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R&D Solutions

Leverage Pharmacokinetic data in PharmaPendium to inform drug development strategies

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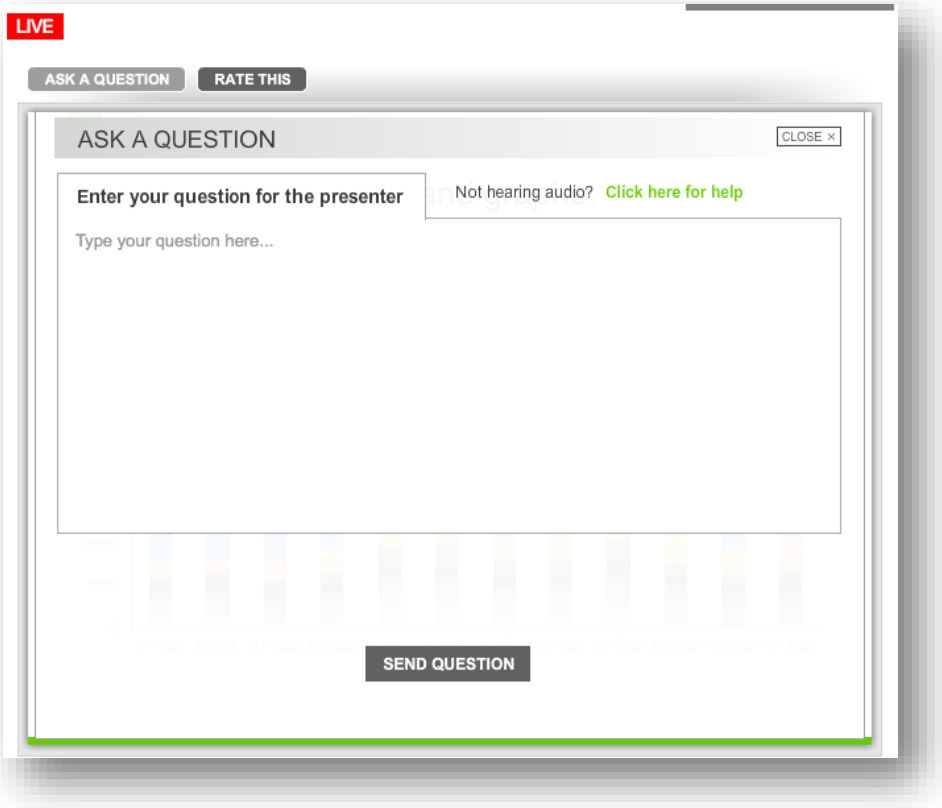
Empowering Knowledge

We suggest viewing the presentation in full screen

Questions?

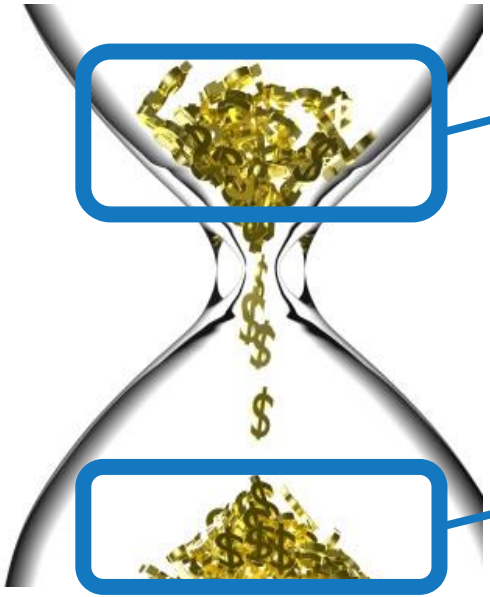
- You are welcome to submit questions by using the “Ask a Question” feature on your screen.
- As many questions as possible will be answered after the webinar.
- Slides and the recording will be sent to you following the webinar and are also available in the PharmaPendium Help section



Agenda

- Brief PharmaPendium overview
- Focus on Pharmacokinetic data in PharmaPendium
- Examples:
  - Finding PK data for similar drugs
  - Finding information on the best preclinical model to use
  - Identifying if different patient populations impact PK data
  - Correlating observed DDI affects with PK data

Critical decision-support



- ✓ Leverage past drug approvals to inform bottleneck issues
- ✓ Design studies that provide the most meaningful data
- ✓ Reduce unnecessary preclinical and clinical costs by comparing your drug to successful ones
- ✓ Rapidly evaluate potential DDI risks

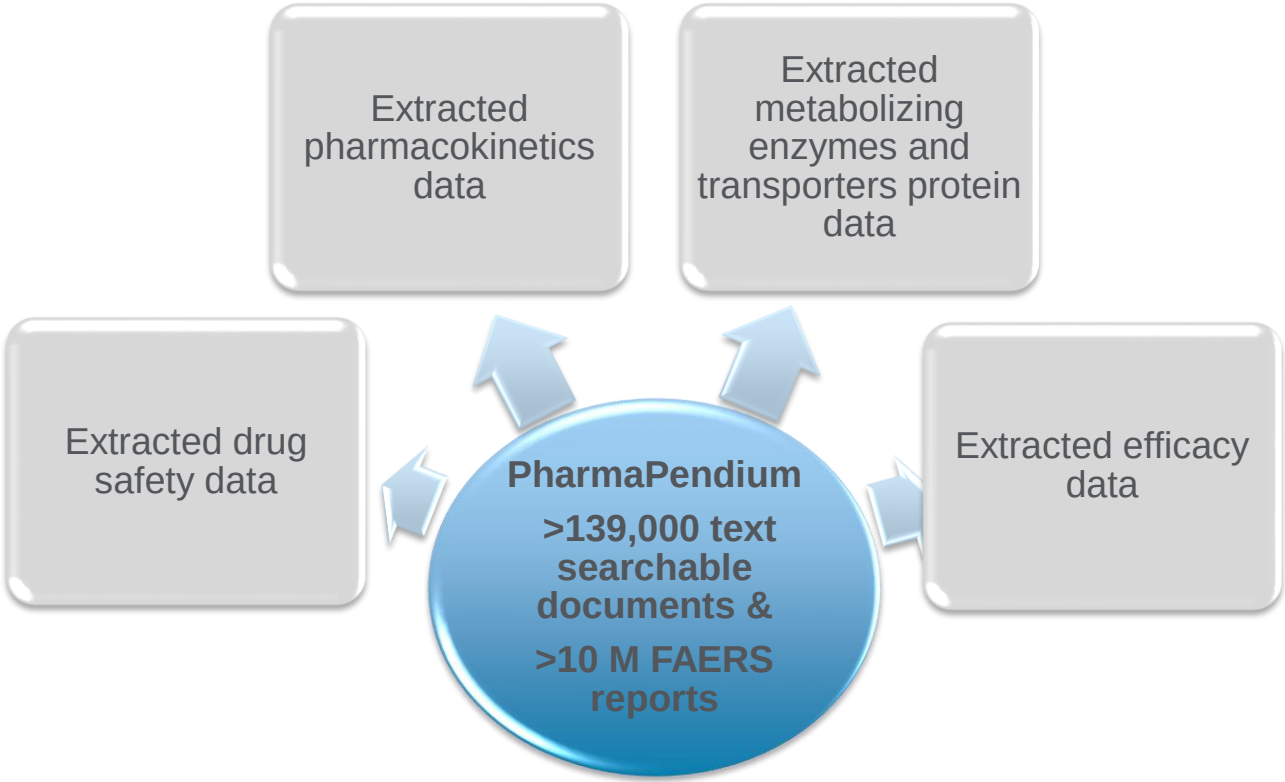
PharmaPendium

PharmaPendium supports decision-making throughout Drug Development

R&D Phase	Information in PharmaPendium helps you to:
Preclinical	• Determine Drug Safety assessments on lead candidates • Anticipate drug-drug interactions and other adverse events • Optimize *in vivo* / *in vitro* study designs, select and prioritize leads • Increase chances of successful submissions to regulatory authorities based on past precedents • Leverage drug precedents to help translate preclinical data into human effects / outcomes
Clinical	• Examine drug approval packages to inform clinical study designs (population, indications, endpoints, etc)

Post-launch	• Leverage lessons learned to:
	  • Develop risk management and strategic programs,
	  • Improve clinical trial design
	• Monitor AERS reports for to identify post marketing safety concerns

Integrated FDA/EMA Drug Approval Docs & extracted data



Content and value is continually growing

Source Documents

2.3M+
pages of FDA approval documents

215K+
pages of EMA approval documents

10.4M+
FDA AERS reports

690K+
Pages from FDA Advisory Committee Meetings

Extracted Data

4485
Drugs indexed & fully searchable

1.64M+
PK data lines

315K+
Metabolizing enzyme and transporter data lines

1.71M+
safety data lines

2.71M+
efficacy data lines

115K
activity data lines

Role	R&D Phase	Challenges
Pharmacokinetic Scientist	Preclinical	• Effectively assessing and prioritizing lead candidates • Determining the best study designs • Interpreting Absorption, Distribution, Metabolism, Excretion (ADME) data on drug candidates and prioritizing candidates on deliverability • Helping to translate animal dosing and safety data to humans

How does PharmaPendium support Pharmacokinetic Scientists?

- Access safety, efficacy, PK and Metabolizing Enzymes and Transporter data to help inform drug development strategies.
  - Inform PK study design by looking at in vivo and in vitro models used to support preclinical and clinical research of similar drugs, drug classes.
  - Leverage lessons learned from precedents found in regulatory documents and extracted preclinical and clinical data from drug approvals.
  - Gain insights from comparative data on the translatability of preclinical experimental data.
  - Build models to compute potential PK properties for their drug candidates

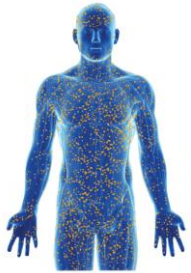
Answer critical drug development questions, including:

- ✓ Is the drug safe and effective within the therapeutic window?
- ✓ How much drug gets to where it needs to go?
- ✓ What is the bioavailability of the drug?
- ✓ Which animal model translated the best to humans in drugs similar to the one in development?
- ✓ What is the maximum tolerated dose for drugs similar to the one under development?
- ✓ What new secondary experiments need to be run prior to submission, if any? How were these experiments designed?
- ✓ Can I cite a previously-run experiment from a similar drug?

Pharmacokinetic module

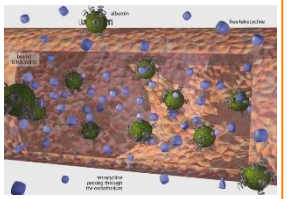
Absorption

Includes:
- % Absorbed
- Bioavailability
- Concentrations
- Fraction absorbed
- Time values



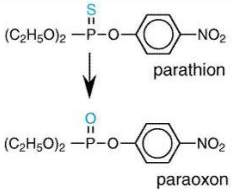
Binding

Includes:
- Cell binding
- Protein binding



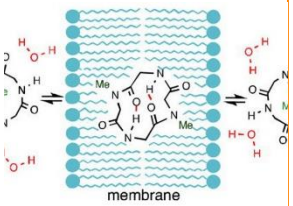
Biotransformation

Includes:
- Enantiomeric ratio
- Metabolic ratio
- Metabolic stability
- Metabolic transformation



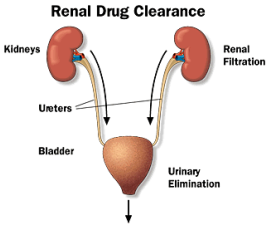
Distribution

Includes:
- Accumulation
- AUC
- Permeation
- Steady state
- Time value
- Tissue distribution
- Volume of distribution



Elimination

Includes:
- Clearance
- Excretion values
- Half life
- Rate constants
- Time



Species

Includes:
- Human (including subpopulation
- Vertebrates
  - Birds
  - Fish
  - Mammals

Demo

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Thank You!

Any Questions?

For more information:

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