EDGE Utility

The EDGE Utility is a validated Excel-based utility that was developed by Sonas Consulting for a large biopharmaceutical sponsor during a consulting engagement in 2014-2015. The sponsor uses this utility to support the controlled process for EDC development of new studies, study amendments, and Global Library (GLIB) volumes within the sponsor's preferred EDC vendor system. Within the past year, EDGE (which stands for "EDC Development and GLIB Enforcement") was used by the sponsor's data managers and EDC programmers for more than 100 new study builds and study amendments, and a manager within the clinical data management group recently provided the following direct quotes about the benefits realized during that year:

Improvements in Efficiency	**Improvements in Quality**	**Improvements in Compliance**
"We have taken almost two weeks off of our build time"	"The peer review and GLIB adherence review, heavily aided by the UR Autochecker, have improved the initial quality of the UR, resulting in fewer rounds of updates."	"Because we have tied the required documentation into the tool, we increase our compliance to our build process by using the tool."
"By not having to re-UAT database elements that were previously tested, we have greatly reduced our UAT time."	"The autocheckers have increased the initial quality of the UR and of the initial build, leading to fewer rounds of back and forth between the data manager and programmer."	
"It has been the automated identification of what needs to be tested that has proven to be most useful."	"Better quality specs, better quality builds and more thorough testing have all contributed to my belief that this has helped reduce the number of migrations we perform."	

Summary of the sponsor's EDC Development process

Data managers and EDC programmers share responsibility for EDC study development. The data managers determine the EDC study design and specify it within a User Requirements (UR) spreadsheet in Microsoft Excel. The EDC programmers use those requirements to build new EDC studies or study amendments, and then use the EDC system to export the study metadata elements into another Microsoft Excel spreadsheet known as the Build file (analogous to an ODM file). These two types of spreadsheet (UR and Build) are the inputs to the EDGE utility.

The EDC standards team periodically updates and releases its validated corporate Global Library volumes known as GLIB's, including a Core GLIB and TA-specific GLIB's. Each release of a GLIB includes three key deliverables:

1. The updated build elements are published into the EDC system's global library, allowing EDC Programmers to copy them into study build environments.
2. An updated UR template spreadsheet (specifying all the GLIB's EDC elements) is distributed to data managers, as a starting point for their study UR files.
3. A GLIB Build file can be used as an input to the EDGE utility, allowing detection of study-specific programming changes in elements copied from the GLIB.

Per SOP, for any EDC study elements (forms, edit checks, etc.) whose requirements and programming are unchanged from the released GLIB, or unchanged from another validated study release, those unchanged elements do not need to be tested during User Acceptance Testing (UAT) of the study. The EDGE utility enforces this process by comparing the latest study UR/Build files against the released GLIB files (or the previously validated study UR/Build files) and assigning the correct EDC elements for testing, when generating the UAT checklists.

What does the EDGE Utility do?

Before any EDC Programming begins, the EDGE utility assists the data manager in developing and finalizing their UR file:

1) UR Autochecker analyzes current UR for errors, inconsistencies, and deviations from sponsor's global and TA-specific standards
2) EDGE utility supports peer review and Global Library (GLIB) adherence review process, by requiring data manager justification for unfixed issues, and then auto-generating review documentation
3) Powerful UR Comparison tool allows easy tracking/reporting of UR changes
4) Generates simplified user requirements export for study team review/approval before UAT

Further, once the EDC programming has begun, the EDGE utility assists the data manager and EDC programmer in managing their build to completion:

5) Build Autochecker compares UR file against Build file, to determine UR-Build mismatches and/or deviations from programming standards
6) Generate detailed edit check testing checklists, directing the testing based on check type (numerical range, date compare, etc.)
7) Automated generation of UAT Checklist includes automatic identification of which EDC elements have changed (and therefore require testing) since previous validation
8) Integrated tracking of UAT testing results (within Excel) enables creation of additional rounds of UAT until all elements are accepted