Marconi Analysis Plan for Short Communication On K65R

Objective: To describe unusually high rates of K65R in a subpopulation of patients taking tenofovir-containing regimens

Exclusion criteria:

1. Every patient must currently be on one of TDF or D4T; that is, CUR\_ARVS must include one of TDF or D4T.  If not, they are excluded.
2. If a patient meets 1., then we look to see if their start date was within the window (3 August 2010 to 17 March 2011).  For example, if a patient is currently on TDF, then we look at their earliest TDF start date (current and pre-ARVs) to see if it is in the time window.  If so, they are included; if not, they are excluded.
3. Per 2, if a patient is currently on TDF, then their earliest D4T start date plays **no** role in the exclusion criteria.  Similarly, if a patient is currently on D4T, then their earliest TDF start date plays **no** role in the exclusion criteria.
4. Per 2, if a patient is currently on TDF but they also have a history of taking TDF, then we need to consider whether their **earliest** TDF start date lies within the time window.  However, when calculating earliest TDF start date, we need to consider the following rare exceptions:
   1. When examining previous experiences on TDF, we exclude those instances where patients took TDF for less than 14 days.  This is because those patients almost certainly switched ARVs due to toxicity.
   2. If a patient is currently on TDF, but was previously on TDF and D4T in that order, then earliest TDF start date is taken from the current ARVs start date. (that is, if PRE\_ARVS has TDF first, D4T second, and CUR\_ARVS is TDF, then earliest TDF start date is the one corresponding to CUR\_ARVS).
   3. If a patient is currently on TDF but has a history of taking TDF as follows: started and stopped TDF before 8/3/2010, then started TDF again after 3 August 2010 but before 17 March 2011. Then, we include this patient in the analysis and take the second start date as their earliest TDF start date.
5. The same logic in 4 applies to D4T as well with the roles of TDF and D4T switched.