Leiden University Medical Center

A.R. Iken[1], R.W. Poolman[1,2], and M.G.J. Gademan[1]
[1] Leiden University Medical Center [2] Onze Lieve Vrouwe

WHAT IS THE DATA QUALITY OF YOUR RESEARCH?

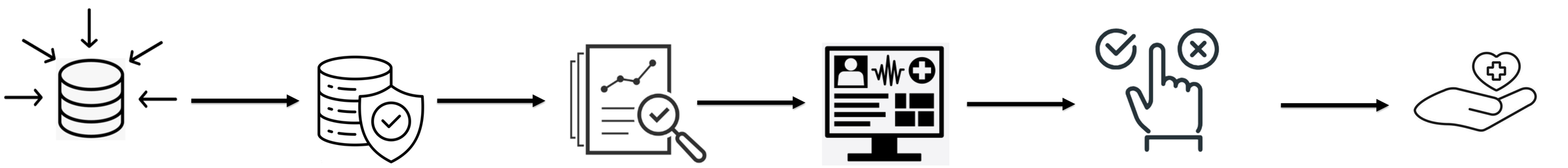
"Data Quality Assessment In Publicly Registered Trials Databases"

INTRODUCTION

High-quality data in clinical trial registries improves the usefulness, validity, and replicability of interpretating trial outcomes and subsequent literature, facilitating evidence-based treatment decisions.

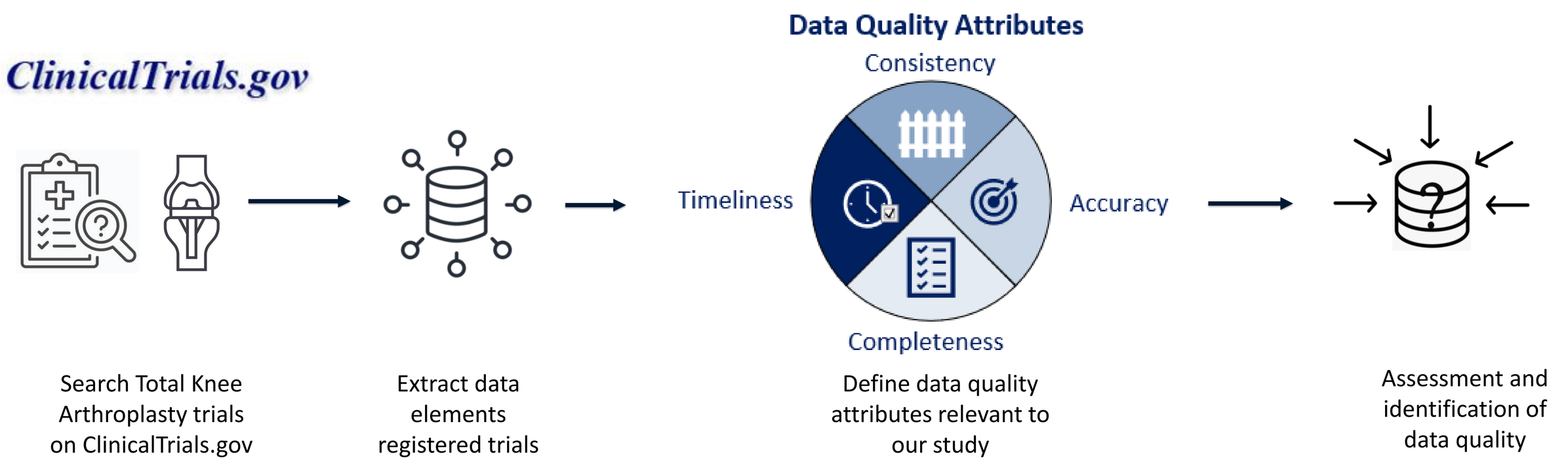
AIM

We aim to identify the data quality of registered Total Knee Arthroplasty trials and outline systematic and practical procedures for defining, assessing and identifying data quality irregularities in trial registries.



METHODS

We searched ClinicalTrials.Gov(CTG) for interventional total knee arthroplasty(TKA) trials between 2000-2015. We extracted required and optional elements and used the CTG's variables' definitions. We searched several bibliographic database to identify the included trials' published literature. Based on a literature overview, we identified the following data irregularities: inconsistency, inaccuracy, incompleteness, and timeliness.



RESULTS

We included 816 registered interventional trials Total Knee Arthroplasty.

Data irregularities varied widely: **0% to 100%.**

Inconsistency ranged from **0% to 36%**.
The highest level of inconsistency being caused by non-randomized labeled allocation combined with a "single group" assignment trial design.

Inaccuracy ranged from **0%** (all trials reporting on biological or dietary supplements) to **100%** (all trials reporting on a combination product or genetics).

Incompleteness ranged from **0% to 61%**.
There were no missing values in "allocation" and "model" trial design.
61% finished TKA trials did not report the outcome.

Irregularities in **timeliness** ranged from **0% to 49%.**
All trials reported the completion date after the start date and 49% were registered more than 3 months after the trial's start date.

CONCLUSION

We found significant variations in the data quality of registered clinical trials.

RECOMMENDATIONS

1. Clinical trial sponsors should be committed to ensuring information they provide is reliable, consistent, up-to-date, transparent and accurate.

1. CTG's users should be critical and mindful to draw conclusions based on the registered data

a.r.iken@lumc.nl