HTA's body perspective on registries

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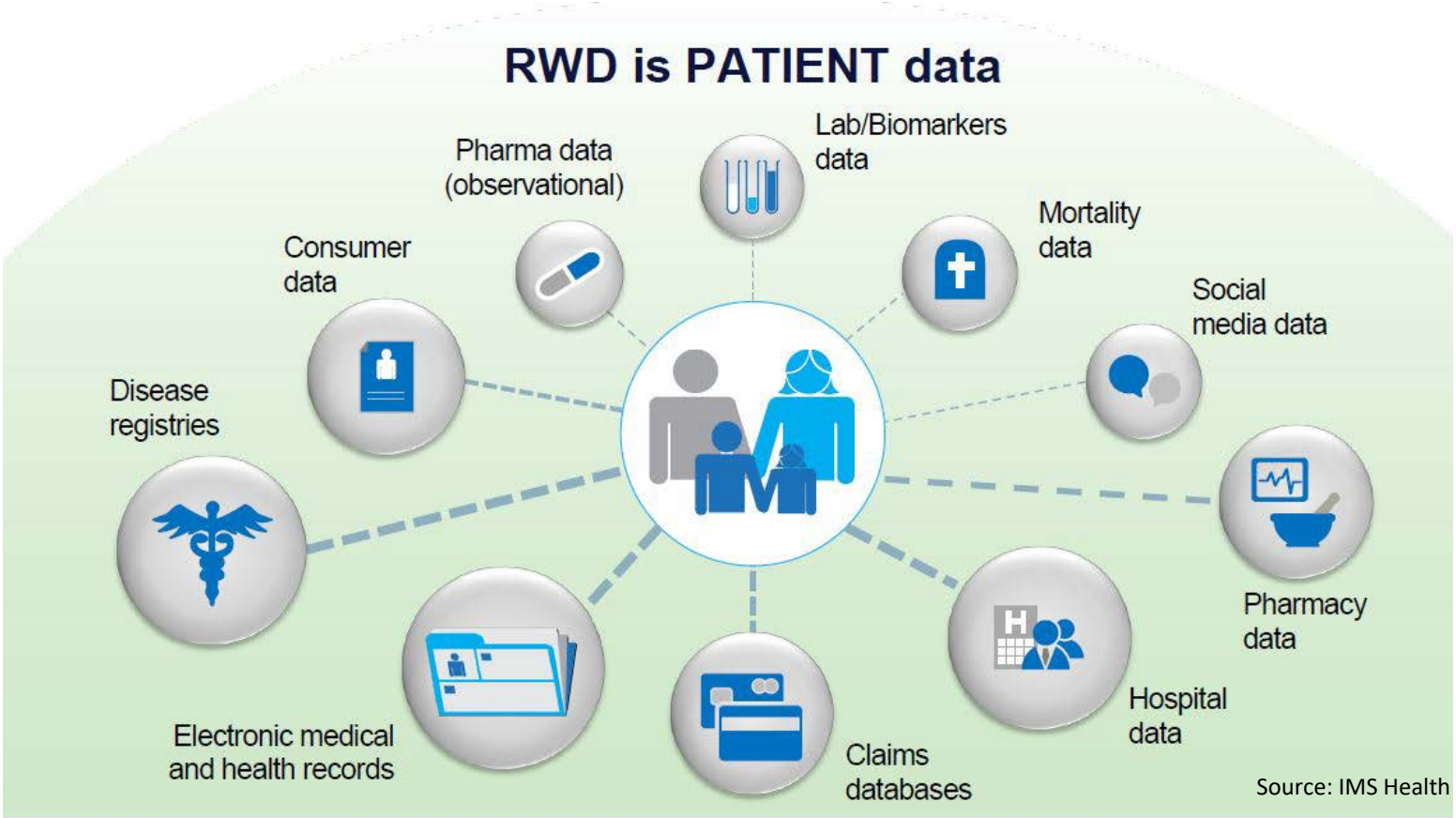
RWD/RWE = Big Data = Registry = ….



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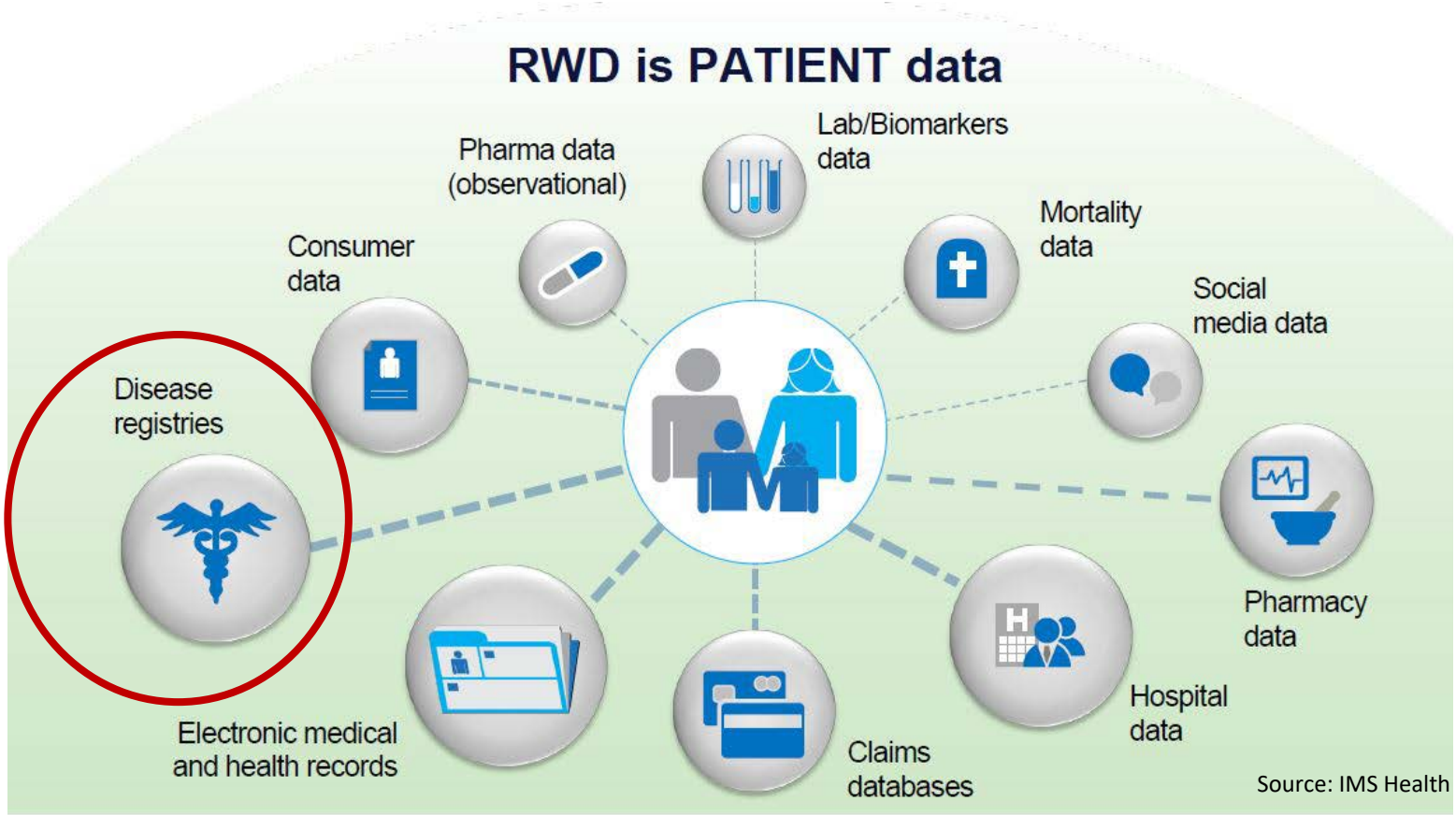


We use both kinds of data already…

- RCT

Efficacy

Does it work in experimental setting

Population selected

Placebo or a selected comparator

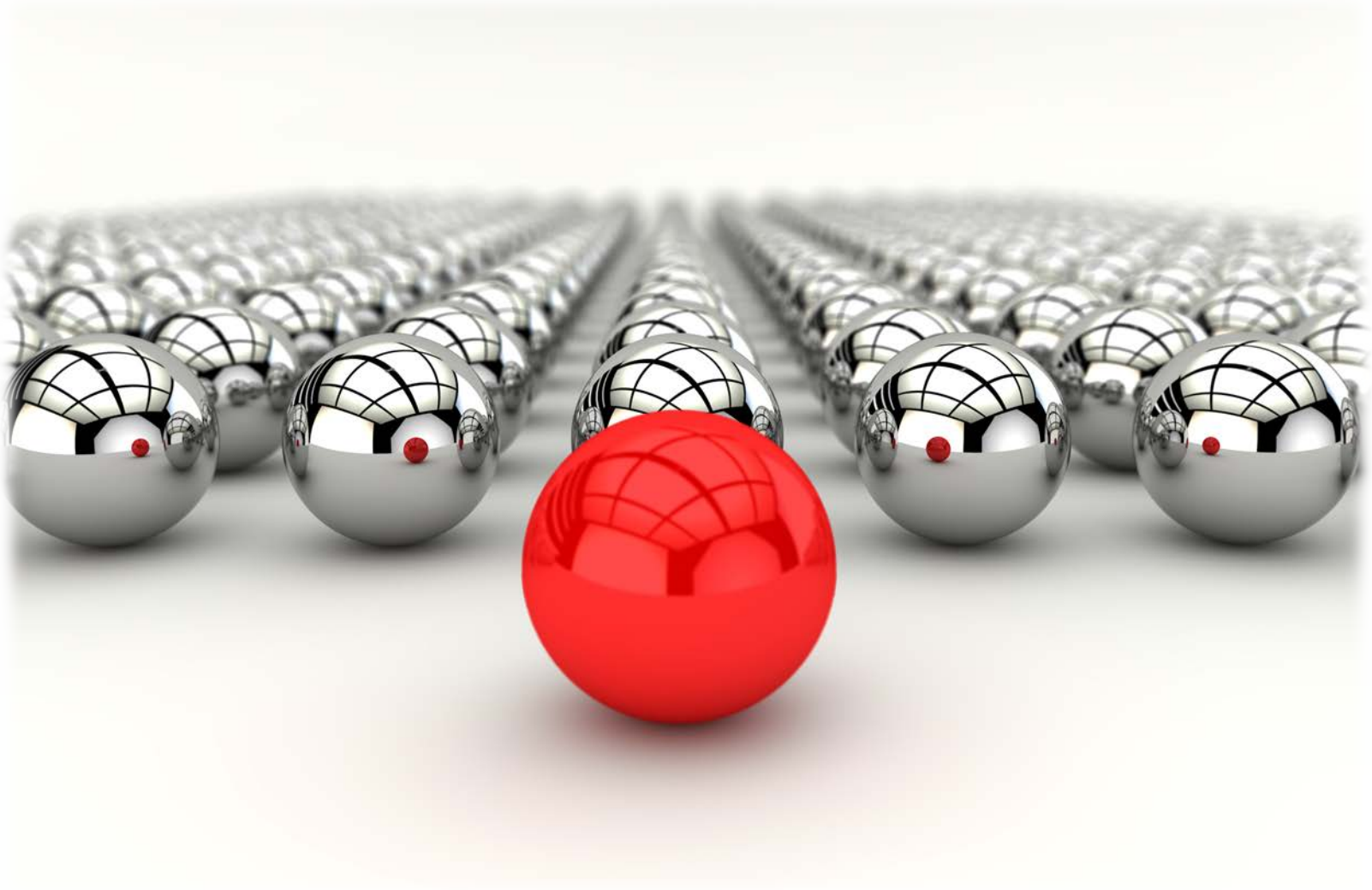
- RWE

Effectiveness

How does it work in medical practice

Patients as they come

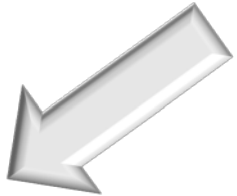
Many alternative treatments



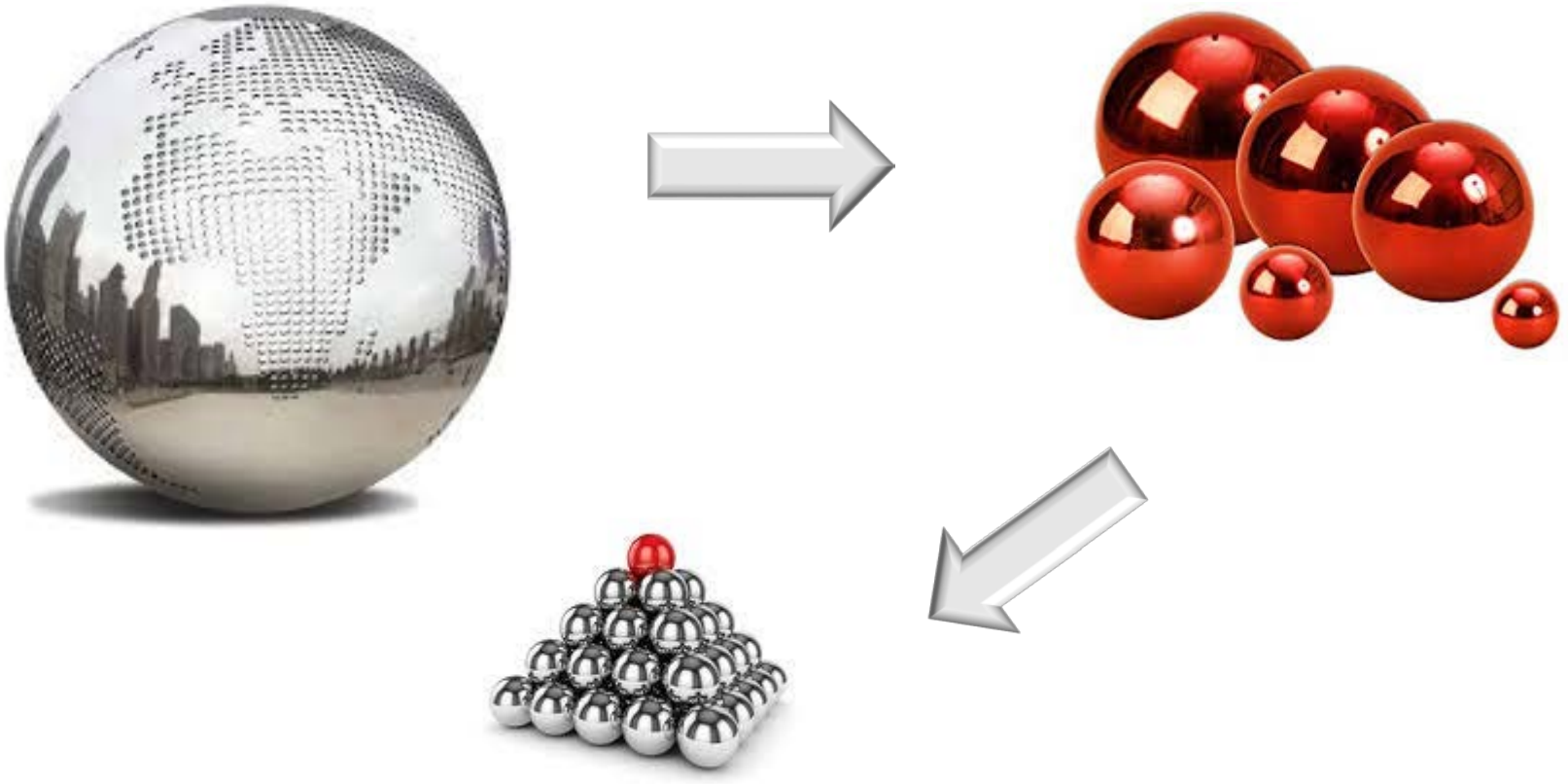
RWE Intensifying Across Product Lifecycle

RCT + Inference

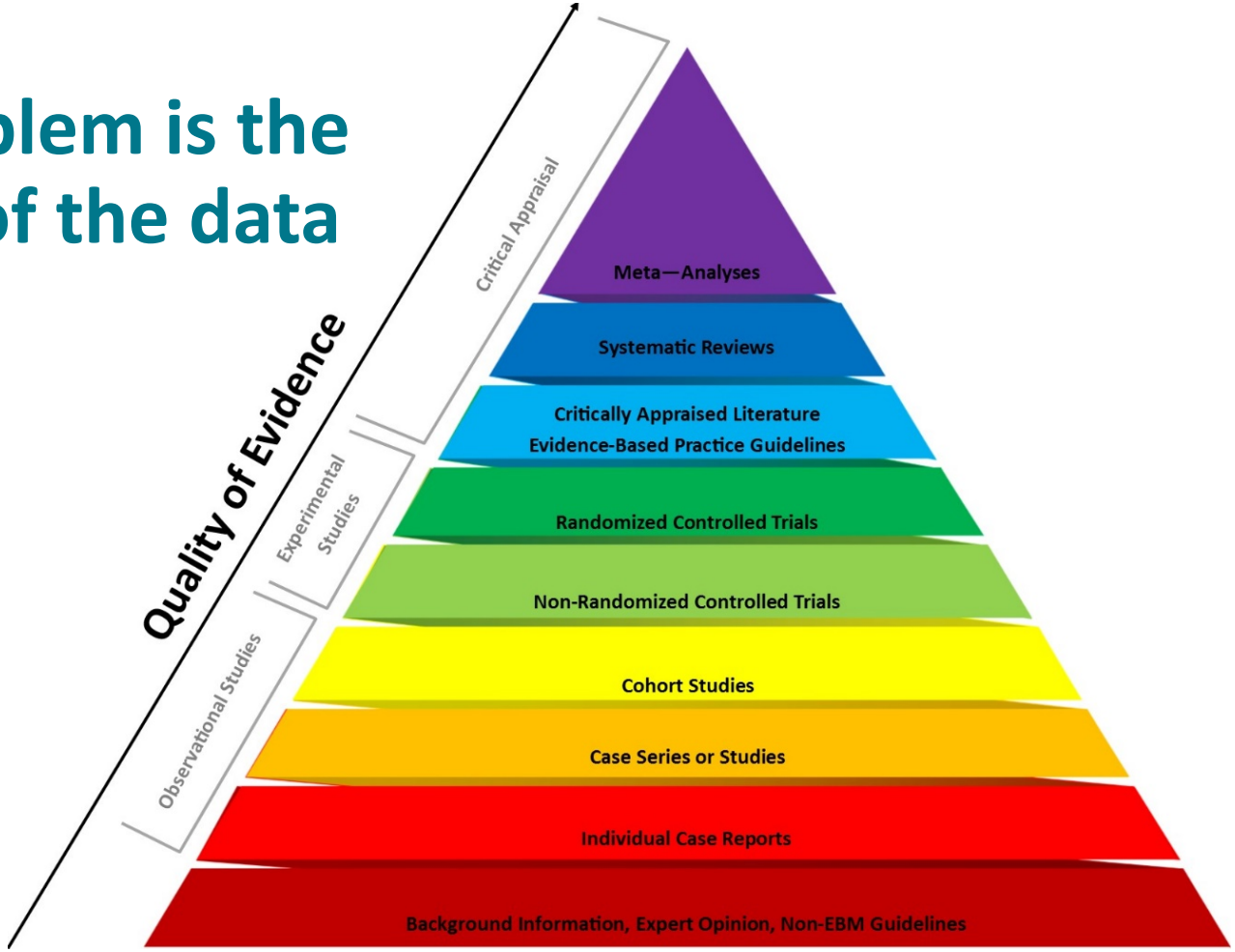
Observational date (RWE)



Observational date (RWE) -> ATMP



The problem is the quality of the data



The above image is based on the **EBM Page Generator** *(2006) from Dartmouth College and Yale University and the Coursera MOOC "***Understanding Clinical Research: Behind the Statistics***"* (2016).

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- Completeness
- Validity of the data -> can the data be used to inform modelling?

What else is needed? Regulators and HTA's need to look beyond the RCT…..

Experimental	Observational
Pragmatic RCT	Cohort
Population enrichment RCT	Case-control
Cohort multiple RCT	Cross-sectional
Comprehensive cohort study (CCS)	Controlled before-and-after
Cluster RCT	Case series, interrupted time-series or before-and-after
Non-randomised controlled trial	Case report

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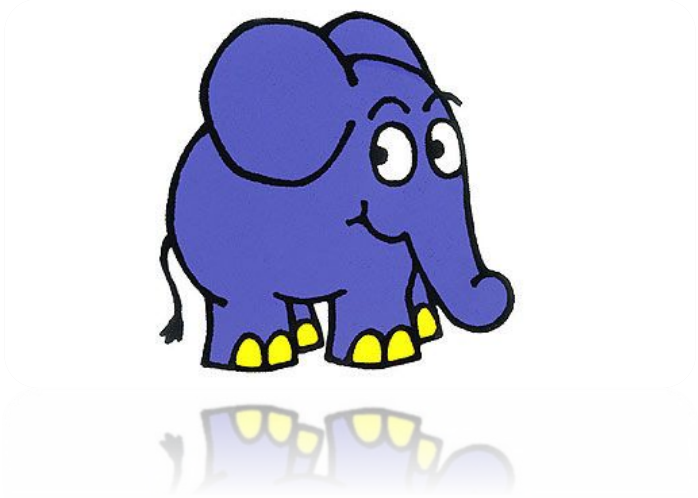
- The  in the Room

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➢ How are we going to finance this?

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