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Ecological validity of biomarkers in drug research

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Stellingen behorende bij het proefschrift

ECOLOGICAL VALIDITY OF BIOMARKERS IN DRUG RESEARCH

- 1 A biomarker sensitive to drug effects does not always predict clinical efficacy or the outcome of patient-reported outcomes. (this thesis)
- 2 The selection of biomarkers for clinical studies should not only be guided by technical aspects, but also by their contextual relevance to real-world functioning and daily activities. (this thesis)
- 3 The introduction of ecological validity as criterium for biomarker selection in drug development may reduce failures in late-phase drug development. (this thesis)
- 4 Lower levels of ecological validity can benefit operational feasibility of clinical trials, possibly at the cost of clinical relevance. (this thesis)
- 5 The path from biomarker to clinical outcome assessment is an intentionally arduous process to protect patients.
- 6 The progression toward registration trials requires outcome measures that are both scientifically robust and clinically meaningful to prevent late-stage failures in drug development.
- 7 Biomarkers play a crucial role in early drug development by providing early signals of efficacy and safety.
- 8 Regulation of on-the-road driving studies is paralyzed due to conflicting scientific, political, and legal responsibilities.
- 9 Academics learn more and more, until they know nothing.
- 10 Procedures are meant to serve people.
- 11 Science in politics is a must, politics in science a scandal.
- 12 Comparison is a thief of joy.