

ABSTRACT

While the evolution of information technology is bringing the data closer to customers for their own exploration, the need of a comprehensive understanding of the therapeutic area knowledge for programmers in clinical development is increasing. Starting with a basic understanding on the medical background, special assessment methods, ways of statistically analyzing and displaying the data, to name a few essential ones enables programmers to interact with partners (e.g. scientist, statisticians etc.) on equal par.

In this intent, activities to collect and provide comprehensive information around the Oncology and Rheumatoid Arthritis Therapeutic Areas (TA) via the [PhUSE Wiki](#) had started in February 2013 and continued throughout the year. Various PhUSE members have spent time and energy to provide and expand their knowledge and make it available to the entire community.

Today, although there is still much to do to complete and maintain the collected material, the two TA Wikis are a useful tool for Statistical Programmers approaching these TA for the first time or who want 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”, be it Statisticians, Programmers, Data Managers or everyone else involved; 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

- ☐ 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



The source of ‘our’ knowledge

THE THERAPEUTIC AREA PhUSE WIKI PAGE

☐ 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

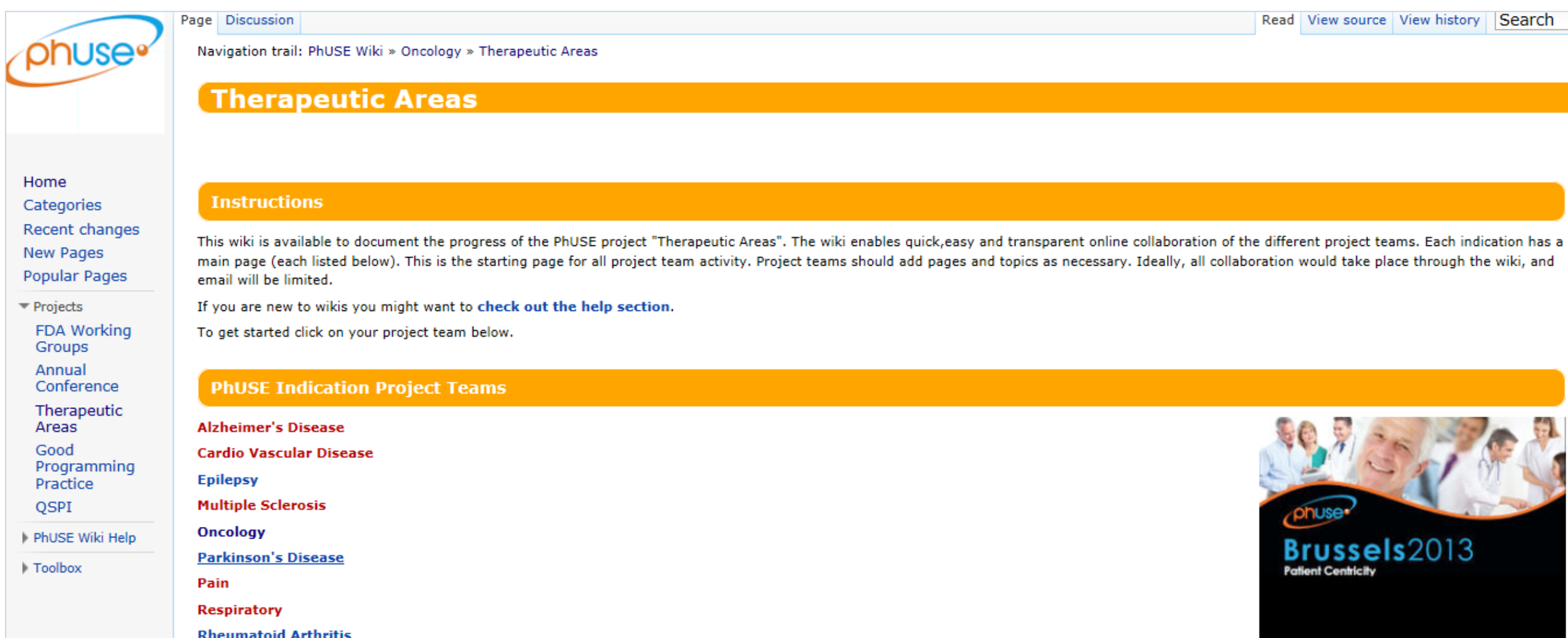
→ Central place to share

- general concepts
- regulatory framework
- implementation of standards
- TA-specific information from all over the internet

☐ Who can benefit from PhUSE TA Wiki

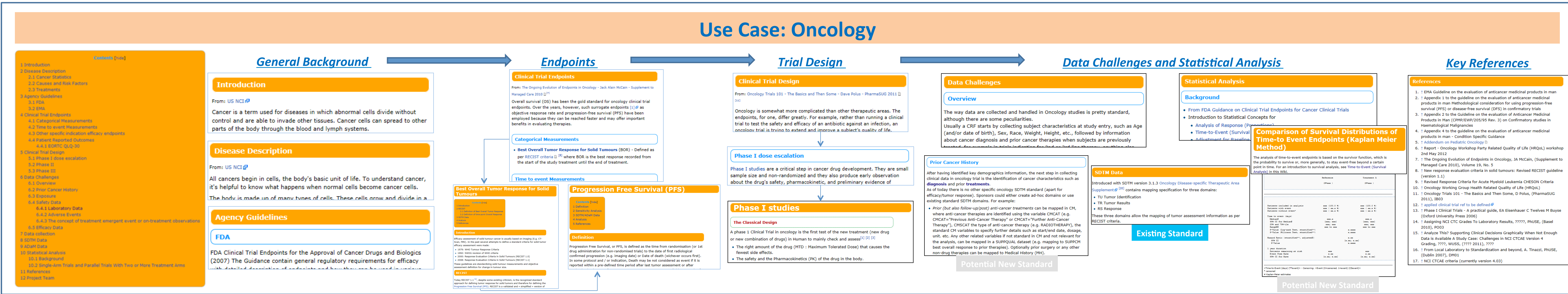
→ Starting point for Beginners in TA

→ Professionals benefit from lessons-learned in real-life and can share their own experience



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

Standards help to collaborate,
the PhUSE Wiki helps to understand



* 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 in Bruxelles
- ☐ An interesting collaboration effort across pharma companies and CROs
- ☐ Seeking for feedback on Structure, Sections, Topics covered
- ☐ Maintenance can be problematic



We're Looking for Contributors/
Reviewers

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