

What makes Oncology special?

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ABSTRACT

Oncology clinical trials provide possibly the most exciting and rewarding work environment there can be among SAS programming jobs. If you are a programmer who likes to dig in deeper and have a full understanding of what the clinical data means, oncology would be a very special experience for you. The main characteristics of oncology clinical trials are: fast work pace as for thousands of people with cancer every day counts, constant search for alternatives to placebo/passive control arm, special data types collected (e.g. biomarkers) as there are as many types of cancer as there are patients, specific efficacy analyses as the best way to show the investigational product works is to show how long the patients survive on treatment and how their tumors stop growing or even shrink.

INTRODUCTION

Whether you are a SAS programmer in pharmaceutical industry, a bank or insurance company your job is to restructure data sets, program statistical analyses and create reports according to the provided requirements and specifications. With a few differences – still SAS is SAS and statistical reporting is still about tables, figures and listings. When looking deeper into pharma industry and the various therapeutic areas one could argue there is no difference. After all, it's about bringing drugs to patients and the drug development process is well defined and applies to all diseases. Well... yes and no. In this paper I will try to convince you that Oncology indeed is special.

SPECIAL DISEASE

Oncology is a very rapidly developing area in medicine, but also in science. The investigation of molecular pathways and genetic mutations involved in tumour genesis is ongoing. When working in Oncology clinical trials one may truly feel a pioneer.

A SENSE OF URGENCY

As many cancers develop very fast, and most clinical trials start as second line treatments of advanced carcinomas there is a general sense of urgency as patients' median survival time can be as short as 6 or 9 months. In Oncology clinical trials are either accelerated, priority or on fast track.

TRIAL DESIGN ETHICS

To demonstrate the effectiveness as well as acceptable safety profile it is best to have a placebo control arm compared with active treatment. For ethical reasons it is debatable whether oncology clinical trials should be placebo controlled at all. This poses a challenge for trial design and statistical analysis and hence in oncology trials one sees a variety of approaches: single arm (investigational product), with active control (standard-of-care regimen), passive control or placebo arm.

SPECIAL DATA

The oncology clinical trials CRF and data sets are relatively complex. Besides the standard safety data, oncology trials collect additional information, which will help precisely identify the subpopulation of patients who benefit from the investigational treatment most. For example angiogenesis biomarkers and PCR results of mutations testing.

In addition, there may be drugs or substances, which influence the metabolism of the investigational product and therefore are not allowed. The intake of these as concomitant medications must be tracked.

CTC GRADES

Patients' laboratory tests are commonly checked against the lower and upper normal limits. In Oncology lab results are additionally flagged according to the Common Terminology Criteria (aka Common Toxicity Criteria) published by the National Cancer Institute (NCI).

DOSING INFORMATION

Dealing with dosing in oncology is specific. Treatment administration in Oncology could be chemotherapy, a biological therapy... and then the dosing information is linked to the treatment, the schedule and the type of therapy.

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SPECIAL ANALYSES

Typical Oncology efficacy analyses are rather specific to this therapeutic area. Primary and secondary endpoints are commonly patients' overall survival and progression free survival and also the analysis of response rates. Response refers to the observed change in patient's tumours or lesions. For solid tumor the golden standard is provided by RECIST (Response Evaluation Criteria In Solid Tumors) criteria published in 2000 by the European Organisation for Research and Treatment of Cancer (EORTC), NCI, and the National Cancer Institute of Canada Clinical Trials Group. As, unfortunately, treatment in Oncology is not always curative, the Quality Of Life (QoL) is often one of the secondary endpoints and results are expected.

Interim analyses and/or DMC (Data Monitoring Committee) may also be planned in Oncology studies. Interim Analysis intended to assess treatment effect with respect to efficacy or safety at any time prior to completion of the clinical trial. A DMC is a group of experts external to the study that reviews on regular basis accumulating data from an ongoing clinical trial

SPECIAL REPORTING

Planning of Programming Activities is challenging. In Oncology, programmers must be flexible as the target is often moving, timelines and resources estimation need to be reviewed regularly. That's why it is important to have standard CRF, Data, output shells and programs to improve efficiency

CONCLUSION

Oncology is very challenging and very exciting for a Statistical Programmer:

- To be one of the pioneers
- To deal with the moving timelines
- To understand and program algorithms such as the Lab Grading and RECIST
- To set-up the macros, programs and all dependencies to be ready for anything
- To unify derivations and naming conventions across studies for easier pooling
- To improve the lives of patients and caregivers

CONTACT INFORMATION

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