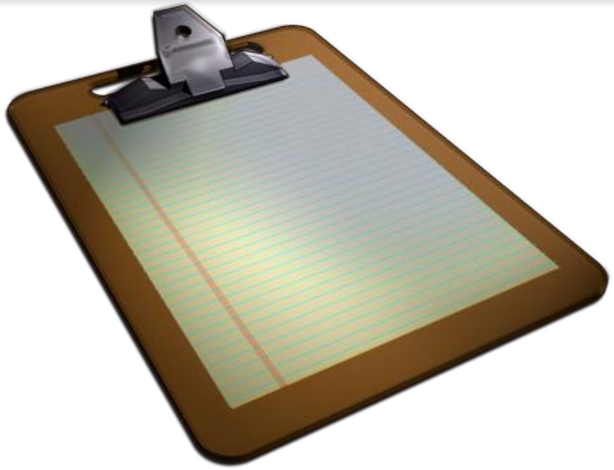
Pediatric Cancer Data Commons

Samuel Volchenboum, MD, PhD

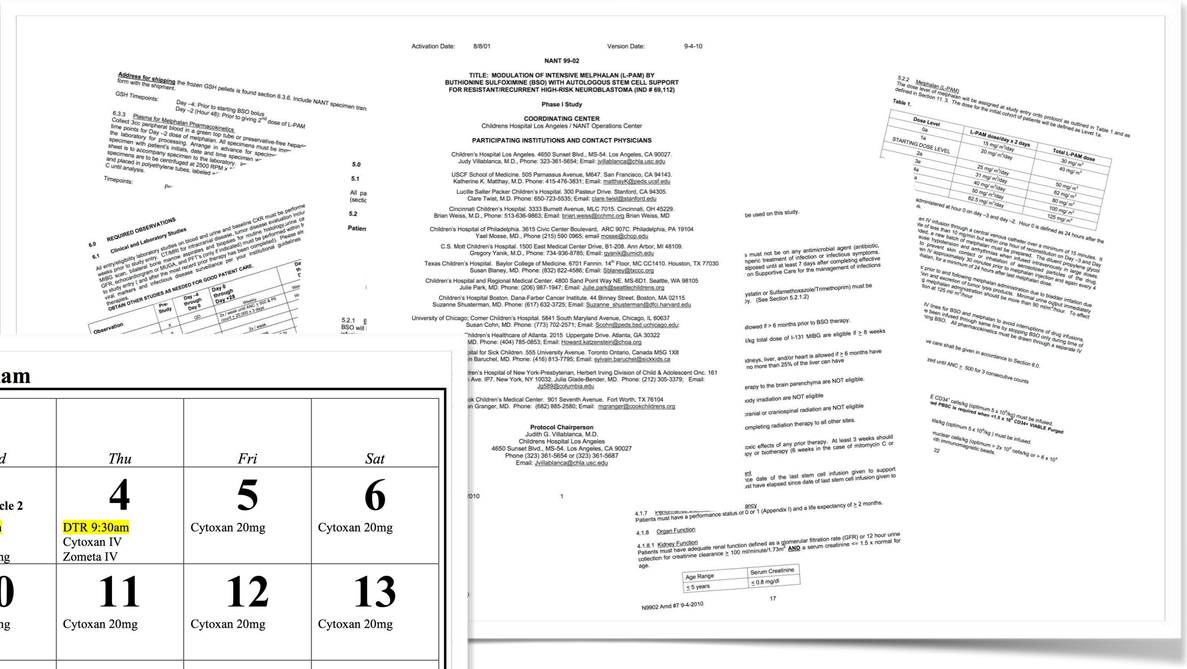
May 15, 2018

Manual processes and lack of data standards plague clinical trials



Manual processes and lack of data standards plague clinical trials

CTCAE CODE (per protocol)	CTCAE SHORT NAME (per protocol)	Current Grade	Maximum Grade This Course* (for occurrence)	Maximum Grade This Occurrence **	Attribu -tion	Date Onset	Resolved Yes / No	Date Resolved	Comments
10020943	Hypo albuminemia	0	1	1	3	05/23	Yes	06/02	
10020943	Hypo albuminemia	0	1	1	3	06/05	Yes	06/09	
10021038	Hypo natremia	0	1	1	3	05/26	Yes	05/27	
10021038	Hypo natremia	0	1	1	3	05/29			
10021059	Hypo phosphatemia	0	1	1	3	05/0			
10021059	Hypo phosphatemia	0	1	1	3	05/23			
10016256	Fatigue	0	1	1	3	05/2			



Activation Date: 8/8/01 Version Date: 9-4-10

NANT 99-02

TITLE: MODULATION OF INTENSIVE MELPHALAN (L-PAM) BY BUTHIONINE SULFOXIMINE (BSO) WITH AUTOLOGOUS STEM CELL SUPPORT FOR RESISTANT/RECURRENT HIGH-RISK NEUROBLASTOMA (IND # 69,112)

Phase I Study

COORDINATING CENTER
Childrens Hospital Los Angeles / NANT Operations Center

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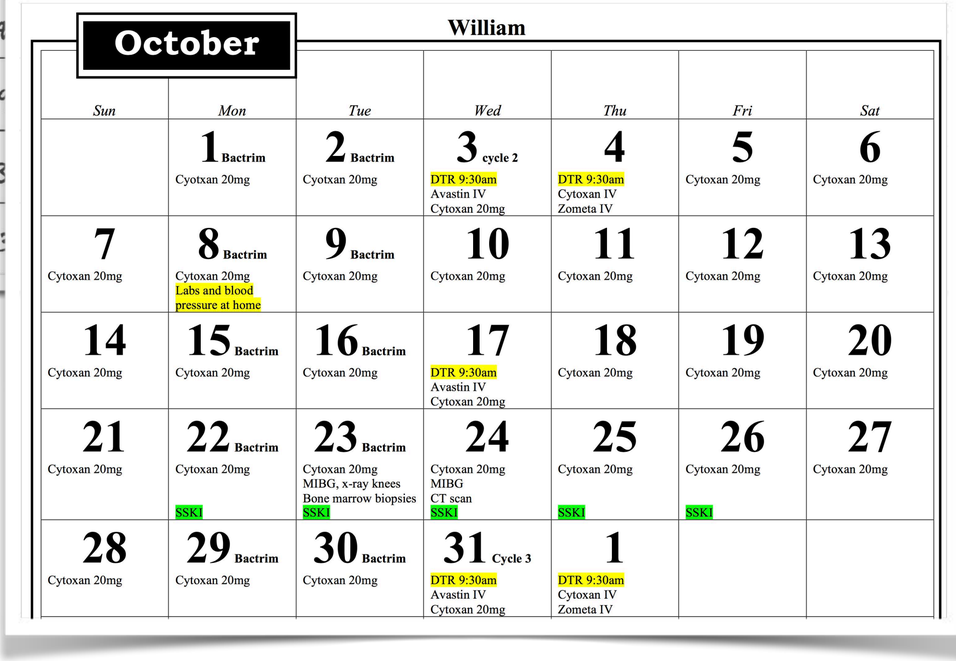


October — William

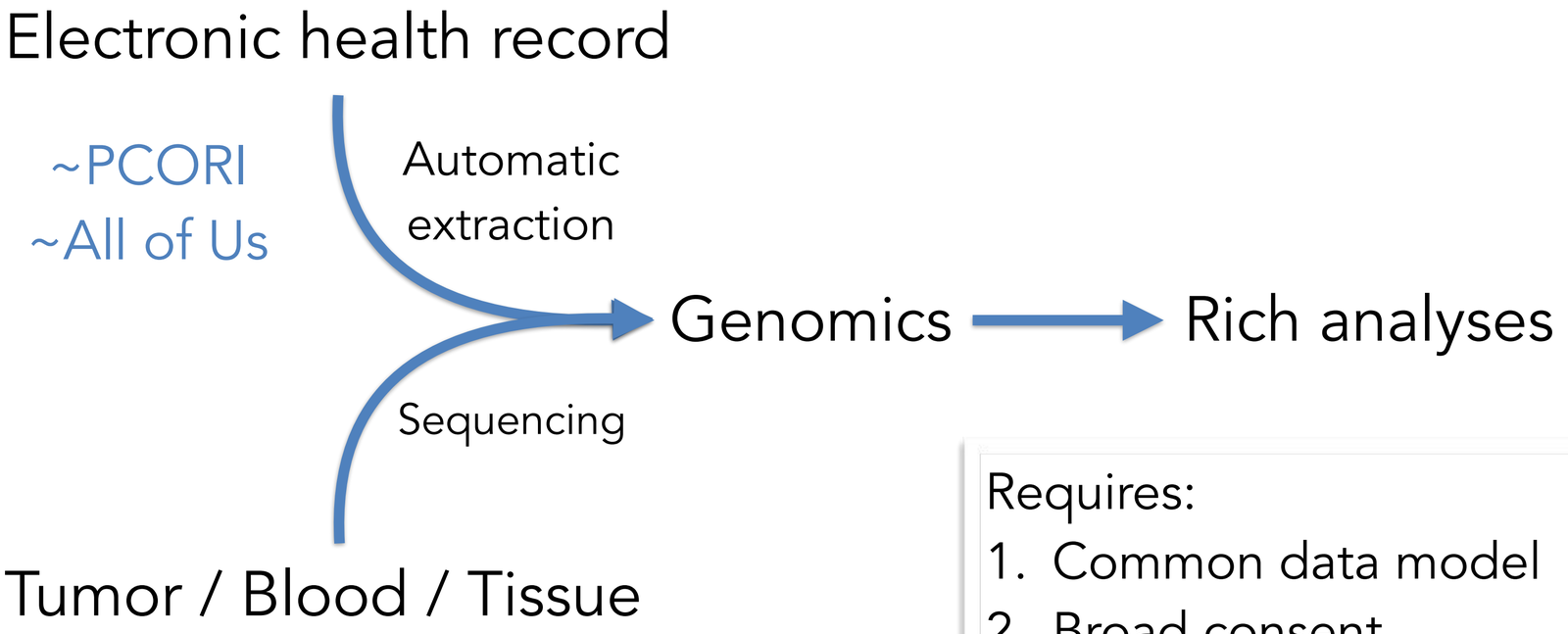
Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1 Bactrim Cyotxan 20mg	2 Bactrim Cyotxan 20mg	3 cycle 2 DTR 9:30am Avastin IV Cytoxan 20mg	4 DTR 9:30am Cytoxan IV Zometa IV	5 Cytoxan 20mg	6 Cytoxan 20mg
7 Cytoxan 20mg	8 Bactrim Cytoxan 20mg Labs and blood pressure at home	9 Bactrim Cytoxan 20mg	10 Cytoxan 20mg	11 Cytoxan 20mg	12 Cytoxan 20mg	13 Cytoxan 20mg
14 Cytoxan 20mg	15 Bactrim Cytoxan 20mg	16 Bactrim Cytoxan 20mg	17 DTR 9:30am Avastin IV Cytoxan 20mg	18 Cytoxan 20mg	19 Cytoxan 20mg	20 Cytoxan 20mg
21 Cytoxan 20mg	22 Bactrim Cytoxan 20mg SSKI	23 Bactrim Cytoxan 20mg MIBG, x-ray knees Bone marrow biopsies SSKI	24 Cytoxan 20mg MIBG CT scan SSKI	25 Cytoxan 20mg SSKI	26 Cytoxan 20mg SSKI	27 Cytoxan 20mg
28 Cytoxan 20mg	29 Bactrim Cytoxan 20mg	30 Bactrim Cytoxan 20mg	31 Cycle 3 DTR 9:30am Avastin IV Cytoxan 20mg	1 DTR 9:30am Cytoxan IV Zometa IV		

Lack of rich phenotype data hinders progress

- Many samples for genomics lack sufficient clinical information
- Without deep phenotype data, analyses are limited
- Deep phenotype data should be collected at the time of sample acquisition, directly from electronic health record systems

Future* ideal state

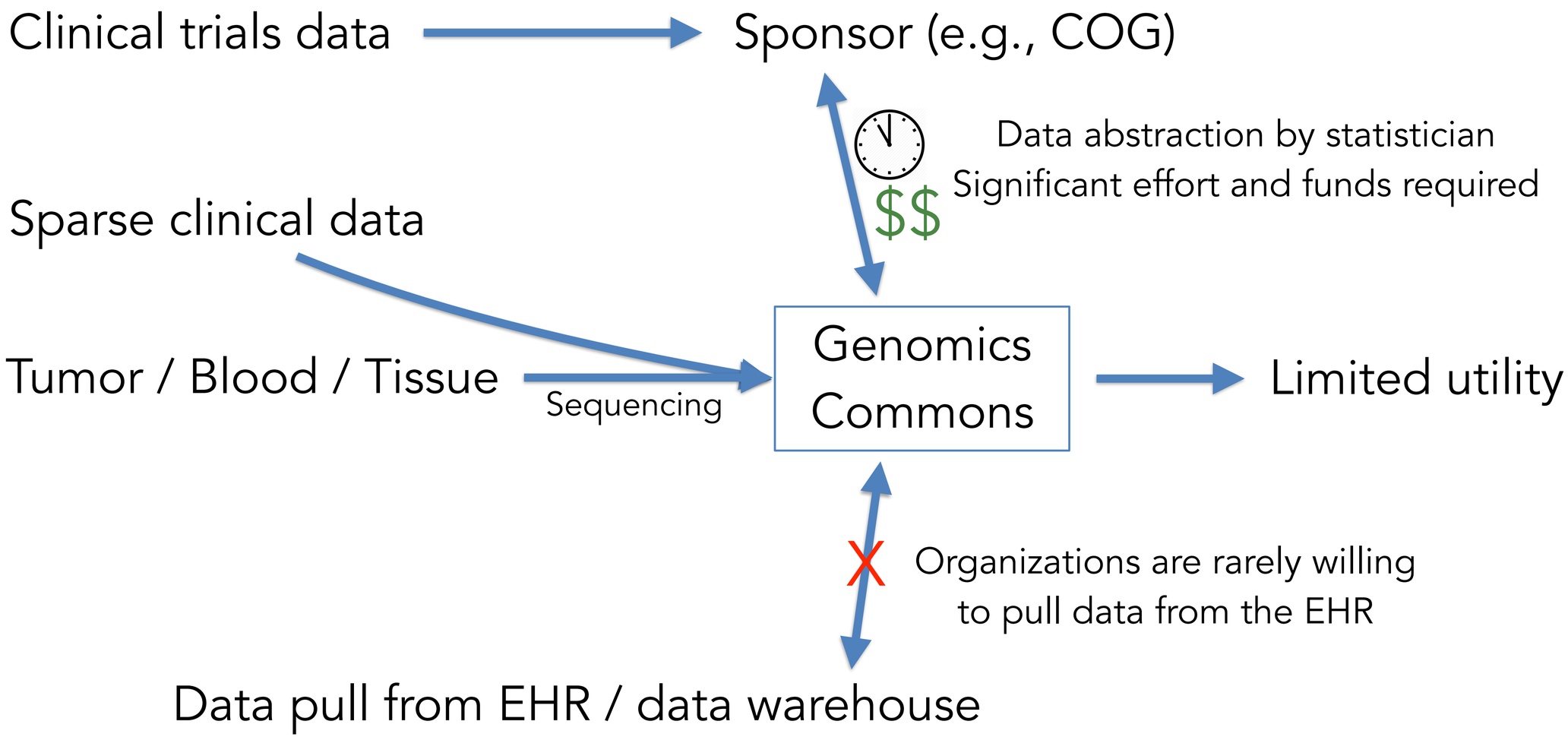
* Way in the future



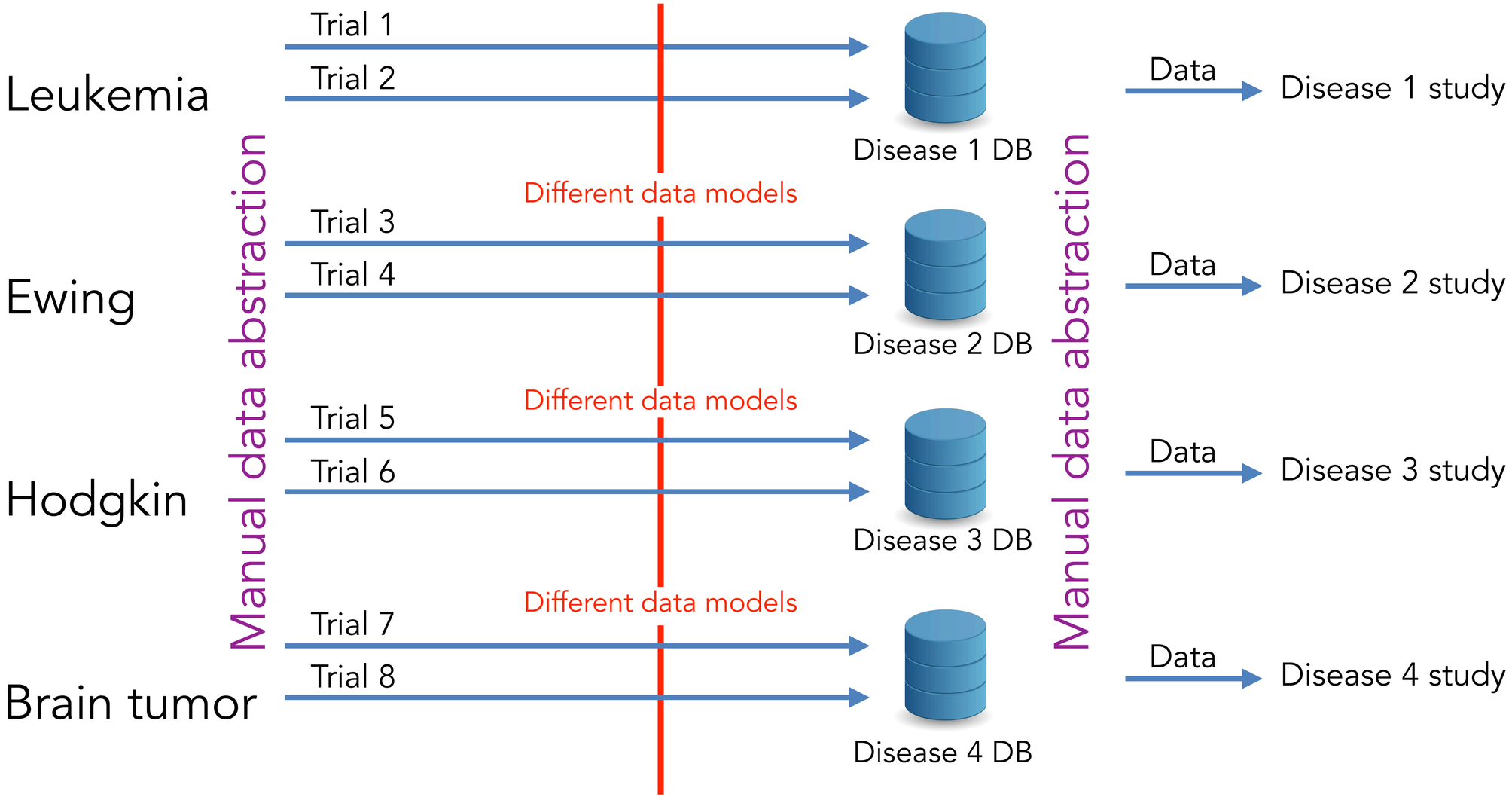
Requires:

1. Common data model
2. Broad consent
3. State-of-the-art data warehouse
4. Foresight and planning

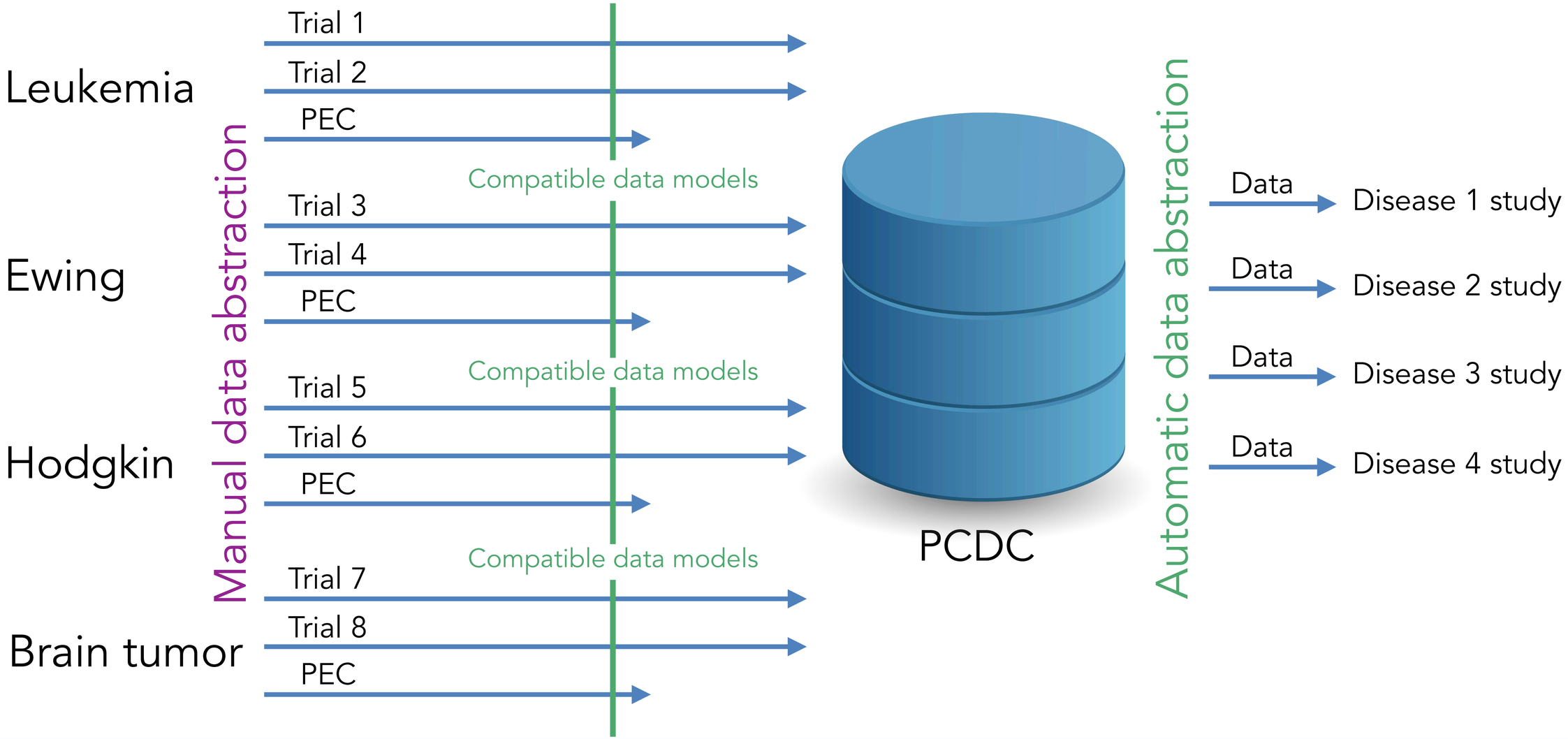
Current state for genomic commons



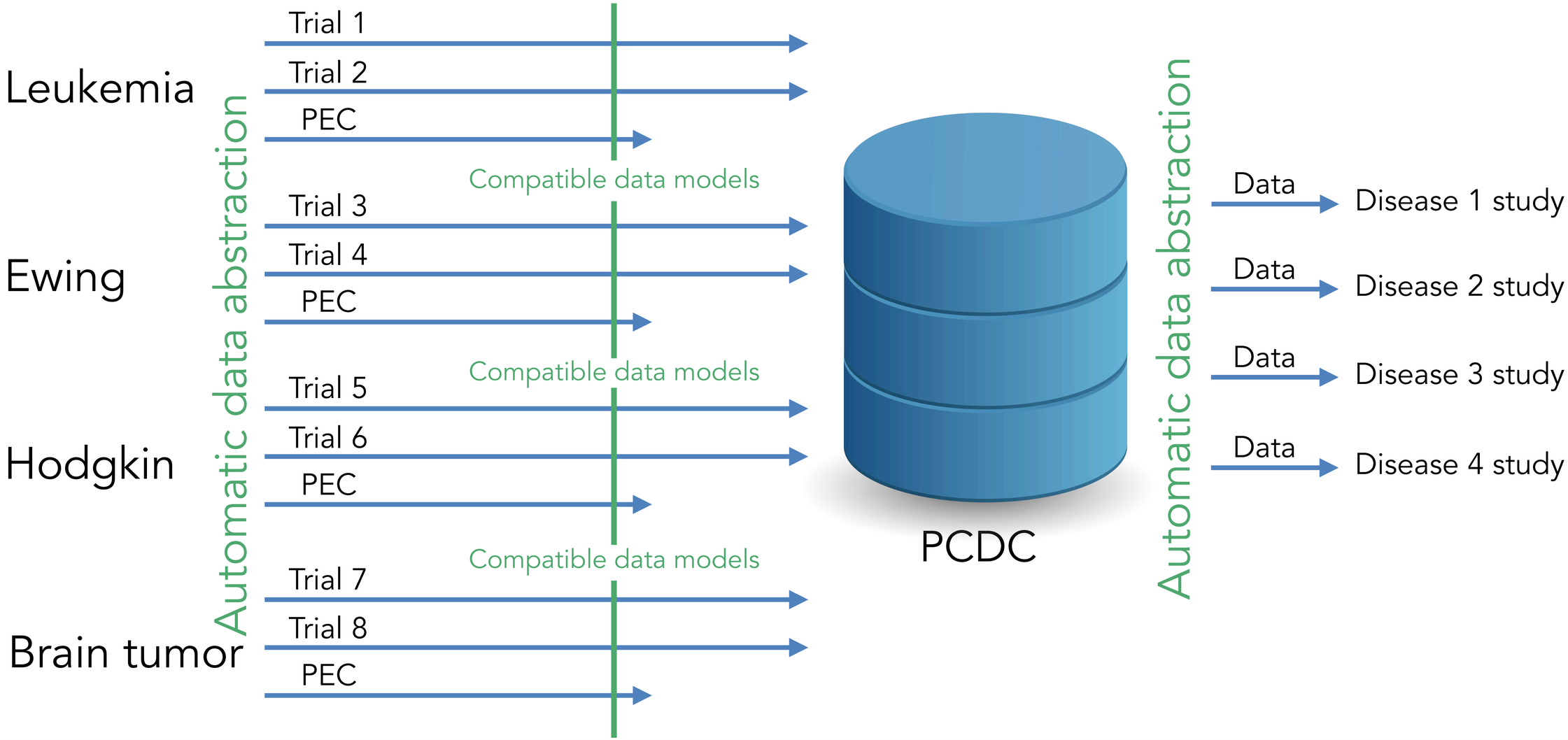
Current paradigm for COG



Goal


Leukemia
Ewing
Hodgkin
Brain tumor
Manual data abstraction
Trial 1
Trial 2
PEC
Compatible data models
Trial 3
Trial 4
PEC
Compatible data models
Trial 5
Trial 6
PEC
Compatible data models
Trial 7
Trial 8
PEC
PCDC
Automatic data abstraction
Data
Disease 1 study
Data
Disease 2 study
Data
Disease 3 study
Data
Disease 4 study

Goal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Trial 1
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Trial 8
PEC
PCDC
Automatic data abstraction
Data
Disease 1 study
Data
Disease 2 study
Data
Disease 3 study
Data
Disease 4 study

Pediatric cancer is rare - making it difficult to study

Adult cancers	annual incidence
All	**1,688,780**
Oral	49,670
GI	310,440
Lung	222,500
Skin	95,360
Breast	255,180
Ovary	22,440
Prostate	161,360
Urinary	146,650
Lymphoma	80,500
Myeloma	30,280
Leukemia	62,130

Source: cancer.org - 2017

Pediatric cancers	annual incidence
All	**15,780**
ALL	3080
CNS	2780
Hodgkin lymphoma	1180
NHL	1040
AML	730
Neuroblastoma	710
Bone	820
Thyroid	570
Wilms	510
Germ cell	540
Rhabdomyosarcoma	340
Retinoblastoma	280
Melanoma	310
Other	2890

Source: CDC - 2014

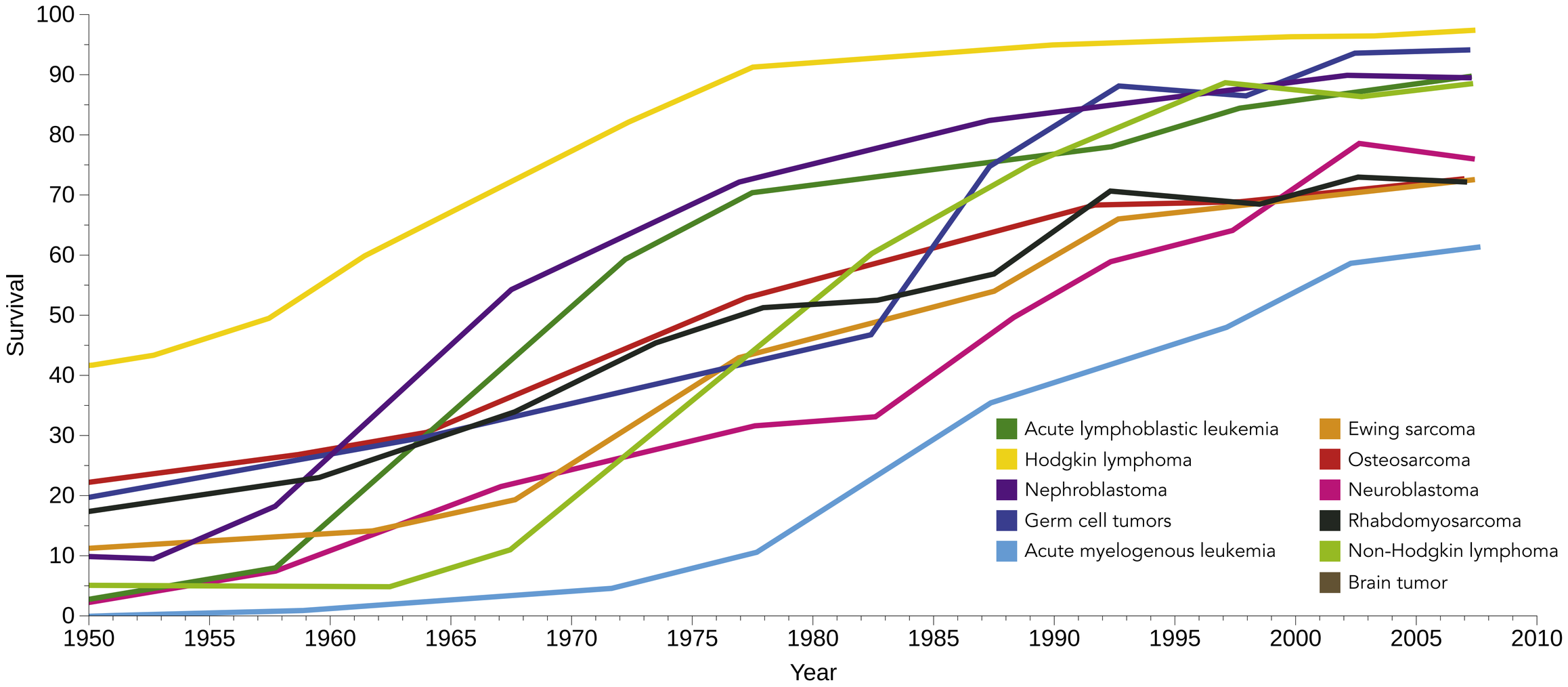
Most children are treated on a Children's Oncology Group (COG) study

1955 Cooperative group system for clinical research

Pediatric Oncology Group (POG)
Children's Cancer Group (CCG)
National Wilms' Tumor Study Group (NWTS)
Intergroup Rhabdomyosarcoma Study Group (IRSG)

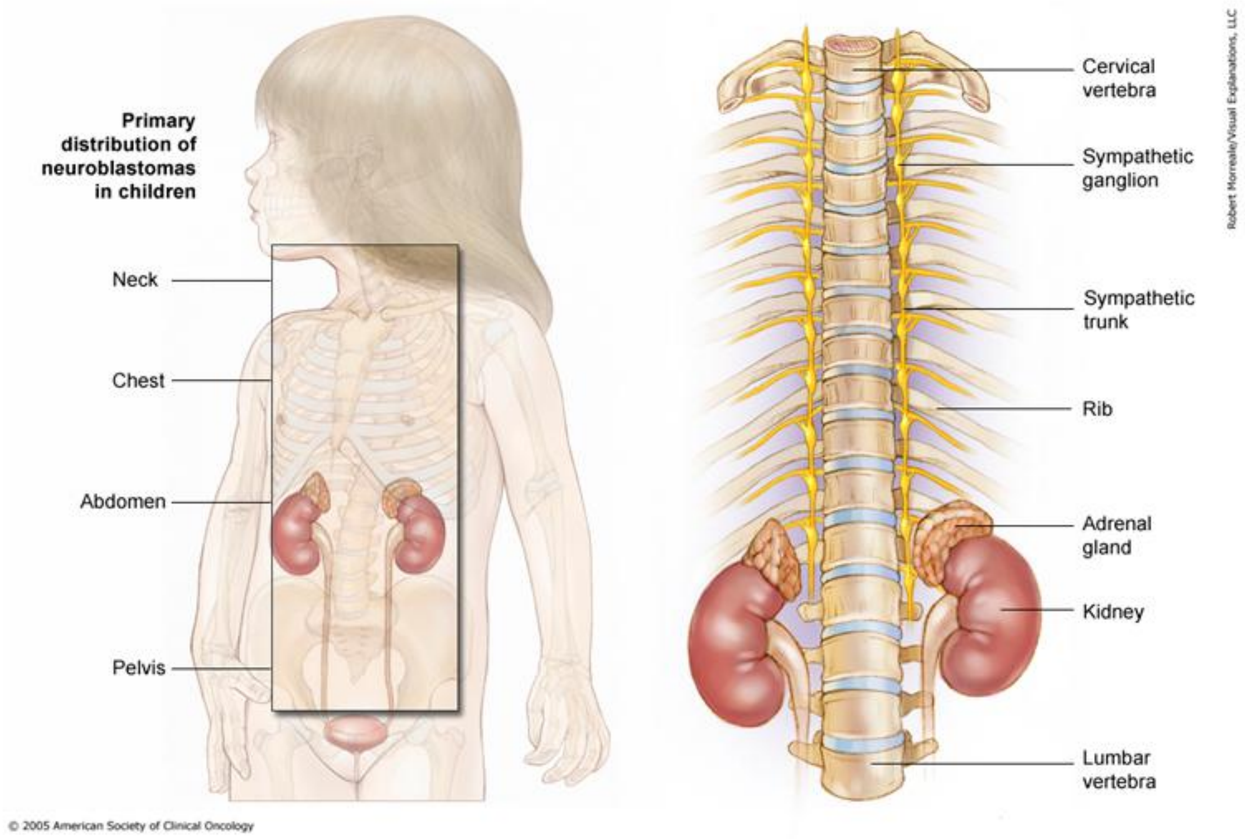
2000 Children's Oncology Group (COG)

Survival - Pediatric cancer - still a long way to go



Neuroblastoma data commons

Neuroblastoma



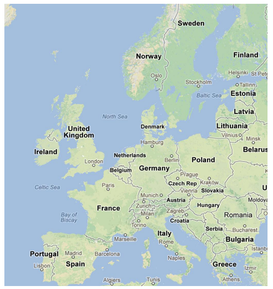
The most common solid tumor in children

International Neuroblastoma Research Group (2004)

Children's Oncology Group (COG)

Germany

Japan

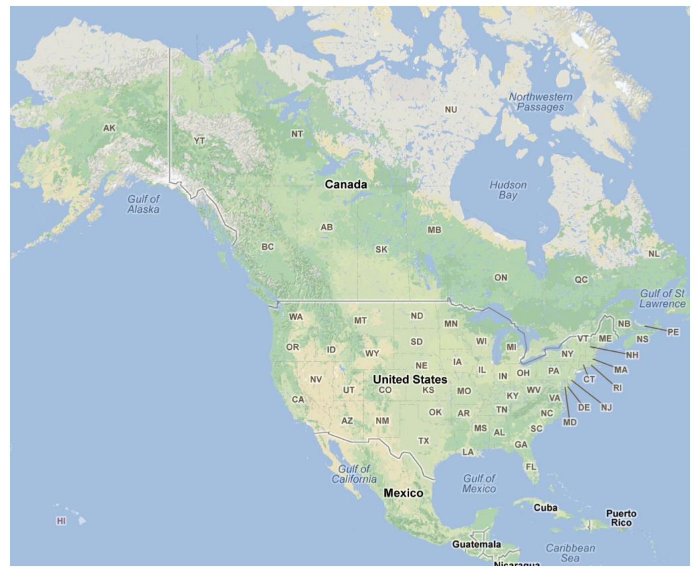


SIOPEN

COG	SIOPEN	Japan	Germany
Study 1	Study 4	Study 7	Study 10
Study 2	Study 5	Study 8	Study 11
Study 3	Study 6	Study 9	Study 12
COG Consensus	**SIOPEN Consensus**	**Japan Consensus**	**Germany Consensus**

Consensus standard

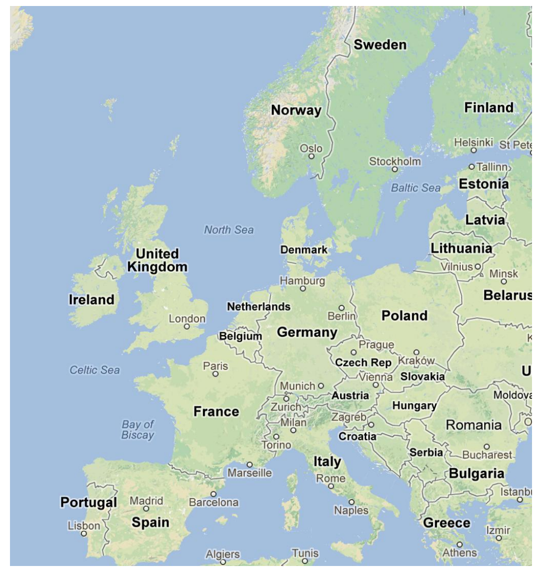
International Neuroblastoma Research Group (2004)




Children's Oncology Group (COG)

Germany

Japan

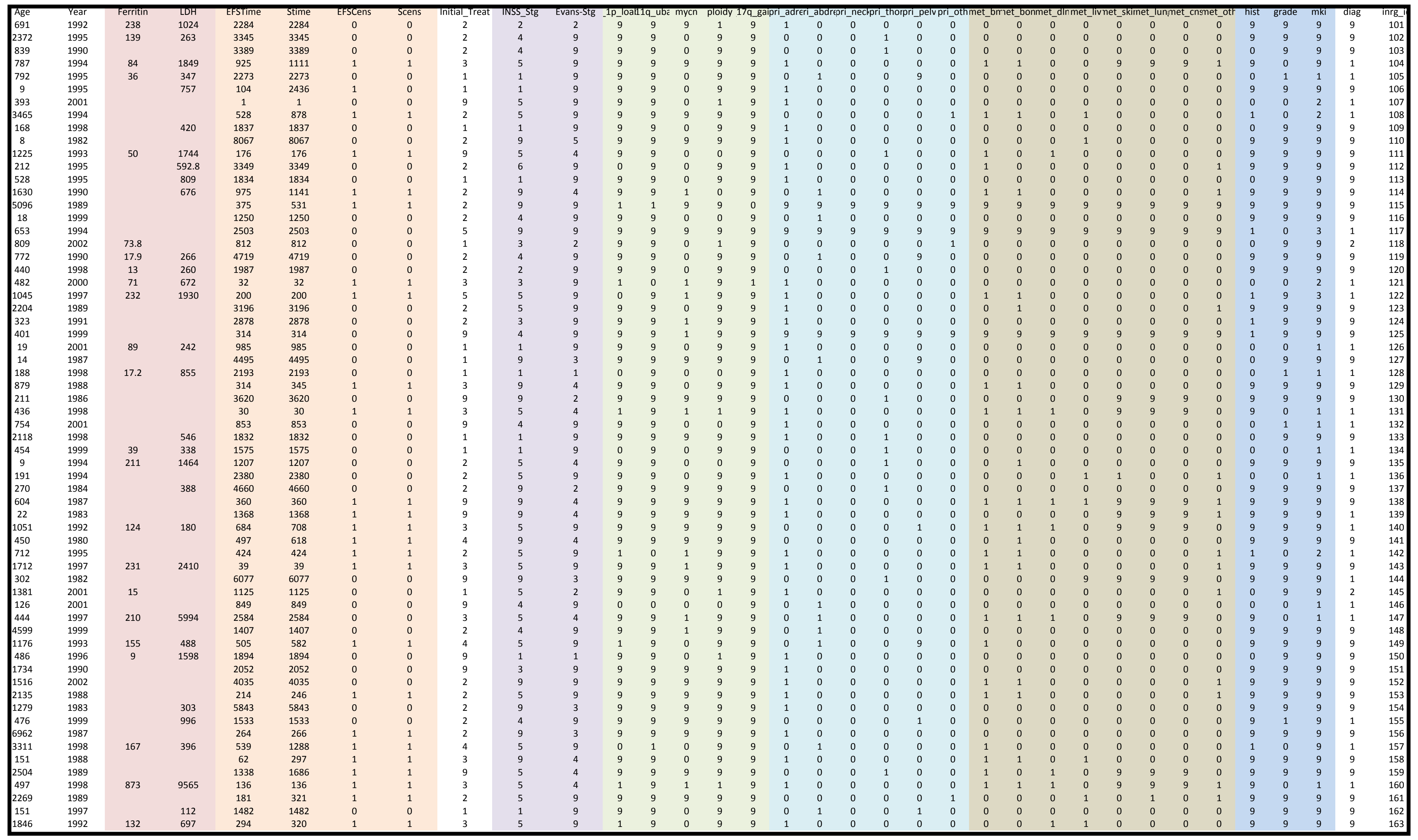


SIOPEN

Group	Number
COG	4235
Germany	1938
Japan	470
SIOPEN	936
Total	8800

The good news: 8800 patients

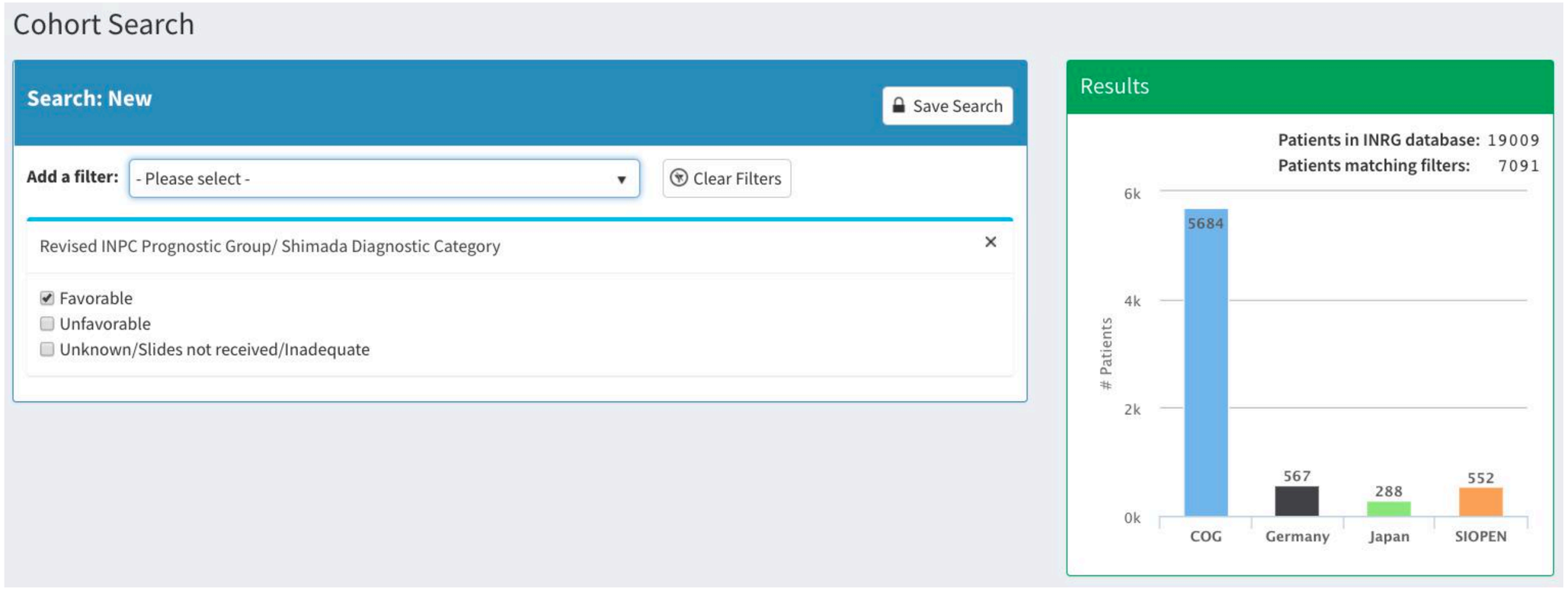
The bad news:
Data in Excel



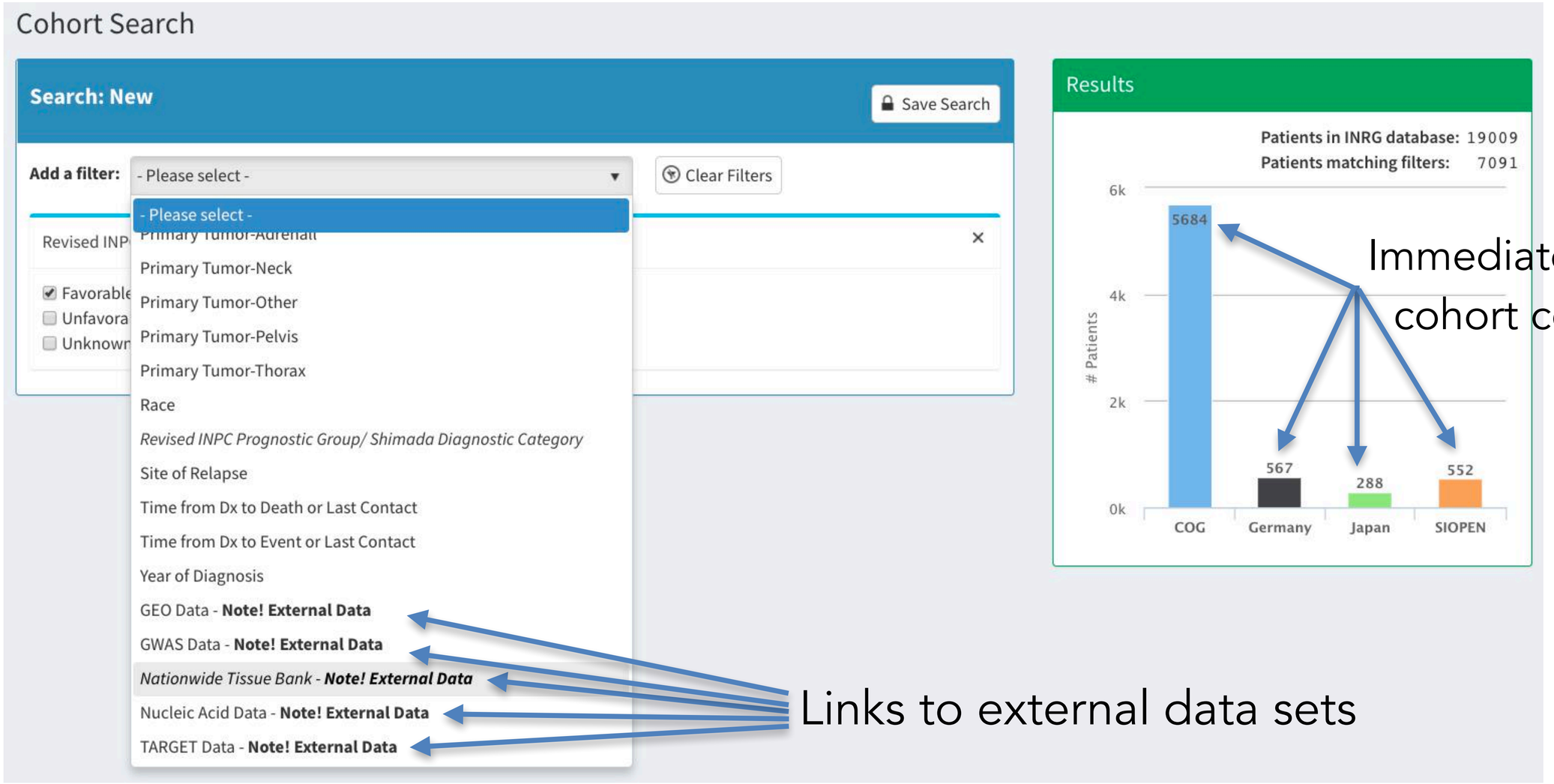
>20 high-impact publications that changed clinical practice

Neuroblastoma Commons Cohort Discovery

Example: Favorable tumor biology, tissue available



Neuroblastoma Commons Cohort Discovery

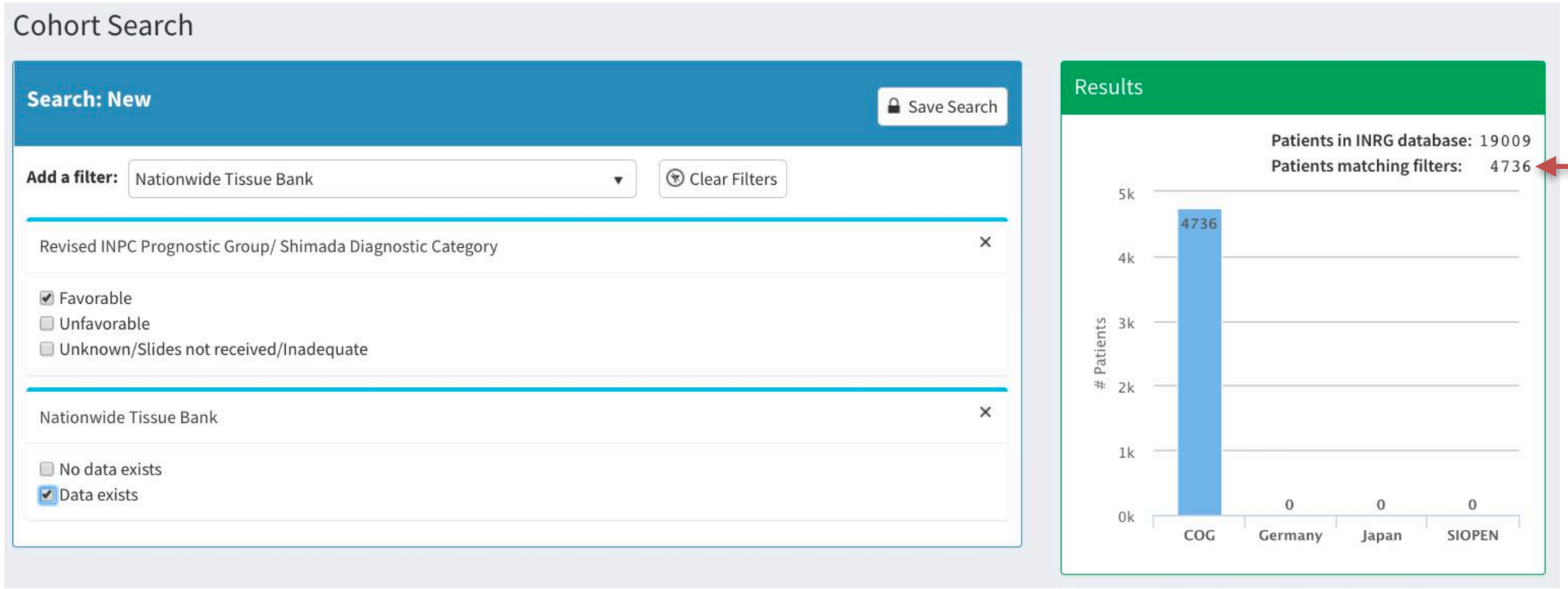


Publicly available at inrgdb.org

THE UNIVERSITY OF CHICAGO MEDICINE & BIOLOGICAL SCIENCES | CENTER FOR RESEARCH INFORMATICS

ITM

Neuroblastoma Commons Cohort Discovery



This used to take weeks.

Now it can be done in seconds.

Example: Favorable biology, tissue available

COG Unique Specimen Identifier (USI)

COG institution

COG Identifier (PHI)

CHILDREN'S ONCOLOGY GROUP

Honest broker

COG ID	USI
34574765	RDASXK
65780454	UFUMZQ
40508620	LKNQHD
62646200	JVMECO

Specimens Data

COG USI number

NATIONAL CANCER INSTITUTE
GENOMIC DATA COMMONS
CAVATICA
THE UNIVERSITY OF CHICAGO
TARGET
SevenBridges genomics

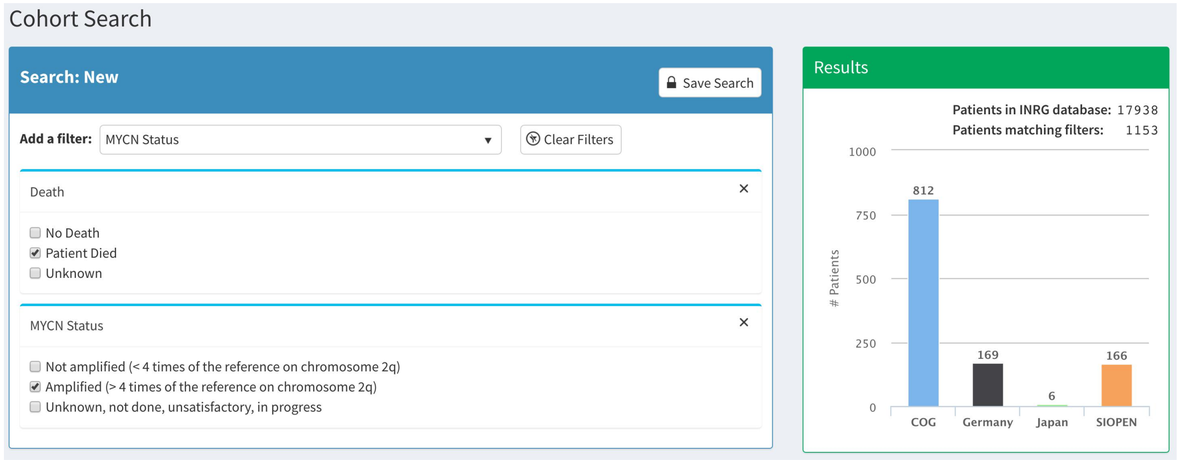
Commons

Neuroblastoma data commons growth

Year	COG	SIOPEN	GPOH	Japan	Total
2004	4235	2157	1938	470	**8800**
2012	6127	2504	1938	470	**11039**
2013	11642	2504	1938	470	**16554**
2015	13060	2504	1938	470	**17972**
2016	13937	2664	1938	470	**19009**
2018	14425	3397	2154	470	**20446**

Data upload can be automated using a standardized data dictionary with error and consistency checking.

Neuroblastoma Data Commons



INRG cohort discovery

```
> idir <- "/home/ubuntu/demo_inrg"
> pheno.file <- file.path(idir, "meta", "clinical.deseq_fmt.filtered.txt")
> count.dir <- file.path(idir, "files", "fmt")
> clin.df <- read.delim(pheno.file, header=TRUE, sep="\t", stringsAsFactors = FALSE)
> count.files <- unlist(lapply(clin.df$pt_id, function(x) paste0(x, ".htseq.counts")))
> count.files
 [1] "PAIPGU.htseq.counts" "PAISNS.htseq.counts" "PAITCI.htseq.counts"
 [4] "PAIVHE.htseq.counts" "PAIXIF.htseq.counts" "PAKYZS.htseq.counts"
 [7] "PALBFW.htseq.counts" "PALCBW.htseq.counts" "PALETP.htseq.counts"
[10] "PALEVG.htseq.counts" "PALIIN.htseq.counts" "PALKUC.htseq.counts"
[13] "PALNVP.htseq.counts" "PALTEG.htseq.counts" "PALUYS.htseq.counts"
[16] "PALVKK.htseq.counts" "PALWVJ.htseq.counts" "PALXTB.htseq.counts"
[19] "PALZZV.htseq.counts" "PAMMXF.htseq.counts" "PAMNLH.htseq.counts"
[22] "PAMVRA.htseq.counts" "PAMYCE.htseq.counts" "PAMZGT.htseq.counts"
[25] "PAMZMG.htseq.counts" "PANBJH.htseq.counts" "PANBMJ.htseq.counts"
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[31] "PANKFE.htseq.counts" "PANNMS.htseq.counts" "PANRRW.htseq.counts"
[34] "PANUKV.htseq.counts" "PANYGR.htseq.counts" "PANZPV.htseq.counts"
[37] "PANZVU.htseq.counts" "PAPBGH.htseq.counts" "PAPBZI.htseq.counts"
[40] "PAPEFE.htseq.counts" "PAPHPE.htseq.counts" "PAPKWN.htseq.counts"
[43] "PAPUAR.htseq.counts" "PAPUEB.htseq.counts" "PAPZYP.htseq.counts"
[46] "PARACM.htseq.counts"
> sample.table <- data.frame(sampleName=clin.df$pt_id,
+                            fileName=count.files,
+                            mycn=as.factor(clin.df$mycn))
>
```
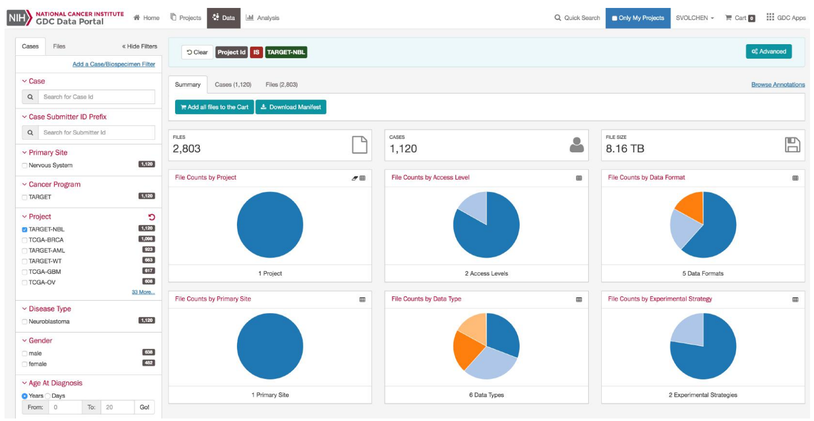
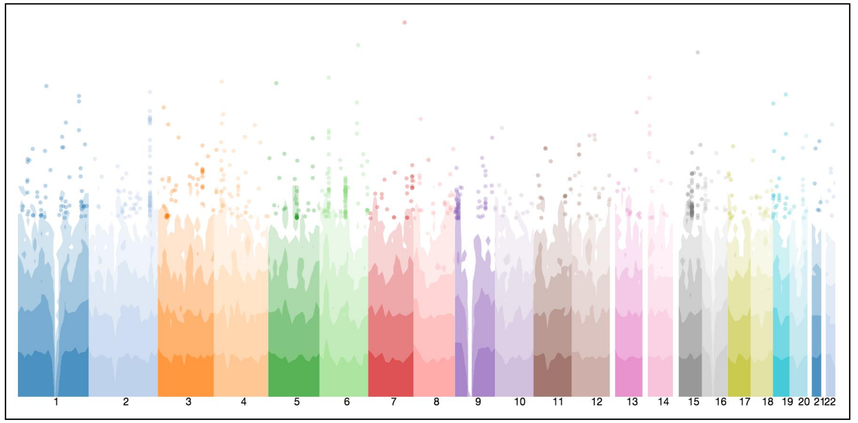

Command-line analysis



Genomic data commons search



Visualization

Paradigm for building a pediatric cancer commons

1. Engage cooperative group(s)
2. Define scope
3. Identify funding source
4. Identify infrastructure
5. Engage project team
6. Identify data sources
7. Establish governance, create policies and procedures
8. Create contributor / use agreements
9. Create standards working group to create data dictionary, map elements
10. Create database
11. Build front-end query engine
12. Create and execute communication and education plans
13. Create sustainability model

Volchenboum SL, Cox SM, Heath A, Resnick A, Cohn SL, Grossman R
"Data Commons to Support Pediatric Cancer Research"

Remapping NBL to a standard ontology

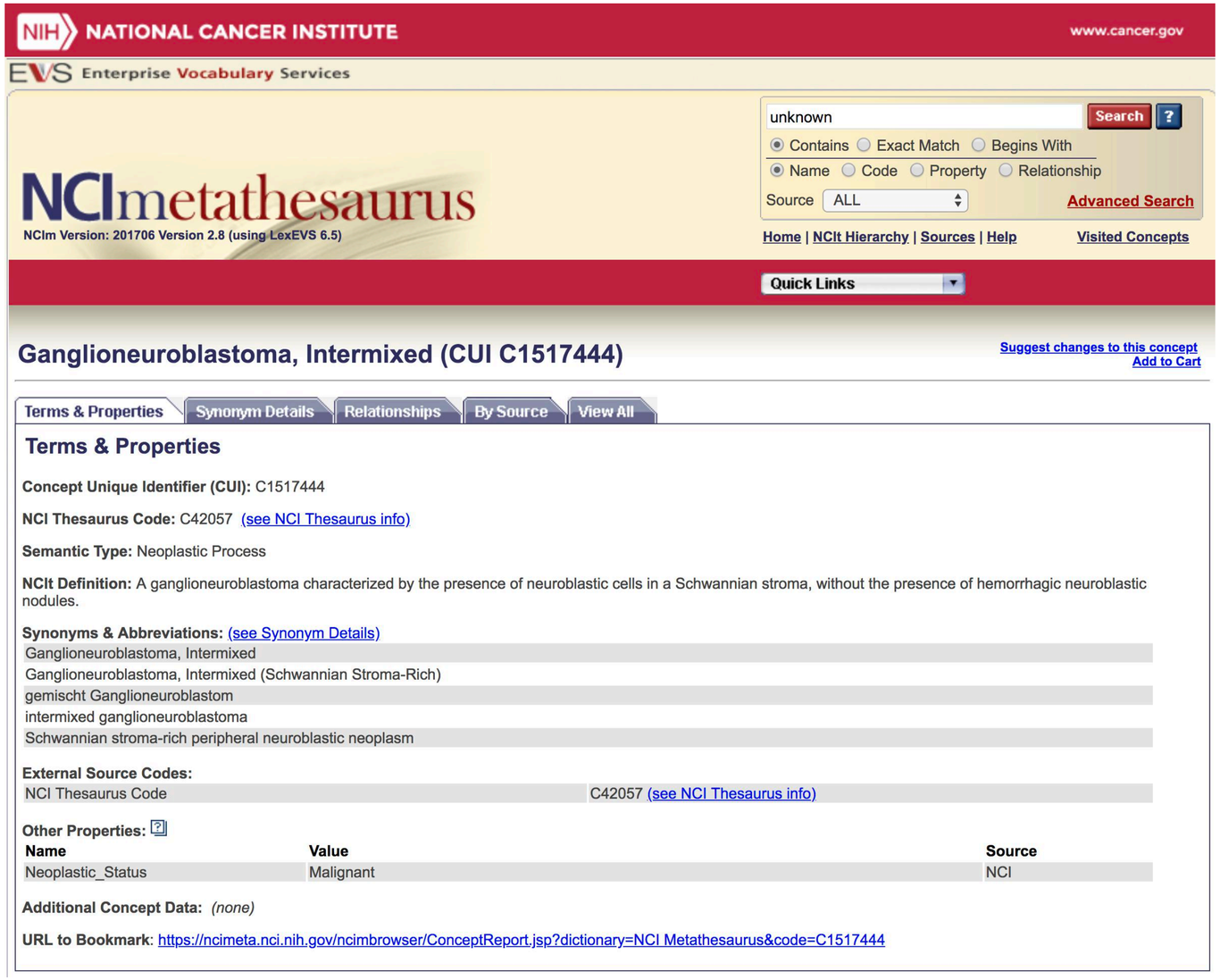
Current

Tumor type	Code
Neuroblastoma (Schwannian stroma-poor)	1
Ganglioneuroblastoma, intermixed (Schwannian stroma-rich)	2
Ganglioneuroma (Schwannian stroma-domiant), maturing subtype OR Ganglioneuroblastoma, well differentiated (Schwannian stroma rich)	3
Ganglioneuroblastoma, nodular (composite)	4
Unknown	9

Proposed

Neuroblastoma	C0017075
Ganglioneuroblastoma - intermixed	C1517444
Ganglioneuroma	C0017075
Ganglioneuroblastoma - nodular	C1517445
Unknown	C0087135

Ganglioneuroblastoma



NIH NATIONAL CANCER INSTITUTE www.cancer.gov

EVS Enterprise Vocabulary Services

NCImetathesaurus

NCIm Version: 201706 Version 2.8 (using LexEVS 6.5)

unknown Search ?

Contains Exact Match Begins With

Name Code Property Relationship

Source ALL Advanced Search

Home | NCIt Hierarchy | Sources | Help Visited Concepts

Quick Links

Ganglioneuroblastoma, Intermixed (CUI C1517444)

Suggest changes to this concept
Add to Cart

Terms & Properties | Synonym Details | Relationships | By Source | View All

Terms & Properties

Concept Unique Identifier (CUI): C1517444

NCI Thesaurus Code: C42057 (see NCI Thesaurus info)

Semantic Type: Neoplastic Process

NCIt Definition: A ganglioneuroblastoma characterized by the presence of neuroblastic cells in a Schwannian stroma, without the presence of hemorrhagic neuroblastic nodules.

Synonyms & Abbreviations: (see Synonym Details)

Ganglioneuroblastoma, Intermixed
Ganglioneuroblastoma, Intermixed (Schwannian Stroma-Rich)
gemischt Ganglioneuroblastom
intermixed ganglioneuroblastoma
Schwannian stroma-rich peripheral neuroblastic neoplasm

External Source Codes:

NCI Thesaurus Code	C42057 (see NCI Thesaurus info)

Other Properties:

Name	Value	Source
Neoplastic_Status	Malignant	NCI

Additional Concept Data: *(none)*

URL to Bookmark: https://ncimeta.nci.nih.gov/ncimbrowser/ConceptReport.jsp?dictionary=NCI Metathesaurus&code=C1517444

Remapping NBL primary site

Current

PRI_ADRE	INTEGER	Primary site of tumor is adrenal	0=No 1=Yes 9=Unknown
PRI_ABDRET	INTEGER	Primary site of tumor is Abdominal/retroperitoneal (non-adrenal)	0=No 1=Yes 9=Unknown
PRI_NECK	INTEGER	Primary site of tumor is neck	0=No 1=Yes 9=Unknown
PRI_THOR	INTEGER	Primary site of tumor is thorax	0=No 1=Yes 9=Unknown
PRI_PELV	INTEGER	Primary site of tumor is pelvic	0=No 1=Yes 9=Unknown
PRI_OTH	INTEGER	Primary site of tumor is “other”	0=No 1=Yes 9=Unknown

Proposed

Adrenal gland	C0001625
Retroperitoneal	CL318004
Neck	C0027530
Thorax	C0817096
Pelvis	C0030797
Not otherwise specified	C1518425
Unknown	C0439673

Data commons in planning and development

Soft-tissue sarcoma

AYA lymphoma

Sickle cell

STS data commons

- Discussions began 1/2017
- First meeting in May, 2017 (Copenhagen)
- Second meeting in October 2017 (Chicago)
- Third meeting in March 2018 (Amsterdam)
- Fourth meeting planned September 2018 (Tübingen)
- Executive and informatics calls every 1-2 months

INSTRuCT meetings

October 2017 - Chicago

March 2018 - Amsterdam

Rhabdomyosarcoma data standardization

	Current	
	Code	Description
SEX	1	Male
	2	Female
HISTOLOGY	1	Alveolar rhabdomyosarcoma
	2	Embryonal rhabdomyosarcoma
	3	Botryoid rhabdomyosarcoma
	4	Not otherwise specified
	5	Undifferentiated sarcoma
	6	Sarcoma, not classifiable
	7	Spindle cell sarcoma
	8	Ectomesenchymoma
	9	Other
	10	Mixed rhabdomyosarcoma
	99	Unknown

Male	C0086582
Female	C0015780
Unknown	C0439673

Alveolar rhabdomyosarcoma (ARMS)	C0206655
Botryoid rhabdomyosarcoma (BRMS)	C1306573
Embryonal rhabdomyosarcoma (ERMS)	C0206656
Pleomorphic rhabdomyosarcoma (PRMS)	C0334480
Rhabdomyosarcoma (RMS), not classifiable	C0035412
Rhabdomyosarcoma (RMS), inadequate tissue for classification	
Rhabdomyosarcoma (RMS), w Mixed Embryonal and Alveolar Features	C1709053
Spindle cell	C0205945

Consensus example: Maximum tumor diameter

Old

Maximum diameter

or

x,y,z

or

>5cm, <5cm

INSTRuCT consensus

- Discrete measurement (in cm)
  - *x* (or max diameter if single)
  - *y*
  - *z*
- Category (if no discrete meas.)
  - <=5 cm
  - >5 cm
  - Unknown

Consensus harmonization of primary site

CWS COG EpSSG

Major Primary Site	CWS	COG	EpSSG/MMT Name
ORBIT	Eyelid	1=Eye	Eyelid
	Orbit	2=Orbit	Orbit
HEAD & NECK (non PM)	Scalp	10=Scalp	Soft tissue of scalp
			External auricular canal
			Ear soft tissue, external ear
			Temporal muscle
	Parotid	9=Paratoid	Parotid, soft tissue
	Oral Cavity	7=Oral cavity	Gum
			Base of tongue
			Lip
			Lower lip
			Upper lip
			Tongue
	Larynx	5=Larynx	Larynx
	Oropharynx	8=Orophaynx	Oropharynx
			Lingual tonsil
			Mandible soft tissue
			Bone of face (Maxillar)
			Masseter
			Oral cavity
	Cheek	3=Cheek	Cheek
	Hypopharynx	4=Hypopharynx	Hypopharynx
	Thyroid & Parathyroid	11=Thyroid & Parathyroid	Thyroid
	Neck	6=Neck	Neck
			Neck Supra-clavicular soft tissues
			Neck, nodes Nos
		12=Other Head & Neck	Chin
			Soft tissue face (non specified region)
			Face specified region
			Nasolabial fold (skin)
			Nostril

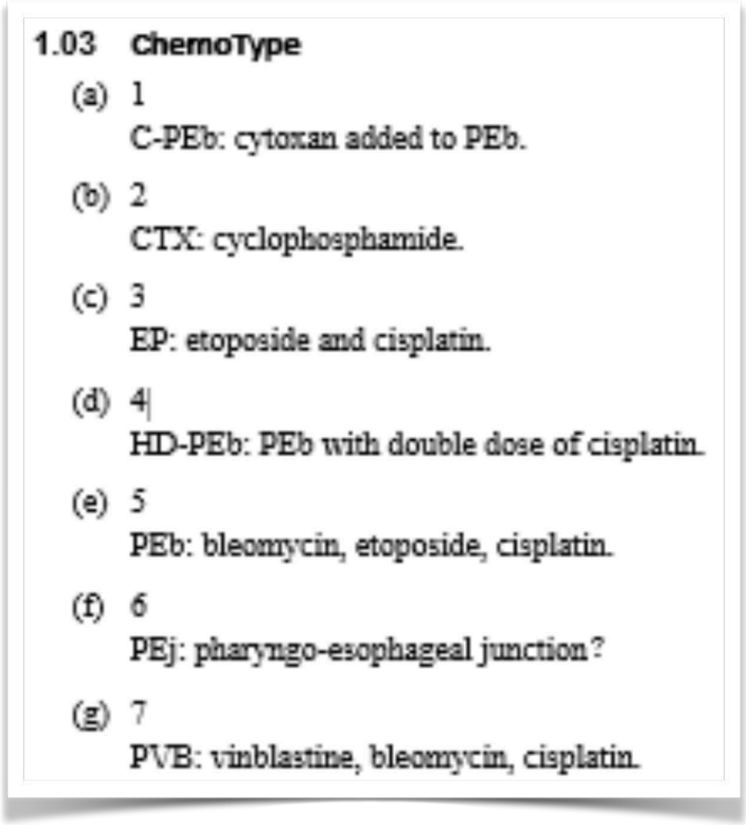
Consensus

Orbit	Eyelid	C0015426
	Orbit	C0700042
	Other orbit	C0700042
Head and neck	Cheek	C0007966
	Hypopharynx	C0020629
	Larynx	C0023078
	Neck	C0027530
	Oral cavity	C1711367
	Oropharynx	C0521367
	Parotid	C3272625
	Scalp	C0036270
	Thyroid and parathyroid	C0574117
	Other face	C0015450
	Other head and neck	C0460004

INSTRuCT consensus data dictionary

- ID
- Sex
- Race
- Ethnicity
- Year of diagnosis
- Age at diagnosis
- Histology
- Stage
- Surgery extent
- Group
- Tumor site
- Metastatic site(s)
- Tumor size
- Invasiveness
- TNM
- Anaplasia
- Fusion status
- Survival
- Age at censor
- Age at death
- Cause of death
- Events
- Secondary metastatic site

Developing a paradigm for treatment data



1.03 ChemoType

(a) 1
C-PEb: cytoxan added to PEb.

(b) 2
CTX: cyclophosphamide.

(c) 3
EP: etoposide and cisplatin.

(d) 4
HD-PEb: PEb with double dose of cisplatin.

(e) 5
PEb: bleomycin, etoposide, cisplatin.

(f) 6
PEj: pharyngo-esophageal junction?

(g) 7
PVB: vinblastine, bleomycin, cisplatin.

(hint: this is not it)

Chemotherapy reference data is not sufficient

ANBL0531 - *Response and Biology-Based Therapy for Intermediate-risk Neuroblastoma.*
Administration of chemotherapy through a reporting period of 3 weeks. [Duration of 1 cycle]
Cycle # 1

DRUG	ROUTE	DOSAGE	DAYS	IMPORTANT NOTES	OBSERVATIONS
CARBOplatin (CARBO)	IV over 1 hour	Pts ≤ 12kg:18.6 mg/kg/dose Pts > 12 kg: 560 mg/m^2/dose	1		a. Physical Exam (Ht., Wt., BSA, VS), b. CBC, differential, platelets[1], Serum creatinine[2]
Etoposide (ETOP)	IV over 1 hour	Pts ≤ 12kg: 4 mg/kg/dose Pts > 12 kg: 120 mg/m^2/dose	1-3	Give following CARBO on Day 1 only	ocol Section 7.0 for complete list rations, including required at study entry ,and Section 15.0 equisition or shipment guidelines
Filgrastim (G-CSF)					OTHER STUDIES AS FOR GOOD PATIENT

Carboplatin/Etoposide (CUI C0280617)

Suggest changes to this concept
Add to Cart

Terms & Properties | Synonym Details | Relationships | By Source | View All

Terms & Properties

Concept Unique Identifier (CUI): C0280617

NCI Thesaurus Code: C10289 (see NCI Thesaurus info)

Semantic Type: Therapeutic or Preventive Procedure

Synonyms & Abbreviations: (see Synonym Details)

Carboplatin/Etoposide
CBDCA/VP-16

External Source Codes:

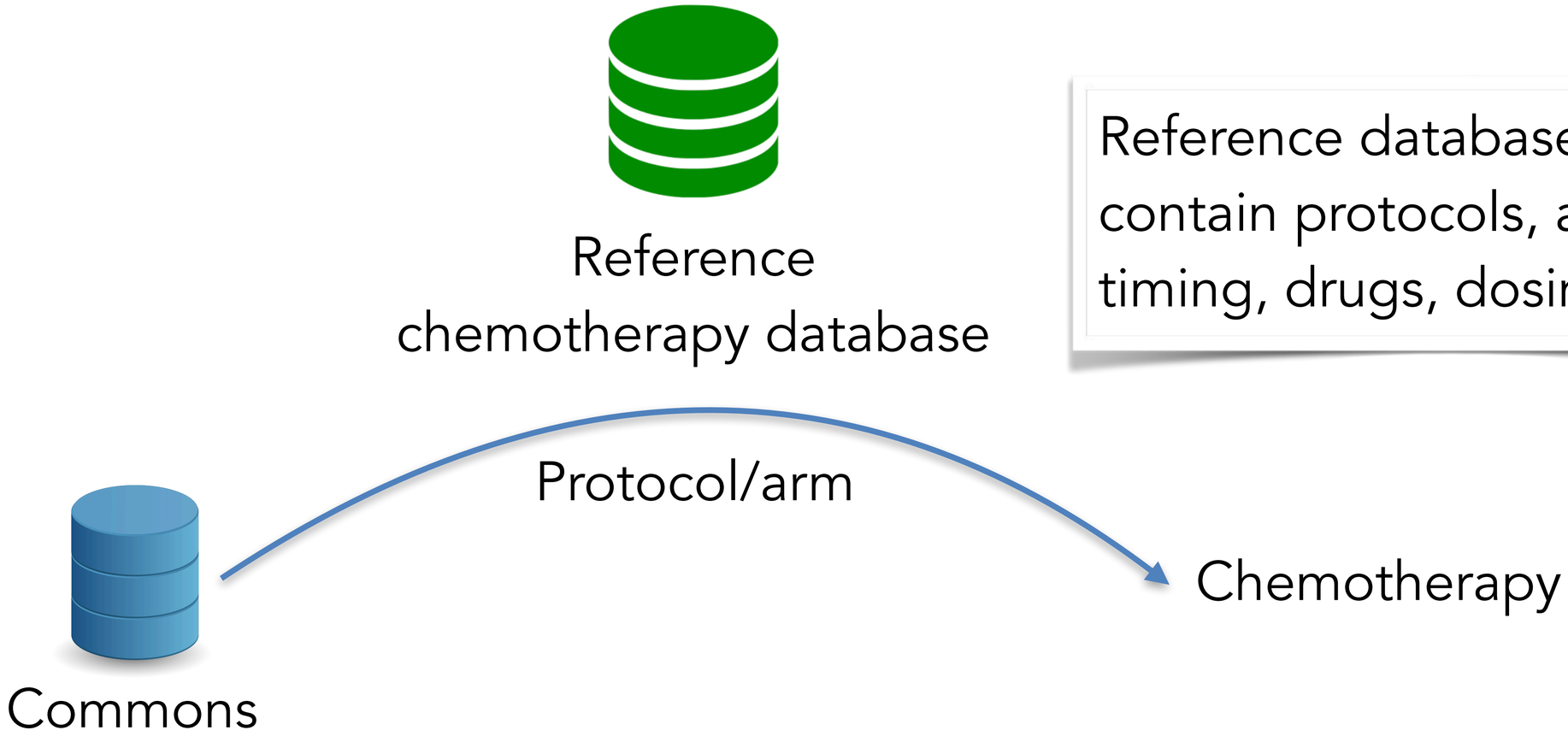
NCI Thesaurus Code	C10289 (see NCI Thesaurus info)

Other Properties:

Name	Value	Source
NCI_THESAURUS_CODE	C10289	PDQ
ORIG_STY	Drug/agent combination	PDQ
PID	4041	PDQ

Does not include dose information or a reference

Paradigm for chemotherapy information



COG data standards workshop

April 10, 2018 - St. Louis

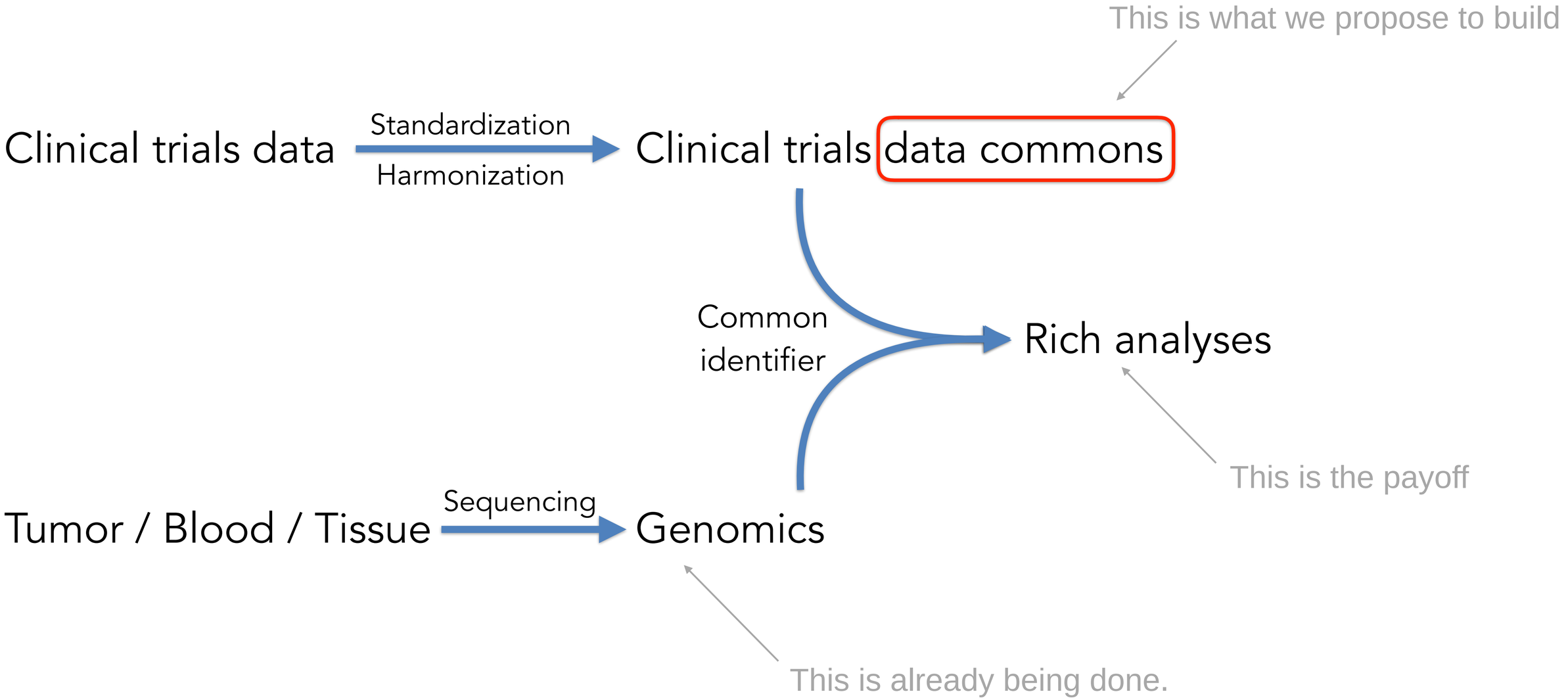
- 45 attendees from COG, NCI, CDISC, St. Baldrick's
- Four breakout sessions
  - Data processes
  - Common data platform
  - Data governance
  - Biospecimen curation

April 10 COG data standards workshop

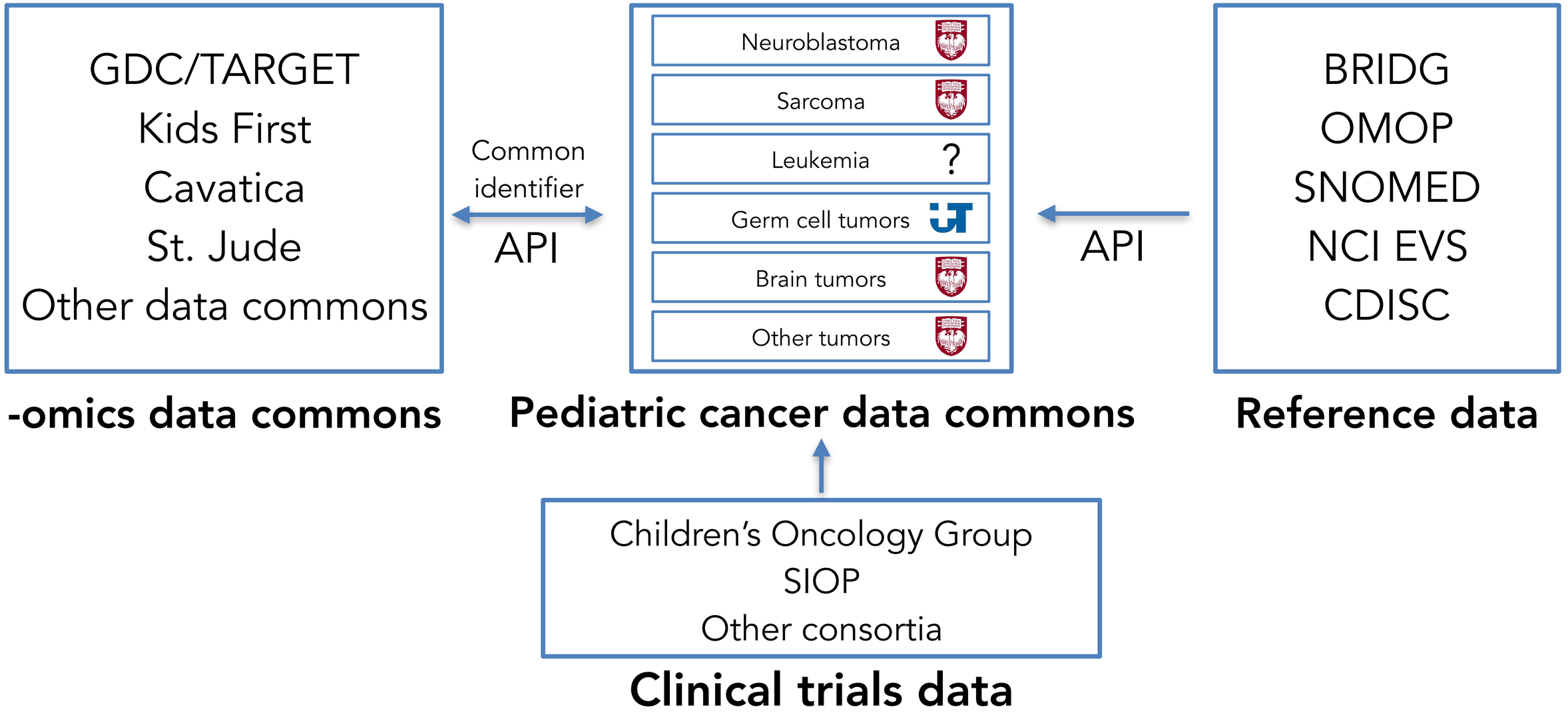
Plan to develop informatics task force for COG

Make recommendations for informatics strategic plan for COG

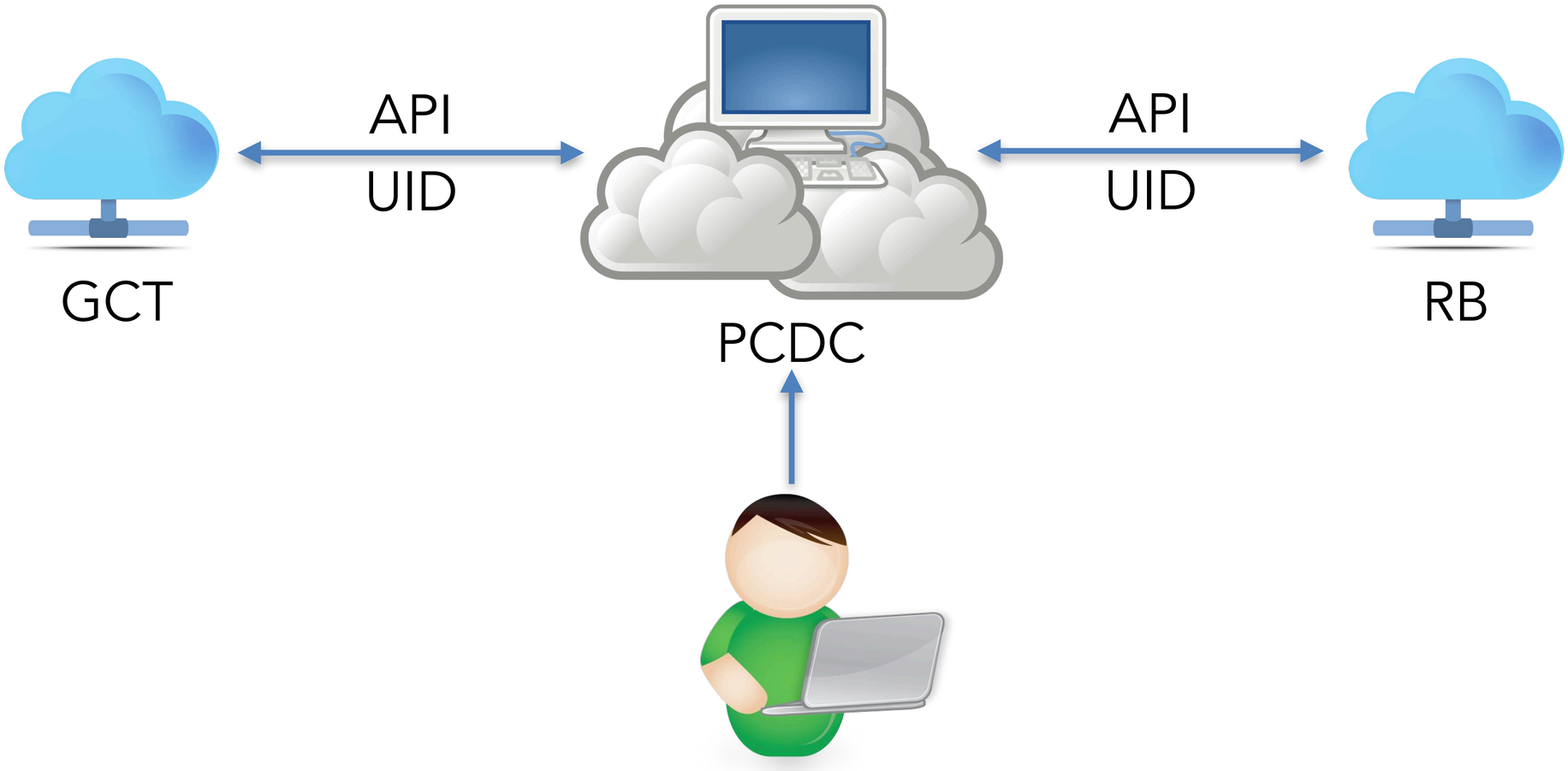
Goal: Build a commons of clinical trials data to enrich the genomic information



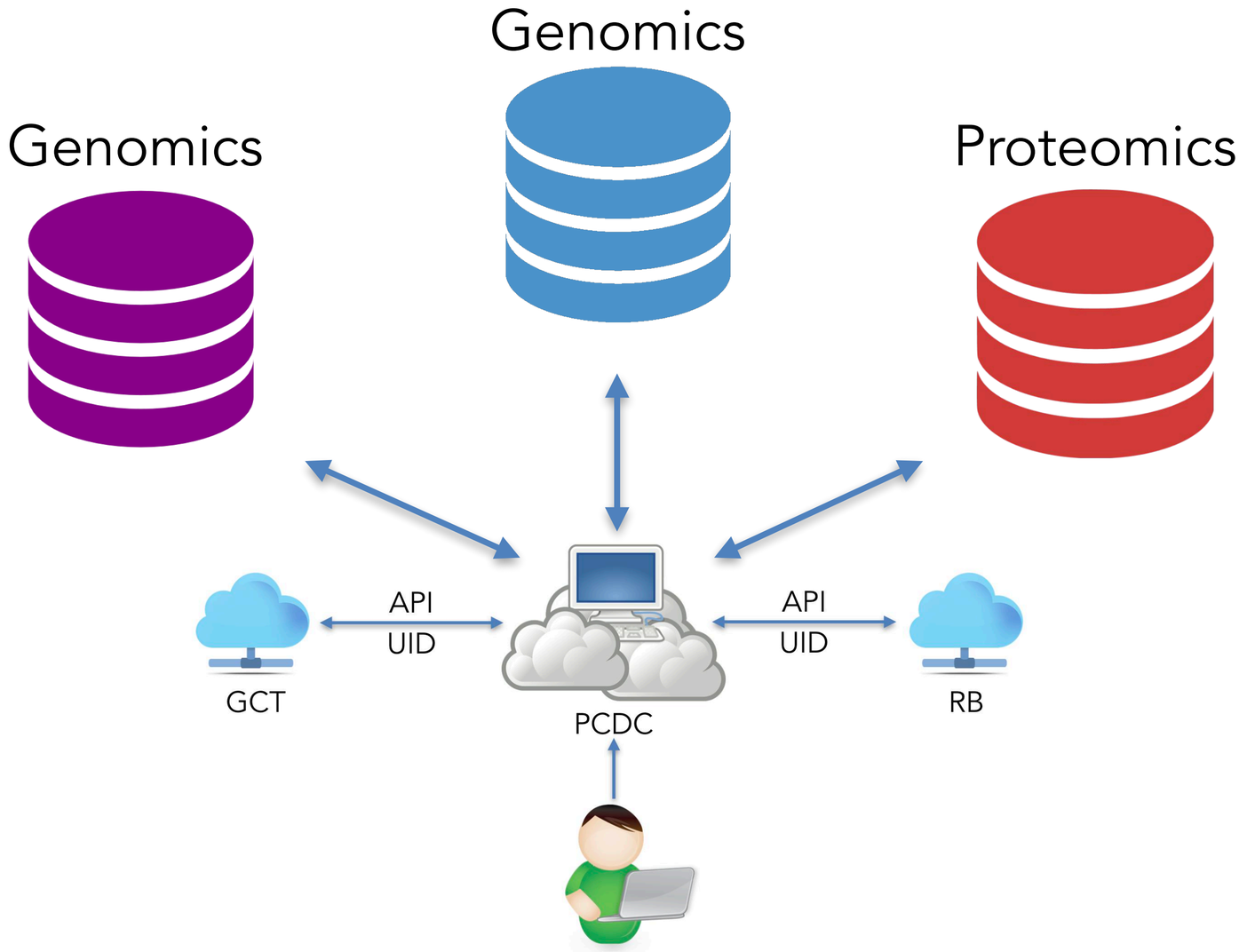
Paradigm for pediatric cancer clinical trials data commons



Interacting commons for clinical data



Interacting commons for clinical data



Summary / Call to action

- Harmonized data leads to shared data
- Data and samples must have universal identifiers
- We must envision data collection and sharing at all stages of care
- The goal is all data from all patients at all times

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Conquer Childhood Cancers

Alex's Lemonade Stand

The Super Jake Foundation

LITTLE HEROES

Children's Neuroblastoma Cancer Foundation