Deliverable 2 – Health Analytics Project Design

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CS-6440 - Introduction to Health Informatics

Georgia Institute of Technology

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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.

CONCEPT SETS

[hxia40] anagrelide

http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/conceptset/456/details

The codes for Anagrelide is found from the ICD-10-CM code, which used to specify a diagnosis of long term (current) use of antithrombotics/antiplatelets, which is Z79.02 ("2020 ICD-10-CM Diagnosis Code Z79.02," 2020). Using this ICD code, I found the concept ID for the corresponding drug, Anagrelide, on Athena.

Concept Id	Concept Code	Concept Name
1797155	253453	peginterferon alfa-2b
1380068	5880	Interferon Alfa-2b
1381258	597855	anagrelide 1 MG Oral Capsule [Agrylin]
1381257	597852	anagrelide 1 MG Oral Capsule
1381259	597857	anagrelide 0.5 MG Oral Capsule [Agrylin]
19122203	597850	anagrelide 0.5 MG Oral Capsule
1381253	596724	anagrelide

The expression JSON is attached as Appendix 1.

- [hxia40] hydroxyurea

http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/conceptset/459/details

The code in anatomical therapeutic chemical (ATC) drug classification system for hydroxyurea is Lo1XXo5, which can be found is this reference ("DRUG: Hydroxyurea,"). Using the ATC code, I then found related drug in Athena, followed by choosing related concepts in Atlas.

Concept Id	Concept Code	Concept	: Name
19007385	105602	hydroxy	vurea 500 MG Oral Capsule [Hydrea]
1377163	197797	hydroxy	vurea 500 MG Oral Capsule
1377169	213284	hydroxy	rurea 400 MG Oral Capsule [Droxia]
19023562	200344	hydroxy	rurea 400 MG Oral Capsule
1377168	213283	hydroxy	rurea 300 MG Oral Capsule [Droxia]
19023561	200343	hydroxy	vurea 300 MG Oral Capsule
1377167	213282	hydroxy	rurea 200 MG Oral Capsule [Droxia]
19023560	200342	hydroxy	vurea 200 MG Oral Capsule
1377171	284561	hydroxy	rurea 1000 MG Oral Tablet [Mylocel]
1377170	283475	hydroxy	vurea 1000 MG Oral Tablet
1377141	5552	hydroxy	/urea

The expression JSON is attached as Appendix 2.

- [hxia40] cancer

http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/conceptset/527/details

As it has been reported that hydroxyurea could cause acquired DNA mutations (Hanft et al., 2000), to investigate on how much cancerous risk is associated with hydroxyurea, all cancer-related concepts on Atlas have been selected:

Concept Id 🍦	Concept Code	Concept Name
4079687	277605001	Tumor lysis syndrome
444219	111254007	Osteitis deformans without bone tumor
434300	255046005	Neuroendocrine tumor
4100425	253001006	Merkel cell carcinoma
196058	188664008	Mast cell malignancy of intra-abdominal lymph nodes
4089655	187716008	Malignant tumor of Waldeyer's ring
73712	188240003	Malignant tumor of vault of bladder
197508	399326009	Malignant tumor of urinary bladder
4095167	188245008	Malignant tumor of ureteric orifice
4094855	187725002	Malignant tumor of upper third of esophagus
4090216	187606005	Malignant tumor of upper labial mucosa
4092524	188219004	Malignant tumor of undescended testis
4095755	188239000	Malignant tumor of trigone of urinary bladder
4095436	187792009	Malignant tumor of tail of pancreas

The expression JSON is attached as Appendix 3.

COHORTS

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

The test view is attached as Appendix 4.

- [hxia40] patients taking Hydroxyurea
 http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cohortdefinition/449
 - The test view is attached as Appendix 5.
- [hxia40] cancer patients exposed to either drug
 http://gt-health-analytics-1.us-east-1.elasticbeanstalk.com/#/cohortdefinition/452

The test view is attached as Appendix 6.

DISCUSSION

The number of records in the four concepts sets are listed below:

Concept set	anagrelide	hydroxyurea	cancer
Num of records	47,344	33,243	2,500,292

The numbers of records in the 100k dataset for the three cohorts are listed below:

Cohort	patients taking Anagrelide	patients taking Hydroxyurea	cancer patients exposed to either drug
Num of records	638	699	172

Although it has been reported that patients are diagnosed with cancer after being exposed to hydroxyurea from 0 to 21 months [ref], it is premature to assume exposure to hydroxyurea could immediately cause cancer – after all, the mutation risk (if significant) of hydroxyurea exposure will take time to be effective. Thus, for the outcome cohort, I defined the observation window to be 3 months – 3 years before index start date, to exclude the patients that are diagnosed with cancer immediately after hydroxyurea exposure.

REFERENCES

2020 ICD-10-CM Diagnosis Code Z79.02. (2020). Retrieved from https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z77-Z99/Z79-/Z79.02

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.

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       "STANDARD_CONCEPT": "S",
       "STANDARD_CONCEPT_CAPTION": "Standard",
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        "VOCABULARY_ID": "SNOMED",
       "CONCEPT_CLASS_ID": "Clinical Finding"
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      "includeDescendants": false,
     "includeMapped": false
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       "CONCEPT_NAME": "Tumor lysis syndrome",
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       "STANDARD_CONCEPT_CAPTION": "Standard",
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      "includeDescendants": false,
      "includeMapped": false
    }
  ]
}
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[hxia40] patients taking Anagrelide

Initial Event Cohort

People having any of the following:

a drug exposure of [hxia40] anagrelide1

with continuous observation of at least 0 days prior and 0 days after event index date, and limit initial events to: earliest event per person.

Limit qualifying cohort to: earliest event per person.

End Date Strategy

No end date strategy selected. By default, the cohort end date will be the end of the observation period that contains the index event.

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days.

Appendix 1: Concept Set Definitions

[hxia40] anagrelide

Concept Id	Concept Name	Domain	Vocabul	ary	Excluded	b	Descen	dants	Mapped
1380068Interfer	on Alfa-2b	Drug	RxNorm	NO	NO	NO			
1381253 anagrel	ide Drug	RxNorm	NO	NO	NO				
19122203	anagrelide 0.5 M	IG Oral Ca	psule	Drug	RxNorm	NO	NO	NO	
1381259 an agrel	ide 0.5 MG Oral C	apsule [Ag	grylin]	Drug	RxNorm	NO	NO	NO	
1381257 anagrel	ide 1 MG Oral Cap	sule	Drug	RxNorm	NO	NO	NO		
1381258anagrel	ide 1 MG Oral Cap	sule [Agr	ylin]	Drug	RxNorm	NO	NO	NO	
1797155 peginte	rferon alfa-2b	Drug	RxNorm	NO	NO	NO			

APPENDIX 5

[hxia40] patients taking Hydroxyurea

Initial Event Cohort

People having any of the following:

a drug exposure of [hxia40] hydroxyurea1

with continuous observation of at least 0 days prior and 0 days after event index date, and limit initial events to: earliest event per person.

Limit qualifying cohort to: earliest event per person.

End Date Strategy

No end date strategy selected. By default, the cohort end date will be the end of the observation period that contains the index event.

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days.

Appendix 1: Concept Set Definitions

[hxia40] hydroxyurea

Concept Id	Concept Nan	ne Domain	Vocabul	ary	Excluded	t	Descend	ants	Mapped
1377141 hydroxy	yurea Dru	g RxNorm	NO	NO	NO				
1377170hydroxy	yurea 1000 M	G Oral Tablet	Drug	RxNorm	NO	NO	NO		
1377171 hydroxy	yurea 1000 M	G Oral Tablet	[Mylocel]	Drug	RxNorm	NO	NO	NO	
19023560	hydroxyurea	200 MG Ora	Capsule	Drug	RxNorm	NO	NO	NO	
1377167 hydroxy	yurea 200 MG	Oral Capsule	[Droxia]	Drug	RxNorm	NO	NO	NO	
19023561	hydroxyurea	300 MG Ora	Capsule	Drug	RxNorm	NO	NO	NO	
1377168hydroxy	yurea 300 MG	Oral Capsule	[Droxia]	Drug	RxNorm	NO	NO	NO	
19023562	hydroxyurea	400 MG Oral	Capsule	Drug	RxNorm	NO	NO	NO	
1377169 hydroxy	yurea 400 MG	Oral Capsule	[Droxia]	Drug	RxNorm	NO	NO	NO	
1377163 hydroxy	yurea 500 MG	Oral Capsule	Drug	RxNorm	NO	NO	NO		
19007385	hydroxyurea	500 MG Oral	Capsule	[Hydrea]	Drug	RxNorm	NO	NO	NO

[hxia40] cancer patients exposed to either drug

Initial Event Cohort

People having any of the following:

a condition occurrence of [hxia40] cancer2

with continuous observation of at least 0 days prior and 0 days after event index date, and limit initial events to: earliest event per person.

Inclusion Rules

Inclusion Criteria #1: exposed to either drug

Having any of the following criteria:

at least 1 occurrences of a drug exposure of [hxia40] anagrelide1

where event starts between 1095 days Before and 90 days Before index start date

or at least 1 occurrences of a drug exposure of [hxia40] hydroxyurea3

where event starts between 1095 days Before and 90 days Before index start date

Limit qualifying cohort to: earliest event per person.

End Date Strategy

No end date strategy selected. By default, the cohort end date will be the end of the observation period that contains the index event.

Cohort Collapse Strategy:

Collapse cohort by era with a gap size of 0 days.

Appendix 1: Concept Set Definitions

1	hxia40	anagre	ماناه
	IIXId4U	anagre	anae

Concept	:Id (Concept Name	Domain	Vocabula	ary	Excluded	b	Descend	dants	Mapped	
1380068	3 Interfero	n Alfa-2b	Drug	RxNorm	NO	NO	NO				
1381253	3 anagrelid		RxNorm		NO	NO					
1912220)3 a	anagrelide 0.5 M	G Oral Ca	psule	Drug	RxNorm	NO	NO	NO		
	_	e 0.5 MG Oral Ca		grylin]	Drug	RxNorm	NO	NO	NO		
	•	e 1 MG Oral Cap		Drug	RxNorm	NO	NO	NO			
1381258	3anagrelid	e 1 MG Oral Cap	sule [Agr	ylin]	Drug	RxNorm	NO	NO	NO		
1797155	peginterf	eron alfa-2b	Drug	RxNorm	NO	NO	NO				
[hxia40]											
Concept		Concept Name			•	Excluded		Descend		Mapped	
	_	euroendocrine tu		Conditio		SNOME		NO	NO	NO	
	_	mor of digestive	_	Conditio		SNOME		NO	NO	NO	
	_	mor of endocrin	•		Conditio		SNOME		NO	NO	NO
	•	mor of lacrimal o	•				SNOME	D	NO	NO	NO
198991	Benign tu NO	ımor of peritoneı	um and re	etroperito	oneum	Conditio	n	SNOME	D	NO	NO
433979	Benign tu NO	mor of respirato	ry and in	trathorac	cic organ	Conditio	n	SNOME	D	NO	NO
201807	Burkitt's t	tumor of intra-ab	dominal	lymph no	odes	Conditio	n	SNOME	D	NO	NO
438376	Burkitt's t	tumor of intratho	oracic lym	nph node:	S	Conditio	n	SNOME	D	NO	NO
433426		tumor of lymph r NO	nodes of a	axilla ANE	O/OR upp	er limb	Conditio	n	SNOME)	NO
437504		tumor of lymph r NO	nodes of I	nead, face	e AND/O	R neck	Conditio	n	SNOME)	NO
444440	Burkitt's 1	tumor of spleen	Conditio	n	SNOME)	NO	NO	NO		
		situ of urinary bl		Conditio		SNOME)	NO	NO	NO	
		tumor of append		Conditio		SNOME)	NO	NO	NO	
		tumor of gastroi			Conditio	n	SNOME	D	NO	NO	NO
		tumor of ileum			SNOME)	NO	NO	NO		

193155 Carcinoid tumor of large intestine	Condition	on	SNOME	D	NO	NO	NO	
198100 Carcinoid tumor of small intestine	Condition	on	SNOME	D	NO	NO	NO	
194306 Carcinoid tumor of stomach	Condition	on	SNOME	D	NO	NO	NO	
433435 Carcinoma in situ Condition	SNOME	D	NO	NO	NO			
436671 Carcinoma in situ of anal canal	Condition	on	SNOME	D	NO	NO	NO	
78110 Carcinoma in situ of anus Condition	on	SNOME	D	NO	NO	NO		
81250 Carcinoma in situ of breast	Conditio		SNOME	D	NO	NO	NO	
4093960 Carcinoma in situ of bronchus and		Conditio		SNOME		NO	NO	NO
75512 Carcinoma in situ of colon Condition	_	SNOME		NO	NO	NO		
4116351 Carcinoma in situ of ear Condition		SNOME		NO	NO	NO		
373732 Carcinoma in situ of eye Condition		SNOME		NO	NO	NO		
192577 Carcinoma in situ of female genita		Condition		SNOME		NO	NO	NO
192291 Carcinoma in situ of intestinal trac			SNOME		NO	NO	NO	110
24897 Carcinoma in situ of larynxCondition		SNOME		NO	NO	NO	NO	
441819 Carcinoma in situ of lip, oral cavity			Conditio	_	SNOME		NO	NO
NO	r anu pna	I YIIX	Conditio	ווע	SINOIVIE	ט.	NO	NO
192292 Carcinoma in situ of liver and/or b	iliary syst	em	Condition	on	SNOME	D	NO	NO
196068 Carcinoma in situ of male genital of	organ	Conditio	nn	SNOME	D	NO	NO	NO
193162 Carcinoma in situ of penis Condition	_	SNOME		NO	NO	NO	NO	110
200970 Carcinoma in situ of penis conditi			SNOME		NO	NO	NO	
75210 Carcinoma in situ of prostate	Condition				_		NO NO	
	Condition		SNOME		NO	NO		NO
261528 Carcinoma in situ of respiratory tr		Condition		SNOME		NO	NO	NO
139766 Carcinoma in situ of scalp and skir				SNOME		NO	NO	NO
138996 Carcinoma in situ of skin Condition		SNOME		NO	NO	NO	NO	NO
434883 Carcinoma in situ of skin of eyelid NO	including	cantnus	Conditio	on	SNOME	.D	NO	NO
133726 Carcinoma in situ of skin of face	Conditio	าท	SNOME	D	NO	NO	NO	
133725 Carcinoma in situ of skin of lip	Condition		SNOME		NO	NO	NO	
134308 Carcinoma in situ of skin of lower		Conditio		SNOME		NO	NO	NO
132862 Carcinoma in situ of skin of trunk,					SNOME		NO	NO
NO	excluding	s scrotuii	Conditio) i i	SINOIVIL	.0	NO	NO
437240 Carcinoma in situ of skin of upper	limb and	shoulder	Condition	on	SNOME	D	NO	NO
NO								
200974 Carcinoma in situ of stomach	Condition		SNOME		NO	NO	NO	
81247 Carcinoma in situ of urinary syster	n Conditio	on	SNOME	D	NO	NO	NO	
194611 Carcinoma in situ of uterine cervix	Condition	on	SNOME	D	NO	NO	NO	
192581 Carcinoma in situ of uterus	Condition	on	SNOME	D	NO	NO	NO	
195513 Carcinoma in situ of vagina	Condition	on	SNOME	D	NO	NO	NO	
438386 Carcinoma in situ of vulva Conditi	on	SNOME	D	NO	NO	NO		
443571 Cervicovaginal cytology: High grad SNOMED NO NO	le squamo NO	ous intra	epithelial	lesion or	carcinor	ma	Conditio	on
4194462 Chorioretinal tumor Condition	_	SNOME	D	NO	NO	NO		
438701 Disseminated malignancy of unknown	_		Conditio	_	SNOME		NO	NO
NO	·		Contact	5 11		.0	110	110
4167696Estrogen receptor positive tumor		on	SNOME	D	NO	NO	NO	
441692 Finding of serum tumor marker le		Condition		SNOME	D	NO	NO	NO
438151 Glaucoma associated with tumors NO	AND/OR	cysts	Conditio	on	SNOME	D	NO	NO
4331508Increased cancer antigen 125	Condition	าท	SNOME	D	NO	NO	NO	
40482859 Malignant carcinoid tumo		Conditio		SNOME		NO	NO	NO
4040379 Malignant mast cell tumor Condition		SNOME		NO	NO	NO		.,0
4180794Malignant retroperitoneal tumor			SNOME		NO	NO	NO	
4095437 Malignant tumor of Islets of Lange		Conditio		SNOME		NO	NO	NO
4094863 Malignant tumor of Meckel's dive						NO	NO	NO
-								
4089655 Malignant tumor of Waldeyer's rir		Condition Condition		SNOME SNOME		NO	NO	NO

400E316 Malignant tumor of abdominal part of acon	bogus	Conditio		CNIONAE	D	NO	NO
4095316 Malignant tumor of abdominal part of esop NO	magus	Conditio)[]	SNOME	D	NO	NO
4090224 Malignant tumor of anterior floor of mouth	Conditio	on	SNOME	D	NO	NO	NO
435754 Malignant tumor of ascending colon	Condition	on	SNOME	D	NO	NO	NO
4095756Malignant tumor of bladder neck Condition	on	SNOME	D	NO	NO	NO	
4092072 Malignant tumor of body of pancreas	Condition	on	SNOME	D	NO	NO	NO
4095320 Malignant tumor of body of stomach	Condition	on	SNOME	D	NO	NO	NO
443391 Malignant tumor of cecum Condition	_	SNOME		NO	NO	NO	
4094854 Malignant tumor of cervical part of esopha	gus	Conditio	n	SNOME	D	NO	NO
NO		_					
198984 Malignant tumor of cervix Condition	SNOME		NO	NO	NO		
4092211 Malignant tumor of glottis Condition	SNOME		NO	NO	NO	NO	NO
4150793 Malignant tumor of lower labial mucosa	Conditio		SNOME		NO	NO	NO
4089656 Malignant tumor of lower third of esophage NO		Conditio	on	SNOME	D	NO	NO
4092060 Malignant tumor of middle third of esopha	gus	Conditio	n	SNOME	D	NO	NO
4177107 Malignant tumor of nasal cavity Condition	วท	SNOME	D	NO	NO	NO	
25189 Malignant tumor of oral cavity Condition	_	SNOME		NO	NO	NO	
4094866 Malignant tumor of pancreatic duct	Conditio		SNOME	_	NO	NO	NO
4094721 Malignant tumor of posterior wall of oroph		Conditio		SNOME		NO	NO
NO							
4092212 Malignant tumor of supraglottis Condition		SNOME		NO	NO	NO	NO
4095436 Malignant tumor of tail of pancreas	Conditio		SNOME		NO	NO	NO
4095755 Malignant tumor of trigone of urinary blade NO	aer	Conditio	n	SNOME	D	NO	NO
4092524Malignant tumor of undescended testis	Conditio	nn.	SNOME	D	NO	NO	NO
4090216Malignant tumor of upper labial mucosa	Conditio		SNOME		NO	NO	NO
4094855 Malignant tumor of upper third of esophag		Conditio		SNOME	_	NO	NO
NO	us	Conditio	,,,,	SIVOIVIE	D	110	110
4095167 Malignant tumor of ureteric orifice Condition	on	SNOME	D	NO	NO	NO	
197508 Malignant tumor of urinary bladder	Conditio		SNOME	_	NO	NO	NO
73712 Malignant tumor of vault of bladder	Conditio	on	SNOME	D	NO	NO	NO
196058 Mast cell malignancy of intra-abdominal lyr	nph node	es	Conditio	on	SNOME	D	NO
NO NO	•						
4100425 Merkel cell carcinoma Condition	SNOME	D	NO	NO	NO		
434300 Neuroendocrine tumor Condition	SNOME	D	NO	NO	NO		
444219 Osteitis deformans without bone tumor	Condition	on	SNOME	D	NO	NO	NO
4079687Tumor lysis syndrome Condition	SNOME	D	NO	NO	NO		
[hxia40] hydroxyurea							
Concept Id Concept Name Domain Vocabu	lary	Exclude	d	Descen	dants	Mappe	t
1377141 hydroxyurea Drug RxNorm NO	NO	NO					
1377170 hydroxyurea 1000 MG Oral Tablet Drug	RxNorm		NO	NO			
1377171hydroxyurea 1000 MG Oral Tablet [Mylocel	_	RxNorm	NO	NO	NO		
19023560 hydroxyurea 200 MG Oral Capsule	U	RxNorm		NO	NO		
1377167hydroxyurea 200 MG Oral Capsule [Droxia]	_	RxNorm		NO	NO		
19023561 hydroxyurea 300 MG Oral Capsule	_	RxNorm		NO	NO		
1377168hydroxyurea 300 MG Oral Capsule [Droxia]		RxNorm		NO	NO		
19023562 hydroxyurea 400 MG Oral Capsule	_	RxNorm		NO	NO		
1377169 hydroxyurea 400 MG Oral Capsule [Droxia]	_	RxNorm		NO	NO		
1377163hydroxyurea 500 MG Oral Capsule Drug	RxNorm		NO ByNorm	NO	NO	NO	
19007385 hydroxyurea 500 MG Oral Capsule	[myurea]	שועו	RxNorm	INU	NO	NO	