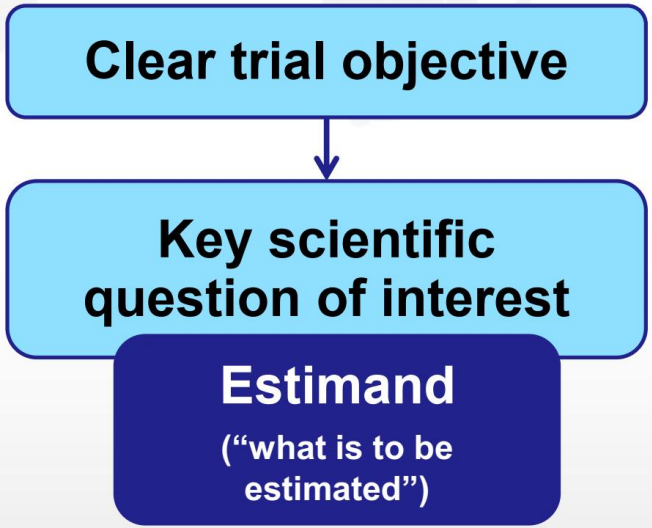
# Experiences with the Estimand
# The regulatory view

**Anja Schiel, PhD, Lead methodologist/Statistician**

Norwegian
Medicines Agency

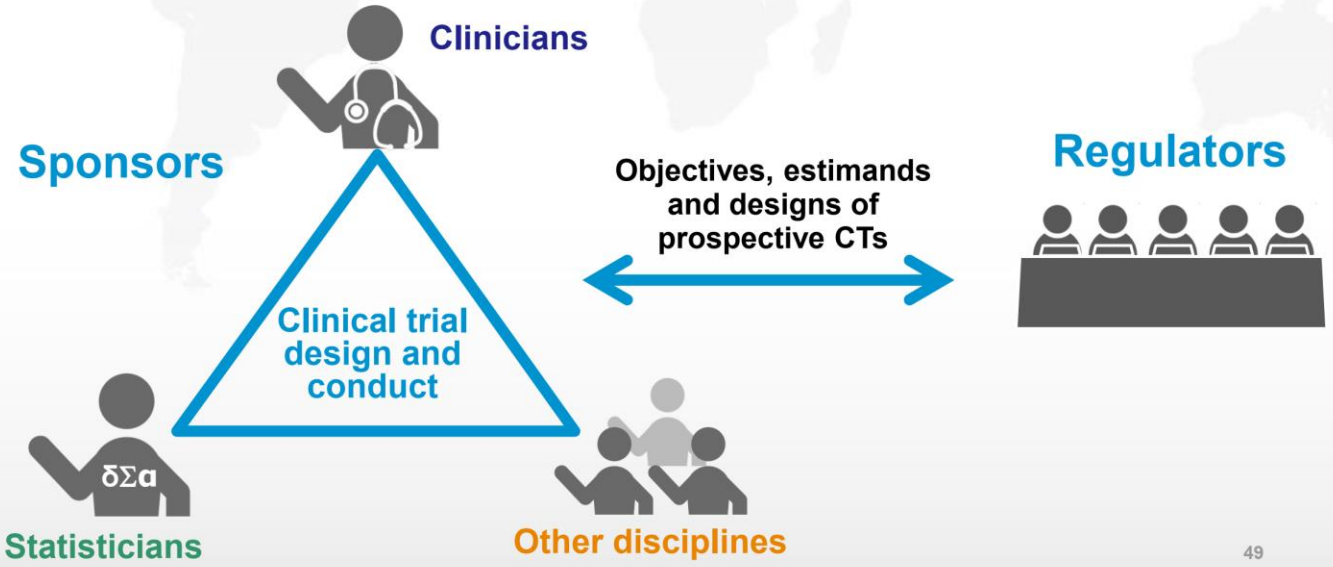
# A 'new' framework

Clear trial objectives should be translated into key scientific questions of interest by defining suitable estimands.



# Construction of an estimand

It is a **multi-disciplinary undertaking** and should be the subject of discussion between sponsors and regulators.






CTs: Clinical Trials

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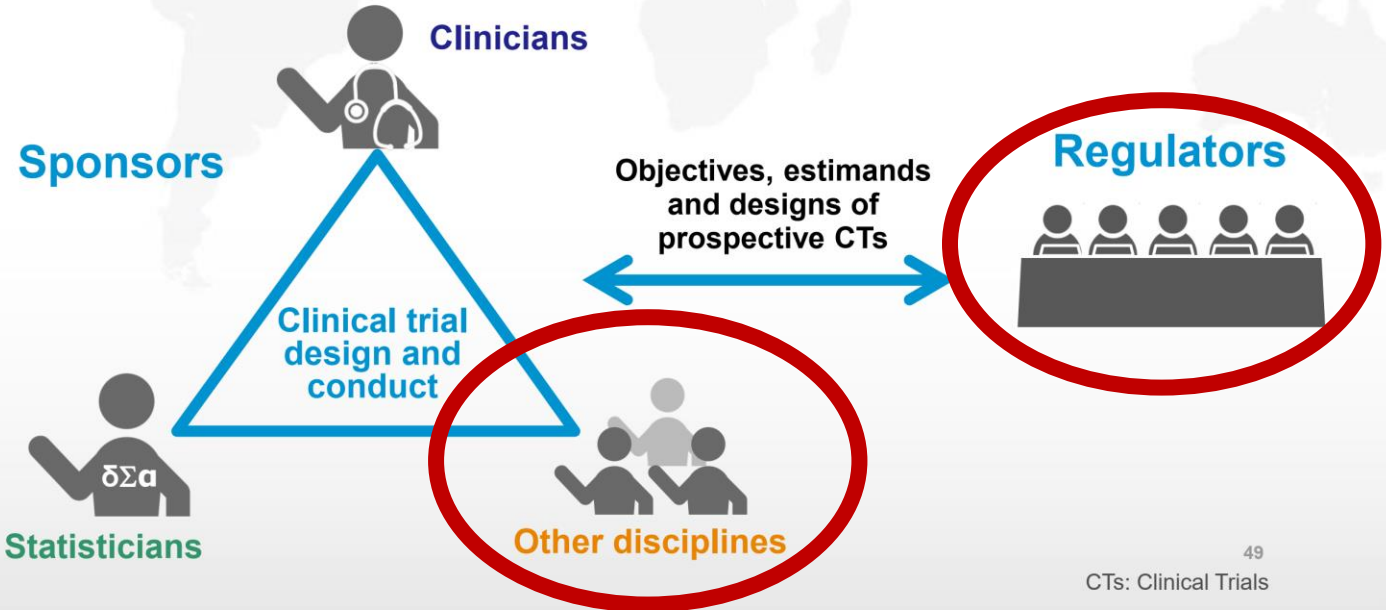
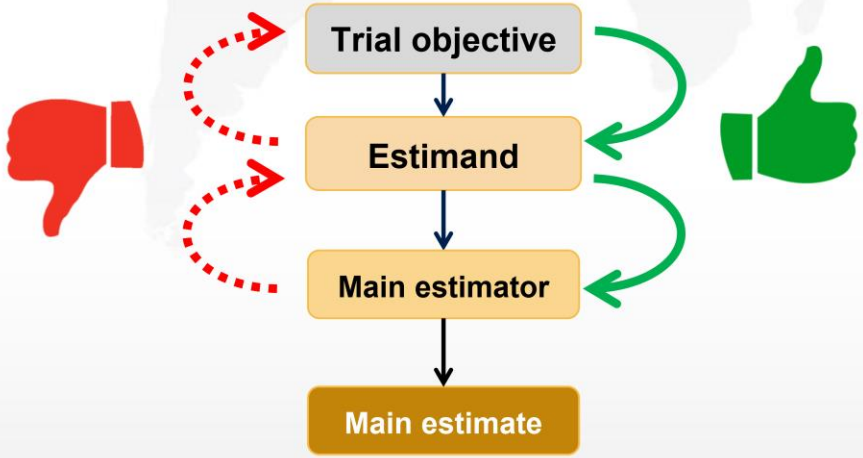





CTs: Clinical Trials

# Aligning target of estimation, method of estimation, and sensitivity analysis, for a given trial objective

In general, it is **important to proceed sequentially**. The trial objective should determine the choice of estimands and the estimands should determine the choice of estimators, not the reverse.

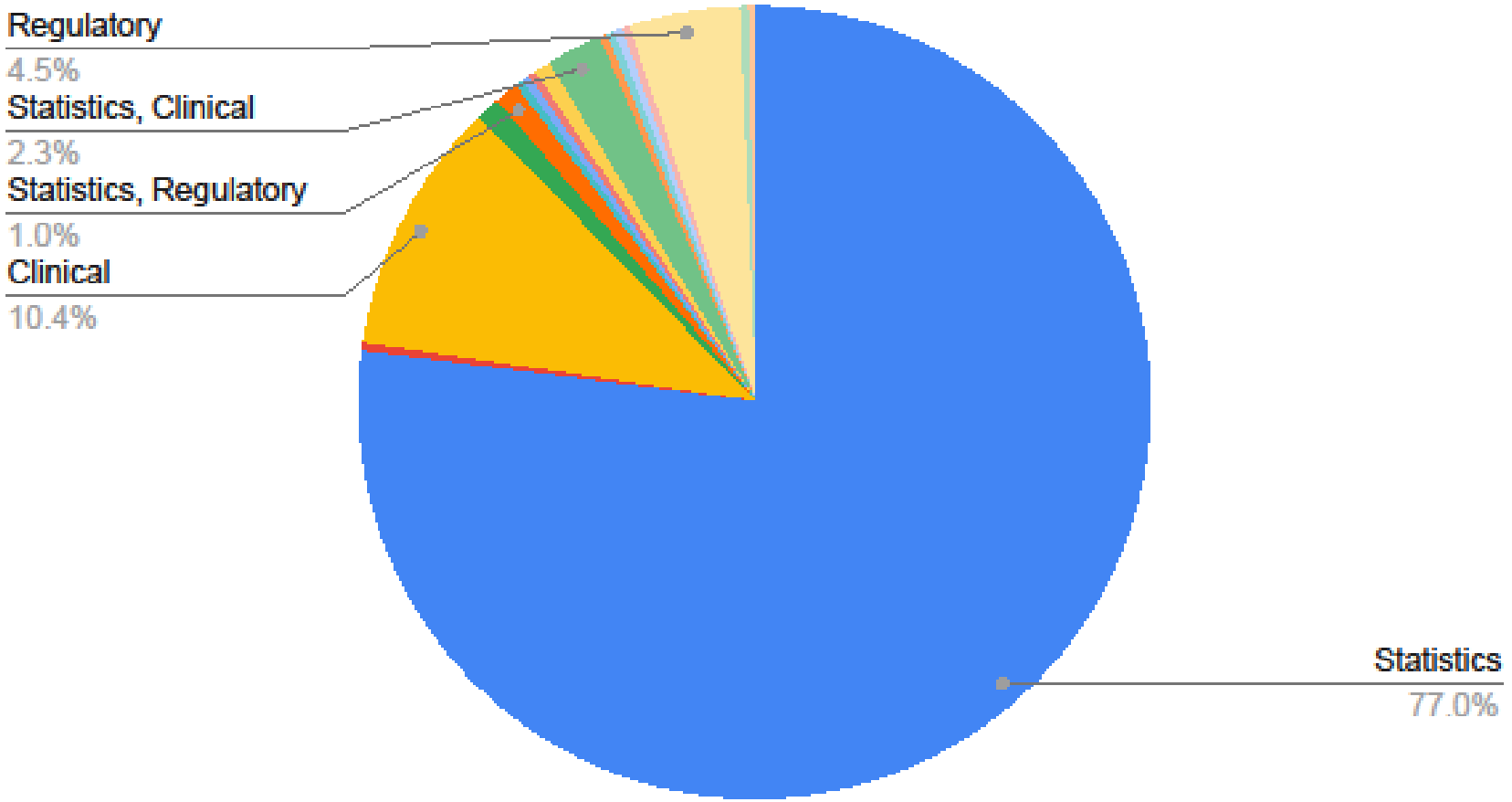



Where significant issues exist to derive a reliable estimate for a particular estimand, the trial objectives need to be re-considered from top-down to main estimator (**green** arrows). The main estimator should never define the trial objective from bottom-up (**red** arrows).

# A new framework

A common language and common understanding of this framework will help sponsors planning trials and regulators in their reviews, enhancing the interactions between these parties when discussing the suitability of designs, and the interpretation of results, to support drug licensing.

# Count of Background



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