

P16 - An attempt to translate estimands into plain language

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INTRODUCTION

The estimand is a detailed description of an outcome measure assessing the treatment effect. The concept of estimands was formally introduced with the ICH E9 (R1) addendum and is part of the ICH M11 and the TransCelerate templates. Consequently, estimands are increasingly incorporated in clinical trial documents, especially in pivotal trials. While trial team members currently struggle to understand the concept and language of estimands, the EUCR Clause 39 mandates the submission of a summary of results, including trial objectives,

understandable to the layperson.

We sought to bridge the gap between the highly technical estimand language and plain language requirements by translating the 5 attributes and 5 strategies for intercurrent event handling into plain language, using published trials.

We aimed to provide these examples to medical writers, who play a pivotal role in managing and writing important clinical trial documents and to enable them to efficiently communicate the 5 attributes and 5 strategies to trial teams and the lay public.

METHODS

We searched clinicaltrials.gov for trials with defined estimands and publicly available protocols. We extracted the primary estimands, their attributes and strategies for intercurrent event handling and tabulated them. We subsequently translated each of the 5 attributes and strategies into plain language and compared the translations of different trials to identify similarities and to generalize.

RESULTS

We selected diverse trial examples with clearly defined estimand attributes. Based on these trials, we propose guidance on how to interpret and translate estimands into plain language suitable for a lay audience.