PharmaPendium®

Release notes December 2021

New toxicity parameters are now available in the Drug Safety Module

To improve support for determining ***first-in-human dosing***, PharmaPendium has added over 20 toxicity parameters in the Drug Safety module.

- These values, such as NOAEL (no observed adverse effects level) and LOAEL (lowest observed adverse effect level) can be difficult to find and are not always in the drug labels.
- These parameters are being extracted from FDA and EMA approval packages from the beginning, and preclinical relevant literature from 2020.
- We have added 49000+ points of data giving PharmaPendium an unprecedented depth of safety toxicity information.

What are the benefits of this release?

- Knowing which species to test is not always obvious, so knowing the NOAEL will help you ***select the most sensitive specie*** for your pre-clinical studies. This data is also critical if regulatory agencies ask for the rationale for the specie that was used.
- With these parameters PharmaPendium will better support preclinical study designs and lead to ***more confident benchmarking of your drug candidate*** vs best-in class approved drugs in the same drug/target class.
- PharmaPendium makes it ***faster and easier*** for you to retrieve information about approved drugs and parameters such as NOAEL, AEs, AE comments, dose, route, and more.

Which toxicity parameters have been added?

Please see the table below

Category	Toxicity Parameters		Definition	Before	Now
No adverse event	NOAEL*	No Observed Adverse Effect Level	The highest dose level of a substance that under defined conditions of exposure causes no observable/detectable adverse effect (alteration) on morphology, functional capacity, growth, development, or life span of the test animals.	✗	✓
No adverse event	NOAEC*	No Observed Adverse Effect Concentration	The highest dose concentration of a substance that under defined conditions of exposure causes no observable/detectable adverse effect	✗	✓

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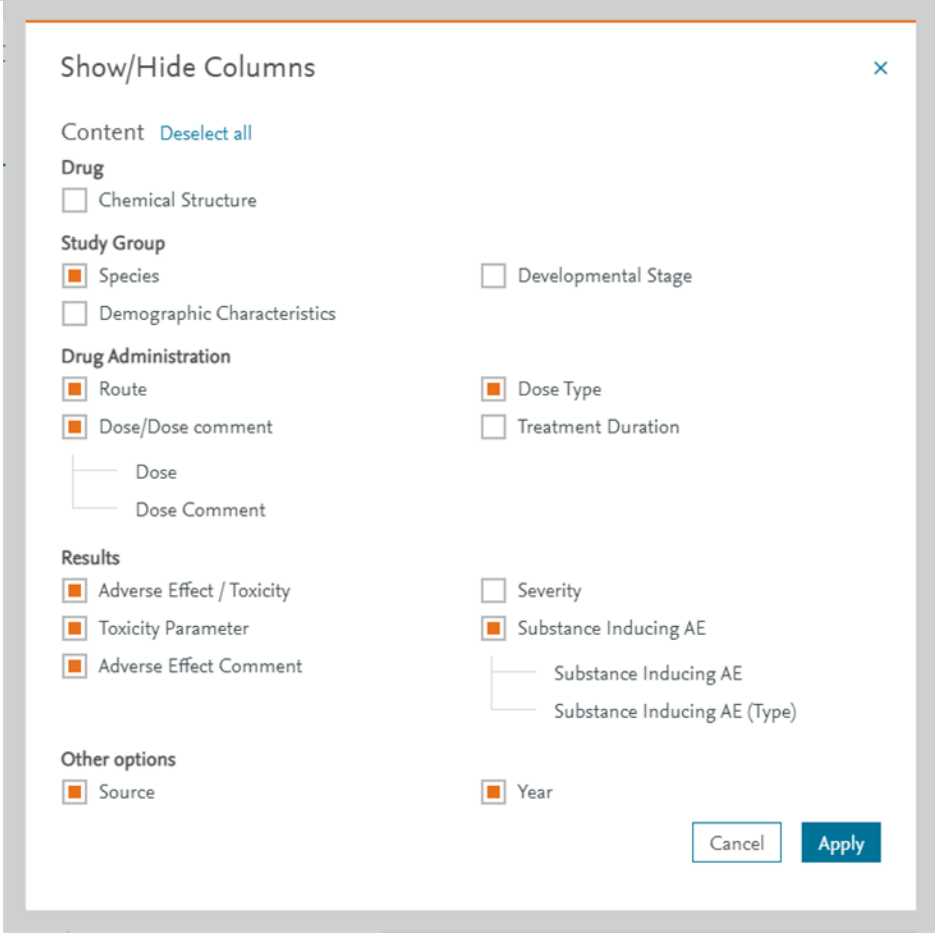
			(alteration) on morphology, functional capacity, growth, development, or life span of the test animals.		
No adverse event	NOEL*	No Observed Effect level	The highest dose level of a substance that under defined conditions of exposure causes no effect (alteration) on morphology, functional capacity, growth, development, or life span of the test animals.	✗	✓
Death	LD10, 20, 50*, 60, 90, 95, 99, 100	Lethal Dose 10, 20, 50*, 60, 90, 95, 99, 100	The dose at which 10, 20, 50*, 60, 90, 95, 99, 100% of the individuals will die	✗ *✓	✓
Death	LDLo	Lethal Dose Low	The lowest dosage of a compound that is introduced to the human body or that of an animal by any means apart from inhalation that will cause the death of the individual.	✗	✓
Death	Maximum sublethal dose	Maximum sublethal dose	The maximum dose of a toxic substance that is "insufficient to cause death"	✗	✓
Adverse drug reaction	LOAEC	Lowest Observed Adverse Effect Concentration	The lowest concentration of a substance where the effects observed in the treated group imply an adverse effect to the subject.	✗	✓
Adverse drug reaction	LOAEL	Lowest Observed Adverse Effect Level	The lowest dose where the effects observed in the treated group imply an adverse effect to the subject.	✗	✓
Adverse drug reaction	LOEL	Lowest Observed Effect Level	The lowest dose where there are differences between the control and the treated group.	✗	✓
Adverse drug reaction	MTD**/MTD50	Maximum Tolerated Dose / Maximum Tolerated Dose 50	The maximum dose that can be administered for the duration of a specific study that will not compromise the survival of the animals by causes other than carcinogenicity	✗	✓
Adverse drug reaction	TC50	Toxic concentration 50	The concentration at which toxicity occurs in 50% of cases	✗	✓
Adverse drug reaction	TD50	Toxic dose 50	The dose at which toxicity occurs in 50% of cases	✗	✓
Adverse drug reaction	TDlo	Toxic dose low	The lowest dose of a substance introduced by any route, other than inhalation, over any given period of time, and reported to produce any toxic effect in humans or to produce tumorigenic or reproductive effects in animals.	✗	✓

Do the Drug Safety tables provide new columns of information?

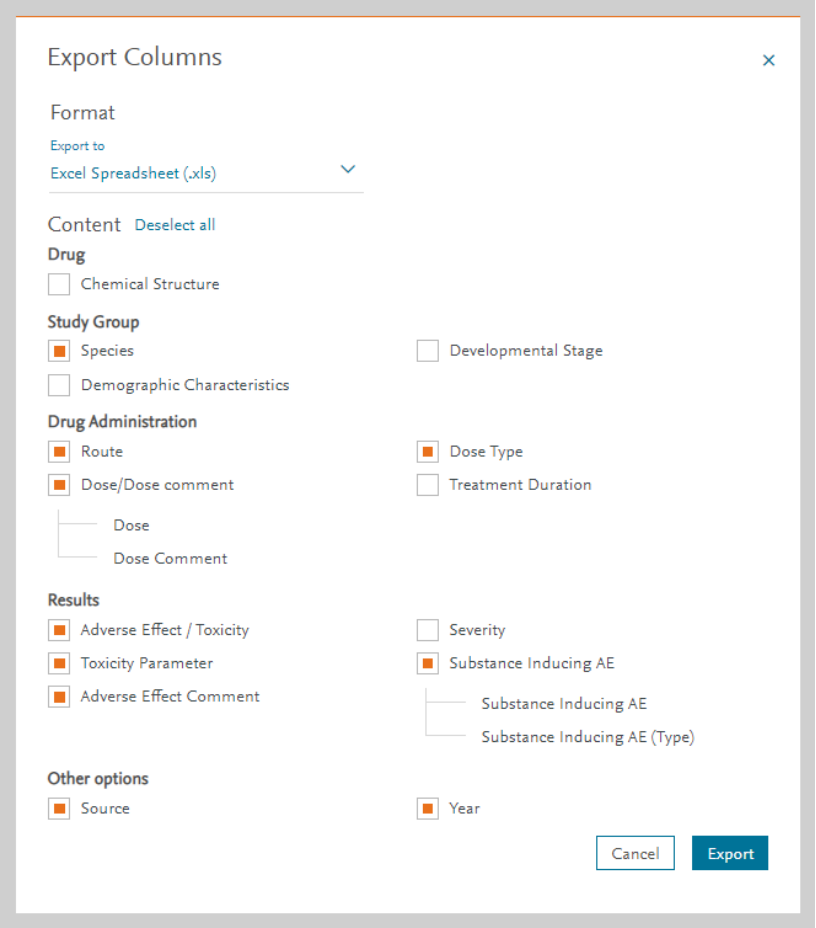
Yes, please see the table below:

Column name	Category	Before	now
Chemistry structure	Drug	✓	✓
Adverse Effect / Toxicity	Results	✓	✓
Toxicity parameter	Results	✗	✓
Adverse Effect comment	Results	✗	✓
Severity	Results	✗	✓
Substance inducing AE	Results	✗	✓
Substance inducing AE (type)	Results	✗	✓
Species	Study Group	✓	✓
Demographic Characteristics	Study Group	✗	✓
Development Stage	Study Group	✗	✓
Route	Drug Administration	✓	✓
Dose	Drug Administration	✓	✓
Dose comment	Drug Administration	✗	✓
Dose Type	Drug Administration	✓	✓
Treatment duration	Drug Administration	✗	✓
Source	Other options	✓	✓
Year	Other options	✓	✓

Toxicity Parameters and related values can be customized in the Show/Hide columns option in the Drug Safety module:



Toxicity Parameters and related values can be customized in the Export option in the Drug Safety module:



These parameters can be exported under the following formats:

Excel Spreadsheet (.xls)

Excel Open XML format (.xlsx)

Tab Separated Values (.tsv)

Or Comma Separated Values (.csv)

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