ABSTRACT
An operational data and submissions strategy is a detailed plan covering “all things clinical data” from collection to submission for a drug program. This will enable optimisation of the use and re-use of the data, maximise efficiencies through upfront planning and ongoing management of the end to end data flow. Changing the way we think will promote efficiency across the data flow to reduce cycle time and improve decision-making, adding speed and efficiency to getting a new drug approved. It will also provide an improved transparency around the benefits and associated risks of the data.

This paper will discuss the key elements of the strategy, such as data collection, standards, quality/integrity, integration, submission plans, transparency, data sharing and de-identification. It will also consider the benefits and associated risks of a data strategy, with the aim to help with upfront planning, reduce the amount of re-work needed later on and also to align all the studies within a drug program.

INTRODUCTION

KEY ELEMENTS OF OPERATIONAL DATA STRATEGY
List and discuss the different elements that make up the data strategy, including but not limited to:

DATA COLLECTION
DATA STRATEGY
RISK ASSESSMENT
DATA QUALITY/ INTEGRATION
DATA SUBMISSIONS PLAN
TRANSPARENCY, DATA SHARING AND DE-IDENTIFICATION
OTHER CONSIDERATIONS

BENEFITS OF PROGRAM-LEVEL OPERATIONAL DATA STRATEGY
Discuss the benefits of the operational data and submissions strategy in place for drug programs.

CONCLUSION