

Much more than TFLs – the evolving role of the Biometrician

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ABSTRACT

At Covance we recognise that planning and running clinical trials is becoming more and more complex. As a result the skills of the Biometrician are being successfully deployed to support and enhance other functional groups, in order to manage our trials more effectively.

This paper will show real life situations where Biometricians at Covance have used projected and actual data to create time saving project management tools. From modeling Data Management Resource requirements, to enabling smooth CRF retrieval from investigator sites, the role of a Biometrician at Covance has diversified. We now do much more than produce tables, figures and listings.

INTRODUCTION

Covance is a large clinical research organisation providing a variety of services to pharmaceutical organisations all around the world. Traditionally, in our industry, Biometricians have been involved in the design of the clinical trial, performed sample size calculations, analysed the data and produced tables, figures and listings (TFLs) as defined in the statistical analysis plan. However, Covance offers an opportunity for a Biometrician to combine this traditional role with that of a provider of quantitative project management tools.

This, along with an expert understanding of the impact of data decisions, allows the Biometrician at Covance to use their unique skill set to influence realistic timeline management and enhance project management decisions pre-study, at study set-up and during the study. In-tern, empowering the entire project team to increase the chances of successful delivery.

"People commonly use statistics like a drunk uses a lamppost: for support rather than for illumination"
Mark Twain

PRE-STUDY

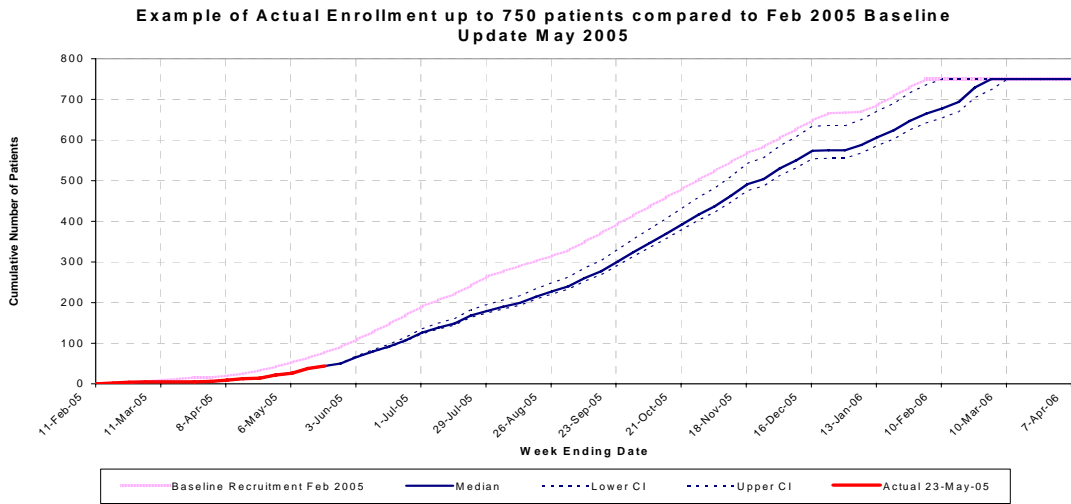
A critical factor of any successful project is the availability and deployment of appropriate resources in accordance to workflow demands

To achieve this, Project Managers require the ability to predict workflow so that they can proactively deploy resources in a timely manner. More specifically, in a Clinical trial environment, functional leads in clinical operations and data management need to know when subject data will be available to be *harvested* from site, entered onto the clinical database, reviewed and cleaned.

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'MODELING'

- Predicting and monitoring recruitment to achieve the correct number of patients, at the correct time. There will be no data and no analysis if we cannot recruit the required patients.



- Modeling CRF flow over time. Where and when a visit will be completed, and how many CRF pages are expected to be available over time – factoring in projected screen failure and withdrawal rates and other influences such as holidays and seasonal variations.

