ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

Taking personalized medicine seriously – biomarker approaches in Phase IIb/III studies in Major depression and Schizophrenia

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Knowing is not enough, we must apply.

Willing is not enough, we must do

- Goethe

(From the front page of the “Evaluation of Biomarkers and Surrogate Endpoints in chronic disease” by the Institute of Medicine of the National Academies)

Individualized medicine has a long tradition:

-Constitution (may come back as genetic predisposition)

-Diagnostic differentiation on the basis of differentiated symptom patterns (i.e. atypical vs. melancholic depression).

WE ARE NOT PRIMARILY TAKING ABOUT THOSE TODAY

Obstacles:

1. Business Model:
- costs
- impact on label

2. Validation:
- technical validation
- medical validation

3. Mindset:
- psychological

vs.

-biological disease model

Further:

Absence of a disease concept

"Drug candidates fail for one of four major reasons:

1) The compound is given to the wrong subjects.
2) The compound is given at the wrong dose or schedule.
3) The favorable effects of the compound are not detected.
4) The compound has a significant effect in laboratory species, but not in humans."

Hurko and Ryan, WYETH, 2006

Examples for widely used and inexpensive biomarkers in clinical trials in psychiatry:

1. Blood pressure
2. Inflammatory markers (CRP)
3. Plasma triglycerides and cholesterol
4. Gender