

Essential Elements of Ethics

Harvard MRCT & The Global Health Network



Background:

This free and open access e-Learning resource has been adapted from the Multi-Regional Clinical Trials Center at Harvard University (Harvard MRCT) Ethics Tool Kit. The Ethics Tool Kit was created to encourage protocol authors to address ethical issues in the design of studies and document their rationale in a section of the protocol that will be easily understood by review boards and investigators. This e-Learning resource guides the development of a dedicated “Ethics section” of the protocol in which these Essential Elements are addressed or cross-referenced to other sections of the protocol. This tool enable a quality and efficient review of a protocol’s ethical considerations by ethics committees.

The 11 Essential Elements of Ethics modules and associated detailed Points to Consider provide guidance and suggestions - not requirements or mandates - on key ethical questions likely to arise in the course of writing a protocol and informed consent (or templates for such documents) for clinical trials and clinical research. This online resource will assist (1) clinical researchers as they write their study protocol to recognize and address common ethical challenges in clinical trials, and (2) ethics committee members as they review and analyse clinical trial protocols in an efficient and comprehensive manner. The guidance provided may also prove useful beyond the protocol, to the extent that it can prompt the protocol author to consider policies, procedures and local regulatory requirements.

User Statistics

November 2014 – December 2017

Total modules taken:

22,048

Total e-Learners:

1,375

Total certificates awarded:

625

Figure 1 provides the overall number of modules taken by the total number of e-Learners, for each year respectively and a combined total.

Figure 2 provides a breakdown by individual module and the total number of e-Learners who have taken that module.

Figure 1

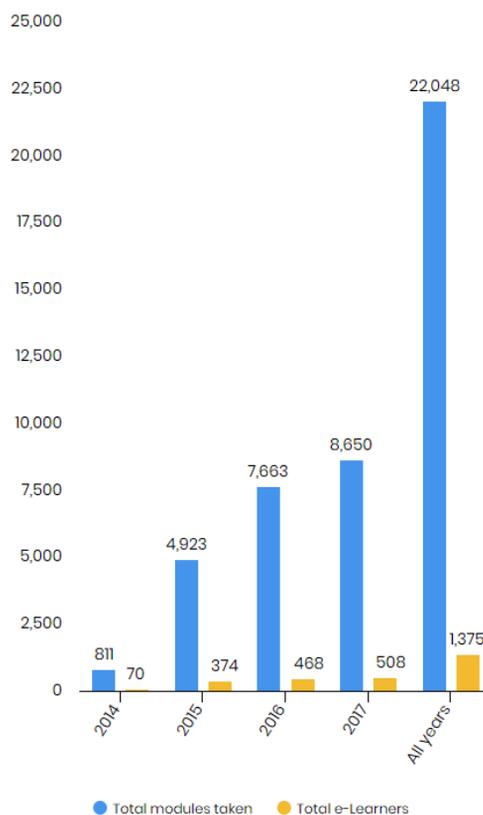
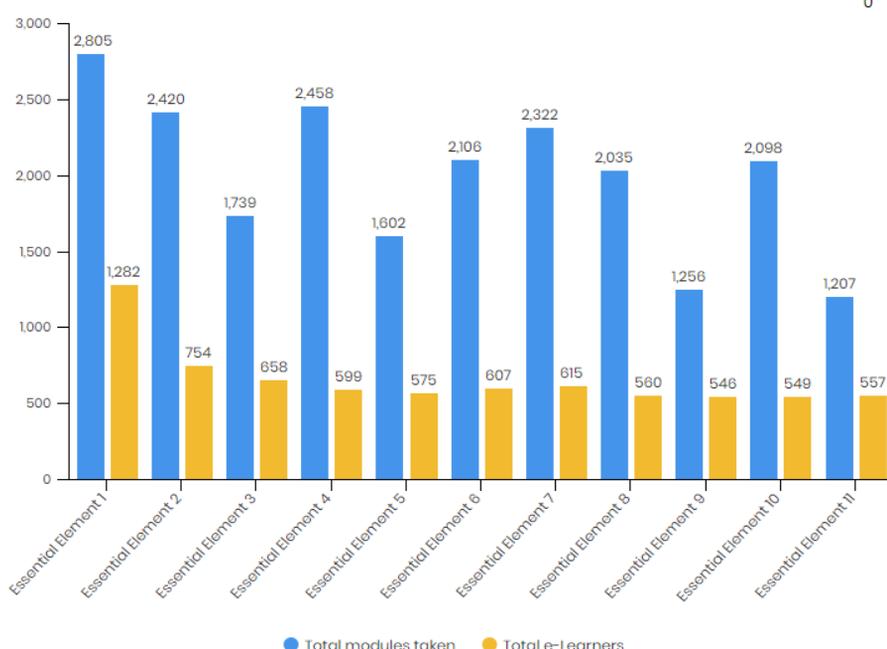


Figure 2



Demographics

Page Views

23,339

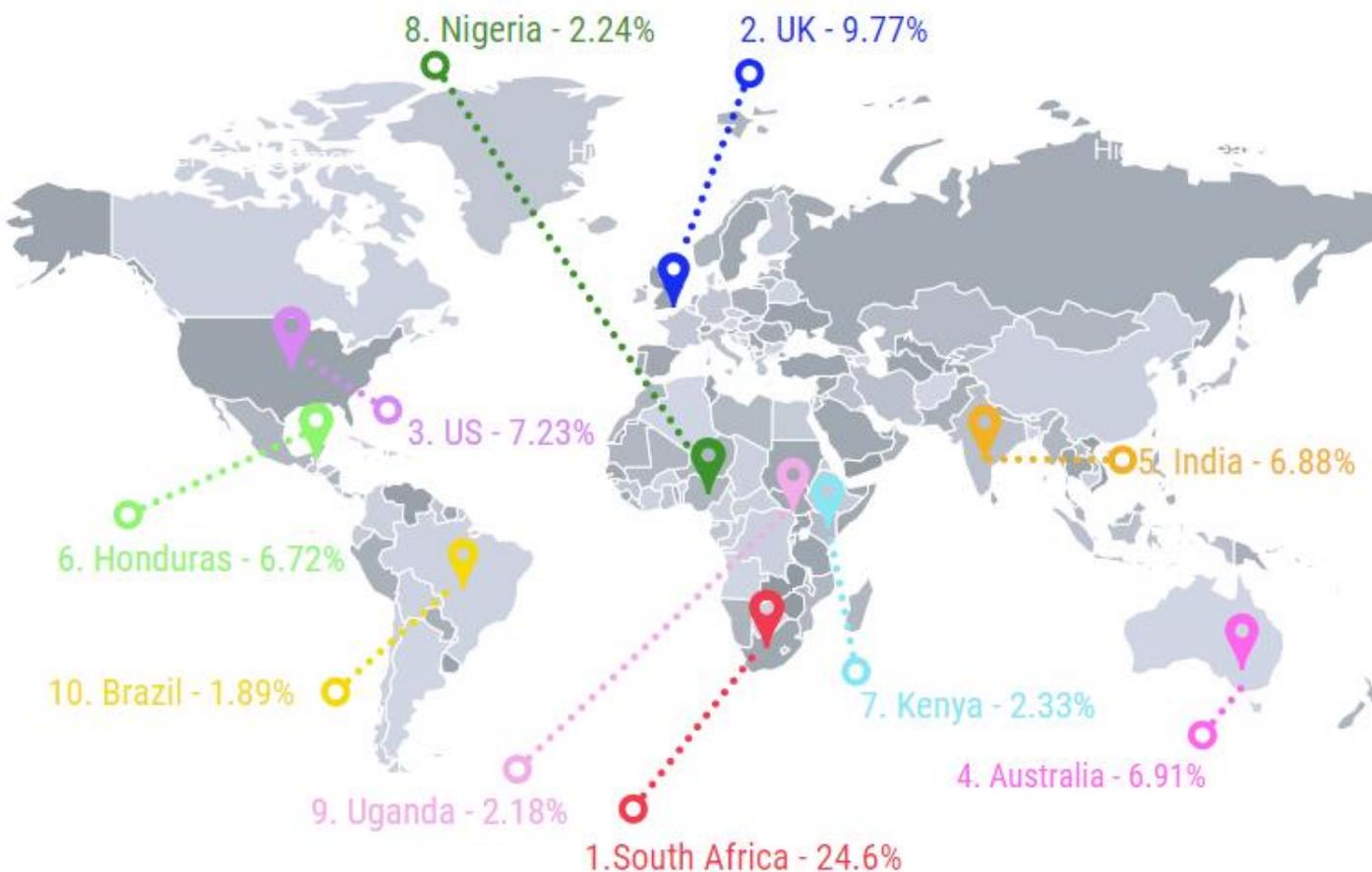
Sessions

9,719

e-Learners

1,375

Country Engagement



Map illustrating top 10 countries accessing Essential Elements of Ethics. Top 5: South Africa (24.6%); UK (9.77%); US (7.23%); Australia (6.91%); India (6.88%).

Access Data: Continent

Africa	Asia	Europe	South America	North America	Oceania
42.61%	14.19%	13.85%	13.4%	7.97%	7.12%

