IB derisk – Pitch KlinFarm

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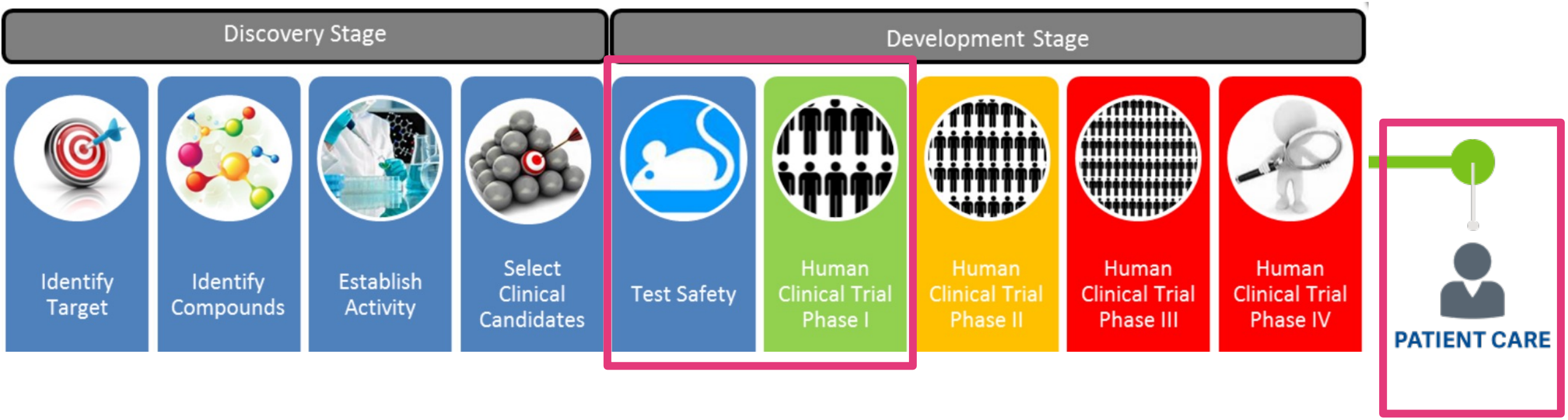
How to choose the clinical dose

Drug development



- Best chance of taking the right dose to patients:
  - Determine safe starting dose for FIH
  - Determine effective dose range in early clinical trials

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Pre-clinical studies

Drug development

- *In vitro* and *in vivo* work in different species
  - Toxicology
  - Pharmacokinetics
  - Pharmacodynamics
- Combined in the Investigators Brochure (IB)
- Crucial document for FIH trial

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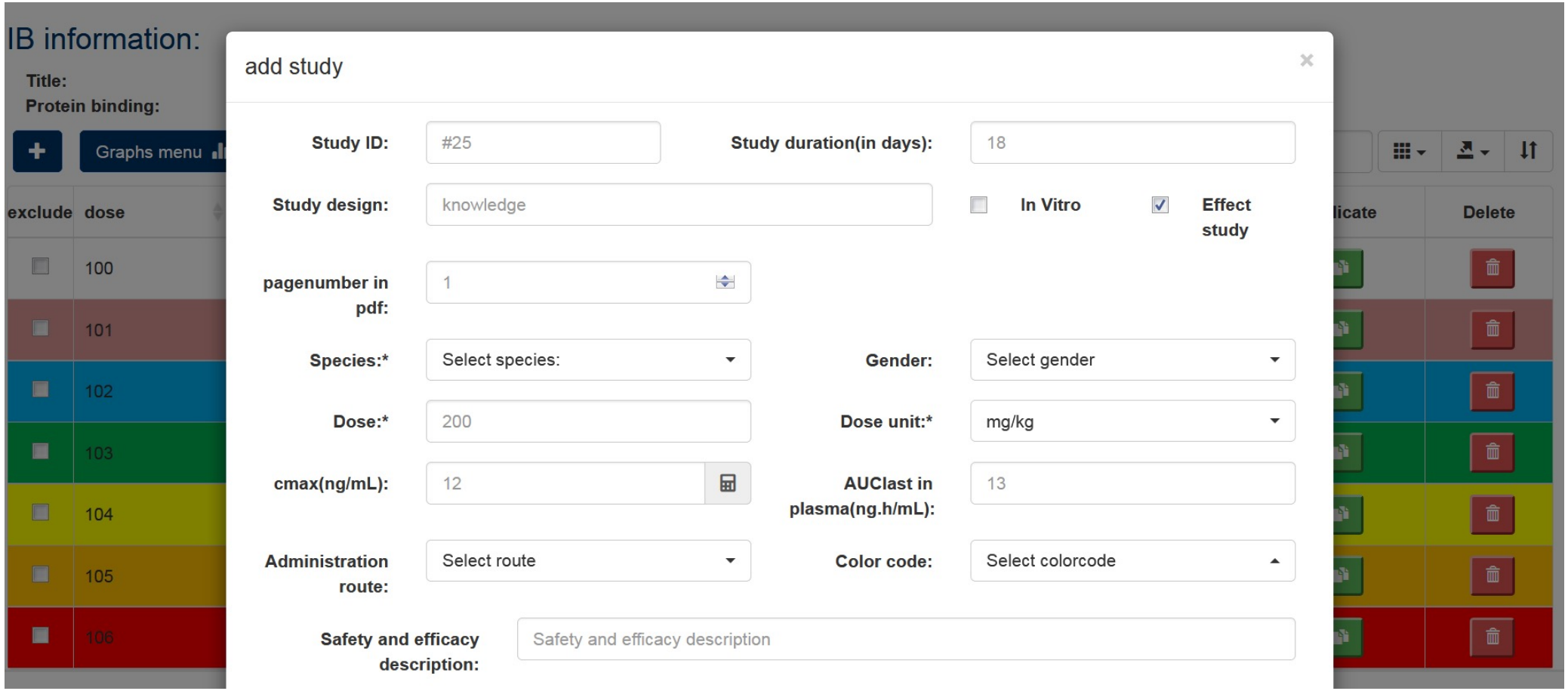
IB-derisk

Tool to structure IB information



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Colour coding

IB-derisk

☐	100	Study without clinical observations			
☐	103	Desirable effect			
☐	104	Undesirable but acceptable effects			
☐	105	More severe adverse effects			
☐	106	Serious irriversible toxicity and/or death			

☐	102	Intended human dose			

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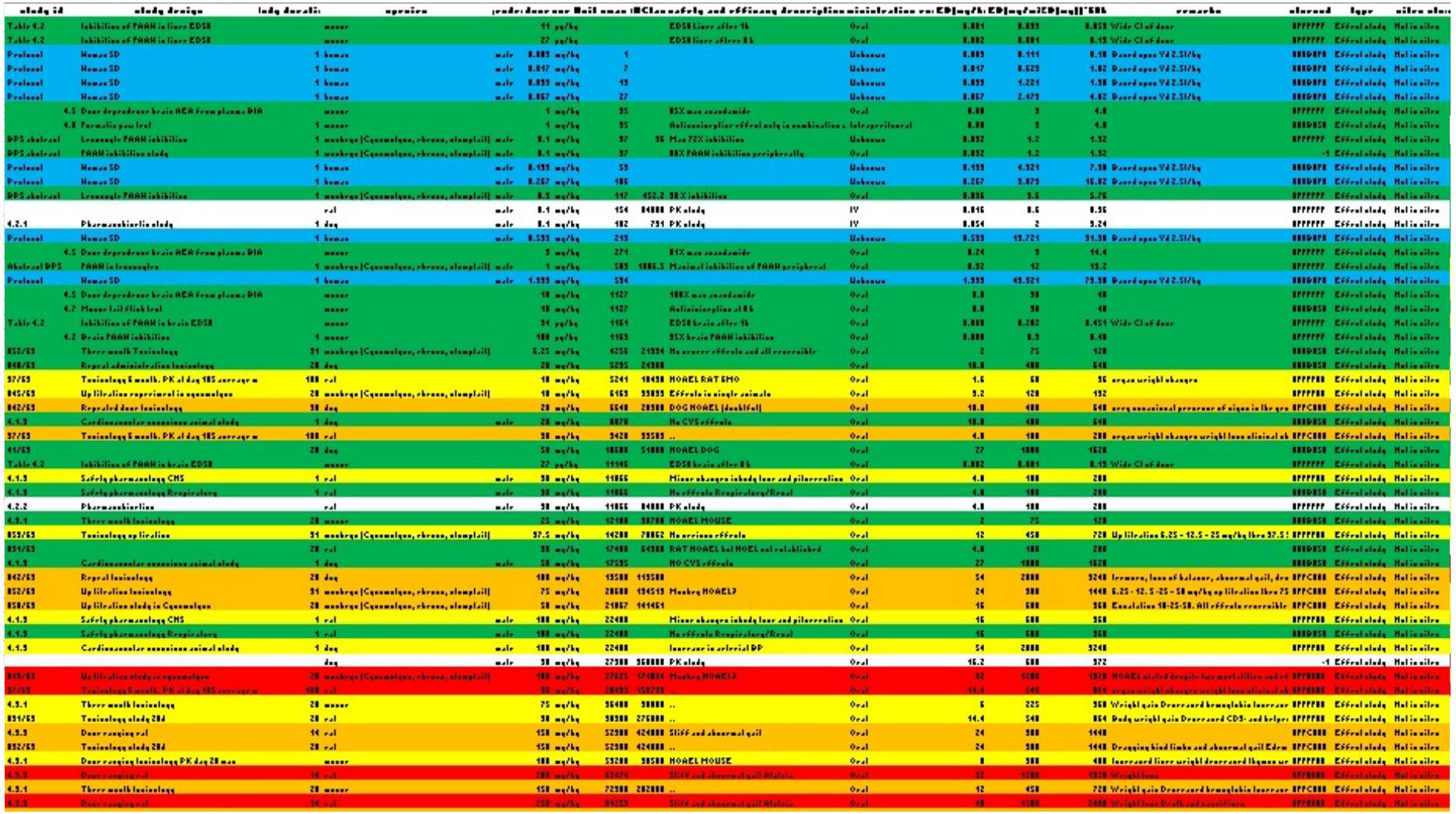
Colour pattern

Pre-clinical data



Starting dose

Adverse effects
(~ 5000 ng/mL)

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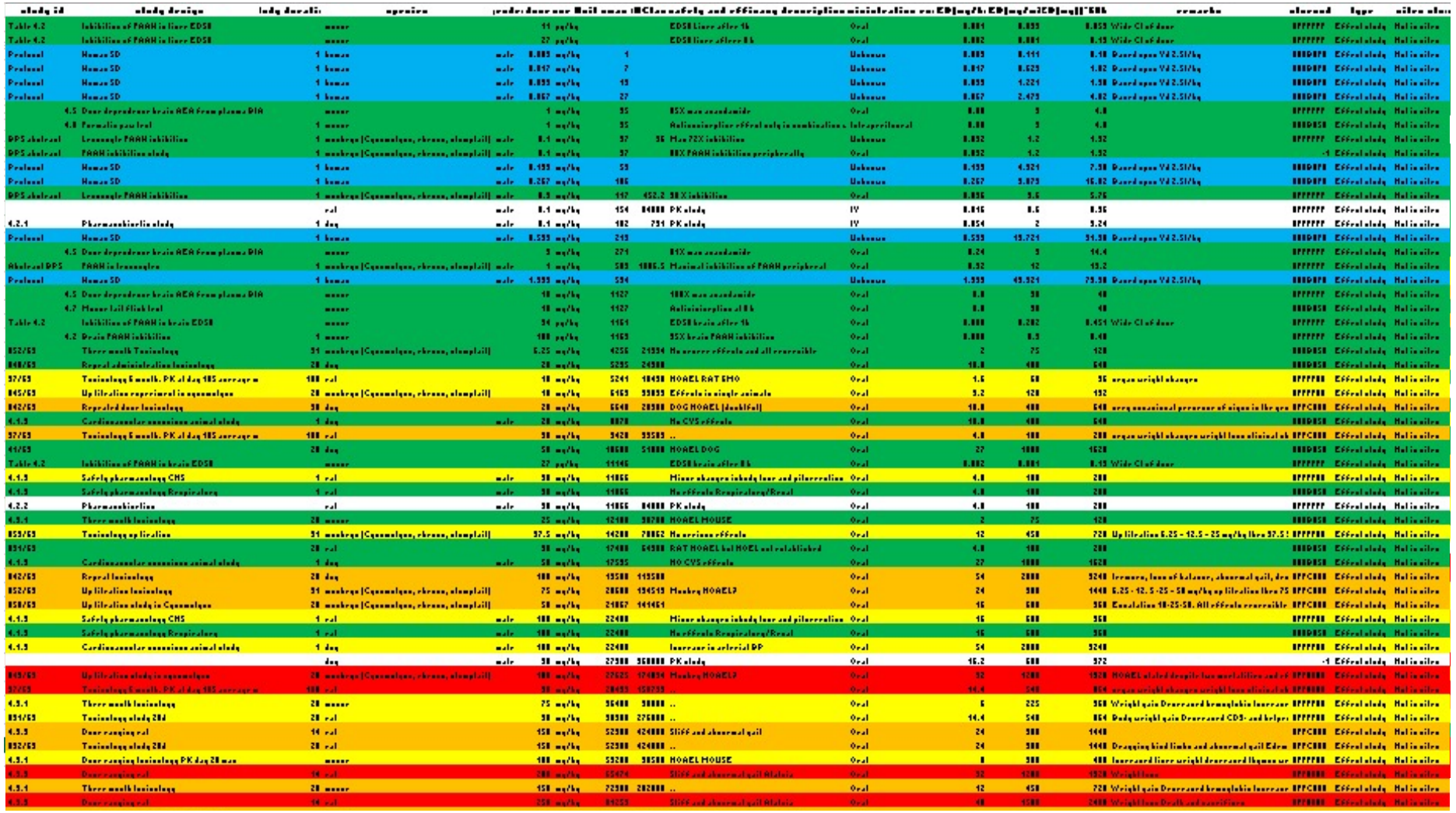
IB-derisk and dose range

Pre-clinical data



MABEL (~1 ng/mL)

Starting dose

ATD (~100 ng/mL)

Adverse effects
(~ 5000 ng/mL)

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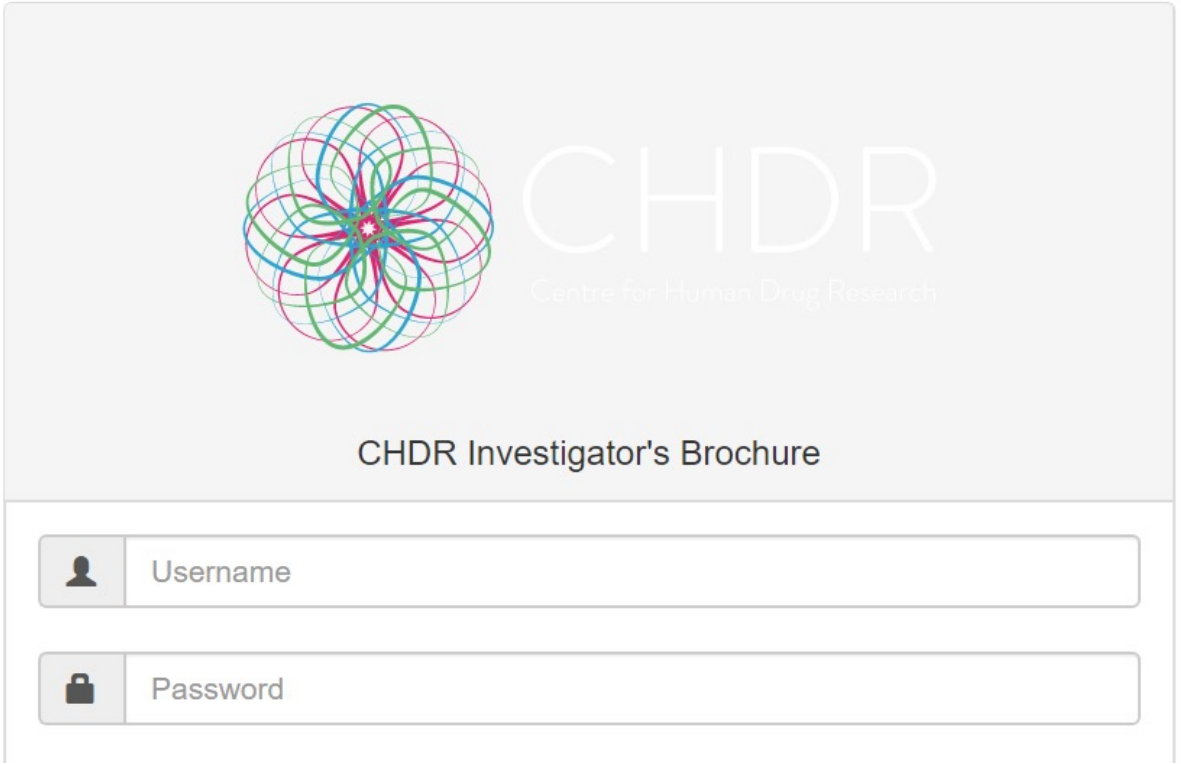
IB derisk as educational tool

NVKFB

<u>Why?</u>

- Understanding of pre-clinical and clinical pharmacology
  - Toxicology
  - Pharmacokinetics
  - Pharmacodynamics
  - Translation
  - Protein binding
  - Interpretation
- Crucial step in drug development
  - Translation from Pre-clinical → Clinical



<u>How to implement in education centres?</u>

- IB-derisk tool freely available
- CHDR could make a set of IB's for this educational purpose available
- Comparison possible between student and study team outcome / dosing plan

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WWW.IB-DERISK.ORG

https://youtu.be/jPvXk7yiuxw

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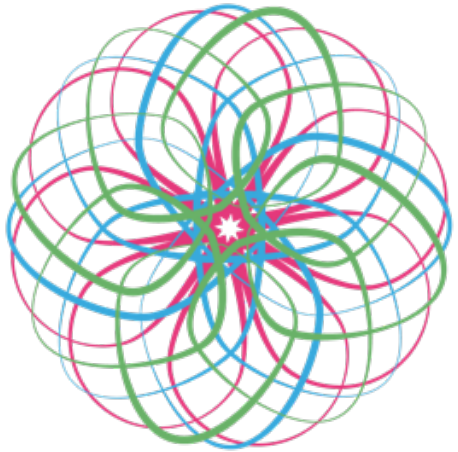

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