Deliverable 2 – Health Analytics Project Design

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CLINICAL QUESTION

Do patients that have been treated with Anagrelide have a higher risk of cancer, compared with a more conventional alternative, Hydroxyurea?

Note that in Deliverable 1, the clinical question was:

In patients undergoing treatment for thrombocythemia, does those that have been treated with Anagrelide has a higher risk of thrombosis, compared with a more conventional alternative, Hydroxyurea? However, the total number of concept records for such clinical question is limited. Thus, another valid clinical question is needed for this deliverable.

One of the driving force for the development of Anagrelide is that Hydroxyurea has been reported for being related with cancer risk. For example, Nand et. al. reported that hydroxyurea has 1–5.9% risk of causing leukemic transformation (Nand, Stock, Godwin, & Fisher, 1996). Hanft et. al. further suggested that in vivo hydroxyurea exposure could cause acquired DNA mutations (Hanft et al., 2000). Thus, whether such suggestions against hydroxyurea is reasonable, and whether the alternatives thereof, such as Anagrelide, could perform better in cancer risk, will need to be investigated.

PATIENT COUNTS

- [hxia40] patients taking Anagrelide

  http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cohortdefinition/446
- [hxia40] patients taking Hydroxyurea

  http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cohortdefinition/449
- [hxia40] cancer patients exposed to either drug

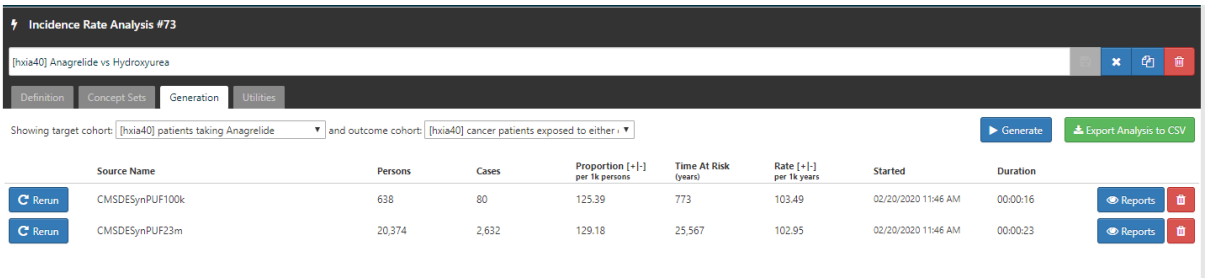
  http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cohortdefinition/452

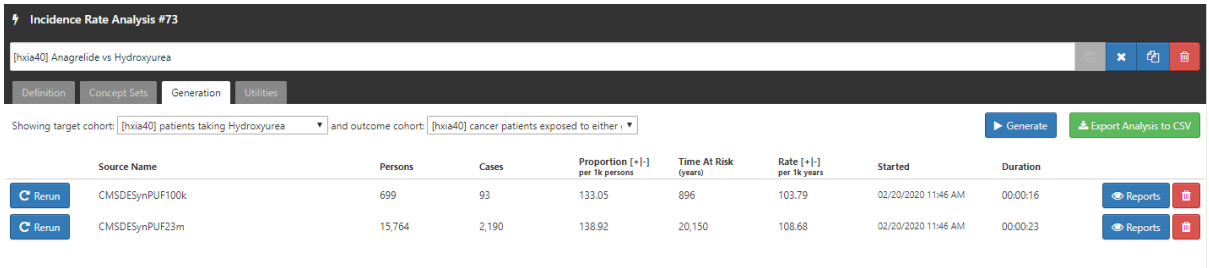
Patient counts in both datasets:

Cohort	Patients taking Anagrelide	Patients taking Hydroxyurea	Cancer patients exposed to either drug
CMSDESynPUF100k	638	699	172
CMSDESynPUF23m	20,392	15,774	4,801

INCIDENCE RATES

Among patients taking Anagrelide, 125.39/1,000 patients in the 100k dataset and 129.18/1000 patients in the 23m dataset were diagnosed with cancer. The incidence rates per 1k years are 103.49 and 102.95. Among patients taking Hydroxyurea, 133.05/1000 in the 100k dataset and 138.92/1000 patients in the 23m dataset were diagnosed with cancer. The incidence rates per thousand years are 103.79 and 108.68. Results are shown as below:



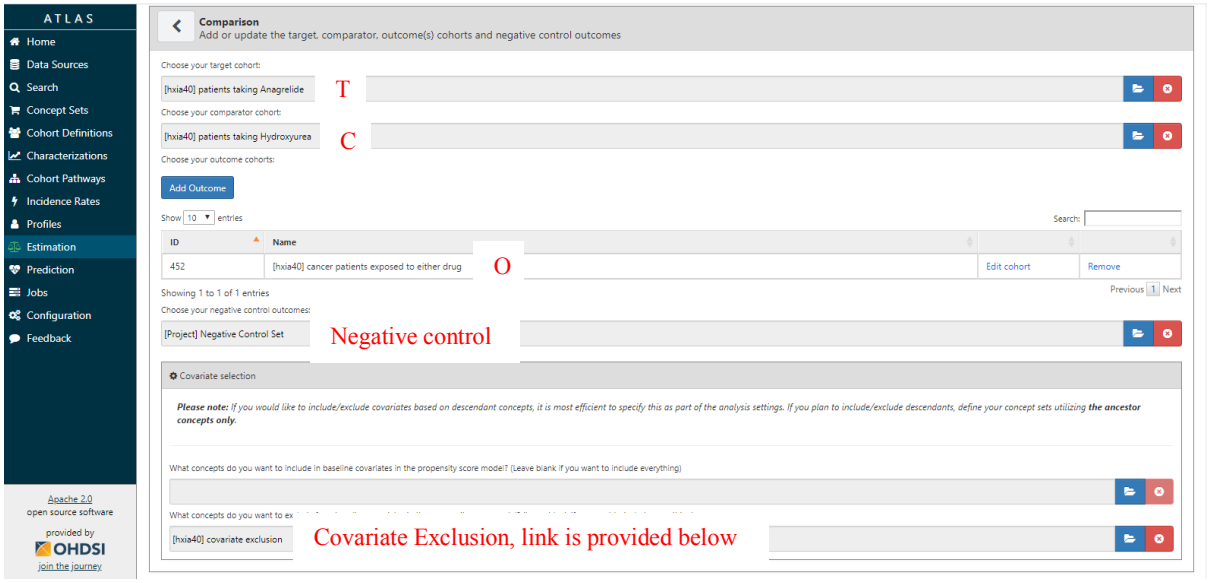


http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/iranalysis/73

COHORT CHARACTERIZATION

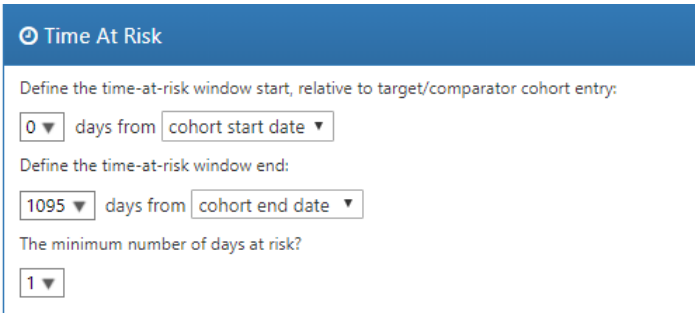
http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cc/characterizations/65/design

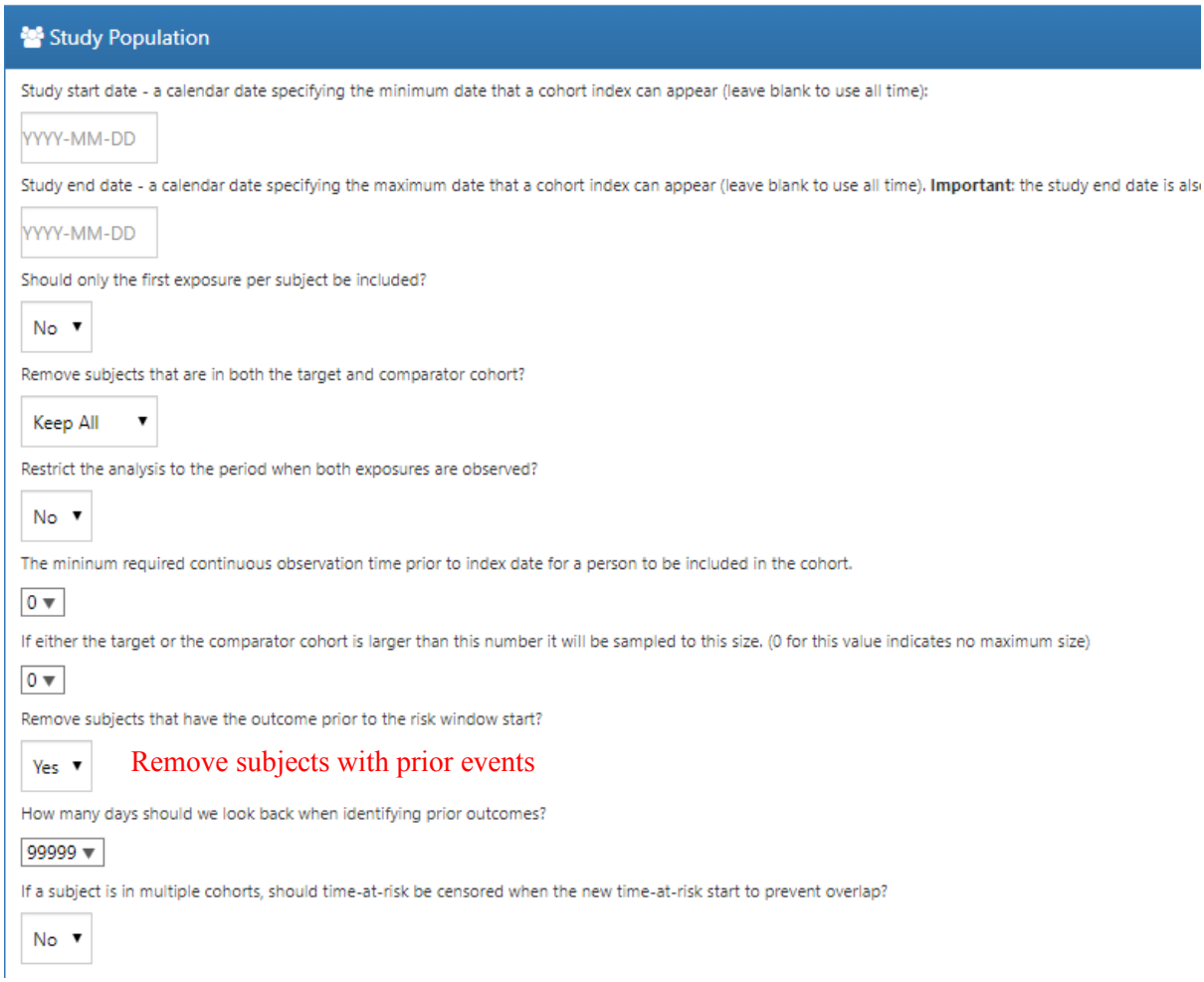
STRETCH POINTS:



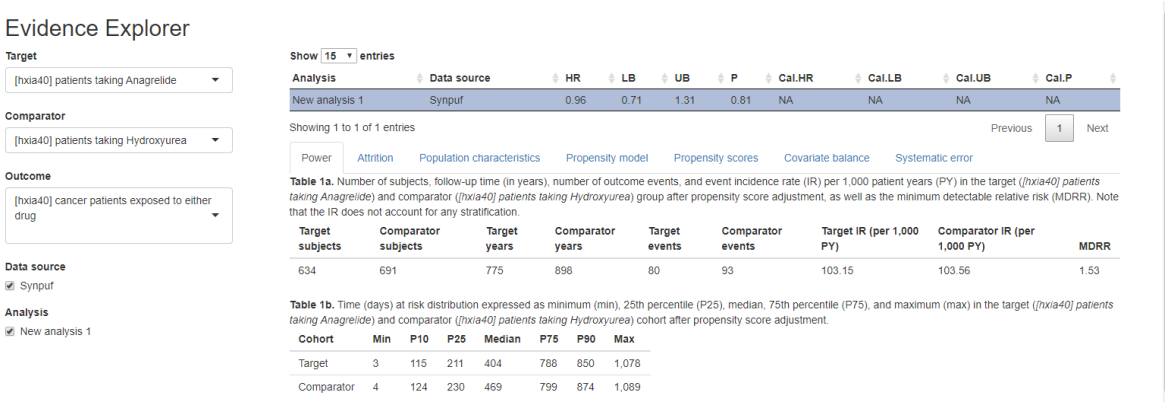
[hxia40] covariate exclusion:

http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/conceptset/799/conceptset-expression





Below is the result I got from estimation study analysis in RStudio. The patient counts for target and comparator cohorts are 634 and 691. The incidence rates are 103.15 and 103.56, accordingly. There numbers are similar to what I got by estimation analysis at Atlas.



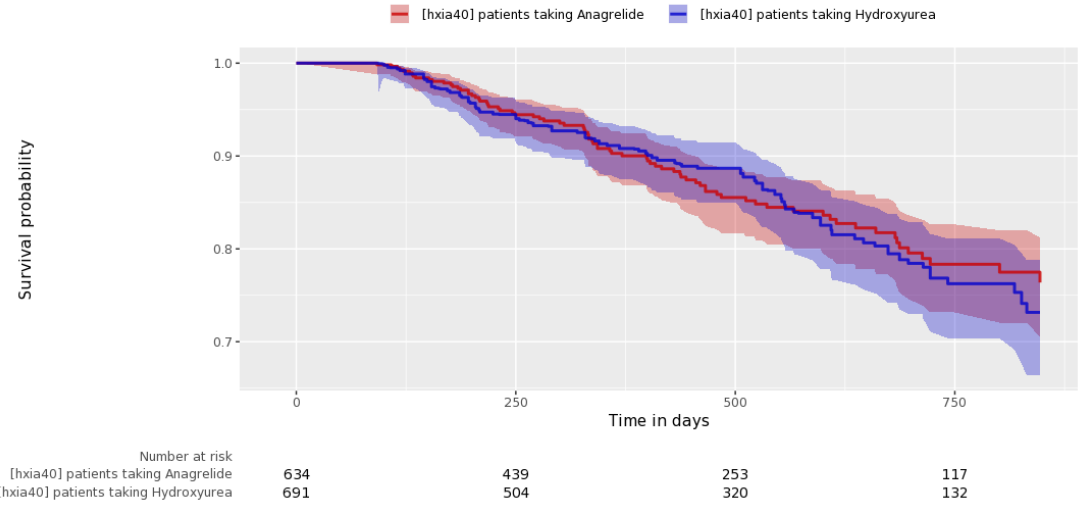


Figure 5. Kaplan Meier plot, showing survival as a function of time. This plot is adjusted using the propensity score: The target curve (*[hxia40] patients taking Anagrelide*) shows the actual observed survival. The comparator curve (*[hxia40] patients taking Hydroxyurea*) applies reweighting to approximate the counterfactual of what the target survival would look like had the target cohort been exposed to the comparator instead. The shaded area denotes the 95 percent confidence interval.

REFERENCES

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DRUG: Hydroxyurea. Retrieved from https://www.genome.jp/dbget-bin/www_bget?dr:D00341

Hanft, V. N., Fruchtman, S. R., Pickens, C. V., Rosse, W. F., Howard, T. A., & Ware, R. E. (2000). Acquired DNA mutations associated with in vivo hydroxyurea exposure. *Blood, 95*(11), 3589-3593.

Nand, S., Stock, W., Godwin, J., & Fisher, S. G. (1996). Leukemogenic risk of hydroxyurea therapy in polycythemia vera, essential thrombocythemia, and myeloid metaplasia with myelofibrosis. *American journal of hematology, 52*(1), 42-46.