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Translating preclinical insights into early psychopharmacology trials: application of the IB-Derisk analyser tool

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Stellingen behorende bij het proefschrift getiteld: Translating Preclinical Insights into Early Psychopharmacology Trials: Application of the IB-Derisk Analyser Tool

1. The Investigator's Brochure (IB) of novel investigational compounds should be supplemented with an IB-Derisk analyser overview, ensuring that clinical investigators are adequately informed about key pharmacological characteristics when designing and conducting clinical trials. *(this thesis)*.
2. Preclinical data are critical for estimating the anticipated safe pharmacologically active dose range of novel investigational compounds in humans, thereby forming the basis for rational dosing strategies during early-phase clinical drug development. *(this thesis)*.
3. Determining the starting dose for a first-in-human trial solely on the NOAEL should be considered outdated and unsafe, although such approach is still very often applied. *(this thesis)*.
4. As with the IB-Derisk analyser overview, there are expressions for which colour conveys meaning more effectively than any other medium. *(this thesis)*.

(I found I could say things with color and shapes that I couldn't say any other way. Adjusted from Georgia O'Keeffe)

5. A comprehensive interpretation of preclinical findings, alongside systematic evaluation of the pharmacokinetic and pharmacodynamic properties of novel compounds in early phase clinical trials, is essential to mitigate the high attrition rates observed in late stages of CNS drug development.
6. Closer collaboration and transparent communication between preclinical and clinical researchers are essential to enhance not only safety but overall efficiency of clinical drug development.
7. The development of translatable imaging and electrophysiological biomarkers to assess neurocircuit modulation represents a valuable strategy for advancing drug development in psychiatry.
8. In contrast to what many may believe, the charm of early phase drug development is its predictability.

(The charm of life is its unpredictability. Adjusted from Amelia Barr)

9. Pursuing a PhD is akin to raising children: it is a journey that cannot be undertaken alone.
10. It is not the speed of your steps that matter, but the steadfastness of your path.

(It does not matter how slowly you go as long as you do not stop. Adjusted from Confucius).