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### The Phuse Therapeutic Area Wiki Page

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## ABSTRACT

Therapeutic Area (TA) knowledge is important for all people in the biometric area. In preparation of the patient centric PhUSE annual conference 2013 in Brussels a small group of volunteers started to gather information about Rheumatoid Arthritis and Oncology. This project group collaborated through the PhUSE Wiki to increase the awareness and to prepare workshops for the conference. Today the PhUSE TA Wiki is not only a useful tool for beginners but it can be also seen as a tool for future development to improve the way professionals in the different TA's work. Several updates in the TA Wiki Page were done since its launch.

## INTRODUCTION

While the evolution of information technology is improving data accessibility for customers for their own exploration, the need for comprehensive understanding of therapeutic area knowledge for programmers in clinical development is increasing. An internet search will yield much information relating to an indication. However, programmers may not be interested in certain details of an indication such as cause of disease, symptoms etc. but may be more interested in gaining a basic understanding of the disease, clinical trial requirements specified in regulatory guidelines, data standards, possible primary outcome measurements and data challenges. A basic understanding of the medical background and any special assessment methods or ways of statistically analyzing and displaying the data would improve interactions between programmers and partners e.g. scientists, statisticians etc. Therefore, with this aim and in preparation for the patient centricity PhUSE conference in Brussels, activities to collect and provide comprehensive information related to Oncology, Parkinson's disease, Rheumatoid Arthritis Therapeutic Areas (TA) via the PhUSE Wiki were begun in the past few years. The TA Wiki pages are well structured and aim to give comprehensive indication specific information related to Agency Guidelines applicable for the corresponding Disease, Clinical Trial Endpoints, Clinical Trial Designs, Data Collection, Data Challenges, SDTM Data, ADaM Data, Statistical Analysis as can be seen on the Wiki page relating to Oncology:

1 Introduction
2 Disease Description
    2.1 Cancer Statistics
    2.2 Causes and Risk Factors
    2.3 Treatments
3 Agency Guidelines
    3.1 FDA
    3.2 EMA
4 Clinical Trial Endpoints
    4.1 Categorical Measurements
    4.2 Time to event Measurements
    4.3 Other specific indication efficacy endpoints
    4.4 Patient Reported Outcomes
        4.4.1 EORTC QLQ-30
5 Clinical Trial Design
    5.1 Phase I dose escalation
    5.2 Phase II
    5.3 Phase III
6 Data Challenges
    6.1 Overview
    6.2 Prior Cancer History
    6.3 Exposure
    6.4 Safety Data
        6.4.1 Laboratory Data
        6.4.2 Adverse Events
        6.4.3 The concept of treatment emergent event or on-treatment observations
    6.5 Efficacy Data
7 Data collection
8 SDTM Data
9 ADaM Data
10 Statistical Analysis
    10.1 Background
    10.2 Single-Arm Trials and Parallel Trials With Two or More Treatment Arms
11 References
12 Project Team

Since the last annual PhUSE conference, these TA pages were further updated and, in addition, information regarding epilepsy has recently been added to the PhUSE Wiki. Various PhUSE members working in different companies and on different compounds have spent time and energy in expanding their knowledge and making it available to the entire community. Although there remains much to do in order to complete and maintain the collected material, Wikis are deemed a useful tool for Statistical Programmers approaching these TA for the first time or for those who wish to improve their knowledge. Moreover, PhUSE Wiki can be seen as a basic tool for future developments to improve the way professionals in the different TA work. An established working relationship across organizations, pharmaceutical companies or external service providers will help to support implementation of TA-specific standards from mapping raw data in SDTM, data analysis using ADaM and finally data presentation in standardized outputs. Thus, PhUSE Wiki could be the central site to share important updates such as new CDISC TA standards or the availability of new TA regulatory guidance. Similarly, we view Wiki as a site to discuss, stimulate and inspire new initiatives among the "SAS-Programming Community".

## CONCLUSION

Collecting information relating to a therapeutic area for PhUSE Wiki allows us see the bigger picture of clinical trials for an indication. It is a useful tool for enabling all statistical programmers to become aware of data standards, data challenges etc. Important updates on TA data standards, terminologies, and regulatory guidelines can be assessed from the PhUSE Wiki. As an initial outcome of the TA Wiki pages, two TA workshops on Oncology and Rheumatoid Arthritis, were delivered at PhUSE conference 2013 in Bruxelles. The PhUSE TA Wiki pages provide for an interesting collaboration possibility across pharma companies and CROs.

## REFERENCES

http://www.phusewiki.org/wiki/index.php?title=Therapeutic_Areas

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Many thanks to my colleagues and programmers from other companies who worked hard to provide valuable information on PhUSE Wiki for Oncology, Parkinson's disease, Rheumatoid Arthritis and Epilepsy. This collaboration with programmers working on different compounds and different companies has given me novel insight relating to the indication I am working on.

## CONTACT INFORMATION

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