How to appreciate clinical data?

MDR @ noon | Webinar 21. October 2020

Jasminka Roth

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Team Exceptional talent

Jasminka Roth
CEO and founder

Deepa Rajagopalan
Quality implementation manager

Markus Reichlin
Quality implementation manager

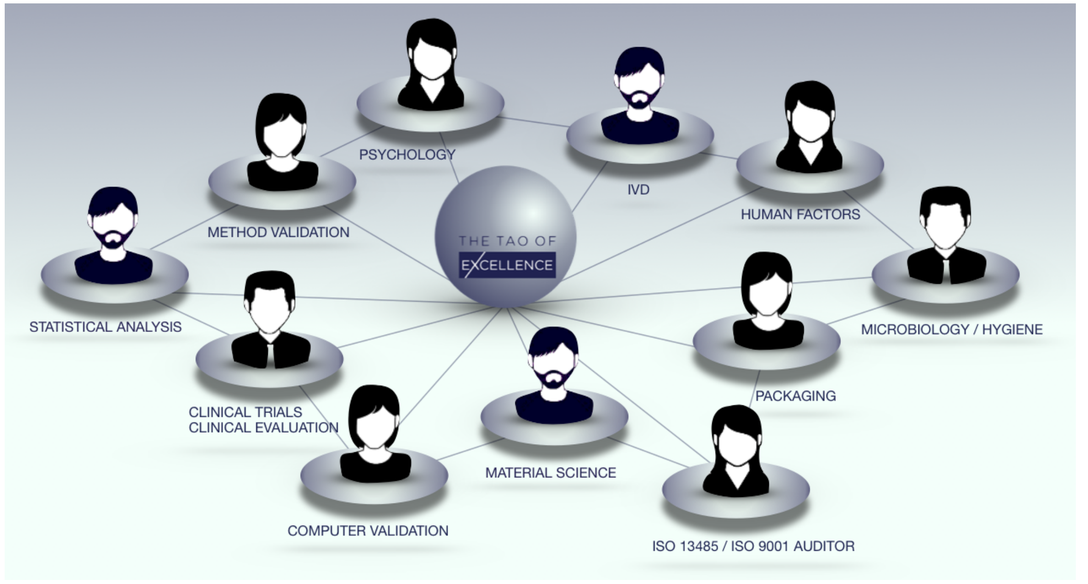
Lassana Diabira
Data analyst

Yannik Messerli
Data scientist

Henrietta Shirley
Editor external affairs

Martina Ehrat
Administrative assistant

Julia Böttcher
Administrative assistant



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Extended team
We operate within an international network particularly strong in the medical device, combination products and pharma industry.

Objective of this presentation

- What is clinical data
- How to use it in the context of MDR
- How to mine clinical data

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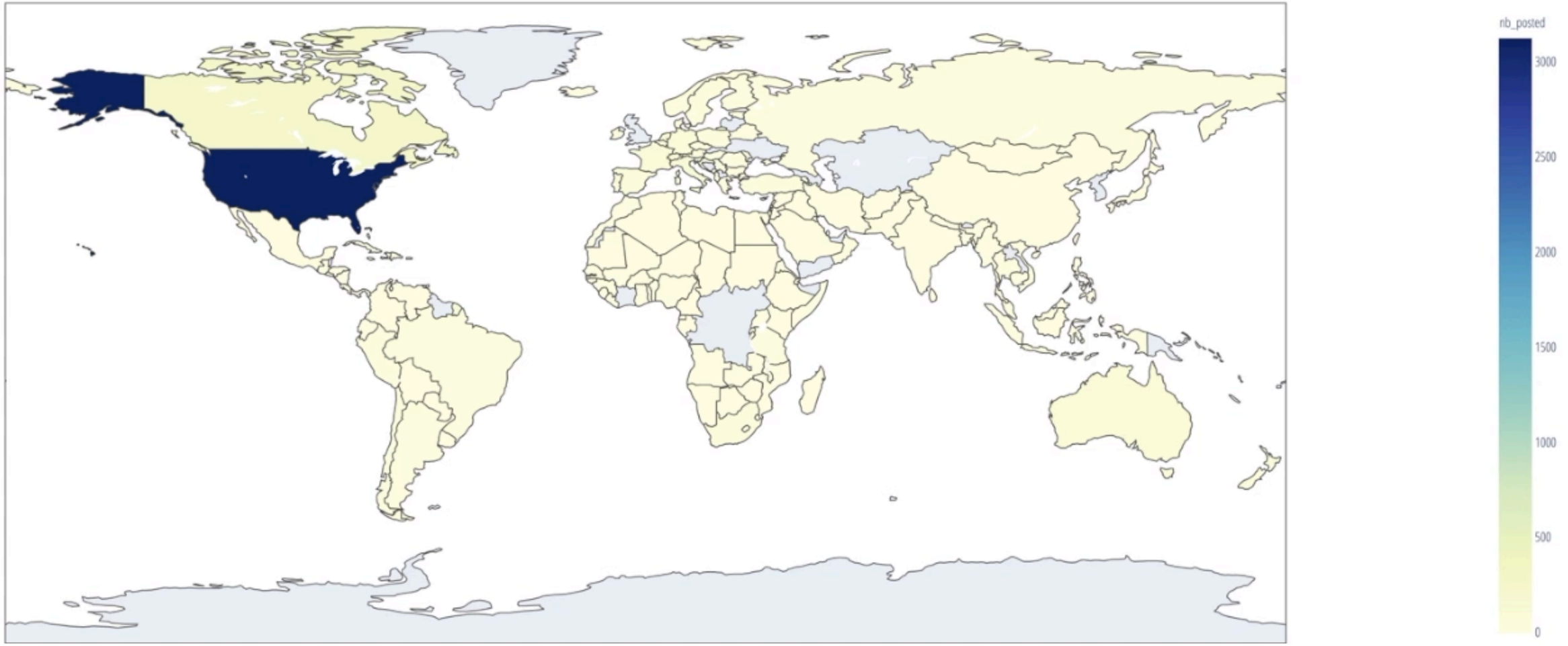
Clinical databases clinical trials on human subjects



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Clinical databases clinical trials on human subjects

Declaration of Helsinki - Developed by MWA. It defines ethical principles for medical research involving human subjects:

WORLD MEDICAL ASSOCIATION

- Research protocols must be submitted for consideration, comment, guidance and approval to the concerned and **independent** research ethics committee before the study begins.
- Every research study involving human subjects must be registered in a **publicly accessible database** before recruitment of the first subject.

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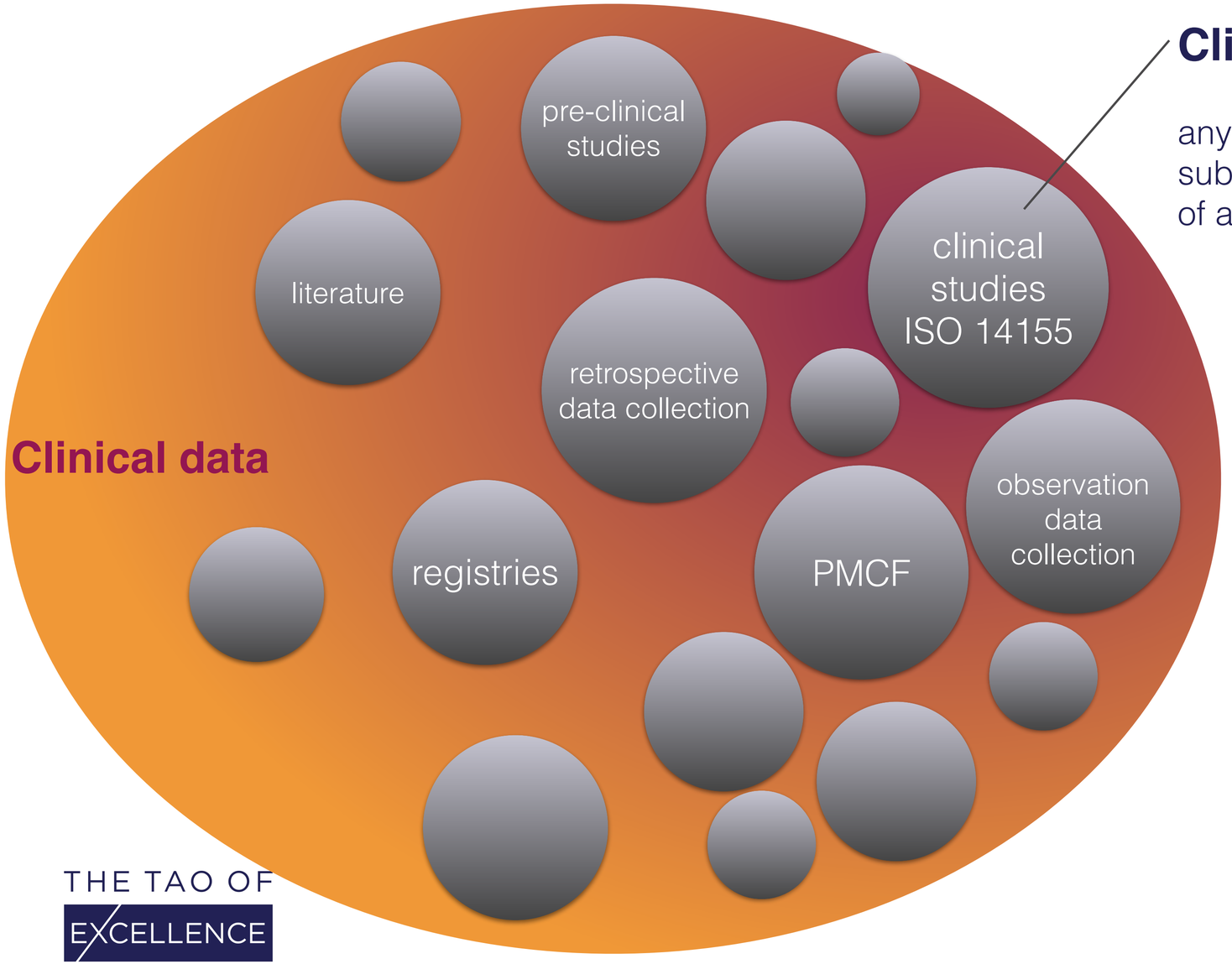
Clinical data according to MDR



Clinical investigation

any systematic investigation involving one or more **human** subjects, undertaken to assess the safety or performance of a device

Clinical evaluation

means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer

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Benefit-risk determination according to MDR

The analysis of all assessments of benefit and risk of possible **relevance** for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer.

Risk:

Combination of probability of occurrence of harm plus severity of that harm.

Benefit:

Positive impact of device on health of patient expressed in terms of a meaningful, measurable, patient-relevant clinical outcome.

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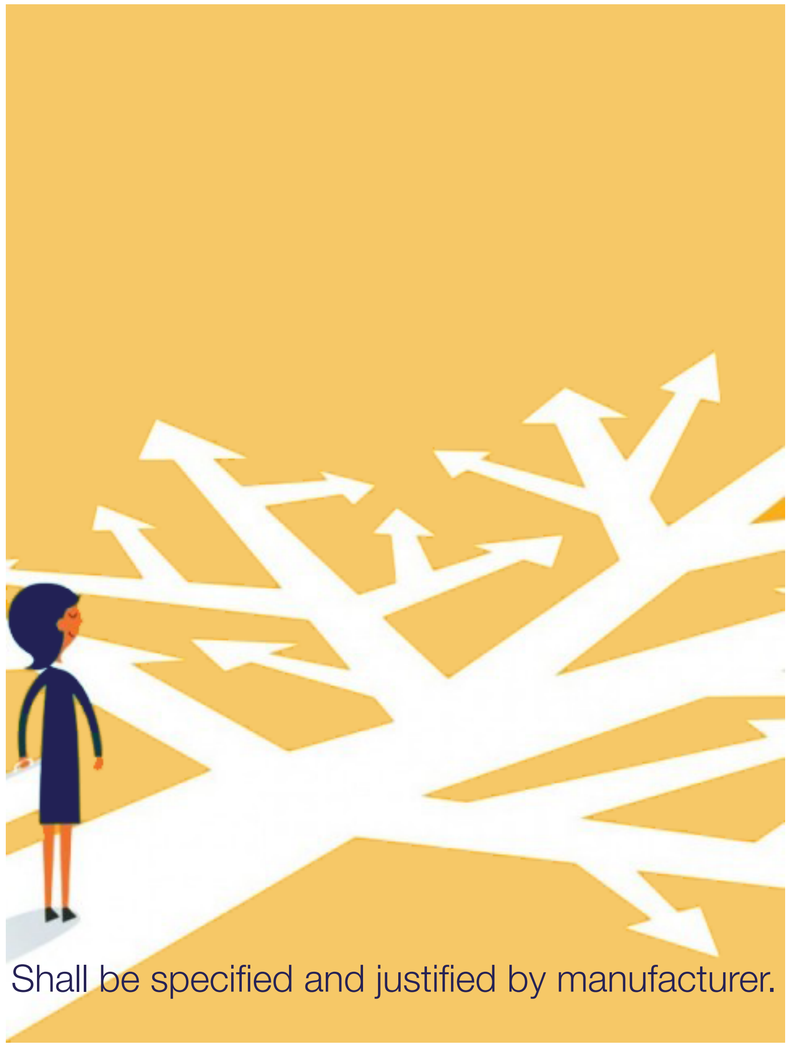
Sufficient data how much is sufficient?



Shall be specified and justified by manufacturer.

Interpretation of Art. 61:

the present result of the qualified assessment which has reached the conclusion that the device is safe and achieves the intended benefits.

- Both **quality** and **quantity**
- **Ongoing process**: to include PMS data

- Know / assume, pre-discuss with NB
- Assume and hope it will pass
- ➡ **Benchmark**

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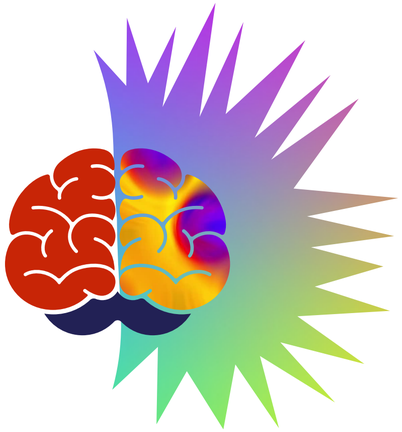
Benchmarking your clinical data

competitors
intended purpose

alternative treatment
state of the art

PMS,
inkl PMCF



study design

- geography
- location
- patient population
- timeline
- etc.

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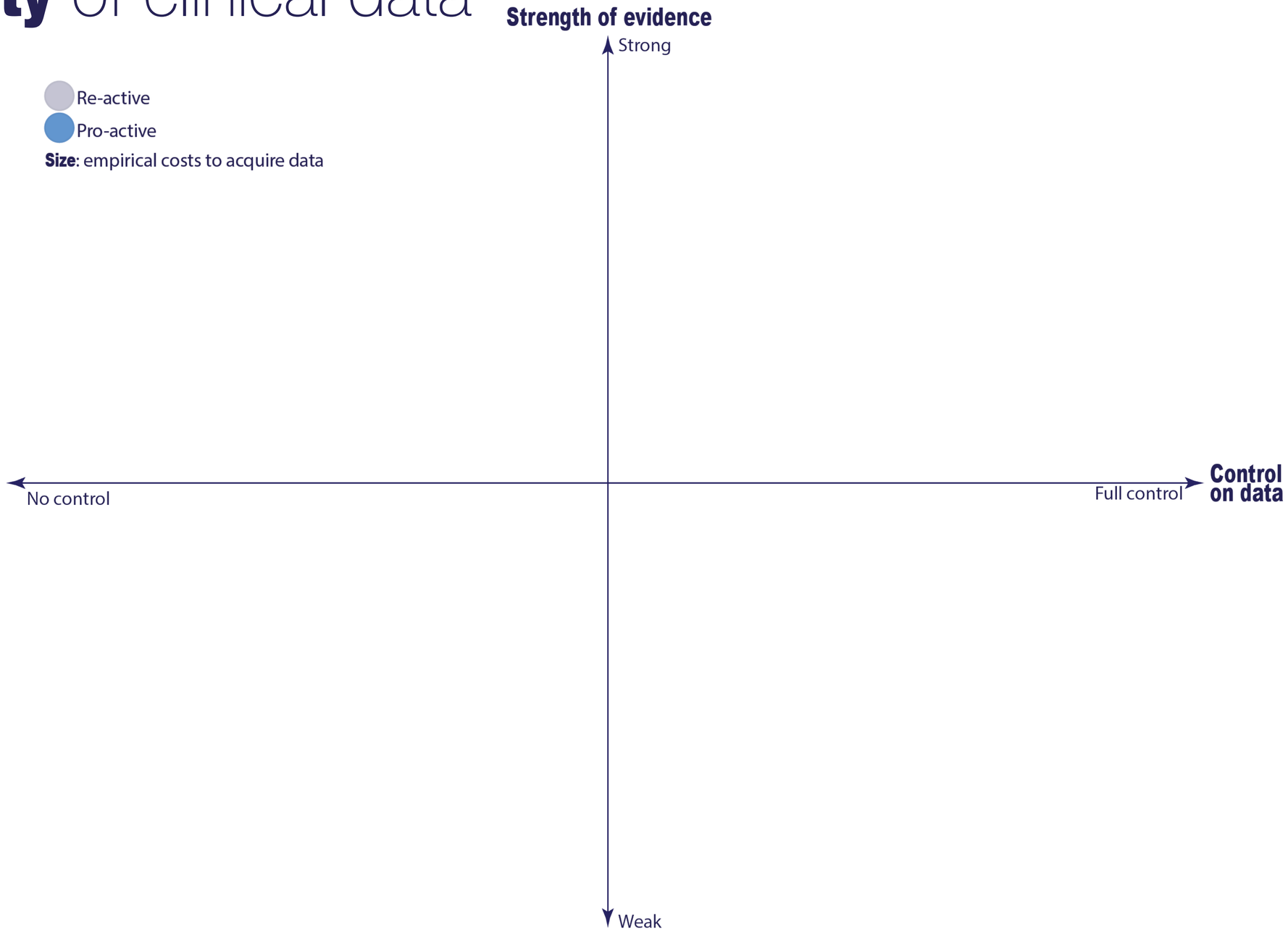
Reliability of clinical data



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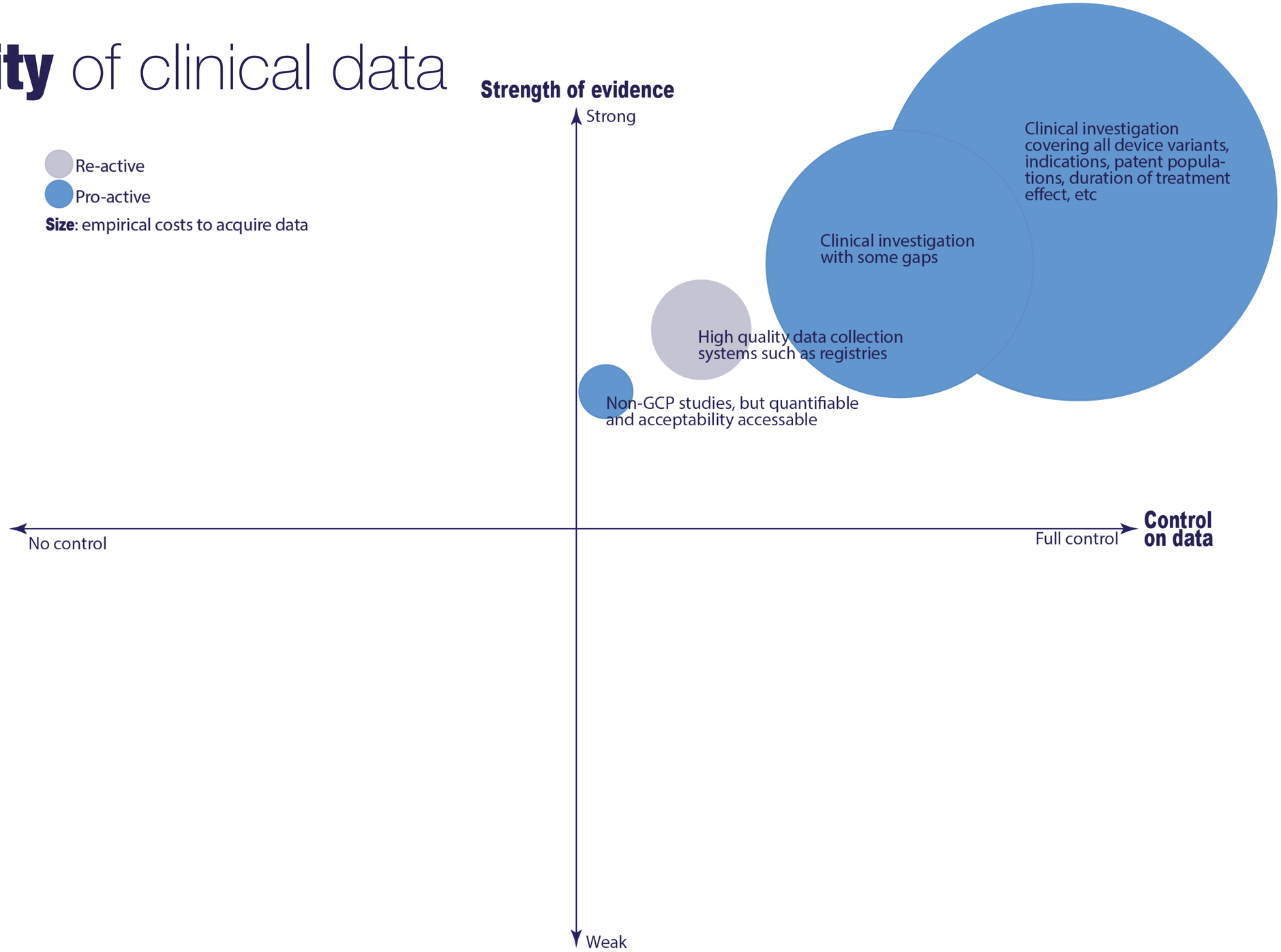
Reliability of clinical data



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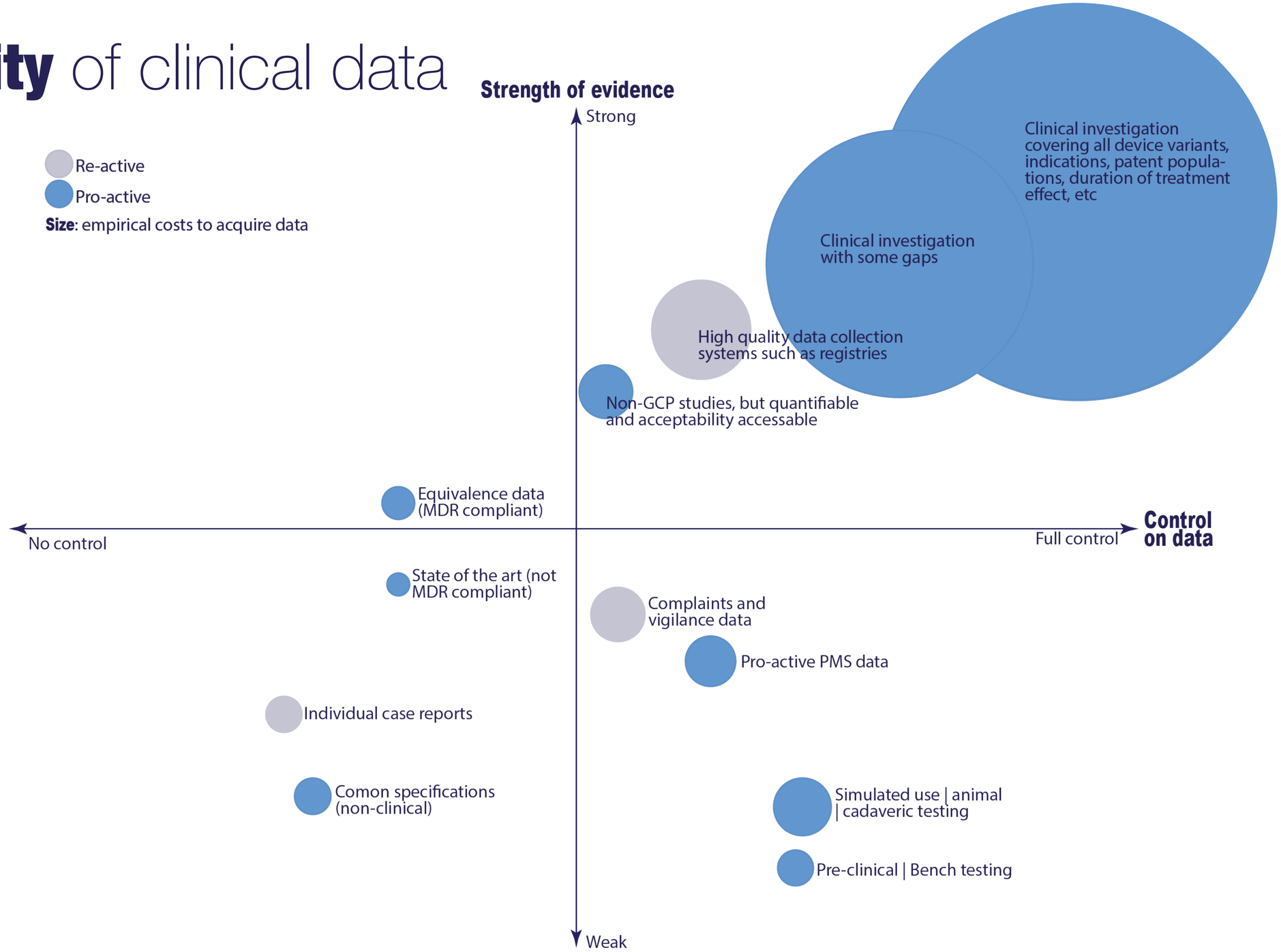
Reliability of clinical data



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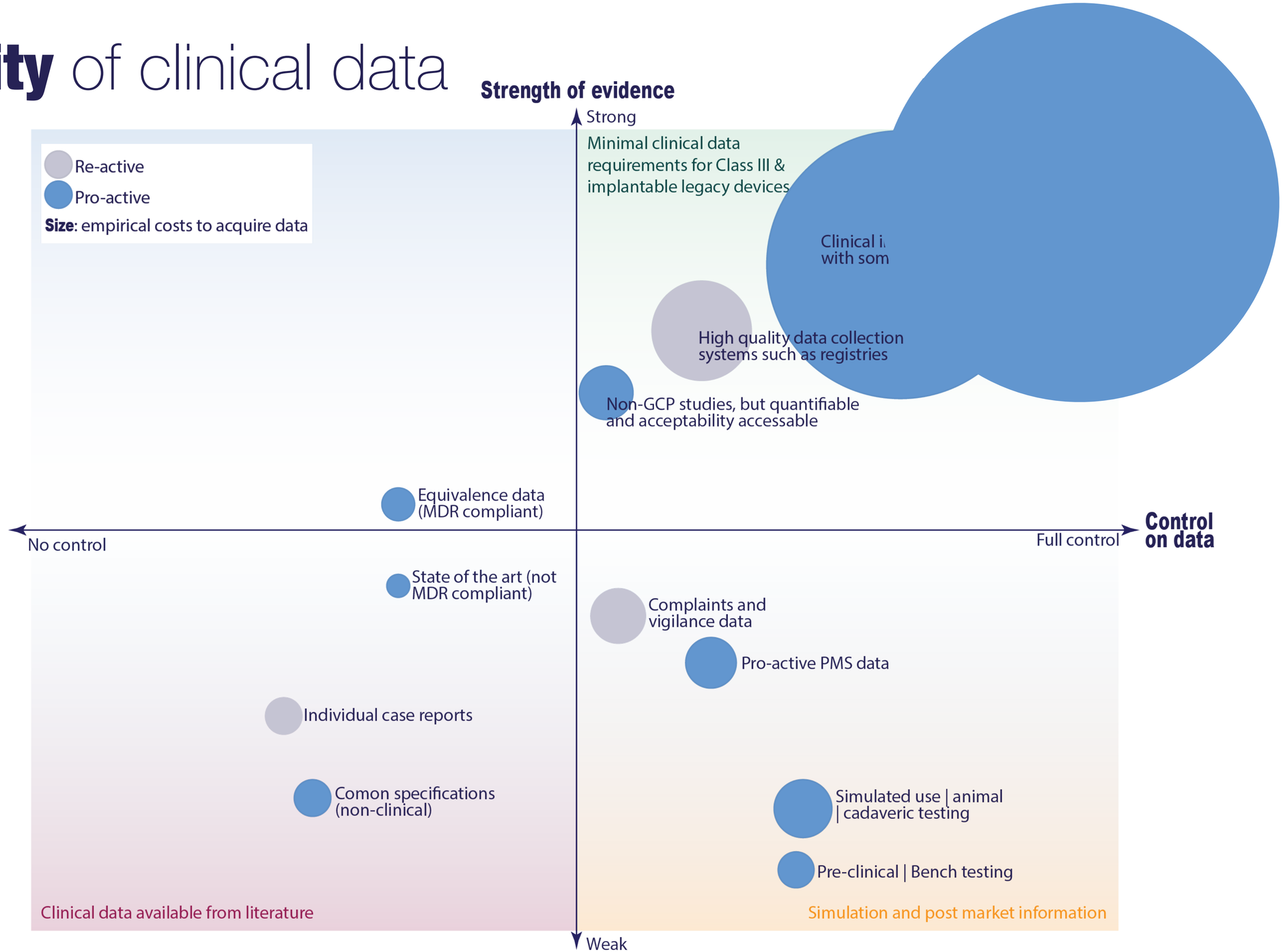
Reliability of clinical data



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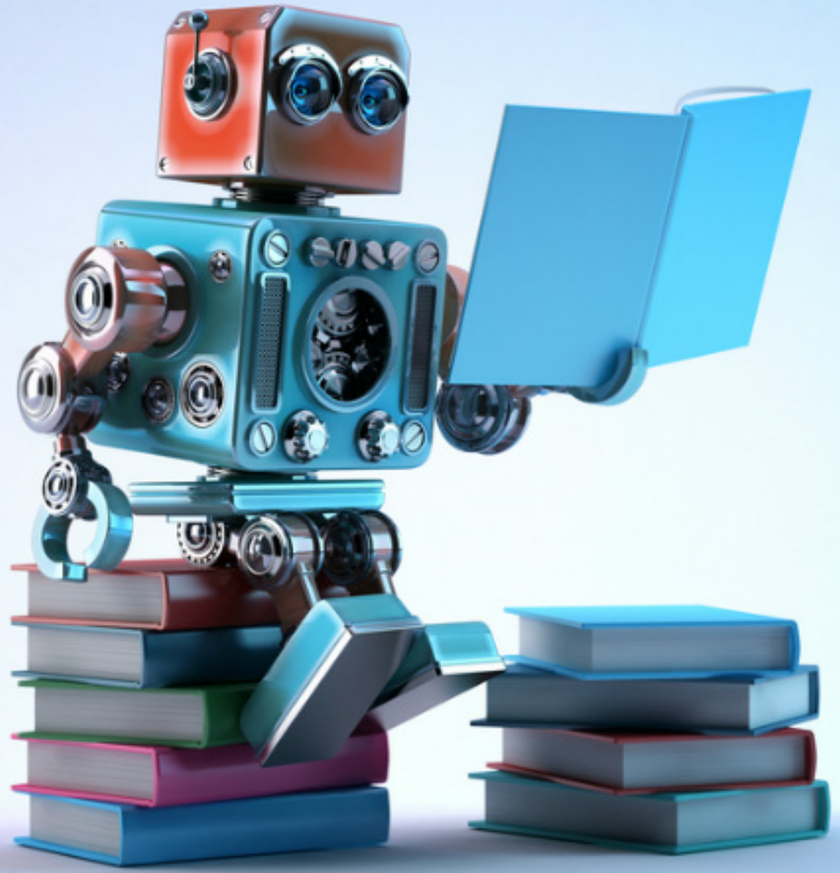
DCM algorithm for data mining your data



- Benchmarking clinical data
- Analysing worldwide clinical trial data
- Advanced computation and big data analytics
- Contextual interpretation
- Customised insights

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www.taoexcellence.ch

meetus@taoexcellence.ch
+41 52 685 51 65

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