The PhUSE Therapeutic Area Wiki Page

Angelo Tinazzi[1], Oliver Wirtz[2] , Christian Mueller[3] , Sascha Ahrweiler[4] , Jothy Kalathilparampil[2]

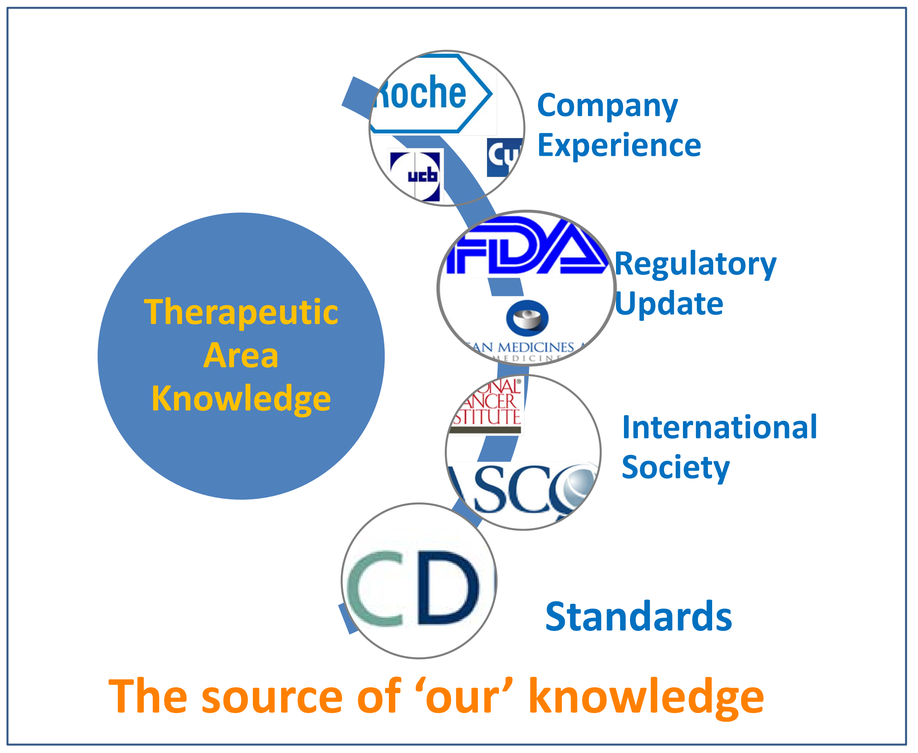
[1]Cytel Inc, Geneva (Switzerland), [2]UCB BioSciences, Monheim (Germany), [3]F. Hoffmann-La Roche Ltd , Basel (Switzerland) , [4] Bayer Healthcare, Wuppertal (Germany)

ABSTRACT

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. 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.

In this intent, activities to collect and provide comprehensive information around the Oncology, Parkinson's disease and Rheumatoid Arthritis Therapeutic Areas (TA) via the PhUSE Wiki had started in the last years. Various PhUSE members have spent time and energy in providing and expanding their knowledge and making it available to the entire community.

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. 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 the 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. The PhUSE Wiki can be the central place to share important updates such as new CDISC TA standards or the availability of new TA regulatory guidance. On the other hand we see the Wiki as a place to discuss, to stimulate and inspire new initiatives among the "SAS-Programming Community". This may include specific TA working related white papers and/or scripts being part of the FDA Working Groups WG5 "Development of Standard Scripts for Analysis and Programming" Project 08 "Create white papers providing recommended display and analysis including Table, List and Figure shells".

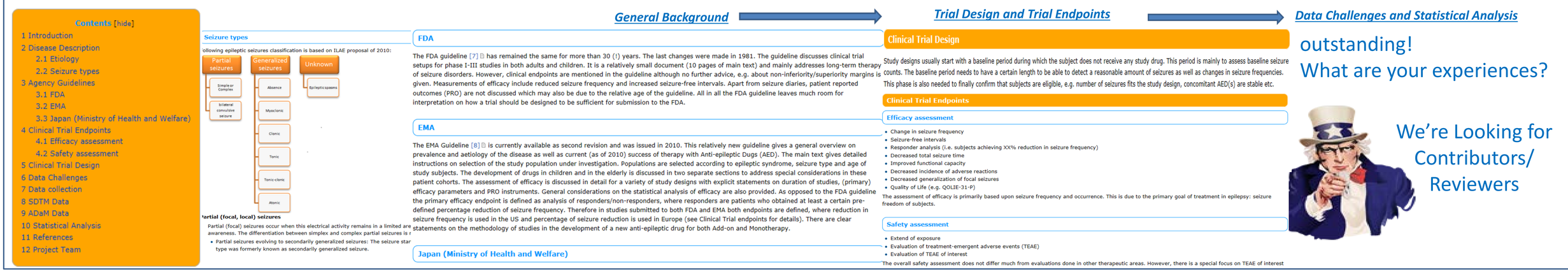


PATIENT CENTRICITY → An attempt to answer → THE THERAPEUTIC AREA PhUSE WIKI PAGE

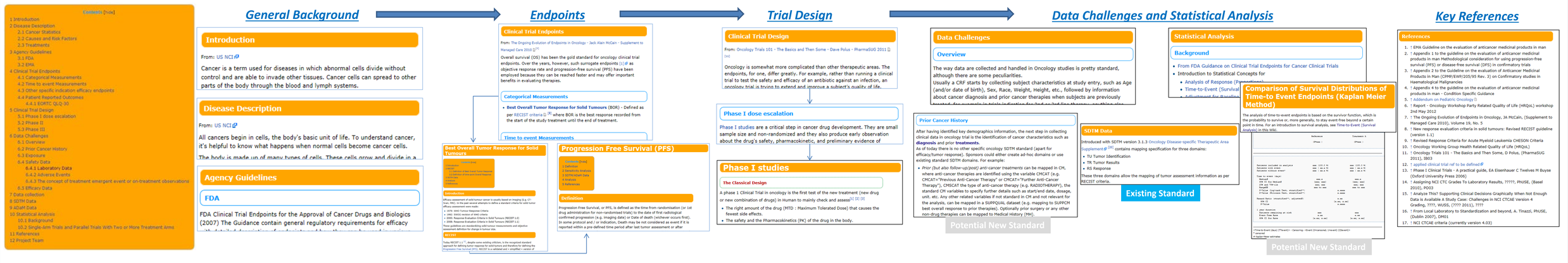
- ❑ Main theme of PhUSE 2013
- ❑ What does patient centricity mean for Statisticians and Statistical Programmers?
- ❑ Understanding the Therapeutic Areas you work on:
  - → Regulatory Environment
  - → Endpoints
  - → Study Designs
  - → Data Collection/Challenges
  - → Use of Standards e.g. CDISC

- ❑ What is Wiki*
  - → A tool to support collaboration
- ❑ What is PhUSE Wiki
  - → A PhUSE/FDA/Industry Wiki tool to share information specifically relating to clinical trial information
- ❑ What is PhUSE TA Wiki
  - → A tool to share TA-specific knowledge and to help improve the way professionals work
  - → Central place to share
    - regulatory framework
    - implementation of standards
    - TA-specific information from all over the internet
- ❑ Who can benefit from PhUSE TA Wiki
  - → Starting point for Beginners in TA
  - → Professionals benefit from lessons-learned in real-life and can share their own experience

Use case: Epilepsy



Use case: Oncology



* A wiki is a website which allows people to add, modify, or delete the content via a web browser usually using a simplified mark-up language or a rich text editor. Wikis use specialized wiki software and are usually created collaboratively. PhUSE 2013 What I Know is N. Guerro (PP16)

CONCLUSION

- ❑ As an initial outcome two TA workshops, Oncology and Rheumatoid Arthritis, were delivered at PhUSE 2013 in Bruxelles
- ❑ Phuse TA Wiki is seen as a useful tool as updates are ongoing and new indications added
- ❑ Adding information related to Epilepsy in PhUSE TA Wiki page led to further insights for contributors
- ❑ An interesting collaboration possibility across pharma companies and CROs
- ❑ Seeking for feedback on Structure, Sections, Topics covered
- ❑ Maintenance can be problematic

Everyone is invited to contribute! http://www.phusewiki.org For further information: wikiadmin@phusewiki.org