Clinical Drug Interaction Dataset

Transforming scientific data into clinical knowledge

SCHOOL OF PHARMACY
UNIVERSITY OF WASHINGTON
The Clinical Drug Interaction Dataset contains study results from drug-drug, drug-food, drug-herb interaction studies, and case reports.

**Detailed study information** regarding design, population, drug dosing, PK, PD, and safety results are extracted from published articles (citations) and NDA reviews. Common metrics (percent changes in AUC, plasma concentrations, oral and renal clearance values) are used across all studies to allow metadata analysis of quantitative results.

**Study results** are organized according to the overall effect and the underlying mechanism(s) of the interaction:
- Enzyme and/or transport inhibition, induction, or no effect
- Other mechanisms, including absorption-based DDI and food-effect

**Comprehensive PK parameters** for object (victim) drugs and their metabolites, as well as precipitant (perpetrator) concentrations (when measured) are available.

**Multiple pre-formulated queries** allow users to retrieve an *in vivo* dataset by drug name, therapeutic class, specific enzyme or transporter, changes in exposure, or toxicity (including QT prolongation).

**Results** can be viewed, customized, and downloaded in multiple formats, allowing users to compile and organize the large body of information available.

[druginteractionsolutions.org](http://druginteractionsolutions.org)
FROM A CITATION OR NDA/BLA REVIEW

The latest, most relevant, peer-reviewed publications and regulatory documents are identified and fully analyzed. Study protocol and results are manually curated to update the knowledgebase on a daily basis.

Most often analyzed files:
- Printed labeling
- Multi-discipline review
- Chemistry review(s)
- Other review(s)
Prior to integration, all data are carefully and critically evaluated. The richness of each citation, including relevant insights, is exploited, generating a highly detailed dataset.

Idelalisib inhibits CYP3A with an AUC increase of 5.2-fold. What other strong CYP3A inhibitors change the AUC of the index substrate midazolam by at least 5-fold?
POWERFUL TOOL FOR **DATA INTEGRATION:**
FROM ONE CITATION TO METADATA ANALYSIS

The data are formatted for immediate use and can be filtered and re-arranged to allow meta-analysis of multiple results.

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Query all strong CYP3A inhibitors exhibiting exposure increases of at least 5-fold of the index substrate midalozam

**Percent Change in AUC or CL**

![Table View of Query Results]

Obtain a complete list of *in vivo* strong inhibitors of CYP3A
CLINICAL DRUG INTERACTION DATASET IN NUMBERS
(as of April 16, 2020)

10,932 / 27,567
in vivo DDI citations / in vivo DDI entries

12,037 / 21,159
positive entries / negative entries

43 in vivo queries with 388 possible searches

2,025 entries involving transporter(s)

2,452 case reports

1,858 / 1,839
objects (victims) / precipitants (perpetrators)

APPLICATIONS OF THE CLINICAL DRUG INTERACTION DATASET

PROVIDES CONTEXT for RESULTS OBTAINED with candidate compounds

HELPS DEVELOP OVERALL REGULATORY STRATEGY and optimize clinical drug interaction trials:
• Guides choice of appropriate index drugs and study design
• Refines inclusion/exclusion criteria
• Helps select dose, duration, and timing of administration of object and precipitant drugs
• Provides PK variability data for power calculations
• Quickly identifies known substrates/perpetrators of enzymes/transporters among marketed drugs to understand DDI risk with common co-medications

SUPPORTS STATIC PREDICTIONS and PBPK MODELING with input parameters

ACCESSSES REGULATORY DDI STUDIES for recently marketed drugs

PROVIDES REFERENCE RESOURCE for ASSESSMENT of DRUG INTERACTION SAFETY

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