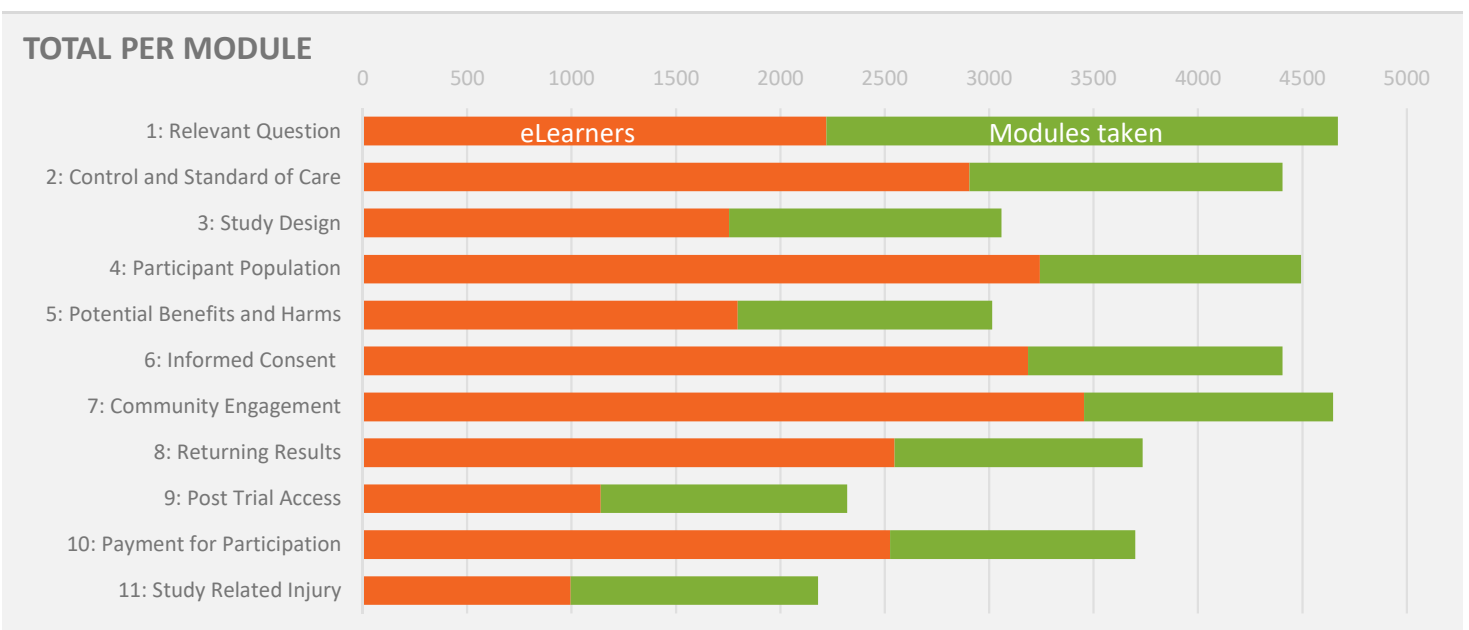
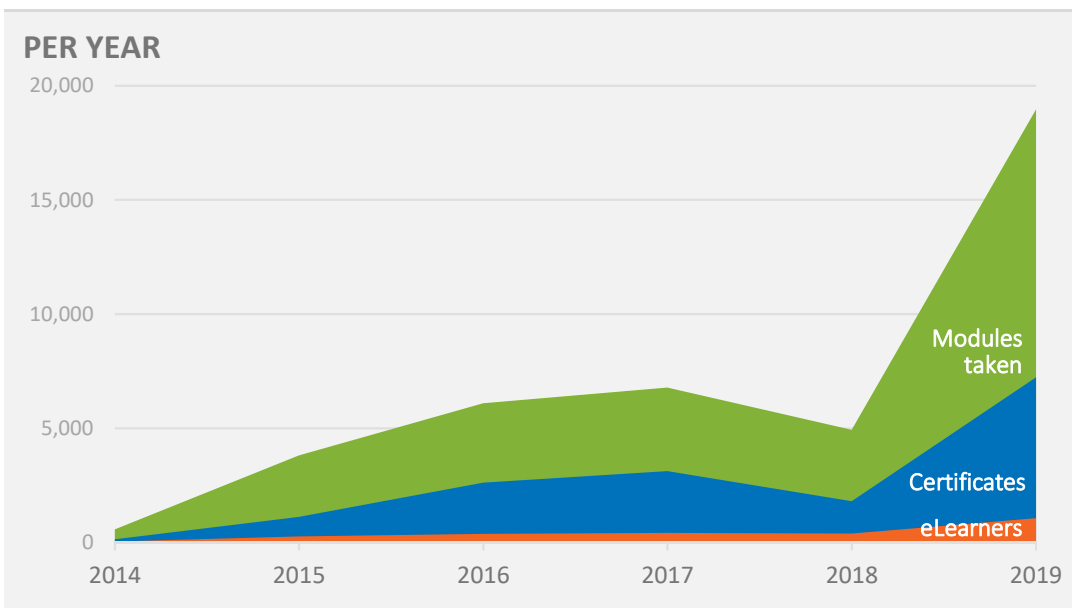


# ESSENTIAL ELEMENTS OF ETHICS

## Background

This free and open access eLearning 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 eLearning 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 enables a high-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 recognise 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.



# ESSENTIAL ELEMENTS OF ETHICS

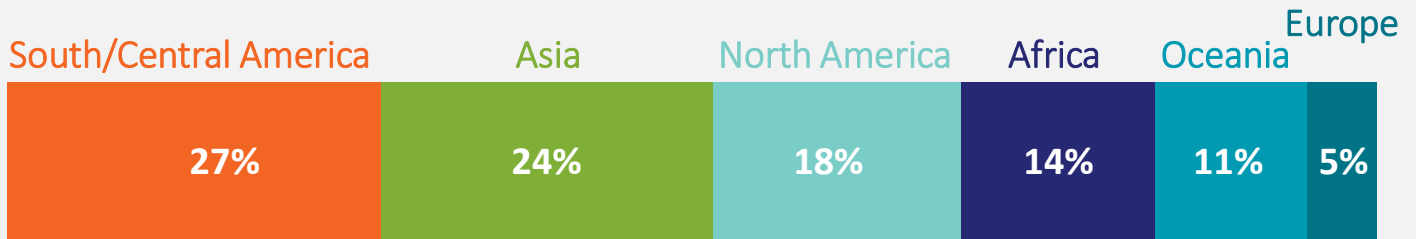
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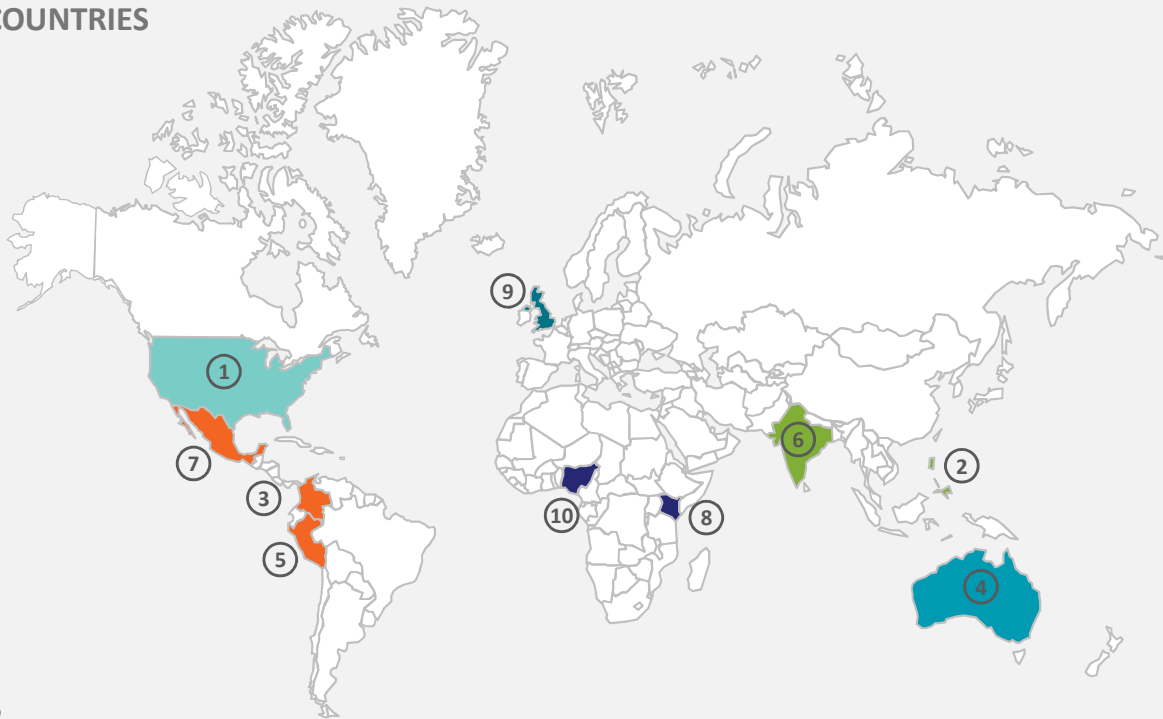
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