USE CASE: *Journal of the Society for Clinical Data Management (JSCDM)*

Clinical Research GLOSSARY

JSCDM
Journal of the Society for Clinical Data Management

MISSION:
The mission of JSCDM is to promote and publish scholarly work with direct relevance to the practice of Informatics and Data Science in clinical research.

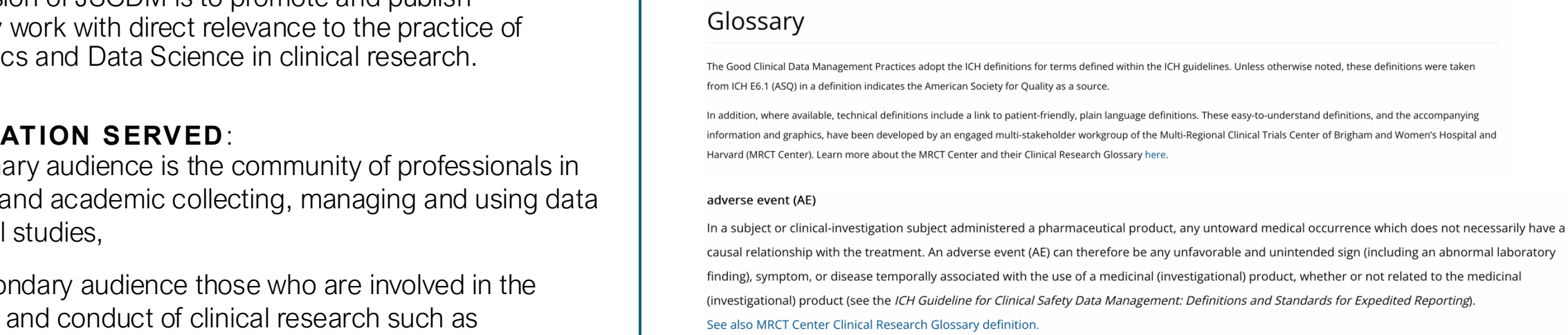
POPULATION SERVED:
The primary audience is the community of professionals in industry and academic collecting, managing and using data in clinical studies,

The secondary audience those who are involved in the planning and conduct of clinical research such as regulatory professionals, research sponsors, care providers, and the general public, as well as researchers developing or evaluating methods for data handling and use in all stages of the clinical study lifecycle.

USE OF THE GLOSSARY:

The Clinical Research Glossary augments the technical definitions used by ICH that are listed in JSCDM's online Glossary.

An example:



Glossary

The Good Clinical Data Management Practices adopt the ICH definitions for terms defined within the ICH guidelines. Unless otherwise noted, these definitions were taken from ICH E6.1 (ASQ) in a definition indicates the American Society for Quality as a source.

In addition, where available, technical definitions include a link to patient-friendly, plain language definitions. These easy-to-understand definitions, and the accompanying information and graphics, have been developed by an engaged multi-stakeholder workgroup of the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT Center). Learn more about the MRCT Center and their Clinical Research Glossary here.

adverse event (AE)

In a subject or clinical-investigation subject administered a pharmaceutical product, any untoward medical occurrence which does not necessarily have a causal relationship with the treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the *ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*).

See also MRCT Center Clinical Research Glossary definition.

https://www.jscdm.org/site/glossary/