R&D Solutions

Leverage Pharmacokinetic data in PharmaPendium to inform drug development strategies
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

<table>
<thead>
<tr>
<th>R&amp;D Phase</th>
<th>Information in PharmaPendium helps you to:</th>
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</thead>
<tbody>
<tr>
<td>Preclinical</td>
<td>• Determine Drug Safety assessments on lead candidates</td>
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<td>• Anticipate drug-drug interactions and other adverse events</td>
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<td></td>
<td>• Optimize <em>in vivo / in vitro</em> study designs, select and prioritize leads</td>
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<td></td>
<td>• Increase chances of successful submissions to regulatory authorities based on past precedents</td>
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<td>• Leverage drug precedents to help translate preclinical data into human effects / outcomes</td>
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<tr>
<td>Clinical</td>
<td>• Examine drug approval packages to inform clinical study designs (population, indications, endpoints, etc)</td>
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<td>Post-launch</td>
<td>• Leverage lessons learned to:</td>
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<tr>
<td></td>
<td>• Develop risk management and strategic programs,</td>
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<td>• Improve clinical trial design</td>
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<td>• Monitor AERS reports for to identify post marketing safety concerns</td>
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Integrated FDA/EMA Drug Approval Docs & extracted data

- Extracted pharmacokinetics data
- Extracted metabolizing enzymes and transporters protein data
- Extracted drug safety data
- Extracted efficacy data

PharmaPendium

>139,000 text searchable documents & >10 M FAERS reports
Content and value is continually growing

### Source Documents

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<tr>
<th>Count</th>
<th>Description</th>
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<tr>
<td>2.3M+</td>
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<td>215K+</td>
<td>Pages of EMA approval documents</td>
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<tr>
<td>10.4M+</td>
<td>FDA AERS reports</td>
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<tr>
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<td>Pages from FDA Advisory Committee Meetings</td>
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### Extracted Data

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<tr>
<td>315K+</td>
<td>Metabolizing enzyme and transporter data lines</td>
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<td>1.71M+</td>
<td>Safety data lines</td>
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<tr>
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<td>Efficacy data lines</td>
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<tr>
<td>115K</td>
<td>Activity data lines</td>
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</table>
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**
- % Absorbed
- Bioavailability
- Concentrations
- Fraction absorbed
- Time values

**Binding**
- Cell binding
- Protein binding

**Biotransformation**
- Enantiomeric ratio
- Metabolic ratio
- Metabolic stability
- Metabolic transformation

**Distribution**
- Accumulation
- AUC
- Permeation
- Steady state
- Time value
- Tissue distribution
- Volume of distribution

**Elimination**
- Clearance
- Excretion values
- Half life
- Rate constants
- Time

**Species**
- Human (including subpopulation)
- Vertebrates
  - Birds
  - Fish
  - Mammals
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Thank You!
Any Questions?

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