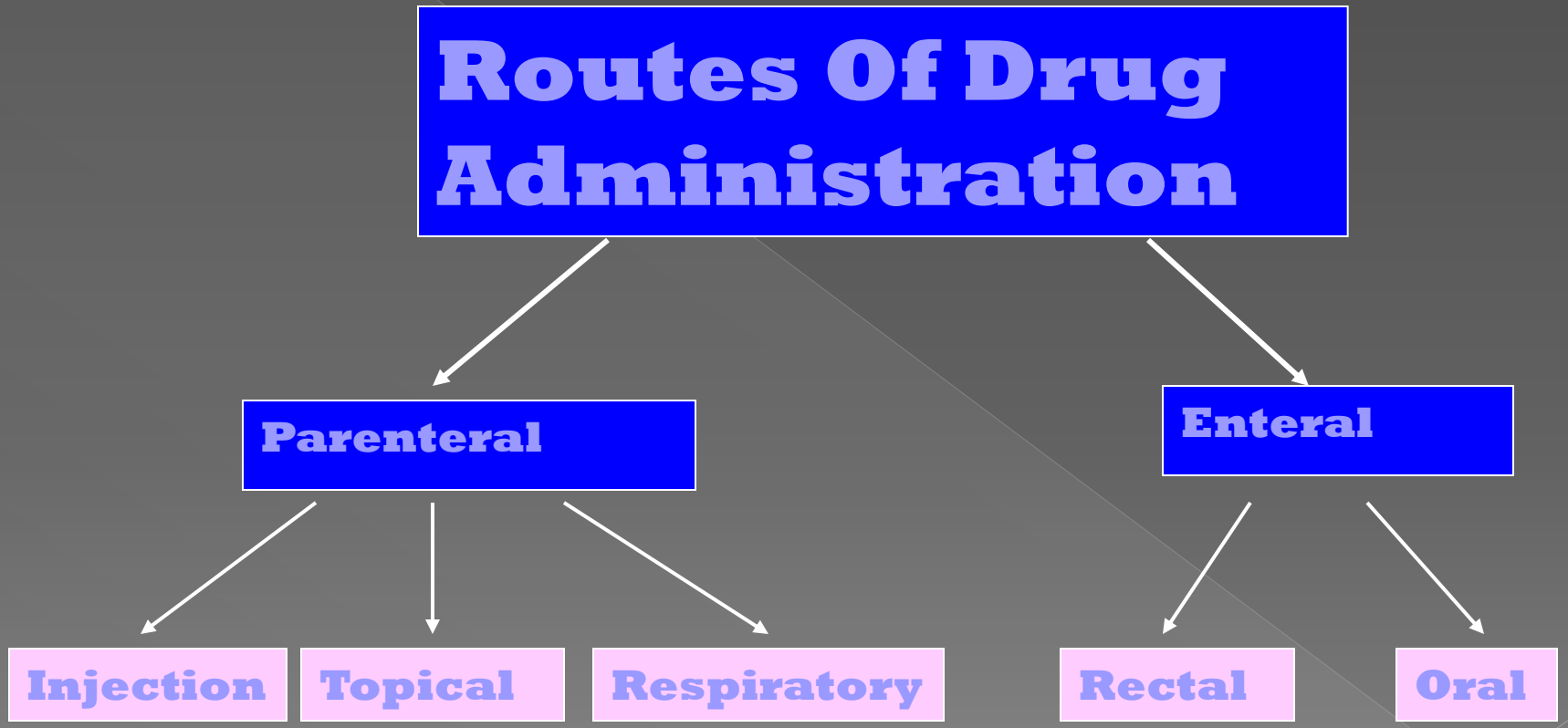
# Why drugs fail



# Importance of PK studies

- **Patients may suffer:**
  - **Toxic drugs may accumulate**
  - **Useful drugs may have no benefit because doses are too small to establish therapy**
  - **A drug can be rapidly metabolized.**

# Routes Of Administration



# Pharmaceutica Analytica Acta
# Related Journals

- Pharmaceutical Regulatory Affairs
- Pharmacovigilance

# Pharmaceutica Analytica Acta Related Conferences

- International Conference and Exhibition on Pharmacovigilance & Clinical Trials
- International Conference and Exhibition on Pharmaceutical Regulatory Affairs
- International Conference and Exhibition on Analytical & Bioanalytical Techniques

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# Signature:

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