**QC of Safety Monitoring Analysis RShiny Tool**

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| **Path of QC data set** | \\APOLLO\Development\Biometrics\Stat\CSE\Projects\Safety Monitoring\QC\adae\_ex  \\APOLLO\Development\Biometrics\Stat\CSE\Projects\Safety Monitoring\QC\adsl\_ex |
| **Path of QC SAS code** | \\APOLLO\Development\Biometrics\Stat\CSE\Projects\Safety Monitoring\QC\Safety test.sas  \\APOLLO\Development\Biometrics\Stat\CSE\Projects\Safety Monitoring\QC\Safety test\_teae.sas |
| **R shiny Link** | http://rshiny.gilead.com/dev/safety\_monitoring/ |

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| **Date** | **Test components** | **RShiny Output** | **Conventional Output** | **Results Match? (Y/N)** | **Resolved? (Y/N)** | **Comment** |
| Nov10,2017 | Import Data Tab | ADAE data  ADSL data  ADAE&ADSL data |  | Y |  |  |
| Nov10,2017 | Import Data Tab | TEAE  ADAE data  ADSL data  ADAE&ADSL data |  | Y |  |  |
| Nov10,2017 | Safety Analysis Tab | Output table with all AEs included |  | Y |  |  |
| Nov13,2017 | Safety Analysis Tab | Output table with all AEs included | No of Subjects w Events (Treatment)  No of Subjects w Events (Control)  Total No of Subjects (Treatment)  Total No of Subjects (Control)  Drug Exposure at Risk (Treatment)  Drug Exposure at Risk (Control)  Incidence Rate (Treatment)  Incidence Rate (Control)  Odds ratio  Odds ratio lower  Odds ratio upper  Relative risk  Relative risk lower  Relative risk upper  Risk difference  Risk difference lower  Risk difference upper  Fisher exact test P value  EAIR (Treatment)  EAIR (Treatment) lower  EAIR (Treatment) upper  EAIR (Control)  EAIR (Control) lower  EAIR (Control) upper  Hazard ratio  Hazard ratio lower  Hazard ratio upper  Logrank test P value | Y with some expected difference b/t production and validation due to different softwares. |  | Due to different algorithm applied in SAS (validation) and R (production), results may differ in some cases.  1. For example, log rank test P values for AE294 and AE30 where only one event in treatment group, SAS calculate rank statistics as missing thus P value is not calculated. But R calculate chi square statistics of 0 on 0 degree of freedom thus p value is 1.  2. When no AE event in one of the arm, the chi- square function calculating lower bound of EAIR will have zero degree of freedom. SAS results in missing value but R returns zero.  3. When no event in one of treatment arm, PHREG in sas will result in very unstable HR estimate, thus has big difference from R result. |
| Nov13,2017 | Safety Analysis Tab | Output table with TEAE included | No of Subjects w Events (Treatment)  No of Subjects w Events (Control)  Total No of Subjects (Treatment)  Total No of Subjects (Control)  Drug Exposure at Risk (Treatment)  Drug Exposure at Risk (Control)  Incidence Rate (Treatment)  Incidence Rate (Control)  Odds ratio  Odds ratio lower  Odds ratio upper  Relative risk  Relative risk lower  Relative risk upper  Risk difference  Risk difference lower  Risk difference upper  Fisher exact test P value  EAIR (Treatment)  EAIR (Treatment) lower  EAIR (Treatment) upper  EAIR (Control)  EAIR (Control) lower  EAIR (Control) upper  Hazard ratio  Hazard ratio lower  Hazard ratio upper  Logrank test P value | Y with some expected difference b/t production and validation due to different softwares. |  | Please see the comment above |